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TRATAMIENTO DEL DOLOR LUMBAR CRÓNICO INESPECÍFICO MEDIANTE EJERCICIO TERAPÉUTICO Y TELEMEDICINA.

CHRONIC NON-SPECIFIC LOW BACK PAIN TREATMENT USING THERAPEUTIC EXERCISE AND TELEMEDICINE.

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A mi familia por todo el apoyo

brindado durante estos años.

Y en especial a Berta,

por ser mi guía en el camino.

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RESUMEN

Introducción.

El dolor lumbar crónico (CLBP) se ha establecido como el mayor generador de discapacidad en el mundo, así como, la sexta causa de gasto sanitario. Además, se estima que el coste económico directo relacionado con el dolor lumbar en países de la Unión Europea se sitúa entre los 188 millones en Bélgica, 4.2 billones en Países Bajos, llegando hasta los 90.6 billones de dólares en Estados Unidos. La presencia de CLBP representa un gran impacto en la vida de los pacientes, los cuales reportan una pérdida de función relacionada con su capacidad de realizar actividades domésticas o recreacionales, deterioro de las relaciones sociales y sensación de aislamiento, necesidad de modificar su actividades laborales o miedo a perder su trabajo. Además, para muchos supone un gran estigma padecer esta patología.

Objetivos.

Evaluar la efectividad del ejercicio terapéutico a través de diferentes programas de abordaje terapéutico (presencial, domiciliario y telemedicina) del paciente con lumbalgia crónica de origen inespecífico en el dolor, la discapacidad, el miedo al movimiento, la calidad de vida, el rango de movilidad en flexión lumbar y la resistencia de la musculatura abdominal.

Material y Métodos.

Dos ensayos clínicos aleatorizados y un protocolo de viabilidad fueron realizados para el desarrollo de esta tesis doctoral. Un total de 138 pacientes con dolor lumbar crónico de origen inespecífico que cumplieron los criterios de inclusión fueron reclutados para los ensayos clínicos de esta tesis. Las variables de medida registradas fueron el dolor (EVA), la discapacidad (RMDQ), el miedo al movimiento (TSK), la calidad de vida (SF-36), la resistencia de la musculatura abdominal (McQuade Test) y el rango de movilidad en flexión lumbar (test dedos-suelo). En el primero de los ensayos clínicos los datos fueron obtenidos antes de comenzar el tratamiento, a los 2 meses y a los 6 meses de haber finalizado el tratamiento, mientras que, en el segundo de ellos, los datos fueron obtenidos antes de comenzar el tratamiento, a los 2 meses desde el comienzo del estudio.

En cuanto al protocolo, se describió un ensayo controlado aleatorizado a doble ciego sobre una intervención de e-salud o telemedicina basado en la autogestión en pacientes

con dolor lumbar crónico de origen inespecífico. En él se describe proceso de captación de pacientes y asignación aleatoria, junto con el programa de intervención de e-salud y el grupo control. Así mismo, se describe el protocolo de tratamiento y evaluación de las variables de medida en los participantes.

Resultados.

El ejercicio terapéutico realizado de manera presencial se presenta como un procedimiento efectivo en la reducción del dolor, la discapacidad y el miedo al movimiento, mejorando la calidad de vida, la resistencia de los músculos abdominales y el rango de movilidad. A su vez, el ejercicio, administrado de manera telemática a través de una plataforma web, muestra resultados positivos en la mejora de las mismas variables frente al ejercicio domiciliario habitual. Por tanto, la Telemedicina se postula como una herramienta útil y efectiva junto con el ejercicio terapéutico en el manejo de pacientes con dolor lumbar crónico inespecífico.

Conclusiones.

La telemedicina y el ejercicio terapéutico pueden considerarse herramientas para el abordaje de pacientes con dolor lumbar crónico inespecífico, mostrando beneficios en el manejo del dolor, la discapacidad, el miedo al movimiento, la calidad de vida, la resistencia de los músculos abdominales y la movilidad lumbar.

ABSTRACT

Introduction.

Chronic low back pain has been established as the largest generator of disability in the world, as well as the sixth cause in terms of health spending. In addition, it is estimated that the direct economic cost related to low back pain in countries of the European Union is between 188 million in Belgium, 4.2 billion in the Netherlands, reaching up to 90.6 billion dollars in the United States. The presence of CLBP represents a great impact on the lives of patients, they report a loss of function related to their ability to carry out domestic or recreational activities, deterioration of social relationships and a feeling of isolation, the need to modify their work activities or fear to lose his job. In addition, for many it is a great stigma to suffer from this pathology.

Aims.

To evaluate the effectiveness of therapeutic exercise through different programs in the approach to patients with chronic low back pain of non-specific origin in terms of pain, disability, fear of movement, quality of life, range of motion in lumbar flexion and resistance of the abdominal muscles. In addition to analyzing the effect of telemedicine in patients with the same problem.

Material and methods.

Two randomized clinical trials and a feasibility protocol were carried out for the development of this doctoral thesis. A total of 138 patients with chronic non-specific low back pain who met the inclusion criteria were recruited for the clinical trials of this thesis. The outcome measures recorded were pain (VAS), disability (RMDQ), fear of movement (TSK), quality of life (SF-36), endurance of abdominal muscles (McQuade Test) and range of mobility in lumbar flexion (finger-floor test). In the first clinical trial, data were collected before starting treatment, at 2 months and 6 months after finishing treatment, meanwhile in the second one, data were obtained before starting treatment, at 2 months from the beginning of the study.

Regarding the protocol, a double-blind randomized controlled trial of an e-health or telemedicine intervention based on self-management in patients with chronic low back pain of non-specific origin was described. It describes the process of patient recruitment and randomization, along with the e-health intervention program and the control group.

Likewise, the protocol of treatment and evaluation of the outcome measures in the participants is described.

Results.

Therapeutic exercise performed in person is presented as an effective procedure in reducing pain, disability and fear of movement, improving quality of life, abdominal muscle endurance and range of motion. In turn, exercise, administered through a web platform, shows positive results in improving the same outcome measures compared to the usual domiciliary exercise. Therefore, Telemedicine is postulated as a useful and effective tool together with therapeutic exercise in the management of patients with chronic non-especific low back pain.

Conclusions.

Telemedicine and therapeutic exercise can be considered tools for managing patients with chronic non-specific low back pain, showing benefits in pain management, disability, fear of movement, quality of life, abdominal muscle endurance and lumbar mobility.

ABREVIATURAS/ABBREVIATIONS

DLC (CLBP)	Chronic Low Back Pain	Dolor lumbar crónico
DLCI (CNSLBP)	Chronic non-specificic low back pain	Dolor lumbar de origen inespecífico.
SD	Derangement síndrome	Síndrome de desarreglo
GABA	Gamma-aminobutyric acid	Ácido gamma-aminobutírico
HIT	High Intensity Training	Ejercicio de alta intesidad
IASP	International Association for the Study of Pain	Asociación internacional para el Estudio del Dolor
IL-1β	Interleukin 1-beta	Interleucina 1-beta
DL	Low Back Pain	Dolor lumbar
MCID	Minimal Clinically Important Difference	Diferencia Mínima clínicamente importante
NMDA	N-metil-D-aspartat	N-metil-D-aspartato
NPRS	Numerical Pain Rating Scale	Escala numérica de puntuación del dolor
AINES (AIDs)	Non-esteroidal antiinflamatory drugs	Antiinflamatorios no esteroideos
NT	Neurotransmisor	Neurotransmisor
ODI	Owestry Disability Index	Índice de Discapacidad de Owestry
PAG	Periaqueductual Grey Matter	Sustancia Gris Periacueductual
RMDQ/RMQ	Roland Morris Disability Questionnaire	Cuestionario de Discapacidad Roland Morris.
RVM	Rostral Ventromedial Medulla	Médula Rostroventral medial
SC	Central Sensibilization	Sensibilización Central
SF-36	Quality of Life Questionnaire SF-36	Cuestionario de Calidad de Vida SF-36
SNC	Central Nervous System	Sistema nervioso Central
TNF-α	Tumor necrosis factor	Factor de necrosis tumoral alfa
TSK	Tampa Scale for Kinesiofobia	Escala Tampa de kinesiofobia

INTRODUCCIÓN

El dolor es una experiencia sensorial y emocional compleja que puede variar ampliamente entre personas e incluso dentro de un individuo, según el contexto y el significado del dolor y el estado psicológico de la persona[1]. La experiencia de dolor puede estar influida por múltiples variables biológicas y psicosociales, además de factores genéticos o variables demográficas, influyendo de manera diferente en cada individuo modificando la respuesta de dolor[2]. Por su parte, el dolor crónico se define como el dolor que persiste o se repite durante más de 3 meses. En los síndromes de dolor crónico, el dolor puede ser el único síntoma o un síntoma principal y requiere un tratamiento y cuidados especiales. Además, este dolor, permanece más allá del tiempo normal de curación de los tejidos, perdiendo así la función protectora que se le presupone como función fisiológica[3]. Este tipo de dolor es caracterizado por una hipersensibilidad nociceptiva permanente con una reducción de los umbrales de dolor, ocasionando reacciones de alodinia e hiperalgesia a los estímulos, tanto en los tejidos donde ha estado la lesión como en los tejidos circundantes[4].

El modelo biopsicosocial sugiere la importancia del contexto en la experiencia dolorosa del individuo, además de una amplia cantidad de variables que podrían actuar como factores de riesgo influyendo en la probabilidad de desarrollar dolor crónico, la gravedad del mismo, la presencia de discapacidad e incluso en el éxito o el fracaso de un tratamiento[5].

La Clasificación Internacional de Enfermedades (ICD-11) incluyó una nueva clasificación del dolor propuesto por la International Association for the Study of Pain (IASP). Atendiendo a esta clasificación podemos encontrar diferentes tipos de dolor en función de sus características[6]:

- Dolor nociceptivo: aquel causado por la activación de los nociceptores, sin afectación de tejido nervioso, que cumple su función fisiológica de alerta ante un peligro potencial o daño estructural en el tejido[7].
- Dolor neuropático: aquel producido por una lesión en el sistema somatosensorial objetivable y que posee características propias de la lesión del tejido nervioso como alteraciones de la sensibilidad, disestesias, parestesias, alodinia, dolor tipo eléctrico y quemante[8].

- Dolor nociplástico/algopático/nocipático: es aquel que no hace referencia a un daño potencial o real del tejido y que podría ser causado por un funcionamiento erróneo de las vías del dolor, es decir, un fenómeno maladaptativo del sistema nervioso central (SNC)[9,10].

Normalmente, el dolor es consecuencia de la activación de los nociceptores a consecuencia de una lesión, proceso inflamatorio o irritante mecánico. Esta señal nociceptiva es dirigida hacia el asta dorsal de la médula espinal a través de las vías ascendentes, donde proseguirán su camino a través de la neurona de segundo orden hasta los centros superiores donde se obtendrá como resultado la percepción de dolor. En consecuencia, el dolor nociceptivo es producto de la estimulación de los nociceptores y el procesamiento en el SNC. El dolor nociplástico, por su parte, podría ser debido a alteraciones de procesamiento del dolor nociceptivo dentro del SNC, debido a un aumento de excitabilidad de las neuronas o una inhibición de los mecanismos moduladores. Por su parte, el dolor neuropático es consecuencia de una lesión directa del nervio[11], pudiendo afectar a nivel periférico o central, en función de la estructura afectada, siendo las manifestaciones más habituales la aparición de dolor espontáneo e intermitente en forma de quemazón, dolor punzante, dolor paroxísitico y alodinia ocasionada por el frío o el tacto[12].

Según la IASP para etiquetar un dolor musculoesquelético como nociplástico el paciente debería cumplir una serie de criterios como: reportar dolor con una duración superior a 3 meses; indicar un dolor como regional en lugar de puntual; el dolor no puede ser explicado por mecanismos nociceptivos ni neuropáticos y, mostrar signos de hipersensibilidad[13,14].

El dolor lumbar (DL) se puede considerar como un síntoma en lugar de una patología, el cual podría ser resultado de diversas patologías o enfermedades. Comúnmente, está definido por aquel dolor localizado entre el borde inferior de la parrilla costal y los pliegues glúteos, pudiendo estar acompañado de dolor en una o las dos piernas, además de poder estar asociado a síntomas neurológicos en las extremidades inferiores[15]. La forma más común de presentación es la denominada “dolor lumbar crónico inespecífico” (DLCI), donde la causa anatomopatológica no está determinada[16]. En este tipo de pacientes, los hallazgos de imagen como pueden ser pequeñas lesiones discales u osteoartritis de las facetas vertebrales, no parecen ser las fuentes de dolor que ocasionen los síntomas de los pacientes, por lo que no podrían considerarse los productores de este

dolor[17]. El DL podría comprender los tres tipos de dolor (nociceptivo, neuropático o nociplástico) sugeridos por la IASP dependiendo del mecanismo subyacente que lo provoque[18].

En 2010, la prevalencia mundial del dolor lumbar era del 9.4% (95% CI 9.0 to 9.8), la cual está aumentando con la edad[19]. En 2017, el porcentaje de prevalencia global se situaba en el 7.5%, mientras que, en Europa central, se presenta en el 12.57% de la población sin apenas distinción entre sexos[20]. Así mismo, las visitas a urgencias por dolor lumbar constituyeron el 4,39% de las consultas médicas (IC 95%: 3.67-5-18)[21]. El grupo de edad principalmente afectado en varones es el de 31 a 40 años, donde el 38.6% sufrió dolor crónico, mientras que en el sexo femenino el grupo con mayor incidencia fue el de 41-58 años representando el 38.1% de ellas[22].

El dolor lumbar crónico (DLC) se ha establecido como el mayor generador de discapacidad en el mundo, así como, la sexta causa en cuanto a gasto sanitario[19]. Además, se estima que el coste económico directo relacionado con el dolor lumbar en países de la Unión Europea se sitúa entre los 188 millones en Bélgica, 4.2 billones en Países Bajos, llegando hasta los 90.6 billones de dólares en Estados Unidos[23]. La presencia de DLC representa un gran impacto en la vida de los pacientes, éstos reportan una pérdida de función relacionada con su capacidad de realizar actividades domésticas o recreacionales, deterioro de las relaciones sociales y sensación de aislamiento, necesidad de modificar su actividades laborales o miedo a perder su trabajo. Además, para muchos supone un gran estigma sufrir esta patología[24].

Tradicionalmente, el dolor lumbar crónico ha sido clasificado en tres categorías, aquellas que se debía a una patología espinal específica, aquellos causados por dolor neuropático o radicular y las lumbalgias no específicas. En relación al dolor lumbar no específico, como se aclaró anteriormente, sería aquel no atribuible a ninguna causa o enfermedad reconocible como, por ejemplo, infección, tumor, osteoporosis, fractura, deformidad estructural, espondilitis anquilosante, síndrome radicular o síndrome de la cauda equina[25].

Por otro lado, las lumbalgias mecánicas, aquellas que tienen su origen intrínsecamente en la columna vertebral, los discos intervertebrales o los tejidos blandos circundantes[26]. Las lumbalgias de origen discogénico se caracterizan por una degeneración discal junto con alteraciones estructurales y cambios celulares en la composición del disco, pudiendo ir acompañado de fisuras en el anillo fibroso. Los pacientes con patología discal parecen

diferir de otros pacientes con lumbalgia crónica en cuanto a intensidad del dolor y una localización más axial[27]. Chun y cols.[28], en su metaanálisis apoyan la hipótesis de que una disminución de la curvatura de la lordosis lumbar está presente en sujetos con dolor lumbar comparados con sujetos sanos. Además, refiere que la presencia de hernia discal o degeneración está relacionada con la pérdida de dicha curvatura[28]. Hildebrandt y cols.[29] encontraron infiltración de grasa en la musculatura multífida lumbar, tanto en pacientes con dolor lumbar crónico y agudo, así como, en sujetos sanos. Dicha infiltración de grasa puede estar relacionado con una disminución del rango de movimiento en flexión lumbar, pero no parece estar relacionado con alteraciones del control motor, la postura, la conciencia corporal o la sensación de discapacidad[29]. La revisión de Ranger y cols.[30] reveló que el corte de sección transversal de los multífidos estaba negativamente asociado con la predicción de aparición de DL, al menos, durante 12 meses. Si bien, no hay consenso sobre la asociación entre el área de sección transversal de los músculos erector espinal, psoas y cuadrado lumbar con la presencia de dolor lumbar[30]. Sadler y cols.[31] realizaron una revisión sistemática de estudio prospectivos de cohorte donde encontraron que la limitación de la inclinación lateral y un descenso en la amplitud de movimiento de los isquiotibiales, junto con una reducción de la lordosis lumbar, podrían ser factores de riesgo para la aparición de lumbalgia[31].

En algunos pacientes con DLC se ha observado unos patrones de reclutamiento alterados de los músculos estabilizadores de la columna lumbar. Estos pacientes presentan dificultades en la activación de la musculatura estabilizadora profunda como el transverso del abdomen, los oblicuos internos y multífidos lumbares, contribuyendo a la cronificación del problema[32]. Así mismo, Cooper y cols.[33] encontraron que los pacientes con dolor lumbar presentaban mayor debilidad de glúteo medio que los controles sanos, además de un signo de Trendelenburg más frecuente y mayor dolor a la palpación de la musculatura glútea, trocánter mayor y paraespinales lumbares[33].

A pesar de que cualquier estructura inervada puede ocasionar sintomatología dolorosa y las mejoras e innovaciones en las herramientas de diagnóstico por imagen, no parecen poder establecer una relación de causa efecto en algunas anomalías encontradas en este tipo de examen. Esto es debido a la gran cantidad de anomalías encontradas en sujetos asintomáticos, incluso en presencia de hernia discal, además, de los falsos positivos[34].

