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EVALUACIÓN Y ASESORAMIENTO DEL DOLOR DE ESPALDA BAJO NO ESPECÍFICO EN FASE SUB-AGUDA. EFECTIVIDAD DE UN PROGRAMA DE TELE-EJERCICIO EN TRABAJADORES DE OFICINA AFECTADOS POR DOLOR DE ESPALDA BAJO NO ESPECÍFICO EN FASE SUB-AGUDA

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EVALUATION AND ASSESSMENT OF NON-SPECIFIC LOWER BACK PAIN IN THE SUB-ACUTE PHASE. EFFECTIVENESS OF A WEB-BASED EXERCISE PROGRAM IN OFFICE WORKERS SUFFERING FROM SUB-ACUTE NON-SPECIFIC LOW BACK PAIN

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A mi familia

UNIVERSIDAD DE EXTREMADURA

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Dr. D. NARCÍS GUSI FUERTES, profesor titular del Área de Educación Física y Deportiva del departamento de Didáctica de la Expresión Musical, Plástica y Corporal de la Universidad de Extremadura,

CERTIFICA:

Que la Tesis Doctoral realizada por **D. Borja del Pozo-Cruz**, con el título: **"Evaluación y asesoramiento del dolor de espalda bajo no específico en fase subaguda. Efectividad de un programa de Tele-ejercicio en trabajadores de oficina afectados por dolor de espalda bajo no específico en fase subaguda"**, bajo mi dirección, reúne los requisitos necesarios de calidad, originalidad y presentación para optar al grado de Doctor, y está en condiciones de ser sometida a valoración de la Comisión encargada de juzgarla.

Y para que conste a los efectos oportunos, firmo la presente en Cáceres, a 26 de Enero de 2012

Dr. D. Narcís Gusi Fuertes

INDEX OF CONTENTS

INDEX OF TABLES AND FIGURES

TABLES

FIGURES

SUMMARY

Lower back pain has in most cases an unknown origin and affects individuals' quality of life, their family and social relationships, and their ability to and capabilities at work. In Spain this problem has significant economic consequences. It is estimated that the total annual average cost of episodes of sickness absence caused by lower back pain surpasses 195 million euros per year, the bulk of which is due to the condition becoming chronic among those who suffer from it. Experts acknowledge the need to manage this ailment, and scientific evidence has demonstrated that physical exercise helps improving health-related quality of life among affected individuals and reduces the socio-economic impact from the disease. We propose that a cost-effective and efficient strategy to deal with this could rely on web-based interventions at the workplace, which have been shown to be effective in improving fitness levels and promoting an active lifestyle among the general population. However, no studies have addressed the effects of these interventions on subjects who experience lower back pain. Besides, there is currently no available tool to test the risk of chronicity of non-specific lower back pain in Spain and no data at all on fitness and quality-of-life profiles or on trunk muscle endurance for workers affected by this condition. Gathering such data is of uttermost importance for the assessment and monitoring of lower back pain among this population.

The aims of this thesis are threefold. Firstly, we investigate and adapt the English Start Back Screening Tool for its potential use in the assessment of the risk of chronicity in non-specific lower back pain in Spain. Secondly, we explore the fitness and quality-of-life profiles of office workers affected by sub-acute, non-specific lower back pain and the validity of the well-established Ito´s trunk muscle endurance test for this subpopulation. Thirdly, we test the effectiveness of a nine-month web-based intervention consisting of exercise and postural education on key lower back pain associated outcomes.

Our sample is composed of 190 office workers from a Spanish university, out of which 118 had been diagnosed with sub-acute, non-specific lower back pain at recruitment. Our treatment is the above mentioned web-based exercise programme and postural education intervention and our outcome measures are musculoskeletal-related fitness, clinical characteristics associated

with lower back pain, and the number of episodes of lower back pain at baseline and after nine months.

Key results indicate that the use of the Start Back Screening Tool can be extended to the Spanish population and that office workers affected by sub-acute, non-specific lower back pain have poorer fitness and quality-of-life profiles than age-matched office workers without this condition. They also show that Ito´s lumbar trunk muscle endurance tests is valid and reliable for use among office workers with sub-acute, non-specific lower back pain and that the intervention we propose enhances quality-of-life, functional and lumbar trunk muscle endurance capacity, and decreases the risk of chronicity and non-specific lower back pain episodes.

Overall, the contents of this thesis advance knowledge on the evaluation and assessment of patients with sub-acute, non-specific lower back pain, contribute to the literature on the adaptation of assessment instruments to the Spanish context, and provide important practical insights on how health-related policy could tackle lower back pain through web-based re-education interventions.

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LIST OF PUBLICATIONS

A. BOOKS CHAPTERS

I. **del Pozo-Cruz B** *y cols.* Ejercicio físico y dolor lumbar inespecífico ocupacional. En Ejercicio Físico y salud en poblaciones especiales: Exernet. Colección Investigación en Ciencias del Deporte número 58. Consejo Superior de Deportes. 2011, (*en prensa*).

B. SCIENTIFIC ARTICLES

II. Gusi N, **del Pozo-Cruz B** *et al*. The Spanish version of the ‘‘STarT Back Screening Tool’’ (SBST) in different subgroups. *Aten Primaria,* 43(7):356-61.

III. Gusi N, **del Pozo-Cruz B**, *et al.* Health-Related Quality of Life and fitness characteristics of office workers affected by sub-acute non-specific low back pain. *Physiotherapy, submitted.*

IV. **del Pozo-Cruz B** *et al.* Reliability and Validity of lumbar and abdominal trunk muscle endurance tests in work-age patients with non-specific, sub-acute low back pain. *J Rehab Med, submitted.*

V. **del Pozo-Cruz B**, *et al*. A web-based intervention to secondary prevention of common low back pain among office workers. *J Orthop Sports Phys Ther, submitted (second revision).*

VI. **del Pozo-Cruz B**, *et al*. An occupational, internet-based intervention to prevent chronicity in sub-acute lower back pain: a randomised controlled trial. *J Rehab Med, accepted.*

VII. **del Pozo-Cruz B**, *et al*. Are clinical changes in EQ-5D-3L reflecting clinical changes in specifics low back pain outcomes? A 9-month web-based randomized controlled trial on sub-acute, non-specific low back pain patients. *Clinical Rehabilitation, preliminary accepted.*

VIII. **del Pozo-Cruz B**, *et al*. A tailored web-based exercise program for office workers with low back pain influences stage of change in behaviour: a randomised controlled trial. *Prepared to be submitted.*

RESEARCH PROJECTS

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III. *"Exercise look after you".* Junta of Extremadura. Date 2007-2011.

IV. University of Extremadura by AFYCAV Group and Occupational Preventive Service.

LIST OF ABBREVIATIONS

ANOVA	Analysis of variance
AP	Atención Primaria
ARR	Absolute Risk Reduction
AUC	Area under the curve
CI	Confidence Interval
CVRS	Calidad de Vida Relacionada con la Salud
DEB	Dolor de espalda bajo
EQ-5D-3L	European Quality of Life Questionnaire, five dimensions, three levels
EVA	Escala Visual Analógica derivada del cuestionario EQ-5D-3L
GP	General Practitioner
HRQoL	Health-Related Quality of Life
ICC	Intra class correlation coefficient
LBP	Low back pain
MPI	Multidimensional Pain Inventory
MICD	Minimum Important clinical change
NLBP	Non-specific low back pain
NNT	Number needed to treat
NNT	Number needed to treat
ODI	Oswestry disability index
OMPQS	Orebro Musculoskeletal Screening
OR	Odd ratio
RMDQ	Roland Morris disability questionnaire
ROC	Receiver operating curve
ROC	Receiving Operating Curve
RRR	Relative Risk Reduction
SBST	STarT back Screening Tool
SD	Standard deviation
SEM	Standard error of measurement
SF-36	Short Form Health Survey
SNS	Sistema Nacional de Salud
SPSS	Statistic Package for Social Science
SRD	Small real difference
TTO	Time-trade-off
VAS	Visual analogical scale from EQ-5D-3L

Tratar de encontrar soluciones al dolor crónico (completas para prevenirlo o parciales para atenuar sus efectos) es uno de los mayores retos de la investigación actual [1]. Cuando el dolor persiste durante semanas o meses, el efecto sobre el bienestar puede ser ingente, llegando a mermar tanto la salud física como mental e incluso el desempeño de las responsabilidades sociales como el trabajo y la familia [2]. Por otro lado, parece que el dolor crónico va en aumento [3, 4], y aunque se ha avanzado en el manejo del mismo [5], encontrar nuevas estrategias que ayuden al diagnóstico y tratamiento es fundamental para atenuar el impacto que este presenta en todos los ámbitos de la vida [6-8]. De entre todas las afecciones que cursan con dolor crónico, las enfermedades reumáticas o musculoesqueléticas son las más comunes en Europa entre la población adulta. Si atendemos al Eurobarómetro de 2006, el 27% de la población europea sufre alguna forma de enfermedad crónica reumática, y entre ellas la lumbalgia es la más frecuente [9]. Según el último estudio realizado por la Sociedad Española de Reumatología, la prevalencia de la lumbalgia es del 44,8%, la de artrosis de rodilla del 10,2%, la de artrosis de manos del 6,2%, la de osteoporosis del 3,4%, la de fibromialgia del 2,4% y la de artritis reumatoide del 0,5%, afectando más a mujeres que hombres y más en personas con bajos niveles tanto socio-culturales como socio-económicos aumentando con la edad (tabla 1); y es que de la población europea que recibe algún tratamiento crónico, en el 32% de los casos es por estas enfermedades, sólo superadas por la hipertensión [10, 11].

Tabla 1. Frecuencia de las enfermedades reumatoides más importantes en la Población española distribuida por edad

	Intervalo de edad						
Afección	20-29	30-39	40-49	50-59	60-69	70-79	≥ 80
Artritis reumatoide	1 (,2)	1 (,2)	2 (,5)	1 (,3)	3 (1,0)	1 (,5)	1 (2,7)
Dolor de espalda bajo	29 (8,9)	53 (16,3)	57 (17,5)	64 (21,2)	69 (21,2)	40 (12,3)	13 (4,0)
Osteoartritis de rodilla	2 (,4)	3 (,7)	13 (3,5)	32 (9,8)	88 (28,1)	69 (33,7)	16 (21,3)
Osteoartritis de mano	--	--	4 (1,1)	22 (6,7)	48 (15,3)	49 (23,9)	13 (17,3)
Fibromialgia	--	7 (1,6)	18 (4,9)	12 (3,7)	9 (2,9)	6 (2,9)	--

Valores expresados como porcentaje (%) ± DE. *(Fuente*: tomada de Carmona y cols. 2001[11])

En España, además de las consecuencias que estas enfermedades presentan sobre la función normal y la calidad de vida de los sujetos que la padecen, el impacto sobre el consumo de recursos sanitarios (consultas médicas, ingresos hospitalarios, medicamentos) es imponente (Tabla 2), representando además una carga a la sociedad en términos de empleo en edad de trabajar.

Tabla 2. Visitas al médico por problemas musculoesqeuléticos, consumo de AINE, y compensaciones por discapacidad relacionada con afecciones musculoesqueléticas específicos en población española

	En el pasado año			
	Consultó al médico por síntomas musculoesqeuléticos			
Afección	*Cualquier número*	≥ 2 médicos	Consumió AINE > 1	Recibió compensaciones por discapacidad
Artritis reumatoide	72,7*	27,3	63,6*	9,1*
Dolor de espalda bajo	61,2*	25,8*	40,9*	8,0*
Osteoartritis de rodilla	66,4*	26,8*	45,7*	5,4*
Osteoartritis de mano	58,8*	22,8*	38,2*	2,2†
Fibromialgia	76,9*	42,3*	55,8*	7,7*
Otras distintas	25,3*	8,1*	14,3*	1,7*

Valores expresados como %; AINE: pastillas anti-inflamatorias no esteroideas; *: *p<.01* y †: *p<.05* referidos a las diferencias existentes entre sujetos que se ven afectados por las condiciones musculoesqueléticas definidas en comparación con aquellos sujetos no afectados por dichas condiciones. (*Fuente*: tomada de Carmona y cols. 2001[11])

Observando los datos parece necesaria una concienciación en el ámbito tanto público como privado para poder mitigar en la medida de lo posible el impacto que estas enfermedades presentan no solo en quienes la padecen sino también en el resto de la sociedad. De entre todas las enfermedades reumáticas, en la presente tesis nos centraremos en el dolor de espalda bajo (DEB).

El problema del dolor de espalda bajo en España

El DEB es una de las afecciones más antiguas y frecuentes en el ser humano, donde el 80% de la población lo padece en algún momento de su vida [12]. Según la Sociedad Española de Reumatología [10], la probabilidad de padecer al menos un episodio en los 6 meses anteriores a la encuesta realizada para dicho estudio [10], es del 44,8% mientras que la población afectada de DEB crónico alcanza un 7,7%. Por sexos, la prevalencia del DEB es mayor en mujeres. Por edad, parece ser que existe un incremento progresivo en la prevalencia conforme avanza la edad hasta 60 años, con lo que parece estar más relacionado con el ámbito ocupacional (figura 1). Para muchas personas el DEB es un problema auto-limitante que puede ser tratado. A pesar de esta declaración, se ha estimado que para un 12% de las personas afectadas, el DEB es lo suficientemente grave como para afectar a la calidad de vida individual, a la familia, las relaciones sociales y a la capacidad para trabajar [13]. La evidencia sugiere que el DEB en España supone un gran problema, y que la experiencia española no es inusual, ya que los porcentajes de prevalencia españoles son similares a los del resto del mundo occidental.

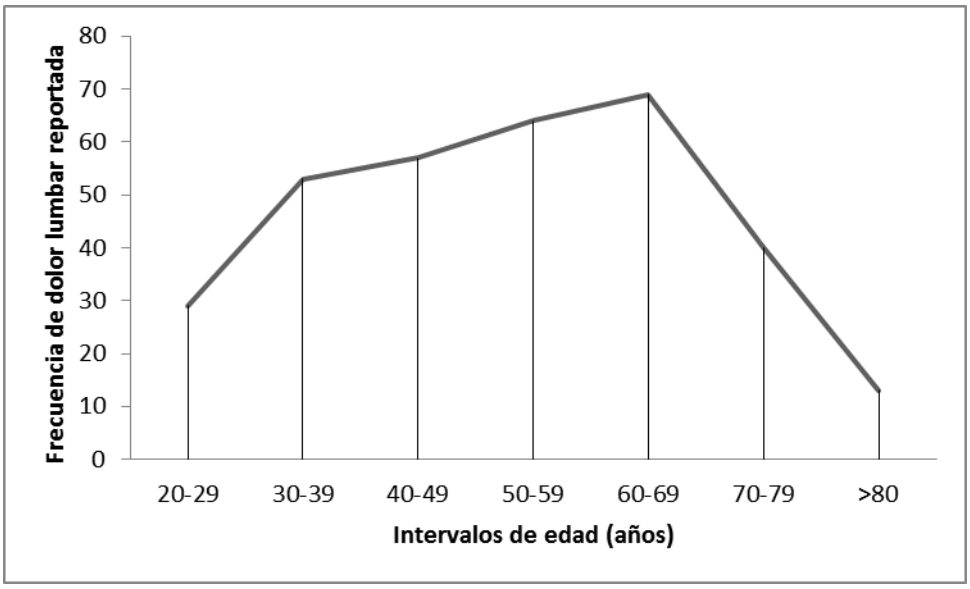

Figura 1. Porcentaje de DEB según la edad en España. (*Fuente: elaboración propia a partir de Humbría y Mediola 2002*[14]*)*

La literatura científica internacional pone de manifiesto que el 80% del total de costes atribuibles al DEB son consumidos por el pequeño grupo (10%) de pacientes que desarrollan síntomas crónicos [15, 16] y sitúa a nuestro país en cabeza en la magnitud del problema (en relación a qué) en comparación con los países de la UE. El DEB es la causa más importante de gasto compensatorio económico en nuestro país [17]. Según los últimos datos nacionales disponibles, el DEB supone un promedio de un 12,54% del total de bajas laborales, con un intervalo que va desde el 11,4% en el año 2000 hasta el 14,1% en 2004 (lo que supone una media anual de 2.214.907 jornadas no trabajadas). El coste medio anual total por las jornadas no trabajadas debido a DEB en el período estudiado representa un 10,67% del dinero devengado en el total por incapacidad temporal, llegando a 195 millones de euros al año [18]. El DEB es por lo tanto, un problema de salud importante debido en parte a su alta prevalencia, pero principalmente a su potencial para causar sufrimiento en las personas y los enormes costes que esto conlleva no sólo al sistema de salud sino a la sociedad en su conjunto.

Aproximación conceptual del dolor de espalda bajo

El DEB puede definirse de diferentes maneras dependiendo de cada escenario contextual, y se debe distinguir entre aquellos pacientes que muestran los síntomas, los que en realidad buscan ayuda médica, aquellos que buscan la incapacidad laboral temporal, o aquellos que tienen

problemas de incapacidad funcional, ya que se diferencian en cuanto a tasas de prevalencia y se ven influenciados por diferentes factores biomédicos, psicológicos y sociales [19]. En los centros de atención especializada y en estudios de investigación epidemiológica, el dolor de espalda suele definirse en términos anatómicos como el dolor experimentado entre los bordes de las costillas y los pliegues de los glúteos inferiores. Sin embargo, en la práctica clínica de atención primaria (AP), se utiliza una definición más pragmática incluyendo todos los pacientes que consultan a un médico con un problema relacionado con estructuras músculo-esqueléticas de la región de la espalda [20]. Los pacientes donde el dolor se irradia hacia la pierna(s) (a menudo denominado "ciática") suelen ser también incluidos en el grupo de pacientes con DEB, donde el dolor emana de las estructuras en la parte posterior [21]. Normalmente, es aceptada una clasificación simple para el DEB en función de la causa: a) patologías específicas del raquis, b) dolor de raíz nerviosa o dolor radicular y c) DEB no específico (sin causa original conocida) [22]. Además, en función de la duración del episodio, es generalmente aceptado que el DEB se vuelve crónico cuando el dolor persiste por más de 3 meses [22, 23]. El DEB se vuelve sub-agudo cuando el dolor presenta una duración de entre 4 a 12 semanas y agudo cuando el episodio de dolor dura de 0 a 4 semanas [24]. Debido a los propósitos de esta tesis, el término DEB se referirá a los pacientes aquejados de dolor en el momento de las mediciones (dolor puntual), en la parte baja de la espalda, subagudo, de carácter musculo-esquelético, con o sin dolor en la pierna, diagnosticado por un médico especialista y sin causa original conocida.

Tabla 3. Clasificación del DEB

En función de la causa del DEB	En función de la duración del episodio del DEB
Patología específica del raquis (enfermedades degenerativas, inflamatorias, infecciosas, metabólicas de los huesos, traumáticas, congénitas o asociadas a algún déficit de tipo neurológico como hernias de disco o estenosis espinal)	**Agudo** (cuando el episodio de DEB dura menos de 6 semanas)
Dolor de la raíz nerviosa o dolor radicular	**Sub-agudo** (cuando el episodio de DEB presenta una duración de entre 6 y 12 semanas)
Dolor no específico (sin causa patológica conocida)	**Crónico** (cuando el episodio de DEB persiste por más de 12 semanas)

DEB: Dolor de espalda bajo. (*Fuente: elaboración propia)*

Manejo del dolor de espalda bajo inespecífico: *diagnóstico y tratamiento*

Si bien existen guías de práctica clínica europea para el manejo del dolor de espalda , existe una variabilidad de práctica clínica considerable en el manejo del DEB inespecífico entre los distintos países de Europa [25, 26]. La mayoría de los estudios sobre el manejo en general del dolor lumbar han sido desarrollados en el Reino Unido, norte de Europa y los Estados Unidos [27, 28]. En este sentido, los determinantes en la discapacidad por DEB inespecífico son diferentes entre los distintos países que corresponden a diferentes zonas de Europa [29]. Existen pocos datos sobre práctica clínica en los países del sur de Europa [30], y solamente un estudio se encuentran disponible del Servicio Nacional de Salud español (SNS) relacionado con el manejo clínico en AP del DEB inespecífico [31]. En el SNS, los médicos de AP son libres de prescribir y aplicar el tratamiento y de diagnosticar o referir a sus pacientes de la manera que consideren más adecuada en cada caso. Los tratamientos son provistos de manera gratuita para los pacientes siempre y cuando estos tratamientos se encuentren listados en la cartera de servicios del SNS. Este es el caso para todos los medicamentos disponibles en el mercado, procedimientos diagnósticos y tratamientos no farmacológicos, excepto para la cirugía cosmética y algunos procedimientos dentales. Además, los médicos de AP no reciben ningún incentivo por ordenar una prueba u otra diagnóstica, tratamientos o por derivar a los pacientes hacia los diferentes especialistas. De forma general, el médico de AP es responsable de la derivación hacia atención especializada y ha de decidir la derivación, aunque el paciente es libre de impugnar la decisión, por lo que esta se suele tomar de manera consensuada médico-paciente. El manejo del DEB inespecífico en el SNS se basa en la exploración física, la revisión de la historia clínica, la recomendación de pruebas diagnósticas, el asesoramiento médico, tratamiento farmacológico, físico, rehabilitación o la remisión a especialistas. En este citado estudio se pone de manifiesto que el 98% de los pacientes reciben tratamiento farmacológico, el 19% algún tipo de terapia física y 10% se deriva a la cirugía, mientras que el 43% de los pacientes son evaluados a través de técnicas radiológicas. Este estudio puso de relieve además que, aunque el manejo de los pacientes está en consonancia con las recomendaciones basadas en la evidencia, después de dos meses de tratamiento, el dolor continuó en un 37% y empeoró en un 10% de los pacientes [31]. En este sentido, si bien la introducción de guías de práctica clínica en el tratamiento del dolor lumbar inespecífico ha

incorporado aspectos sobre diagnóstico, eficacia farmacológica y no farmacológica y otras modalidades en el manejo de pacientes con DEB inespecífico, puede ser necesario estudiar otras modalidades de estrategias multidisciplinares de tratamiento (físico, psicológico y social/laboral) que se aplique a pacientes con esta afección a nivel subagudo para evitar la cronicidad de la enfermedad, así como reducir el impacto individual social y económico que este problema supone actualmente [32].

Diagnóstico del DEB inespecífico

EL DEB inespecífico no presenta un diagnóstico bien establecido ni bien definido lo que puede conducir a no ofrecer garantías de éxito en la recuperación del mismo, a ofrecer un tratamiento inadecuado y por tanto a la incertidumbre sobre el pronóstico de la enfermedad [33]. El diagnóstico del DEB inespecífico tiene su fundamentación en la propia clasificación de la patología. Más arriba se ha descrito que en la mayoría de los casos el DEB suele ser inespecífico, de hecho, tan solo el 1-2% de la población aquejada de DEB presenta síntomas cuya causa es conocida, refiriéndose a una causa mecánica del raquis (bandera roja, que quiere decir causas de extrema importancia). Aproximadamente el 5-10% presenta causas del DEB relacionadas con dolor de raíz nerviosa (bandera roja) y aproximadamente un 85-90% de los pacientes aquejados de DEB son de causa inespecífica. Es precisamente éste el fundamento del diagnóstico del DEB inespecífico. Por consenso experto, aquellos pacientes que no presentan banderas rojas (normalmente asociados con causas específicas del DEB) son diagnosticados como pacientes con DEB inespecífico o común. Este proceso ha sido denominado “Triage” (Figura 2) [24, 34].

Si bien existen otras pruebas diagnósticas del DEB inespecífico como el diagnóstico por imagen, electromiografía o pruebas de alivio; ninguna de ellas ha mostrado ser efectiva en el diagnóstico del DEB inespecífico, por lo que no se deben recomendar en estos casos.

Tratamiento del DEB inespecífico en la fase sub-aguda

El DEB inespecífico puede producir incapacidad funcional [35], afectando al desarrollo normal de las actividades de la vida diaria, y mermando como consecuencia a la calidad de vida relacionada con la salud [36]. Además, esta situación puede provocar que el sujeto afectado

torne hacia un estilo de vida aún más sedentario, y como consecuencia puedan surgir enfermedades crónicas propias de estilos de vida sedentarios como sobrepeso, obesidad, diabetes o hipertensión [37]. Ante este panorama, los posibles objetivos que se pretenden con los tratamientos del DEB inespecífico son, por un lado, aliviar el dolor en la medida de lo posible, optimizar la capacidad funcional y favorecer el desarrollo de las actividades de la vida diaria (entre ellas el trabajo), reducir las alteraciones psicológicas y conductuales (ansiedad, depresión y evitación o miedo al dolor), evitar la asunción del rol de enfermo y aumentar el estado de salud global del paciente [38]; y por otro lado, una vez se ha conseguido restablecer el estado funcional normal del paciente, provocar en él un estilo de vida más activo y saludable, para evitar nuevos episodios o atenuar los efectos que el DEB inespecífico crónico pueda tener sobre el paciente.

El tratamiento de pacientes en la fase sub-aguda es considerado como una "ventana de oportunidad" [39]. Es en este momento cuando el responsable de la salud del paciente ha de aplicar de forma intensiva los tratamientos basados en la evidencia para el DEB inespecífico en esta fase. Dado a que no existen guías claras de tratamiento del DEB inespecífico sub-agudo, el tratamiento debe proveerse de forma escalonada, continuando desde el punto donde se dejó antes de la re-evaluación y aumentando la intensidad del mismo paso a paso usando los diferentes métodos que han mostrado su efectividad en estos casos [33]. La evidencia científica, bajo el modelo bio-psico-social del dolor de espalda [40], reconoce la contribución de factores biológicos, psicológicos y sociales como componentes del dolor de espalda y el riesgo de cronicidad del mismo, re-emplazando al modelo biomédico tradicional en el entendimiento y manejo de dicha afección [41]. Por tanto, es necesario atender a dichos componentes cuando se trata el dolor lumbar común. De hecho, cuando un paciente no mejora en unas 2 a 6 semanas tras un episodio agudo de DEB inespecífico, se evalúan los indicadores psicosociales de un mal pronóstico funcional que son: creencia de que el dolor es una lesión grave e irreversible, el miedo y la evitación hacia el dolor de espalda, factores laborales (satisfacción y otros) o problemas emocionales [42-45]. En este sentido, la combinación de tratamientos farmacológicos (mediante el uso del paracetamol y el uso de los antinflamatorios no esteroideos, entre otros) [31] junto a otras terapias no farmacológicas, como las terapias físicas (pasivas o activas – ejercicio físico-) [22, 24, 46], terapias cognitivo-conductuales o de

educación para la salud [47], parecen ser efectivas en la prevención tanto primaria como secundaria en pacientes afectados por DEB inespecífico. De entre las terapias físicas más usadas como tratamiento en pacientes afectados por DEB inespecífico sub-agudo destacan: La terapia interferencial, definida actualmente como un agente electro físico que se produce mediante la aplicación de una frecuencia media alternada con frecuencias bajas por encima de 150 Hercios [48]; el Láser, que consiste en la aplicación de ondas de calor para aliviar los dolores [49]; el soporte lumbar, definido como corrector ortopédico para evitar rangos de movimientos peligrosos y usado en ámbitos ocupacionales de riesgo para evitar lesiones lumbares [50]; la terapia de ultrasonido, que consiste en la aplicación de ondas electromagnéticas en la zona lumbar [51]; la aplicación de calor en la zona afectada por DEBI, la acupuntura [52]; la electro estimulación nerviosa [53], el masaje [54] y el ejercicio físico (este apartado se desarrollará posteriormente) [55]. Pese a existir un gran número de terapias disponibles en este tipo de pacientes, no existe evidencia en la efectividad de ninguna de ellas comparadas entre sí [24], aunque sí parece ser que lo más efectivo es la combinación de dichas terapias [56].

El rol del ejercicio físico para el tratamiento del DEB subagudo

Desde hace tiempo, se admite, de forma consensuada, que el ejercicio físico es una terapia activa que desempeña un papel clave en el tratamiento de del DEB inespecífico [57], además de representar una terapia relativamente barata. Mucho se ha especulado sobre la forma concreta en que actúa el ejercicio físico en pacientes con DEB inespecífico y qué efectos se desprenden de su aplicación durante el tratamiento. En este sentido no existe una fuerte evidencia científica de que el ejercicio físico pueda aliviar el dolor, aunque sí puede aumentar la tolerancia al mismo [58], lo que puede servir de base para la realización de un ejercicio físico continuado y beneficiarse así de una mejora en las alteraciones de las propiedades morfo funcionales de la musculatura, en especial la extensora, estabilizar segmentos raquídeos logrando un control automático y subconsciente de las secuencias normales de activación y relajación muscular y evitando sinergias inadecuadas; aumentar el rendimiento cardiovascular y la capacidad funcional; y reducir la incapacidad funcional (también denominada discapacidad) producida por el dolor [59], a parte de los conocidos efectos que el ejercicio físico tiene sobre

los individuos [60]. A nivel preventivo, lo factores por los que el ejercicio físico puede ser beneficioso ante el DEB inespecífico son varios: fortalecimiento de la musculatura de la espalda, incremento de la flexibilidad del tronco, aumento del aporte sanguíneo regional para reducir posibles lesiones locales y favorecer la reparación tisular; y mejora del estado anímico, mejorando por ello la percepción del dolor [61]. Pero estos beneficios dependen de cada sujeto y del tipo en que el DEB inespecífico se presenta (agudo, subagudo o crónico) y es que en función de las características biológicas, psicológicas y sociales el impacto del DEB inespecífico puede ser diferente. A nivel de evidencia científica, se admite que el ejercicio físico es más beneficioso en pacientes crónicos que en agudos y subagudos [38], aunque en estos también es posible reducir el nivel de riesgo de cronicidad de la afección así como la incapacidad funcional asociada a la misma [62]. Existen muy pocos estudios que contemplen de forma específica el tratamiento del DEB inespecífico en su fase sub-aguda. En este sentido, si bien el ejercicio físico parece ser eficaz en dicha afección (en combinación con terapias conductuales o ergonómicas – intervenciones multidisciplinares-) aunque existen resultados controvertidos al respecto [63], no existe evidencia alguna a favor de un tipo u otro de ejercicio físico [64]. Algunas guías de práctica clínica como la "*Paris Task Force for Back Pain*" recomiendan la realización de ejercicio físico de fortalecimiento, flexibilidad y movilidad de la zona afectada para prevenir nuevos episodios en la fase sub-aguda del DEB inespecífico [65]. En lo que sí parecen coincidir los expertos es en que hay que mantener activos a los pacientes y hacerlos partícipes y responsables de su propio tratamiento para disminuir el riesgo de cronicidad e impacto que supone dicha afección [33].

Intervenciones en el puesto laboral para el DEB inespecífico

La promoción de la salud en el puesto laboral se define como la combinación de esfuerzos de empleados, jefes y de la sociedad en general para mejorar la salud y el bienestar en el trabajo [66]. La combinación entre las mejoras organizativas y ambientales a nivel laboral y la participación activa de las personas implicadas en el trabajo a través de su participación en actividades saludables y de desarrollo personal hacen posible alcanzar este objetivo. Tradicionalmente, el concepto de salud laboral hacía referencia a la protección de la salud en el puesto laboral sin intención de promocionar la salud. Recientemente, las empresas tienen

como objetivo la promoción de la salud para aumentar la productividad laboral y disminuir el absentismo y persentismo laboral [66]. En este sentido, el ejercicio físico en el puesto de trabajo se ha convertido en eje central de los programas de promoción de la salud en el puesto laboral para incrementar la salud de los trabajadores además de la productividad laboral y la disminución del absentismo y persentismo laboral [67]. Aunque el rol del ejercicio físico en la prevención del DEB inespecífico no está del todo claro [68, 69], las guías existentes que estudian y abordan esta cuestión en el puesto de trabajo abogan por el uso del ejercicio físico en las intervenciones para la prevención (primaria, secundaria o terciaria) del DEB inespecífico en el puesto laboral [68-71]. Este tipo de guías están basadas en intervenciones que necesariamente no están llevadas a cabo en el puesto de trabajo, aunque sí incluyen intervenciones hospitalarias y de centros concretos que evalúan las medidas de resultado principales relacionadas con el DEB [72-75]. La investigación ha demostrado que lo que más afecta a la duración a la vuelta al trabajo y a la incapacidad laboral, es el miedo y el sentimiento de los pacientes ante tal causa, la auto-percepción de incapacidad laboral [76, 77]. Fomentar una vuelta temprana a la actividad normal y favorecer el apoyo en el puesto de trabajo ha resultado ser beneficioso en términos de costes y de efectividad [78] y de reducción de tiempos de baja laboral por miedo relacionado con el dolor de espalda [79]. En la tabla 3 se muestra el análisis de diferentes intervenciones que han usado el ejercicio físico como método de prevención (primaria, secundaria o terciaria) en el puesto laboral. Con un objetivo pragmático, las intervenciones han sido analizadas y presentadas en base a los siguientes resultados: tipo de programa de ejercicio físico usado, incapacidad funcional por dolor lumbar, días de baja laboral por dolor lumbar, incidencia y nivel de dolor lumbar y costes asociados a la patología. La mayoría de los estudios revisados establecen el programa de ejercicios basados en los conceptos de refuerzo lumbar y abdominal, estiramientos y flexibilidad además de, algunos de ellos, la capacidad cardiovascular. Sin embargo en los estudios analizados, la duración del ejercicio así como la intensidad y frecuencia de las sesiones propuestas es heterogénea. A este respecto, parece existir un consenso de que para la implementación de programas de ejercicio físico en el puesto laboral es preferible la realización de sesiones diarias de corta duración [55]. En esta línea, la evidencia científica sugiere por ejemplo que intervenciones con una media de 10 minutos por sesión, durante la jornada laboral, es efectivo para reducir el

grado de dolor o el grado de incapacidad funcional del DEB inespecífico. Las diferentes intervenciones analizadas presentadas arrojan resultados controvertidos. Parece ser que las intervenciones para tratar el DEB en el puesto laboral a través del ejercicio físico son más efectivas cuando se combinan con otras medidas ocupacionales habituales. El ejercicio físico en el puesto laboral puede ayudar a disminuir la incapacidad funcional y la severidad del DEB, además de ayudar a disminuir el grado de dolor. Aunque existen pocos estudios que evalúen la CVRS, ésta puede mejorar debido, posiblemente a que mejorar la capacidad de realización de las actividades de la vida diaria y a que el ejercicio físico puede ayudar a disminuir el dolor. Por último, la evidencia científica sugiere que intervenciones basadas en subgrupos (agudo, sub-agudo o crónico) de DEB inespecífico pueden ser más efectivas que intervenciones no basadas en tal división [80].

Tabla 4. Análisis de las intervenciones llevadas a cabo en el puesto laboral para la prevención del dolor lumbar

Autor	Emplazamiento	Número	Nivel de incapacidad	Clasificación	Medidas	Intervención	Cumplimiento	Efectos encontrados
Horneij y cols.[81]	Mujeres enfermeras (cuidadoras en domicilio)	Total: 282 Intervención 1: 90 Intervención 2: 93 Control: 99	No se reporta	Sub-agudo y crónico	Incidencia del DEB, dolor e Interferencia en las actividades diarias por DEB a los 12 y 18 meses	Intervención 1: Estiramiento/fuerza/ejercicio aeróbico Intervención 2: Manejo del estrés Control: no intervención 12 semanas	Intervención 1: 87,2% Intervención 2: 98,3%	Incidencia del DL a los 12 y 18 meses: no diferencias significativas de ninguna intervención con respecto al control Interferencia en las actividades diarias por DEB y nivel de dolor: con la intervención 1, menos interferencias por DEB
Larsen y cols.[82]	Hombres militares	Total: 249 Intervención: 132 Control: 117	No se reporta	No se reporta	Incidencia del DEB, visitas al médico por DEB y costes relacionados con DEB a los 10 meses	Intervención: siguió una sesión/semana de 40 minutos de la escuela de la espalda y 2 sesiones de 15 extensiones de espalda por día durante 10 meses Control: no intervención	No se reporta	Disminución estadísticamente significativa en la incidencia del DEB y en las visitas al médico por DEB así como en los costes.
Helmhout y cols.[83]	Hombres empleados militares y civiles	Total: 81 Intervención: 41 Control: 40	Intervención: 7,1 RMDQ Control: 7,9 RMDQ	Dolor crónico no específico	RMDQ, ODI, SF36, miedo al dolor y fuerza muscular a los 1,2,3,6 y 9 meses	Intervención: 12 semanas de entrenamiento progresivo de alta intensidad de fuerza lumbar (5 a 10 minutos, 1 a 2 veces/semana) Control: ejercicio de baja intensidad para la fuerza de la espalda	Intervención: 71% Control: 48%	RMDQ, ODI, SF36: no diferencias estadísticamente significativas (ambos mejoraron) Fuerza isométrica lumbar: Incremento en 1,2,3,6 y 9 meses Miedo al dolor: disminución en 2 y 9 meses
Daltroy y cols.[84]	Mujeres y hombres empleados de correos	Total: 4000 Intervención: 2668 Control: 1332	No se reporta	Agudo y crónico	Incidencia del DEB, costes por DEB y días de baja laboral por DEB a los 5,5 años	Intervención: 2 x 15 horas de sesiones de educación además de ejercicios de estiramiento y fuerza en horario laboral Control: no intervención	No se reporta	Incidencia del DEB, costes por DEB y días de baja laboral por DEB a los 5,5 años: no diferencias estadísticamente significativas
Gundewall y cols.[85]	Mujeres y hombres enfermeros y auxiliares de enfermería geriátrica	Total: 60 Intervención: 28 Control: 32	No se reporta	No se reporta	Intensidad del DEB, Incidencia por DEB, día de baja por DEB, dolor, fuerza lumbar, resistencia lumbar y coordinación a los 13 meses	Intervención: 6 minutos/día laboral de fuerza, resistencia lumbar y coordinación en horario laboral Control: no intervención	No se reporta	Intensidad del DEB, Incidencia por DEB, día de baja por DEB, dolor, fuerza lumbar, resistencia lumbar y coordinación a los 13 meses: diferencias estadísticamente significativas entre grupos (a favor del grupo de intervención)

Tabla 4. ***Continuación***

Autor	Emplazamiento	Número	Nivel de incapacidad	Clasificación	Medidas	Intervención	Cumplimiento	Efectos encontrados
Kellet y cols.[86]	Hombres y mujeres trabajadores y managers de una fábrica	Total: 111 Intervención: 58 Control: 53	No se reporta	No se reporta, DEB no específico	Incidencia por DEB, días de baja por DEB y capacidad cardiovascular a los 18 meses	Intervención: 8 minutos/día laboral en horario laboral de ejercicio de fuerza lumbar, estiramientos y aeróbico Control: no intervención	No se reporta	Incidencia por DEB, días de baja por DEB a los 18 meses: diferencias estadísticamente significativas entre grupos (a favor del grupo de intervención) Capacidad cardiovascular a los 18 meses: no diferencias estadísticamente significativas entre grupos
Sjogren y cols.[87]	Hombres y mujeres trabajadores de oficina	Total:36	No se reporta	Sub-agudo y crónico no específico	Intensidad del DEB e interferencias en las actividades de la vida diaria a los 12 meses	Intervención: 5 minutos/día laboral en horario laboral de ejercicio de fuerza lumbar, estiramientos y aeróbico Control: no intervención 15 semanas	Total: 69%	Intensidad del DEB e interferencias en las actividades de la vida diaria a los 12 meses: mejoras en todas las medidas
Hlobil y cols.[88]	Hombres y mujeres trabajadores aéreos	Total: 134 Intervención: 67 Control: 67	Intervención: 13,3 RMDQ Control: 13 RMDQ	Crónico no específico	Incidencia del DEB, RMDQ, VAS y día de baja por DEB a los 3,6 y 12 meses	Intervención: 1h/sesión 2 veces/semana de ejercicio físico para la espalda de fuerza y resistencia Control: cuidados de fisioterapia estándar (no definido)	No se reporta	Incidencia del DEB, RMDQ, VAS y día de baja por DEB a los 3,6 y 12 meses: no diferencias estadísticamente significativas
Donchin y cols.[89]	Hombres y mujeres trabajadores de un hospital	Total: 142 Intervención 1: 46 Intervención 2: 46 Control: 50	Intervención 1: 25,9 en ODI Intervención 2: 29 en ODI Control: 26 en ODI	Crónico (causas específicas y no específicas)	Incidencia del DEB, fuerza y flexibilidad de la espalda	Intervención 1: 45 minutos, 3sesiones/semana durante 3 meses Intervención 2: Escuela de la espalda con énfasis en ejercicio físico 5 sesiones de 90 minutos	No se reporta	Incidencia del DEB, fuerza y flexibilidad de la espalda: diferencias estadísticamente significativas a favor del grupo de intervención 1 respecto al 2 y el grupo control pero no del 2 respecto del control
Macedo y cols.[90]	Hombres y mujeres trabajdores de oficina	Total: 50 Intervención: 29 Control: 21	No reportado	Crónico no específico	Grado de dolor	Intervención: 15 minutos/día laboral 3 veces semana en horario laboral durante 8 meses mediante ejercicios de Pilates, estiramiento y relajación	100% en ambos grupos	Grado de dolor: diferencias significativas en la percepción del grado de dolor
Oldervoll y cols[91].	Mujeres trabajadoras de un hospital	Total: 65 Intervención 1: 22 Intervención 2: 24 Control: 19	No reportado	No se reporta, DEB no específico	Incidencia del DEB, dolor, interferencia con las actividades diarias, capacidad aeróbica a las 15 semanas y 7 meses	Intervención 1: ejercicio cardiovascular, 1 hora al día 2 veces/semana Intervención 2: ejercicio de fuerza, 17 1 hora al día 2 veces/semana Control: lista de espera 15 semanas	Intervención 1: 81% Intervención 2: 77%	Incidencia del DEB, dolor: tanto la intervención 1 como la 2 mejoraron de forma significativa en comparación con el control Capacidad aeróbica: mejoró más la intervención 1

Tabla 4. *Continuación*

Autor	Emplazamiento	Número	Nivel de incapacidad	Clasificación	Medidas	Intervención	Cumplimiento	Efectos encontrados
Shinozaki y cols[92].	Hombres trabajadores en una fundición de cobre	Total: 315 Intervención: 27 conductores de maquinaria Control 1: 233 (trabajadores activos de la fábrica) Control 2: trabajadores en oficina	No reportado	No reportado	Incidencia del DEB a los 15 y 24 meses	Intervención: primero siguieron los ejercicios para la espalda de “Williams” y a los 9 meses una intervención ergonómica Control 1 y 2: no intervención	No reportado	Incidencia del DEB a los 15: diferencias estadísticamente significativas a favor del grupo intervención. los autores atribuyen el efecto a la intervención ergonómica pero los resultados no están claros
Dehlin y cols[93].	Mujeres auxiliares de enfermería	Total: 45 Intervención: 15 Control 1: 14 Control 2: 16	No reportado	Crónico no específico	Duración, intensidad, frecuencia e influencia del DEB en la capacidad de trabajo	Intervención: ejercicios de fuerza y resistencia cardiovascular y muscular 2 veces/semana durante 8 semanas en horario laboral Control 1: Curso ergonomía y de manipulación manual de cargas 2 veces/semana durante 8 semanas en horario laboral Control 2: no intervención	Intervención: 86,7% Control 1: 78,6% Control 2: 93,8%	No se encontraron mejoras significativas en ninguna de las medidas comparando los grupos
Dehlin y cols[94].	Mujeres auxiliares de enfermería	Total: 61 Intervención: 13 Control 1: 14 Control 2: 14 Control 3:20	No reportado	No reportado, DEB no específico y algunos sujetos presentaban lumbago y ciática por causas específicas	Duración, intensidad, frecuencia e influencia del DEB en la capacidad de trabajo.	Intervención: ejercicios de fisioterapia 2 veces/semana durante 8 semanas en horario laboral Control 1: Curso de cuidados geriátricos 2 veces/semana durante 8 semanas en horario laboral Control 2: no intervención Control 3: no intervención (no presentaban dolor lumbar)	Intervención: 72,2% Control 1: 100%	Se encontró una reducción de la incidencia del DEB del grupo intervención respecto del Control 1 pero no respecto al control 2
Hilyer y cols[95].	Hombres bomberos	Total: 469 Intervención. 230 Control: 239	No reportado	No reportado	Costes y nivel de flexibilidad	Intervención: 6 meses 30 minutos diarios de flexibilidad en horario laboral Control: no intervención	No reportado	Se encontró una reducción de los costes por visitas médicas y bajas laborales por DEB y un aumento de la flexibilidad.

RMDQ: Cuestionario de incapacidad Roland Morris; ODI: Cuestionario de incapacidad de Oswestry; DEB: dolor lumbar; VAS: Escala Visual Analógica de dolor. (*Fuente:* elaboración propia).

Impacto del DEB en población afectada. Medidas de resultado asociadas

En los primeros apartados de la presente Tesis ya ha sido comentado el impacto que el DEB inespecífico presenta desde la perspectiva social y económica. Pero también presenta un gran impacto a nivel individual, familiar o comunitario. Esto incluye dolor, limitación para la realización de las actividades diarias, restricción en la participación social, síndrome del cuidador quemado, uso de recursos del sistema socio-sanitario; todo ello traducido en un impacto a nivel financiero altísimo. El impacto varía enormemente de una población a otra (y también en una misma población) dependiendo de factores socio-económicos, el acceso a los servicios de salud, la distribución ocupacional, la percepción del dolor y otros factores que se asocian con el primer episodio de DEB inespecífico (factores de riesgo) o con el curso clínico de la afección (factores pronósticos) (tabla 4). Los factores de riesgo son los que condicionan la probabilidad de presentar una enfermedad determinada. Dichos factores pueden estar presentes en población sana y aumentan el riesgo de tener la enfermedad. La identificación de los factores de riesgo es imprescindible para la prevención primaria. Los factores pronósticos son aquellos que predicen el curso clínico de un padecimiento una vez que la enfermedad está presente. La identificación de estos factores son de gran interés para la prevención secundaria y terciaria [96].

Tabla 5. Factores de riesgo y pronósticos del DEB

	Factores de riesgo	Factores pronósticos
Factores individuales	Edad, nivel de fitness, nivel de fuerza de la espalda y hábito tabáquico	Obesidad, bajo nivel educativo, altos niveles de dolor e incapacidad
Factores psicosociales	Estrés, ansiedad, estado de ánimo, funcionalidad y comportamiento ante el dolor	Angustia, estado depresivo del estado de ánimo, somatización y miedo al dolor
Factores ocupacionales	Carga de materiales pesados, vibraciones mecánicas, flexión y torsión en el trabajo, insatisfacción laboral, tareas repetitivas, relaciones laborales/soporte social y control laboral	Insatisfacción laboral, incapacidad para desarrollar de forma adecuada las tareas laborales y manejo de peso en el trabajo durante ¾ partes de la jornada laboral

(Fuente: elaboración propia a partir de van Tulder 2002[97])

Factores de riesgo del DEB inespecífico

La edad es uno de los factores de riesgo más comunes en el DEB inespecífico. Algunos estudios internacionales encontraron que la prevalencia de la enfermedad crecía con la edad hasta los 60 o 65 años y a partir de esa edad decrecía [98, 99]. Otros autores además reportaron que la intensidad de la enfermedad crecía con la edad [100]. Por otro lado, existe también gran número de estudios que reportan DEB en adolescentes [100, 101].en cuanto al riesgo asociado al género, existe cierta controversia en los resultados hallados por los diferentes estudios diseñados al efecto. Mientras que algunos estudios no encontraron diferencias en cuanto al riesgo de prevalencia entre mujeres y hombres [102, 103], una revisión sistemática reciente señala que el DEB es más prevalente entre las mujeres [104]. Consistentes con esta revisión han sido los resultados observados por otros estudios desarrollados en el ámbito ocupacional, que encontraron que las mujeres consumían más recursos sociales (en términos de bajas laborales) y socio-sanitarios que los hombres por DEB [102, 103, 105]. Esta diferencia en género no ha sido, sin embargo, tan claramente observada en países subdesarrollados o en vías de desarrollo [104]. Respecto al nivel educativo, se ha observado que un bajo nivel educativo se asocia con una prevalencia del DEB inespecífico más elevada que en sujetos con un nivel educativo más alto [106]. Además, el nivel educativo ha mostrado ser un buen factor pronóstico de la duración del episodio y de gravedad de la afección [107]. Por otro lado, el peor estatus socioeconómico también parece posicionarse como factor de DEB inespecífico [108]. El peso corporal y el nivel de fitness parecen igualmente influir en la presencia y prevalencia del DEB [109, 110], y más en mujeres que en hombres [20]. Las demandas físicas del trabajo parecen tener mucho que ver también con la ocurrencia de episodios de DEB [105]. En este sentido, parece ser que la manipulación manual de cargas y las vibraciones a las que se someten los trabajadores en algunos tipos de ocupación, son factores de riesgo establecidos para el DEB [111]. Pero también lo son los trabajos más sedentarios, como los de oficina [112]. Además de los factores biológicos o físicos, existen otros factores sicosociales que han mostrado su asociación con la ocurrencia del DEB. En este sentido la ansiedad, estrés o depresión han mostrado tener influencia en la aparición del DEB, aunque la dirección de esta asociación no está del todo clara [113, 114]. En el trabajo, algunos de los factores psicosociales que han sido estudiados han aparecido

también como factores de riesgo para el DEB. En este sentido, la no satisfacción con el trabajo, las tareas repetitivas, las malas relaciones laborales, la falta de soporte social en el trabajo, las propias tareas laborales, el estrés o la habilidad percibida para desarrollar las tareas han mostrado su asociación con la ocurrencia de nuevos episodios de DEB [115].

