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Postnatal Lifestyle Intervention For Overweight Women With Previous Gestational Diabetes: A Randomized Controlled Trial

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Background: Gestational diabetes mellitus (GDM) is associated with a 7-fold increased lifetime risk of type 2 diabetes. Excessive gestational weight gain and postpartum weight retention are established predictors of long-term obesity.

Objective: To determine the impact of a postnatal lifestyle intervention programme for overweight women with previous gestational diabetes mellitus (PAIGE).

Design: Postnatal overweight women with previous GDM participated in a multi-center randomized controlled trial between June 2013 and December 2014. The intervention comprised a one-hour educational programme, a free three-month referral to a commercial weight management organization (Slimming World), a pedometer and structured telephone and text support, in addition to usual care. The control group received usual care only. The primary outcome was weight loss at 6 months.

Results: A total of 60 women were randomized (29 intervention; 31 control) in two centers based on their week of attendance. The intervention group demonstrated significant weight loss at 6 months post-randomization: mean (SD) 3.9(±7.0)kg, compared with the control group: mean 0.7(±3.8)kg, p=0.02. No significant difference was observed in blood glucose levels. With respect to wellbeing measures, a significant reduction in bodily pain was observed in the intervention group (*P*=0.007).

Conclusions: PAIGE resulted in significantly greater weight loss at 6 months compared with usual care. Such weight loss could prove beneficial in terms of better long-term health and subsequent prevention of type 2 diabetes in overweight women with previous GDM. Future interventions need to consider recruitment strategies, timing of the intervention and the inclusion of partners and/or other family members.

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Précis: A multi-component post-partum lifestyle intervention that resulted in significant weight loss at 6 months in overweight women with a history of gestational diabetes

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Introduction

Almost half of all women are overweight or obese at the beginning of pregnancy, significantly increasing their risk of a number of adverse outcomes including gestational diabetes mellitus (GDM) (1). GDM currently affects 2-18 % of all pregnancies globally (2,3), and results in a 7-fold increased lifetime risk of type 2 diabetes (4). Additionally, excessive gestational weight gain is associated with postpartum weight retention, with both being established predictors of long-term obesity (5).

Lifestyle modification can prevent or delay the development of type 2 diabetes mellitus in those at high risk (6), with a meta-analysis reporting a relative risk reduction of developing type 2 diabetes of 0.55 (0.44-0.69) (7). Diet and exercise together appear to be more effective than diet alone in promoting weight loss after childbirth (8) and inclusion of individual or group counselling combined with written and telephone contact or food and exercise diaries may be of benefit (9). In the 10 year follow-up of the Diabetes Prevention Program (DPP), women with a history of GDM lost less weight than the general DPP population but still experienced a 35% reduction in the development of type 2 diabetes through an intense lifestyle intervention, compared with the control group (10).

Recently the Gestational Diabetes' Effects on Moms (GEM) cluster randomized controlled trial (RCT) demonstrated that a DPP-derived lifestyle intervention initiated during pregnancy modestly reduced postpartum weight retention and increased physical activity in women with GDM (11). In this trial, women received telephone sessions between 6 weeks gestation and 24 weeks postpartum and were encouraged to set weekly diet and physical activity goals. Primary outcomes included reaching pregravid weight (if pregravid BMI<25.0kg/m^2) or losing 5% of pregravid weight (if BMI ≥25.0kg/m^2). Significantly more women in the intervention group met the weight loss goal and had greater increases in physical activity

compared with the usual care group. The National Institute for Health and Care Excellence (NICE) recently concluded that additional studies are urgently needed to assess the effectiveness and cost effectiveness of weight management interventions after childbirth to prevent the development of type 2 diabetes following GDM (12). In addition, there is no consensus as to the components of the 'optimal' postnatal intervention and questions remain in relation to the role of diet, physical exercise, group and individualized therapy (13-17). The aim of this trial was to determine the impact of a pragmatic lifestyle intervention programme (PAIGE), incorporating a DPP-derived lifestyle intervention and utilizing a community-based commercially available weight management organization on postnatal overweight women with a history of GDM.