Una revisión reciente como la de Goubert y cols.[35], no ha podido demostrar que este tipo de lumbalgia sea debida a cambios estructurales de la musculatura lumbar. Aunque se encontró una evidencia moderada en la atrofia de los músculos multífidos, la evidencia en cuanto a la atrofia de la musculatura paraespinal y del erector espinal fue inconcluyente. Tampoco encontraron evidencia de infiltración de grasa en la musculatura en la lumbalgia crónica ni recurrente, y, tampoco observaron alteraciones en el tipo de fibras de la musculatura paraespinal[35]. Así mismo, existe una débil correlación (R=0.37) y una baja asociación significativa (ANOVA, p = 0.001, 95% CI 2.07–8.14) entre el grado de degeneración de los discos lumbares y el grado de infiltración grasa de los músculos multífidos lumbares, por lo que estos cambios podrían ser cambios normales producidos por la edad[36]. El metaanálisis de Brinjikji y cols.[37] encontró que los cambios degenerativos discales y la espondilólisis tenían asociaciones significativas en adultos de 50 años o menos con dolor lumbar, aunque los hallazgos de imagen no podían interpretarse como una relación de causalidad respecto al dolor. Si bien, podrían ser biomarcadores útiles en el diagnóstico de DL en pacientes jóvenes[37]. Otros autores, sin embargo, refieren una asociación entre la disminución del espacio intrevertebral y el dolor lumbar, acrecentándose en los pacientes varones[38]. En referencia al dolor lumbar, se pueden distinguir los tres tipos de dolor descritos con anterioridad. El dolor nociceptivo que vendría determinado por un daño real o amenazante en el tejido no neural y que provoca la activación de los nociceptores, o bien, el dolor provocado por la activación de las terminaciones periféricas de las neuronas aferentes primarias en respuesta a la acción de sustancias químicas, acciones mecánicas o estímulos térmicos nocivos. Se podría calificar como “dolor capaz de generar una lesión real”. El dolor neuropático es el que afecta al tejido neuronal, en el caso del DLC, se trataría del dolor radicular. Ambos tipos de dolor, nociceptivo y neuropático, podrían catalogarse dentro de las lumbalgias con origen específico. Los dolores lumbares de origen inespecífico (85% de los casos) se enmarcarían dentro del tercer tipo de dolor, y dado que no se puede establecer un diagnóstico con certeza, podríamos categorizarlo dentro del denominado dolor nocipástico[17], de esta manera, el mecanismo de sensibilización del sistema nervioso podría explicar los síntomas que sufren los pacientes de dolor crónico en ausencia de input nociceptivo ni daño tisular[39].

Los avances en neurociencia han revelado que el dolor lumbar crónico no se limita únicamente a la columna vertebral, sino que, se han hallado en los pacientes cambios en

regiones cerebrales relacionados con el dolor. Estos cambios incluyen desde una reorganización de la conectividad en distintas regiones cerebrales hasta un aumento de la actividad en las áreas de la llamada "matriz del dolor"[40]. Es probable que estos cambios a nivel central produzcan un fenómeno de sensibilización central (SC), provocado por un procesamiento neuronal erróneo, generando dolor persistente en ausencia de daño o lesiones de las estructuras anatómicas[41]. Las alteraciones en el SNC observadas en la SC incluyen un procesamiento sensorial alterado en las áreas cerebrales, un funcionamiento erróneo de los mecanismos antinociceptivos descendentes, un aumento de las vías facilitadores del dolor y el aumento de la simultaneidad temporal del dolor secundario o wind-up[42].

Cada día, la evidencia muestra cada vez más que el DL es un trastorno multifactorial. El dolor lumbar persistente e incapacitante no se trataría, por tanto, de una patología o daño tisular en sí misma, sino que podría ser consecuencia de un mecanismo protector regido por los sistemas neuroinmune y endocrino ante una respuesta de peligro o amenaza percibida por el individuo, o una alteración de la homeostasis. Estos sistemas, actúan involuntaria y permanentemente, siendo influenciados por el estilo de vida, factores físicos, psicológicos, sociales y de salud[43].

El tratamiento del DLC es muy amplio y variado, siendo los principales métodos el enfoque farmacológico[44,] La rehabilitación y la terapia física[45], educación del paciente[46,47], terapia cognitivo-conductual[48], punción seca[49], Kinesiotaping[50], Masaje[51] Terapia manipulativa[52] y el ejercicio[53]. A su vez, la guía de práctica clínica de la American Physical Therapy Association destaca como intervenciones el empleo de la terapia manual, ejercicios de fortalecimiento, resistencia y coordinación de tronco, ejercicios de centralización y preferencia direccional, ejercicios de flexión, movilización neural en flexión, educación y consuelo del paciente, fortalecimiento progresivo y actividades de fitness[34]. Por su parte, la guía europea para el manejo del dolor lumbar crónico recomienda principalmente el tratamiento conservador a través de medios físicos, el tratamiento farmacológico a través de antiinflamatorios no esteroideos (AINEs) y opioides débiles para el manejo del dolor, no recomendando el tratamiento invasivo, siendo la cirugía la última opción tras el fracaso de todos los tratamientos propuestos en un periodo de 2 años[54]. Si bien, se hace necesario dotar al paciente de las capacidades de automanejo del dolor para la reducción de la discapacidad[55]. Siendo la terapia con mayor grado de evidencia el ejercicio, a la que se podría incluir la terapia manipulativa y

movilización más masaje como modificador de síntomas a corto plazo, unido con la educación del paciente[56].

Evidencia sobre el empleo de ejercicio en el abordaje del paciente con dolor lumbar crónico.

El enfoque multidisciplinario se presenta la elección más acertada para el manejo del dolor lumbar, a través de la terapia conductual y el ejercicio físico[45]. La guía europea para el manejo del DLCI recomienda el empleo del ejercicio físico como el tratamiento de primera línea para el dolor lumbar. Si bien, aconseja su empleo acompañado de un enfoque cognitivo-conductual, donde se realicen ejercicios de manera gradual. El tipo de ejercicio a realizar deberá ajustarse a las preferencias tanto del paciente como del terapeuta[54]. Por tanto, el ejercicio físico se muestra como una de las herramientas más potentes en la mejora del dolor y la función, pero no está claro que haya tipos de ejercicios mejores que otros[57].

El ejercicio regular produce un alivio del dolor consecuencia de la reducción en la fosforilación del receptor NMDA, reduciendo la sensibilización central. Además, se reduce la expresión del transportador de la serotonina, aumentando los niveles de serotonina y opioides en las vías inhibitorias centrales, incluyendo la sustancia gris periacueductual (PAG) y la médula rostroventral medial (RVM), lo que sugiere la activación de los sistemas inhibitorios endógenos para la reducción del dolor[58]. En modelos animales con lesiones en nervios periféricos se ha observado que el ejercicio de baja intensidad consistente en correr en cinta mejora la expresión de neurotransmisores relacionados con la serotonina provocando disminución de los niveles de citoquinas inflamatorias (TNF-α y IL-1β)[59]. Además, el ejercicio produce un aumento de los umbrales del dolor debido a la liberación de opioides endógenos y la activación de los mecanismos inhibidores nociceptivos a través de la liberación de β endorfinas en la hipófisis y el hipotálamo lo que permite la activación de los receptores opioides. El hipotálamo a su vez activará los mecanismos inhibitorios descendentes a través de la PAG[60].

El ejercicio parece influir positivamente en las variables psicológicas del dolor crónico, mejorando la discapacidad autopercibida, el miedo al movimiento y el catastrofismo[61]. Otros efectos reportados son la reducción de la ansiedad y la depresión, mejoras de la

capacidad física, aumentado de la independencia y la reducción de la morbilidad y mortalidad[62].

En el manejo del dolor crónico, existe una falta de consenso, así como, en las guías de la práctica clínica en la administración de ejercicio, por lo que existe una gran variedad de formas de prescripción, aunque esto, es preferible a un estilo de vida sedentario[63]. El ejercicio de fuerza mediante levantamiento con altas cargas, junto con el control motor en bajas cargas se han mostrado efectivos en la mejora del dolor, la discapacidad y la calidad de vida, si bien, no parece haber diferencias significativas entre ambos[64]. El ejercicio de fuerza, a su vez, no mostró diferencias en cuanto al diámetro muscular ni a la infiltración de grasa en la musculatura erectora lumbar, aunque se encontraron mejoras con respecto a la fuerza y el dolor. En aquellos pacientes donde sí hubo un aumento del diámetro de sección transversal de la musculatura para espinal y un descenso de la grasa infiltrada, se obtuvieron mejoras en la discapacidad, ansiedad y depresión[65].

Otro tipo de ejercicio muy común en el manejo del dolor lumbar crónico son los ejercicios de Pilates, los cuales presentan una evidencia baja/moderada en la mejora del dolor y la discapacidad, aunque no parece ser superior a otro tipo de ejercicios[66]. Los ejercicios estabilizadores de CORE, se muestran más efectivos en la mejora del dolor y la función a corto plazo con respecto al ejercicio general, sin embargo, no presentan diferencias significativas en el largo plazo[67]. A su vez, los ejercicios de control motor proporcionan mejoras ligeramente superiores que el ejercicio general en el dolor, la función, la sensación de recuperación y la calidad de vida en el corto y medio plazo, sin embargo, existe escasa evidencia de que sea superior en el largo plazo[68]. Además, los ejercicios de control motor a baja carga se muestran superiores a los de alta carga en la mejora del control del movimiento y la resistencia, pero no son superiores en cuanto a la disminución de la intensidad del dolor o al aumento de la fuerza[69]. Además, junto con los ejercicios de estabilización, podría añadirse ejercicio aeróbico en forma de caminata para potenciar su efecto[70].

Existe una evidencia alta/moderada respecto al Método McKenzie, ya que parece ser superior a otras intervenciones de rehabilitación en la reducción del dolor y la discapacidad[71], junto con una mayor sensación de recuperación por parte de los pacientes[72].

Owen encontró evidencia científica de baja calidad en la efectividad del ejercicio a través de los ejercicios de Pilates, ejercicios de estabilización o control motor, ejercicio de fuerza y el ejercicio aeróbico, pero sin embargo, son más efectivos que el tratamiento mediante terapia manual[53].

La combinación de diferentes tipos de ejercicio como pueden ser el fortalecimiento muscular, la flexibilidad y el ejercicio aeróbico en un único programa podrían resultar beneficiosos en la rehabilitación del dolor lumbar a través de la mejora de la fuerza muscular, el rango de movimiento y la aceleración del proceso curativo derivado del ejercicio aeróbico[73]. La variable "intensidad" también debe tenerse en cuenta en la realización de ejercicio puesto que el ejercicio de alta intensidad (HIT) mostró mejores resultados en cuanto a dolor y discapacidad frente a ejercicio similar realizado a una intensidad moderada[74].

Los ejercicios de fortalecimientos realizados en grupo muestran resultados superiores en la tasa de recurrencia, como los ejercicios fuerza de la musculatura extensora lumbar sobre el dolor y la discapacidad frente a los programas de escuela de espalda que se pueden encontrar en atención primaria[75]. Sin embargo, una revisión sistemática reciente no se encontraron diferencias entre la realización de ejercicio en grupo frente a otras intervenciones realizadas de manera individualizada[76]. Incluso, el ejercicio domiciliario se presenta como un tratamiento interesante en pacientes con DLCI influyendo sobre la intensidad del dolor y la limitación funcional, aunque se necesita más investigación para poder comparar su efectividad frente al entrenamiento supervisado convencional[77].

Evidencia del empleo de Telemedicina en el tratamiento del dolor lumbar crónico de origen inespecífico.

Se define la telemedicina como la prestación de atención médica y el intercambio de información sobre el cuidado de la salud a distancia[78]. La telemedicina se basa en la incorporación de tecnologías para proporcionar atención médica al usuario a través de la comunicación por vías electrónicas[79]. La telemedicina o e-salud puede ser administrada de diferentes formas, desde la navegación en páginas web, aplicaciones móviles de salud, consultas en línea, herramientas de apoyo, monitorización electrónica o empleo de las redes sociales[80].

La pandemia por COVID-19 ha supuesto un problema para la población con dolor crónico debido a la interrupción de los tratamientos, presentándose la telemedicina como

una alternativa[81]. La pandemia ha promovido la aplicación de la telemedicina, permitiendo la prestación de servicios sanitarios durante la pandemia[82].

El empleo de aplicaciones, telemedicina o programas de e-salud podrían ser una herramienta interesante para la mejora de las variables en pacientes con diferentes enfermedades crónicas[83]. El empleo de plataformas web o app que proveen al paciente de la capacidad de automanejo ante el dolor parecen tener cierta evidencia de eficacia terapéutica[81]. Aunque es cierto que la literatura es demasiado heterogénea y este tipo de intervenciones han sido vagamente descritas en el dolor lumbar crónico[84]. El propósito de la telerrehabilitación es dotar al paciente de la capacidad de manejar distintos componentes de la salud como la independencia funcional, el autocuidado y el automanejo de la enfermedad[85]. Aun así, los sistemas de e-salud basados en el automanejo por parte del paciente parecen tener una influencia prometedora en la reducción del dolor y la discapacidad[86], además de que podrían suponer un ahorro en cuanto a gasto sanitario se refiere[87].

Chhabra y cols.[83] desarrollaron una aplicación para smartphones para la autogestión de DLC. A través de la aplicación, los pacientes recibieron prescripción de ejercicio en función de su estado de salud, actividades de la vida diaria y su progreso. Los resultados fueron positivos, obteniendo en ambos grupos (grupo de atención tradicional y app) mejoras significativas en el dolor y la discapacidad ($p>0,05$). El grupo que empleó la aplicación también mostró una mayor mejoría en la discapacidad ($p>0.001$)[83]. Nicholl y cols.[84] realizaron una revisión sistemática sobre el empleo de apoyo digital en automanejo en pacientes con DL. Los principales métodos que empleaban los estudios analizados fueron la provisión de contenido para la educación en dolor, incluyendo información sobre el origen de la patología, la gestión de la misma, la epidemiología y los aspectos psicológicos, incluyeron también, consejos sobre bienestar, recomendando la realización de meditación, relajación, actividad física e higiene del sueño. Otros estudios analizados incluyeron consejos sobre la realización de ejercicio físico. La creación de una E-comunidad a través de un foro también estuvo presente. Y, por último, un estudio incluyó la narrativa de pacientes como parte del contenido[84]. Chen y cols.[88], en su metaanálisis de ensayos clínicos aleatorizados encontraron que el empleo de sistemas de e-salud (teléfonos móviles, ordenadores, sensores de biofeedback, consolas de videojuegos) junto con la terapia convencional (ejercicio y/o consejo) obtuvo mejoras importantes en el dolor medido en escala EVA, frente a la terapia convencional o el placebo (MD –0.85, 95% CI

–1.29 to –0.40; I2=9%; P<.001). La misma tendencia pareció ocurrir con la discapacidad medida en el Roland Morris Disability Questionnaire (RMDQ) (MD –1.54, 95% CI –2.35 to –0.73; I2 =31%; P<.001)[88].

Es evidente que la telemedicina o e-salud presenta ciertas limitaciones, pero también, existen fortalezas significativas que podrían mejorar la atención de los pacientes con dolor crónico más allá de la pandemia por COVID-19[89]. Aunque la telemedicina pueda tener beneficios en el dolor crónico, las intervenciones mediante la misma deberán ajustarse al contexto del dolor, debiendo de tener en cuenta que, una intervención que ha hecho efecto en persona, podría no tenerlo como intervención de e-salud[90].

Evidencia del empleo de corriente TENS en el tratamiento del dolor lumbar crónico de origen inespecífico.

La estimulación nerviosa eléctrica transcutánea (TENS) es un procedimiento no farmacológico consistente en la aplicación de corriente eléctrica a través de electrodos situados en la piel con la finalidad de reducir el dolor agudo y crónico. La corriente estimula las vías inhibitorias centrales disminuyendo la excitabilidad neuronal mediante la estimulación de las vías inhibitorias descendentes del mesencéfalo y tronco encefálico para inhibir la excitabilidad de las neuronas nociceptivas medulares[91,92].

Tradicionalmente han sido descritos tres tipos de aplicaciones TENS. El TENS convencional de alta frecuencia y baja intensidad, que pretende la estimulación selectiva de las fibras A-Beta de gran calibre con frecuencia entre los 50-100Hz y un tiempo de pulso de 50-200µs. El TENS tipo acupuntura, de baja frecuencia y alta intensidad cuyo objetivo es la estimulación de las fibras pequeñas A-Delta músculo-eferentes con frecuencia entre 2-4Hz. Por último, el TENS intenso que pretende activar las fibras aferentes cutáneas A-delta de pequeño calibre mediante la administración de la corriente sobre los nervios periféricos[93].

Wall sugirió como mecanismo de acción la teoría del "Control Gate", inicialmente propuesta por Melzak[94] para la producción de analgesia, sugiriendo el efecto espinal de la estimulación eléctrica[95]. El control gate proponía que la estimulación de las fibras Alfa-Beta de gran diámetro inhiben la transmisión nociceptiva a nivel central consiguiendo una disminución de la percepción dolorosa[94]. Por tanto, la estimulación de las vías neurales y estructuras aferentes podría ser uno de los mecanismos por los que el TENS induce analgesia. Además, el TENS podría tener otros efectos a nivel espinal como una

disminución de la sensibilización de las neuronas del asta dorsal medular[96] producida por inflamación, niveles alterados de neurotransmisores (NT) como el ácido gammaaminobutírico (GABA) y la glicina, los cuales están involucrados en la inhibición del tráfico nociceptivo y la modulación de la actividad de las células gliales[97-100]. Otro posible mecanismo es la mediación de los centros superiores del sistema nervioso central a través de la reducción de la actividad inhibitoria relacionada con la PAG y la RVM, junto con la analgesia inducida por la estimulación de las vías opioides. Si bien, los mecanismos de acción del TENS podrían ser similares a los efectos producidos de tipo placebo[100].

Las vías anteriormente descritas han sido bien estudiadas en modelos animales, pero existe cierta controversia respecto a los mecanismos de acción del TENS en sujetos humanos. El estudio de Peng y cols.[101] comparó el TENS convencional y acupuntura frente al placebo, estimulando a su vez las fibras alfa-delta y C mediante pulsos de láser de calor radiante. Estos investigadores encontraron que el TENS convencional tuvo efectos analgésicos máximos producidos principalmente cuando se administraba junto a un estímulo nociceptivo homolateral. El TENS acupuntura produjo un efecto analgésico más difuso, pero en cambio, se hallaron cambios duraderos en la corteza primaria sensoriomotora y en la conectividad funcional entre esta corteza y la corteza prefrontal media, ambas con una función principal en la modulación del dolor[101].

Las corrientes tipo TENS parece obtener resultados beneficiosos en el control del dolor. Buchmuller y cols.[102], obtuvieron una mejora del dolor no radicular de al menos un 50% en el 25% de los pacientes del grupo experimental, frente al 6,7% en el grupo control (p=0.0003). En lo referente al dolor radicular, el 33,8% del grupo experimental obtuvo una mejora superior al 50% en el dolor a diferencia del grupo placebo donde se obtuvo que tan solo el 15% de los sujetos reflejó un descenso del dolor superior al 50%[102]. Facci et al.[103] también reflejaron resultados positivos con el empleo de TENS en la variable de dolor con una mejora de 39,18mm en escala visual analógica (EVA), frente al 8,53mm en el grupo control. Además, reflejaron una mejora de la discapacidad de 6,59 puntos en el RMDQ frente al 0.70 del control. Por último, el 84% del grupo TENS redujo el consumo de medicamentos después del tratamiento[103]. En lo referente a la discapacidad funcional, el TENS proporciona resultados positivos en un corto periodo de tiempo, siendo significativamente más efectivo que el placebo (SDM = −1.24; 95% CI, −1.83 to −0.65; P < 0.001), si bien, en seguimientos superiores a 6 semanas no parece haber

diferencias significativas[104]. En esa misma línea, Jauregui, puntualiza que el TENS parece tener una mejora significativa del dolor en tratamientos con una duración inferior a 5 semanas, mientras que en aquellos que se extendieron por encima de 5 semanas, la mejora del dolor no fue significativa[105]. Si bien, el tratamiento mediante TENS por sí solo no parece ser tan efectivo como en combinación con otros tratamientos[106].

