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Clinical Obesity (ISSN 1758-8103, eISSN 1758-8111)
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Citation Details

Citation for the version of the work held in 'OpenAIR@RGU':

ROLLAND, C., LULA, S., JENNER, C., DYSON, L., MACDONALD, I., JOHNSTON, K. L. and BROOM, I., 2013. Weight loss for individuals with type 2 diabetes following a very-low-calorie diet in a community-based setting with trained facilitators for 12 weeks. Available from <i>OpenAIR@RGU</i>. [online]. Available from: http://openair.rgu.ac.uk

Citation for the publisher's version:

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Title: Weight loss for individuals with type 2 diabetes following a very low calorie diet in a community based setting with trained facilitators for 12 weeks.

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Keywords: diabetes, weight loss, very low calorie diets

Running title: Weight loss in type 2 diabetes.

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What is already known about this subject

- Approximately 80% of people with T2DM are overweight or obese
- Weight loss produces numerous benefits in T2DM
- People with T2DM have difficulty losing and maintaining weight

What this study adds

- Provision of a VLCD with group support and behaviour therapy for patients with T2DM is feasible within a community-based setting with trained facilitators
- VLCD approaches for weight management in T2DM can achieve more than 90% of weight loss as compared to obese individuals without T2DM
- Identification of the need to investigate the full impact of this approach in patients with T2DM by assessing changes in glycaemia, liver function and medication.

Abstract

Approximately 80% of people with type 2 diabetes mellitus (T2DM) are overweight or obese, and obesity compounds the cardiovascular risk of T2DM. The aim of this retrospective study was twofold: first to investigate whether a 12 week, community based VLCD programme can result in important weight loss; and second to investigate any potential difference in the weight loss achieved using this community based approach in individuals with and without T2DM. Three hundred and fifty five participants with T2DM were matched for age, BMI and gender to participants without T2DM (Total cohort comprised 204 males: 506 females; (mean \pm standard deviation) age (years) 54.0 ± 9.1 ; BMI (kg/m^2) 41.6 ± 8.1 ; weight (kg) 116.1 ± 25.1). The programme included a daily intake of 550kcal in addition to group support and behaviour therapy provided by trained facilitators within a community-based setting. After 12 weeks, there was significant weight loss within each group when compared to baseline (T2DM: 115.0 ± 24.4 kg vs 96.7 ± 21.4 kg, $p < 0.0001$; non-T2DM: 117.2 ± 25.8 kg vs 97.3 ± 22.2 kg, $p < 0.0001$). At 12 weeks, weight change (-18.3 ± 7.3 kg vs -19.9 ± 7.0 kg, $p = 0.012$) and BMI change (-6.7 ± 2.9 kg/m^2 vs -7.1 ± 2.1 kg/m^2 , $p = 0.011$) were significantly less in the T2DM group when compared to the non-T2DM group. Our results suggest that the use of VLCD approaches for weight management in T2DM can achieve more than 90% of the weight loss seen in obese individuals without T2DM.

Introduction

Among those individuals with type 2 diabetes mellitus (T2DM) approximately 80% are overweight or obese (1). Obesity compounds the cardiovascular risk of T2DM, such that T2DM individuals 20–30% above their ideal body weight have a 2.5–3 fold increase in premature mortality compared to people with diabetes who have a healthy body weight. Premature mortality rises to greater than a fivefold increased risk for individuals >40% above their healthy weight (2). Furthermore, obesity complicates the management of T2DM, increasing insulin resistance and glucose intolerance, making diabetes in

the obese population difficult to treat pharmacologically and also increases the likelihood of individuals with diabetes developing hypertension and cardiovascular complications (3-8).

