Shame and disgust-sensitivity in adult dialysis patients:

Are these variables predictive of psychological morbidity, body image disturbance and quality of life?

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by

Claire Leonard

Department of Clinical Psychology

University of Leicester

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Declaration

I declare that the work contained within this thesis is my own, and has not been submitted for any other academic award or to any other institution.

Thesis Abstract

Shame and disgust-sensitivity in adult dialysis patients; Are these variables predictive of psychological morbidity, body image disturbance and quality of life?

Author: Claire Leonard

Section one: Literature Review

Previous reviews have focussed on psychosocial adjustment, with an assumption that psychological morbidity is present in patients with a stoma. A single review of psychological morbidity was identified with significant limitations in reporting the search process (White & Hunt, 1997).

Search criteria were systematically applied to electronic databases. After consideration of inclusion and exclusion criteria, 11 relevant studies were identified.

Findings indicated psychological morbidity is present, although has not been compared to the general population so conclusions must be interpreted with caution. Psychological morbidity was not a primary focus of the studies and the psychometric adequacy of the measures used has been drawn into question. Further research clarifying the nature of psychological morbidity compared with other populations is recommended, so as to provide targeted psychological support.

Section two: Research Report

Renal replacement therapies are not without personal cost. Psychological morbidity, diminished quality of life and body image disturbance are reported in dialysis patients, yet predictors of these are relatively understudied. This study aimed to measure shame and disgust in dialysis patients, and consider association with psychological difficulties.

The study employed a cross-sectional survey design. Questionnaires were sent to dialysis patients via routine appointments and by post, with 93 returned. Data were examined using correlation and multiple regression analyses.

Participants demonstrated significantly higher levels of psychological difficulties than the general population. General shame and disgust-sensitivity were not significantly elevated, however specific measures of body shame and disgust accounted for 18-61% of variance in psychological difficulties.

Body shame and disgust were advanced as a marker of psychological difficulty in this population. Further research is necessary to develop the measure used, to facilitate a clinical tool to support professionals in recognising and managing psychological distress.

Section three: Critical Appraisal

Reflections on the research process are summarised and critically appraised.

Acknowledgments

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Word Count

	Text only	Text including Tables/Figures	References
Thesis abstract	300	300	-
Literature review abstract	236	236	-
Literature review	7146	9725	1257
Research report abstract	206	206	-
Research report	8688	9490	1910
Critical appraisal	4049	4049	-
Total	20 625	24 006	
Appendices (excluding mandatory appendices)	5004		
Overall Total (excluding mandatory appendices)	25 629	29 010	

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N.B. For copyright reasons copies of questionnaires are not included

Section One

Literature Review

The measurement of psychological morbidity in patients with a stoma: A review.

Target Journal: The British Journal of Health Psychology

The measurement of psychological morbidity in patients with a stoma: A review

Author: Claire Leonard

1. Abstract

1.1 Purpose

Stoma formation has increasingly become the focus of research considering psychosocial adjustment. Previous reviews have been conducted in this area; however there is an inherent focus on adjustment, with an assumption that psychological morbidity will be present. A single review focussing on psychological morbidity was identified with significant limitations in reporting search process (White & Hunt, 1997). Therefore this review aimed to replicate and extend the findings of the previous review.

1.2 Methods

Specific search criteria were outlined and systematically applied to seven electronic databases. After consideration of inclusion and exclusion criteria, 11 relevant studies were identified.

1.3 Results

Findings indicated that psychological morbidity has received focus in the literature, however it has not been compared to general population figures so conclusions must be interpreted with caution. Psychological morbidity however was not a primary focus in any of the studies. The psychometric adequacy of the measures are also drawn into question as several studies created novel measures specific to the population, or used standardised measures to give indirect measures of psychological morbidity.

1.4 Conclusions

Findings demonstrated a need for research to clarify the level of psychological morbidity, against what would be expected in the general population and in other chronic illnesses. Without this knowledge it is difficult to gain an understanding of the difficulties faced by patients with a stoma, and support other health professionals to recognise and provide support to patients experiencing difficulties.

2. Introduction

The relationship between physical and mental health has received increasing focus in the literature with physical illness often associated with increased incidence of psychological symptoms (Sharpe & Curran, 2006). Results from World Mental Health surveys carried out across 17 countries demonstrated anxiety and depression to be significantly associated with physical conditions, with participants more likely to have both anxiety and depression when they had several co-morbid physical conditions (Scott et al. 2007). There is variation in presentation across different conditions and different hypotheses regarding the factors affecting psychological morbidity In patients with renal conditions for example, depression and anxiety are thought to occur due to substantial lifestyle changes required by treatment, change in independence and feelings of being in control (Cotera & Alvarez, 2008; Hutchinson, 2005; Tsay & Hung, 2004).

Recognising symptoms of anxiety and depression in patients with physical illness can be complex given that many symptoms are analogous with illness, for example sleep difficulties. Despite the added complexity, the National Institute for Clinical Excellence do not specifically recommend use of psychometric measures in assessing depression in patients with chronic physical conditions, however do recommend a comprehensive assessment that is more thorough than a symptom count (National Institute of Clinical Excellence [NICE], 2009).

Stoma formation incurs a substantial physical change often due to illness and the literature regarding stoma formation is growing. However understanding psychological

morbidity in patients with a stoma appears less well known. Given the potential for variation in assessment of psychological morbidity it is also useful to understand the methods by which psychological morbidity has been measured within this body of literature and consider the relative psychometric adequacy of the methods used.

2.1 Stoma formation

Stoma formation occurs in response to a physical illness or trauma which has affected normal functioning of the digestive or urinary pathways in the body, most often from organic disease, malignancy or problems with continence or obstruction (Brown & Randle, 2005; Burch, 2008, 2011; Taylor, 2005).

A 'stoma', also referred to as an 'ostomy', is an aperture created on the surface of the skin, through which bodily excretions are re-diverted from their usual pathway. Once a stoma has been formed, an appliance can then be attached which allows a 'pouch' or 'bag' to be fitted to collect bodily excretions. This process involves regular self-care and monitoring by the patient to ensure the appliance is correctly fitted, and attached pouches are regularly changed (Taylor, 2005).

Ostomies can be broadly divided into three main categories; Colostomy, Ileostomy and Urostomy. A Colostomy refers to an opening formed in the colon (large intestine), an Ileostomy refers to an opening formed in the ileum (small intestine), and a Urostomy refers to an opening in the urinary tract (Burch, 2011; Taylor, 2005). Current estimates from the UK Department of Health suggest 102,000 people are living with a stoma, and approximately 21,000 patients undergo stoma formation every year, of which half will be permanent (Coloplast, 2010). Whilst there is financial cost, estimated to be upwards

of £200 million pounds a year on appliances and stoma care, there is also significant personal burden, acknowledged by service provision of Clinical Nurse Specialists to support patients in their self-care, alongside helping to manage adjustment to the stoma and physical, psychological and social consequences encountered (Coloplast, 2010; Foskett, 2012; McLeod, Johnson, Robertson & Lawson, 2009).