Factores pronósticos del DEB inespecífico (Riesgo de cronicidad).

Es importante identificar tan pronto como sea posible aquellos pacientes con DEB que se encuentran en riesgo de mantener la afección por un largo de tiempo (riesgo de cronicidad del DEB), porque un tratamiento de forma temprana y específico puede ayudar a minimizar el efecto de esta enfermedad sobre el paciente [116]. Tal y como ha sido descrito con anterioridad, la mayoría de los pacientes se recuperan transcurridos un par de días o semanas. Sin embargo, en aquellos pacientes que no consiguen recuperarse, los síntomas se agravan y persisten durante largos periodos de tiempo. Estos pacientes son los que al final consumen más del 80% del gasto social y sanitario procedente el DEB [15]. Encontrar aquellos factores que hacen que el DEB pueda volverse crónico, se hace indispensable para la identificación de pacientes en riesgo de cronicidad. En este sentido, la evidencia sugiere que los factores psicosociales juegan un papel importante en el riesgo de cronicidad y en el aumento de la incapacidad por DEB [44]. En este sentido, factores psicosociales como miedo al dolor, somatización, depresión del estado de ánimo o angustia han mostrado su correlación con el aumento del riesgo de transición de DEB agudo a crónico [44, 117]. Por otro lado, existen factores individuales y ocupacionales como la insatisfacción laboral, el bajo nivel educativo o altos niveles de dolor e incapacidad han mostrado también tener una influencia negativa en la transición hacia la cronicidad del DEB [118]. Un estudio de cohorte encontró que, la obesidad, la incapacidad funcional, un mal estado de salud, la incapacidad para realizar las tareas del trabajo en su retorno al mismo o trabajos duros relacionados con carga y descarga de objetos pesados estaban relacionados con el riesgo de cronicidad del DEB. Este mismo estudio reveló la inexistencia de relación entre la insatisfacción laboral o la falta de relaciones en el trabajo y riesgo de cronicidad del DEB [119]. Otro estudio de cohorte, desarrollado en trabajadores que llevaban 3-4 meses de baja por DEB, encontró que un peor estado de salud, una baja satisfacción con el trabajo, una menor edad o una alta intensidad del dolor, estaban relacionados eran factores pronósticos para una vuelta al trabajo. Estos autores concluyeron

que los factores psicosociales relacionados con aspectos de estado de salud individual y laboral en combinación con aspectos económicos presentan un gran hándicap en la vuelta al trabajo cuando se comparan estos factores con factores más físicos o de incapacidad individuales o de demandas físicas del trabajo [120].

Evaluación del Riesgo de cronicidad del DEB inespecífico

Bajo el modelo bio-psicosocial de entendimiento del DEB [40] la identificación de pacientes con riesgo de cronicidad de DEB depende de la identificación de los factores pronósticos asociados a este proceso. En este sentido existen diferentes herramientas que intentan desvelar cuando un paciente se encuentra en riesgo de cronicidad del DEB, a través de la identificación de los factores que influyen en tal riesgo para poder tratar de forma específica estos pacientes (subgrupos de pacientes), lo que puede mejorar las medidas de resultados asociadas al proceso de DEB [121]. Aunque este proceso es complejo [122], existen diferentes herramientas que intentan identificar estos subgrupos de pacientes basándose en el la valoración del riesgo de cronicidad del DEB. En la tabla 5 se observan los instrumentos más usados a nivel internacional en la literatura científica para la consecución de dicho objetivo.

Tabla 6. Herramientas para la identificación de subgrupos de pacientes en base al riesgo de cronicidad del DEB

Autor/año (referencia)	Nombre de la herramienta	Consideración para su uso en la práctica clínica
Linton SJ y cols. / 1998 [123]	Orebro Musculoskeletal Pain Screening Questionnaire (OMPQS)	Sí
Johansson E y cols. /2000 [124]	Multidimensional Pain inventory (MPI)	No
Neubauer E y cols. /2006 [125]	Heidelberger Short Early Risk Assesment Questionnaire	Sí
Jellema P y cols. /2007 [126]	Clinical Prediction Rule (CPR)	No
Hill JC y cols. 2008 [21]	STarT Back Screening Tool (SBST)	Sí

DEB: dolor de espalda bajo. (*Fuente*: elaboración propia a partir de Hill JC 2008[127])

Aunque es la herramienta más antigua que cumple con el objetivo de identificación de subgrupos de pacientes basada en el riesgo de cronicidad del dolor de espalda bajo el modelo biopsicosocial de entendimiento de la afección, la *Orebro Musculoskeletal Pain Screening Questionnaire* (OMPQS) [123] es una de las herramientas más populares. Se basa en 5 constructos (función física, dolor, factores psicosociales, miedo al dolor y otros) compuestos por 5 ítems cada uno excepto los dos últimos constructos, compuestos por 3 ítems cada uno. Cada ítem usa una escala de puntuación de 11 puntos excepto el primer ítem que usa una escala de 22 puntos posibles. En total, 210 puntos posibles. La división en subgrupos de población fue desarrollada años más tarde, con una subdivisión en 2 posibles grupos de población; aquellos pacientes con más de 90 puntos en la escala (alto riesgo de cronicidad) o menos (bajo nivel de riesgo de cronicidad) [128]. Más tarde, ese mismo punto de corte fue identificado como pacientes con riesgo de baja laboral también [129]. Además, esta herramienta ha mostrado ser efectiva en su uso en el plano clínico [130]. Johansson y Lindberg [124] validaron la herramienta *Multidimensional Pain inventory* (MPI), desarrollada originariamente para identificar los componentes psicosociales y de comportamiento de pacientes clínicos [131], para la identificación de 3 posibles subgrupos de pacientes; pacientes angustiados, adaptados y no funcionales. La *Heidelberger Short Early Risk Assessment* [125], es una herramienta alemana compuesta por 27 ítems que provee 6 posibles subgrupos de pacientes en base al riesgo de cronicidad de pacientes con un episodio de DEB agudo de forma progresiva, mostrándose útil también en el plano clínico. A pesar de las ventajas que ofrece, respecto a la OMPQS presenta ciertas desventajas, tales que es más larga y más difícil de puntuar. Además, la validez externa aún no ha sido reportada por los autores Jellema y cols. [126] validaron el uso de una regla de predicción clínica para identificar pacientes con alto riesgo de que el DEB persistiera basada en una escala de valoración de recuperación del dolor en pacientes afectados. Como conclusión los autores establecieron que faltaba validez externa de dicha regla de predicción clínica además reportaron que, por la dificultad de uso, su aplicabilidad en la práctica clínica diaria era compleja. Más recientemente, Hill y cols desarrollaron el *STarT Back Screening Tool* (SBST) como una herramienta para identificar subgrupos de pacientes en base al riesgo de cronicidad y poder tratar de forma temprana dichos pacientes en base a los factores pronósticos incluidos

en cada subgrupo de pacientes [21]. El SBST identifica 3 posibles subgrupos de pacientes; bajo, medio y alto riesgo de pacientes a través de 9 ítems y un sistema de fácil puntuación. Esta herramienta ha mostrado similares características psicométricas que la OMPQS, aunque tiene la ventaja de ser más corta y fácil de puntuar, por lo que su uso potencial es mayor [132]. Por otro lado, el SBST ha mostrado ser aplicable en la práctica clínica diaria, incluso reduciendo costes como muestra la publicación reciente en *The Lancet* [133]. Recientemente el SBST también está también disponible en versión española, para su uso en la práctica clínica e investigación con población afectada por DEB inespecífico [116]. Esta adaptación forma parte de uno de los objetivos de esta tesis.

Incapacidad funcional. Evaluación

Como ha sido comentado previamente, el DEB en cualquiera de sus formas, tiene influencia en la funcionalidad de los pacientes que lo sufren, incidiendo de forma negativa en dicha capacidad [134]. Con el fin de comprender y documentar el impacto del dolor y los síntomas que los pacientes con DEB tienen sobre su vida la evaluación del estado funcional se ha convertido en una tarea indispensable [135]. En este sentido, el tratamiento del DEB tiene como objetivo primario mejorar/restaurar la función de los pacientes [136]. Por otro lado, la restricción de la funcionalidad es inherente a cada paciente y por tanto pueden existir variaciones en la funcionalidad reportada de un paciente a otro, pero también de un tipo de paciente a otro (en función del tipo de DEB, por ejemplo). Normalmente, la evaluación de la funcionalidad de un paciente pasa por preguntarle, a través de cuestionarios diseñados al efecto, sobre la capacidad de realizar diferentes actividades de la vida diaria, tales como asearse, acostarse etc. (atendiendo a la dificultad que tiene un individuo en la realización de dichas actividades) [137, 138]. Estas medidas pueden ser genéricas o específicas para las diferentes condiciones patológicas (que son sensibles a los cambios de estado de funcionalidad en cada enfermedad en concreto, refiriéndose a ésta. Este proceso se ha denominado responsabilidad del instrumento). En esta tesis nos centraremos en la evaluación de la funcionalidad desde el punto de vista específico de la enfermedad del DEB. A pesar de que existen diferentes cuestionarios desarrollados para evaluar dicho estado de funcionalidad en sujetos afectados por DEB, no existe una evidencia clara de que los clínicos, en su práctica diaria, usen estas herramientas para monitorizar la función de sus pacientes [139]. En este

sentido, ha sido estipulado que para que un cuestionario pueda ser usado por un clínico para monitorizar la funcionalidad de los pacientes afectados por DEB debe cumplir con los siguientes requisitos: que pueda ser auto-administrado, corto y fácil de completar y puntuar, sin claros efectos techo o suelo en la población general. Además de tener validez y fiabilidad de resultado [134]. En esta línea, los cuestionarios más usados para valorar la funcionalidad de los pacientes (tanto en estudios de cohorte como en estudios longitudinales o de práctica clínica diaria) han sido el cuestionario de discapacidad de Roland Morris (RMDQ) y el índice de incapacidad de Oswestry (ODI), recomendados por los expertos en DEB [140]. El cuestionario RMDQ [141], previamente adaptado y validado para población española afectada por DEB [29], es una medida de salud diseñada para ser completada por los pacientes para evaluar el la incapacidad física debida al DEB. Inicialmente, fue diseñada para su uso en investigación, aunque ha mostrado ser útil en la monitorización de pacientes en la práctica clínica. Además, ha mostrado ser útil con independencia del emplazamiento, la edad y el sexo [140]. La responsabilidad del cuestionario RMDQ puede variar dependiendo del grado de incapacidad de los pacientes, variando el cambio mínimo en el instrumento para considerarse clínicamente relevante (MIC). Stratford y cols. [142]. Sugirieron que para pacientes con una pequeña incapacidad un MIC de 1-2 puntos en RMDQ era suficiente, mientras que un cambio de 7-8 puntos es reconocido como el MIC en paciente con un alto grado de incapacidad funcional. En ensayos clínicos, 2-3 puntos en RMDQ puede ser un buen referente para efectuar cálculos de muestra. El otro cuestionario que mayoritariamente se ha usado para evaluar (y monitorizar) los cambios en el estado de funcionalidad en pacientes con DEB es el ODI [143], también adaptado y validado para su uso en población española [144]. Al igual que el RMDQ, el ODI es una medida de salud diseñada para ser completada por los pacientes para evaluar el la incapacidad física debida al DEB a la hora de realizar las actividades de la vida diaria. Aunque inicialmente fue diseñado para evaluar el estado funcional en pacientes crónicos, también ha mostrado su utilidad en la población en general [145]. Un 10% en este cuestionario ha sido determinado como un MIC deseable tanto a nivel clínico como de investigación. Existen algunas diferencias, aunque no significativas, entre ambos instrumentos. Por ejemplo, aunque ambos instrumentos fueron diseñados para ser auto-administrados, pueden administrarse vía telefónica, aunque por el diseño y la posibilidad múltiple de respuesta, el ODI es más complejo

de administrar por esta vía. Por el efecto techo en el RMDQ, parece que en pacientes con un alto grado de incapacidad funcional o en DEB persistente el cuestionario ODI parece más sensible que el RMDQ a los cambios, mientras que el RMDQ es más sensible en pacientes con una afección menos severa o persistente. Esta información tiene que usarse en términos de elección del instrumento adecuado en cada situación [140].

Calidad de Vida Relacionada con la Salud. Evaluación

La CVRS es un concepto holístico que hace referencia a la definición desarrollada por la Organización Mundial de la Salud sobre el concepto de salud [146]. Dado que el impacto del DEB sobre los pacientes que sufren esta afección resulta en más que sobre la incapacidad funcional (por ejemplo, la dificultad en un buen rol social o familiar), es importante poder evaluar dicho impacto para determinar la eficacia por ejemplo de intervenciones diseñadas para disminuir los problemas relacionados con el DEB [147]. A este respecto, existen instrumentos específicos de evaluación del estado de salud y calidad de vida de los pacientes afectados por DEB específicos (RMDQ y ODI; analizados en el apartado anterior), que incluyen sólo aquellos aspectos o dimensiones de la CVRS que son importantes para este tipo de población. Por tanto estas medidas no permiten comparaciones entre poblaciones con distintas características o patologías, pero presentan una mayor sensibilidad en la población específica para la que han sido desarrollados. Sin embargo, los instrumentos genéricos tienen como objetivo evaluar la CVRS tanto en población general como en poblaciones con características o patologías específicas. Esto permite la realización de comparaciones entre poblaciones patológicas y población general posibilitando analizar y comparar el impacto de una enfermedad en concreto sobre las distintas dimensiones de la CVRS. Sin embargo, a la hora de evaluar a poblaciones con patologías específicas, los instrumentos genéricos pueden pasar por alto o no otorgar la magnitud o detalle requerido para monitorizar algunos aspectos específicos de una población en particular, pero que afectan a la CVRS de estos individuos. Por ejemplo, las personas que padecen un problema específico de salud o calidad de vida suelen ser más sensibles a aquellas que más les afecta comparativamente respecto a personas que no tienen esos problemas específicos. No existe un instrumento para evaluar la CVRS que sea ideal para todas las poblaciones y situaciones posibles, sino que en cada estudio se deberán seleccionar el o los instrumentos más apropiados en función de las

características del estudio, de los sujetos y de lo que se pretenda medir. Los instrumentos específicos y genéricos miden diferentes aspectos de la CVRS y son complementarios entre sí, por lo que su uso combinado proporciona mayor información que utilizando tan solo uno de estos tipos de instrumento, recomendando su uso para cubrir un mayor espectro de las dimensiones importantes en la CVRS [148]. De hecho bastantes estudios relacionados con el DEB usan tanto instrumentos específicos como genéricos [149-151]. Las técnicas usadas para la evaluación de la CVRS por estos instrumentos varían entre sí. Estos pueden ser: 1) escalas visuales analógicas (EVA), consistentes en una escala graduada a modo de termómetro en la que se pide a la persona evaluada que indique su estado sobre la variable que se está midiendo con respecto al mejor estado de salud posible percibido por esa persona. 2) Instrumentos basados en perfiles de salud que son instrumentos para evaluar la CVRS con los que se obtiene una puntuación para cada una de las dimensiones que mide, así como una puntuación o índice general obtenido a partir de estas [152] Alguno de los más usados en la literatura científica son el perfil de salud de Nottingham [153] y el Short Form 36 Health Survey (SF-36) o cuestionario de salud SF-36 [154, 155] o sus versiones más cortas SF-12. Sin embargo, no permiten generar índices útiles para propósitos económicos o políticos y 3) Instrumentos basados en medidas de utilidad, que son instrumentos que además de desarrollar los perfiles de salud permiten evaluar la CVRS. Su puntuación final se basa en las preferencias o utilidades que los individuos asignan a diferentes estados de salud y su medida se establece en una escala que va desde el 0 (el peor estado de salud posible, incluso la muerte en algunos cuestionarios) hasta el 1 (el mejor estado de salud imaginable). Este tipo de instrumentos ha mostrado ser útil para propósitos de toma de decisiones políticas y, aunque menos usado, el SF-6 también. El EQ-5D-3L es uno de los cuestionarios genéricos de CVRS más utilizados internacionalmente debido a su rápida aplicación, su viabilidad y a las utilidades que tiene asociadas, las cuales nos proporcionan una única puntuación total basada en la medida de las preferencias sociales de la CVRS. Su desarrollo comenzó en mayo de 1987, cuando un grupo de 23 investigadores de 5 países europeos con un interés común en la valoración de la CVRS se reunieron para desarrollar un instrumento estandarizado, no específico para una determinada dolencia, que pudiera describir y valorar la CVRS [156]. Durante su diseño y validación se hizo gran énfasis en que fuera una herramienta simple y genérica, con propósitos

de evaluación clínica y económica y que posibilitara comparaciones internacionales e interculturales de las valoraciones del estado de salud. Está basado en 5 dimensiones: movilidad, auto-cuidado, actividades habituales, dolor-malestar y ansiedad-depresión [156]. Muy pocos estudios evalúan la relación existente entre la incapacidad funcional y la CVRS en pacientes afectados por DEB. En estudios transversales los resultados son controvertidos. Las investigaciones realizadas en España, señalan que después de 2 semanas de dolor, se producen cambios en los factores que afectan al grado de incapacidad funcional y a la calidad de vida [150]. El mismo estudio asocia el grado de incapacidad funcional y la baja CVRS (evaluada con el cuestionario EQ-5D-3L) con la percepción de duración del dolor, más que con el grado del dolor. Otro estudio conducido en población española, la incapacidad funcional parece ser el mayor determinante en la puntuación de la CVRS (evaluada mediante el instrumento SF-12) [149], aunque esto no ocurre con pacientes en edades más avanzadas [157]. En estudios longitudinales, se ha observado que diferentes tratamientos para el DEB pueden mejorar la CVRS (evaluados con el SF-36) [83, 158]. Por otro lado, el EQ-5D-3L ha sido usado en ensayos clínicos para evaluar la coste-utilidad de las diferentes intervenciones propuestas [159, 160]. Pese a estos resultados no está del todo claro el uso de estos instrumentos en la valoración de pacientes afectados por DEB y la interpretación de los resultados derivados de estos instrumentos necesita hacerse con cautela [148].

Nivel de Condición Física (Fitness). Evaluación

La evidencia científica ha descrito suficientemente el peso que los efectos de los estilos de vida, como ser activo o el hábito tabáquico o alcohólico, presentan sobre la incapacidad funcional, tanto en población general como específica [161]. Por otro lado, el nivel de actividad física ha mostrado su relación con el fitness. Aunque el nivel de fitness de una persona no parece ser determinante en la persistencia de los síntomas del DEB, sí que ha mostrado influenciar la aparición de nuevos episodios de DEB por lo que un mantenimiento adecuado del nivel el de fitness es importante para la prevención de esta afección [23, 162, 163]. Por ejemplo, un estudio de cohorte mostró que los jóvenes que hacían más ejercicio físico y tenían una mejor condición física tenían menos probabilidad de padecer episodios de LBP que sus pares inactivos y con un peor perfil de fitness [164]. En ámbito ocupacional, por ejemplo, los trabajadores de oficina comparten multitud de patrones de comportamiento: trabajan sin

moverse sentados durante largos periodos de tiempo, manteniendo en muchos casos una mala postura y usando solamente la musculatura de sus miembros superiores [165]. Esta condición de inactividad física ha sido identificada como un factor de riesgo predecible y modificable asociado al total de costes sanitarios consumidos en esta población [166]. Estas características laborales generan problemas musculo-esqueléticos que producen malestar y dolor (entre los que destaca el dolor de espalda baja) [165] produciendo un importante impacto en el desarrollo de las actividades de la vida diaria [167] y en su calidad de vida [31]. La evaluación del fitness parece pues un aspecto clave en los estudios relacionados con el DEB. En este sentido se han evaluado diferentes componentes del Fitness en pacientes con DEB, desde la fuerza de prensión manual, a la capacidad aeróbica o la flexibilidad y la fuerza (de resistencia) de la espalda o la capacidad de levantar cargas [81, 168]. Pero de todos ellos, lo que ha mostrado tener una relación con el dolor y nivel de incapacidad y ha mostrado su capacidad diagnóstica ha sido la evaluación de la resistencia de la musculatura tanto lumbar como abdominal [169, 170].De hecho, La resistencia de los músculos del tronco (abdominal y lumbar) ha sido frecuentemente usada para evaluar las intervenciones relacionadas con el dolor de espalda así como una herramienta de predicción de la salud de la espalda [167], e incluso ha sido reportado como una herramienta de discriminación mejor que la evaluación de la fuerza de la espalda [171]. En un estudio llevado a cabo en adolescentes, ha sido reportado que el resultado obtenido en la prueba de resistencia del tronco [172] se posiciona como un indicador de riesgo biológico de padecer dolor de espalda inespecífico subagudo [173]. En este sentido, diferentes herramientas han sido utilizadas para evaluar la resistencia de los músculos del tronco. Los métodos que más comúnmente han sido utilizados son; la evaluación isométrica de la fuerza del tronco (estática), o la evaluación dinámica de la resistencia del tronco. De entre ellas, parece que la evaluación isométrica estática de la fuerza del tronco es la que ha mostrado mayor relación tanto con el dolor como con la incapacidad funcional, aunque existen datos controvertidos acerca de esta declaración [174]. Además, diferentes técnicas existen para evaluar la fuerza muscular isométrica; El test de Biering Sorensen, el test validado por Ito y cols. y los test validado por McIntosh y cols, todos ellos bien descritos en la literatura científica y su uso como medida clínica en intervenciones relacionadas con el DEB inespecífico parece razonable [170].

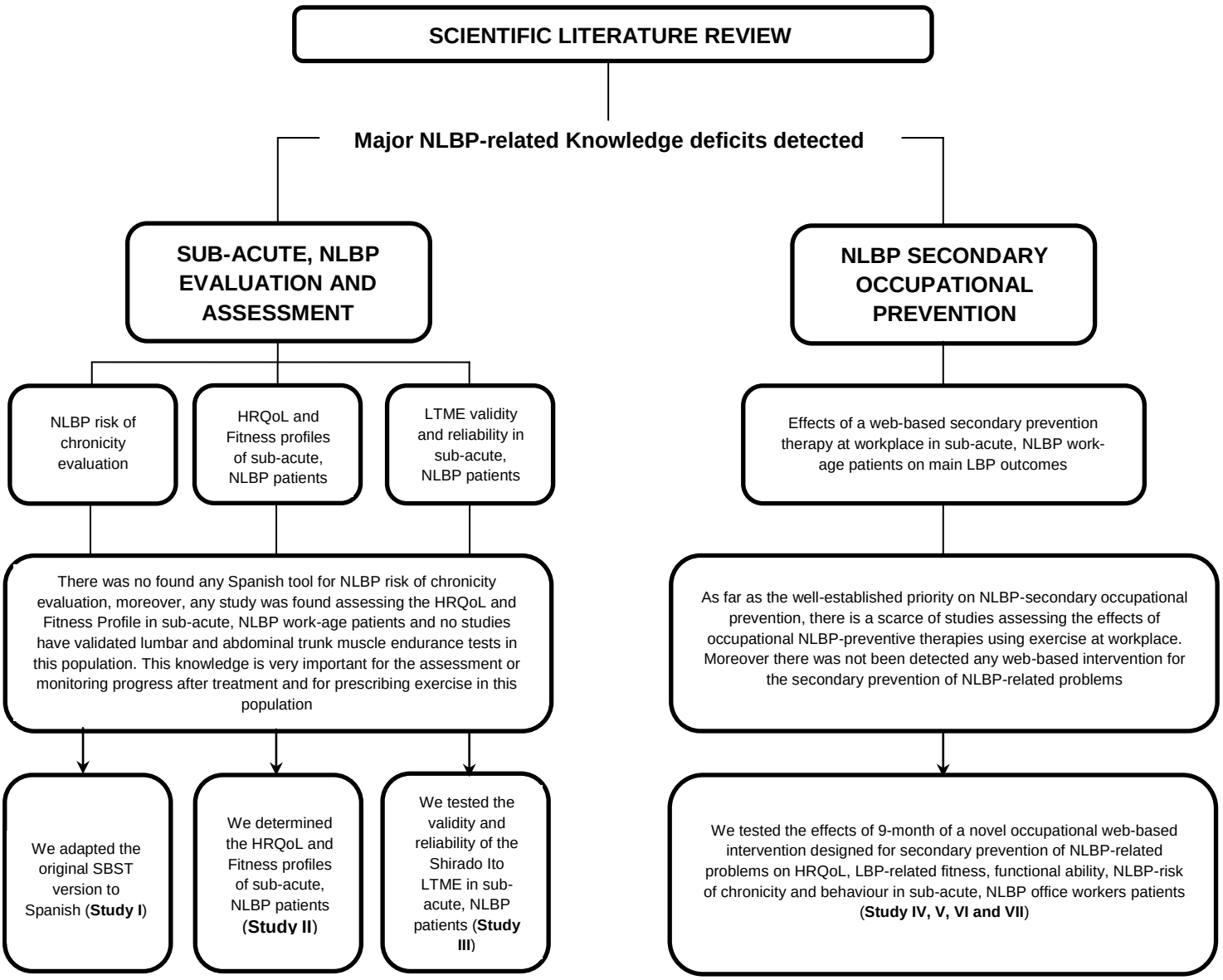

Figure 2. Rationale of the thesis work. LBP: Lower back pain; NLBP: non-specific lower back pain; SBST: STarT Back Screening Tool; HRQoL: Health-related Quality of Life; LTME: lumbar trunk muscle endurance tests

GENERAL AIM AND HYPOTHESES TESTED

The current thesis dissertation consisted of a series of studies conducted to innovate and investigate a new Spanish culturally adapted tool to screen and assess non-specific LBP, to characterize the fitness and HRQoL profile of workers with non-specific sub-acute LBP and the effects of a novel occupational web-based multidisciplinary intervention to secondary prevention of sub-acute, non-specific LBP in affected office workers.

We tested several hypotheses distributed in the following reported studies:

- The Spanish version of SBST is a reliable and feasible version for the evaluation of risk of chronicity of non-specific LBP in adults and elderly (**Study I**).
- Office workers suffering from sub-acute non-specific LBP have different fitness profile and HRQoL levels to those of an age-matched group of office workers without the condition, which could influence the design of specific exercise programs (**Study II**).
- Lumbar and abdominal trunk muscle endurance tests are a reliable and valid measurement in the assessment of work-age patients during the sub-acute phase of non-specific LBP. A correlation exists between the test scores and self-reported functional disability (**Study III**).
- The addition to usual preventive care of a 9-month occupational web-based multidisciplinary intervention is feasible, safe and effective to increase functional ability, HRQoL, trunk muscle endurance and to decrease episodes of sub-acute non-specific LBP office workers affected when compared to conventional treatment (**Study IV**).
- The addition to usual preventive care of a 9-month occupational web-based multidisciplinary intervention is feasible, safe and effective to decrease the risk of chronicity of sub-acute non-specific LBP office workers affected when compared to conventional treatment (**Study V**).
- The addition to usual preventive care of a 9-month occupational web-based multidisciplinary intervention is feasible, safe and effective to improve overall HRQoL and HRQoL dimensions of sub-acute non-specific LBP office workers affected when compared to conventional treatment. Clinical changes in HRQoL show a weak association with clinical changes in LBP outcomes (**Study VI**).

- The addition to usual preventive care of a 9-month occupational web-based multidisciplinary intervention effective to increase back pain-related behaviour of sub-acute non-specific LBP when compared to conventional treatment (**Study VII**).

A detailed description of the material and method section could be seen in the publication section of this work. This dissertation has been developed using different research phases. Research design, sampling procedure, setting, participation rates and procedures regarding each sub-study are presented in the Table 6.

Data collection took place during one academic year. In the south-west of Spain, The region of Extremadura was the geographical sampling area. The four cities of Extremadura (Badajoz, Mérida, Cáceres and Plasencia) were chosen for data collection. The study was performed according to the principles established with the Declaration of Helsinki as revised in 2000 [175], and approved by the local Research Ethics Committees of Extremadura (Bioethical and Biosecurity commission of the University of Extremadura 32/2010). Written informed consent was obtained from the participants in the research. All participants also gave verbal consent.

Participants

The basic characteristics of the participants and the variables examined in each sub-study are presented in Table 6. In overall, participants in the investigation were asked to complete a fitness battery and to fill out different questionnaires. The fitness tests were administered by a physical fitness tester which did not take part in the study as researcher.

Socio-demographic, LBP history and health care consumption

A self-designed questionnaire was used to collect socio-demographic, LBP history and health care consumption information. The socio demographic characteristics that were measured included the following: age and gender of participants in the study, Academic degree reached, smoking habits, history of non-specific LBP (episodes), history of sick leave due to non-specific LBP, and number of visits to a general practitioner occasioned by non-specific LBP.

Table 7. Summary table of the methods used in the current thesis work

Study	Research design	Intervention	Main variables analysed	Participants	Procedures description
I	Translation and cultural adaptation of a questionnaire	Not applicable	Risk of chronicity of LBP (SBST)	20 young adults (35 to 55 years old); 10 women (5 with non-specific LBP and 5 healthy) and 10 men women (5 with non-specific LBP and 5 healthy) and 20 older adults (55 to 80 years old); 10 women (5 with non-specific LBP and 5 healthy) and 10 men women (5 with non-specific LBP and 5 healthy)	The recommended methology for the translation and cultural adaptation of questionnaires was used in this study including direct and inverse translations and cognitive interviews [176, 177]
II	Cross-sectional	Not applicable	Self-reported functional disability (ODI and RMDQ), Health-related Quality of life (EQ-5D-3L) and fitness (lumbar trunk muscles endurance, upper extremities flexibility, hand grip force and leg and trunk flexibility)	72 Healthy office workers: 30 males (27 to 64 years old) and 42 females (33 to 62 years old) and 118 office workers with non-specific, sub-acute LBP: 47 males (27 to 59 years old) and 71 females (28 to 62)	Physically inactive office workers with current LBP episode (first or recurrent with the current episode lasting less than 12 weeks and more than 6 weeks) were compared with healthy office workers. Inclusion criteria: 18-65-year office workers working more than 6 hours a day at a computer, physically inactive, and without any physical problems that would preclude their ability to complete a battery of fitness tests. In LBP patients, exclusion criteria were specific LBP-related disease and pregnancy. LBP patients were recruited at a Preventive Medicine Service from the University of Extremadura (through scanning data-base patients). One hundred and thirty eight patients were invited through email after revising criteria for inclusion and exclusion in the current study. Finally, after in-person revising criteria for inclusion and exclusion in the current study by the clinician of the preventive medicine service, 118 persons fully complied with the inclusion and exclusion criteria and were included in the study. Healthy workers were recruited from different administrative centres (n=4) of the University of Extremadura and informed of the protocol by a technical assessor. Of the 100 healthy workers that showed interest in the study, 72 persons fully complied with the inclusion criteria and were included in the study.
III			Self-reported functional disability (ODI and RMDQ) and fitness (lumbar trunk muscles endurance)		

Table 6. (cont.) Summary table of the methods used in the current thesis work

Study	Research design	Intervention	Main variables analysed	Participants	Procedures description
IV	Randomized controlled trial	9-month web-based multidisciplinary intervention at workstation (physical exercise and postural education)/ 11 min Monday to Friday at 10 am *(Intervention is detailed in Table 7)*	Self-reported functional disability (RMDQ), Health-related Quality of life (EQ-5D-3L) fitness (lumbar trunk muscles endurance) and sick leave	100 office workers with non-specific, sub-acute LBP; 50 intervention group: 8 males (27 to 59 years old) and 42 females (28 to 59 years old) and 50 control group: 7 males (35 to 51 years old) and 43 females (28 to 59 years old)	Individuals with sub-acute NLBP were recruited via the University Preventive Medicine Service. An advertisement alerted potential participants to the project. Low back pain is defined as pain localised between the 12th rib and the inferior gluteal folds, with or without leg pain [23]. For the purposes of the present thesis, sub-acute NLBP was defined as current low back pain with or without pain radiating to one or both legs, in the absence of any specific pathological condition. The back pain episode was either the first such episode or a recurrence, with the current episode having lasted more than 6 weeks and less than 12 weeks [150]. The study inclusion criteria were as follows: a diagnosis of sub-acute NLBP in the absence of any major neurological deficit; an age of 18 to 64 years; physical inactivity (less than two sessions or bouts of exercise totalling 30 minutes per week)[178]; a willingness to provide informed consent; employee status; and more than 6 hours work per day at a computer workstation. The exclusion criteria were as follows: a diagnosed cause of backache (infection, tumour, disc herniation with an associated neurological deficit, osteoporosis, ankylosing spondylitis, fracture, an inflammatory process, radicular syndrome, or cauda equina syndrome); chronic backache; any other major disease [24]; or a lack of fluency in Spanish. All individuals working at the university were informed about the study via email messages, posters, and internal newsletters (2883). A total of 342 interested persons sent an email with their contact data and were contacted by the research team. After reviewing the Preventive Medicine database, a total of 138 individuals were found to fulfil the inclusion criteria. These individuals were invited via email and telephone to participate in the study. After revision of the inclusion and exclusion criteria by the clinical Head of the Preventive Medicine Service, 38 individuals were excluded from the final list of participants. A technician allocated the remaining 100 patients to one of the two study groups using a computer generated random allocation data processing programme and a 1:1 ratio (intervention: control).
V			Risk of chronicity of back pain (SBST), self-reported functional disability (RMDQ) and Health-related Quality of life (EQ-5D-3L),		
VI			Health-related Quality of life (EQ-5D-3L), self-reported functional disability (ODI) and risk of chronicity of back pain (SBST)		
VII			Back pain-related behaviour domain (stage of change questionnaire), Health-related Quality of life (EQ-5D-3L) and Self-reported functional disability (ODI)		

Control group: group that had access to the usual treatment; Intervention group: group that had access to the proposed multidisciplinary intervention and to the usual care; NLBP: non-specific low back pain; SBST (STarT Back Screening Tool); ODI: Oswestry disability questionnaire; RMDQ: Roland Morris disability questionnaire and EQ-5D-3L: European Quality of Life questionnaire five dimensions three levels.

Tabla 8. Description of the 9-month web-based multidisciplinary intervention, structure and exercise routine explanations

A. Email reminder explanation	
A short email was sent every day of the program (Monday to Friday during 9-month intervention) at 10 am with a reminder message (which did not change through the intervention) concerning the instructions and the URL-link to access at the on line session of the day.	
B. Structure description and order of application of the 9-month web-based multidisciplinary intervention-video-sessions	
Parts (time per part, s)	Description
1. Postural reminder (120)	In this part of the video was explained in detail the how an individual must sit at worksite in the office and the exact placement of the computer screen and other modifiable environment elements (e.g. seat height or height of the armrest of the chair). Also were gave some advice on proper placement of complementary material such the footrest or the mouse pad computer. The explanation of this part was in oral and written (subtitle).
2. Addressed exercise session (420)	In this part of the video was shown in detail the exercise routine of each day. In all sessions was exercising in combination the main postural stability muscles (abdominal, lumbar, hip and thigh muscles) involving strengthening, flexibility, mobility and stretching exercises in this order respectively in all performed sessions. Mobility exercises were carried out using large movements of the joints associated with postural stability muscles. Flexibility exercises were carried out using a static work methodology. Strength exercises were carried out using different shortening-stretching speed motion ratios combined with slight isometric contractions of the muscle involved in the exercise. Finally, stretching exercises were carried out by moderate stretching of the muscles involved in the session. The explanation of this part was in oral and written (subtitle).
3. Postural reminder (120)	In this part of the video was explained in detail the proper way to sit at worksite in the office and the exact placement of the computer screen and other modifiable environment elements (e.g. seat height or height of the armrest of the chair). Also gave some advice on proper placement of complementary material such the footrest or the mouse pad computer. The explanation of this part was in oral and written (subtitle).

Table 7. (cont.)

	Type of Exercise	Month 1			Month 2			Month 3			Month 4			Month 5			Month 6			Month 7			Month 8			Month 9		
		S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)
Week 1	**Mobility**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
	Flexibility	**4/20/6**	**t,th,f**	**--**	**4/20/6**	**t,th,f**	**--**	**5/20/6**	**t,th**	**--**	**5/20/6**	**t,th**	**--**	**4/20/6**	**t,th**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**
	Strengthening	**2/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w,f**	**1/1**	**3/20/6**	**m,w,f**	**2/1**	**4/20/6**	**m,w,th,f**	**3/1**	**3/30/5**	**m,w,th,f**	**3/1**	**2/40/5**	**m,w,th,f**	**1/2**	**2/40/5**	**All**	**1/2**	**2/40/5**	**All**	**1/3**
	Stretching	**6/20/6**	**All**	**--**	**5/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
Week 2	Mobility	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--
	Flexibility	4/20/6	t,th,f	--	4/20/6	t,th,f	--	5/20/6	t,th	--	5/20/6		--	4/20/6	t,th	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--
	Strengthening	2/20/6	m,w	1/1	3/20/6	m,w	1/1	3/20/6	m,w,f	1/1	3/20/6	m,w,f	2/1	4/20/6	m,w,th,f	3/1	3/30/5	m,w,th,f	3/1	2/40/5	m,w,th,f	1/2	2/40/5	All	1/2	1/80/5	All	1/3
	Stretching	6/20/6	All	--	5/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--
Week 3	**Mobility**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
	Flexibility	**4/20/6**	**t,th,f**	**--**	**4/20/6**	**t,th,f**	**--**	**5/20/6**	**t,th**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**t,th**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**
	Strengthening	**2/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w,f**	**2/1**	**4/20/6**	**m,w,f**	**2/1**	**3/30/5**	**m,w,th,f**	**3/1**	**3/30/5**	**m,w,th,f**	**1/2**	**2/40/5**	**m,w,th,f**	**1/2**	**2/40/5**	**All**	**1/3**	**1/80/5**	**All**	**1/3**
	Stretching	**6/20/6**	**All**	**--**	**5/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
Week 4	Mobility	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--
	Flexibility	4/20/6	t,th,f	--	4/20/6	t,th,f	--	5/20/6	t,th	--	4/20/6	m,w,f	--	4/20/6	t,th	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--
	Strengthening	2/20/6	m,w	1/1	3/20/6	m,w	1/1	3/20/6	m,w,f	2/1	4/20/6	m,w,f	2/1	3/30/5	m,w,th,f	3/1	3/30/5	m,w,th,f	1/2	2/40/5	m,w,th,f	1/2	2/40/5	All	1/3	4/20/5	All	1/3
	Stretching	6/20/6	All	--	5/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--

S/T/R: number of series/seconds per series/Rest seconds between series per day; F: days of the week; I (s/s): Intensity (shortening-stretching speed motion ratio); All: (Monday to Friday); m: Monday; t: Tuesday; w: Wednesday; th: Thursday f: Friday; --: not applicable

Musculoskeletal-related fitness

A previous validated back-health fitness battery was used [179]. Handgrip strength was evaluated by means of a manual dynamometer (TKK, Tokyo, Japan), taking the average value of both hands as the final result. An intraclass correlation coefficient (ICC) of 0.95 for this instrument has previously been reported [180]. The flexibility of legs and trunk was evaluated by means of the Sit-and-Reach Test, which has a reported ICC of 0.89 [181]. The distance between the ends of the fingers in the final position during flexion of the trunk was taken as the value of flexibility. The best result of the three tests undertaken was considered the definitive result. Lumbar trunk muscle endurance was evaluated by the Ito Shirado tests, which have reported ICCs of 0.95 and 0.97, respectively [172]. To evaluate the flexor muscles, the subject was asked to recline in a supine position and elevate the lower extremities to 90º flexion of the hip and knee joints. To evaluate extensor muscles, the subject was asked to take a prone position keeping the breastbone on the surface of the ground. In both procedures, the subject was requested to hold the position for as long as possible. The flexibility of the Upper Extremities was evaluated with a 'back scratch test' [182]. In the absence of a reliability measure for this test in working age adults, the ICC was determined in our laboratory, resulting in ICCs of 0.96 in the upper right extremity and 0.80 in the upper left extremity. The subject was placed in a standing position with one hand behind the back stretching as far as possible up the spinal column. The subject was asked to extend the other arm behind the head with the elbow bent and to try to reach the other hand. This was carried out twice. The vertical distance between the two middle fingers was taken as the evaluation rate.

Self-reported functional disability

The Roland Morris questionnaire (RMDQ) and the Oswestry disability index (ODI), the two most commonly questionnaires used to assess self-reported functional disability in LBP patients [140]. The Oswestry disability index was used to assess the self-reported functional disability related to LBP [144], that has been previously validated in Spanish language [143]. It consists of a list of items that reflect limitation in different activities of daily living. The questionnaire is filled out by the patient who has to indicate those items reflecting his/her current state. In the Oswestry questionnaire total scores were obtained by applying the following formula: total

points / 50 (or the number of question answered)* 100. The application of the formula gives a percentage of disability due to back pain ranging from 0% (no disability) to 100% (maximum disability). The Roland Morris questionnaire was also used to assess the self-reported functional disability related to LBP [141], which has been previously validated in Spanish [29]. It consists of a list of 24 items that reflect limitation in different activities of daily living and has a score that ranges from 0 (no disability) to 24 (maximum disability). Also, was collected the change status in self-reported functional disability after treatment, with 3 possible scores: -1, considered as negative change; +1 considered as positive change and 0 considered as no change.

Risk of chronicity

We used a Spanish version of the SBST to evaluate the severity and the risk of chronicity of common LBP [183]. The SBST has 9-items selected as predictive of 'poor prognosis' following a literature review and secondary analysis to identify strong independent predictors for persistent (chronic) disabling back pain. The predictive validity and external validity of the SBST has been reported, as well as its reliability, with a Kappa of 0.79 [21]. Also, was collected the change status in risk of chronicity after treatment, with 3 possible scores: -1, considered as negative change; +1 considered as positive change and 0 considered as no change.

Health-related quality of life

The European Quality of Life Questionnaire three levels (EQ-5D-3L) [184] was used to assess HRQoL. The EQ-5D-3L assessed the generic functional health-related quality of life (HRQOL) of participants. The EQ-5D-3L includes five dimensions, each one measuring a different dimension of HRQOL: mobility, self-care, daily activities, pain and discomfort, and anxiety or depression. Three levels for answering are included (no problems, some problems, or extreme problems/unable to), ranging from 1 to 3. The juxtaposition of the levels for these five dimensions correlate to five-digit numbers, which reflect 243 possible health status values that can be collapsed to a health functional index or a 'utility' using time-trade off values (EuroQolutility; 1=fully functional quality of life, 0=death). The EQ-5D-3L includes a vertical 20 cm visual analogue scale (VAS) on which respondents rate their own health between 0 (worst imaginable health state) and 100 (best imaginable health state) thereby providing an overall numeric estimate of their HRQoL [185]. Also, was collected the change status after treatment in

EQ-5D-3L utility index, with 3 possible scores in the overall (utility index and VAS) and each dimension of the HRQoL: -1, considered as negative change; +1 considered as positive change and 0 considered as no change. The same case of distribution was used for each dimension.

Behaviour

The stage of change questionnaire was used to assess the back pain-related behaviour change. This is a common instrument to assess the effectiveness of a health promotion program in terms of change in the behaviour dimension [186]. The stage of change questionnaire assessed change in the behaviour domain in terms of exercise. A specific mathematics algorithm was used to classify the participants into five possible stages of motivational readiness to change: pre-contemplation, contemplation, preparation, action, and maintenance [187]. At the end of the 9-month study period, the global stage of change status was determined according to three possible scores: -1, considered a negative behavioural change; +1 considered a positive behavioural change; and 0, considered no change. At the end of the study, all participants in the intervention group were asked if they would like to continue with the programme

Statistics

The descriptive statistics are presented as means and standard deviations (SD) for continuous variables and as frequencies and percentages for categorical variables in each sub-study. The distribution of the data was examined by the Kolmogorov-Smirnov test with Lilliefors correction in each sub-study. Differences between office workers with sub-acute, non-specific LBP and asymptomatic office workers were tested using the Mann-Whitney U-test for continuous variables and the chi-square test for categorical variables adjusted by age. To standardize the scores, the difference between the raw score of office workers suffering from sub-acute non-specific LBP and the mean score of the control group was calculated. This difference was then divided by the SD of the control group. These standard scores (z-scores) express the individual's distance from the reference group in terms of the distribution (Size effect). Thus, any score equal to the mean of the reference group will be equivalent to an effect size of zero. Negative or positive values indicate an individual who falls below or above the mean,

respectively. A correlation between HRQoL dimensions and trunk muscles endurance scores in office workers with and without LBP was tested with Spearmen correlation coefficient (Study II).

Test-retest reliability was assessed in symptomatic group (randomly chosen from the total symptomatic sample) using a 7-day interval between tests to avoid any influence of learning, fatigue or pain on the second application of the test. All participants were asked to not take pain medication 24 hours before the trunk muscle endurance assessment. Also the inclusion/exclusion criteria was confirmed the same day of the retest (day 2) by the physician. An external technician (who did not take part in the research team and was blinded to the patients) performed all tests in the day 1 and day 2. First, the stability coefficient was analysed using the Intra-class Correlation; ICC2,1 [188]. One interpretation of the reliability measures using ICCs suggests that a value greater than 0.70 represents good reliability whereas a value less than 0.70 represents moderate to poor reliability. It has been suggested that the ICC should be greater than 0.90 to ensure reasonable validity [189]. The ICC is based on Analysis of Variance so the results must be interpreted with caution because of the non-normality found in the data. The reliability and temporal stability of the diagnosis was also assessed based on optimal cut-off points selected according to the ROC analysis. For this analysis, Cohen's Kappa index was used. A Cohen's Kappa index of 1 indicates perfect stability of the diagnosis after removed the agreement due to chance [190]. Data were analysed by sex for both tests. The absolute reliability was determined with the standard error measurement (SEM) [SEM= SD$\sqrt{}$((1-ICC)], where SD is the average SD of day 1 and day 2, and the real minimum change (SRD) (1.96 X $\sqrt{}$2 X SEM)]. On the basis of the SEM and SRD values, a decision as to whether a genuine change has occurred would need to be made clinically by taking all aspects of patient assessment into account [191]. Bland-Altman plots were constructed to illustrate a random relationship between 31 individual differences and trunk muscle endurance tests scores of day 1 and day 2 [192]. ROC curve analysis was used to assess predictive validity of the tests used [29]. The ROC curve is a plot of sensitivity versus specificity of a variable assessed against an external criterion, and is therefore a representation of the trade-off between sensitivity and specificity. The presence of non-specific low back pain using the study inclusion criteria was used as the external criterion for constructing the ROC curves. Sensitivity and specificity were used to determine the cut-off value (giving equal weight to both parameters) for each test

performed. AUC and its significance for the ROC curve was then determined through the non-parametric estimation method due the binormal method might bias the results because the data were not normally distributed. Trunk muscle endurance tests were conducted in men and women with and without low back pain. Construct validity, the extent to which the instruments correlate with other measures with which it should be related to, was estimated by studying correlation between the trunk muscle endurance tests, the RMDQ and the ODI scores. For the construct validity, Spearmen correlation was used between self-reported functional status and the tests performed (Study III).

Differences between intervention group and control group (treatment conditions) in trunk muscle endurance tests, self-reported functional disability, HRQoL, risk of chronicity and pain history were assessed using a two-way analysis of variance (ANOVA) for repeated measures adjusted by baseline characteristics of the participants. Further to per-protocol analysis, intention-to-treat analysis was performed. The mean of change (95% confidence interval) and the treatment effect were provided. Effect size was used to determine the magnitude of change on and was calculated as the difference between means divided by the pooled standard deviation. Cohen's coefficient was used to assess the change [193]. (Studies IV, V and VI). The main outcomes of the study (Roland Morris and SBST) were MCID-based dichotomized and the Number Needed to Treat (NNT) was calculated; the Absolute Risk Reduction (ARR) and Relative Risk Reduction (RRR) (globally termed Risk Reduction) were also calculated, as recommended by experts in the physical therapy field [194] (Study IV and V). The null hypothesis of no difference in the proportion of prevention of risk of chronicity (Study V) and each stage of change (Study VII) between the treatment conditions was evaluated by a chi-squared test. In this case, odd ratios (95% CI) were undertaken to assess the treatment effect. Correlations between outcomes in the trial phase of the current thesis were tested using Pearson correlation coefficient (Study V and VII).

To determine whether the intervention reduced patients' overall risk status for chronicity we compared using chi-squared the proportions of patients in each group who, at 9-month follow up, were low risk on the SBST (Study V).

A linear regression model was used to give a better understanding of changes in self-reported functional disability, HRQoL, and episodes of LBP after treatment (Studies IV and VI). To

determine which individual predictive factors were key treatment mediators for this risk reduction, a binary logistic regression was performed using changes within the eight predictive factor items measured by the SBST to explore which items were most associated with low-risk of chronicity status. (Study V). Also, a binary logistic regression was performed to assess the relationship between positive clinical changes in utility index from EQ-5D-3L and the positive (clinical) change in self-reported functional disability/risk of chronicity of LBP, using the backward logistic model and controlling for baseline characteristics (Study VI).

