Patient-reported outcome measures in follow-up care after bariatric surgery

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Preface

When I first started on this PhD journey, I was excited to be part of a project that aimed to change the structure of the follow-up of patients undergoing bariatric surgery. It was intriguing to be part of an innovation project that would immediately affect the patient care and four years seemed like plenty of time to produce the results we anticipated. However, the start of the journey was a bumpy one and, due to organisational negotiations between the Health Trust and manufacturer of the feedback system, the project start was significantly delayed. This resulted in a different production of articles and thesis than originally planned, as the collection of data was, consequently, delayed. In our third paper, we used data collected before the implementation of the clinical feedback system. Nevertheless, the data is relevant for this thesis, as we studied the patients' overall treatment satisfaction and associations with variables that could possibly affect patient satisfaction. The overarching themes in this thesis are follow-up care after bariatric surgery, Health-Related Quality of Life (HRQOL), overall treatment satisfaction and mental health. There has been, and continues to be, a need to find effective tools and strategies to address challenges with HRQOL and mental health in follow-up. Hopefully, the work in this thesis can contribute to this.

Abstract

Background: Bariatric Surgery (BS) is acknowledged as an effective long-term treatment for patients with obesity. Even though most patients experience significant improvements in comorbidities and health-related quality of life (HRQOL), some patients do not experience improvement and some even experience a deterioration of HRQOL or mental health after surgery. This knowledge has been implemented in several guidelines for follow-up care after BS that emphasise the importance of focusing on HRQOL and mental health. However, there is a lack of concrete recommendations for how healthcare professionals can include HRQOL and mental health assessments in their daily practice.

Aim: The aim of this research was to implement a patient-reported outcome monitoring with a clinical feedback system (PRO/CFS) in BS follow-up care. The specific aims were to assess the effectiveness of PRO/CFS on HRQOL through a review of systematic reviews (Study 1), to provide a detailed description of the PRO/CFS implemented in the bariatric surgery outpatient clinic and plans for evaluating the feasibility of this PRO/CFS (Study 2), to assess the patients' overall treatment satisfaction five years after surgery (Study 3) and to assess whether a digital questionnaire developed for use in mental health services (the Norse Feedback (NF)) was valid for a population of patients undergoing BS (Study 4).

Results: A PRO/CFS was implemented in the BS outpatient clinic at Helse Førde Hospital Trust on 1 February 2018. In study 1, five systematic reviews exploring the effectiveness of the PRO/CFS on HRQOL in patients in mental health treatment and in cancer care were included. The synthesis demonstrated inconsistent findings, however effectiveness of a PRO/CFS was found in patients undergoing mental health treatment and for symptom burden in patients with cancer. A key finding was the variability in how the concept of the PRO/CFS was understood in the individual trials included in the systematic reviews. In study 2, a detailed description was provided of the PRO/CFS implemented in two BS outpatient clinics. Furthermore, this paper provided a study protocol for planned quantitative and qualitative inquiries of

patients' and healthcare professionals' experiences with the PRO/CFS in the clinical consultations. In study 3, higher body-mass index, reduced mental component of HRQOL and reduced obesity-specific HRQOL were associated with reporting to be dissatisfied or unsure about the overall treatment outcomes. In study 4, 12 out of 19 scales in the NF demonstrated satisfactory psychometric properties, but with large floor effects in several of the scales. In addition, 19 out of 21 scales in the NF showed moderate to small correlation with the Obesity-related Problems scale. The overall finding was that the NF is a promising tool in a PRO/CFS, but that the questionnaire needs to be adapted to the population of patients undergoing BS.

Conclusion: Through the studies included in this thesis, the importance of including aspects such as HRQOL, mental health and treatment satisfaction in the clinical consultations after BS is emphasised. A digital PRO/CFS seems to be a feasible tool for including such assessments in follow-up care.

Abbreviations used in the thesis

BDI – Beck Depression Inventory

BMI – Body Mass Index

BPD/DS – Biliopancreatic Diversion with Duodenal Switch

BS – Bariatric Surgery

CFA – Confirmatory Factor Analysis

CI – Confidence Interval

GS-PEQ – Generic Short Patient Experiences Questionnaire

GSRS – Gastrointestinal Symptoms Rating Scale

HADS – Hospital Anxiety and Depression Scale

HRQOL – Health-Related Quality of Life

LSG – Laparoscopic Sleeve Gastrectomy

MCS – Mental Component Score

N – Frequencies

NF – Norse Feedback

OP- Obesity-related Problems Scale

OR – Odds Ratio

PCA – Principal Component Analysis

PCS – Physical Component Score

PREMS – Patient-Reported Outcome Measures

PROs – Patient-Reported Outcomes

PRO/CFS – Patient-Reported Outcome Monitoring with a Clinical Feedback System

PROMS – Patient-Reported Outcome Measures

PROS – Patient-Reported Outcomes in Obesity

ROM/CFS – Routine Outcome Monitoring with a Clinical Feedback System

RYGB – Roux-en-Y Gastric Bypass

SD – Standard Deviation

SF-36 – Short Form 36

WEL-SF – Weight Efficacy Lifestyle Questionnaire Short Form

List of publications

Paper 1

Hegland, P.A., Aasprang, A., Hjelle Øygard, S., Nordberg, S., Kolotkin, R.L., Moltu, C., Tell G.S., Andersen, J.R. (2018). A review of systematic reviews on the effects of patient-reported outcome monitoring with clinical feedback systems on health-related quality of life —implications for a novel technology in obesity treatment. *Clinical Obesity, 8*(6), 452-464. doi:10.1111/cob.12277

Paper 2

Hegland, P. A., Aasprang, A., Kolotkin, R. L., Moltu, C., Tell, G. S., & Andersen, J. R. (2020). A novel patient-reported outcome monitoring with clinical feedback system in bariatric surgery care: study protocol, design and plan for evaluation. *BMJ Open, 10*(6), e037685. doi:10.1136/bmjopen-2020-037685

Paper 3

Hegland, P.A., Aasprang, A., Kolotkin, R.L., Tell, G.S., & Andersen, J.R. (2020). Overall Treatment Satisfaction 5 Years After Bariatric Surgery. *Obesity Surgery, 30*(1), 206-213. doi:10.1007/s11695-019-04141-7

Paper 4

Hegland, P.A., McAleavey, A., Aasprang, A., Moltu, C., Kolotkin, R.L., Andersen, J.R. (Submitted for review). The Norse Feedback in a population of patients undergoing bariatric surgery – psychometric properties of a digital computer-adaptive questionnaire assessing mental health.

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1. Introduction

1.1. Theme for exploration

The prevalence of obesity across the world is increasing (1, 2), including in Norway (3). In 2016, the prevalence of obesity among Norwegian adults was 23.1% and had tripled over the previous 30 years (4). Obesity may lead to such comorbidities as diabetes mellitus, hypertension, cardiovascular disease and pain (5). Health-Related Quality of Life (HRQOL) and mental health are also negatively affected in many persons with obesity (6, 7). We therefore need to establish strategies to improve these concerns in patients with obesity.

The goal of treatment for obesity is to reduce the risk of developing comorbidities and for the patient to live an active life (8). Bariatric surgery (BS) is the most effective treatment for obesity available today (9). Although effective, there is growing awareness that some patients experience challenges with HRQOL and mental health after surgery (10–12) and that the follow-up of these aspects in BS care must be enhanced (13). The structure of follow-up care after BS varies around the world and there are no uniform recommendations on how to include assessments of HRQOL and mental health in this care. The aim of this thesis was therefore to investigate whether patient-reported outcome monitoring with a clinical feedback system (PRO/CFS) would be feasible in BS follow-up care, with a special focus on HRQOL and mental health.

1.2. Obesity

The World Health Organisation defines obesity as "*abnormal or excessive fat accumulation that may impair health*" (2). The relationship between a higher body mass index (BMI) and comorbidities or mortality is well documented (14) and patients with a BMI of between 40–45 kg/m^2 experience an average of two to four years reduced life expectancy (15). Obesity has various personal and societal consequences, as it is linked to such comorbid diseases as cardiovascular disease, diabetes mellitus, hypertension, some types of cancer and pain (5, 16, 17), and a

stronger association with reduced disease-free years is found with more severe obesity (18).

BMI (weight in kilos divided by height in meters squared: kg/m^2), which is the most widely used measure to classify obesity, (19) is used as the classification in this thesis. Obesity is defined as having a BMI ≥30 kg/m^2 (20). Obesity is further subdivided into three classifications: Class 1 BMI 30–35 kg/m^2, Class 2 BMI 35–40 kg/m^2 and Class 3 BMI > 40 kg/m^2 (20). Severe obesity refers to BMI > 40 kg/m^2 or BMI 35–39.9 kg/m^2 with obesity-related comorbidities and is associated with the most severe health consequences (15).

However, BMI may be an unreliable measure because, for some people and population groups, the obesity classifications do not correlate with the amount of harmful body fat. This applies to people who, due to a high muscle mass, have a high body weight or for some Asian populations (19, 21). Due to these uncertainties, other measures like waist circumference or waist-hip ratio are useful additional measures to indicate the amount of harmful abdominal fat (22, 23). More advanced procedures like body scanning are also available (24).

Furthermore, patients with obesity have been shown to have a higher prevalence of mental health concerns compared to a population with normal BMI (7, 25, 26) and depression and eating disorders in particular are associated with obesity (25, 27). The relationship between mental health illnesses and obesity is not fully understood (28–30), but the association between obesity and depression seems to be bidirectional (29, 31, 32). A Norwegian cohort study found an association between waist-hip ratio and depression (33). Obesity has also been linked to reduced physical and mental aspects of HRQOL (6).

Due to the possible negative consequences of obesity, as well as the multifaceted causes, obesity is now widely recognised as a chronic disease (34, 35). The simple explanation for the aetiology of obesity is that the individual consumes more energy than is expended. However, the energy balance is now recognised as a complex interaction of genes, hormones and metabolic and psychological factors that affect the

energy balance in the individual (5, 36–40). The content of food and how the food is processed are also factors that contribute to the development of obesity (41, 42). Furthermore, an important finding is that the body increases the production of appetite hormones when a person is losing weight (43, 44).

1.3. Treatment of obesity

Due to the complex aetiology of obesity (45, 46), various treatments are available and there is no one treatment that is optimal for all patients (47). The treatment of obesity is mainly divided into two modalities: conservative lifestyle modification or BS. Common to both treatment modalities are a lifelong focus on weight management through increased activity and a healthy diet. In addition, pharmaceutical treatment is an option for weight loss, either in combination with lifestyle modification or BS or as a standalone treatment. Common to all treatment strategies is the need for a patient-centred focus that incorporates the patient's goals and preferences (48).

1.3.1 Conservative lifestyle modification

Conservative lifestyle modification is often the first choice of treatment, as this is less invasive compared to BS. Conservative lifestyle modification often consists of intensive lifestyle interventions over weeks or months. The therapies may comprise special diets, often with a very restricted calorie content, intensive physical activity treatment, behaviour modification or often a combination of all three (49). The advantages of lifestyle modification treatments are that they are accessible to many patients, an option for patients who do not satisfy the inclusion criteria for surgery, they are often inexpensive and have been found to be safe (49).

On the positive side, a weight loss of 5–15% of the patient's initial weight has positive effects on diabetes, blood pressure and lipids (50, 51), thereby improving metabolic syndrome (52). Despite broad access to the treatment, the positive effects and low risks of intensive lifestyle modification, the long-term effects of this intervention are disappointing, as patients struggle to maintain the weight loss after the intervention has been terminated (53, 54). A systematic review found that there was a minor non-significant difference in weight after 48 months when comparing

lifestyle intervention to no intervention (49) and these findings have also been documented by others (55–57). However, a recent publication by the Look AHEAD study group documented that intensive lifestyle intervention reduced the risk of non-fatal cardiovascular events after ten years in patients with a known cardiovascular disease at baseline (58). A challenge with conservative lifestyle interventions may be poor adherence to the programmes, resulting in weight regain (5, 59). Consequently, effective lifestyle treatments and follow-up strategies that lead to sustained changes in the patients' lives must be established.

1.3.2 Pharmacological interventions

Various medications have been developed to induce weight loss in people with obesity. What they have in common is a lack of robust evidence for the effectiveness of these medications in the long term (60). There is, however, some evidence that the medications induce weight loss and contribute to improvements in obesity-related quality of life. Furthermore, the medications are associated with more negative side effects than lifestyle-interventions alone, but these side effects are not severe for most patients (60–62). Recent studies have investigated the utility of pharmacotherapy after BS to prevent weight regain (63). Further research should explore the utility of medications as a supplement to conservative lifestyle interventions or BS to maintain long-term weight loss.

1.3.3 Bariatric surgery

A treatment for obesity that is growing in popularity is BS. Internationally accepted criteria for patients undergoing BS as a treatment are a BMI ≥ 40.0 or 35.0–39.9 kg/m2 with obesity-related diseases. There are several different procedures available that can be divided into restrictive procedures and malabsorptive procedures (9, 64). Restrictive procedures refer to procedures in which only the size of the stomach is reduced, whereas malabsorptive procedures refer to operations in which part of the small intestine is bypassed in addition to limiting the size of the stomach. This bypass of the small intestine contributes to a reduced uptake of nutrients (9). BS is found to be a safe treatment (65) and is the only treatment option today that contributes to

sustainable weight loss for the majority of patients (9, 66, 67). There are, however, also serious possible complications to the surgery, such as anastomotic leakage and bleeding, even though these are relatively rare (9, 65). Nutritional deficiencies are a more common negative side effect after surgery and often require long-term follow-up (68).

Surpassing the restrictive and malabsorptive effects of the surgery, recent evidence has documented that an alteration to appetite-regulating hormones is an additional effect of the surgery. The hormones that increase appetite are shown to decrease, whereas hormones that reduce appetite are shown to increase (69). The hypothesis is that the effect is due to the removal of the part of the stomach where the appetite hormones are produced.

The organisation of follow-up after BS varies considerably around the world. Most common is follow-up at a bariatric centre for the first two years after surgery. The patients may meet with different healthcare professionals during the consultations, often depending on the resources of the bariatric clinic. The bariatric team most typically consists of surgeons, physicians, nurses, dietitians and physical therapists, although psychologists may also be included in the teams. This multidisciplinary approach is in line with recommendations in European guidelines to provide the best care for patients after BS (70). BS is offered in all health regions in Norway and a national register (SOReg-Norge) has been established to evaluate the outcomes of surgical treatment in Norway (71).

BS consists of a variety of procedures. The most common procedures worldwide are the Roux-en-Y Gastric Bypass (RYGB) and Laparoscopic Sleeve Gastrectomy (LSG) (72), which is in line with the popularity of the procedures performed in Norway in 2018 (73). A less popular but effective procedure is the Biliopancreatic Diversion with Duodenal Switch (BPD/DS) (74).

The work carried out for this thesis involved the LSG and BPD/DS, which are explained below.

Laparoscopic Sleeve Gastrectomy (LSG)

The LSG is a procedure in which the size of the stomach is reduced. The LSG was originally introduced as the first step of a two-stage procedure of biliopancreatic diversion in the early 1990s. However, the developer, Marceau, found that patients lost weight and had few complications after the first procedure (75). The procedure was further modified by Ganger in the late 1990s (76) and is now accepted as a standalone procedure. When performing an LSG, the stomach is divided vertically from the oesophagus to the duodenum. This creates a small sleeve and only 10–20% of the stomach is kept (77, 78). Weight loss results from the restrictive procedure and it has also been hypothesised that the removal of the fundus contributes to changes in satiety hormones (77).

The LSG is found to be a safe procedure, with positive weight and metabolic outcomes and remission of comorbidities and complications compared to other procedures, including RYGB and BPD/DS (79–82). A recently published study found that patients operated with LSG experienced greater weight loss and were more satisfied than patients operated with gastric banding (83)

Biliopancreatic Diversion with Duodenal Switch (BPD/DS)

BPD/DS is a procedure in which the size of the stomach is reduced to contain 150–250 ml, somewhat larger than the LSG. In addition, the first part of the duodenum is bypassed (duodenal switch) to reduce the uptake of nutrients (84). BPD/DS have demonstrated superiority when it comes to weight loss and remission of comorbidities, but the occurrence of such severe complications as nutritional deficiencies, abdominal pain, diarrhoea and dumping syndrome is higher with BPD/DS than with RYGB and LSG. BPD/DS is also a more technically complicated procedure (74). Due to these aspects, BPD/DS is not widely performed worldwide. At Helse Førde Hospital Trust, BPD/DS was the procedure performed when BS was established as a treatment at the hospital, whereas the procedure of choice is currently LSG.

1.4 Patient-Reported Outcome Measures (PROMS)

Patient-Reported Outcome Measures (PROMS) refers to health issues reported by the patient, typically by means of a questionnaire (85, 86). PROMS can be defined as *'an outcome reported directly by patients themselves and not interpreted by an observer*' (87). To elaborate on this definition, this means that the data collected from the patients is their subjective perceptions of a construct and not something that can be measured objectively (as, for example, blood pressure, weight or blood sugar). PROMS are often used to measure how patients experience symptoms related to a disease, their perceived mental health or HRQOL. Furthermore, PROMS may be both generic and disease-specific. The generic questionnaires measure a construct across patient populations, whereas disease-specific instruments measures constructs that are particularly relevant for a specific disease (85). These aspects make PROMS suitable for implementation in routine care after BS to facilitate a structured assessment of HRQOL and mental health. In addition to PROMS, the patients frequently respond to patient-reported experience measures (PREMS), which measure patients' experiences with, for example, a clinical consultation or organisation of healthcare services. Patient-reported outcomes (PROs) and patient-reported outcomes measures (PROMS) are used synonymously so, for reasons of consistency, PROMS is used throughout this thesis.

Various questionnaires have been developed that measure HRQOL and are applied in research after BS. The most common questionnaires are the Short Form 36 (SF-36) and RAND 36-Item Short Form Health Survey (RAND-36), which are generic measures, and the Impact of Weight on Quality of Life-Lite Questionnaire (IWQOL-Lite) and Obesity-related Problems scale (OP), which are disease-specific measures (6, 88). There exists a broad range of other validated measures that are commonly used in both research and clinical consultations, but a full overview of these would be outside the scope of this thesis.

PROMS were initially developed for research purposes in order to obtain information from patients that could not be objectively assessed, whereas PROMS are currently

regarded as valuable tools to enhance patient involvement in clinical practice (85, 89). A desire to make the services more patient-centred and, subsequently, evidence on the effectiveness of discussing PROMS with patients may have influenced the increase in the use of PROMS in clinical practice. However, although acknowledged as a valuable tool to enhance patient-provider communication and to empower patients, the systematic use of PROMS in clinical practice is not well implemented (89, 90). This means that, even though patients frequently respond to PROMS in their contact with healthcare services, PROMS are most typically collected for quality improvement or registry purposes and are not frequently integrated into clinical conversations between the patient and healthcare professional. Another paradox is that PROMS that were not originally designed to enhance communication between the patient and healthcare professional in clinical consultations are used for exactly this purpose. This requires further investigation.

1.5 Patient-Reported Outcome Monitoring with a Clinical Feedback System (PRO/CFS)

Patient-Reported Outcome Monitoring refers to a systematic collection of Patient-Reported Outcome Measures (PROMS) and is widely applied in healthcare services (85). As described above, PROMS were originally developed for research purposes but, in the late 1980s and early 1990s, a systematic application of PROMS in clinical practice was recommended to improve the outcomes of patients in mental health treatment (91–95). Several PRO/CFS have been developed and found valid in mental health services (96). Even though it has been relatively long since the PRO/CFS was first introduced to routine clinical practice, PROMS are most typically implemented for research purposes or quality improvement initiatives in today's healthcare services (94).

Based on the aforementioned mental health challenges in some patients after BS, it can be assumed that the PRO/CFS in the follow-up after BS would contribute to improving the follow-up care for these patients. To inform the communication between patients and healthcare professionals, patients respond to a set of

questionnaires prior to the consultation. The information obtained from these questionnaires is fed back to the healthcare professional, patient or preferably both (97). Systems that collect PROMS and provide feedback are referred to as the PRO/CFS, Routine Outcome Monitoring with a Clinical Feedback System (ROM/CFS) or measurement feedback systems. For reasons of consistency in the thesis and the published articles, we use the term PRO/CFS, whereas all search terms were used when searching for relevant literature.

The concept of providing patients with feedback from PROMS has already been investigated, but whether it is effective in the treatment of mental health disorders has not yet been established. In a Cochrane review, Kendrick et al. (96) found insufficient evidence to conclude a positive effect in terms of symptom burden in patients who receive feedback compared to patients who do not receive feedback. On the other hand, a more recent systematic review and meta-analysis found significant effects in favour feedback compared to practice as usual (98). This positive finding has also been found by others (93, 97, 99). In a qualitative study exploring patient experiences with the PRO/CFS, the patients reported that a PRO/CFS could be a useful part of treatment under certain conditions. The patients needed to know the purpose of collecting this information and how the results could affect their treatment. They also highlighted the importance of the healthcare professional paying close attention to what they had reported (100). The importance of receiving information about the purpose of the PRO/CFS was also a key finding in a recent systematic review (101). Discussing with the patient what he or she has reported is therefore a crucial aspect of making the PRO/CFS a useful part of treatment. This aspect is supported by the feedback intervention theory that emphasises a discussion of the PROMS with the patient during the consultation. The conversation should include the patient's goals and preferences and, when interpreting the results, the patient's responses must be viewed in light of empirical standards (92). It can also be expected that the outcome of a treatment is better when the patient experiences that the PRO/CFS addresses issues that correspond with his or her goal with the treatment, making it important to involve patients and healthcare professionals when designing the PRO/CFS.

The PRO/CFS has traditionally been analogous, with patients completing paper questionnaires. However, a digital PRO/CFS appear to be advantageous due to the possibility to generate summary reports in which patient responses are compared to normative data (94). Furthermore, a digital PRO/CFS provides the possibility to personalise the PROMS to be relevant during the course of treatment (102). This is referred to as idiographic adaptation, which means that the patients' current responses are viewed in light of their previous responses (99, 102, 103). Through a system using idiographic adaptation, the adaptation to the patient can take place as follows: the patient answers a full set of items the first time he or she completes the questionnaire. If the patient responds below or above an empirically predefined trigger level, several items are 'closed' the next time the patient completes the questionnaire, thereby reducing the number of items to those most relevant for the individual. The patient then responds only to trigger items, as long as he or she do not show deterioration of symptoms. Personalisation is also relevant when the healthcare professional evaluates the summary report prior to the clinical consultation. In mental health treatment, two patients can demonstrate the same symptom burden in one area, but experience these areas very differently. For example, patients with a high symptom burden on depression with good social support may experience this as less problematic than patients with limited social support. Such patterns are important to explore in patients who have undergone BS in order to establish norms for this population of patients. For example, an increased risk of depression and suicidal ideation have been found in patients after BS compared to patients with obesity who have not been operated (10). However, the reasons for this association and whether any patterns of challenges are more harmful than others have not yet been established.

2. Summary of previous research

2.1. Follow-up care for patients undergoing bariatric surgery

The concept of follow-up care in this thesis is understood to be the manner in which the patient is supported by the healthcare services when undergoing BS. This includes any preparations organised by the healthcare services before surgery and any contact between the patient and healthcare services after BS. This contact may be both planned consultations and unplanned consultations due to unforeseen events. In the Nordic guidelines, lifelong follow-up is recommended after bariatric surgery to assess levels of vitamins and minerals and to monitor weight (104, 105).

The different comorbidities patients might present with, as well as the variability of unwanted outcomes after the surgery, make it important to tailor the follow-up to the individual patient (13, 106). After surgery, patients may need follow-up with regard to various aspects, such as nutritional challenges, altered body image (68, 107), reduced mental component of HRQOL (108) and psychological concerns like anxiety, depression and alcohol dependence (109, 110). A systematic review of qualitative studies found that patients experienced several challenges after BS and that they strived for normality and control of their situation. The review authors concluded a need for the long-term follow-up of psychological concerns after surgery to maintain positive changes and prevent negative mental health outcomes (111). These findings were confirmed in another qualitative review (112). The knowledge of the concerns that some patients experience after BS has been implemented into guidelines for BS follow-up (70, 113, 114).

In a rapid review of qualitative studies, the review authors found that patients experienced the time after BS as a rollercoaster of changes and emphasised the need for follow-up by competent healthcare professionals with specific knowledge of the patient's concerns (115). A qualitative study not included in the review found that patients who attended follow-up consultations appreciated the specialised care and possibility to contact the healthcare professionals by phone or email. The patients also had higher trust in the bariatric team than in their general practitioner. Barriers

for attending the follow-up consultations were a lack of personalised care and relevance for their specific concerns, a lack of continuity of the healthcare professional and distance from the clinic (116). Continuity of care and the availability of the healthcare professionals were also found to be important aspects of the follow-up in another qualitative study exploring experiences with follow-up care (117). However, in that study, several of the patients experienced a lack of support from the bariatric team with regard to the challenges they experienced after BS. The authors concluded that there was a need for long-term and personalised follow-up by a multidisciplinary team (117). One reason for these experiences of unmet needs could be differences in what the patients and the healthcare professionals defined as important outcomes (118).

Even though many high-quality follow-up programmes are offered, it is often challenging to get patients to attend the follow-up consultations. Bariatric care in general suffers from fairly high attrition rates in the postoperative follow-up (119–121). Some studies have found that poor adherence to the follow-up is linked to poorer weight loss, whereas others have not found this association (119, 122, 123). A retrospective study of 148 patients that investigated predictors for successful weight loss up until 40 months after RYGB found that follow-up visits with a surgeon and attending support groups after surgery were positively correlated with successful weight loss (124). Support from the bariatric team was also found to be a facilitator for adherence to consultations in a qualitative study exploring patient experiences with follow-up care (125). However, for the consultations to be relevant for the patients, the healthcare professionals must be prepared and updated on the patients' conditions and the topics addressed during the consultation must be relevant for the patients (126). As reasons for not attending the follow-up care, depression, pain, distance to the clinic, younger age, male gender and work issues have all been found to be important (119, 125, 127).

Adherence to follow-up after BS also entails far more than attending consultations. A systematic review by Hood et al. (128) identified recommendations regarding vitamin use, physical activity, alcohol use and dietary compliance as important areas to assess

adherence, in addition to the appointment attendance adherence. A study of patients one year after LSG showed that patients who had attended follow-up sessions with a dietitian experienced greater weight loss, were more physically active and had less pain than patients who did not meet with a dietitian (129).

As described above, follow-up care after BS must be tailored to the patient, as whether or not patients experience negative side effects and what these might be varies significantly. Undergoing BS is a life-changing event and most patients need guidance both before and after surgery. The best way to organise this preparation and follow-up has yet to been documented and further research needs to explore feasible structures and interventions for this follow-up.

2.2 Health-Related Quality of Life (HRQOL) after bariatric surgery

Studies have shown that persons with obesity are at increased risk of reduced HRQOL compared to persons with BMI in the normal range. This applies especially to the physical domain of HRQOL, whereas reduced mental HRQOL is present mainly in persons with BMI > 40 kg/m² (6). Particularly noteworthy is that Kolotkin and Andersen (6) a review of systematic reviews showed that HRQOL was lower in persons who were interested in BS than in patients seeking other treatments for obesity and in persons with obesity who did not seek any treatment at all. HRQOL is an important measure in patients with obesity, as reduced HRQOL has been associated with negative clinical outcomes (130).

One systematic review (88) and one review of systematic reviews (6) assessed how HRQOL changed from before surgery until after surgery and both included studies with a follow-up period of up to five years. Kolotkin and Andersen (6) had no limitations on the bariatric procedure in the reviews they included and found that BS patients had improved HRQOL measured with SF-36 when compared to patients undergoing other weight loss measures. Obesity specific measures on HRQOL improved more than generic measures at five years. Rausa et al. (88) only included studies that compared LRYGB and LSG in their review and found that HRQOL was

improved significantly from before surgery and remained improved at five years. However, the authors noted that there was a decrease in HRQOL from year two and onwards in several studies. Szmulewicz et al. (11) found in their systematic review of randomised controlled trials that the mental component of HRQOL was not improved in the long term. This trend is also found in other studies (12, 83, 108).

A prospective study conducted in Norway measured HRQOL from before and up to two years after surgery in patients with and without obesity-related diseases (131). The findings were that both groups of patients experienced improvements in HRQOL in terms of both the physical and mental components. The group of patients without any diseases experienced greater improvement in the mental component of HRQOL than patients with obesity-related diseases. Another Norwegian study found that HRQOL was associated with weight loss four years after surgery (132), contrary to what Aasprang et al. found in their analyses after both five (133) and ten years (134) in patients who had undergone BPD/DS. A study of younger adults aged 18–25 also found that HRQOL was associated with weight loss at three years (135). A prospective Dutch study of nearly five thousand patients who reported HRQOL before and twelve months after surgery showed a significant improvement in the physical component score of the RAND-36, although with a minor change in the mental health score. The authors also found that suboptimal weight loss influenced HRQOL scores negatively (136). It should be noted, however, that the study had a relatively short follow-up period. Another interesting study, although limited by the small number of patients, evaluated the effect of moderate to intense physical activity on HRQOL and weight loss. The authors found that physical activity significantly improved HRQOL in patients three years after surgery (137).

Even though most studies find an improvement in the physical component score and obesity-specific HRQOL compared to patient baseline measures, it is noteworthy that most studies also find that HRQOL is still below the scores in the general population – especially in the mental HRQOL dimensions.

There is a distinction between the 'mental component' of HRQOL and 'mental health'. The mental component of HRQOL refers to how the patients' mental well-being affects their quality of life, whereas mental health refers to the consequences of mental health illness and is more oriented towards a diagnosis (138).

2.3 Mental health after bariatric surgery

In a population of patients accepted for BS, a higher prevalence of depression and anxiety was found than in a norm population (139). A recent systematic review and meta-analysis of 104 included studies found that perceived weight stigma was a strong factor for decreased mental health and quality of life (140). With this in mind, it is quite alarming that people with obesity face stigma both in society and from healthcare professionals (141–144).

Furthermore, whether BS contributes to this higher presence of mental health concerns or whether the concerns are masked psychopathology from before surgery also seems somewhat uncertain. A prospective cohort study of nearly 25 000 patients who had undergone BS in Australia showed that there was an increase in the use of mental health services after BS compared to the use of these services before surgery. Self-harm in particular increased (145). Several studies show that patients are at a higher risk of depression, eating disorders, substance abuse and suicidal ideation after BS (10, 146–150), whereas others have documented a decreased prevalence and severity of depression after BS at least the first three years (7). The authors of a recent systematic review found initial improvement in anxiety, depression and disordered eating patterns, but also found that these changes did not sustain (151). Particularly alarming are the findings that suicidal ideation and problematic substance may increase after surgery (152–154), which requires urgent attention.

A recent review found that the prevalence of most eating pathologies decreased after BS, with the exception of 'grazing', which means that the patient eats unplanned food frequently during the day (155). Similarly, Spirou et al. (151) found that most patients experienced improvement in terms of binge-eating diagnoses, but stated that, due to the physical restrictions after BS, binge eating patterns changed to other disordered

eating patterns like grazing or vomiting. Eating psychopathology clearly affects patient lives and has been associated with suboptimal weight loss and weight regain after BS (139, 156).

The British Obesity Metabolic Surgery Society recently published guidelines in which all bariatric services are advised to offer preoperative mental health screening and triage of patients eligible for BS (13). Postoperative screening between six to nine months is also recommended. The authors emphasised that all members of a bariatric team should have expertise in the psychological challenges after surgery and that bariatric services should have access to specially trained personnel (i.e. psychologists) for patients with severe concerns (13). Other guidelines also recommend focusing on mental health in BS care (70, 114). The rationale for this screening of mental health concerns serves several purposes. One is to detect psychopathology that must be treated prior to the surgery, such as substance abuse or severe eating disorders (110).

Several qualitative studies have aimed at exploring how patients experience the changes that occur after BS. A review of qualitative studies found that many patients experienced challenges in coping with the rapid changes in their appearance after surgery (112). Self-image and how this affected their identity was an important theme. Another theme was how challenging patients felt it was to gain control over how the treatment affected their lives. Several patients struggled with feelings of guilt or blame for having ended up obese while, on the other hand, experienced a sense of responsibility to succeed with this treatment. These feelings were especially prominent in patients in whom BS had failed (112). A qualitative study with nine focus groups involving 76 patients previously operated with BS found that many patients experienced an improvement in mental health concerns like depression and anxiety, whereas others experienced a worsening of mental health and a new onset addiction to alcohol and drugs (125). Natvik and colleagues (107) presents one patient's story from an in-depth interview and discuss his experiences in light of previous research. Interestingly, although the patient had lost a large amount of weight and experienced a lot of new possibilities as a result, he was still stuck in old

habits in which his large body restricted him in everyday life due to space. Changing these perceptions of his body image and space perception demanded his active attention.

Back in 2012, Weineland, Hayes and Dahl (157) had already highlighted the need for interventions targeting psychological health in patients undergoing BS. Even though different interventions addressing psychological concerns after BS have been developed, there is still a lack of long-term data on their effectiveness (148). A systematic review including 44 studies that investigated the effectiveness of psychosocial interventions before and after surgery found that interventions after BS did indeed improve symptoms of depression and anxiety and also improved quality of life (mental, social and physical quality of life), as well as satisfaction with treatment. Preoperative interventions that were not continued after surgery showed, not surprisingly, no long-term effect (158). Mental health is complex and to expect to identify simple causal relationships between obesity and mental health or bariatric surgery and mental health is unreasonable. Instead, these constructs must be viewed as bidirectional, by which they affect each other differently in different situations.

All in all, the importance of screening patients for mental health challenges before and after surgery is quite evident. Interventions to address these challenges must be investigated in order for the healthcare professionals to have effective tools when dealing with patient concerns after BS.

2.4 Patient-Reported Outcomes and PRO/CFS in the follow-up to bariatric surgery

A systematic review assessing the use of PROMS after BS identified several validated questionnaires assessing satisfaction and HRQOL (159). The authors did not describe whether the PROMS were used for research purposes or as part of clinical practice in the included studies, but they concluded a need for validated questionnaires to assess patients in clinical practice. Generally, when PROMS are applied in the follow-up after BS, they are implemented for research purposes,

thereby providing the healthcare professionals with knowledge as to how to treat their patients. Examples can be found in two Norwegian studies, the one a randomised controlled trial (160) and the other cohort study (161) in which PROMS assessing HRQOL, mental health and eating habits were collected in order to evaluate the effectiveness of different treatment modalities. The findings from the PROMS were not discussed with the patient.

In a prospective cohort study, the researchers assessed physical HRQOL in patients before and after BS through a digital PROMS instrument (162). All patients completed the digital questionnaire before each clinical consultation. Again, the collection of PROMS was performed for research purposes and not for clinical use. The authors report future plans to implement feedback from the PROMS into the clinical consultations, as well as a qualitative assessment of patient experiences. Such studies are welcome.

Some studies, however, used feedback from PROMS in clinical practice with specific outcomes. One randomised controlled trial compared internet-based guided self-help with face-to-face cognitive behavioural therapy in patients with obesity and binge eating disorders. The authors concluded that face-to-face therapy was superior to internet-based guided self-help groups in reducing binge eating symptoms (163). Furthermore, in a prospective study, 37 patients who reported the amount and content of the food they had eaten received feedback through a web-based application on whether they had consumed the recommended amount of proteins. The authors reported that satisfaction with this application was high. However, the patients with an adequate intake of proteins were more likely to use the application (164) and knowledge as to whether this helps the patients who need guidance is still uncertain.

As the PRO/CFS is a new concept in the follow-up after BS, findings from other patient populations may inform its utility in BS care. In a systematic review exploring patient experiences with PRO/CFS in mental health treatment, the review authors found that the patients experienced that the PRO/CFS facilitated collaborative practice between the patient and healthcare professional and also empowered the

patients, provided that they felt safe about the purpose of the PRO/CFS. To accomplish this, the patients highlighted the importance of discussing the results during therapy sessions and wanted the questionnaires to not only measure their symptoms, but also their resources and positive aspects of life (101). In a qualitative study, also from mental health treatment, patients reported that, when answering questionnaires, they began reflecting on their treatment progress and found it easier to address the topics that were important for them to discuss (165). The same research group tested the effectiveness of a PRO/CFS in a randomised controlled trial and found no overall effect of the PRO/CFS on treatment outcomes. However, subgroup analyses of patients who were not on track in treatment showed lower attrition rates from therapy in the intervention group (166).

PRO/CFS has also been implemented into some somatic services, most recently in the follow-up care of patients with diabetes mellitus (167) and in patients undergoing ostomy care (168). In a pilot study in the diabetes outpatient clinic, the researchers explored the utility of a PRO/CFS in clinical consultations and found that such a system was both technically and practically feasible in patient care (169).

As PRO/CFS has proven to be feasible in several areas of mental health services and also appears to be feasible in diabetes outpatient care, PRO/CFS may be a tool for facilitating patient-centred care in BS follow-up.

3.0 Aims of the thesis

The overall aim of this project was to gain knowledge that could be used to improve the follow-up care of patients undergoing BS. Specifically, this knowledge is aimed at aiding the implementation of a novel PRO/CFS in follow-up at the BS outpatient clinic at Helse Førde Hospital Trust. The aims of the different parts of the project were as follows:

Study 1: To summarise evidence from systematic reviews exploring the effectiveness of PRO/CFS on HRQOL and to discuss the utility of a PRO/CFS in the follow-up after BS.

Study 2: To provide a detailed description of the development of and plans for implementation and to assess the feasibility of the PRO/CFS at Førde Hospital Trust.

Study 3: To explore the overall satisfaction with treatment outcomes and the association with HRQOL and BMI five years after BS.

Study 4: To explore the validity and reliability of the Norse Feedback in a population of patients accepted for or who have already undergone BS.

4.0 Methods

4.1 The innovation and its implementation

A digital PRO/CFS was developed and implemented in the BS outpatient clinic at Helse Førde Hospital Trust from 1 February 2018 as a standard part of treatment for all patients. The planning of the PRO/CFS started in June 2016, when relevant questionnaires were identified by the doctoral student and two of the supervisors (JRA and AAa). A panel was then established to further determine the questionnaires and to pilot test the PRO/CFS. The panel consisted of two patients who had undergone BS, one nurse working in the BS outpatient clinic and three researchers (one professor, one PhD candidate (later associate professor) and the doctoral student). The involvement of the two patients and outpatient nurse was considered crucial to ensure the ecological validity of the PRO/CFS. The feedback from the patients contributed to important changes to the questionnaires. For example, the patients emphasised that a focus on support from family and friends and negative side effects of the surgery were not covered well enough by the initial questionnaires.

The manufacturer Checkware was chosen as the software provider, as they already had an agreement with Helse West and delivered the software for the Norse Feedback in the mental health department at Helse Førde. An individual working with implementation of a PRO/CFS in the mental health department was also assigned the task of working in this project. Furthermore, to secure the safety of patient information, the patients needed two-factor identification authentication to access the PRO/CFS and only a limited number of healthcare professionals and researchers had access to the database.

