

Short Report: Care Delivery

A web-based pedometer programme in women with a recent history of gestational diabetes

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Abstract

Aims Women with remote histories of gestational diabetes mellitus can reduce their diabetes risk through lifestyle changes, but the effectiveness of interventions in women with more recent histories of gestational diabetes has not been reported. Therefore, we conducted a pilot study of a low-intensity web-based pedometer programme targeting glucose intolerance among women with recent gestational diabetes.

Methods Women with a gestational diabetes delivery within the past 3 years were randomized to a 13-week intervention consisting of a structured web-based pedometer programme which gave personalized steps-per-week goals, pedometers and education regarding lifestyle modification, or to a letter about diabetes risk reduction and screening after delivery for gestational diabetes (control condition). The main outcome measures were change in fasting plasma glucose and 2-h glucose levels on a 75-g oral glucose tolerance test between baseline and 13-week follow-up. Weight was a secondary outcome and behavioural constructs (self-efficacy, social support, risk perception) were also assessed.

Results Forty-nine women were enrolled. At 13-week follow-up, women randomized to the intervention did not have significant changes in behavioural constructs, physical activity or anthropometrics compared with women in the control group. Changes in fasting plasma glucose (-0.046 mmol/l vs. 0.038 mmol/l, $P = 0.65$), 2-h glucose values (-0.48 mmol/l vs. -0.42 mmol/l, $P = 0.91$) and weight (-0.14 kg vs. -1.5 kg, $P = 0.13$) were similar between the control and intervention groups, respectively.

Conclusions Structured web-based education utilizing pedometers is feasible although uptake may be low. Such programmes may need to be supplemented with additional measures in order to be effective for reduction of diabetes risk.

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Keywords gestational diabetes, internet, intervention, pedometers, physical activity

Introduction

Interventions to improve lifestyle have been shown to reduce the risk of diabetes among adults with glucose intolerance, including women with remote histories of gestational diabetes mellitus [1]. To date, no reports examine whether such interventions can improve glucose levels among women with more recent histories of gestational diabetes. Lifestyle changes may be difficult to implement in this population; women with recent gestational diabetes cite multiple barriers to lifestyle

change, including low perception of risk [2], caregiving for young children and fatigue [3].

Pedometer programmes, particularly those that offer individualized goals, reduce post-challenge glucose levels among adults with impaired glucose tolerance [4]. Such programmes have not been attempted in newly postpartum women, but focus group work has suggested that flexible programmes that address the issues specific to women with young children might address barriers to behaviour change [5]. Therefore, the aim of this pilot study was to examine the feasibility of such a programme and its impact upon behavioural constructs such as self-efficacy, behaviours such as physical activity, anthropometrics, and insulin and glucose levels.

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Patients and methods

Participants

Potential participants were recruited from a university health system, a large non-profit managed care plan, and several private practices in south-eastern Michigan through a combination of targeted mailings and directed referrals from providers (Figure 1). Recipients of targeted mailings had an administrative discharge code (648.8) consistent with a gestational diabetes pregnancy within the past 3 years. The one-page mailings contained the study website address, information regarding gestational diabetes and diabetes risk and recommendations regarding lifestyle modification. On the website, women were asked to confirm their gestational diabetes diagnosis within the past 3 years, lack of a current diagnosis of diabetes or pregnancy, age > 18 years, < 150 min of self-reported physical activity per week and ability to walk, fluency in English, and a working e-mail address and Windows XP or Vista platform. If eligible by the web-based screen, women were then contacted by e-mail and telephone to arrange a baseline face-to-face visit and to confirm that they were at least 6 weeks postpartum. Women were required to have

clearance from their medical provider confirming that they had a gestational diabetes pregnancy within the past 3 years and had no contraindications to participation.