The five dimensions from EQ-5D-3L were collapsed in no problems (value 1 of the dimension) and problems (values 2 and 3 of the dimension) for analysis reasons. The null hypothesis of no difference in HRQoL dimensions between the treatment conditions was evaluated by a chi squared analysis. In this case, odd ratios (OR) with 95% Confidence Interval were undertaken to assess the treatment effect. The chi-square test (ORs; 95% Confidence Interval OR) was also used to determine statistically significant associations between intervention/ control group and the change (positive, negative or no change) in HRQoL, self-reported functional disability and risk of chronicity. Also, chi-square test (ORs; 95% Confidence Interval OR) was used to determine statistically significant associations between the positive (clinical) change in self-reported functional disability/risk of chronicity of LBP and each dimension, VAS and utility from EQ-5D-3L (Study VI).

For all tests performed in the current thesis work, the analyses were performed using Statistical Package for Social Science (SPSS, v 18.0 & 19.0 for WNDOWS; SPSS Inc., Chicago, IL) and the level of significance was set to 0.05.

More extended information on studies´ results and discussion could be found in the publications section of the current thesis work, at the end of the document. Overall, results from the current thesis show a fitness and HRQoL deficit in office workers with sub-acute LBP when are compared with those age-matched office workers without LBP. These data were used as reference in the development of a new occupational web-based multidisciplinary intervention in office workers with sub-acute, non-specific LBP. Results from the trial revealed that the addiction of 9-month of this intervention to usual preventive treatment is safe, feasible and effective to improve functional ability, HRQoL, exercise-related behaviour and trunk muscle endurance (validated in this thesis as complementary measure for assessing patients with non-specific LBP in the sub-acute phase, giving optimal cut-off points in this population) and also to decrease the number of episodes and risk of chronicity of LBP (measured with the Spanish version of SBST developed in this thesis). Moreover, the results of the current thesis show the feasibility on use, although with cutely, of the EQ-5D-3L utility index as health outcome measure in non-specific sub-acute LBP patients.

Spanish SBST (Study I)

The Spanish version of the "STarT Back Screening Tool" (SBST) in different subgroups [116]**.** In this first study the original version of SBST was translated and culturally adapted into Spanish language.

The rationale behind this study was that despite evidence of the importance of assessment of risk of chronicity in non-specific LBP patients to guide the provision of early intervention and decrease progression to chronicity of the ailment by tackling factor influencing on [21], no available tool in Spanish exits with similar properties.

Results from this sub-study have been reported elsewhere [116]. The results from the two independent forward translations of the SBST (phase 1) are provided in Table 8. Following a joint discussion between the translators about some of the words, concepts and terms used, a few small changes were made to produce version 1: In the 9th item, was decided to use *"estado molestando"* instead of *"como de molesto".* In the first item, was used *"se ha irradiado"*

instead of "*se ha extendido".* In the 3th item, was used *"he tenido"* instead of *"yo he* tenido'' to reflect a more colloquial Spanish style. For item 4, was used the word *"debido a"* instead of *"a causa de"* again to reflect a more colloquial form of Spanish. For item 6 was used the word *"por mucho tiempo"* instead of *"un montón de tiempo"* as this would be better understood. For item 7, was used the *verb "notar"* instead of *"sentir"* again to reflect a more colloquial form of Spanish. For item8, was decided to use *"habitualmente"* instead of *"normalmente"* because it was agreed that this sounded better.

Table 9. Items in the Spanish version of the STarT Back Screening Tool.

1. Mi dolor de espalda ''se ha extendido a lo largo de mi pierna(s) '' en alguna ocasión en las últimas dos semanas.
2. Me ha dolido el ''hombro'' o ''cuello'' en alguna ocasión en las últimas dos semanas.
3. En las últimas dos semanas, solo he ''caminado distancias cortas'' por mi dolor de espalda.
4. En las últimas dos semanas, me he ''vestido más lentamente'' de lo normal por mi dolor de espalda.
5. No es seguro ser ''físicamente activo'' con mi dolor de espalda.
6. Me he ''preocupado'' mucho por mi dolor de espalda en las últimas dos semanas.
7. Noto que ''mi dolor de espalda es terrible'' y que ''nunca irá a mejor''.
8. En general, en las dos últimas semanas, no he ''disfrutado'' de las cosas, de lo que habitualmente disfruto.
9. En general, como le ha ''molestado su espalda'' en las últimas dos semanas.

Table 9 shows the second version of the questionnaire. In the cognitive interviews (phase 2), patients did not identify any major difficulties in comprehension of first version, as all the participants reported the questionnaire as clear and comprehensible on the dichotomous response options. However, the more sensitive measure of the numerical response rating revealed that there was a degree of greater difficulty of understanding for items 5 and 6 (disability and anxiety items) across the younger and older age groups (Figure 3). Therefore these items were slightly modified; for item 5 (disability) the wording was changed from *"no es realmente seguro para una persona como yo ser físicamente activo"* to the more direct phrasing of *"no es seguro ser físicamente activo con dolor de espalda".* For the 6th item the wording was changed from *"preocupaciones han estado pasando a través de mi mente durante mucho tiempo en las últimas dos semanas"* to an active voice form of *"me he preocupado mucho por mi dolor de espalda en las últimas dos semanas".*

The investigation of individuals' interpretations of SBST items and paraphrasing exercise verified that the majority of people interviewed fully understood each of the SBST items. However, it was observed that a number of participants used a direct question that included the infinitive form of the verbs included and the items written in the perfect past tense were repeated when using their own words with the simple past tense. Therefore, it was decided to use the infinitive and simple past verb forms as much as possible in the definitive version. Nevertheless, during the re-formulation (paraphrasing) of the items by the subjects, they consistently re-phrased the referred leg pain item translated as *"irradiar a través de mi pierna"* to *'extender a través de mi pierna"*, and so for this reason the verb 'extending' was used instead of 'radiating'. In addition, the results from the cognitive interviews revealed that participants were more likely to recommend changes if they had experienced a recent episode of LBP or were in the older age category (Figure 3).

Regarding phase 3 of the process; back-translation, when items from table 2 were presented to the authors of the original English version of the tool, no further additional changes were required.

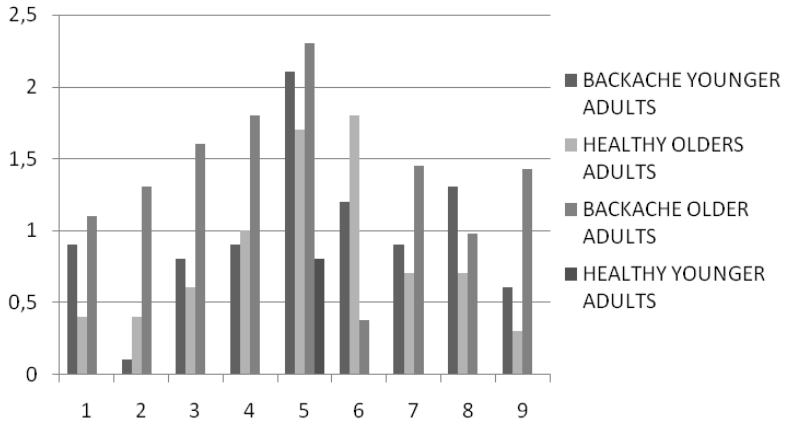

Figure 3. Average difficulty stratified by age and presence/absence of backache of 1-9 items. Scale range was 0 to 10 (0 very easy to understand to 10 very difficult to understand)

This tool can add value to assess the effects of interventions such as physical therapies or pharmacological treatments that can identify subgroups of patients to guide the provision of early secondary prevention in primary care [21]. Furthermore, this translated Spanish version of the SBST will provide a practical and user friendly tool to identify prognostic subgroups of patients with LBP that require targeted and increasing complexity of treatment, which is a major reason for visits to primary care.

Looking for fitness and HRQoL reference data in office workers with sub-acute, non-specific LBP. General results and discussion (Studies II and III)

Common results from each sub-study comprising this cross-sectional phase of the current thesis work are presented and discussed under current subheading. Table 10 shows the socio-demographic and healthcare consumption characteristics of the participants in the study stratified by gender and ailment. A total of 190 participants between the ages of 27 and 64 years were included in the study. Of these, 72 were healthy workers (without LBP) and 118 were office workers with sub-acute non-specific LBP. Table 9 reveals that office workers diagnosed with sub-acute non-specific LBP consume more healthcare resources than healthy workers. On the other hand, in both men and women with this diagnosis, there were significant differences with respect to healthy workers concerning the history of episodes of non-specific LBP, the history of sick leave associated with non-specific LBP, and the number of visits to a general practitioner occasioned by non-specific LBP.

Table 10. Socio-demographic, non-specific LBP history and health characteristics of participants in the study (n=190)

	Healthy-workers (n=72)		NLBP-workers (n=118)		*p a (males)*	*p a (females)*
CHARACTERISITICS	Males	Females	Males	Females		
Age-yr*	41.17 (13.04)	47.95 (8.55)	45.85 (9.17)	46.01 (8.15)	.056	.301
Sex, n (%)	30 (41,66)	42 (58.34)	47 (39.84)	71(69.16)	--	--
Smoke						
Smoker, n (%)	4 (13.30)	7 (16.70)	25 (53.20)	37 (52.10)	--	--
Not smoker, n (%)	26 (86.70)	35 (83.30)	22 (46.80)	34 (47.90)	--	--
Level of studies						
Secondary studies, n (%)	0 (0.00)	5 (11.90)	5 (10.60)	2 (2.80)	--	--
Professional studies, n (%)	3 (10.00)	15 (35.70)	39 (54.9)	39 (54.90)	--	--
University studies, n (%)	27 (90.00)	22 (52.40)	30 (42.3)	30 (42.30)	--	--
Episodes last 9 months-NLBP*	0.67 (1.39)	0.76 (0.85)	1.85 (9.17)	2.07 (0.64)	*p*<.001	<0.001
Visits to GP last 9 months-NLBP*	0.13 (0.34)	0.05 (0.21)	0.47 (0.50)	0.51 (0.60)	.003	.001
Sick Leave last 9 months-NLBP*	0.67 (1.39)	0.48 (0.80)	1.36 (1.15)	1.27 (1.25)	.002	*p*<.001

*Value expressed as Mean ±SD; Episodes last 9 months-NLBP: number of episodes of NLBP; Visits to GP last 9 months-NLBP: visits to the general practitioner due to NLBP in the last 9 months; Sick Leave last months-NLBP: number sick leave due to NLBP in the last 9 months; --: not computable; p *a*: Mann-Whitney *U*-test adjusted by age.

In representative terms, our study show similar rates of distributed LBP than determinate in other European studies. The prevalence of LBP in office workers ranging from 39% in northern European countries to 62% in southern European countries, with about 10% more females than males being affected [112].

Fitness and HRQoL characteristics of office workers with sub-acute, non-specific LBP (Study II)

Health-Related Quality of Life and fitness characteristics of office workers affected by sub-acute non-specific low back pain. Although different studies have explored the use of exercise programs [55] there has been little examination of the criteria that exercise-based programs need to address to improve the physical function of workers suffering from LBP [167]. Identifying the major fitness and HRQoL deficits of workers suffering from sub-acute non-specific LBP is a prerequisite for designing appropriate fitness and health promotion programs. Therefore, in this second study, the aim was to detect fitness and HRQoL differences between office workers with sub-acute, non-specific LBP when compared with those age-matched healthy office workers.

Main results (table 11) regarding back pain-related fitness show that both men and women suffering from sub-acute non-specific LBP showed a poor fitness profile compared with those without this condition, although significant differences were not fully detected in the “sit and reach” test in men. Similar results were achieved regarding HRQoL. Men affected by sub-acute non-specific LBP reported decreased overall HRQoL and decreased scores for each of the five HRQoL dimensions (mobility, personal care, daily tasks, pain/discomfort and anxiety/depression) compared to men without this condition, both in the VAS ($p<.001$) and EQ-5D-3L utility index ($p<.001$). This was also the case for women, with the single exception of the pain/discomfort dimension, where significant differences were not detected. Furthermore in both men and women affected by sub-acute non-specific LBP showed a worse disability index than those without this condition as determined by the RMDQ ($p<.001$) and the ODI ($p<.001$).

Table 11. Differences between groups on back pain-related fitness tests stratified by sex of the participants in the study (n = 190)

	Health-workers (n = 72)		NLBP-workers (n = 118)		*p a* (males)	*p a* (females)	Size effect (males)	Size effect (females)
Outcome measure	Males (n = 30)	Females (n = 42)	Males (n = 47)	Females (n = 71)				
Hand strength: handgrip (kg m^{-2})*	43.05 (7.13)	34.03 (11.42)	31.22 (12.37)	25.56 (5.22)	p<.001	.001	-1.65	-0.74
Endurance: flexor trunk (s)*	94.63 (37.94)	77.42 (46.47)	62.06 (36.87)	46.06 (29.28)	p<.001	.001	-0.85	-0.67
Endurance: extensor trunk (s)*	109.36 (24.18)	101.80 (36.92)	79.57 (30.66)	75.49 (28.97)	p<.001	p<.001	-1.23	-0.69
Lower limb flexibility: sit –and-reach (cm)*	19.54 (6.50)	21.15 (4.82)	15.17 (7.01)	15.50 (7.79)	.072	p<.001	-0.24	-1.17
Upper limb right flexibility: back scratch test (cm)*	-5.31 (4.91)	-3.00 (3.45)	-1.39 (2.54)	1.42 (6.53)	p<0.001	.001	-1.36	-0.45
Upper limb left flexibility: back scratch test (cm)*	-2.92 (4.18)	-2.42 (4.18)	2.13 (7.28)	6.28 (9.88)	.003	p<.001	-0.18	-0.90
Mobility, *problems, n (%)*	0	0	35 (74.50)	53 (74.60)	p<.001	p<.001	--	--
Personal care, *problems, n (%)*	0	0	21 (44.70)	23 (32.40)	p<.001	p<.001	--	--
Daily activities, *problems, n (%)*	2 (6.70)	15 (35.70)	26 (55.30)	33 (46.50)	p<.001	p<.001	--	--
Pain/discomfort, *problems, n (%)*	3 (10.00)	15 (35.70)	26 (55.30)	35 (49.30)	p<.001	.221	--	--
Anxiety/depression, *problems, n (%)*	2 (6.70)	9 (21.40)	12 (25.50)	27 (38.00)	p<.001	p<.001	--	--
VAS*	79.96 (11.02)	73.38 (16.32)	57.76 (14.17)	57.39 (12.44)	p<.001	p<.001	-1.98	-0.97
EQ-5D-3L-Utility index *	0.92 (0.09)	0.83 (0.16)	0.71 (0.13)	0.77 (0.10)	p<.001	.004	-2.3	-0.37
RMDQ (points)*	0	0	11.21 (2.22)	12.04 (2.40)	p<.001	p<.001	3.16	3.01
ODI (%)*	0	0	29.93 (1.49)	28.12 (2.52)	p<.001	p<.001	4.29	2.85

*Values expressed as mean ± (SD); Health-workers: workers without NLBP condition; NLBP-workers: workers with NLBP condition; NLBP: non-specific low back pain; EQ-5D-3L Utility index: Time trade off-EuroQoL-5D-3L questionnaire; VAS: visual analogical scale of health-related quality of life; RMDQ: Roland Morris questionnaire score; ODI: Oswestry questionnaire score; --: not computable; p a: p values from x^2 or Mann-Whitney adjusted by age.

It has been reported that chronic LBP patients had a lower rate of back muscle fatigue than healthy subjects [195]. However, in similar studies, other authors did not find significant differences in back muscle fatigue [196] . One hypothesis to explain these conflicting results is that chronic LBP subjects might adopt alternative neuromuscular strategies to modulate fatigue of the back extensor muscles and increase the contribution of hip extensor muscles during back endurance tests [197]. The relative contribution of these neuromuscular strategies could vary in patients suffering from sub-acute LBP, depending on the specific nature of the LBP in the population under study [198]. Also was found differences between healthy and LBP subjects in the other tests performed, such as back scratch and handgrip strength, which is consistent with other studies [179]. These results can be explained, at least in part, by the functional limitations that back pain produces in affected individuals [199]. Another explanation for why our findings differ from studies focused on other specific LBP conditions, e.g., chronic LBP [168], might be variations in the way that other variables, such as psychological aspects, influence different specific LBP populations [198]. The low rates found in our LBP workers affected regarding HRQoL could be due in part to their experience of disability as reported in the disability indices discussed above [150]. Decrease in RMDQ score was similar to another study using Spanish patients [31]. Although no comparable ODI data exist for the Spanish population, we obtained similar values to those found in other international studies involving workers with sub-acute non-specific LBP [198]. Studies involving participants with chronic back pain have reported worse disability scores with both questionnaires than those in our sub-acute population, which may be due to the way different types of LBP impact disability [200].

In practical, as far as expert recommendations that patients suffering from non-specific LBP should be physically active and continue on working rather than resting, exercise programs for office workers may need to focus more on developing the endurance of the trunk and on improving the mobility and flexibility of the trunk and upper and lower limbs but further work investigating the relationships prospectively between trunk muscle endurance and LBP is required in this special population. Also was detected low levels of anxiety/depression, which could impair the HRQoL of patients suffering from sub-acute non-specific LBP [31], and it also encourage group programs and professional support to minimize psychosocial impacts.

Lumbar and abdominal trunk muscle endurance tests validity in sub-acute, non-specific LBP (Study III)

Reliability and Validity of lumbar and abdominal trunk muscle endurance tests in work-age patients with non-specific, sub-acute low back pain (study III). Despite the importance given to trunk muscle endurance tests for the assessment of LBP in both the literature and in clinical practice, the validity of, and establishment of reference data for, trunk muscle endurance tests has only been studied in working-age, LBP patients in the general population [172, 201]. Only one study has evaluated the capacity of these tests in discriminating between patients with and without LBP [170]. However, there are no disaggregated data on the use of trunk muscle endurance tests in office workers with sub-acute LBP; this group is likely to differ from chronic patients and general population in the range of factors that affect back function [24]. Therefore, in this third study was aim to test the reliability and validity of the prone isometric chest raise tests (lumbar and abdominal) in male and female office workers with sub-acute non-specific LBP.

Table 12. Reliability analysis of the test performed in NLBP workers (n=48)

Trunk muscle endurance test	Group	Day1	Day2	*p*	ICC	95%CI of the ICC	SEM	%SEM	SRD	%SRD	Kappa
Abdominal	Male NLBP-workers (n=12)	56.50 (37.85)	54.66 (36.93)	.73	.97	(.96 to .99)	3.53	4.70	9.78	12.95	1
	Female NLBP-workers (n=12)	48.78 (29.73)	46.15 (28.98)	.74	.96	(.92 to .99)	2.67	3.40	7.41	9.50	1
Lumbar	Male NLBP-workers (n=12)	80.83 (24.92)	83.95 (25.34)	.69	.97	(.94 to .98)	6.54	6.70	19.33	18.75	1
	Female NLBP-workers (n=12)	82.68 (30.69)	85.95 (31.35)	.65	.96	(.94 to .98)	6.92	13.00	19.17	36.20	1

ICC: intra-class correlation coefficient; SEM: standard error of measurement; SRD: small real difference; Kappa: stability diagnosis criteria used in each test performed-based Kappa coefficient; NLBP-workers: office workers affected by sub acute non-specific low back pain; Healthy workers: office workers without health problems; CI: Confidence Interval; Day1: test; Day2: retest; *p*: p values from Mann-Whitney U-test.

The reported ICC of this study is above .90 in all tests conducted in women and men with and without low back pain. Reliability in regard to temporal stability of the diagnostic criteria was excellent, with Kappa index of one in all cases (table 12). These data also differ from those reported by Arab et al (which were over .80) due in part to differences in the time the tests (test-retest). In our study, we used a 7-day interval between each measurement (inter-session

reliability), while Arab et al. used a 15-min interval (intra-session reliability). Our ICC values are also consistent with the ICC values reported previously for chronic low back pain patients [201]. A novel feature of our study was the reporting of absolute reliability indices. To our knowledge, this is the first study to report these indices, which can enhance the interpretation of the results of interventions aimed at improving functional capacity in subacute low back pain.

Table 13. The cut-off score, sensitivity, specificity and area under the ROC curve for the performed tests (n=190)

Measures	Cutt-off	Sensibility (%)	Specificity (%)	AUC (cm^2)	*p*	SE	95% Interval Confidence
Abdominal trunk muscle endurance test							
Males	<105.50	91,50	70	.78	<.001	.06	.66 to .89
Females	<107.50	97,20	52,40	.69	<.001	.06	.58 to .80
Lumbar trunk muscle endurance test							
Males	<111.50	91,50	83,30	.86	<.001	.05	.76 to .95
Females	<117.00	90,10	73,80	.78	<.001	.06	.67 to .89

AUC: area under the ROC curve (maximum_1.0); SE: standard error; *p:* statistic significance set at 0.05.

Through the predictive validity, the ROC curve (table 13) reveals that for men and women, the lumbar trunk muscle flexion test had greater sensitivity and specificity than the test for abdominal trunk muscles, although the results for both show acceptable sensitivity and specificity (except lumbar flexion for women). In addition, the results suggest that both trunk muscle endurance tests are better predictors of LBP in men than in women (Figure 4). A similar result was obtained for the AUC, in which both tests recorded an AUC above .70 for both men and women (except the Ito Shirado Abdominal test in women, which had an AUC slightly below .70). The results for AUC values are in accordance with the one other reported study on trunk muscle endurance tests and LBP [170]. However, although this latter study focused on working-age patients with LBP, the type of the LBP was not reported in accordance with LBP guidelines [24]. Also, the functional status of the patients was not reported [202]. These two factors suggest that it may be difficult to apply the results reported by Arab et al to other clinical and functional manifestations of LBP (e.g., subacute LBP patients) [24].

Sensitivity and specificity values for the cut-off points in the current study were good, with the exception of the abdominal protocol in women. Arab et al found similar lower sensitivity and specificity values for this protocol. Despite this similarity, our cut-off points differ from those reported by Arab et al, possibly because the nature of the LBP in their study population was presumably different, and may have been influenced by other factors [183]. In addition, the selected cut-off points in this study were based on giving equal importance to sensitivity and specificity, which could also explain the difference in cut-off points [203] in the two studies, but we cannot test this because the method for selecting the cut-off point was not reported by Arab et al. The level of correlation between Functional disability (measured with RMDQ and ODI) and the results from the two test performed confirm the concurrent validity of these tests for work-age patients with sub-acute, non-specific LBP (table 14)

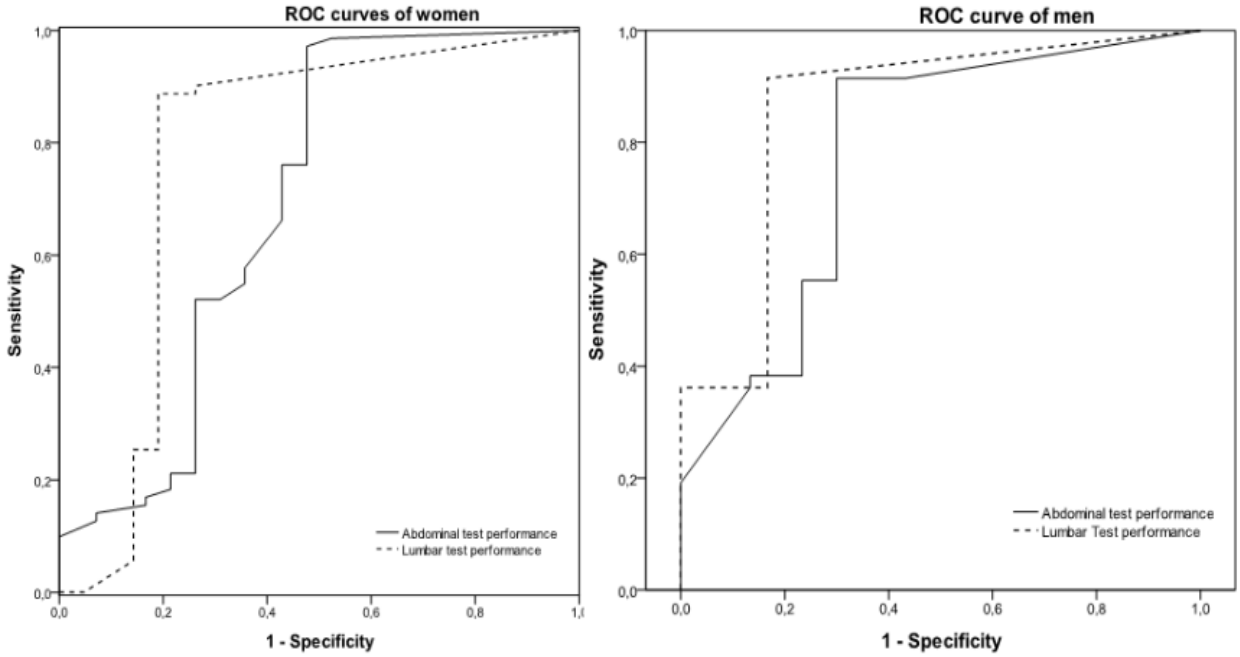

Figure 4. ROC curve for trunk muscle endurance tests for men (left side) and women (right side)

Table 14. Correlation between functional disability levels and physical fitness tests in males and female workers with sub-acute non-specific low back pain * (n=118)

***Males** (n=47)*				
Measures	**RMDQ**	**ODI**	**Lumbar test**	**Abdominal test**
Roland Morris Questionnaire	1.000	.59**	-.58**	-.57**
Oswestry Disability Index		1.000	-.44**	-.34**
Lumbar trunk endurance test			1.000	.28*
Abdominal trunk endurance test				1.000
***Females** (n=71)*				
Measures	**RMDQ**	**ODI**	**Lumbar test**	**Abdominal test**
Roland Morris Questionnaire	1.000	.74**	-.47**	-.33**
Oswestry Disability Index		1.000	-.50**	-.35**
Lumbar trunk endurance test			1.000	.63**
Abdominal trunk endurance test				1.000

*Spearman correlations coefficients. RMDQ: Roland Morris disability Questionnaire; QDI: Oswestry disability Questionnaire; Lumbar test: lumbar trunk endurance test; Abdominal test: Abdominal trunk endurance test; **: Correlation is significant at 0.001 level.

This study shows that lumbar and abdominal trunk muscle endurance tests are reliable and valid measures in the assessment in the work-age population affected by sub-acute, non-specific low back pain for both men and women. The present study has generated novel data, which will assist physicians, therapists, and clinicians in the functional status assessment in this special population.

A new occupational web-based intervention to secondary prevention of non-specific LBP. General results and discussion (Studies IV, V, VI and VII)

Common results from each sub-study comprising this trial phase of the thesis work are presented and discussed under current subheading. One-hundred subjects were finally randomized (Figure 5). There were no statistically significant differences between the intervention and control groups at baseline (Table 15). None of the participants in the intervention group reported any negative health effects during treatment. A session was considered to have been completed if the participant remained logged in for at least 11 minutes. Participants in the intervention group remained logged in for at least 11 minutes for 85.71% of all sessions. In the intervention group, 92% (46 of 50) of all participants completed the 9 month programme. Of the four intervention group participants who dropped out of the programme, three were women who changed jobs and the other was a woman who stopped due to

pregnancy. In the control group, 88% (44 of 50) of the participants completed the 9 month period. The remaining six dropped out through an apparent lack of interest.

Table 15. Baseline characteristics of participants in the trial * (n=90)

Group	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	*p†*
Age (years)	45.50 (7.02)	46.83 (9.13)	.44
Sex (%)	11.4 (M); 88.6 (F)	15.2 (M); 84.8 (F)	.59
Smoke (%)	50 (Y); 50 (N)	56.5 (Y); 43.5 (N)	.53
RMDQ (points)	11.65 (2.14)	12.28 (2.63)	.22
ODI (%)	28.77 (2.69)	28.13 (2.23)	.220
Pre-contemplation, yes (%)	20 (45.43)	21 (45.65)	.830
Contemplation, yes (%)	21 (47.71)	19 (41.30)	.669
Preparation, yes (%)	3 (6.81)	6 (13.04)	.291
Action*, yes, n (%)*	0	0	--
Maintenance*, yes, n (%)*	0	0	--
VAS (0-100 points)	59.22 (11.96)	59.25 (11.38)	.961
EQ-5D-3L utility (points)	.78 (.08)	.75 (.11)	.23
SBST total score (points)	4.38 (1.67)	4.36 (1.28)	.95
SBST psychological score (points)	2.36 (1.03)	2.28 (.98)	.70

*Value expressed as Mean (SD); Roland Morris questionnaire: Roland Morris questionnaire score; ODI: Oswestry disability questionnaire score; VAS: EQ-5D-3L visual analogical scale; TTO: Euroqol-5D-3L quality of life questionnaire utility index. Time Trade Off; Smoke: Percentage of smokers; M: male; F: Female; Y: yes; N: not; SBST total score: STarT Back Screening Tool total score; SBST psychological score: STarT Back Tool psychological score; pre-contemplation, contemplation and preparation: stages of behaviour changes; Control group: group that had access to the usual treatment; Reminder group: group that had access to the proposed treatment and to the usual care; p †: p values from t-test for independents measures or chi square test.

At 100 patients, our sample size could seem small; however, we completed the trial with numbers within the estimated sample size (calculated in this study based on main outcomes of each sub-study study before the beginning) needed to demonstrate clinically significant effects with the methods used. Also, the timing and nature of this intervention was in accordance with current clinical guidelines, which recommend multidisciplinary interventions (based on functional exercise combined with postural education) to improve physical function, and include psychosocial factors, which have been determined as risk factors in the transition from sub-acute to chronic LBP [119]. It is also potentially possible to reach a large population of office workers with non-specific LBP to prevent the chronicity of the ailment using the chosen mode of

delivery of the interventions [204-206]. In the present study, each session of exercise was 11 minutes in duration, including 7 minutes of targeted physical exercise (five sessions per week).

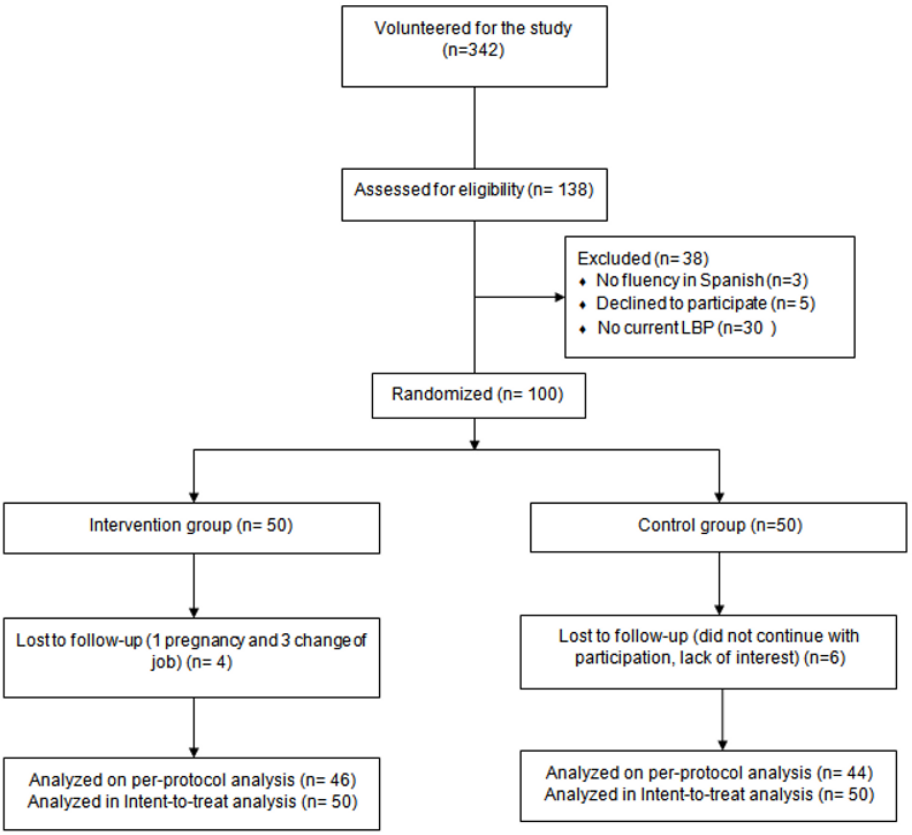

Figure 5. CONSORT flow diagram of participants in the randomized controlled trial phase of the thesis work

Consistent with our doses of training, one high quality study [87] found that 5 min of light resistance training each working day was effective. Training doses of mean 10 min per day were sufficient to produce significant decreases in LBP intensity and incidence. [82, 93]. In exercise programs conducted during work time [85-87], an average training dose of 6 min per working day resulted in significant improvements in primary outcome measures for LBP (e.g. pain intensity, sick leave or disability). A high level of adherence to the exercise program was obtained in the intervention group. This is consistent with other studies in which a high level of

adherence to activities designed to promote healthy lifestyles was achieved through the use of intervention emails at the workplace [207, 208].

Effects of the intervention on trunk muscle endurance, functional disability, global HRQoL and LBP-episodes in office workers with non-specific LBP in the sub-acute phase (Study IV)

A web-based intervention to secondary prevention of common low back pain among office workers. Although there is some uncertainty about the most effective specific exercise programs for the secondary prevention of LBP [55], interventions based on functional physical activity combined with postural education are recommended by experts as a fundamental part of multi-component interventions [46]. On the other hand, poor lumbar and abdominal muscle endurance may contribute to functional disability in chronic non-specific LBP patients [209]. Also, HRQoL could be affected by the ailment. But to our knowledge, this has not been tested in longitudinal studies involving LBP patients in the sub-acute phase. Therefore, in this fourth study, the effects of a 9-month occupational web-based multidisciplinary intervention on LBP history, global HRQoL, trunk muscle endurance and self-reported functional disability were tested.

Table 14 shows a statistically significant 18% improvement ($p < 0.001$) in the Shirado Ito lumbar test and a 36% improvement in the Shirado Ito abdominal test. Results also show that RMDQ improved by 77% ($p < .001$) in the intervention group but no differences were detected in the control group (table 17). Risk reduction for RMDQ was; NNT, 7 (95% CI, 4.20 to 28.60); and ARR, 13.60% (95% CI, 3.50% to 23.80%). Since no bad outcome occurred in the intervention group, RRR was equal to 100%. Change from the baseline Roland Morris Questionnaire score was associated with the results of both the Shirado Ito lumbar test and the Shirado Ito abdominal test (table 17). The intervention group also improved by 29% in the EQ-5D-3L utility index ($p < 0.001$) (table 17). This change was associated with the change in the degree of disability, as measured by the Roland Morris Questionnaire (Table 17). Moreover, an 85.57% reduction ($p < 0.001$) in the number of episodes of NLBP was observed in the intervention group during the 9 month study period ($p < 0.001$) (Table 16). For both the Roland Morris and the EQ-5D-3L change from baseline score was independently correlated with the level of this reduction

(Table 17). Similar results were achieved in the intent-to-treat analysis (Table 15). Following both the per-protocol analysis and the intent-to-treat analysis, the Cohen coefficient was very large in all measures (Table 16).

Table 16. Effects of 9-month of web-based multi-factor program on non-specific low back pain in office workers*

Outcomes measure	Baseline		Post-treatment				
	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	Treatment effect Mean (95%CI)	p †	Effect size
Per-protocol analysis (n=90)							
EQ-5D-3L utility (points)	0.78 (0.08)	0.75 (0.11)	0.75 (0.11)	0.97 (0.04)	0.16 (0.069 to 0.191)	<.001	2.60
RM (points)	11.65 (2.14)	12.28 (2.63)	13.54 (2.09)	4.93 (2.59)	-9.23 (-10.57 to -7.89)	<.001	-2.80
Shirado Ito Lumbar (s)	77.52 (28.06)	77.17 (30.53)	78.52 (26.64)	96.30 (30.53)	20.10 (13.07 to 23.19)	<.001	0.68
Shirado Ito Abdominal (s)	49.75 (31.11)	48.10 (32.16)	51.34 (31.09)	67.95 (29.35)	21.43 (14.25 to 22.26)	<.001	0.63
Episodes last 9-month	2.07 (.58)	2.02 (.68)	2.39 (.65)	.59 (.58)	-1.75 (-2.09 to -1.49)	<.001	-2.90
Intent-to-treat Analysis (n=100)							
EQ-5D-3L utility (points)	0.77 (0.90)	0.75 (0.11)	0.78 (0.13)	0.96 (0.60)	0.19 (0.14 to 0.24)	<.001	2.50
RM (points)	11.70 (2.04)	12.18 (2.55)	13.54 (2.09)	4.93 (2.59)	-9.23 (-10.57 to -7.89)	<.001	-2.80
Shirado Ito Lumbar (s)	77.80 (28.29)	78.80 (30.62)	72.58 (29.78)	92.36 (27.89)	18.78 (9.57 to 27.98)	<.001	0.50
Shirado Ito Abdominal (s)	52.72 (31.18)	48.06 (32.96)	48.30 (30.29)	64.36 (30.71)	20.72 (13.58 to 27.85)	<.001	0.50
Episodes last 9-month	1.94 (.91)	2.18 (.72)	2.12 (.96)	.60 (.57)	-1.76 (-2.01 to -1.50)	<.001	-1.92

*Values expressed as mean (SD); TTO: Euroqol-5 dimensions health-related quality of life questionnaire utility. Time Trade Off; RM: Rolland Morris questionnaire: Episodes last 9-month: Episodes of non-specific low back pain occurred in the last 9-month both at baseline (over the 9 month prior to enrollment) and at 9 month (post treatment). Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care; p †: p values from ANOVA for repeated measures adjusted by baseline characteristics to compare different between groups after 9-month web-based multi-factor program.

Table 17. Predictive linear regressions models of changes in functional disability (model A), Health-related Quality of life (model B) and episodes of low back pain (model C) after 9-month of web-based multi-factor program (n=90)

Model A				
dRMDQ				
Model (R= .67; R^2 = .44)				
	Beta	SE	ST Beta	*p*
dShirado Ito Abdominal	-.218	.038	-.512	<.001
dShirado Ito Lumbar	-.096	.033	-.259	.005
CONSTANT	.528	.598		.374
Model B				
dTTO				
Model (R =.67; R^2 = 0.37)				
	Beta	SE	ST Beta	*p*
dRMDQ	-.018	.002	-.612	<.001
CONSTANT	.054	.015		.001
	Beta	SE	ST Beta	*p*
Model C				
dEpisodes last 9-month				
Model (R= .72; R^2 = .53)				
	Beta	SE	ST Beta	*p*
dRMDQ	.087	.018	.459	<.001
dEQ-5D-3L utility index	-2.252	.608	-.346	<.001
CONSTANT	-.095	.094		.312

dRMDQ: Roland Morris questionnaire score difference after treatment; dShirado Ito Abdominal: score of Shirado Ito Abdominal after treatment; dShirado Ito Lumbar: score of Shirado Ito Lumbar after treatment; dEQ-5D-3L utility index: Euroqol 5D-3L utility difference after treatment; dEpisodes last 9-month: number of episodes of non-specific low back pain difference after treatment; ***p*:** statistics significance from ANOVA for adjusted by baseline characteristics.

Achieved trunk muscle endurance tests results in this study are consistent with a previous study carried out at a hospital workplace, in which a land-based multi-component therapy was applied to reduce LBP symptoms in symptomatic LBP patients. However, the magnitude of improvement in trunk muscle endurance was not as great as that obtained in this study [85]. The improvement in RMDQ score in patients allocated in the intervention group was 9.23 points. According to Stratford et al. [142], the minimum clinically important change in Roland Morris Score from baseline is 5 points. Thus, the post-treatment Roland Morris scores in the present cohort may be considered clinically relevant and are in accordance with available Spanish data [210]. However controversial exists regarding effectiveness of exercises interventions for the prevention of low back pain. One study carried out for the prevention of low back pain using a back school-based education worksite intervention compared with the routine care demonstrated no added benefit [84]. By contrast, a reduction in LBP symptoms in

symptomatic LBP patients and occurrence of LBP symptoms in asymptomatic workers was achieved by an ergonomic intervention using a brochure on correct posture at computer workstations [211]. Furthermore, trunk muscle endurance tests have been frequently used to assess interventions to treat LBP and related symptoms [201], and the results correlate strongly with the degree of disability measured by the Roland Morris questionnaire. It has also been suggested that trunk muscle tests may predict the degree of functional disability and future episodes of LBP [170]. An explanatory model of the lumbar and abdominal muscle endurance tests was established to explain the differences found in the degree of disability between the control and the intervention group. As a result, we can explain the change after the intervention in the degree of disability as measured by Roland Morris questionnaire through the change after intervention in trunk muscle endurance tests. In the other hand, two previous studies reported that a face-to-face, supervised, land-based program delivered a beneficial effect on HRQoL, as measured by SF-36 in patients affected by both, chronic NLBP [83] and healthy workers [158]. The current study also reported a significant correlation between disability and HRQoL, in accordance with previous cross sectional studies involving patients with acute, sub-acute [150, 212] and chronic NLBP [212]. In our study, the observed changes in HRQoL measured with EQ-5D-3L are predicted by the Roland Morris questionnaire. These results are consistent with the significant correlation between the decrease in the number of episodes and the improvements in HRQoL and functional incapacity in the intervention group achieved in our subjects. In practical, these results provide new knowledge that may be directly applicable to health promotion in the workplace to improve back pain-related problems and associated costs.

Effects of the intervention on risk of chronicity prevention in office workers with non-specific LBP in the sub-acute phase (Study V)

An occupational, internet-based intervention to prevent chronicity in sub-acute lower back pain: a randomized controlled trial. Fewer studies have been conducted to tackle progression to chronicity in LBP patients and no studies in Spain exist on. Furthermore, despite importance [213], fewer studies have reported on treatment mediators of LBP outcome than have investigated prognostic factors [214]. However, there are no reports of real-time internet-based interventions focused specifically on secondary prevention of chronic LBP by targeting key modifiable prognostic indicators among office workers, to reduce costs and improve efficacy [215, 216]. Thus, in this sixth study we test the overall hypothesis that our model of occupational management for office workers with sub-acute, non-specific LBP reduced patients' overall risk status for chronicity when compared to conventional treatment, and, also determining which individual predictive factors were acting as the key treatment mediators for this risk reduction intervention.

Further the positive effects achieves on RMDQ and EQ-5D-3L (previously reported) after 9-month of the proposed treatment in the intervention group, were also achieve positive effects in the risk of chronicity (SBST 23% change; $p = 0.019$) respect to the control group. Significant reductions in the risk of chronicity of LBP, measured with SBST, were seen in the intervention group compared with the control group: 60.9% patients in the intervention group were SBST low-risk at 9 months, compared to 27.9% patients in the control group ($p < 0.01$). The ITT analysis (data not shown) gave similar results to the per-protocol analysis for all outcome measures of the current trial (table 18). A high level of correlation between outcomes of the study was observed (table 19). Also, the nine SBST items remained unchanged among the control intervention group, while the intervention group showed significant positive effects in disability items 4 and 5, and fear item 6 (p = 0.017, 0.008 and 0.049 respectively). There was a trend towards a decrease in all nine SBST items in the intervention group (table 20). The binary regression model demonstrated that the reduction in chronicity was primarily due to changes in SBST disability and fear avoidance items resulting from the intervention. This resulted in a 52%

change in the proportion who were low risk, with odds ratios of 0.166 (0.0638 to 0.431) ($p < .001$), 0.092 (.027 to 0.313) ($p < .001$), and 0.302 (0.107 to 0.853) ($p<.024$), respectively.

Table 18. Effects of 9-month of web-based multidisciplinary intervention on risk of chronicity of non-specific sub-acute low back pain among office workers *(n=90)

	Baseline		Post-treatment				
Outcomes measure	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	Treatment effect Mean (95%CI) or OR (95%CI)	*p* †	Effect size
SBST total score (points)	4.40 (1.71)	4.38 (1.48)	4.38 (1.03)	3.39 (1.39)	-1.01 (-1.790 to .118)	**.019**	.80
SBST psychological score (points)	2.36 (1.03)	2.28 (.98)	2.31 (1.09)	1.84 (.86)	-.39 (-.993 to -.215)	.201	.47
Risk of Chronicity							
Low risk, Yes (%)	31.8	23.9	27.9	60.9	3.38 (1.591 to 9.501)**	**.005**	--
Medium risk, Yes (%)	54.5	65.2	57.5	34.8	.40 (.169 to .946)**	.059	--
High risk), Yes (%)	13.7	10.9	14.8	4.3	.28 (.055 to 1.511)**	.122	--

*Values expressed as mean (SD); Tto: Euroqol-5 dimensions health-related quality of life questionnaire utility. Time Trade Off; RMDQ: Roland Morris questionnaire score; SBST: StarT Back Screening Tool; Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care; Item 1 is scored as positive if "very much" or "extremely" bothered is marked. Items 2–9 are positive if "agree" is marked. Psychosocial subscale items are 1, 4, 7, 8, and 9. Patients are allocated to the high risk group if the psychosocial subscale score is ≥4. The remaining patients are allocated to the low risk group if the overall tool score is <4 and to the medium risk group if the overall tool score is ≥4; --: not computable; ***p* †:** p values from ANOVA for repeated measures adjusted by baseline characteristics or x^2 to compare different between groups after 9-month web-based program; OR: Odd Ratios (Control group/Reminder group); **Applicable OR

Table 19. Correlation between severity of pain, risk of chronicity of pain, self-reported functional disability and self-reported health-related quality of life after treatment among office workers suffering by sub-acute, non-specific low back pain *(n=90)

Outcomes Measures	dSBST total score	dSBST psychological score	dRMDQ	dTTO	dLow risk	dMedium risk	dHigh risk
dSBT total score	1.000	**.699****	**.299****	**-.212***	**-.776****	**.449****	**.474****
dSBT psychological score		1.000	.111	-.117	**-.525****	.114	**.631****
dRMDQ			1.000	**-.612****	**-.361****	**.247***	.159
dTto				1.000	**.239***	-.151	-.126
dLow risk					1.000	**-.807****	**-.236***
dMedium risk						1.000	**-.384****
dHigh risk							1.000

*Pearson Correlations coefficients. dSBST total score: StarT Back Tool score total score difference after treatment; dSBST psychological score: StarT Back Tool psychological score difference after treatment; dRMDQ: Roland Morris questionnaire score difference after treatment; dTto: Time Trade off points differences after treatment; dLow risk: Low risk differences after treatment; dMedium risk: Medium risk differences after treatment; dHigh risk: High risk differences after treatment; *: Correlation is significant at .01 level; **: Correlation is significant at 0.001 level.

Research suggests that there is limited evidence supporting the use of exercise to prevent LBP episodes in the workplace [55]. There is a need to know, therefore, whether adequate, timely physical therapy in combination with psychosocial tasks has value as a secondary prevention [217]. In this regard, our results suggest that a real-time internet-based multidisciplinary intervention could prevent chronicity of LBP. These results are in agreement with some previous research showing improvements in back pain-related outcomes when exercise is combined with other modalities, such as cognitive behaviour intervention [217], functional movements, relaxation, or the integration of coping skills [218]. There were no differences in the psychological score of SBST between groups after treatment in our study, which was possibly due to the fact that treatment mediators associated with this part of the instrument were not strongly affected at baseline in our subjects [213]. In the other hand, in previous studies carried out in patients with sub-acute non-specific LBP, significant correlations between risk of chronicity, self-reported functional disability, and health-related quality of life were reported [150, 212]; these results are in accordance with our data when we the correlation coefficients

between these variables are taken into account. Furthermore, the results highlighted through the logistic binary regression model performed in this study are in accordance with other studies, where a multidisciplinary intervention has been shown to be effective in decreasing the risk of chronicity by improvements in prognostic factors of persistent LBP, such as fear avoidance [219] or disability [88]. These results could be explained in part by the design of our intervention, where we introduced a graded exercise series (with variation in the density of the exercises) in order to decrease fear-avoidance beliefs and disability values reported at baseline in our subjects, and thus increase the effectiveness of our intervention in reducing the risk of chronicity [213]. George and colleagues [219] performed a randomised trial comparing standardised physical therapy with or without the inclusion of graded exercises designed to reduce pain-related fear. A significant interaction between elevated fear avoidance beliefs and treatment outcome was reported, suggesting the baseline level of fear-avoidance beliefs was a treatment effect modifier for physical therapy incorporating graded exercises [122]. In practical terms, this study supports the feasibility and potential utility of a well-accepted real-time occupational web-based intervention for preventing progression to chronicity of sub-acute non-specific LBP among office workers. The current study provides new insights that could help private and public office environment managers in the prevention of negative consequences of non-specific LBP in sub-acute phases.

