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The Use of a Pre-operative Psychosocial Patient Education Course to Improve Health-related Quality of Life after Bariatric Surgery: A Pilot Study

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Abstract

Introduction: Patient education is a valuable resource in bariatric surgery, there is limited evidence within the literature about its utility in research studies. In particular, no clinical trials have studied the use of pre-operative psychosocial education in an effort to improve post-operative Health Related Quality of Life (HRQOL).

Methods: A pilot study was performed in order to test the feasibility and acceptability of using a newly designed psychosocial educational course in a controlled clinical trial. A two-session course designed to enhance multiple aspects of health related quality of life including relationships with food, dealing with guilt and shame, and improving support networks was provided to patients in an intervention group. HRQOL outcomes were compared to a control; patients who did not undergo extra education. Follow up was performed at three, six and twelve months using the BAROS and PHQ-9 tools.

Results: 49 patients were recruited; 25 to the control and 24 to the intervention. Seventeen of the intervention patients attended the educational course. Feedback regarding acceptability and utility was excellent. Within the control, 16 patients completed their 3-month follow up, 14 at 6-months and 13 at 12-months. In the intervention group, 19 completed their 3-month follow up, and 18 at 6 and 12-months. Although statistical significance between groups was not sought, both groups showed a trend towards an improvement in BAROS and PHQ-9 scores between 3 and 12 month time points.

Conclusion: Educational interventions of this type are acceptable to patients, and a study of this nature would be feasible to perform in a hospital setting. Further research regarding the effects of patient education on health related quality of life following bariatric surgery within larger controlled clinical trials is warranted.

Introduction

Obesity has long been labeled a "global Health Epidemic [1], with figures from 2017 showing that 27% adults in the UK are obese and a further 30% overweight [2,3]. Lifestyle interventions including dietary management, increasing physical activity physical activity, behavioral therapies and pharmacological treatments are common [4], but often less successful at achieving significant weight loss or reduction of co-morbidities (particularly type 2 diabetes) than bariatric surgery [5,6]. Within the UK, all patients undergo lifestyle management programmes before being offered surgery [7] and pre operative education regarding diet and the risks/benefits of surgery is mandatory in the public healthcare system.

To patients, HRQOL, which can be thought of as having physical, mental and social components [8], is arguably the most important measure of any successful medical intervention, including bariatric surgery [9-12]. However, there appears to be a significant gap within both practice and in the literature regarding education of the more psychosocial aspects of bariatric surgery [8], which can significantly impact upon HRQOL. A lack of insight into how patients deal with lifestyle changes, or in other words, how their psychosocial functioning is affected by surgery, demonstrates the need for more research.

Patient education has, over the last few decades, become of increasing value when considering Health-Related Quality Of Life (HRQOL) for patients with chronic disease [13]: obesity is a prime example. In order to be successful with surgical weight loss and achieve a meaningful improvement in HRQOL, patients require high levels of self-management, understanding and lifestyle adjustment. Although there is clear evidence that bariatric surgery can significantly improve physical and mental health [14-17], there is a relative lack of understanding or research regarding the effects of psychosocial functioning from either an objective or subjective perspective. Given the importance patients have been shown to place on the lifestyle and psychosocial effects of bariatric surgery [18,19], educating them about what to expect, the lifestyle changes that will be afforded to them and how to adapt could be considered a critical and essential part of the bariatric service. Potentially, educational support could help patients to adapt more quickly and successfully after surgery [8]. Additionally, providing improved education and

