TESIS DOCTORAL

Universidad de Granada

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EVALUACIÓN E INTERVENCIÓN DE TERAPIA OCUPACIONAL EN PERSONAS CON DOLOR CRÓNICO

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Granada, 2021

Editor: Universidad de Granada. Tesis Doctorales
Autor: María José Ariza Mateos
ISBN: 978-84-1117-206-6
URI: http://hdl.handle.net/10481/72365

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Granada, 1 de septiembre de 2021.

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ABREVIATURAS

ACT: Terapia de aceptación y compromiso

AINES: Antiinflamatorios no esteroideos

ANOVA: análisis de varianza

COPM: Medida de desempeño ocupacional canadiense

CSQ: Cuestionario de estrategias de afrontamiento

DPC: Dolor pélvico crónico

EAU: Asociación Europea de Urología

EVA: Escala visual analógica

FABQ-PA: subescala de actividad física del Cuestionario de creencias de evitación del miedo

GET: Terapia de exposición gradual

GnRHa: Hormonas agonistas liberadoras de la gonadotropina

IASP: Asociación Internacional para el Estudio del Dolor.

ICS: *International Continence Society*

IPAQ: Cuestionario internacional de actividad física

LUNA: Ablación laparoscópica de los ligamentos uterosacros

MPA: Acetato de medroxiprogesterona

MT: Terapia manual

PCS: Síndrome de congestión pélvica

PTNS: Estimulación nerviosa tibial percutánea

RCOG: *Royal College of Obstetricians and Gynecologist*

SCS: Estimulación de la médula espinal

SDPC: Síndrome del dolor pélvico crónico

SNC: Sistema nervioso central

SNM: Neuromodulación sacra

SNP: Neuromodulación pudenda

TCC: Terapia cognitivo-conductual

tDCS: Estimulación transcraneal

TENS: Estimulación nerviosa eléctrica transcutánea

TRH: Terapia de reemplazo hormonal

RESUMEN

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Esta tesis doctoral aporta una perspectiva novedosa en el abordaje del dolor crónico basada en el enfoque biopsicosocial, concretamente en el dolor pélvico crónico, llegando a formar parte de las estrategias terapéuticas dentro del ámbito de la terapia ocupacional.

El dolor crónico es una experiencia sensorial y emocional negativa asociada a un daño tisular actual o potencial con una duración superior a 3 meses. Se asocia con unos índices muy elevados de prevalencia a nivel mundial y supone enormes costes para el sistema sanitario. La mayoría de los tratamientos están dirigidos a mitigar el dolor, sin embargo, el dolor crónico se encuentra fuertemente ligado a un impacto psicosocial, generando malestar emocional, alteración comportamental y deterioro funcional en las personas que lo sufren. En el caso del dolor pélvico crónico, este impacto se exacerba por su elevada complejidad, su carácter multidimensional, el retraso en el diagnóstico y la falta de protocolo asistencial. Por ello, el objetivo de esta tesis doctoral fue evaluar la eficacia terapéutica de diferentes intervenciones basadas en un enfoque biopsicosocial desde la terapia ocupacional en personas con dolor crónico, y sus efectos a largo plazo.

En el primer ensayo clínico se aplicó la terapia de exposición gradual a la actividad añadida a la terapia manual en comparación a la terapia manual sola, con mejoras sustanciales en cuanto al mantenimiento de las mejoras en el comportamiento relacionado con el dolor y el funcionamiento físico, con la finalidad de evitar el miedo al movimiento por dolor a largo plazo en mujeres con dolor pélvico crónico.

El segundo ensayo clínico incluyó una intervención centrada en la complejidad del paciente mostrando que las mujeres con dolor pélvico crónico obtuvieron mejoras significativas en la calidad de vida relacionada con la salud, los comportamientos de afrontamiento, el

dolor, el desempeño ocupacional percibido y los niveles de actividad, en comparación con las mujeres que recibieron un folleto informativo acerca del dolor, la actividad física, el miedo al movimiento, las falsas creencias y el estilo de vida activo.

Ante la situación actual, en la que las estrategias terapéuticas han girado su mirada hacia intervenciones de telemedicina, se desarrolló una revisión sistemática en la que observamos que las intervenciones basadas en nuevas tecnologías, que incluyen la terapia cognitivo-conductual y/o psicoeducativa, podrían ser útiles en el tratamiento de mujeres con dolor crónico. Sin embargo, la mayoría de los ensayos incluidos tenían un alto riesgo de sesgo. Por lo tanto, es necesario el desarrollo de ensayos clínicos controlados cuya calidad metodológica sea mayor y poder, de este modo, afirmar que las intervenciones basadas en el uso de internet pueden superar las limitaciones actuales de la atención presencial tradicional.

De forma global, nuestros resultados apuntan a la necesidad de un abordaje biopsicosocial multimodal centrado en el paciente con dolor crónico, que contemple medidas dirigidas a la mejora de la calidad de vida y el bienestar emocional, como complemento del tratamiento convencional. La mayoría de las personas con dolor crónico desconocen cómo afrontar su dolor y sus miedos, y a menudo recurren a estrategias desadaptativas que empeoran su condición. Por esta razón, es muy importante que los programas de intervención en el dolor crónico incluyan un componente biopsicosocial para que las personas aprendan a gestionar su dolor.

INTRODUCCIÓN

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1. DOLOR PÉLVICO CRÓNICO

La Asociación Internacional para el Estudio del Dolor *(International Association for the Study of Pain, IASP)* definió el dolor crónico como una experiencia sensorial y emocional displacentera asociada a un daño tisular actual o potencial con una duración mayor de 3 ó 6 meses[1]. Esta definición ha sido empleada por diversos autores como referente en la descripción del dolor crónico[2-4]. Existe un consenso limitado acerca de la duración del dolor crónico[2], ya que algunos estudios defienden una duración mayor de 3 meses[5, 6] y otros a partir de 6 meses[7, 8].

El dolor crónico se encuentra entre las condiciones de salud más costosas en el mundo desarrollado con una prevalencia mundial estimada entre el 20-30%[9, 10]. Esta condición afecta aproximadamente al 20% de la población europea, siendo más frecuente en mujeres, personas de edad avanzada y bajo estatus socioeconómico. Así mismo, depende de los antecedentes geográficos y culturales, la situación laboral y los factores ocupacionales, y las historias de abuso o violencia interpersonal[10].

El síndrome de dolor pélvico crónico (DPC) se ha definido de múltiples formas. El *Royal College of Obstetricians and Gynaecologists (RCOG)* describe el DPC como "dolor intermitente o constante en la parte inferior del abdomen o pelvis de al menos 6 meses de duración, que no ocurre exclusivamente con la menstruación o el coito y no está asociado con el embarazo". El *American College of Obstetricians and Gynaecologists* considera el DPC como "dolor no cíclico de al menos 6 meses de duración que aparece en lugares como la pelvis, la pared abdominal anterior, la espalda baja o los glúteos, y es lo suficientemente grave

como para causar discapacidad o conducir a la atención médica"[11]. La mayor parte de los estudios epidemiológicos se refieren a DPC como "dolor abdominal inferior cíclico o no cíclico de al menos 6 meses de duración, que no está relacionado con el embarazo y no se debe exclusivamente a la dismenorrea o dispareunia"[12].

Los diferentes términos empleados siguen las recomendaciones actuales de la *International Continence Society (ICS)*, basadas en la estructura de clasificación de la IASP[13].

Tabla 1. Clasificación del SDPC de la IASP (adaptación al castellano)[13].

<table>
<tr><th colspan="4">SÍNDROME DE DOLOR PÉLVICO</th></tr>
<tr><td rowspan="8">Urológico</td><td colspan="2">Síndrome de dolor de vejiga</td><td>Cistitis intersticial</td></tr>
<tr><td colspan="3">Síndrome de dolor uretral</td></tr>
<tr><td colspan="3">Síndrome de dolor de pene</td></tr>
<tr><td colspan="3">Síndrome de dolor de próstata</td></tr>
<tr><td rowspan="3">Síndrome de dolor escrotal</td><td colspan="2">Síndrome de dolor testicular</td></tr>
<tr><td colspan="2">Síndrome de dolor post-vasectomía</td></tr>
<tr><td colspan="2">Síndrome de dolor epididimario</td></tr>
<tr><td rowspan="5">Ginecológico</td><td colspan="3">Síndrome de dolor asociado a endometriosis</td></tr>
<tr><td colspan="3">Síndrome de dolor vaginal</td></tr>
<tr><td rowspan="3">Síndrome de dolor vulvar</td><td colspan="2">Síndrome de dolor vulvar generalizado</td></tr>
<tr><td rowspan="2">Síndrome de dolor vulvar localizado</td><td>Síndrome de dolor vestibular</td></tr>
<tr><td>Síndrome de dolor clitorial</td></tr>
<tr><td rowspan="3">Anorrectal</td><td colspan="3">Proctalgia fugaz</td></tr>
<tr><td colspan="3">Síndrome de dolor anorrectal</td></tr>
<tr><td colspan="3">Anismo</td></tr>
<tr><td>Neurológico</td><td colspan="3">Síndrome de dolor pudendo</td></tr>
</table>

Muscular	Síndrome de dolor perineal
	Síndrome de dolor del músculo del suelo pélvico
Ejemplos de condiciones bien definidas que produce el dolor	
Urológico	Cistitis infecciosa
	Prostatitis infecciosa
	Uretritis infecciosa
	Epidídimo-orquitis infecciosa
Ginecológico	Endometriosis
Anorrectal	Proctitis
	Hemorroides
	Fisura anal
Neurológico	Neuropatía pudenda
	Patología de la médula espinal sacra
Otros	Vascular
	Cutáneo
	Psiquiátrico

Es posible que esta condición se plantee mejor desde un punto de vista psicosocial. La enfermedad orgánica, las creencias de la persona, sus estrategias de afrontamiento y las interacciones sociales influyen en la experiencia de dolor. Como consecuencia, el DPC puede causar discapacidad, afectando a la función en el trabajo, en las actividades de la vida diaria, en los roles y en las relaciones sociales[14, 15].

1.1. Epidemiología y cifras de interés

La prevalencia del DPC en la población femenina de todo el mundo es del 6-27%, siendo comparable con la prevalencia global de asma (4,3-8,6%) y de dolor lumbar (23,2 ± 2,9%)[11, 16]. Se estima que un 12% de las mujeres en edad reproductiva y un 3,8% de las mujeres a cualquier edad experimentan dolor crónico en la zona inferior de la pelvis[17]. Esta condición supone más del 25% de las consultas médicas[14]. Algunos estudios han reportado las tasas de prevalencia de la DPC de algunos países, siendo del 6,4% en Méjico, 25,4% en Nueva Zelanda, 14,7% en Estados Unidos, 24% en Reino Unido, 21,5% en Australia, 5,2% en India, 43,2% en Tailandia y 8,8% en Pakistán[11, 12].

Los científicos sugieren que el 14% de las mujeres experimentarán dolor pélvico por lo menos una vez en la vida, el 15% de las mujeres lo sufrirán durante un año, y el 33% tendrán que vivir con este dolor durante el resto de su vida[18, 19]. Se estima que la duración media del DPC es de 2,5 años[20].

Probablemente, la prevalencia del DPC también puede estar influenciada por las posibles causas del mismo, de manera que la endometriosis supondría el 11% de los casos de DPC[19], el dolor miofascial del suelo pélvico queda estimado en un 9-24% de los casos[21], la vulvodinia representaría entre el 8,3% y el 16%[22], y la cistitis intersticial entre 1,2-4,5% de cada cien mil casos de DPC[23]. En relación al DPC también se ha estimado la prevalencia de los trastornos de dismotilidad (50-80%), trastornos musculoesqueléticos (30-70%), problemas urológicos (5-10%) y diagnósticos múltiples (30-50%)[24]. Por otro lado, no existe evidencia científica que correlacione el DPC con el número de embarazos, de partos, el grupo étnico o el nivel educativo[19].

Además, se han encontrado correlaciones entre el DPC y el consumo de drogas, alcohol, abortos espontáneos, menstruaciones muy dolorosas, cesáreas previas, alteración de los patrones posturales y comorbilidades

psicológicas[15, 25]. El 60% de las mujeres con DPC presentan trastornos psicológicos, hallándose una gran prevalencia de depresión (25-50%), de trastornos somatomorfos (10-20%), de ansiedad (10-20%) y diagnósticos psicológicos múltiples (20-30%)[24].

Además del impacto psicológico, es importante destacar el enorme impacto psicosocial asociado al DPC, ya que gran parte de los pacientes sufren aislamiento social y efectos negativos en sus relaciones sociales[15, 24]. Por lo general, el DPC provoca efectos devastadores en la calidad de vida de las personas, reportando menores puntuaciones en los valores de salud física general que las personas sin dolor[15]. Adicionalmente, tiene una alta incidencia de comorbilidad, fatiga y trastornos de sueño. El 41% de las mujeres con este dolor no acuden al médico hasta pasado el año, lo que sugiere que la mayoría están haciendo frente a su condición sin contar con el sistema sanitario[15].

Los diagnósticos más comunes en el DPC son el síndrome del colon irritable (19,8%), el estrés (9,5%), los quistes ováricos (8,4%), la endometriosis (7,4%), la cistitis (7,2%), la enfermedad inflamatoria pélvica (6,5%), el estreñimiento (6,5%), el dolor de espalda (5,7%), los fibromas uterinos (5,1%), las adherencias (4,6%), apendicitis (2,5%), la enfermedad inflamatoria intestinal (2,1%). El resto de diagnósticos suponen solo el 12,2% de los casos[12].

El impacto económico asociado al DPC es bastante elevado. En EEUU se estiman unos costes directos e indirectos asociados al DPC de más de 3 mil millones de dólares anuales. En Reino Unido, los costes que supone la atención del DPC al Servicio Nacional de Salud son aproximadamente de 326 millones de dólares anuales. El DPC supone el 40% de las laparoscopias ginecológicas, lo que constituye la derivación más frecuente a los servicios de salud de la mujer[12, 14]. Además de los gastos en atención sanitaria, el DPC también tiene un gran impacto en la productividad y en el absentismo laboral, ya que disminuye la capacidad

de trabajo y puede provocar la pérdida de días de trabajo. Este hecho representa del 15 al 45% de las mujeres afectadas en EEUU. El 13-32% de las mujeres con esta condición pierden repetidamente su trabajo. Otro aspecto económico a tener en cuenta es que el 45-64% de las mujeres con DPC sufren la disminución de la fertilidad, que supone un coste de aproximadamente 65 mil millones de dólares[11, 12].

Por lo tanto, la prevalencia del DPC es bastante elevada en todo el planeta; es una condición incapacitante que afecta a la calidad de vida de las personas que lo sufren; conlleva un enorme impacto económico, ya que supone elevados costes, tanto directos como indirectos; y en la mayoría de los casos no existe un diagnóstico médico.

1.2. Etiología

La etiología del DPC no ha sido definida ni aclarada completamente. En un intento de aclarar las posibles causas, el *RCOG* ha realizado una clasificación de los diferentes factores etiológicos que provocan el dolor, dividiéndolos en ginecológicos y extra-ginecológicos. Los ginecológicos incluyen la endometriosis/adenomiosis, el síndrome de congestión pélvica, los fibromas uterinos, los tumores ováricos y la enfermedad inflamatoria pélvica. Y dentro de los factores extra-ginecológicos se encuentran las cirugías colindantes y los problemas urológicos, gastrointestinales, neuromusculares y psicosomáticos[17].

Endometriosis/Adenomiosis

Tanto la endometriosis como la adenomiosis son afecciones muy frecuentes en personas con DPC. Son enfermedades ginecológicas que se caracterizan por la presencia de tejido endometrial en lugares que no son fisiológicamente los apropiados[26]. La endometriosis consiste en la presencia de tejido endometrial fuera del útero, mientras que la adenomiosis se distingue por la presencia de glándulas endometriales y

estroma en el interior del miometrio[27]. El desarrollo de ambas enfermedades depende de los niveles de estrógeno y progesterona[26].

La endometriosis afecta aproximadamente al 7-10% de las mujeres[28], mientras que la adenomiosis tiene una prevalencia entre 8% y 27%[29]. La incidencia de estas dos afecciones en mujeres en edad reproductiva (15-50 años) es de 0,14%[26].

Ambas son enfermedades crónicas inflamatorias que ocasionan graves consecuencias sintomatológicas y de fertilidad[30]. Entre los efectos que ocasionan estas afecciones destacan la dismenorrea, la dispareunia, la disquecia, el DPC, la infertilidad, la discapacidad, la disminución de la calidad de vida, del estado de salud y del rendimiento laboral[19, 24, 31, 32].

Síndrome de congestión pélvica (PCS)

El PCS fue descrito por primera vez en el siglo XIX como la presencia de la dilatación de las venas del útero y de los ovarios, acompañado del enlentecimiento del flujo sanguíneo y de dolor[33]. Es reconocido como un trastorno de la circulación venosa pélvica asociado a una de las posibles causas del DPC[34]. El 10% de todas las mujeres presentan venas varicosas, y el 60% de ellas sufren DPC. Aunque esta incidencia sea relativamente alta, es muy frecuente que el PCS no suela diagnosticarse correctamente[35].

Este síndrome puede ir acompañado de una gran variedad de síntomas, como la pesadez pélvica, la dismenorrea, la dispareunia, abdomen bajo y sensible, hinchazón bulbar, neuropatía, secreción vaginal, dolor lumbar, varices perivulvares, irritabilidad de la vejiga, malestar rectal, micción frecuente y trastornos psicosociales[34, 35].

Fibromas uterinos

Los fibromas uterinos, también conocidos como miomas o leiomiomas, son tumores benignos situados en el útero, constituidos por células benignas o neoplasias compuestas por células musculares lisas y fibroblastos, con gran cantidad de matriz extracelular[36]. Los fibromas uterinos son dependientes de los esteroides ováricos. Aunque su origen es desconocido, son considerados como tumores monoclonales que proceden de la mutación de una célula madre somática miometrial tras varios periodos de crecimientos seguidos de involución bajo la influencia hormonal[37]. Los fibromas uterinos se pueden clasificar en función de su relación anatómica con el miometrio y el endometrio, dividiéndose en tres categorías: fibroides submucosos, intramurales y subserosos[37].

La prevalencia de los fibromas uterinos depende de la edad, más común en mujeres en edad reproductiva; son más frecuentes en mujeres con ascendencia africana; y constituyen el 39% de todas las histerectomías que se realizan anualmente en EEUU[38]. Además, la prevalencia de fibromas aumenta en mujeres infértiles[37].

Muchas veces se detecta accidentalmente, y es que el 20-50% de las mujeres con fibromas son asintomáticas[38]. Los pacientes con sintomatología asociada pueden sufrir sangrado menstrual abundante o prolongado, anemia, aumento en el tamaño del útero, síntomas urinarios (micción frecuente, nicturia, retención urinaria), distensión abdominal, dolor lumbar, síntomas gastrointestinales (estreñimiento, diarrea), infertilidad y dispareunia[36, 39].

Tumores ováricos

Los tumores de ovario pueden ser benignos o malignos. Los tumores benignos son considerados quistes, sin embargo, no todos los quistes son tumores benignos. Pueden ser orgánicos o funcionales (quistes del folículo o del cuerpo lúteo). Pueden presentar complicaciones como la torsión

axial, la ruptura de quistes, la hemorragia intraquística, e incluso puede desencadenar en un síndrome compresivo[40].

Por otro lado, los tumores ováricos malignos son el quinto cáncer más letal del mundo, el séptimo cáncer más común y el tercer cáncer femenino más frecuente, seguido del cáncer de mama y de cuello de útero, con una incidencia de 10 a 15 mujeres de cada100 mil[41]. Se clasifican en tres grupos: tumores epiteliales, de células germinales y del cordón sexual/estromal. Los diferentes subtipos histológicos son el carcinoma seroso, el mucinoso, el endometrioide y el de células claras. Su etiología no se conoce, pero se asocia con la nuliparidad, la menarquia temprana y la menopausia tardía, mientras que el consumo de anticonceptivos orales, el embarazo y la lactancia se asocian con un menor riesgo de padecer cáncer de ovario. El factor de riesgo más común es el factor genético, que representa el 20% de los casos[42]. Los síntomas más frecuentes del cáncer de ovario son la distensión abdominal, el dolor pélvico o abdominal, dificultad para comer, urgencia o frecuencia urinaria, sangrado vaginal, dismenorrea y dispareunia[43, 44].

