

ABORDAJE CLINICO DEL DOLOR LUMBAR
CRONICO MEDIANTE TRES TERAPIAS
FISICAS ALTERNATIVAS: TERAPIA
MANIPULATIVA, ELECTROPUNCION SECA
Y TELEMEDICINA

TESIS DOCTORAL

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Almería, Julio de 2022



DEPARTAMENTO DE ENFERMERÍA, FISIOTERAPIA Y MEDICINA
FACULTAD DE CIENCIAS DE LA SALUD
UNIVERSIDAD DE ALMERÍA



**ABORDAJE CLÍNICO DEL DOLOR LUMBAR CRÓNICO
MEDIANTE TRES TERAPIAS FÍSICAS ALTERNATIVAS: TERAPIA
MANIPULATIVA, ELECTROPUNCIÓN SECA Y TELEMEDICINA**

**CLINICAL APPROACH TO CHRONIC LOW BACK PAIN THROUGH THREE
ALTERNATIVE PHYSICAL THERAPIES: MANIPULATIVE THERAPY,
ELECTRICAL DRY NEEDLING AND TELEMEDICINE**

**Tesis doctoral por compendio de publicaciones
Programa de Doctorado en Salud, Psicología y Psiquiatría (SAPP)**

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ÍNDICE

ÍNDICE	05
TESIS POR COMPENDIO DE TRABAJOS PREVIAMENTE PUBLICADOS	07
RESUMEN	08
ABREVIATURAS	10
INTRODUCCIÓN	11
INTRODUCCIÓN	12
Aspectos conceptuales del dolor lumbar crónico.....	12
Epidemiología del dolor lumbar crónico.....	13
Patogenia y factores de riesgo para el dolor lumbar crónico inespecífico.....	14
Estrategias de tratamiento.....	17
Evidencia para la utilización de la terapia manipulativa en pacientes con dolor lumbar crónico.....	19
Evidencia para la utilización de la electropunción seca en pacientes con dolor lumbar crónico.....	22
Evidencia para la utilización de la telemedicina en pacientes con dolor lumbar crónico.....	25
REFERENCIAS	28
OBJETIVOS	52
OBJETIVOS	53
Objetivo general.....	53

Objetivos específicos.....	53
METODOLOGÍA.....	54
METODOLOGÍA.....	55
Tabla 1. Resumen de la metodología utilizada en los manuscritos incluidos en la tesis doctoral.....	56
RESULTADOS Y DISCUSIÓN.....	60
RESULTADOS Y DISCUSIÓN.....	61
ARTÍCULO I.....	62
Manipulative therapy of sacral torsion versus myofascial release in patients clinically diagnosed posterior pelvic pain: a consort compliant randomized controlled trial.....	63
ARTÍCULO II.....	74
Electrical dry needling versus conventional physiotherapy in the treatment of active and latent myofascial trigger points in patients with nonspecific chronic low back pain.....	75
ARTÍCULO III.....	87
Efficacy of e-Health Interventions in Patients with Chronic Low-Back Pain: A Systematic Review with Meta-Analysis.....	88
CONCLUSIONES.....	108
CONCLUSIONES.....	109
AGRADECIMIENTOS.....	111

TESIS POR COMPENDIO DE TRABAJOS PREVIAMENTE PUBLICADOS

La presente Tesis Doctoral, autorizada mediante informe por los Directores de Tesis y el Órgano responsable del Programa de Doctorado en Salud, Psicología y Psiquiatría, comprende un compendio de tres trabajos científicos previamente publicados.

Los artículos que comprenden el cuerpo de esta tesis doctoral son los siguientes:

I. Castro-Sánchez AM, Gil-Martínez E, Fernández-Sánchez M, Lara-Palomo IC, Nastasia I, de los Ángeles Querol-Zaldívar M, Aguilar-Ferrándiz ME. Manipulative therapy of sacral torsion versus myofascial release in patients clinically diagnosed posterior pelvic pain: a consort compliant randomized controlled trial. *Spine J.* 2021 Nov;21(11):1890-1899.

Factor de impacto: 4.166 / Ranking: 15/82 (Q1)

II. Lara-Palomo IC, Gil-Martínez E, Antequera-Soler E, Castro-Sánchez AM, Fernández-Sánchez M, García-López H. Electrical dry needling versus conventional physiotherapy in the treatment of active and latent myofascial trigger points in patients with nonspecific chronic low back pain. *Trials.* 2022 Mar 28;23(1):238.

Factor de impacto: 2.279 / Ranking: 91/140 (Q3)

III. Lara-Palomo IC, Gil-Martínez E, Ramírez-García JD, Capel-Alcaraz AM, García-López H, Castro-Sánchez AM, Antequera-Soler E. Efficacy of e-Health Interventions in Patients with Chronic Low-Back Pain: A Systematic Review with Meta-Analysis. *Telemed J E Health.* 2022 May 9. doi: 10.1089/tmj.2021.0599. Epub ahead of print.

Factor de impacto: 3.536 / Ranking: 36/107 (Q2)

RESUMEN

El dolor lumbar crónico es uno de los problemas de salud más comunes en los países industrializados desde la segunda mitad del siglo XX, y se considera la principal causa de años vividos con discapacidad, muy por encima de cualquier otra enfermedad. Se calcula que entre un 70-90% de la población padecerá un episodio de dolor lumbar al menos una vez en la vida, y constituye la segunda causa en frecuencia de visitas médicas, la quinta en frecuencia de hospitalización y la tercera en frecuencia de intervención quirúrgica.

Se prevé que, a medida que la población mundial envejezca, la magnitud del problema irá en aumento, con el consiguiente incremento de la carga socio-sanitaria y económica. Está considerado como la principal causa de limitación de la actividad en personas menores de 45 años, y es la patología músculo-esquelética más prevalente en mayores de 65 años. Según datos del Ministerio de Trabajo de España, el dolor lumbar es el motivo de desembolso económico más importante, suponiendo entre el 19-25% de los gastos de incapacidad laboral, sin contar con los costos que suponen las pruebas para el diagnóstico y el tratamiento.

El dolor lumbar crónico supone uno de los desafíos más conocidos a los que se enfrentan los fisioterapeutas, representando más del 50% de las derivaciones de consultas externas a fisioterapia. El hecho de que un 85% de los dolores de espalda sean inespecíficos, parece ser parte de la causa de que exista una gran variabilidad de teorías fisiopatológicas y de métodos de tratamiento propuestos por distintos profesionales, entre los que parece haber poco consenso. A pesar de que se ha producido un crecimiento exponencial en las modalidades de tratamiento dirigidas a controlar la lumbalgia crónica, la realidad es que, actualmente, no hay opciones definitivas de manejo intervencionista, conservador o quirúrgico para tratar este tipo de dolor.

El objetivo principal de la presente tesis fue evaluar los efectos de tres modales de fisioterapia en el dolor lumbar crónico de origen inespecífico: terapia manipulativa, electropunción seca y telemedicina, sobre el dolor, la funcionalidad y la calidad de vida.

Un total de 156 pacientes con lumbalgia crónica inespecífica, que cumplieron los criterios de inclusión y fueron seleccionados mediante muestreo aleatorio simple, participaron en los estudios de esta tesis. Las variables de medida registradas fueron la escala de incapacidad por dolor lumbar de Oswestry, el cuestionario de Roland-Morris para valoración de la discapacidad por lumbalgia, la escala visual analógica del dolor, la escala de Tampa de kinesiofobia, el cuestionario de calidad de vida SF-36, el test de McQuade de resistencia isométrica abdominal, el test de movilidad en anteflexión del tronco, el cuestionario de Pittsburgh de calidad del sueño, la escala de ansiedad y depresión hospitalaria, y la algometría de presión.

La terapia manipulativa, la electropunción seca y la telemedicina son intervenciones terapéuticas eficaces para el abordaje del paciente con lumbalgia crónica inespecífica. Los pacientes que recibieron manipulación espinal experimentaron una mayor reducción en la discapacidad en todos los períodos de seguimiento, y mayores beneficios en la calidad de vida y en la movilidad lumbar en flexión al mes de seguimiento, en comparación con el grupo control. Los resultados del estudio de la eficacia de la electropunción seca frente a la fisioterapia convencional en pacientes con dolor lumbar crónico, pueden ayudar a los fisioterapeutas a comprender si este tipo de intervención puede reducir significativamente la discapacidad y el absentismo laboral. La telemedicina es tan efectiva como otras intervenciones de fisioterapia, tanto en el dolor como en la función específica de la espalda, y la combinación con la atención presencial podría asegurar la adherencia y mejorar los efectos de las intervenciones administradas a pacientes con lumbalgia crónica inespecífica.

ABREVIATURAS

(Por orden alfabético)

AINEs	Antiinflamatorios no esteroideos
APTA	American Physical Therapy Association; Asociación Americana de Fisioterapia
ASI	Articulación Sacro-Iliaca
AVD	Actividades de la Vida Diaria
CLBP	Chronic low back pain; Dolor lumbar crónico
ECA	Ensayo Clínico Aleatorizado
GPC	Guía de Práctica Clínica
LBP	Low back pain; Dolor lumbar
PENS	Percutaneous Electrical Nerve Stimulation; Neuroestimulación eléctrica percutánea
PGM	Punto gatillo miofascial
ROM	Límite del rango de movimiento restringido
TIC	Tecnologías de la Información y la Comunicación
VIH	Virus de la inmunodeficiencia humana

INTRODUCCIÓN

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Aspectos conceptuales del dolor lumbar crónico

El dolor lumbar crónico (en adelante, CLBP) se define como un conjunto de síntomas caracterizados por la presencia de dolor, tensión muscular o rigidez de intensidad variable, localizada en la región final de la columna vertebral (región lumbar), pudiendo comprometer en ocasiones a la región glútea, con o sin irradiación hacia las piernas, y desencadenando disminución o impotencia funcional. Los episodios de dolor lumbar crónico suelen ser recurrentes en el tiempo, con períodos de remisión seguidos de cuadros de reagudización^{1,2}.

La naturaleza del dolor crónico es compleja y multifactorial, considerándose como CLBP cuando el dolor persiste durante un período igual o superior a 3 meses, pudiendo continuar tras la recuperación de la lesión inicial. En la cronicidad pueden influir factores de diversa índole, tales como anatómicos, emocionales, cognitivos, sociales y de comportamiento, entre otros los que se incluyen: las alteraciones a nivel estructural y/o músculo-esquelético, la mala o nula adaptación del puesto de trabajo, los estados de ansiedad, depresión y estrés, hábitos de vida como el sedentarismo, y la manera de percibir y afrontar el dolor, que difiere mucho de una persona a otra. A pesar de ello, en cuanto a su etiología, cabe destacar que, hasta en el 85% de los casos, es de origen desconocido o inespecífico, ya que no es posible establecer la fuente del dolor en la mayoría de los casos^{1,2}.

Por otro lado, aproximadamente del 10% al 25% de los pacientes con CLBP persistente pueden tener dolor procedente de las articulaciones sacroilíacas (ASI)³. El síndrome de la ASI se caracteriza por dolor localizado en la cara posterior de la ASI, que varía en gravedad, y que puede referirse a las extremidades inferiores y/o a la región lumbar^{4,5}. El origen exacto relacionado con la ASI aún no se ha determinado.

Epidemiología del dolor lumbar crónico

El CLBP es uno de los problemas de salud más comunes en los países industrializados desde la segunda mitad del siglo XX, y se considera la principal causa de años vividos con discapacidad, muy por encima de cualquier otra enfermedad⁶⁻⁸. Se calcula que entre un 70-90% de la población padecerá de lumbalgia al menos una vez en la vida. Con una prevalencia global del 20-30%, el 50% de los afectados experimentarán dolor lumbar recurrente y entre el 10-20% desarrollarán dolor crónico y discapacidad relacionada con el dolor. Además, tan solo un 10-15% de los pacientes consiguen un diagnóstico definitivo^{1,9-13}. Esto se debe a que no existe correlación lineal entre la clínica referida por el paciente y la alteración anatómica hallada mediante técnicas de imagen, por lo que llegar a un diagnóstico etiológico sólo es posible en un porcentaje pequeño de los casos; lo que da lugar a que entre el 85% y el 95% de las lumbalgias serán clasificadas como inespecíficas, ya que el dolor no se atribuye a patología específica reconocida¹⁴⁻¹⁶.

El dolor lumbar (en adelante, LBP) constituye la segunda causa en frecuencia de visitas médicas, la quinta en frecuencia de hospitalización y la tercera en frecuencia de intervención quirúrgica¹⁴⁻¹⁶. Aproximadamente, uno de cada dos individuos que experimentan LBP buscan atención médica durante un episodio, lo cual supone un alto impacto socio-económico. A pesar de la enorme carga económica que supone como enfermedad, no hay suficiente atención médica, y la financiación es inadecuada. Esto se debe, posiblemente, al hecho de que las enfermedades músculo-esqueléticas se perciben como menos graves (respecto a las enfermedades cardiovasculares, VIH o cáncer) y no mortales, y se asume, que su cronicidad va asociada al proceso de envejecimiento normal. Se prevé que, a medida que la población mundial envejezca, la magnitud del problema irá en aumento, con el consiguiente incremento de la carga socio-sanitaria¹⁷⁻²⁰.

El CLBP incide gravemente en la calidad de vida y en las capacidades laborales de hasta el 85% de los pacientes, alterando la funcionalidad hasta en un 11-12% de los casos². Está considerado como la principal causa de limitación de la actividad en personas menores de 45 años, y es la patología músculo-esquelética más prevalente en mayores de 65 años. Dado que los pacientes que no pueden trabajar debido a su patología espinal y siguen sintomáticos después de 1 año, tienen menos del 25% de posibilidades de regresar a su actividad laboral habitual, el dolor de espalda se ha convertido en la segunda causa principal de baja por enfermedad^{1,9-13}. Según datos del Ministerio de Trabajo de España, el

LBP es el motivo de desembolso económico más importante, suponiendo entre el 19-25% de los gastos de incapacidad laboral, sin contar con los costos que suponen las pruebas para el diagnóstico y el tratamiento²¹⁻²⁶.

Estudios previos han demostrado que, en los pacientes con LBP, la calidad de vida y el rendimiento físico van a depender de factores como la intensidad del dolor, el miedo al movimiento y el grado de incapacidad resultante (es decir, el grado de limitación para realizar actividades cotidianas de la vida diaria), que van aumentando con el tiempo²⁷⁻³⁵. De hecho, muchos pacientes con CLBP tienen fuertes creencias sobre el dolor y temen que ciertas actividades puedan incrementarlo y/o causar lesiones más severas. Incluso, muchos proveedores de atención médica aconsejan a los pacientes que eviten actividades y movimientos que estimulen el dolor, reforzando así las restricciones de actividad y entrando en un círculo vicioso en el que, a medida que se restringe la actividad de forma persistente, se incrementa el desacondicionamiento físico, el dolor y la discapacidad en las actividades de la vida diaria (AVD)³⁶⁻⁴⁶.

El CLBP supone uno de los desafíos más conocidos a los que se enfrentan los fisioterapeutas, representando más del 50% de las derivaciones de consultas externas a fisioterapia⁴⁷.

Patogenia y factores de riesgo para el dolor lumbar crónico inespecífico

El intento de comprender el dolor representa uno de los desafíos más antiguos en la historia de la medicina, y supone un debate mundial que continúa en la actualidad. Según John J. Bonica, fundador de la medicina del dolor, el dolor es una experiencia sensorial y emocional desagradable asociada con daño tisular real o potencial, o descrita en los términos de dicho daño⁴⁸. La naturaleza del dolor es compleja, ya que es una herramienta biológicamente protectora, pero puede perder su función adaptativa y convertirse en un dolor patológico, que influya negativamente en la calidad de vida⁴⁹. En función de su duración, el dolor se clasifica en agudo o crónico, siendo este último aquel dolor que persiste más allá del tiempo normal de curación de una lesión aguda, o que se repite a intervalos durante meses o años^{48,50,51}. El dolor crónico es una condición incapacitante que puede afectar a todos los aspectos de la vida del paciente, lo que contribuye a la pérdida de la función tanto física como emocional, en el ámbito familiar,

social y laboral, un aumento del gasto sanitario y la potencial disminución de los ingresos económicos por tal circunstancia⁵², problemas de salud mental, laborales, de calidad de sueño y en las relaciones personales⁵³.

A pesar de que el CLBP tiene un origen inespecífico, se han identificado varios factores como posibles desencadenantes del mismo o de su evolución posterior. Hoy en día, se reconoce que el dolor persistente conlleva una reorganización patológica del sistema neural⁵⁴. Este proceso puede deberse a varios factores, como una predisposición genética⁵⁵⁻⁵⁷, mecanismos de sensibilización central⁵⁸, y otros factores que están en el centro del estudio de la etiología del dolor patológico⁵⁹.

En cuanto a las estructuras anatómicas implicadas en el dolor, existe evidencia de la asociación entre el LBP y la degeneración discal lumbar observada mediante pruebas de imagen^{60,61}. Además, la aparición de osteofitos en los rebordes articulares pueden causar estenosis espinal o foraminal, y los cambios degenerativos también afectan a la cápsula articular y al hueso subcondral, pudiendo desencadenar sintomatología dolorosa⁶². Sin embargo, las anomalías anatómicas pueden no corresponder a la sintomatología que presenta el paciente, como muestra el estudio de Enden et al⁶³ en el que no pudo determinarse que la existencia de lesiones encontradas mediante resonancia magnética fuesen la causa del dolor, ya que estas mismas lesiones también se observan en pacientes asintomáticos. Dado que, en ocasiones, es difícil correlacionar los hallazgos de las pruebas de imagen con el origen del dolor del paciente, éstas deben interpretarse con precaución.

Otra de las posibles causas del LBP es la degeneración de las articulaciones facetarias existentes a nivel vertebral, más común en áreas de mayor estrés y/o movilidad. Hay evidencia de la presencia de terminaciones nerviosas encapsuladas en las facetas vertebrales y terminaciones nerviosas libres nociceptivas en el tejido capsular y en la sinovial facetarias^{64,65}, y el pequeño número de receptores encontrados en las cápsulas facetarias torácica y lumbar sugiere que su campo receptivo es relativamente grande, por lo que el daño de un área pequeña podría denervar la faceta.⁶⁴⁻⁶⁶

A nivel muscular, durante muchos años se ha estudiado la relación entre la disfunción de los músculos ventrales y dorsales del tronco y el dolor lumbar. Varios estudios destacan la importancia de la musculatura multífida lumbar en la estabilidad de la columna^{67,68}, y se ha encontrado una asimetría significativamente mayor en la forma de

los músculos multifidos en el lado doloroso en pacientes con dolor lumbar agudo unilateral, usando ecografía en tiempo real⁶⁹, así como también, se ha observado atrofia generalizada y aumento relativo en el área transversal de los músculos multifidos en el lado sintomático en pacientes con CLBP, mediante tomografía computarizada⁷⁰. Además, existe una mayor activación de los músculos paraespinales en pacientes con CLBP⁷¹, atrofia de las fibras tipo II (contracción rápida) e hipertrofia de las fibras tipo I (contracción lenta)⁷². Muchos músculos del tronco son capaces de contribuir a la estabilización y protección de la columna lumbar, y existe evidencia de que el transverso del abdomen puede estar involucrado de manera muy importante⁷³, encontrando un inicio tardío de la contracción del mismo en pacientes con CLBP, lo que indica un control motor deficitario y resulta en una estabilización muscular ineficiente de la columna vertebral⁷³.

El factor predisponente informado con mayor frecuencia para el CLBP es un episodio previo de dolor lumbar. Esta condición suele ser autolimitada, pero a menudo se vuelve crónica^{74,75}. En cuanto a los factores de estilo de vida, el consumo de tabaco, alcohol y drogas, la falta de ejercicio y el sedentarismo⁷⁴, aumentan el riesgo de desarrollar LBP. Maher et al⁷⁶, informó que el tabaquismo (OR 1.30 [1.16–1.45]), la obesidad (OR 1.53 [1.22–1.92]) y los síntomas depresivos (OR 1.59 [1.26–2.01]) aumentaron el riesgo de desarrollar LBP en una cantidad modesta.

La ausencia de actividad física conduce a atrofia muscular, y a la disminución del control neuromuscular de la postura y el movimiento, por lo que la inactividad total no debe postergarse más allá de 48 horas, momento a partir del cual se producen una serie de cambios fisiológicos que conducen a condiciones patológicas afectando, no sólo al sistema musculoesquelético, sino también al sistemas cardiovascular, neurológico y cutáneo⁷⁷⁻⁸⁰.

La mayoría de las correlaciones significativas con CLBP reportadas en la literatura se han derivado de una combinación de factores biológicos y psicosociales, que incluyen: conductas de miedo y evitación, en las que el paciente asocia el dolor con la existencia de una lesión grave y/o irreversible, reduciendo la actividad más allá de lo que limita el propio dolor, lo cual se asocia de manera estadísticamente significativa con el dolor y la discapacidad^{74,75,77}; factores relacionados con el entorno laboral, como la falta de motivación, la existencia de conflictos, un ambiente hostil o la ausencia de apoyo

social en el trabajo^{74,77-79}; y factores emocionales como los estados de ansiedad, depresión, estrés o aislamiento social⁷⁹.

Durante mucho tiempo se ha pensado que los factores mecánicos tienen un papel causal en el dolor lumbar. Según la evidencia encontrada en revisiones sistemáticas recientes, son factores que aumentan el riesgo de dolor lumbar aquellos trabajos que implican girar o flexionar el tronco, el manejo manual de materiales o la vibración⁸¹⁻⁸⁴. Sin embargo, Balagué et al¹⁶ informó que era poco probable que sentarse, permanecer de pie, caminar, mantener malas posturas, la manipulación manual de cargas, y los movimientos de flexión y rotación del tronco fueran causas independientes de dolor lumbar en las poblaciones estudiadas. Otros hallazgos¹⁶ muestran que las personas con sobrepeso tienen un mayor riesgo de dolor lumbar, con la asociación más fuerte para la búsqueda de atención para el dolor lumbar y para el dolor lumbar crónico, pero son controvertidos o se limitan a unos pocos estudios⁷⁴.

Estrategias de tratamiento

Aunque durante las últimas décadas, han surgido una gran cantidad de opciones de tratamiento para el dolor de espalda y un depósito cada vez mayor de datos procedentes de ensayos clínicos y publicaciones científicas, los resultados de estas investigaciones son a menudo contradictorios y de calidad variable. Esta heterogeneidad en los datos implica que, para un médico/fisioterapeuta, en la búsqueda de la mejor práctica clínica, entender la literatura pueda ser difícil y desconcertante⁸⁵.

El hecho de que un 85% de los dolores de espalda sean inespecíficos, parece ser parte de la causa de que exista una gran variabilidad de teorías fisiopatológicas y de métodos de tratamiento propuestos por distintos profesionales, entre los que parece haber poco consenso. A pesar de que se ha producido un crecimiento exponencial en las modalidades de tratamiento dirigidas a controlar el CLBP, la realidad es que, actualmente, no hay opciones definitivas de manejo intervencionista, conservador o quirúrgico para tratar este tipo de dolor.

Según los resultados derivados de un estudio transversal, en el que se envió un cuestionario vía postal a 2085 médicos de atención primaria que ejercían en Suiza, las terapias convencionales más útiles para el CLBP según los facultativos eran: la

fisioterapia, antiinflamatorios no esteroideos (AINEs) y terapia manual, mientras que los tratamientos convencionales percibidos como menos útiles fueron los bloqueos espinales⁸⁶.

Respecto a la prescripción de fármacos de primera línea, solo existe evidencia de nivel A en la eficacia de la administración de antiinflamatorios por vía sistémica para disminuir el dolor en episodios transitorios, no como tratamiento habitual de fondo⁷⁸. De acuerdo con una revisión sistemática y un metanálisis de 2017 que incluyeron 35 ensayos clínicos aleatorizados, los AINEs redujeron el dolor y la discapacidad de forma inmediata y a corto plazo, pero no tuvieron efectos clínicamente importantes sobre la intensidad del dolor⁸⁷. En cuanto a los opioides, otra revisión sistemática y metanálisis de 2016 mostró un efecto a corto plazo sobre el dolor, pero el efecto fue pequeño y no relevante clínicamente⁸⁸. Además, los efectos secundarios y las complicaciones del tratamiento, como la adicción a los analgésicos opioides, la insuficiencia renal o el sangrado gastrointestinal debido al uso prolongado de medicamentos, dificultan el manejo del dolor crónico⁸⁹.

