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**Effect of a low-resource-intensive lifestyle modification program incorporating
gymnasium-based and home-based resistance training on type 2 diabetes risk in
Australian adults**

Running title: Lifestyle modification and type 2 diabetes risk

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3507 words and 2 tables

Abstract**Objectives**

To assess the effectiveness of a low-resource-intensive lifestyle modification program incorporating resistance training (RT), and to compare a gymnasium-based to a home-based RT program, on diabetes diagnostic status and risk.

Research design and methods

A quasi-experimental two-group study was undertaken with 122 participants with diabetes risk factors—36.9% had impaired glucose tolerance (IGT) or impaired fasting glucose (IFG) at Baseline. The intervention included: a 6-week group self-management education program; a gymnasium-based or home-based 12-week resistance training program; and a 34-week maintenance program. Fasting and 2-hour plasma glucose (FPG, 2hrPG), blood lipids, blood pressure, body composition, physical activity and diet were assessed at Baseline and Week 52.

Results

Mean 2hrPG and FPG fell by 0.34 mmol/l (95% CI: -0.60, -0.08) and 0.15 mmol/l (95% CI: -0.23, -0.07) respectively. The proportion of participants with IFG or IGT decreased from 36.9% to 23.0% ($p=0.006$). Mean weight loss was 4.07 kg (95% CI: -4.99, -3.15). The only significant difference between resistance training groups was a greater reduction in systolic blood pressure for the gymnasium-based group ($p=0.008$).

Conclusions

This intervention significantly improved diabetes diagnostic status and reduced diabetes risk to a comparable degree to other low-resource-intensive lifestyle modification programs and more intensive interventions applied to people with IGT. Home-based and gymnasium-based RT did not differ significantly in their effects.

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Introduction

Randomised controlled studies of people with impaired glucose tolerance (IGT) have reported reductions in diabetes incidence in lifestyle modification groups compared to control groups of 42–58% (1, 2, 3). All subjects in these studies had IGT but those with other recognised risk factors such as elevated body mass index (BMI), elevated waist circumference, history of high plasma glucose, physical inactivity and poor diet (4, 5), but without IGT, were excluded. These studies involved considerable intervention efforts including: individualised counseling; tailored physical activity guidance; individual case manager meetings; supervised group exercise; home visits; additional group classes; loans of exercise equipment; exercise club membership; and inter-session support (1, 2, 3, 6), which may not be sustainable in clinical practice (6).

The applicability of these findings needs testing in ‘real-world’ clinical settings using less-resource-intensive interventions (6, 7). Recent studies of the effectiveness of low-resource-intensive lifestyle modification interventions (8, 9) have yielded inconsistent findings. The GOAL study (8) with individuals at risk of type 2 diabetes, but not necessarily with IGT, reported reductions in many diabetes risk factors at 12 months but no beneficial effect on fasting plasma glucose (FPG) or post-load glucose (2hrPG) levels. The Greater Green Triangle study (GGTS), reported significant reductions, for program completers only, in: FPG; 2hrPG; weight; and waist circumference (9). Also, in contrast to the landmark Finnish Diabetes Prevention Study (FDPS), which provided gym memberships for regular resistance training (RT), neither the GOAL study nor the

GGTS included structured RT. This is important, as RT has been shown to reduce plasma glucose levels in people with IGT (10) and type 2 diabetes (11).

Previously effective interventions (1, 2, 3, 8, 9) were based in clinical settings, which may reduce access for socio-economically disadvantaged or geographically isolated groups, both of which have a relatively high risk of diabetes (12). Home-based interventions with appropriate professional support could address these barriers (12).

The primary goal of the Ballarat Diabetes Prevention Pilot Initiative (BDPPI) was to assess the effectiveness of a low-resource-intensive lifestyle modification program incorporating RT on diabetes diagnostic status and risk, in individuals at elevated risk of diabetes (but not necessarily with IGT). The secondary goal was to compare the effectiveness of gymnasium-based and home-based RT programs.

Research Design and Methods

The BDPPI methodology was based on National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus developed by the Australian National Health & Medical Research Council (NHMRC) (7). When the NHMRC guidelines provided only general guidance, other appropriate methods and targets were adopted (14, 15, 16). University and health service human research ethics committees approved the study.