When the final version of the PRO/CFS was ready, the training of the outpatient nurse started in December 2017. This training consisted of two of the researchers serving as proxy patients in several ‘consultations’ in order to train the nurse in incorporating the results from the summary report into the clinical consultation and

how to provide feedback. Furthermore, the nurse received guidance on how to interpret the Norse Feedback questionnaire, as this measure entailed a broader assessment of mental health than the questionnaires with which the outpatient nurse was already familiar. After the PRO/CFS was implemented into routine practice, the doctoral student attended the first consultations with patients to support the outpatient nurse. The person employed to work with the implementation of the PRO/CFS in Helse Førde was available for technical support after the project launch.

The patients were able to access the PRO/CFS either on their own computer or tablet or on a tablet available in the outpatient clinic area. After accessing the PRO/CFS via the patient's personal two-factor identification device, the questionnaires automatically appear in an order predefined by the project group. After the questionnaires are completed, the nurse generates a summary report. The healthcare professional has access to both the summary report and the scoring in the individual questionnaires if there are responses that warrant further investigation. Prior to the consultation, the healthcare professional prepares by assessing the summary report. At the start of the consultation, the healthcare professional views the summary report together with the patient and starts by discussing the areas in which the patient has reported experiencing the greatest challenges. See Figure 1 for the consultation process.

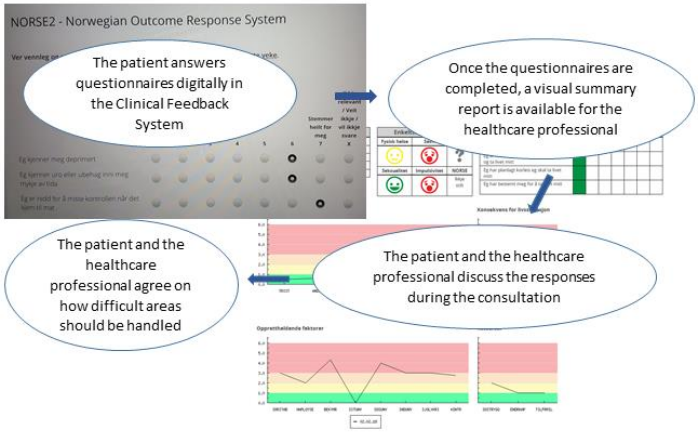

Figure 1 Process of the clinical consultation with a PRO/CFS as an integrated component (reprinted from paper II with permission from BMJ Open)

During the implementation process, there were various challenges that had to be overcome. The implementation of the intervention was significantly delayed due to negotiations between the Regional Health Trust and the manufacturer on the joint agreement for using PRO/CFS in clinical practice throughout the Regional Health Trust. The negotiations resulted in a satellite solution in which the data is stored in a secure database at the manufacturer. This solution is acceptable to most health trusts in Norway. Another challenge at the start of the project was to communicate to patients that they needed to complete the PRO/CFS prior to the consultation. This was solved by adding a description in the letter inviting them to the consultation on the purpose of self-reporting and how to access the system from home. As a significant number of patients did not initially respond to the PRO/CFS prior to the consultation, a text message was sent by phone the day before the consultation to those patients who had not responded. Patients who had not responded to the PRO/CFS when meeting for the consultation were given the opportunity to complete the PRO/CFS on a tablet in a private area in the outpatient clinic. Some patients had

also forgotten their device to log in securely to the system when meeting for the consultation. To prevent these patients from being unable to complete the PRO/CFS, a personalised solution for the generation of secure log-in information was provided by the manufacturer of the PRO/CFS.

With regard to those patients who needed an interpreter, the outpatient clinic did not have a solution to offer interpretation services to these patients while completing the PRO/CFS. This is a limitation of the project.

4.1.1 Questionnaires incorporated into the PRO/CFS

As a result of the work carried out by the joint panel, the final PRO/CFS consists of six questionnaires that assess health-related quality of life, mental health, eating self-efficacy and bowel symptoms.

Health-Related Quality of Life (HRQOL)

The Short-Form 36 (SF-36) version 1.0 is a generic measurement of HRQOL and consists of 36 items that explore such areas as general health, physical health and mental health (170). The results of the questionnaire can be interpreted as eight sub scores (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health) and two summary scores (Mental Component Score (MCS) and Physical Component Score (PCS)). The scores range from 0 to 100, with higher scores indicating better functioning. In this project, we applied t-scores, with a score of 50 as the average for the general population. The questionnaire is used and found valid in research on BS in Norway (134) and is frequently used to assess HRQOL across diseases (171). In the summary report, the cut-off values were set to green over 45, yellow 42.1–45 and red below 42 based on the findings of significant impairment from previous research.

The Obesity-related Problems scale (OP) is an obesity-specific HRQOL questionnaire that measures the psychosocial consequences of obesity (172). The questionnaire consists of eight items measuring social activities like arranging or attending parties, trying on or buying clothes and intimate situations. The items have

four-point response categories ranging from *Definitely not bothered* to *Definitely bothered.* The total scores range from 0 to 100 and lower scores indicate better psychosocial functioning. In clinical use, the individual items provide useful information on which areas of social life the patient experiences as challenging. The questionnaire is widely used in research on obesity and has been validated for use after BS in Norway (173). The cut-off values in the summary report were set based on recommendations from Karlsson et al. (172), by which a score under 19 was green, 20–59.9 yellow and 60–100 red.

The Patient-Reported Outcomes in Obesity (PROS) form is an obesity-specific HRQOL questionnaire that measures the physical, mental and psychosocial consequences of obesity (174). The questionnaire consists of eight items measuring how obesity affects physical activities, cause pain, whether the patient experiences discrimination and whether obesity affects sleep or sexuality. The items have four-point response categories ranging from *Considerably bothered* to *Not bothered*. A total score for the eight items is calculated but, in clinical practice, the individual items contribute the most information on the patient's concerns. The questionnaire was developed in Norway and found valid in a population with obesity (174). As a result of input from the two patients in the panel, one item on negative side effects, one item on excess skin, one item om social support and one item on overall treatment satisfaction were added to the questionnaire. Each item is presented in the summary report and the cut-off was set as follows: *Not bothered* green, *Mildly bothered* yellow, *Moderately bothered* and *Considerably bothered* red. To assess overall treatment satisfaction, the patients are asked the question *How satisfied are you, all things considered, with the treatment outcome after bariatric surgery?* The item has the response choices *Very satisfied*, *Satisfied*, *Unsure* and *Dissatisfied*. This item have previously been used in research on BS in Norway (134).

Mental health

The Norse Feedback (NF) version 2.0 is a questionnaire developed for clinical use in mental health treatment (175). The questionnaire consists of 23 scales in the four

domains of symptom expression, dysfunctional processes, functional consequences and resources. The questionnaire was designed for a digital PRO/CFS and the initial version of the NF was developed in collaboration between patients, therapists and researchers. The questionnaire is under iterative development using the plan-do-study-act methodology, involving both qualitative and quantitative assessments of the questionnaire (176, 177). The plan-do-study-act methodology in refining the NF includes qualitative methodology organised as interviews and workshops with patients and therapists in mental health services and quantitative analyses through Item-Response Theory and classical testing for psychometric properties. The version used in this project consists of 93 items loading to 21 different scales and four single items not loading on any scale (physical health, sleep, sexuality and impulsivity). The scales *Alliance* and *Needs in treatment* were not included in the PRO/CFS, as the items loading to these scales were not considered relevant for the follow-up of patients undergoing BS.

The items have seven-point response categories ranging from *This is true for me* to *This is not at all true for me* and include the possibility for the patient to answer *Not relevant/Do not know/Refuse to answer*. The summary report displays the raw scores from the patient's responses, with cut-off values for the colours red, yellow or green used in the mental health services.

Eating self-efficacy

The Weight Efficacy Lifestyle Questionnaire Short Form (WEL-SF) is an eight-item questionnaire that measures the patient's perceived ability to resist overeating (178). The patients respond to a 10-point scale ranging from *Not confident* to *Very confident.* The scores range from 0 to 80, with higher scores indicating better self-efficacy. The cut-off values were set based on clinical judgement, with scores 70–80 green, 60–69.9 yellow and below 60 red. The questionnaire is validated for patients who have undergone BS in Norway (178).

Bowel symptoms

The Gastrointestinal Symptom Rating Scale (GSRS) is a questionnaire that measures gastrointestinal symptoms like abdominal pain, reflux and diarrhoea (179). The questionnaire consists of 15 items in five domains (Abdominal Pain, Reflux, Indigestion, Diarrhoea and Constipation), with total scores ranging from 15 to 105, with higher scores indicating more gastrointestinal symptoms. The seven-point response categories vary from *Not bothered at all* to *Severely bothered.* Each domain is presented in the summary report and the cut-off values were set based on clinical judgement with the following thresholds (total score in the dimension/number of items): 1–2 green, 3–5 yellow and >5 red. The questionnaire has been used in research after BS (180).

4.2 Study characteristics

Given that the different studies in this thesis have different aims, populations and methods, the study characteristics are presented separately for each study.

4.2.1 Study 1: Effect of PRO/CFS on HRQOL, a review of systematic reviews

The methodology in Study 1 was a review of systematic reviews. The methodological criteria for a review of systematic reviews are identical to those relevant for a systematic review. A specific research question, comprehensive search for literature and transparency in how the studies are selected from the initial screening of references until the final inclusion are considered key methodological elements. Further, a rigorous assessment of quality and a structured analysis of data from the reviews are required (181–183).

Sample: Inclusion criteria were systematic reviews that summarised controlled clinical trials on the effectiveness of PRO/CFS on HRQOL in any patient population. The reviews were included regardless of publication year. Furthermore, the reviews had to be assessed as having good or moderate quality in order to be eligible for inclusion (assessed with two different checklists). We also conducted separate systematic searches to identify individual trials from the field of obesity treatment.

Screening and identification of studies: Systematic searches for systematic reviews were conducted in the following databases: Cochrane Central Register of Controlled Trials, PROSPERO, Epistemonikos, Health Technology Assessment, DARE, CINAHL, Medline, Embase, PsycINFO, BMJ Clinical Evidence, PDQEvidence and PubPsych. The search strategies were designed to meet the specific requirements of each individual database using Boolean and Proximity operators and truncations (184). Filters for maximum sensitivity for systematic reviews were applied in all databases. Furthermore, searches for ongoing or unpublished studies and grey literature were conducted in cllinicaltrials.gov and Google Scholar. Reference lists of relevant studies were screened for studies eligible for inclusion. Two experts in the field were also contacted for any studies not identified through the systematic

searches. These are all measures recommended for a comprehensive literature search (185). In addition, two review authors independently screened the results of the systematic searches, read relevant studies in full text and decided on the final inclusion of the systematic reviews. Data from the included reviews were extracted by one review author and quality-checked by a third review author. These steps are crucial to ensure quality in the screening and analysis process (186).

Quality assessment and statistical analyses: The quality of the included reviews was assessed using the PRISMA checklist (187) and a checklist for systematic reviews from the Norwegian Knowledge Centre for the Health Services (188).

Since the statistical data in the systematic reviews were presented in a manner that did not enable meta-analyses, narrative analyses were conducted. In addition, we accessed the individual trials included in the systematic reviews and presented the findings in forest plot analyses. Heterogeneity in the primary trials were assessed through population characteristics, type of intervention and study design. Bias refers to the risk of systematic errors that can affect the results of a study. There are various tools to assess bias in primary trials, such as the Cochrane Collaboration Risk of Bias Tool (189). In reviews of systematic reviews, the quality assessment involves an evaluation as to whether the included reviews have conducted risk of bias assessments in the included trials (181, 182). A bias that is particularly relevant for all types of reviews is selection bias, which refers to the review authors not identifying and including eligible studies in the review.

4.2.2 Study 2: PRO/CFS in bariatric surgery care – study protocol and design

The purpose of this study was to provide a detailed description on the PRO/CFS implemented in the BS follow-up and plans for evaluation of the PRO/CFS. This paper included a study protocol in which we described the plans to assess the feasibility of the PRO/CFS in the follow-up of patients undergoing BS.

Sample: The following participants were considered eligible in the study protocol: Patients operated with BS at Helse Førde Hospital Trust or St. Olavs Hospital are eligible for inclusion in the planned quantitative and qualitative inquiries of their

experiences with a PRO/CFS integrated in the consultations. Healthcare professionals working in the outpatient clinics at the same hospitals are eligible for inclusion in the qualitative inquiries. The patients and healthcare professionals are eligible for inclusion if they have experience using the PRO/CFS as part of the clinical consultation.

Measures and analyses: The Generic Short Patient Experiences Questionnaire (GS-PEQ) will be administered to patients after the consultations for purposes of quantitative assessments of their experiences with the consultation. The GS-PEQ is a questionnaire developed to measure patient experiences with the specialist healthcare in Norway (190). The version used in this project was developed for use in somatic outpatient clinics and includes 12 items that ask patients about how they experience the information they receive about the treatment and their condition, how the healthcare professionals communicate, whether the patient has been able to influence the treatment and whether they experience that the treatment is adapted to their situation. The patients' responses will be rated on a five-point scale ranging from *Not at all* to *To a very large extent*. In this study, the responses *To a very large extent* and *To a large extent* are regarded as indications that the patients experience consultations in which a PRO/CFS is a part of the treatment as useful. To further assess the healthcare professionals' compliance with the intervention, a question asking whether the patient received feedback on their PROMS during the consultation will be added. Univariate and multivariable analyses of patient experiences and association with variables as biological sex, age, BMI, HRQOL, bowel symptoms and complications from the treatment will be conducted.

The qualitative assessments of patient and healthcare professional experiences are planned through four focus group interviews with patients and one focus group with healthcare professionals accrued from both outpatient clinics. Six to eight participants are to be accrued in each group. The recruitment of patients will be performed by the clinical staff at the outpatient clinics, whereas the healthcare professionals will be recruited through an informational meeting followed by an invitation by email. Two researchers will conduct the interviews, during which one will be the moderator while

the other will be responsible for audio recording and notetaking. The data material from the interviews will initially be extracted separately by the two researchers, followed by a workshop during which agreement on the analyses will be reached. Participants in this workshop will be the two researchers and a third experienced qualitative researcher who was not involved in the initial data extraction. The data will be analysed through systematic text condensation according to Malterud's adaptation of the procedure (191). This involves four steps, by which the first step is to read through the material to gain an overall impression and the second step is to start coding units of related meanings. The third step is to create a condensate of units from the different participants, while the final step is to synthesise these condensates into a more overall meaning of the material (191).

4.2.3 Study 3: Overall treatment satisfaction

Patients operated at Helse Førde Hospital Trust during 2001–2012 were prospectively included in the study. We accessed data from the local obesity registry on patients who had reached their five-year follow-up consultation after surgery during 2005–2017. Overall treatment satisfaction five years after surgery was assessed, as long-term outcomes after BS is important information considering the feasibility of BS as a treatment for obesity.

Data from all patients who consented to having their information registered in the local obesity registry for research purposes were included in the analyses. Clinical information such as the type of surgery, BMI, excess weight loss, presence of any comorbid conditions and medication use, as well as any complications from treatment were registered. Further, HRQOL measured with the SF-36 and OP were registered in the database.

Sample: Patients who had attended the five-year consultation after bariatric surgery (BPD/DS or LSG) were eligible for inclusion.

Measures: The primary outcome was overall treatment satisfaction measured by means of the item *How satisfied are you, all things considered, with the treatment outcome after bariatric surgery?* with the response choices of *very satisfied*, *satisfied*,

unsure and *dissatisfied*. Independent variables were BMI (weight measured at the outpatient clinic in light clothing without shoes to the nearest 0.1 kg, and height measured to the nearest 0.01 meter), generic and obesity-specific HRQOL measured with the SF-36 and OP. Covariates were age (years), biological sex (female/male), surgical procedure (LSG or BPD/DS) and reoperations (yes/no).

Analyses: Univariate and multivariable analyses (192) were performed using the software SPSS (193). Demographic information was presented as frequencies (N) and percentages (%) or means and standard deviations (SD). Results from the univariate and multivariable regression analyses were presented as odds ratios (OR) and 95% confidence interval (95% CI). A p-value < 0.05 indicated statistical significance. If clinical information was missing in the database, the information was accessed through the electronic documentation system in the hospital by the outpatient nurse. If this information was not accessible, the patient was excluded. The patients were included in the analyses if more than 50% of the items in the SF-36 and OP were completed according to previous practice (131, 170). The missing items were computed by calculating the average of the completed items on each dimension in the SF-36 and on the total of completed items in the OP.

4.2.4 Study 4: Validity of the Norse Feedback in patients undergoing BS

Study 4 is a validation paper of the Norse Feedback (NF) in BS follow-up care. The aim was to assess the psychometric properties of the NF in a population of patients undergoing BS and to test whether the NF correlated with the OP in the same population.

Sample: Patients who were accepted for or had already undergone BS and had attended a consultation with the outpatient nurse from February 2018 until January 2020 were eligible and included prospectively. To be accepted for BS, the patients had to fulfil the criteria of either BMI ≥ 40 or 35–39.9 with obesity-related diseases. In addition, the PRO/CFS had to be completed prior to the consultation with the nurse.

Analyses: To assess the validity and reliability of the NF, we conducted Principal Component Analyses (PCA). PCA loadings, explained variance, corrected item-total correlation and eigenvalue were reported. Floor and ceiling effects were estimated for all scales and the four single items. Cronbach's alpha was reported for each scale. The analyses were performed using the SPSS version 26 (193). To determine satisfactory psychometric properties, we applied the following reference values: Loadings ≥ 0.4 (194) and only one eigenvalue 1 or above per scale (194). For the explained variance, there is no uniform agreement on the cut-off. Some authors argue that the main component should account for at least 20% of the variance, whereas others argue in favour of at least 40% (195). We considered an explained variance of 40% or above as satisfactory. Cronbach's alpha ≥ 0.7 was considered acceptable (196). Floor and ceiling effects below 15% were considered optimal (194).

4.3 Ethical consideration

In studies 3 and 4, written informed consent was obtained from all participants and is planned for all patients to be accrued in Study 2.

Studies 2 and 4 were approved by the Norwegian Centre for Research Data, Department of Data Protection Services (ref. no. 282738) and have undergone Data Protection Impact Assessments, both at Førde Hospital Trust and St. Olav Hospital (registration no. 2016/3912). Study 3 was approved by the Regional Committee for Medical and Health Research Ethics (REK 2009-2174).

Study 1 did not require ethical approval, as this was a review of systematic reviews, although ethical considerations should be performed by the authors of the included reviews.

5.0 Summary of findings

As regards the descriptions of the characteristics of the four studies, the results will be presented separately for each study.

5.1 Study 1: Effect of PRO/CFS on HRQOL, a review of systematic reviews

Five systematic reviews, including studies investigating PRO/CFS in cancer treatment and mental health treatment, were included. No systematic reviews or primary trials from obesity treatment were identified. See Figure 2 for the screening process and study selection.

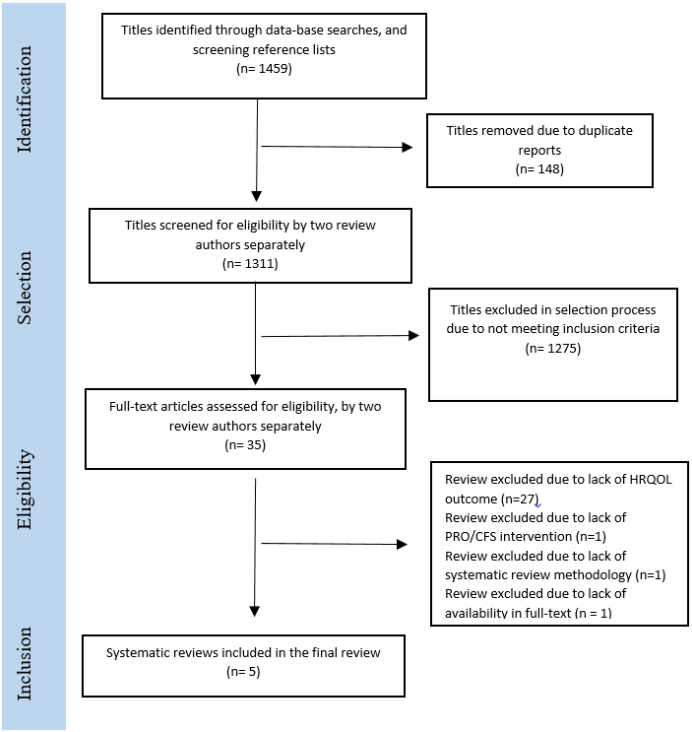

Figure 2 Screening and study selection (reprinted from Paper I with permission from Clinical Obesity)

The quality of the included reviews was assessed as good (n=2), moderate to good (n=1) and moderate (n=2).

The results from the narrative review showed that three out of the five reviews found an effect in favour of the intervention group (PRO/CFS), whereas the remaining two reviews found no differences between the two groups. Due to differences in how the statistics were reported in the included reviews, the primary trials from the reviews were accessed to conduct forest-plot and meta-analyses. The meta-analyses showed a trend in effectiveness in favour of the PRO/CFS group, although not statistically significant. Overall, the conclusion of the review of systematic reviews was that the effectiveness of PRO/CFS on HRQOL seemed promising. However, no clear conclusions could be drawn due to statistically insignificant findings and a high risk of bias in the included trials. A key finding was also that the concept of the PRO/CFS was understood and implemented very differently in the primary trials. Consequently, there was uncertainty as to whether the real phenomena of feedback were studied.

5.2 Study 2: PRO/CFS in bariatric surgery care – study protocol and design

In Study 2, a detailed description of the development of the PRO/CFS was provided. We described how a panel consisting of two patients who had undergone BS, one nurse working in the bariatric outpatient clinic and three researchers collaborated to choose the most appropriate questionnaires to be included in the PRO/CFS.

The experiences of patients and nurse were important when assessing whether the questionnaires were relevant for the themes important to the patients, whether the nurse found the questionnaires to be relevant for the clinical consultations, whether the patients thought any important matters were not covered through the questionnaires or whether any of the items were experienced as offending. This was important to ensure that the PRO/CFS was relevant for follow-up care after BS. The patients, outpatient nurse and two of the researchers pilot-tested the PRO/CFS to assess the time spent in completing the questionnaires and user-friendliness. Furthermore, the nurse was trained to interpret the summary report and implement the

findings into the clinical conversation. The first author attended the first consultations to assist the nurse. Technical support was also provided by a person dedicated to work with implementation of the PRO/CFSs in the Health Trust.

Furthermore, the implementation of the PRO/CFS is scheduled to be evaluated qualitatively through focus group interviews with both patients and healthcare professionals and quantitatively of patients by means of the questionnaire GS-PEQ (190). To assess fidelity, data on attrition to follow-up consultations, number of patients who completed the PRO/CFS, whether there is missing data within the questionnaires of the PRO/CFS and the proportion of referrals to other specialities as a consequence of the patient responses will be evaluated.

5.3 Study 3: Overall treatment satisfaction

Study 3 included 261 patients with a follow-up of five years after BS. Most of the included patients (66.3%) were men. The mean preoperative BMI in the sample was 47.1 kg/m^2 and the mean age was 48 years. The BMI decreased on average by 15.6 units in the sample. The included patients had been operated with BPD/DS or LSG. The analyses showed that 82.4% of patients reported being very satisfied or satisfied with their overall treatment outcome. The multivariable analyses showed that reports of being unsure or dissatisfied were associated with higher BMI, lower scores on MCS from the SF-36 and higher scores in the OP. The variables of age, biological sex and PCS from the SF-36 and whether the patients had been re-operated showed no significant associations with overall treatment satisfaction at five years. See Table 1for univariate and multivariable analyses.

Table 1 Univariate and multivariable analyses of treatment satisfaction (reprinted with permission from Obesity Surgery)

Variable	Univariate model			Multivariable model		
	OR	95 % CI	p-value	OR	95 % CI	p-value
Age (per 2 SD)	0.7	0.4 – 1.4	0.31	1.2	0.5 – 2.7	0.70
Men (reference women)	0.7	0.4 – 1.5	0.39	1.9	0.8 – 4.8	0.16
Body Mass Index (per 2 SD)	7.1	3.4 – 14.5	<0.001	6.1	2.7 – 14.0	< 0.001
Obesity Problem Scale (per 2 SD)	7.6	3.7 – 15.5	<0.001	3.0	1.1 – 7.8	0.03
Physical Component Score (per 2 SD)	0.3	0.1 – 0.5	<0.001	0.8	0.3 – 2.1	0.65
Mental Component Score (per 2 SD)	0.2	0.1 – 0.4	<0.001	0.3	0.1 – 0.8	0.02
LSG (DS reference)	2.6	1.3 – 5.4	0.01	3.3	1.3 – 8.8	0.01
Reoperation at baseline*	1.5	0.5 – 4.8	0.51	1.9	0.5 – 8.3	0.34
Reoperation after baseline**	1.5	0.6 – 4.1	0.38	1.3	0.3 – 4.6	0.72

The odds-ratio represent the odds for being dissatisfied/unsure
OR= Odds Ratio
CI= Confidence Interval
SD= Standard deviation
LSG= Laparoscopic Sleeve Gastrectomy
DS= The Duodenal Switch
Physical and Mental Component Score from the Short-Form 36
* Reference is not re-operated. 17 patients had a reoperation as the baseline operation due to inadequate weight loss from a previous surgery.
** Reference is not re-operated. Of those re-operated after baseline 68 % had a re-operation due to surgical complications, 32 % due to weight regain
A two-tailed p-value < 0.05 indicated statistical significance

5.4 Study 4: Validity of the Norse Feedback in patients undergoing BS

Out of a total of 259 patients, 213 were included in the study. The main reason for exclusion was that the patients had not completed the PRO/CFS prior to the consultations (n = 44), while two were excluded due to not consenting to participate in the study. We performed PCA on 19 scales of the NF (see Table 2 for information on the structure of the scales). The scale *Medication* consists of only two items and, consequently, the psychometric properties could not be assessed. Furthermore, only 20 patients responded to the scale *Substance Recovery*, so a PCA or reliability analyses were not performed on this scale.

The PCA analyses showed satisfactory loadings, explained variance, eigenvalues and Cronbach's alpha in the scales *Sad Affect, Somatic Anxiety, Substance Use,*

Suicidality, Social Safety, *Need for Control, Internal Avoidance, Self-Criticism, Situational Avoidance; Social Avoidance; Worry* and *Cognitive Problems*. The remaining scales showed unsatisfactory psychometric properties. The scales *General functioning* and *Readiness for recovery* demonstrated Cronbach's alpha of 0.51 and 0.40 and a low component value in one out of three items in each scale. The scale *Irritability* demonstrated Cronbach's alpha 0.40 and low loadings in two out of three items.

The floor and ceiling analyses showed floor effects ranging from 5.7% to 88.2% and ceiling effects ranging from 0% to 13.1%. Seven scales demonstrated a satisfactory floor effect, whereas the remaining scales and single items all showed floor effects above 15%. The high floor effect in some of the scales, such as *Sad Affect* and *Suicidality,* were somewhat surprising, as we would have expected greater variety in the responses. The ceiling effect was satisfactory for all scales and the four single items.

Table 2 Structure of domains, scales and number of items included in each scale in the Norse Feedback questionnaire (retrieved from Paper IV)

Domains and scales included in the Norse Feedback	Number of items
Symptom Expression	
Eating Problems	5
Sad Affect	3
Somatic Anxiety	5
Substance Use	4
Suicidality	4
Trauma Reactions	4
Resources	
Readiness for Recovery	3
Recovery Environment	5
Social Safety	6
Problem-maintaining Processes	
Need for Control	4
Hopelessness	5
Internal Avoidance	5
Irritability	3
Self-Criticism	8
Situational Avoidance	3
Social Avoidance	3
Worry	3
Personal Consequences	
Cognitive Problems	6
General Functioning	3
Substance Recovery	4
Treatment Process Scales	
Alliance*	4
Needs in treatment*	5
Medication	2
Individual Items	
I take care of my physical health.	
I am sleeping very badly at the moment.	
My sexuality and/or sex life is difficult for me.	
I am impulsive in a way that troubles me.	
*Scales not included in the clinical feedback system, as the items were not considered relevant for follow-up to bariatric surgery.	

The correlation analyses on the NF and OP showed moderate correlations on the scales *Eating Problems*, *Sad Affect*, *Somatic Anxiety*, *Need for Control*, *Hopelessness*, *Internal Avoidance*, *Self-Criticism*, *Situational Avoidance* and *Social Avoidance*. The scales *Suicidality*, *Trauma Reactions*, *Readiness for Recovery*, *Recovery Environment*, *Social Safety*, *Irritability*, *Worry*, *Cognitive Problems*, and *General*

Functioning showed small correlations, whereas the scales *Substance Use* and *Medication* showed trivial correlations. For the single items, one item showed moderate correlation (*sexuality*) and three items showed small correlations (*physical health*, *sleep* and *impulsivity)* with the OP.

6 Discussion

The implementation of the PRO/CFS in the outpatient clinic has been an important part of this project. This thesis therefore starts with a general discussion of the questionnaires incorporated into the PRO/CFS. This is followed by a discussion of the importance and content of follow-up care for patients undergoing bariatric surgery and the utility of a PRO/CFS in this follow-up care. Finally, the methodological strengths and limitations of the studies are discussed before the implications of this research and future perspectives are provided.

6.1 Questionnaires incorporated into the PRO/CFS

Decisions when choosing questionnaires to be included in the PRO/CFS

The PRO/CFS comprises six questionnaires that measure various aspects that often are negatively affected in patients with obesity and after BS and the questionnaires were decided on by a panel consisting of patients and outpatient nurse. This increases the ecological validity of this project by making the PRO/CFS more clinically relevant to patients and healthcare professionals. The questionnaires measuring HRQOL, eating self-efficacy and bowel symptoms are well known and validated for patients with obesity and patients who have undergone BS (170, 172, 174, 178, 179).

The total amount of questionnaires was based on several issues. The most important one, as already discussed, was to make the PRO/CFS relevant for the clinical consultation. However, there are three questionnaires measuring various aspects of HRQOL and further analyses of the PRO/CFS will seek to explore whether any of the questionnaires are superfluous. The SF-36 questionnaire was included in the PRO/CFS because the original plan of the project was to perform analyses with a historical control group. The PRO/CFS also comprises two obesity-specific HRQOL measures. The OP is a valid and well-used questionnaire in research on obesity and BS. The PROS is a questionnaire developed locally by two of the researchers involved in the project. The PROS builds on the OP but, in addition to the

psychosocial aspects the PROS, it also assesses the physical consequences of obesity. The PROS was found valid and reliable in a population of patients undergoing BS, although the sensitivity to change is unclear due to the cross-sectional design of the study and lack of prospective data (174). Both questionnaires were incorporated into the PRO/CFS, as it was necessary to further validate the PROS in patients undergoing BS. Future studies will seek to explore whether one of them contributes sufficient information in the clinical consultation.

For assessing mental health, a novel questionnaire developed for clinical use in mental health services was used. The NF (175, 176) was chosen even though it had not been validated for patients undergoing BS because it measures various dimensions of mental health that were considered relevant for this patient population. Examples of these dimensions are depression, anxiety, suicidality, eating disorders and problematic substance use. The domains measured by the NF are much broader than in the questionnaires most frequently used in research on obesity. Furthermore, the NF was developed to fit a digital PRO/CFS and is adaptive to the patient's responses, also referred to as idiographic adaptation (103). Thus far in the project, we have chosen to not use the idiographic adaptation opportunity of the NF. The reason for this is that data from full sets of items were requisite to test the validity and reliability of the NF in this patient population. Future plans are to further validate the NF and possibly create a version adapted to this patient population. The qualitative inquiries may also contribute valuable information on patient experiences with this questionnaire for further adaptations.

Possible consequences of the number of questionnaires

The total number of items in the PRO/CFS might represent a burden to patients when completing the PRO/CFS, especially those who have difficulty reading or writing or do not speak Norwegian fluently. However, these patients have the opportunity to complete the PRO/CFS at the outpatient clinic with assistance from the healthcare professional.

Another challenge with the total number of items is that the patient may grow tired of answering and not read the questions thoroughly when responding. This will possibly be discovered during the consultation, but will most likely reduce the validity of the findings in terms of research. When the panel of two patients, nurse and researchers selected the questionnaires for the PRO/CFS, the patients confirmed that it was a high number of items to respond to, but that they were relevant for them. Hopefully, this matter has been properly addressed as a result. If the number of items is too high is a topic that will be sought elucidated during the qualitative interviews.

As one of the members of the research team in this project was one of the developers of the NF, there are several potential limitations to the project. The team of developers had an interest in receiving full datasets from these patients. This resulted in the full questionnaire being incorporated, instead of only using the trigger items, thereby increasing the total workload on patients when completing the PRO/CFS. The trigger items may possibly provide enough information for the clinical consultation. On the other hand, it is necessary to test whether the trigger items are sensitive enough for the challenges that this population of patients may experience. Another possible limitation may be that the researchers may tend to overestimate the positive findings when validating the questionnaire. To prevent this bias, the researcher who is also a member of the development team was not involved in performing the validity or reliability analyses of the NF. However, the close link to the developers has definitely strengthened the project through a deeper knowledge of the development of the NF. The NF is not a traditional questionnaire, as items have been included in the questionnaire even though they demonstrated poor psychometric properties because the patients or therapists found the items useful for opening a conversation about certain themes. Knowledge about which items performed poorly has been valuable when testing the psychometric properties in the population of patients operated with BS.

When using data from the PRO/CFS for research purposes, an uncertainty about the findings is whether the respondent has replied carefully to the items. A qualitative study exploring patient experiences with the NF as part of their treatment in mental

health services showed that patients found the PRO/CFS useful in their treatment process and put an effort into answering the items thoroughly (197). However, some patients in this study also stated that they sometimes over- or underestimated their challenges. This is, however, a possible bias that is relevant for all PROMS used for research purposes and therefore any unexpected findings in results or any ‘outliers’ in the data material should receive special attention when analysing the findings. On the other hand, PROMS are considered reliable and a valid measure to assess self-report data from patients (85, 86, 198).

6.2 Follow-up care after bariatric surgery

Importance of addressing more than just physiologic aspects during follow-up

To date, the focus of BS follow-up has been primarily on the physical aspects of the surgery, such as weight loss, remission of comorbidities and the negative consequences of the surgical procedure. A positive development is that healthcare professionals in clinical practice have a higher focus on such consequences as mental health, HRQOL and treatment satisfaction in their meetings with patients (199, 200), in addition to weight and comorbidities. Apart from contributing to more holistic patient care, screening for mental health illness may save both money and time in clinical practice (201). This broad focus, however, is not implemented equally in guidelines for patient follow-up after surgery (70, 114, 202). In these guidelines, it is quite apparent that the physical effects of surgery are the main focus, as mental health and HRQOL are only briefly mentioned. Following the same line of thought, it is quite interesting that a recent Delphi method statement on priorities in BS research does not include optimal follow-up of patients after surgery or even mention mental health or HRQOL as important areas for investigation (203). The authors themselves state that the members of the consensus group only consisted of surgeons and that other healthcare professionals would probably have other priorities. It is hard to not agree with the authors on this.

There are, however, promising exceptions to the lack of focus on mental health. The British Obesity & Metabolic Surgery Society published guidelines in 2019 with specific recommendations for how to provide psychological support to patients before and after surgery (13). The guidelines were developed through a review of the literature and the involvement of patients, experts in the field and healthcare professionals with a broad range of specialities. The main messages in the guidelines are pre-operative information about mental health provided to patients, preoperative screening of mental health concerns and mental health screening at several time points after BS. These aspects fit in well with the purpose of the PRO/CFS implemented in the follow-up after surgery in this project, where mental health is

assessed through the NF during every consultation. Furthermore, the recently updated American guidelines for perioperative support of patients undergoing BS recommend a continuous follow-up on mental health concerns (114).

Even though the focus on mental health and HRQOL after surgery could clearly be more prominent in most of the published guidelines, the focus on these topics are increasing in research. A prospective cohort study found that pre-surgery screening for depression was associated with a smaller Hazard Ratio for postoperative depression compared to patients who did not undergo such screening (150). In a literature review, Sarwer and Heinberg (110) state that mental health screening is also important after surgery. Furthermore, they recommend that the summary of the screening be shared with the other participants of the bariatric team. A PRO/CFS is, in our opinion, a feasible way to generate and share this summary, as the summary report provides a visual view of the patient's mental health concerns. I would also add to the recommendations to not only share the findings with the bariatric team, but also with the patient during the consultation. Sarwer and Heinberg (110) also recommend that future research focus on specific mental health interventions in the follow-up after BS. This is an important aspect, as the screening of mental health itself is not a goal but provides additional tools for the healthcare professionals to address patient concerns.

Duration of follow-up

A lifelong follow-up of patients is recommended (70), although there is no consensus on the frequency or content of this follow-up. Continuous follow-up of the patients is important, as attrition to follow-up is linked to adverse patient outcomes in long term (114).

The follow-up care of patients after BS varies greatly worldwide, including in Norway. Due to the rapid and dramatic changes that many patients experience as a consequence of the treatment, there is a need for a good preparation of patients before BS. This preparation must focus on the physical, social and mental health changes the patients may face, as well as the effort that is needed on the part of the patient in the

longer term to prevent negative effects of the surgery and to maintain the positive changes over time. The authors of a review of qualitative studies concluded that the dramatic changes patients face required a thorough pre-treatment education (204). This preparation is important, as a study found that up to 5% of patients reported that they regretted undergoing RYGB five years after surgery (205). This is alarming considering the fact that BS procedures are often irreversible. Although this is not a large number of patients, this accounts for many patients worldwide each year if we assume that the number of patients regretting BS in general is around the same level.

The majority of patients would, in my opinion, benefit from a more thorough preparation on the possible negative consequences of BS than many patients receive today. These preparations could consist of online preparation material, clinical one-on-one consultations and support groups.

There are several challenges to the follow-up after BS. One of them is the manner in which the consultations are organised. To get patients to want to participate, they must experience that attending the consultations benefits them. In a qualitative study, patients stated that they needed to be confident that the consultations at the bariatric outpatient clinic would provide them with useful information for them to want to attend. Otherwise, the patients may just as well consult their general practitioner (116). Patient expectations regarding the content of the consultation may also affect their willingness to attend. Patients may think that the healthcare professional is most interested in weight and eating habits and not so much in their mental health, sexual concerns or family relations. If the healthcare professional is prepared in advance regarding the patient's concerns, the consultation will probably be experienced as more relevant. This is in line with Fastenau et al. (48), who developed a disease-illness model for the treatment of obesity in which they highlighted that the treatment should focus on what concerns the patient most. For some patients, this could be satisfaction with treatment or mental health, while other patients may be more interested in the weight loss aspect. The need to facilitate patient-centred consultations in the follow-up is therefore important (116).

6.3 PRO/CFS as a tool to structure follow-up after BS

Utility of a PRO/CFS in follow-up care

As we documented through Study 1, the understanding of the concept of PRO/CFS varies considerably across studies, possibly due to the lack of a universally accepted definition. In studies 1 and 2, we proposed some key features we believe should be present if the feedback phenomena were to be studied. The features entailed a collection of PROMS prior to each consultation, followed by a joint assessment of the responses with the patient and healthcare professional during the consultation, as well as a discussion on the implications of these findings for the patient. The responses should also be interpreted in light of normative data and the patient's goals with the treatment.