Enfermedad inflamatoria pélvica

La enfermedad inflamatoria pélvica es una infección polimicrobiana del tracto genital superior (el endometrio, las trompas de Falopio, los ovarios o el peritoneo pélvico) que suele afectar a mujeres jóvenes y sexualmente activas[45, 46]. Esta enfermedad se asocia con una gran variedad de complicaciones, como el DPC, la infertilidad, abscesos tubo-ováricos, embarazo ectópico, el sangrado postcoital, dispareunia y disuria[47].

La enfermedad inflamatoria pélvica es causada por el ascenso repentino de microbios desde la vagina o el cuello del útero hasta el endometrio, las trompas de Falopio y las estructuras

adyacentes. Aproximadamente, el 85% de estas infecciones son causadas por microbios asociados con la vaginosis bacteriana o patógenos cervicales de transmisión sexual. El 15% de los casos se producen por organismos entéricos que colonizan el tracto genital inferior[46]. *Mycobacterium tuberculosis, Chlamydia trachomatis* y *Neisseria gonorrhoeae* son los microorganismos más comúnmente implicados en esta infección[47].

Cirugías colindantes

Las intervenciones quirúrgicas en DPC pueden variar desde los enfoques conservadores (conservan la fertilidad), hasta las terapias extirpativas[48]. El dolor postquirúrgico crónico puede originarse después de cualquier procedimiento quirúrgico, siendo muy común tras la cirugía abdominal y pélvica, con una prevalencia de entre el 10% y el 40%. Esto probablemente ocurra a causa de la combinación del daño a los nervios y tejidos, y las modificaciones en el procesamiento central del dolor[49]. Y es que, aunque la entrada periférica del daño tisular local pueda dar lugar a la respuesta nociceptiva primaria, con el paso del tiempo el sistema nervioso central puede quedar sensibilizado[48].

Las cirugías abdominales y pélvicas forman parte de los principales factores de riesgo del DPC. Además, el papel del abordaje quirúrgico tiene resultados controvertidos. El leiomioma, las adherencias pélvicas, la adenomiosis y las varicosidades pélvicas son manifestaciones clínicas muy susceptibles del abordaje quirúrgico. La histerectomía se emplea cuando el tratamiento conservador falla, y se asocia con el éxito y la satisfacción del paciente; sin embargo, después de esta operación las mujeres pueden sufrir dispareunia persistente o dolor crónico en el ápice vaginal[48]. El tratamiento quirúrgico del DPC a partir de la endometriosis se consigue mediante la resección de las lesiones ectópicas o la extirpación de los ovarios[14]. La colocación de mallas vaginales sintéticas como una de las cirugías reconstructivas pélvicas se ha relacionado con

el DPC, debido a que puede producir espasmos musculares del suelo pélvico, neuralgia pudenda, dispareunia, erosión e infección[48].

En conclusión, el abordaje quirúrgico podría ser una solución para algunos problemas de DPC, pero dado el nivel de sensibilización central y las complicaciones asociadas, se cuestiona su eficacia en la práctica clínica.

Problemas urológicos

Los problemas urológicos asociados al DPC incluyen la cistitis intersticial, la inflamación urinaria crónica, la urolitiasis y el síndrome de uretra[17]. La cistitis intersticial es considerada como una afección crónica de la vejiga que cursa con dolor y síntomas del tracto urinario, como la frecuencia y urgencia urinaria[50]. La enfermedad litiásica se caracteriza por la formación de urolitos (piedras) en el tracto urinario y afecta al 10-12% de las personas en países desarrollados[51, 52]. El síndrome de uretra consiste en la aparición de dolor en la zona uretral de forma episódica persistente o recurrente, normalmente durante el vaciado con frecuencia diurna y nocturna[53].

Problemas gastrointestinales

Los problemas gastrointestinales relacionados con el DPC son el síndrome del intestino irritable, el estreñimiento y las enfermedades inflamatorias del intestino[17].

El síndrome del intestino irritable es un trastorno intestinal crónico y, en muchos casos es incapacitante. Se caracteriza por dolor abdominal (comúnmente con hinchazón) recurrente asociado a la defecación o al cambio en la frecuenta o forma de las deposiciones, y al estreñimiento y diarrea[54].

La enfermedad inflamatoria crónica incluye la enfermedad de Crohn, la colitis ulcerosa y la colitis indeterminada. Constituye un trastorno

heterogéneo con antecedentes genéticos, microbiota y otros factores ambientales[55]. La enfermedad de Crohn es una enfermedad sistémica recidivante que afecta al tracto gastrointestinal con trastornos inmunitarios asociados y manifestaciones gastrointestinales; cursa con dolor abdominal, diarrea crónica, fatiga y pérdida de peso[56, 57]. La colitis ulcerosa es una inflamación crónica del colon, cuya respuesta inmune no está clara, y sus factores de riesgo son los genéticos, ambientales y alimenticios. Cursa con hematoquecia (sangre en las heces), dolor abdominal y diarrea. En comparación con la enfermedad de Crohn, la colitis ulcerosa se limita a la inflamación de la mucosa del colon[58]. La colitis indeterminada es una enfermedad inflamatoria de la mucosa cuyas manifestaciones clínicas no se pueden distinguir de la enfermedad de Crohn ni de la colitis ulcerosa[59].

Alteraciones musculoesqueléticas y neuromusculares

Las alteraciones neuromusculares asociadas al DPC se pueden clasificar en función de su origen como alteraciones miofasciales, esqueléticas y neurológicas[60].

Las alteraciones miofasciales cursan con una variedad de diagnósticos, como el síndrome del músculo elevador del ano, las mialgias por tensión, el síndrome de dolor miofascial de músculos extrínsecos asociados (aductor, piriforme e iliopsoas), disinergia de los músculos del suelo pélvico, vaginismo, dispareunia, afecciones iatrogénicas (por ejemplo la infección por malla sintética).[61] El síndrome de dolor pélvico miofascial es una condición de mialgia con patrones de dolor localizado y referido[61]. Dado que el sistema nervioso regula la percepción del dolor, la sensibilización central y el dolor miofascial son una fuente de iniciación, aumento y perpetuación del dolor. Los puntos de activación sensibles a la palpación (puntos gatillo) que refieren el dolor más allá del tejido local y que se encuentran en bandas tensas de fibras musculares, se relacionan con el dolor miofascial. Por tanto, el dolor

miofascial incluye el dolor a la palpación del músculo, tanto local como referido; la presencia de un punto gatillo activo; la pérdida de la amplitud de movimiento del músculo; y la pérdida de función[62].

Entre las alteraciones esqueléticas asociadas al DPC destacan la insuficiencia pélvica, fractura por estrés, procesos sacroilíacos, asimetría pélvica, sinfisitis púbica, , separación de la sínfisis púbica, coccigodinia, enfermedad degenerativa del disco lumbar, espondilosis o espondilolistesis, artrosis de cadera, fractura de cadera, condrosis, displasia de cadera, compresión acetabular femoral, desgarros del labrum acetabular, necrosis avascular de la cabeza femoral y metástasis óseas[60].

Las enfermedades neurológicas más comunes en el DPC son la radiculopatía, la plexopatía, la neuropatía periférica, la neuropatía pudenda, la neuralgia sacral postherpética[60].

Otros

El origen del dolor puede ser explicado por el modelo biopsicosocial del dolor, cuya hipótesis sugiere la interdependencia entre los factores genéticos y ambientales que provocan cambios a largo plazo en los sistemas biológicos y psicológicos reguladores del dolor. Los factores estresantes y físicos son determinantes en el proceso de adaptación del dolor. Las demandas en el sistema de respuesta al estrés a largo plazo pueden moderar el procesamiento central del dolor e intervenir en las señales serotoninérgicas y noradrenérgicas descendentes del tronco cerebral, gestionando el procesamiento nociceptivo[63].

Entre los elementos causales del DPC se encuentran los trastornos psicosomáticos, tales como la ansiedad, depresión, trastornos de somatización, de estrés postraumático, disfunción psicosexual y abuso sexual[64].

Los científicos han demostrado que los estados de ánimo depresivos, los pensamientos catastróficos y el bajo nivel de apoyo social están muy relacionados con la gravedad del dolor y con una peor calidad de vida, y que la ansiedad y la depresión influyen en la amplificación del dolor central[65].

La evidencia científica ha demostrado la importancia del dominio de abuso como parte de los factores psicológicos que influyen en el DPC, especialmente el historial de abuso físico y sexual; que forman parte de la vorágine de angustia, depresión, ansiedad y trastornos psicosomáticos determinantes en el DPC[12].

En resumen, existen claros indicios que confirman la fuerte asociación entre los factores somáticos y psicosociales que intervienen en la gravedad de los síntomas y la calidad de vida de las personas con DPC[65]

1.3. Abordaje terapéutico

En la práctica clínica existen dos enfoques de tratamiento del DPC: el tratamiento del dolor en sí mismo y el tratamiento de enfermedades o trastornos que podrían ser los causantes del dolor. Estos enfoques de tratamiento no se excluyen mutuamente, e incluso a veces se combinan para conseguir una mayor eficacia terapéutica[66].

El objetivo del tratamiento consiste en maximizar la calidad de vida y la función general de la persona, haciendo énfasis en involucrar al paciente en el proceso de autogestión[16]. A diferencia del dolor agudo, el dolor crónico requiere la aceptación del concepto de manejo del dolor en lugar de curación del dolor[66].

La terapia basada en la evidencia para el DPC es limitada y, normalmente solo se centra en el alivio de los síntomas[16]. Un dolor después de 4 a 6 meses puede convertirse en una enfermedad y, por lo tanto, las personas con DPC sufren una enfermedad, no un síntoma[66]. Y

como cualquier enfermedad evidente debe tratarse, aunque el tratamiento dirigido no resulte en una resolución del dolor[16].

Las causas y consecuencias del dolor pueden incluir una gran variedad de mecanismos, con lo cual el tratamiento requiere la aplicación de un enfoque holístico que aborde adecuadamente los componentes físicos, psicológicos, comportamentales y sexuales. Los tratamientos pueden incluir un abordaje farmacológico y/o no farmacológico[16, 67].

1.3.1. Tratamiento farmacológico

El tratamiento farmacológico pretende abordar la causa subyacente al dolor pélvico y se administra con el objetivo de aliviar la sintomatología[16]. Este tipo de tratamiento se fundamenta en que la recepción y transmisión del dolor involucra determinados enlaces neuronales y neurotransmisores, lo que facilita la interrupción o disminución de la transmisión de información nociceptiva y, por tanto, que la persona perciba un alivio en el dolor[66].

El abordaje farmacológico para el DPC incluye los analgésicos, la supresión hormonal, los antidepresivos y los estabilizadores de membrana que, a menudo suelen mejorar los componentes de amplificación del dolor periférico y central del dolor ginecológico. Sin embargo, también son muy comunes los síntomas residuales asociados a ese tratamiento farmacológico, lo que repercute en la calidad de vida de la persona afectada[68].

Analgésicos y antiinflamatorios no esteroideos (AINES)

Los analgésicos tradicionales, los AINES y el paracetamol constituyen la primera línea de tratamiento farmacológico contra el dolor. Estos medicamentos son versátiles, se pueden emplear solos o combinados con otros medicamentos[69]. Además, son accesibles, económicos, bien tolerados, con efectos secundarios limitados y existen abundantes datos que respaldan su eficacia[70]. Sin embargo, los AINES y el paracetamol no han demostrado proporcionar suficiente eficacia en el abordaje del DPC[67]. Especialmente, parece ser que los AINES no son eficaces para tratar el DPC relacionado con la endometriosis[16], pero sí para el tratamiento de la dismenorrea. El consumo de AINES se asocia al riesgo de padecer efectos adversos en el sistema renal, hepático, cardiovascular y gastrointestinal[69].

Los analgésicos opioides son aceptados en episodios de dolor agudo y de dolor relacionado con el cáncer o el cuidado paliativo al final de la vida. Su eficacia en el tratamiento del dolor crónico no relacionado con el cáncer (incluido el DPC) no ha sido concluyente, y coincide en que los beneficios del uso prolongado de opioides en el dolor crónico no asociado al cáncer son compensados por los riesgos[70]. Los pacientes, a menudo presentan tolerancia o dependencia, al igual que efectos adversos, tales como hiperalgesia, estreñimiento, náuseas, vómitos, estado mental alterado, sedación, depresión respiratoria, hipogonadismo, prurito y mioclonías[67, 70]. Aunque son considerados como excelentes analgésicos, el riesgo de padecer efectos secundarios es elevado, debiendo mostrarse especial precaución en mujeres en edad reproductiva con DPC[69].

Supresión hormonal

La supresión hormonal constituye un tratamiento de primera línea para el DPC, especialmente en endometriosis o en cualquier causa de dolor pélvico con menstruaciones exacerbadas. El objetivo de este tratamiento

consiste en la inducción de amenorrea u oligomenorrea, o en el alivio sintomático de la dismenorrea[69]. La mayor parte de la literatura presta especial atención al dolor asociado con la endometriosis y la dismenorrea, asegurando el éxito de la supresión hormonal en la reducción de los síntomas[70].

Las hormonas esteroideas sexuales intervienen en muchos sitios del cuerpo humano, incluido el sistema nervioso central y periférico, siendo capaz de repercutir en la experiencia del dolor, tanto a nivel local como central. Por tanto, la sintomatología que refleja variaciones clínicas puede ser sensible al tratamiento hormonal, incluso si el origen no es ginecológico. La elección del tratamiento hormonal apropiado debe realizarse junto con el paciente, ya que las creencias o malentendidos acerca de la menstruación pueden hacer imposible el cumplimiento de los regímenes de amenorrea[71].

La supresión hormonal ha conseguido tradicionalmente mediante la combinación de píldoras anticonceptivas orales de estrógeno y progesterona[70]. El uso de anticonceptivos orales se considera el tratamiento médico de primera línea para el DPC relacionado con la endometriosis. Inhibe la producción de estrógeno gonadal mediante un sistema de retroalimentación negativa y, como suprime la actividad ovárica, también desciende la producción de prostaglandinas inducidas por estrógenos, aliviando la inflamación de la endometriosis[72].

Las hormonas agonistas liberadoras de la gonadotropina (GnRHa) reducen la liberación de la hormona luteinizante y la foliculoestimulante, provocando una disminución de la función ovárica, dando lugar al hipogonadismo hipogonadotrópico y amenorrea[70]. Sin embargo, la amenorrea se ha asociado con multitud de efectos secundarios, como la atrofia vaginal, síntomas vasomotores y trastornos del sueño[69].

Los andrógenos también regulan la liberación de la hormona luteinizante y foliculoestimulante, lo que produce un estado

hipoestrogénico y atrofia del endometrio. También provoca amenorrea, resultando en una mejoría de la dismenorrea y de los síntomas del DPC. Los efectos segundarios de los andrógenos son la aparición de acné, edema y aumento de peso[69].

El sistema intrauterino liberador de levonorgestrel (Mirena) disminuye la aparición de dismenorrea si se aplica después del tratamiento laparoscópico de la endometriosis, pero se asocia con un alivio del dolor a corto plazo e insatisfacción a causa de los efectos adversos de la progesterona[16].

En mujeres con DPC también se suelen emplear el acetato de medroxiprogesterona (MPA) y la terapia de reemplazo hormonal (TRH) [70, 71]. Cada vez los pacientes están optando más por el uso de métodos alternativos de administración, como los implantes, dispositivos intravaginales, intrauterinos e inyecciones intramusculares[70].

Antidepresivos

Los antidepresivos tricíclicos se emplean en el tratamiento de diversas condiciones de dolor crónico[70]. Su mecanismo de acción consiste en incrementar los niveles de norepinefrina y de serotonina a través de la inhibición de la recaptación. Al parecer, la disfunción del sistema modulador del dolor descendente tiene gran importancia en la sensibilidad al dolor y en el mantenimiento del dolor crónico. Se cree que ese aumento de norepinefrina y serotonina en las vías moduladoras del dolor descendente disminuye la sensibilidad al dolor[69]. El uso de los antidepresivos está condicionado por los efectos adversos anticolinérgicos (fatiga, sequedad de boca y estreñimiento) que, a menudo interrumpen su uso[69, 70]. Existen pocos datos sobre su eficacia en DPC, pero los resultados que se han obtenido en muchos pacientes con DPC han sido muy beneficiosos para los síntomas relacionados con el dolor[69].

Fármacos estabilizadores de membrana

La gabapentina y la pregabalina son bloqueadores de los canales de calcio y reducen la recaptación de norepinefrina, glutamato y sustancia P. En su función como estabilizadores de membrana pretenden reducir la hiperexcitabilidad del sistema nervioso central y periférico. Su uso es común en pacientes con dolor neuropático, aunque también se emplea en dolor musculoesquelético primario (como la fibromialgia). Los datos acerca de su eficacia en DPC son limitados, pero se han encontrado mejoras significativas en los síntomas asociados al dolor[69].

Los bloqueadores de los canales de sodio, fenitoína oxcarbazepina, carbamacepina, tigabina, lamotrigina y topiramato también son empleados frecuentemente en el tratamiento del dolor neuropático. Su objetivo es reducir la excitabilidad de la membrana neuronal y disminuir el impulso espontáneo de las neuronas sensoriales[73].

La toxina botulínica A se emplea a modo de inyección en los puntos de activación del abdomen para aliviar el dolor a largo plazo. Este fármaco induce parálisis muscular local temporal y es probable que reduzca los mediadores de la inflamación neurogénica. El bloqueo nervioso con esta toxina puede ser diagnosticado y tratado en varias patologías, como el dolor tras la histerectomía por el daño a un nervio genitofemoral o ilioinguinal, la lesión del nervio pudendo del parto o una operación vaginal[74].

1.3.2. Intervenciones quirúrgicas

La intervención quirúrgica adecuada requiere un diagnóstico apropiado. Los errores procedentes del diagnóstico provienen de la presunción de que el DPC es de origen ginecológico/reproductor, cuando puede proceder del resto de categorías[75]. Frecuentemente los cirujanos ginecológicos se encuentran con personas con DPC porque, tanto los proveedores de atención médica remitentes como los propios pacientes anticipan que la cirugía es la solución definitiva[68]. Sin embargo, en ocasiones los procesos quirúrgicos suponen un factor de riesgo que origina o agrava la condición del paciente con dolor crónico. Y muchas mujeres con DPC han sido sometidas a una segunda cirugía, lo que incrementa el riesgo de complicaciones[71].

Las intervenciones quirúrgicas más empleadas son la histerectomía[76], la ablación laparoscópica de los ligamentos uterosacros (LUNA) [77], la cistectomía, la neurectomía presacra, la escisión, la ablación endométrica[78], la miomectomía[79], la adhesiolisis[80, 81], la ooforectomía bilateral[82], la embolización o escleroterapia de las venas pélvicas[83]. La mayoría de estas intervenciones se realizan a través de laparoscopia, por lo que se han reducido las complicaciones resultantes de la cirugía.

Los tratamientos quirúrgicos que incluyen la histerectomía, la extirpación de la endometriosis, la adhesiolisis y la neurectomía presacra parecen proporcionar alivio a determinados pacientes[84]. La histerectomía es el último recurso dada su alto nivel de morbilidad y beneficio limitado. La mitad de las mujeres con sensibilidad uterina en la valoración pélvica obtienen mejoras en la salud física, mental y en el funcionamiento social tras someterse a la histerectomía. Sin embargo, la otra mitad tienen dolor persistente o empeoramiento del dolor[16]. En mujeres que son operadas de endometriosis, las intervenciones laparoscópicas son preferibles a la laparotomía cuando se emplea de manera conservadora a través de la ablación o escisión de las lesiones.

