



## **UNIVERSIDAD DE EXTREMADURA**

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**Departamento de Fisiología**

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# **EFFECTOS DE UN PROGRAMA DE EJERCICIO VIBRATORIO CORPORAL SOBRE EL EQUILIBRIO ESTÁTICO Y DINÁMICO, LA FUERZA, EL DOLOR Y LA CALIDAD DE VIDA EN MUJERES CON EL SÍNDROME DE FIBROMIALGIA**

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Dirigida por:  
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**Cáceres, 2011**



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**CERTIFICA:**

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Que la Tesis Doctoral realizada por **D. José Alberto Frade Martins Parraça**, con el título: “**Efectos de un programa de ejercicio vibratorio corporal sobre el equilibrio estático y dinámico, la fuerza, el dolor y la calidad de vida en mujeres con el síndrome de Fibromialgia**”, 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 10 de octubre de 2011



Dr. D. Narcís Gusi Fuertes



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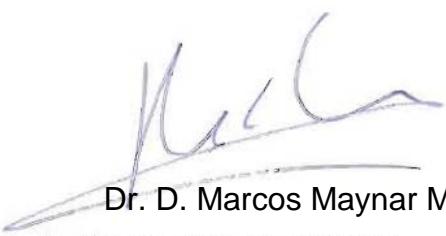
**Dr. D. MARCOS MAINAR MARIÑO**, profesor titular del Área de Fisiología del Ejercicio del departamento de Fisiología de la Universidad de Extremadura,

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a 10 de octubre de 2011



Dr. D. Marcos Maynar Mariño



## **MÉRITOS CIENTÍFICOS DE ESTA TESIS DOCTORAL**

La presente tesis doctoral es un estudio de investigación científica financiada por la Universidad de Extremadura, y por el Laboratorio de Actividad Física y Calidad de Vida y Salud de la Universidad de Extremadura.

**La producción científica que conforma la presente tesis doctoral es:**

1. **Tilt vibratory exercise improves the dynamic balance in fibromyalgia: A randomized controlled trial.** Gusi N, **Parraca JA**, Olivares PR, Leal A, Adsuar JC. Arthritis Care & Research (Hoboken). 2010 Aug;62(8):1072-8.doi: 10.1002/acr.20180
2. **Tilting Whole Body Vibration improves Quality of Life in women with Fibromyalgia: a randomized controlled trial.** Olivares PR, Gusi N, **Parraca JA**, Adsuar JC, Del Pozo-Cruz B. Journal of Alternative and Complementary Medicine. 2011 Aug;17(8):723-728. DOI: 10.1089/acm.2010.0296
3. **Whole Body Vibration improves the single-leg stance static balance in patients with fibromyalgia.** Adsuar JC, del Pozo-Cruz, B, **Parraca JA**, Olivares PR, Gusi N. Journal of Sports Medicine and Physical Fitness – Id nr.: JSMPF-2010-3424 – IN PRESS.
4. **Tilt vibratory exercise improves pain, strength and somatosensory function in patients with fibromyalgia: A randomized**

**controlled trial.** Parraca JA; Adsuar JC; Olivares PR; del Pozo-Cruz B; Gusi, N. Arthritis Care & Research – AC&R – 11 – 0760 – Submitted.

**Este último artículo aún no puede ser considerado un merito de esta tesis atendiendo a que está en proceso de revisión en la revista antes mencionada, pero por sus resultados y, por el aporte científico que transmite, consideramos que sería importante añadirlo a este documento.**

#### Premios

1. Authors: Gusi N, **Parraca JA**, Adsuar JC, Olivares PR, Del-Pozo Cruz B.

**Title:** **"Vibración y Fibromialgia"** Efectos de un programa de ejercicio vibratorio sobre la calidad de vida y el equilibrio estático monopodal en mujeres con Fibromialgia.

**Foundation:** **Prémio “AFICRO-VALL”** – Real Academia de Medicina y Cirugía de Valladolid.

**Place:** Valladolid / Spain

**Year:** 2011.

2. Authors: **Parraca JA**, Olivares PR, Adsuar JC, Del-Pozo Cruz B, Gusi N

**Title:** Efectos de un programa de ejercicio de bajo impacto sobre la calidad de vida y el equilibrio en mujeres afectadas con el síndrome de Fibromialgia: Ensayo controlado aleatorizado. **Mejor Comunicación Oral**

**Congress:** 1º Congreso de Actualización y avances en Fibromialgia

**Place:** Madrid / Spain

**Year:** 2011.

3. **Authors:** Adsuar JC, Parraca JA, Olivares PR, Serrano C, Madruga M, Prieto J, Gusi N

**Title:** Un entrenamiento vibratorio corporal en mujeres con Fibromialgia influye en su percepción del dolor. **Mejor Comunicación Oral**

**Congress:** V Congreso Nacional de Ciencias del Deporte y Educación Física

**Place:** Pontevedra / Spain

**Year:** 2009.

4. **Authors:** Parraca JA, Olivares PR, Adsuar JC, Saez C, Gusi N

**Title:** Efectividade de um programa de vibração no incremento do equilíbrio em pacientes com fibromialgia. **Mejor Comunicación Oral**

**Congress:** XVI Jornadas Internacionais do Instituto Português de Reumatologia

**Place:** Lisboa / Portugal

**Year:** 2008.



**E se um dia hei-de ser pó, cinza e nada.  
Que seja a minha noite uma alvorada,  
Que me saiba perder... pra me encontrar...**

*“Florbelo Espanca*



## Agradecimientos

Sin ti, querido padre (**JOSÉ ALBERTO**), no hubiese sido posible hacer ni esta tesis ni todo lo demás.

Es muy difícil hablar de mi padre, porque todo lo que diga será poco, quiero agradecerte por, en todos los momentos de mi vida encender la luz en mi obscuridad, por ser mi amigo, mi hermano mayor, por nunca dejarme solo en la adversidad. Si hay Grandes entre los Grandes, padres como mi padre ahí tienen un lugar.

Echo de menos cuando yo era pequeño y el llegaba a casa me daba un beso diciendo “- no hay padre -”, y yo respondía con una sonrisa en los labios “-para mi padre-”

Hoy siendo ya un Hombre educado a su imagen no tengo vergüenza de decir recordando aquel niño. **“NãO HÀ PAI PARA O MEU PAI...”**

Gracias...

Porque no existe una fecha especial para venerar aquellos que merecen toda nuestra admiración y respeto, quiero agradecer esta tesis a la persona a quien dedico cada día de mi vida, sabiendo igualmente que ella me los dedica a mí, enseñándome todos los días el significado de la palabra amor, no teniendo límites a un pedido de ayuda mío, una criatura maravillosa que trabaja, que lucha, que llora cuando algo está mal con sus hijos. Sí mamá (**NATALINA**)...estoy hablando de ti.

Para ser mujer hay que tener determinación. Para ser madre, hay que tener respeto, saber dar, aguantar y amar a cada segundo. Sé que

## AGRADECIMIENTOS

---

cualquiera de las dos funciones es difícil y compleja, pero tú las haces con la misma facilidad con que cada mañana el sol nos brinda la luz.

Gracias por existir y por toda la fuerza que me has dado, levantándome la cabeza siempre que mi mirada se dirigía para al suelo.

A mi hermana **CARLA** y su marido **SERGIO** porque siempre han estado ahí para todo, y cuando digo todo es todo, amigos, confidentes, consejeros. Pero mi hermana es mi hermana tiene un brillo en los ojos que me contagia encada mirada. “Aihhh José solo tú me comprendes...”  
“Aihhhh y tú a mi manica...”

Ya no está entre nosotros pero mientras estaba en esta vida me enseño el verdadero significado de la palabra personalidad. Igual que las estrellas, no siempre lo veo pero sé que esté donde esté, está ahí luchando por mí y por todos aquellos que amó mientras vivía, gracias por hacer de mí un Hombre, esta tesis también es tuya abuelo **ALFREDO**.

A mi súper-abuela **ANA MARIA**, por ser lo que es... “UNA MÁQUINA” constantemente empeñada en no incomodar a nadie. Cuando yo era pequeño me enseñaste a comer, a caminar, hacer el nudo en los cordones de los zapatos, me peinaste el pelo, etc. Ahora con 90 años que tienes, ya tardas en abrir la puerta, ya te manchas al comer, no te acuerdas bien cómo se hace un nudo a los cordones de los zapatos, o tiemblas al peinarte el pelo, me da igual, no te incomodaré, simplemente estaré a tu lado, tendré paciencia, generosidad y retribuiré todo lo que me has dado en la vida para que tu corazón se sienta siempre calentito como me calientas el mío en todos los momentos, no sé si te das cuenta pero

siempre que te falta el equilibrio te doy mi mano, y me encanta caminar contigo los dos respetando tu ritmo, de igual modo que respetaste el mío cuando me enseñabas a andar. Estaré siempre en tú vida, como tú siempre has estado en la mía, sufriendo por mí, luchando por mí, viviendo por mí. Esta tesis es tuya abuela Aníca.

A mi sobrina **SARA** que desde hace 3 años, es la responsable de que tenga una nueva energía en mi vida, mi corazón se llena de alegría y felicidad cada vez que siento unas pequeñas mañas abrazándome las piernas y una voz aguda que grita “Tiiiiiiiioooooo...”, y a la sobrina que está por llegar, que sea igual a este pequeño huracán que nos toca diariamente los corazones.

A **VANDA** porque si a uno le gusta lo dulce al otro le gusta lo salado, si uno quiere ciudad otro quiere el campo, si uno mira azul el otro mira verde, pero son estas diferencias que nos hacen desafiarnos diariamente y querer siempre más uno del otro, con una mirada que se toca constante mas allá de lo que las palabras pueden explicar, gracias por permitirme vivir todos los días sabiendo a qué sabe el amor...

A **CARLOS LOURINHO** por ser mi mejor amigo y compartir su vida conmigo permitiendo que comparta la mía con él, por hacerme sentir que no hace falta que 2 personas sean de la misma sangre para que sean hermanos. Por todo...gracias hermano.

A **MARIA JOSÉ** por ser una excelente amiga, una dulce compañía que no podré olvidar en mí vida, gracias por tus sonrisas, los libros, los coches y los toros.

## AGRADECIMIENTOS

---

A **TIAGO COCHICHO** y **MARCO PASCOA** por ser mis eternos compañeros de piso, y por aquí me quedo.

A **GONÇALO GARCIA (ESPANTA)** y **su madre** por esas noches inolvidables de trabajo donde me daba a conocer el “peso” del saber y su madre por ser una segunda madre en mi periodo de estudiante, **BRUNO MARIANITO** por esa ERASMUS y por estar siempre a mi lado en todo.

A todos los demás **COMPAÑEROS DE CARRERA**, por esas guitarreadas en el *bêco*, por las entradas clandestinas en las residencias femeninas, por esas borracheras, todos los momentos de alegría y por asumir en todos los momentos la diferenciación entre las bromas y la seriedad.

A las **CHICAS DE LA CARRERA** por todo lo que han sufrido con tantos hombres y principalmente conmigo.

A todos los profesores que me han impartido clases durante la carrera y los cursos de doctorado especialmente a **PETER VOUGLAERE** y **ORLANDO FERNANDES**, por su forma de ser y de enseñar.

A mis **COMPAÑEROS DEL FUTBOL**, por hacer que mi vida pueda salir de la rutina, por las alegrías, los goles y la educación continua de determinados valores, como la amistad y el respeto mutuo.

A todos los elementos del **GRUPO DE GIMNASIA** por la formación y por decirme en todos momentos “*Venga Portugués que tu puedes...*” incluso después de 200 hostias en el mismo entrenamiento.

A **ANDONI PENACHO** por su amistad, su personalidad, espíritu luchador y sus ganas de trabajar para y por las personas afectadas por el síndrome de la Fibromialgia.

Especialmente a **NARCÍS GUSI** por aceptarme para realizar esta tesis con él y por todo el demás apoyo prestado durante mi ERASMUS en la carrera y en el doctorado. Has sido un elemento fundamental en mi formación investigadora y eres el padre de esta tesis. Me has apoyado en todos los momentos, confiando en mi trabajo, y tu capacidad para guiar mis ideas es incommensurable. En muchos casos sentimos la necesidad de tener ideas propias y la ansiedad de querer ir más lejos, yo no he sido excepción, pero tú siempre estabas ahí para orientar oportunamente y con rigor mis ideas, dotándome siempre de los medios necesarios para el desarrollo de las actividades propuestas, siendo esa orientación la clave del buen trabajo. Y en los momentos más duros, estabas ahí haciendo más que una función de tutor, un amigo, substituyendo muchas veces un parent o una madre. No puedo dejar de agradecer a su familia **YOLANDA** y **QUERALT** porque han sido para mí una segunda familia. Y quiero pedirles disculpa por todo el tiempo robado a Narcís, que dejó muchas veces en segundo plano a su familia para ayudarme.  
“Perdóname Yolanda!”.

A **MARCOS MAYNAR** por también aceptar ser mi tutor en la elaboración de esta tesis confiando en mí trabajo, y por darme siempre que se lo he solicitado su ayuda.

## AGRADECIMIENTOS

---

A **ARMANDO RAIMUNDO** (**El padrino**) de mis primeros pasos en la vida universitaria y en la investigación, te debo mucho de lo que soy y tengo hoy.

A **PABLO TOMÁS CARÚS** gracias por los consejos y colaboraciones, por el empeño en enseñarme en el laboratorio, por la sonrisas, las bromas y por la amistad verdadera.

A **RAFAEL TIMÓN, GUILLERMO OLCINA, DIEGO, JAVIER BRAZO, PETER, DAVID BARBADO, CONCHI, TOÑO, ANA, ALMUDENA, KIKO LEON, TOMÁS y CHAPI** por su colaboración y ayuda siempre que la solicité.

Al grupo de investigación AFYCAV por todo el apoyo y ayuda prestada. A **MARGARITA GOZALO** por su cordialidad y disposición a compartir todos sus conocimientos y especialmente por ser mi psicóloga en los momentos malos. **JOSUÉ PRIETO** por no poder parar de reírme a su lado, por todos nuestros “Súper hits”, por el “Huevo Codo” y por nuestro código eterno “*Mira Píru, E.Y.M.L.F.Y.*”. **MIGUEL MADRUGA** por estar siempre ahí. **CARLOS SERRANO** por ser un amigo verdadero. **HÉCTOR CORZO** por su extrema humildad en dejar que los demás le enseñen como se dan los primeros pasos en el laboratorio. **FAICO** por esas partidas donde un portugués te funde siempre, **CRISTINA SÁEZ** por su agresividad cariñosa, **ENMA** por la fuerza que tiene, por la metodología de trabajo que imprime en todo, por las sonrisas y por ser un ejemplo de vida, **NATALIA** por su paciencia en escuchar tantas tonterías al día y por su simplicidad, cariño y amistad, **MIGUEL MOCHOLÍ** por su

honestidad, humildad, confianza y por la inquietud en querer más y más, **BORJA DEL POZO** por su constancia en todo lo que hace, por ser un luchador incesante en la conquista de un determinado objetivo. **SERAFÍN DELGADO, MIGUEL SOUSA, DAVID CORCHERO, DÉSIRÉE, SABINA, CARLOS** (*gestor de día, Dj de noche*) y **CONSUELO**.

A **PEDRO OLIVARES**, por su constante presencia en todo lo que se hace en el laboratorio, su profesionalidad, por me hacer ver que todo es posible. Siempre que desesperaba por encontrar aquel artículo imposible de conseguir surge Pedro y en 2 minutos lo tengo en la mano. Este trabajo sin duda que también te pertenece amigo.

A **VIRGINIA APARICIO** y **ANA CARBONELL** nos conocimos en una estancia y la amistad no dejó de crecer desde entonces, surgieron las colaboraciones, los artículos y los congresos, especialmente lo de Málaga. “*Viva nuestra PEPA y su 4 pilas.*”

A **JOSÉ CARMELO ADSUAR** podía quedarme aquí hablando de ti todo el día, todo el mes, todo el año, pero acabaría por ser un poco pesado, así que, solo quiero decirte que te considero mi mejor amigo. Jamás olvidaré todos los momentos que pasamos juntos, todas nuestras discusiones, nuestras bromas, nuestra confidencialidad, nuestras alegrías y tristezas, etc. etc. etc. En tu tesis decías que yo contagiaba la gente por tener una visión optimista del mundo y estar siempre cerca. Pero todo eso, y sin darte cuenta, me lo enseñaste tú. Principalmente después del nacimiento del Gengiscan (**Gabriel**). Sin ti esta tesis no existiría

## AGRADECIMIENTOS

---

considérala tuya también. ***Gracias por todo amigo...*** Déjame solo decirte que hay congresos en que debes tener más paciencia, je, je.

A todas las **participantes** en el estudio por su disposición y por sus ganas de luchar contra esta enfermedad.

Posiblemente me haya olvidado de alguien, quiero agradecer a todo aquel que no teniendo su nombre aquí, sienta que me ha ayudado de una u otra forma y que esta tesis también es fruto de su colaboración.

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### **III. ABREVIATURAS**

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**ACR:** Colegio Americano de Reumatología

**CVRS:** Calidad de Vida Relacionada con la Salud

**15-D:** El cuestionario de evaluación de la salud de 15 dimensiones

**FIQ:** Cuestionario de Impacto de la Fibromialgia

**FM:** Fibromialgia

**WBV:** Ejercicio Vibratorio Corporal (whole body vibration)

**ED:** Equilibrio Dinámico

**EE:** Equilibrio Estático

**BBS:** Biodex Balance System

**MLSI:** Índice de estabilidad medio-lateral

**APSI:** Índice de estabilidad antero-posterior

**OSI:** Índice de estabilidad global

**MLSI:** Índice de estabilidad medio-lateral

**SS:** Escala de gravedad de síntomas

**WPI:** Escala de umbral y grado del dolor

**SFC:** Síndrome de Fatiga Crónica



## LA COSA, MALDITA SEA...

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*Extraído del Blog de la Web de Paisajes Literarios, la Web de Mariano Estrada  
basado en el libro “Me llamo Marta y soy fibromiálgica” de Víctor Claudín.*

*Madrid: 2002. Editorial La Esfera de los Libros S.L*



### **LA COSA, MALDITA SEA...**

Sigue aquí.

Esta mañana (o esta tarde, según se mire), me he despertado con la ya inconfundible e indefinible sensación de que seguía conmigo, formando parte de mí. No sé qué es ni cómo llamarla, porque no hemos sido ni formal ni informalmente presentadas, y ella se muestra renuente a darme ningún dato, así que desde hace tiempo la llamo "la cosa".

Hace años llegó a mi vida, por sorpresa y sin previa invitación, y aprovechando un cambio de guardia de mi atenta vigilancia (yo, tan cuidadosa en algunos de mis asuntos y sin embargo tan descuidada para otros), se instaló en mí definitivamente. Poco a poco ha ido ganando terreno, ocupando espacios hasta entonces deshabitados y conquistando otros previamente colonizados por mí, desterrándome de ellos a golpe de confusión y agotamiento, utilizando tácticas claramente reprobables y difíciles de esquivar.

A veces me golpea con saña, a veces se apiada por unos momentos de mí, y a veces es más yo que yo misma. Cuando toma el mando, me sorprende haciendo y diciendo cosas hasta hace unos años impensables en mí: me enemista con la gente que quiero, me hace dudar, enfurruñarme, impacientarme...tomo decisiones de las que a menudo, cuando vuelvo a ser yo, me arrepiento. Lo malo es que en algunas ocasiones no hay vuelta atrás.

## LA COSA, MALDITA SEA...

Extraído del Blog de la Web de Paisajes Literarios, la Web de Mariano Estrada basado en el libro "Me llamo Marta y soy fibromialgica" de Víctor Claudín. Madrid: 2002. Editorial La Esfera de los Libros S.L

Como buena okupa desocupada, nunca deja sus deberes sin hacer:



Figura 1. "Me llamo Marta y soy fibromialgica"

si hay que machacarme,  
me machaca, si tiene  
que despertarme de  
madrugada para  
atormentarme, no duda  
en hacerlo. Si le apetece  
atenazarme la garganta  
o el estómago hasta  
hacerme llorar, se

recrea en ello con un virtuosismo digno de elogio. ¿Por qué iba a privarse de semejante placer? La reconozco en cada lágrima, en cada dolor, en cada decepción, porque está hecha de muchas cosas. Es un ensayo cotidiano de la muerte que me saca de la vida.

En ocasiones se queda callada, agazapada, como dormida. Entonces salgo del secuestro interior que me impone y vuelvo a ser yo misma durante unos instantes fugaces, similares a flashes que me ciegan, pero que paradójicamente me devuelven a la realidad perdida. Pero pronto vuelve exigiendo su espacio y su dominio sobre mí. Posee una llave que yo no le he dado, un código secreto que sólo ella descifra y del cual cambia la combinación de forma caprichosa, cada vez que advierte que estoy cerca de descubrir.

Hay días en que me da por pensar cómo sería mi vida si de repente desapareciera o consiguiera arrancarla de raíz (las podas, selectivas o

drásticas, no han surtido ningún efecto definitivo, se reproduce a una velocidad de vértigo). ¿Me dejaría desnuda e indefensa frente al mundo, como a un recién nacido? ¿Tendría que reconstruirme a partir de cero, o me dejaría pistas y señales de lo que un día fui, que me permitieran reconocerme y volver al punto en que se apoderó de mí?

No puedo luchar contra ella, lo tengo comprobado: se hace más fuerte, se alimenta de mi rabia y mi desesperación, como un tumor invisible que extiende sus tentáculos hasta la última y más recóndita de mis células. Se alimenta de mí misma.

Se me ocurre una idea: Voy a cambiar de estrategia con ella. Seré amable, condescendiente, la mimaré y le daré todos los caprichos, a ver si así se harta de mí y se larga de una vez. Suele funcionar con algunas personas desagradecidas. Quizá también funcione con ella.

Es una posibilidad.

**Lidia**

*Extraído del Blog de la Web de Paisajes Literarios, la Web de Mariano Estrada basado en el libro "Me llamo Marta y soy fibromiálgica" de Víctor Claudín. Madrid: 2002. Editorial La Esfera de los Libros S.L*



## **IV. RESUMEN**

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#### IV. RESUMEN

La Fibromialgia (FM) es un síndrome al cual está aliado entre otros síntomas al de dolor crónico, la falta de fuerza muscular y problemas de equilibrio, generalmente están asociados a problemas de ansiedad y depresión, que afectan de forma bastante significativa a la calidad de vida relacionada con la salud (CVRS) de estos pacientes.

En los últimos años ha surgido el interés por el estudio de un método de entrenamiento basado en vibraciones, el llamado ejercicio vibratorio corporal o whole body vibration -por su sigla en inglés- (WBV). El WBV se ha aplicado en distintas poblaciones como son deportistas de élite, población general, tercera edad o pacientes afectados por distintas enfermedades. El WBV se suele realizar con instrumentos especializados. Uno de los más utilizados es una plataforma horizontal que vibra alrededor de un eje medio para permitir que cuando el lado derecho se eleva el izquierdo baje, y viceversa una vez que los pies distan igual del eje.

Sabiendo que la fuerza es un predictor de la función física y de la CVRS en enfermedades reumáticas, y, sabiendo que las personas con FM tienen un déficit de fuerza muscular con respecto a las personas sanas, hemos evaluado la fuerza muscular de piernas en personas con FM. El dinamómetro isocinético es un instrumento bastante fiable para medir dicho parámetro y ha sido el instrumento utilizado para medir la fuerza en este colectivo de personas, diversos estudios han utilizado

dinamómetros semejantes para cuantificar los déficits de fuerza en distintas poblaciones, así como para evaluar los efectos de distintos programas de entrenamientos relacionados con la fuerza muscular, la tesis doctoral del Dr. José Carmelo Adsuar Sala ha sido la primera en utilizar un dinamómetro isocinético para evaluar la fiabilidad test-retest en FM.

El sentido del equilibrio, o sea, aquellas sensaciones que nos informan en todo momento de la posición de nuestra cabeza con respecto al espacio tridimensional en que nos movemos, se ve también afectado en los pacientes con FM, ya sea el equilibrio estático o el dinámico. El equilibrio dinámico (ED), es el que mantiene nuestro cuerpo en equilibrio cuando realizamos movimientos de giro y aceleración. El equilibrio estático (EE), es el que mantiene el cuerpo equilibrado cuando este permanece quieto o se desplaza de forma rectilínea. Para evaluar estas cualidades físicas se utilizó el Biodek Balance System (BBS), (Biodek, USA). El BBS se ha usado para evaluar y entrenar la estabilidad postural y el equilibrio postural. Es un dispositivo multi-axial que mide objetivamente y registra la capacidad de un individuo para estabilizar una articulación afectada por un estrés dinámico. Es una plataforma circular que se mueve libremente sobre los ejes antero-posterior y medio-lateral simultáneamente. El BBS permite hasta 20º de inclinación de la plataforma para los pies, lo que permite una máxima estimulación de los mecano-receptores de la articulación del tobillo. Es un dispositivo que mide, en grados, la inclinación de cada eje durante condiciones dinámicas y calcula

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un índice de estabilidad medio-lateral (MLSI), índice de estabilidad antero-posterior (APSI), y un índice de estabilidad global (OSI), que está compuesto por MLSI y APSI. Estos índices son desviaciones estándar de la evaluación de las fluctuaciones sobre un punto cero establecido antes de la prueba cuando la plataforma esta estable. Una puntuación alta indica un pobre equilibrio. Para obtener el índice de equilibrio dinámico, se llevó a cabo una prueba de riesgo de caídas, de acuerdo con las instrucciones del fabricante. Hay muchas posibles variedades de protocolos posturales BBS, incluido el grado de inestabilidad de la plataforma; brazos cruzados o libres; una o dos piernas apoyadas y con ojos abiertos o cerrados. En el estudio actual, los participantes fueron instruidos para mantener la proyección vertical de su centro de gravedad en el centro de la plataforma mediante la observación de una pantalla vertical situada a 30 cm delante de su cara. Cada ensayo fue de 20 segundos de duración, con períodos de descanso de 10 segundos entre los ensayos. Todas las pruebas fueron realizadas mientras los participantes estaban con los pies descalzos en la plataforma, en un ajuste de inestabilidad constante (nivel 8), con los ojos abierto.

Los pacientes de FM tienen afectada la CVRS, en esta tesis se utilizaron dos cuestionarios específicos para medir esta función en estos pacientes siendo ellos el Fibromyalgia Impact Questionnaire (FIQ) y el 15-D Questionnaire (15-D).

El objetivo de la presente memoria de tesis es, evaluar la influencia de una terapia de WBV y sus efectos en el equilibrio dinámico, en la CVRS , equilibrio unipodal, dolor, fuerza y sistema somato-sensorial en pacientes con fibromialgia.

