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Weight loss on a structured hypocaloric diet with or without exercise improves emotional distress and quality of life in overweight and obese patients with type 2 diabetes

Thomas Philip Wycherley¹, Peter Marshall Clifton², Manny Noakes³, Grant David Brinkworth^{3*}

¹Sansom Institute for Health Research, Division of Health Sciences, University of South Australia, ²Baker IDI Heart and Diabetes Institute, and ³Preventative Health Flagship, Commonwealth Scientific and Industrial Research Organisation – Animal, Food and Health Sciences, Adelaide, Australia

Keywords

Lifestyle intervention, Well-being, Caloric restriction

*Correspondence

Grant D Brinkworth
Tel: +61-8-8303-8830
Fax: +61-8-8303-8899
E-mail address: grant.brinkworth@csiro.au

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ABSTRACT

Aims/Introduction: To evaluate the effects of a caloric restricted weight loss program with or without supervised resistance exercise training (EX) on diabetes-related emotional distress and quality of life (QOL) in overweight and obese patients with type 2 diabetes.

Materials and Methods: In a parallel design, 106 men and women with type 2 diabetes were randomized to a prescriptive 16-week caloric restricted diet (D; 6,000–7,000 kJ/day), with ($n = 65$) or without ($n = 41$) EX (three times per week). Bodyweight, glycated hemoglobin, diabetes-specific emotional distress (Problem Areas in Diabetes [PAID] questionnaire) and QOL (Diabetes-39 [D-39] questionnaire) was assessed pre- and post-intervention.

Results: A total of 84 participants completed the study (D $n = 33$, D + EX $n = 51$). Weight loss was significantly greater in D + EX compared with D (-11.4 ± 5.8 vs -8.8 ± 5.8 kg, $P = 0.04$ time \times diet). Overall, there were significant improvements in glycated hemoglobin, PAID total score and the D-39 dimensions of 'diabetes control', 'anxiety and worry', 'sexual functioning', 'energy and mobility', 'overall rating of QOL' and 'severity of diabetes' ($P \leq 0.01$ for time). The D-39 dimension, 'social burden', did not change ($P = 0.07$ for time). There was no difference between groups in the response for any of these variables ($P \geq 0.10$).

Conclusion: A structured caloric restricted diet with or without EX improves emotional distress and QOL in overweight and obese patients with type 2 diabetes. This trial was registered with Australian New Zealand Clinical Trials Registry (<http://www.anzctr.org.au>; ACTRN No: ACTRN12608000206325).

INTRODUCTION

Quality of life (QOL) is a product of physical, mental and social well-being that is reduced in patients with type 2 diabetes¹. The reduced QOL is likely related to difficulties in coping with a daily diabetes management regime and concerns about developing complications later in life¹. Specifically, patients with type 2 diabetes might experience psychological and social

stress relating to disease-specific aspects, including the need to maintain blood glucose control and prevent longer-term concomitant health problems². This highlights the importance of incorporating disease-specific measures of QOL when developing and assessing the effectiveness of interventional therapies.

Previous studies have shown that lifestyle modification programs incorporating dietary weight loss and exercise training (EX) improve QOL and emotional wellbeing in overweight and obese patients including patients with type 2 diabetes^{3–5}. Other

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studies have also shown that EX alone, independent of weight loss⁶⁻⁸ and weight loss achieved by caloric restriction^{9,10}, separately improve QOL in type 2 diabetes, suggesting that the addition of EX to a dietary weight loss program might be superior to diet alone in improving QOL outcomes. However, there is limited data available evaluating the additive effect of EX to a caloric restricted diet on psychological well-being and QOL in patients with type 2 diabetes. An 18-month follow up of a 10-week behavior modification and education program showed no additional benefit of EX when added to a calorie restricted diet on QOL in patients with type 2 diabetes¹¹. However, participants were not supervised or provided with any professional support after the 10-week program had ceased, and whether the possibility of a subsequent lack of sustained program compliance could have reduced the treatment efficacy remains unclear. Furthermore, no known studies to date have compared the effects of a lifestyle modification incorporating diet alone with diet plus EX on diabetes specific QOL outcomes. Therefore, the purpose of the present study was to assess the additive effects of EX, when combined with a moderate hypocaloric weight loss diet under supervised conditions, on emotional distress and QOL using disease-specific validated questionnaires in overweight and obese patients with type 2 diabetes.