La neurectomía presacra parece ser útil, y la LUNA no es considerada como un tratamiento eficaz del DPC relacionado con la endometriosis. La histerectomía puede ser útil, sobre todo si se combina con la extirpación de la endometriosis[78].

A pesar de la popularidad de los procedimientos laparoscópicos empleados, el 20% de las mujeres experimentan resultados insatisfactorios[75]. La probabilidad de que el dolor persista o se formen nuevas adherencias debe ser tenida en cuenta cuando el paciente se plantee someterse a una cirugía[84].

1.3.3. Abordaje no farmacológico

La disfunción en el sistema musculoesquelético puede ser el origen del DPC. Al parecer, el 75% de las personas con DPC tienen alteraciones musculoesqueléticas[71]. Las estrategias terapéuticas pueden variar en función de los síntomas individuales y, por tanto, el tratamiento debe ser individualizado[69]. Para elaborar un correcto plan de tratamiento es imprescindible realizar una correcta valoración del sistema musculoesquelético y resolver cualquier problema para conseguir una óptima respuesta al tratamiento[71]. En primer lugar, el terapeuta debe realizar una revisión del estado corporal en función de la edad, las necesidades y el diagnóstico médico.

Existen diferentes abordajes que se han descrito en la literatura científica. Entre ellos, la terapia manual está adquiriendo un papel muy relevante en los últimos años. Esta terapia incluye varias técnicas, como por ejemplo la liberación miofascial, el masaje Thiele, la compresión isquémica y la fricción transversa profunda[85-87].

Terapia física

La liberación miofascial tiene como finalidad mejorar la integridad del tejido, la circulación, disminuir la tensión neural y la isquemia. Adicionalmente, la compresión isquémica es una técnica que se aplica para el tratamiento de los puntos de activación sensibles a la palpación, y consiste en ejercer una presión creciente sobre el punto gatillo activo[88]. La movilidad articular y las técnicas de energía muscular también se emplean frecuentemente[89]. En otros estudios se ha descrito el el masaje Thiele, que consiste en la realización de masajes transvaginales y/o transrectales. El Dr. Thiele basó sus tratamientos en el masaje longitudinal de fibras musculares con el nivel de presión que toleraban los pacientes, e iba incrementando progresivamente la presión ejercida a lo largo de las sesiones[90]. Diferentes estudios han obtenido buenos resultados en los niveles de dolor de personas con dispareunia, cistitis intersticial, hipertonía e hipersensibilidad muscular del suelo pélvico cuando han recibido esta intervención[87, 91, 92].

El ejercicio terapéutico se incluye en el tratamiento del DPC. Se recomienda con la finalidad de promover la postura y el equilibrio muscular, evitando la hiperactividad de la musculatura y la recurrencia del dolor[89]. Casi todas las personas pueden beneficiarse del ejercicio físico, independientemente de su estado de salud, de la etiología del DPC, de la comorbilidad del dolor y de las afecciones médicas. Las actividades físicas recomendadas son caminar, realizar ejercicios aeróbicos, entrenamiento de fuerza, natación, yoga, pilates o cualquier actividad en la que el paciente disfrute y pueda adaptarse a su estado de salud individual. Los mejores ejercicios para pacientes con DPC incluyen el ritmo, el establecimiento de metas y una progresión adaptada a cada paciente. Lo ideal es mantener un régimen centrado en actividades frecuentes, de corta duración y baja intensidad, e ir progresando la duración e intensidad a medida que los pacientes incrementen su fuerza y tolerancia. Un régimen de alta intensidad

probablemente exacerba el dolor, y puede conllevar a un abandono del ejercicio por parte del paciente[68].

Específicamente, los ejercicios de Kegel consisten en contracciones del elevador del ano y parecen estar dando buenos resultados para los síntomas de incontinencia urinaria. Sin embargo, pueden provocar una contracción repetitiva de los músculos del suelo pélvico hipercontráctiles relacionados con el dolor pélvico de origen miofascial[68, 69, 89]. Como parte del ejercicio del suelo pélvico es importante destacar los dispositivos de biorretroalimentación, que se emplean como ayuda para asegurar la relajación total de los músculos tras su reclutamiento durante el ejercicio[89]. Los datos acerca de las intervenciones de ejercicio en personas con DPC son limitados, sin embargo, se han registrado mejoras en los niveles de dolor, la calidad de vida, el estado de ánimo, la función física, el sueño y la autoeficacia en personas con otras condiciones de dolor crónico[68, 93].

A menudo, se observan alteraciones musculoesqueléticas, posturales y del movimiento en personas con DPC, por eso es importante la evaluación postural detallada[94, 95]. La postura típica en bipedestación asociada al DPC incluye una hipercifosis torácica, hiperlordosis lumbar, inclinación anterior de la pelvis y rotación externa de caderas[89]. Se cree que los cambios posturales que se observan en estos pacientes se deben a un círculo vicioso de dolor y posturas antiálgicas que han ido adquiriendo con el tiempo. Aunque estos cambios puedan no ser la causa principal de la condición clínica, pueden contribuir notablemente al empeoramiento del dolor[94]. Las intervenciones que incluyan la postura son necesarias para disminuir el patrón recurrente de tensión pasiva en el tronco, cintura pélvica y la musculatura intrínseca de la cadera. De este modo, el paciente debe intentar aprender a integrar en sus hábitos una alineación postural correcta y la simetría en sedestación y bipedestación[89].

En los últimos años, la neuromodulación ha supuesto uno de los grandes avances científicos en el ámbito sanitario. Es una tecnología que impacta en la interfaz neural y que actúa regulando la actividad eléctrica o química del sistema nervioso central, periférico o autónomo[96].

Neuromodulación

Las técnicas de neuromodulación en dolor crónico incluyen técnicas periféricas y centrales. La neuromodulación periférica implica la aplicación de la estimulación eléctrica a un nervio sensorial que supuestamente inhibe el procesamiento nociceptivo del estímulo de dolor. Las técnicas de neuromodulación periférica son la estimulación eléctrica transcutánea (TENS), la estimulación nerviosa tibial percutánea (PTNS), la neuromodulación sacra (SNM) y la pudenda (SNP). La neuromodulación central emplea una corriente eléctrica de baja intensidad en el cerebro con la finalidad de modular la excitabilidad neuronal y activar el sistema de inhibición descendente para reducir la nocicepción. La técnica de neuromodulación central más empleada es la estimulación transcraneal (tDCS) [68].

La TENS activa una red neuronal compleja con la finalidad de aliviar el dolor a través de la activación de sistemas inhibitorios descendentes del SNC para disminuir la hiperalgesia[97]. Consiste en un dispositivo conectado a electrodos que se adhieren a la piel, cerca de la zona dolorosa para aplicar una corriente a las fibras nerviosas periféricas. Estos dispositivos emiten impulsos eléctricos de bajo voltaje, y su frecuencia e intensidad son regulables[98, 99]. Es considerada como una intervención no farmacológica, no invasiva, de bajo coste, no es adictivo ni produce anestesia y, además puede ser empleada tanto en dolor agudo como crónico[97, 99]. Se ha demostrado que la TENS es una técnica segura y que no genera afectos adversos, excepto una posible dermatitis de contacto en algunos casos[97].

La PTNS, por su parte, es una técnica no invasiva en la que se estimula el nervio tibial posterior de forma intermitente para atacar los circuitos neurales en el SNC[97]. Esta técnica se realiza colocando una aguja con un calibre 34, de 3 a 5 cm encima del maléolo interno. La aguja se conecta a un dispositivo electroestimulador de bajo voltaje y se coloca una almohadilla a modo de toma de tierra en la parte inferior del pie, debajo del quinto dedo. El nervio tibial es un nervio mixto que contiene las fibras L4-S3, y su origen se encuentra en los segmentos espinales de las inervaciones de la vejiga y del suelo pélvico, lo que puede modular el reflejo miccional. Aún no se conoce exactamente el mecanismo de acción de la PTNS, pero al parecer estimula las vías aferentes a la médula espinal sacra y la modulación de la salida de las vías eferentes hacia el tracto urinario inferior[100]. La PTNS se emplea para tratar la disfunción del tracto urinario inferior, el síndrome de vejiga hiperactiva, la retención urinaria no obstructiva, la incontinencia urinaria y diferentes trastornos del suelo pélvico, pero también se ha demostrado su eficacia en DPC[99-102].

La SNM consiste en la estimulación de las raíces nerviosas sacras a través de la colocación de un cable y un generador. Emplea un dispositivo electroestimulador especializado implantado para proporcionar una estimulación eléctrica constante a la raíz nerviosa S3[99]. Es una opción de tratamiento poco invasiva que pretende restablecer el equilibrio entre los reflejos inhibitorios y excitadores. Su efecto terapéutico en el abordaje del dolor se asocia con la reactivación de la autorregulación del tronco cerebral y, además ayuda a reestablecer la función del suelo pélvico y la unidad neuromuscular asociada. Se usa en el tratamiento de la incontinencia urinaria de urgencia, la frecuencia urinaria y la retención urinaria no obstructiva. Su uso en el tratamiento del DPC aún está sin poder confirmarse por completo[103].

La SNP es similar a la SNM, pero en este caso el electrodo implantado aplica una estimulación constante al nervio pudendo en la columna isquial, lo que estimula las raíces nerviosas S2, S3 y S4. Esta técnica se

aplica a los pacientes que no han encontrado alivio con la SNM[99, 104]. La estimulación de la raíz del nervio S3 se ha aprobado para el tratamiento de la urgencia, frecuencia y retención urinaria, la incontinencia fecal, y ha demostrado resultados prometedores en el tratamiento del DPC. Sin embargo, se cree que la estimulación del nervio pudendo es más amplia ya que incluye las raíces nerviosas S2, S3 y S4. Además, dados los resultados obtenidos se considera que la SNP es más efectiva que la SNM[99].

La tDCS es una alternativa no invasiva que aplica corrientes eléctricas débiles (1-2 mA) a través del cráneo con el objetivo de modular la actividad neuronal en el cerebro. Se ha relacionado con una reducción del dolor en pacientes con diversas condiciones de dolor crónico, como por ejemplo en lesiones de la médula espinal, fibromialgia, esclerosis múltiple y DPC[105]. Aunque los resultados sean positivos, no están claros los mecanismos exactos por los cuales esta estimulación influye sobre el dolor crónico. La principal hipótesis se fundamenta en que la modulación de la actividad de la corteza motora primaria a través del uso del tDCS conlleva a la modulación secundaria de las regiones neurales asociadas con el dolor, como los núcleos talámicos[106]. Las complicaciones asociadas al uso de esta técnica se deben fundamentalmente a una infección en el sitio del generador, y con casos aislados de convulsiones en el periodo postoperatorio. Aunque la tDCS pueda ser una herramienta eficaz en el tratamiento del DPC, se necesitas más estudios antes de incluir esta técnica como una parte formal en el abordaje del DPC[99].

Una técnica de estimulación central, no tan popular como la transcraneal, es la estimulación de la médula espinal (SCS), cuyo éxito ha sido limitado en el caso del tratamiento del DPC[107]. Este procedimiento se emplea en pacientes que son refractarios a otras técnicas de neuromodulación o en aquellos que sienten una reducción en el efecto de la neuromodulación a largo plazo. La SCS consiste en la colocación de electrodos longitudinalmente en el espacio epidural dorsal, ya sea

mediante laminectomía o por vía percutánea proporcionando una estimulación eléctrica constante[99].

Enfoques psicológicos

Además de las alteraciones musculoesqueléticas, los problemas psicosociales suelen ser factores importantes que perpetúan el DPC[71]. El tratamiento basado en enfoques psicológicos pretende mejorar las habilidades de afrontamiento y aliviar el sentimiento de angustia asociado al dolor[108]. Existe la teoría de que si la persona puede explorar sus problemas en un entorno no amenazador podría mejorar la experiencia del dolor, al mismo tiempo que desarrolla su propio plan de gestión del dolor[71].

Actualmente las terapias psicológicas más empleadas son las intervenciones conductuales, el método de atención plena (*Mindfulness*) y la terapia de aceptación y compromiso.

Las terapias conductuales se han desarrollado a causa de los problemas de habilidades de afrontamiento y las conductas de evitación desadaptativas derivadas de la larga duración del dolor crónico[68]. Debido al papel de los procesos cognitivos y emocionales en el desarrollo y modulación del dolor, los enfoques terapéuticos basados en la terapia cognitivo -conductual (TCC) han demostrado ser prometedores[109]. La TCC es un método terapéutico dirigido a objetivos en los que el paciente puede aprender a identificar sus pensamientos y comportamientos asociados a su trastorno, y a modificarlos a través del entrenamiento en habilidades cognitivas y conductuales[68]. En pacientes con DPC, la TCC tiene como objetivo aliviar el dolor y el miedo, y restablecer las experiencias sexuales satisfactorias enseñando al paciente el efecto de sus pensamientos y sus emociones sobre el dolor y enseñándole a afrontar las creencias catastróficas disfuncionales acerca del dolor y la evitación de la intimidad empleando técnicas de desensibilización sistémica[109]. Existe escasa evidencia sobre el uso de la TCC en DPC sin embargo, es

comúnmente empleada con éxito en la práctica clínica en otras afecciones de dolor crónico centralizado[69].

Aunque los enfoques tradicionales de TCC sean muy populares en la práctica clínica, hay un creciente interés por las intervenciones basadas en la atención plena[109]. Este tipo de terapia consiste en "prestar atención a propósito, en el momento presente, sin prejuicios", con la finalidad de mejorar la salud psicológica y física. Los pacientes centran su atención en una actividad cotidiana, incrementando el nivel de conciencia cuando la atención se desvía y volviendo a centrarse en el objetivo[110]. En personas que sufren de dolor genital, este tipo de meditación incita a prestar atención al dolor con una mentalidad no reactiva y sin prejuicios, y a separar la sensación física de la emocional y cognitiva del dolor, ya que se aleja emocionalmente de los pensamientos catastróficos y del miedo que entra en la conciencia[109]. La atención plena se emplea a menudo como parte de un programa de intervención más amplio, y está demostrando que puede disminuir los síntomas de dolor, mejorar el funcionamiento físico, social y sexual, reducir los niveles de ansiedad, mejorar el estado de ánimo y la calidad de vida[109, 110].

La terapia de aceptación y compromiso (ACT) es otro tipo de intervención muy popular, que consiste en la aceptación de pensamientos, sentimientos y sensaciones relacionados con el dolor. Actualmente no se han establecido los protocolos de actuación de la ACT en pacientes con DPC, sin embargo, las estrategias de aceptación están siendo incorporadas cada vez más en los tratamientos de personas con dolor crónico[109].

Es importante mencionar que, durante el último año, la pandemia por COVID-19 ha transformado la práctica sanitaria. El uso de sistemas telemáticos puede facilitar la accesibilidad y podrían ser una solución potencial para las personas que viven en zonas alejadas sin acceso presencial a profesionales sanitarios especializados, los que prefieren

terapias domiciliarias o tienen dificultades para el desplazamiento. Además, ha sido fundamental debido a la necesidad de distanciamiento y aislamiento sociosanitario, en especial en aquellas personas con patologías preexistentes, como podría ser el DPC, ya que las intervenciones a distancia pueden proporcionar acceso a la terapia sin exponerlos al virus[111, 112].

1.3.4. Enfoque biopsicosocial

Dado que el tratamiento médico por sí solo no puede abordar todos los síntomas asociados con la sensibilización central, se recomienda una perspectiva biopsicosocial en la que los componentes psicosociales son considerados como modificadores y perpetuadores de la sintomatología[113]. Un abordaje biopsicosocial considera la manera en que los componentes biológicos, psicológicos y sociales funcionan independientemente y conjuntamente para determinar la experiencia de la persona y se conceptualiza, de esta forma, como el camino más efectivo para un tratamiento exitoso[114]. Este enfoque sugiere que, para prestar una adecuada atención a las personas con condiciones crónicas, sea cual sea el diagnóstico, deben tenerse en cuenta los factores biológicos, psicológicos y sociales, además de los contextuales[115, 116].

1.3.5. Abordaje multidisciplinar

El Real Colegio de Obstetras y Ginecólogos recomienda un abordaje multidisciplinar para manejar el DPC, sobre todo cuando es imposible identificar una patología previa[117]. Till SR y cols. (2017) ponen de manifiesto la importancia del enfoque multidisciplinar alegando que es imprescindible establecer expectativas realistas dirigidas a la mejora de la sintomatología y de la calidad de vida, en lugar de encontrar una "cura" al DPC[68]. Un equipo multidisciplinar que aborde el DPC debe incluir ginecólogos, médicos especializados en el manejo del dolor, enfermeras de la clínica del dolor, psicólogos, fisioterapeutas y terapeutas ocupacionales[108].

Se recomienda un enfoque integrado que comience validando la preocupación de los pacientes de que el dolor es real y que necesita un tratamiento combinado. Tras explorar las expectativas y establecer los objetivos del tratamiento, se debe realizar una exhaustiva entrevista clínica que analice el historial médico, psicosexual y del dolor, y esclarecer los factores que podrían estar contribuyendo al dolor y a la angustia relacionada con el mismo[109].

JUSTIFICACIÓN

JUSTIFICACIÓN

Dada la gran variedad de complicaciones asociadas al dolor crónico, tanto a nivel psicosocial, como socioeconómico y de bienestar, es importante explorar modalidades de tratamiento que ayuden a las personas a gestionar su dolor de forma eficiente.

En la mayoría de los casos, la dolencia no solo se limita al dolor local, sino que también hay otros factores que determinan tanto el desarrollo, como el pronóstico de su patología, como es el componente emocional (miedo, ansiedad, angustia, frustración), el educativo (conocimiento de su condición y del manejo de la misma) y la condición física (nivel de proactividad o sedentarismo, control corporal, genética).

Con respecto a las modalidades de tratamiento existentes para abordar el dolor crónico, cabe destacar la escasez de evidencia científica que se centre en las intervenciones a través de un enfoque psicosocial que modere los comportamientos y emociones asociados al mismo, especialmente en personas con DPC, que genera las mismas emociones que otras condiciones de dolor crónico, pero con el elemento añadido de que las personas que lo sufren se sienten especialmente frustradas por la incomprensión de su sintomatología y el retraso en el diagnóstico por parte del sistema sanitario.

Además, hasta la fecha, no existen suficientes estudios que demuestren la eficacia de la terapia ocupacional en personas con dolor crónico. Por lo tanto, es necesario desarrollar enfoques de tratamiento destinados a mejorar la calidad de vida, la sintomatología, la funcionalidad, las emociones y los comportamientos asociados al dolor.

OBJETIVOS

OBJETIVOS

Objetivo general

El principal objetivo de esta tesis doctoral es la evaluación de la eficacia de una intervención de terapia ocupacional en personas con dolor crónico.

Objetivos específicos

- Explorar los efectos de una intervención de exposición gradual centrada en el paciente, añadida a la terapia manual, en mujeres con dolor pélvico crónico y miedo al movimiento/(re) lesión.
- Evaluar los efectos de una intervención centrada en el paciente, basada en el modelo de complejidad acumulativa sobre la calidad de vida relacionada con la salud, los comportamientos de afrontamiento, el dolor, el desempeño ocupacional percibido y los niveles de actividad.
- Evaluar los efectos de las intervenciones basadas en internet sobre los resultados físicos y psicosociales en mujeres con dolor crónico a través de una revisión sistemática.

PUBLICACIONES CIENTÍFICAS

ARTÍCULO 1

Effects of a patient-centered graded exposure intervention added to manual therapy for women with chronic pelvic pain: a randomized controlled trial

[Ariza-Mateos MJ, Cabrera-Martos I, Ortiz-Rubio A, Torres-Sánchez I, Rodríguez-Torres J, Valenza MC. *Archives of physical medicine and rehabilitation.* 2019;100(1):9-16. https://doi.org/10.1016/j.apmr.2018.08.188].

