

## Obesity

Identification, assessment and management of  
overweight and obesity in children, young people and  
adults

*Update of CG43*

*Appendix O*

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**Disclaimer**

Healthcare professionals are expected to take NICE clinical guidelines fully into account when exercising their clinical judgement. However, the guidance does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of each patient, in consultation with the patient and/or their guardian or carer.

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## Appendix O: GRADE tables

### O.1 Very-low-calorie diets (VLCD)

#### O.1.1 Effectiveness

**Table 1: Clinical evidence profile: VLCD versus standard dietary advice for overweight and obese people**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	VLCD	Standard dietary advice	Relative (95% CI)	Absolute		
<b>% 'ideal' weight loss (follow-up mean 18 months; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	57	53	-	MD 2.1 higher (3.4 lower to 7.6 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Withdrawals (follow-up 12-24 months)</b>												
7	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	53/247 (21.5%)	22.9%	RR 0.86 (0.63 to 1.18)	32 fewer per 1000 (from 85 fewer to 41 more)	⊕○○○ VERY LOW	CRITICAL
<b>Weight in kg, change (start of study to end of weight maintenance period) (follow-up 12-24 months; Better indicated by lower values)</b>												
7	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	194	179	-	MD 0.96 lower (1.66 to 0.25 lower)	⊕⊕○○ LOW	IMPORTANT
<b>Weight in BMI, change (start of study to end of VLCD period) (follow-up mean 12 months; Better indicated by lower values)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	55	57	-	MD 2.09 lower (3.29 to 0.9 lower)	⊕⊕○○ LOW	IMPORTANT

Weight in BMI, change (start of study to end of weight maintenance period) (follow-up mean 12 months; Better indicated by lower values)												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	17	16	-	MD 1.26 lower (4.17 lower to 1.65 higher)	⊕○○○ VERY LOW	IMPORTANT
Weight in kg, change (start of study to end of VLCD period) - intermittent VLCD (follow-up 10-52 weeks; Better indicated by lower values)												
5	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	136	129	-	MD 4.3 lower (5.99 to 2.62 lower)	⊕○○○ VERY LOW	IMPORTANT

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias

<sup>2</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs

<sup>3</sup> Downgraded due to heterogeneity, I<sup>2</sup>= 83%, P= 0.0001, unexplained by subgroup analysis

### O.1.2 Safety

**Table 2: Clinical evidence profile: VLCD vs LCD for overweight or obese people**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	VLCD	LCD (both with behavioural therapy)	Relative (95% CI)	Absolute		
Binge eating score (follow-up mean 52 weeks; measured with: Binge eating scale (BES); range of scores: 0-46; Better indicated by lower values)												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	23	17	-	MD 6.32 higher (1.68 to 10.96 higher)	⊕○○○ VERY LOW	CRITICAL
Depression score (follow-up 4-5 months; measured with: Beck's Depression Inventory (BDI); Better indicated by lower values)												
2	randomised trials	very serious <sup>1</sup>	serious <sup>3</sup>	no serious indirectness	very serious <sup>2</sup>	none	24	22	-	MD 2.03 lower (11.09 lower to 7.03 higher)	⊕○○○ VERY LOW	CRITICAL

<b>Depression score (follow-up mean 52 weeks; measured with: Beck's Depression Inventory (BDI); Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	23	17	-	MD 3.32 higher (1.22 lower to 7.86 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Depressive tendencies (follow-up mean 16 weeks)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	6/86 (7%)	3.4%	RR 2.07 (0.53 to 8.01)	36 more per 1000 (from 16 fewer to 238 more)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life</b>												
0	No evidence available											CRITICAL
<b>Constipation (follow-up mean 16 weeks)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>2</sup>	none	28/86 (32.6%)	28.1%	RR 1.16 (0.74 to 1.82)	45 more per 1000 (from 73 fewer to 230 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Gall stones</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	4/6 (66.7%)	0%	OR 17.97 (1.86 to 173.95)	-	⊕⊕○○ LOW	IMPORTANT
<b>Serum uric acid (follow-up mean 8 weeks; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	20	25	-	MD 23.6 lower (72.17 lower to 24.97 higher)	⊕○○○ VERY LOW	IMPORTANT
<b>Marked serum acid levels during the study (follow-up mean 8 weeks)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	7/20 (35%)	0%	OR 13.53 (2.72 to 67.32)	-	⊕○○○ VERY LOW	IMPORTANT
<b>Diarrhoea (follow-up mean 16 weeks)</b>												
1	randomised	very	no serious	no serious	very	none	4/86	3.4%	RR 1.38 (0.32	13 more per 1000	⊕○○○	IMPORTANT