Entre las principales herramientas destinadas a mejorar la práctica clínica con base en la evidencia científica, existen diversas guías de práctica clínica para el abordaje más adecuado del dolor lumbar. Según la versión española de la Guía de Práctica Clínica (en adelante, GPC) de Lumbalgia Inespecífica del Programa Europeo COST B13, los tratamientos del CLBP aplicados por un equipo de rehabilitación multidisciplinar en el que participa un fisioterapeuta, disminuyen la intensidad del dolor, la incapacidad y el tiempo de retorno a la actividad laboral (nivel de evidencia A), y resultan más efectivos que el tratamiento ambulatorio tradicional (nivel de evidencia B)⁷⁹. Las guías europeas para el manejo del dolor lumbar crónico inespecífico de Airaksinen et al⁹⁰, recomiendan intervenciones fisioterapéuticas como el ejercicio terapéutico supervisado, la manipulación y la movilización espinal, la escuela de espalda para el alivio del dolor a corto plazo (<6 semanas), intervenciones educativas breves proporcionadas por un fisioterapeuta o un fisioterapeuta y un facultativo, y la neuroestimulación eléctrica percutánea o PENS (nivel de evidencia A). Chou et al⁹¹, en su revisión de las terapias no farmacológicas para el tratamiento del LBP, para una GPC de la American College of Physicians, encuentra evidencia de nivel A de que el ejercicio, la rehabilitación interdisciplinaria y la manipulación espinal, son eficaces para el dolor lumbar crónico o subagudo (>4 semanas de duración), y la terapia manual es similar en eficacia a otras

intervenciones no invasivas para el dolor lumbar crónico. En el proceso de desarrollo de una guía interdisciplinaria de Rossignol et al⁹², se recomiendan las intervenciones terapéuticas para el dolor lumbar subagudo (4-12 semanas) mediante ejercicio terapéutico, manipulación vertebral, y terapia manual con un nivel de evidencia A. En cuanto al LBP persistente (12 semanas o más), hay evidencia de la efectividad del ejercicio terapéutico, de la escuela de espalda, de la terapia manual, y de la manipulación espinal. La GPC sobre Lumbalgia elaborada en 2007 por Pérez Irazusta et al⁹³, recomienda el ejercicio terapéutico supervisado y la manipulación vertebral realizada por profesionales con alta experiencia y formación acreditada. Otra guía para el manejo temprano del dolor lumbar persistente e inespecífico⁹⁴ elaborada en 2009, encuentra evidencia de nivel A en el ejercicio, la escuela de espalda, la manipulación espinal y la terapia manual. Para prevenir la ocurrencia y recurrencia de LBP, la guía Alberta⁹⁵ recomienda la actividad física, y para el CLBP recomienda el ejercicio terapéutico y la terapia manual como complemento de un programa de rehabilitación activa más amplio, y no encuentra evidencia concluyente para recomendar a favor o en contra de la manipulación y la movilización espinal. Por su parte, la guía APTA⁹⁶ recomienda la utilización de ejercicios de coordinación, fortalecimiento y resistencia del tronco, la escuela de espalda y la terapia de manipulación y movilización espinal para mejorar la movilidad, reducir el dolor y la discapacidad en pacientes con CLBP y dolor en las extremidades inferiores relacionado con la espalda. En resumen, las técnicas de fisioterapia alternativas más recomendadas en las guías sobre el manejo del LBP, son el ejercicio y la manipulación vertebral. El ejercicio se muestra con un alto nivel de evidencia, mientras que la manipulación está indicada en pacientes específicos, aunque existe cierta controversia en su recomendación.

Evidencia para la utilización de la terapia manipulativa en pacientes con dolor lumbar crónico

La terapia manipulativa es un procedimiento terapéutico común empleado en pacientes con LBP^{97,98}, y se cree que es particularmente útil para acelerar el proceso de recuperación y regreso al trabajo⁹⁹⁻¹⁰³. Las pautas para el tratamiento de la lumbalgia crónica de las principales GPC⁹⁰⁻⁹⁶, recomiendan la terapia de manipulación espinal como una opción de tratamiento en pacientes que sufren CLBP, al igual que varias revisiones

sistemáticas recientes han informado evidencia favorable para la manipulación y/o movilización.¹⁰⁴⁻¹⁰⁶

La terapia manipulativa incorpora técnicas de manipulación específicas para las articulaciones con el fin de restaurar la dinámica articular normal. En general, estas técnicas pueden subdividirse en dos categorías: las no basadas en impulsos, como las terapias de puntos gatillo y las técnicas músculo-energía; y las basadas en movilizaciones e impulsos, que centran la mayoría de los estudios publicados sobre la terapia manipulativa¹⁰⁷. En concreto, el término “manipulación” en esta tesis, se refiere específicamente a aquellas técnicas que son ejecutadas con un empuje de pequeña amplitud y alta velocidad en el límite del rango articular del paciente, de modo que la articulación se lleve brevemente más allá del límite del rango de movimiento restringido (ROM)⁹⁹.

Ha habido muchos intentos de explicar la fisiología de los efectos de la manipulación de la columna, y existe evidencia reciente de que tanto la movilización como la manipulación de la columna lumbar dan como resultado una atenuación transitoria significativa de la actividad de las motoneuronas alfa^{108,109}. La manipulación de distintos niveles de la columna vertebral produce un efecto hipoalgésico localizado e inmediato y una disminución del dolor¹¹⁰⁻¹¹⁵. La analgesia que se produce tras la manipulación puede ser el resultado de las influencias beneficiosas en el entorno químico de las articulaciones periféricas, la facilitación de los procesos de reparación tisular, los procesos inhibidores segmentarios dentro del sistema nervioso central y la activación de las vías inhibitorias descendentes¹¹⁶. Muchos científicos y médicos han postulado durante mucho tiempo que la manipulación espinal ejerce sus efectos biológicos sobre los componentes segmentarios del sistema nervioso central¹¹⁷⁻¹²⁹. Los estudios neurofisiológicos, basan el efecto terapéutico de la manipulación en la tensión generada sobre los ligamentos y otras estructuras periarticulares durante la manipulación articular, lo que provoca la estimulación de los mecanorreceptores aferentes musculares y articulares, generando una relajación refleja de los músculos, así como acciones reflejas que inhiben los receptores del dolor a nivel segmentario^{123,130,131}.

Después de la manipulación cigoapofisaria, se han demostrado reducciones en la actividad electromiográfica espontánea paraespinal^{132,133} y reducción de la hiperalgesia de los puntos gatillo miofasciales paraespinales¹³⁴, y esta manipulación no solo reduce el

dolor en sujetos con síntomas¹³⁴⁻¹³⁶, sino también en sujetos asintomáticos en los que se produce un aumento del umbral de dolor paraespinal a un estímulo nocivo¹³⁷.

La efectividad de este tipo de intervenciones en pacientes con CLBP, está siendo recientemente respaldada por un numeroso incremento de revisiones sistemáticas y ensayos clínicos de elevada calidad, en los cuales se demuestra la efectividad de la terapia manipulativa como terapéutica en el abordaje de la lumbalgia. Aun así, su uso clínico es mucho más extendido, que las recomendaciones que se hacen en las GPC para el abordaje del CLBP.

Entre las revisiones más recientemente publicadas encontramos a Rubinstein et al¹³⁸, que encontraron que la terapia manipulativa producía efectos similares a otras terapias recomendadas en el dolor lumbar (como los AINEs, el ejercicio terapéutico, la escuela de espalda, la fisioterapia convencional y la atención médica conservadora), mientras que la terapia manipulativa parece ser mejor para mejorar la función a corto plazo, en comparación con otras intervenciones no recomendadas (como el placebo, la diatermia de onda corta y el ultrasonido). Otra revisión de Coulter et al¹³⁹ evidencia que la manipulación y la movilización reducen el dolor y mejoran la función en pacientes con CLBP, con un efecto mayor a favor de la manipulación espinal. En la revisión de Mohseni-Bandpei et al¹⁴⁰, informaron que la manipulación puede ser más eficaz que otras intervenciones en el tratamiento del LBP, tanto a corto como a largo plazo, siendo los tratamientos de referencia comparados las intervenciones mediante diatermia de onda corta, ultrasonido, ejercicio, radiación infrarroja, corsé, terapia manual, AINEs, analgésicos o terapia con placebo. En otro estudio más reciente¹⁴¹, la aplicación de terapia de manipulación espinal junto a un programa de ejercicios mostró un mayor beneficio en el dolor, la discapacidad funcional y la movilidad tanto a corto como a largo plazo, en comparación con la aplicación de ultrasonidos junto al mismo programa de ejercicios.

Respecto al tratamiento de la disfunción sacroilíaca, la literatura actual sugiere que la mayoría de los pacientes con disfunción de la ASI se benefician de la manipulación¹⁴²⁻¹⁴⁸. Sin embargo, los datos de resultados tras el abordaje de la disfunción de la ASI son limitados, y no existen guías ni protocolos terapéuticos apropiados para este síndrome. De hecho, solo unos pocos estudios han buscado comparar la efectividad de diferentes modalidades terapéuticas^{149,150}.

En un ECA realizado por Kamali et al¹⁵¹, que comparó los efectos de la manipulación frente a los efectos de los ejercicios de estabilización en disfunción de la ASI, ambos grupos mostraron una mejoría significativa en el dolor evaluado y la discapacidad por LBP, aunque no hubo diferencias estadísticamente significativas entre los grupos tras la intervención. En un ensayo de Nejati et al¹⁵², informan de que el ejercicio y la terapia de manipulación parecen ser efectivos para reducir el dolor y la discapacidad en pacientes con síndrome de la ASI, y que la combinación de ambas terapias no parece generar resultados significativamente mejores que cualquiera de los enfoques implementados por separado. En otro estudio de Shokri et al¹⁵³, se investigó el efecto de la manipulación a nivel lumbar y de la ASI, informando de una mejoría significativamente mayor en el dolor y la discapacidad funcional durante el tratamiento y un mes después de la finalización del mismo.

Evidencia para la utilización de la electropunción seca en pacientes con dolor lumbar crónico

En los últimos años, la punción seca ha ido ganando terreno en las técnicas utilizadas para tratar el dolor musculoesquelético¹⁵⁴, y las pautas para el tratamiento de la lumbalgia de varias guías de práctica clínica^{90,92,94,95} la contemplan como una opción de tratamiento en pacientes con CLBP.

La punción seca es un procedimiento mínimamente invasivo que consiste en insertar una pequeña aguja de monofilamento en un punto gatillo activo o latente para provocar una contracción local y eliminar un punto gatillo miofascial (PGM)^{155,156}. Un PGM se describe como un punto hiperirritable ubicado en una banda tensa de músculo esquelético, que cuando se comprime produce un dolor referido¹⁵⁷.

Según la profundidad a la que se introduzca la aguja, la técnica se puede clasificar como punción seca superficial, en la que la aguja no penetra más de 1 centímetro de tejido, o como punción seca profunda, en la que la aguja penetra más profundamente, hasta atravesar el PGM¹⁵⁸.

Las técnicas de punción seca más conocidas son tres¹⁵⁸: la de entrada y salida rápida de Hong (o técnica del picoteo del gorrión), la de estimulación intramuscular de Gunn y la de Baldry. En la primera, la aguja se introduce en el punto gatillo hasta

provocar la primera respuesta de espasmo local, para pasar a mover la aguja hacia arriba y hacia abajo hasta conseguir más respuestas de contracción breve y repentina de la banda tensa del PGM, procediendo de este modo hasta que se elimina la respuesta de espasmo local¹⁵⁸. La segunda técnica consiste en la punción de la musculatura paravertebral profunda de los segmentos relacionados con las zonas de dolor del paciente, y en la punción de la musculatura periférica con acortamiento evidente¹⁵⁸. Por último, la tercera técnica consiste en la punción superficial en el tejido celular subcutáneo suprayacente al PGM (a profundidad máxima de 1 cm), sin llegar a penetrar a nivel muscular¹⁵⁸. Además de las distintas técnicas de punción seca superficial y profunda descritas, existe otra opción terapéutica denominada punción seca eléctrica, electropunción seca o neuroestimulación eléctrica percutánea (PENS)¹⁵⁹, que trata de eliminar el PGM activo mediante la estimulación de los nervios sensoriales periféricos en los niveles dermatómicos correspondientes a la patología local⁹⁰, usando las agujas con la ayuda de unos electrodos-pinza o “cocodrilos” que se sujetan en la parte de la aguja que queda por encima de la piel y a un aparato de estimulación nerviosa eléctrica transcutánea (TENS).

Se ha demostrado que la punción seca aumenta de forma inmediata el umbral de dolor por presión y el rango de movimiento, disminuye el dolor y el tono muscular en pacientes con afecciones musculoesqueléticas,¹⁶⁰⁻¹⁶³ y hay evidencia de que la punción seca es más efectiva que un control sin tratamiento o una punción seca simulada para reducir el dolor y aumentar el umbral de dolor por presión y los resultados funcionales durante el período de seguimiento inmediato de 12 semanas¹⁶⁴⁻¹⁶⁹.

Para explicar los efectos terapéuticos de esta técnica, se ha sugerido que la punción seca puede provocar respuestas neurales tanto locales como centrales para restaurar la homeostasis en el sitio de los PGM, lo que resulta en una disminución de la sensibilidad al dolor central y periférico¹⁷⁰⁻¹⁷². Existe evidencia de que los pacientes con dolor crónico responden a la punción de forma diferente a los sujetos sanos, a través de una red límbica coordinada que incluye el hipotálamo y la amígdala^{173,174}, y de que la manipulación de la aguja modula la actividad del sistema límbico y las estructuras subcorticales¹⁷⁵.

A nivel vascular, los efectos de la punción seca están bien documentados. Así, Loaiza et al¹⁷⁶, demostró una microcirculación mejorada alrededor de la articulación de la rodilla después de la intervención, los trabajos de Shinbara¹⁷⁷ y Sandberg¹⁷⁸ encontraron

una mejoría del flujo sanguíneo muscular después de la punción en las extremidades inferiores, y el ensayo de Kubo et al¹⁷⁹ sugiere que hay una mejora del flujo sanguíneo en el área tratada tras retirar la aguja, así como un aumento de la saturación de oxígeno que se mantiene hasta 30 minutos tras finalizar la intervención.

En cuanto a los efectos mecánicos, hay evidencia de que la punción supone un estímulo mecánico que provoca la remodelación del citoesqueleto de fibroblastos, con un aumento en el área transversal del cuerpo celular, que implica mecanismos basados en la mecanotransducción (capacidad de las células para percibir e interpretar bioquímicamente estas fuerzas) y la remodelación de la matriz del tejido conectivo, modulando el input mecanosensorial y nociceptivo aferente¹⁸⁰⁻¹⁸².

La evidencia actual revela la efectividad de la punción seca como terapéutica en el abordaje del LBP. Entre las revisiones más recientemente publicadas encontramos a Hu et al¹⁸³, que encontró que la punción seca disminuyó el dolor y la discapacidad por dolor lumbar de forma más significativa que la punción simulada. Otra revisión de Gattie et al¹⁸⁴, encontró un efecto significativo a favor de la punción seca versus placebo o no intervención sobre el dolor, el umbral de dolor a la presión y la capacidad funcional a las 12 semanas de la intervención, y sugiere que la punción es más efectiva para reducir el dolor a las 4 y 12 semanas en comparación con otros tratamientos. El trabajo de Wang-Price et al¹⁸⁵ revela que la punción seca, con o sin manipulación de la aguja, reduce la intensidad del LBP y que la manipulación de la aguja aumenta el umbral de dolor a la presión. Tellez-García et al¹⁸⁶, en su estudio para determinar los efectos a corto plazo de la punción seca en pacientes con LBP, encuentra efectos beneficiosos a corto plazo en la intensidad del dolor, en el umbral de dolor a la presión, la discapacidad por dolor lumbar y la kinesiofobia o miedo al movimiento. Otros estudios en los que se usa la punción seca sola o junto a otras técnicas de fisioterapia convencional¹⁸⁷⁻¹⁸⁹, encuentran disminuciones significativas en la intensidad del dolor, el umbral de dolor a la presión y la discapacidad posterior a la intervención y a corto plazo.

En cuanto a la electropunción seca, varios estudios demuestran que el uso de esta técnica a baja frecuencia resulta en una reducción de la lumbalgia¹⁹⁰⁻¹⁹², y que podría mejorar la estimulación eléctrica de ciertas reacciones fisiológicas, para obtener efectos analgésicos y anestésicos más rápido que las reacciones fisiológicas obtenidas con la punción manual tradicional¹⁹³. Lee et al, mediante el uso de flujometría de láser Doppler,

encontró que la microcirculación por encima del PGM había aumentado más del doble tras la electropunción de los PGM en pacientes con síndrome de dolor miofascial cervical y del hombro, y que este flujo sanguíneo parece correlacionarse con el dolor, de tal modo que la reducción de la microcirculación interviene en la fisiopatología del síndrome de dolor miofascial¹⁹⁴. Por su parte, Ahsin et al¹⁹⁵ encontraron que la electropunción en osteoartritis de rodilla provoca cambios a nivel endocrino, como aumentos en las beta-endorfinas y disminución en el cortisol.

Evidencia para la utilización de la telemedicina en pacientes con dolor lumbar crónico

La tecnología ha revolucionado todos los aspectos de la atención médica. A medida que la investigación y el desarrollo tecnológico se trasladan a la práctica, los usuarios pueden optar a una amplia gama de opciones terapéuticas salvando, incluso, la distancia física entre el paciente y el promotor del servicio de salud. Las tecnologías de la información y la comunicación (TIC) se pueden utilizar para ampliar el alcance de los fisioterapeutas más allá de las paredes físicas de un hospital o de una clínica de rehabilitación, pudiendo atender directamente a los pacientes en sus propios domicilios, llegando a zonas rurales, a zonas sin atención especializada y a personas con dificultades en el desplazamiento¹⁹⁶, mejorando la equidad en salud al facilitar el acceso a la información y los servicios de salud¹⁹⁷. Sumado a lo anterior, la pandemia de COVID-19 ha supuesto un punto de inflexión, acelerando el uso de la telemedicina para proteger la salud tanto de los pacientes como de los profesionales sanitarios que los atienden, así como para fortalecer los servicios de rehabilitación afectados durante la pandemia¹⁹⁸.

La última década ha visto un tremendo crecimiento de la teleasistencia o asistencia telemática, y es probable que esta tendencia continúe. El término telemedicina se refiere a la transferencia o intercambio de información sanitaria utilizando las TIC¹⁹⁶. Específicamente, la telerehabilitación se refiere a la prestación de servicios de rehabilitación a través de telemedicina¹⁹⁶. Independientemente de la terminología, la telerehabilitación no es una disciplina nueva^{199,200}, sino que supone una forma novedosa de prestar la atención al paciente. Desde sus comienzos, en los que se realizaba atención y seguimiento telefónicos^{201,202}, pasando por la asistencia con material audiovisual^{203,204}, hasta llegar al uso de videoconferencias^{204,205}, la telerehabilitación ha demostrado ser un

método eficaz para proporcionar diversas intervenciones dentro del campo de la rehabilitación^{207,208}. La telerehabilitación supone una opción innovadora para resolver los problemas que enfrentan los sistemas de salud ante una demanda creciente de sus servicios, debido al envejecimiento de la población y al aumento de patologías de carácter crónico²⁰⁹⁻²¹¹, entre las que se encuentra el CLBP, objeto de estudio en esta tesis.

Hay evidencia de que los pacientes generalmente aceptan e incluso pueden preferir los modos de prestación de servicios de telemedicina a las interacciones cara a cara²¹², y se ha sugerido que la telemedicina en la atención del trauma, en regiones desprovistas de profesionales de la salud especializados, genera confianza y gran alta aceptación social, especialmente para el diagnóstico en tiempo real y el tratamiento remoto²¹³. Según diversos estudios, las intervenciones de autocuidado para el dolor crónico se han asociado con altos niveles de satisfacción del paciente^{212,214}, menos dolor^{212,215}, y mejor calidad de vida²¹⁵, y pueden desempeñar un papel positivo en la mejora del dolor y la discapacidad a corto plazo en pacientes con CLBP²¹⁶. Además, se ha demostrado que la telerehabilitación fortalece la conexión paciente-terapeuta, mejora el conocimiento del paciente y su contexto, facilita el intercambio de información y la educación sanitaria, pudiendo establecer planes de acción y metas compartidas²¹⁷.

En el ámbito de la traumatología y de la neurología, existen investigaciones científicas que han estudiado los efectos de la rehabilitación a distancia en diversas patologías. En la revisión sistemática y metanálisis de Shukla et al²¹⁸, encuentra evidencia de la eficacia de la telerehabilitación en pacientes sometidos a artroplastia de rodilla, con una mejoría en la funcionalidad y en la actividad física similar a la obtenida mediante la atención presencial. Otra revisión y metanálisis de Anwer et al²¹⁹, encuentra evidencia alta de que las intervenciones a distancia disminuyen el dolor y la discapacidad en pacientes con osteoartritis de rodilla. Ortiz Piña et al²²⁰, encontró mejores efectos sobre la independencia funcional y el rendimiento físico en adultos mayores tras fractura de cadera que habían seguido un programa multidisciplinario de telerehabilitación, en comparación con el tratamiento presencial domiciliario proporcionado por el Sistema Andaluz de Salud. En la revisión de Sarfo et al²²¹, sugiere que la telerehabilitación proporciona efectos iguales o mejores que el tratamiento presencial, en pacientes que han sufrido accidente cerebrovascular. Otro estudio de Delioğlu et al²²², encontró que la telemedicina ayudó a gestionar el confinamiento y las preocupaciones de las familias de niños con parálisis obstétrica del plexo braquial menores de 3 años, especialmente en el

grupo de 0 a 1 año, y todos los padres enfatizaron la necesidad de servicios remotos en situaciones similares al confinamiento por Covid-19. De hecho, el escenario pandémico vivido promovió una declaración de posición de la World Confederation for Physical Therapy, sobre el uso de la telerehabilitación para mejorar la accesibilidad a la atención de rehabilitación, ofreciendo a la comunidad de fisioterapeutas la oportunidad de reflexionar sobre este nuevo método de atención²²³.

Las intervenciones de telerehabilitación han demostrado ser beneficiosas para mantener la mejora en el CLBP, a través de sesiones de refuerzo proporcionadas mediante videoconferencia²²⁴ y mediante una aplicación de teléfono móvil²²⁵. Un ensayo recomienda realizar un programa de ejercicios específico mediante telerehabilitación en el lugar de trabajo, para ayudar a atenuar el tiempo de trabajo perdido relacionado con la lumbalgia²²⁶, y otro estudio concluye que la telemedicina fue menos costosa y más efectiva para reducir el tiempo de trabajo perdido por lumbalgia, en comparación con la supervisión directa del ejercicio²²⁷. Dos estudios exploraron la eficacia de una aplicación móvil en el autocontrol del LBP, encontrando mejoras clínicamente significativas en el dolor y la discapacidad, demostrando además que es una herramienta rentable con capacidad de llegar a un gran número de personas^{228,229}. Otro estudio determinó que la adherencia de los pacientes con LBP a los programas de ejercicios domiciliarios, podría facilitarse mediante la retroalimentación que ofrecen las nuevas tecnologías, haciéndolos más atractivos, aunque no sustituyen la relación paciente-terapeuta²³⁰. La evidencia más reciente concluye que el uso simultáneo de “mobile-health” y las intervenciones de atención habitual tienen una mayor eficacia que la atención habitual sola para reducir la intensidad del dolor y la discapacidad en pacientes con LBP²³¹, y que puede ser un método conveniente y efectivo para tratar el CLBP²³².

Dado el bajo costo y la gran disponibilidad que supone para los pacientes, los profesionales que tratan a pacientes con dolor crónico podrían considerar el uso de intervenciones de telemedicina como parte de una estrategia multidisciplinaria de tratamiento del dolor²³³.

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OBJETIVOS

OBJETIVOS

OBJETIVO GENERAL

Evaluar los efectos de la terapia manipulativa, la electropunción seca y la telemedicina en sujetos con dolor lumbar crónico inespecífico.

OBJETIVOS ESPECÍFICOS

- Analizar la efectividad de la terapia manipulativa de la torsión sacra versus terapia miofascial sobre la discapacidad, intensidad del dolor, kinesiofobia, calidad de vida, resistencia isométrica de los músculos flexores del tronco y movilidad lumbar en personas con CLBP. **(Artículo I)**
- Evaluar la eficacia de la electropunción seca frente a la fisioterapia convencional sobre la discapacidad, intensidad del dolor, calidad de vida, kinesiofobia, calidad del sueño, ansiedad, depresión, resistencia isométrica abdominal, movilidad de la columna lumbar, y umbral de dolor a la presión en pacientes con CLBP. **(Artículo II)**
- Analizar la efectividad de las intervenciones de e-Salud sobre el dolor, la funcionalidad y la calidad de vida en pacientes con CLBP. **(Artículo III)**

METODOLOGÍA

METODOLOGÍA

Para cumplir los objetivos de esta tesis doctoral, se han desarrollado las siguientes fases:

- I. Realización de un ensayo clínico para comparar los efectos de la terapia manipulativa versus la terapia de inducción miofascial, en pacientes diagnosticados con CLBP.
- II. Desarrollo de un protocolo de ensayo clínico para comparar los efectos de la electropunción seca versus la fisioterapia convencional en pacientes diagnosticados con CLBP. Se ha escogido este tipo de trabajo dada la dificultad de reclutar pacientes de forma presencial durante la pandemia de Covid-19, para optimizar el tiempo y seguir investigando en el campo del abordaje del CLBP, y controlar la calidad de todos los aspectos de un futuro ensayo clínico aleatorizado.
- III. Revisión sistemática y metanálisis para analizar los efectos de las intervenciones de telemedicina en pacientes con CLBP, dado a que esta modalidad de asistencia estaba aumentando su frecuencia en los últimos tiempos, y la pandemia ha estimulado su uso al suponer una alternativa a la atención presencial durante el confinamiento.