2.2 Impact of stoma formation

Stoma formation is recognised to have many physical, psychological and social effects on a patient's life, demonstrating a significant impact on general wellbeing and lifestyle of the patient and family/close relationships, irrespective of age (Deeny & McCrea, 1991; Waller, 2008).

The physical consequences are extensive and include considerable alteration to routines for managing bodily excretions, establishing daily stoma care, appearance change and concern and the physical management of leaks or odours (Burch, 2008; Deeny & McCrea, 1991). Complications can also infer difficulties including skin sensitivity, bleeding, constipation or diarrhoea (Burch, 2008).

Alongside troubling physical consequences for patients, the social impact has too been demonstrated. Patients reported significant limitations in social life post-stoma formation, with an avoidance of previously enjoyed activities, and impaired spousal relationships (Bekkers et al., 1995). Difficulties in spousal relationships have in part been attributed to sexual difficulties, with patients with a stoma reporting to feel less sexually-attractive, whereas avoidance of activities appears more focused on adapting

to the physical limitation of the stoma, and fear of others asking difficult questions (Bekkers et al., 1995; Brown & Randle, 2005).

2.3 Psychological morbidity

Psychological morbidity, namely anxiety and depression, has been widely documented in patients with physical health conditions, as has its' relationship to increased illness symptoms and poorer long-term outcomes (Vriezekolk et al., 2010). A growing body of research suggests numerous psychological consequences of stoma formation. Studies of psychological consequences appear broadly divided into studies of psychological adjustment, body image, quality of life, and relationship and sexual difficulties (Brown & Randle, 2005; Oades-Souther & Olbrisch, 1984). Research into psychological consequences has been driven by recognition of poorer outcomes in some patients with a stoma, and an increasing need for support from Stoma Care Clinical Nurse Specialists and other therapeutic approaches (Coloplast, 2010; Foskett, 2012; McLeod, Johnson, Robertson & Lawson, 2009).

It has been estimated a quarter of patients undergoing stoma formation will experience psychological consequences, especially in the first three months post-surgery, and that psychological morbidity negatively impacts on post-surgical recovery (Wade, 1990; White & Hunt, 1997). Psychological morbidity has been hypothesised to occur as a result of patients coming to terms with what has been termed a radical disfigurement, loss of an important bodily function and subsequent changes in personal hygiene and daily living, alongside changes in social relationships and activities (Bekkers et al., 1995). Stoma cognitions have also been demonstrated to contribute to the variance in psychological morbidity noted across this patient group. Moreover, it has been

suggested that three main cognitions regarding the stoma ruling their life, being a complete person and in control on their body have been shown to account for 60% of the variance in psychological morbidity (White & Unwin, 1998)

More specific psychological effects of stoma surgery have also been noted by several other studies. Rates of anxiety for patients with a stoma have been documented as higher than would be expected within the general population, with between 18 and 25% of patients experiencing significant levels of anxiety post-surgery (Thomas, Madden & Jehu, 1987a, 1987b; Wade, 1990;). Such high levels were also documented up to a year following surgery (Wade, 1990). Interventions to manage state-anxiety in patients with a stoma have been examined, and a randomised-controlled trial using progressive muscle relaxation training has been shown to reduce anxiety by 43% compared with a 25% reduction in anxiety over time in the control group (Cheung, Molassiotis & Chang, 2001). However, despite interventions being investigated, further explanations or predictors of increased anxiety scores in patients with a stoma are still somewhat unclear.

Alongside anxiety, higher rates of depression than would be expected in the general population have long been documented in patients with a stoma (Thomas, Madden & Jehu, 1987a, 1987b). It has been estimated that up to 50% of the population with a stoma may have depression, frequently due to the overwhelming fear of the pouch leaking, but it is often unrecognised and undiagnosed by health professionals (Turnbull, 2007). Additionally when compared with patients without a stoma, those with a stoma have significantly higher rates of depression regardless of the initial reason for their stoma formation (Ross et al., 2007). However it is noted that there does appear less

research focussing on depression than anxiety in patients with a stoma. This may in part be due to the lack of recognition by health professionals of depression in this population, perhaps because of the emphasis on frequently managing medical complications (Burch, 2008; Deeny & McCrea, 1991; Turnbull, 2007).

2.4 Reviews of the impact of stoma formation

There have been several reviews focussing on the impact of stoma formation on wellbeing. Oades-Souther & Olbrisch (1984) presented a review aiming to understand psychological adjustment to stoma surgery, further updated by Bekkers et al. (1995) who further aimed to describe demographic, medical and psychological variables influencing adjustment. Oades-Souther & Olbrisch (1984) identified adjustment difficulties in specific areas namely; physical health, employment, social activities, marital and sexual functioning, and emotional adaptation. Bekkers et al. (1995) also outlined four similar, specific areas requiring adaptation namely; social, interpersonal and sexual relationships, and emotional problems. In addition Bekkers et al. (1995) advanced four categories in which variables influence adaptation including socio-demographic, stoma-specific, illness-related and personality related. Oades-Souther & Olbrisch (1984) also identified factors predictive of adjustment with independence, peer support, satisfaction with medical staff and provision of stoma-related information suggested as possible influencing variables. However the authors do not draw any firm conclusions from the articles reviewed, and appear to place a greater emphasis on the biological and social adjustments identified, at the expense of considering psychological distress and adjustment. There also appears an underlying assumption regarding psychological morbidity, as there is no attempt made to outline the nature of psychological morbidity in this patient group, despite adaptation to emotional

difficulties being identified as important. Indeed, the methods by which emotional problems are measured and synthesised were not considered at all within the review.

Psychosocial adjustment to stoma surgery was also reviewed by Brown & Randle (2005). This review aimed to consider psychological and social effects of stoma surgery. The reviewed articles were summarised into five areas in which stoma surgery had an impact, namely quality of life, body image, sexuality and sexual concern, psychosocial and practical adjustment. No firm conclusions are drawn from the articles reviewed, though the authors did suggest stoma patients experience negative feelings post-surgery. However this assertion appears to be drawn from limited evidence, and no clear conclusion about the nature of psychological morbidity, how this has been measured, or predictors of psychological morbidity have been made.

A single review was identified that aimed to summarise the prevalence of psychological morbidity in patients with a stoma (White & Hunt, 1997). They identify that 18-26% of patients who undergo stoma formation experience significant psychological difficulties post-surgery. They also note the detection of psychological morbidity by health professionals is poor, and identify a number of variables associated with psychological morbidity including illness-related, stoma-related and psychological factors. The psychometric adequacy of the measures of psychological morbidity was also not considered, although methodological flaws were noted. However, despite presenting a number of articles within this review, there is no explanation of the review search process, inclusion and exclusion criteria, or search terminology used which made it impossible to replicate and extend this review. It was also unknown whether a systematic search process had been utilised, meaning the review was evaluated with

some caution. As such, it was decided that a systematic, replicable review needed to be undertaken in this area to understand the nature of psychological morbidity in patients with a stoma, and the methods by which this has been measured as this had not been referred to in the White & Hunt (1997) review. Additionally the current review also served to replicate and advance the understanding initially outlined by White & Hunt (1997).