Mención de calidad obtenido de JCR:

Factor de Impacto (2019): 3.098

Categorías: Rehabilitation (9/68; Q1), Sport Sciences (17/85; Q1)

EFFECTS OF A PATIENTE-CENTERED GRADED EXPOSURE INTERVENTION ADDED TO MANUAL THERAPY FOR WOMEN WITH CHRONIC PELVIC PAIN: A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objective: To explore the effects of a 6-week patient-centered graded exposure intervention added to manual therapy in women with chronic pelvic pain (CPP) and fear of movement/(re)injury.

Design: Prospective 3-armed randomized controlled trial.

Setting: Faculty of Health Sciences.

Participants: A total of 49 women with CPP and substantial fear of movement were randomly allocated to 1 of 3 groups: (1) patient-centered graded exposure intervention added to manual therapy; (2) manual therapy; (3) control group.

Interventions: The 6-week intervention consisted of 12 sessions in the group receiving manual therapy and 6 additional sessions of graded exposure therapy in the group receiving both interventions.

Main Outcome Measures: Primary outcomes were fear-avoidance behavior assessed using the Fear-Avoidance Beliefs Questionnaire and pain interference and severity evaluated with the Brief Pain Inventory. The secondary outcome was disability evaluated with the Oswestry Disability Index. All the variables were assessed in a blinded manner at baseline, after the treatment, and at 3-month follow-up.

Results: Our results show interaction effects ($P<.05$) for all the outcomes. Graded exposure added to manual therapy is distinctly superior to

manual therapy alone in maintaining improvements for long-term fear-avoidance behavior and physical functioning.

Conclusions: Graded exposure added to manual therapy is a promising approach with long-term effects for women with CPP and fear of movement/(re)injury.

Introduction

Chronic pelvic pain (CPP) in women is a complex syndrome involving noncyclic pain lasting for at least 6 months localized in the anatomic pelvis, anterior abdominal wall, below the umbilicus, the lumbosacral back and/or the buttocks with sufficient severity to cause functional disability or lead to medical care[1] Up to 2-thirds of women in the general population have experienced CPP, often without diagnosis and management, high lighting the needs for clinical attention.[2]

The challenge of chronic pain lies in its multidimensional character, being influenced by psychosocial factors such as previous experiences, cultural issues, emotional factors, and behavioral responses, in addition to biological factors like sensory input.[3,4] The fear-avoidance model of chronic pain has received significant attention and empirical support in the past two decades.[5] This model assumes that when a person responds to pain with catastrophic interpretations about the cause and consequences, pain-related fear is likely to develop.[5,6]

A treatment based upon this model suggests that pain behaviors can be relieved by a systematic desensitization by exposing the individual to the feared movements and tasks that have been avoided.[5,7] The design of the procedure is personalized to the patient's individual hierarchy starting with activities associated with mild to moderate levels of fear before confronting activities that provoke high levels of fear.[8] Previous studies have demonstrated the effectiveness of graded exposure therapy

(GET) in patients with pain located in low back,[9-11] neck[12] and upper extremity,[13] and with complex regional pain syndrome,[14] not only in reducing pain- related fear, but also improving pain catastrophizing and pain related disability.

A previous study has shown a relationship between pain catastrophizing, pain levels, and quality of life in women with CPP.[15] Indeed, there is some evidence for an association of pain catastrophizing with alterations in gray matter morphology, resting state functional connectivity and task-related brain activation in brain areas involved in pain processing, emotion and motor activity, and reduced engagement of the descending pain modulatory system.[16] Thus, a patient-centered intervention based on information gleaned from the patient and targeting these factors in combination with manual therapy (MT) may be of relevance for providing adequate relief.[17]

The aim of this study was to examine the effects of a GET added to MT in women with CPP and fear of movement/(re)injury by the application of a 3-armed randomized controlled trial, directly and 3 months after treatment. We hypothesized that GET added to a MT 6-week program would reduce fear-avoidance beliefs, pain intensity and interference with daily activities, perceived occupational performance, and disability.

Methods

Participants

A randomized controlled trial was carried out in a population of 49 women with CPP. They were recruited from the Gynecology Service of a University Hospital in Granada (Spain) from September 2017 to January 2018. The inclusion criteria were female sex, age between 18 and 65 years, diagnosis of CPP with at least 6 months of evolution and the presence of fear of movement evaluated with the Tampa Scale for Kinesiophobia (score >33).[18] The exclusion criteria were: other syndromes and/or diseases

involving chronic pain, active urogenital infection, pregnancy, prior urogenital malignancy, cancer, surgical intervention involving lumbo-pelvic region over the past year, vaginal prolapsed exceeding second degree, chronic fatigue syndrome, fibromyalgia, psychiatric disorders, dementia, and substance abuse interfering with treatment.

Before being included in the study, participants signed a written informed consent. Ethical approval was granted by the Ethics Committee of the Hospital District. The protocol was conformed to the standards for human experiments set by the Declaration of Helsinki. This clinical trial was registered at http://www.clinicaltrials.gov under the identifier of NCT03590236.

One investigator was responsible for the eligibility assessment, consent, and interview. Randomization into 3 groups was performed by an independent researcher, different from the researcher involved in eligibility assessment, using a computer-generated number sequence using block sizes to avoid substantial imbalances in the number of patients assigned to each group. All the data were collected by a therapist who was blinded to the allocation of the patients in the laboratory of the Faculty of Health Sciences.

Outcomes

Measures were administered at the baseline, after the intervention and at 3-month follow-up in the Laboratory of Health Sciences by a blinded assessor. Demographic and clinical data including age, body mass index, marital status, educational level, duration of pain, use of medication, kinesiophobia score, and level of physical activity assessed with the International Physical Activity Questionnaire were recorded at baseline.[19] The presence of depressive symptoms was also assessed using the Beck Depression Inventory,[20] which consists of 21 groups of 4 statements designed to assess severity of current symptoms of depressive disorders, with total scores ranging from 0 to 63. Primary outcomes for this

clinical trial were fear-avoidance beliefs, pain interference with activities of daily living and severity of pain. The secondary outcome was the disability.

The Fear-Avoidance Beliefs Questionnaire-Physical Activity (FABQ-PA) subscale was used to quantify fear-avoidance beliefs related to physical activities.[21] This subscale is more appropriate when some patients in the sample do not work. It comprised 4 items ranging from 0 to 24. Higher scores indicate higher levels of fear-avoidance beliefs and scores greater than 4 points define clinically meaningful changes. It shows good comprehensibility, internal consistency, and reliability.[21]

The pain was evaluated using the short form of the Brief Pain Inventory (0-10).[22] This instrument consists of 2 subscales that evaluate the degree to which the pain interferes with the activities of daily living and the intensity of pain. In addition, the Interference Scale has been recommended by Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials for the assessment of physical functioning.[23] Higher values represent worse pain. It has shown appropriate psychometric properties that support its inclusion in clinical research.[24] For the interference subscale, the minimally clinically important change is set at ≥0.6 points. For the pain intensity 0-10 numerical rating scale, a decrease of 10-20% is considered minimally important, a ≥ 30% decrease moderately important, and a ≥ 50% decrease a substantial change.[25]

Disability was assessed with the Oswestry Disability Questionnaire. It includes 10 items that assess how pain affects common daily activities. The scores range from 0 (no disability) to 100 (completely disabled), with higher scores indicating higher disability.[25] This is internally consistent with overall excellent construct validity scale, and with the ability to discriminate the severity of functional disability with an acceptable degree of internal consistency. The minimal clinically important difference is 10 percentage points.[26]

Procedure

The intervention was conducted in the laboratory of the Faculty of Health Sciences for 6 weeks. Attendance was registered weekly. In order to enhance participant adherence, patients were contacted via text messages the day before to remind them about their appointments.

Two treating therapists were involved in the study, 1 who conducted the MT intervention for all the patients, and a therapist experienced in exposure therapy who conducted the GET.

All the women included in the MT and the graded exposure therapy added to MT (GET+MT) groups received an intervention of 45 minutes, twice per week, consisting of manual techniques to increase flexibility, decrease trigger point-related pain, reduce tension, and increase balance and stability. This intervention was proposed based on previous findings of MT outcomes in patients with CPP.[27] Each session included soft tissue mobilizations and myofascial release (20 min) to improve circulation, restore tissue integrity, decrease ischemia, and decrease adverse neural tension.

This was combined with deep-pressure massage (15 min) to reduce trigger point-related pain and tension. In addition, muscle energy techniques (10 min) were used to strengthen weak muscles and to stretch tight muscles, and to promote joint muscle balance and stability. The duration of each technique was adapted to the patient's tissue response.

Those women in the GET+MT group received additionally a patient-centered graded exposure intervention, with an added 45-minute session per week. This intervention included a first session of education about pain causes and mechanisms conducted in an interactive way. Additionally, the distinction between acute and chronic pain, the available treatment strategies and the impact of behavior on pain experience were provided. The Canadian Occupational Performance

Measure was used to identify and prioritize issues that restrict or impact the performance of everyday living. The 5 tasks ranked as most fearful were selected for implementation in the protocol.[28,29] This protocol was a modified version of the graded exposure intervention described by George et al.[30] Standardization of the activities was not possible because of the variability in clinical presentation and individual tasks. The sessions followed the GET principles for position, intensity, and frequency encouraging patients to maintain the achievements made in the clinic. Patients were gradually exposed to the 5 most fearful tasks of personal importance selected, starting with the task rated as the less fearful at a self-selected level. Progression was determined based on within-session changes in the fear assessed with a visual analog scale. Patients acquire skills to transfer these tasks performance to everyday life during the treatment period, learning how to deal with perceived obstacles in order to generalize and maintain treatment gains.

Those women included in the control group receive a booklet with CPP information to minimize potential dropout.

Statistical analysis

Statistical analysis was performed using SPSS, version 21.ª Baseline descriptive statistics for each intervention group and differences were assessed using analysis of variance (ANOVA) for continuous data and chi-square tests for categorical data. Two-way mixed ANOVAs (3x3) were conducted to determine the significance of any group effect (between subjects), time effect (within subject), and interaction effect (group x time). The number of completed sessions was included as a covariate in the analyses. For any significant between-subjects' effects difference, a 1-way ANOVA was performed followed by a post hoc analysis in each assessment period. Significant interaction effects were plotted to facilitate interpretation. To highlight any significant within-subject change, repeated measures ANOVA with further contrast analysis was conducted

in each group. The level of significance was set at *P*<.05. Intention-to-treat analyses were employed. A power analysis based on within-between interaction effects and the primary outcome FABQ-PA for a repeated measures ANOVA with 3 measurements (power of 0.80, an alpha level of 0.05, and effect size of 0.21 based on a pilot study carried out before initiation of the research in a subsample of 9 patients) revealed that at least 16 patients were needed for each arm. Accommodation for possible dropout at follow-up (10%) resulted in a requirement of 55 patients.

Results

A total of 49 women were finally included in the study. Figure 1 shows the CONSORT flow diagram. There were no adverse events reported during this trial.

Descriptive variables collected at baseline are included in table 1. Not significant differences were found at baseline for any measure.

The results of the 2-way mixed ANOVA are included in table 2 and plots of significant interaction effects are shown in figure 2.

Sub-groups did not differ in outcome measures at baseline. Significant interaction effects were found for all the outcomes (*P*<.05).

Fear-avoidance behavior

Statistical analysis revealed a significant time x group interaction for the fear-avoidance behavior (FZ6.178, *P*Z.003). In addition, significant between-subject and within-subject effect was found for this variable. Between-group significant differences were found between the GET+MT and control and the MT groups and among the 3 groups at 3-month follow-up. Additionally, within-groups differences were found in the GET+MT and the MT groups from pre to post- intervention and from pre to 3-month follow-up assessments.

Pain interference and severity

The ANOVA revealed a significant time x group interaction for pain interference (FZ2.870, *P*Z.029) and severity (FZ10.227, *P*Z.003). Significant within-subject effect was also found for both subscales(*P*<.05).

For pain interference, significant differences were found at 3-month follow-up between the GET+MT and the MT groups and between the GET+MT and the control groups. Within-group significant improvement was found in the GET+MT group.

For pain severity, the results show significant differences at 3-month follow-up between the GET+MT and MT groups. Significant differences were also found between the MT and the control groups. Additionally, a within-group significant change was found between pre- and post-assessment and the preassessment and the follow-up assessment in the GET MT group. Also, the MT group shows a significant within-group improvement from preassessment to 3-month follow-up score.

Disability

Statistical analysis revealed a significant time x group interaction for the Oswestry Disability Index (FZ4.507, *P*Z.014). No significant within or between-subject effects were found.

Main effects show between-group differences between the GET+PT and the MT and control group after the intervention. At 3-month follow-up, significant differences were found among the 3 groups. Pre-to postintervention within-group improvement was found in the GET+MT group. Besides, from baseline to 3-month follow-up a significant within-group improvement was found in the GET+MT and the MT groups.

Discussion

The objective of this study was to examine the effects of a patient-centered graded exposure intervention added to MT in women with CPP and fear of movement/(re)injury by the application of a randomized

controlled trial, directly, and 3 months after treatment. Our results show a between and within interaction effect for all the outcomes. Additionally, a significant between-subjects effect was found in the FABQ-PA and significant within-subject effects in the pain subscales. At 3-month follow-up significant between-group differences were found between the GET+MT and the MT in the FABQ-PA, pain interference, and disability. Also, significant differences between the GET+MT and control groups were found for all the outcomes.

Pain-related fear could act as a key interacting mechanism underpinning the development and maintenance of chronic pain, limiting the performance of the basic activities of daily life in the long-term avoidance behaviors.[5] Previous studies have reported a reduction in psychological factors to be associated with a reduction in disability, even after controlling for pain intensity.[31,32] Most of these treatment programs are offered in combination oras an adjunct to physical approaches. In this line, Sparkes et al[33] and Rantonen et al[34] utilized only psychoeducation in patients with low back pain, without graded exercise program proposing that psychoeducation strategies alone are not effective in decreasing fear-avoidance beliefs.

A recent study has reported the need of a trial focused on catastrophizing in addition to treatments that directly reduce pain for CPP patients to determine whether they have an additive or multiplicative effect on outcomes.[35] Physiotherapy can contribute significantly to assessing and treating women with CPP, and clinical and scientific research indicate its efficacy and safety.[30] Our study has explored the effect of adding GET to MT. When compared to the MT, the GET+MT intervention show a significant improvement in fear-avoidance behavior, pain interference with daily activities, and disability.

There are no previous studies that consider an approach including limitations caused by pain-related behaviors in women with CPP. Most of

the previous studies using graded exposure interventions for chronic pain have focused on low back pain.[9-11] Linton et al[36] reported that graded exposure therapy was more effective than a wait list control group receiving usual care for improvements in function, but not for pain intensity or pain-related fear. Our results show that a combination of GET and MT, can be effective for fear-avoidance behavior, pain, and disability with significant effects when compared to a control group at 3-month follow-up. In addition, this combination shows significant improvements when compared to a MT program.

By adopting a broader conceptualization of chronic pain, a hybrid approach gives the flexibility to develop rehabilitation plans based on individual needs rather than relying on predetermined protocoled treatment strategies.[37] Patient-centered approaches allow empowering the patient by expanding his or her role in the rehabilitation process.[38] Our study proposed a patient-centered approach including skills to deal with future fears that may arise with positive results at 3-monthfollow-up.

Study limitations

This study protocol has some limitations. First, women were recruited from the same medical unit and this could be resulting in potential selection bias. The implementation of graded exposure was based on the Canadian Occupational Performance Measure to set intervention goals. This procedure differs from previous studies that use the Photograph Series of Daily Activities.[39] Moreover, a longer follow-up period may be needed to detect longer-term changes. Future studies should include women with acute and sub-acute pain with elevated pain-related fear; as such individuals may have a higher likelihood of developing chronic pain.

Conclusions

GET added to MT is effective for women with CPP and fear of movement/(re)injury showing significant time x group interaction effects.

This approach results distinctly superior to MT alone in maintaining improvements for long-term fear-avoidance behavior and physical functioning.

Supplier

IBM SPSS, version 21.0; IBM.

Keywords

Activities of daily living; Chronic pain; Fear; Rehabilitation; Women

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Fig1 CONSORT flow diagram.

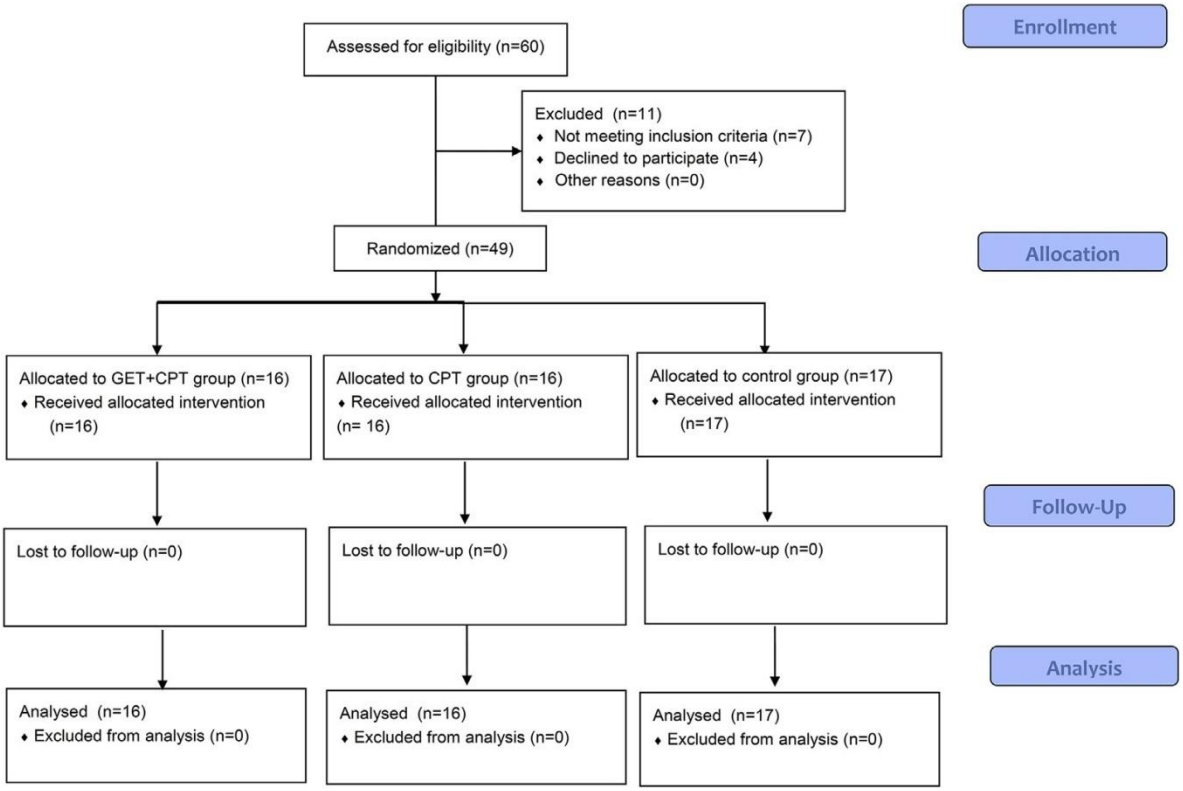


Table 1. Baseline characteristics

Variables	GET+MT Group (n=16)	MT Group (n=16)	Control Grupo (n=17)	P Values Among the 3 Groups
Age,meanT ± SD(y)	42.26±T9.57	40.67±T11.70	42.40±T6.15	.853
BMI, mean ± SD (kg/m2)	25.92±T4.12	24.46±T2.55	23.26±T2.78	.055
Marital status (%)				.160
Single	37.5	18.75	29.4	
Married	43.75	56.25	70.6	
Divorced/separated	18.75	25	.	
Education (%)				.173
No primary education completed	-	18.75	11.76	
Primary education	31.25	31.25	52.94	
Secondary education	50	25	23.54	
Tertiary studies	18.75	25	11.76	
Work status (%)				.675
Work	68.75	50	64.71	
Sick leave	6.25	6.25	-	
Disability pension	.	.	5.88	
Other (eg, study, household, unemployed)	25	43.75	29.41	
Duration of pain, mean T ± SD (y)	9.10±T7,81	9.58±T5.38	7.27±T5.35	.637
Kinesiophobia (TSK), mean ± SD	36.16±3,35	34,90±2.19	35.75±3.06	.549
Use ofmedication (%)	89.5	91.7	75	.335
Daily activity level, meanT± SD(MET/min)	1121.24±T534.56	968.20±T779.38	765.70±T701.04	.274
Depressive symptoms(BDI),meanT±SD	15.84±T9.93	16.33±T9.41	11.00±T5.27	.115