Table 20. Effects of 9-month of web-based multidisciplinary program on SBST 9-item scores * (n=90)

Outcomes measure	Baseline		Post-treatment			
	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	*p* †	OR (95% Interval confidence)
	Mean ± (SD)	Mean ± (SD)	Mean ± (SD)	Mean ± (SD)		
SBST global-related items (low risk)						
Referrer leg pain (item 2)	43.2	47.8	45.5	39.1	.544	.771 (.334 to 1.784)
Co-morbid pain (item 3)	40.9	45.7	36.4	37.0	.953	1.026 (.435 to 2.419)
Functional Disability (item 5)	61.5	63.0	68.2	43.5	**.008**	.308 (.127 to .748)
Functional Disability (item 6)	56.8	52.2	54.5	34.8	**.049**	.444 (.190 to 1.058)
SBST psychosocial-related items (Medium/High risk)						
Bothersomeness (item 1)	22.7	26.1	25.0	23.9	.905	.943 (.360 to 2.466)
Fear avoidance (item 4)	72.7	73.9	70.5	45.7	**.017**	.352 (.148 to .840)
Catastrophising (item 7)	52.3	50.0	50.0	43.5	.535	.769 (.335 to 1.764)
Anxiety (item 8)	43.2	52.2	47.7	47.8	.993	1.004 (.439 to 2.296)
Depression (item 9)	45.5	39.1	38.6	23.9	.132	.499 (.201 to 1.239)

*Values expressed as percentage (%) of agreement; SBST: Start Back Screening Tool; Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care; Item 1: question 1 of SBST; Item 2: question 2 of SBT; Item 3: question 3 of SBST; Item 4: question 4 of SBST; Item 5: question 6 of SBST; Item 7: question 7 of SBST; Item 8: question 8 of SBST; Item 9: question 9 of SBST; OR: Odds Ratios (Control group/Reminder group); *p* †: p values from x^2 test to compare different between groups after 9-month intervention

Association between clinical changes in HRQoL and specific outcomes in non-specific, LBP in the sub-acute phase after intervention (Study VI)

Are clinical changes in EQ-5D-3L reflecting clinical changes in specifics low back pain outcomes? A 9-month web-based randomized controlled trial on sub-acute, non-specific low back pain patients. Since non-specific lower back pain is associated with a lower HRQoL [36], increased functional disability [35], and increased time off work [36], its prevention is a priority [220]. Self-rated recuperation from back pain has been shown to depend on the cognitive judgment of the individual regarding the impact of symptoms on their ability to successfully perform daily activities [221], and functional tasks were found to be important outcome markers for patients with back pain [222]. HRQoL is also unique to the individual, and thus the relevant domains that comprise HRQoL constructs must take into account the issues that are important to the individual. Moreover, if function plays an important role in HRQoL [151, 223], there should be a clear association between changes in functional ability and changes in general health. Proving that such a link exists would allow patient-specific HRQoL scores to serve as an aim of treatment, which may improve the outcomes of the disease. However, it remains unclear whether EQ-5D-3L can be used for such purposes. Moreover, the association between physical and psychological clinical changes and HRQoL in patients with LBP after interventions is not fully understood.

Further to the improvements achieved in specific LBP outcome chosen in this study after 9-month treatment (self-reported functional disability and risk of chronicity), relative to the control group, the intervention group participants improved significantly in terms of most of the EQ-5D-3L components (table 21). In overall, relative to the control group, the intervention group participants were more likely to exhibit improvements LBP-related outcomes and HRQoL components (table 22). Moreover, compared to the control group, intervention group participants whose self-reported functional disability improved were also more likely to experience changes in the EQ-5D-3L mobility dimension and clinically changes EQ-5D-3L utility score. Similarly, intervention group participants whose self-reported risk of chronicity improved were more likely to experience changes in the EQ-5D-3L pain/discomfort dimension, the EQ-5D-3L anxiety/depression dimension, and the EQ-5D-3L VAS and clinically changes in EQ-5D-3L utility score when compared to the control group (table 22).

Outcomes measure	Baseline		Post-treatment			
	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	Treatment effect Mean (95%CI) or OR (95%CI)	p †
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
ODI (%)	28.77 (2.69)	28.13 (2.23)	33.72 (3.14)	19.80 (2.23)	13.28 (7.341 to 16.451)	<.001
SBST (score)	4.40 (1.71)	4.38 (1.48)	4.38 (1.03)	3.39 (1.39)	-1.01 (-1.790 to .118)	.019
VAS (points)	59.22 (11.96)	59.25 (11.38)	55.97 (12.97)	67.34 (10.54)	4.84 (2.121 to 6.451)	<.001
EQ-5D-3L utility (points)	.78 (.08)	.75 (.11)	0.75± (0.11)	0.97± (0.04)	0.16 (0.069 to 0.191)	<.001
Mobility, n, problems (%)*	33 (75)	34 (73,1)	30 (68.2)	21 (45.7)	.392 (.166 to .926)**	.031
Personal care, n, problems (%)*	11 (25)	17 (37)	15 (34.1)	13 (28.3)	.762 (.311 to 1.863)**	.550
Daily tasks, n, problems (%)*	16 (36.4)	14 (30.4)	14 (31.8)	4 (8.7)	.204 (.061 to .682)**	.006
Pain/Discomfort, n, problems (%)*	17 (38.6)	24 (52.2)	26 (31.8)	11 (23.9)	.218 (.088 to .538)**	<.001
Anxiety/ Depression, n, problems (%)*	13 (29.5)	17 (37)	15 (34.1)	7 (15.2)	.347 (.125 to .960)**	.037

ODI: Oswestry disability questionnaire; SBST: StarT Back Screening Tool (score); VAS: Visual analogical score from Euroqol-5D quality of life questionnaire (0, worst health status to 100, best health status); EQ-5D-3L utility: Euroqol-5D-3L quality of life questionnaire utility index. Time Trade Off; *: Dimensions from Euroqol-5D quality of life questionnaire collapsed in no problems (value 1 of the dimension) and problems (values 2 and 3 of the dimension); Control group: group that had access to usual

Table 21. Effects of intervention on Health-related Quality of life dimensions and outcomes (n=90)

treatment; Intervention group: group that had access to the proposed treatment and usual care ;--: not computable; p †: p values from ANOVA for repeated measures adjusted by baseline characteristics or x2 to compare different between groups after 9-month web-based program; OR: Odd Ratio (Control group/Intervention group); **Applicable OR

Linear regression models revealed that the change in EQ-5D-3L utility score after the 9-month intervention can be predicted (45%; p<.001) by the Oswestry disability index after the 9-month treatment; it can also be predicted by the change in the SBST after the 9-month treatment (19%; p<.001). Oswestry disability index (p=.003) and SBST (p=.035) changes after 9-month treatment predicted changes in EQ-5D-3L utility score (45%) after 9-month treatment. Table 23 displays the data of the binary logistic regressions that were performed to determine how much of the variance in clinical changes in EQ-5D-3L utility score after the 9-month treatment can be explained by the Oswestry disability index and the SBST values. Thus, the clinical changes in EQ-5D-3L utility score can be explained by clinical changes in the Oswestry disability index (20%, p=0.009), by the SBST (17%, p=.001), and by both the Oswestry disability index (p=.011) and the SBST (p=.002) (32%). The binary regression model shows that when EQ-5D-3L utility score exhibits a clinical change, the Oswestry disability index and the SBST scores are 15.5- and 4.5-times more likely, respectively, to exhibit clinical changes as well.

Table 22. Association between positive changes in EQ-5D-3L components after the 9-month treatment and positive clinical changes in self-reported functional disability or positive clinical changes in the risk of chronicity (n= 90)

	ODI clinical positive change after 9-month treatment			StarT Back Screening Tool clinical positive change after 9-month treatment		
Health-related quality of life components	Odd Ratio yes/no (95% Confidence Interval)	Percentage (%) of the risk for the association	*p†*	Odd Ratio yes/no (95% Confidence Interval)	Percentage (%) of the risk for the association	*p†*
Mobility*	**2.782 (1.001 to 7.849)**	**73**	**.048**	1.733 (.749 to 4.007)	63	.197
Self-care*	1.710 (.559 to 5.262)	63	.343	2.082 (.742 to 5.843)	67	.159
Daily tasks*	2.154 (.724 to 6.404)	68	.162	1.773 (.653 to 4.816)	64	.258
Pain/Discomfort*	**4.125 (1.454 to 11.702)**	**80**	**.006**	**4.066 (1.501 to 11.010)**	**80**	**.004**
Anxiety/Depression*	2.361 (.787 to 7.084)	70	.119	**2.771 (1.002 to 8.044)**	**73**	**.050**
VAS	1.314 (.467 to 3.696)	43	.605	**2.780 (.1.161 to 6.655)**	**74**	**.020**
EQ-5D-3L utility	**16 (2.029 to 126.182)**	**94**	**.001**	**4.933 (1.928 to 12.624)**	**83**	**.001**

*: Dimensions collapsed in no problems (value 1) and problems (values 2 and 3); ODI: Oswestry disability questionnaire; VAS: Visual analogical score from Euroqol-5D quality of life questionnaire (0, worst health status to 100, best health status) after treatment; EQ-5D-3L utility: Euroqol-5D-3L quality of life questionnaire utility index positive clinical change; p ***†*****:** p values from chi square test.

Percentage (%) of the risk for the association calculated as Odd ratio/Odd ratio+1

Table 23. Binary logistic regressions examining the ability of functional disability and/or risk of lower back pain chronicity to explain the variance in EQ-5D-3L utility index changes after the 9-month web-based multidisciplinary intervention (n=90)

MODEL A (-2 Log likelihood= 104.462; Cox & Snell R Square= .14; Nagelkerke R Square= .20)					
	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
ODI clinical positive change	2,773	1,054	6,924	16 (2.029 to 126.182)	.009
Constant	-5,717	2,066	7,658	.003	.006
MODEL B (-2 Log likelihood= 106.110; Cox & Snell R Square= .13; Nagelkerke R Square= .17)					
	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
SBST clinical positive change	1,596	,479	11,084	4.933 (1.928 to 12.62)	.001
Constant	-3,010	,803	14,061	.049	<.001
MODEL C (-2 Log likelihood= 94.249; Cox & Snell R Square= .24; Nagelkerke R Square= .32)					
	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
ODI clinical positive change	2.725	1.074	6.439	15.258 (1.859 to 125.208)	.011
SBST clinical positive change	1.558	.508	9.405	4.748 (1.754 to 12.848)	.002
Constant	-8.035	2.287	12.338	.000	<.001

ODI: Oswestry disability questionnaire; SBST: StarT Back Screening Tool; OR: Odd ratios; CI: confidence interval; ***p †*:** p values from chi square adjusted by baseline characteristics.

Results found in the current study are in line with the outcomes of another multidisciplinary intervention that exercised the same muscles trained by the present intervention and that was developed to improve the self-reported health status of subjects with chronic lower back pain [224]. The positive effects observed in the subjects participating in the present study may be due in part to the reduction in their functional disability, and in part to the relationship between functional disability and the expectations patients have regarding their health [223]. Subjects who experienced a clinical change in the Oswestry disability questionnaire were more likely to experience a clinical change in the EQ-5D-3L index than patients who experienced a change in the SBST. This may reflect the nature of the intervention used in the present study, which

focused on physical exercise but did not employ any specific psychological approaches. Supporting this is that the psychological domain of the SBST did not exhibit any significant changes at the end of the intervention (data not shown). Moreover, the Oswestry disability index and the SBST associated with different EQ-5D-3L dimensions: clinical changes in the Oswestry disability index questionnaire were associated with the mobility dimension while SBST changes were associated with the anxiety/depression dimension. Unsurprisingly, however, both the Oswestry disability index and SBST clinical changes showed similarly strong associations with the pain/discomfort dimension. Thus, this dimension appears to relate to the severity of the disease [151]. The logistic regressions performed in the present study showed that the two specific outcomes used here complement each other in explaining the clinical changes in the EQ-5D-3L: the clinical changes in these specific outcomes explained more of the variance of the clinical change in the health index when they were combined than when they were used in isolation. However, the linear regressions also showed that clinical changes in the Oswestry disability index that were achieved by the intervention were lower than the non-clinical changes. This suggests that higher intensity programs may be required to produce clinical changes in those who did not achieve them with the present intervention. With regard to the SBST, the clinical changes achieved by the intervention were similar in size to the non-clinical changes; this reinforces the idea that more psychosocial components are needed. Thus, rehabilitation programs that differ in intensity and components may exert different effects on HRQoL dimensions [224]. This suggests in turn that intervention programs should be developed in line with the demands of different lower back pain manifestations (e.g., acute or chronic lower back pain) [24]. This study shows, for the first time, that EQ-5D-3L may be a useful health outcome measure for patients with non-specific sub-acute lower back pain. Thus, therapists could target patient-specific HRQoL scores as an aim of treatment (although this should be done with caution), which could improve the specific lower back pain outcomes of patients. Greater awareness of the cost-effectiveness and cost-utility of this approach is also required at the political level to encourage appropriate health and social policies.

Effects of the intervention on exercise-related behaviour in office workers with non-specific LBP in the sub-acute phase (Study VII)

A tailored web-based exercise programme for office workers with low back pain influences stage of change in behaviour: a randomised controlled trial. Several studies in the general population have evaluated web-based work-place health promotion interventions aimed at improving self-reported health status, promoting a healthy lifestyle, or improving lifestyle-behaviour [215, 216, 225]. Some studies have used an e-mail reminder to improve patient´s adherence [206, 226, 227]. However, the effectiveness of such interventions in special populations is not yet established. Therefore, in this seventh study, we hypothesised that this online, real-time intervention would improve exercise-related behaviour in this population, and that this improvement would be correlated with improvements in functional ability and self-reported health status.

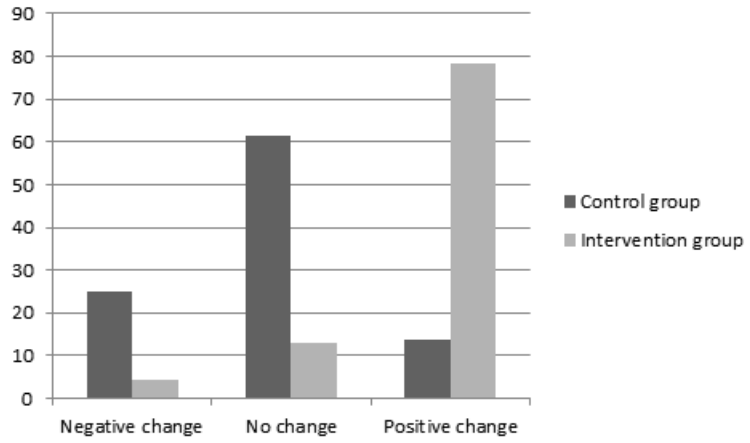

Figure 6. Global changes in exercise-related behaviour among participants in the study

In the intervention group, significant positive effects were found for mean scores for all phases in the behaviour domain (Table 24). Figure 6 shows the difference between treatments in terms of the global stage of change. In the intervention group, significant positive effects were found for stage of change in behaviour at 9-month follow up ($p<.001$). Table 25 shows the Pearson correlation coefficients for the study outcome measures. A high correlation was found between VAS and global stage of change at 9-months (r= -.612). Moderate correlation was found between ODI and global stage of change at 9-months (r= .388).

Table 24. Effects of 9-month of web-based intervention on behaviour domain* (n=90)

	Baseline		Post-treatment		
Outcomes measure	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	*p* **†**
Stage of Change					
Pre-contemplation, *yes, n* (%)	20 (45.43)	19 (41.30)	28 (63.64)	2 (4.34)	**<.001**
Contemplation, *yes, n* (%)	21 (47.71)	19 (41.30)	3 (6.81)	6 (13.04)	**.291**
Preparation, *yes*, *n* (%)	3 (6.81)	6 (17.40)	11 (25.00)	3 (6.52)	**.020**
Action, *yes, n (%)*	0	0	2 (4.55)	11 (23.91)	**.007**
Maintenance, *yes, n (%)*	0	0	0 (0)	24 (52.20)	**<.001**

*Values expressed as %; *p* **†:** p values chi square analysis

Table 25. Pearson correlation coefficient between global stage of change, self-reported functional disability levels and self-reported health status after treatment among office workers suffering sub-acute non-specific low back pain * (n=90)

Outcomes Measures	Global stage of change (%)	dODI	dVAS
Global stage of change (%)	1.000	**.388****	**-.612****
dODI		1.000	**-.522****
dVAS			1.000

*Pearson Correlations coefficients. Global stage of change: participants whose change their behavior status after treatment; dOswestry questionnaire: Oswestry disability questionnaire score difference after treatment; VAS: Visual analogical scale points differences after treatment; **: Correlation is significant at 0.001 level.

Although our University offers a range of out-of-work general physical activity programmes to its employees and its occupational preventive service offers advice concerning enhancement of physical activity, all of the study participants were physically untrained at baseline. The high level of adherence observed in the intervention group may have been due to the specificity of our occupational intervention (for secondary prevention of LBP) [228]. Participants in the intervention group performed an 11-min session addressing health education and physical activity 5-days per week. Previous research suggests that exercise programmes of short duration are preferable for employees who work long shifts [55]. The current intervention has previously revealed the effectiveness on improve self-reported health status and functional disability perception. The correlation model used to determine the correlation between the investigated variables revealed that the change in the behaviour domain was correlated with functional disability perception and self-reported health status. Maybe the improvement observed in the intervention group regarding functional disability perception could affect self-reported health status [151] and these improvements affect the behaviour of participants in the study. Current work-place health promotion programmes attempt to combine traditional methods of addressing health and safety through legislation and regulation with the tackling of voluntary lifestyle practices [66]. The guidelines underlying these programmes stress the need for transfer of knowledge and clarification of where health promotion resources can be found [229]. Within this context, the present intervention could be viewed as a strategy for tackling LBP-associated problems among office workers by increasing exercise-related behaviour at workplace.

Study limitations

The Spanish version of SBST was obtained using a sample from the general population of equally distributed younger and older adults and participants with and without non-specific LBP. However, one weakness was that the current study did not test the translated tool's ease of understanding among individuals with cognitive difficulties or whose pain was controlled using pain medication [230]. According to Andresen EM et al., subjects with previous episodes of non-specific LBP and elderly people report a poor self-rated Health and it is very important to study cognitive responses in elderly people in health related questionnaires [231], and some authors propose developing questionnaires with help of elderly people as their comprehension is essential [232]. The measurement of the properties of the translated SBST including reliability, validity and feasibility among the Spanish population is necessary. (Study I).

Related to cross-sectional phase of study, selection bias need to be addressed in this study since a cross-sectional study comparing two different groups is used and could produce a systematic error due to a non-random sample of a population. Despite this, we choose an age-matched group of control participants in order to minimize the selection biases [233] (Studies II and III). Although the sample size in cross-sectional phase of the current work was in accordance with our calculations and was sufficient to detect differences in most measures, it was unable to detect differences in the sit-and-reach test in men. There is some controversy regarding this test in the scientific literature. The inability to detect significant differences in this test could be due to the influence of the gastrocnemius muscles, which play an important role in the sit-and-reach test, and could be due to differences between men and women in this test [234]. The greater hamstring muscle extensibility of women and its influence on the hip range of motion and spinal curvature could partly explain these differences [235]. The absence of any significant difference in pain and discomfort as measure by EQ-5D-3L could be due to irregular menstrual cycles or unhealthy lifestyles (e.g., low fitness, smoking habits) causing pain and discomfort [236], although we have little evidence to support this explanation. We did not control for menstrual cycle, and the levels of physical inactivity and smoking were similar in both groups (Study II). Regarding validity of lumbar and abdominal trunk muscle endurance as screening tools, the design of this sub-study does not allow us to generalise in determining cut-off points for the more physically active LBP patients, and more studies are needed to

determine the cut-off point in these patients. Finally, the selection of cut-off points in our study was based on an equivalent relative assignment of importance for sensitivity and specificity. Additional cost-utility studies are required to obtain criteria for similar studies under different sensitivity and specificity conditions, with the aim of adjusting the diagnostic criteria based on the allocation of resources in the different possible cases. Additional studies are also needed to determine if the test scores obtained in this study are consistent in other populations affected by LBP (e.g., chronic) (Study III). The external validity of this phase also needs to be considered. Population-based sample strategies, which limit any generalizations about normative values, were not used. However, the socio demographic, functional disability and HRQoL profiles of patients suffering from sub-acute, non-specific LBP were consistent with those reported in a large study that was performed in Spain by the National Health System [31].

The randomised controlled trial phase of this thesis work also present several limitations. First, we did not take in to account factors that may affect feasibility such as participant satisfaction, context, and dose received [237]. However, we experienced a high level of compliance, suggesting these factors have a positive influence on the level of feasibility found in our study. The gender bias in the study, with considerably more females than males enrolled, reflects the higher percentage of female workers affected by this ailment [112]. Emails reminder was used in the intervention group and high adherence was reach in this group. A limitation in this sense need to be acknowledge regarding the real effectiveness of this method in LBP population due we did not compare the effects with a group without email reminder. On the other hand, since the EQ-5D-3L in a generic HRQoL measure and was not specifically designed for low back patients, the lack of association between clinical changes in specifics outcomes for LBP with the majority of dimensions may reflect this limitation (Studies IV, V, VI and VII). However, the positive association between the overall EQ-5D-3L (utility index) and the specific outcomes for LBP take into account in this study, although with cutely, suggest the useful of EQ-5D-3L utility index as a health outcome in LBP patients. It may therefore be time to develop of a LBP-specific HRQoL instrument and further studies in this direction should be encouraged [238] (Study VI). Back pain-related behaviour need also to be limit. An e-mail containing a link to the URL of the session of the day was sent to remind the intervention group participants each day, and to encourage performance of the exercises. Although this reinforcement was done by non-

behaviour stage of change-based message, our data indicate that there was a positive improvement in the behaviour domain in terms of exercise. In accordance with our data, Heelen et al. [239] found that a web-based physical activity intervention carried out at the work-place improved the level of physical activity and lifestyle-behaviour among a population of healthy office workers, although addition of a tailored e-mail in comparison with standard advice did not influence outcome. Further research is needed to determine whether tailored interventions including an e-mail reminder that are based on behaviour change theories are more effective than the present intervention. Since most of the participants in the intervention group wished to continue with the present programme, we did not enquire whether they would like to participate in other types of exercise programmes. Despite this, a first step towards greater physical activity among physically untrained office workers was successfully achieved in the intervention group. Further research is warranted to elucidate whether this strategy for promoting LBP-specific exercise in physically-untrained office workers could be used to promote a more physically active lifestyle in general, or other types of exercise. (Study VII). The external validity of the trial phase also needs to be well thought-out. First, this intervention was delivered in the Preventive Occupational Service of the University; only one setting was used, and we did not know if this intervention would be feasible and effective in other setting. However, the scientific literature shows that specific medical counseling seems to be a key element in the delivery of interventions to enhance inactive people's physical activity [240]. Second, this study was conducted in a predominantly white, urban, south European community; therefore, it may not be possible to generalize the outcomes to workplace programs in all communities. Cross-cultural analyses testing the effectiveness of our intervention are warranted. Further studies are also needed to compare the efficacy of our intervention in different patient populations affected by LBP (e.g., chronic patients) and to examine its cost effectiveness as a public health strategy for preventing persistent LBP in the workplace and its associated costs. Despite this limitation, this study provides practical information of importance to worksite programs in the large number of communities with similar demographic characteristics (Studies IV, V, VI and VII).

CONCLUSIONS

I. The Spanish version of SBST is a reliable and feasible version for the evaluation of risk of chronicity of non-specific LBP in adults and elderly (**Study I**).

II. Office workers with sub-acute non-specific LBP have poor fitness profile (especially in regard of lumbar and abdominal trunk muscle endurance) and poor HRQoL levels (except pain in women) than those age-matched office workers without LBP (**Study II**).

III. Lumbar and abdominal trunk muscle endurance tests are reliable and valid measures in the assessment in the work-age population affected by sub-acute, non-specific low back pain for both men and women (**Study III**)

IV. The addition to usual preventive care of a 9-month of our developed occupational web-based multidisciplinary intervention is feasible, safe and effective to increase functional ability, HRQoL, trunk muscle endurance and to decrease episodes of sub-acute non-specific LBP office workers affected when compared to conventional treatment (**Study IV**).

V. The addition to usual preventive care of a 9-month of our developed occupational web-based multidisciplinary intervention is feasible, safe and effective to for preventing progression to chronicity of sub-acute non-specific LBP among office workers (**Study V**).

VI. The addition to usual preventive care of a 9-month of our developed occupational web-based multidisciplinary intervention is effective to improve HRQoL dimensions of non-specific, sub-acute LBP patients. Furthermore, clinical EQ-5D-3L changes related to clinical changes in specific lower back pain outcomes (**Study VI**).

VII. The addition to usual preventive care of a 9-month of our developed occupational web-based multidisciplinary intervention improved exercise-behaviour among physically untrained office workers with non-specific sub-acute LBP. Moderate to high correlation was found between behaviour respect to the Oswestry disability index and self-reported health status (**Study VII**).

SPANISH SUMMARY AND CONCLUSIONS [RESUMEN Y CONCLUSIONES EN ESPAÑOL]

RESUMEN

El dolor de espalda bajo (en la mayoría de los casos de causa desconocida) afecta a la calidad de vida individual, a la familia, las relaciones sociales y a la capacidad para trabajar. A nivel económico, el impacto es muy alto en España. Se estima que el coste medio anual total por las jornadas no trabajadas debido a dolor de espalda bajo inespecífico representa un 11% del dinero devengado en el total por incapacidad temporal, llegando a 195 millones de euros al año. Este coste es soportado por el escaso porcentaje de pacientes que desarrollan síntomas crónicos (10%). En trabajadores de oficina, el dolor de espalda bajo inespecífico está presente en un 35% de los casos. Existe una necesidad de ayudar a controlar el impacto que éste produce. La evidencia científica sugiere que el ejercicio físico como parte de intervenciones multidisciplinares, puede ayudar a mejorar la calidad de vida de quienes padecen ésta enfermedad y a controlar el gasto derivado de la misma. En este sentido, un recurso económico y que ya ha mostrado ser efectivo en población general para incrementar los niveles de condición física son las intervenciones en el puesto laboral a través de internet. Aunque esto no este tipo de intervenciones no han sido probadas en población con de espalda bajo. Por otro lado, no existen herramientas disponibles para valorar el riesgo de cronicidad del dolor lumbar inespecífico adaptadas a nuestra lengua. Además, no existen referencias sobre los perfiles de condición física y calidad de vida relacionada con la salud en pacientes afectados por dolor de espalda bajo inespecífico en la fase subaguda. Se carecen además de datos de validez respecto a las pruebas usadas para valorar la resistencia de los músculos del tronco, importantes para monitorizar el progreso de la funcionalidad de los pacientes afectados por de espalda bajo.

El objetivo general de la presente memoria de Tesis es en primer lugar investigar y adaptar la herramienta anglosajona SBST para su uso en población española con el fin de evaluar el riesgo de cronicidad de dolor de espalda bajo inespecífico. En segundo lugar; caracterizar los perfiles de condición física y calidad de vida de trabajadores de oficina y validar el test de evaluación de la resistencia tanto lumbar como abdominal (Shirado Ito) en esta población. Por

último, testar los efectos de 9 meses de una intervención vía web basada en ejercicio físico y recordatorio postural sobre los problemas asociados al dolor lumbar inespecífico en la fase subaguda.

La muestra que ha participado en los estudios incluidos en la presente memoria de tesis está compuesta por 190 hombres y mujeres (72 asintomáticos y 118 diagnosticados con dolor de espalda bajo inespecífico en fase subaguda en el momento de la inclusión en los estudios) trabajadores (administrativos) de la Universidad de Extremadura. Las medidas tomadas fueron: características sociodemográficas, una batería de condición física relacionada con la condición musculo-esquelética, los cuestionarios Roland Morris, Oswestry, EQ-5D-3L, SBST, Estadio de cambio de comportamiento y el número de episodios de dolor de espalda bajo en línea base y tras 9 meses.

Los principales resultados de la presente memoria de tesis sugieren: a) el potencial uso de la herramienta SBST en población española, b) los trabajadores de oficina afectaos por dolor de espalda bajo inespecífico en fase subaguda presentan peores perfiles de calidad de vida y de fitness que sus pares sin dicha afección, c) el test de Shirado Ito (lumbar y abdominal) es válido y fiable para su uso en trabajadores de oficina afectaos por dolor de espalda bajo inespecífico en fase subaguda y d) la intervención diseñada mejoró la calidad de vida relacionada con la salud, la capacidad funcional, la resistencia muscular del tronco y disminuyo el riesgo de cronicidad de la afección y los episodios de dolor de espalda bajo de los pacientes tratados en comparación con el tratamiento preventivo habitual.

En conclusión la presente memoria de tesis aporta nuevo conocimiento en relación a la evaluación y el asesoramiento de pacientes afectados por dolor de espalda bajo inespecífico en fase sub-aguda. Por otro lado, la nueva intervención diseñada es segura, aplicable y efectiva para tratar el dolor de espalda bajo inespecífico y minimizar sus problemas asociados en trabajadores afectados por esta patología en fase subaguda.

CONCLUSIONES

I. La versión española del SBST es utilizable para evaluar el riesgo de cronicidad del DEB inespecífico en población adulta y población mayor (**Estudio I**).

II. Los trabajadores de oficina afectados por DEB inespecífico en fase sub-aguda presentan peores perfiles de condición física y calidad de vida relacionada con la salud que sus pares sin dicha afección (**Estudio II**).

III. Tanto el test de resistencia lumbar y abdominal han mostrado ser válidos y fiables para su aplicación en trabajadores afectados por DEB inespecífico en fase sub-aguda (**Estudio III**).

IV. La adición al cuidado habitual de 9 meses de nuestra intervención multidisciplinar basada en la web es segura, aplicable y efectiva para incrementar los niveles de funcionalidad, CVRS y de resistencia tanto lumbar como abdominal además de reducir los episodios de DEB de trabajadores de oficina afectados por DEB inespecífico en fase sub-aguda cuando lo comparamos con los cuidados estándar (**Estudio IV**).

V. La adición al cuidado habitual de 9 meses de nuestra intervención multidisciplinar basada en la web es segura, aplicable y efectiva para reducir el riesgo de cronicidad del DEB de trabajadores de oficina afectados por DEB inespecífico en fase sub-aguda cuando lo comparamos con los cuidados estándar (**Estudio V**).

VI. La adición al cuidado habitual de 9 meses de nuestra intervención multidisciplinar basada en la web es segura, aplicable y efectiva para mejorar las diferentes dimensiones de CVRS. Además los cambios clínicos en el EQ-5D-3L reflejan los cambios en las medidas principales para el DEB. (**Estudio VI**).

VII. La adición al cuidado habitual de 9 meses de nuestra intervención multidisciplinar basada en la web es segura, aplicable y efectiva para mejorar el nivel de comportamiento relacionado con el ejercicio físico de DEB de trabajadores de oficina afectados por DEB inespecífico en fase sub-aguda cuando lo comparamos con los cuidados estándar. Existe una relación de moderada a alta entre estas mejoras y los cambios observados en el nivel de funcionalidad y de CVRS tras la intervención diseñada (**Estudio VII**).

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PUBLICATIONS

Under this section are presented the full version of the publications comprising this thesis work in the form that has been previously published/submitted (or prepared to be submitted) in international scientific journals and books.

EJERCICIO FÍSICO Y SALUD EN POBLACIONES ESPECIALES. EXERNET

CAPÍTULO: *EJERCICIO FÍSICO Y DOLOR LUMBAR INESPECÍFICO OCUPACIONAL*

(En prensa)

Resumen: El dolor lumbar (en muchos casos de causa desconocida) afecta a la calidad de vida individual, a la familia, las relaciones sociales y a la capacidad para trabajar. A nivel económico, el impacto es muy alto. Se estima que El coste medio anual total por las jornadas no trabajadas debido a dolor lumbar inespecífico representa un 11% del dinero devengado en el total por incapacidad temporal, llegando a 195 millones de euros al año. Este coste es soportado por el escaso porcentaje que se vuelve crónico (10%). Existe una necesidad de ayudar a controlar el impacto que el dolor lumbar produce. En este sentido, la evidencia sugiere que el ejercicio físico puede ayudar a mejorar la calidad de vida de quienes padecen ésta enfermedad y a controlar el gasto derivado de la misma. En este capítulo se muestran resultados prometedores procedente de dos investigaciones gestadas en el grupo de investigación AFYCAV: un programa basado en la web para trabajadores de oficina con dolor lumbar inespecífico subagudo y un programa de vibraciones corporales para pacientes con dolor lumbar inespecífico crónico. Estos estudios pueden servir como puntos de partida para desarrollar futuras estrategias para la prevención de los dolores lumbares.

Palabras clave: dolor lumbar, puesto laboral, calidad de vida relacionada con la salud, enfermedad musculo esquelética.

CHAPTER X: PHYSICAL EXERCISE AND OCCUPATIONAL LOWER BACK PAIN

Abstract: Lower back pain (in most cases from unknown origin) affects to individual's quality of life, family and social relationships, and ability to work. In economic terms, the problem is huge in Spain. It is estimated that total annual average cost for the sickness absence caused by lower back pain accounts 195 million of euros/year. The bulk of the total cost from the disease is caused by patients who turn to chronic conditions. Experts acknowledge the necessity to management of this ailment. Take this statement into account, scientific evidence support that physical exercise can help to improve health-related quality of life of patients who have affected and reduce the socio-economic impact from the disease. This chapter shows promising results from two studies generated in the AFYCAV research group: a 9-month web-based program for office workers with non-specific sub-acute lower back pain and a 12-week whole body vibration program applied in non-specific chronic lower back pain patients. The results from the studies could serve as case-studies to develop future Public Health Strategies in the lower back pain prevention field.

Key words: backache, workplace, health-related quality of life, musculoskeletal disorder

Tratar de encontrar soluciones al dolor crónico (completas para prevenirlo o parciales para atenuar sus efectos) es uno de los mayores retos de la investigación actual (1). Cuando el dolor persiste durante semanas o meses, el efecto sobre el bienestar puede ser ingente, llegando a deteriorar tanto la salud física como mental e incluso el desempeño de las responsabilidades sociales como el trabajo y la familia (2). Por otro lado, parece que el dolor crónico va en aumento (3, 4), y aunque se ha avanzado en el manejo del mismo (5), encontrar nuevas estrategias que ayuden al diagnóstico y tratamiento es fundamental para atenuar el impacto que este presenta en todos los ámbitos de la vida (6-8). De entre todas las afecciones que cursan con dolor crónico, las enfermedades reumáticas o musculoesqueléticas son las más comunes en Europa entre la población adulta. Si atendemos al Eurobarómetro de 2006, el 27% de la población europea sufre alguna forma de enfermedad crónica reumática, y entre ellas la lumbalgia es la más frecuente (9). Según el último estudio realizado por la Sociedad Española de Reumatología (estudio EPISER), la prevalencia de la lumbalgia es del 44,8%, la de artrosis de rodilla del 10,2%, la de artrosis de manos del 6,2%, la de osteoporosis del 3,4%, la de fibromialgia del 2,4% y la de artritis reumatoide del 0,5%, afectando más a mujeres que hombres y más en personas con bajos niveles tanto socio-culturales como socio-económicos aumentando con la edad (tabla 1); y es que de la población europea que recibe algún tratamiento crónico, en el 32% es por estas enfermedades, sólo superadas por la hipertensión (10, 11).

Tabla 1. Frecuencia de las enfermedades reumatoides más importantes en la Población española distribuida por edad

	Intervalo de edad						
Afección	20-29	30-39	40-49	50-59	60-69	70-79	≥ 80
Artritis reumatoide	1 (.2)	1 (.2)	2 (.5)	1 (.3)	3 (1.0)	1 (.5)	1 (2.7)
Dolor de espalda bajo	29 (8.9)	53 (16.3)	57 (17.5)	64 (21.2)	69 (21.2)	40 (12.3)	13 (4.0)
Osteoartritis de rodilla	2 (.4)	3 (.7)	13 (3.5)	32 (9.8)	88 (28.1)	69 (33.7)	16 (21.3)
Osteoartritis de mano	--	--	4 (1.1)	22 (6.7)	48 (15.3)	49 (23.9)	13 (17.3)
Fibromialgia	--	7 (1.6)	18 (4.9)	12 (3.7)	9 (2.9)	6 (2.9)	--

Valores expresados como porcentaje (%)± DE

Fuente. Adaptado de Carmona y cols. (2001)

En España, además de las consecuencias que estas enfermedades presentan sobre la función normal y la calidad de vida relacionada con la salud (CVRS) de los sujetos que la padecen, el impacto sobre el consumo de recursos sanitarios (consultas médicas, ingresos hospitalarios, medicamentos) es imponente, representando además una carga a la sociedad en términos de empleo en edad trabajadora.

Tabla 2. Visitas al médico por problemas musculoesqeuléticos, consumo de AINE, y compensaciones por discapacidad relacionada con afecciones musculoesqueléticas específicos en población española

	En el pasado año			
	Consultó al médico por síntomas musculoesqueléticos			
Afección	*Cualquier número*	≥ 2 médicos	Consumió AINE > 1	Recibió compensaciones por discapacidad
Artritis reumatoide	72.7*	27.3	63.6*	9.1*
Dolor de espalda bajo	61.2*	25.8*	40.9*	8.0*
Osteoartritis de rodilla	66.4*	26.8*	45.7*	5.4*
Osteoartritis de mano	58.8*	22.8*	38.2*	2.2†
Fibromialgia	76.9*	42.3*	55.8*	7.7*
Otras distintas	25.3*	8.1*	14.3*	1.7*

Valores expresados como %; AINE: pastillas anti-inflamatorias no esteroideas; *: *p<.01* y †: *p<.05* referidos a las diferencias existentes entre sujetos que se ven afectados por las condiciones musculoesqueléticas definidas en comparación con aquellos sujetos no afectados por dichas condiciones.

Fuente. Adaptado de Carmona y cols. (2001)

Observando los datos (procedentes del estudio EPISER del año 2002) parece necesaria una concienciación en el ámbito tanto público como privado para poder mitigar en la medida de lo posible el impacto que estas enfermedades presentan no solo en quienes la padecen sino también en el resto de la sociedad. De entre todas las enfermedades reumáticas, en el presente capítulo nos centraremos en el dolor lumbar inespecífico.

1. Definición del dolor lumbar inespecífico e impacto en España

1.1. Definición del dolor lumbar inespecífico

El dolor lumbar (DL) puede definirse de diferentes maneras dependiendo de cada escenario contextual, y se debe distinguir entre aquellos pacientes que muestran los síntomas, los que en realidad buscan ayuda médica, aquellos que buscan la incapacidad laboral temporal, o aquellos que tienen problemas de incapacidad funcional, ya que se diferencian en cuanto a tasas de prevalencia y se ven influenciados por diferentes factores biomédicos, psicológicos y sociales (12). En los centros de atención especializada y en estudios de investigación epidemiológica, el dolor de espalda suele definirse en términos anatómicos como el dolor experimentado entre los bordes de las costillas y los pliegues de los glúteos inferiores. Sin embargo, en la práctica clínica de atención primaria, se utiliza una definición más pragmática incluyendo todos los pacientes que consultan a un médico con un problema relacionado con estructuras músculo-esqueléticas de la región de la espalda (13). Los pacientes donde el dolor se irradia hacia la pierna(s) (a menudo denominado "ciática") suelen ser también incluidos en el grupo de pacientes con DL, donde el dolor emana de las estructuras en la parte posterior (14). Normalmente, es aceptada una clasificación simple para el dolor lumbar en función de la causa: a) patologías específicas del raquis, b) dolor de raíz nerviosa o dolor radicular y c) dolor lumbar no específico (sin causa original conocida) (DLI) (15). Además, en función de la duración del episodio, es generalmente aceptado que el DL se vuelve crónico cuando el dolor persiste por más de 3 meses (15, 16). El DLI se vuelve subagudo cuando se produce de repente después de un periodo de al menos 6 meses sin dolor lumbar, existiendo una variabilidad de criterio en la duración, que va desde 2 a 6 semanas y agudo cuando el dolor dura entre 1 y 2 semanas.

1.2. Impacto socio-económico del dolor lumbar inespecífico en España

El DLI es una de las afecciones más antiguas y frecuentes en el ser humano, donde el 80% de la población lo padece en algún momento de su vida (17). Según el último estudio de la Sociedad Española de Reumatología (10), la probabilidad de padecer al menos un episodio en los 6 meses anteriores a la encuesta realizada para dicho estudio, es del 44,8% mientras que la población afectada de DLI crónico alcanza un 7,7%. Por sexos, la prevalencia del DLI es mayor en mujeres y en personas en edad trabajadora tanto en pacientes crónicos como en el caso de la probabilidad de DLI en los 6 meses anteriores a la encuesta. Para muchas personas el DLI es un problema auto-limitante que, aunque es desagradable, puede ser tratado. De hecho, En la mayoría de las ocasiones el dolor es transitorio, con tendencia a la mejora completa de forma espontánea, progresiva y rápida (18). A pesar de esta declaración, se ha estimado que para un 12% de las personas afectadas, el DLI es lo

suficientemente grave como para afectar a la calidad de vida individual, a la familia, las relaciones sociales y a la capacidad para trabajar. La evidencia sugiere que el DLI en España supone en un gran problema, y que la experiencia española no es inusual, ya que se reportan porcentajes de prevalencia similares a los del resto del mundo occidental. En este sentido, la literatura científica internacional pone de manifiesto que el 80% del total de costes atribuibles al DLI son consumidos por el pequeño grupo (10%) de pacientes que desarrollan síntomas crónicos (19, 20) y sitúa a nuestro país en cabeza en la magnitud del problema en comparación con los países de la UE, convirtiendo además al DLI en la causa más importante de gasto compensatorio económico en nuestro país (21). Según los últimos datos nacionales disponibles, el DLI supone un promedio de un 12,54% del total de bajas laborales, con un intervalo que va desde el 11,4% en el año 2000 hasta el 14,1% en 2004 (lo que supone una media anual de 2.214.907 jornadas no trabajadas). El coste medio anual total por las jornadas no trabajadas debido a DLI en el período estudiado representa un 10,67% del dinero devengado en el total por incapacidad temporal, llegando a 195 millones de euros al año (22). El DLI es por lo tanto, un problema de salud importante debido en parte a su alta prevalencia, pero principalmente a su potencial para causar sufrimiento en las personas y los enormes costes que esto conlleva no sólo al sistema de salud sino a la sociedad en su conjunto.

2. Intervenciones basadas en ejercicio físico para la prevención (primaria, secundaria y terciaria) del dolor lumbar en el puesto de trabajo.

La evidencia científica, bajo el modelo bio-psico-social del DL (23), reconoce la contribución de factores biológicos, psicológicos y sociales como componentes del DL y el riesgo de cronicidad del mismo, reemplazando al modelo biomédico tradicional en el entendimiento y manejo de dicha afección (24). Por tanto, es necesario atender a dichos componentes cuando se trata el DLI. En este sentido, la combinación de tratamientos farmacológicos (apartado no examinado en este capítulo) (25) junto a otras terapias no farmacológicas, como las terapias físicas (pasivas o activas – ejercicio físico-) (15, 26, 27), terapias cognitivo-conductuales o de educación para la salud (28), parecen ser efectivas en la prevención tanto primaria como secundaria o terciaria en pacientes afectados por DLI. Desde hace tiempo, se admite, de forma consensuada, que el ejercicio físico es una terapia activa que desempeña un papel clave en el tratamiento de del DLI (29), además de representar una terapia relativamente barata. Mucho se ha especulado sobre la forma concreta en que actúa el ejercicio físico en pacientes con DLI y que efectos se desprenden de su aplicación durante el tratamiento. En este sentido no existe una fuerte evidencia científica de que el ejercicio físico pueda aliviar el dolor, aunque sí de que puede aumentar la tolerancia al mismo (30), lo que puede servir como base para la realización de un programa de ejercicio físico continuado y beneficiarse así de una mejora en las alteraciones de las propiedades morfo funcionales de la musculatura, en especial la extensora, estabilizar segmentos raquídeos logrando un control automático y subconsciente de las secuencias normales de activación y relajación muscular y evitando sinergias inadecuadas; aumentar el rendimiento cardiovascular y la capacidad funcional; y reducir la incapacidad funcional (también denominada discapacidad) producida por el dolor (31), a parte de los conocidos efectos que

la actividad física tiene sobre los individuos (32). A nivel preventivo, los factores por los que el ejercicio físico puede ser beneficioso ante el DLI son varios: fortalecimiento de la musculatura de la espalda, incremento de la flexibilidad del tronco, aumento del aporte sanguíneo regional para reducir posibles lesiones locales y favorecer la reparación tisular; y mejora del estado anímico, mejorando por ello la percepción del dolor (33). Pero estos beneficios dependen de cada sujeto y de la fase en que el DLI se presenta (agudo, subagudo o crónico) y es que en función de las características biológicas, psicológicas y sociales el impacto del dolor lumbar común puede ser diferente. Por tanto, la utilidad de los programas de ejercicio físico en estos pacientes dependerá de las características biológicas, psicológicas y sociales de cada individuo. A nivel de evidencia científica, se admite que el ejercicio físico es más beneficioso en pacientes crónicos que en agudos y subagudos (34), aunque en estos también es posible reducir el nivel de riesgo de cronicidad de la afección (35). En este apartado se desarrollará una revisión de las diferentes intervenciones – y sus principales efectos- que han usado el ejercicio físico (como única medida o junto a otro tipo de intervenciones) como terapia física activa en el co-tratamiento del DLI ocupacional en el puesto de trabajo.

Con un objetivo pragmático, las intervenciones han sido analizadas y presentadas en base a los siguientes resultados: tipo de programa de ejercicio físico usado, incapacidad funcional por dolor lumbar, días de baja laboral por dolor lumbar, incidencia y nivel de dolor lumbar y costes asociados a la patología. La mayoría de los estudios revisados establece el programa de ejercicios basados en los conceptos de refuerzo lumbar y abdominal, estiramientos y flexibilidad además de, algunos de ellos, la capacidad cardiovascular. Sin embargo en los estudios analizados en este capítulo, la duración del ejercicio así como en la intensidad y frecuencia de las sesiones propuestas es heterogénea. A este respecto, parece existir un consenso de que para la implementación de programas de ejercicio físico en el puesto laboral es preferible – e igual de efectivo en aspectos clínicos del DL- la realización de sesiones diarias de corta duración (36). En esta línea, la evidencia científica sugiere por ejemplo que intervenciones con una media de 10 minutos por sesión, durante la jornada laboral, es efectivo para reducir la incidencia del DL, el grado de dolor o el grado de incapacidad funcional. De hecho, los empleados prefieren los ejercicios de corta duración para no sentir que pueden estar perdiendo tiempo de trabajo. Lo que es también preferido por los jefes (36). Las diferentes intervenciones analizadas presentadas arrojan resultados controvertidos. Parece ser que las intervenciones para tratar el DL en el puesto laboral a través del ejercicio físico son más efectivas cuando se combinan con otras medidas ocupacionales habituales. En este sentido, la literatura científica, muestra que un programa de ejercicio físico junto a un programa de entrenamiento cognitivo o de enfrentamiento al dolor. El ejercicio físico en el puesto laboral puede ayudar a disminuir la incapacidad funcional y la severidad del DL, además de ayudar a disminuir el grado de dolor. Aunque existen pocos estudios que evalúen la CVRS, ésta puede mejorar debido, posiblemente a que mejorar la capacidad de realización de las actividades de la vida diaria y disminuye el dolor. Por último, la evidencia científica sugiere que intervenciones basadas en subgrupos de DL inespecífico pueden ser más efectivas que intervenciones no basadas en tal división (37).

3. Innovación en el campo del ejercicio físico para la prevención secundaria y terciaria del dolor lumbar inespecífico

Desde el grupo de investigación AFYCAV (http://www.afycav.es/) se ha apostado por líneas de investigación dirigidas a la prevención (en cualquiera de sus formas) de las dolencias musculo-esqueléticas más prevalentes a través de la aplicación de intervenciones innovadoras que pretenden mejorar la CVRS y la clínica de los pacientes intervenidos. A continuación se presentan dos de las intervenciones que han concluido y los resultados asociados.

3.1. Intervención a través de la web para la prevención secundaria del dolor lumbar inespecífico

Los resultados de esta investigación se encuentran en proceso de investigación. Aunque investigaciones previas han usado internet para aumentar el nivel de actividad física en población general en el puesto de trabajo (38-42), ningún estudio ha evaluado la efectividad de un programa a través de internet en el puesto laboral en poblaciones especiales. Bajo el pseudónimo “cuida tu espalda”, nuestro grupo de investigación en colaboración con el Servicio de Prevención de la universidad ha diseñado una intervención a través de la web para la prevención secundaria del DL inespecífico en trabajadores de oficina. El programa se llevaba a cabo en el mismo puesto de trabajo en horario laboral. El programa consistió en 2 minutos de un recordatorio postural (dedicado a como sentarse de forma efectiva delante del ordenador), 7 minutos de ejercicio físico (destinado al refuerzo, flexibilidad y movilidad de los músculos que intervienen en la postura) y 2 minutos del recordatorio postural comentado con anterioridad durante 9 meses 5 días a la semana. Se comparó un grupo control de 50 personas (tenía acceso a los cuidados estándar del servicio de prevención) con 50 personas pertenecientes al grupo intervención (tuvieron también acceso a los cuidados estándar además de al programa).

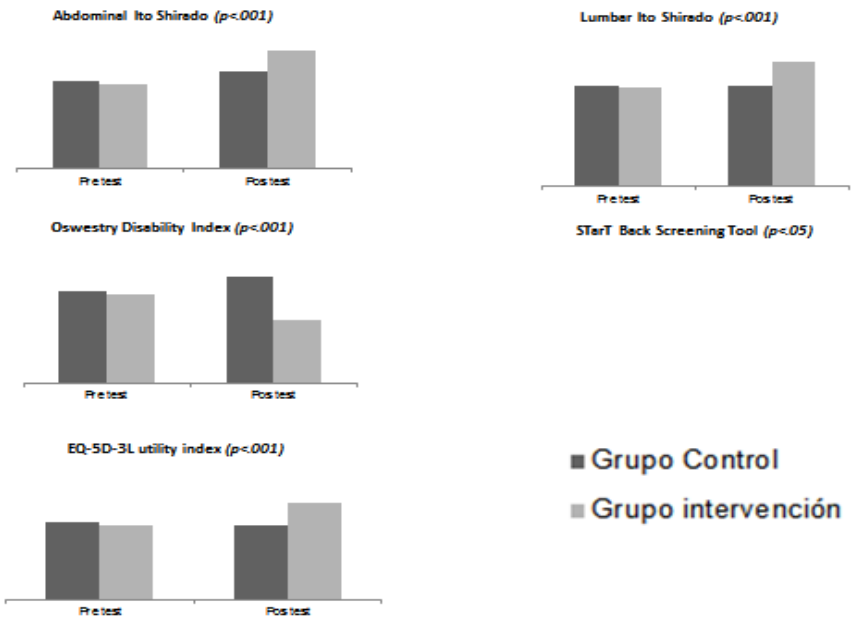

Figura 1. Efectos del programa “cuida tu espalda” en trabajadores de oficina.