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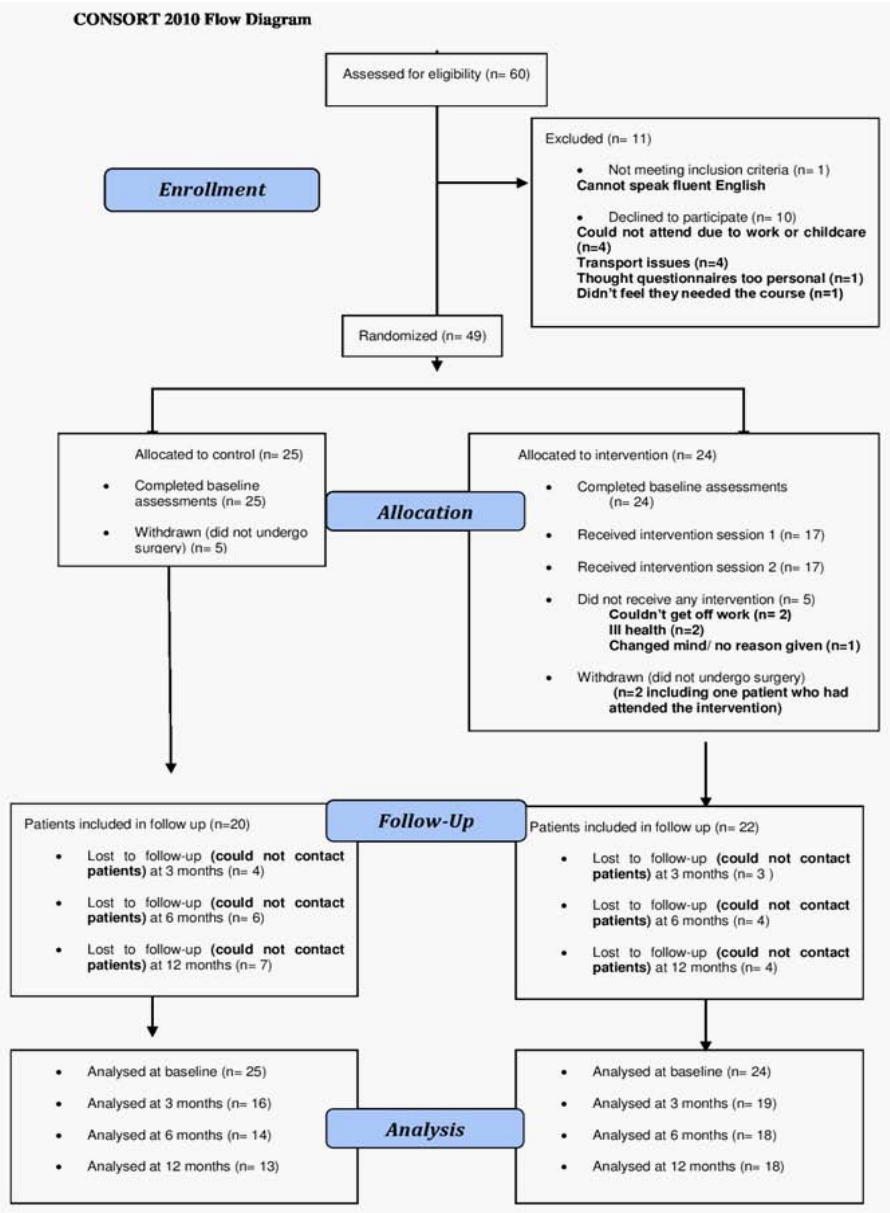

Figure 1: Recruitment and follow up rates for this study.

support could help to prevent weight regain and the resurgence of co-morbidities, improving overall HRQOL in the longer term [20-22]. For this reason it seems appropriate that pre-operative education should focus as much on behaviors as it does on weight loss, dietary aspects of surgery and potential complications.

To date, there is no consensus from the governing bodies around the UK including the National Institute for Health and Clinical Excellence (NICE), the Department of Health (DoH) or the British Obesity and Metabolic Surgery Society (BOMSS) about what education needs to be provided for patients prior to bariatric surgery. Most education is determined by individual hospital services, with little consistency between units as to what psychosocial education they provide (owers ET AL THESIS).

It is therefore crucial that ways to evaluate and improve the education that patients receive are sought, ideally aiming to standardize education so that patients receive the same service wherever they undergo surgery.