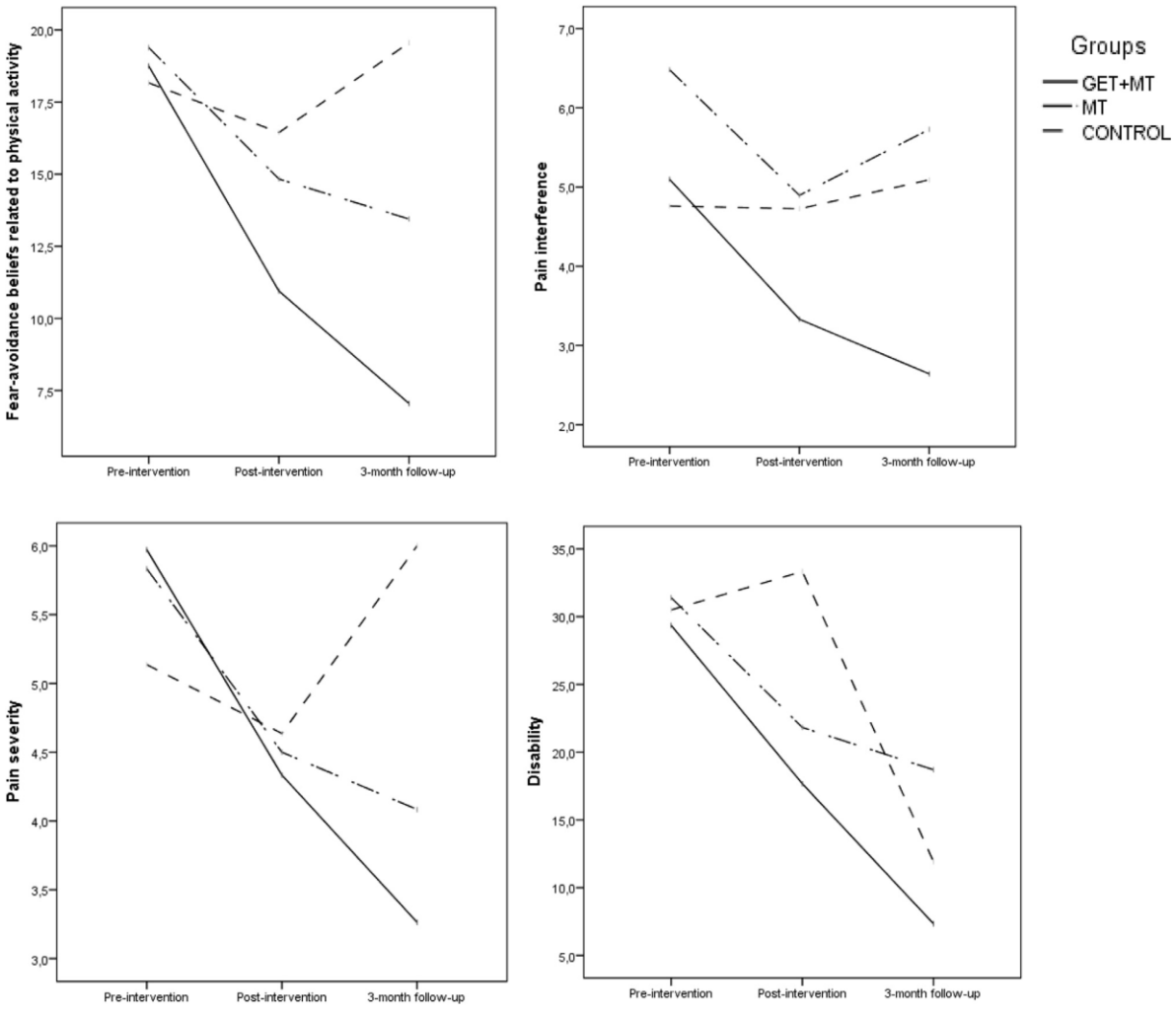
Abbreviations: BDI, Beck Depression Inventory; BMI, body mass index; TSK, Tampa Scale of Kinesio phobia

Table 2. Results of 2-way mixed ANOVA

Variable	GET+MT Group (n=16) Baseline Mean ± SD Postintervention Mean ± SD 3-month Follow-up Mean ± SD	MT Group (n=16) Baseline Mean ± SD Postintervention Mean ± SD 3-month Follow-up Mean ± SD	Control Group (n=17) Baseline Mean ± SD Postintervention Mean ± SD 3-month Follow-up Mean ± SD	Between-subject Effect F Value (P Value)	Within-subject Effect F Value (P Value)	Interaction Effect F Value (P Value)
Primary outcomes						
FABQ-PA	18.74± T2.75 10.47 ±T7.61[*] 6.37± T7.54[y]	19.39 ±T2.40 14.83 ±T4.23[*] 13.44 ±T6.36[y]	18.21 ±T2.23 17.33± T6.59 19.58 ±T3.63	4.433 (.040) Postintervention[z,x] 3-month follow-up[k,x]	7.214 (.001)	6.178 (.003)
BPI interference	5.09± T2.45 3.33± T1.66[*] 2.64± T2.41	6,48± T1.49 5.06 ±T1.53 5.73 ±t0.65	4.76± T2.36 4.72 ±t3.03 5.09 t1.51	1.421 (.255) 3-month follow-up[z,x]	6.345 (.003)	2.870 (.029)
BPI severity	6.01± T1.95 4.33± T2.16[*] 3.26T±1.97[y]	5.83± T2.02 4.50 ±T1.78 4.08± T1.16[y]	5.14 ±T1.66 4.63± T2.75 6.00 ±T1.89	0.826 (.370) 3-month follow-up[k,z]	7.347 (.010)	10.227 (.003)
Secondary outcomes						
Oswestry Index	29.36 ±T13.74 17.67 ±T6.69[*] 7.33±T5.84[y]	31.40 ±T8.17 21.82 ±T12.02 11.92 ±T6.71[y]	30.50 ±T17.66 33.33 ±T14.02 28.70 ±T11.88	0.245 (.624) Postintervention[z,k] 3-month follow-up[z,x,k]	1.009 (0.370)	4.507 (.014)

NOTE. Values are in mean T SD or F value (*P* value).
Abbreviation: BPI, Brief Pain Inventory.
[*] Statistically significant differences between the preassessment and the postassessment (*P*<.05).
[y] Statistically significant differences between the preassessment and the follow-up assessment (*P*<.05).
[z] Statistically significant differences between the group GET+MT and the control group (*P*<.05).
[x] Statistically significant differences between the group GET+MT and MT (*P*<.05).
[k] Statistically significant differences between the group MT and control group (*P*<.05).

Fig 2. Plot of significant interaction effects.



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ARTÍCULO 2

Effects of a patient-centered program including the cumulative-complexity model in women with chronic pelvic pain: a randomized controlled trial

[Ariza-Mateos MJ, Cabrera-Martos I, López-López L, Rodríguez-Torres J, Torres-Sánchez I, Valenza MC. Effects of a patient-centered program including the cumulative-complexity model in women with chronic pelvic pain: a randomized controlled trial. *Maturitas*. 2020;137:18-23. https://doi.org/10.1016/j.maturitas.2020.04.005].

Mención de calidad obtenido de JCR:

Factor de Impacto (2020): 4.342

Categorías: Obstetrics & Gynecology (12/83; Q1), Geriatrics & Gerontology (18/53; Q2)

Effects of a patient-centered program including the cumulative-complexity model in women with chronic pelvic pain: a randomized controlled trial

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ABSTRACT

Objectives: To evaluate the effects of a patient-centered intervention including the cumulative-complexity model on quality of life related to health, coping behaviors, pain, self-perceived occupational performance and activity levels.

Study design: Randomized controlled trial. Forty-four women with a clinical diagnosis of chronic pelvic pain were randomized into two groups. Patients in the experimental group (n = 22) were included in a patient-centered intervention that involved relevant activities proposed by participants. Patients in the control group (n= 22) received a leaflet with information about chronic pelvic pain, physical activity, fear of movement, false beliefs, active lifestyle and behavioral advice.

Main outcome measures: The primary outcome measures were health-related quality of life assessed with the EuroQol-5D and coping behavior using the Coping Strategies Questionnaires. Secondary outcomes included severity of pain using a Visual Analogue Scale, self-perception of occupational performance using the Canadian Occupational Performance Measure and physical activity levels assessed by the International Physical Activity Questionnaire.

Results: An analysis of variance with repeated measures showed, in the experimental group compared with the control group, significantly

greater improvement from baseline to post-intervention in health-related quality of life (EuroQol-5D Visual Analog Scale values of 70.06 ± 16.44 vs. 57.38 ± 16.40, p = 0.026) and coping behavior (adaptive coping 113.00 ± 31.89 vs. 83.24 ± 16.69, p = 0.002). Pain, self-perception of performance and physical activity levels also significantly improved.

Conclusions: A patient-centered intervention considering the workload of patients and their capacity for performing health behaviors provides benefits regarding quality of life and coping behavior. Additionally, pain, self-perceived performance of relevant tasks and physical activity levels improved.

1. Introduction

Chronic pelvic pain (CPP) is a complex pain syndrome defined as noncyclical pain of at least 6 months' duration, located in the pelvis, lower back, buttocks and/or the anterior abdominal wall that affects14%–24% of women worldwide [1]. CPP may involve gynecologic, musculoskeletal, gastroenterologic and urologic systems, with significant presence of psychosocial and somatic comorbidities [2]. Women diagnosed with CPP frequently report a negative impact on quality of life, physical functioning, and the ability to work or perform activities of daily living [3]. Moreover, CPP is associated with considerable economic burden to patients and their families due to medication use, physician visits, emergency visits, surgical interventions and hospital admissions [4].

Given the multidimensional etiology of CPP, effective treatment requires a multifaceted approach. Pharmacologic strategies include analgesics, hormonal suppression, anesthetics, antidepressants, membrane stabilizers, and anxiolytics [5]. However, many of these options have limited evidence of efficacy [5]. Many patients also benefit from nonpharmacologic approaches adjuncts to pharmacologic therapy, including physical therapy, exercise and lifestyle modifications [6]. Tillet al.

[6] indicate in their review the need of high-quality research focused on improvements in quality of life.

An intervention involving individualized self-care and health may improve the individual's ability to manage the symptoms, physical and psychosocial consequences inherent in living with a chronic condition [7]. Previous studies have shown that programs considering pain self-efficacy, adaptive coping skills and solving patient-identified problems are effective in improving health functioning and quality of life while reducing health care resource utilization in patients with chronic low back pain [8, 9]. In this sense, Shippee et al. (2012) [10] proposed a patient-centered model of patient complexity emphasizing functional mechanisms to promote innovative care delivery. Patient complexity implies a dynamic state in which the personal, social, and clinical aspects of the patient's experience act as complicating factors that accumulate over time [10]. This model describes workload and capacity as two factors that affect patients' experiences with care and self-management. In addition, Bryan et al. [11] affirmed that CPP is associated with low levels of pain self-efficacy and explained the need of a biopsychosocial approach including communication with patients in order to engage them in effective management of their pain. According to the model proposed, successful interventions should consider the work load of patients and seek to enhance their capacity for performing health behaviors without adding an unsustainable workload of demands.

Thus, this study aims to evaluate the effects of a patient-centered intervention based on the model of cumulative complexity in women with CPP. We hypothesized that a patient-centered intervention including this model would improve quality of life, coping strategies, pain severity, self-perception of occupational performance and levels of physical activity.

2. Methods

2.1. Study design

A randomized controlled trial was conducted from 23 July 2018 to29 April 2019. This study received ethical approval from the Hospital Ethics Committee and was registered in www.clinicaltrials.gov, reference NCT03617627. Before being included in the study, patients were informed about the purpose and course of the study and gave written informed consent to participate. The protocol complied with the standards for human experiments set by the Declaration of Helsinki.

2.2. Study participants

Women with CPP were recruited from the Gynecology Service of the University Hospital of Granada, Spain. Women were selected according to the following inclusion criteria: women aged 18-65 years and clinical diagnosis of chronic pelvic pain by a gynecologist specializing in pelvic pain through history and physical examination. The diagnostic criteria included lower abdominal noncyclical pain (located within the pelvis, the anterior abdominal wall below the umbilicus, the lumbosacral back or the buttocks), which lasted for six months or more, not caused by pregnancy and not exclusively associate with intercourse, with in-complete relief by most previous treatments and significantly impaired function at home or at work. The exclusion criteria were: clinical diagnosis of other syndromes and/or diseases involving chronic pain, active urogenital infection, pregnancy, prior urogenital malignancy, cancer, a surgical intervention involving lumbo-pelvic region over the past year, vaginal prolapsed exceeding second degree, chronic fatigue syndrome, fibromyalgia, major psychiatric disorders, dementia and substance abuse interfering with treatment.

Participants were randomly allocated (1:1 ratio) to either the experimental or control group. The randomization sequence was performed by an independent researcher who was not aware of the purpose of the study, using a computer program. The participants' distribution and progress through the study is shown in Fig 1.

2.3. Outcome measures

The assessment was conducted at baseline and after 6 weeks of treatment in the Laboratory of Health Sciences by a blinded assessor. This person conducted the initial interview that included items assessing age, academic studies, marital status, employment status (yes/no answer including working full or part time) sexual activity (lack of interest, satisfaction and pain or discomfort during or after sexual activity), previous treatments and disease duration. In addition, their height and weight were recorded to calculate body mass index. Anxious and depressive symptoms were assessed using the Beck Anxiety Inventory [12] and Beck Depression Inventory, respectively [13].

Primary outcomes were quality of life and coping behaviors. Secondary outcomes were the severity of pain, self-perception of occupational performance and physical activity levels. The assessor gave the instructions and was available if there were any doubts.

Quality of life was assessed using the EuroQol-5D instrument. It comprises two sections: the health state of the respondent at the time of completion based on five dimensions (mobility, self-care, usual activity, pain/discomfort and anxiety/ depression) and a Visual Analogue Scale (VAS) that estimates overall health status from 0 (worst) to 100 (best). This is a simple, valid and practical measure for its use as an outcome variable in clinical research [14].

The coping strategies were evaluated using the Coping Strategies Questionnaire (CSQ), a self-rated instrument that assess the frequency in which individuals use specific cognitive and behavioral strategies to cope with pain. It includes eight different coping strategies involving two main types of coping: adaptive coping (self-instructions, cognitive distraction, distractor behaviors, reinterpreting the pain, ignoring the pain and hope) and maladaptive coping (catastrophization, and faithing and supplication). Participants score each item using a 7-point scale to

indicate how often they use the different strategies to manage their pain (0 = never, 3 = sometimes, and 6 = always). This questionnaire has shown to be a reliable and valid measure of coping strategies for chronic pain population [15].

Pain severity was assessed using a visual analogue scale (VAS). It consisted of a 10 cm long line, from 0 cm (no pain) to 10 cm (the worst imaginable pain) [16]. Patients were asked to mark their pain on its average.

Self-perception of occupational performance was assessed using the Canadian Occupational Performance Measure (COPM) with the help of the assessor. This instrument is useful to identify and prioritize issues relevant in the areas of self-care, productivity and leisure. For each of the selected activities the participants rated their perceived performance and satisfaction with the performance on a 10-point scale. Higher ratings indicate greater importance, better performance and increased satisfaction. The five goals selected by each participant were sent by email to the therapists of the experimental group by an in-dependent researcher. In patients included in the control group, this scale was used only as a pre–post intervention measure. The COPM showed good evidence of concurrent criterion validity and sensitivity to change as an outcome of a pain management program [17].

Physical activity levels were evaluated by the International Physical Activity Questionnaire (IPAQ). This measure evaluates physical activity in work, transportation, housework/gardening and leisure-time. The frequency and time spent on vigorous, moderate and intense activities were registered for each category. The IPAQ is considered to be a reliable and valid questionnaire for vigorous and sedentary activities [18].

Information regarding the questionnaires used is included in a Supplementary table.

2.4. Interventions

2.4.1. Experimental group

Our intervention is included in a patient-centered framework that emphasizes the work load-capacity balance and incorporates treatment and illness burdens. Duration of treatment was 6 weeks and the sessions took place once a week. Time spent for each session was 45 minutes. The intervention was leaded by a specialized therapist with education in pain management and more than seven years' experience in areas related to the evaluation and management of patients with chronic pain conditions.

For the implementation of the intervention, in the first session the workload-capacity difficulties were identified by interviewing the participant in order to recognize what consumed patients' time, energy, and attention, and what limited their ability to manage demands. Secondly, interview focused on how patients balanced self-care and functional limitations. Intervention searched for a balance between the patient's work load of demands and patient capacity taken into account individual characteristics. Finally, the patients received information about self-management and were given an explanation about pain definition, the mechanisms of pain, the differences between acute and chronic pain and the transition from acute to chronic pain with the expectation that greater knowledge would lead to appropriate changes in behavior for individuals to better manage their pain.

In this group, the therapists had a specific set of functional goals they were aiming for. The main goals identified by participants were divided into the occupational performance categories of self-care, productivity and leisure are included. The main goals reported by participants is included in Table 1.

In the second session, action plans for individualized goals were constructed including modeling of self-management and adaptive

coping skills to improve adjustment to pain. Treatment strategies were embedded into patients' lives to minimize burden and ensure adherence and toward preventing workload-capacity imbalances. In the sessions 3to 6 patients action plans were evaluated and adjusted through guided mastery practice. Standardization of the activities was not possible because of the variability in clinical presentation and level of functional activity by a particular patient. The initial level of activity was determined through patient history or by having the patient perform the activity at a self-selected level. The task was recorded with a tablet in order to provide feedback to the patient. Activities rated as highly painful were initially included in the treatment plan at positions, frequencies, and durations that did not increase pain. Patient activity was progressed if a decreased pain rating was reported following exposure to a painful activity. Then, the position, frequency, and/or duration of these tasks was increased for the subsequent session. Patients were offered feedback from the therapist in overcoming obstacles they faced. Those problems related to workload-capacity were reviewed during clinical encounters and solutions for minimizing patient burdens were selected.

2.4.2. Control group

The control group received advice in the form of a leaflet and continued with usual activities. The leaflet was based on information about CPP, physical activity, fear of movement, false beliefs, active lifestyle and behavioral advice.

2.4. Analysis of data

Based on a previous pilot study of 10 participants (unpublished)carried out by authors and the group parameters obtained for EuroQol-5D Visual Analog Scale, we sampled for an effect size of at least 0.45. This required a sample size of 42 (80% power, 0.05 level of significance). Taking into account a hypothetical drop-out of 10%, 46 women were required. Descriptive statistics was expressed as mean (standard deviation) in the non-categorical and number of cases (per-centage) in the categorical variables to determine participants' characteristics. Demographic data and initial assessment results were com-pared with T-tests using the Statistical Package for the Social Sciences (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version20.0. Armonk, NY: IBM Corp). Prior to statistical analysis, the Kolmogorov–Smirnov test was performed to assess the normality of continuous data. An analysis of variance (ANOVA) with repeated measures was used to determine the effects of treatment on the outcome measures. Confidence interval was set at 95%. The alpha level was 0.05.

3. Results

A total of 44 patients were finally included in the study. There were no dropouts, no adverse effects were referred and all patients completed the study. All questionnaires were completed by all participants.

The main sociodemographic and clinical characteristics of the study sample are included in the Table 2.

There were no significant differences between both groups.

