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"REVISIÓN SISTEMÁTICA SOBRE LA EFECTIVIDAD DE LOS EJERCICIOS DEL SUELO PÉLVICO EN GESTANTES DEL 2DO Y 3ER TRIMESTRE CON INCONTINENCIA URINARIA."

TRABAJO DE SUFICIENCIA PROFESIONAL PARA OPTAR EL TÍTULO DE LICENCIADA EN TERAPIA FISICA Y REHABILITACION

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DEDICATORIA

A nuestros padres.

Por los ejemplos de perseverancia y constancia que los caracterizan y que nos han infundado siempre, por el valor mostrado para salir adelante y por su amor.

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A nuestros profesores por su excelente nivel académico y su gran experiencia pedagógica.

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RESUMEN

Objetivo: Analizar la efectividad de los ejercicios del suelo pélvico en gestante del 2do y 3er trimestre con incontinencia urinaria a través de una revisión sistemática.

Metodología: Se realizó una búsqueda sistemática de artículos en la base de datos: PUBMED, PEDro, Ebsco, Scielo y google académico, se tuvo en consideración los artículos que hacen mención sobre el entrenamiento muscular del suelo pélvico (EMSP) como tratamiento de la incontinencia urinaria en gestantes. De los 83 artículos revisados, sólo 7 estudios cumplieron los criterios de inclusión, los artículos revisados fueron estudios clínicos aleatorizados (ECA).

Resultados: De los 7 artículos revisados, 5 estudios mostraron efectividad significativa al tratamiento de la incontinencia urinaria en gestantes y 2 estudios no resultaron significativos al tratamiento, así mismo presentaron una calidad metodológica aceptable.

Conclusión: La información aportada en la presente, resulta útil en el tratamiento de la incontinencia urinaria en gestantes, disminuye el índice de pérdida de orina e impacto en la calidad de vida de las gestantes afectas y proporciona tomas de decisiones clínicas al momento de abordar este tipo de pacientes.

Palabras claves: Entrenamiento muscular, Suelo pélvico, Gestante, Incontinencia urinaria, Fisioterapia.

SUMMARY

Objective: To analyze the effectiveness of pelvic floor exercises in pregnant women in the 2nd and 3rd trimesters with urinary incontinence through a systematic review.

Methods: A systematic search of articles in the database PUBMED, PEDro, Ebsco, Scielo and academic google was taken into account articles that mention the pelvic floor muscle training as a treatment of incontinence Urinary tract infection in pregnant women. Of the 83 articles reviewed, only 7 studies met the inclusion criteria, the articles reviewed were randomized clinical trials.

Results: Of the 7 articles reviewed, 5 studies showed significant effectiveness in the treatment of urinary incontinence in pregnant women and 2 studies were not significant to the treatment, and they presented an acceptable methodological quality.

Conclusion: The information provided herein is useful in the treatment of urinary incontinence in pregnant women, decreases the rate of urine loss and impact on the quality of life of affected pregnant women, and provides clinical decision making at the time of addressing this Type of patients.

Key words: Muscular training, Pelvic floor, Pregnant woman, Urinary incontinence, Physical therapy.

CAPÍTULO I: INTRODUCCIÓN

1.1 MARCO TEORICO

La incontinencia urinaria es un problema frecuente que afecta a todos los grupos de población, edades y sexo, se presenta con mayor frecuencia en el sexo femenino, estimándose que una de cada cinco mujeres de 30 a 50 años ha pasado por algún episodio. Se trata de una patología importante por su frecuencia, gravedad, connotaciones psicosociales y económicas. (1)

La Incontinencia Urinaria (IU), según la International Continence Society (ICS), en el 2012 ¨perdida de orina de manera involuntaria, objetivamente demostrable y que constituye un problema social e higiénico¨. (2)

El embarazo y el parto vaginal son considerados uno de los principales factores de riesgo para la incontinencia urinaria, puesto que implican un importante traumatismo para el periné, pudiendo afectar diversas estructuras del piso pélvico. (3)

Los cambios que ocurren con el embarazo y el parto, en relación a la continencia son el aumento de la presión intra-abdominal y compromiso del espacio vesical debido al crecimiento del útero, cambios significativos en la función del esfínter de la uretra (músculo alrededor de la uretra que con su contracción impide el escape de orina), incluso antes del parto ya se evidencia una menor función de este músculo, el cual empeora después del parto y disminución de la fuerza de la musculatura de piso pélvico en relación al número de hijos: Se ha señalado que con el primer hijo la fuerza de esta musculatura disminuye entre un 22 y 35%.(3)

Asì mismo, el aumento de la pérdida de orina durante el embarazo en etapas tempranas es de 17 a 25% y en etapas posteriores de 36 a 67%. Esto puede explicarse por los cambios fisiológicos del aparato urinario en este periodo, caracterizado por un aumento del 50% en la filtración glomerular y de 60 a 80% en el flujo plasmático renal. (4-5)

El tratamiento de las disfunciones del suelo pélvico se basa en restaurar su anatomía funcional y mantener la continencia y función sexual (6-7). El primer abordaje terapéutico debe ser el tratamiento conservador el cual debe incluir medidas educacionales, consejos para mejorar la continencia, revisión de la dieta e ingesta de líquidos, tratamiento farmacológico, cinesiterapia, biofeedback y electroestimulación neuromuscular(8-9). En cuanto al tratamiento quirúrgico, sólo se realiza en pacientes con síntomas graves y anormalidades anatómicas identificadas. (10)

El instituto nacional de excelencia clínica en España aconseja a todas las mujeres, desde el primer trimestre del embarazo, los ejercicios musculares de suelo pélvico para la prevención de incontinencia urinaria de esfuerzo. (11)

Los programas específicos de ejercicios de suelo pélvico, incluidos en el seguimiento habitual del embarazo y el postparto reducen la incidencia de incontinencia urinaria y aumentan significativamente la fuerza y función de los músculos pélvicos (12-13) .En las mujeres con incontinencia urinaria de esfuerzo, la reeducación de los músculos del suelo pélvico es el tratamiento conservador más utilizado (14). Un estudio afirma que el fortalecimiento de la musculatura del suelo pélvico es una herramienta válida para la prevención y tratamiento de la IU durante el embarazo, asimismo un programa de ejercicio físico supervisado, de intensidad moderada y que incluya ejercicios de

fortalecimiento del suelo pélvico durante toda la gestación favorece que la mujer tenga una buena percepción de su salud y, a su vez, es efectivo en la prevención primaria de la IU durante el embarazo. (15)

1.2. Justificación

Se considera importante la realización de este trabajo de investigación, ya que vamos analizar la efectividad de los ejercicios del suelo pélvico en gestantes del 2do y 3er trimestre con incontinencia urinaria. Por estudios realizados podemos manifestar que los ejercicios del suelo pélvico ayudan a la mujer embarazada a mejorar su calidad de vida, mejorar estado físico, psíquico y mental. Considerando que la preparación del suelo pélvico brinda a la gestante los conocimientos sobre los cambios propios del embarazo, así como ejercicios de respiración, relajación física, relajación mental y un adecuado entrenamiento que fortalecerá los músculos que intervienen en el canal del parto; proporcionará cambios de conducta y hábitos volviéndolos más saludables. Pretendiendo una mejor actitud de la gestante en esta etapa tan importante de su vida reproductiva. Además se evitará posibles traumatismos maternos y complicaciones que convierten al parto en un proceso patológico.

1.3. Objetivos

La revisión sistemática tiene como objetivo, responder a la siguiente interrogante: ¿Serán efectivos los ejercicios del suelo pélvico en gestantes del 2do y 3er trimestre con incontinencia urinaria?

El enunciado del objetivo será:

Analizar la efectividad de los ejercicios del suelo pélvico en gestantes del 2do y 3er trimestre con incontinencia urinaria a través de una revisión sistemática.

CAPÍTULO II: MÉTODOS

Para la elaboración de esta revisión sistemática fueron utilizadas las directrices propuestas por el PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) (16) y sus extensiones. (16-17)

PRISMA es un conjunto mínimo de elementos basado en evidencia para escribir y publicar revisiones sistemáticas y meta análisis, consta de 27 items terminología, formulación de la pregunta de investigación, identificación de los estudios y extracción de datos, calidad de los estudios y riesgo de sesgo, cuando combinar datos, meta análisis y análisis de la consistencia, y sesgo de publicación selectiva de estudios o resultados. (17)

2.1. Criterios de Elegibilidad.

Se utilizaron como criterios de elegibilidad conforme a la estructura Población, Intervención, Comparación y Outcome (PICO):

- Población : gestantes del 2do y 3er trimestre con incontinencia urinaria
- Intervención : Ejercicios del suelo pélvico
- Comparación : Tratamiento convencional
- Outcome (resultados) : perdida de orina e impacto en la calidad de vida.

Además se incluyeron otros criterios de elegibilidad:

- Publicaciones de los últimos 10 años para estimar la evidencia en este espacio de tiempo.
- Publicaciones en todos los idiomas.
- Estudios clínicos controlados aleatorizados

2.2. Fuentes de Información.

Se realizó una revisión sistemática de la literatura para verificar la efectividad de los ejercicios del suelo pélvico en pacientes gestantes con incontinencia urinaria. Se realizó la búsqueda de las bases de datos y buscadores especializados hasta el 9 julio de 2016: PUDMED, PEDro Database, Ebsco host, SciELO-Scientific Electronic Library Online y Google Académico, los cuales se muestran en la tabla 1.

Tabla 1

Fuente de Información	Enlace web	Tipo	Accesibilidad	Propietario/ administrador
PUBMED	http://www.ncbi.nlm.nih.gov/pubmed	Motor de búsqueda y Base de Datos	Libre	Biblioteca Nacional de Medicina de los Estados Unidos
PEDro Database	http://www.pedro.org.au/spanish/	Motor de búsqueda y Base de Datos especializada en fisioterapia	Libre	Centro de Fisioterapia Basada en la Evidencia en el George Institute for Global Health
EBSCO host	https://www.ebscohost.com/	Base de datos multidisciplinaria, académica y de investigación, contiene: SPORTDiscus MedicLatina Academic Search Premier	Suscripción	Elton B. Stephens Company
SciELO - Scientific Electronic Library Online	http://www.scielo.org/	Biblioteca electrónica publicación electrónica de ediciones completas de las revistas científicas	Libre	FAPESP (http://www.fapesp.br) - la Fundación de Apoyo a la Investigación del Estado de São Paulo, BIREME (http://www.bireme.br) - Centro Latinoamericano y del Caribe de Información en Ciencias de la Salud
Google académico	https://scholar.google.com/	Buscador especializado en literatura científica-académica	Libre	Google Inc.

2.3. Búsqueda.

Los términos de búsqueda que se utilizaron tuvieron en un primer momento la identificación como terminología MESH (Medical Subject Headngs) y DeCS (Descriptores en Ciencias de la Salud) bajo desambiguación en español e inglés, identificando sus sinónimos, de no ubicarse se aproximó la terminología a su denominación técnica más común.

Tabla 2

Búsqueda de Terminología Mesh/Desh				
	Término 1	Término 2	Término 3	Término 4
Término Español	incontinencia urinaria	ejercicio	suelo pélvico	Gestante del segundo y tercer trimestre
DeCS	si	si	no	no
Término Inglés	Urinary Incontinence	Exercise	Pelvic Floor	Pregnancy during the second or third trimester
MESH	si	si	si	si
Sinónimos	Incontinence, Urinary	Exercises Exercise, Physical Exercises, Physical Physical Exercise Physical Exercises Exercise, Isometric Exercises, Isometric Isometric Exercises Isometric Exercise Exercise, Aerobic Aerobic Exercises Exercises, Aerobic Aerobic Exercise	Floor, Pelvic Pelvic Diaphragm Diaphragm, Pelvic Diaphragms, Pelvic Pelvic Diaphragms	Pregnancies Gestation the second or third trimester

Se realizó la estrategias de búsqueda en las bases de datos: PUBMED, PEDro, Ebsco, Scielo y Google Académico (Tabla 3). Todas las búsquedas se restringieron desde el 2006 hasta el día 9 de julio del 2016 debido a que queríamos centrarnos específicamente en las literaturas publicadas en los últimos 10 años y en varios idiomas.

Tabla 3

Estrategia de Búsqueda

Base de datos/ fuentes	Estrategia	Entrada
PUBMED (A)	Búsqueda de estudios sobre ejercicios del suelo pélvico en gestantes del segundo y tercer trimestre con incontinencia urinaria, últimos 10 años, ensayos clínicos.	("Pelvic Floor"[Mesh] AND "Urinary Incontinence"[Mesh]) AND "Pregnancy the second or third trimester "[Mesh] AND (Clinical Trial[ptyp] AND "2006/07/06"[PDat] : "2016/07/02"[PDat])
Ebsco host	Búsqueda de estudios sobre ejercicios del suelo pélvico en gestantes del segundo y tercer trimestre con incontinencia urinaria, últimos 10 años, término del tesauro “pelvic floor”.	pelvic floor AND exercise AND pregnancy AND urinary incontinence
PEDro database	Búsqueda de estudios sobre ejercicios del suelo pélvico en gestantes del segundo y tercer trimestre, últimos 10 años, ensayos clínicos.	Therapy: strength training Problem: incontinence Body Part: perineum or genito-urinary system Subdiscipline: continence and women's health
Scielo - Scientific Electronic Library Online	Búsqueda de estudios sobre ejercicios del suelo pélvico en gestantes del segundo y tercer trimestre con incontinencia urinaria, últimos 10 años, en toda la Red Scielo	pelvic floor pregnancy urinary incontinence
Google Académico	Búsqueda de estudios sobre ejercicios del suelo pélvico en gestantes con incontinencia urinaria, últimos 10 años, no incluir patentes ni citas.	pelvic floor urinary incontinence pregnancy

2.4 Selección de los estudios

El proceso de selección de estudios tuvo las siguientes etapas:

- **Registro de salidas a las estrategias de búsqueda:** A las salidas (listado de estudios) determinadas por las estrategias de búsqueda establecidas en los buscadores y bases de datos consultadas, se incluyó el dato de fecha, hora de búsqueda y número de estudios identificados.

El tratamiento de este listado se realizó en una base de datos que consignaba a cada artículo según título, autor, journal, fecha, volumen y número.

- **Fase eliminación de duplicados:** se procedió a depurar los resultados, eliminando los estudios duplicados e integrándolos en una base de datos preladas alfabéticamente según el título.
- **Fase de análisis y selección:** Una vez obtenida la lista de estudios no duplicados se procedió a ordenar la base de datos según autor y año y título, se analizaron los artículos en base a sus títulos y resúmenes, finalmente las copias del texto completo para determinar la elegibilidad de acuerdo a los criterios de inclusión y exclusión. Se clasificaron según la elegibilidad de los estudios, en tres categorías: estudios incluidos, estudios eliminados por no cumplir algún criterio de inclusión y estudios eliminados por cumplir algún criterio de exclusión. Esta fase culmina cuando se obtuvo un listado de estudios seleccionados los cuales fueron ordenados por Autor/Año y Título.

2.5. Riesgo de sesgo en los estudios individuales.

El riesgo de selección en los estudios individuales fue realizado analizando la calidad metodológica según la escala de Pedro (18–20) que contiene 11 criterios de los cuales él Nº11 no se puntúa.

La puntuación total va del 0 al 10, según los siguientes criterios:

Tabla 4

ITEMS	
1	Los criterios de elección fueron especificados
2	Los sujetos fueron asignados al azar a los grupos (en un estudio cruzado, los sujetos fueron distribuidos aleatoriamente a medida que recibían los tratamientos)
3	La asignación fue oculta
4	Los grupos fueron similares al inicio en relación a los indicadores de pronóstico más importantes
5	Todos los sujetos fueron cegados
6	Todos los terapeutas que administraron la terapia fueron cegados
7	Todos los evaluadores que midieron al menos un resultado clave fueron cegados
8	Las medidas de al menos uno de los resultados clave fueron obtenidas de más del 85% de los sujetos inicialmente asignados a los grupos
9	Se presentaron resultados de todos los sujetos que recibieron tratamiento o fueron asignados al grupo control, o cuando esto no pudo ser, los datos para al menos un resultado clave fueron analizados por "intención de tratar"
10	Los resultados de comparaciones estadísticas entre grupos fueron informados para al menos un resultado clave
11	El estudio proporciona medidas puntuales y de variabilidad para al menos un resultado clave

La escala PEDro considera dos aspectos de la calidad de los ensayos, a saber la "credibilidad" (o "validez interna") del ensayo y si el ensayo contiene suficiente información estadística para hacerlo interpretable. No mide la "relevancia" (o "generalización" o "validez externa") del ensayo, o el tamaño del efecto del tratamiento. (21)

La mayor parte de los criterios de la lista "se basan en la lista Delphi, desarrollada por Verhagen y sus colegas. La lista Delphi es una lista de características de ensayo que se consideran que están relacionadas con la "calidad" del ensayo por un grupo de expertos de ensayos clínicos. La escala PEDro contiene elementos adicionales sobre la adecuación del seguimiento y comparaciones estadísticas entre grupos. Un elemento presente en la lista Delphi (relativo a los criterios de elegibilidad) está relacionada con la validez externa, por lo que no se

corresponde con las dimensiones de la calidad evaluada por la escala de PEDro. Este elemento no se emplea para calcular la puntuación del método que se muestra en los resultados de búsqueda (es por lo que una escala de 11 elementos tan solo ofrece una puntuación sobre 10). Este elemento, sin embargo, se ha conservado por lo que todos los elementos de la lista Delphi están presentes en la escala PEDro.” (22)

CAPÍTULO III: RESULTADOS

3.1. Selección de estudios.

Los estudios identificados fueron 83: en PubMed(24), PEDro(11), Ebsco(23), Scielo(9) y en Google Académico(16).

En el tamizaje se encontraron 17 estudios duplicados y en el proceso de elegibilidad fueron excluidos 59 estudios por no cumplir algún criterio de inclusión. Finalmente fueron incluidos 7 estudios.

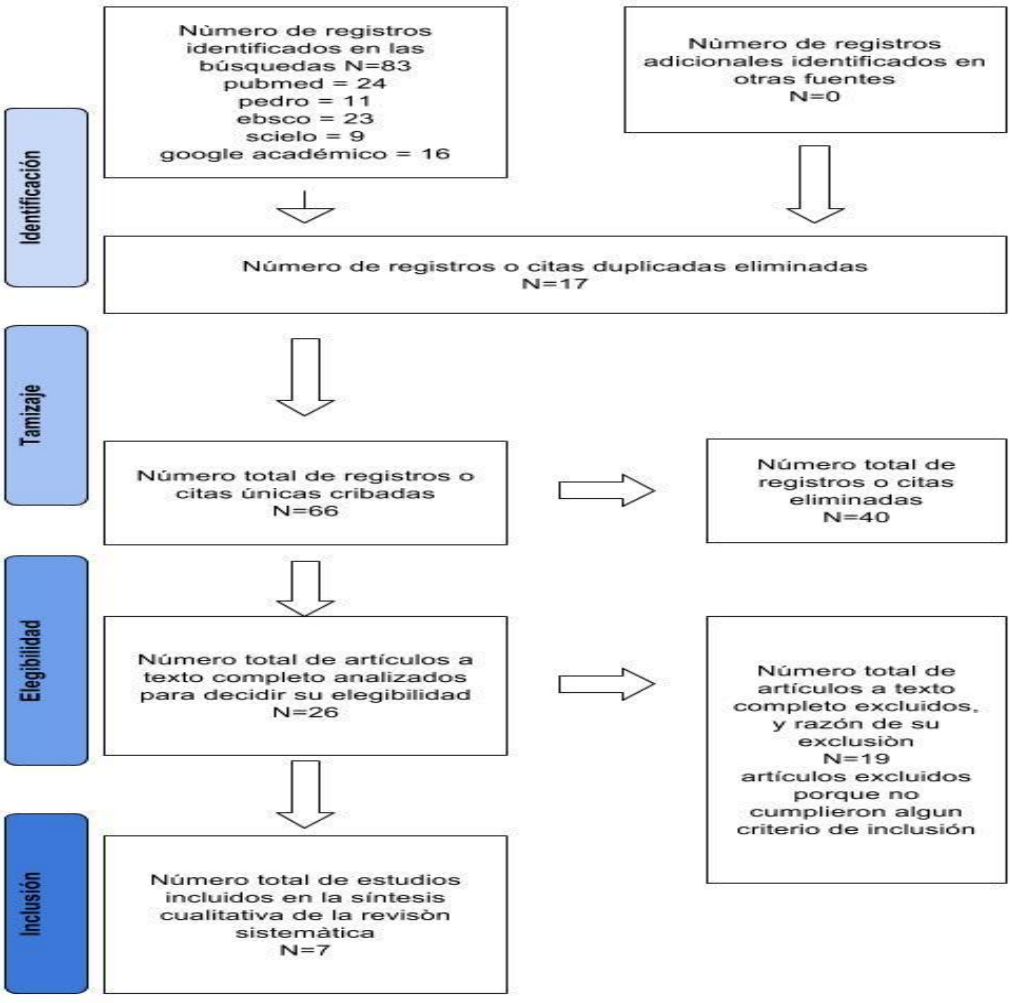


Gráfico 1

Fuente: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

3.2. Características de los estudios

Los estudios seleccionados fueron en su totalidad estudios clínicos controlados y randomizados, a nivel espacio fueron realizados en Istanbul, República de China, Noruega, Tailandia, España, Holanda y Francia, a nivel tiempo fueron realizados en enero, julio y agosto fueron publicados entre 2006, 2009 - 2010, 2012-2013 y 2015. 2 fueron multicéntricos, la población mayor de 855 (SN Stafne, KÅ Salvesen.2012) y según pico puede apreciarse en la tabla 5.

Tabla 5

Año y Autor	Titulo	Población	Intervención	Variable de Salida
Ko P-C, Liang C-C, Chang S-D, Lee J-T, Chao A-S, Cheng P-J,2011	A randomized controlled trial of antenatal pelvic floor exercises to prevent and treat urinary incontinence	300 participantes	Participaron con un tiempo de 12 semanas. **G.I**: Fueron instruidos individualmente por un fisioterapeuta acerca de la anatomía y el EMSP. Los ej. constan de 3 rep. de 8 contracciones durante 6 seg. con 2 min. de descanso entre rep. Se repiten en casa 2 v/d y 1 v/s en una sesión de 45 min. en grupo (10 muj.) e instruidos por un fisioterapeuta. **G.C**: Recibieron una atención prenatal y posparto con instrucciones escritas habituales que no incluían el EMSP.	Impacto en la Calidad de Vida

Año y Autor	Titulo	Población	Intervención	Variable de salida
SN Stafne, KÅ Salvesen, 2012	Does regular exercise including pelvic floor muscle training prevent urinary and anal incontinence during pregnancy? A randomised controlled trial	855 participantes	Fue un programa de ej. de 12 semanas. Las sesiones de entrenamiento son de 60 min., en grupos de 8 y 15, instruido por un fisioterapeuta **G.I:** Realizaron 3 series /10 rep. 1. 30-35 min. de actividad aeróbica de bajo impacto. 2. 20-25 min. de entrenamiento de fuerza. 3. 5-10 min. de estiramiento junto con la respiración y ej. de relajación. Fueron instruidas individualmente por un fisioterapeuta para la correcta contracción a la palpación vaginal, a realizar 3 series de 8-12 contracciones máx. durante 6-8 seg. (3 d/s) y realizar en casa 45 min. 2 v/s (30 min. de entrenamiento de resistencia y 15 min. de ej. de fuerza y equilibrio). **G.C**: Recibieron atención prenatal e instrucciones escritas de contracción del suelo pélvico.	Perdida de orina

Año y Autor	Titulo	Población	Intervención	Variable de Salida
Dinc, NK Beji, O Yalcin,2009	Effect of pelvic floor muscle exercises in the treatment of urinary incontinence during pregnancy and the postpartum period	80 participantes	Se llevó a cabo en tres etapas: **G.I**: 1º etapa: fue entrenado por un fisioterapeuta al realizar los ej. que consisten en una sesión en 3 grupos de ej., 10 lentas contracciones y relaja 10, 10 rápidas contracciones y relaja 10, realizando unas 30 contracciones lentas y 30 contracciones rápidas. 2º etapa: fueron evaluados después de 1 semana (68% realizaban correctamente los ej.) 3º etapa: fueron reevaluados en la 6ta y 8va semana de postparto. **Ambos grupos** entre la 36-38 semana de embarazo se realizó una segunda ev. para evaluar la fuerza del suelo pélvico. **G.C:** no recibieron información sobre los ejercicios.	Perdida de orina

Año y Autor	Titulo	Población	Intervención	Variable de Salida
Bussara Sangsawang, N Sangsawang,2016	Is a 6-week supervised pelvic floor muscle exercise program effective in preventing stress urinary incontinence in late pregnancy in primigravid women?	70 participantes	Programa de ejercicio en 6 semanas. **G.I:** se distribuyeron en 4 - 5 participantes durante 45 min. por sesión 1v/2 semanas, el programa incluye 10 lentas contracciones con 10 seg. de descanso, 10 rápidas contracciones con 10 seg. de descanso, 10 rápidas y lentas contracciones alternativamente y en diferentes posiciones, por último les enseño a repetir 20 juegos del EMSP 2v/d en un total de 40 juegos por día por 5 días. **G.C:** recibió sólo atención prenatal y realiza los ejercicios en su casa.	Perdida de orina

Año y Autor	Titulo	Población	Intervención	Variable de Salida
Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R,2014	Pelvic floor muscle training included in a pregnancy exercise program is effective in primary prevention of urinary incontinence: a randomized controlled trial	169 gestantes que fueron atendidas en el hospital local donde llevan su atención prenatal (Madrid).	**G.I**: participaron como mínimo por 22 semanas (14°-36° semana de gestación),70-78 sesiones grupales realizadas en el hospital con un ambiente favorable(8-12 mujeres),3 v/s, duración 55-60 min.(8 min. de calentamiento,30 min. de aeróbico de bajo impacto que incluye 10 min. de entrenamiento general de fuerza ,10 min. de EMSP y 7 min. de enfriamiento) **G.C**: tratamiento habitual que incluye un seguimiento por la obstetra e información sobre el EMSP	Impacto en la calidad de vida (I.U)

Año y Autor	Titulo	Población	Intervención	Variable de Salida
Woldringh C, van den Wijngaart M, Albers-Heitner P, Lycklama à Nijeholt AA, Lagro-Janssen T,2007	Pelvic floor muscle training is not effective in women with UI in pregnancy: a randomised controlled trial.	264 participantes	**G.I**: 4 sesiones individuales a cargo de terapeutas (3 sesiones entre la semana 23°-30° de embarazo y una 4° sesión a la 6° semana post-parto) que incluyen información general, auto-palpación de la zona perineal y un manual hecho especialmente para este estudio con información sobre incontinencia, función de los músculos del suelo pélvico e instrucción detallada sobre los ejercicios para el EMSP. **G.C**: tratamiento habitual para gestantes, además casi dos tercios del GC recibió algunas instrucciones sobre el EMSP.	Perdida de orina Impacto en la calidad de vida (I.U)

Año y Autor	Titulo	Población	Intervención	Variable de Salida
Fritel X, de Tayrac R, Bader G, Savary D, Gueye A, Deffieux X, Fernandez H, Richet C, Guilhot J, Fauconnier A, 2015	Preventing urinary incontinence with supervised prenatal pelvic floor exercises: a randomized controlled trial 282 participantes	282 participantes	**G.I**: 8 sesiones individuales a cargo de fisioterapeutas (6°-8° mes de gestación) 1 v/s, duración de 20-30 min.(examinación vaginal,5 min. de contracciones de pie ,10 min. de contracciones acostada e instrucciones escritas sobre anatomía del suelo pélvico y ejercicios de contracción del suelo pélvico) **G.C**: instrucciones escritas sobre anatomía del suelo pélvico y ejercicios de contracción del suelo pélvico.	Perdida de orina Impacto en la calidad de vida (I.U)

4.3. Evaluación de la calidad.

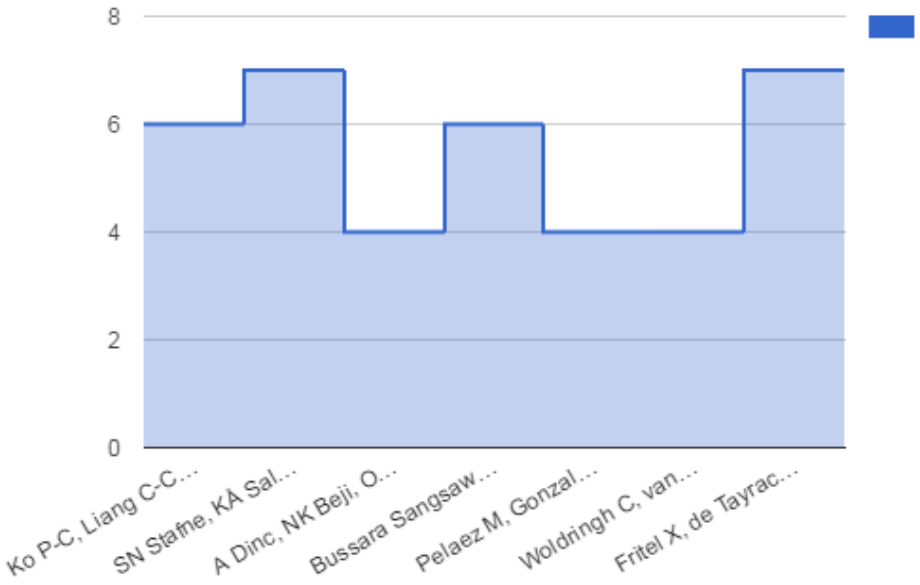
La evaluación de la calidad según la escala de PEDro obtuvo en promedio un puntaje de 5/10 según se detalla en la siguiente tabla:

Tabla 6

Evaluación de la calidad - Ensayos Clínicos Controlados								
Ítems		Ko P-C, Liang C-C, Chang S-D, Lee J-T, Chao A-S, Cheng P-J,2011	SN Stafne, KÅ Salvesen.2012	A Dinc, NK Beji, O Yalcin.2009	Bussara Sangsawang, N Sangsawang. 2016	Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R. 2014	Woldringh C, van den Wijngaart M, Albers-Heitner P, Lycklama à Nijeholt AA, Lagro-Janssen T.2007	Fritel X, de Tayrac R, Bader G, Savary D, Gueye A, Deffieux X, Fernandez H, Richet C, Guilhot J, Fauconnier A. 2015
1	Los criterios de elección	Si	Si	Si	Si	Si	Si	Si
2	Asignación aleatoria	Si	Si	Si	Si	Si	Si	Si
3	La asignación fue oculta	Si	Si	No	Si	No	No	Si
4	Comparabilidad inicial	Si	Si	Si	Si	No	Si	Si
5	Todos los sujetos fueron cegados	No	No	No	No	No	No	No
6	todos los terapeutas fueron cegados	No	No	No	No	No	No	No
7	todos los evaluadores fueron cegados	No	No	No	No	No	No	Si
8	Seguimiento adecuado	Si	Si	No	Si	Si	No	No
9	Por intensión de tratar el análisis	No	Si	No	No	No	No	Si
10	Entre el grupo de las comparaciones	Si	Si	Si	Si	Si	Si	Si
11	Apunte estimaciones y variabilidad	Si	Si	Si	Si	Si	Si	Si
		6	7	4	6	4	4	7

PROMEDIO	Ko P-C, Liang C-C, Chang S-D, Lee J-T, Chao A-S, Cheng P-J,2011	SN Stafne, KÅ Salvesen.2012	A Dinc, NK Beji, O Yalcin.2009	Bussara Sangsawang, N Sangsawang. 2016	Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R. 2014	Woldringh C, van den Wijngaart M, Albers-Heitner P, Lycklama à Nijeholt AA, Lagro-Janssen T.2007	Fritel X, de Tayrac R, Bader G, Savary D, Gueye A, Deffieux X, Fernandez H, Richet C, Guilhot J, Fauconnier A. 2015
5,42	6	7	4	6	4	4	7

Gráfico 2


8
6
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Ko P-C, Liang C-C...
SN Stafne, KA Sal...
A Dinc, NK Beji, O...
Bussara Sangsaw...
Pelaez M, Gonzal...
Woldringh C, van...
Fritel X, de Tayrac...