At the baseline visit, women underwent anthropometric testing by study staff blinded to randomization assignment, along with a 75-g oral glucose tolerance test and urine pregnancy testing. Women were excluded from the randomized trial if they had a positive pregnancy test, a fasting glucose value of > 7 mmol/L, a 2-h glucose value > 11.0 mmol/L, or reported current metformin or oral glucocorticoid use. Women were also asked to complete a baseline on-line survey enquiring about medical history and behavioural constructs including self-efficacy for physical activity [6] and weight management [7], as well as perception of risk [8]. At the conclusion of the intervention at 13 weeks, women were asked to undergo repeat anthropometric testing, an oral glucose tolerance test, and on-line surveys, and to rate satisfaction with the intervention. For each visit, women received \$60 to help defray costs of transportation, parking and childcare. Study procedures were approved by the University of Michigan Institutional Review Board.

Randomization was automated and determined by a randomly generated number sequence. Women assigned to the control arm

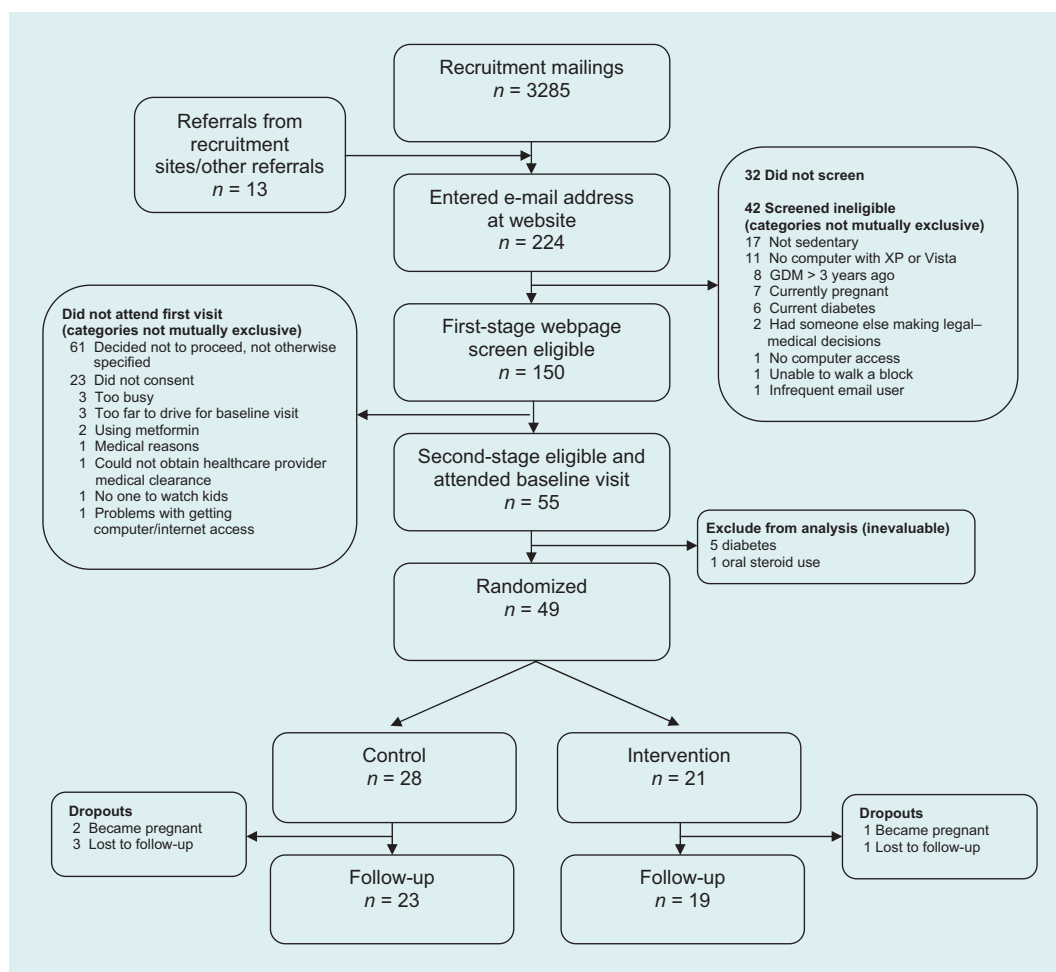


FIGURE 1 Study flow diagram.

were not given any additional materials or information, but at study conclusion received a pedometer and a free subscription to a commercially available web-based walking programme.

