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Patients' experiences of life after bariatric surgery and follow-up care: A qualitative study.

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Abstract

Objectives: Bariatric surgery is the most clinically effective treatment for people with severe and complex obesity, however, the psychosocial outcomes are less clear. Follow-up care after bariatric surgery is known to be important, but limited guidance exists on what this should entail, particularly related to psychological and social well-being. Patients' perspectives are valuable to inform the design of follow-up care. This study investigated patients' experiences of life after bariatric surgery including important aspects of follow-up care.

Design: A qualitative study using semi-structured individual interviews. A constant comparative approach was used to code data and identify themes and overarching concepts.

Setting: Bariatric surgery units of two publicly funded hospitals in the South of England.

Participants: Seventeen adults (10 women) that underwent a primary operation for obesity (mean time since surgery 3.11 years), including Roux-en-Y gastric bypass, adjustable gastric band and sleeve gastrectomy, agreed to participate in the interviews.

Results: Experiences of adapting to life following surgery were characterised by the concepts of 'normality' and 'ambivalence', while experiences of 'abandonment' and 'isolation' dominated participants' experiences of follow-up care. Patients highlighted the need for more flexible, longer-term follow-up care that addresses social and psychological difficulties post-surgery and integrates peer support.

Conclusions: This research highlights unmet patient need for more accessible and holistic follow-up care that addresses the long-term multi-dimensional impact of bariatric surgery. Future research should investigate effective and acceptable follow-up care packages for patients undergoing bariatric surgery.

1 Article Summary - strengths and limitations of this study

- 2 • Patients who had undergone all three main types of bariatric procedures across two UK
3 centres were included in the research.
- 4 • A detailed qualitative approach was used, allowing participants to relate their own
5 experiences in terms that were relevant for them.
- 6 • A rigorous approach to analysis was undertaken, including independent coding of initial
7 transcripts by three researchers, and agreement of emergent themes throughout analysis
8 with at least one other qualitative researcher.
- 9 • It is not known whether similar themes would be found with participants in other centres.
- 10 • Findings relating to follow-up care may be less generalisable to healthcare systems with
11 different service pathways and funding structures.

1 Introduction

2 Over 650 million or 13% of adults worldwide suffer from obesity (body mass index (BMI) ≥ 30 kg/m²),
3 representing a tripling of figures since 1975.¹ Obesity is associated with an increased risk of type 2
4 diabetes, cardiovascular disease, certain cancers, and premature death.^{2,3} Within this population,
5 people with severe and complex obesity (BMI ≥ 40 kg/m², or 35-40 kg/m² with another significant
6 health problem that could be improved by weight loss) suffer the greatest health burdens and are at
7 the highest risk of premature death.^{4,5} In addition to the physical and metabolic health burdens,
8 people with severe and complex obesity are more likely to suffer with psychological disorders such
9 as depression, anxiety and disordered eating, and reduced health-related quality of life (HRQL).^{6,7}
10 These individuals also suffer from social stigma and discrimination related to their weight ^{6,8} which is
11 in turn associated with adverse physical and psychological outcomes.^{8,9} Thus, any interventions to
12 treat severe and complex obesity should consider the impact on these psychosocial outcomes in
13 addition to traditional clinical and metabolic outcomes.^{10,11}
14 Bariatric surgery, combined with behaviour change and dietary management, is the most clinically
15 effective treatment for people with severe and complex obesity, in terms of weight loss and the
16 improvement of co-morbidities such as type 2 diabetes.^{5,12,13} However the impact of bariatric surgery
17 on HRQL is less clear, with some aspects of HRQL improving but others not.^{11,12,14} Previous qualitative
18 research has highlighted the complex and changeable nature of the psychosocial impact of bariatric
19 surgery, helping to shed light on some of these inconsistencies in the HRQL literature, and
20 emphasising the importance of long-term post-operative support in helping patients manage these
21 changes.^{10,15} Previous research has also reported attendance at follow-up visits to be associated with
22 better weight loss outcomes after bariatric surgery.¹⁶
23 Follow-up care is thus important to optimise clinical and psychosocial outcomes of bariatric surgery.
24 However, bariatric surgery follow-up care has been reported to vary greatly across the UK,¹⁷ and

1
2
3 1 current UK and US bariatric surgery guidelines focus on surgical and metabolic outcomes, with
4
5 2 limited guidance on how to support psychological, social and lifestyle changes that affect patients'
6
7 3 HRQL.^{5 18} Nevertheless, previous work has highlighted the importance of these multi-faceted aspects
8
9 4 of HRQL to patients that have undergone bariatric surgery and recommendations are needed on
10
11
12 5 how best to support patients after surgery to optimise these outcomes.^{19 20}

13
14
15 6 In seeking to evaluate and provide recommendations on bariatric surgery follow-up care, the
16
17 7 patient's perspective can provide valuable information.²¹ Qualitative research is useful to explore
18
19 8 patients' perspectives as it seeks to gain the insider's view on how people view, experience, and
20
21 9 make sense of their social world.²²⁻²⁴ Previous qualitative studies have identified patient need for
22
23 10 longer follow-up after bariatric surgery, better access to psychological support, and access to health
24
25 11 professional advice between routine appointments.^{15 25-32} However, these studies are limited in that
26
27 12 most are single-centre and report findings from select groups, for example patients that had
28
29 13 undergone one type of bariatric procedure only (e.g. adjustable gastric band) or those that had
30
31 14 experienced negative outcomes such as weight re-gain or substance abuse issues. There is a need to
32
33 15 understand the most important aspects of bariatric surgery follow-up care from the perspectives of
34
35 16 a range of patients that have undergone different bariatric procedures and at different timepoints
36
37 17 post-surgery to provide recommendations for follow-up care. This is the objective of the study
38
39 18 presented here.

19 Methods

20 Patients who had undergone a primary operation for obesity at two publicly funded bariatric surgery
21 centres in the South of England were eligible to participate in the research. Patients were identified
22 by health professionals at each hospital using databases and clinic lists and sent information about
23 the research. Interested patients contacted the researcher directly (KDC). For initial interviews,
24 patients were sampled purposively, aiming for maximum variation in gender, age, starting body

1
2
3 1 mass index (BMI), type of operation, and time since operation. Emerging findings from analysis of
4
5 2 initial interviews guided sampling for remaining interviews.³³ Sampling continued until themes were
6
7 3 well-established with few or no new insights gained from additional data collection.^{23 33} Ethical
8
9 4 approval for the study was obtained from Northwest - Preston Research Ethics Committee (Ref
10
11 5 12/NW/0844). This study was undertaken as part of a wider study to develop a core outcome set for
12
13 6 bariatric surgery (see **document S1** for protocol).^{19 20}
14
15
16
17 7 Data were collected through semi-structured interviews, mostly conducted in participants' homes.
18
19 8 Written informed consent was taken and interviews conducted according to an outline topic guide,
20
21 9 which evolved iteratively as the research progressed (see **document S2** for final versions). Relevant
22
23 10 demographic and clinical information were also collected (**document S3**). All interviews were
24
25 11 conducted and audio-recorded between February 2013 and November 2014, by a female researcher
26
27 12 (KDC) who was a PhD student and registered dietitian. KDC underwent training in qualitative
28
29 13 research methods and was supervised by two experienced qualitative researchers (AOS, FM). An
30
31 14 initial telephone conversation was held with each participant to discuss the study and arrange the
32
33 15 interview. Participants were otherwise not previously known to the researcher prior to interview.
34
35 16 The researcher introduced herself as a PhD student to participants. She did not reveal her
36
37 17 professional background as a registered dietitian unprompted but did not seek to hide it if
38
39 18 participants asked. Field notes, which provided important contextual information to aid data
40
41 19 analysis, were made as soon as possible after each interview.³⁴
42
43
44
45
46
47 20 Recorded interviews were transcribed verbatim, and transcriptions checked for accuracy by KDC.
48
49 21 Thematic analysis was undertaken, using techniques of constant comparison to code data and
50
51 22 identify emerging themes.³³ Coding was completed for all transcripts by KDC, with a sample of
52
53 23 transcripts independently coded by two other experienced qualitative researchers (AOS and JLD)
54
55 24 (see **document S4** for final coding framework). Differences in interpretation were resolved through
56
57 25 discussion. Coding and data management were facilitated using NVivo 10 software.³⁵ Detailed
58
59
60

1
2
3 1 descriptive accounts were written by KDC for each small batch of interviews, whereby emergent
4
5 2 themes were identified and further investigated in subsequent interviews. Finally, large matrices
6
7 3 were created to compare themes across all participants and identify concepts overarching all
8
9 4 themes.³⁶ AOS, FM, JLD and JMB reviewed all descriptive accounts and made suggestions about
10
11
12 5 further links between themes and concepts.
13
14

15 6 Two patient research partners who had themselves undergone NHS-funded bariatric surgery
16
17 7 reviewed and provided feedback on the research proposal, the interview topic guide, and all written
18
19 8 patient information (including study recruitment documents, and the final study summary
20
21 9 disseminated to participants).
22
23
24

25 26 10 Results

27
28
29 11 Of 48 patients invited, 17 agreed to take part in interviews (mean time since surgery 3.11 years),
30
31 12 although two others (spouses of existing participants) were opportunistically recruited as the
32
33 13 research was ongoing. Interviews lasted between 44 and 110 minutes. Twelve of the 19 participants
34
35 14 were female, and the mean age was 51.1 years. All reported their ethnicity to be 'White British', and
36
37 15 17 had already undergone surgery (**Table 1**). The analysis presented draws on interview data from
38
39 16 the 17 participants that had undergone surgery.
40
41
42

43 17 Bariatric surgery was a life-changing journey for participants, impacting on several different areas of
44
45 18 their lives. The overarching concepts of 'normality' and 'ambivalence' emerged from analysis of data
46
47 19 on patients' experiences of adapting to life after surgery. Analysis of data relating to experiences of
48
49 20 follow-up care was conducted separately and characterised by two concepts – 'abandonment' and
50
51 21 'isolation'. Results are presented according to overarching concept with participant quotes used to
52
53 22 support the description of each concept.
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1 Adapting to life after surgery – normality and ambivalence

2 Throughout several areas of their lives, participants were striving to be more “normal” after bariatric
3 surgery. This related to their physical and psychological health, eating patterns, weight, and social
4 functioning. Participants experienced many positive changes that undeniably brought them closer to
5 their idea of normality. However, participants also described things that did not change, for which
6 they still felt abnormal. Some also experienced changes perceived as negative or difficult to deal
7 with, which made them feel more abnormal and required a process of adjustment. This was
8 acknowledged as a “trade-off”, or the “price to pay” (P08) for the benefits gained. The complexity of
9 the changes experienced highlighted the ambivalence of living with the results of bariatric surgery.
10 Despite the challenges, all participants felt the surgery was a good decision: “I don’t regret it for a
11 minute. Despite all the complications and issues.” (P14)

12 *Normality*

13 All participants reported an improvement in activity and mobility levels and/or their ability to carry
14 out ‘normal’ activities of daily living following surgery: “I’m more mobile, I can tie my shoelaces,
15 shower properly...my life has changed for the better.” (P10). Participants also reported several
16 positive changes related to physical and psychological health including a reduction in medications
17 required (e.g. for diabetes), an improvement in physical symptoms (such as joint pain), self-
18 confidence, and psychological well-being: “I feel healthier mentally in my head, like I want to get out
19 there.” (P09).

20 Some participants described an improved or more ‘normal’ relationship with food after surgery,
21 whereby they had retrained their mind to focus on “eating more sensibly” rather than thinking they
22 were “on a diet” (P11). Others experienced no real change to their relationship with food, feeling as
23 though they still had to be “on a permanent diet” (P19), or continued to use food as way of coping
24 with difficult emotions which remained: “I still have an awkward relationship with food...still have
25 the same demons...I probably rely on food to deal with certain emotions” (P14).

1
2
3 1 All 17 of the participants had lost a large amount of weight since having surgery, however, eight had
4
5 2 re-gained some of this weight. Participants reported feeling distressed by this as they did not want
6
7 3 to return to the way they were: "That was a real horrendous thing for me to see my weight go up a
8
9 4 bit after all I'd gone through to get it down..." (P07). However, a couple described being reassured
10
11 5 by health professionals that it was normal to experience some weight re-gain. The majority related
12
13 6 their weight re-gain to a gradual increase in appetite and/or portion sizes over time (which had
14
15 7 initially decreased after surgery), and a feeling that the surgery was not as effective as it had been: "I
16
17 8 don't seem to be getting the urge to stop quicker, like I did before" (P18).

18
19 9 The majority of participants reported developing loose-hanging excess skin following their massive
20
21 10 weight loss, which challenged their sense of normality. Although they were pleased to be a more
22
23 11 'normal' size, some felt ashamed of how abnormal their body looked without clothes on. Skin
24
25 12 removal surgery was a costly option, so some had learned to live with the excess skin; however, a
26
27 13 few found the excess skin to be particularly problematic, impacting on their mental health and
28
29 14 relationships: "My husband doesn't like the excess skin...and that's one of the reasons why I must do
30
31 15 something about it, because...I know I look like a bag of s**t" (P12).

32 33 34 35 36 37 38 16 *Ambivalence*

39
40 17 Although improvements to existing health problems were important benefits of the surgery, five
41
42 18 participants reported developing new health problems post-surgery, including micronutrient
43
44 19 deficiencies, menstrual problems, brittle bones, low blood pressure and cardiac issues: "...you give
45
46 20 up one set of health implications but you get given another set in its place..." (P07). Some
47
48 21 participants still suffered with several food intolerances and/or frequent gastrointestinal symptoms
49
50 22 many years after surgery, which they reported resulted in a poorly balanced diet: "I can't eat bread
51
52 23 or meat...That's one of the small prices I have to pay...my intake of food is nowhere near balanced..."
53
54 24 (P08).

1
2
3 1 Difficulties were described in developing new coping strategies to replace food, which had
4
5 2 previously been a “comfort blanket”: “...all your insides are different but your brain...no different
6
7 3 whatsoever...that for me was the hardest thing to adjust to, because my brain was still telling my
8
9 4 stomach I was hungry but obviously I couldn’t [eat]...” (P03). One patient described developing an
10
11 5 alcohol dependency post-surgery (which they had eventually overcome), and two participants
12
13 6 mentioned the need for more psychological input to help with their adjustment following surgery:
14
15 7 “There was no formal counselling...and that might be a good idea to find out why we eat so much,
16
17 8 why are we addicted to food...” (P04).

9 Social functioning and stigma

10 Ambivalence was also evident in participants’ experiences of social functioning and stigma.
11 Participants reported receiving positive attention due to their weight loss: “...people tell you ‘you
12 look brilliant’...that is the good side of it” (P17), however, for some, this led to mixed emotions at the
13 revelation of “how negative people saw you before” (P07). Others described receiving less negative
14 attention and feeling less socially stigmatised due to their obesity: “I can walk down the road now
15 and not get such the bad looks as I used to.” (P04). However, a number of participants had
16 experienced a new type of social stigma at having taken the “easy way out” (P02) by having surgery
17 (e.g. not achieved weight loss through the ‘normal’ means) or being ashamed to tell others they had
18 undergone surgery for fear of this reaction.

19 Family relationships were impacted in different ways following surgery. Some participants felt more
20 able to participate in parenting and family life; for example, P09 described being able to “plan things
21 as a family” due to improved health and mobility. However, others experienced marital conflict, with
22 some thinking their partners felt insecure due to their changed appearance and improved
23 confidence: “I think my husband was expecting me to lose weight and...go out and find another
24 man...we went through a very bad...4 or 5 months...” (P03).

