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"EFECTO DE LA ACTIVIDAD FÍSICA EN GESTANTES CON SOBREPESO y OBESIDAD"

REVISIÓN SISTEMÁTICA

TESIS PARA OPTAR EL TÍTULO DE LICENCIADA EN TERAPIA FISICA Y REHABILITACION

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DEDICATORIA

El presente trabajo lo dedicamos a nuestros padres, quienes son ejemplo de lucha indesmayable y sus ganas de vivir para ver hecho realidad sus frutos producto de su buena siembra.

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RESUMEN

Objetivo: Determinar el efecto de la actividad física en gestantes con sobrepeso y obesidad.

Métodos: Se ha realizado una revisión sistemática analizando cuatro bases de datos; Pedro Database, Scielo, Pubmed y Ebsco. Los cuales fueron publicados en distintos idiomas entre 2006 y 2016, estos estudios miden la efectividad de la actividad física en toda gestante con sobrepeso u obesidad y verificar su efectividad en la mejora de su condición física, estilo de vida, disminución del peso, disminución de los riesgos de aborto y aminorar el riesgo de desarrollo de diabetes gestacional. La metodología utilizada fue PRISMA. Se encontraron 100 artículos de los cuales se seleccionaron 7 de ellos para su análisis.

Resultados: Se utilizó 07 estudios clínicos controlados, que utilizaron el ejercicio físico o la actividad física en gestantes con sobrepeso u obesidad, para medir su efectividad en esta población.

Conclusión: La actividad física, el ejercicio físico y los estilos de vida saludable son efectivos en la reducción del peso, disminución del riesgo de desarrollar diabetes mellitus, favorecen la regulación de presión arterial, favorece al trabajo de parto y regulan el peso gestacional, y aumentan las probabilidades de nacer con peso promedio normal. Sin embargo, la poca calidad de los estudios revisados no puntúa homogeneidad en los resultados. Se sugiere más estudios y con mayor calidad referentes al tema.

Palabras Claves: Mujer embarazada, sobrepeso, obesidad, actividad física.

SUMMARY

Objective: To determine the effect of physical activity in overweight and obese pregnant.

Methods: A systematic review has been carried out analyzing four databases; Pedro Database, Scielo, Pubmed and Ebsco. Which were published in different languages between 2006 and 2016, these studies measure the effectiveness of physical activity in all overweight or obese pregnant women and verify their effectiveness in improving their physical condition, lifestyle, weight reduction, decrease in the risks of abortion and reduce the risk of developing gestational diabetes. The methodology used was PRISMA. There were 100 articles of which 7 of them were selected for analysis.

Results: We used 07 controlled clinical studies, which used physical exercise or physical activity in overweight or obese pregnant women, to measure its effectiveness in this population.

Conclusion: Physical activity, physical exercise and healthy lifestyles are effective in reducing weight, reducing the risk of developing diabetes mellitus, favoring the regulation of blood pressure, favoring labor and regulating gestational weight, and increasing odds of being born with normal average weight. However, the poor quality of the studies reviewed does not indicate homogeneity in the results. We suggest more studies and with higher quality references to the subject.

Keywords: Pregnant woman, overweight, obesity, physical activity.

CAPÍTULO I

INTRODUCCIÓN

El sobrepeso y la obesidad se vienen incrementando progresivamente tanto en los países desarrollados como en los en vías de desarrollo[1]. La obesidad predispone al desarrollo de varias enfermedades crónicas tales como la hipertensión arterial, enfermedades cardiovasculares, diabetes tipo 2, problemas articulares entre otras[2]. Según la OMS el sobrepeso y la obesidad son el quinto factor de riesgo principal de muerte en el mundo. Cada año fallecen por lo menos 2,8 millones de personas adultas como consecuencia del sobrepeso o la obesidad [3].

En la actualidad, el sedentarismo y los malos hábitos alimenticios provocan un sobrepeso u obesidad en toda la población en general, lo que se extiende también a las mujeres en edad reproductiva[4]. La proporción de obesidad en mujeres embarazadas está aumentando lo cual repercute en posibles complicaciones asociadas con el propio embarazo y con el feto tales como, diabetes gestacional, hipertensión inducida por el embarazo, macrosomía, partos por cesárea, y otros efectos adversos para la salud a largo plazo de la madre y del niño[5,6,7].

En vista de la epidemia global de sedentarismo y enfermedades relacionadas con la obesidad, la actividad física prenatal ha sido útil para la prevención y tratamiento de esas condiciones[8].Por lo que La actividad física puede contribuir a la prevención de diabetes mellitus gestacional y es crucial para evitar esas complicaciones y romper el círculo vicioso relacionado con obesidad infantil y del adulto y diabetes futura[9].

En la actualidad, las mujeres piden una atención en el proceso de gestación, parto y puerperio más personalizada y participativa. Son conocidas las múltiples ventajas que aporta a la salud la práctica de una actividad física de forma continuada; aunque es importante en todas las etapas de la vida, cuando llega la gestación aparecen algunas

dudas sobre la conveniencia de realizar ejercicio físico, así como del tipo de actividad, de su frecuencia, intensidad y duración[10]; Este incierto criterio da lugar, según reporta la literatura, a que se incrementen las tasas de inactividad física durante el embarazo; los cuales oscilan entre el 64,5% y el 91,5%, y tiende a ser mayor en el tercer trimestre del embarazo[11].

La inactividad física durante el embarazo se asocia con una mayor probabilidad de ingreso de los lactantes en las unidades de cuidados intensivos neonatales, de parto pre término, de bajo peso al nacer, de restricción del crecimiento intrauterino y, por último, de cesárea[12].

Los estudios efectuados y que se relacionan con el aparato locomotor establecen que el ejercicio físico se puede llevar a cabo de forma segura. Los últimos han demostrado que el ejercicio físico en las embarazadas, no solo previene la ganancia excesiva de peso en esta etapa, sino también la hipertensión arterial y la diabetes gestacional[13, 14, 15]. El beneficio, no es solo para la madre, sino también para el bebé, pues disminuye el riesgo de peso elevado, lo que podría acarrear un parto distócico[16]. La actividad física se ha identificado como un factor importante para un embarazo saludable en las mujeres de todos los rangos de peso. Las directrices actuales de actividad física sugieren para los adultos, incluidas las mujeres embarazadas, estar activos con un ejercicio de intensidad moderada, durante 30 minutos y casi todos los días. Algunos trabajos vinculan la actividad física con una reducción en el número de cesáreas y de partos instrumentados[17]. Está demostrado en la población en edad reproductiva, principalmente en los grupos de alto riesgo de desarrollo de diabetes mellitus tipo 2 (DMT2), que los cambios en el estilo de vida como el ejercicio regular, el peso saludable y la conducta alimentaria, pueden prevenir su desarrollo[18,19].

1.1. Justificación.

El presente estudio pretende conocer el efecto de la actividad física en gestantes con sobrepeso y obesidad, porque es muy importante en todo el proceso de gestación ya que la obesidad predispone el incremento de varias enfermedades crónicas. Es así que la investigación se considera conveniente y útil, porque es novedosa, considerando que no hay estudios anteriores realizados con respecto al presente tema.

Por otro lado, esta revisión sistemática se enmarca en la prevención e intervención en salud pública, en la etapa de vida de la mujer gestante, desde el punto de vista de la atención en salud se justifica sustentar las acciones preventivo promocionales por medio del actividad física que disminuyan el impacto del sobrepeso y obesidad en el proceso de gestación, dado el riesgo que esta condición tiene sobre la madre gestante, más aun cuando en la actualidad los sistemas de salud carecen de intervenciones en atención primaria o primer nivel de atención específicas para esta condición. Los hallazgos de la revisión sistemática permitirán dar evidencia sobre la actividad física en gestantes con sobrepeso y obesidad, lo cual repercutirá en la salud y prevención de daños en ellas mismas reduciendo así la predisposición al desarrollo de varias enfermedades como: hipertensión arterial, enfermedades cardiovasculares, diabetes tipo 2, entre otras.

Su mayor beneficio será el hecho de cambiar estilos de vida que puedan conducir a enfermedades, que puedan ser evitadas simplemente con la realización de ejercicio físico durante el embarazo, lo cual ayudará a evitar el desarrollo de enfermedades crónicas.

1.2. Planteamiento del Problema.

¿Cuál es el efecto de la actividad física en gestantes con sobrepeso y obesidad?

1.2. Objetivo.

Determinar el efecto de la actividad física en gestantes con sobrepeso y obesidad.

CAPÍTULO II

MÉTODOS

Para la elaboración de esta revisión sistemática fueron utilizadas las directrices propuestas por el PRISMA y sus extensiones.

PRISMA es un conjunto mínimo de elementos basado en evidencia para escribir y publicar revisiones sistemáticas y metanálisis, consta de 27 ítems 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, metaanalisis y análisis de la consistencia, y sesgo de publicación selectiva de estudios o resultados.

2.1. Criterios de Elegibilidad.

Se buscaron estudios clínicos controlados, en los cuales se incluyó a toda gestante con sobrepeso u obesidad, cuyo objetivo fue verificar la efectividad la actividad física, como medidas de resultado se incluyeron a la condición física y estilo de vida, disminución peso, disminución de los riesgos de aborto y la disminución del riesgo de desarrollo de la diabetes gestacional. La fecha de publicación incluida fue desde el año 2006 en adelante; las búsquedas se realizaron en las bases de datos: Pedro Database, Scielo, Pubmed, Ebsco; la información obtenida fue obtenida en todos los idiomas

2.2. Fuentes de Información.

Se utilizaron cuatro fuentes de información: Pedro Database, Scielo, Pubmed Y Ebsco, cuyas características podemos apreciar en la tabla siguiente.

TABLA N°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
EBSCOhost	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

2.3. Búsqueda.

La búsqueda inició con la determinación de las palabras clave “mujer embarazada”, “sobrepeso” y “actividad física” en idioma español y luego ubicando sus sinónimos y terminología MESH o encabezados de términos médicos en idioma ingles a fin de estructurar la búsqueda en las bases de datos seleccionadas, encontrando que las tres palabras clave se encuentran en terminología Mesh.

TABLA N°2

Palabras clave en terminología Mesh y sinónimos en inglés

Término español	mujer embarazada	sobrepeso	actividad física
Término inglés	pregnant women	overweight	physical activity
MESH	si	no	no
Sinónimos	Women, Pregnant		
	Pregnant Woman		
	Woman, Pregnant		

Las estrategias de búsqueda variaron de acuerdo al buscador utilizado y sus características o filtros.

TABLA Nº3

PUBMED

Estrategia	Búsqueda de palabras clave “pregnant women”,”overweight”, “physical activity”, últimos 10 años, solo estudios clínicos controlados.
Entradas	(("motor activity"[MeSH Terms] OR ("motor"[All Fields] AND "activity"[All Fields]) OR "motor activity"[All Fields]OR ("physical"[All Fields] AND "activity"[All Fields]) OR "physical activity"[All Fields]) AND ("overweight"[MeSH Terms]OR "overweight"[All Fields]) AND ("pregnant women"[MeSH Terms] OR ("pregnant"[All Fields] AND "women"[All Fields])OR "pregnant women"[All Fields])) AND (Clinical Trial[ptyp] AND "2006/04/07"[PDat] : "2016/04/03"[PDat])

TABLA Nº4

PEDRO

Estrategia	Búsqueda de palabras clave “pregnant women”,”overweight”, “physical activity”, últimos 10 años, solo estudios clínicos controlados.
Entradas	Abstract & Title: Overweight pregnant women Method: clinical trial New records added since:01/01/2006

TABLA Nº5

EBSCO

Estrategia	Búsqueda de palabras clave “pregnant women”,”overweight”, “physical activity”, últimos 10 años, solo estudios clínicos controlados.
Entradas	physical activity in overweight pregnant women

TABLA Nº6

SCIELO

Estrategia	Búsqueda de palabras clave “pregnant women”,”overweight”, “physical activity solo estudios clínicos controlados.
Entradas	physical activity in overweight pregnant women método: integrada donde: regional

2.4 Selección de los estudios

Todos los estudios deben tener la principal característica el de ser una población gestante con sobrepeso, en quienes se medirá la efectividad de la actividad física, la cual repercutirá beneficiosamente o no en cada una de ellas y haber sido publicados en los últimos de 10 años para ser incluido en la revisión sistemática.

Se excluyeron todos los artículos con una población muestra gestante con problemas cardíacos, también a aquellas que tenían riesgo de aborto y asimismo a toda gestante con hipertensión arterial y haber sido publicado hace más de 10 años atrás.

TABLA N°7

Los criterios de inclusión y exclusión

Inclusión:	Mujeres gestantes con sobrepeso y obesidad
Exclusión:	Mujeres gestantes con problemas cardiacos
	Mujeres gestantes con riesgo de aborto
	Mujeres gestantes con HTA

2.5. Riesgo de sesgo en los estudios individuales.

El riesgo de selección fue realizado analizando la calidad metodológica según la escala de Pedro(11–13) que contiene 11 criterios de los cuales él Nº11 no se puntúa. La puntuación total va del 0 al 10, según los siguientes criterios

ITEMS	
1	Los criterios de elección
2	Asignación aleatoria
3	La asignación fue oculta
4	Comparabilidad inicial
5	Todos los sujetos fueron cegados
6	Todos los terapeutas fueron cegados
7	Todos los evaluadores fueron cegados
8	Seguimiento adecuado
9	Por intención de tratar el análisis
10	Entre el grupo de las comparaciones
11	Apunte estimaciones y variabilidad (no se suma a la puntuación total)

CAPÍTULO III

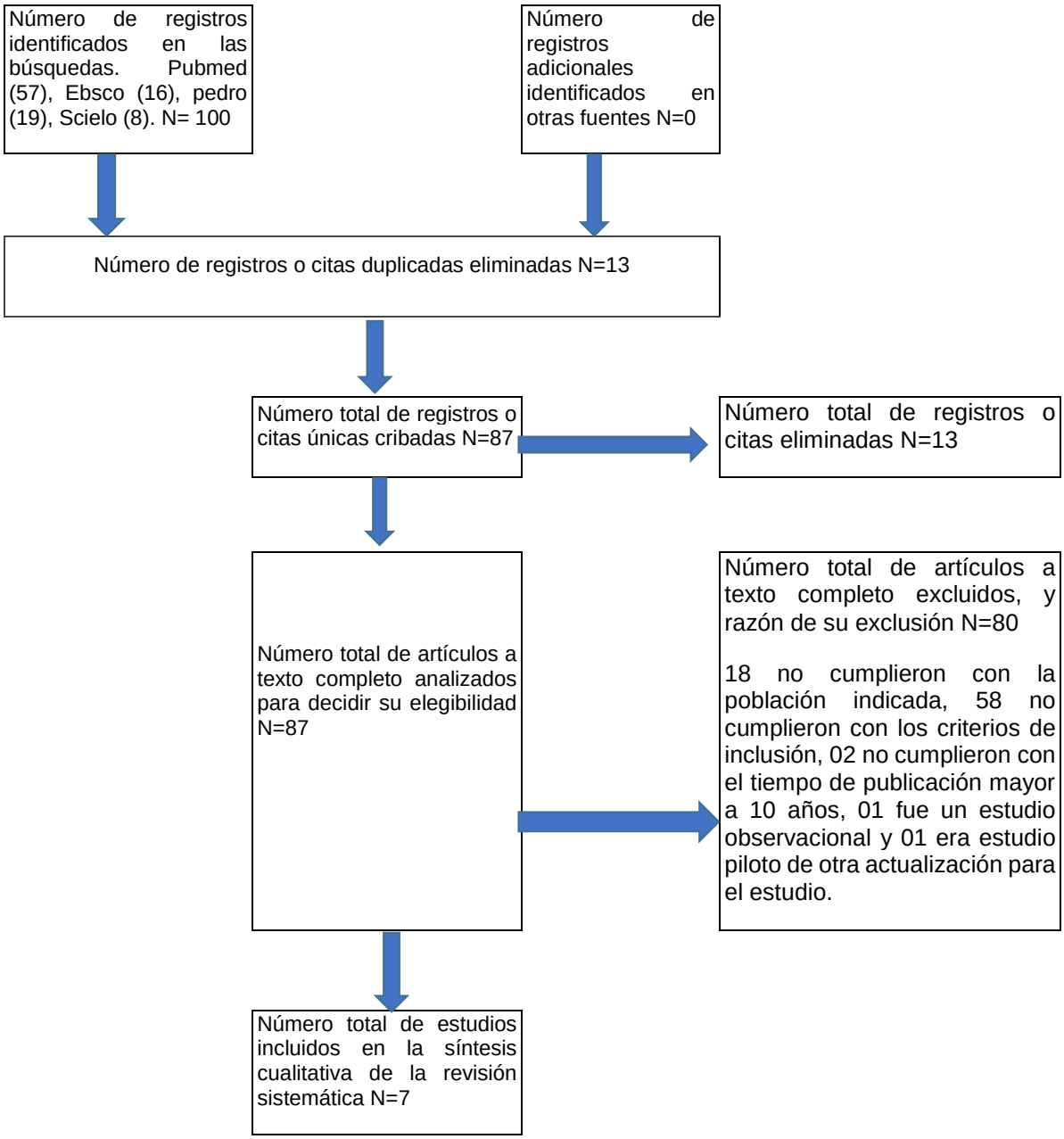
RESULTADOS

3.1. Selección de estudios.

En total se encontraron 100 estudios, después de la eliminación de los duplicados, se escrutaron 87 estudios, de los cuales; 18 no cumplieron con la población indicada, 58 no cumplieron con los criterios de inclusión, 02 no cumplieron con el tiempo de publicación mayor a 10 años, 01 fue un estudio observacional y 01 era estudio piloto de otra actualización para el estudio. Después se leyeron los textos completos, siete artículos cumplieron los criterios de inclusión y fueron incluidos en el estudio.

Los países que participaron en estos estudios fueron: Canadá, Estados Unidos, Finlandia, Brasil, Holanda Y Reino Unido.

GRÁFICO Nº1



3.2. Características de los estudios.

Se utilizaron 7 estudios clínicos controlados, los cuales son caracterizados según la población, intervención, comparación y resultado.

TABLA Nº 8

año y autor	título	población	intervención	resultado
Hui AL et al. 2014	Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy Body Mass Index in a randomized control trial.	116 mujeres embarazadas	sesiones de ejercicio físico y asesoramiento dietético	El programa de intervención de estilo de vida disminuyó la ganancia de peso gestacional excesiva y el peso de los bebés al nacer fue con normalidad.
Jeffries K et al. 2009	Reducing excessive weight gain in pregnancy: a randomised controlled trial	236 mujeres embarazadas	Se les dio una tarjeta de medición de peso personalizado y las instrucciones para registrar su peso en 16, 20, 24, 28, 30, 23 y 34 semanas de gestación.	La medición del peso regular durante el embarazo fue eficaz para las personas gestantes con sobrepeso pero no para las que tienen obesidad.
KAI LING K et al. 2014	A Pilot Walking Program Promotes Moderate-Intensity Physical Activity during Pregnancy	37 mujeres embarazadas con sobrepeso u obeso.	actividad física	la actividad física moderada resultó favorable en el momento del parto
Kinnunen TI et al. 2012 d	Preventing excessive gestational weight gain -- a secondary analysis of a cluster-randomised controlled trial	399 mujeres gestantes	actividad física y alimentación saludable	Tuvo efectos positivos en mujeres con peso gestacional excesiva reduciendo el riesgo de que desarrolle diabetes mellitus gestacional.
Nascimento S et al. 2011	The effect of an antenatal physical exercise programme on maternal/perinatal outcomes and quality of life in overweight and obese pregnant women: a randomised clinical trial	82 mujeres embarazadas	ejercicio físico, asesoramiento y supervisión de ejercicio,	El ejercicio no afectó a la variación de la presión arterial o percepción de la calidad de vida, pero si fue beneficioso para el aumento de peso gestacional y disminuyó el peso en mujeres con sobrepeso.
Oostdam N et al. 2012 b	No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk	121 mujeres	entrenamiento físico(ejercicios aeróbicos y de fuerza)	el ejercicio realizado durante el segundo y tercer trimestre del embarazo no tuvo efectos sobre la glucemia en ayunas, la sensibilidad a la

	for gestational diabetes: results of a randomised controlled trial.			insulina y el peso al nacer, muy probablemente debido al bajo cumplimiento
Stutzman SS et al. 2010	The effects of exercise conditioning in normal and overweight pregnant women on blood pressure and heart rate variability	22 mujeres embarazadas	ejercicio físico (caminar)	en mujeres embarazadas mostraron cambios en la presión arterial y en la función cardiaca

3.3. Evaluación de la calidad.

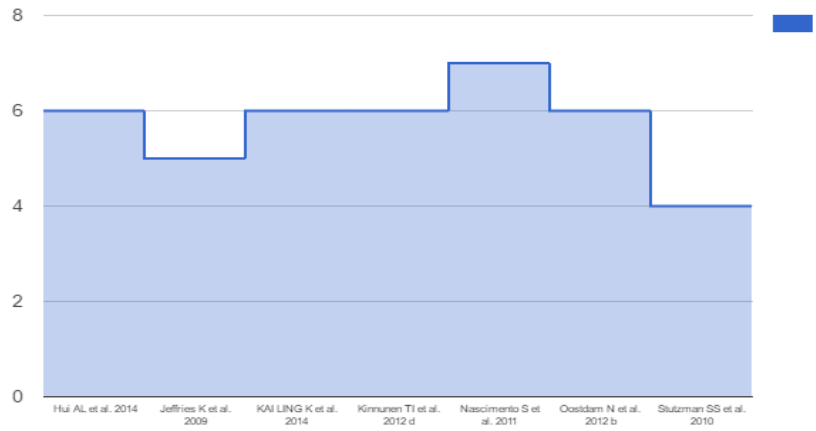
La evaluación de la calidad según la escala de Pedro obtuvo en promedio un puntaje de 6/10.

TABLA N°9

ITEMS		Hui AL et al. 2014	Jeffries K et al. 2009	KAI LING K et al. 2014	Kinnunen TI et al. 2012 d	Nascimento S et al. 2011	Oostdam N et al. 2012 b	Stutzman SS et al. 2010
1	Los criterios de elección	SI	SI	SI	SI	SI	NO	SI
2	Asignación aleatoria	SI	SI	SI	SI	SI	SI	NO
3	La asignación fue oculta	SI	SI	SI	SI	SI	SI	NO
4	Comparabilidad inicial	SI	SI	SI	SI	SI	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	SI	NO
8	Seguimiento adecuado	SI	NO	SI	SI	SI	NO	SI
9	Por intención de tratar el análisis	NO	NO	NO	NO	SI	SI	NO

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	5	6	6	7	6	4

GRAFICO N° 2



3.4. Síntesis de los resultados.

3.4.1.- Estilo de vida y cambio de hábito:

Con respecto al estilo de vida, recibir asesoramiento dietético y ejercicio físico disminuye la ganancia de peso gestacional[20].

La medición del peso regular durante el embarazo fue eficaz para las personas gestantes con sobrepeso pero no para las que tienen obesidad[21].

El programa que incluye asesoramiento sobre actividad física y alimentación saludable en 5 visitas rutinarias, tuvo efectos positivos sobre aquellas mujeres que tenían mayor riesgo para el desarrollo de diabetes gestacional[22].

3.4.2.-Actividad física:

La actividad física moderada en las mujeres embarazadas con sobrepeso u obesidad se realizó mediante caminatas significativas de 80 pasos por minutos, resultando favorable en el momento del parto[23].

3.4.3.- Ejercicio físico:

Con respecto al ejercicio físico, recibir asesoramiento y supervisión de ejercicio físico aumenta el peso gestacional, disminuyó el peso en las mujeres con sobrepeso y no afectó a la variación de presión arterial o la percepción de la calidad de vida[24].

Un programa de ejercicios físicos para embarazadas con sobrepeso u obesidad y riesgo de diabetes mellitus gestacional, el cual consistió en ejercicio aeróbico y de fuerza no redujo los niveles de glucosa en sangre en ayunas materna muy probable debido a la baja de cumplimiento[25]. Sin embargo otro estudio del autor: Kinnunen Ti et al. (20012); en la cual se incluyó asesoramiento de alimentación saludable y actividad física en cinco visitas rutinarias, si mostró efectos positivos sobre la ganancia de peso gestacional y aquellas con riesgo de desarrollar diabetes gestacional.

Un estudio prospectivo en la que se midieron los efectos de un programa de ejercicios, (caminar), en embarazadas con sobrepeso u obesidad, sobre la presión arterial y función cardiaca, dando como resultados que las mujeres con sobrepeso si mostraron cambios en la presión arterial por lo que la variabilidad del ritmo cardíaco se redujo pero no en las que caminaban[26].

TABLA Nº 10

Autor y año	Propósito	Muestra	Medición	Intervención	Resultados	Hallazgos
Hui AL et al. 2014	Los objetivos de este estudio fueron evaluar la eficacia de la intervención del estilo de vida en gestación	116 mujeres embarazadas	Los participantes completaron un cuestionario de actividad física y un registro de alimentos de 3 días en la inscripción y 2 meses después de la inscripción.	Las mujeres del grupo de intervención recibieron sesiones de ejercicio, y asesoramiento dietético. Las Participantes en el grupo de control no recibieron la intervención. Todos los participantes completaron un cuestionario de actividad física y un registro de alimentos de 3 días en la inscripción y 2 meses después de la inscripción.	Los participantes en el grupo de intervención con pre-embarazo normal IMC (≤24.9 kg / m2, n = 30) tuvieron una menor ganancia de peso gestacional (GTG), peso al nacer bebés y la ganancia de peso gestacional excesiva (EGWG) sobre el embarazo El aumento de peso en comparación con el grupo de control (n = 27, p <0,05). No se detectaron En comparación con el grupo control (p <0,05 o 0,01). El aumento de la actividad física y Se detectaron reducción de la ingesta de hidratos de carbono en las mujeres con normal (p <0,05), pero no por encima, pre-embarazo normal BMI a los 2 meses después del inicio de la intervención en comparación con el grupo control.	en este estudio se demostró que el programa de intervención de estilo de vida disminuyó EGWG, GTG, el peso al nacer bebés en las mujeres embarazadas con normalidad, pero no por encima de lo normal, IMC antes del embarazo, que se asoció con un aumento de la actividad física y la disminución de la ingesta de carbohidratos.
Jeffries K et al. 2009	Determinar si la medición de peso regular durante el embarazo puede reducir el aumento excesivo de peso.	236 mujeres embarazadas	Se le dio a cada gestante una tarjeta de medición de peso personalizado y las instrucciones para registrar su peso al final todo fueron cegadas.	Las mujeres asignadas al grupo de intervención se les dio una tarjeta de medición de peso personalizado, advertido de su aumento de peso gestacional óptima, y las instrucciones para registrar su peso en 16, 20, 24, 28, 30, 32 y 34 semanas de gestación. El grupo de control se pesó al momento del reclutamiento, pero no se les dio instrucciones acerca de la	En la población de estudio, se observó una tendencia a una menor ganancia de peso en el grupo de intervención. Las mujeres en el grupo de intervención experimentaron una media La intervención redujo significativamente la ganancia de peso durante la gestación en el grupo de mujeres que tenían sobrepeso, pero no obesos al momento del reclutamiento: los que están en el grupo de intervención (20 mujeres) ganaron una media (DE) de 0,42 (0,153) kg / semana y el grupo de control (18 mujeres) ganaron 0,54 (0,123) kg / semana.	se halló que la medición de peso normal durante el embarazo no es eficaz en la reducción de la ganancia de peso, excepto entre las mujeres que tenían sobrepeso pero no obesidad antes del embarazo

				medición del peso normal. Todos los participantes fueron cegados a la finalidad del estudio.		
KAI LING K et al. 2014	Este estudio tuvo como objetivo promover el MPA entre las mujeres embarazadas con sobrepeso y obesidad, a través de a pie, y para evaluar el efecto de la intervención sobre los resultados maternos y de nacimiento	37 mujeres embarazadas con sobrepeso u obeso.	Se utilizó la prueba de Kolmogorov-Smirnov para caminar análisis de distribución de intensidad, y se utilizó la prueba exacta de Fisher para resultados maternos y neonatales análisis. de correlación de Pearson se utilizó para examinar la asociación entre el índice de masa corporal antes del embarazo y la ganancia de peso durante la gestación y ANOVA se utilizó para determinar las diferencias en la cantidad y paseos a pie significativas,	Las gestantes fueron asignadas al azar a un grupo de intervención o control a pie. Datos objetivos PA (StepWatch ™ Activity Monitor) antropométrica y se recogieron durante cuatro períodos de 1 sem: 10-14 semanas (V1), semanas 17-19 (V2), semanas 27-29 (V3), y las semanas 34-36 (V4) de la gestación. Los participantes proporcionaron información sobre los resultados maternos y de nacimiento. Una cadencia de ≥ 80 pasos por minuto se definió como MPA, y "caminar significativa" se definió como caminar moderado en combates ≥ 8 min.	Hubo significativamente más MPA entre las mujeres en el grupo de intervención en comparación con los del grupo de control en V2 (sobrepeso, P <0,0001; obesos, P <0,025), V3 (sobrepeso, p <0,0001), y V4 (sobrepeso, P < 0,0001; obesos, P <0,025). Las mujeres en el grupo de intervención aumentaron significativamente su significativa paseos en V2 (P = 0,054), V3 (P = 0,01), y V4 (P = 0,014). Hubo una tendencia para las mujeres del grupo de intervención que tienen los resultados maternos y de natalidad más favorables en comparación con el grupo control. Las tasas de GTG en los puntos de medición durante el embarazo se asociaron significativamente con las tasas anteriores de GTG.	El piloto, la intervención caminar sin supervisión aumenta el AMP de las mujeres con sobrepeso y obesidad durante el embarazo
Kinnunen TI et al. 2012 d	Hemos examinado si la intervención del estilo de vida diseñado para evitar	399 mujeres gestantes	Los análisis estadísticos se realizaron utilizando modelos de regresión lineal y	La intervención incluyó asesoramiento sobre GTG, la actividad física y la alimentación saludable en cinco visitas rutinarias	El grupo de intervención tuvo una media menor GTG por semanas de gestación que en el grupo de atención habitual (coeficiente ajustado por las diferencias entre los grupos -0.016 kg por día,	La intervención tuvo efectos menores sobre GTG entre las mujeres que tenían un mayor riesgo para la diabetes gestacional. A fin de evitar la excesiva GTG, puede ser necesario un enfoque adicional en la

	DMG fue eficaz para reducir el aumento de peso gestacional excesiva (GTG).		logística multinivel ajustados por semanas de gestación en la última medición de peso, índice de masa corporal previo al embarazo y el consumo de tabaco.		P = 0,041). No hubo diferencias en la media (± S.D.) GWG entre la intervención y los grupos habituales de atención (13,7 ± 5,8 vs 14,3 ± 5,0 kg, p = 0,64). En total el 46,8% del grupo de intervención y el 54,4% del grupo de atención habitual superado las recomendaciones GTG. El odds ratio ajustado por excesiva GTG (IC del 95%: 12:53-1:26, P = doce y treinta y seis) de 0,82 en el grupo de intervención con la comparación del grupo de atención habitual.	restricción de la ingesta energética.
Nascimento S et al. 2011	Evaluar la eficacia y seguridad de ejercicio físico en términos de los resultados maternos y perinatales / la percepción de calidad de vida (CV) en mujeres embarazadas obesas y con sobrepeso.	82 mujeres embarazadas	Todas las mujeres embarazadas completaron el cuestionario WHOQOL-BREF, en dos ocasiones: en la inclusión del estudio y al final de las 36 semanas de gestación. Los dominios de este cuestionario se califica en una escala de 0-100 puntos. Los valores más cercanos a 0 eran indicativos de peor CV y valores más cercanos a 100 refleja una mejor calidad de vida.	Las mujeres se asignaron al azar en dos grupos: las mujeres en un grupo realizadas en ejercicio de la supervisión y recibieron asesoramiento de ejercicios en casa (el "grupo de estudio", n = 40) y mujeres en el otro grupo siguió el programa de atención prenatal de rutina (el "grupo de control"; n = 42).	En el grupo de estudio, el 47% de las mujeres embarazadas tuvieron ganancias de peso por encima del límite recomendado, con la comparación del 57% de las mujeres en el grupo de control (P = 12:43). No hubo diferencia en la ganancia de peso durante la gestación entre los grupos. Las mujeres con sobrepeso embarazadas que hacían ejercicio ganaron menos peso durante todo el embarazo (10,0 ± 1,7 kg vs. 16,4 ± 3,9 kg, respectivamente; p = 0,001) y después de la entrada en el estudio (5.9 ± 4.3 kg vs. 11,9 ± 1,5 kg, respectivamente; p = 0021) en comparación con las mujeres del grupo de control. La presión arterial fue similar entre los grupos en el tiempo. No hubo diferencia en el resultado perinatal o la calidad de vida.	El programa de ejercicios no se asoció con el control de ganancia de peso durante la gestación en la muestra en su conjunto, pero era beneficioso para el aumento de peso gestacional menor en las mujeres con sobrepeso. El ejercicio no se asoció con resultados perinatales adversos y no afectó a la variación de la presión arterial o la percepción de la calidad de vida.
Oostdam N et al. 2012 b	Evaluar la efectividad de un programa de ejercicios para las mujeres	121 mujeres	Las medidas de resultado materna fueron la glucemia en ayunas (mmol / l) La	Programa de entrenamiento físico durante el embarazo. El entrenamiento consistió en ejercicios	Análisis por intención de tratar Mostró Que el programa de ejercicio no redujo los niveles de glucosa en sangre en ayunas materna ni sensibilidad a la insulina. Además, no se encontró	La intervención de ejercicios realizados a lo largo del segundo y tercer trimestre de embarazo tenía los efectos sobre la glucemia en ayunas, sensibilidad a la insulina, y el peso al nacer, muy probablemente debido a la

	embarazadas que tenían sobrepeso u obesidad y el riesgo de la diabetes mellitus gestacional (DMG).		insulina en ayunas (pmol / l) y la HbA1c (%) Peso corporal (kg), el índice de masa corporal (kg / m) (2), y la actividad física diaria (minuto / semana). Las medidas de resultado descendientes eran el peso al nacer y el crecimiento fetal	aeróbicos y de fuerza,	efecto sobre el peso al nacer.	baja de cumplimiento. La alta prevalencia de las mujeres en situación de riesgo para la diabetes gestacional requiere una mayor investigación sobre posibles intervenciones Que puede prevenir la diabetes gestacional, y otros tipos de intervenciones para participar este grupo objetivo de la actividad física y el ejercicio.
Stutzman SS et al. 2010	El propósito de este estudio prospectivo fue medir los efectos de un programa de ejercicios en el peso normal y las mujeres embarazadas con sobrepeso / obesidad sobre la presión arterial (PA) y la función autonómica cardiaca, determinado por la variabilidad del ritmo cardíaco (HRV) y la sensibilidad barorrefleja (BRS)	22 mujeres embarazadas	BP, la VFC y BRS se midieron en reposo y durante el ejercicio al principio (20 semanas de EG) y el final (36 semanas GA) del programa de caminar.	Los pacientes fueron asignados de forma sistemática a un ejercicio (caminar) o grupo control (no caminar)	Los resultados indicaron Que las mujeres en los grupos de control (especialmente las mujeres con sobrepeso) mostraron cambios en la presión arterial, la VFC, BRS y otra vez Que el embarazo no se observaron en el grupo de caminantes. Las mujeres con sobrepeso en el grupo de control aumentaron la PA en reposo sistólico en 10 mmHg y la diastólica por 7 mmHg. HRV se redujo en el grupo de control, pero no en el grupo de caminar. La reducción de BRS y el intervalo R-R en reposo se encuentra en todos los grupos excepto el grupo de caminar de peso normal	Los resultados sugieren un programa de ejercicios atenuar Que Podría el aumento de la PA y la pérdida de tono parasimpático asociado con el embarazo, especialmente en las mujeres con sobrepeso.

