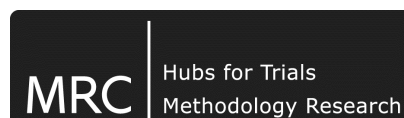


Developing a core outcome set for studies in weight loss surgery

Round one questionnaire



Completing the survey

Thank you for agreeing to take part in this study. We are interested in knowing what outcomes or end-results you think are most important for researchers to measure when evaluating weight loss surgery. By collecting your responses, we aim to determine the most important outcomes that should be measured after weight loss surgery. This is so we can better evaluate the operations and give patients better information about each operation.

We will be collecting information by means of a survey, made up of two rounds. In the first round (this one) we will ask you to rate how important you think it is that certain things are measured. Everyone's opinions from this first round will be pooled. The second round of the survey will include the same list as the first but will also include the results of the first round and we will ask you to re-vote taking into account other people's views. The final list will consist of the things considered most essential by the whole group. The survey includes questions about the effectiveness of surgery as well as potential complications of surgery which doctors measure. Doctors and other health professionals are also being asked to complete this survey.

In order for our results to be valid, it is very important that you complete both rounds. If people drop out between rounds, their opinions will not be able to carry through to the end of the study and the final results may over- or under-estimate how much the group agreed on this topic.

Please answer all of the questions yourself. This should take you a maximum of 30 minutes. **Don't spend too long on the questions, we are looking for your immediate feelings. The information that you provide will remain anonymous.** When you have completed the questionnaire, please return it in the pre-paid envelope provided.

SECTION 1 First, a few things about you

To allow us to analyse the results of the study, we need some brief information about you and the type of surgery you have had or are hoping to undergo. Please tick the most appropriate box(es).

1. Your initials:.....

2. Your gender: Male Female

3. Your date of birth (day/month/year): / /

4. Which of the following most accurately describes your ethnic background?

- White British White other
- Black Asian
- Mixed Chinese
- Other

please specify.....

5. Which of the following most accurately describes your educational background?

- GCSE (or equivalent) Vocational qualifications
- A level (or equivalent) Higher degree
- University degree Other

please specify.....

6. Which of the following most accurately describes your marital status?

- Single (never married) Separated
- Divorced Widowed
- Married Co-habiting

7. Which of the following most accurately describes your employment status?

- Working full-time Housewife/househusband
- Retired Unemployed on sickness/disability
- Unemployed and seeking work Other
- Doing voluntary work please specify.....

8. Are you waiting to undergo weight loss surgery or have you already undergone surgery?

- Awaiting surgery Already undergone surgery

(Please go to question 11)

9. Which operation for weight loss surgery did you undergo?

- Adjustable gastric band Roux-en-Y gastric bypass
- Sleeve gastrectomy Other
- Not sure (please specify).....
- More than one type

(please explain).....

.....
.....

10. Date of your weight loss surgery (month/year): □□/□□□□

(If you have had more than one type of operation, please list the date of the first operation.)

11. If you are awaiting surgery, which operation are you hoping to undergo?

- Adjustable gastric band Roux-en-Y gastric bypass
- Sleeve gastrectomy Other
- Not sure (please specify).....

SECTION 2 Medical effectiveness of weight loss surgery

The following section lists different ways to measure the medical 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.

		Not important	(Please circle)					Extremely important		
		1	2	3	4	5	6	7	8	9
	For example: Less pain when walking	1	2	3	4	5	6	7	8	9
	Body measurements (anthropometry)									
1	A measurement of weight	1	2	3	4	5	6	7	8	9
2	Body dimensions such as waist and hip measurements	1	2	3	4	5	6	7	8	9
3	Body mass index	1	2	3	4	5	6	7	8	9
	Obesity related disease									
4	Improvement in abnormal or irregular heartbeat (arrhythmia)	1	2	3	4	5	6	7	8	9
5	Reduction/lowering of blood pressure to a healthy level, or a reduction in blood pressure medication (hypertension)	1	2	3	4	5	6	7	8	9
6	Reduction in the chance of having heart problems in the future (adjusted cardiovascular risk)	1	2	3	4	5	6	7	8	9
7	Improvement in diabetes, diabetes no longer being present, or a reduction in diabetic medication (measure of diabetes e.g. HbA1c)	1	2	3	4	5	6	7	8	9
8	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
9	Being able to breathe easily when sleeping / using a sleep mask less (obstructive sleep apnoea)	1	2	3	4	5	6	7	8	9
10	Improvement in joint disease	1	2	3	4	5	6	7	8	9

SECTION 3 Short and long term medical 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. Some of these events are extremely rare. 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.