Se encontraron efectos positivos respecto al grupo control en el grupo de intervención (Figura 1) en cuanto a la incapacidad funcional (evaluada mediante el cuestionario de incapacidad de Oswestry), la resistencia lumbar y abdominal (evaluada mediante el test de Shirado Ito lumbar y abdominal), muy relacionado en la literatura científica con el nivel de incapacidad funcional. Además se redujo de forma significativa el riesgo de cronicidad de la dolencia (evaluado mediante el STarT Back Screening Tool) e incremento la CVRS de los pacientes (evaluado con el cuestionario EQ-5D-3L). Reconocida la necesidad de implementar medidas adicionales a las existentes, este estudio puede servir como punto de partida para aplicar en entornos similares al nuestro como medida de Salud Pública.

3.2. El entrenamiento vibratorio de cuerpo completo en la prevención terciaria del dolor lumbar inespecífico

Los resultados de esta investigación han sido reportados con anterioridad (43). Si bien la investigación relacionada con vibraciones corporales (*WBV* por sus siglas en inglés) ha tomado mucho auge en los últimos tiempos, no sólo como método de entrenamiento para aumentar el rendimiento sino también como método de tratamiento en diferentes enfermedades que cursan con dolor crónico, como la fibromialgia, (44) nunca antes había sido aplicado en pacientes con DL inespecífico. En nuestro grupo de investigación analizamos los efectos de un programa de *WBV* progresivo durante 12 semanas en 50 pacientes con DL inespecífico crónico (25 pertenecientes al grupo control, que seguía los cuidados estándares de la unidad del dolor y 25 pertenecientes al grupo intervención que además de los cuidados estándares recibió la terapia *WBV*).

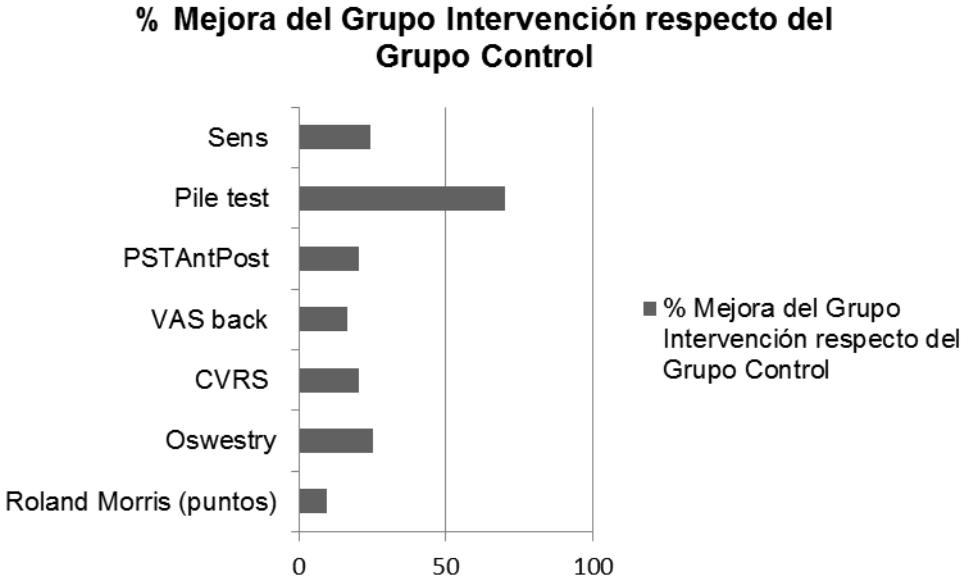

Figura 2. Efectos de 12 semanas de *WBV* en pacientes con DL inespecífico crónico

En el grupo de terapia de *WBV* se produjo una mejora estadísticamente significativa la incapacidad funcional relacionada con el DL (evaluado con el cuestionario de incapacidad de Oswestry y Roland Morris), en el índice de estabilidad postural antero-posterior (evaluado con el Biodex Balnce System) en la CVRS (evaluado con el cuestionario EQ-5D-3L). Además redujo el grado de dolor (evaluado mediante escala visual analógica VAS back) y aumento la sensibilidad periférica a la vibración. Así mismo incrementó la capacidad de carga (evaluada mediante el test de Pile). Por el tiempo de aplicación y los resultados observados, este tipo de técnicas pueden ser útiles como medida de apoyo en Salud Pública en el tratamiento del DLI inespecífico.

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ORIGINAL

The Spanish version of the ''STarT Back Screening Tool'' (SBST) in different subgroups

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KEYWORDS
Low back pain;
Primary care;
Spanish;
Adults;
Classification

Abstract
Objective: The aim of this study was to translate and culturally adapt the original version of the STarT Back Screening Tool (SBST) to Spanish for different population subgroups.
Design: Translation and cultural adaptation of a questionnaire.
Setting: Primary care settings.
Method: Thirty-eight people distributed by: gender; adults and elderly; and with or without pain. Phases: a) Forward translation (English-Spanish); b) Evaluation of the clarity, the acceptability and the familiarity of the content of the obtained Spanish version by means of cognitive interviews to participants, and c) Translation of the final Spanish version of the questionnaire back into the original language.
Results: The participants interviewed indicated that most of the items of the questionnaire were clear and comprehensible, showing greater difficulty in understanding in the dimensions of disability and anxiety. Furthermore, the questionnaire was more difficult to understand by the elderly and patients with a previous non-specific low back pain episode.
Conclusion: The Spanish version of the SBST questionnaire was obtained, which was shown to be comprehensible and adapted to the general population in Spain. Due to being short and easy to use, it is a potentially useful tool for use in primary care.

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PALABRAS CLAVE
Dolor de espalda baja;
Atención Primaria;
Español;
Adultos;
Clasificación

La versión de *STarT Back Screening Tool* (SBST) al español en diversos subgrupos

Resumen
Objetivo: El objetivo de este estudio fue traducir y adaptar culturalmente la versión original del *STarT Back Screening Tool* (SBST) al español en diversos subgrupos de población.
Emplazamiento: Centros de Atención Primaria.
Diseño: Traducción y adaptación de un cuestionario.
Método: Treinta y ocho personas, distribuidos por: género, adultos y ancianos, y con o sin dolor. Fases: a) la traducción (inglés-español); b) evaluación de la claridad, la aceptabilidad y la familiaridad de los contenidos de la versión en español obtenidos por medio de entrevistas cognitivas a los participantes, y c) retro-traducción de la versión final en español del cuestionario de nuevo en el idioma original.
Resultados: Los participantes entrevistados indicaron que los ítems del cuestionario fueron claros y comprensibles en la mayoría de ellos, mostrando una mayor dificultad de comprensión de las dimensiones de la discapacidad y la ansiedad. Además, el cuestionario ha mostrado mayor dificultad de comprensión en los ancianos y las personas con un anterior episodio de dolor lumbar.
Conclusión: Se obtuvo la versión española del cuestionario SBST. El cuestionario español SBST ha demostrado ser comprensible y adaptado a la población general en España. Debido a su nivel más bajo y facilidad de uso es una herramienta potencialmente útil para su uso en Atención Primaria.

Introduction

Non-specific low back pain (of unknown origin) is one of the most frequent ailments in primary care consultations, with visit rates ranging between 7 and 9% of affected by lumbar ailments in the general population.[1] It is impossible to know the original cause of 80 per cent of these episodes.[2,3] Low back pain consumes an enormous amount of health care resources through consultations, checkups, and prescriptions, and also societal resources, predominantly from sick leave.[4] A majority of the costs attributable to low back pain is caused by the small proportion of patients who develop chronic symptoms.[4] As a consequence, there is consensus among the research community that the provision of methods to help clinicians identify patient subgroups that are at risk of persistent pain and disability is a high research priority.[5]

The STarT Back Screening Tool (SBST) was recently published as a prognostic stratification method to identify subgroups of patients to guide the provision of early secondary prevention in primary care.[6] The tool uses prognostic indicators that are potentially modifiable by treatment within a brief screening tool format, with established scoring rules to classify patients into one of three subgroups; low, medium and high risk.[6] The SBST has been demonstrated as having equivalent psychometric properties to the popular tool ''Orebro Musculoskeletal Pain Screening Questionnaire'' (OMPSQ),[7] in addition to being shorter and simpler.[8]

The SBST, while available in the English language, is currently not available in Spanish. We therefore designed this study to translate and culturally adapt the SBST into Spanish and to obtain a reliable and feasible Spanish version of SBST.

Material and methods

We applied the recommended methodology for the translation and cultural adaptation of Health Related Quality of Life (HRQoL) questionnaires used in others studies,[9] including direct and inverse translation and cognitive interviews.[10,11] An overview of the translation used and cultural adaptation processes are described in the scheme of the study image.

Phase 1; Forward translation

First, two native Spanish translators, bilingual in the language of the original tool (English), performed two forward translation versions of the SBST: each translator independently produced a forward translation of the original items, instructions and response options. To produce a combined version (version 1) both translators and one local project manager discussed the two translations and agreed on a single version with the aim to produce a conceptually, semantic and easy to understand equivalent translation[12,13] of the original questionnaire. This process led to additional changes to the original version where words or concepts were untranslatable, or where words or terms had a specific meaning in one language but a semantically different or secondary meaning in the Spanish language.

Phase 2; Patient testing using cognitive interviews

The next step (patient testing) was to administer the translated questionnaire to a sample of adult respondents to determine whether the translation (items, instructions and

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Table 1 Number of men and women in the interview sample stratified by younger and older adults and whether or not they had experienced a recent episode of low back pain.

	Younger adults (Aged 35 to 55)		Older adults (Aged 55 to 80)		Total (Mean age = 59 ± 4.2)	
	Healthy	Backache	Healthy	Backache	Healthy	Backache
Women	5	5	5	4	10	9
Men	5	5	4	5	9	10

responses options) was acceptable, easy to understand, and to evaluate the tool's clarity. This was tested by means of cognitive interviews using ''probing and paraphrasing'' methodology[10,11] to provide patient feedback in respect to errors or misunderstandings produced by the translation process. Such cognitive interview techniques are known to minimise measurement error introduced by the translation process and enable respondent misunderstandings to be rectified.[14]

Cognitive interviews were face to face and were conducted in an egalitarian manner by a native Spanish speaker with 38 adults aged 35 to 80 years old, and findings were collated and stratified using gender (male or female), age (35-54 or 55-80 years) and ailment (healthy or back pain) (Table 1). All participants signed a written informed consent.

The interviews consisted of:

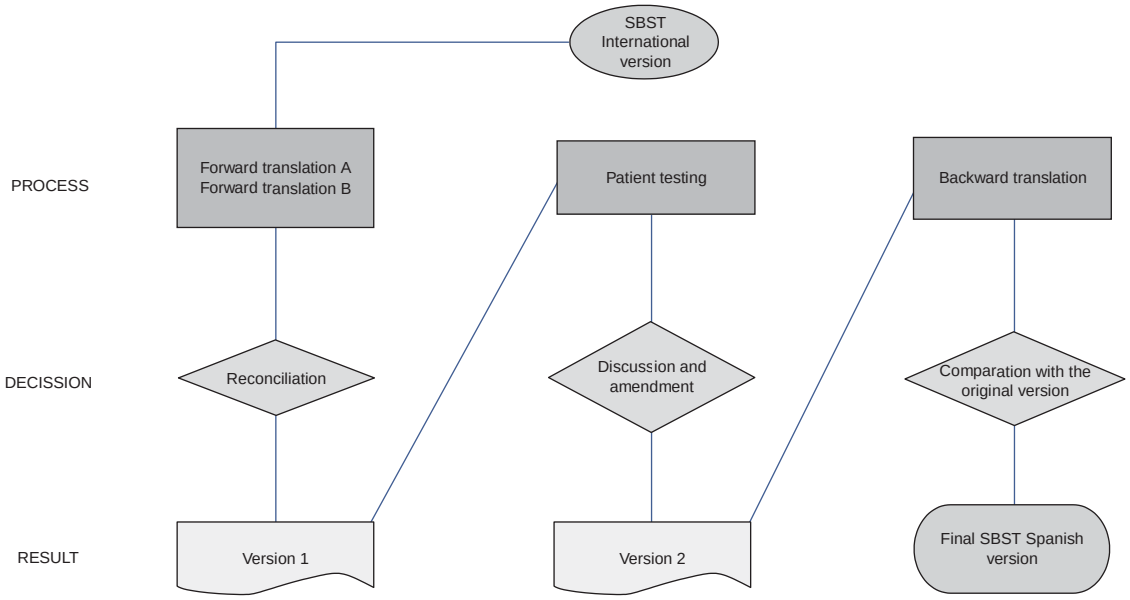
a) An evaluation of the ease of comprehension of each item using dichotomous response options of either: 1) clear and comprehensible or 2) difficult to understand.
b) An evaluation of the ease of comprehension of each item using a numerical rating scale from 0 to 10 (0 very easy to understand to 10 very difficult to understand).
c) An investigation of individuals' interpretations of SBST items with suggestions for improvements by asking those interviewed to express in their own words the perceived meaning of each item and then to re-phrase each item to verify their understanding.

Where problems were identified, alternative linguistic changes were proposed and following this process version 2 of the questionnaire was obtained.

Phase 3; Back-translation

The final phase was to back-translation of the Spanish version 2 of the SBST into English using a local professional translator, who was a native speaker of English and fluent in Spanish) and was blind to the original English version of the SBST questionnaire. The back-translated SBST was then compared to the original by the local project manager and the author of the original English SBST to detect any misunderstandings or inaccuracies in the translation process.

The translation methodology used was designed to reduce the cultural and social bias that may have resulted if only one translator was responsible for the translation, and aimed to ensure that the final version obtained had conceptual and semantic equivalence to the English SBST with respect to the items, instructions and response options.



General scheme of the study. STarT Back Screening Tool.

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Results

Phase 1; Forward translation

The results from the two independent forward translations of the SBST are provided in Table 2. Following a joint discussion between the translators about some of the words, concepts and terms used, a few small changes were made to produce version 1:

- In the 9th item, we decided to use *''estado molestando''* instead of *''como de molesto''*.
- In the first item, we used *''se ha irradiado''* instead of *''se ha extendido''*.
- In the 3th item, we used *''he tenido''* instead of *''yo he tenido''* to reflect a more colloquial Spanish style.
- For item 4, we used the word *''debido a''* instead of *''a causa de''* again to reflect a more colloquial form of Spanish.
- For item 6 we used the word *''por mucho tiempo''* instead of *''un montón de tiempo''* as this would be better understood.
- For item 7, we used the *verb ''notar''* instead of *''sentir''* again to reflect a more colloquial form of Spanish.
- For item 8, we decided to use *''habitualmente''* instead of *''normalmente''* because it was agreed that this sounded better.

Phase 2; Patients testing using cognitive interviews

The second version of the questionnaire obtained is presented in Table 2. Patients did not identify any major difficulties in comprehension of first version, as all the participants reported the questionnaire as clear and comprehensible on the dichotomous response options. However, the more sensitive measure of the numerical response rating revealed that there was a degree of greater difficulty of understanding for items 5 and 6 (disability and anxiety items) across the younger and older age groups (Figure 1). Therefore these items were slightly modified; for item 5 (disability) the wording was changed from *''no es realmente seguro para una persona como yo ser físicamente activo''* to the more direct phrasing of *''no es seguro ser físicamente activo con dolor de espalda''*. For the 6th item the wording was changed from *''preocupaciones han estado pasando a través de mi mente durante mucho tiempo en las últimas dos semanas''* to an active voice form of *''me he preocupado mucho por mi dolor de espalda en las últimas dos semanas''*.

Table 2 Items in the Spanish version of the STarT Back Screening Tool

1. Mi dolor de espalda se ha extendido a lo largo de mi pierna(s) en alguna ocasión en las últimas dos semanas
2. Me ha dolido el hombro o cuello en alguna ocasión en las dos últimas semanas
3. En las últimas dos semanas, solo he caminado distancias cortas por mi dolor de espalda
4. En las dos últimas semanas, me he vestido más lentamente de lo normal por mi dolor de espalda
5. No es seguro ser físicamente activo con mi dolor de espalda
6. Me he preocupado mucho por mi dolor de espalda en las dos últimas semanas
7. Noto que mi dolor de espalda es terrible y que nunca irá a mejor
8. En general en las últimas dos semanas, no he disfrutado de las cosas lo que habitualmente disfruto
9. En general, ¿como le ha molestado su espalda en las dos últimas semanas?

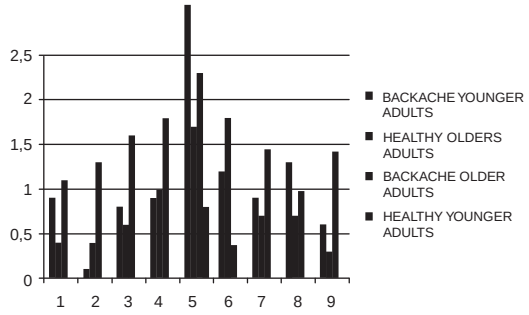

Figure 1 Average difficulty of items 1-9 by age and ailment. Scale range was from 0 to 10 (0 very easy to understand to 10 very difficult to understand).

The investigation of individuals' interpretations of SBST items and paraphrasing exercise verified that the majority of people interviewed fully understood each of the SBST items. However, it was observed that a number of participants used a direct question that included the infinitive form of the verbs included and the items written in the perfect past tense were repeated when using their own words with the simple past tense. Therefore, it was decided to use the infinitive and simple past verb forms as much as possible in the definitive version. Never the less, during the re-formulation (paraphrasing) of the items by the subjects, they consistently re-phrased the referred leg pain item translated as *''irradiar a través de mi pierna''* to *''extender a través de mi pierna''*, and so for this reason the verb 'extending' was used instead of 'radiating'. In addition, the results from the cognitive interviews revealed that participants were more likely to recommend changes if they had experienced a recent episode of low back pain or were in the older age category (Figure 1).

Phase 3; Back-translation

The back-translation of the SBST is included in Table 2. When this was presented to the authors of the original English version of the tool, no further additional changes were required.

Discussion

The main objective of this study was to translate and culturally adapt the original version of the SBST into Spanish.

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This was performed using a sample of younger and older adults with and without recent low back pain to ensure the translated version had face validity and was easily understood. To our knowledge, this is the first Spanish screening tool for idiopathic low back pain in primary care and provides a standardised methodology with which to develop future translations and cultural adaptations of this tool.

This study has been carried out using a sample from the general population of equally distributed younger and older adults and participants with and without idiopathic low back pain. The strength of this methodology is that it is likely to provide a translation that is comprehensible and generalisable to the Spanish general population. However, one weakness was that the current study did not test the translated tool's ease of understanding among individuals with cognitive difficulties or whose pain was controlled using pain medication. According to Andresen EM et al.,[15] subjects with previous episodes of non-specific low back pain and elderly people report a poor Self-rated Health and it is very important to study cognitive responses in elderly people in health related questionnaires,[16] and some authors propose developing questionnaires with help of elderly people as their comprehension is essential.[17]

Further studies need to analyse the measurement properties of the translated SBST including reliability, validity and feasibility among the Spanish general population and among patients with idiopathic low back pain. However, this tool can add value to assess the effects of interventions such as physical therapies or pharmacological treatments.that can identify subgroups of patients to guide the provision of early secondary prevention in primary care.[6] Nevertheless, this translated Spanish version of the SBST will provide a practical and user friendly tool to identify prognostic subgroups of patients with low back pain that require targeted and increasing complexity of treatment, which is a major reason for visits to primary care.

Key points

What is already known on this subject?

- SBST is one of the most internationally used tools for screening low back pain and is noted for its ease of administration, validity and reliability, development in different cultures and applicability in economic analysis.
- There is not a direct and specific Spanish version of SBST.

What does this study contribute?

- The Spanish version of SBST for adult and elderly.

Conflict of interest

The authors have no conflict of interest to declare.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.aprim.2010.05.019.

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Health-Related Quality of Life and fitness characteristics of office workers affected by sub-acute non-specific low back pain

Physiotherapy, submitted

ABSTRACT

Objective: we compare the HRQoL and musculoskeletal-related fitness of office workers suffering from non-specific low back pain with an age-matched group of unaffected office workers to inform the design of appropriate worksite health promotion programs. Methods: A cross-sectional study was conducted in inactive office workers, within 118 suffering from non-specific low back pain and 72 unaffected who were assessed by the EQ-5D-3L, Oswestry, and Roland Morris questionnaires, and a battery of back pain-related fitness tests. Data for both genders and conditions were then compared. Results: Workers suffering from sub-acute non-specific low back pain showed a poor fitness profile compared with unaffected workers, although significant differences were not detected in the sit-and-reach test in men. HRQoL profile of affected workers was worse than that of those without the condition, both as a whole and per dimension, with the exception of the pain/discomfort dimension in women, where significant differences were not detected. Our data showed that the perceived disability, pain history and use of healthcare resources were much greater in affected office workers than in age-matched unaffected workers. Conclusion: In accordance to standard exercise programs designed for the general population, exercise programs for office workers may need to focus more on developing the endurance of the trunk extensors but further work investigating the relationships prospectively between trunk muscle endurance and low back pain is required in this special population. A supervised exercise group programs and appropriate professional support could also help to minimize the psychosocial components that affect the HRQoL. Keywords: backache, work-age population, worksite health promotion, exercise

Introduction

Non-specific low back pain has been recognized as a public health priority (1). Promoting an early return to normal activity and encouraging support in the workplace leads to reduced costs and less time off work caused by anxiety over back pain (8).In the other hand, office workers share several patterns of behaviour: they work seated without moving for long periods; they use only a few specific muscles of their arms, wrists and hands; and they keep an overall poor body posture (9). This condition of physical inactivity has been described as a predictive and modifiable risk factor associated with the total healthcare costs of office workers (10). These working patterns generate musculoskeletal disorders and produce discomfort or pain (9) with an important impact on the performance of daily tasks in individuals who present the condition (11) and on their quality of life (12).

Karjalainen et al. reported that multidisciplinary bio-psycho-social rehabilitation reduced sub-acute low back pain among working age adults, and that a worksite visit increased effectiveness (13). Although different studies have explored the use of exercise programs (with or without behavioral components) (14), to our knowledge, there has been little examination of the criteria that exercise-based programs need to address to improve the physical function of workers suffering from low back pain (11). Identifying the major fitness deficits of workers

suffering from sub-acute non-specific low back pain is a prerequisite for designing appropriate fitness programs. We assessed the health-related quality of life, pain history, healthcare consumption and physical fitness of office workers suffering from sub-acute non-specific low back pain relative to an age-matched group of office workers without this condition.

PATIENTS AND METHODS

We used a cross-sectional study design in which office workers suffering from non-specific low back pain were compared with office workers without this condition. Participants from both groups did not exercise regularly (less than two sessions of 30 min exercise per week) (15). For this investigation, the "case study" (office worker suffering by sub-acute non-specific low back pain) was defined as a participant with current low back pain with or without radiating pain to one or both lower legs, without any specific pathological conditions. The back pain episode could be the first or recurrent with the current episode lasting less than 12 weeks and more than 6 weeks (16). This diagnostic was confirmed the by the physician of the Preventive Medicine Service of the University of Extremadura in the case of participants referring low back pain symptoms. Participants with no low back pain (in any of its forms) were considered to be healthy workers. To be eligible to participate in the study, participants needed to be the following: 18-65-year office workers working more than 6 hours a day at a computer, physically inactive, and without any physical problems that would preclude their ability to complete a battery of fitness tests, as assessed by the Physical Activity Readiness Questionnaire (PAR-Q) (17). For the low back pain sample, exclusion criteria were low back pain caused by specific pathological conditions and pregnancy. Participants suffering from non-specific low back pain were recruited at a Preventive Medicine Service from the University of Extremadura (through scanning data-base patients). One hundred and thirty eight patients were invited through email after revising criteria for inclusion and exclusion in the current study. Finally, after in-person revising criteria for inclusion and exclusion in the current study by the clinician of the preventive medicine service, 118 persons fully complied with the inclusion and exclusion criteria and were included in the study. Healthy workers were recruited from different administrative centers of the University of Extremadura and informed of the protocol by a technical assessor. Of the 100 healthy workers that showed interest in the study, 72 persons fully complied with the inclusion criteria and were included in the study.

Measures

The socio demographic and socioeconomic characteristics that were measured included the following: age, level of study, smoking habits, gender, history of non-specific low back pain, history of sick leave due to non-specific low back pain, and number of visits to a general practitioner occasioned by non-specific low back pain. ***Musculoskeletal-related fitness tests***: *Handgrip strength* was evaluated by means of a manual dynamometer (TKK, Tokyo, Japan), taking the average value of both hands as the final result. An intraclass correlation coefficient (ICC) of 0.95 for this instrument has previously been reported (18). The *flexibility of legs and trunk* was evaluated by means of the Sit-and-Reach Test, which has a reported ICC of 0.89. The distance between the ends of the fingers in the final position during flexion of the trunk was taken as the value of flexibility. The best result of the three tests undertaken was considered the definitive result. *Lumbar trunk muscle endurance* was evaluated by the Ito Shirado tests, which have reported ICCs of 0.95 and 0.97, respectively (19). To

evaluate the flexor muscles, the subject was asked to recline in a supine position and elevate the lower extremities to 90º flexion of the hip and knee joints. To evaluate extensor muscles, the subject was asked to take a prone position keeping the breastbone on the surface of the ground. In both procedures, the subject was requested to hold the position for as long as possible. The flexibility of the Upper Extremities was evaluated with a 'back scratch test' (20). In the absence of a reliability measure for this test in working age adults, the ICC was determined in our laboratory, resulting in ICCs of 0.96 in the upper right extremity and 0.80 in the upper left extremity. The subject was placed in a standing position with one hand behind the back stretching as far as possible up the spinal column. The subject was asked to extend the other arm behind the head with the elbow bent and to try to reach the other hand. This was carried out twice. The vertical distance between the two middle fingers was taken as the evaluation rate. ***Questionnaires***: To assess the Health-Related Quality of Life (HRQoL), the EQ-5D-3L (21). The Roland Morris Questionnaire, previously validated in the Spanish language (22), was used to assess the level of disability associated with back pain. We use also the Oswestry disability questionnaire to assess the functional disability related to low back pain, which has been previously validated in Spanish language (23).

Data analysis

The descriptive statistics are presented as means and SDs for continuous variables and as frequencies and percentages for categorical variables. Differences between groups were tested using the *Mann-Whitney U-test* for continuous variables and the *chi-square test* for categorical variables adjusted by age. To standardize the scores, the difference between the raw score of office workers suffering from subacute non-specific low back pain and the mean score of the control group was calculated. This difference was then divided by the SD of the control group. These standard scores (z-scores) express the individual's distance from the reference group in terms of the distribution (effect size). Thus, any score equal to the mean of the reference group will be equivalent to an effect size of zero. Negative or positive values indicate an individual who falls below or above the mean, respectively. It was tested the correlation between the musculoskeletal-related fitness tests and the level of self-reported health-related quality of life. Spearman correlation was used in this analysis according with the distribution of the data presented. For all tests, the significance level was set at $p< 0.05$. The analyses were performed using SPSS 18.0 (SPSS, Inc., Chicago, IL).

RESULTS

Table 1 reveals that office workers diagnosed with subacute non-specific low back pain consume more healthcare resources than healthy workers: in both men and women with this diagnosis, there were significant differences with respect to healthy workers concerning the history of episodes of non-specific low back pain, the history of sick leave associated with non-specific low back pain, and the number of visits to a general practitioner occasioned by non-specific low back pain.

Back pain-related fitness tests: Table 2 shows the scores obtained in the back pain-related fitness tests performed in both groups stratified by gender. Both men and women suffering from sub-acute non-specific low back pain showed a poor fitness profile compared with those without this condition, although significant differences were not fully detected in the "sit and reach" test in men.

Health-Related Quality of life: Table 3 shows the parameters and component scales of the HRQoL as reported by the participants. Men affected by sub-acute non-specific low back pain reported decreased overall HRQoL and decreased scores for each of the five HRQoL dimensions (mobility, personal care, daily tasks, pain/discomfort and anxiety/depression) compared to men without this condition, both in the VAS (p<0.001) and EQ-5D-3L utility index (p<0.001). This was also the case for women, with the single exception of the pain/discomfort dimension, where significant differences were not detected. Table 4 reveals the Spearman correlation coefficient between HRQoL and Trunk muscle endurance. As it can be observed in the table, there is a strong relation between self-reported HRQoL and the results achieved in the trunk muscle endurance test performed in the participants.

Level of disability associated with back pain**:** Table 3 shows the results of measurements of the level of functional disability related to back pain stratified by gender. Both men and women affected by sub-acute non-specific low back pain showed a worse disability index than those without this condition as determined by the Roland Morris Disability Questionnaire (p<.001) and the Oswestry Questionnaire (p<.001).

DISCUSSION

There is increased interest in delivering worksite health promotion programs (mostly involving physical exercise) to reduce musculoskeletal disorders in office workers, particularly low back pain, which is one of the most frequent of these disorders (4). An important prerequisite in implementing these programs is determining the specific physical fitness criteria that need to be addressed, but few studies have done so in relation to low back pain (11). Although there are current published prospective studies in the literature exploring the main deficits that could affect exercise programs in chronic low back pain patients in work-age population (24), there are no studies focused in the sub-acute phase of non-specific low back pain in office workers involving musculoskeletal-related fitness data, which is expected to be affected by other different factors (25). To our knowledge, this is the first study of the musculoskeletal deficits that are revealed by comparing inactive office workers suffering from non-specific low back pain with those without this condition. These findings provide a useful basis for the assessment and delivery of prevention programs specifically aimed at diminishing low back pain in office workers. Our study shows that office workers suffering from sub-acute non-specific low back pain have reduced health-related quality of life, reduced back pain-related fitness and a higher disability index than those without this specific condition.

There is evidence that the best discriminators between healthy workers and adults suffering from low back pain are back extensor endurance and musculoskeletal-fitness program participation (26). These findings support the use of measurements of trunk flexion, abdominal muscular endurance, back extensor endurance and physical activity participation as indicators of back fitness in the evaluation of back health (11). We found that in both lumbar and abdominal trunk endurance tests, office workers suffering from sub-acute non-specific low back pain perform worse than those without this condition. This contrasts with the findings of some authors who observed that patients with chronic low back pain had a lower rate of back muscle fatigue than healthy subjects (27). However, in similar studies, other authors did not find significant differences in back muscle fatigue (28). One hypothesis to explain these conflicting results is that chronic low back pain

subjects might adopt alternative neuromuscular strategies to modulate fatigue of the back extensor muscles and increase the contribution of hip extensor muscles during back endurance tests (29). The relative contribution of these neuromuscular strategies could vary in patients suffering from sub-acute low back pain, depending on the specific nature of the low back pain in the population under study (25). We also found differences between healthy and LBP subjects in the other tests performed, such as back scratch and handgrip strength, which is consistent with other studies (30). These results can be explained, at least in part, by the functional limitations that back pain produces in affected individuals (31). Another explanation for why our findings differ from studies focused on other specific low back pain conditions, e.g., chronic low back pain (32), might be variations in the way that other variables, such as psychological aspects, influence different specific low back pain populations (25).

To assess low back pain-related disability, we used the Roland Morris Disability Questionnaire and the Oswestry Disability Index, both of which are recommended by experts for measuring the impact of back pain (33). It was found that office workers suffering from sub-acute non-specific low back pain recorded worse scores than those without the condition in both questionnaires. The results for the RMDQ were similar to another study using Spanish patients (34). We obtained similar values to those found in other international studies involving workers with sub-acute non-specific low back pain (25). Studies involving participants with chronic back pain have reported worse disability scores with both questionnaires than those in our sub-acute population, which may be due to the way different types of LBP impact disability (24).

Our findings on self-reported heath status were similar to those reported in studies of sub-acute non-specific low back pain in the general population (35). We found that office workers suffering from sub-acute non-specific low back pain have a worse HRQoL profile than those without the condition, which could be due in part to their experience of disability as reported in the disability indices discussed above (36). Although the overall HRQoL score in both genders who suffered from sub-acute non-specific low back pain was poor compared with the healthy participants, there were no significant differences in the pain/discomfort dimension in women. One partial explanation might be that women in the control group also had a high level of pain/discomfort and then the differences were not detected (Table 3). We also found a correlation between Mobility, daily task, pain/discomfort, EQ5D utility and VAS and the most affected fitness parameters. Although most low back pain interventions are assessed using trunk muscle endurance (26), little is known about the relationship between the change in these variables and the change in HRQoL. Therefore, it might be of interest in low back pain preventive interventions to check the relationship between these variables after treatment in different low back pain populations to better understanding of changes after interventions (37).

In terms of the representativeness of our data, they are in accordance with the few studies that describe the prevalence of low back pain in office workers and support previous assertions that female office workers are more prone to low back pain than male workers. These other studies report a prevalence of LBP in office workers ranging from 39% in northern European countries to 62% in southern European countries, with about 10% more females than males being affected (4). Regarding the healthy subjects, our results for

fitness (19, 38) and HRQoL (39) are in accordance with other studies, but the scores reported for the disability index are slightly higher than reported elsewhere (40), might be due to the range of age of healthy people reported in our study is slightly higher than the range of age reported in the cited study (41).

This study has several limitations. First, selection bias need to be addressed in this study since a cross-sectional study comparing two different groups is used and could produce a systematic error due to a non-random sample of a population. Despite this, we choose an age-matched group of control participants in order to minimize the selection biases. The inability to detect significant differences in this test in the sit-and-reach test in men could be due to the influence of the gastrocnemius muscles, which play an important role in the sit-and-reach test, and could be due to differences between men and women in this test (42). The greater hamstring muscle extensibility of women and its influence on the hip range of motion and spinal curvature could partly explain these differences (43). The absence of any significant difference in this measure could be due to irregular menstrual cycles or unhealthy lifestyles (e.g., low fitness, smoking habits) causing pain and discomfort. Also, as far as psychosocial factors such fear avoidance are important factors influencing in non-specific low back pain impact (44) in this study we did not take in to account it measure and the differences reported in the current study might be due to that .

The external validity of our study also needs to be considered. Population-based sample strategies, which limit any generalizations about normative values, were not used. However, the socio demographic, functional disability and HRQoL profiles of patients suffering from subacute non-specific low back pain were consistent with those reported in a large study that was performed in Spain by the National Health System (34). Further population-based research is needed on the risk factors for low back pain in these office workers in order to devise appropriate intervention strategies.

Practical implications and conclusion

Our study provides new information that will help general practitioners, sport physicians, sport professionals and occupational physicians to devise appropriate exercise programs for office workers with sub-acute non-specific low back pain. Musculoskeletal-related exercise programs for office workers may need to focus more on developing the endurance of the trunk extensors (where the differences to healthy workers are very large) and on improving the mobility and flexibility of the trunk and upper and lower limbs but further work investigating the relationships prospectively between trunk muscle endurance and low back pain is required in this special population. Finally, we detected low levels of anxiety/depression, which could impair the HRQoL of patients suffering from sub-acute non-specific low back pain (34), and then we would also encourage group programs and professional support to minimize psychosocial impacts.

Ethical Approval

The study was performed according to the principles established with the Declaration of Helsinki (1964) as revised in 2000 in Edinburgh, and approved by the Research Ethics Committees of the University of Extremadura (32/2010).

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Table 1. Socio-demographic, non-specific low back pain history and health characteristics of participants in the study (n=190)

	Healthy-workers (n=72)		**NLBP-workers (n=118)**		***p a (males)***	***p a (females)***
CHARACTERISITICS	Males	Females	Males	Females		
Age-yr*	41.17 (13.04)	47.95 (8.55)	45.85 (9.17)	46.01 (8.15)	0.056	0.301
Sex, n (%)	30 (41,66)	42 (58.34)	47 (39.84)	71(60.16)	--	--
Smoke						
Smoker, n (%)	4 (13.30)	7 (16.70)	25 (53.20)	37 (52.10)	--	--
Not smoker, n (%)	26 (86.70)	35 (83.30)	22 (46.80)	34 (47.90)	--	--
Level of studies						
Secondary studies, n (%)	0 (0.00)	5 (11.90)	5 (2.8)	2 (2.80)	--	--
Proffesional studies, n (%)	3 (10.00)	15 (35.70)	39 (54.9)	39 (54.90)	--	--
University studies, n (%)	27 (90.00)	22 (52.40)	30 (42.3)	30 (42.30)	--	--
Episodes last 9 months-NLBP*	0.67 (1.39)	0.76 (0.85)	1.85 (9.17)	2.07 (0.64)	p<0.001	p<0.001
Visits to GP last 9 months-NLBP*	0.13 (0.34)	0.05 (0.21)	0.47 (0.50)	0.51 (0.60)	0.003	0.001
Sick Leave last 9 months-NLBP*	0.67 (1.39)	0.48 (0.80)	1.36 (1.15)	1.27 (1.25)	0.002	P<0.001

*Value expressed as Mean ±SD; Episodes last 9 months-NLBP: number of episodes of NLBP; Visits to GP last 9 months-NLBP: visits to the general practitioner due to NLBP in the last 9 months; Sick Leave last months-NLBP: number sick leave due to NLBP in the last 9 months; --: not computable; p ***a*****:** Mann-Whitney *U*-test adjusted by age.

Table 2. Differences between groups on back pain-related fitness tests stratified by sex of the participants in the study (n = 190)

	Healthy-workers (n = 72)		**NLBP-workers (n = 118)**		***p a* (males)**	***p a* (females)**	**Size effect (males)**	**Size effect (females)**
Outcome measure	Males (n = 30)	Females (n = 42)	Males (n = 47)	Females (n = 71)				
Hand strength: handgrip (kg m^{-2})*	43.05 (7.13)	34.03 (11.42)	31.22 (12.37)	25.56 (5.22)	p<.001	.001	-1.65	-0.74
Endurance: flexor trunk (s)*	94.63 (37.94)	77.42 (46.47)	62.06 (36.87)	46.06 (29.28)	p<.001	.001	-0.85	-0.67
Endurance: extensor trunk (s)*	109.36 (24.18)	101.80 (36.92)	79.57 (30.66)	75.49 (28.97)	p<.001	p<.001	-1.23	-0.69
Lower limb flexibility: sit –and-reach (cm)*	19.54 (6.50)	21.15 (4.82)	15.17 (7.01)	15.50 (7.79)	.072	p<.001	-0.24	-1.17
Upper limb right flexibility: back scratch test (cm)*	-5.31 (4.91)	-3.00 (3.45)	-1.39 (2.54)	1.42 (6.53)	p<0.001	.001	-1.36	-0.45
Upper limb left flexibility: back scratch test (cm)*	-2.92 (4.18)	-2.42 (4.18)	2.13 (7.28)	6.28 (9.88)	.003	p<.001	-0.18	-0.90

*Values expressed as mean ± (SD); Health-workers: workers without NLBP condition; NLBP-workers: workers with NLBP condition; NLBP: non-specific low back pain; ***p a*:** p values from Mann-Whitney *U*-test adjusted by age

Table 3. Differences between groups on Health-related quality of life and disability index from NLBP stratified by sex of participants (n = 190)

	Healthy-workers (n = 72)		**NLBP-workers (n = 118)**		**p a (males)**	**p a (females)**	**Size effect (males)**	**Size effect (females)**
Outcome measure	Males (n= 30)	Females (n= 42)	Males (n= 47)	Females (n= 71)				
HRQOL (EQ-5D)								
Mobility*								
Problems, n (%)	0 (0.00)	0. (0.00)	35 (74.50)	53 (74.60)	p<.001	p<.001	--	--
Personal care *								
Problems, n (%)	0 (0.00)	0 (0.00)	21 (44.70)	23 (32.40)	p<.001	p<.001	--	--
Daily Tasks *								
Problems, n (%)	2 (6.70)	15 (35.70)	26 (55.30)	33 (46.50)	p<.001	p<.001	--	--
Pain/ Discomfort *								
Problems, n (%)	3 (10.00)	15 (35.70)	26 (55.30)	35 (49.30)	p<.001	.221	--	--
Anxiety/ Depressions *								
Problems, n (%)	2 (6.70)	9 (21.40)	12 (25.50)	27 (38.00)	p<.001	p<.001	--	--
VAS*	79.96 (11.02)	73.38 (16.32)	57.76 (14.17)	57.39 (12.44)	p<.001	p<.001	-1.98	-0.97
EQ-5D-3L-Utility index *	0.92 (0.09)	0.83 (0.16)	0.71 (0.13)	0.77 (0.10)	p<.001	.004	-2.3	-0.37
DISABILITY INDEX								
RM (points)*	0 (0)	0 (0)	11.21 (2.22)	12.04 (2.40)	p<.001	p<.001	--	--
Oswestry (%)*	0 (0)	0 (0)	29.93 (1.49)	28.12 (2.52)	p<.001	p<.001	--	--

*Values expressed as mean ± (SD); NLBP: sub-acute non-specific low back pain; Health-workers: workers without NLBP condition; NLBP-workers: workers with NLBP condition; NLBP: non-specific low back pain; EQ-5D-3L Utility index: Time trade off-EuroQoL-5D-3L questionnaire; VAS: visual analogical scale of health-related quality of life; RM: Roland Morris questionnaire; Oswestry: Oswestry questionnaire; --: not computable; p a: p values from x^2 or Mann-Whitney adjusted by age.

Table 4. Spearmen correlation between Health-related Quality of life and Musculoskeletal-related Fitness (n=190)

HRQoL dimensions	**Endurance: flexor trunk (s)***	**Endurance: extensor trunk (s)***
Mobility	-.349**	-.343**
Self-care	-.039	-.121
Daily tasks	-.167*	-.267**
Pain/Discomfort	-.144*	-.186*
Anxiety/Depression	.037	-.138
EQ-5D-3L-Utility index	.195**	.350**
VAS	.134*	.156**

EQ-5D-3L Utility index: Time trade off-EuroQoL-5D-3L questionnaire; VAS: visual analogical scale of health-related quality of life; *Correlation is significant at 0.05 level; **Correlation is significant at 0.001 level

Reliability and Validity of lumbar and abdominal trunk muscle endurance tests in work-age patients with non-specific, sub-acute low back pain

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ABSTRACT

Aim: to determine the reliability and validity of lumbar and abdominal trunk muscle endurance tests in work-age population (office workers) with sub-acute, non-specific low back pain.

Methods: A cross-sectional, non-experimental design involving 190 subjects. Subjects were categorised into four groups: men without low back pain (*N*=30), women without low back pain (*N*=47), men with sub-acute common low back pain (*N*=42) and women with sub-acute common low back pain (*N*=71). Each group undertook prone isometric chest raise tests, as validated by Ito Shirado et al., and the Roland Morris and Oswestry questionnaires.

Setting: Occupational preventive medicine

Results: The reported ICC of this study is above .90 in all tests conducted in both sexes. Reliability in regard to temporal stability of the diagnostic criteria was excellent, with Kappa index of one in all cases. ROC analyses revealed an AUC above .70 for both men and women (except the Ito Shirado Abdominal test in women, which had an AUC slightly below .70). There was a statistically significant negative correlation between ODI score and Lumbar (r=-.442, p <.001 in men and r=-.502 , p<.001 in women) and abdominal trunk muscle endurance test (r=-.342, p < .001 in men and r=-.346, p<.001 in women) and a statistically significant negative correlation between RMDQ score and Lumbar (r=-.581, p < .001 in men and r=-.474, p<.001 in women) and abdominal (r=-.567, p < .001 in men and r=-.331, p<.001 in women) trunk muscle endurance test.

Conclusions: This study shows that lumbar and abdominal trunk muscle endurance tests are reliable and valid measures in the assessment in the work-age population affected by sub-acute, non-specific low back pain for both men and women.

KEY WORDS: backache, screening, lower back pain, occupational assessment

INTRODUCTION

Non-specific low back pain is one of the most frequent ailments in primary care consultations, with visit rates of 7–9% in the general adult population (1), and a point prevalence of 33% in office workers (2). Studies suggest that 80% of the total costs attributable to low back pain are consumed by the 10% of patients who develop chronic symptoms, therefore, prevent it chronicity has been established as a priority (3, 4).

Trunk muscle endurance (abdominal and lumbar) has been frequently used as a major outcome measure in longitudinal studies of low back pain interventions (5). In cross-sectional studies, trunk muscle endurance has also been identified as a good predictor of back health (6), and has even been proposed as a superior measure of back strength for the assessment of low back pain (7). Conversely, poor lumbar and abdominal muscle endurance may contribute to functional disability in chronic low back pain (8). In this sense, should be a negative correlation between trunk muscle endurance and self-reported functional status also in

the sub-acute phase of low back pain. Therefore, measuring trunk muscle endurance is likely to be a useful technique for the prediction, prevention and rehabilitation of low back pain.

Despite the importance given to trunk muscle endurance for the functional assessment of low back pain in both the literature and in clinical practice, the validity of, and establishment of reference data for, trunk muscle endurance tests has only been studied in working-age, patients with low back pain in the general population (5, 9). Only one study has evaluated the capacity of these tests in discriminating between patients with and without low back pain (10). However, there are no disaggregated data on the use of trunk muscle endurance tests in the work-age population with subacute low back pain; this group is likely to differ from patients with chronic low back pain in the range of factors that affect back function(11). Reference data on this specific patient population could be useful in assessing intervention programs for secondary prevention of low back pain. Although, these tests have been show a good predictive and discriminative ability between patients with and without chronic low back pain in different occupational and cultural groups, this capacity to discriminative between patients with and without low back pain has not been yet tested in patients with low back pain in the sub-acute phase which could help physicians and other health-related professionals to identify and treat patients with this ailment. Therefore, the aims of this study were: to determine the reliability and validity of lumbar and abdominal trunk muscle endurance tests in work-age population (office workers) with sub-acute, non-specific low back pain, and to collect reference data on lumbar and abdominal trunk muscle endurance tests in this population.

METHODS

Participants

A cross-sectional non-experimental study was used on office workers with and without sub-acute, non-specific low back pain. Participants from both groups did not exercise regularly (less than two 30-min exercise sessions per week) (12). For this investigation, the "case study" (office worker with sub-acute non-specific low back pain) was defined as a participant with current low back pain with or without radiating pain to one or both lower legs, without any specific pathological conditions. The back pain episode could be the first or recurrent with the current episode lasting less than 12 weeks and more than 6 weeks (13). Diagnosis of sub-acute, non-specific low back pain was confirmed by the physician of the Preventive Medicine Service of the University of Extremadura in the case of participants with low back pain symptoms. To be eligible to participate in the study, participants needed to be the following: 18–65-year-old office workers working at a computer for more than 6 hours per day, physically inactive as assessed by the International Physical Activity Questionnaire (14); not to perform any formal exercise program of more than two 30-min exercise sessions per week, and without any physical problems that would preclude them from completing a battery of fitness tests, as assessed by the Physical Activity Readiness Questionnaire (PAR-Q) (15). For the low back pain group, exclusion criteria were low back pain caused by specific pathological conditions and pregnancy. Participants with non-specific low back pain were recruited at the Preventive Medicine Service of the University of Extremadura (through scanning the patient database). One hundred and thirty-eight patients were invited by email to participate in the study after reviewing the criteria for inclusion and exclusion. After further in-person assessment against the exclusion and inclusion criteria by the physician of the Preventive Medicine Service, 118 participants were included in the study. Healthy

workers were recruited from various administrative centres of the University of Extremadura and informed of the protocol by a technical assessor. Of the 100 healthy workers who showed interest in the study, 72 persons fully complied with the inclusion criteria and were included in the study.

All participants provided written informed consent. The study was performed according to the principles established in the Declaration of Helsinki (1964) as revised in 2000 in Edinburgh, and was approved by the Research Ethics Committees of the University of Extremadura.

Measures

The socio-demographic and lifestyle characteristics that were measured included the following: age, level of study and smoking habits. Each subject was evaluated during a single session by an external technician (who did not take part in the research)

Trunk muscle endurance tests: Trunk muscle endurance was assessed using the two prone isometric chest raise tests validated by Ito Shirado et al. (9). To evaluate abdominal endurance, the subject was asked to lie in a supine position and to raise the lower extremities with 90° flexion of the hip and knee joints. To evaluate lumbar endurance, the subject was asked to lie in a prone position while holding the sternum off the floor. During both procedures, the subjects were asked to maintain the elevated positions for as long as possible but not exceeding a 2-min time limit. The time (s) the time that the participant maintained each position was the outcome measure. All participants were asked to not take pain medication 24 hours before the trunk muscle endurance assessment.

Self-reported functional status: The subjects completed a questionnaire battery defined for the study. The RMDQ [16], previously validated in the Spanish language (16), was used to assess the level of disability associated with back pain. In the Roland Morris questionnaire, the score ranges from 0 (minimal disability) to 24 (maximum disability). The ODI was also used, which has previously been validated in the Spanish language (17), to assess functional disability related to low back pain (18). This questionnaire consists of a list of limitations in different daily living activities and is filled out by the patient who has to indicate those limitations that reflect his/her current state. Total scores in the Oswestry questionnaire were obtained by applying the following formula: total points / 50 (or the number of question answered) x 100. The application of the formula gives a percentage of disability due to back pain ranging from 0% (no disability) to 100% (maximum disability).