En la Tabla 1 se incluye un resumen de la metodología empleada en los artículos que componen la presente tesis.

Tabla 1. Resumen de la metodología utilizada en los manuscritos incluidos en la tesis doctoral

ARTÍCULO	DISEÑO DEL ESTUDIO	PARTICIPANTES	INTERVENCIÓN	PRINCIPALES VARIABLES ESTUDIADAS	MÉTODOS
I. Manipulative therapy of sacral torsion versus myofascial release in patients clinically diagnosed posterior pelvic pain: a consort compliant randomized controlled trial	Ensayo clínico prospectivo, aleatorizado, simple ciego.	64 CLBP y síndrome ASI	Terapia manipulativa de torsión sacra una vez por semana durante un total de 12 semanas (Grupo Experimental)	Discapacidad	Roland Morris Disability Questionnaire (RMDQ) (discapacidad autoadministrada calificada en una escala de 24 puntos)
		Grupo Experimental (n = 32)		Intensidad del dolor	Dolor en una escala analógica visual de 10 cm (EVA)
		Grupo Control (n = 32)	Terapia de liberación miofascial lumbrosacra una vez por semana durante un total de 12 semanas (Grupo Control)	Miedo al movimiento	Escala Tampa de Kinesiofobia (TSK) (consta de 17 ítems)
				Calidad de vida autopercebida	Cuestionario de Salud SF-36
				Resistencia isométrica de la musculatura abdominal	Test de McQuade (mide la resistencia isométrica abdominal en segundos)
				Movilidad lumbar en flexión	Test distancia dedos-suelo (mide la distancia dedos-suelo en cm)

ARTÍCULO	DISEÑO DEL ESTUDIO	PARTICIPANTES	INTERVENCIÓN	PRINCIPALES VARIABLES ESTUDIADAS	MÉTODOS
II. Electrical dry needling versus conventional physiotherapy in the treatment of active and latent myofascial trigger points in patients with nonspecific chronic low back pain	Protocolo de estudio controlado, aleatorizado, de dos brazos	92 CLBP Grupo Experimental (n = 46) Grupo Control (n = 46)	Electropunción seca una vez por semana durante un total de 6 semanas (Grupo Experimental) Fisioterapia convencional (compresión isquémica, estiramiento analítico y educación postural) una vez por semana durante un total de 6 semanas (Grupo Control)	Discapacidad Limitaciones en la actividad de la vida diaria Intensidad del dolor Miedo al movimiento Calidad de vida autopercebida Calidad del sueño Ansiedad y Depresión	Roland Morris Disability Questionnaire (RMDQ) (discapacidad autoadministrada calificada en una escala de 24 puntos) Oswestry Disability Index (ODI) (evalúa las limitaciones de la actividad de la vida diaria en 10 dimensiones) Dolor en una escala analógica visual de 10 cm (EVA) Escala Tampa de Kinesiofobia (TSK) (consta de 17 ítems) Cuestionario de Salud SF-36 Pittsburgh Sleep Quality Index (PSQI) (evalúa la calidad del sueño mediante 19 preguntas) Hospital Anxiety and Depression

					Scale (HADS) (consta de dos subescalas: HADA (evalúa la ansiedad) y HADD (evalúa la depresión))
				Resistencia isométrica de la musculatura abdominal	Test de McQuade (mide la resistencia isométrica abdominal en segundos)
				Movilidad lumbar en flexión	Test distancia dedos-suelo (mide la distancia dedos-suelo en cm)
				Estática y dinámica del raquis	Spinal Mouse® (mide la curvatura del raquis y evalúa la movilidad segmentaria lumbar)
				Umbral de dolor a la presión	Algometría de presión (algómetro Wagner FPI 10) en PGM lumbares según Travell y Simons)

ARTÍCULO	DISEÑO DEL ESTUDIO	PARTICIPANTES	INTERVENCIÓN	PRINCIPALES VARIABLES ESTUDIADAS	MÉTODOS
III. Efficacy of e-Health Interventions in Patients with Chronic Low-Back Pain: A Systematic Review with Meta-Analysis	Revisión sistemática con metanálisis. Herramienta AMSTAR 2 para evaluar la calidad de la revisión sistemática	3.180 adultos con CLBP (Sumatorio de todos los sujetos de los artículos considerados en el Meta-análisis)	E-salud / telesalud / telemedicina / telerehabilitación	<p>Discapacidad</p> <p>Limitaciones en la actividad de la vida diaria</p> <p>Intensidad del dolor</p> <p>Calidad de vida autopercebida</p>	<p>Roland Morris Disability Questionnaire (RMDQ) (discapacidad autoadministrada calificada en una escala de 24 puntos)</p> <p>Oswestry Disability Index (ODI) (evalúa las limitaciones de la actividad de la vida diaria en 10 dimensiones)</p> <p>Dolor en una escala analógica visual de 10 cm (EVA) y en escala numérica de calificación del dolor (NPRS)</p> <p>Cuestionario de Salud SF-36 y SF-12</p>

RESULTADOS Y DISCUSIÓN

RESULTADOS Y DISCUSIÓN

Los resultados y la discusión de la tesis están incluidos en los artículos presentados, en la misma forma en la que han sido publicados.

ARTÍCULO I

MANIPULATIVE THERAPY OF SACRAL TORSION VERSUS MYOFASCIAL RELEASE IN PATIENTS CLINICALLY DIAGNOSED POSTERIOR PELVIC PAIN: A CONSORT COMPLIANT RANDOMIZED CONTROLLED TRIAL.

Castro-Sánchez AM, Gil-Martínez E, Fernández-Sánchez M, Lara-Palomo IC, Nastasia I,
de los Ángeles Querol-Zaldívar M, Aguilar-Ferrándiz ME.

Spine J 2021; 21(11): 1890-1899.

Factor de impacto: 4.166 / **Ranking:** 15/82 (Q1)



The SPINE JOURNAL

Volume 21

Issue 11

November 2021

www.thespinejournalonline.com

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ADVANCING GLOBAL SPINE CARE

CLINICAL STUDIES

1784 Comparison of surgical invasiveness and morbidity of adult spinal deformity surgery to other major operations

Nikita Lakomkin, MD, Blaine Stannard, BA, Jeremy L. Fogelson, MD, Anthony L. Mikula, MD, Lawrence G. Lenke, MD, Scott L. Zuckerman, MD, MPH

1793 Does vertebral body tethering cause disc and facet joint degeneration? A preliminary MRI study with minimum 2-years follow-up

Altug Yucekul, MD, Burcu Akpunarli, MD, Atahan Durbas, MBBS, Tais Zulemyan, MSc, Irem Havlucud, Gokhan Ergene, MD, Sahin Senay, MD, Pinar Yalinay Dikmen, MD, Sule Turgut Balci, MD, Ercan Karaarslan, MD, Yasemin Yavuz, PhD, Caglar Yilgor, MD, Ahmet Alanay, MD

1812 Modified-frailty index does not independently predict complications, hospital length of stay or 30-day readmission rates following posterior lumbar decompression and fusion for spondylolisthesis

Aladine A. Elsamadley, MD, Isaac G. Freedman, MPH, Andrew B. Koo, MD, Wyatt B David, MS, Benjamin C. Reeves, BS, John Havlik, BS, Zach Pennington, BS, Luis Kolb, MD, John H. Shin, MD, Daniel M. Schubba, MD

1839 Impact of inhalational anesthetic agents on the baseline monitorability of motor evoked potentials (MEPs) during spine surgery: a review of 22,755 cervical and lumbar procedures

W. Bryan Wilent, PhD, Eric A. Tesdahl, PhD, Julie T. Trott, MS, Shakira Tassone, BS, James S. Harrop, MD, Eric O. Klineberg, MD, MS, Anthony K. Sestokas, PhD

1890 Manipulative therapy of sacral torsion versus myofascial release in patients clinically diagnosed posterior pelvic pain: A consort compliant randomized controlled trial

Adekaiida Maria Castro-Sánchez, PhD, PT, Esther Gil-Martínez, PT, Manuel Fernández-Sánchez, PhD, PT, Inmaculada Carmen Lara-Palomo, PhD, PT, Iuliana Nastasia, PhD, PT, María de los Angeles Querol-Zaldivar, PT, María Encarnación Aguilar-Ferrández, PhD, PT

BASIC SCIENCE

1938 Exercise attenuates low back pain and alters epigenetic regulation in intervertebral discs in a mouse model

Yiya Kawarai, MD, PhD, Seon Ho Jang, Seunghwan Lee, PhD, Mogali Millicamps, PhD, HyungMo Kang, Stephanie Gregoire, PhD, Miyako Suzuki-Narita, MD, PhD, Seiji Ohtori, MD, PhD, Laura S Stone, PhD



Clinical study

Manipulative therapy of sacral torsion versus myofascial release in patients clinically diagnosed posterior pelvic pain: A consort compliant randomized controlled trial

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Received 16 October 2020; revised 29 April 2021; accepted 1 May 2021

Abstract

BACKGROUND CONTEXT: Chronic low back pain represents a health care problem with substantial costs. It is generally accepted that approximately 10% to 25% of patients with persistent chronic low back pain may have pain arising from the sacroiliac joints.

PURPOSE: This study aimed to analyze the effects of manipulative therapy of sacral torsion versus myofascial release on disability, pain intensity, and mobility in patients with chronic low back pain and sacroiliac joints.

STUDY DESIGN/SETTING: A prospective, single-blinded randomized clinical trial.

PATIENT SAMPLE: Sixty-four patients (mean±SD age: 51±9; 60% female) with chronic low back pain and sacroiliac joints comprised the patient sample. No participant withdrew because of adverse effects.

OUTCOME MEASURES: Self-reported disability (primary), pain intensity, scale of kinesiophobia, quality of life, isometric endurance of trunk flexor muscles, and lumbar mobility in flexion were assessed at baseline, post-treatment, and one month follow-up.

METHODS: Participants were randomly assigned to a sacral torsion manipulation group or myofascial release group, receiving a total of 12 sessions (once weekly).

RESULTS: ANCOVA did not show a statistically significant difference between groups for disability (95% CI -2.40–1.90, $p=0.177$). Effect sizes were large in both groups at both follow-up periods. Similar results were achieved for all secondary outcomes ($p<0.05$). The linear model longitudinal analyses showed significant improvements in both groups over time for all outcomes with the exception of fear of movement (manipulative: Minimum within-groups change score 1.91, $p<0.001$; myofascial: 1.66, $p<0.001$).

CONCLUSION: Manipulative and myofascial release therapy in patients with clinically diagnosed sacroiliac joints syndrome resulted in a similar short-term benefits on patient reported dis-

Abbreviations: ANCOVA, Analysis of covariance; CLBP, Chronic low back pain; MCID, Minimum clinically important difference; NPRS, Numerical Pain Rating Scale; ODI, Oswestry Disability Index; RMQ, Roland Morris Disability Questionnaire; SIJ, Sacroiliac joints; TSK, Tampa Scale of Kinesiophobia; VAS, Visual Analogue Scale

Funding Disclosures: This research did not receive any specific grant from any public funding agencies, commercial, or not-for-profit sectors, and therefore there is not risk of bias.

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ability. Both groups experienced similar decrease in the intensity of pain over time, although no clinically meaningful effects were demonstrated in either group. © 2021 Elsevier Inc. All rights reserved.

Keywords: Low Back Pain; Pelvic Pain; Sacroiliac Joint; Musculoskeletal Manipulations; Randomized Clinical Trial; Myofascial Release

Introduction

Chronic low back pain (CLBP) represents a significant health care problem that results in substantial costs to society [1,2]. It is generally accepted that approximately 10% to 25% of patients with suspected sacroiliac joint (SIJ) pain have a subsequent positive diagnostic intra-articular SIJ injection with anesthetic [3]. SIJ syndrome is characterized by pain over the posterior aspect of SIJ varying in severity, which can also refer pain to the greater trochanter, groin, posterior thigh, knee, lateral or posterior calf to the ankle, foot, and toes [4]. The exact origin of SIJ related pain has not been clarified. One postulated origin is accidental minor subluxation and repeated movements of the SIJ may damage the joint capsule and the posterior ligamentous region [5].

Manipulative therapy has been used in the treatment of patients with CLBP and significant improvement has been reported with thrust manipulative techniques in disability versus non-thrust application [6]. Spinal manipulation has been also reported to be more effective than placebo in the treatment of CLBP, with high-velocity low-amplitude thrust manipulation the most effective modality [7]. In addition, myofascial therapy is an effective manual technique to release areas of impaired gliding fascial mobility and to improve pain perception over a short-term duration in CLBP [8]. Specifically, Ajimsha et al. [9] have reported that myofascial release reduces LBP in 53.3% and disability in 29.7% compared to placebo.

Conventional treatment for chronic SIJ pain includes manual therapy, activity modification, analgesic and anti-inflammatory medications, and arthrodesis [10]. It has been demonstrated that posterior pelvic tilt taping intervention favorably affected the pelvic inclination and sacral horizontal angle, leading to beneficial effects on SIJ dysfunction and medial buttock pain [11]. Several studies have reported results in muscle inhibition, improved functional disability, gait symmetry, and decrease pain from SIJ manipulation techniques [12–15]. Recently, a single session of SIJ and lumbar manipulation was more effective for improving functional disability than SIJ manipulation alone in patients with SIJ syndrome [13]. In spite of this, there are currently no definitive interventional, conservative, or surgical management options for managing SIJ pain [16–19]. In addition, few randomized clinical trials have analyzed the effectiveness of SIJ manipulative therapy [12,15]. In our concern, there is neither previous research on the comparative effects between manipulative therapy and myofascial release in SIJ.

The purpose of the study was to analyze the effectiveness of manipulative therapy of sacral torsion versus myofascial approach on disability, pain intensity, kinesiophobia, quality of life, isometric endurance of trunk flexor muscles, and mobility in individuals with CLBP, and SIJ syndrome.

Materials and methods

Study design and participants

A randomized single-blind clinical trial with intention-to-treat analysis and subject masked to treatment allocation was designed and conducted following CONSORT guidelines. The protocol was approved by the local human research committee of the University of XXX (XXX). It was conducted following the declaration of Helsinki and was registered on clinicaltrials.gov (NCT02065531). All subjects signed an informed consent.

A total of 88 participants with CLBP and SIJ syndrome were recruited and evaluated by two therapists with more than 10 years of clinical experience at the clinical unit of Faculty of Health Sciences of the University of XXX (XXX) based on predefined inclusion and exclusion study criteria. CLBP was defined as pain that continues for 12 weeks or longer localized between the costal margin and the inferior gluteal crease. While SIJ syndrome was defined as pain commonly perceived in the gluteal region, which can be referred to the lower limbs and/or lumbar region [20]. To confirm the presence of SIJ syndrome Compression test, Thigh thrust test, Distraction test, Gaenslen's test, Sacral test, and Sacroiliac motion spring test were performed. Three or more positive pain provocation SIJ tests have discriminative power for diagnosis and showed high specificity and sensitivity [21].

To be eligible patients had to meet the following inclusion criteria: (1) LBP for and/or over three months; (2) age between 18 and 60 years; (3) subacute unilateral or bilateral SIJ syndrome ≥ 6 weeks; (4) $x \geq 4$ points on the Roland Morris Disability Questionnaire; (5) not currently receiving physical therapy. Exclusion criteria included: (1) presence of lumbar stenosis; (2) diagnosis of spondylolisthesis; (3) diagnosis of fibromyalgia; (4) treatment with corticosteroid or oral medication within the past two weeks; (5) a history of spinal surgery; (6) contraindication to manipulative therapy; (7) having previously undergone manipulative therapy; (8) disease of the central or peripheral nervous system; (9) clinical signs of radiculopathy.

Randomization

Patients were blinded and randomly assigned to receive either manipulative therapy or a protocol of myofascial release for a total of 12 sessions in each group (one and/or weekly). Both groups were treated by two physical therapists with more than 10 years of experience in the management of individuals with chronic pain. Concealed allocation was performed using a computer-generated randomized table of numbers created before the start of data collection by a researcher not involved in the recruitment or treatment of patients. Individual and sequentially numbered index cards with the random assignment were prepared. The index cards were folded and placed in sealed opaque envelopes. Another therapist, blinded to baseline examination, opened the envelope and proceeded with treatment according to the group assignment.

Outcomes measures

Firstly, subjects provided demographic and clinical information. Outcome measures were assessed before the first treatment session (baseline data), immediately after treatment (at week 12) and one month after the last treatment session (follow-up).

The primary outcome of this study was the Roland-Morris Disability Questionnaire (RMQ) for assessing disability due to LBP [22–24]. The total score ranges from 0 (no disability) to 24 (maximum possible disability) [22,25–27]. A change in 2–3 points on the RMQ represents the minimum clinically important difference (MCID) [28,29].

A 10-point Numerical Pain Rating Scale (NPRS; 0: no pain, 10: Maximum pain) was used to assess the patients' current level of pain. The MCID for the NPRS has been reported in 2.5 points [30].

The Tampa Scale of Kinesiophobia (TSK) is a 17-item questionnaire developed to measure the fear of movement and (re)injury [26]. Ratings are summed to yield a total score (ranging from 17 to 68 points) where higher values reflect greater fear of (re)injury [26,30,31].

The SF-36 quality of life questionnaire assesses 8 domains including physical functioning, physical role, bodily pain, general health, vitality, social functioning, role-emotional, and mental health [32]. This scale ranges from 0 (lowest level of functioning) to 100 (highest level) [33,34].

To test isometric endurance of trunk flexor muscles we used the McQuade test [35]. Subjects were supine with their arms crossed over the chest, hands on the opposite shoulders, hips bent, and knees, and feet apart. They were asked to nod and continue to lift their head and shoulders until the inferior angle of the scapula lifted from the table and maintain the position as long as possible [36]. We recorded the number of seconds that the position was maintained for a maximum of 120 sec.

Lumbar mobility in flexion was determined by measuring the finger-to-floor distance with a tape [37]. Participants performed a straight-legged forward trunk flexion from a

standing position. Both arms stretched toward the floor with the palms facing the legs. They maintained the maximal forward bending position for 2 sec before the measurement. The assessor measured the distance (cm.) from the tip of the third finger to the floor [38].

Intervention

Patients underwent one session per week for a total of 12 weeks at Health Sciences School of XXX University. The details of the interventions are provided below.

Sacral manipulative therapy

All patients received the sacral mobilization with impulse manipulative technique on the day of their initial examination. Manipulation was performed by an oblique force which was applied to the inferior lateral angle of the sacrum, taking less than 5 minutes per patient. The technique was carried out as follow:

The technique began with the patient side lying with their feet together and their shoulders perpendicular to the stretcher, while the therapist standing at one side of the stretcher near the patient's pelvis with a slight orientation toward the patient's head. In that position, an extension and an axial traction were made to patient's lower and upper limbs in contact with the stretcher. A hip and knee flexion were done to the contralateral lower limb, and the therapist did a trunk rotation of the patient toward the ceiling, inducing a slight bend trunk to push posterior the sacral base. The therapist's pisiform of the caudal hand pressed the patient's inferior lateral angle (ILA) of the sacrum in contact with the stretcher, while the therapist's cranial hand stabilized on the groove between the patient's deltoid and pectoralis major. The barrier was engaged with the therapist's cranial hand contacting the patient's deltopectoral groove and the caudal hand contacting the ILA of the sacrum (the side situated on the stretcher), with the pisiform in the direction of the contralateral shoulder. The thrust was made by a body drop on the rotating pelvis, a mobilization with impulse thrust was provided in a scooping fashion with the caudal hand on the ILA of the sacrum in the direction of the resistant on the contralateral shoulder [21] (*Fig. 1*).

Myofascial soft tissue protocol

Patients in the myofascial group received a protocol which includes the following techniques (mean session duration of 60 min). These myofascial induction techniques were based on the study by Ajimsha (2014) [9] and the book by Andrzej Pilat (2003) [39]: (1) Lumbo-sacral decompression; (2) Diaphragmatic release (transverse application); (3) Lumbar square fascia release (phase A, relaxation); (4) Lumbar square fascia release (phase B, elongation); (5) Release of gluteus fascia; (6) Deep release of pubic region; (7) Release of deep fascia at psoas level; (8) Pelvic floor release (*Fig. 2*)



Fig. 1. Sacral manipulative therapy.

Statistical analysis

Statistical analysis was performed using *SPSS statistical software, version 18.0*, and it was conducted according to the intention-to-treat analysis. The Kolmogorov-Smirnov test showed a normal distribution of the data. Baseline demographic and clinical variables were compared between both groups using Student t-tests for continuous data and Chi-square tests for categorical data. Analysis of covariance (ANCOVA) was used to analyze for differences between the two groups in all patient-rated outcomes (RMQ as primary outcome) at post-treatment and one month follow-up. Baseline values were used as covariates. A p-value <.05 was considered statistically significant. The sample size was calculated using the *Ene 3.0 software (Autonomic University of Barcelona, pain)*. The calculations were based on detecting differences of 2.5 points in the RMQ (MCID) [27], assuming a standard deviation of 2.5 points, a 2-tailed test, an alpha level (α) of 0.05, and a desired power (β) of 85%. The estimated desired sample size was calculated to be 32 subjects per group.

Results

Four hundred and ninety-one patients were eligible for screening, and eighty-eight (n=88) consecutive patients were screened for eligibility criteria. Sixty-four patients (mean±SD age: 51±9; 60% female) satisfied all the

eligibility criteria and were randomized to either the manipulative therapy (n=32) or myofascial release group (n=32). Reason for ineligibility can be found in *Fig. 3*, which provides a flow diagram of patients. Baseline features between both groups were similar for all variables at the beginning of the study (*Table 1*).

ANCOVA did not show a statistically significant differences between groups for the RMQ (Post-treatment: $F=2.23$, $p=.140$; One-month follow-up: $F=1.87$, $p=.177$). The linear model longitudinal analyses showed significant improvements in both groups over time ($F=22.56$, manipulative: $p<.001$; myofascial: $F=10.87$, $p<.001$), however patients receiving spinal manipulation experienced greater reduction in the RMQ (within-groups change score 5.2) than those receiving myofascial release technique (within-groups change score 2.7) at all follow-up periods (*Table 2*). The patients who achieved 50% pain relief were 7 (95% CI: 2,8) in the experimental group and 4 (95% CI: 3,7) in the control group immediate post-treatment, and 3 (95% CI: 3,8) in the experimental group and 3 (95% CI: 1,5) in the control group one month follow-up. Patients achieving 80% pain relief were 2 (95% CI: 0,5,9) in the experimental group and 4 (95% CI: 1,5) in the control group immediate post-treatment, and 2 (95% CI: 1,8) in the experimental group and 3 (95% CI: 1,7) in the control group one month follow-up. In addition, one patient in the experimental (95% CI: 0,7) and control group (95% CI: 0,4) registered 100% pain



Fig. 2. Myofascial induction techniques.

relief immediate post-treatment, and only one patient in the experimental group (95% CI: 0,7) one month follow-up.

The ANCOVA analysis did not indicate statistically significant differences between groups for pain intensity or fear to movement. However, linear longitudinal analysis showed a main effect over time within-groups (manipulative: $F=16.77$, $P<0.001$; myofascial: $F=8.41$, $p<0.001$) experiencing similar decrease in the intensity of pain in both groups (manipulative within-groups change score 1.91; myofascial within-groups change score 1.66) but not on fear to movement (manipulative: $F=2.343$, $P<0.113$; myofascial: $F=0.290$, $p<0.750$) at all follow-up periods (Table 2).

The ANCOVA analysis also did not found significant differences between groups in either domain of the SF-36 quality of life questionnaire, finger-to-floor distance immediately post-treatment; and McQuade Test at all follow-up periods. Only significant differences between groups were achieved for general health ($F=8.47$, $p=0.005$), social functioning ($F=4.07$, $p=0.048$), and finger-to-floor distance at one month follow-up ($F=8.26$, $p=0.006$). There was a main effect for time in both groups experiencing an increase on SF-36 subscales: physical function (manipulative: $F=20.828$, $p<0.001$; myofascial: $F=23.282$, $p<0.001$), physical role

(manipulative: $F=3.316$, $p<0.050$; myofascial: $F=10.900$, $p<0.001$), bodily pain (manipulative: $F=16.768$, $p<0.001$; myofascial: $F=8.411$, $p<0.001$); and McQuade Test (manipulative: $F=8.317$, $p<0.001$; myofascial: $F=7.021$, $p<0.003$), and finger-to-floor distance (manipulative: $F=25.008$, $p<0.001$; myofascial: $F=4.475$, $p<0.020$) at both follow-up (Table 2 and 3). In addition, there were significant differences for time only in manipulative group on general health ($F=4.285$, $p<0.018$). Also, there were significant differences for time only in myofascial release group on vitality ($F=3.902$, $p<0.031$), and social functioning ($F=4.533$, $p<0.019$). No main effect over time was observed for the rest of subscales SF-36. No adverse events were reported by any patient during the course of the study or at the time of the one-month follow-up.