4.4. Síntesis de los resultados.

Tabla 7

Año y Autor	Propósito y participantes	Intervención y medición	Resultados
Ko P-C, Liang C-C, Chang S-D, Lee J-T, Chao A-S, Cheng P-J,2011	Evaluar el efecto del ej. prenatal muscular del suelo pélvico (EMSP) en la prevención y el tratamiento de la I.U durante el período de embarazo y el postparto. Participantes=300 GI=150 GC=150	**G.I**: Fueron instruidos individualmente por un fisioterapeuta acerca de la anatomía y el EMSP. Los ej. constan de 3 repeticiones de 8 contracciones durante 6 seg. con 2 min. de descanso entre repeticiones. Se repiten en casa 2 v/d y 1 v/s una sesión de 45 min. en grupo (10 mujeres) **G.C**: Recibieron una atención prenatal, posparto y con instrucciones escritas habituales que no incluían los del EMSP **Medición:** incidencia de la I.U y calidad de vida	Indica que el EMSP parece ser beneficioso para la restauración de la continencia en mujeres con parto vaginal.

Año y Autor	Propósito y participantes	Intervención y medición	Resultados
SN Stafne, KÅ Salvesen, 2012	Evaluar si las mujeres embarazadas después de un curso general de ej., incluyendo el EMSP, eran menos propensos a informar de la I.U y anal a finales del embarazo que un grupo de mujeres que reciben atención estándar. Participantes=762 GI=397 GC=365	**G.I:** Participaron por 12 semanas (entre el 20 y 36 semana de gestación) .Se realiza 3 d/s o más con 3 series de 10 repeticiones. 1) 30-35 min. de actividad aeróbica de bajo impacto. 2) 20-25 min. de entrenamiento de fuerza. 3) 5-10 min. de estiramiento junto con la respiración y ej. de relajación. Fueron instruidas individualmente por un fisioterapeuta en la anatomía del suelo pélvico para una correcta contracción a la palpación vaginal, a realizar 3 series de 8-12 contracciones máx. durante 6-8 seg. (3 d/s) y realizar en casa 45 min. 2 v/s (30 min de entrenamiento de resistencia y 15 min de ej. de fuerza y equilibrio). **G.C:** Recibieron atención prenatal e instrucciones escritas de contracción del suelo pélvico **Medición**: severidad y prevalencia de la I.U	Menos mujeres en el GI informaron de cualquier tipo de I.U semanal (11 frente a 19%, p = 0,004).

Autor y Año	Propósito y Participantes	Intervención y Medición	Resultados
A Dinc, NK Beji, O Yalcin.2009	Determinar la efectividad del EMSP durante el embarazo y el periodo del post-parto Participantes=68 GI=35 GC =33	**GI**: **1º etapa:** fue entrenado por un fisioterapeuta al realizar los ej. que consisten en una sesión en 3 grupos de ej., 10 lentas contracciones y relaja 10, 10 rápidas contracciones y relaja 10, realizando unas 30 contracciones lentas y 30 contracciones rápidas **2º etapa:** fueron evaluados después de 1 semana (68% realizaban correctamente los ej.) **3º etapa:** fueron reevaluados en el 6ta y 8va semana de postparto. **Ambos grupos** entre la 36-38 semana de embarazo se realizó una segunda evaluación para evaluar la fuerza del suelo pélvico. **GC:** no recibieron información sobre los ej. **Medición:** Prevalencia de la I.U	En este estudio el 43.2% del G.I tenia I.U en la semana 36-38 de embarazo que se redujo hasta el 17,1% en la 6ta y 8va semana del post-parto, en el G.C el 71.4% tenían I.C pero el 39,49% todavía tenia I.U en el 6to y 8vo semana del post-parto lo cual el resultado del presente estudio demuestra que los ejercicios de los músculos del suelo pélvico aplicadas en el embarazo y el puerperio son muy eficaces en el tratamiento y la reducción de la I.U mediante la mejora de la fuerza del suelo pélvico.

Autor y Año	Propósito y Participantes	Intervención y Medición	Resultados
Bussara Sangsawang, N Sangsawang. 2016	El estudio investigo el efecto de un programa de ejercicios de EMSP supervisado en 6 semanas para prevenir la I.U a las 38 semanas de gestación. Participantes = 63 GI = 33 GC = 30	**G.I:** se les instruyó sobre la IUE y el EMSP, consistió por sesión de 45 minutos una vez cada dos semanas en un periodo de 6 semanas, el programa de entrenamiento incluye 10 lentas contracciones con 10 seg de descanso, 10 rápidos contracciones con 10 seg de descanso, 10 rápidas y lentas contracciones alternativamente y en diferentes posiciones **G.C** recibió sólo atención prenatal y realiza los ejercicios en su casa.	Los resultados del G.I muestran una cantidad significativamente menor que el G.C: 9 de los 33 (27,3%) frente a 16 de los 30 (53,3%) a las 38 semanas, por consiguiente el estudio demostró la eficacia de las 6 semanas de programa de EMSP es capaz de prevenir prenatal la IUE

Autor y Año	Propósito y Participantes	Intervención y Medición	Resultados
Pelaez M, Gonzalez-Cerron S, Montejo R, Barakat R. 2014	Investigar el efecto del EMSP enseñado en una clase general de ejercicio durante el embarazo en la prevención de IU en gestantes nulíparas Participantes:169 GI:73 GC:96	**GI** : participaron como mínimo por 22 semanas (14°-36° semana de gestación),70-78 sesiones grupales realizadas en el hospital con un ambiente favorable(8-12 mujeres),3 v/s, duración 55-60 min.(8 min. de calentamiento,30 min. de aeróbico de bajo impacto que incluye 10 min. de entrenamiento general de fuerza ,10 min .de EMSP y 7 min. de enfriamiento) **GC** : tratamiento habitual que incluye un seguimiento por la obstetra e información sobre el EMSP **Medición:** frecuencia , cantidad e impacto en la vida diaria (IU)	frecuencia (IU) --> NUNCA GC 54/60.7% - GI 60/95.2% (P<0.001) -cantidad de perdida -->NINGUNA GC 45/60.7% - GI 60/95.2% (P<0.001) -puntaje del ICIQ-UI SF --> GC 2.7(SD 4.1) - GI 0.2(SD 1.2) (P<0.001

Autor y Año	Propósito y Participantes	Intervención y Medición	Resultados
Woldringh C, van den Wijngaart M, Albers-Heitner P, Lycklama à Nijeholt AA, Lagro-Janssen T.2007	Comprobar el efecto a corto y largo plazo del EMSP durante el embarazo en mujeres con riesgo y que fueron afectadas de IU Participantes=264 GI=112 GC=152	**GI**: 4 sesiones individuales a cargo de terapeutas (3 sesiones entre la semana 23°-30° de embarazo y una 4° sesión a la 6° semana post-parto) que incluyen información general, auto-palpación de la zona perineal y un manual hecho especialmente para este estudio con información sobre incontinencia, función de los músculos del suelo pélvico e instrucción detallada sobre los ejercicios para el EMSP. **GC**: tratamiento habitual para gestantes, además casi dos tercios del GC recibió algunas instrucciones sobre el EMSP. **Medición:** severidad e impacto en la vida diaria (IU)	El EMSP no muestra ningún efecto a un año después del parto.

Autor y Año	Propósito y Participantes	Intervención y Medición	Resultados
Fritel X, de Tayrac R, Bader G, Savary D, Gueye A, Deffieux X, Fernandez H, Richet C, Guilhot J, Fauconnier A. 2015	Comparar, en una población no seleccionada de gestantes nulíparas, el efecto post-parto del EMSP pre-natal supervisado con instrucciones escritas para el post-parto sobre IU. Participantes:282 GI:140 GC:142	**GI** : 8 sesiones individuales a cargo de fisioterapeutas (6°-8° mes de gestación) 1 v/s, duración 20-30 min.(examinación vaginal,5 min. de contracciones de pie ,10 min. de contracciones acostada e instrucciones escritas sobre anatomía del suelo pélvico y ejercicios contracción del suelo pélvico) **GC** : instrucciones escritas sobre anatomía del suelo pélvico y ejercicios de contracción del suelo pélvico. **Medición:** severidad y prevalencia (IU)	No hay diferencia entre los dos grupos sobre la severidad, prevalencia o problemas iniciales del suelo pélvico de la IU al terminar la gestación y al 2° y 12° post-parto. -12° mes post-parto,1° outcome - 190 mujeres(67.4%) -->1.9 GI - 2.1 GC (p=.38)

CAPÍTULO IV: DISCUSIÒN

4.1. Resumen de la evidencia.

Esta revisión sistemática incluye 7 ECAs que analizan la evidencia publicada sobre la efectividad del entrenamiento muscular del suelo pélvico como tratamiento de la incontinencia urinaria en gestantes. La idea inicial fue realizar una revisión que incluyera el método de EMSP óptimo para la IU pero no se ha encontrado un programa de entrenamiento definido como el mejor. Esto es debido a que el programa debe adaptarse al estado del paciente. Por último nos hemos centrado en cuál es la mejor forma de realizar el EMSP para que resulte más efectivo aunque las investigaciones no se muestran coincidentes. El hecho de que cada uno emplease unas medidas de resultado diferentes hace que sus resultados no puedan compararse estadísticamente y se presenten en forma de resúmenes.

Efectividad del EMSP en la IU en gestantes del 2do y 3er trimestre

Dinc et al. (23) compararon la eficacia del EMSP con un tratamiento habitual. El estudio se llevó a cabo en tres etapas: en la primera etapa ambos grupos se sometieron a análisis de orina y a diferentes pruebas y fueron instruidos en la correcta contracción muscular del suelo pélvico, en el grupo control (G.C) no se les brindo las instrucciones para realizar correctamente los ejercicios. Los ejercicios del EMSP consisten en una sesión en 3 grupos de ejercicios, 10 lentas contracciones, relaja, 10 rápidas contracciones y relaja 10, realizando de unas 30 contracciones lentas y 30 contracciones rápidas. En la segunda etapa el grupo de intervención (G.I) fueron evaluados después de una semana para que observen si realizan correctamente los ejercicios, de la cual, el 68% lo realizaban correctamente, fueron revisados cada vez que venían por visita prenatal. En la

semana 36 – 38 del embarazo se realizó en ambos grupos una segunda evaluación para evaluar la fuerza de los músculos del suelo pélvico y quejas de incontinencia. En la tercera etapa todas las mujeres fueron reevaluadas en el 6to y 8vo semana del post-parto. En este estudio el 43.2% del G.I tenia I.U en la semana 36-38 de embarazo que se redujo hasta el 17,1% en la 6ta y 8va semana del post-parto, en el G.C el 71.4% tenían I.C pero el 39,49% todavía tenía I.U en el 6to y 8vo semana del post-parto lo cual el resultado del presente estudio demuestra que los ejercicios de los músculos del suelo pélvico aplicadas en el embarazo y el puerperio son muy eficaces en el tratamiento y la reducción de la I.U mediante la mejora de la fuerza del suelo pélvico.

Sangsawang et al. (24) compararon el efecto de un programa de 6 meses del EMSP supervisado en la prevención y la gravedad de la IU en gestantes. En dicho estudio la intervención se realizó en dos grupos, el G.I de forma grupal, individual y con supervisión y el G.C en casa de forma individual y sin supervisión. Por lo tanto el G.I se les instruyo sobre la IU y el EMSP, consistió por sesión de 45 minutos una vez cada dos semanas en un periodo de 6 semanas, el programa de entrenamiento incluye 10 contracciones lentas con 10 segundos (seg.) de descanso, 10 contracciones rápidas con 10 seg. de descanso, 10 contracciones rápidas y lentas alternativamente y en diferentes posiciones. El G.C recibió sólo atención prenatal y realiza los ejercicios en su casa. Los resultados del G.I muestran una cantidad significativamente menor que el G.C: 9 de los 33 (27,3%) frente a 16 de los 30 (53,3%) a las 38 semanas, por consiguiente el estudio demostró la eficacia de las 6 semanas de programa de EMSP es capaz de prevenir prenatal la IU.

Stafne SN (25) compararon el EMSP de manera individual o en grupo durante 12 semanas. El G.I recibieron un programa de ejercicios estandarizados, incluyendo los ejercicios del EMSP, para enfatizar la fuerza del SP esto se realiza 3 días a la semana o más en intensidad moderada alta. El protocolo de entrenamiento consistió en: una sesión de 60 minutos en grupos, instruidos por un fisioterapeuta que se ofreció a realizar una vez por semana. Cada sesión constaba de 3 partes (actividad aeróbica, entrenamiento de fuerza incluyendo el EMSP y estiramientos), en la cual se realizaron 3 series de 10 repeticiones de cada ejercicio y a su vez fueron instruidas individualmente en la anatomía del SP y en la contracción correcta que se controló con la palpación vaginal. En el EMSP se decidió aumentar la resistencia realizando 3 series de 12 contracciones máximas y mantener la contracción durante 6 – 8 segundos y si era posible añadir 3 contracciones rápidas al final de la contracción que se llevó a cabo en diferentes posiciones. El G.C recibió la información y recomendaciones escritas en un folleto, realizo el tratamiento individual en casa y sin supervisión. Los resultados indican que menos mujeres en el G.I informaron de cualquier tipo de IU semanal (11 frente a 19%, p = 0,004).

Po Chon Ko et al. Examinaron la efectividad del EMSP para reducir la I.U a largo plazo. Para ello evaluaron la continencia y la calidad de vida de las mujeres a los 6 meses de haber finalizado la terapia. El G.I realizo 2 posiciones para el EMSP esto se repitieron 2 veces al día en casa con una formación adicional en grupo 1 vez por semana durante 45 minutos en un periodo de 12 semanas. En los resultados se encontró que en el EMSP condujo a una mejoría de la I.U y calidad de vida al final del embarazo y hasta los 6 meses después del parto.

Pelaez et al. (26) compararon el EMSP incluido en un programa de ejercicios con un tratamiento habitual como prevención de la IU en gestantes. Ambos grupos recibían el tratamiento en un hospital .El GC realizo de 8 a 12 sesiones individuales y el GI realizo de 70 a 78 sesiones grupales .Además el GI durante el EMSP inicio con una serie de 8 contracciones, incrementando el número de contracciones a 100, dividida en diferentes series de contracciones lentas y rápidas diariamente en diferentes posiciones. Los resultados muestran una diferencia estadística significativa a favor del GI.

Woldringh et al. (27) compararon el EMSP con un tratamiento habitual realizado como tratamiento de la IU en gestantes. Ambos grupos recibieron un tratamiento individual. El GI realizo 4 sesiones y la última sesión se realizó 6 semanas después del parto. Además el GI recibió una manual escrito sobre incontinencia, función de los músculos del suelo pélvico y detalladas instrucciones sobre los ejercicios del EMSP .Los resultados muestran que no hay efecto del EMSP a un año después del parto ya que la IU descendió fuertemente después del parto, independientemente del tratamiento habitual o del EMSP durante el embarazo. La razón de este resultado podría deberse al utilizar diferentes cuestionarios, criterios de inclusión para los participantes y la frecuencia del EMSP.

Fritel et al. (28) compararon el EMSP con aquellos que recibieron solo instrucciones escritas como prevención de la IU en gestantes .El estudio se realizó en 5 centros hospitalarios. El GI cumplió 8 sesiones individuales en las cuales realizaba contracciones en diferentes posiciones: 5 min. en bipedestación y 10 min. en decúbito supino. Los resultados muestran que no hay diferencia entre los 2 grupos .La razón de este resulto podría deberse a que se realizó en

diferentes centros hospitalarios donde trabajaron varios fisioterapeutas realizando diferentes prácticas, por tal motivo reduce el estándar del estudio.

Tratamiento con supervisión fisioterapéutica frente a tratamiento sin supervisión

SN Stafne et al. (25) y Po-Chun Ko et al. (29) tras comparar los resultados del EMSP en el tratamiento de la IU llegan a la conclusión que es un tratamiento efectivo ya que los resultados de los dos estudios muestran una mejora en la pérdida de orina y la calidad de vida. Además llegaron a la conclusión que es mejor el tratamiento supervisado, ya que en sus estudios muestran diferencias significativas entre el grupo supervisado y el no supervisado.

Tratamiento individual frente a tratamiento colectivo

Peláez et al. (26), Sangsawang et al. (24) y Dinc et al. (23) comparan los efectos del EMSP de forma individual o en grupo en el tratamiento de la IU. En los estudios hubo mejoras en la calidad de vida y disminución en la perdida de orina. Lo que nos lleva a la conclusión de que la aplicación de tratamiento individual o colectivo es igual de efectiva. Es cierto que en el tratamiento colectivo es muy gratificante para la mujer con incontinencia urinaria porque se relaciona con mujeres con la misma afección. También es importante destacar que, para el servicio de salud, programas de entrenamiento colectivo le supondría menos gasto en el tratamiento de la IU que programas de entrenamiento individuales.

Tratamiento del EMSP según su duración

Fritel et al. (28), Woldringh et al. (27) y Dinc et al. (23) trabajaron en sus estudios con una baja intensidad en el tratamiento de la IU. Dinc et al. demuestra que al realizar el entrenamiento muscular del suelo pélvico una vez por semana en 12 sesiones, la pérdida de orina disminuye . Por otro lado, Fritel et al. y Woldringh

et al. en el estudio que realizaron no muestran diferencias significativas en los resultados de la pérdida de orina y la mejora de la calidad de vida al realizar el entrenamiento una vez por semana en 8-4 sesiones respectivamente. Esto quiere decir que la intensidad del entrenamiento influye en el EMSP para la mejora de la incontinencia urinaria.

4.2. Limitaciones

No se encontraron limitaciones.

4.3. Conclusiones

Se concluye, después de una revisión sistemática de 7 estudios acerca de los programas de EMSP resulta útil en el tratamiento de la incontinencia urinaria en gestantes, disminuyendo el índice de pérdida de orina, impacto en la calidad de vida de las gestantes afectas y proporciona tomas de decisiones clínicas al momento de abordar este tipo de pacientes, siendo igual de efectivo la aplicación de este programa de manera individual y/o grupal, es importante tener en cuenta que en los estudios que se realiza el EMSP bajo supervisión fisioterapéutica tienen mejores resultados que en los programas de entrenamiento que se realizan sin supervisión. Además el entrenamiento de alta intensidad de la musculatura del suelo pélvico (MSP) es efectivo para la incontinencia urinaria porque en los estudios se comprueba que es importante la frecuencia con que se realiza el entrenamiento.

El tratamiento en la práctica clínica, presenta un costo menor institucional y mejora las relaciones sociales de las mujeres con IU, es recomendable realizar un programa de entrenamiento bajo supervisión de manera que se pueda producir una adaptación del programa a medida que la paciente va progresando.

Al aplicar el EMSP, es aconsejable informar a la paciente que no debe interrumpir las sesiones programadas, siendo que si se interrumpe la aumentaría el riesgo de padecer IU para ello se recomiendo realizar programas donde le permita al participante, realizar ejercicios dinámicos basado a un enfoque preventivo asistencial, que permita al participante tomar conciencia acerca de la importancia que tiene en su salud física.

En cuanto a la investigación se requiere aumentarla e idear un único método de EMSP para el tratamiento de la IU. Si bien es cierto que es muy difícil realizar dicho EMSP ya que cada paciente tiene una valoración de la IU diferente y lo más indicado es adaptar el EMSP a cada paciente e ir aumentando la dificultad a medida que el paciente va progresando. Es importante realizar estudios sobre el efecto a largo plazo del EMSP en la IU para demostrar la durabilidad de los resultados.

CAPÍTULO V: FINANCIAMIENTO

Este trabajo fue financiado íntegramente por los autores, quienes participaron conjuntamente con el asesor Lic. Sergio Bravo Cucci en el diseño del estudio, la recolección y análisis de los datos y la preparación del manuscrito.

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Los autores declaran no tener conflicto de interés para la realización de este estudio.

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ANEXOS

INSTRUMENTOS UTILIZADOS EN LA MEDICION DE LOS ESTUDIOS INVOLUCRADOS

My Bladder Diary

Keeping a daily bladder diary will help you and your healthcare professional better understand your Overactive Bladder (OAB) symptoms. See instructions on the back of this page.

Date: _____

Time	Drinks		Trips to the bathroom		Accidental leaks	Did you feel a strong urge to go?	What were you doing at the time?
	What kind?	*How much?*	*How many times?*	*How much urine?*	*How much?*	*Yes / No*	*Sneezing, exercising, etc.*
2-9 p.m.	soda	12 oz. can	✔ ✔	about 8 oz.	yes - large amount	yes	sitting at computer

CUESTIONARIO I-QOL DE CALIDAD DE VIDA EN INCONTINENCIA URINARIA

	1	*2*	*3*	*4*	*5*
1. Me preocupa el hecho de no ser capaz de ir al servicio a tiempo	☐	☐	☐	☐	☐
2. Me preocupa toser o estornudar debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
3. Tengo que tener cuidado al ponerme de pie después de estar sentado debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
4. Me preocupa donde están los servicios en lugares nuevos	☐	☐	☐	☐	☐
5. Me siento deprimido debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
6. Debido a mis problemas urinarios o de incontinencia, no me siento capaz de salir de mi casa durante largos períodos de tiempo (viajar)	☐	☐	☐	☐	☐
7. Me siento frustrado porque mis problemas urinarios o de incontinencia me impiden hacer lo que quiero	☐	☐	☐	☐	☐
8. Me preocupa que otros puedan sentir el olor de la orina en mí	☐	☐	☐	☐	☐
9. La incontinencia está siempre en mi mente	☐	☐	☐	☐	☐
10. Es importante para mí hacer viajes frecuentes al servicio	☐	☐	☐	☐	☐
11. Debido a mis problemas urinarios o de incontinencia es importante planear cada detalle con anticipación	☐	☐	☐	☐	☐
12. Me preocupan mis problemas urinarios o de incontinencia, que se empeoran a medida que envejezco	☐	☐	☐	☐	☐
13. Tengo dificultad para conciliar el sueño durante toda la noche debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
14. Me preocupa estar avergonzado o humillado debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
15. Mis problemas urinarios o de incontinencia me hacen pensar que no soy una persona sana	☐	☐	☐	☐	☐
16. Mis problemas urinarios o de incontinencia me hacen sentir indefenso	☐	☐	☐	☐	☐
17. No me siento a gusto debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
18. Me preocupa orinarme encima	☐	☐	☐	☐	☐
19. Siento que no tengo control sobre mi vejiga	☐	☐	☐	☐	☐
20. Tengo que controlar, qué o cuánto bebo debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐
21. Mis problemas urinarios o de incontinencia limitan mis opciones de ropa	☐	☐	☐	☐	☐
22. Me preocupan mis relaciones sexuales debido a mis problemas urinarios o de incontinencia	☐	☐	☐	☐	☐

Contestación de cada pregunta: 1 = Siempre 2 = Casi siempre 3 = Moderado 4 = Un poco 5 = Nunca

El cuestionario I-QOL se ha utilizado por diferentes grupos con las siguientes conclusiones:

Patrick DL et al[39]: El objetivo era traducir y validar una medida específica de incontinencia urinaria de calidad de vida (I-QOL) en francés, español, sueco y alemán y proporcionar sólo siete traducciones de otras lenguas similares. Conclusión: El I-QOL se ha adaptado con éxito en 11 idiomas y seis variantes de estos idiomas.

Coyne KS et al[36]: La experiencia de urgencia urinaria tiene un efecto negativo en HRQL y un incremento en la molestia de los síntomas y que en una muestra de la comunidad es más que una simple incontinencia, frecuencia o nicturia.

Patrick DL et al[38]: En un ensayo clínico, el I-QOL resultó válido, reproducible y sensible para el tratamiento de IU en mujeres (validación en inglés).

Wagner TH et al[44]: El I-QOL resultó válido y reproducible como una medida de autocuestionario para evaluar la calidad de vida de pacientes con incontinencia urinaria.

Matza LS et al[37]: La vejiga hiperactiva (OAB) y la incontinencia urinaria de esfuerzo tienen un profundo impacto en la calidad de vida relacionada con la salud (HRQL).

INCONTINENCE IMPACT QUESTIONNAIRE - 7

Has urine leakage affected your...	Not at all	Slightly	Moderately	Greatly
Ability to do household chores (cooking, housecleaning, laundry)?	0	1	2	3
Physical recreation such as walking, swimming, or other exercise?	0	1	2	3
Entertainment activities (movies, concerts etc.)?	0	1	2	3
Ability to travel by car or bus more than 30 minutes from home?	0	1	2	3
Participation in social activities outside your home?	0	1	2	3
Emotional health (nervousness, depression, etc.)?	0	1	2	3
Feeling frustrated?	0	1	2	3

PRAFAB score

Protection
1. I never use protection for urine loss
2. I use protection sometimes, or I have to change my underwear because of urine loss
3. I normally use protection, or I change my underwear several times a day because of urine loss
4. I always have to wear protection because of urinary incontinence

Amount
1. The amount of urine lost is just a drop
2. Sometimes I loose a small quantity of urine
3. Urine loss is so great that it wets my protective pad or clothing noticeably
4. Urine loss is so great that my protective pad is soaked or leaks

Frequency
Involuntary loss of urine occurs:
1. Once a week or less
2. More than once but less than three times a week
3. More than three times a week, but not every day
4. Every day

Adjustment
Implications of urine loss:
1. My normal daily activities have not been restricted
2. I have stopped some activities, such as some sports and some physically demanding activities
3. I have stopped most physical activities that cause involuntary urine loss
4. I almost never go out

Body (or self) image
1. I do not worry about urine loss
2. I think urine loss is annoying and troublesome, but I am not greatly bothered by it
3. I find urine loss disgusting
4. I am disgusted by myself because of my urine loss

CUESTIONARIO DE INCONTINENCIA URINARIA ICIQ-SF

El ICIQ (International Consultation on Incontinence Questionnaire) es un cuestionario autoadministrado que identifica a las personas con incontinencia de orina y el impacto en la calidad de vida. Puntuación del ICIQ-SF: sume las puntuaciones de las preguntas 1+2+3. Se considera diagnóstico de IU cualquier puntuación superior a cero

1. ¿Con qué frecuencia pierde orina? (marque sólo una respuesta).

Nunca 0
Una vez a la semana 1
2-3 veces/semana 2
Una vez al día 3
Varias veces al día 4
Continuamente . . . . . .

2. Indique su opinión acerca de la cantidad de orina que usted cree que se le escapa, es decir, la cantidad de orina que pierde habitualmente (tanto si lleva protección como si no). Marque sólo una respuesta.

No se me escapa nada 0
Muy poca cantidad 2
Una cantidad moderada 4
Mucha cantidad 6

3. ¿En qué medida estos escapes de orina, que tiene, han afectado su vida diaria?

1	2	3	4	5	6	7	8	9	10
Nada									Mucho

4. ¿Cuándo pierde orina? Señale todo lo que le pasa a Ud.

- **Nunca.**
- **Antes de llegar al servicio.**
- **Al toser o estornudar.**
- **Mientras duerme.**
- **Al realizar esfuerzos físicos/ejercicio.**
- **Cuando termina de orinar y ya se ha vestido.**
- **Sin motivo evidente.**
- **De forma continua.**

UROGENITAL DISTRESS INVENTORY

UDI-6: Indique si tiene los siguientes problemas y, si es así, cuánto le molestan:

1. La necesidad de orinar frecuentemente
2. Pérdidas de orina unidas a una sensación de urgencia (necesidad urgente de ir al WC)
3. Pérdidas de orina cuando realiza una actividad física, estornuda o tose
4. Pérdida de orina en pequeñas cantidades (es decir, gotas)
5. Dificultad para vaciar su vejiga
6. Dolor o incomodidad en la parte inferior del abdomen o en la zona genital

«nada», «poco», «moderadamente», «mucho»

TEXTOS COMPLETOS DE ESTUDIOS INVOLUCRADOS

Original Research

Preventing Urinary Incontinence With Supervised Prenatal Pelvic Floor Exercises

A *Randomized Controlled Trial*

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OBJECTIVE: To compare, in an unselected population of nulliparous pregnant women, the postnatal effect of prenatal supervised pelvic floor muscle training with written instructions on postpartum urinary incontinence (UI). METHODS: In a randomized controlled trial in two parallel groups, 282 women were recruited from five university teaching hospitals in France and randomized during the second trimester of pregnancy. The physiotherapy group received prenatal individually supervised exercises. Both groups received written instructions about how to perform exercises at home. Women were blindly assessed at baseline, end of pregnancy, and 2 and 12 months postpartum. The primary outcome measured was UI severity, assessed with an International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form score (range 0-21;1-5 is slight UI) at 12 months postpartum;other outcomes were UI prevalence and pelvic floor troubles assessed using self-administered questionnaires. To give a 1-point difference in UI severity score, we needed 91 women in each group (standard deviation 2.4, a=0.05, p=0.20, and bilateral analysis). RESULTS: Between February 2008 and June 2010, 140 women were randomized in the physiotherapy group and 142 in the control group. No difference was observed between the two groups in UI severity, prevalence, or pelvic floor troubles at baseline, end of pregnancy, and at
2 and 12 months postpartum. At 12 months postpartum, the primary outcome was available for 190 women (67.4%); mean UI severity was 1.9 in the physiotherapy group compared with 2.1 in the control group (P=.38). CONCLUSION: Prenatal supervised pelvic floor training was not superior to written instructions in reducing postnatal UI.
CLINICAL TRIAL REGISTRATION: ClinicalTrials.gov; www.clinicaltrials.gov, NCT00551551.

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LEVEL OF EVIDENCE: I

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Urinary incontinence (UI) is a common condition in women that can affect quality of life and lead to significant health costs.[1] Pregnancy is one of the major causal factors of UI in women. Urinary incontinence

onset often occurs during pregnancy or postpartum with 30-50% women affected.[2]

Pelvic floor muscle training supervised by a therapist is an effective treatment for UI in women.[3-5] It has been demonstrated effective in treating the discomfort associated with postpartum UI.[6] Although pelvic floor training has a recognized therapeutic effect, its value in preventing postnatal UI is less well established. Several clinical trials have sought to evaluate whether prenatal pelvic floor training supervised by a physiotherapist had a preventive effect on UI.[6] The results of some trials suggest efficacy in late pregnancy and postpartum.[7,8] In the majority of these trials, pelvic floor training was supervised by teams specializing in this type of care. We wondered whether it was possible to generalize these results in clinical practice by carrying out a pragmatic multicenter trial in which the women have the choice of therapist like in daily practice. In view of the previous trials, we hypothesized that supervised prenatal pelvic floor exercises would prevent or reduce the severity of postnatal UI compared with written instructions only.

Our primary objective was to evaluate the postpartum effect of written instructions only compared with written instructions with supervised pelvic floor exercises on UI severity 12 months after first delivery.

