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# 'Perceptions of weight, diabetes and willingness to participate in randomised controlled trials of bariatric surgery for patients with type 2 diabetes mellitus and body mass index 30-39.9kg/m<sup>2</sup>'

## **Original Research**

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Short running title: 'Patient views on obesity, diabetes and surgery'

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#### Introduction/Purpose

Evidence supports bariatric surgery as an intervention for improving and/or correcting type 2 diabetes mellitus (T2DM) in those with obesity [1-5]. However, most research has investigated the effects of bariatric surgery in people with a BMI  $\geq$ 40kg/m<sup>2</sup> [6]. Many patients with BMI 30-39.9kg/m<sup>2</sup> also have T2DM and given the limited effectiveness of non-surgical strategies [5, 7] there is a need to assess the role of bariatric surgery in such patients. Whilst evidence is growing in this area indicating beneficial results in this group, there have been few European trials and evidence of the longer-term costs and benefits of bariatric surgery in this group is still lacking [2, 3, 8-13].

Patient recruitment is a key issue affecting the conduct of RCTs [14-16] and recruitment to bariatric trials is no exception, with Courcoulas et al [9] reporting recruitment and randomisation to their United States-based RCT of bariatric surgery for T2DM, BMI 30-40kg/m<sup>2</sup>, as challenging. Sarwer et al's [17] survey of US patients suggested such difficulty, with less than 20% of responders being willing to participate in an RCT of bariatric surgery. Little work on this group has been undertaken in the UK, where the expense of funding treatment costs makes RCTs of bariatric surgery problematic. Evidence on acceptability and willingness to participate in UK bariatric surgery trials in this group is needed to indicate feasibility and support decision making amongst researchers and funders. Our qualitative study of patient perceptions in a United Kingdom (UK) sample, suggested that there was interest in bariatric surgery amongst this group and that certain perceptions might influence willingness to participate; specifically, the impact of their weight on life, impact of diabetes on life, ability to control their weight, ability to control their diabetes and satisfaction with their ability to lose weight, [18]; however, willingness amongst this group on a representative level is unknown. This study aimed to quantify the perceptions of patients with a BMI 30-

39.9kg/m<sup>2</sup> and T2DM in England, on their weight, diabetes, and their willingness to participate in bariatric surgery RCTs.

### **Materials and Methods**

A questionnaire survey of obese patients (BMI 30-39.9kg/m<sup>2</sup>) with T2DM, approved by Berkshire Research Ethics Committee, was conducted in primary care practices in England, September 2011-January 2012.

Thirty-nine Family Doctor's offices from one of four geographically diverse regions (South West England, North West London, Midlands and West Yorkshire) participated. Patients were eligible if they were aged 18-74 years, had a diagnosis of T2DM for  $\geq$ 2 years, and a BMI 30-39.9kg/m<sup>2</sup> or 27.5-39.9kg/m<sup>2</sup> for South Asian participants. A lower BMI threshold was for identifying South Asian participants since this population are at a higher risk of both type two diabetes and cardiovascular disease at lower BMIs [19]. Patients were excluded if they had a severe respiratory, cardiac, neurological or mental health disorder, active or recent ( $\leq$ 1year) cancer, recent ( $\leq$ 1year) myocardial infarction, previous bariatric surgery, or if they were judged to be unsuitable by their family doctor.

A self-completion questionnaire was developed based on data collected from a previous qualitative study [18]. The survey considered 4 domains; patient views on their diabetes, their weight and weight management, weight loss surgery and their willingness to participate in research, both generally and bariatric surgery RCTs specifically. Items reflecting these factors used a combination of Likert and categorical measurement scales. Likert items were

measured on a 5 scale where '1' represented a strongly affirmative response and '5' a strongly negative response.