Materials and Methods

Trial design

A pragmatic cluster RCT with two parallel arms conducted in two joint diabetes-antenatal clinics in Northern Ireland between June 2013 and December 2014.

This research was approved by the Northern Ireland Research Ethics Committee (13/NI/0026). Each participant gave written informed consent and was advised that they had the right to withdraw at any time.

Participants

Overweight or obese pregnant women with a history of GDM in their recent pregnancy (diagnosed by 75g oral glucose tolerance test [OGTT] or high random blood glucose), who

were referred to the participating joint diabetes-antenatal clinics, were identified by their diabetes care team around 38 weeks gestation and given a patient information sheet. Eligible women (including those who delivered before identification at the antenatal clinic) were sent a letter by the diabetes care team at 4-6 weeks postpartum reminding them of the importance of attending for their routine postnatal OGTT, and inviting them to take part in the study. At the postnatal visit, following written informed consent, women were randomized on the basis of their week of attendance either to standard care or to the PAIGE programme.

Inclusion criteria included overweight or obese women (BMI $\geq$ 25 kg/m^2) aged 18 years and older with a history of GDM in their recent pregnancy. GDM was defined by the International Association of Diabetes in Pregnancy Study Group /2013 World Health Organization (WHO) criteria (18) (fasting glucose $\geq$5.1 mmol/l or 1h plasma glucose $\geq$10.0 mmol/l or 2h plasma glucose $\geq$8.5 mmol/l during pregnancy). Women with a history of GDM directly preceding the most recent pregnancy, and who were given lifestyle advice and were performing self-monitoring of blood glucose from early pregnancy, were also included if capillary glucose monitoring exceeded target values (fasting $\geq$ 5.3 mmol/l (95 mg/dl); 1h post prandial $\geq$7.8 mmol/l (140 mg/dl)) (12), thus negating the need for an OGTT. Women were included if they had a BMI $\geq$25 kg/m^2 at booking if <12 weeks (otherwise inclusion was based on reported pre-pregnancy weight) and a BMI $\geq$25 kg/m^2 at their postnatal OGTT visit (or equivalent to 25 kg/m^2 for non-Caucasian subjects) (19). Women were only included if their postnatal OGTT did not meet the diagnostic criteria for overt diabetes outside of pregnancy; thus women with normal glucose tolerance, impaired glucose tolerance or impaired fasting glucose (IGT/IFG) were invited to participate.

Exclusion criteria included: a pregnancy outcome resulting in anomaly or stillbirth; a history of diabetes outside pregnancy or diagnosis of diabetes on the postnatal OGTT; history of

heart, liver or chronic renal disease; medications that adversely affect glucose tolerance (e.g. steroids); inability to participate in moderate physical activity; moderate/severe depressive illness or excess alcohol consumption; inability to adequately understand verbal explanations or written information in English, or have special communication needs. Women who were planning another pregnancy within the next 6 months or taking part in other research or already attending any commercial weight management organization (CWMO) were also excluded. Women who were diagnosed with diabetes at the postnatal OGTT were referred to the local diabetes care team and excluded from the study post-randomization.

Intervention

The control arm received usual care alone, which included an educational DVD that is provided routinely to women upon diagnosis of GDM. This resource is used to educate on the likely symptoms, causes, consequences, and management of GDM, including information on weight management and physical activity both before and after pregnancy as recommended by NICE guidelines (12,20). The intervention arm, in addition to usual care, (which included the DVD) was enrolled in the PAIGE Programme as detailed below.