	trials	serious <sup>1</sup>	inconsistency	indirectness	serious <sup>2</sup>		(4.7%)		to 5.99)	(from 23 fewer to 170 more)	VERY LOW	
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1 Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias

2 Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.

3 Downgraded by one increment heterogeneity (I<sup>2</sup>=50%, p= 0.04), unexplained by subgroup analysis.

4 Study size very small.

### O.1.3 Maintenance

**Table 3: Clinical evidence profile: standard or pre-packaged food re-feeding (time dependent or weight dependent) (all with behaviour therapy)**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Behaviour and refeeding	Control	Relative (95% CI)	Absolute		
<b>Weight in kg - STD food re-feeding (TD) vs STD re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	45	41	-	MD 0.4 higher (4.61 lower to 5.41 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Weight in kg - STD food re-feeding (TD) vs PPG re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	45	42	-	MD 5.4 lower (12 lower to 1.2 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Weight in kg - STD food re-feeding (WD) vs PPG food re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	41	42	-	MD 5.8 lower (12.34 lower to 0.74 higher)	⊕○○○ VERY LOW	CRITICAL



<b>Weight in kg - PPG re-feeding (TD) vs PPG food re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	34	42	-	MD 3.2 lower (9.87 lower to 3.47 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Withdrawals - STD food re-feeding (TD) vs STD re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	3/50 (6%)	4.3%	RR 1.41 (0.25 to 8.07)	18 more per 1000 (from 32 fewer to 304 more)	⊕○○○ VERY LOW	CRITICAL
<b>Withdrawals - STD food re-feeding (TD) vs PPG re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	3/50 (6%)	10.2%	RR 0.59 (0.15 to 2.33)	42 fewer per 1000 (from 87 fewer to 136 more)	⊕○○○ VERY LOW	CRITICAL
<b>Withdrawals - STD food re-feeding (WD) vs PPG food re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	2/47 (4.3%)	10.2%	RR 0.42 (0.09 to 2.05)	59 fewer per 1000 (from 93 fewer to 107 more)	⊕○○○ VERY LOW	CRITICAL
<b>Withdrawals - PPG re-feeding (TD) vs PPG food re-feeding (WD) (all with behaviour therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	7/45 (15.6%)	10.2%	RR 1.52 (0.52 to 4.46)	53 more per 1000 (from 49 fewer to 353 more)	⊕○○○ VERY LOW	CRITICAL
<b>Weight in kg - STD food vs PPG food re-feeding (all with behavioural therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	86	76	-	MD 3.59 higher (0.47 lower to 7.65 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Weight in kg - TD re-feeding vs WD re-feeding (all with behavioural therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 28 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	79	83	-	MD 0.9 higher (3.11 lower to 4.9 higher)	⊕○○○ VERY LOW	CRITICAL

Withdrawals - STD food versus PPG food (all with behavioural therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	5/97 (5.2%)	12.9%	RR 0.4 (0.15 to 1.09)	77 fewer per 1000 (from 110 fewer to 12 more)	⊕○○○ VERY LOW	CRITICAL
Withdrawals - TD re-feeding versus WD re-feeding (all with behavioural therapy) (VLCD 3 mo + main. 9 mo + 6 mo) (follow-up mean 18 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	10/95 (10.5%)	7.2%	RR 1.49 (0.6 to 3.72)	35 more per 1000 (from 29 fewer to 196 more)	⊕○○○ VERY LOW	CRITICAL
Quality of life												
0	No evidence available											CRITICAL

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and by two increments if the majority of the evidence was at very high risk of bias.

<sup>2</sup> The majority of the evidence had indirect outcomes.

<sup>3</sup> Downgraded by one increment if the confidence interval cross one MID or by two increments if the confidence interval crossed both MIDs.