CAPÍTULO IV

DISCUSIÒN

Según Kinnunen TI et al. (2012d), la actividad física y la alimentación saludable tuvo efectos positivos en mujeres con peso gestacional excesiva reduciendo el riesgo de que desarrolle diabetes mellitus gestacional.

Pero según Oostdam N et al. (2012b), en un programa de entrenamiento físico (ejercicio aeróbico y de fuerza) realizado durante el segundo y tercer trimestre del embarazo, nos dice que no se obtuvo efectos sobre la glucemia en ayunas, ni la sensibilidad a la insulina y el peso al nacer, por lo que es importante incluir esquemas nutricionales y al ejercicio físico desde el primer trimestre.

En el estudio realizado por Nascimento S et al. (2011), el ejercicio físico, asesoramiento y supervisión del ejercicio, no afectó a la variación de la presión arterial o percepción de la calidad de vida, pero si fue beneficioso para el aumento de peso gestacional y disminuyó el peso en las mujeres con sobrepeso.

Mientras que Stutzman S et al. (2010), nos dice que el ejercicio físico (caminar) en mujeres embarazadas mostró cambios en la presión arterial y la función cardiaca.

En los estudios realizados por Jeffries K et al. (2009), se utilizó una tarjeta de medición de peso personalizada y las instrucciones para registrar su peso, la medición del peso regular durante el embarazo fue eficaz para las personas gestantes con sobrepeso pero no para las que tienen obesidad.

Por su parte Hui AL et al. (2014), menciona que las sesiones de ejercicio físico y asesoramiento dietético disminuyó la ganancia de peso gestacional excesiva y el peso de los bebés al nacer fue con normalidad.

En el estudio realizado por Kailing K et al. (2014), muestra que la actividad física moderada resulta favorable en el trabajo de parto.

4.1. Limitaciones.

Se ha encontrado como limitación la baja calidad metodológica de un estudio que obtuvo un puntaje menor a 5, estimando que la estadística de pedro el promedio de los estudios clínicos la base es 5, lo que puede limitar la validez interna de los resultados de este estudio.

No se encontraron muchos artículos de investigación adecuados y acordes al tema, para la medición de la actividad física en gestantes, ya que en la mayoría de las investigaciones que se encontraron fueron estudios basados en cuestionarios.

No se realizó la búsqueda de artículos en la base de datos; SCOPUS, EMBASE y COCHRANE, debido a que se requiere de un registro y previo pago.

Así mismo, las publicaciones de la información son repetidas y el acceso al texto completo es restringido en algunas bases de datos.

4.2. Conclusiones.

Sobre la actividad física en gestantes con sobrepeso y obesidad

- La actividad física moderada favorece el trabajo de parto.
- La práctica de la medición del peso en una tarjeta personalizada fue eficaz en la disminución del peso de las gestantes con sobrepeso, pero no tuvo resultados en las gestantes con obesidad.
- La actividad física y la alimentación saludable reducen el riesgo de desarrollar diabetes mellitus gestacional.

Sobre ejercicio físico en gestantes con sobrepeso y obesidad

- El ejercicio físico supervisado aumenta el peso gestacional y disminuye el sobrepeso de las gestantes.

- El ejercicio físico mediante caminatas muestra cambios en la presión arterial regulando la función cardiaca.
- Las sesiones de ejercicio físico más asesoramiento dietético regulan el peso gestacional, y aumentan las probabilidades de nacer con peso promedio normal.

CAPÍTULO V

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

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ANEXOS

BMC Pregnancy & Childbirth

RESEARCH ARTICLE Open Access

Effects of lifestyle intervention on dietary intake, physical activity level, and gestational weight gain in pregnant women with different pre-pregnancy Body Mass Index in a randomized control trial

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Abstract

Background: The objectives of this study were to assess the efficacy of lifestyle intervention on gestational weight gain in pregnant women with normal and above normal body mass index (BMI) in a randomized controlled trial.

Methods: A total of 116 pregnant women (<20 weeks of pregnancy) without diabetes were enrolled and 113 pregnant women completed the program. Participants were randomized into intervention and control groups. Women in the intervention group received weekly trainer-led group exercise sessions, instructed home exercise for 3-5-times/week during 20-36 weeks of gestation, and dietary counseling twice during pregnancy. Participants in the control group did not receive the intervention. All participants completed a physical activity questionnaire and a 3-day food record at enrolment and 2 months after enrolment.

Results: The participants in the intervention group with normal pre-pregnancy BMI (≤24.9 kg/M2, n = 30) had lower gestational weight gain (GWG), offspring birth weight and excessive gestational weight gain (EGWG) on pregnancy weight gain compared to the control group (n = 27, $p < 0.05$). Those weight related-changes were not detected between the intervention (n = 27) and control group (n = 29) in the above normal pre-pregnancy BMI participants. Intervention reduced total calorie, total fat, saturated fat and cholesterol intake were detected in women with normal or above normal pre-pregnancy BMI compared to the control group ($p < 0.05$ or 0.01). Increased physical activity and reduced carbohydrate intake were detected in women with normal ($p < 0.05$), but not above normal, pre-pregnancy BMI at 2 months after the onset of the intervention compared to the control group.

Conclusion: The results of the present study demonstrated that the lifestyle intervention program decreased EGWG, GWG, offspring birth weight in pregnant women with normal, but not above normal, pre-pregnancy BMI, which was associated with increased physical activity and decreased carbohydrate intake.

Trial registration: NCT00486629

Keywords: Pregnancy, Gestational diabetes, Nutrition, Pregnancy weight gain

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Background

Obesity has been recognized as a health issue, which increases risk for several common chronic diseases [1-3]. The guidelines of the Canadian Medical Association Institute for the management and prevention of obesity have recommended the measurement of both body mass index (BMI) and waist circumference to assess the level and distribution of adiposity in adults [4]. BMI was calculated as weight in kilograms divided by height in meters squared. Health Canada defines underweight as a BMI less than 18.5 kg/m [2], normal weight as a BMI of 18.5-24.9, overweight as a BMI of 25.0-29.9, class I obesity as a BMI of 30.0 - 34.9, class II obesity as a BMI of 35.0 -39.9, and class III obesity as a BMI ≥ 40.0 [1]. In Canada, it was estimated that approximately 8.6 million of adults with age >18 years were overweight and 5.5 million were obese in 2005 [5]. The rising prevalence of obesity has increased the percentage of obesity in women at childbearing age in Canada. The 2006-2007 Canadian Maternal Experience Survey estimated that approximately 23% and 18% of the women began their pregnancy as overweight or obese [6]. Pre-pregnancy BMI ≥25 or above normal BMI increases the risk of poor outcomes of pregnancy including gestational diabetes, preeclampsia, hypertension and cesarean section [7].

In 2009, the Institute of Medicine (IOM) revised the 1990 guidelines of recommended weight gain during pregnancy in response to the worldwide epidemic of obesity and the demand to reduce obesity [7]. The guidelines have been endorsed by the American College of Obstetricians and Gynecologists [8] and the Health Canada [9]. Behavioral interventions such as weight awareness and dietary pattern improvement may mitigate the risks of pregnancy complications. Several studies examined the impact of lifestyle interventions (dietary intervention with or without added physical activity) on excessive gestational weight gain (EGWG) using the IOM 2009 guidelines. The results of those studies, either randomized controlled trials (RCT) or clinical studies, were not homogenous [10-19]. We hypothesize that normal weight and above normal weight pregnant women may have different responses to a lifestyle intervention in terms of gestational weight gain (GWG).

In order to test this hypothesis, we examined the impact of a lifestyle intervention program on pregnant women in normal and above normal pre-pregnancy BMI categories. EGWG, physical activity levels, dietary intake were compared between the control and intervention groups in each BMI category via a RCT.

Methods

Subjects

This study recruited 116 pregnant women who lived in Winnipeg, Manitoba between May 2009 and December 2011. This sample size was based on two previous studies that using Pre-pregnancy BMI subgroups and detected significant gestational weight gain difference between two BMI groups [13,16]. Inclusion criteria were: less than 20 weeks of pregnancy, no existing diabetes during pregnancy and signed consent form. These participants were recruited from prenatal classes or community clinics through posters or local newspaper advertisements in Winnipeg. The study protocol and consent form were approved by the Research Ethics Board of the University of Manitoba. Three applicants were excluded from the study because of the existence of medical or obstetric contraindication for exercise during pregnancy. One hundred and thirteen eligible participants were randomized into control or intervention group (Figure 1). Randomization was performed using a computer-generated randomization allocation table by a staff member without involvement in the study design. After randomization, participants received a sealed envelope labelled with the assigned randomization number, which contained instructions for participants. The nature of the study meant that participants and study staff were not blinded to the types of interventions. None of the participants discontinued during the participation. No complain to the program was reported by the participants.

Intervention program

Instructed exercise

Participants in the intervention group received community-based weekly exercise program which was developed in our previous studies [19,20]. The exercise program included mild-to-moderate aerobic exercise, stretching, and strength exercise, and was delivered in weekly group exercise class or a DVD format to assist home exercise. Participants were encouraged to exercise for 3-5 times a week, 30-45 minutes/time, including attending group exercise class or following the exercise DVD instruction at home. The exercise intervention period was from 20-26 gestational weeks to 36 gestational weeks. Participants kept a logbook on their exercise activities as a motivator for exercise. Attendance less than 3 times at the group exercise, showed no interest to exercise at home or no record of exercise in logbook were considered as withdraw from the study.

Dietary intervention

Participants in the intervention group received one-on-one private dietary consultation at baseline and at two months after. The dietary consultation was performed using a Food Choice Map (FCM) software. The FCM has been proved to be a valid tool for assessing dietary intake [21]. During the consultation, participants recalled their food intakes in a typical week. Participants and dietitians jointly placed food stickers on a magnetic board. The

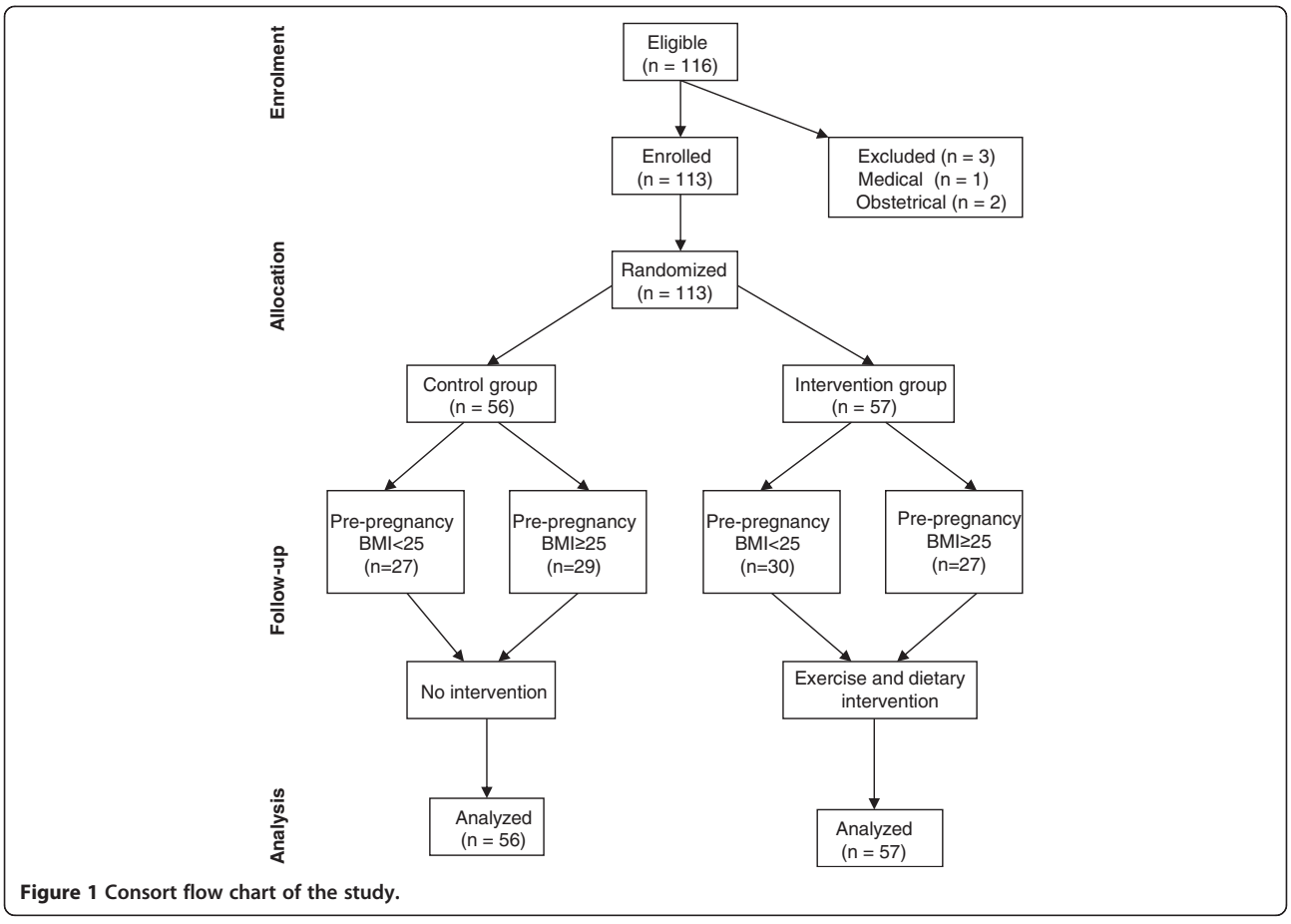

Figure 1 Consort flow chart of the study.

nutritional information on the food sticker, including food items, portion sizes, the frequency of each food, was scanned into the computer at the end of each interview [22]. Daily calorie intake and macronutrients were analyzed instantly. Nutritional recommendations were based on the dietary intake analysis and Health Canada guidelines for food intake in pregnancy [23,24] with considerations on personal food preference, food beliefs, and food budgeting. Weight gain goal was discussed and emphasized through consultation. FCM is an effective way to identify factors that are relevant to a particular health behavior in a population under investigation. Such a tool allows the participants to comment on all the foods that she consumed in real life, without missing or neglecting certain foods cognitively. Results from this kind of data collection could capture the whole picture of food choice decision makings in the participants. Food Choice Map (FCM) interview tool provided such an opportunity to obtain a complete weekly intake and reasons behind food choices. This approach is unique in the literature. Because of this approach, the nutrition intervention was not simply making dietary assessment and deliver education, but to create a personalized, achievable dietary plan with consideration of participants reasons for food choice decision making. A copy of the FCM with agreed changed written on the copy was given to the participant. This copy was served as the diet plan to promote dietary behavior changes. A follow-up dietary consultation was performed at 2 months later to reinforce the recommendations.

Control group

Participants in the control group did not receive the exercise and dietary interventions. Participants in the control group received standard prenatal care recommended as by the Society of Obstetricians and Gynecologists of Canada. They were also provided with a package of current information on physical activity and healthy eating during pregnancy from the Health Canada [25].

Data collection

Data on delivery route, maternal weight at delivery room, birth weight and birth weight-related obstetric procedures (induction, forceps or caesarean section) were collected from hospital medical charts by student assistants without knowledge in study design. Diagnosis of

gestational diabetes was done by the participant's attending health care team according to the 2008 guidelines of the Canadian Diabetes Association [26]. Large-for-gestational-age was determined based on birth weight and gestational age as previously described [27]. Pre-pregnancy weights of participants, height and BMI were obtained from the Manitoba Prenatal Care Record. If the pre-pregnancy weight was missing on the record, the weight at the first contact of study participation (less than 10 weeks gestation) was used as pre-pregnancy weight. GWG was defined as maternal weight at delivery subtracts pre-pregnancy weight. EGWG was calculated by subtracting the upper limit of normal weight gain for corresponding pre-pregnancy BMI according to the 2009 guidelines of IOM [7] from the actual weight gain (difference between pre-pregnancy weight and bodyweight at delivery room).

Physical activity levels at the enrolment and 2 months thereafter were assessed subjectively in all participants using a PARMed-X form for Pregnancy designed by the Canadian Society of Exercise Physiology, which was validated previously using peak oxygen consumption [28]. Unfit (physical activity index = 0) during pregnancy was defined as recreational activity <1–2 times/week plus <20 minutes/time. Active (physical activity index = 1) was defined as recreational activity 1–2 times/week, >20 minutes/time or >2 times/week but <20 minutes/time. Fit (physical activity index = 2) was defined as recreational activity >2 times/week plus >20 minutes/time [19].

Food intakes of all participants were assessed using 3-day food records at enrolment and 2 months after the enrolment [29]. The results of self-reported food intake were analyzed using NutriBase 6.0 software containing Canadian Food Database (Cyber- Soft, Inc., Phoenix, AZ, USA).

Statistical methods

The statistical analyses were performed by a third party. Quantitative data were expressed in mean ± SD. The comparisons for continuous data between 2 groups were conducted using the Student t-test. Categorical data were analyzed using non-parametric Fisher's exact test. The significant difference was pre-set at $p < 0.05$.

Results

One hundred and thirteen participants (56 in the control group and 57 in the intervention group) completed their program and delivered babies before December 31, 2011. All participants in the intervention group met with the dietitian at baseline and at 2 months after. These women attended the group exercise and exercise regularly at home according to the protocol. No withdraw from both intervention and control groups. In the intervention group, 30 women had their pre-pregnancy BMI ≤24.9, and 27 women had their pre-pregnancy BMI ≥25. In the control group, 27 women had their pre-pregnancy BMI ≤24.9 and 29 women had pre-pregnancy BMI ≥ 25. No significant difference was detected in pre-pregnancy BMI, the proportions of First Nations women, or annual family income between the control and intervention groups (Table 1).

In the normal pre-pregnancy BMI subgroups, the amount of GWG was approximately 20% lower in the intervention group compared to that in the control group (16.23 ± 4.38 kg vs. 12.9 ± 3.72 kg, $p < 0.05$). The rate of EGWG was significantly lower in the intervention group compared to that in the control group (10% versus 37%, $p < 0.05$). Birth weights of offspring of participants in the intervention group were significantly lower than that in the control group (3 633 ± 555 g vs. 3 356 ± 474 g, $p < 0.05$).

Table 1 Demographic and outcome data

	Pre-pregnancy BMI ≤ 24.9			Pre-pregnancy BMI ≥ 25		
Variables	**Control n = 27**	**Intervention n = 30**	**P-value**	**Control n = 29**	**Intervention n = 27**	**P-value**
Age (years)	29 ± 6	31 ± 3	0.06	32 ± 5	31 ± 4	0.41
Length of intervention (weeks)	0	27.83 ± 5.67		0	26.74 ± 6.17*	
Family annual income ($)	54,404 ± 33,689	53,564 ± 24,128	0.91	50,992 ± 23,199	56,772 ± 26,355	0.39
First Nations (number %)	1/27	2/30	0.62	4/29	3/27	0.92
Pre-pregnancy BMI	22.6 ± 1.9	21.6 ± 2.2	0.06	29.7 ± 1.3	29.5 ± 5.1	0.92
Gestational weeks (week)	39.6 ± 0.9	39.7 ± 1.1	0.78	39.8 ± 1.1	39.7 ± 1.3	0.92
Gestational weight gain (kg)	16.23 ± 4.38	12.9 ± 3.72	0.03	14.39 ± 7.05	15.21 ± 7.5	0.26
EGWG (2009 IOM guidelines number %)	10/27 (37%)	3/30 (10%)	0.03	20/29 (69%)	18/27 (67%)	0.67
Birth weight (g)	3,633 ± 555	3,356 ± 474	0.047	3650 ± 481	3,665 ± 506	0.92
Large-for-gestational-age (n %)	3/27 (11%)	2/30 (7%)	0.902	1/29 (3%)	4/27 (15%)	0.13
Gestational diabetes (n %)	0/27	0/30	NS	3/29 (10%)	1/27 (4%)	0.307
Cesarean section (n %)	0/27	0/30	NS	2/29 (7%)	0/27	0.503

Values were expressed in mean ± SD or case/total (0%). P values with underline are statistical significant.
*The p value between the pre-pregnancy BMI ≤ 24.9 intervention group and the Pre-pregnancy BMI ≥ 25 intervention group is 0.49.

These variables were not significantly different between the intervention and control groups in the above normal pre-pregnancy BMI women. No significant difference was detected in the prevalence of large-for-gestational age baby, gestational diabetes or cesarean section requirement between the intervention and control groups in women with different pre-pregnant women BMI categories (Table 1).

All participants returned food records and physical activity questionnaires at baseline and at 2 months after. At baseline, no significant difference in nutritional intake or physical activity was detected in normal pre-pregnancy BMI women with and without the lifestyle intervention. The lifestyle intervention significantly improved the pattern of nutritional intake in the normal pre-pregnancy BMI participants compared to the control group. Significantly lower daily intakes of total calorie (2 016 ± 496 kcal vs. 2 551 ± 1 044 kcal), carbohydrate (286.3 ± 80.7 g vs. 355.2 ± 147.6 g), total fat (63.1 ± 23.2 g vs. 87.5 ± 41.6 g), saturated fat (20.0 ± 9.5 g vs. 29.52 ± 16.7 g), and cholesterol (225.0 ± 115.9 mg vs. 340 ± 224.9 mg) were detected in normal pre-pregnancy BMI women who received the lifestyle intervention compared to that in the control group ($p < 0.03$-0.008, Table 2). Among participants with pre-pregnancy BM I ≥ 25, significantly lower intakes of total calorie (1 986 ± 470 kcal vs. 2 258 ± 546 kcal), total fat (65.7 ± 27.1 g vs. 83.5 ± 30.3 g), saturated fat (20.6 ± 10.3 g vs. 27.8 ± 10.6 g) and cholesterol intake (202.0 ± 104.3 mg vs. 305.7 ± 215.2 mg), but not carbohydrate intake, were detected between above normal pre-pregnancy BMI women with and without intervention at 2 months after the onset of the intervention ($p \leq 0.05$-0.01, Table 3).

At baseline, no significant differences in physical activity level were detected among any group. However, only women with pre-pregnant BMI ≤ 24.9 had significantly higher physical activity units at 2 months after the start of the exercise intervention (intervention group: baseline 1.4 ± 0.81 versus 2 months after, 1.87 ± 0.35, $p < 0.05$). No significant difference in physical activity was observed in the above normal pre-pregnant BMI group between baseline and 2 months after (control: baseline 1.70 ± 0.61 versus 2 months after 1.56 ± 0.51, Figure 2).

Discussion

The results of previous studies on the efficacy of lifestyle interventions on gestational weight gain or EGWG in overweight or obese women were inconsistent. Two studies that were similar to our study design were Polley et al. and Wolff et al. [13,16] Polley et al. reported that education about weight and exercise reduced EGWG in normal weight pregnant women, but not in overweight pregnant women, in a RCT [16]. Wolff et al. described that dietary counseling significantly reduced GWG in obese pregnant women, but did not affect the rate of EGWG between control and intervention group in another RCT [13]. The present RCT demonstrated that pregnant women with normal pre-pregnancy BMI, but not those with above normal pre-pregnancy BMI, had better weight-related pregnancy outcomes including EGWG, GWG and birth weight of offspring following the lifestyle intervention compared to the control group. The results from the present study support the findings that women with above normal pre-pregnancy BMI are relatively resistant to the lifestyle intervention in terms of GWG reported by Polley et al. [13], which is possibly related to the response of the pregnant women to lifestyle education on food intake and physical activity. Normal pre-pregnancy weight appears to be more perceptive to the lifestyle education to improving weight-related pregnancy outcomes during pregnancy. The current study had different results in pregnancy outcomes compared to Wolff's study. However, total calorie, fat, saturated fat, and cholesterol intake reduction were significantly reduced in the above normal pre-pregnancy BMI group; the pre-pregnancy outcome significance may be detected when the sample size increases.

The nutrition intervention component in this study is unique compared to other nutrition interventions reported in the literature, which used newsletters, group education sessions, personal counselling provided calories and nutrients goals [11-18]. The results showed that all participants in the intervention group made dietary changes regardless with pre-pregnancy BMI. The FCM interview approach ensured a complete review and discussion of a weekly eating pattern. The FCM in-depth interview could explore meanings behind the food choices

Table 2 Nutrition data of participants with pre-pregnancy BMI ≤ 29.4

Daily intake	Baseline			2 months		
	Control (n = 27)	Intervention (n = 30)	P value	Control (n = 27)	Intervention (n = 30)	P value
Toatal calorie	2239 ± 654	1982 ± 496	0.12	2551 ± 1044	2016 ± 496	0.01
Carbohydrate (g)	302.4 ± 77.7	272.8 ± 64.1	0.12	355.2 ± 147.6	286.3 ± 80.7	0.03
Protein (g)	90.9 ± 42.8	89.0 ± 27.4	0.85	96.8 ± 40.7	88.7 ± 25.1	0.36
Fat (g)	77.9 ± 30.4	64.4 ± 34.5	0.13	87.5 ± 41.6	63.1 ± 23.2	0.008
Saturated (g)	26.2 ± 12.5	21.17 ± 1.1	0.11	29.52 ± 16.7	20.0 ± 9.5	0.008
Cholesterol (mg)	275.4 ± 182.2	247.6 ± 114.8	0.49	340 ± 224.9	225.0 ± 115.9	0.02

Values are expressed in mean ± SD and analyzed. a: Control versus Intervention at baseline; b: Control versus Intervention at 2 months after enrollment.

Table 3 Nutrition data of participants with pre-pregnancy BMI ≥ 25

Daily intake	Baseline			2 months		
	Control (n = 29)	Intervention (n = 27)	P value	Control (n = 29)	Intervention (n = 27)	P value
Total calorie	2089 ± 517	2204 ± 693	0.48	2258 ± 546	1986 ± 470	0.05
Carbohydrate (g)	280.1 ± 77.2	303.0 ± 93.8	0.32	294.4 ± 86.7	278.5 ± 64.0	0.44
Protein (g)	91.2 ± 26.1	86.2 ± 25.0	0.46	92.0 ± 26.1	83.1 ± 22.1	0.17
Fat (g)	68.0 ± 23.3	77.8 ± 35.3	0.22	83.5 ± 30.3	65.7 ± 27.1	0.02
Saturated fat (g)	24.7 ± 8.3	22.6 ± 10.4	0.41	27.8 ± 10.6	20.6 ± 10.3	0.01
Cholesterol (mg)	268.8 ± 162.19	193.3 ± 111.6	0.05	305.7 ± 215.2	202.0 ± 104.3	0.03

Values are expressed in mean ± SD and analyzed. a: Control versus Intervention at baseline; b: Control versus Intervention at 2 months after enrollment.

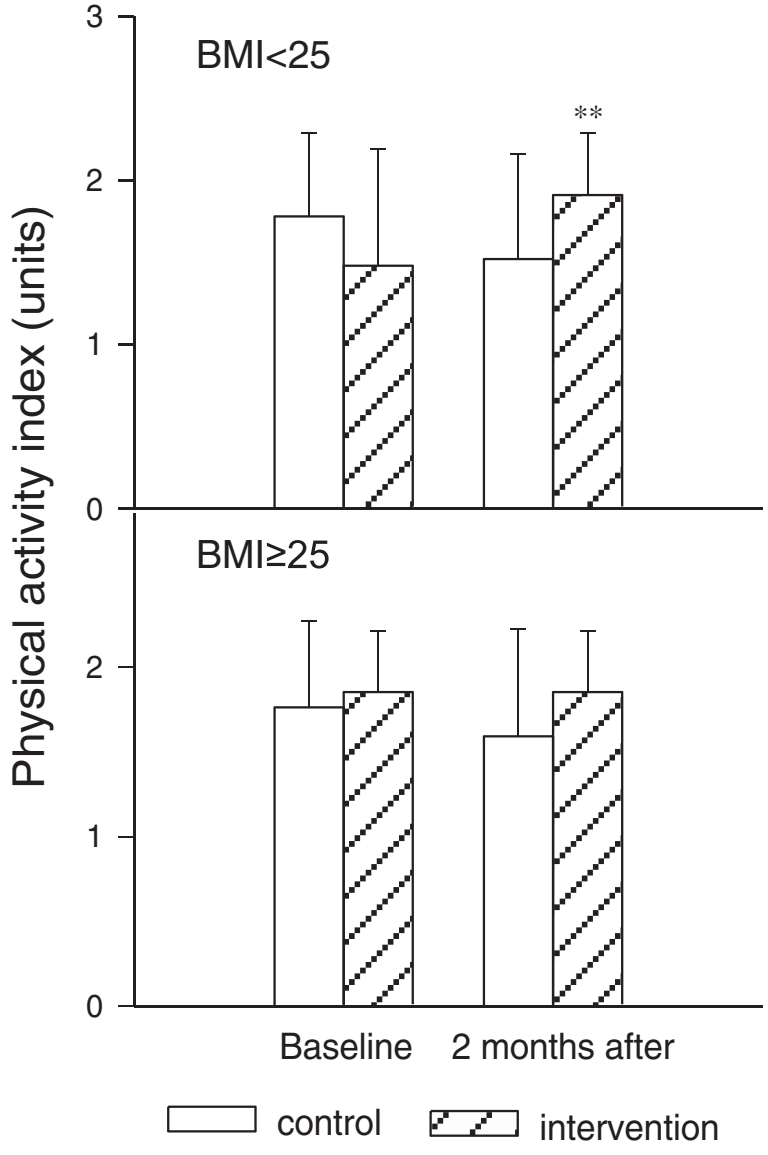

Figure 2 Effect of lifestyle intervention on physical activity index levels in pregnant women with normal or above normal pre-pregnancy BMI at base line and 2 months after enrolment. Upper: normal pre-pregnancy BMI (control n = 27, intervention n = 30); bottom: above normal pre-pregnancy BMI (control n = 29, intervention n = 27). Values were expressed in mean ± SD. **: $p < 0.01$ versus control group with corresponding pre-pregnancy BMI.

and is an unique approach in the literature. Results from this kind of data collection could capture the whole picture of food choice decision-makings in the participants. This is a good indicator that the FCM promoted dietary changes with good understanding of the reasons of participant's food decision making. Women with high pregnancy BMI could have long-term lifestyle habits that influence their food choice, although could be identify through FCM, it might be harder to correct in a limited of time to show significant improvements in gestational weight gain.

Exercise intervention in the literature was either a general encouragement of mild exercise such as walking, or gave verbal or written information on exercise [11-18]. The exercise intervention in this study was a combination of feasible exercise at home and group exercise to strengthen the adherence to the exercise routine. A specifically designed video exercise instruction guided the home exercise which ensured the participant can exercise at the appropriate intensity level on regular basis. This was extremely helpful when the participant could not come to the group exercise due to conflict appointments or weather changes. Weekly group exercise led by a professional trainer helped participants to acquire and validate knowledge and skills for exercise during pregnancy. Group exercise may also help to develop acceptance and adhesion of pregnant women to the healthy lifestyle program. The activity logbook and follow-up visits helped the monitoring of physical activity in participants.

Homogenous recommendation on total calorie intake for normal and overweight pregnant women could be one of reasons for inappropriate GWG and related outcomes in pregnant women with above normal pre-pregnancy BMI. The IOM Food and Nutrition Board published Dietary Reference Intake information for pregnant women in 2006 [23]. Health Canada adapted those recommendations and provided information on key nutrients that are important for maternal and fetal health. The energy requirement recommended for pregnant women with normal pre-pregnancy BMI was 1 900 kcal/day in the first trimester, an extra 452 kcal in the second or third trimester [25]. The extra calorie intake was intended to support fetal growth and development. Our study showed that women in the intervention group with normal pre-pregnancy BMI had a total intake of 2 016 kcal/day in the third trimester, which was close to that recommended by the Health Canada for this group of women. As a result, 90% participants with normal pre-pregnancy BMI obtained weight gain within the recommended limit in the pre-pregnancy BMI category. Women in the control group with normal pre-pregnancy BMI had significantly higher intakes (2 551 kcal/day in average). The majority of the intake in these women also met the total calorie requirement of Health Canada guidelines for pregnant women. This unnecessary level of total intake could partially contribute to increased GWG, EGWG and offspring birth weight in pregnant women with normal pre-pregnancy BMI without intervention.

Calorie recommendation for overweight or obese pregnant women to achieve the IOM recommended pregnancy weight gain has not been defined. Studies in the past had experienced the same difficulties using lifestyle intervention to achieve proper weight gain in pregnant women with high pre-pregnancy BMI women compared to those with normal pre-pregnancy BMI [14]. Two studies [13,15] specifically targeted pregnant women with higher pre-pregnancy BMI showed successes on weight gain control by setting up meal plans or calorie intake goals. One of the studies reported averages of calorie intake in 1 743 and 1 784 kcal/day for the second and third trimester in pregnant women in the intervention group with no instructed exercise [13]. The other reported an average of 1 900 kcal/day intake with 3-4 times/week walking in pregnant women in the intervention group through pregnancy [15]. These findings suggest that restricted calorie intake could help pregnant women with high –pre-pregnant BMI to achieve recommended GWG. The present study demonstrated that the participants in the intervention group with normal and above normal pre-pregnancy BMI had similar calorie intakes a months after the intervention (2 016 kcal/d versus 1 986 kcal/d). Normal pre-pregnancy BMI, but not above normal BMI, pregnant women receiving the intervention had lower carbohydrate and higher physical activity compared to the control group. The lifestyle intervention reduced EGWG, GWG and birth weight of offspring only in the normal BMI group, but not in high BMI subgroup. It may be speculated that, more intensive intervention to reduce carbohydrate intake and to increase physical activity might be required in order to achieve the goal of normal pregnancy weight gain recommended by the 2009 IOM guidelines [7].

Study limitations

The sample size of the present study limited the possibility to further divide the study subjects to more detailed subgroups in pre-pregnancy BMI, such as overweight, obese and massive obese, which may weaken the discrimination of the responses from subjects with various intensity of obesity on the lifestyle intervention.