The PAIGE Programme

The PAIGE Programme is a pragmatic, theory driven, motivationally-targeted, education programme customized to the postnatal period. PAIGE was adapted from the DPP Lifestyle Intervention, sponsored by the US National Institutes of Health and supported by the Centre for Disease Control and Prevention (21). The programme was informed by focus groups composed of overweight/obese postpartum women with previous GDM. Feedback from these groups directed the tone and content which comprised an initial 60 minute educational

session, delivered by a health educator trained in motivational interviewing at the 6-week postnatal visit. The session was delivered in small groups in a hospital setting between the fasting and 2-hour postnatal OGTT blood samples. Programme delivery was modelled on the person-centred philosophy using learning techniques designed to promote lifestyle change and self-management in line with the Medical Research Council framework for complex interventions (22). Using motivational interviewing techniques, each session was adapted to the needs of the group, taking into account socioeconomic status and ethnicity. The content of the session was broadly divided into three equal time periods: the first addressing the causes, consequences, complications, timelines and implications of GDM and overweight/obesity, the second offering advice regarding a healthy dietary approach for both mother and baby, and the third targeted to address the importance of physical activity as a treatment for the prevention of diabetes and future GDM, physical activity recommendations, barriers, action plans and diaries. At the end of the education session, two individualized PAIGE Programme goals were agreed: 5% weight loss through lifestyle change over a 6-month period and 150 minutes of brisk physical activity each week. The PAIGE Programme included a booklet describing the programme under the section headings: Healthy Eating, Physical Activity, Triggers and Desires for Food, Breastfeeding, and Planning your next Pregnancy. In addition the booklet contained blank pages for questions and notes, and a pedometer step log to record proposed daily step increases, target daily steps and actual daily steps. Women in the intervention group were given a free voucher for 12-weeks membership of the CWMO Slimming World (SW). Women were guided as to their preferred centre and encouraged to join within the first 3 months of the 6 month follow-up period. Whilst the overall programme weight loss goal was 5% weight loss over 6 months, women were encouraged to set individual weight loss targets with their SW leader within the context of the overall programme target. After the 12-week SW programme, women were allowed to continue to

attend the programme for the remainder of the study if they so desired, but at their own expense. In addition, women in the intervention group were given a sealed piezoelectric pedometer with a 7-day memory (NL-800; NEW-LIFESTYLES, Lee's Summit, MO) to help them to reach the physical activity goal. Sedentary participants were encouraged to increase their activity levels incrementally using proximal objectives by at least 3,000 steps per day, equivalent to approximately 30 minutes of walking (23). Women were encouraged to wear the pedometer daily to self-monitor their ambulatory activity using a 'steps per day' log, and were prompted to document this by weekly texts and monthly telephone calls. Finally, women were contacted intermittently by a health educator by text and telephone. Text messaging was weekly for the first month (primarily to encourage the women to register for SW) and then fortnightly. Structured telephone calls utilizing motivational interview techniques took place monthly, and included documentation of pedometer activity, barriers to compliance with diet and activity and suggested solutions. At the end of the study, the control group was offered free referral to SW (12 weeks duration), and a copy of the PAIGE Programme handbook.

Slimming World

The trial utilized a CWMO as one component of the postpartum lifestyle intervention that was underpinned by the central need of accessibility. NICE recognizes the role of CWMOs which follow guidance criteria for best practice. SW meets these criteria (24), and has an extensive community-based infrastructure of around 14,000 support groups held each week, at different times and days across the UK, including Northern Ireland. The organization makes provision for members with specific needs such as those with diabetes, heart disease and pregnancy and is willing to work in close collaboration with health care professionals. While much of the emphasis is on behaviour change for weight management and healthier food choices, there is advice and support on a graded approach to physical activity (25).

Randomization

Women were cluster-randomized to treatment group according to the week they attended for their routine OGTT, to avoid contamination through women potentially discussing treatment allocation and additionally allowed the programme to be delivered to the largest possible number of women on any given day. Delivery of the PAIGE programme took place on 2 out of every 4 weeks at each site, which was allocated at random, using a restricted randomization approach drawn up in advance. The allocations were only made available to recruitment centres at a sufficient time in advance for necessary administrative arrangements and, of note, only after women had received their OGTT appointment. Women who were willing to participate were assessed for eligibility on arrival, and full written informed consent was obtained. Women were then informed of their treatment group. Due to the nature of the intervention, the study was not blinded.