El empleo de programas de alivio del dolor puede ser una propuesta interesante en pacientes con dolor al movimiento o alteración de patrones motores, pues permite aumentar la tolerancia del paciente al ejercicio[11]. Aunque la aplicación de TENS por sí solo, ya sea convencional o de tipo acupuntura, a pesar de mejorar el dolor, no evidencia tener influencia en la mejora de la funcionalidad[102]. Con todo, existe una pequeña evidencia, aunque inconsistente, que podría justificar el empleo del TENS en el alivio de los síntomas y la reducción de la discapacidad en la DLC[107].

De demostrarse su eficacia, el TENS se plantea como una herramienta interesante en el manejo del dolor persistente, dado que, es de fácil empleo, portátil, autoadministrable y relativamente barato[108]. Aunque, es cierto, que la evidencia actual es difícil de cotejar con otros estudios dada la heterogeneidad de las investigaciones, se sugiere el empleo del TENS junto con otros tratamientos principales en el manejo del dolor, siendo necesaria una mayor investigación al respecto[109].

Evidencia del empleo de ejercicios de McKenzkie en el tratamiento del dolor lumbar crónico de origen inespecífico.

El método McKenzie es reconocido como uno de los tratamientos más populares y efectivos en el abordaje conservador del dolor lumbar. Se trata de un sistema de clasificación y prescripción de ejercicio que busca la centralización del disco, asignando a los pacientes en tres grupos: síndrome postural, disfunción y desarreglo[110]. La clasificación de los síndromes se basa en los patrones de dolor y los cambios que ocurren durante el tratamiento. El fenómeno de centralización se puede definir como la situación en la que el dolor se "centraliza" hacia la espalda dejando de ser referido mediante movimientos específicos realizados según la preferencia del movimiento[111].

El síndrome postural es aquel donde el dolor se localiza en los tejidos blandos debido a posiciones y posturas mantenidas durante periodos prolongados, donde los movimientos repetidos no deberían afectar a los síntomas, encontrándose alivio con la corrección de la postura. El síndrome de disfunción es causado por daño estructural del tejido blando a

consecuencia de procesos anteriores, se identifica por la pérdida de movimiento y dolor al final del rango de movimiento. Los ejercicios para este síndrome se enfocan según la dirección de la disfunción, concretamente hacia el alivio del dolor. El síndrome de desarreglo es el más frecuente, donde existe una dislocación del tejido articular, provocando una alteración en la posición de las estructuras articulares. Se encontrará dolor y limitación del movimiento en la dirección del desplazamiento, apareciendo el dolor en movimientos provocativos como flexión o extensión de columna[112].

Lam y cols.[71] llevaron a cabo una revisión con metaanálisis donde encontraron 11 artículos susceptibles de análisis, en ellos encontraron que para pacientes con DLC, el método Mckenzie obtenía diferencias significativas en la mejora de la discapacidad frente al ejercicio. Sin embargo, no encontraron diferencias entre este método y la terapia manual más ejercicio en el dolor y la discapacidad[71]. Szulc y cols.[113]realizaron un ensayo aleatorizado donde comparó tres tipos de intervenciones, Mckenzie junto con técnica de músculo-energía (MET), método McKenzie por sí solos y fisioterapia convencional. Estos autores encontraron que el primer grupo obtuvo los mejores resultados, además, afirman que el método McKenzie sólo o junto con la MET presentaron resultados significativos en discapacidad evaluada mediante Owestry Disability Index (ODI) y un descenso significativo del dolor (medido en EVA)[113]. Halliday y cols.[72] por su parte, no encontraron diferencias significativas entre los ejercicios de control motor y el Método McKenzie, si bien, los pacientes pertenecientes al grupo de McKenzie refirieron tener una mayor sensación de recuperación[72]. En esta línea, no parece haber evidencia de que los ejercicios de McKenzie sean superiores a los ejercicios de estabilización lumbar en DLCI, pero, ambos parecen tener mayor efectividad que el ejercicio convencional en la mejora de la discapacidad funcional[114]. Otra revisión de la literatura muestra efectos similares, mostrando que este método es efectivo en la mejora del dolor, la discapacidad y la calidad de vida en los seguimientos a largo plazo frente al tratamiento farmacológico e instrumental, aunque muestra efectos similares a otros tipos de tratamiento activos[115].

Narciso-García y cols.[116] compararon el método McKenzie frente a la escuela de espalda en pacientes con DLCI en un ensayo controlado aleatorizado, encontrado que el grupo de McKenzie obtuvo mayor mejora de la discapacidad, pero no del dolor un mes después de finalizar el tratamiento[116]. Sin embargo, en una reciente revisión, se refirieron a la escuela de espalda y al método McKenzie como inefectivos en el abordaje del dolor lumbar

crónico no específico, sugiriendo una mayor investigación enfocada al paradigma biopsicosocial[117].

Un reciente metaanálisis mostró un efecto moderado de los ejercicios de Mckenzie junto con pilates y ejercicio funcional en la reducción del dolor y las limitaciones funcionales, sugiriendo al final de éste que los ejercicios seleccionados deberían ser del agrado del paciente para promover la adherencia[118]. No parece haber evidencia sobre que un tipo de ejercicio sea superior a otro, si bien, el ejercicio se ha mostrado con el tratamiento de primera línea en el manejo del dolor lumbar en detrimento de las terapias pasivas convencionales[45,54,57,119]. Además, se sugiere que el tipo de ejercicio seleccionado siga las preferencias del paciente y del terapeuta para una mayor efectividad[54,118].

Bajo el contexto anteriormente desarrollado, el propósito de esta tesis doctoral es observar la eficacia del ejercicio terapéutico y la telemedicina en el dolor lumbar crónico de origen inespecífico a través de un programa de ejercicios presencial, domiciliario y un programa de ejercicio prescrito a través de plataforma web.

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OBJETIVOS

OBJETIVO GENERAL

En esta Tesis Doctoral se pretenden dos objetivos principales. En primer lugar, evaluar la efectividad del ejercicio terapéutico a través de diferentes programas en el abordaje del paciente con lumbalgia crónica de origen inespecífico en el dolor, la discapacidad, el miedo al movimiento, la calidad de vida, el rango de movilidad en flexión lumbar y la resistencia de la musculatura abdominal. Y, en segundo lugar, analizar el efecto de la telemedicina en pacientes con el mismo problema.

OBJETIVOS ESPECÍFICOS

- Comparar la efectividad de un programa de ejercicio supervisado vs no supervisado en el dolor, la discapacidad, el miedo al movimiento, la funcionalidad y la calidad de vida en pacientes con dolor lumbar de origen no específico. **(Artículo I).**
- Diseñar un protocolo viable para la implementación de un programa de Telemedicina a través de un ensayo clínico aleatorizado. **(Artículo II).**
- Analizar la efectividad de los ejercicios de McKenzie administrados junto a electroanalgesia a través de un programa de telemedicina frente a un programa de ejercicio domiciliario en el dolor, la discapacidad, la funcionalidad, el miedo al movimiento y la calidad de vida en pacientes con lumbalgia crónica no específica. **(Artículo III).**

METODOLOGÍA

Para desarrollar y poder cumplir todos los objetivos descritos, esta tesis doctoral tuvo que desarrollarse en dos fases. Una primera fase, en la que se realizó un ensayo clínico en el que se comparó un programa de ejercicio supervisado frente a otro domiciliario.

A raíz de la pandemia ocasionada por la COVID-19 y las dificultados aparecidas para la administración de tratamientos de salud de forma presencial, se decidió dar un giro en el propósito de la Tesis Doctoral, planteándose así la opción del abordaje del paciente mediante la Telemedicina o e-salud.

Para redirigir la tesis doctoral hacia los nuevos objetivos planteados, se determinaría una segunda fase donde, en primer lugar, se realizó un protocolo de vaibilidad para iun esnayo clínico aleatorizado basado en una intervención de Telemedicina. A tenor de los resultados encontrados, se llevó a cabo la realización del ensayo clínico aleatorizado para obtener mayor información sobre la efectividad de la telemedicina. A través de dicho ensayo se pudieron perseguir dos de los objetivos de la presente Tesis, el análisis de la efectividad de la telemedicina y la comparación de diferentes programas de ejercicio sobre las variables estudiadas en personas con dolor lumbar crónico.

Fase I. Ejercicio supervisado vs ejercicio domiciliario.

A continuación, se muestra una tabla resumen con la metodología de la fase 1 (Tabla I):

PAPER	**DISEÑO DE ESTUDIO**	**PARTICIPANTES**	**INTERVENCIÓN**	**VARIABLES PRINCIPALES**	**METODOLOGÍA**
Comparison of efficacy of a supervised vs non-supervised physical therapy exercise program on the pain, functionality and quality of life in patients with non-specific chronic low-back pain: a randomized controlled trial.	ECA	64 DLCI Grupo ejercicio supervisado (n=32) Grupo ejercicio domiciliario (n=32)	Ejercicios de estabilidad lumbopélvica y control motor, fortalecimiento del tronco y estiramientos. . Ejercicio domiciliario con mismos ejercicios al grupo supervisado. Ambos grupos, 3 sesiones por semana durante 8 semanas.	Dolor Discapacidad Miedo al movimiento Calidad de vida Resistencia de los músculos del tronco Movilidad del tronco en anteflexión.	Escala visual analógica RMDQ TSK SF-36 McQuade Test Test Dedos-suelo.

Fase II. Telemedicina.

Para la fase II, se comenzó por la realización de un protocolo de viabilidad que constabala de dos partes. Una primera parte donde se desarrolló un estudio cualitativo que pretendía observar la percepción de profesionales y pacientes sobre la implementación de un programa de telemedicina, este artículo no ha sido incluido por no formar parte de la presente tesis. La segunda parte de dicho protocolo consistió en la descripción de un ensayo clínico aleatorizado acerca de una intervención de e-salud en pacientes con dolor lumbar crónico de origen inespecífico, el cual se incluye en esta tesis y cuya metodología se describe a continuación:

PAPER	**DISEÑO DE ESTUDIO**	**PARTICIPANTES**	**INTERVENCIÓN**	**VARIABLES PRINCIPALES**	**METODOLOGÍA**
Comparing an e-Health program vs home rehabilitation program in patients with non-specific low back pain: A study protocol randomized feasibility trial	Study protocol randomized feasibility trial	(n= ¿) DLCI Criterios de inclusion: individuos con edades entre 30 y 67 años, con dolor lumbar de al menos 3 meses de duración; RMDQ > 4 y no pueden recibir otro tratamiento simultáneo. Criterios de exclusión: contraindicación de ejercicio, radiclopatía o espondilolistesis, estenosis vertebral o fibromialgia, patología central o periférica, historial de cirgugía espinal y tratamiento previo con medicación.	Intervención: Corriente TENS + ejercicios Mckenzie a través de la aplicación web Control: Ejercicio domiciliario mediante un folleto informado, explicado previamente en la primera sesión. Ambos grupos, 3 sesiones por semana durante 8 semanas.	Dolor Discapacidad Miedo al movimiento Calidad de vida Resistencia de los músculos del tronco Movilidad del tronco en anteflexión.	Escala visual analógica RMDQ TSK SF-36 McQuade Test Test Dedos-suelo.

A continuación, se muestra una tabla resumen de la metodología empleada en el tercer artículo (Tabla III):

Tabla III: Metodología del ensayo clínico aleatorizado.

PAPER	**DISEÑO DE ESTUDIO**	**PARTICIPANTES**	**INTERVENCIÓN**	**VARIABLES PRINCIPALES**	**METODOLOGÍA**
Comparison of the effectiveness o fan e-health program versus a home rehabilitation program in patients with chronic low back pain: a double blind randomized controlled trial.	ECA	74 DLCI Grupo e-salud (n=39) Grupo ejercicio domiciliario (n=35)	Corriente TENS + ejercicios Mckenzie a través de la aplicación web Ejercicio domiciliario mediante un folleto informado, explicado previamente en la primera sesión. Ambos grupos, 3 sesiones por semana durante 8 semanas.	Dolor Discapacidad Miedo al movimiento Calidad de vida Resistencia de los músculos del tronco Movilidad del tronco en anteflexión.	Escala visual analógica RMDQ TSK SF-36 McQuade Test Test Dedos-suelo.

RESULTADOS Y DISCUSIÓN

Los resultados y discusión de la tesis se detallan a continuación a través de los artículos específicos.

PAPER I

COMPARISON OF EFFICACY OF A SUPERVISED VERSUS NON-SUPERVISED PHYSICAL THERAPY EXERCISE PROGRAM ON THE PAIN, FUNCTIONALITY AND QUALITIY OF LIFE OF PATIENTS WITH NON-SPECIFIC CHRONIC LOW-BACK PAIN: A RANDOMIZED CONTROLLED TRIAL.

Matarán-Peñarrocha GA, Lara-Palomo IC, Antequera-Soler E, Gil-Martínez E, Fernández-Sánchez M, Aguilar-Ferrándiz ME, Castro-Sánchez AM.

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Comparison of efficacy of a supervised versus non-supervised physical therapy exercise program on the pain, functionality and quality of life of patients with non-specific chronic low-back pain: a randomized controlled trial

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Abstract

Objective: To compare the effectiveness of supervised physical therapy program versus non-supervised on pain, functionality, fear of movement and quality of life in patients with non-specific chronic low back pain.

Design: A randomized double-blind clinical trial.

Setting: Clinical outpatient unit; home.

Subjects: A total of 64 participants with non-specific chronic low back pain were randomized into either supervised exercise group ($n = 32$) or non-supervised home exercise group ($n = 32$).

Interventions: The supervised group was treated with therapy exercises (strengthen lumbopelvic musculature), while the non-supervised received an informative session of the exercises, which were performed un-supervised at home. Both groups received three weekly sessions for eight weeks.

Main Measures: Pain, disability, fear of movement, quality of life, trunk muscle endurance and trunk anteflexion motion were assessed at baseline, two, and six months of follow-up.

Results: Although analysis of variance (ANOVA) test showed statistically significant differences between groups for pain ($P = 0.028$; supervised: 2.5 ± 2.1; non-supervised: 3.5 ± 1.5) and disability for Roland–Morris

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Disability Questionnaire ($P = 0.004$; supervised: 3.1 ± 2.2; non-supervised: 5.1 ± 3.0) and for Oswestry Disability Index ($P = 0.034$; supervised: 14.5 ± 7.1; non-supervised: 19.2 ± 10.0) at 8 weeks immediately posttreatment, there were no differences between the groups in patient-rated pain, functionality, fear of movement and quality of life at six months of follow-up.

Conclusion: Patients with chronic low back pain who received supervised exercise showed more improvement in both the short and long term in all patient-rated outcomes over the non-supervised group, but the differences were small and not clinically significant.

Keywords

Exercise physical therapy, supervision, musculoskeletal pain, chronic disease, low back pain, randomized controlled trial

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Introduction

Chronic low back pain is a common musculoskeletal health problem in industrialized countries since the 20th century and is considered the main cause of years lived with disability, far above any other disease.[1–3] In 85%–95% of cases, the chronic low back pain is classified as "non-specific" because it is not attributable to recognized specific pathology.[4]

Given that the causes of low back pain are still the subject of discussion, the last years' opinion has varied as to what treatment should be recommended. A wide variety of therapeutic interventions have been proposed for the treatment of patients with chronic low back pain, but the recent guidelines and reviews regularly recommend the use of physical exercise.[5,6] Considering the strength, flexibility and endurance of the trunk are altered in many people with chronic low back pain, it is expected that an exercise program that addresses these deficiencies would lead to an improvement in symptoms.[7] However, due to the heterogeneity of exercises included (ranging from general exercises, training programs or Pilates method to core stability exercise), duration, intensity and the variety of outcomes measures evaluated, the results are varied and unclear in the systematic reviews.[8–10] Although it is clear that this therapy is effective for chronic low back pain, there is no evidence that any type of exercise is clearly more effective than others.

Numerous clinical trials based on core exercise and lumbopelvic stabilization programs have been introduced in recent years to treat chronic low back pain, most of them finding that exercise therapy is superior to any other therapy (e.g. spinal manipulation, advice to stay active, no treatment and other conservative treatment) in improving pain, posttreatment disability, increasing muscle strength, and long-term function.[8,9,11,12]

Therefore, in chronic low back pain, the physical therapy exercise should routinely be used, and the home exercise, as self-care intervention, could be less costly and less time-consuming that supervised exercise.[13] However, is the non-supervised exercise at home as effective as the supervised exercise by therapist? Bronfort et al.,[14] comparing supervised exercise with un-supervised exercise and manipulative therapy in patients with chronic low back pain with or without radiating pain, reported that supervised exercise was significantly better than home exercise only in terms of patients satisfaction, trunk strength and endurance, but would not differ significantly from those who received spinal manipulation or home exercise in terms of pain and other individual patient-classified outcomes, both short and long term. The evidence for supervised exercise therapy versus non-supervised is limited, and the conclusion is not yet consistent. Consequently, our hypothesis is that a non-supervised physical therapy exercise program at home be just as effective as a supervised program performed similarly.

The purpose of this randomized trial was to compare the effectiveness of supervised exercise physical therapy program versus non-supervised on

pain, functionality outcome (disability, strength and endurance muscular, and range of trunk anteflexion motion), fear of movement and quality of life in patients with chronic non-specific low back pain.

Methods

We performed a randomized double-blind clinical trial with concealed allocation, intention-to-treat analysis and assessor and statistic researcher masked to treatment allocation. The clinical trial was conducted to compare the effects of an exercise physical therapy program between two groups: supervised versus non-supervised. This study was performed at the Clinical Unit of the Health Sciences School of the Almeria University (Spain), between 1 February 2018 and 1 November 2018. The study was approved by the institutional ethics and research committee of the Almeria University. The trial was adhered to the guidelines established by the Helsinki Declaration and was registered on clinicaltrials.gov (NCT03420196).

