

Developing a core outcome set for studies in weight loss surgery

Round three questionnaire

Please answer all the questions yourself. The information that you provide will remain anonymous.

When you have completed the questionnaire, please return it in the pre-paid envelope.



Musgrove Park Hospital



MRC

Hubs for Trials
Methodology Research

ConDuCT-II Hub



Southampton 
University Hospitals NHS Trust

Completing the survey

Thank you for continuing to take part in this study. This questionnaire is much shorter than the previous two questionnaires. In this short questionnaire you will see your own rating (green column), those of surgeons (pink column), other clinicians (which includes doctors, nurses, dietitians, and psychologists) in the yellow column and patients (blue column). We are asking you to re-rate each item taking into account other people's views. We need your help to prioritise a small number of essential items. **The final items selected will be measured in all studies of weight loss surgery as a minimum, we hope this will be about 10 items.**

The information that you provide will remain anonymous. When you have completed the questionnaire, please return it in the pre-paid envelope provided. Thank you again so much for all your time and help with this survey, which will help us with future research.

SECTION 1 Short and long term complications

This section lists events that may occur during, or after, weight loss surgery. Please note, these are only possibilities and do not occur in everyone. The words in brackets are the medical terminology. Please rate how important you think it is that the following events are measured in studies of weight loss surgery and circle the number that best represents your opinion.

		Previous ratings												
		Surgeons	Other clinicians	Patients	Your own	Not important			(Please circle)			Extremely important		
For example: Less pain when walking		4	5	6	5	1	2	3	4	5	6	7	8	9
Complications that might occur during the operation		Surgeons	Other HCPs	Patients	Your own	Not important			(Please circle)			Extremely important		
1	The risk of accidentally damaging other organs during the operation (organ injury)					1	2	3	4	5	6	7	8	9
Infection														
2	Infection inside the body where the operation was carried out (deep abscess)					1	2	3	4	5	6	7	8	9
3	Problems with the wound such as infection, oozing, or failure to heal properly (wound infection or dehiscence)					1	2	3	4	5	6	7	8	9
4	Whole body infection which requires prolonged admission to hospital (septicaemia)					1	2	3	4	5	6	7	8	9
Haemorrhage														
5	Bleeding problems inside the abdomen or within the bowel (intra-abdominal bleeding/gastrointestinal bleeding/staple line bleed)					1	2	3	4	5	6	7	8	9

		Previous ratings												
Surgical joins between internal organs (anastomosis)		Surgeons	Other clinicians	Patients	Your own	Not important			(Please circle)			Extremely important		
6	Leaking of bowel/stomach contents through a hole at the site of the operation (anastomotic leak/gastric fistula)					1	2	3	4	5	6	7	8	9
7	Abnormal narrowing of the bowel caused by scar tissue or stapling, which might cause a blockage (stricture)					1	2	3	4	5	6	7	8	9
8	Ulcers developing at the new join between the two pieces of bowel (anastomotic ulceration)					1	2	3	4	5	6	7	8	9
Band related complications														
9	Problems with the gastric band such as infection or eroding/growing into the stomach. This may lead to further surgery (band infection, erosion and revisions)					1	2	3	4	5	6	7	8	9
10	Problems with the port or tubing, such as flipping, needing to be relocated, infection and/or needing further surgery (port malfunction/ revisions/infection)					1	2	3	4	5	6	7	8	9
11	The band slipping out of place and needing more surgery to correct it (band slippage)					1	2	3	4	5	6	7	8	9
Obstruction / hernia														
12	Twisting or abnormal movement of the bowel or intestines, which can cause blockages, pain or nausea and may need additional surgery (internal hernia)					1	2	3	4	5	6	7	8	9
13	Build-up of scar tissue in the bowel causing obstruction or abdominal pain (adhesional obstruction)					1	2	3	4	5	6	7	8	9