Aims of the Research

This study aimed to pilot test a controlled clinical trial to see if an educational intervention and selected methods were appropriate and suitable to explore the affect of education on HRQOL following bariatric surgery. Following this, the aim was to consider how it could be taken forward into a larger controlled clinical trial. Given that this was a pilot study, primary outcome measures related to data regarding recruitment and follow up rates. Secondary outcome measures related to attendance at the educational intervention, patient evaluation of the

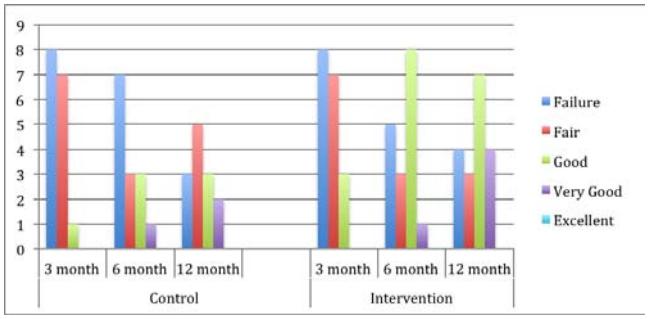

Figure 2: BAROS data showing numbers of patients with each outcome (ranging from failure to excellent) at each follow up time point.
X axis: Number of patients.

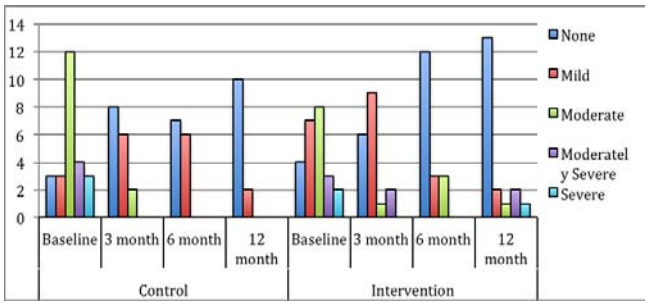

Figure 3: PHQ-9 data demonstrating number of patients experiencing each outcome ranging (from no depression to severe) at each time point.
X axis: Number of patients.

course and the overall results from the patient questionnaires. Given its nature, this study did not intend to provide statistical analysis of the questionnaire data, or to seek clinical significance.

Methods

As part of a previous study [8], an educational course was designed using patient-focused qualitative research, and clinical and educational experience [23]. This work explored what participants believed new bariatric patients should be told regarding post-operative lifestyle. Findings provided valuable insight when designing the pre-operative educational course, the main content of which is described in Table 1.

Recruitment took place between June 2014 and March 2015. Participants included all newly referred patients to the bariatric service within one Yorkshire Teaching hospital; recruitment occurred after they had been listed for surgery by one of the two consultant surgeons. Patients who were already under the care of the bariatric psychologist, or whom spoke limited English, were excluded. Patients were randomized to either the intervention group where they attended a two-session educational course (lasting approximately eight hours in total) or the control group where they did not undergo any extra education. A block randomization technique was used for logistical reasons due to resource limitations, to ensure patients did not undergo surgery before attending the intervention course.

Assessment tools used for follow up at 3, 6 and 12-months post operatively included the Bariatric Analysis and Reporting Outcome System (BAROS) [24]. This tool seeks information on change in weight, change in medications/co morbidities, and complications or returns to theatre. It also includes a self-reported lifestyle questionnaire (the Moorhead-Ardalt Quality of Life Questionnaire), meaning that the BAROS includes a patient perspective component. At baseline and each follow up point, patients were also asked to complete the PHQ-9 depression inventory [25,26].

Follow up was performed either in clinic (face-to-face) or by phone. In each case, medical records were reviewed to collect weights, medication changes and clinically assess for any post-operative complications. Table 2 shows the data collected at each time point

Analysis was performed using Excel spreadsheet on an intention to treat analysis was performed, as these theoretically better estimates the effects of drop outs, protocol deviations, treatment withdrawal and non-compliance [27]. On an intention to treat basis.

The study was approved by the South Yorkshire Regional Ethics Committee: 12/YH/0384. Written informed consent was taken by the researcher for each patient.

Results

Forty-nine patients were recruited to the study. Demographic characteristics of participants can be seen in Table 3.

The CONSORT diagram below (Figure 1) shows the recruitment and follow up rates for this study.