2.5 Rationale and aims

Given psychological morbidity appears to have received increasing research focus in patients with a stoma, there are few studies attempting to draw together this research. The reviews undertaken did not describe the nature of psychological morbidity, choosing to focus on the factors affecting psychosocial adjustment, appearing to make an assumption of psychological morbidity in the population (Bekkers et al., 1995; Brown & Randle, 2005; Oades-Souther & Olbrisch, 1984).

The single review study identified that focussed on describing the nature of psychological morbidity did not describe the review search process undertaken meaning the results were interpreted with caution, and rendering replication and extension of their review impossible (White & Hunt 1997). Given limited understanding of whether a systematic review process was undertaken and that the review was undertaken more than fifteen years ago, this current review sought to describe psychological morbidity in patients with a stoma. Furthermore the current review sought to identify the methods by which psychological morbidity has been measured, their psychometric adequacy, and identify possible biopsychosocial predictors of psychological morbidity in patients with a stoma.

3. Method

3.1 Search strategy

A scoping search was conducted in September 2012 to establish the range of literature available for review. Search terminology were verified with National Institute of Clinical Excellence (NICE) guidance and Medical Subject Headings (MeSH).

Search terms; 'bio*', 'psycho*', 'social', 'biopsychosocial', 'predict*', 'psychological distress', 'depression', 'anxiety', 'psychological morbidity', 'stoma', '*ostomy', '*ostomies', 'colostomy', 'urostomy', 'ileostomy'; were systematically inputted into the following computerised databases covering a range of medical and psychological literature; PsycINFO, Web of Science, Medline, The Cochrane Library, National Library for Health (covering CINAHL and AMED), and Science Direct (Appendix B). Databases were interrogated between the 15th and the 29th April 2013, with no exclusion placed on study dates given the paucity of literature revealed in the scoping search, and to enable full replication of the previous review (White & Hunt, 1997).

3.2 Eligibility criteria

A number of eligibility criteria were applied to the searches to allow homogeneity of research studies to facilitate drawing comparisons and these are outlined below. The review focussed on peer-reviewed literature, with adult participants, specifically 18+ years old, with a full text article available in English.

In addition studies must;

- Have reported on patients who have had a stoma formed for the elimination of bodily excretions, namely a colostomy, ileostomy or urostomy. Comparative

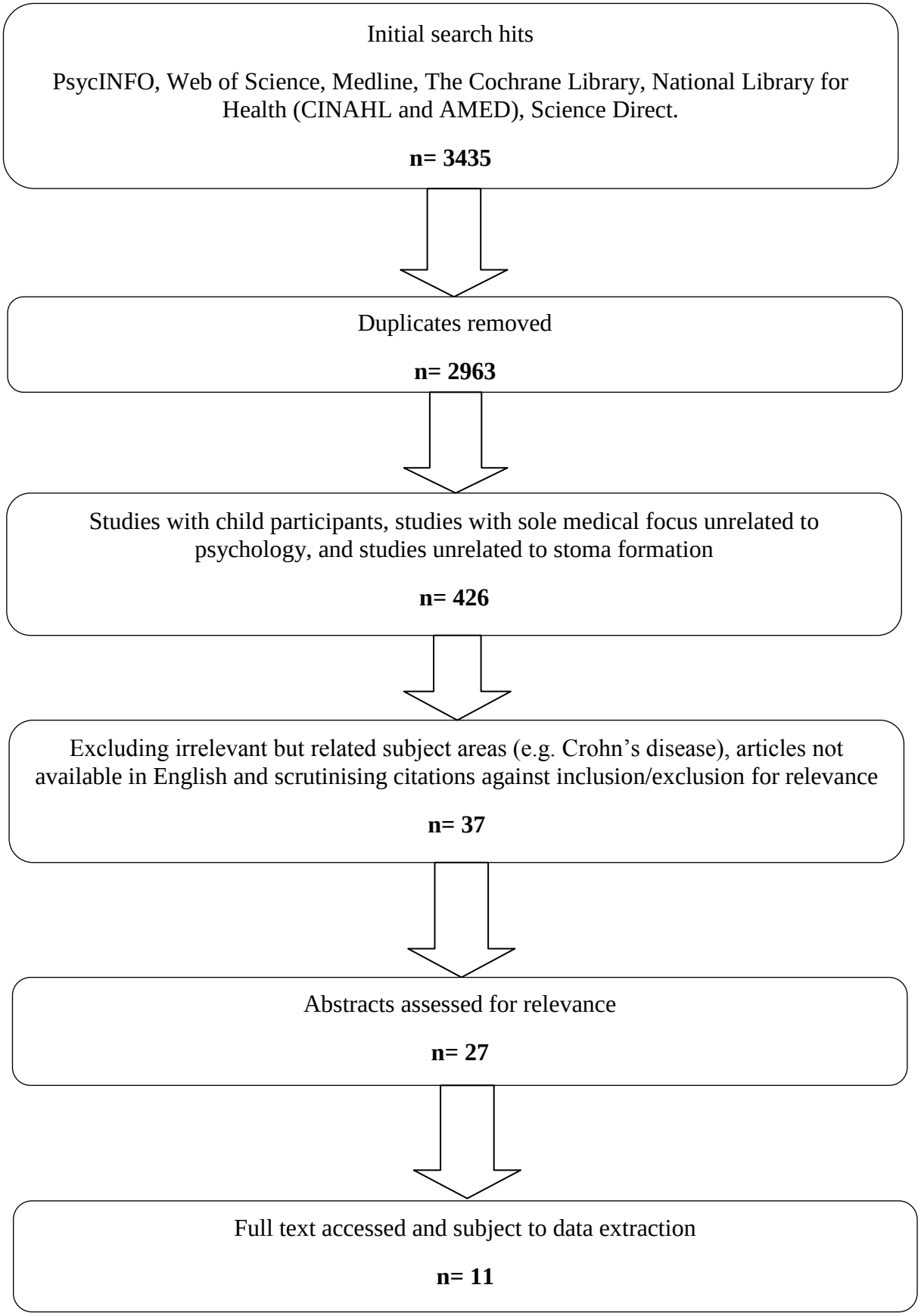
studies examining psychological status of those with and without stomas were also accepted for review.

- Have defined and measured psychological distress, psychological wellbeing, psychological morbidity, depression or anxiety using standardised, quantitative methodology.