Whether or not a digital PRO/CFS is feasible in clinical consultations after BS needs further investigation. A retrospective cohort study that assessed changes in HRQOL after BS provided a description of how digital PROMS are routinely collected in a BS centre in the United States (162). Patients are surveyed before each consultation and have the opportunity to complete the measures at their own computer or on a tablet at the outpatient clinic. However, it does not appear as the information from the PROMS is discussed with the patient during the clinical consultation. As future perspectives, the authors state that they plan to implement the PROMS into the point-of-care setting. When this research group implements the PROMS into the clinical consultation, their approach seems comparable to what we have chosen in this project.

As to our knowledge, one previous study described a PRO/CFS in the treatment after BS. Greene and Hutter (206) described a project in which PROMS were to be collected before each consultation and the healthcare professional was encouraged to discuss the findings with the patient during the clinical consultation. As far as we know, no results from this research group assessing this PRO/CFS have been published and we welcome these results in the future. This research group may be a future collaboration partner when developing a PRO/CFS for BS care.

Another study described an intervention in a weight maintenance programme in which the participants reported their weight weekly (207). The study had two intervention arms, by which the patients were offered face-to-face contact in one arm and internet-based via chatrooms in the other. Both interventions resulted in a significant prevention of weight regain compared to the control group and a minor insignificant difference between the intervention arms favouring the face-to-face group. In a study including patients treated with intragastric balloon, the authors reported that patients who received an online follow-up with real-time access to healthcare professionals had equivalent weight loss to patients who attended standard follow-up consultations (208). In these two latter studies, however, the authors did not assess other outcomes than excess weight loss.

How a PRO/CFS might facilitate patient involvement

The value of a face-to-face consultation was described in a qualitative study with in-depth interviews of 46 patients who had undergone BS. The patients stated that continuity and a relationship with the healthcare professional was important in follow-up care. They also highlighted the importance of personalised care and ongoing monitoring of their treatment progress (116). These findings fit in well with the concept of PRO/CFS, in which the goal of the treatment is personalised follow-up through the monitoring and clinical discussion of patient responses. Again, the individualisation of the patient care is a core element in the disease-illness model developed by Fastenau et al. (48), as each patient demonstrates different areas of challenges. A digital PRO/CFS with an idiographic approach may therefore be a suitable tool to achieve this goal of patient-centred care.

In a qualitative study of patients undergoing treatment for obesity, one key finding was that patients were aware of whether or not the healthcare professional was actually interested in their situation and treated them as whole person (209). A PRO/CFS in follow-up care may facilitate such communication between the patient and healthcare professional because the focus of the consultation is on the greatest concerns of the patient at that time. On the other hand, a PRO/CFS may be an

obstacle to this professional relationship if the healthcare professional does not handle the technical equipment sufficiently or if he or she does not feel confident in how to interpret what the patient has reported in the various questionnaires. In a qualitative study assessing patient and therapist experiences with a PRO/CFS in mental health treatment, a key finding was that the PRO/CFS itself was not enough to improve communication and empower the patient. The manner in which the therapist integrated the findings into the clinical conversation was important. The therapists also stated that the feedback had to be provided differently according to the patient's preferences and situation (210). In another qualitative study in which the patients had experiences with the same PRO/CFS as in the latter study, the patients emphasised the importance of receiving feedback from the therapists. Those patients who had not received feedback described feeling disappointed that their effort to complete to the PRO/CFS was not valued by the therapist (211).

In our experience, a PRO/CFS will add value to the clinical consultations in BS follow-up care. The content of the PRO/CFS has the potential to be adapted to the preferences of users, in this case patients and healthcare professionals. Furthermore, the idiographic adaptation facilitates the surveying of patients with regard to aspects relevant for their situation. In addition, interest is growing in the use of PROMS in clinical consultations (212), making a digital PRO/CFS even more relevant.

As mentioned above, the planning of the PRO/CFS and involvement of service users are viewed as important to the implementation process of a PRO/CFS (213). The involvement of patients and healthcare professional in designing the PRO/CFS in this project is a considerable strength. This also applies to the planned evaluations of the PRO/CFS, in which the patients and healthcare professionals are included in a panel evaluating the questionnaires included in the PRO/CFS, as well as the content of items in the NF adapted to patients with obesity.

6.4 Methodological considerations

When acquiring knowledge in a field through research, the traditional approach is to choose either a quantitative or a qualitative approach, depending on the aim of the study. When the methodological approach is chosen, the researchers start to design the specific study. This approach has led to different researchers often defining themselves as either qualitative or quantitative researchers, by which quantitative researchers are in the positivist paradigm and qualitative researchers in the constructivist paradigm (214). These two paradigms have different ontological and epistemological assumptions in that the positivists view reality as something that can be measured and counted, whereas the constructivists see the world as subjective (215). Luckily, the research community has begun to recognise each other's knowledge as valuable, enabling researchers to study a phenomenon in different ways using different methods. This is often referred to as mixed methods, by which the phenomenon is explored through qualitative and quantitative methods. Using different approaches to acquire knowledge is also called 'multimethod', which refers to the methods used rather than the combining of ontological and epistemological assumptions (216). A multimethod approach means that the researchers can combine several quantitative methods, several qualitative methods or a combination of both qualitative and quantitative methods to explore the phenomenon. The phenomenon in this thesis is follow-up care for patients undergoing BS. Due to the complexity of this group of patients, this phenomenon can best be explored using different methodology. This has led to different methods being included in this thesis in order to gain broader access to this phenomenon.

As mentioned above, the methods, sample and statistical analyses are different in the four studies and, consequently, the methodological strengths and limitations of the individual studies are discussed separately.

6.4.1 Study 1: Effect of PRO/CFS on HRQOL, a review of systematic reviews

Study 1 is a review of systematic reviews that assess the effects of PRO/CFS on HRQOL. A review of systematic reviews is an appropriate approach in fields where

several systematic reviews have been published and the aim is to perform a meta-synthesis of the findings in the systematic reviews (181, 182). The advantage of this methodology is that it provides the reader with an overview, for example of the effects of an intervention in several patient populations. The aims of a review of systematic reviews are often broader than in ordinary systematic reviews (181). No systematic reviews from the field of treatment for obesity were identified and one may question whether this methodological approach was appropriate for this theme. The aim of this study was to summarise the effects of the PRO/CFS on HRQOL in any patient population, making this approach eligible. Furthermore, no primary trials assessing effects of PRO/CFS on HRQOL in patient under treatment for obesity were identified, so a systematic review would not have contributed with further evidence in this patient population.

A strength of this project was that The Cochrane Handbook for Systematic Reviews of Interventions version 5.1.0 (217) was used as the methodological guideline. This entails a rigorous literature search in relevant databases, screening of reference lists in relevant articles, searching for grey literature and contacting experts in the field. Another strength of this study is that two authors performed the critical steps in the review process independently, including the screening of titles and selection of articles for full-text reading. Both read the selected articles in full text before arriving at agreement on final inclusion. During the screening process, one author was inexperienced in the field in terms of investigations, whereas the other was very familiar with the field. This is considered a strength of the review process (184). Searches were performed in databases designated for systematic reviews and databases indexing journals in the field of medicine, nursing and psychiatry. The separate searches to identify systematic reviews and primary trials from obesity treatment strengthen the study.

Data extraction was performed by one author and quality checked by a third author. This may represent a limitation of the study, as, optimally, data is extracted by two authors independently, followed by an agreement on which data to analyse (218). Another limitation of this study is the lack of a universally accepted definition of

PRO/CFS methodology. As a result, studies that were eligible for inclusion were perhaps not identified, as the authors of the systematic reviews may have used different terms to describe the intervention. To prevent this bias, we used several synonyms for the PRO/CFS in our searches, including the most commonly used terms. However, this may represent a selection bias to this study.

Quality assessments were performed with two well-used checklists (187, 188) by two review authors separately and reviews assessed as having good and moderate quality were included. This is a strength of this study because a limitation of the review of systematic reviews methodology is that the result of the synthesis largely depends on how rigorously the authors have been in conducting the included systematic reviews (181, 182).

Analyses

Each systematic review was synthesised narratively due to differences in the way in which the findings were reported. A challenge to narrative summaries is to present the findings in a rigorous manner and to synthesise the findings in a way that gives the reader a good overview of the aggregate findings. When conducting meta-analyses, the weight of the individual study, depending on the number of included participants in each study, affects the combined effect estimates and thereby increases the precision of these estimates (219). To add to the narrative analyses, the individual studies from the systematic reviews were accessed and forest-plot and meta-analyses were conducted. This strengthens the study because the reader can use this information in addition to the narrative summary to evaluate the findings. Furthermore, conducting forest-plot and meta-analyses of individual studies ensured that each study was included only once in the analyses. If one study is included in the meta-analyses in several systematic reviews, this leads to overestimating the impact of that study in the review of systematic reviews (182).

On the other hand, a limitation of the presentation of meta-analyses in this study is that the interventions, methods and populations in the individual trials are quite heterogeneous and the summarised effect estimates in the meta-analyses may have

been affected by this clinical heterogeneity. This means that the effect of the interventions might be affected by factors not measured if the settings, populations and interventions vary considerably across the studies (219). Due to this heterogeneity in the primary trials, the meta-analyses were conducted using a random effect model suitable for use when the interventions are not identical (219). The forest-plot analyses in this study were presented as a visual summary for the reader rather than evidence of the effectiveness of the intervention.

6.4.2 Study 2: PRO/CFS in bariatric surgery care – study protocol and design

Study 2 presents the design of the PRO/CFS and is a study-protocol for evaluation of its feasibility. Consequently, the discussion will entail the planned studies. We are planning to conduct both quantitative and qualitative analyses in order to assess the feasibility of a PRO/CFS in BS care.

Quantitative approach

This is a prospective cohort study in which patients who have undergone BS are included at two outpatient clinics, situated in hospitals representing different levels of the Norwegian healthcare system (university hospital versus district general hospital). The strengths of this study are that the quantitative assessments of patient experiences will be performed at two outpatient clinics in two different health trusts. This increases the generalisability of the findings (220) and the included patients will likely be representative for the population, as the clinics are situated in different parts of the country. Furthermore, the intervention is implemented for all patients with an appointment at the outpatient clinics. This ensures that the healthcare professionals do not treat the patients participating in the study differently due to the intervention.

For the quantitative assessment, the Generic Short Patient Experiences Questionnaire (GS-PEQ) was chosen. The GS-PEQ was developed to measure how appointments in outpatient clinics are organised, how the healthcare professionals communicate and whether the patients are able to influence the treatment. The strength of this questionnaire is that it is developed and validated for evaluations of services at Norwegian outpatient clinics (194). The questionnaire is to be used to evaluate the

feasibility of a PRO/CFS in follow-up care after BS. There will, however, be some uncertainties as to the findings because patient experiences may be affected by other factors than the PRO/CFS, such as whether or not the patients have appointments with healthcare professionals with the competence to deal with their challenges. Furthermore, the alliance with the healthcare professional may also affect patient responses.

A limitation of this study is that the patients are not compared to patients in a control group. Non-experimental designs are weak in detecting causal relationships and, instead, are eligible for identifying correlations (220). Preferably, a randomised controlled trial should be carried out to test the effectiveness of the PRO/CFS. However, in this phase of the project, we aim to explore the feasibility of the PRO/CFS and further investigate the need for any adjustments to the PRO/CFS. Another limitation of this study may be a limited number of eligible participants, as more included patients would have provided more robust estimates of associations (221), but the power analyses show that a N=100 makes us able to detect a small effect size.

Qualitative approach

The qualitative assessments of patient and healthcare professional experiences are planned as focus group interviews at both outpatient clinics. For patient interviews, we are planning to have two focus groups at each outpatient clinic and, for healthcare professionals, we are planning one focus group with healthcare professionals from both outpatient clinics. Focus group methodology is suitable for gaining knowledge about the experiences with a PRO/CFS as an integrated part of the consultation, as the informants can expand on each other's experiences (222). We have considered this topic as being not particularly sensitive for participants attending the interview, making this methodology appropriate. However, in conducting the interview, the facilitator needs to be aware that all participants may contribute their experiences (222). This is especially challenging in groups in which some participants are very talkative, whereas others are less talkative. The topic may also be more demanding to

elaborate on if one of the healthcare professionals has different experiences than the rest of the group or if the healthcare professional struggles to implement the PROMS in the clinical conversation due to technical or professional issues (222). In these cases, individual interviews would possibly generate richer findings.

The strengths of the project are the involvement of patients and healthcare professionals in developing the interview guide and planned pilot interview, as these aspects may increase reflexivity (223). When analysing the data from the interviews, quotes from the participants will be included to ensure that the analyses are true to the informants' perspectives and enable readers to assess the researchers' interpretations of the findings. Other strengths of this project are that two researchers will conduct the analyses independently and discuss them with an experienced researcher in a workshop.

Additional strengths of the study are the planning of four focus group interviews of patients at two outpatient clinics. This will probably increase the external validity of the findings and increase the information power (224). Only one focus group interview is planned for healthcare professionals due to a limited number hired at the two outpatient clinics and no quantitative assessment of their experiences is planned. This is a limitation of the study.

A limitation of the project is that only one healthcare professional is using the PRO/CFS in one of the outpatient clinics and, consequently, there is only one eligible participant from that hospital. This will result in skewness in the representation of healthcare professionals in the two health trusts. Furthermore, the patients at one of the outpatient clinics meet with the same healthcare professional during all consultations, whereas they meet with different healthcare professionals at the other outpatient clinic. Consequently, patient experiences may be influenced by other aspects than the PRO/CFS itself. On the other hand, this might produce richer findings during the interviews. Another limitation is that the healthcare professional at one of the outpatient clinics has been a part of the implementation process and is physically situated closer to the researchers. This might affect how this healthcare

professional experiences the PRO/CFS or what information is shared by this person during the interviews.

6.4.3 Study 3: Overall treatment satisfaction

Patients operated with BS at Helse Førde Hospital Trust were prospectively included in the study and surveyed at their five-year follow-up consultation. Strengths of this strategy are that the patients are included before the course or effectiveness of the treatment is known and the information is collected in real time (220). All patients who were operated were invited to the study, increasing representativeness (220), however we lack information on 26% of the patients that attended the five-year consultation. A limitation of this study was a relatively limited number of participants. Higher numbers of included patients would have provided more robust findings (221). Furthermore, we did not contact the patients who did not attend the five-year consultation. Contacting these patients could have prevented a selection bias if the reason for these patients not attending the consultation was due to any particular reason. The study was conducted at only one centre, reducing the generalisability of the findings. Helse Førde Hospital Trust was one of the few centres operating patients with BS at the time and the patients came from all over Norway. This increases the geographical representativeness in the study, but the findings are affected by the organisation of the treatment and follow-up and the fact that the patients were operated by a limited number of surgeons.

Analyses

When assessing overall satisfaction with treatment outcomes, a single item was used. This might represent a limitation of the study. Single item ‘questionnaires’ may have lower validity, as multiple item questionnaires inhibit a possibility to clarify to the respondent the topic under investigation (225). On the other hand, using single items for assessing satisfaction is the most frequent measure in the studies that we identified. Another potential limitation of this item is that patient satisfaction may be affected by aspects not related to the BS itself. This may be events in the patient’s personal life or whether the patient and healthcare professional do not have a good

alliance. A limitation may thereby be that the patients were asked to rate their satisfaction without the possibility to elaborate on what they were dissatisfied or satisfied with. A systematic review assessing determinants of patient satisfaction found that the interprofessional relationship and organisational aspects were strong predictors of patient satisfaction (226). Patients may also avoid choosing the best or worst response (called end-aversion) and may tend to respond more positively than the actual reality (called positive skewness) (195, 227). In this study 82% of the patients reported to be very satisfied or satisfied, which is comparable to other studies, nevertheless represents a high level of satisfaction.

Another limitation of this study was the lack of baseline measures for HRQOL, as these measures were implemented during the period of data collection and were therefore not available as a co-variate in the analyses. As reduced HRQOL at five years showed to be associated with a reporting of dissatisfaction, baseline measures on HRQOL would clearly have provided useful information as to whether baseline HRQOL was associated with satisfaction five years after BS. Future studies should explore this association. Furthermore, another important co-variate in this study would have been whether the patients experienced reflux at baseline and five years after surgery, as a study showed that the severity of gastroesophageal reflux disease at one year after LSG affected patient satisfaction (228). A limitation was also the lack of PROMS assessing patient mental health. This variable would possibly have added value to the analyses in light of the association between reduced mental HRQOL and satisfaction.

6.4.4 Study 4: Validity of the Norse Feedback in patients undergoing BS

Patients with an appointment with a nurse at the bariatric surgery outpatient clinic were eligible for inclusion in the study. A strength of the study is the prospective inclusion of patients, as the data are collected in real time and recall bias is avoided. Furthermore, this enables measurements at several time points for each patient, thereby ensuring researchers whether the outcome appeared after the exposure (220). Another strength is that the intervention is standard for all patients in the outpatient

clinic, ensuring that the healthcare professional does not treat the included patients differently.

Limitations of the study include the fact that only patients from one outpatient clinic have been included, who attended consultations with one outpatient nurse. This reduces the generalisability of the results, as the findings may have been different at other outpatient clinics. The NF therefore needs to be tested out in several outpatient clinics in order to establish the validity and reliability of the questionnaire in a population undergoing BS. Furthermore, the number of included patients could clearly have been higher, as the number of included patients is the lower limit of what is recommended when performing PCA. A higher number of patients would have made the findings more robust.

Analyses

In this study, we did not implement a gold standard questionnaire measuring mental health in this patient population. Such questionnaires could have been the Hospital Anxiety and Depression Scale (HADS) or the Beck Depression Inventory (BDI), which measure anxiety and depression. Implementing one of these questionnaires would have provided the opportunity to test criterion validity in this population of patients. The face validity of the NF is therefore only evaluated at the item level by the panel of patients, nurse and researchers who were involved in creating the PRO/CFS.

The NF is a complex questionnaire that measures numerous aspects of mental health. Due to the manner in which the questionnaire is structured, some items were kept in the questionnaire despite poor psychometric properties because patients or therapists believed that the items added value to the consultation. As a result, the findings from the PCA analyses in the present study may be affected by choices made in the original development of the NF. The involvement of one of the developers of the original NF was valuable when assessing the psychometric properties in this population of patients.

Another limitation to testing the validity and reliability of the NF is that the questionnaires consist of scales that include two or three items. As the structure of the NF is already established in populations in mental health care, confirmatory factor analyses (CFA) could have been performed to test construct validity, as PCA is mainly suited for item reduction, whereas CFA is the preferred method for assessing correlations among variables (229). However, the scales with fewer than four items cannot be assessed with CFA. We therefore chose PCA as the analysis on all scales. The final structure of the NF in a population of patients undergoing bariatric surgery is not established. PCA analyses are thereby feasible for assessing the unidimensionality in the scales and a CFA can be performed once the final structure is established. CFA could, however, have been performed as sensitivity analyses to the PCA on scales with four or more items in this study. Furthermore, the lack of repeated measures on the patients made us unable to assess test-retest reliability (194).

If a higher number of patients had been included in the study, item-response theory analyses could have been performed. The psychometric properties in the original version of the NF are evaluated using this approach and evaluating the properties of the NF between the patient populations would have been possible. Furthermore, due to the number of patients in the various time points of follow-up and that only about 20% of patients included in the study were assessed at their pre-operative consultation, we were not able to test how the NF performs at different times during follow-up. The NF also needs to be explored in a population with obesity who have not been accepted for BS in order to evaluate whether the NF is a valid measure for patients with obesity in general.

6.4.5 Validity and reliability

Internal validity

The internal validity of a study refers to the extent to which the measured outcome is a result of the independent variable or whether there are any competing variables that affect the outcome, also called confounding factors (230). Study 3 had a quasi-

experimental design that is especially vulnerable to confounding factors. This means that the dependent variable of overall treatment satisfaction could have been affected by variables that were not controlled for in the study.

Patient-Reported Outcome Measures

The validity and reliability of the PROMS included in the various studies in this thesis are generally high. The quality of the self-report instruments may clearly affect the findings in a study and so questionnaires found valid for the purpose should preferably be used (231). In Study 3, the SF-36 and OP questionnaires were used, whereas the OP was used in Study 4. Both questionnaires have been found valid for research on patients who have undergone BS and are frequently used around the world. Furthermore, the item used to measure overall treatment satisfaction in Study 3 has not been validated for a population of patients undergoing BS, but has been used in research on this population of patients. However, the validity and reliability of this item need to be explored. For the questionnaires incorporated in the PRO/CFS, the SF-36, OP, GSRS and WEL-SF have all been validated and found reliable for patients undergoing BS. The PROS has also been validated in a population of patients undergoing BS, but is still not commonly used in this patient population. The validity and reliability of the NF are discussed elsewhere in this thesis (section 6.4.4).

6.5 Implications for practice and need for future exploration

BS is a safe treatment and contributes to sustaining positive changes in physical comorbidities and HRQOL (232). At the same time, there are still many patients who do not have optimal outcomes of the treatment. Due to possible negative lifelong consequences of the treatment, there is a need to identify strategies to follow up patients in a way that is experienced as meaningful by the patients and that are effective for healthcare professionals. The care after BS currently suffers from high attrition rates and limited resources in healthcare services.

In the four studies we carried out, we explored different aspects of BS and follow-up to this treatment. Study 1 showed that a digital PRO/CFS in the follow-up after BS is

a tool that may add value to clinical consultations. For patients, the PRO/CFS may strengthen their possibility to interact during their treatment. Patients are given the possibility to report their primary concerns and to learn about the broad range of topics that the healthcare professionals are interested in discussing during the consultation. For healthcare professionals, the PRO/CFS may be a tool to help them prepare for meeting the patient and to start by discussing those areas reported by the patient as challenging.

In Study 1, we also demonstrated that the concept of feedback was poorly reported and perhaps also poorly understood in many of the included studies. This resulted in Study 2, in which we described how we developed and implemented a digital PRO/CFS in the follow-up care after BS and how we plan to evaluate the feasibility of this PRO/CFS.

Study 3 showed that patient overall satisfaction with treatment outcomes was high in accordance with other studies. This underpins the belief that BS is a good treatment for many patients. This study is one of the few that assesses which variables may affect patient overall satisfaction, which is important when improving the healthcare services. The finding that BMI was an important factor was not surprising, as weight loss is the motivation for many patients undergoing BS. Furthermore, the finding that reduced mental HRQOL is associated with being dissatisfied or unsure is important and fits in well with the overall project in this thesis, in which both HRQOL and mental health are assessed routinely during clinical consultations.

In Study 4, we report that the NF is a valid instrument for assessing mental health in patients after BS, but that it needs some adjustments in order to be more suited to this patient population. Using the NF in a PRO/CFS may satisfy patient requests for a regular assessment of mental health and may also be a tool for the healthcare professionals to start a discussion with patients about mental health.

Future perspectives

There is no question that BS is a life-changing event that affects patients in positive and negative ways. These dramatic changes trigger a need for counselling and long-term follow-up in many patients. However, it is necessary to establish which type of follow-up care is optimal in terms of content and frequency and this is an important topic for future research. Making the consultations relevant for patients would benefit both the patients and healthcare services. In a letter to the editor, Chiappetta, Stier and Weiner (233) proposed that structured follow-up programmes be developed. However, they also stated that the surgeons themselves do not have the capacity to perform this follow-up. The authors suggest enhancing general knowledge of obesity treatment in general physicians. In our view, the surgeon plays an important role in follow-up, but the follow-up should best be organised as a team of healthcare professionals that includes nurses, nutritionists and psychologists and strengthens the primary healthcare services. As research has shown that patients may experience a variety of negative side effects after surgery, this multi-professional approach is important in our opinion and also supported by a recent systematic review (234). Chiappetta et al. (233) further suggest applying the same follow-up period as for cancer patients, with a five-year follow-up period after BS. Research has shown that the self-reported HRQOL is relatively stable between five and 10–12 years after BS (108, 134). This may indicate that follow-up may be concluded at five years for patients with little to no negative side effects after the BS. Furthermore, one qualitative study found that, over time, some patients did not experience a need for follow-up, as they had adapted to their new life (116). Contrary to this, another qualitative study of patients five years after BS found that some patients still felt a need for guidance on what they should eat (235). This shows how challenging eating may be for some patients after BS. Future research should therefore investigate the safety of a shorter follow-up period than lifelong follow-up and which patients who would not be harmed by a shorter follow-up than today.

With the increasing accessibility of PRO/CFS and telemedicine, further research should also investigate the feasibility and safety of remote follow-up as an alternative

to patients meeting at the outpatient clinic. A study investigating 30-day complications found that the complications were detected when the patients contacted the healthcare services and not during the scheduled consultations. The authors concluded that telemedicine was safe for follow-up in the first 30 days (236). A review article that assessed studies with remote interventions aimed at preventing weight regain, targeting maladaptive eating patterns and increasing physical activity found that remote interventions were feasible in the follow-up after BS (237). On the other hand, in other studies, patients emphasised the importance of in-person follow-up (238) and the importance of a good relationship with the healthcare professional (116). A combination of in-person and remote follow-up after BS may be optimal, but future research should explore the feasibility of such follow-up. Remote consultations via telemedicine would probably be particularly feasible in rural areas where the patients must travel a long way to the outpatient clinic and for working patients, so they do not have to leave work to attend consultations. Whether this combination of follow-up visits will prevent attrition to consultations also warrants further exploration.

The effectiveness of a PRO/CFS in BS care has not been established. A broad implementation of the PRO/CFS in the follow-up after BS is therefore not yet recommended. Implementing a PRO/CFS in follow-up care is costly, both economically and in terms of time. In a healthcare system short on both, the utility of a PRO/CFS needs to be explored in more detail before a broad implementation can be recommended. There are probably few negative consequences for the patients to attending consultations in which a PRO/CFS is an integral part. However, if the patient completes the PRO/CFS and the healthcare professional does not acknowledge this, this may affect the alliance between the patient and healthcare professional. Some patients have reported being disappointed when their efforts to complete the PRO/CFS was not valued by the healthcare professional (211). Furthermore, if implementing a PRO/CFS, the healthcare services should ensure sufficient training of the healthcare professionals in using the system, interpreting the findings and integrating them into the clinical consultation. The barriers reported by

healthcare professionals to using the PRO/CFS actively in treatment are technical challenges and limited time (239). These aspects need to be addressed during the implementation process.

Implementing a digital PRO/CFS into healthcare services is resource demanding and therefore requires adequate planning of the implementation. Good planning clearly includes the involvement of service users, i.e. patients and healthcare professionals, in designing the PRO/CFS, appropriate questionnaires and how to implement the PRO/CFS in clinical practice. Such actions that enable the development of a PRO/CFS that is relevant for the patients and healthcare professionals will probably have the potential to empower patients and increase the patients' ability to influence treatment.

7. Conclusion

This thesis contributes knowledge that may inform the phenomenon of follow-up care of patients undergoing BS from different perspectives. The findings in the different studies have shown that the follow-up in this population needs to focus on far more than weight loss and nutrition, even though both are important. We have demonstrated that HRQOL and mental health are important additional aspects in the follow-up, assessments that until now have been too poorly implemented in follow-up care.

Due to the complexity of the patient population and the diversity in outcomes the patients experience after BS, the follow-up care must be adapted to the individual patient. This applies to both the content of the consultations and length of follow-up. This is a challenging task in a healthcare system in which effectiveness and economy play an important role. New strategies to include both patient involvement and effectiveness when delivering good patient care are therefore pivotal and can only be achieved by including patients in the planning of new interventions.

In Study 1, we conclude that a PRO/CFS may be feasible in the follow-up care for patients undergoing BS as a tool to include HRQOL and mental health assessments in the clinical consultation, but the feasibility of this tool clearly needs more exploration. In Study 2, we provide a detailed description of a digital PRO/CFS, which we find addresses the phenomena of feedback and enables the clinical conversation to be adapted to patient needs and expectations. We also provide a study protocol in which we describe the plans for evaluating the feasibility of the PRO/CFS at a BS outpatient clinic. In Study 3, we found that the mental component of HRQOL, obesity-specific HRQOL and BMI were associated with overall treatment satisfaction five years after BS. This demonstrates the importance of focusing on many aspects of the patient's life in the clinical meeting with patients undergoing BS. In Study 4, we found that the NF is a promising tool for a PRO/CFS in the follow-up care to assess mental health in patients undergoing BS.

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Review Article

A review of systematic reviews on the effects of patient-reported outcome monitoring with clinical feedback systems on health-related quality of life—implications for a novel technology in obesity treatment

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Summary

Patient-reported outcome monitoring with clinical feedback systems (PRO/CFS) has been employed in many disease states to measure and improve health-related quality of life (HRQOL). Exploring the role of PRO/CFS in treatment for obesity may prove valuable. Systematic reviews were summarized to determine the effectiveness of PRO/CFS on HRQOL in any disease area. Primary studies evaluating the effect of PRO/CFS on HRQOL in treatment for obesity were also considered for inclusion. Systematic searches were performed in The Cochrane Library, PROSPERO, Epistemonikos, HTA, DARE, CINAHL, Medline, Embase, PsycINFO, BMJ Clinical Evidence, PDQ-Evidence and PubPsych. Two reviewers independently screened references until final inclusion and critically appraised included reviews using PRISMA checklist. Five systematic reviews and no primary studies met inclusion criteria. Although results were inconsistent, effectiveness of PRO/CFS on HRQOL was demonstrated in some diseases/treatments (e.g. psychiatric treatment; symptom burden in cancer treatment). No trials using PRO/CFS in treatment for obesity were identified. In some trials, PRO/CFS was not fully integrated into consultations, thereby PRO/CFS was not extensively studied. General effectiveness of PRO/CFS on HRQOL is inconclusive due to heterogeneous and statistically insignificant findings, and lack of stringency in conceptualization and execution of PRO/CFS. There are no data relevant to treatment for obesity. Future studies should use rigorous methodology to examine the effectiveness of PRO/CFS in treatment for obesity.

Keywords: Clinical feedback systems, health-related quality of life, HRQOL, obesity treatment, routine outcome monitoring, overview of systematic reviews.

Introduction

Patient-reported outcome monitoring with clinical feedback systems (PRO/CFS) is a method of improving health outcomes through the systematic collection of patient-reported data, followed by provider feedback on those data to patients (1). This procedure is referred to by different terms in the literature, such as *routine outcome monitoring* (*ROM*) with *clinical feedback*, *progress monitoring* or *measurement-based care*. Patient-reported outcome measures (PROMs) are acknowledged as valuable for informing optimal treatment and follow-up for patients (2–4). Two recently published articles (1, 5) call for the

importance of monitoring patient-reported outcomes over time and incorporating clinical feedback, which consists of sharing self-reported outcomes with the patient, to direct clinical consultations toward relevant domains (6–8). A clinical feedback system collects patient-reported outcomes before, during, and after treatment, and is easily implemented using an electronic device, such as a tablet, that displays visual data for both patient and the health professional (5). Traditionally, the process of using patient-reported outcomes to guide patient care has typically been carried out in three discrete steps. First, the patient completes a paper questionnaire, then the healthcare provider reviews the results, and finally he/she shares the findings with the patient during consultation. New technologies, such as PRO/CFS, have the potential for making patient-reported outcomes more immediately accessible to the healthcare provider, and therefore more easily integrated into the patient's treatment (1).

PRO/CFS has been employed in many disease states to optimize treatment and improve health outcomes, including health-related quality of life (HRQOL). This review of systematic reviews examines the effectiveness of PRO/CFS on HRQOL in any disease area, with particular emphasis on any studies relevant to treatment for obesity and/or bariatric surgery.

HRQOL has been defined as '…a multidimensional construct of the individual's perception of the impact of an illness, capturing the physical, psychological, and social dimensions of health' (9). HRQOL impairments are common among patients with severe obesity (10, 11), and for a majority of patients sustained improvements in HRQOL occur after bariatric surgery (9), but not always after other treatments for obesity (11). A possible novel method to improve outcomes in obesity treatment could be to assess HRQOL on a routine basis and use this information in clinical conversations with patients.

Why might consultations informed by patient feedback, inherent in PRO/CFS, lead to better outcomes in treatment for obesity? Feedback Intervention Theory (FIT) (5) aims to understand and improve these practices. FIT, developed from theories such as control theory and goal setting theory, argues that the feedback needs to be related to patient goals or standards in order to affect behaviour. A focus on the gap between the current situation and an established standard is thus considered facilitative of behavioural change. FIT theorizes that behavioural change as well as an increased sense of control may be accomplished by changing a patient's locus of attention through feedback interventions (12).

PRO/CFS has been used more frequently in mental health settings to measure psychological domains than in somatic health care settings, and the most commonly used tools fall into the three broad categories: disorder-specific, unidimensional and multidimensional. While disorder-specific tools target one specific category of suffering (such as depression), unidimensional measures often target the global construct of burden-of-suffering, and multidimensional tools monitor patterns in symptoms and functioning. A tension between unidimensional and multidimensional measures has been noted in the research literature, followed by recommendations to use both general (unidimensional or disorder-specific) and multidimensional measures in PRO/CFS strategies (13). McAleavey *et al.* (13) further suggest that particularly significant items should be brought to the patients' attention and discussed in order to assess their experience relative to their report.

The psychological aspects of HRQOL are of particular interest after bariatric surgery, with a recently published study showing that, despite significant improvements in psychological HRQOL 10 years after bariatric surgery, as much as 43% of patients reported low psychological HRQOL, compared to 16% in the general population (14). These findings are supported by other studies of long-term follow-up after bariatric surgery (15–17). Such post-operative challenges do not seem to only relate to poor weight loss (18), but also to weight-regain, malnutrition or worsening of comorbid diseases (17, 19). The concepts of mental health and psychological HRQOL are different constructs from each other; however, they seem to be related as studies have shown that the mental component summary in the questionnaire SF-36 could be used to screen for depressive symptoms in various patient populations (20, 21).

A recent meta-analysis by Dawes *et al.* (22) shows that mental health issues, such as depression and anxiety, are common among patients seeking bariatric surgery. Another study shows a higher risk for new-onset depression and anxiety after bariatric surgery, when compared to patients undergoing medical treatment for obesity (23). Furthermore, a higher incidence of suicide has been found in patients after bariatric surgery, compared to both persons with obesity and healthy controls (24). Studies also suggest a higher prevalence of alcohol-use disorder after bariatric surgery compared to baseline measures and matched controls (25, 26). Combined, these findings highlight a need to develop better strategies for mental health follow-ups of patients after bariatric surgery (16, 27–29).

Our aims with this overview of systematic reviews were threefold: (i) to investigate the effectiveness of PRO/CFS on patients' HRQOL, regardless of diagnosis or treatment; (ii) since our main interest is treatment for obesity, to investigate whether PRO/CFS has been tested in treatment for obesity and (iii) to discuss the rationales and possibilities for using PRO/CFS in this setting.

Methods

A published protocol for this review can be found at the Centre for Reviews and Dissemination with registration number CRD42016047349.

Inclusion and exclusion criteria

We included systematic reviews summarizing evidence on the effectiveness of PRO/CFS on HRQOL in any patient population, e.g., treatment for obesity, psychiatric treatment or treatment for cancer. Building on the first search, we also searched for systematic reviews or primary studies on the effectiveness of PRO/CFS on HRQOL in treatment for obesity. Inclusion criteria are presented in Table 1.

Identification of studies

Systematic searches were performed in The Cochrane Central Register of registered trials, PROSPERO, Epistemonikos, Health Technology Assessment, DARE, CINAHL, Medline, Embase, PsycINFO, BMJ Clinical Evidence, PDQ-Evidence and PubPsych. Search words such as routine outcome monitoring, clinical feedback, PROM, HRQOL and quality of life, among others were used. See S1 for search strategy. We screened reference lists of relevant articles for eligible studies. We applied the filters for systematic reviews, maximum sensitivity for all database searches. As our field of interest is obesity, we made a search limited to obesity to identify primary trials that used this approach in treatment for obesity. No restrictions on language or time of publication were applied to any of the searches. We also searched clinicaltrial.gov and Google Scholar for ongoing or unpublished trials, using the text words 'routine outcome monitoring' and 'clinical feedback.' Moreover, two experts in the field were contacted for identification of relevant studies. All references from the systematic searches were imported to a reference manager system (EndNote X8), and duplicates were removed before the screening process.

Selection of studies

Two authors (PAH, SHØ) independently screened all titles and abstracts for articles in full text. Subsequently, two authors (PAH, AA) independently read all full-text articles, and decided on final inclusion or exclusion. Any disagreement in all stages was resolved through discussions. A third author (JRA) was available for consultation in case of uncertainties.

Table 1 Inclusion criteria for systematic reviews and primary studies of HRQOL in PRO/CFS

Systematic reviews
Evaluated PRO/CFS in any disease area
HRQOL as primary or secondary outcome
Included patients aged 18 and older
Review determined to be good to moderate quality
Primary studies in treatment for obesity
Evaluated PRO/CFS in treatment for obesity
HRQOL as primary or secondary outcome
Included patients aged 18 and older

HRQOL, health-related quality of life; PRO/CFS, patient-reported outcome monitoring with clinical feedback systems.

Quality assessment

We assessed the quality of the selected systematic reviews using the PRISMA checklist (30) and a checklist from the Norwegian Knowledge Centre for the Health Services (31). Moderate quality or better systematic reviews were included in our analysis.

Data extraction and analysis

One author (PAH) extracted data from the included reviews, and another author (JRA) quality-checked the extraction. We planned for a meta-analysis, if appropriate, or a descriptive analysis of the reviews. We extracted the following data: author(s), year, country, intervention, study design, outcome(s), included trials in total (*n*), included trials eligible for our review (*n*), included patients in total (*n*), included patients eligible for our review (*n*), quality assessment and results (inferential or descriptive statistics).

None of the included reviews reported statistics in a way that enabled us to perform a meta-analysis, with results presented as text or *P*-values with 95% confidence intervals (CIs). We therefore decided to perform a narrative analysis of the reviews. We furthermore extracted statistical data from 11 out of 16 single trials included in the reviews in order to perform a random effects meta-analysis with standardized mean difference (SMD) and 95% CI. HRQOL had to be a primary or secondary outcome in the single trials, and mean with standard deviation (SD) had to be included in the manuscript to enable us to perform a forest-plot analysis. We extracted mean as the difference between baseline and the last measurement point; and we extracted SD. We used the software Review Manager 5.3 (The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark) (32) to analyse the extracted statistics. We extracted global HRQOL where this was presented, psychological HRQOL from trials in psychiatry, and physical HRQOL in trials from cancer care.