A power calculation of 85% was considered for all non-statistical differences.

Discussion

The results of this randomized controlled trial suggest that manipulative therapy of sacral torsion and myofascial release therapy resulted in a similar reduction in disability, and intensity of pain. Also, both therapies improved quality

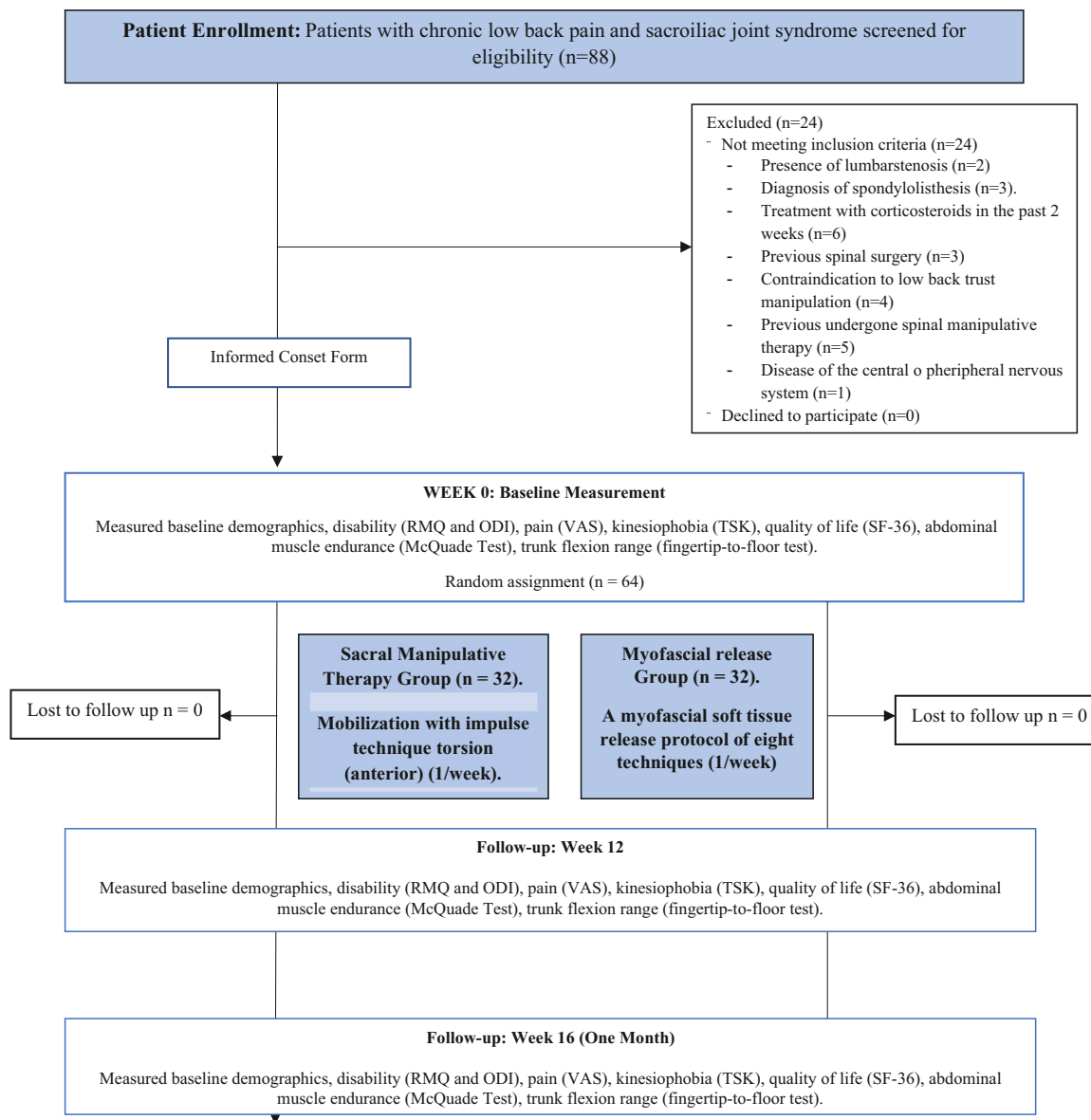


Fig. 3. Design and flow of participants through the trial.

of life, and finger-to-floor distance immediately after and at one month follow-up. The differences between groups were not clinical and statistically meaningful in any of the reported measures except for lumbar mobility in flexion, where manipulative therapy of sacral torsion exhibited greater benefits over myofascial release therapy at one month follow-up. This group was also slightly superior in quality of life.

Patients that receiving manipulative therapy of sacral torsion did not show statistically significant better reduction in disability than those receiving myofascial release; however, in both groups within-group change score surpass the MCID ≥ 2.5 established for RMQ [29]. Further, one-month after intervention, it remained the effectiveness on disability in those patients. These results are similar to those found with a single session of SIJ manipulation in patients with

SIJ syndrome [13]. However, this study showed that lumbar and SIJ manipulation offers no additional benefit in relation to pain and disability, as compared with SIJ alone, in patients with SIJ syndrome [13]. The authors presumed that the treatment of sacroiliac joint involvement corrected the lumbar spine dysfunction. SIJ is integrated in the complex lumbar-pelvic-hip, and it should be considered as a mechanical unit [40,41]. In our study, the isolate treatment of sacral torsion also demonstrated better lumbar flexion than a widely protocol of myofascial release which included 8 techniques. To our knowledge, no previous studies have investigated the short-term effectiveness of the myofascial release in patients with SIJ syndrome. A recent study on the effectiveness of myofascial release in the management of CLBP in nursing professionals exhibited that subjects receiving myofascial release in adjunct with specific back

Table 1
Baseline demographics for both groups*

	Sacral Manipulative Therapy (n=32)	Myofascial release (n=32)	p values
Gender (m/f)	11/21	14/18	.793
Age (years)	53±8	50±5	.083
Time with pain (mo)	10.91±4.28	11.91±4.55	.531
Self-reported measures			
RMQ (0–24)	9.91±4.65	8.16±3.71	.101
Pain (NPRS, 0–10)	5.64±2.30	4.66±1.77	.060
TSK (17–68)	43.78±10.26	41.03±8.09	.238
Quality of life (SF-36 questionnaire)			
Physical functioning (0–100)	68.75±23.49	73.43±13.16	.329
Physical role (0–100)	42.97±42.23	55.00±21.14	.155
Bodily pain (0–100)	50.63±23.72	49.38±16.84	.809
General health (0–100)	54.38±16.50	60.47±13.76	.114
Vitality (0–100)	51.25±12.70	53.28 ± 15.22	.564
Social functioning (0–100)	75.39±21.88	78.52±16.26	.519
Role emotional (0–100)	80.0±38.67	78.3±20.1	.214
Mental health (0–100)	71.13±19.40	63.88±13.99	.091
Physical outcomes			
McQuade test (seconds)	40.47±28.32	50.53±27.49	.067
Finger-to-floor distance (cm)	17.84±11.36	13.45±10.48	.113

* Data are mean ± SD except for gender NPRS, numerical pain rate scale; ODI, Oswestry low back pain disability index; RMQ, roland-morris disability questionnaire; TSK, tampa scale of kinesiophobia

exercises displayed significant improvements in pain and functional disability when comparing to the pre-treatment level [9]. These results support the conclusion reported by Aure et al. that manual therapy and exercises can improve low back functional disability [42].

In this clinical trial, both groups also exhibited a reduction in pain intensity, but the mean decrease did not surpass

the MCID (>2.5) established for patients with LBP, at all follow-up periods [43]. Another study exhibited significant differences within groups in pain intensity after a single session of high-velocity low-amplitude manipulation to the sacroiliac joint alone, and SIJ and lumbar manipulation to both sacroiliac joint and lumbar spine in a single session [12]. This clinical effect can be associated to

Table 2
Immediate post-treatment, One Month follow-up, and change score between groups for disability, pain, kinesiophobia, isometric resistance of abdominal muscles and finger-to-floor distance

Outcome and/or Group	Immediate Post-Treatment	Between-Group Difference in Score Change (95% CI)	p Value	One Mo Follow-up	Between-Group Difference in Score Change (95% CI)	p Value
Roland-Morris Disability Questionnaire (0-24)						
Manipulative	4.7±3.8	-0.8(-2.3,0.8)	.140	5.2±4.7	-0.3(-2.4,1.9)	.177
Myofascial	5.5±2.0			5.4±3.7		
Pain intensity (NPRS, 0–10 points)						
Manipulative	3.7±2.5	0.6(-0.6,1.8)	.331	2.7±2.4	-0.4(-1.5,-0.7)	.496
Myofascial	3.2±2.2			3.1±1.9		
Tampa Scale of Kinesiophobia (17–68)						
Manipulative	42.1±9.4	0.6(-3.6,4.8)	.768	42.1±10.2	0.7(-3.8,5.2)	.761
Myofascial	41.5±7.4			41.4±7.7		
McQuade Test (seconds)						
Manipulative	53.8±28.5	-13.1(-26.7,0.6)	.071	55.3±28.7	-14.6(-27.5,-1.7)	.060
Myofascial	66.8±26.1			69.8±22.4		
Finger-to-floor distance (cm)						
Manipulative	14.9±12.2	2.9(-2.8,8.6)	.311	12.3±10.7	1.0(-4.3,6.2)	.006*
Myofascial	12.0±10.5			11.3±10.4		

Values are expressed as mean ± standard deviation for immediate post-treatment and one month follow-up and as mean (95% confidence interval) for between-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

* p<.05 significant ANCOVA adjusted from baseline values for differences among groups.

Table 3
Immediate post-treatment, one month follow-up, and change score between groups for quality-of-life SF-36

Quality of life SF-36/group	Immediate Post-Treatment	Between-Group Difference in Score Change (95% CI)	p Value	One Mo Follow-up	Between-Group Difference in Score Change (95% CI)	p Value
Physical Function						
Manipulative	79.2±17.3	-5.2(-12.4,2.1)	.159	78.3±18.7	-5.3(-13.1,2.5)	.178
Myofascial	84.4±10.9			83.6±11.7		
Physical Role						
Manipulative	64.1±37.3	-11.7(-28.2,4.8)	.161	70.3±42.3	-1.6(-19.5,16.4)	.863
Myofascial	75.8±28.0			71.9±28.2		
Body Pain						
Manipulative	74.8±25.3	0.63(-9.9,11.1)	.906	70.2±27.6	-1.4(-12.3,9.5)	.798
Myofascial	74.1±15.6			71.6±14.0		
General Health						
Manipulative	62.1±16.4	0.8(-7.6,9.2)	.0853	62.8±17.9	3.1(-4.8,11.1)	.005*
Myofascial	61.7±17.3			59.7±13.6		
Vitality						
Manipulative	58.1±19.4	-0.6(-9.5,8.2)	.888	57.3±18.0	-2.8(-11.3,5.7)	.510
Myofascial	58.8±15.8			60.2±15.9		
Social Functioning						
Manipulative	81.3±25.0	-3.1(-13.8,7.6)	.562	76.6±20.5	-9.8(-18.9, -0.6)	.048*
Myofascial	84.4±17.1			86.3±15.7		
Mental Health						
Manipulative	72.8±20.7	3.4(-5.3,12.1)	.442	73.0±19.5	2.5(-5.9,10.9)	.554
Myofascial	69.4±13.5			70.5 ± 13.7		
Emotional Role						
Manipulative	85.4±31.6	5.2(-11.1,21.5)	.526	80.2±35.8	-0.8(-18.2,16.5)	.924
Myofascial	80.2±33.7			81.0±33.5		

Values are expressed as mean ± standard deviation for immediate post-treatment and one month follow-up means and as mean (95% confidence interval) for between-group change scores.

* $p < .05$ significant ANCOVA adjusted from baseline values for differences among groups.

neurophysiologic responses determined by the type of the technique in relation to velocity and amplitude thrust manipulation [44,45]. A comparison between manual and mechanical force manipulation on patients with SIJ syndrome in four session showed similar improvement in NPRS and disability over a 2-weeks period and a 1-week follow up [45]. However, a comparison between program of back school therapy and spinal manipulative therapy exhibited that back school therapy was a better treatment modality than the spinal manipulative therapy, according to the clinical measures of rehabilitation [46] Galm et al. founded that a 73.9% of patients with low back pain and sciatica and imaging-proven disc herniation and dysfunction in sacroiliac joint reported an improvement of lumbar and sciatic pain, and five patients were pain free [47]. This study concluded that in the presence of lumbar and ischial symptoms, the data suggest consideration of SIJ dysfunction, requiring manual examination, and in the presence of SIJ dysfunction, appropriate therapy should be considered.

The improvement in pain intensity could be associated with mechanical, spine, neurophysiological and supraspinal mechanisms [48]. The movements of the joint in the manual therapy reduce the transmission of stimuli by the ligaments and articular capsules, which decrease pain sensitive

tissues. In addition, the increase of the diameter in the intervertebral foramen relieves the pressure on nervous tissues, and increases the blood flow in spinal nerves, and paraspinal muscles and ligaments are extended to reduce myofascial pain [41]. However, a review on the role of physical therapy or manipulation in the management of SIJ dysfunction reported controversial results. It shows that manipulations can be successful in this population, but some studies remain uncertain on the recurrence of pain due to sacroiliac dysfunction [49]. Respect to myofascial therapy, Meltzer et al. have reported that myofascial release intervention after repetitive strain injury resulted in a normalization of apoptotic rate, reorientation of fibroblasts, and cell morphology changes [50]. Also, according to Schleip, pain can be decreased due to myofascial intervention generates a normative length in fascial tissue by collagen reorganization [51].

One of the limitations of our study is that, in order to improve our understanding of SIJ syndrome, a control group should be implemented. The second limitation is that only two clinicians performed the interventions, which might limit the generalizability of the results. The third limitation is that we did not maintain blinding of the researchers providing the intervention. The fourth limitation is that we collected outcome measures at a short-term follow-up.

Further studies should be performed using a longer period of follow-up and including a control or placebo group.

Conclusion

Manipulative and myofascial release therapy in patients with clinically diagnosed SIJ syndrome resulted in a similar short-term benefits on patient reported disability. Both groups experienced similar decrease in the intensity of pain over time, although no clinically meaningful effects were demonstrated in either group. Only significant differences between groups were achieved for general health, social functioning, and finger-to-floor distance at one month follow-up.

Conflict of interest

The authors have declared no potential conflict of interest with respect to the research, authorship, and/or publication of this article.

Supplementary materials

Supplementary material associated with this article can be found in the online version at <https://doi.org/10.1016/j.spinee.2021.05.002>.

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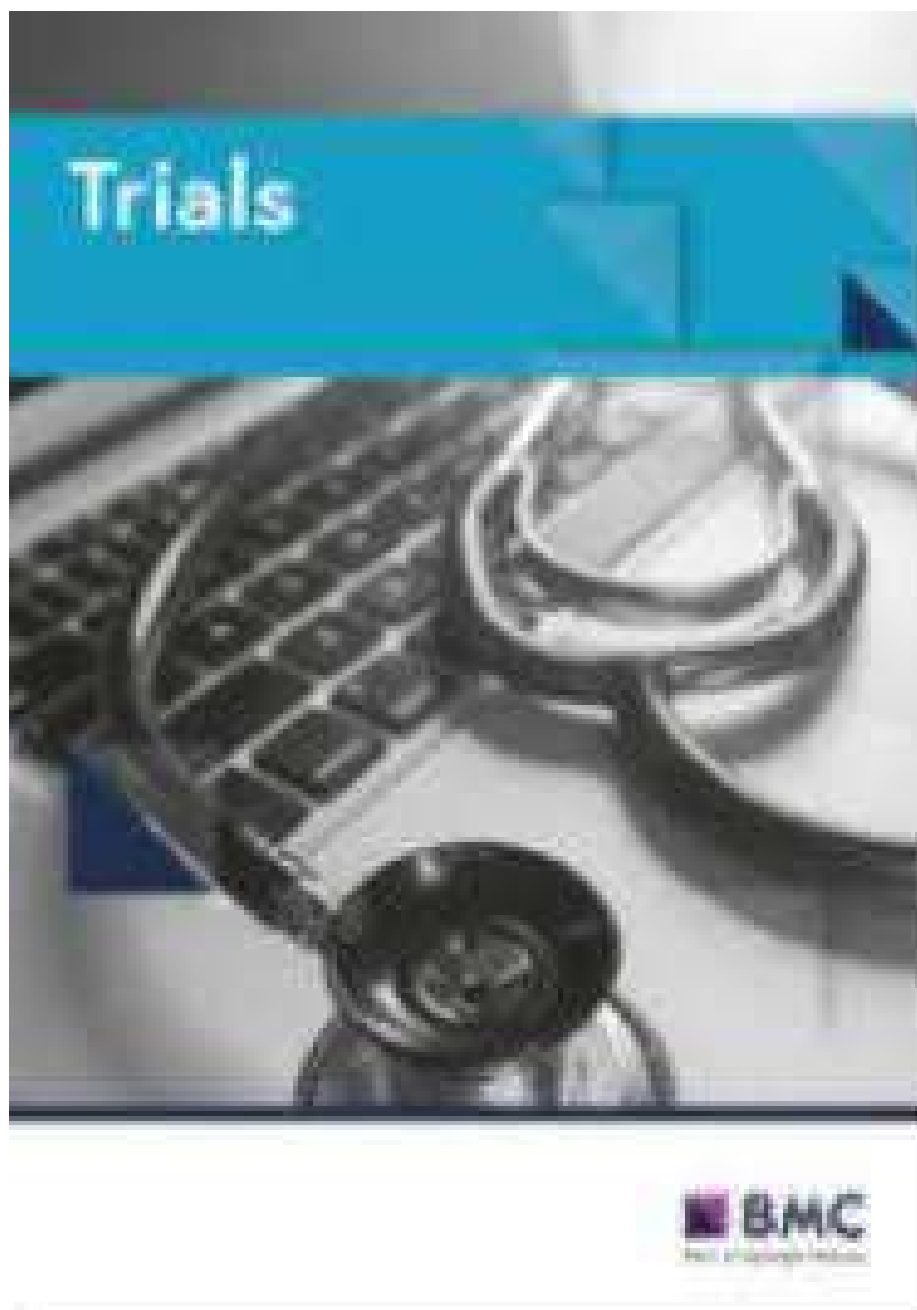
ARTÍCULO II

ELECTRICAL DRY NEEDLING VERSUS CONVENTIONAL PHYSIOTHERAPY IN THE TREATMENT OF ACTIVE AND LATENT MYOFASCIAL TRIGGER POINTS IN PATIENTS WITH NONSPECIFIC CHRONIC LOW BACK PAIN.

Lara-Palomo IC, Gil-Martínez E, Antequera-Soler E, Castro-Sánchez AM,
Fernández-Sánchez M, García-López H.

Trials 2022; 23(1): 238.

Factor de impacto: 2.279 / **Ranking:** 91/140 (Q3)



STUDY PROTOCOL

Open Access



Electrical dry needling versus conventional physiotherapy in the treatment of active and latent myofascial trigger points in patients with nonspecific chronic low back pain

Inmaculada Carmen Lara-Palomo*, Esther Gil-Martínez, Eduardo Antequera-Soler, Adelaida María Castro-Sánchez, Manuel Fernández-Sánchez and Héctor García-López

Abstract

Background: Chronic low back pain is considered to be one of the main causes of absenteeism from work and primary and specialized consultations. The symptoms of nonspecific chronic low back pain may be accompanied by the activation of myofascial trigger points in the muscles, together with local and/or referred pain. Electrical dry needling is increasingly used in the treatment of lumbar myofascial pain. Conventional physiotherapy, however, is a popular approach to chronic pathologies, and there is evidence of different modalities of physiotherapy being used in the treatment of chronic low back pain. The aim of this study has been to determine the effectiveness of electrical dry needling versus conventional physiotherapy when applied to active and latent myofascial trigger points in patients with nonspecific chronic low back pain.

Methods: This is a controlled, randomized, two-arm, double-blind study. A total of 92 patients with chronic low back pain (time to onset ≥ 3 months, Roland Morris Disability Questionnaire score ≥ 4) will be recruited from the University of Almería. Participants will be divided into two study groups ($n = 40$) to receive treatment of low back pain with electrical dry needling and conventional physiotherapy (ischaemic compression, analytic stretching and postural education training dossier). A total of 6 sessions will be administered once a week for 6 weeks. Pain intensity, disability, fear of movement, quality of life, quality of sleep, anxiety and depression, pressure pain threshold, abdominal strength and lumbar mobility will be recorded at 6 weeks (post-immediate) and 2 months after the end of treatment.

Discussion: We believe that an approach including electrical dry needling to chronic low back pain dysfunction will be more effective in these patients. The results of this study will inform clinicians on which type of treatment is more beneficial for patients with chronic low back pain.

Trial registration: [ClinicalTrials.gov](https://clinicaltrials.gov) NCT04804228. Registered on 14 January 2021

Keywords: Chronic low back pain, Conventional physiotherapy, Electrical dry needling

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Background

Low back pain is a major public health problem in industrialized countries that causes individual suffering, absenteeism from work and, in some cases, early retirement. Since it is a common pathology that is difficult to treat effectively, low back pain represents a high economic burden for both society and the health system [1–3] and is considered one of the main causes of primary and specialized care consultations [4]. In Europe, the direct and indirect costs of low back pain account for between 1.7 and 2.1% of the annual gross domestic product [8, 9].

Back pain, which affects up to 23% of the population worldwide, is the most common chronic disease in people under 65 years of age. With a lifetime prevalence of up to 85% in industrialized countries [3], estimates suggest that between 24 and 80% of patients have at least one recurrence per year, being more frequent and persistent in older adults [2, 5, 6]. In any given 6-month period, 72% of adults in the general population will report low back pain, and 11% will report disabling low back pain [7].

Pain intensity, degree of pain interference with activities of daily living (resulting in disability), and health-related quality of life are among the primary outcomes in studies in patients with low back pain [1]. In the 2010 Global Burden of Disease Study, which includes 291 diseases, low back pain ranked first in terms of disability and sixth in terms of overall burden [10]. In addition to age, psychological factors such as emotional distress and dysfunctional pain coping mechanisms play an important role in the development and/or persistence of non-specific chronic low back pain (CLBP) [6].

The symptoms of CLBP may be accompanied by the activation of myofascial trigger points (MTrPs) in the lumbar and proximal muscles, together with local and/or referred pain [11, 12]. Clinically, MTrPs present as palpably taut bands with a local twitch response and pain on pressure [12–14]. When the points are active, digital palpation causes pain to radiate to a distant site (referred pain); when they are latent, palpation may be locally painful, but no radiation occurs (local pain) [11, 12].

The MTrPs of each muscle have their own characteristic pain pattern; therefore, the spread of the pain can help identify the muscles that may contain active and latent trigger points [15]. CLBP is associated with the presence of MTrP in the quadratus lumborum muscle, and often also in the lumbar and superficial paraspinal multifidus muscles [13].

Noninvasive treatment options for CLBP remain controversial, and there is no general consensus on the best approach [16]. Some trials in CLBP and electrical dry needling conclude that there is still no strong evidence

to support the clinical effectiveness of electrical dry needling on LBP versus any other treatment modality [17–20].

Dry needling is typically used to treat soft tissues, such as muscles, ligaments, tendons, fascia, scar tissue, peripheral nerves and neurovascular bundles involved in a variety of neuromusculoskeletal pain syndromes [21, 22]. Dry needling involves the insertion of fine monofilament needles without the use of injectables, and its therapeutic effect is based on stimulating specific reactions in the target tissue [23–27]. It is a relatively new treatment modality used by physical therapists around the world as part of the complex treatment of chronic musculoskeletal pain [23]. The effectiveness of this approach has been confirmed in numerous studies and systematic reviews on the management of chronic lumbar MTrPs and myofascial pain [28–30]. In electrical dry needling, needle electrodes are used to deliver an electric current to the taut muscle band or the pain-generating MTrP [25, 26, 31]. Low-frequency currents are thought to improve the physiological effects of the therapy by using electrical stimulation to enhance certain physiological reactions and achieve a speedier analgesic and anaesthetic effect than that obtained with standard dry needling in patients with low back pain [32, 33]. Despite the popularity of electrical dry needling in clinical physiotherapy, there is insufficient scientific evidence to show its therapeutic effects in the treatment of CLBP [16, 34, 35].

Various treatment approaches beyond the scope of physiotherapy have been proposed to reduce the recurrence of low back pain and its associated care costs. Clinical practice guidelines provide strong evidence that cognitive behavioural therapy, exercise, spinal manipulation and rehabilitation with various physiotherapy procedures are all moderately effective in chronic or subacute low back pain (> 4 weeks duration) [34–36]. Recent systematic reviews and meta-analyses recommend exercise therapy to improve back strength, flexibility, range of motion and fitness in chronic low back pain [37–39]. However, there is no evidence to show whether invasive approach like the electrical dry needling is more effective than a conventional physiotherapy in patients with non-specific CLBP.