Pre- and pre- to post intervention values for primary outcome measures are included in Table 3. At baseline, the groups exhibited similar values, at the end of the study, both groups were significantly different with better results in the group that received self-management treatment. After

intervention, a significant improvement was found in perceived quality of life regarding mobility (Cohen's d = 0.97), self-care (Cohen's d = 0.65) and estimates overall health (Cohen's d = 0.77).

Pre- to post- significant between-group differences were found inadaptive coping behavior with a large effect size (Cohen's d = 1.16) and a significant increase in self-instructions, cognitive distraction, distractor behaviors, reinterpreting and ignoring the pain subscales in favor of the experimental group. Additionally, this group improved significantly the maladaptive coping with a large effect size (Cohen's d= 1.08) showing significant between-group difference in catastrophization.

Pre- and pre- to postintervention values for secondary outcome measures are included in Table 4.

The control group showed similar pre-intervention values in pain, physical activity levels and psycho-emotional symptoms at baseline. The between-group analysis revealed significant differences ($p < 0,05$) on secondary outcomes after the intervention with a large effect size (Cohen's $d > 0.8$).

4. Discussion

The purpose of this study was to evaluate the effects of a patient-centered intervention including the model of cumulative complexity in women with CPP. The results show that a 6-week intervention improves quality of life (mobility, self-care and overall health status), reduces maladaptive coping (decrease of catastrophization) and increases adaptive coping (self-instructions, cognitive distraction, distractor behavior, reinterpreting the pain, ignoring the pain and hope). In addition, pain, self-performance and activity levels improves significantly.

Previous findings have shown that functional impairment is common among patients experiencing CPP [19]. Sleep, household activities, tasks

related to work, and sexual relations are the most common areas where CPP patients experience impairment [20]. The most common prioritized problems identified by participants in our study also included household activities such as carry weight in household tasks (69.23%) or cleaning the house (38.46%). Our intervention focused on individual goals that were individually targeted through a multimodal program. After 6-week intervention, those women included in the experimental group improved significantly adaptive coping strategies and perceived health status. A study con-ducted by Wessels et al. [21] aimed to evaluate which changes in treatment process variables predict outcome of exercise, behavioral and multimodal treatment of chronic low back pain, showing that behavioral variables and reductions of disability which facilitate an improvement in function may be more important than physical performance factors for successful treatment of chronic low back pain.

The perception of pain and its psychological factors varies from one individual to another [22]. However, pain beliefs and coping have been reported to be important determinants of adjustment to chronic pain [23]. Sewell et al. reported a significant association between increased catastrophizing scores and reduced odds of good quality of life showing the potential for further studies to investigate management targeting catastrophizing to improve outcomes in women with CPP [22].

A previous study reported that workers with chronic pain frequently perceive lack of control (high pain intensity, high self-perceived dis-ability, and high self-rated depression) and significant amounts of both "catastrophizing" and "praying and hoping" strategies, leading to poor recovery outcomes [24]. In addition, a critical review of the pain coping literature showed that patients who believe they can control their pain, who avoid catastrophizing about their condition, and who believe they are not severely disabled appear to function better than those who do not [25]. In our intervention, we included education about chronic pain and action plans for individualized goals including modeling of self-

management and adaptive coping skills to improve adjustment to pain. The education component in combination with patient-led goal setting may have been a useful strategy to underpin these active cognitive and behavioral strategies. Therefore, interventions should consider the ability to manage demand, improve functionality and build patients' capacity to routinize, adapt to their chronic conditions and successfully implement behavior change into their lives.

Wilson & Cramp [26] showed that a multimodal intervention including physiotherapy and psychology was statistically significantly superior in improving physical functioning over physiotherapy alone in adults with chronic pain. In this line, numerous studies have supported an integrated concept encompassing both psychological support and somatic aspects of the disease in women with CPP [27]. Additionally, the EAU Guidelines on CPP propose an approach that integrates the medical, psychosocial, and sexual elements of care to engage the patient in a collaborative journey towards self-management when pain persists [28]. However, no previous study has focused on the effects of a patient-centered intervention considering complexity of disease.

Recent meta-analyses have shown the effectiveness of self-management programs to facilitate behavioral adjustment in patients with chronic pain improving outcomes, such as well-being and adaptive lifestyle changes [29, 30]. In our intervention, the patients identify and face their obstacles through the use of coping strategies and achieve relevant tasks through a controlled exposure to the painful activity. Gardner et al. [9] suggested that a goal-setting approach may allow participants to reconceptualized pain, changing their perception of the pain, and leading to re-engagement with activities and cognitive reframing.

Despite these strong beneficial effects of the intervention in patients with CPP, certain limitations of the study must be acknowledged. Women were recruited from the same medical unit and this could be resulting in

potential selection bias. Women were also volunteers, suggesting a high level of motivation to participate in goal setting, adherence to chosen strategies, and behavior change, which may not be representative of a clinical population. Although this small sample size and exclusion criteria might limit generalizability to populations with overlapping psychiatric or chronic pain syndromes, it highlights the importance of providing support in a patient-centered framework that emphasizes the work load-capacity balance and incorporates treatment and illness burdens. Thus, future research should examine the long-term effects of this intervention including a follow-up and a larger sample in comparison with a standardized treatment. Moreover, given the high percentage of women reporting sexual activity dysfunction, sexual health metrics will be included.

In conclusion, a patient-centered intervention considering the workload of patients and their capacity for performing health behaviors provide benefits regarding quality of life and coping behavior. Additionally, severity of pain, self-perceived performance of relevant tasks and physical activity levels improved.

Conflict of interest

The authors declare that they have no conflict of interest.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Ethics

The study protocol was approved by the Ethics Committee of University Hospital of Granada, Spain. Written informed consent regarding all study procedures was obtained from each woman before baseline.

Data sharing and collaboration

There are no linked research data sets for this paper. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Provenance and peer review

This article has undergone peer review.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi: https://doi.org/10.1016/j.maturitas.2020.04.005

Fig 1. Progress of participants through the study.

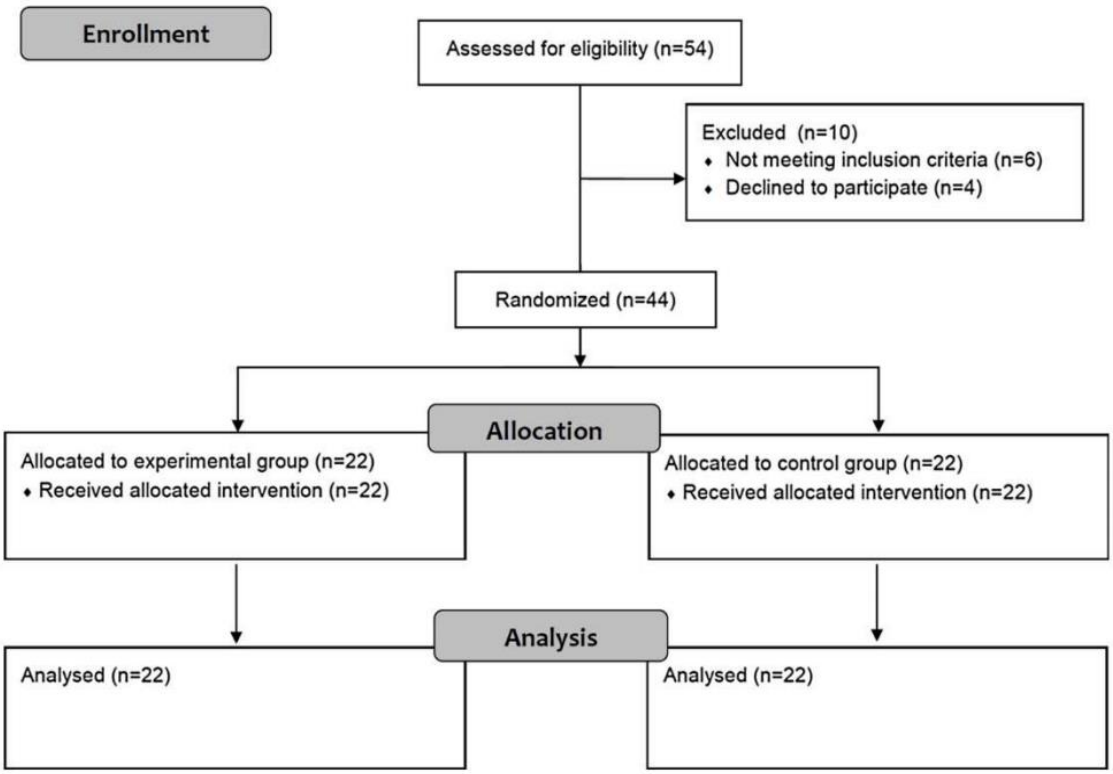

Table 1. Prioritized problems identified by participants divided into the occupational performance categories of self-care, productivity and leisure.

Domains	Occupational performance issues	Prioritized problems identified	Percentage of participants (%)
Self- Care	Personal Care	Dressing	30.76
	Functional mobility	Positioning in bed	38.46
		Walking outdoors	30.76
		Transfer from sitting to standing	10.38
Productivity	Household management	Cleaning	38.46
		Cooking	53.84
		Doing laundry	37.45
		Make the bed	7.69
		Carry weight	69.23
	Paid/unpaid work	Office work	30.76
		Standing positions when working	15.42
Leisure	Personal hobbies	Reading books	10.76

Table 2. Descriptive characteristics of participants.

	Experimental group	Control group	p-value
Age (years) mean ± SD	42.62 ± 8.57	45.35 ± 9.49	0.351
BMI (Kg/m2) mean ± SD	23.41 ± 2.87	25.15 ± 3.898	0.245
Education (%)			
No primary education completed	3 (13.65)	4 (28.28)	0.116
Primary education	7 (40.91)	6 (27.27)	
Secondary education	9 (31.81)	8 (36.36)	
Tertiary education	3 (13.64)	4 (18.18)	
Marital status (%)			
Single	3 (13.64)	4 (18.18)	0.086
Married	14 (63.64)	12 (54.55)	
Divorced/separated	5 (22.73)	6 (27.27)	
Employment (%)	15 (68.18)	12 (54.54)	0.268
Treatment history for pain (%)			
Analgesics	27 (77.27)	16 (72.72)	0.500
Analgesics + hot packing	18 (81.82)	16 (72.72)	0.368
Physiotherapy	4 (28.28)	10 (45)	0.061
Sexual activity (%)			
Lack of interest	9 (40.91)	13 (59.09)	0.183
Unsatisfied	12 (54.54)	16 (72.72)	0.174
Pain or discomfort	7 (31.82)	5 (22.73)	0.368
Disease duration (years) mean ± SD	6.79 ± 3.21	6.36 ± 6.17	0.827
Beck Anxiety Inventory mean ± SD	20.21 ± 9.67	15.52 ± 10.41	0.150
Beck Depression Inventory mean ± SD	16.53 ± 9.69	13.33 ± 8.65	0.290

BMI, Body Mass Index; SD, Standard Deviation.

Table 3. Pre-to post-intervention values of primary outcome measures.

Variables	Experimental group		Control group		Pre-intervention between groups p-value	Post-intervention between groups p-value	Effect size (Cohen's d)
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention			
	Health-related quality of life (EQ-5D) mean ± SD						
EQ-5D mobility	1.47 ± 0.51	1.00 ± 0.00*	1.29 ± 0.46	1.33 ± 0.48	0.231	0.005	0.97
EQ-5D self-care	1.42 ± 0.51	1.11 ± 0.32*	1.28 ± 0.56	1.38 ± 0.49	0.430	0.046	0.65
EQ-5D usual activities	1.74 ± 0.56	1.32 ± 0.48*	1.67 ± 0.48	1.62 ± 0.50	0.673	0.057	0.61
EQ-5D pain/discomfort	2.32 ± 0.75	2.00 ± 0.75*	2.19 ± 0.51	2.25 ± 0.44	0.537	0.208	0.41
EQ-5D anxiety/depression	1.89 ± 0.74	1.26 ± 0.45*	1.52 ± 0.60	1.67 ± 0.80	0.088	0.059	0.63
EQ-5D VAS	53.44 ± 14.91	70.06 ± 16.44*	58.57 ± 15.58	57.38 ± 16.40*	0.319	0.026	0.77
Coping behavior (CSQ) mean ± SD							
Catastrophization	15.14 ± 8.31	9.40 ± 7.79*	18.05 ± 6.85	18.98 ± 5.12	0.271	P<0.001	1.45
Distractor behaviors	16.25 ± 3.97	21.58 ± 7.08*	14.61 ± 2.66	15.56 ± 4.13	0.148	0.003	1.04
Self-instructions	20.30 ± 4.03	21.80 ± 5.71	18.21 ± 5.29	17.44 ± 6.57	0.173	0.035	0.71
Ignoring the pain	25.42 ± 6.24	28.85 ± 6.16*	24.79 ± 6.09	21.26 ± 3.41*	0.759	P<0.001	1.52
Reinterpreting the pain	16.40 ± 7.17	17.25 ± 8.05	16.42 ± 3.52	11.89 ± 5.60*	0.991	0.021	0.77
Hope	11.30 ± 5.05	13.55 ± 3.24*	10.53 ± 3.12	10.53 ± 3.11	0.571	0.011	0.95
Faithing and suplication	4.65 ± 4.71	4.00 ± 4.78	6.00 ± 5.66	3.18 ± 4.19*	0.422	0.588	0.18
Cognitive distraction	12.70 ± 10.36	10.25 ± 5.16	8.63 ± 4.15	6.68 ± 4.68	0.120	0.030	0.72
Adaptative coping	102.35 ± 20.39	113.00 ± 31.89*	93.10 ± 16.63	83.24 ± 16.69	0.133	0.002	1.17
Maladaptive coping	20.05 ± 9.54	13.79 ± 7.49*	23.53 ± 8.04	21.71 ± 7.18	0.228	0.003	1.08

*Significant within-group differences $p < 0.05$; CSQ: Coping Strategies Questionnaire; EQ-5D: EuroQol-5 Dimensions: SD: Standard Deviation; VAS: Visual Analogue Scale.

Table 4. Pre-to post-intervention values of secondary outcome measures.

Variables	Experimental group		Control group		Pre-intervention between-groups p-value	Post-intervention between-groups p-value	Effect size (Cohen's d)
	Pre-intervention	Post-intervention	Pre-intervention	Post-intervention			
Pain (mean ± SD)							
VAS	5.39 ± 1.95	2.21 ± 1.81*	6.47 ± 1.78	4.60 ± 1.51	0.166	0.003	1.43
Self-perception of performance (mean ± SD)							
COMP Performance	4.04 ± 1.29	6.97 ± 1.73*	4.66 ± 1.03	3.31 ± 0.56*	0.103	P<0.001	2.85
COMP Satisfaction	4.67 ± 1.65	7.28 ± 1.70*	4.88 ± 1.28	3.79 ± 1.96*	0.647	P<0.001	1.90
Physical activity levels (mean ± SD)							
IPAQ (METs)	1563 ± 918.15	2248.53 ± 1145.21	1220.85 ± 1040.32	1150.55 ± 573.54	0.299	0.001	1.21

* Significant within-group differences $p < 0.05$; SD: Standard deviation; COMP: Canadian Occupational Performance Measure; VAS: Visual Analogue Scale.

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ARTÍCULO 3

A systematic review of internet-based interventions for women with chronic pain

[Ariza-Mateos MJ, Cabrera-Martos I, Prados-Román E, Granados-Santiago M, Rodríguez-Torres J, Valenza CM. *British Journal of Occupational Therapy*. 2020. https://doi.org/10.1177/0308022620970861].

Mención de calidad obtenido de JCR:

Factor de Impacto (2020): 1.243

Categoría: Rehabilitation (62/68; Q4)

A SISTEMATIC REVIEW OF INTERNET-BASED INTERVENTIONS FOR WOMEN WITH CHRONIC PAIN

María José Ariza-Mateos, Irene Cabrera-Martos, Esther Prados-Román, María Granados-Santiago, Janet Rodríguez-Torres, Marie Carmen Valenza.

Abstract

Introduction: To evaluate the effects of internet-based interventions on physical and psychosocial outcomes in women with chronic pain through a systematic review.

Method: A search of the following electronic databases: PubMed/MEDLINE, ScienceDirect, and Web of Science. Two different authors separately tabulated the indices selected in identical predetermined forms. The methodological quality of all randomised trials was assessed using the Cochrane Collaboration's tool for assessing the risk of bias.

Results: Seven articles were finally included. The main features of interventions included online cognitive-behavioural and/or psychoeducation therapy to improve health with an interactive component. The methodological quality showed a high risk of bias, mainly from a lack of blinding.

Conclusion: There are indicators that suggest that internet-based interventions may be useful for women with chronic pain. However, the validity of such a conclusion is limited as most trials included had a high risk of bias. More rigorous research is required before stating that such interventions can overcome the current limitations of traditional face-to-face care.

Keywords: Women, chronic pain, systematic review, internet, therapy

Introduction and literature review

Chronic pain is a distressing experience associated with actual or potential tissue damage, including sensory, emotional, cognitive and social components (Williams and Craig, 2016) that persists beyond 3 months. It is among the most costly health conditions in the developed world and has an estimated worldwide prevalence of 30% (Elzahaf et al., 2012). Currently, the financial cost of treating chronic pain is estimated at more than e200 billion per year in Europe and $150 billion per year in the United States (Van Hecke et al., 2013).

The aetiology of chronic pain includes a wide range of causes and courses that can be influenced by behavioural, psychological, environmental and social factors (Van Hecke et al., 2013). From a clinical viewpoint, previous studies have shown that women are more likely than men to report recurrent pain in multiple body areas; such pain is often described as being more severe and frequent in women compared to men (Pieretti et al., 2016). In particular, musculoskeletal pain has been reported to be frequently associated with the onset of the menopause (Watt, 2018). Previous studies from a variety of geographical regions have also shown higher prevalence rates in fibromyalgia and widespread chronic pain in women compared to men (Wijnhoven et al., 2016). Chronic pain carries a high level of disease burden, including disability affecting activities of daily living, work performance and health related quality of life (Duenas et al., 2016).

Interventions for chronic pain are often long term and costly (Duenas et al., 2016). Interdisciplinary pain management protocols, particularly those employing a biopsychosocial framework, have been among the most successful approaches including a variety of therapeutic modalities, such as medication management, cognitive-behavioural therapy, manual therapy and guided exercise (Gatchel et al., 2014).

Patients with chronic pain usually report having a limited amount of money and time, which makes self-management support programmes important choices for their chronic conditions (Rod, 2016).

Information and communication technologies offer new possibilities for clinical interventions and a service delivery model within occupational therapy (Cason, 2012; Renda and Lape, 2018). In particular, internet-based systems can address accessibility and cost issues and are therefore a potential solution for women who live in remote areas, prefer home-based care or working at their own pace, and experience a loss of their independence (Rod, 2016). Moreover, some authors (Nes et al., 2017) concluded that by reporting their symptoms electronically, participants increased their awareness, thereby influencing their behaviour positively and leading to symptom reduction. Salaffi et al. (2015) reported that the internet opens many opportunities for self-care as it can be used as a powerful means to promote a healthy lifestyle and increase patients' understanding of their condition. At present, the coronavirus disease 2019 (COVID-19) pandemic has transformed healthcare practice. The internet makes it possible to conduct many consultations remotely (Smith et al., 2020). For people not infected with the COVID-19 virus, especially those with pre-existing pathologies, such as chronic pain conditions, internet-based interventions can provide convenient access to their therapy without overtly exposing them to the virus (Smith et al., 2020). In addition, the study conducted by Perez-Lopez et al. (2020) showed a high incidence of COVID-19 among women in European countries, which makes them a focus for the development of this kind of intervention.