Participants, location and study design

One hundred and twenty two adults were recruited from the regional city of Ballarat (population 86,977) in the state of Victoria, Australia. The 52-week BDPPI used a quasi-experimental two-group repeated measures design.

Recruitment and eligibility

Participants were recruited through a media campaign and promotional materials distributed in socio-economically disadvantaged localities. Primary health care professionals were encouraged to refer eligible participants.

Eligibility criteria were based on the NHMRC guidelines on diabetes case detection and diagnosis (7), and included: people with IGT or Impaired Fasting Glucose (IFG); Aboriginal or Torres Strait Islanders aged ≥ 35 ; people from the Pacific Islands, Indian subcontinent or of Chinese origin aged ≥ 35 ; people aged ≥ 45 who were either obese (BMI $\geq 30\text{kg/m}^2$) or hypertensive or both; people with clinical cardiovascular disease (myocardial infarction, angina or stroke); obese women with polycystic ovary syndrome; women with previous gestational diabetes; people aged ≥ 55 ; and people aged ≥ 45 who had a first degree relative with type 2 diabetes (7). Participants with medically unstable conditions; uncorrected visual or hearing impairment; or unable to attend regularly were excluded.

Intervention

Consistent with previous diabetes prevention trials (1, 2, 9), the 12-month intervention had participant goals of: loss of $>5\%$ of body weight; ≥ 150 weighted minutes and ≥ 5

sessions of at least moderate physical activity each week (in addition to the RT program); and a diet with a fat content <30% and saturated fat content <10%, of total energy intake.

Self-management education program (Weeks 1–6)

The intervention started with six, 1.5-hour group education sessions, conducted in a regional, clinical outpatient facility. This program used self-management principles (17) to develop participant problem-solving, decision-making, self-monitoring, goal-setting, and thought/emotion management skills (17, 18). Motivational interviewing components (e.g. decisional balance and motivational scaling) were also used to strengthen commitment to change (19). This program was group-based, consistent with self-management principles which propose that modeling and social persuasion can enhance self-efficacy, and therefore the capacity of individuals to maintain behaviour change (17).

Sessions included physical activity and dietary components prepared and presented jointly by a dietitian, a psychologist and an exercise therapist to groups of 15–20.

Following the Australian National Physical Activity Guidelines (15), the aerobic physical activity component of the program focused on encouraging participants to achieve ≥ 5 sessions and ≥ 150 weighted minutes per week of physical activity of at least moderate intensity. The dietary component was based on the principles of the Commonwealth Scientific and Industrial Research Organisation's Total Well Being Diet (16).

Participants were provided with a booklet describing the diet and tools to use to promote

compliance with the diet. Strategies to assist participants to achieve the nutrition recommendations included food label reading, meal planning and recipe modification.

(See Online Appendix Table A)

Resistance training programs (Weeks 7–18)

Participants were allocated to either a gymnasium-based or home-based, 12-week RT program after the self-management education program. For convenience, family members were allocated to the same RT setting. Allocation of individuals/families to RT settings was randomised. Participants were advised to do at least two, but ideally three, RT sessions per week and to achieve the aerobic physical activity goals for the BDPPI.

The gymnasium-based RT program was conducted in the clinical outpatient facility of a hospital and was informed by the protocol of Dunstan and colleagues (11), consisting of 45 minutes of high-intensity RT and five minutes each of low-intensity aerobic warm-up and cool-down and stretching exercises. The program used eight exercise stations, each focused on selected major muscle groups. One repetition maximum (1RM) chest and leg press tests were conducted during Weeks 7–8 to determine training load. The program was offered up to 12 times per week; the average staff to participant ratio was 1 to 15.

During Weeks 7–10, gymnasium-based participants increased their workload to three sets of 10 repetitions, at 60% 1RM or Rating of Perceived Exertion (RPE) (20) 3–6. In Weeks 11–14, participants progressed to four sets of 10 repetitions, at 75–85% 1RM or

RPE 7–9. During Weeks 15–18, participants increased the weight lifted as tolerated and were encouraged to achieve four sets of 10 repetitions at 85% 1RM. Participants rested for up to 30 seconds between sets. On-going progress review was provided. During Weeks 16–18, participants planned their post-program aerobic and RT activities.