The IOM 2009 guidelines on weight gain recommendations in pregnancy were based on assumptions that a 0.5-2 kg weight gain in the first trimester [7]. Since some participants had no record on pre-pregnancy weight, their earliest weight in pregnancy (<10 weeks of pregnancy) was used as pre-pregnancy weight. This could mildly affect the accuracy of the calculation of total GWG and EGWG.

Although self-reported food records have been commonly used to collect food intake data, there is a possibility that the women with above normal BMI might underreport their intake. It has been reported in the literature that overweight women tended to underreport their daily intake [30]. This could affect the accuracy of the nutrition intake.

Conclusion and future implementation

The lifestyle intervention program in this RCT effectively reduced EGWG, GWG and offspring birth weight in pregnant women with normal pre-pregnancy BMI, but not in women with above normal pre-pregnancy BMI. Better adaptation to education on food intake and physical activity may contribute to the weight gain control in normal pre-pregnancy BMI women than in those with above normal pre-pregnancy BMI. Future studies may rationalize the level of carbohydrate intake and physical activity for pregnant women with above normal pre-pregnancy BMI, and further explore the effect of enhanced dietary education and physical activity program on GWG in pregnant women with above normal pre-pregnancy BMI. A qualitative study that explores the barriers of women with above normal pre-pregnancy BMI in achieving recommended gestational weight gain may be necessary to understand this population and developing better client-centered education tools.

Abbreviations

BMI: Body mass index; GWG: Gestational weight gain; EGWG: Excessive gestational weight gain; IOM: Institute of Medicine; RCT: Randomized controlled trial; FCM: Food choice map.

Competing interests

The authors declare that there are no competing interests.

Authors' contributions

Study conception and design, AH, SL,PG, GS, HD, ES, JM, MM, GS. Coordination and implementation of the study AH, GS. Data collection, AH. Data analysis, DJ. Preparation of the manuscript, AH. Editorial assistance, all authors. All authors read and approved the final manuscript.

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Reducing excessive weight gain in pregnancy: a randomised controlled trial

Kirby Jeffries, Alexis Shub, Susan P Walker, Richard Hiscock and Michael Permezel

ABSTRACT

Objective: To determine if regular weight measurement throughout pregnancy can reduce excessive gestational weight gain.

Design: A randomised controlled trial.

Setting: A tertiary obstetric hospital in Melbourne, between July 2007 and May 2008.

Participants: 236 pregnant women recruited at ⩽ 14 weeks' gestation.

Intervention: Women allocated to the intervention group were given a personalised weight measurement card, advised of their optimal gestational weight gain (based on their body mass index at the time of recruitment and the United States Institute of Medicine guidelines), and instructed to record their weight at 16, 20, 24, 28, 30, 32 and 34 weeks' gestation. The control group were weighed at recruitment, but were not given instructions about regular weight measurement. All participants were blinded to the purpose of the study.

Main outcome measure: Weight gain from recruitment to follow-up at 36 weeks' gestation.

Results: In the study population, there was a trend to less weight gain in the intervention group. The women in the intervention group experienced a mean (SD) per-week weight gain of 0.44 (0.173) kg compared with those in the control group, who gained 0.46 (0.156) kg/week (mean difference, 0.02 kg/week; 95% CI, –0.02 to 0.07 kg/week). The intervention significantly reduced gestational weight gain in the group of women who were overweight but not obese at recruitment: those in the intervention group (20 women) gained a mean (SD) of 0.42 (0.153) kg/week and the control group (18 women) gained 0.54 (0.123) kg/week (mean difference, 0.12 kg/week; 95% CI, 0.03 to 0.22 kg/week; $P = 0.01$).

Conclusion: Regular weight measurement in pregnancy was not found to be effective in reducing weight gain, except among women who were overweight but not obese before pregnancy.

Trial registration: Australian Clinical Trials Registry ACTRN12607000272493

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For editorial comment, see page 421. See also page 425

Excessive gestational weight gain has been shown to be associated with higher rates of caesarean delivery, failed induction, instrumental delivery, pre-eclampsia and gestational diabetes mellitus. For the neonate, it increases the incidence of hypoglycaemia, hyperbilirubinaemia, high birthweight, and infant obesity.[1-5] Excess gestational weight gain is also associated with postpartum weight retention up to 10 years after pregnancy.[6] Unfortunately, excessive weight gain during pregnancy is common, particularly among women who are overweight before pregnancy.[7,8] A study in the United States found that 37% of normal weight women and 64% of overweight women experienced excessive gestational weight gain.[8]

In 1990, the US Institute of Medicine (IOM) published gestational weight-gain guidelines based on body mass index (BMI) before pregnancy (Box 1).[9] These guidelines have been widely adopted in clinical practice and are supported by studies showing that weight gain within these guidelines is associated with optimal pregnancy outcomes.[1,5,7,10]

Few studies have examined measures that may aid women in appropriate gestational weight control and none have examined a simple intervention of regular self-weighing.[8,11-15] Outside of pregnancy, the value of frequent self-weighing has been demonstrated.[16]

The Royal College of Obstetricians and Gynaecologists (London) recommends that, in clinical practice, maternal weight should not be routinely measured during pregnancy. They caution that frequent weighing and feedback may cause undue anxiety among women, with no additional benefit.[17] However, this has been refuted for adults who are not pregnant.[18]

Our aim was to assess the effect on gestational weight gain of regular weight measurement combined with advice about the recommended weight-gain range.

METHODS

We performed a randomised controlled trial at a public tertiary obstetric hospital in Melbourne between July 2007 and May 2008. Ethics approval was provided by the Mercy Health Human Research Ethics Committee.

Objective

Our aim was to assess the effect on total weight gain during pregnancy of a personalised gestational weight-gain recommendation (based on early pregnancy BMI) and regular weight measurement. We hypothesised that personalised weight-gain recommendations and awareness of weight change during pregnancy would reduce excessive gestational weight gain.

Participants

Pregnant women were recruited by the student researcher (KJ) at their first antenatal appointment in the outpatients clinic at or before 14 weeks' gestation. The exclusion criteria were: age < 18 years or > 45 years, type 1 or type 2 diabetes mellitus, multiple pregnancy, or non-English speaking. All women were given a patient information and consent form, offering participation in an observational study of diet and exercise in pregnancy. Participants were unaware that the primary aim of the study was the effect of regular weight measurement on gestational weight gain.

Randomisation

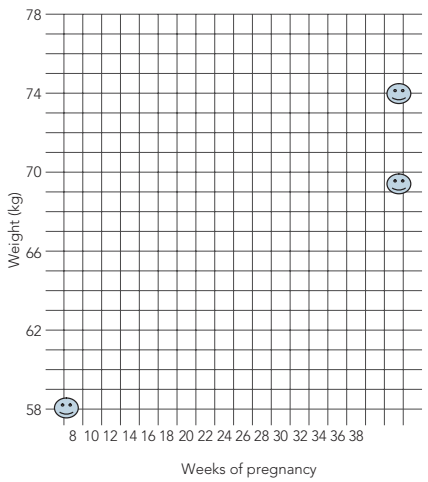
The randomisation sequence was obtained using a computer random number generator. Blocking (which is used to ensure that comparison groups will be of approximately the same size) was not used. Numbered cards allocating women to either the intervention or control group were placed in

1 IOM guidelines for total weight gain in pregnancy by prepregnancy body mass index (BMI) category[9]

Weight-for-height category (BMI, kg/m^2)	Recommended weight gain (kg)
Underweight (≤ 19.8)	12.5–18.0
Normal (> 19.8, ≤ 26.0)	11.5–16.0
Overweight (> 26.0, ≤ 29.0)	7.0–11.5
Obese (> 29.0)	> 6.8

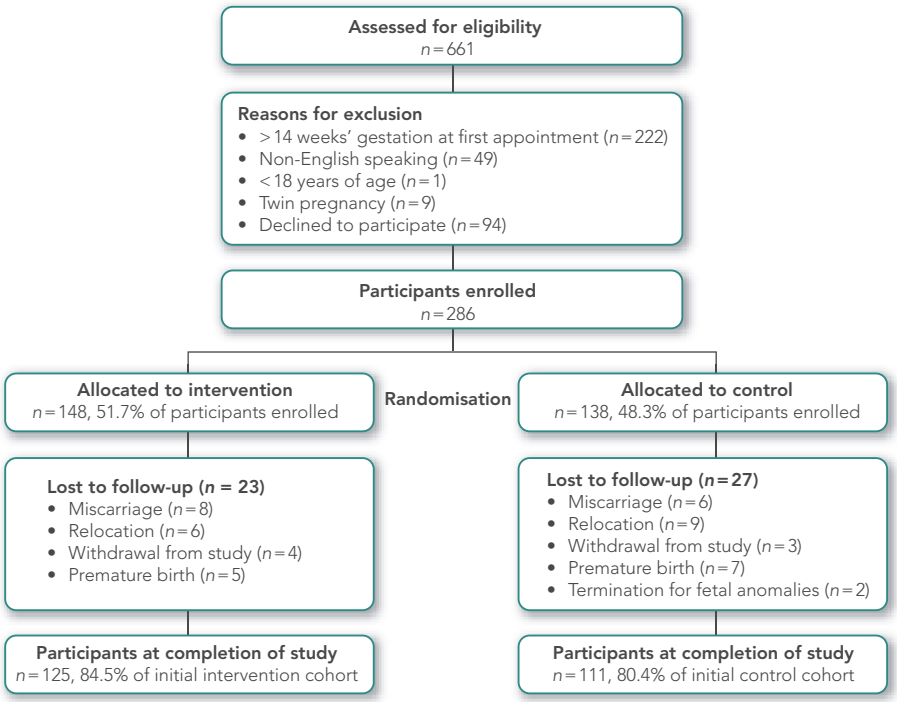
IOM = Institute of Medicine (United States). ◆

2 Personalised weight-measurement card for recording weight



Sample patient record — a patient with a weight at recruitment of 58 kg, a body mass index of 22 kg/m^2, and an ideal weight gain of 11.5–16.0 kg. ◆

3 Flow diagram of the recruitment and randomisation of trial participants



opaque, sequentially numbered envelopes: 138 women were allocated to the control group and 148 women were allocated to the intervention group. The person generating the allocation sequence was also responsible for participant recruitment; however, allocation concealment was maintained.

Study design

Participants were seen at recruitment and at 36 weeks' gestation. They were blinded to the purpose of the study. Of necessity, the researcher conducting the study was not blinded to treatment group after allocation.

Recruitment

All women enrolled in the study received standard antenatal care, including a brief dietary history taken by midwives and written information on healthy eating. Women were weighed at their first antenatal appointment using balance-beam scales, but standard antenatal care did not involve further routine weight measurement. Weight and height were measured in street clothing without shoes. For two women, self-reported weight at the time of recruitment was used, as the scales measured a maximum weight of 125 kg and these women weighed 129 and 157 kg, respectively.

All participants completed two previously validated questionnaires about eating habits and energy expenditure in the 12 months before pregnancy and the first trimester of pregnancy. These questionnaires were primarily used to distract participants' attention from the primary aim of the project.

Intervention

Women assigned to the intervention group were given an optimal gestational weight-gain range for their pregnancy, defined by their BMI and the IOM guidelines for weight gain during pregnancy.[9] This ideal weight range, together with their weight as measured at recruitment, was recorded on a personalised weight-measurement card (Box 2). Participants were told to record their own weight at 16, 20, 24, 28, 30, 32 and 34 weeks' gestation, using either a tabular or graphical format provided on the measurement cards. Weight measurements during pregnancy were done on either the participants' own scales at home or those at the hospital, according to patient preference. Women in the control group were weighed at recruitment and at 36 weeks' gestation, but were not given any further advice regarding optimal weight gain or regular weighing.

Follow-up

All women were weighed at about 36 weeks' gestation, using the same scales used at the initial weight measurement. Seventeen women cared for in a satellite clinic or in hospital were unable to be weighed on the same scales, and were weighed on different scales that had been calibrated to the balance-beam scales. For a further 12 women (eight intervention and four control), self-reported weight at 36 weeks' gestation was recorded (two were too heavy for the hospital scales, and the remainder had changed clinics during their pregnancy). Participants again completed the questionnaires regarding diet and exercise.

Further data collection

Demographic information (eg, age, parity, socioeconomic status) was obtained from participants' medical records at recruitment and by direct questioning. Gestational age was determined by the treating clinician by routine obstetric methods and obtained from the medical record.

Obstetric records were reviewed after delivery to obtain infant birthweight, gestational age at delivery, Apgar scores, and any complications during pregnancy and delivery. Records were complete except for one woman who delivered at another hospital. Obstetric outcomes were defined by, and obtained through, the Mercy Hospital's Birthing Outcomes System (the hospital's data collection process).

Sample size justification and statistical analysis

Sample size was set so that the study had a power of 0.8 to show a weight difference of 2 kg between the control and intervention groups. At a power of 0.8, a mean weight gain of 16.8 kg, standard deviation of 4.9, and a type I error rate of 0.05, a sample size of 192 women (96 in each group) was required. A total of 286 women were recruited to allow for loss to follow-up.

Data are presented as mean (SD), median (25th–75th percentile) or number (%) according to distribution. The primary outcome was weight gain per week of observation; secondary outcomes were the proportion of women exceeding the IOM guidelines, and pregnancy outcomes. For obese women, the IOM recommends a weight gain of 6.8 kg or above. We considered obese women who exceeded 11.5 kg to be above the IOM guidelines, based on the upper limit assigned to overweight women.[9]

Statistical tests used were the two-sided Fisher's exact test for numerical data, and the independent two-samples *t* test or the Wilcoxon rank-sum test for continuous variables according to their distribution. Subgroup analysis based on BMI categories was also performed for weight gain per week, and the proportion of participants exceeding IOM guidelines.

For all statistical analyses, we used Stata (version 10, StataCorp, College Station, Tex, USA). Data were analysed on an intention-to-treat basis. Statistical significance was defined as (two-sided) $P \leq 0.05$, and was adjusted for multiple comparisons in the subgroup analyses using the Bonferroni correction.

RESULTS

Flow of participants

Recruitment took place from July to October 2007. Of the 661 women approached, 281 women were excluded from the study (the reasons are given in Box 3), and 94 women declined to participate (concerns about time and convenience, anxiety about pregnancy, issues about their diet and weight, and plans to deliver at another institution). Of the 286 participants enrolled, 236 completed the study. Those women who were lost to follow-up (Box 3) were not weighed at 36 weeks' gestation and excluded from the analysis. Participants excluded from the analysis were similar in weight, BMI, age, parity and socioeconomic status to those who completed the study (data not shown).

Baseline characteristics

Baseline characteristics and BMI distribution of the participants are shown in Box 4. There were no clinically meaningful differences between the women in the control and intervention groups in terms of demographic characteristics — age, smoking status, parity, marital status or educational attainment. The ranges of gestational age at recruitment and follow-up were 7.1–14.8 weeks and 36.3–38.3 weeks, respectively.

Weight gain

Overall, the control group had a mean (SD) weight gain of 0.46 (0.156) kg/week, compared with 0.44 (0.173) kg/week in the intervention group, a mean difference of

4 Baseline characteristics of study participants

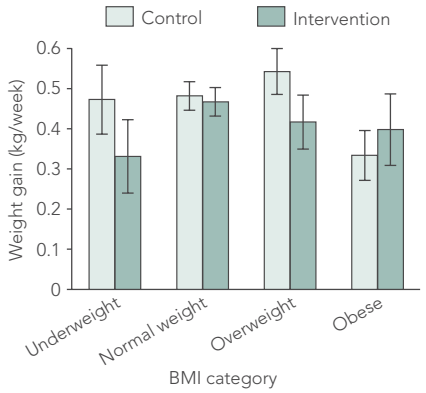
Variable	Intervention (*n* = 125)	Control (*n* = 111)
Mean (SD) weight at recruitment (kg)	68 (15.8)	68 (12.9)
Body mass index category (kg/m^2), no. (%)		
Underweight (≤ 19.8)	5 (4%)	5 (5%)
Normal (> 19.8, ≤ 26.0)	75 (60%)	67 (60%)
Overweight (> 26.0, ≤ 29.0)	20 (16%)	18 (16%)
Obese (> 29.0)	25 (20%)	21 (19%)
Mean (SD) gestation at recruitment (weeks)	11.6 (1.96)	11.4 (2.00)
Mean (SD) gestation at follow-up (weeks)	36.2 (0.62)	36.3 (0.73)
Mean (SD) duration of study participation (weeks)	25.0 (1.90)	25.0 (2.10)

5 Gestational weight gain within body mass index (BMI) categories

BMI category (kg/m^2)	Weight gain per week: Mean (SD) weight gain (kg)		Weight gain per week: Between-group difference (mean, 95% CI)	Weight gain per week: *P**	Total weight gain: Mean (SD) weight gain (kg)		Total weight gain: Proportion gaining more weight than IOM guidelines†		Total weight gain: *P*‡
	Intervention	Control			Intervention	Control	Intervention	Control	
Underweight (≤ 19.8)	0.33 (0.104)	0.47 (0.098)	0.14 (–0.00 to 0.29)	0.06	8.3 (2.55)	12.8 (2.87)	0/5	0/5	—
Normal weight (> 19.8, ≤ 26.0)	0.47 (0.157)	0.48 (0.149)	0.01 (–0.04 to 0.07)	0.58	11.5 (3.95)	12.0 (3.84)	7/75 (9%)	11/67 (16%)	0.22
Overweight (> 26.0, ≤ 29.0)	0.42 (0.153)	0.54 (0.123)	0.12 (0.03 to 0.22)	0.01	10.0 (3.63)	13.3 (3.57)	7/20 (35%)	10/18 (56%)	0.33
Obese (> 29.0)	0.40 (0.226)	0.33 (0.145)	–0.06 (–0.18 to 0.05)	0.27	9.5 (5.17)	8.2 (3.02)	9/25 (36%)	5/21 (24%)	0.52
Total	0.44 (0.173)	0.46 (0.156)	0.02 (–0.02 to 0.07)	0.28	10.7 (4.21)	11.5 (4.03)	23/125 (18%)	26/111 (23%)	0.42

* Between-group difference tested using an unpaired *t* test. † Institute of Medicine guidelines.[9] ‡ Difference in proportions tested using Fisher's exact test. ◆

6 Weight gain per week (95% CI) in the control and intervention groups by body mass index (BMI) category*



* See Box 5. ◆

0.02 kg/week (95% CI, –0.02 to 0.07 kg/week). There was a statistically significant reduction in gestational weight gain in the overweight group (BMI, >26.0, ⩽29.0 kg/m^2), with a mean difference of 0.12 kg/week (95% CI, 0.03 to 0.22 kg/week; $P = 0.01$) between the intervention and the control groups.

For participants classified as underweight, normal or obese, there was no significant difference in weight gain between intervention and control groups (Box 5). Weight gain for each BMI category is presented in Box 5 and Box 6. The number of women gaining more weight than the IOM-recommended amount was 26/111 (23%) in the control group compared with 23/125 (18%) in the intervention group (Fisher's exact test, $P = 0.42$) (Box 5).

Pregnancy outcomes

Pregnancy outcomes are shown in Box 7. There were no significant differences in obstetric or neonatal outcomes between the intervention and control groups.

DISCUSSION

The aim of our study was to prevent excessive weight gain during pregnancy. The intervention included the regular measurement and recording of weight throughout pregnancy from recruitment at ⩽14 weeks' to 36 weeks' gestation. The control group received standard antenatal care that did not include regular weighing. To our knowledge, this is the first study of its kind to consider routine weight measurement, without diet and exercise counselling, as a tool to reduce excessive gestational weight gain.

7 Pregnancy outcomes in the intervention and control groups

Pregnancy outcome	Intervention ($n = 124$)*	Control ($n = 111$)	P	Relative risk (95% CI)
Birthweight				
Mean (SD) birthweight (g)	3416 (452.4)	3421 (504.7)	0.95	
< 10th centile†	9 (7.3%)	12 (10.8%)	0.37	0.68 (0.30–1.56)
> 90th centile†	8 (6.5%)	11 (9.9%)	0.47	0.66 (0.28–1.59)
Delivery				
Weeks' gestation at delivery (median, 25th–75th percentile)	39.6 (38.6–40.7)	39.7 (38.7–39.8)	0.65	
Preterm (< 37 weeks)	3 (2.4%)	4 (3.6%)	0.71	0.67 (0.15–2.93)
Instrumental delivery	29 (23.4%)	18 (16.2%)	0.19	1.44 (0.85–2.45)
Caesarean	41 (33.1%)	30 (27.0%)	0.32	1.25 (0.85–1.86)
Pregnancy complications				
Pre-eclampsia	6 (4.8%)	2 (1.8%)	0.29	2.68 (0.55–13.0)
Pregnancy-induced hypertension	4 (3.2%)	1 (0.9%)	0.37	3.58 (0.41–31.6)
Gestational diabetes mellitus	13 (10.5%)	10 (9.0%)	0.83	1.16 (0.53–2.54)
Neonatal complications				
Apgar score < 7 at 5 min	1 (0.8%)	2 (1.8%)	0.60	0.45 (0.04–4.87)
Hypoglycaemia	3 (2.4%)	1 (0.9%)	0.62	2.68 (0.28–25.4)
Shoulder dystocia	1 (0.8%)	1 (0.9%)	0.99	0.89 (0.06–14.1)

Data are presented as number (%) unless otherwise indicated.
* The pregnancy outcomes of one participant in the intervention group were unavailable, as she delivered at another hospital. † Birthweight corrected for gestational age and sex. ◆

In the total study population, there was a trend towards less weight gain in women in the intervention group in all BMI subgroups, except for the obese group (those with a BMI >29 kg/m^2). Women with a BMI >29 kg/m^2 before pregnancy were told to gain at least 6.8 kg, but, in accordance with IOM recommendations, these women were not given an upper weight-gain limit, and this advice may explain the lack of effect in this group.[9] A concerning finding was that in the small group of underweight women in our study, there was a non-statistically significant trend towards gaining less weight than the IOM guidelines ($P = 0.06$; adjusted for multiple comparisons, $P = 0.01$).

There are two other published randomised controlled trials of interventions to reduce gestational weight gain, both of which showed reduction in some subgroups. These studies included intensive diet and exercise counselling throughout pregnancy and neither were adequately powered (120 and 50 participants, respectively) to demonstrate differences in obstetric or neonatal outcomes.[8,15]

The limitations of our study include the timing of the first and final weight measurements. The total weight gain in our study was calculated from early pregnancy (⩽14 weeks' gestation) until 36 weeks' gestation. Little weight is gained before 12 weeks' or after 36 weeks' gestation, but ideally recruitments should have been before pregnancy, and follow-up continued until labour.[19] Our study was also limited by inadequate power to demonstrate differences in obstetric and neonatal outcomes. Moreover, although our finding of reduced weight gain in overweight women in the intervention group reached statistical significance, this result needs to be interpreted with caution, as it was not a pre-specified endpoint for which the study was appropriately powered.

We did not assess the emotional effect that routine weight measurement had on women during pregnancy, or the effect of self-weighing versus weighing by a health professional. Although weight measurement has been shown to have no impact on depressive symptoms in the general population,[18] this needs to be further assessed in pregnant women.

Additionally, the advice given to the intervention group may have had more impact and authority if it had been delivered by a member of the treating team, rather than a medical student researcher. Thus, our results may give a conservative indication of the effect of regular weight measurement on weight gain during pregnancy.

All interventional studies conducted thus far have included intensive diet and exercise counselling. An ideal intervention does not affect consultation length, is easy to administer, and is accepted by pregnant women. Our intervention is a simple and inexpensive option for the promotion of appropriate weight gain during pregnancy.

Larger studies are needed to confirm the findings of our study, to establish the effects on obstetric outcomes and thus the safety of the intervention, especially in underweight women, and to determine the long-term effects on postpartum weight.

Our study shows that if overweight women are made aware of their personalised recommended weight gain, and encouraged to monitor and record their weight change over their pregnancy, excessive gestational weight gain may be reduced. This may help decrease the incidence of adverse pregnancy outcomes and postpartum weight retention. Routine weighing and advising women of optimal weight gain should be reconsidered for inclusion into standard antenatal care for overweight women.

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COMPETING INTERESTS

None identified.

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A Pilot Walking Program Promotes Moderate-Intensity Physical Activity during Pregnancy

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[1]Department of Food Science and Human Nutrition, Iowa State University, Ames, IA; [2]Interdepartmental Graduate Program in Nutritional Sciences, Iowa State University, Ames, IA; [3]Department of Statistics, Iowa State University, Ames, IA; and [4]Department of Kinesiology, Iowa State University, Ames, IA

ABSTRACT

KONG, K. L., C. G. CAMPBELL, R. C. FOSTER, A. D. PETERSON, and L. LANNINGHAM-FOSTER. A Pilot Walking Program Promotes Moderate-Intensity Physical Activity during Pregnancy. *Med. Sci. Sports Exerc.*, Vol. 46, No. 3, pp. 462–471, 2014. **Introduction**: Walking may be a strategy for increasing moderate-intensity physical activity (MPA) during pregnancy. **Purpose**: This study aimed to promote MPA among overweight and obese pregnant women, via walking, and to evaluate the effect of the intervention on maternal and birth outcomes. **Methods**: Thirty-seven overweight or obese pregnant women were randomly assigned to a walking intervention or control group. Anthropometric and objective PA (StepWatch™ Activity Monitor) data were collected for four 1-wk periods: weeks 10–14 (V1), weeks 17–19 (V2), weeks 27–29 (V3), and weeks 34–36 (V4) of gestation. Participants provided information about maternal and birth outcomes. A cadence of ≥80 steps per minute was defined as MPA, and "meaningful walking" was defined as moderate walking in ≥8-min bouts. ANOVA was used to determine the differences in walking amount and meaningful walks, the Kolmogorov–Smirnov test was used for walking intensity distribution analysis, and Fisher's exact test was used for maternal and infant outcomes analyses. Pearson correlation was used to examine the association between prepregnancy body mass index and gestational weight gain (GWG). **Results**: There was significantly more MPA among women in the intervention group compared with those in the control group at V2 (overweight, $P < 0.0001$; obese, $P < 0.025$), V3 (overweight, $P < 0.0001$), and V4 (overweight, $P < 0.0001$; obese, $P < 0.025$). Women in the intervention group significantly increased their meaningful walks at V2 ($P = 0.054$), V3 ($P = 0.01$), and V4 ($P = 0.014$). There were trends for intervention group women to have more favorable maternal and birth outcomes compared with the control group. Rates of GWG at measurement points during pregnancy were significantly associated with preceding rates of GWG. **Conclusion**: The pilot, unsupervised walking intervention increased the MPA of overweight and obese women during pregnancy. **Key Words:** WALKING CADENCE, GESTATIONAL WEIGHT GAIN, BIRTH OUTCOMES, OBESITY

In the United States, approximately two-thirds of childbearing age women are either overweight or obese (24). There is increased risk of adverse maternal and fetal health outcomes, such as gestational diabetes, gestational hypertension or preeclampsia, and labor/delivery complications among overweight and obese pregnant women (37). Excessive gestational weight gain (GWG) is another concern in the field of maternal and child health. Excessive GWG can be particularly concerning for overweight and obese women due to their already increased risk for adverse pregnancy outcomes. In addition, maternal obesity and GWG are two of the main causes of giving birth to large-for-gestational-age infants (birth weight ≥90th percentile) (19). The influence of maternal obesity on offspring obesity may be sustained into adulthood (35).

Healthy eating habits and regular physical activity (PA) are two modifiable targets in managing and preventing weight gain. These behaviors should be encouraged among pregnant women. In recent years, PA during pregnancy has been viewed as an important part of reproductive health. The risks of moderate-intensity PA (MPA) performed by healthy women during pregnancy are very low and do not appear to increase the risk of low birth weight, preterm delivery, or early miscarriage (7). In addition, observational studies have supported the role of PA in helping pregnant women to minimize excessive GWG (13,20,29).

According to the American College of Obstetrics and Gynecology 2002 guidelines, in the absence of either medical or obstetric complications, pregnant women are encouraged to accumulate 30 min or more of MPA on most, if not all days of the week (1). More recently, the U.S. Department of Health and Human Services issued the first-ever PA guidelines for Americans (PAG) in 2008, which included recommendations for healthy pregnant women and suggested a total of 150 min

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of MPA per week (spread throughout the week) during pregnancy (34). Despite these recommendations, the evidence of U.S. pregnant women meeting PA guidelines is low (9,10). According to NHANES 2003–2006 data, pregnant women only participated in an average of 12.0 ± 0.86 min·d^{-1} of MPA and 0.3 ± 0.08 min·d^{-1} of vigorous activity when their PA participation was objectively measured by an ActiGraph accelerometer (10). With the higher risk of adverse maternal and fetal health outcomes along with an increased possibility of gaining excessive weight during gestation, it is imperative that strategies to promote MPA during pregnancy be identified.

Walking is a common and popular PA choice during pregnancy because of its lower intensity and higher accessibility (15,22), and walking at a brisk pace has been shown to reduce the risk of gestational diabetes (38), preeclampsia (26), excessive GWG (29), and macrosomia (21). Few studies have investigated the use of walking among overweight and obese pregnant women as a strategy for meeting the PA recommendations during pregnancy. Therefore, we conducted a pilot randomized controlled trial (RCT) to evaluate the feasibility of increasing MPA participation of previously nonexercising, overweight, and obese pregnant women by walking. The objectives of this study were 1) to promote MPA participation among previously nonexercising, overweight, and obese pregnant women via walking; 2) and to evaluate the effect of the intervention on pregnancy and birth outcomes. The hypotheses of the current study were that previously nonexercising, overweight, and obese women could increase MPA participation during pregnancy via a walking intervention, and those who participated in the intervention would have more favorable pregnancy and birth outcomes.

METHODS

Participants

The study was approved by the institutional review board of the Iowa State University. Recruitment for participants occurred through mass e-mail service provided by the Iowa State University to the students, staff, and faculty on campus, online advertisement (i.e., Craigslist), and flyers posted throughout the community (i.e., restaurants, public libraries, and grocery stores) as well as our partnership with local hospitals and obstetric clinics. Each participant was provided with an informed consent document for review, which was signed before participation. Mothers provided informed consent for each infant.

All participants were recruited before week 15 of gestation. Gestational age was calculated based on the self-reported date of the patients' last normal menstrual cycle or medical provider ultrasound. Forty-six pregnant women enrolled in the study, and the final number of women who completed the study was 37 (n = 18 in intervention group and n = 19 in control group; Fig. 1). Participants met the following criteria: maternal age between 18 and 45 yr, singleton pregnancy, nonsmoker, self-reported overweight (body mass index [BMI] ≥

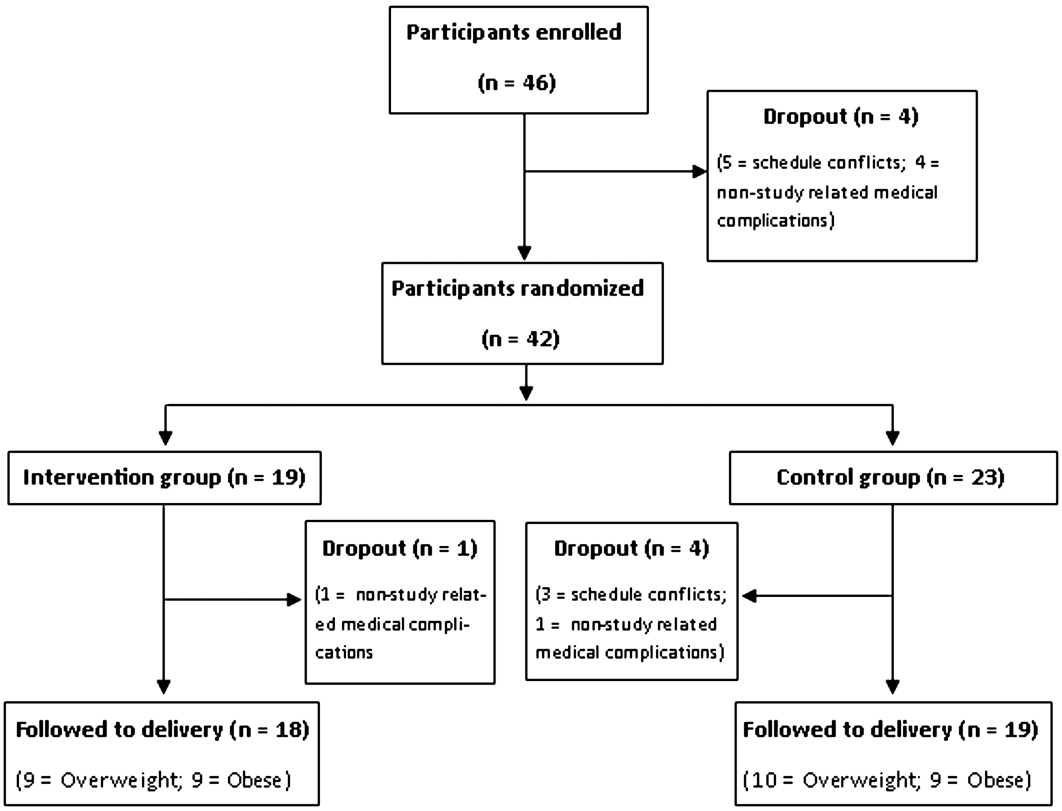

FIGURE 1—Participant flow chart.

25.0 kg·m^{-2}) or obese (BMI ≥ 30.0 kg·m^{-2}) before pregnancy, no prior history of chronic diseases (including type 1 diabetes, cardiovascular disease, thyroid, or lung disorder), and no prior history of gestational diabetes. In addition, only women who engaged in less than three 30-min bouts of leisure PA for 6 months preceding enrollment were recruited. Prepregnancy PA participation was self-reported, and leisure PA was defined as activities beyond normal daily routines.

Study Design

Procedure. During the enrollment, participants filled out a medical history questionnaire and provided their medical providers' contact information. Height and weight of the women were measured by a trained staff member. All participants were approved by their medical providers to join the study. After the initial enrollment, participants were randomly assigned to the intervention or control group using a computer-based random number generator (Microsoft Excel 2010, WA). All participants and research staff were blinded to the group allocation. Group assignment was revealed to participants at the baseline data collection visit by the study coordinator. Anthropometric and objective PA data were collected for 1-wk periods at each of the following gestational time points: weeks 10–14 (V1, which served as baseline), weeks 17–19 (V2), weeks 27–29 (V3), and weeks 34–36 (V4) of gestation. All participants filled out a postpartum questionnaire regarding the infant's delivery and birth outcomes.