Previous systematic reviews have explored the benefits of internet-based interventions in various populations with chronic pain and shown an improvement in pain severity, activity limitation (Buhrman et al., 2016), pain interference (Slattery et al., 2019) and empowerment (Garg et al., 2016). Although the results are promising, the literature is heterogeneous, as the types of internet treatments are diverse. In addition, it is not clear

yet which types of patients benefit most, given that the studies included patients with heterogeneous pain complaints (Bender et al., 2011). Women are high utilisers of healthcare. Considering biological and sociocultural characteristics, including specific work and family-related demands, they have gender-specific healthcare needs that may benefit from specific internet-based interventions (Goldstein et al., 2018). In this regard, performing a gender analysis is relevant to determine the effectiveness of internet-based interventions, which may lead women to adopt a more proactive behaviour in the treatment, maintenance and follow-up of their pain.

In the current context, it is worth noting the high prevalence of women with chronic pain and the different patterns exhibited by women in health and help-seeking patterns and use of care (Arman et al., 2019; Osika Friberg et al., 2016). Considering the above, an updated systematic review applying a gender perspective is needed to help occupational therapists to choose the appropriate intervention for specific chronic conditions. To our knowledge, no previous study has focused on the effects of internet-based interventions for women with chronic pain. Therefore, the aim of this review was to evaluate the effects of internet-based interventions in women with chronic pain focusing on physical and psychosocial outcomes.

Method

This systematic review was conducted from January to March 2018 according to the guidelines outlined in the preferred reporting items for systematic reviews and meta-analyses (PRISMA) statement (Moher et al., 2009). It was registered in PROSPERO (CRD42015030227). The searches were updated in November 2019 to identify papers that may have potentially been published during the preparation of this paper for submission. The objective was to update the systematic review conducted by Bender et al. (2011) to identify all the clinical trials focused on women

with chronic pain and internet-based interventions in the PubMed/MEDLINE, ScienceDirect and Web of Science databases published from 1 January 2010 to 1 November 2019 to identify the recent areas of interest and scientific evidence in this area. The search terms used were 'chronic pain', 'internet-based', 'internet-delivered', 'internet-assisted', 'web-based', 'web-delivered', 'web-assisted', 'computer', 'computerised', 'online', 'app', 'mobile applications', 'women', 'treatment', 'intervention' and 'program'. Reference lists of the articles were also examined to find additional studies.

Articles were included if they met the following inclusion criteria: prospective randomised controlled trials, a percentage of women higher than 90% among participants included, chronic pain for more than 18 years without restrictions of ethnicity or setting and internet-based interventions for chronic pain management delivered alone or supplemented by an additional modality compared to a control group or other types of interventions not using the internet. This review aimed to combine information from studies using different outcome measures to provide an overview to clarify the effects on physical and psychosocial outcomes. We excluded studies that included participants with cancer pain, visceral pain, radiculopathy and postoperative pain. We also excluded animal studies, reviews, commentaries, case studies and conference presentations. The languages of the articles included in this review were limited to English, Spanish and French.

The data and results of the articles included were extracted by two independent reviewers and discussed with a third reviewer if there was a lack of consensus. The first step was to find and exclude duplicated articles from the different databases. Next, titles and abstracts were screened to identify relevant articles. Subsequently, the full texts of relevant articles were read in detail to determine their eligibility (Figure 1).

A data extraction form was developed to ensure that all relevant information was captured. Descriptive information included first author, year of publication, number of participants, aim, age of women, inclusion criteria and the number and percentage of dropouts overall and per attrition from random allocation to post-intervention assessment. The characteristics of interventions were also recorded, including the description of the interventions delivered, duration and frequency, main outcomes and results.

Methodological quality was assessed using the Cochrane Collaboration's tool for assessing the risk of bias (Higgins et al., 2011). This scale includes the following in its score: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome, incomplete outcome data, selective reporting and other forms of bias. Two reviewers independently assessed the items as having a 'high risk of bias', 'low risk of bias' or 'unclear risk of bias'. Discrepancies were solved by discussion and, if consensus could not be reached, a third reviewer was invited to make a final judgement.

It was not possible to undertake a meta-analysis due to the low number of studies addressing similar outcomes and the broad differences in the measures used to assess them.

Results

The initial literature search resulted in 2369 articles. After removing duplicates, 2201 titles were screened. After that, 137 full-text articles were assessed for eligibility and 130 were excluded. A total of seven articles were included in this systematic review (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Nes et al., 2017; Salaffi et al., 2015; Simister et al., 2018; Tavallaei et al., 2018; Vallejo et al., 2015) (Figure 1).

Table 1 shows the general characteristics of the studies selected. These studies included a total of 562 women with chronic pain whose mean age

ranged between 32 and 67 years. No overall summaries of age were included in the studies conducted by Salaffi et al. (2015), Nes et al. (2017) or Tavallaei et al. (2018). In addition, there was no information on the age of specific groups in the study by Simister et al. (2018), and the mean age of participants in the control group was not reported in the study by Nes et al. (2017). Five studies included women with fibromyalgia (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Salaffi et al., 2015; Simister et al., 2018; Vallejo et al., 2015), one study included women with chronic primary headaches (Tavallaei et al., 2018) and one included women with chronic widespread pain (Nes et al., 2017). The aim of most studies was to assess the efficacy of internet-based or smartphone-delivered treatments in the health of women with chronic pain. Dropout rates in web-assisted trials varied significantly.

The main characteristics of the interventions proposed are reported in Table 2. Cognitive-behavioural therapy (Friesen et al., 2017; Vallejo et al. 2015), exposure therapy (Hedman-Lagerlof et al., 2018), acceptance therapy (Nes et al., 2017), mindfulness (Tavallaei et al., 2018) and multicomponent therapy (Salaffi et al., 2015; Simister et al., 2018) were the main interventions. The authors proposed a multimodal approach including psychoeducation, information and exercise (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Nes et al., 2017;Salaffi et al., 2015; Simister et al., 2018; Vallejo et al., 2015). The interventions were delivered in a period ranging between 8 and 12 weeks. The studies used web pages, internet software, applications or smartphones. The results of studies showed improvements in pain, self-efficacy, pain-related fear and avoidance, pain acceptance, positive feelings, fibromyalgia symptoms, disability, quality of life, anxiety, depression, fatigue and psychological flexibility when internet-delivered programmes were administered (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Nes et al., 2017; Salaffi et al., 2015; Simister et al., 2018; Tavallaei et al., 2018; Vallejo et al., 2015).

Improvements were maintained at follow-up in the main outcomes (Friesen et al., 2017; Vallejo et al., 2015).

Details regarding the risk of bias are shown in Table 3. Five trials were at low risk of bias due to random sequence generation (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Salaffi et al., 2015; Simister et al., 2018; Vallejo et al., 2015) and incomplete outcome data (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Salaffi et al., 2015; Tavallaei et al., 2018; Vallejo et al., 2015). However, six studies were at high risk of bias in relation to the blinding of participants and personnel (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Nes et al., 2017; Salaffi et al., 2015; Simister et al., 2018; Tavallaei et al., 2018) and five were at high risk of bias regarding the blinding of the outcome assessment (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Nes et al., 2017; Salaffi et al., 2015; Vallejo et al., 2015). In addition, four trials had an unclear risk of bias related to allocation concealment (Friesen et al., 2017; Nes et al., 2017; Tavallaei et al., 2018; Vallejo et al., 2015) and selective reporting (Nes et al., 2017; Salaffi et al., 2015; Tavallaei et al., 2018; Vallejo et al., 2015).

Discussion and implications

The purpose of the present systematic review was to assess published randomised controlled trials that explored the effects of internet-based interventions in women with chronic pain. Seven clinical trials were identified as addressing the impact of internet-based interventions in this population. These trials were assessed as having poor to fair quality, with small sample sizes; many of them were not blinded. The most frequent diagnosis was fibromyalgia, one article focused on chronic widespread pain and one article focused on chronic primary headaches. The delivery, format and timeline of the interventions also varied. The main features of interventions included online cognitive-behavioural and/or psychoeducation therapy to improve health with an interactive component.

In our review, most studies that used internet-based interventions to treat women with chronic pain showed improvements in pain intensity, depression and pain-related fear and avoidance (Friesen et al., 2017; Hedman-Lagerlof et al., 2018; Nes et al., 2017; Simister et al., 2018; Vallejo et al., 2015). These findings are relevant given that fear of movement is associated with functional outcomes, pain severity and depressed mood in individuals with chronic pain (Nijs et al., 2013).

All studies used psychoeducation to treat women, but it was always combined with other therapies. For example, two trials included cognitive-behavioural therapy (Friesen et al., 2017; Vallejo et al., 2015) and both showed improvements in depression and catastrophising. Vallejo et al. (2015) demonstrated that the group receiving internet-delivered cognitive-behavioural therapy improved in several self-efficacy measures (i.e. global, pain and coping with symptoms), whereas the cognitive-behavioural group did not improve in these measures.

Behaviour change strategies have been shown to be reliably delivered in an internet-based healthcare environment and have been perceived to build client engagement (Nalder et al., 2018). Internet-delivered therapy is carried out in patients' home environments. This setting could be a facilitator for the generalisation of treatment effects. A previous review (Macea et al., 2010) reported that cognitive-behavioural therapy is also useful to treat pain-related depression. Women who underwent this therapy also exhibited better self-pain management and attitudes toward their pain. The internet delivery may lead to an increase in the personal power of the patient with chronic pain. Nes et al. (2017) combined acceptance and commitment therapy with exercises through web pages and smartphones and showed improvements in self-efficacy, fear, pain acceptance and positive feelings. Various authors (Buhrman et al., 2016; Trompetter et al., 2016) have demonstrated the benefits of online acceptance and commitment therapy for chronic pain patients, with changes in pain intensity, pain interference, depressive symptoms,

acceptance of pain, psychological distress, pain catastrophising, psychological inflexibility and satisfaction. In addition, Hedman-Lagerlof et al. (2018) combined exposure therapy with psychoeducation and obtained improvements in fear, disability, pain, quality of life, anxiety, depression, fatigue and sleep, but they did not assess self-efficacy. Vugts et al. (2018) showed that computer-based interventions that facilitate compliance and exposure are indicated for relatively young, highly educated female patients with depressed mood. However, there is not enough scientific evidence to verify these results, so future clinical trials are needed to assess internet-delivered exposure therapy in women with chronic pain. A previous study explored the differences between male and female patients with the same level of pain, severity of symptoms, discomfort and somatic health. The results showed a significantly higher activity level, pain acceptance and social support in women while men reported higher kinesiophobia, mood disturbances and lower activity levels (Rovner et al., 2017). The results could potentially be useful to consider while designing rehabilitation programmes.

Internet-based interventions make it possible to tailor healthcare considering gender-specific healthcare needs. According to a recent review, there is a need to examine the effects, efficiency and acceptability of telehealth for women to inform efforts to implement it (Goldstein et al., 2018). In our review, we focused on the effects of internet-based interventions for women with chronic pain in order to analyse the options, results and methodological quality of research.

Previous systematic reviews (Bender et al., 2011; Macea et al., 2010) have reported high quality in their selected trials including both men and women. Regarding the methodological quality of the studies included, most had a high risk of bias.

There is a need for future studies with larger sample sizes and better methodological designs.

This systematic review has certain limitations. For example, the relevant literature published in other languages may have been excluded. We combined studies with different arms of treatment as there are not yet sufficient data within the same comparison group. Moreover, different measures were included in the articles. In addition, the studies selected had small sample sizes and most of them were not blinded. Another limitation was that women in the trials included only had fibromyalgia, chronic primary headaches or widespread chronic pain. Nevertheless, the aim was to provide a summary of the results and main effects to encourage quality research in this area, given the importance and novelty of internet-based treatments now.

Conclusion

There are indicators that suggest that internet-based interventions may be useful for women with chronic pain. However, the validity of such a conclusion is limited as most trials included had a high risk of bias. More rigorous research including adequately powered double-blinded controlled clinical trials is required before it can be stated that such interventions can overcome the current limitations of traditional face-to-face care.

Key findings

• Internet-based interventions are a promising approach for women with chronic pain.

• Although some benefits were found in women receiving internet-based interventions, more rigorous research is needed in this area.

What the study has added

There are indicators that internet-based interventions may be useful for women with chronic pain; however, more rigorous research is required given the high risk of bias shown.

Research ethics

Ethical approval was not required for this manuscript as it is a systematic review that involves no participants.

Consent

This study was a systematic review and did not involve human participants.

Declaration of conflicting interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of the article. Funding None declared.

Contributorship

All named authors have contributed to and take shared accountability for the study.

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Figure 1. Categorization flowchart showing clinical trial selection

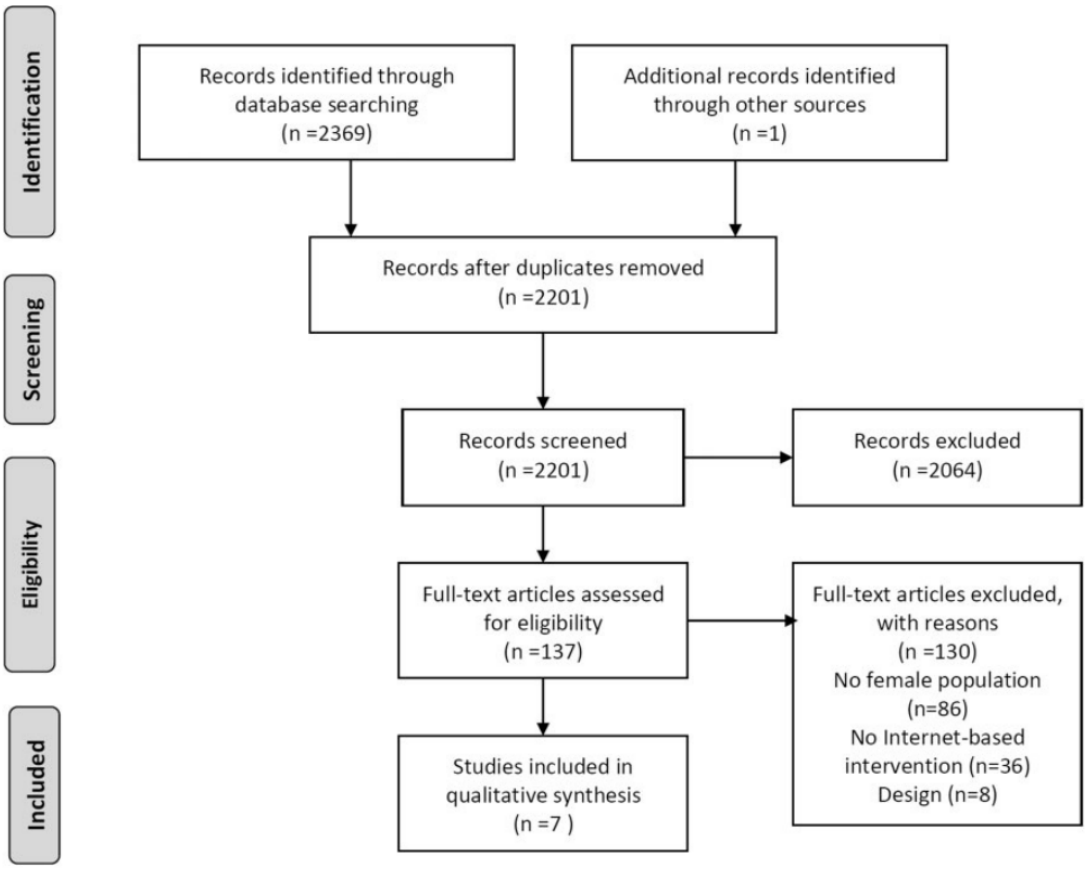

Table 1. Main characteristics of the articles selected

Article (first author, year, country)	Disease	Number of groups	Sample Size	Mean age for total sample and groups (standard deviation)	Inclusion Criteria	n (% dropouts) at post-intervention
Salaffi, 2014, Italy	Fibromyalgia	2: EG and CG	76: EG= 38; CG=38	Total sample: Not reported. EG: 48.3 (11.3) CG: 49.6 (12.3)	Had an average numerical rating scale pain score of ≥4; had been on stable doses of fibromyalgia medications for ≥4 w	Overall: 4 (5.26) EG: 2 (5.26) CG: 2 (5.26)
Vallejo, 2015, Spain	Fibromyalgia	3: CBT, ICBT and WLG	60: CBT=20; ICBT= 20; WL=20	Total sample: 51.55 (9.87) WLG: 51.33 (10.03) CBT: 53.50 (8.56) ICBT: 49.82 (11.01)	Meet the American College of Rheumatology research classification criteria for fibromyalgia, age ≥18-y, adequate reading comprehension and access to and ability to use a computer.	Overall: 7 (11.6) WLG: 0 (0) CBT: 3 (15) ICBT: 4 (20)
Friesen, 2017, Canada	Fibromyalgia	2: EG and WLG	60: EG=30; CG=30	Total sample: 48 (11) EG: 49 (10) WL: 46 (13)	Age ≥18-y, diagnosis of fibromyalgia, pain for more than 3 months, clinically significant symptoms of fibromyalgia and at least mild symptoms of depression or anxiety.	Overall: 8 (13.33) EG: 5 (16.67) WLG: 3 (10)
Hedman-Lagerlöf, 2017, Sweden	Fibromyalgia	2: iExp and CG	140: iExp=70; CG=70	Total sample: 50.3 (10.9) EG: 51.8 (10.7) WLG: 49. 3 (10.0)	Age ≥ 18-y with a confirmed fibromyalgia diagnosis who had Internet access and who would agree to refrain from any other psychological treatment for the duration of the study.	Overall: 2 (1.43) EG: 2 (2.86) WLG: 0 (0)
Nes, 2017, Norway	Chronic widespread pain	2: SMI and CG	88: SMI=48; CG=40	Total sample: Not reported. SMI: 43 (11.12) CG: Not reported.	Not reported	Overall: 28 (20) SMI: 22 (31.43) CG: Not reported
Simister, 2018, Canada	Fibromyalgia	2: ACT+TAU and TAU	67: ACT+TAU=33; TAU=34	Total sample: 39.7 (9.36) Groups: Not reported.	Age ≥ 18-y, formal diagnosis of fibromyalgia, and self-reported pain intensity rating of at least 4/10	Overall: 9 (13.43) Act+TAU: 6 (18.18) TAU: 3 (8.82)
Tavallaei, 2018, Iran	Chronic primary headaches	2: EG and CG	30: EG=15: CG=15	Total sample: Not reported. EG: 32.47 (9.11) CG: 34.87 (9.12)	Diagnosis by expert physician, age 18-50-y, least education degree of diploma and access to Internet and social network of Telegram.	Overall 0 (0) EG: 0 (0) CG: 0 (0)

ACT: Acceptance and Commitment therapy; CBT: Cognitive-behavioral therapy; CG: control group; EG: experimental group; ICBT: Internet-delivered cognitive-behavioral therapy; iExp: Internet-based exposure therapy; SMI: smartphone maintenance intervention; TAU: Treatment as usual; WLG: waiting-list group; w: weeks; y: years.