Results

Inclusion of studies

We completed database searches on 16 August 2016, with an updated search on 08 May 2018. We identified 1459 titles from database searches, screening of reference lists and contact with experts. We screened 1311 potentially relevant studies for inclusion after duplicates were removed, and 35 articles were chosen for full-text-reading. One article

could not be obtained in full-text copy, making 34 full-text articles available for possible inclusion. Main reasons for ineligibility were irrelevant outcome measures, interventions not aimed at PRO/CFS, or study not being a systematic review. Ultimately, we included five systematic reviews in this overview. Excluded articles are presented in S2. For the screening process, see Fig. 1. Moreover, from the searches limited to treatment for obesity, 259 titles were identified after duplicate removal. These titles were combed for eligible systematic reviews and primary trials by three authors (PAH, SHØ, AA). The search for trials in treatment for obesity revealed no systematic reviews, only one trial having used clinical feedback in a population with obesity, and two studies having used this approach in a population with obesity and binge eating disorder or in a community population. None of these three trials met our inclusion criteria.

Quality of included reviews

Two reviews (33, 34) were assessed as being of good quality due to a comprehensive literature search in relevant databases, contact with experts in the field, and searches for grey literature. In addition, two or more authors had screened references, decided upon inclusion, and analysed the data.

Two reviews (35, 36) were assessed as being of moderate to good quality. The Howell *et al.* (35) review neither noted whether included studies had been critically appraised nor whether experts within the relevant field had been contacted. The Li *et al.* (36) review lacked methodological details concerning the independence of reviewers in the processes of screening, inclusion and analysis.

Finally, one review (37) was assessed as being of moderate quality because it had only one author and no details

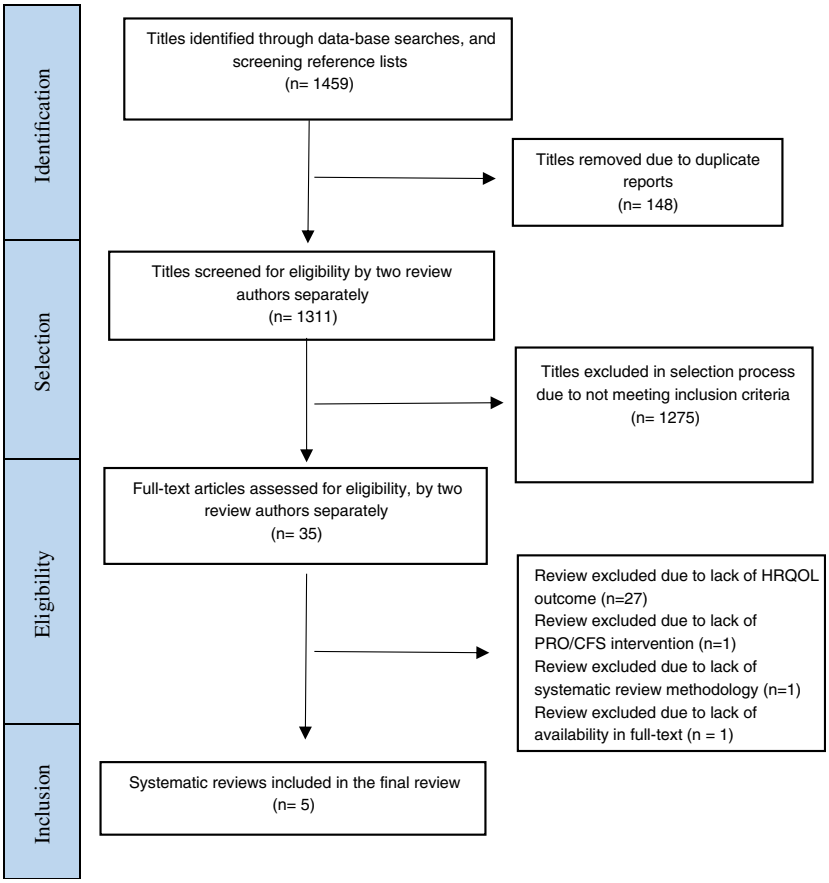


Figure 1 Screening and selection of studies. [Colour figure can be viewed at wileyonlinelibrary.com]

Table 2 Characteristics of included reviews

Author, year, country	No. of included studies, participants, setting, design	Intervention and comparison	Outcome measures	Interventions described in review, yes/no	Quality of review	Main findings of the review
Alsaleh, 2013, Saudi Arabia	Six primary trials, 1632 patients, QOL measures in oncology clinics, RCT	Patients completed questionnaires on QOL. These findings were administered to health-care provider, which initiated feedback to patient. Control were standard care with no questionnaire	Improvement in QOL, reduction in morbidity, reduction. In stress, improvement in communication, improved patient satisfaction	Yes	Moderate	Lack of evidence to state that routine administration of QOL questionnaires improves patient's QOL
Howell *et al.*, 2015, Canada	30 primary trials (5 trials eligible for our review), 3138 patients (838 patients eligible for our review), PROMs in cancer treatment, controlled trials	Routine use of PROMs and feedback. Control either got routine use of PROMs without feedback, or no routine use of PROMs	Evaluated outcomes at the patient, clinical practice, or care process, or system-level, or barriers/enablers to the uptake or use of PROMs	Yes	Moderate to good	One trial found results significantly in favour of intervention, whereas three found no difference. Communication was improved in feedback group
Kendrick *et al.*, 2016, UK	17 primary trials (2 trials eligible for our review), 6137 patients (2247 patients eligible for our review), feedback of PROMs in mental health, RCT	Feedback of routinely collected PROMs to participant and therapist. Controls received no feedback	Mean improvement in symptom scores, HRQOL, Adverse events as primary outcomes; changes in the management of CMHDs, social functioning, and costs as secondary outcomes	Yes	Good	No statistically significant difference between the intervention feedback group, and the control group, however, results in favour of intervention
Kontronoulas *et al.*, 2014, UK	24 primary trials (10 trials eligible for our review), 6279 patients, patients in cancer treatment, controlled trials (20 RCT, 4 CT)	Routine use of PROMs and feedback. Control group received usual care, or completed PROM but results were hidden from therapist	Patient outcomes, process of care, health services outcomes	Yes	Good	Seven trials found no significant difference between groups. Two trials found significant effect of intervention ($P = 0.006$; $P = 0.048$). One trial found worsened QOL in intervention group. Communication was improved in intervention groups
Li *et al.*, 2014, China	33 primary trials (1 trial eligible for our review), 5960 patients, cancer patients, RCT	Routine feedback of PRO to clinicians, completion of PRO without feedback. Control group did not receive PRO-questionnaires	Psycho-education, case management, exercise, feedback of PRO	Yes	Moderate to good	Intervention group had significantly better HRQOL than control group ($P = 0.006$)

CMHD, common mental health disorders; CT, controlled trial; HRQOL, health-related quality of life; PRO, patient-reported outcome; PROMs, patient-reported outcome measures; QOL, quality of life; RCT, randomized controlled trial.

were provided regarding whether any other person had been involved in the reviewing process.

The quality grading for each review is presented in Table 2.

Description of included reviews

Characteristics of included reviews are presented in Table 2.

The Cochrane review by Kendrick *et al.* (33) included 17 randomized controlled trials (RCTs) from psychotherapy settings, all evaluating the effect of feedback of PROMs on improvement in symptom scores, HRQOL, number of adverse events, changes in the management of mental health, social functioning and costs. Only two of the included trials were eligible for our review, collectively comprising 2247 patients in psychotherapy. Kendrick *et al.* (33) performed a narrative analysis on these two trials and found no statistical difference in HRQOL between intervention and control groups in either trial. However, the results tended to favour the feedback-receiving group, with a slightly higher score in mental HRQOL. The included trials were assessed by the primary authors as having moderate to high risks of bias, making their findings inconclusive.

Howell *et al.* (35) made a comprehensive literature search and included 30 trials that all investigated the effectiveness of PROMs at the patient, provider and system levels. The study-population was patients in cancer treatment. Five of the included trials reported patients' HRQOL outcomes and were thus eligible for inclusion in the present review. Four of these trials were RCTs and one was a sequential controlled trial. The studies included a total of 838 patients, ranging from 48 to 219. One RCT found a significant effect of PROMs and feedback on patients' HRQOL, while the remaining four found no statistical difference between intervention and control groups. The main conclusion in the review was that the use of PROMs and feedback in oncology treatment improves communication between patient and therapist, making HRQOL-issue-related discussions more frequent. However, robust evidence that the use of PROM and feedback in oncology treatment improves patients' HRQOL is lacking.

Kotronoulas *et al.* (34) included randomized and non-RCTs assessing the effects of using PROMs in cancer treatment. A comprehensive literature search revealed 24 primary trials, of which 10 were eligible for our review (9 RCTs, 1 longitudinal sequential two-arm cohort; 1180 patients in total). A descriptive analysis found that two RCTs showed a statistically significant difference in favour of the intervention, seven trials found no statistical differences between groups, and one RCT reported that the intervention group had significantly lower quality of life scores. Most of the included trials had unclear to high risks of bias in several domains, whereas two of the RCTs had low risk of bias in most domains.

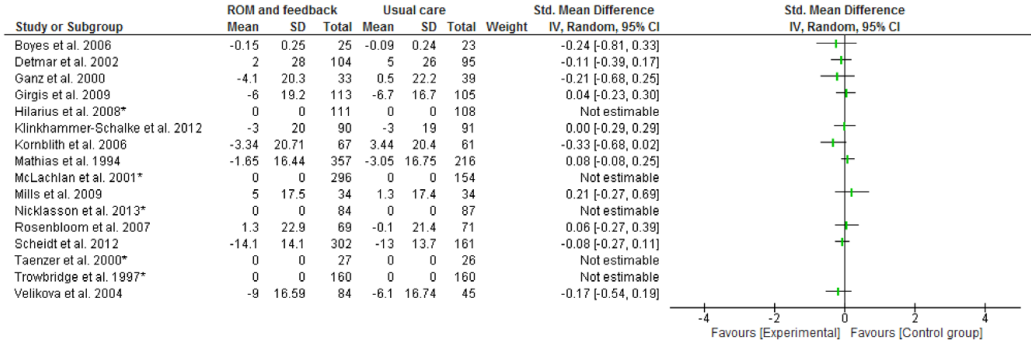
The systematic review by Li *et al.* (36) evaluated several outcomes in cancer treatment, whereas only 1 RCT of 33 included trials evaluated effects of feedback of PROMs on patients' HRQOL. The relevant trial included 286 patients with a 6-month follow-up. The authors found a statistically significant effect of routine collection of PROM and feedback, when compared to a control group not receiving HRQOL assessment ($P = 0.006$). However, there was no difference between a group receiving HRQOL-assessment-related feedback and one being HRQOL assessed but not receiving feedback of the assessment ($P = 0.80$). The authors found that the positive effects were linked to the patient being assessed, and not whether the information from the individual patient was fed back to the therapist or not. The authors of the review assessed the quality of included trial as moderate.

Alsaleh (37) included RCTs measuring quality of life in patients undergoing cancer treatment. Six trials with varying designs were included: cluster randomisation ($n = 1$), sequence randomization ($n = 1$), crossover ($n = 1$) and parallel groups ($n = 3$). All included studies were eligible for our review. The number of included patients ranged from 57 to 510, with a total of 1632 patients. Alsaleh (37) did not perform a meta-analysis due to the heterogeneity of the included trials. Five of the included trials used the EORTC QLQ-C30 questionnaire to measure the quality of life. The quality of included studies were assessed using GRADE, with two studies being of very low, two of low, and two of moderate quality. The main reasons for these low ratings were issues with randomization and allocation concealment, blinding of patients and healthcare providers, as well as high dropout rates that were not accounted for. The results of the included trials varied from positive ($n = 3$), to no ($n = 1$), or even negative ($n = 2$) intervention effect. The main conclusion of Alsaleh (37) was that there is lack of evidence that routine administration of quality of life questionnaires improves patients' quality of life.

None of the included systematic reviews reported statistics from the primary trials in a way that enabled us to make a statistical summary for the outcome HRQOL. We therefore accessed the primary trials ($n = 16$) included in the reviews to extract statistical data if available (references to primary trials are presented in S3). Eleven of the 16 primary trials presented results as mean and SD in a way that they could be extracted and inserted in a forest plot. Fig. 2 is a forest plot of all 16 trials.

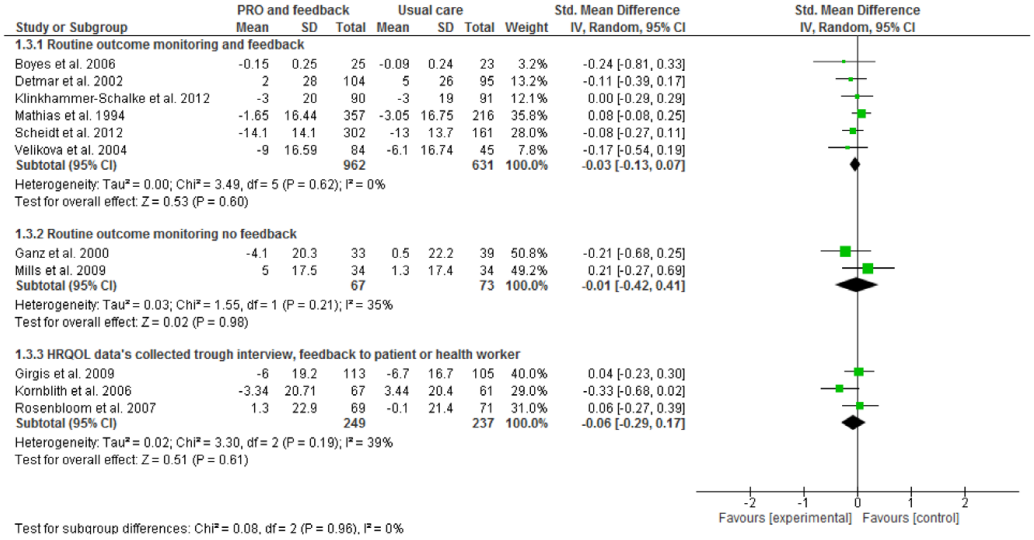
We further performed meta-analyses on subgroups of primary trials, depending on whether feedback to the patient was given or not (Fig. 3). These meta-analyses show no statistically significant differences between experimental and control groups. However, a possible small effect was observed favouring the experimental group in the subgroup where feedback was given (SMD: –0.03, 95% CI: –0.13 to 0.07), and no difference (SMD: –0.01, 95% CI: –0.42 to 0.41) in trials where feedback was not given.

We furthermore performed a subgroup analysis in three trials where the HRQOL data were collected through interviews, and feedback was given to either patient or health worker. In this analysis there was a small but again statistically insignificant trend favouring the experimental group (SMD: –0.06, 95% CI: –0.29 to 0.17).



Mean presented as mean difference from baseline to last measuring point
SD = Standard deviation
*Statistical data for HRQOL not reported appropriate for extraction as mean and SD
ROM = Routine outcome monitoring

Figure 2 Forest plot primary trials included in systematic reviews. [Colour figure can be viewed at wileyonlinelibrary.com]



Mean presented as mean difference from baseline to last measuring point
SD = Standard deviation
PRO = Patient Reported Outcomes

Figure 3 Meta-analysis effect of routine outcome monitoring and feedback on patients HRQOL. [Colour figure can be viewed at wileyonlinelibrary.com]

In all three subgroup analyses, however, there was statistical heterogeneity in results, with some trials reporting results in favour of the experimental group and others in favour of the control group. One should also be aware of a substantial clinical heterogeneity in the interventions used in the primary trials, comprising computer-based outcome monitoring over time in some and a single phone call in others. The ways in which PROM data are used were also quite diverse, with some trials using data in a structured manner in consultations, whereas others used it more randomly. This makes the comparisons highly unsure, and these meta-analyses can thus not be

used as evidence either for or against the effectiveness of the interventions.

PRO/CFS in studies from obesity treatment

In our search for trials in treatment for obesity, we identified only one RCT evaluating the PRO/CFS approach, whereas another RCT used PRO/CFS in a population with binge-eating disorder.

In an RCT, De Niet *et al.* (38) included 141 children undergoing treatment for obesity. The intervention consisted of a short message service and personalized feedback within an already-established obesity-treatment programme. After completing the treatment programme, the children had lowed BMIs and better HRQOLs, but no statistically significant differences between intervention and control groups were found; a positive trend, however, favouring the intervention group was detected. Another RCT conducted by de Zwaan *et al.* (39) investigated an internet-based guided self-help programme for patients with obesity and binge-eating disorder. In the intervention group, the coach had access to PROMs and gave feedback through e-mail and one monthly face-to-face contact over 4 months. The control group received cognitive-behavioural therapy (CBT). At 6 months follow-up the primary outcome 'days with binge-eating disorder symptoms', were significantly lower in the CBT group, whereas HRQOL did not differ between the two groups. At 1.5 years, there were no differences between the groups in neither of the outcomes. We found no primary trials investigating PRO/CFS in treatment for adults with obesity.

Discussion

In this review of PRO/CFS, three out of five included reviews concluded with a benefit of using this methodology to increase patients' HRQOL, whereas the remaining two concluded that the evidence was inconsistent. Results from the reviews included in our review are thereby inconclusive. Heterogeneity in results was apparent in the reported trials, varying from an effect in favour of the intervention (n = 8), no statistical differences between intervention and control group (n = 14), to lower quality of life scores in the intervention group (n = 3). One of the primary trials reporting a significant effect of PRO/CFS is included in four of the five systematic reviews (34–36). Five of the primary trials reporting no significant difference were included in two of the five systematic reviews, and finally one of the trials reporting negative findings was included in two of the five systematic reviews (34, 37). Only one review (36) concluded a significant positive effect of PRO/CFS on HRQOL, but they only found one primary trial assessing PROM on patients' HRQOL. The authors of the other systematic reviews noted a lack of robust evidence for this methodology due to heterogeneity in results and low quality of the evidence due to a high risk of bias. In our analysis, we found little correspondence between results in the primary trials and the risk of bias in the same trials.

In our forest-plot analysis of the primary trials (Fig. 2), this review confirms the heterogeneity in statistical results reported in the reviews, but we found no statistically significant differences between experimental and control groups in any of the trials, contrary to the conclusions reported in the included reviews. The reason for this may be that we report mean differences in score between baseline and last observation in both groups, whereas the reviews may have reported group differences in last observations. The reviews could also have summarized different items from the questionnaires than we have. A level of uncertainty thus remains, especially since the included reviews vary in their reporting of statistical analyses and findings. Our analysis of primary trials shows a small, non-significant trend favouring the experimental groups when feedback was given to both patient and health professional.

Two of the included reviews (34, 36), reporting the same primary trial, state that the results of the intervention seem to be influenced by whether HRQOL is discussed during the consultation or not. This suggests a significant variation in how the concept of routine outcomes measurement and clinical feedback is understood and employed in clinical settings. This variation may lead systematic reviews to compare significantly different concepts under the same heading. In our opinion, this underlines the importance of providing feedback of PROM results to both the patient and the healthcare provider and using the patient response as an integral part of the consultation. This notion is supported by the theory developed by Kluger and DeNisi (12), which emphasizes that the patient-reported information has to be used actively in the meeting with the patient to have a meaningful effect for him or her.

Similarly, in our analysis of the primary trials, we found substantial diversity in how the PRO results were used in consultations. As such, some of the trials might not have studied the actual phenomenon of PRO/CFS, given that the results of routine monitoring were not integrated into consultations and hence not activated within clinical conversation; or, in other words, given that this significant key element of FIT (12) was not met. One hypothesis is that this partial use might have affected the results on the effectiveness of PRO/CFS. In turn, and from a research point of view, this calls for further conceptual work to establish what the necessary core components of PRO/CFS are, followed by a standardized protocol for what clinical feedback interventions should entail in practice.

Another interesting finding from the reviews—despite not being the focus of our overview—is that the use of PRO/CFS shows a significantly positive effect on the experienced quality or usefulness of the communication

between patient and therapist (35). These findings have been documented in other reviews focusing on patient or organizational outcomes (40, 41). Furthermore, two reviews stated that HRQOL was discussed more often during consultations when PROM results were collected and fed back to therapist and patient (34, 35), thus establishing a basis for the utility of this practice. It seems that this type of information is important to patients and facilitates discussions concerning worries that may not be brought up by patients otherwise (42). Furthermore, a qualitative trial on patients in psychiatric treatment found that open conversation and collaboration were considered important features in a clinical feedback system for patients and therapists alike (43).

One reason for the primary-trial researchers not being able to detect a significantly positive effect of PRO/CFS as an intervention may be related to participant characteristics. Recent reviews have shown that the effect of ROM in mental health settings is influenced by patient as well as provider characteristics. If patients are doing well in treatment, effects of PRO/CFS are small to minimal. However, if patients are responding poorly to psychiatric treatment, the use of PRO/CFS has been shown to yield clinically important effects on treatment outcome (1, 5, 44, 45). The positive effect on poor responders might be a result of early discovery of treatment effect or failure, as shown in a literature review by Fortney *et al.* (46). We therefore hypothesize that if a sub-group analysis had been performed on patients not doing well in therapy, researchers might have been able to detect significant effects of PRO/CFS on outcome HRQOL, just as Gondek *et al.* (44) found in a subgroup analysis on the outcome *treatment effectiveness*. Taken together, these findings may be applicable to obesity treatment, as the follow-up of patients after bariatric surgery to a large degree fails to help those patients showing no improvement or even decline in HRQOL after bariatric surgery (11, 15–17).

Assuming that PRO/CFS is more useful for patients not responding optimally to treatment, one may consider whether this type of intervention should be used routinely, i.e., for all patients. When offered to all patients PRO/CFS provides the ability to detect early signs of treatment failure, and allows for revised treatment plans with improved outcomes (47). Identifying patients at risk of failure is challenging (46), making conditional administration of PRO/CFS unfeasible. In addition, multidimensional measures such as PRO/CFS have an impressive scope, as they may indicate worsening in specific HRQOL-related subdomains that unidimensional measures regularly miss.

The reviews included in this overview summarized evidence from patients with cancer ($n = 4$) and patients in psychiatric treatment ($n = 1$). We found no difference in effectiveness of the intervention between these populations. In the process of conducting the current review, we identified several systematic reviews assessing PRO/CFS in diabetes care, cardiology, rheumatology and other patient populations; however, as these reviews focused on symptomatic, activity-related, or organizational outcomes, they were not eligible for inclusion. Several of these reviews, e.g., in psychiatric treatment, found that PRO/CFS is effective for positive developments in psychiatric conditions and symptom burden. Furthermore, several of the reviews found that communication between patient and therapist was positively affected by the intervention.

Although our results carry some uncertainty, our findings may be clinically important for patients in obesity treatment, as impaired HRQOL obviously affects daily living. The importance of PROMs in clinical consultations after bariatric surgery has been highlighted in a study investigating both patients' and health professionals' views on the importance of outcomes after surgery (48). These authors found a discrepancy between patients and professionals in terms of which outcomes were rated as important, e.g., quality of life, which was rated as more important by patients than health professionals. Based on the summarized research (22), a valid expectation when meeting patients with obesity would be that a significant portion of patients suffers from mental health distress of some sort. Additionally, although unidimensional instruments (i.e. those targeting the global construct of burden-of-suffering) may indicate patients' distress, they have specificity limitations unless clinicians take time to provide feedback at the item level. In contrast, a multidimensional instrument might indicate elevations on multiple subscales but fail to capture the overall distress of the patient. Thus, the type of instrument may inadvertently influence the quality of feedback and its potential impact.

Our research group is currently implementing clinical feedback systems in follow-up after bariatric surgery, mental health treatment and patients operated with stoma. The system we use in treatment for obesity incorporates measures on areas frequently affecting the patients' life after surgery, including measures of mental-health, alcohol habits, HRQOL, eating habits and side-effects of the surgical procedure.

Despite considerable use of patient-reported outcomes in research on obesity treatment, particularly bariatric surgery (11), only few studies are using PROMs in actual clinical consultations for obesity treatment (38, 39). The focus on success after surgery has largely been on clinical parameters such as weight loss, remission of comorbid diseases or complications (49), whereas recent guidelines recommend that follow-up include psychological variables and HRQOL (29). Busetto *et al.* (29), also state that there probably is an under-recognition of mental health disorders before and after bariatric surgery. PRO/CFS can in our opinion facilitate the use of this valuable information in treatment for obesity. Another explanation for PROMs being rarely applied in the obesity field is that patients have

been reporting on paper questionnaires, and healthcare providers have had to interpret results from a paper format. The new approach with electronic reporting of PROMs will make results easier to interpret as the technology creates a visual summary report, and thereby makes this information more accessible for use in a clinical setting in obesity treatment follow-up.

There are several reasons that patients might prefer personalized follow-ups such as ROM and clinical feedback. A survey has shown that patients who have undergone bariatric surgery are interested in receiving interventions that may help them to maintain their weight (50). The majority of the 154 patients in the survey preferred in-person treatment, with 70% also feeling that interventions could be at least partly internet-based (50). Furthermore, a qualitative study investigating the views of both patients and practitioners regarding the post-bariatric surgery experience found that patients reported unmet needs, most specifically, psychological aftercare to facilitate adjustment following drastic weight loss and excess skin, acceptance of their non-obese self and perceived stigma (49).

Despite our inconclusive findings, both patient dissatisfaction and procedural issues with the current process of using PROs suggest the need to explore novel technologies, such as PRO/CFS. These systems have been proven effective in symptom management in patients with psychiatric diseases (1, 33), and may be useful for patients seeking treatment for obesity, given their high prevalence of psychological issues (22). Such a system collects patient-reported outcomes before, during and after treatment, and is easily implemented using an electronic device, such as a tablet, that displays visual data for both patient and healthcare provider (5). A recent review of qualitative studies of PRO/CFS in mental health services shows that patients value this technology as long as it captures the complexity of challenges and facilitates collaborative conversation with the healthcare provider (51). This more patient-centred technology has the potential to empower healthcare providers to immediately integrate patient-reported data into consultations, thereby more effectively engaging patients.

Strengths and limitations

For the present paper, we conducted a thorough literature search in relevant databases, on relevant web pages, and searched for grey literature. Reference lists of included reviews and other relevant articles have also been screened. Furthermore, all critical stages of the review process have been undertaken by at least two authors in accordance with the Cochrane handbook for systematic reviews (52). We have also contacted experts in the field for supplemental information. This makes us confident that we followed guidelines for ensuring good quality in reviews (53).

A weakness to any *overview of systematic reviews* is that the findings extracted from included literature are influenced by the thoroughness of the original reviews (54, 55). This is why we assessed the quality of the included reviews and only included those deemed moderate to good. For quality assessment, we have used a checklist developed by the Norwegian Knowledge Centre for the Health Services (31). This checklist is based on the criteria developed by Moher *et al.* (30) for reporting systematic reviews. Furthermore, we have used the PRISMA checklist (30) as a supplement to guide our quality assessment. Together, these tools ensure a rigid quality assessment, making our analyses more trustworthy. Regardless, a small degree of uncertainty remains, as we have no means for establishing whether all relevant primary trials were identified and included in our source papers.

A weakness of some of the included reviews is the absence of statistics from the primary trials. Two of the included reviews presented only *P*-values, and three others simply stated that findings were significantly in favour of the experimental group, or that no significant difference between groups were found. This lack of reported statistics was in some cases due to the way in which the primary trials reported their statistics. We consider this a limitation of the included reviews.

We originally planned to conduct a meta-analysis of included reviews, but due to the aforementioned lack of reported statistics and the absence of any meta-analyses within out subject area, we had to resort to descriptive analyses. Nevertheless, we managed to identify the primary trials included in the five best-quality systematic reviews, extract the data, and present results in a forest plot. We must, however, stress the uncertainties pertaining to this venture, given the significant clinical heterogeneity in the primary trials (56).

Another challenge for our overview is that the reviewers in the included reviews used different tools for evaluating the quality of included trials. Some used the Cochrane Collaboration's Risk-of-Bias tool, and one used criteria developed by the Effective Public Health Practice Project. This makes any quality comparison of the included primary trials in the reviews challenging (54), and it makes our overview somewhat less robust.

Implications for future feedback interventions and research

We have documented a need to establish a common definition of the concept PRO/CFS, and based on the literature on PRO/CFS, we propose the following: (i) patient-reported outcomes should be routinely collected before all consultations, preferably via electronic devices, (ii) both patient and clinician should have the report available during the consultation and (iii) patient-reported findings and

their implications should be discussed with the patient during the consultation.

The characteristics of feedback systems should be standardized to ensure efficiency in patient treatment. First, the specific measures used to monitor patient outcomes have to be relevant for the patient population, and the questionnaires should be validated for the specific population and setting. Second, the presentation of the outcome measures has to be easily accessible for the healthcare professional and the patient, enabling uniform and unequivocal understanding and easy analysis. Third, the results of outcome monitoring should be used continuously in a structured fashion in the consultation, thus facilitating the addressing of areas of struggle and the development of plans of action. Finally, health professionals need thorough training in using the feedback system, analysing results, and responding to specific problem areas. This should all be included in a system that is designed to meet the needs of the patient.

A major implication of the present overview is that the lack of stringency in how PRO/CFS technology is conceptualized and carried out yields difficulties when comparing results. A clear definition of the practice of PRO/CFS should hence be sought. As a working hypothesis for future research, we suggest that any PRO/CFS should be found on three constituent themes as described above.

Our included reviews carry no clear conclusions as to whether PRO/CFS is an effective strategy for enhancing patients' HRQOL. However, some reviewers have noted that this type of intervention is positively related to outcomes (e.g. treatment effectiveness and patient–therapist communication), which, in our opinion and in turn, should be positively related to HRQOL. However, it is clear that more research on the topic is needed.

Future trials should have a robust quantitative design to be able to detect differences between groups, and follow design rules strictly. The intervention should be pilot- or feasibility tested (57) to ensure elimination of potential weaknesses that may ultimately influence results. Future trials should also perform sub-group analyses, paying special attention to groups of patients not responding well to therapy; these patients seem most likely to respond positively to PRO/CFS treatment. Finally, it would be interesting to investigate the potential efficiency of PRO/CFS in the context of surgical as well as non-surgical treatment for obesity. Complimentary to the above, studies employing solid qualitative designs would provide valuable information into patients' experiences of consultations that employ PRO/CFS methods.

Conclusion

Although three out of the five included reviews indicated that PRO/CFS was positively related to patients' HRQOL, the remaining two concluded that the evidence was inconsistent. A lack of stringency in conceptualization and execution of PRO/CFS might have contributed to these findings. Future studies should use rigorous methodology to determine the effectiveness of PRO/CFS on HRQOL in treatment for obesity. For successful application of PRO/CFS we have proposed the following: (i) patient-reported outcomes should be routinely collected before consultations, (ii) both patient and clinician should have the report available during the consultation and (iii) patient-reported findings and their implications should be discussed with the patient during the consultation. Because new technologies, such as PRO/CFS, have the potential for making patient-reported outcomes more immediately accessible to the healthcare provider and are therefore more easily integrated into the patient's treatment, they may be of benefit in the treatment of chronic, refractory diseases such as obesity. We are encouraged by the documented effectiveness of this technology in symptom management in patients with psychiatric disease. The high prevalence of psychiatric comorbid conditions in persons with obesity also suggests that PRO/CFS may be of utility in this population.

Conflict of Interest Statement

No conflict of interest was declared.

Author contributions

All authors have been involved in the writing and critical reviewing of the paper. PAH did the majority of writing of the manuscript and was involved in all stages of the review process. SHØ and PAH did the selection of references, AA and PAH did the final inclusion, and critical appraisal of the reviews. PAH and JRA did the extraction and statistical analyses of the reviews.

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Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

Appendix S1. Example search-strategies embase (OVID).
Appendix S2. Excluded articles.
Appendix S3. List of primary trials included in the systematic reviews.
Appendix S4. Summary of findings table primary-studies included in meta-analysis.

BMJ Open

A novel patient-reported outcome monitoring with clinical feedback system in bariatric surgery care: study protocol, design and plan for evaluation

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ABSTRACT

Background Consultations before and after bariatric surgery should include structured assessments of patients' health-related quality of life (HRQOL) and mental health. One way to conduct this assessment is to implement patient-reported outcome monitoring with a clinical feedback system (PRO/CFS).

Aim We will explore patients' and healthcare professionals' experiences when a PRO/CFS is an integrated part of bariatric surgery care.

Methods and analyses This is a design paper in which a PRO/CFS will be implemented in two bariatric outpatient clinics. All patients who have an appointment with a healthcare professional prior to, and 3 and 12 months after surgery, will be asked to complete six digital questionnaires measuring HRQOL, mental health, bowel symptoms and eating self-efficacy prior to each consultation. A digital summary report generated from the patient's responses will form the basis for the clinical consultation. A team of patient representatives, healthcare professionals and researchers will be involved in all phases of designing the PRO/CFS to ensure its relevance for clinical consultations. The patients' experiences will be explored with a generic 12-item questionnaire, developed for use in outpatient clinics, prior to and 12 months after bariatric surgery. We will conduct focus-group interviews with patients and healthcare professionals to explore their experiences when PRO/CFS is integrated into the consultations.

Ethics and dissemination Written informed consent will be obtained for all participants in the study. The project is approved by the Norwegian Centre for Research Data, Department of Data Protection Services (ref. no. 282738). The project has also undergone Data Protection Impact Assessments, both at Førde Hospital Trust and at St. Olav Hospital (registration no. 2016/3912). Data from the qualitative and quantitative studies will be kept in de-identified form in a secured research database, and the findings will be published in international peer-reviewed journals and presented at scientific conferences.

Strengths and limitations of this study

- The involvement of patients and healthcare professionals in the design of the patient-reported outcome monitoring with a clinical feedback system (PRO/CFS) is a strength.
- A strength of the evaluation of the PRO/CFS is that it combines qualitative and quantitative methods to explore patients' experiences.
- A limitation may be differences in follow-up procedures in the two outpatient clinics.
- Another limitation is that the experiences of the healthcare professionals are explored using qualitative methods only.

BACKGROUND

The term patient-reported outcome monitoring with a clinical feedback system (PRO/CFS) refers to the systematic collection of patient-reported outcome measures (PROMS) for immediate use in clinical consultations.[1] PRO/CFS is synonymous with the term 'routine outcome monitoring and clinical feedback systems' (ROM/CFS), which is mostly used in mental health settings. For consistency in the present paper, we use the term PRO/CFS for both concepts/contexts. In PRO/CFSs, the patient responds to a set of questionnaires providing psychometrically valid information prior to consultation with a healthcare professional.[1] The PROMS are collected before each clinical consultation, and clinical information from the patient, as well as comparisons to normative data, are fed back to the healthcare professional to be used in the clinical conversation.[2] PRO/CFSs have been implemented in several healthcare services to assess mental health, somatic symptoms and health-related quality of life (HRQOL).[3] A systematic review of qualitative studies found that healthcare professionals experienced clinical use of PROMS as useful when they were intended to guide patient management and when findings were presented clearly. Sufficient training in use and interpretation were also considered

important. Barriers were lack of technical support, workload and when the PROMS were not considered relevant.[4] In a recent qualitative study of patients' and healthcare professionals' experiences with PROMS, patients found that the PROMS helped them to address topics that were important for them. Furthermore, they could track their changes in symptoms and problems. Disease-specific measures were considered to be most relevant. Barriers for both patients and healthcare professionals were lengthy questionnaires, and complicated summary reports that were difficult to interpret. This could serve as a hindrance for communication and professional relations.[5] Common findings in both studies were the potential of PROMS to give patients a sense of control and facilitate patient-centred care.

PROMS can be collected on paper or digitally; however, a digital PRO/CFS has the advantage of providing instantaneous availability of the patient's responses,[1] and, in novel systems, comparison to relevant norm data. An important feature for a PRO/CFS is the ability to combine nomothetic and idiographic approaches to understanding a given patient. In the nomothetic approach, individuals are characterised in terms of traits or dimensions that are based on mean scores of known groups. In the idiographic approach, the focus is on the individual and emphasises his/her unique personal experience, in PRO/CFS concretised, for example, by measuring person-generated goals.[6] The flexibility of PRO/CFS and its adaptation to the patient's needs and resources was found to be important in a qualitative study in mental health treatment, as patients experienced feedback as being part of treatment if their responses were discussed in the consultation.[7] New approaches to PRO/CFS aim to contain both nomothetic and idiographic strategies through computer-adaptive testing.

Numerous studies from the field of psychotherapy have explored PRO/CSF both qualitatively and quantitatively, and therefore, they inform the use of PRO/CSF in bariatric surgery care. Meta-analyses and reviews show that PRO/CFS have a small to moderate general positive effect on patient outcomes, particularly for patients not responding well to treatment interventions in its initial phases of psychotherapy.[8 9] However, the results are not uniform, and some clinicians manage to use feedback better than others.[10]

To facilitate positive effects of PRO/CFS, the topics addressed have to be relevant for the group of patients. A review of systematic reviews found positive effects of bariatric surgery on HRQOL, especially with respect to obesity-specific and physical health concerns.[11] Although improvements were seen in both the mental and physical domains of HRQOL, changes in the physical domains were greater.

Strategies to include assessments of psychological outcomes in the follow-up after treatment of obesity have been called for by patients[12] and healthcare professionals.[13] The European Association for the Study of Obesity guidelines for postbariatric surgery medical management recommend a structured mental health assessment,[14] although they make no specific recommendations for how this assessment should be conducted. One strategy to structure the follow-up of patients after bariatric surgery is to implement a PRO/CFS to optimise HRQOL and mental health outcomes.[3]

In a recent overview of systematic reviews assessing the effectiveness of PRO/CFS on HRQOL, the authors found that the understanding and use of a PRO/CFS was quite variable across the included studies in both somatic and mental health services. The authors recommended that future studies should include detailed descriptions on how the concept of PRO/CFS is understood by the researchers[3] to clarify if the actual phenomenon of PRO/CFS is being studied. Based on a systematic review of the PRO/CFS literature, the authors proposed three elements as being important for the successful implementation of PRO/CFS: (*i*) *patient-reported outcomes should be routinely collected before all consultations, preferably digitally, (ii) the report should be available to both the patient and clinician during the consultation* and (*iii*) *patient-reported data and their implications should be discussed during the consultation.*[3] Considering these suggestions for the current study, we argue that in addition patient-reported outcomes should be understood in the context of normative data—that is, how similar or different is this patient's scores from other patients with the same condition and/or the healthy population.

Integrating knowledge from the mental health field with experiences from somatic health services, this project aims to develop, implement and evaluate a PRO/CFS for use in an outpatient setting in bariatric surgery in Western Norway. The purpose of this article is, therefore, to describe the development and implementation of the PRO/CFS, and our plan to evaluate the feasibility of the PRO/CFS in bariatric surgery care. We hypothesise that using a digital PRO/CFS will add value to the collaborative relationship between patients and healthcare professionals in bariatric surgery care. The following research questions will be addressed in the planned study:

1. How do patients experience the clinical consultation when a PRO/CFS is an integrated part it?
2. How do healthcare professionals experience the clinical consultation when a PRO/CFS is an integrated part of it?