3.3 Study selection

The study selection process is outlined in Figure 1. Articles emergent from the scrutiny of electronic databases were first examined for relevance. On removing 472 duplicates, 2963 articles remained. Further exclusion criteria were applied removing research undertaken with child populations (933), or those deemed to be solely focussed on medical status with no reference to psychology (1127), or not related to stoma formation (477), leaving 426 articles. Further papers related to bowel disorders but without stoma formation as a focus (304) and articles not available in English (85) were removed leaving 37 articles. Abstracts were then assessed against the inclusion and exclusion criteria, identifying 27 articles may be suitable for inclusion. Full text copies of the 27 articles were then retrieved and assessed, with references scanned for further relevant citations. After further evaluating the articles and references identified as appropriate against the inclusion and exclusion criteria, eleven articles were deemed suitable for review.

Figure 1: Process of selecting articles for the review



3.4 Quality assessment and synthesis

The final eleven articles shortlisted were subject to data extraction processes using the Centre for Reviews and Dissemination's guidance for undertaking reviews in health care (2008), and the categories used for data extraction are summarised in Appendix D.

Methodological quality was assessed using 'strengthening the reporting of observational studies in epidemiology' (STROBE) initiative checklist of criteria to be met in the reporting of cohort, cross-sectional, and case-control studies (Vandenbroucke et al., 2007). STROBE outlines 22 set criteria to ensure rigorous, scientific reporting of empirical research. Studies were assessed against STROBE criteria, to ascertain whether all recommended areas were reported and thus deemed to be a high quality, empirical report. Studies were given either a negative or affirmative for each of the criteria met in each article which were then summed into a total score. A cut-off of 18 was used to ensure all studies were of a similar quality and the results of this assessment can be found in Appendix C (Vandenbroucke et al., 2007).

A meta-synthesis was not possible due to the heterogeneity of variables and populations considered in the studies reviewed, therefore narrative synthesis was conducted.

4. Results

The eleven studies were reviewed regarding participants and settings of the study, psychological morbidity identified, the methodological designs and psychometric adequacy of measures utilised within the studies, possible predictors of psychological morbidity and study limitations.

4.1 Key characteristics

The main characteristics of the eleven studies included for review were assessed and summarised in Table 1.

Of the eleven review studies, five used a cross-sectional design and six used a longitudinal design. The cross-sectional studies used two main recruitment methods; postal surveys (three studies) and recruitment in person during attendance to appointments (two studies). The postal studies had return rates of 31%, 33% and 51.2%.

The longitudinal studies all recruited participants via appointment attendance, and measured variables at differing intervals with three studies measuring pre-intervention (surgery or education) and post-intervention (one month in one study, six weeks in another, and three months in two of the studies). The remaining three longitudinal studies measured variables post-diagnosis or surgery, with one study measuring variables at five months and five years post-diagnosis, and the second two studies measuring variables at three time-points (1 week, 4 months and 1 year).

Table 1: Summary of key characteristics of review studies

Authors & location	Primary focus & theoretical perspective (if noted)	Participants & setting	Study design	Overview of findings	Predictors identified	Critique
1. Altundas et al., (2012). Istanbul, Turkey	Understanding the impact of group education on quality of life.	72 patients with a stoma, 38.9% female with mean age of 56.8 years. Recruited participants from Kartel Education & Research Hospital	Longitudinal design, measures taken pre-education programme and several months after completion of programme (exact timescales not specified). Patients contacted by telephone to complete measure. MEASURES USED: - Short-Form 36	Statistically significant improvement role-emotional and mental health subscales and Mental Health Component score pre to post education programme.	-Education -Spousal support -Living in rural districts.	Findings not compared with normative or other chronic illness sample to identify if scores are lower than would be expected in other populations and no control group to measure change over time.

2. Anaraki et al., (2012). India	Understanding the impact of stoma surgery on quality of life.	102 patients with a stoma, 43.1% female with a mean age of 53.5 years. Recruited participants from Iranian Ostomy Society.	Cross-sectional design, unclear how exactly participants were recruited. MEASURES USED: - City of Hope Quality of Life-Ostomy	63% of sample reported feelings of depression. Depression statistically significant in predicting QOL score.	-Time of ostomy -Underlying disease leading to stoma formation -Depression -Location of stoma -Change in clothing style.	No analysis of whether sample is representative which limits generalisability. Indirect measure of psychological morbidity with focus on quality of life rather than morbidity.

3. Bekkers, van Knippenberg, van den Borne, van Berge Henegouwen. (1996). Netherlands.	Understanding the role of self-efficacy in psychosocial adaptation to stoma surgery. Bandura, 1977, 1986; Theory of self-efficacy (Social learning theory).	59 patients with a stoma, 47.5% female with a mean age of 44 years. Participants recruited from eight different hospitals.	Longitudinal design, patients asked to participate by Enterostomal Therapist. Measures completed post-operatively; one week, four months and one year. MEASURES USED: - Psychosocial Adjustment to Illness Scale - Stoma Self-Efficacy Scale	Psychological distress reduces over time, social self-efficacy statistically significant in predicting psychological outcomes.	-Stoma complications -Problems in stoma care -Stoma care Self-Efficacy -Age -Pre-operative physical problems -Diagnosis -Education -Social Self-Efficacy.	High attrition reduced statistical power, as data from participants who dropped-put were removed. Findings not compared with normative or other chronic illness sample to identify if scores show significant differences.

4. Bullen et al., (2012). Sydney, Australia	To understand whether body image disturbance predicts psychological difficulties in patients undergoing colorectal surgery.	67 patients undergoing stoma colorectal surgery, 53.7% females with a mean age of 59.9 years. Participants recruited from pre-surgical clinics.	Longitudinal design, participants approached prior to surgery to complete questionnaires, and again at three-month follow-up. MEASURES USED: - Hospital Anxiety and Depression Scale - Short-Form 36 - Body Image Ideals - Appearance Schemas Inventory-Revised	Stoma formation associated with statistically significant deterioration in depression, anxiety, emotional quality of life and body image disturbance.	-Presence of stoma -Body image disturbance (pre and post surgical) -Physical quality of life -Self-evaluation and appearance schemas.	Small sample size means caution must be exercised in interpreting the results. Number of participants meeting clinical ranges for psychological morbidity is also not identified.

5. Chambers et al., (2011). Australia	To assess and compare quality of life and psychological distress in colorectal cancer patients. Dispositional optimism and response shift theory.	763 patients diagnosed with colorectal cancer, 14.8% of whom had a stoma. 45.7% were female. Participants recruited from across Queensland.	Longitudinal design, participants entered study five months post-diagnosis requiring stoma formation, and assessed again five-year post-diagnosis. MEASURES USED: - Revised Life Orientation Test - Constructed Meaning Scale - Brief Social Support - Functional Assessment of Cancer Therapy - Satisfaction with Life Scale - Brief Symptom Inventory	Emotional wellbeing improved over time, however psychological distress was stable over time. Less than 10% of participants reported psychological distress. Predictors for greater levels of psychological distress identified.	-Being in a relationship -Presence of a pet -Diagnosis -Optimism -Quality of life -Permanent stoma	Subjective nature of self-report assessments rely on participant's perception. Findings not compared with normative or other chronic illness sample to assess differences.