Study objectives

The objective of this randomized controlled trial is to evaluate the effectiveness of electrical dry needling versus conventional physiotherapy in the treatment of patients with nonspecific chronic lower back pain.

The specific objectives are (i) to compare the effectiveness of electrical dry needling versus conventional physiotherapy in improving pain, functionality, lumbar spine mobility and quality of life in patients with non-specific chronic low back pain and (ii) to evaluate the

effect of this therapy on active myofascial trigger points in terms of the pressure tolerance threshold following electrical dry needling versus conventional physiotherapy.

Methodology

Study design and ethical approval

This is a controlled, randomized, two-arm, double-blind study comparing (i) patients with chronic low back pain treated with electrical dry needling and (ii) patients with chronic low back pain treated with conventional physiotherapy consisting of ischaemic compression, analytical stretching and a dossier of home lumbar spine exercises. Study participants will be randomly assigned to two groups (electrical dry needling group or conventional physiotherapy group) with a 1: 1 ratio.

This protocol has been drawn up following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (Additional file 4). The study will be carried out in partnership with the physiotherapy department of the University of Almería. Ethical approval for this trial was granted by the University of Almería Research Ethics Committee (UALBIO2020/044). The study protocol was registered in an international clinical trial registry, [ClinicalTrials.gov](https://clinicaltrials.gov) (protocol number NCT04804228).

Participants

A total of 92 patients aged between 30 and 65 years, diagnosed with nonspecific chronic low back pain lasting more than 3 months [40] who are not currently undergoing any type of treatment, will be recruited. Patients will be randomized to two treatment groups (electrical dry needling or conventional physiotherapy). Participants will receive treatment once a week for 6 weeks in the physiotherapy laboratories of the University of Almería, with a follow-up evaluation at 6 weeks and 2 months after the start of treatment. During their first visit, participants will be screened for study eligibility according to the study inclusion and exclusion criteria and will be assessed by a therapist blinded to the interventions. After this face-to-face evaluation, patients will be randomly assigned to one of the two groups and will receive the corresponding treatment for low back pain administered by two researchers trained in the techniques used. All participants will sign the informed consent form, which complies with the Declaration of Helsinki of the World Health Organization (schedule of enrolment, interventions and assessments is shown in Fig. 1).

Inclusion criteria

Both male and female patients aged between 30 and 65 years with chronic low back pain lasting 3 months or more, with a low back pain disability score ≥ 4 on the

Roland-Morris Disability Questionnaire (RMQ) and not receiving any other physiotherapy treatment are eligible for inclusion.

Exclusion criteria

Patients with sensory and/or coagulation disorders, a history of spinal surgery, heart complications, concurrent severe central or peripheral nervous system disease, epilepsy, needle phobia, serious pathologies that can be the main cause of chronic low back pain (for example, presence of lumbar stenosis, spondylolisthesis, tumours, etc.), or patients contraindicated for transcutaneous electrical stimulation (TENS) will be excluded.

Randomization and blinding

Participants will be randomized to two groups using a computer-generated (Epidat 4.2) table of random numbers generated. After randomization, participants will be assigned to either the experimental electrical dry needling group or the conventional physiotherapy control group in a ratio of 1:1. Randomization will be performed by the principal investigator.

There will be 46 participants in each group. The randomly generated group allocations will be placed in sealed opaque envelopes before being delivered to the participants and stored in locked cabinets.

The outcome assessor and study statistician will be blinded to the entire process. The outcome assessor will make no attempt to guess the participant's treatment group. The computer-generated outcome measures transmitted to the statistician will not contain any information that identifies the patient's group.

Interventions

After the initial evaluation, 92 patients with CLBP will be randomly assigned to one of the two groups and will receive electrical dry needling (experimental group) or conventional physiotherapy (control group). All participants will receive 1 session per week for 6 weeks, until they have received a total of 6 sessions. Patients must complete 100% of their scheduled face-to-face treatment sessions, and those in the control group must also complete 80% of the home exercise sessions in order to remain in the intention-to-treat analysis.

During the study, participants can only receive their assigned treatment; they cannot combine the study treatment with medications or any other treatment. Any interference in the treatment will be grounds for exclusion. Patients may abandon the study at any time, and the assigned interventions may be suspended or modified in a particular trial patient in response to improvement or deterioration (adverse effects) of low back pain. Adverse events will be reported to the principal

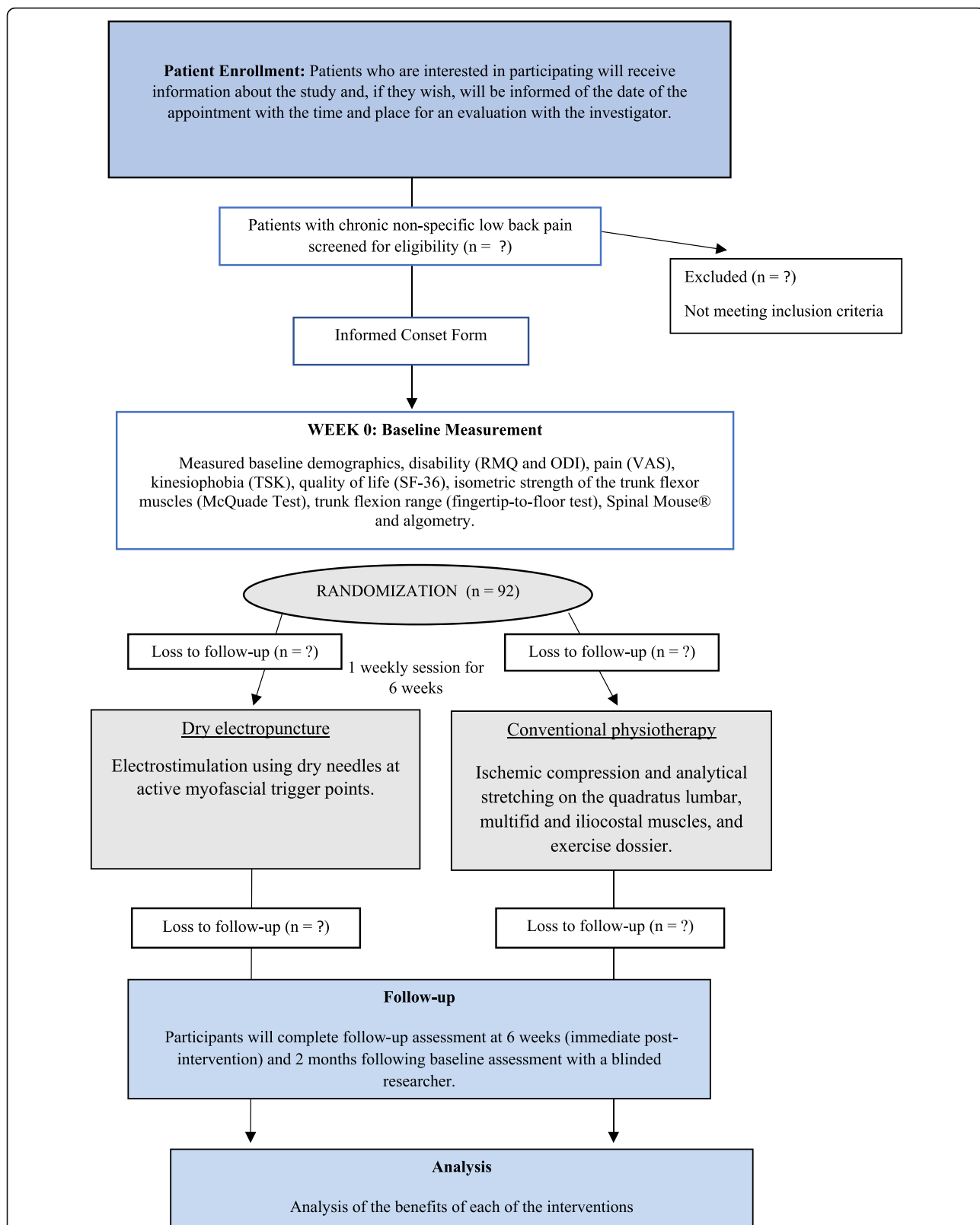


Fig. 1 Design and flow of participants through the trial. RMQ, Roland-Morris Low Back and Disability Questionnaire; ODI, Oswestry Disability Index; VAS, Visual Analogue Scale; TSK, Tampa Scale for Kinesiophobia

investigator, who will monitor the affected patients and the possible causes of these events.

Electrical dry needling group

Patients assigned to the electrical dry needling group ($n = 46$) will receive up to three 30-min treatment sessions (1 session per week for 6 weeks). Electrical stimulation will be applied bilaterally to the active and latent myofascial trigger points of the following muscles, following the MTrPs maps described by Travell and Simons: [2, 14] quadratus lumborum, multifidus and iliocostalis. The number of needle insertion sites will vary in each patient; the treating therapist will determine the points to be treated in each session based on whether they are active, latent or absent. Prior to needle insertion, the site will be sterilized with 70% alcohol using a cotton swab (Fig. 2).

Two sizes of sterilized disposable stainless steel acupuncture needles will be used: 0.25 mm \times 30 mm or 0.30 mm \times 40 mm. The size of the needle will depend on the patient's physical constitution (i.e. muscle and/or connective tissue thickness). The needle will be inserted until it reaches the active or latent MTrP or taut band that causes the local twitch response [41]. The needles will then be connected to an electric current and left in situ for 30 min (TensMed S82-Enraf Nonius) [42, 43]. A low-frequency current (2 Hz) will be generated by a TENS device with a moderate pulse duration (250 μ s) and a continuous biphasic waveform at an intensity described by the patient as "mild to moderate" [44].

Conventional physiotherapy group

Patients assigned to the conventional physiotherapy group ($n = 46$) will receive ischaemic compression and analytical stretching of the quadratus lumborum, multifidus and iliocostal muscles once a week for a total of 6 weeks.

Ischaemic compression will consist of constant pressure stimulation with the thumb on each MTrP for between 30 s and 2 min. This compression sequence will be repeated several times. The intensity of the pressure will be adjusted to a level at which each subject reports "comfortable pain", in other words, between the pain threshold and the maximum tolerable pain [36, 45] (see Additional file 1 for the analytical stretching procedure).

These patients will also be given a dossier of home lumbar spine exercises to be performed 5 days a week for a total of 6 weeks (Additional file 2: dossier of home exercises). To monitor compliance, patients will be instructed to note down in a booklet the dates on which they complete the exercises in the dossier.

Data collection

At the beginning of the study, the following demographic data will be collected: age, sex, weight, height, education and clinical presentation. Primary and secondary outcome measures will be evaluated at baseline prior to randomization to different groups. This will be followed by an immediate post-treatment assessment (1 day after the final intervention) and an evaluation 2 months after the end of the intervention (short-term follow-up).

Primary outcome measures

The following are the primary outcome measures:

- Roland Morris Disability Questionnaire (RMDQ): This self-reported questionnaire consists of 24 items that rate limitations in different activities of daily life attributed to low back pain, such as walking, bending over, sitting, lying down, dressing, sleeping, personal care and daily activities. Disability is rated from 0 points (best) to 24 points (worst) [46].
- Oswestry Disability Index (ODI): The Oswestry Disability Index assesses the limitations in activities of daily living in 10 dimensions, each rated on a 6-point scale (0–5 points). The higher the score, the greater the disability. The overall score is expressed as a percentage and is used to classify people as minimally disabled (0–10%), moderately disabled (20–40%), severely disabled (40–60%), crippling back pain (60–80%) or bedridden (80–100%) [47].
- Visual analogue scale (VAS): Study participants will indicate the intensity of their pain on a 100-mm VAS. They are asked to situate their pain on a 100-mm horizontal line, where 0 mm indicates "no pain", and 100 mm indicates "the worst pain imaginable" [48].

Secondary outcome measures

The following are the secondary outcome measures:

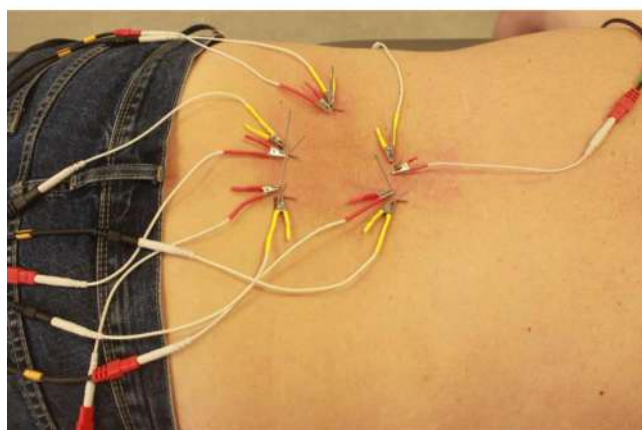
- Quality of life using the SF-36 Questionnaire: The SF-36 is a short-form, multipurpose health survey with only 36 questions. The instrument contains eight subscales (physical function, physical role, body pain, general health, vitality, social function, emotional role and mental health) and two summary scores: physical and mental health. Scores range from 0 to 100% and indicate the self-perceived health-related quality of life [49, 50].
- Tampa Scale for Kinesiophobia (TSK): This is a 17-item questionnaire that measures fear of movement and (re) injury. Patients rate their beliefs about their kinesiophobia on a 4-point scale ranging from strongly disagree to strongly agree [51, 52].



* Location and signaling of active and latent MTrP.



* Placement of dry needles in active and latent MTrP.



* Dry electrical needling technique in active and latent MTrPs.

Abbreviation: Myofascial Trigger Point (MTrP)

Fig. 2 Electrical dry needling group. Location and signalling of active and latent MTrP. Placement of dry needles in active and latent MTrP. Dry electrical needling technique in active and latent MTrPs. MTrP, myofascial trigger point

- Pittsburgh Sleep Quality Index (PSQI): This is a 10-item questionnaire with a total of 19 questions related to sleep habits in the previous month. The questions are divided into 7 areas, each with a score of between 0 and 3 points. The overall score ranges from 0 (no difficulty sleeping) to 21 points (severe difficulty sleeping) [53].
- Hospital Anxiety and Depression Scale (HADS): This scale consists of 14 items related to emotional distress (anxiety, depression) in populations suffering from a physical illness. It consists of two subscales (HADA: anxiety and HADD: depression) with seven items each that score from 0 (normal) to 3 (abnormal) [54, 55].
- McQuade Test: This test evaluates the isometric resistance of the flexor muscles of the trunk. The patient is placed supine and asked to flex the head and shoulders until the scapula is lifted off the table. The number of seconds they hold that position is recorded [56].
- Anterior trunk flexion. Standing, with legs straight, the patient is asked to bend forward and attempt to touch the ground. They are told to stop when pain or limitation of movement appear. The distance, in centimetres, between the fingers and the ground is measured [57].
- Spinal Mouse®: This is a safe, practical and easy-to-use instrument to measure the curvature of the spine in the frontal and sagittal planes and to assess the segmental mobility of the lumbar region [58].
- Pressure algometry (Wagner FPI 10 Algometer) in MTrPs: The algometer consists of a rubber tip and a dial that measures the pressure applied to the MTrP in increments of 0.5 kg. The pressure pain threshold will be assessed following the illustrations published by Travell and Simons [14].

Sample size

The sample size was calculated according to the specifications established by Willian [59]. The calculations were based on the detection of differences of 2.5 points in the RMDQ (minimum detectable difference between means for a variance of 10 points in patients with chronic low back pain), 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 following specifications will be considered: $\alpha = 0.05$, statistical power of 85% and loss to follow-up of 15%. The sample size calculation yielded a total of 92 participants to be randomized to two intervention groups.

Data analysis

Statistical analysis will be performed using SPSS© version 21.0 and STATA 14 using the principles of

intention to treat. Comparisons will be made between the two study arms. We will calculate the difference between the groups after the final treatment session and at 2 months post-intervention (short-term results).

The efficacy variable for this clinical trial is the difference between continuous variables (i.e., RMDQ, ODI, VAS, TSK, SF-36, PSQI, HADS, pressure algometry, McQuade test and trunk range of movement) at baseline and at predetermined time points (electric dry needling treatment vs conventional physiotherapy):

The Kolmogorov-Smirnov test will be used to assess the normality of continuous variables.

The equality of means of the intragroup hypotheses will be analysed using Student's *t* test for paired clinical variables in the case of parametric distributions and the Kruskal-Wallis *H* test in the case of nonparametric distributions.

One-way analysis of variance (ANOVA) will be used to test the intragroup hypothesis in the case of parametric distributions, and the Kruskal-Wallis *H* test will be used in nonparametric distributions.

Post hoc analysis will be obtained for parametric distributions and Mann-Whitney *U* for nonparametric distributions.

The confidence interval will be set at 95% and the level of significance at 0.05.

Adverse effects

No potential risks have been described so far, given that these can be prevented by the operator's knowledge of anatomy, training and experience [60]. Researchers will notify study participants of possible adverse events in the informed consent and record any adverse events that occur over the course of the study. If such events are observed, the frequency of occurrence will be analysed between the groups, and if patients have any questions or require additional information about any symptoms, they will be able to contact the physiotherapists by phone or email. Periodic reviews of security protocols will be carried out with staff.

Ethics and dissemination

All participants will receive verbal and written information about the study before giving their consent to participate. They will be informed that they can leave the study at any time. Participants who agree to take part in the study will sign two copies of the informed consent form, one for the research and evaluation team and one for the participant.

All hard copies will be confidential and stored in a locked filing cabinet in the research group office and in electronic format in a password-protected database. The research team will monitor the integrity of the trial data. All participants, group assignments, treatment records

Table 1 Time point of each assessment index

Time point	Study period					
	Enrolment		Active treatment (post-allocation)			Follow-up
	0 W	1W	2W	4W	6W	2M
	May to August 2021		September 2021			November 2021
Screening and enrolment						
Eligibility screen RPTs	✓					
Informed consent	✓					
Eligibility screen face to face to blinded evaluator		✓				
Allocation principal investigator		✓				
Interventions						
Electrical dry needling (experimental group)					1 times per week	
Conventional physical therapy (control group)					1 times per week	
Assessments						
Demographic variables:		✓				
Age, gender, education, occupational and marital status						
Clinical presentation of TrPs:		✓				✓ ✓
Location						
Interrogation						
Worsens						
Improvement						
Clinical variables:		✓				✓ ✓
RMDQ						
ODI						
SF-36						
VAS						
TSK						
PSQI						
HADS						
McQuade Test						
Fingertip-to-floor						
Spinal Mouse®						
Algometry						

and sociodemographic data will be coded, and the results of the questionnaires will be scored.

The data collected on each participant will be kept under lock and key by the evaluator. If the data are in digital format, they will be stored in a computer with a secret access code known only to the evaluator.

The eligibility criteria, results and analyses will not be modified once the first participant has been enrolled in the study. Any amendment to the protocol, including changes in the eligibility criteria, the results or the analyses, will be communicated to the Institutional Research Committee of the University of Almería and reported in articles and presentations disseminating the results of the trial.

The feasibility results will be published in peer-reviewed journals and presented at academic, clinical and health services conferences.

Discussion/conclusions

Although physiotherapy with dry needling and electrical dry needling has proven positive effects on chronic low

back pain [22–31], the results of studies into the duration of the analgesic effect and the dose required, for example, are contradictory [61, 62]. Therefore, further research is required to evaluate the specific components of the treatments administered by physical therapists.

This study can contribute to our understanding of the effectiveness of electrical dry needling versus conventional physiotherapy in patients with nonspecific chronic low back pain at short term. The results can help physiotherapists understand whether low back pain treated with electrical dry needling can significantly reduce disability and absenteeism due to chronic low back pain. Improving chronic low back pain without absenteeism will reduce labour costs and waiting lists for rehabilitative physiotherapy.

Due to the growing prevalence of chronic conditions such as low back pain and their impact on individuals, their circumstances and society in general, it is becoming increasingly important to provide evidence-based, cost-effective interventions [63, 64]. These interventions must first be designed, adapted and tested to determine

their feasibility and cost before being evaluated in a high-quality effectiveness trial. The trial design will be reviewed based on the findings of this study before performing a definitive trial.

Timeline

Patients will be recruited between May 2021 and August 2021. The study is expected to be completed in November 2021. Data analysis, writing of the scientific manuscript and submission to peer-reviewed scientific journals will take place from January 2022. A summary of the study outline is shown in Table 1.

Abbreviations

LBP: Low back pain; MTrPs: Myofascial trigger points; ODI: Oswestry Disability Index; RMDQ: Roland-Morris Low Back and Disability Questionnaire; SF-36: Short-format health survey questionnaire; PSQI: Pittsburgh Sleep Quality Scale; HADS: Hospital Anxiety and Depression Scale; SPSS: Statistical Software Package for the Social Sciences; TENS: Transcutaneous electrical nerve stimulation; TSK: Tampa Scale of Kinesiophobia; VAS: Visual analogue scale

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13063-022-06179-y>.

Additional file 1: Analytical stretching exercise protocol (lumbar segment).

Additional file 2: Dossier of exercises for low back pain (home program).

Additional file 3: Informed Consent. Information sheet for participants.

Additional file 4: Reporting checklist for protocol of a clinical trial.

Acknowledgements

Not applicable.

Authors' contributions

ICLP: conceptualization, methodology, writing—original draft, writing—review and editing, supervision and project administration. HGL: conceptualization, methodology, investigation, formal analysis, and writing—review and editing. EGM, EAS, AMCS and MFS: conceptualization, methodology, and writing—review and editing. All authors read and approved the final manuscript.

Funding

Subsidies for the Financing I+D+i of Instituto de Salud Carlos III through the project "PI18/00562" (co-funded by the European Regional Development Fund/European Social Fund "A way to make Europe"/"Investing in your future") and Biomedical and Health Sciences in Andalusia [PC-0185-2017, PC-0267-2017 and PC-0536-2017 (coordinated project)]. The process will be independent of the sponsor.

Availability of data and materials

Not applicable.

Declarations

Ethics approval and consent to participate

This study complies with the Helsinki guidelines for human research and has been approved by the Human Research and Local Ethics Committee of the University of Almería. Participants can only be included in the study after informed consent has been obtained.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Received: 31 May 2021 Accepted: 16 March 2022

Published online: 28 March 2022

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ARTÍCULO III

EFFICACY OF E-HEALTH INTERVENTIONS IN PATIENTS WITH CHRONIC LOW-BACK PAIN: A SYSTEMATIC REVIEW WITH META-ANALYSIS

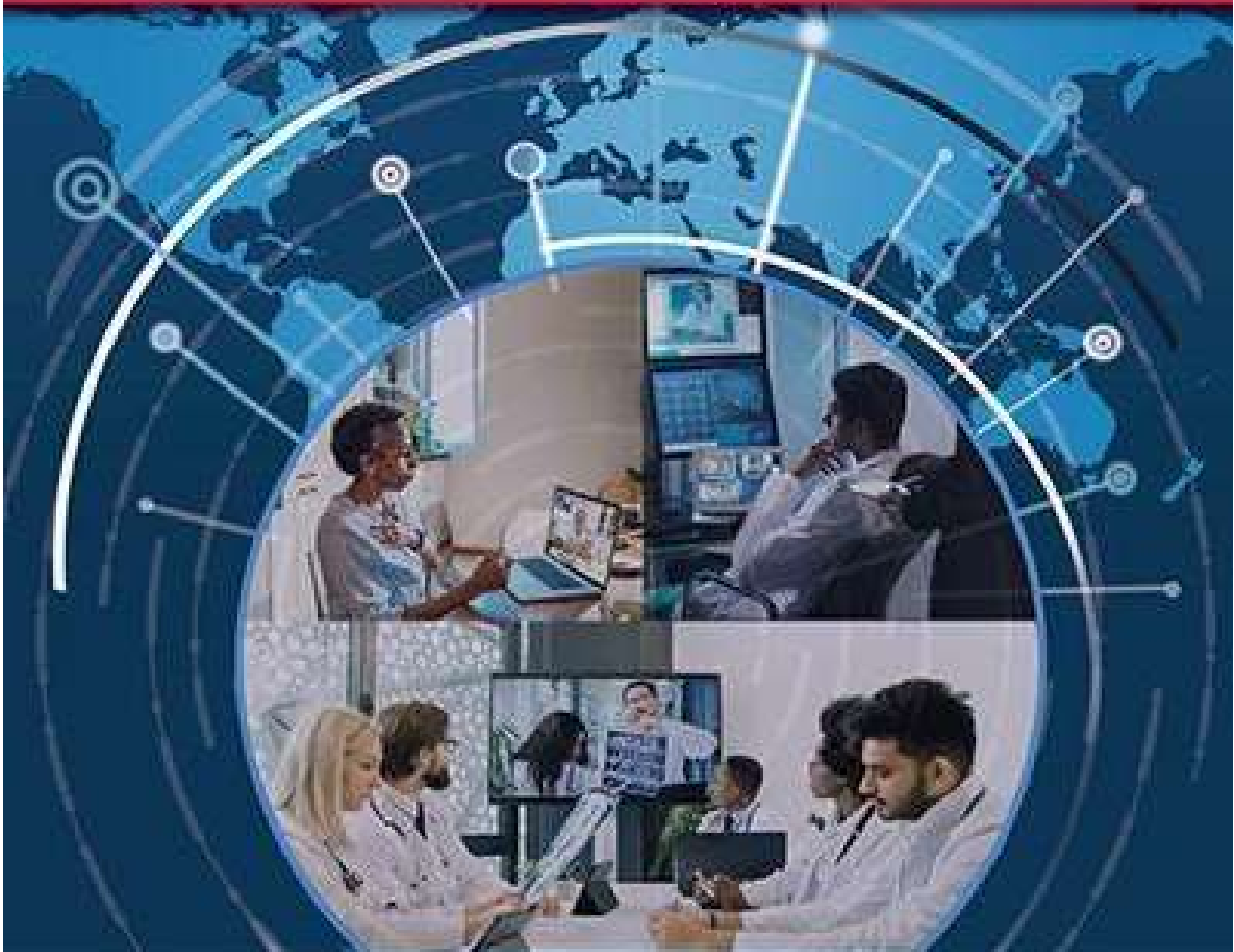
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Telemed J E Health 2022 May 9.