Women assigned to the intervention received a 13-week programme that provided web-based education, pedometer messaging, and an internet forum (see Appendix S1) [9]. The intervention curriculum targeted the following domains: perception of diabetes risk; self-efficacy for weight and physical activity; benefits of and barriers to lifestyle change (particularly incorporating tips for mothers with young children); and self-regulatory strategies. The curriculum was displayed on the website and messages changed daily. Women received a study pedometer and instructions to upload weekly to a computer program, which in turn translated pedometer data into individualized step-count goals and progress made towards these goals. This information was delivered through each woman's personal study webpage and via e-mail. Feedback about progress toward goals was displayed graphically and via text messages. All graphs displayed total steps; success or failure in achieving goals was based only on total step counts. Women received credit for any and all walking during the day. Goals were not necessarily monotonically increasing; if a woman had low step counts for one week, the subsequent week's goals would be lower than the goal for the previous week. The maximum allowable goal was 10 000 steps per day. Women were also able to access an on-line message board that allows study participants to interact with each other under a pseudonym.

The main outcome measures were the change in glucose levels between baseline and follow-up between control and intervention women. Change in weight between study arms was a secondary outcome. Owing to the pilot nature of this investigation, we also examined changes in purported mediators such as self-efficacy, risk perception, and physical activity levels. The Michigan Diabetes Research and Training Center Chemistry Core performed glucose assays. Glucose assays used the Cobas Mira Chemistry Analyzer (Roche Diagnostics Corporation, Indianapolis, IN, USA). Intra-assay variabilities were 2% at both 4.6 mmol/l and 15.7 mmol/l. Inter-assay variabilities were 2.9% at 4.6 mmol/l and 2.6% at 15.4 mmol/l. Insulin was measured using a double-antibody radioimmunoassay with a ^{125}I -human insulin tracer (Linco Research, St. Charles, MO, USA). The limit of sensitivity for the assay was 14.6 pmol/l, and inter-assay and intra-assay variabilities were 3.4% and 2.7%, respectively, at 174 pmol/l.

Comparisons between control and intervention women at baseline, at follow-up, and change in outcomes between baseline and 13 weeks were conducted using χ^2 tests and *t*-test procedures. All tests were two-sided. All analyses were conducted using STATA 11.0 (Stata Corp., College Station, TX, USA).

Results

The study recruitment and flow diagram is illustrated in Figure 1. Of the 3285 recruitment mailings and 13 direct referrals

from providers, 49 women (49/3298 or 1.5%) were eventually randomized. Specifically, 224 women who received information regarding the intervention chose to access the website (224/3298 or 6.8%). Of these 224 women, 150 (67%) were eligible at this stage; six women reported having been diagnosed with diabetes and/or being currently pregnant. Of the 150 eligible women, only 55 chose to attend the baseline visit, with the majority of women not citing a specific reason for participating. For the majority of women who received information regarding the intervention, we do not have their reasons for not participating. Of the 74 women for whom we have specific information for not proceeding (those women who chose to take the web-site screening tool), the most common reason for not proceeding was that they were not sedentary.

Characteristics of women by randomization arm are illustrated in Table 1, along with baseline measures for demographics, behavioural constructs, behaviours, anthropometrics, insulin and glucose. There were no significant differences between randomization arms in any of the measured variables at baseline. The population participating was, in general, well-educated and affluent and primarily non-Hispanic white. The majority of women were overweight or obese.

Table 1 notes baseline and follow-up measures for potential mediators of glucose tolerance. In summary, no significant changes from baseline to follow-up were noted in the behavioural constructs or behaviours, particularly physical activity, between study arms. Compared with the control arm, women in the intervention arm had slightly greater declines in weight and insulin resistance, but differences from the control arm were not statistically significant. No changes in point estimates were observed in either fasting or 2-h glucose.

In the intervention group, women uploaded an average number of 1.6 ± 0.64 times per week. Only three women posted on the forum, and these posts were directed at the study team, rather than at other participants. Upon conclusion of their participation, women randomized to the intervention arm noted that they were satisfied with the intervention, while acknowledging that they were unable to institute the activity changes and other recommended behaviours.