1
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3 1 Although many social interactions improved, social eating situations caused anxiety for some due to
4
5 2 attracting attention for only eating very small amounts, or unpleasant and embarrassing
6
7 3 gastrointestinal symptoms which could arise when eating. This caused some to avoid social events
8
9 4 involving food, and/or eat alone at home, separately to family. For some this had remained an issue
10
11 5 several years following surgery causing disruption to relationships: "It disrupts life because I can be
12
13 6 eating and whether it's the wrong food, a mouthful too much...I've got to go out and she can hear
14
15 7 me retching, and it puts her off her food" (P08). Others were able to adapt or reported their social
16
17 8 life had "come back" (P10) gradually as food tolerance improved.
18
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21

22 9 Experiences of follow-up care – abandonment and isolation

23
24
25 10 Participants explained that follow-up care received after surgery was mainly provided by the
26
27 11 specialist bariatric surgery team (although what this entailed was highly variable), with little support
28
29 12 from their GPs (general practitioners). Only a few participants described feeling well-supported
30
31 13 overall, and all of these had undergone their surgery less than two years previously. However, most
32
33 14 described at least one aspect of follow-up care which they found helpful. These included: 1) the
34
35 15 routine monitoring of certain measures (e.g. weight, nutritional blood tests); 2) the availability of
36
37 16 one key health professional (generally a specialist dietitian or nurse), who was easy to contact on an
38
39 17 ad-hoc basis; 3) the ability to contact the bariatric team using a range of contact options (e.g.
40
41 18 telephone, email); 4) good communication between team members; and 5) continuity of care (e.g.
42
43 19 being able to see the same professionals at every appointment) (**Table 2**).
44
45
46
47

48 20 Overall, however, there was a sense of abandonment and isolation in participants' accounts of
49
50 21 follow-up care. Participants felt that health professionals didn't always appreciate the long-term
51
52 22 implications of life after surgery, or even if they did, services were not set up to support them
53
54 23 adequately: "It happened eight years ago so no one thinks you may have any hang-ups, issues,
55
56 24 concerns about it...the implications of the changes it makes people don't really appreciate, it's an old
57
58 25 record, old news." (P07).
59
60

1
2
3 1 *Abandonment*
4

5
6 2 Some participants felt that problems or complications they experienced following surgery were
7
8 3 ignored or not dealt with properly, or there was a lack of clarity in terms of who to go to if they
9
10 4 experienced problems. P07, for example, felt her post-operative problems were dismissed by the
11
12 5 specialist team, and that she “was upsetting someone’s figures by having complications”. P12
13
14 6 experienced a problem with one of her surgical wounds which wouldn’t heal and wasn’t sure who to
15
16 7 go to about it. She felt “quite abandoned” and dealt with it mainly on her own. Abandonment also
17
18 8 related to the feeling they had been given inadequate information or guidance about life following
19
20 9 surgery: “They give you loads of information about what to do in the first six weeks and then there’s
21
22 10 nothing...” (P04).
23
24

25
26 11 Most participants also reported feeling abandoned by their GPs who were not usually supportive of
27
28 12 them having undergone bariatric surgery and did not “fully appreciate the struggles that you have”
29
30 13 (P14) in the long-term. However, a minority of participants described feeling well-supported by their
31
32 14 GPs who recognised the long-term health benefits of bariatric surgery: “...with being my dad’s
33
34 15 doctor, he sees that hopefully I won’t have the same problems...he’s done everything he can to help
35
36 16 me...” (P05).
37
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40
41 17 *Isolation*
42

43
44 18 Two participants (P09, P15) commented that although the follow-up care they had received from the
45
46 19 specialist team had been very good, they had had to make the effort to ask for it: “I feel that as long
47
48 20 as you didn’t contact them then you will be left alone...” (P15). Concerns were raised for others
49
50 21 whom they perceived less likely to seek help proactively: “...these people aren’t coming forward to
51
52 22 explain that they’re having problems because they don’t want to feel like a failure...” (P09). P18
53
54 23 expressed disappointment that he had not been sent any appointments post-operatively and felt he
55
56 24 had been left “in limbo” to “get on with it” himself. He had not asked for help and was under the
57
58 25 impression that it would only be appropriate to contact the team if you were having complications:
59
60

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2
3 1 "...obviously if I was in excruciating pain from the operation I suppose, I could have gone back..."
4
5 2 (P18).
6
7

8 3 Several participants did not live locally to the hospital where the specialist team were located. This
9
10 4 presented a barrier to accessing follow-up care, which some felt could contribute to feelings of
11
12 5 isolation: "From this side of the county it's (hospital) extremely difficult to get to...I can understand
13
14 6 an awful lot of people thinking "if I ring [hospital] they're going to say come over and see me and
15
16 7 that is so difficult to get to...I won't bother." (P15)
17
18

19
20 8 Isolation was also apparent in participants' experiences of bariatric surgery peer support groups.
21
22 9 Although not part of medical care, these represented an important source of support. These groups
23
24 10 were typically run by patient volunteers, with limited or no input from health professionals. Some
25
26 11 participants had access to these groups in their local areas, whereas others did not. Those unable to
27
28 12 access a group felt this contributed to their sense of isolation post-surgery: "...there's meetings
29
30 13 where you can meet other people who've had the [gastric] band...but there's no local ones for me...if
31
32 14 people said, 'If you do eat it, it's going to hurt but it will go, and this is the reason it's hurting,' then I
33
34 15 could have dealt with it a little bit better." (P17). Those that had accessed these groups described
35
36 16 variable experiences. Some found them supportive, for example P01 who continued to attend
37
38 17 several years post-surgery, whereas others had negative experiences and felt quite isolated from
39
40 18 other members. P19, for example, described her local group as being very "cliquey" with members
41
42 19 using the group mainly to emphasize negative experiences or "how to cheat the band". Many felt
43
44 20 that peer support groups should be part of routine clinical care to improve accessibility, and that "a
45
46 21 chairman" knowledgeable in the results of bariatric surgery was needed to "control the questions
47
48 22 and answer session" (P15) and ensure consistency.
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1 Discussion

2 This in-depth qualitative study found that bariatric surgery impacted participants' physical and
3 psychological health, eating behaviours, weight, and social functioning. The overarching concepts of
4 normality and ambivalence represented their lived experience following bariatric surgery. Normality
5 was evidenced through participants' relief at feeling more normal in some ways (e.g. improved
6 ability to undertake daily activities), yet feeling less normal in other areas, including the
7 development of excess skin and difficulties eating 'normally' in social situations. Although
8 participants experienced many positive health changes, they also experienced changes which were
9 negative or difficult to adapt to, such as an inability to rely on emotional eating as an entrenched
10 coping mechanism, perceived bodily deformity as a result of excess skin, and the destabilisation of
11 important relationships. This highlights the ambivalence of living with the outcomes of bariatric
12 surgery. In coping with these changes, participants received varying levels of care from specialist
13 health professionals and GPs. Although there were some positive experiences, 'abandonment' and
14 'isolation' characterised most follow-up care experiences. This included feeling unsupported with
15 post-surgery problems (other than serious complications), lack of guidance with long-term lifestyle
16 changes, lack of understanding from GPs, and limited peer support. However, all participants felt
17 that undergoing the surgery was a good decision despite the difficulties. These findings are
18 important in helping to define future follow-up care packages to better address the complex
19 changes experienced after bariatric surgery.

20 Our findings are consistent with the results of two recent systematic reviews of qualitative research
21 studies which described the multi-dimensional impact of bariatric surgery on patients' lives and the
22 complexity of patient follow-up care needs.^{10 15} However, this study contributed additional insights,
23 including highlighting the individual and complex nature of how bariatric surgery changes people's
24 relationship with food in different ways, and changes over time, indicating the need for
25 individualised/tailored support at different timepoints. The importance placed by participants on

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3 1 social and family eating, and the difficulties experienced after bariatric surgery was also notable and
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5 2 should be given more attention in follow-up care.
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8 3 Our study confirms previous qualitative findings on the importance of continuity of care,¹⁵ the ability
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10 4 to access professional advice (often from the specialist dietitian) between appointments via
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12 5 telephone or email,²⁸ the lack of psychological support,^{15 25-27 29 30 37} and the need for moderation in
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14 6 patient support groups accessed by patients.^{30 31} Previous studies have related patients' views that
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16 7 GPs were not equipped to adequately support them post-surgery.^{15 27 28 38} This was also evident in
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18 8 our study with most participants describing negative experiences with GPs in relation to bariatric
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20 9 surgery, and feeling they were unable to offer adequate support. Despite this, several participants
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22 10 would have preferred to access support locally due to living remotely.
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27 11 Our study highlighted patients' views that bariatric surgery services were not set up to support them
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29 12 with long-term issues, with their experiences of follow-up care characterised by concepts of
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31 13 'abandonment' and 'isolation'. These echo the concept of recursivity described in the broader help-
32
33 14 seeking literature concerning vulnerable groups.^{39 40} Recursivity refers to how an individual's
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35 15 previous experience of health services shapes their future help-seeking behaviour.^{39 40} In studies of
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37 16 'hard to reach' groups with mental health difficulties, reticence to seek help was influenced by
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39 17 participants' previous experiences with health professionals not recognising or being dismissive of
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41 18 their problems, being made to feel their problems were their "own fault", and concerns they would
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43 19 be discriminated against or stigmatised.^{39 41 42} Previous research in obese individuals suggests they
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45 20 also may delay or avoid seeking healthcare due to societal and medical stigmas.^{43 44} This has also
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47 21 been reported by Throsby who conducted a UK-based ethnographic study within a surgical weight
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49 22 management clinic.⁴⁵ She described examples of patients struggling with their eating habits and
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51 23 weight post-surgery, and the shame they felt at doing 'badly' after undergoing publicly-funded
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53 24 surgery. The author argued that this "moral weight" could lead to patients not seeking help when
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55 25 most needed.⁴⁵ Similarly, feelings of shame and failure at not having met the perceived post-
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3 1 operative expectations was one reason cited by Australian patients for non-attendance in bariatric
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5 2 surgery aftercare.²⁷
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8 3 The main strength of this research is that a detailed qualitative approach to data collection was
9
10 4 used, whereby participants were given the time and flexibility to relate their own experiences in
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12 5 terms that were relevant for them. A rigorous approach to analysis was undertaken, including
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14 6 independent coding of initial transcripts by three researchers, and discussion and agreement of
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16 7 emergent themes throughout analysis with at least one other qualitative researcher. An additional
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18 8 strength was that patients who had undergone all three main types of bariatric procedures across
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20 9 two UK centres were included in the research; however, it is not known whether similar themes
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22 10 would be found with participants in other centres. The findings relating to follow-up care may be
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24 11 less generalisable to healthcare systems with different service pathways and funding structures.
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29 12 Taken together with previous literature, our findings highlight that current bariatric surgery follow-
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31 13 up care provision is not often aligned with patient need. Patients highlighted the need for a flexible
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33 14 and long-term approach to follow-up care from a multi-disciplinary health professional team. This
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35 15 includes both routine and open appointments, moderated peer support groups, and different
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37 16 methods of contact (e.g. telephone, online in addition to face-to-face). In addition to individual
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39 17 dietary and psychological support, services should consider how to better support patients in
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41 18 developing strategies to cope with family and social difficulties post-surgery. This may include
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43 19 actively engaging family and close friends in pre-operative preparation and/or post-operative
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45 20 interventions. Future research is needed to define and evaluate an effective and acceptable follow-
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47 21 up care package that could be consistently applied across bariatric surgery centres. This may include
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49 22 the optimal systems or pathways to identify and support those who need the most help but are the
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51 23 least likely to seek it, ways of engaging family and social support, and delivering moderated peer
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53 24 support groups. The relative merits of delivering follow-up care in specialist or community-based
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55 25 health services or how it might be shared between the two should also be investigated.
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1 Author contributions

2 KDC led the study design, data collection and data analysis as part of her PhD research, and drafted
3 this manuscript. AOS, FM and JMB were KDC's PhD supervisors and advised on study design, data
4 collection and analysis, and provided comments on this manuscript. JLD advised and contributed to
5 data analysis and provided comments on this manuscript. All authors approved the final submitted
6 manuscript.

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10 Data sharing

11 Anonymised participant data can be made available on reasonable request to the corresponding
12 author at karen.coulman@bristol.ac.uk.

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For peer review only

1 **Table 1: Characteristics of participants**

Participant	Gender	Age range (years)	Marital status	Employment status	Type of surgery	Time since surgery (years)
P01	Female	60-70	Married	Retired	RYGB	>5
P02	Female	50-60	Married	Unemployed	RYGB	<1
P03	Female	30-40	Married	Employed*	RYGB	1-2
P04	Female	60-70	Married	Retired	AGB	>5
P05	Male	40-50	Married	Employed	RYGB	<1
P06	Female	30-40	Married	Employed	Awaiting surgery	N/A
P07	Female	40-50	Married	Employed	RYGB	>5
P08	Male	60-70	Married	Employed	AGB	>5
P09	Female	40-50	Married	Unemployed	SG	1-2
P10	Male	30-40	Co-habiting	Self-employed	SG	2-5
P11	Female	40-50	Married	Employed	SG	<1
P12	Female	50-60	Married	Self-employed	SG	1-2
P13	Male	50-60	Widowed	Employed	RYGB	<1
P14	Female	40-50	Married	Employed	AGB & RYGB	>5
P15	Male	60-70	Married	Retired	RYGB	1-2
P16	Female	60-70	Married	Retired	Awaiting surgery	N/A
P17	Male	40-50	Married	Employed	AGB	2-5
P18	Male	50-60	Co-habiting	Employed	AGB	1-2
P19	Female	30-40	Separated	Employed	AGB	1-2

2 **AGB=Adjustable gastric band, RYGB=Roux-en-Y gastric bypass, SG=Sleeve gastrectomy**

3 ***'Employed' status includes those employed both full-time and part-time**

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1 **Table 2: Participant quotes to support positive experiences of follow-up care**

Positive aspects of care	Quotes
Routine monitoring of certain measures	"It was good having my bloods done so I could check what my levels were like, that was quite useful for me...routine monitoring was good." (P07)
The availability of a key health professional; Ability to contact the team using a range of contact options	"If I couldn't get hold of her (dietitian) straight away on the phone I'd send an email and it would either be answered the same day or the next day." (P09)
Good communication between team members	"It's quite a tight little team....you might not necessarily speak to the best person, but they will come together in their meeting and you'll get the best outcome." (P19)
Continuity of care	"You didn't see twenty different people. It was 'the team'...the same faces...I like that. I don't want to see somebody who's different don't know you..." (P08)
Overall positive view of care	"The follow-up care I've had has just been 110%, if I've had a problem I would ring and...I would get an appointment...Someone has always been there for me..." (P01)

2

Study Protocol version 2.0 (7/7/14)

Document S1 (Study protocol)

The patient perspective of living with surgery for morbid obesity: Creating a patient 'core' outcome set, and investigating ways to improve follow-up care

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Lay Summary

Surgery is increasingly being used as a treatment for obesity. Studies report many different outcomes, often measured in different ways, and little is known about what outcomes are important to patients. This study aims to explore the outcomes that are important to patients and to use this information to develop a short list of the most important outcomes to health professionals and patients (a core outcome set), which can be used to evaluate surgical treatments for obesity. In addition, this study will investigate patients' experiences of obesity surgery to provide recommendations for how post-operative support can be improved in the NHS. This will be achieved by interviewing obesity surgery patients to determine whether published outcomes reflect those outcomes patients themselves consider important, and to obtain views on living with surgery and ways to improve post-operative support. A list of patient-centred outcomes will be created from the literature and the interviews which will be added to a list of 'medical' outcomes of obesity surgery. This long list of outcomes will be reduced into a "core" set of outcomes, using a scientific process to reach agreement, which involves 2 rounds of questionnaires completed by health professionals and patients. The final core outcome set will be agreed in separate consensus meetings with a small group of health professionals and patients. This core outcome set will be useful to researchers in choosing outcomes for research trials that are important to both health professionals and patients. Use of the core outcome set would also improve the overall quality of reporting in trials. This research will also be useful for health professionals to ensure health services are designed based on patient priorities.