Sample size

The required sample size was calculated to give statistical power of 0.8 for the detection of differences in the area under the curve (AUC) at the level of $\alpha = 0.05$ for a hypothetical curve with an AUC of at least 0.7 (19). This indicated that a minimum of 82 subjects with low back pain were required. We sought to use the same ratio of case study to healthy subject as reported in previous studies of workers [2, 21], which meant including 50 subjects without low back pain. In addition, the same sex ratio as found in previous studies was targeted (2, 20). For the reliability analysis, the minimum sample size was determined according to the following criteria. The study power and alpha level were set at the same values as for the receiver operating characteristic (ROC) curve analysis. The effect size was determined through the null and alternative hypothesis, respectively 0.7 (the minimum value to consider a high reliability) and 0.9 (the habitual value reported by Arab et al). These

calculations give 19 as a minimum for symptomatic group using the method proposed by Walter et al (21).

Statistical analysis and evaluation methods

All tests were performed using SPSS version 19.0. (SPSS Inc., Chicago, IL). The level of significance was set at $p < 0.05$. Descriptive statistics were presented as mean and standard deviation for continuous variables, and as frequency and percentages for categorical variables. Moreover, the Kolmogorov-Smirnov test was conducted to assess normality from different subgroups data.

Reliability assessment: Test-retest reliability was assessed in 31 participants in symptomatic group (randomly chosen from the total symptomatic sample) using a 7-day interval between tests to avoid any influence of learning, fatigue or pain on the second application of the test. All participants were asked to not take pain medication 24 hours before the trunk muscle endurance assessment. Also the inclusion/exclusion criteria was confirmed the same day of the retest (day 2) by the physician. An external technician (who did not take part in the research team and was blinded to the patients) performed all tests in the day 1 and day 2. First, the stability coefficient was analysed using the Intra-class Correlation; ICC2,1 (22). One interpretation of the reliability measures using ICCs suggests that a value greater than 0.70 represents good reliability whereas a value less than 0.70 represents moderate to poor reliability. It has been suggested that the ICC should be greater than 0.90 to ensure reasonable validity (23). The ICC is based on Analysis of Variance so the results must be interpreted with caution because of the non-normality found in the data. The reliability and temporal stability of the diagnosis was also assessed based on optimal cut-off points selected according to the ROC analysis. For this analysis, Cohen's Kappa index was used. A Cohen's Kappa index of 1 indicates perfect stability of the diagnosis after removed the agreement due to chance (24). Data were analysed by sex for both tests. The absolute reliability was determined with the standard error measurement (SEM) [$SEM = SD\sqrt{(1-ICC)}$], where SD is the average SD of day 1 and day 2, and the real minimum change (SRD) ($1.96 \times \sqrt{2} \times SEM$)]. On the basis of the SEM and SRD values, a decision as to whether a genuine change has occurred would need to be made clinically by taking all aspects of patient assessment into account (25). Bland-Altman plots were constructed to illustrate a random relationship between 31 individual differences and trunk muscle endurance tests scores of day 1 and day 2 (26).

Validity assessment: predictive and construct validity were tested in the present study. ROC curve analysis was used to assess predictive validity of the tests used [29]. The ROC curve is a plot of sensitivity versus specificity of a variable assessed against an external criterion, and is therefore a representation of the trade-off between sensitivity and specificity. The presence of non-specific low back pain using the study inclusion criteria was used as the external criterion for constructing the ROC curves. Sensitivity and specificity were used to determine the cut-off value (giving equal weight to both parameters) for each test performed. AUC and its significance for the ROC curve was then determined through the non-parametric estimation method due the binormal method might bias the results because the data were not normally distributed. Trunk muscle endurance tests were conducted in men and women with and without low back pain. Construct validity, the extent to which the instruments correlate with other measures with which it should be related to, was estimated by studying correlation between the trunk muscle endurance tests, the RMDQ and the ODI scores. For the construct

validity, a Spearmen correlation was used between self-reported functional status and the tests performed. The level of relationship was determined based on the recommendations of Cohen (27). A coefficient of between 0.1 and 0.29 was considered low; a coefficient between 0.3 and 0.49 were considered moderate and more than 0.5 was considered high.

RESULTS

Table I shows the socio-demographic characteristics of the participants in the study stratified by gender. A total of 190 participants between the ages of 27 and 64 years were recruited to the study, including 72 healthy workers (without low back pain) and 118 workers with subacute non-specific low back pain.

Reliability assessment

Table II presents the results from the analysis of reliability of lumbar and abdominal trunk muscle endurance tests scores in the original variable and the category that is predicted by the ROC. The reported ICC of this study is above .90 in all tests conducted in women and men with and without low back pain. Reliability in regard to temporal stability of the diagnostic criteria was excellent, with Kappa index of one in all cases. Figure 1 shows Bland-Altman plots of the lumbar and abdominal trunk muscle endurance tests on day 1 and day 2. The bias represents the average difference for trunk muscle endurance score between day 1 and day 2. Most of bias in the present study was negative indicating that day 2 had higher trunk muscle endurance values than day 1.

Validity assessment

Predictive validity: Table III shows the cut-off points, sensitivity, specificity and area under the ROC curve values for each test. The ROC curve reveals that for men and women, the lumbar trunk muscle flexion test had greater sensitivity and specificity than the test for abdominal trunk muscles, although the results for both show acceptable sensitivity and specificity (except lumbar flexion for women). In addition, the results suggest that both trunk muscle endurance tests are better predictors of low back pain in men than in women (Figure 2). A similar result was obtained for the AUC, in which both tests recorded an AUC above .70 for both men and women (except the Ito Shirado Abdominal test in women, which had an AUC slightly below .70).

Construct validity: Table IV reveals the Spearman correlation coefficient between the main outcomes measures in this study. There was a statistically significant negative correlation between ODI score and Lumbar ($r=-.442$, $p<.001$ in men and $r=-.502$, $p<.001$ in women) and abdominal trunk muscle endurance test ($r=-.342$, $p < .001$ in men and $r=-.346$, $p<.001$ in women) and a statistically significant negative correlation between RMDQ score and Lumbar ($r=-.581$, $p < .001$ in men and $r=-.474$, $p<.001$ in women) and abdominal ($r=-.567$, $p < .001$ in men and $r=-.331$, $p<.001$ in women) trunk muscle endurance test. According to Cohen´s coefficient, this analysis revealed a moderate negative relationship between both questionnaires used and the abdominal trunk muscle endurance test in men and women. Also, this analysis revealed a high level of negative relationship between both questionnaires used and the abdominal trunk muscle endurance tests in men and women.

DISCUSSION

This study was designed with two purposes in mind: first, to determine the test-retest reliability of selected tests' data of trunk muscle endurance, and second, to evaluate the predictive and construct validity of these tests in office workers with sub-acute non-specific low back pain. To our knowledge, this is the first study analysing the reliability and validity of this tests in this

special population. Our data concerning the test score of our patients in in the lumbar and abdominal trunk endurance tests are different from those reported by Arab et al (10). However, our results are consistent with those of Ito Shirado et al in chronic low back pain patients (9), and reinforce the use of these tests.

Reliability of the ICC values in our study was high, mostly above .95. These data also differ from those reported by Arab et al (which were over .80) due in part to differences in the time the tests (test-retest). In our study, we used a 7-day interval between each measurement (inter-session reliability), while Arab et al. used a 15-min interval (intra-session reliability). Our ICC values are also consistent with the ICC values reported previously for chronic low back pain patients (5). A novel feature of our study was the reporting of absolute reliability indices. To our knowledge, this is the first study to report these indices, which can enhance the interpretation of the results of interventions aimed at improving functional capacity in subacute low back pain.

In regard of predictive validity, the main finding of this study was that the two tests performed in this study gave acceptable AUC values (28) for both men and women, indicating good predictive validity of the tests performed. The results are consistent with other studies showing a significant decrease in the endurance of the trunk muscles in patients with low back pain (9, 29). Because these muscles are rich in larger diameter type I muscle fibres (30), they are suited to supporting low levels of activity for long periods of time. The decreased muscle endurance in patients with low back pain has been attributed to higher levels of muscle metabolites resulting from prolonged muscle tension and spasm, muscle deconditioning and inhibition of the paraspinal muscles in response to pain and decreased activity (31, 32). Our results for AUC values are in accordance with the one other reported study on trunk muscle endurance tests and low back pain (10). However, although this latter study focused on working-age patients with low back pain, the type of the low back pain was not reported in accordance expert guidelines in low back pain (11). Also, the functional status of the patients was not reported (33). These two factors suggest that it may be difficult to apply the results reported by Arab et al to other clinical and functional manifestations of low back pain (e.g., patients with sub-acute low back pain) (11).

Sensitivity and specificity values for the cut-off points in our study were good, with the exception of the abdominal protocol in women. Arab et al found similar lower sensitivity and specificity values for this protocol. Despite this similarity, our cut-off points differ from those reported by Arab et al, possibly because the nature of the back pain in their study population was different, and may have been influenced by other factors (34). In addition, the selected cut-off points in our study were based on giving equal importance to sensitivity and specificity, which could also explain the difference in cut-off points (28) in the two studies, but we cannot test this because the method for selecting the cut-off point was not reported by Arab et al.

Decrease Lumbar trunk muscle endurance has been frequently associated with functional disability in patients with chronic non-specific low back pain (8), but this relationship has not been studied during the subacute phase of low back pain. Although both questionnaires used in this study have been largely validated in the literature for the self-reporting of functional disability in patients with low back pain, the ODI seems to be more accurate in more affected patients, while the RMDQ seems to be more accurate in less affected patients (35). Therefore, the current study shows a moderate to high level of correlation between self-reported functional disability measured

with both RMDQ and ODI, and the results of the trunk muscle endurance tests performed in this study. Other international studies confirm this relationship. For example Chok et al. reported a weak correlation between the trunk muscle endurance tests scores and the RMDQ scores in subjects with low back pain (36). Thus, trunk muscle endurance training has been recommended to improve performance, thus increasing functional status.

This study has several limitations. First, there may have been selection bias since this is a cross-sectional study comparing two different groups, which could lead to a systematic error due to bias in the study population. To minimise possible selection bias, we used an age-matched group of control participants (37). Although we determined the required sample size before the study was performed, we did not use population-sample techniques, which could affect the applicability of the results. Despite this, the socio-demographic characteristics and the degree of self-reported functional status are in agreement with the only other study carried out in the Spanish National Health System involving patients with non-specific, sub-acute low back pain (38). Another limitation is that participant in the study were asked to report the number of hours of computer use. Previous studies have shown that office workers overestimate their duration of computer use at work, as compared with the recorded duration of computer use at work (39, 40). This issue could limit the generalization of the results to individuals who use a self-reported measure to report the computer use at work. The design of the present study does not allow us to generalise in determining cut-off points for the more physically active low back pain patients, and more studies are needed to determine the cut-off point in these patients. Additional studies are also needed to determine if the test values in this study are consistent with other populations affected by back pain (e.g., chronic). Finally, the selection of cut-off points in our study was based on an equivalent relative assignment of importance for sensitivity and specificity. Additional cost-utility studies are required to obtain criteria for similar studies under different sensitivity and specificity conditions, with the aim of adjusting the diagnostic criteria based on the allocation of resources in each case.

Conclusions

This study shows that lumbar and abdominal trunk muscle endurance tests are reliable and valid measures in the assessment in the work-age population affected by sub-acute, non-specific low back pain for both men and women. The present study has generated novel data, which will assist physicians, therapists, and clinicians in the functional status assessment in this special population.

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COMPETING INTEREST: None to declare

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Tables and figure legends

Figure 1. Bland-Altman plots of the lumbar and abdominal trunk muscle endurance tests

Figure 2. Roc curve for men and women

Table I. Socio-demographic, health characteristics and test values performed in the study of participants in the study (n=190)*

Table II. Reliability analysis of the test performed in NLBP workers (n=48)

Table III**.** The cut-off score, sensitivity, specificity and area under the ROC curve for the performed tests (n=190)

Table IV. Correlation between functional disability levels and physical fitness tests in males and female workers with sub-acute non-specific low back pain * (n=118)

Table I. Socio-demographic, health characteristics and test values performed in the study of participants in the study (n=190)*

	Healthy-workers (n=72)		**NLBP-workers (n=118)**	
Characteristics	Males	Females	Males	Females
Age (years)	41.17 (13.04)	47.95 (8.55)	45.85 (9.17)	46.01 (8.15)
Sex, n (%)	30 (41.66)	42 (58.34)	47 (39.84)	71(69.16)
Smoke habit				
Smoker, n (%)	4 (13.30)	7 (16.70)	25 (53.20)	37 (52.10)
Not Smoker, n (%)	26 (86.70)	35 (83.30)	22 (46.80)	34 (47.90)
Level of studies				
Secondary studies, n (%)	0 (0.00)	5 (11.90)	5 (10.60)	2 (2.80)
Professional studies, n (%)	3 (10.00)	15 (35.70)	39 (54.90)	39 (54.90)
University studies, n (%)	27 (90.00)	22 (52.40)	30 (42.30)	30 (42.30)
Hours per day of computer use	7.6 (1.31)	8.8 (1.22)	8.4 (1.91)	7.9 (1.53)
Test performed				
Endurance: abdominal trunk muscle (s)	94.63 (37.94)	77.42 (46.47)	62.06 (36.87)	46.06 (29.28)
Endurance: lumbar trunk muscle (s)	109.36 (24.18)	101.80 (36.92)	79.57 (30.66)	75.49 (28.97)
Roland Morris Questionnaire	0 (0)	0 (0)	11.21 (2.22)	12.04 (2.40)
Oswestry Disability Index	0 (0)	0 (0)	29.93 (1.49)	28.12 (2.52)

*Value expressed as Mean ±SD; NLBP-workers: office workers affected by sub-acute non-specific low back pain; Healthy workers: office workers without health problems; Hours per day of computer use: Self-reported hours per day of computer use.

Table II. Reliability analysis of the test performed in NLBP workers (n=48)

Trunk muscle endurance test	Group	Day1	Day2	*p*	ICC	95%CI of the ICC	SEM	%SEM	SRD	%SRD	Kappa
Abdominal	Male NLBP-workers (n=12)	56.50 (37.85)	54.66 (36.93)	.73	.97	(.96 to .99)	3.53	4.70	9.78	12.95	1
	Female NLBP-workers (n=12)	48.78 (29.73)	46.15 (28.98)	.74	.96	(.92 to .99)	2.67	3.40	7.41	9.50	1
Lumbar	Male NLBP-workers (n=12)	80.83 (24.92)	83.95 (25.34)	.69	.97	(.94 to .98)	6.54	6.70	19.33	18.75	1
	Female NLBP-workers (n=12)	82.68 (30.69)	85.95 (31.35)	.65	.96	(.94 to .98)	6.92	13.00	19.17	36.20	1

ICC: intra-class correlation coefficient; SEM: standard error of measurement; SRD: small real difference; Kappa: stability diagnosis criteria used in each test performed-based Kappa coefficient; NLBP-workers: office workers affected by sub-acute non-specific low back pain; Healthy workers: office workers without health problems; CI: Confidence Interval; Day1: test; Day2: retest; *p*: p values from Mann-Whitney U-test.

Table III**.** The cut-off score, sensitivity, specificity and area under the ROC curve for the performed tests (n=190)

Measures	**Cutt-off**	**Sensibility (%)**	**Specificity (%)**	**AUC (cm^2)**	***p***	**SE**	**95% Interval Confidence**
Abdominal trunk muscle endurance test							
Males	<105.50	91,50	70	.78	<.001	.06	.66 to .89
Females	<107.50	97,20	52,40	.69	<.001	.06	.58 to .80
Lumbar trunk muscle endurance test							
Males	<111.50	91,50	83,30	.86	<.001	.05	.76 to .95
Females	<117.00	90,10	73,80	.78	<.001	.06	.67 to .89

AUC: area under the ROC curve (maximum_1.0); SE: standard error; *p:* statistic significance set at 0.05.

Table IV. Correlation between functional disability levels and physical fitness tests in males and female workers with sub-acute non-specific low back pain * (n=118)

***Males** (n=47)*				
Measures	**RMDQ**	**ODI**	**Lumbar test**	**Abdominal test**
Roland Morris Questionnaire	1.000	.59**	-.58**	-.57**
Oswestry Disability Index		1.000	-.44**	-.34**
Lumbar trunk endurance test			1.000	.28*
Abdominal trunk endurance test				1.000
***Females** (n=71)*				
Measures	**RMDQ**	**ODI**	**Lumbar test**	**Abdominal test**
Roland Morris Questionnaire	1.000	.74**	-.47**	-.33**
Oswestry Disability Index		1.000	-.50**	-.35**
Lumbar trunk endurance test			1.000	.63**
Abdominal trunk endurance test				1.000

*Spearman correlations coefficients. RMDQ: Roland Morris disability Questionnaire; QDI: Oswestry disability Questionnaire; Lumbar test: lumbar trunk endurance test; Abdominal test: Abdominal trunk endurnace test; **: Correlation is significant at 0.001 level.

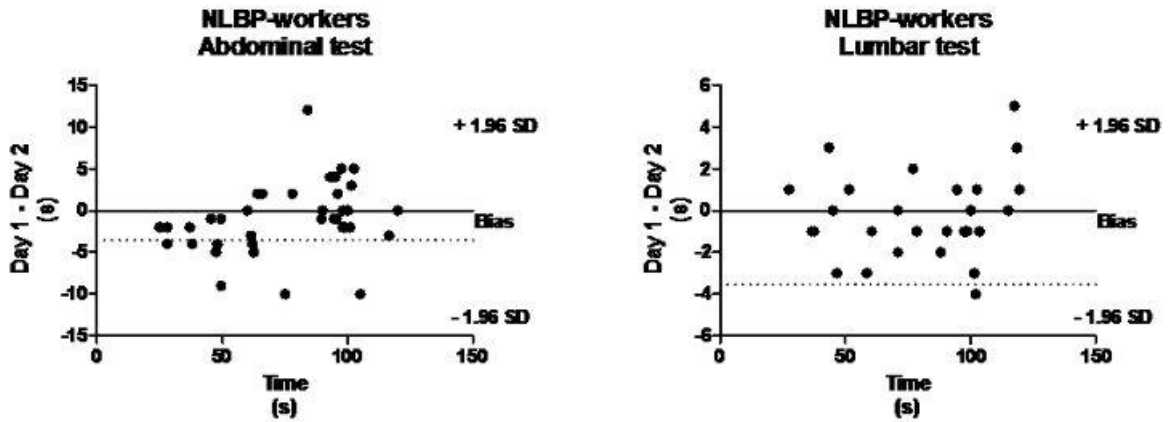
NLBP-workers
Abdominal test
Day 1 - Day 2 (s)
+1.96 SD
Bias
-1.96 SD
Time (s)
NLBP-workers
Lumbar test
Day 1 - Day 2 (s)
+1.96 SD
Bias
-1.96 SD
Time (s)

Figure 1

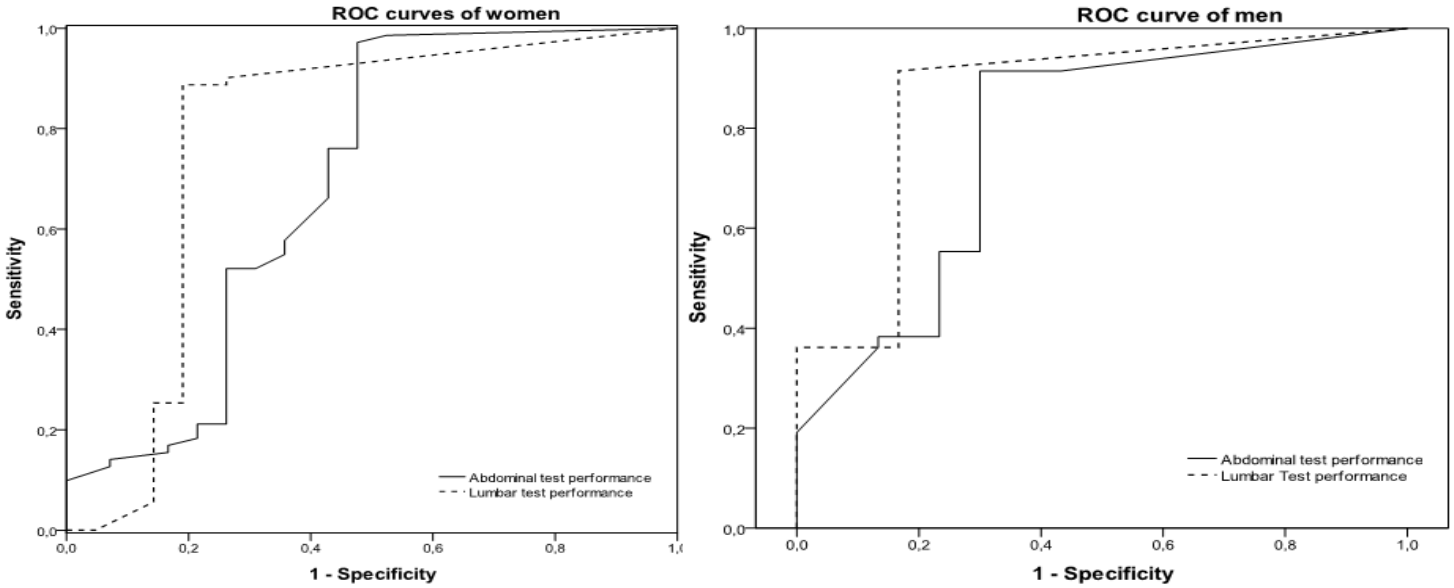
ROC curves of women
Sensitivity
1 - Specificity
Abdominal test performance
Lumbar test performance
ROC curve of men
Sensitivity
1 - Specificity
Abdominal test performance
Lumbar Test performance

Figure 2

A Web-based Intervention for Secondary Prevention of Non-specific Low Back Pain in Office Workers: Randomized Controlled Trial

Journal of Orthopaedic & Sports Physical Therapy, submitted (second revision)

ABSTRACT

Purpose: To test the feasibility, safety, and efficacy of a web-based multidisciplinary intervention for office workers with sub-acute non-specific low back pain. Methods: A 9 month single-blind randomised controlled trial (ISRCTN40949689) was conducted involving 100 office workers with sub-acute low back pain. The intervention group had access to both the study intervention and standard care. The control group had access to standard care only. Standard care was defined as all existing non-web-based interventions offered by the University Preventive Medicine Service. The web-based programme was offered via the Preventive Medicine Service website. Intervention group participants were asked to engage in the intervention at their worksite for 11 minutes each day, 5 days a week. Primary outcomes were health-related quality of life (HRQoL) and functional disability, as measured by the EQ-5D-3L and the Roland Morris Questionnaire, respectively. Secondary outcomes were the number of episodes of low back pain and the results of trunk muscle endurance tests. Outcomes were measured before and after the 9 month intervention period. Results: In the intervention group, functional disability improved by 77%, with a pre- to post-treatment mean difference of -9.23 (-10.57 to -7.89, 95% CI) ($p<0.001$); and HRQoL improved by 29%, with a pre- to post-treatment mean difference of 0.16 (0.069 to 0.191, 95% CI) ($p<0.001$). Conclusions: Use of a web-based treatment and education programme to reduce low back pain and related problems among office workers is a logical and feasible approach. The effectiveness of the present programme suggests that it could be implemented routinely in this population.

KEYWORDS: secondary backache prevention, worksite health promotion, occupational rehabilitation, randomised controlled trial

INTRODUCTION

Low back pain is one of the most frequent presentations in primary care, with between 7% and 9% of all primary care appointments involving patients with lumbar ailments [9]. In 80% of low back pain cases, the aetiology is unclear [8]. The care of patients with non-specific low back pain (NLBP) impacts substantially on the primary health care budget through the cost of consultations, examinations, and prescriptions. The impact on social resources is also considerable, particularly through the effects of lost working days [11]. However, the bulk of the costs attributable to NLBP are due to the small proportion of patients who develop chronic symptoms [11]. Office workers in particular display several behavioural patterns that predispose them to musculoskeletal disorders such as low back pain and related disorders[28]. These include protracted periods of sitting and immobility; limited use of body musculature except for certain muscles of the arms, wrists and hands; and the maintenance of poor posture. The point prevalence of low back pain among office workers has been estimated to be 33% [38]. Implementation of a exercise programme is thus a low-cost strategy to reduce and

prevent low back pain among office workers has therefore been proposed[4]. Although convincing data show that multidisciplinary interventions can improve physical function and psychosocial factors, their effectiveness in terms of reducing low back pain has not been proven [16]. Exercise usually forms a part of multidisciplinary interventions for individuals with low back pain and holds promise in low back pain management. Thus, exercise is recommended for workers [5], both at home and at the workplace [4]. However, it is unclear which specific exercise programme is most effective for the secondary prevention of low back pain [29]. Since poor lumbar and abdominal muscle endurance (factors associated with postural stability) may contribute to functional disability in NLBP patients [18], exercises to improve trunk muscle endurance may improve function in patients with chronic low back pain [30]. However, few data are available concerning the effectiveness of trunk muscle endurance training and its relationship with functional status in patients with sub-acute low back pain. Chok et al. investigated the effectiveness of trunk muscle endurance training in this population and reported a weak association between improvement in trunk muscle endurance scores and functional status, as measured with the Roland Morris Questionnaire[6].

A recent systematic review [4] suggested that exercise programmes of short duration are preferable for employees who work long shifts, and that long periods of exercise are needed to prevent low back pain. However, this review clearly established that further specific trials are warranted to resolve this issue.

The internet and email are promising media for the delivery of health information and health promotion programmes. Previous studies have shown that web-based exercise programmes with email reminders interventions are useful for increasing fitness in the general population[45, 46]. However, their effectiveness in other populations, including individuals with low back pain (and consequently lower levels of fitness), and in terms of improving function and health-related quality of life (HRQoL), is unknown. This approach could make a major contribution to public health, since it is considerably less expensive than traditional methods and can be delivered to a large number of specifically targeted individuals [32]. The aim of the present study was to determine whether a 9 month web-based multidisciplinary programme (including exercise and postural education) to improve trunk muscle endurance and HRQoL and to reduce functional disability could be successfully conducted at the worksite among office workers with sub-acute NLBP.

METHODS

Design

Figure 1 shows the flow of participants through the present single-blind (blinded for researchers) randomised controlled trial (ISRCTN40949689). The study population was recruited from staff in the administrative offices of a university in southern Spain. To ensure correct implementation, a manual describing the study protocol was produced and made available to all researchers involved in the study. Prior to the commencement of the study, the two study technicians received 2 weeks training in all aspects of the protocol. The study was performed in accordance with the principles of the Declaration of Helsinki as revised in 2000 in Edinburgh and was approved by the research ethics committees.

Participants

Individuals with sub-acute NLBP were recruited via the University Preventive Medicine Service. An advertisement alerted potential participants to the project. Low back pain is defined as pain localised between the 12th rib and the inferior gluteal folds, with

or without leg pain[27]. For the purposes of the present study, sub-acute NLBP was defined as current low back pain with or without pain radiating to one or both legs, in the absence of any specific pathological condition. The back pain episode was either the first such episode or a recurrence, with the current episode having lasted more than 6 weeks and less than 12 weeks [24]. The study inclusion criteria were as follows: a diagnosis of sub-acute NLBP in the absence of any major neurological deficit; an age of 18 to 64 years; physical inactivity (less than two sessions or bouts of exercise totalling 30 minutes per week)[43]; a willingness to provide informed consent; employee status; and more than 6 hours work per day at a computer workstation. The exclusion criteria were as follows: a diagnosed cause of backache (infection, tumour, disc herniation with an associated neurological deficit, osteoporosis, ankylosing spondylitis, fracture, an inflammatory process, radicular syndrome, or cauda equina syndrome); chronic backache; any other major disease [41]; or a lack of fluency in Spanish. All individuals working at the university were informed about the study via email messages, posters, and internal newsletters (2883). A total of 342 interested persons sent an email with their contact data and were contacted by the research team. After reviewing the Preventive Medicine database, a total of 138 individuals were found to fulfill the inclusion criteria. These individuals were invited via email and telephone to participate in the study. After revision of the inclusion and exclusion criteria by the clinical Head of the Preventive Medicine Service, 38 individuals were excluded from the final list of participants. A technician allocated the remaining 100 patients to one of the two study groups using a computer generated random allocation data processing programme and a 1:1 ratio (intervention: control).

Procedure

The exercises and postural interventions used in the web-based programme were recorded in a laboratory setting using a standard video camera [Sony HDR-XR550VE (http://www.sony.es/)]. These recordings were then uploaded to a dedicated section of the Preventive Medicine Service website.

The physical exercise routine was designed by a clinical exercise physiologist. Interventions for adopting an optimal posture (postural interventions) at a computer workstation were designed by the University preventive medicine clinician. The programme was structured to allow the participants to follow in real-time at their worksites during office hours. The programme involved the viewing of a video of postural interventions (2 minutes), followed by a video of the daily exercise (7 minutes), and finished with a repetition of the postural interventions. Each daily session included exercises to promote the strength, flexibility, mobility, and stretching of the abdominal, lumbar, hip, and thigh muscles to promote postural stability. Mobility exercises involved large movements of the joints associated with the postural stability muscles. Flexibility exercises were carried out using a static work methodology. Strength exercises were carried out using progressive shortening, and involved stretching speed:motion ratios (1:1, 1:2, 1:3, 2:1, 3:1) combined with slight isometric contractions of the muscles involved in the exercises. Finally, stretching exercises were performed that involved moderate stretching of the muscles involved in the session. Detailed information regarding the programme structure and the 9 month exercise routine is provided in Table 1 and Table 2, respectively. The videos were available daily (Monday to Friday) over the 9 month study period. The programme was explained to each participant, who was then assigned a username and a password to access the system. Participants were asked not to perform any additional formal physical

exercise routine during the 9 month intervention period.

Intervention

The participants were assigned to either the intervention group or the control group. The intervention group had access to the web-based programme and personal email interventions plus standard care (with patients visits -at least once per year, at the beginning of the academic year -and self-care web-based information- i.e. how to manage their own workstation to limit the damage on the visual system or how to lifting heavy loads-). Participants in the control group had access to standard care only. As we aimed to mimic real-life implementation as much as possible, only one email, which always contained the same information, was sent per day to participants in the intervention group [10] (Table 1). Both groups were evaluated at baseline and at the end of 9 month intervention period. Data on participation in the programme were collected automatically by recording the number of times each participant accessed the programme and checked by telephone. Participants in the intervention group were asked to report any adverse health effects noted during the intervention period. For participants who abandoned the programme, the reasons were recorded.

Measurements

Socio-demographic and health characteristics, including age, smoking habits, and sex, were recorded. At baseline, all participants were asked to complete the study questionnaires and to perform a low back pain-related fitness test. Outcome measurements were repeated at the worksite at the conclusion of the 9 month study period. The physical tests were administered by an experienced physical fitness tester who was not a member of the research team [15].

Low back pain-related fitness test: Trunk muscle endurance was evaluated using the Shirado Ito lumbar and abdominal tests[20]. To evaluate the endurance of flexor muscles, the participant was requested to recline in a supine position and to elevate the lower extremities to 90º flexion of the hip and knee joints. To evaluate the endurance of extensor muscles, the participant was requested to adopt a prone position, while keeping the breastbone on the supporting surface. During both procedures, the participant was requested to maintain the position for as long as possible for a maximum of 2 minutes. A 7-day reliability test was tested in our laboratory. The smallest real difference (%SRD), representing the smallest change to indicate a real improvement for a single individual, was 7.5% for lumbar trunk muscle endurance and 23.5% for abdominal muscle endurance.

Questionnaires: All participants were asked to complete the study questionnaires at the start and the end of the 9 month study period. The Roland Morris Questionnaire [26] was used to assess the level of disability associated with the sub-acute NLBP. In the Roland Morris Questionnaire, total scores are obtained by computing the sum of all responses scored with the value 1. The total value ranged from 0 (minimal disability) to 24 (maximum disability). Taking into account the baseline functional status of the participants, a difference of 5 points in the Roland Morris score was considered either a good (when the score decreased by 5 points) or bad (when the score increased by 5 points) outcome, since this is the recommended minimal clinically important difference (MCID) for this questionnaire [39]. The EQ-5D-3L questionnaire[2, 25] was used to assess health-related

quality of life (HRQoL). This questionnaire has five dimensions, and each dimension is scored from 1 (best possible health) to 3 (worst possible health). The EQ-5D-3L utility index (Time Trade off-TTO- method) was used for scoring. At the following two time-points, the participants were asked to report the number of episodes of NLBP experienced: (i) baseline (i.e., number of episodes experienced over the 9 month period prior to enrollment); and (ii) 9 months post-enrollment (i.e., number of episodes experienced during the 9 month study period).

Sample size

The primary outcome measure was the change in the Roland Morris Disability Questionnaire score at the end of the 9 month study period. A difference of 2.5 points is considered to be the minimum clinically important difference in the Roland Morris Disability Questionnaire score[23]. A sample size of 62 patients (31 per group) would enable detection of a 2.5 point difference between groups given 80–90% power, a 5% (two-tailed) significance level, and a conservative standard deviation of 5 points. However, 100 patients were included to allow for potential study drop-outs.

STATISTICAL ANALYSIS

Prior to the commencement of the present randomised trial, a study was conducted to determine the reliability of the physical condition tests. This involved 46 participants. The relative reliability across two sessions was determined according to $ICC_{3,1}$ [36]. The absolute reliability was determined according to the SEM [SEM= SD√ (1-ICC), where SD is the average SD of day 1 and day 2; and the real minimum change (1.96 X √2 X SEM)] [42]. The different variables were compared at baseline using Student's *t*-test for independent samples, and the distribution of the data was examined by the Kolmogorov-Smirnov test with Lilliefors correction. After confirming that the distribution of all variables was parametric, the comparisons between groups were performed using a two-way ANOVA for repeated measures, adjusted for the baseline characteristics of the participants. The significance level was set at p <0.05. A per-protocol analysis and an intention-to-treat analysis were performed to maintain the randomisation effect [44]. The intention-to-treat analysis can also be used for comparative purposes (meta-analysis or economic analysis) and is considered more useful for decision-making in healthcare [14]. An intent-to-treat analysis was performed to determine the effects of the intervention on the main outcome measure, taking into account the possibility of drop-outs after randomisation. This was carried out using the "baseline carried forward" approach (assigning zero change from baseline as an endpoint) [19]. In addition to the p values, detailed statistics including the mean and 95% confidence interval were calculated to provide a better depiction of both the change within each group during the course of the study and the treatment effect. The mean and 95% confidence intervals were calculated using Student's *t*-test. The main outcome of the study (Roland Morris) was MCID-based dichotomised and the Number Needed to Treat (NNT) was calculated; the Absolute Risk Reduction (ARR) and Relative Risk Reduction (RRR) (globally termed Risk Reduction) were also calculated, as recommended by experts in the physical therapy field [33]. Linear regression was used to provide a better understanding of the correlation between changes in the disability index due to back pain, HRQoL, and the number of episodes of NLBP. Effect size was used to determine the magnitude of change and was calculated as the difference between means divided by the pooled standard deviation. Cohen's coefficient was used to assess the change. A change of 0–0.2 was considered very small; a change of 0.2–0.6 was considered small;

a change of 0.6–1.2 was considered moderate; a change of 1.2–2 was considered large; and a change of >2.0 was considered very large [3]. All tests were performed using SPSS version 19.0.

RESULTS

The key baseline measures of the study participants were compared (Table 3). No statistically significant differences between the intervention and control groups were observed after taking into account participants who completed the study and all enrolled participants.

Safety, feasibility, adherence, and compliance

One hundred subjects were finally randomised (Figure 1). None of the participants in the intervention group reported any negative health effects during treatment. A session was considered to have been completed if the participant remained logged in for at least 11 minutes. Participants in the intervention group remained logged in for at least 11 minutes for 85.71% of all sessions. In the intervention group, 92% (46 of 50) of all participants completed the 9 month programme. Of the four intervention group participants who dropped out of the programme, three were women who changed jobs and the other was a woman who stopped due to pregnancy. In the control group, 88% (44 of 50) of the participants completed the 9 month period. The remaining six dropped out through an apparent lack of interest.

Effects of Intervention

Effects on the degree of back pain-related disability

Table 4 shows the effects of the 9 month study programme on the degree of back pain-related disability. Degree of disability, as measured by the Roland Morris Questionnaire, improved by 77% in the intervention group, with a pre- to post-treatment mean difference of -9.23 ($p < 0.001$). Change from the baseline Roland Morris Questionnaire score was associated with the results of both the Shirado Ito lumbar test and the Shirado Ito abdominal test (Table 5). Similar results were obtained in the intent-to-treat analysis (Table 4). In both the per-protocol analysis and the intent-to-treat analysis, the Cohen coefficient was very large (Table 4). Risk Reduction was calculated for the Roland Morris, and the following results were obtained for this trial: NNT, 7 (95% CI, 4.20 to 28.60); and ARR, 13.60% (95% CI, 3.50% to 23.80%). Since no bad outcome occurred in the intervention group, RRR was equal to 100%.

Effects on HRQoL

The impact of the 9 month study period on HRQoL is shown in Table 4. In the intervention group, HRQoL (as measured by EQ-5D-3L) improved by 29%, with a pre- to post-treatment mean difference of 0.16 ($p < 0.001$). This change was associated with the change in the degree of disability, as measured by the Roland Morris Questionnaire (Table 5). Similar results were achieved in the intent-to-treat analysis (Table 4). Following both the per-protocol analysis and the intent-to-treat analysis, the Cohen coefficient was very large (Table 4).

Effects on low back pain-related fitness

Table 4 shows the effects of the 9 month study period on back pain-related physical fitness. In the intervention group, a statistically significant 18% improvement ($p < 0.001$) in the Shirado Ito lumbar test and a 36% statistically significant improvement in the Shirado Ito abdominal test were observed, with a pre- to post-treatment mean difference of 20.10 ($p < 0.001$) and 21.43 ($p < 0.001$), respectively, according to the per-protocol analysis. Similar results were obtained in

the intent-to-treat analysis (Table 4). Following both the per-protocol analysis and the intent-to-treat analysis, the Cohen coefficient was small (Table 4).

Effect on the number of episodes of NLBP

In the per-protocol analysis, an 85.57% reduction (p <0.001) in the number of episodes of NLBP was observed in the intervention group during the 9 month study period, with a pre- to post-treatment mean difference of -1.75 (p <0.001) (Table 4). For both the Roland Morris and the EQ-5D-3L, change from baseline score was independently correlated with the level of this reduction (Table 5). Following the intent-to-treat analysis, differences in the number of episodes of NLBP that occurred that occurred during the 9 month study period remained (Table 4). Following both the per-protocol analysis and the intent-to-treat analysis, the Cohen coefficient was large (Table 4).

DISCUSSION

The present web-based multi-component programme, which was provided at the worksite in addition to standard preventive care, was feasible, safe, and effective in reducing functional disability and the number of episodes of back pain, and in increasing HRQoL in office workers with sub-acute NLBP. To our knowledge, this is the first web-based multidisciplinary worksite intervention using intervention emails for physical exercise and posture education for the secondary prevention of non-specific low back pain in this population.

Each exercise session was 11 minutes in duration, and this included seven minutes of targeted physical exercise (five sessions per week). In accordance with our data, a previous study reported that five minutes of light resistance exercise each working day was effective in improving low back pain-related outcome measures (i.e., physical wellbeing and pain intensity) in office workers with NLBP (sub-acute and chronic)[37]. These types of interventions are effective when undertaken at the workplace. An average of six minutes of physical activity per day at the workplace led to significant improvements in the incidence and intensity of low back pain among symptomatic LBP workers[13, 22]. Therefore, it has been suggested that exercise programmes of short duration are most appropriate for employees who work long shifts [4].

A high level of adherence to the exercise programme was observed in the intervention group. This is consistent with previous studies, in which a high level of adherence to activities designed to promote healthy lifestyles in asymptomatic office workers was achieved through the use of intervention emails at the workplace[45, 46].

Significant improvements in the endurance of the trunk (lumbar and abdominal) muscles were observed in the intervention group. These improvements were greater than the minimal real change of 10.5% for the lumbar endurance test and 12.5% for the abdominal endurance test. This outcome is consistent with a previous study conducted in a hospital workplace, in which a land-based multi-component therapy was applied to reduce LBP symptoms in symptomatic LBP participants. However, the magnitude of the improvement in trunk muscle endurance was less than that observed in the present study [13].

The Roland Morris Questionnaire was used to measure the level of disability associated with sub-acute NLBP. This is the most widely used questionnaire for the evaluation of disability due to back pain [12]. The mean baseline Roland Morris score in the present study population was similar to that reported in another study of Spanish patients with NLBP (acute, sub-acute, and chronic)[25]. The mean

improvement in the Roland Morris Questionnaire score in the intervention group was 9.23 points. According to Stratford et al. [39], the minimum clinically important change in Roland Morris Score from baseline is 5 points. Thus, the post-treatment Roland Morris scores in the present cohort may be considered clinically relevant and are in accordance with available Spanish data[23]. Previous randomised controlled trials of interventions for the prevention of low back pain have yielded inconsistent results. These inconsistencies may relate to differences in the occupations of the study participants, a focus on different types of low back pain, differences in the interventional programmes applied, and methodological issues, all of which render comparisons between studies difficult. One study carried out to compare a back school-based education worksite intervention with routine care for the primary and secondary prevention of low back pain demonstrated no added benefit[7]. In contrast, a reduction in both LBP symptoms among symptomatic LBP patients and the occurrence of LBP symptoms among asymptomatic workers was achieved by an ergonomic intervention, which involved the provision of a brochure on correct posture at computer workstations[34]. Trunk muscle endurance tests have been widely used to assess interventions to treat LBP and related symptoms[31], and the results correlate strongly with the degree of disability measured by the Roland Morris Questionnaire. Trunk muscle tests may also predict the degree of functional disability and future episodes of LBP[1]. We have established An explanatory model of the lumbar and abdominal muscle endurance tests has been established to explain differences in the degree of disability observed between the control and intervention group. As a result, we can explain the post-intervention change in the degree of disability (as measured by the Roland Morris Questionnaire) through the post-intervention change in trunk muscle endurance. Further studies are required to investigate the influence of other variables, such as psychosocial factors, which may influence the level of functional disability due to LBP [21].

In this pioneering study, a web-based intervention led to improvements in HRQoL in office workers with sub-acute NLBP, as measured by EQ-5D-3L. Two previous studies reported that a face-to-face, supervised, land-based programme resulted in a beneficial effect on HRQoL (as measured by SF-36) in patients with chronic NLBP[17] and in healthy workers[35]. The present study also identified a significant correlation between disability and HRQoL, in accordance with previous cross sectional studies involving patients with acute-, sub-acute-[24, 40], and chronic NLBP[40]. In the present study, the observed changes in HRQoL, as measured with EQ-5D-3L, were predicted by the Roland Morris Questionnaire scores. These results are consistent with the significant correlation observed between the decrease in the number of episodes of NLBP and both the improvements in HRQoL and functional incapacity in the intervention group.

The present study had several limitations. Considerably more females than males were enrolled, which reflects the fact that female office workers are more commonly affected by low back pain than their male counterparts [38]. The perception of HRQoL among individuals with low back pain differs from that of the general population [25], and there may be some differences between what is reported by an evaluation of the disability index (measured with the Roland Morris Questionnaire) and by the EQ-5D-3L. The EQ-5D-3L index is adapted for use in the general population, and may therefore be unsuitable for judging the impact on the HRQoL in individuals with NLBP[47]. Despite this, the EQ-5D-3L is a valid instrument for making decisions relating to general health care [2, 25]. A further limitation was that we did not

take into account other factors that may affect feasibility, such as participant satisfaction, context, and dose received. However, a high level of compliance was observed. The external validity of the present study must also be considered. The study was conducted in a predominantly white, urban, south European community. Therefore, it may not be possible to generalise the outcomes to worksite programmes in all communities. Despite these limitations, the present study provides practical information concerning the implementation of worksite programmes, which is of relevance to the large number of communities with similar demographic characteristics. Further studies are warranted to compare the efficacy and effectiveness of our web-based programme in different back pain populations (e.g., chronic patients) and to examine its cost effectiveness as a public health strategy for preventing low back pain in the workplace.

Conclusion

The use of a web-based treatment and education programme and an email reminder to reduce low back pain-related problems among office workers was feasible and effective.

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FIGURE LEGEND

Figure 1. Diagram of the flow of participants through the study

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Figure 1. Flow diagram of participants

Table 1. Description of the 9-month web-based multidisciplinary intervention

C. Email reminder explanation	
A short email was sent every day of the program (Monday to Friday during 9-month intervention) at 10 am with a reminder message (which did not change through the intervention) concerning the instructions and the URL-link to access at the on line session of the day.	
D. Structure description and order of application of the 9-month web-based multidisciplinary intervention-video-sessions	
Parts (time per part, s)	Description
4. Postural reminder (120)	In this part of the video was explained in detail the how an individual must sit at worksite in the office and the exact placement of the computer screen and other modifiable environment elements (e.g. seat height or height of the armrest of the chair). Also were gave some advice on proper placement of complementary material such the footrest or the mouse pad computer. The explanation of this part was in oral and written (subtitle).
5. Addressed exercise session (420)	In this part of the video was shown in detail the exercise routine of each day. In all sessions was exercising in combination the main postural stability muscles (abdominal, lumbar, hip and thigh muscles) involving strengthening, flexibility, mobility and stretching exercises in this order respectively in all performed sessions. Mobility exercises were carried out using large movements of the joints associated with postural stability muscles. Flexibility exercises were carried out using a static work methodology. Strength exercises were carried out using different shortening-stretching speed motion ratios combined with slight isometric contractions of the muscle involved in the exercise. Finally, stretching exercises were carried out by moderate stretching of the muscles involved in the session. The explanation of this part was in oral and written (subtitle).
6. Postural reminder (120)	In this part of the video was explained in detail the proper way to sit at worksite in the office and the exact placement of the computer screen and other modifiable environment elements (e.g. seat height or height of the armrest of the chair). Also gave some advice on proper placement of complementary material such the footrest or the mouse pad computer. The explanation of this part was in oral and written (subtitle).

Table 2. 9-month web-based intervention-exercise part of the video-session explanation

	Type of Exercise	Month 1			Month 2			Month 3			Month 4			Month 5			Month 6			Month 7			Month 8			Month 9		
		S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)	S/T/R	F	I (s/s)
Week 1	**Mobility**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
	Flexibility	**4/20/6**	**t,th,f**	**--**	**4/20/6**	**t,th,f**	**--**	**5/20/6**	**t,th**	**--**	**5/20/6**	**t,th**	**--**	**4/20/6**	**t,th**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**
	Strengthening	**2/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w,f**	**1/1**	**3/20/6**	**m,w,f**	**2/1**	**4/20/6**	**m,w,th,f**	**3/1**	**3/30/5**	**m,w,th,f**	**3/1**	**2/40/5**	**m,w,th,f**	**1/2**	**2/40/5**	**All**	**1/2**	**2/40/5**	**All**	**1/3**
	Stretching	**6/20/6**	**All**	**--**	**5/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
Week 2	Mobility	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--
	Flexibility	4/20/6	t,th,f	--	4/20/6	t,th,f	--	5/20/6	t,th	--	5/20/6		--	4/20/6	t,th	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--
	Strengthening	2/20/6	m,w	1/1	3/20/6	m,w	1/1	3/20/6	m,w,f	1/1	3/20/6	m,w,f	2/1	4/20/6	m,w,th,f	3/1	3/30/5	m,w,th,f	3/1	2/40/5	m,w,th,f	1/2	2/40/5	All	1/2	1/80/5	All	1/3
	Stretching	6/20/6	All	--	5/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--
Week 3	**Mobility**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
	Flexibility	**4/20/6**	**t,th,f**	**--**	**4/20/6**	**t,th,f**	**--**	**5/20/6**	**t,th**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**t,th**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**	**4/20/6**	**m,w,f**	**--**
	Strengthening	**2/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w**	**1/1**	**3/20/6**	**m,w,f**	**2/1**	**4/20/6**	**m,w,f**	**2/1**	**3/30/5**	**m,w,th,f**	**3/1**	**3/30/5**	**m,w,th,f**	**1/2**	**2/40/5**	**m,w,th,f**	**1/2**	**2/40/5**	**All**	**1/3**	**1/80/5**	**All**	**1/3**
	Stretching	**6/20/6**	**All**	**--**	**5/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**	**4/20/6**	**All**	**--**
Week 4	Mobility	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--
	Flexibility	4/20/6	t,th,f	--	4/20/6	t,th,f	--	5/20/6	t,th	--	4/20/6	m,w,f	--	4/20/6	t,th	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--	4/20/6	m,w,f	--
	Strengthening	2/20/6	m,w	1/1	3/20/6	m,w	1/1	3/20/6	m,w,f	2/1	4/20/6	m,w,f	2/1	3/30/5	m,w,th,f	3/1	3/30/5	m,w,th,f	1/2	2/40/5	m,w,th,f	1/2	2/40/5	All	1/3	4/20/5	All	1/3
	Stretching	6/20/6	All	--	5/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--	4/20/6	All	--

S/T/R: number of series/seconds per series/Rest seconds between series per day; F: days of the week; I (s/s): Intensity (shortening-stretching speed motion ratio); All: (Monday to Friday); m: Monday; t: Tuesday; w: Wednesday; th: Thursday f: Friday; --: not applicable

Table 3. Baseline characteristics of participants with non-specific low back pain *.

