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A Population-based, Shared Decision Making Approach to Recruit for a Randomized Trial of Bariatric Surgery versus Lifestyle for Type 2 Diabetes

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Abstract

Background—Randomized trials of bariatric surgery vs. lifestyle treatment likely enroll highly motivated subjects, which may limit the interpretation and generalizability of study findings.

Objective—To assess the feasibility of a population-based, Shared Decision Making (SDM) approach to recruitment for a trial comparing laparoscopic Roux-en-Y gastric bypass surgery to intensive lifestyle intervention among adults with mild-to-moderate obesity and type 2 diabetes.

Setting—A non-profit health system in King County, Washington that integrates care and coverage.

Methods—Adult members with a body mass index (BMI) between 30 and 45 kg/m² taking diabetes medications were identified in electronic databases and underwent a multi-phase screening process. Candidates were given a telephone survey, education about treatment options for obesity and diabetes using decision aids, and an SDM phone call with a nurse practitioner in addition to standard office-based consent.

Results—We identified 1,808 members, and 828 (45.7%) had a BMI 30–34.9 kg/m². Among these, 1,063 (59%) agreed to the telephone survey, 416 (23%) expressed interest in education about treatment options, and 277 (15%) completed the SDM process. The preferred treatment

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options were: 21 (8%) surgery; 149 (53.8%) diet and exercise; 5 (2%) pharmacotherapy; 8 (3%) none of the above; and 94 (34%) unsure. Ultimately, 43 participants were randomized to the trial. Significant differences were observed among people who did and did not agree to participate in our trial, mainly related to sex, disease severity, and hypoglycemic medication use.

Conclusions—This population-based, SDM-based recruitment strategy successfully identified, enrolled, and randomized subjects who had balanced views of surgery and lifestyle management. Even with this approach, selection biases may remain, highlighting the need for careful characterization of non-participants in all future studies.

Keywords

gastric bypass; diabetes; randomized trial; Shared Decision Making; recruitment

Introduction

Several randomized controlled trials (RCTs) have demonstrated the superiority of bariatric surgery compared to non-surgical treatments for type 2 diabetes mellitus (T2DM), even among patients with a body mass index (BMI) as low as 27 kg/m².^(1–3) These findings appear to validate longstanding clinical observations that bariatric procedures are effective treatment options for patients with T2DM and obesity.⁽⁴⁾

However, the applicability of these results to all obese patients with T2DM is questionable because RCTs such as these often include participants with unique characteristics that may favorably influence the outcome of interventions and durability of effects, reducing generalizability.^(5–7) Evidence of this discordance is that the national use of bariatric surgery among people with severe obesity is <1%;⁽⁸⁾ however, in recently published RCTs, relatively small numbers of candidates were screened to achieve recruitment goals, with 38%⁽¹⁾, 68%⁽²⁾, and 83%⁽³⁾ of screened subjects participating. Our pilot work on Shared Decision Making (SDM) in bariatric surgery suggests that roughly 100 severely obese people in a general medical practice need to be approached to find one who would consider participating in an RCT, but this has not been validated in a trial recruitment setting.⁽⁹⁾

Executing an RCT requires recruiting well informed participants who are sufficiently educated about the relevant topic to make rational (though appropriately inherently subjective) decisions whether the randomization arms are truly equally beneficial for them, individually. A major barrier to conducting definitive clinical trials in bariatric surgery is identifying adequate numbers of informed patients who are willing to be randomized to options as diverse as surgical vs. non-surgical treatments, having a funding source for the included interventions, and avoiding coercion of participants. There has been debate about whether one can be in equipoise between such fundamentally different treatments, i.e., surgical and behavioral,^(10, 11) although it has become easier as surgery has become safer.^(12, 13) Equipoise is always relevant in trials because inclination towards one treatment or another may help mediate the intervention's efficacy, especially for behavioral interventions. For example, patients who actively choose surgery might be more motivated overall to improve their health and also pursue better lifestyles and medication compliance than those who do not choose surgery. This potential allocation bias beclouds results of even the superb Swedish Obese Subjects study, where indeed the surgical group was sicker than the regular treatment group.⁽¹⁴⁾ A standard method to identify informed patients in surgical trials has been developed but, unfortunately, has not been widely used.⁽¹⁵⁾ Lastly, one approach to recruiting for RCTs is to pay for surgery among those who cannot afford it. However, this strategy might be considered coercive, especially if participants' decisional equipoise and knowledge of outcomes are not clearly established through standardized and effective educational activities before randomization.