MATERIALS AND METHODS

Women between 20 and 28 weeks of gestation referred to one of the five participating centers (Nîmes, Poissy-Saint-Germain, Clermont-Ferrand, Clamart, and Saint-Denis-de-la-Réunion) were invited to participate in the study. Inclusion required the women to be nulliparous, at least 18 years of age, covered by health insurance, able to read French, carrying an uncomplicated singleton pregnancy, and without or with UI (including UI before pregnancy). Exclusion criteria were previous delivery or abortion after 22 weeks of gestation, high-risk pregnancy, any condition contraindicating further long-distance travel, or previous pelvic floor muscle training less than 6 months prior. All women gave written consent before participating.

Women were randomly assigned to a group at a 1:1 ratio. Stratification was performed according to the center. The randomized list was generated using the Proc Plan from SAS (block of six). The block sizes were blinded for research and health professionals (information not divulged in the study protocol). The random allocation sequence was secured in sequentially numbered sealed envelopes not accessible to the obstetrician. In each center, the participant allocation was undertaken by a research professional, thus ensuring that the obstetrician was blinded for group allocation.

For the pelvic floor muscle training group supervised by a therapist (hereafter termed "physiotherapy group"), rehabilitation was given by a physiotherapist or midwife chosen by the woman from the list drawn up in each center. Before the start of the study, physiotherapists and midwives practicing perineal rehabilitation in each center were invited to participate in the study and to take part in an initial training course given by a physiotherapist specializing in pelvic floor training (C.R.). The rehabilitation standards required in the study and presented during the training session were as follows. The eight pelvic floor training sessions were to be conducted between the sixth and eighth month of pregnancy at a frequency of one session per week. Each session lasted between 20 and 30 minutes and was performed alone with the therapist present throughout. An evaluation of pelvic floor muscle contraction was performed at each session through vaginal examination.[9] Sessions consisted of standing contractions (5 minutes), lying contractions (10 minutes), and learning how to start a pelvic floor contraction just before exerting intraabdominal pressure (knack exercise). Electrostimulation or biofeedback was not used. Women were encouraged to perform daily muscle exercises. There were no specific instructions on the number or intensity of the contractions.

The control group received written information on pelvic floor anatomy and pelvic floor contraction exercises, which were given at the time of inclusion. These instructions were also given to the physiotherapy group.

A self-competed questionnaire was given to patients on the inclusion visit, at the end of pregnancy, and during the visit 2 months postpartum. A final questionnaire was mailed 12 months after childbirth. Clinical examination with a Pelvic Organ Prolapse Questionnaire measurement, clinical assessment of pelvic floor muscle strength (between 0 and 5 according to Laycock),[9] and a 24-hour pad test (pad test quantify urine loss by measuring the weight gain of absorbent pads) were performed at baseline and at the 2-month postpartum visit.

Clinical examination was performed by an obstetrician blinded to the groups. No information about the randomized groups was given to staff responsible for prepartum, peripartum, or postpartum care. Women were asked not to reveal their randomized group to caregivers, whether during pregnancy, childbirth, or postpartum care. The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form questionnaire calculates a score for UI and is validated in French. The International Consultation on Incontinence Questionnaire-Urinary Incontinence Short

Form score is the primary outcome.[10] A pelvic floor symptoms questionnaire (Female Pelvic Floor Questionnaire) validated in French clarifies other urinary and pelvic floor disorders and calculates a score in four areas (bladder, prolapse, bowel, and sex).[11] Quality of life was assessed using a specific questionnaire (Contilife)[12] and a generic questionnaire (EuroQoL-5D). Voluntary exercises of pelvic floor contractions were measured in both groups through a self-administered questionnaire at the end of pregnancy, at 2 months postpartum, and at 12 months postpartum. Women in the physiotherapy group received an additional questionnaire to verify their participation in prenatal pelvic floor muscle training sessions.

The number of participants to include was based on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form score. This score ranges from 0 (no incontinence) to 21 ("all the time" incontinence, with a large amount of losses and maximum discomfort of 10 out of 10); a score between 1 and 5 is considered as slight incontinence.[13] The score found in the female population in general is between 1.3 and 2.9 with a standard deviation of 2.4.[10,14] Considering that 0 corresponds to no incontinence and
3 is incontinence occurring more than once a week with a small amount of urine and resulting in zero discomfort, we considered a difference of less than 1 point was not clinically significant. To give a (International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form) difference of 1 point 12 months postpartum, 182 patients were needed (standard deviation [SD] 2.4, a=0.05, b=0.20, and bilateral formulation). Based on previous work,[15] we estimated the loss of patients to be approximately one third. Therefore, 280 women were invited to take part in the study.

The main analyses focus on the primary (International Consultation on Incontinence Questionnaire- Urinary Incontinence Short Form score) and secondary outcomes (UI prevalence, urinary Female Pelvic Floor Questionnaire score, quality-of-life score, pad test, pelvic floor contraction exercises, pelvic floor muscle strength, additional postnatal pelvic floor muscle training, number of postnatal medical visits) and are performed with intention to treat, according to a bilateral formulation and a significance level of 5%, according to what was planned and published.[16] In univariate analysis, statistical tests provided for categorical variables were the x^2 test or Fisher's test according to the verification of the conditions of application of the X^2 test and for quantitative variables the Student's *t* test or Wilcoxon tests according to normality of distributions. The center effect on UI prevalence was analyzed using the Cochran-Mantel-Haenszel test. Statistical analysis was performed using SAS 9.

The study received institutional review board approval by the Comité de Protection des Personnes Sud-Ouest-et-Outre-Mer in September 2007 (#2007- A00641-52). This project was funded by the French Ministry of Health through the Programme Hospitalier de Recherche Clinique in 2007 (project #31-15). The study is registered by the Agence Nationale de Sécurité du Médicament and in ClinicalTrials.gov under number NCT00551551 (http://clinicaltrials. gov/show/NCT00551551).

RESULTS

Of the 282 pregnant women recruited between February 2008 and June 2010, 140 were randomized into the physiotherapy group and 142 into the control group (Fig. 1). The recruitment ended when the required number of patients was reached. The characteristics of women at inclusion did not differ between randomized groups (Table 1); the analysis of the 190 women available for the primary outcome also showed no difference (Appendix 1 available online at http://links.lww.com/AOG/A666). Of the 140 women in the physiotherapy group, 116 completed at least one pelvic floor muscle training session (4-8, median 8) and 97 completed all planned prenatal sessions (Fig. 1). Rehabilitation was supervised by 37 different therapists (physiotherapists and midwives). No adverse effects related to the treatment were reported in the physiotherapy group. The primary outcome was collected from 190 women (67.4%) at 12 months postpartum (93 in the physiotherapy group and 97 in the control group; Fig. 1). Women for whom results could not be collected at 12 months postpartum were younger, less educated, and more often smokers than those who completed the study (Appendix 2 available online at http://links.lww.com/AOG/A666).

The prevalence of UI was 37.6% (100/266) at inclusion to the study (Table 1), 44.2% (99/224) in late pregnancy, 36.0% (76/211) 2 months postpartum, and 35.8% (68/191) at 1 year after birth (Table 2). There were no significant differences in prevalence of UI or severity (International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form score) between groups (physiotherapy compared with control) at the end of pregnancy (odds ratio [OR] 1.0, 95% confidence interval [CI] 0.6-1.7; mean difference —0.2, 95% CI —1.2 to +0.8), at 2 months postpartum (OR 0.8 [0.5-1.4]; mean difference —0.6 [—1.4 to +0.3]), and at the end of the study (OR 0.7 [0.4-1.3]; mean difference —0.2 [—1.2 to +0.7]; Table 2; Fig. 2). We did not find any difference between centers for UI prevalence.

At the end of pregnancy, women in both randomized groups reported a similar frequency and duration of

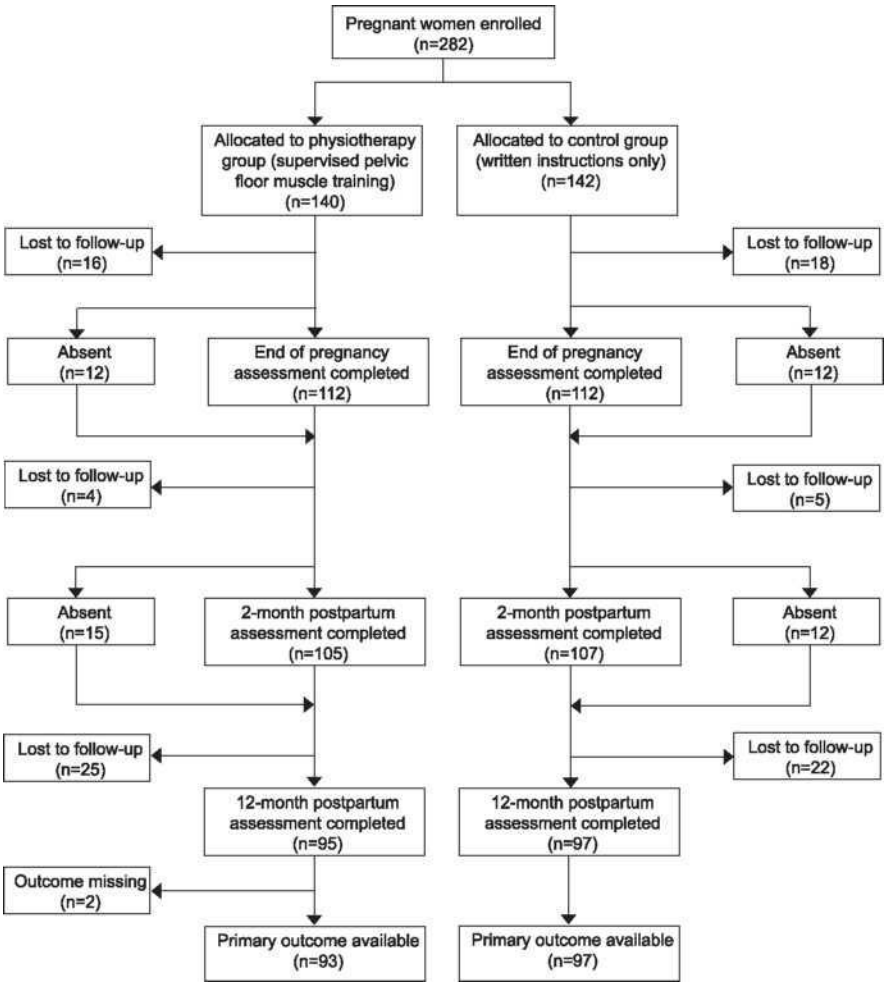

Fig. 1. Study flowchart. The term "lost to follow-up" designates women who did not participate in any subsequent assessments. Women absent for one assessment but who completed one of the following assessments were not considered as having dropped out at this point.

Fritel. Prenatal Pelvic Floor Training and UI. Obstet Gynecol 2015.

voluntary pelvic floor muscle contraction exercises as well as the number of contractions each time; only six women in the physiotherapy group and 15 in the control group reported doing pelvic floor contraction exercises at home everyday (nonsignificant difference, P=.37).

The blinded clinical evaluation of the value of pelvic floor muscle strength at 2 months postpartum showed no significant differences between randomized groups (Table 2). The matched analysis shows a significant decrease of a quarter point in average muscle strength between inclusion and 2 months postpartum in the control group (—0.25, P=.015, signed rank test), whereas it remained unchanged in the physiotherapy group (+0.08, P=.59, signed rank test), but the difference was not statistically different between the two groups (Table 2).

Secondary analysis based on UI at inclusion showed that among women who reported UI on inclusion, the remission rate was 46.9% in the physiotherapy group and 30.6% in the control group; the difference was not significant (P=.17).

The secondary per-protocol analysis comparing the 116 women who actually carried out their prenatal rehabilitation supervised by a therapist with the 142 women in the control group who received only written instructions found no significant difference in UI severity and in the prevalence of UI at the end of pregnancy (mean International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form score reduction —0.2 [95% CI —1.2 to 0.8]; 44.6 compared with 43.7%; OR 1.0 [95% CI 0.6—1.8]), at 2 months postpartum (—0.6 [—1.4 to 0.3]; 33.7 compared with 38.3%; OR 0.9 [0.5-1.5]), and at 1 year postpartum (—0.2 [—1.2 to 0.7]; 32.3 compared with 39.2%; OR 0.7 [0.4-1.4]).

DISCUSSION

Prevalence and severity of postpartum UI in primip- arous women was not altered by supervised prenatal pelvic floor training compared with those who only received written instructions. This result rejects the

Table 1. Baseline and Delivery Characteristics of Women Included During Their First Pregnancy

Characteristic	Physiotherapy Group (n=140)	Control Group (n=142)	P
Baseline			
Age at inclusion (y)	29.465.1 (28.8; 140)	29.465.1 (28.6; 142)	.79
BMI (kg/m^2)	22.364.4 (21.5; 139)	22.663.6 (22.0; 142)	.28
Education			
Higher than high school	84.1 (111/132)	82.1 (110/134)	.66
Smoking	9.8 (13/132)	9.0 (12/133)	.81
UI (ICIQ-UI SF score higher than 0)	37.9 (50/132)	37.3 (50/134)	.92
UI type			
Stress	38.0 (19/50)	46.0 (23/50)	.51
Urge	18.0 (9/50)	8.0 (4/50)	
Mixed	34.0 (17/50)	10.0 (5/50)	
Other	10.0 (5/50)	10.0 (5/50)	
ICIQ-UI SF score (0-21)	2.563.9 (0; 132)	2.663.8 (0; 134)	.89
FPFQ bladder score (0-10)	1.661.3 (1.4; 132)	1.661.3 (1.1; 133)	.55
FPFQ bowel score (0-10)	1.461.1 (1.2; 132)	1.561.3 (0.9; 135)	.61
FPFQ prolapse score (0-10)	0.461.1 (0; 132)	0.461.1 (0; 135)	.71
Sexually active	89.3 (117/131)	88.0 (118/134)	.75
FPFQ sex score (0-10)	2.461.7 (2.0; 109)	2.861.8 (2.7; 117)	.09
Pad test (g)	1.361.9 (0; 113)	1.865.5 (0; 117)	.62
Pelvic floor muscle strength (0-5)	3.361.5 (4; 135)	3.361.4 (4; 135)	.92
Specific quality of life (Contilife score; 0-10)	9.361.0 (9.8; 128)	9.361.0 (9.7; 130)	.57
Generic quality of life (EuroQoL-5D; 0-100)	78.8621.1 (85; 131)	78.3620.7 (80; 135)	.67
Delivery			
Newborn weight (g)	3,2066486 (3,240; 137)	3,1976492 (3,220; 136)	.99
Cesarean delivery before labor	8.0 (11/137)	8.8 (12/136)	.55
Cesarean delivery during labor	18.2 (25/137)	12.5 (17/136)	
Spontaneous vaginal delivery	52.6 (72/137)	52.9 (72/136)	
Instrumental delivery	21.2 (29/137)	25.7 (35/136)	
3rd-degree perineal tear	0.0 (0/138)	2.2 (3/138)	.12

BMI, body mass index;UI, urinary incontinence;ICIQ-UI SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form;FPFQ, Female Pelvic Floor Questionnaire.
Data are % (n/N) or mean±standard deviation (median;n) unless otherwise specified.
X^2 and Fisher's exact test for qualitative variables;Wilcoxon test for continuous variables.

hypothesis of a preventive effect of antenatal physiotherapy on the occurrence or exacerbation of UI 1 year after first delivery. Results of the per-protocol analysis also supported this conclusion.

In our trial, the variance in the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form score was higher than expected (SD 3.5 against 2.4 expected). To show a difference of 1 point with this variance and a power of 80%, twice as many patients would have been required. Insufficient power can make a difference appear as not significant; however, the difference observed on the UI score, —0.2 at 12 months postpartum, was very low and well below the threshold considered to be clinically significant (1 point).

Approximately one third of patients dropped out. The effect of this is probably limited because it was similar in both groups. Furthermore, women who dropped out had similar characteristics at baseline than those who did not drop out. It is therefore unlikely that this would have changed the conclusions of our study.

In France, postpartum pelvic floor muscle training is commonplace (54% of women in the physiotherapy group and 63% in the control group performed postnatal sessions). Postpartum pelvic floor muscle training sessions could mask the effect of the effect of postnatal sessions, but the difference was not significant, thus eliminating this bias.

Women in both groups reported a similar exercise frequency at home. It is possible that as a result of the voluntary nature of this study, women were particularly receptive or conscious to the prevention of UI, which would explain why exercises were carried out in the control group. Six years after the end of the a randomized trial carried out by Glazener et al,[17] which focused on postnatal pelvic floor exercises, women in the control group were more likely to continue doing daily contractions that women in the physiotherapy group (12% compared with 6%).

Table 2. End of Pregnancy and Postpartum Results on Urinary Incontinence and Quality of Life

Outcome		Physiotherapy Group (n=140)		Control Group (n=142)		P
End of pregnancy						
UI (ICIQ-UI SF score higher than 0)		44.6	(50/112)	43.7	(49/112)	.89
ICIQ-UI SF score (0-21)		2.7±3.7	(0; 112)	2.9±4.0	(0; 112)	.99
FPFQ bladder score (0-10)		1.7±1.3	(1.4; 112)	2.0±1.4	(1.7; 111)	.08
FPFQ bowel score (0-10)		1.3 ± 1.1	(1.0; 112)	1.4±1.1	(0.9; 112)	.31
FPFQ prolapse score (0-10)		0.7±1.2	(0; 112)	0.7±1.4	(0; 112)	.89
Sexually active		74.1	(83/112)	62.5	(70/112)	.06
FPFQ sex score (0-10)		2.7±1.8	(2.0; 79)	3.1 ±2.1	(2.7; 68)	.21
Specific quality of life (Contilife score;	0-10)	9.3±1.1	(9.8; 108)	9.2±1.3	(9.8; 109)	.51
Generic quality of life (EuroQoL-5D; 0	-100)	76.4±20.4	(80; 111)	77.9±16.3	(80; 112)	.93
2 mo postpartum						
UI (ICIQ-UI SF score higher than 0)		33.7	(35/104)	38.3	(41/107)	.48
ICIQ-UI SF score (0-21)		1.7±2.9	(0; 104)	2.3±3.4	(0; 107)	.26
FPFQ bladder score (0-10)		0.8±0.9	(0.6; 105)	0.9±1.0	(0.6; 107)	.48
FPFQ bowel score (0-10)		1.2±1.2	(0.9; 104)	1.4±1.2	(1.2; 107)	.22
FPFQ prolapse score (0-10)		0.3±1.1	(0; 104)	0.5±1.3	(0; 107)	.11
Sexually active		71.2	(74/104)	74.5	(79/106)	.58
FPFQ sex score (0-10)		3.1 ±2.1	(2.7; 73)	3.5±2.2	(3.3; 77)	.27
Pad test (g)		0.9±1.6	(0; 78)	1.3±3.3	(0; 85)	.93
Pelvic floor muscle strength (0-5)		3.5±1.5	(4; 105)	3.3±1.3	(4; 107)	.24
Changes in muscle strength		+0.08±1.32	(0; 101)	−0.25±1.11	(0; 103)	.09
Specific quality of life (Contilife score;	0-10)	9.6±0.8	(9.9; 102)	9.5±0.8	(9.7; 101)	.06
Generic quality of life (EuroQol-5D; 0-	-100)	82.8±18.2	(90; 105)	80.4±17.0	(85; 107)	.13
12 mo postpartum						
UI (ICIQ-UI SF score higher than 0)		32.3	(30/93)	39.2	(38/97)	.32
ICIQ-UI SF score (0-21)		1.9±3.7	(0; 93)	2.1 ±3.3	(0; 97)	.38
FPFQ bladder score (0-10)		0.9±1.1	(0.6; 94)	1.0±1.1	(0.6; 97)	.76
FPFQ bowel score (0-10)		1.0±1.0	(0.6; 94)	1.1±1.0	(0.9; 97)	.24
FPFQ prolapse score (0-10)		0.4±1.2	(0; 95)	0.4±1.0	(0; 97)	.78
Sexually active		93.7	(89/95)	93.8	(91/97)	1.0
FPFQ sex score (0-10)		2.4±1.8	(0; 86)	2.7±2.0	(0; 83)	.36
Specific quality of life (Contilife score;	0-10)	9.5±1.2	(9.9; 91)	9.5±1.0	(9.9; 89)	.07
Generic quality of life (EuroQol-5D; 0-	-100)	86.8±13.1	(90; 94)	82.9±14.8	(85; 97)	.05
Additional postnatal pelvic floor muscle training		54.3	(50/92)	62.9	(61/97)	.23
Medical visits since delivery		3±2.5	(2; 84)	3±2.2	(2; 83)	.48

UI, urinary incontinence;ICIQ-UI SF, International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form;FPFQ, Female Pelvic Floor Questionnaire.
Data are % (n/N) or mean6standard deviation (median;n) unless otherwise specified.
Intention to treat analysis. x^2 or Fisher's exact test for qualitative variables;Wilcoxon test for continuous variables.

Sampselle et al[18] showed that written and verbal instructions during pregnancy may have a preventive effect. On the other hand, Bo's[19] trial comparing a procedure combining written instructions and fitness classes with a control group showed no difference. In our study, only 5% of women in the physiotherapy group did daily exercises at the end of pregnancy (28% if we count the one participant who reported doing the exercises almost everyday). Adherence to exercises in the physiotherapy group seems low and, in our opinion, partly explains why results are not better in this group.

Strengths of our study include the use of a validated and reliable self-administered questionnaire to assess UI and a long postpartum follow-up. Another strength was the pragmatic design. Women had a choice of therapist, which allowed results to be evaluated as if in general clinical practice. To avoid any bias related to the use of inappropriate pelvic floor training techniques, we took the precaution of standardizing the procedure through preliminary training of therapists by a specialist in the field of pelvic floor training. Furthermore, we used evidence-based practices: intensive exercises supervised by a therapist.[20]

Our results contradict previous studies that show a preventive effect of supervised pelvic floor training on postpartum UI.[7,8,21,22] The Cochrane review is in favor of pelvic floor training during pregnancy.[6] However, other studies, including ours and those with the largest number of patients, show negative results (Appendix 3 available online at http://links.lww.com/AOG/A666).[23,24] Key

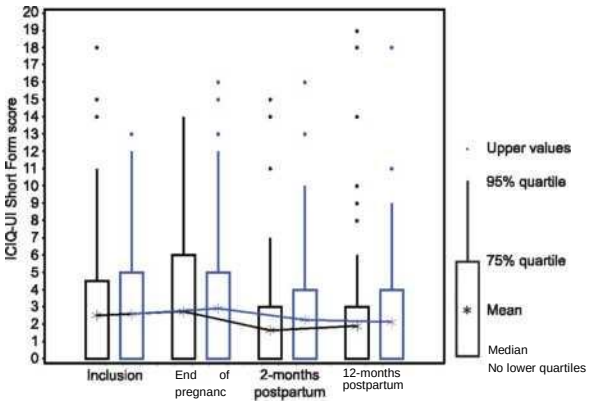

Fig. 2. Changes in urinary incontinence severity (International Consultation on Incontinence Questionnaire-Urinary Incontinence [ICIQ-UI] Short Form score: median, mean, 75% and 95% quartiles, and upper values) in the physiotherapy group *(black)* and the control group *(blue)* during the entire follow-up (inclusion, end of pregnancy, 2 months postpartum, and 12 months postpartum).
Fritel. Prenatal Pelvic Floor Training and UI. Obstet Gynecol 2015.

differences between our study and previous works is the number of centers and physiotherapists in charge of rehabilitation. The positive earlier trials were singlecenter and only one to five skilled physical therapists supervised the rehabilitation sessions.[7,8,21] The larger number of centers and therapists could induce differences in practices despite our efforts to standardize the procedure and reduce its effect. However, our results show that the preventive effect of antenatal perineal rehabilitation, if it exists, disappears when it becomes widespread outside a specialized center.

Our disappointing results should be compared with those of Hilde and Bo, which did not find a preventive effect for postpartum rehabilitation in a sample comprising women with or without UI (a mixed trial like our study).[25] One of the supposed mechanisms of physiotherapy in the treatment of UI is to reinforce pelvic floor muscle strength. However, we do not know whether muscle training has a preventive effect in asymptomatic women. One may wonder through which pathophysiologic mechanism prenatal pelvic floor training could play a preventive role in late postpartum UI. It is, in our opinion, implausible that such a mechanism exists because it assumes that prenatal rehabilitation in the physiotherapy group would be sufficiently effective to avoid obstetric trauma.[2,7,26] Our study may suggest that antenatal pelvic floor training prevents postnatal decrease in muscle strength. Our interpretation is that the physiotherapy contributes to muscle reinforcement, but this alone is not sufficient to exert a preventive effect on urinary continence.

Our conclusion is that supervised pelvic floor contraction exercises are not superior to written instructions in preventing postpartum UI in primipa- rous women.

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ORIGINAL ARTICLE

Pelvic floor muscle training is not effective in women with UI in pregnancy: a randomised controlled trial

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Abstract The objective of this study was to test the short- and long-term effects of pelvic floor muscle training (PFMT) during pregnancy in women at risk, i.e. women who were already affected by urinary incontinence (UI) during pregnancy. The intervention consisted of three sessions of PFMT between week 23 and 30 during pregnancy and one session 6 weeks after delivery, combined with written information. The research design was a randomised, controlled trial with four follow-ups up to 1 year after delivery. Participants in the study were 264 otherwise healthy women with UI during pregnancy, allocated at random to the intervention (112) or usual care (152) group. The main outcome measure was a UI severity scale and a 7-day bladder diary. No effect of pelvic floor muscle training was shown in this study at (half) a year after pregnancy. UI decreased strongly after pregnancy, irrespective of usual care or PMFT during pregnancy. For most women, usual care appears to be sufficient. The results support a 'wait and see' policy: wait for the urinary incontinence to take its natural course and see if, for women still incontinent half a year after pregnancy, pelvic floor muscle training is effective.

Keywords Urinary incontinence . Pregnancy ■ Pelvic floor muscle training . Long-term effects

Abbreviations
PFMT Pelvic floor muscle training UI Urine incontinence

Introduction

Urinary incontinence (UI) is a common health complaint amongst young women. In women 25-65 years of age, UI gradually increases from 24 to 46% [1]. Pregnancy and vaginal delivery are main risk factors contributing to a weakening of the pelvic floor muscles [2-4]. Women already suffering from stress urinary incontinence (SUI) during pregnancy are especially at risk to be affected by postpartum UI complaints, even long after delivery. At 5 years after delivery, the risk is four times as high [5]; at 15 years, it is two times as high [6].

As shown in a systematic literature review [7], pelvic floor muscle training (PFMT) given by skilled physiotherapists is an effective method to treat SUI. Furthermore, in women not especially selected on incontinence, PFMT received during pregnancy [8, 9] and after delivery [10, 11] can also have a positive preventive effect. The effect of PFMT in the high-risk group of women with SUI during pregnancy is not known. In view of the application of the

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intervention in general practice, we were especially interested in the effects of a feasible four session training program.

Materials and methods

The intervention, given by 25 physiotherapists specialised in PFMT and practicing in the proximity of the homes of the participating women, consisted of four sessions of individual therapy: three sessions (with 2-week interval) between week 23 and 30 of pregnancy and a fourth session
6 weeks after delivery. A manual, especially for this study and in accordance with guidelines of the KNGF (Royal Dutch Society of Physiotherapists), was written for the physiotherapists to use in these sessions [12]. The sessions consisted of information aimed to raise the women's awareness of pelvic floor muscles and to encourage them to exercise these. In view of the advanced pregnancies, the physiotherapists did not perform vaginal palpation but observation and palpation of the perineal body. They also encouraged women to practice self-palpation. In addition to the information of the physiotherapists, the women were provided with a 40-page handbook, especially designed for this study, with information on incontinence, the functioning of the pelvic floor muscles, and detailed instruction on PFMT exercises [13]. Women in the control group received the routine care for pregnant women. Nearly two-thirds of the women in the control group received some instruction on PFMT.

To select women with UI, all women visiting a midwife for their second regular checkup in week 1720 of the pregnancy were screened on incontinence. This screening was executed at 18 midwife practitioner's centres, situated in the west, south and east of the Netherlands. For each woman, the midwife filled in a screening list especially designed for this study, with data on involuntary urine loss, actual medical treatment of UI, treatment by a gynaecologist or other medical treatments, and knowledge of the Dutch language. All screening lists were sent to the research institute. Women who proved to meet the criteria of UI were eligible for inclusion: at least two times involuntary loss of urine during the last month. Women, who were already receiving medical treatment for their UI, were suffering from comorbidity or who had insufficient knowledge of the Dutch language, were excluded from the study. Enrollment of women in the study took place between April 2000 and July 2002.

The research design was a randomised, controlled trial. The study consisted of five measurements: T0 at week 22 of pregnancy immediately before the first three training sessions, T1 at week 35 immediately after these sessions, T2 8 weeks postpartum immediately after the fourth (and last) training session, T3 6 months postpartum and T4 1 year postpartum. Information was gained by means of self-administered questionnaires and bladder diaries.

Using stratification by the midwife centre, women who met the criteria were allocated to an intervention or control group by computerised randomisation. Women were informed to which group they were allocated just after T0.

The aim was to include 100 women with UI in both the intervention and the control groups. Assuming in the usual care situation a decrease from 100% of women affected by UI during pregnancy to 75% postpartum, these sample sizes are sufficient to detect a beneficial difference of 20% (to 55%) in the intervention group, with an α of 0.05 and a ft of 0.80. To account for dropout of 20% during the study period, the sample size at T0 was set at 120 women in each group.

The primary outcome was the severity of UI. This outcome was constructed using an objective and a subjective assessment. The objective assessment was based on bladder diaries: on a daily basis and during a whole week, each episode of UI had to be recorded, including the amount of urine loss. The amount was scored from 1 to 3: a few drops, a little, a lot. The objective severity of UI was scored by adding the separate scores of the amount of each episode of UI. We used the validated PRAFAB score consisting of five questions relating to the use of protective pads or garments, the amount of UI, frequency of UI, adjustment in daily activities because of UI, and body image as a subjective assessment [14]. Answers to these questions were scored from 1 to 4. The scores were added up, resulting in a score ranging from 5 to 20. Correlations between the objective and subjective measures were high, ranging from Pearson's r=0.56 in T0 to 0.64, 0.80, 0.76, and 0.66 in T1-T4, respectively. We combined the objective and subjective assessments into a new outcome score: severity of UI. The total score ranged from 0 to 10. Finally, two dichotomous variables were constructed based on these scores: (1) 'no UI at all' (score 0) vs 'any UI' (score 1-10) and (2) 'mild UI' (score 0-4) vs 'moderate/ severe UI' (score 5-10).

