National Clinical Guideline Centre

Draft for consultation

Obesity

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

Update of CG43

Appendix O

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Draft for Consultation

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Royal College of Physicians

The Royal College of Surgeons of England

RCGP Royal College of General Practitioners

Royal College of Nursing

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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		
% 'ideal' weight loss (follow-up mean 18 months; range of scores: 0-100; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	57	53	-	MD 2.1 higher (3.4 lower to 7.6 higher)	⊕OOO VERY LOW	CRITICAL
Withdrawals (follow-up 12-24 months)												
7	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	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)	⊕OOO VERY LOW	CRITICAL
Weight in kg, change (start of study to end of weight maintenance period) (follow-up 12-24 months; Better indicated by lower values)												
7	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	194	179	-	MD 0.96 lower (1.66 to 0.25 lower)	⊕⊕OO LOW	IMPORTANT
Weight in BMI, change (start of study to end of VLCD period) (follow-up mean 12 months; Better indicated by lower values)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	55	57	-	MD 2.09 lower (3.29 to 0.9 lower)	⊕⊕OO 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[1]	no serious inconsistency	no serious indirectness	serious[2]	none	17	16	-	MD 1.26 lower (4.17 lower to 1.65 higher)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	serious[2]	none	136	129	-	MD 4.3 lower (5.99 to 2.62 lower)	⊕OOO VERY LOW	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] Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs
[3] Downgraded due to heterogeneity, I2= 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[1]	no serious inconsistency	no serious indirectness	serious[2]	none	23	17	-	MD 6.32 higher (1.68 to 10.96 higher)	⊕OOO 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[1]	serious[3]	no serious indirectness	very serious[2]	none	24	22	-	MD 2.03 lower (11.09 lower to 7.03 higher)	⊕OOO VERY LOW	CRITICAL

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

	trials	serious[1]	inconsistency	indirectness	serious[2]		(4.7%)		to 5.99)	(from 23 fewer to 170 more)	VERY LOW	

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 (I2=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		
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	45	41	-	MD 0.4 higher (4.61 lower to 5.41 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	45	42	-	MD 5.4 lower (12 lower to 1.2 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	41	42	-	MD 5.8 lower (12.34 lower to 0.74 higher)	⊕OOO VERY LOW	CRITICAL

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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	34	42	-	MD 3.2 lower (9.87 lower to 3.47 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	3/50 (6%)	4.3%	RR 1.41 (0.25 to 8.07)	18 more per 1000 (from 32 fewer to 304 more)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	3/50 (6%)	10.2%	RR 0.59 (0.15 to 2.33)	42 fewer per 1000 (from 87 fewer to 136 more)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	86	76	-	MD 3.59 higher (0.47 lower to 7.65 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	79	83	-	MD 0.9 higher (3.11 lower to 4.9 higher)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO VERY LOW	CRITICAL
Quality of life												
0	No evidence available											CRITICAL

[1] 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.
[2] The majority of the evidence had indirect outcomes.
[3] 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[1]	no serious inconsistency	no serious indirectness	serious[2]	none	31	29	-	MD 3 lower (7.92 lower to 1.92 higher)	⊕OOO 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[3]	no serious inconsistency	serious[4]	no serious imprecision	none	11	15	-	MD 0.2 lower (12.56 lower to 12.16 higher)	⊕OOO 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[3]	no serious inconsistency	no serious indirectness	serious[3]	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)	⊕OOO 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[3]	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)	⊕⊕OO LOW	CRITICAL
								44.4%		147 more per 1000 (from 93 fewer to 555 more)		
Quality of life												
0	No evidence available											CRITICAL

[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 of the confidence interval crossed both MIDS
[3] No explanation was provided
[4] 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[1]	no serious inconsistency	serious[2]	serious[3]	none	24	27	-	MD 5.8 lower (11.88 lower to 0.28 higher)	⊕OOO VERY	CRITICAL