To address these concerns, we sought to assess the feasibility of a novel SDM-based recruitment approach to develop a randomization cohort of well informed adults who have sufficient equipoise to accept randomization to either Roux-en-Y gastric bypass (RYGB) or intensive lifestyle intervention for diabetes and obesity. Here we report the results in the context of an ongoing RCT.

Materials and Methods

Study Setting

Recruitment for this prospective, randomized trial was conducted between July 2011 and June 2012 at Group Health Cooperative (GHC), a large, mixed-model, nonprofit health care system that coordinates health care and insurance coverage. The GHC system includes more than 600,000 enrolled members. GHC contracts with the Group Health Physicians medical group to provide care within an integrated group practice (IGP) for approximately 70% of the plan's enrollees. The remaining 30% receive care from non-GHC provider networks located in geographic areas not served by GHC medical centers. The study was approved by the GHC, University of Washington, and Fred Hutchinson Cancer Research Center Human Subjects Review Committees. The trial is registered with ClinicalTrials.gov.

Participants and Eligibility

In our SDM-based recruitment strategy, potentially eligible GHC members were identified from electronic databases. Computerized data are available on more than 2.8 million former and current Group Health members, thanks to automated data systems that track diagnoses and services using electronic medical record and claims databases. The primary data sources used for research are: 1) enrollment and demographics, 2) patient encounters, 3) diagnosis and procedures, 4) vital signs, 5) pharmacy, and 6) labs. Members were considered candidates if they were 25–64 years old, had a recent BMI in the electronic medical record of 30–45 kg/m², were currently taking medications for T2DM, were covered by insurance that had a bariatric-surgery rider (if BMI 35–45 kg/m²), and had no evidence within the past six months in our electronic medical databases of contraindications for participation in the trial. International Classification of Diseases-9-based contraindications for participation in our trial included: pregnancy, cancer (except non-melanomatous skin cancer), ascites, peritoneal effusion, dementia, bipolar, schizophrenia, cirrhosis, end-stage renal disease, human immunodeficiency virus, and inflammatory bowel disease. We excluded anyone with prior bariatric or major gastrointestinal surgery or organ transplant. We relied on previously collected electronic database information only, and subjects were not prospectively screened for these health conditions. Through these exclusions we sought to eliminate subjects who were deemed by our study team to be at greater than average risk for complications, disease-related weight change, or non-adherence to treatment and follow-up visits.

Recruitment and Randomization Process

We then used a multi-phase recruitment process to carefully screen potential participants. In Phase One, we mailed a letter inviting identified members to participate in a telephone survey about their weight and experience with weight-loss programs. We hypothesized that most members contacted would not currently be seeking bariatric surgery, so the letter did not mention surgery or our RCT. The main goal of the telephone survey was to assess interest in learning more about weight-loss and diabetes treatment options by asking: "There are many different ways to get information about the risks and benefits of different medical treatment options to lose weight. Would you be interested in receiving more information about how diet and exercise programs, prescription medications, and weight-loss surgery can help people lose weight and control their diabetes?"

Individuals responding affirmatively to this question were invited to participate in Phase Two, which involved a) re-reviewing exclusion criteria by phone, b) educating them about their treatment options using mailed decision aids, and then c) participating in a SDM phone call with an Advanced Registered Nurse Practitioner (ARNP). SDM is a collaborative process that allows patients and their providers to make healthcare decisions together, taking into account the best scientific evidence available, along with the patient's values and preferences. ⁽¹⁶⁾

Individuals who were invited to Phase Two and lacked reasons for exclusion were mailed a high-quality decision aid consisting of a DVD and educational booklet on treatment options for obesity, developed by the Informed Medical Decisions Foundation, ⁽⁹⁾ plus a separate booklet on RYGB and behavioral treatment for diabetes. The decision aid materials described lifestyle, medical, and surgical approaches, including information on both RYGB and laparoscopic adjustable gastric banding. Approximately two weeks later, the ARNP conducted a 30–45-minute SDM call with each participant to determine their treatment preferences and Decisional Conflict, using a previously validated scale. ^(17, 18) Decisional Conflict scores range from 0 (no conflict) to 100 (extremely high conflict). Decisional Conflict scores <25 are associated with implementing decisions; scores >37.5 are associated with decisional delay. People who remained undecided about treatment after the SDM call or favored any surgical treatment were invited to participate in the RCT (to be described in subsequent publications).