Background

Obesity surgery

The NHS Information Centre has released figures showing that just over one quarter of the adult population of England was obese in 2010, an increase from 13-16% of the population in 1993¹. It is predicted that one third of adults in England will be obese by 2015 and more than 700 million adults will be obese worldwide by 2015^{1,2}. Obesity is associated with an increased risk of type 2 diabetes, heart disease, cancer, reduced quality of life and premature death^{1,3}. As such, obesity is a major public health concern. Various treatments for obesity exist including lifestyle modifications, pharmacotherapy, and more recently, surgical interventions. Obesity surgery operations have rapidly increased in the UK, and worldwide, with the most common operations being the adjustable gastric band and the Roux-en-Y gastric bypass^{1,4}. In 2009, a Health Technology Assessment report (including a Cochrane systematic review) concluded that obesity surgery is more clinically effective than other treatments for obesity in terms of weight loss, improvement of co-morbidities such as type 2 diabetes and hypertension, and is also cost effective⁵.

The patient perspective of outcomes of obesity surgery

Although clinical outcomes are important to measure, patient-reported outcome (PRO) measures, such as measures of health-related quality of life (HRQL), provide a means for capturing how a patient feels about their health or condition⁶. The Food and Drug Administration (FDA) has published guidance on the development of PRO measures to support claims of treatment benefit⁶. PRO measures should be developed based on rigorous qualitative research with patients to ensure content validity (authenticity to patients)^{6,7}. Despite this, the development of PRO measures is variable and not always transparent⁷.

The lead researcher has recently undertaken a systematic review of PROs in obesity surgery studies, which identified 68 different validated questionnaires used to assess PROs amongst the 86 identified studies⁸. Due to the heterogeneity of the items and scales within the questionnaires used amongst the various studies, a meta-analysis to determine the effect of obesity surgery on PROs was unable to be undertaken. The lead researcher then looked in further depth at the development of those questionnaires which were classified as obesity-specific (19 questionnaires). Although 14 (74%) reported to have involved patients in questionnaire development, only 3 (16%) specified that obesity surgery patients were involved. Only 6 (32%) specified that qualitative interviews/focus groups were used to obtain patient views and none specified that a qualitative analysis of resulting data was undertaken. Thus, it is not certain whether the majority of PRO questionnaires being used to assess obesity surgery are grounded in patient views.

Although well-developed PRO measures can provide valuable information about the patient's perspective of outcomes of treatment, primary qualitative studies can also yield rich information; however, these types of studies are rarely included in Cochrane reviews of quantitative evidence. The lead researcher is currently undertaking a review of qualitative research studies where the patient perspective of obesity surgery was sought. Although qualitative studies have focused on patient experiences of surgery, none have explicitly investigated patients' views of important outcomes of obesity surgery.

There is clearly more work needed to clarify the outcomes of obesity surgery from the patient perspective.

A 'core' outcome set for obesity surgery

As described above, heterogeneity of PROs in obesity surgery studies is an issue, which limits cross-study comparison and amalgamation of study results, which in turn limits the ability to make recommendations to clinicians and policymakers about the impact of obesity surgery on outcomes

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3 important to patients. This issue is not unique to PROs, but also to clinical outcome measures with a
4 Cochrane review of obesity surgery unable to undertake a meta-analysis due to a lack of consistency
5 in outcomes reported⁵.
6

7 Recent years have seen an increasing interest in the establishment of 'core outcome measures' to
8 promote consistency in the reporting of clinical trials. Of particular interest is the development of
9 the COMET (Core Outcome Measures in Effectiveness Trials) initiative through the MRC Hubs for
10 Trials Methodology Research whose aim is to bring together researchers interested in the
11 development and application of core outcome sets for specific conditions^{9,10(1)}. Another notable
12 initiative is OMERACT (Outcome Measures in Rheumatology Clinical Trials) in rheumatology¹¹. Core
13 outcome sets are not meant to be a restrictive list, but a minimum set of outcomes that should be
14 reported on in every trial of a particular disease/condition. By standardising outcomes to be
15 reported on in trials, results can be compared, contrasted and synthesised (e.g. meta-analysis) to
16 inform health policy. No core outcome set for obesity surgery currently exists.
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19 Recent research demonstrates that patients' perceptions of important outcomes may differ
20 considerably from clinicians' perspectives, and therefore incorporating the patient perspective is
21 crucial to contribute to and validate core outcome sets¹². Creating a core outcome set for obesity
22 surgery based on both health professional and patient views will help in the ordering of research and
23 health service priorities to include the patient perspective, and ultimately improve long-term
24 outcomes.
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27 ***The patient perspective of follow-up care after obesity surgery***

28 Follow-up care after obesity surgery varies greatly across centres. There is no consensus as to what
29 optimum follow-up care is, although most clinicians recognise that good follow-up care is integral in
30 achieving good outcomes from obesity surgery¹³⁻¹⁵. Understanding the outcomes of most
31 importance to patients, and their experiences of follow-up care would provide invaluable
32 information to design effective follow-up care programmes tailored to patients needs to maximise
33 the benefits of surgery in the long-term. Qualitative research with obesity surgery patients in the UK
34 context has focused on the experiences of patients, including difficulties they encounter after
35 obesity surgery^{16,17} but to our knowledge, no studies have specifically focused on patients'
36 experiences of follow-up care and ways to improve follow-up care in the health services.
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39 There is clearly more work needed to clarify optimum follow-up care from the patient perspective,
40 and its influence on outcomes. As obesity and the number of obesity surgery operations increase, it
41 is imperative that research in this area is of high quality, and takes into account the patient
42 perspective.
43
44

45 **Aims**

46 The overall aims are to develop a core outcome set for obesity surgery including both health
47 professional and patient perspectives and to investigate patients' experiences of living with the
48 results of obesity surgery including ways to improve post-operative follow-up care.
49

50 **Objectives**

- 51 1. Semi-structured qualitative interviews with obesity surgery patients will be conducted to:
 - 52 a. Investigate outcomes of importance to obesity surgery patients that may not have
53 been documented in the literature previously, and to add these to a comprehensive
54 list of PROs of obesity surgery previously compiled from systematic literature
55 reviews.
56
 - 57 b. Investigate patients' experiences of living with obesity surgery and ways to improve
58 post-operative support.
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- 2.
2. The list created in objective 1a above will be added to a list of clinical outcomes which will be used within a Delphi survey of health professionals and patients which will ask them to prioritise the outcomes and produce a shorter list. The short list will be considered at separate meetings with health professionals and patients who will agree and finally ratify the content of the core outcome set.

Methods

Semi-structured qualitative interviews

To supplement the literature reviews previously undertaken by the lead researcher, patients' views of important outcomes of obesity surgery and experiences of existing follow up care will be investigated using semi-structured interviews within a qualitative paradigm.

Identification and selection of patients

Patients who are about to undergo and who have undergone a primary operation for obesity will be identified by health professionals from participating obesity surgery services at NHS healthcare Trusts using departmental databases and clinic lists. The main criteria for selection will be: The patient is undergoing obesity surgery within the next three months (pre-surgery group), or has undergone obesity surgery (post-surgery group). Including patients at both the pre- and post-operative stage will allow us to compare views and assess differences. Patients will initially be purposively sampled to obtain maximum variation for gender, age, ethnicity, starting BMI, type of operation, and time since operation, however further sampling will be guided by emerging findings from interviews.

Patient recruitment

Identified patients will be sent a letter from their local NHS obesity surgery team including an invitation letter and patient information sheet from the lead researcher, informing them of the research and inviting them to participate in the interviews. A reply slip and stamped addressed envelope will be included for patients to indicate whether or not they are interested in participating in the research to post back to the lead researcher. The number of patients recruited will depend on when theoretical saturation is reached (i.e. when the themes relevant to the research have been thoroughly investigated); however it is estimated that approximately 30 patients will be interviewed in total.

Data collection and analysis

Patients who agree to take part in the interviews will be able to choose the location of the interview, either in their own home, at one of the two participating hospitals, or the University of Bristol. Should any participants request to be interviewed at their GP surgery instead, permission will be sought by the chief investigator from the surgery's practice manager to conduct the interview at the surgery. Any travel costs will be reimbursed. Consent will be obtained face-to-face prior to the interview beginning. Should any participants request to be interviewed via telephone, participants will be mailed two copies of the consent form and asked to sign and return them to the chief investigator who will then sign them and return one copy to the participant prior to the interview. An interview topic guide will be applied flexibly to guide interviews. The following broad themes will be explored in interviews: 1) Motivations to undergo surgery; 2) Expected outcomes of surgery; 3) Actual outcomes of surgery (post-op group only); 4) Expectations of follow-up care; 5) Actual experiences of follow-up care (post-op group only). It is anticipated that interviews will last approximately 60 minutes, including 10 minutes dedicated to recording socio-demographic and relevant clinical data at the end of the interview. Interviews will be audio-recorded and transcribed in full. Separate consent will be sought to potentially re-contact them in the future for a follow-up interview.

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3 Interviews will be analysed thematically using a grounded theory approach¹⁸. Data will be analysed
4 using descriptive and explanatory coding to explore and inter-relate categories arising in the data.
5 Data management will be facilitated using the program NVivo 9¹⁹. Descriptive accounts will be
6 written up relating to each batch of interviews, and matrices will be drawn up to compare the
7 occurrence of themes across interviews. Data analysis will run in parallel with data collection so that
8 emerging themes can be followed up to enrich subsequent interviews. A small sample of the
9 interview transcripts will be independently coded by both the chief investigator and her primary
10 supervisor. The coding structures will then be discussed in a supervision meeting and revised as
11 appropriate. The analysis will also be reviewed with the chief investigator's co-supervisor, and
12 patient research partners.
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15 Findings from the qualitative interviews will be combined with findings from a previous review of
16 qualitative literature in this area, and written up for publication as soon as possible. Particular
17 attention will be paid to ensuring that recommendations relating to the improvement of follow-up
18 care are disseminated as soon as possible to clinicians and policymakers.
19
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21 Important outcomes identified by patients in the semi-structured interviews will be added to the
22 outcomes previously identified from systematic literature reviews undertaken by the lead researcher
23 to create a comprehensive 'long' list of outcomes important to obesity surgery patients. The list will
24 be reviewed by the lead researcher, her supervisors, and patient research partners to make sure it is
25 comprehensive such that potentially important outcomes have not been omitted. This will form the
26 basis of the next stage of the research (Delphi process).
27
28

29 ***Delphi process***

30 This comprehensive list of outcomes will be refined into a 'core' outcome set using a Delphi process
31 consisting of two questionnaire rounds where health professionals and patients individually rate
32 each outcome for its value of being included in the core outcome set, followed by consensus
33 meetings to discuss any potential areas of disagreement with regard to which outcomes to include
34 and to ratify the final core outcome set.
35
36

37 **Ethical issues arising**

38 ***Informed consent***

39 Written, informed consent will be obtained from all participants prior to the qualitative interviews.
40 Confidentiality and anonymity will be assured at this stage and the purposes and possible uses of the
41 research will be explained. It will be made clear that participants are free to drop out or delay
42 participation in research at this stage. Separate consent will be sought to digitally-record interviews,
43 and to potentially re-contact the participants in future for a follow-up interview.
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49 ***Data protection***

50 The principles of the Data Protection Act (1998) will be complied with and data obtained from
51 interviewees will be anonymised using unique study codes. Documents to interpret the codes and
52 personal data will be stored in separate encrypted files in separate locations on the University of
53 Bristol server. All hard copy study documents will be stored in locked filing cabinets. Only data
54 necessary to the purposes of the research will be obtained and stored.
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Study Protocol version 2.0 (7/7/14)

Confidentiality

Confidentiality and anonymity outside of the interviews will be discussed and assured prior to beginning each interview. It will also be assured through the processes of data storage outlined above and the use of only fully anonymised quotations in all presentations of research findings.

Protection from distress

It is understood that living with morbid obesity and making the decision to undergo obesity surgery are personal and sensitive issues for patients. Therefore interviews will be undertaken sensitively and patients will only be encouraged to talk about aspects of their illness and care that they feel comfortable with. In the event that a participant becomes distressed during a research interview, the researcher will offer to take a short break from the interview and will remind participants that they do not have to discuss any topics they are uncomfortable with and are free to withdraw their consent to participate in the research at any time. If any patients express particular distress relating to their condition or treatment, a distress protocol will be followed (Appendix 1). The interviewer previously worked as a health professional in a NHS obesity surgery service and has experience of dealing with sensitive issues that may be brought up by this patient population. In addition, the interviewer will be supervised by a trained qualitative researcher who has experience in interviewing morbidly obese patients.

Integrity of research data

The MRC principles of Good Research Practice will be adopted with all primary data being retained so that there is an auditable trail from results back to data. Results will be fully and accurately reported at the end of the project.

Independence and impartiality

Every attempt will be made to maintain reflexivity at every stage of the research and to acknowledge the potential impact of the researcher upon the findings.

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Appendix 1: Distress protocol - Interviews

All interviews will be prefaced with a statement about confidentiality and the duty of care. Participants will be told that interview is strictly confidential but should they disclose information to suggest that they are at significant risk of harm the researcher *may* have to discuss this with a clinical advisor.

In the event that a participant appears to be distressed during the interview (eg. becomes silent, cries) or discloses information to provoke concern about suicide risk, the following procedures will be followed:

- Participants will be offered the opportunity to pause for a break from the interview and will then be asked if they would like to resume.
- If necessary, the interview will be terminated and recording equipment stopped.
- At first, the interviewer will listen to the interviewee and offer support in situ. This will allow the researcher to assess whether further action is necessary.
- Should the interviewer remain concerned, they will reflect this to the interviewee and depending on the nature of the situation:
 1. Offer information about local help services
 2. Ask the interviewee if there is anyone they should contact, and if so attempt to make contact
 3. Offer to make initial contact with clinical services (primary or secondary) on behalf of the individual and with their consent
- In cases of particular concern the interviewer will
 1. If necessary, remain with the person until their distress has subsided or someone else is present
 2. Contact a local study clinician for advice/ assistance
 3. Provide a written report of the incident to AOS/JB (PhD supervisors), including information about the nature of the distress and the actions taken

Interviewees will be advised to contact their GP should they find subsequently that the interview provokes issues that they need to discuss.

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1 Document S2: Topic guides

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3 **Pre-operative patient interviews**

4
5 **NB This guide is necessarily provisional, as its application will depend on the experience of individual participants.**

6
7 **Introduction**

- 8 ❖ *Researcher explains research, asks if any queries on PIS, and takes consent.*

9 **Motivations to undergo surgery**

- 10 - To start off, I was just wondering if you could tell me a bit about what factors led to your decision to go for surgery?

11 **Expected outcomes of surgery**

- 12 - How are you feeling about going forward for surgery now?
 13 *Probe: Which operation are you hoping to have?*
 14 *Probe: Is there anything you're worried about? [Prompt on risks/side-effects of surgery]*
 15 *Probe: What do you think will change for the better after you have had surgery?*
 16 *Probe: Is there anything you are hoping to prevent by having surgery?*
 17 - To you, what are the most important results of surgery?
 18 *If they say weight loss, Probe: What does weight loss mean for you?*
 19 *Probe on any aspects they don't elaborate on eg. What does that mean for you?*
 20 *Probe: Would you say these are the same things that other people undergoing weight loss surgery think are*
 21 *important?*
 22 - Are there any things about the surgery or life afterwards that you would have liked the healthcare team to give you
 23 more information about?
 24 *Probe: Do you think other people who are undergoing surgery would say the same things?*

25
26
27 **Experiences of care so far and expectations of follow-up care**

- 28 - What happened when you decided to go for surgery?
 29 *Probe: Where did you first hear about surgery?*
 30 - *Probe: When did you make the decision to put yourself forward for surgery?*
 31 *Probe: Who did you talk to first?*
 32 *Probe: What happened next? [Prompt on healthcare professionals they have seen [GP practice, local weight*
 33 *management team, surgical team]*
 34 *Probe: Would you say this is the same or different to the process that others have gone through?*
 35 - How do you feel about the care/support you have received from the healthcare team around weight loss surgery up
 36 until this point? *[Prompt on the surgical team, the local weight management team, GP practice]*
 37 *Probe: Do you think others have had similar experiences?*
 38 - Do you have any ideas about the care you will receive after surgery? *[Prompt on short-term inpatient care and long-*
 39 *term care]*
 40 - Could you say at this stage what kind of care you're hoping for after surgery?
 41 *Probe: Who would be the best person/people to do that?*
 42 *Probe: What would be the best setting for this? [Prompt on hospital/ another setting]*
 43 *Probe: Would this be the same as what others would say?*
 44 - What about support groups – have you been involved with any of these?
 45 *If yes Probe: Do you tend to go to meetings or do you use online forums?*
 46 *Probe: How do you find these? [Prompt on positive and negative aspects]*
 47 *If no Probe: What's stopped you from getting involved?[ie. prompt on if unaware of them, none convenient, don't*
 48 *find helpful]*

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50
51 **Clarifications, etc.**

- 52 ❖ *Researcher asks participant to provide more information where points of interest were not previously probed.*

53
54 **Wind-down**

- 55 ❖ *Researcher checks topic guide for omissions and prompts informant back towards areas of discussion where they*
 56 *seemed most comfortable.*

57 **Case report form**

- 58 ❖ *Researcher records participant details using the case report form.*

59
60 **Closing**

- ❖ *Researcher asks if patient would be interested in being contacted about a possible follow-up interview – to be recorded on consent form*

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❖ *Researcher thanks interviewee for participating and asks if they would like a summary of the study results once complete*

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Post-operative patient interviews

NB This guide is necessarily provisional, as its application will depend on the experience of individual participants.