La muestra que ha participado en los estudios incluidos en la presente memoria de tesis está compuesta por 41 mujeres con FM, que cumplieron con los criterios diagnósticos del Colegio Americano de Reumatología (ACR) (1990).

Los principales resultados de esta memoria de tesis sugieren que la terapia de WBV propuesta es fiable y útil para incrementar el equilibrio dinámico en mujeres con FM (estudio I) las diferencias en los índices de equilibrio dinámico se pueden predecir a través del siguiente modelo de regresión lineal:  $(0.027 \times \text{peso}) - (0.800 \times \text{equilibrio dinámico en línea base}) - (0.632 \times \text{grupo})$  (estudio I), se verificó un incremento de 12% en los resultados de la CVRS medidos con el FIQ pero no se encontraron resultados significativos en las dimensiones del 15-D (estudio II), con respecto al equilibrio estático se obtuvo un incremento de 57.1% en OSI y 66.6% en el APSI (estudio III), se verificó una disminución en el dolor generalizado del 23.5% y un 40% en las rodillas (estudio IV), la fuerza en extensión y flexión concéntrica incrementó en comparación con la línea base más de 19% (estudio IV) y el equilibrio con ojos cerrados sufrió una ganancia de 25% en el OSI y un 40% en el APSI (estudio IV). Si bien el estudio IV está en proceso de revisión en la revista Arthritis Care &

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Research, aun no puede ser considerado como un merito de la tesis dado que todavía no está publicado.

En conclusión, la presente tesis aporta nuevo conocimiento sobre la aplicación y los efectos del WBV en algunos de los factores determinantes del manejo de la FM.



## **V. INTRODUCCIÓN**

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## V. INTRODUCCIÓN

Esta tesis es fruto de una investigación en pacientes de Fibromialgia (FM) gracias a la línea de investigación abierta por el Dr. Narcís Gusi en la Universidad de Extremadura, el formato de presentación de este documento se corresponde con la modalidad de “*tesis por reagrupamiento de trabajos de investigación en una memoria*”, recogido en el artículo 30 de la normativa reguladora de los estudios de tercer ciclo y doctorado de la Universidad de Extremadura, que indica: “... Asimismo, podrá constituir la Tesis Doctoral, el reagrupamiento en una memoria de los trabajos publicados por el doctorando sobre el Proyecto de su Tesis Doctoral... Asimismo se podrán contemplar resultados que no hayan sido publicados. En tal caso, dichos resultados se incluirán siguiendo el formato tradicional de una publicación”. Las referencias bibliográficas siguen el formato de la “American Medical Association” conocida como normativa AMA, dado que los artículos son del área de ciencias biomédicas. En el presente documento constan 4 estudios que relacionan la aplicación de una terapia de WBV en pacientes con FM :

### **1) Equilibrio Dinámico evaluado con estabilometría (Estudio 1);**

Al realizar la revisión de la literatura verificamos que había un elevado porcentaje de mujeres con FM que sufrían de problemas de equilibrio, y a la vez un déficit de estudios enfocados a esa problemática, sabiendo que el equilibrio se puede mejorar con las terapias físicas,

hemos planteado evaluar este colectivo de pacientes recurriendo a estabilómetros, porque según nuestro conocimiento hasta la fecha, aún no se había utilizado este tipo de aparatos en FM. Se realizó un estudio para verificar la fiabilidad y la eficacia de la terapia de WBV en el equilibrio dinámico en FM utilizando el test de *riesgo de caídas -Fall risk test-*.

**2) Calidad de vida relacionada con la salud (CVRS) evaluada con los cuestionarios 15D y FIQ (Fibromyalgia Impact Questionnaire) (Estudio 2);**

Dimensiones como el sueño, la función mental o la función sexual, son de gran importancia en FM y están directamente relacionadas con la CVRS, hemos verificado en la revisión de la literatura que no se había aplicado en FM un cuestionario genérico que permitiese cálculos económicos e incluyese las dimensiones antes referenciadas u otras de importancia en este colectivo, así nos pareció importante investigar la utilidad de un instrumento para evaluar la CVRS, como el cuestionario 15-D® en FM. Según nuestro conocimiento, hemos sido los primeros en dar un perfil del 15-D® propio de las personas con FM (tesis del Dr. José Carmelo Adsuar Sala) y en utilizar el cuestionario 15-D® para evaluar los efectos de una intervención con WBV en FM.

**3) Equilibrio Estático unipodal evaluado con estabilometría (Estudio 3);** En consonancia con todo lo que se ha dicho antes hemos evaluado el equilibrio estático, con un estabilómetro utilizando para ello,

el test de estabilidad postural unipodal -*unipodal postural stability test* - (Estudio 3),

4) Función neuromuscular: fuerza evaluada con dinamometría isocinética, dolor evaluado con algometría y equilibrio con ojos cerrados (sistema somato-sensorial) evaluado con estabilometría (Estudio 4).

Es común la utilización de la dinamometría isocinética en FM, en este último estudio nos hemos centrado en la función neuromuscular evaluando también con dinamometría isocinética momentos de fuerza isométricos, concéntricos y excéntricos de flexión y extensión de las rodillas, en nuestras pacientes, muchos son los estudios donde se evalúa el dolor pero recurriendo a métodos poco seguros y de forma subjetiva.

En este estudio hemos intentado medir el dolor de manera más objetiva recurriendo a un algómetro electrónico que registra la presión en los puntos referenciados en la bibliografía, con respecto al equilibrio con ojos cerrados (sistema somato-sensorial) hemos utilizado un estabilómetro con el test de estabilidad postural -*Postural stability test*- pero indicando al paciente que se mantenga en todo el momento con ojos cerrados.



## **VI. JUSTIFICACIÓN**

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## VI. JUSTIFICACIÓN

### VI.1 Concepto

La Fibromialgia (FM) es un síndrome que cursa con “*la presencia de dolor difuso de más de 3 meses de evolución y sensibilidad al dolor aumentada a la palpación digital en al menos 11 de 18 localizaciones anatómicas propuesta, a una presión de 4 kg·m<sup>2</sup>*”<sup>4</sup>. Así mismo estos pacientes tienen un perfil específico en depresión y ansiedad<sup>5</sup>. Los síntomas de la FM incluyen dolor crónico, fatiga, debilidad, hiperalgia o el sueño no reparador<sup>6</sup> y por lo tanto puede producir una incapacidad para trabajar<sup>7</sup>.

Generalmente los síntomas suelen aparecer ante el frío, la humedad o el estrés; también es muy común que aparezca el dolor ante la actividad física, siempre que no sean cumplidos algunos principios básicos y siempre que no sea prescrito de forma individualizada<sup>8</sup>. Sin embargo, el ejercicio físico diseñado de forma correcta respetando unos principios de actuación basados en la evidencia científica es una herramienta importante para mejorar la sintomatología de estos pacientes<sup>9</sup>. Tal como la prescripción de los fármacos debe ser controlada por un médico, también la prescripción de un programa de ejercicio físico debe ser diseñado y controlado por un profesional de la motricidad especialista en esta enfermedad.

### VI.2 Historia de la Fibromialgia

En la Grecia Antigua se hablaba de reumatismo creyéndose que los dolores reumáticos eran provocados por una sustancia que se creaba

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en la cabeza y al caer en los músculos y articulaciones generaba dolor esa sustancia más tarde se denominó de catarro<sup>10</sup>.

En el siglo XVIII se establece que el reumatismo no podría ser considerado una enfermedad por si sola sino que podría ser una manifestación de múltiples “males” que generaban dolor muscular. Asimismo cuando los padecimientos reumáticos provocaban inflamación de las articulaciones se les empezó a llamar artritis fijándose a si el término. Se empezaron a reconocer problemas de ámbito reumático específicos, como la fiebre reumática, la artritis reumatoide y la gota, entre otras<sup>10</sup>.

Es en el siglo XIX cuando se diferencia entre los síntomas de reumatismo articular (artritis) y los de reumatismo muscular<sup>11</sup>. En el año 1815 William Balfour, ha descubierto nódulos en los músculo, y lo atribuyó a una inflamación en el tejido conectivo<sup>12</sup>. En 1841 François Valleix, describe con precisión los puntos de dolor<sup>12</sup>. Dos años más tarde en 1843 Froriep, encuentra unas masas las cuales define como lugares “duros” en los músculos de sus pacientes con reumatismo de las partes blandas, donde muchos de ellos eran dolorosos a la presión<sup>13</sup>. Las terminologías en la historia de la FM nunca han sido de fácil resolución, en el siglo XX surgen varios términos para designar en síndrome de FM, todos ellos acabados en “itis” (fibrositis, miofibrositis o fibromiositis). Sin que ninguno se impusiera para denominar el síndrome atendiendo a que la terminación “itis” está asociada a las inflamaciones musculares. Sin

embargo el término fibrositis fue el que más triunfó y en 1904 William Gowers, acuño el término fibrositis en la conferencia “Lumbago: It's lessons and analogs”<sup>14</sup>. A medio del siglo XX se empieza a hablar de puntos gatillo, en 1904 Ralph Stockman, indica que entre las uniones fibrosas del músculo y el hueso se producían inflamaciones, combinó el concepto de los nódulos con el concepto del tejido conectivo inflamado, etiquetó los nódulos como inflamatorios y ha propuesto una definición de “hiperplasia inflamatoria del tejido conectivo”<sup>14</sup>. En 1909, William Osler, defiende que este tipo de pacientes presentaban frecuentemente reumatismo muscular, lo que no significaba que la enfermedad estuviese localizada en los tejidos musculares<sup>12</sup>. Albee en 1927, define esta afectación como “miofibrositis o fibromiositis” y asume el desconocimiento de su etiología<sup>13</sup>. Se empieza realmente a hablar de “*punto gatillo*” o “*trigger point*” en 1945 cuando Lewis & Kellgren, desmontan que el dolor muscular sigue pautas de acuerdo con el dolor neurológico y denominan de “parestesias” a las sensaciones de adormecimiento y hormiguero<sup>15</sup>. El término de Fibromialgia (FM) surge finalmente en la segunda mitad del siglo XX, para justificar la necesidad de tener unos criterios de diagnóstico universales. Así en 1975 Moldofsky y cols., ha definido el término “*síndrome del sueño no reparador*” porque han verificado que algunos de sus pacientes con fibrosis tenían problemas en la fase IV del sueño<sup>16</sup>. Los primeros en utilizar el término FM han sido Hench & Mitler en el año 1976 para resaltar la existencia de fenómenos dolorosos musculares y la ausencia de signos inflamatorios, ese momento ha sido

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importante en la terminología de la enfermedad, porque fue cuando se dejó de utilizar el término Fibrosis<sup>17-18</sup>. En 1983 Travell, define los “*puntos gatillo*” como aquella zona del músculo cuya presión desencadena dolor en el mismo punto o distancia<sup>19</sup>. También en 1983, Yunus habla por primera vez de la necesidad de establecer unos criterios de diagnóstico para la FM<sup>20</sup>.

Ya en la década de los 90 (1990) el ACR publicó los criterios de clasificación para el diagnóstico de la FM<sup>4</sup>. Dos años más tarde en 1992 la FM es reconocida por la Organización Mundial de la Salud como enfermedad tipificándola con el código M79.0 en el manual de Clasificación Internacional de Enfermedades (ICD-10)<sup>21</sup>. En 1994 la FM fue reconocida por la Asociación Internacional para el Estudio del Dolor clasificándola con el código X33.X8a<sup>22</sup>. Existen factores psicosociales con los cuales se caracterizan los pacientes de FM, y en 1999 se señalaron esos factores<sup>23</sup>.

En el año 2001 en la reunión de la Subcomisión de Prestaciones/Calidad, coordinada por la Subdirección General de Programas Sanitarios y Sociosanitarios y de Acreditación, Calidad y Prestaciones, celebrada el 28 de mayo, se estudiaron diversas propuestas de actuaciones a realizar sobre la FM.

Un año más tarde en el 2002 se define la FM como: “*un estado doloroso generalizado no articular, que afecta principalmente a las zonas musculares y raquis, y que presenta una exagerada sensibilidad en*

*múltiples puntos predefinidos*" (de acuerdo con los criterios de diagnóstico del ACR de 1990) esta definición fue publicada en el primer documento de consenso sobre el diagnóstico y tratamiento de la FM en España<sup>24</sup>. Los criterios son válidos, igualmente, para los pacientes con enfermedad reumatólogica concomitante o sin ella (el diagnóstico de la FM debe ser válido con independencia de otros diagnósticos asociados).

El estudio de la genética en FM tiene un punto fuerte en 2003 cuando en una investigación de Gursoy S. y cols. se verifica que en el gen COMT situado en el cromosoma 22, responsable del origen de la enzima catecol-O-metiltransferasa, presenta una mutación en el 50% de las personas, concretamente esta mutación se localiza en el codón 158. La mutación de este Gen provoca en un 25% (met-158-met) de los casos que la enzima que origina no realice adecuadamente su función de "limpieza" hormonal. En el otro 25% (val-158-val) de los casos provoca la producción de una enzima que degrada de una forma eficaz. El 50% de la población restante posee un gen heterocigoto. Las afectadas de FM tienen con menos frecuencia el tipo de gen COMT val-158-val, que es el gen que está asociado al dolor<sup>25</sup>.

En el 2004, el Ministerio de Sanidad y Consumo publicó un documento de consenso realizado dentro de la Subcomisión de Prestaciones del Consejo Interterritorial del Sistema Nacional de Salud, en las que se hayan representadas todas las comunidades autónomas, y en el que se marcan todas las directrices para el correcto diagnóstico de

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la FM, el estudio de su impacto vital, familiar, laboral y sobre el sistema sanitario, y las estrategias terapéuticas a utilizar. En este documento se incluye al médico de familia como el elemento clave en el manejo de los pacientes con FM<sup>26</sup>.

El Congreso de los Diputados aprobó en 10 de mayo del 2005 una proposición de ley en la que, se instaba al Gobierno, a elaborar protocolos de evaluación de las incapacidades que afectan el desarrollo de las profesiones habituales de los pacientes de FM y del síndrome de fatiga crónica<sup>26</sup>.

En el 2006 se creó un nuevo modelo de atención para las personas con FM en Cataluña.

El 28 de mayo del 2008 en el parlamento gallego se instó al gobierno español a que se reconocer la FM como una enfermedad incapacitante.

Con la evolución de los estudios se verificó que los pacientes de FM presentaban un conjunto de síntomas que tornaban extremadamente difícil para el médico su diagnóstico, también con respecto a los criterios de diagnóstico presentados por el ACR (1990), principalmente los “*puntos de dolor*” se tornaban difíciles algunas evaluaciones a los pacientes siendo que la mayoría de las evaluaciones eran incorrectas y el diagnóstico era muy a menudo resultado de los síntomas<sup>27</sup>. Atendiendo a la necesidad del desarrollo de un instrumento de trabajo con criterios más simples y prácticos para el diagnóstico clínico de la FM, Wolfe, F. y cols

en el 2010 desarrollaron una investigación con 829 pacientes de FM, con el objetivo de definir nuevos criterios de diagnóstico que sean aptos para el uso en atención primaria y especializada, que no requieran un examen de los puntos sensibles al dolor y que proporcionen una escala de gravedad para los síntomas que caracterizan la FM, como resultado de esta investigación surge una escala de gravedad de síntomas (SS)<sup>28</sup>, escala esta que permite la valoración de la gravedad de los síntomas de FM en personas con FM actual o previa, y en aquellas donde los criterios aún no han sido aplicados. Estos investigadores se creen que la SS será bastante útil en las evaluaciones longitudinales de los pacientes de FM y que tienen una gran variabilidad sintomática<sup>28</sup>.

### **VI.3 Criterios de diagnóstico de la Fibromialgia**

Al largo de los años se ha trabajado mucho en el diagnóstico de la FM estipulándose los siguientes criterios de diagnóstico:

Historia de dolor generalizado. Se consideró el dolor como generalizado cuando se presentaba en el lado izquierdo y derecho del cuerpo, por encima y por debajo de la cintura. Además, debía existir dolor en el esqueleto axial (columna vertebral, pared torácica anterior, columna dorsal o lumbar). En esta definición, el dolor de hombro o nalga se consideró como dolor para cada lado implicado. Este síntoma debía estar presente durante al menos 3 meses.

Dolor a la presión en al menos 11 de los 18 puntos elegidos (nueve pares). La presión digital debía realizarse con una fuerza aproximada de 4 kg·cm<sup>2</sup>. Para que un punto se considere “positivo” el sujeto explorado

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tenía que afirmar que la palpación era dolorosa. No se considera dolorosa la palpación sensible. Los pares de puntos usados son los siguientes:

- a. Occipucio: en las inserciones suboccipitales de los músculos.
- b. Cervical bajo: en la cara anterior de los espacios intertransversos a la altura de C5-C7.
- c. Trapecio: en el punto medio del borde superior.
- d. Segunda costilla: en la unión osteocondral.
- e. Supraespinoso: en sus orígenes, por encima de la espina de la escápula, cerca del borde medial.
- f. Epicóndilo: a 2 cm. Distales del epicóndilo.
- g. Glúteo: en el cuadrante superoexterno de la nalga.
- h. Trocánter mayor: en la parte posterior de la prominencia trocantérea.
- i. Rodillas: en la almohadilla grasa medial próxima a la línea articular.

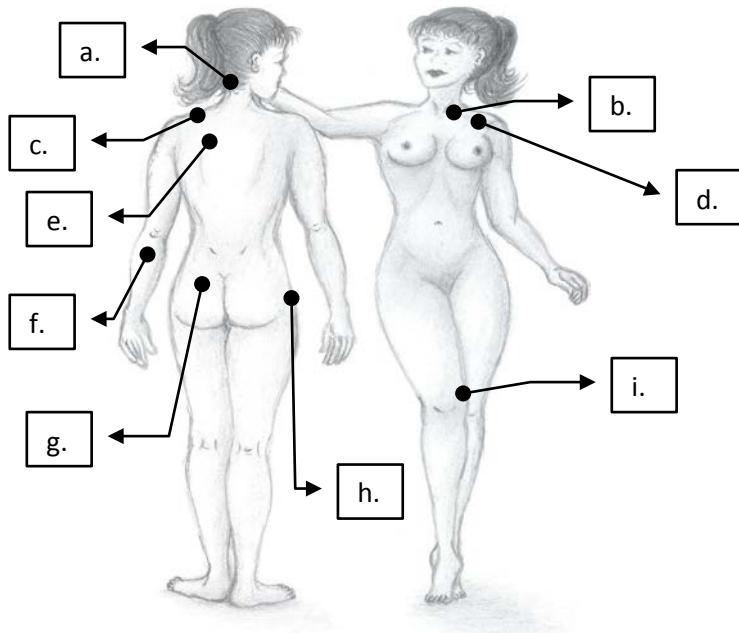


Figura 2. Puntos sensibles al dolor.

Han pasado veinte años desde la publicación de los criterios para la clasificación de FM desde la década de los 90<sup>4</sup>. Pero en el 2010 el ACR ha definido nuevos criterios de evaluación de la Fibromialgia<sup>28</sup>.

Así los nuevos criterios son los siguientes<sup>29</sup>.

1. Quitar puntos sensibles al dolor de los criterios dejando este punto de ser el elemento central en la definición de la FM.
2. Cambiar la definición de la FM.
3. Reconocer la importancia de una medida cuantitativa de dolor generalizado, índice o escala de dolor generalizado (WPI – Widespread Pain Index -por su sigla en inglés-).
4. Incorporar los síntomas clave de la FM en los criterios.
5. Proporcionar escalas severas para medir el grado de dolor generalizado y la gravedad de los síntomas.
6. Poner a disposición un concepto alternativo a la FM para aquellos que la FM no es una entidad diagnóstica válida.

Los nuevos criterios tienden a establecer un concepto aparentemente contradictorio de una enfermedad que tiene un criterio estricto, y proporciona una alternativa sin que se observe un punto claro divisorio.

Los nuevos criterios de diagnóstico del ACR no deben ser vistos como un respaldo a la legitimidad y la existencia de la FM – siendo estos criterios neutros en este punto-. La existencia y la legitimidad son conceptos que tienen componentes existenciales, filosóficos y sociales,

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que no se resolvió con la publicación de estos criterios y las cuestiones que son preocupantes sobre la FM continúan en el mismo estado<sup>30</sup>.

A nivel práctico, los nuevos criterios pretenden abandonar el examen de los puntos sensibles al dolor, siendo este un examen difícil y bastante subjetivo. Encontrar determinados puntos sensibles al dolor puede distraer al observador del objetivo más importante, que es, entender los problemas del paciente. Los nuevos criterios reemplazan la dicotomía de tener, o no, los 11 puntos de dolor, así como la dicotomía de tener, o no, dolor generalizado, por una escala de dolor continua que proporciona mucha más información sobre el umbral del dolor y el grado del dolor (WPI). Pero cuando hay la necesidad de un indicador de dolor generalizado, fácilmente se pueden apoyar en las variables de la WPI. Esto no significa que el examen físico no sea necesario. De hecho, es muy recomendable como parte del examen de rutina. Sin embargo, ya no es una parte de los criterios diagnósticos. Los nuevos criterios requieren por parte del examinador un completo conocimiento de los problemas del paciente, actualmente es imposible diagnosticar la FM sin prestar especial atención al paciente, no se puede adivinar el grado de fatiga, sueño no reparador, problemas cognitivos, la multiplicidad de los síntomas y el grado de dolor, sin una entrevista detallada.

Los nuevos criterios ACR introducen una Escala de Gravedad de los Síntomas (SS – Symptom Severity Scale), que es una puntuación resumen de las escalas para medir el grado de fatiga, de sueño no reparador, problemas cognitivos y multiplicidad de los síntomas. La

puntuación de la SS se correlaciona con la WPI y el con el número de puntos sensibles al dolor, siendo la SS una parte de los criterios de la FM. La escala de captura y el contenido esencial de la FM le han llamado "fibromyalgianess"<sup>31</sup>. Sea con el diagnóstico antiguo o con el nuevo diagnóstico ACR, los pacientes pueden entrar o salir del diagnóstico ya que el diagnóstico se basa en el grado de afectación de los síntomas y no en la fijación de las características.

#### VI.4 Síntomas de la Fibromialgia

Es muy común que la FM se confunda con otro tipo de enfermedades como por ejemplo el Síndrome de Fatiga Crónica (SFC), donde el principal síntoma es la fatiga, la FM implica dolor independientemente de que haya otra sintomatología. Generalmente el dolor nunca aparece de forma aislada sino asociado con otros síntomas. Según Bennett aunque existe una gran variedad de síntomas, los más frecuentes y característicos de los pacientes con FM son los dolores generalizados<sup>32</sup>.

**Tabla 1. Variedad de síntomas las personas que tienen FM.**

(Bennett et al 2007).

Dolor de espalda baja	63%
Dolores de cabeza	47%
Artritis	46%
Espasmos musculares	46%
Hormigueros	46%
Problemas de equilibrio	45%
Síndrome de colon irritable	44%
Entumecimiento	44%
Fatiga crónica	40%
Hinchazón	40%

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Depresión	40%
Ansiedad	38%
Problemas nasales	37%
Problemas dentales	32%
Piernas inquietas	32%
Tinnitus	30%
Dolores mandibulares	29%
Problemas de vejiga	26%

Estos son algunos de los síntomas que las personas con FM presentan propuesto por Bennett, pero existen una multitud de otros síntomas propuestos por otros autores que acompañan a este colectivo de pacientes, tales como:

- ✓ La Rigidez variable matutina o tras reposo(76-84%) <sup>33-36</sup> ;
- ✓ Alteraciones del sueño: insomnio, sueño ligero, despertar frecuente, bruxismo y sueño no reparador. <sup>33, 36-37</sup> ;
- ✓ Fatiga crónica <sup>38-39</sup>;
- ✓ Parestesias e inflamación subjetiva con frecuencia bilateral. (sensación subjetiva de hinchazón) <sup>34, 40</sup>;
- ✓ Cefalea tensional <sup>33, 41</sup>;
- ✓ Distrés psicológico (pánico o fobias) <sup>42</sup>;
- ✓ Síntomas genitourinarios, dismenorrea, síndrome premenstrual y vejiga irritable. <sup>43-44</sup>;
- ✓ Fenómeno de Raynaud. <sup>45-48</sup>.

Este síndrome tiene una clara repercusión en la calidad de vida de quien lo padece, tal y como lo indican distintas investigaciones en las que se han utilizado diferentes instrumentos de medida de la CVRS, sean genéricos como específicos de esta población. <sup>49-58</sup>.

Los síntomas de la FM tales como el dolor crónico, fatiga, debilidad, hiperalgia puede producir una discapacidad para trabajar<sup>7</sup>.

Los problemas cognitivos y los problemas emocionales que parecen estar presentes en la mayoría de pacientes con FM muestran una buena correlación con el dolor<sup>28</sup>.

#### **VI.5 Prevalencia de la Fibromialgia**

Diferentes estudios epidemiológicos recogen cifras alrededor del 11% de la población afectada de dolor persistente situando la prevalencia de la FM del 2 al 3% de la población general, siendo las personas de sexo femenino las más afectadas, llegando a ser el 90% de las afectadas

59-61.

La prevalencia en la población española según los criterios del ACR es de un 4,2% para sexo femenino y un 0,2% para el masculino en un total de 2,7%<sup>24</sup>.

En otros países varía desde el 2% al 10,5% en mujeres<sup>62</sup>. Estos datos contrastan con prevalencias cercanas al 10% en países como Israel, EE.UU., Gran Bretaña o Canadá<sup>63</sup>.

Su prevalencia se incrementa con la edad, más drásticamente en mujeres desde los 50 a los 70 años (7,4- 10%)<sup>64</sup>. La incidencia anual se estima que es de alrededor de 0,6% en mujeres previamente libres de dolor entre 26 y 55 años<sup>65</sup>.

La incidencia real de estos procesos es desconocida, aunque la podemos considerar un problema muy común en la población general. Sí podemos afirmar que entre algunos de los factores de riesgo para su desarrollo se incluyen los traumas físicos, enfermedades febres o una historia familiar de FM<sup>66</sup>.

Recientemente se ha realizado un estudio sobre la prevalencia de la FM en 5 países europeos (España, Francia, Portugal, Italia y Alemania) en población general, siendo la prevalencia media del 3,6 % en mujeres y del 2,1% en hombres<sup>67</sup>. Según el estudio citado anteriormente en España la prevalencia es del 2,7% para hombres y del 5,2 % para mujeres.

La totalidad de los estudios realizados sobre la prevalencia en FM refieren una prevalencia mayor en mujeres con respecto a los hombres, este dato es importante ya que no se conoce la causa de este hecho, ni si las diferencias entre los sexos en cuanto a fisiopatología, presentación, curso de la enfermedad, comportamientos para acudir a servicios sanitarios, percepción de la enfermedad u otros factores culturales y/o socioeconómicos puedan explicar la diferencia<sup>68</sup>.