In Phase Three of the process, final eligibility for the RCT was confirmed by conducting insurance coverage review by health plan staff and detailed chart review by our two study surgeons, which sought to identify people with contraindications mentioned previously, high operative risk, or inability to participate in intensive exercise program. Eligible participants attended an in-person appointment at Group Health Research Institute in Seattle, where standard informed consent was obtained by a study physician, verifying that the patient had fully understood the alternatives. Randomization was performed by study staff using a computer-generated algorithm.

Data Analysis

Patient characteristics were examined at each step of the process (Figure 1) using means and frequencies to compare characteristics across groups. Multivariable regression identified associations between patient characteristics and levels of interest in the recruitment process. Analyses were conducted in Stata 12.0 (College Station, Texas).

Results

Figure 1 demonstrates the flow of participant recruitment. We identified 1,808 (Box A) members from GHC's electronic databases who appeared eligible, and mailed these individuals an invitation to participate in a telephone survey about their weight and experience with weight-loss programs [828 (45.7%) of these had a BMI 30–34.9 kg/m²]. Among these, 745 (41%) could not be contacted or, when contacted, refused to participate (Box B). The remaining 1,063 (59%) began our telephone survey (Box C). Appendix 1 describes the unadjusted differences between survey responders (Box C) and non-responders (Box B). In multivariable analyses, only age [Odds Ratio (OR): 1.02 for each additional year; 95% Confidence Interval (CI): 1.01–1.03; P=0.002], female sex (OR 1.27; 95% CI: 1.04–1.56; P=0.02) and metformin use (OR: 1.46, 95% CI: 1.11–1.92; P=0.007) were statistically significant independent predictors of responding to our screening call, although the magnitude of the differences were likely not clinically significant.

Following the telephone survey, 304 (17%) people were deemed ineligible to proceed for various reasons (not being a current member, not planning to remain a member, denied having T2DM, BMI outside range; Box D), and 304 (17%) were not interested in receiving more information about weight-loss and diabetes treatment options (Box F). The remaining individuals were invited to participate in Phase Two (described above), but 39 (2%) refused participation in this step (Box E). A total of 416 people (23%) remained eligible and agreed to complete the SDM call with a study ARNP (Box G); however, 139 (8%) refused or did not complete the SDM call when contacted.

Among the 277 (15%) who completed the entire SDM process, their preferred treatment choices were as follows: 21 (8%) surgery; 149 (54%) diet and exercise; 5 (2%) pharmacotherapy; 8 (3%) none of the above; and 94 (34%) unsure. The 115 (6%) who were either unsure about the best treatment approach or preferred surgery were invited to participate in our RCT (Box K). The 162 (9%) individuals who preferred non-surgical treatment were not invited to participate in the trial (Box J).

Among the 115 individuals who were provisionally invited to participate in our trial, 72 were not randomized for various reasons (Box L): 16 were determined to be ineligible (BMI outside study range, tobacco users unwilling to quit, unable to achieve a Hemoglobin A1c (HbA1c) >9.2% [deemed higher risk of post-operative complications and treatment nonadherence], recent pulmonary embolus, illicit drug use, unwilling to discontinue anticoagulation therapy, and uncontrolled major depression); 47 refused randomization; and 9 with a BMI between 30 kg/m² and 34.9 kg/m² were eligible but not randomized, because we had reached our recruitment goal. Ultimately, 43 participants met all eligibility criteria, completed informed consent, and were randomized (Box M).

Table 1 illustrates the unadjusted differences between people who wished to learn more about weight-loss and diabetes treatments (Figure 1, Box G) and those who were eligible but not interested in learning more (Box F). In our multivariable model, significant independent predictors of being interested in learning more about weight-loss and diabetes treatments included female gender (OR: 2.03; 95% CI: 1.36–3.03; P=0.001), higher BMI (OR: 1.16 per kg/m²; 95% CI: 1.09–1.23; P<0.001), higher HbA1c (OR: 1.32 per each %; 95% CI: 1.15–1.51; P<0.001), metformin use (OR: 0.49; 95% CI: 0.27–0.86; P=0.01), other oral hypoglycemic use (OR: 0.31; 95% CI: 0.18–0.52; P<0.001), dyslipidemia (OR: 2.06; 95% CI: 1.35–3.14; P=0.001), heart disease (OR: 0.38; 95% CI: 0.19–0.73; P=0.004), and sleep apnea (OR: 1.67; 95% CI: 1.11–2.49; P=0.01).