Introduction

❖ *Researcher explains research, asks if any queries on PIS, and takes consent.*

Motivations to undergo surgery

- To start off, I was just wondering if you could tell me a bit about what factors led to your decision to go for surgery?

Expected outcomes of surgery

- If you can think back to a few weeks before you had the surgery, can you remember how you were feeling about having surgery?

Probe: Was there anything you were worried about? [Prompt on risks/side-effects of surgery]

Probe: Was there anything you hoped would change for the better by having the surgery?

Probe: Was there anything you were hoping to prevent by having surgery?

Actual outcomes of surgery

- How do you feel about having had surgery now?

Probe: Which operation did you have?

Probe: How long ago was it now?

Probe: What's happened since? [Prompt on the things they said they were worried about/hoped would change/hoped they would prevent by having surgery]

Probe: Was there anything that happened that you didn't expect? [Prompt on during surgery and after surgery]

Probe: Are you glad you had the surgery?

Probe: Do you think having the operation has changed your relationships with people who are important to you?

- To you, what are the most important results of surgery?

If they say weight loss, Probe: What does weight loss mean for you?

Probe: Are these things different to what you would have said before having surgery?

Probe: What results of surgery might be most important to other people undergoing the surgery?

If yes, Probe: How are they different?

- Are there any things that you didn't know beforehand that you wished you had?

- What do you think will happen in the future?

Expectations of follow-up care

- If you can think back to a few weeks before you had the surgery, can you remember if you had any expectations or ideas about the care you would receive after surgery? *[Prompt on short-term inpatient care and long-term care]*

Actual experiences of follow-up care

- Since you've had your surgery, have you been back to the hospital? *[Prompt on the surgical and weight management teams,]*

Probe: What about your GP practice, have you seen anyone there since your surgery?

Probe: Do you think there is a role for more follow-up care from primary care?

- What do you think will happen next?

- How do you feel about the NHS care you have received since your surgery?

Probe: Tell me about the things you found most helpful

Probe: Tell me about the things you found least helpful

Probe: Is there anything you would have preferred to have been done differently?/Is there anything you think the NHS could have done to better support you since you've had your surgery?

- Could you say what you thought the most important things of good care after weight loss surgery were?

Probe: Who would be the best person/people to do that?

Probe: What would be the best setting for this? [Prompt on hospital/ another setting]

Probe: Do you think these are the same things that others who've had surgery would say?

- What about support groups – have you been involved with any of these?

If yes Probe: Do you tend to go to meetings or do you use online forums?

Probe: How do you find these? [Prompt on positive and negative aspects]

If no Probe: What's stopped you from getting involved? [ie. prompt on if unaware of them, none convenient, don't find helpful]

If used to be involved but now no longer involved Probe: What's led to this?

Clarifications, etc.

1 ❖ *Researcher asks participant to provide more information where points of interest were not previously probed.*

2 **Wind-down**

3 ❖ *Researcher checks topic guide for omissions and prompts informant back towards areas of discussion where they*
4 *seemed most comfortable.*

6 **Case report form**

7 ❖ *Researcher records relevant socio-demographic and clinical details using the case report form.*

8 **Closing**

9 ❖ *Researcher asks if patient would be interested in being contacted about a possible follow-up interview – to be*
10 *recorded on consent form*

11 ❖ *Researcher thanks interviewee for participating and asks if they would like a summary of the study results once*
12 *complete*

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Document S3: Case Report Form - Patient views about weight loss surgery

Participant identification number:		<i>If patient has consented to GP being informed about participation in study:</i>
Date of birth: __/__/____		
Initials:		
Today's date: __/__/____		
1.	What is the gender of the participant? 1=Male, 2=Female	<input type="checkbox"/>
2.	What is the patient's ethnicity? 1=White British, 2=White other, 3=Black, 4=Asian, 5=Mixed, 6=Chinese, 7=Other	<input type="checkbox"/>
3.	Who does the participant live with? 1=alone, 2=with family, 3=with other adults	<input type="checkbox"/>
4.	What is the participant's marital status? 1=single, 2=married, 3=separated, 4=divorced, 5=widowed	<input type="checkbox"/>
5.	What is the highest level of education completed? 1=less than compulsory school education, 2=compulsory school education, 3=post-compulsory school education below university level, eg. advanced technical school/advanced vocational, 4=university level	<input type="checkbox"/>
6.	What is the employment status of the participant? 1=employed full-time (could be on sick leave), 2=employed part-time, 3=homemaker, 4=student, 5=unemployed, 6=retired, 7=self-employed, 8=other (specify).....	<input type="checkbox"/>
7.	What is the current or last occupation of the participant?.....	
8a.	What is the patient's surgical status? 1=Awaiting surgery, 2=Undergone surgery (go to 8e.)	<input type="checkbox"/>
b.	If the participant is awaiting surgery, what operation are they hoping to undergo? 1=LAGB, 2=RYGB, 3=SG, 4=Other (specify).....	<input type="checkbox"/>
c.	If the participant is awaiting surgery, do they have a date? 1=Yes, 2=No	<input type="checkbox"/>
d.	If yes, what is the date?	__/__/____
e.	If the participant has undergone surgery, what operation have they undergone? 1=LAGB, 2=RYGB, 3=SG, 4=Other (specify).....	<input type="checkbox"/>
f.	If the participant has undergone surgery, what date did it occur?	__/__/____
9a.	What was/is the participant's weight prior to surgery (self-reported)?	<input type="text"/> Stones <input type="text"/> lbs <input type="text"/> Kg
b.	If the participant has undergone surgery, what is their weight now (self-reported)?	<input type="text"/> Stones <input type="text"/> lbs <input type="text"/> Kg
10.	What is the participant's height (self-reported)?	<input type="text"/> feet <input type="text"/> inches <input type="text"/> cm

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11.	Does the participant have any co-morbidities? List as many as needed. 1=diabetes, 2=hypertension, 3=hyperlipidaemia, 4=cardiac disease (excluding 2 and 3), 5=sleep apnoea, 6=asthma, 7=joint problems (eg. arthritis), 8=urinary incontinence, 9=infertility, 10=other, 11=None. If other, please specify.....	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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Document S4: Final coding structure used in NVivo

Name of code	Code related to
General NHS comments not related to surgery	Aspects of care
Guidelines from health professionals	Aspects of care
Follow-up care	Aspects of care
Factors leading to decision to have surgery	Life pre-surgery
Past struggles with weight	Life pre-surgery
Pre-op feelings about surgery	Life pre-surgery
Expectations of surgery	Life pre-surgery
Pre-surgery preparation	Life pre-surgery
Liver shrinking pre-op diet	Life pre-surgery
Other people's perceptions of obesity	Life pre-surgery
NHS funding of surgery	Life pre-surgery
Criteria to fulfill to obtain surgery	Life pre-surgery
Background	Life pre-surgery
Choice of operation	Life pre-surgery
Social impact of obesity	Life pre-surgery
Treatment from health professionals around obesity	Life pre-surgery
Other people's experiences of surgery	Life post-surgery
Future expectations and hopes	Life post-surgery
Peri-operative experience	Life post-surgery
Factors that help maintain motivation post-surgery	Life post-surgery
Support groups	Life post-surgery
Outcome - Activity, mobility	Life post-surgery
Outcome - Body image	Life post-surgery
Outcome - Comorbidity	Life post-surgery
Outcome - Eating	Life post-surgery
6 week post-op diet	Life post-surgery
Outcome - GI symptoms	Life post-surgery
Bowel movements	Life post-surgery
Wind or gas	Life post-surgery
Dumping or sickness	Life post-surgery
Outcome - Hunger	Life post-surgery
Outcome - Psychological	Life post-surgery
Outcome - Social impact of surgery	Life post-surgery
Family reactions to surgery	Life post-surgery
Outcome - Weight	Life post-surgery
In-hospital side-effects of surgery	Life post-surgery
Post-discharge side-effects of surgery	Life post-surgery
Most important outcomes of surgery	Life post-surgery
Outcome - Normality	Life post-surgery
Outcome - Clothing	Life post-surgery
Outcome - increased work options	Life post-surgery

COREQ checklist

No	Item	Guide questions/description	Location in text
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 6, line 9
2.	Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 6, line 11
3.	Occupation	What was their occupation at the time of the study?	Page 6, line 11
4.	Gender	Was the researcher male or female?	Page 6, line 10
5.	Experience and training	What experience or training did the researcher have?	Page 6, line 11
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Page 6, line 14
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. <i>personal goals, reasons for doing the research</i>	Page 6, line 15
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. <i>Bias, assumptions, reasons and interests in the research topic</i>	Page 6, lines 10-17
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. <i>grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	Page 6, line 20

Participant selection			
10.	Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 5, line 24
11.	Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 5, line 21
12.	Sample size	How many participants were in the study?	Page 7, line 10
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Page 7, line 10
Setting			
14.	Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 6, line 6
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 7, line 11
16.	Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 7 lines 10-17, and Table 1
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 6, lines 7-8 Page 7, line 6
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Page 6, line 13
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 6, line 10
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Page 6, line 17
21.	Duration	What was the duration of the interviews or focus group?	Page 7, line 12

22.	Data saturation	Was data saturation discussed?	Page 6, lines 1-2
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Page 6 line 19.
Domain 3: Analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	Page 6, line 21
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Page 6, line 23 and supplementary document S4
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Page 6, lines 20-21
27.	Software	What software, if applicable, was used to manage the data?	Page 6, line 24
28.	Participant checking	Did participants provide feedback on the finding?	Page 7, lines 5-8
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? <i>eg. participant number</i>	Pages 7-13
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Pages 7-13
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Pages 7-13
32.	Clarity of minor themes	Is there description of diverse cases or discussion of minor themes?	Pages 7-13

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Abstract

Objectives: Bariatric surgery is the most clinically effective treatment for people with severe and complex obesity, however, the psychosocial outcomes are less clear. Follow-up care after bariatric surgery is known to be important, but limited guidance exists on what this should entail, particularly related to psychological and social well-being. Patients' perspectives are valuable to inform the design of follow-up care. This study investigated patients' experiences of life after bariatric surgery including important aspects of follow-up care, in the long-term.

Design: A qualitative study using semi-structured individual interviews. A constant comparative approach was used to code data and identify themes and overarching concepts.

Setting: Bariatric surgery units of two publicly funded hospitals in the South of England.

Participants: Seventeen adults (10 women) that underwent a primary operation for obesity (mean time since surgery 3.11 years, range 4 months-9 years), including Roux-en-Y gastric bypass, adjustable gastric band and sleeve gastrectomy, agreed to participate in the interviews.

Results: Experiences of adapting to life following surgery were characterised by the concepts of 'normality' and 'ambivalence', while experiences of 'abandonment' and 'isolation' dominated participants' experiences of follow-up care. Patients highlighted the need for more flexible, longer-term follow-up care that addresses social and psychological difficulties post-surgery and integrates peer support.

Conclusions: This research highlights unmet patient need for more accessible and holistic follow-up care that addresses the long-term multi-dimensional impact of bariatric surgery. Future research should investigate effective and acceptable follow-up care packages for patients undergoing bariatric surgery.

1 Article Summary - strengths and limitations of this study

- 2 • Patients who had undergone all three main types of bariatric procedures across two UK
3 centres were included in the research.
- 4 • A detailed qualitative approach was used, allowing participants to relate their own
5 experiences in terms that were relevant for them.
- 6 • A rigorous approach to analysis was undertaken, including independent coding of initial
7 transcripts by three researchers, and agreement of emergent themes throughout analysis
8 with at least one other qualitative researcher.
- 9 • It is not known whether similar themes would be found with participants in other centres.
- 10 • Findings relating to follow-up care may be less generalisable to healthcare systems with
11 different service pathways and funding structures.

1 Introduction

2 Over 650 million or 13% of adults worldwide suffer from obesity (body mass index (BMI) ≥ 30 kg/m²),
3 representing a tripling of figures since 1975.¹ Obesity is associated with an increased risk of type 2
4 diabetes, cardiovascular disease, certain cancers, and premature death.^{2,3} Within this population,
5 people with severe and complex obesity (BMI ≥ 40 kg/m², or 35-40 kg/m² with another significant
6 health problem that could be improved by weight loss) suffer the greatest health burdens and are at
7 the highest risk of premature death.^{4,5} In addition to the physical and metabolic health burdens,
8 people with severe and complex obesity are more likely to suffer with psychological disorders such
9 as depression, anxiety and disordered eating, and reduced health-related quality of life (HRQL).^{6,7}
10 These individuals also suffer from social stigma and discrimination related to their weight^{6,8} which is
11 in turn associated with adverse physical and psychological outcomes.^{8,9} Thus, any interventions to
12 treat severe and complex obesity should consider the impact on these psychosocial outcomes in
13 addition to traditional clinical and metabolic outcomes.^{10,11}
14 Bariatric surgery, combined with behaviour change and dietary management, is the most clinically
15 effective treatment for people with severe and complex obesity, in terms of weight loss and the
16 improvement of co-morbidities such as type 2 diabetes.^{5,12,13} The three main types of bariatric
17 operations performed in the UK include the Roux-en-Y gastric bypass (RYGB, 53.9% in 2011-13), the
18 sleeve gastrectomy (SG, 21.4%), and the adjustable gastric band (AGB, 21.4%).¹⁴ More recent
19 international data indicate that the SG (46.0%) and RYGB (38.2%) are the most common bariatric
20 operations worldwide with AGB decreasing in recent years (5.0%), and the one-anastomosis gastric
21 bypass now gaining popularity.¹⁵ Each of these procedures works slightly differently; mechanisms
22 include restriction in the amount of food able to be consumed, reduction in hunger, improvement in
23 satiety, shift in food preferences, as well as altered gut hormones, bile acids, and vagal signalling.¹⁶
24 Whilst there are lots of non-randomised studies in this field, there are very few well designed and

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3 1 conducted randomised controlled trials with long-term follow-up. This means that true comparative
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5 2 assessments of RYGB, SG and AGB are absent from the literature. A current UK study has recently
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7 3 completed recruitment (n=1351), with the primary end point at three years. This will be the first
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9 4 pragmatic large-scale study examining all three procedures.¹⁷

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13 5 Studies which have examined HRQL after each procedure are often poorly conducted with few
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15 6 including baseline data and comprehensive assessments of HRQL. Some show certain aspects of
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17 7 HRQL to improve but not others.^{11 12 18} Previous qualitative research has highlighted the complex and
18
19 8 changeable nature of the psychosocial impact of bariatric surgery, helping to shed light on some of
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21 9 these inconsistencies in the HRQL literature, and emphasising the importance of long-term post-
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23 10 operative support in helping patients manage these changes.^{10 19} Previous research has also reported
24
25 11 attendance at follow-up visits to be associated with better weight loss outcomes after bariatric
26
27 12 surgery.²⁰ Follow-up care is thus important to optimise clinical and psychosocial outcomes of
28
29 13 bariatric surgery. However, bariatric surgery follow-up care has been reported to vary greatly across
30
31 14 the UK,²¹ and current UK and US bariatric surgery guidelines focus on surgical and metabolic
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33 15 outcomes, with limited guidance on how to support psychological, social and lifestyle changes that
34
35 16 affect patients' HRQL.^{5 22} Nevertheless, previous work has highlighted the importance of these multi-
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37 17 faceted aspects of HRQL to patients that have undergone bariatric surgery and recommendations
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39 18 are needed on how best to support patients after surgery to optimise these outcomes.²³

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45 19 In seeking to evaluate and provide recommendations on bariatric surgery follow-up care, the
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47 20 patient's perspective can provide valuable information.²⁴ Qualitative research is useful to explore
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49 21 patients' perspectives as it seeks to gain the insider's view on how people view, experience, and
50
51 22 make sense of their social world.²⁵⁻²⁷ The primary focus of most previous qualitative research in
52
53 23 bariatric surgery has been on patient experiences of outcomes of surgery rather than experiences of
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55 24 follow-up care.^{10 19} Studies that have reported on aspects of care have identified patient need for
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57 25 longer follow-up after bariatric surgery, better access to psychological support, and the ability to
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3 1 communicate with health professionals between routine appointments.^{19 28-36} However, most of
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5 2 these studies were single-centre^{29-32 34 36} or reported findings from select groups, such as patients
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7 3 that had undergone one type of bariatric procedure only (e.g. adjustable gastric band)^{29 30 32-35} or had
8
9 4 experienced negative outcomes such as weight re-gain or substance abuse issues.^{28 29 32 34} A recent
10
11 5 systematic review by Parretti *et al* identified few studies focusing on patients' experiences of follow-
12
13 6 up care after bariatric surgery in the longer-term, and recommended that primary studies in this
14
15 7 area were needed.¹⁹ The objectives of this study were to: 1) Investigate experiences of life after
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17 8 bariatric surgery including follow-up care in the long-term across people that had undergone all
18
19 9 three main types of UK bariatric procedures, and 2) Use these findings to provide recommendations
20
21 10 for follow-up care.