METHODS

Participants and Study Design

The enrolment criteria, study design and primary study outcomes have been previously described in detail elsewhere^{12,13}. In brief, 106 sedentary men and women with type 2 diabetes were recruited by a public advertisement (Table 1). The study was approved by the Human Research Ethics Committees of the Commonwealth Scientific and Industrial Research Organiza-

sation (CSIRO) and the University of Adelaide. Participants provided written informed consent before commencement.

In a parallel study, participants were blocked, matched for age, sex and weight, then randomized to follow an energy-restricted diet alone (D; *n* = 41) or an isocaloric diet plus EX (D + EX; *n* = 65) for 16 weeks.

At baseline (week 0) and week 16, participants attended the research clinic for outcome assessment. At each clinic testing visit, measurements of height (week 0 only, using a stadiometer [SECA, Hamburg, Germany]) and bodyweight (using calibrated electronic digital scales [Mercury; AMZ 14, Tokyo, Japan]) were taken before a venous blood sample was drawn for determination of glycated hemoglobin (HbA_{1c}; IMVS, Adelaide, Australia). Participants then completed two validated questionnaires designed to assess diabetes-related QOL and distress in patients with a broad range of type 2 diabetes progression^{2,14-17}. The Diabetes-39 (D-39) instrument² includes dimensions to assess the severity of diabetes, diabetes control, anxiety/worry, social burden, sexual function, energy/mobility and overall QOL. The Problem Areas in Diabetes (PAID) questionnaire¹⁷ is a measure of diabetes-related emotional distress. Scales of the D-39 and PAID questionnaires range from 0 to 100, with 0 and 100 assigned to the lowest and highest scores, respectively. Throughout the study, participants were asked not to modify their lifestyle patterns, other than necessary to comply with the study protocol.

Diet and Exercise Interventions

All participants followed a supervised moderate energy restricted diet (females 6,000 kJ/day, males 7,000 kJ/day) based on a fixed menu plan. To facilitate dietary compliance, detailed dietary advice was provided at baseline and every 2 weeks by a qualified dietician.

Table 1 | Baseline (week 0) characteristics, and change in bodyweight and glycated hemoglobin in response to a 16-week calorie restricted diet program with or without supervised resistance exercise training

		D	D + EX	P-value		
				Baseline†	Time‡	Time × group§
Age (years)	Week 0	56.9 ± 6.8	55.6 ± 7.7	0.43		
Sex (male/female)	Week 0	17/16	32/19	0.31		
Height (m)	Week 0	1.72 ± 0.10	1.69 ± 0.10	0.12		
Bodyweight (kg)	Week 0	101.0 ± 16.5	104.1 ± 14.9	0.36	<0.001	0.04
	Week 16	92.2 ± 14.0	92.7 ± 13.3			
	Change	-8.8 ± 5.8	-11.4 ± 5.8			
Body mass index (kg/m ²)	Week 0	35.5 ± 4.8	35.2 ± 4.4	0.73	<0.001	0.05
	Week 16	32.5 ± 4.4	31.3 ± 3.9			
	Change	-3.0 ± 1.8	-3.9 ± 1.9			
HbA _{1c} % (mmol/mol)	Week 0	7.8 ± 1.5 (62 ± 16)	7.2 ± 1.6 (55 ± 18)	0.07	<0.001	0.45
	Week 16	6.5 ± 0.9 (47 ± 10)	6.0 ± 1.0 (42 ± 11)			
	Change	-1.4 ± 1.2 (-15 ± 13)	-1.2 ± 1.2 (-13 ± 12)			

Data are mean ± standard deviation; 16-week calorie restricted diet program (D) *n* = 33, D with supervised resistance exercise training (D + EX) *n* = 51. †Comparison of baseline characteristics at week 0 (one-way analysis of variance [ANOVA]). ‡Time effect (ANOVA for age, height, weight, body mass index and glycated hemoglobin [HbA_{1c}], Pearson's χ^2 for sex). §Group effect (ANOVA).

Participants randomized to the D + EX group followed a progressive resistance exercise training program in which eight exercises (two sets/exercise) were carried out to fatigue (8–12 repetitions) on three non-consecutive days per week. Compliance to EX was defined as a percentage of the number of completed sessions divided by the total prescribed sessions, with a minimum requirement of 75% for inclusion in the data analysis. All training sessions were carried out under supervision at the CSIRO Research Gymnasium.