Factor de impacto: 3.536 / **Ranking:** 36/107 (Q2)

ISSN 1539-5627 • Volume 26, Number 5
May 2022

Telemedicine and e-Health



The Official Research Journal

An Official Journal

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www.liebertpub.com/tmj



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Efficacy of e-Health Interventions in Patients with Chronic Low-Back Pain: A Systematic Review with Meta-Analysis

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Abstract

Introduction: Low-back pain (LBP) is the leading cause of disability worldwide. Around 75–84% of the world’s population will experience LBP at some point, establishing it as a major global health problem. e-Health is the remote delivery of therapeutic services, clinical information, and medical care, and may prove a very useful approach to tackle this pathology.

Objectives: To evaluate the efficacy of e-health-based interventions in improving the symptoms of chronic LBP.

Methods: A systematic review with meta-analysis was performed in PubMed, Web of Science, and PEDro until January 2022 through the assessment of methodological quality of systematic reviews (AMSTAR). Studies were included in which e-health interventions were used as experimental treatment compared to physical therapy to determine changes in back-specific functional status and pain in patients with chronic LBP. Two reviewers examined the sources individually, calculated the risk of bias, and extracted the data (PROSPERO number CRD42022306130). The effect size was calculated using the standardized mean difference (SMD) and its confidence interval (95% CI).

Results: A total of 9 randomized controlled trials with 3,180 participants were included. The results of the findings showed an effect of e-health compared to other physical therapy on short-term (SMD=−0.59, 95% CI: −1.77 to 0.59) and in-

termediate short-term (SMD=−0.40, 95% CI: −0.91 to 0.11) pain intensity and back-specific functional status in the short term (SMD=−0.20, 95% CI: −0.81 to 0.41) and intermediate short term (SMD=−0.30, 95% CI: −0.74 to 0.14). The effect of e-health compared to minimal intervention on short-term intermediate pain intensity (SMD=−0.64, 95% CI: −1.72 to 0.45) and short-term intermediate back-specific functional status (SMD=−0.39, 95% CI: −0.87 to 0.09).

Conclusions: e-Health interventions based on self-maintenance and education are as effective on pain and back-specific functional status as other face-to-face or home-based interventions in patients with chronic LBP, with moderate scientific evidence.

Keywords: low-back pain, rehabilitation, telerehabilitation, e-health, telehealth, telemedicine, app

Introduction

Low-back pain (LBP) is defined as pain or discomfort located below the costal margin and above the inferior gluteal fold, with or without referred pain in the legs. LBP is considered chronic and nonspecific when it is not attributable to a specific known pathology, is of variable intensity, and persists for 12 weeks or more.^{1–3} Furthermore, the lack in many cases of a correlation between an individual’s clinical signs and imaging test results renders it even difficult to determine any pathological origin.⁴ There is a direct relationship between LBP and the sensation of fatigue in the back muscles, together with stiffness in the hamstrings or quadriceps femoral, which can give rise to neuromuscular deficits that result in uncontrolled intervertebral movements and increased spinal instability. This reduces the individual’s proprioceptive ability and stability.^{5–7}

In addition, chronic pain causes emotional, cognitive, and somatic impairment. It is associated with symptoms such as insomnia, depression, a decreased attention span and an increase in body weight or body mass index. Sometimes, pain or discomfort in the affected area may give rise to misperceptions of the actual state of health, which can hinder treatment planning and lead to overuse of pharmacological therapy in an attempt to alleviate fears.^{6,8-10} Patients with LBP may develop central sensory dysfunction such as a decreased pain threshold and even tissue hyperalgesia.⁸

Advances in neuroscience have revealed that besides the spine, chronic LBP also affects patients' pain-related brain regions: changes have been observed ranging from a reorganization of connectivity in various brain regions to increased activity in areas of the so-called "pain matrix."¹¹ It is likely that these changes induce central sensitization as a result of abnormal neural processing, generating persistent pain in the absence of damage or injury to anatomical structures.¹² In central sensitization, observed changes in the central nervous system include altered sensory processing in brain areas, dysfunction of descending antinociceptive mechanisms, increased activation of pain facilitatory pathways, and increased temporal summation of second pain (wind-up).¹³

LBP is arguably the leading cause of disability worldwide, with one of the highest prevalence rates in the world. Around 75–84% of the world's population will experience LBP at some point.¹⁴⁻¹⁶ Recent decades have witnessed a significant rise in the prevalence of chronic LBP, with a threefold increase in prevalence between 1992 (3.9%, 95% CI: 3.4–4.4) and 2006 (10.2%, 95% CI: 9.3–11.0).¹⁷ Approximately 23% of the population has chronic nonspecific LBP, and it is estimated that 50% of all people will experience at least 10 episodes of LBP in their lifetime.^{15,18}

According to data from North America, 25% of adults report having had an episode of LBP in the past 3 months,^{19,20} while in Spain, 44% of the adult population experienced LBP in the 2000s.²¹ Various studies have reported data as striking as the fact that LBP costs the United States 7,400 million dollars a year as a result of direct work-related effects, and some have estimated figures of between 84,000 and 624,000 million dollars annually when factoring in the indirect costs.^{22,23} In the 1990s, LBP cost Spain ~75 million euros.²⁴

The drugs available to treat LBP include nonsteroidal anti-inflammatory drugs, antidepressants, epidural steroid injections and muscle relaxants. Although these successfully reduce pain initially, their side effects can pose a problem as regard to long-term tolerability in patients with chronic LBP.²⁵

e-Health is defined as the remote delivery of health care services, treatment and clinical information through technology, and telecommunications systems such as the internet, wireless technology, satellite, and telephones.^{26,27} Thus, it offers patients remote access to rehabilitation programs and the possibility of managing various components such as self-care, functional independence, and knowledge of the pathology. The greatest advantage of e-health is that it eliminates distance, time, and travel to receive treatment.^{28,29}

It is precisely these characteristics that render e-health an outstanding potential means to bridge gaps in service provision, especially in areas where staff shortages, lack of resources, and other issues hinder access to rehabilitation and physiotherapy services.²⁸

The aim of this systematic review was to analyze the effectiveness of e-health interventions in the treatment of chronic LBP, given that such a service would help promote active patient participation in treatment and compliance—which has been shown to achieve earlier and longer-lasting benefits than passive therapies—and could reduce the high economic and sociohealth costs that LBP generates worldwide as a result of hospital demand, sick leave, and the provision of in-person physiotherapy.

Methods

PROTOCOL AND REGISTRY

A systematic review and meta-analysis on the efficacy of e-health in patients with chronic LBP was carried out using the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) 2 tool.³⁰ Systematic review registration: www.crd.york.ac.uk/PROSPERO. PROSPERO registration number: CRD42022306130.

Table 1. Research Question PICO: Participants, Interventions, Comparisons, and Outcomes

PARTICIPANTS	ADULTS WITH CHRONIC LBP
Interventions	e-Health
Comparisons	No intervention
	Placebo
	Advice and information
	Other therapies
Outcomes	Outcome in pathology symptomatology, not specified because all outcome measures were considered to be of interest.

LBP, low-back pain.

SEARCH AND INFORMATION SOURCES

As a starting point for the search strategy, we formulated the following research question: do e-health interventions have a beneficial effect on patients with chronic nonspecific LBP? We then reformulated the question using the PICO³¹ format (Table 1).

The literature search was carried out from inception to January 2022, in accordance with recent declaration of “preferred reporting items for systematic reviews and meta-analyses” (PRISMA).³²

We consulted three databases—PubMed, Web of Science, and PEDro—to identify randomized clinical trials published in Spanish and English within the past 6 years that analyzed the effectiveness of e-health interventions in the treatment of chronic LBP. For the search, the Boolean operators “AND” and “OR” were combined with the following MeSH terms and keywords: “low back pain” (MeSH), “rehabilitation” (MeSH), “telerehabilitation,” “e-Health,” “telehealth,” “telemedicine,” and “app.” In addition, we assessed the references given in other reviews and publications to identify any that might be relevant to this study, but had not been retrieved in the electronic search, thus complementing our electronic database search with the snowball method.

In each database, the search was limited to articles where terms appeared only in the title or abstract. Duplicate items identified in multiple database searches were eliminated from the selection. Table 2 below shows the search strategy.

STUDY SELECTION CRITERIA

The inclusion and exclusion criteria were defined using the PICO process [Patient, Problem or Population, Intervention, Comparison, Control or Comparator, Outcome(s)].

Types of studies selected: studies had to be randomized controlled trials (RCT) published as full reports examining the effectiveness of e-health-based interventions compared to no intervention or any other treatment for LBP. Quasi-experimental controlled trials, randomized clinical trial protocols, systematic reviews, and case studies were excluded. In addition, the following inclusion criteria were considered: RCT published from 2015 onward, written in Spanish or English, available in full-text version, and focused on the ongoing effects of e-health interventions in patients with chronic LBP. All studies that did not meet these characteristics were excluded.

Types of participants: the study subjects had to consist of individuals older than 18 years, who had experienced chronic LBP for >12 weeks. We excluded RCT that included participants with chronic LBP caused by pathologies such as infection, neoplasia, fractures, or coagulation disorders.

Table 2. Search Strategy for the Different Databases

	RESULTS	SELECTED
PUBMED		
("low back pain/rehabilitation" [MeSH] AND "telemedicine")	9	Mbada et al. ²⁸ Fatoye et al. ²⁹ Suman et al. ³⁴ Amorim et al. ³⁵ Yang et al. ³⁶ Irvine et al. ³⁷ Toelle et al. ³⁸ Shebib et al. ³⁹
("low back pain/rehabilitation" [MeSH] AND "telerehabilitation" [MeSH])	3	
"lumbar" AND "telehealth"	59	
+ clinical trial	6	
"low back pain" OR "lumbalgia" AND "e-health" OR "telehealth" OR "telemedicine" OR "telerehabilitation"	44,349	
+ clinical trial	3,449	
+ free full text	1,597	
"low back pain" AND "telerehabilitation"	16	
"low back pain" AND "e-health"	15	
"low back pain" AND "app"	58	
WEB OF SCIENCE		
"low back pain" AND "telemedicine"	131	Chhabra et al. ⁴⁰
"low back pain" AND "e-health"	1,966	
+ free full text + clinical trial + 6 years	18	
PEDRO		
"low back pain" AND "e-health"	127	
"low back pain" AND "telerehabilitation"	1	

Types of interventions: studies evaluating e-health as the main intervention for chronic LBP were incorporated, including studies that compared e-health with other interventions or with nonintervention control groups. The “e-Health” was defined as information, computer, and communication technology applied to distance rehabilitation programs or self-manage between providers and/or patients. We excluded studies in which e-health was not the main treatment or was combined with other therapies. The comparisons of interest were as follows:

Types of outcome measures: outcome measures relevant to the assessment of nonspecific chronic LBP were selected so that the results of this review could be compared with the results of other systematic reviews dealing with the management of LBP. The primary outcomes were pain intensity (e.g., measured with visual analog scale [VAS] for pain) and disability (e.g., measured with the Oswestry Disability Index [ODI] or Roland-Morris Disability Questionnaire [RMDQ]).

Two researchers independently assessed the studies identified for inclusion or exclusion, and where disagreement arose concerning inclusion, the study in question was discussed until reaching consent.

DATA EXTRACTION

Two reviewers independently screened the titles and abstracts of references retrieved from the electronic searches performed. The full text was obtained for those clinical trials that either author considered to be of significant interest. The full texts of the selected studies were independently assessed for inclusion and exclusion criteria. Disagreements were discussed with a third author, and final decisions were reached by consensus.

One researcher completed a standardized summary sheet with the extracted data, in accordance with Cochrane recommendations.³³ Subsequently, a second researcher reviewed the extracted data for greater efficacy. Extracted data included the following: (1) study characteristics, authors and date of completion, study design, study setting, type of population and age, sample size, and recruitment method; (2) type of intervention implemented (type of therapy, frequency and duration, and level of supervision); (3) follow-up; (4) drop-outs; (5) outcome measures; and (6) outcomes.

RISK OF BIAS ASSESSMENT

Two researchers independently performed risk of bias assessment of all RCT using the Cochrane risk of bias tool.³³ Clinical trials were classified as low risk, high risk, or unclear risk according to the following seven items: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other biases.

STATISTICAL ANALYSIS

A heterogeneity analysis of the selected studies was performed. Heterogeneity within RCT was examined using the I^2 test, considering $I^2 \geq 50\%$ as a sign of substantial heterogeneity. Once there were >2 homogeneous studies, RevMan 5.4 (Cochran Collaboration, London, United Kingdom) software was used to perform meta-analyses. Sensitivity analyses were conducted for the robustness of the result of meta-analyses.

To test for overall effects, Z -statistics at a 5% alpha-error-probability level were calculated for overall (main) effects and quantitative subgroup analyses. For the overall effect calculation of continuous data, each intervention group effect was calculated in contrast to the comparator/control group, using standardized mean difference (SMD) and confidence interval (95% CI). If more than one sustainability time point was as-

sessed, the postintervention term sustainability effect was selected for the main analysis. For the quantitative subgroup calculations, analyses were performed separately for sensitivity of time that takes the following evaluation periods: short-term between 4 and 6 weeks and short-intermediate term between 3 and 6 months, and sensitivity of comparator. Data were displayed using forest plots.

Results

SELECTION OF STUDIES

From a total of 779 potential articles identified in the literature search, 9 scientific articles were included in this systematic review. We excluded 661 articles by title and 77 by abstract, leaving 41 articles. After applying the selection criteria, a further 32 articles were excluded because they did not meet the established requirements for the following reasons: they are not RCT 17, they do not use e-health interventions 8, and pain, disability, or quality of life were not analyzed 7 (Fig. 1; Flow Diagram).

CHARACTERISTICS OF STUDIES INCLUDED

Nine RCT^{28,29,34-40} met the inclusion criteria, with a total of 3,180 participants. Sample size varied between studies, ranging from the smallest sample of 8 subjects in Yang et al.³⁶ to the largest of 779 subjects in Suman et al.³⁴ Two studies^{28,29} were conducted in Nigeria, two^{37,39} in the United States, one³⁶ in China, one³⁴ in the Netherlands, one³⁵ in Australia, and another one³⁸ in Germany. *Table 3* shows the main characteristics of each of the studies and *Table 4* characteristics of interventions used.

All studies reported that the mean age of participants was between 18 and 65 years and the average age of the participants was between 40 and 50 years. Two studies did not report the percentage of participants who were female or male.^{29,40} In the remaining studies, the percentage of females ranged from 40% to 70%.^{28,34-39}

Regarding the recruitment methods employed, the RCT included the following: patients attending outpatient physiotherapy departments^{28,29,34,35} through advertisements on websites and social networks such as Facebook,^{37,38} university rehabilitation clinics,³⁵ and through pain centers or spine departments.^{38,40} As can be seen, recruitment methods varied widely between studies, and in some cases, more than one method was used.

Patients in control groups received different types of intervention, which were compared in all studies with an e-health intervention. All of them were grouped into two groups, with the exception of Irvine et al.,³⁷ where three groups were compared, the experimental group, alternative

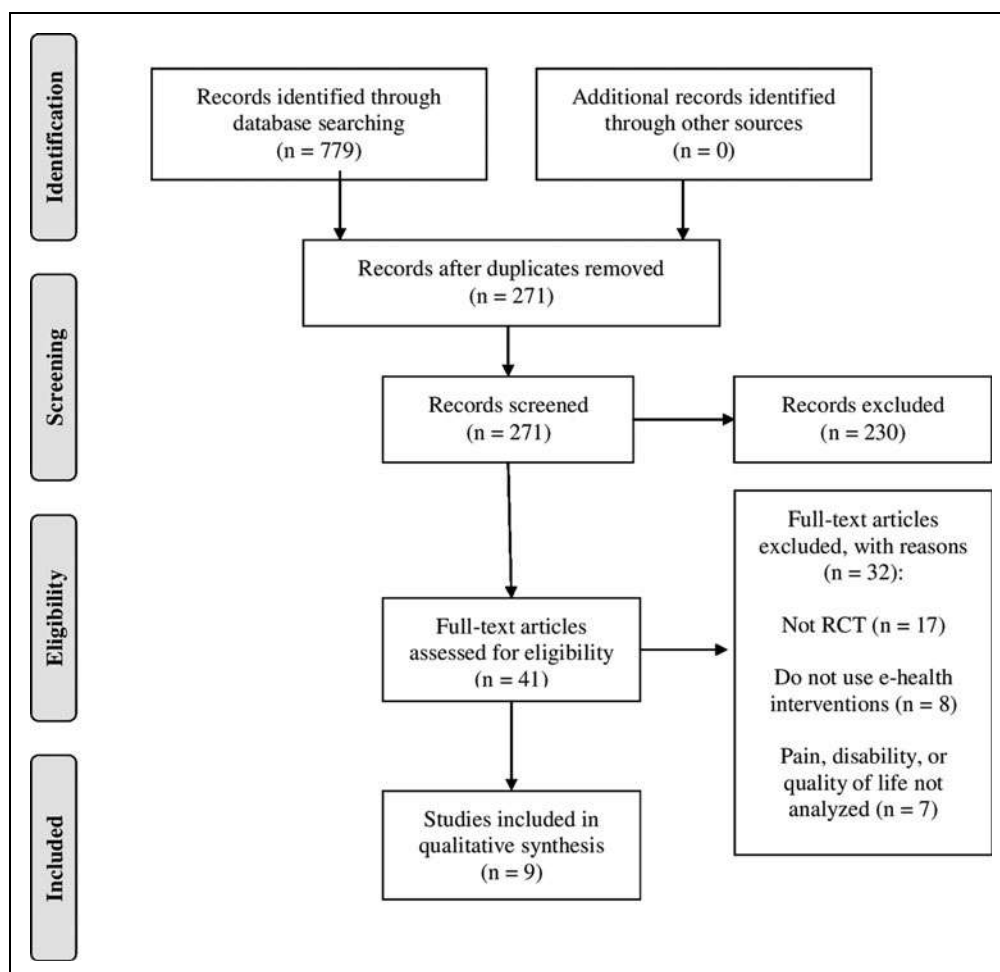


Fig. 1. Eligibility and data synthesis PRISMA flow diagram. PRISMA, preferred reporting items for systematic reviews and meta-analyses.

care group, and control group. Interventions in control groups were heterogeneous, written prescription of physical exercise was given for the patients in two studies.^{35,40} McKenzie Method exercise was developed at clinic in other two studies; meanwhile,^{28,29} three digital education articles were given to patients in Shebib et al.'s³⁹ study and a digital information letter was sent to patients in Suman et al.'s³⁴ study.

Face-to-face physiotherapy sessions were given to patients in two studies,^{36,38} in one of them, patients also received online education.³⁸ In Irvine et al.,³⁷ alternative treatment group received Web-based information, while control group received usual care. In one study, patients had to do exercise following the recommendations given in a booklet working.³⁵ On the other hand, patients in the control group of Chhabra et al.⁴⁰ followed their personalized exercise, written prescription by the physician during 12 weeks.

e-Health interventions were also very heterogeneous in all the studies analyzed.^{28,29,34-40} Mbada et al.²⁸ and Fatoye et al.²⁹ carried out an intervention based on a McKenzie Method exercise program plus education through a mobile application, patients performed the exercises three times per week during 8 weeks.^{28,29} Suman et al.³⁴ provided individual attention to patients, the intervention was based in an e-health strategy providing patients monthly digital sources for self-management and knowledge.³⁴

The Intervention group in the Amorim et al.'s³⁵ study received an information booklet plus an individualized exercise program, e-health intervention was made through 12 fortnight telephone calls with health coaching, monitoring exercise with an activity tracker (Fitbit), and employing a mobile app with patient progression and objectives; the duration of the intervention was 6 months.³⁵ Treatment in Yang et al.'s³⁶

Table 3. Summary of Results: Main Characteristics of Each of the Studies

STUDY	PARTICIPANT (N)	AGE (YEARS)	DESIGN	INTERVENTIONS	EVALUATION	OUTCOMES	MEASURING INSTRUMENTS	RESULTS
Mbada et al. ²⁸	N=56	47.3 (11.6) 50.0 (10.7)	EG=24 CG=32	EG=e-Health-based McKenzie Therapy and back care Education CG=Clinic-Based McKenzie Therapy and back care education.	T1=4 weeks T2=8 weeks	Pain Back-Specific Functional Status Quality of life	QVAS ODI SF-12	No significant differences were observed in treatment effects between groups ($p>0.05$), except for "vitality" scale ($p=0.011$) on the SF-12.
Fatoye et al. ²⁹	N=56	47.3 (11.6) 50.0 (10.7)	EG=24 CG=32	EG=e-Health-based McKenzie Therapy and back care Education CG=Clinic-based McKenzie Therapy and back care education.	T0=4 weeks T1=8 weeks	Back-Specific Functional Status	ODI	No significant mean in ODI score difference in the measurements at weeks 4 and 8 between the EG and CG groups ($p>0.05$).
Suman et al. ³⁴	N=779	55.7 (13.9) 56.6 (14.6)	EG=331 CG=448	EG=e-Health strategy based in knowledge and self-management. CG=Digital patient information letter.	T0=Baseline T1=3 months T2=6 months T3=12 months	Back-Specific Functional Status	RMDQ	No significant difference in back-specific functional status at any point. Difference between intervention and control based on intention-to-treat analysis for male -1.13 CI (0.93-1.37) and female -0.79 CI (0.69-0.93).
Amorim et al. ³⁵	N=68	59.5 (11.9) 57.1 (14.9)	EG=34 CG=34	EG=Physical activity plus information and advice supported by internet-based application and activity tracker (Fitbit). CG=Physical activity plus information and advice.	T0=Baseline T1=6 month	Pain Back-Specific Functional Status	VAS RMDQ	No significant difference between groups for pain ($p=0.815$) and Functional Status ($p=0.722$). Although mean difference was not significant statistically, there was an improvement between baseline and follow-up assessments in both groups.
Yang et al. ³⁶	N=8	35.00 (10.9) 50.3 (9.3)	EG=4 CG=4	EG=Smartphone App-Based Remote Self-Management and physiotherapy. CG=Physiotherapy (manual therapy, electrophysical therapy, and traction).	T0=Baseline T1=2 weeks T2=4 weeks	Pain Back-Specific Functional Status Quality of Life	VAS RMDQ SF-36	There was no significant difference for pain in group effects ($p=0.24$) and within-group effects. RMDQ score showed a significant difference between groups ($p=0.035$) and BP in SF-36 ($p=0.008$).

continued →

Table 3. Summary of Results: Main Characteristics of Each of the Studies *continued*

STUDY	PARTICIPANT (N)	AGE (YEARS)	DESIGN	INTERVENTIONS	EVALUATION	OUTCOMES	MEASURING INSTRUMENTS	RESULTS
Irvine et al. ³⁷	N= 597	Not described	EG = 199 AG = 199 CG = 199	EG = Fitback app (physical activity, education, and advice). AG = Links to back pain information websites through e-mail. CG = usual care.	T0 = Baseline T1 = 8 weeks T2 = 16 weeks	Pain	NPRS	Three groups had an improvement in back pain at 16 weeks [EG: from 2.59 (1.15) to 2.11 (1.46), AG: from 2.63 (1.17) to 2.23 (1.30), CG: from 2.84 (1.18) to 2.55 (1.41)].
Toelle et al. ³⁸	N= 101	41 (10.6) 43 (11)	EG = 53 CG = 48	EG = Kaia App based in education, exercise program, and relaxation techniques. CG = Back exercise in physiotherapy sessions plus education.	T0 = Baseline T1 = 6 weeks T2 = 12 weeks	Pain	NPRS	ANOVA analysis with the between-factor group (EG vs. CG) and the within-factor measure point (baseline vs. 6 weeks vs. 12 weeks) revealed a significant main effect of measure point, $F(2, 168) = 31.38$, $p < 0.001$, $\eta = 0.492$. Both groups reported a significant decrease in pain symptoms over time (baseline vs. 6 weeks and 6 weeks vs. 12 weeks) ($p < 0.01$).
Shebib et al. ³⁹	N= 177	43 (11) 43 (12)	EG = 113 CG = 64	EG = DCP (App: sensor-guided exercise therapy, education, cognitive behavioral therapy, team and individual behavioral coaching, activity tracking, and symptom tracking). CG = Three digital education articles.	T0 = Baseline T1 = 12 weeks	Pain Back-Specific Functional Status	VAS ODI	Participants in EG experienced statistically significantly greater improvements at week 12 on pain [means difference from 43.6 (20.5) to 16.5 (15.5) in EG; from 42.6 (19.4) to 39.2 (23.6) in CG] and BSFS [means differences from 19.7 (11.4) to 13.5 (9.46) in EG; from 18.9 (7.4) to 19.7 (10.6) in CG] compared to the control group ($p < 0.001$).
Chhabra et al. ⁴⁰	N=93	41.4 (14.2) 41.0 (14.2)	EG = 45 CG = 48	EG = Written medical prescription plus physical activity and motivation and goals through app. CG = Written medical prescription and physical activity.	T0 = Baseline T1 = 12 weeks	Pain Back-Specific Functional Status	NPRS MODI	Both groups showed significant improvement in pain and BSFS ($p < 0.05$), while EG showed a significant decrease in BSFS ($p < 0.001$).