The financial cost of diabetes in the UK has been estimated to be 10% of the NHS budget (9) and 7% of all prescription costs per year (10), thus making the treatment of obesity and diabetes of primary concern. Weight loss produces numerous benefits in T2DM including improved glucose metabolism; reduction in glycated haemoglobin, fasting insulin levels and increased insulin sensitivity; reduction in blood pressure; and improvements in lipid profile with decreased triacylglycerols, increased high density lipoprotein cholesterol (HDL-C) and reduced low density lipoprotein cholesterol (LDL-C) (11,12). Due to the well documented association between obesity and increased health risks, utilising weight-loss as an effective strategy is a recommendation by public health authorities and many physicians (12). Studies assessing the effects of weight loss medication such as fenfluramine and phentermine (13), orlistat (14) and sibutramine (15), have demonstrated the relatively small, but clinically significant weight loss which resulted in improvements in HbA_{1c}, although only a moderate improvement was observed with the use of sibutramine. Studies on the use of different dietary approaches have yielded mixed results. For example, the use of a combination of weight loss therapies (including meal replacements, low calorie diet and sibutramine) resulted in a 4.6kg weight loss and decrease in HbA_{1c} of 0.5% at 2 years (16), whereas in the study by Milne et al (17) three sets of dietary guidelines for type 2 diabetes were compared (a weight-management diet, a high-carbohydrate/fibre diet, or a modified-lipid diet) and no significant changes in body weight were observed at 18 months. Distchuneit et al (18), reported a weight loss of 11.3% of starting weight at 27 months by using meal replacements. It appears that conventional methods of dietary treatment result in individuals with T2DM losing approximately 50% less weight than their non-T2DM counterparts (19,20), confirming the original observations of Wing et al (21) in a 20-week behavioural weight control program consisting of self monitoring, stimulus control, cognitive restructuring and contingency contracting.

Nevertheless, dietary modification remains the first line treatment in the management of obese people with T2DM (22) and patients with type 2 diabetes do show improvements in weight, fasting glucose, HbA_{1c}, insulin sensitivity and blood pressure following the use of a very low calorie diet (VLCD) (23,24). Although these diets have been associated with side effects such as nausea, halitosis, constipation and transient hair loss (25), Dhindsa et al (23) have suggested giving greater consideration in the use of VLCDs (<800 kcal/day) in the treatment of the 'difficult-to-manage and symptomatic patient group'. This is supported by a recent systematic review which suggested the need for further standardised research of VLCD use in obese but otherwise healthy, and at risk groups, the results of which could better inform best practice (26).

We hypothesise that the use of a VLCD in combination with behaviour therapy could result in important weight loss in patients with and without T2DM. The aim of this retrospective study was twofold: first to investigate whether a 12 week, community based VLCD programme can result in

important weight loss; and second to investigate any potential difference in the weight loss achieved using this community based approach in individuals with and without T2DM.

Materials and Methods

Source of Data

For this retrospective analysis, data were included from participants with complete data at baseline and 12 weeks and who were recruited onto the weight loss programme between 2007 and 2010. Ethical permission for this analysis was obtained from the Robert Gordon University Ethics Committee.

Study Population

Participants were self-referred, and prior to starting the programme, their fitness to participate was assessed by their GP using a standardised form provided by LighterLife which assesses health status. Potential clients were included if they met the requirements above or were excluded from taking part in the LighterLife Total programme if they met any of the following criteria: type 1 diabetes; porphyria; total lactose intolerance; major cardiovascular or cerebrovascular disease; history of renal disorder or hepatic disease; active cancer; epilepsy, seizures, convulsions, major depressive disorder, psychotic episodes, schizophrenia, bipolar disorders, delusional disorders; current suffering from anorexia, bulimia or undergoing treatment for any other eating disorder; are pregnant or breastfeeding; have given birth or had a miscarriage in the last 3 months.

Participants with T2DM (n=355) were then matched for age, BMI and gender to participants without T2DM (n=355). The groups were first matched within the tolerance of ± 1 BMI unit and an exact match for age and gender (n = 284 individuals). For those individuals in the T2DM group who did not have a corresponding match, the BMI tolerance was increased up to ± 2 BMI units and an exact match for age and gender were obtained (n=71 individuals). Baseline demographics and 12 week changes in weight were compared for the two groups.

Weight loss programme

For those individuals who were eligible, the intervention was carried out within a community based setting and not in a specialist unit. Appointments and treatments were managed by lay, but trained behaviour change facilitators. Requirement for drug change was determined by the participant's GP or diabetic specialist nurses. Where required, patients' insulin doses were halved and sulfonylureas were stopped prior to the commencement of the diet. Participants attended their GP/diabetic specialist nurse at least monthly for ongoing review of medication requirements whilst losing weight.

The intervention used was a commercial weight-management programme (LighterLife Total). This is a tripartite approach for individuals with $\text{BMI} \geq 30 \text{ kg/m}^2$ comprising of a VLCD and group support, along with behaviour therapy. The programme aims to achieve weight loss and to identify personal

psychological motivation for over-consumption, thereby enabling participants to develop robust strategies for more successful weight management in the future.