A total of 100 participants with chronic non-specific low back pain were recruited and evaluated by two therapists with more than six years of clinical experience at the Faculty of Health Sciences of the University of Almeria (Spain) based on predefined inclusion and exclusion study criteria. Chronic non-specific low back pain is defined as pain that cannot clearly be attributed to a specific pathology, and it is characterized by pain or localized tension between the lower edge of the rib cage and the sacrum that persists for three months or more.

Participants were considered for the study if they had the following inclusion criteria: (1) persistent non-specific chronic low back pain ⩾three months, (2) aged between 18 and 65 years because of limitations in the recruitment of the sample size, (3) score of ⩾4 on the Roland–Morris Disability Questionnaire (RMQ) and (4) not receiving any other physiotherapy treatment.

Exclusion criteria were as follows: (1) presence of lumbar stenosis, (2) presence of clinical signs or symptoms of radiculopathy, (3) diagnosis of spondylolisthesis, (4) diagnosis of fibromyalgia, (5) treatment with corticosteroids or other drugs in the previous two weeks, (6) history of spinal surgery and (7) presence of central or peripheral system pathology (i.e. stroke, peripheral nerve etc.).

The sample size was calculated according to Ene 3.0 software (Autonomous University of Barcelona, Spain). The calculations were based on the detection differences of 2.5 points in the RMQ (MCID (minimal clinically important difference)) (estimated for a variance in patients with chronic low back pain of 10 points),[15] assuming a standard deviation (SD) of 2.5 points, a two-tailed test, an alpha (α) level of 0.05, and a desired potency (beta) of 80%. The estimated desired sample size has been calculated in 32 subjects per group. Subjects were advised to refrain from medications, alcohol, physical therapy treatment and heavy physical activities for at least 12 hours prior to the test. After giving their informed consent, patients carried out an initial examination, data were collected, including self-reported outcome measures. Following the baseline examination, patients were randomly assigned to receive supervised physical therapy exercise (control group) or non-supervised physical therapy exercise (experimental group). Concealed allocation (ratio 1:1) was performed using a 64 cards printed and placed in opaque envelopes for randomization/allocation process created prior to the start of data collection by a researcher who was not involved in either recruitment or treatment of patients. Of these, 32 cards contained the word "supervised" and 32 the word "non-supervised." After performing the baseline evaluation, patients chose an envelope at random containing the name of their assigned group.

The nature of the intervention did not allow blinding of physical therapist and participants. Consenting participants were randomly assigned in two groups to receive physical therapy by core exercise through a supervised (face-to-face) or non-supervised program (at home). Both groups will perform three sessions per week, to complete a total of 24 sessions over eight weeks. The duration of the sessions ranged from 30 to 35 minutes. Patients had performed 90% of their scheduled treatment sessions to be considered and remained in the intention-to-treat analysis. The details of the interventions are provided below. These exercises were based on the study by Hodges[16] and Jeong

et al.[11] Two experienced physical therapists were trained by a researcher of study to provide the same orders to the participants.

Supervised core exercise group

This group received supervised exercise program conducted by a physical therapist. The exercise program consisted mainly of three types: stability and control motor pelvic exercise, trunk muscle strengthening and stretching. The exercise included different sit-up exercises for trunk flexor muscles and an extension exercise for trunk extensor muscles. The latter was performed to stretch abdominal and back muscles. The following exercises were performed (Supplementary Appendix 1 includes photographs and descriptions of the exercises performed):

1. Diaphragmatic breathing technique (for 2–3 minutes).
2. Activation of the transverse abdominal muscle (3×15 repetitions).
3. Pelvic girdle (3×15 repetitions).
4. Glute bridge (3×15 repetitions).
5. Erector spinae strengthening (Prone Superman) (3×8^{-10} repetitions).
6. Front plank (3×30 seconds).
7. Side plank (3×30 seconds for each side).
8. Lateral leg-raise for gluteus medius (3×10^{-15} repetitions).
9. Spinal column mobility (Quadruped Cat Camel exercise) (3×10 repetitions).

The program was guided by an experienced physiotherapist with the help of a PowerPoint presentation that showed the exercises. Also, the therapist instructed the patients about appropriate body mechanics. Patients underwent three treatment sessions per week for a total of 8 weeks at Health Sciences School of Almeria University.

Non-supervised home exercise group

The patients in the home exercise group underwent a baseline evaluation and attended one 1-hour session with a physical therapist. The non-supervised home program focused performing same exercises as the supervised group (Supplementary Appendix 1): (1) diaphragmatic breathing technique; (2) activation of the transverse abdominal muscle; (3) exercises to improve pelvic stability; (4) strength exercises for lower back, abdominal, and gluteus medius; (5) exercise of mobility and flexibility of the spine. The program was individualized in terms of patients' abilities, tolerance and availability to perform them throughout the day.

The instructions for patients to perform the exercises on their own were delivered and explained one by one by a therapist. Patients were instructed to do 10 to 15 repetitions of each exercise in the series, once a day and three times per week for a total of eight weeks. A booklet and laminated cards with detailed photographs of each prescribed exercise were provided.

Home exercise program adherence was defined as having performed the exercises three times each week for at least eight weeks; in order to control adhesion, the participants were instructed to take note on the booklet of the dates when the sessions were carried out all weeks.

All 64 subjects provided clinical and demographic information (Table 1), completed a number of self-report measures and underwent a physical examination by the same assessor blinded to treatment of the participants at baseline, immediately after treatment (at week 8) and six months of follow-up (Figure 1).

Subjects also filled out the RMQ for assessing disability;[17] Oswestry Disability Index to measure daily life activity limitations;[18] the Visual Analogue Scale for assessing the intensity of pain, and the subjects were asked to rate their pain level for the last 24 hours;[19] Tampa Scale for Kinesiophobia to assess fear of movement;[20] and the SF-36 health questionnaire to assess self-perceived health-related quality of life.[21,22] Also, the evaluation performed included the range of trunk anteflexion motion and muscular endurance. Lumbar flexion was evaluated by measuring the distance achieved in the fingertip-to-floor test,[23] and the isometric resistance of abdominal muscles was evaluated by the McQuade test.[24]

The data collected from each patient were stored in closed locker, and only the evaluator had access

Table 1. Demographic characteristics of subjects.

Variable	Supervised group ($n=32$)	Non-supervised group ($n=32$)	P value
Gender (m/f)	15/17	17/15	0.624
Age (years)	54.3 ± 7.9	53.2 ± 8.0	0.583
Time with pain (months)	53.2 ± 9.0	51.5 ± 8.9	0.446
Education level (%)			0.652
No studies	8/32 (25%)	8/32 (25%)	
School level	8/32 (25%)	10/32 (31.33%)	
Bachelor level	8/32 (25%)	8/32 (25%)	
University level	8/32 (25%)	6/32 (18.8%)	

Values are mean ± standard deviation.

to that information. Later, data were entered and saved on a laptop with password protection to maintain confidentiality, and only the researcher who performed the statistical analysis had access.

After completing the intervention and collecting all data, the statistical analysis was performed using SPSS v.23, and it was conducted following intention-to-treat analysis by a researcher blinded to treatment allocation who were not external to the investigation. Mean, SD, and/or 95% confidence intervals (CI) were calculated for each variable. The Kolmogorov–Smirnov test showed a normal distribution of the data for all baseline variables ($P > 0.05$). The primary outcome measure was the change in the RMQ score at the end of the eight weeks of study period. A difference of 2.5 points is considered to be the MCID in the RMQ score.

Baseline demographic and clinical variables were examined between both groups by independent Student's t test for continuous data and χ^2 tests of independence for categorical data. Separate 2×3 mixed model analysis of variance (ANOVA) with time (baseline, immediately and six months after last session) as the within-subjects factor, group (exercise supervised program or non-supervised home program) was used to determine the effects of the treatment. Effect size was test using Cohen's d. An effect size <0.2 reflects a negligible difference, between $\geqslant 0.2$ and $\leqslant 0.5$ a small difference, between $\geqslant 0.5$ and $\leqslant 0.8$ a moderate difference and $\geqslant 0.8$ a large difference. A P value less than 0.05 was considered to indicate a statistically significant difference.

Results

For this randomized trial, a total of 100 ($n=100$) patients with low back pain were screened for eligibility. In all, 64 patients (mean age ± SD: 54 ± 7.88; 50% female) who fulfilled all the inclusion criteria and agreed to participate were randomized to either the supervised ($n=32$) or non-supervised ($n=32$) physical therapy exercise group. Of all subjects, a quarter (25%) had basic education, 28.1% had completed secondary education, 25% had upper secondary-level education and 21.9% had university studies. No patients presented mental disorders or depression/anxiety. Reasons for exclusion are shown in Figure 1, which is a patient recruitment and inclusion flow chart.

Overall, adherence to study interventions was high with 95% of the supervised group, 92% of the non-supervised group, attending the predefined compliance threshold (90% of their treatment visits). Baseline parameters for all variables were similar in both groups at the start of the study (Table 1). All two groups completed good outcomes during the 32-week treatment period. Consistent trends were observed for all outcomes, the supervised group and non-supervised home group performing similarly, although with greater reduction in the supervised group. However, the only outcome measures showed that statistically significant differences between groups were pain and the general health dimension of the SF-36. Tables 2 and 3 display mean values for all patient-rated outcome measures at each time point.

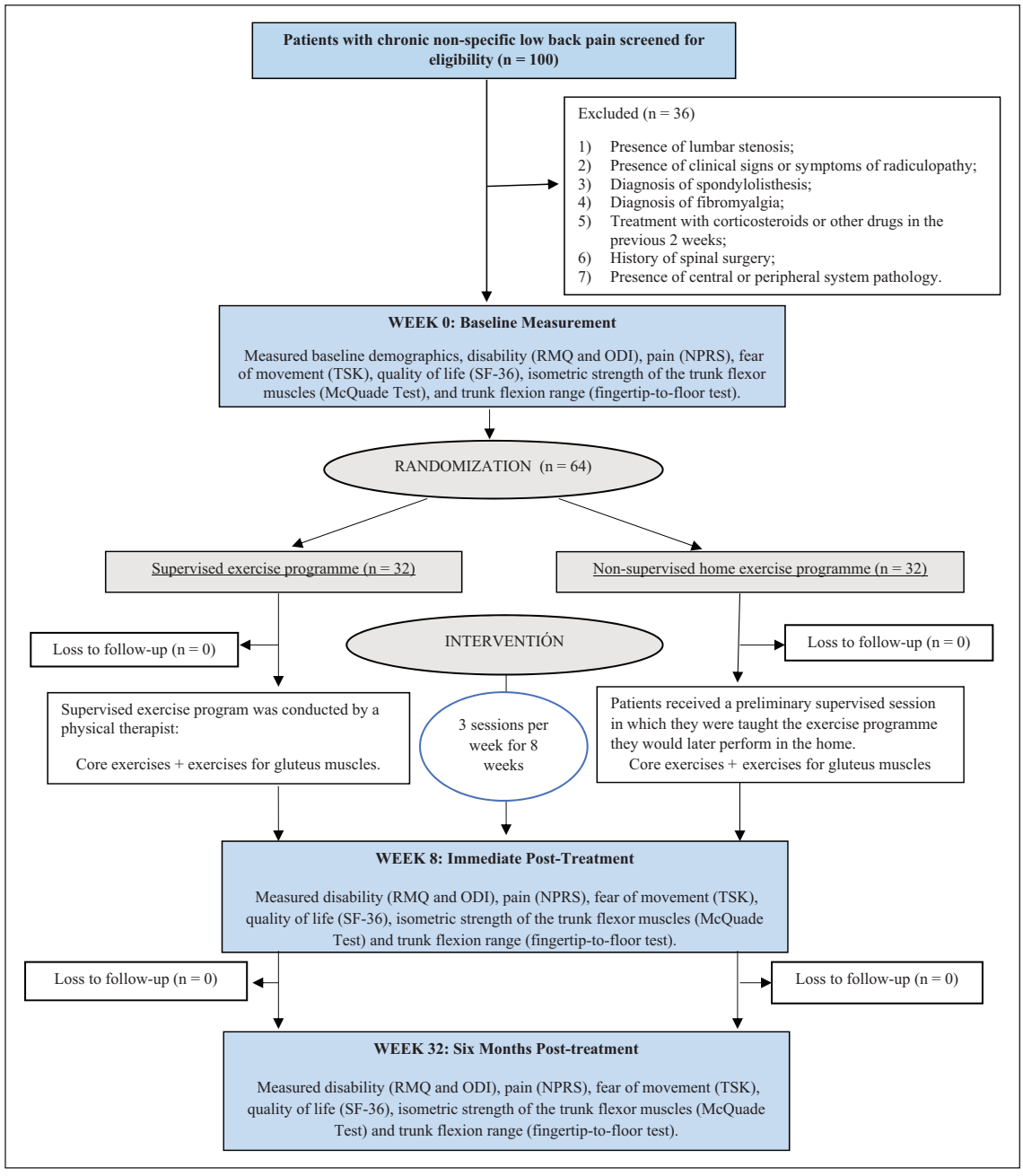

Figure 1. Design and flow of participants through the trial.
RMQ: Roland–Morris Low Back and Disability Questionnaire; ODI: Oswestry Disability Index; VAS: Visual Analogue Scale; TSK: Tampa Scale for Kinesiophobia.

Table 2. Changes baseline, posttreatment and six months of follow-up for disability, pain, fear of movement, isometric strength of abdominal muscles and mobility in lumbar flexion.

Outcome/group	Supervised	Non-supervised	Mean differences and CI between groups over time	*P* value	Cohen's *d*
		Self-reported measures			
		RMQ (0–24)			
Baseline (Week 0)	8.2 ± 2.7	9.9 ± 2.8	−1.7 (−3.1, −0.4)	0.014	
Posttreatment (Week 8)	3.1 ± 2.2	5.1 ± 3.0	−2.0 (−3.3, −0.7)	0.004*	0.65*
Follow-up (Week 32)	3.0 ± 2.9	4.9 ± 3.0	−1.8 (−3.3, −0.4)	0.016*	0.53*
		ODI (0–50)			
Baseline (Week 0)	28.1 ± 7.5	28.4 ± 8.9	−0.3 (−5.4, 2.8)	0.526	
Posttreatment (Week 8)	14.5 ± 7.1	19.2 ± 10.0	−4.7 (−9.1, −0.4)	0.034	0,47
Follow-up (Week 32)	15.9 ± 7.8	20.0 ± 8.7	−4.1 (−8.2, 0.0)	0.051*	0.41
		VAS (0–10 points)			
Baseline (Week 0)	5.6 ± 1.8	5.2 ± 1.8	0.4 (−0.4, 1.3)	0.332	
Posttreatment (Week 8)	2.5 ± 2.1	3.5 ± 1.5	−1.0 (−1.9, −0.1)	0.028*	0.43
Follow-up (Week 32)	2.2 ± 2.0	3.2 ± 2.0	−1.0 (−2.0, 0.0)	0.055	0.41
		TSK (17–68)			
Baseline (Week 0)	42.3 ± 7.5	41.2 ± 7.7	1.1 (−2.6, 4.9)	0.545	
Posttreatment (Week 8)	41.6 ± 5.4	40.3 ± 6.7	1.3 (−1.7, 4.4)	0.382	0.18
Follow-up (Week 32)	42.0 ± 6.8	40.3 ± 5.6	1.7 (−1.4, 4.8)	0.289	0.22
Physical outcomes					
		McQuade test (seconds)			
Baseline (Week 0)	45.0 ± 21.8	52.9 ± 25.6	−7.9 (−19.8, 3.9)	0.187	
Posttreatment (Week 8)	62.8 ± 23.9	63.8 ± 24.3	−1.0 (−13.1,11.1)	0.869	0.03
Follow-up (Week 32)	59.3 ± 21.6	65.6 ± 23.3	−6.3 (−17.1, 4.9)	0.266	0.23
		Finger-to-floor distance (cm)			
Baseline (Week 0)	15.2 ± 8.6	18.4 ± 7.6	−3.2 (−7.2, 0.9)	0.123	
Posttreatment (Week 8)	11.2 ± 10.2	14.9 ± 9.2	−3.7 (−8.5, 1.2)	0.137	0.19
Follow-up (Week 32)	11.1 ± 10.2	13.6 ± 9.8	−2.5 (−7.5, 2.5)	0.326	0.20

Values are expressed as mean ± standard deviation for immediate posttreatment and six months of follow-up and as mean (95% confidence interval) for between-group change scores. CI: confidence interval; RMQ: Roland–Morris Low Back and Disability Questionnaire; ODI: Oswestry Disability Index; VAS: Visual Analogue Scale; TSK: Tampa Scale for Kinesiophobia.
*$P < 0.05$—significant ANCOVA adjusted from baseline values for differences among group.

At all follow-up periods, ANOVA test showed no statistically significant differences between groups for main outcome measure. However, the RMQ showed significant differences within groups with a consistent linear regression (supervised group: $P < 0.001$; non-supervised group: $P < 0.001$). In addition, patients in the supervised program showed greater reduction in disability scores (change score: 5.2) than those who were not supervised (change score: 5.0) (Table 2).

No significant differences between groups were found for Oswestry Disability Index, but an ANOVA test showed significant intra-group differences in both groups ($P < 0.001$). But a greater improvement in Oswestry Disability Index was found in subjects in the supervised exercise group (change score: 12.2) compared with the non-supervised exercise group (change score: 9.4) at six months of follow-up (Table 2).

The only outcome measures for which ANOVA showed statistically significant differences between groups were pain ($P = 0.010$) and the general health dimension of the SF-36 ($P = 0.002$) at six months. Significant differences were found within group

Table 3. Changes baseline, posttreatment and six months of follow-up of quality of life SF-36.