											LOW	
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	20	22	-	MD 1.3 higher (6.87 lower to 9.47 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	23	27	-	MD 2.3 lower (9.53 lower to 4.93 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	26	22	-	MD 0.8 lower (7.14 lower to 5.54 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	24	23	-	MD 3.5 lower (11.43 lower to 4.43 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	20	26	-	MD 2.1 higher (5.15 lower to 9.35 higher)	⊕OOO VERY LOW	CRITICAL
Withdrawals - DC + walking (1000 kcal/week) vs DC only (VLCD 3 mo + 24 mo) (follow-up mean 24 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO VERY LOW	CRITICAL
Withdrawals - DC + walking (1200 kcal/week) vs DC only (VLCD 2 mo + main. 6 mo + 23 mo) (follow-up mean 31 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	5/25 (20%)	24.1%	RR 0.83 (0.3 to 2.29)	41 fewer per 1000 (from 169 fewer to 311 more)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	very serious[3]	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)	⊕OOO 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[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	5/25 (20%)	7.1%	RR 2.8 (0.6 to 13.17)	128 more per 1000 (from 28 fewer to 864 more)	⊕OOO VERY LOW	CRITICAL
Quality of life												
0	No evidence available											CRITICAL

[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 had indirect outcomes.
[3] 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[1]	serious[2]	none	156	153	-	MD 2.4 lower (4.16 to 0.64 lower)	⊕⊕OO 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[3]	no serious inconsistency	serious[4]	no serious imprecision	none	56	36	-	MD 0.4 lower (8.32 lower to 7.52 higher)	⊕OOO 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[1]	serious[4]	none	156	153	-	MD 2.2 lower (3.84 to 0.56 lower)	⊕⊕OO 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[4]	none	58/156 (37.2%)	51/153 (33.3%)	RR 1.12 (0.82 to 1.51)	40 more per 1000 (from 60 fewer to 170 more)	⊕⊕⊕O MODERATE	CRITICAL
								33.3%		40 more per 1000 (from 60 fewer to 170 more)		
Withdrawals - Orlistat versus meal replacement (VLCD 3 mo + main. ~8 mo) (follow-up mean 1 years)												
1	randomised trials	very serious[4]	no serious inconsistency	no serious indirectness	very serious[4]	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)	⊕OOO VERY LOW	CRITICAL
								46.3%		83 fewer per 1000 (from 204 fewer to 83 more)		
Quality of life												
0	No evidence available											CRITICAL

[1] The majority of evidence had indirect outcomes
[2] Downgraded by one increment if the confidence interval crossed one MID or by two increments of the confidence interval crossed both MIDS
[3] 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.
[4] 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 againt no treatment	Control	Relative (95% CI)	Absolute		
Weight in kg - Fibre versus no treatment (VLCD 2 mo + 14 mo) (follow-up mean 14 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	20	11	-	MD 2 higher (6.77 lower to 10.77 higher)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	31	39	-	MD 2.9 lower (3.39 to 2.41 lower)	⊕⊕OO LOW	CRITICAL
BMI - Fibre versus no treatment (VLCD 2 mo + 14 mo) (follow-up mean 14 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	serious[2]	serious[3]	none	20	11	-	MD 1.35 higher (2.23 lower to 4.93 higher)	⊕OOO VERY LOW	IMPORTANT
Withdrawals - Fibre versus no treatment (VLCD 2 mo + 14 mo) (follow-up mean 14 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	5/25 (20%)	21.4%	RR 0.93 (0.26 to 3.33)	15 fewer per 1000 (from 158 fewer to 499 more)	⊕OOO VERY LOW	CRITICAL
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)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	22/53 (41.5%)	35%	RR 1.19 (0.74 to 1.9)	67 more per 1000 (from 91 fewer to 315 more)	⊕⊕OO LOW	CRITICAL
Quality of life												
0	No evidence available											CRITICAL