Diet and nutrition

The VLCD provides a daily intake of 550kcal (50g protein, 50g carbohydrate, mean 17g fats i.e. 36% Energy from protein, 36% carbohydrate and 28% fat) in the form of food packs (soups, shakes, textured meals and bars) which contain $\geq 100\%$ recommended daily allowances (RDA) for vitamins and minerals including Vitamins A, C, D, E, K, thiamine, riboflavin, niacin, B6, B12, folic acid, biotin, and pantothenic acid, calcium, phosphorous, iron, zinc, magnesium, iodine, potassium, sodium, copper, manganese, selenium, molybdenum, chromium, chloride, fluoride). Clients were also able to purchase an ancillary “fibre mix” to add to their water which contains inulin as the source of fibre.

Participants undertook the VLCD alongside a unique behaviour-change programme developed specifically for weight management in the obese. This is informed by concepts from cognitive behavioural therapy and transactional analysis (transactional cognitive behavioural therapy – TCBT®) and addiction/change theory (27-30). It is delivered in small, single-sex, weekly groups by weight-management counsellors who are specifically trained in the facilitation of behaviour change for the treatment of obesity.

Measurements

Measurements of height and weight took place in LighterLife centres and were carried out by the facilitators who have been trained and provided with protocols developed within LighterLife. The actual types of equipment used for these measurements was not recorded. Measurements were taken during weekly meetings which occurred at the same location and time each week.

Statistical Analysis

All variables were assessed for normality. The only variables normally distributed were waist circumference at baseline and waist circumference at 12 weeks. All of the other variables required the use of non-parametric tests. Baseline comparisons were carried out by independent t-test or Mann-Whitney U test for continuous data and by Chi square for categorical data. Paired t-tests or Wilcoxon matched pairs test were carried out to assess within group changes. Comparison of rate of weight loss between the two groups was also assessed using the Mann-Whitney U test. A sensitivity analysis was performed by removing participants who were not matched exactly for gender, age and ± 1 BMI unit ($n = 71$). In addition, a sub-analysis was carried on Caucasian subjects alone in order to avoid any effects due to ethnicity. Data were analysed using SPSS for Windows (version 17.0) (SPSS Inc., Chicago, IL, USA)

Power

The sample size (355 per group) for this retrospective analysis provided a power greater than 80% to detect a minimum difference in weight change between the two groups of 1.69kg.

Results

A total of 1246 individuals with T2DM undertook the LighterLife Total VLCD programme from 2007-2010. Of these, 698 followed the diet for at least 12 weeks, 355 (102 men, 253 women) of which we were able to match adequately for gender, age and BMI against a group of men and women without T2DM. Mean age, BMI, weight, height and ethnicity are described in Table 1 (mean \pm standard deviation). As a result of the matching there were no significant differences between the participants with and without T2DM at baseline (Table 1).

After 12 weeks on the VLCD, there was significant loss of weight within each group when compared with baseline (T2DM group 115.0 ± 24.4 kg vs 96.7 ± 21.4 kg, $p < 0.0001$; non-T2DM group 117.2 ± 25.8 kg vs 97.3 ± 22.2 kg, $p < 0.0001$). There was a significant difference in weight change (-18.3 ± 7.3 kg vs -19.9 ± 7.0 kg, $p = 0.012$) and BMI change (-6.7 ± 2.9 kg/m² vs -7.1 ± 2.1 kg/m², $p = 0.011$) at 12 weeks between the two groups. Similarly, percent weight loss was significantly greater in the non-T2DM group when compared to the T2DM at 12 weeks ($17.1 \pm 4.4\%$ vs $15.5 \pm 10.0\%$, $p = 0.006$).