**Table 4: Clinical evidence profile: hypocaloric diets with/without VLCD or meal replacement**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hypocaloric diets with or without VLCD	Control	Relative (95% CI)	Absolute		
% weight in kg - HD (1600kcal of which 220kcal VLCD) versus HD (1600kcal) (VLCD 3 mo + 12 mo) (follow-up mean 1 years; Better indicated by lower values)												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>2</sup>	none	31	29	-	MD 3 lower (7.92 lower to 1.92 higher)	⊕○○○ VERY LOW	CRITICAL
Weight in kg - HD (1600kcal) versus Meal replacement (1600kcal + 238kcal VLCD) (VLCD 2 mo + 24 mo) (follow-up mean 28 months; Better indicated by lower values)												
1	randomised trials	very serious <sup>3</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	11	15	-	MD 0.2 lower (12.56 lower to 12.16 higher)	⊕○○○ VERY LOW	CRITICAL

Withdrawals - HD (1600kcal of which 220kcal VLCD) versus HD (1600kcal) (VLCD 3 mo + 12 mo) (follow-up mean 1 years)												
1	randomised trials	very serious <sup>3</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	5/31 (16.1%)	2/29 (6.9%)	RR 2.34 (0.49 to 11.13)	92 more per 1000 (from 35 fewer to 699 more)	⊕○○○ VERY LOW	CRITICAL
								6.9%		92 more per 1000 (from 35 fewer to 699 more)		
Withdrawals - HD (1600kcal) versus Meal replacement (1600kcal + 238kcal VLCD) (VLCD 2 mo + 24 mo) (follow-up mean 28 months)												
1	randomised trials	very serious <sup>3</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	16/27 (59.3%)	12/27 (44.4%)	RR 1.33 (0.79 to 2.25)	147 more per 1000 (from 93 fewer to 556 more)	⊕⊕○○ LOW	CRITICAL
								44.4%		147 more per 1000 (from 93 fewer to 555 more)		
Quality of life												
0	No evidence available											CRITICAL

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

<sup>2</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments of the confidence interval crossed both MIDS

<sup>3</sup> No explanation was provided

<sup>4</sup> The majority of evidence had indirect outcomes

**Table 5: Clinical evidence profile: exercise and dietary counselling vs dietary counselling only**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Dietary counselling with or without exercise	Control	Relative (95% CI)	Absolute		
Weight in kg - DC + walking (1000 kcal/week) versus DC only (VLCD 3 mo + main. ~9 mo + 24 mo) (follow-up mean 24 months; Better indicated by lower values)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	24	27	-	MD 5.8 lower (11.88 lower to 0.28 higher)	⊕○○○ VERY	CRITICAL

												LOW	
<b>Weight in kg - DC + walking (1200 kcal/week) versus DC only (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months; Better indicated by lower values)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	20	22	-	MD 1.3 higher (6.87 lower to 9.47 higher)	⊕○○○ VERY LOW		CRITICAL
<b>Weight in kg - DC + walking (2000 kcal/week) versus DC only (VLCD 3 mo + main. ~9 mo + 24 mo) (follow-up mean 24 months; Better indicated by lower values)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	23	27	-	MD 2.3 lower (9.53 lower to 4.93 higher)	⊕○○○ VERY LOW		CRITICAL
<b>Weight in kg - DC + resistance training versus DC only (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months; Better indicated by lower values)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	26	22	-	MD 0.8 lower (7.14 lower to 5.54 higher)	⊕○○○ VERY LOW		CRITICAL
<b>Weight in kg - DC + walking (1000 kcal/week) versus DC +walking (2000 kcal/week) (VLCD 3 mo + main. ~9 mo + 24 mo) (follow-up mean 24 months; Better indicated by lower values)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	24	23	-	MD 3.5 lower (11.43 lower to 4.43 higher)	⊕○○○ VERY LOW		CRITICAL
<b>Weight in kg - DC + walking (1200 kcal/week) versus DC + resistance training (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months; Better indicated by lower values)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	20	26	-	MD 2.1 higher (5.15 lower to 9.35 higher)	⊕○○○ VERY LOW		CRITICAL
<b>Withdrawals - DC + walking (1000 kcal/week) vs DC only (VLCD 3 mo + 24 mo) (follow-up mean 24 months)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	2/26 (7.7%)	6.9%	RR 1.12 (0.17 to 7.36)	8 more per 1000 (from 57 fewer to 439 more)	⊕○○○ VERY LOW		CRITICAL
<b>Withdrawals - DC + walking (1200 kcal/week) vs DC only (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months)</b>													
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	5/25 (20%)	24.1%	RR 0.83 (0.3 to 2.29)	41 fewer per 1000 (from 169 fewer to 311 more)	⊕○○○ VERY LOW		CRITICAL

