Original Article

Sustainability of lifestyle changes following an intensive lifestyle intervention in insulin resistant adults: follow-up at 2-years

Kelly S Dale PhD[1], Jim I Mann PhD[1, 2], Kirsten A McAuley PhD[1, 2], Sheila M Williams DSc[3] and Victoria L Farmer MSc[2]

[1]*Department of Human Nutrition, University of Otago, Dunedin, New Zealand*
[2]*Edgar National Centre for Diabetes Research, University of Otago, Dunedin, New Zealand*
[3]*Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand.*

The objective of this study was to determine whether overweight insulin resistant individuals who lost weight and improved cardiovascular risk factors during a 4-month lifestyle intervention could sustain these lifestyle changes in the long-term. Seventy-nine insulin resistant adults were randomised to a control group or either a modest or intensive lifestyle intervention group for 4-months. Thereafter the two intervention groups were combined and all participants were followed-up at 8, 12 and 24 months. Anthropometry, blood pressure, fasting glucose, lipids, insulin and aerobic fitness were measured and dietary intake was assessed. An interview was conducted to determine factors which participants perceived facilitated or hindered maintenance of healthy lifestyle habits. Seventy-two (91.1%), sixty-nine (87.3%) and sixty-two (78.5%) participants were retained at 8, 12 and 24-month respectively. At 4-months the adjusted difference in weight between the modest and control groups was -3.4 kg (95% CI -5.4, -1.3) *p*=0.002 and intensive and control groups was -4.7 kg (-6.9, -2.4) *p*=0.0001 respectively. At 2-years there were no significant differences for weight when the initial 3 groups were compared or when the combined intervention group was compared with the control group. At 2-years, 64% of participants reported that more frequent follow-up would have helped them to maintain healthy lifestyle habits. Even intensive counselling for 4-months with 4-monthly and then yearly monitoring were not enough for maintaining lifestyle changes sufficient to sustain weight loss. More frequent monitoring for an indefinite period was perceived by two-thirds of participants as necessary for them to maintain their initial lifestyle changes.

Key Words: Weight maintenance, insulin resistance, obesity, diet, physical activity

INTRODUCTION

The epidemic increase in obesity and type 2 diabetes in New Zealand and throughout the world has lead to considerable attention being focused on the treatment of obesity and the prevention of diabetes and other comorbidities. The consequences of obesity represent an enormous cost to society in terms of treating the adverse health outcomes and lost years of working life, and to the individual in terms of reduced quality of life, increased risk of illness and potential reduction of income. Obesity is the leading cause of the increase in the prevalence of type 2 diabetes which accounts for over 40% of those starting dialysis for end stage renal disease.[1, 2] Even in the absence of type 2 diabetes, obesity is associated with reduced insulin sensitivity and altered glucose and lipid metabolism and this constellation of abnormalities constituting the metabolic syndrome is now a leading cause of cardiovascular disease.[3]

Many lifestyle interventions that incorporate a combination of dietary, physical activity and behaviour modification approaches have reported reasonable short term success during the intervention period in terms of reduced weight, improved biochemical variables and improved fitness.[4-10] However, of greater importance is the issue of sustaining these lifestyle changes in the long term to maintain a lower body weight and reduced risk of developing diabetes and other comorbidities. Most studies suggest that weight loss is not maintained in the long term.[7, 11-13] Two of the most successful lifestyle interventions are the Finnish Diabetes Prevention Study (DPS) and the American Diabetes Prevention Program (DPP) which intensively modified physical activity behaviours and eating habits in people with impaired glucose tolerance.[9, 10] By three years, both lifestyle interventions reduced the conversion from impaired glucose to type 2 diabetes by 58% in association with maintained weight loss. The enormous costs involved with implementing these life

Corresponding Author: Dr Kelly S Dale, Department of Women's and Children's Health, University of Otago, PO Box 913, Dunedin, New Zealand.
Tel: + 64 3 470 3850; Fax: + 64 3 474 7817
Email: kelly.dale@otago.ac.nz; kswhiteford@hotmail.com

style interventions due to the frequent and intensive long term follow-up and support of participants however has prevented the universal adoption of these approaches. [14, 15]

We achieved modest weight loss and improvement in insulin sensitivity after four months of fairly intensive intervention in normoglycaemic insulin resistant individuals.[16] The purpose of this study was to determine whether the intensive education and support provided over 4 months produced sustained lifestyle changes and maintenance of weight loss and if not to determine the reason for failure.