METHODS

Design

This paper describes the design of a PRO/CFS that will be implemented in the bariatric surgery outpatient clinics at Førde Hospital Trust and St. Olav Hospital Trust in Norway, and a plan for evaluating the feasibility of this intervention. The aims of the planned study are to evaluate experiences of patients and healthcare professionals with the consultations, using quantitative and qualitative methods. The quantitative assessment of patients' experiences started August 2019 and will be completed during

Table 1 The organisation of the bariatric surgery follow-up in the two outpatient clinics

Helse Førde Hospital Trust	St. Olav Hospital Trust
First contact with the specialist healthcare services Patients attend a one-day preoperative information course. A bariatric surgeon, nutritionist, physical therapist, psychologist and bariatric outpatient nurse provides information about BS and a lifestyle intervention programme during the course.	***First contact with the specialist healthcare services*** Patients seeking BS have a consultation with a physician and a nurse during which the choice of treatment is decided.
Patients who seeks BS as preferred treatment are referred to a psychologist for a mental health assessment before surgery.	Patients eligible for BS attend mandatory group sessions over 4 months, where a physician, psychologist, nurse and nutritionist educate the patients.
The patients meet for a preoperative consultation with a bariatric surgeon and a nurse, where the best choice of treatment for the patient is decided.	After the mandatory group sessions, the patient will meet with the surgeon for preoperative information.
Follow-up after surgery At: ► 6 weeks, telephone consultation with a nurse; ► 3 months, consultation with a bariatric surgeon and a nurse; ► 6 and 12 months, consultation with a nurse; ► 12–18 months, a one-day group-based course at the outpatient clinic; ► 24, 60 and 120 months, consultation with a nurse. Other healthcare specialities are consulted as needed. The GP is intended to follow up the patient yearly in between.	***Follow-up after surgery*** At: ► 1 week, telephone consultation with a nurse; ► 6 weeks, consultation with a bariatric surgeon; ► 1–3 months, one group session with a nutritionist; ► 6 months, consultation with a nutritionist; ► 12 months, consultation with a medical doctor; ► 24 months, consultation with a medical doctor; ► 36, 48 and 60 months, consultations with a nurse.

BS, bariatric surgery; GP, general practitioner.

December 2022. For the qualitative inquiries, we plan to recruit informants and conduct the focus-group interviews during autumn 2020.

Patient and public involvement

Two patients have been involved in choosing the appropriate questionnaires in the PRO/CFS and have also been involved in the pilot-testing of the PRO/CFS.

The standard bariatric care programme at the outpatient clinics

Patients with severe obesity are referred from their general practitioner (GP) to the bariatric outpatient clinic. An evaluation of the best choice of treatment to the individual patient (surgical vs non-surgical treatment) is then performed by the specialist healthcare services. Furthermore, the preparation before surgery and the follow-up consultations in the two outpatient clinics are somewhat different from each other (see table 1 for further details).

Designing the PRO/CFS

Because user involvement is a key element in evidence-based medicine,[15] to ensure that the research is relevant and ecologically valid for users of the services,[16 17] we had a panel consisting of two patients who had undergone bariatric surgery, and one nurse working at the bariatric outpatient clinic to assist in the design of the PRO/CFS. The panel also included three researchers with experience in obesity treatment and research. One of the nurse researchers (PhD) had a combined position in obesity outpatient clinic and research, whereas the other two (PhD student and Professor) worked as researchers.

The purpose of the included questionnaires was that they should be clinically relevant for both patients and healthcare professionals, facilitate patient-centred care and improve patient-clinician communication. To achieve this end patients, outpatient nurse and researchers held a workshop where the relevance and utility of each of the questionnaires were assessed. Special attention was paid to whether the questionnaires included aspects that the patients considered important for the follow-up, or if any questionnaires were found offensive for the patients.

Intervention

The theoretical basis for the intervention in this study is Feedback Intervention Theory (FIT),[18] which considers it important to have a discussion between the patient and healthcare professional, and focuses on the gap between the patient's current situation and an established benchmark. FIT is a theory commonly applied to the field of PRO/CFS implementation.[2]

The intervention is a digital PRO/CFS, composed of questionnaires assessing HRQOL,[19–21] mental health,[22] bowel-specific symptoms[23] and eating self-efficacy[24] (see online supplementary file 1 for details on the questionnaires).

The invitation letter asks the patients to complete the PRO/CFS prior to the consultation with a healthcare professional. The patients can enter the PRO/CFS via a link in the hospitals' web page, on either their own

computer or a tablet in the waiting area in the clinic. To access the system, we will use the highest public data security-level in Norway—password-protected two-factor authentication system. If the patient does not have access to this system, the healthcare professional can generate a unique login for the patient. The PRO/CFS platform is delivered by the manufacturer CheckWare in Norway.

Method for completing the PROMs

Using the PRO/CFS-software, the patients answer a set of questionnaires. As not all questionnaires include the possibility for the patient to answer *Not relevant/Do not want to answer*, the patient can choose not to respond to an item in all questionnaires except the Norse Feedback. If the patient has reported one or more *Not relevant/Do not want to answer* in the Norse Feedback, the average of the other items in the scale is shown in the summary report. In the other questionnaires, the average of the items is shown if >50% of the items are completed. On completion, a digital report becomes available for the healthcare professional. The report represents a summary of each questionnaire, colour-coded red, yellow and green (see online supplementary file 2). The responses in the red areas are domains in which the patient has the most concerns. The yellow responses are domains where the patient has some concerns and green responses are domains where the patient has few or no concerns. The thresholds for the colour categories are defined by norm-population standards, where available, or by the clinical judgement of the research group (see online supplementary file 1 for further details). The thresholds are set to be sensitive for impairment, as we find it important that the healthcare professionals do not overlook any concerns the patient may have. Prior to the consultation, the healthcare professional will be provided with an overview of the patient's responses, and during the consultation, the patient and the healthcare professional are instructed to begin by discussing the domains in which the patient has reported the most concerns (see figure 1). The different questionnaires incorporated into the PRO/CFS will be evaluated separately, within their separate interpretative frameworks during the consultations. The patient's responses from the current and earlier consultations are visualised in the same report, to enable evaluation of the patient's progression in treatment. The patient and the healthcare professional will agree on how to deal with any concerns that cannot be addressed adequately during the initial consultation. In most cases, the solution will be a detailed clinical report to the GP. If the concerns are urgent, the GP will be called to discuss further. In other cases, the healthcare professional may refer the patient to consult with the specialist healthcare services if this level of expertise is required. Another alternative is to offer the patient a new consultation with the healthcare professional at the obesity clinic.

Implementation phase

We will start the implementation of the PRO/CFS at Førde Hospital Trust.

Focus on change management is vital for a successful implementation of this intervention. To that end, we have secured management commitment in both outpatient clinics. Furthermore, informational sessions, training and follow-up is planned for all healthcare professionals at project launch and throughout the programme. We have planned up to 3 days of training of the healthcare professionals, depending on the needs of the individual. Average training duration will be measured.

Prior to implementing the project, a team of patients, outpatient nurses, and researchers will fill out the PRO/CFS to test the functionality and feasibility of the system. The outpatient nurse will receive further training to interpret the results from the report, and learn how to incorporate these findings in clinical conversations with the patient. Such training is recommended for a successful implementation.[25 26] Two researchers serving as proxy patients will conduct the training of the nurse. This training will have special attention on interpreting the mental health findings, as the assessment of the patient's mental health is more thorough than the healthcare

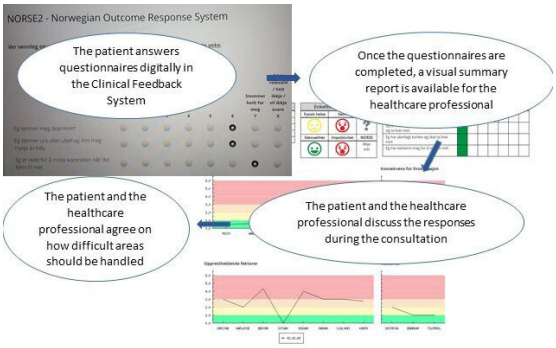

Figure 1 Flow diagram of the process and use of the patient-reported outcome monitoring with a clinical feedback system (PRO/CFS) in consultation between the patient and the healthcare professional in the bariatric outpatient clinic at two Norwegian hospitals.

professional has experience with. After implementation starts, the first author will join the initial patient consultations to guide the outpatient nurse in the interpretation and use of the PRO/CFS. Moreover, a person hired by the hospital to work on the implementation of PRO/CFS will be available to answer technical questions. The first author also will continue to join selected consultations to: evaluate adherence to the incorporation of patient-reported information in the clinical consultations; support the healthcare professional; serve as a fidelity check of how the feedback is being incorporated into the consultation. Such follow-up over time has been shown to be important to facilitate successful implementation in complex systems.[27] At St. Olav Hospital Trust, the implementation of the PRO/CFS will also include training of all involved healthcare professionals in how to interpret the report, and to incorporate these findings in the conversation with the patient. The healthcare professionals will have the assistance of a researcher with experience with the PRO/CFS, as well as technical support. Fidelity to the use of PRO/CFS is defined as the healthcare professional and the patient studying the summary report together and discussing the patient's responses during the consultation. Adherence to fidelity will be evaluated by the researcher attending the consultations. Furthermore, the healthcare professionals will complete a fidelity checklist for a random selection of consultations, and a separate question will be added to the Generic Short Patient Experiences Questionnaire (GS-PEQ) asking the patient whether feedback was given during the consultation.

Outcomes and analyses in the feasibility study

The aim of the study is to assess the feasibility of this PRO/CFS in bariatric surgery care. We plan to accomplish this by assessing patients' experiences using both quantitative and qualitative methods, and the healthcare professionals' experiences using qualitative methods. We will collect data on number of planned consultations, attrition to the follow-up, whether the patient has completed the PRO/CFS prior to the consultation and the presence of any missing data within the completed PRO/CFS. In addition, we record the proportion of consultations requiring contact with, or referral to, other healthcare specialties to assess how the PRO/CFS affects the course of the follow-up. The qualitative interviews and the quantitative findings of the experiences will be used to evaluate the utility of the PRO/CFS. Indications that PRO/CFS is operating as intended are if satisfaction with consultations are high as measured with GS-PEQ, and if the overall impression from the qualitative interviews is positive. An overall impression of dissatisfaction in the qualitative interviews or low scores in the GS-PEQ indicates a need for refinement of the PRO/CFS.

Quantitative assessments and analyses of patient experiences

The GS-PEQ[28] is a set of 10 core items developed to measure patient-reported experience measures in different somatic and psychiatric health services in Norway. We will use the version validated for use in somatic outpatient services, which consists of 12 items measuring experiences regarding information and communication (eg, *Did the clinicians talk to you in a way that was easy to understand?*), whether the patient had any influence on the treatment (eg, *Were you involved in decisions regarding your treatment?*) and the perceived benefit from the treatment (*Overall, was the help and treatment you received at the institution satisfactory?*). The items are rated on a 5-point scale ranging from *Not at all* to *To a very large extent*. The items will be analysed separately, without a total score, and the responses *To a large extent* and *To a very large extent* will be regarded as an indication that the PRO/CFS is operating as intended. We will pay special attention to the following four questions: *Did the clinicians talk to you in a way that was easy to understand?; Did you perceive the treatment as adapted to your situation?; Were you involved in decisions regarding your treatment?* and *Overall, was the help and treatment you received at the institution satisfactory?* as indicators of the utility of the PRO/CFS. This questionnaire will not be incorporated in the PRO/CFS but will be answered by pen and paper after the consultation and delivered to the healthcare professional in a closed envelope.

The patients' experiences will be presented through descriptive statistics. Further, their associations in relation to gender, age, body mass index, HRQOL, complications of the surgery and bowel symptoms (from the Gastrointestinal Symptoms Rating Scale) will be investigated using univariate and multivariable regression analyses. Analyses will be conducted on patients with at least 1 year of follow-up after surgery. Given sample size=100, power=0.8 and p=0.05, the study would be able to detect an unadjusted standardised coefficient=0.27 (G*power 3.1.9.4). This corresponds to a small effect size.[29] The computer software IBM SPSS statistics[30] will be used for the statistical analyses.

Qualitative inquiries into patients' and healthcare professionals' experiences with PRO/CFS

We plan to conduct separate focus group interviews of patients and healthcare professionals in the obesity outpatient clinic to explore their experiences when the PRO/CFS is an integrated part of the consultation. Focus group methodology is particularly apt for health service research, as different participants can expand on each other's perspective in formulating their experiences in the shared context. The participants for the focus group interviews will be recruited from obesity outpatient clinics at the two hospitals. The patients will be recruited by clinical staff, whereas the healthcare professionals will be recruited on an information meeting, followed by an invitation on email. We plan to report how many patients and healthcare professionals are invited to the study, and how many accept/decline to participate.

We plan four focus group interviews with patients, two from each outpatient clinic, and one focus group with healthcare professionals in the initial data collection. We plan to accrue six to eight participants in each group.

Follow-up focus groups will be implemented after 12 months. The interviews will be audio-recorded and transcribed verbatim for analyses.

A researcher will serve as the moderator of the focus groups, and a co-researcher will be present to take notes and handle the audio-recording. The role of the moderator is to make sure that all participants get to tell their story, to stimulate interaction between different perspectives in the group and to make sure that the conversations relate experiences relevant to the research questions. The interviews will be implemented within the hospital areas, but not in the outpatient clinic. This will be done to allow the participants to convey their own perspectives. We will prepare a brief introduction stating the aim of the conversation, and a schedule of open-ended questions for the group to discuss. An interview guide will be developed in collaboration with patient-representatives and an outpatient nurse (see online supplementary file 3 for interview guide). We will conduct a pilot interview to evaluate the relevance of the interview guide.

For analysis of the transcribed data, we plan to apply systematic text condensation (STC),[31] where we will synthesise the data in four steps. STC is a structured qualitative method for analyses that is well documented for research in medical settings. The first step is to get an overall impression of the transcribed text to get familiar with the content and create themes. The next step is to identify units of meaning and code these to sort out units of text related to each other. The third step is to abstract the units of text into a condensate of units from the different participants. In the final step, the content from the condensates are synthesised, which means that the condensates are interpreted by the researches. The interpretation must be loyal to the voices of the participants, and at the same time be influenced by the researcher's interpretation.[31] We will have two researchers conducting the analyses separately and come to agreement through discussion. In addition, we will present the anonymous transcribed interviews and the preliminary analyses to an experienced qualitative researcher, to perform the role of independent critical auditor, to secure correspondence between results and data.[32]

DISCUSSION

The purpose of this project is to implement a PRO/CFS in bariatric surgery care. We aim to explore the patients' and healthcare professionals' experiences with consultations, where PRO/CFS is an integrated part of the clinical conversation.

Structured assessment

This project is a novel approach to meeting the challenges of a structured assessment of patients' HRQOL and mental health, as called for by both patients and healthcare professionals, and highlighted in guidelines for follow-up after bariatric surgery.[12 14] The measures of mental health symptoms are more thorough than the measures previously used in this patient population in Norway. The multidimensionality of Norse Feedback ensures that clinical constructs are not evaluated alone but are viewed through their relationships with other clinical dimensions within the measure, the patient's ability to change and social support. This means, for example, that two patients who have the same symptom load on depressive symptoms but experience their situations differently because one has good social support whereas the other has not, are viewed differently. Furthermore, for a patient with an elevated suicidality score, the situation will often be more concerning if he or she at the same time has elevated scores in the scales Hopelessness and Social avoidance, than if he or she scores low on these same scales. We hypothesise that this will allow for a more detailed understanding of mental health processes and better decisions in the clinical conversation.

Because the PRO/CFS incorporates questionnaires assessing diverse issues related to bariatric surgery, such as bowel symptoms and eating self-efficacy, the battery of questionnaires will make the PRO/CFS clinically relevant to the patients and healthcare professionals.

PRO/CFS methodology

To simplify the integration of PROMS in clinical consultations, we have chosen a digital PRO/CFS, as this has the advantage of instant and easy to interpret summary reports.[1] The summary report from the PRO/CFS is colour-coded to make the results more comprehensible for patients and healthcare professionals in order to facilitate more active use of the PROMS during consultations. The active use of the PRO/CFS methodology that focuses on the feedback process is an important aspect of the FIT, as described by Kluger and DeNisi,[18] as feedback has been found to improve communication between patients and healthcare professionals[3] and to improve treatment outcomes.[33 34] Patients have also emphasised the importance of feedback and discussion about their responses.[7] Through this conversation the healthcare professional can address the topics and highlight whether the patient's responses have changed surprisingly in one way or another.

Technology as a barrier

As described by Bradley *et al*,[35] technology can be a barrier for patients and healthcare professionals. This might affect how patients respond to the questionnaires, as well as whether they complete the PRO/CFS prior to the consultation. However, our initial experiences are that the system is easy to log into and navigate. Most patients are familiar with using tablets in their daily life. As an attempt to overcome this potential barrier, we have secured technical support for the healthcare professionals, as well as training for them about using the system and interpreting the PRO/CFS results. A recent qualitative study which explored the implementation of Norse Feedback found that training and support were important for the clinicians to incorporate the PRO/CFS in consultation.

The psychologists reported that learning and incorporating a new technological system was challenging in their everyday work, and characterised it as an overwhelming workload.[36]

Strengths and limitations

The PRO/CFS package chosen for this project needs to be adapted and validated for the population of patients in surgical treatment for obesity, as its relevance to the patients and healthcare professionals is crucial for the PRO/CFS to be useful.[37 38] A strength of this project is the involvement of both patients and healthcare professionals who, in collaboration with researchers, will design and evaluate the PRO/CFS. This involvement of patient representatives and outpatient nurses is considered important for producing the final version of the PRO/CFS—thereby increasing the ecological validity of this project. Other strengths include tutoring healthcare professionals about how to incorporate the PRO/CFS in clinical conversations with patients, and the availability of both technical and methodological support.

The two outpatient clinics have organised their bariatric care differently, as the clinic at St. Olav Hospital has a mandatory course for the patients over 4 months before surgery. Furthermore, at Førde Hospital Trust the patients always have consultations with a nurse, and the surgeon meets the patients after 3 months and is consulted when it is beneficial for the patient. These differences in the organisation of bariatric care may strengthen the generalisability of the quantitative findings, as the results of the study will not be solely determined by the characteristics of a single clinic. Such differences may also contribute to richer findings in the qualitative inquiries. However, a potential limitation is that patients in one clinic meet primarily with the same healthcare professional, whereas patients at the other clinic meet with a larger number of healthcare professionals. It is possible that as more healthcare professionals are involved, there may be greater variability in how the PRO/CFS is used. We need to be aware of these differences when reporting results from the study. Furthermore, the recruitment of patients for the qualitative interviews may result in a selection bias. We will be aware of this possible bias when conducting the interviews and synthesising the findings, and report this as a potential limitation of the study.

In this project, we do not conduct a quantitative measure of how the healthcare professionals manage the feedback process, display provider empathy or demonstrate self-efficacy. This may represent a limitation. However, these aspects will be addressed during the qualitative inquiries.

Future perspectives

If we find that PRO/CFS is appropriate in bariatric surgery follow-up, and that patients and healthcare professionals believe it adds value to the consultations, the effectiveness of the PRO/CFS will be tested on a larger scale, preferably as a randomised controlled trial. Whether some clinicians use feedback in a more effective way than others, demonstrate greater provider empathy, create a stronger working alliance or demonstrate self-efficacy will be important measures when we test the PRO/CFS on a larger scale.

In conclusion, PRO/CFS may be a useful tool for the structured assessment of HRQOL and mental health before and after bariatric surgery. The consultations at the outpatient clinic are intended to be more patient-centred and may thus improve the follow-up rates over time at clinical consultations. As obesity is considered a complex chronic disease, and the positive effects of bariatric surgery go beyond weight loss in itself, a patient-centred model for follow-up is recommended.[39] Ultimately, using PRO/CFS in clinical consultations may lead to improvements in patients' mental health and HRQOL after bariatric surgery.

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Supplementary file 1 Patient-reported outcome measures included in the PRO/CFS

Obesity-specific HRQOL

The Obesity-related Problems Scale (OP) is an 8-item HRQOL questionnaire measuring how obesity affects psychosocial functioning. It includes eight aspects of psychosocial functioning with a 4-point scale that has response categories ranging from *Definitely not bothered* to *Definitely bothered*. The scores range from 0 to 100, where lower scores indicate better psychosocial functioning. The eight individual items are useful in the clinical conversation with the patient. The questionnaire has been used in a Norwegian setting. Based on recommendations from the developer, cut-off levels for the summary report were set as follows: A score under 19 was designated green, 20-59.9 yellow, and 60-100 red. (Karlsson, J., Taft, C., Sjostrom, L., Torgerson, J. S., & Sullivan, M. (2003). Psychosocial functioning in the obese before and after weight reduction: construct validity and responsiveness of the Obesity-related Problems scale. *International Journal of Obesity, 27*(5), 617-630).

The Patient Reported Outcomes in Obesity (PROS) is a 10-item questionnaire measuring the impact obesity has on a person's daily life. It was developed and validated in a Norwegian setting. The questionnaire has eight questions on daily activities and two questions on the consequences of bariatric surgery, such as negative side effects and excess skin. The response categories are rated on a 4-point scale from *Considerably bothered* to *Not bothered*. The total score can be used to discuss overall obesity-specific HRQOL; however, the individual scores are preferred for use in clinical consultation as they give more specific information about the source of the negative impact of obesity. In addition to the 10 items measuring HRQOL, the questionnaire has one question on social support and one on overall treatment satisfaction, both measured on 4-point scales, with the response categories *Very satisfied*, *Satisfied*, *Unsure* and *Dissatisfied*. In the summary report each item is presented with set cut-off values as follows: *not bothered* green, *mildly bothered* yellow, and *moderately* and *considerably bothered* as red.

Generic HRQOL

The Short Form-36 (SF-36), Norwegian version 1.2, is a 36-item questionnaire measuring HRQOL, which is widely used for research on obesity. The questionnaire has eight dimensions of physical and mental functioning, with a total score ranging from 0 to 100,

where higher scores indicate better HRQOL. The dimensions are divided in two summary-scores — the Physical Component Score (PCS) and the Mental Component Score (MCS) — based on factor analysis with oblique rotation. For the analyses of both the sub-scores and summary scores, we used T-scores where a score of 50 approximates the average of the general population. Thresholds for the cut-off values in the summary report were set according to the norm-score (T-score 50), and previous research on clinical significance of impairment. This resulted in cut-off values as follows: Over 45 was designated as green, 42.1-45.0 yellow and under 42.0 red. (Loge et al., 1998).

Mental health

Norse Feedback (NF) is a multidimensional computer-adaptive questionnaire developed primarily to assess PROMS for use in mental health treatment (20). Structured interviews of the needs of patients and clinicians in treatment for mental health disorders were the basis for the development of Norse Feedback. Responding to clinicians' and patients' needs, Norse Feedback aims to measure discrete clinical phenomena, such as sad affect, rumination and interpersonal problems, for use in clinical conversations. In turn, multidimensional patterns of scores on discrete scales form hypotheses of higher order constructs, such as depression in a diagnostic context. Moreover, the measure adapts to the individual's presentation after an initial broad screening.

In addition to the factorial structure of the measure, information values within constructs for individual items in the questionnaire are evaluated through item-response theory (30, 31). The questionnaire consists of 93 items assessing symptoms related to mental health and addiction. Norse Feedback assesses 20 different dimensions in four domains (symptom expression, dysfunctional processes, functional consequences and resources). The questions use 7-point response categories, which range from *Is not correct for me at all* to *Is correct for me;* the patient can also choose the response *Not relevant/do not know/refuse to answer*.

The visual report of the NF is presented as raw scores in the obesity setting. Visually the categories green, yellow and red are carried over from a mental health treatment setting. In mental health the Y-axis presents standard deviations from a norm population, matching the colour categories. In this project, the presentation as raw scores in the summary report was chosen to represent face valid information for the healthcare professionals in the exploratory phase. Through the current project, data for establishing new standard deviations for a patient

population after bariatric surgery will be collected, and a presentation where Y-axis and colour categories match will result.

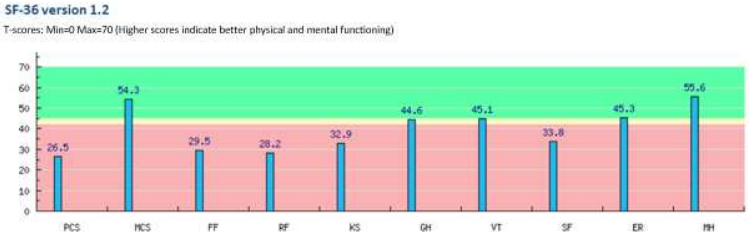
Eating self-efficacy

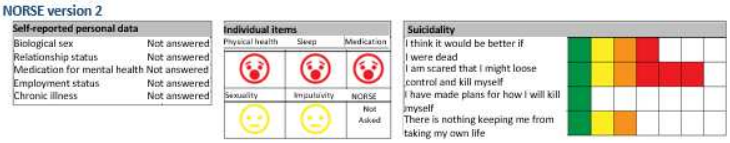
The Weight Efficacy Lifestyle Questionnaire - Short Form (WEL-SF) is a questionnaire that measures the confidence patients have in their ability to resist overeating in various situations. There are eight questions that are rated on a 10-point scale, from *Not confident* to *Very confident* about their eating self-efficacy, with a total score ranging from 0 to 80. Higher scores indicate better eating self-efficacy. The questionnaire is used for patients after bariatric surgery in Norway. Based on clinical judgement, we defined the following thresholds in the summary report: 70-80 green, 60-69.9 yellow, and under 60 red.

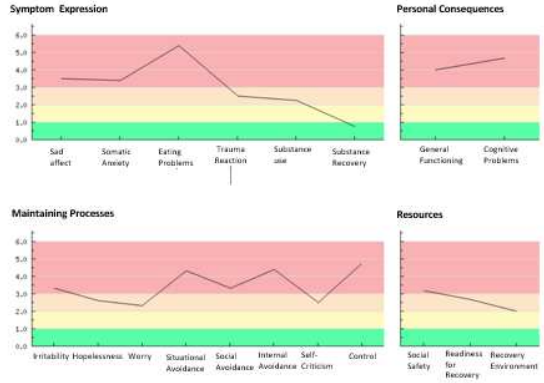
Bowel symptoms

The Gastrointestinal Symptoms Rating Scale (GSRS) measures gastrointestinal symptoms relevant to patients after bariatric surgery. The questionnaire measures 15 bowel symptoms on a 7-point scale (ranging from 1 to 7), with response categories ranging from *Not bothered at all* to *Severely bothered*. The 15 symptoms can be interpreted as 5 dimensions; *Abdominal pain*, *Reflux*, *Indigestion, Diarrhoea* and *Constipation*, or a total score that ranges from 15 to 105. The questionnaire has been used for research on patients after bariatric surgery in Norway. For the colour categories in the summary report we set the following thresholds for cut-off of the five dimensions, based on clinical judgement: 3-6 green, 9-12 yellow, and 15-21 red.

Supplementary file 2. The visual report available for the healthcare professional after the patient has completed all questionnaires in the PRO/CFS* at two Norwegian Hospitals







*PRO/CFS = Patient-reported outcome monitoring with a clinical feedback system

Datatilsynet

Villy Våge
Kirurgisk avdeling
Førde Sentralsjukehus
6807 FØRDE

Deres ref	Vår ref (bes oppgitt ved svar)	Dato
200200738 GHA/RH	2002/1732-2 RVB/-	15.10.02

KONSESJON TIL Å BEHANDLE HELSEOPPLYSNINGER

Datatilsynet viser til Deres søknad av 30.08.2002, innsendt av Norsk samfunnsvitenskapelig datatjeneste 20.09.2002 om konsesjon til å behandle helseopplysninger.

Datatilsynet har vurdert søknaden og gir Dem med hjemmel i helseregisterloven § 5, jf. personopplysningsloven § 33, jf. § 34, konsesjon til å behandle helseopplysninger til følgende formål: Prosjektet "Kirurgisk behandling av sjukleg overvekt".

Konsesjonen er gitt under forutsetning av at behandlingen foretas i henhold til søknaden og de bestemmelser som følger av helseregisterloven med forskrifter.

Dersom det skjer endringer i behandlingen i forhold til de opplysninger som er gitt i søknaden, må dette fremmes i ny konsesjonssøknad.

I medhold av helseregisterloven § 5, jf. § 36, jf. personopplysningsloven § 35, fastsettes i tillegg følgende vilkår for behandlingen:

1. Den databehandlingsansvarlige skal hvert tredje år sende Datatilsynet bekreftelse på at behandlingen skjer i overensstemmelse med søknaden og helseregisterlovens regler.

Med hilsen

Knut-Brede Kaspersen (e f)
avdelingsdirektør

Rune V. Bråthen
rådgiver
(saksbehandler,
telefon 22 39 69 07)

Kopi : - Datafaglig sekretariat, Bergen

Postadresse:	Kontoradresse:	Telefon:	Telefaks:	Org.nr:	Hjemmeside:
Postboks 8177 Dep 0034 OSLO	Tollbugt 3	22 39 69 00	22 42 23 50	974 761 467	www.datatilsynet.no

Norsk samfunnsvitenskapelig datatjeneste
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Villy Våge
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6807 FØRDE

Prosjektnummer : 9372

Vår dato: 20.09.2002 Vår ref: 200200738 GHA / RH Deres dato: Deres ref:

FORSKNINGSPROSJEKT SOM OMFATTES AV KONSESJONSPLIKT

Vi viser til mottatt meldeskjema, 10.09.2002, for behandling av personopplysninger. Prosjektet utløser konsesjonsplikt i henhold til Lov om behandling av personopplysninger § 33, første ledd. All nødvendig informasjon om prosjektet forelå i sin helhet 19.09.2002.

Søknaden er behandlet ved Datafaglig sekretariat og ble oversendt Datatilsynet 20.09.2002 for endelig behandling av konsesjonssøknaden. Datafaglig sekretariat har anbefalt at prosjektet gis konsesjon. Datatilsynet opplyser overfor Datafaglig sekretariat at saksbehandlingstiden er ca. fire uker. Vi gjør oppmerksom på at datainnsamling ikke kan startes før konsesjon fra Datatilsynet foreligger.

Dersom noe er uklart ber vi deg kontakte oss, gjerne over telefon.

Kopi av innstilling følger vedlagt.

Kontaktperson: Grethe Halvorsen tlf: 55583542

Vennlig hilsen
Datafaglig sekretariat

Bjørn Henrichsen

Grethe Halvorsen
Grethe Halvorsen

Innstilling til Datatilsynet

§ 33

Melding mottatt Datafaglig sekretariat:
10.09.2002
Innstilling oversendt Datatilsynet:
20.09.2002
Saksbehandler:
Grethe Halvorsen 55583542

Behandlingsansvarlig

Villy Våge

Kirurgisk avdeling
Førde Sentralsjukehus

6807 FØRDE

Databehandler

Villy Våge

Kirurgisk avdeling
Førde Sentralsjukehus

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9372 Kirurgisk behandling av sjukleg overvekt

FORMÅL
Formålet med prosjektet er å opprette et pasientregister:
1. For å kunne overvåke konsekvenser og resultat av kirurgisk behandling av sykelig overvekt (kvalitetskontroll og behandling).
2. Som vil bli benyttet til forskning om overvekt og behandling av overvekt.

Operasjonen som pasientene gjennomgår utføres uavhengig av etableringen av registeret. Det er derfor kun etableringen av registeret som meldes.

UTVALG
Utvalget består av pasienter som henvises til Førde sentralsjukehus for kirurgisk behandling av sykelig overvekt. Inklusjonskriteriene er:
- Kroppsmasseindeks > 40 (definert som kg/m2) eller
- kroppsmasseindeks 35- 40 med alvorlig comorbiditet som kan bedres med vektreduksjon. Dette kan være alvorlig kardiopulmonal tilstand (alvorlig søvn apne, Pickwickian syndrom, cardimyopati), diabetes mellitus type II, fysiske problem på grunn av overvekten (leddsykdom, vanskeligheter med yrke- eller familieforpliktelser)
- Alder mellom 18 og 55 år. Over denne alderen vil spørsmålet om inklusjon vurderes individuelt.
- Motiverte pasienter som er i stand til å samarbeide.
Pasienter som har en sykehistorie med alkoholmisbruk eller alvorlig psykiatrisk sykdom ekskluderes.

På bakgrunn av henvisningen blir pasientene vurdert av lege ved sentralsykehuset. Etter vurderingen får pasientene skriftlig innkalling til operasjonen. Førstegangskontakt med pasientene angående registeret vil bli foretatt ved at et informasjonsskriv legges ved innkallingen til operasjon. På den måten får pasienten flere uker å bestemme seg på om han eller hun ønsker å bli registrert.

Det vil kontinuerlig bli registrert pasienter i registeret. Prosjektleder anslår 25- 35 pasienter per år.

DATAINNSAMLING
Opplysningene samles inn gjennom spørre- og registreringsskjema. Opplysningene samles inn før og etter operasjon. Opplysningene som registreres omfatter kjønn, alder, sivilstatus, utdanning, hvor pasienten får sin inntekt fra, sykdommer, medisinbruk, kliniske data, biokjemiske data og operasjonstekniske data (se vedlagte spørre- og registreringsskjema).

Når det gjelder opplysningene om hvor pasienten får sin inntekt fra, utdanning og sivilstatus opplyser prosjektleder om at dette er opplysninger som alltid dokumenteres i sykejournaler. I forhold til behandling av overvekt er dette relevante variabler i forhold til behandlingens effekt. For eksempel kan behandlingen vise seg å få noen pasienter fra uføretrygd og over i arbeid.

I tillegg til dette tas blod- og urinprøver 1, 3, 6, 9, 12 og 24 måneder etter operasjon, og deretter årlig livet ut. Dette på grunn av at operasjonen medfører dårligere opptak av næringsstoffer, og at langtidseffekten av dette ikke er kjent.

Prosjektleder ønsker også å registrere bilde av pasienten. Dette for å bedre kunne huske pasienten.

Det registreres sensitive opplysninger i form av helseopplysninger (jf. Pol § 2 pkt. 8 c).

REGISTRERING OG OPPBEVARING
Opplysningene registreres på pc i nettverk. Prosjektleder ønsker å registrere direkte personidentifiserbare opplysninger sammen med det øvrige datamateriale. Prosjektleder opplyser om at dataene vil lagres, oppbevares og behandles som alle andre sykehusdata, det vil si i henhold til sykehusets sikkerhetsprosedyrer, og at det er kun de som behandler pasientene som vil ha tilgang til dataene.

Opplysninger som sendes over fra primærlegene til sykehuset sendes som andre pasientdata, det vil si med vanlig post. Prosjektleder opplyser om at dette er vanlig prosedyre for oversendelser av pasientdata.

Det er ikke satt noen dato for hvor lenge registeret skal eksistere. Som nevnt over må pasientene følges livet ut.

Alle forskningsprosjekt som skal gjøre bruk av opplysninger fra registeret meldes til Datatilsynet. (NSD) Bergen

INFORMASJON OG SAMTYKKE
Ved operasjoner ved norske sykehus er det vanlig å gi muntlig informasjon om selve operasjonen, fordeler og risiko. Ved denne operasjonen gis pasientene i tillegg skriftlig informasjon. Dette er informasjon som som sagt gis i tilknytningen til den medisinsk behandlingen og derfor uavhengig av etableringen av registeret.

Pasientene får skriftlig og muntlig informasjon om etableringen av og innsamlingen av opplysninger til registeret. Informasjonsskrivet gjør rede for alle sider av prosjektet.

KOMMENTAR
Førde Sentralsjukehus er det første sykehuset som tar i bruk denne typen behandling mot overvekt. Prosjektleder opplyser om at det derfor er viktig å få dokumentert behandlingseffektene. Opprettelsen av et register som kan brukes både til kvalitetskontroll og forskning vil være et viktig virkemiddel i så henseende.

Opplysningene kan registreres med hjemmel i Pol § 8 første ledd og § 9 pkt. a. Pasientene informeres om alle sider ved opprettelse av registeret og samtykker til deltakelse.

I og med at pasientene må følges livet ut skal registeret eksistere på ubestemt tid. Pasientene følges opp årlig med kontroller. Det innebærer at pasientene har flere konkrete muligheter til å trekke seg fra registeret, samtidig med at prosjektleder har flere muligheter til å komme i kontakt med pasientene ved rekruttering til forskningsprosjekt.

Regional komité for medisinsk forskningsetikk- Helseregion Vest, har uttalt til prosjektleder at innsamlingen av opplysningene og etableringen av registeret ikke skal meldes dem. Alle forskningsprosjekt som gjør bruk av registerdata skal imidlertid meldes på vanlig måte.

ANBEFALNING
Datafaglig sekretariat anbefaler at prosjektet gis konsesjon med hjemmel i Helseregisterloven § 5, Pol § 33.

REGISTER FOR PASIENTAR BEHANDLA MED KIRURGI FOR SJUKLEG OVERVEKT

Informasjonsskriv med samtykkeerklæring

Formål:
For lettare å kunne ha oversikt over endringar i sjukdomsbiletet, endringar i blodprøver, evt. biverknader av behandlinga som kan krevje behandlingstiltak for den einskilde pasient ynskjer vi å nytte eit register der slike opplysningar vert registrerte kontinuerleg på ein systematisk måte saman med pasientopplysningar. For lettare å kunne hugse den einskilde pasient ynskjer vi også å arkivere eit bilete av deg i registeret.

Opplysningane vil og verte nytta for å overvåke og presentere resultata av denne behandlinga generelt (klinisk forskning). Registeret vil kunne nyttast til vidare forskning om overvekt og behandling av overvekt, og vil eventuelt kunne koplast til andre registre om helse og sjukdom. Forskning som skal gjerast med utgangspunkt i registeret vil bli meldt til Datatilsynet og eventuelt regional etisk komite.

Innhenting av opplysningar:
Føre operasjonen vil opplysningane bli innhenta av den kirurgen som skal operere deg (pasientansvarleg lege), etter operasjonen vil opplysningane bli innhenta av den lege som kontollerar deg. Informasjonen vil bli sendt vidare til behandlingsansvarleg lege.

Behandlingsansvarleg og dataansvarleg lege
Dr. Villy Våge, kirurgisk avdeling, Førde Sentralsjukehus, 6807 FØRDE, tlf 57839000

Frivillig
Det er frivillig om du vil delta, og det vil ikkje få konsekvensar for behandlinga di om du let vere å delta. Du har til ei kvar tid rett til å trekke deg frå registeret utan å måtte oppgje grunn for dette, og utan at dette får konsekvensar for deg. Sidan pasientar operert for sjukleg overvekt i prinsippet skal følgast opp med kontrollar livet ut ynskjer vi å oppretthalde registeret på ubestemt tid.

Konfidensielt
Alle opplysningar vil bli behandla konfidensielt. Opplysningane vil kun kunne sjåast av helsepersonell som direkte er involvert i behandlinga av deg. Rapportar / publikasjonar med bakgrunn i dette registeret vil ikkje kunne sporast attende til den einskilde pasient. Registeret er godkjent av datatilsynet.

Eg har motteke skriftleg og muntleg informasjon og er viljug til å bli med i registeret.

_____	_____	_____
Dato	Namn (pasient)	Signatur (pasient)

I tilfelle samtykke:
Original av informasjonsskriv med samtykkeerklæring skal leggast i journal.