Table 2 compares the unadjusted characteristics of people who were invited to participate in the RCT (i.e., were undecided or preferred surgery after the SDM call, Figure 1, Box K) vs. those who were not invited (i.e., preferred non-surgical treatment, Figure 1, Box J). In our multivariable regression model, only participants' Decisional Conflict score (OR: 1.08; 95% CI: 1.05–1.12; P<0.001) was a significant independent predictor of being invited to participate in the trial.⁽¹⁷⁾

The final randomized cohort of 43 participants (2.4% of those initially potentially eligible; Figure 1, Box M) had a mean age of 53 years; 61% female; 65% Caucasian. The majority (89%) had completed at least some college education, and 69% were currently married. The average BMI was 38.4 kg/m², with 14% having a BMI<35 kg/m². Mean HbA1c was 7.9%. 93% were taking metformin, 65% were on a second oral hypoglycemic agent, and 40% were on insulin. Most patients had multiple co-morbidities, with 63% having hypertension, 77% dyslipidemia, 40% obstructive sleep apnea, and 23% arthritis. The Decisional Conflict score was 52±17 (Standard Deviation), with an inter-quartile range of 41 and 66.

Discussion

There are many important barriers to conducting randomized trials of bariatric surgery vs. non-surgical treatment. Herein, we tested a pragmatic, SDM recruitment strategy for a randomized trial of RYGB vs. an intensive lifestyle intervention for diabetes and obesity in a defined health plan population. Based on our prior study of SDM in bariatric surgery we hypothesized that we would need to contact ~100 people to identify one who was willing to be randomized. Ultimately, we randomized 43 participants after outreach to 1,808 people. This is a 2.4 times higher ratio of outreach-to-randomized subjects of 42:1 (2.4%). Therefore, we conclude that population-based recruitment for such a trial is easier than originally considered. Whether this recruitment approach yields high retention and low cross-over rates at one-year follow-up remains to be determined. It is possible that physician or surgeon-led outreach strategies would yield higher rates of recruitment, and future studies should assess whether such alternative recruitment strategies would yield higher rates of interest in bariatric operations among eligible subjects.

A major strength of a population-based recruitment strategy for a randomized trial is that data collected in the process provides informative details about the characteristics of individuals who ultimately do or do not participate in the trial. We found that both non-responders and study participants who were not interested in learning more about weight loss treatment were significantly different than responders and those who expressed interest in our study. The main implication of these findings is that data obtained from most randomized trials are insufficient to allow generalization to everyone who appears eligible for bariatric surgery based on existing criteria. ⁽¹⁹⁾

One concern that health systems, insurers, and purchasers have about expanding coverage of bariatric surgery is that it might release a “flood gate”, and the system will be overwhelmed by interested patients. In fact, if the ~14 million people in the United States who are eligible for surgery based on BMI and diabetes alone actually sought surgery, there is general agreement that the demand could not be met. However, when we performed outreach to 1,808 individuals with T2DM and a BMI between 30 and 45 kg/m², only 21 (1.2%) clearly preferred surgery. This suggests that, surprisingly, our current targeted outreach strategy to raise awareness of bariatric surgery as a treatment option for T2DM would probably not dramatically increase demand. Other strategies, such as those that involve media advertisements and direct outreach to patients by medical providers, may yield higher rates of uptake of bariatric surgery, and these warrant future investigation.

Our study has potential limitations. First, it was based in a single healthcare system in Washington State that is predominantly Caucasian, employed, and well-educated. While our population was predominantly Caucasian (78%), this is comparable to the distribution in Washington state (72%) and to the United States as a whole (72%) in 2010. We do not know whether our findings are generalizable to other populations and settings, including those with lower socioeconomic status and lower health literacy; these are important questions that deserve further study. We also do not know whether inviting patients who had expressed a preference for medical/lifestyle treatment of diabetes and obesity would have yielded different response rates. Second, ongoing follow-up is needed to determine whether these subjects followed through on their preferred treatment options and whether their long-term diabetes-related health outcomes are different from those who preferred non-surgical treatment.