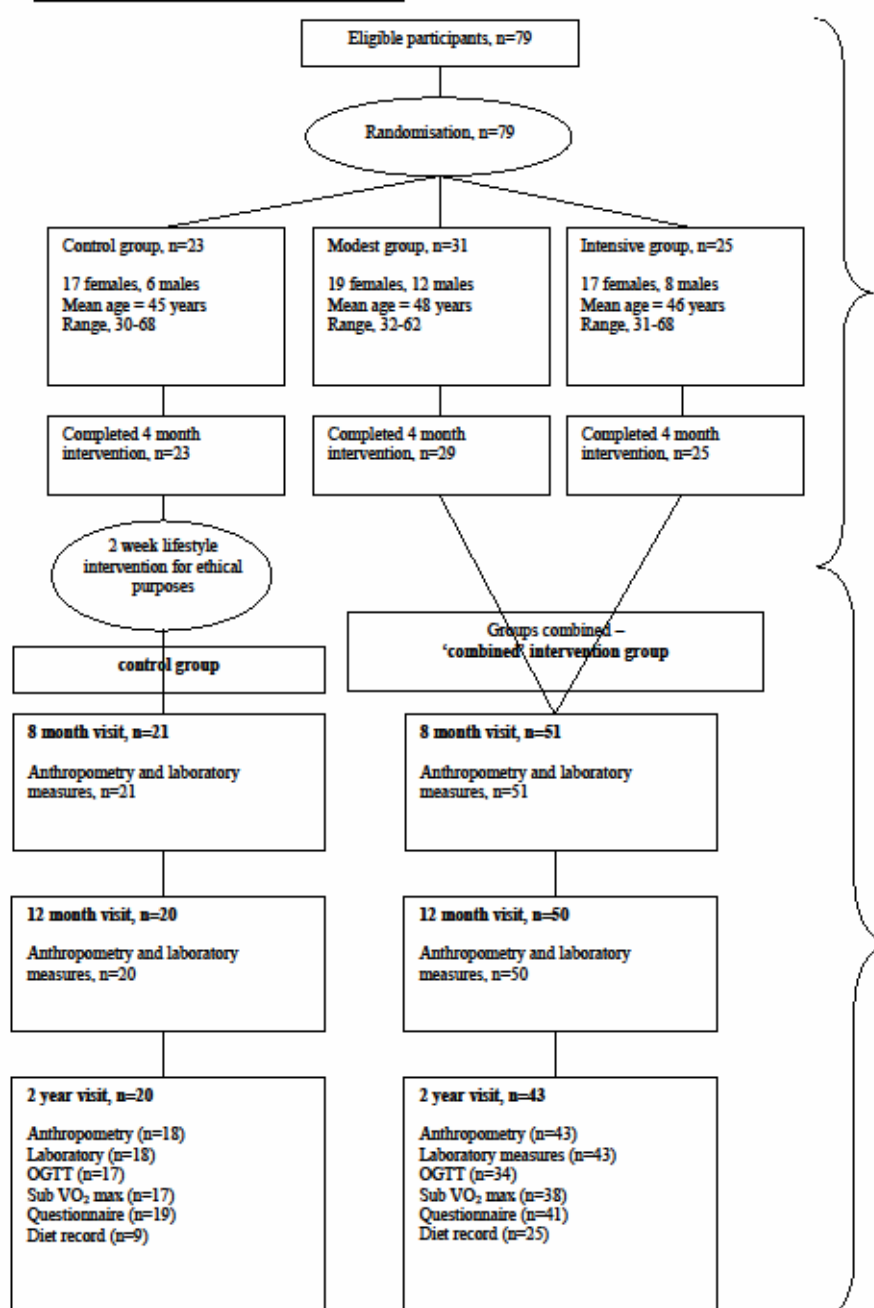## MATERIALS AND METHODS
Participants and study design
The participants, study design and exercise and dietary interventions examined in this follow-up study have previously been described.[16] In brief, 79 normoglycaemic insulin resistant (as determined by euglycaemic insulin clamp) Caucasian men and women were randomised to one of three groups: a control group, a 'modest' intervention group or an 'intensive' intervention group.