	Completers (n=90)			All enrolled subjects (n=100)		
Group	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	*p†*	Control group (n=50) Mean (SD)	Intervention group (n=50) Mean (SD)	*p†*
Age (years)	45.50 (7.02)	46.83 (9.13)	.44	45.90 (6.92)	46.63 (9.13)	.70
Sex (%)	11.4 (M); 88.6 (F)	15.2 (M); 84.8 (F)	.53	16 (M); 84 (F)	14 (M); 86 (F)	.59
Smoke (%)	50 (Y); 50 (N)	56.5 (Y); 43.5 (N)	.47	54 (Y); 46(N)	56 (Y); 40 (N)	.53
RM (points)	11.65 (2.14)	12.28 (2.63)	.22	11.70 (2.04)	12.18 (2.55)	.30
TTO (points)	0.78 (.08)	0.75 (.11)	.23	0.77 (.9)	0.75 (.11)	.46
Shirado Ito Lumbar (s)	77.52 (28.06)	77.17 (30.53)	.95	77.80 (28.29)	78.80 (30.62)	.86
Shirado Ito Abdominal (s)	49.75 (31.11)	48.10 (32.16)	.80	52.72 (31.18)	48.06 (32.96)	.45
Episodes last 9-month	2.07 (.58)	2.02 (.68)	.73	1.94 (.91)	2.18 (.72)	.15

*Value expressed as Mean (SD); RM: Roland Morris questionnaire; TTO: Euroqol-5D-3L quality of life questionnaire utility index. Time Trade Off; Smoke: Percentage of smokers; M: male; F: Female; Y: yes; N: not; Episodes last 9-month: Episodes of non specific low back pain occurred in the last 9-month prior to enrollment; Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care; p ***†*****:** p values from t-test for independents measures.

Table 4. Effects of 9-month of web-based multi-factor program on non-specific low back pain in office workers*

	Baseline		Post-treatment				
Outcomes measure	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	Treatment effect Mean (95%CI)	p †	Effect size
Per-protocol Analysis (n=90)							
TTO (points)	0.78 (0.08)	0.75 (0.11)	0.75 (0.11)	0.97 (0.04)	0.16 (0.069 to 0.191)	<.001	2.60
RM (points)	11.65 (2.14)	12.28 (2.63)	13.54 (2.09)	4.93 (2.59)	-9.23 (-10.57 to -7.89)	<.001	-2.80
Shirado Ito Lumbar (s)	77.52 (28.06)	77.17 (30.53)	78.52 (26.64)	96.30 (30.53)	20.10 (13.07 to 23.19)	<.001	0.68
Shirado Ito Abdominal (s)	49.75 (31.11)	48.10 (32.16)	51.34 (31.09)	67.95 (29.35)	21.43 (14.25 to 22.26)	<.001	0.63
Episodes last 9-month	2.07 (.58)	2.02 (.68)	2.39 (.65)	0.59 (.58)	-1.75 (-2.09 to -1.49)	<.001	-2.90
Intent-to-treat Analysis (n=100)							
TTO (points)	0.77 (0.90)	0.75 (0.11)	0.78 (0.13)	0.96 (0.60)	0.19 (0.14 to 0.24)	<.001	2.50
RM (points)	11.70 (2.04)	12.18 (2.55)	13.54 (2.09)	4.93 (2.59)	-9.23 (-10.57 to -7.89)	<.001	-2.80
Shirado Ito Lumbar (s)	77.80 (28.29)	78.80 (30.62)	72.58 (29.78)	92.36 (27.89)	18.78 (9.57 to 27.98)	<.001	0.50
Shirado Ito Abdominal (s)	52.72 (31.18)	48.06 (32.96)	48.30 (30.29)	64.36 (30.71)	20.72 (13.58 to 27.85)	<.001	0.50
Episodes last 9-month	1.94 (.91)	2.18 (.72)	2.12 (.96)	0.60 (.57)	-1.76 (-2.01 to -1.50)	<.001	-1.92

*Values expressed as mean (SD); TTO: Euroqol-5 dimensions health-related quality of life questionnaire utility. Time Trade Off; RM: Rolland Morris questionnaire: Episodes last 9-month: Episodes of non-specific low back pain occurred in the last 9-month both at baseline (over the 9 month prior to enrollment) and at 9 month (post treatment). Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care; p †: p values from ANOVA for repeated measures adjusted by baseline characteristics to compare different between groups after 9-month web-based multi-factor program.

Table 5. Predictive linear regressions models of changes in functional disability (model A), Health-related Quality of life (model B) and episodes of low back pain (model C) after 9-month of web-based multi-factor program (n=90)

Model A				
dRoland Morris				
Model (R= .67; R^2 = .44)				
	Beta	SE	ST Beta	*p*
dShirado Ito Abdominal	-.218	.038	-.512	<.001
dShirado Ito Lumbar	-.096	.033	-.259	.005
CONSTANT	.528	.598		.374
Model B				
dTTO				
Model (R =.67; R^2 = 0.37)				
	Beta	SE	ST Beta	*p*
dRoland Morris	-.018	.002	-.612	<.001
CONSTANT	.054	.015		.001
	Beta	SE	ST Beta	*p*
Model C				
dEpisodes last 9-month				
Model (R= .72; R^2 = .53)				
	Beta	SE	ST Beta	*p*
dRoland Morris	.087	.018	.459	<.001
dEQ-5D-3L	-2.252	.608	-.346	<.001
CONSTANT	-.095	.094		.312

dRoland Morris: Roland Morris questionnaire score difference after treatment; dShirado Ito Abdominal: score of Shirado Ito Abdominal after treatment; dShirado Ito Lumbar: score of Shirado Ito Lumbar after treatment; dEQ-5D-3L: Euroqol 5D-3L utility difference after treatment; dEpisodes last 9-month: number of episodes of non-specific low back pain difference after treatment; ***p*:** statistics significance from ANOVA for adjusted by baseline characteristics.

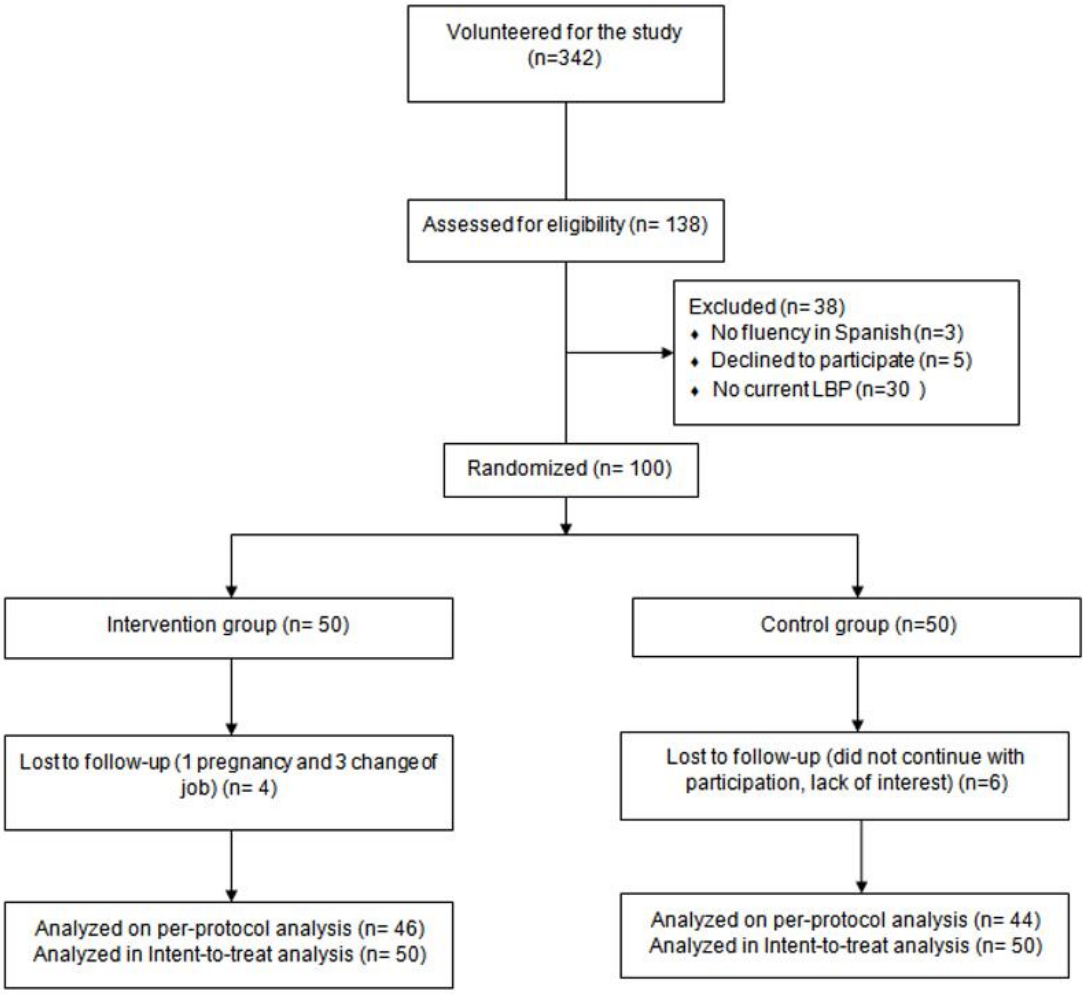
Volunteered for the study (n=342)
Assessed for eligibility (n= 138)
Excluded (n= 38)
No fluency in Spanish (n=3)
Declined to participate (n= 5)
No current LBP (n=30)
Randomized (n= 100)
Intervention group (n= 50)
Control group (n=50)
Lost to follow-up (1 pregnancy and 3 change of job) (n= 4)
Lost to follow-up (did not continue with participation, lack of interest) (n=6)
Analyzed on per-protocol analysis (n= 46)
Analyzed in Intent-to-treat analysis (n= 50)
Analyzed on per-protocol analysis (n= 44)
Analyzed in Intent-to-treat analysis (n= 50)

Figure 1

An occupational, internet-based intervention to prevent chronicity in subacute lower back pain: a randomised controlled trial

Journal of Rehabilitation Medicine (accepted)

ABSTRACT

Objective: the aim was to investigate whether the intervention reduced patients' overall risk status for chronicity when compared to conventional treatment, and, if so, to determine which individual predictive factors were acting as the key treatment mediators for this risk reduction intervention. We also test hypothesis that changes in risk of chronicity could correlate with changes in theses outcomes for LBP.

Design: Prospective, single-blinded randomised intervention study.

Subjects/Patients: University office workers with subacute non-specific LBP (N = 100) were randomised 1:1 to an intervention group, who received an online occupational postural and exercise intervention, and controls.

Methods: Exercise and education materials used in the intervention were developed as an online resource, and included video demonstrations recorded in a laboratory. Resources were loaded onto a dedicated section of the university preventive medicine service website. The physical exercise routine was designed and arranged by an experienced professional in physical activity and supervised by the clinical lead of the Preventive Medicine Service. All sessions included exercises combining postural stability (for abdominal, lumbar, hip and thigh muscles) strengthening, flexibility, mobility, and stretching. Outcome measures included SBST, Roland Morris score, and EQ-5D-3L. At 9 months, SBST was analysed and compared with the baseline and controls.

Results: Significant positive effects were found on mean scores recorded in the online occupational exercise intervention group for risk of chronicity (p < 0.019). A strong relation between functional disability, HRQoL and risk of chronicity of LBP (except was observed. The online intervention group showed significant positive effects in SBST disability items 4 and 5, and fear item 6 (p = 0.017, 0.008 and 0.049 respectively) compared with controls.

Conclusion: This study supports the feasibility and potential utility of a real-time occupational internet-based intervention for preventing progression to chronicity of subacute non- specific LBP among office workers.

MESH keywords: Occupational therapy, LBP, internet, chronic illness, rehabilitation

INTRODUCTION

Non-specific low back pain (LBP) is one of the most common health problems encountered in primary care (1), with an estimated point prevalence of 33% among office workers (2). Evidence suggests that 80% of the total costs attributable to LBP are consumed by a relatively small group (10%) of patients who develop chronic symptoms (3). Chronic LBP is associated with lower self-reported health status (4), increased functional disability (5), and increased time off work (4). Prevention of chronicity is therefore a priority (6). Research is increasingly focused on improving the effectiveness of secondary prevention interventions, through better identification of modifiable prognostic factors involved in the transition from acute back pain to chronic symptoms (7). While key prognostic factors

are well documented (8), fewer studies report interventions specifically designed to tackle these risk factors (9, 10). Multidisciplinary interventions (based on functional exercise packages of advice and education) are effective in reducing disability and addressing the psychosocial factors known to be influential in the progression to chronic LBP (11). Recent online interventions have demonstrated the clinical effectiveness of using real-time workplace advice (including regular email reminders) to help patients make healthy lifestyle choices, improve fitness levels and achieve an early return to work (12). In addition, the subacute phase of LBP has been recommended as an optimal secondary prevention intervention window (13). Treatment mediators are those factors that need to change following treatment to influence outcome (14). Fewer studies have reported on treatment mediators of LBP outcome than have investigated prognostic factors. A key message from the existing research is the importance of psychosocial factors, alongside physical factors (15). Although cognitive behavioral interventions exist for tackle chronic pain (16), , there are no reports of real-time internet-based interventions focused specifically on secondary prevention of chronic LBP by targeting key modifiable prognostic indicators among office workers, to reduce costs and improve efficacy.

We therefore developed a new occupational intervention for workers with subacute LBP. The intervention consists of two complementary components. The first constitutes email reminders that are sent to improve patient adherence (12). The second component is an internet-based, physical secondary prevention intervention, focused on increasing physical exercise levels and providing postural education relevant to the work place. As far as the effectiveness of this intervention on Health-related Quality of life (HRQoL) and functional status of LBP, in this trial, we test the overall hypothesis that our model of occupational management for office workers with subacute LBP, delivered through an online, real-time intervention is feasible, safe and effective in improving physical function. In this line, our aim was to investigate whether the intervention reduced patients' overall risk status for chronicity when compared to conventional treatment, and, if so, to determine which individual predictive factors were acting as the key treatment mediators for this risk reduction intervention. We also test hypothesis that changes in risk of chronicity could correlate with changes in functional status and HRQoL.

METHODS

Figure 1 shows the flow of participants through the study, which was a single-blind randomised controlled trial (ISRCTN40949689). The study was based in the four administrative offices of a university in the south of Spain. To ensure proper implementation of the protocol, a manual describing the study protocol was produced and made available to all researchers involved in the study. Before the study commenced, two technicians received 2 weeks training in all aspects of the study protocol. The study was performed in accordance with the Declaration of Helsinki as revised in 2000 in Edinburgh, and was approved by the Research Ethics Committees.

Participants

Participants suffering subacute non-specific LBP were recruited via the preventive medicine service of the university. An advertisement alerted potential participants to the project. Sub-acute non-specific LBP was defined as current LBP, with or without radiating leg pain, without any specific pathological conditions, and with a first or recurrent episode having lasted from 6 to 12 weeks (17). Inclusion criteria were as follows: a

diagnosis of subacute LBP in the absence of any major neurological deficit; an age between 18 and 64 years; physical inactivity (less than two exercise sessions of 30 min per week) (18); a willingness to provide informed consent; being an employee; and a requirement to work more than 6 hours per day on a computer workstation. Participants were excluded if they reported a diagnosed cause of backache; chronic backache; disc disease or any other major disease; or a lack of fluency in Spanish. A total of 138 individuals who fulfilled the criteria were invited via email and telephone to participate in the study, and 38 were subsequently excluded. The remaining 100 patients were randomly allocated 1:1 to two groups: an online occupational exercise intervention group and a control group.

Treatments

The exercise and education reminders used in the treatment program were developed as an online resource, and included video demonstrations recorded in a laboratory. The resources were loaded onto a dedicated section of the university preventive medicine service website. The physical exercise routine was designed and arranged by an experienced professional in physical activity and supervised by the clinical lead of the Preventive Medicine Service. All sessions included exercises combining postural stability (for abdominal, lumbar, hip and thigh muscles) strengthening, flexibility, mobility, and stretching. Mobility exercises were carried out using large movements of the joints associated with postural stability muscles. Flexibility exercises were carried out using a static work methodology. Strength exercises were carried out using progressive shortening:stretching speed:motion ratios (1:1, 1:2, 1:3, 2:1, 3:1) combined with slight isometric contractions of the muscles involved in the exercises. Finally, stretching exercises were carried out by moderate stretching of the muscles involved in the session. All the exercises were explained both by oral instruction and by written subtitles. The postural education reminders, addressing and promoting how best to sit at a computer and the adjustment and rearrangement of the office workstation layout (19), were designed by the university preventive medicine service clinician. Data on participation in the program was collected automatically by registering access to the program. The reasons why people abandoned the program were also collected. Both the online occupational exercise intervention group and the control group had access to the usual routine care provided by the university preventive medicine service. This included a routine annual medical examination by the lead clinician of the preventive medicine service, and specific online information on self-care at the workplace.

Online occupational exercise intervention group: A short email was sent every day with a reminder message (which did not change throughout the intervention) containing a link to the online 'session of the day.' The sessions were structured in real-time, first playing a video of postural reminders (2 minutes), then a video of the exercise(s) for the day (7 min), followed by postural reminders once again (2 min). The videos were available Monday to Friday, weekly, for 9 months. Each participant was assigned a user name and password to access the system, and the treatment program was explained to them. Participants were asked not to perform any formal physical activity routine during the training period.

Control group: The control group only had access to standard preventive medicine care.

Measurement

Both groups were evaluated at baseline and on completion of the 9-month intervention. Socio-demographic and health characteristics including age, smoking habits and sex were recorded. The questionnaires were administered by a trained technician (20) who was independent from the study team and blind to treatment allocation. A Spanish version of the Keele STarT Back Screening Tool (SBST) was used to evaluate the severity and the risk of chronicity of common LBP (21). The SBST has nine items, selected as predictive of 'poor prognosis' following a literature review and secondary analysis to identify strong independent predictors for persistent (chronic) disabling LBP. The predictive validity and external validity of the SBST have been reported, as has its reliability, with a Kappa of 0.79 (22). Two outcome measures for low back pain were used to assess the hypothesis that changes in risk of chronicity could correlate with changes in theses outcomes. In this sense the Roland Morris Questionnaire was used to assess the functional disability related to LBP (23), which has been previously validated in Spanish (24). Validity and Reliability with a Intraclass correlation coefficient (ICC) of 0.87 of this instrument has also been previously reported (24).It consists of a list of 24 items that reflect limitation in different activities of daily living, and has a score ranging from 0 (no disability) to 24 (maximum disability). Also the European Quality of Life Questionnaire - three levels (EQ-5D-3L) (25) was used to assess the Health-related Quality of Life (HRQoL). The validity of this instrument has been reported, as has its reliability, with an ICC of 0.73 (26). Five domains, encompassing mobility, self-care, usual activities, pain/discomfort and anxiety/depression, plus an overall description of health status, can be assessed using the EQ-5D-3L utility index Time Trade Off (TTO) (27).

Sample size

Prior to the beginning of this trial, the sample size was estimated based on the Roland-Morris Disability Questionnaire desired change at 9 months. A difference of 2.5 points in Roland-Morris Disability Questionnaire change scores is considered to be a minimum clinically important difference in a Spanish population (28). A sample size of 62 patients (31 per group) would enable detection of a between-group difference of 2.5 Roland and Morris Disability Questionnaire points, given 80– 90% power, a 5% (two-tailed) significance level, and a conservative standard deviation of 5 points (29). However, 100 patients were selected to allow for potential dropouts, estimated at 20%.

Statistical analysis

an intention to treat (ITT) analysis and a per protocol analysis were conducted. ITT analysis was done to report the effects of the intervention on main outcome measure within the possibility of drop-outs after randomization and was done under the "baseline carried forward" approach (assigning zero change from baseline as an endpoint) (30). Variables were compared at baseline using Student's t-test for independent measures in quantitative variables, and the chi-squared test for qualitative variables. The distribution of the data was examined using the Kolgomorov-Smirnov test with the Lilliefors correction. After confirming that the distribution of all variables was parametric, the inter-group comparison of the quantitative study variables was performed with two-way ANOVA for repeated measures. The significance level was set at $p < 0.05$. In addition to the p values, we provided detailed statistics including the mean and 95% confidence interval for better depicting the change within each intervention group from baseline to 9 months, and the treatment effect.. The differences between pre- and post-test variables were used to describe the changes from baseline to 9 months. The

differences between individual changes over 9 months in one group and these individuals' changes in the other group were used to estimate the treatment effect in the case of quantitative variables. The mean and 95% confidence interval (CI) of changes were calculated using Student's t-test for independent samples in each. The null hypothesis of no difference in the proportion of prevention of risk of chronicity between the treatment conditions was evaluated by a chi-squared test. To confirm or reject our hypothesis we also performed a post hoc analysis. In this case, odd ratios (95% CI) were undertaken to assess the treatment effect. Number needed to treat (NNT) was calculated for the outcomes measures of this trial. Effect sizes were calculated for quantitative variables, to determine the magnitude of change, and Cohen's coefficient was used to assess the change. A change from 0 to 0.2 was considered small, a change of 0.2–0.5 was considered medium, a change of 0.5–0.8 was considered large(31)(32). The strength of relationship between the risk of chronicity of pain, functional disability and HRQoL was investigated using a Pearson coefficient. To determine whether the intervention reduced patients' overall risk status for chronicity we compared using chi-squared the proportions of patients in each group who, at 9-month follow up, were low risk on the SBST. To determine which individual predictive factors were key treatment mediators for this risk reduction, a binary logistic regression was performed using changes within the eight predictive factor items measured by the SBST to explore which items were most associated with low-risk outcomes. All tests were undertaken using SPSS version 19.0 (IBM).

RESULTS

One-hundred subjects were randomised (Figure 1). There were no statistically significant differences between the intervention and control groups at baseline (Table I). No participants showed any significant adverse events related to the treatments, and compliance was high (92%) for the online occupational exercise intervention group. Of the four participants in the online occupational exercise intervention group who dropped out of the program, three changed jobs and one stopped due to pregnancy. Six participants in control group were lost through apparent lack of interest, with a total of 88% compliance achieved in the group.

Effects of the intervention on the risk of chronicity prognosis factors

Table II reveals the comparative effects between groups on the main outcomes at 9 months. Significant positive effects were found on mean LBP severity scores recorded in the online occupational exercise intervention group (SBST 23% change; 2.12 NNT; 0.80 Effect Size; -1.01 [-1.790 to 0.118] treatment effect; $p = 0.019$). Significant reductions in the risk of chronicity of LBP, measured with SBST, were seen in the intervention group compared with the control group: 60.9% patients in the online occupational exercise intervention group were SBST low-risk at 9 months, compared to 27.9% patients in the control group ($p < 0.01$). The ITT analysis (data not shown) gave similar results to the efficacy analysis for all outcome measures of the current trial.

The nine SBST items remained unchanged among the control intervention group, while the online occupational exercise intervention group showed significant positive effects in disability items 4 and 5, and fear item 6 ($p = 0.017$, 0.008 and 0.049 respectively). Post hoc analyses confirm these results. There was a trend towards a decrease in all nine SBST items in the intervention group (Table III). Table

IV shows the Pearson correlation coefficients between main outcomes. A strong relation between functional disability, HRQoL, risk of chronicity of LBP (except with psychological score) was observed. Our binary regression model demonstrated that the reduction in chronicity was primarily associated to changes in SBST disability and fear avoidance items resulting from the intervention. This resulted in a 51% change in the proportion who were low risk, with odds ratios of 0.166 (0.0638 to 0.431) ($p < 0.001$), 0.092 (0.027 to 0.313) ($p < 0.001$), and 0.302 (0.107 to 0.853) ($p<.024$), in the 4, 5 and 6 SBST items respectively (Table V).

DISCUSSION

This is the first study to analyse the effects of a real-time, occupational, internet-based intervention on the prevention of chronicity of non-specific LBP among office workers. To our knowledge, it is also the first instance of monitoring of the risk of chronicity and the change in prognostic factors after treatment using the SBST. The main findings of this study were that this intervention was effective to reduce the risk of progression to chronicity among office workers with subacute non-specific LBP. Other internet-based interventions using real-time email reminders have been conducted, with the aim of increasing the quality of patients' lifestyles. However, to our knowledge, there are no other internet-based studies using a physical intervention conducted at the workplace that are designed to prevent the chronicity of non-specific LBP among office workers.

At 100 patients, our sample size could seem small; however, we completed the trial with numbers within the estimated sample size needed to demonstrate clinically significant effects with the methods used. Also, the timing and nature of this intervention was in accordance with current clinical guidelines, which recommend multidisciplinary interventions (based on functional exercise combined with postural education) to improve physical function, and include psychosocial factors, which have been determined as risk factors in the transition from (sub)acute to chronic LBP (11). It is also potentially possible to reach a large population of office workers with non-specific LBP to prevent the chronicity of the ailment using the chosen mode of delivery of the interventions (33).

The high level of adherence observed in the intervention group may have been due to the target of our occupational interventionfor secondary prevention of LBP (34). Also the short sessions used in this trial could explain the level of adherence. In this sense, previous research suggests that exercise programmes of short duration are preferable for employees who work long shifts. Thus reaching positive outcomes in low back pain patients (35). A major determinant of the high retention of the intervention could be the use of email reminder sent to improve patient adherence. This is consistent with other studies in which a high level of adherence to activities designed to promote healthy lifestyles in asymptomatic office workers was achieved through the use of intervention emails at the workplace (12, 36)

The SBST was recently developed to help clinicians objectively measure the severity of the domains screened by the nine-item tool (determined as predictive factors of persisting disabling back pain), and determine the risk of the chronicity of LBP (22). This tool has been adapted for use among the general Spanish population (21). There was statistically significant improvement in the SBST total score at 9 months in the active intervention group compared with the controls. This shows that participants in the internet-based intervention decreased their risk of chronicity when compared with those allocated to standard treatment. In our study, intervention group

participants, compared with control group participants, were more likely to experience enhanced progression to a low risk of back pain chronicity. Recovery rate, defined in terms of transition to a low risk of chronicity of pain, was 77% higher in the intervention group when compared with the control group. Physical therapy, a common treatment for LBP, was taken as part of a multidisciplinary intervention, because activity is a keystone of early intervention and rehabilitation (37). However, there are controversial results across the scientific literature on the value of physical therapy at an early juncture. For example, a systematic review concluded that exercise therapy was ineffective (moderate evidence) and that several other physical therapy techniques had limited effectiveness (38). One possible discriminating factor may be whether the intervention is an active or a passive treatment. Indeed, working on the patient's apprehension about keeping active may be a key point (39). Another systematic review addressed the strong evidence that most specific exercises programs designed to prevent LBP are ineffective in isolation (40). In any case, research suggests that there is limited evidence supporting the use of exercise to prevent LBP episodes in the workplace (35). There is a need to know, therefore, whether adequate, timely physical therapy in combination with psychosocial tasks has value as a secondary prevention (10). In this regard, our results suggest that a real-time internet-based physical intervention could prevent chronicity of LBP. These results are in agreement with some previous research showing improvements in back pain-related outcomes when exercise is combined with other modalities, such as cognitive behaviour intervention (10), functional movements, relaxation, or the integration of coping skills (41). The relatively large effects found in this study regarding the prevention of chronicity are supported by other studies that employed multidisciplinary management of LBP. These include combinations of cognitive behavioural interventions and exercise to prevent chronicity of LBP among patients in the subacute phase (9, 42). There were no differences in the psychological score of SBST between groups after treatment in our study, which was possibly due to the fact that treatment mediators associated with this part of the instrument were not strongly affected at baseline in our subjects (14). On the other hand, in previous studies carried out in patients with subacute non-specific LBP, significant correlations between risk of chronicity, self-reported functional disability, and health-related quality of life were reported (17, 43); these results are in accordance with our data when we the correlation coefficients between these variables are taken into account.

To better explain the results regarding the transition to low risk of chronicity after treatment, we performed a binary logistic regression within the SBST items 4 (fear avoidance), 5 and 6 (functional disability). A change over time in favour of the active intervention group has already been observed for these items. Within these results, the variance between the two groups in the proportion who transitioned to a low risk of chronicity was 51%, which is in favour of active intervention group participants. The findings of our physical intervention are in accordance with other studies that shown to be effective in decreasing the risk of chronicity by improvements in prognostic factors of persistent LBP, such as fear avoidance using a multidisciplinary-based intervention (44) or disability using a graded-based exercise intervention (45). These results could be explained in part by the design of our intervention, where we introduced a graded exercise series (with variation in the density of the exercises) in order to decrease fear-avoidance beliefs and disability values reported at baseline in our subjects, and thus increase the effectiveness of our

intervention in reducing the risk of chronicity (14). George and colleagues (45) performed a randomised trial comparing standardised physical therapy with or without the inclusion of graded exercises designed to reduce pain-related fear. A significant interaction between elevated fear avoidance beliefs and treatment outcome was reported, suggesting the baseline level of fear-avoidance beliefs was a treatment effect modifier for physical therapy incorporating graded exercises (46). However, more research is needed to identify relevant psychosocial baseline findings that can direct the choice of treatment strategies to improve clinical outcomes.

We acknowledge some limitations in this study. First, this intervention was delivered in the Preventive Medicine Service of the University: only one setting was used, and we did not know if this intervention would be feasible and effective in other setting. However, the scientific literature shows that specific medical counselling seems to be a key element in the delivery of interventions to enhance inactive people's physical activity (47). Second, we did not take in to account factors that may affect feasibility such as participant satisfaction, context, and dose received (48). However, we experienced a high level of compliance, which led us to suppose that these factors have a positive influence on the level of feasibility found in our study. The external validity of our study must also be considered. This study was conducted in a predominantly white, urban, south European community; therefore, it may not be possible to generalise the outcomes to workplace programs in all communities. Cross-cultural analyses on this are warranted. Further studies are also needed to compare the efficacy of our internet-based program in different patient populations affected by back pain (e.g., chronic patients), and to examine its cost effectiveness as a public health strategy for preventing persistent LBP in the workplace and its associated costs.

Conclusion and practical implications

This study supports the feasibility and potential utility of a real-time occupational web-based intervention for preventing progression to chronicity of subacute non-specific LBP among office workers. The current study provides new insights that could help private and public office environment managers in the prevention of negative consequences of non-specific LBP in subacute phases.

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Tables and Figure legends

Figure 1: Flow diagram of participants

Table I. Baseline characteristics of participants in the study * (n=90)

Table II. Effects of 9-month of web-based intervention on risk of chronicity of non-specific subacute low back pain among office workers *

Table III. Effects of 9-month of web-based program on SBST 9-item scores * (n=90)

Table IV. Correlation between severity of pain, risk of chronicity of pain, self-reported functional disability and self-reported health-related quality of life after treatment among office workers suffering by sub acute non-specific low back pain * (n=90)

Table V. Binary Logistic Regression of change in low risk of chronicity of low back pain after 9-month of web-based intervention (n=90)

Table I. Baseline characteristics of participants in the study * (n=90)

Group	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	*p†*
Age (years)	45.50 (7.02)	46.83 (9.13)	.44
Sex (%)	11.4 (M); 88.6 (F)	15.2 (M); 84.8 (F)	.59
Smoke (%)	50 (Y); 50 (N)	56.5 (Y); 43.5 (N)	.53
Roland Morris Questionnaire (points)	11.65 (2.14)	12.28 (2.63)	.22
TTO (points)	.78 (.08)	.75 (.11)	.23
SBT total score (points)	4.38 (1.67)	4.36 (1.28)	.95
SBT psychological score (points)	2.36 (1.03)	2.28 (.98)	.70

*Value expressed as Mean (SD); Roland Morris questionnaire: Roland Morris questionnaire score; TTO: Euroqol-5D-3L quality of life questionnaire utility index. Time Trade Off; Smoke: Percentage of smokers; M: male; F: Female; Y: yes; N: not; SBT total score: StarT Back Tool total score; SBT psychological score: StarT Back Tool psychological score; p ***†*****:** p values from t-test for independents measures or chi square test.

Table II. Effects of 9-month of web-based multidisciplinary intervention on risk of chronicity of non-specific subacute low back pain among office workers *

Outcomes measure	Baseline		Post-treatment				
	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	Treatment effect Mean (95%CI) or OR (95%CI)	*p* †	Effect size
SBST total score (points)	4.40 (1.71)	4.38 (1.48)	4.38 (1.03)	3.39 (1.39)	-1.01 (-1.790 to .118)	**.019**	.80
SBST psychological score (points)	2.36 (1.03)	2.28 (.98)	2.31 (1.09)	1.84 (.86)	-.39 (-.993 to -.215)	.201	.47
Risk of Chronicity							
Low risk, Yes (%)	31.8	23.9	27.9	60.9	3.38 (1.591 to 9.501)**	**.005**	--
Medium risk, Yes (%)	54.5	65.2	57.5	34.8	.40 (.169 to .946)**	.059	--
High risk), Yes (%)	13.7	10.9	14.8	4.3	.28 (.055 to 1.511)**	.122	--

*Values expressed as mean (SD); SBST: StarT Back Screening Tool; Item 1 is scored as positive if “very much” or “extremely” bothered is marked. Items 2–9 are positive if “agree” is marked. Psychosocial subscale items are 1, 4, 7, 8, and 9. Patients are allocated to the high risk group if the psychosocial subscale score is ≥4. The remaining patients are allocated to the low risk group if the overall tool score is <4 and to the medium risk group if the overall tool score is ≥4; --: not computable; ***p* †:** p values from ANOVA for repeated measures adjusted by baseline characteristics or x^2 to compare different between groups after 9-month web-based multi-factor program; OR: Odd Ratios (Control group/Reminder group); **Applicable OR

Table III. Effects of 9-month of web-based multidisciplinary program on SBST 9-item scores * (n=90)

	Baseline		Post-treatment			
Outcomes measure	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	*p* †	OR (95% Interval confidence)
SBST global-related items (low risk)						
Referrer leg pain (item 2)	43.2	47.8	45.5	39.1	.544	.771 (.334 to 1.784)
Co-morbid pain (item 3)	40.9	45.7	36.4	37.0	.953	1.026 (.435 to 2.419)
Functional Disability (item 5)	61.5	63.0	68.2	43.5	**.008**	.308 (.127 to .748)
Functional Disability (item 6)	56.8	52.2	54.5	34.8	**.049**	.444 (.190 to 1.058)
SBST psychosocial-related items (Medium/High risk)						
Bothersomeness (item 1)	22.7	26.1	25.0	23.9	.905	.943 (.360 to 2.466)
Fear avoidance (item 4)	72.7	73.9	70.5	45.7	**.017**	.352 (.148 to .840)
Catastrophising (item 7)	52.3	50.0	50.0	43.5	.535	.769 (.335 to 1.764)
Anxiety (item 8)	43.2	52.2	47.7	47.8	.993	1.004 (.439 to 2.296)
Depression (item 9)	45.5	39.1	38.6	23.9	.132	.499 (.201 to 1.239)

*Values expressed as percentage (%) of agreement; SBST: Start Back Screening Tool; Item 1: question 1 of SBT; Item 2: question 2 of SBT; Item 3: question 3 of SBST; Item 4: question 4 of SBT; Item 5: question 6 of SBST; Item 7: question 7 of SBST; Item 8: question 8 of SBT; Item 9: question 9 of SBT; OR: Odds Ratios (Control group/Intervention group); *p* †: p values from x^2 test to compare different between groups after 9-month intervention

Table IV. Correlation between severity of pain, risk of chronicity of pain, self-reported functional disability and self-reported health-related quality of life after treatment among office workers suffering by sub-acute non-specific low back pain * (n=90)

Outcomes Measures	dSBST total score	dSBST psychological score	dRoland Morris	dTTO	dLow risk	dMedium risk	dHigh risk
dSBST total score	1.000	**.699****	**.299****	**-.212***	**-.776****	**.449****	**.474****
dSBST psychological score		1.000	.111	-.117	**-.525****	.114	**.631****
dRoland Morris			1.000	**-.612****	**-.361****	**.247***	.159
dTTO				1.000	**.239***	-.151	-.126
dLow risk					1.000	**-.807****	**-.236***
dMedium risk						1.000	**-.384****
dHigh risk							1.000

*Pearson Correlations coefficients. dSBST total score: StarT Back Tool score total score difference after treatment; dSBST psychological score: StarT Back Tool psychological score difference after treatment; dRoland Morris: Roland Morris questionnaire score difference after treatment; dTTO: Time Trade off points differences after treatment; dLow risk: Low risk differences after treatment; dMedium risk: Medium risk differences after treatment; dHigh risk: High risk differences after treatment; *: Correlation is significant at .01 level; **: Correlation is significant at 0.001 level.

Table V. Binary Logistic Regression of change in low risk of chronicity of low back pain after 9-month of web-based multidisciplinary intervention (n=90)

-2 Log likelihood= 68.43; Cox & Snell R Square= .36; Nagelkerke R Square= .52

	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
dFear avoidance (item 4)	-1.797	.487	13.592	.166 (.0638 to .431)	<.001
dFunctional Disability (item 5)	-2.386	.625	14.588	.092 (.027 to .313)	<.001
dFunctional Disability (item 6)	-1.197	.530	5.107	.302 (.107 to .853)	.024
Constant	-1.927	.451	18.217	.146 (.060 to .353)	<.001

dLow risk: Low risk differences after treatment; Item 4: question 4 of StarT Back Screening Tool difference after treatment; Item 5: question 6 of StarT Back Screening Tool difference after treatment; Item 7: question 7 of StarT Back Screening Tool difference after treatment; OR: Odd ratios; CI: confidence interval; ***p†*:** p values from chi square

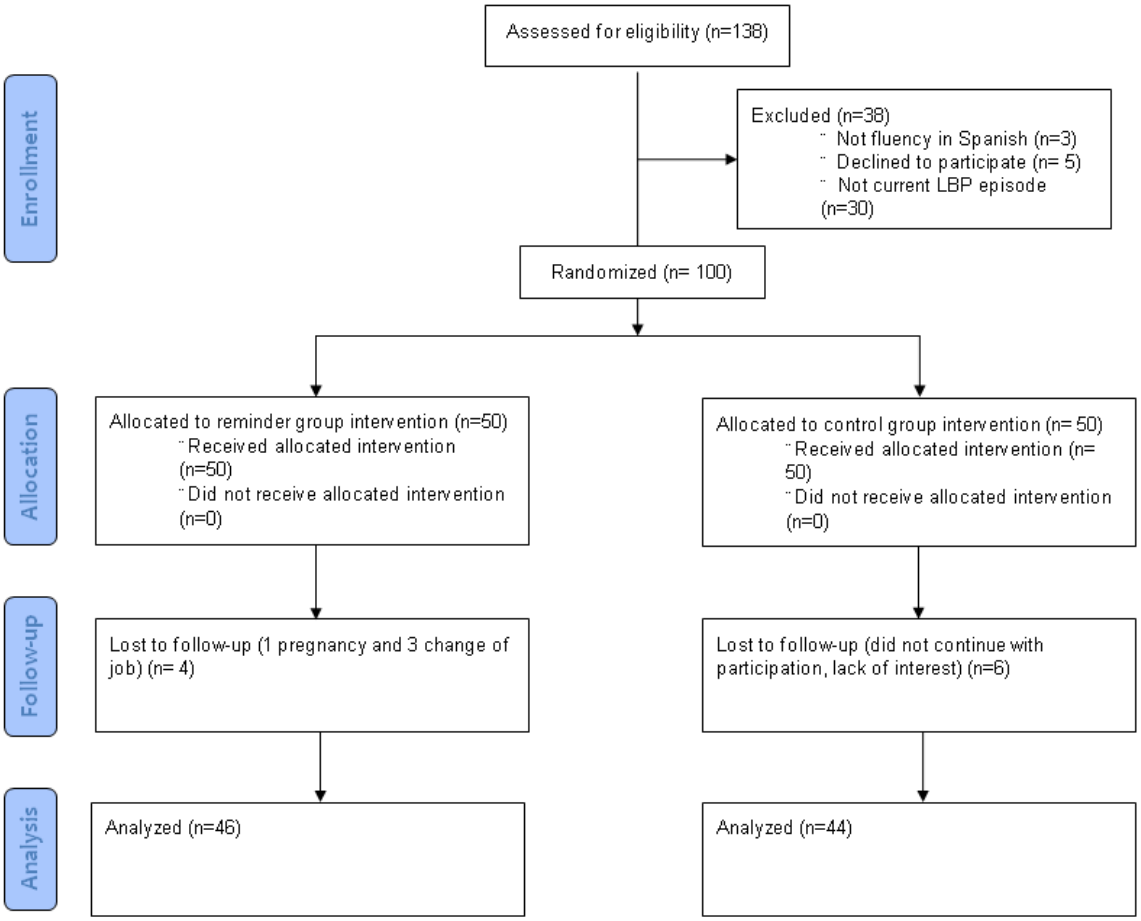
Enrollment
Assessed for eligibility (n=138)
Excluded (n=38)
Not fluency in Spanish (n=3)
Declined to participate (n= 5)
Not current LBP episode (n=30)
Randomized (n= 100)
Allocation
Allocated to reminder group intervention (n=50)
Received allocated intervention (n=50)
Did not receive allocated intervention (n=0)
Allocated to control group intervention (n= 50)
Received allocated intervention (n= 50)
Did not receive allocated intervention (n=0)
Follow-up
Lost to follow-up (1 pregnancy and 3 change of job) (n= 4)
Lost to follow-up (did not continue with participation, lack of interest) (n=6)
Analysis
Analyzed (n=46)
Analyzed (n=44)

Figure 1

Do quality of life changes measured by EQ-5D-3L reflect clinical changes in lower back pain? A randomized controlled trial on a 9-month web-based intervention for patients with sub-acute non-specific lower back pain

Clinical Rehabilitation, submitted

ABSTRACT

Objective: to test the effect of a web-based lower back pain intervention on quality of life and selected lower back pain outcomes. Associations between these outcomes and general quality of life were also explored.

Design: A prospective single-blinded randomized intervention study was performed.

Setting: Occupational preventive service.

Subjects: 100 university office workers with non-specific subacute lower back pain.

Intervention: The 50 intervention group subjects were educated daily about sitting correctly and asked to perform exercises shown by video demonstrations on the university website. The exercise routines included strengthening, flexibility, mobility, and stretching exercises that focused on the postural stability muscles. The 50 control group subjects only received standard occupational care.

Measures: Outcomes were measured by the European Quality of Life questionnaire five dimensions three levels (EQ-5D-3L), the Oswestry disability index, and the StarT Back Screening Tool (SBST) questionnaires. At 9 months, the intervention group outcomes were compared to the baseline data and the control group outcomes.

Results: The intervention significantly improved the mean EQ-5D-3L, Oswestry and SBST scores (p<0.001). Binary regression analysis revealed that if clinical changes were observed in the overall EQ-5D-3L scores, the Oswestry and SBT were respectively 15.5- and 4.5-times more likely to show clinical changes too.

Conclusions: The intervention improved the quality of life of office workers with non-specific subacute lower back pain. Therapists could, with some caution, employ patient-specific health-related quality of life scores as an aim of treatment, thereby improving lower back pain outcomes.

KEYWORDS

Occupational therapy, backache, health outcome, chronic illness, monitoring, public health, health promotion, quality of life measure, musculoskeletal disorders and health-related quality of life outcome.

Introduction

Health-related quality of life (HRQoL) is the subjective assessment of people regarding their well-being. It has been widely accepted as a health indicator and plays a significant role in the assessment of health interventions (1). Indeed, measuring the success with which an intervention changes the health of a patient is a key element in both research and clinical practice. HRQoL has also been shown to be useful in the context of physical function, medication use, and mental wellbeing (2-3).

Since non-specific lower back pain is associated with a lower HRQoL (4), increased functional disability (5), and increased time off work (4), its prevention is a priority (6). Self-rated recuperation from back pain has been shown to depend on the cognitive judgment of the individual regarding the impact of symptoms on

their ability to successfully perform daily activities (7), and functional tasks were found to be important outcome markers for patients with back pain (8). HRQoL is also unique to the individual, and thus the relevant domains that comprise HRQoL constructs must take into account the issues that are important to the individual. Moreover, if function plays an important role in HRQoL (9-10), there should be a clear association between changes in functional ability and changes in general health. Proving that such a link exists would allow patient-specific HRQoL scores to serve as an aim of treatment, which may improve the outcomes of the disease.

The European Quality of Life questionnaire five dimensions three levels (EQ-5D-3L) is a valid general instrument for assessing HRQoL in the general population; it is also valid for cost-effectiveness analyses (11). Since the policy decisions of governments and health insurers rely increasingly on such cost-effectiveness analyses, it would be useful to be able to predict the EQ-5D score on the basis of other clinical outcomes of lower back pain that can be used to determine the distribution of resources and to assign priorities.

Several longitudinal studies have assessed the ability of lower back pain interventions to improve HRQoL by using the SF-36 Health Survey (12-13). However, it remains unclear whether EQ-5D-3L can also be used for such purposes. Moreover, the association between physical and psychological clinical changes and HRQoL in patients with lower back pain after interventions is not fully understood. Therefore, our aims were two-fold. First, we identified office workers who had lower back pain and randomized them into a control group or a group who received a web-based lower back pain intervention. We then explored the effect of the intervention on HRQoL dimensions and specific lower back pain outcomes, namely functional disability and risk of chronicity. Second, we compared the sensitivity with which changes in these outcomes associated with clinical changes in the general quality of life.

METHODS

Design

A single-blind randomized controlled trial (ISRCTN40949689) was performed according to the principles established in the Declaration of Helsinki and revised in 2000 in Edinburgh. This study was approved by the Research Ethics Committees of Extremadura. All subjects provided informed consent to participate in the study. To ensure proper implementation of the protocol, a manual describing the study protocol was produced and made available to all researchers involved in the study. Before the study commenced, two technicians involved in the project were trained for 2 weeks in all aspects of the study protocol.

Setting and participants

Figure 1 shows the distribution of participants in the study. The participants all came from four administrative offices of the University of Extremadura in the south of Spain. Participants suffering sub-acute non-specific lower back pain were recruited *via* the Preventive Medicine Service of the university. An advertisement alerted potential participants of the project. Sub-acute non-specific lower back pain was defined as current lower back pain (with or without radiating leg pain), without any specific pathological conditions, with the first or recurrent episode having lasted more than 6 weeks but less than 12 weeks (14). The inclusion criteria were: a diagnosis of sub-acute lower back pain in the absence of any major neurological deficit; age between 18 and 64 years; physical inactivity (fewer than two 30-minute exercise

sessions per week) (15); willingness to provide informed consent; being an employee; and working more than 6 hours per day on a computer workstation. The criteria for exclusion were: a diagnosed cause of backache; reported chronic backache; clinical red flags such as disc disease; any other major disease; and a lack of fluency in Spanish. In total, 138 individuals who fulfilled these criteria were invited by email and telephone to participate in the study.

Randomization and intervention

After the clinical leader of the Preventive Medicine Service checked that the inclusion criteria were met, 38 patients were excluded. A technician proceeded to allocate the remaining 100 patients in a 1:1 ratio to one of two groups, the intervention group and the control group, according to a code generated by a computer-generated random allocation data-processing program. The web-based intervention, which consisted of education about how best to sit at a computer, daily reminders regarding this educational point, and daily exercises, was explained to the intervention group participants and each was assigned a user name and password with which they could access the relevant section of the university Preventive Medicine Service website. A short email was then sent every day of the working week (Monday to Friday) for 9 months with the same reminder message and an URL-link that would allow the participant to access the online 'session of the day'. Each session was structured in real-time as follows: a video reminding the participant of key postural issues (2 minutes), followed by a video of the exercise of the day (7 minutes), after which the participant was again reminded of the key postural issues (2 minutes). The participants were asked not to perform any formal physical activity routine during the training period. The control group had only access to the usual preventive medical care. This was provided by the university occupational service and included routine patient visits (once per year in September, when a general medical examination was performed by the leading clinician of the Preventive Medicine Service) and specific web-information regarding self-care at the worksite. The intervention group also had access to this preventive medical care.

Details of the intervention

The education, daily reminders, and exercises were developed as an online resource and included video demonstrations that were recorded in a laboratory. They were loaded on the dedicated section of the university preventive medicine service website. The physical exercise routine was designed and arranged by an experienced physical activity professional and supervised by the clinical leader of the Preventive Medicine Service. All daily exercise sessions focused on the postural stability muscles (the abdominal, lumbar, hip and thigh muscles) and were strengthening, flexibility, mobility, and stretching exercises. The mobility exercises involved large movements of the joints associated with the postural stability muscles. The flexibility exercises involved a static work methodology. Strengthening exercises employed shortening and stretching motions that progressively changed in speed (1:1, 1:2, 1:3, 2:1, 3:1) combined with slight isometric contractions of the muscles involved in the exercises. The stretching exercises involved moderate stretching of the muscles involved in the session. The explanation of this part was in oral and written form. The postural education reminders directed at how best to sit at a computer were designed by the university Preventive Medicine Service clinician. Data on participation in the program were collected automatically by registering access to the program. The reasons people gave for abandoning the program were collected.

Outcomes

The socio-demographic and health characteristics, including age, smoking habits and gender, of each participant were recorded. The subjects were asked to complete the battery of questionnaires chosen for this study before randomization at the start of the program and 9 months later, when the program finished. The questionnaires were administered by a trained researcher (16) who was independent of the study team and blind to treatment allocation.