Outcomes

The primary outcome was weight loss at 6-months post-randomization. Secondary outcomes included fasting glucose and 2-hour OGTT glucose (optional), waist circumference, BMI and pedometer counts (change from baseline at 6 months (intervention group only). Questionnaire data were recorded at baseline and 6 months and included details of nutrient intake (as estimated by completion of a 7-day food diary) along with a series of standardized questionnaires, including the long last (7-day) International Physical Activity Questionnaires (IPAQ) (26), General Health and Well-Being Survey (SF-12v2™ Health Survey) (27), Exercise Self-efficacy Survey (28) and the Risk Perception Survey for Developing Diabetes (RPS-DD) (29). Postpartum depression was assessed at both time-points using the Edinburgh

Postnatal Depression Scale (EPDS) (30). All these measures have established reliability and validity.

Pedometer counts are not reported due to incomplete data. The nutrient intake data will be reported separately.

Other outcomes included SW involvement, such as attendance, number of visits and weight at first and last visits (intervention group only). A planned subgroup analysis for the primary outcome was examined for the differential weight loss among women attending six or more SW meetings versus women attending five or fewer SW meetings.

Sample size

Assuming an inter-patient standard deviation of 4.5kg for weight loss (17), a study of 100 women (randomized to two groups) had 95% power at the 5% significance level to detect a differential 5% weight loss between groups (equivalent to 4kg) assuming the mean baseline weight is 80kg and allowing for a 33% dropout rate (i.e. 33 women per group completing the study). A 5% weight loss was selected given its association with clinically meaningful health benefits (31).

Statistical analysis

Primary and secondary outcomes were compared between the intervention and control groups at 6 months by the intention to treat principle. The data from the returned questionnaires were entered into the SPSS version 21 (IBM Corp., Armonk, NY). Descriptive statistics were used to display the baseline characteristics of the participants and both descriptive and inferential statistics (independent samples t-tests on changes in anthropometric results and analyses of covariance for other outcomes) were performed to determine if there were any significant differences in outcomes between randomized groups. Comparisons were adjusted for the cluster randomization using the cluster option in the regress command of Stata release 12

(StataCorp, College Station, TX), but this made little difference to conclusions and so uncorrected results are reported throughout. A *p*-value of <0.05 was considered statistically significant

Results

A total of 404 women were screened for eligibility, of which 344 were excluded (184 did not meet the inclusion criteria, 60 did not wish to take part, 61 did not attend for the OGTT, and 39 were excluded for other reasons). In total, 60 women were randomized (control group, n=31; intervention group, n=29). Nine women were lost to follow-up and six were excluded at visit 2. The final analysis was conducted on the data from 45 women **(Figure 1)**. Of the 60 women randomized, 56 were newly diagnosed with GDM during pregnancy, with the remaining women (n=4) having previous GDM and abnormal glucose results. Women were aged 22-45 years; mean±SD age in the usual care group was 33.2±5.3 years and in the intervention group 34.2±4.3 years. Mean±SD years in education was slightly higher in the intervention group 17.1±3.0 years versus 16.3±3.1 years in the usual care group. The majorities in both groups were white, employed and had a partner **(Table 1)**. The intervention group had a mean±SD baseline weight of 89.6 ±16.8 kg, and BMI 34.1±6.3kg/m^2; corresponding values in the control group were 90.2±16.4 kg /m^2 and 33.6±5.4 kg/m^2, respectively (Table 1). Rates of breastfeeding at randomization were also higher, although not significantly, in the control group, with 45% breastfeeding in the control group compared to 24% in the intervention group reporting having breast fed at least initially after birth.

The intervention group lost significantly more weight than the control group (mean±SD weight change: -3.9 ±7.0 kg vs 0.7±3.8 kg; mean difference (95% confidence interval): -4.5 (-8.1;-0.9) p= 0.02). The reductions in BMI and waist circumference were also significantly greater in the intervention group compared to the control group **(Table 2)**. No significant

difference was observed between the groups for fasting and 2-hour plasma glucose levels at baseline or at 6 months (Table 2). Analysis of covariance of 6-month results adjusting for baseline differences showed that serum lipids, CRP, serum insulin or HbA1c did not differ significantly between the intervention and control group (see **Supplemental Table 1**).

