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# Impact of compliance on weight loss and health profile in a very low energy diet program

## Background

Although intuitive, little data links program compliance with weight loss and health profile changes in obese Australians.

## Methods

Obese males (n=308) and females (n=734) from one clinic using a very low energy diet intervention were studied over 26 weeks. Physical and health profiles were assessed. Low compliance completed 1–12 weeks, medium 13–20 weeks and high 21–26 weeks.

## Objective

Overall, 52% achieved high compliance (females: 53%, males: 49%). Greater compliance was associated with greater weight loss and health profile changes in both genders. Mean male weight loss approximated 12 kg, 21 kg and 26 kg with low, medium and high compliance; mean female values were 8 kg, 15 kg and 20 kg. Body mass index, waist-hip ratios, and blood pressure, cholesterol, triglyceride and glucose changes were all more marked with high compliance.

## Discussion

Unsurprisingly, high compliance in both genders was consistently associated with more substantial reductions (>15%) of body weight and greater health profile improvements.

**Keywords:** obesity; research; caloric restriction; diet therapy; patient compliance



Worldwide, 1 billion people are overweight, with 30% being obese.<sup>1</sup> In Australia, recent data reported 19% of males and 22% of females as obese.<sup>2</sup> With the disease burden associated with obesity, health care costs are concerning.<sup>2–5</sup> Commonly, treatment for obesity is a very low energy diet (VLED). These have been researched since the 1920s,<sup>6–10</sup> with VLEDs inducing significant weight loss and improving cardiovascular risk factors.<sup>10–12</sup> Often, VLEDs are used in small groups, with studies typically reporting 70–80% of female participants.<sup>9,11,13</sup> However, Adams<sup>14</sup> found males participating in group sessions usually lost more weight than females. Furthermore, there is some data demonstrating that attendance at more group sessions correlates to greater weight loss.<sup>14</sup>

There is little Australian literature linking compliance differences with weight loss and health profile changes. A lack of research evaluating commercial weight loss programs has also recently been emphasised.<sup>6</sup> Therefore our aim was to assess compliance, weight, and health profile changes from a VLED in obese males and females attending a private clinic in Perth, Western Australia.

## Methods

Obese females (n=734) and males (n=308) were retrospectively analysed by arrangement with the clinic. Before treatment all were medically evaluated by the clinic doctor: medical history, resting electrocardiogram (ECG), urinalysis and fasting blood profile. Program entry required a

body mass index (BMI) of 30 kg/m<sup>2</sup> or greater, with no contraindications to treatment (recent myocardial infarction or major surgery, current steroid use, eating disorders, type 1 diabetes, pregnancy, lactose intolerance and certain medications). Clinic entry was by self referral, a friend, or by the participant's general practitioner. All participants had given informed consent, allowing their data to be used for research and agreement to undertake the program.

All participants set out to attend the clinic for 26 consecutive weeks, but could withdraw at any stage. All received the same treatment program in small groups (n=8–10). The program was similar to previous VLED studies<sup>13</sup> and complied with Australian guidelines.<sup>15</sup> Both genders were managed the same within their group, although there was a 70/30% female bias.

For weeks 1–12 all participants consumed Optifast 800 (Novartis®), which replaced all normal food, providing 800 kcal/day (3360 kJ) (70 g protein, 13 g fat, 100 g carbohydrate) and 100% of the recommended daily allowance of vitamins, minerals and essential elements. In weeks 13–20, normal food gradually replaced the number of sachets used weekly. By week 20, all participants were consuming 1100–1200 kcal/day of normal food, within an eating plan. In weeks 21–26 (maintenance) participants consumed 1200–1300 kcal/day, attending the clinic weekly. In weeks 1–20, participants were examined weekly by the clinic doctor and nurse, with the full medical evaluation performed again in week 26.

Weight (±100 g) and resting blood pressure (BP) were measured weekly, but girth (waist and hip)<sup>16</sup> and blood measures were taken only in weeks 1, 12, 20 and 26, representing the start and end of program phases. Height was measured by a wall mounted tape measure for

calculation of BMI (kg/m<sup>2</sup>). Systolic and diastolic BP were measured (right arm while seated) using a mercury column sphygmomanometer. Blood samples were taken (12 hour fast) for cholesterol, triglyceride and glucose levels then analysed at the same pathology laboratory.