Withdrawals - DC + walking (2000 kcal/week) versus DC only (VLCD 3 mo + 24 mo) (follow-up mean 24 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	4/27 (14.8%)	6.9%	RR 2.15 (0.43 to 10.79)	79 more per 1000 (from 39 fewer to 676 more)	⊕○○○ VERY LOW	CRITICAL
Withdrawals - DC + resistance training versus DC only (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	2/28 (7.1%)	24.1%	RR 0.3 (0.07 to 1.3)	169 fewer per 1000 (from 224 fewer to 72 more)	⊕○○○ VERY LOW	CRITICAL
Withdrawals - DC + walking (1000 kcal/week) versus DC + walking (2000 kcal/week) (VLCD 3 mo + 24 mo) (follow-up mean 24 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	2/26 (7.7%)	14.8%	RR 0.52 (0.1 to 2.6)	71 fewer per 1000 (from 133 fewer to 237 more)	⊕○○○ VERY LOW	CRITICAL
Withdrawals - DC + walking (1200 kcal/week) versus DC + resistance training (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months)												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	5/25 (20%)	7.1%	RR 2.8 (0.6 to 13.17)	128 more per 1000 (from 28 fewer to 864 more)	⊕○○○ VERY LOW	CRITICAL
Quality of life												
0	No evidence available											CRITICAL

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

<sup>2</sup> The majority of the evidence had indirect outcomes.

<sup>3</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments if the majority of the evidence crossed two MIDs.

**Table 6: Clinical evidence profile: orlistat**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Orlistat	Control	Relative (95% CI)	Absolute		

Weight in kg - DLC + orlistat versus DLC only (VLCD 2 mo + 36 mo) (follow-up mean 3 years; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1</sup>	serious <sup>2</sup>	none	156	153	-	MD 2.4 lower (4.16 to 0.64 lower)	⊕⊕⊕ LOW	CRITICAL
Weight in kg - Orlistat versus meal replacement (VLCD 3 mo + main. ~8 mo) (follow-up mean 1 years; Better indicated by lower values)												
1	randomised trials	very serious <sup>3</sup>	no serious inconsistency	serious <sup>4</sup>	no serious imprecision	none	56	36	-	MD 0.4 lower (8.32 lower to 7.52 higher)	⊕⊕⊕ VERY LOW	CRITICAL
Weight in kg from before VLCD lead in - DLC + orlistat versus DLC only (VLCD 2 mo + 36 mo) (follow-up mean 3 years; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	serious <sup>1</sup>	serious <sup>4</sup>	none	156	153	-	MD 2.2 lower (3.84 to 0.56 lower)	⊕⊕⊕ LOW	IMPORTANT
Withdrawals - DLC + orlistat versus DLC only (VLCD 2 mo + 36 mo) (follow-up mean 3 years)												
1	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	58/156	51/153	RR 1.12 (0.82 to 1.51)	40 more per 1000 (from 60 fewer to 170 more)	⊕⊕⊕⊕ MODERATE	CRITICAL
							(37.2%)	(33.3%)		40 more per 1000 (from 60 fewer to 170 more)		
								33.3%				
Withdrawals - Orlistat versus meal replacement (VLCD 3 mo + main. ~8 mo) (follow-up mean 1 years)												
1	randomised trials	very serious <sup>4</sup>	no serious inconsistency	no serious indirectness	very serious <sup>4</sup>	none	34/90	31/67	RR 0.82 (0.56 to 1.18)	83 fewer per 1000 (from 204 fewer to 83 more)	⊕⊕⊕ VERY LOW	CRITICAL
							(37.8%)	(46.3%)		83 fewer per 1000 (from 204 fewer to 83 more)		
								46.3%				
Quality of life												
0	No evidence available											CRITICAL