6. Follick, Smith & Turk. (1984). USA	Understanding the relationship between education and social support with adjustment in patients with a stoma. Biopsychosocial model.	131 patients with a stoma, 54.9% female, two thirds over age of 45 years. Participants recruited through registration with Rhode Island cancer society.	Cross-sectional design, questionnaires posted to patients with an ostomy registered with the Rhode Island Cancer Society, 33% returned questionnaires. MEASURES USED: - Novel measure created for study	50% of the sample reported experiencing a significant level of emotional stress post-surgery, 33% had depression, with 8% reporting experiencing major emotional problems.	-Social adjustment -Marital/family adjustment -Sexual adjustment -Education	Convenience sample based on registration with a society and not compared with ostomy population reduces generalisability. Novel measure lacks reliability and validity analyses and is therefore non-standardised.

7. Mitchell et al., (2007). USA	To understand the relationship between demographic, clinical and quality of life variables and embarrassment in military veterans with a stoma.	239 military veterans with a stoma, 94% male, with a mean age of 69 years. Participants recruited from three military veteran medical centres in Arizona, Indiana and Los Angeles.	Cross-sectional design, questionnaires posted to participants, with second questionnaire sent if not returned within four weeks. MEASURES USED: - City of Hope Quality of Life-Ostomy	Using the psychological subscale, participants with significantly higher levels of embarrassment had significantly higher levels of anxiety and depression.	-High embarrassment -Being in a relationship	Measure findings not compared with normative or other chronic illness sample to identify if scores are lower than would be expected in other populations. Numbers of participants meeting 'caseness' on measure also not reported.

8. Richbourg, Thorpe & Rapp. (2007). USA	To understand the nature of difficulties patients experience after stoma formation.	43 patients following stoma formation, 59% female, with a mean age of 53 years. Participants were recruited from a tertiary care health system serving North Carolina.	Cross-sectional design, questionnaires posted to participants, with reminder seven days later. MEASURES USED: - Novel measure created for study	Of the sample, 53% experienced anxiety/depression, and were most likely to go to medical doctor for support with this.	-None identified	Convenience sampling method may reduce generalisability. Novel questionnaire does not appear to have been subject to any reliability or validity analyses, therefore may be non-standardised.

9. Sharma, Sharp, Walker & Monson. (2007). Hull, UK	To understand possible predictors of post-operative quality of life in patients with colorectal cancer.	104 patients undergoing surgery for colorectal cancer, 40.4% of whom had a stoma formed. 32.7% were female with a mean age of 67.6 years. Participants recruited from Castle Hill Hospital.	Longitudinal design, participants recruited and completed baseline assessments 5-12 pre-surgery and again 6-10 weeks post-surgery (six weeks following discharge). MEASURES USED: - Functional Assessment of Cancer Therapy - EuroQol - Hospital Anxiety and Depression Scale - Positive and Negative Affect Scale - Mood Rating Scale	Depression scores significantly higher at six weeks post-surgery. Predictors of anxiety and depression were identified.	-Diagnosis and stage of illness -Social support	Findings not compared with normative or other chronic illness sample to identify if scores are lower than would be expected in other populations.

10. Sharpe, Patel & Clarke. (2011). Sydney, Australia	To understand the impact of having a stoma on body image, and consider the relationship between body image and distress.	99 patients diagnosed with colorectal cancer, 34.3% of whom had a stoma. 39.4% were female with a mean age of 65.8 years. Participants recruited from seven hospital sites.	Longitudinal design, with participants being approached post-surgery but during admission, or their first post-surgery review appointment. Follow-up was either at the end of treatment or six months post-surgery, whichever was sooner. MEASURES USED: - Body Image Scale - Hospital Anxiety and Depression Scale - Distress Thermometer	Presence of a stoma linked with significantly lower body image scores, and significantly higher rates of anxiety. No effect found for depression.	-Presence of stoma at later stage -Body image disturbance	Sample too small for statistical power, and do not take into account pre-morbid difficulties. Findings not compared with normative or other chronic illness sample to identify if scores are lower than would be expected in other populations.

11. Tal et al., (2012). Israel	To identify predictors of self-care and subsequent impact on quality of life.	65 patients with a stoma, 20% female with a mean age of 72 years. Participants recruited from Beilinson Hospital and Rabin Medical Centre.	Cross-sectional design, unclear how exactly participants were recruited. MEASURES USED: - Novel measure created for study	Psychological difficulty experienced by 77.4% of sample and has significant association with reduced self-stoma care.	-Gender -Education -Self-stoma handling -Quality of life	Retrospective self-report measures used which rely on memory and may not necessarily be accurate. Also, novel questionnaire was used with no reference to any reliability or validity analyses, therefore may be non-standardised.

4.2 Participants and settings

Samples sizes across the eleven studies vary from 43 to 763 giving a range of 720 participants. The participants were majority male, with percentage figures for females varying from 6% to 54.9%. In terms of age, the samples means demonstrated were between 40 years and 69 years, with a range of 29 years. Only four of the eleven studies reported any form of ethnicity demographics, therefore any generalisations of results to the wider population should be interpreted with caution. Also, only one study reported using a power analysis to calculate sample or effect size and increase the reliability of the findings, meaning the remaining ten studies should be interpreted with caution (Sharpe, Patel & Clarke, 2011).

Other demographics reported included marital status, living status and location, income and occupational status, education level, physical health diagnosis, symptoms and complications, surgery type, lifestyle changes and Body Mass Index (BMI).

4.3 Psychological morbidity

The studies reported wide variation of psychological morbidity within their sample from 3.8 – 63%, however no study compared psychological morbidity scores with other clinical populations or community norms to scores against what might be expected in other populations. The findings regarding psychological morbidity are summarised in Table 2.

Table 2: Psychological morbidity and psychometric adequacy

Study	Measures used	Power analysis	Breakdown of psychological morbidity results		Significance	Reliability analysis	Methodological limitations
1. Altundas et al., (2012).	Short-Form 36	None reported	BASELINE: Role-emotional subscale mean=34.2, SD=14.1, mental health subscale mean 48.2, SD=10.7, and Mental Component Score mean=44.6, SD=10.6	FOLLOW-UP: Role-emotional subscale mean=43.8, SD=11.1, mental health subscale mean 53.2, SD=7.9, and Mental Component Score mean=49.6, SD=6.7	Improvement in scores between pre- and post-education sig at .01 level.	None reported	Lack of power analysis restricts reliability of conclusions, lack of control group, lack of qualitative self-report from participants.
2. Anaraki et al., (2012).	City of Hope Quality of Life-Ostomy Questionnaire	None reported	Depression was reported by 63% of participants and was demonstrated as a significant predictor of psychological subscale score and overall quality of life total score.		Relationships between depression, psychological and overall quality of life sig at .05 level.	None reported	Sample selection through an ostomy society, and cross-sectional design.