Initial 4-month intervention
Participants in both the 'modest' and 'intensive' intervention groups received detailed diet and exercise advice from an experienced dietitian and physical activity instructor. The terms 'modest' and 'intensive' relate principally to the extent to which they were asked to change their diet and exercise patterns rather than the intensity of the intervention.[16] Participants in the control group were advised to continue their usual diet and exercise routine over the 4-month study period. Full anthropometric measurements were made, blood pressure taken and fasting blood samples were collected for lipid measurements at monthly intervals. Participants in both intervention

Figure 1 – Flow chart of study period

groups were seen weekly by the researchers for weight measurements and a short dietary and exercise assessment. No contact was made with the control group until the end of the 4-month study period. At the end of the 4-month intervention participants were strongly encouraged to maintain their lifestyle changes.

After the 4-month intervention period, those in the control group received some advice regarding healthy lifestyle changes as it was considered unethical not to do so. Following the 4-month intervention the 'modest' and 'intensive' intervention groups were combined for follow-up analysis and were consequently renamed the 'combined' intervention group. The study received ethical approval from the Otago Ethics Committee.

8, 12 and 24 month follow-up visits

All 79 participants were invited to return for the 8, 12 and 24-month visits. At 8 and 12 months diet and exercise were discussed and participants were encouraged to maintain lifestyle changes. At each of the three visits, weight, waist circumference, BMI and blood pressure were measured. Fasting blood samples were analysed for cholesterol, triglycerides, glucose and insulin. In addition at the 2-year follow-up visit a 75g Oral Glucose Tolerance Test (OGTT) was conducted and aerobic fitness was assessed using a sub maximal VO_2 treadmill test (Quinton Series 90 Q65; Quinton Instrument Company, Seattle, USA) based on a modified Bruce protocol. Participants were asked to fill-out a 4-day estimated diet record. Participants attended a 90-minute interview which included a standard lifestyle questionnaire, which was developed specifically for the 2 year follow-up visit. The questionnaire contained 80 qualitative and semi-quantitative questions. The questionnaire was developed to assess physical activity and eating behaviour patterns over the previous 2 weeks, changes in lifestyle habits since the end of the initial 4-month intervention and maintenance of the advised lifestyle habits. Participants also answered questions regarding their level of motivation, control, confidence, and support. Questions regarding goal setting, barriers to maintaining lifestyle changes, contributors to the maintenance of lifestyle change, financial effects and previous weight issues were also included. Finally, the usefulness of the lifestyle programme and perceived additional strategies for future interventions were assessed.

Statistical Analysis

The available data for weight were analysed with the intention to treat analysis using a mixed model, with a random effect for person. The baseline measure was used as covariates and indicator variables were used to compare each treatment group with the control group. Initially this analysis included a test for an interaction effect between time and treatment but as the interaction effect was not significant the interaction term was not included in the final model. Adjusted differences between the treatment groups and the control group with 95% confidence intervals are presented for each time period.