BSFS, Back-Specific Functional Status; CG, Control group; CI, confidence interval; DCP, Digital care program; EG, Experimental group; MODI, Modified Oswestry Disability Index; NPRS, Numeric Pain Rating Scale; ODI, Oswestry Disability Index; RMDQ, Roland Morris Disability Index; SF-12, 12 Item Short-Form Survey; SF-36, The Short-Form 36 Health Survey Questionnaire; VAS, Visual Analog Scale.

Table 4. Characteristics of Interventions Used in the Included Studies

STUDY	TYPE OF E-HEALTH INTERVENTION	COMPONENTS OF E-HEALTH INTERVENTION	HOW E-HEALTH INTERVENTION WAS DESIGNED
Mbada et al. ²⁸	Mobile health TBMT	McKenzie protocol Back care education	The intervention group performed McKenzie therapy based on telerehabilitation combining McKenzie extension and back care education protocols using a smartphone. The total duration of the application is ~5 min with a frequency of 8 weeks. Adherence and utilization of the TBMT app were monitored through phone calls and SMS to participants.
Fatoye et al. ²⁹	Mobile health TBMT	McKenzie protocol. Back care education	The telerehabilitation group received a mobile application designed for LBP patients combining the McKenzie extension protocol (i.e., prone extension, prone extension, and standing extension) and back care education. The exercises were performed thrice per week for a period of 8 weeks.
Suman et al. ³⁴	Multifaceted eHealth strategy (mobile website, digital monthly newsletters, and social media platforms)	Back pain-specific education Physical exercise	The intervention group consisted in a multifaceted e-health strategy that included a website (mobile), monthly digital newsletters, and social media platforms. The website offered information on back pain, postural ergonomics tips and therapeutic exercises, indicated by videos from expert LBP health care professionals. Follow-up was carried out at 3, 6, and 12 months from the beginning of the intervention.
Amorim et al. ³⁵	Integrating Mobile health Activity tracker (Fitbit)	Booklet developed Health coaching Physical Activity	The intervention group received an informational booklet on physical activity and sedentary behavior, and then completed an individualized physical activity plan tailored to the participants' goals, physical ability, and preferences. Each participant received an initial 1- to 2-h in-home face-to-face training session, follow-up every 2 weeks (12 phone calls) for 6 months, and support from a Fitbit activity tracker to assess progress.
Yang et al. ³⁶	App for back pain (Pain Care App)	Pain record evaluator's report self-management program based on exercises	The intervention group received physiotherapy (manual therapy, electrophysical therapy, and traction) and a self-management program based on therapeutic exercises through an APP called Pain Care, they had to perform the exercises four times a day for 4 weeks, a reminder of the exercises was sent to the participants along with a pain diary.
Irvine et al. ³⁷	Mobile-Web FitBack	Health coaching Physical Activity	The intervention group received through the FitBack online program education and behavioral strategies to control current pain and prevent future episodes of pain in NLBP. The duration of the program was 8 weeks with a weekly e-mail with content and prompts related to NLBP self-management.
Toelle et al. ³⁸	Multidisciplinary App for back pain (Kaia App)	Back pain-specific education Physical exercise Relaxation techniques	The intervention group used the Kaia application, a cross-platform m-health app consisting of three therapeutic modules: specific education on back pain, physiotherapy/physical exercise, and relaxation techniques. Each section is independent and there is no obligation to perform all three therapy modules in one session. The procedure is carried out at least four times a week for 3 months.
Shebib et al. ³⁹	Mobile application DCP	Sensor-guided exercise therapy Back care education Cognitive behavioral therapy	The treatment group received a tablet with the DCP app installed, and two Bluetooth motion sensors for the lower back, each week, participants were required to complete three sessions of sensor-guided physical exercise, read one to two educational articles, record their symptoms at least twice weekly, for 12 weeks.
Chhabra et al. ⁴⁰	Mobile health Smartphone app Snapcare	Medical prescription Physical activity (back and aerobic exercises)	The Snapcare app intervention aimed to motivate, promote, and guide participants to gradually increase their level of physical activity and exercise adherence through gamification and reminders. The consulting physician set 4 km daily walking and two daily sets of seven back exercises during 12 weeks of treatment.

NLBP, Non-specific Low Back Pain; DCP, Digital Care Program; TBMT, Telerehabilitation-Based McKenzie Therapy.

study consisted of physiotherapy and self-management (individual exercise program prescribed by the therapist), a mobile app was given to the patients, it consisted in an exercise reminder and pain and activity register; patients were reminded for performing exercise four times per week for 4

weeks.³⁶ Irvine et al.³⁷ provided patients an online program that provides LBP education and behavioral strategies for managing pain during 16 weeks.³⁷

Patients in Toelle et al.'s³⁸ study were encouraged to access the Kaia App four times a week during 3 months; this app

consists in education, exercise, and relaxation techniques.³⁸ Shebib et al.'s³⁹ intervention duration was 12 weeks where patients received a tablet computer with an app with education articles, behavioral therapy, and exercise monitoring; patients should complete three monitored exercise sessions and three aerobic activities per week.³⁹ Intervention group in Chhabra et al.'s⁴⁰ study received Snapcare app and an exercise program based on patient's health status; app intervention was aimed for motivating, promoting, and guiding the patients into physical activity for 12 weeks intervention.⁴⁰

In terms of follow-up, five studies^{35,38-40} followed up at two points in time: at baseline and at 12 weeks^{38,39,40}; and at baseline and at 6 months.³⁵ Another four studies^{28,29,36,37} followed up on three time points: at baseline, at 4 weeks, and at 8 weeks^{28,29}; at baseline, at 2 months, and at 4 months³⁷; and at baseline, at 2 weeks, and at 4 weeks.³⁶ Only Suman et al.³⁴ followed up at four points in time: at baseline, at 3 months, at 6 months, and after 1 year.

With regard to the primary measures analyzed, seven studies analyzed pain intensity^{28,35-40} using different measurement scales, including the VAS in Irvine et al.,³⁷ Amorim et al.,³⁵ Yang et al.,³⁶ Shebib et al.,³⁹ and Mbada et al.,²⁸ and the Numeric Pain Rating Scale in Chhabra et al.⁴⁰ and Toelle et al.³⁸ Only one study employed the Korff Scale (Shebib et al.³⁹). Disability was analyzed in eight articles,^{28,29,34-37,39,40} again using different scales, including the Modified Oswestry Disability Index in Chhabra et al.,⁴⁰ the ODI scale in Mbada et al.,²⁸ Shebib et al.,³⁹ and Fatoye et al.,²⁹ the RMDQ in Suman et al.,³⁴ Yang et al.,³⁶ and Mbada et al.,²⁸ the Multidimensional Prognostic Index in Irvine et al.,³⁷ and the Korff Scale (Korff) in Shebib et al.³⁹

On the other hand, there are important aspects that several studies took into account and assessed, such as the quality of life was analyzed using scales such as the Interference Scale of the Brief Pain Inventory and the Dartmouth Primary Care Cooperative Information Project Scale (CO-OP) in Irvine et al.,³⁷ the European Quality of Life 5 Dimensions (EQ-5D) in Suman et al.,³⁴ and the Short Form 12 Scale (SF-12) in Mbada et al.²⁸

The functional capacity was only analyzed in two studies,^{29,38} which used the Hanover Functional Ability Questionnaire. A wide range of other variables were analyzed, including work productivity,³⁷ back extensor muscle strength,²⁸ disability-adjusted life years,²⁹ cost-effectiveness,²⁹ patient anxiety using the Depression Anxiety Stress Scale, physical activity using the International Physical Activity Questionnaires,³⁵ and beliefs about back pain using the Back Beliefs Questionnaire.³⁸

RISK OF BIAS

Table 5 shows the risk of bias of the included studies. For most of the included RCT, random sequence generation and other sources of bias were rated as low risk of bias, according to the Cochrane risk of bias tool: five articles showed a low risk of bias^{34-37,40} and the remaining four an unclear risk of bias.^{28,29,38,39} In combination, the included studies accounted for 3,180 subjects. One was published in 2015,³⁷ another in 2018,⁴⁰ six in 2019,^{28,34-36,38,39} and one in 2020.²⁹ According to the Cochrane tool,^{33,41} eight articles^{28,29,34-36,38-40} presented a low risk of bias for random sequence generation, leaving only one study³⁷ with an unclear risk of bias for this item.

Table 5. Cochrane Risk of Bias

STUDY	RANDOM SEQUENCE GENERATION	ALLOCATION CONCEALMENT	BLINDING OF PARTICIPANTS AND PERSONNEL	BLINDING OF OUTCOME ASSESSMENT	INCOMPLETE OUTCOME DATA	SELECTIVE REPORTING	OTHER BIAS	RISK OF BIAS
Mbada et al. ²⁸	Low	Low	Low	Unclear	Low	Low	Low	Low
Fatoye et al. ²⁹	Low	Low	Unclear	High	Low	Low	Low	Moderate
Suman et al. ³⁴	Low	Low	Low	Low	Low	Low	Low	Low
Amorim et al. ³⁵	Low	Low	Low	Low	Low	Low	Low	Low
Yang et al. ³⁶	Unclear	Unclear	High	High	Unclear	Low	Low	High
Irvine et al. ³⁷	Unclear	Unclear	High	Unclear	Low	Low	Low	High
Toelle et al. ³⁸	Unclear	High	High	Unclear	Low	Low	Low	High
Shebib et al. ³⁹	Low	Low	High	Unclear	Low	Low	Low	Moderate
Chhabra et al. ⁴⁰	Low	Low	Low	Low	Low	Low	Low	Low

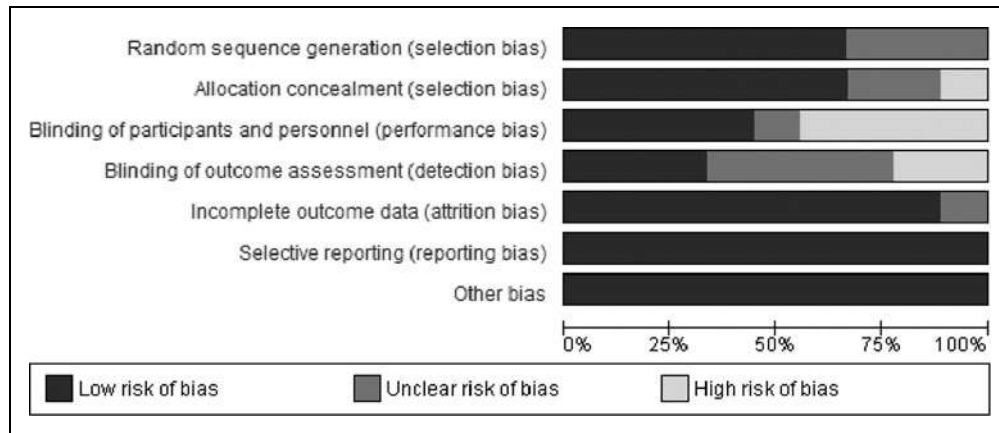


Fig. 2. Risk of bias graph: review authors' judgments about each risk of bias item presented as percentages across all included studies.

In terms of allocation concealment, eight studies^{28,29,34-37,39,40} had a low risk of bias and one a high risk.³⁸ The results for blinding of participants and personnel were more varied, with four studies^{28,29,37,39} obtaining a high-risk rating and five^{34-36,38,40} a low-risk rating. All nine articles obtained a low risk of bias score for incomplete outcome data, selective reporting, and other biases (Fig. 2; Risk of bias graph and Fig. 3; Risk of bias summary).^{28,29,34-40}

EFFECTS OF INTERVENTIONS

See Summary of findings 1 for the main comparison e-health compared with other physical therapy for chronic nonspecific LBP and Summary of findings 2 e-health compared with minimal intervention controls for chronic non-specific LBP.

E-HEALTH COMPARED TO OTHER PHYSICAL THERAPY

Six studies compared an e-health intervention-based self-management, education and physiotherapy through app or/ and tracker to the same intervention of experimental group, but performed at clinic or at home, without support internet-based application.^{28,29,35,36,38,40} We analyzed these studies together (total 358 participants) because we believe that e-health and control conditions are clinically comparable across studies.

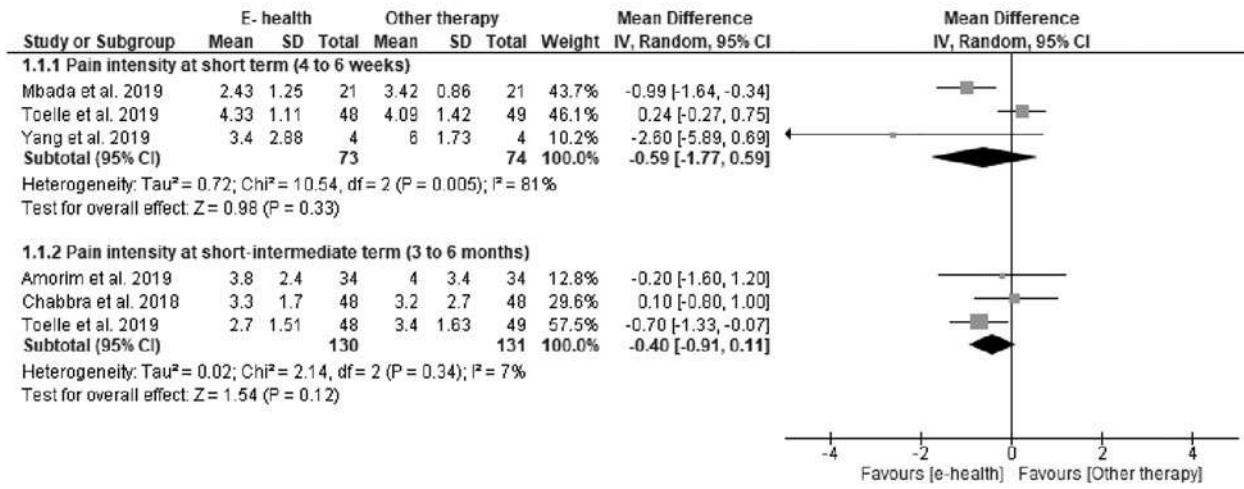
PRIMARY OUTCOMES

Pain. Five trials examined the effect of e-health compared with other physical therapy on pain (Analysis 1.1).^{28,35,36,38,40} At 4 to 6 weeks and 3 to 6 months, there was no statistically or clinically significant difference in pain between the e-health and other physical therapy performed without app or internet support. There was moderate-certainty evidence at 4 to 6

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Amorim et al. 2019	+	+	+	+	+	+	+
Chabbra et al. 2018	+	+	+	+	+	+	+
Fatoye et al. 2020	+	+	?	-	+	+	+
Irvine et al. 2015	?	?	-	?	+	+	+
Mbada et al. 2019	+	+	+	?	+	+	+
Shebib et al. 2018	+	+	-	?	+	+	+
Suman et al. 2019	+	+	+	+	+	+	+
Toelle et al. 2019	?	-	-	?	+	+	+
Yang et al. 2019	?	?	-	-	?	+	+

Fig. 3. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.

Analysis 1.1. Comparison 1 E-health versus other physical therapy, Outcome 1 Pain.



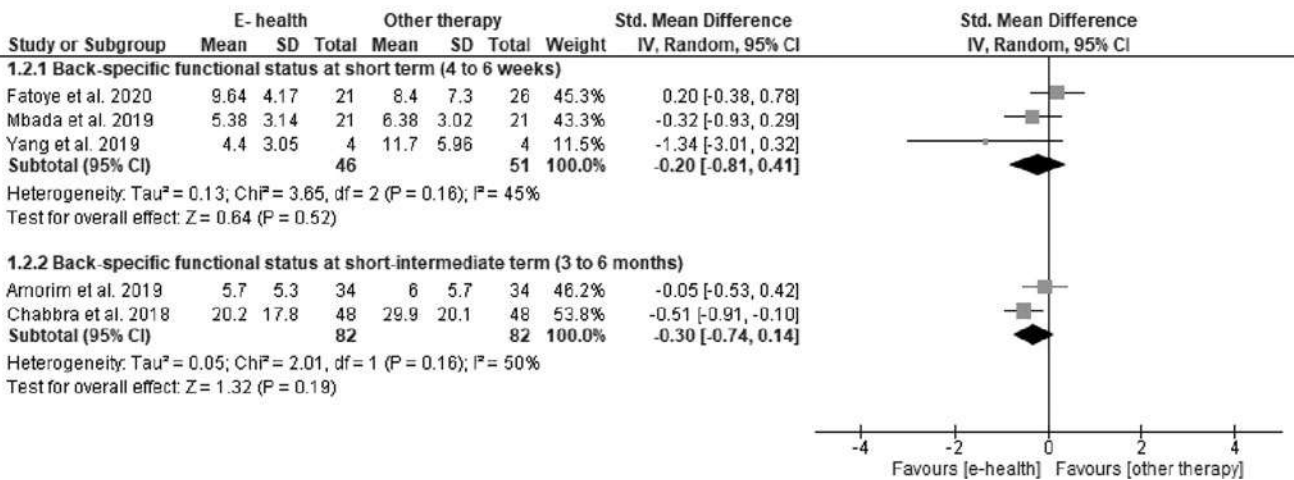
weeks (MD -0.59, 95% CI -1.77 to 0.59; I² = 81%; 3 studies, 147 participants; Analysis 1.1.1) and moderate-certainty evidence at 3 to 6 months (MD -0.40, 95% CI -0.91 to 0.11; I² = 7%; 3 studies, 261 participants; Analysis 1.1.2).

When the overall results for pain at 4 to 6 weeks were compared to a sensitivity analysis including only studies at lower risk of bias, the estimate of effect was more beneficial (MD -0.99,

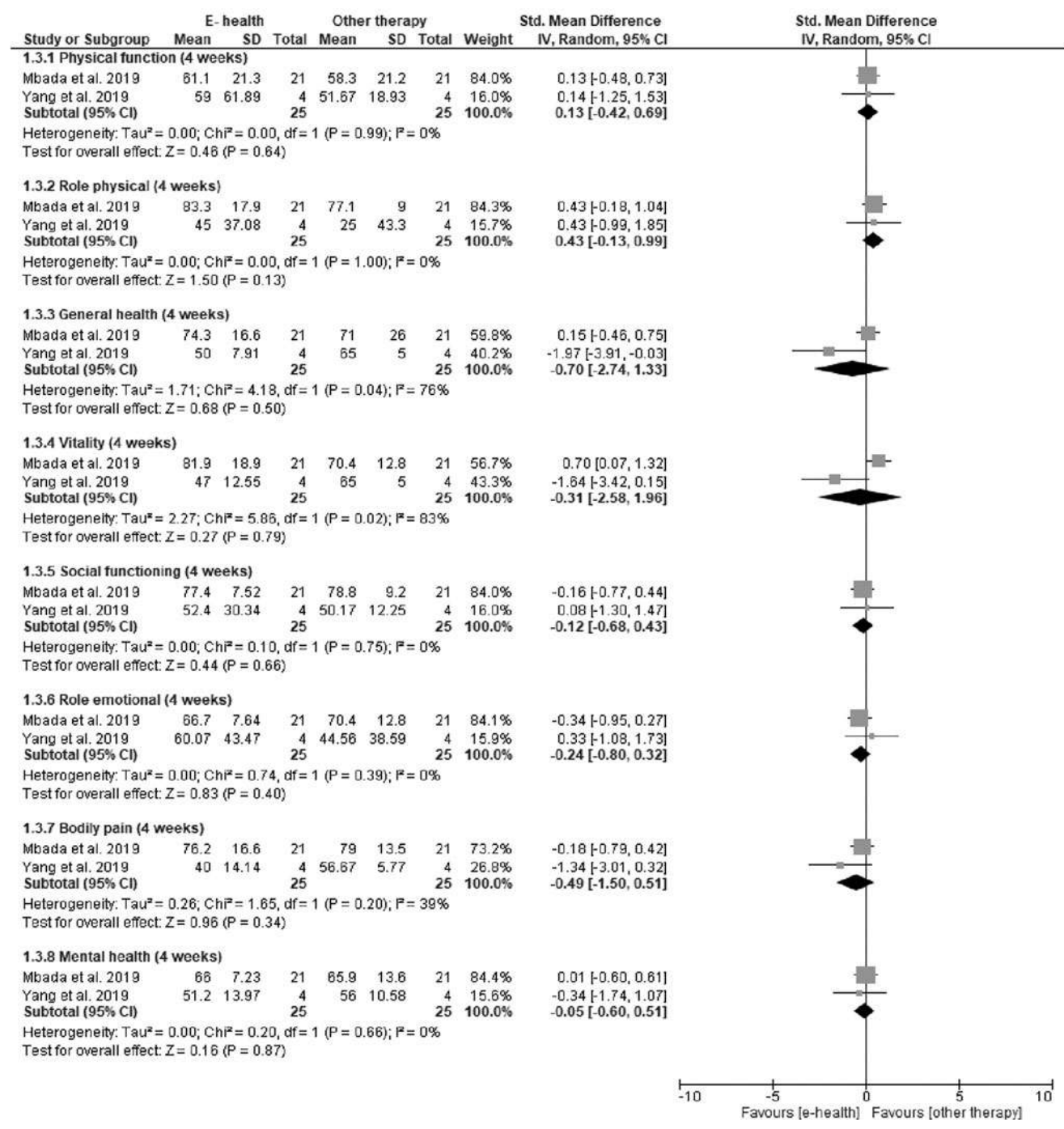
95% CI -1.64 to -0.34; 1 study, 42 participants; Analysis 3.1.1). At 3 to 6 months, the sensitivity analysis showed no significant change in heterogeneity and effect size (Analysis 3.1.2).

Back-specific functional status. Five trials examined the effect of e-health compared with other physical therapy on back-related function (Analysis 1.2).^{28,29,35,36,40} There was

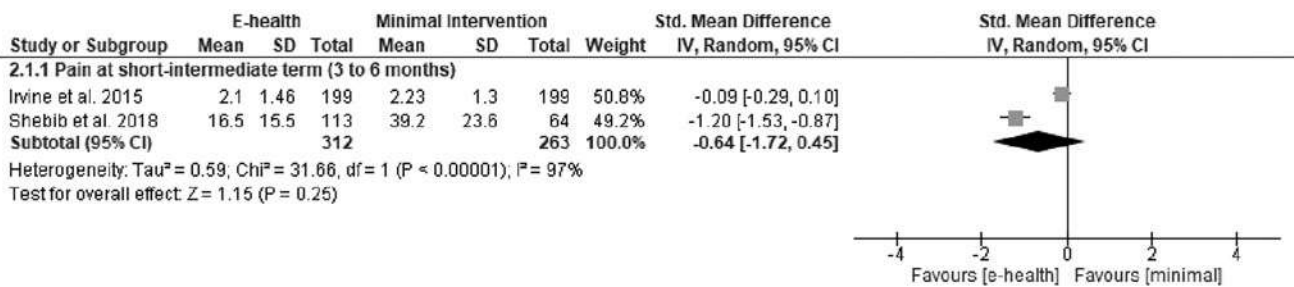
Analysis 1.2. Comparison 1 E-health versus other physical therapy, Outcome 2 Back-specific functional status.



Analysis 1.3. Comparison 1 E-health versus other physical therapy, Outcome 3 Quality of life.



Analysis 2.1. Comparison 2 E-health versus minimal intervention, Outcome 1 Pain.



moderate certainty evidence that e-health was as effective as other physical therapy at 4 to 6 weeks (SMD -0.20, 95% CI -0.81 to 0.41; I² = 45; 3 studies, 97 participants; Analysis 1.2.1), and high certainty at 3 to 6 months (SMD -0.30, 95% CI -0.74 to 0.14; I² = 50; 2 studies, 164 participants; Analysis 1.2.2). The certainty of the evidence was lower at 4 to 6 weeks for risk of bias and inconsistency of the studies. At short term, the sensitivity analysis showed no significant change in heterogeneity and effect size (SMD -0.05, 95% CI -0.56 to 0.46; I² = 32; 2 studies, 89 participants; Analysis 3.2.1).