Data analysed from the SF-12v2™ Health Survey revealed no important differences at baseline between the groups with regards to general, physical, social and emotional health, however at 6 months, the intervention group had significantly higher levels of physical functioning meaning that, for example, they could climb several flights of stairs more easily than the control group. Bodily pain (consisting of reported pain that interfered with normal work inside or outside the home) was reported to be significantly lower in the intervention group than in the control group at 6 months **(Table 3)**. There were no significant differences in exercise self-efficacy (Table 3) or risk perception for developing diabetes **(Supplemental Table 2)** between the two groups at baseline or at 6 months. Two women in each group at 6 months had symptoms suggestive of postnatal depression as self-reported through the EPDS. Valid data from the IPAQ questionnaire were available for 14 women in the intervention group and 20 women in the control group (data from 12 women were excluded as per the IPAQ guidelines as they reported > 960 minutes per week physical activity). All 14 women in the intervention group were categorized as "active" at 6 six months using the IPAQ questionnaire (i.e. being active for at least 150 minutes per week according to Chief Medical Officers guidelines) (32). In the usual care group 17 women were "active", two were "somewhat active" (60-100 minutes per week) and one woman was "inactive" (< 60 minutes per week).

Although most women used step counts initially to provide an index of their activity, very few women recorded their step counts or texted counts to the research team during the study,

thus no data on step counts are reported. No adverse consequences were reported by any of the participants.

Participation in the CWMO

The intervention group (n=29) were given vouchers to attend a local SW group of their choice for 12 weeks without charge. Twenty women registered and 12 completed the course (attended 10 or more weeks out of the 12), giving a 41% compliance rate with this aspect of the intervention. Among this group, one woman achieved >10% weight loss, four women achieved between 5-10% weight loss and three women achieved between 3-4.9% weight loss while four women did not lose any weight at the end of their 12 week SW programme. Women (n=8) in the intervention group who attended five or fewer SW classes did not achieve any weight loss or weight loss was less than the 5% target needed to achieve clinical meaningful health benefits.

Discussion

The aim of this trial was to evaluate the effect of a pragmatic lifestyle modification programme on weight loss in overweight postnatal women with a recent history of GDM. Women randomized to the PAIGE programme lost significantly more weight and had significantly lower BMI after 6 months compared to those women receiving usual care. Overall, attrition rates from this study were 25%, which is in line with other studies in this patient group (33,34).

The PAIGE intervention programme consisted of four elements: a one hour education programme delivered at the time of the early postnatal OGTT, referral to SW, a pedometer and supportive texts and phone calls. This combination is supported in the literature as having

an effect on weight loss in women postpartum (9,35-39). A recent systematic review also concluded that effective interventions are generally composed of dietary and physical activity elements (40). The extent to which each of the individual elements of the intervention group 'menu' contributed to the successful outcome is uncertain. Two thirds of women who completed the SW programme achieved some degree of weight loss, while 42% achieved the target 5% weight loss or more, which is known to translate into clinically meaningful health benefits (31). This is in keeping with a website survey involving 590 members attending SW up to 2 years postnatally which reported that 43% of respondents had reached their pre-pregnancy weight and 41% stated that they were now lighter than before becoming pregnant (41).

In the current study, weight loss was not associated with a significant reduction in plasma glucose levels, which is contrast to some previous studies (42,43), and may relate to study size or our inclusion of subjects with both normal and impaired glucose tolerance. There were no significant differences in psychosocial factors, quality of life and lifestyle, with the exception of significantly reduced bodily pain after 6 months reported by the women assigned to the intervention. Previous evidence in other populations has highlighted the benefit of weight loss interventions on bodily pain and other quality of life indicators (44-46). It is also of note that, despite the control group having significantly higher rates of breast feeding at baseline, the intervention group still lost significantly more weight, possibly reflecting evidence from a recent systematic review challenging the common belief that breastfeeding promotes weight loss (47).