The secondary outcome was the impact of UI on daily life. This outcome was constructed by means of the validated 'Incontinence Impact Questionnaire' (IIQ) [15, 16]. The IIQ consists of 30 items covering social relations, emotional health, physical activity and mobility. After factor analysis resulting in four domains, four sub-scales were constructed: impact on social relations (contact with friends), on emotional health (feeling angry or depressed), on recreational activities (going to places without toilets) and on physical activities (domestic activities). The Cronbach's alpha's of the items underlying the subscales ranged from 0.72 to 0.87. The sub-scales

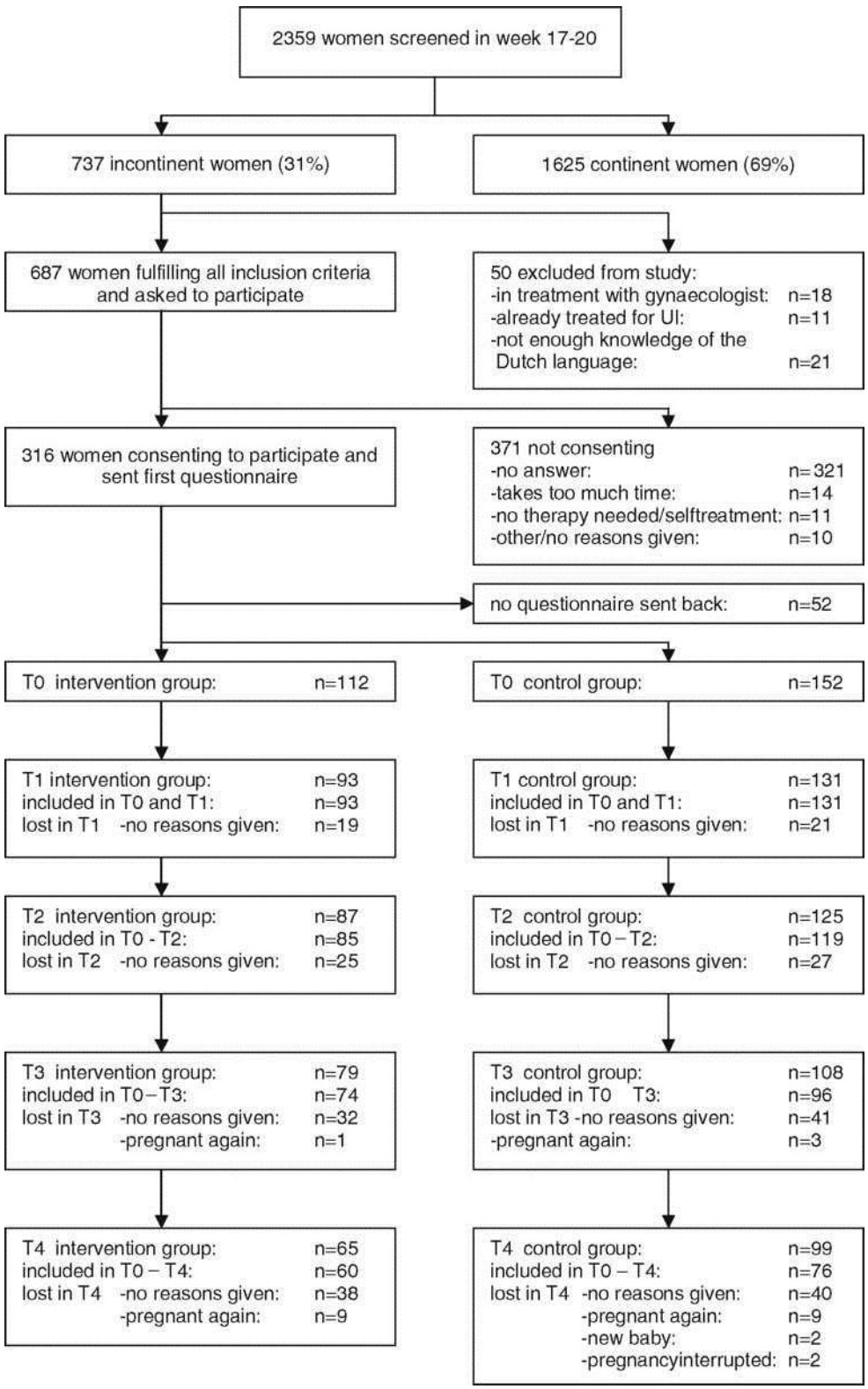

Fig. 1 Flowchart of the study population

were constructed by calculating the means of the items. Finally, dichotomous variables were constructed: no impact at all vs any impact.

Baseline values of the intervention and control groups were compared to check whether the randomisation had been successful, using two-sample t tests, Mann-Whitney tests or chi-square tests.

Differences between the intervention and control groups were analysed with Fisher's exact test and two-sample t tests. To eliminate selectivity of non-response as a

Table 1 Characteristics of the study population at baseline

Characteristics	Intervention group (n=112)	Control group (n=152)
Mean age (95% CI; (years)	31.9 (31.1-32.7)	32.6 (32.G-33.3)
Level of education (%)		
Low	44	34
Middle	9	15
High	47	51
Mean body mass index (95% CI)	24.G (23.2-24.S)	23.5 (22.9-24.1)
Mean functional health status (score 1-5; 5: very bad; 95% CI) Doing already at least once a week pelvic floor muscle exercises (%) Following prenatal exercises (%)	2.G (1.8-2.2)	2.G (1.9-2.2)
	27	3G
	7G	67
Nulliparous women (%)	3S	34
Urinary infections (%)	7G	61
Periods of involuntary UI before pregnancy (%)	53	52
Type of incontinence at baseline (%)		
Stress	55	65
Mixed	4G	3G
Urge	3	1
None	2	5
Severity of UI at baseline (score 0-10; 95% CI)	5.S (5.4-6.2)	5.6 (5.2-5.9)

possible cause of differences between both research groups, differences in outcomes were also tested with the 'repeated measure' procedure, an analysis of variance applied when the same measure is made several times on each subject. Results were checked for potential confounders as the severity of incontinence at baseline and damage to pelvic floor musculature during delivery. The dichotomous variable 'damage to pelvic floor musculature' was constructed by adding three variables relating to the damage caused by the recent delivery: a prolonged second stage (>1 h) during delivery, a vaginal rupture/episiotomy, or a baby weighing over 4,000 g. A woman scored positively if she fulfilled any of these conditions.

At each measurement women, in both study groups were asked with what frequency and how long they did PFMT exercises at home. A variable 'training intensity' was constructed based on these two variables with the categories: 'no exercises at all', 'sometimes' (less than three times a week for less than 5 min), regularly with low intensity (nearly every day for less than 5 min) and 'intensive training' (training nearly every day for more than 5 min).

Table 2 Characteristics of the delivery

Characteristic	Intervention group (n=ll2)	Control group (n=l52)
Mean birth weight of baby (kg)	3.56G (3.47G-3.65G)	3.657 (3.555-3.759)
Deliveries with prolonged second stage (>60 min; %)	19	2G
Vaginal rupture or episiotomy (%)	72	74

Results

To reach a total number of 240 women with UI during pregnancy, 2,359 women had to be screened by midwife practitioners. Seven hundred thirty-seven women proved to meet the criteria of UI. Of these, 50 women were excluded, resulting in 687 women fulfilling all inclusion criteria (Fig. 1). Three hundred sixteen agreed to participate and were sent a questionnaire, which was returned by 264 women: 112 of the intervention group and 152 of the control group. During the study, the number of respondents decreased to 65 for the intervention group and 99 for the control group. Of these, 60 respondents in the intervention group and 76 respondents in the control group participated during the whole study period.

Women who met the inclusion criteria but did not participate in the study could, on some aspects, be compared with those who sent in the T0 questionnaire. There were no differences found on frequency and severity of UI and number of former pregnancies.

Characteristics of the women at baseline are shown in Table 1: demographic characteristics, clinical and physical characteristics, previous periods of involuntary UI, type of incontinence and severity of UI baseline, and experiences with pelvic floor muscle exercises or pre-natal exercises. Women in the intervention group and control group are comparable. We also compared characteristics of the delivery in both groups: delivery with prolonged second

Table 3 Severity of incontinence during the study period

	Intervention group [n (%)]	Control group [n (%)]	Difference (95% CI of difference)	P level Fisher's exact test
T0 (week 22 of the pregnancy)				
Any urinary incontinence (score 1—10)[a]	108 (100)	145 (100)		
Moderate/severe urinary incontinence (score 5-10)	79 (73)	102 (70)	3% (-8 to 19%)	0.674
T1 (week 35 of the pregnancy)				
Any urinary incontinence (score 1-10)	74 (88)	113 (93)	5% (-12 to 3%)	0.329
Moderate/severe urinary incontinence (score 5-10)	31 (37)	56 (46)	9% (-22 to 5%)	0.251
T2 (week 8 postpartum)				
Any urinary incontinence (score 1-10)	50 (62)	74 (68)	6% (-20 to 8%)	0.442
Moderate/severe urinary incontinence (score 5-10)	18 (22)	17 (16)	7% (-5 to 18%)	0.261
T3 (half a year postpartum)				
Any urinary incontinence (score 1-10)	39 (56)	57 (60)	4% (-20 to 11%)	0.633
Moderate/sever urinary incontinence (score 5-10)	10 (14)	8(8)	6% (-4 to 16%)	0.313
T4 (1 year after postpartum)				
Any urinary incontinence (score 1-10)	35 (58)	59 (63)	5% (-21 to 11%)	0.610
Moderate/severe urinary incontinence (score 5-10)	9(15)	8 (9)	6% (-4 to 17%)	0.292

[a] *P* level was not computed.

stage, vaginal rupture/episiotomy during delivery, and mean birth weight of the baby. As shown in Table 2, women in the intervention and control groups are comparable.

Two major findings are illustrated in Table 3. We found no difference between the intervention and control groups with respect to the severity of incontinence. Furthermore, the severity of UI decreased strongly during the study period. At T0 (week 22 of the pregnancy), 73% of the intervention group (70% of the control group) suffered moderately/seriously from UI. The percentage of women with moderate/serious UI decreased to 37% (46%) at T1 and 22% (16%) at T2. From T3 on, the severity of UI stabilised. Six months after delivery 14% (8%) of the women had moderate or serious UI; a year after delivery, 15% (9%).

These results did not change when they were controlled using the repeated measures procedure, resulting in a significant decrease in the mean score of UI (F=85,9; ^<0.001) in both groups (Fig. 2). These results were checked with the variables 'damage to pelvic floor musculature during delivery' and 'severity of UI at baseline'. The damage to the pelvic floor musculature (assessed by the damage score) did not influence the abovementioned results shown in Fig. 2. Urinary incontinence at baseline appeared to act as a confounder on the course of UI (F=4,4; P<0.01): at each of the measurements T1 to T4, the severity of UI was higher in women who already suffered more seriously from UI at baseline.

Table 4 shows the impact of UI on daily life. The same conclusions can be drawn as before: the impact of urinary incontinence on activities and emotions of women decreased strongly over time, and in this respect, no difference existed between the intervention and control groups. It is also illustrated that the impact on emotional health and recreational activities was stronger than on social relations and physical activities.

Women in the intervention group varied in their adherence to the training program: after the three sessions

Fig. 2 Severity of urinary incontinence in time

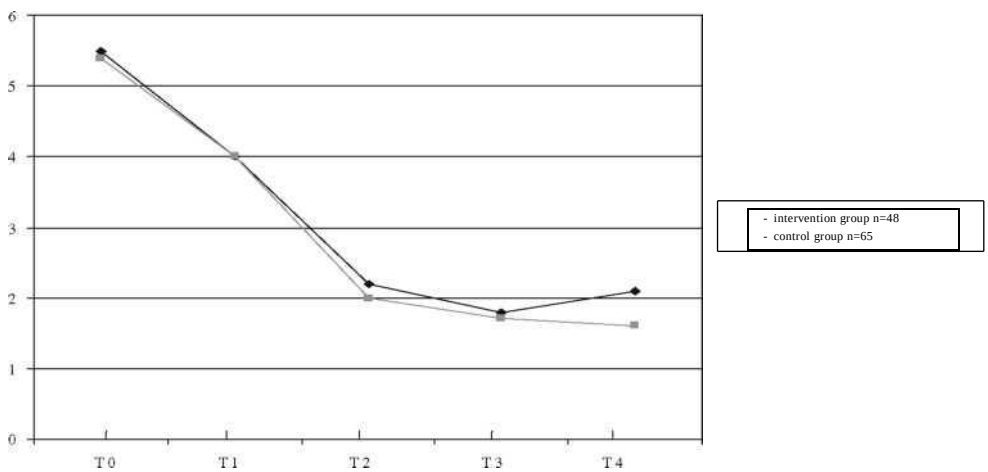

Table 4 Impact of incontinence on daily life during the study period

	Intervention group [n (%)]	Control group [n (%)]	Difference (95% CI of difference)		P level Fisher's exact test
T0 week 22 of the pregnancy)					
Any impact on social relations	29 (26)	39 (26)	0%	-10 to 11%)	0.538
Any impact on emotional health	77 (69)	99 (65)	4%	-8 to 15%)	0.315
Any impact on recreational activities	72 (64)	89 (59)	5%	-6 to 18%)	0.207
Any impact on physical activities	37 (33)	50 (33)	0%	-11 to 12%)	0.542
T1 (week 35 of the pregnancy)					
Any impact on social relations	21 (23)	29 (22)	1%	-11 to 12%)	0.532
Any impact on emotional health	39 (42)	49 (37)	5%	-8 to 18%)	0.292
Any impact on recreational activities	36 (39)	48 (37)	2%	-11 to 15%)	0.430
Any impact on physical activities	19 (20)	37 (28)	8%	-19 to 4%)	0.120
T2 (week 8 postpartum)					
Any impact on social relations	8(9)	8(6)	3%	-5 to 10%)	0.308
Any impact on emotional health	17 (20)	20 (16)	4%	-7 to 14%)	0.312
Any impact on recreational activities	20 (23)	18 (14)	9%	-2 to 20%)	0.078
Any impact on physical activities	7(8)	13 (10)	2%	-10 to 6%)	0.372
T3 (half a year postpartum)					
Any impact on social relations	4(5)	8 (7)	2%	-9 to 5%)	0.371
Any impact on emotional health	14 (18)	13 (12)	6%	-5 to 16%)	0.189
Any impact on recreational activities	15 (19)	12(11)	8%	-3 to 19%)	0.097
Any impact on physical activities	5 (6)	6 (6)	0%	-6 to 8%)	0.531
T4 (1 year postpartum)					
Any impact on social relations	2(3)	5 (5)	2%	-8 to 4%)	0.425
Any impact on emotional health	11 (17)	14 (14)	3%	-8 to 14%)	0.393
Any impact on recreational activities	10 (15)	10 (10)	5%	-5 to 16%)	0.220
Any impact on physical activities	4 (6)	7(7)	1%	-9 to 7%)	0.543

during pregnancy, 6% indicated not to exercise at all; 17% only sometimes; 40% regularly, but not intensively; and 37% intensively nearly every day. They exercised significantly more often than women in the control group (p<0.001), 36% of whom did not do any exercises at all; 25% only sometimes; 26% regularly, but not intensively; and 14% intensively nearly every day. Because of this variation, the effectiveness of the intervention was also analysed by relating the training intensity to the outcome measures. Results are presented in Table 5. No longitudinal effect of the exercises performed at T1 (week 35-36 of the pregnancy) was found in the intervention group. Cross

Table 5 Correlations (Pearsons' r) between training intensity and outcome measures

	Training intensity			
	T1	T2	T3	T4
T1 week 35 of the pregnancy)	n=81			
Severity of incontinence	0.16			
Impact on emotional health	0.02			
Impact on recreational activities	-0.03			
T2 week 8 postpartum)	n=76	n=80		
Severity of incontinence	0.14	0.22*		
Impact on emotional health	0.16	0.18**		
Impact on recreational activities	0.19	0.22*		
T3 half a year postpartum)	n=67	n=67	n=61	
Severity of incontinence	0.06	0.20	-0.06	
Impact on emotional health	0.12	0.28*	-0.09	
Impact on recreational activities	0.14	0.24*	-0.14	
T4 1 year postpartum)	n=58	n=58	n=50	n=56
Severity of incontinence	0.06	0.16	-0.06	-0.27*
Impact on emotional health	0.12	0.24**	-0.13	-0.17
Impact on recreational activities	0.04	0.22**	-0.14	-0.22**

*p<0.05
**p<0.10

sectional analysis showed more results. At T4 (1 year after delivery), the correlation between training intensity and severity of incontinence is negative, as expected: women who intensively exercised were less affected by incontinence than women who did not exercise intensively (r=-0.27, ^<0.05). Contrary to the results at T4, at T2 (8 weeks after delivery) the correlation between training intensity and severity of incontinence was positive (r=0.22, ^<0.05). The more women trained, the more they were affected by incontinence. Or more plausible: the more women were affected by incontinence, the more they trained. The correlation between training intensity and the two best discriminating secondary outcome measures (impact on emotional health and on recreational activities) are comparable to these results.

Discussion

The objective of this study was to test the short- and longterm effects of pelvic floor muscle training (PFMT) during pregnancy in women at risk, i.e. women who were already affected by urinary incontinence (UI) during pregnancy.

The first remarkable finding of this study is that no effect was demonstrated of PFMT on severity of incontinence and on impact of UI on daily life in women with UI halfway through pregnancy: the women who, in earlier studies, were noticed to be at risk to suffer from UI after delivery [5, 6]. The effect of PFMT on this specific group of women was not studied before. Earlier studies concentrated on the preventive effect of PFMT during pregnancy in women not selected on incontinence [8, 9] or on women not selected on incontinence but belonging to the high-risk group of women with increased bladder neck mobility [17]. Contrary to our results, they found positive effects of PFMT. This may be caused by the fact that in our study, all participating women were affected by UI during pregnancy, whilst in the other studies women were not selected on UI.

It is also possible that the training programs in the studies where positive results were found were more intensive. Indeed, in Morkveds et al. [9] study, the training group attended an intensive 12-week PFMT program of 60 min once a week, whilst in our study the intervention consisted of four training sessions of half an hour. However, in Reilly et al.'s [17] study, the frequency of the training (once a month from week 20 until delivery) does not differ from the frequency in our study. Perhaps, the monitoring of the adherence to the training program between sessions is more important than the total number of sessions followed. In both mentioned studies, compliance to the PFMT program was monitored using personal training diaries. In our study, diaries were used to monitor incontinence, but not as a registration of daily exercises. The use of diaries may be important not only as a registration device, but also as a stimulus to adhere to a training program. In our study, no more than 37% of the women intensively trained their pelvic floor muscles.

The effectiveness of the intervention was analysed by the intention to treat principle: once assigned to the intervention group women stayed in this group, whether they followed therapy and exercised or not. Nearly all women (95%) attended the theraphy sessions. The lack of results may be caused by the lack of compliance to the prescribed exercises. However, in our study the expected longitudinal effects of the intensity with which women in the intervention group performed their exercises during pregnancy were not found. Only 1 year after delivery, in a cross-sectional analysis, the expected negative correlations were found between training intensity and outcome measures. Apparently, the percentage of women in the intervention group training intensively was not large enough to influence the overall lack of results of the intervention.

A second important finding is that, in both studied groups of otherwise healthy women, UI strongly decreased towards the end of pregnancy and after delivery. To be more specific, we found a strong reduction of incontinence from week 22 of the pregnancy up to 8 weeks after delivery, with a stabilisation 6 months after delivery. Besides, no influence could be established from damage to the pelvic floor during partus.

The results of this study are in concordance with several studies on the course of incontinence in the postpartum period. One study, focusing on the risk factors of postpartum incontinence, mentions a general decrease of severity of incontinence in the 12-month postpartum period. Factors not associated with postpartum incontinence included, amongst others, performing postpartum pelvic floor exercises [2]. In a study amongst women with UI postpartum, a decrease of prevalence to 60% was found 1 year after delivery in the intervention group (which got advice by nurses on pelvic floor exercises at 5, 7 and 9 months after delivery) and 69% in the control group [18, 19]. After 5 years, no effect was found [19]. All in all, in our opinion prevalence and severity of incontinence in women with UI during pregnancy are more affected by factors like hormonal changes during and after pregnancy than by the intervention as such.

It seems to us that pelvic floor training is not indicated during gravidity and in the first months postpartum. Four training sessions of half an hour and a handbook with detailed instructions on how to perform PFMT exercises do not help, and a full training program is perhaps too much effort. With pregnant, incontinent, but otherwise healthy women, one should let the incontinence run its natural course. However, special attention should be given to women still incontinent after 6 months. In those women, pelvic floor training is justly indicated.

At T0, 264 women participated but no more than 136 returned all five successive questionnaires and diaries. A weakness of this study is this decreasing number of women returning the questionnaires and the diaries during the study period, lessening the power of the analyses from the expected 0.80 to 0.69. Also, one may speculate that perhaps the impact of our intervention, consisting of four sessions, is too weak and that a more intensive intervention with monitoring of the training efforts could give more results.

Nevertheless, this is a study of some importance. It is the first study on the effect of PFMT in women with UI during pregnancy. Moreover, for women affected by urinary incontinence, the results support a 'wait and see' policy: wait for the urinary incontinence to run its natural course and see if, for women still incontinent 6 months after pregnancy, pelvic floor muscle training is effective.

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Pelvic Floor Muscle Training Included in a Pregnancy Exercise Program Is Effective in Primary Prevention of Urinary Incontinence: A Randomized Controlled Trial

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Aims: To investigate the effect of pelvic floor muscle training (PFMT) taught in a general exercise class during pregnancy on the prevention of urinary incontinence (UI) in nulliparous continent pregnant women. **Methods:** This was a unicenter two armed randomized controlled trial. One hundred sixty-nine women were randomized by a central computer system to an exercise group (EG) (exercise class including PFMT) (n = 73) or a control group (CG) (n = 96). 10.1% loss to follow-up: 10 from EG and 7 from CG. The intervention consisted of 70-75 sessions (22 weeks, three times per week, 55-60 min/session including 10 min of PFMT). The CG received usual care (which included follow up by midwifes including information about PFMT). Questions on prevalence and degree of UI were posed before (week 1014) and after intervention (week 36-39) using the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF). **Results:** At the end of the intervention, there was a statistically significant difference in favor of the EG. Reported frequency of UI [Never: CG: 54/60.7%, EG: 60/95.2% *(P* < 0.001)]. Amount of leakage [None: CG: 45/60.7%, EG: 60/95.2% (P < 0.001)]. There was also a statistically significant difference in ICIQ- UI SF Score between groups after the intervention period [CG: 2.7 (SD 4.1), EG: 0.2 (SD 1.2) (P < 0.001)]. The estimated effect size was 0.8. **Conclusion:** PFMT taught in a general exercise class three times per week for at least 22 weeks, without former assessment of ability to perform a correct contraction was effective in primary prevention of UI in primiparous pregnant women. *Neurourol. Urodynam.* © 2013 Wiley Periodicals, Inc.

Key words: gestation; nulliparous; physical exercise; physical therapy; prevention

INTRODUCTION

Urinary incontinence (UI) is a well recognized health problem that significantly reduces the quality of life and affects women of all ages.[1-3] Pregnancy and childbirth are considered to be important risk factors in the development and the worsening of UI.[1,4]

Pelvic floor muscle training (PFMT) is an effective technique in the prevention and treatment of UI in the general popula- tion[4] and its effectiveness has also been found during preg- nancy.[1] Moreover, based on different studies, it has been found to be as effective as other treatments[5,6] and according to a review by Cochrane, it should be included in the first line of conservative management and of primary prevention of UI.[7]

In most studies, PMFT is conducted by physiotherapists and its efficacy when taught by other professionals such as fitness instructors has not been found.[8] To quote B0 and Haakstad[8] it would be less time-consuming, more cost-effective and possibly more motivating if PFMT could be taught in a group setting by fitness instructors. However the professional who should design and lead the session must meet different requirements. A Physical Activity and Sport Sciences graduate has both the theoretical and practical knowledge to design exercise programs taking into account the training principles, and moreover has a pedagogical background which could enhance motivation and long-term learning.

We hypothesized that PFMT taught by a Physical Activity and Sport Sciences graduate and included in a pregnancy exercise program is effective in primary prevention of UI.

MATERIALS AND METHODS Design

This was a unicenter, two armed, open label, randomized controlled trial.

Participants

Pregnant women attending the local hospital for antenatal care were asked to participate in the study. Recruitment took place between October 2009 and October 2011, and final data collection finished on June 2011. Inclusion criteria were: being healthy and primiparous pregnant with singleton fetus, being in gestational week 10-14, not suffering from UI, able to communicate in Spanish and able to give informed written consent. Exclusion criteria were: planning not to give birth in Fuenlabrada University Hospital and any contraindication according to the American College of Obstetricians and Gynecologists Guidelines.[9] One hundred sixty nine women were included in the study. It was approved by the Ethical

Conflict of interest: none.
Mickey Karram led the peer-review process as the Associate Editor responsible for the paper.
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Committee of Fuenlabrada University Hospital (Madrid, Spain) and followed the ethical guidelines outlined in the Declaration of Helsinki (last modified in 2008). All women provided written informed consent. The study is listed in ClinicalTRials.gov (NCT 01578369).

Intervention

Women in the exercise group (EG) were asked to participate in a structured exercise program for at least 22 weeks (14-36 weeks of gestation). The program consisted of 70-78 group sessions (8-12 women). The sessions were held three times per week and were 55-60 min in duration. The sessions were performed in the hospital, in a well-lit room under favorable environmental conditions (altitude 600 m; temperature, 19- 21°C; humidity, 50-60%).

Each session consisted of 8 min of warm-up; 30 min of low impact aerobics (performing different choreographies) including 10 min of general strength training (e.g., core muscles, pectoralis, gluteus, quadriceps, calves, biceps); 10 min of PFMT and 7 min of cool down, which included stretching, relaxation or massage. All subjects used a heart rate monitor (Accurex Plus, Polar Electro OY, Finland) during the training sessions to control the exercise intensity (65-70% age predicted maximum heart rate value). The Borg Rating of Perceived Exertion Scale was also used to guide exercise intensity (12-14 "somewhat hard'').[10]

The whole session, including PFMT was designed and taught by a Physical Activity and Sport Sciences graduate. At the beginning of the program, women received information of anatomy and function of the PFM and why the muscles may prevent and treat the UI. At first, women learned to perceive their pelvic floor, and then learned how to do adequate contractions. There was no former assessment of ability to perform a correct contraction or any measurement of pelvic floor muscle strength. Women were asked to test themselves at home by trying to stop the flow while urinating, touching the vaginal and anal openings and using a mirror to see if they could squeeze around the pelvic openings and upward lift.

The PFMT followed a progression, starting with one set of eight contractions and increasing the number of total contractions to one hundred, divided in different sets of slow (6 sec) and fast contractions (five contractions as fast as possible). To increase motivation and abilities, we used different exercises (Fig. 1), positions and sometimes music to follow the beat. Women were encouraged to perform 100 contractions distributed in different sets every day.

To enhance motivation and adherence, group dynamics and exercises in pairs were included. Talking about needs and feelings were also allowed and encouraged.

Women in the control group (CG) received usual care (which included follow up by midwifes including information about PFMT) and were not asked not to train their pelvic floor muscles.

Randomization

A statistical randomization computer program was used to perform a simple randomization to allocate women into each group.

Outcome Measures

The primary outcomes were (i) the reported frequency, (ii) amount, and (iii) impact on daily life of UI. These outcomes were measured by the validated International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF).[11] Women completed the forms at the end of

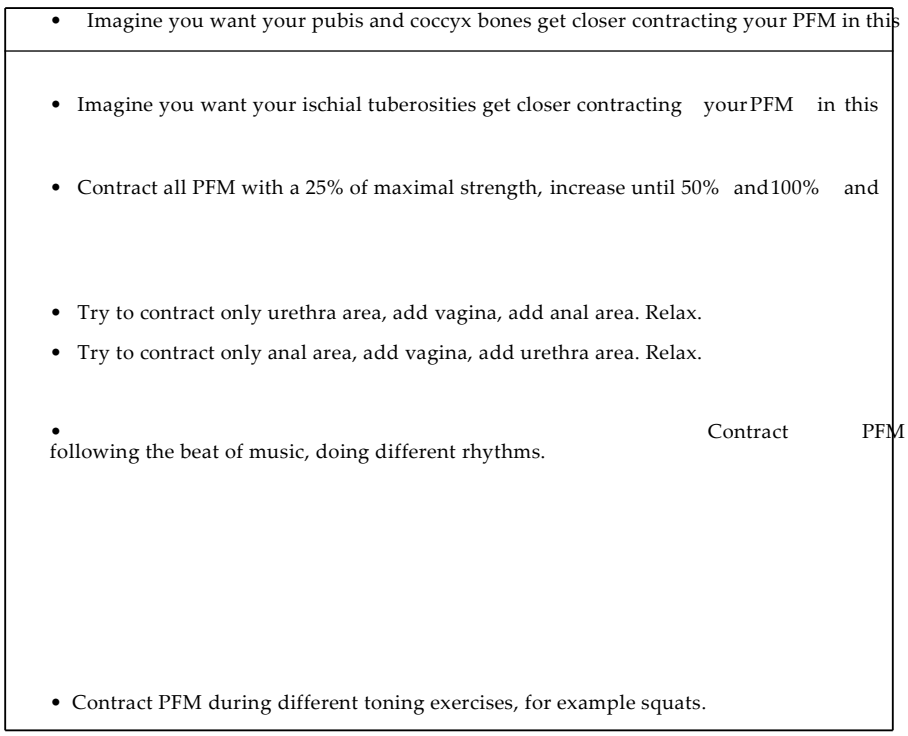

Fig. 1. Examples of some of the proposed exercises in pelvic floor muscle training. PFM, pelvic floor muscles.

intervention (between 36 and 40 weeks of gestation). Before intervention, women were interviewed to provide maternal characteristics such as education level or pre-pregnancy physical activity habits. To enhance the quality of measurements, the three interviewers were trained and informed about how to make women feel comfortable talking about their UI.

Power Calculations

To estimate the sample size, a 95% confidence level, 80% statistical power, and a 20% of losses were accepted. Assuming, in the usual care situation, a prevalence of 39% of women affected by UI at the end of gestation (week 36)[3] and estimating a reduction of 20% of women affected by UI in the treatment group, it was considered that 156 women should be included.

Statistical Analyses

Background variables are given as frequencies and percentages, and means with standard deviations (SD). Chi-squared and Mann-Whitney tests were used to analyze differences in categorical variables and *t*-test for quantitative variables. *P*- values <0.05 were considered to be statistically significant.

Effect size was also calculated on ICIO-Score using t-stats and sample size.

RESULTS

Initially, 169 women were included in the study. Data from 152 women were analyzed (10.1% loss to follow-up: 10 from the EG and 7 from the CG). Figure 2 shows the study flow chart with the numbers of drop-outs and their reasons. All women included on analysis attended at least 80% of 70-78 exercise sessions during at least 22 weeks.

Background variables at baseline are shown in Table I. There were no differences between groups in mean age, pre-pregnancy BMI, education, and pre-pregnancy physical exercise habits at baseline.

At the end of intervention (week 36 of pregnancy) there were statistically significant differences in favor of the EG as shown in Table II). 95.2% of women in the EG reported no leakage versus a 60.7% of women in the CG. Only women of CG had a frequency of leakage more than of once a week (17/19.1%). The amount of leakage reported by incontinent women in the EG is referred as a ''a small amount'' (3/4.8%) but in the CG, women reported ''a small amount'' (27/30.6%), ''a moderate amount'' (5/ 5.6%), and even ''a large amount'' (3/3.4%).