3. Bekkers, van Knippenberg, van den Borne & van Berge Henegouwen. (1996).	Psychosocial Adjustment to Illness Scale	None reported	Psychological distress subscale scores by gender at 4 months and 1 year respectively reduced from 1.4 to 0.8	n.s.	CA=0.9	It is noted that the baseline measure is not taken pre-operatively, however baseline scores are not reported in the analyses.

4. Bullen et al., (2012).	Hospital Anxiety and Depression Scale	None reported	BASELINE: anxiety mean=7.7, SD=5.2, depression mean=5.5, SD=4.6 in stoma patients, anxiety mean=6.4, SD=3.5, depression mean=3.3, SD=3.8 in non-stoma patients	FOLLOW-UP: anxiety mean=7.8, SD=3.7, depression mean=6.6, SD=4.1 in stoma patients, anxiety mean=5.1, SD=3.8, depression mean=3.4, SD=2.8 in non-stoma patients	n.s. difference between stoma and non-stoma patients at BL. At FU difference in anxiety sig at .05, depression sig at .01	None reported	Limited sample size and high attrition, some measures not validated with within illness populations, noticeable baseline differences between stoma and non-stoma groups suggests they were not well matched and results should be interpreted with caution.
	Short-Form 36		BASELINE: Mental Component Score mean=44.9, SD=14.3, in stoma patients, mean=48.7, SD=10.6 in non-stoma patients	FOLLOW-UP: Mental Component Score mean=44.1, SD=9.6, in stoma patients, mean=48.5, SD=11.0 in non-stoma patients	n.s. difference between stoma and non-stoma patients at BL or FU	None reported	

5. Chambers et al., (2011).	Functional Assessment of Cancer Therapy Questionnaire	BASELINE: Emotional subscale (mean=21.7, SD=2.9).	FOLLOW-UP: Emotional subscale (mean=22.2, SD=2.7).	Difference in emotional subscale between BL & FU sig at .01	BASELINE CA 0.7, FOLLOW-UP CA 0.9.	Low response rate and number of participants completing all assessments noted leading to a reduction in generalisability. Subjective nature of self-report questionnaires may obscure clinical meaningfulness.
	Brief Symptom Inventory	BASELINE: 3 subscales, 8.5% reported depression, 5.8% reported anxiety, 4.6% reported somatisation, total (Global Severity Index) 7.0%	FOLLOW-UP: 3 subscales, 6.8% reported depression, 3.8% reported anxiety, 4.9% reported somatisation, total (Global Severity Index) 5.0%	n.s.	BASELINE CA 0.9, FOLLOW-UP CA 0.9.	

6. Follick, Smith & Turk. (1984).	Novel measure created for study	None reported	Percentages of responses recorded per question. Emotional stress was reported by 50% of the sample. Depression was reported by 33%, anger and irritability by 24% and 8% identified major emotional difficulties.	n.s.	None reported	Small, convenience sample may introduce bias. Questionnaire is self-report and retrospective meaning subjective perception rather than objective assessment may be present, and results should be interpreted with caution.

7. Mitchell et al., (2007).	City of Hope Quality of Life-Ostomy Questionnaire	None reported	Overall significant difference in psychological domains scores comparing those reporting high (mean=4.8, SD=1.8) or low (mean=7.6, SD=1.8) embarrassment. Specifically significant differences in anxiety (high mean=3.6, SD=2.5, low mean=7.5, SD=2.9), depression (high mean=3.9, SD=2.9, low mean=8.0, SD=2.5), appearance satisfaction (high mean=4.3, SD=2.8, low mean=6.8, SD=2.7) and meeting new people (high mean=5.0, SD=3.7, low mean=9.2, SD=1.9).	Difference between high and low embarrassment all sig at .01	Overall CA=0.9, CA for domains: physical (0.9), psychologic al (0.8), social (0.9) and spiritual (0.8)	Noted cross-sectional correlation design as limitation. Generalisability limited due to largely male, military veteran population used for study.
8. Richbourg, Thorpe & Rapp. (2007).	Novel measure created for study	None reported	Percentages of responses recorded per individual question. Not overall totals calculated. Mental health questions reported: depression or anxiety in 53%, poor coping with ostomy in 48%, sleep problems in 35% and sexual problems in 26%.	None reported	None reported	Sampling and non-response error may be present. Use of convenience sample may introduce bias.

9. Sharma, Sharpe, Walker & Monson. (2007).	Hospital Anxiety and Depression Scale	None reported	BASELINE: anxiety mean=6.7, SD=4.4, depression mean=3.6, SD=3.3	FOLLOW-UP: anxiety mean=5.7, SD=3.8, depression mean=4.8, SD=3.8	Difference in depression between BL & FU sig at .05	None reported	None reported by the authors. Lack of power analysis and indication of validating measures with patients with a stoma are considered limitations.
	Positive and Negative Affect Schedule		BASELINE: positive affect mean=29.8, SD=7.7, negative affect mean=18.7, SD=7.3	FOLLOW-UP: positive affect mean=30.1, SD=8.4, negative affect mean=16.2, SD=6.3	n.s.	None reported	
	Mood Rating Scale		BASELINE: mean=533.8, SD=166.3	BASELINE: mean=541.2, SD=174.2	n.s.	None reported	

10. Sharpe, Patel & Clarke. (2011).	Hospital Anxiety and Depression Scale		BASELINE: Compared stoma (anxiety= 5.3 (4.4), depression=3.8 (3.4)) and non-stoma (anxiety= 4.1 (3.5), depression=3.5 (3.0)) with t-tests anxiety t= -1.4, *p*=0.2, depression t= -0.5, *p*=0.6	FOLLOW-UP: Compared stoma (anxiety= 6.1 (4.5), depression= 4.2 (4.3)) and non-stoma (anxiety= 3.8 (3.6), depression=3.0 (2.9)) with t-tests anxiety t= -2.4, *p*=0.0, depression t= -1.2, *p*=0.3	n. s. at BL difference in anxiety between stoma and non-stoma sig at .05 at FU.	CA= anxiety 0.9, depression 0.8	Sample under-powered which may have affected effect sizes demonstrated therefore results to be interpreted with caution.
	Distress Thermometer		BASELINE: Compared stoma (2.7 (2.8)) and non-stoma (2.6 (2.5)) with t-test t= -0.2, *p*=0.9	FOLLOW-UP: Compared stoma (2.8 (3.0)) and non-stoma (1.5 (2.1)) with t-test t= -2.0, *p*=0.5	n.s.	None reported	
11. Tal et al., (2012).	Novel measure created for study	None reported	Percentages of responses recorded per individual question. No overall totals calculated. Psychological difficulty (body image disturbance, avoidance, disgust and denial) reported by 77.4%.		None reported	None reported	Use of proprietary questionnaire is a limitation as lacks validation.