An internal pilot involving 3 practices in the South West region was conducted. Practices mailed out study invitations, information sheets and surveys to all eligible patients. A second mail out was implemented 3-4 weeks later. Pilot results indicated a 30% response rate. No changes to the survey or process of implementation were made during the pilot and pilot data were included in the full data set. Family Doctors' Offices (n=39) identified a total of 3054 eligible participants. Our sampling varied by the number of eligible patients identified, with all participants being invited from practices identifying <50 eligible participants, and 50% and 25% of eligible patients being selected randomly using computer generated numbers in practices identifying 50-149, or 150 or more patients, respectively. Figure 1 provides an overview of the screening procedure. Family Doctors' Offices provided demographic information for all patients invited including age, sex, BMI, diabetes duration, insulin status, most recent HbA1c and estimated glomerular filtration rate (eGFR). The index of multiple deprivation (IMD), an aerial proxy measure of socio-economic status, was derived from participants' postcodes [20].

Data were analysed using SPSS, version 20. Descriptive statistics were used and significance between groups was assessed using Chi square tests for categorical data and Mann-Whitney U tests for continuous data. During analysis, Likert responses '1' and '2' were grouped as signifying agreement, '3' as a neutral position and '4' and '5' as signifying disagreement. Group differences are presented. Regarding management of items relating to research participation, respondent interest in research (any form) was first established. Only those answering 1-3 were invited to answer subsequent questions relating to research. Participants indicating no interest in research (answering '4' or '5'), did not answer subsequent questions on research participation and were automatically included in the analysis of subsequent items on research as 'no' responses. Multiple logistic regression analysis was used to model associations of trial participation with demographic characteristics and perceptions relating to both diabetes and weight control and impact included. Clinically relevant demographics and perceptions towards diabetes and weight control were included. Backwards stepwise selection was used to identify the most parsimonious model. Age and BMI were retained in the model irrespective of significance.

#### Results

Of 365 692 patients in the 39 practices, 11182 (4.4%) of those aged 18-74 were identified with T2DM. Nearly half of those with T2DM, of 2 years duration, in this age range (48% 3734/7837), had a BMI 30-39.9kg/m<sup>2</sup> (see Fig 1). A total of 614/1820 patients responded to the survey (34%). There were no differences in sex, age, BMI, duration of diabetes, eGFR and HbA1c between responders and non-responders (Table 1); however responders were more frequently from less deprived areas based on the IMD score. The recording of ethnicity between practices was highly variable and prevented responder versus non-responder comparison. However, among responders 513/597 (86%) were white (self-reported).

#### Concern over diabetes & Impact of diabetes

Diabetes was a major concern for 58% (n=343) of participants, 15% disagreed, reporting that diabetes was not a major concern, and 27% expressed uncertainty (Table 2). 69% of responders reported diabetes had had a 'positive' or 'no impact' on their lives and, overall, most felt able to control their diabetes, with only 107 (18%) being unable or somewhat able

(Table 2). One hundred and eighty (31%) participants expressed that having T2DM had had a negative impact on their life. For 68%, diabetes had prompted a change in diet for the 'better' in contrast to 32% who reported 'no change' or a change for the worse. 58% thought that their diabetes was irreversible, in contrast to 21% who were uncertain and 20% who disagreed that diabetes was irreversible.

#### Satisfaction regarding weight and impact of weight

74% described themselves as 'overweight', 17% as 'very overweight', 8% as 'about right' and 0.2% as 'underweight'. Sixty-three per cent perceived their weight to negatively affect their life (Table 2), and 90% of respondents reported having attempted to lose weight either currently or in the past by multiple methods. 80% reported feeling either 'not able at all' to lose weight or 'somewhat able' to lose weight, with only 5% feeling 'mostly able' and 15% 'completely able' to lose weight. Furthermore, 45% reported being 'unsatisfied/ very unsatisfied' with their ability to lose weight (Table 2).

#### Views on bariatric surgery and willingness to participate in RCTs involving surgery

84% of responders reported having heard of bariatric surgery prior to the study, though only 12.5% had previously considered surgery as an option. 67% were willing to consider surgery if it could improve/cure their T2DM. However, only 46% thought bariatric surgery could improve or reverse diabetes, whereas 29% were unsure and 25% remained unconvinced. Importantly, 58% agreed that their diabetes was irreversible in contrast to 21% who were uncertain and 20% who disagreed.