Discussion

Women with recent gestational diabetes have a sevenfold increase in risk for diabetes [10], but no reports address risk reduction in this population. Internet interventions have the potential for low cost and high-efficacy, particularly for interventions that involve large populations [11,12]. In a pilot-test of this programme, we found that out of a large potential candidate population, relatively few women who received information about the intervention proceeded to access the website to learn more about the intervention. Of women who did access the website to read about the study, relatively few proceeded to enrolment. We also found that the programme had minimal impact upon behavioural constructs, behaviours or

Table 1 Characteristics of participants at baseline and changes between baseline and follow-up for behavioural constructs, behaviours, anthropometrics, insulin, and glucose. Means \pm standard deviations shown

	Control (<i>n</i> = 28)	Intervention (<i>n</i> = 21)	<i>P</i> -value
Demographics			
Age (years)	35.5 \pm 4.7	35.9 \pm 3.3	0.71
Race/ethnicity (%)			0.89
Non-Hispanic white	68	76	
Asian (Southern and East)	14	10	
African-American	11	10	
Other	7	6	
Education (%)			0.92
High school or less	0	0	
Some university	25	24	
University or more	75	76	
Annual household income (%)			0.39
< \$40 000	16	11	
\$40,000-\$69,999	52	37	
> \$70,000	32	53	
Employed full-time (%)	36	33	0.86
Employed part-time (%)	25	38	0.33
Married or living with partner (%)	93	100	0.21
Child < 8 years in home (%)	100	100	1.0
Months since gestational diabetes mellitus pregnancy	20 \pm 13	14 \pm 9	0.09
Parity (%)			0.78
< = 2	39	48	
3	29	29	
\geq 4	32	24	
Family history of diabetes (%)	50	57	0.40
Behavioural constructs			
Baseline risk perception for diabetes (%)			0.50
Almost no chance of diabetes	4	5	
Slight chance of diabetes	29	14	
Moderate chance of diabetes	43	38	
High chance of diabetes	25	43	
Follow-up risk perception for diabetes (%)			0.56
Almost no chance of diabetes	13	11	
Slight chance of diabetes	35	26	
Moderate chance of diabetes	35	26	
High chance of diabetes	17	37	
Any social support for physical activity at baseline (%)	64	67	0.86
Any social support for physical activity at follow-up (%)	74	84	0.42
Self-efficacy for weight at baseline (range 20–100)*	68.9 \pm 11.4	73.0 \pm 11.5	0.23
Change in self-efficacy for weight from baseline to follow-up†	-0.4 \pm 10.0	2.4 \pm 7.7	0.33
Self-efficacy for physical activity at baseline (range 7–49)*	21.7 \pm 8.1	22.4 \pm 6.5	0.74
Change in self-efficacy for activity from baseline to follow-up†	3.2 \pm 7.1	1.8 \pm 4.8	0.47
Behaviours			
Any physical activity (minutes/week) at baseline (%)			0.61
0	4	0	
Some, but < 60	57	52	
\geq 60	39	48	
Any physical activity (minutes/week) at follow-up (%)			0.25
0	4	5	
Some, but < 60	39	16	
\geq 60	57	79	
Mild physical activity (minutes/week) at baseline (%)			0.26
0	43	29	
Some, but < 60	43	38	
\geq 60	14	33	
Mild physical activity (minutes/week) at follow-up (%)			0.20
0	35	58	
Some, but < 60	39	16	

Table 1 (continued)