In the home-based program, RT was made comparable to the gymnasium-based program through the careful selection of exercises and exercise progressions, using body weight exercises and conveniently available hand-held weights (e.g. cans of food, weighing approximately 500g). During Weeks 7–12, home-based participants progressed to four sets of 10 repetitions with RPE 3–6. During Weeks 13–18, Theraband® and Swiss Ball® exercises were introduced. Participants attempted these more challenging exercises when their existing exercise RPE was <5. Home-based participants were telephoned in Week 8 (exercise therapist), Week 10 (dietitian), and Week 15 (psychologist) to review progress. They also attended a two-hour review in Week 12.

Maintenance program (Weeks 19–52).

The intervention included a 34-week maintenance program. Participants were encouraged to continue the recommended regimen and to attend three two-hour group reinforcement sessions. They were also sent two newsletters containing self-management, healthy eating and physical activity advice. (See Online Appendix Table

B)

Assessment tools

Assessments were conducted at Baseline (Week 1) and Week 52 using the following tools. Intermediate assessments of all but the plasma glucose and dietary indicators were also conducted at Week 6 and/or Week 18.

Plasma glucose

FPG and 2hrPG levels were determined through a standard 75g oral glucose tolerance test (OGTT). Samples were analysed using standard laboratory methods in two nationally accredited laboratories.

Cardiovascular disease indicators

Blood pressure and blood lipids were assessed using standard laboratory methods in two nationally accredited laboratories.

Body composition measures

Height (cm); weight (kg) using electronic scales (Transcell Technology® T1500); BMI (kg/m^2); waist circumference (cm) using non-elastic measuring tape at the mid-point between the lower border of the rib cage and iliac crest.

Physical activity measures

Questionnaire-based self-report of sessions/week and weighted minutes/week (15).

Dietary measures

Food Frequency Questionnaire including: total energy intake (kJ/day); total fat (%); saturated fat (%); and fibre (g) (21).

Diabetes status

Following the NHMRC guidelines (7), diabetes classification was based on FPG and 2hrPG, with one variation: all but four BDPPI participants were administered the OGTT regardless of their FPG (according to the NHMRC guidelines this is done only if $FPG \geq 5.5$ mmol/l). Consequently, 19 participants with $FPG < 5.5$ mmol/l, who would have been classified as “Diabetes Unlikely” according to the NHMRC guidelines, were classified as having IGT on the basis of the measured 2hrPG. The categories and respective criteria (in mmol/l) used in the BDPPI were *Diabetes Unlikely* ($FPG < 5.5$ and 2hrPG unknown, or $FPG < 6.1$ and $2hrPG < 7.8$); *IFG* ($6.1 \leq FPG \leq 6.9$ and $2hrPG < 7.8$); *IGT* ($FPG \leq 6.9$ and $7.8 \leq 2hrPG \leq 11.0$); and *Diabetes* ($FPG \geq 7.0$ or $2hrPG \geq 11.1$).

Statistical design and analysis

The recruitment target was set at 128. Assuming a SD of 2.0 mmol/l (2), with a two-sided significance level of 0.05 this provided power of 0.80 for detecting a mean change of 0.5 mmol/l in 2hrPG from Baseline—Post-intervention,, representing an effect size of 0.25, and power of 0.80 for detecting a difference of 1.0 mmol/l in the mean change in 2hrPG between two RT settings (each $n=64$), representing an effect size of 0.5.

Baseline—Post-intervention changes in key indicators were tested using repeated measures ANOVAs. RT group differences were tested using independent samples t-

tests at Baseline and for Baseline—Post-intervention changes. Changes in proportions were tested using McNemar-Bowker chi-square tests. Differences between proportions in RT groups were tested using Pearson chi-square tests.

The basis of the analysis was intention to treat (ITT). The designated post-intervention data collection point was Week 52. In cases where no Week 52 data were available (lost to follow-up), the last available data were carried forward. The extent to which this was done is indicated in the compliance and adherence section of the results.