Outcome/group	Supervised	Non-supervised	Mean differences and CI between groups over time	*P* value	Cohen's *d*
Quality of life SF-36 questionnaire					
Physical function					
Baseline (Week 0)	73.4 ± 13.2	68.7 ± 23.5	4.7 (−4.8, 14.2)	0.330	
Posttreatment (Week 8)	84.4 ± 11.0	79.2 ± 17.3	5.2 (−2.1, 12.4)	0.159	0.32
Follow-up (Week 32)	79.8 ± 12.3	77.8 ± 18.6	2.0 (−5.9, 9.9)	0.609	0.11
Physical role					
Baseline (Week 0)	52.9 ± 21.2	42.9 ± 34.3	10.0 (−4.3, 24.3)	0.167	
Posttreatment (Week 8)	75.8 ± 28.0	65.5 ± 38.4	10.3 (−6.5, 27.1)	0.224	0.26
Follow-up (Week 32)	72.7 ± 28.7	68.0 ± 41.3	4.7 (−13.1, 22.4)	0.600	0.11
Body pain					
Baseline (Week 0)	49.4 ± 16.8	50.6 ± 23.7	−1.2 (−11.5, 9.0)	0.809	
Posttreatment (Week 8)	74.1 ± 15.6	74.8 ± 25.3	−0.6 (−11.1, 9.9)	0.906	0.03
Follow-up (Week 32)	70.9 ± 13.9	69.8 ± 27.4	1.1 (−9.8, 12.0)	0.841	0.05
General health					
Baseline (Week 0)	60.5 ± 13.7	54.4 ± 16.5	6.1 (−1.5, 13.7)	0.114	
Posttreatment (Week 8)	61.7 ± 17.3	62.5 ± 16.4	−0.8 (−9.2, 7.6)	0.853	0.04
Follow-up (Week 32)	58.7 ± 13.7	61.7 ± 18.1	−3.0 (−11.0, 5.1)	0.462	0.16
Vitality					
Baseline (Week 0)	53.3 ± 15.2	51.2 ± 12.7	2.1 (−4.9, 9.0)	0.564	
Posttreatment (Week 8)	58.8 ± 15.8	58.1 ± 19.4	0.6 (−8.2, 9.5)	0.888	0.03
Follow-up (Week 32)	60.2 ± 15.2	56.7 ± 17.7	3.4 (−4.8, 11.7)	0.407	0.18
Social functioning					
Baseline (Week 0)	78.5 ± 16.3	75.4 ± 21.9	3.1 (−6.5, 12.8)	0.519	
Posttreatment (Week 8)	82.8 ± 16.7	77.3 ± 25.3	5.5 (−5.2, 16.2)	0.312	0.22
Follow-up (Week 32)	84.1 ± 15.2	78.7 ± 17.8	5.4 (−2.9, 13.7)	0.198	0.27
Mental health					
Baseline (Week 0)	64.2 ± 14.5	71.1 ± 19.4	−6.9 (−15.5, 1.6)	0.110	
Posttreatment (Week 8)	69.4 ± 13.5	72.8 ± 20.7	−3.4 (−12.1, 5.3)	0.442	0.17
Follow-up (Week 32)	69.9 ± 13.3	72.6 ± 19.2	−2.7 (−11.0, 5.6)	0.523	0.14
Emotional role					
Baseline (Week 0)	78.3 ± 20.1	80.2 ± 38.7	−1.9 (−17.4, 13.6)	0.804	
Posttreatment (Week 8)	77.1 ± 33.3	82.3 ± 31.7	−5.2 (−21.4, 11.0)	0.523	0.13
Follow-up (Week 32)	74.8 ± 38.5	77.1 ± 38.3	−2.3 (−21.5, 16.9)	0.812	0.05

Values are expressed as mean ± standard deviation for immediate posttreatment, and six months of follow-up, and as mean (95% confidence interval) for between-group change scores. CI: confidence interval.

comparison. For intensity of pain, the MCID is ⩾2 for clinical improvement (supervised group change score: 3.1 posttreatment, and 3.4 at follow-up; non-supervised group change scores 1.7 posttreatment, and 2.0 at six months).

The ANOVA analysis did not find significant intra- or inter-group differences in the fear of movement, or in the Social Functioning and Emotional Role dimensions of the SF-36 questionnaire. For fear of movement, the change score in supervised group was 0.7 immediately posttreatment, and 0.4 at six months of follow-up, while it was 0.9 immediately posttreatment, and 0.9 at six months of follow-up in non-supervised group. This shows a minimal

improvement for this outcome measure in both groups and slightly greater in non-supervised group.

The McQuade test showed significant differences in supervised group ($P=0.002$) only, with a change score of 14.3 at six months of follow-up. The fingertip-to-floor distance test showed significant intra-group differences in supervised group ($P=0.001$) and non-supervised group ($P=0.002$) (Table 2).

In reference to quality of life, ANOVA analysis only showed significant differences between groups in the SF-36 general health dimension ($P=0.002$) at six months of follow-up. For the other dimensions, statistically significant change scores were found in supervised group for physical functioning ($P=0.001$), physical role ($P=0.001$), bodily pain ($P=0.001$), vitality ($P=0.032$) and mental health ($P=0.027$). In addition, non-supervised group showed statistically significant scores for physical functioning ($P=0.001$), physical role ($P=0.037$), bodily pain ($P=0.001$) and general health ($P=0.006$). Table 3 illustrates the mean group differences.

Discussion

The results of this randomized clinical trial suggest that the supervised group and non-supervised group had similar effects for pain, functionality, fear of movement and quality of life. Both groups were not significantly different in terms of any patient-rated outcomes, suggesting that it is not necessary for patients with non-specific chronic low back pain to attend for supervision of physical therapy, which could reduce the socioeconomic costs.

Although this study cannot draw any conclusions about the benefit of exercise because you did not have a control group without exercise to compare with the other two groups, the core exercises are commonly used in the treatment of low back pain, getting good results.[25–27] A review study that compared this kind of exercise with general exercise concluded that core exercises were more effective in alleviating pain in patients with chronic low back pain. The authors observed significant differences between groups, with a reduction of pain (main difference: −1.29) and disability (main difference: −7.14) immediately after treatment, but not at six months of follow-up.[8]

For acute low back pain, it does not seem to have a difference between methods of treatment; however, in chronic conditions (duration >12 weeks), the therapies in which the patient is actively involved seem to achieve a more lasting effect and better relieve pain. Therefore, given available evidence,[27,28] we decided to include in our exercise program the core exercises, together with other exercises that we considered necessary in low back pain, as are the exercises for gluteus muscles.

Numerous studies have found a relationship between gluteus muscles and pelvis stabilization, its activity seems to influence during the flexion–extension cycle of the lumbar spine.[11,29,30] Amabile et al.[30] in his study found a correlation between women with low back pain and gluteus maximus atrophy. Another study that included gluteus muscle strengthening plus lumbar stabilization exercises, the Oswestry Disability Index score changed almost double (9.9 ± 3.2 points) in the gluteus strengthening + lumbar stabilization group in comparison with the lumbar stabilization group alone (4.5 ± 2.4). The gluteus strengthening + lumbar stabilization group also achieved greater improvement in isometric lumbar flexion strength, 23.7 ± 17.4, compared with the lumbar stabilization group, with a mean difference of 14.5 ± 9.8.[11]

The exercises used in this study appear to have provided satisfactory results; however, the variety of exercise types, program designs, delivery methods, and dosages evaluated for chronic low back pain makes it difficult to compare our results with other studies. The most comparable study is an earlier trial performed by Bronfort et al.,[14] in which the supervised trunk exercise, spinal manipulation and home exercise unsupervised were compared. That study found results very similar to ours, the patients with chronic low back pain who received supervised trunk exercise were experimented improvements in both the short and long term in patient-rated pain, disability, general health status and trunk strength and endurance over the other groups, but as in our study, the differences were relatively small and not statistically significant. However, these findings are contradictory to

those found in a study conducted on neck pain in which home exercise, exercise therapy combined with spinal manipulation therapy and supervised exercise therapy alone were compared, and it was found that supervised strengthening exercise with and without spinal manipulation gave better outcomes than home exercise particularly in the short term.[31] These results could have been because authors did not measure patients' long-term adherence with exercise and thus do not know whether that affected outcomes.

For fear of movement, we did not find significant within or between groups differences. This measure has not been evaluated in similar studies comparing supervised and non-supervised exercise.[13,31,32] We think that it is an important measure since it is a psychological aspect which can affect compliance with the exercise program.

Both the supervised exercise group and the non-supervised home exercise group did benefit from a specific core stability exercises program based on muscle force, control motor, functional mobility and flexibility. We believe that an important factor that could have influenced these results was the follow-up of the participants who performed the physical therapy exercise at home. We used a booklet where the non-supervised group had to record when they performed the sessions throughout the week. This factor made it possible to maintain compliance with treatment at home and improve results, how it has been shown in similar studies.[32] Since all participants performed the same exercises with the same criteria and any group failed sessions scheduled (90%), this improved the outcomes in both groups.

A limitation of the study is the lack of blinding of patients and physical therapists, which is not feasible in exercise therapy clinical trials, even less when a group performs exercise therapy at home. However, our trial was designed to the patients in all two groups that had the same expectations of improvement for supervised exercise and non-supervised exercise, since the exercise program is the same. That sets it apart from other studies, in which there are significant differences between groups, because the home exercise group was given a minimal intervention of low-dose exercise, only so that it could serve as a control.[31] Another limitation is no control group without intervention, which do not allow us to know the impact of the attentional influence on the outcomes—especially pain or the true adherence or effort in the home exercise program.

In conclusion, our results suggest that the supervision conferred little additional benefit compared with the non-supervision. The supervised group exercise is effective at improving endurance, pain intensity, functional mobility, flexibility and quality of life, whereas non-supervised home exercise was found to be effective in the same variables but slightly worse. Our hypothesis has been confirmed and the exercises employed in this study provided satisfactory results in both groups; this study gave us a scientific evidence to support exercise physical therapy for patients with chronic non-specific low back pain. Therefore, given the economic advantages and the ease of participation, we suggest that non-supervised physical therapy exercises may be preferable to the supervised.

Future clinical trials are needed to investigate the cost-effectiveness of these approaches (supervised and non-supervised exercise), as well as other studies investigating the individual preferences related to supervised exercise programs and exercises at home and its relationship with program adherence. It would also be important to ask physical therapists if they feel prepared to follow up remotely and if they trust their patients to do the exercise program at home.

Clinical Messages

- Supervised physical therapy exercises are statistically superior to non-supervised home program for improving pain, functionality, fear of movement or quality of life of patients with non-specific chronic low back pain.
- But the difference between supervised and non-supervised exercises was relatively small, not worth the extra effort involved.

Authors' Note

The results of the study are presented clearly, honestly, and without fabrication, falsification or inappropriate data manipulation.

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Author Contributions

I.C.L.P., G.A.M-P., A.M.C-S., M.F-S. and E.A.S. contributed to conception and design, draft of article, critical revision for important intellectual content critical and final approval of the version to be published. E.G-M. and M.E.A-F. to analysis and interpretation of the data.

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Supplemental Material

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PAPER II

COMPARING AN E-HEALTH PROGRAM VS HOME REHABILITATION PROGRAM IN PATIENTS WITH NON-SPECIFIC LOW BACK PAIN: A STUDY PROTOCOL RANDOMIZED FEASIBILITY TRIAL.

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Study Protocol

Comparing an e-Health program vs home rehabilitation program in patients with non-specific low back pain: A study protocol randomized feasibility trial

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Abstract.
BACKGROUND: There is little evidence on the reliability of the web application-based rehabilitation systems to treat chronic low back pain (CLBP).
METHODS: This protocol describes a double-blind, randomized controlled feasibility trial of an e-Health intervention developed to support the self-management of people with CLBP in primary care physiotherapy. Three Hospitals with primary care for outpatients will be the units of randomisation, in each Hospital the participants will be randomized to one of two groups, a pragmatic control group receiving either the usual home program based on electrostimulation and McKenzie Therapy and e-Health intervention. Patients are followed up at 2 and 6 months. The primary outcomes are (1) acceptability and demand of the intervention by GPs, physiotherapists and patients and (2) feasibility and optimal study design/methods for a definitive trial. Secondary outcomes will include analysis in the clinical outcomes of pain, disability, fear of movement, quality of life, isometric resistance of the trunk flexors, lumbar anteflexion and lumbar segmental range of motion.
DISCUSSION: The specific e-Health programs to home could increase adherence to treatment, prevent stages of greater pain and disability, and improve the painful symptomatology.
CONCLUSIONS: The e-Health programs could be an effective healthcare tool that can reach a large number of people living in rural or remote areas.

Keywords: Low back pain, chronic disease, e-Health, home exercise, randomised controlled trial

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1. Background

Non-specific low back pain (LBP) is one of the most common health problems worldwide and is the leading cause of years suffering from a disability in western countries [1]. Non-specific LBP is characterized by

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a mechanical pain of musculoskeletal origin, with no defined cause, which lasts more than 12 weeks [2,3].

The most recent review in the adult general population estimated the global point prevalence at 11.9%, the monthly prevalence at 23.2%, and the annual prevalence at 38%, being greater in females and individuals aged between 40 to 80 years [4,5]. In Spain, LBP ranks first among the causes of temporary disability in the population over 50 years of age [6]. Furthermore, as the population ages over the coming decades, it is more than likely that the number of people with non-specific LBP will increase significantly.

In European countries, the total cost of LBP has been estimated at 1.7% to 2.1% of gross domestic product [6, 7], since it is among the health problems responsible for the majority of sick leave and the top five most expensive disorders of the musculoskeletal system [8,9]. In Spain, LBP accounts for over 2 million visits to a Primary Care Center (PCC) per year [9].

Although the European international guidelines recommend non-pharmacological treatments for chronic musculoskeletal conditions [10–12], the health services require strong evidence of their clinical and profitability before the implementation of widespread rehabilitation programs.

Several possible interventions exist for the treatment and management of LBP, including exercise, patient education, manual therapy and electrotherapy; these are often used alone or combined [10,13–18].

Transcutaneous electrical nerve stimulation (TENS) is an inexpensive non pharmacological intervention used in chronic pain conditions. The research evidence, TENS reduces hyperalgesia through both peripheral and central mechanisms, reducing the need for medication in these patients [19,20]. However, the different systematic reviews have examined the efficacy of TENS for low back pain with conflicting results [21–28].

Also exercises are recommended in all guidelines for chronic LBP; these determine that patients with chronic LBP should exercise and maintain a physically active lifestyle [2,13]. The specific back exercise programs have been found to be moderately effective in reducing pain and improving function in chronic LBP, especially if programs are individually designed/tailored and supervised by a physiotherapist [16,17].

The McKenzie Therapy (MT) is a treatment in which exercise is prescribed individually based on the classification made of patients with low back pain [29]. This method of diagnosis and mechanical therapy associated with an educational component has been considered a more effective intervention in reducing pain and disability than other standard therapies in the short term [30–32]. However, the availability of secondary rehabilitation centers in the public health system could be insufficient to meet the demand of these patients in a supervised way [33].

The interventions performed electronically have been shown to be effective in patients with chronic musculoskeletal disease [34], since they can provide educational information beyond traditional paper-based media, such as audio and video material that patients can consult at any time. This facilitates goal setting, adherence, self-monitoring and behavioral and symptom-related feedback [35–38]. Also, the studies suggest that interventions supported by virtual materials are more accessible to patients than many traditional face-to-face services [38,39].

These data lead us to believe that patients who have the support of an online platform to perform the intervention at home, have the potential to obtain greater adherence and long-term effects than those who perform the same physiotherapy intervention without supervision in the home and without computerized support. There is also the need to explore the effectiveness, adherence, usefulness and support of interventions in primary care supported by an online platform designed exclusively for patients with chronic LBP.

The aim of this randomized controlled trial is to evaluate the feasibility of providing an e-Health rehabilitation program through a web platform performing electroanalgesia and an exercise program following the MT for patients with chronic LBP in primary care, compared with the same home rehabilitation program but without the support of an electronic program.

2. Objectives

Our primary objectives are: (1) to evaluate the acceptability and demand of the e-Health intervention for patients and physiotherapists for the optimization of their design, development and delivery; (2) to analyze the feasibility of the trial procedures. See Table 1 below for details on feasibility aspects.

The secondary objectives are: (3) to assess medium-term changes in pain intensity, disability, fear of movement, quality of life, resistance of the trunk flexors, lumbar segmental range of motion in both arms.

3. Materials and methods

This randomized controlled feasibility trial with an allocation ratio 1:1, double-blind, clinical trial divided

Table 1
Feasibility aspects related to e-Health intervention and trial procedures

Feasibility	e-Health intervention	Trial procedures
Acceptability		
Participants	The extent to which participants who have received the intervention through a web application consider that the content and support materials (web application and initial learning sessions) are appropriate and satisfactory to obtain the expected results.	The extent to which participants believe that their eligibility, outcome measures, follow-up and intervention by the physiotherapist have been satisfactory.
Physiotherapists	The extent to which the physiotherapists who have administered the intervention consider that the training, content and support materials are appropriate to meet their needs and those of their patients within the primary care service.	The extent to which physiotherapists who have participated in the trial consider recruitment, outcome measures, evaluation follow-ups and appropriate and satisfactory intervention procedures.
General practitioners		The extent to which the GPs who have carried out the first screening of patients, consider that the eligibility criterio and recruitment are suitable for detecting the potential sample.
Demand		
Participants	The extent to which participants adhere to the e-Health intervention, complying with the weekly sessions.	The extent to which participants perceive the burden of participating in follow-up and completing specific outcome measures within the trial.
Physiotherapists	The extent to which physiotherapists perceive the demand to complete their tasks required to participate in the trial, including intervention procedures.	The extent to which physiotherapists perceive the demand of completing their required tasks for participating in the trial.
Practicality		
Physiotherapists		The factors that influence the implementation of the e-Health intervention in a variety of health environments due to variations in personnel, facilities, equipment and the environment.
Adaptation		
Participants	The extent to which the content of the e-Health intervention, support materials and learning classes should be modified to improve their acceptability and implementation for a future definitive trial	The extent to which recruitment, follow-up procedures and the number and outcome measures should be modified during/at the end of the trial to improve its acceptability and implementation for a definitive future trial.
Physiotherapists	The extent to which the e-Health intervention training, the content of the program, the classes previously conducted for its learning and the support materials (web application) should be modified during/at the end of the test to improve its acceptability and implementation for a definitive future proof.	The extent to which the recruitment and fidelity procedures of the trial, including the tasks of physiotherapists, should be modified during/at the end of the trial to improve the acceptability and implementation of a definitive future trial.

into two groups (Fig. 1) was designed to assess the methodology proposed for use in a definitive RCT. This study protocol followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) Guidelines (Additional file 1) [40]. The trial was registered under registration number: NCT04283370.

The GPs of three Hospital Centers (HC) of the Andalusian Health Service that include physical therapy in primary care for outpatients have agreed to participate. These HCs are publicly financed and include the metropolitan areas of Southern Spain.

3.1. Participants

A Consolidated Standards of Reporting Trials (or CONSORT) [40] flow diagram is provided in Fig. 1. Eligible participants are intentionally selected by GPs according to the eligibility criteria provided by the research team.

The inclusion criteria will be: individuals of both genders aged between 30 and 67 years old; presenting with low back pain for at least 3 months; low back pain disability $\geqslant 4$ on the Roland-Morris Disability Questionnaire (RMQ); and not receiving any other physiotherapy treatment are eligible for inclusion. Subjects will be excluded if they: have any contraindications for MT exercise or electroanalgesia; presence of clinical signs of radiculopathy; medical diagnosis of spondylolisthesis, spinal stenosis or fibromyalgia; inflammatory or metabolic disease; central or peripheral system pathology (i.e., stroke); history of spinal surgery; or treatment with drugs in the previous 2 weeks.