Table 2. Characteristics of interventions

Article (first author, year, country)	Description of Internet-based interventions	Duration/ Frequency	Main outcomes	Secondary Outcomes	Main results
Salaffi, 2014, Italy	Exercise (aerobic, muscle strength and stretching training exercises) and education covering topics related to the characteristics of fibromyalgia.	45 min/s 2 times/w 12-w	Fibromyalgia symptoms and impact: FIQ	Fatigue and the quality of sleep: FAS	EG: significantly improved the FIQ (p=0.0006), fatigue and quality of sleep (p=0.0002) in comparison with the standard approach according to the Mann-Whitney U-test. Increased the time-integrated area under the curve of the FAS scores.
Vallejo, 2015, Spain	Internet-delivered cognitive-behavioral therapy: including psychoeducation about fibromyalgia, relaxation and breathing training through a Web application.	120 min/s 10 times/w 10-w	Fibromyalgia symptoms and impact: FIQ	Psychological distress: HADS; Catastrophizing: PCS; Self-efficacy: CPSS; Coping: CPCI	CBT group: significant improvement in the primary outcome (p<0.001); ICBT group: improvement in self-efficacy; CBT and ICBT groups: significant improvement in psychological distress, depression, catastrophizing, using relaxation as a coping strategy (p<0.05); CBT and ICBT groups were dissimilar in efficacy at follow-up. The effect of the three treatment groups in the pre- and post-treatment comparisons was assessed using a mixed model repeated measures ANOVA. The ICBT group maintained or improved scores 6- and 12-month follow-up according to ANOVA analyses.
Friesen, 2017, Canada	Pain management program that consists of online lessons focused on information, cognitive behavioral model; and pain management strategies.	5-10 min/w 8-w	Fibromyalgia severity and symptomatology: FIQR; Pain severity and interference: BPI; Anxiety: GAD-7; Depression: PHQ-9	Anxiety and depression: HADS; Pain self-efficacy: PSEQ; Catastrophizing and coping: PRSS; Fatigue: FSI; Fear of movement and re-injury: TSK; Quality of life: SF-12	EG: pre- to post-treatment significant improvements in measures of Fibromyalgia, depression, pain and fear of pain compared to very minimal changes for the WLG. The range of improvement in primary and secondary outcomes was 8%-28% and 7%-24% in the EG and -4% to 5% and -5% to 10%, respectively, in the WLG according to a generalized estimation equation analysis. Large between-group effect sizes (Cohen's d) in BPI Severity, BPI-Interference, PRSS-Coping, and TSK.
Hedman-Lagerlöf, 2017, Sweden	Internet-based exposure therapy through a web platform. The protocol included psychoeducation, case examples on exposure and mindfulness exercises and treatment progression based on valued based goals in everyday life.	1-3times/w 10-w	Fibromyalgia symptoms and impact: FIQ	Fatigue: FSS; Disability: WHODAS II; Quality of life: BBQ; Depressive symptoms: PHQ-9; General anxiety symptoms: GAD-7; Insomnia: Insomnia Severity Index; Pain-related distress: PRS; Avoidance behaviors: PIPS	iExp group: superior improvements and significant interaction effects of group and time compared to WLG on fibromyalgia symptoms and impact, and on secondary outcomes based on mixed-effects model analyses, with sustained results. Medium to large effect sizes were shown for most of the measures.
Nes, 2017, Norway	Smartphone-delivered maintenance intervention with daily electronic diaries and personalized written feedback based on acceptance and commitment therapy following a 4w rehabilitation program.	9-w	Pain Catastrophizing: PCS	Pain intensity: VAS; Pain acceptance: CPAQ General Health: GHQ; Chronic pain values: CPVI, Performed physical activity, Pain Self-management, Pain fear and avoidance and Positive Feelings: 5-Likert scale (strongly agree-strongly disagree)	SMI: Participants´ pain fear and avoidance decreased. Self-management, pain acceptance, and positive feelings increased significantly. Participants´ performance of physical activity decreased slightly, but the level of commitment was high. The analysis performed was multilevel modeling.
Simister, 2018, Canada	Online acceptance and commitment therapy focused on psychoeducation, acceptance, values, cognitive defusion, mindfulness and willingness and committed action.	8-w	FM impact: FIQR	Depression: CES-D Pain: McGill Pain Questionnaire Sleep: Pittsburgh Sleep Quality Index Physical measures: 6-minute walk test and 1-minute sit to stand test	ACT+TAU: Significant improvement (P<0.001) on fibromyalgia impact compared to TAU participants, with large effect sizes. Increases in pain acceptance significantly mediated these improvements. Significant improvements in favor of online intervention on measures of depression (p=0.020), pain (p=0.010) and kinesiophobia (P=0.001). The results were analyzed using linear mixed effects modeling.
Tavallaei, 2018, Iran	Mindfulness-based stress reduction developed using an Internet-based bibliotherapy intervention	8-w	Pain intensity: DASS-21; distress: MIDAS; disability: MPQ-SF; mindfulness: MAAS	-	EG: Significant difference between the mean scores of the EG and CG in pain intensity index (P=0.035), distress (P<0.0001), disability (P<0.0001) and mindfulness (P<0.0001), being higher the in the EG. The analyses were based on multivariate analysis of covariance test at inferential level.

ANOVA: Analysis of variance; ACT+TAU: Acceptance and Commitment Therapy + treatment as usual; BBQ: Brunnsviken Brief Quality of Life Scale; BPI: Brief Pain Inventory; CBT: cognitive-behavioral therapy; CES-D: Center for Epidemiological Studies Depression Scale; CPAQ: Chronic Pain Acceptance Questionnaire; CPCI: Chronic Pain Coping Inventory; CPSS: Chronic Pain Self-efficacy Scale; CPVI: Chronic Pain Values Inventory; DASS-21: Depression, Anxiety, Stress Scale - Short Form; EG: experimental group; FAS: Fibromyalgia Activity Score; FSS: Fatigue Severity Scale; FIQ: Fibromyalgia Impact Questionnaire; FIQR: Fibromyalgia Impact Questionnaire-Revised; FSI: Fatigue Symptom Inventory; GAD-7: Generalized Anxiety Disorder 7-Item; GHQ: General Health Questionnaire; HADS: Hospital Anxiety and Depression Scale; ICBT: Internet-delivered cognitive-behavioral therapy; iExpG: internet-based exposure therapy; MAAS: Mindfulness Inventory; MIDAS: Migraine Disability Assessment Scale; MPQ-SF: McGill's Short Form Questionnaire; PCS: Pain Catastrophizing Scale; PHQ-9: Patient Health Questionnaire 9-item; PIPS: Psychological Inflexibility in Pain Scale; PRS: Pain Reactivity Scale; PRSS: Pain Responses Self-Statements; PSEQ: Pain Self-Efficacy Questionnaire; S: session; SF-12: Medical Outcomes Study Short Form-12; SMI: smartphone maintenance intervention; TSK: Tampa Scale of Kinesiophobia; TAU: treatment as usual; VAS: visual analogue scale; w: weeks; WHODAS II: WHO Disability Assessment Schedule; WLG: waiting-list group.

Table 3. Quality assessment using the Cochrane Collaboration's tool for assessing risk of bias

Article (first author, year, country)	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias
Salaffi, 2014, Italy	Low	Low	High	High	Low	Unclear	Low
Vallejo, 2015, Spain	Low	Unclear	Unclear	High	Low	Unclear	Low
Friesen, 2017, Canada	Low	Unclear	High	High	Low	Low	Low
Hedman-Lagerlöf, 2017, Sweden	Low	Low	High	High	Low	Low	Low
Nes, 2017, Norway	Unclear	Unclear	High	High	High	Unclear	Low
Simister, 2018, Canada	Low	Low	High	Low	High	Low	Low
Tavallaei, 2018, Iran	Unclear	Unclear	High	Unclear	Low	Unclear	Unclear

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RESUMEN DE LOS RESULTADOS Y DISCUSIÓN

RESUMEN DE LOS RESULTADOS Y DISCUSIÓN

El principal objetivo de esta tesis doctoral fue valorar la eficacia de una intervención de terapia ocupacional en personas con dolor crónico, específicamente en DPC, y proporcionar una visión psicosocial a los enfoques de tratamiento existentes.

En el primer ensayo clínico, nuestros resultados mostraron que una combinación de terapia de exposición gradual a la actividad y terapia manual en mujeres con DPC puede ser eficaz para mejorar comportamientos de evitación del miedo, el dolor y la discapacidad, tanto a corto como a largo plazo. Estos resultados respaldan la teoría de que el miedo al movimiento relacionado con el dolor podría actuar como un mecanismo de interacción importante que facilita el desarrollo y el mantenimiento del dolor crónico, generando comportamientos de evitación a largo plazo y repercutiendo en el desempeño de las actividades de la vida diaria[5]. Al igual que nuestro programa de intervención, otros científicos también han empleado este tipo de programas combinados o como complemento de los enfoques físicos[118, 119], sin embargo, la mayoría de los estudios que utilizan la terapia de exposición gradual para el dolor crónico se centran en el dolor lumbar[120, 121]. Hasta la fecha, nuestro ensayo clínico es el único que utiliza la terapia de exposición gradual a la actividad para tratar mujeres con DPC.

Por otro lado, los resultados del ensayo clínico en el que utilizamos un modelo de complejidad acumulativa centrado en el placiente en mujeres con DPC mostraron mejoras en la calidad de vida, el comportamiento de afrontamiento, el dolor, el rendimiento percibido y los niveles de actividad física. Hallazgos anteriores han demostrado que el deterioro funcional es frecuente entre las personas con DPC[39]. Además, los metanálisis recientes han demostrado la eficacia de los programas de autogestión para facilitar el ajuste del comportamiento en personas con dolor crónico y mejorar los resultados, como el bienestar y

los cambios adaptativos en el estilo de vida[122, 123]. Gardner y col[124]. propusieron un enfoque de establecimiento de objetivos que permitiera a los participantes reconceptualizar el dolor, cambiar su percepción del dolor y conducir a un nuevo compromiso con las actividades y el encuadre cognitivo. En nuestra intervención, incluimos educación sobre el dolor crónico y planes de acción para objetivos individualizados, incluyendo modelos de autocontrol y habilidades de afrontamiento adaptativo para mejorar el ajuste al dolor.

En la revisión sistemática encontramos una mejora en la intensidad del dolor, la depresión, el miedo y la evitación relacionados con el dolor en la mayoría de los estudios que utilizaron las intervenciones basadas en internet para tratar a mujeres con dolor crónico[125-129]. Además, esas intervenciones incluían la terapia cognitivo-conductual y/o psicoeducativa en línea con un componente interactivo. Macea et al., 2010[130], en una revisión anterior, destacó la utilidad de la terapia cognitivo-conductual para tratar la depresión asociada al dolor, obtuvieron mejoras en el manejo del dolor y las actitudes hacia el dolor, lo que puede indicar que la entrega a través de Internet puede conducir a un aumento en el empoderamiento personal hacia el dolor crónico. En cuanto a la calidad metodológica, las revisiones sistemáticas realizadas anteriormente[130, 131] informaron de una alta calidad de sus ensayos seleccionados, que incluían tanto mujeres como hombres. La calidad metodológica de los estudios incluidos en nuestra revisión, que sólo incluyeron mujeres, tuvo un alto riesgo de sesgo. Por lo tanto, es necesario realizar futuros estudios con muestras más grandes y mejores diseños metodológicos. No obstante, esta revisión ha permitido conocer los diferentes abordajes terapéuticos utilizados en mujeres con dolor crónico. Futuros estudios podrían desarrollar un ensayo clínico controlado aleatorizado que evalúe los efectos de una intervención a distancia en mujeres con DPC.

Futuras perspectivas

Esta tesis doctoral recaba información sobre nuevos abordajes psicosociales en personas con dolor crónico, y se basa en el modelo biopsicosocial centrado en el paciente, que podría ayudar a la comprensión de su condición y al manejo de su dolor.

Este trabajo abre una ventana para la investigación de otras modalidades de tratamiento que apliquen enfoques biopsicosociales en el dolor crónico y el dolor pélvico crónico. Además, el enfoque que hemos aplicado en el tratamiento del DPC podría ser eficaz en otras condiciones de dolor, tanto agudo, como subagudo o crónico, y en diferentes localizaciones de dolor. En el caso de aplicarse en dolor agudo o subagudo podría ayudar a evitar la cronificación del dolor.

Por otro lado, las intervenciones basadas en internet podrían ser una buena forma de administración del tratamiento no presencial, lo que parece estar adquiriendo especial relevancia en la actualidad, tanto por la limitación en el tiempo y dinero que supone una atención presencial, como por la actual situación de pandemia por COVID-19, y que, de este modo, las personas puedan evitar la exposición al virus. Con lo cual, sería muy interesante seguir indagando acerca de la eficacia de las intervenciones basadas en internet.

Además, es necesario continuar investigando la eficacia de los diferentes abordajes biopsicosociales desde la terapia ocupacional en diferentes condiciones de dolor para que puedan ser incluidos en la práctica clínica habitual.

CONCLUSIONES

CONCLUSIONES

CONCLUSIONES ESPECÍFICAS

1. La terapia de exposición gradual a la actividad, junto con un programa de terapia manual, es efectiva en mujeres con DPC y miedo al movimiento/(re) lesión mostrando efectos significativos de interacción de tiempo x grupo. Este enfoque resulta claramente superior a la terapia manual sola en el mantenimiento de mejoras en el comportamiento y el funcionamiento físico para evitar el miedo a largo plazo.

2. Una intervención centrada en el paciente que considera la carga de trabajo de los pacientes y su capacidad para realizar comportamientos saludables proporciona beneficios con respecto a la calidad de vida y el comportamiento de afrontamiento. Además, mejora la gravedad del dolor, el desempeño percibido en las tareas relevantes para ellas y los niveles de actividad física.

3. Hay indicadores que sugieren que las intervenciones basadas en internet pueden ser útiles para las mujeres con dolor crónico. Sin embargo, la validez de tal conclusión es limitada ya que la mayoría de los ensayos incluidos tenían un alto riesgo de sesgo. Se requiere una investigación más rigurosa que incluya ensayos clínicos controlados con un doble ciego adecuado antes de que se pueda afirmar que tales intervenciones pueden superar las limitaciones actuales de la atención presencial tradicional.

CONCLUSIÓN GENERAL

Una intervención de terapia ocupacional que emplee un enfoque biopsicosocial en personas con dolor crónico, específicamente en mujeres con DPC, podría ser una forma eficaz de tratamiento tanto a corto como a largo plazo, y podría ser incluida en la práctica clínica habitual.

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PRODUCCIÓN CIENTÍFICA

Producción científica

Publicaciones científicas

Ariza-Mateos MJ, Cabrera-Martos I, Ortiz-Rubio A, Torres-Sánchez I, Rodríguez-Torres J, Valenza MC. Effects of a patient-centered graded exposure intervention added to manual therapy for women with chronic pelvic pain: a randomized controlled trial. Archives of physical medicine and rehabilitation.2019;100(1):9-16.

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Asistencia a congresos de divulgación científica y comunicaciones

I Congreso Internacional de Intervención e Investigación en Salud

- Eficacia de una intervención basada en el modelo biopsicosocial en personas con dolor cervical crónico.
- Terapia de exposición en dolor crónico pélvico: Estudio de caso.
- Afectación de la mecánica neural por dominancia en personas con dolor cervical crónico.
- Kinesiofobia y amplitud de movimiento voluntario en personas con dolor cervical crónico y personas sin dolor cervical.

I Jornadas de Investigadores en Formación. Fomentando la interdisciplinariedad (JIFFI). Escuela Internacional de Posgrado. Universidad de Granada.

- Modelo de miedo-evitación en mujeres con dolor crónico pélvico

II Jornadas de Investigadores en Formación Fomentando la Interdisciplinariedad (JIFFI)

- Asociación entre el miedo al movimiento y la afectación del equilibrio en mujeres con dolor crónico pélvico.

III Congreso Internacional en Contextos Clínicos y de la Salud.

- Eficacia de las intervenciones tecnológicas en dolor crónico. Una revisión sistemática.
- Modalidad de intervenciones tecnológicas en dolor crónico.
- Eficacia de la musicoterapia en dolor crónico.
- Relación entre composición corporal, dolor, rigidez y funcionalidad en mujeres postmenopáusicas con artrosis de rodilla.

- Efectos de un programa de ejercicio acuático versus danza en mujeres obesas postmenopáusicas con osteoartritis de la rodilla.

I Jornadas Internacionales de actualización del conocimiento en Ciencias de la Salud

- Eficacia de la intervención de Terapia Ocupacional adicional a un programa de analgesia y reeducación postural en mujeres con dolor crónico pélvico.

I Congreso Internacional y VI encuentros Hispano-Cubanos en Ciencias de la salud. Facultad de Ciencias de la Salud. Universidad de Granada

- Eficacia de programas de intervención terapéutica con el modelo de miedo-evitación en color crónico. Una revisión sistemática.
- Desempeño ocupacional y modelo de miedo-evitación, intervención en dolor crónico pélvico. Estudio de caso.
- Relación entre el número de puntos gatillo, dolor y funcionalidad en mujeres con dolor crónico pélvico.

XVIII Congreso Nacional de Fisioterapia UCAM: Fisioterapia Cardiorrespiratoria. Universidad Católica San Antonio de Murcia (UCAM).

- Repercusión de la duración de un programa de terapia acuática en mujeres con artrosis de rodilla.

V Jornada de Fisioterapia Especializada en Osteogénesis Imperfecta.

II Congreso Internacional y VII Encuentros Hispano-Cubanos en Ciencias de la Salud "Salud y Género".

- Eficacia de una intervención multidisciplinar basada en un enfoque biopsicosocial en dolor cervical crónico.

IV Congreso Internacional de Contextos Clínicos y de la Salud.

- Afectación en el equilibrio de mujeres con dolor crónico pélvico.
- Aplicación del enfoque biopsicosocial mediante un programa interdisciplinar en personas con dolor cervical crónico.
- Asociación entre la discapacidad, el número de puntos gatillo activos y el dolor en mujeres con dolor crónico pélvico.
- Eficacia de la relajación con musicoterapia en personas con dolor cervical crónico.
- Eficacia de la terapia de exposición graduada en mujeres con dolor crónico pélvico: estudio de caso.
- Eficacia de los ejercicios de estabilización central en una mujer con dolor crónico pélvico.
- Evaluación de la tensión neural en mujeres con dolor crónico pélvico.
- Papel de las intervenciones tecnológicas en pacientes con dolor crónico pélvico.
- Los efectos de la terapia acuática en la movilidad de personas con enfermedades neurológicas: una revisión sistemática.

II Congreso Internacional de Intervención e Investigación en Salud.

- Afectación del dolor cervical crónico en el desempeño ocupacional.
- Asociación entre el perfil clínico y la mecanosensibilidad en pacientes con dolor cervical crónico.
- Asociación entre el equilibrio estático y dinámico: la fuerza muscular del cuádriceps en personas con osteoartritis de rodilla.

- Efectividad de la actividad física aeróbica en los síntomas clínicos de la fibromialgia: revisión bibliográfica.
- Efecto del dolor en la actividad física y el sedentarismo en adultos con condromalacia rotuliana.
- Eficacia de la estimulación eléctrica transcutánea del cuádriceps en una persona con condromalacia rotuliana: estudio de caso.
- Eficacia de un tratamiento de autogestión basado en ejercicios en un paciente con osteoartritis de rodilla.
- Intervención biopsicosocial en dolor cervical crónico.
- Intervenciones basadas en Internet en mujeres con dolor crónico: una revisión sistemática.
- Musicoterapia en personas con dolor cervical crónico a través de un programa de relajación: estudio de caso.
- Revisión bibliográfica sobre la eficacia de las inyecciones intraarticulares de Metilprednisolona en personas con osteoartritis de rodilla.
- Terapia de exposición graduada en dolor cervical crónico: estudio de caso.

III Jornadas/ Congreso Nacional de Investigadores en Formación: Fomentando la interdisciplinariedad (JIFFI).

- Eficacia de la terapia expositiva en una persona con dolor cervical crónico. Estudio de caso.

AGRADECIMIENTOS

Agradecimientos

Quiero expresar mi agradecimiento a todas las personas que han hecho posible este trabajo y este sueño.

Especialmente a mis directoras de tesis, Carmen Valenza e Irene Cabrera Martos por haberme enseñado tanto y ser mis guías durante estos últimos años.

A mis compañer@s de despacho en la Universidad, por su compañía y por ayudarme siempre que los he necesitado.

A mis compañer@s de la Asociación Granadina de Esclerosis Múltiple, por valorar mi trabajo y por ser tan buenos compañeros.

A mis amig@s, por regalarme su tiempo y por enseñarme a luchar.

A mis mascotas, Bahules, Comando, Freya, Floky, Jocker, Pícaro y Marie Curie, por alegrarme todos los días.

A mis cuñaillos Ángel, por su optimismo, y Jaime, por su cariño y talento, que han hecho que esta tesis sea aún más especial para mí.

A mi pareja, Nacho, por caminar conmigo, escucharme siempre y darme fuerza en los momentos más duros.

Finalmente, siempre estaré agradecida a mi familia, Mª Ascensión, Luis Miguel, Mariascen y Lola, por su apoyo incondicional, por ser el cimiento más estable de mi vida y por quererme tanto.