As the data at two-years were of most interest, the remainder of the analysis was based on those who completed the study. In this analysis the two treatment groups were combined and compared with the original control group (who had received a 2-week intensive lifestyle intervention). Regression analysis or ANCOVA was conducted to estimate the differences between the 4-month lifestyle intervention group and the control group adjusting for both baseline and the 4-month intervention values. STATA Statistical Software Package Release 7.0 (StataCorp, College Station, TX, USA) was used.

RESULTS

Figure 1 illustrates participant flow throughout the study. Of the 79 who participated in the initial 4-month intervention, 72 (91.1%) participated in the 8-month visit, 69 (87.3%) participated at 12-months and 62 (78.5%) participated in the 2-year follow-up visit. The changes which occurred during the initial 4-month lifestyle intervention have previously been described.[16] In brief during the initial 4 months both the 'intensive' and 'modest' intervention groups lost weight and reduced waist circumference (differences in weight and waist between the control and modest groups were -3.4 kg, $p=0.002$ and -3.5 cm, $p=0.02$ respectively, and the differences between the control and intensive groups were -4.7 kg, $p=0.0001$ and -4.1 cm, $p=0.01$ respectively). Weight remained unchanged in the control group. Insulin sensitivity was improved only in the 'intensive' intervention group.

Results for the 'combined' intervention group showed their mean weight at baseline, at the end of the 4-month intervention and at 2-years to be 91.5 kg, 86.5 kg and 90.5 kg respectively and the control group mean weight at these time points was 99.3 kg, 98.9 kg and 98.5 kg (Table 1). After adjusting for baseline and end of intervention values the difference between the 2 groups was 2.5 kg (95% CI -0.9, 5.9, $p=0.14$) (Table 2).

At 8, 12 and 24-months of all of the variables examined the only difference between the groups was for triglycerides (Table 2). At 24-months there were no sig-

Table 1. Mean (SD) weight in the intensive, modest and control groups over the 2-years

	Baseline	4 month[†‡]	8 month	12 month	24 month
Intensive group weight (kg)	91.1 (16.2)	85.9 (15.4)	86.9 (15.4)	88.4 (15.6)	88.5 (14.7)
Modest group weight (kg)	95.1 (12.2)	90.6 (12.2)	92.0 (14.1)	92.8 (14.6)	92.1 (13.6)
Control group weight (kg)	102.8 (15.4)	101.5 (15.1)	101.8 (16.7)	95.8 (12.6)	98.5 (15.2)

[†] Significant difference between control and modest groups, $p=<0.05$
[‡] Significant difference between control and intensive groups, $p=<0.005$

Table 2. Mean (SD) anthropometric, body composition, and biochemical variables in the control group and the 'combined' lifestyle intervention group at baseline, end of the 4-month intervention and 2-years