All patients completed their baseline assessment (PHQ-9). Five were withdrawn from the control group as they did not undergo surgery; a further two were withdrawn from the intervention for the same reason (one after attending the course). In the intervention group, 17 of the 24 patients completed the intervention (both sessions).

From the control group, follow up data was collected from 16 patients at 3 months, 14 patients at six-months and 13 patients at 12-months. Within the intervention group, follow up data was collected from 19 patients at three months, 18 patients at six and 12 months.

BAROS and PHQ-9 data is presented categorically (i.e. number of patients within each category at each time point (Figure 2).

Within both groups, there was a general trend towards improved outcomes between baseline and 12-months, i.e. the number of patients in each group scoring 'very good' increased, where as the number of 'failures' decreased between time-points. However, the numbers involved are too small to present any statistically or clinically significant outcomes (Figure 3).

Again, although not tested for statistical significance, the number of patients with moderate, moderately severe and severe depression decreased in both groups between baseline and 12-months. The number of patients experiencing no depressive symptoms at all went from 3 to 10 in the control group and 4 to 13 in the intervention improvement in depressive symptoms post operatively in both groups.

Participants in the intervention group completed a written evaluation form. All patients indicated that they believed they were either well educated or very well educated following the course,

Table 1: Topics used to design educational course.

Topic	Points covered
Expectations of surgery	What to expect in terms of weight loss ('hopes' versus 'realities'); what to expect during post-operative recovery; goal setting
Side effects of surgery and how to deal with them (including loose skin)	Hair loss, teeth and nail changes, malabsorption, constipation and diarrhoea, how to minimize the appearance of loose skin; realities of obtaining skin removal surgery
How to deal with weight regain	What to do when weight gain recurs; where to seek support; how to evaluate lifestyle and activities and make positive changes
Improving physical activities	Finding ways of improving activity without going to the gym; energy input and output
Guilt and shame regarding surgery, including the public perception of bariatric surgery	How to deal with negativity from others; self-esteem; the definition of guilt and shame and what they mean; working towards positive emotions
Improving a support network and accessing psychosocial support	Where to seek help for individual issues; how to improve communication with friends and family or other support networks
Addiction transference	How to spot and deal with addiction transference
Understanding our relationship with food and eating habits	Learning about individual eating habits: emotional and physical triggers; learning to change habits and develop new coping mechanisms
Changes to relationships	How relationships with friends, family, partners, work and health professionals may change; how to deal with issues in relationships; the sexual relationship including pregnancy
Researching bariatric surgery	Where to access information on bariatric surgery; what to research
Eating out/social life	How social life may be affected by surgery; how to learn to eat out in public (where to go, how to minimise disruption to lifestyle)
Returning to work	When to return; what to do; dealing with colleagues

Table 2: Data collected at each time point [8].

Data collection	Baseline	Following intervention	3 months	6 months	12 months
Number of patients approached	✓				
Number of patients recruited	✓				
BAROS (using MAQOL tool)			✓	✓	✓
PHQ-9	✓		✓	✓	✓
Patient weight	✓		✓	✓	✓
Patient medications	✓		✓	✓	✓
Obesity related co-morbidities	✓		✓	✓	✓
Number of patients attending educational intervention (intervention group only)		✓			
Written feedback from patients attending educational course (intervention group only)		✓			
Complications of surgery			✓	✓	✓

and that they were well prepared for the challenges that faced them following surgery. Ten patients said they got more than they'd hoped from the sessions; the remaining six indicated that they got what they had expected. No patient indicated dissatisfaction. Free text responses were also collected, which were complimentary and demonstrated patient's enthusiasm for educational interventions such as this.

Discussion

Education is paramount in improving outcomes from all aspects of healthcare, including bariatric surgery [28,29], having been shown to improve treatment compliance [30], reduce complications and complaints [31], improve patient satisfaction and improve psychosocial functioning [32].