### **VI.6 Etiopatogenia de la Fibromialgia**

La etiopatogenia de la FM todavía no está suficientemente descrita<sup>69</sup>. Se piensa que la FM puede ser causada por un conjunto de factores genéticos, musculares, psicológicos, así como por problemas en el sistema nervioso central<sup>70</sup>.

Actualmente no se dispone de un tratamiento que sea efectivo en la “curación” de la FM por lo que hasta el momento la gran mayoría de los tratamientos que se llevan a cabo con estos pacientes son paliativos y se centran básicamente en 3 vertientes: 1) terapia farmacológica, 2) terapia cognitivo conductual y 3) terapia física.

#### **VI.6.1 Terapia farmacológica**

Existen fármacos que en general aumentan los niveles generales de serotonina, que modulan el sueño y el dolor. Estas medicinas son la amitriptilina, la ciclobenzaprina y otras similares, se utilizan en dosis bajas y tardan un cierto tiempo en producir mejoras. Los analgésicos pueden ayudar de forma puntual. La mayor parte de los pacientes con FM lo toman pero su eficacia es parcial y no debe ser el único tratamiento. Los antiinflamatorios no esteroideos no producen mejorías substanciales. Las inyecciones locales en los puntos dolorosos con anestésicos locales, aliados al masaje localizado ayudan en los dolores puntuales intensos.

#### **VI.6.2 Terapia psicológica-educativa (cognitivo conductual)**

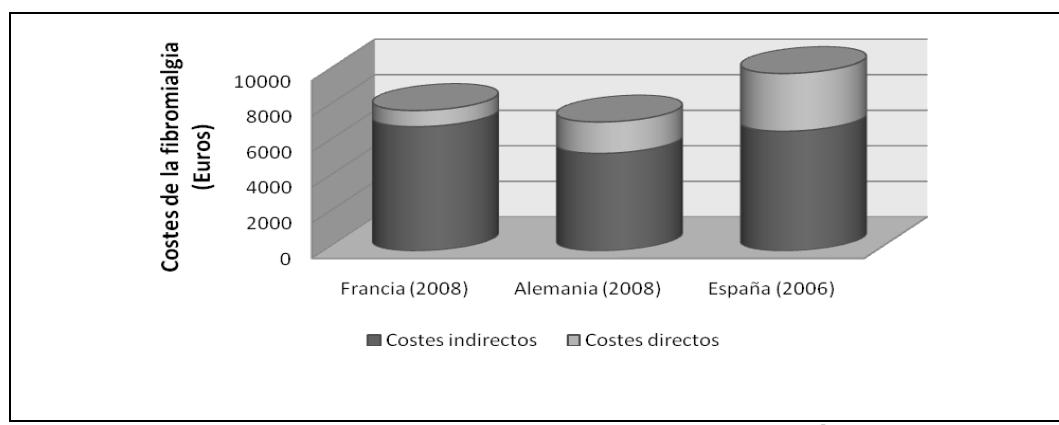
La terapia cognitivo conductual supone una opción de tratamiento no farmacológico para el dolor crónico. La terapia cognitivo conductual puede utilizarse para incrementar las habilidades de afrontamiento, aliviar el dolor, promover patrones de sueño reparador, aumentar la sensación de control y bienestar, reducir la fatiga y mejorar la salud general.

#### **VI.6.3 Terapia física**

Dentro de la terapia física se han postulado numerosos tratamientos para la mejora de la calidad de vida del paciente con esta dolencia crónica. Se ha estudiado por ejemplo el yoga <sup>71</sup>, el taichí <sup>72</sup>, la relajación <sup>73</sup>, o el biofeedback <sup>74</sup>. Sin embargo los tratamientos que reportan mayor evidencia científica de ser beneficiosos para mejorar la función física y algunos síntomas de la FM son aquellos en los que incluyen ejercicios aeróbicos con bajo impacto mecánico para reducir el dolor en suelo liso de gimnasio <sup>75</sup> o en agua caliente <sup>55, 76-78</sup>.

### VI.7 Costes de la Fibromialgia

Los costes de la FM son elevados llegando a superar los 6000€ por paciente al año en los países desarrollados <sup>79</sup>. Un estudio indica que en España en el año de 2006 los costes ascendieran a 9982€<sup>80</sup> por paciente. En la siguiente figura podemos apreciar una comparativa entre los gastos directos e indirectos de la FM en tres países europeos.



**Figura 3. Costes de la FM (directos e indirectos) en tres países europeos.**

(Realizada a partir de Winkelmann et al. <sup>79</sup> y Rivera et al. <sup>80</sup>)

Generalmente los pacientes con FM tienen asociados problemas de depresión llegando los costes de estos pacientes a ser de 11899 dólares al año<sup>81</sup>.

En otro estudio los mismos autores han definido un coste económico para la FM en 5945 dólares, donde solamente el 6% era atribuible a las demandas específicas de la FM. Por cada dólar gastado en demandas específicas de la FM, el empleador gastaba de 57 a 143 dólares en costes directos e indirectos adicionales, los costes ocultos de la incapacidad y la comorbilidad aumentan de forma significativa los gastos reales de la FM con costes muy elevados para los pacientes<sup>82</sup>.

En un estudio realizado en Canadá, se verificó que las pacientes con FM usaban el doble de medicamentos y de los servicios de salud en FM con respecto a los controles sanos<sup>83</sup>.

En el estudio epidemiológico EPISER 2000<sup>60</sup>, realizado en España se expone que las dos afectaciones asociadas a un mayor consumo de tratamientos crónicos son la FM (87%) y la artritis reumatoide (82%).

Numerosos estudios<sup>84-86</sup> han constatado que en países con escasas coberturas sanitarias y precarios o inexistentes sistemas de pensiones por invalidez como Sudáfrica o Pakistán, la FM presenta una prevalencia superior a la de países tan avanzados en prestaciones sociales como son los nórdicos<sup>34, 87</sup>.

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En Estados Unidos<sup>88-89</sup>, Canadá<sup>90</sup> y algunos países nórdicos<sup>36</sup>, la tasa de incapacidad laboral en los pacientes con FM alcanza el 25%, mientras que sólo llega al 3% en la población general<sup>36</sup>. El dato más preocupante para las autoridades americanas es que las tasas de incapacidad subieron desde el 6%, en 1988<sup>91</sup>, hasta el 26%, en 1997<sup>89</sup>. Este fuerte incremento en tan poco tiempo ha conducido a que en algunos estados americanos el diagnóstico de FM esté proscrito cuando se hace una demanda por incapacidad laboral.

En España, un estudio realizado en la Comunidad de Madrid<sup>92</sup> acerca de bajas laborales de origen osteomuscular, se comprobó que de 16279 casos de incapacidad laboral transitoria sólo 57 (0,35%) se debían a FM y no hubo ningún caso de incapacidad permanente.

En el estudio de la epidemiología de las enfermedades reumáticas en España<sup>93</sup>, la tasa de incapacidad laboral en los pacientes con FM fue superior que en el resto de la población 11,5 frente a 3,2%.

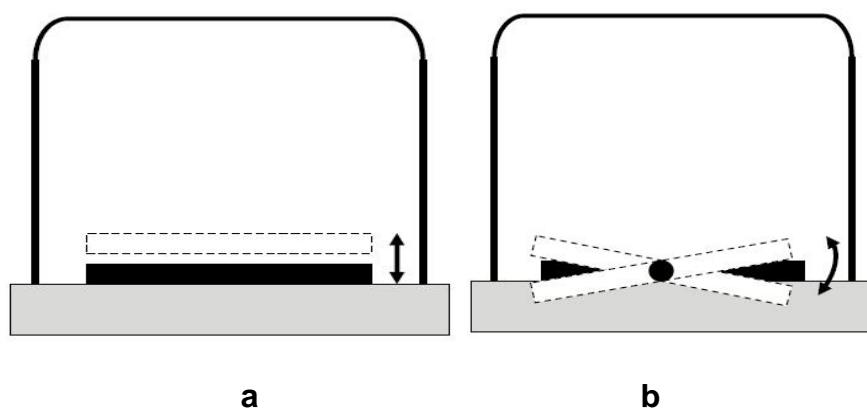
Llama la atención la baja tasa de incapacidad laboral en los pacientes españoles con FM en comparación con la de los países antes mencionados, a pesar de que la prevalencia de la FM es la misma.

### **VI.8 Ejercicio Vibratorio Corporal**

En los últimos años ha surgido el interés por el estudio de un nuevo método de entrenamiento basado en vibraciones mecánicas transmitidas al cuerpo entero, el llamado ejercicio vibratorio corporal de cuerpo

completo (WBV por su sigla en inglés whole body vibration), se considera WBV todo el ejercicio que se hace sobre una plataforma que oscila de modo sinusoidal provocando estímulos mecánicos que aumentan la carga gravitacional del sistema neuromuscular.

Hay distintas plataformas en el mercado (Galileo, Power Plate®, Kuntotäry, Newform, etc), pero se distinguen especialmente por la forma de aplicación del estímulo. Unas generan la vibración de forma vertical sinusoidal sobre el eje longitudinal (fig.a), mientras que otras (las plataformas basculantes u oscilantes) lo hacen vibrando en torno a un eje central o sagital, por lo cual cuando una pierna se encuentra en la parte superior, la otra está en la parte inferior y cambian alternadamente de modo basculante (fig.b).



**Figura 4. Tipos de plataformas vibratorias.**

(a) la plataforma oscila uniformemente hacia arriba y hacia abajo; (b) en la técnica de vibración basculante, los desplazamientos verticales se alternan hacia arriba y hacia abajo en los lados derecho e izquierdo del eje frontal de la plataforma.

El WBV es un tipo de ejercicio físico practicado en plataformas y las variables que influyen en la vibración son clasificadas en **extrínsecas** (aquellas independientes del cuerpo humano) e **intrínsecas** (aquellas dependientes del cuerpo humano).

#### **VI.8.1. Variables extrínsecas:**

**La amplitud:** *Desplazamiento total que es efectuado en cada ciclo del movimiento, y está expresado en milímetros (mm).*

**La frecuencia:** *Número de ciclos de movimientos completos efectuados en un segundo, y está expresada en Hertzios (hz). Hay algunas variaciones entre las posibilidades a elegir segundo los modelos o instrumentos de cada marca.*

**El tiempo de trabajo:** *Periodo de esfuerzo seguido o por la suma de los periodos anteriores.*

**El tiempo de descanso intermedio:** *Tiempo transcurrido entre cada periodo de trabajo dentro de cada sesión.*

#### **VI.8.2. Variables intrínsecas**

**Intrasujeto:** *Postura corporal, posición y orientación del cuerpo.*

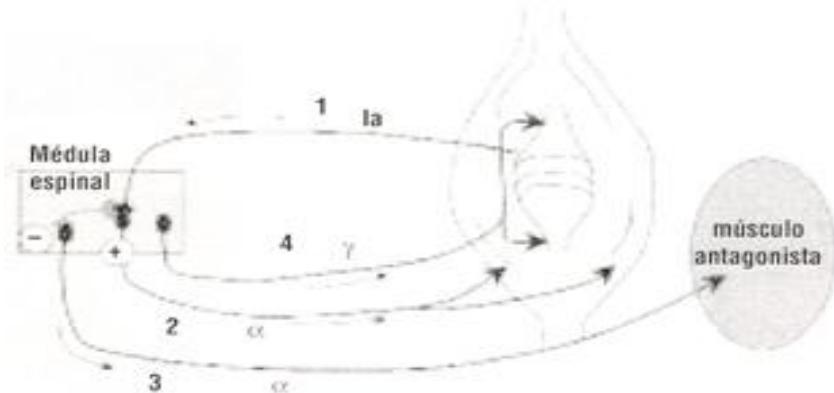
**Intersujeto:** *Tamaño y peso corporal, respuesta biodinámica corporal, edad, sexo, actitud, personalidad, nivel de forma física.*

#### **VI.8.3. Efectos Motores**

La vibración directa sobre el músculo o tendón provoca 3 efectos motores:

1. **El reflejo tónico vibratorio (RTV):** Se traduce en una contracción activa en el músculo cuando este es sometido a vibración, es una respuesta que depende de 4 factores (*localización de la vibración, longitud inicial del músculo, estado de excitabilidad del sistema nervioso*)

central (SNC) e los parámetros del estímulo vibratorio). La contracción refleja del RTV se inicia en las terminaciones primarias de los husos musculares por su alta sensibilidad a los cambios de longitud, desde los husos musculares sale un impulso por las fibras laferentes hasta la médula espinal, donde se realizan las sinapsis con las  $\alpha$ -motoneuronas, éstas emiten una señal de vuelta, vía eferente a las fibras musculares extrafusales que provoca la contracción muscular (*figura 5*)<sup>94-95</sup>.



**Figura 5. Reflejo Tónico Vibratorio**

Se sabe también que la vibración aplicada al músculo o al tendón induce un aumento significativo de los potenciales motores evocados, lo que indica que la vibración afecta la modulación de la excitabilidad de la corteza motora, pudiendo verse afectados los impulsos voluntarios<sup>96</sup>

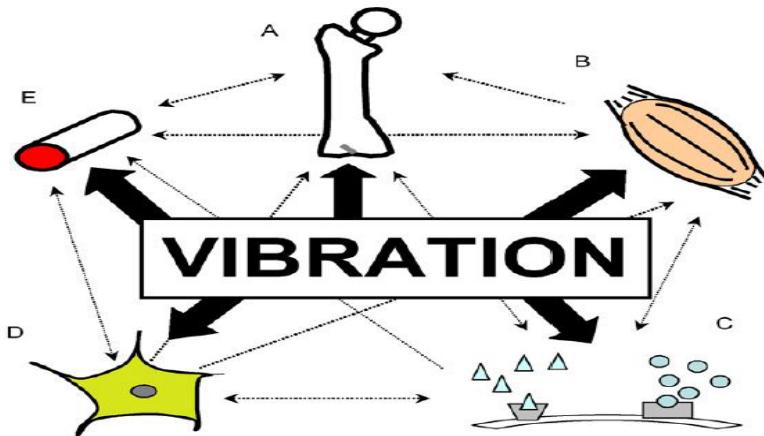
**2. Reducción vía inhibición recíproca de la excitabilidad de las motoneuronas que inervan los músculos antagonistas:** Según algunos la vibración produce una mayor co-activación del par agonista-antagonista durante<sup>97</sup> y después de ser aplicada<sup>98</sup>, lo que se traduce en un efecto positivo en la estabilización activa de la articulación<sup>99</sup>.

**3.      *Supresión de los reflejos monosinápticos del músculo:***

Cuando un músculo es sometido a vibración los reflejos monosinápticos se quedan suprimidos durante la aplicación del estímulo<sup>100</sup>, por ejemplo queda suprimido el reflejo del tendón de Aquiles cuando el músculo Gástrico es sometido a un estímulo vibratorio.

Las vibraciones se pueden diferenciar según las características del estímulo, su control y posibles implicaciones, son una constante en nuestra vida cotidiana, estando presentes en algunos medios de transporte como autobuses, embarcaciones, motos, coches, etc. y otras prácticas laborales donde las vibraciones eran aplicadas de forma no controlada con frecuencias muy bajas o muy altas, altas amplitudes y largas duraciones temporales con períodos de descanso reducidos (trabajadores de la construcción, taladros y otras herramientas, etc.). A lo largo de los años se ha intentado desarrollar aplicaciones de las vibraciones adaptando las variables que se pueden controlar como son la frecuencia, la amplitud, el tiempo de exposición, los períodos de descanso y las posturas, variables estas que condicionan la respuesta del cuerpo humano cuando sometido a las vibraciones<sup>101</sup>.

Existen efectos casi en todos los sistemas corporales como indica la figura 3.



**Figura 6. Efectos del WBV en los sistemas fisiológicos.**

A – Sistema Óseo; B – Sistema Muscular; C – Sistema Endocrino; D – Sistema Nervioso y E – Sistema Vasculares.<sup>102</sup>

A partir de año 1970, se empieza a utilizar el ejercicio vibratorio en el ámbito deportivo en Rusia<sup>103</sup>. Los efectos de la vibración en el rendimiento deportivo despertaron el interés de los investigadores como medio de aumentar la prestación deportiva, se constata que sometiendo el cuerpo a vibraciones controladas con frecuencias moderadas, amplitudes pequeñas, tiempos de exposición cortos y periodos de descanso considerables, se pueden conseguir cambios extremadamente validos en el ámbito del entrenamiento y rendimiento deportivo<sup>104-109</sup>.

Sin embargo, la relación entre las características o dosis del WBV como, por ejemplo, la amplitud, la frecuencia y el tiempo de oscilación, y sus efectos sobre los niveles de salud y condición física eran poco conocidos. Surge entonces la necesidad de verificar los efectos en el ámbito de la salud encontrado efectos positivos en calidad de vida, fitness y rehabilitación en población general<sup>110</sup>, en el colectivo de la tercera edad<sup>111</sup>, en pacientes con Fibromialgia<sup>112-115</sup> o pacientes afectados por distintas enfermedades<sup>116-117</sup>.

La adaptación al estímulo del entrenamiento está relacionada con la modificación inducida por la repetición del ejercicio efectuado varias veces y esta adaptación es específica para cada movimiento ejecutado. Algunas investigaciones apuntan que cuanto más se flexionen las rodillas menor será el estímulo mecánico<sup>118-119</sup> pero en contrapartida, la actividad muscular aumentará<sup>119</sup>.

Con el avance de las investigaciones a nivel mundial se verifica que el WBV provoca cambios en el hueso y en los factores determinantes de las fracturas óseas<sup>102, 120-124</sup>, teniendo también un rol importante en las terapias para prevenir la osteoporosis<sup>122-123, 125-127</sup>. Sin embargo una reciente revisión de la literatura afirma que el WBV no tiene ningún efecto global sobre el tratamiento de la densidad mineral ósea en mayores<sup>128</sup>

Se investigó sobre los efectos del WBV en el tratamiento rehabilitador de pacientes con problemas en el sistema cardiovascular<sup>129-130</sup>, en el comportamiento del VO<sub>2</sub>max<sup>131</sup> o en el control del flujo sanguíneo<sup>132</sup>, más recientemente estudios hablan de una resistencia capilar aumentada que tenía como respuesta una apertura de los capilares, mayor intercambio de gases y un aumento del metabolismo muscular<sup>133</sup>. También se verifica que el WBV es un método efectivo para aumentar el flujo de sangre y para activar la masa muscular en pacientes con ataxia de Friedreich<sup>134</sup> o pacientes con lesiones de la medula espinal<sup>135</sup>.

Otros autores informan que a nivel metabólico se verificaron alteraciones agudas en el metabolismo tras 24h en corredores jóvenes y bien entrenados<sup>136</sup>.

Varios han sido los estudios que comprobaron alteraciones en el sistema endocrino<sup>137</sup>, se han visto incrementos en los niveles de la hormona del crecimiento (GH, del inglés: growth hormone) en sangre<sup>138</sup>, o los niveles circulantes de la proteína factor de crecimiento semejante a la insulina tipo 1 (IGF-1, del inglés Insulin-like growth factor 1) y cortisol<sup>139</sup> si bien que en mujeres con Fibromialgia la utilización de la vibración como medida para el incremento de la IGF-1 aún no se ha podido demostrar<sup>114</sup>. También se ha visto un incremento en la Creatine Kinase en sujetos sedentarios tras una terapia de entrenamiento vibratorio<sup>140</sup>.

Han sido muchos los autores que han utilizado las vibraciones en el estudio del sistema sensorial, propioceptivo y en el control postural, parece que el efecto de los estímulos vibratorios afectan la propriocepción y provocan efectos duraderos en la postura en adultos sanos<sup>141</sup> y mayores<sup>142</sup>. También en sujetos que habían sufrido infarto cerebrales los efectos de las vibraciones se han mostrado efectivos en mejorar el control postural<sup>143-144</sup>, otros autores han comprobado efectos positivos en algunas pruebas de equilibrio (Tinetti test y timed up and go)<sup>145</sup> y en equilibrio unipodal de mayores<sup>111</sup>, en pacientes con esclerosis múltiple un reciente estudio afirma que el WBV es beneficioso para el incremento del equilibrio y la postura<sup>146</sup> no teniendo este tipo de terapia efectos adversos en esta población<sup>147</sup>. Autores defienden también que el WBV

con una adición de vitamina D en mayores tiene efectos positivos en la marcha<sup>148</sup>. En pacientes con parkinson también la marcha y el equilibrio se han visto mejorados tras un entrenamiento con vibraciones.<sup>149</sup>.

El rendimiento muscular también se ha visto afectado de manera positiva con el WBV<sup>150</sup>, principalmente la fuerza y la flexibilidad de las piernas<sup>105</sup>, algunos autores apuntan que las mejoras en términos de fuerza muscular se producen en un espacio de tiempo más corto, aumentando también la tonicidad muscular<sup>151</sup>.

En general las poblaciones donde se han visto mejoras utilizando terapias de WBV se han beneficiado de una mejora de la calidad de vida y de la salud de modo general general<sup>104, 112, 138, 152-153</sup>.

### **VI.8.4. Efectos perjudiciales**

El conocimiento científico sigue siendo escaso respecto al efecto del ejercicio vibratorio en poblaciones distintas, atendiendo a edad, sexo, patología, etc. El efecto que provoca una determinada frecuencia y/o amplitud sobre el sistema neuromuscular, huesos, equilibrio y otras variables, sigue siendo difícil de generalizar. Algunos autores han hecho estudios con animales y encontraron efectos perjudiciales. Necking ha sometido ratas a una frecuencia de vibración de 80Hz durante 5 horas y verificó una degeneración fibrilar en algunos músculos<sup>154</sup>, parece existir una relación directa entre algunos problemas de salud y la utilización de herramientas vibratorias de uso manual<sup>155</sup>. Parece que la aplicación del WBV de forma prolongada tiene relación con el dolor de espalda<sup>156-157</sup>.

Sin embargo estudios recientes refieren que personas con un historial

médico de dolor lumbar crónico pueden beneficiarse del WBV Rittweger ha hecho un experimento durante 12 semanas de entrenamiento a una amplitud de 6mm y una frecuencia de 18Hz y constató una reducción de la percepción al dolor y una mejora en la flexión lumbar<sup>158</sup>, también recientemente del Pozo-Cruz et al aplicaron una terapia de 12 semanas de WBV en pacientes con dolor de espalda baja a una frecuencia de 20Hz y comprobó mejoras en varios aspectos relacionados con la enfermedad<sup>159</sup> mostrándose el WBV efectivo para la aliviar el dolor de espalda.

Aunque la utilización del ejercicio vibratorio sea un método reciente, ya se encuentran descritos en diversos estudios algunos resultados interesantes en referencia a la utilización de este método como terapia física o entrenamiento deportivo, en cualquier caso, es poco conocida la relación dosis/respuesta óptima para obtener las indicaciones o mejoras previamente descritas en los parámetros referenciados, así como los posibles efectos secundarios.

Por lo tanto se propone ser cautos a la hora de utilizar este tipo de ejercicio en personas que presenten las siguientes características:

- Prótesis en la cadera o rodilla.
- Hernias, discopatías o espondilosis.
- Presencia de heridas.
- Diabetes severa.
- Portar un marcapasos.
- Nuevas inflamaciones.
- Epilepsia.

- Haber sufrido una fractura ósea reciente.
- Embarazo.

## **VI.9. Calidad de vida relacionada con la salud**

### **VI.9.1. Concepto**

El término calidad de vida es un término de las ciencias sociales que surge en la década de los 50 del siglo pasado, existen cuatro conceptualizaciones del concepto de Calidad de Vida <sup>160</sup>:

1. La calidad de las condiciones de vida de una persona.
2. La satisfacción experimentada por la persona con dichas condiciones vitales.
3. La calidad de las condiciones de vida de una persona junto a la satisfacción que ésta experimenta.
4. La combinación de las condiciones de vida y la satisfacción personal ponderadas por la escala de valores, aspiraciones y expectativas personales.

Cuando se empieza a aplicar el término de calidad de vida en la salud se empieza a denominar Calidad de Vida Relacionada con la Salud (CVRS).

Con el paso del tiempo los indicadores tradicionales de salud como la mortalidad, la morbilidad y la esperanza de vida comienzan a quedarse obsoletos, poco sensibles a las necesidades de los pacientes crónicos no evaluando su satisfacción, su estado de ánimo, las estrategias de

afrontamiento de las diversas situaciones y el soporte social<sup>161</sup>. Debido a una evolución dinámica de la realidad social de los países desarrollados donde cada vez más existe una prevalencia de las enfermedades crónicas.

La Organización Mundial de la Salud en 1952 define salud como “... *un estado de completo bienestar físico, psíquico y social y no meramente la ausencia de enfermedad*”<sup>162</sup>. Con esta definición de salud se torna necesario crear indicadores adicionales a los tradicionales que permitan conocer el nivel de bienestar físico, psíquico y social de una persona o población específica. En este contexto surge el concepto de CVRS.

Una de las primeras definiciones del término CVRS fue: “*la medida en que se modifica el valor asignado a la duración de la vida en función de la percepción de limitaciones físicas, psicológicas, sociales y de disminución de oportunidades a causa de la enfermedad, sus secuelas, el tratamiento y/o las políticas de salud*”<sup>163</sup>.

Más tarde la Organización Mundial de la Salud define calidad de vida como la “*percepción del individuo de su posición en la vida en el contexto de la cultura y sistema de valores en los que vive y en relación con sus objetivos, expectativas, estándares y preocupaciones*”<sup>164</sup>.

Se puede entonces definir la CVRS como “*la percepción subjetiva, influenciada por el estado de salud actual, de la capacidad para realizar aquellas actividades importantes para el individuo*”<sup>165</sup>.

El propósito fundamental del uso y medición de la CVRS es proporcionar una evaluación más comprensiva, integral y válida del estado de salud de un individuo o grupo, y una valoración más precisa de los posibles beneficios y riesgos que pueden derivarse de la atención médica<sup>166</sup>.

Estas aplicaciones pueden ir orientadas al paciente, al profesional sanitario o a la investigación.

### **VI.9.2. Impacto de la enfermedad en la CVRS de los pacientes**

Un estudio reciente concluye que los pacientes con FM reportan un alto impacto en su CVRS. En dicho estudio el nivel de incapacidad percibida parecía estar explicada por su condición mental: los niveles de distrés psicológico eran más altos en pacientes con FM que en pacientes con otros síndromes [47].

Esta reducción en la CVRS afecta principalmente a la actividad intelectual, la función física, el estado emocional y a la calidad del sueño (lo que influye de forma determinante sobre la capacidad para el trabajo y en la actividad socio-familiar). Así, un número significativo de personas presenta un síndrome de dolor crónico incapacitante con intensa afectación de la CVRS, que lleva a la pérdida parcial o completa de la actividad laboral en un porcentaje aproximado de 25-50% [48-49].