There were significant differences in the rate of weight loss between the two groups at certain time points, and overall as shown in Figure 1. Greatest weight loss was achieved after the first week of weight loss where individuals with T2DM lost 4.3 ± 8.2 kg and the non-T2DM lost 3.8 ± 2.3 kg. The least amount of weight loss achieved was in the last week of weight loss where individuals with T2DM lost 0.6 ± 4.9 kg and the non-T2DM lost 0.9 ± 1.7 kg. There was no significant difference in weight loss between the two groups for the first 3 weeks. From week 4 to week 12, weight loss was significantly less in the T2DM group than the non-T2DM group (P values were 0.036, 0.022, 0.015, 0.016, 0.007, 0.015, 0.010, < 0.0001 for weeks 4-12 respectively). Average rate of weight loss was significantly slower in the T2DM group than in the non-T2DM group (-1.27 ± 0.9 kg/week vs -1.47 ± 0.6 kg/week, $p = 0.005$). Interestingly, the difference in weight loss at 12 weeks was reduced slightly when non-Caucasians were removed from the analysis (from 1.6 to 0.4kg) and was no longer significant between the two groups (T2DM group -18.5 ± 7.4 kg vs non-T2DM group -19.9 ± 7.1 kg; $p = 0.075$).

A secondary analysis was carried out by comparing the outcomes by gender (Table 2). In both the T2DM and non T2DM groups, men were taller and heavier than their female counterpart but BMI was not significantly different. Weight change at 12 weeks was significantly greater in males than in females for both the T2DM and non-T2DM groups. Percent weight change at 12 weeks was not significantly different between men and women in the T2DM group, but was significantly different in the non-T2DM group ($p = 0.009$).

When females in the T2DM group were compared to females in the non-T2DM, there were no differences in baseline variables, absolute or percentage weight change at 12 weeks (Table 2).

When males in the T2DM group were compared to males in the non-T2DM group, no significant differences were observed at baseline. However, absolute and percentage weight change were significantly greater in the non-T2DM group at 12 weeks (Table 2).

Sensitivity analysis

Following a sensitivity analysis, where individuals were matched exactly for gender, age and within ± 1 BMI unit, there were no significant differences in changes in weight between patients with and without T2DM. Percent weight change at 12 weeks, however, remained significantly greater in the non-T2DM (T2DM 15.7 ± 10.8 % vs non-T2DM 17.0 ± 4.6 %, $p= 0.045$). There were no differences between T2DM and non-T2DM in either absolute weight change or % change in the individual gender groups'

Discussion

Previous observations in individuals with T2DM demonstrated that the weight loss achieved was approximately 50% less than seen in the non-diabetic patient (14,19,21,31-34) when the best diet and lifestyle advice and support is given, either with or without anti-obesity drug therapy. However, there is emerging evidence that individuals with T2DM can achieve similar weight loss to their non-T2DM counterparts (35,36). Our findings are of particular interest because, although this was a retrospective analysis, the results demonstrate that a community based VLCD programme, carried out by trained facilitators, can result in important weight loss. In addition, although we observed a significant difference in weight loss between individuals with and without T2DM, this was an average difference of 1.6 kg which was less than 10% of the non-T2DM weight loss, compared to the previously reported differences of 50%. This emphasises the applicability of this weight loss programme for individuals with T2DM.

Our findings also suggest that there may be a gender influence on the rate of weight change seen in people with T2DM. While women with and without T2DM showed a similar absolute and percentage weight loss over the 12 weeks, men with T2DM had significantly smaller absolute and percentage weight losses than men without T2DM. This difference in gender response to weight loss for patients with and without T2DM has not been reported before. This could be due to a different sample sizes between the two groups; however there may also be differences in medication use or duration of T2DM which we are unable to correct for. Nevertheless, this difference would be interesting to investigate in future studies. Our results also suggested that there is an ethnic difference in the rate of weight loss. Unfortunately, the numbers for non-Caucasian ethnic groups were limited here and we were unable to assess the impact of ethnicity to its full extent.

Our sensitivity analysis demonstrated that there no longer was a difference in absolute and percentage weight loss between individuals with and without T2DM. However, the interpretation of

this sensitivity analysis remains limited due to the reduced power and results should be confirmed in future studies with larger sample size

The weight loss observed in our study was much greater (and more rapid) than observed in previous dietary (36-38) and drug studies (15,39) in patients with T2DM. This is important as recent evidence clearly demonstrates the implications of weight loss in terms of possible benefits to insulin sensitivity. Lim et al (40) demonstrated that following a VLCD, the resulting acute negative energy balance reverses T2DM by normalising both hepatic insulin sensitivity and beta cell function through the reduction of fat in the liver and pancreas. This is in line with our previous findings which demonstrated improvements in liver enzymes following a VLCD (25). It seems likely that these improvements would occur earlier with a VLCD, where rapid weight loss is achieved, as compared to gradual weight loss, but this remains to be determined. In addition, Anderson et al (41) also demonstrated that after twelve weeks of an energy-restricted diet, significant improvements in fasting plasma glucose, serum cholesterol, serum triacylglycerols, systolic blood pressure, and diastolic blood pressure were observed. They also commented that larger weight losses were associated with larger reductions in these values (41), and greater weight loss maintenance (42).