SECONDARY OUTCOMES

Quality of life. Two studies reported quality of life outcomes in the comparison e-health versus other physical therapy.^{28,36} There was no statistically significant difference at 4 weeks (SMD ranged from -0.70 to 0.43, 95% CI ranged from -2.23 to 1.96; I² = 0 to 83; 2 studies, 50 participants; Analysis 1.3). The evidence for each item was low for risk of bias and imprecision. Our sensitivity analyses revealed no marked difference between the RCT analyses, regardless of the risk of bias (Analysis 3.3).

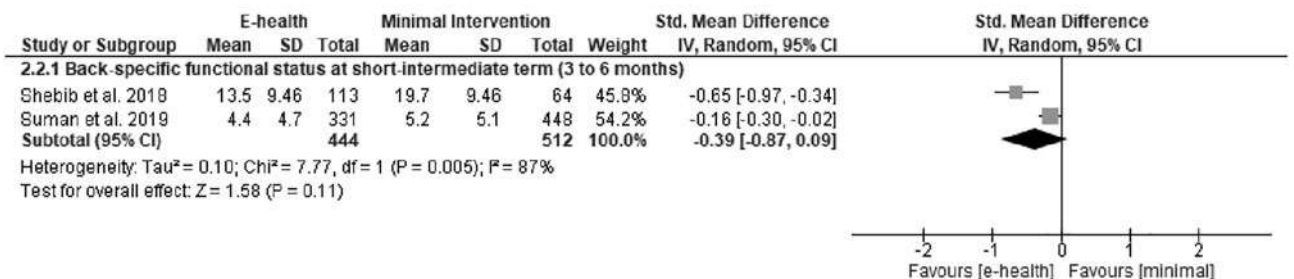
E-HEALTH COMPARED TO MINIMAL INTERVENTION

Three studies compared an e-health intervention to a minimal intervention (e.g., web information).^{34,37,39} The intervention in one study was for 4 weeks, and the intervention in two studies was for 12 weeks (see comparison 2 e-health vs. minimal intervention, Analysis 2.1 and Analysis 2.2). We analyzed these studies together (total 1,354 participants) because we believe that e-health and control conditions are clinically comparable across studies.

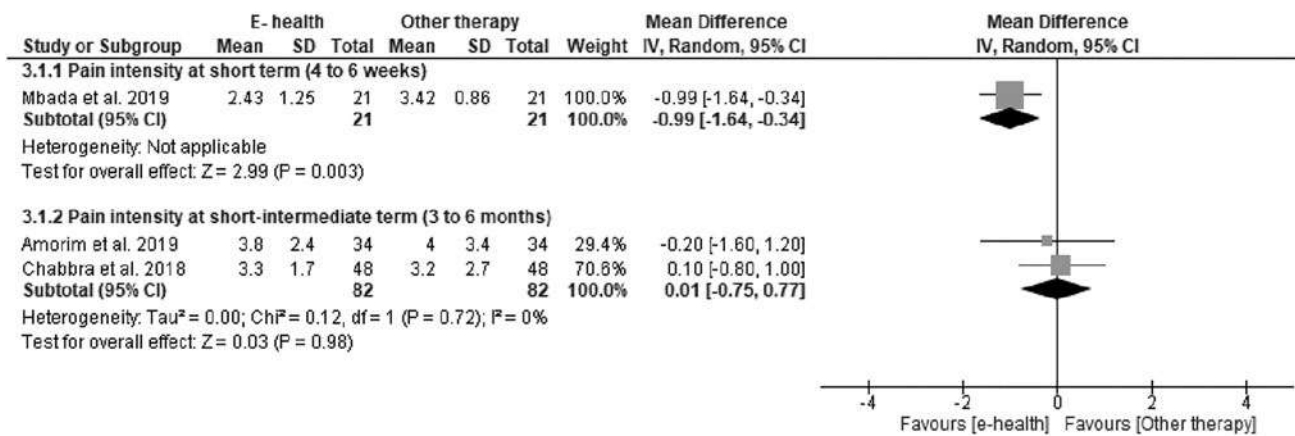
PRIMARY OUTCOMES

Pain. Two studies reported this outcome at short-intermediate term (3 to 6 months).^{37,39} There was no significant difference between groups (SMD -0.64, 95% CI -1.72 to 0.45; I² = 97; 2 studies, 575 participants; Analysis 2.1.1). The certainty of evidence was low to moderate for risk of bias and inconsistency; sensitivity analyses had only one study included, making interpretation difficult. In the sensitivity analyses, the effect estimates were significant (SMD -1.20, 95% CI -1.53 to -0.87; 1 study, 177 participants; Analysis 4.1.1).

Analysis 2.2. Comparison 2 E-health versus minimal intervention, Outcome 2 Back-specific functional status.



Analysis 3.1. Comparison 1 Sensitivity and subgroup analyses for e-health versus other physical therapy, Outcome 1 Pain sensitivity analysis.

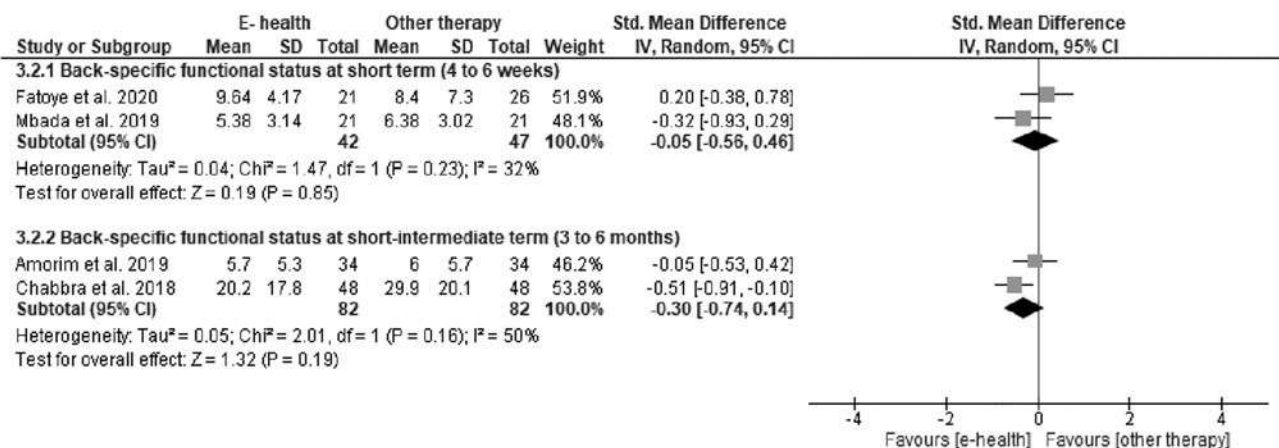


Back-specific functional status. Two studies examined the effect of e-health compared with a minimal intervention on back-specific function of patients with chronic LBP.^{34,39} Although there were significant differences between groups (SMD -0.39, 95% CI -0.87 to 0.09; I² = 87; 2 studies, 956 participants; Analysis 2.2.1), the certainty evidence was low by very serious risk of bias and imprecision. The sensitivity analysis showed changes in the effect size (SMD -0.16, 95% CI -0.30 to -0.02; 1 study; 779 participants; Analysis 4.2.1).

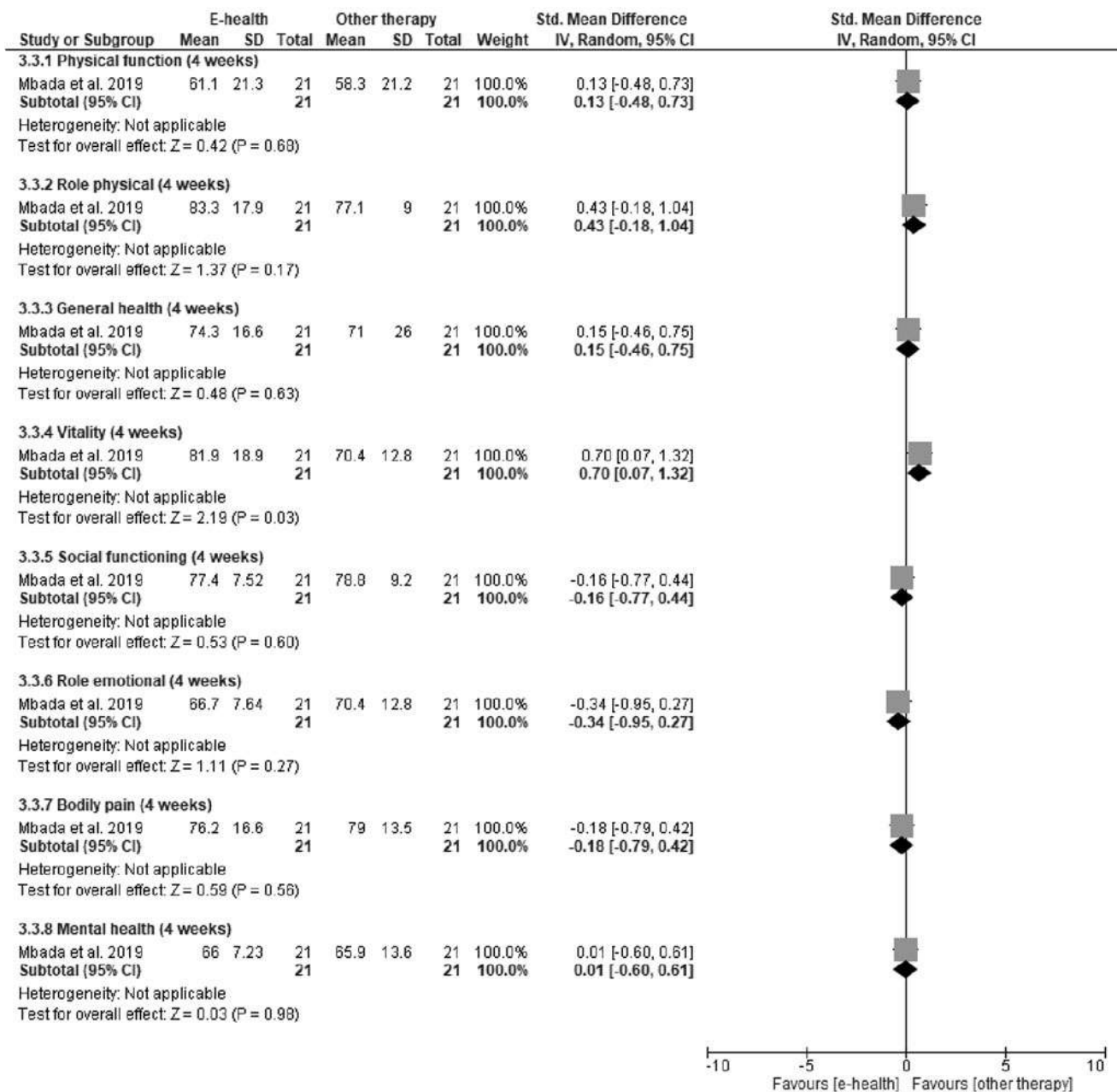
SUBGROUP AND SENSITIVITY ANALYSES

Our sensitivity analyses revealed no marked difference between the RCT analyses, regardless of risk of bias, with two exceptions (Analysis 4.1; Analysis 4.2). In the comparison of e-health and minimal intervention, both analysis of pain and back-specific function at short-intermediate term showed lower effect estimate when included studies were restricted to those at low risk of bias. This may be due to the size of the population and because the only included study had a lower risk of bias.

Analysis 3.2. Comparison 1 Sensitivity and subgroup analyses for e-health versus other physical therapy, Outcome 2 Back- specific functional status sensitivity analysis



Analysis 3.3. Comparison 1 Sensitivity and subgroup analyses for e-health versus other physical therapy, Outcome 3 Quality of life sensitivity analysis

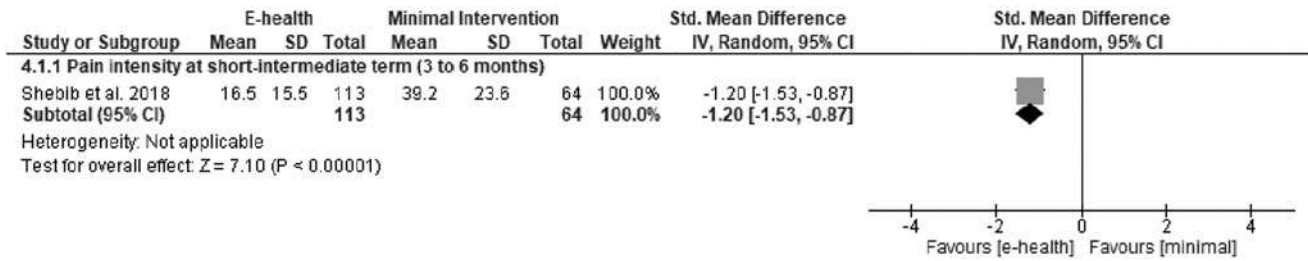


Otherwise, in the comparison of e-health to other physical therapy, the effect estimates in the sensitivity analyses were similar, indicating that the overall results for analyses, including a mix of studies at higher and lower risk of bias, are robust to influence from study risk of bias.

Discussion

We set out to conduct a unique, up-to-date review on the effectiveness of e-health interventions as regard to improving the symptoms of chronic LBP. We found evidence moderate that e-health results are just as effective as other physical

Analysis 4.1. Comparison 2 Sensitivity analyses for e-health versus minimal interventions, Outcome 1 Pain



therapy interventions, both on pain and on back-specific function. The evidence was of low certainty on quality of life at short term, only two studies reported it, so the information is inconsistent and the results inconclusive. If e-Health is as effective as other physical therapy performed at home or at clinic, the choice to use e-health may depend on availability, cost, and participant or provider preference.

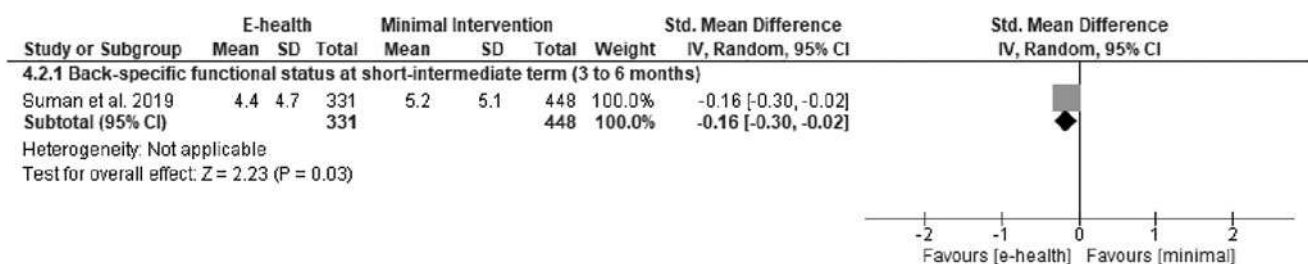
For e-health compared to minimal intervention, we found three studies of doubtful quality. The evidence is very low certainty due to serious risk of bias and imprecision, and we are uncertain about the effects of e-health compared with a minimal intervention (web information, three digital education articles and digital patient information letter). There was high heterogeneity between the included studies; however, the number of included subjects was very big in these studies.

The trials included in this review were carried out in Germany, Nigeria, the United States, China, Netherlands, and Australia, with a mix of primary care and community participants. Although the delivery, format, and timeline of the e-health interventions were very heterogeneous in all the analyzed studies, eight of the nine studies in this review in-

cluded exercise and education designed for people with LBP within the e-health strategy. There is considerable concern with external validity for these study results. The results of this review about e-health strategy (app or tracker) based in specific exercise, knowledge, and self-management for chronic LBP could be generalized across cautiously.

Chronic LBP is a complex problem rarely cured, which represents a challenge for the different health systems, where there are long waiting lists. Factors such as distance, time, and cost have caused numerous barriers to attaining the self-management skills and resources required by patients with chronic musculoskeletal conditions.^{42,43} Self-management through e-health strategies have made it possible to address this problem in patients with chronic LBP.⁴⁴⁻⁴⁶ Despite some differences in included studies, outcomes assessed, and choices of outcome time points, our findings are in broad agreement with other reviews of e-health treatment for LBP. Garg et al.⁴⁷ evaluated the impact of web-based interventions on chronic LBP, and found three of these studies reported a reduction in disability and two of the studies also appeared to show improvement in pain levels.

Analysis 4.2. Comparison 2 Sensitivity analyses for e-health versus minimal interventions, Outcome 2 Back-specific functional status



However, the authors did not perform a quantitative analysis of the data, and the therapy was not compared with other physical interventions performed in clinic or at home. On the other hand, according to our study, Du et al.⁴⁸ found moderate-quality evidence that e-health-based self-management programs showed immediate and short-term effects on both pain and disability; however, this study did not consider the comparison of efficacy between e-health-based self-management programs and traditional self-management programs, which we considered.

Regarding the comparison of telehealth versus minimal intervention, Dario et al.⁴⁹ obtained results similar to ours; current telehealth-based interventions (mainly based on supporting patients' behavior change or to self-manage their condition) are not more effective than minimal interventions for reducing pain and disability in chronic LBP when used as a sole treatment strategy. However, most of the intervention groups included in this review with meta-analysis were based mainly on supporting patients' behavior change or to self-manage the participants' symptoms.

Although there was a similar effectiveness between e-health interventions and those carried out face-to-face or at home, it would be advisable to assess how to improve the effects of this intervention. There is no doubt that new technologies allow physical therapists to provide their patients with the remote follow-up and contact that they demand⁵⁰; however, accessibility and handling of patients with electronic systems may differ according to the age range, and this affects the results.⁴³

Also, a recent study reported that patients prefer a previous practice or an individually supervised face-to-face physiotherapy session, in which the participants can practice movements that they will perform at home with tele-rehabilitation tools.⁵¹ Dario et al.⁴⁹ suggested in their review that an underresearched area is the integration of telehealth with face-to-face management programs for LBP. Based on our results, we agree that combining both programs could ensure adherence and improve the effects of interventions administered to patients with chronic LBP.

STRENGTHS AND LIMITATIONS

This systematic review presents some limitations, which should be considered. First, we only identified a small number of studies presenting a low risk of bias. Furthermore, sample size varied widely between the included studies, as did type of therapeutic intervention, variables analyzed, secondary outcomes, and follow-up period, preventing comparison of these aspects. A relevant aspect that was not considered in the included studies was patient compliance with therapy. Some trials have found that adherence to treatment in patients with

LBP could be facilitated by the use of computer-based systems; however, none of the included studies reported this outcome measure. Finally, only a small number of studies to date have investigated e-health as a therapeutic method.

This study supports the notion that e-health-based interventions alone or combined with a few face-to-face interventions are cost-effective health care tools that can reach a large number of people.

Conclusions

This review provides moderate-quality evidence that e-health interventions based on self-maintenance and education are as effective on pain and back-specific functional status as other face-to-face or home-based interventions in patients with chronic LBP. However, regarding improvement of quality of life, the current scientific evidence is poor and inconsistent, as few studies and of questionable quality assessed this outcome measure. On the other hand, there was low evidence that e-health interventions are as effective as minimal interventions for the reduction of pain and functional status in chronic LBP.

Our systematic review indicates the need for further, more standardized research in terms of the outcomes analyzed, sample size, and type of intervention, to establish more clearly the positive effects of e-health on all outcomes in patients with chronic LBP, and thus to determine with certainty whether this new form of therapy, alone or combined, is suitable for application in patients with this condition.

Authors' Contributions

Conceptualization: E.A.-S., J.D.R.-G., A.M.C.-S., and I.C.L.-P.; data curation: J.D.R.-G. and A.M.C.-A.; formal analysis: H.G.-L., A.M.C.-S., I.C.L.-P., and E.G.-M; methodology: E.A.-S., J.D.R.-G., and A.M.C.-S.; supervision: A.M.C.-S. and I.C.L.-P.; writing—original draft preparation: E.A.-S. and J.D.R.-G.; and writing—review and editing: H.G.-L., A.M.C.-S., and I.C.L.-P. All authors have read and agreed to the published version of the article.

Disclosure Statement

No competing financial interests exist.

Funding Information

This work was supported by the project "PI18/00562" (Co-funded by FEDER - European Regional Development Fund/ European Social Fund "A way to make Europe"/"Investing in your future") and I+D+i of Biomedical and Health Sciences in Andalusia [(PC-0185-2017, PC-0267-2017 and PC-0536-2017) (Coordinated Project)].

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Received: December 10, 2021

Revised: March 11, 2022

Accepted: March 24, 2022

Online Publication Date: May 10, 2022

CONCLUSIONES

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- La terapia manipulativa y la liberación miofascial en pacientes con CLBP y síndrome sacroilíaco clínicamente diagnosticado, dieron como resultado beneficios similares a corto plazo en la discapacidad informada por el paciente. Ambos grupos experimentaron una disminución significativa similar en la intensidad del dolor si bien, esta mejoría no llegó a alcanzar la diferencia clínicamente significativa en ninguno de los grupos. Al mes de seguimiento, se lograron diferencias significativas entre los grupos para la salud general, el funcionamiento social y la distancia de los dedos al suelo. **(Artículo I)**
- Protocolo basado en un enfoque que incluya la electropunción seca para la disfunción del dolor lumbar crónico versus la fisioterapia convencional en el tratamiento de los PGM activos y latentes en pacientes con CLBP. Los resultados de este estudio informarán sobre qué tipo de tratamiento es más beneficioso para los pacientes con CLBP. **(Artículo II)**
- Las intervenciones de telemedicina basadas en el automantenimiento y la educación son efectivas, mostrando una evidencia científica moderada, sobre el dolor y el estado funcional específico de la columna vertebral en pacientes con CLBP. **(Artículo III)**
- La terapia manipulativa, la electropunción seca y la telemedicina son intervenciones terapéuticas eficaces para el abordaje del paciente con CLBP. A pesar de que la terapia manipulativa y la liberación miofascial obtuvieron resultados similares tras la intervención en la discapacidad y a lo largo del tiempo en la intensidad del dolor, los pacientes que recibieron manipulación espinal experimentaron una mayor reducción en la discapacidad en todos los períodos de seguimiento, y mayores beneficios en la calidad de vida y en la movilidad lumbar en flexión al mes de seguimiento, en comparación con el grupo control. Los resultados del estudio de la eficacia de la electropunción seca eléctrica frente a la fisioterapia convencional en pacientes con CLBP, pueden ayudar a los

fisioterapeutas a comprender si este tipo de intervención puede reducir significativamente la discapacidad y el absentismo laboral por CLBP. La telemedicina es efectiva en el dolor y la función específica de la zona lumbar, y la combinación con la intervención fisioterapéutica presencial podría asegurar la adherencia y mejorar los efectos de las intervenciones administradas a pacientes con CLBP.

AGRADECIMIENTOS

“Me enseñaron que el camino del progreso no es ni rápido ni fácil” *Marie Curie*.

Parecía que no llegaría nunca, pero llegó. Tras sortear muchas piedras en el camino, sumergida en una espiral de ilusiones y emociones, solo me queda agradecer, agradecer y AGRADECER.

A Adelaida M^a Castro Sánchez por introducirme en esta aventura, a Manuel Fernández Sánchez por ser el mejor profesor que una alumna pueda tener, a Encarnación Aguilar Ferrándiz por su disposición y, especialmente, a Inmaculada C. Lara Palomo, quien me guió en este duro recorrido. Sin tu paciencia, tu aliento y tu conocimiento esto no hubiera sido posible. Gracias de nuevo.

A mis pacientes, amigas y amigos, que han acudido a mis manos siempre que los he necesitado, siempre fieles, sin importar día, hora y sitio: Puri, Luis Alcázar, Paco, Inma Alcaraz y su familia, mis pacientes y amigos de Ciudad Jardín, Regiones Devastadas, Pescadería, compañeras de Bola Azul, Torrecárdenas, mi querida Ibermutua... gracias.

A mi amiga Alba por escucharme y aconsejarme casi en bucle. A Marijose por estar siempre ahí. A Eva por las charlas interminables arreglando el mundo. Gracias a todas mis flores. Y a mis compañeros de rastreo covid, por vivir parte de esta experiencia (y de otras tantas) juntos.

A mi familia presente, en especial a mi madre Esther, que sacrificó siempre su vida por sus “niñas”, contra viento y marea, y a mi hermana Irene, por animarme cuando la energía decaía. Y a mi marido Pedro, mi compañero de vida, por ser un ejemplo de superación y no perder nunca la sonrisa: gracias por tu apoyo incondicional, ayer, hoy y siempre.

Y por último a mi familia que, aunque no está presente en cuerpo, siempre lo está en mente, mi tía Olga y mi abuela Ana, ya que fuisteis vosotras las que me empujasteis a ésto. Aunque vuestra marcha me hizo pensar en tirar la toalla, vuestro recuerdo me ha seguido dando fuerzas cada día. Gracias por creer en mí.

En definitiva, GRACIAS a todas y cada una de las personas que han colaborado en este trabajo, por ayudar a convertir en realidad mi sueño. Y es que...

“Hay que hacer de la vida un sueño, y de un sueño la realidad” *Pierre Curie*.