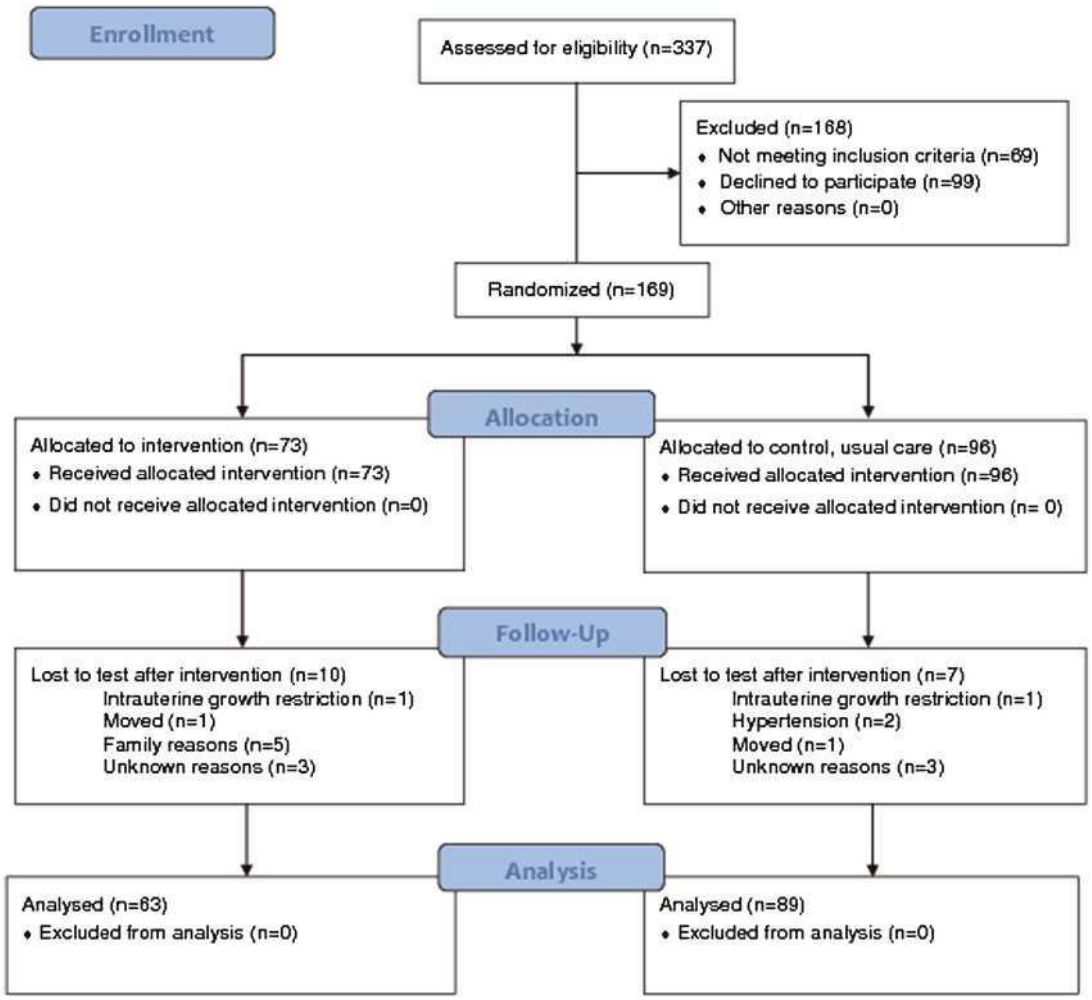

Fig. 2. Study flow chart with the number of drop-outs and their reasons.

TABLE I. Background Variables Before Intervention in the Exercise and Control Groups

	Exercise (n = 63)	Control (n = 89)	P-value
Age (years)	29.9 (3.3)	29.1 (4.5)	0.23
Pre-pregnancy BMI	23.6 (4.3)	22.7 (3.8)	0.23
Educational level			
College	23/37.1	23/25.8	0.07
High school	29/46.8	38/42.7	
<High school	10/16.1	28/31.5	
Pre-pregnancy PA			
Inactive	33/53.2	56/62.9	0.15
Active	29/46.8	33/37.1	

BMI, body mass index; PA, physical habits.
Mean with standard deviation (SD) and numbers (n) with percentages (%) (n = 152).

In regards to how much leaking affects their daily lives, the mean in the CG was higher than in the EG (0.9 (SD 1.8) vs. 0.1 (SD 0.6), respectively. Finally, ICIO-UI SF Score shows statistically significant differences between the groups and the estimated effect size was 0.8.

DISCUSSION

The major finding of the present study was that PFMT included in a pregnancy exercise program, with three sessions per week over the course of at least 22 weeks, is effective in primary prevention of UI in pregnancy, without individual assessment of the ability to contract the pelvic floor muscles.

The strengths of the present study include the use of an RCT design, high adherence and the implementation of an exercise program following ACOG recommendations, conducted by a Physical Activity and Sport Sciences graduate. Some of the limitations of the study are: no pad test, no assessment of PFM strength and the non-blinded design.

The prevalence rates of UI in the CG were very similar to those that we took into account to estimate the sample size. We assumed a prevalence of 39% of women affected by UI at the end of gestation (week 36)[3] and in our study we found that a 39.3% of women in the CG were affected by UI, which was in accordance with these data. We also estimated a reduction of 20% of women affected by UI in the EG, and the reduction obtained was higher: a 34.5%.

TABLE II. Results From ICIO-UI SF Questionnaire After Intervention in Exercise and Control Groups

	Exercise (n = 63)	Control (n = 89)	P-value
Reported frequency of UI			
Never	60/95.2	54/60.7	0.0001
Once a week	3/4.8	18/20.2	
2-3 times per week	0/0.0	9/10.1	
Once a day	0/0.0	7/7.9	
Several times per day	0/0.0	1/1.1	
Amount of leakage			
None	60/95.2	54/60.7	0.0001
A small amount	3/4.8	27/30.3	
A moderate amount	0/0.0	5/5.6	
A large amount	0/0.0	3/3.4	
How much does leaking affect daily life	0.10 (0.64)	0.97 (1.8)	0.0001
ICIO-Score	0.24 (1.2)	2.66 (4.1)	0.0001

Mean with standard deviation (SD) and numbers (n) with percentages (%) (n = 152).

The reduction of UI found in the EG is in accordance with other studies in which PFMT is lead by physiotherapists. M0rkved et al.[1] found 16% difference in the prevalence of UI in favor of the training group in pregnant nulliparous women. However this study included incontinent women (32% and 31% in training and CG respectively) at baseline and there was only one supervised session per week. Stafne et al.[12] found fewer women in the intervention group reporting any weekly UI (11% vs. 19%) at the end of intervention (32-36 weeks of gestation). Only one weekly group session was led by physiotherapists during the 12-week exercise program.

To date, we have only found two studies in which PFMT was not conducted by physiotherapists. The first one by Brubaker et al.[13] shows the feasibility of a pelvic fitness and education class for affected and non pregnant women. The women in this study trained twice a week for 11 weeks. The results showed statistically and clinically significant improvement in pelvic floor and sexual function. The second study, by B0 and Haakstad[8] had a RCT design and PFMT were led by certified aerobics instructors. No effect of PFMT was found and that is in contrast with our results.

We found common points in B0 and Haakstad[8] and the present study. An important point is that there was no former assessment of ability to perform a correct contraction. The second common point was the exercise program structure. Perhaps, one of the main differences was the adherence to the program. Only 40% of women in the aforementioned study attended at least 80% of exercise sessions. In our study, all women included on analysis (100%) attended at least 80% of sessions. Other differences were the length of the program (12 weeks vs. 22 in the present study) and the total number of pelvic floor muscle contractions per day (36 vs. 100 respectively). Furthermore, in the B0 et al. study, there were incontinent women at baseline (26.9% in the EG and 20.7% in the CG).

These results show the importance that a Physical Activity and Sport Sciences graduate design and lead the exercise programs to make them effective and motivating for the pregnant population. They also suggest that the three times per week frequency is well accepted. Although there were positive results without individual assessment, it may well be that the effect would have been far stronger if there had been individual assessment of the ability to contract the pelvic floor muscles.

Usual care for pregnant women includes 8-12 sessions with a midwife in which women learn about the pelvic floor as well as other issues concerning labor, breastfeeding and child care, but there is no standardized protocol. These results suggest the need for accompaniment, monitoring and motivation through the whole gestation period for PFMT to be effective and the importance of the development of multidisciplinary teams composed of different professionals to monitor and nurture pregnant women through gestation to ensure the highest quality of life as possible.

In future, it would be of interest to compare the prevalence of UI between groups 2 years after delivery as well as other aspects regarding the quality of life of these women; and to study the effectiveness of this type of program in the treatment of UI in affected women.

CONCLUSION

This study shows the effectiveness of PFMT included in a pregnancy exercise program on primary prevention of UI during pregnancy in nulliparous continent women. It also

suggests the importance of both the program design and the role of a Physical Activity and Sport Sciences graduate in enhancing adherence to the program.

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ORIGINAL ARTICLE

Effect of pelvic floor muscle exercises in the treatment of urinary incontinence during pregnancy and the postpartum period

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Abstract
Introduction and hypothesis The aim of this study was to determine the effectiveness of pelvic floor muscle exercises on urinary incontinence during pregnancy and the postpartum period.
Methods The study was carried out on 80 pregnant women (study group, 40 subjects; control group, 40 subjects).The study group was trained by the researcher on how to do the pelvic floor muscle exercises. Both groups were evaluated for pelvic floor muscle strength and urinary complaints in their 36th to 38th week of pregnancy and postpartum sixth to eighth week.
Results The study group had a significant decrease in urinary incontinence episodes during pregnancy and in the postpartum period, and their pelvic floor muscle strength increased to a larger extent. Control group had an increase in the postpartum muscle strength and decrease in the incontinence episodes in the postpartum period. *Conclusions* Pelvic floor muscle exercises are quite effective in the augmentation of the pelvic floor muscle strength and consequently in the treatment of urinary incontinence.

Keywords Pelvic floor muscle exercise • Pregnancy. Postpartum • Urinary incontinence

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Introduction

Pregnancy and delivery-related factors have been considered to be the main risk factors for the development of urinary incontinence. The rate of urinary incontinence during pregnancy is reported to be in the range of 23-67% [1], while postpartum urinary incontinence is 6-38% [2]. Urinary incontinence increases with parity, and in primíparas who deliver vaginally, it has been associated with decreases in pelvic muscle strength of 22-35% between pregnancy and the postpartum period [3].

Pelvic floor muscle exercises are reported in the literature to be one of the treatment methods for urinary incontinence during pregnancy [3-6]; however, studies on the efficacy of pelvic floor muscle exercises done in this period are rather limited, and opinions differ widely.

The aim of this study was to determine the effectiveness of pelvic floor muscle exercises on urinary incontinence during pregnancy and the postpartum period.

Materials and methods

The present study was planned as an experimental research and was carried out in the Urogynecology Unit of Istanbul

University, Istanbul Faculty of Medicine, Department of Obstetrics and Gynaecology. Prior to the study, ethical approval was obtained from the ethical review board of the Faculty of Medicine at Istanbul University.

The theoretical basis for pelvic floor muscle exercise to treat and prevent stress urinary incontinence is based on muscular changes that may occur after specific strength training. This change is supposed to be a neural adaptation during the first 6 to 8 weeks and muscle hypertrophy after a further period of strength training. The effect begins to occur 2 weeks after exercise [7]. For this reason, women until their 34th week of pregnancy were included in the study. There were 705 pregnant women who were interviewed in the antenatal outpatient clinics during the study. Of these women, 60% (n=423) were continent and 40% (n=282) had urinary incontinence complaints. Of the women with urinary incontinence, 143 met the inclusion criteria. Women in their 20th to 34th week of pregnancy, having complaints of stress/mixed urinary incontinence in their history, not having any genitourinary system pathology or urinary tract infection, and who had at least a primary school education were included in the study. These women were informed of this research and were invited to the Urogynecology unit. Exclusion criteria were pregnancy complications, high risk for preterm labor, pain during pelvic floor muscle contractions, or a disease that could interfere with participation. In addition, women not able to attend for regular treatment for various reasons were excluded from the study.

We had interviews with eight to ten pregnant women a day for 6 months in the antenatal outpatient clinic. Usually, three to four pregnant women a day reported urinary incontinence. The women who came to the Urogynecology unit were randomly allocated to a pelvic floor muscle training group or to control group using envelopes. As a result 71 subjects were included in the study group and 72 in the control group. Before the first evaluation, 25 women in the study group and 26 women in the control group refused to participate in the study, stating that they were too busy or had some family problems. Informed consent was obtained from all women participating in the study. Consequently, 46 women remained for the study and the control groups. Six subjects in the study group and six in the control group dropped out. Finally, we had 40 women in the study and 40 women in the control group who completed the initial stage of the study. During the follow- up study, five women in the study and seven women in the control group dropped out for reasons such as being too busy, moving away, family problems, or resolution of their incontinence (Fig. 1).

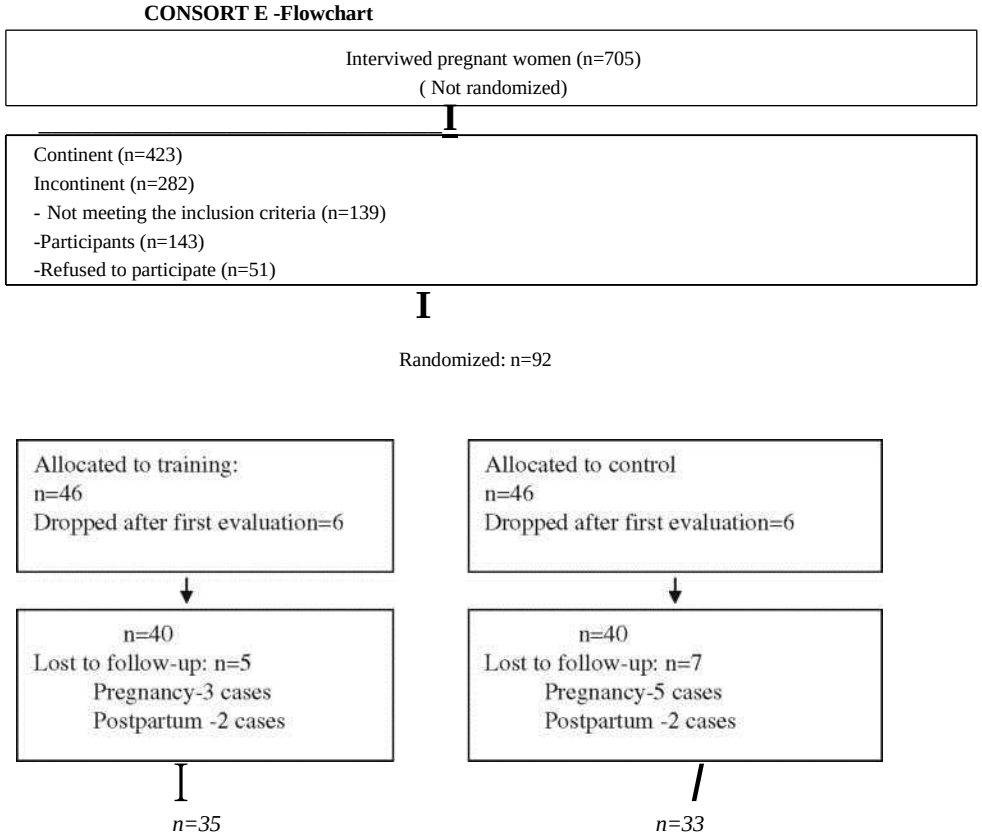

Fig. 1 Population studied Ô

Power calculations were done for the purpose of determining the number of cases that formed the study and control groups required for our research. Power calculation was calculated only by continence status. Pregnant women who reported no incontinence symptoms were defined as "Continent." Pregnant women who reported symptoms of incontinence were defined as "Incontinent."

In accordance with the data given in the literature, the possibility of urinary incontinence after delivery was taken as 15% for the study group who were taught how to do the pelvic floor muscle exercises and as 50% for the control group. Accordingly, the sample size to represent the population of our research was calculated as follows: p_1 = 0.15 (study group), ^$_2$=0.50 (control group) with 95% confidence interval, a=0.05, ft=0.20, and so power=0.80 (1B) and n=27 cases (for each group); finally, the number of the total patients was determined as 54.

The study was carried out in three stages. In the first stage, the subjects in both groups were subjected to urinalysis, 3-day urinary diary [8], pelvic floor muscle strength (the Peritron 9300 Precision Perineometer), and 1-h pad tests (using a standard protocol according to the definitions of International Continence Society) [9]. All subjects were instructed in correct pelvic floor muscle contraction before strength measurements. The study group was trained by the researcher how to do the pelvic floor muscle exercises in accordance with the booklet of pelvic floor muscle exercises [10]. Whether the pregnant woman contracted the right muscle group or not was determined with the digital palpation method [11]. All of the women were trained until they were contracting the right muscle group. Later, this was included in the study. The control group, as planned, was not given training about these exercises.

In the second stage of the study, the pregnant women in the study group were evaluated 1 week later in the Urogynecology unit to see if they were doing the exercises properly. Sixty-eight percent of the pregnant women were doing their exercises properly by contracting the proper muscle group. The rest were given training again and reevaluated 1 week later.

The exercises of the pregnant women in the study group were checked every time they came for antenatal visit. In the 36th to 38th week of pregnancy, the second intermediate evaluation was done to assess the pelvic floor muscle strength and to evaluate the continuation of incontinence complaints. The pregnant women in the control group underwent the same evaluation.

In the third stage, all of the pregnant women were reevaluated in the sixth to eighth week postpartum.

The main outcome measures were leakage episodes, amount of leakage measured on pad testing, number of voiding (daytime/nighttime), urgency, and pelvic floor muscle strength.

The protocol for the pelvic floor muscle exercise administered in the study group is shown in Fig. 2. After the women were taught how to contract the pelvic floor muscles properly, they were informed about the administration period for the daily exercise and about the number of exercises in each period.

An exercise session included three sets of exercise. Each set included the exercise of contracting and relaxing the pelvic floor muscles repeated ten times. We asked the women to contract their pelvic muscles as hard as possible and asked them to hold until ten. Participants were assigned according to their previous values, and progression was recorded.

SPSS 10.0 for Windows statistic package computer program was used for the statistical analysis. The data were evaluated in percentage, mean, median, minimum, maximum, standard deviation, chi-square (x^2), Fisher exact test, Yates corrected x analysis and Student's t test, Wilcoxon signed-rank test, Mann-Whitney U test, and correlation.

Results

The mean age of the study group and the control group was 26.05±4.8 and 27.7±7.2 years, respectively. Of the pregnant women in the study group, 32.5% were primary school graduates, 55% were secondary school graduates and 12.5% were university graduates. Of the pregnant women in control group, 42.5% were primary school graduates, 42.5% were secondary school graduates, and 15% were university graduates. Ninety percent of the study group and 80% of the control group were housewives. Eighty-five percent of the study group and 82.5% of the control group had health insurance. There were no differences between the two groups in terms of demographic data (age, x^2=2.91, SD=2, p=0.23; education level, x^2=1.26, SD=2, p=0.53; profession, Fisher p=0.17; social insurance, x^2=0.92, SD=1, p=0.76).

The mean gestational weeks of the study and the control group are 27.23 ±4.85 and 26.2±4.43; maximum infant birth weight of the study and the control group was 3,381 ±

	Exercise	Number of Exercises	Endurance (contract and hold) Hold/Release	Strength (quick contraction) Sessions Hold/Release
	Per day	Per Period	(in seconds)	(in seconds)
Level 1	*2 per day*	*3 sets of 10*	*3 sec/ 3 sec*	*1 sec/1 sec*
Level 2	*2 per day*	*3 sets of 10*	*5 sec/ 5 sec*	*2 sec/ 2 sec*
Level 3	*3 per day*	*3 sets of 15*	*10 sec/ 10 sec*	*2 sec/ 2 sec*

Fig. 2 The protocol for the pelvic floor muscle exercise [10]

567.3 g and 3,346±523.8 g, and 37.5% of pregnant in study group and 47.5% of control group had at least one pregnancy, which was reached to term. There was no any difference between the groups in terms of age of pregnancy, maximal birth weight, and number of pregnancy, which was reached to term (mean week of pregnancy, *t* -1.66, *p*=0.10; mean birth weight, *t* -0.22, *p*=0.82; numbers of pregnancy reaching the term, x^2 = 1.35, SD=2, *p*=0.50). Eighty-eight percent of study group and 95.2% of control group had spontaneous deliveries. There were no differences between the two groups in terms of episiotomy, stillbirth, abortion, medical abortion, and a history of gynecological operation (types of the previous delivery, Fisher *p*=0.37; episiotomy, Fisher *p*=0.57; dead delivery, Fisher *p*=0.50; abortion, Fisher *p*=0.50; medical abortion, Fisher *p*=0.35; previous gynecological operation, Fisher *p*=0.50).

The baseline mean pad test (grams of leakage) of the study and the control group are 3.7±4.5 and 4±4.3; the mean perineometer values (CmH_20) of the study and the control group are 28.08±12.95 and 30.05±11.05.There was no any difference between the groups in terms of the baseline mean values pad test and perineometer (pad test, *t* -0.35, *p*=0.73; perineometer, *t* -0.73, *p*=0.47).

Of the pregnant women, 48.75% complained of urinary incontinence in the first trimester. In both groups, ten women (25%) had urinary incontinence before pregnancy. Of the pregnant women, 32.5% began to have urinary incontinence complaints in the second trimester, and 18.75% of the pregnant women began to complain of urinary incontinence in the third trimester.

The data gathered from the bladder diaries at the baseline, 36th to 38th week of pregnancy and sixth to eighth weeks postpartum, including the median values and comparison of the groups about the episodes of urinary incontinence, urgency, number of voids, and nocturia in both groups are presented in Table 1.

Sixteen pregnant women (43.2%) in 36-38 weeks of gestation and six postpartum women (17.1%) were incontinent in the study group. On the other hand, 25 pregnant women (71.4%) in 36-38 weeks of gestation and 13 postpartum women (38.4%) were continent in the control group. The study and control groups were compared in terms of the episodes of urinary incontinence. It was found that the incontinence episodes in the 36th to 38th week of pregnancy and sixth to eighth week postpartum were decreased to be statistically significant in the study group than in the control group (baseline-pregnancy, 36th to 38th week, *p*=0.008; baseline, postpartum, sixth to eighth week, *p*=0.014).

The urgency episodes in both groups decreased in the postpartum period. A comparison between the study and control groups in terms of this parameter showed that urgency had decreased to a greater extent than that of the subjects in the control group (Table 1).

The nocturia episodes decreased in the postpartum period in both groups. A comparison of the two groups revealed that there was no statistically significant difference between the results at the baseline, the 36th to 38th week of pregnancy, and the sixth to eighth week postpartum (Table 4; baseline, pregnancy, 36th to 38th week,*p*=0.71; baseline, postpartum, sixth to eighth week, *p*=0.41; Table 1).

The number of voids both in the study and control groups were increased at the 36th to 38th week of pregnancy and decreased in the postpartum period. A comparison of the two groups revealed that the number of voids in the study group had decreased to a larger extent than that of the control group according to the results of the baseline, the control at the 36th to 38th week of pregnancy, and the control at the sixth to eighth week postpartum (baseline-pregnancy, 36th to 38th week, *p*=0.46; baseline, postpartum, sixth to eighth week, *p*=0.02; Table 1).

There was a significantly greater decrease in the amount of urine in the pad tests of the study group during the pad tests in follow-up controls than that of the subjects in the control group (baseline-pregnancy, 36th to 38th week, *p*=0.00; baseline, postpartum sixth to eighth week, *p*=0.002; Table 2).

There was a significant increase in the perineometer values of the study group during the follow-up controls than the ones in the control group (baseline-pregnancy, 36th to 38th week, *p*=0.00; baseline, postpartum, sixth to eighth week, *p*=0.00; Table 2).

The results of the pad test, perineometer, and the number of urinary incontinence episodes of the two groups were evaluated in Table 3. In study group, there were statistically significant differences between baseline and postpartum values in terms of pad test, perineometer values, and the number of episodes of urinary incontinence. There were also the same results in terms of perineometer values and the number of episodes of urinary incontinence in control group (Table 3).

Also the change of data was evaluated for any correlation between them (Table 4). In study group, there was no correlation between the baseline and postpartum difference results of the pad test, perineometer, and the mean number of urinary incontinence episodes. On the contrary, there was a statistically significant correlation between the baseline and postpartum results of the control group in terms of differences of values of pad test, perineometer, and the numbers of episodes of urinary incontinence.

Discussion

The results of the present study demonstrate that pelvic floor muscle exercises applied during pregnancy and the

Table 1 Number of voiding during daytime and night in the baseline, the 36th to 38th week of pregnancy and the postpartum sixth to eighth week controls as determined in their urinary diary reports and distribution of the data concerning them

	n	Experimental				Control			
		Median	Minimum	Maximum		Median	Minimum	Maximum	
Number of incontinence episodes in a day									
Baseline	40	1.00	0	5	40	1.00	0	6	
Pregnancy 36th to 38th week	37	0.00	0	5	35	1.00	0	5	
Postpartum 6th to 8th week	35	0.00	0	2	33	0.00	0	5	
Difference									
Baseline-pregnancy 36th to 38th week	37	−1.00	-4	1	35	-0.05	-5	1	*U*= 423[a], Z=-2.63, p=0.008
Baseline-postpartum 6th to 8th week	35	−1.00	-5	1	33	-0.36	-3	3	i7=382[a], Z=-2.45,p=0.014
Number of urgency in a day									
Baseline	40	3.00	1	5	40	3.00	1	4	
Pregnancy 36th to 38th week	37	2.00	1	5	35	3.00	1	5	
Postpartum 6th to 8th week	35	1.50	1	3	33	2.00	1	3	
Difference									
Baseline-pregnancy 36th to 38th week	37	37	-2	4	35	0.00	0	2	*U*= 194[a], Z=-2.46, p=0.014
Baseline-postpartum 6th to 8th week	35	−1.00	-3	1	33	0.00	-1	1	[/=44[a], Z=-2.63, p=0.008
Number of voiding in a day									
Baseline	40	8.50	5	16	40	8.0	5	13	
Pregnancy 36th to 38th week	37	10.0	6	17	35	8.0	6	13	
Postpartum 6th to 8th week	35	6.00	4	10	33	6.00	5	10	
Difference									
Baseline-pregnancy 36th to 38th week	37	1.00	-3	5	35	0.00	-3	4	U=548[a], Z=-0.72, *p=0.46*
Baseline-postpartum 6th to 8th week	35	-3.00	-10	2	33	−1.00	-8	1	(7=392, Z=2.29, *p=0.02*
Number of nocturia in a day									
Baseline	40	2.00	0	8	40	2.00	0	6	
Pregnancy 36th to 38th week	37	2.00	1	8	35	2.00	1	6	
Postpartum 6th to 8th week	35	1.00	0	3	33	1.00	0	4	
Difference									
Baseline-pregnancy 36th to 38th week	37	0.00	-6	4	35	0.00	-6	4	U=616.5[a], Z=-0.37, *p=0.1l*
Baseline-postpartum 6th to 8th week	35	-2.00	-7	0	33	-2.00	-7	0	U=513[a], Z=-0.81, p=0.41

[a] Mann-Whitney *U* test

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Table 2 Distribution of the data of pad test, perineometer results of the pregnant women in the baseline, the 36th to 38th week of pregnancy, and the postpartum sixth to eighth week and their comparison

	n	Experimental			*n*	Control			
		Median	Minimum	Maximum		Median	Minimum	Maximum	
Pad test (grams of leakage)									
Baseline	40	3.00	0	12	40	1.50	0	15	
Pregnancy 36th to 38 th week	37	0.00	0	10	35	5.00	0	15	
Postpartum 6th to 8th week	35	0.00	0	10	33	2.00	0	15	
Difference									
Baseline-pregnancy	37	0.00	-7	0	35	0.00	-5	10	U=294[a], Z= -4.31, p=0.00
Baseline-postpartum 6th to 8th week	35	0.00	-12	4	33	0.00	-12	14	U=328[a], Z =3.17
Perineometer (cmH_2O)									
Baseline	40	28.00	12	60	40	23.50	15	60	
Pregnancy 36th to 38th week	37	38.00	18	68	35	20.00	10	60	
Postpartum 6th to 8th week	35	46.00	20	72	33	30.00	15	60	
Difference									
Baseline-pregnancy 36 th to 38 th week	37	10.00	0	22	35	-2.00	-13	16	U=32[a], Z= -6.96, p=0.00
Baseline-postpartum 6th to 8th week	35	16.00	2	30	33	3.00	-13	16	U=106[a], Z= -5.78, p=0.00

[a] Mann-Whitney *U* test

postpartum period are effective in the reduction of urinary incontinence in women. In control group, there was an improvement in the strength of muscle of pelvic floor and the number of urinary incontinence. This changes supported the impact of pregnancy with its hormonal and mechanics effects.

The relevant literature reports that urinary incontinence is common during pregnancy and increases with increasing gestation until term [12, 13]. After delivery, the symptoms promptly decrease, indicating that the pregnant uterus may play a role [13].

Morkved and Bo [2] reported an incontinence rate of 42% during pregnancy. Two months after delivery, the number of women with urinary incontinence (38%) was nearly the same as during pregnancy. Pelvic floor muscle training for childbirth has been demonstrated to be effective in the prevention and treatment of urinary incontinence [1416]. Wilson and Herbison [15] reported a significantly lower prevalence of urinary incontinence in a group of women who performed postpartum pelvic floor muscle exercises compared with a control group. However, there was no significant difference between the groups in perineometer readings. A high dropout rate may have flawed the result of the mentioned study. A lack of statistically significant difference in pelvic floor muscle strength between a pelvic floor muscle training group and a control group was also reported by Sampselle et al. [3]. However, they had a high dropout rate and ended up comparing the muscle strength in ten and six women. Because the training period, training protocol, adherence rates, and the evaluation methods are different, it is difficult to compare the results of previous studies with the present study.

In this study, 43.2% of the women in the study group had incontinence at their 36th to 38th week of pregnancy, which decreased to 17.1% at the sixth to eighth week postpartum. However, 71.4% of the women in the control group had incontinence at the 36th to 38th week of pregnancy, and 39.4% still had urinary incontinence at the sixth to eighth week postpartum, which is a significant difference from the study group. Also in control group, the improvement of values in terms of pad test, the average number of urinary incontinence in the postpartum period, showed the importance of pregnancy on this subject. Wilson et al. [17] and Sampselle et al. [3] determined that the women who did the pelvic floor muscle exercises in the antenatal period had a decreased prevalence of urinary incontinence in the third month postpartum.

The amount of urine in the pad tests of the study group decreased to a larger extent than that of the subjects in the control group. This result is parallel to the reports in the literature, indicative of the fact that pelvic floor muscle exercises are effective [2, 4].