73% of participants were interested in participating in some form of weight management research and two thirds (64%) answered 'yes' (30%) or 'maybe' (34%) to being willing to consider participating in an RCT involving bariatric surgery. Table 3 presents demographics of those willing to consider bariatric surgery ('yes'/'maybe' group).

In multivariate analysis, age, impact of weight & satisfaction with weight loss ability, were significant influences on participants' willingness to consider participating in an RCT. Older participants were less likely to consider entering an RCT (odds ratio [OR] 0.95 [0.93-0.97] P<0.001). Weight perceptions were influential, those who reported 'yes' to weight negatively impacting on life were more likely to be willing to consider a bariatric surgery RCT (OR 2.55 [1.68-3.68] p<0.001) compared to those who reported 'no'. Being 'very unsatisfied/ unsatisfied' with ability to lose weight was also associated with an increased likelihood (OR 2.47 [1.55-3.95] p<0.001) of willingness to consider participation, compared to those who were 'very satisfied/. Neither BMI nor diabetes perceptions significantly influenced willingness.

#### Conclusions

To our knowledge, this is the first study to evaluate attitudes towards participation in an RCT to assess the effectiveness of bariatric surgery in treating T2DM, amongst UK patients with a BMI 30-39.9kg/m<sup>2</sup>. These findings confirm patient interest in bariatric surgery research and provide clinicians, commissioners and providers of health services insight regarding patient perspectives in support of the need for such research. Younger age, perceived adverse impact of weight on life and lack of satisfaction with weight loss ability were significant influences on participant attitudes towards participation in a trial. These latter two perceptions were

common in this population with 45% unsatisfied with their ability to lose weight and 63% perceiving their weight to negatively affect their life. Understanding influential factors in patient attitudes towards participating in bariatric surgery trials will be important for the design of trials, and maximising recruitment.

Our results differ from those of Sarwer et al [17] suggesting a greater proportion of UK patients may be willing to enter such an RCT. This may be due to several key differences between the two studies. Our samples differed with regards to ethnicity (46% white in the US study versus 86% white) and study setting. In contrast to the US study, information explaining randomisation and the pros/cons associated with surgery were provided to patients. Therefore, participants in our study may have been better informed and more similar in responses to patients during trial recruitment, who would also receive such information. Finally, we grouped those responding 'yes' and 'maybe' together in relation to willingness to consider trial entry whereas, Sarwer et al [17] only accepted definite 'yes' responses as indicative of willingness. However, even taking the 'yes' responses alone and excluding those who were uncertain, the number willing to consider surgery is still almost double those reported in the US study, 30% versus 16% respectively [17].

The finding that weight perceptions are influential, adds to previous research [21, 22]. Most patients had tried, unsuccessfully, to lose weight using a variety of methods which supports evidence suggestive of limited effectiveness of non-surgical interventions in this group [5, 7]. Importantly, we found no evidence that perceptions surrounding the impact of T2DM, or the ability to control T2DM, influenced willingness to participate in bariatric RCTs. This may seem counterintuitive given the morbidity and mortality associated with diabetes [23] and the high levels of T2DM-related concern reported by respondents both in our study and another

[24]. However T2DM is usually asymptomatic until other organ damage ensues, which may make lifestyle change and maintenance in this group challenging, since beneficial consequences may not be immediately discernible [25, 26].

Most patients reported a willingness to consider bariatric surgery. However, despite being provided with information on the potential benefit of surgery, over half of respondents were unsure or sceptical of the potential of bariatric surgery to alter T2DM. One potential explanation for this uncertainty may relate to a failure to provide adequately explanations in our study education materials, although this seems unlikely as we involved patients with T2DM in the development of the questionnaire and recruitment materials. Another explanation may relate to patients' T2DM beliefs, specifically those around the permanency/irreversibility of T2DM.

The concept that T2DM is permanent is reflected in earlier literature [25-28] and may have implications for recruiting to trials. If the ability of bariatric surgery to improve/cure diabetes is a motivating factor, patient beliefs regarding the permanency of their diabetes may represent a barrier for patients considering surgery. Ensuring information provided gives a clear account of the benefits of surgery as well as the disadvantages, particularly those relating to increased sense of control, substantial weight loss and reduction to weight-associated comorbidities, may positively influence recruitment.