11 Methods

12 Patients who had undergone a primary operation for obesity at two publicly funded bariatric surgery
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14 13 centres in the South of England were eligible to participate in the research. Patients were identified
15
16 14 by health professionals at each hospital using databases and clinic lists and sent information about
17
18 15 the research. Interested patients contacted the researcher directly (KDC). For initial interviews,
19
20 16 patients were sampled purposively, aiming for maximum variation in gender, age, starting body
21
22 17 mass index (BMI), type of operation, and time since operation. Emerging findings from analysis of
23
24 18 initial interviews guided sampling for remaining interviews.³⁷ Sampling continued until themes were
25
26 19 well-established with few or no new insights gained from additional data collection.^{26 37} Ethical
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28 20 approval for the study was obtained from Northwest - Preston Research Ethics Committee (Ref
29
30 21 12/NW/0844). This study was undertaken as part of a wider study to develop a core outcome set for
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32 22 bariatric surgery (see **document S1** for protocol).²³
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34 23 Interviews were chosen as the method of data collection for this study due to the sensitive and
35
36 24 complex nature of living with bariatric surgery, and to allow individual participants' experiences to
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1 be explored in detail. Interviews were semi-structured to provide some consistency in topics
2 discussed between interviews, while allowing flexibility to adapt each interview to the participant.
3 Thirteen participants were interviewed in their homes, four in a private research room at one of the
4 two participating hospitals, one in a private room at the University, and one over the telephone at
5 their request. Interviews lasted between 44 and 110 minutes.

6 Written informed consent was taken and interviews conducted according to an outline topic guide,
7 which evolved iteratively as the research progressed (see **document S2** for final version). Findings
8 reported in this paper mainly relate to the sections of the topic guide 'Actual outcomes of surgery'
9 and 'Actual experiences of follow-up care'. Relevant demographic and clinical information were also
10 collected (**document S3**). All interviews were conducted and audio-recorded between February 2013
11 and November 2014, by a female researcher (KDC) who was a PhD student and registered dietitian.
12 KDC underwent training in qualitative research methods and was supervised by two experienced
13 qualitative researchers (AOS, FM). An initial telephone conversation was held with each participant
14 to discuss the study and arrange the interview. Participants were otherwise not previously known to
15 the researcher prior to interview. The researcher introduced herself as a PhD student to participants.
16 She did not reveal her professional background as a registered dietitian unprompted but did not
17 seek to hide it if participants asked. Field notes, which provided important contextual information to
18 aid data analysis, were made as soon as possible after each interview.³⁸
19 Recorded interviews were transcribed verbatim, and transcriptions checked for accuracy by KDC.
20 Thematic analysis was undertaken, using techniques of constant comparison to code data and
21 identify emerging themes.^{37 39} As the aim of the study was to broadly investigate patients'
22 experiences of surgery, including outcomes and aspects of care, this inductive approach to analysis
23 was chosen to ensure that themes developed were strongly linked to the data. Coding was
24 completed for all transcripts by KDC, with a sample of transcripts independently coded by two other
25 experienced qualitative researchers (AOS and JLD) (see **document S4** for final coding framework).

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3 1 Differences in interpretation were resolved through discussion. Initial codes were built into coding
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5 2 structures and themes were identified. Coding and data management were facilitated using NVivo
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7 3 10 software.⁴⁰ Detailed descriptive accounts were written by KDC for each small batch of interviews,
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9 4 which described data relating to each theme and its constituent codes. It was at this stage that
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11 5 relationships between themes were identified, leading to the development of higher-order
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13 6 categories which encompassed inter-related themes. The coding and descriptive account were
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15 7 completed for each batch of interviews prior to recruiting additional patients so that emerging
16
17 8 themes could be followed up to enrich subsequent interviews. Finally, large matrices were created
18
19 9 to compare themes and categories across all participants and summary descriptive accounts were
20
21 10 written wherein the concepts overarching all themes and categories crystallized.³⁹ AOS, FM, JLD and
22
23 11 JMB reviewed all descriptive accounts and made suggestions about further links between themes,
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25 12 categories and concepts.

30 13 Patient and Public Involvement

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33 14 The idea for this research was based on the lead author's experience of working with patients over
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35 15 several years in a bariatric surgery service, as well as discussion with a representative from a
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37 16 relevant patient charity. This patient representative reviewed and provided feedback on the
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39 17 research proposal submitted for funding. After the study received funding, two patients who had
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41 18 undergone NHS-funded bariatric surgery were recruited as patient research partners and reviewed
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43 19 and provided feedback on the interview topic guide, and all written patient information (including
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45 20 study recruitment documents, and the final study summary disseminated to participants).

50 21 Results

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54 22 Of 48 patients invited, 17 agreed to take part in interviews (mean time since surgery 3.11 years,
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56 23 range four months to nine years), although two others (spouses of existing participants) were
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58 24 opportunistically recruited as the research was ongoing. Interviews lasted between 44 and 110
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1 minutes. Twelve of the 19 participants were female, and the mean age was 51.1 years. All reported
2 their ethnicity to be 'White British', and 17 had already undergone surgery (**Table 1**). The analysis
3 presented draws on interview data from the 17 participants that had undergone surgery.
4 Bariatric surgery was a life-changing journey for participants, impacting on several different areas of
5 their lives. The overarching concepts of 'normality' and 'ambivalence' emerged from analysis of data
6 on patients' experiences of adapting to life after surgery (**Figure 1**). Analysis of data relating to
7 experiences of follow-up care was conducted separately and characterised by two concepts –
8 'abandonment' and 'isolation' (**Figure 2**). Results are presented according to overarching concept
9 with participant quotes used to support the description of each concept.

10 Adapting to life after surgery – normality and ambivalence

11 Throughout several areas of their lives, participants were striving to be more "normal" after bariatric
12 surgery. This related to different aspects of their lives categorised as physical health, psychological
13 health, eating patterns and hunger, body image, weight, and social functioning (**Figure 1**).
14 Participants experienced many positive changes that undeniably brought them closer to their idea of
15 normality. However, participants also described things that did not change, for which they still felt
16 abnormal. Some also experienced changes perceived as negative or difficult to deal with, which
17 made them feel more abnormal and required a process of adjustment. This was acknowledged as a
18 "trade-off", or the "price to pay" (P08) for the benefits gained. The complexity of the changes
19 experienced highlighted the ambivalence of living with the results of bariatric surgery. Despite the
20 challenges, all participants felt the surgery was a good decision: "I don't regret it for a minute.
21 Despite all the complications and issues." (P14)

22 Normality

23 All participants reported an improvement in activity and mobility levels and/or their ability to carry
24 out 'normal' activities of daily living following surgery: "I'm more mobile, I can tie my shoelaces,

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2
3 1 shower properly...my life has changed for the better." (P10). Participants also reported several
4
5 2 positive changes related to physical and psychological health including a reduction in medications
6
7 3 required (e.g. for diabetes), an improvement in physical symptoms (such as joint pain), self-
8
9 4 confidence, and psychological well-being: "I feel healthier mentally in my head, like I want to get out
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11 5 there." (P09).

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15 6 Some participants described an improved or more 'normal' relationship with food after surgery,
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17 7 whereby they had retrained their mind to focus on "eating more sensibly" rather than thinking they
18
19 8 were "on a diet" (P11). Others experienced no real change to their relationship with food, feeling as
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21 9 though they still had to be "on a permanent diet" (P19), or continued to use food as way of coping
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23 10 with difficult emotions which remained: "I still have an awkward relationship with food...still have
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25 11 the same demons...I probably rely on food to deal with certain emotions" (P14).

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29 12 All 17 of the participants had lost a large amount of weight since having surgery, however, eight had
30
31 13 re-gained some of this weight. Participants reported feeling distressed by this as they did not want
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33 14 to return to the way they were: "That was a real horrendous thing for me to see my weight go up a
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35 15 bit after all I'd gone through to get it down..." (P07). However, a couple described being reassured
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37 16 by health professionals that it was normal to experience some weight re-gain. The majority related
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39 17 their weight re-gain to a gradual increase in appetite and/or portion sizes over time (which had
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41 18 initially decreased after surgery), and a feeling that the surgery was not as effective as it had been: "I
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43 19 don't seem to be getting the urge to stop quicker, like I did before" (P18).

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48 20 The majority of participants reported developing loose-hanging excess skin following their massive
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50 21 weight loss, which challenged their sense of normality. Although they were pleased to be a more
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52 22 'normal' size, some felt ashamed of how abnormal their body looked without clothes on. Skin
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54 23 removal surgery was a costly option, so some had learned to live with the excess skin; however, a
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56 24 few found the excess skin to be particularly problematic, impacting on their mental health and
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1 relationships: "My husband doesn't like the excess skin...and that's one of the reasons why I must do
2 something about it, because...I know I look like a bag of s**t" (P12).

3 Ambivalence

4 Although improvements to existing health problems were important benefits of the surgery, five
5 participants reported developing new health problems post-surgery, including micronutrient
6 deficiencies, menstrual problems, brittle bones, low blood pressure and cardiac issues: "...you give
7 up one set of health implications but you get given another set in its place..." (P07). Some
8 participants still suffered with several food intolerances and/or frequent gastrointestinal symptoms
9 many years after surgery, which they reported resulted in a poorly balanced diet: "I can't eat bread
10 or meat...That's one of the small prices I have to pay...my intake of food is nowhere near balanced..."
11 (P08).

12 Difficulties were described in developing new coping strategies to replace food, which had
13 previously been a "comfort blanket": "...all your insides are different but your brain...no different
14 whatsoever...that for me was the hardest thing to adjust to, because my brain was still telling my
15 stomach I was hungry but obviously I couldn't [eat]..." (P03). One patient described developing an
16 alcohol dependency post-surgery (which they had eventually overcome), and two participants
17 mentioned the need for more psychological input to help with their adjustment following surgery:
18 "There was no formal counselling...and that might be a good idea to find out why we eat so much,
19 why are we addicted to food..." (P04).

20 Ambivalence was also evident in participants' experiences of social functioning and stigma.
21 Participants reported receiving positive attention due to their weight loss: "...people tell you 'you
22 look brilliant'...that is the good side of it" (P17). For some, however, this led to mixed emotions at
23 the revelation of "how negative people saw you before" (P07). Others described receiving less
24 negative attention and feeling less socially stigmatised due to their obesity: "I can walk down the
25 road now and not get such the bad looks as I used to." (P04). However, a number of participants had

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3 1 experienced a new type of social stigma at having taken the “easy way out” (P02) by having surgery
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5 2 (e.g. not achieved weight loss through the ‘normal’ means). Some were ashamed to tell others they
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7 3 had undergone surgery for fear of this reaction.
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10 4 Social and family eating situations could also cause anxiety for some due to attracting attention for
11
12 5 only eating very small amounts, or unpleasant and embarrassing gastrointestinal symptoms which
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14 6 could arise when eating. For some this had remained an issue several years following surgery causing
15
16 7 disruption to relationships: “It disrupts life because I can be eating and whether it’s the wrong food,
17
18 8 a mouthful too much...I’ve got to go out and she can hear me retching, and it puts her off her food”
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20 9 (P08). Others were able to adapt or reported their social life had “come back” (P10) gradually as
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22 10 food tolerance improved.
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27 11 Experiences of follow-up care – abandonment and isolation

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30 12 Participants explained that follow-up care received after surgery was mainly provided by the
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32 13 specialist bariatric surgery team (although what this entailed was highly variable), with little support
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34 14 from their GPs (general practitioners). Only a few participants described feeling well-supported
35
36 15 overall, and all of these had undergone their surgery less than two years previously. However, most
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38 16 described at least one aspect of follow-up care which they found helpful. These included: 1) the
39
40 17 routine monitoring of certain measures (e.g. weight, nutritional blood tests); 2) the availability of
41
42 18 one key health professional (generally a specialist dietitian or nurse), who was easy to contact on an
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44 19 ad-hoc basis; 3) the ability to contact the bariatric team using a range of contact options (e.g.
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46 20 telephone, email); 4) good communication between team members; and 5) continuity of care (e.g.
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48 21 being able to see the same professionals at every appointment) (**Table 2**).
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53 22 Overall, however, there was a sense of abandonment and isolation in participants’ accounts of
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55 23 follow-up care. This related to their experiences of post-operative support from the specialist team,
56
57 24 primary care professionals, and peer support groups (**Figure 2**). Participants felt that health
58
59 25 professionals didn’t always appreciate the long-term implications of life after surgery, or even if they

1 did, services were not set up to support them adequately: "It happened eight years ago so no one
2 thinks you may have any hang-ups, issues, concerns about it...the implications of the changes it
3 makes people don't really appreciate, it's an old record, old news." (P07).

4 Abandonment

5 Some participants felt that problems or complications they experienced following surgery were
6 ignored or not dealt with properly, or there was a lack of clarity of who to go to if they experienced
7 problems. P07, for example, felt her post-operative problems were dismissed by the specialist team,
8 and that she "was upsetting someone's figures by having complications". P12 experienced a problem
9 with one of her surgical wounds which wouldn't heal and wasn't sure who to go to about it. She felt
10 "quite abandoned" and dealt with it mainly on her own. Abandonment also related to the feeling
11 they had been given inadequate information or guidance about life following surgery: "They give you
12 loads of information about what to do in the first six weeks and then there's nothing..." (P04).

13 Abandonment was also evident in accounts of support only being provided when patients
14 themselves initiated contact: "I feel that as long as you didn't contact them then you will be left
15 alone..." (P15). Concerns were raised for others whom they perceived less likely to seek help
16 proactively: "...these people aren't coming forward to explain that they're having problems because
17 they don't want to feel like a failure..." (P09). P18 expressed disappointment that he had not been
18 sent any appointments post-operatively and felt he had been left "in limbo" to "get on with it"
19 himself. He had not asked for help and was under the impression that it would only be appropriate
20 to contact the team if you were having complications: "...obviously if I was in excruciating pain from
21 the operation I suppose, I could have gone back..." (P18).