Conclusions

Randomized trials of bariatric surgery are expensive endeavors and challenging to conduct. However, our study provides further evidence that a pragmatic, SDM-based recruitment strategy is feasible for randomized trials of bariatric surgery vs. intensive lifestyle intervention. Our study also clearly describes the selection biases inherent in recruitment for trials of bariatric surgery, which brings into question the validity of all published trials that fail to report detailed characteristics of patients who do not enroll.^(1–3) Longer-term follow-up of this cohort is ongoing to determine if our recruitment approach yields high retention and low cross-over rates.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.
Subject identification and recruitment flow diagram
* SDM = Shared Decision Making

Table 1

Unadjusted characteristics of subjects who responded to screening call, stratified by those who were eligible and interested in learning more about obesity and diabetes treatment options and those who were not (Box G vs. Box F, from Figure 1)

	Eligible for study and interested in learning more about treatment options (Box G)	Eligible for study but not interested in learning more about treatment options (Box F)	P-value
Number of subjects	416	304	
Female, N (%)	234 (56.3%)	116 (38.2%)	<0.0001
Age, years, mean (SD)	53.9 (7.7)	55.8 (7.2)	0.0008
County of residence			
Pierce, N (%)	92 (22.1%)	28 (9.2%)	<0.0001
King, N (%)	284 (68.3%)	256 (84.2%)	
Snohomish, N (%)	40 (9.6%)	20 (6.6%)	
Body mass index (kg/m ²), mean (SD)	36.6 (3.6)	34.5 (3.3)	<0.0001
BMI category			
30.0 to 34.9 kg/m ² , N (%)	119 (28.6%)	169 (55.6%)	<0.0001
35.0 to 39.9 kg/m ² , N (%)	211 (50.7%)	111 (36.5%)	
40.0 to 44.9 kg/m ² , N (%)	86 (20.7%)	24 (7.9%)	
HbA1c (%), mean (SD)	7.9 (1.8)	7.5 (1.5)	0.0009
Current diabetes treatment			
Metformin, N (%)	349 (83.9%)	257 (84.5%)	0.82
Other oral hypoglycemic, N (%)	215 (51.7%)	198 (65.1%)	0.0003
Insulin, N (%)	145 (34.9%)	112 (36.8%)	0.58
Race/Ethnicity			
Hispanic, N (%)	26 (6.3%)	19 (6.3%)	0.99
American Indian or Alaska Native, N (%)	9 (2.2%)	3 (1.0%)	0.67
Asian	15 (3.6%)	13 (4.4%)	
African American	49 (11.9%)	35 (11.8%)	
Native Hawaiian or Pacific Islander	5 (1.2%)	7 (2.4%)	
Caucasian	264 (63.9%)	196 (66.0%)	
Other	16 (3.9%)	11 (3.7%)	
Multiple/mixed race	55 (13.3%)	32 (10.8%)	
Currently married, N (%)	287 (69.3%)	200 (65.8%)	0.32
Education level, N (%)			
High school or less	79 (19%)	44 (14.5%)	0.44
Some college	176 (42.4%)	136 (44.7%)	
College graduate	101 (24.3%)	81 (26.6%)	
Graduate degree	59 (14.2%)	43 (14.1%)	
Income, N (%)			
Less than \$20,000	28 (7.1%)	16 (5.8%)	0.40

	Eligible for study and interested in learning more about treatment options (Box G)	Eligible for study but not interested in learning more about treatment options (Box F)	P-value
\$20,000 to \$50,000	122 (31.0%)	79 (28.5%)	
\$50,000 to \$100,000	152 (38.7%)	125 (45.1%)	
More than \$100,000	91 (23.2%)	57 (20.6%)	
Health Conditions, N (%)			
Hypertension	290 (69.7%)	210 (69.3%)	0.91
Dyslipidemia	299 (72.0%)	178 (59.3%)	0.0004
Heart disease	37 (9.0%)	45 (14.8%)	0.016
Sleep apnea	157 (38.2%)	79 (26.5%)	0.001
Prior heart attack	21 (5.1%)	23 (7.6%)	0.17
Stroke	21 (5.0%)	15 (4.9%)	0.94
Arthritis	163 (39.4%)	88 (29.0%)	0.004
Current attitude towards weight loss			
I am already working on it	240 (58.0%)	180 (59.6%)	<0.0001
I plan on starting in next 30 days	110 (26.6%)	44 (14.6%)	
I plan on starting in the next 6 months	45 (10.9%)	30 (9.9%)	
I have no plans to work on weight loss	19 (5.1%)	48 (15.9%)	