It was interesting to observe that the T2DM lost weight more rapidly during the first 2-3 weeks and then slowed down compared to non-T2DM group. A similar observation was made by Baker et al (35) who suggested that this may have been in relation to reversal of sodium retention associated with hyperinsulinemia, or greater reductions in glycogen storage.

One of the main limitations of this study was the lack of information on medication as well as changes in glycaemia and insulin sensitivity. Information about these two aspects would have shed more light on the effects of acute weight loss on the potential reversal of the disease. Nevertheless, as mentioned above, there is evidence in the literature to support such beneficial effects. The lack of information on medications is also of importance in terms of ability to lose weight. Although insulin dose is halved prior to engaging on the VLCD, some patients may have remained on insulin which would have limited the magnitude of the weight loss. Also, there was no information available on frequency of hypoglycaemia, the treatment of which would be expected to attenuate weight loss in these individuals.

In addition, glucose tolerance status for the individuals included in the matched non-diabetic group was not verified. This may have resulted in the inclusion of individuals with undiagnosed type 2 diabetes in the non-diabetic group which in turn may have diminished the difference between the two groups.

Another limitation of this study was the lack of assessment of changes in physical activity, and this should be addressed in future research. Nevertheless, given the average BMIs of both groups was

greater than 40kg/m², it is unlikely that individuals in this study were able to undertake the regular exercise required to achieve weight loss (43).

Finally, we are aware that there may be bias introduced by the selection of individuals who completed twelve weeks of weight loss, which therefore renders an intention to treat analysis impossible. However, this does assess the actual efficacy of the intervention when individuals are able adhere to it.

Conclusion

Unlike standard dietary, lifestyle and pharmacological approaches, the use of VLCD approaches for weight management in T2DM can achieve more than 90% of the weight loss seen in obese individuals without T2DM. The amount of weight lost (>15% of start weight) is known to be associated with the reversal of the diabetic state to either impaired fasting glycaemia or normal glucose metabolism. VLCD therapy therefore offers approaches to dealing with T2DM and could be used as part of therapy in obese T2DM.

Conflicts of interest

CR has received lecture honoraria and has attended national/international meetings as a guest of LighterLife Ltd, UK.

CR, IB have been involved with other companies with an interest in obesity.

IB, KLJ, CJ, SL and LD are employed by LighterLife Ltd, UK. IM was an adviser to LighterLife Ltd, UK

Acknowledgements

Funding for this study was provided by LighterLife Ltd, UK.

CR and IB designed the study. Data were collected by SL, CJ, LD. Data analysis and writing of manuscript were carried out by CR. CR, IB, IM and KLJ interpreted the data and commented on drafts of the manuscript. All authors had final approval of the submitted and published versions.

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Table 1 – Baseline characteristics of participants

Variable	All (710)	T2DM (n=355)	No-T2DM (n=355)
Gender			
M	204	102	102
F	506	253	253
Age (years)	54.0 ± 9.1	54.0 ± 9.1	54.0 ± 9.1
Height (m)	1.67 ± 0.1	1.67 ± 0.1	1.67 ± 0.1
Weight (kg)	116.1 ± 25.1	115.0 ± 24.4	117.2 ± 25.8
BMI (kg/m ²)	41.6 ± 8.1	41.5 ± 8.6	41.7 ± 7.5
BMI categories (kg/m ²)			
30.0 -34.9	129	68	61
35.0 – 39.9	222	113	109
40.0 – 44.9	169	81	88
45.0 – 49.9	109	53	56
50.0+	81	40	41
Ethnicity			
Black African	1	1	0
Black Caribbean	3	3	0
Black Other	6	4	2
Caucasian	619	305	314
Chinese	1	1	0
Indian	14	12	2
Pakistani	9	5	4
Undisclosed	57	24	33

Measurements are reported as absolute numbers or as means ± standard deviation); BMI – body mass index

Table 2: Comparison of outcomes by gender.