Results

Baseline participant characteristics

One hundred and twenty two participants (78% female) with a mean age of 52.6 years (SD 8.6) commenced the program. Participants had completed a mean of 13.6 years (SD 2.9) of full-time education and had occupational classifications of: managers and administrators (7.3%) professionals and associate professionals (51.1%); and trades/clerical and other (41.6%)(22).

The mean diabetes risk score (DRS) of participants was 16.0 (SD 3.5, n=122), equating to a one in three chance of developing type 2 diabetes during the following 10 years (5).

The Baseline FPG and 2hrPG classified: 63.1% of the participants as being Diabetes Unlikely; 4.9% as having IFG; and 32.0% as having IGT (n=122). One person with diabetes was referred to a diabetes education program and excluded from the study.

Changes in the key measures

Table 1 shows the mean changes in the key measures of interest from Baseline—Post intervention. For 2hrPG and FPG, results are also shown for participants with and without IGT at baseline. As a consequence of the real-world setting, not all baseline measurements were obtained for all participants, and so even with baseline data being carried forward in the ITT analysis, the full sample size of n=122 was not achieved for all measures.

Insert Table 1 about here

Changes in proportions of participants in key clinical categories

Table 2 shows the proportions of participants who achieved clinically significant targets or fell into particular clinical categories at Baseline and Post-intervention. Key changes included significant reductions in the proportion of participants who were: IFG or IGT; obese Class II or III; insufficiently physically active; and hypertensive. There were also significant increases in the proportions who met body composition and dietary goals.

Insert Table 2 about here

Resistance training groups

The two RT groups were: gymnasium-based (n=62) and home-based (n=60). The only statistically significant difference between RT groups was in systolic blood pressure, which was reduced significantly more for gymnasium-based than home-based participants (mean changes: -13.98, -7.07; p=0.046). For all key variables except HDL-

cholesterol, the difference between the mean change scores of the two RT groups was smaller in magnitude than (and in most cases <50% of) the mean change from baseline to post-intervention. Furthermore, the differences were not all in the same direction.

For 14 of the 18 key variables the gymnasium-based group achieved better results than the home-based group, and the reverse occurred for four variables, including one of the primary outcome measures (FBG). (See Online Appendix Table C.) There were no statistically significant differences between the RT groups with regard to key clinical targets or categories at either baseline or post-intervention. (See Online Appendix Table D.)

Compliance and Adherence

Program adherence was assessed by proxy, on the basis of compliance with participation in clinical measurements and completion of questionnaires at Week 52. Of 122 participants at Baseline, 98 (80.3%) participated in clinical assessments at Week 52 and 84 (68.9%) completed questionnaires ($p < 0.001$). This difference in clinical and questionnaire compliance rates may have been due to participants having greater personal responsibility for completion and return of questionnaires, and hence a lower level of compliance. The clinical compliance rate is considered more indicative than the questionnaire compliance rate of adherence to the program per se. There were no significant differences between compliers and non-compliers in key measures at Baseline.

There were significant differences between gymnasium-based and home-based RT groups in clinical (55; 88.7% of n=62 v 43; 71.7% of n=60; p=0.016) and questionnaire (48; 77.4% of n=62 v 36; 60.0% of n=60; p=0.030) compliance. These differences in compliance may have been greater than the actual differences in adherence to the intervention. This is because the gymnasium-based group may have been more willing to attend the facility for measurement purposes than the home-based group, as they were more familiar with the facility and program staff. Assuming “positive” (i.e. beneficial) changes in key measures in both RT groups, this differential compliance is also likely to bias the ITT-based comparisons between RT groups in favour of the gymnasium-based group. This is because calculated mean changes will be more attenuated for the home-based group than for the gymnasium-based group, because of the higher proportion of baseline data being carried forward in the case of the home-based group.

Discussion

Given the previous inconsistency of findings about the effect of low-resource-intensive lifestyle modification diabetes preventions on diabetes risk among those already at elevated diabetes risk (8, 9), the findings of the BDPPi study should provide practitioners with greater confidence in offering such programs in real-world clinical settings. These findings also support those of previous randomized controlled studies that were more resource-intensive (1, 2, 3).