Los factores que contribuyen a que esta enfermedad sea una importante causa de incapacidad y de los altos costes que origina son: la

alta prevalencia, la percepción de malestar experimentado por el paciente, la pobre función referida por éste, la astenia, la alteración de la memoria y de la capacidad de concentración y la frecuente asociación con la migraña y el colon irritable [50-51]. La gran comorbilidad de la FM aumenta de sobremanera los costes de la sanidad [52].



## **VII. OBJETIVOS**

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El objetivo general de esta tesis fue verificar si una terapia de WBV auto-administrada consistente en 3 sesiones semanales a una intensidad de 12.5 Hz, con 6 repeticiones de 45-60seg (incremento mensual) en posición lateral, un descanso de 60seg entre repeticiones por sesión y una duración de 12 semanas es aplicable, eficaz, seguro y tolerado por esta población de mujeres con FM.

Los objetivos específicos de este trabajo fueron:

1. Evaluar la eficacia de esta terapia de WBV sobre el equilibrio dinámico en pacientes con FM (*estudio 1*).
2. Analizar los efectos de esta terapia de WBV sobre la CVRS evaluada mediante los cuestionarios FIQ y 15D® (*estudio 2*).
3. Evaluar los efectos de esta terapia de WBV sobre el equilibrio estático unipodal evaluado mediante estabilometría (*estudio 3*).
4. Analizar la relación entre los índices obtenidos mediante el test de estabilometría unipodal, el número de caídas sufridas durante el último año y la CVRS evaluada mediante el cuestionario específico FIQ (*estudio 3*).
5. Evaluar los efectos de esta terapia de WBV sobre la fuerza de los pacientes de FM evaluada a través de dinamometría isocinética, en flexo-extensión de rodilla mediante acciones isométricas, concéntricas y excéntricas (*estudio 4*).

## OBJETIVOS

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6. Evaluar los efectos de esta terapia de WBV sobre el equilibrio con ojos cerrados -sistema somato-sensorial- y el dolor tanto generalizado como en las rodillas medido mediante algometría (*estudio 4*).

## **VIII. HIPÓTESIS**

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### **Hipótesis 1**

La terapia propuesta de WBV de vibración lateral a 12,5Hz de intensidad es aplicable y eficaz para mejorar el equilibrio dinámico en los pacientes con FM.

### **Hipótesis 2**

La mejora obtenida con una terapia basada en WBV lateral a 12,5Hz de intensidad está relacionada con las mejoras en la CVRS en las pacientes con FM.

### **Hipótesis 3**

Las mejoras en el equilibrio estático unipodal de los pacientes de FM se deben a la aplicación de una terapia basada en WBV lateral a 12,5Hz de intensidad existiendo una relación entre los datos obtenidos, las caídas en el último año y la CVRS en las pacientes con FM.

### **Hipótesis 4**

Una terapia basada en WBV lateral a 12,5Hz de intensidad, mejora la eficacia de los sistemas neuromuscular (fuerza) y somato-sensorial (equilibrio ojos cerrados) y disminuye el dolor general y de rodillas en pacientes con FM.



**IX. STUDY 1: Tilt Vibratory Exercise and the  
Dynamic Balance in Fibromyalgia: A Randomized  
Controlled Trial**

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Arthritis Care & Research  
Vol. 62, No. 8, August 2010, pp 1072–1078  
DOI 10.1002/acr.20180  
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ORIGINAL ARTICLE

## Tilt Vibratory Exercise and the Dynamic Balance in Fibromyalgia: A Randomized Controlled Trial

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**Objective.** To evaluate the feasibility and efficacy of tilt whole-body vibration (WBV) for improving dynamic balance in women with fibromyalgia (FM).

**Methods.** Forty-one women (ages 41–65 years) were randomly assigned to either a vibration ( $n = 21$ ) or control ( $n = 20$ ) group. The vibration intervention consisted of a 30-minute session of instruction plus 3 sessions of WBV per week over a period of 12 weeks. Each vibration session consisted of 6 repetitions of a 45–60-second 12.5-Hz vibration. The posture of the patient was lateral. Dynamic balance was assessed with a balance platform, and the level of stability could be controlled. We performed intent-to-treat (ITT) analysis and efficacy analysis in participants who completed the study (vibration,  $n = 18$ ; control,  $n = 18$ ).

**Results.** Based on ITT analysis, the dynamic balance of the vibration group improved by 36% as compared with baseline, whereas that of the control group was unchanged. Differences in the dynamic balance index were predicted (61%;  $P < 0.001$ ) by the following linear model:  $(0.027 \times \text{body weight}) - (0.800 \times \text{dynamic balance at baseline}) - (0.632 \times \text{group})$ .

**Conclusion.** The vibration program was useful and feasible for improving dynamic balance in women with FM. These novel results support further research aimed at the development of physical therapy programs that utilize controlled vibration.

### INTRODUCTION

The prevalence of fibromyalgia (FM) is 2–3% in the general population, and women are disproportionately affected (90% of individuals with FM are women) (1–3). FM is characterized by mainly persistent, widespread musculoskeletal pain and regions of localized tenderness (4). However, most patients with FM have multiple symptoms. Impaired balance is the sixth most frequent symptom, affecting 45% of patients, and is fifteenth in terms of severity (5). Previous studies have shown that patients with FM have significantly impaired balance as compared with healthy adults (6–8). Recent works have shown the benefits of aquatic training on static balance performance measured by the blind flamingo test (which measures the number of trials required to achieve a total time of 30 seconds on 1 leg with the eyes closed [9]), and the ameliorations of on-land aerobics in improving static balance, as assessed by the flamingo balance test (which measures

time in seconds balanced on 1 leg stance with the eyes open [10]). However, most daily activities require dynamic balance (e.g., walking, climbing stairs, preventing falls, etc.). On-land exercise with moderate mechanical impact and aquatic training have each been shown to be effective in preventing painful experiences in people with FM (11–13), but these individuals may also require complementary physical activities that provide osteogenic mechanical strain for preventing bone mass density loss (14).

Whole-body vibration (WBV) has recently emerged as an intervention that can have positive effects on the neural, muscular, and skeletal systems (15). In WBV, a patient stands on a platform that oscillates at a particular frequency and amplitude, causing muscle contractions through stimulation of sensory receptors (16). Devices that are currently on the market deliver sinusoidal vibration to the whole body via 2 different types of vibrating plates (17): a vertical platform, in which the whole plate oscillates up and down, and a tilt platform with reciprocal vertical displacement on the left and right side of a fulcrum, increasing lateral accelerations. Recent clinical studies of WBV have shown a positive effect of controlled WBV on the balance, bone mass, and motor capacity of postmenopausal women and nursing home residents (18–21). In fact, tilt WBV was more effective on balance than walking in postmenopausal women (20). A recent study reported that twice-weekly mixed WBV exercises on a vertical platform plus on-land exercise in individuals with

ISRCTN: 16950947.

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Submitted for publication March 15, 2009; accepted in revised form February 23, 2010.

# STUDY 1. TILT VIBRATORY EXERCISE AND THE DYNAMIC BALANCE IN FIBROMYALGIA: A RANDOMIZED CONTROLLED TRIAL

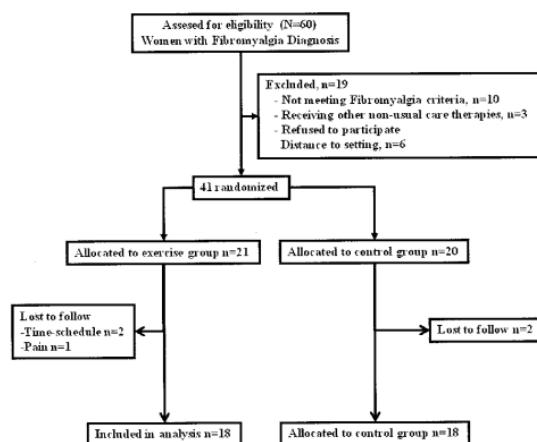


Figure 1. Flow of participants throughout the trial.

FM lowered visual analog scale pain scores and fatigue ratings, whereas an on-land exercise only or a control treatment did not (22). In addition, WBV was shown to be well tolerated by participants (22). To date, there have been no reported randomized, controlled studies of the feasibility and efficacy of intensive WBV ( $\geq 3$  sessions per week) using a tilt platform in patients with FM. In the current study, we investigated whether tilt WBV is feasible and effective for improving the dynamic balance of women with FM.

## PATIENTS AND METHODS

**Recruitment.** Women who participated in a local FM association were recruited into the study. The women were eligible if FM had been diagnosed by a rheumatologist in accordance with the diagnostic criteria of the American College of Rheumatology (4). Exclusion criteria included history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illness, other diseases that prevent physical loading, pregnancy, participation in another psychological or physical therapy program, or participation in regular physical exercise more than once a week for  $\geq 30$  minutes during any 2-week period in the last 5 years.

Sixty potentially eligible participants requested additional information (Figure 1). Of these, 19 were excluded based on the following criteria: participation in other therapies (either manual therapy and/or psychological treatment) that could influence the current intervention (3 candidates), failure to meet the inclusion criteria (other severe diseases; 10 candidates), and excessive distance from the intervention setting (6 candidates). Following an explanation of the study protocol, 41 female patients ages 41–65 years gave written informed consent to participate, in accordance with the updated Declaration of Helsinki. The project protocol was approved by the Biomedical Ethical Committee of the University of Extremadura.

**Study design.** The study design was a randomized controlled trial. Immediately after verification of inclusion/exclusion criteria, participants were randomly and sequentially assigned to either the vibration group ( $n = 21$ ) or the control group ( $n = 20$ ) by a research assistant according to a random number table, and the participants were assigned a code number. Participants were blinded to group assignment before baseline measurements, after which all participants were informed of their assignment. Research team members (JAP and PRO) who were also blinded to the group assignments of the participants conducted the measurements of dynamic balance at baseline and 12 weeks. Different members of the research team (NG and JCA) administered the intervention and performed the statistical analysis.

**Intervention.** All participants received standard care that included medical attention through the public health system (hospital and outpatient clinic, including primary care) and social support through the local FM association. Patients in the vibration group also received WBV therapy using the Galileo Fitness Platform (Novotec Medical), which, in contrast to other commercial platforms that move up and down, oscillates on the medial axis.

The vibration intervention included a 30-minute session of instruction on how to self-administer the 36 vibration sessions (3 times per week over a period of 12 weeks). Each session included a 10-minute warmup of slow walking and then 6 repetitions of vibration at 12.5 Hz, with a rest interval of 60 seconds between repetitions. We set the frequency at 12.5 Hz because it has been shown to improve body balance and bone mass density in women of a similar age using a tilt vibratory platform (20). The lower pain threshold of patients with FM and the novelty of the exercise technique also prompted us to be cautious with the frequency setting. The vertical amplitude of the vibrations was set at 3 mm.

The duration of each repetition was 30 seconds during the first 4 weeks, 45 seconds during the second 4 weeks, and 60 seconds during the third 4 weeks. Being that the tilt vibratory platform mainly produces lateral mechanical forces (20), we set the stance of participants to align the mechanical stimulus with the action line or vector of the knee extensors and flexors, because they are involved in major daily activities such as walking and climbing stairs. The stance of the participants on the platform alternated between 2 stances, stance A and stance B, for each repetition to train both sides of the body; the soles of both feet were always in contact with the platform in both stances (Figure 2).

In stance A, participants were told the following. Begin with the feet planted perpendicular to the midline axis of the platform with the right foot placed slightly ahead of the left foot. Lift the toes of the right foot and the heel of left foot 4 mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

In stance B, participants were told the following. Begin with the feet planted perpendicular to the midline axis of the platform with the left foot placed slightly ahead of the



**Figure 2.** Posture of the subjects on the vibratory platform.

right foot. Lift the toes of the left foot and the heel of the right foot 4 mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

Each participant was required to sign a logbook, which included the date, after completing a vibration session. A research assistant spoke to each participant once a week in a 3-minute phone conversation to monitor progression through the program, provide instruction, and give emotional support. During the 12-week study period, participants in the control group continued their daily activities, which did not include any form of physical exercise that resembled the exercises performed by participants in the vibration group, and they did not receive a weekly phone call.

The vibration program was designed without reference to any explicit behavioral model or theory, and was intended as a pragmatic intervention that could easily be implemented within a population of patients with FM.

**Data collection.** Sample characteristics and the number of reported falls in the last 6 months were obtained. The vibration program was implemented at the local FM association, and the dynamic balance measurements were performed at the Fitness and Quality of Life Laboratory at the University of Extremadura (Spain). The balance assessments were carried out using a Biomedex Balance System (BBS; Biomedex). In a recent report, the BBS was used to evaluate and train postural balance and postural stability (23). It is a multiaxial device that objectively measures and records an individual's ability to stabilize an involved joint under dynamic stress. It is a circular platform that moves freely along the anteroposterior and mediolateral axes simultaneously. The BBS allows up to 20 degrees of foot platform tilt, which permits maximal stimulation of the ankle joint mechanoreceptors. The device measures, in degrees, the tilt about each axis during dynamic conditions and calculates a mediolateral stability index, an anteroposterior stability index, and an overall stability index, which is a composite of the mediolateral stability index and the anteroposterior stability index (24). These indices are SDs assessing fluctuations around a zero point established prior to testing when the platform is stable rather than around the group mean. A high score indicates poor balance. Given that individuals with FM report widespread alterations, we selected the overall stability index as the parameter for analysis because it reflects fluctuations in both axes rather than a single direction. The dynamic tilting platform BBS differs from a static force plate system in that the center of pressure resulting from a vertical ground reaction force remains constant.

All participants were evaluated on the BBS at baseline and 12 weeks after the initiation of the study. The BBS could be set at 12 different levels of stability, with a setting of 1 being the least stable and a setting of 12 being the most stable. To obtain the dynamic balance index, we carried out a fall risk test (25) according to the manufacturer's instructions, consisting of 3 trials performed on the BBS at level 8. There are many possible variations in the BBS stance protocol, including degree of instability of the platform (23), crossed (23) or free (26) arms, 1- or 2-leg stances (27), and open- or closed-eye stances (28). In the current study, participants were instructed to maintain the vertical projection of their center of gravity in the center of the platform by observing a vertical screen placed 30 cm in front of their face. Each trial was 20 seconds long, with 10-second rest periods between the trials. All tests were performed while the participants stood barefoot with both feet on the platform, at a constant instability setting (level 8), with open eyes. The posture of the arms was not regulated. The average of 3 trials was subjected to analysis.

We selected free arms during the BBS test for security (i.e., it is easier to rebalance using the arms), and because it more closely mimics imbalance in everyday life, where rebalancing is generally performed using the whole body.

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**Table 1.** Characteristics of women with fibromyalgia who completed the protocol of the vibration-based exercise program and controls\*

Group	Control group (n = 18)	Exercise group (n = 18)	P
Age, years	53.0 ± 12.0	52.4 ± 10.8	0.860
Weight, kg	70.0 ± 10.6	73.7 ± 14.4	0.384
Height, cm	156.0 ± 4.7	156.4 ± 5.0	0.782
Number of tender points (range 1–18)	15 ± 5	15 ± 4	0.943
Duration of symptoms, years	13.7 ± 6.2	12.7 ± 6.7	0.672
FIQ total score	53.6 ± 12.3	59.2 ± 9.7	0.681

\* Values are the mean ± SD unless otherwise indicated. FIQ = Fibromyalgia Impact Questionnaire.

including the arms, thereby increasing the ecologic validity of the test. Allowing or not allowing the use of the arms during testing of postural stability affects the score (29), so it should be considered for comparison purposes.

The reliability of the test used in this study was measured in our laboratory in 30 women with FM (mean ± SD age 51 ± 10 years) using a 7-day test-retest protocol. The intraclass correlation coefficient was 0.77 (95% confidence interval 0.52, 0.89) and the coefficient of variation of method error (CVME) (30) was 33.90%.

**Statistical analysis.** We carried out an efficacy analysis that included data only from subjects who completed the intervention, and an intent-to-treat (ITT) analysis for comparative purposes (e.g., meta-analysis, economic studies, etc.). The ITT analysis is more useful for making decisions in health care settings, whereas the efficacy analysis is more representative of the effects of individual treatment.

After verifying the parametric criteria for homogeneity and distribution of the data, we compared changes in the dynamic balance index of both groups using an analysis of variance adjusted for body weight (in kilograms) and performance on the BBS at baseline. In-depth analysis of changes in dynamic balance index was done using a step-by-step regression test. A significance level of less than 0.05 was required in order to introduce a new variable into the prediction model.

## RESULTS

The participant characteristics for this study are summarized in Table 1. Of the participants, 25% fell ≥2 times in the last 6 months, and 34.4% fell almost once in the last 6

months. These values were much higher than for healthy people in a similar age group, but similar to individuals with FM (8).

**Feasibility and safety.** There was a high level of feasibility for the proposed low-frequency vibration program in patients with FM. In the vibration group, 18 participants (86%) of 21 completed the program. Of the 3 participants who quit the program, 2 (10%) did so because their work schedule was not compatible with the platform exercise schedule and 1 (5%) quit the program because of pain. Two participants were lost from the control group because of lack of interest. A detailed comparison of the baseline data (age, tender points, muscular strength, and balance index) between participants who dropped out and participants who completed the program did not reveal any relevant differences. There were no statistically significant differences ( $P > 0.05$ ) between participants who completed the protocol, in the control or vibration group, and those who did not. There were no reports of secondary health discomforts related to the low-frequency vibration program. Overall, 95% of participants in the vibration group did not report health problems with the WBV program.

**Effects.** In ITT analysis, the dynamic balance index of participants in the vibration group improved by 36% as compared with baseline (43% of treated participants with a treatment effect of 46%), whereas in the control group it was unchanged (Table 2). This improvement was higher than the reported CVME (33.9%); thus, it could be considered a real change in magnitude from a statistical perspective. The falls-related clinical relevance of these changes

**Table 2.** Effects of 12 weeks of whole-body vibration training on dynamic balance in women with FM syndrome\*

	Baseline, mean ± SD	Change to 12 weeks, mean (95% CI)	Treatment effect, mean (95% CI)	P†
Efficacy				
Exercise (n = 18)	1.49 ± 0.67	-0.64 (-0.36, -0.93)	-0.69 (-1.10, -0.27)	< 0.001
Control (n = 18)	1.47 ± 0.55	0.44 (-0.28, 0.37)		
Intent-to-treat			-0.60 (-0.97, -0.23)	0.002
Exercise (n = 21)	1.59 ± 0.73	-0.57 (-0.31, -0.82)		
Control (n = 20)	1.40 ± 0.55	0.03 (-0.25, 0.32)		

\* Values are the degrees of displacement. FM = fibromyalgia; 95% CI = 95% confidence interval.

† Of analysis of variance for repeated measures, adjusted by baseline data and weight to compare differences between groups at 12 weeks.

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**Table 3.** Predicted models of changes in the dynamic balance after 12 weeks of vibratory exercise: efficacy analysis of participants who completed the protocol in the exercise group ( $n = 18$ ) and control group ( $n = 18$ )

	Model 1 ( $R^2 = 0.611$ )			Model 2 ( $R^2 = 0.569$ )		
	$\beta$	SE	P	$\beta$	SE	P
Balance index at baseline	-0.809	0.137	< 0.001	-0.676	0.128	< 0.001
Group*	-0.689	0.145	< 0.001	-0.670	0.152	< 0.001
Weight, kg	0.018	0.008	0.041	-	-	-
Constant	-0.737	0.559	0.197	0.367	0.220	0.105

\* Control group = 0, vibratory exercise group = 1.

partly depends on the baseline score of each person. Small improvements in persons with poor balance could be more relevant than those obtained in persons with better balance scores. The study of the number of falls requires longer studies than the current research. The efficacy analysis of participants who completed the program is summarized in Table 3. We used 2 efficacy models, one that included weight as an independent variable and one that did not, in order to explore the influence of weight, which is one of the major determinants of training load in WBV. Model 1 (differences in dynamic balance index =  $0.018 \times$  body weight -  $0.809 \times$  dynamic balance at baseline -  $0.689 \times$  group) predicted 61% of the observed variability in the dynamic balance index. Model 1 quantified the positive effect of treatment (group variable,  $P < 0.001$ ) in 69% of each unit gained in the dynamic balance index. Participants with the worst balance and heaviest weight at baseline improved more than the others ( $P < 0.001$ ). Model 2, in which the body weight variable was dropped, predicted 57% of each unit gained in the dynamic balance index. Similar results in the ITT analysis are shown in Table 4. The results suggested that the use of model 1 was more appropriate, because weight is easily measured and contributes to a better prediction.

## DISCUSSION

We have demonstrated the efficacy, safety, and feasibility of a proposed low-frequency vibration program in women with FM. The program was reasonably safe: only 5% of the participants ( $n = 1$ ) dropped out of the program because of acute pain in the legs. The program was completed by 85% of the participants, without secondary adverse effects. Although the program was performed individually and self-administered, the retention rate was similar to that in other

group-based exercise programs for patients with FM (70–90%) (31). The intervention included vibratory exercise plus phone call reinforcement as compared with a control group that received neither. The 12-week program was easily self-administered in a small room after a 30-minute instructional session and was maintained with one 3-minute phone call per week. Thus, the current vibration program could serve as an additional resource for patients with FM that can easily be implemented in different settings (e.g., at the patient's FM association, in primary care settings, welfare institutions, clinics, or gyms). This aspect of the program is particularly important for patients living in sociodemographic areas with few resources (e.g., warm-water pools or highly specialized technicians) (32,33). It is important to note, however, that the cost of a commercial system is approximately \$11,900, which is potentially cost prohibitive for individuals and local FM associations with low-to-moderate income. Further studies analyzing cost-effectiveness of different commercial machines and/or health care settings (e.g., clinics, gyms, etc.) are warranted.

Previous studies have shown that WBV is effective for improving static and dynamic balance in the elderly, as measured by timed up-and-go, chair rise, and Tinetti tests (18,34,35), as well as in patients with neuromuscular disorders such as Parkinson's disease (36,37) or multiple sclerosis (38). It has also been reported that increased sway in the mediolateral direction, one of the components of the overall index, is a sensitive biomarker for determining the functional capacity of elderly individuals (39). Postural dynamic balance, measured using the BBS with the arms crossed on the chest, is associated with functional disability (23). In a cross-sectional study in patients with arthritis, postural dynamic balance was dependent on body mass index, age, and sex (23). We reported here the positive effects of tilt platform vibration on dynamic balance in

**Table 4.** Predicted models of changes in the dynamic balance after 12 weeks of vibratory exercise: intent-to-treat analysis of participants who initialized the protocol in the exercise group ( $n = 20$ ) and control group ( $n = 21$ )

	Model 1 ( $R^2 = 0.607$ )			Model 2 ( $R^2 = 0.449$ )		
	$\beta$	SE	P	$\beta$	SE	P
Balance index at baseline	-0.800	0.132	< 0.001	-0.492	0.123	< 0.001
Group*	-0.632	0.139	< 0.001	-0.515	0.159	0.002
Weight, kg	0.027	0.007	< 0.001	-	-	-
Constant	-0.689	0.407	0.099	0.727	0.206	0.001

\* Control group = 0, vibratory exercise group = 1.

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patients with FM characterized by pain. This finding is novel and important because it raises the possibility of adding a new technology with potential health benefits to the usual exercise regimes recommended for patients with pain (e.g., on-land aerobics with moderate mechanical impact, aquatic training, tai chi, yoga) in order to help reduce bone mass loss (20) and improve strength and speed, which are critical for reacting and preventing stumbles and falls (40).

The equations could be used to predict the expected changes with this WBV protocol and to modulate the therapy. Persons with FM with poorer scores at baseline will improve more than patients with better scores. In addition, the load and efficacy of therapy could progress by adding weight to a back-bag carried by patients. This modulation of the program could promote the assessment by health professionals through conventional consults or online (e.g., Web-based consultancies).

This study had limitations. Differences in the parameters of the BBS protocol (i.e., platform stability level, 1- or 2-leg stance, arm position, open or closed eyes) in different studies limit comparisons of the magnitude of changes or normative references. The balance improvements reported in the current study were influenced by the level of dynamic balance at baseline; therefore, greater improvements would be expected in patients with worse balance at baseline. We could not analyze the influence of previous training because one of our inclusion criteria was that the participant be physically untrained. The effects of WBV in a physically trained population remain unknown. On the other hand, the 10 minutes of easy walking prior to each WBV session could have influenced fitness in patients who were very deconditioned at baseline. Furthermore, we must caution against generalizing the current findings from a self-administered program performed at a local FM association to a home-based program; the high rate of participation in the present study could partially be explained by peer support from other members of the local FM association and by the weekly phone call from a research assistant. Therefore, additional studies are needed in order to evaluate whether the current program is effective in other settings, such as the home. The current findings suggest that WBV is feasible and effective for improving the dynamic balance of women with FM; however, the clinical implications of the obtained balance improvements cannot be determined in the present study. To explore them, studies of longer duration (i.e., more than 6 months) are needed to explore whether balance improvements are associated with a lower number of falls. Additionally, a larger study population is required to fully understand the interactions between changes in dynamic balance and pain, being that only 1 patient dropped out because of pain, and between dynamic balance and pain range (measured by pain thresholds at tender points). Further studies are also needed to assess different vibratory devices (i.e., those with tilt or up and down mechanisms) (41), different postures that induce different lines or vectors of vibration (e.g., lateral, vertical, etc.), and different levels of vibration for different durations of time.

In conclusion, the proposed WBV program, which utilized a tilt platform with low-frequency (12.5 Hz) antero-

posterior vibration, is useful and applicable for improving the dynamic balance of women with FM. The current study supports the development of novel approaches to physical therapy programs that utilize vibration therapy.

## ACKNOWLEDGMENT

The authors thank Désirée Möller for her contribution in preserving blinded data and administrative tasks.

## AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be submitted for publication. Dr. Gusi had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Study conception and design.** Gusi, Parraca, Olivares, Adsuar.

**Acquisition of data.** Parraca, Olivares.

**Analysis and interpretation of data.** Gusi, Parraca, Olivares, Leal, Adsuar.

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**X. STUDY 2: Tilting Whole Body Vibration  
Improves Quality of Life in Women with  
Fibromyalgia: A Randomized Controlled Trial**

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## Tilting Whole Body Vibration Improves Quality of Life in Women with Fibromyalgia: A Randomized Controlled Trial

Pedro R. Olivares, MSc, Narcis Gusi, Jose Parraca, Jose Adsuar, and Borja del Pozo-Cruz

### Abstract

**Objectives:** The aim of this study was to analyze the effect of 12-week tilting Whole Body Vibration therapy (WBV) on Health Related Quality of Life (HRQoL) in fibromyalgia (FM) within the context of a randomized control trial (ISRCTN16950947).