Data are shown as proportion or mean ± 95% CI. Independent and dependent t-tests were used, with significance accepted at *p*<0.05. Odds ratios were also calculated on participants who lost

15% or more of their initial body weight. Program compliance was defined as low (weeks 1–12), medium (weeks 13–20) or high (weeks 21–26).

The University of Western Australia Ethics Committee approved the study.

### Results

At entry men were older, heavier and taller than women (Table 1). Overall, 52% of participants completed the full program and compliance was

similar in both genders (Table 1).

Table 2 shows 81% of high compliance males lost 15% or more of initial weight, compared to 64% and 21% for medium and low compliance. High compliance males were 2.4 times (compared to medium) and 15.5 times (low) more likely to achieve this weight loss. For high compliance females, 77% lost 15% or more of their initial weight, compared to 50% and 4% for medium and low compliance, and high

**Table 1. Sample characteristics at program entry by gender and program compliance, expressed as mean (95% CI)**

	Low compliance (1–12 weeks)	Medium compliance (13–20 weeks)	High compliance (21–26 weeks)	Total sample
<b>Men</b>	<b>(n=61)</b>	<b>(n=96)</b>	<b>(n=151)</b>	<b>(n=308)</b>
Age (years)	44.9 (42.4–47.5)	43.4 (41.3–45.5)	45.3 (43.5–47.0)	44.6 (43.4–45.8)
Weight (kg)	124.2 (119.3–129.0)	121.0 (116.5–125.4)	125.1 (121.4–128.9)	123.6 (121.2–126.1)
Height (cm)	178.5 (177.0–179.9)	177.7 (176.3–179.0)	179.0 (177.9–180.1)	178.5 (177.7–179.2)
BMI (kg/m <sup>2</sup> )	39.0 (37.5–40.5)	38.3 (37.0–39.6)	39.0 (38.0–40.0)	38.8 (38.1–39.5)
<b>Women</b>	<b>(n=148)</b>	<b>(n=199)</b>	<b>(n=387)</b>	<b>(n=734)</b>
Age (years)	39.4 (37.5–41.4)*	41.8 (40.2–43.4)	42.4 (41.3–43.5)	41.6 (40.8–42.5)
Weight (kg)	102.0 (99.2–104.9)	101.3 (98.9–103.7)	103.9 (102.2–105.6)	102.8 (101.6–104.1)
Height (cm)	165.4 (164.2–166.6)	164.9 (164.0–165.9)	165.1 (164.4–165.7)	165.1 (164.6–165.6)
BMI (kg/m <sup>2</sup> )	37.3 (36.3–38.2)	37.2 (36.4–38.0)	38.1 (37.5–38.7)	37.7 (37.3–38.1)

\* Women: low vs. high compliance (*p*<0.01)

**Table 2. Weight loss (as a percentage of initial weight) by gender and program compliance, expressed as percentage of sample**

Weight loss (%)	Low compliance (1–12 weeks)	Medium compliance (13–20 weeks)	High compliance (21–26 weeks)	Total sample
<b>Men</b>	<b>(n=61)</b>	<b>(n=96)</b>	<b>(n=151)</b>	<b>(n=308)</b>
<10.00	57.4	16.7	4.0	18.5
10.01–15.00	21.3	19.8	15.2	17.9
15.01–20.00	14.8	29.2	26.5	25.0
20.01–25.00	4.9	22.9	29.1	22.4
25.01–30.00	1.6	10.4	18.5	12.7
30.01+	0.0	1.0	6.6	3.6
Total	100.0	100.0	100.0	100.0
<b>Women</b>	<b>(n=148)</b>	<b>(n=199)</b>	<b>(n=387)</b>	<b>(n=734)</b>
<10.00	66.2	25.1	5.7	23.2
10.01–15.00	29.7	25.1	17.3	21.9
15.01–20.00	3.4	27.6	31.5	24.8
20.01–25.00	0.7	17.1	29.5	20.3
25.01–30.00	0.0	4.5	13.2	8.2
30.01+	0.0	0.5	2.8	1.6
Total	100.0	100.0	100.0	100.0

compliance females were 3.4 times (medium) and 79.2 times (low) more likely to achieve this weight loss.