UNIVERSITETET I BERGEN
Regional komité for medisinsk og helsefaglig forskningsetikk, Vest-Norge (REK Vest)

Villy Våge
villy.vage@helse-forde.no
Kirurgisk avdeling, Førde Sentralsjukehus

Kopi:
Forskingsansvarleg: post@helse-forde.no
Biobankregisteret: biobankregisteret@fhi.no

Vår ref	Dato
2009/2174	10.12.09

Ad. prosjekt: Helse og livskvalitet før og etter kirurgisk behandling for sjukleg overvekt (2009/2174)

Ein syner til din prosjektsøknad, dagsett 09.11.09.

Komiteen handsama søknaden i møte 26.11.09.

Forskingsansvarleg for prosjektet er Helse Førde HF. REK Vest føresetjar at dette vedtaket vert lagt fram før den forskingsansvarlege til orientering. Sjå helseforskingslova § 6, jfr. § 4 bokstav e.

Føremålet med denne prospektiv kohortstudien er å skaffe kunnskap om korleis kirurgisk behandling av sjukleg overvekt påverkar stoffskiftet og korleis pasientar opplever eiga helse og livskvalitet før og etter behandling. Datagrunnlaget vil bestå av sjukdomshistorier, kliniske undersøkingar, blodprøvar og ulike spørjeskjema.

REK Vest finn prosjektet interessant og meiner det har eit viktig formål. Komiteen hadde gjerne sett at studien også hadde inkludert undersøking om psykisk helse.
Ein har ingen innvendingar mot at det vil bli oppretta ny spesifikk forskingsbiobank eller at avidentifiserte prøver vert send til Finland som del av eit internasjonalt analysesamarbeid.

Komiteen meiner setninga " Pasienten har sjølv eit ansvar for å passe på at kontrollane vert utført til rett tid." i informasjonsskrivet må bli sletta. Det er rimeleg at pasienten får ein innkalling til kontrollane.
Nokre mindre feil i informasjonsskrivet bør bli korrigert – sjå vedlegg.

Det vert søkt om å oppbevare datamateriale saman med personidentifikasjon etter prosjektslut i 04.01.2023. Når det gjeld oppbevaring av datamateriale skal helseopplysningane som vert nytta i prosjektet ikkje oppbevarast lenger enn det som er

nødvendig før å gjennomføre prosjektet. Komiteen set som vilkår at opplysningane vert sletta eller anonymisert etter prosjektslut.

Vedtak:

- *Prosjektet vert godkjent dersom nemnte vilkår blir tatt til følgje.*
- *Forskingsbiobanken* "Helse og livskvalitet før og etter operasjon for sjukleg overvekt" *vert godkjend i samsvar med innsendt søknad. Godkjenninga gjeld inntil 5 år etter at prosjektet er avslutta.*
- *REK Vest godkjenner utførsel av avidentifisert biologisk materiale til Finland.*

Komiteen ber om å få tilsendt slutrapport evt. trykt publikasjon for studien.

Vennleg helsing

Jon Lekven
leder

Camilla Gjerstad
rådgjevar

Ny ordning fra 01.07.09:

En gjør oppmerksom på at denne søknaden er vurdert i henhold til helseforskningsloven, som ble satt i kraft 01.07.09. Dette innebærer at REK fra og med denne dato har kompetanse til å godkjenne opprettelse og endring av forskningsbiobank, å innvilge dispensasjon fra taushetsplikt og å gi tillatelse til bruk av personopplysninger til forskning. Saker som er søkt Helsedirektoratet, NSD eller Datatilsynet vedrørende ovennevnte, vil utelukkende bli behandlet av REK. Dette for å unngå parallellbehandling av saker nå i overgangsfasen.

REK Vest forutsetter at dette vedtaket blir forelagt den forskningsansvarlige til orientering. Se helseforskningsloven § 6, jfr. § 4 bokstav e.

De regionale komiteene for medisinsk og helsefaglig forskningsetikk foretar sin forskningsetiske vurdering med hjemmel i helseforskningsloven § 10, jfr. forskningsetikkloven § 4.

Saksbehandlingen følger forvaltningsloven. Komiteenes vedtak etter forskningsetikklovens § 4 kan påklages (jfr. forvaltningsloven § 28) til Den nasjonale forskningsetiske komité for medisin og helsefag. Klagen skal sendes REK Vest (jfr. forvaltningsloven § 32). Klagefristen er tre uker fra den dagen du mottar dette brevet (jfr. forvaltningsloven § 29).

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK vest	Camilla Gjerstad	55978499	05.03.2012	2009/2439/REK vest
			Deres dato:	
			19.02.2012	

Vår referanse må oppgis ved alle henvendelser

Villy Våge
Kirurgisk avdeling
Førde Sentralsjukehus

2009/2439 Livskvalitet før og etter kirurgisk behandling av sjukleg overvekt

REK Vest syner til søknad om prosjektendring, datert 19.02.12.

Prosjektendring
Pasientar som vert operert for sjukleg overvekt ved Førde Sentralsjukehus kjem til kontroll ved sjukehuset eit, to, fem og ti år etter operasjonen. I denne aktuelle studien vart data på helserelatert livskvalitet samla inn før operasjonen, samt eit, to og fem år etter. Studien var tenkt avslutta ved femårskontrollen, men prosjektleiar ynskjer no å samle inn data på helserelatert livskvalitet også i samband med tiårskontrollen på sjukehuset.

REK Vest v/ leiar sakshandsama søknaden.
Vi har ingen merknader til endringsprotokollen. Informasjonsskrivet bør likevel bli forbetra med informasjon om korleis deltakar kan trekkje seg (kontaktinformasjon) og dato for når data vert sletta eller gjort anonyme. Skrivet skal merkast med logo til den forskingsansvarlege institusjonen og REK-nummer (2009/2439).

Vedtak
Prosjektendringa vert godkjent dersom dei nemnde vilkåra vert tatt til følgje.

Med vennlig helsing

Jon Lekven (sign.)
komitéleiar

Camilla Gjerstad
rådgjevar

Kopi til: *post@helse-forde.no*

Regelverk
Saksbehandsaminga følgjer forvaltningsloven. Du kan klage på komiteen sitt vedtak (jf. forvaltningsloven § 28) til Den nasjonale forskingsetiske komité for medisin og helsefag. Klagen skal sendast til REK Vest (jf. forvaltningsloven § 32). Klagefristen er tre veker frå den dagen du mottar dette brevet (jf. forvaltningsloven § 29). Dei regionale komiteane for medisinsk og helsefaglig forskingsetikk vurderar prosjektet med heimel i helseforskningsloven § 11, jf. forskingsetikkloven § 4. Vi ber om at alle søknader, tilbakemeldingar eller spørsmål sendes inn via vår saksportal: http://helseforskning.etikkom.no eller på e-post til: post@helseforskning.etikkom.no. Vi ber om at du merker korrespondansen med referansenummeret.

Besøksadresse: Haukeland Universitetssykehus, Sentralblokken, 2. etg, Rom 4617
Telefon: 55975000
E-post: rek-vest@uib.no
Web: http://helseforskning.etikkom.no/

Helse Førde

Forespørsel om deltakelse i forskningsprosjektet
"Helse og livskvalitet før og etter kirurgisk behandling for sykelig overvekt"

Bakgrunn og hensikt
Dette er en invitasjon til deg om å delta i en forskningsstudie for å undersøke helse og livskvalitet før og etter operasjon for sykelig overvekt. Bakgrunnen for dette er at vi ønsker å få mer kunnskap om effekter av behandlingen og hvordan denne oppleves. Målet er å ha kontinuerlig fokus på kvalitet og forbedring slik at pasienter som lider av sykelig overvekt kan få et enda betre behandlingstilbud.

Helse Førde er ansvarlig for studien.

Hva innebærer studien?
Studien innbærer at du gir oss tillatelse til at de helseopplysninger som uansett blir samlet inn om deg i forbindelse med behandlingen, kan brukes i dette forskingsprosjektet. Dette er for eksempel hvilke sykdommer du har, blodprøveverdier og kroppsvekt. Dersom du velger å delta i studien vil vi i tillegg ta en ekstra blodprøve samt at du svarer skriftlig på en del spørsmål om helse og livskvalitet.

Den ekstra blodprøven håper vi skal kunne gi oss kunnskap om hvordan stoffskifte endrer seg etter behandling for sykelig overvekt. Målet er at vi skal kunne få mer nøyaktig kunnskap om kroppens stoffskifte enn dagens blodprøver gir. Analysen av denne blodprøven må gjøres i Finland siden man ikke har det nødvendige utstyr for dette i Norge enda. Finske forskere som vi kjenner godt samarbeider derfor med oss om dette.

Spørsmålene om egen vurdering av ulike sider ved helse og livskvalitet tar omtrent 5-10 minutter å fylle ut. Alle spørsmål har avkryssingsalternativer. Spørreskjemaet fylles ut før operasjon samt 1, 5 og 10 år etter operasjonen.

Mulige fordeler og ulemper
Fordelen med å delta i studien er at vi får mer konkret kunnskap om hvordan behandlingen har virket på akkurat deg. Vi vet ikke om noen forhold som skulle medføre ulemper for deg med å delta i studien. All innsamling av opplysinger skjer i forbindelse faste undersøkelser. Merk at den ekstra blodprøven (et lite glass) tas i forbindelse med at du skal ta andre blodprøver.

Hva skjer med prøvene og informasjonen om deg?
Prøvene tatt av deg og informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste. Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten, og som kan finne tilbake til deg. Det vil

ikke være mulig å identifisere deg i resultatene av studien når disse publiseres. Når studien er ferdig vil alle opplysninger som er knytt til prosjektet bli slettet.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst, og uten å oppgi noen grunn, trekke ditt samtykke til å delta i studien. Data og prøver på deg blir da slettet. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på neste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling.

Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du ta kontakt med den ansvarlige for studien som er:

Villy Våge, overlege kirurgisk avdeling, Førde Sentralsjukehus, 6807 FØRDE, tlf: 57839274.

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Dato, Signatur)

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK nord			13.06.2018	2018/993/REK nord
			Deres dato:	Deres referanse:
			07.05.2018	

Vår referanse må oppgis ved alle henvendelser

Christian Moltu
Psykiatrisk klinikk

2018/993 NORSE: Klinisk tilbakemelding og psykometri i psykiske og somatiske helsetenester

Vi viser til søknad om forhåndsgodkjenning av ovennevnte forskningsprosjekt. Søknaden ble behandlet av Regional komité for medisinsk og helsefaglig forskningsetikk (REK nord) i møtet 31.05.2018. Vurderingen er gjort med hjemmel i helseforskningsloven § 10.

Forskningsansvarlig institusjon: Helse Førde HF
Prosjektleder: Christian Moltu

Prosjektleders prosjektomtale (original):
NORSE er eit andregenerasjons system for rutinemessig utkommemåling og klinisk tilbakemelding i helsetenester. NORSE har fått høg nasjonal og internasjonal merksemd, som dynamisk lærande og persontilpassa gjennom empiriske algoritmer. NORSE stiller pasientar spørsmål digitalt om korleis dei opplever ulike livsområder, behov i behandlinga og korleis dei opplever denne, på ein strukturert måte som gir valide målingar av lidingstrykk, ressursar og behov. Dette vert nytta i behandlingsplanlegginga. Klinisk tilbakemelding kan tredoble nytta av behandling for utvalde pasientgrupper i psykisk helsevern. Tidlege profilar kan predikere utfall og behandlingsbehov. I fedmebehandlingsfeltet er behovet for strukturert psykisk helsekunnskap ein nasjonal prioritet men kunnskapen låg. Prosjektet vil utvikle klinisk kunnskap som forbetrer tenester gjennom prediktive mønsteranalyser av behandlingsløp. Det vil utgreie kva behov for psykisk helsekunnskap som finnast i fedmefeltet, og prøve ut denne.

Framleggingsplikt
Søker beskriver at man gjennom dette prosjektet *«vil utvikle klinisk kunnskap som forbetrer tenester gjennom prediktive mønsteranalyser av behandlingsløp. Det vil utgreie kva behov for psykisk helsekunnskap som finnast i fedmefeltet, og prøve ut denne.»*

Søker beskriver datainnsamlingen slik:

«Prosjeketet samlar inn kliniske data i tre arbeidspakkar, på fastlegekontor, i psykisk helsevern og på fedmepoliklinikk i spesialisthelsetenesta, samt ein frisknormpopulasjon. Merk at pasientar som inkluderast i studien brukar dei inkluderte instrumenta som er brukt i deira vanlege kliniske kontekst, sett bort frå ei sub-gruppe som deltek med svar på yttarlegare nokre psykometriske instrument for å etablere konvergent validitet for Norse Feedback. Det vil seie at forskingsprosjektet ikkje vil krevja av pasientane ekstra innsats eller bidrag, utover det som dei nyttar seg av i behandlinga.»

De prosjektene som skal framlegges for REK er prosjekt som dreier seg om "medisinsk og helsefaglig forskning på mennesker, humant biologisk materiale eller helseopplysninger", jf. helseforskningsloven (h) § 2. "Medisinsk og helsefaglig forskning" er i h § 4 a) definert som "virksomhet som utføres med

vitenskapelig metodikk for å skaffe til veie ny kunnskap om helse og sykdom". Det er altså formålet med studien som avgjør om et prosjekt skal anses som framleggelsespliktig for REK eller ikke.

REK vurderer at prosjektet ikke faller innenfor helseforskningsloven. Datainnsamlingen skal skje med hjemmel i samtykke og det er derfor heller ikke behov for dispensasjon fra taushetsplikten/eller samtykke.

Godkjenning fra andre instanser
Det påhviler prosjektleder å undersøke hvilke eventuelle godkjenninger som er nødvendige fra eksempelvis personvernombudet ved den aktuelle institusjon eller Norsk senter for forskningsdata (NSD).

Kvalitativ del av prosjektet
Det opplyses at «*Protokollen inneheld i tillegg ei kvalitativ studie der ein inviterer pasientar frå fedmebehandlingskonteksten til individuelle intervju og/eller fokusgruppeintervju om deira opplevingar av psykisk helse og uhelse, og behov for dette integrert i behandlinga. Dette kvalitative prosjektet er knytt til ei post.doc-stilling. Kandidaten som er tilsett i post.doc-stillinga startar opp juli 2018. Vedkommande vil definere innhald, intervjuguide og design i detalj etter oppstart, og denne delen av prosjektet vil ettersendast til REK for vurdering når kandidaten har starta*.»

Komitéen har ikke grunnlag til å ta stilling til denne delen av prosjektet. Denne delen av prosjektet må sendes som selvstendig søknad, dersom prosjektleder mener at den er fremleggingspliktig.

Vedtak

Etter søknaden fremstår prosjektet ikke som et medisinsk og helsefaglig forskningsprosjekt som faller innenfor helseforskningsloven. Prosjektet er ikke framleggingspliktig, jf. hfl § 2.

Klageadgang
Du kan klage på komiteens vedtak, jf. helseforskningsloven § 10 og forvaltningsloven § 28 flg. Klagen sendes til REK nord. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK nord, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Med vennlig hilsen

May Britt Rossvoll
sekretariatsleder

Kopi til:taryn.seta.malkhassian@helse-forde.no;post@helse-forde.no

1. Hensikt

Dersom det er sannsynlig at en type behandling, særlig ved bruk av ny teknologi og idet det tas hensyn til behandlingens art, omfang, formål og sammenhengen den utføres i, vil medføre en høy risiko for fysiske personers rettigheter og friheter, skal den behandlingsansvarlige før behandlingen foreta en vurdering av hvilke konsekvenser den planlagte behandlingen vil ha for personopplysningsvernet.

Styringssystem for informasjonssikkerhet og personvern har omtalt hvordan en utfører en vurdering av konsekvenser i dokumentene GXY – 21.6 og GXY. Hvis en vurderer behov utover de minimumskrav som der er oppstilt har direktoratet for e-helse utarbeidet en mer omfattende mal for vurdering.

2. Ansvar/målgruppe

Utforming/vedlikehold av rutinen	:	Regionalt IKT sikkerhetsutvalg
Utførelse	:	Dataansvarlig v/ daglig leder

3. Gjennomføring

Mal for
Data Protection Impact Assessment (DPIA) – Personvernkonsekvensutredning etter GDPR

Denne malen er utviklet på bakgrunn av krav i GDPR. Det er tatt hensyn til Datatilsynets veiledning om DPIA. En del av teksten er hentet fra Datatilsynets sjekkliste for vurdering av personvernkonsekvenser. Malen gir et bilde av momentene som **bør** vurderes i en DPIA. Den enkelte virksomhet som bruker malen må selv konkret vurdere innhold og omfang av egen DPIA. Tabellene i malen er ikke uttømmende og må tilpasses de enkelte behandlingene som omfattes av en DPIA.

DEL I. Vurdering av behov for DPIA

[I denne delen er det kun nødvendig å besvare spørsmålene i tabellen nedenfor, ingen analyse.]

Når må DPIA gjennomføres?

> *«Dersom det er sannsynlig at en **type behandling**, særlig ved bruk av ny teknologi og idet det tas hensyn til behandlingens **art, omfang, formål og sammenhengen den utføres i**, vil medføre en **høy risiko** for fysiske personers **rettigheter og friheter**, skal den behandlingsansvarlige før behandlingen foreta en vurdering av hvilke konsekvenser den planlagte behandlingen vil ha for vernet av personopplysninger.»*
> (GDPR art.35.1)

Kriterier når DPIA *kan* bli et krav:

1. **Evaluering eller scoring**, spesielt knyttet til arbeidsresultater, økonomisk situasjon, helse, personlige preferanser eller interesser, oppførsel og adferd, lokasjon og bevegelser osv.
2. **Automatiserte beslutninger** med juridisk eller tilsvarende betydning.
3. **Systematisk overvåking** av registrerte.
4. **Særlige kategorier personopplysninger** eller **andre sensitive personopplysninger av høy personlig karakter** (sistnevnte spesielt knyttet de enkeltes «friheter», men kan også omfatte f.eks. økonomiske og finansielle opplysninger).
5. **Databehandling i stort omfang**, som at det er et stort antall registrerte involvert, store mengder data, mange ulike typer data, lang varighet av behandlingen, stor geografisk utbredelse av behandlingen osv.

6. **Kombinering eller sammenstilling av datasett**.
7. Personopplysninger vedrørende **spesielt sårbare registrerte** (som barn, ansatte, psykisk syke, asylsøkere, eldre, pasienter mv.).
8. **Innovativ eller nyskapende bruk av personopplysninger,** som f.eks. bruk av biometriske data for tilgangskontroll, Internet of Things-løsninger, velferdsteknologi osv.
9. Når behandlingen i seg selv **forhindrer eller begrenser de registrertes mulighet til å utøve sine rettigheter** etter loven eller avtale, eller **bruke tjenester**.

Vurderingsspørsmål om behov for DPIA:

Nr.	Vurderingsspørsmål	Ja/Nei
1.	Er dette et nytt prosjekt eller prosess?	Ja
2.	Vil prosjektet innebære innsamling av ny informasjon om enkeltpersoner?	Ja
3.	Vil prosjektet be enkeltpersoner om å gi informasjon om seg selv?	Ja
4.	Vil informasjon om enkeltpersoner bli delt med organisasjoner eller personer som ikke tidligere har hatt rutinemessig tilgang til informasjonen?	Ja
5.	Skal du bruke informasjon om enkeltpersoner som er innsamlet for et formål, men der opplysningene for tiden ikke er eller ikke lenger er i bruk (ikke behandles utover lagring)?	Nei
6.	Innebærer prosjektet at du bruker ny teknologi som kan oppfattes som inngripende for personvernet? For eksempel, bruk av biometri eller ansiktsgjenkjenning?	Nei
7.	Vil prosjektet resultere i at du tar beslutninger eller gjennomfører tiltak mot enkeltpersoner på måter som kan ha en betydelig innvirkning på dem?	Nei
8.	Basert på typen informasjon om enkeltpersoner, er det spesielt sannsynlig at bekymringen for eller forventninger til personvernet vil øke?	Ja
9.	Vil prosjektet kreve at du kontakter personer på måter som de kan finne inngripende?	Nei

Dersom svaret er "ja" på ett eller flere av spørsmålene ovenfor, kan det bety at det er behov for DPIA. Forsett til DEL II.

DEL II. Grunnleggende utgangspunkter og beskrivelser

II.1. Bakgrunn

Forutsetninger og avgrensning

Grunnlaget for dette DPIA-dokumentet er gjennomføringa av forskingsprosjektet «NORSE: Building bridges between psyche and soma through personalized and dynamic mental health systems» (heretter «Prosjektet»). Prosjektet går frå 2018-2023 og er finansiert av Helse Førde, Noregs Forskingsråd, Høgskulen på Vestlandet, Førde Kommune og St. Olavs Hospital. Helse Førde er prosjekteigar og forskingsansvarleg institusjon. Prosjektet hentar sjølvrapporterte data frå pasientar for å gjennomføre forskingsaktivitetar og utbetre nye og betre tenester og tenesteteknologi.

To eksterne instantsar har tidlegare vurdert ulike sider ved forskingsprosjektet. Norsk forskingsråd har vurdert prosjektet til å høg vitskaplege kvalitet og nytteverdi. På grunnlag av dette tildelte dei prosjektet 10 millionar kroner.
https://www.forskningsradet.no/prosjektbanken/#/project/NFR/269097

Prosjektet er også vurdert av Regional komite for medisinsk og helsefaglig forskningsetikk (REK) (saksnummer: 2018/993) der ein konkluderte med at prosjektet fell utanfor REK sitt mandat. Prsaka er prosjektet er ein obervasjonsstudie der ein skal nytte opplysningar som uansett samlast inn som ein del av behandlinga.
https://helseforskning.etikkom.no/prosjekterirek/prosjektregister/prosjekt?p_document_id=1017645&p_parent_id=1029900&_ikbLanguageCode=n

Helse Førde gjer difor ei sjølvstedig vurderinga av projektet.

Kven tek del i DPIA-teamet?

Prosjektleiar Christian Moltu, forskingskoordinator John Roger Andersen, seksjonsleiar forsking og innovasjon Guro Mjanger, personvernombod Frode Hatten, datatryggleiksansvarleg Lars Inge Eikefjord, foretaksjurist Bård Eikeset. Alle desse er tilsett i Helse Førde.

Interessentar

- Pasientar i Klinikk for psykisk helse (PHV), tverrfagleg fedmepoliklinikk (KIR), fedmepoliklinikken St.Olavs Hospital (STO) og Førde legesenter (FL) som samtykkar og tek del i prosjektet med sine data.
- Klinisk tilsette og leiing ved dei inkluderte klinikkane nemd i første kulepunkt.
- Institusjonane Helse Førde, St.Olavs Hospital og Førde Legesenter.

II.2. Løsning, tjeneste og system

Prosjektet samlar inn sjølvrapporterte data elektronisk frå pasientar som er i pågåande behandling, eller frå den genrelle befolkinga etter fullstendig informert samtykke. Datainnsamlinga skjer gjennom to teknologiske løysingar. Høgaste tryggleiksnivå i Noreg (nivå 4) blir brukt til pålogging.

1. **Checkware AS**
   Checkware AS, organisasjonsnummer 990 808 414, er eit firma som utviklar teknologi for digitalisering av pasientskjema for helsesektoren. Checkware AS har sidan 2015 hatt ein rammeavtale med Helse Vest, og leverer desse tenestene til dei fire føretaka gjennom HVIKT. Checkware AS inngår i regional portefølje i Helse Vest, og har vore vurdert i HVIKT med tanke på datalagring, datatryggleik og risiko. Checkware er rulla ut i dei fire foretaka for klinisk bruk. Prosjektet nyttar ikkje Checkware på anna måte enn slik det vert brukt i klinisk drift.

   For detaljert informasjon om Checkware, driftsmiljø, ROS-analyse og vidare visast det til Checkware i regional portefølje i Helse Vest.

2. **Norse Feedback AS**
   Norse Feedback AS, organisasjonsnummer 921 192 622, er eit firma som utviklar teknologi for å levere det digitale persontilpassa pasientsystemet NORSE til helsevesenet. Norse Feedback AS har sidan 2018 utvikla teknologien i møte med ønske frå helseorganisasjonar om å ta i bruk fullversjon av systemet NORSE. Norse Feedback er forprosjektkandidat i den regionale porteføljа i Helse Vest, og dokumentasjon med mål om regional utrulling i vanleg klinisk drift er under utvikling.Prosjektet skal nytte Norse Feedback AS sin teknologi for datafangst ved Førde Legesenter.

   Informasjon om Norse Feedback, driftsmiljø, og ROS-analyse blir ettersendt.

Dataflyt

Pasientar som inngår i prosjektet er i ordinær behandling ved ein av dei deltakande klinikkane. I det vanlege behandlingsløpet brukar dei ei rekke sjølvrapporterte skjema for å følgje med på effekt og opplevd nytte i behandlinga. Pasientar vil verte informert om målsetnandene og innhaldet i prosjektet og invitert til å samtykke til deltaking. Ved eksplisitt skriftleg samtykke vert den gjeldande pasient sine data merkt som tilgjengeleg for prosjektet sine forskingsspørsmål. Berre opplysningar som er naudsynte for prosjektet vert nytta.

Checkware lagrar pasientdata fullidentifisert på eigne servarar. På desse ligg kliniske data med gjeldande sletterutiner for den ordinære driftssituasjonen. For dei pasientar som har samtykka til forsking vil prosjektet bruke Checkware sitt system for å transportere data frå dette miljøet til Helse Vest sin forskingsserver ein gang i kvartalet i prosjektperioden. Kliniske data vil etter dette ligge att på det kliniske driftsmiljøet til Checkware og vert handtert etter ordinære kliniske rutiner.

Norse Feedback AS lagrar ikkje identifiserbare data på eigne servarar. Data samla inn over Norse Feedback AS lagrast fullidentifisert på helseorganisasjonens eigne servarar. For dei

pasientar som har samtykka til forsking vil Førde Legesenter i tråd med partnarkontrakt utlevere data til prosjektet. Norse Feedback sitt system for å transportere data Førde Legesenter til Helse Vest forskingsserver ein gang i kvartalet i prosjektperioden, vil nyttast til dette.

Norse Feedback AS tek ut anonyme data (svar på einskildspørsmål utan identifiserande informasjon, sjå detaljar om innhald i kapittel under) og lagrar på eigne servarar. Desse dataene brukast til å kalibrere spørsmålsformuleringar kontinuerleg, for optimal validitet. Eit forklarande døme kan vere frå eteforstyrringsdomenet. Eit av spørsmåla som pasientar svarar på kan vere formulert slik: «Eg brukar for mykje tid på å tenkje på og planlegge måltid slik at dette går utover det sosiale livet mitt». Spørsmålet er meint å gi empirisk informasjon som hjelper med graderingar av vanskar med høg alvorsgrad innanfor domenet. Kontinuerlege analyser kan vise at denne formuleringa gir mest diskriminant informasjon rundt den moderate alvorsgrada av vansken. På bakgrunn av denne anonyme informasjonen om korleis dette spørsmålet fungerer empirisk kan Norse Feedback AS endre spørsmålet noko, til dømes til: «Eg brukar lange tidsperiodar kvar dag på å tenkje på og planlegge måltid slik at dette går utover det sosiale livet mitt». Statistikk som ligg til grunn for slike analyser går under namnet Item Respons Theory, og gir informasjonskurver for ulike alvorsgrader for alle einskildspørsmål i eit sjølvrapportert instrument.

Data som er samtykka til bruk i prosjektet og transportert til Helse Vest forskingsserver vil ligge der for analyser i SPSS etter ordinære system for lagring og trygg bruk av forskingsdata i Helse Vest. Helse Vest si prosedyre/teneste for trygg lagring vil bli nytta når ein treng mellomlagring før endeleg plassering på foreskingserver. Data blir lagra utan personidentifiserbare kjenneteikn. Ein koplingsnøkkel knyt pasientane til desse opplysningane. Koplingsnøkklen vert oppbevart seperat frå dei andre opplsyingane på eige område på ein server i samvar med Helse vest sine rutinar. Koplingsnøkkelen vert sletta ved prosjektslutt. Prosjektleiar og arbeidspakkeleiarar (Christian Moltu og John Roger Andersen) vil ha full tilgang til forskingsdata, og har ansvaret for å gjere desse tilgjengeleg for prosjektdeltakarar som skal gjere analyser på materialet etter prosjektplan. Tilgang til forskingsdata vil berre bli gitt innanfor Helse Førde sitt IKT-system ved at det vert gjeve tilgang til spesifikt område på forskingsver, men ikkje område for koplingsnøkkel.

Prosjektdeltakarar som har samtykka til prosjektet samtykker i utgangspunktet til at personopplsyingar kan lagrast i den definerte datalagringsperioden. Denne er definert til å vare fram til prosjektslutt 31.12.2022. Grunnlaget for at data lagrast identifisert fram til prosjektslutt er at ein må kunne kople nye innsamlingstidspunkt med eksisterande data for individ over tidsperioden som datainnsamlinga varer.

Dersom ein deltakar ønskjer å trekkje sitt samtykke kan dette gjerast utan konsekvensar og utan å oppgi grunn gjennom heile datalagringsperioden. Framgangsmåte for å gjere dette vert oppgitt i samtykkeskjema, og på prosjektetskildringa på Noregs Forskingsråd sine sider. For å få sletta data må ein sende ein epost til prosjektleiar, som søkjer i data som ligg transportert til Helse Vest sin forskingsserver, og slettar manuelt alt vedkomande har bidrege til prosjeket. I tråd med sedvane i forsking vil data som har inngått i analyser som

har blitt publisert ikkje kunne slettast fullt, men anonymiserast på forskingsserver slik som definerast i neste avsnitt.

Ved publisering av vitskaplege artiklar i prosjektperioden kan det komme førespurnad frå redaktørar i tidskrift, andre forskarar eller kontrollorgan, om å få undersøke grunnlagsmaterialet publikasjonen byggjer på. Dette er ein del av kontrollmekanismane i forsking, og på rimeleg førespurnad vil vi derfor dele data utan direkte personidentifiserbare kjenneteikn. Dersom dette skulle bli aktuelt i prosjektperioden, vil PVO vil bli rådspurt for vidare sakshansaming.

Den 31.12.2022 vil heile datamaterialet i prosjektet anonymiserast ved at koplingsnøkkelen blir sletta. For at datamaterialet skal være heilt anonymt, vil vi saman med NSD—Norsk senter for forskningsdata AS, sikre at ingen kombinasjonar av bakgrunnsopplysningar svarar til færre enn tre til fem personar. Etter dette kan data gjerast tilgjengeleg for open deling for andre forskarar ved førespurnad. Data vil bli lagra hos NSD, i samsvar med Norsk Forskingsråd sine retningsliner for «Tilgjengeliggjøring av forskningsdata».

II.3. Behandlingens omfang

Prosjektet skal samle inn data inntil 6000 deltakarar. Prosjektet følgjer dei behandlingsprosessane som pasienten er i i sitt vanlege behandlingsløp. Prosjektet samlar inn data ved skjemaet NORSE for alle deltakarar. For dei om lag 800 som er ein fedmekontekst samlar ein i tillegg inn data frå dei normerte skjema Short Form 36, Obesity related problem scale, PROSURG, Gastrointestinal Symptom Rating Scale, og Weight Efficacy Short Form. For ei subgruppe på 500 personar frå deltakarar som ikkje er i fedmekonteksten samlar prosjektet inn tilleggsdata (ikkje som del av helsehjelp) på dei normerte skjema BDI, BAI og SCL90, som ikkje ordinært ville bli innsamla, for å sikre konvergent validitet for NORSE data. Desse samtykkar til tilleggsdata for validering ved ein eigen eksplisitt signatur til dette på samtykkeskjema.

Alle dei ulike skjema som benyttast i prosjektet samlar inn opplysingar som fell under særlege kategoriar. I tillegg samlast demografiske data som namn, alder, arbeidslivsstatus, relasjonsstatus, sosioøkonomisk status og utdannningsnivå, for å kunne beskrive utvalet og for å kunne undersøke om det er helseforsjellar vi må vere merksame på. Alle data i prosjektet handlar om deltakarane sjølv, som har samtykka til å gi denne informasjonen til prosjektet. Ingen data handlar om tredjepersonar. Alle data (unnateke valideringsdata for BDI, BAI og SCL90) som vert innsamla vert allereie bruk i ordinær klinisk behandling, slik at innsamlinga ikkje fører til vesentleg tilleggsbelastning for deltakarar anna enn noko meir tid på utfylling av skjema (om lag 15 minuttar). Prosjektet vil samle inn data når dei elles ville blitt innsamla i klinikken. For fedme- og primærhelsetenestekonteksten vil difor data bli samla inn ved eitt til tre møtepunkt, medan i PHV-konteksten vil data kunne verte samla inn ved NORSE vekentleg i ein behandlingsperiode.

Her følgjer informasjon om kva som inngår i dei ulike skjema som ein samlar data frå:

NORSE samlar ein inn strukturert kunnskap om psykisk helse, ressursar og behov gjennom 95 spørsmålsledd. Desse 95 spørsmålsledda utgjer dei empiriske faktorane/dimensjonane: 1. Depressiv affekt, 2. Somatisk angst, 3. Ete- og kroppsbiletevanskar, 4. Traumereaksjonar, 5. Rusvanskar, 6. Rusmeistring, 7. Irritabilitet, 8. Håpløyse/demoralisering, 9. Kognitiv ruminering, 10. Situasjonell unnviking, 11. Sosial unnviking, 12. Indre unnviking, 13. Sjølvkritiske prosessar, 14. Kontrollbehov. 15. Daglegdags sjølvopplevd fungering 16. Vanskar med merksemd og hukommelse 17. Sosial tryggleik, 18. Endringskapasitet og 19. Tilfriskningsmiljø

Short-Form-36 måler generell helsestatus ved hjelp av 36 spørsmål som utgjer dimenasjonane: 1. Fysisk funksjon, 2. Fysisk rollefunskjon, 3. Kroppsmerter, 4. Generell helse, 5. Vitalitet, 6. Sosial funksjon, 7. Emosjonell rollefuksnjon, 8. Mental helse.

Obesity-related problem scale måler i kva grad kroppsvekt eller kroppsform påverkar psykososial funskjon ved hjelp av åtte spørsmål knytt til vanlege sosiale aktivitetar i dagleglivet, slik som å gå på fest, ete ute, handle klede og bade offentleg.

PROSURG måler i kva grad kroppsvekt eller kroppsform plagar ein ved hjelp av åtte spørsmål knytt til: 1. fysisk aktivitet, 2. Smerter, 3. Diskriminering, 4. Søvn, 5. Seksualliv, 6. Sosial omgang, 7. Arbeid/skule, 8. Sjølvkjensle. PROSURG måler også tilfredsheit med behandlinga og grad av biverkander etter fedmekirurgi. I tillegg vert kroppsvekt, kroppshøgde og om ein får behandling for psykisk lidingar (depresjon og angst) og fedmerelaterte sjukdommar (diabetes o.s.b) kartlagt.

Gastrointestinal Symptom Rating Scale nyttar 16 spørsmål for å kartlegge i krad ein er plaga av 6 hovudgrupper av gastrointestinale symptom.

Weight Efficacy Short Form er eit kort spørreskjema på 8 spørsmål som kartlegg eigenmeistring kring mat.

BDI er eit mykje brukt validert skjema som måler affektivt og kognitivt depresjonstrykk over 21 spørsmål.

BAI er eit mykje brukt validert skjema som måler affektiv og kogntiv angstsymptomatologi over 21 spørsmål.

SCL90 er eit mykje brukt validert skjema som er eit screeninginstrument over symptomdimensjonane somatisering, tvangssymptomer, interpersonleg sensitivitet, depresjon, angst, fiendtligheit, fobisk angst, paranoid tankegang og psykotisisme.

Tabell 1. Oversikt over dei fire delstudiane i prosjektet

Utval	Datakjelder/lagring	Lagring av data i prosjektperioden	Lagring av data etter prosjektslutt
NORSE Feedback – tilbakemelding om psykisk helse i behandling **Personar i psykisk helsevern i Helse Førde, n = 2000.**	**Data er personidentifiserbare.** Data blir samla inn via Checkware og NORSE FEEDBACK. Høgaste tryggleiksnivå i Noreg (nivå 4) blir brukt til pålogging. Data blir brukt i pasientbehandling.	**Data er utan direkte personidentifiserbare kjenneteikn.** Data har separat lagra koplingsnøkkel. Data er lagra på Helse Førde sin forskingsserver.	**Data er anonyme fordi personidentifiserbare kjenneteikn og koplingsnøkkelen er sletta.** Data blir lagra hos Norsk samfunnsvitskapleg datateneste. Det er open tilgang på data for alle forskarar på førespurnad.
NORSE Feedback - om psykisk helse. **Personar frå den generelle norske befolkninga, n= 2500.**	**Data er personidentifiserbare.** Data blir inn via NORSE FEEDBACK og høgaste tryggleiksnivå i Noreg (nivå 4) blir brukt til pålogging. Data blir ikkje brukt i pasientbehandling.	**Data er utan direkte personidentifiserbare kjenneteikn.** Data har separat lagra koplingsnøkkel. Data er lagra på Helse Førde sin forskingsserver.	**Data er anonyme fordi personidentifiserbare kjenneteikn og koplingsnøkkelen er sletta.** Data blir lagra hos Norsk samfunnsvitskapleg datateneste. Det er open tilgang på data for alle forskarar på førespurnad.
NORSE Feedback Obesity – tilbakemelding om psykisk helse i fedme behandling **Helse Førde, n = 400** **St. Olav Hospital, n = 400.**	**Data er personidentifiserbare.** Data blir samla inn via Checkware og høgaste tryggleiksnivå i Noreg (nivå 4) blir brukt til pålogging. Det blir laga avtale om tilgang på data til prosjektet frå St. Olav hospital. Data blir brukt i pasientbehandling.	**Data er utan direkte personidentifiserbare kjenneteikn.** Data har separat lagra koplingsnøkkel. Data er lagra på Helse Førde sin forskingsserver.	**Data er anonyme fordi personidentifiserbare kjenneteikn og koplingsnøkkelen er sletta.** Data blir lagra hos Norsk samfunnsvitskapleg datateneste. Det er open tilgang på data for alle forskarar på førespurnad.
NORSE Feedback – tilbakemelding om psykisk helse i fastlegekonsultasjonen i Førde kommune, n=700.	**Data er personidentifiserbare.** Data blir samla inn via NORSE FEEDBACK og høgaste tryggleiksnivå i Noreg (nivå 4) blir brukt til pålogging. Det blir laga avtale om tilgang på data drå Førde kommune Førde kommune. Data blir brukt i pasientbehandling.	**Data er utan direkte personidentifiserbare kjenneteikn.** Data har separat lagra koplingsnøkkel. Data er lagra på Helse Førde sin forskingsserver.	**Data er anonyme fordi personidentifiserbare kjenneteikn og koplingsnøkkelen er sletta.** Data blir lagra hos Norsk samfunnsvitskapleg datateneste. Det er open tilgang på data for alle forskarar på førespurnad.

II.4. Formålsbeskrivelser

Formålet med databehandlinga er å gjennomføre forskingsprosjektet «NORSE: Building bridges between psyche and soma through personalized and dynamic mental health systems». Formålet til forskingssprosjektet er definert til å svare på forskingsspørsmåla:

Psykisk helsefeltet

Kva er psykometrisk valide normar for menneske med psykiske helseplager for Norse Feedback?