Table 3 The results of the comparison within groups in terms of the baseline, pregnancy 36th to 38th week and postpartum pad test, perineometer, and the number of urinary incontinence episodes results

	Experimental MeaniSD	Control MeaniSD
Pad test (grams of leakage)		
Baseline	4i4.34	3.65i4.52
Pregnancy 36th to 38th week	2.68i3.20	5i4.86
Postpartum 6th to 8th week	1.29i2.73	4i4.76
Difference: baseline-pregnancy 36th to 38th week	1.65i2.20	-1.28i3.14
Difference: baseline-postpartum 6th to 8th week	2.80i3.91	-0.52i5.24
Wilcoxon signed-rank test (baseline-postpartum 6th to 8th week)	Z = -3.43, *p*=0.001	Z=-5.89, *p*=0.56
Perineometer (cmH_20)		
Baseline	30.05i11.05	28.08i12.95
Pregnancy 36th to 38th week	40.97i13.21	25.17i12.35
Postpartum 6th to 8th week	46.83i15.08	30.93i12.49
Difference (baseline-pregnancy 36th to 38th week)	-10.43i5.20	1.88i4.44
Difference (baseline-postpartum 6th to 8th week)	-15.8i6.8	-3.57i6.45
Wilcoxon signed-rank test (baseline-postpartum 6th to 8th week)	Z=-5.16, *p*=0.00	*Z*=-2.99, *p*=0.003
Number of incontinence episodes in a day		
Baseline	2.23i0.8	2.13i0.85
Pregnancy 36th to 38th week	1.62i0.79	2.14i0.85
Postpartum 6th to 8th week	1.22i0.55	1.79i0.89
Difference (baseline-pregnancy 36th to 38th week)	0.65i0.79	0.05i0.76
Difference (baseline-postpartum 6th to 8th week)	1.03i0.86	0.39i1.08
Wilcoxon signed-ranks test (baseline-postpartum 6th to 8th week)	*Z*=-4.4, *p*=0.00	*Z*=-2.06, *p*=0.04

Similar to our findings, studies in the literature indicate The relevant literature reports that, as the stage of that urgency decreases in the postpartum period [12, 18, pregnancy progresses, the prevalence of frequent voiding 19]. In our study, urgency decreased in the study group to a increases, and this prevalence decreases in the postpartum larger extent than in the control group. It is reasonable to period. Stanton et al. [20] reported in their study on conclude that pelvic floor muscle exercises played a pregnant women that the number of voids is 45% in the significant role in reducing urgency. first trimester, 61% in the second trimester, 96% in the third

Table 4 The results of correlation analysis within groups in terms of the changes in the baseline and postpartum perineometer, pad test, and the number of urinary incontinence episodes results

	Perineometer difference Baseline-postpartum 6th to 8th week	Number of incontinence episodes in a day difference Baseline-postpartum 6th to 8th week
Experiment group		
Pad test difference	-0.06	0.20
Baseline-postpartum 6th to 8th week	*p*=0.75	*p*=0.24
Perineometer difference	1.00	-0.17
Baseline-postpartum 6th to 8th week		*p*=0.34
Control group		
Pad test difference	-0.36	0.49
Baseline-postpartum 6th to 8th week	*p*=0.04	*p*=0.004
Perineometer difference	1.00	-0.26
Baseline-postpartum 6th to 8th week		*p*=0.14

*Pearson correlations

trimester, and 17% in the postpartum period. Similarly, Cardozo and Cutner [12] also reported the number of voids as 58.8% in the 20th week of pregnancy, as 70.6% in the 36th week of pregnancy, and as 16.8% in the postpartum period. These reports are consistent with the findings of our study. However, a comparison between both groups showed that the number of voids had decreased in the study group to a larger extent than the control group.

It is further reported that nocturia increases in the third trimester and decreases in the postpartum period. Stanton et al. [20] gives the frequency of voiding twice or more a night as 39.3% in the second trimester, as 64% in the third trimester, and as 6% in the sixth to eighth week postpartum. Likewise, Cardozo and Cutner [12] recorded this frequency as 40% in the 28th week of pregnancy, as 57.1% in the 36th week of pregnancy, and as 9.2% in the 3rd month postpartum.

While a rapid increase was seen in the pregnancy and postpartum perineometer values of the study group, there was a decrease in the perineometer values of the control group at the 36th to 38th week of pregnancy and an increase again in the postpartum period. In the control group, perineometer values improved in the postpartum period. The desirable positive increase in the perineometer values of the group that did the exercises is again consistent with the literature findings [3, 4].

A comparison between the study and control groups in terms of the perineometer values showed that the perineometer values in the study group increased to a larger extent than those of the control group. Parallel to our findings, Morkved et al. [4] found out that, in the controls they did in the third month postpartum, pelvic floor muscle strength was stronger in the study group who did the pelvic floor muscle exercises in the antenatal period. Reilly et al. [5], in a study with 230 primigravidae (training group, *n*= 120; control group, *n* = 110), found that fewer women in the training group reported postpartum urinary incontinence (19.2% versus 32.7% in the control group). However, they studied only women in a high risk group (with diagnosed bladder neck mobility) and found no difference in pelvic floor muscle strength between the groups after exercise. Woldringh et al. [6] reported that there was no effect of pelvic floor muscle training half a year after childbirth. Sampselle et al. [3] did not find a difference between groups in vaginal speculum values after the intervention period.

The results of our research have shown that pelvic floor muscle exercises applied in pregnancy and the postpartum period are quite effective in the treatment of and reduction in urinary incontinence by enhancing the pelvic floor muscle strength. Although improvement in pelvic muscle strength cannot be the definite cause of reduced incontinence, their co-existence is the major conclusion of this study. The improvement of the control group in postpartum period showed that pregnancy with its hormonal and mechanic effects is a very important risk factor in urinary incontinence.

No evaluation was conducted 6 months postpartum in this study. This point may be considered to be a limitation of this study. Another limitation of this study was not knowing the pelvic muscle strength of the women before they became pregnant.

Determination of pelvic floor muscle strength measurements of women who plan to get pregnant and determination of changes in pregnancy and the postpartum period are suggested for a further study.

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Conflicts of interest None.

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Does regular exercise including pelvic floor muscle training prevent urinary and anal incontinence during pregnancy? A randomised controlled trial

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Objective To assess whether pregnant women following a general exercise course, including pelvic floor muscle training (PFMT), were less likely to report urinary and anal incontinence in late pregnancy than a group of women receiving standard care.

Design A two-armed, two-centred randomised controlled trial.

Setting Trondheim University Hospital (St. Olavs Hospital) and Stavanger University Hospital, in Norway.

Population A total of 855 women were included in this trial.

Methods The intervention was a 12-week exercise programme, including PFMT, conducted between 20 and 36 weeks of gestation. One weekly group session was led by physiotherapists, and home exercises were encouraged at least twice a week. Controls received regular antenatal care.

Main outcome measures Self-reported urinary and anal incontinence after the intervention period (at 32-36 weeks of gestation).

Results Fewer women in the intervention group reported any weekly urinary incontinence (11 versus 19%, $P = 0.004$). Fewer women in the intervention group reported faecal incontinence (3 versus 5%), but this difference was not statistically significant ($P = 0.18$).

Conclusions The present trial indicates that pregnant women should exercise, and in particular do PFMT, to prevent and treat urinary incontinence in late pregnancy. Thorough instruction is important, and specific pelvic floor muscle exercises should be included in exercise classes for pregnant women. The preventive effect of PFMT on anal incontinence should be explored in future trials.

Keywords Exercise, incontinence, pelvic floor muscle training, pregnancy, prevention, treatment.

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Introduction

Pregnancy and delivery are risk factors for urinary and anal incontinence in later life.[1,2] Urinary incontinence is defined as a 'complaint of involuntary loss of urine',[3] whereas the term anal incontinence is defined as a 'complaint of involuntary loss of feces or flatus'.[3]

The pelvic floor plays an important part in maintaining continence.[4] Contraction of the pelvic floor muscles (PFMs) causes an inward lift and squeeze around the urethra, vagina and rectum,[5] resulting in closure, stabilisation and resistance to downward movement.[6] Randomised controlled trials have documented the effects of intensive pelvic floor muscle training (PFMT) and close follow-up with

physiotherapists in the prevention and treatment of pregnancy-related urinary incontinence.[7-11] Nevertheless, one Cochrane review and two other systematic reviews conclude that the efficacy of PFMT during pregnancy in preventing urinary and anal incontinence is still open to question.[12-14] The Cochrane review strongly recommends that all future trials of PFMT during pregnancy should collect data on faecal incontinence, and highlights the need for large, pragmatic trials of population-based approaches, using intensive PFMT and recruiting antenatal women, regardless of continence status or parity.[12] There has been a lack of trials investigating the effect of implementing PFMT in a more general training programme for pregnant women.

We conducted the present study as one part of a randomised controlled trial aimed to investigate the effects of regular exercise during pregnancy in the prevention of pregnancy-related diseases and complications during labour. The primary outcome measures were gestational diabetes and glucose metabolism.[15] Another important research question was whether it was possible to prevent urinary and anal incontinence by including specific PFM exercises in the general exercise course, to improve the continence mechanisms before the problem arises (primary prevention), and also to detect incontinence at an early stage and thereby stop the development of the condition (secondary prevention).

The aim of this study was to assess whether pregnant women following a general exercise course including PFMT were less likely to report urinary and anal incontinence in late pregnancy than a group of women receiving standard care.

Methods

We conducted a two-armed, two-centre randomised controlled trial of a 12-week regular exercise programme versus standard antenatal care. The procedures followed were in accordance with ethical standards of research and the Declaration of Helsinki. The women received written information about the trial and signed informed consent forms. The participants were not compensated financially. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK 4.2007.81), and was registered in Clinical.Trials.gov (NCT 00476567).

Pregnant women booking for routine ultrasound at Trondheim University Hospital (St. Olavs Hospital) and Stavanger University Hospital were invited to participate in the trial. Women in Trondheim were recruited from April 2007 to June 2009, and women in Stavanger were recruited from October 2007 to January 2009. More than 97% of Norwegian pregnant women attend a routine scan at around 18 weeks of gestation, and these examinations are free of charge. During the inclusion period approximately 12 000 pregnant women had routine scans at the two hospitals. Inclusion criteria were age >18 years and a singleton live fetus. Exclusion criteria were high-risk pregnancies and/or diseases that could interfere with participation. For practical reasons we also excluded women who lived too far from the hospitals to attend weekly training groups (judged as more than 30-minutes drive).

Concealed randomisation in blocks of 30 was performed at the Unit for Applied Clinical Research, Norwegian University of Technology and Science, by a web-based computerised procedure. The staff involved with training or outcome assessments had no influence on the randomisation procedure. Because of the nature of the study it was not blinded.

Women in the intervention group received a standardised exercise programme, including aerobic activity, strength training (including specific PFM exercises) and balance exercises. The training protocol followed recommendations from The American College of Obstetricians and Gynecologists and the Norwegian National Report on Physical Activity and Health.[16,17] Training sessions of 60 minutes, in groups of between eight and 15 women, instructed by a physiotherapist were offered once a week over a period of 12 weeks (between 20 and 36 weeks of gestation). Each group session consisted of three parts:

1 30-35 minutes of low-impact aerobics (no running or jumping). Step length and body rotations were reduced to a minimum, and crossing legs and sharp and sudden changes of position were avoided. The aerobic dance programme was performed at moderate intensity, defined as 13 and 14 on Borg's rating scale of perceived exertion.[18]

2 20-25 minutes of strength exercises, using body weight as resistance, including exercises for the upper and lower limbs, back extensors, deep abdominal muscles and PFMs. Three sets of ten repetitions of each exercise were performed.

3 5-10 minutes of light stretching, body awareness, breathing and relaxation exercises.

In addition, women were encouraged to follow a written 45-minute home exercise programme, including PFMT, at least twice a week (30 minutes of endurance training and
15minutes of strength and balance exercises).

Women in the intervention group were individually instructed in pelvic floor anatomy and how to contract the PFMs correctly by a physical therapist. Correct contraction was controlled by vaginal palpation. The PFMT followed principles for increasing the strength of skeletal muscles.[19] Women were encouraged to perform three sets of eight to twelve close to maximum contractions of the PFMs, and were encouraged to hold the contraction for 6-8 seconds and, if possible, to add three fast contractions at the end of the contraction.[20] PFMT was performed in different

positions, with legs apart, to emphasise specific strength training of the PFMs and the relaxation of other muscles.

Adherence to the protocol was defined as exercising 3 days per week or more at moderate to high intensity. Performing the exercise programme was strongly emphasised, and recorded in the women's personal training diary and through reports from the physiotherapists leading the training groups.

Women in the control group received standard antenatal care and the customary information given by their midwife or general practitioner. They were not discouraged from exercising on their own. Women in both groups received written information and recommendations on PFMT, diet and pregnancy-related lumbopelvic pain. The PFMT brochure includes detailed information about the pelvic floor and an evidence-based PFMT programme.[9]

Pre-tests were performed between 18 and 22 weeks of gestation, and post-tests took place between 32 and 36 weeks of gestation. The main outcomes were urinary and anal incontinence, as measured by self-report. All participants answered a questionnaire, including questions related to urinary incontinence (Sandvik's severity index),[21,22] and anal incontinence (St. Marks score),[23] at both the start (18-22 weeks of gestation) and the end (32-36 weeks of gestation) of the intervention period. Women were asked to report their urinary leakage for the following situations with a 'yes' or 'no': (A) when coughing, sneezing or laughing; (B) while being physically active (running or jumping); (C) when making sudden changes in position or lifting; or (D) any leakage accompanied by a strong urgency to void. Urinary leakage was subclassified according to the definitions given in the standardised terminology of lower urinary tract symptoms.[3] Women confirming any type of urinary leakage (A, B, C or D) were referred to as having urinary incontinence (UI). Women confirming loss of urine in association with A, B or C were defined as having stress urinary incontinence (SUI), whereas women confirming loss of urine in association with D were defined as having urge urinary incontinence (UUI). The outcome measures of UI were further divided into two severity categories with respect to frequency: 'urinary leakage < once per week' or 'urinary leakage > once per week (severe UI)'. Anal incontinence was registered as faecal and flatal incontinence during the previous 4 weeks, based on one question from the St. Marks score.[23] Women reporting leakage of solid and/or liquid stool during the last 4 weeks were categorised as faecally incontinent, and women reporting flatus during the last 4 weeks were categorised as flatally incontinent.

Frequency, intensity and type of physical activity, including PFMT, were recorded for both groups at inclusion and at follow-up by self-report in a questionnaire. In addition, women in the intervention group registered PFMT in a training diary.

Based on a prevalence estimate of gestational diabetes of 9%, with a reduction to 4% (primary outcome of the trial), a study population of 381 patients in each group was needed in a two-sample comparison test with a 5% significance level and a power of 0.80. This sample size was able to detect a 0.2 SD difference on continuous variables, with a power of 0.80. Given the study population, we had a power of 0.79 to detect a risk of reduction in urinary incontinence of 10% from 50 to 40% in the two groups.

The statistical analyses were performed with spss 19. The data were analysed according to the 'intention-to-treat' principle using a chi-square test and binary logistic regression. The results were presented as crude and baseline- adjusted estimates, with 95% confidence intervals.

Women in the intervention and control groups were primarily analysed according to type of incontinence (UI, SUI, UUI, and faecal and flatal incontinence). Subgroup analyses were based on urinary, faecal and flatal continence status at the time of inclusion, for estimating the primary and secondary preventive effects of the intervention.

Results

In all, 875 women consented to participate in the trial. Twenty women were excluded or withdrew before the first examination: thirteen did not meet the inclusion criteria, five miscarried and two had twin pregnancies. A total of 855 women were randomly allocated to an intervention group or a control group (Figure 1). However, 32 women in the intervention group and 61 in the control group were lost to follow-up. Data from 397 women in the intervention group and 365 women in the control group were included in a complete case analysis.

The groups were similar in baseline characteristics except for severe UI and SUI, which were more frequent in the control group (P = 0.05 and 0.01, respectively; Table 1). After the intervention period, significantly less women in the intervention group reported UI and SUI, irrespective of severity (Table 2). The findings were consistent when adjusting for baseline values. A lower proportion of women in the intervention group (3%) than in the control group (5%) reported faecal incontinence; however, the difference was not statistically significant (Table 2). There were no differences in weight or body mass index (BMI) between groups at follow-up.

Subgroup analyses were performed for nulliparous and multiparous women. At baseline, the prevalences of severe UI and SUI were lower in the intervention group among nulliparous women. After the intervention (at 32-36 weeks of gestation) the prevalence of UI among nulliparous women was 35 versus 47% in the intervention and control groups, respectively (OR 0.6, adjusted for baseline values; 95% CI 0.4-0.9; $P = 0.03$),

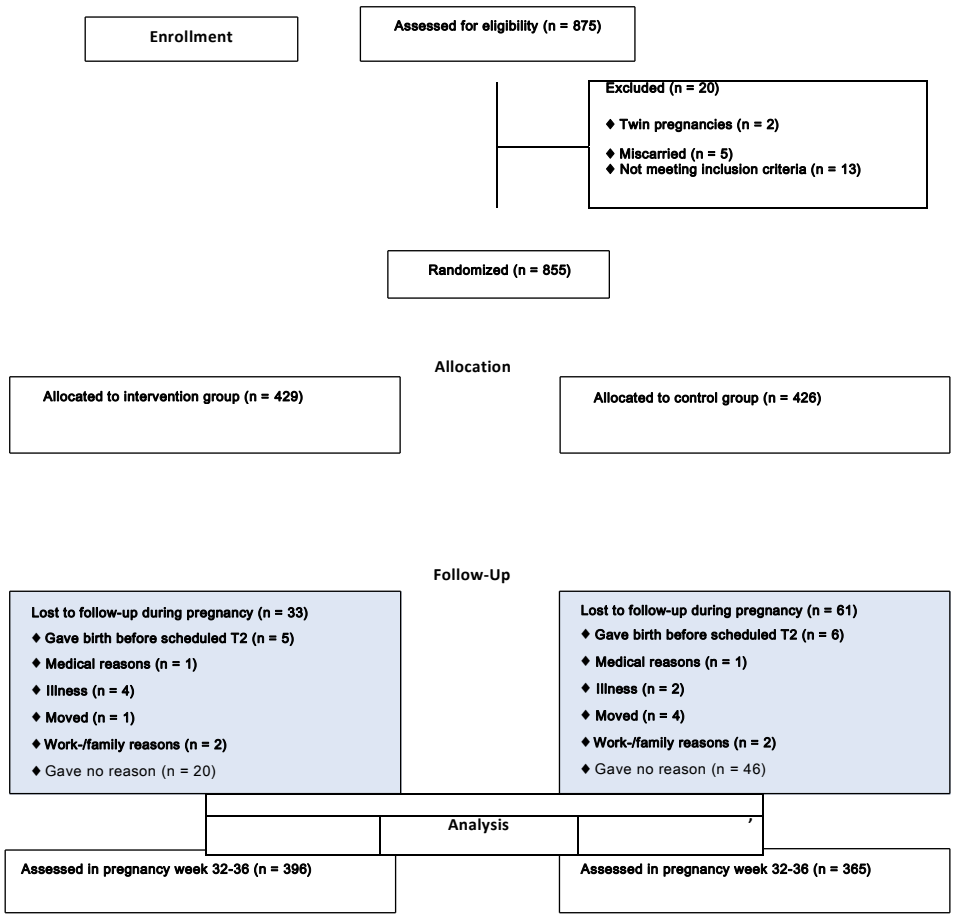

Figure 1. Flow chart of study participants.

and the prevalence of severe UI was 6 versus 14% (OR 0.4, adjusted for baseline values; 95% CI 0.2-0.9; P = 0.02). In multiparous women, the prevalence of faecal incontinence at 32-36 weeks of gestation was lower in the intervention group: 3 versus 8% (OR 0.2, adjusted for baseline values; 95% CI 0.1-0.8; P = 0.03). No other significant differences were seen in a subgroup analysis according to parity.

Baseline characteristics of subgroups based on groups stratified according to urinary continence status at inclusion are presented in Table 3. Sixty-nine percent of the women who were continent and 40% of the women who were incontinent were nulliparous. The subgroup analyses showed that in women who were continent for urine at inclusion, the proportions of women reporting SUI > once per week and UUI were significantly lower (P = 0.03 and 0.006, respectively) in the intervention group after the intervention period (Table 4). Furthermore, in women in either group who were incontinent for urine at inclusion, the proportion reporting UI, UI > once per week and SUI after the intervention period was lowest in the intervention group (P = 0.002, 0.03 and 0.007, respectively). These findings were consistent when adjusting for baseline values (Table 4).

There were no differences in age, parity, weight and BMI based on groups stratified according to faecal continence status at inclusion. Among women who were faecally continent at inclusion, 2% (8/359) in the intervention group and 4% (13/332) in the control group reported faecal incontinence at follow-up (OR 0.6; 95% CI 0.2-1.4; P = 0.20). Among women reporting faecal incontinence at inclusion, 19% (4/21) in the intervention group and 20% (3/15) in the control group reported faecal incontinence at follow-up (OR 0.9; 95% CI 0.2-5.0; P = 0.94).

Women reporting flatal incontinence at inclusion were younger than flatally continent women (30.0 ± 4.1 versus 30.7 ± 4.4 years), and a larger proportion of them was nul- liparous (65 versus 54%). Among women who were flatally continent at inclusion the proportion of flatal incontinence in both groups after the intervention period was 21% (58/ 275 versus 53/258; OR 1.0; 95% CI 0.7-1.6; P = 0.88). Among women reporting flatal incontinence at inclusion, 69% (75/109) in the intervention group and 74% (69/93)

Table 1. Baseline maternal characteristics of the study population

	Intervention group	Control group
Maternal characteristics	(n = 429)	(n = 426)
Mean age - years	30.5 ± 4.4	30.4 ± 4.3
Parity - no. (%)		
0	247 (58)	239 (56)
1	125 (29)	129 (30)
2+	57 (13)	58 (14)
Previous vaginal delivery - no. (%)	168 (39)	171 (40)
Gestational week at booking	20.3 ± 1.5	20.3 ± 1.7
Booking BMI - kg/m^2	24.7 ± 3.0	25.0 ± 3.4
Booking weight - kg	70.4 ± 9.8	70.8 ± 10.3
Exercise regularly - no. (%)	228 (53)	216 (51)
Exercise regularly > 3 times per week at moderate to high intensity - no. (%)	60 (14)	50 (12)
PFMT - no. (%)	249 (59)	272 (64)
PFMT > 3 times per week - no. (%)	101 (24)	110 (26)
UI*	172 (40)	180 (43)
UI > 1 times per week - no. (%)*	44 (10)	63(15)
SUI**	108 (26)	120 (30)
SUI > 1 times per week - no. (%)**	23 (5)	43 (10)
UUI	16(4)	16(4)
UUI > 1 times per week - no. (%)	1 (0.2)	2 (0.5)
Faecal incontinence - no. (%)***	22 (5)	17 (4)
Flatal incontinence - no. (%)****	118 (28)	111 (27)

Data are means ± SDs.
*Data missing in 0.5% of cases. **Data missing in 3.6% of cases. ***Data missing in 2.5% of cases. ****Data missing in 2.0% of cases.

Table 2. Urinary incontinence (UI) at 32-36 weeks of gestation in the intervention group and control group, including women who did or did not report urinary leakage at inclusion

	Intervention group		Control group		Unadjusted for baseline			Adjusted for baseline		
	n = 397		n = 365							
	n	%	n	%	OR	95% CI	P-value	OR adjusted	95% CI	P-value
UI*	166	42	192	53	0.7	(0.5, 0.9)	0.004	0.6	(0.4, 0.9)	0.004
UI > 1 time per week*	44	11	68	19	0.5	(0.4, 0.8)	0.004	0.5	(0.3, 0.8)	0.006
SUI**	102	28	128	37	0.7	(0.5,0.9)	0.01	0.7	(0.5, 0.9)	0.02
SUI > 1 time per week**	25	7	45	13	0.5	(0.3, 0.8)	0.006	0.5	(0.3, 0.9)	0.03
UUI***	11	3	20	6	0.5	(0.2, 1)	0.06	0.4	(0.2, 0.9)	0.04
UUI > 1 time per week***	0	0	3	1	1	(1, 1)	0.07	-	-	-
Faecal incontinence******	12	3	18	5	0.6	(0.3, 1.3)	0.18	0.6	(0.3, 1.4)	0.24
Flatal incontinence*******	136	35	124	35	1	(0.7, 1.4)	0.97	0.9	(0.7, 1.3)	0.73

*Data missing in 0.7% of cases.
**Data missing in 6.0% of cases.
***Data missing in 1.0% of cases.
****Data missing in 2.8% of cases.
*****Data missing in 2.2% of cases.

Table 3. Baseline characteristics of subgroups stratified according to continence status at inclusion

	Intervention group		Control group	
	Continent	Incontinent	Continent	Incontinent
	n = 256	n = 172	n = 244	n = 180
Mean age - years	30.1 ± 4.0	31.2 ± 4.9	30.0 ± 4.4	31.0 ± 4.1
Parity - no. (%)				
0	177 (69)	69 (40)	166 (68)	72 (40)
1	50 (20)	75 (44)	56 (23)	72 (40)
2+	29 (11)	28 (16)	22 (9)	36 (20)
Booking weight - kg	70.0 ± 10.0	71.0 ± 9.5	70.3 ± 10.1	71.6 ± 10.7
Booking BMI - kg/m²	24.5 ± 3.0	24.9 ± 3.1	24.9 ± 3.4	25.2 ± 3.5
UI	-	172 (100)	-	180 (100)
UI £ 1 times per week - no. (%)	-	44 (26)	-	63 (35)
SUI	-	108 (67)	-	120 (74)
SUI £ 1 times per week - no. (%)	-	23 (14)	-	43 (26)
UUI		16(9)		16(9)
UUI £ 1 times per week - no. (%)	-	1 (0.6)	-	2 (1)

Data are means ± SDs.

Table 4. Subgroup analysis of urinary incontinence (UI) at 32-36 weeks of gestation in the intervention group (IG) and control group (CG). Subgroups are based on groups stratified according to continence status at inclusion

	IG		CG		Unadjusted for baseline			Adjusted for baseline		
	n	%	n	%	OR	95% CI	P	OR	95% CI	P
Continent at inclusion	**n = 235**		**n = 208**							
UI	55	23	59	28	0.8	(0.5-1.2)	0.23			
UI > 1 time per week	6	3	13	6	0.4	(0.1-1.0)	0.06			
SUI	38	17	40	20	0.8	(0.5-1.4)	0.49			
SUI > 1 time per week	3	1	10	5	0.3	(0.1-1)	0.03			
UUI	2	1	11	5	0.2	(0.03-0.7)	0.006			
UUI > 1 time per week	0	0	1	0.5	1	(1.0-1.0)	0.29			
Incontinent at inclusion	**n = 157**		**n = 156**							
UI	111	71	133	85	0.4	(0.2-0.7)	0.002	0.4	(0.2-0.7)	0.002
UI > 1 time per week	38	24	55	35	0.6	(0.4-1)	0.03	0.5	(0.3-1.0)	0.04
SUI	64	45	88	61	0.5	(0.3-0.8)	0.007	0.5	(0.3-0.8)	0.008
SUI > 1 time per week	22	15	35	24	0.6	(0.3-1)	0.06	0.7	(0.3-1.3)	0.20
UUI	9	6	9	6	1	(0.4-2.5)	0.97	0.8	(0.3-2.5)	0.77
UUI > 1 time per week	0	0	2	1	1	(1.0-1.0)	0.15	-	-	-

in the control group reported flatal incontinence at follow- up (OR 0.8; 95% CI 0.4-1.4; *P* = 0.40).

In the intervention group, 95% reported weekly PFMT at follow-up, compared with 79% in the control group (P < 0.001). The proportion of women in the intervention group performing PFMT three times per week or more was 67%, compared to 40% in the control group (P < 0.01).

Adherence to the general exercise protocol (i.e. exercising 3 days per week or more at moderate to high intensity) in the intervention group was 55% (n = 217). In comparison, 10% of women in the control group exercised 3 days per week or more at moderate to high intensity at follow-up (P < 0.001). In the intervention group, 72% exercised at least once per week. UI and anal incontinence were not

more frequent among women in the intervention group who adhered to the protocol (n = 217), compared with the total control group at the end of the intervention.

No serious adverse events related to physical exercise were seen, and the outcomes of pregnancy were similar in the two groups.[15]

Discussion

This trial demonstrates that pregnant women who followed a 12-week course of regular exercise including PFMT were less likely to report UI and SUI in late pregnancy than women given standard care, including written instructions for PFMT. Among pregnant women who were continent for urine at the time of inclusion, significantly fewer women in the intervention group reported SUI once per week or more and UUI at follow-up, indicating a primary preventive effect of the intervention. In the subgroup of pregnant women categorised as incontinent for urine at inclusion, significantly fewer women in the intervention group reported UI, SUI once per week or more, and SUI in late pregnancy, compared with women in the control group (secondary prevention). A lower proportion of women in the intervention group reported faecal incontinence compared with the control group; however, the difference was not statistically significant. A subgroup analysis of multiparous women showed a significantly lower prevalence of faecal incontinence in the intervention group after the intervention.

The strengths of the present trial are the large number of participants, the high follow-up rate and the use of a computerised randomisation procedure. Despite the randomised design, some of the baseline characteristics were significantly different between the groups. This was probably the result of chance, and was accounted for in the statistical analysis. The investigators were aware of group allocation; however, as the prevalence of incontinence was based on self-reporting, the lack of blinding of investigators should not have had any impact on the results.

The prevalence of urinary leakage in pregnancy has been reported to vary between 9 and 74%.[24,25] This variation probably arises from different study populations (various proportions of nulliparous/parous women), different definitions of incontinence (self-reports or standardised pad tests) and different pregnancy lengths. In the Norwegian Mother and Child Cohort Study including 43 279 women from 1999 to 2006, 58% of the women reported any UI, and 35% of women reported any UI weekly or more in gestational week 30.[26] Anal incontinence is less studied in pregnancy, but a prevalence of 6% in late pregnancy has been reported.[27]

The prevalence of urinary leakage in mid and late pregnancy in the present trial was lower than in a previous trial conducted in the same geographic area 10 years ago, using the same outcome measures to classify women as continent or incontinent as used in the present trial.[9] Mørkved et al.[9] found that 32% of nulliparous women in the intervention group and 48% in the control group reported leaking urine once per week or more in gestational week 36. In the present trial, leaking urine once per week or more in gestational weeks 32-36 was reported by 6% versus 14% of nulliparous women in the two groups, respectively. As PFMT is known to have a high cure rate,[28] the difference between these studies may be the result of an increased focus on PFMT in pregnant women and health care professionals, following the results of the previous trial. In the current trial 60% of the study participants reported doing any PFMT at the time of inclusion, and 25% reported doing PFMT three times per week or more. In the previous trial 30% performed any PFMT at inclusion.[9]

The success of training depends on the ability to effectively contract the PFMs. It is estimated that 30% of women are unable to contract the PFMs on a first attempt.[29,30] Bump et al.[29] found that only 49% performed an ideal voluntary PFM contraction after brief standardised verbal instruction. In the present trial all women in the intervention group were individually instructed in pelvic floor anatomy, and the correct contraction was controlled with vaginal palpation. Women in both groups received written information on PFMT, including an evidence-based exercise programme, and at follow-up the number of women performing PFMT had increased in both groups. At follow-up, a large proportion of women in the control group reported doing regular PFMT during the intervention period. Still, the intervention group demonstrated significantly less UI in late pregnancy. This finding suggests that thorough instructions in correct PFM contraction, intensive PFMT and close follow-up are important to increase the success rate.

Another possible explanation of a low prevalence in the current trial may be differences in study populations. In the trial by Mørkved et al.[9] pregnant women were invited to participate with the explicit goal to study the effects of PFMT on UI. The aims of the current trial were to assess the effects of a more general exercise programme on several pregnancy-related conditions. Women experiencing urinary leakage may have been more likely to sign up in the previous trial aiming to improve continence, and women with severe urinary leakage may have been less likely to sign up for a general exercise trial including activities or situations that often cause incontinence. In the previous trial 32% of the study population reported weekly UI at inclusion,[9] compared with 13% in the current trial. The study population in the present trial was found to be representative for pregnant women in Norway regarding age, BMI, parity and level of exercise.[15]

Three previous trials have addressed primary prevention of UI during pregnancy.[8,31,32] Two trials reported highly significant preventive effects of PFMT.[8,32] The third trial had conflicting results,[31] but the response rate of participants was low (about 50%). The Cochrane review addressing prevention of urinary and faecal incontinence included mixed prevention and treatment trials.[12] Data from subgroups of previously continent women were added to the analyses of a primary preventive effect of PFMT on UI,[7,9] and the results indicated that for women having their first baby, antenatal PFMT appears to reduce the prevalence of UI in late pregnancy.[12] Thus, the review suggested new, large, pragmatic trials using intensive PFMT and recruiting antenatal women regardless of continence status or parity, and collecting data on both urinary and faecal incontinence.[12] Subgroup analyses in the present trial support the Cochrane review conclusions that the prevention and treatment effects on UI in late pregnancy were predominantly seen in women bearing their first baby, with a 40-60% reduction in risk.