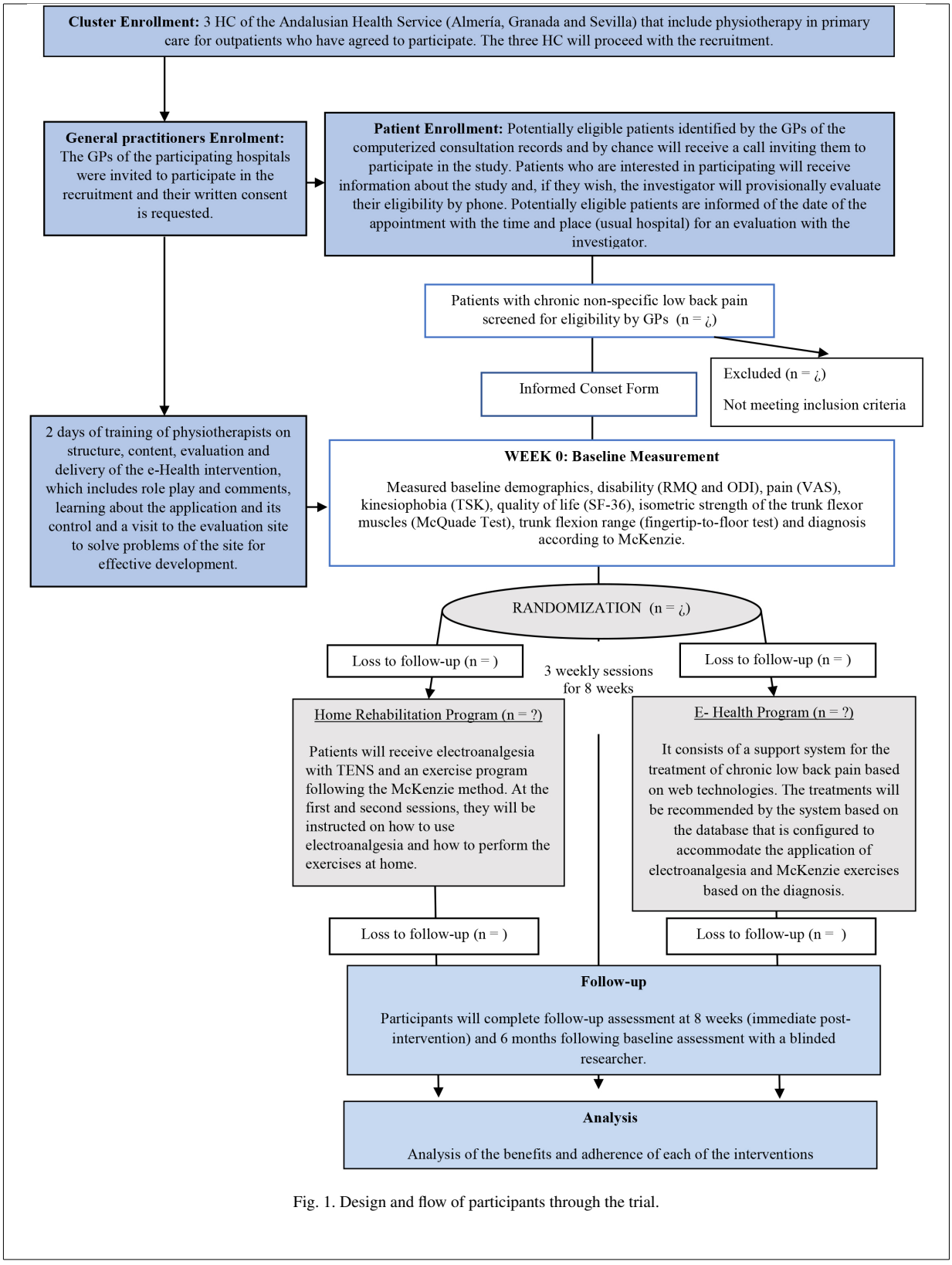

Fig. 1. Design and flow of participants through the trial.

3.2. Randomization

The computer software (Epidat 4.2) will automate the randomization process for this trial. The randomization sequence is automatically generated, using a table of random numbers generated by the software, which randomizes participants to each intervention group. As the software randomizes participants, a researcher will inform the participants about their assignment. The feasibility protocol will remain blind to the assignment until the full analysis is completed.

3.3. Interventions

Consenting participants will be randomly assigned in two groups to receive electro-analgesia therapy with TENS and MT exercise through an e-Health program (telemedicine) or through a home rehabilitation program. Within both groups, patients will be distributed in three subgroups (postural, dysfunction and disorder) according to the therapeutic classification of MT. Both groups will perform three sessions per week, to complete a total of 24 sessions over eight weeks.

3.3.1. Home rehabilitation program

It consists of a home rehabilitation program. Participants will receive TENS and an exercise program following the MT. At the first and second sessions, 1-hour per session, patients will be instructed by a RPT on how to use electroanalgesia and how to perform the exercises.

Each participant will be instructed in the use of a portable TENS (TENStem eco basic, schwa-medico Medizinische Apparate Vertriebsgesellschaft mbH, Wetzlarer/35630/Ehringshausen, Deutschland) of low frequency, high phase duration (80 Hz/200 μs) and setting at a strong but comfortable intensity (below the pain threshold), which generate a non-painful tingling sensation. The intensity used will depend on the tolerance of the patient, likewise, when an accommodation of the sensation of the current occurs, the intensity will be increased again. Four electrodes (5 $\times$ 9 cm) will be applied directly in the lumbar paravertebral level bilateral [41]. The electrostimulation treatment will be applied simultaneously to the performance of the exercises [28].

The exercise program will be individualized according to the results obtained in the initial evaluation, and which consists of the following exercises (Fig. 2):

Patients with Postural Syndrome: exercises 1, 2 and 3.

Patients with Dysfunction Syndrome: exercises 3, 6 and 7.

Patients with Disorder Syndrome (DS): according to the dysfunction syndrome, the following exercises are established for each subgroup:

- DS 1: exercises 1-4 and 6, with extension in recumbency.
- DS 2: the exercises will begin in the prone position and patients will continue with the DS1 protocol and exercise 5.
- DS 3: DS1 protocol, exercise 7 and rotation maintained for 2 minutes.
- DS 4: exercise 7, exercise 2 and 3, and DS 1 protocol.
- DS 5: exercise 7 and 8, and exercise 1–3.
- DS 6: DS4 Protocol, and then the protocol of DS1 and DS3.
- DS 7: exercises 7–10.

3.3.2. e-Health program

It is a support system for the treatment of chronic LBP based on web technology, accredited as a health web. This system has a structure based on four sections: database treatment, database of user profiles, recommendations, and feedback procedures. This system allows users to register and enter a subject and modify an electroanalgesia and exercise treatment plan according to the symptomatic evolution of pain. It is based on an initial patient assessment system (Fig. 3).

A multimedia database will be developed with examples of specific treatments (according to symptomatic evolution) for postural syndrome, dysfunction syndrome and derangement syndrome. The videos of the application will be shown to patients with combined electroanalgesia and exercise therapy; patients can access the platform using their computer or mobile devices with internet access. The database is configured to accommodate the application of TENS and MT exercises based on the diagnosis according to the Mckenzie method, so that the treatments will be recommended by the system individually. The system calculates and recalculates the recommendations and updates the values of the relevant recommendations for the recommended treatments.

Since many of the patients do not have a tablet to access the study platform entitled “Stop Lumbalgia”, participants in the e-Health group will be given a tablet to each. To ensure patient adherence, control of its inputs is made to the “Stop Lumbalgia” application and the time they spend on it each login. In addition, participants of both groups are called each two weeks to re-

Fig. 2. Description of the McKenzie exercises prescribed for home.

Fig. 3. Treatment plan according to the symptomatic evolution of pain.

mind and encourage them to perform the exercises. Table 1 summarizes the content of the program e- Health.

The RPTs will complete a 2 days of training on structure, content, evaluation and delivery of the e-Health intervention, which includes role play and comments, learning about the application and its control and a visit to the evaluation site to solve problems of the site for effective development.

3.4. Outcome measures

At baseline, demographic data including age, gender, education, occupational and marital status and clinical presentation according a MT evaluation will be documented.

The primary outcomes are related to the feasibility of the e- Health intervention and trial design and procedure. For participants, this will be assessed by questionnaires (see Table 2) of treatment acceptability and demand of treatment and trial participation. For physiotherapists, a variety of aspects of feasibility will be evaluated according to the expectations of the treatment questionnaires.

In addition, the feasibility of the design and trial procedures will be assessed through experimentation of methodological procedures, recruitment, intervention procedures, the number and reasons for withdrawal during the treatment process, the feasibility outcome measurement, follow-up and fidelity procedures, refining factors that influence the implementation of the intervention.

The selected secondary outcome measures are the disability will be evaluated using Roland Morris Disability Questionnaire (RMDQ) [42,43] and the Oswestry Disability Index (ODI) [44,45]; quality of life will be assessed using the SF-36 Quality of Life Questionnaire [46,47] and the EuroQol (EQ) 5D-5L [48,49], the pain intensity and days that pain incapacitates for work by the by Visual Analogic Scale (VAS) [50,51] and an ítem developed specifically for this feasibility protocol; kinesiophobia (fear of movement and reinjury) will be assessed using the Tampa Scale Kinesiophobia (TSK) [52,53], isometric resistance of the abdominal muscles will evaluated by the McQuade test [54]; and range of motion of the trunk in flexion and in the sagittal plane by the fingertip-to-floor test and the SpinalMouse® [55,56].

Measurement variables will be evaluated before the first treatment session (baseline data), after the 8-week intervention period (immediately after the last session, i.e. 2 months), and after six months after the last session (follow-up).

The patients' adherence to the internet intervention will be explored by a brief questionnaire developed for this trial that will examine the data of use of the objective intervention automatically collected by the internet intervention e-Health. While the group that performs the program at home without electronic support will use a diary to record the same data as the e-Health group.

3.5. Timeline

The recruitment of patients started on September 05, 2020 and will be completed by April 30, 2021. All data for all follow-up occasions is expected to be collected before to October 31, 2021. The data analysis, writing of scientific manuscripts and submissions to peer-reviewed scientific journals will be carried out during 2021–22.

3.6. Sample size

The sample size was calculated according to the specifications established by Willian [57]. Assuming a standard deviation of 2.5 points, a 2-tailed test, an alpha (α) level of 0.05, and a desired potency (beta) of 85%, the estimated sample size was 270 patients with low back pain per group to detect a 2.5 point absolute difference in the primary outcome measure the in the RMQ (MCID) (estimated for a variance in patients with chronic LBP of 10 points) [58], score at 6 months post intervention between the group intervention home rehabilitation arms. In each study center (Almeria, Granada and Sevilla) 180 patients with chronic low back pain will be recruited. There will be a minimum of three groups in each arm, participating in two waves of recruitment with the objective of recruiting forty-five participants in each group per wave, resulting in 540 participants with chronic low back pain (90 per arm). Recommendations for feasibility studies suggest that at least 30 participants per arm be included for the analysis of the data set [59–61]. If the effect of the cluster design is taken into account and an ICC coefficient of 0.03 is assumed, an effective sample size of 30 would require 36 participants per arm [62]. Given a 25% loss during follow-up, we would need to recruit 48 participants per arm (96 in total). Therefore, this study size will be large enough to allow an accurate estimate of the ICC coefficient.

3.7. Data analysis plan

An a priori data analysis plan will be implemented by the trial statistician on completion of data collection.

Table 2
Variables, measures and their characteristics

Variable	Measure	Items	Details	Reliability where available
Back-specific physical disability	RMDQ [43]	24	This is a self-reported questionnaire consisting of 24 items reflecting limitations in different activities of daily living attributed to low back pain, including walking, bending over, sitting, lying down, dressing, sleeping, self-care and daily activities.	Internal consistency range: 0.77–0.93 [43]
Quality of life	EuroQol EQ-5D [48]	6	The state of health is defined in 3 Parts. Part 1 define the health status in five dimensions (mobility, personal care, daily activities, pain/discomfort and anxiety/depression mobility). Part 2 features a VAS that records patient's ratings of overall health. Part 3 is a demographic characterization.	Internal consistency range: 0.67–0.85 [49]
	SF-36 Health questionnaire [46,47]	36	The SF-36 is a multipurpose, short-form health survey with only 36 questions. It yields an eight-scale profile of scores as well as physical and mental health summary measures.	Internal consistency range: 0.74–0.92 [47]
Disability	ODI [44]	10	The Oswestry disability index evaluates daily life activity limitations in 10 dimensions, each scored on a 6-point scale (0–5 points); the total points scored are expressed as a percentage, used to classify individuals as minimally disabled (0–10%), moderately disabled (20–40%), severely disabled (40–60%), crippled (60–80%), or bedbound (80–100%).	Internal consistency range: 0.69–0.87 [45]
Pain intensity	VAS [50]	1	Patients rate their average pain over the past 2 weeks on a horizontal line with 11 marks on it –from 0 to 10 –where, measuring pain severity, 0 indicates "no pain" and 10 indicates "the worst possible pain".	Test-retest reliability: 0.67–0.96 [51]
Days in pain	Developed specifically for this study		The patients are asked about the number of troublesome days they have spent in pain and which have resulted in absence at work over the previous two months.	No reliability data available
Fear of movement and (re)injury	TSK [52]	17	Patient rate beliefs about their pain on a 4-point scale ranging from strongly disagree to strongly agree.	Internal consistency range: 0.70–0.83 [53]
Isometric resistance of abdominal muscles	McQuade Test [54]	1	The purpose of this test is to compile the times of isometric resistance of the subjects by performing a trunk flexion exercise with flexed knees, and the patient supine.	Internal consistency: 0.97 [54]
Forward bending	Fingers-floor distance [55]	1	The patient flexes the trunk forward from the standing position, and the distance from the fingers to the ground is measured.	Internal consistency: 0.82 [55]
Lumbar mobility	Range of motion and segmental mobility [56]		This variable is quantified using the SpinalMouse® device (Phisiotech, Spain). It is an electronic computer-aided measuring device that measures sagittal spinal amplitude of movement (ROM) and intersegmental angles in a non-invasive way.	Internal consistency range: 0.92–0.95 [56]
Adherence to specific activities for LBP	Questionnaire developed for this trial	6	Patients are asked about the number of weeks that they have fully completed the program. They are also asked for an estimate of how many days a week they did Mckenzie exercises and the electroanalgesia protocol with TENS. Patients are also asked if they stopped doing the activities because they are no longer experiencing pain.	No reliability data available

*Abbreviations: EQ-5D-3L: EuroQol 5 Dimensions 3 Levels; RMDQ = Roland-Morris Low Back and Disability Questionnaire; ODI = Oswestry Disability Index; VAS = Visual Analogue Scale; TSK = Tampa Scale for Kinesiophobia; PETS = Problematic Experiences of Therapy Scale.

The test statistician will carry out an a priori data analysis plan at the end of the data collection. For the primary analysis, as it is a feasibility study, an exhaustive descriptive analysis of the data is performed. A combination of quantitative (i.e., direct observation and audio recording by researcher, RPT and GPs self-report) and qualitative methods (interviews with intervention RPTs and participants) will be used to respond to the objectives related to the feasibility of the intervention and the trial procedures. Fidelity will be assessed and reported by separate evaluators from the outcome evaluators [63]. These data will determine the feasibility and will improve the study design for a future definitive trial.

Data will be analyzed with SPSS version 21.0 and STATA 14 software and will follow intention-to-treat principles. The analysis of the data of the secondary outcome measure will be carried out at the end of the trial and will be performed by the statistician who will remain blinded to the identification of the group until the analysis is completed. Baseline demo-graphic and clinical variables will be examined between both groups' independent Stu-dent t-test for continuous data and $\chi 2$ tests of independence for categorical data in the parametric variables, and with the Mann-Whitney U test for non-parametric data. The data normality will be tested with the Kolmogorov-Smirnov test and if we find non-normally distributed data, we will use the Kruskal-Wallis test. To investigate the effect of treatment (e-Health vs home rehabilitation) and the interaction terms between treatment group versus time, the repeated measures analysis of variance (ANOVA) with time (baseline, at 2 (post-treatment) and 6 months follow up (after last session) will be used. The confidence interval will be established at 95%, and the significance level at 0.05.

3.8. Adverse effects

The risk of adverse events occurring as a consequence of the interventions in this trial is low. All activities and their intensity (specific McKenzie exercises for the lower back and TENS) will be recommended based on the individual signs and symptoms of each participant and will be described in detail in paper format or through internet support in group e-Health. Patients will be reminded that the assigned level should be comfortable for them. It will be amended quickly if the patient feels that the initial level is too high.

Participants must inform the RPTs of any adverse effects/events, and they will be responsible for communicating it immediately to the IP. The treatment will be modified or interrupted if necessary, and the type, frequency and duration of the effect will be documented if it occurs.

3.9. Ethics, data security and dissemination

The protocol was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Human Research and Local Ethics Committee of the "Hospital Complex Torrecárdenas of Almeria, University Hospital Complex of Granada and Virgen Macarena de Sevilla Hospital – Andalusian Health Service" (CFS/apg).

All patients, GPs and RPTs will receive specific information on the study in writing and will have a chance to discuss procedures with a member of the study team before consenting to take part. Participants that agree to participate in the study will sign two copies of the informed consent, one that will be kept in the trial records and one for the participant. Informed consent has been obtained for the clinical and personal images and details of patients included in this study (Fig. 2).

The data collected from each patient will be stored in a closed locker in an office of the University of Almeria and only the RPTs evaluators will have access to that information. Subsequently, the data will be entered and saved by the statistician on a laptop with password protection to maintain confidentiality. Eligibility criteria, results and analysis will not be modified after registration of the first participant. The feasibility results will be published in journals indexed in the Journal Citations Report and presented at national and international conferences.

4. Discussion

In this randomized controlled trial we intend investigate the effectiveness of an e-Health programs versus home rehabilitation programs in patients with chronic LBP. The difference between both programs is that the e-Health group has constant and remote information on the exercises through a web platform.

4.1. Strengths

Considering that the adherence to home exercise programmes ranges from 50% to 70% [64,65], and that some studies have shown that patients who do not adhere to home exercise regimens benefit less from treatment than those that do [66]. That lack of adherence

to treatment in patients with low back pain could be facilitated by using computer systems to make exercise programs more attractive [67]. Previous studies show that patients prefer short, simple exercise programmes, and prefer their therapist to be knowledgeable about their disease, encourage feedback, motivate them to learn, give them re-minders and monitor their results and adherence to the programme [68]. As can be seen in Table 2, also through this study we intend to know the preferences and adherence of the patient and the opinion of physiotherapists and GPs on the e-Health intervention (web applications and learning sessions), maintaining a constant feedback with the patient, and recording if the sessions are appropriate and satisfactory to obtain the expected results.