Table 3 demonstrates the weight and health profile changes in detail with several significant

factors. Mean male weight loss approximated 12, 21 and 26 kg with low, medium and high compliance; female values were 8, 15 and 20 kg. Initial BMI (>37 kg/m<sup>2</sup>) fell to 34–35 kg/m<sup>2</sup> with low compliance and to 30–32 kg/m<sup>2</sup>

(medium and high) in both genders. Male waist-hip ratio ( $\approx$ 1.00 at entry) reduced ( $p<0.05$ ) to 0.97 with low compliance and to 0.94 (medium and high). Female waist-hip ratio decreased ( $p<0.05$ ) from 0.83–0.84 at entry to 0.81–0.82 across all

**Table 3. Change in body weight, girth and health status by gender and program compliance, expressed as mean (95% CI)**

	n	Low compliance (1–12 weeks)		n	Medium compliance (13–20 weeks)		n	High compliance (21–26 weeks)	
		Before	After		Before	After		Before	After
<b>Men</b>									
Weight (kg)	61	124.2 (119.3–129.0)	111.8 (107.4–116.3)	96	121.0 (116.5–125.4)	100.1* (96.5–103.6)	151	125.1 (121.4–128.9)	99.2** (96.2–102.2)
Initial BMI (kg/m <sup>2</sup> )	61	39.0 (37.5–40.5)	35.1 (33.8–36.5)	96	38.3 (37.0–39.6)	31.7 (30.6–32.7)	151	39.0 (38–40)	31.0** (30.1–31.8)
Waist (cm)	9	123.7 (113.4–133.9)	112.2 (102.0–122.3)	49	122.2 (118.1–126.3)	103.8 (100.3–107.3)	137	125.2 (122.8–127.6)	104.1** (101.6–106.6)
Hip (cm)	9	122.1 (111.9–132.3)	115.7 (105.7–125.6)	49	121.8 (117.8–125.8)	110.8 (108.1–113.5)	137	124.1 (121.8–126.5)	110.6** (108.6–112.6)
Waist/hip ratio	9	1.01 (0.97–1.05)	0.97 (0.93–1.01)	49	1.00 (0.99–1.02)	0.94 (0.92–0.95)	137	1.01 (1.00–1.02)	0.94 (0.93–0.95)
Systolic BP (mmHg)	58	137 (132–141)	126 (121–130)	94	140 (136–144)	128 (125–132)	150	144 (141–146)	127 (125–130)
Diastolic BP (mmHg)	50	86 (83–88)	80 (78–83)	85	90 (88–93)	82 (80–84)	139	89 (87–91)	79** (77–80)
Cholesterol (mmol/L)	9	5.7 (5.1–6.3)	5.4 (4.8–6.0)	57	5.8 (5.6–6.1)	5.3 (5.0–5.5)	135	5.9 (5.7–6.1)	5.0** (4.8–5.2)
Triglycerides (mmol/L)	8	1.9 (1.0–2.9)	2.0 (1.1–2.9)	58	1.8 (1.6–1.9)	1.2 (1.1–1.4)	133	2.2 (1.9–2.5)	1.1** (1.00–1.22)
Fasting glucose (mmol/L)	44	5.5 (5.3–5.8)	5.1 (4.8–5.3)	86	5.8 (5.3–6.2)	5.3 (5.1–5.5)	147	5.9 (5.6–6.1)	5.3 (5.1–5.5)
<b>Women</b>									
Weight (kg)	148	102.0 (99.2–104.9)	94.1 (91.4–96.9)	199	101.3 (98.9–103.7)	86.6 (84.3–88.9)	387	103.9 (102.2–105.6)	83.8 (82.3–85.3)
Initial BMI (kg/m <sup>2</sup> )	148	37.3 (36.3–38.2)	34.4 (33.5–35.3)	199	37.2 (36.4–38.0)	31.8* (31.0–32.6)	387	38.1 (37.5–38.7)	30.7** (30.2–31.2)
Waist (cm)	27	102.7 (96.5–108.9)	96.6 (90.4–102.7)	105	103.2 (100.8–105.5)	91.8* (89.6–94.0)	345	105.8 (104.6–107.1)	90.1** (88.9–91.3)
Hip (cm)	27	122.3 (117.0–127.6)	116.7 (111.2–122.2)	105	123.4 (121.4–125.4)	111.7* (109.7–113.8)	343	127.0 (125.7–128.3)	111.2** (110.0–112.4)
Waist/hip ratio	27	0.84 (0.81–0.86)	0.82 (0.80–0.85)	105	0.84 (0.82–0.85)	0.82 (0.81–0.83)	343	0.83 (0.83–0.84)	0.81 (0.80–0.82)
Systolic BP (mmHg)	132	129 (126–132)	122 (120–125)	190	130 (127–132)	120 (118–123)	378	131 (129–132)	120** (119–121)
Diastolic BP (mmHg)	112	81 (79–83)	77 (75–79)	161	81 (80–82)	76 (75–78)	364	83 (82–84)	75** (74–76)
Cholesterol (mmol/L)	19	5.9 (5.4–6.4)	5.5 (5.0–6.0)	99	5.6 (5.4–5.8)	5.1 (4.9–5.3)	356	5.4 (5.3–5.5)	5.0 (4.9–5.1)
Triglycerides (mmol/L)	17	1.9 (1.2–2.5)	1.2 (0.8–1.6)	95	1.4 (1.2–1.6)	1.1 (0.9–1.2)	351	1.3 (1.3–1.4)	1.0 (0.9–1.1)
Fasting glucose (mmol/L)	95	5.3 (5.1–5.5)	5.3 (5.1–5.5)	176	5.4 (5.2–5.5)	5.2 (5.1–5.3)	377	5.4 (5.3–5.5)	5.0** (4.9–5.1)