This is the first study to systematically design and test the use of a psychosocial educational course as part of preparation for bariatric surgery, with the intention of improving HRQOL [8,23]. This study has demonstrated that a trial using a psychosocial educational course is acceptable to patients, and indeed, desired. The attendance rate of 71% to both sessions of the course showed that patients attending the first session were keep to attend the second; there were no patient drop-outs between sessions. Designed as a pilot study, statistical or clinical significance of the findings was not established. Trends towards an improvement in outcomes for both groups demonstrate the psychosocial impact of bariatric surgery, but patient evaluations from this study support the need or desire for increased and improved education.

When seeking to provide the scientific evidence to support a change in clinical practice, controlled trials are often needed. The design of such trials can be complex and costly, with literature searches, intervention and protocol design being only a few of many challenges [33]. As such, many funding bodies require pilot work to test methods [34] and demonstrate feasibility [35]. Given the lack of reporting in the literature that psychosocial education in obese patients has been tested, a pilot study was warranted. For this reason, this study has focused on outcome measures such as recruitment and follow-up rates, alongside patient evaluation, rather than aiming to provide statistical evidence for the introduction of improved pre-operative bariatric education.

Some methodological flaws were identified within this pilot study, which would need to be rectified before moving to a larger scale controlled clinical trial. Within this pilot study, a 'block randomization' technique was used [36] in an attempt to equalize

Table 3: Participant demographics in pilot study.

	Control (n)	Intervention (n)
Sex M: F	2:23	9:15
Mean age (years)	56.3 (26-67)	47 (25-71)
BMI (kg/m^2)	46.3 (37.2-62.9)	39.5 (35.8-55.2)
Mean weight (kg)	132.6 (102.0-210.5)	121.1 (105.6-191.0)
Listed operation-SG: RYGB	11:09	12:10

SG: Sleeve Gastrectomy; RYGB: Roux-en-Y Gastric Bypass.

recruitment to each group; this was also done for logistical purposes, to try and prevent patients undergoing surgery before attending the course. However, a "cluster randomization" may be preferable in a larger trial: this would have the added benefit of minimizing bias from, for example, patients in both groups mixing on the surgical ward.

Although the numbers of patients recruited to the trial (82%), and the numbers of patients attending the intervention (71%) were considered acceptable, 20 patients were either withdrawn or lost to follow up. Withdrawals were due to either patients declining surgery (two patients) or anaesthetic issues (five patients). Anaesthetic issues are difficult to anticipate in advance unless the patient undergoes anaesthetic assessment prior to recruitment. Within this study, this was not logistically feasible and therefore in any future trial, a provision would have to be made for attrition due to anaesthetic problems. For patients who did undergo surgery, the dropout rate however may have been influenced by the decision to follow patients up either by phone or face-to-face only. Consideration needs to be given to adequate resourcing of follow-up data collection. In this study attending surgical clinics where patient follow up occurred was a challenge. Alternate follow up was performed by phone which allowed contact with several of the participants who were not seen in clinic. To improve the response rate further, alternative methods for completion of the questionnaire should be considered such as using the internet.

Although the BAROS is the only HRQOL assessment tool designed specifically to measure HRQOL in post-bariatric patients, a detailed review in 2015 [37] highlighted numerous flaws with the tool including scoring of the tool and the clinical significance of BAROS scores. Arguably, the most commonly used, and appropriate assessment tool to measure HRQOL outcomes in this population, is now the Impact of Weight on Quality of Life [38,39]. Including this tool in a future trial may be prudent.

Conclusion

Findings from this pilot study suggest that educational interventions can be used successfully in research to determine the impact of psychosocial education on HRQOL following bariatric surgery. In addition to demonstrating feasible methods for recruitment, delivery of an intervention and participant follow-up, findings are promising, suggesting that patients have a desire for more education, and that education has the potential to further improve the positive HRQOL effects that bariatric surgery has already been demonstrated to offer. Undoubtedly, improving the education we deliver to patients will ensure that patients are exposed to opportunities that will facilitate positive lifestyle change resulting in weight loss and maintenance with associated co-morbidity resolution.

The potential clinical advantages, alongside standardization of patient education in bariatric centers across the UK (and beyond), offers potential improvement in patient outcomes and experience. Further research that measures the extent of these benefits is now warranted.

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