		Previous ratings												
		Surgeons	Other clinicians	Patients	Your own	Not important			(Please circle)			Extremely important		
General complications of surgery														
14	Problems with breathing so that a machine to help with breathing is needed (ventilation)					1	2	3	4	5	6	7	8	9
15	Problems with the blood supply to the heart, causing pain/heart attack/irregular or abnormal heart beat (angina/myocardial infarction/arrhythmia)					1	2	3	4	5	6	7	8	9
16	Blood clot in the leg or lung (venous thromboembolism)					1	2	3	4	5	6	7	8	9
17	Stroke (cerebrovascular accident)					1	2	3	4	5	6	7	8	9
18	Kidney failure (renal failure)					1	2	3	4	5	6	7	8	9
Mortality														
19	Death (during the operation or within 30 days of surgery)					1	2	3	4	5	6	7	8	9
20	Death (more than 30 days after surgery)					1	2	3	4	5	6	7	8	9
Other measures														
21	Problems swallowing or bringing food back up (dysphagia/regurgitation)					1	2	3	4	5	6	7	8	9
22	A measurement of vitamin and mineral levels (micronutrient levels)					1	2	3	4	5	6	7	8	9
23	Unexpected return to hospital for unplanned procedures or urgent review (re-admission rates)					1	2	3	4	5	6	7	8	9

SECTION 2 Effectiveness of weight loss surgery

The following section lists different ways to measure the effectiveness of weight loss surgery. Please rate how important you think it is that the following information is collected to measure the impact/effectiveness of the surgery and circle the number that represents your opinion. The words in brackets are the medical terminology.

		Previous ratings																	
		Surgeons	Other clinicians	Patients	Your own	Not important (Please circle) Extremely important													
											1	2	3	4	5	6	7	8	9
Body measurements (anthropometry)																			
24	Reduction in weight					1	2	3	4	5	6	7	8	9					
25	Maintaining weight loss/preventing weight regain					1	2	3	4	5	6	7	8	9					
Obesity related disease																			
26	Reduction/lowering of blood pressure, or a reduction in blood pressure medication (hypertension)					1	2	3	4	5	6	7	8	9					
27	Reduction in the chance of having heart problems in the future (adjusted cardiovascular risk)					1	2	3	4	5	6	7	8	9					
28	Improvement in diabetes, or a reduction in diabetic medication (measure of diabetes e.g. HbA1c)					1	2	3	4	5	6	7	8	9					
29	Reduction in the amount of fat and cholesterol in the blood, or a reduction in medication (measure of dyslipidaemia)					1	2	3	4	5	6	7	8	9					
30	Being able to breathe easily when sleeping / using a sleep mask less (obstructive sleep apnoea)					1	2	3	4	5	6	7	8	9					
31	Improvement in joint disease					1	2	3	4	5	6	7	8	9					

SECTION 3 Issues relating to quality of life and wellbeing after surgery

The following section lists some other areas of life that can be affected by having weight loss surgery. These issues are all patient reported, i.e. issues that are reported directly from the patient themselves and are not interpreted by clinicians or anyone else.

Please rate how important you think it is, that the following issues are measured in research studies of weight loss surgery, and circle the number that best represents your opinion.

		Previous ratings												
Activities of daily living and work/employment		Surgeons	Other clinicians	Patients	Your own	Not important (Please circle) Extremely important								
						1	2	3	4	5	6	7	8	9
32	Being able to carry out usual activities (not related to paid employment) such as personal hygiene, housework, managing finances													
33	Mobility (e.g. being able to walk, climb stairs, bend, cross legs, get up from chairs)													
34	Fitness (strength and endurance)													
35	Being able to accomplish work tasks, or to take up work/paid employment													
Body image														
36	Feeling in control of weight and appearance													
37	Excess skin or skin folds following weight loss													
Eating behaviour														
38	Having a healthy/balanced eating pattern													

Previous ratings

		Surgeons	Other clinicians	Patients	Your own	Not important (Please circle) Extremely important								
						1	2	3	4	5	6	7	8	9
39	Being able to stop eating when feeling full													
Psychological and emotional wellbeing														
40	Improvement in self-esteem and self-confidence													
Mental health														
41	Depression													
42	Anxiety													
43	Suicidal thoughts													
44	Other addictive behaviours (e.g. alcohol, drugs, gambling, shopping)													
Sleep														
45	Overall quality of sleep													
Social														
46	Relationship with partner/spouse, friends, and/or ability to care for children													
Overall health, wellbeing and life														
47	Normality (feeling able to live a 'normal' life)													
48	Feeling in control of health and wellbeing													
49	Having a positive outlook on life and expectations for the future													

SECTION 4 Top five outcomes to measure

Please write five outcomes you consider essential to measure when evaluating weight loss surgery:

1. _____
2. _____
3. _____
4. _____
5. _____

Thank you for your contribution to this round of the survey. Please now return the questionnaire in the pre-paid envelope provided.

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