In general, most previous studies have focused on metabolic and anthropometric endpoints individually, while only a small number have both investigated metabolic and anthropometric as well as psychosocial and lifestyle changes. However, the true efficacy of our intervention is not entirely clear, as the number of subjects studied was relatively small due to recruitment

issues. These problems have been reported previously (48) and are a challenge for testing interventions. In addition, more women than anticipated had a BMI within the normal range at their recruitment visit and a significant number also had mental health issues, which excluded them from the study.

The strengths of PAIGE include the randomized controlled study design and the multicomponent nature of the intervention informed by focus groups, targeted to the early postnatal period and delivered in conjunction with a CWMO with an extensive community-based infrastructure. This novel approach has highlighted key issues, which will inform future lifestyle interventions in this population.

Study weaknesses include the well-recognized high rate of non-attendance for routine postnatal OGTT appointments (49). This impacted on recruitment and may also limit generalizability of our study findings and go some way to explaining the relatively high levels of educational attainment and employment among the participants. Additionally, the majority of participants were of white ethnicity, contrasting with the higher risk of GDM in women from ethnic minorities. Data from pedometers was also limited, as women did not continue with these consistently during the study, thus these counts were not seen as a good assessment of compliance to lifestyle change. Finally, even though referral to the CWMO was free, which may not be possible in all circumstances, fewer than half of women attended and completed the course.

This high rate of non-attendance, along with the most recent UK NICE guidelines (12), which recommend that a 75g OTT should not routinely be offered to postnatal women with a history of GDM during pregnancy, has further implications for the best time to recruit women in the postnatal period. Sixty women declined to participate in the study for reasons, which included time constraints, unavailability of childcare, or they did not want to leave their baby. This

highlights the recognized barriers faced by women in the postpartum period regarding participation in a lifestyle intervention (46). All of these factors will need careful consideration in future research.

In conclusion this RCT involving a pragmatic lifestyle modification programme among overweight women with a recent history of GDM delivered in conjunction with the CWMO Slimming World and the NHS resulted in a significant reduction in weight and BMI at 6 months post-partum compared with women randomized to routine care. This novel approach has highlighted key issues, which will inform future lifestyle interventions in this population. Larger definitive trials are now urgently required to confirm the validity of the intervention and importantly to determine if the PAIGE programme is effective in the long term at reducing the risk of type 2 diabetes.

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Conflict of Interest

No potential conflicts of interest relevant to this article were reported. Slimming World kindly provided complimentary referral scheme vouchers for use in this trial, but were not involved in the design or implementation of the research, data collection or analysis of the data.

Author Contributions

DRM, VAH, CRD, BF, MMcC, CP and MD a contributed to the study design; CRD, LF, JI and SFB conducted the research; CRD, VAH, CP, OMcS and ACW contributed to analysis and interpretation of data; VAH, CRD, OMcS, ACW and DRM drafted the article and all authors edited and revised the article.

*****The authors present this study on behalf of a larger team, **The PAIGE study group**:

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Table 1: Baseline characteristics of PAIGE participants (n=60)

	Intervention (n=29)	**Control** (n=31)
Age (years)	34.2 (4.3)	33.2 (5.3)
Weight (kg)	89.6 (16.8)	90.2 (16.4)
BMI (kg/m^2)	34.1 (6.3)	33.6 (5.4)
Waist Circumference (cm)	103.7 (11.2)	105.8 (12.1)
Hip circumference (cm)	116.8 (12.9)	116.2 (11.4)
Fat mass (kg)	39.7 (12.8)	39.1 (11.9)
Fat free mass (kg)	49.9 (5.7)	51.2 (6.5)
White Ethnicity, n (%)	25 (86.0)	26 (84.0)
Employed, n (%)	22 (76.0)	20 (65.0)
Education (years)	17.1 (3.0)	16.3 (3.1)
Married/Co-habiting, n (%)	24 (83.0)	27 (87.0)
Smoker, n (%)	3 (10.0)	4 (13.0)
Parity	2.5 (1.2)	2.3 (1.2)
Primiparous, n (%)	5 (17.0)	8 (26.0)
Breastfeeding, n (%)	7 (24.0)	14 (45.0)
Diet only treatment of GDM in most recent pregnancy, n (%)	8 (28.0)	9 (29.0)
Time since delivery (weeks)*	9.8 (3.2)	9.3 (2.2)
Fasting Plasma Glucose (mmol/l)	5.05 (0.56)	5.15 (0.66)
2h Plasma Glucose post OGTT (mmol/l)	6.09 (1.76)	6.14 (2.28)
Fasting serum Insulin mU/L †	11.7 (6.3 to 19.1)	12.6 (7.7 to 13.9)
2h serum Insulin mU/L ‡	41.1 (18.2 to 56.4)	33.3 (16.9 to 46.4)