		Not important	(Please circle)							Extremely important
Complications that might occur during the operation										
11	Bleeding problems, such as a collection of blood or loss of blood during the operation (peri- operative haemorrhage)	1	2	3	4	5	6	7	8	9
12	The risk of accidentally damaging other organs during the operation (organ injury)	1	2	3	4	5	6	7	8	9
13	The likelihood of needing to use a large cut/incision during surgery, rather than planned keyhole surgery (conversion to open surgery)	1	2	3	4	5	6	7	8	9
Infection										
14	Infection inside the body where the operation was carried out (deep abscess)	1	2	3	4	5	6	7	8	9
15	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
16	Whole body infection which requires prolonged admission to hospital (septicaemia)	1	2	3	4	5	6	7	8	9
Haemorrhage										
17	Bleeding problems in stomach or bowel which may cause blood to be seen in bowel movements (gastrointestinal bleeding)	1	2	3	4	5	6	7	8	9

		Not important (Please circle) Extremely important								
18	Bleeding inside the abdomen where the operation was carried out (intra-abdominal bleeding)	1	2	3	4	5	6	7	8	9
19	Bleeding from the wound (wound bleeding / port site haematoma)	1	2	3	4	5	6	7	8	9
Surgical joins between internal organs (anastomosis)										
20	Leaking of stomach contents through a hole in the stomach (gastric fistula)	1	2	3	4	5	6	7	8	9
21	Leaking of bowel contents into the abdomen through a hole where the bowel is joined or stapled (anastomotic leak)	1	2	3	4	5	6	7	8	9
22	Abnormal narrowing of the bowel caused by scar tissue or stapling, which might cause a blockage (stenosis)	1	2	3	4	5	6	7	8	9
23	Bleeding from the internal bowel staples (staple line bleed)	1	2	3	4	5	6	7	8	9
24	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										
25	Infection of the gastric band (band infection)	1	2	3	4	5	6	7	8	9
26	Problems with the port, such as flipping or needing the port to be relocated (port erosion or revisions)	1	2	3	4	5	6	7	8	9
27	Infection of the port which is used to change the band size (port infection)	1	2	3	4	5	6	7	8	9
28	The gastric band eroding/growing into the stomach (band moves from outside to the inside of stomach) leading to the need for further surgery (band erosion)	1	2	3	4	5	6	7	8	9
29	The band slipping out of place and needing more surgery to correct it (band slippage)	1	2	3	4	5	6	7	8	9
30	Intolerance of the band	1	2	3	4	5	6	7	8	9
31	Pain in the stomach caused by overeating/too much food stretching the stomach above the band (pouch dilation)	1	2	3	4	5	6	7	8	9
32	Damage to the band, which might require band replacement (iatrogenic injury [device])	1	2	3	4	5	6	7	8	9
33	Failure of the port or tube to work properly (port malfunction)	1	2	3	4	5	6	7	8	9

		Not important				(Please circle)			Extremely important	
		1	2	3	4	5	6	7	8	9
34	The need for further surgery to make changes to the band (band revisions)	1	2	3	4	5	6	7	8	9
Obstruction / hernia										
35	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
36	A lump or bulge in the skin through the scar where the surgery was performed (external hernia, incisional)	1	2	3	4	5	6	7	8	9
37	Build up of scar tissue in the bowel causing obstruction or abdominal pain (adhesional obstruction)	1	2	3	4	5	6	7	8	9
38	Vomiting or excessive bloating after the operation whilst still in hospital (ileus)	1	2	3	4	5	6	7	8	9
General complications of surgery										
39	One or more areas of the lungs collapsing or not inflating properly (atelectasis)	1	2	3	4	5	6	7	8	9
40	Needing a machine to help with breathing (ventilation)	1	2	3	4	5	6	7	8	9
41	Chest infection (lower respiratory tract infection)	1	2	3	4	5	6	7	8	9
42	Heart's blood supply is blocked, or interrupted, by a build-up of fatty substances in the heart's arteries (ischaemic/coronary heart disease)	1	2	3	4	5	6	7	8	9
43	Irregular or abnormal heart beat (arrhythmia)	1	2	3	4	5	6	7	8	9
44	Blood clot in the leg or lung (venous thromboembolism)	1	2	3	4	5	6	7	8	9
45	Stroke (cerebrovascular accident)	1	2	3	4	5	6	7	8	9
46	Kidney failure (renal failure)	1	2	3	4	5	6	7	8	9
47	Bladder infection in 'wee/pee' (Urinary tract infection)	1	2	3	4	5	6	7	8	9
48	Unintentional passing of urine (incontinence)	1	2	3	4	5	6	7	8	9