	Group	Baseline	4 months	2-years	Difference at 2-years[‡]	95% CI	*p* value
Weight	control	99.3 (13.3)	98.9 (13.4)	98.5 (15.2)			
(kg)	combined	91.5 (13.3)	86.5 (13.3)	90.5 (14.0)	2.5	-0.9, 5.9	0.14
Waist	control	113 (8)	111 (9)	111 (9)			
(cm)	combined	103 (11)	99 (10)	102 (12)	2	-1, 6	0.19
BMI	control	36.1 (4.5)	35.9 (4.4)	35.3 (5.1)			
(kg/m^2)	combined	33.0 (4.4)	31.2 (4.4)	32.3 (4.7)	0.8	-0.4, 2.1	0.19
Systolic BP	control	132 (14)	136 (19)	131 (7)			
(mmHg)	combined	135 (15)	128 (17)	130 (13)	-1	-7, 5	0.70
Diastolic BP	control	85 (7)	83 (8)	87 (8)			
(mmHg)	combined	85 (10)	78 (9)	86 (8)	2	-2, 6	0.33
Glucose	control	5.2 (0.6)	5.3 (0.6)	5.2 (0.9)			
(mmol/L)	combined	5.2 (0.7)	5.1 (0.6)	5.1 (0.7)	-0.1	-0.4, 0.3	0.81
Insulin	control	22.3 (13.7)	22.0 (14.9)	25.6 (17.0)			
(mIU/l)	combined	25.9 (27.4)	14.3 (7.4)	17.7 (10.8)	9.7	-3.9, 23.4	0.16
Insulin	control	5.0 (1.0)	5.4 (1.0)	5.1 (1.1)			
sensitivity[§]	combined	5.6 (1.2)	6.2 (1.4)	5.6 (1.6)	-0.1	-0.8, 0.6	0.85
Total chol	control	5.4 (1.0)	5.3 (0.9)	5.6 (0.9)			
(mmol/L)	combined	5.9 (1.2)	5.3 (1.1)	5.5 (1.0)	-0.2	-0.7, 0.2	0.34
HDL chol	control	1.0 (0.2)	1.0 (0.2)	1.1 (0.2)			
(mmol/L)	combined	1.1 (0.3)	1.0 (0.3)	1.1 (0.3)	0.1	-0.1, 0.2	0.52
TAG	control	1.7 (0.7)	1.6 (0.8)	2.0 (0.9)			
(mmol/L)	combined	1.8 (0.7)	1.6 (0.7)	1.7 (0.7)	-0.3	-0.6, -0.01	0.044
LDL chol	control	3.7 (0.8)	3.6 (0.7)	3.6 (0.8)			
(mmol/L)	combined	3.9 (1.0)	3.6 (0.9)	3.5 (0.8)	-0.2	-0.5, 0.2	0.41
Apo-B	control	1.0 (0.2)	1.0 (0.2)	1.0 (0.2)			
(g/L)	combined	1.1 (0.2)	1.0 (0.2)	1.0 (0.2)	0.01	-0.1, 0.1	0.79

Abbreviations: control, control group; combined, combined lifestyle intervention group; BMI, Body Mass Index; BP, blood pressure; chol, cholesterol; TAG, triglycerides; Apo-B, Apolipoprotein B.

[‡]Adjusted for baseline and end of intervention values. [§]Insulin sensitivity index = exp[2.63-0.28 ln(insulin)-0.31ln (triglyceride)]

nificant differences in predicted maximal VO$_2$ between the 'combined' intervention group and the control group (Table 3). There were also no significant differences between the 'combined' intervention group and the control group for total energy, percentage of total energy from fat, saturated fat, carbohydrate, and dietary fibre intake (Table 3).

A small number of participants developed impaired glucose tolerance (control group n=2, 11.8%; combined intervention group n=6, 15.4%) and type 2 diabetes (control group n=2, 11.8%; combined intervention group n=2, 5.1%) by the 2 year visit. There were no significant differences between the 'combined' intervention group and the control group with respect to progression from insulin resistance to impaired glucose tolerance and type 2 diabetes (*p*=0.75).

General responses to the questionnaire

At 2-years, almost all of the participants (92%) reported they had found it useful during the intervention to have their weight checked. Many participants (47%) reported that having their weight regularly checked and a brief discussion about their progress would have helped them remain on track during the follow-up period between the initial 4-month intervention and the 2-year visit. A high proportion of participants (64%) reported that more frequent follow-up would have helped them maintain healthy lifestyle habits. Some participants considered that more group activities (26%) and a buddy system (22%), such as a walking partner, would have helped them to

remain physically active. A cooking class was also mentioned by 23% as an aid which would have helped to change and maintain a healthy diet. Most of the participants (70%) reported that it was important for them to modify their eating and physical activity habits for health reasons and the second most frequently stated reason (28%) was for weight loss.