Intervention: unsupervised walking program. The intervention in this study was an unsupervised walking program. Following V1, intervention group participants attended a training session. The instructions and safety of using a treadmill was discussed. Participants were verbally given the 2008 U.S. physical activity guidelines (accumulate a minimum of 150 min·wk^{-1} of moderate PA during pregnancy) and were advised to spread their walking throughout the week, such as 30 min of walking 5 d·wk^{-1} (1). Participants were also given permission to walk in shorter bouts; however, they were advised to keep the bouts to at least 10 min (36). Walking could occur in any setting, but treadmills were also provided for intervention women for home use during the study and were returned at the end of the walking program. Treadmills were provided to eliminate some of the prenatal PA barriers pregnant women faced such as lack of childcare support and weather-related concerns (8). A total of 16 treadmills were provided to women in the intervention group. Two women had their own treadmills at home; therefore, they requested not to be sent a treadmill. The treadmill manuals of these two participants were reviewed by the study coordinator to ensure user's safety. Participants were provided with logs to report the location and duration of their walks. The intensity of walks was not reported by the participants. They were encouraged to turn in their logs at each time point visit. Participants in the control group were also given PA logs, which they were asked to report any leisure-time PA performed during pregnancy. However, because of the inconsistency, with PA logs returned at each time point visit, the self-reported leisure-time PA of the control group was not analyzed.

The unsupervised walking program began no earlier than week 12 and no later than week 15 of gestation and lasted until at least week 35. Depending on the length of each participant's pregnancy, all the intervention participants were able to complete at least 20 wk. The first 2 wk of the intervention program served as an acclimation period whereby participants were asked to walk for 50 min in week 1, followed by 100 min in week 2. By the third week, all participants were encouraged to be at their walking goal of 30 min most days of the week for an overall total of at least 150 min of weekly MPA. Women in the control group were not provided with PA recommendations, but they were not restricted from PA participation during pregnancy.

Data Collection

Anthropometric and demographic data. Height was measured during enrollment, and weight was measured at each visit, with shoes removed and light clothing. Height was measured to the nearest 0.1 cm (Ayrton 226 Hite-Rite Precision Mechanical Stadiometer; Quick Medical GS, Snoqualmie, WA), and weight was measured to the nearest 0.1 kg (Detecto Model 6855 Cardinal Scale, Manufacturing Co., Webb City, MO). Prepregnancy BMI was determined by using height measured at enrollment and women's self-reported weight before conception. Total GWG was calculated by subtracting weight measured at V4 from self-reported prepregnancy weight. This value was used to determine whether participants met the 2009 Institute of Medicine (IOM) recommendation after adjusting for their weeks of gestation at V4. The rate of GWG was determined by dividing the weight difference between two time points with the total weeks between the time points. Four different rates of GWG were calculated for the study: weight gain per week before baseline data collection at V1 (considered as the rate of weight gain before the intervention), weight gain per week between V1 and V2 (rate V1–V2), weight gain per week between V2 and V3 (rate V2–V3), and weight gain per week between V3 and V4 (rate V3–V4). Participants reported their age, education level, employment, race, marital status, income level, and parity. Infant birth weights and sex were obtained from the postpartum questionnaire. To maintain consistency, account for sex differences, and enable comparison of effect sizes, birth weights were adjusted to gestational age and sex-specific *z*-score (birth weight *z*-score) using U.S. reference data (18).

Objective PA data: StepWatch™ Activity Monitor. PA was monitored using the StepWatch™ Activity Monitor (SAM), an ankle-worn accelerometer-based measurement tool. A previous study has reported high accuracy and precision of SAM in measuring walking steps in lean and obese individuals (12). In the current study, it was worn on the ankle 24 h·d^{-1} for 1 wk. The SAM contains a microprocessor that uses a combination of acceleration, position, and timing to detect steps; therefore, the outputs of the SAM are based on the amount,

rate, and pattern of walking. It is calibrated to the individual's height. PA participation was determined using step data (counts) from the SAM. Instructions regarding the proper use (especially orientation) of the monitor were given to participants.

Data processing. SAM measured step data in 1-min epochs (number of steps taken by the participants for each minute). The sample rate of the SAM is preset, and there are no options to change the sampling settings. Individual primary SAM files were examined visually by graphing the data to detect nonwear time. There is no known existing guideline to distinguish nonwear from wear time for SAM. Because time spent sitting and lying down does not produce steps, it was decided that data were excluded for a day if the participant did not wear the monitor (no steps or improper placement) for ≥300 consecutive minutes during typical waking hours (i.e., 7:00 a.m. to 10:00 p.m. for most participants). Step count data were collected during 24-h periods for seven consecutive days. In adults, at least 3 d of monitoring using accelerometry is required to provide a reliable estimation of habitual PA (30); therefore, at each time point, women who provided at least three valid days of step counts were included. The raw step data were smoothed using an exponential smoother (R: Moving averages, R Foundation for Statistical Computing, Vienna, Austria) to determine cadence (steps per minute) and bouts of walking among the participants. The weight used in the smoother formula was 1/10. The goal of smoothing was to help account for random stops (i.e., waiting at a stop light) during bouts of walking.

Meaningful walk determination. To determine the intensity of the walks, the number of steps taken per minute (cadence) was used. For a nonpregnant population, approximately 100 steps per minute equals a cadence of 3 METs of task with a walking range between 2.4 and 3 mph (32); however, this value was reported in laboratory conditions and was commonly measured using treadmills. It has been reported that the MET value of pregnant women (10–14 wk of gestation) who walked at 2 mph at 0% incline was 3.12 ± 0.32 METs (4). Therefore, in this study, a cadence ≥80 steps per minute was defined as moderate intensity walking for pregnant women under free-living conditions with the assumption that women might also walk outdoors (i.e., parks and walking trails). Accumulated short bouts of brisk walking can improve aerobic fitness and physiological outcomes and that these bouts should be continuous activities for ≥10 min in duration in the nonpregnant population (36). In addition to the use of cadence ≥80 steps per minute as the moderate activity cut point, slowing down from a walk and/or brief rest during a walk was accounted for; therefore, the definition of meaningful walk in this study would be any steps taken at moderately intense cadence (≥80 steps per minute) and must also be in bouts of at least 8 min. Using these definitions, meaningful walks include walking that should be counted toward meeting the PA guidelines, which include total time, bouts, and intensity.

Postpartum questionnaire. All participants completed a postpartum questionnaire. The questionnaire included pregnancy risks and labor procedures (i.e., use of epidural and C-section delivery) as well as infant's birth outcomes (sex, anthropometric data, and Apgar [appearance, pulse, grimace, activity, respiration] scores).

Statistical Analysis

Demographic data were analyzed by descriptive analysis. Multivariate ANOVA was conducted to examine differences in demographic variables (age, height, prepregnancy weight, prepregnancy BMI, education, employment, race, marital status, total household income, and parity) between the groups. Two-way ANOVA was used to determine the differences in total steps per day (average steps per day), average minutes of meaningful walk ($\text{min}\cdot\text{wk}^{-1}$), total GWG (kg), birth weight (g), gestational length at delivery (wk), birth weight *z*-score, and Apgar score (min) by treatment group and prepregnancy BMI category. Absolute difference (diff) between groups was reported when there was significant difference. Pairwise comparison tests (all pairs Tukey–Kramer $P = 0.05$) were then performed to further determine the differences among overweight women in the intervention group (Int-OW), overweight women in the control group (Con-OW), obese women in the intervention group (Int-OB), and obese women in the control group (Con-OB) on the aforementioned variables. Fisher's exact tests were used to analyze differences in meeting 2009 IOM GWG recommendations, pregnancy complications, and infant outcomes among Int-OW, Con-OW, Int-OB, and Con-OB women. All moderately intense cadences (≥80 steps per minute) taken by participants for any bout length at each time point were visualized graphically (Matlab, Mathworks, Natick, MA). The Kolmogorov–Smirnov test was used to compare the probability distribution of the bouts of moderately intense cadence between the intervention and the control groups by prepregnancy BMI category. A Pearson correlation coefficient analysis was also conducted to examine the association between prepregnancy BMI and rates of GWG at different time points across pregnancy. Significance was defined as $P < 0.05$. Results are presented as mean ± SD. Data analyses were conducted using JMP, Version 7 (SAS Institute Inc., Cary, NC).

RESULTS

Participant Characteristics

Among the 46 overweight and obese women enrolled in the program, 9 of them dropped out due to schedule conflicts and non–study-related medical complication such as miscarriages (19.6% dropout rate) (Fig. 1). The characteristics of the remaining 37 participants are shown in Table 1 by treatment and BMI category. Multivariate ANOVA showed there were no significant differences between groups for age, height, gestational length at V1, education, employment, race, marital status, total household income, and parity. Prepregnancy

TABLE 1. Participant demographic characteristics.

	Intervention		Control	
	Overweight	Obese	Overweight	Obese
Variable	(*n* = 9)	(*n* = 9)	(*n* = 10)	(*n* = 9)
Age (yr)	26.2 ± 2.6	28.6 ± 5.3	27.3 ± 3.6	25.7 ± 4.0
Height (cm)	163.8 ± 7.4	165.2 ± 7.1	169.3 ± 6.8	165.1 ± 6.5
Prepregnancy weight (kg)*	71.5 ± 8.9	94.8 ± 14.4	78.8 ± 7.8	93.4 ± 11.2
Prepregnancy BMI ($kg \cdot m^{-2}$)*	26.5 ± 1.2	34.7 ± 4.6	27.4 ± 1.4	34.2 ± 3.6
Gestational length at V1 (wk)	12.6 ± 1.3	12.3 ± 0.8	12.3 ± 1.4	12.4 ± 1.8
Employment (*n*)				
Full time ≥ 40 h	2	5	4	3
Part time < 40 h	4	2	4	2
Nonemployed = 0 h	3	2	2	4
Total household Income (*n*)				
<$25,000	1	2	0	3
$25,000–$50,000	6	2	3	3
$50,000–$75,000	1	1	4	3
>$75,000	1	4	3	0
Nulliparas (*n*)[a]	3	3	5	3
Paras ≥ 1 (*n*)[b]	6	6	5	6

Values are presented as mean ± SD, unless otherwise indicated.
*Prepregnancy weight and BMI significantly different between overweight and obese women.
[a]Nulliparas refers to first-time pregnant women.
[b]Paras ≥ 1 refers to women with at least one pregnancy.

weight and prepregnancy BMI were significantly different between overweight and obese participants. Overall, participants in the study were predominantly married, educated, and Caucasian.

Objectively Measured Step Counts Using StepWatch™

Participants in this study were compliant in wearing the PA monitor. The number of participants who provided at least three valid days of data at each gestational time point was V1 ($n = 31$), V2 ($n = 36$), V3 ($n = 35$), and V4 ($n = 35$). SAM data that were not included in the final analysis were mainly due to missing data and misplacement of the monitor. Participants' files, which were included in the final PA analysis, had on average 6 d of data at each time point. Statistical analysis showed that there was no significant difference in participant's compliance among the groups. The treadmills, both provided through the research program and owned by the participants, had a 33.8% usage according to the self-reported walking logs among women in the intervention group. Other reported locations of walks included outdoors, malls, and stores.

Walking amount: total steps per day. At V1 (baseline) and V2, there was no significant difference between the treatment groups, prepregnancy BMI category, or interaction effect in total steps per day ($F = 1.049$, $P = 0.387$ for V1; $F = 0.834$, $P = 0.485$ for V2). At V3, there was a significant difference between the prepregnancy BMI category (OW = 10,016 steps, OB = 7931 steps, diff = 2130 steps, $P = 0.011$), but not the treatment groups or interaction effect in total steps per day ($F = 3.227$, $P = 0.036$). Similar patterns were observed at V4 with significant difference between the prepregnancy BMI category (OW = 8703 steps, OB = 7036, diff = 1667, $P = 0.025$) but not the treatment groups or interaction effect in total steps per day ($F = 2.519$, $P = 0.076$). Pairwise comparison tests showed that only Int-OW versus Int-OB at V3 was significantly different, but not for other visits among the groups (Table 2).

Walking intensity: moderately intense cadence. The walking intensity characteristics of the women were determined using cadence (steps per minute). Cadence ≥80 steps per minute was considered a moderately intense cadence; therefore, any wear times that had ≥80 steps per minute were extracted. Figure 2 shows the length of time spent walking at cadence ≥80 steps per minute, shown by color intensity, separated into bouts of lengths given on the *x*-axis. This demonstrates the patterning of lengths of bouts of all women walking at moderate intensity achieved while under observation. At V1, the Kolmogorov–Smirnov test showed no significant difference between the distributions of cadence ≥80 steps per minute among the intervention and the control groups for obese women, but there was a trend of more moderate walking between intervention and control group for the overweight women ($P = 0.062$). At V2, there was a significantly higher amount of cadence ≥80 steps per minute in the intervention group for both overweight ($P < 0.0001$) and obese ($P < 0.025$) women. At V3, overweight women in the intervention group had significantly more cadence ≥80 steps per minute than the control group ($P < 0.0001$), and a trend of significance was observed among obese women ($P = 0.072$). At V4, there were significantly higher amounts of cadence ≥80 steps per minute in the intervention group for both overweight ($P < 0.0001$) and obese ($P < 0.025$) women. In addition, overweight women in the intervention group at V3 ($P < 0.01$) and V4 ($P < 0.005$) had a significantly higher amount of cadence ≥80 steps per minute than obese women in the same treatment.

Meaningful walks: moderately intense cadence for at least 8 min. Any moderately intense cadences taken

TABLE 2. PA outcome measures by treatment group and prepregnancy BMI category.

	Overweight		Obese	
	Intervention	Control	Intervention	Control
Variables	**(*n* = 9)**	**(*n* = 10)**	**(*n* = 9)**	**(*n* = 9)**
Total steps (steps per day)†				
V1	8534 ± 2104[a]	7964 ± 2300[a]	7737 ± 1693[a]	6758 ± 1635[a]
V2	9346 ± 1826[a]	8496 ± 2104[a]	7751 ± 2065[a]	8520 ± 2561[a]
V3	10,912 ± 1582[a]	9210 ± 3040[ab]	7867 ± 1475[b]	7996 ± 2581[ab]
V4	9327 ± 1976[a]	8078 ± 2378[a]	7416 ± 1439[a]	6655 ± 2341[a]
Participants with no min of meaningful walks* (%)				
V1	37.5	50.0	62.5	71.4
V2	11.1	60.0	44.4	75.0
V3	22.2	60.0	50.0	75.0
V4	33.3	60.0	62.5	100.0
Average min of meaningful walks (min·wk^{-1})*,†				
V1	23.3 ± 26.7[a]	11.9 ± 18.6[a]	6.5 ± 10.5[a]	13.9 ± 24.3[a]
V2	76.7 ± 51.1[a]	13.2 ± 25.6[b]	28.9 ± 37.2[ab]	27.3 ± 73.5[ab]
V3	81.3 ± 75.4[a]	10.2 ± 14.1[b]	8.4 ± 11.1[b]	5.4 ± 12.0[b]
V4	70.1 ± 68.5[a]	13.3 ± 22.6[b]	14.1 ± 32.6[b]	0.0 ± 0.0[b]

Values are presented as mean ± SD.
*Meaningful walks = moderately intense walk (≥ 80 steps per minute) in bout of eight consecutive minutes.
†Different letters indicate significant differences (all pairs Tukey–Kramer $P = 0.05$).
V1, weeks 10–14 of gestation; V2, weeks 17–19 of gestation; V3, weeks 27–29 of gestation; V4, weeks 34–36 of gestation.

for at least 8 min in length of bout were further extracted to identify the amount of time (minutes) participants spent in meaningful walks. In other words, any time spent walking at cadence ≥80 steps per minute after the 8-min mark on Figure 2 would be considered meaningful walks. Generally, there were higher percentages of overweight and obese women in the control group who had 0 min of meaningful walks across pregnancy (Table 2). When the average of minutes of meaningful walks was examined using a two-way ANOVA, there was no significant difference between the treatment groups, prepregnancy BMI category, or interaction effect at V1 ($F = 0.954$, $P = 0.428$). At V2, there were strong trends of significance between treatment groups (Int = 52.8 min, Con = 20.2 min, diff = 32.6, $P = 0.054$) and interaction effect ($P = 0.066$), but not prepregnancy BMI categories ($F = 2.983$, $P = 0.046$). At V3, significant differences were observed between the treatment groups (Int = 44.9 min, Con = 7.8 min, diff = 37.1 min, $P = 0.01$), prepregnancy BMI (OW = 45.8 min, OB = 6.9 min, diff = 38.9 min, $P = 0.007$), and interaction effect ($P = 0.002$) ($F = 7.556$, $P < 0.001$). At V4, treatment groups (Int = 42.1 min, Con = 6.7 min, diff = 35.4 min, $P = 0.014$) and prepregnancy BMI categories (OW = 41.7 min, OB = 7.1 min, diff = 34.6 min, $P = 0.016$) were significantly different, but there was no interaction effect ($F = 5.341$, $P = 0.004$). Table 2 shows the pairwise comparison tests for all groups of participants at each time point. Int-OW participants had significantly higher amounts (minutes) of meaningful walks compared with Con-OW participants at V2 (diff = 62.1 min, $P = 0.046$), V3 (diff = 78.1 min, $P = 0.002$), and V4 (diff = 65.1 min, $P = 0.010$).

Gestational weight gain. There was no significant difference in total GWG ($F = 0.253$, $P = 0.859$) among the

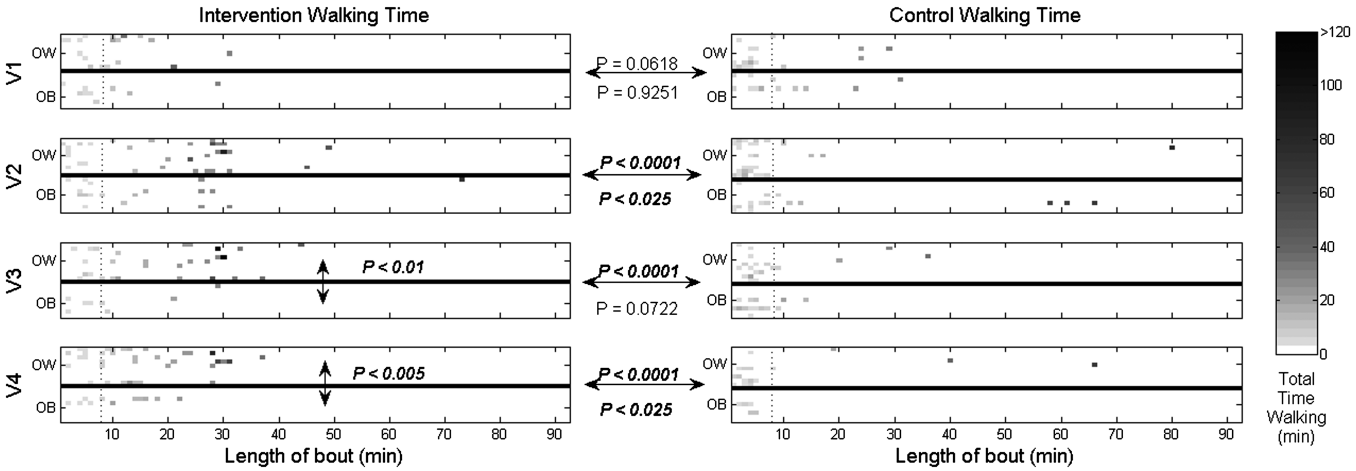

FIGURE 2—Walking bouts distribution for each participant in the intervention and control groups. All bouts of walking at cadence ≥80 steps per minute are shown for all participants at each gestational data collection time point. Each segment on the *y*-axis across the panel represents a week's worth of step count data for a single participant. All participants are represented in the same order on the four panels across measurement periods. The length of time spent walking at cadence ≥80 steps per minute, shown by intensity, separated into bouts of lengths given on the *x*-axis. Bouts after dotted lines (at 8-min mark) represent meaningful walking. OW, overweight women; OB, obese women; V1, weeks 10–14 of gestation; V2, weeks 17–19 of gestation; V3, weeks 27–29 of gestation; V4, weeks 34–36 of gestation.

TABLE 3. Pregnancy and infant outcomes by treatment group and prepregnancy BMI category.

	Overweight		Obese	
	Intervention	Control	Intervention	Control
Variables	(*n* = 9)	(*n* = 9)	(*n* = 9)	(*n* = 10)
Total GWG (kg)	10.53 ± 5.37	9.94 ± 6.14	12.07 ± 9.01	12.48 ± 8.51
Meeting 2009 IOM guidelines				
Exceeded IOM (%)	44.4	50.0	77.8	77.8
Within IOM (%)	55.6	20.0	0.0	11.1
Below IOM (%)	0.0	30.0	22.2	11.1
Birth weight (kg)	3.76 ± 0.44	3.59 ± 0.46	3.54 ± 0.51	3.94 ± 0.48
Gestational length at delivery (wk)	39.7 ± 0.7	39.2 ± 1.6	39.0 ± 1.2	39.7 ± 0.7
Birth weight *z*-score	0.68 ± 0.94	0.54 ± 0.67	0.46 ± 0.99	1.09 ± 1.19
Low birth weight <2500 g (*n*)	0	0	0	0
Macrosomia >4000 g (*n*)	3	1	2	5
Apgar score				
1 min	7.9 ± 0.6	8.1 ± 0.9	8.0 ± 0.9	7.3 ± 1.8
5 min	8.9 ± 0.6	8.6 ± 1.0	8.6 ± 0.7	8.4 ± 1.8
Pregnancy complications				
Preterm delivery, <37 wk (*n*)	0	1	0	0
Cesarean delivery (*n*)	0	4	5	5
Preeclampsia (*n*)	0	0	1	0
Maternal hypertension (*n*)	0	0	0	0
Gestational diabetes (*n*)	1	1	0	0

Values are presented as mean ± SD, unless otherwise indicated.
GWG, gestational weight gain; IOM, Institute of Medicine; Apgar, appearance, pulse, grimace, activity, respiration.

women in the intervention group compared with women in the control group for both prepregnancy BMI categories (Table 3). However, it appeared that overweight women in the intervention group were more likely to gain within the 2009 IOM recommendations compared with the control group, according to the Fisher's exact test ($P = 0.163$). Table 4 is a correlation matrix, which demonstrates the association between prepregnancy BMI and rates of GWG at different time points during pregnancy. The rate of GWG between V1 and V2 (rate V1–V2) was significantly correlated with the rate of weight gain before the women joined the study ($r = 0.49$, $P < 0.01$), rate V2–V3 was significantly correlated with rate V1–V2 (0.46, $P < 0.01$), rate V3–V4 was significantly correlated with rate V1–V2 (0.36, $P < 0.05$), and rate V2–V3 (0.47, $P < 0.01$).

Pregnancy Complications and Infant Outcomes

There were no significant differences in pregnancy complications and infant outcomes among groups (Table 3); however, lower birth weight *z*-scores and lower risk of macrosomia were observed among obese women who were in the intervention group compared with the control group according to pairwise comparison test (birth weight *z*-score: Int-OB = 0.46 ± 0.99, Con-OB = 1.09 ± 1.19, $P = 0.239$; macrosomia risk: Int-OB = 22.2%, Con-OB 55.6%, $P = 0.335$).

TABLE 4. Correlations between prepregnancy BMI and weekly GWG rates before walking intervention and between visits.

	Pre-BMI	Before Intervention	Rate V1–V2	Rate V2–V3	Rate V3–V4
Pre-BMI	1.00				
Rate before intervention	0.07	1.00			
Rate V1–V2	0.09	0.49**	1.00		
Rate V2–V3	−0.25	0.24	0.46**	1.00	
Rate V3–V4	−0.01	0.21	0.36*	0.47**	1.00

*$P < 0.05$, **$P < 0.01$.
Pre-BMI, prepregnancy BMI; V1, weeks 10–14 of gestation; V2, weeks 17–19 of gestation; V3, weeks 27–29 of gestation; V4, weeks 34–36 of gestation; rate before intervention, weekly gestational weight gain (GWG) rate before joining walking intervention; rate V1–V2, weekly GWG rate between V1 and V2; rate V2–V3, weekly GWG rate between V2 and V3; rate V3–V4, weekly GWG rate between V3 and V4.

DISCUSSION

One of the hypotheses of the current study was that participation in the walking intervention would help previously nonexercising, overweight, and obese women to increase their MPA during pregnancy. The results showed that women in the intervention group were able to significantly increase their moderately intense walking cadence, especially among the overweight women. In fact, there were overweight women in the intervention group who met the minimum recommendation of 150 min·wk^{-1} of MPA ($n = 2$ at V2, $n = 3$ at V3, and $n = 2$ at V4); however, none of the overweight women in the control group met the recommendation. In addition, when at least 8-min bouts of walking were examined for meaningful walk, women in the intervention group had more minutes of meaningful walks than those in the control group. In comparison, more than 50% of the overweight and obese women in the control group had 0 min of meaningful walks across pregnancy. Perhaps, the current intervention was successful in helping pregnant women increased their MPA participation during pregnancy, particularly the overweight women. These women walked at a higher intensity and, most importantly, were able to sustain these habits until late pregnancy.

Overall, the amount of MPA engaged in by the overweight and obese women in the current intervention was substantially higher than other reported PA trends among pregnant and nonpregnant populations. When prenatal PA participation was objectively measured using an ActiGraph accelerometer in the NHANES 2003–2006 cross-sectional data ($n = 359$) (10), the

results showed that pregnant women only participated in an average of 12.0 ± 0.86 min·d^{-1} of moderate activity and 0.3 ± 0.08 min·d^{-1} of vigorous activity. When a cadence of nonpregnant populations were examined by Tudor Locke et al. (31) using the 2005–2006 NHANES data (n = 1963 females), women only accumulated 12.78 min·d^{-1} of cadence ≥ 80 steps per minute. Furthermore, it has been well documented that PA participation decreases as pregnancy progresses (23). It was reported by Evenson and Wen (10) that U.S. pregnant women spent 11.5 min·d^{-1} during the first trimester, 14.3 min·d^{-1} during the second trimester, and 7.6 min·d^{-1} during the third trimester in moderate to vigorous PA. In the current study, overweight women in the intervention group successfully maintained their duration of moderately intense walking throughout pregnancy, even during the late third trimester.

We further hypothesized that those participants who increased their MPA participation via the walking intervention would have more favorable GWG outcomes. Overall, the total GWG between intervention and control groups for both overweight and obese women was not significantly different. When percentage of participants meeting 2009 IOM GWG guidelines was examined at V4, a greater proportion of overweight women in the intervention group gained within the recommendations, although it was not statistically significant. The findings of the present study are supported by a meta-analysis conducted by Streuling et al. (28), which evaluated trials that only involved increased PA as the means to minimize GWG. Twelve RCT were included in this analysis with interventions varying by intensity, duration, and mode of activity. Seven of the trials reported a trend for lowering GWG in the intervention group, one trial showed significant reductions in GWG, and five trials showed no significant effect on GWG. When all RCT were combined, the overall meta-analysis finding demonstrated that PA modification resulted in significant GWG reduction (mean difference = −0.61, 95% confidence interval = −1.17 to −0.06, P = 0.03). The walking program of the current study significantly increased the moderately intense steps of women in the intervention group, especially the overweight women, during pregnancy; therefore, the trend of a higher percentage of women in Int-OW group meeting the GWG guidelines may be partly explained by the increased MPA during pregnancy.

The present study also suggests a "cascade effect" of weight gain throughout pregnancy. The rate of GWG at any point during pregnancy was significantly influenced by the preceding rate of weight gain. In this study, weight gain after enrollment into the walking intervention was affected strongly by the weight already gained before the start of the intervention. This observed effect could be especially discouraging to investigators who hope to introduce lifestyle modifications during pregnancy to prevent excessive GWG. One such example is the NELIP study conducted by Mottola et al. (16), a personalized walking program to reach 30% peak HR reserve of the participant. This program began between 16 and 20 wk of gestation, and walking was performed three to four times a week (40 min per session). The results of this intervention showed that 80% of the participants did not exceed 2009 IOM recommendations on NELIP and their average total weight gain on NELIP was only 6.8 ± 4.1 kg. Unfortunately, many women had gained excessive weight before they joined the program; therefore, their average total weight gain was 12.0 ± 5.7 kg, which exceeded the total GWG range recommended by IOM for both overweight and obese women.

Our final hypothesis was that those participants who increased their MPA participation via the walking intervention would have more favorable birth outcomes. The walking program in this study did not cause any adverse effects on labor/delivery complications and birth outcomes. In fact, there was a trend for obese women who participated in the walking program to have lower infant birth weight z-scores and decreased odds of fetal macrosomia compared with obese women in the control group. More recently, evidence shows that maternal PA helped reduce the risk of giving birth to large-for-gestational-age infants by not increasing the odds for an SGA infant (17). Thus, because the obese women in the intervention group significantly increased their moderately intense walking, the increase in favorable child outcomes may be due partly to the increase in MPA.

Little information is available about the feasibility and benefits of previously nonexercising overweight and obese pregnant women increasing their MPA via walking. Different from the NELIP study, the present intervention was a randomized controlled trial, and it was an unsupervised PA-only intervention. Diet counseling was not provided nor was caloric restriction emphasized in the study. Any positive maternal and child health outcomes observed in the study would be primarily attributed to the increased PA participation during pregnancy. Therefore, this intervention added unique contributions in the field of maternal and child health. This study objectively measured walking of pregnant women to evaluate MPA participation and patterns during pregnancy. Because walking is the most common activity practiced among pregnant women, being able to objectively measure step counts and use the cadence to determine activity intensity could provide further insight into the relationship between MPA participation during pregnancy and health outcomes of the mother and fetus. Studies reported the use of SAM for measuring walking in various populations (3,11,27); however, to the best of our knowledge, no study has reported the use of SAM among pregnant population. In recent years, the use of cadence in intervention and behavioral research has been promoted due to its easily interpretable results (33). Thus, SAM is an ideal research pedometer for pregnant population as it could provide step data in the form of cadence. In addition, the placement of SAM is on the ankle and pedometer tilt is minimized with the growing stomach among pregnant women using this device (5). Also, the current intervention was an unsupervised, free-living walking program. The women were provided with a treadmill for home use. Thus far, most successful interventions that have targeted overweight and obese pregnant women consist of fully or partially supervised activities (2,6,16). This type of intervention

required trained staff members to supervise the workout sessions, which can be expensive, labor intensive, and time consuming. With positive results observed through our pilot study, a treadmill could be a relatively cost-effective intervention tool to help pregnant women to increase their PA to meet the current recommendations. Despite a low usage (33.8%) of the treadmill, by having a treadmill at home may have increased the participant's self-efficacy to overcoming barriers, for instance lack of childcare support or weather-related concerns, during pregnancy to be physically active (14).

It is acknowledged that the present pilot study has some limitations. The study had a small sample size and high variability among the groups. These factors could potentially reduce the ability to detect statistically significant effects of the intervention. Second, there is no known study that has been conducted to measure the walking cadence/intensity of the pregnant population. As a result, the present study used the evidence in the literature to define the moderately intense cadence for pregnant women, which was a cadence ≥80 steps per minute of the participants. Further research in this area is needed. Third, self-reported prepregnancy BMI was used in the study, which could lead to inaccurate data because evidence has shown that overweight women are more likely to underreport their weight compared with normal or underweight women (25). Lastly, the StepWatch™ monitor may not have accounted for other activities the women participated in during the intervention period, such as running, biking, or swimming. Considering that the intervention was focused on walking, the StepWatch™ monitor was viewed as an acceptable measurement tool for quantifying the intervention effect.

In conclusion, this pilot unsupervised walking program significantly increased MPA among pregnant women, especially overweight women via walking to meet the current maternal PA recommendations. There was a nonsignificant trend for women in the intervention group to have more favorable pregnancy and birth outcomes compared with the control group. The findings of the present study provide important preliminary results in understanding walking patterns during pregnancy and health outcomes of mother and baby. Because the study of the relationship between cadence and one's free-living patterns of ambulatory activity is a new and innovative area, future research is needed to examine the relationship between mother's cadence intensity and pregnancy outcomes.

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The authors report no conflict of interest.

The results of the present study do not constitute endorsement by the American College of Sports Medicine.

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ORIGINAL ARTICLE

Preventing excessive gestational weight gain—a secondary analysis of a cluster-randomised controlled trial

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BACKGROUND: Healthy diet, physical activity and modest weight gain during pregnancy may prevent developing gestational diabetes mellitus (GDM). We examined whether a lifestyle intervention designed to prevent GDM was effective in reducing excessive gestational weight gain (GWG).

METHODS: A cluster-randomised controlled trial ($n = 399$) was conducted in maternity clinics in 14 municipalities in Southern Finland. Pregnant women with at least one risk factor for GDM (for example, overweight) but no pre-existing diabetes were recruited at 8–12 weeks' gestation. The intervention included counselling on GWG, physical activity and healthy eating at five routine visits. Usual counselling practices were continued in the usual care municipalities. Statistical analyses were performed using multilevel linear and logistic regression models adjusted for weeks' gestation at last weight measurement, pre-pregnancy body mass index and smoking status.

RESULTS: The intervention group had a lower mean GWG by weeks' gestation than the usual care group (adjusted coefficient for the between-group difference −0.016 kg per day, $P = 0.041$). There was no difference in mean (±s.d.) GWG between the intervention and the usual care groups (13.7 ± 5.8 vs 14.3 ± 5.0 kg, $P = 0.64$). In total, 46.8% of the intervention group and 54.4% of the usual care group exceeded the GWG recommendations. The adjusted odds ratio for excessive GWG was 0.82 (95% CI 0.53–1.26, $P = 0.36$) in the intervention group as compared with the usual care group.

CONCLUSIONS: The intervention had minor effects on GWG among women who were at increased risk for GDM. In order to prevent excessive GWG, additional focus on restriction of energy intake may be needed.

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Keywords: pregnancy; gestational weight gain; cluster randomized controlled trial; dietary counselling; physical activity counselling; gestational diabetes mellitus

INTRODUCTION

High gestational weight gain (GWG) is an important risk factor for adverse pregnancy outcomes, such as caesarean section and high birth weight infants.[1–3] High GWG may also increase the risk of gestational diabetes mellitus (GDM)[4–6] or impaired glucose tolerance during pregnancy, possibly by reducing insulin sensitivity.[7] In addition to being strongly associated with long-term weight retention and risk of overweight in the mother,[2,8,9] high GWG also increases the risk of overweight in the offspring.[10–13] The US Institute of Medicine (IOM) published the body mass index (BMI) specific recommendations for GWG in 1990(ref. 14) and revised them slightly in 2009(ref. 15) taking into consideration a wide range of long-term consequences, such as weight retention in the mother. These US recommendations have been adopted in many European countries.[16]

Several trials have aimed to restrict GWG by dietary and physical activity interventions and the results of these trials have recently been reviewed by a roughly similar number of systematic reviews and/or meta-analyses.[17–27,28] The reviews have reported mixed results, mainly due to different inclusion criteria for individual trials. The individual trials have been heterogeneous and in most of them the sample size has been small. Larger trials are still needed to explore the effects of lifestyle counselling on prevention of excessive GWG and its adverse consequences.