<sup>1</sup> The majority of evidence had indirect outcomes

<sup>2</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDS

<sup>3</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

<sup>4</sup> No explanation was provided

**Table 7: Clinical evidence profile: interventions vs no treatment**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Studies against no treatment	Control	Relative (95% CI)	Absolute		
<b>Weight in kg - Fibre versus no treatment (VLCD 2 mo + 14 mo) (follow-up mean 14 months; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	very serious <sup>3</sup>	none	20	11	-	MD 2 higher (6.77 lower to 10.77 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Weight in kg - HP diet (18-20% of energy/day) versus no treatment (VLCD 1 mo + main. 6 mo + 6 mo) (follow-up mean 13 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	31	39	-	MD 2.9 lower (3.39 to 2.41 lower)	⊕⊕○○ LOW	CRITICAL
<b>BMI - Fibre versus no treatment (VLCD 2 mo + 14 mo) (follow-up mean 14 months; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	20	11	-	MD 1.35 higher (2.23 lower to 4.93 higher)	⊕○○○ VERY LOW	IMPORTANT
<b>Withdrawals - Fibre versus no treatment (VLCD 2 mo + 14 mo) (follow-up mean 14 months)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	very serious <sup>3</sup>	none	5/25 (20%)	21.4%	RR 0.93 (0.26 to 3.33)	15 fewer per 1000 (from 158 fewer to 499 more)	⊕○○○ VERY LOW	CRITICAL
<b>Withdrawals - HP diet (18-20% of energy intake/day) versus no treatment (VLCD 1 mo + main. 6 mo + 6 mo) (follow-up mean 13 months)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>3</sup>	none	22/53 (41.5%)	35%	RR 1.19 (0.74 to 1.9)	67 more per 1000 (from 91 fewer to 315 more)	⊕⊕○○ LOW	CRITICAL
<b>Quality of life</b>												
0	No evidence available											CRITICAL

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

<sup>2</sup> The majority of the evidence had indirect outcomes.

<sup>3</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.

**Table 8: Clinical evidence profile: high protein diet vs high carbohydrate diet**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	High protein versus high carbohydrate diet	Control	Relative (95% CI)	Absolute		
<b>Weight in kg - HP diet (30% of energy /day) versus HC diet (VLCD 3 mo + 12 mo) (follow-up mean 15 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	42	40	-	MD 1.3 lower (1.85 to 0.75 lower)	⊕⊕○○ LOW	CRITICAL
<b>Weight in kg including VLCD lead in - HP diet (30% of energy /day) vs. HC diet (VLCD 3 mo + 12 mo) (follow-up mean 15 months; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	serious <sup>3</sup>	no serious imprecision	none	42	40	-	MD 0.5 lower (1.27 lower to 0.27 higher)	⊕⊕○○ LOW	CRITICAL
<b>Withdrawals - HP diet (30% of energy/day) versus HC diet (VLCD 3 mo + 12 mo) (follow-up mean 15 months)</b>												
1	randomised trials	serious <sup>3</sup>	no serious inconsistency	no serious indirectness	very serious <sup>4</sup>	none	34/90 (37.8%)	31/67 (46.3%)	RR 0.82 (0.56 to 1.18)	83 fewer per 1000 (from 204 fewer to 83 more)	⊕○○○ VERY LOW	CRITICAL
								46.3%		83 fewer per 1000 (from 204 fewer to 83 more)		
<b>Quality of life</b>												
0	No evidence available											CRITICAL

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

<sup>2</sup> The majority of evidence had indirect outcomes

<sup>3</sup> No explanation was provided

<sup>4</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments of the confidence interval crossed both MIDS