Healthy Eating responses

Most participants (77%) at 2-years reported having changed their eating habits since the end of the intervention. Only 10% of participants reported sustaining "all" of the dietary changes they had made during the 4-month intervention. The majority of participants (80%) were able to sustain more moderate ("some") dietary changes over time. At 2-years, participants reported that they were able to sustain eating more fruit and vegetables, pasta, rice and low fat dairy products. Conversely, at 2 years, participants struggled to maintain eating nuts, seeds, beans and lentils and were eating more sweet food again. Almost half of the participants (43%) found it "hard" after the intervention as they no longer had the study coordinators checking their progress. The other most common barriers reported by participants to maintaining healthy eating habits included; putting partner's and children's eating preferences before their own (33%), stress and negative moods (20%), social settings such as eating in a restaurant (20%), lack of time (17%), and the expense of healthy food (17%). The most common contributors reported by participants to maintaining healthy eating

Table 3. Mean (SD) exercise and dietary variables in the control group and the 'combined' lifestyle intervention group at baseline, end of the 4-month intervention and 2-years

	Group	Baseline	4 months	2-years	Difference at 2-years[‡]	95% CI	*p* value
Pred VO$_2$max	control	29.4 (7.3)	33.3 (6.0)	30.9 (6.6)			
(ml.min^{-1}.kg^{-1})	combined	31.5 (7.9)	34.7 (7.6)	32.0 (7.8)	-0.7	-3.3, 1.8	0.56
Heart rate	control	138 (12)	136 (15)	135 (14)			
(bpm)	combined	136 (14)	138 (14)	133 (13)	-1	-7, 4	0.64
Total energy	control	9834 (3476)	9167 (1897)	8875 (2759)			
(kJ)	combined	8569 (2353)	7450 (2005)	7816 (2057)	465	-707, 1638	0.42
Total fat	control	32 (5)	33 (6)	29 (7)			
(%)	combined	32 (6)	26 (5)	28 (5)	1	-2, 9	0.18
Saturated fat	control	13 (4)	16 (6)	10 (4)			
(%)	combined	13 (3)	9 (2)	10 (3)	1	-3, 5	0.58
Carbohydrate	control	47 (6)	46 (7)	47 (6)			
(%)	combined	51 (5)	51 (5)	49 (5)	1	-4, 6	0.72
Protein	control	17 (4)	16 (2)	19 (4)			
(%)	combined	16 (2)	19 (3)	19 (3)	-1	-4, 2	0.40
Cholesterol	control	278 (123)	260 (100)	243 (114)			
(mg)	combined	237 (118)	167 (72)	208 (110)	42	-38, 121	0.29
Fibre	control	28 (9)	25 (7)	32 (15)			
(g/24 h)	combined	26 (7)	28 (6)	27 (8)	-5	-13, 2	0.15

Abbreviations: Pred, Predicted; control, control group; combined, combined lifestyle intervention group.
[‡] Adjusted for baseline and end of intervention values.

habits included; recording eating habits (70%), good family and partner support (22%), achieving goals such as losing weight (17%), and feeling positive (13%).

Physical Activity
At 2-years, 70% of participants reported that they had not been able to maintain their physical activity habits since the end of the intervention. Specifically, participants reported that they were not attending a gym, not aqua-jogging and doing less walking. Only a small number of participants (19%) reported that they were able to maintain "all" of the habits developed in the intervention. While 65% were able to maintain "some", with some walking, gardening and a more active lifestyle being the most commonly cited types of activity maintained. The most common barriers reported by participants to maintaining physical activity included; lack of time (42%), bad weather (30%), family time as more of a priority (27%), lack of motivation (20%) and work commitments (20%). The most common contributors to maintaining physical activity included; good weather (20%), having a dog to walk (13%), support from family and partners (10%), and having a friend to exercise with (10%).

DISCUSSION
Despite receiving an intensive 4-month lifestyle intervention, with occasional follow-up over 2-years, weight regain occurred. These results confirm those of many other intervention studies which have shown that participants typically regain 30-50% of their initial weight loss in the first year following an intervention.[17-19] There are data which suggest an increase in weight over time in middle-aged overweight individuals.[7, 12] The fact that by 2-years, none of the 3 groups had gained weight above their baseline value (and only 5% of the 'combined' intervention group and 12% of the control group had developed type 2

diabetes by 2 years) suggests that some overall benefit is likely to have accrued from the intervention.