Statistical Analysis

Statistical analyses were carried out using SPSS for Windows (Version 18.0; SPSS, Chicago, IL, USA). Before hypothesis testing, data were examined for normality. Differences in baseline characteristics were compared by a non-parametric independent samples Kruskal–Wallis test for continuous variables with non-normal distribution (questionnaire responses) and one-way analysis of variance (ANOVA) for continuous variables with normal distribution (bodyweight and HbA_{1c}), and χ^2 -tests were used to assess categorical variables (dropout rates and the number of participants reporting a maximum score for a questionnaire response). For variables with non-normal distribution, changes over time in groups were assessed using a related-samples Wilcoxon signed-rank test; effects of the treatments on changes were assessed using an independent samples Kruskal–Wallis test with treatment (D, D + EX) as a between-subject factor. The effects of time and treatment group on continuous variables were assessed using repeated measures ANOVA with

time as the within-subject factor and treatment as a between-subject factor. Spearman's correlation coefficients were used to determine relationships between changes in weight and HbA_{1c}, and changes in D-39 dimensions and the PAID response. Statistical significance was set at $P < 0.05$. Data for bodyweight and HbA_{1c} (normal distribution) are means \pm standard deviation. Data for QOL outcomes (non-normal distribution) are medians and interquartile range.

RESULTS

A total of 84 of the 106 randomized participants completed the study and were included in the analysis (D: $n = 33$, D + EX: $n = 51$). There was no difference in dropout rate between the groups ($P = 0.80$). At baseline, all outcome variables including the number of participants reporting maximum D-39 domain scores or PAID total score were similar between the groups and between participants who did or did not complete the study. Compliance criteria for EX was achieved by all participants in the D + EX group, who completed on average 93% (44 ± 4 out of 47) of the prescribed sessions.

There was a significant greater reduction in bodyweight in the D + EX group (D -8.7% vs D + EX -11.0% ; $P < 0.001$ time, $P = 0.04$ time \times group interaction; Table 1). The reduction in HbA_{1c} was similar in both groups ($P < 0.001$ time; $P = 0.45$ time \times group; Table 1). Overall, there were significant improvements in the PAID total score ($P < 0.001$) and all of the D-39 dimensions ($P \leq 0.01$) except for 'Social Burden' ($P = 0.07$); with no differences in response between the inter-

Table 2 | Diabetes-39 questionnaire dimensions and the Problem Areas in Diabetes questionnaire total score in response to 16-week calorie restricted diet program with or without supervised resistance exercise training

Questionnaire component	Group	Week 0 (/100) [% reporting maximum score]	Week 16 (/100) [% reporting maximum score]	Change	Time†	Group‡
D-39 Overall Rating of QOL	D	67 (25) [9]	67 (33) [9]	0 (25)	0.001	0.10
	D + EX	67 (33) [6]	83 (17) [22]	8 (17)		
D-39 Severity of Diabetes	D	33 (50) [6]	33 (33) [12]	0 (25)	0.01	0.14
	D + EX	33 (33) [18]	17 (42) [25]	0 (33)		
D-39 Diabetes Control	D	28 (31) [0]	14 (22) [15]	-7 (17)	<0.001	0.23
	D + EX	19 (31) [0]	8 (21) [8]	-10 (15)		
D-39 Anxiety Worry	D	46 (38) [0]	29 (29) [12]	-8 (26)	<0.001	0.75
	D + EX	33 (29) [2]	21 (33) [10]	-8 (21)		
D-39 Social Burden	D	7 (28) [33]	3 (18) [39]	0 (20)	0.07	0.84
	D + EX	5 (13) [35]	0 (15) [51]	0 (12)		
D-39 Sexual Function	D	33 (42) [18]	6 (33) [42]	-11 (33)	<0.001	0.15
	D + EX	17 (44) [37]	6 (33) [45]	0 (11)		
D-39 Energy Mobility	D	23 (25) [3]	12 (17) [6]	-4 (16)	<0.001	0.13
	D + EX	19 (27) [2]	6 (13) [10]	-10 (19)		
PAID Score	D	40 (37) [0]	15 (27) [3]	-6 (15)	<0.001	0.94
	D + EX	24 (25) [0]	15 (21) [2]	-8 (15)		

Data are medians (interquartile range); 16-week calorie restricted diet program (D) $n = 33$, D with supervised resistance exercise training (D + EX) $n = 51$. †Time effect (related-samples Wilcoxon signed-rank test). ‡Group effect (independent samples Kruskal–Wallis test). D-39, Diabetes-39 questionnaire; PAID, Problem Areas in Diabetes questionnaire.

vention groups ($P \geq 0.10$; Table 2). The number of participants reporting a maximum score for any D-39 dimension or the PAID response was similar between intervention groups ($P \geq 0.13$; Table 2).

