

Can the onset of type 2 diabetes be delayed by a group-based lifestyle intervention in women with prediabetes following gestational diabetes mellitus (GDM)? Findings from a randomized control mixed methods trial.

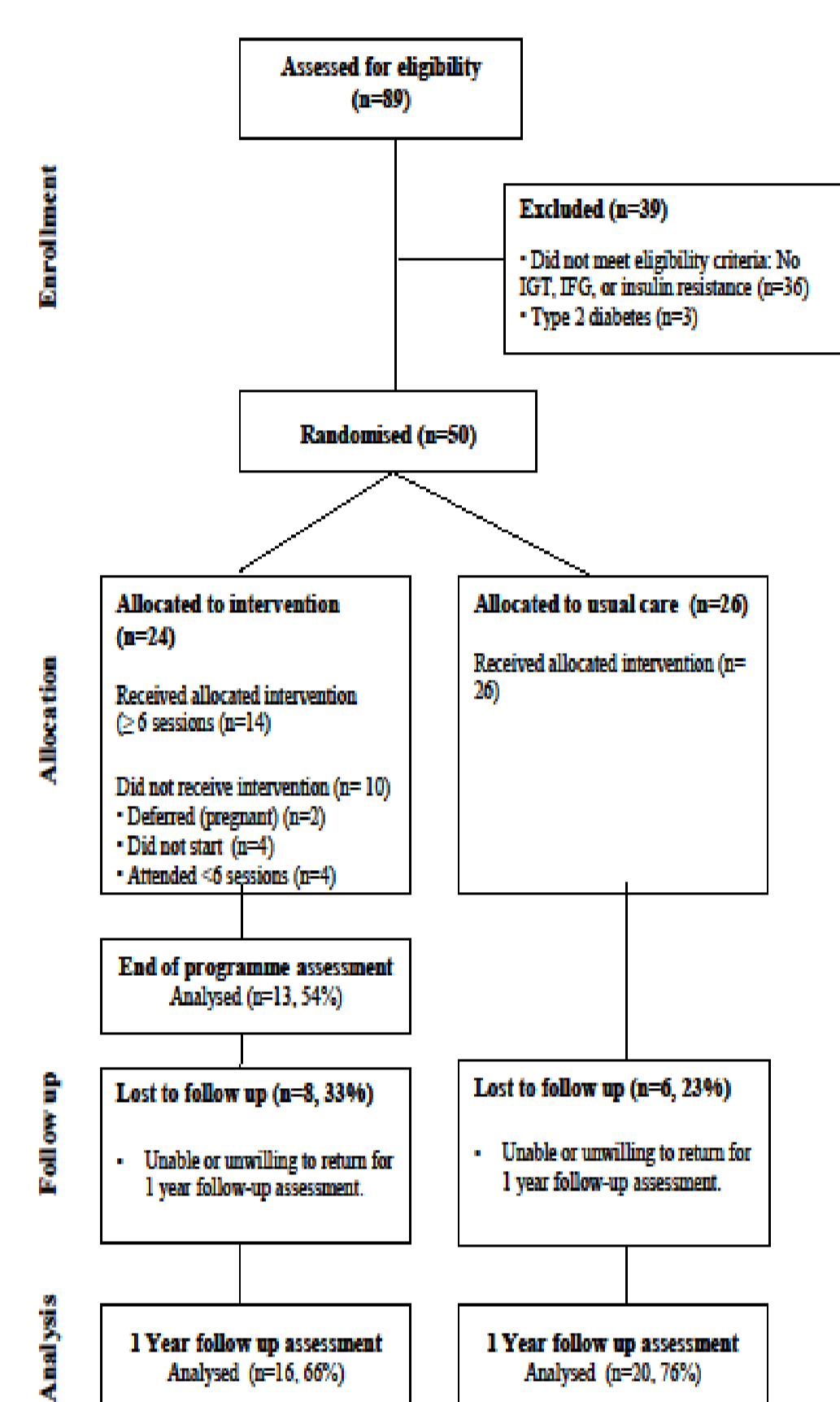
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OBJECTIVES

The aim of this study was to evaluate the effectiveness of a group-based lifestyle intervention programme for reducing the risk factors associated with diabetes in women with pre diabetes following gestational diabetes. We expected that the group based intervention through its educational and supportive approach would enable improvements in psychosocial health, health behaviours, anthropometry and glucose function.