One of the most consistent findings from the 2-year interview was the desire for more frequent follow-up following the initial 4-month intervention. This was reinforced by the observation that more than half of the participants reported that they found it "hard to stay on track" with their lifestyle changes following the intervention. Participants specifically reported that this was due to no longer having the "study co-ordinators checking up on them". Approximately two-thirds of the participants reported that more frequent follow-up after the intensive period of intervention would have helped them to maintain lifestyle changes and over half specified that they would have liked weekly contact.

The initial intensive 4-month intervention period followed by occasional follow-up in the present study was used to test an approach that was considered to be more feasible for widespread implementation than that adopted in the DPS or DPP. Comparatively both the DPS and the DPP employed very intensive dietary, exercise and behavioural approaches to encourage lifestyle change coupled with frequent follow-up of participants over many years.[9, 10] It is likely that this intensive follow-up resulted in the maintenance of initial weight loss and substantial reductions in the progression to type 2 diabetes. Routine implementation of the DPS and DPP however at this stage is not feasible in routine clinical practice due to the enormous costs and resources involved.[14, 20]

At two years, more than half of the participants desired more regular follow-up following the initial intensive 4-month intervention. As reported by participants, the ideal follow-up would include having their weight regularly checked and a brief discussion with a health professional. The question remains, however, for how long and how intensively should people at risk for type 2 diabetes and other comorbidities of obesity be supported to ensure the

sustainability of healthy lifestyle changes. These findings suggest that an approach rather simpler and less costly than that employed in the DPS and the DPP, including regular weight checks by a health professional such as a practice nurse might be a practical approach to weight loss maintenance. This suggestion needs to be tested in an intervention trial.

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AUTHOR DISCLOSURES

None declared.

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[1]*Department of Human Nutrition, University of Otago, Dunedin, New Zealand*
[2]*Edgar National Centre for Diabetes Research, University of Otago, Dunedin, New Zealand*
[3]*Department of Preventive and Social Medicine, University of Otago, Dunedin, New Zealand.*

有胰島素阻抗性的成人接受密集的生活型態介入後對其後續生活型態的改變：追蹤 2 年

此研究目的為評估有胰島素阻抗且體重過重的人，在 4 個月的生活型態介入，降低體重及改善心血管疾病危險因子之後，是否能長期維持那些生活型態改變。79 名胰島素阻抗的成年人，隨機分配為控制組、或者是 4 個月的適度或是密集生活型態介入組。之後合併 2 組介入組。追蹤所有參與者在第 8、12 及 24 個月的情形。測量他們的體位、血壓、禁食血糖、血脂、胰島素及有氧體適能，並評估飲食攝取。面訪參與者以找出那些對維持健康的生活習慣之自覺促進或是阻礙的因子。在第 8、12 及 24 個月，分別有 72 名(91.1%)、69 名(87.3%)及 62 名(78.5%)參與者仍在這個研究中。在 4 個月時，適度介入組及控制組之間的調整體重差異為-3.4 kg (95% CI: -5.4, -1.3)，p=0.002，密集介入組與控制組為-4.7 kg (95% CI: -6.9, -2.4)，p=0.0001。在 2 年時，三組間或是介入組與控制組相比，體重均沒有顯著差異。在 2 年時，64%的參與者報告顯示較頻繁的追蹤可以幫助他們去維持健康的生活習慣。甚至 4 個月的密集介入及後繼每 4 個月的一次諮詢及每年的監測對於維持生活型態改變以致於降低體重是不夠的。三分之二的參與者認為不定期的頻繁監測對於維持他們最初的生活型態改變是必要的。

關鍵字：維持體重、胰島素阻抗、肥胖、飲食、體能活動