Anal incontinence is less prevalent, but this condition is clearly a social and psychological burden that reduces the quality of life.[33] The preventive effect of PFMT on the development of anal incontinence has been sparsely studied. One previous trial included PFMT in a general fitness programme. This trial demonstrated no difference in urinary or anal incontinence between the intervention and control groups. However, this trial was underpowered and included no control of the women's ability to contract the PFMs correctly.[34]

In the present trial, the proportion of women reporting faecal incontinence in the intervention group was reduced from 5 to 3% after the intervention period. In the control group the proportion reporting faecal incontinence increased from 4 to 5% at follow-up. Although this difference was not statistically significant, it may suggest a possible clinically significant effect of the intervention. Another interesting finding was the preventive effect on faecal incontinence in multiparous women. This finding indicates that in women with possible previous birth-related injury to the PFMs, PFMT might prevent faecal incontinence in a later pregnancy.

In the present trial, women in the intervention group were encouraged to follow a general exercise protocol three times per week or more during the 12-week intervention period. Fifty-five percent of the women in the intervention group adhered to the protocol, and 72% of the women in the intervention group exercised at least once per week. For comparison, 10% of women in the control group reported exercising 3 days per week or more, and 30% exercised at least once per week. Women who are physically active are more frequently exposed to higher and more repetitive increases in abdominal pressure compared with more sedentary women. The exercise protocol in the present trial included physical fitness exercises designed for pregnant women, and did not include running or jumping. However, the aerobic part of the programme consisted of weight-bearing exercises causing increased abdominal pressure and increased risk of urinary leakage. Nevertheless, fewer women in the intervention group reported UI, and women adhering to the exercise protocol reported less UI than women who did not adhere in the intervention group at follow-up.

In addition to better structural support for the bladder neck with PFMT, the intervention group may have developed increased awareness and skill of timing the contraction with the event that elicits leakage. Miller et al.[35] found that 80% of women with de novo stress incontinence in gestational week 35 were able to reduce leakage during coughing by using the Knack maneuver (i.e. tighten the PFMs in preparation for a known leakage-provoking event), with 55% eliminating leakage completely.

An epidemiological study including 27 936 women reported a prevalence of any urinary incontinence of 25% in the adult population, with the prevalence of incontinence increasing with age.[36] Among the nulliparous women in that study (n = 3339), 10% reported UI.[37] Data suggest that pregnancy contributes to pelvic floor dysfunction later in life,[38] and that the first pregnancy and delivery is associated with a high prevalence of objective and subjective bowel dysfunction.[39] In a cohort study it was found that most women experiencing postpartum UI had symptoms of UI during the third trimester.[25] Another study found that 5 years after the first delivery, 33% of women reported UI.[40] Although UI is common, it reduces the quality of life and affects social, physical, occupational and leisure activi- ties.[41] The present trial demonstrates that PFMT during the second half of pregnancy reduced the prevalence of UI in late pregnancy. However, it is important to assess any possible long-term effects postpartum. When comparing the prevalence of UI in the present trial with a previous trial from the same area,[9] we found a significant reduction over the last 10 years. This may be linked to different study populations, but may also be the result of an increased awareness and knowledge about prevention and treatment of UI among healthcare professionals and the general population, indicating a preventive effect of information, instructions and encouragement to exercise the PFMs.

Anal incontinence is less prevalent, but this condition is clearly a social and psychological burden that reduces the quality of life.[23] No previous trial has assessed the preventive effect of PFMT on the development of faecal incontinence. In the intervention group, the proportion of women reporting faecal incontinence was reduced from 5 to 3% after the intervention period. In the control group the proportion reporting faecal incontinence increased from 4 to

5% at follow-up. Although this difference was not statistically significant, it may suggest a possible clinically significant effect of the intervention.

The prevalence of faecal incontinence during pregnancy is low, and the present trial was slightly underpowered to assess faecal incontinence properly, as shown by the wide confidence intervals. One important issue for future research is to assess whether PFMT in pregnancy can reduce faecal incontinence in pregnancy. Furthermore, it is important to assess the effects of regular exercise, including PFMT, during pregnancy on the duration of labour, the long-term effects on urinary and anal continence, and to investigate the associations between outcome, prior continence status and parity.

Conclusion

The results from the present trial indicate that pregnant women should do PFMT to prevent and treat UI in late pregnancy. Thorough instruction in correct PFM contraction and PFMT is important, and specific PFM exercises should be included in exercise classes for pregnant women. Any possible long-term effects on UI and the preventive effect of PFMT on anal incontinence should be explored further.

Disclosure of interests

None of the authors have a conflict of interest to declare.

Contribution to authorship

SNS, physiotherapist and PhD student, participated in planning the main study, coordinated the data collection, organised the training programme, analysed the data, wrote the first draft and finalised the article. KAS, Professor of Obstetrics and Gynaecology, participated in the planning of the main study, and revising and finalising the article. PRR, Professor of Epidemiology, participated in the data analyses, and in revising and finalising the article. IHT, physiotherapist, participated in the interpretation of data, and in revising and finalising the article. SM, Professor of Physiotherapy and principal investigator, initiated and planned the main study, supervised the training programme and participated in the interpretation of the data, as well as drafting and finalising the article.

Details of ethics approval

The study was approved by the Regional Committee for Medical and Health Research Ethics (REK 4.2007.81). Clinical trial registration: www.clinicaltrials.gov, NCT00476567.

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Supporting Information

Additional Supporting Information may be found in the online version of this article.

Data S1. Powerpoint slides summarising the study.

Please note: Wiley-Blackwell are not responsible for the content or functionality of any supporting information supplied by the authors. Any queries (other than missing material) should be directed to the corresponding author. ■

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Journal Club

Discussion points

1. Background: Describe what is currently known about the prevalence of urinary and anal incontinence in pregnancy, and women in general. What is the existing evidence for the efficacy of pelvic floor muscle training (PFMT) on the prevention and treatment of incontinence?

2. Methods: This trial used self-reported symptoms of incontinence as its primary outcome measure, in line with the most recent Cochrane review.[1] Discuss the advantages and disadvantages of this approach. There was a difference between the two groups concerning the proportion of women with severe urinary incontinence at baseline. The authors addressed this imbalance by adjusting odds ratios for baseline differences. Another approach would have been to ensure the comparability of the two groups for key prognostic variables, using stratified randomisation or minimisation. Describe and compare these methods.

3. Results and implications: Almost 80% of the women in the control group performed PFMT at least once a week, a high proportion compared with other estimates of PFMT in pregnant women.[2] Still, a significant reduction in urinary incontinence was seen in the intervention group compared with controls. Explore what features of the intervention may have increased its effectiveness. The loss to follow-up was much higher in the control group, particularly for 'reasons unknown'. Discuss the implications in terms of bias. This study investigates the effects of PFMT during pregnancy - consider the need for longer-term follow-up. Based on the findings, should this intensive exercise programme be recommended routinely? (Data S1) ■

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ORIGINAL ARTICLE

A randomized controlled trial of antenatal pelvic floor exercises to prevent and treat urinary incontinence

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Abstract
Introduction and hypothesis The aim of the study was to evaluate the effect of antenatal pelvic floor muscle exercise (PFME) in the prevention and treatment of urinary incontinence during pregnancy and postpartum period. *Methods* Three hundred women were randomly assigned to the PFME group and control group. Urinary symptoms were measured by Urogenital Distress Inventory-6 (UDI-6), Incontinence Impact Questionnaire-7 (IIQ-7), and question of self-reported urinary incontinence. Questionnaire scores of the PFME and the control groups were compared and analyzed.
Results During late pregnancy and the postpartum period, the PFME group had significantly lower total UDI-6 and IIQ-7 scores; their self-report rate of urinary incontinence was also less than the control group. Additionally, we found whether in PFME or control, women who delivered vaginally were more likely to develop postpartum urinary leakage than women who delivered by cesarean section. *Conclusions* PFME applied in pregnancy is effective in the treatment and prevention of urinary incontinence during pregnancy, and this effect may persist to postpartum period.

Keywords Pelvic floor muscle exercise · Pregnancy · Postpartum · Urinary incontinence

Abbreviations
SUI Stress urinary incontinence
PFME Pelvic floor muscle exercise IIQ-7
Incontinence Impact Questionnaire UDI-6
Urogenital Distress Inventory

Introduction

Pregnancy and birth trauma are risk factors for urinary incontinence, which commonly develops during pregnancy or following delivery. Incidences of stress urinary incontinence (SUI) during pregnancy have been reported to range from 19.9% to 70% in nulliparous women [1-3], while in the postpartum period, the prevalence in primipara is between 0.7% and 35% [4, 5]. Pelvic floor muscle exercise (PFME) has been documented in the literature to be one of the treatment methods for urinary incontinence during pregnancy [6, 7]. Previous epidemiological data showed that the first delivery contributes the most to the development of SUI [8]. Therefore, the National Institute of Clinical Excellence [9] recommends PFME for all women in a first pregnancy for prevention of SUI. Antenatal PFME has been shown to reduce the incidence of postpartum SUI in the short term [6, 7, 10]; however, studies on the efficacy of PFME done in the antenatal period are rather limited. So, we conducted a randomized controlled trial to evaluate the effect of antenatal PFME in the prevention and treatment of urinary incontinence during pregnancy and after birth.

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Methods

Nulliparous women, at 16 to 24 gestational weeks, receiving regular prenatal care in the obstetrics clinic at a university hospital, were invited to participate in the study. Women who agreed to join the study provided written informed consent. The study protocol (No. 96-1224B) was approved by our institutional review board. Exclusion criteria included multiparity, multiple gestations, severe pregnancy complications, high risk for preterm labor, pain during PFME, diseases that could interfere with participation, or would be unavailable for follow-up.

Women were recruited into the trial from April 2008 to October 2008, and followed up until October 2009. Three hundred fifteen women gave their signed consent to participate in this trial. Fifteen women were excluded or withdrew before the first examination: Five had pregnancy complications, four had twin pregnancies, and six withdrew for unknown reasons. Three hundred women were randomly allocated to a PFME group or to a control group. Randomization was achieved by selection of sealed envelopes, which were opened at entry. Women of the PFME group were individually instructed by a physical therapist about pelvic floor anatomy and how to contract the pelvic floor muscles correctly before exercise. Correct contraction was assessed by observation of inward movement of perineum during contraction. The exercise group followed a specially designed pelvic floor muscle training course, as published previously by Reilly et al. [10]. However, we did not ask pregnant women to increase the number of contractions per repetition from eight to 12 at the third trimester as Reilly et al. did. The exercises comprised three repetitions of eight contractions each held for 6 s, with 2-min rest between repetitions. These were repeated twice daily at home with additional training in groups once a week for 45 min by a physical therapist, and lasted throughout a 12-weeks' period. Each training group included around 10 women. Group training was performed in sitting and standing positions with legs apart to emphasize specific strength training of the pelvic floor muscles and relaxation of other muscles. Motivation was strongly emphasized by the physiotherapist. Compliance in the PFME group was monitored using diaries to record the number of daily exercises performed from the first examination to 36 gestational weeks. We considered women in the exercise group who reported practice PFME at least 75% as adherent. Women of the control group also received regular prenatal care and received the customary written postpartum instructions that did not include PFME from the hospital. If women performed PFME before entry, they were excluded from the study; however, out of ethic consideration, pregnant women were not discouraged from performing PFME on their own.

At entry, all participants were asked to complete two validated questionnaires, including Incontinence Impact Questionnaire (IIQ-7) (a seven-item measure of urogenital distress) and Urogenital Distress Inventory (UDI-6) (a six- item measure of incontinence effect) [11]. Total scores of IIQ-7 and UDI-6 as well as individual scores of six questions of the UDI-6 were calculated as previously reported [12]. In addition to the IIQ-7 and UDI-6, we asked all women two questions: "Did you go urinate more than 7 times during the day" and "Do you leak urine at any time: never, seldom, weekly or daily?" Both urinary frequency and urinary incontinence were registered in accordance with the International Continence Society's definitions [13]. Women reporting urinary incontinence once per week or more during the last month were categorized as incontinent. All women were interviewed by a research nurse and administered the questionnaires via face-to-face method at 36 gestational weeks and postpartum day 3, and via telephone 6 weeks and 6 months postpartum. Participant characteristics abstracted from patient charts included age, body mass index, delivery method, and baby birth weight.

Previous reports demonstrated that the incidence of urinary incontinence during pregnancy was 42% [5], so we assumed that the effect of PFME in treatment of urinary incontinence was 50%. In order to achieve 85% power to detect the difference in self-reported urinary incontinence between groups of PFME and control, a sample size of at least 290 was required. Characteristics of the PFME group and the control group were assessed by paired Student *t* test for continuous data and Chi-square test for proportions. Comparison of questionnaire scores of UDI-6 and IIQ-7 between the PFME group and the control group was assessed by the Mann-Whitney *U* test. The association of self-reported urinary incontinence and PFME were assessed by the Chi-square test. We used the generalized estimating equations to evaluate the odds ratios of self-reported urinary incontinence between the PFME group and the control group. We also used the generalized estimating equations to evaluate the odds ratios of self-reported urinary incontinence between groups of vaginal delivery and cesarean section. A P value of <0.05 was considered statistically significant. Statistical analyses were performed using SPSS 15.0 for Windows (SPSS, Inc., Chicago, IL, USA).

Results

Three hundred women were randomly assigned to the PFME group (n =150) or the control group (n = 150) (Fig. 1). Over 80% women of exercise group attended entire group training program, and none were absent from the training more than twice. All women were followed up

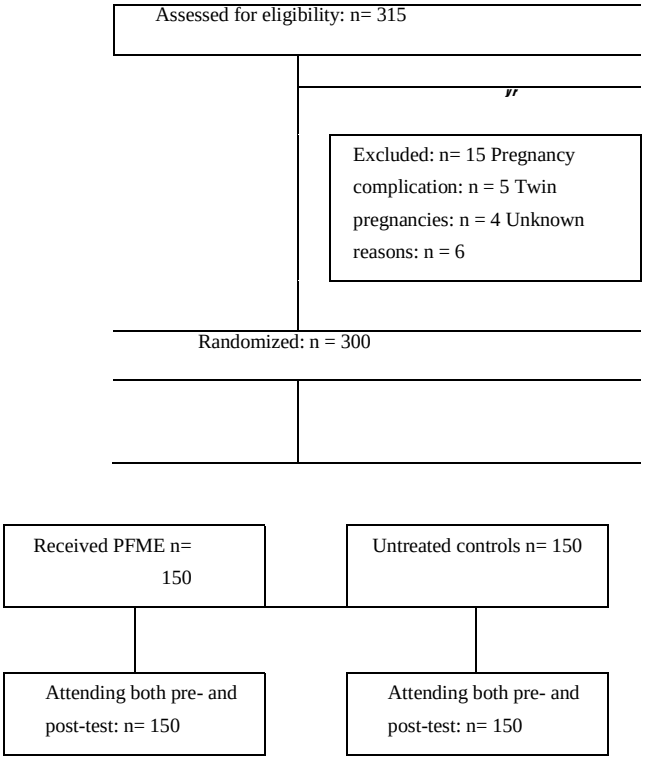

Fig. 1 Patient flow chart

for 6 months after delivery. At 36 gestational weeks, 87% of the treatment group reported practice of PFME at least 75% of the time. Participant characteristics are shown in Table 1. Patient's age, body mass index, delivery method, baby birth weight, labor duration, episiotomy, instrument assisted delivery, and severe perineal laceration of degree 3 or 4 were not significantly different between the two groups. During late pregnancy and the postpartum period, the PFME group had significantly lower total UDI-6 and IIQ-7 scores as well as lower scores for questions 2, 3, and 4 of the UDI-6 Questionnaire (Table 2). Question 2 concerns urine leakage related to the feeling of urgency; question 3 looks into urine leakage related to activity, coughing, or sneezing; question 4 investigates small amounts of urine leakage. Total IIQ-7 scores show that quality of life related to incontinence is significantly better in the PFME group compared with the control group at 36 pregnancy weeks, and 6 weeks and 6 months postpartum.

The incidence of self-reported urinary incontinence was analyzed by the generalized estimating equations with results produced as follows: There is a significantly lower incidence of self-reported urinary incontinence in the PFME group than the control group (odds ratio =1.63, 95% confidence interval between 1.52 and 1.74, $P<0.05$) during late pregnancy (36 pregnancy weeks) and 6 months postpartum (Table 3); with regard to the incontinence- delivery method relationship, we found that in either the PFME group (Table 4) or the control group (Table 5), women with vaginal delivery had a higher self-reported urinary incontinence rate than women with cesarean delivery; overall (putting both groups together), in the postpartum period, women experienced urinary incontinence more frequently if they delivered through the vagina route than by cesarean section (odds ratio=4.89, 95% confidence interval between 4.37 and 5.46, $P<0.05$).

Discussion

Using the validated UDI-6 and IIQ-7 questionnaires, we found that PFME led to improvement of urinary incontinence and quality of life in late pregnancy and up to 6 months postpartum. Reilly et al. [10] found no difference between the study groups on any scale of the Kings Health Questionnaire, but a higher score for the general health measure in the Short Form-36 in the PFME group. After factor analysis, which resulted in four domains of Incontinence Impact Questionnaire-30 [14], Woldringh et al. [15] reported that the impact on emotional health and recreational activities was stronger than on social relationships and physical activities, but no difference existed between the PFME and control groups. The reasons for different results among the three studies might be due to different questionnaires, inclusion criteria for participants, and the frequency of the pelvic floor muscle training.

Table 1 Characteristics of patients

Group	PFME (*n* =150)	Control (n =150)	*P* value
Age	31.66±3.42	31.29±3.78	0.38
BMI before pregnancy	21.78±4.10	22.18±3.38	0.35
BMI after pregnancy	27.24±5.14	27.71±3.41	0.34
Vaginal delivery	102 (68)	107 (71)	0.53
Baby birth weight	3,121±532.58	3,145.91±415.26	0.65
Labor duration (min)[a]	319±176	326±149	0.52
Episiotomy[a]	99 (97)	104 (97)	0.87
Instrumental delivery[a]	6(6)	7(7)	0.44
Severe perineal laceration[a]	10 (10)	10(9)	0.63

Data are presented as mean ± standard deviation or *n* (%), and calculated with the paired Student *t* test or Chi-square test

BMI body mass index

[a]Data of women who delivered vaginally are shown in 102 of PFME group and 107 of control group

Table 2 Comparisons of UDI-6 and IIQ-7 between PFME group and control group

Questionnaire	PFME	Control	*P* value
UDI-6[a]	1.27±1.54	1.36±1.55	0.49
UDI-6[b]	3.44±3.26	4.66±3.32	<0.01
UDI-6[c]	1.42±2.04	2.31±2.16	<0.01
UDI-6[d]	0.81±1.36	1.54±1.59	<0.01
UDI-6[e]	0.35±0.84	0.86±1.14	<0.01
IIQ-7[a]	1.11±2.47	1.21±2.44	0.18
IIQ-7[b]	3.77±6.01	5.28±5.61	<0.01
IIQ-7[d]	1.73±3.57	2.86±3.52	<0.01
IIQ-7[e]	0.77±2.07	1.56±2.20	<0.01

Data are presented as mean ± standard deviation and calculated with Mann-Whitney *U* test [a] Pregnancy at 16 to 24 weeks [b] Pregnancy at 36 weeks [c] Three days after delivery [d] Six weeks after delivery [e] Six months after delivery

In addition to total scores of UDI-6 and IIQ-7, individual scores for question 2 (urge incontinence), question 3 (stress incontinence), and question 4 (drops) in UDI-6 were also found to have showed significant difference between the PFME group and the control group at 36 gestational weeks and up to 6 months postpartum. Our results are similar to those of several previous randomized controlled trials [6, 7, 10, 16]. Sampselle et al. [6] reported significantly less urinary incontinence in the training group at 35 weeks' pregnancy, 6 weeks postpartum, and 6 months postpartum when compared with the control group. In the study by Morkved et al. [7], following attendance in an intensive 12- week PFME program, the training group had significantly less urinary incontinence than control group at 36 weeks' pregnancy (32% versus 48%) and 3 months after delivery (20% versus 32%). Reilly et al. [10] studied only women with bladder neck mobility and found that fewer women in the training group reported urinary incontinence at 3 months postpartum, 19.2% compared with 32.7% in the control group. In their study of 80 pregnant women with urinary incontinence in their 20th to 34th weeks of pregnancy who were randomly allocated to PFME group or to control group, Dinc et al. [16] reported that 43.2% of the women in the PFME group continued to have urinary incontinence at 36 to 38 gestational weeks, which decreased to 17.1% at 6 to 8 weeks postpartum; but that in the control group, as high as 71.4% of the women had persistent urinary incontinence at 36 to 38 gestational weeks; and even 6-8 weeks postpartum, 39.4% still had it.

Results from a randomized controlled trial [15] addressing antenatal PFME in women with urinary incontinence during pregnancy are inconsistent with those of the aforementioned trials. Using urinary incontinence severity scale and a 7-day bladder diary for outcome measurement, Woldringh et al. [15] reported that PFME did not lower the incidence of urinary incontinence in pregnant women any more than the control group did. However, in their series, women in the control group received some instruction on PFME as well. In our series, the PFME group had significantly lower urinary incontinence than the control group in late pregnancy (34% versus 51%) and at 6 months postpartum (16% versus 27%), but did not demonstrate the same result at early postpartum. We speculated that vaginal delivery might contribute to pelvic floor damage through muscular, fascial, and nervous injuries, in which tissue damage took time to restore through the early postpartum period. In a previous study, there was electromyographic evidence of re-innervation in the pelvic floor muscles after first vaginal delivery in 80% of those studied during early postpartum period [17]. It is possible that episiotomy interferes with PFME at immediate postpartum period; however, there were similar episiotomy rates in both groups of exercise and control, thereby rendering the influence on the outcome insignificant. Other potential obstetric risk factors of postpartum urinary incontinence consistently reported in the medical literature included birth weight, duration of labor, and forceps delivery [18, 19].

SUI in young women is usually the result of pelvic floor damage during vaginal delivery. Whether cesarean delivery may prevent such damage and consequent development of postpartum urinary incontinence is uncertain. Rortveit et al. [20] investigated the association between urinary incontinence and childbirth in a community-based cohort of 15,307 women. Their study demonstrated an increased risk of urinary incontinence among women who delivered by cesarean section as compared with nulliparous women who never delivered. On this result, Rortveit et al. [20] commented that the mechanical strain accumulated antenatally may add to the risk associated with pregnancy itself. In one study, cesarean section seemed to protect against the development of postpartum urinary incontinence, but

Table 3 Self-reported urinary incontinence during pregnancy and after birth

Time	PFME	Control	*P* value
16-24 weeks	41 (27)	45 (30)	0.61
36 weeks	52 (34)	76 (51)	<0.01
3 days after delivery	46 (30)	62 (41)	0.07
6 weeks after delivery	38 (25)	53 (35)	0.06
6 months after delivery	25 (16)	42 (27)	0.04

Data are presented as *n* (%) and calculated with Chi-square test

Table 4 Self-reported urinary incontinence in PFME group delivered by vaginal or cesarean delivery

Time	VD (n = 102)	CS (n=48)	*P* value	Odds ratio (95% CI)
16-24 weeks	28 (27)	13 (27)	0.96	1.02 [0.47, 2.21]
36 weeks	34 (33)	18 (38)	0.62	0.83 [0.41, 1.71]
3 days after delivery	39 (38)	7(15)	<0.01	3.63 [1.48, 8.88]
6 weeks after delivery	32 (31)	6(13)	0.01	3.2 [1.24, 8.29]
6 months after delivery	21 (21)	4(8)	0.06	2.85 [0.92, 8.83]

Data are presented as *n* (%) and calculated with generalized estimating equations *VD* vaginal delivery, *CS* cesarean section, *CI* confidence interval

3 months after delivery, the statistically significant influence of the mode of delivery had disappeared [19]. In our study, the mode of delivery showed a significant difference in the prevalence of self-reported urinary incontinence between women who had vaginal delivery and those who delivered by cesarean section in the PFME group (Table 4) and the control group (Table 5) at postpartum period. However, at 6 months postpartum, the difference had disappeared in the PFME group but not in the control group, indicating that pelvic floor muscle training seems to be beneficial to the restoration of continence in women who delivered vaginally. Using the generalized estimating equations analysis to assess urinary incontinence rate, we found the PFME group had a significantly lower selfreported urinary incontinence rate than the control group. Likewise, by the generalized estimating equations, vaginal delivery was associated with a significantly higher postpartum urinary incontinence rate than cesarean delivery.

The limitations of our study included lack of data from long-term follow-up and no objective assessments such as the measurement of pelvic floor muscle strength, pad test, perineal ultrasound, or urodynamic study. In addition, for ethic consideration, we cannot forbid women of control group to perform exercise by themselves that possibly have an impact of antenatal PFME on urinary incontinence. Longterm follow-up is important to assess continence following further pregnancies; hence, we believe in using diagnostic tests and outcome measurements that would cause just minimal discomfort to the participants if any because they are all healthy pregnant women. In our study, only subjective questionnaires were used as outcome measurement. Several studies investigating the effect of antenatal PFME on pregnancy-related urinary incontinence showed poor compliance to receive invasive tools for survey [5, 6, 10]. Regarding the measurement of pelvic floor muscle strength, previous studies were inconsistent: Some investigators found that pelvic floor muscle strength was stronger in the study group who did the PFME in the antenatal period [7, 16]. Other studies showed no difference in pelvic floor muscle strength between the groups PFME and control [6, 10]. However, the strength of pelvic floor muscle is not necessarily related to the rate of postpartum urinary incontinence. Previous studies showed fewer women in the training group reporting significantly lower postpartum urinary incontinence but no difference in pelvic floor muscle strength between the groups after exercise [6, 10]. The monitoring of the adherence to the training program between sessions is more important than the total number of session followed [14]. In this study, all women of exercise group were individually instructed about correct pelvic floor muscle contractions. The exercise group followed a 12-week designed PFME course, including group training once per week and daily training at home. Skilled physiotherapists led the training groups, giving instructions on PFME. They especially emphasized the importance of adherence to the training protocol and urged the pregnant women to follow the program strictly. Over 80% of our participants were adherent in that they reported practice of PFME at least 75% of the time.

Table 5 Self-reported urinary incontinence in the control group who delivered by vagina or cesarean section

Time	VD (n = 107)	CS (n=43)	*P* value	Odds ratio (95% CI)
16-24 weeks	31 (29)	14 (33)	0.67	0.84 [0.39, 1.81]
36 weeks	52 (49)	24 (56)	0.42	0.75 [0.37, 1.52]
3 days after delivery	57 (52)	5(12)	<0.01	8.34 [3.05, 22.8]
6 weeks after delivery	48 (45)	5 (12)	<0.01	6.18 [2.26, 16.9]
6 months after delivery	39 (35)	3(7)	<0.01	7.05 [2.04, 24.3]

Data are presented as *n* (%) and calculated with generalized estimating equations *VD* vaginal delivery, *CS* cesarean section, *CI* confidence interval

Conclusion

PFME applied in pregnancy is effective in the treatment and prevention of urinary incontinence during pregnancy, and this effect may persist to the postpartum period. The delivery method also makes an impact on urinary incontinence: In both PFME and control groups, more women who delivered vaginally experienced postpartum urinary leakage than those delivered by cesarean section.

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Conflicts of interest None.

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Is a 6-week supervised pelvic floor muscle exercise program effective in preventing stress urinary incontinence in late pregnancy in primigravid women?: A randomised controlled trial

Bussara Sangsawang and Nucharee Sangsawang

Abstract

Objective: The study investigated the effect of a 6-week supervised pelvic floor muscle exercise (PFME) programme to prevent stress urinary incontinence (SUI) at 38 weeks' gestation.

Study Design: We conducted a randomized controlled trial into two arms design: one intervention group and one control group, using the randomly computer-generated numbers. A research assistant, who was not involved with care of the participants, randomly drawn up and opened the envelope for each participant to allocate into the intervention group and the control group. The investigators could not be blinded to allocation. Seventy primigravid women who had continent with gestational ages of 20-30 weeks were randomly assigned to participate in the intervention (n = 35) and control groups (n = 35). The intervention was a supervised 6-week PFME program with verbal instruction and a handbook, three training sessions of 45 minutes with the main researcher (at 1st, 3rd and 5 th week of the program) and self-daily training at home for an overall period of 6 weeks. The control condition was the PFME and the stop test had been trained by the main researcher to all of the participants in the intervention group.

Outcomes: The primary outcome was self-reported of SUI, and the secondary outcome was the severity of SUI in pregnant women which comprises of frequency, volume of urine leakage and score of perceived severity of SUI in late pregnancy at 38th weeks of pregnancy.

Statistical analysis was performed using Chi-square test, Independent-sample t-test, and Mann-Whitney U-test. Significance P-value was < 0.05.

Results: At the end of the intervention, 2 of 35 women in the intervention group and 5 of 35 women in the control group dropped out of the study. Therefore, the total of the study participants consisted of 63 pregnant women (33 in the intervention group and 30 in the control group). Fewer women in the intervention group reported SUI than the control group: 9 of 33 (27.3%) versus 16 of 30 (53.3%) at 38 weeks' gestational age (OR 3.05, 95% CI 1.07 to 8.70, P=0.018).

Conclusions: The 6-week supervised PFME programme was effective in preventing SUI and decreasing the SUI severity in pregnant women who reported SUI at late pregnancy. The women who performed PFME program under the training sessions once every two weeks found that the program demands less time, incurs lower costs and possibly offers more motivation to exercise. This 6-week supervised PFME programme may be suitable in real clinical situation.

Keywords:

6-week supervised training, pelvic floor muscle exercise, pregnancy, prevention, randomized controlled trial, severity, stress urinary incontinence

Title:

Is a 6-week supervised pelvic floor muscle exercise program effective in preventing stress urinary incontinence in late pregnancy in primigravid women?: A randomised controlled trial

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1. Introduction

Pelvic floor muscle exercise (PFME), the repetitively selective voluntary contraction and relaxation of specific pelvic floor muscles (PFM) [1], is used to increase the strength of the PFM and periurethral muscles which these are leading to improve the efficiency of the supportive function by immobilized the urethra, and improve the sphincteric function by increases intraurethral closure pressure during physical activities [2,3]. Therefore, PFME is considered the first-line intervention of prevention and treatment for stress urinary incontinence (SUI) during pregnancy before consideration of other treatments [4]. The National Institute of Clinical Excellence (NICE) also suggests PFME for all women in their first pregnancy for the prevention of SUI [5].

According to the Cochrane review, PFME should be recommended as the first-line management for the prevention and treatment SUI during pregnancy and postpartum period. In addition, it has been concluded that pregnant women without prior UI who practice intensive supervised antenatal PFME are 56% less likely to report UI in late pregnancy than women who do not practice PFME [6]. These are evidences of the effectiveness of intensive supervised PFME in preventing the antenatal UI.