Overall, changes in weight correlated with changes in the D-39 dimensions 'Severity of Diabetes' ($r = 0.22$, $P = 0.05$) and 'Energy and Mobility' ($r = 0.27$, $P = 0.01$). Changes in HbA_{1c} correlated with changes in the D-39 dimension 'Energy and Mobility' ($r = 0.22$, $P = 0.04$).

DISCUSSION

The present study showed that weight loss on a structured hypocaloric diet with or without supervised EX similarly improved diabetes-related emotional distress and QOL in overweight and obese adults with type 2 diabetes. The improved health-related QOL achieved through participation in a structured lifestyle intervention weight loss program supports findings from the Look AHEAD Trial (Action for Health in Diabetes Trial) that also showed a combined dietary modification and EX program improved QOL assessed using the Medical Outcomes Study 36-Item Short-Form (SF-36) Health Survey physical component summary and the Beck Depression Inventory II score⁵. The present study extends this understanding of the impact of lifestyle modification on these outcomes in type 2 diabetes by showing that no additional improvements in QOL are evident when EX is added to a structured dietary weight loss diet program.

The present results are consistent with those reported by Kaplan *et al.*¹¹ that observed in an 18-month follow up to the provision of a 10-week behavior modification and education program that incorporated a caloric restricted diet, that there was no additional benefit on QOL to patients with type 2 diabetes when EX (consisting of stretching and aerobic activities) was added to the program. Similarly, Thomson *et al.*¹⁸ reported an overall improvement in QOL and depression symptoms in response to a 20-week program of a hypocaloric diet prescribed either alone or combined with EX (either aerobic or combined aerobic and resistance exercise) in overweight and obese women with polycystic ovary syndrome, with no difference between treatment groups. Collectively, these data suggest that when combined with a hypocaloric dietary intervention program, EX might not offer any observable additional benefit for improving QOL scores. Without an exercise-only control group, however, we were unable to evaluate the magnitude of any effects of EX independent of dietary weight loss, this requires further investigation.

It is worth noting that as minimum and maximum scores exist for a QOL questionnaire, there is a ceiling/flooring effect present for the degree in which scores can be improved/reduced¹⁹. In the present study, baseline QOL scores were at the lower end of the scale, indicating relatively high levels of QOL and low levels of diabetes-related distress at baseline. For instance, for the D-39 questionnaire domain of 'Social Burden', 37% of participants reported the highest possible QOL score at

baseline. Consequently, the ability to register further improvement in response to the intervention was limited. Hence, it is possible in the present study that the measurement of any further improvement above that achieved with the caloric restriction induced weight loss program could have been masked by a ceiling/flooring effect¹⁹. Whether the pattern of results would have been similar in individuals with poorer health-related QOL at baseline requires further investigation.

The specific mechanism responsible for the positive changes observed is not entirely clear. The lack of any correlation between changes in weight and glycemic control with changes in several D-39 QOL dimensions (other than 'Energy and Mobility' and 'Severity of Diabetes') and PAID scores suggests the improvements observed might have been attributable to alternative factors. It has been previously reported that participation in a supervised lifestyle intervention program can improve mood and depression during the early stages before any significant weight loss is realized²⁰ that could be attributable to improved feeling of self-control and perception²¹. This suggests the possibility that factors relating to participation in a structured and professionally supported program, and not just success in achieving weight loss and/or improvements in diabetes control *per se*, could at least be partly responsible for the effects observed. Further research that incorporates a weight stable, but professionally supported and structured, control group is required to confirm this.

A limitation of the study was the isolated use of disease-specific QOL and distress questionnaires, which restricts interpretation of the results compared with other healthy or diseased populations that have been assessed using generic questionnaires²². However, the D-39 questionnaire dimensions have been previously reported to correlate well with the reciprocal dimensions from the most common generic QOL assessment tool; the SF-36 Health Survey². As the present study only evaluated changes over a relatively short study duration, further research is required to evaluate interventions of longer duration, or whether the improvements in QOL and diabetes distress are sustained after the completion of the intervention.

In conclusion, in overweight and obese individuals with type 2 diabetes, participation in a structured and supervised caloric restricted diet program improves diabetes-specific QOL, but participation in EX provided no additional benefit. The present study provides further support for the importance of lifestyle modification and participation in structured weight loss programs for the management of type 2 diabetes.

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