The present study is a part of a cluster-randomized controlled trial primarily aimed at preventing GDM by counselling pregnant women on GWG, physical activity and diet.[29,30] The effects of the intervention on prevention of GDM and high-birth-weight infants (the primary outcomes)[30] as well as physical activity and diet (secondary outcomes)[31,32] have been reported previously. The main results of the study showed that the intervention was able to reduce mean birthweight and the proportion of large-for-gestational-age infants, although it did not have an effect on the proportion of women diagnosed with GDM by 26 to 28 weeks' gestation.[30] The present paper describes the effects of the intervention on the proportion of women exceeding the IOM's recommendations for GWG,[14] the mean total GWG and the mean weight gain by weeks' gestation. We hypothesised that a lower proportion of the intervention group exceeds the GWG recommendations as compared with the usual care group.

MATERIALS AND METHODS

Study design

This study was a non-blinded cluster-randomized controlled trial conducted in Pirkanmaa region, Southern Finland. The methods of the study have been described previously in detail.[29,30] The study was conducted in municipal maternity clinics in 14 municipalities, which

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Contributors: TIK, MA and RL designed research and conducted research; JR and TIK performed statistical analyses; TIK wrote the paper and TIK and RL have the primary responsibility for final content. All authors read, commented and approved the final paper.

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were arranged into pairs and matched for the size and the socioeconomic level of the population, annual number of births, incidence of GDM and the location (rural/urban area). The municipalities were then randomised by computer within each pair to the intervention or to the usual care municipalities. The purpose of the cluster-randomisation was to reduce the possibility of contamination of counselling practices of the public health nurses. The ethical approval for the study protocol was obtained from the ethical committee of Pirkanmaa Hospital District. All participants gave a written informed consent.

Participants

Public health nurses ($n = 53$) recruited pregnant women for the study at their first visit (8–12 weeks' gestation) to the maternity clinic. Recruitment took place between 1 October 2007 and 31 December 2008 and all participants had given birth by September 2009. In Finland, public health nurses (later referred as nurses) are registered nurses who are specialized, for example, in health promotion and have completed 4 year training.

The pregnant women were eligible if they had at least one of the following risk factors for GDM: BMI $\geqslant 25\,kg/m^2$, age $\geqslant 40$ years, GDM or any sign of glucose intolerance or a macrosomic baby ($\geqslant 4500\,g$) in any previous pregnancy, or type 1 or type 2 diabetes in first-or second-grade relatives. They were excluded if they had at least one of the following: a pathological result in the baseline oral glucose tolerance test (75 g glucose) at 8–12 weeks' gestation,[33] pre-pregnancy type 1 or 2 diabetes, inability to speak Finnish, age <18 years, twin pregnancy, physical restriction that prevents from exercising, substance abuse, or treatment or clinical history for major psychiatric illness, or other chronic disease.

The flow of participants is shown in Figure 1. Of women preliminarily eligible to the study, 343 (88.2%) in the intervention group and 297 (88.1%) in the usual care group gave informed consent to participate. However, 81 (23.6%) of the participants in intervention group and 93 (31.3%) of the participants in the usual care group were found ineligible and excluded due to an abnormal result in oral glucose tolerance test at baseline (8–12 weeks' gestation). The final number of participants in the analyses was 219 in the intervention group and 180 in the usual care group (89.0% and 91.8% of participants receiving the allocated intervention or the usual care, respectively).

Intervention

The intervention consisted of individual counselling on weight gain, physical activity and diet by the nurses at five routine visits to the maternity clinics (Table 1). The counselling procedures and materials have been described in detail previously.[29] The general aim of the counselling was to help the participants to achieve the recommendations on GWG, physical activity and diet during pregnancy. At the first visit, the nurses first calculated the participants' BMI based on measured height and self-reported pre-pregnancy weight and then informed them about the GWG range recommended for their BMI. The participants also received follow-up notebooks, including BMI-specific charts, for monitoring their weight gain until the end of pregnancy. Weight gain was recorded on the chart and the participants received feedback on their weight gain from the nurses at each of the five visits. The participants were also encouraged to self-monitor their weight gain between the visits by weighing themselves and recording the weight on the chart.

The contents of the physical activity and dietary counselling are also shortly described in Table 1. The participants were also offered an opportunity to participate in monthly thematic meetings on physical activity, including group exercise conducted by physiotherapists. The participants were not provided specific goals for energy intake or expenditure. Usual counselling practices were continued in the usual care clinics.

Outcome variables and data collection

The outcomes were the proportion of women with excessive GWG (that is, proportion of women exceeding the IOM's 1990 recommendations on GWG),[14] the mean total GWG, the mean weight gain by weeks' gestation and the proportion of women who exceeded IOM's revised recommendations for GWG,[15] which were published after all participants were enroled. The revised recommendations are 12.5–18.0 kg for women with pre-pregnancy BMI $<18.5\,kg/m^2$, 11.5–16.0 kg for women with BMI 18.5–24.9 kg/m^2, 7.0–11.5 kg for women with BMI 25.0–29.9 kg/m^2 and 5.0–9.0 kg for women with BMI $\geqslant 30\,kg/m^2$.

Data on age, parity, anthropometric measurements and other pregnancy data were obtained from the standard maternity card used in all maternity clinics. Pre-pregnancy weight was self-reported and height was measured at the first visit. Body weight was measured at all visits during pregnancy and recorded to one decimal place. The measurements were performed in light clothing and without shoes. Total GWG was calculated as the difference between the last measured weight during pregnancy (at mean 38.5, s.d. 2.2, weeks' gestation) and pre-pregnancy weight. A questionnaire was used to collect information on education and working status at the first maternity clinic visit and on smoking status both at the first visit and the 36–37 weeks' visit.

Statistical methods

Statistical analyses were conducted using STATA software (version 11.2; StataCorp. LP, TX, USA). The data was analysed in the originally randomised groups whenever the outcome data were available for participants. Descriptive information was reported as means (s.d.) for continuous variables and as frequencies (%) for categorical variables. All statistical analyses were performed using multilevel models enabling correction of the results for between-municipality, between-clinic and between-nurse variation.

Multilevel linear regression models were used to analyse between-group differences in the mean weight gain by weeks' gestation, the mean timing of the last weight measurement and the mean total GWG. The between-group differences in these outcomes were described as coefficients (95% confidence intervals) or means (s.d.) and *P*-values. When comparing the mean weight gain by weeks' gestation between the groups, the model included the self-reported pre-pregnancy weight, all measured weights, the timing of each weight measurement (weeks' gestation), the interaction term between the group and the timing variables, and the model was also adjusted for pre-pregnancy BMI and smoking status. The between-group difference in the proportion of participants exceeding the GWG recommendations (vs below or within recommendations) were analysed using multilevel logistic regression model and the results were described as odds ratios (95% confidence intervals) and *P*-values. When comparing the mean total GWG or the proportion of participants exceeding the GWG recommendations, the models were adjusted for weeks' gestation at last weight measurement, pre-pregnancy BMI (both continuous), and smoking status (categorised) as of all background variables these variables remained significant in the multivariable models. The analyses were conducted separately among normal weight and overweight participants. The number of underweight participants was too low for the stratified analysis. In a sensitivity analysis, the multilevel logistic regression model was also performed using achievement of the IOM's GWG recommendations in 2009 as the outcome variable (exceeding vs below or within recommendations).

RESULTS

The participants had similar age, pre-pregnancy weight, height and BMI on average in both groups at baseline (Table 2). The intervention group had a slightly lower proportion of overweight participants than the usual care group. The proportions of participants with no previous children, a university degree or a fulltime job or who were non-smokers were higher in the intervention group than in the usual care group. The prevalence of each of the inclusion criteria was fairly similar in both groups except that the intervention group had more often relatives with diabetes than the usual care group.

Figure 2 shows the mean weight gain in the intervention and the usual care groups by weeks' gestation until the end of pregnancy. The mean weight gain seems to differ between the groups only after 30 weeks' gestation. Based on the multilevel mixed effects linear regression model, the intervention group had a lower mean weight gain by weeks' gestation than the usual care group (adjusted coefficient for the between-group difference -0.016 kg per day, $P = 0.041$). However, the total GWG by the end of pregnancy was not statistically significantly different between the groups (Table 3).

Similarly, although a lower proportion of the intervention group (46.8%) than of the usual care group (54.4%) exceeded the

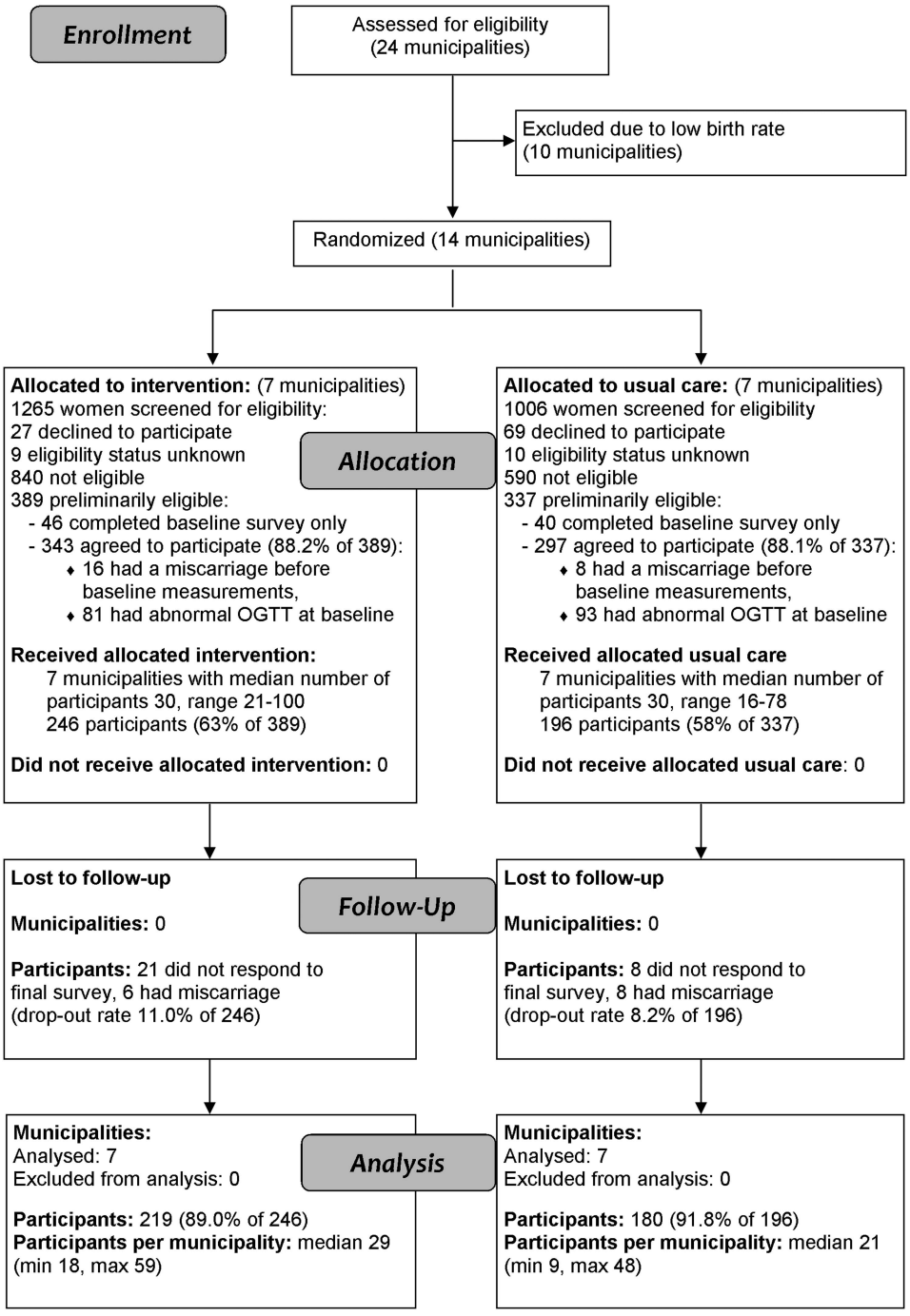

Figure 1. Flow diagram of the cluster randomized controlled trial.

recommendations given by IOM in 1990, the odds ratio for excessive GWG was not statistically significant between the groups regardless of whether adjusted for confounders or not (Table 3). The results were similar when the data was stratified by pre-pregnancy BMI status. As compared with the usual care group, the participant in the intervention group had an odds ratio of 0.84 (95% CI 0.46–1.54, $P = 0.58$) among normal weight women and an odds ratio of 0.74 (95% CI 0.29–1.92, $P = 0.54$) among overweight women for excessive GWG, when adjusted for weeks' gestation at last weight measurement, pre-pregnancy BMI (as continuous) and smoking status.

In the sensitivity analyses including participants from all BMI categories, 115 (54.0%) participants in the intervention group and 106 (62.7%) participants in the usual care group gained weight more than recommended by IOM in 2009. When adjusted for the same confounders, the intervention did not have a statistically significant effect on the proportion of participants exceeding these IOM's revised recommendations (adjusted OR 0.75, 95% CI 0.49–1.24, $P = 0.26$).

DISCUSSION

To our knowledge, this study is the largest randomised controlled trial to date reporting the effects of lifestyle counselling on prevention of excessive GWG. The intervention group had a lower mean weight gain by weeks' gestation, although mainly from 30

Table 1. Timing and content of the counselling visits and the recommendations used in the counselling in the intervention municipalities

Weeks' gestation	*Content of counselling*	*Recommendations*
8–12	GWG: the participant's pre-pregnancy BMI was calculated, her BMI-specific GWG recommendation was discussed, the participant was weighed, weight gain by that time was recorded on the chart in her follow-up notebook and feedback was given Physical activity (primary counselling session): a detailed personal plan for leisure time physical activity was agreed and written down in the follow-up notebook	GWG: BMI $<20\,kg/m^2$: 12.5–18.0 kg BMI 20.0–26.0 kg/m^2: 11.5–16.0 kg BMI $>26.0\,kg/m^2$ 7.0–11.5 kg.[14] Physical activity: to achieve (or maintain) the physical activity recommendations for health.[39] The recommended minimum weekly amount of leisure-time physical activity corresponded to 800 MET (multiples of resting metabolic equivalents) minutes, which is equivalent, for example, to moderate intensity activity ~for 30 min five times a week.[40,41]
16–18	GWG: the participant was weighed, weight gain by that time was recorded on the chart in her follow-up notebook and feedback was given Physical activity: realisation of the plan was discussed based on participant's records and the plan was revised when needed Diet (primary counselling session): a detailed personal plan for changes in diet was agreed and written down in the follow-up notebook	Diet: to achieve (or maintain) a diet containing saturated fat $\leqslant$10 E%[a], polyunsaturated fat 5 to 10 E%, total fat 25 to 30 E%, saccharose $<$10 E% and fibre 25 to 35 g per day.[42–46] In practice, the participants were advised to (1) to use vegetables, fruits and berries, preferably at least five portions (a total of 400 g) a day, (2) to select mostly high fibre bread ($>$6 g fibre/100 g) and other whole-meal products, (3) to select mostly fat-free or low-fat milk and milk products and of meat and meat products, (4) to eat fish at least twice per week, (5) to use moderate amounts of soft vegetable spreads on bread, oil-based salad dressing in salad and oil in cooking and baking, (6) to use foods high in fat seldom and only in small portion sizes and (7) to use snacks containing lots of sugar and/or fat seldom and only in small portion sizes.
22–24, 32–34 and 36–37	GWG: the participant was weighed, weight gain by that time was recorded on the chart and feedback was given Physical activity and diet: realisation of the plan was discussed based on participant's records and the plan was revised when needed.	

Abbreviations: GWG, gestational weight gain; BMI, body mass index. [a]E%: percentage of energy intake.

weeks' gestation onwards. However, the intervention did not have a statistically significant effect on mean total GWG or the proportion of participants exceeding the GWG recommendations. The results were the same when normal weight and overweight women were analysed separately and when achievement of the IOM's revised recommendations[15] were used as the outcome variable.

The primary aim of this trial was to prevent development of GDM, which should be kept in mind when interpreting these results. Although appropriateness of weight gain was discussed and weight was measured at each of the five visits, the dietary counselling focused on improving diet with regard to the quality of dietary fat, and fibre and saccharose intake instead of aiming to restrict energy intake to reduce GWG. The counselling was effective in improving diet with several qualitative respects both by 26–28 and 36–37 weeks' gestation,[31] although no between-group differences were observed in changes in energy intake. The physical activity counselling helped the participants to maintain the frequency of leisure-time activity sessions until 26 to 28 weeks' gestation, but did not have effect on total leisure-time activity level.[32] Based on these changes in lifestyle, perhaps larger effects on GWG could not even have been expected. Nevertheless, the present study with five counselling sessions incorporated in usual care was effective in reducing the proportion of large-for-gestational-age infants, a typical adverse consequence of GDM.[30]

Although the total GWG may be a more relevant outcome from the clinical viewpoint, the results related to the weight gain by weeks' gestation could be utilised, for example, when developing the counselling methods further. The intervention group had a lower weight gain by weeks' gestation than the usual care group but apparently only after 30 weeks' gestation (Figure 2), which is understandable considering the timing of counselling and the changes obtained in diet and physical activity. In order to have an effect on weight gain earlier in pregnancy (and thus also on total GWG), more frequent visit in early pregnancy with more emphasis on controlling energy intake and increasing total physical activity may be needed.

In theory, GDM might be a confounder in the analyses if the participants with GDM received additional advice on diet and activity and if there was a difference between the intervention and the usual care groups in the proportion of participants with GDM. We did not include the GDM variable in the final multivariable models because there were no between-group differences in the incidence of GDM (15.8% in the intervention vs 12.4% in the usual care group, $P=0.16$)[30] or in the proportion of participants receiving additional dietary advice from a nurse specialised in diabetes care (7.9% vs 3.8%, respectively, $P=0.11$, χ^2-test), and the GDM variable was not statistically significantly associated with GWG in any of the multivariable models.

The effects of previous lifestyle interventions on GWG have been mixed. Based on the review by Herring *et al.*,[24] two of the previous systematic reviews and meta-analyses concluded that the interventions did not have effect on mean GWG,[17,22] two concluded that the interventions were effective in reducing GWG in certain subgroups only and not to the level recommended by IOM[18,19] and three concluded that the interventions were able to

Table 2. Background characteristics of the study population, means (s.d.) or numbers (%)

	Intervention group (n = *219*)[a]	*Usual care group* (n = *180*)[b]
Age, years	29.5 ± 4.8	30.0 ± 4.7
Pre-pregnancy weight (kg)	72.4 ± 15.1	72.6 ± 12.6
Height (m)	1.66 ± 0.06	1.66 ± 0.06
Pre-pregnancy BMI, (kg/m^2)	26.2 ± 4.9	26.4 ± 4.4
BMI categories, n *(%)*		
Underweight, BMI < 20.0 kg/m^2	12 (5.5)	8 (4.4)
Normal weight, BMI 20.0–26.0 kg/m^2	109 (50.0)	82 (45.6)
Overweight, BMI > 26.0 kg/m^2	97 (44.5)	90 (50.0)
Parity, n *(%)*		
0	103 (47.0)	73 (40.6)
1	76 (34.7)	62 (34.4)
⩾2	40 (18.3)	45 (25.0)
Education, n *(%)*		
Basic or secondary education	107 (49.5)	92 (52.6)
Polytechnic education	51 (23.6)	47 (26.9)
University degree	58 (26.9)	36 (20.6)
Working fulltime at baseline, *n* (%)	147 (67.1)	104 (57.8)
Smoking status, n *(%)*		
Non-smoker	169 (77.2)	128 (71.1)
Smoker during the year before pregnancy[c]	36 (16.4)	41 (22.8)
Smoker during the year before pregnancy and during pregnancy[c]	14 (6.4)	11 (6.1)
The inclusion criteria		
BMI ⩾25 kg/m^2, *n* (%)	128 (58.4)	110 (61.5)
Age ⩾40 years, *n* (%)	5 (2.3)	5 (2.8)
Macrosomia (⩾4500 g) in any previous pregnancy, *n* (%)	6 (2.7)	5 (2.8)
Gestational diabetes or glucose intolerance in any previous pregnancy, *n* (%)	26 (11.9)	19 (10.6)
Type 1 or 2 diabetes in first- or second-grade relatives, *n* (%)	126 (57.5)	90 (50.3)

[a]Number of missing values: age, height, BMI and BMI categories ($n = 1$), education ($n = 3$). [b]Number of missing values: education ($n = 5$). [c]Includes daily or occasional smoking.

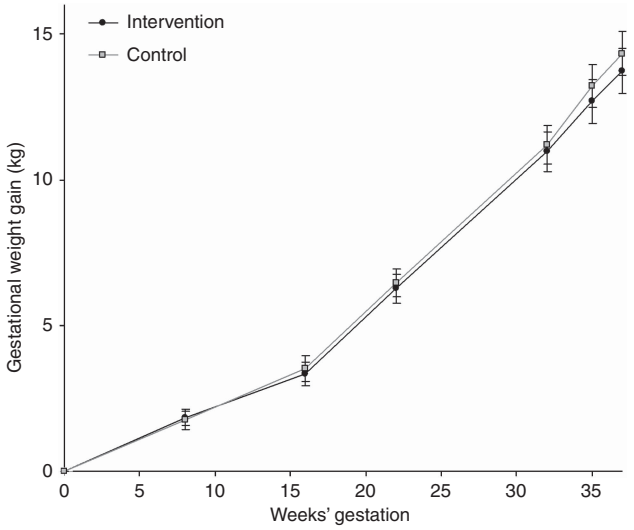

Figure 2. Mean (95% CI) weight gain by weeks' gestation in the intervention ($n = 192$–216) and the usual care groups ($n = 160$–171), adjusted for pre-pregnancy BMI, and smoking status (coefficient for between-group difference −0.016, $P = 0.041$).

reduce mean GWG but did not report their effect on the proportion of participants achieving the recommended GWG.[20,23,27] Additionally, two meta-analyses[25,26] on dietary interventions to prevent excessive GWG concluded that the interventions were effective in reducing mean GWG. Tanentsaph *et al.*[26] suggested that more intensive interventions that focus on caloric restriction are needed to restrict GWG at least in overweight and obese women. On the other hand, Herring *et al.*[24] and a recent Cochrane review[28] concluded that none of the previous intervention strategies have been particularly effective or ineffective in general. As most of these previous reviews used different selection criteria for individual trials, heterogeneous conclusions can be expected.

Of all previous individual randomized controlled trials to prevent excessive GWG, the study by Phelan *et al.*[34] was the largest ($n = 363$ in the analyses). The intervention in this US study consisted of one baseline face-to-face counselling session and weekly mailed materials about appropriate GWG, healthy diet and exercise, individual graphs of GWG and telephone-based feedback for participants. The intervention reduced the proportion of women gaining excessively weight among normal weight women (40.2% in the intervention group vs 52.1% in the control group, $P = 0.003$), but not among overweight or obese women.

The results have also been quite promising in two other recent randomized controlled trials that were not included in the above mentioned reviews. A Danish study including 304 obese women[35] found that the lifestyle intervention had effect on median GWG (7.0 vs 8.6 kg, $P = 0.01$) and the proportion of women exceeding IOM's recommendations (35.6% vs 46.6%, $P = 0.058$). Similar to our study, women with a positive oral glucose tolerance test in early pregnancy were excluded from the intervention. In a Canadian study ($n = 190$ non-diabetic women), the dietary and physical activity counselling intervention was able to reduce the proportion of women exceeding the GWG recommendations

Table 3. Gestational weight gain in the intervention and the usual care groups, means (s.d.), numbers (%) or odds ratios (95% CI)

	Intervention group (n = 219)	*Usual care group (n = 180)*	P-*value*	*Intra-cluster correlation coefficient*
Timing of the last weight measurement (weeks' gestation)[a]	38.3 ± 2.6	38.7 ± 1.7	0.12[b]	
Total gestational weight gain (kg)[c]	13.7 ± 5.8	14.3 ± 5.0	0.64[d]	<0.001
Gestational weight gain				
Below recommendations	59 (27.3%)	30 (17.8%)		
Within recommendations	56 (25.9%)	47 (27.8%)		
Exceeding recommendations	101 (46.8%)	92 (54.4%)		
Crude odds ratio for exceeding recommendations[e]	0.73 (95% CI 0.48–1.11)	1.00	0.14[b]	0.008
Adjusted odds ratio for exceeding recommendations[c]	0.82 (95% CI 0.53–1.26)	1.00	0.36[d]	0.002

[a]Number of missing values: intervention group ($n = 3$), usual care group ($n = 10$). [b]Multilevel linear regression model for comparing means and multilevel logistic regression model for odds ratios taking into account the between-municipality, between-clinic and between-nurse variation. [c]Number of missing values: intervention group ($n = 4$), usual care group ($n = 11$). [d]Multilevel linear regression model for comparing means and multilevel logistic regression model for odds ratios taking into account the between-municipality, between-clinic and between-nurse variation and adjusting for weeks' gestation at last weight measurement, pre-pregnancy BMI (both continuous), and smoking status (categorical). [e]Number of missing values: intervention group ($n = 3$), usual care group ($n = 11$).

(35.3% vs 54.5%, $P < 0.01$), although it did not have effect on mean GWG.[36] On the other hand, a smaller exercise intervention in the Netherlands had no effect on mean GWG at 32 weeks' gestation in overweight or obese pregnant women at risk for GDM ($n = 84$).[37]

We also analysed the effects of the intervention on the proportion of participants exceeding the revised recommendations for GWG.[15] The results were essentially similar except that a higher proportion of the participants exceeded the revised recommendations in both groups. This finding is in line with a US observational study ($n = 11\,688$), in which a higher proportion of pregnant women were classified as excessive weight gainers and a lower proportion of women as inadequate weight gainers when using the IOM's revised recommendations as the criterion.[38] This derives from the fact that when using the revised recommendations with WHO's BMI-categories, a higher proportion of women are classified as overweight and a lower proportion of women as underweight, normal weight and obese as compared with the previous IOM's BMI-categories.

The present study had some strengths compared with the previous trials. In addition to being the largest randomized controlled trial reporting the effects of a lifestyle counselling intervention on prevention of excessive GWG (though as a secondary outcome) to date, the intervention was incorporated in the routine visits to public maternity clinics suggesting that the counselling procedures are likely to be more transferable to maternity care practices. The participation rate was very high in both groups (88%). The dropout rate was also relatively low as data on GWG was missing only for 30 (12.2%) participants in the intervention group and 27 (13.8%) participants in the usual care group of all participants who were eligible and signed the informed consent.

There are also some limitations that need to be addressed. First, the power calculations were made based on the primary outcome of the trial (GDM) only and not based on any of the secondary outcomes (for example, GWG).[30] Even if the present trial was larger than any of the previous trials aiming to prevent excessive GWG, its small sample size and/or effect size may have been too small for the GWG outcome (partly due to the cluster randomisation) as can be seen from the wide confidence intervals for the odds ratios and the means. Second, there were some differences in background characteristics of the participants between the groups suggesting the possibility of a selection bias. After all only few of these variables were actual confounders and were included in the multivariable models. Nevertheless, it is possible that the intervention group may have been more health conscious and motivated to improve their lifestyle during pregnancy as they were more often highly educated, working full-time and first-time mothers. Third, although the dropout rate was low, intention-to-treat analyses were not done due to missing values (12.2–13.8%) in the weight data. Fourth, as in most studies on GWG, self-reported pre-pregnancy weight may cause some inaccuracy in measurement of GWG. However, the difference between the pre-pregnancy weight and the weight measured at the first visit was similar in the intervention and the usual care groups (Figure 2) and therefore, it is not likely that there were major differences between the groups in the accuracy of reporting pre-pregnancy weight. The scales of the maternity clinics were not calibrated but possible inaccuracies are more likely to have occurred at random than systematically between the groups. The nurses who made the body weight measurements were also aware of the participants' intervention status, which may be a potential weakness. However, we find the possibility of a bias unlikely, as the nurses were performing their usual work and recording the weights in the usual maternity cards, which was nothing extra for the purposes of the present study. Finally, the participants were women at increased risk for GDM. Even if overweight and other risk factors for GDM are common nowadays, the results may not be generalisable to all pregnant women.

In conclusion, the intervention including counselling on GWG, physical activity and diet had minor effects on GWG among women who were at increased risk for GDM. In order to prevent excessive GWG, additional focus on restriction of energy intake may be needed.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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Trial registration: Current Controlled Trials ISRCTN33885819.

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The effect of an antenatal physical exercise programme on maternal/perinatal outcomes and quality of life in overweight and obese pregnant women: a randomised clinical trial

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Objective To evaluate the effectiveness and safety of physical exercise in terms of maternal/perinatal outcomes and the perception of quality of life (QoL) in pregnant obese and overweight women.

Design A randomised controlled clinical trial.

Setting The Prenatal Outpatient Clinic of the Women's Integral Healthcare Centre (CAISM-UNICAMP) at the University of Campinas, Campinas, Brazil.

Population Eighty-two pregnant women (age ≥ 18 years; pre-gestational body mass index ≥ 26 kg/m^2; gestational age 14–24 weeks).

Methods Women were randomised into two groups: women in one group exercised under supervision and received home exercise counselling (the 'study group'; $n = 40$) and women in the other group followed the routine prenatal care programme (the 'control group'; $n = 42$).

Main outcome measures Primary outcomes were gestational weight gain during the programme and excessive maternal weight gain. Secondary outcomes were increased arterial blood pressure, perinatal outcomes and QoL (WHOQOL-BREF).

Results In the study group, 47% of pregnant women had weight gains above the recommended limit, compared with 57% of women in the control group ($P = 0.43$). There was no difference in gestational weight gain between the groups. Overweight pregnant women who exercised gained less weight during the entire pregnancy (10.0 ± 1.7 kg versus 16.4 ± 3.9 kg, respectively; $P = 0.001$) and after entry into the study (5.9 ± 4.3 kg versus 11.9 ± 1.5 kg, respectively; $P = 0.021$) compared with women in the control group. Arterial blood pressure was similar between the groups over time. There was no difference in perinatal outcome or QoL.

Conclusions The exercise programme was not associated with control of gestational weight gain in our sample as a whole, but was beneficial for lower gestational weight gain in overweight women. Exercise was not associated with adverse perinatal outcomes and did not affect variation in arterial blood pressure or the perception of QoL.

Keywords Body mass index, exercise, obesity, pregnancy, quality of life.

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Introduction

Obesity is increasing in prevalence worldwide, and is now considered a global epidemic. It has become a significant threat to health in all sectors of the population, including women of reproductive age.[1] According to the World Health Organization (WHO), the prevalence of obesity, defined as a body mass index (BMI) ≥ 30 kg/m^2, during pregnancy ranges from 1.8 to 25.3%.[1,2] In Brazil, a study conducted in six cities found that 5.5% of 5564 pregnant women evaluated were obese, and 25% were either overweight or obese.[3]

The Institute of Medicine (IOM)[4] defines obesity during pregnancy as a pre-pregnancy BMI ≥ 30 kg/m^2 and considers a range of gestational weight gains for each BMI category. For BMI ≥ 30 kg/m^2 this range is 5–9 kg.

Obesity during pregnancy increases the risk of morbidity and mortality in both the mother and the fetus during pregnancy and adversely affects gestational outcome.[5,6]

During pregnancy and delivery, the maternal complications associated with obesity include gestational diabetes mellitus, gestational arterial hypertension and pre-eclampsia, venous thromboembolic disease, induction of labour and caesarean section. Clinical and surgical complications can also occur, such as infections, haemorrhage, anaemia, urinary tract infection and endometritis; in addition, stress urinary incontinence, depression and even difficulties with breastfeeding have been associated with obesity.[2,6,7]

An association has also been described between obesity during pregnancy and adverse neonatal outcomes, such as macrosomia, metabolic syndrome and a predisposition to obesity secondary to gestational diabetes in children,[8,9] in addition to neural tube defects and congenital anomalies.[10,11]

While the negative impact of obesity on obstetric and perinatal outcomes is well established in the literature, information on how such adverse effects can be minimised through the use of specific interventions is still limited. Among diverse approaches, physical exercise has been indicated as an alternative for the management of obese pregnant women, although controversy remains regarding its effects during pregnancy.[12]

Physical exercise during pregnancy has been part of the recommendations of the American College of Obstetricians and Gynecologists (ACOG) since the mid-1990s. It is recognised as a safe practice, indicated for healthy pregnant women, as long as the intensity, duration and frequency of the exercise are tailored to the requirements of each woman.[13] Light to moderate exercise is recommended for all women, even those with a sedentary lifestyle who wish to engage in some type of physical activity during pregnancy.[14]

Clinical trials have suggested that a change in lifestyle, as well as adherence to a suitable diet and exercise regimen, should be recommended for obese women to prevent excessive gestational weight gain, postpartum weight retention and adverse outcomes associated with obesity and excessive weight gain.[12,15,16]

In this study, we evaluated the effect of an exercise programme on gestational weight gain, maternal arterial blood pressure and perinatal outcome in overweight/obese pregnant women and their perception of quality of life (QoL).

Methods

A randomised controlled clinical trial was conducted in pregnant women seen at the Prenatal Outpatient Clinic of the Women's Integral Healthcare Centre (CAISM-UNICAMP) from August 2008 to March 2010. Inclusion criteria were pregnancy, pre-gestational BMI categorised as overweight (26.0–29.9 kg/m^2) or obese (≥30.0 kg/m^2), age ≥ 18 years, and gestational age between 14 and 24 weeks. Exclusion criteria were multiple gestations, exercising regularly and conditions that contraindicate exercise, such as cervical incompetence, severe arterial hypertension, diabetes with vascular disease and risk of abortion.

Selected pregnant women were invited to participate in the study. The full study protocol was explained to these women and written informed consent was obtained. Subsequently, the women were randomly assigned to two groups: in the 'study group', the women exercised under supervision and received home exercise counselling, and in the 'control group' the women followed the routine prenatal programme provided by CAISM-UNICAMP. The results were analysed by treatment scheduled (intention-to-treat analysis).

The pregnant women were randomised to the groups using the SAS statistical program (SAS Institute, Cary, NC, USA), which generated a list of random numbers based on a uniform distribution. To ensure blinding, the sequence was randomly distributed in opaque envelopes, which were sealed and sequentially numbered. Each participant received a sequence number corresponding to a sealed envelope.

After randomisation, sociodemographic and obstetric data for the pregnant women were obtained.

The exercise programme was designed to enable pregnant women to increase their level of physical activity and to improve their QoL through simple exercises that could be performed without supervision and that did not present a risk to the mother or the fetus.

The women were counselled on recommended weight gain for their BMI category; the importance and effects of physical activity during pregnancy; the optimal amount and intensity of home exercise; nutrition; suitable clothing to wear when exercising; the recommended duration of exercise; signs and symptoms to look out for during exercise; and when to interrupt physical activity. The exercise programme consisted of two components.