* SD = standard deviation; BMI = body mass index; HbA1c = Hemoglobin A1c

Table 2

Unadjusted characteristics of subjects who completed the Shared Decision Making call about obesity and diabetes treatment, stratified by those who were invited to participate in the randomized trial and those who were not invited to be randomized (Box K vs. Box J, from Figure 1)

	Total Invited (Box K)	Total Not Invited (Box J)	P-value
Number of subjects	115	162	
Female, N (%)	75 (65.2)	94 (58.0%)	0.23
Age, years, mean (SD)	53.4 (7.6)	54.9 (7.4)	0.10
County of residence			
Pierce, N (%)	29 (25.2%)	33 (20.4%)	0.2457
King, N (%)	71 (61.7)	115 (71.0%)	
Snohomish, N (%)	15 (13)	14 (8.6%)	
Body mass index (kg/m ²), mean (SD)	37.9 (3.3)	36.3 (3.8)	0.0002
BMI category			
30.0 to 34.9 kg/m ² , N (%)	20 (17.4%)	50 (30.9%)	0.03
35.0 to 39.9 kg/m ² , N (%)	64 (55.7%)	79 (48.8%)	
40.0 to 44.9 kg/m ² , N (%)	31 (27.0%)	33 (20.4%)	
HbA1c (%), mean (SD)	8.0% (1.8)	7.8% (1.7)	0.33
Current T2DM treatment			
Metformin, N (%)	96 (83.5%)	140 (86.4%)	0.50
Other oral hypoglycemic, N (%)	65 (56.5%)	79 (48.8%)	.20
Insulin, N (%)	46 (40.0%)	51 (31.5%)	0.14
Race/Ethnicity			
Hispanic, N (%)	10 (8.7%)	6 (3.7%)	0.08
American Indian or Alaska Native, N (%)	1 (0.9%)	2 (1.2%)	0.77
Asian	3 (2.6%)	6 (3.7%)	
African American	11 (9.6%)	24 (14.9%)	
Caucasian	81 (71.1%)	104 (64.6%)	
Other	5 (4.4%)	5 (3.1%)	
Multiple/mixed race	13 (11.4%)	20 (12.4%)	
Currently married, N (%)	81 (70.4%)	117 (72.7%)	0.68
Education level, N (%)			
High school or less	23 (20.0%)	20 (12.4%)	0.14
Some college	50 (43.5%)	62 (38.5%)	
College graduate	28 (24.3%)	49 (30.4%)	
Graduate degree	14 (12.2%)	30 (18.6%)	
Income, N (%)			
Less than \$20,000	6 (5.5%)	7 (4.5%)	0.58
\$20,000 to \$50,000	39 (35.5%)	44 (28.2%)	
\$50,000 to \$100,000	43 (39.1%)	67 (42.9%)	

	Total Invited (Box K)	Total Not Invited (Box J)	P-value
More than \$100,000	22 (20.0%)	38 (24.4%)	
Health Conditions, N (%)			
Hypertension	75 (65.2%)	113 (69.8%)	0.43
Dyslipidemia	85 (73.9%)	113 (70.2%)	0.50
Heart disease	11 (9.7%)	15 (9.4%)	0.92
Sleep apnea	55 (48.2%)	59 (37.1%)	0.07
Prior heart attack	8 (7.0%)	9 (5.6%)	0.63
Stroke	6 (5.2%)	6 (3.7%)	0.54
Arthritis	48 (42.1%)	61 (37.9%)	0.48
Current attitude towards weight loss			
I am already working on it	58 (50.4%)	105 (64.8%)	0.07
I plan on starting in next 30 days	34 (29.6%)	35 (21.6%)	
I plan on starting in the next 6 months	17 (14.8%)	13 (8.0%)	
I have no plans to work on weight loss	6 (5.2%)	9 (5.6%)	
Decisional conflict score, mean (SD) *	48.4 (16.4)	38.3 (12.9)	<0.0001
Bariatric knowledge score, mean (SD) *	74.3 (12.8)	74.3 (13.5)	0.98

* Decisional conflict score range 0–100, higher equals worse decisional conflict; Bariatric knowledge score range 0–100; higher equals better knowledge of bariatric surgery; SD = standard deviation; BMI = body mass index; HbA1c = Hemoglobin A1c; T2DM = type 2 diabetes mellitus