**Subjects and methods:** Thirty-six (36) women with FM were randomly allocated to either an exercise or a control group. The women in the exercise group were assigned to a 12-week course of tilting WBV (12.5-Hz frequency; 3-mm amplitude). HRQoL was assessed using the Fibromyalgia Impact Questionnaire (FIQ) and a 15D questionnaire.

**Results:** A 12-week course of tilting WBV therapy was associated with improvements in FIQ scores (12%) but not in the 15D questionnaire.

**Conclusions:** Tilting WBV was a feasible intervention that prevented the loss of HRQoL in previously physically untrained women with FM.

### Introduction

FIBROMYALGIA (FM) IS A CHRONIC DISORDER that is characterized by generalized pain and tenderness in a minimum of 11 of 18 specific tender points.<sup>1</sup> The disorder is associated with reduced physical activity and decreased health-related quality of life (HRQoL).<sup>2</sup> Previous research has investigated the effects on FM of a range of physical therapies, including yoga,<sup>3</sup> *t'ai chi*,<sup>4</sup> and exercising in warm water.<sup>2,5,6</sup> Several therapies have been shown to be effective in reducing FM symptoms and improving HRQoL. The latter has usually been evaluated using the Fibromyalgia Impact Questionnaire (FIQ), the Short Form 36, or the EuroQol five-dimension questionnaire.<sup>7</sup>

Studies in healthy individuals have shown that Whole Body Vibration therapy (WBV) improves physical capacity,<sup>8</sup> hormonal production,<sup>9</sup> bone mass,<sup>10,11</sup> balance, proprioception, and HRQoL.<sup>12</sup> Although WBV has been applied in a number of studies of adults, postmenopausal women, and individuals with neuromuscular disorders,<sup>13</sup> only three studies have investigated the efficacy of this therapy in patients with FM.<sup>14–16</sup> Of these, only one study assessed the effects of WBV on HRQoL,<sup>14</sup> as assessed by the FIQ, Visual Analog Pain Scales, and measures of fatigue, stiffness, and depression. The authors reported statistically significant differences in pain, fatigue, and stiffness, although no effects on depression or FIQ scores were observed. The authors

concluded that a longer course of WBV may improve HRQoL in this population.

The aim of the present study was to investigate the effect of a 12-week course of tilting WBV on HRQoL, as measured by the FIQ and the 15D questionnaire,<sup>17</sup> to test the hypothesis that tilting WBV increases HRQoL in women with FM. Verification of this hypothesis would validate the use of tilting WBV in FM.

### Patients and Methods

#### Subjects

All of the study participants were female members of a local FM association. The inclusion criterion was the assignment of a diagnosis of FM by a rheumatologist in accordance with the diagnostic criteria of the American College of Rheumatology.<sup>1</sup> The following exclusion criteria were applied: a history of severe physical trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic disease, severe psychiatric illness, any comorbid disease that may prevent physical loading, pregnancy, participation in another psychologic or physical therapy program, or a history of regular physical exercise during the previous 5 years (i.e., more than once a week, for a minimum of 30 minutes, over a 2-week period).

A total of 60 women responded and requested additional information (Fig. 1). Of these, 19 were subsequently excluded: 3 had received other therapies (massage and psychologic treatment) that

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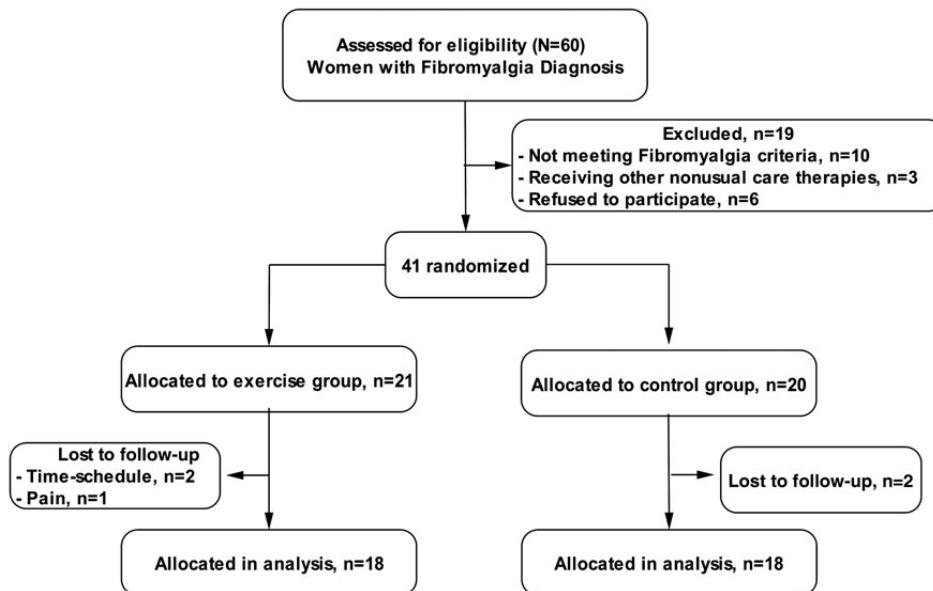


FIG. 1. Flow diagram of participants.

could interact with the present intervention; 10 had severe comorbid disease; and 6 were living too far away from the intervention setting. Following an explanation of the study protocol, the 41 remaining patients, who were aged between 41 and 65 years, provided written informed consent in accordance with the updated Declaration of Helsinki. The study was approved by the Biomedical Ethics Committee of the University of Extremadura.

### Study design

A randomized controlled trial was performed (trial register number: ISRCTN16950947). The participants were randomly assigned to either the tilting WBV group ( $n=21$ ) or the control group ( $n=20$ ). Randomization was performed by one of the research assistants using a random number table and the assignment to each participant of a code number. Neither the participant nor the investigator was aware of the group allocation prior to the baseline measurements. The participant was only informed of their group allocation once all baseline measurements had been completed. During the 12-week study period, all measurements were performed by other members of the research team, who were blind to the group assignment of each participant.

### Risk of bias

The risk of bias was assessed using the Physiotherapy Evidence Database (PEDro).<sup>18</sup> A total score of 9 was obtained. The present study complies with all PEDro criteria except for (1) criterion 5 (there was blinding of all subjects), and (2) criterion 6 (there was blinding of all therapists).

### Treatment groups

All participants were receiving standard care, which included clinical management through the public health

system (primary care, hospital, and outpatient clinic) and social support through the local FM association. A Galileo Fitness training device (Novotec Medical GmbH, Pforzheim, Germany) was used to administer the tilting WBV. This tilting WBV platform oscillates through the medial axis, in contrast to other commercial platforms, which oscillate uniformly up and down (oscillating WBV platforms).

The tilting WBV was self-administered. Thus, each participant from the exercise group attended an initial 30-minute instruction session to familiarize them with the equipment and explain the training protocol. The WBV sessions were performed 3 times a week for a period of 12 weeks. Each session included a 10-minute period of warm-up, which involved slow walking and slight movements. This was followed by six repetitions of tilting WBV at a frequency of 12.5 Hz, with a rest interval of 60 seconds between each repetition. The duration of each repetition was 30 seconds during weeks 1–4, 45 seconds during weeks 5–8, and 60 seconds during weeks 9–12. At each repetition, the stance of the participant on the platform alternated between stance A and stance B:

- Stance A: Begin with the feet placed perpendicular to the midline axis of the platform, with the right foot positioned slightly ahead of the left foot. Lift the toes of the right foot and the heel of the left foot 4 mm above the surface of the platform. Bend the knees and maintain a 45° knee angle. Keep the back and head straight.
- Stance B: Begin with the feet placed perpendicular to the midline axis of the platform, with the left foot positioned slightly ahead of the right foot. Lift the toes of the left foot and the heel of the right foot 4 mm above the surface of the platform. Bend the knees and maintain a 45° knee angle. Keep the back and head straight.

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For both stances A and B, the soles of both feet remained in contact with the platform.

Following the completion of each tilting WBV session, the participant was required sign out in a dated notebook. A research assistant telephoned each tilting WBV participant once a week for 3 minutes to check their progress and to provide instructions and emotional support. The control group continued their usual daily activities during the 12-week study period, which excluded any form of physical exercise comparable to the exercises being performed by the tilting WBV group.

The WBV intervention was performed at the local FM association building.

#### Data collection

The HRQoL was measured using one general questionnaire and one questionnaire specific to FM.

The FM-specific HRQoL questionnaire was the Spanish version of the FIQ. This is a reliable and valid questionnaire for the measurement of health status and physical function in Spanish-speaking FM patients, and it has been shown to be responsive to change.<sup>19</sup>

The general HRQoL questionnaire was the 15D. This evaluates 15 dimensions: moving, seeing, hearing, breathing, sleeping, eating, speech, eliminating usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity.<sup>17</sup> The decision theory approach attempts to weight the various dimensions of health to provide a single expression of health status.<sup>20</sup> The 15D score has been shown to be a highly reliable and sensitive measure that is both responsive to change and generalizable across several populations.<sup>17,21-23</sup> It is particularly valid for determining a gain in quality-adjusted life years for the purposes of resource allocation. This instrument is recommended by the Washington Panel, and is available in several languages for use in population- and clinical economic-evaluation studies. The 15D compares favorably with other instruments of this type.<sup>17,24,25</sup> Previous studies have shown that the total 15D score was correlated with the FIQ score, the number of tender points, and the sum of the mean pressure pain threshold at 18 tender points.<sup>7</sup>

#### Statistical analysis

The means and standard deviations were calculated for the descriptive statistics. Student's *t* test for independent samples was used to compare all baseline characteristics. The Kolmogorov-Smirnov test with Lilliefors significance was used to examine the distribution of the data.

The analysis of variance (ANOVA) for repeated measures was used to test the effects of the intervention on FIQ and total 15D scores. The ANOVA for repeated measures, with Bonferroni corrections for multiple comparisons, was used to test for effects on the various 15D dimensions. A paired *t* test was used as an additional analysis of change.

The level of significance was set at  $p < 0.05$ . All analyses were performed using SPSS software (version 15).

#### Results

Table 1 shows the characteristics of all study participants at baseline. No statistically significant differences were observed between the two groups.

TABLE 1. CHARACTERISTICS OF WOMEN WITH FIBROMYALGIA WHO FOLLOWED THE VIBRATION-BASED EXERCISE PROGRAM AND CONTROLS AT BASELINE ( $n=36$ )<sup>a</sup>

Group	Control (n=18) (mean $\pm$ SD)	Exercise (n=18) (mean $\pm$ SD)	P
Age (years)	53.0 (12.0)	52.4 (10.8)	0.860
Weight (kg)	70.0 (10.56)	73.3 (14.4)	0.384
Height (cm)	156.0 (4.7)	156.4 (5)	0.782
Number of tender points (1-18)	15 (5)	15 (4)	0.943
Duration of symptoms (years)	13.7 (6.2)	12.7 (6.7)	0.672
FIQ total score	53.6 (12.3)	59.2 (9.7)	0.681
Total score 15D	0.65 (0.1)	0.63 (0.1)	0.74

<sup>a</sup>Values expressed as mean (standard deviation [SD]).  
FIQ total score, Fibromyalgia Impact Questionnaire total score.

Following the 12-week intervention period, a statistically significant difference in the FIQ score was observed between the two groups ( $p = 0.033$ ) (Table 2). The paired *t* test revealed a significant decrease in HRQoL in the control group, whereas HRQoL in the exercise group was preserved. The treatment effect on the FIQ score was 12% in the efficacy analysis and 9.5% in the intent-to-treat analysis, as analyzed by ANOVA. No significant change was observed in the 15D scores ( $p > 0.05$ ) (Fig. 2).

#### Discussion

The main finding was that a 12-week course of tilting WBV therapy was a feasible intervention that prevented the loss of HRQoL in deconditioned women with FM. At baseline, the characteristics of the present participants were similar to those reported in other FM studies, as were the mean FIQ and 15D scores.<sup>26-30</sup> However, both the mean FIQ score at baseline and treatment compliance (85.7%) were slightly less than those reported in other studies of WBV in FM.<sup>14,15</sup> These studies involved the use of an oscillating WBV platform for 6 weeks at medium frequencies (30 Hz), and this therapy was not associated with an improvement in FIQ score. The present study is the first to have shown a positive effect on FIQ scores and mobility for low-frequency tilting WBV. Differences in the present FIQ results and those reported by Alentorn-Geli et al. may be attributable to the longer duration of therapy in the present study, or to the use of a different WBV platform and intensity. Furthermore, Alentorn-Geli et al. used more traditional exercises during WBV. Further studies are thus warranted to analyze differences between the two types of WBV platform using identical training protocols.

The postintervention decrease in HRQoL in the control group may be partly explained by seasonal changes. The study began in October and ended in December, and a pronounced difference in weather conditions is observed during that time. Although there is no objective evidence that the weather, or a change in the weather, has a direct effect on disease status, many FM patients report that the weather affects the severity of their disease,<sup>31</sup> and it may therefore have an influence on the FIQ score.

To the authors' knowledge, only one previous study has used the 15D questionnaire with patients with FM,<sup>32</sup>

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TABLE 2. EFFECTS OF 12 WEEKS OF WHOLE-BODY VIBRATION TRAINING ON FIQ IN WOMEN WITH FM SYNDROME<sup>a</sup>

	Baseline (mean $\pm$ SD)	After 12 weeks' training (mean $\pm$ SD)	p <sup>b</sup>	Treatment effect, mean (95% CI)	p <sup>c</sup>
<b>Efficacy</b>					
Exercise (n=18)	59.28 $\pm$ 9.79	56.72 $\pm$ 11.10	0.375	-6.42 (-12.30–0.53)	0.033
Control (n=18)	53.63 $\pm$ 12.35	57.49 $\pm$ 11.17 <sup>b</sup>	0.012		
<b>Intent-to-treat</b>					
Exercise (n=21)	56.89 $\pm$ 10.38	55.40 $\pm$ 11.41	0.477	-5.35 (-10.58–0.13)	0.046
Control (n=20)	55.27 $\pm$ 12.73	59.13 $\pm$ 11.71 <sup>b</sup>	0.022		

<sup>a</sup>Values are expressed in points.

<sup>b</sup>p of t test.

<sup>c</sup>p values of analysis of variance for repeated measures to compare differences between groups after 12 weeks of whole-body vibration training.

FIQ, Fibromyalgia Impact Questionnaire Score (score from 0 [best] to 100 [worst]); FM, fibromyalgia; 95% CI, 95% confidence interval.

although this study also included patients with arthralgia. The present study is the first to have used the 15D questionnaire to monitor physical therapy-associated changes in HRQoL in patients with FM. The results indicate that the total 15D score is less sensitive to changes in FM than the disease-specific FIQ. However, the 15D questionnaire may be a useful tool for comparing a particular treatment between patients with FM and patients with other diseases, for which the FIQ is inappropriate. The dimensions of the 15D appear to be more sensitive to change than the FIQ, and indicate which particular dimension of HRQoL has improved. The present study has extended a new line of research within the field of complementary medicine, and has generated evidence in support of using tilting WBV in patients with FM. The participants received no financial reimbursement, and

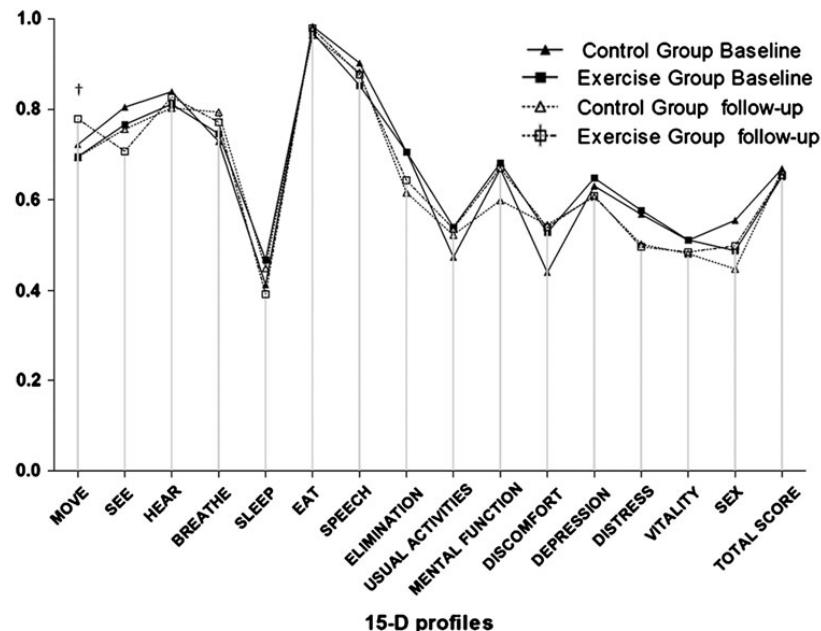
the high compliance rate (86%) compared to that of previous studies<sup>14</sup> may suggest that the patients were satisfied with this form of therapy.

Further studies are required to determine the optimal dose-response for WBV in FM, and to compare the effects of differing WBV platforms and frequencies.

Greater awareness of the cost-effectiveness and cost-utility of WBV is also required at the political level to encourage appropriate health and social policies.

The present study had several limitations. First, although nonsignificant differences were observed among some 15D dimension scores, further effects of tilting WBV could not be excluded due to the small sample size. Second, the control group did not receive a weekly telephone call, a factor that may have improved the motivation of the exercise group.

FIG. 2. The 15D profiles of all patients (intent-to-treat analysis) (n=41) for groups (control group, n=20 and Whole Body Vibration therapy exercise group, n=21) at baseline and at a 3-month follow-up. Mean values were used. <sup>†</sup>Denotes significant improvement from baseline at the p<0.05 level without Bonferroni correction. After making the Bonferroni correction, there was no significant difference in any variable.



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Third, the participants were physically untrained at inclusion, and the 10-minute warm-up at the start of each tilting WBV session may have helped to reduce pain.<sup>33</sup> For this reason, the warm-up was considered to be an integral component of the intervention. Furthermore, individuals with FM are usually less physically active than individuals from the general population,<sup>34</sup> and the effects of tilting WBV may have been partly attributable to reconditioning of the previously sedentary participants. Further studies are warranted to analyze the effects of tilting WBV in FM patients who are more physically active than the present participants. In fact, this exercise program included a workload progression in time of WBV exercise. Although previous studies have reported the benefits of low-frequency WBV in physically weak individuals such as the elderly,<sup>12</sup> the low dose limits the response in young, healthy, nonathletic volunteers,<sup>10,35</sup> who appear to require a higher workload.<sup>8</sup> Knowledge of WBV dose-response is poor due to variability among the devices, frequencies, amplitudes, and target populations used in the few available published articles, particularly for patients with specific disorders.<sup>36</sup> Despite these limitations, the present study contributes to knowledge concerning physically inactive female FM patients by reporting the feasibility and efficacy of tilting WBV as an initial physical therapy.

### Conclusions

In conclusion, a 12-week course of tilting WBV was a feasible intervention that prevented the loss of HRQoL in previously physically untrained women with FM.

### Disclosure Statement

No competing financial interests exist.

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## STUDY 2. TILTING WHOLE BODY VIBRATION IMPROVES QUALITY OF LIFE IN WOMEN WITH FIBROMIALGIA: A RANDOMIZED CONTROLLED TRIAL

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**XI. STUDY 3: Whole Vibration Improves the  
Single-Leg Stance Static Balance in Women  
with Fibromyalgia: A Randomized Controlled  
Trial**

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## ORIGINAL ARTICLE

# Whole Body Vibration Improves the Single-Leg Stance Static Balance in Women with Fibromyalgia: A Randomized Controlled Trial

*Jose C. Adsuar, PhD; Borja del Pozo-Cruz MSc, Jose A Parraca, MSc; Pedro R. Olivares, PhD; Narcis Gusi PhD*

## ABSTRACT

**Aim:** Fibromyalgia is a chronic disorder characterized by widespread pain. Fibromyalgia is associated with balance problems and increased fall frequency. Whole-body vibration therapy had been used for improve balance in special populations but not in fibromyalgia. The main objective of this study was to analyze the effects of 12 weeks of tilting whole-body vibration therapy on static balance in fibromyalgia patients.

**Methods:** Women with fibromyalgia were randomly and sequentially assigned to either the vibration group ( $n=21$ ) or the control group ( $n=20$ ) based on a randomly generated number table, and a code number was assigned to each participant. All participants received standard care that included medical care through the public health system (hospital and outpatient clinic, including primary care) and social support through the local fibromyalgia association. Participants in the exercise group received whole-body vibration therapy (12 weeks, 12.5 Hz frequency and 3 mm amplitude). Outcome measure was determined using postural stability indices (overall, anterior-posterior and medial-lateral) assessed by the Biodex Balance System in a single dominant limb stance.

**Results:** treatment effect after 12-weeks of

tilting whole body vibration therapy were 57.1% on overall stability and 66.6% on anterior-posterior stability.

**Conclusion:** Tilting whole-body vibration therapy effectively improves static balance in patients with fibromyalgia.

**Key words:** vibration; falls; fibromyalgia; postural balance.

## INTRODUCTION

Fibromyalgia (FM) is a chronic disorder characterized by widespread pain in combination with tenderness in at least 11 of 18 specific sites<sup>1</sup>. Epidemiologic studies report that the prevalence of FM is approximately 2% in North America<sup>2, 3</sup> and that more than 90% of FM patients are female<sup>4</sup>. In one survey study of 2596 FM patients, the incidence of reported balance problems was 45%<sup>5</sup>, and two recent reports by Jones et al.<sup>6</sup> and Russek et al.<sup>7</sup> associated FM with balance problems and increased fall frequency. Whole-body vibration (WBV) therapy is implemented by standing the subject on a platform that oscillates at a controlled frequency and amplitude, which causes muscle contractions through the stimulation of sensory receptors<sup>8</sup>. There are two commonly used types of commercial

WBV platforms: those that provide vertical vibration and those that tilt on a medial fulcrum. WBV has been used to improved balance in elderly<sup>9-11</sup> and clinical populations (cerebral palsy, parkinson and stroke patients)<sup>12-15</sup>. In FM, the combination of vertical-WBV platform therapy and a land-based exercise program was shown to reduce pain and fatigue<sup>16</sup>, although health-related quality of life (HRQOL) and hormonal response did not change<sup>16, 17</sup>.

WBV might represent an ideal method for improving balance in patients with FM for several reasons: a) previous studies have shown WBV is feasible and safe for FM patients<sup>16, 17</sup>, b) WBV stimulated plantar cutaneous afferents<sup>18</sup> that play an important role in dynamic postural responses<sup>19</sup>, c) WBV increased the efficiency of agonist/antagonist coupling<sup>20, 21</sup>, which may be affected in FM<sup>22, 23</sup> and d) WBV increased synchronization of motor units<sup>20</sup>.

This article is part of a larger study (ISRCTN16950947) which also evaluated the effects of WBV therapy on other outcomes as bipodal dynamic balance<sup>24</sup>. The study of the effects on monopodal balance is very interesting because many of the activities performed in daily life such as walking or climbing stairs have a high monopodal balance component. Previously balance has been measured in FM patients using questionnaires<sup>6</sup> and the Flamingo balance test (FBT)<sup>25, 26</sup>. This test consists of instructing the patient to lift one foot and stand on one leg. The duration in seconds<sup>25</sup> or the number of trials required to complete 30 seconds are recorded<sup>26</sup>. In this study, we utilized a similar one leg test conducted on a stabilometry platform, the Biodex Balance

System (BBS; Biodex, USA). This instrument measures 3 indices: the medial-lateral stability index (MLSI), the anterior-posterior stability index (APSI) and the overall stability index (OSI), which is a composite of the MLSI and APSI<sup>27</sup>. This test is more sensitive than the FBT because it also measures anterior-posterior and medial-lateral balance. The current study is the first to use the one leg test with the BBS in FM patients, and will provide health and exercise professionals with precise information on balance issues of persons with fibromyalgia.

The aims of this study were: 1) to analyze the effects of 12-weeks of WBV therapy on static balance in FM patients assessed by the one-leg balance test with the BBS, and 2) to analyze the relationship of the BBS indices obtained from the one-leg static test with the number of falls in the last year and overall HRQOL as assessed by the Fibromyalgia Impact Questionnaire (FIQ)

## MATERIALS AND METHODS

### Patients

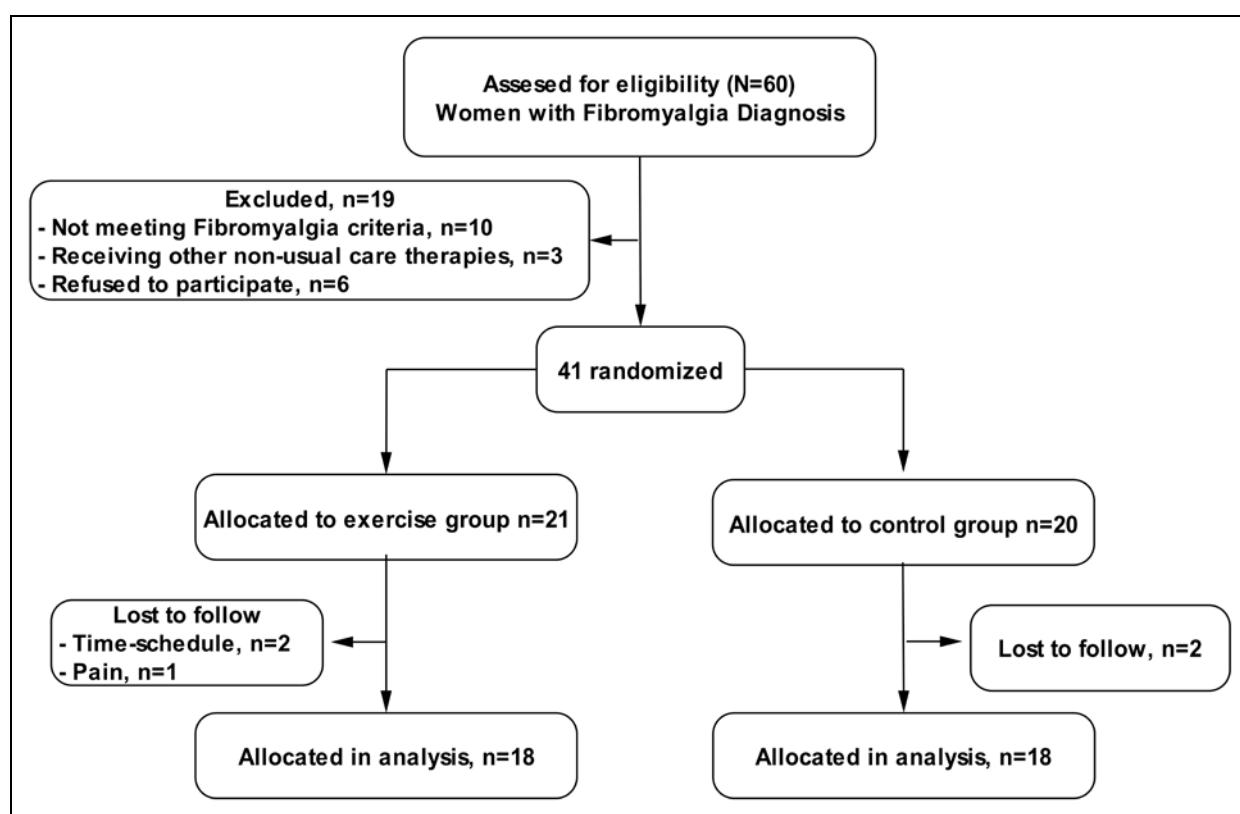
Women who were members of a local FM association were recruited to the study. The women were eligible if FM had been diagnosed by a rheumatologist in accordance with the diagnostic criteria of the American College of Rheumatology (ACR)<sup>1</sup>, so long as they did not meet the following exclusion criteria: history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illness, disease that prevents physical loading, pregnancy, participation in a psychological or physical therapy program, or participation in regular physical exercise

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more than once a week for 30 min or longer over a 2-week period in the last 5 years.