HbA1c(mmol/mol) §	35.0 (4.2)	37.4 (4.1)
LDL (mmol/l) ‖	3.0 (0.7)	3.4 (0.9)
HDL (mmol/l) ¶	1.5 (0.4)	1.5 (0.3)
Cholesterol (mmol/l) ¶	5.3 (0.8)	5.6 (1.1)
Triglycerides (mmol/l) ¶	1.4 (0.9 to 2.1)	1.3 (0.7 to 1.6)

OGTT Oral Glucose Tolerance Test. Data are mean (SD), median (interquartile range) or n (%). *Data available on 28 women (intervention) and 31 women (control). †Data available on 29 women (intervention) and 30 women (control). ‡Data available on 15 women (intervention) and 21 women (control). §Data available on 15 women (intervention) and 20 women (control). ||Data available on 23 women (intervention) and 27 women (control). ¶Data available on 24 women (intervention) and 27 women (control).

Table 2: Group differences in anthropometric and blood glucose measurements from baseline to 6-months post-intervention*

	Intervention n=20			**Control n=25**			**Intervention effect~**	
	Baseline	**6-months post-intervention**	**Change**	**Baseline**	**6-months post-intervention**	**Change**	**Estimate (95%CI)**	**P Value (2 tailed)**
Weight (kg) †	91.6 (17.3)	87.7 (17.8)	-3.9 (7.0)	90.6 (16.4)	91.2 (17.8)	0.7(3.9)	-4.5(-8.1;-0.9)	0.02
BMI (kg/m^2) ‡	34.8 (6.7)	33.4 (6.9)	-1.4 (2.7)	33.5 (5.6)	33.8 (6.2)	0.2 (1.4)	-1.6(-3.0;-0.2)	0.03
Waist Circumference (cm) §	106.2 (10.1)	103.3 (12.0)	-2.9 (6.7)	106.8 (13.3)	108.4 (12.4)	1.7 (5.3)	-4.5 (-8.4;-0.7)	0.02
Hip Circumference (cm) §	117.9 (13.8)	115.8 (14.4)	-2.1 (6.3)	115.9 (11.0)	114.9 (10.6)	-1.0 (4.5)	-1.2(-4.7;2.4)	0.51
Fat mass (kg) §	41.0 (12.8)	38.4 (14.5)	-2.6 (7.5)	37.9 (11.5)	38.0 (12.7)	0.1 (5.7)	-2.7 (-6.9;1.6)	0.22

Fat free mass (kg) §	51.5 (4.9)	50.4 (6.9)	-1.0 (6.1)	51.7 (6.9)	51.9 (6.4)	0.1 (5.4)	-1.2 (-4.8;2.5)	0.52
Fasting Plasma Glucose (mmol/l) ‖	5.1 (0.5)	5.3 (0.9)	0.2 (0.5)	5.0 (0.4)	5.1 (0.5)	0.1 (0.4)	0.1 (-0.2;0.4)	0.49
2h Plasma Glucose post OGTT (mmol/l) ¶	5.9 (1.8)	6.3 (2.5)	0.4 (1.8)	5.7 (1.4)	5.6 (0.9)	-0.1 (0.9)	0.5 (-0.4;1.4)	0.27
Fasting serum Insulin (mU/L) #	14.9 (8.1)	15.5 (7.5)	0.6 (4.8)	10.1 (4.1)	14.5 (8.1)	4.4 (7.0)	-1.8 (-6.3;2.7)	0.43