1 The exercise protocol. Exercise was performed by the women under the guidance of a trained physical therapist, in weekly classes. The protocol consisted of light-intensity to moderate-intensity exercises. According to the ACOG recommendations (2002),[13] the woman's heart rate did not exceed 140 beats per minute. Group or individual exercises consisted of 10 minutes of general stretching, 22 minutes of exercises to strengthen the lower and upper limb muscles, and 10 minutes of supervised relaxation, totalling 40 minutes. The exercises followed a standardised

research protocol with a sequence of 22 exercises (see Supporting Information, Table S1).

2 Home exercise counselling. All pregnant women in the study group received counselling on home exercise to be performed five times a week. This exercise could consist of exercises from the protocol described above or walking. The women recorded the type (protocol or walking) and number of minutes of exercise in each session in a monthly exercise journal.

Pregnant women from the control group did not receive physical activity counselling and followed routine prenatal care advice. Both groups received standardised nutritional counselling from the Service of Nutrition and Dietetics (CAISM).

Follow-up data (gestational age, weight and arterial blood pressure) were recorded each time the woman attended the sessions until the end of pregnancy. In the study group, data were recorded on the days on which exercises were performed, at the beginning and end of sessions.

All pregnant women completed the WHOQOL-BREF questionnaire, on two occasions: at study inclusion and at the completion of 36 weeks of gestation. The domains of this questionnaire were scored on a scale of 0–100 points. Values closer to 0 were indicative of worse QoL and values closer to 100 reflected a better QoL.[17]

Data related to delivery (mode of delivery) and perinatal outcomes (weight of the newborn, Apgar index and adequacy of weight for gestational age) were collected using charts after the end of pregnancy.

The sample size was 41 women in each group. Sample size was calculated using a comparison between two proportions of excessive weight gain in obese women with gestational diabetes following a diet and exercise regimen (53.8 versus 78.9%)[18] and the chi-square test; assuming a ratio between groups of 1:1, a significance level of 5% and power of test of 70%.

Demographic characteristics were described using frequencies, percentages, means and standard deviations. The groups were compared in terms of homogeneity using Student's t test or the Mann–Whitney U test for continuous variables and the chi-square test for categorical variables. To determine the effectiveness of the intervention, the significance of differences between the groups in total weight gain (the difference between the pre-gestational weight reported by the pregnant woman and the weight measured at the last visit before the end of the pregnancy) and weight gain during the programme (the difference between the weight measured at study entry and the weight at the final visit, determined using a mechanical scale) was evaluated using Student's t test or the Mann–Whitney U test.

Excessive gestational weight gain was defined as a weight gain of >11.5 kg for overweight pregnant women and >9.0 kg for obese pregnant women, according to IOM recommendations.[4] Arterial blood pressure was measured using a mercury column sphygmomanometer and a stethoscope with the pregnant woman lying on her left side; the systolic and diastolic blood pressures were recorded. The adequacy of birthweight for gestational age was assessed according to the Alexander curve, and categorised as adequate, small or large (LGA) for gestational age, respectively, for measurements between the 10th and 90th percentiles.[19] The effect of exercise in WHOQOL domains was evaluated by analysis of variance for repeated measures.

To evaluate the normal distribution in variables, the Kolmogorov–Smirnov test and histograms were used. The significance level was set at 5% and the software used in the analysis was SAS version 9.1.

Pregnant women who abandoned the study over time were discontinued from the study. Some pregnant women delivered in other maternity hospitals and it was difficult to capture data for these women so these data are not included in the tables related to perinatal outcome.

This study was approved by the Institutional Review Board of the UNICAMP Medical School (FCM-UNICAMP) under registration number 542/2008.

Results

From August 2008 to October 2009, 93 pregnant women were considered eligible for inclusion in the study. Eighty-two

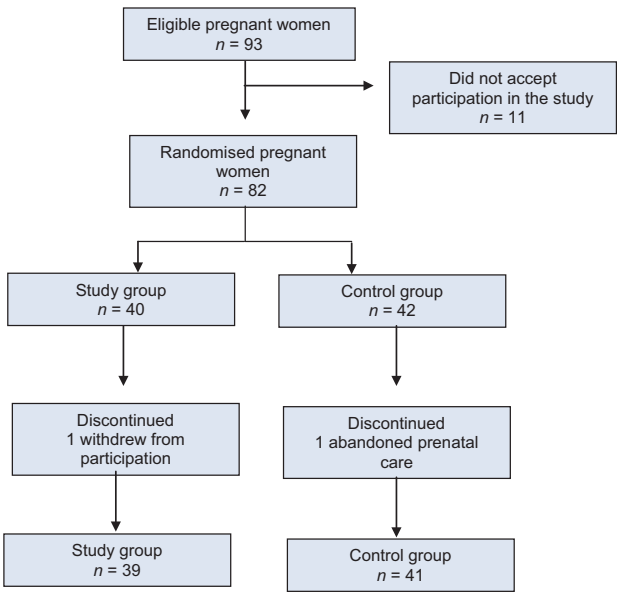

Figure 1. Flow chart showing the inclusion and follow up of pregnant women in the study.

pregnant women were randomised to the groups, of whom two later discontinued their participation in the study. Therefore, 39 women in the study group and 41 in the control group completed the follow up (Figure 1).

The groups did not differ significantly with respect to sociodemographic characteristics, weight, height, BMI, gestational age and the presence of co-morbidities at study inclusion (Table 1).

There was no significant difference between the groups in the number of visits, with a mean number of 8.0 visits in the study group and 7.1 in the control group. The follow-up period lasted on average 19 weeks in both groups.

There was no significant difference between the groups in terms of excessive weight gain. In the study group, 47.5% of the women gained more weight than recommended by the IOM, compared with 57.2% in the control group ($P = 0.43$).

Regarding gestational weight gain, there was no significant difference between the groups. Total weight gain, weight gain after enrolment in the study and weekly weight gain were similar in the two groups. However, the women in the study group had a lower BMI average (38.6 ± 6.2 kg/m^2) than those in the control group (41.4 ± 6.6 kg/m^2) at the end of pregnancy ($P = 0.04$). (Table 2)

The data were also analysed after stratification for pregestational BMI, with women being categorised as overweight (BMI 26.0–29.9 kg/m^2) or obese (BMI ≥ 30.0 kg/m^2). Among obese pregnant women, none of the variables showed a significant difference between the study and control groups. In contrast, overweight women from the study group benefited from exercise, gaining significantly less weight during their entire pregnancy when compared with women from the control group (10.0 ± 1.7 versus 16.4 ± 3.9 kg, respectively) and after enrolment in the study (5.9 ± 4.3 versus 11.9 ± 1.5 kg, respectively), with a mean weekly weight gain that was also smaller (0.28 ± 0.22 versus 0.57 ± 0.17 kg/week, respectively) (Table 2).

During pregnancy, no differences were found in the variables weight, BMI and arterial blood pressure between groups, as shown in Figure 2.

Concerning perinatal outcomes, no significant differences attributable to exercise were found between the groups. Both groups had high rates of caesarean section and LGA newborns (Table 3).

Adherence to home exercise counselling was 62.5% ($n = 25$), based on the percentage of pregnant women in the study group who completed an exercise journal. These women carried out a mean of 12.3 weeks of exercise, with means (±SD) of 57 ± 22.2 and 79.8 ± 48.6 minutes/week for exercises from the study protocol and walking, respectively. The majority (60%) of pregnant women did from 9 to 16 weeks of home exercise.

Table 1. Sociodemographic characteristics, ponderal index, obstetric history and pathological conditions of overweight or obese pregnant women who did and did not participate in the exercise programme

Variable	Study group ($n = 40$)	Control group ($n = 42$)	*P* value
Age (years) (mean ± SD)	29.7 ± 6.8	30.9 ± 5.9	0.479
School education (%)			
<8 years	15.0	23.8	0.603
8–11 years	42.5	38.1	
>12 years	42.5	38.1	
Occupation (%)			
With remuneration	40.0	42.5	0.820
Without remuneration	60.0	57.5	
Parity (%)			
0	30.0	23.8	0.141
≥1	70.0	76.2	
Diabetes (%)	20.0	35.7	0.417
Hypertension (%)	37.5	52.4	0.176
Lower back pain (%)	82.5	90.5	0.289
GA at initiation of PNC (weeks) (mean ± SD)	14.3 ± 4.5	13.6 ± 3.5	0.431
GA at initiation of programme (mean ± SD)	17.6 ± 4.2	17.8 ± 3.7	0.472
Height (m) (mean ± SD)	1.63 ± 0.07	1.60 ± 0.06	0.116
Pre-gestational weight (kg) (mean ± SD)	92.6 ± 18.9	94.0 ± 19.2	0.660
Pre-gestational BMI (kg) (mean ± SD)	34.8 ± 6.6	36.4 ± 6.9	0.259

BMI, body mass index; GA, gestational age; PNC, prenatal care.

Table 2. Weight and BMI in overweight and obese pregnant women, according to whether they participated in the exercise programme

Variable	Study group (n = 39) (mean ± SD)	Control group (n = 41) (mean ± SD)	P value
Combined			
Final weight (kg)	103.4 ± 18.9	106.0 ± 19.6	0.621
Final BMI	38.6 ± 6.2	41.4 ± 6.6	0.004
Total weight gain (kg)	10.3 ± 5.0	11.5 ± 7.4	0.543
Weight gain in programme (kg)	7.7 ± 4.3	8.1 ± 4.3	0.947
Weekly weight gain (kg)	0.36 ± 0.22	0.38 ± 0.21	0.974
Obese	**(n = 30)**	**(n = 36)**	
Total weight gain (kg)	10.4 ± 5.6	10.9 ± 7.6	0.757
Weight gain programme (kg)	8.2 ± 4.3	7.7 ± 4.3	0.646
Weekly weight gain (kg)	0.39 ± 0.22	0.36 ± 0.21	0.577
Overweight	**(n = 9)**	**(n = 5)**	
Total weight gain (kg)	10.0 ± 1.7	16.4 ± 3.9	0.001*
Weight gain in programme (kg)	5.9 ± 4.3	11.9 ± 1.5	0.021*
Weekly weight gain (kg)	0.28 ± 0.22	0.57 ± 0.17	0.038*

*P value significant according to Student's t test.

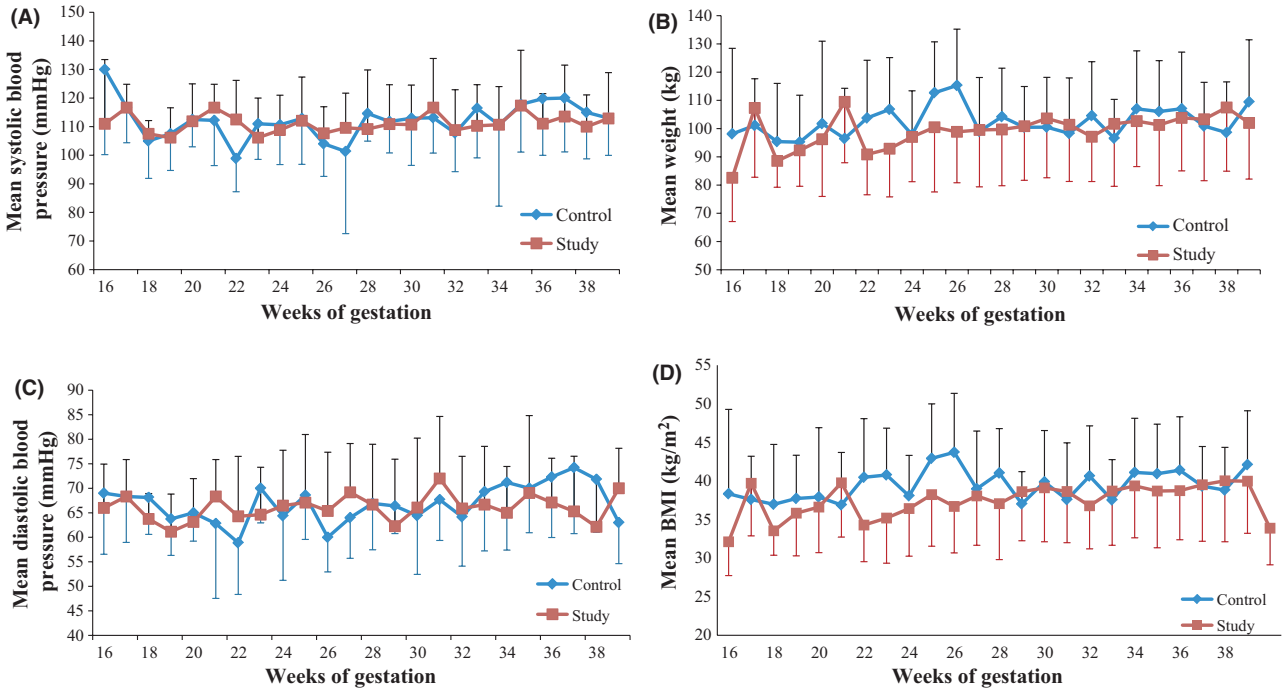

Figure 2. Changes in arterial blood pressure, weight and body mass index (BMI) over the course of pregnancy in women in the study and control groups. (A) Systolic blood pressure, (B) weight, (C) diastolic blood pressure and (D) BMI.

Quality of life was evaluated according to four domains (physical, psychological, social and environmental) in addition to two general questions about perception of QoL and satisfaction with health. Concerning the effect of time, the physical and social domains had significantly lower scores at the end of pregnancy, indicating worsening QoL in these aspects. There were no significant differences between the groups (Table 4).

During the performance of the exercise protocol under supervision, unexpected events, such as hypotension, falls and musculoskeletal lesions, were not observed.

Table 3. Perinatal outcomes in women who did and did not participate in the exercise programme

Variable	Study group	Control group	*P* value
Caesarean rate, *n* (%)	25 (65.8)	29 (72.5)	0.521
Newborn weight (g) (mean ± SD)	3267.4 ± 700.4	3228.4 ± 591.3	0.790
Gestational age at birth (mean ± SD)	38.5 ± 2.6	38.5 ± 1.5	0.488
Apgar, 1 minute, *n* (%)			
<7	6 (16.7)	4 (10.8)	0.515
>7	30 (83.3)	33 (89.2)	
Apgar, 5 minutes, *n* (%)			
<7	1 (2.8)	0 (0)	0.493
>7	35 (97.2)	37 (100)	
Adequacy, *n* (%)			
Adequate for gestational age	23 (65.7)	24 (58.5)	1.000
Large for gestational age	8 (24.2)	8 (24.2)	
Small for gestational age	2 (6.1)	1(3.0)	

Table 4. Assessment of the effects of time and intervention on the perception of quality of life in pregnant women at the beginning and end of pregnancy using WHOQOL-Bref

Domain	Study group		Control group		Time effect	Intervention effect
	Mean	SD	Mean	SD		
Physical						
Initial	58.2	16.9	52.9	16.4	<0.0001*	0.0971
Final	49.8	17.1	42.2	16.1		
Psychological						
Initial	59.5	14.1	61.2	18.30	0.9381	0.8371
Final	63.1	17.5	58.7	17.8		
Social						
Initial	74.0	12.3	70.0	20.7	0.0171*	0.3546
Final	69.7	17.0	64.2	21.7		
Environmental						
Initial	55.2	11.4	53.7	13.5	0.1221	0.5969
Final	58.3	15.0	55.6	13.7		
Perception of quality of life						
Initial	71.2	14.1	70.7	16.6	0.5071	0.5992
Final	74.2	13.9	72.8	15.5		
Satisfaction with health						
Initial	56.8	18.0	63.6	22.7	0.3684	0.8867
Final	66.7	21.1	58.8	22.9		

*Repeated measures analysis of variance; initial, $n = 79$; final, $n = 71$.

Discussion

The results of this study indicated that physical activity was not associated with control of gestational weight gain when the data were analysed as a whole. However, when the data were stratified according to BMI, with the women being divided into overweight and obese categories, it was found that the exercise programme was effective in terms of control of weight gain in the overweight women, despite the reduced sample size.

The statistical power of the overweight subgroup results for the variables total weight gain, weight gain during protocol exercises and weekly weight gain was 98, 81 and 62%, respectively, showing that only the results for weekly weight gain had low statistical power. However, the results for the overweight subgroup should be treated with caution because of the small number of women in the sample.

With respect to excessive weight gain based on IOM recommendations, there was a smaller proportion of women with excessive weight gain in the study group (47.5 versus 57.2%), but the difference was not significant, and so was insufficient to show that exercise had an effect on weight gain control.

Similar findings were obtained in studies using only educational programmes to encourage physical activity, which failed to prevent excessive gestational weight gain.[16,20–23] In two randomised studies, low adherence rates to IOM recommendations were observed among obese pregnant women.[16,23] In a study by Polley et al.,[16] the opposite result from that expected was found in pregnant women with a BMI > 26 kg/m^2: 59% of pregnant women in the intervention group exceeded the recommended weight gain limit, compared with 32% in the control group. In the study by Asbee et al.,[23] weight gain was within the recommended limits in only 33.3% of women, similar to the results obtained in this study. The findings of these studies and those of the present study highlight the difficulty of achieving satisfactory results concerning weight control in obese pregnant women. Most studies have evaluated interventions

that combined diet and exercise, in comparison with control groups without any intervention other than routine prenatal care.[16,21–25] In contrast, our study was designed with the intention of isolating the exercise effect, ensuring that both groups received the same nutritional counselling which made it difficult to compare our results with those of other studies.

Comparison of our results with those of previous studies is difficult because of the different cut-off points used to evaluate excessive gestational weight gain. Until the latest revision of the IOM guidelines in 2009, an upper limit for weight gain in obese pregnant women had not been established. Mottola et al.[25] considered as excessive weight gain >11.5 kg (the upper limit of the overweight range), these authors found 80% of pregnant women had adequate weight gain. In other studies in which weight gain control was not found to be successful, 6.8 kg was considered the upper limit of normal weight gain.[16,22–25] Both of these limits differed from that used in this study, where we analysed excessive weight gain according to the new IOM range for obese women (5–9 kg). Artal et al.[26] considered that the IOM recommendations for obese pregnant women are overestimated.

Overweight and obese pregnant women who gained <8 kg during pregnancy had lower rates of LGA newborns, pre-eclampsia, caesarean section and operative vaginal delivery than those who gained a significant amount of weight during pregnancy.[27]

The exercise programme was not associated with adverse outcomes in either the mother or the fetus, and did not affect systolic or diastolic arterial blood pressure or perinatal outcomes. Exercise performed by previously sedentary overweight and obese pregnant women seemed to be safe.

The route of delivery and the birthweight of the newborn were not influenced by exercising in obese women, which is similar to the findings of other studies examining exercise as a form of intervention during pregnancy.[16,18,20,21,24,25] Gestational obesity and excessive maternal weight gain are associated with high rates of low birthweight and LGA newborns, and high rates of caesarean section.[9,10,28,29] Kinnunen et al.,[22] evaluating a programme to encourage physical activity, found a rate of LGA newborns of 15% in the control group. Nevertheless, gestational age at birth, the Apgar index and the proportion of LGA newborns were similar between the groups in our sample. We believe that the high rates of caesarean section and LGA newborns are related to population characteristics, as these are high-risk pregnant women with co-morbidities, such as diabetes.

The results of the present study suggest that exercise is safe in overweight and obese pregnant women as, contrary to concerns expressed in the long-running debate on the benefits of exercise in these women, exercise was not associated with low birthweight or preterm delivery. However, doubt remains about whether this type and intensity of intervention is effective at decreasing the rate of LGA newborns in high-risk pregnant women and the rate of caesarean sections. This study was not designed to address this question, and specific studies must be carried out to investigate the issue.

Regarding QoL, the significant decrease in the mean scores of the physical and social domains observed in both groups over time could be explained by the inconveniences typical of the end of pregnancy, arising from weight gain, pain and fatigue, as a consequence of the greater load on the musculoskeletal system. The perception of QoL was most strongly affected by the evolution of pregnancy, and was not affected by whether the women exercised during pregnancy. It is probable that QoL is affected by multiple factors, and so it is difficult to determine the effects of individual variables. It is worth mentioning that the literature is scarce on the assessment of QoL in this population.

In relation to overload on the musculoskeletal system in obese pregnant women, a previous study demonstrated that increased weight and a higher pre-gestational or gestational BMI were related to a higher prevalence of lower back pain during and up to 6 months after pregnancy.[30] This finding is in agreement with the high prevalence of lower back pain in this sample (82.5% in the study group and 90.5% in the control group). This is one more indication that exercise should prove to be beneficial in this population.

A limitation of the study was that pre-gestational weight as reported by the pregnant women was used in determining pre-gestational BMI and total weight gain, which may have resulted in bias in these variables. However, this is a common limitation present in the majority of such studies because of the lack of records before pregnancy.[17,21,23,24,27] Another significant limitation was the small sample size, which yielded low power in the analysis of the results, as already discussed. Nevertheless, our results can be used as a foundation for future clinical trials in this population, for which there is a lack of studies in the literature.

Another limitation of the study relates to difficulties in the management of obese pregnant women. In this study, the women had low adherence to the exercise programme and active lifestyle counselling. We believe that, for the obese women in particular, higher adherence would have increased the effectiveness of the intervention. Resistance to exercise may have been reinforced by the ancient cultural tradition that pregnancy should be a time of seclusion and rest.

In obese pregnant women, the evidence suggests that interventions should focus specifically on behavioural changes. Improving knowledge through educational programmes does not seem to be sufficient, and individualised interventions that combine diet and physical activity counselling seem to be required.[18,24]

Because weight gain during pregnancy is a strong determinant of postpartum weight retention,[17] the prevention of excessive weight gain during pregnancy is fundamental to avoiding the development of obesity in pre-obese women of reproductive age. Furthermore, it can interrupt a vicious cycle of gradual increases in BMI between pregnancies that can lead to complications in subsequent pregnancies and a higher risk of diseases related to obesity in the future.

Conclusion

Although in this study we did not find significant differences in the control of weight gain between women who did and did not exercise, exercise was not related to adverse perinatal outcomes and did not affect arterial blood pressure or the perception of QoL. In future research, obese and morbidly obese women should not be excluded from programmes designed to encourage a healthy lifestyle during pregnancy. These programmes should include supervised exercise, as well as individualised nutritional and weight gain counselling. Pregnancy may be the best time to introduce such lifestyle changes.

Disclosure of interests

The authors have no disclosures of interests to make.

Contribution to authorship

SLN developed the research design, was involved in data collection, interpretation of the results and wrote the paper. FGCS contributed to the preparation of the research project, data collection, interpretation of the results and manuscript preparation. MÂP contributed to the preparation of the research project and the interpretation of the results. SS contributed to the analysis of the results and performed the statistical analysis of the data. JLPS contributed to the final editing of the manuscript.

Details of ethics approval

This study was approved by the Research Ethics Committee of the UNICAMP Medical School (FCM-UNICAMP) under registration number 542/2008 on 27 July 2008.

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Supporting Information

The following supplementary materials are available for this article:

Table S1. Summary of the exercise protocol performed by pregnant women in the study group.

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

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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No effect of the FitFor2 exercise programme on blood glucose, insulin sensitivity, and birthweight in pregnant women who were overweight and at risk for gestational diabetes: results of a randomised controlled trial

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Objective To evaluate the effectiveness of an exercise programme for pregnant women who were overweight or obese and at risk for gestational diabetes mellitus (GDM).

Design Randomised controlled trial.

Setting Hospitals and midwifery practices in the Netherlands.

Population Pregnant women who were overweight or obese and at risk for GDM between 2007 and 2011.

Methods Normal care was compared with an exercise training programme during pregnancy. The training consisted of aerobic and strength exercises, and was aimed at improving maternal fasting blood glucose, insulin sensitivity, and birthweight. Linear regression analyses were performed to determine the effects.

Main outcome measures Maternal outcome measures were fasting blood glucose (mmol/l), fasting insulin (pmol/l) and HbA1c (%), body weight (kg), body mass index (kg/m^2), and daily physical activity (minute/week). Offspring outcome measures were birthweight and fetal growth.

Results A total of 121 women were randomly allocated to either a control (n = 59) or an intervention (n = 62) group. Intention-to-treat analysis showed that the exercise programme did not reduce maternal fasting blood glucose levels nor insulin sensitivity. Also, no effect was found on birthweight.

Conclusions The exercise intervention performed over the second and third trimester of pregnancy had no effects on fasting blood glucose, insulin sensitivity, and birthweight, most probably because of low compliance. The high prevalence of women at risk for GDM calls for further research on possible interventions that can prevent GDM, and other types of interventions to engage this target group in physical activity and exercise.

Keywords Exercise, gestational diabetes mellitus, glucose, insulin, physical activity, pregnancy.

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Introduction

The prevalence of gestational diabetes mellitus (GDM) is increasing worldwide,[1] in parallel with the increase in type-2 diabetes (T2D). Essentially, women who are at risk for T2D are also at risk for GDM.[2] GDM is a risk factor for pregnancy-related maternal and perinatal morbidity: both mothers and their offspring have an increased risk for developing T2D.[3] It is becoming increasingly important to identify high-risk populations and to implement

strategies that delay or prevent the onset of (gestational) diabetes.

Lifestyle modification (including 30 minutes of daily moderate physical activity) is one of the strategies that could delay or prevent diabetes.[4,5] Exercise improves glucose tolerance and insulin sensitivity in non-pregnant individuals, an effect that is maintained as long as regular exercise is continued.[6–8] It is also known that increased exercise improves both insulin sensitivity and blood glucose levels in women with GDM.[9–12] A recent systematic review of controlled trials summarised the effectiveness of different interventions to prevent GDM.[13] The results of this systematic review indicated that dietary counselling can reduce the incidence of GDM, and that a low glycaemic index diet can reduce the risk of infants being born with a high birthweight (i.e. large for gestational age). In three controlled trials it was demonstrated that an exercise programme significantly reduced the rate of infants born with a high birthweight, but had no effect on the levels of maternal fasting blood glucose or incidence of GDM. It was concluded that more well-designed studies are required before recommendations can be made with regard to the best intervention for the prevention of GDM.

The primary aim of the present randomised controlled trial was to examine the effectiveness of an exercise programme for pregnant women at risk for GDM. We hypothesised that women who exercise during the second half of pregnancy have lower fasting blood glucose, better insulin sensitivity, and deliver babies of lower birthweight than women who do not exercise.

Methods

Study design

This randomised controlled trial was conducted at the EMGO+ Institute, Department of Public and Occupational Health, VU University Medical Center, Amsterdam, the Netherlands, after being granted approval from The Medical Ethics Committee of VU University Medical Center, Amsterdam. The study was performed between January 2007 and January 2011. A complete description of the study design and methods has been published elsewhere.[14]

Participants

Participants were pregnant women at increased risk for GDM. Women were considered to be at an increased risk for GDM if they were obese (body mass index, BMI ≥ 30) or overweight (BMI ≥ 25) AND had at least one of the three following characteristics: (1) history of macrosomia (offspring with a birthweight above the 97th percentile of gestational age); (2) history of GDM; or (3) first-grade relative with T2D. Exclusion criteria included: recruitment after 20 weeks of gestation; age under 18 years; inadequate knowledge of the Dutch language; having been diagnosed with (gestational) diabetes mellitus before randomisation; hypertension; alcohol abuse; drug abuse; use of any medication that affects insulin secretion or insulin sensitivity; serious pulmonary, cardiac, hepatic, or renal impairment; malignant disease; and serious mental or physical impairment (i.e. that could prevent the woman from understanding or implementing the study protocol). After providing written informed consent and baseline measurements, participants were randomly allocated to the control or intervention groups. The participants were followed for 9 months: from 15 weeks of gestation until 12 weeks after delivery.

Exercise intervention

Women in the intervention group received an exercise programme on 2 days of the week during the remaining duration of their pregnancy. Each exercise session lasted for 60 minutes. The exercise sessions consisted of aerobic and strength exercises aimed to control blood glucose levels. The training intensity was carefully and individually controlled. All exercise sessions were completed under the guidance and supervision of a specifically trained physiotherapist. The exercise sessions were located at the Department of Physiotherapy in the participating hospitals (VUmc, OLVG, SLAZ, MST, and Isala). Details of the exercise programme have been described by Oostdam et al.[14]

Non-exercise control group

Women in the control group were not offered an exercise programme and received normal care from obstetricians and/or midwives. The primary task of the Dutch midwife is to closely follow the health status of the pregnant woman and her unborn child. In the Netherlands, women who are overweight or obese receive the same care as women of healthy weight. The control group was followed up throughout the entire pregnancy period.

Outcomes

Participants in both the intervention and the control groups were invited for four measurement appointments. Outcome measurements were assessed at baseline (around 15 weeks of getstation), and at 24 and 32 weeks of gestation, by means of physical measurements, laboratory tests, and self-administered questionnaires. The maternal outcome measures under study were fasting blood glucose (mmol/l), fasting insulin (pmol/l) and HbA1c (%), body weight (kg), BMI (kg/m^2), and daily physical activity (min/week). The offspring outcome measures were birthweight and fetal growth.

Blood was drawn from the antecubital vein after the participant had fasted for at least 10 hours. From these blood samples glucose, insulin, and HbA1c levels were measured.

Insulin sensitivity, as defined by the homeostasis model assessment (HOMA) (=22.5/[fasting glucose concentration, mmol/l × fasting insulin concentration, pmol/l]), was calculated.

Maternal body weight was measured using calibrated electronic scales, with participants wearing only indoor clothing and no shoes. Pre-pregnancy weight was self-reported. If the weight had not been measured on the calibrated electronic scales we used the self-reported weight from the questionnaire. On the first measurement maternal body height was measured with bare feet and a (wall-mounted) height scale. The measured height and weight values were used to calculated the BMI (kg/m^2).

Daily physical activity was measured objectively by an accelerometer (ActiTrainer accelerometer; ActiGraph™, Pensacola, FL, USA). The accelerometer is a compact, lightweight, uniaxial device that measures and records time-varying acceleration. Physical activity is reported as total minutes per week of moderate and vigorous activity. To measure the time spent in each intensity category we used the metabolic equivalent task (MET) cut-off values from the American College of Sports Medicine (ACSM) statement,[15] converted to activity counts by using the equation published by Freedson et al.[16]

Birthweight was self-reported in the last questionnaire. Large for gestational age (LGA) was defined as a newborn with a birthweight above the 97th percentile of gestational age.

Demographics and other covariates were also determined. Race/ethnicity was derived from the country of birth of the participant's parents. An individual was considered to be white European when both parents were born in Europe (with the exception of Turkey and Morocco, two groups with a higher risk for GDM) or North America. Furthermore, level of education was assessed as the highest level an individual reported to have achieved, which was then divided into lower, middle, or higher educational levels. Moreover, participants were asked to report on their status of employment (yes or no).

Blinding and randomisation

Eligible women were randomised into the intervention or control group. Randomisation was stratified by the hospital where participants were measured or performed the exercise programme (VUmc, OLVG, SLAZ, MST, and Isala). Within each stratum, a block randomisation of four was used to make sure that each group had an equal number of participants. We did not stratify for physical activity levels, as we assumed that by randomising the women this would be evenly distributed between groups. Women were recruited by midwifes and gynaecologists who were unaware of the allocation of other women within the same strata, with no risk of compromising allocation concealment. By the nature of the intervention the researcher and research assistant could not be blinded for allocation after randomisation. All outcome measures were assessed by independent examiners, unaware of group allocation.

Statistical analyses

A power calculation was made for the primary outcome measure of maternal fasting glucose level. It was determined that an adequate power (>0.80) and a 5% significance level would be achieved with 80 pregnant women in both groups. The power calculation allowed for a 20% drop-out rate.

The maternal characteristics of the study sample by group (control and intervention) were presented as means and standard deviations for continuous variables, and as percentages for ordinal variables. For group comparisons, continuous variables were analysed with an independent Student's *t*-test and with a chi-square test for nominal data.

The effect of the intervention was estimated based on the intention-to-treat principle, including all participants who had attended the baseline measurement and at least one follow-up measurement. Participants with high blood glucose (>6.0 mmol/l) at baseline and with a twin pregnancy were excluded from the analyses. The residuals of the outcome variables were checked for normality: they were normally distributed. For all continuous outcome measures, standard linear regression analysis was used to test the differences between the intervention and control groups at 24 and 32 weeks of gestation. The variable of interest at the follow-up measurement was defined as the dependent variable. Baseline values and group allocation were independent variables in the regression models. The parameters of interest were the regression coefficients, indicating the effect of the intervention of interest compared with the control group, adjusted for baseline values of the dependent variable.

The analyses were checked for effect modification by age, BMI, parity, and ethnicity. It was concluded that effect modification was present in case the *P* value of the interaction term was significant ($P < 0.10$). None of the interaction terms were significant, so no adjustments were made (except for outcome weight change).

All analyses were performed using SPSS 15.0 (Statistical Package for the Social Sciences, SPSS Inc., Chicago, IL, USA) for WINDOWS, and the level of significance was set to ≤0.05.

Results

Baseline characteristics

Figure 1 presents the flow chart for the study population through the trial. Between November 2007 and April 2010, 121 pregnant women at risk for GDM provided informed consent and follow-up measurements. No adverse events resulting from the intervention were reported. The baseline characteristics of the study population are presented in

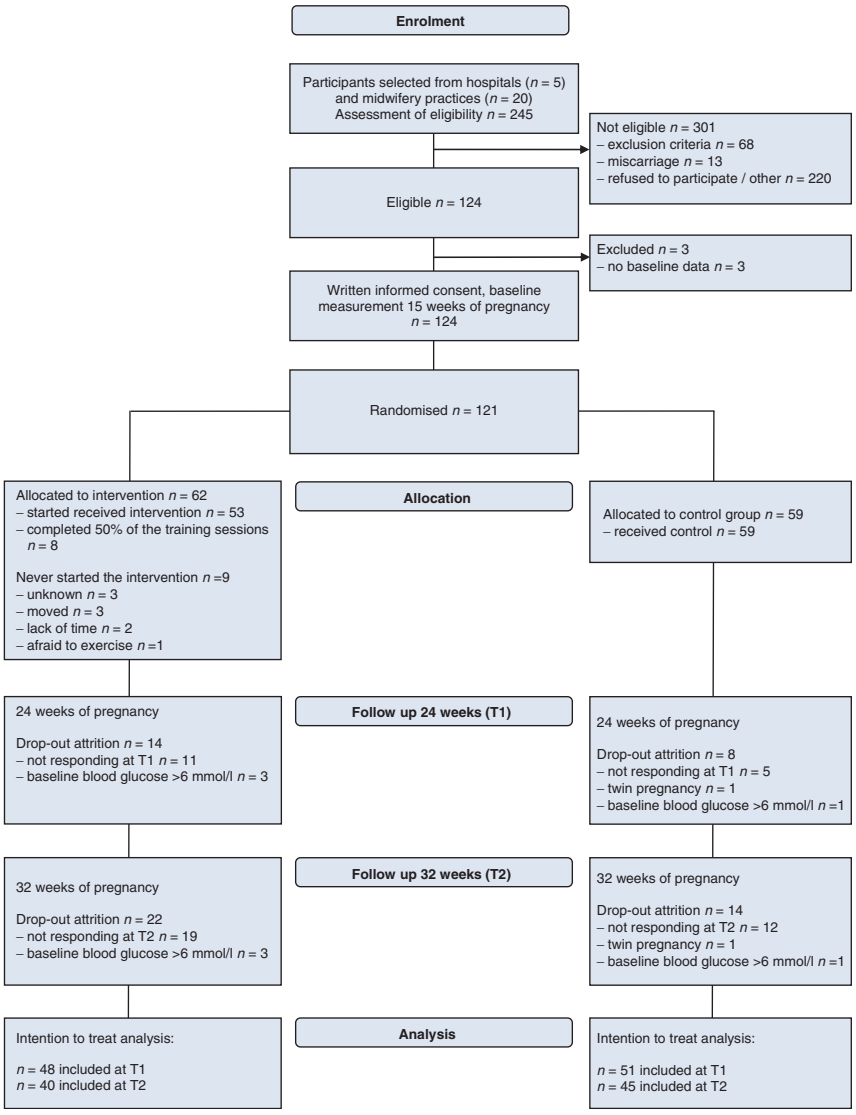

Figure 1. Flow diagram of the study population.