A total of 60 potentially eligible participants responded and requested additional information (Figure 1), and 19 of those candidates were later excluded based on the previously outlined criteria: 3 had participated in other therapies (massages or psychological treatment), 10 had been diagnosed with other severe

diseases, and 6 were living in municipalities that were too far from the intervention setting. After the study protocol was explained, the 41 remaining female patients, aged 41 to 65 years, gave written informed consent to participate according to the updated Declaration of Helsinki, and the project protocol was approved by the Biomedical Ethical Committee of the University of Extremadura.



**Figura 1.** Flow diagram of participants.

### Study Design

This randomized controlled trial was designated ISRCTN16950947. Following verification of the criteria for inclusion or exclusion in the study, the participants were randomly and sequentially assigned to either the vibration group ( $n=21$ ) or the control group ( $n=20$ ) based on a randomly

generated number table, and a code number was assigned to each participant. Members of the research team that were blinded to the group assignment of each participant measured static balance in a single dominant limb stance. Additional members of the research team applied the intervention and performed statistical analyses.

## Interventions

All participants received standard care that included medical care through the public health system (hospital and outpatient clinic, including primary care) and social support through the local FM association. Patients in the vibration group also received WBV with the Galileo Fitness Vibration Training Plate (Novotec Medical GmbH, Pforzheim, Germany), a tilting WBV platform that oscillates through the medial axis.

The WBV intervention began with a 30-minute session to instruct participants on how to auto-administer the 36 vibration

sessions, which were conducted 3 times a week over a period of 12 weeks. Each session included a 10-minute warm-up of slow walking and slight movement followed by 6 repetitions of WBV at a frequency of 12.5 Hz<sup>28-30</sup> with a rest interval of 60 seconds between each repetition. The duration of each repetition was 30 seconds during the first 4 weeks, 45 seconds during the second 4 weeks, and 60 seconds during the third 4 weeks (Table I). The stance of the participants on the platform alternated between stance A and stance B (described below) for each repetition. The foot soles maintained contact with the platform in both stances:

**Table I.** Characteristics of WBV therapy

Weeks	Session	Time series (sec)	No. series	Frequency (Hz)	Rest (sec)	WBV		Total time training program (min)	Posture (series)	
						Total time(min)			A	B
1-4	1-12	30	6	12.5	60	3		8	3	3
5-8	13-24	45	6	12.5	60	3		8	3	3
9-12	15-36	60	6	12.5	60	3		8	3	3

**Stance A:** Begin with the feet planted perpendicular to the midline axis of the platform with the right foot placed slightly ahead of the left foot. Lift the toes of the right foot and the heel of left foot 4mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

**Stance B:** Begin with the feet planted perpendicular to the midline axis of the platform with the left foot placed slightly ahead of the right foot. Lift the toes of the left foot and the heel of the right foot 4mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

WBV: Whole Body Vibration

- Stance A: The feet were planted perpendicular to the midline axis of the platform with the right foot placed slightly ahead of the left foot. The toes of the right foot and the heel of left foot were then lifted approximately 4mm above the surface of the platform, and the knees were bent and maintained at a 45-degree knee angle while the back and head were kept straight.

- Stance B: The feet were planted perpendicular to the midline axis of the platform with the left foot placed slightly ahead of the right foot. The toes of the left foot and the heel of the right foot were then lifted approximately 4mm above the surface of the platform, and the knees were bent and maintained at a 45-degree knee angle while the back and head were kept straight.

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Each participant was required to sign-out in a notebook after completing each vibration session. Each participant was also interviewed once a week during a 3-minute phone conversation to research assistant their progression through the program, provide additional instructions or assistance and give emotional support. During the 3-month study period, participants in the control group continued their daily activities, which did not include any form of physical exercise similar to the exercises performed by participants of the vibration group.

This vibration program was designed without reference to any explicit behavioral or theoretical model and was intended as a pragmatic intervention that could easily be implemented in a large population of patients with FM.

Vibration therapy was performed at the local FM association, and measurements were performed at the Fitness and Quality of Life Laboratory at the University of Extremadura (Spain).

**Table II.** Characteristics of women with fibromyalgia who followed the vibration-based exercise program and controls (n=36)

Group	Control (n=18) Mean (SD)	Exercise (n=18) Mean (SD)	p
Age (years)	53.0 (12.0)	52.4 (10.8)	.86
Weight (kg)	70.0 (10.5)	73.3 (14.4)	.38
Height (cm)	156.0 (4.7)	156.4 (5)	.78
Number of tender points (1-18)	15 (5)	15 (4)	.94
Duration of symptoms (years)	13.7 (6.2)	12.7 (6.7)	.67
FIQ (points)	53.6 (12.3)	59.2 (9.7)	.68
OSI (°)	1.3 (0.5)	1.5 (0.5)	.39
APSI (°)	0.8 (0.3)	1.0 (0.5)	.11
MLSI (°)	0.9 (0.4)	0.9 (0.4)	.68

FIQ: The Fibromyalgia Impact Questionnaire total score; Num. falls: Number of falls in the last year; OSI: Overall Stability Index; APSI: Anterior-Posterior Stability Index; MLSI: Medial-Lateral Stability Index; (°) degrees from 0° (best) to 20° (worst).

#### Data collection

The disability index of FM was measured with the Spanish version of the Fibromyalgia Impact Questionnaire (FIQ), which is widely accepted as a reliable, valid and dynamic questionnaire for measuring health status and physical function in FM patients<sup>31</sup>.

In the postural stability test (PS), the platform remains static in the anterior-posterior and medial-lateral axes, which allows three variables to be measured: the

overall stability index (OSI), the anterior-posterior stability index (APSI), and the medial-lateral stability index (MLSI)

(more information about the measures of this device can be found in the article of Arnold et al.<sup>32</sup>). The test consists of three trials of 20 seconds each and one minute between each trial. Only was tested one leg by economics reasons, in previous studies had been reported that the balance results are similar with both, dominant and non-dominant leg<sup>33</sup>. The trials were performed in a single limb dominant stance while maintaining slight flexion in the knees (15°). To determine the dominant leg the subjects were asked with which leg they preferred to kick a ball<sup>34</sup>. The posture of the arms was not regulated. The mean value of the three trials was calculated for each index (OSI, APSI and MLSI). Participants were also asked to report the number of falls suffered in the last year. The reliability of the test used in this paper was measured in our laboratory in 30 women with FM (average age 51±10 years) using a 7-day test-retest protocol. The intraclass correlation coefficient (ICC) was 0.82 and the small real difference (SRD) was 0.59 in OSI index. In the APSI index, the ICC was 0.77 and the SRD was 0.45. In the case of MLSI index, the ICC was 0.83 and the SRD was 0.39.

### Statistical analysis

All analyses were performed with SPSS software, version 15.0. Mean and standard deviation (SD) were calculated as descriptive statistics. Baseline characteristics were compared using the Student's t-test for independent samples and the distribution of data was examined by the Kolgomorov-Smirnov test, with Lilliefors significance. After verification of parametric conditions, comparisons

between groups were performed using ANOVA for repeated measures.

The significance level was set at  $p < .05$ . In addition to the p-values, we produced detailed statistics including the mean and 95% confidence interval in order to more thoroughly assess the change within each group from baseline to 12-weeks.

The differences between pre- and post-test values were used to describe the changes from baseline to 12-weeks, and the differences in the changes between the 2 groups throughout the 12-week study period were used to estimate the treatment effect. The mean and 95% confidence intervals were calculated using Student's t-test for independent samples.

Pearson's correlation was performed to establish the relationships between balance score, number of falls and FIQ at baseline.

Effect size was calculate to determine the magnitude of change observed by the sum of the means divided by the average deviations. Cohen's coefficient was determined to assess the change. A change from 0 to 0.2 was considered very small, a change of 0.3 to 0.5 was considered small, a change of 0.6-1.1 was considered a moderate, a change of 1.2-2 was considered large and a change  $> 2.0$  was considered very large<sup>35</sup>.

## RESULTS

There was a high level of feasibility for the proposed low-frequency vibration program in patients with FM. In the vibration group, 18 participants (86%) of 21 completed the program. Of the 3 participants who quit the program, 2 did so because their work schedule was not compatible with the platform exercise schedule and 1 (5%) quit

the program because of pain. Two participants were lost from the control group because of lack of interest.

No differences were observed between the groups at baseline in any outcome measure

**Table III.** Pearson's Correlation between FIQ, Num. falls and stability indices at baseline (n=41)

	FIQ	Num. falls
OSI in dominant single limb stance	.423 (*)	.427 (*)
APSI in dominant single limb stance	.467 (*)	.386 (*)
MLSI in dominant single limb stance	.197	.272
Num. falls	.427(*)	

(\*) Correlation is significant at the 0.05 level.

FIQ: The Fibromyalgia Impact Questionnaire score; Num. falls: Number of falls in the last year; OSI: Overall Stability Index; APSI: Anterior-Posterior Stability Index; MLSI: Medial-Lateral Stability Index.

(overall stability index, anterior-posterior stability index or medial-lateral stability index), and the sociodemographic characteristics of the participants in both groups were comparable at baseline (Table II). Both OSI and APSI correlated with the number of falls in the last year ( $R= 0.427$  and  $0.386$  respectively,  $p<0.05$ ). Furthermore, FIQ scores correlated with OSI and APSI ( $R= 0.423$  and  $0.467$  respectively,  $p<0.05$ ; Table III).

After 12 weeks of WBV treatment, a significant improvement was observed in the OSI (57%) and the APSI (66%) of participants in the exercise group, although no significant improvement was apparent in the MLSI ( $p= 0.231$ ; Table IV).

## DISCUSSION

The major finding of this study was that a 12-week tilting WBV program improved static balance in a dominant single limb stance. According with the force lines development during this training. Previous studies in FM have reported positive

effects of several therapies, including aquatic training <sup>36</sup> or resistance training combined with chiropractic treatment <sup>37</sup> as assessed by the Flamingo test <sup>36</sup> and the 10-item Continuous Scale Physical Functional Performance test <sup>37</sup>, but to our knowledge, this is the first study to evaluate one-leg balance as assessed by stabilometry in FM. In addition, the OSI was positively correlated with the number of falls in the last year and the FIQ score.

The characteristics of the participants in this study are similar to those reported in other FM studies. The mean FIQ score was similar to that obtained in several previous FM studies <sup>38-42</sup>, and the percentage of participants that had suffered two or more falls in the last year was 44.4 %, similar to the percentage of FM patients with balance problems <sup>5</sup>. The mean FIQ score at baseline and the treatment adherence (85.7%) were slightly smaller than those reported in two other studies using WBV therapy in FM <sup>16, 17</sup>; however, neither of these studies evaluated balance.

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Balance has been measured in previous studies in FM using questionnaires<sup>6</sup> and the Flamingo balance test (FBT)<sup>25, 26</sup>. In the current study balance was measured using a stabilometry platform. This platform measures stability in the anterior-posterior and medial-lateral planes, providing thorough information on the balance of persons with fibromyalgia.

During data analysis, we separated measures of overall balance in the medial-lateral and anterior-posterior axes, and found that APSI correlated with the number of falls in the last year, in agreement with previous studies on patients with muscle weakness<sup>43</sup>. Based on this result, lateral positioning was used during WBV therapy.

**Table IV.** Effects of 12-week of tilting whole body vibration therapy on single leg static balance (n=36)

Outcome measure	Baseline		Post- treatment			Treatment effect Mean (95%CI)	p†	Effect size
	Control Mean (SD)	Exercise Mean (SD)	Control Mean (SD)	Exercise Mean (SD)				
OSI (°)	1.36 (0.50)	1.53 (0.56)	1.40 (0.50)	0.88 (0.41)	0.65 (0.23 to 1.07)	.003	1.32	
APSI (°)	0.80 (0.29)	1.05 (0.49)	0.96 (0.47)	0.56 (0.31)	0.64 (0.30 to 0.97)	<.001	1.19	
MLSI (°)	0.94 (0.43)	0.88 (0.37)	0.83 (0.26)	0.55 (0.22)	0.19 (-0.13 to 0.51)	.231	1.08	

OSI: Overall Stability Index; APSI: Anterior-Posterior Stability Index; MLSI: Medial-Lateral Stability Index; (°) degrees from 0° (best) to 20° (worst). p †: p values of ANOVA for repeated measures compare different between groups after 12-week of tilting whole body vibration therapy.

Previous studies have also shown a correlation between balance measured by one-leg tests and the number of falls<sup>44, 45</sup>. Improvement of balance could help to reduce the number of falls suffered by FM patients. However, additional studies of longer duration are necessary to support this hypothesis, because 6 to 12 months of therapy are needed in order to see a real decrement in the number of falls.

Previous studies have shown a correlation between HRQOL and balance in the elderly<sup>46</sup>. To our knowledge, this is the first study to correlate HRQOL and balance in FM.

This study presented here has several limitations. First, only participants in the experimental group received weekly telephone calls during the WBV program. The social contact and support provided by these calls may have improved the motivation of this group. In addition, only members of the exercise group did a 10-minute warm-up of slow walking, so we cannot confirm that the observed improvements were solely due to WBV training.

More studies are necessary in order to determine the optimal amount of WBV therapy according to the level of disability in FM, as well as studies comparing the effects of WBV

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therapy on anterior-posterior and medio-lateral balance using different postures on titling, vertical and stochastic platforms.

In addition, a thorough assessment on the cost-effectiveness and cost-utility of WBV treatments is needed in order to ensure that this therapy can be provided to large populations of patients suffering from FM.

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### CONCLUSION

In conclusion, a 12-week tilting WBV program improved static balance in persons with FM. The novel findings presented in this study will aid professionals in sports medicine and rehabilitation in the treatment of impaired balance and prevention of falls in FM patients.

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**XII. STUDY 4: Tilt Vibratory Exercise Improves  
Pain, Strength and Somatosensory Function in  
Patients with Fibromyalgia: A Randomized  
Controlled Trial**

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## ORIGINAL ARTICLE

# Tilt Vibratory Exercise Improves Pain, Strength and Somatosensory Function in Patients with Fibromyalgia: A Randomized Controlled Trial

**Jose A Parraca, MSc, Jose C. Adsuar, PhD, Pedro R. Olivares, PhD, Borja del Pozo-Cruz MSc, MSc; Narcis Gusi PhD**

## ABSTRACT

**Objective:** The main objective of this study was to analyse the effects of 12 weeks of tilting whole body vibration therapy on pain, strength and somatosensory function in patients with fibromyalgia syndrome.

**Design:** Randomized controlled trial with assessor blinding.

**Participants and methods:** Thirty-six women with fibromyalgia were randomly allocated to exercise or control groups. The exercise group received a 12-week program of tilting whole body vibration therapy at 12.5-Hz frequency and 3 mm amplitude.

**Outcome measures:** Muscle strength was assessed with an isokinetic dynamometer, pain with a digital algometer and the somatosensory system with a stabilometry platform.

**Results:** The treatment induced a 23.5% improvement in widespread pain ( $P<.05$ ) and 40% improvement in knee pain ( $P<.05$ ).

The concentric knee extension and flexion strength improved by greater than 19% ( $P<.05$ ), and balance with eyes closed showed a 25% improvement in the overall stability index ( $P<.05$ ) and a 40% improvement in the antero-posterior

stability index ( $P<.05$ ) for all positions evaluated.

**Conclusion:** Twelve weeks of tilting whole body vibration therapy 3 times a week at a frequency of 12.5 Hz could be an effective therapy to improve strength, somatosensory function and pain in women with fibromyalgia.

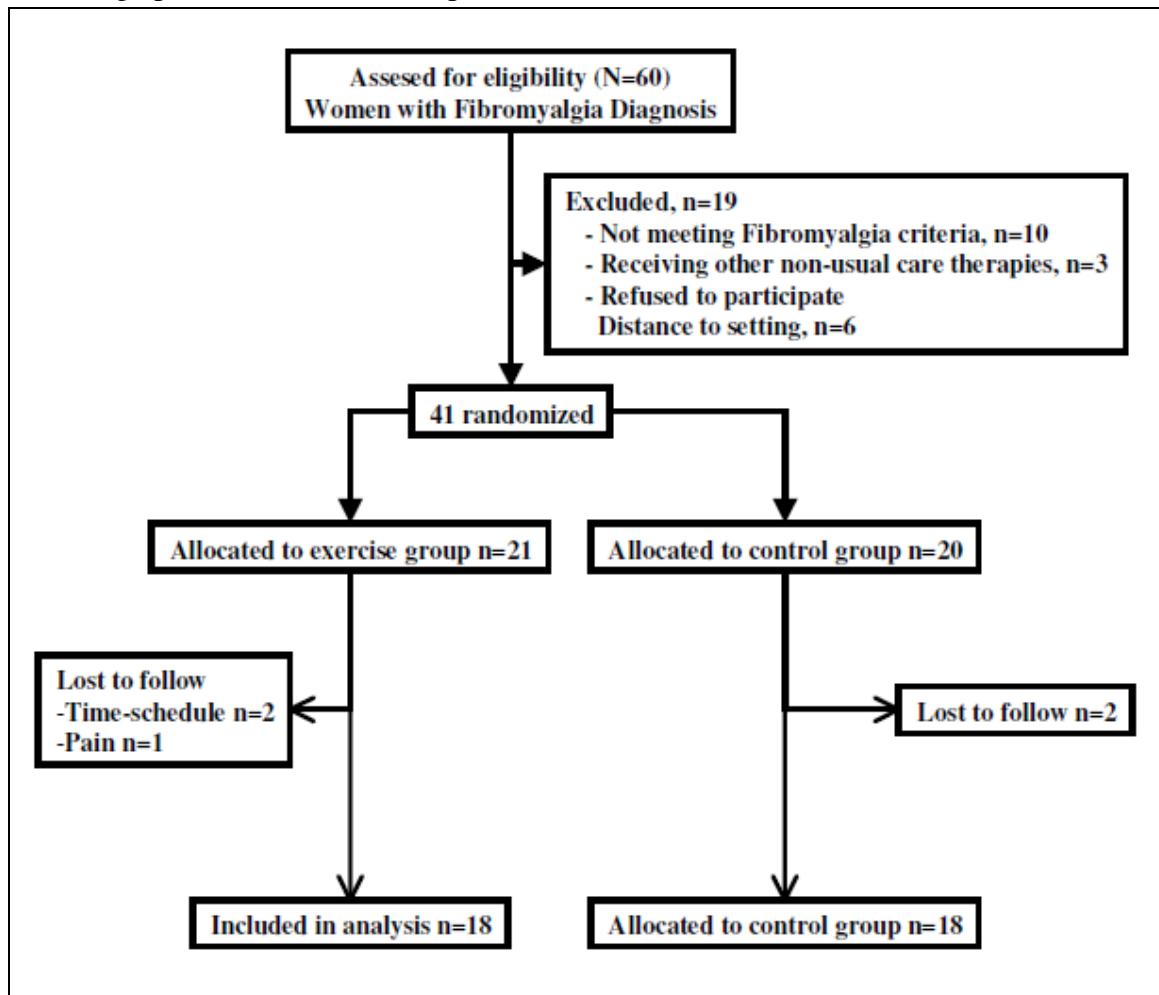
## INTRODUCTION

Fibromyalgia (FM) is a rheumatological syndrome of unknown aetiology. FM is characterized by widespread non-inflammatory musculoskeletal pain present for at least 3 months and an acute response to digital palpation with 4 kg/cm of pressure in at least 11 out of 18 tender points 1. It is generally accompanied by sleep disturbances, stiffness, fatigue, depression, and anxiety. For treatment of pain associated with FM, several therapies have been used including pharmacologic interventions with antidepressants, non-steroidal anti-inflammatory drugs, sedatives, muscle relaxants and opiates 2 and non-pharmacologic therapies such as Tai Chi, yoga, low impact aerobics, walking, water aerobics and whole-body vibration (WBV) 3-6. WBV is a mode of exercise that has recently been utilized for its positive effects on pain, balance, and neural, muscular and skeletal systems in different populations 7-9.

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WBV has been used to reduce chronic pain in several populations 10,11, including FM 12. It is not clear how vibration therapies lead to reductions in pain. One possible explanation is that vibrations activate skin somatic sensory receptors, thereby masking pressure and touch processes.

According to the gate control hypothesis 13, subsequently modified by Kerr (1975) 14, the vibrations can mask pain in a fashion similar to transcutaneous electrical nerve stimulation (TENS) 15, however have only one hypothesis.



**Figure 1. Flow diagram of participants.**

Muscle strength depends on both the cross-sectional area of the muscle and on neural activity. The cross-sectional area of the quadriceps femoris muscle is within the normal range in persons with FM 16,17; however, several studies have found that women with FM have significantly lower isometric and isokinetic muscle strength than healthy individuals 18-20. Reduced maximal muscle strength of knee extensors

in FM has been associated with poor outcomes in functional tests related to daily living activities (sitting up and down on a chair, walking and ladder climbing) 21. In WBV, the first adaptation affects neurological mechanisms. These adaptations are independent of increased muscle mass. There are several possible explanations for these effects, including increased motor unit synchronization, co-

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contraction of synergistic muscles, increased inhibition of antagonistic muscles, and a repetitive motion leading to a large boost in musculoskeletal structures due to changes in muscle stiffness in response to the vibration 22. The decline of knee extensor strength in FM has been associated with gait disorders and pain,

and may also contribute to balance problems. This is an important disease mechanism since balance problems are the sixth most frequent symptom in FM, affecting 45% of patients 23. Patients with FM have impaired balance 24,25, increased risk of falling 26, and gait problems 27.

**Table 1.** Characteristics of women with fibromyalgia who followed the Whole body vibration exercise program and controls\* (n=36)

Group	Control (n=18) (Mean±SD)	Exercise (n=18) (Mean±SD)	p
Age (y)	53.0 (12.0)	52.4 (10.8)	.860
Weight (kg)	70.0 (10.5)	73.3 (14.4)	.384
Height (cm)	156.0 (4.7)	156.4 (5)	.782
Number of tender points (1-18)	15 (5)	15 (4)	.943
Duration of symptoms (years)	13.7 (6.2)	12.7 (6.7)	.672
FIQ total score (points)	53.6 (12.3)	59.2 (9.7)	.681
Isometric knee extension strength (Nm)	79.4 (25.9)	74.3 (28.7)	.585
Isometric knee flexion strength (Nm)	28.0(12.3)	24.8 (10.5)	.407
SP18TP (Kg/cm <sup>2</sup> )	20.3 (7.8)	17.9 (6.8)	.959
<b>2 leg eyes-closed</b>			
Overall SI (°)	2.3 (1.0)	2.0 (1.2)	.368
Anterior-Posterior SI (°)	1.5 (0.7)	1.4 (0.8)	.543
Medio-Lateral SI (°)	1.4 (0.9)	1.1 (0.9)	.332
<b>Single dominant leg eyes-closed</b>			
Overall SI (°)	2.7 (0.7)	2.9 (0.7)	.583
Anterior-Posterior SI (°)	1.8 (0.6)	2.2 (0.7)	.253
Medio-Lateral SI (°)	1.5 (0.5)	1.4 (0.4)	.552
<b>Single no dominant leg eyes-closed</b>			
Overall SI (°)	3.1 (1.1)	2.7 (0.8)	.297
Anterior-Posterior SI (°)	2.3 (1.2)	2.0 (0.8)	.461
Medio-Lateral SI (°)	1.7 (0.5)	1.5 (0.4)	.578

\*Values expressed as mean (SD); FIQ total score, Fibromyalgia Impact Questionnaire total score

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**Table 2.** Effects of 3-month Whole Body Vibration program in fibromyalgia (n = 36). Efficacy analysis.

Outcome measure	Baseline		Post-treatment		Treatment effect Mean (95%CI)	p †	Effect size
	Control (n=18) Mean (SD)	Exercise (n=18) Mean (SD)	Control (n=18) Mean (SD)	Exercise (n=18) Mean (SD)			
Isometric knee extension strength (Nm)	79.42 (25.93)	81.66 (33.13)	77.81 (24.70)	90.21 (33.28)	10.16 (0.16 to 20.15)	.047	0.50
Isometric knee flexion strength (Nm)	28.07 (12.30)	24.16 (9.86)	26.63 (9.58)	27.92 (11.43)	4.58 (0.64 to 9.74)	.025	0.36
Concentric knee extension strength (Nm)	61.97 (23.02)	58.78 (21.85)	66.80 (24.39)	75.28 (19.93)	11.68 (1.64 to 21.70)	.024	0.82
Concentric knee flexion strength (Nm)	25.86 (9.97)	21.72 (6.86)	26.61 (9.43)	27.94 (8.84)	5.47 (2.01 to 8.93)	.003	1.11
Eccentric Knee flexion strength (Nm)	112.68 (35.42)	90.34 (31.01)	109.53 (37.73)	106.24 (32.87)	19.05 (-0.23 to 38.34)	.050	0.46
Knee R + Knee L (Kgf)	3.09 (1.87)	2.08 (1.02)	2.26 (1.11)	2.28 (1.18)	1.03 (0.12 to 1.94 )	.028	0.51
Algometer Score (Kgf)	20.37 (7.82)	17.90 (6.88)	17.58 (6.63)	19.61 (7.52)	4.51 (1.31 to 7.69)	.007	0.24
<b>2 leg eyes-closed</b>							
Overall SI (°)	2.37 (1.08)	2.02 (1.20)	2.25 (1.21)	1.14 (0.70)	-0.75 (-1.40 to -0.10 )	.023	-0.78
Anterior-Posterior SI (°)	1.57 (0.71)	1.41 (0.84)	1.52 (0.83)	0.76 (0.37)	-0.14 (-1.13 to -0.05)	.031	-0.75
Medio-Lateral SI (°)	1.48 (0.59)	1.17 (0.90)	1.37 (0.87)	0.71 (0.65)	-0.75 ( -1.19 to -0.30)	.113	-1.23
<b>Single dominant leg eyes-closed</b>							
Overall SI (°)	2.74 (0.80)	2.90 (0.76)	2.86 (0.82)	1.54 (0.68)	-1.48 (-2.24 to -0.73 )	<.001	-1.45
Anterior-Posterior SI (°)	1.88 (0.68)	2.20 (0.79)	1.93 (0.91)	1.10 (0.59)	-1.56 (-1.91 to -0.37)	.005	-1.09
Medio-Lateral SI (°)	1.56 (0.53)	1.45 (0.40)	1.67 (0.60)	0.82 (0.32)	-0.75 ( -1.19 to -0.30)	.002	-1.23
<b>Single no dominant leg eyes-closed</b>							
Overall SI (°)	3.17 (1.19)	2.77 (0.80)	2.85 (0.80)	1.62 (0.79)	-0.81 (-1.66 to 0.01 )	.049	-0.73
Anterior-Posterior SI (°)	2.30 (1.21)	2.01 (0.89)	2.17 (0.77)	0.99 (0.50)	-8.89 ( -1.74 to -0.03)	.040	-0.77
Medio-Lateral SI (°)	1.73 (0.53)	1.50 (0.48)	1.44 (0.48)	1.06 (0.56)	-0.27 (-0.78 to 0.22)	.500	-0.40

\*Values expressed as mean (SD); p †: p values from ANOVA for repeated measures adjusted by baseline data to compare different between groups after 3-month Whole Body Vibration program in fibromyalgia .