If data are obtained on patient preferences, and adequate feedback is given to achieve adherence, the new technologies could allow physical therapists to provide their patients with the treatment, follow-up and remote contact they require.

Through the specific e-Health programs at home, could increase adherence to treatment, patients could learn to control and self-manage the evolution of their LBP, preventing its evolution to stages of greater pain and disability. If the painful symptomatology improves could be cost-effective healthcare tool that can reach a large number of people living in rural or remote areas.

4.2. Limitations

The main limitation of the present study is the problem of adherence to the e-Health program due to the difficulty of accessing the web application in certain population centers, such as those belonging to rural population groups. This limitation is mitigated by providing 15 tablets of 10,1" Quad Core (Supernova Qi16, Leotec) in each study center, together with a 5-session course on their use.

Authors should discuss the results and how they can be interpreted from the perspective of previous studies and of the working hypotheses. The findings and their implications should be discussed in the broadest context possible. Future research directions may also be highlighted.

5. Conclusions

The new technologies could allow physical therapists to provide their patients with the treatment, follow-up and remote contact they require. Through the specific e-Health programs at home, could increase adherence to treatment, patients could learn to control and self-manage the evolution of their LBP.

Author contributions

AMCS: Conceptualization, methodology, writing-original draft, writing-review and editing, supervision, and project administration ICLP: Conceptualization, methodology, investigation, formal analysis, and writing-review and editing EAS, GAMP, DHO, JMC and HGL: Conceptualization, methodology, and writing–review and editing. All authors read and approved the final manuscript. All authors have read and agreed to the published version of the manuscript."

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Conflict of interest

The authors declare no conflict of interest.

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PAPER III

COMPARISON OF THE EFFECTIVENESS OF AN E-HEALTH PROGRAM VERSUS A HOME REHABILITATION PROGRAM IN PATIENTS WITH CHRONIC LOW BACK PAIN: A DOUBLE BLIND RANDOMIZED CONTROLLED TRIAL.

Lara-Palomo IC, Antequera-Soler E, Matarán-Peñarrocha GA, Fernández-Sánchez M, García-López H, Castro-Sánchez AM, Aguilar-Ferrándiz ME.

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Comparison of the effectiveness of an e-health program versus a home rehabilitation program in patients with chronic low back pain: A double blind randomized controlled trial

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Abstract

Objetive: We conducted a randomized double blind clinical trial, to compare the effectiveness of McKenzie exercises and electroanalgesia via an e-Health program versus a home rehabilitation program on functionality, pain, fear of movement and quality of life in patients with non-specific chronic low back pain.

Methods: Seventy-four participants with non-specific chronic low back pain were randomized to either the e- Health program group (n = 39) or the home rehabilitation program group (n = 35). The interventions consisted of the e-Health program group performing McKenzie exercises and received transcutaneous electrical nerve stimulation, while the home rehabilitation group attended an information session to explain the exercises, which they then performed at home with printed instructions. Both groups performed 3 weekly sessions for 8 weeks. The following were analyzed main measures: pain, disability, fear of movement, quality of life, trunk muscle endurance and trunk anteflexion motion were assessed at baseline and at 2 months.

Results: Independent samples Student's t-tests showed that although the patients who followed the e-Health program showed significantly greater improvement than those who followed the home disability rehabilitation program in terms of intensity of pain, lumbar flexion mobility ($P < 0.001$), and the following dimensions of quality of life ($P < 0.005$), both groups improved significantly in the immediate post-treatment follow up compared with baseline scores.

Conclusions: Patients with chronic low back pain who followed an unsupervised home intervention supported by an individualized video exercise program showed greater post-treatment improvement than those who followed the same program with printed instructions.

Keywords

Chronic low back pain, general, telemedicine, home rehabilitation, McKenzie exercises, transcutaneous electrical nerve stimulation, randomized controlled trial

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Introduction

Low back pain (LBP) is the main cause of activity limitation and absence from work in most countries. It is associated with a considerable economic burden,[1,2] and has been considered the main contributor to years lived with disability.[3]

Although nonspecific LBP has no known pathoanatomical cause, treatment focuses on reducing pain and its consequences. Spinal instability has been an important clinical factor in back pain. Different studies have shown that people with back pain appear to have different recognition patterns for the control of deep lumbar stabilizing muscles.[4,5] Given the relationship between alterated neuromuscular function and LBP, there is clearly a need for reeducation exercises to correct lumbo-pelvic stabilization, as well as other treatments that improve pain.[6,7]

Studies and clinical practice guidelines recommend several possible interventions for the treatment and management of LBP, ranging from active participation through exercise to passive methods such as electroanalgesia.[8,9] Evidence has shown that transcutaneous electrical nerve stimulation (TENS) is a cost-effective intervention that activates both central and peripheral mechanisms to reduce hyperalgesia.[10,11] Facci et al.[12] found that applying 30 min of TENS current at a comfortable intensity, adjusted according to each patient's sensitivity, reduced pain intensity, improved disability, and reduced drug use in patients with nonspecific chronic low back pain. Furthermore, others studies has obtained beneficial results of TENS current in the control of non-radicular pain with respect to a control group or to other more conventional treatments in patients with chronic low back pain.[13] Regarding functional disability, the TENS current has also shown positive results in a short period of time, on the other hand, in follow-ups longer than 6 weeks the evidence is limited.[14]

Clinical practice guidelines recommend self-care exercises as a key strategy in the treatment of patients with chronic LBP, and prioritize primary care triage for the management of patients with LBP. Triage consists of classifying patients according to their signs and symptoms in order to prescribe certain exercises, give advice to patients who remain active, and provide information on effective self-care options.[15,16] The McKenzie Method is a widely-used, comprehensive approach to chronic LBP that includes both an evaluation and intervention component. The evaluation component of the McKenzie Method classifies patients with LBP into subgroups, each with a specific management approach.[17] There is also evidence that home rehabilitation programs with good compliance are moderately effective in reducing pain and improving function in chronic LBP, and also reduce healthcare costs.[18] Recent evidence has shown that a McKenzie therapy program based on telerehabilitation obtained clinical results comparable to traditional McKenzie therapy performed under supervision, and could reduce the healthcare burden of LBP.[19]

Currently, digital health systems are considered a promising innovation to solve the demand for health resources as a consequence of the aging of the population and the scarce material and human resources available to health institutions.[20,21] In chronic disease such as low back pain, the telemedicine can be an effective alternative of intervention for patients can manage different components of their health such as functional independence, self-care, and self-maintenance of their disease.[22–24] In addition to being a scalable, universally accessible and low-cost approach within the multidisciplinary treatment of low back pain.[25]

The objective of this study was to compare the effectiveness of an e-health program versus home rehabilitation based on McKenzie exercises and TENS treatment to reduce disability, pain, fear of movement, and improve quality of life and spinal mobility in patients with chronic LBP.

Methods

Study design and study setting

We conducted a double blind randomized controlled comparative trial with a 6-month follow-up period between January 2018 and December 2020. The study protocol was approved by the Human Research Ethics Committee of the "Hospital Complex Torrecárdenas of Almeria, University Hospital Complex of Granada and Hospital Virgen Macarena of Sevilla – Andalusian Health Service" (CFS/apg), and registered on clinicaltrials.gov (protocol number NCT03469024)

Two hundred and seventy patients with nonspecific chronic LBP treated in the outpatient physiotherapy departments of 3 Andalusian Health Service hospitals were selected to participate in this trial. After referral by a general practitioner, patients were interviewed by phone to determine whether they met the inclusion or exclusion criteria. After telephone and face-to-face screening, only 80 of the patients that had agreed to participate were eligible for the study. All patients provided written informed consent to participate in the study. (Figure 1) shows a brief outline of the design of the trial.

Participants

Patients with non-specific LBP for at least 3 months, who were aged between 30 and 67 years, had a disability score of 4 or more on the Roland Morris Disability Questionnaire (RMQ) for LBP, and were not receiving any other physiotherapy treatment were eligible for inclusion. Exclusion criteria were: contraindication for McKenzie exercises or TENS such as fracture, infection, cancer, or cauda equina syndrome; presence of clinical signs or symptoms of radiculopathy; known medical diagnosis of spondylolisthesis, spinal stenosis, inflammatory

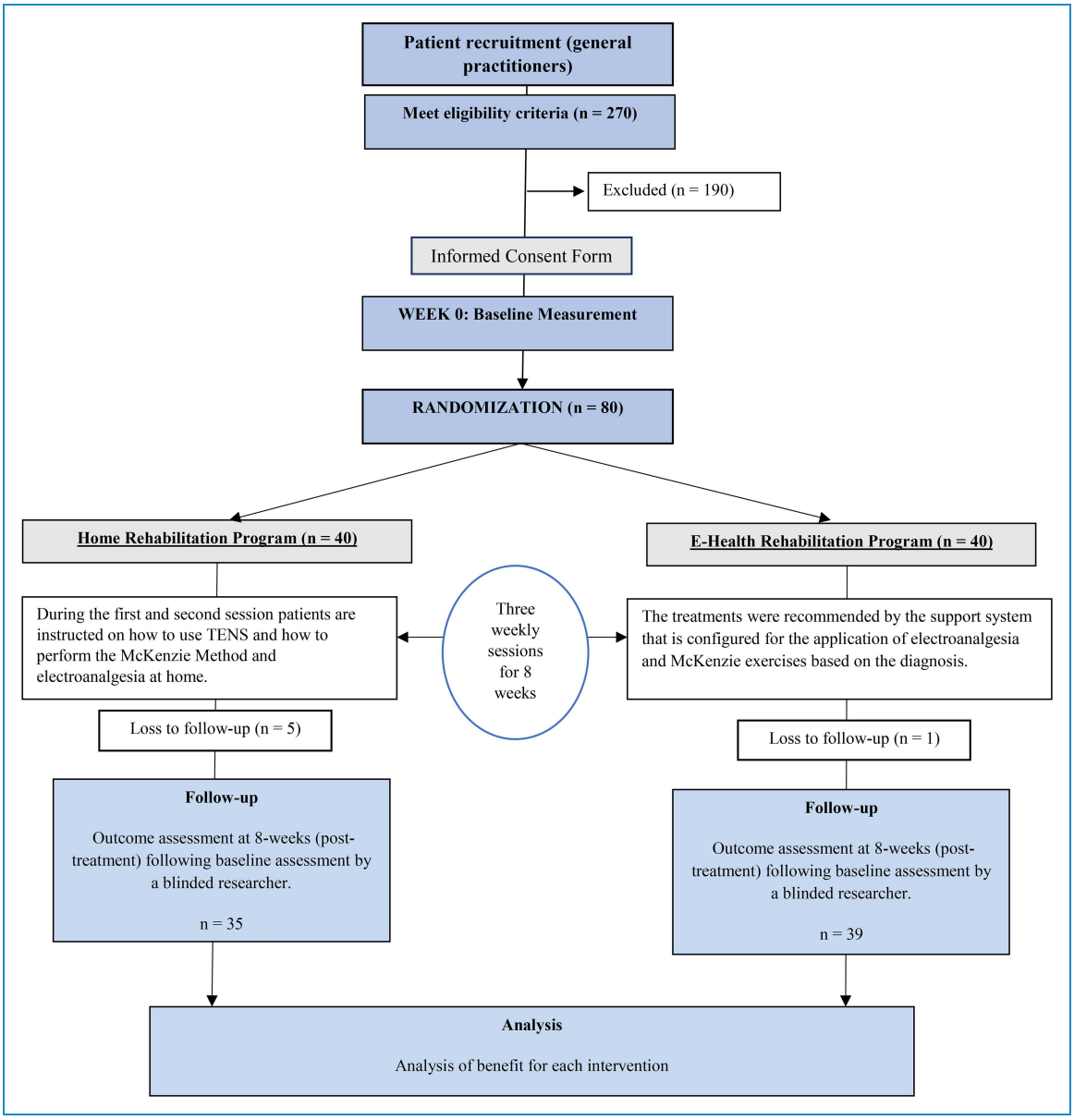

Figure 1. Brief outline of the design of the trial.

or metabolic disease, fibromyalgia, presence of central or peripheral system pathology (i.e, stroke, peripheral nerve, etc.) or history of spinal surgery; and no corticosteroids or other drug therapy in the preceding 2 weeks.

Sample size

The sample size was based on the estimates established by Willian.[26] The calculations have been based on the detection of differences of 2.5 points in the RMQ score (minimum clinically important difference),[27] assuming a standard deviation of 2.5 points, a 2-tailed test, an alpha (α) of 0.05, and a target power (beta) of 85%. The estimated sample size was 80 subjects (40 per group).

Randomization

After a baseline examination, patients were randomly assigned to follow a telemedicine program that included TENS and McKenzie Method exercises, or the same program with no online support. Allocation was concealed using a computer-generated randomized table of numbers (software Epidat 4.2) created prior to the start of data collection by a researcher not involved in either recruitment or treatment. Index cards sequentially numbered according to the random assignment were printed, folded, and placed in sealed opaque envelopes. A third therapist, blinded to baseline examination findings, opened the envelope, assigned the patient to the corresponding study group, and booked their first treatment session. Patients were assessed by 2 blinded

physical therapists associated with Almeria University who had more than 10 years' experience in the clinical management of patients with chronic LBP.

Outcomes measures

All data were gathered before the first treatment session (baseline) and immediately after the final treatment session by a physical therapist blinded to the patient's treatment allocation. Patients provided demographic and clinical information and completed a number of self-administered questionnaires: the Roland Morris Disability Questionnaire,[28] the SF-36 Health Questionnaire,[29,30] the Oswestry Disability Index,[31] the Visual Analog Scale,[32] the Tampa Scale for Kinesiophobia,[33] the McQuade test,[34] Spinal movement was assessed using the Fingertip-to-Floor Distance test.[35]

Adherence to treatment was evaluated on the basis of diary entries made by patients in the Home rehabilitation group, and according to the number of logins and time spent on the online program by patients in the E-health group.

The main independent variable was the Roland Morris Disability Questionnaire – a 24-item patient-reported disability measure with a score ranging from 0 = no disability to 24 = severe disability.[28] SF-36 Health Questionnaire scores range from 0% to 100% and indicate the self-perceived health-related quality of life.[29,30] The Oswestry disability index evaluates limitations in activities of daily living in 10 dimensions, each scored on a 6-point scale (0–5 points). The total score is expressed as a percentage that classifies individuals as minimally disabled (0%–10%), moderately disabled (20%–40%), severely disabled (40%–60%), crippled (60–80%), or bedbound (80%–100%).[31] The visual analogue scale for pain intensity ranges from 0 = no pain to 10 = worst imaginable pain.[32] The Tampa Scale of Kinesiophobia is a 17-item questionnaire that rates the respondent's fear of movement or recurrent lesion. Each item is scored on a 4-point Likert scale, ranging from "completely disagree" to "completely agree".[33] The McQuade test measures the isometric resistance of abdominal muscles in seconds.[34] Lumbar mobility in flexion was determined by measuring the distance from the tip of the third finger to the floor with a tape measure.[35]

Both the outcome assessor and statistician were blinded to the entire study. The outcome assessor was not involved in treatment and did not attempt to guess the participant's group. The computerized outcome measures received by the statistician did not contain any information identifying patients as belonging to either group.

Intervention

The McKenzie treatment was planned individually after the pretreatment physical assessment and before randomization; therefore, patients in each group were divided into 3 subgroups (postural, dysfunction and derangement) according to the McKenzie therapeutic classification, which divides them according to symptoms and their frequency of appearance; limitation of mobility; results of dynamic tests and persistence of symptoms when mechanical loading (static or dynamic) is withdrawn. All patients were treated by 2 physical therapists with more than 10 years of clinical experience with patients, and with at least 5 years certified application of the McKenzie Method after completing their physical therapy degree. Both groups performed 3 sessions weekly for 8 weeks. The protocol was as follows (Figure 2).

Home rehabilitation program group. This consisted of an unsupervised home rehabilitation program with no online support. During first and second 60 min session, a therapist taught the patients how to use a portable low-frequency, high intensity TENS (80 Hz/200 μs) device applied directly to the lumbar region by means of 4 electrodes (5 × 9 cm) placed bilaterally at the paravertebral level, and how to perform their exercises, which were individualized according to the diagnosis and mechanical therapy of the McKenzie Method. The patient continued the protocol at home until completing the 24 sessions.

Each subgroup of patients performed the following exercises simultaneously with TENS:

Patients with Postural Syndrome: exercises 1, 2 and 3 (posture correction and prophylaxis).
Patients with Dysfunction Syndrome: exercises 3, 6 and 7.
Patients with Derangement Syndrome (DS):
☐ DS 1: exercises 1–4 and 6, with prone extension.
☐ DS 2: the exercises begins in the prone position and the patients continue with protocol DS1 and exercise 5.
☐ DS 3: DS1 protocol, exercise 7 and rotation maintained for 2 min.
☐ DS 4: exercise 7, exercise 2 and 3, and DS 1 protocol.
☐ DS 5: exercise 7 and 8, and exercise 1–3.
☐ DS 6: DS4 protocol, followed by the DS1 and DS3 protocol.
☐ DS 7: exercises 7–10.

A booklet and laminated cards with detailed photographs of each exercise prescribed were provided.