OGTT Oral Glucose Tolerance Test. *Data are mean (standard deviation). †Data available on 20 women (intervention) and 25 women (control). ‡Data available on 20 women (intervention) and 24 women (control). §Data available on 19 women (intervention) and 22 women (control). ‖Data available on 19 women (intervention) and 21 women (control). ¶Data available on 16 women (intervention) and 21 women (control). #Data available on 19 women (intervention) and 20 women (control). ~From independent samples t-test on changes (anthropometric data only) or analysis of covariance of 6 month results with baseline as covariate

Table 3. Results from the SF-12 questionnaire and the Exercise Self-efficacy questionnaire at six months in the intervention and control groups

	Intervention n=20			**Control n=25**			**Intervention effect~**	
	Baseline	**6-months post-intervention**	**Change**	**Baseline**	**6-months post-intervention**	**Change**	**Estimate (95%CI)**	**P Value (2 tailed)**
SF-12								
General health*	51.6 (20.1)	46.1 (21.8)	-5.5 (25.3)	57.5 (23.3)	55.2 (24.6)	-2.3 (22.3)	-6.3 (-19.5; 7.0)	0.35
Mental health†	56.9 (18.8)	55.0 (10.3)	-1.9 (16.4)	60.7 (10.9)	57.1 (12.4)	-3.8 (13.8)	-0.9 (-7.6; 5.8)	0.79
Physical functioning‡	85.0 (22.1)	94.1 (10.2)	9.1 (18.9)	86.4 (21.4)	79.3 (23.0)	-7.0 (22.6)	15.3 (5.1; 25.5)	0.004
Bodily pain§	55.4 (31.3)	5.4 (10.6)	-50.0 (31.0)	57.7 (27.7)	36.5 (37.7)	-21.2 (38.0)	-30.6 (-51.9; -9.3)	0.007
Vitality ‖	45.8 (23.1)	50.0 (21.0)	4.2 (32.4)	51.1 (17.6)	52.2 (21.2)	1.1 (26.6)	-2.2 (-15.9; 11.6)	0.75
Role emotional ¶	84.2 (19.9)	82.2 (22.9)	-2.0 (23.7)	85.3 (21.5)	88.0 (21.1)	2.7 (21.3)	-5.3 (-17.7; 7.2)	0.40
Social functioning¶	86.8 (22.6)	81.6 (27.4)	-5.3 (28.5)	82.6 (23.2)	81.5 (28.4)	-1.1 (33.3)	-1.3 (-18.5;15.9)	0.88

Role physical #	71.7 (23.5)	85.5 (15.7)	13.8 (26.6)	78.0 (25.3)	82.5 (25.5)	4.5 (28.6)	4.6 (-8.5; 17.8)	0.48
Exercise self-efficacy								
Sticking to it #	3.4 (0.8)	3.4 (0.8)	-0.1 (0.6)	3.3 (0.6)	2.9 (0.8)	-0.4 (0.8)	0.4 (0.0; 0.8)	0.07
Making time to exercise #	3.7 (0.7)	3.5 (0.7)	-0.3 (0.9)	3.6 (0.7)	3.3 (0.8)	-0.3 (0.9)	0.1 (-0.3; 0.6)	0.52

Data are mean (SD). *Data available on 19 women (intervention) and 24 women (control). †Data available on 20 women (intervention) and 23 women (control). ‡Data available on 20 women (intervention) and 22 women (control). §Data available on 14 women (intervention) and 13 women (control). ||Data available on 18 women (intervention) and 23 women (control). ¶Data available on 19 women (intervention) and 23 women (control). #Data available on 19 women (intervention) and 25 women (control). ~From analysis of covariance of 6 month results with baseline as covariate.