Figure 1. Trial flow Diagram



METHODS

A two-group, mixed methods randomized controlled trial in which 50 women with a history of GDM and abnormal glucose tolerance postpartum were randomly assigned to *MyAction* (n=24) or wait control (n=26). The primary outcome variable was the change in fasting plasma glucose (FPG) from study entry to one-year follow-up. Secondary outcomes were: glucose tolerance (2 hour), insulin resistance, lipid profile, weight, shape, diet and exercise levels. The role of mood, cognition and wellbeing were also explored. Table 1. shows the definitions, measurement techniques and time points for each of the outcomes. Figure 1. shows the flow of participants through the trial.

Table 1. Primary and secondary outcomes and measurement time points

Outcome	Definition and measurement	Timepoint		
		Baseline	End of programme	1 year follow up
Fasting Plasma Glucose (FPG 0- hour)	Reduction in FPG (0-hour) on a 75 gram oral glucose tolerance test (OGTT)	✓		✓
Glucose tolerance (GT2 hour)	Reduction in post-load glucose tolerance (2-hour) blood glucose on a 75 gram OGTT	✓		✓
Insulin resistance (IR)	Reduction in IR as measured by Homeostasis Model Assessment (HOMA2- IR)] on a 75 gram OGTT	✓		✓
Lipid profile	Reduction in triglycerides, LDL and total cholesterol, Improvement in HDL cholesterol.	✓	✓	✓
Diet adherence	Improvement in overall Mediterranean Diet Score	✓	✓	✓
Weight and shape	Reduction in weight (kilograms) Reduction in waist circumference (CM)	✓	✓	✓
Physical activity and fitness	Total exercise per week (frequency x duration) Change in cardiorespiratory fitness (METmax)	✓	✓	✓
Mood	Positive mental health Nonspecific psychological distress Depression, anxiety and stress (DASS-21)	✓		✓
Cognition	Perceived social support Motivation to change: Diabetes-related self-efficacy	✓		✓
Wellbeing	General health Quality of life	✓		✓

RESULTS

Baseline comparison: Mean GT2h was significantly higher for the control than for the intervention group (p=0.025). Randomisation was not successful in ensuring groups were comparable in terms of baseline glycaemic abnormalities.

End of Programme (EOP) analysis: There were significant improvement in weight, BMI, waist circumference, fitness (METmax), total cholesterol, and LDL cholesterol. There was a significant disimprovement in mean HDL cholesterol (p=0.02) and no significant change in mean triglycerides (p=0.54), at EOP.

1 year follow up analysis: There was no evidence of an effect of the intervention on FPG or IR. Analysis of simple differences suggested an effect of the intervention on GT2h however the effect disappeared when adjustments were made for baseline values and multicollinearity between predictors. There were no significant differences in improvement between groups on weight, BMI, waist circumference, diet adherence, physical activity or lipid profile. Significant differences between groups were observed on stress, diet self-efficacy and quality of life with the intervention group improving significantly over the control group. ANCOVA revealed a significant negative effect of depression at baseline on improvement in BMI.

Analysis of completers versus non completers

Intervention completers scored more favourably than non-completers on physical activity, quality of life, motivation to change, and perceived social support from family, at baseline (p<0.05). Binary logistic regression identified two variables as potentially useful predictors of completion: perceived social support from family (p<.0.05) and perceived social support from significant other (p=0.07).

CONCLUSIONS

Women with recent GDM face multiple barriers to participation in lifestyle intervention, and to behaviour change. Optimal approaches for preventative measures must tackle the issue of barriers to participation faced by this population. Home-based interventions via mail, telephone or internet/email may be more feasible and successful. There is a need to develop and test theoretical models of change for psychosocial factors in health outcomes. Strategies for promoting health self-management need to be developed and tested in order to support self-directed behaviour change that will be sustainable in the long term.

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