HRQoL assessment*:* The EQ-5D-3L (11) was used to assess HRQoL. The EQ-5D-3L assessed the generic functional health-related quality of life (HRQOL) of participants. The EQ-5D-3L includes five dimensions, each one measuring a different dimension of HRQOL: mobility, self-care, daily activities, pain and discomfort, and anxiety or depression. Three levels for answering are included (no problems, some problems, or extreme problems/unable to), ranging from 1 to 3. The juxtaposition of the levels for these five dimensions correlate to five-digit numbers, which reflect 243 possible health status values that can be collapsed to a health functional index or a 'utility' using time-trade off values (EuroQolutility; 1=full functional quality of life, 0=death).

Assessment of specific lower back pain outcomes*:* To measure lower back pain-related functional disability, the Oswestry disability index questionnaire in the Spanish language (18) was used. This questionnaire has been validated previously (19). It consists of a list of items that reflect limitation in different daily living activities. The questionnaire is completed by the patient who has to answer according to his or her current condition. Oswestry questionnaire total scores are obtained by applying the following formula: total points / 50 (or the number of questions answered) × 100. This formula yields a percentage of back pain-related disability that ranges from 0% (no disability) to 100% (maximum disability). To measure the risk of lower back pain chronicity, a Spanish version of the Keele STarT Back Screening Tool (SBST) was used (20). The SBST was developed after a literature review and secondary analysis that identified strong independent predictors for persistent (chronic) disabling back pain. It thus consists of nine items that are predictive of 'poor prognosis'. Its predictive validity and external validity, as well as its reliability, has been reported with a Kappa index of 0.79 (21).

Statistical analysis

With regard to the sample size, the primary outcome measure for this trial was the change in the EQ-5D-3L utility index after 9 months. A difference of 0.081 points in EQ-5D-3L utility index change scores is considered to be the minimum clinically important difference for back pain populations (22). A sample size of 96 patients (45 per group) would enable detection of a between-group difference of a 0.081 EQ-5D-3L utility index change given 70–80% power, a 5% (two-tailed) significance level, and a conservative standard deviation of 0.319 points (22).

Statistical analysis was performed by using the Statistical Package for the Social Sciences (SPSS for Windows, version 19.0, SPSS Inc., Chicago, IL, USA). The different variables were compared at baseline by using Student's t-test for independent measures in quantitative variables and the chi square test in qualitative variables, and the distribution of the data was examined by the Kolgomorov-Smirnov test with Lilliefors correction. After confirming that the distribution of all variables was parametric, the comparison between groups regarding the quantitative study variables was performed by a two-way ANOVA for repeated measures adjusted by baseline characteristics. In addition to the p values, detailed statistics, including the mean and 95% confidence

interval, are provided to better depict the change within each intervention group from baseline to 9 months, and the effect of treatment. Differences between pre- and post-test values were used to indicate the changes from baseline to 9 months. Differences in the changes over 9 months of the individuals in one group relative to the changes of the individuals in the other group were used to estimate the treatment effect in the case of quantitative variables (the means and 95% confidence intervals of changes of each group were calculated by using Student's t-test for independent samples). For analytical purposes, the five dimensions of EQ-5D-3L were collapsed into no problems (value 1 of the dimension) and problems (values 2 and 3 of the dimension). The null hypothesis of no difference in HRQoL dimensions between the treatment conditions was evaluated by a chi-squared contingency table. In this case, odd ratios with 95% confidence intervals were generated to assess the treatment effect. The chi-square test and odds ratio (95% confidence interval) were used to determine statistically significant associations between the intervention/control group and the changes in the study variables. In addition, chi-square test and odds ratio (95% confidence interval) were used to determine statistically significant associations between positive (clinical) changes in functional disability or risk of lower back pain chronicity and each dimension, Visual Analogical Scale (VAS) and utility of EQ-5D-3L. Linear regression models were used to explain the variance of changes in HRQoL that was due to functional incapacity and risk of chronicity. In addition, binary logistic regression was performed to assess the relationship between positive clinical changes in EQ-5D-3L utility and positive (clinical) changes in functional disability or risk of lower back pain chronicity by using the backward logistic model and controlling for baseline characteristics. The significance level was set at 5%.

Results

One hundred subjects were randomized (Figure 1). There were no statistically significant differences between the intervention and control groups at baseline (Table 1). None of the participants had any significant treatment-related adverse events and compliance was high (92%) for the intervention group. Of the four intervention group participants who dropped out of the program, three changed jobs and the other stopped due to pregnancy. Six participants in the control group were lost, apparently due to lack of interest; thus, the compliance achieved with this group was 88%.

Effect of the 9-month intervention on specific lower back pain outcomes and HRQoL

Table 2 compares the two groups in terms of the main outcomes at 9 months. The intervention group improved significantly in terms of the mean functional disability ($p<0.001$) and risk of chronicity ($p=0.019$) scores. They also improved significantly in terms of most of the EQ-5D-3L components (VAS, $p<0.001$; EQ-5D-3L utility score, $p<0.001$; mobility, $p=0.031$; daily tasks, $p=0.006$; pain/discomfort, $p<0.001$; anxiety/depression, $p=0.037$).

Changes in specific lower back pain outcomes and HRQoL after the 9-month intervention

Table 3 shows how the study variables changed over 9 months for the two study groups. Relative to the control group, the intervention group participants were more likely to exhibit improvements in functional disability (Oswestry questionnaire clinical change, 85%, $p=0.001$), risk of chronicity (SBT clinical change, 75%, $p<0.001$), and most of the EQ-5D-3L components (VAS, 73%, $p<0.001$; EQ-5D-3L utility score clinical change, 78%, $p<0.001$; mobility, 77%,

p<0.001; self-care, 79%, p=0.003; pain/discomfort, 88%, p<0.001 and anxiety/depression, 84%, p<0.001). However, participants allocated to the intervention group were not more likely to improve their daily task perception (p=0.103).

Association between the clinical changes in specific lower back pain outcomes and the HRQoL changes after the 9-month intervention

Table 4 reveals that there is a statistically significant association between clinical changes in functional disability/risk of chronicity and self-reported health status changes. Compared to the control group, intervention group participants whose self-reported functional disability improved were also more likely to experience changes in the EQ-5D-3L mobility dimension (73%, p=0.078) and the EQ-5D-3L pain/discomfort dimension (80%, p=0.006). They were also more likely to experience clinically significant changes in EQ-5D-3L utility score (94%, p=0.001) when compared with the control group. Similarly, compared to the control group, intervention group participants whose self-reported risk of chronicity improved were more likely to experience changes in the EQ-5D-3L pain/discomfort dimension (80%, p=0.004), the EQ-5D-3L anxiety/depression dimension (73%, p=0.050), and the EQ-5D-3L VAS (74%, p=0.020). They were also more likely to exhibit clinically changes in EQ-5D-3L utility score (94%, p=0.001) when compared to the control group.

Explanation of the associations between study outcomes

Linear regression models revealed that the change in EQ-5D-3L utility score after the 9-month intervention can be predicted (45%; p<0.001) by the Oswestry disability index after the 9-month treatment; it can also be predicted by the change in the SBST after the 9-month treatment (19%; p<0.001). Oswestry disability index (p=0.003) and SBT (p=0.035) changes after 9-month treatment predicted changes in TTO (45%) after 9-month treatment. Table 5 displays the data of the binary logistic regressions that were performed to determine how much of the variance in clinical changes in EQ-5D-3L utility score after the 9-month treatment can be explained by the Oswestry disability index and the SBT values. Thus, the clinical changes in EQ-5D-3L utility score can be explained by clinical changes in the Oswestry disability index (20%, p=0.009), by the SBT (17%, p=0.001), and by both the Oswestry disability index (p=0.011) and the SBT (p=0.002) (32%). The binary regression model shows that when EQ-5D-3L utility score exhibits a clinical change, the Oswestry disability index and the SBST scores are 15.5- and 4.5-times more likely, respectively, to exhibit clinical changes as well.

Discussion

This is the first study to analyze the effect of a real-time occupational web-based intervention on EQ-5D-3L-measured HRQoL in office workers with non-specific lower back pain. It is also the first time associations between EQ-5D-3L components and specific lower back pain outcomes have been assessed. The main finding of this study was that the intervention, when used together with standard occupational preventive care, was a feasible and effective tool that improved HRQoL components and reduced functional disability and the risk of chronicity among office workers who suffer from sub-acute non-specific lower back pain. This observation suggests that the inclusion of this kind of program into preventive medicine could improve the outcome of normal care for sub-acute non-specific back pain among office workers. In addition, we observed that clinical change in the EQ-5D-3L utility index shows a

good, but not detailed, association with clinical lower back pain outcomes. This means that this general instrument should be used with caution as a specific health outcome in sub-acute non-specific lower back pain patients. However, Table 4 also shows that there is a higher association between changes in back pain-specific tools and the EQ-5D-3L dimensions of pain/discomfort and mobility.

Several longitudinal studies that assess the effectiveness of different lower back pain-specific interventions on pain or disability have been conducted (23). However, those studies that have evaluated the ability of interventions to limit deterioration in HRQoL have yielded inconsistent results. This may be because of differences between the studies in terms of the type of job and tasks that were performed by the participants, the lower back pain population that was studied, the prevention program itself, and methodological issues. These differences make it difficult to compare these studies. Nevertheless, one high quality randomized controlled trial of patients with chronic lower back pain that was conducted at the workplace (12) did not find any significant differences in HRQoL between a high intensity progressive back-strengthening program and a low intensity back-strengthening program; however, both groups exhibited an improvement in HRQoL as measured by SF-36. Another randomized controlled trial conducted with chronic back pain patients found that HRQoL was significantly improved by a back school, which consisted of an educational and skill acquisition program, including exercise, whose lessons were given to groups of patients and supervised by a qualified therapist (24-25). In the present study, the occupational web-based multidisciplinary intervention we employed resulted in greater improvements in HRQoL when compared to the control treatment. This is in line with the outcomes of another multidisciplinary intervention that exercised the same muscles trained by the present intervention and that was developed to improve the self-reported health status of subjects with chronic lower back pain (26). The positive effects observed in the subjects participating in the present study may be due in part to the reduction in their functional disability, and in part to the relationship between functional disability and the expectations patients have regarding their health (10).

The restoration of normal function is considered the key outcome of therapy for lower back problems (27).There are various questionnaires that measure activity limitation. Activity limitation is defined as difficulty in executing particular activities and it is affected by various physical and psycho-social aspects (28). Two questionnaires that measure activity limitation were employed in the present study, namely the Oswestry disability questionnaire and SBST. The Oswestry disability questionnaire uses items that relate more to the physical functions associated with activity limitation than to the psycho-social functions (there is only one item in the psycho-social plane, entitled “social life”). By contrast, the recently developed SBST has two important domains that measure the impact of lower back pain on daily activities and include both psycho-social and physical functions. In fact, SBST effectively captures the opinions of those people who are most affected by the psycho-social domain. This probably explains why, in the novel analysis performed in the present study, the Oswestry disability index was more strongly associated with clinical changes in the EQ-5D-3L index than the SBST: in other words, subjects who experienced a clinical change in the Oswestry disability questionnaire were more likely to experience a clinical change in the EQ-5D-3L index than patients who experienced a change in the SBST. This may reflect the nature of the intervention used in the present study, which focused on physical exercise

but did not employ any specific psychological approaches. Supporting this is that the psychological domain of the SBST did not exhibit any significant changes at the end of the intervention (data not shown). Moreover, the Oswestry disability index and the SBST associated with different EQ-5D-3L dimensions: clinical changes in the Oswestry disability index questionnaire were associated with the mobility dimension while SBST changes were associated with the anxiety/depression dimension. Unsurprisingly, however, both the Oswestry disability index and SBST clinical changes showed similarly strong associations with the pain/discomfort dimension. Thus, this dimension appears to relate to the severity of the disease (9).

The logistic regressions performed in the present study showed that the two specific outcomes used here complement each other in explaining the clinical changes in the EQ-5D-3L: the clinical changes in these specific outcomes explained more of the variance of the clinical change in the health index when they were combined than when they were used in isolation. However, the linear regressions also showed that clinical changes in the Oswestry disability index that were achieved by the intervention were lower than the non clinical changes. This suggests that higher intensity programs may be required to produce clinical changes in those who did not achieve them with the present intervention. With regard to the SBST, the clinical changes achieved by the intervention were similar in size to the non-clinical changes; this reinforces the idea that more psychosocial components are needed. Thus, rehabilitation programs that differ in intensity and components may exert different effects on HRQoL dimensions (26). This suggests in turn that intervention programs should be developed in line with the demands of different lower back pain manifestations (e.g., acute or chronic lower back pain) (29).

We acknowledge that this study suffers from some limitations. The EQ-5D-3L is a generic HRQoL measure and was not specifically designed for lower back patients, which may explain why the clinical changes in specific lower back pain outcomes did not associate with some of the EQ-5D-3L dimensions. However, the fact that there is a positive association between the overall EQ-5D-3L score (TTO) and the specific lower back pain outcomes suggests that the EQ-5D-3L utility index can serve as a health outcome for lower back pain patients, although it should be used with caution. Thus, while EQ-5D-3L does not provide specific details that monitor low back pain, it could be useful for comparisons with other health problems that help decision-making. It may therefore be time to develop a lower back pain-specific HRQoL instrument, and further studies in this direction should be encouraged (30). The external validity of our study must also be considered. Cross-cultural analysis of the outcomes of this study is warranted.

Practical implications and conclusions

In conclusion, a 9-month web-based intervention effectively improved the HRQoL of subjects with non-specific sub-acute lower back pain. Furthermore, clinical EQ-5D-3L changes related to clinical changes in specific lower back pain outcomes. This study shows, for the first time, that EQ-5D-3L may be a useful health outcome measure for patients with non-specific sub-acute lower back pain. Thus, therapists could target patient-specific HRQoL scores as an aim of treatment (although this should be done with caution), which could improve the specific lower back pain outcomes of patients. Greater awareness of the cost-effectiveness and cost-utility of this approach is also required at the political level to encourage appropriate health and social policies.

CLINICAL MESSAGES

- A web-based occupational intervention is effective to improve quality of life and severity of low back pain
- Health-related quality changes are associated with changes in the outcomes in sub acute non specific low back pain patients
- Health-related quality of life is a key possible outcome for monitoring the progress of low back pain in specific interventions

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CONFLICTS OF INTERESTS

The authors declare they have no competing interests.

FINDING SUPPORT

There was no external support for this work.

AUTHORS CONTRIBUTIONS

NG, BP, JA, JP, MH and JAP participated in the design and conception of the study. BP, JP and JAP collected de data. BP, MH and JA read, coded, and analyzed the data. NG checked the coding and analysis. BP, JA, JP and JAP helped to draft the manuscript. All authors read, revised, and approved the final manuscript.

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Table 1. Baseline characteristics of participants (n=90).

Group	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	*p†*
Age (years)	45.50 (7.02)	46.83 (9.13)	0.442
Sex (%)	11.40 (M); 88.60 (F)	15.20 (M); 84.80 (F)	0.534
Smoke (%)	50 (Y); 50 (N)	56.50 (Y); 43.50 (N)	0.471
Oswestry Questionnaire (percentage)	28.77 (2.69)	28.13 (2.23)	0.220
VAS (points)	59.22 (11.96)	59.25 (11.38)	0.961
EQ-5D-3L utility (points)	0.78 (.08)	0.75 (0.11)	0.461
Mobility, n, *problems (%)**	33 (75)	34 (73,1)	0.952
Personal care, n, *problems (%)**	11 (25)	17 (37)	0.221
Daily tasks, n, *problems (%)**	16 (36.4)	14 (30.4)	0.551
Pain/Discomfort, n, *problems (%)**	17 (38.6)	24 (52.2)	0.135
Anxiety/ Depression, n, *problems (%)**	13 (29.5)	17 (37)	0.221

Oswestry questionnaire: Oswestry disability questionnaire; VAS: Visual analogical score from Euroqol-5D quality of life questionnaire (0, worst health status to 100, best health status); EQ-5D-3L utility: Euroqol-5D-3L quality of life questionnaire utility index; *: Dimensions from Euroqol-5D quality of life questionnaire collapsed in no problems (value 1 of the dimension) and problems (values 2 and 3 of the dimension); Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care ; p †: p values from t-test for independents measures or chi square test.

Table 2 Effect of a 9-month web-based multidisciplinary intervention on the risk of lower back pain chronicity, lower back pain-related disability, and self-reported health status in office workers *

	Baseline		Post-treatment			
Outcomes measure	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	Control group (n=44) Mean (SD)	Intervention group (n=46) Mean (SD)	Treatment effect Mean (95%CI) or OR (95%CI)	*p* †
ODI (percentage)	28.77 (2.69)	28.13 (2.23)	33.72 (3.14)	19.80 (2.23)	13.28 (7.341 to 16.451)	**<0.001**
StarT Back Screening Tool (score)	4.40 (1.71)	4.38 (1.48)	4.38 (1.03)	3.39 (1.39)	-1.01 (-1.790 to .118)	**0.019**
VAS (points)	59.22 (11.96)	59.25 (11.38)	55.97 (12.97)	67.34 (10.54)	4.84 (2.121 to 6.451)	**<0.001**
EQ-5D-3L utility (points)	0.78 (0.08)	0.75 (0.11)	0.75± (0.11)	0.97± (0.04)	0.16 (0.069 to 0.191)	**<0.001**
Mobility, n, *problems (%)**	33 (75)	34 (73.10)	30 (68.20)	21 (45.70)	0.392 (.166 to .926)**	**0.031**
Personal care, n, *problems (%)**	11 (25)	17 (37)	15 (34.10)	13 (28.30)	0.762 (.311 to 1.863)**	0.550
Daily tasks, n, *problems (%)**	16 (36.40)	14 (30.40)	14 (31.80)	4 (8.70)	0.204 (.061 to .682)**	**0.006**
Pain/Discomfort, n, *problems (%)**	17 (38.60)	24 (52.20)	26 (31.80)	11 (23.90)	0.218 (.088 to .538)**	**<0.001**
Anxiety/ Depression, n, *problems (%)**	13 (29.50)	17 (37)	15 (34.10)	7 (15.20)	0.347 (.125 to .960)**	**0.037**

ODI: Oswestry disability questionnaire; VAS: Visual analogical score from Euroqol-5D five dimensions three levels quality of life questionnaire (0, worst health status to 100, best health status); EQ-5D-3L utility: Euroqol-5D-3L quality of life questionnaire utility index; *: Dimensions from Euroqol-5D quality of life questionnaire collapsed in no problems (value 1 of the dimension) and problems (values 2 and 3 of the dimension); Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care ;--: not computable; p †: p values from ANOVA for repeated measures adjusted by baseline characteristics or x2 to compare different between groups after 9-month web-based program; OR: Odd Ratio (Control group/Intervention group); **Applicable OR

Table 3. Changes in study variables after 9 months of treatment (n=90).

	Improvement, n (%)		Not improvement or deterioration, n (%)			
Outcomes measured	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Odd Ratio Intervention group improvements/control group improvements (95% Confidence Interval)	*p* †
ODI (%)	17 (37)	3 (6.80)	29 (63)	41 (93.20)	**5.420 (1.707 to 17.216)**	**0.001**
SBST (score)	35 (76.1)	11 (25)	11 (23.9)	33 (75)	**3.043 (1.779 to 5.206)**	**<0.001**
Health-related Quality of life						
VAS	40 (87)	14 (31.80)	6 (13)	30 (68.20)	**2.733 (1.748 to 4.272)**	**<0.001**
EQ-5D-3L utility (points)	45 (97.80)	12 (27.30)	1 (2.2)	32 (72.70)	**3.587 (2.210 to 5.823)**	**<0.001**
Mobility*	32 (69.60)	9 (20.50)	14 (30.40)	35 (79.50)	**3.401 (1.842 to 6.280)**	**<0.001**
Self-care*	16 (34.80)	4 (9.10)	30 (65.20)	40 (90.90)	**3.826 (1.387 to 10.555)**	**0.003**
Daily tasks*	14 (30.40)	7 (15.90)	32 (69.60)	37 (84.10)	1.913 (.853 to 4.290)	0.103
Pain/Discomfort*	24 (52.20)	3 (6.80)	22 (47.80)	41 (93.20)	**7.652 (2.480 to 23.613)**	**<0.001**
Anxiety/Depression*	17 (37)	6 (13.63)	29 (63)	38 (86.34)	**5.420 (1.707 to 17.21)**	**<0.001**

* Dimensions from Euroqol-5D quality of life questionnaire were collapsed in no problems (value 1 of the dimension) and problems (values 2 and 3 of the dimension): Control group: group that had access to usual treatment; Intervention group: group that had access to the proposed treatment and usual care.; VAS: Visual analogical score from Euroqol-5D quality of life questionnaire (0, worst health status to 100, best health status) after treatment; EQ-5D-3L utility: Euroqol-5D-3L quality of life questionnaire utility index positive clinical change; ODI: Oswestry clinical positive change after 9-month treatment SBST: StarT Back Screening Tool clinical positive change after 9-month treatment; ***p* †:** p values from chi square test.

Table 4. Association between positive changes in EQ-5D-3L components after the 9-month treatment and positive clinical changes in self-reported functional disability (measured by the Oswestry questionnaire) or positive clinical changes in the risk of lower back pain chronicity (measured by the StarT Back Screening Tool) after the 9-month treatment (n=90).

	ODI clinical positive change after 9-month treatment			StarT Back Screening Tool clinical positive change after 9-month treatment		
Health-related quality of life components	Odd Ratio yes/no (95% Confidence Interval)	Percentage (%) of the risk for the association	*p†*	Odd Ratio yes/no (95% Confidence Interval)	Percentage (%) of the risk for the association	*p†*
Mobility*	**2.782 (1.001 to 7.849)**	**73**	**.048**	1.733 (.749 to 4.007)	63	.197
Self-care*	1.710 (.559 to 5.262)	63	.343	2.082 (.742 to 5.843)	67	.159
Daily tasks*	2.154 (.724 to 6.404)	68	.162	1.773 (.653 to 4.816)	64	.258
Pain/Discomfort*	**4.125 (1.454 to 11.702)**	**80**	**.006**	**4.066 (1.501 to 11.010)**	**80**	**.004**
Anxiety/Depression*	2.361 (.787 to 7.084)	70	.119	**2.771 (1.002 to 8.044)**	**73**	**.050**
VAS	1.314 (.467 to 3.696)	43	.605	**2.780 (.1.161 to 6.655)**	**74**	**.020**
EQ-5D-3L utility	**16 (2.029 to 126.182)**	**94**	**.001**	**4.933 (1.928 to 12.624)**	**83**	**.001**

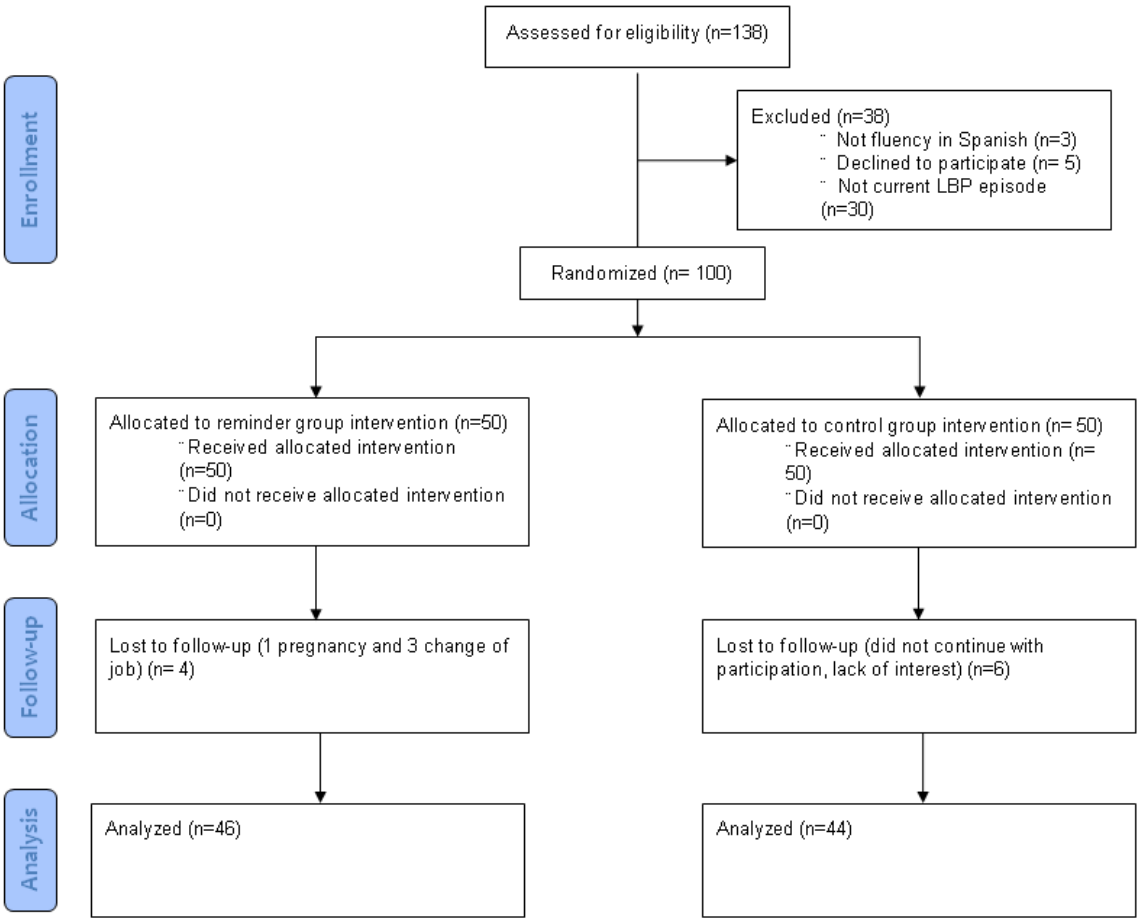
*: Dimensions collapsed in no problems (value 1) and problems (values 2 and 3); ODI: Oswestry disability questionnaire; VAS: Visual analogical score from Euroqol-5D quality of life questionnaire (0, worst health status to 100, best health status) after treatment; EQ-5D-3L utility: Euroqol-5D-3L quality of life questionnaire utility index positive clinical change; p ***†*****:** p values from chi square test.

Percentage (%) of the risk for the association calculated as Odd ratio/Odd ratio+1

Table 5. Binary logistic regressions examining the ability of functional disability and/or risk of lower back pain chronicity to explain the variance in EQ-5D-3L utility index changes after the 9-month web-based multidisciplinary intervention (n=90)

MODEL A (-2 Log likelihood= 104.462; Cox & Snell R Square= .14; Nagelkerke R Square= .20)					
	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
ODI clinical positive change	2,773	1,054	6,924	16 (2.029 to 126.182)	.009
Constant	-5,717	2,066	7,658	.003	.006
MODEL B (-2 Log likelihood= 106.110; Cox & Snell R Square= .13; Nagelkerke R Square= .17)					
	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
SBST clinical positive change	1,596	,479	11,084	4.933 (1.928 to 12.62)	.001
Constant	-3,010	,803	14,061	.049	<.001
MODEL C (-2 Log likelihood= 94.249; Cox & Snell R Square= .24; Nagelkerke R Square= .32)					
	Coefficient	SE	Wald Statistic	OR (95% CI)	*p†*
ODI clinical positive change	2.725	1.074	6.439	15.258 (1.859 to 125.208)	.011
SBST clinical positive change	1.558	.508	9.405	4.748 (1.754 to 12.848)	.002
Constant	-8.035	2.287	12.338	.000	<.001

ODI: Oswestry disability questionnaire; SBST: StarT Back Screening Tool; OR: Odd ratios; CI: confidence interval; ***p †*: p values from chi square adjusted by baseline characteristics.


Enrollment
Assessed for eligibility (n=138)
Excluded (n=38)
¨ Not fluency in Spanish (n=3)
¨ Declined to participate (n= 5)
¨ Not current LBP episode (n=30)
Randomized (n= 100)
Allocation
Allocated to reminder group intervention (n=50)
¨ Received allocated intervention (n=50)
¨ Did not receive allocated intervention (n=0)
Allocated to control group intervention (n= 50)
¨ Received allocated intervention (n= 50)
¨ Did not receive allocated intervention (n=0)
Follow-up
Lost to follow-up (1 pregnancy and 3 change of job) (n= 4)
Lost to follow-up (did not continue with participation, lack of interest) (n=6)
Analysis
Analyzed (n=46)
Analyzed (n=44)

A tailored web-based exercise programme for office workers with low back pain influences stage of change in behaviour: a randomised controlled trial

(Prepared to be submitted)

ABSTRACT

Objective: To evaluate the efficacy of a web-based intervention for physically untrained office workers with sub-acute non-specific low back pain. Design: Randomised controlled trial. Setting: Occupational Preventive Medicine of University. Methods: Participants were randomised to an intervention group (proposed intervention plus standard care) or a control group (standard care only). The intervention exercise and education materials were developed as an online resource, and included video demonstrations recorded in a laboratory. Resources were loaded onto a dedicated section of the University Preventive Medicine Service website. All sessions included stretching, and exercises to improve postural stability (abdominal, lumbar, hip, and thigh muscles) strength, flexibility, and mobility. Outcome measures were self-reported health status (visual analogue scale (VAS) of the Euroquol-5D questionnaire); functional health status (Oswestry Disability Questionnaire); and the stage of change questionnaire. At 9 months, outcomes in the intervention group were analysed and compared with baseline and outcomes in controls. Results: In the intervention group, significant positive effects were observed at 9-month follow up for stage of change in the behavioural domain for all phases except for the contemplation phase. The positive change in the stage of change questionnaire correlated with the improvement observed in Oswestry (r= .388) and VAS (r= -.612). Conclusions: This novel intervention improved exercise-behaviour, self-reported health status, and functional disability in the present population.

BACKGROUND

Physical inactivity is correlated with an increased risk of morbidity and premature mortality secondary to metabolic and musculoskeletal disease in the general population (1). In office workers, physical inactivity was shown to have a negative impact on health (2). The physically-inactive nature of office work predisposes to musculoskeletal disorders such low back pain (LBP) and discomfort (3). This impact on the quality of life of affected individuals (4), and on their ability to perform tasks of daily living (5, 6). Therefore, effective interventions to promote an active lifestyle and physical activity among high-risk groups and the general population are warranted (7). As well as evaluating the clinical outcome of work-place health promotion programmes in special populations, it is necessary to evaluate outcomes such as exercise-related behaviour. Within the context of health promotion, the transtheoretical model is the standard model used to assess the effectiveness of physical activity interventions in terms of change in the behaviour dimension (8)

Traditionally, business and public-office managers have tended to focus on productivity, and have attributed little importance to the health of employees. However, major absenteeism due to work-related diseases has led to increased attention to this issue (3). Furthermore, several studies show the effectiveness and cost-effectiveness of health promotion programmes in the work-place (9-13). Research suggests that exercise programmes of short duration are most appropriate for employees who work long shifts(14).

The internet and e-mail are promising media for the delivery of health information and health promotion programmes. The internet is useful for providing health information to large specific populations (15-17). Use of the internet and e-mail is increasing among the work-age adult population (18). Research suggests that the internet is becoming the preferred method of obtaining health information in both the general population (19) and specific populations (20). Furthermore, the internet enables low-cost and wide dissemination of interventions (21). We therefore consider the internet a potential channel for delivering a worksite health promotion intervention to specific populations.

Several studies in the general population have evaluated web-based work-place health promotion interventions aimed at improving self-reported health status, promoting a healthy lifestyle, or improving lifestyle-behaviour (22-24). Some studies have used an e-mail reminder to improve patient´s adherence (17, 25, 26). However, the effectiveness of such interventions in special populations is not yet established. We therefore developed a novel occupational web-based intervention for physically untrained office workers with sub-acute LBP. We hypothesised that this online, real-time intervention would improve exercise-related behaviour in this population, and that this improvement would be correlated with improvements in functional ability and self-reported health status.

METHODS

A single-blind randomised controlled trial was performed (ISRCTN40949689). Figure 1 shows the flow of participants through the study. The study population was recruited from the four administrative offices of the University of xxx in southern Spain. To ensure correct implementation, a manual describing the study protocol was produced and made available to all study researchers. Prior to the commencement of the study, two technicians received 2 weeks training in all aspects of the study protocol. The study was performed in accordance with the Declaration of Helsinki, as revised in 2000 in Edinburgh, and was approved by the research ethics committee of the University of xx.

Participants

Participants were recruited via the University Preventive Medicine Service. An advertisement alerted potential participants to the project. Sub-acute non-specific LBP was defined as current LBP with or without radiating leg pain of 6-12 weeks duration (5). The study inclusion criteria were: a diagnosis of sub-acute LBP in the absence of any major neurological deficit; age 18 to 64 years; physical inactivity (less than two 30 minute exercise sessions per week) (27); informed consent; office-employee status; and more than 6 hours computer work per day. Exclusion criteria were: a diagnosed cause of backache; chronic backache; disc or other major disease; or lack of fluency in Spanish. A total of 138 individuals fulfilled these criteria and were invited via e-mail and telephone to participate. Of these, 38 were subsequently excluded. The remaining 100 patients were randomly allocated 1:1 to an online occupational exercise intervention group or a control group.

Interventions

The exercise and education reminders used in the intervention programme were developed as an online resource, and included video demonstrations recorded in a laboratory. The resources were loaded onto a dedicated section of the University Preventive Medicine Service website. The physical exercise routine was designed and arranged by an experienced

physical training instructor under the supervision of the head of the Preventive Medicine Service. All sessions included stretching, and exercises to improve postural stability (abdominal, lumbar, hip, and thigh muscles), muscle strength, flexibility, and mobility. Mobility exercises involved large movements of the joints and the postural stability muscles. Flexibility exercises were performed according to static work methodology. Strength exercises were performed using progressive shortening:stretching and speed:motion ratios (1:1, 1:2, 1:3, 2:1, 3:1) and slight isometric contractions of all involved muscles groups. The session ended with moderate stretching of all muscles used during the session. The video provided a verbal and subtitled explanation of all exercises. Postural education reminders (how best to sit at a computer) were designed by the University Preventive Medicine Service clinician. Data on programme participation were collected automatically when access to the programme was registered. Both study groups had access to the usual routine care offered by the University Preventive Medicine Service. This included a routine annual medical examination by the lead clinician, and specific online information on self-care in the work-place.

Intervention group: All participants received a brief daily e-mail. This contained a reminder message (which remained unchanged throughout the intervention) and a link to the online 'session of the day.' The sessions were structured in real-time. First a video of postural reminders was viewed (2 minutes). This was followed by a video of the exercise(s) for the day (7 min). Finally, a repetition of postural reminders was provided (2 min). The videos were available Monday to Friday every week for 9 months. Each participant was assigned a user name and a password to access the system, and received a detailed explanation of the treatment programme (in written and verbal forms). Participants were asked not to engage in any formal physical activity routine during the 9-month study period.

Control group: The control group had access to standard preventive medicine care only.

Measurement

Both groups were evaluated at baseline and on completion of the 9-month study period. Socio-demographic and health characteristics were documented at baseline, including age, sex, and smoking habits. The study questionnaires were administered by a trained researcher (28) who was independent of the study team and blind to treatment allocation. The stage of change questionnaire assessed change in the behaviour domain in terms of exercise. A specific mathematics algorithm was used to classify the participants into five possible stages of motivational readiness to change: pre-contemplation, contemplation, preparation, action, and maintenance (29). At the end of the 9-month study period, the global stage of change status was determined according to three possible scores: -1, considered a negative behavioural change; +1 considered a positive behavioural change; and 0, considered no change. At the end of the study, all participants in the intervention group were asked if they would like to continue with the programme. The Visual Analogue Scale (VAS) from the Euroquol-5D questionnaire (EQ-5D) (30) was used to assess the generic functional self-reported health status of all participants. The participants used this vertical 20-cm scale to rate their own health between 0 (worst imaginable health state) and 100 (best imaginable health state), thereby providing an overall numerical estimate of their health-related quality of life (31). This scale was developed to provide a self-report rating of general health that can be

conducted via a postal survey. Functional disability was assessed using the Oswestry Disability Index (ODI), which is one of the most widely recommended condition-specific outcome measures for spinal disorders (32, 33). The ODI is comprised of 10 questions. For each question, six possible responses are listed. These are scored from zero to five. Zero indicates minimum acuity and five indicates maximum acuity. If more than one box is marked in any section, the highest score is used. The final score may be summarised as: (total score/ (5 * number of questions answered)) * 100%.

STATISTICAL ANALYSIS

All analyses were performed using SPSS version 19.0. (SPSS, Inc., Chicago, IL). For independent measures, baseline comparisons were made using the Student t-test for quantitative variables, and the chi square test for qualitative variables. The distribution of the data was examined using the Kolmogorov-Smirnov test with Lilliefors correction. The null hypothesis of no difference in the stage of change between treatment conditions at 9-months was evaluated using chi square analysis. The same analysis was used to evaluate differences in the global stage of change at 9-months. Correlations between the main study outcomes were evaluated using the Pearson correlation coefficient. The significance level was set at p <.05 for all tests.

RESULTS

One hundred subjects were randomised (Figure 1). In the intervention group, 92% (46 of 50) of the participants completed the programme. Of the four intervention group participants who dropped out, three were women who changed jobs, and the other was a woman who stopped due to pregnancy. In the control group, 88% (44 of 50) of the participants completed the study. The remaining six participants dropped out through apparent lack of interest. No statistically significant differences in baseline measurements were found between the two study groups (Table I). In the intervention group, a positive association was found between the wish to continue with the programme and maintenance-phase-status according to the stage of change questionnaire (Odd Ratio 5.4–1.372 to 21.260-95% Confidence Interval; p=.012). In the intervention group, significant positive effects were found for mean scores for all phases in the behaviour domain (Table II). Figure 2 shows the difference between treatments in terms of the global stage of change. In the intervention group, significant positive effects were found for stage of change in behaviour at 9-month follow up (p<*.001*). Table III shows the Pearson correlation coefficients for the study outcome measures. A high correlation was found between VAS and global stage of change at 9-months (r= -.612). Moderate correlation was found between ODI and global stage of change at 9-months (r= .388).

DISCUSSION

The present pioneering study examined the effects of an educational web-based programme in a special population setting. Our findings demonstrate the effectiveness of this intervention in improving exercise-behaviour in office workers with non-specific LBP, i.e., physically untrained office workers in the intervention group became more physically active in the work-place. This improvement was moderately and highly correlated with improvements in self-reported health status and self-reported functional disability, respectively.

Although our University offers a range of out-of-work general physical activity programmes to its employees and its occupational preventive service offers advice concerning enhancement of physical activity, all of the study participants were physically untrained at

baseline. The high level of adherence observed in the intervention group may have been due to the specificity of our occupational intervention (for secondary prevention of LBP) (34). Participants in the intervention group performed an 11-min session addressing health education and physical activity 5-days per week. Previous research suggests that exercise programmes of short duration are preferable for employees who work long shifts (14).

The present study was performed under 'real Internet conditions' and, thus no personal contact between participants and the research team was necessary during the period of training. Since office work involves receipt of multiple e-mails daily, employees may have been expected not to react to e-mail contact from the study team, and to be reluctant to enroll in a study that has little direct relevance to their work (35, 36). However, to mimic the real-life implementation as much as possible, only one e-mail was sent per day to improve adherence (37).

The current intervention has previously revealed the effectiveness on improve self-reported health status and functional disability perception. The correlation model used to determine the correlation between the investigated variables (Table III) revealed that the change in the behaviour domain was correlated with functional disability perception and self-reported health status. Maybe the improvement observed in the intervention group regarding functional disability perception could affect self-reported health status (38) and these improvements affect the behaviour of participants in the study.

The present study had several limitations. An e-mail containing a link to the URL of the session of the day was sent to remind the intervention group participants each day, and to encourage performance of the exercises. Although this reinforcement was done by non-behaviour stage of change-based message, our data indicate that there was a positive improvement in the behaviour domain in terms of exercise. In accordance with our data, Heelen et al. (39) found that a web-based physical activity intervention carried out at the work-place improved the level of physical activity and lifestyle-behaviour among a population of healthy office workers, although addition of a tailored e-mail in comparison with standard advice did not influence outcome. Further research is needed to determine whether tailored interventions including an e-mail reminder that are based on behaviour change theories are more effective than the present intervention. Since most of the participants in the intervention group wished to continue with the present programme, we did not enquire whether they would like to participate in other types of exercise programmes. Despite this, a first step towards greater physical activity among physically untrained office workers was successfully achieved in the intervention group. Further research is warranted to elucidate whether this strategy for promoting LBP-specific exercise in physically-untrained office workers could be used to promote a more physically active lifestyle in general, or other types of exercise.

The present study was conducted in a predominantly white, urban, south European community; therefore, the results cannot be generalised to work-place programmes in all populations. Although our results cannot be generalised to other racial groups, environments (rural), or specific population settings (other types of LBP and employment), the present study provides data with practical implications for work-place health promotion programmes in similar populations.

Practical implications

Current work-place health promotion programmes attempt to combine traditional methods of addressing health and safety through legislation and regulation

with the tackling of voluntary lifestyle practices (7). The guidelines underlying these programmes stress the need for transfer of knowledge and clarification of where health promotion resources can be found (40). Within this context, the present intervention could be viewed as a strategy for tackling LBP-associated problems among office workers.

Conclusion

The present intervention improved exercise-behaviour among physically untrained office workers with non-specific sub-acute LBP. Moderate to high correlation was found between behaviour respect to the Oswestry disability index and self-reported health status.

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Table I. Characteristics of participants in the study at baseline (n=100)

Group	Control group (n=44)	Intervention group (n=46)	*p†*
Age (years)*	45.50 (7.02)	46.83 (9.13)	.441
Sex (%)	11.4 (M); 88.6 (F)	15.2 (M); 84.8 (F)	.590
Smoke (%)	50 (Y); 50 (N)	56.5 (Y); 43.5 (N)	.532
ODI (percentage)*	28.77 (2.69)	28.13 (2.23)	.220
VAS (points)*	59.22 (11.96)	59.25 (11.38)	.961
Pre-contemplation, *yes, n* (%)	20 (45.43)	21 (45.65)	.830
Contemplation, *yes, n* (%)	21 (47.71)	19 (41.30)	.669
Preparation, *yes*, *n* (%)	3 (6.81)	6 (13.04)	.291
Action, *yes, n (%)*	0	0	
Maintenance, *yes, n (%)*	0	0	

*Value expressed as Mean (SD); ODI: Oswestry disability questionnaire score; VAS: Visual analogical score from Euroqol-5D quality of life questionnaire; Smoke: Percentage of smokers; M: male; F: Female; Y: yes; N: not; p ***†:*** p values from t-test for independents measures or chi square test.

Table II. Effects of 9-month of web-based intervention on behavior domain (n=100)

	Baseline		Post-treatment		
Outcomes measure	Control group (n=44)	Intervention group (n=46)	Control group (n=44)	Intervention group (n=46)	*p* †
Stage of Change					
Pre-contemplation, *yes, n* (%)	20 (45.43)	19 (41.30)	28 (63.64)	2 (4.34)	**<.001**
Contemplation, *yes, n* (%)	21 (47.71)	19 (41.30)	3 (6.81)	6 (13.04)	**.291**
Preparation, *yes*, *n* (%)	3 (6.81)	6 (17.40)	11 (25.00)	3 (6.52)	**.020**
Action, *yes, n (%)*	0	0	2 (4.55)	11 (23.91)	**.007**
Maintenance, *yes, n (%)*	0	0	0 (0)	24 (52.20)	**<.001**

*Values expressed as %; ***p* †:** p values chi square analysis

Table 3.Pearson correlation coefficient between global stage of change, self-reported functional disability levels and self-reported health status after treatment among office workers suffering sub-acute non-specific low back pain * (n=90)

Outcomes Measures	Global stage of change (%)	dOswestry questionnaire	dVAS
Global stage of change (%)	1.000	**.388****	**-.612****
dOswestry questionnaire		1.000	**-.522****
dVAS			1.000

*Pearson Correlations coefficients. Global stage of change: participants whose change their behavior status after treatment; dOswestry questionnaire: Oswestry disability questionnaire score difference after treatment; VAS: Visual analogical scale points differences after treatment; **: Correlation is significant at 0.001 level.

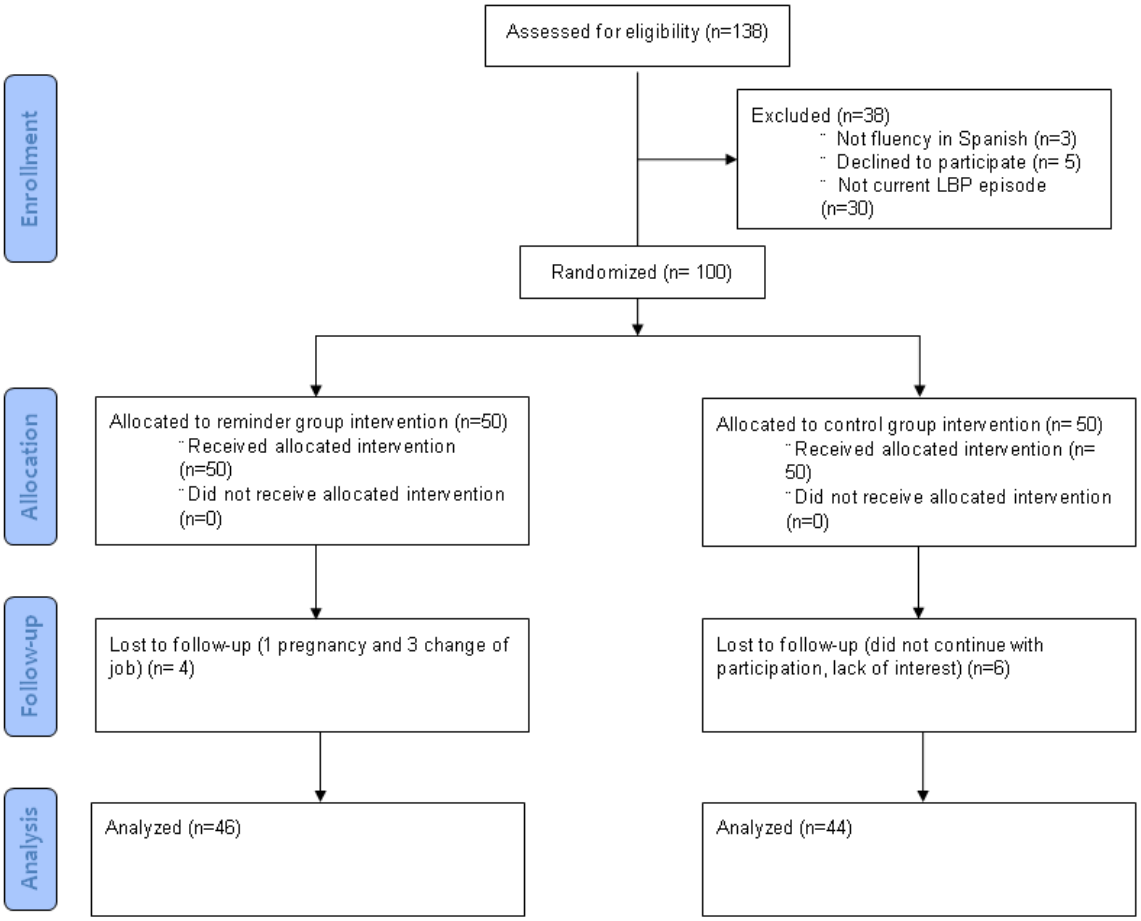
Enrollment
Assessed for eligibility (n=138)
Excluded (n=38)
¨ Not fluency in Spanish (n=3)
¨ Declined to participate (n= 5)
¨ Not current LBP episode (n=30)
Randomized (n= 100)
Allocation
Allocated to reminder group intervention (n=50)
¨ Received allocated intervention (n=50)
¨ Did not receive allocated intervention (n=0)
Allocated to control group intervention (n= 50)
¨ Received allocated intervention (n= 50)
¨ Did not receive allocated intervention (n=0)
Follow-up
Lost to follow-up (1 pregnancy and 3 change of job) (n= 4)
Lost to follow-up (did not continue with participation, lack of interest) (n=6)
Analysis
Analyzed (n=46)
Analyzed (n=44)

Figure 1

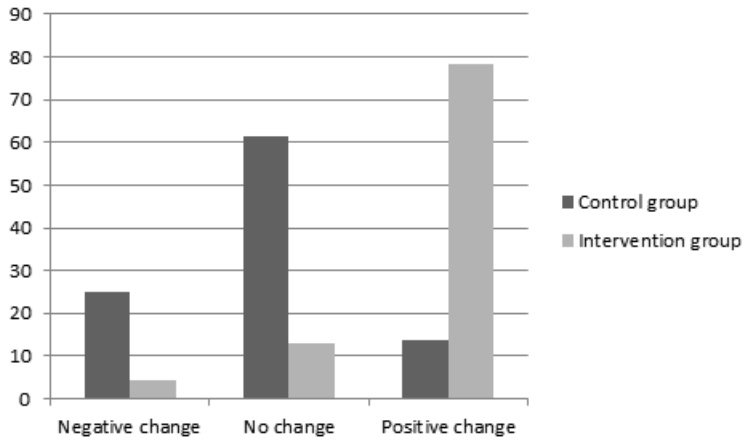
90
80
70
60
50
40
30
20
10
0
Negative change
No change
Positive change
Control group
Intervention group

Figure 2