\*  $p<0.05$ , medium vs. low; \*\*  $p<0.05$ , high vs. low; #  $p<0.05$ , high vs. medium

compliance levels. Overall, BP decreased ( $p < 0.05$ ) from 141/89 to 127/80 in men and from 130/82 to 121/76 in women. Blood cholesterol, triglyceride and glucose also reduced ( $p < 0.05$ ) in both genders, more so in medium or high compliance.

## Discussion

With obesity levels rising in Australia<sup>2</sup> evidence based treatment is increasingly important. Commercial weight loss clinics now operate in many areas, but research evaluation of their outcomes is lacking.<sup>6</sup> For medical practitioners and other health professionals working in the area of obesity, data on the specific regimens and success of clinics may assist in counselling obese individuals.

Our results show the effectiveness of high program compliance in providing greater improvements in weight and health profiles. While not unexpected that greater compliance produced better outcomes, the odds ratios may provide a powerful message for clinicians. With high compliance, men were 2.4 times and women 3.4 times more likely to lose 15% or more of their initial weight than with medium compliance, and 15.5 times and 79.2 times more likely to achieve this weight loss compared to low compliance participants. The results also show consistent trends for greater positive changes in health measures (ie. BP, girth, blood cholesterol, triglycerides and glucose) with high compliance compared to low compliance.

Weight losses recorded here with high compliance ( $\approx 20$  kg) resemble other VLED programs of similar duration.<sup>9,11,17–18</sup> However, it is acknowledged that within 3–5 years many program participants have regressed toward or returned to their initial weight.<sup>19</sup> Unfortunately, the clinic database used prevented any follow up, but there is no evidence that VLED programs lead to worse long term weight outcomes than other treatments.<sup>17,20</sup>

Modest weight loss (5–10% of initial weight) has positive effects on BP, cholesterol and glucose levels.<sup>20–22</sup> Substantial weight loss (15–20% of initial weight) can reverse type 2 diabetes risk within 1 year of diagnosis.<sup>22–23</sup> Our data indicated positive changes in these measures, particularly with high compliance, although these obese participants were not markedly hypertensive or high in cholesterol,

triglycerides or fasting glucose at entry.

It is acknowledged that a potential limitation of this study is that participants were all drawn from one clinic and could only be assessed over a 6 month period; most were from higher socioeconomic groups, which may partly explain their relatively normal coronary risk and health profile, with the exception of obesity; and that 65% had private health insurance.

## Conclusion

The results of this study emphasise the importance of high program compliance in providing greater improvements in weight and health profiles. The odds ratios presented for losing 15% or more of initial body weight may provide a powerful and practical message for clinicians to use when seeing obese patients. Strategies to maximise compliance in weight loss programs and comparisons of different approaches to managing obesity require ongoing research.

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