Not important (Please circle) Extremely important

Mortality

49	Risk of death during the operation (peri-operative mortality)	1	2	3	4	5	6	7	8	9
50	Risk of death from surgical complications whilst still in hospital (in hospital mortality)	1	2	3	4	5	6	7	8	9
51	Risk of death <u>within a month</u> of surgery, in hospital or at home (≤ 30 day mortality)	1	2	3	4	5	6	7	8	9
52	Risk of death <u>more than a month</u> after surgery, in hospital or at home (>30 day mortality)	1	2	3	4	5	6	7	8	9

SECTION 4 Physical signs, symptoms and other measures

The following section lists some physical signs and symptoms that some people may experience before or after weight loss surgery. It also lists some measurements that may be taken. Some of these signs and symptoms may get better after surgery. Some may get worse, or remain the same. 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 symptoms are measured in research studies of weight loss surgery, and circle the number that best represents your opinion.

		Not important	(Please circle)							Extremely important
Signs										
53	Hair loss	1	2	3	4	5	6	7	8	9
54	Problems hearing	1	2	3	4	5	6	7	8	9
55	Problems with gums or teeth	1	2	3	4	5	6	7	8	9
56	Problems with vision	1	2	3	4	5	6	7	8	9
57	Swelling or retaining water (oedema)	1	2	3	4	5	6	7	8	9
58	Skin problems or irritations (such as rashes, sores or loose skin, ulcers)	1	2	3	4	5	6	7	8	9
59	Loss of sensation in hands and feet (peripheral neuropathy/paraesthesia)	1	2	3	4	5	6	7	8	9
Symptoms										
60	Feeling out of breath (breathlessness)	1	2	3	4	5	6	7	8	9
61	Belching, bloating, or gas (flatulence)	1	2	3	4	5	6	7	8	9
62	Constipation or difficulty passing stool	1	2	3	4	5	6	7	8	9
63	Diarrhoea or loose bowel motion	1	2	3	4	5	6	7	8	9

		Not important	(Please circle)						Extremely important	
64	Pain or discomfort in the body	1	2	3	4	5	6	7	8	9
65	Feeling hot or sweaty	1	2	3	4	5	6	7	8	9
66	Feeling light-headed or dizzy	1	2	3	4	5	6	7	8	9
67	Feeling sick or vomiting (nausea)	1	2	3	4	5	6	7	8	9
68	Numbness or tingling in the body	1	2	3	4	5	6	7	8	9
69	Heartburn or acid indigestion (reflux)	1	2	3	4	5	6	7	8	9
70	Problems swallowing or bringing food back up (dysphagia/regurgitation)	1	2	3	4	5	6	7	8	9
71	Problems controlling the bladder (urinary incontinence)	1	2	3	4	5	6	7	8	9
72	Appearing physically tired or lacking in energy (physical fatigue)	1	2	3	4	5	6	7	8	9
73	Pain or discomfort in stomach area	1	2	3	4	5	6	7	8	9

Other Measures

74	A measurement of <u>vitamin</u> levels	1	2	3	4	5	6	7	8	9
75	How many calories consumed (energy intake)	1	2	3	4	5	6	7	8	9
76	A measurement of <u>mineral</u> levels	1	2	3	4	5	6	7	8	9
77	The length of time spent in hospital after admission for surgery (length of hospital stay)	1	2	3	4	5	6	7	8	9
78	How long the operation takes (operative time)	1	2	3	4	5	6	7	8	9
79	Unexpected return to hospital for unplanned procedures or urgent review (re-admission rates)	1	2	3	4	5	6	7	8	9

SECTION 5 Impact of surgery on quality of life and wellbeing

The following section lists some other areas of life that can be affected by having weight loss surgery. Please rate how important you think it is, that the following information is measured in research studies of weight loss surgery, and circle the number that best represents your opinion.