22 Most participants also reported feeling abandoned by their GPs who were not usually supportive of
23 them having undergone bariatric surgery and did not "fully appreciate the struggles that you have"
24 (P14) in the long-term. However, a minority of participants described feeling well-supported by their
25 GPs who recognised the long-term health benefits of bariatric surgery: "...with being my dad's

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2
3 1 doctor, he sees that hopefully I won't have the same problems...he's done everything he can to help
4
5 2 me..." (P05).
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8 3 Isolation

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11 4 Several participants did not live locally to the hospital where the specialist team were located. This
12
13 5 presented a barrier to accessing follow-up care, which some felt could contribute to feelings of
14
15 6 isolation: "From this side of the county it's (hospital) extremely difficult to get to...I can understand
16
17 7 an awful lot of people thinking "if I ring [hospital] they're going to say come over and see me and
18
19 8 that is so difficult to get to...I won't bother" (P15). Equally participants described how local primary
20
21 9 care services were unable to support them compounding their feelings of isolation: "Unless they've
22
23 10 (GP surgery) read my notes they don't even know I've got one (a gastric band)" (P04), and "They (GP
24
25 11 surgery) were very much like 'it's a secondary care issue, it's not primary care'" (P07).
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30 12 Isolation was also apparent in participants' experiences of bariatric surgery peer support groups.
31
32 13 Although not part of medical care, these represented an important source of support. These groups
33
34 14 were typically run by patient volunteers, with limited or no input from health professionals. Some
35
36 15 participants had access to these groups in their local areas, whereas others did not. Those unable to
37
38 16 access a group felt this contributed to their sense of isolation post-surgery: "...there's meetings
39
40 17 where you can meet other people who've had the [gastric] band...but there's no local ones for me...if
41
42 18 people said, 'If you do eat it, it's going to hurt but it will go, and this is the reason it's hurting,' then I
43
44 19 could have dealt with it a little bit better." (P17). Those that had accessed these groups described
45
46 20 variable experiences. Some found them supportive, for example P01 who continued to attend
47
48 21 several years post-surgery, whereas others had negative experiences and felt quite isolated from
49
50 22 other members. P19, for example, had disengaged from her local group which she described as
51
52 23 being very "cliquey" with members using the group mainly to emphasize negative experiences or
53
54 24 "how to cheat the band". Many felt that peer support groups including "a chairman" (P15)
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1 knowledgeable in the results of bariatric surgery should be part of routine clinical care to improve
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1 knowledgeable in the results of bariatric surgery should be part of routine clinical care to improve
2 accessibility of peer support and ensure consistency of information discussed.

3 Discussion

4 This qualitative study found that bariatric surgery impacted participants' physical and psychological
5 health, eating behaviours, weight, and social functioning. The overarching concepts of normality and
6 ambivalence illustrated their lived experience following bariatric surgery. Normality was evidenced
7 through participants' relief at feeling more normal in some ways (e.g. improved ability to undertake
8 daily activities), yet feeling less normal in other areas, including the development of excess skin and
9 difficulties eating 'normally' in social situations. Although participants experienced many positive
10 health changes, they also experienced changes which were negative or difficult to adapt to, such as
11 an inability to rely on emotional eating as an entrenched coping mechanism, perceived bodily
12 deformity as a result of excess skin, and the destabilisation of important relationships. These
13 complexities highlight the ambivalence of living with the outcomes of bariatric surgery. In coping
14 with these changes, participants received varying levels of care from specialist health professionals
15 and GPs. Although there were some positive experiences, 'abandonment' and 'isolation'
16 characterised most follow-up care experiences. This included feeling unsupported with post-surgery
17 problems (other than serious complications), lack of guidance with long-term lifestyle changes, lack
18 of understanding from GPs, and limited peer support. However, all participants felt that undergoing
19 the surgery was a good decision despite the difficulties. These findings are important in helping to
20 define future follow-up care packages to better address the complex changes experienced after
21 bariatric surgery.

22 Our findings are consistent with previous qualitative research on patient experiences of living with
23 outcomes of bariatric surgery which depicted the complexities on patients' sense of normality and
24 the 'give and take' or ambivalent nature of the changes experienced.^{10 41-43} This study strengthens

1
2
3 1 the evidence for the individual and nuanced nature of how bariatric surgery changes people's
4
5 2 relationship with food in different ways, and changes over time, indicating the need for
6
7 3 individualised dietary and psychological support at different time-points.^{10 28 41 43 44} The importance
8
9 4 placed by participants on the social impact of bariatric surgery was also noted in a recent UK study
10
11 5 by Graham *et al.*⁴⁵ These issues, including difficulties with social and family eating should be given
12
13 6 more attention in follow-up care. Our study confirms previous qualitative findings on the
14
15 7 importance of continuity of care,¹⁹ the ability to access professional advice (often from the specialist
16
17 8 dietitian) between appointments via telephone or email,³¹ the lack of psychological support after
18
19 9 surgery,^{19 28-30 32 33 36 46} and the need for moderation in patient support groups.^{33 34} Previous studies
20
21 10 have related patients' views that GPs were not equipped to adequately support them post-surgery.¹⁹
22
23 11 ^{30 31 47} This was also evident in our study with most participants describing negative experiences with
24
25 12 GPs in relation to bariatric surgery, and feeling they were unable to offer adequate support. Despite
26
27 13 this, several participants would have preferred to access support locally due to living remotely.
28
29 14 Our study expanded the findings on patient experiences of bariatric surgery follow-up care as being
30
31 15 characterised by feelings of abandonment and isolation, with views that services were not set up to
32
33 16 support long-term issues. Abandonment was also evident in a study by Jumbe & Meyrick who
34
35 17 described a "post-surgical cliff" with patients receiving intensive support prior to bariatric surgery
36
37 18 and then feeling abandoned after surgery.³⁶ Similar to our study, they described how post-operative
38
39 19 support was reliant on patient-initiated contact. Previous research with people living with obesity
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41 20 suggests they may delay or avoid seeking healthcare due to societal and medical stigmas.^{48 49} This
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43 21 has also been reported by Throsby who conducted a UK-based ethnographic study within a surgical
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45 22 weight management clinic.⁵⁰ She described examples of patients struggling with their eating habits
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47 23 and weight post-surgery, and the shame they felt at doing 'badly' after undergoing publicly-funded
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49 24 surgery. The author argued that this "moral weight" could lead to patients not seeking help when
50
51 25 most needed.⁵⁰ Similarly, feelings of shame and failure at not having met the perceived post-

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3 1 operative expectations was one reason cited by Australian patients for non-attendance in bariatric
4
5 2 surgery aftercare.³⁰
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7
8 3 The main strength of this research is that a detailed qualitative approach to data collection was
9
10 4 used, whereby participants were given the time and flexibility to relate their own experiences in
11
12 5 terms that were relevant for them. A rigorous approach to analysis was undertaken, including
13
14 6 independent coding of initial transcripts by three researchers, and discussion and agreement of
15
16 7 emergent themes throughout analysis with at least one other qualitative researcher. A limitation of
17
18 8 this study is the lack of ethnic diversity represented within the sample. Low numbers of people from
19
20 9 ethnic minority groups undergo bariatric surgery in the UK (1303 between 2011-2013, 7.7% of total
21
22 10 procedures), making it difficult to identify eligible people for qualitative studies.¹⁴ A strength of this
23
24 11 research is that we were able to over-represent male participants within our sample (41% of the 17
25
26 12 post-operative participants compared with 24% who undergo bariatric surgery nationally), which has
27
28 13 been a limitation of previous qualitative studies in this area.^{14 28 30 32 34-36} An additional strength was
29
30 14 the inclusion of a clinically diverse group of patients who had undergone all three main types of
31
32 15 bariatric procedures in the UK and who were at a broad range of timepoints post-surgery.
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34 16 Participants were also recruited from two UK centres with different follow-up programmes and
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36 17 health professional teams. It is not known, however, whether similar themes would be found with
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38 18 participants in other centres. The findings relating to follow-up care may be less generalisable to
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40 19 healthcare systems with different service pathways and funding structures.
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47 20 Taken together with previous literature, our findings highlight that current bariatric surgery follow-
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49 21 up care provision is not often aligned with patient need. Patients highlighted the need for a flexible
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51 22 and long-term approach to follow-up care from a multi-disciplinary health professional team. This
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53 23 includes both routine and open appointments, moderated peer support groups, and different
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55 24 methods of contact (e.g. telephone, online in addition to face-to-face). These recommendations are
56
57 25 also in accordance with the recently published 2019 UK psychological guidelines for bariatric surgery
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2
3 1 which recommend a flexible and individualised approach to post-operative psychological support,
4
5 2 including routine screening at 6-9 months post-surgery to identify support needs.⁵¹ In addition to
6
7 3 individual dietary and psychological support, services should consider how to better support patients
8
9 4 in developing strategies to cope with family and social difficulties post-surgery. This may include
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11 5 actively engaging family and close friends in pre-operative preparation and/or post-operative
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13 6 interventions. Future research is needed to define and evaluate an effective and acceptable follow-
14
15 7 up care package that could be consistently applied across bariatric surgery centres. This may include
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17 8 the optimal systems or pathways to identify and support those who need the most help but are the
18
19 9 least likely to seek it, ways of engaging family and social support, and delivering moderated peer
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21 10 support groups. The relative merits of delivering follow-up care in specialist or community-based
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23 11 health services or how it might be shared between the two should also be investigated.
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29 12 Author contributions

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31
32 13 KDC led the study design, data collection and data analysis as part of her PhD research, and drafted
33
34 14 this manuscript. AOS, FM and JMB were KDC's PhD supervisors and advised on study design, data
35
36 15 collection and analysis, and provided comments on this manuscript. JLD advised and contributed to
37
38 16 data analysis and provided comments on this manuscript. All authors approved the final submitted
39
40 17 manuscript.
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47
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49
50 20 valuable input, as well as the study participants who gave up their time to take part in the research
51
52 21 and the health professionals at the centres who helped with study recruitment.
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Data sharing

Anonymised participant data can be made available on reasonable request to the corresponding author at karen.coulman@bristol.ac.uk.

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1 **Table 1: Characteristics of participants**

Participant	Gender	Age range (years)	Marital status	Employment status	Type of surgery	Time since surgery (years)
P01	Female	60-70	Married	Retired	RYGB	>5
P02	Female	50-60	Married	Unemployed	RYGB	<1
P03	Female	30-40	Married	Employed*	RYGB	1-2
P04	Female	60-70	Married	Retired	AGB	>5
P05	Male	40-50	Married	Employed	RYGB	<1
P06	Female	30-40	Married	Employed	Awaiting surgery	N/A
P07	Female	40-50	Married	Employed	RYGB	>5
P08	Male	60-70	Married	Employed	AGB	>5
P09	Female	40-50	Married	Unemployed	SG	1-2
P10	Male	30-40	Co-habiting	Self-employed	SG	2-5
P11	Female	40-50	Married	Employed	SG	<1
P12	Female	50-60	Married	Self-employed	SG	1-2
P13	Male	50-60	Widowed	Employed	RYGB	<1
P14	Female	40-50	Married	Employed	AGB & RYGB	>5
P15	Male	60-70	Married	Retired	RYGB	1-2
P16	Female	60-70	Married	Retired	Awaiting surgery	N/A
P17	Male	40-50	Married	Employed	AGB	2-5
P18	Male	50-60	Co-habiting	Employed	AGB	1-2
P19	Female	30-40	Separated	Employed	AGB	1-2

2 **AGB=Adjustable gastric band, RYGB=Roux-en-Y gastric bypass, SG=Sleeve gastrectomy**

3 ***'Employed' status includes those employed both full-time and part-time**

4

1 **Table 2: Participant quotes to support positive experiences of follow-up care**

Positive aspects of care	Quotes
Routine monitoring of certain measures	"It was good having my bloods done so I could check what my levels were like, that was quite useful for me...routine monitoring was good." (P07)
The availability of a key health professional; Ability to contact the team using a range of contact options	"If I couldn't get hold of her (dietitian) straight away on the phone I'd send an email and it would either be answered the same day or the next day." (P09)
Good communication between team members	"It's quite a tight little team....you might not necessarily speak to the best person, but they will come together in their meeting and you'll get the best outcome." (P19)
Continuity of care	"You didn't see twenty different people. It was 'the team'...the same faces...I like that. I don't want to see somebody who's different don't know you..." (P08)
Overall positive view of care	"The follow-up care I've had has just been 110%, if I've had a problem I would ring and...I would get an appointment...Someone has always been there for me..." (P01)

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1 **Figure legends**

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3 **Figure 1:** Concepts and categories illustrating the adaptation to life after bariatric surgery including
4 an example of supporting themes for one category

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6 **Figure 2:** Concepts and categories illustrating the experiences of follow-up care after bariatric
7 surgery including supporting themes

8

For peer review only

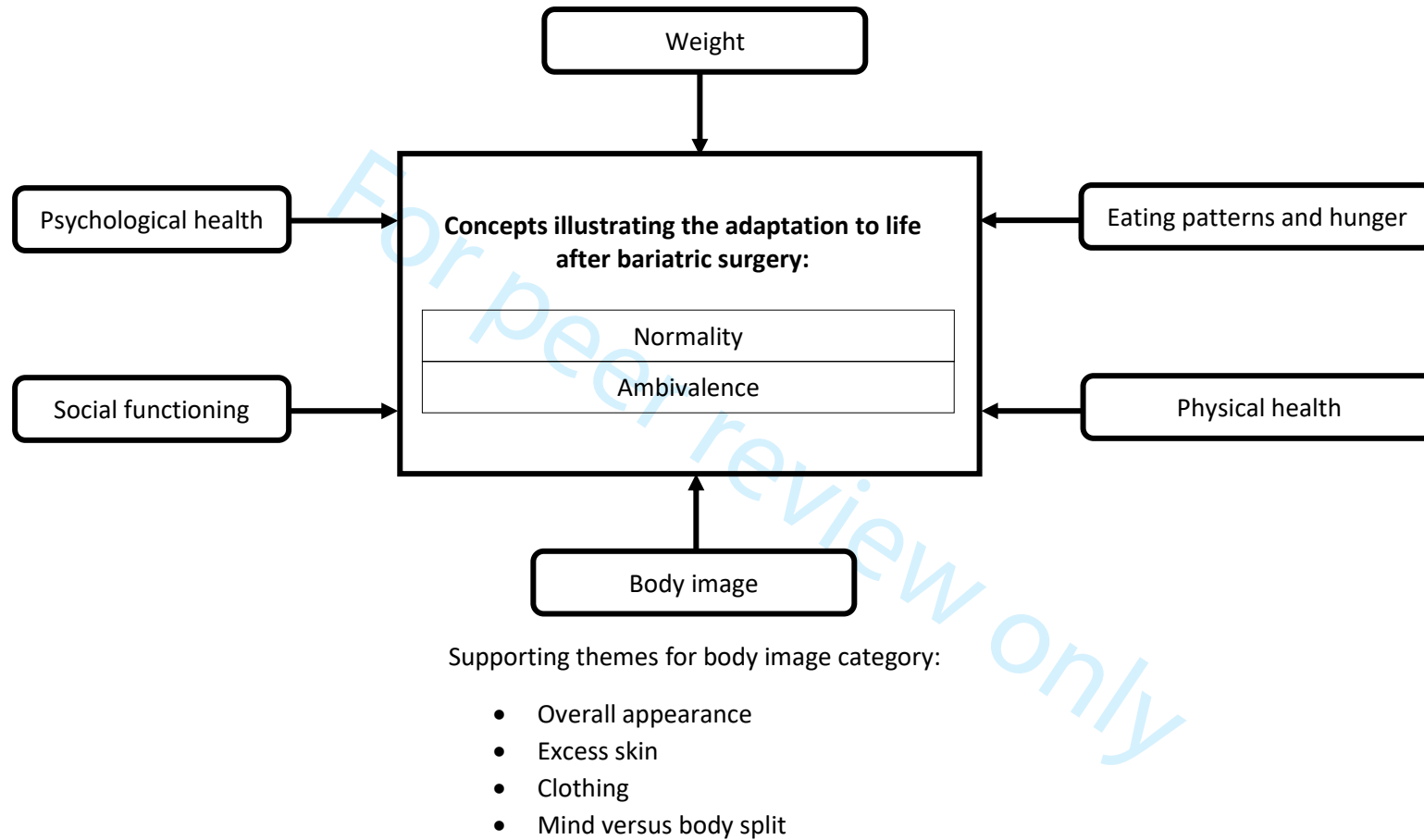


Figure 1: Concepts and categories illustrating the adaptation to life after bariatric surgery including an example of supporting themes for one category