Korleis samsvarer Norse Feedback med andre mål på helse?

Korleis er psykisk helse i Noreg samanlikna med USA?

Utvikle prediktive analyser for betre kliniske beslutningar.

Overvektsfeltet

Kva er psykometrisk valide normar for mennesker med behandlingstrengande overvekt for Norse Feedback?

Utvikle kunnskap om når psykiske helsevanskar for menneske i behandling for alvorleg overvekt treng merksemd og behandlign

Utvikle prediktive analyser for å betre kliniske beslutningar.

Kva treng pasientar og klinikarar i overvektsfeltet frå ein psykisk helse-system?

Utvikle protokoll for gode psykise helsetenester integrert i overvektsklinikkar.

Fastlegefeltet

Korleis kan psykisk helsekunnskap gjerast meir tilgjengeleg i fastlegemøtet for å betre tenester?

Utvikle protokoll for gode psykiske helsetenster integrert i fastlegemøta.

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Hva er formålet med behandlingen?	Samtykkebasert forsking. Sjå punkt II.4.
2.	Vil formålet være å treffe avgjørelser om enkeltpersoner basert på systematisk og omfattende analyse av personlige aspekter?	Nei. Forskinga skal bidra til å utvikle betre helsetenester.
3.	Vil behandlingen av personopplysninger ha som mål å ta beslutninger som får betydning for den registrerte?	Nei. Forskinga skal bidra til å utvikle betre helsetenetster.
4.	Skal opplysningene brukes til å profilere den registrerte?	Nei. Forskinga fokuserar på analysar for å nå studien sine føremål.
5.	Brukes personopplysninger for å avdekke ukjente sider eller for å gjenkjenne mønstre ved den registrerte?	Nei. Forskinga fokuserar på analysar for å nå studien sine føremål.

DEL III. Behandlingens lovlighet

III.1. Hjemmelsgrunnlag

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Finnes det hjemmelsgrunnlag i forskrift eller lov for behandlingen av personopplysninger?	Ja, Personopplysningslova 2018.
2.	Finnes det annet rettsgrunnlag for behandlingen (for eksempel samtykke, avtale, verne vitale interesser, utførelse av myndighetsoppgave, oppfylle rettslig forpliktelse, jf. GDPR art.6)?	Informert samtykke. GDPR artikkel 6(1)a og artikkel 9(2)a
3.	Finnes det konsesjon eller forhåndsgodkjenning fra REK eller Datatilsynet, eller dispensasjon fra taushetsplikten?	Nei. Fritak frå teieplikta vert gitt ved samtykke, jf. Helsepersonellova §22.

III.2. Samtykke

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Forutsettes det samtykke for behandlingen?	Ja, fordi opplsysingane vert brukt til anna enn behandling.
2.	Hvordan vil samtykke bli innhentet?	Infomert skriftleg samtykke , sjå vedlagt informasjonsbrev og samtykkeskjema.
3.	Er alle kravene til samtykke oppfylt? Samtykke fra den registrerte må være frivillig, spesifikk, informert og utvetydig (GDPR art.4).	Ja. Sjå vedlagt informasjonsbrev.
4.	Dokumenteres samtykke?	Ja, skriftleg/elektronisk.
5.	Kan samtykke trekkes tilbake like enkelt som det gis?	Ja. Melding til prosjektansvarlege om dette gir sletting av data frå forskingsserver.
6.	Foreligger det informasjon til den registrerte om muligheten til å trekke tilbake samtykke?	Ja, sjå vedlagt informasjonsbrev.
7.	Omfatter samtykket alle behandlinger og behandlingsformål som nevnt i DEL IV?	Ja, sjå vedlagt informasjonsbrev.

- Gjennomgang av samtykke og vilkår for samtykke. Kontroller at samtykke ikke sammenblandes med kontrakt eller personvernerklæring.
- Gjennomgang av begrensninger eller mulighetsrom som samtykket gir. Beskriv hvordan den registrertes rettigheter ivaretas i vilkårene for samtykke.

III.3. Viderebehandling

[Dette punktet besvares kun dersom behandlingen er en viderebehandling av personopplysninger som tidligere er samlet inn for et formål.]

Nr.	Vurderingsspørsmål	Svar (forklar svar)
~~1.~~	Behandles opplysninger videre til andre formål enn opprinnelig formål (for eksempel forskning)?	Ja. Opplysingar som er brukt som ein del av praksis vil også bli brukt til forsking.
~~2.~~	Dersom rettsgrunnlag for opprinnelig behandling av personopplysninger er lov eller forskrift, åpner lov eller forskrift for viderebehandling av personopplysninger?	Ja. Helseregisterlova §. 9.
~~3.~~	Dersom opprinnelig behandling er basert på samtykke, dekker samtykket viderebehandlingen av de samme personopplysningene?	Ja, samtykket dekkar dette.
~~4.~~	Viderebehandles personopplysninger for statistiske formål?	Nei. Personopplysningar nyttast berre for forskingsmessige formål.

III.4. Vurdering av formålet sett opp mot rettsgrunnlag

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Er formålet eller formålene klart definert?	Ja. Sjå punkt. II.4.
2.	Er formålet nedfelt i forskrift eller lov?	Ja. Sjå punkt III. 1-3.
3.	Vil det være kontrollformål (for eksempel i annen lovgivning innenfor skatt, NAV, toll, politi, forsikring?)	Nei. Sjå punkt III. 1-3.
4.	Er det noe i egen forskrift eller andre forskrifter eller lover som begrenser formålet?	Nei. Sjå punkt III. 1-3.
5.	Er formålet beskrevet i løsning, tjeneste eller system utfordrende sett opp mot rettsgrunnlaget?	Nei. Sjå punkt III. 1-3.
6.	Omfatter rettslig grunnlag både egne formål og utlevering?	Utlevering av personopplysingar er ikkje

Nr.	Vurderingsspørsmål	Svar (forklar svar)
		aktuelt. Det kanvere aktuelt med tilgjengeleggjering av anonyme datasett for vitskaplege tidsskrift saman med publikasjonar etter 31.12.2022.
7.	Er formålet definert slik at det samsvarer med forventningene de registrerte kan ha ut fra egen forskrift, lov eller samtykkevilkår?	Ja, sjå også vedlagt informasjonsbrev.

III.5. Oppsummering

Forskingsprosjektet «NORSE: Building bridges between psyche and soma through personalized and dynamic mental health systems» samlar inn data frå 6000 mennesker om ulike helseaspekt, som definert i denne utgreiinga, for å svare på forskingsspørsmåla som er definert over. Målet er å betre helsetenster. REK Vest har vurdert at prosjektet ikkje fell inn under helseforskingslova. Det påligg ansvarleg institusjon Helse Førde å ivareta personvernmessige og etiske aspekt ved prosjektet. Lovheimelsgrunnlaget til dette er eksplisitt samtykke etter Personopplysingslova 2018, og GDPR artikkel 6(1)a og artikkel 9(2)a. Det er ikkje aktuelt med vidarebehandling av data utover formålet, og identifiserbare data skal ikkje delast.

DEL IV. Behandling av personopplysninger

IV.1. Oversikt over behandling og behandlingsaktiviteter

Nr.	Behandling	Detaljert beskrivelse av behandlingsaktiviteter
1.	Innsamling	Skildra i II.2, Tabell 1 og informasjonsbrev.
2.	Lagring	Skildra i II.2, Tabell 1 og informasjonsbrev.
3.	Deling	Skildra i II.2, Tabell 1 og informasjonsbrev.
4.	Gi tilgang til	Skildra i II.2, Tabell 1 og informasjonsbrev.
5.	Retting	Skildra i II.2, Tabell 1 og informasjonsbrev.

Nr.	Behandling	Detaljert beskrivelse av behandlingsaktiviteter
6.	Sletting	Skildra i II.2, Tabell 1 og informasjonsbrev.

IV.2. Systematisk beskrivelse og vurdering av behandling av personopplysninger

Denne delen av malen er gjennomgått over i detalj, og det visast gjennomgåande til punkt II om ikkje anna er definert.

IV.2.1. Innsamling

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Hvilke typer personopplysninger samles inn?	Demografi, helseopplysingar og vurderingar av helsetenestetilbodet (sjå punkt II.3.).
2.	Er noen av personopplysningene over kategorisert som særlige kategorier av personopplysninger? (for eksempel helseopplysninger, rase, fagforening osv.)	Helseopplysingar (sjå punkt II.3.).
3.	Hvordan samles personopplysningene inn?	Ved overføring av data frå e-plattform til forskingsserver innan Helsevest sitt IKT system. Eigne avtalar vert gjort med Førde kommune og St.Olav Hospital om overføring av data frå dei. Skildra i II.2, Tabell 1 og informasjonsbrev.
4.	Samles personopplysningene inn direkte fra de registrerte selv eller fra andre kilder?	Ja, direkte frå den registerte, via Checkware og/eller NORSE FEEDBACK.
5.	Er det noe som er særlig inngripende ved måten personopplysningene samles inn (for eksempel ved hjelp	Nei¸(sjå punkt II.3.).

Nr.	Vurderingsspørsmål	Svar (forklar svar)
	av fingeravtrykk, kamera- eller lydopptak, eller sporing av en persons lokasjon, biometri)?	
6.	Samles det inn flere opplysninger enn det som er nødvendig ut fra formålet?	Nei, berre opplsyingar knytt til foremålet med prosjektet (sjå punkt II.3.).
7.	Får den registrerte all informasjon som er påkrevd etter GDPR art.13 og 14?	Ja, sjå vedlagt informasjonsbrev.

IV.2.2. Lagring

Sjå også tabell 1.

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Hvordan skal opplysningene lagres?	På Helse Førde sin forskingssever.
2.	Hvor og hvor lenge lagres personopplysningene?	På Helse Førde sin forskingssever til prosjektslutt 31.12.2022.
3.	Hvilke kriterier brukes for å bestemme lagringstid?	Ferdigstilling av valide datasett med alle planlagte måletidspunkt.
4.	Når skal personopplysningene slettes?	Kodenøkkel slettast ved prosjektslutt 31.12.2022.
5.	Etter at formålet ved behandlingen er oppnådd, hvor lenge lagres personopplysningene før de slettes?	Personopplysingar blir ikkje lagra etter at behandlinga er oppnådd.
6.	Er det utarbeidet rutiner for sletting?	Ja. Personopplysingar blir sletta av Christian Moltu og John Roger Andersen ved prosjektslutt.
7.	Gis det informasjon til den registrerte om muligheten til å slette opplysninger og hvordan sletting kan gjøres?	Ja, sjå vedlagt informasjonsbrev.

IV.2.3. Deling

Nr.	Vurderingsspørsmål		Svar (forklar svar)
1.	Utleveres eller tilgjengeliggjøres det personopplysninger til andre utenfor virksomheten?		Nei personopplysingar vil ikkje bli delt. Men data er utan direkte personidentifiserbare kjenneteikn blir gjort tilgjegeleg for samarbeidspartnar i prosjektet. Sjå punkt 2- 4 nedanfor.
2.	Hvordan utleveres eller tilgjengeliggjøres personopplysningene (dataflyt)?		Personopplysingar blir ikkje utlevert. Data utan direkte personidentifiserbare kjenneteikn blir delt innafor Helse Førde sitt IKT-system.
3.	Er alle mottakere av personopplysninger identifisert og dokumentert (for eksempel ansatte, databehandlere, tredjeparter, eksterne virksomheter osv.)?		Ja, Christian Moltu og John Roger Andersen, er anvarlege for dette.
4.	a.	Hvordan deles personopplysningene mellom avdelinger internt i virksomheten?	Personopplysingar blir ikkje utlevert.
	b.	Hvilke personopplysninger deles med hvilke avdelinger og hva er formålet med hver av disse delingene?	Personopplysingar blir ikkje utlevert.
5.	a.	Hvilke eksterne virksomheter deles personopplysningene med (private, offentlige myndigheter osv)?	Personopplysingar blir ikkje utlevert.
	b.	Hvilke personopplysninger deles eksternt, for hvilket formål og med hvilke rettslige grunnlag?	Personopplysingar blir ikkje utlevert.
6.	Vil personopplysningene overføres til andre land utenfor EU/EØS-området, og hva er det rettslige grunnlaget for overføringen?		Nei.
7.	Vil personopplysninger overføres til tredjestater eller internasjonale organisasjoner (GDPR art.44-49)?		Personopplysingar blir ikkje utlevert.
8.	Hvordan sikres etterlevelse av forordningen ved overføring til utlandet?		Personopplysingar blir ikkje utlevert.

9	Finnes det annet regelverk, atferdsnormer/bransjenormer og retningslinjer som må følges?	Ikkje aktuelt. Personopplysingar blir ikkje delt.

IV.2.4. Tilgang

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Hvem har tilgang til opplysninger?	Christian Moltu og John Roger Andersen
2.	Finnes det dokumentert rutiner for tilgangsstyring?	Ja jmfr Helse Vest sine rutinar.
3.	Vil tilgangsstyringen for brukergruppene være rollebasert og tidsbegrenset?	Ja jmfr Helse Vest sine rutinar.
4.	Dersom det gis tilgang utenfor virksomheten, er det signert databehandleravtaler eller taushetserklæring?	Dette vil bli gjort ved behov for data er utan direkte personidentifiserbare kjenneteikn. Sjå punkt I.V. 2-3.

IV.2.5. Retting

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Finnes det mulighet for retting av feil i den registrertes opplysninger?	Ja, opplysingar kan rettast manuelt på forskingsserver.
2.	Gis det informasjon til den registrerte om muligheten til å rette opplysninger og om hvordan retting kan gjøres?	Ja, i informasjonsbrevet.
3.	Finnes det dokumenterte rutiner for retting?	Ja, sjå punkt II og informasjonsbrev.
4.	Dersom den registrerte ikke selv kan rette feil i egne personopplysninger, finnes det andre måter å gjøre det på?	Den registrerte kan ikkje rette feil i eigne personopplysninger. Dette må gjerast av Christian Moltu eller John Roger Andersen.

IV.2.6. Sletting

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Finnes det mulighet for sletting av den registrertes opplysninger?	Ja, før data annonymiserast ved prosjektslutt.
2.	Gis det informasjon til den registrerte om muligheten til å slette opplysninger og om hvordan sletting kan gjøres?	Ja, dette er beskrive informasjonsbrevet.
3.	Finnes det dokumenterte rutiner for sletting?	Ja, er beskrive i informasjonsbrevet. Sjå også punkt IV.2.2.
4.	Dersom den registrerte ikke selv kan slette egne personopplysninger, finnes det andre måter å gjøre det på?	Ja, ved å kontakte Christian Moltu eller John Roger Andersen.
5.	Finnes det rettsgrunnlag i lov eller forskrift som gir grunnlag for å nekte sletting?	Nei, opplysingar vil alltid bli sletta når den registerte ønskjer det.

IV.3. Vurdering av sammenheng behandlingen utføres i (kontekst)

[I denne delen vurderes behandlingen i et større bilde. Alle interne og eksterne faktorer som kan påvirke forventninger eller konsekvenser vurderes her.]

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Vil det behandles personopplysninger fra ulike datasett, som er innsamlet for ulike formål og fra ulike behandlingsansvarlige?	Nei, berre data til formåla i prosjektet vil bli behandla (sjå punkt II.3).
2.	Hvilke kilder brukes for innhenting av personopplysninger?	Klinisk tilbakemeldingssystem (Checkware og NORSE FEEDBACK). Sjå punkt II.2 og tabell 1.

3.	a.	Kobles systemene der opplysninger behandles opp mot andre informasjonssystemer?	Nei, data som skal samlast inn er kun på forskingsserver som beskrive.
	b.	Finnes det tidligere erfaring med tilsvarende type behandling?	Ja, liknande prosedyrar for lagring og handtering av data har blitt nytta før i Helse Førde.
4.		Finnes det noen nåværende tilfeller av allmenn bekymring for den beskrevne måten å behandle personopplysninger på?	Nei. Ingen slike er kjende.
5.		Hvilken relasjon har den behandlingsansvarlige med de registrerte? Beskriv maktforholdet mellom dem.	Christian Moltu driv pasientbehandling i psykisk helsevern, medan John Roger Andersen ikkje gjer dette.
6.		Med tanke på at kompleksitet i den sammenheng behandlingen utføres i (kontekst), i hvilken grad har de registrerte kontroll over sine opplysninger?	Vi brukar berre opplsysnigar som beskrive til formålet, og den registerte kan få innsyn i sine opplysingar gjennom Christian Moltu eller John Roger Andersen.
7.		Beskriv hvordan behandlingen vil oppfattes fra den registrertes synsvinkel. Kan for eksempel de registrerte oppfatte behandlingen som lite forutsigbar?	Behandlinga er stabil og beskrive i informasjonsbrev.
8.		Vil den registrerte ha en særskilt forventning om konfidensialitet (for eksempel dersom det omhandler helse, velferd, arbeidsforhold, kommunikasjon, lokasjon)?	Ja, dei vil forvente at vi vernar om deira personopplysingar i høve til gjeldane regelverk og informasjonsbrev.

IV.4. Innebygd personvern

Nr.	Vurderingsspørsmål	Svar (forklar svar)

1.	Hvordan tenkes innebygd personvern og personvern som standardinnstilling ivaretatt i løsningen med tanke på:		Det ligg føre godkjent ROS analyse på Chekware og forskingsserver. ROS analyse på NORSE FEEDBACK plattform vil ligge føre før bruk. Begge verktøy vil vere ein del av vanleg praksis i Helse Førde.
	a.	kravene til design?	Ivaretatt som ein del av praksis. Sjå punkt. 1.
	b	sikker koding?	Ivaretatt som ein del av praksis. Sjå punkt. 1.
	c.	testing og godkjenning før produksjonssetting?	Ivaretatt som ein del av praksis. Sjå punkt. 1.
	d.	kontinuitets- og beredskapsplaner?	Ivaretatt som ein del av praksis. Sjå punkt. 1.
	e.	jevnlige revisjoner?	Ivaretatt som ein del av praksis. Sjå punkt. 1.
	f.	opplæring?	Ivaretatt som ein del av praksis. Sjå punkt. 1.
2.	Er alle prinsippene for behandling av personopplysninger ivaretatt i løsningen? – Se DEL V.1		Ja.
3.	Hvordan er den registrertes rettigheter ivaretatt i løsningen? – Se DEL V.2 for hvilke rettigheter er det snakk om.		Er ivaretatt tilfrestillande. Sjå punkt II.2, Tabell 1 og informasjonsbrev.
4.	Tas ny teknologi i bruk?		Sjå punkt.1.1. og 1.2. Teknologien alt er i bruk som ein del av klinisk praksis i Helse Førde.
5.	Brukes eksisterende teknologi på en ny måte?		Teknologien alt i bruk i klinisk praksis i Helse Førde.

IV.5. Ansvarsforhold*

Nr.	Vurderingsspørsmål	Svar (forklar svar)

1.	a.	Er det noen avtale eller kontrakt med eksterne virksomheter om gjensidig forståelse for ansvar og roller?	Naudsynte databehandlaravtalar med Førde kommune og St. Olav hospital vil ligge føre innan datasamlinga startar. PVO vil blir rådspurt.
	b.	Gjenspeiler avtalen hvilke begrensninger som gjelder for behandling av personopplysningene?	Det vil den gjere, jamnfør dette dokumentet og informasjonsbrev. Sjå også punkt a ovenfor.
2.	a.	Brukes det databehandler?	Ja, i prosjektet med Førde kommune og St.Olav hospital vil Helse Førde vere databehandlar.
	b.	Er alle databehandlerne identifisert og er forholdet til dem avklart gjennom avtaler (GDPR art.28 nr.3)?	Sjå punkt 1. a–b og 2.a.
3.	Om databehandleravtale:		
	a.	Gir databehandleren tilstrekkelige garantier for at egnede tekniske og organisatoriske tiltak som sikrer at behandlingen er i samsvar med forordningen (GDPR art.28 nr.1) vil gjennomføres?	Ja, det er ein føresetnad at dette ligg føre.
	b.	Er personvernprinsippene, for eksempel formålsbegrensning, dataminimering, lagring med videre ivaretatt i avtalen?	Ja, avtalar skal ivareta dette.
	c.	Er de registrertes rettigheter og friheter ivaretatt i avtalen?	Ja, avtalar skal ivareta dette.

Merknad: Helse Førde skal ta imot data frå Førde kommune og St. Olav hospital som ein del av prosjeket (vere databehandlar). Desse organisasjonane vil gjere sine sjølvstendige vurderingar om dette etter at Helse Førde si DPIA ligg føre. Etter dette vil avtalar om overføring av data til Helse Førde bli utvikla.

IV.6. Vurdering av behandlingene samlet

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1.	Vil planlagte behandlinger gjøre det lett eller vanskelig for den registrerte å utøve sine rettigheter?	Lett. Sjå punkt II.2, tabell 1 og informasjonsbrev.
2.	Vil planlagte behandlinger ut fra den registrertes synsvinkel preges av uforutsigbarhet eller lite åpenhet?	Nei. Sjå punkt II-2, tabell 1 og informasjonsbrev.
3.	Er det usikkerhet knyttet til hvordan grunnleggende prinsipper for behandling av personopplysninger ivaretas (GDPR art.5)?	Nei. Det er ikkje utryggleik relatert til dette.

Her oppsummeres vurderingene om behandlingene som er gjort i DEL IV.

Del V. Nødvendighet og forholdsmessighet av behandlingen

[Denne delen inneholder en vurdering av om behandlingsaktivitetene er nødvendige og står i rimelig forhold til formålene med behandlingen.]

V.1. Personvernprinsippene

Nr.	Vurderingsspørsmål	Svar (forklar svar)
1	Er behandlingen basert på lovlighet, rettferdighet og åpenhet (GDPR art.5.1 bokstav a og art.6 og 9)?	Ja, sjå punkt. II.2-3, tabell 1 og informasjonsbrev.
	a. Kommer det rettslige grunnlaget/behandlingsgrunnlaget tydelig frem?	Ja, sjå punkt. II.2-3, tabell 1 og informasjonsbrev.
	b. Vurder rimeligheten av behandlingen: Hva er forventede fordeler ved behandlingen? For virksomheten, den registrerte, samfunnet for øvrig osv.	Behandlinga er rimelig, sjå punkt. II.2-3. Prosjektet skal gi betre og meir forsvarlege helsetenester. Noko helsetenesta er pålagt å arbeide med.

	c.	Hva vil konsekvensene være dersom behandlingene ikke gjennomføres?	Forsking på utvikling av betre helsetenester blir ikkje gjort. Dette kan poensielt føre til pasientskadar og unødvendig liding.
	d.	Vurder hvordan åpenhet ivaretas i behandlingen.	God informasjon til implserte partar om alle forhold. Sjå punkt II.2, tabell 1 og informasjons-brev.
2	Formålsbegrensninger		
	a.	Er formålet definert slik at det samsvarer med forventningene til de registrerte?	Ja, sjå punkt. II.2-4 og informasjonsbrev.
	B	Har det vært vurdert andre alternativer for å oppnå formålet med behandlingen?	Det finnest ingen andre gode alternativ.
	c.	Finnes det mindre personverninngripende alternativer for å oppnå det samme formålet?	Nei. Vi har lagt stor vekt på å gjere dette så lite inngripande som mogleg.
	D	Vurder hvorvidt formålet kan oppnås med anonyme eller pseudonyme alternativer.	Ikkje mogleg pga hantering av reperte målingar og at høgaste tryggleiknivå (nr 4) skal nyttast i datasamlinga.
3	Dataminimering. Kan formålet oppnås ved for eksempel:		
	a.	å begrense innsamling av personopplysninger?	Nei, minimum er som planlagt.
	b.	med mindre detaljerte personopplysninger?	Nei, minimum er som planlagt.
	c.	uten fortrolige eller sensitive personopplysninger?	Nei, minimum er som planlagt.
	Begrunn nødvendighet og relevans relatert til formål for alle opplysninger som behandles.		Sjå punkt. II.2-4 og informasjonsbrev. Det kjem fram at

			datasanlinga er naudsynt for å forske på utvikling av betre helsetenester.
4	Riktighet		
	a.	Vurder hvordan personopplysninger holdes korrekte og oppdaterte, med og uten den registrertes involvering.	Ivaretatt som ein del av praksis, samt ved dobbeltsjekking av forskingsserver av dei ansvarlege.
	b.	Vurder om det finnes nødvendig funksjonalitet for å rette og slette uriktige personopplysninger, ref. punkt IV.2.5 og IV.2.6.	Ja, sjå punkt. II.2.
	c.	Har dere rutiner som ivaretar kravet til korrekte og oppdaterte personopplysninger?	Ja, ivaretatt som ein del av praksis.
5	Lagringsbegrensning		
	a.	Vurder om personopplysninger lagres etter at formålet er oppnådd og når opplysningene slettes.	Data blir annonymisert ved prosjektslutt.
	b.	Vurder når personopplysninger anonymiseres eller pseudonymiseres som muliggjør videre lagring.	Data blir annonymisert ved prosjektslutt.
	c.	Vurder hvilke garantier som må være plass dersom personopplysninger skal lagres i lenger perioder grunnet arkivformål i allmennhetens interesse, for formål knyttet til vitenskapelig eller historisk forskning eller for statistiske formål (GDPR art.89 nr.1).	Ikkje aktuelt.
6.	Integritet og konfidensialitet – se DEL VI.1.		Er ivaretatt.

V.2. Ivaretakelse av de registrertes rettigheter

Nr.	Vurderingstemaer	Vurdering
1.	Vurder hvordan informasjon til de registrerte gis (prinsippet om rettferdighet og åpenhet i behandlingen) (GDPR art.12, 13 og 14).	Informasjonsbrev, sjå vedlegg.
2.	Vurder hvordan den registrertes rett til innsyn ivaretas (GDPR art.15).	Ved å kontakte Christin Moltu eller

		John Roger Andersen. Evt. kontakte personvernombodet.
3.	Vurder hvordan den registrertes rett til retting og sletting ivaretas (GDPR art.16 og 17).	Ved å kontakte Christian Moltu eller John Roger Andersen. Dei kan også kontakte personvernombodet.
4.	Vurder hvordan den registrertes rett til innsigelser og begrensning av behandling ivaretas (GDPR art.18, 19 og 21).	Ved å kontakte Christian Moltu eller John Roger Andersen. Evt kontakte personvernombodet.
5.	Vurder hvordan den registrertes rett til dataportabilitet ivaretas (GDPR art.20).	Den registerte kan få tilgang til alt som er registert på forskingsserver om seg sjølv.
6.	Vurder hvordan forbud mot automatiserte individuelle avgjørelser, herunder profilering håndheves (GDPR art.22).	Ikkje aktuelt, då alle vurderingar inkluderer menneskleg deltaking.

V.3. Ivaretakelse av de registrertes friheter

Nr.	Vurderingstemaer	Svar (forklar svar)
1.	Vurder hvordan de registrertes friheter i forhold til Den europeiske menneskerettskonvensjonen (EMK) er tatt hensyn til:	
	• Retten til privatliv og kommunikasjonsvern	Deltaking er frivillig samtykkebasert.
	• Retten til ikke å bli diskriminert	Deltaking er utan betyding for helsetenstetilbodet

		og fører ikkje til forskjellbehandling.
	• Tanke-, tros- og religionsfrihet	Ingen forhold ved prosjektet skal truge dette.
	• Ytrings-, og informasjonsfrihet	Ingen forhold ved prosjektet skal truge dette.

V.4. Oppsummering

Her oppsummeres vurderingene om prinsippene, ivaretakelse av de registrertes rettigheter og ivaretakelse av de registrertes friheter som er gjort i DEL V.

Del VI. Personvern risikoanalyse og planlagte tiltak

[Denne delen inneholder vurdering av risiko for de registrertes rettigheter og friheter, samt planlagte tiltak for å håndtere risikoene].

VI.1. Risiko, konsekvenser og sannsynlighet

VI.1.1. Sikkerhet ved behandlingen

[Fokuset i denne delen bør være sikkerhet i løsningen]

Nr.	Vurderingsspørsmål		Svar (forklar svar)
1.	Er personopplysningssikkerheten tilstrekkelig ivaretatt?		
	a.	Er det gjort en risikovurdering av løsningen (også ved endringer)? Ved vurderingen av egnet sikkerhetsnivå skal det særlig tas hensyn til risikoene forbundet med behandlingen, særlig som følge av utilsiktet eller ulovlig tilintetgjøring, tap, endring eller ikke-autorisert utlevering av eller tilgang til personopplysninger som er overført, lagret eller på annen måte behandlet.	Innhenting av data med Checkware/ NORSE FEEDBACK baserast på ROS analysar for bruk i klinisk praksis. Når mellomlagring av data (Checkware/NORSE FEEDBACK og forskingsserver) er

			naudsynt, blir Helse vest si løsing «Trygg lagring» brukt. Data på sever for «Trygg lagring» blir sletta når data er komt på forskinsgserver.
	b.	Er det gjennomført tiltak for å håndtere risiko? Ved valg av tiltak skal det tas hensyn til den tekniske utviklingen, gjennomføringskostnadene og behandlingens art, omfang, formål og sammenhengen den utføres i, samt risikoene av varierende sannsynlighets- og alvorlighetsgrad for fysiske personers rettigheter og friheter.	Ja, det er lagt vekt på å berre samle inn naudsynte data og bruke standard løysingar som er rekna som er vuerdert som trygge av Helse Vest IKT.
	c.	Er restrisiko håndterbar og akseptabel?	Ja.
2.	Er alle iverksatte og planlagte tekniske og organisatoriske tiltak egnet til å sikre personopplysningenes konfidensialitet, integritet og tilgjengelighet?		Ja. Sjå punkt II.2. tabell 1 og informasjonsbrev.
3.	Beskriv hvilke forhåndsregler som tas for å beskytte personopplysninger (taushetserklæringer, databehandleravtale, atferdsnormer/bransjenormer, sikkerhetstiltak osv).		Sjå punkt II.2, tabell 1 og informasjonsbrev. Vi føl dei til ei kvar tid gjeldande reglar for å beskytte personopplysningar gitt i eller i medhald av helselovgjevinga og personvernlovgjeinga.

VI.1.2 Personopplysningsvernet

Nr.	Vurderingstemaer		Vurdering
1.	Med utgangspunkt i den registrertes perspektiv for hver risiko kan for eksempel følgende vurderes:		
	a.	Manglende reell medbestemmelse - den registrerte har ikke et valg, får ikke informasjon, får ikke innsyn, og så videre.	Nei. Sjå punkt II.2 og informasjonsbrev.

	b.	Manglende reell åpenhet - virksomheten evner ikke å forklare komplekse behandlinger eller forventet resultat ved sammenstilling av personopplysninger med andre datasett og så videre	Nei. Sjå punkt II.2 og informasjonsbrev.
	c.	Manglende forutsigbarhet ved behandlingen - behandlingen er utenfor det den registrerte vil forvente og så videre.	Nei. Sjå punkt II.2 og informasjonsbrev.
2.	Hvilke konkrete rettigheter og friheter står i fare for å ikke innfris, jf. GDPR art.12-22 (rettigheter) og retten til privatliv, kommunikasjonsvern, ytringsfrihet, tanke-, tros- og religionsfrihet, retten til ikke å bli diskriminert og så videre (friheter)?		
			Ingen. Sjå punkt II og informasjonsbrev.

Generelt for vurdering av "Sikkerhet ved behandlingen" og "Personopplysningsvernet":

- Vurder risikoens opprinnelse, art, særegenhet og alvorlighetsgrad.
- Avklar potensielle **konsekvenser** for den registrertes personopplysningsvern for hvert risikoscenario.
- Anslå **alvorlighetsgrad** for hver risiko, særlig avhengig av hvilken inngripen en potensiell virkning har på den registrerte.
- Identifiser **trusler** og egenskaper ved løsningen som kan føre til hendelser og hvilke risikokilder som kan forårsake dem. Hvordan kan dette skje?
- Anslå **sannsynlighet** for at en hendelse oppstår, særlig ut fra en sårbarhetsvurdering og hva slags evne en risikokilde kan ha for å utnytte dem.

VI.2. Vurdering av planlagte tiltak

Nr.	Vurderingstemaer		Vurdering
1.	Beskriv tiltak for å håndtere risikoene for de registrertes og andre berørte personers rettigheter og berettigede interesser. Eksempler på tiltak kan være: - Garantier: krav til fornyet samtykke, rett til reservasjon osv. - Sikkerhetstiltak: tilgangskontroll, anonymisering, kryptering osv. - Mekanismer: funksjonalitet som er personvernfremmende for eksempel logging og sperring av tilgang eller sperring av informasjon		Sjå punkt II.2, tabell 1 og informasjonsbrev for detaljar. Studien har tydeleg føremål om betring av helsetenester og er basert på informert skriftleg samtykke. Prosjektet har vedlagt informasjonmsbrev med rutinar for innsyn, å gjere korreksjonar og til å trekke seg undervegs. Trygg avindetifisert av datalagring på forskingsserver med seperat lagring av ID-nøkkel. Avgrensa tilgang til forskingsserver (Christian Moltu og John Roger Andersen). Data blir anonymisert ved prosjektslutt.
2.	Ut fra tiltakene, vurder om:		
	a.	sikringen av vernet av personopplysninger er tilstrekkelig	Er tilstrekkeleg. Sjå ovanfor og punkt II.2.
	b.	de registrertes og andre berørte personers rettigheter og berettigede interesser er hensyntatt	Er tilstrekkeleg. Sjå ovanfor og punkt II.2.

	c.	identifiserte risikoer er håndtert og akseptable	Er tilfredstillande ivaretatt. Sjå ovanfor og punkt II.2.
	d.	det er restrisiko etter alle planlagte tiltak	Nei.

Kontroller om det er nødvendig eller mulig å forbedre hvert tiltak etter personvernregelverket og beste praksis innen sikkerhet. Hvis ikke, foreslå ytterligere tiltak og revurder nivået for hver risiko i lys av de nye tiltakene for å fastslå restrisiko.

Vedlegg

1. Prosjektsøknaden som fekk 10 mill NOK hos Norsk Forskingsråd.
2. Den vitskaplege kommiten hos Norsk Forskingsråd si vurdering av prosjektet basert på kvalitet og nytte.
3. Etisk komite si vurdering av prosjektet.
4. Fire informasjonsbrev.

Del VII. Involvering av personvernombudet

[I denne delen legges det opp til en vurdering fra personvernombudet. Personvernombudet involveres etter at DEL I – VI av denne malen er gjennomført.]

Vurdering fra personvernombudet
NSD har gått gjennom personvernkonsekvensvurderingen og anbefalt enkelte endringer og presiseringer i vurdering og informasjonsskriv. Vurderingen og informasjonsskrivene er revidert i henhold til dette, og NSD stiller seg bak vurderingen slik den foreligger. Det er dermed NSDs vurdering at behandlingen kan gjennomføres i samsvar med personvernforordningen, uten behov for forhåndsdrøfting med Datatilsynet. Med vennlig hilsen Lasse Raa Seniorrådgiver | Senior Adviser Seksjon for personverntjenester | Data Protection Services T: (+47) 55 58 20 59 NSD - Norsk senter for forskningsdata AS | NSD - Norwegian Centre for Research Data Harald Hårfagres gate 29, NO-5007 Bergen T: (+47) 55 58 21 17 postmottak@nsd.no www.nsd.no

Del VIII. Ledelsens godkjenning og forhåndsdrøftelse med Datatilsynet

[I denne delen legges opp til en validering av DPIA av ledelsens gjennomgang, beslutning og godkjenning.]

Nr.	Vurderingstemaer	Vurdering
1.	Ledelsen vurderer hvorvidt de planlagte tiltakene, restrisikoen og handlingsplan er akseptable.	Ein tek NSD si vurdering til vitende, og legg denne til grunn

		for godkjenninga
2.	Ledelsen beslutter og begrunner om DPIA er o Godkjent/validert: Behandling kan starte opp. o Betinget av forbedringer (forklar på hvilken måte): Revidert DPIA skal legges frem for ledelsen på nytt. o Avvist: Virksomheten beslutter ikke å gjennomføre behandlingen.	Godkjent. Validert. Behandling kan starte opp.

Dersom en DPIA har blitt behandlet i ledergruppen mer enn én gang, risikoen fremdeles er høy og viljen til å gjennomføre fremdeles er stor, må dere anmode Datatilsynet om forhåndsdrøftelse i tråd med GDPR art.36. Virksomheten må dokumentere at den ikke greier å gjøre risikoen lavere. Det er ledelsen som tar beslutningen om å anmode Datatilsynet om forhåndsdrøftelse.

FORESPØRSEL OM DELTAKELSE I FORSKNINGSPROSJEKTET

NORSE FEEDBACK OBESITY – TILBAKEMELDING OM PSYKISK HELSE I FEDMEBEHANDLING

Du blir med dette invitert til å delta i et forskningsprosjekt i regi av Helse Førde. Bakgrunnen er at forekomsten av psykiske plager ofte er høy blant personer som gjennomgår fedmekirurgi. Tiltak for å som kan gi bedre oppfølging i behandlingsforløpet er derfor blitt etterlyst av pasienter, helsepersonell og forskere.

Formålet med prosjektet er å fremskaffe kunnskap som gir helsehjelp som er bedre tilpasset den enkelte, slik at vi kan øke kvalitet på, og effekt av, behandlingen i tverrfaglig fedmepoliklinikk.

Fordi det er viktig å ha med pasienter både med og uten psykiske plager i prosjektet, går denne invitasjonen i utgangspunktet til alle pasienter som skal gjennomgå eller har gjennomgått fedmekirurgi i Helse Førde.

HVA INNEBÆRER PROSJEKTET?

På konsultasjonene på fedmepoliklinikken er det en del av behandlingen å svare på et digitalt skjema om hvordan du har det på ulike områder i livet, hvordan helsen din er, hvilke ressurser du opplever å ha tilgang til for å støtte helsen din, hva du opplever som utfordrende og din tilfredshet med behandlingen. Disse spørsmålene inngår i et klinisk system som heter «Norse Feedback Obesity» som på en visuell og oversiktlig måte beskriver din situasjon og respons på behandling over tid. I tillegg blir opplysninger om alder, kjønn, arbeidssituasjon, utdanning, sivilstatus, kroppsvekt, kroppshøgde og om du får behandling for psykisk lidelser og fedmerelaterte sykdommer kartlagt som en del av behandlingen.

Forespørselen gjelder om vi kan få din tillatelse til forske på disse opplysningene, som blir samlet inn i perioden d.d. til 31.12.2022.

Kunnskapen som vi får fra prosjektet vil bli delt på konferanser i forskingsartikler slik at andre sykehus også kan øke sin kvalitet på, og effekt av, behandlingen i tverrfaglige fedmepoliklinikker.

MULIGE FORDELER OG ULEMPER

Siden vi i prosjektet kun bruker opplysninger som uansett blir samlet inn som en del av behandlingen, medfører ikke deltakelse noe ekstra arbeid eller andre ulemper for deg.

En fordel med å delta i prosjektet er at du bidrar til en utvikling som kan hjelpe oss å forbedre den tverrfaglige fedmebehandlingen. Dette kan være til direkte nytte for deg eller noen du bryr deg om ved eventuelt behov for hjelp i fremtiden, og det vil være til nytte for fremtidens kvalitet på denne type helsehjelp mer generelt.