	T2DM			Non-T2DM			P between groups (males)	P between groups (females)
	Males	Females	P value	Males	Females	P value		
Age (years)	54.2 ± 9.3	53.9 ± 9.1	0.787	54.2 ± 9.3	53.9 ± 9.1	0.776	0.989	0.996
Height (m)	1.78 ± 0.06	1.62 ± 0.07	<0.001	1.77 ± 0.06	1.62 ± 0.06	<0.001	0.962	0.526
Weight (kg)	126.8 ± 25.9	110.2 ± 22.1	<0.001	130.2 ± 25.1	112.0 ± 24.2	<0.001	0.467	0.418
BMI (kg/m ²)	41.3 ± 11.0	41.6 ± 7.5	0.190	41.1 ± 7.4	42.0 ± 7.6	0.250	0.604	0.540
Weight change at 12 weeks (kg)	-20.3 ± 9.3	-17.4 ± 6.2	0.01	-23.7 ± 8.6	-18.4 ± 5.6	<0.001	0.020	0.173
% weight change at 12 weeks	14.5 ± 17.1	15.9 ± 4.9	0.878	18.1 ± 4.9	16.7 ± 4.2	0.009	0.014	0.116

Measurements are reported as means ± standard deviation; BMI – body mass index

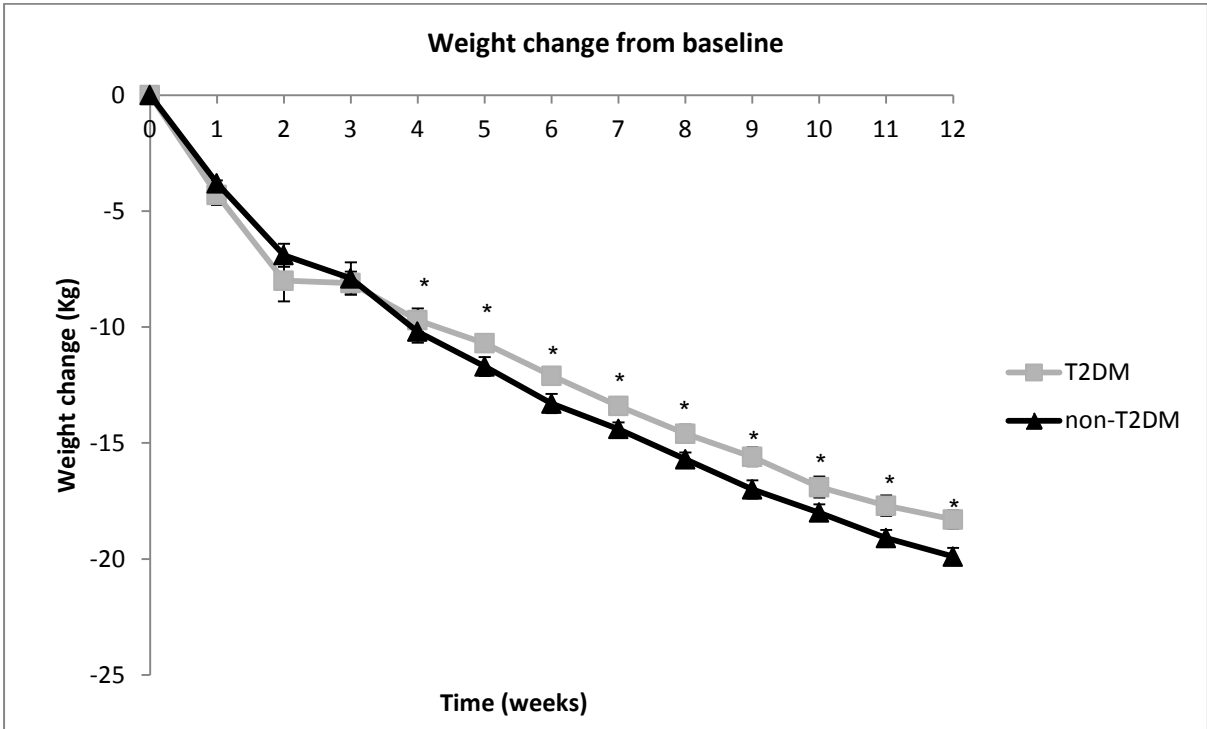


Figure 1: Weekly weight change for patients with and without type 2 diabetes mellitus (T2DM) following a very low calorie diet for 12 weeks. * displays a significant difference in weight change between the two groups (P < 0.05).