	Control (n = 28)	Intervention (n = 21)	P-value
≥60	26	26	
Moderate physical activity (minutes/week) at baseline (%)			0.81
0	50	57	
Some, but < 60	32	24	
≥60	18	19	
Moderate physical activity (minutes/week) at follow-up (%)			0.51
0	52	42	
Some, but < 60	17	11	
≥60	30	47	
Vigorous physical activity (minutes/week) at baseline (%)			0.81
0	50	57	
Some, but < 60	32	24	
≥60	18	19	
Vigorous physical activity (minutes/week) at follow-up (%)			0.65
0	87	89	
Some, but < 60	4	0	
≥60	9	11	
Baseline pedometer steps/week (intervention group only)		5076 ± 1321	
Follow-up pedometer steps/week (intervention group only)		543 ± 2074	
Anthropometrics			
Baseline weight (kg)	82.1 ± 20.1	80.8 ± 18.8	0.81
Change in weight from baseline to follow-up (kg)	-0.1 ± 2.2	-1.5 ± 3.4	0.13
Baseline body mass index (BMI) (kg/m ²)	30.5 ± 7.5	29.8 ± 6.8	0.74
Change in BMI from baseline to follow-up (kg/m ²)	-0.1 ± 0.8	-0.5 ± 1.3	0.16
Baseline waist circumference (cm)	93 ± 14	93 ± 17	0.88
Change in circumference from baseline to follow-up (cm)	1.3 ± 6.7	0.3 ± 5.2	0.62
Insulin and glucose measures			
Log fasting insulin	2.8 ± 0.44	3.1 ± 0.76	0.1
Change in log fasting insulin	0.0 ± 0.4	-0.2 ± 0.4	0.18
Fasting plasma glucose (mmol/l)	5.1 ± 0.7	5.1 ± 0.5	0.95
Change in fasting plasma glucose (mmol/l)	-0.0 ± 0.6	0.0 ± 0.6	0.65
2-Hour glucose (mmol/l)	7.0 ± 2.0	6.8 ± 1.9	0.66
Change in 2-hour glucose (mmol/l)	-0.5 ± 1.6	-0.4 ± 1.8	0.91

*Higher scores indicate greater self-efficacy.

†Positive scores indicate an increase in self-efficacy.

glucose. While favourable trends were observed in weight and insulin levels, differences between arms did not reach the level of statistical significance.

Although explanations are speculative, we may have observed low enrolment rates for several reasons. Internet access may have been a barrier, particularly because women with gestational diabetes tend to have lower socioeconomic status than women without this condition[13]. However, the candidate population for our study had access to care and was insured, and thus may have been more likely to have internet access than other disadvantaged groups. The requirement for a face-to-face visit at baseline and at follow-up, which in turn entailed anthropometrics and oral glucose tolerance tests, may have also decreased interest. However, the most commonly cited reason for not participating was that women perceived that they were actually physically active and thus an intervention aimed primarily at physical activity could have been less appealing.

Tate [14] found that participants in an internet-based weight loss intervention could achieve weight loss with weekly

behavioural weight loss lessons, self-monitoring diaries with individualized therapist feedback and an on-line forum. Yates *et al.* [4] found that individualized pedometer feedback could reduce post-challenge glucose levels, although no changes in weight and fasting glucose were achieved. Neither of these studies focused upon women with recent gestational diabetes. Our intervention included individualized pedometer feedback but did not include therapist contact or diaries, and it is possible that regular contact with an interventionist or more intensive self-monitoring, via the internet or other media, is also needed to change behaviour. Although we expected that these mothers would be more frequent posters to the internet support page than has been previously observed, few women posted to the internet forum; this is consistent with previous research that over 250 participants are optimal to maintain an active on-line community [15,16]. As our study was a pilot study and enrolled a small number of participants, it may be that we would have seen more significant differences in a larger sample. However, the magnitude of change in glucose was extremely small and

suggests that the programme was lacking in effectiveness, rather than the pilot lacking adequate sample size. In addition, no changes in the point estimates of key mediators, such as physical activity, were observed. Based on the mean changes and standard deviations in glucose observed in this pilot study, and assuming that rates of eligibility and uptake were similar to the pilot study, a larger study would have required a recruitment sample exceeding 6000 women to detect a significant change in 2-h glucose between groups.

In conclusion, this pilot test of a pedometer programme via the internet could not demonstrate any clinically meaningful impact on footsteps behaviours, body weight or insulin levels in women with recent gestational diabetes. Moreover, although we demonstrated feasibility, uptake of the intervention was relatively low, which would make dissemination less cost-effective. Supplementing internet interventions with more traditional methods of delivery, such as individualized counselling, with a greater emphasis upon nutritional intake and weight loss, may be more effective and cost-effective.

Competing interests

Nothing to declare.

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Supporting Information

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

Appendix S1. Development of a web-based pedometer programme

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