The methodology used in the BDPPI was substantially informed by the FDPS (2) and was similar to that used in the GGTS (9). However, there were several important differences between the BDPPI and the FDPS or the GGTS. Firstly, the baseline diabetes status of BDPPI and FDPS participants differed (FDPS: all had IGT, BDPPI: 32.0% had IGT and 4.9% had IFG). Secondly, fewer intervention resources were used for the BDPPI than were used for the FDPS. When compared to the GGTS, although both studies included six, structured 90 minute group sessions, the BDPPI sessions were conducted over six weeks compared to the GGTS program of five sessions within the first three months and the sixth session at eight months. In addition, both the BDPPI and the FDPS included RT and the BDPPI incorporated a three-session and two newsletter maintenance program. Statistical analyses were based on ITT for BDPPI, and on completers for FDPS and GGTS.

Methodological differences aside, the BDPPI, the FDPS (2) and the GGTS (9) all reported significant decreases in mean FPG (BDPPI 0.15 mmol/l (all participants), 0.19 mmol/l (participants with IGT at baseline); FDPS 0.22 mmol/l; GGTS 0.14 mmol/l) and mean 2hrPG (BDPPI 0.34 mmol/l (all participants), 0.94 mmol/l (participants with IGT at baseline); FDPS 0.84 mmol/l; GGTS 0.58 mmol/l). The confidence intervals for the changes in both measures in the BDPPI (Table 1), the FDPS (2) and the GGTS (9), suggest that there were no significant differences between the plasma glucose concentration outcomes achieved in participants with IGT in the three studies over a similar 12-month period.

In addition, all three studies demonstrated significant reductions in mean values of body weight, BMI, and waist circumference (2, 9, 23). The published means suggest that the changes achieved in mean body weight and BMI were considerably greater for BDPPI participants (4.2% in each case) than for GGTS participants (2.7% and 2.8% respectively) (9).

With one exception (systolic blood pressure), the changes measured in the two RT groups did not exhibit statistically significant differences. Whilst it is acknowledged that the power to detect a difference between the two groups was limited, for most key variables, the differences between the changes in the two groups were considerably smaller in magnitude than the overall change from baseline to post-intervention, and the group differences were not consistently in one direction. This lack of substantial differences in outcomes suggests that home-based participation has a similar effect to gymnasium-based participation in reducing diabetes risk. This is encouraging for anyone unwilling or unable to attend gymnasium-based programs and for service providers without the capacity to offer gymnasium-based programs. These results support those reported by King and colleagues (13), who found that home-based older adult exercise training participants achieved similar improvement in treadmill exercise test performance when compared to community-facility-based participants. However, the BDPPI home-based participants displayed lower compliance levels than the gymnasium-based participants. This contrasts with the findings of King et al (13) that home-based exercise training participants had better twelve-month adherence rates when compared to the community-facility-based participants, and suggests that the

home-based BDPPI participants did not receive sufficient on-going support to maximise adherence.

The BDPPI results are potentially important within a broader public health context. As well as reducing diabetes risk, the intervention had a positive impact on a range of clinical indicators pertaining to obesity and cardiovascular disease. These results have implications for other aspects of public health, above and beyond the demonstrated reduction in diabetes risk.

As with other studies (9, 24), a “no treatment” control was not included in the BDPPI study design. It was considered inappropriate to do so given existing evidence that lifestyle modifications effectively reduce diabetes risk (1, 2, 3, 9). Rather, a novel treatment (home-based RT) was compared to traditional treatment (gymnasium-based RT). However, it should be noted that changes in the proportions of BDPPI participants in some key diabetes risk categories were counter to Australian population trends reported for a similar period. From 1999/2000–2004/05, the incidence of obesity (BMI ≥ 30 kg/m²) in Australia increased by 1.9% per year (95% CI: 1.8, 2.1) and the incidence of hypertension increased by 3.0% per year (95% CI: 2.8, 3.2) (25). Clearly, the decreases in obesity and hypertension among BDPPI participants were substantially different to these Australian community trends. In addition, the proportion of BDPPI participants who undertook sufficient physical activity rose from 29.3% to 55.2% and was counter to the trend for the Australian adult population aged 45–59 from 1997–

2000 which saw the proportion of individuals undertaking sufficient physical activity decrease from 53.8% to 49.7% (15).