Table 1. No significant differences were found between the control and intervention groups in any of the variables.

Maternal outcomes

The outcome measures are presented in Table 2. The mean fasting blood glucose level at baseline was 4.7 ± 0.43 mmol/l in the intervention group and 4.8 (±0.48) mmol/l in the control group. The mean fasting blood glucose level at 24 and 32 weeks of gestation slightly increased to 4.8 and 4.9 mmol/l, respectively, in both groups. Regression analyses showed that the exercise training had no effect on the changes in fasting blood glucose at 24 and 32 weeks of gestation ($B = 0.07$, 95% CI −0.11 to 0.26; $B = 0.05$, 95% CI −0.13 to 0.23), adjusted for baseline measures.

The mean fasting insulin level at baseline was 79 ± 42 pmol/l in the intervention group and 83 ± 38 pmol/l in the control group. Regression analyses showed no effect of exercise training on changes in fasting insulin at 24 and 32 weeks of gestation. There were also no significant differences during follow-up in insulin sensitivity (IS_{homa}) between the intervention and control groups.

Mean Glycated Haemoglobin (HbA1c) at baseline was 5.29 ± 0.37% in the intervention group and 5.19 ± 0.33% in the control group. Mean HbA1c at 24 weeks of gestation did not change in both groups. Mean HbA1c at 32 weeks of gestation slightly increased: to 5.50 ± 0.30% in the intervention group and to 5.33 ± 0.36% in the control group. Exercise training had no effect on the changes in HbA1c.

No significant differences were observed between the intervention and control group with regards to gestational

Table 1. Baseline characteristics of the study population

Maternal characteristics	Control group	Intervention group	*P*
	Means ± SDs *n* = 52	Means ± SDs *n* = 49	
Age (years)	30.1 ± 4.5	30.8 ± 5.2	0.48
BMI pp (kg/m^2)	33.9 ± 5.6	33.0 ± 3.7	0.38
	% (*n*)	% (*n*)	
Parity			
Nulliparous	28.0 (14)	38.3 (18)	0.28
Multiparous	72.0 (36)	61.7 (29)	
Race/ethnicity			
White European	50.0 (25)	44.7 (21)	0.60
Non-white	50.0 (25)	55.3 (26)	
Educational level			
Lower	34.7 (17)	34.0 (16)	0.81
Middle	34.7 (17)	40.4 (19)	
Higher	30.6 (15)	25.5 (12)	
Employment status			
Employed	70.0 (35)	59.6 (28)	0.28
Unemployed	30.0 (15)	40.4 (19)	

Continuous variables (presented as means ± SDs) were analysed by using an independent Student's *t*-test; categorical variables (presented as percentages [*n* values]) were analysed using the chi-square test.
BMI pp, pre-pregnancy body mass index, based on self-reported weight and height.

weight gain. On average, women gained 6.2 ± 5.0 kg in the intervention group and 5.6 ± 3.5 kg in the control group.

Daily physical activity (PA) measured with accelerometers showed no significant differences in the number of minutes of moderate and vigorous PA per week between the two groups. In both groups, the minutes spent per week performing moderate and vigorous PA reduced during the pregnancy. At baseline, the mean number of minutes of moderate and vigorous PA spent per week in the intervention group was 202 ± 116 minutes and in the control group was 218 ± 109 minutes ($P = 0.63$). At baseline, the intervention group spent fewer minutes performing PA per week, and this difference was maintained during the pregnancy. At 32 weeks of gestation the mean number of minutes of moderate and vigorous PA performed per week had decreased to 151 ± 114 and 178 ± 89 minutes/week, respectively ($P = 0.44$).

Offspring and obstetrical outcomes

Characteristics in the offspring are detailed in Table 3. This exercise training had no effect on gestational age, birthweight, and LGA. Data on birthweight were available for 105 women. The mean birthweight was 3438 g. This is in accordance with the mean birthweight (3485 g) in the Netherlands.[17] There was no significant difference between the intervention and control groups regarding mean birthweight (3524 ± 591 g versus 3352 ± 591 g, $P = 0.14$) or LGA ($n = 6$ versus $n = 1$).

Fetal growth (head circumference, femur length, abdominal circumference, biparietal diameter, and expected fetal weight) was not significantly different between the two groups, either at 24 or 32 weeks of gestation.

Between the intervention and control groups there was no significant difference in the rates of caesarean delivery (RR = 0.99; 95% CI 0.41–2.41) and numbers of participants with GDM (RR = 0.65; 95% CI 0.27–1.55).

Compliance with exercise programme

Compliance with the exercise programme was based on the number of women who had attended half of the sessions in total, and in the first half (up to 24 weeks of gestation) or the second half (from 24 weeks of gestation to delivery) of pregnancy. It appeared that only a small proportion of the women had attended half of the training sessions (16.3%). During the first period this rate was higher (33.3%) than during the second period (11.1%). Many women had stopped exercising during the course of their pregnancy because of physical (pregnancy-related) limitations. The characteristics of the compliant women in the first period were comparable with those women in the control group.

Table 2. Intervention effects at 24 and 32 weeks of gestation on maternal outcomes, determined by linear regression analysis adjusted for baseline measures, in the total study population of the FitFor2 study

Outcome	Baseline mean (SD)	24 weeks of gestation mean (SD)	β (95% CI) 24 weeks of gestation	32 weeks of gestation mean (SD)	β (95% CI) 32 weeks of gestation
Fasting glucose (mmol/l)					
Intervention group	4.71 (0.43) *n* = 49	4.80 (0.5) *n* = 48	0.07 (−0.11 to 0.26)	4.88 (0.49) *n* = 40	0.05 (−0.13 to 0.23)
Control group	4.77 (0.48) *n* = 52	4.79 (0.56) *n* = 51		4.88 (0.47) *n* = 45	
Fasting insulin (pmol/l)					
Intervention group	79.2 (41.9) *n* = 48	96.4 (46.3) *n* = 45	1.95 (−12.1 to 16.0)	110.2 (57.2) *n* = 37	−0.75 (−20.3 to 18.8)
Control group	83.2 (37.8) *n* = 45	98.0 (39.8) *n* = 41		121.6 (50.8) *n* = 39	
IShoma					
Intervention group	0.077 (0.039) *n* = 48	0.062 (0.035) *n* = 45	0.004 (−0.008 to 0.016)	0.052 (0.029) *n* = 37	0.03 (−0.008 to 0.013)
Control group	0.076 (0.06) *n* = 45	0.058 (0.024) *n* = 41		0.045 (0.022) *n* = 39	
HbA1c (%)					
Intervention group	5.29 (0.37) *n* = 49	5.27 (0.33) *n* = 47	0.04 (−0.04 to 0.12)	5.50 (0.3) *n* = 40	0.11 (−0.00 to 0.21)
Control group	5.19 (0.33) *n* = 52	5.16 (0.35) *n* = 49		5.33 (0.36) *n* = 44	
		24 weeks–baseline		**32 weeks–baseline**	
Weight gain (kg)					
Intervention group		2.7 (4.3) *n* = 47	0.475 (−1.26 to 2.21)*	6.2 (5.0) *n* = 43	0.65 (−1.23 to 2.52)
Control group		2.8 (2.26) *n* = 49	−0.625 (−2.78 to 1.53)**	5.6 (3.5) *n* = 41	
Physical activity (min/wk)					
Intervention group	202.0 (116.1) *n* = 20	204.0 (121.6) *n* = 22	0.81 (−95.7 to 97.3)	150.8 (114.0) *n* = 15	−32.5 (−119.9 to 54.9)
Control group	217.7 (109.1) *n* = 31	201.3 (135.6) *n* = 23		177.7 (89.0) *n* = 19	

Insulin data excludes outliers.
Weight gain includes interactions (randomisation × BMI): *effect for BMI category 25–33; **effect for BMI category 33–51.
$P < 0.05$.

However, women who were compliant in the second period were primarily white (87.5%), nulliparous (62.5%), educated to a higher level (62.5%), and were all working. The compliant group was too small for per protocol analyses of intervention effects.

Discussion

Principal findings

This study examined the effects of an exercise programme for pregnant women at risk for GDM. We hypothesised that women who exercise during the second half of pregnancy have lower fasting blood glucose, better insulin sensitivity, and deliver infants with lower birthweight than women who do not exercise. This randomised controlled trial demonstrated that an exercise programme provided during the second half of pregnancy had no effect on maternal fasting blood glucose levels and insulin sensitivity. In addition, no significant differences were found in neonatal outcomes between the intervention and control groups.

Only a small proportion of the women (16.3%) attended at least half of the training sessions. Unfortunately, this compliant group was far too small for per protocol analyses.

Overall evidence

Three other (recently published) randomised controlled trials compared exercise programmes with normal care.[18–20] In all three studies, the exercise training programme started in the second trimester and continued for 10 weeks,[20] or until delivery.[18,19] The exercise programme described by Ong and Hopkins consisted of a home-based stationary cycling programme, and in Barakat's study the programme consisted of resistance and toning exercises. None of these three studies found a measurable effect on aspects of maternal glucose metabolism, insulin, or macr-

Table 3. Obstetrical and neonatal outcomes in the intervention and control groups

Outcomes	Control group	Intervention group	*P*	RR (95% CI)
Gestational age, weeks (SD)	39.4 (1.7) *n* = 53	39.6 (1.0) *n* = 53	0.58	
Birthweight, g (SD)	3352 (591) *n* = 53	3524 (591) *n* = 52	0.14	
LGA (P97), % (*n*)	2.0 (1)	12.8 (6)	n/a	6.38 (0.79–51.1)
Caesarean section, % (*n*)	23.5 (8)	23.3 (7)	0.99	0.99 (0.41–2.41)
GDM, % (*n*)	21.6 (11)	14.6 (7)	0.37	0.65 (0.27–1.55)

Continuous variables (presented as means ± SDs) were analysed by using an independent Student's *t*-test; categorical variables (presented as percentages [*n* values]) were analysed by chi-square test.

osomia. A lack of statistical power might have been the reason for not finding an effect. In a recent meta-analysis,[13] the power was increased by combining the results of these three studies, and a significant reduction in the risk of macrosomia was found. However, also in the meta-analysis no effect of an exercise programme was found in lowering maternal fasting blood glucose and reducing the risk of GDM. These last findings are in line with the results of our study.

There may be several explanations for not finding any differences in our study results: the characteristics of the participants; the intervention itself; or the methodological characteristics of the study.

Participants

We included pregnant women who were overweight or obese, as those women are at risk for developing GDM. This is reflected by the relatively high incidence of GDM in our study. These women were probably not physically active before and in early pregnancy,[21] and might have had more negative attitudes and lower self-efficacy for being physically active than the general population of pregnant women. Only a small proportion (16.3%) of the women in our intervention group attended at least half of the training sessions. Many women had stopped exercising during the course of their pregnancy because of physical (pregnancy-related) complaints and limitations. In addition, a lack of motivation and time were also mentioned. This was also seen in a qualitative study that determined the relative importance of identified barriers and facilitators to exercise in pregnancy.[22] They found that a lack of energy and motivation, physical limitations and restrictions on physical activity, a lack of resources, and a lack of time were powerful barriers to exercise among both Latin and non-Latin white women.

Intervention

Our exercise programme started in the second trimester and continued until the end of the pregnancy. Starting in the second trimester is possibly too late to achieve an effect of exercise on insulin and glucose levels. A recently published systematic review and meta-analyses demonstrated that greater total physical activity before or during early pregnancy is significantly associated with a lower risk of GDM, with the magnitude of the association being stronger for pre-pregnancy physical activity.[23]

The exercise sessions of our programme were twice weekly, and were located at the participating hospitals. Locations where the training was offered and the times when the training was offered were limited. Furthermore, the content of the training sessions was limited by protocol, and the participants could not choose the type of activities they went to. This approach was chosen to minimise the variation in the training sessions. However, the fixed place and times of the intervention reduced accessibility, and could explain the low compliance with the intervention. Hopkins' and Ong's studies both used a home-based stationary cycling programme, and both showed good compliance.[19,20] It might be that such a programme appeals more to overweight or obese pregnant women. However, despite good compliance, they also found no effect on insulin and glucose metabolism.

Another factor to consider is the intensity of the exercise programme. A recent study has determined that increasing energy expenditure through physical activity to a minimum of 16 MET hours per week reduces the risk of GDM, compared with less vigorous exercise.[24] To achieve the target expenditure of 16 MET hours per week, one should walk at 3.2 km/hour for 6.4 hours/week (2.5 METs, light intensity), or preferably perform exercise on a stationary bicycle for 2.7 hours/week (6–7 METs, vigorous intensity). Unfortunately, we cannot compare our data with these new guidelines, because we have used other measures. In our study, the intensity of the exercise programme was based on previous guidelines from the American Congress of Obstetricians and Gynecologists (ACOG) and the Canadian authorities. They recommend the use of ratings of perceived exertion (RPE) of 12–14, in addition to a target heart-rate zone.[25–28] These target heart-rate zones during

pregnancy represent approximately 60–80% of aerobic capacity, based on age.[26]

Methodological considerations

The power calculation determined that 80 pregnant women were needed in both groups, which allowed for a dropout rate of 20%, but we only managed to include a total of 121 participants, which does not give sufficient power for our analysis. However, a larger study group would not have made any difference, as no changes in the mean values were found in favour of the intervention group.

Generilisability

Recruitment took place in hospitals and midwifery practices in different cities in the Netherlands. Our study sample consisted of a higher number of non-white, multiparous, overweight, and obese women compared with the general Dutch pregnant population. This can be explained by the inclusion criteria of the study. In the Netherlands, women from ethnic groups are more likely to be overweight or obese,[29] and have more relatives with T2D: both factors associated with a higher risk of GDM. And, by definition, only multiparous women have already had the chance to develop GDM or deliver a macrosomic baby: both factors that are also associated with a higher risk of GDM. The results of our study are generalisable to all women at risk of GDM. Of course, the results cannot be extrapolated to the whole population of pregnant women.

Implications for further research

The intervention used in our study had low compliance and showed no significant effects on fasting blood glucose, insulin, and birthweight. To examine the effect of exercise on the prevention of GDM it is important to have a good rate of compliance with the intervention. To achieve a better rate of compliance in this difficult to motivate target group we recommend counselling,[30–34] which would include a discussion of the risks associated with GDM for the health of the women and their babies, and to make access to the intervention programme as easy as possible (such as a home-based intervention). Also, as suggested by Marquez et al.,[22] social support and other resources, such as the accessibility of affordable fitness facilities, were identified as powerful exercise facilitators to help overcome barriers.

Another avenue for further research is to look at the effect of the timing of an exercise programme. Starting exercise before and during early pregnancy might lead to better results than starting an exercise programme later in pregnancy. However, the opportunities for healthcare providers to refer women before or in early pregnancy to exercise programmes are limited, as in most cases they have their first contact no earlier than at the end of the first trimester of pregnancy.

As exercise programmes are apparently difficult to implement for pregnant women who are obese, other interventions might be more successful in reducing GDM risk in this target group. A recent systematic review included six types of interventions for the prevention of GDM: metformin therapy; low glycaemic index diet; dietary counselling; probiotics; self-monitoring of weight gain; and exercise.[13] Although more evidence is required, the available data do suggest that dietary counselling is effective in reducing GDM risk, and that probiotics might be promising.

Conclusion

The study has demonstrated that (during the second and third trimester) an exercise programme for pregnant women who are overweight and at risk for GDM did not have significant effects on fasting blood glucose, insulin sensitivity, and birthweight. Most likely, this lack of effect was the result of low compliance with the intervention, and we feel that other types of intervention are necessary to engage this target group in physical activity and exercise. Although previous studies and our study do not provide evidence for the effectiveness of exercise programmes in the prevention of GDM, the high prevalence of overweight and obesity among women of childbearing age in Western societies, and therefore the high prevalence of pregnant women at risk for GDM, calls for further research on possible interventions that can prevent GDM.

Disclosure of interests

The authors declare that they have no competing interests.

Contribution to authorship

NO was responsible for data collection, performed statistical analyses, and drafted the first version of the article. MvP. conceived the study. NO, MvP, MW, EE, and WvM thoroughly revised the article and helped with data interpretation. All authors read and corrected draft versions of the article, and approved of the final submission.

Details of ethics approval

The study was approved by the Medical Ethics Committee of VU University Medical Center, Amsterdam (protocol number 07/133, 12 September 2007), and local permission was obtained in the other centers. Trial registration: NTR1139; www.trialregister.nl/trialreg/admin/rctview.asp?TC=1139.

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Is there a role for physical activity-based interventions to manage weight and improve maternal and fetal outcomes in pregnancy?

Ootsdam et al.'s study adds to the growing evidence evaluating the role of physical activity-based interventions in pregnancy. Their randomised study of physical activity-based interventions in pregnant women who were overweight and obese showed no effects on fasting glucose, insulin, birthweight and other obstetric outcomes. This is consistent with our findings from a systematic review on the effects of dietary and lifestyle interventions on weight and pregnancy outcomes, commissioned by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (Thangaratinam et al., *Health Technol Assess* 2012; in press). Meta analysis of studies showed that the reduction in gestational weight gain in pregnancy was less with physical activity-based interventions compared with those based on diet. Furthermore, dietary interventions reduced the risk of gestational diabetes by 60%, and also significantly reduced the risk of gestational hypertension and preterm birth without any increase in the rates of small-for-gestational-age babies (Thangaratinam et al., *BMJ* 2012; 344:e2088). We did not observe this benefit with physical activity-based interventions in pregnancy.

This observation could occur for various reasons. The compliance of participants with the intervention is a significant problem for physical activity-based interventions compared with diet in pregnancy. In the FitFor2 study only 16% of the women had followed at least half of the training sessions. Factors such as concerns for the safety of the baby, physical limitations, and lack of energy, motivation or resources contribute to the lack of compliance. There is evidence that diet has specific benefits that are not evident with other interventions: for example, a high-fibre diet is associated with a reduced risk of pre-eclampsia (Qui et al. *Am J Hypertens* 2008;21:903–909); such a benefit may not be observed with physical exercise. Women can be reassured that these interventions in pregnancy, including physical activity, are not associated with any evidence of harm: in particular there is no evidence of growth restriction.

Current recommendations in pregnancy for weight management focus on both diet and physical activity. The paper by Ootsdam et al. adds to the growing body of evidence on the reduced effectiveness of physical activity-based interventions in pregnancy for either weight management or improving pregnancy outcomes. There is a strong case for the introduction in primary and secondary care for interventions in pregnancy, mainly based on diet rather than physical activity, with a service evaluation alongside.

Future research is needed to assess the differential effect of weight management interventions for weight-related and pregnancy outcomes in various groups categorised by body mass index (BMI), ethnicity, teenage pregnancy, parity and pre-existing medical conditions like diabetes. Individual patient data (IPD) meta analysis can overcome the limitations imposed by the paucity of detail in the published data for aggregate data meta analysis, or by the additional cost and time needed for a large primary trial to detect a genuine subgroup effect. The recently established i-WIP (International Weight Management in Pregnancy) IPD collaborative network of primary investigators in this field have agreed to share primary data to generate valid, reliable answers for the above questions. ■

Disclosure of interests

I have no competing interests to disclose apart from the fact that I have completed an HTA funded project evaluating the effects of weight management interventions in pregnancy (HTA no. 09/27/06).

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The Effects of Exercise Conditioning in Normal and Overweight Pregnant Women on Blood Pressure and Heart Rate Variability

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Abstract

Pre-pregnancy obesity is a risk factor for preeclampsia, gestational diabetes, and hypertension. Regular exercise during pregnancy has been shown to decrease the risk of these obstetrical complications. The purpose of this prospective study was to measure the effects of an exercise program in normal-weight and overweight/obese pregnant women on blood pressure (BP) and cardiac autonomic function, determined by heart rate variability (HRV) and baroreflex sensitivity (BRS). Twenty-two sedentary pregnant women, recruited at 20 weeks gestational age (GA), were grouped as normal weight or overweight/obese. They were systematically assigned to an exercise (walking) group or control (nonwalking) group after the first participants were randomly assigned. Women in the walking groups participated in a 16-week, low-intensity walking program. BP, HRV, and BRS were measured at rest and during exercise at the beginning (20 weeks GA) and end (36 weeks GA) of the walking program. Results indicated that women in the control groups (especially overweight women) showed changes in BP, HRV, and BRS over pregnancy that were not seen in the walking group. Overweight women in the control group increased resting systolic BP by 10 mmHg and diastolic BP by 7 mmHg. HRV declined in the control group but not in the walking group. A reduction in BRS and R-R interval at rest was found in all groups except the walking normal-weight group. The results suggest that an exercise program could attenuate the increase in BP and the loss of parasympathetic tone associated with pregnancy, especially in overweight women.

Keywords

exercise, pregnancy, blood pressure, heart rate variability

Obesity is a growing problem for women of childbearing age. Pre-pregnancy obesity is a risk factor for preeclampsia (Walsh, 2007), gestational diabetes, and hypertension (Doherty, Magann, Francis, Morrison, & Newnham, 2006). The risks increase as maternal body mass index (BMI) increases beyond the normal BMI category of $\leq$25.0 kg/m^2 (e.g., Kumari, 2001; Lu et al., 2001; Sebire et al., 2001). Researchers (e.g., Kumari, 2001; Lu et al., 2001; Sebire et al., 2001; Stephansson, Dickman, Johansson, & Cnattingius, 2001) have shown that as pregnancy progresses, obese and overweight women are at increased risk for the development of hypertensive disorders, whereas Brown and associates (Brown, Lee, Hains, & Kisilevsky, 2008) have shown that women in late gestation diagnosed with hypertension and preeclampsia (Swansburg, Brown, Hains, Smith, & Kisilevsky, 2005) have significantly higher BMI than their normotensive counterparts.

Pregnancy is associated with maternal cardiovascular and hemodynamic changes. In normal pregnancies, there is an increase in resting heart rate (HR), a 50% increase in total blood volume (Silver, Seebeck, & Carlson, 1998), and an increase in peripheral vascular resistance resulting in a gradual increase in arterial blood pressure (BP) after the 28th week of gestation (Paller, 1998). In pregnancies complicated by hypertension, there is an additional marked increase in peripheral vascular resistance causing a further increase in BP (American College of Obstetricians and Gynecologists, 2002). These changes may be partially due to changes in maternal cardiac autonomic function (Ekholm, Piha, Antila, & Erkkola, 1993;

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Greenwood, Scott, Stoker, Walker, & Mary, 2001; Wolfe, Preston, Burggraf, & McGrath, 1999).

Short-term adjustments in HR and BP are regulated primarily by the autonomic nervous system and the arterial baroreflex. Autonomic regulation of HR can be assessed noninvasively through measurement of heart rate variability (HRV) and baroreflex sensitivity (BRS; Akselrod et al., 1981; Blaber, Yamamoto, & Hughson, 1995; Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology [TFESCNASPE], 1996). HRV primarily reflects the physiological level of tonic autonomic modulation, whereas BRS indicates the capacity of reflex autonomic regulation. Efferent parasympathetic (parasympathetic nervous system [PNS]) and sympathetic (sympathetic nervous system [SNS]) divisions of the autonomic nervous system usually act reciprocally, so that changes in HR occur as a result of both PNS and SNS output to the sinoatrial (SA) node. The brief latency and rapid decay of PNS responses enable the vagus nerve to exert beat-by-beat control of SA nodal function. Consequently, HR fluctuates on a beat-by-beat basis due to rapidly acting PNS influence (Akselrod et al., 1981). This beat-by-beat HRV allows for the cardiovascular system to adjust and adapt rapidly to changing and unpredictable stimuli.

The arterial baroreflex regulates BP via efferent autonomic output to the heart and blood vessels, thus influencing HR, cardiac contractility, venous capacitance, and systemic vascular resistance (Hainsworth, 1996; Smit, Wieling, & Karemaker, 1996). BRS reflects the magnitude of the HRV response to a change in BP. Spontaneous variations in BRS can be observed at rest and during normal daily activities or elicited experimentally by postural changes, deep breathing, mental stress, or exercise in healthy individuals (Blaber et al., 1995; Parlow, Viale, Annat, Hughson, & Quintin, 1995).

In nonpregnant populations, Laederach-Hofmann, Mussgay, and Ruddel (2000) found a decrease in PNS and SNS responses as well as a reduction in baroreflex function in obese individuals. In contrast, Rossi and colleagues (1989) found a decrease in PNS response but no difference in SNS response in obesity, whereas Piccirillo et al. (1998) found an increase in SNS response. The SAPALDIA study (Felber Dietrich et al., 2008) gives some norms obtained from 1,703 participants for a number of HRV measures in normal and overweight participants who were either sedentary or exercised regularly. In general, investigators found that being overweight was associated with higher systolic BP and diastolic BP compared with normal-weight participants. They also found that overweight and obese participants who exercised had higher HRV and its constituent components of low frequency (LF), high frequency (HF), and total power (TP) than sedentary overweight participants but similar SNS levels. Inactive obese participants had lower HRV than inactive normal-weight participants. Reduced HRV reflects an imbalance in the competing influences of the PNS and SNS divisions of the autonomic nervous system on the modulation of HR. Such an imbalance reduces the ability of the cardiovascular system to adapt quickly to changing stimuli (e.g., standing posture, exercise), increases the potential for sympathetically mediated cardiac dysrhythmias and augments vasoconstriction (TFESCNASPE, 1996).

Researchers have identified autonomic changes in pregnant women (e.g., Charlesworth, Wolfe, & Davies, 2006; Miyake et al., 2002). For example, Avery, Wolfe, Amara, Davies, and McGrath (2001) found that PNS modulation was significantly lower at rest in pregnant women in late gestation than in nonpregnant women. Kuo, Chen, Yang, Lo, and Tsai (2000) and Voss and colleagues (2000) also found lower PNS activity and a shift toward higher SNS activity by the third trimester of pregnancy. In contrast, Eneroth-Grimfors, Westgren, Ericson, Ihrman-Sandahl, and Lindblad (1994) found no differences in HRV or BRS in healthy pregnant women in late gestation compared to nonpregnant healthy women. In a review of 23 studies, from 1985 to 2006, on the effect of obesity during pregnancy, Helmreich, Hundley, and Varvel (2008) reported that autonomic responsiveness was lower in obese pregnant women compared with normal-weight pregnant women, suggesting the potential for diminished autonomic adaptation and cardiovascular response to environmental stimuli. The reason for the discrepancies in findings is unknown.

Epidemiological studies show that exercise during pregnancy is associated with decreased incidence of obstetrical complications, including excessive maternal weight gain, gestational diabetes, hypertension, and preeclampsia (Clapp, 1996; Damm, Breitowicz, & Hegaard, 2007; Sorensen et al., 2003; Weissgerber, Wolfe, & Davies, 2004). Regular physical activity is recommended for nonpregnant individuals (Feldman et al., 1999) and pregnant women (Davies, Wolfe, Mottola, & MacKinnon, 2003). In individuals with hypertension, it reduces systolic and diastolic BP by 5−7 mmHg and improves neural regulatory mechanisms by increasing the gain of the arterial baroreflex (Pagani et al., 1988). Moreover, exercise conditioning reduces resting and exercise HR, lowers serum low-density lipoprotein, increases serum high-density lipoprotein, and helps to control weight. Reviewing the literature on exercise during pregnancy, Weissgerber, Wolfe, Davies, and Mottola (2006) found epidemiological evidence showing that the incidences of gestational diabetes (e.g., Dye, Knox, Artal, Aubry, & Wojtowycz, 1997) and preeclampsia (e.g., Sorensen et al., 2003) were lowest in women who reported being the most physically active.

There are no reported prospective studies on the effects of chronic exercise on BP, HRV, and BRS in overweight pregnant women. Given that chronic exercise (i.e., exercise conditioning) has been shown to improve cardiac autonomic function in both pregnant and overweight individuals and that cardiac autonomic function is influenced by both pregnancy (Avery et al., 2001) and obesity (Felber Dietrich et al., 2008), it may be that exercise conditioning will improve cardiac autonomic function in obese pregnant women. Thus, the purpose of this prospective study was to measure the effects of a 16-week low-intensity walking program in healthy, normal weight, and overweight/obese pregnant women on BP, HRV, and BRS.

Method

Participants

We recruited 25 healthy pregnant women at 20 ($\pm$ 2) weeks gestational age (GA) through regional family physicians' offices, outpatient antenatal clinics, posted announcements, and newspaper advertisements. Inclusion criteria were (a) singleton pregnancy, (b) sedentary lifestyle (defined as $\leq$ 2 sessions of aerobic exercise per week; American College of Sports Medicine [ACSM], 2006), and (c) approval of the attending physician. Exclusion criteria were (a) alcohol or drug dependence, (b) hypertension, diabetes, or comorbid medical conditions, or reasons that contraindicated exercise, (c) cigarette smoking during pregnancy, and (d) medical reasons or treatments that would confound the measurement of HRV and BRS. Of the initial 25 women recruited, 2 were excluded for medical reasons (i.e., diagnosed with having a small-for-gestational-age baby and unable to perform the acute exercise test) and 1 woman withdrew from the study. The remaining 22 sedentary pregnant women (normal weight, $n = 10$; overweight/obese, $n = 12$) completed the 16-week study and were tested at 20 and 36 weeks GA.

GA was calculated from the first day of the last menstrual period if periods were reliable or from early ultrasound scan at 8–12 weeks GA. Participants were categorized as normal weight or overweight/obese based on pre-pregnancy BMI (Canadian Guidelines for Body Weight Classification in Adults, 2003). The normal-weight participants had a pre-pregnancy BMI of 18.5–24.9 kg/m^2 and the overweight/obese participants included women with a pre-pregnancy BMI $\geq$ 25.0 kg/m^2. The pre-pregnancy weights were obtained by self-report from the women and confirmed from medical records. Participants were assigned to one of four groups based on exercise group and BMI category. The first two subjects within each weight group, normal or overweight/obese, were randomized by coin toss to either an exercise (walking) group or a nonexercise control group. Subsequent participants were then assigned to either the exercise (walking) group ($n = 11$ [normal weight, $n = 5$; overweight/obese, $n = 6$]) or the nonexercise control group ($n = 11$ [normal weight, $n = 5$; overweight/obese, $n = 6$]) based on BMI so that the weight categories were equally represented in each exercise group. Sample size was based on the literature in which a sample of eight participants per group allows for findings of significant differences in HRV between conditioned and unconditioned groups (Myslivecek, Brown, & Wolfe, 2002). The study was conducted in accordance with ethics approval from the University and Affiliated Teaching Hospitals Health Sciences Human Research Ethics Board. Eligible pregnant women provided written, informed consent prior to participation.

Equipment/Instruments

We used the Physical Activity Readiness Medical Examination for Pregnancy© (PARmed-X for PREGNANCY; Canadian Society for Exercise Physiology, 2002) to screen potential participants. It is an instrument developed by the Canadian Society for Exercise Physiology and endorsed by the Society of Obstetricians and Gynecologists of Canada for screening women who wish to participate in physical activity during pregnancy (Davies et al., 2003). The pregnant woman fills out the patient information and the pre-exercise health checklist portion of the PARmed-X for PREGNANCY. The physician checks the information provided by the woman for accuracy and fills out the contraindications to exercise section based on current medical information. If no exercise contraindications exist, the form is completed and signed by the physician for approval for participation in the prenatal exercise program.

To calculate maternal BMI, maternal weight and height were obtained using a Seca 700 (Seca Corporation, Hanover, Maryland) mechanical weighing and measuring scale. Maternal BP (arm) and HR were measured using a BpTRU (Model BPM-300, VSM MedTech Ltd., Coquitlam, BC, Canada) BP monitor. The BpTRU is an automated, noninvasive monitor that has been shown to be an accurate and reliable BP device as compared to the recognized standard, ausculatory mercury sphygmomanometer in nonpregnant healthy adults (Mattu, Heran, & Wright, 2004). The BpTRU takes six measurements of BP and HR, discards the first, and displays the average of the remaining five.

For the purpose of calculating BRS, beat-by beat finger arterial BP was measured continuously during testing using a Finapres® 2300 (Ohmeda, Englewood, Colorado) digital automated BP monitor by finger photoplethysmography. The reliability of the Finapres® 2300 in detecting beat-by-beat changes in BP has been established in nonpregnant individuals (Iellamo et al., 1994; Parati, Casadei, Groppelli, Di Rienzo, & Mancia, 1989) and in pregnant women (Amara & Wolfe, 1998).

For HRV measurements, beat-by-beat R-R intervals were obtained and recorded continuously during testing using three latex-free standard surface electrocardiographic (ECG) electrodes and a Spacelab 514T cardiac monitor (Squibb Vitatek Inc., Hillsboro) with a QRS detector. The cardiac monitor records electrical activity in the heart caused by an action potential and depicts ventricular depolarization as a QRS complex. Thus, the duration between consecutive ventricular depolarizations, as measured by the R waves of the QRS complexes, is defined as the R-R interval. An analog-digital converter (DAS-16, Metrabyte Corp., Multitest Electronics, Scarborough, ON, Canada) digitized the analog R-R interval output from the cardiac monitor. This provided an R-R interval accuracy of 1 ms through a sampling rate of 1,000 Hz (Yamamoto & Hughson, 1991). The digital R-R interval output was analyzed using a custom computer software program for spectral analysis of R-R interval variability (Yamamoto & Hughson, 1991).