FRIVILLIG DELTAKELSE OG MULIGHET FOR Å TREKKE SITT SAMTYKKE

Det er frivillig å delta i prosjektet. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke. Dette vil ikke ha noen negative konsekvenser for din videre behandling.

Dersom du trekker deg fra prosjektet, kan du kreve å få slettet innsamlede opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Dersom du senere ønsker å trekke deg eller har spørsmål til prosjektet kan du kontakte forskningsleder: John Roger Andersen, forsker i Helse Førde og professor ved Høgskulen på Vestlandet, på epost: john.roger.andersen@helse-forde.no eller på telefon 48278186.

HVA SKJER MED INFORMASJONEN OM DEG?

Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med prosjektet. Du har rett til innsyn i hvilke opplysninger som er registrert om deg og rett til å få korrigert eventuelle feil i de opplysningene som er registrert.

Dersom du samtykker til å delta i forskningsprosjektet vil de relevante opplysningene som blir brukt i pasientbehandlingen kopieres over til forskingsserveren i Helse Førde, der dataanalysene i forskingsprosjektet gjennomføres. Opplysningene på forskningsserven blir behandlet og analysert uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger.

En kode som knytter deg til dine opplysninger på forskingsserveren gjennom en navneliste, blir oppbevart på sikker dataløsning i Helse Førde, separat fra de øvrige opplysningene om deg. Koden brukes til å systematisere opplysningene som blir samlet inn over tid, og for å kunne sjekke og korrigere eventuelle feil. Koden blir kun bli brukt til disse formålene.

Det er prosjektleder og Christian Moltu og forskningsleder John Roger Andersen som jobber i Helse Førde, som har ansvaret for den daglige driften av forskningsprosjektet og at opplysninger om deg blir behandlet på en sikker måte, som har tilgang til denne koden.

Koden vil bli destruert, og informasjonen om deg i prosjektet anonymisert ved prosjektslutt (31.12.2022). Etter denne datoen vil det ikke lenger være mulig å koble opplysningene på forskningsserven til din person. Personopplysningene i prosjektet, og som er en del av behandlingen,

vil derimot finnes i pasientjournalen din, på samme måte som hos pasienter som eventuelt ikke har deltatt i prosjektet.

UTLEVERING AV OPPLYSNINGER TIL ANDRE

Under prosjektperioden vil prosjektleder Christian Moltu og forskningsleder John Roger Andersen gi tilgang på opplysninger til andre forskere innen Helse Førde når dette er nødvendig for å gjøre statistiske analyser. Opplysningene vil derimot alltid ligge på Helse Førde sin forskingsserver. Merk at ingen utenom Moltu og Andersen vil ha tilgang til ditt navn og fødselsnummer eller andre direkte gjenkjennende opplysninger.

Når prosjektperioden er slutt (31.12.2022) vil vi fjerne informasjon i datasettet, og ødelegge koblingsnøkkelen, slik at ingen skal kunne koble opplysningene vi har til din person. For at datamaterialet skal være helt anonymt, vil vi sammen med NSD—Norsk senter for forskningsdata AS, sikre at ingen kombinasjoner av bakgrunnsopplysninger svarer til færre enn tre til fem personer. Dette datasettet vil deretter bli oppbevart hos NSD og gjort tilgjengelig for andre forskere ved forespørsel.

GODKJENNING

På oppdrag fra Helse Førde har NSD vurdert at behandlingen av personopplysninger i dette prosjektet er i samsvar med personvernregelverket. Prosjektet har gjennomgått en personvernkonsekvensvurdering i tråd med personvernforordningen art. 35, og at lovlig behandlingsgrunnlag foreligger i personvernforordningen art. 6-1a og 9-2a.

DINE RETTIGHETER

I tillegg at du kan tekke ditt samtykke når som helst i prosjektperioden har du også rett til innsyn i alle opplysninger som er blitt registret om deg, og få gjort retting og/eller sletting av opplysninger. Dersom du ønsker å få utlevert dine opplysninger vil du motta en Excel-fil sammen men en hjelpetekst som forklarer innholdet. Personvernombudet i Helse Førde eller Datatilsynet er klageinstans i forhold til ivaretakelsen av dine rettigheter.

KONTAKTOPPLYSNINGER

Dersom du har spørsmål om prosjektet og dine rettigheter kan du ta kontakt med:

John Roger Andersen, forsker i Helse Førde og professor ved Høgskulen på Vestlandet.
Epost: john.roger.andersen@helse-forde.no
Telefon: 48278186.

Frode Hatten, Personvernombudet i Helse Førde.
Epost: personvernombodet@helse-forde.no
Telefon: 57831321.

SAMTYKKE TIL DELTAKELSE I PROSJEKTET

JEG ER VILLIG TIL AT DATA FRA MIN BRUK AV NORSE FEEDBACK OBSESITY OG ANDRE SPØRSMÅL SOM JEG SVARER PÅ I BEHANDLINGEN (SOM BESKREVET I INFORMASJONSBREVET) BRUKES I FORSKNINGSPROSJEKTET

Sted og dato

Deltakers signatur

Deltakers navn med trykte bokstaver

Deltakers mobiltelefonnummer

Pasientopplysninger registrert i lokal fedme-database

PASIENTOPPLYSNINGAR VED KIRURGISK BEHANDLING
AV SJUKLEG OVERVEKT (___ MÅNADER ETTER OPER.)

Fornamn: **Etternamn:** **Kjønn:**

Fødselsdato: **Personnummer:**

Adresse: **Postnummer:** **Poststad:**

Telefon: **Mobiltelefon:** **e-mail:**

Sivilstatus: ☐ Gift / sambuar
☐ Einsleg
☐ Skilt / separert
☐ Enke / enkemann

Bur åleine ? ☐ Nei ☐ Ja

Utdanning: ☐ Grunnskule
☐ Real / middels / yrkesskule
☐ Artium / øk. gymnas / allmennfag
☐ Høgskule / universitet mindre enn fire år
☐ Høgskule / universitet fire år eller meir

Innkome: % innkome:
Lønna arbeid: %
Attføring: %
Uføretrygd: %
Sosialstønad: %
Studielån/stipend: %
Anna: %

Antall arbeidsdagar sjukmeld siste 12 månader: _____
(Kun føre operasjonen og ved heilårlege kontrollar etter operasjonen).

Sjukdommar: **Faste medisinar:** **Dose:**

Medisinar ved behov: **Dose:** **Vitamin / mineraltilskot:** **Dose:**

Fastlege: **Legesenter:** **Telefon:**

Kontoradresse: **Postnummer:** **Poststad:**

Dato: **Signatur pasient:**

Preoperativt kontrollskjema ved sjukleg overvekt

Namnelapp: **Kjønn:** 1 = Kvinne 2 = Mann

Høgde: **Vekt:** **KMI (kg/m²):** **Vektendring (kg, 6 mnd):** **Blodtrykk:**

Sjukdommar (sett ring rundt):
Hypertensjon: 1 = Nei 2 = Ja, ubehandla
(Def: BT ≥ 140/90): 3 = Behandla med eit medikament 4 = Behandla med to eller fleire med.
Angina pectoris: 1 = Nei 2 = Ja Hjartesvikt ? 1 = Nei 2 = Ja
Diabetes mellitus (type II): 1 = Ikkje kjent DM 2 = Kostregulert 3 = Tablettregulert 4 = Insulin 5 = Diabetes mellitus type I
Dersom diabetes (1 eller II); Kjent sidan:…….. Insulin sidan:……
Lipidsenkande medisin? 1 = Nei 2 = Ja Thyroxin? 1 = Nei 2 = Ja, i så fall sidan:……
Astma? 1=Nei 2 = Med v/behov 3 = Fast medisin Snorker du?: 1 = Nei 2 = Ja 3 = Veit ikkje
Bruker CPAP? 1=Nei 2=Ja BiPAP? 1=Nei 2=Ja Pickwickian syndrom? 1 = Nei 2 = Ja
Hatt gallesteinsplager ? : 1 = Nei 2 = Ja Nyrestein ? : 1 = Nei 2 = Ja
Antall oppkast pr. veke (tall): Antall avføringar pr. døgn (tall):
Fast medisin mot diare ? 1=Nei 2 = Ja Plagsomt illeluktande avføring ? 1 = Nei 2 = Ja
Urinlekkasje ? 1 = Nei 2 = Ja ubehandla 3 = behandla
Belastningssmerter i hofte /kne/ ankler: 1 = Nei 2 = Smertestillande v/behov 3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Låge ryggsmerter: 1 = Nei 2 = Smertestillande v/behov 3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Hatt blodpropp? 1 = Nei 2 = Ja Hatt lungeemboli:? 1 = Nei 2 = Ja
Depresjon: 1 = Ubehandla 2 = Under behandling, i så fall plager sidan:….. . Behandla sidan:……..
Angst: 1 = Ubehandla 2 = Under behandling, i så fall plager sidan:…… Behandla sidan:……..
Kvinner: Infertilitet (Def: Ubeskytta samleie gjennom to år utan å bli gravid) 1 = Nei 2 = Ja
: Amenorhe: 1 = Nei 2 = Ja 3 = Menopause
Einingar insulin pr. dag: Røyk ? 1 = Nei 2 = Ja Om ja, tal sig/dag:
Allmenntilstand: 1 = God 2 = Mindre god 3 = Dårleg Dersom 2 eller 3 spesifiser:
Mat du ikkje toler ? 1 = Nei 2 = Ja Dersom ja , spesifiser (bruk evt. baksida).
Har / har hatt sårinfeksjon ? 1 = Nei 2 = Ja Ventralhernie ? 1 = Nei 2 = Ja

Blodprøver:
Na, K, Ca, Fosfat, Mg, Alb, Kreat, Bili, Urat, ASAT, ALAT, ALP, GGT, Ferritin
Kobalamin (B12), Folat, CRP, LPK, Hb, Tpk, INR, Cephotest, Blodgruppe, Forlik.
Sink, PTH, Vitamin D, Vitamin D metabolitter, Vitamin E, Karoten.
Bestille til neste dag *(fastande)*: Blodsukker, HbA1c, Kol, Trigl, HDL, Insulin, Insulin C-peptid
og (forutsatt signert samtykke): Serum for nedfrysing merka: "Adipositas

Urinstix (albumin, sett ring rundt):
0 = Ikkje albumin 1 = +1 Albumin 2 = + 2 Albumin 3 = + 3 Albumin

ALLE PASIENTANE SKAL TA:
EKG
RØNTGEN THORAX

EVENTUELT:
BLODGASS
SPIROMETRI

Kontrollskjema etter overvektsoperasjon. **Tid postop (mnd):**

Namnelapp: **Kjønn:** 1 = Kvinne 2 = Mann

Høgde: **Vekt:** **KMI (kg/m²):** **Blodtrykk:**

Sjukdommar (sett ring rundt):
Hypertensjon: 1 = Nei 2 = Ja, ubehandla
(Def: BT ≥ 140/90): 3 = Behandla med eit medikament 4 = Behandla med to eller fleire med.
Angina pectoris: 1 = Nei 2 = Ja Hjartesvikt ? 1 = Nei 2 = Ja
Diabetes mellitus (type II): 1 = Ikkje kjent DM 2 = Kostregulert 3 = Tablettregulert
4 = Insulin 5 = Diabetes mellitus type I
Lipidsenkande medisin? 1 = Nei 2 = Ja Thyroxin? 1 = Nei 2 = Ja
Astma? 1=Nei 2 = Med v/behov 3 = Fast medisin Snorker du?: 1 = Nei 2 = Ja 3 = Veit ikkje
Bruker CPAP? 1=Nei 2=Ja BiPAP? 1=Nei 2=Ja Pickwickian syndrom? 1 = Nei 2 = Ja
Hatt gallesteinsplager ? : 1 = Nei 2 = Ja Nyrestein ? 1 = Nei 2 = Ja
Antall oppkast pr. veke (tall): Antall avføringar pr. døgn (tall):
Fast medisin mot diare ? 1=Nei 2 = Ja Plagsomt illeluktande avføring ? 1 = Nei 2 = Ja
Urinlekkasje ? : 1 = Nei 2 = Ja ubehandla 3 = behandla
Belastningssmerter i hofte /kne/ ankler: 1 = Nei 2 = Smertestillande v/behov
3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Låge ryggsmerter: 1 = Nei 2 = Smertestillande v/behov
3 = Fast smertestillande 4 = Fysioterapi 5 = Smertestillande og fysioterapi
Hatt blodpropp? 1 = Nei 2 = Ja Hatt lungeemboli:? 1 = Nei 2 = Ja
Depresjon: 1 = Ubehandla 2 = Under behandling Angst: 1 = Ubehandla 2 = Under behandling
Kvinner: Infertilitet (Def: Ubeskytta samleie gjennom to år utan å bli gravid) 1 = Nei 2 = Ja
: Amenorhe: 1 = Nei 2 = Ja 3 = Menopause
: Født barn etter overvektsop? 1 = Nei 2 = Ja Dersom ja, antall månader etter op:
Einingar insulin pr. dag (tall): Røyk ? 1 = Nei 2 = Ja Om ja, tal sig/dag:
Allmenntilstand: 1 = God 2 = Mindre god 3 = Dårleg Dersom 2 eller 3, spesifiser:
Mat du ikkje toler ? 1 = Nei 2 = Ja Dersom ja , spesifiser (bruk evt. baksida).
Har / har hatt sårinfeksjon ? 1 = Nei 2 = Ja Ventralhernie ? 1 = Nei 2 = Ja
Sidan forrige kontroll: Hatt tilsyn av lege eller vore innlagt på sjukehus pga. overvektsoperasjonen? .....

Blodprøver (antall månader postoperativt):
1, 3, 9 mnd: Hb, Lpk, Na, K, Ca, Fosfat, Mg, Alb, Kreat, Bili, ASAT, ALAT, ALP, GGT, INR, CRP, HbA1c
I tillegg ved 6, 12, 18, 24 mnd og årleg: Cephotest, Tpk, Urat, Kobalamin (B12), Folat, PTH
Vitamin D, Vit D metabolitter, Vit E, Karoten. (*Fastande*): Glucose, Kolesterol, Trigl, HDL, HbA1c
12 mnd, 24 mnd, 5 år, 10 år: (*Fastande*): S-Insulin, S-Insulin C-Peptid.

Urinstix (albumin, sett ring rundt):
0 = Ikkje albumin 1 = +1 Albumin 2 = + 2 Albumin 3 = + 3 Albumin

Norse Feedback versjon 2.0

Norse 2.0
SYMPTOMUTTRYKK
Trist/nedfor
Eg kjenner meg deprimert
Eg føler meg nedfor mesteparten av tida
Eg er verdilaus
Eg klarer ikkje å kjenne at noko har meining
Somatisk angst
Eg kjenner uro eller ubehag inni meg mykje av tida
Eg opplever å vere kortpusta, ha hjartebank, vere nummen eller ha prikking i hender og ansikt
Eg kjenner ofte at eg er redd/engesteleg utan å heilt vite kvifor
Kroppen min er så anspent at det gir smerter
Eg har ingen augneblink i løpet av dagen utan angst i kroppen
Etevanskar
Eg er redd for å miste kontrollen når det kjem til mat
Eg bruker altfor mykje tid på å lese om mat eller planlegge måltid
Det er svært viktig for meg å kontrollere kva og kor mykje eg et
Eg bekymrar meg altfor mykje for vekta mi
Forholdet mitt til mat gjer at eg ikkje kan vere så sosial som eg vil
Traumereaksjon
Eg har svært skremmande mareritt som vekker meg opp i frykt for tida
Eg vert overvelda av skremmande minner
Eg innrettar livet mitt for å ha kontroll på skremmande minner
Eg er meir oppmerksam på fare enn dei fleste eg kjenner
Rus
Eg tenkjer eg bør kutte ned på bruken av alkohol eller narkotika
Bruken min av alkohol eller narkotika gjer at eg ikkje fungerer så godt som eg kan
Andre menneskjer er uroa for drikkinga mi/bruken av rusmidlar
Eg er bekymra for om eg er avhengig av alkohol eller narkotika
Rus-meistring
Eg kan klare meg utan alkohol/narkotika gjennom dagen
Eg er på rett veg til ikkje å ha eit rusproblem
Eg kan handtere behovet mitt for å ruse meg
Eg har trua på at eg kan meistre hendingar i livet utan alkohol eller narkotika
Suicdalitet
Eg tenkjer det ville vore betre om eg var død
Eg er redd for at eg kan miste kontrollen og ta livet mitt
Eg har planlagt korleis eg skal ta livet mitt
Eg har bestemt meg for å ta livet mitt
OPPRETTHALDANDE FAKTORAR
Irritabilitet
Eg lar meg lett irritere av andre menneskje
Eg har mange konflikter med dei som er rundt meg

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Problema mine er hovudsakleg forårsaka av andre
Håpløyse/demoralisering
Eg har gitt opp håpet om ei betre framtid
Eg kjenner heile tida at eg er på kanten til ikkje å klare meir
Det kjennes som eg er fanga i situasjonen min og ikkje veit kva eg skal gjere
Eg har håp om at eg skal få det betre no
Uansett kva eg gjer så blir det ikkje betre
Bekymring
Ofte kjenner eg at eg ikkje kan stoppe å uroe meg, sjølv når eg prøvar
Eg trenger å gruble mindre på ting som gjer meg vondt
Eg grublar konstant, og det gjer meg utslitt
Situasjonsunnviking
Eg er så redd for enkelte ting (f.eks. insekt, å fly, heiser) at eg gjer alt for å unngå dei
Eg avlyser ofte avtalar og planar på grunn av redsel/frykt
Eg har unngått bestemte plassar eller situasjonar så mykje eg kunne den siste veka
Sosial unnviking
Eg kjenner meg så ukomfortabel saman med andre at eg ofte held meg for meg sjølv
Eg vil vere sosial, men eg får det ikkje til
Eg vil unngå merksemd for einkvar pris
Indre unnviking
Følelsane mine hjelper meg til å vite kva som er viktig/rett for meg
Eg prøver hardt å unngå å kjenne eller vise enkelte følelsar
Eg brukar mykje energi på ikkje å tenkje på ting som er vanskeleg
Eg stenger av følelsane mine
Eg unngår å snakke om ting som er vanskeleg, for ikkje å bli overvelda
Sjølvkritikk
Eg synast generelt eg er ein person eg kan like
Eg fortel meg sjølv heile tida om alle tinga eg gjer gale
Eg gjer dumme feil heile tida
Eg er verdilaus
Eg skammar meg over den personen eg er
Eg trur ikkje nokon kan elske meg
Eg kjenner avsky ovanfor meg sjølv
Dersom folk viste kven eg verkeleg var, ville dei ikkje hatt noko med meg å gjere
Kontroll
Ofte er det så viktig for meg å få det heilt riktig, at det går ut over evna mi til å få gjort ting
Eg bekymrar meg ofte for om eg har vore uforsiktig eller slurvete
Det er vanskeleg å gje andre kontrollen over noko som gjeld meg
Eg er vanskeleg å leve med fordi eg må ha ting på min måte
KONSEKVENS FOR LIVSSITUASJON
Fungering
Eg er fornøgd med det eg får utretta
Eg fungerer godt i dei rollene som er viktigast for meg (f.eks. ektefelle, kjærast, barn, jobb, vener)

Eg er redd for å slutte å fungere på viktige områder i livet
Kognitive problem/konsentrasjonsvanskar
Den siste veka har eg hatt vanskar med å halde fokus
Eg strevar med å hugse ting
Eg har streva med å få med meg ting den siste veka
Eg gløymer så mykje at det påverkjer kvardagen min
Hjernen min fungerer ikkje lengre
Eg klarer ikkje å tenkje klart
RESSURSAR
Sosial tryggleik
Eg synast det er lett å snakke med vener om kven eg verkeleg er
Eg er flink til å la andre få vite kva som er viktig for meg
Eg kjenner det er lett å stole på menneskjer eg møter
Eg har gode vener som verkeleg kjenner meg
Eg kan vise følelsar saman med andre
Eg kan enkelt setje grenser for det eg ikkje aksepterer/synast er greit
Endringskapasitet
Dersom eg bestemmer meg for noko, kan eg få det til
Eg veit akkurat kva eg skal gjere for å få det betre
Eg er klar for endring
Tilfriskingsmiljø
Livssituasjonen min ligg til rette for at eg kan jobbe med vanskane mine
Økonomien min hindrar meg i å jobbe med vanskane mine
Eg er fornøgd med busituasjonen min
Eg har moglegheit til å drive med ting eg liker
Eg har familie/vener rundt meg som støttar meg når eg treng det
Enkeltståande utsegn
Eg tek vare på den fysiske helsa mi
Tilbakemeldingssystemet (NORSE) er nyttig for meg i behandlinga
Eg søv veldig dårleg for tida
Seksualitet og/eller seksualliv er vanskeleg for meg
Eg er impulsiv på ein måte som er uheldig for meg
Medikamentelle spørsmål
Eg kjenner at medisinen min hjelper meg med mine psykiske vanskar
Eg har bekymringar for ting knytt til medisinen eg tek som eg bør drøfte med nokon
Behandlingsbehov
Eg kunne trenge at behandlaren min brukte færre/meir teknikkar og øvingar
Eg kunne trenge at behandlaren min var meir personleg / var meir formell
Eg kunne trenge at behandlaren min jobba mindre med tankane mine / meir med tankane mine
Eg kunne trenge at behandlaren min jobba mindre med følelsene mine / meir med følsene mine
Eg kunne trenge at behandlaren fokuserte mindre/meir på forholdet mellom oss
Allianse
Eg har fått ei forståing for korleis behandling skal hjelpe meg

Eg opplever at behandlar forstår meg og forstår kvifor eg er i behandling no
Det kjennes som om behandlaren min akseptere meg som person
No forstår eg kva eg må gjere eller jobbe med for å få det betre

Obesity-Related Problems Scale (OP)

Føler du at din vekt eller kroppsform plager deg i forbindelse med aktivitetene og situasjonene nedenfor?

Kryss av det alternativet som passer best for deg i dagens situasjon

	Mye plaget	*En del plaget*	*Ikke spesielt plaget*	*Ikke plaget i hele tatt*
Ha fest, tilstelling hjemme	1 ☐	2 ☐	3 ☐	4 ☐
Gå ut på fest, tilstelling hos andre	1 ☐	2 ☐	3 ☐	4 ☐
Spise på restaurant	1 ☐	2 ☐	3 ☐	4 ☐
Delta i foreningsliv, kurs eller lignende	1 ☐	2 ☐	3 ☐	4 ☐
Reise på ferie	1 ☐	2 ☐	3 ☐	4 ☐
Prøve og kjøpe klær	1 ☐	2 ☐	3 ☐	4 ☐
Bade offentlig (svømmehall, badeplass)	1 ☐	2 ☐	3 ☐	4 ☐
Seksuelt samvær, intime situasjoner	1 ☐	2 ☐	3 ☐	4 ☐

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Patient-Reported Outcomes in Obesity (PROS)

- Føler du at di *vekt eller kroppsform* plagar deg innanfor områda nedanfor?
(kryss av det alternativet som passar best for deg i dagens situasjon)

Områder	Betydeleg plaga	Moderat plaga	Mildt plaga	Ikkje plaga
1. Vanlege fysiske aktivitetar (spasere, gå opp trapper og liknande)	○	○	○	○
2. Smerter i kroppen	○	○	○	○
3. Diskriminering eller ufin oppførsel	○	○	○	○
4. Søvn	○	○	○	○
5. Seksualliv	○	○	○	○
6. Vanleg sosial omgang	○	○	○	○
7. Arbeid, skulegang eller andre daglege gjeremål	○	○	○	○
8. Sjølvkjensle	○	○	○	○

- Er du plaga med *biverknader* etter at du har gjennomgått fedmekirurgi?

Betydelig plaga	Moderat plaga	Mildt plaga	Ikkje plaga
○	○	○	○

- Er du plaga med *overskotshud* i etter at du har gjennomgått fedmekirurgi?

Betydelig plaga	Moderat plaga	Mildt plaga	Ikkje plaga
○	○	○	○

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- Kor nøgd er du med *den sosiale støtta frå familie og vener* i forhold til valet om å gjennomgå fedmekirurgi?

Svært nøgd	Nøgd	Usikker	Missnøgd
○	○	○	○

- Kor nøgd er du med *den sosiale støtta frå familie og vener* etter fedmekirurgi?

Svært nøgd	Nøgd	Usikker	Missnøgd
○	○	○	○

- Kor nøgd er du, når du ser på alt under eitt, med *behandlingsresultatet* etter fedmekirurgi?

Svært nøgd	Nøgd	Usikker	Missnøgd
○	○	○	○

The Short Form 36 (SF-36) Versjon 1

SF-36 SPØRRESKJEMA OM HELSE

Dette spørreskjemaet handler om hvordan du ser på din egen helse. Disse opplysningene vil hjelpe oss til å vite hvordan du har det og hvordan du er i stand til å utføre dine daglige gjøremål.

Hvert spørsmål skal besvares ved å krysse av det svaralternativet som passer best for deg. Hvis du er usikker på hva du skal svare, vennligst svar så godt du kan.

1. Stort sett vil du si din helse er

Utmerket…….....	1 ☐
Meget god…….	2 ☐
God…….....	3 ☐
Nokså god…….	4 ☐
Dårlig…….	5 ☐

2. Sammenlignet med for ett år siden, hvordan vil du si at din helse stort sett er nå?

Mye bedre enn for ett år siden….....	1 ☐
Litt bedre enn for ett år siden……	2 ☐
Omtrent den samme som for ett år siden	3 ☐
Litt dårligere nå enn for ett år siden…..	4 ☐
Mye dårligere nå enn for ett år siden….	5 ☐

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3. De neste spørsmålene handler om aktiviteter som du kanskje utfører i løpet av en vanlig dag. Er din helse slik at den begrenser deg i utførelsen av disse aktivitetene nå? Hvis ja, hvor mye?

AKTIVITETER	Ja, begrenser meg mye	Ja. Begrenser meg litt	Nei, begrenser meg ikke i det hele tatt
a. Anstrengende aktiviteter som å løpe, løfte tunge gjenstander, delta i anstrengende idrett	1☐	2☐	3☐
b. Moderate aktiviteter som å flytte et bord, støvsuge, gå en tur eller drive med hagearbeid	1☐	2☐	3☐
c. Løfte eller bære en handlekurv	1☐	2☐	3☐
d. Gå opp trappen flere etasjer	1☐	2☐	3☐
e. Gå opp trappen en etasje	1☐	2☐	3☐
f. Bøye deg eller sitte på huk	1☐	2☐	3☐
g. Gå mer enn to kilometer	1☐	2☐	3☐
h. Gå noen hundre meter	1☐	2☐	3☐
i. Gå hundre meter	1☐	2☐	3☐
j. Vaske deg eller kle på deg	1☐	2☐	3☐

4. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av din fysiske helse?

	JA	NEI
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1☐	2☐
b. Du har **utrettet mindre** enn du hadde ønsket	1☐	2☐
c. Du har vært hindret i å utføre **visse typer** arbeid eller gjøremål	1☐	2☐
d. Du har hatt **problemer** med å gjennomføre arbeidet eller andre gjøremål (f.eks. fordi det krevde ekstra anstrengelser).	1☐	2☐

5. I løpet av de siste 4 ukene, har du hatt noen av de følgende problemer i ditt arbeid eller i andre av dine daglige gjøremål på grunn av følelsesmessige problemer (som for eksempel å være deprimert eller engstelig).

	JA	NEI
a. Du har måttet **redusere tiden** du har brukt på arbeid eller på andre gjøremål	1☐	2☐
b. Du har **utrettet mindre** enn du hadde ønsket	1☐	2☐
c. Du har utført arbeidet eller andre gjøremål **mindre grundig** enn vanlig?	1☐	2☐

6. I løpet av de siste 4 ukene, i hvilken grad har din fysiske helse eller følelsesmessige problemer hatt innvirkning på din vanlige sosiale omgang med familie, venner, naboer eller foreninger?

Ikke i det hele tatt…….. 1☐

Litt ……... 2☐

En del.……..... 3☐

Mye…….……. 4☐

Svært mye…..…… 5☐

7. Hvor sterke kroppslige smerter har du hatt i løpet av de siste 4 ukene

Ingen…….…….. 1☐

Meget svake ……..... 2☐

Svake...……..... 3☐

Moderate.…….…… 4☐

Sterke……..…… 5☐

Meget sterke…….. 6☐

8. I løpet av de siste 4 ukene, hvor mye har smerter påvirket ditt daglige arbeid (gjelder både arbeid utenfor hjemmet og husarbeid)?

Ikke i det hele tatt……..	1☐
Litt ……...	2☐
En del.…….....	3☐
Mye…….…….	4☐
Svært mye…..……	5☐

9. De neste spørsmålene handler om hvordan du har følt deg og hvordan du har hatt det de siste 4 ukene. For hvert spørsmål, vennligst velg det svaralternativet som best beskriver hvordan du har hatt det. Hvor ofte i løpet av de siste 4 ukene har du:

	Hele tiden	Nesten hele tiden	Mye av tiden	En del av tiden	Litt av tiden	Ikke i det hele tatt
a. Følt deg full av tiltakslyst?	1☐	2☐	3☐	4☐	5☐	6☐
b. Følt deg veldig nervøs?	1☐	2☐	3☐	4☐	5☐	6☐
c. Vert så langt nede at ingenting har kunnet muntre deg opp?	1☐	2☐	3☐	4☐	5☐	6☐
d. Følt deg rolig og harmonisk	1☐	2☐	3☐	4☐	5☐	6☐
e. Hatt mye overskudd?	1☐	2☐	3☐	4☐	5☐	6☐
f. Følt deg nedfor og trist?	1☐	2☐	3☐	4☐	5☐	6☐
g. Følt deg sliten?	1☐	2☐	3☐	4☐	5☐	6☐
h. Følt deg glad?	1☐	2☐	3☐	4☐	5☐	6☐
i. Følt deg trett?	1☐	2☐	3☐	4☐	5☐	6☐

10. I løpet av de siste 4 ukene, hvor mye av tiden har din fysiske helse eller følelsesmessige problemer påvirket din sosiale omgang (som å besøke venner, slektninger osv)?

Hele tiden……....	1☐
Mye av tiden…….…….	2☐
En del av tiden……...	3☐
Litt av tiden……..…….	4☐
Ikke i det hele tatt……	5☐

11. Hvor RIKTIG eller GAL er hver av følgende påstander for deg?

	Helt riktig	Delvis riktig	Vet ikke	Delvis gal	Helt gal
a. Det virker som jeg blir syk litt lettere enn andre	1☐	2☐	3☐	4☐	5☐
b. Jeg er like frisk som de fleste jeg kjenner	1☐	2☐	3☐	4☐	5☐
c. Jeg tror helsen min vil forverres	1☐	2☐	3☐	4☐	5☐
d. Jeg har utmerket helse	1☐	2☐	3☐	4☐	5☐

Vennligst kontroller at du har besvart alle spørsmålene

Weight Efficacy Lifestyle Questionnaire Short-Form (WEL-SF)

Ames, G.E., et al., Eating self-efficacy: Development of a short-form WEL, Eating Behaviors (2012), doi: 10.1016/j.eatbeh.2012.03.013.

MESTRINGSFORVENTNING - SPISEVANER

Norsk versjon av "Weight Efficacy Lifestyle Questionnaire Short-Form" (WEL-SF)

(Flolo T.N., et al., 2012)

Les igjennom situasjonene som er beskrevet nedenfor. Velg ETT tall på skalaen, fra 0 (ikke sikker i det hele tatt) til 10 (veldig sikker), som beskriver hvor sikker du er på å lykkes med å motstå å spise for mye. Skriv dette tallet etter hvert spørsmål.

0	1	2	3	4	5	6	7	8	9	10
Ikke sikker i det hele tatt										**Veldig** sikker

JEG ER SIKKER PÅ AT:	**Tall for hvor sikker du er**
1. Jeg kan motstå å spise for mye når jeg er engstelig eller nervøs	_____
2. Jeg kan motstå å spise for mye i helgene	_____
3. Jeg kan motstå å spise for mye når jeg er trøtt	_____
4. Jeg kan motstå å spise for mye når jeg ser på TV	_____
5. Jeg kan motstå å spise for mye når jeg er deprimert eller nedstemt	_____
6. Jeg kan motstå å spise for mye når jeg er i sosiale sammenkomster eller på fest	_____
7. Jeg kan motstå å spise for mye når jeg er sint eller irritabel	_____
8. Jeg kan motstå å spise for mye når andre presser meg til å spise	_____

THE GASTROINTESTINAL SYMPTOM RATING SCALE (GSRS)

Les dette først:

Undersøkelsen inneholder spørsmål om hvordan du har det, og hvordan du har hatt det DEN SISTE UKEN. Sett kryss, (X) ved det alternativ som best passer på deg og din situasjon.

1. Har du i løpet av den siste uken vært plaget av SMERTER ELLER UBEHAG FRA DEN ØVRE DEL AV MAGEN?

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

2. Har du i løpet av den siste uken vært plaget av HALSBRANN? (Med halsbrann menes en sviende eller brennende følelse av ubehag bak brystbeinet.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

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3. Har du i løpet av den siste uken vært plaget av SURE OPPSTØT? (Med sure oppstøt menes plutselige oppstøt av surt mageinnhold.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

4. Har du i løpet av den siste uken vært plaget av SUG I MAGEN? (Med sug i magen menes her en følelse i magen av behov for å spise mellom måltidene.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

5. Har du i løpet av den siste uken følt deg UVEL? (Med å føle seg uvel menes ubehagsfølelse som kan gå over i kvalme og brekninger/oppkast.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

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6. Har du i løpet av den siste uken vært plaget av RUMLING I MAGEN? (Med rumling menes vibrasjoner eller "buldring" i magen.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

7. Har du i løpet av den siste uken vært plaget av OPPBLÅSTHET? (Med oppblåsthet menes utspiling, ofte forbundet med en følelse av luft i magen.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

8. Har du i løpet av den siste uken vært plaget av RAPING? (Med raping menes behov for "utlufting", ofte forbundet med lindring av følelse av oppblåsthet.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

9. Har du i løpet av den siste uken vært plaget av LUFTAVGANG? (Med luftavgang menes her behov for å "slippe seg", ofte forbundet med lindring av følelse av oppblåsthet.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

10. Har du i løpet av den siste uken vært plaget av FORSTOPPELSE? (Med forstoppelse menes minsket avføringshyppighet.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

11. Har du i løpet av den siste uken vært plaget av DIARÉ? (Med diaré menes økt avføringshyppighet.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

12. Har du i løpet av den siste uken vært plaget av LØS AVFØRING? (Hvis du har hatt vekslende hard og løs avføring, gjelder dette spørsmålet bare i hvilken utstrekning du har følt deg plaget av at avføringen har vært løs.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

13. Har du i løpet av den siste uken vært plaget av HARD AVFØRING? (Hvis du har hatt vekslende hard og løs avføring, gjelder dette spørsmålet bare i hvilken utstrekning du har følt deg plaget av at avføringen har vært hard.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

14. Har du i løpet av den siste uken vært plaget av TVINGENDE AVFØRINGSBEHOV? (Med tvingende avføringsbehov menes raskt oppståtte behov for å gå på toalettet, ofte forbundet med en følelse av mangelfull kontroll.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

15. Har du i løpet av den siste uken i forbindelse med AVFØRING HATT EN FØLELSE AV UFULLSTENDIG TØMMING AV TARMEN? (Med ufullstendig tømming av tarmen menes at det trass i anstrengelser i forbindelse med avføring gjenstår en følelse av ufullstendig tømming.)

- ☐ Ingen plager i det hele tatt
- ☐ Ubetydelige plager
- ☐ Milde plager
- ☐ Moderate plager
- ☐ Ganske alvorlige plager
- ☐ Alvorlige plager
- ☐ Meget alvorlige plager

The Generic Short Patient Experiences Questionnaire

[Fedmepoliklinikken, Førde Sentralsjukehus]

Hvilke erfaringer hadde du på Fedmepoliklinikken?

Ettersom du nylig har hatt kontakt med Fedmepoliklinikken, Førde Sentralsjukehus, spør vi deg med dette om du vil besvare dette spørreskjemaet.

De 12 spørsmålene handler om hvilke erfaringer du hadde ved avdelingen.

Svarene blir brukt som informasjon om kvaliteten på tjenestene, sett med brukernes øyne.

Det er helt frivillig å svare.

Med "behandlerne" mener vi:

De som har hatt hovedansvar for undersøkelser og behandling. Oftest er dette leger, men mange får behandling av psykologer eller annet helse- og sosialpersonale.

		Ikke i det hele tatt	I liten grad	I noen grad	I stor grad	I svært stor grad	Ikke aktuelt
1	Snakket behandlerne til deg slik at du forsto dem?	☐	☐	☐	☐	☐	☐
2	Har du tillit til behandlernes faglige dyktighet?	☐	☐	☐	☐	☐	☐
3	Fikk du vite det du syntes var nødvendig om hvordan prøver, tester eller undersøkelser skulle foregå?	☐	☐	☐	☐	☐	☐
4	Fikk du tilstrekkelig informasjon om din diagnose / dine plager?	☐	☐	☐	☐	☐	☐
5	Opplevde du at behandlingen var tilpasset din situasjon?	☐	☐	☐	☐	☐	☐
6	Var du involvert i avgjørelser som angikk din behandling?	☐	☐	☐	☐	☐	☐
7	Opplevde du at institusjonens arbeid var godt organisert?	☐	☐	☐	☐	☐	☐
8	Fikk du inntrykk av at institusjonens utstyr var i god stand?	☐	☐	☐	☐	☐	☐
9	Var hjelpen og behandlingen du fikk på institusjonen, alt i alt, tilfredsstillende?	☐	☐	☐	☐	☐	☐

| | Ikke i det hele tatt | I liten grad | I noen grad | I stor grad | I svært stor grad | Ikke aktuelt |

Spørreskjemaet er utviklet av

kunnskapssenteret

Nasjonalt kunnskapssenter for helsetjenesten

10	Mener du at du på noen måte ble feilbehandlet (etter det du selv kan bedømme)?	☐	☐	☐	☐	☐	☐

		Nei	Ja, men ikke lenge	Ja, ganske lenge	Ja, altfor lenge
11	Måtte du vente for å få tilbud ved institusjonen?	☐	☐	☐	☐

		Ikke noe utbytte	Lite utbytte	En del utbytte	Stort utbytte	Svært stort utbytte	Ikke aktuelt
12	Hvilket utbytte har du hatt, alt i alt, av behandlingen på institusjonen?	☐	☐	☐	☐	☐	☐

Spørreskjemaet er utviklet av
kunnskapssenteret
Nasjonalt kunnskapssenter for helsetjenesten

Errata

Paper 2: In Supplementary file 1, the description of thresholds for colour categories for the Gastrointestinal Symptom Rating Scale questionnaire has been corrected: *For the colour categories in the summary report, we set the following thresholds for cut-off of the five dimensions (total score in the dimension/number of items), based on clinical judgement: 1-2 green, 3-5 yellow, and >5 red*

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