The study design did not enable a test of the relative contributions of different intervention components (self-management education, dietary change, physical activity change, weight loss etc) to the reduction in diabetes risk. Furthermore, it is acknowledged that the findings of this study are only directly applicable to the Australian health care system, and that people with low socio-economic position were under-represented. Nevertheless, the underlying principles of reducing costs and improving access by providing less-resource-intensive lifestyle modification diabetes prevention programs incorporating group-based self-management education and home-based RT are widely generalisable.

It is also acknowledged that the use of carried forward data in the ITT analysis assumes no further change after the last observation. This may result in an under- or over-estimate of the true outcome, depending on the subsequent unobserved behaviour of the non-complier. A non-complier may have either adhered or not adhered to the intervention program and either improved or worsened their profile.

The BDPPI findings regarding the effectiveness of home-based RT settings may lead to the provision of less-resource-intensive, and therefore more cost-effective (24) diabetes prevention interventions. They also offer the potential to overcome some of the access barriers (dislike of gymnasiums, cost, transport etc) for participants, particularly those

with limited financial resources or who are geographically isolated, by enabling home-based participation using relatively inexpensive equipment. However, future similar programs should implement and evaluate strategies to improve adherence among home-based participants.

This low-resource-intensive group program, conducted in a 'real life' setting and focused upon the development of self-management skills to improve participants' capacity to engage in evidence-based nutrition and physical activity (walking plus resistance training) programs, reduced diabetes risk. Further, there was no evidence that supervised RT offered greater benefits than those achieved in home-based programs. This finding may increase the access of individuals at risk of diabetes to effective risk reduction programs.

Acknowledgements

The authors acknowledge the contributions of the Project Advisory Committee together with those who provided endorsement of, and assistance to develop and implement, the study. We thank the two anonymous reviewers for their perceptive and helpful comments. The Australian Government Department of Health and Aging, Canberra, funded this study.

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Table 1: Changes in key measures

Measure	n*	Week	Mean	St Dev	Change from baseline	95% CI for change in the mean	p-value
Plasma glucose							
All participants							
FPG (mmol/l)	122	Baseline	5.30	0.52			
		Post-intervention	5.15	0.58	-0.15	(-0.23, -0.07)	0.001
2hrPG (mmol/l)	118	Baseline	6.73	1.75			
		Post-intervention	6.39	1.83	-0.34	(-0.60, -0.08)	0.011
Participants with IGT at baseline							
FPG (mmol/l)	39	Baseline	5.52	0.55			
		Post-intervention	5.33	0.65	-0.19	(-0.39, 0.01)	0.063
2hrPG (mmol/l)	39	Baseline	8.82	0.85			
		Post-intervention	7.88	1.79	-0.94	(-1.46, -0.42)	0.001
Participants without IGT at baseline							
FPG (mmol/l)	83	Baseline	5.20	0.47			
		Post-intervention	5.07	0.53	-0.13	(-0.22, -0.05)	0.003
2hrPG (mmol/l)	79	Baseline	5.70	0.98			
		Post-intervention	5.66	1.35	-0.04	(-0.32, 0.23)	0.763
Cardiovascular							
Systolic Blood Pressure (mm Hg)	119	Baseline	148.21	22.82			
		Post-intervention	137.72	19.42	-10.50	(-13.94, -7.05)	<0.001
Diastolic Blood Pressure (mm Hg)	119	Baseline	82.12	11.85			
		Post-intervention	78.09	11.04	-4.03	(-5.92, -2.15)	<0.001
Total cholesterol (mmol/l)	120	Baseline	5.53	1.09			
		Post-intervention	5.30	1.03	-0.23	(-0.36, -0.10)	0.001
Triglycerides (mmol/l)	120	Baseline	1.74	0.83			
		Post-intervention	1.58	0.75	-0.17	(-0.28, -0.05)	0.004
HDL-cholesterol (mmol/l)	101	Baseline	1.32	0.35			
		Post-intervention	1.34	0.35	0.02	(-0.03, 0.06)	0.422
LDL-cholesterol (mmol/l)	98	Baseline	3.44	0.97			
		Post-intervention	3.23	0.93	-0.21	(-0.36, -0.06)	0.005