		Not important	(Please circle)							Extremely important
Activities of daily living and work/employment										
80	Being able to carry out usual activities (not related to paid employment) such as personal hygiene, housework, managing finances	1	2	3	4	5	6	7	8	9
81	Being able to shop for clothes that fit	1	2	3	4	5	6	7	8	9
82	Being able to fit into spaces in public places (e.g. fit into seats or through aisles)	1	2	3	4	5	6	7	8	9
83	Mobility (e.g. being able to walk, climb stairs, bend, cross legs, get up from chairs)	1	2	3	4	5	6	7	8	9
84	Fitness (strength and endurance)	1	2	3	4	5	6	7	8	9
85	Being able to participate in, and enjoy physical activities	1	2	3	4	5	6	7	8	9
86	Being able to accomplish work tasks, or to take up work/paid employment	1	2	3	4	5	6	7	8	9
87	Satisfaction and recognition at work (if in paid employment)	1	2	3	4	5	6	7	8	9
88	Relationships with work colleagues (if in paid employment)	1	2	3	4	5	6	7	8	9
Body image										
89	Feeling satisfied and confident with one's body	1	2	3	4	5	6	7	8	9
90	Feeling in control of weight and appearance	1	2	3	4	5	6	7	8	9
91	Feeling like the mind and body are in tune with each other	1	2	3	4	5	6	7	8	9
92	Excess skin or skin folds following weight loss	1	2	3	4	5	6	7	8	9

Not important

(Please circle)

Extremely
important**Eating behaviour**

93	Having a healthy/balanced eating pattern	1	2	3	4	5	6	7	8	9
94	Being able to recognise hunger feelings	1	2	3	4	5	6	7	8	9
95	Being able to stop eating when feeling full	1	2	3	4	5	6	7	8	9
96	Time spent thinking about food	1	2	3	4	5	6	7	8	9
97	Eating for emotional reasons	1	2	3	4	5	6	7	8	9
98	Feeling guilty or upset after eating	1	2	3	4	5	6	7	8	9
99	Eating in secret	1	2	3	4	5	6	7	8	9
100	Eating differently in social situations than normal	1	2	3	4	5	6	7	8	9

Psychological and emotional wellbeing

101	How individuals feel others perceive them	1	2	3	4	5	6	7	8	9
102	Self-esteem and self-confidence (how someone perceives themselves)	1	2	3	4	5	6	7	8	9
103	Mood swings	1	2	3	4	5	6	7	8	9
104	Stress levels	1	2	3	4	5	6	7	8	9
105	Coping (how someone feels with stress or difficulties)	1	2	3	4	5	6	7	8	9
106	Feeling in control of emotional or psychological wellbeing	1	2	3	4	5	6	7	8	9

Mental health

107	Depression	1	2	3	4	5	6	7	8	9
108	Anxiety	1	2	3	4	5	6	7	8	9
109	Hostility (level of anger, and ability to manage this)	1	2	3	4	5	6	7	8	9

		Not important			(Please circle)					Extremely important
110	Fears or phobias	1	2	3	4	5	6	7	8	9
111	Suicidal thoughts	1	2	3	4	5	6	7	8	9
112	Other addictive behaviours (e.g. alcohol, drugs, gambling, shopping)	1	2	3	4	5	6	7	8	9
Sex life										
113	Interest in and enjoyment of sex	1	2	3	4	5	6	7	8	9
114	Ability to physically participate in sex	1	2	3	4	5	6	7	8	9
115	Sexual confidence	1	2	3	4	5	6	7	8	9
116	Sexual attention from others	1	2	3	4	5	6	7	8	9
Sleep										
117	Ability to fall asleep at night	1	2	3	4	5	6	7	8	9
118	Overall quality of sleep	1	2	3	4	5	6	7	8	9
119	Sleepiness during the day	1	2	3	4	5	6	7	8	9
120	Snoring which affects others	1	2	3	4	5	6	7	8	9
Social										
121	Relationship with partner/spouse	1	2	3	4	5	6	7	8	9
122	Relationship with, and/or ability to care for, children	1	2	3	4	5	6	7	8	9
123	Relationship with other family members	1	2	3	4	5	6	7	8	9
124	Relationship with friends	1	2	3	4	5	6	7	8	9
125	Treatment from people in wider society	1	2	3	4	5	6	7	8	9
126	Having confidence to participate in social activities	1	2	3	4	5	6	7	8	9
127	Feeling in control of social life	1	2	3	4	5	6	7	8	9

ID

Not important (Please circle) Extremely important

Overall health, wellbeing and life

128	Normality (feeling able to live a 'normal' life)	1	2	3	4	5	6	7	8	9
129	Feeling in control of health and wellbeing	1	2	3	4	5	6	7	8	9
130	Having a positive outlook on life and expectations for the future	1	2	3	4	5	6	7	8	9

SECTION 6 Additional things to measure

Please write down anything else relating to obesity surgery not included above that you think is important to measure in research studies. We welcome all your views.

Thank you for your contribution to this round of the survey. We look forward to providing you with the results in the next round!

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