Patients with chronic pain disorders like FM have associated structural changes in the central nervous system (CNS), including parts of the somatosensory and motor systems 28. The somatosensory system is an integral component of the motor control system that facilitates the recognition of location and experience of peripheral stimuli and body position. In chronic pain, this system may be disrupted by alterations in peripheral and cortical processing, and FM patients with chronic pain typically describe diverse alterations of the somatosensory system 29.

Balance is a complex process that involves the reception and integration of sensory stimuli from three systems (somatosensory, vestibular and visual). When the visual system offers limited references, the development of balance is dependent on the other two systems. Previous studies reported the effects of visual aids on balance (29), but there is a lack of knowledge about the effects of reciprocal WBV on balance in FM patients with impaired vision.

The effects of WBV on patients with FM was previously studied using vertical platforms, but the effects of WBV using a tilt platform with reciprocal vertical displacement on the left and right side of the fulcrum on pain, strength and the somatosensory system in FM have not studied. The purpose of this study was to investigate the effects of 3 weekly sessions of tilting WBV (6 repetitions of 45-60 seconds at 12.5 Hz), over a 12 week period, on pain, strength and the somatosensory system in FM patients.

## MATERIAL AND METHODS

### Participants Recruitment

The population comprised women who participated in a local FM association. The women were eligible if FM had been diagnosed by a rheumatologist in accordance with the diagnostic criteria of the American College of Rheumatology (ACR) [13]. Several exclusion criteria were applied: history of severe trauma, frequent migraines, peripheral nerve entrapment, inflammatory rheumatic diseases, severe psychiatric illness, other diseases that prevent physical loading, pregnancy, participation in another psychological or physical therapy program, and participation in regular physical exercise more than once a week for 30 minutes or longer during a 2-week period in the last 5 years.

A total of 60 potentially eligible participants responded and requested additional information (Figure 1), but 19 of those candidates were subsequently excluded: three had participated in other therapies (massages and psychological treatment) that could potentially interact with the current intervention, ten did not meet the inclusion criteria (other severe diseases), and six lived too far from the intervention setting. After the study protocol was explained, the 41 remaining female patients aged 41 to 65 years old gave their written informed consent to participate according to the updated Declaration of Helsinki. The project protocol was approved by the Biomedical Ethical Committee of the University of Extremadura.

## Design

We conducted a blinded randomized controlled trial (ISRCTN16950947). The participants were randomly assigned to either the vibration group ( $n=21$ ) or the control group ( $n=20$ ) by a research assistant using a random number table. Each participant was assigned a code number. Other members of the research team, who were blinded to the group assignment of each participant, conducted the measurements of isometric, concentric and eccentric knee extension and flexion strength; the pressure at which they felt pain in each of the 18 tender points according to ACR criteria; and balancing with both legs, with the dominant leg, and the with non-dominant leg with eyes closed at the baseline and 12 weeks later. Additional members of the research team applied the intervention, and other team members performed the statistical analyses.

## Intervention

All the participants received standard care that included medical attention through the public health system (hospital and outpatient clinic, including primary care) and social support through the local FM association. Patients in the vibration group had a 30-minute instruction session on how to self-administer the 36 vibration sessions with the reciprocating Galileo Fitness Platform (Novotec Medical GmbH, Pforzheim, Germany), which oscillates through the medial axis, in contrast to other oscillating commercial platforms that oscillate uniformly up and down.

The intervention consisted of 3 sessions per week over a 12-week period. Each session included a 10-minute warm-up of slow walking and easy movements, and

then 6 repetitions of WBV with a frequency of 12.5 Hz, with a 60 second rest interval between repetitions. The duration of each repetition was 30 seconds during the first month, 45 seconds during the second month, and 60 seconds during the third month. The stance of the participants on the platform alternated between stance A and stance B for each repetition:

- Stance A: Begin with the feet planted perpendicular to the midline axis of the platform with the right foot placed slightly ahead of the left foot. Lift the toes of the right foot and the heel of the left foot 4 mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.
- Stance B: Begin with the feet planted perpendicular to the midline axis of the platform with the left foot placed slightly ahead of the right foot. Lift the toes of the left foot and the heel of the right foot 4 mm above the surface of the platform. Bend the knees and maintain a 45-degree knee angle. Keep the back and head straight.

Each participant was required to sign and date a notebook after completing each vibration session. A research assistant also spoke to each participant once a week during a 3-minute phone conversation in order to check progression through the program, provide instructions, and give emotional support. During the 3-month study period, the participants of the control group continued their daily activities, which did not include any form of physical exercise similar to the exercises performed by the participants of the vibration group. The vibration program was implemented at

the local FM association, and the measurements were performed at the Fitness and Quality of Life Laboratory at the University of Extremadura (Spain).

#### **Outcome measures:**

##### **Pain**

Pain was assessed by measuring the pressure at which participants felt pain at each of 18 tender points according to ACR criteria 1. Pain was measured by the same trained person for each participant, using a Wagner FDIX™ Digital Algometer (Wagner, USA). The sum of the threshold pressure at all tender points was calculated. The pain threshold at each tender point was determined by applying increasing pressure with the algometer perpendicular to the tissue, at a rate 1Kg/s. Patients were asked to say “STOP” at the moment pressure became painful. The mean of two successive measurements at each tender point was used for the analysis. Tender points were scored as positive when the patient noted pain at a pressure of 4 kg/cm<sup>2</sup> or less. A 7-day reliability test was conducted with 10 participants in our laboratory; the smallest real difference was 14.9 % for widespread pain and 15.2 % for knee pain.

##### **Strength**

Isometric, concentric and eccentric knee strength (flexion and extension) was always measured by the same trained person, using an isokinetic dynamometer (Biodex System 3). A 7-day reliability test was previously conducted in our laboratory 30.

##### **Somatosensory System**

The somatosensory system was evaluated using a stabilometry platform, the Biodex Balance System (BBS; Biodex, USA).

This instrument measures 3 indices: the medial-lateral stability index (MLSI), the anterior-posterior stability index (APSI) and the overall stability index (OSI), which is a composite of the MLSI and APSI 31. The patients are evaluated with both feet on the platform, with the dominant leg on the platform and with the non-dominant leg on the platform, and all the trials were performed with closed eyes. The duration in seconds 32 or the number of trials required to complete 30 seconds were recorded 33. A 7-day reliability test was performed with 10 participants in our laboratory: the smallest real difference for OSI was 19.6% with both feet on the platform, 27.8% with the dominant leg and 31.2% with the non-dominant leg; and the smallest real difference for APSI was 18.7% with both feet on the platform, 26.3% with the dominant leg and 30.6% with the non-dominant leg.

##### **Data analysis**

A 7-day reliability study on pain and balance tests was conducted with 10 participants before the start of the study. The relative reliability was determined with ICC1,1 in two sessions 34. The absolute reliability was determined with the SEM [SEM= SD $\sqrt{1 - ICC}$ , where SD is the average SD of day 1 and day 2, and the real minimum change (1.96 X  $\sqrt{2} \times$  SEM)] 35. Mean and standard deviation (SD) are given as descriptive statistics. Baseline characteristics were compared using Student's t-test for independent samples and the distribution of data was examined by Kolmogorov-Smirnov, with Lilliefors significance correction. Since the pre- and post-test measures are paired measures from the same subjects, we used the ANOVA for repeated measures.

Results were considered statistically significant when the significance values, p, were  $< .05$ . In addition to the p values, we provided detailed statistics including the mean and 95% confidence interval for better depicting the change within each group from baseline to 3 months, and the treatment effect. If the null value of the comparative measure, the mean, lies inside the confidence interval then the result is not statistically significant. These additional statistics are recommended for biomedical journals 36 for helping readers to determine the size of differences and to compare results with other studies. The differences between post- and pre-test were used to describe the changes from baseline to 3 months, and the differences between groups in the change from baseline to 3 months were used to estimate the treatment effect. The mean and 95% confidence intervals of changes were calculated using Student's t-test for independent samples. In order to be useful to a wider spectrum of readers, we performed an efficacy analysis including persons who completed the intervention to study the specific effects of the protocol, and we also reported an intent-to-treat analysis. 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  $>2.0$  was considered very large 37. All analyses were performed with SPSS software, version 16.0.

## RESULTS

The participant characteristics for this study are summarized in Table 1. The control and experimental group were

comparable with respect to all variables at baseline.

In efficacy analysis (table 2), the treatment effect on widespread pain was an improvement of 23.5 % ( $P<.05$ ) and on knee pain, an improvement of 40 % ( $P<.05$ ).

In the efficacy analysis (Table 2), treatment resulted in an improved strength of greater than 19% ( $P<.05$ ) in concentric knee extension and flexion. The treatment effect on balance with eyes closed was an improvement in OSI of greater than 25% ( $P<.05$ ) and in APSI of greater than 40% ( $P<.05$ ) in all positions evaluated.

In the intent to treat (ITT) analysis (Table 3), the treatment effect was a 20% improvement in widespread pain ( $P<.05$ ) and a 31% improvement in knee pain ( $P<.05$ ). The treatment effect on strength was an improvement in concentric knee extension and flexion of greater than 15% ( $P<.05$ ; Table 3). The treatment effect on balance with eyes closed was an improvement in OSI of greater than 20% ( $P<.05$ ) and in APSI of greater than 35 % ( $P<.05$ ) in all positions evaluated.

## DISCUSSION

Previous studies reported the feasibility and effectiveness of WBV in FM patients 12,38, including the effects of the WBV program used in the present study on health related quality of life and dynamic balance with visual feedback 6,39. The present study showed that WBV also has beneficial effects on widespread pain, the somatosensory system and muscular strength (isometric, concentric and eccentric knee contractions). Our results allow a more detailed study of the mechanism of adaptation to tilting WBV in FM.

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**Table 3.** Effects of 3-month Whole Body Vibration program in fibromyalgia (n = 41). Intent-to-treat analysis.

Outcome measure	Baseline		Post-treatment		Treatment effect Mean (95%CI)	p †	Effect size
	control (n=20) Mean (SD)	exercise (n=21) Mean (SD)	control (n=20) Mean (SD)	exercise (n=21) Mean (SD)			
Isometric knee extension strength (Nm)	79.28 (25.73)	80.14 (34.15)	77.68 (24.58)	87.28 (34.89)	8.13 (-0.11 to 17.59)	.053	0.62
Isometric knee flexion strength (Nm)	27.53 (12.25)	25.93 (10.02)	26.33 (9.74)	29.26 (11.01)	4.52 (0.56 to 8.49)	.026	0.34
Concentric knee extension strength (Nm)	61.21 (22.32)	58.51 (22.29)	65.44 (23.86)	72.34 (21.83)	9.6 (0.45 to 18.75)	.040	0.68
Concentric knee flexion strength (Nm)	24.67 (10.17)	22.48 (6.57)	25.40 (9.70)	27.84 (8.12)	4.63 (1.51 to 7.75)	.005	0.64
Eccentric Knee flexion strength (Nm)	111.25 (34.01)	95.79 (31.73)	108.08 (36.18)	108.67 (31.18)	16.05 (-0.89 to 33.01)	.063	0.62
Knee R + Knee L	28.74 (18.84)	2.30 (1.16)	2.10 (1.12)	2.35 (1.19)	0.81 (8.09 to 66.00)	.047	0.66
Algometer Score (Kgf)	19.82 (7.64)	19.58 (7.47)	17.00 (6.58)	20.46 (71.86)	3.70 (0.09 to 16.22)	.014	0.83
<b>2 leg eyes-closed</b>							
Overall SI (°)	2.48 (1.04)	2.20 (1.28)	2.20 (1.15)	1.43 (1.07)	-0.76 (-1.40 to 1.10)	.024	-0.67
Anterior-Posterior SI (°)	1.58 (0.71)	1.47 (0.83)	1.53 (0.82)	0.91 (0.95)	-0.97 (-1.66 to -0.28)	.037	-0.07
Medio-Lateral SI (°)	1.61 (1.07)	1.35 (0.99)	1.51 (1.01)	0.93 (0.89)	-0.31 (-0.71 to 0.08)	.118	-0.50
<b>Single dominant leg eyes-closed</b>							
Overall SI (°)	2.79 (0.80)	2.96 (0.75)	2.91 (0.81)	1.81 (0.95)	-0.70 (-1.96 to -0.56)	<.001	-1
Anterior-Posterior SI (°)	2.03 (0.77)	2.31 (0.81)	2.08 (0.96)	1.38 (0.91)	-0.97 (-1.66 to -0.28)	.007	-0.88
Medio-Lateral SI (°)	1.64 (0.55)	1.46 (0.42)	1.76 (0.61)	0.93 (0.45)	-0.63 (-1.03 to -0.23)	.003	-0.71
<b>Single no dominant leg eyes-closed</b>							
Overall SI (°)	3.06 (1.16)	2.84 (0.84)	2.73 (0.83)	1.82 (0.89)	-0.70 (-1.42 to 0.02)	.050	-0.66
Anterior-Posterior SI (°)	2.26 (1.13)	2.11 (0.90)	2.13 (0.73)	1.21 (0.74)	-0.77 (-1.51 to -0.03)	.041	-0.21
Medio-Lateral SI (°)	1.72 (0.49)	1.46 (0.46)	1.44 (0.44)	1.05 (0.53)	-0.12 (-0.50 to 0.26)	.517	-0.22

\*Values expressed as mean (SD); p †: p values from ANOVA for repeated measures adjusted by baseline data to compare different between groups after 3-month Whole Body Vibration program in fibromyalgia .intent-to-treat analysis.

The current vibration program could serve as an additional resource for patients with FM that can easily be implemented in different settings (e.g. primary care, FM associations, clinics or gyms.) because the program can be readily self-administered in one small room after an initial instruction session. This is a particular advantage for patients living in sociodemographic areas lacking key resources such as gyms, warm-water pools, clinics or highly specialized FM technicians 40,41. Only one participant dropped out of the program (5.5%) and this was due to pain in the legs. The remaining participants completed the program without secondary adverse affects (94.5%); this is an important outcome since 92–93% treatment adherence rates are not usually obtained in intervention programs with FM patients, thus distinguishing this study from other studies with FM patients 42,43.

Previous studies have reported beneficial effects of WBV in a variety of populations, for example, the elderly 9,44-46, untrained females 47,48 postmenopausal women 49,50, Parkinson's disease 51-53, multiple sclerosis 54 and stroke 55-57.

Previous studies suggest that the traditional exercise program alone has no effect on pain in patients with FM 12,41,58. Water therapy has been identified as an important therapy for pain in FM. Balneotherapy and dry-land training

both deliver improvements in pain such as the number of tender points 59,60. Eight weeks of training with 5 different sessions per week (including one water session) led to a 40% improvement in body pain measured by the questionnaire Short Form 36 41. Jentoft et al. 61 detected reductions in pain after 2 sessions per week in a heated pool for 20 weeks, while Gusi et al. 62 found that three sessions per week in warm water decreased pain measured on VAS (29%) and pain/discomfort item of the EQ-5D (16%). Mannerkorpi et al. 63 achieved a 15% reduction in pain with one pool-based session per week over a 6 month period. WBV is a new therapeutic approach and to our knowledge the study by Alentorn-Geli et al. 12 is the only one study to investigate the effect of WBV on FM-related pain; these authors propose exercise plus supplementary vertical WBV as an effective approach for improving pain in FM. However, the study by Alentorn-Geli et al. is limited by the inclusion of an exclusive WBV group. Our study used an intervention exclusively based on tilting WBV therapy and achieved a positive effect on pain relief measured by a digital algometer, indicating that WBV therapy alone can be effective in treating one of the most important FM symptoms. In turn, this novel therapeutic approach may have beneficial effects on quality of life, physical functioning and health status in FM patients. An inherent

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problem in pain assessment is the subjective nature of the measurement, and many studies utilize the singly document VAS scale or manual palpation, but these methods do not account for individual differences in pain perception. We aimed to avoid this problem by assessing pain with a digital algometer, which is a quantitative tool for assessment of pain commonly used in clinical practice 64. We measured pain over the whole body, but also focused specifically on the knees, which predominantly absorb the impacts transmitted by the platform, and we found a statistically significant increase.

Previous studies suggest an increase in pain in lower limbs (gastrocnemius and anterior tibialis) in FM 65.

Vibration strongly affects the afferent discharge from fast adapting mechanoreceptors and muscle spindles, and this is a likely mechanism to reduce the perception of pain. In addition to its effects on pain, we believe this process is related to improvement in balance because the gastrocnemius muscle is the agonist for control of forward postural sway, and the anterior tibialis muscle is the agonist for control of backward postural sway.

Patients with FM are deconditioned compared with normal subjects, with a reduction in maximal voluntary isokinetic strength in the quadriceps muscle that is thought to result from

a primary muscle dysfunction 66. FM patients with many tender points have a significant reduction (45%) in peak torque isokinetic knee extension and flexion. Possible mechanisms for this reduced muscle function include pain, negative feedback on motor unit recruitment, peripheral neurogenic problems and lack of motivation 66. The increase in voluntary peak torque isokinetic strength (19%) in our study is probably due to the observed improvements in pain at tender points, allowing an improvement in the feedback to motor units, together with increased motivation to develop strength and to improve functions related to daily living (stair climbing, walking or sitting up and down on a chair).

Some studies using land-based resistance training have shown that exercise is effective for improving strength in FM 67,68, but Gusi et al. 62 have verified that warm water therapy improves knee extensor and flexor strength for concentric actions at slow speed. In our study, we obtained similar results using self-administered therapy and rather more expensive when applied to institutions or associations of FM.

Balance problems are one of the 10 most debilitating symptoms of FM and occur in 45-68% of patients 69. We propose that several factors contribute to balance problems in FM patients including vision problems, vestibular problems and changes in somatosensory impulses

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for pain 28. The somatosensory response is dependent on specific clinical and demographic factors such as reduction in muscle strength, and sensory or motor deficits 70, and is also altered in FM 65.

The first sensory inputs used in automatic postural control and postural orientation are the somatosensory input from muscle spindles, Golgi tendons, and superficial and deep cutaneous afferent 71. However, proper balance also requires rapid and automatic corrections from the CNS. FM patients have abnormal perception of pain and slight somatosensory stimulation, and since our proposed therapy stimulates the CNS and may enhance activation of the somatosensory system, this may contribute to better postural control in FM patients.

The positive effect of WBV on the somatosensory system in patients with FM is a novel and important finding. This new technology has great potential to improve the quality of life in patients with pain and could help to clarify the specific mechanisms and adaptations of the somatosensory system, especially in FM patients.

Other authors have reported improvements in balance in FM when balance was measured with the eyes open. These improvements are likely due to training of the somatosensory system and to effects of vision 6. In our study, the improvements in balance occurred

independent of visual inputs, suggesting that the therapy improves balance through stimulation of the somatosensory system.

We propose that interventions that combine balance training with exercise and stimulation of these systems with vibratory exercise may be effective in improving balance and somatosensory function in FM.

#### LIMITATIONS

This study has several limitations. We relied on self-administration of the vibratory therapy, including auto-adjustment of the knee angles. Only participants in the experimental group received weekly telephone calls during the WBV program. The social contact and support provided by these calls may have improved the motivation of this group in contrast to the control group, which did not receive the calls. In addition, members of the exercise group did a 10-minute warm-up of slow walking, so we cannot confirm that the observed improvements were solely due to WBV. The balance test was performed with eyes closed, thereby excluding effects of vision, and in this situation balance is maintained through the vestibule and the somatosensory system. Therefore, we cannot determine whether the improvements achieved were due solely to improvements in the somatosensory system or whether the vestibular system was also involved. Another possible limitation

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is that the gait with eyes open and closed was not evaluated. In the current study we checked the effects of the WBV on balance with closed eyes, would be important control the medications used by FM patients that have influence in the postural control.

Further studies will be necessary to determine the optimal amount of WBV therapy and its relationship to the level of disability in FM. It will also be important to compare the effects of WBV therapy on anterior-posterior and medio-lateral balance using different postures on titling, vertical and stochastic platforms. Finally, a thorough assessment of the cost-effectiveness and cost-utility of WBV treatments is needed in order to ensure that this therapy can be provided to large populations of patients suffering from FM.

## CONCLUSIONS

Twelve weeks of tilting whole body vibration therapy 3 times a week, with a frequency of 12.5 Hz, had a positive effect on muscle strength, the somatosensory system and pain in women with fibromyalgia. This study supports the development of novel approaches to physical therapy programs that utilize vibration therapy.

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**STUDY 4: TEST-RETEST RELIABILITY OF ISOMETRIC AND ISOKINETIC KNEE EXTENSION AND FLEXION IN PATIENTS WITH FIBROMYALGIA: EVALUATION OF THE SMALLEST REAL DIFFERENCE**

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### **XIII. DISCUSIÓN**

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## DISCUSIÓN GENERAL DE LOS RESULTADOS OBTENIDOS EN LOS DISTINTOS TRABAJOS

Estudios previos han reportado efectos beneficiosos de programas de WBV en una gran variedad de poblaciones, por ejemplo, mayores<sup>142, 145, 148</sup>, mujeres no entrenadas<sup>152, 167</sup>, mujeres post-menopáusicas<sup>120, 123</sup>, enfermos de Parkinson<sup>116, 168-169</sup>, esclerosis múltiple<sup>170</sup> y accidente cerebro vascular<sup>143-144, 171</sup>.

Con la realización de esta tesis hemos podido demostrar la eficacia y aplicabilidad del programa vibratorio de baja frecuencia (12,5Hz) en mujeres con FM. Solo 5% de los participantes (n=1) se retiraron del programa por dolor intenso en las piernas. El programa se completó con 85% de los participantes, sin efectos secundarios adversos. Aunque el programa se haya llevado a cabo de forma individual y auto-administrada, la tasa de retención fue similar a la de otros grupos con terapias de ejercicio físico para pacientes con FM (70-90%)<sup>172</sup>, pero ligeramente inferiores a otros estudios de WBV en pacientes de FM<sup>114-115</sup>. El grupo de intervención ha recibido una intervención de WBV y un refuerzo por llamada telefónica, en comparación con un grupo control, que no recibió nada.

El programa actual de vibración podría servir como un recurso adicional para los pacientes con FM y puede fácilmente ser implementado en diferentes lugares (p.e. atención primaria, asociaciones de FM, clínicas o gimnasios) el programa se puede llevar a cabo en una pequeña

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habitación después de un sesión inicial formativa. Esto es una ventaja a destacar para pacientes que viven en lugares sin acceso a gimnasios, piscinas de agua caliente, clínicas o técnicos altamente especializados en FM. Es importante realzar, que el coste del aparato utilizado en este estudio es de aproximadamente \$11.900, que es potencialmente un costo prohibitivo para las personas y asociaciones locales de FM con bajos a moderados ingresos. Sería importante la realización de estudios de coste-efectividad en diferentes aparatos comerciales y/o terapias para promover políticas de implementación de este tipo de aparataje.

Hemos verificado que el porcentaje de participantes que han sufrido dos o más caídas en el último año fue de 44.4%, porcentaje similar al presentado por otros autores en un estudio con pacientes de FM que presentaban problemas de equilibrio<sup>173</sup>. Estudios anteriores han comprobado que WBV es eficaz para mejorar el equilibrio estático y dinámico de los mayores, teniendo como medida los tests de levantarse y caminar – “*timed up-and-go*”, levantarse y sentarse en una silla – “*chair rise*” y el test de Tinetti, así como en pacientes con alteraciones neuromusculares como Parkinson<sup>142, 145, 174</sup> o esclerosis múltiple<sup>170</sup>. También se ha visto un incremento en el equilibrio principalmente en el eje medio-lateral, que es uno de los componentes del índice general de equilibrio aplicado en este estudio, siendo este un biomarcador sensitivo determinante de la capacidad funcional de los mayores<sup>175</sup>. En otro estudio, con pacientes con artritis, se ha considerado que el equilibrio dinámico dependía del índice de masa corporal, de la edad y del sexo, y

que el equilibrio dinámico medido usando la BBS con los brazos cruzados en el pecho estaría asociado a una disfunción funcional<sup>1</sup>.

Hemos encontrados efectos positivos tras la aplicación de la terapia de WBV en el equilibrio dinámico de estos pacientes que están mayoritariamente caracterizados por el dolor. Este hallazgo puede ser la génesis de la aplicación de estas nuevas terapias de WBV en los servicios de salud para personas con dolor crónico ayudando, a la vez, a una reducción de la pérdida de masa ósea<sup>120</sup> debido a las características del estímulo propuesto. La promoción del incremento de la fuerza y la velocidad son aspectos fundamentales en la reacción y prevención ante un tropezón y una eventual caída<sup>174</sup>. Los nuevos resultados obtenidos sugieren que WBV es fiable y eficaz para mejorar el equilibrio dinámico de las mujeres con FM.