For steady-state exercise testing, an Ergometrics er800S (Ergoline GmbH, Lindenstrabe, Germany) upright electronic cycle ergometer was used. This equipment is a computer controlled, speed independent, cycle ergometer. To rate and monitor the overall perception of exertion during exercise, the Borg Rating of Perceived Exertion (RPE) 15-point scale (Borg, 1982) was used (ACSM, 2006; Wolfe, 2005). This scale is a

category scale that allows the individual to rate exercise intensity on a scale of 6–20 and uses verbal cues from *very, very light* to *very, very hard*. This RPE scale was designed to describe perceptions of physical exertion during exercise; it has demonstrated validity for monitoring exercise in nonpregnant adults (Robertson & Noble, 1997) and pregnant women (Pivarnik et al., 1990).

Procedure

Interested pregnant women were screened for eligibility via phone by the researcher (S.S.) prior to enrollment in the study. Eligible participants were then screened using the PARmed-X for PREGNANCY and received written approval to participate from their family physicians or obstetricians. Subsequently, each participant was tested in a laboratory visit at 20 and 36 weeks GA. Participants were asked to refrain from caffeine consumption for 12 hr prior to testing.

Laboratory testing protocol. Prior to testing, we obtained demographic data from each participant, including education, marital status, occupation, age, health, and obstetrical history. Height and weight were measured with shoes removed. Next, we recorded six resting BP and HR measurements with participants in the seated position and averaged the measurements using the BPtru automated BP monitor. We measured the BP by placing the BP cuff around the left upper arm and used the average BP (arm) as the resting BP.

Laboratory testing at 20 and 36 weeks GA included continuous measurement of maternal HRV and BRS under two test conditions: (a) semi-recumbent (supine) rest and (b) acute low-intensity steady-state exercise. During testing, we obtained beat-by-beat R-R interval data for calculation of HRV by ECG using Lead II. We obtained beat-by-beat finger arterial BP data for the calculation of BRS by Finapres® 2300, positioning a finger cuff on the middle phalanx of the middle finger of the left hand that was connected to a transducer that we placed on top of the participant's hand and aligned with the left ventricle of the heart. We asked the participants not to speak during testing to avoid stimuli during data collection.

For the semi-recumbent (supine) rest condition, after 3 min of equilibration, we measured beat-by-beat R-R interval and beat-by-beat finger arterial BP continuously for 10 min, with the participant lying in a semi-recumbent left lateral position. This is the standard position used for pregnant women in laboratories in Canada (Amara & Wolfe, 1998; Brown et al., 2008) for two reasons: First, this position minimizes the compromising effects of pregnancy on maternal circulation and the consequent autonomic responses, thus preventing a vasovagal response due to femoral artery compression (Amara & Wolfe, 1998; Avery et al., 2001; Brown et al., 2008). Second, a 30° elevation of the head of the bed facilitates breathing and improves ventilatory mechanics by promoting optimum downward contraction of the diaphragm and expansion of the thoracic cavity.

For the acute low-intensity exercise condition, following the supine rest test, we measured maternal beat-by-beat R-R interval and finger arterial BP data during acute, low-intensity, steady-state exercise for ~600 cardiac cycles. Each participant was in the sitting position on the upright electronic cycle ergometer with the BP arm stabilized. The steady-state testing protocol involved a 3-min warm-up at 20 W, followed by a ramp increase in work rate within 30 s to a level corresponding to 40% of the maximal heart rate reserve (HRR) using the Karvonen method for calculation of intensity (ACSM, 2006; Myslivecek et al., 2002; Wolfe, 2005). The Karvonen method determines a target exercise HR that is based on age, resting HR, and percentage of desired exercise intensity (target HR = [40%] [$HR_{max} - HR_{rest]} + HR_{rest}$).

Maternal exercise-conditioning protocol. At the end of the pretest laboratory visit at 20 weeks GA, we assigned participants to one of four groups, using the procedure described above. These groups were walking/normal BMI, nonwalking/normal BMI, walking/overweight/obese BMI, and nonwalking/overweight/obese BMI. We gave participants in the two exercise groups verbal and written instructions for a 16-week, progressive, low-intensity walking program, an exercise log, and the Borg 15-point (6–20) RPE scale and taught them how to monitor their HR response to exercise by radial artery palpation (Brown, Wolfe, Hains, Pym, & Parker, 1994). A combination of the revised HR target zone and RPE is recommended as the best method for monitoring exercise intensity in pregnant women because of the cardiovascular changes that occur in pregnancy (ACSM, 2006; Davies et al., 2003; Wolfe, 2005; Wolfe & Weissgerber, 2003).

The 16-week low-intensity (≤40% HRR) exercise conditioning program for sedentary women, consistent with ACSM (2006) guidelines, was modified for pregnant women (Davies et al., 2003) from Brown et al. (1994), Myslivecek et al. (2002), and Hua, Brown, Hains, Godwin and Parlow (2009). Beginning at 20 weeks GA, we gave participants written and oral instructions to walk to RPE 11–13 (fairly light to somewhat hard; ACSM, 2006; Wolfe, 2005), 5 days/week, beginning at 0.6 km/day, with a gradual progression to 3.0 km/day by the end of the 16 weeks. We instructed the women to begin each walking session with a 5- to 10-min warm-up and end with a 5- to 10-min cooldown including stretching and range-of-motion exercises. Each participant was advised to stop walking and seek medical attention if any of the following symptoms occurred: excessive shortness of breath, chest pain, painful uterine contractions (more than 6–8/hr), vaginal bleeding, any sudden discharge of fluid from vagina, dizziness, or faintness (Davies et al., 2003). No participant reported experiencing such symptoms during the exercise protocol.

We confirmed each participant's ability to use the exercise log and monitor HR accurately prior to them leaving the laboratory. The researcher (S.S.) accompanied each participant in the walking group on the first day of the walking program to assess her ability to monitor HR and RPE; perform warm-up, cooldown, and walking exercises; use the exercise log; and monitor

Table 1. The Means (±SD) for the Characteristics of the Participants in Each Walking and Weight Group Prior to the Beginning of the Study

	Control Group		Walking Group	
Measure	Normal Weight ($n = 5$)	Overweight ($n = 6$)	Normal Weight ($n = 5$)	Overweight ($n = 6$)
Gestational age (weeks)	21.1 (1.7)	20.2 (1.4)	19.9 (1.0)	20.3 (1.6)
Maternal age (years)	25.8 (3.0)	26.2 (5.6)	30.4 (4.2)	28.8 (6.9)
Years postsecondary education	2.4 (1.9)	2.3 (1.6)	3.8 (3.2)	2.3 (1.3)
Gravida	1.8 (0.8)	1.3 (0.5)	1.4 (0.5)	1.8 (0.9)
Parity	0.6 (0.9)	0.3 (0.5)	0.4 (0.5)	0.5 (0.8)
Pre-pregnancy BMI (kg/m^2)	20.9 (2.1)	30.6 (4.0)	22.2 (1.7)	30.6 (5.5)

Note. BMI = body mass index; SD = standard deviation.

Table 2. Means (±SD) for BMI and Blood Pressure of the Participants in Each Walking and Weight Group When Tested at 20 and 36 Weeks Gestation

	Control Group		Walking Group	
Measure and Timepoints	Normal Weight ($n = 5$)	Overweight ($n = 6$)	Normal Weight ($n = 5$)	Overweight ($n = 6$)
BMI (kg/m^2)				
Pre-pregnancy	20.9 (2.3)	30.62 (4.0)	22.16 (1.7)	30.60 (5.5)
20 weeks GA	22.54 (2.1)	32.18 (4.3)	24.44 (1.0)	32.83 (6.3)
36 weeks GA	25.22 (2.5)	35.46 (4.2)	28.24 (1.0)	35.45 (6.5)
Systolic BP_{arm} (mmHg)				
20 weeks GA	109 (7)	107 (8)	111 (12)	114 (14)
36 weeks GA	113 (7)	117 (7)	113 (4.3)	112 (12)
Diastolic BP_{arm} (mmHg)				
20 weeks GA	74 (4)	72 (4)	76 (11)	75 (10)
36 weeks GA	75 (6)	80 (6)	78 (7)	78 (10)

Note. BMI = body mass index; BP = blood pressure; GA = gestational age.

walking. All participants met the criterion of at least three exercise sessions per week.

Participants in the nonwalking control groups were given an activity log to record daily physical activity. All participants received a biweekly call or e-mail from the researcher (S.S.) to answer any questions and to assess/promote compliance. All logs were collected at completion of the 16-week period.

Spectral Analysis of HRV

HRV characterizes fluctuations in consecutive R-R intervals in a cardiac cycle (TFESCNASPE, 1996). We used the power spectral analysis method of Yamamoto & Hughson (1991) for HRV analysis of R-R interval data. Power spectral analysis, recommended for short-term data recordings, reduces beat-by-beat heart rate signals into frequency components and then quantifies them in terms of power (variance; TFESCNASPE, 1996). The three main spectral components in short-term recordings are very low frequency (VLF), LF, and HF. The physiological explanation of the VLF is not well understood or defined, and it is recommended that it should be avoided when interpreting short-term recordings (TFESCNASPE, 1996). In this study, we used the HF band (0.15–0.5 Hz) as a reflection of rapidly acting PNS activity, the LF band (0.04–0.15 Hz) as a reflection of both PNS and SNS activity (Akselrod et al., 1981; Akselrod et al., 1985; TFESCNASPE, 1996; Yamamoto & Hughson, 1991), the ratio of HF to TP (HF/TP) as a reflection of the PNS indicator, or PNS modulation, and the ratio of LF to HF power (LF/HF) as a reflection of the SNS indicator, or sympathovagal balance (TFESCNASPE, 1996; Yamamoto & Hughson, 1991).

Sequence Analysis of BRS

BRS reflects the magnitude of the HRV, or R-R interval, response to a 1-mmHg change in systolic BP (Blaber et al., 1995; Brown, Wolfe, Hains, Ropchan, & Parlow, 2004; Parlow et al., 1995). We used the sequence method to calculate BRS, evaluating beat-by-beat arterial BP recordings from the Finapres® 2300 and R-R interval data from the electrocardiograph (ECG) for sequences of at least three consecutive heart beats in which systolic arterial BP and R-R intervals both increased or both decreased (Blaber et al., 1995). A computer software program (Blaber et al., 1995) identified the baroreflex sequences and used linear regression to calculate the slope of each sequence. We used the mean slope of the baroreflex sequences to represent BRS.

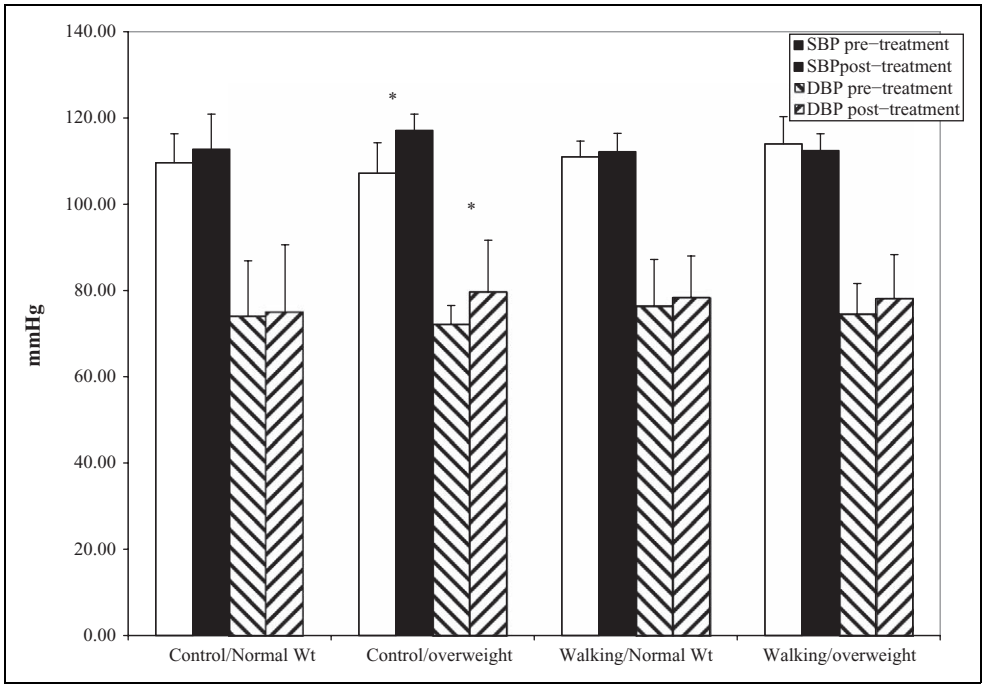

Figure 1. The systolic and diastolic blood pressure for each walking and body mass index (BMI) weight group at 20 (pretreatment) and 36 weeks (posttreatment) gestational age (GA).
*Significant change over time ($p < .05$).

Table 3. The Means ($\pm$SD) for the Effects of an Exercise Program on Maternal Heart Rate Variability Measures in Each Test Condition at 20 and 36 Weeks GA for the Walking and Weight Groups Separately

Measure and Test Condition	Control Group				Exercise Group			
	Normal Weight		Overweight		Normal Weight		Overweight	
	20 Weeks	36 Weeks	20 Weeks	36 Weeks	20 Weeks	36 Weeks	20 Weeks	36 Weeks
HF power (ms^2/Hz)[a]								
Supine	361.9 (370)	111.8 (161)	376.1 (723)	122.2 (265.7)	278.9 (504)	290.8 (606)	101.1 (99.7)	25.36 (23.8)
Exercising	2.37 (1.2)	1.94 (1.1)	3.13 (.91)	2.74 (2.1)	3.54 (2.1)	2.15 (1.6)	2.60 (2.6)	1.49 (1.1)
LF power (ms^2/Hz)								
Supine	184.2 (176)	83.4 (76)[ab]	141.1 (181)[ab]	107.5 (202.1)	194.4 (242)	116.2 (148)	126.56 (143.7)	37.76 (15.0)
Exercising	6.68 (7.1)	6.26 (5.8)	11.03 (4.7)	8.71 (6.5)	13.57 (9.1)	11.44 (10.7)	7.69 (3.6)	9.14 (7.1)
Total power (ms^2/Hz)								
Supine	746.3 (667)	461.3 (583)	652.1 (984)[a]	326.1 (506)	777.14 (1072)	787.8 (1042)	523.24 (621.0)	231.9 (203.5)
Exercising	27.04 (14.6)	33.6 (23.4)	42.4 (14.3)[a]	36.2 (17.4)	53.83 (36.7)	77.1 (48.6)	30.49 (15.8)	56.4 (59.6)
PNS indicator (HF/TP)								
Supine	0.396 (.16)	0.175 (.09)	0.365 (.19)	0.188 (.19)	0.217 (.15)	0.187 (.22)	0.207 (.12)	0.120 (.06)
Exercising	0.098 (.06)	0.07 (.03)	0.078 (.03)	0.08 (.07)	0.11 (.08)	0.044 (.05)	0.08 (.05)	0.043 (.03)
SNS indicator (LF/HF)								
Supine	0.970 (.92)	2.26 (2.1)	1.30 (1.7)	2.18 (1.3)	2.02 (1.6)	3.51 (3.16)	1.66 (1.1)	2.08 (1.3)
Exercising	2.83 (1.8)	2.92 (.95)	3.70 (1.6)	4.4 (2.2)	4.23 (2.6)	5.90 (.50)	4.64 (2.5)	7.20 (5/3)

Note. GA = gestational age; HF = high frequency; LF = low frequency; PNS = parasympathetic nervous system; SNS = sympathetic nervous system; TP = total power.
[a] Change over time.
[b] Difference between supine and exercising conditions.

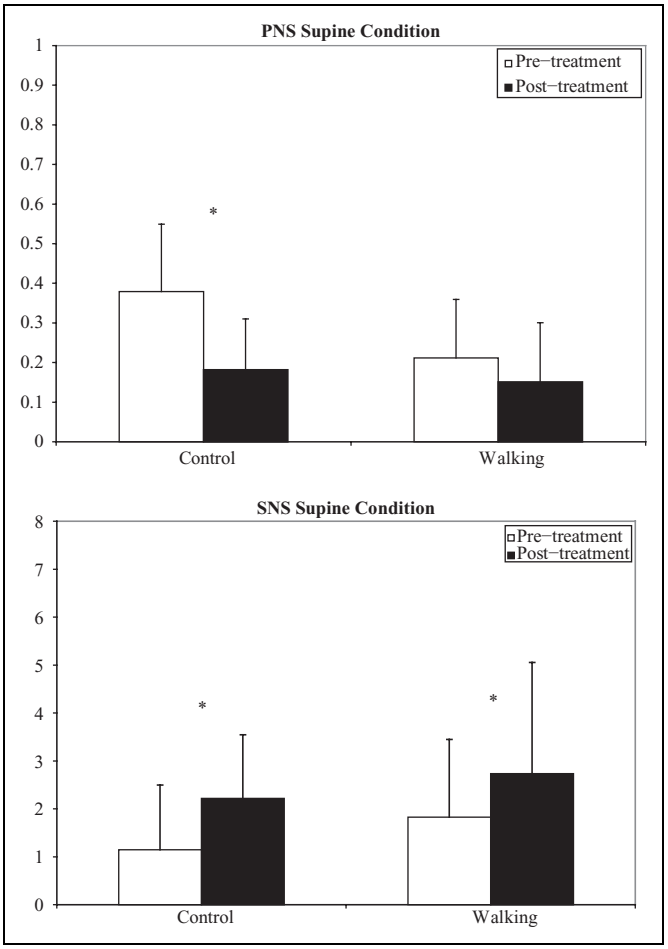

Figure 2. The parasympathetic nervous system (PNS) and sympathetic nervous system (SNS) indicators for each walking group in the supine resting condition at 20 and 36 weeks gestational age (GA).
*Significant change over time ($p < .05$).

Results

Maternal Demographic, Obstetrical, and BP Measures

The means ($\pm$SD) for GA at testing, maternal age, education level, gravida, parity, and pre-pregnancy BMI are shown in Table 1. There were no significant differences in any of these measures among the groups except for the intended difference in BMI.

Table 2 shows the means ($\pm$SD) for BMI, sitting systolic BP (arm), and diastolic BP (arm) at each time of testing for each BMI weight group and walking group separately. These data were analyzed using a two-between (walking group, BMI weight group), one-within (time) analysis of variance (ANOVA). In the omnibus analysis, no significant differences between the groups were found in resting sitting systolic BP (arm), although as can be seen in Figure 1, the control overweight BMI group showed a significant systolic BP (arm) increase of 10 mmHg, $F(1, 5) = 7.42$, $p < .05$, not shown by the other three groups. Again from Figure 1, sitting resting diastolic BP (arm) increased significantly over time only for the overweight BMI control group, $F(1, 5) = 12.83$, $p < .05$.

HRV Measures at Supine Rest and Exercise at 20 Vs. 36 Weeks GA

The means ($\pm$SD) for the maternal HRV measures are shown in Table 3. Log transformations were used in the data analyses because of skewness and/or outliers in the raw data. Two-between (walking group, BMI weight group), two-within (Time: 20 weeks GA, 36 weeks GA; Condition: supine rest, exercise) ANOVAs showed the expected decrease in all measures from 20 to 36 weeks GA except for the SNS indicator, which increased. Also all measures were lower in the exercise condition than in the supine rest condition except the SNS indicator, which was higher.

PNS indicator. More importantly, there was a Time $\times$ Condition $\times$ Walking Group interaction for the PNS indicator $F(1, 18) = 6.51$, $p < .05$. As can be seen from Figure 2, supine rest PNS was lower at 36 weeks GA than at 20 weeks GA for both control normal BMI weight, $t(1, 4) = 7.01$, $p < .01$, and control overweight BMI, $t(1, 5) = 2.69$, $p < .05$, groups, whereas the walking groups showed no significant change.

SNS indicator. As shown in Table 3 and Figure 2, there was a significant increase in SNS over time in the omnibus analysis, $F(1, 18) = 9.49$, $p < .01$, with no significant group differences. However, when the data for each group were analyzed separately, the change over time was seen to be due mainly to a significant increase in the control normal BMI weight group, $F(1, 5) = 12.39$, $p < .01$.

When we examined the components of PNS and SNS indicators for LF power, the overweight BMI participants in the control group showed a reduction in LF power over time, $F(1,5) = 10.49$, $p < .05$, and the Normal-Weight BMI participants in the control group showed a Time $\times$ Condition interaction, $F(1,4) = 39.10$, $p < .01$, such that the reduction of LF power in the supine rest condition was greater than that in the exercise condition. In contrast, the walking groups showed no change over time. For HF power, the control groups showed a reduction in HF power over time and a greater reduction in the exercise condition than in the supine rest condition (Time $\times$ Condition interaction, normal weight, $F(1, 4) = 16.63$, $p < .05$; overweight, $F(1, 5) = 10.47$, $p < .05$). The walking groups showed the same reduction in both supine and exercise conditions (no interaction), though the overweight BMI group showed an overall reduction over time, $F(1, 5) = 8.70$, $p < .05$. For TP, the overweight BMI control group showed a significant decrease over time, $F(1, 5) = 11.912$, $p < .05$.

BRS

The data for the BRS measures are shown in Table 4. As can be seen from Figure 3, there was the expected change in supine BRS, but not during exercise, from 20 weeks GA to 36 weeks GA for both control and walking groups resulting in a Time $\times$ Condition interaction, $F(1,16) = 33.65$, $p < .01$. For the components of the BRS, there were changes in both the beat-by-beat

Table 4. The Means (±SD) for the Effects of an Exercise Program on Maternal Baroreflex Sensitivity (BRS) Measures in Each Test Condition (supine and exercising) at 20 Weeks and 36 Weeks GA for the Walking and Weight Groups Separately

	Control Group				Exercise Group			
	Normal Weight		Overweight		Normal Weight		Overweight	
Measure and Condition	20 Weeks	36 Weeks	20 Weeks	36 Weeks	20 Weeks	36 Weeks	20 Weeks	36 Weeks
BRS slope (ms/mmHg)								
Supine[a]	15.23 (7.9)	8.90 (6.39)	11.08 (7.3)	5.67 (5.7)	11.05 (9.1)	8.12 (9.2)	8.89 (5.4)	4.29 (1.9)
Exercising	1.21 (.37)	1.11 (.45)	1.49 (.67)	1.21 (.65)	1.25 (.13)	1.23 (.50)	1.23 (.48)	1.02 (.29)
ABP_{finger} (mmHg)								
Supine	116.8 (16.1)	98.9 (7.1)	100.6 (11.0)	98.0 (11.0)	104.2 (18.5)	95.0 (12.9)	109.9 (24.5)	104.4 (12.1)
Exercising	137.1 (20.3)	138.2 (12.3)	134.5 (16.8)	133.9 (16.0)	155.2 (26.9)[a]	129.1 (20.9)	132.6 (37.4)	141.2 (11.4)
R-R interval (ms)								
Supine	751.3 (68.5)[a]	682.9 (73.7)	722.3 (102.9)[a]	619.8 (72.2)	760.5 (89.4)	706.6 (135.4)	743.5 (195.2)[a]	656.8 (53.2)
Exercising	477.3 (17.6)	138.2 (12.3)	488.7 (22.7)	483.4 (36.7)	483.8 (16.9)	129.1 (20.9)	481.5 (24.2)	476.7 (31.7)

Note. ABP_{finger} = arterial blood pressure measured via finger photoplethysmography; GA = gestational age.
[a] Change over time.
[b] Difference between supine and exercising conditions.

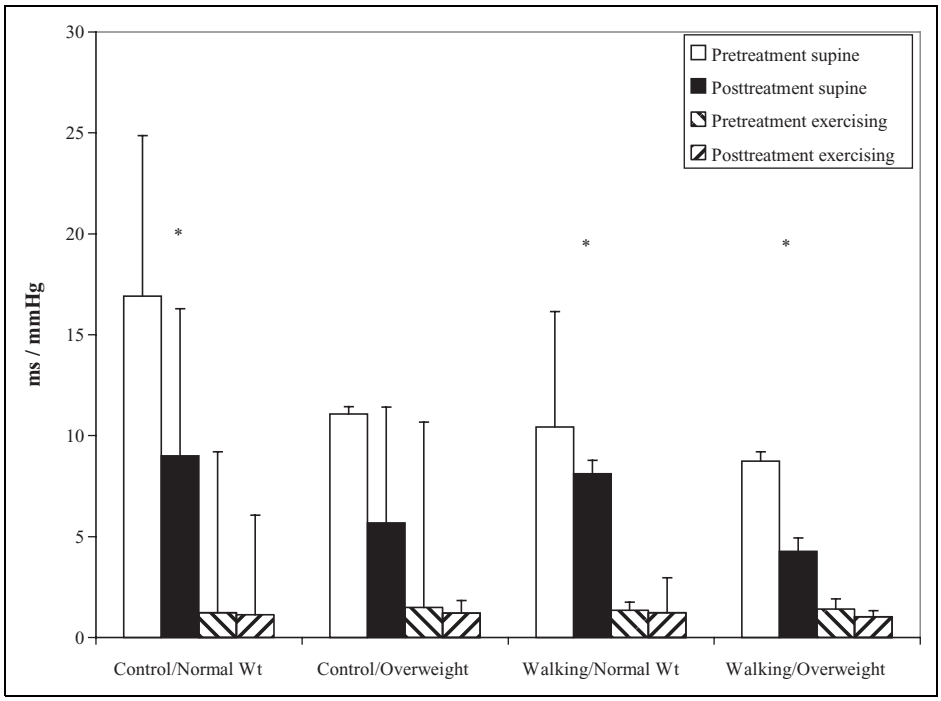

Figure 3. Baroreflex sensitivity (BRS) for each walking and body mass index (BMI) weight group in supine and exercise condition at 20 and 36 weeks gestational age (GA).
*Significant change over time ($p < .05$).

arterial BP (finger) and the R-R interval. For beat-by-beat arterial BP (finger), there was a Time × Condition × Walking Group × BMI Weight Group interaction, $F(1,18) = 6.217$, $p < .05$. This interaction was due primarily to the walking group, normal-weight BMI participants showing a significant reduction over time in arterial BP (finger) in the exercise condition, $F(1,4) = 11.934$, $p < .05$, not seen in the other groups. R-R interval decreased from 20 to 36 weeks gestation, $F(1, 18) = 39.17$, $p < .01$, but again, the walking group normal-weight BMI participants differed from the other groups. For this group, there was no significant change in R-R interval from 20 weeks GA to 36 weeks GA.

Discussion

The primary purpose of this prospective, longitudinal study was to examine the effects of a low-intensity exercise conditioning program on maternal BP, HRV, and BRS in healthy pregnant women who were overweight/obese compared with those who were of normal weight, as classified by BMI

category. To our knowledge, this is the first report of the effects of exercise conditioning on cardiac autonomic measures over gestation at supine rest and during acute exercise in overweight pregnant women compared with those of normal weight. Results indicated that women in the control nonwalking groups (especially those who were overweight) showed increases in BP and decreases in HRV and BRS over pregnancy, which were not seen in the walking groups. The overweight women in the control group increased average resting systolic BP by 10 mmHg and average diastolic BP by 7 mmHg. Moreover, PNS modulation declined in the control group but did not decline in the walking group. Finally, a reduction in BRS and R-R interval at rest was found in all groups except for the walking normal-weight group. These results suggest that exercise conditioning attenuated the decrease in PNS modulation of HR from 20 to 36 weeks gestation. The study was conducted over a 16-week period during which there are naturally occurring changes taking place in pregnancy. Thus, the findings of this study should be considered in light of these changes.

The most obvious change seen as pregnancy progresses is a weight gain resulting in an increase in BMI. The expected increase in BMI of approximately 3 kg/m^2 was found when comparing the average BMIs among groups at 36 weeks GA vs. 20 weeks GA, with no significant differences between the groups. This finding is in contrast to those of other studies (Bianco et al., 1998; Edwards, Hellerstedt, Alton, Story, & Himes, 1996; Stephansson et al., 2001) that have shown that obese women tend to gain less weight during pregnancy than normal-weight women. However, the discrepancy may be due to the fact that in this study obese and overweight participants were included in the same group.

A second typical effect of pregnancy is an increase in BP over time. Paller (1998) showed that there is a gradual increase in BP after the beginning of the second trimester and into the third trimester. In the current study, this effect was shown only by the overweight women in the control group whose average resting systolic BP (arm) increased by 10 mmHg. For those women in the control group who were not overweight and the women in the walking group, whether or not they were overweight, such was not the case, their systolic BP (arm) did not change over the study period. Furthermore, the overweight women in the control group increased average diastolic BP (arm) by 7 mmHg. These results suggest that, for overweight pregnant women, the low-intensity exercise conditioning program used in this study attenuated the typical increases in systolic and diastolic BP that occur as pregnancy progresses (Clapp, 1996; Clapp & Dickstein, 1984; Dye et al., 1997; Sorensen et al., 2003). Attenuation of increases in BP in overweight women would seem to be especially important, as their increased BMI puts them at increased risk of developing hypertension during pregnancy (Kumari, 2001; Lu et al., 2001; Sebire et al., 2001; Stephansson et al., 2001).

PNS activity was lower in late gestation compared to early pregnancy for the control groups but not for the walking groups, which showed no decline over gestation. The observation of lower PNS activity in late pregnancy compared to the nonpregnant state has been reported (Avery et al., 2001; Helmreich et al., 2008; Kuo et al., 2000; Voss et al., 2000). Thus, it might be expected that PNS would be lower at 36 weeks GA than at 20 weeks GA. However, the lack of decline in the walking group implies that exercise conditioning attenuated the decrease in PNS modulation over pregnancy. PNS activity is calculated as the ratio of HF to TP and differences between the control and walking groups were seen in both the HF and TP components. Exercise conditioning seemed to have a greater effect when the participants were actively exercising (i.e., during acute exercise). The control group showed a greater reduction in HF power in the exercise test than in the supine rest condition over time, whereas the walking group showed the same reduction in both supine rest and exercise test conditions. The effect of being overweight was seen in that the overweight participants in the control group showed a significant decrease in TP over time.

Coupled with a lower PNS indicator (HF/TP), an increase in the SNS indicator (LF/HF) may be seen as pregnancy progresses (Kuo et al., 2000; Voss et al., 2000), though Eneroth-Grimfors et al. (1994) found no change. At the same time, it is thought that cardiovascular complications in obesity may be a result of altered SNS activity (Amano, Kanda, Ue, & Moritani, 2001; Laederach-Hofmann et al., 2000; Tuck, 1992). In this study, except for the control normal-weight BMI group, no significant effects of either walking or BMI category were found for SNS indicator. The findings from the current study with essentially healthy pregnant women indicate that the SNS indicator increases over gestation regardless of exercise or BMI, reflecting an increase in sympathovagal balance. This reflects a relative increase in SNS activity, caused by either an increase in SNS activity or a reduction in PNS activity.

Although there were no differences between the groups on SNS activity, there were effects of BMI weight group and walking on the LF and HF components of SNS. The control group participants who were overweight showed a significant reduction in LF power over time, consistent with other studies (e.g., Avery et al., 2001), whereas the walking group showed no change. There were no group differences in HF power at rest, but with acute exercise there was a greater decrease in the control group than in the walking group.

Although we could find no other studies that compared maternal BRS measures over gestation, Avery et al. (2001) did compare BRS measures in pregnant women in late gestation to those in nonpregnant women. They found that BRS was lower at rest in the pregnant group compared to the nonpregnant group, indicating decreased PNS activity. In the current study, a GA-related reduction in BRS measures at rest was found in all groups except for the walking normal-weight group; BRS and R-R interval decreased over time. A reduction in R-R interval implies an increase in HR at rest. The decreases in BRS and R-R interval are related to the decrease in PNS activity from mid to late gestation. However, the walking group participants who were of normal weight did not show a reduction in either PNS or R-R interval, implying that their resting HR did not increase or decrease. This latter

Table 5. Summary of the Significant Changes in Each Measure Between 20 and 36 Weeks Gestational Age (GA)

	Control		Walking	
Measure	Normal Weight ($n = 5$)	Overweight ($n = 6$)	Normal Weight ($n = 5$)	Overweight ($n = 6$)
SBP_{arm} (mmHg)	↑	↑	–	–
DBP_{arm} (mmHg)	–	↑	–	–
PNS (HF/TP)	↓	↓	–	–
SNS (LF/HF)	↑	–	–	–
LF (ms^2/Hz)	–	↓	–	–
HF (ms^2/Hz)	↓	↓	–	–
ABP_{finger} (mmHg)	–	–	↓	–
R-R interval (ms)	↓	↓	–	↓
BRS (ms/mmHg)	↓	↓	–	–

Note. ↑ = significant increase over time; ↓ = significant decrease over time; – = no change; ABP_{finger} = arterial blood pressure measured via finger photoplethysmography; BRS = baroreflex sensitivity; DBP = diastolic blood pressure in arm; HRV = heart rate variability;HF = high-frequency HRV; LF = low-frequency HRV; PNS = parasympathetic nervous system; SBP = systolic blood pressure in arm.

finding is consistent with the results of Wolfe et al. (1999) that physical conditioning during pregnancy does not decrease resting HR, in contrast to the effect in nonpregnant populations. They concluded that the cardiovascular effects of aerobic conditioning are masked by the normal cardiovascular effects of pregnancy. This finding suggests that the low-intensity exercise-conditioning program used in this study attenuated decreases in PNS modulation and R-R interval that were seen in the control groups.

Table 5 conveys a summary of the changes from 20 weeks GA to 36 weeks GA in this study. What is most obvious is that the significant changes in almost all measures were confined to the control groups, who showed the changes that occur over gestation. Our results show that a 16-week walking regimen had benefits for systolic BP and PNS activity in particular, whereas being overweight was detrimental to diastolic BP, LF power, and TP, especially in the control nonwalking group. We are the first to report the effects of exercise conditioning on maternal cardiac autonomic measures over gestation at rest and during acute exercise in overweight pregnant women compared with those of normal weight. Despite the relatively small number of participants, the effects of low-intensity exercise conditioning on maternal BP, HRV, and BRS were demonstrated. The results of this study suggest that although obesity plays a role in the autonomic control of HR during pregnancy, the effects may be mitigated by regular exercise. They indicate that a low-intensity walking program may have a beneficial effect on maternal physiology during pregnancy, especially for overweight women, which may improve cardiovascular and autonomic adaptation to internal and external stimuli (Akselrod et al., 1981; Helmreich et al., 2008).

In summary, being overweight in pregnancy can have a detrimental effect on the autonomic control of HR and result in an increase in BP. An increase in regular physical activity by walking as little as 3 km/day may offset this increase in BP and may lead to a reduction in the incidence of gestational hypertension. Further research is needed with a larger sample to verify these promising findings.

Author's Note

This study was conducted in the Exercise Physiology Laboratory (CAB) in the Queen's University Centre for Studies in Primary Care at Hotel Dieu Hospital.

Declaration of Conflicting Interests

The author(s) declared no conflicts of interest with respect to the authorship and/or publication of this article.

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