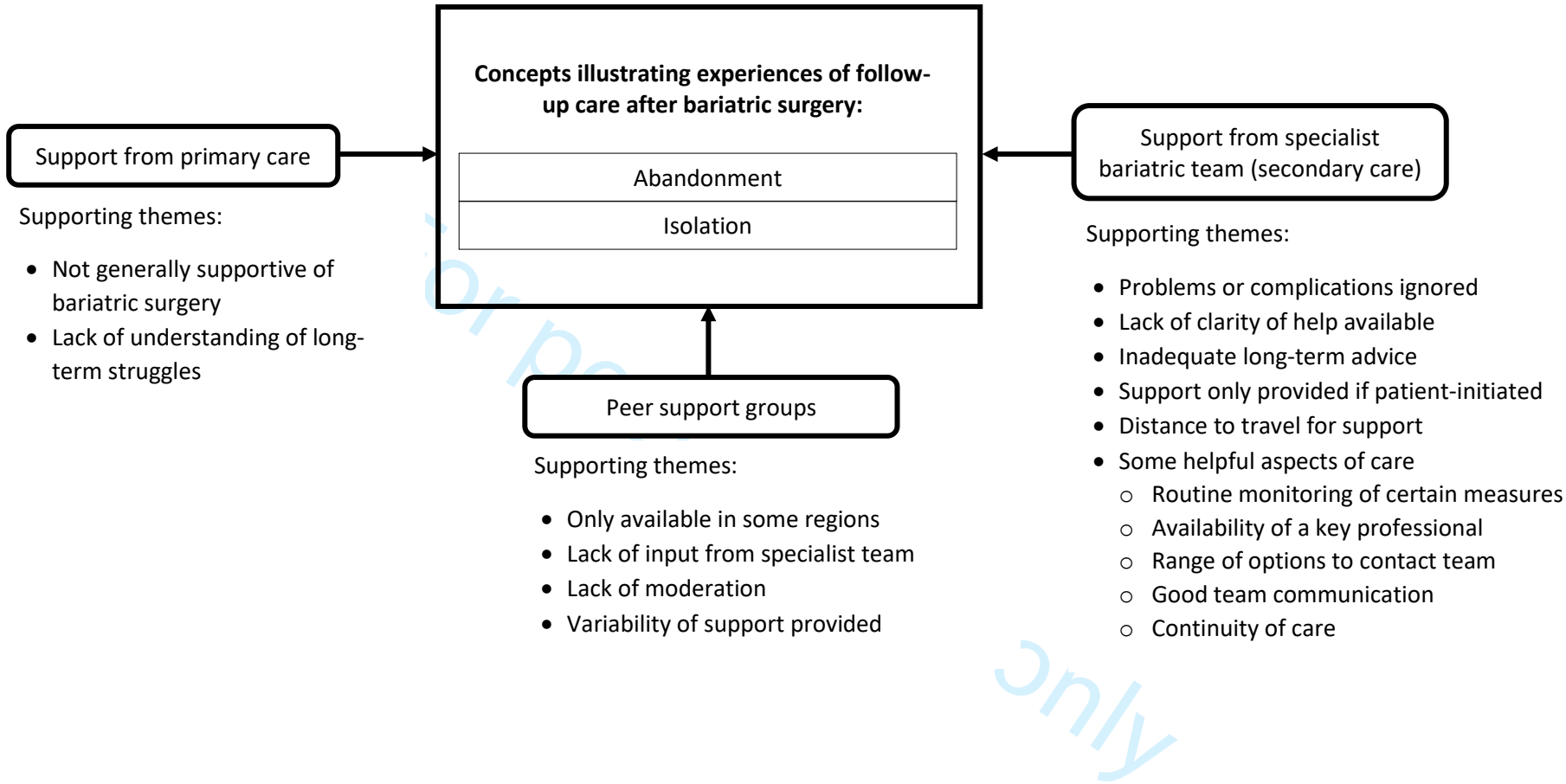


Figure 2: Concepts and categories illustrating the experiences of follow-up care after bariatric surgery including supporting themes

Study Protocol version 2.0 (7/7/14)

Document S1 (Study protocol)

The patient perspective of living with surgery for morbid obesity: Creating a patient 'core' outcome set, and investigating ways to improve follow-up care

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Study Protocol version 2.0 (7/7/14)

Lay Summary

Surgery is increasingly being used as a treatment for obesity. Studies report many different outcomes, often measured in different ways, and little is known about what outcomes are important to patients. This study aims to explore the outcomes that are important to patients and to use this information to develop a short list of the most important outcomes to health professionals and patients (a core outcome set), which can be used to evaluate surgical treatments for obesity. In addition, this study will investigate patients' experiences of obesity surgery to provide recommendations for how post-operative support can be improved in the NHS. This will be achieved by interviewing obesity surgery patients to determine whether published outcomes reflect those outcomes patients themselves consider important, and to obtain views on living with surgery and ways to improve post-operative support. A list of patient-centred outcomes will be created from the literature and the interviews which will be added to a list of 'medical' outcomes of obesity surgery. This long list of outcomes will be reduced into a "core" set of outcomes, using a scientific process to reach agreement, which involves 2 rounds of questionnaires completed by health professionals and patients. The final core outcome set will be agreed in separate consensus meetings with a small group of health professionals and patients. This core outcome set will be useful to researchers in choosing outcomes for research trials that are important to both health professionals and patients. Use of the core outcome set would also improve the overall quality of reporting in trials. This research will also be useful for health professionals to ensure health services are designed based on patient priorities.

Background

Obesity surgery

The NHS Information Centre has released figures showing that just over one quarter of the adult population of England was obese in 2010, an increase from 13-16% of the population in 1993¹. It is predicted that one third of adults in England will be obese by 2015 and more than 700 million adults will be obese worldwide by 2015^{1,2}. Obesity is associated with an increased risk of type 2 diabetes, heart disease, cancer, reduced quality of life and premature death^{1,3}. As such, obesity is a major public health concern. Various treatments for obesity exist including lifestyle modifications, pharmacotherapy, and more recently, surgical interventions. Obesity surgery operations have rapidly increased in the UK, and worldwide, with the most common operations being the adjustable gastric band and the Roux-en-Y gastric bypass^{1,4}. In 2009, a Health Technology Assessment report (including a Cochrane systematic review) concluded that obesity surgery is more clinically effective than other treatments for obesity in terms of weight loss, improvement of co-morbidities such as type 2 diabetes and hypertension, and is also cost effective⁵.

The patient perspective of outcomes of obesity surgery

Although clinical outcomes are important to measure, patient-reported outcome (PRO) measures, such as measures of health-related quality of life (HRQL), provide a means for capturing how a patient feels about their health or condition⁶. The Food and Drug Administration (FDA) has published guidance on the development of PRO measures to support claims of treatment benefit⁶. PRO measures should be developed based on rigorous qualitative research with patients to ensure content validity (authenticity to patients)^{6,7}. Despite this, the development of PRO measures is variable and not always transparent⁷.

The lead researcher has recently undertaken a systematic review of PROs in obesity surgery studies, which identified 68 different validated questionnaires used to assess PROs amongst the 86 identified studies⁸. Due to the heterogeneity of the items and scales within the questionnaires used amongst the various studies, a meta-analysis to determine the effect of obesity surgery on PROs was unable to be undertaken. The lead researcher then looked in further depth at the development of those questionnaires which were classified as obesity-specific (19 questionnaires). Although 14 (74%) reported to have involved patients in questionnaire development, only 3 (16%) specified that obesity surgery patients were involved. Only 6 (32%) specified that qualitative interviews/focus groups were used to obtain patient views and none specified that a qualitative analysis of resulting data was undertaken. Thus, it is not certain whether the majority of PRO questionnaires being used to assess obesity surgery are grounded in patient views.

Although well-developed PRO measures can provide valuable information about the patient's perspective of outcomes of treatment, primary qualitative studies can also yield rich information; however, these types of studies are rarely included in Cochrane reviews of quantitative evidence. The lead researcher is currently undertaking a review of qualitative research studies where the patient perspective of obesity surgery was sought. Although qualitative studies have focused on patient experiences of surgery, none have explicitly investigated patients' views of important outcomes of obesity surgery.

There is clearly more work needed to clarify the outcomes of obesity surgery from the patient perspective.

A 'core' outcome set for obesity surgery

As described above, heterogeneity of PROs in obesity surgery studies is an issue, which limits cross-study comparison and amalgamation of study results, which in turn limits the ability to make recommendations to clinicians and policymakers about the impact of obesity surgery on outcomes

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3 important to patients. This issue is not unique to PROs, but also to clinical outcome measures with a
4 Cochrane review of obesity surgery unable to undertake a meta-analysis due to a lack of consistency
5 in outcomes reported⁵.
6

7
8 Recent years have seen an increasing interest in the establishment of 'core outcome measures' to
9 promote consistency in the reporting of clinical trials. Of particular interest is the development of
10 the COMET (Core Outcome Measures in Effectiveness Trials) initiative through the MRC Hubs for
11 Trials Methodology Research whose aim is to bring together researchers interested in the
12 development and application of core outcome sets for specific conditions^{9,10}(1). Another notable
13 initiative is OMERACT (Outcome Measures in Rheumatology Clinical Trials) in rheumatology¹¹. Core
14 outcome sets are not meant to be a restrictive list, but a minimum set of outcomes that should be
15 reported on in every trial of a particular disease/condition. By standardising outcomes to be
16 reported on in trials, results can be compared, contrasted and synthesised (e.g. meta-analysis) to
17 inform health policy. No core outcome set for obesity surgery currently exists.
18

19
20 Recent research demonstrates that patients' perceptions of important outcomes may differ
21 considerably from clinicians' perspectives, and therefore incorporating the patient perspective is
22 crucial to contribute to and validate core outcome sets¹². Creating a core outcome set for obesity
23 surgery based on both health professional and patient views will help in the ordering of research and
24 health service priorities to include the patient perspective, and ultimately improve long-term
25 outcomes.
26

27 ***The patient perspective of follow-up care after obesity surgery***

28 Follow-up care after obesity surgery varies greatly across centres. There is no consensus as to what
29 optimum follow-up care is, although most clinicians recognise that good follow-up care is integral in
30 achieving good outcomes from obesity surgery¹³⁻¹⁵. Understanding the outcomes of most
31 importance to patients, and their experiences of follow-up care would provide invaluable
32 information to design effective follow-up care programmes tailored to patients needs to maximise
33 the benefits of surgery in the long-term. Qualitative research with obesity surgery patients in the UK
34 context has focused on the experiences of patients, including difficulties they encounter after
35 obesity surgery^{16,17} but to our knowledge, no studies have specifically focused on patients'
36 experiences of follow-up care and ways to improve follow-up care in the health services.
37
38

39
40 There is clearly more work needed to clarify optimum follow-up care from the patient perspective,
41 and its influence on outcomes. As obesity and the number of obesity surgery operations increase, it
42 is imperative that research in this area is of high quality, and takes into account the patient
43 perspective.
44

45 **Aims**

46 The overall aims are to develop a core outcome set for obesity surgery including both health
47 professional and patient perspectives and to investigate patients' experiences of living with the
48 results of obesity surgery including ways to improve post-operative follow-up care.
49

50 **Objectives**

- 51 1. Semi-structured qualitative interviews with obesity surgery patients will be conducted to:
 - 52 a. Investigate outcomes of importance to obesity surgery patients that may not have
53 been documented in the literature previously, and to add these to a comprehensive
54 list of PROs of obesity surgery previously compiled from systematic literature
55 reviews.
56
 - 57 b. Investigate patients' experiences of living with obesity surgery and ways to improve
58 post-operative support.
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- 2.
2. The list created in objective 1a above will be added to a list of clinical outcomes which will be used within a Delphi survey of health professionals and patients which will ask them to prioritise the outcomes and produce a shorter list. The short list will be considered at separate meetings with health professionals and patients who will agree and finally ratify the content of the core outcome set.

Methods

Semi-structured qualitative interviews

To supplement the literature reviews previously undertaken by the lead researcher, patients' views of important outcomes of obesity surgery and experiences of existing follow up care will be investigated using semi-structured interviews within a qualitative paradigm.

Identification and selection of patients

Patients who are about to undergo and who have undergone a primary operation for obesity will be identified by health professionals from participating obesity surgery services at NHS healthcare Trusts using departmental databases and clinic lists. The main criteria for selection will be: The patient is undergoing obesity surgery within the next three months (pre-surgery group), or has undergone obesity surgery (post-surgery group). Including patients at both the pre- and post-operative stage will allow us to compare views and assess differences. Patients will initially be purposively sampled to obtain maximum variation for gender, age, ethnicity, starting BMI, type of operation, and time since operation, however further sampling will be guided by emerging findings from interviews.

Patient recruitment

Identified patients will be sent a letter from their local NHS obesity surgery team including an invitation letter and patient information sheet from the lead researcher, informing them of the research and inviting them to participate in the interviews. A reply slip and stamped addressed envelope will be included for patients to indicate whether or not they are interested in participating in the research to post back to the lead researcher. The number of patients recruited will depend on when theoretical saturation is reached (i.e. when the themes relevant to the research have been thoroughly investigated); however it is estimated that approximately 30 patients will be interviewed in total.

Data collection and analysis

Patients who agree to take part in the interviews will be able to choose the location of the interview, either in their own home, at one of the two participating hospitals, or the University of Bristol. Should any participants request to be interviewed at their GP surgery instead, permission will be sought by the chief investigator from the surgery's practice manager to conduct the interview at the surgery. Any travel costs will be reimbursed. Consent will be obtained face-to-face prior to the interview beginning. Should any participants request to be interviewed via telephone, participants will be mailed two copies of the consent form and asked to sign and return them to the chief investigator who will then sign them and return one copy to the participant prior to the interview. An interview topic guide will be applied flexibly to guide interviews. The following broad themes will be explored in interviews: 1) Motivations to undergo surgery; 2) Expected outcomes of surgery; 3) Actual outcomes of surgery (post-op group only); 4) Expectations of follow-up care; 5) Actual experiences of follow-up care (post-op group only). It is anticipated that interviews will last approximately 60 minutes, including 10 minutes dedicated to recording socio-demographic and relevant clinical data at the end of the interview. Interviews will be audio-recorded and transcribed in full. Separate consent will be sought to potentially re-contact them in the future for a follow-up interview.