Measure	n*	Week	Mean	St Dev	Change from baseline	95% CI for change in the mean	p-value
Chol:HDL ratio	100	Baseline	4.40	1.22			
		Post-intervention	4.20	1.26	-0.21	(-0.34, -0.07)	0.003
Body composition							
Weight (kg)	122	Baseline	96.19	21.11			
		Post-intervention	92.12	21.71	-4.07	(-4.99, -3.15)	<0.001
BMI (kg/m ²)	122	Baseline	35.03	6.80			
		Post-intervention	33.57	7.13	-1.46	(-1.81, -1.11)	<0.001
Waist circumference (cm)	120	Baseline	109.76	15.02			
		Post-intervention	105.08	16.05	-4.68	(-5.89, -3.47)	<0.001
Physical activity							
Physical activity (sessions/wk)	116	Baseline	4.65	3.85			
		Post-intervention	7.73	11.33	3.09	(0.98, 5.19)	0.004
Physical activity (weighted min/wk)	116	Baseline	253.10	297.196			
		Post-intervention	334.98	314.36	81.88	(22.93, 140.83)	0.007
Dietary							
Total energy intake (kJ/day)	121	Baseline	8987	4457			
		Post-intervention	7929	4037	-1057	(-1570, -544)	<0.001
Total fat (%)	121	Baseline	35.54	4.78			
		Post-intervention	33.41	5.44	-2.13	(-2.96, -1.30)	<0.001
Saturated fat (%)	121	Baseline	14.08	2.75			
		Post-intervention	12.65	2.83	-1.43	(-1.88, -0.97)	<0.001
Fibre (g)	121	Baseline	25.17	10.97			
		Post-intervention	24.91	9.42	-0.25	(-1.72, 1.21)	0.732

* Intention to treat analysis. "Post-intervention" values were from Week 52 wherever available. Otherwise, the last available data (Week 18, Week 6 or Baseline) were used. Sample sizes <122 indicate that data were not collected for all participants at baseline.

Table 2: Changes in proportions of participants in key clinical categories

	n*	Proportions		
		Baseline %	Post- intervention %	p-value
Diabetes diagnostic status	122			0.006
Diabetes unlikely		63.1	77.0	
Impaired fasting glucose (IFG)		4.9	1.6	
Impaired glucose tolerance (IGT)		32.0	20.5	
Diabetes		0.0	0.8	
Body Mass Index Criteria	122			<0.001
Normal (18.5–24.9)		4.1	9.8	
Overweight (25.0–29.9)		18.0	22.1	
Obesity Class I (30.0–34.9)		32.8	34.4	
Obesity Class II (35.0–39.9)		24.6	17.2	
Obesity Class III (>40)		20.5	16.4	
Weight decreased by at least 5%	122	—†	39.3‡	—†
Waist circumference \leq 100 cm (M) or \leq 90 cm (F)	120	9.2	20.8	<0.001
Physical activity (\geq 5 sessions/wk and \geq 150 weighted min/wk)	116	29.3	55.2	<0.001
Hypertensive (SBP \geq 140 or DBP \geq 90 or BP medication)	117	75.2	65.8	0.007
All fat (<30% of total energy intake)	121	11.6	20.7	0.003
Saturated fat (<10% of total energy intake)	121	5.0	18.2	<0.001

* Intention to treat analysis. Post-intervention values were from Week 52 wherever available. Otherwise, the last available data (Week 18, Week 6 or Baseline) were used. Sample sizes <122 indicate that data were not collected for all participants at baseline.

† The weight target was framed, not in absolute terms, but in terms of a decrease from the baseline weight. Hence there was no baseline proportion with which to compare the proportion who achieved the target post-intervention. Instead, a confidence interval is provided for the proportion post-intervention.

‡ 95% confidence interval: 30.5%–47.7%