[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 had indirect outcomes.
[3] 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		
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)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	42	40	-	MD 1.3 lower (1.85 to 0.75 lower)	⊕⊕OO LOW	CRITICAL
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)												
1	randomised trials	serious[3]	no serious inconsistency	serious[3]	no serious imprecision	none	42	40	-	MD 0.5 lower (1.27 lower to 0.27 higher)	⊕⊕OO LOW	CRITICAL
Withdrawals - HP diet (30% of energy/day) versus HC diet (VLCD 3 mo + 12 mo) (follow-up mean 15 months)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	very serious[4]	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)	⊕OOO VERY LOW	CRITICAL
								46.3%		83 fewer per 1000 (from 204 fewer to 83 more)		
Quality of life												
0	No evidence available											CRITICAL

[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 evidence had indirect outcomes
[3] No explanation was provided
[4] 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		
% weight change (follow-up median 2 years; range of scores: 0-100; Better indicated by lower values)												
5	randomised trials	very serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	235	182	-	MD 20.54 lower (22.13 to 18.96 lower)	⊕OOO VERY LOW	CRITICAL
Use of diabetes medications (dichotomous) (follow-up median 3 years)												
2	randomised trials	serious[1]	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)	⊕⊕⊕O MODERATE	CRITICAL
Use of diabetes medications (continuous) (follow-up median 3 years; Better indicated by lower values)												
2	randomised trials	very serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	97	40	-	MD 2.14 lower (2.48 to 1.8 lower)	⊕OOO VERY LOW	CRITICAL
Quality of life												
0	No evidence available											CRITICAL
Remission of diabetes (follow-up median 2 years)												
6	randomised trials	very serious[1]	no serious inconsistency	serious[2]	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)	⊕OOO VERY LOW	IMPORTANT
Improvement in glycaemic control (continuous) (follow-up median 2 years; Better indicated by lower values)												

5	randomised trials	very serious[1]	no serious inconsistency[3]	no serious indirectness	no serious imprecision	none	236	162	-	MD 1.32 lower (1.60 to 1.04 lower)	⊕⊕OO LOW	IMPORTANT
Mortality (follow-up median 1 years)												
6	randomised trials	very serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	0/269 (0%)	0%	See comment	-	⊕OOO VERY LOW	IMPORTANT
Weight by BMI (follow-up median 1 years; Better indicated by lower values)												
4	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	139	164	-	MD 4.19 lower (4.62 to 3.76 lower)	⊕⊕OO LOW	NOT IMPORTANT
Weight in kg (follow-up median 2 years; Better indicated by lower values)												
5	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	236	162	-	MD 19.48 lower (22.61 to 16.36 lower)	⊕⊕OO 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 (I2>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**		
% 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)												
1	randomised trials	very serious[1]	no serious inconsistency	very serious[2]	serious[3]	none	15	15	-	MD 26 higher (15.26 to 36.74 higher)	⊕OOO VERY LOW	CRITICAL

% 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)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	13	16	-	MD 4.9 higher (2.43 to 7.37 higher)	⊕⊕OO LOW	CRITICAL
Weight at 3 years (kg) - Immediately post-surgery (36 months follow up) (follow-up mean 3 years; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	15	15	-	MD 18.3 lower (27.73 to 8.87 lower)	⊕OOO VERY LOW	CRITICAL
Weight at 3 years (kg) - Three years post-surgery (12 months follow up) (follow-up mean 12 months; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[4]	none	13	16	-	MD 3 lower (9.17 lower to 3.17 higher)	⊕OOO VERY LOW	CRITICAL

[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 population included an indirect population (downgraded by one increment) or a very indirect population (downgraded by two increments).
[3] Downgraded by one increment due to small sample size in the included evidence.
[4] Downgraded by one increment if the confidence interval crossed one MID or by two increments if the confidence interval crossed both MIDs.