**CA=Cronbach's alpha, BL=baseline, FU=follow-up, sig=statistical significance, n. s.=not significant, SD=standard deviation

4.3.1 Cross-sectional studies

Of the eleven studies, five utilised a cross-sectional design. Follick, Smith & Turk (1984) created a novel questionnaire, measuring six subscales including emotional stress; asking for example if 'the patient felt they experience more frequent depressions'. Emotional stress was experienced by 50% of participants particularly in the post-operation period, and 33% identified feeling depressed. This is in line with the results of the review by White & Hunt (1997) who identified 18-26% of patients experienced psychological difficulties post-stoma formation. These findings are also supported by Richbourg, Thorpe & Rapp (2007), who demonstrated again using a novel measure, that depression and/or anxiety affected 53% of participants, who would be most likely to seek help from a medical doctor. Tal et al. (2012) further suggested 77.4% of their sample reported psychological difficulties in the form of avoidance, denial, disgust or body image disturbance, often avoiding self-care as a result. They asserted that those who received appropriate education and achieved self-stoma care had significantly improved psychological difficulty scores compared to those who did not. However, despite novel questionnaires allowing more tailored questions to be applied to these samples, no reliability or validity analyses were reported for any study, leading the results to be interpreted with caution. Also, the questionnaires reported being retrospective, self-report measures relying on subjective perception of past difficulties which may lead to bias.

Mitchell et al. (2007) administered the City of Hope Quality of Life-Ostomy (COHQOL-O) standardised questionnaire to military veterans with a stoma. They demonstrated moderate to high levels of embarrassment found to be significantly correlated with higher levels of psychological morbidity in patients with a stoma. This

measure was also used by Anaraki et al. (2012) who assessed 102 patients with a stoma formed at least 3 months, measuring physical, psychological, social and spiritual subscales. They too assert that the psychological implications of stoma formation were high, with 63% of the sample reporting difficulties with depression which is considerably higher than the 18-36% identified in the White & Hunt (1997) review. Depression was also noted to significantly predict overall quality of life scores. Despite the COHQOL-O being specifically created for patients with a stoma, it is an indirect measure of psychological morbidity, as it primarily measures quality of life. In contrast to Anaraki et al. (2012), Mitchell et al. (2007) reported high internal consistency suggesting the measure is reliable, however no validity analysis is given in either study. Further weaknesses are noted in the lack of reporting statistics, specifically levels of 'caseness' within the samples to allow for comparison against wider populations.

4.3.2 Longitudinal studies

Several longitudinal studies also identified psychological morbidity. Bekkers, van Knippenberg, van den Borne & van Berge Henegouwen (1996) measured psychological distress using the standardised Psychosocial Adjustment to Illness Scale (PAIS). Psychological distress was noted to have particular statistically significant relationships with problems in stoma and social self-efficacy. The authors do use an illness-related measure, however the PAIS is not specific for ostomy patients or for measuring psychological morbidity, therefore it is possible that it may not demonstrate an accurate measure of psychological morbidity in this population. Nevertheless, Cronbach's alpha output of 0.94 is reported showing high internal consistency of the measure.

Chambers et al. (2011) also administered a standardised measure, the Brief Symptom Inventory-18. The results demonstrated a non-significant reduction in psychological morbidity over time (5 month and 5 year follow-up), whereas quality of life increased. This was supported by a significant increase in scores on the emotional wellbeing subscale of the Functional Assessment of Cancer Therapy questionnaire. Despite neither of these measures being designed specifically for use with patients with an ostomy, the consistency across the results serves to validate both questionnaires. All Cronbach's alpha scores are above the recommended .7 cut-off and therefore also demonstrated good internal consistency within the measures.

Quality of life measures have also been used to give an indication of psychological morbidity, with Altundas et al. (2012) reporting a longitudinal study assessing change in quality of life pre- and post- education programme for 72 patients undergoing stoma formation. Psychological morbidity was measured indirectly using the Mental Health Component score, Mental Health and Role-Emotional subscale scores in the standardised Short Form 36 Health Survey. Scores demonstrated a statistically significant increase from pre- to post- education programme. However, despite this measure being widely used in health settings, scores were not compared with community or other population norms, therefore it is unclear the percentage of participants meeting 'caseness'. Cronbach's alpha was also not reported, meaning the internal consistency of the measure could not be assessed with this population and therefore should be interpreted with caution.

Several longitudinal studies did report using more direct measures of psychological morbidity. Bullen et al. (2012) used the Short Form 36 Health Survey (SF36) similarly

to Altundas et al. (2012) alongside the Hospital Anxiety and Depression Scale (HADS) to directly measure psychological morbidity. Results demonstrated that patients with a stoma reported statistically significant higher levels of anxiety and depression than patients without a stoma. Depression scores were significantly lower than patients with other long term conditions at baseline and follow up for stoma (baseline z=6.47, p=0.01, follow up z=4.71, p=0.01) and non-stoma patients (baseline z=13.68, p=0.01, follow up z=12.5, p=0.01) when compared using z-tests (Bambauer, Locke, Aupont, Mullan & McLaughlin, 2005). However anxiety and depression were significantly higher than community samples for stoma patients at baseline (anxiety z=-3.06, p=0.01; depression z=-3.92, p=0.01) and at follow up (anxiety z=-4.60, p=0.01; depression z=-6.99, p=0.01) with no significant difference found between non-stoma patients and community samples (Crawford, Henry, Crombie & Taylor, 2001). This suggests anxiety and depression levels are greater in the study sample when compared with the community, however score are lower than other long term conditions. However there is a noticeable difference between stoma and non-stoma groups at baseline and participant were recruited from pre-surgical clinics therefore it is important to consider that the psychological morbidity scores may be positively or negatively affected by these factors which are different to other long-term condition and community samples.

The comparative and longitudinal approaches give the study greater empirical status and explanatory power than studies previously described, although there is no Cronbach's alpha reported to give a measure of internal consistency. Similarly, Sharpe, Patel & Clarke (2011) previously reported similar findings as patients with stomas were demonstrated to have higher anxiety scores than patients without stomas. There were no significant differences between stoma and non-stoma patients or study participants

and community samples for depression (Crawford et al. 2001). When compared with other long term conditions, stoma and non-stoma patients scored significantly lower for anxiety and depression at baseline (anxiety stoma patients z=6.52, p=0.01, non-stoma patients z=11.47, p=0.01) (depression stoma patients z=13.78, p=0.01, non stoma patients z=16.71, p=0.01) and at follow up (anxiety stoma patients z=4.53, p=0.01, non-stoma patients z=11.94, p=0.01) (depression stoma patients z=9.98, p=0.01, non stoma patients z=18.60, p=0.01) (Bambauer et al. 2005). However the HADS demonstrated good internal consistency in this sample but may not be sensitive enough as a measure to fully demonstrate psychological morbidity in the sample as reflected in previous HADS and SF36 scores.