## O.2 Bariatric surgery in people with type 2 diabetes

**Table 9: Clinical evidence profile: Surgical versus non-surgical management**

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Surgery versus non surgical management	Control	Relative (95% CI)	Absolute		
<b>% weight change (follow-up median 2 years; range of scores: 0-100; Better indicated by lower values)</b>												
5	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	235	182	-	MD 20.54 lower (22.13 to 18.96 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Use of diabetes medications (dichotomous) (follow-up median 3 years)</b>												
2	randomised trials	serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	45/126 (35.7%)	2.5%	RR 0.37 (0.28 to 0.48)	16 fewer per 1000 (from 13 fewer to 18 fewer)	⊕⊕⊕○ MODERATE	CRITICAL
<b>Use of diabetes medications (continuous) (follow-up median 3 years; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	97	40	-	MD 2.14 lower (2.48 to 1.8 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Quality of life</b>												
0	No evidence available											CRITICAL
<b>Remission of diabetes (follow-up median 2 years)</b>												
6	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	144/269 (53.5%)	15/234 (6.4%)	RR 7.26 (4.65 to 11.34)	401 more per 1000 (from 234 more to 663 more)	⊕○○○ VERY LOW	IMPORTANT
<b>Improvement in glycaemic control (continuous) (follow-up median 2 years; Better indicated by lower values)</b>												

5	randomised trials	very serious <sup>1</sup>	no serious inconsistency <sup>3</sup>	no serious indirectness	no serious imprecision	none	236	162	-	MD 1.32 lower (1.60 to 1.04 lower)	⊕⊕⊕⊕ LOW	IMPORTANT
<b>Mortality (follow-up median 1 years)</b>												
6	randomised trials	very serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	no serious imprecision	none	0/269 (0%)	0%	See comment	-	⊕⊕⊕⊕ VERY LOW	IMPORTANT
<b>Weight by BMI (follow-up median 1 years; Better indicated by lower values)</b>												
4	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	139	164	-	MD 4.19 lower (4.62 to 3.76 lower)	⊕⊕⊕⊕ LOW	NOT IMPORTANT
<b>Weight in kg (follow-up median 2 years; Better indicated by lower values)</b>												
5	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	236	162	-	MD 19.48 lower (22.61 to 16.36 lower)	⊕⊕⊕⊕ LOW	NOT IMPORTANT

1 Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias

2 The majority of the evidence included an indirect population (downgrade by one increment) or a very indirect population (downgrade by two increments)

3 There was heterogeneity (I<sup>2</sup>>50%, P<0.04) but this was explained when biliopancreatic diversion (Mingrone 2012) was removed from the results. It was felt appropriate to remove this study for this outcome as this procedure is only very rarely used in the UK.

### O.3 Follow-up care packages after bariatric surgery

Table 10: Clinical evidence profile: care package versus usual care

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nutritional monitoring, avoiding weight regain, and specialist educational support	Nutritional monitoring only	Relative (95% CI)	Absolute		
<b>% excess weight loss (kg) - Immediately post-surgery (36 months follow up) (follow-up mean 3 years; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	very serious <sup>2</sup>	serious <sup>3</sup>	none	15	15	-	MD 26 higher (15.26 to 36.74 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL

<b>% excess weight loss (kg) - Three years post-surgery (12 months follow up) (follow-up mean 12 months; range of scores: 0-100; Better indicated by higher values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	no serious imprecision	none	13	16	-	MD 4.9 higher (2.43 to 7.37 higher)	⊕⊕⊕⊕ LOW	CRITICAL
<b>Weight at 3 years (kg) - Immediately post-surgery (36 months follow up) (follow-up mean 3 years; Better indicated by lower values)</b>												
1	randomised trials	serious <sup>1</sup>	no serious inconsistency	serious <sup>2</sup>	serious <sup>3</sup>	none	15	15	-	MD 18.3 lower (27.73 to 8.87 lower)	⊕⊕⊕⊕ VERY LOW	CRITICAL
<b>Weight at 3 years (kg) - Three years post-surgery (12 months follow up) (follow-up mean 12 months; Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>1</sup>	no serious inconsistency	no serious indirectness	serious <sup>4</sup>	none	13	16	-	MD 3 lower (9.17 lower to 3.17 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL

<sup>1</sup> Downgraded by one increment if the majority of the evidence was at high risk of bias, and downgraded by two increments if the majority of the evidence was at very high risk of bias.

<sup>2</sup> The majority of the population included an indirect population (downgraded by one increment) or a very indirect population (downgraded by two increments).

<sup>3</sup> Downgraded by one increment due to small sample size in the included evidence.

<sup>4</sup> Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.