Con respecto al equilibrio unipodal el principal hallazgo de esta tesis fue que el programa propuesto mejora el equilibrio estático unipodal con pierna dominante. Estudios previos realizados pacientes con FM con terapias en agua caliente<sup>76</sup>, resistencias combinadas o tratamientos quiroprácticos<sup>176</sup> han reportado efectos positivos en el equilibrio estático unipodal utilizando como instrumento de medida la prueba de equilibrio del Flamingo<sup>77, 177</sup> y/o cuestionarios<sup>173</sup>, nuestro estudio también aporta efectos beneficiosos y, es el primero que mide el equilibrio unipodal con la pierna dominante utilizando un estabilometro en FM. Hemos verificado también que el índice de equilibrio antero-posterior se correlaciona con el número de caídas en el último año, estando estos resultados en

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concordancia con otros estudios en pacientes con debilidad muscular<sup>178-</sup><sup>179</sup>. El FIQ se correlacionó con los índices de estabilidad siendo este el primer estudio que correlaciona la CVRS y el equilibrio en FM, hasta ahora solo Laas y cols. habían mostrado una correlación entre CVRS y el equilibrio pero en mayores<sup>180</sup>.

El sistema somatosensorial implicado en el control automático de la postura se ve afectado en los pacientes con FM<sup>173, 181-182</sup>. Posiblemente a causa del dolor, el hecho de que hemos mejorado el dolor con esta terapia, posiblemente haya tenido influencia en las mejoras observadas en el sistema somatosensorial, pero la elevada estimulación que el WBV induce en el sistema nervioso central también habrá contribuido para las mejoras observadas. El efecto positivo del WBV en el sistema somatosensorial en pacientes con FM es un hallazgo novedoso e importante. Esta nueva tecnología tiene un gran potencial para mejorar la calidad de vida en pacientes con dolor y puede ayudar a clarificar los mecanismos específicos y adaptaciones del sistema somatosensorial, especialmente en pacientes con FM.

Las mejoras que hemos observado con los ojos abiertos están muy relacionadas con la visión y el biofeedback visual de la maquina, pero estas mejoras en el equilibrio ocurren independientemente de los estímulos visuales, lo que sugiere que la terapia utilizada es eficaz para mejorar el equilibrio estimulando y desarrollando el sistema somatosensorial.

Estudios previos sugieren que un programa de entrenamiento tradicional por sí solo no tiene efectos sobre el dolor en pacientes con FM<sup>78, 115, 183</sup>. Las terapias en agua caliente la balneoterapia y algunas terapias en seco han sido identificadas como importantes para reducir el dolor en FM cuando evaluado a través del los puntos gatillo<sup>55, 184</sup>.

Ocho semanas de tratamiento con 5 sesiones diferentes por semana (incluyendo una sesión de agua) llevó a una mejora del 40% en el dolor corporal medido con el cuestionario SF-36<sup>78</sup>. Se ha verificado una reducción en el dolor después de 2 sesiones por semana en una piscina climatizada durante 20 semanas<sup>185</sup>, Gusi y cols. encontraron una reducción del dolor medido con la escala VAS (29%) y en el ítem dolor/malestar del cuestionario EQ-5D (16%) en una terapia de 3 sesiones semanales en agua caliente<sup>55</sup>. Mannerkorpi y cols. han obtenido una reducción de un 15% en el dolor con un grupo que realizó una sesión de agua a la semana durante un periodo de 6 meses<sup>186</sup>. Sólo Alentorn-Geli y cols. han utilizado el WBV, proponiendo la adicción del WBV a un entrenamiento tradicional, creemos que sería interesante en el estudio de Alentorn-Geli y cols. la inclusión de otro grupo exclusivo de WBV<sup>115</sup>. Nuestro estudio usa una intervención basada exclusivamente en WBV y encontró un efecto positivo sobre el dolor evaluado con un algómetro digital, lo que indica que una terapia de WBV por sí misma podría ser efectiva en el tratamiento del dolor, que es uno de los más importantes síntomas en FM, por otra parte, este tratamiento novedoso ha tenido

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efectos beneficiosos sobre la CVRS en este colectivo de pacientes, con incrementos en las puntuaciones del FIQ.

Un problema inherente a la evaluación del dolor es la naturaleza subjetiva de la medición, y muchos estudios utilizan una escala VAS o la sensibilidad a la palpación manual, pero son métodos dudosos y que muchas veces no se hacen de modo correcto, en nuestro estudio hemos utilizado un algómetro digital<sup>187</sup>. Hemos medido el dolor en todo el cuerpo, pero como estudios previos sugieren un incremento en el dolor en las piernas (gastrocnemius y anterior tibialis) en FM<sup>181</sup>, nos enfocamos específicamente sobre las rodillas, no solo por lo referido antes, sino porque son las que normalmente absorben los impactos transmitidos por las plataformas vibratorias, y encontramos un aumento estadísticamente significativo en la presión que las pacientes podían soportar sin dolor, lo que significa una disminución del dolor.

Sé sabe que el WBV afecta en gran medida las descargas aferentes de los mecanorreceptores de adaptación rápida y los husos musculares, siendo este un mecanismo que puede disminuir la percepción al dolor, pero además de sus efectos en el dolor, creemos que este proceso estará relacionado con mejoras en el equilibrio atendiendo a las mejoras en la coordinación del par agonista-antagonista de los músculos gastrocnemius y tibial en el control del equilibrio antero-posterior.

Sería interesante la realización de un estudio más amplio y con una muestra poblacional mayor para entender completamente las

interacciones entre los cambios en el equilibrio dinámico y el dolor, (ya que en este estudio solo un paciente abandonó a causa del dolor), y entre el equilibrio dinámico y el rango del dolor (umbral de dolor en puntos sensibles).

Los pacientes con FM tienen peor condición física, caracterizada por una reducción de la fuerza máxima voluntaria del cuádriceps, comparadas con las personas normales<sup>188</sup>, existiendo una reducción bastante significativa (45%) en el pico torque de los extensores de rodillas, varias pueden ser las razones para este fenómeno de función muscular reducida (dolor, reducido reclutamiento de unidades motoras, problemas neuromusculares periféricos, falta de motivación, etc.), en nuestro estudio se verificó un incremento del pico torque isocinético (19%) posiblemente debido a las mejoras observadas en el dolor, que ha permitido un mejor reclutamiento de unidades motoras que podrían estar inhibidas por dolor, aliado a una mayor motivación para generar fuerza, situación esta que se traduce en una mejoría de las capacidades para la realización de las tareas del cotidiano (subir escaleras, caminar o levantarse y sentarse de una silla) como sugieren los autores que han comprobado incrementos de la fuerza en programas en suelo<sup>189-190</sup>.

Otros estudios han verificado incrementos en la fuerza de los flexores y extensores de las rodillas en acciones concéntricas a baja velocidad en pacientes de FM después de una terapia de agua caliente<sup>55</sup>, nosotros hemos verificado mejoras similares, pero recurriendo a una

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terapia auto-administrada que podría tornarse a lo largo del tiempo más barata que la terapia en piscina de agua caliente.

Es importante referir que las características de los pacientes en este estudio son similares a las muestras presentadas por otros estudios, así como las medias de los resultados del FIQ obtenidos en otros estudios<sup>183, 191-193</sup>.

Con respecto a la CVRS, el hallazgo más importante de este trabajo es que la terapia propuesta ha sido eficaz para prevenir la pérdida de la CVRS en mujeres desentrenadas y con FM, en la línea-base las características de estos pacientes se presentaron similares a las características presentadas por otros autores en las medias de los cuestionarios FIQ y 15-D<sup>183, 191-193</sup>. Otros estudios han utilizado una terapia de WBV de 6 semanas y una media de frecuencias de intensidad de 30Hz, pero no se ha demostrado un incremento en el score del FIQ<sup>115</sup>. Nuestro estudio es el primero que obtiene efectos positivos en el FIQ y en la movilidad utilizando bajas frecuencias de vibración. Las diferencias que se han obtenido en este estudio en comparación con las que ha obtenido Alentorn-Geli y cols con sus estudios podrán ser debido al tiempo de aplicación de la terapia y también a la diferencia de los estímulos mecánicos y intensidades de las plataformas utilizadas, además Alentorn-Geli y cols utilizan ejercicios tradicionales durante la aplicación de la terapia de WBV<sup>114-115</sup>.

Se verificó que después de la terapia ha habido una disminución de la CVRS en el grupo control posiblemente por los cambios climáticos de

las estaciones de año, atendiendo al periodo del año en que se ha realizado el estudio (Octubre – Diciembre), aunque no es una evidencia objetiva, los cambios climatéricos tienen una influencia directa en el estado de los pacientes de FM<sup>194</sup>, y posiblemente en los resultados obtenidos con el FIQ influenciándolos.

Según nuestro conocimiento hasta ahora solo existe un estudio usando el 15-D en pacientes con FM aunque en ese estudio también se hayan incluido pacientes con artralgia<sup>180</sup>. Nuestro estudio es el primero que utiliza el 15-D como herramienta de medida en los cambios de la CVRS después de la aplicación de una terapia física en FM. Los resultados indican que el cuestionario 15-D es menos sensible a los cambios en CVRS que el FIQ en FM. Sin embargo el 15-D es un cuestionario apropiado para comparar los efectos de una determinada terapia entre pacientes con FM y pacientes con otros tipos de enfermedades, capacidad esa que el FIQ no tiene. Las dimensiones del 15-D parecen ser más sensibles a los cambios que el FIQ e indican que dimensión particular de la CVRS ha mejorado.

Proponemos que se hagan nuevos estudios donde se evalúe la influencia de diferentes dispositivos de vibración (oscilación vertical o mixtas)<sup>195</sup>, diferentes posturas atendiendo a que estos factores inducen a diferentes líneas o vectores del estímulo vibratorio, bien como, el estudio de la aplicación de diferentes niveles de intensidad y diferentes duraciones de tiempo y de descanso.

Este estudio abre una nueva línea de investigación en las ciencias complementarias y alternativas de la medicina, y marca la eficacia de la utilización de las terapias de WBV en FM.

### XIII.1. Limitaciones

Las diferencias en los parámetros del protocolo de BBS (es decir, el nivel de estabilidad de la plataforma, o la postura de la pierna, la posición de los brazos, los ojos abiertos o cerrados) ha limitado las comparaciones de la magnitud de los cambios o las referencias normativas con otros diferentes estudios. Las mejoras en el equilibrio reportado en el presente estudio fueron influenciados por el nivel de equilibrio dinámico en la línea-base, por lo tanto, cabría esperar una mayor mejora en los pacientes con peor equilibrio al inicio del estudio.

No podríamos analizar la influencia de la capacidad previa de los pacientes ya que uno de los criterios de inclusión fue que los participantes estén físicamente capacitados. Los 10 minutos de caminar suave antes de cada sesión WBV podrían haber influido en la aptitud de los pacientes que estaban en muy baja forma al inicio del estudio, bien como ayudado en la reducción del dolor (*estudio 2*).

Siendo este un programa auto-administrado por cada paciente, debemos advertir para la generalización de los resultados obtenidos.

La alta tasa de participación en el presente estudio podría explicarse en parte por el apoyo mutuo de otros miembros de la

asociación local de FM y por la llamada telefónica semanal. Por lo tanto, se necesitan estudios adicionales para evaluar si el programa actual es eficaz en otros ámbitos, como el hogar.

La prueba de equilibrio con los ojos cerrados, excluye los efectos de la visión, y en esta situación, el equilibrio se mantiene a través del vestíbulo y del sistema somatosensorial. Por lo tanto, no podemos determinar si las mejoras alcanzadas se debieron únicamente a las mejoras en el sistema somatosensorial o si el sistema vestibular también estaba involucrado.

Otra posible limitación es que el modo de andar con los ojos abiertos y cerrados, no se evaluó.

En el presente estudio hemos comprobado los efectos de la WBV en equilibrio con los ojos cerrados, sería importante un control de los medicamentos utilizados por pacientes con FM que pueden tener influencia en el control postural.

La no significación estadística de algunos de los resultados de esta tesis se pueden deber a la pequeña muestra.

El hecho de que el grupo control no haya recibido la llamada telefónica puede haber tenido influencia en la motivación pudiendo este factor afectar a los resultados obtenidos en los parámetros relacionados con la CVRS.



## **XIV. CONCLUSIONES**

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## XII. CONCLUSIONES

1. El programa de WBV propuesto, donde se utilizó una plataforma de vibración sinusoidal, con una frecuencia baja (12,5 Hz) aplicando la vibración en los pacientes de modo antero-posterior, es útil y aplicable para mejorar el equilibrio dinámico en mujeres con FM (*estudio 1*).
2. Una intervención de 12 semanas de WBV es aplicable y evita la pérdida de la CVRS en mujeres con FM sedentarias (*estudio 2*).
3. Un programa de 12 semanas de WBV mejora el equilibrio estático de las personas con FM (*estudio 3*).
4. Doce semanas de terapia de WBV, 3 veces por semana, con una frecuencia de 12,5Hz, tuvo un efecto positivo sobre la fuerza muscular, el sistema somatosensorial y el dolor en mujeres con FM. (*estudio 4*).



## **XV. SUMMARY AND CONCLUSIONS**

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Fibromyalgia (FM) is a syndrome which is allied with other symptoms of chronic pain, lack of muscle strength and balance problems that are generally associated with anxiety disorders and depression, affecting quite significantly the related quality of life (HRQoL) of these patients.

In recent years there has been interest in the study of a training method based on vibration, vibration exercise called body or whole-body vibration according to its acronym in English-(WBV). The WBV has been applied to several populations such as athletes, general population, the elderly or patients with various diseases. The vibration training is usually performed with specialized instruments. One of the most used is a horizontal platform which vibrates around a middle axis to allow the right side to lower when the lower left side rises and vice versa, once the feet are placed at an equal distance from the shaft.

Knowing that the force is a predictor of physical function and HRQL in rheumatic diseases, and knowing that people with FM have a deficit of muscle strength compared to healthy people, we are involved in assessing the muscle strength in legs in people with FM. The isokinetic dynamometer is a reliable instrument to measure that parameter enough and has been the instrument used to measure the strength in this group of people. Several studies have used similar dynamometers to quantify the strength deficits in different populations, as well as to evaluate the effects of various training programs related to muscle strength. Dr. José Carmelo

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Adsuar Hall's doctoral thesis was the first one to use an isokinetic dynamometer to assess test-retest reliability in FM.

The sense of balance, either static or dynamic, that is, those feelings that inform us at any time of the position of our head over the three-dimensional space in which we move, is also affected in patients with FM. The dynamic balance (ED) is the one that keeps our body in balance when performing movements of rotation and acceleration. The static balance (EE), is the one which keeps the body balanced when it stays still or moves in a straight line. The Bidex Balance System (BBS), (Bidex, USA), was used to evaluate these physical attributes. The BBS has been used to evaluate and train the postural stability and postural balance. It is a multi-axial device that measures and records objectively an individual's ability to stabilize a joint affected by a dynamic stress. It is a circular platform that moves freely over the anteroposterior and the mediolateral axis simultaneously. The BBS allows up to a 20 ° tilt of the foot on the platform, which allows the maximum stimulation of the mechanoreceptors of the ankle joint. It is a device that measures, in degrees, the inclination of each axis during dynamic conditions, and calculates an index of medial-lateral stability (MLSI), an anteroposterior stability index (APSI), and a global stability index (OSI) which is composed of MLSI and APSI. These indices are standard deviations from the evaluation of zero-point fluctuations on a set before the test, when the platform is stable. A high score indicates poor balance. To get the index of dynamic balance, a test for risk of falls was taken out, according to the

manufacturer's instructions. There are many possible varieties of BBS postural protocols, including the degree of instability of the platform, the arms being folded or free, one or two legs resting and with the eyes open or closed. In the current study, the participants were instructed to keep the vertical projection of their centre of gravity in the centre of the platform through the observation of a vertical screen located 30 cm in front of their face. Each trial was 20 seconds long, with rest periods of 10 seconds between trials. All tests were performed while participants were barefoot on the platform, in a fit of constant instability (Level 8), with open eyes.

FM patients have impaired HRQOL. In this thesis, two specific questionnaires were used to measure this function in these patients, including the Fibromyalgia Impact Questionnaire (FIQ) and the 15-D Questionnaire (15-D).

The aim of this thesis report is to assess the influence of WBV therapy and its effects on the dynamic balance, the quality of life related to health, the single-leg balance, pain, strength and the somatosensory system in patients with fibromyalgia.

The sample that participated in the studies included in this thesis is composed of 41 women with FM, who met the diagnostic criteria of the American College of Rheumatology (ACR) (1990).

The main results of this thesis suggest that memory of WBV therapy is a reliable and useful proposal to increase the dynamic balance in women with FM (Study I). Differences in dynamic balance indices were

## SUMMARY AND CONCLUSIONS

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predicted by the following the linear model:  $(0.027 \times \text{weight}) - (0.800 \times \text{dynamic balance at baseline}) - (0.632 \times \text{group})$  (Study I), there was an increase of 12% in the results of HRQOL as measured by the FIQ but not significant results verify the dimensions of the 15-D (study II). As far as the static balance is concerned there was an increase of 57.1% in OSI and 66.6% in APSI (study III). We verify a generalized decrease of 23.5% in general pain and of 40% in the knees pain (study IV), the concentric extension and flexion strength increased over 19% compared to baseline (study IV) and the balance with closed eyes suffered a 25% gain in the OSI and 40% in the APSI (study IV). While study IV is not a merit of the thesis yet and it hasn't been published yet, being the process of review in the journal Arthritis Care & Research, we believe that the results obtained in this study are of extreme importance in the management of FM.

In conclusion, this thesis provides new knowledge about the implementation and effects of WBV on some of the determinants of FM management.

### **Hypothesis 1**

The WBV therapy proposed with 12,5Hz of lateral vibration intensity is applicable and effective in improving the dynamic balance in patients with FM.

### **Hypothesis 2**

The improvement with the therapy based on WBV with 12,5Hz of lateral intensity is associated with improvements in HRQL in patients with FM.

### **Hypothesis 3**

Improvements in static unipodal balance of FM patients are due to the application of a therapy based on lateral WBV with 12,5Hz of intensity, there is a relationship between the data obtained with falls in the last year and the HRQL in patients with FM.

### **Hypothesis 4**

WBV therapy with intensity lateral of 12,5Hz improves the neuromuscular system performance (strength) and somatosensory (balance with eyes closed) and decreases knees pain and general pain in patients with FM.

### **Conclusions**

1. The proposed WBV program, which utilized a tilt platform with low frequency (12.5 Hz) antero-posterior vibration, is useful and applicable for improving the dynamic balance of women with FM (*study 1*).
2. A 12-week course of tilting WBV was a feasible intervention that prevented the loss of HRQoL in previously physically untrained women with FM (*study 2*).
3. A 12-week tilting WBV program improved static balance in persons with FM (*study 3*).
4. Twelve weeks of tilting whole body vibration therapy 3 times a week, with a frequency of 12.5 Hz, had a positive effect on muscle strength, the somatosensory system and pain in women with fibromyalgia (*study 4*).

## **XVI. SUMÁRIO E CONCLUSÕES**

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A fibromialgia (FM) é um síndrome que está aliado com outros sintomas, tais como: a dor crónica, falta de força muscular e problemas de equilíbrio, todos estes factores estão geralmente associados com problemas de ansiedade e depressão, afetando de forma bastante significativa a qualidade de vida relacionada com a saúde (QVRS) desses pacientes.

Nos últimos anos tem havido bastante interesse no estudo de uma metodologia de treino baseado nas vibrações mecânicas, WBV pela sua sigla em inglês. O WBV tem sido aplicado a diversas populações, tais como: atletas, população geral, idosos ou pacientes com variadas doenças. O treino com vibração é geralmente realizado com instrumentos especializados. Um dos mais usados é uma plataforma horizontal que vibra em função de um eixo central para permitir que o lado direito baixe quando o lado esquerdo sobe e vice-versa, sendo os pés colocados a uma distância igual desse eixo.

Sabendo que a força é um preditor da função física e da QVRS nas doenças reumáticas, e sabendo que as pessoas com FM têm um déficit de força muscular em comparação com pessoas saudáveis, envolvemos na avaliação da força muscular de pernas em pessoas com FM. O dinamómetro isocinético é um instrumento bastante fiável para medir esse parâmetro e tem sido o instrumento usado para medir a força neste colectivo de pessoas. Vários estudos têm utilizado dinamómetros similares para quantificar o déficit de força em diferentes populações, bem como para avaliar os efeitos de vários programas de treino ou terapias

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relacionados com a força muscular. Os estudos da tese de doutoramento do Dr. José Carmelo Adsuar Sala foram os primeiros a usar um dinamómetro isocinético para avaliar a fiabilidade test-r-test em pacientes com FM.

O sentido do equilíbrio seja ele estático ou dinâmico, ou seja, aqueles sentimentos que nos informam em todo o momento da posição de nossa cabeça em relação ao espaço tridimensional em que nos movemos, também está afetada nos pacientes com FM. O equilíbrio dinâmico (ED) é o que mantém nosso corpo em equilíbrio ao executar movimentos de rotação e aceleração. O equilíbrio estático (EE), é o que mantém o corpo equilibrado quando permanece imóvel ou se move em linha reta. O sistema de equilíbrio Biodeix Balance (BBS), (Biodeix, EUA), tem sido usado para avaliar e treinar a estabilidade postural e equilíbrio postural. É um dispositivo multi-axial que mede e registra objetivamente a capacidade do indivíduo para estabilizar uma articulação afetada por uma força dinâmica. É uma plataforma circular que se move livremente sobre os eixos ântero-posterior e meio-lateral de forma simultânea. A BBS permite uma inclinação do pé de até 20°, o que permite a máxima estimulação dos mecanorreceptores da articulação do tornozelo. É um aparelho que mede, em graus, a inclinação de cada eixo durante condições dinâmicas, e calcula um índice de estabilidade meio-lateral (MLSI), um índice de estabilidade antero-posterior (APSI), e um índice de estabilidade global (OSI), que é composto pelos dois índices: MLSI e APSI. Estes índices são os desvios-padrão a partir da avaliação das

flutuações do ponto zero estipulado antes do teste, quando a plataforma está estável. Uma pontuação alta indica falta de equilíbrio. Para obter o índice de equilíbrio dinâmico, existe um teste ao qual se lhe deu o nome de “risco de quedas”, e está estipulado de acordo com as instruções do fabricante. A BBS possui numerosos protocolos de estabilidade postural, e permite controlar o grau de instabilidade da plataforma, além disso podem utilizar-se diferentes protocolos jogando com as posturas dos pacientes: braços cruzados ou livres, um ou 2 apoios, olhos abertos ou fechados, etc. No estudo atual, os participantes foram instruídos para manter a projeção vertical do seu centro de gravidade no centro da plataforma através da observação de um ecrã localizado a 30 cm do seu rosto. Cada ensaio foi de 20 segundos de duração, com períodos de descanso de 10 segundos entre series. Todos os testes foram realizados com os participantes descalços sobre a plataforma, e com um grau de instabilidade constante (Nível 8).

Os pacientes com FM geralmente têm afetada a sua QVRS. Nesta tese, utilizamos dois questionários específicos para medir essa função sendo eles o Fibromyalgia Impact Questionnaire (FIQ) e o Questionário de saúde de 15-Dimensões (15-D).

O objetivo desta tese foi avaliar a influência de uma terapia de WBV e os seus efeitos no equilíbrio dinâmico, na qualidade de vida relacionada com a saúde, no equilíbrio a uma só perna, na dor, na força e no sistema somatossensorial em pacientes com FM.

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A amostra utilizada nos estudos que compõem esta tese, é composta de 41 mulheres com FM, estando os pacientes de acordo com os critérios de diagnóstico do American College of Rheumatology (ACR) (1990).

Os principais resultados desta tese sugerem que a terapia de WBV proposta é fiável e útil para aumentar o equilíbrio dinâmico em mulheres com FM (estudo I). Diferenças nos índices de equilíbrio dinâmico se podem prever respeitando o modelo de regressão linear:  $(0.027 \times \text{peso}) - (0.800 \times \text{equilibrio dinâmico na linha base}) - (0.632 \times \text{grupo})$  (estudo I), houve um aumento de 12% nos resultados da QVRS medidos com o questionário FIQ, no entanto não se verificaram resultados significativos nas dimensões do questionário 15-D (estudo II). Quanto ao equilíbrio estático, houve um aumento de 57,1% no OSI e 66,6% no APSI (estudo III). Verifica-se uma diminuição de 23,5% da dor em geral e de 40% nos joelhos (estudo IV), força concêntrica em extensão e flexão aumentou mais de 19% em relação à linha de base (estudo IV) e o equilíbrio com os olhos fechados teve um incremento de 25% no OSI e 40% no APSI (estudo IV). O estudo IV ainda não é um mérito da tese visto que o mesmo ainda não foi publicado, estando este em processo de revisão na revista *Arthritis Care & Research*, decidimos divulgar os resultados deste artigo, porque acreditamos que os mesmos são de extrema importância na gestão da FM.

Em conclusão, esta tese fornece novos conhecimentos sobre a aplicação e os efeitos do WBV em aspectos determinantes para a FM.

### **Hipótese 1**

A terapia de WBV proposta com 12,5Hz de intensidade de vibração lateral é aplicável e eficaz na melhoria do equilíbrio dinâmico em pacientes com FM.

### **Hipótese 2**

As melhorias obtidas com a terapia de WBV, a 12,5Hz de intensidade lateral, estão associadas com uma melhoria da Qualidade de Vida Relacionada com a Saúde (QVRS) em pacientes com FM.

### **Hipótese 3**

Melhorias no equilíbrio estático unipodal dos pacientes com FM são devido à aplicação de uma terapia baseada em WBV lateral, com 12,5Hz de intensidade, e existe uma relação entre os dados obtidos, as quedas no último ano e a QVRS em pacientes com FM.

### **Hipótese 4**

A terapia de WBV com uma intensidade lateral de 12,5Hz melhora o desempenho do sistema neuromuscular (força), do sistema somatossensorial (equilíbrio com os olhos fechados) e diminui a dor de joelhos e as dores em geral nos pacientes com FM.

## **Conclusões**

1. O programa proposto de WBV, onde se utilizou uma plataforma basculante, com uma frequência baixa (12,5 Hz) e com aplicação da vibração de modo antero-posterior, é útil e aplicável para melhorar o equilíbrio dinâmico em mulheres com FM (*estudo 1*).

2. Podemos afirmar que a aplicação de uma terapia de 12 semanas de intervenção com WBV foi viável, evitando a perda da QVRS em mulheres com FM e fisicamente não treinadas (*estudo 2*).

3. Uma terapia de 12 semanas de WBV melhora o equilíbrio estático em pacientes com FM (*estudo 3*).

4. Doze semanas de uma terapia de vibração aplicada ao corpo inteiro, 3 vezes por semana, com uma frequência de 12,5 Hz, teve um efeito positivo na força muscular, no sistema somatossensorial e na dor em mulheres com FM (*estudo 4*).

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