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3 Interviews will be analysed thematically using a grounded theory approach¹⁸. Data will be analysed
4 using descriptive and explanatory coding to explore and inter-relate categories arising in the data.
5 Data management will be facilitated using the program NVivo 9¹⁹. Descriptive accounts will be
6 written up relating to each batch of interviews, and matrices will be drawn up to compare the
7 occurrence of themes across interviews. Data analysis will run in parallel with data collection so that
8 emerging themes can be followed up to enrich subsequent interviews. A small sample of the
9 interview transcripts will be independently coded by both the chief investigator and her primary
10 supervisor. The coding structures will then be discussed in a supervision meeting and revised as
11 appropriate. The analysis will also be reviewed with the chief investigator's co-supervisor, and
12 patient research partners.
13
14

15 Findings from the qualitative interviews will be combined with findings from a previous review of
16 qualitative literature in this area, and written up for publication as soon as possible. Particular
17 attention will be paid to ensuring that recommendations relating to the improvement of follow-up
18 care are disseminated as soon as possible to clinicians and policymakers.
19
20

21 Important outcomes identified by patients in the semi-structured interviews will be added to the
22 outcomes previously identified from systematic literature reviews undertaken by the lead researcher
23 to create a comprehensive 'long' list of outcomes important to obesity surgery patients. The list will
24 be reviewed by the lead researcher, her supervisors, and patient research partners to make sure it is
25 comprehensive such that potentially important outcomes have not been omitted. This will form the
26 basis of the next stage of the research (Delphi process).
27
28

29 ***Delphi process***

30 This comprehensive list of outcomes will be refined into a 'core' outcome set using a Delphi process
31 consisting of two questionnaire rounds where health professionals and patients individually rate
32 each outcome for its value of being included in the core outcome set, followed by consensus
33 meetings to discuss any potential areas of disagreement with regard to which outcomes to include
34 and to ratify the final core outcome set.
35
36

37 **Ethical issues arising**

38 ***Informed consent***

39 Written, informed consent will be obtained from all participants prior to the qualitative interviews.
40 Confidentiality and anonymity will be assured at this stage and the purposes and possible uses of the
41 research will be explained. It will be made clear that participants are free to drop out or delay
42 participation in research at this stage. Separate consent will be sought to digitally-record interviews,
43 and to potentially re-contact the participants in future for a follow-up interview.
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49 ***Data protection***

50 The principles of the Data Protection Act (1998) will be complied with and data obtained from
51 interviewees will be anonymised using unique study codes. Documents to interpret the codes and
52 personal data will be stored in separate encrypted files in separate locations on the University of
53 Bristol server. All hard copy study documents will be stored in locked filing cabinets. Only data
54 necessary to the purposes of the research will be obtained and stored.
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Confidentiality

Confidentiality and anonymity outside of the interviews will be discussed and assured prior to beginning each interview. It will also be assured through the processes of data storage outlined above and the use of only fully anonymised quotations in all presentations of research findings.

Protection from distress

It is understood that living with morbid obesity and making the decision to undergo obesity surgery are personal and sensitive issues for patients. Therefore interviews will be undertaken sensitively and patients will only be encouraged to talk about aspects of their illness and care that they feel comfortable with. In the event that a participant becomes distressed during a research interview, the researcher will offer to take a short break from the interview and will remind participants that they do not have to discuss any topics they are uncomfortable with and are free to withdraw their consent to participate in the research at any time. If any patients express particular distress relating to their condition or treatment, a distress protocol will be followed (Appendix 1). The interviewer previously worked as a health professional in a NHS obesity surgery service and has experience of dealing with sensitive issues that may be brought up by this patient population. In addition, the interviewer will be supervised by a trained qualitative researcher who has experience in interviewing morbidly obese patients.

Integrity of research data

The MRC principles of Good Research Practice will be adopted with all primary data being retained so that there is an auditable trail from results back to data. Results will be fully and accurately reported at the end of the project.

Independence and impartiality

Every attempt will be made to maintain reflexivity at every stage of the research and to acknowledge the potential impact of the researcher upon the findings.

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Appendix 1: Distress protocol - Interviews

All interviews will be prefaced with a statement about confidentiality and the duty of care. Participants will be told that interview is strictly confidential but should they disclose information to suggest that they are at significant risk of harm the researcher *may* have to discuss this with a clinical advisor.

In the event that a participant appears to be distressed during the interview (eg. becomes silent, cries) or discloses information to provoke concern about suicide risk, the following procedures will be followed:

- Participants will be offered the opportunity to pause for a break from the interview and will then be asked if they would like to resume.
- If necessary, the interview will be terminated and recording equipment stopped.
- At first, the interviewer will listen to the interviewee and offer support in situ. This will allow the researcher to assess whether further action is necessary.
- Should the interviewer remain concerned, they will reflect this to the interviewee and depending on the nature of the situation:
 1. Offer information about local help services
 2. Ask the interviewee if there is anyone they should contact, and if so attempt to make contact
 3. Offer to make initial contact with clinical services (primary or secondary) on behalf of the individual and with their consent
- In cases of particular concern the interviewer will
 1. If necessary, remain with the person until their distress has subsided or someone else is present
 2. Contact a local study clinician for advice/ assistance
 3. Provide a written report of the incident to AOS/JB (PhD supervisors), including information about the nature of the distress and the actions taken

Interviewees will be advised to contact their GP should they find subsequently that the interview provokes issues that they need to discuss.

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1 Document S2: Topic guide

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3 Post-operative patient interviews4
5 NB This guide is necessarily provisional, as its application will depend on the experience of individual participants.

7	Introduction
8	❖ <i>Researcher explains research, asks if any queries on PIS, and takes consent.</i>
9	Motivations to undergo surgery
10	- To start off, I was just wondering if you could tell me a bit about what factors led to your decision to go for surgery?
11	Expected outcomes of surgery
12	- If you can think back to a few weeks before you had the surgery, can you remember how you were feeling about
13	having surgery?
14	<i>Probe: Was there anything you were worried about? [Prompt on risks/side-effects of surgery]</i>
15	<i>Probe: Was there anything you hoped would change for the better by having the surgery?</i>
16	<i>Probe: Was there anything you were hoping to prevent by having surgery?</i>
17	Actual outcomes of surgery
18	- How do you feel about having had surgery now?
19	<i>Probe: Which operation did you have?</i>
20	<i>Probe: How long ago was it now?</i>
21	<i>Probe: What's happened since? [Prompt on the things they said they were worried about/hoped would</i>
22	<i>change/hoped they would prevent by having surgery]</i>
23	<i>Probe: Was there anything that happened that you didn't expect? [Prompt on during surgery and after surgery]</i>
24	<i>Probe: Are you glad you had the surgery?</i>
25	<i>Probe: Do you think having the operation has changed your relationships with people who are important to you?</i>
26	- To you, what are the most important results of surgery?
27	<i>If they say weight loss, Probe: What does weight loss mean for you?</i>
28	<i>Probe: Are these things different to what you would have said before having surgery?</i>
29	<i>Probe: What results of surgery might be most important to other people undergoing the surgery?</i>
30	<i>If yes, Probe: How are they different?</i>
31	- Are there any things that you didn't know beforehand that you wished you had?
32	- What do you think will happen in the future?
33	Expectations of follow-up care
34	- If you can think back to a few weeks before you had the surgery, can you remember if you had any expectations or
35	ideas about the care you would receive after surgery? <i>[Prompt on short-term inpatient care and long-term care]</i>
36	Actual experiences of follow-up care
37	- Since you've had your surgery, have you been back to the hospital? <i>[Prompt on the surgical and weight</i>
38	<i>management teams,]</i>
39	<i>Probe: What about your GP practice, have you seen anyone there since your surgery?</i>
40	<i>Probe: Do you think there is a role for more follow-up care from primary care?</i>
41	- What do you think will happen next?
42	- How do you feel about the NHS care you have received since your surgery?
43	<i>Probe: Tell me about the things you found most helpful</i>
44	<i>Probe: Tell me about the things you found least helpful</i>
45	<i>Probe: Is there anything you would have preferred to have been done differently?/Is there anything you think the</i>
46	<i>NHS could have done to better support you since you've had your surgery?</i>
47	- Could you say what you thought the most important things of good care after weight loss surgery were?
48	<i>Probe: Who would be the best person/people to do that?</i>
49	<i>Probe: What would be the best setting for this? [Prompt on hospital/ another setting]</i>
50	<i>Probe: Do you think these are the same things that others who've had surgery would say?</i>
51	- What about support groups – have you been involved with any of these?
52	<i>If yes Probe: Do you tend to go to meetings or do you use online forums?</i>
53	<i>Probe: How do you find these? [Prompt on positive and negative aspects]</i>
54	<i>If no Probe: What's stopped you from getting involved?[ie. prompt on if unaware of them, none convenient, don't</i>
55	<i>find helpful]</i>
56	<i>If used to be involved but now no longer involved Probe: What's led to this?</i>

1	Clarifications, etc.
2	❖ <i>Researcher asks participant to provide more information where points of interest were not previously probed.</i>
3	
4	Wind-down
5	❖ <i>Researcher checks topic guide for omissions and prompts informant back towards areas of discussion where they</i>
6	<i>seemed most comfortable.</i>
7	Case report form
8	❖ <i>Researcher records relevant socio-demographic and clinical details using the case report form.</i>
9	
10	Closing
11	❖ <i>Researcher asks if patient would be interested in being contacted about a possible follow-up interview – to be</i>
12	<i>recorded on consent form</i>
13	❖ <i>Researcher thanks interviewee for participating and asks if they would like a summary of the study results once</i>
14	<i>complete</i>

For peer review only

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Document S3: Case Report Form - Patient views about weight loss surgery

Participant identification number:		<i>If patient has consented to GP being informed about participation in study:</i>
Date of birth: __/__/____		
Initials:		
Today's date: __/__/____		
1.	What is the gender of the participant? 1=Male, 2=Female	<input type="checkbox"/>
2.	What is the patient's ethnicity? 1=White British, 2=White other, 3=Black, 4=Asian, 5=Mixed, 6=Chinese, 7=Other	<input type="checkbox"/>
3.	Who does the participant live with? 1=alone, 2=with family, 3=with other adults	<input type="checkbox"/>
4.	What is the participant's marital status? 1=single, 2=married, 3=separated, 4=divorced, 5=widowed	<input type="checkbox"/>
5.	What is the highest level of education completed? 1=less than compulsory school education, 2=compulsory school education, 3=post-compulsory school education below university level, eg. advanced technical school/advanced vocational, 4=university level	<input type="checkbox"/>
6.	What is the employment status of the participant? 1=employed full-time (could be on sick leave), 2=employed part-time, 3=homemaker, 4=student, 5=unemployed, 6=retired, 7=self-employed, 8=other (specify).....	<input type="checkbox"/>
7.	What is the current or last occupation of the participant?.....	
8a.	What is the patient's surgical status? 1=Awaiting surgery, 2=Undergone surgery (go to 8e.)	<input type="checkbox"/>
b.	If the participant is awaiting surgery, what operation are they hoping to undergo? 1=LAGB, 2=RYGB, 3=SG, 4=Other (specify).....	<input type="checkbox"/>
c.	If the participant is awaiting surgery, do they have a date? 1=Yes, 2=No	<input type="checkbox"/>
d.	If yes, what is the date?	__/__/____
e.	If the participant has undergone surgery, what operation have they undergone? 1=LAGB, 2=RYGB, 3=SG, 4=Other (specify).....	<input type="checkbox"/>
f.	If the participant has undergone surgery, what date did it occur?	__/__/____
9a.	What was/is the participant's weight prior to surgery (self-reported)?	<input type="text"/> Stones <input type="text"/> lbs <input type="text"/> Kg
b.	If the participant has undergone surgery, what is their weight now (self-reported)?	<input type="text"/> Stones <input type="text"/> lbs <input type="text"/> Kg
10.	What is the participant's height (self-reported)?	<input type="text"/> feet <input type="text"/> inches <input type="text"/> cm

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11.	Does the participant have any co-morbidities? List as many as needed. 1=diabetes, 2=hypertension, 3=hyperlipidaemia, 4=cardiac disease (excluding 2 and 3), 5=sleep apnoea, 6=asthma, 7=joint problems (eg. arthritis), 8=urinary incontinence, 9=infertility, 10=other, 11=None. If other, please specify.....	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
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For peer review only

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Document S4: Final coding structure used in NVivo

Name of code	Code related to
General NHS comments not related to surgery	Aspects of care
Guidelines from health professionals	Aspects of care
Follow-up care	Aspects of care
Factors leading to decision to have surgery	Life pre-surgery
Past struggles with weight	Life pre-surgery
Pre-op feelings about surgery	Life pre-surgery
Expectations of surgery	Life pre-surgery
Pre-surgery preparation	Life pre-surgery
Liver shrinking pre-op diet	Life pre-surgery
Other people's perceptions of obesity	Life pre-surgery
NHS funding of surgery	Life pre-surgery
Criteria to fulfill to obtain surgery	Life pre-surgery
Background	Life pre-surgery
Choice of operation	Life pre-surgery
Social impact of obesity	Life pre-surgery
Treatment from health professionals around obesity	Life pre-surgery
Other people's experiences of surgery	Life post-surgery
Future expectations and hopes	Life post-surgery
Peri-operative experience	Life post-surgery
Factors that help maintain motivation post-surgery	Life post-surgery
Support groups	Life post-surgery
Outcome - Activity, mobility	Life post-surgery
Outcome - Body image	Life post-surgery
Outcome - Comorbidity	Life post-surgery
Outcome - Eating	Life post-surgery
6 week post-op diet	Life post-surgery
Outcome - GI symptoms	Life post-surgery
Bowel movements	Life post-surgery
Wind or gas	Life post-surgery
Dumping or sickness	Life post-surgery
Outcome - Hunger	Life post-surgery
Outcome - Psychological	Life post-surgery
Outcome - Social impact of surgery	Life post-surgery
Family reactions to surgery	Life post-surgery
Outcome - Weight	Life post-surgery
In-hospital side-effects of surgery	Life post-surgery
Post-discharge side-effects of surgery	Life post-surgery
Most important outcomes of surgery	Life post-surgery
Outcome - Normality	Life post-surgery
Outcome - Clothing	Life post-surgery
Outcome - increased work options	Life post-surgery

COREQ checklist

No	Item	Guide questions/description	Location in text
Domain 1: Research team and reflexivity			
Personal characteristics			
1.	Interviewer/facilitator	Which author/s conducted the interview or focus group?	Page 7, lines 8-9
2.	Credentials	What were the researcher's credentials? E.g. PhD, MD	Page 7, line 9
3.	Occupation	What was their occupation at the time of the study?	Page 7, line 9
4.	Gender	Was the researcher male or female?	Page 7, line 9
5.	Experience and training	What experience or training did the researcher have?	Page 7, lines 10-11
Relationship with participants			
6.	Relationship established	Was a relationship established prior to study commencement?	Page 7, lines 11-13
7.	Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. <i>personal goals, reasons for doing the research</i>	Page 7, lines 13-15
8.	Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. <i>Bias, assumptions, reasons and interests in the research topic</i>	Page 7, lines 8-15; page 8 lines 12-13
Domain 2: Study design			
Theoretical framework			
9.	Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. <i>grounded theory, discourse analysis, ethnography, phenomenology, content analysis</i>	Page 7, lines 18-19

Participant selection			
10.	Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Page 6, lines 14-16
11.	Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Page 6, lines 12-14
12.	Sample size	How many participants were in the study?	Page 8, line 20
13.	Non-participation	How many people refused to participate or dropped out? Reasons?	Page 8, line 20
Setting			
14.	Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Page 7, line 1-3
15.	Presence of non-participants	Was anyone else present besides the participants and researchers?	Page 8, line 21-22
16.	Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Page 8 lines 20-24; Table 1
Data collection			
17.	Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Page 7, lines 4-7; Page 8, lines 15-17; Document S2
18.	Repeat interviews	Were repeat interviews carried out? If yes, how many?	Page 7, lines 11-12
19.	Audio/visual recording	Did the research use audio or visual recording to collect the data?	Page 7, lines 8-9
20.	Field notes	Were field notes made during and/or after the interview or focus group?	Page 7, lines 15-16
21.	Duration	What was the duration of the interviews or focus group?	Page 7, line 3

22.	Data saturation	Was data saturation discussed?	Page 6, lines 17-18
23.	Transcripts returned	Were transcripts returned to participants for comment and/or correction?	Page 7 line 17.
Domain 3: Analysis and findings			
Data analysis			
24.	Number of data coders	How many data coders coded the data?	Page 7, lines 21-23
25.	Description of the coding tree	Did authors provide a description of the coding tree?	Page 7, line 23; Document S4
26.	Derivation of themes	Were themes identified in advance or derived from the data?	Page 7, lines 18-21
27.	Software	What software, if applicable, was used to manage the data?	Page 7, line 7; page 8, line1
28.	Participant checking	Did participants provide feedback on the finding?	Page 8, lines 15-18
Reporting			
29.	Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? <i>eg. participant number</i>	Pages 9-14
30.	Data and findings consistent	Was there consistency between the data presented and the findings?	Pages 9-14
31.	Clarity of major themes	Were major themes clearly presented in the findings?	Pages 9-14; Figures 1 and 2
32.	Clarity of minor themes	Is there description of diverse cases or discussion of minor themes?	Pages 9-14; Figures 1 and 2