E-Health program group. This is an internet-based system for the treatment of chronic LBP, accredited as a healthcare website. The system registers the subjects and provides individualized treatment of electroanalgesia and exercise using the McKenzie Method. Patients access the platform on a computer or mobile device and watch electroanalgesia and exercise videos with a duration of 1 to 3 min depending on the time of completion. The videos are preceded by an explanatory image and audio instructions during playback. The number of exercises and treatment are recommended by the system from the database that is configured to

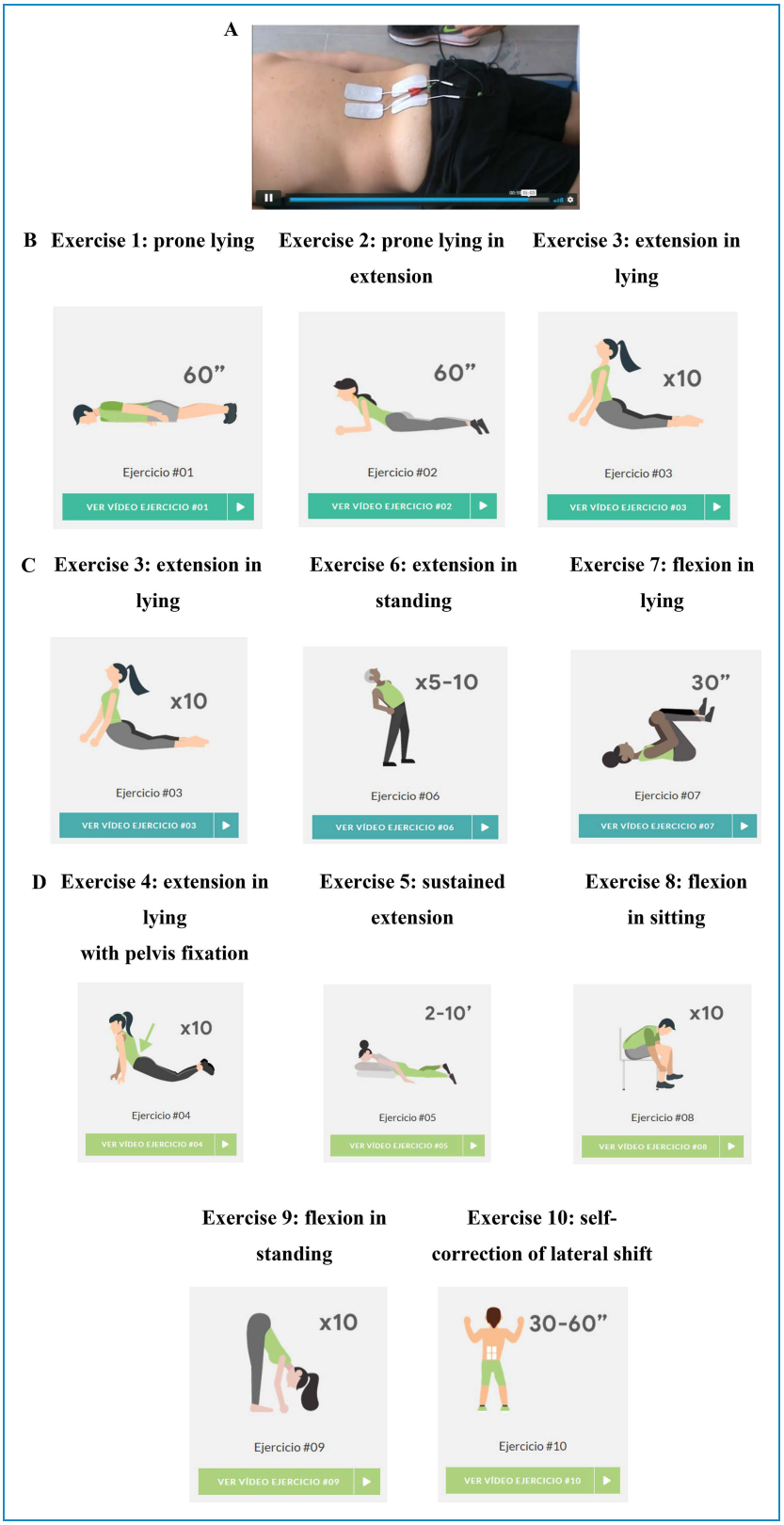

Figure 2. Protocol of mcKenzie exercise and transcutaneous electrical nerve stimulation. (A) Transcutaneous electrical nerve stimulation (80 Hz/200 μs) applied directly in the lumbar area by four electrodes (5 × 9 cm) at the paravertebral level bilateral. (B) Patients with Postural Syndrome: Exercises 1, 2 and 3. (C) Patients with Dysfunction Syndrome: Exercises 3, 6 and 7. (D) Patients with Derangement Syndrome (DS): Exercises 1 to 10 (according to type of derangement syndrome).

accommodate the application of electroanalgesia and McKenzie exercises, depending on the diagnosis made according to the McKenzie Method, programs of 3 to 9 exercises can be established.

In the first 5 sessions, the patient receives instructions on how the app works and records his or her data. He then continues the treatment at home until 24 sessions have been completed.

Both the app and the booklet given to the control group included information on the specific characteristics of the diagnosed syndrome and explained the benefits of these exercises for chronic low back pain.

Statistical analysis

Data were analyzed with SPSS© version 21.0, using intention-to-treat analysis. When post-intervention data were missing, baseline scores were used. The analysis of the data from the outcome measures was performed by the statistician who remained blinded to group allocation until the analysis was completed. The sample was size was calculated before the start of the study. The primary outcome measure was the change in the RMQ score at the end of the 8-week study period (post-treatment follow-up after the last session).

The data were tested for normality using the Kolmogorov-Smirnov test. The independent samples t-test was used to compare the effect of treatment (E-health vs. Home rehabilitation). The paired t-test was used to compare variables before (baseline) and after (post-treatment) treatment in each group. The confidence interval was established at 95%, and the significance level at 0.05. Effect size was tested using Cohen's d. An effect size < 0.2 indicates a negligible difference, between ≥0.2 and ≤0.5 a small difference, between ≥0.5 and ≤0.8 a moderate difference, and ≥0.8 a large difference.

Results

Two hundred seventy consecutive patients were screened for eligibility. Eighty patients (mean ± SD age: 47.96 ± 12.85) satisfied all the eligibility criteria, agreed to participate, and were randomized to the E-Health (telemedicine) (n = 40) or Home rehabilitation (n = 40) program; 6 participants dropped out before completion due to inability to comply with required study visits; change of residence and illness due to Covid-19. The reasons for ineligibility and withdrawal are shown in (Figure 1). A summary of demographic characteristics for the 74 enrolled subjects is shown in (Table 1). There were no significant differences between the baseline data of both groups ($p > 0.05$).

Table 2 shows the mean outcomes by group at all time points and inter-group differences with a 95% confidence interval (CI). The results showed that although the patients who received telemedicine (E-health group) showed significantly greater improvement than those who following the Home rehabilitation program in most outcomes, both groups improved significantly in the immediate post-treatment follow-up compared with baseline scores: E-health group (score changes for Roland Morris: 7.4; Oswestry: 11.4; Visual analog scale: 4.5; Tampa Scale for Kinesiophobia: 10; McQuade Test: 17.1; Lumbar mobility flexion: 11.6; Physical function: 16.6; Physical role: 30.7; Bodily pain: 12.6; General Health: 16.7; Vitality: 21.5; Social functioning: 8.3; Emotional role: 23.3; and Mental health: 22.2) and Home rehabilitation group (score changes for Roland Morris: 1.9; Oswestry: 5.1; Visual analog scale: 2.2; Tampa Scale for Kinesiophobia: 4.4; McQuade Test: 17.7; Lumbar mobility flexion: 1.7; Physical function: 9.2; Physical role: 18.2; Bodily pain: 15.6; General Health: 5; Vitality: 3.3; Social functioning: 3.2; Emotional role: 8.9; and Mental health: 5.7).

Table 1. Baseline demographic data of patients.

	Baseline		Pre
Parameters	E-health program (n = 39)	Home program (n = 35)	*P* Value
Gender (m/f)	17/22	14/21	0.543
Age (y) (Mean ± SD)	41.9 ± 9.4	54.6 ± 12.9	0.097
Level of studies			
Primary	5	7	
High school or institute	15	11	
University studies	19	17	
McKenzie classification			
Postural Syndrome	0	0	
Dysfunction Syndrome	9	11	
Derangement Syndrome	30	24	

p-value of 0.05.

The outcome measures with statistically significant differences between groups according to the Student's t-tests were: disability (Roland Morris and Oswestry), intensity of pain, lumbar flexion mobility ($p < 0.001$), and the following dimensions of the SF-36: physical function, physical role, vitality, social functioning, emotional role, and mental health ($p < 0.005$).

However, the Student's t-test analysis found no significant inter-group differences in the Tampa Scale for

Table 2. Outcome measures for subjects by groups and time.

Outcome/group	e-health program (n = 39)	Home rehabilitation program (n = 35)	Inter-group difference in score change	*P* Value	Cohen's d
RMDQ (0–24)					
Baseline	9.92 ± 4.35	9 ± 3.98	0.92 (−1.01, 2.86)	0.346	
Post-treatment	2.49 ± 2.19	7.03 ± 4.59	−4.54 (−6.18, −2.90)	0.001[a]	1.16
ODI (0–50)					
Baseline	17.53 ± 11.91	21.80 ± 11.63	−4.26 (−9.73, 1.21)	0.125	
Post-treatment	6.10 ± 5.76	16.71 ± 10.07	−10.61 (−14.36, −6.85)	0.001[a]	1.16
VAS (0–10 points)					
Baseline	6.72 ± 1.29	6.71 ± 1.15	0.00 (−0.56, 0.57)	0.990	
Post-treatment	2.20 ± 1.39	4.48 ± 2.03	−2.28 (−3.08, −1.48)	0.001[a]	1.14
TSK (17–68)					
Baseline	37.64 ± 8.07	34.40 ± 8.73	3.24 (−0.65, 7.13)	0.101	
Post-treatment	27.59 ± 6.68	30.00 ± 8.02	−2.41 (−5.82, 0.99)	0.163	0.28
Quality of life SF-36/group (0–100)					
Physical function					
Baseline	76.41 ± 16.58	72.14 ± 11.39	4.27 (−2.40, 10.94)	0.206	
Post-treatment	93.08 ± 8.71	81.43 ± 12.28	11.64 (6.75, 16.54)	0.001[a]	0.95
Physical role					
Baseline	58.72 ± 21.29	59.57 ± 18.60	−0.85 (−10.17, 8.46)	0.856	
Post-treatment	89.48 ± 17.00	77.86 ± 16.90	11.63 (3.76, 19.50)	0.004[a]	0.56
Body pain					
Baseline	59.83 ± 19.84	53.21 ± 14.93	6.62 (−1.59, 14.83)	0.113	
Post-treatment	72.45 ± 17.97	68.78 ± 13.38	3.66 (−3.75, 11.07)	0.328	0.18
General health					
Baseline	65.89 ± 17.01	63.28 ± 14.85	2.61 (−4.83, 10.05)	0.486	
Post-treatment	67.41 ± 17.86	68.28 ± 15.24	−0.87 (−8.61, 6.86)	0.822	0.04
Vitality					
Baseline	61.28 ± 14.35	67.28 ± 13.79	−6.00 (−12.54, 0.53)	0.071	

(continued)

Table 2. Continued.

Outcome/group	e-health program (n = 39)	Home rehabilitation program (n = 35)	Inter-group difference in score change	*P* Value	Cohen's d
Post-treatment	82.82 ± 12.24	70.57 ± 12.59	12.25 (6.49, 18.01)	0.001[a]	0.81
Social functioning					
Baseline	78.51 ± 22.60	71.78 ± 16.69	6.73 (−2.57, 16.02)	0.154	
Post-treatment	86.86 ± 19.23	75.00 ± 17.41	11.86 (3.32, 20.39)	0.007[a]	0.52
Emotional role					
Baseline	71.54 ± 26.85	76.72 ± 24.94	−5.17 (−17.23, 6.88)	0.395	
Post-treatment	94.88 ± 12.17	85.71 ± 23.27	9.16 (0.68, 17.64)	0.035[a]	0.45
Mental health					
Baseline	71.43 ± 13.85	74.63 ± 11.43	−3.19 (−9.12, 2.73)	0.286	
Post-treatment	93.64 ± 7.98	80.34 ± 10.59	13.29 (8.97, 17.62)	0.001[a]	1.22
Physical measurements					
McQuade test (s)					
Baseline	46.28 ± 13.82	42.71 ± 11.14	3.57 (−2.29, 9.43)	0.229	
Post-treatment	63.38 ± 17.58	60.48 ± 9.12	2.89 (−3.70, 9.50)	0.384	0.15
Lumbar flexion mobility (cm)					
Baseline	19.15 ± 13.83	16.36 ± 8.28	2.78 (−1.53, 7.09)	0.203	
Post-treatment	7.55 ± 4.98	12.40 ± 7.74	−4.86 (−7.84, −1.87)	0.002[a]	0.66

[a]Values are expressed as mean ± standard deviation for baseline and immediate post-treatment and as mean (95% confidence interval) for inter-group change scores. Abbreviations: ODI = Oswestry Disability Index; RMDQ = Roland-Morris Low Back and Disability Questionnaire; TSK = Tampa Scale for Kinesiophobia; VAS = Visual Analogue Scale.

Kinesiophobia ($p < 0.163$), or the McQuade test ($p < 0.384$); patients in both groups experienced similar improvements in fear of movement and isometric resistance of abdominal muscles: E-health group (Kinesiophobia: $p < 0.001$; McQuade: $p < 0.001$) and Home rehabilitation group (Kinesiophobia: $p < 0.001$; McQuade: $p < 0.001$).

Discussion

Although the main findings of our study revealed significant inter-group differences, and the e-health intervention appeared to be the more favorable method of treatment, post-treatment improvements were observed in all outcomes in both the E-health group and the Home rehabilitation group.

The intra-group comparison of participants in the E-health and Home program groups in the post-treatment period (2 months from the start of treatment / after the last session) revealed that exercise therapy based on the McKenzie Method combined with TENS performed at home without or with the help of a tablet or mobile phone application had a significant effect on disability, pain intensity, isometric resistance of the abdominal muscles, lumbar anteflexion mobility, and quality of life. These findings are consistent with previous studies in the use of the McKenzie protocol,[19,36–38] and in transcutaneous electrical nerve stimulation,[39,40] although few authors have used both therapies simultaneously.[41] In Deyo et al.[41] transcutaneous electrical nerve stimulation was no more effective than placebo, and added no apparent benefit to exercise alone.

The positive results observed in both study groups could also be due to good compliance with both interventions, irrespective of the use of online support. Various studies have shown that treatment compliance determines the

effectiveness of home exercise programs.[42–44] We believe that the performance of simple, easily mastered exercises individualized to each patient that gave perceptible benefits might have boosted our patient's confidence in the treatment prescribed, and improved the rate of compliance – a finding that has also been reported in other studies.[45]

Our results indicated that the rehabilitation program with online support (E-health group) provided greater improvement in disability, pain, physical function, vitality, and mental health than the same program without online support (Home group) (Cohen's $d \geq 0.8$); the remaining outcome measures showed small or moderate effect size. The differences could be due to the help and motivation in performing the exercises and placing the electrodes that the telemedicine group received from the online program. There is evidence that interventions in patients with chronic musculoskeletal disease performed online (telehealth) through video and audio materials can be as effective as those based on traditional printed instructions.[46] The audiovisual instructions helped patients understand the exercises and perform them correctly, and this could have improved compliance, self-control and symptoms, and helped them achieve their targets.[47–49]

This leads us to believe that the support of an online platform during the home program increased patient motivation and interest in the intervention, making it more effective in the short and medium term than the same home physiotherapy program performed without online support.

One of the limitations of our study is that follow-up was only performed in the short term, so we cannot be sure that our results would be maintained in the long-term, and more extensive longitudinal studies are needed. Although studies have shown that telehealth outcomes are comparable to face-to-face programs, and online applications can improve home treatment for people with chronic illnesses,[50,51] evidence also suggests that outcomes and patient satisfaction improve with a program that combines telehealth and traditional healthcare.[52]

Our conclusions suggest that unsupervised interventions at home supported by simple online health technologies based on individualized exercise videos may be more beneficial in improving symptoms in patients with non-specific chronic LBP than traditional home programs based on printed instructions. However, high-quality randomized trials with long-term follow-up that explicitly address the same type of home rehabilitation program are needed.

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Ethical approval: The Human Research Ethics committee of the "Hospital Complex Torrecárdenas of Almeria, University Hospital Complex of Granada and Hospital Virgen Macarena of Sevilla – Andalusian Health Service" (CFS/apg), and registered on clinicaltrials.gov (protocol number NCT03469024).

Guarantor: GLH.

Informed consent: Not applicable, because this article does not contain any studies with human or animal subjects.

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CONCLUSIONES

- Tanto el ejercicio supervisado como no supervisado parecen ser efectivos en el manejo de pacientes con dolor lumbar crónico inespecífico. El grupo de intervención supervisada obtuvo un pequeño beneficio adicional en comparación con el no supervisado. En el grupo supervisado, el ejercicio es eficaz para mejorar la resistencia de los músculos del tronco, la intensidad del dolor, la movilidad, la flexibilidad y la calidad de vida, mientras que el ejercicio domiciliario no supervisado resultó ser efectivo en las mismas variables, pero, con puntuaciones ligeramente inferiores. **(ARTÍCULO I).**
- La telemedicina podría ser eficaz en la mejora de la sintomatología de los pacientes con dolor lumbar crónico inespecífico. Las nuevas tecnologías podrían permitir a los fisioterapeutas brindar a sus pacientes el tratamiento, seguimiento y contacto remoto que requieren. A través de los programas específicos de e-Salud en el hogar, se podría aumentar la adherencia al tratamiento, los pacientes podrían aprender a controlar y autogestionar la evolución de su dolor. **(ARTÍCULO II).**
- Las intervenciones domiciliarias no supervisadas respaldadas por tecnologías de e-Salud basadas en videos de ejercicios individualizados pueden ser beneficiosas para mejorar los síntomas en pacientes con dolor lumbar crónico inespecífico en contraste con los programas domiciliarios tradicionales basados en instrucciones impresas. Sin embargo, se necesitan ensayos aleatorios de alta calidad con seguimiento a largo plazo que aborden explícitamente el mismo tipo de programa de terapia física domiciliaria. **(ARTÍCULO III).**

OTRAS APORTACIONES CIENTÍFICAS DERIVADAS DIRECTAMENTE DE LA TESIS DOCTORAL.

De la presente Tesis Doctoral se han derivado otras producciones científicas. La primera de ellas ha sido la realización de un metaanálisis con título "Efficacy of e-Health interventions in patients with chronic low back pain: a systematic review with meta-analysis" analizando la efectividad de las diferentes intervenciones de e-salud y telemedicina en pacientes con dolor lumbar crónico de origen inespecífico. Dicho metaanálisis está en proceso de revisión en la revista "Telemedicine and E-Health" (Impact Factor: 3.536; Rank: 31/150, Q1).

Otra de las aportaciones realizadas fue la participación como asistente y como miembro del comité científico de las "VIII Jornadas Internacionales de Graduados en Ciencias de la Salud" realizadas en la Facultad de Ciencias de la Salud de la Universidad de Almería los días 8 y 9 de Julio de 2021. En las mencionadas jornadas se presentó una comunicación tipo póster denominada "Efectividad de los diferentes tipos de ejercicio física en pacientes con dolor lumbar crónico: una revisión bilbiográfica" para la cual, se llevó a cabo una revisión de la literatura actual acerca del ejercicio en el dolor lumbar crónico.

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