As currently advocated [14], our study questionnaire was grounded in rigorous qualitative work. Our practice sampling was diverse in terms of geography and underlying socioeconomic which will enhance generalizability of our findings. However, the study has several limitations. Firstly, respondents in this study were predominantly 'white' and whilst ethnicity was not identified as significantly influencing willingness, this is an important difference. Secondly, whilst the results suggest a willingness to participate, there is a recognised difference between intention and behaviour. As such there is no guarantee that such a proportion would participate in such a trial. Finally, the survey's non-response rate was high despite efforts to minimise this. Although we found few significant differences between responders and non-responders, there is a potential for non-response bias [29].

In summary, a significant proportion of patients expressed interest in participating in bariatric surgery RCTs, suggesting UK-based trial recruitment would be feasible. Those who are younger, feel that their weight negatively impacts on their life or are unsatisfied with their ability to lose weight may be more inclined to participate. Objective information provision which highlights the potential for increased weight control and quality of life benefits associated with bariatric surgery, may positively influence participation in future trials.

#### **Conflict of Interest Disclosure Statement**

No conflicts of interest.

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#### Figure 1: Survey recruitment flow diagram legend

Abbreviation/symbol	Definition
Ν	Number
GP	General Practitioner
BMI	Body Mass Index
Inc.	Including
<	Less than
>	More than

# Table 1: Responder versus non-responder baseline characteristics

Variable		Responders (N=614)	Non-responders (N=1206)
Gender (male)	N (%)	338 (55.0)	662 (54.9)
Age years	Median	63	61
	LQ to UQ	56 to 68	54 to 68
BMI kg/m <sup>2</sup>	Median	33	33
	LQ to UQ	31 to 36	31 to 36
Duration of	Median	6	6
diabetes (years)	LQ to UQ	4 to 10	4 to 9
	Missing N(%)	15 (2.4%)	44 (3.6%)
IMD score	Median	14	19
	LQ to UQ	10 to 27	11 to 36
	Missing N(%)	107 (17.4%)	257 (21.3%)
HbA1c %	Median	7	7
	LQ to UQ	6 to 8	7 to 8
	Missing N(%)	86 (14.0%)	248 (20.6%)
eGFR	Median	81	81
$ml/min/1.73m^2$	LQ to UQ	63 to 90	61 to 90
	Missing N(%)	91 (14.8%)	251 (20.8%)

## Table 2: Perceptions of diabetes and weight

Perception area	Response	N (Valid %)
<b>Impact of diabetes</b> Missing N=40(6.5%)	Positive	178 (31%)
	No impact	216 (37.6)
	Negative	180 (31.4%)
<b>Concern over diabetes</b> Missing N=21 (3.4%)	Yes	343 (57.8%)
	Neutral	160 (27%)
	No	90 (15.2%)
<b>Ability to control diabetes</b> Missing N=14(2.3%)	Completely	154 (25.7%)
	Mostly able	339 (56.5%)
	Somewhat able	96 (16%)
	Not able at all	11 (1.8%)
Weight impacts on life Missing N=16(2.6%)	No	219 (36.6%)
	Yes	379 (63.4%)
Ability to lose weight Missing N=30(4.9%)	Completely able	86 (14.7%)
	Mostly able	30 (4.9%)
	Somewhat able	168 (28.8%)
	Not able at all	300 (51.4%)
Satisfaction with ability to lose weight Missing N=36(5.9%)	Very satisfied/satisfied	203 (35.1%)
	No feeling	114 (19.7%)
	Unsatisfied/very unsatisfied	261 (45.2%)

Table 3: Characteristics of those willing to consider bariatric surgery trial participation