The intensive supervised PFME training is a weekly exercise interventions provided under either individually supervised or group training session by a physiotherapist over a period of 8 to 12 weeks [7].

Although, the intensive supervised PFME is effective to prevent and treat SUI, some physicians disagree. They suggest that the weekly follow-up by the therapist cannot be implemented into real clinical practice, because some women may not want to take much effort or time in PFME training classes [8]. It is likely that the success of the randomized controlled trials reported in the literature would not be repeated in the ‘real situations’ [9]. Freeman [10] suggested that this exercise is impractical for all pregnant women to receive intensive

supervised PFME from a physiotherapist or continence expertise during pregnancy. Nevertheless, there was a previously published study showed the 6-week antenatal PFME combined with group supervised training by midwife once every two weeks has been demonstrated as significantly effective in treating SUI during pregnancy by decreased severity of SUI symptoms in pregnant women [11]. As well, they also emphasized the possibility of the implementation of 6-week supervised PFME by midwife into real clinical practices.

To date, although, the studies on the efficacy of the supervised antenatal PFME to prevent SUI during late pregnancy are rather limited. Therefore, this study has aimed to determine the effectiveness of the 6-week antenatal PFME program with supervised training by midwife in preventing the development of SUI during late pregnancy in continent primigravidae women.

2. Materials and Methods

2.1. Study design and participants

A randomized controlled trial (RCT) with two arms study design: one intervention group and one control group, using the randomly computer-generated numbers was conducted. This study was approved by the Research Ethics Committee (RAJ-IRB 080/2555). Informed consent was obtained from all participants.

Between July 2012 and October 2012 with follow-up until March of 2013, primigravida women who attended in the antenatal care unit and met the inclusion criteria were recruited to participate in this study. The inclusion criteria were as follows: pregnant women who were age 18 years and older, gestational ages of 20-30 weeks, singleton fetus and pre-pregnancy body mass index (BMI) of <30 kg/m^2. Pregnant women with SUI symptoms during pregnancy, the pregnancy complications such as preterm labor, pregnancy induced hypertension (PIH), gestational diabetes mellitus (GDM), antenatal hemorrhage, etc.,

pain during pelvic floor muscle contraction, or diseases that could interfere with the participant were excluded. The women who withdrawn from the study before the end of the study by various reasons such as lack of time, changing hospital, or move to other provinces were included in drop out criteria. In addition, the women who failed to perform PFME for a period of 6 weeks or < 28 days, or those who came to follow-up appointments less than twice were excluded to analyze data.

2.2. Sample size calculation and randomization

The sample size was predetermined by using power calculation with the G*power program version 3.1.3. Power analysis involved a one-tailed t-test for two groups independent mean with a power of .80, a significance level of .05, and an effect size of .70. The minimum number per group was calculated to be 26 participants. We added 35% of the 26 participants to prevent loss of the sample, finally, a total of 35 participants who were recruited for each group.

The 70 participants who met the inclusion criteria were randomly allocated by computer-generated numbers into two groups: the intervention group and the control group. Written informed consent was obtained from all patients before randomization.

Before the study had begun, the principle investigator used the www.randomizer.org/form.htm (2013) to prepare the sealed opaque envelopes was used to perform a simple randomization (not block) to allocate women into each group. The sealed opaque envelopes contained the randomly computer-generated numbers to generate 35 sets of numbers: each set containing two numbers ranging from 1 to 2 with random order. A total of 70 unique codes were generated based on the 35 sets of randomly ordered {1, 2} (e.g. Set 1 Group 1, Set 1 Group 2).

A random number table found in a statistics book or computer-generated random

After written informed consent forms were obtained, a research assistant, who was not involved with care of the participants, randomly drawn up and opened the envelope for each participant to ensure the 70 participant were equally allocated into two groups based on the group number of each code: group 1 (the intervention group), and group 2 (the control group).

Once randomization occurred it was not possible to blind participants or health providers (who were also the research investigators) to treatment group. Outcome assessment was not blind because all the outcomes were patient-reported.

The CONSORT diagram of the participants' flow of this study is shown in Figure 1.

2.3. Treatment protocol

The intervention group followed a specially designed, 6-week supervised PFME program as previously published by Sangsawang & Serisathien [11]. All women in the intervention group were trained by one midwife (main researcher) in small groups of 4-5 participants for 45 minutes per session once every 2 weeks for a period of 6 weeks (at the 1st, 3rd and 5th week of the program). Therefore, the program consisted of three sessions at the first, third and fifth week of the program. A day before each session (at the 3rd and 5th week) of program, the researcher made an appointment via telephone to remind time and date of the class for the women to return to hospital and meet the researcher.

At the beginning of the program, the women who participated in the PFME instruction session were led to a health education room. They were instructed about the introduction of SUI and PFME during pregnancy, in the following topics: 1) risk factors of SUI, 2) how pregnancy can cause SUI, 3) the functions of the PFM, 4) how the PFME can prevent SUI, 5) the benefits of PFME and 6) performance of PFME. Before pregnant women begin PFME, they must be ascertained to exercise the correct muscles, by using "stop test". The stop test is ability of controlling the PFM to stop or slow urinary flow over a toilet for a

one or two seconds, then relax and finish emptying without straining. Pregnant women who performed correct PFM contractions would able to stop urine flow for a brief moment [12]. In cases of incorrect perform of PFME, they were instructed until they were able to make an accurate contraction. In this study, therefore, the correct contraction of PFM was affirmed by only after the instruction of stop test.

After all participants in the intervention group could correctly contract their PFM, the researcher trained them to repeat 20 sets of PFME exercises twice a day for a total of 40 sets per day, at least 5 days per week for an overall period of 6 weeks, and to practice PFME in various positions including lying down, sitting, and standing, regardless how strong contraction of the PFM. This means that all pregnant women in the intervention group were told to strictly perform PFME follow the protocol and thoroughly all six weeks, without increasing the number of contraction per set.

One set of PFME consists of 1 slow contraction followed by 1 fast contraction. In which, 1 slow contraction is contracting the perivaginal and perianal muscles by holding a strong contraction for 10 second and 1 fast contraction is briefly contracting and relaxing the muscles rapidly for a total of 10 time.

Prior leaving the clinic, the specially designed 25-page PFME handbook was provided to each participant. The handbook contained the information of SUI, PFM function, detailed instructions on PFME and the table record for self-reported, frequency and volume of SUI at 38^{th} weeks of pregnancy.

The control group, they received only regular prenatal care by health professionals, obstetricians or midwives. They were instructed by midwives who did not involve with the study, regarding the topic of general prenatal practice such as eating, sleeping, breastfeeding, and antenatal exercise for the benefit of preparation for childbirth. These pregnant women,

however, did not receive instructions about SUI during pregnancy and had no training to support the performance of correct PFME.

The intervention group, in addition to the control group, the PFME was trained by the researcher.

In brief, both control and intervention groups had received the same regular prenatal care according to the hospital guideline. This regular prenatal care was instructed by the health profession who did not involve with the study. The researcher had been scheduled to meet the participants in the control group for 2 times at the time of randomization to instruct how to record the urinary incontinence, and 38th weeks of pregnancy for assessment of the urinary incontinence. In addition to regular prenatal care, the experimental group had 4 additional meetings with the researcher, 3 for PFME training (1st, 3rd and 5th week of the PFME program) and 1 for assessment after 6 weeks PFME program (at 38th weeks of pregnancy).

2.4 Control condition

The PFME and the stop test had been trained by the main researcher to all of the participants in the intervention group.

2.5. Outcome measurements

2.5.1 The primary outcome

The primary outcome is the effects of the 6-week supervised PFME program on the prevention of SUI which is measured by self-reported of SUI in late pregnancy at 38th weeks of pregnancy.

The pregnant women who report SUI symptoms (involuntary leakage of urine on sneezing, coughing, effort or physical exertion) one or more times per week at 38th weeks of pregnancy will be categorized as incontinent.

2.5.2 The secondary outcomes

The secondary outcome is the severity of SUI in pregnant women who reported SUI symptoms. The severity of SUI comprises of frequency, amount of urine leakage and score of perceived severity of SUI at 38th weeks of pregnancy.

The severity of SUI is self-reported which is recorded in the specially designed tables. These tables are helping pregnant women to record the frequency and volume of urine leakage involuntary during physical exertion, or on sneezing or coughing at 38th weeks of pregnancy.

The frequency of SUI is defined by the weekly average times of urinary leakage. The volume of urine leakage is a qualitative measure which is categorized into three levels: minimal (a few drops of urine), moderate (urine leakage wetting only the underwear) and large (urine leakage sufficient to dampen outer clothing) [13]. Therefore, the pregnant woman has to do daily record the urinary leakage in one week at 38th weeks of pregnancy. This record has been developed for helping the pregnant women in both groups to record the frequency and volume of urine leakage, as shown in Figure 2.

In contrast, the self-perceived severity of SUI is a weekly report which is measured by visual analog scale (VAS). The VAS measures the perception of severity of SUI in pregnant woman [14]. The VAS will be recorded at time of appointment, at the end of 38th week of pregnancy. The VAS has score of 0 at the left end where represents no severity, and 10 at the right end, 10 centimeters apart, where represents the worst possible severity, as shown in Figure 3. The VAS has been divided into 1 to 10 which each scale is 1 centimeter apart. Each subject was asked to mark an ‘X’ on the line reflecting the level of perceived SUI severity.

The distance of the participants marked from the left end was measured and reported in centimeters.

The summary of research procedures and data collection of this study is shown in Figure 4.

2.6. Statistical analysis

The analysis of the sample group's personal data was performed by using descriptive statistics. After the intervention, Independent-sample t-test was use to analyze comparison on the mean SUI frequency and the mean scores of perceived SUI severity between the two groups. Comparisons of the amount of urine leakage between the two groups were analyzed by using a Mann-Whitney U-test. Odds ratio (OR) and 95% confidence interval (CI) were also analyzed for self-report SUI. The comparison of the mean differences between groups was analyzed using 95% CI. $P<0.05$ was considered statistically significant.

3. Results

Seventy pregnant women without SUI symptoms at the beginning of the study were randomized to the trial which they were divided into intervention and control groups of 35 participants each. However, two pregnant women in the intervention group were dropped out because they had moved to other provinces. In the control group, five pregnant women were also dropped out, as well, three of them changed the hospital, one of them moved to other provinces and the last one were lost to contact. Therefore, the total of the study participants consisted of 63 pregnant women (33 women in the intervention group and 30 women in the control group). None of the participants in the intervention group was failed by performing PFME for <28 days. The flow diagrams of the participants through each stage of the procedure of the study comparing the intervention and the control groups are shown in Figure 1. No

negative side effects had been reported in pregnant women who participated in the intervention.

The baseline demographic and obstetric characteristics of the pregnant women in both groups were shown in Table 1. The average age of the intervention group was 27.6 years whereas the average age in the control group was 28.2 years. Nearly half (42.5%) of the pregnant women in the intervention group and about one-third (33.4%) of the women in the control group had completed senior high school. Most of the pregnant women in the both groups had full time-work (72.7% in the intervention group and 83.3% in the control group). During pregnancy, most of the pregnant women in both groups had not smoking, not intake alcohol and not intake caffeine (93.9%, 81.8% and 69.7% in the intervention group and 96.7%, 86.7% and 60% the control group, respectively). The average pre-pregnancy BMI in the intervention group was 21.7 kg/m^2 compared to 22.0 kg/m^2 in the control group. At the beginning of the study, the pregnant women in the intervention group had an average gestational age of 23.6 weeks whereas the average gestational age in the control group was 24.1 weeks.

Chi-square tests revealed no statistically significant differences in age, education, occupation, smoking, alcohol intake, caffeine intake, pre-pregnancy BMI and gestational age between two groups ($P>0.05$).

The number of women reporting SUI during pregnancy was shown in Table 2. At the time of follow-up, the intervention group showed significantly fewer than the control group. The intervention group reported SUI 9 out of 33 (27.3%) versus 16 out of 30 (53.3%) at 38 weeks' gestational age.

Tables 3 and 4 showed the SUI severity after participation in the 6-week supervised PFME program. At the time of follow-up, 38 weeks' gestational age, the mean frequency of SUI was significantly lower in the intervention group (12.44 versus 23.06). In addition, the

mean score for self-perceived severity of SUI at 38 weeks' gestational age had similar results, lower in intervention group (5.02 versus 6.30) (Table 3).

Interestingly, the majority of the participants in the intervention and the control group at 38 weeks' gestational age had no urinary leakage (72.7% versus 46.7%). Nonetheless the urinary leakage showed the contrast. The intervention group obviously showed fewer participants with moderate volume of urinary leakage, which means urine leakage wetting only the underwear age (12.1% versus 26.7%). Moreover, the volume of urine leakage after participation in less supervised 6-week PFME was significantly lower in the intervention group (Table 4).

4. Comments

Pregnant continent primigravid women who were randomized to a 6 week supervised PFME programme in the second half of their pregnancy were less likely to report SUI in late pregnancy at 38th weeks than control group who received standard antenatal care.

PFME is aimed at strengthening the striated musculature that is part of the striated urogenital sphincter muscle to improve the continence mechanism [15]. The women who correctly and continually perform PFME will have hypertrophy of these muscle fibers resulting in strengthening of the PFM and periurethral muscles. These are leading to the improvement of the sphincteric function efficiency which can reduce urine leakage [16]. The muscles are strengthened by muscle fiber hypertrophy which may occur after specific strengthening exercises for at least 4 weeks [17]. These changes are supposed to be a neural adaptation for muscle hypertrophy during the first 6 to 8 weeks of muscle strength training [18]. Morkved et al. [19] found that pregnant women who performed antenatal PFME had PFM strength significantly higher than in the control group at gestational age 36 week and 3 months after delivery (p=.008 and p=.048, respectively).

PFM strength can improve the supportive function for the bladder neck and urethra as well as the sphincteric function of the external urethral sphincter which can prevent or improve SUI symptoms [20]. Dinc et al. [16] found that pregnant women with PFME had a significant decrease in UI episodes during pregnancy and the postpartum period. Furthermore, Reilly et al. [21] found pregnant women with bladder neck mobility, who performed PFME for at least 28 days, report only 19.2% postpartum SUI at 3 months after delivery compared with 32.7% in the control group (RR 0.59, 95% CI 0.37-0.92).

Although PFME has been recommended as the most effective conservative treatment for pregnant women with SUI, there is no consensus in the published literature about the strength and duration of the muscle contractions, the number of contraction repetitions per session, the number of sessions performed per day, the duration of exercise and the type of instruction provided [9].

A number of previous studies and systematic reviews have concluded that high intensive supervised training dosages and weekly follow-up with physiotherapists are more effective to prevent and treat UI during pregnancy and postpartum than lower intensive supervised training dosages [14,19]. Group exercise programs with only one supervised individual or group training session/week are named intensive supervised training [7]. PFME under the direction of a physiotherapist (or midwife) reduces the prevalence of UI in the short term compared with simple advice about individual PFME [4]. However, some physicians suggest that weekly follow-up with a physiotherapist is not practical in clinical practice [8]. The SUI instruction provided by physiotherapists might not be suitable for actual implementation in pregnant women because most pregnant women who attended antenatal care do not meet physiotherapists.

However, although intensive supervised PFME have been known to be more effective than only verbal instruction, this intervention would not available to all women due to a lack

of physiotherapist to provide PFME [21]. Therefore, in some unfortunate hospitals where physiotherapists are not available, midwives and GPs involved in the care of women could be trained to deliver this intervention in women to prevent and treat UI [22].

In the present study, the intervention was carried out by midwife in a tertiary care setting in Thailand where more than half of pregnant women received antenatal care by midwives or nurses, but all of the pregnant women never see physiotherapists in each appointment. Only self-report was used as outcome measurement and the classification of continence and incontinence in pregnant women. In this study, we found the intervention group had significantly reported less SUI than the control group at 38th week of pregnancy (27.3% versus 53.3%; P=0.018). Moreover, the severity of SUI (frequency, VAS perceived SUI severity and urine leakage) in the intervention group were significantly lower at 38 weeks' gestational age *(*$P < 0.001$, $P < 0.01$, $P = 0.03$, respectively).

These finding are consistent with previously several published studies. They have demonstrated that the women who weekly perform PFME for less than 12 weeks or less supervised PFME by the researchers (either physiotherapists or midwifes) have better SUI prevention compared with the women who do not perform PFME. For example, Felicissimo et al. [23] demonstrated that the first choice of conservative treatment for women with SUI was an 8-week PFME in their home without the supervision and follow-up by a physiotherapist once a week. Ahlund et al. [24] had shown that home-based exercise with regular follow-up under the guidance of a midwife would be more effective than the written instructions received by the control group. Another study of the effectiveness of PFME to reduce SUI symptoms conducted by midwives, Sangsawang and Serisathien [11] had concluded that a 6-week supervised PFME program was effective in decreasing the severity of SUI symptoms in pregnant women, possibly indicating that PFME with a short duration of

6 weeks and supervised by nurses once every two weeks can treat the severity of SUI

symptoms in pregnant women compared with those in the control group. In the studies mentioned above, they showed the intensive supervised and less supervised PFMEs appear to be equally effective in improving female SUI. If training sessions are provided, less supervised therapy has the advantages of low cost to the public health system and the patients [23].

Regarding to the aforementioned, several studies have shown that less supervised PFMEs with either verbal or handbook instruction appear to be equally effective in improving SUI symptoms in women [11,23,24]. Less time-consuming PFME would be more cost effective, and possibly more motivating to exercise [25]. Pregnant women who do not perform exercise under intensive weekly training sessions will demand less time, lower costs and possibly more suitable for implement into real clinical situation. Therefore, pregnant women and health professionals can choose the exercise option that best fit their lifestyle.

Notably, the significant effects on the SUI prevention after attending the 6-week supervised PFME program in this present study might be explained by the components of the program, including instruction about SUI, training skills to perform correct PFME, distribution of a handbook and specific training from the researcher once every 2 weeks for a total period of 6 weeks to assess the outcomes and problems of the PFME. The instructions and handbook were important sources of information that helped the women understood the causes and SUI prevention during pregnancy. These were enhancing their understanding of the benefits of PFME in order to prevent SUI [26, 27].

On the other hand, the pregnant women in the control group who did not receive SUI instruction during pregnancy had no training to support the performance of correct PFME. In the present study, the researchers found a high prevalence of SUI in the control group during the third trimester and increasing at gestational ages of 38 weeks (53.3%; Table 2). These results concurred with those previously reported by Wijma et al. [28] They found the

incidence of UI increased with the gestational age from 30% at gestational ages of 28-32 weeks to 35% at gestational ages of 36-38 weeks, which is similar to that reported by Thorp et al. [29], They found the SUI frequency and severity of urine leakage steadily worsened throughout pregnancy.

Although the present study showed the effectiveness of the 6-week supervised PFME program is able to prevent antenatal SUI, the PFM strength had not been measured. This point may be considered to be a limitation of the study.

5. Conclusion

In conclusion, the pregnant women who participated in the intervention group followed a 6-week supervised PFME program with verbal instruction and a handbook, consisted of three supervised training sessions of 45 minutes with the midwife once every two weeks, and daily performed PFME at home have a lower self-reported of SUI at gestational ages of 36 and 38 weeks than the pregnant women who did not perform PFME. The pregnant women who performed exercise under the training sessions once every two weeks found the program demands less time, incurs lower costs and possibly offers more motivation to exercise. Moreover, this 6-week supervised PFME program may be suitable in clinical practice.

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- Project development, Data Collection, Data analysis, Manuscript writing/ editing

N Sangsawang:

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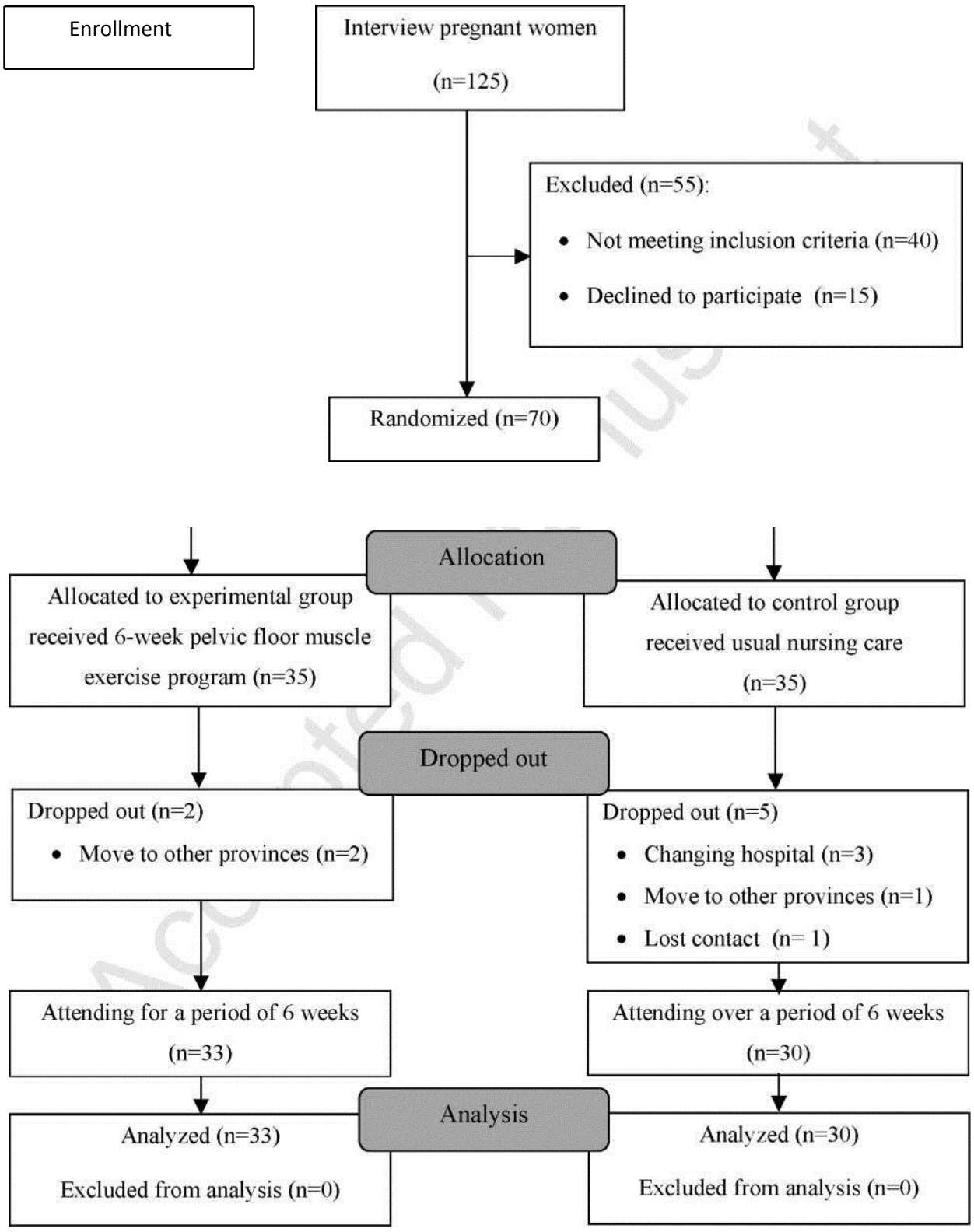

Figure 1 The flow diagrams of the participants through each stage of the study follow

CONSORT guidelines

Frequency and urinary leakage of SUI at 38th week of pregnancy			
Date	Frequency	Total	Severity
Grand total			

Figure 2 Table record for frequency and volume of SUI at 38th weeks of pregnancy in this study

Figure 3 Visual Analogue Scale in this study

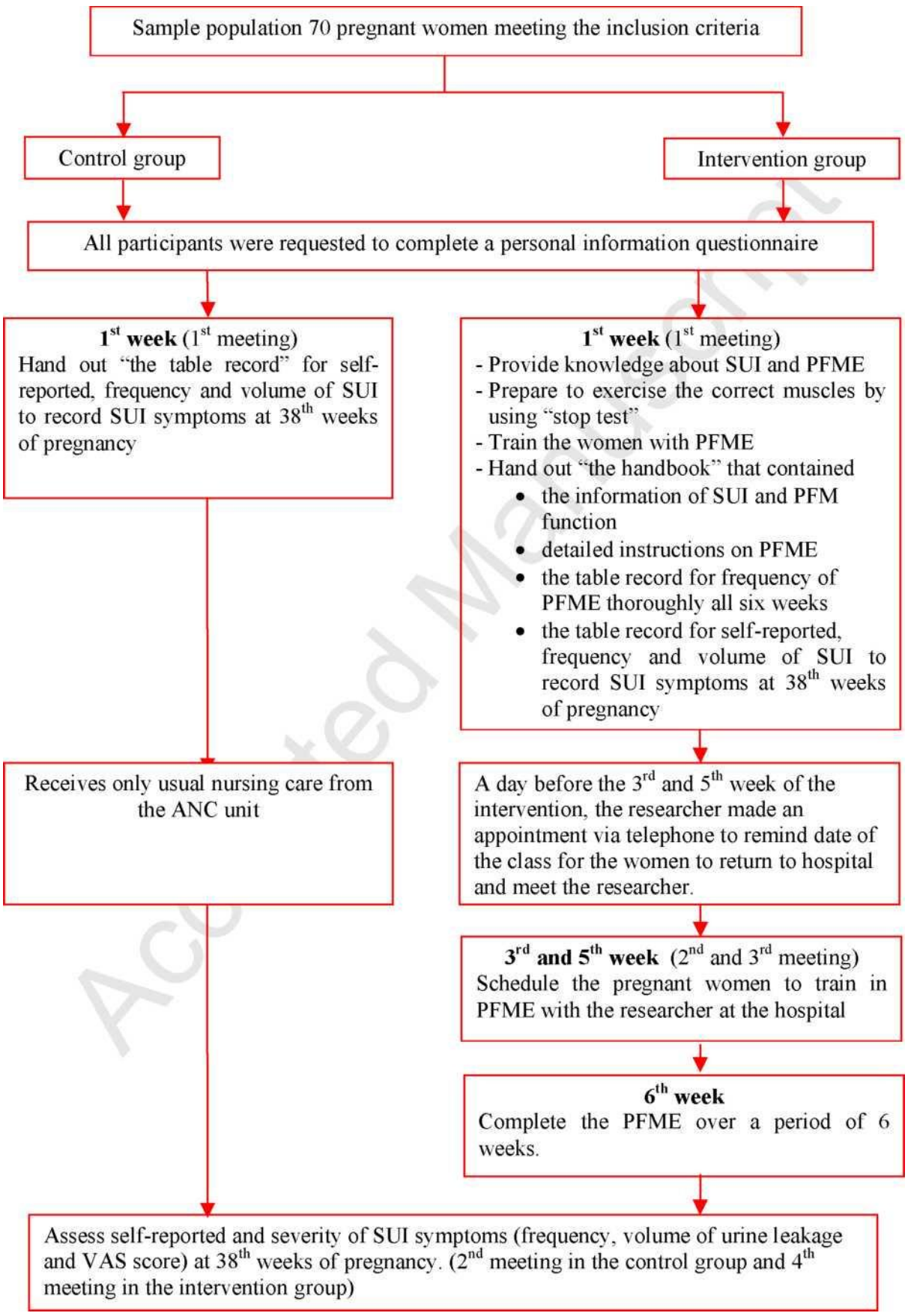

Figure 4 Summary of research procedures and data collection.

Condensation

The 6-week supervised PFME program is effective in preventing SUI at late pregnancy, and this program may be suitable in clinical practice.

Table 1 Comparison of demographic characteristics between the exercise and the control groups.

	Experimental group (N= 33)	Control group (N= 30)
Age range (years): n (%)	18-41 (Mean = 27.6, SD = 5.09)	19-43 (Mean = 28.2, SD = 5.01)
18-25	12 (36.3%)	10 (33.3%)
26-35	19 (57.6%)	19 (63.4%)
36-45	2 (6.1%)	1 (3.3)
Education level: n (%)		
Primary school	8 (24.2%)	7 (23.3%)
Junior high school	8 (24.2%)	9 (30.0%)
Senior high school	14 (42.5%)	10 (33.4%)
College or above	3 (9.1%)	4 (13.3%)
BMI before pregnancy	18.6-28.7 (Mean = 21.7, SD = 1.89)	18.1-29.2 (Mean = 22, SD = 1.92)
range (km/m): n (%)		
18-20	12 (36.3%)	8 (26.7%)
21-25	20 (60.6%)	21 (70.0%)
26-29	1 (3.1%)	1 (3.3%)
Gestational age range	20-30 (Mean= 23.6, SD = 2.65)	20-30 (Mean = 24.1, SD = 2.68)
(weeks): n (%)		
20-23	15 (45.5%)	11 (36.7%)
24-27	16 (48.5%)	16 (53.3%)
28-30	2 (6.0%)	3 (10.0%)

BMI body mass index; No statistically significant differences were found (P>0.05).

Table 1 Comparison of demographic characteristics between the exercise and the control groups. (Cont.)

	Experimental group (N= 33)	Control group (N= 30)
Occupational: n (%)		
Full time	24 (72.7%)	25 (83.3%)
Part-time	4 (12.1%)	2 (6.7%)
Not working	5 (15.2%)	3 (10.0%)
Smoking: n (%)		
Yes	2 (6.1%)	1 (3.3%)
No	31 (93.9%)	29 (96.7%)
Alcohol intake: n (%)		
Yes	6 (18.2%)	4 (13.3%)
No	27 (81.8%)	26 (86.7%)
Caffeine intake: n (%)		
Yes	10 (30.3%)	12 (40.0%)
No	23 (69.7%)	18 (60%)

BMI body mass index; No statistically significant differences were found (P>0.05).

Table 2 Number of pregnant women with self reporting stress urinary incontinence at 38 weeks'gestational age.

	Exercise group (N=33)	Control group (N=30)		
	n %	n %	Significance	Odd Ratio (95% CI)
38 wk of pregnancy	9 27.3	16 53.3	X^2=4.46, P=0.018	3.05 (1.07, 8.70)

N = total number of pregnant women; n = number of pregnant women with stress urinary incontinence; % = proportion of incontinent pregnant women; CI = confidence interval

Table 3 Severity of stress urinary incontinence (SUI) in pregnant women who reported SUI in the exercise and control groups after participation in the pelvic floor muscle exercise programme at 38 weeks'gestational age.

	Exercise group			Control group					
	Mean	SD	n	Mean	SD	n	Significance	Mean difference	(95% CI)
Frequency SUI (times/week)									
38 weeks	12.44	5.27	9	23.06	5.72	16	t = -3.653, P<0.001	-8.91	-13.7, -4.03
Perceived SUI (scores)									
38 weeks	5.02	0.89	9	6.30	1.20	16	t = -2.788, P<0.01	-1.99	-3.42, -0.56

t and P= comparison between after intervention in the control and experimental groups; CI = confidence interval

Table 4 Number of the subjects having different volumes of urine leakage in pregnant women who reported SUI in the experimental and control groups after participation in the PFME programme at 38 weeks'gestational age.

	Exercise group (N=33)		Control group (N=30)		
	n	%	n	%	Significance
Volumes of urine leakage at 38 weeks'gestational age					
No leakage	24	72.7	14	46.7	U = 359 [a], Z=–2.132, P=0.03
Small amount	2	6.1	2	6.7	
Moderate amount	4	12.1	8	26.7	
Large amount	3	9.1	6	20.0	

PFME, Pelvic floor muscle exercise

[a] Mann–Whitney's U-test.

U and P = comparison between after intervention in the control and experimental groups.