Variable	Yes/maybe group N (%)	No group N (%)	Odds ratio (95% CI)	p value
DEMOGRAPHICS				
Sex				
Male	203 (62.1%)	124 (37.9%)		0.33
Female	176 (65.9%)	91 (34.1%)	0.846 (0.604 to 1.186)	1
Age (years)				
<50	56 (83.6%)	11 (16.4%)	Reference	<0.001
50-59	123 (73.2%)	45 (26.8%)	0.537 (0.26 to 1.12)	1
60-69	146 (58.6%)	103 (41.4%)	0.278 (0.14 to 0.56)	
≥70	54 (49.1%)	56 (50.9%)	0.19 (0.09 to 0.40)	1
Ethnicity (Self-reported)				
White	320 (64.1%)	179 (35.9%)		0.658
Non-white	54 (66.7%)	27 (33.3%)	1.119 (0.68 to 1.84)	-
Index of Multiple Deprivation (IMD)				
1-25	235 (64%)	132 (36.0%)	Reference	
26-50	62 (64.6%)	34 (35.4%)	1.02 (0.64 to 1.64)	0.919
51-75	19 (67.9%)	9 (32.1%)	0.68 (0.522 to 2.696)	1
BMI (kg/m <sup>2</sup> )				
27.5-30.99	42 (50.0%)	42 (50.0%)	0.60 (0.36 to 0.99)	< 0.001
31-33.99	149 (62.6%)	89 (37.4%)	Reference	
34-35.99	69 (61.6%)	43 (38.4%)	0.96 (0.60 to 1.52)	-
36-39.99	119 (74.4%)	41 (25.6%)	1.73 (1.12 to 2.70)	-
Duration of diabetes (Years)				
<10	260 (62.5%)	156 (37.5%)		0.334
≥10	118 (66.7%)	59 (33.3)	1.20 (0.83 to 1.74)	
Insulin Status				
Yes	62 (66%)	32 (34.0%)		0.613
No	233 (63.1%)	136 (36.9%)	1.13 (0.70 to 1.82)	1
HbA1c (%)				0.129
≤7	184 (64.3%)	102 (35.7%)	Reference	0.128

7.1-8	67 (58.3%)	48 (41.7%)	0.77 (0.50 to 1.21)	
8.1%-9	33 (61.1%)	21 (38.9%)	0.87 (0.48 to 1.58)	-
>9	43 (76.8%)	13 (23.2%)	1.83 (0.94 to 3.57)	-
eGFR				0.295
<60	37 (57.8%)	27 (42.2%)		-
>=60	286 (64.6%)	157 (35.4%)	1.33 (0.78 to 2.27)	_
PERCEPTIONS				
Impact of diabetes on life				
Positive	113 (65.3%)	60 (34.7%)	Reference	0.004
No impact	119 (56.4%)	92 (43.6%)	0.69 (0.45 to 1.04)	_
Negative	127 (72.6%)	48 (27.4%)	1.41 (0.89 to 2.22)	_
Ability to control diabetes				
Completely able	76 (50.7%)	74 (49.3%)	Reference	0.002
Mostly able	223 (67.8%)	106 (32.2%)	2.05 (1.38 to 3.04)	_
Somewhat able	62 (68.9%)	28 (31.1%)	2.16 (1.25 to 3.73)	_
Not sure	8 (72.7%)	3 (27.3%)	2.60 (0.66 to 10.17)	_
Negative impact of weight on life				
No (reference)	88 (41.9%)	122 (58.1%)		< 0.001
Yes	280 (75.9%)	89 (24.15)	4.36 (3.03 to 6.27)	_
Ability to lose weight				
Completely able	57 (69.5%)	25 (30%)	Reference	0.011
Mostly able	16 (53.3%)	14 (46.7%)	0.50 (0.21 to 1.18)	_
Somewhat able	89 (54.3%)	75 (45.7%)	0.52 (0.30 to 0.91)	-
Not able at all	198 (68%)	93 (32%)	0.93 (0.55 to 1.59)	_
Satisfaction with ability to lose weight				
Very Satisfied/Satisfied (Reference)	103 (51.2%)	98 (48.8%)	Reference	< 0.001
No feeling	53 (50%)	53 (50%)	0.95 (0.59 to 1.52)	1
Very Unsatisfied/Unsatisfied	205 (80.4%)	50 (19.6%)	3.90 (2.58 to 5.90)	