Sharma, Sharp, Walker & Monson (2007) examined the differences between patients who had undergone stoma formation and those who had not, using several measures of psychological morbidity including the HADS, Mood Rating Scale and the Positive and Negative Affect Scale. Only the HADS demonstrated significant differences between groups, with depression significantly higher six weeks following surgery and no effect seen for anxiety. On comparison with other long term conditions using z-tests anxiety and depression were significantly lower than other long term conditions at baseline (anxiety z=3.18, p=0.01, depression z=14.85, p=0.01) and at follow up (anxiety z=6.32, p=0.01, depression z=9.74, p=0.01) (Bambauer et al. 2005). However when compared with community samples using z-tests there were no significant differences between scores at baseline or follow up (Crawford et al. 2001). This is in contrast to previously reported results of the HADS which again begs the question of the sensitivity of this measure in detecting psychological morbidity in this population. Internal consistency is not reported by the authors and therefore cannot be assessed.

4.3.3 Summary of psychological morbidity

In summary, a wide variety of measures of psychological morbidity are used within the literature, with eight studies using indirect or non-standardised measures such as component scores of quality of life or novel measures of psychological distress. Three studies used more direct measures of psychological distress such as the Hospital Anxiety and Depression Scale (HADS), however the use of this measure has been drawn into question as despite the good internal consistency reported, across the three studies very different findings were reported, suggesting that this measure may not be as sensitive for use within this population. This is in line with the results of the review conducted by White & Hunt (1997) which this paper served to replicate.

4.4 Predictors

A number of biopsychosocial predictors were advanced in the studies. The most frequently presented statistically significant biological markers included the diagnosis of an underlying disease, the presence of the stoma itself, problems in self-efficacy regarding stoma care, and physical quality of life (Anaraki et al. 2012; Bekkers et al. 1996; Chambers et al. 2011; Follick et al. 1984; Tal et al. 2012; Sharma et al. 2007). This demonstrates the influence of physical health status on mental health, however it must be considered that given the unavoidable interrelationship between stoma formation and the presence of an underlying disease, it is difficult to disentangle which variable the psychological distress relates to. This is in line with previous research in the identification of illness-related predictors such as physical symptoms or complications being a risk factor for poorer psychological wellbeing (White & Hunt, 1997; White & Unwin, 1998).

Statistically significant psychological markers were advanced which included body image disturbance, education, embarrassment, optimism and self-evaluation (Altundas et al. 2012; Bekkers et al. 1996; Bullen et al. 2012; Chambers et al. 2011; Mitchell et al. 2007; Tal et al. 2012; Sharpe et al. 2011). These markers are consistent with the stoma-related and psychological factors identified in the related review (White & Hunt, 1997). These demonstrate that psychological morbidity may come about in response to other psychological variables, and it may be possible to use these as a marker for psychological morbidity screening in patients with a stoma. Past psychiatric history has also been demonstrated as a risk factor for poorer psychological wellbeing however information regarding this was not available in the review studies (White & Unwin, 1998).

Furthermore, several statistically significant social markers were also identified within the review studies including supportive spousal relationship, social adjustment and living in rural locations (Altundas et al. 2012; Chambers et al. 2011; Follick et al. 1984; Mitchell et al. 2007; Sharma et al. 2007). These indicators demonstrate the influence of a person's social environment on psychological difficulties, a factor which was not identified in the White & Hunt (1997) review.

4.5 Limitations of the studies

Longitudinal studies do demonstrate significant strengths in assessing change over time in patient with a stoma, rather than assessing a single time-point as is the case for cross-sectional studies (Mitchell et al. 2007). However, there are limitations which are not noted within the articles. Given the often short follow up time (between 3 and 5 months) between pre- and post-measures, and that it is known from other chronic

illness populations that a normal adjustment process occurs over a considerable length of time, it is possible that normal adjustment is a confounding variable which may diminish the effect of the independent variable (Altundas et al. 2012; Sharpe & Curran, 2005). This study did assert however that the use of a control group may have been useful, and indeed this would have reduced the likelihood of confounding variables. Attrition rates are also problematic within a longitudinal study as they decrease statistical power as attrition increases, which are further compounded by the lack of power analyses.

A further limitation of all eleven review studies is the reliance on closed-question, retrospective, self-report measures, as this may introduce a completion bias. It is also noted that only three studies used specific standardised measures of psychological morbidity, whereas the remaining eight studies either used novel measures created for the purpose of the study, or indirect, secondary measures of psychological morbidity. This introduces generalisability bias into the results, as they are not standardised, reliable and valid measures to draw information from to compare other populations. This methodological weakness was also noted within the White & Hunt (1997) review which may suggest a longstanding difficulty with use of appropriate measures for this population.

It is noted that several studies either lacked a power analysis, or failed to report any power analysis undertaken (Altundas et al. 2012; Anaraki, et al. 2012; Bekkers et al. 1996; Sharma et al. 2007). This draws the reliability of the results into question as it is unknown whether the studies have appropriate statistical power to be able to report significant findings, and therefore must be interpreted with caution. However, it is also

noted that larger sample sizes are not without bias. Chambers et al. (2011) noted approaching a large sample size, with a low uptake (31%) and high proportion of incomplete assessments thus reducing the generalisability of their findings.

All studies demonstrated some flaws within their recruitment procedures for obtaining a sample. When random sampling was used, it was not explained how the process was undertaken, therefore reducing the transparency and how replicable the study is (Anaraki et al. 2012). In the majority of the studies (8 out of 10) a volunteer sample was used, which may introduce bias based on the characteristics and difficulties of those who volunteer. Specific populations used within each study also affect generalisability, for example military veterans (Mitchell et al. 2007).

Similarly none of the studies compared the sample population to any other clinical or community population, although two studies did compare stoma and non-stoma patients. This means only limited inferences can be drawn about the nature and extent of the relationship between psychological morbidity and the stoma itself, compared with psychological morbidity in chronic health conditions and this had previously been noted within the White & Hunt (1997) paper which brings into consideration populations that might serve as a control or comparison.

5. Discussion

This review served to describe psychological morbidity in patients with a stoma. The review gave particular focus to identifying the psychometric adequacy of the methods by which psychological morbidity has been measured and possible biopsychosocial predictors of psychological morbidity in patients with a stoma.

5.1 Psychological morbidity and psychometric adequacy

On review of the eleven studies, it was concluded that psychological morbidity is present in participants with a stoma which is in agreement with the previous review on psychological morbidity and demonstrates the need for support from Clinical Nurse Specialists and other therapeutic approaches (Coloplast, 2010; Foskett, 2012; McLeod et al. 2009; White & Hunt, 1997). However, much wider variation in scores were noted than White & Hunt (1997), 3.8-63% compared to 18-26%, which draws the methods by which psychological morbidity has been measured into question. The view that psychological morbidity is present is however in line with other physical health populations, therefore it must be considered that it may have an impact on physical symptoms and long-term outcomes (Vriezekolk et al. 2010). In two of the review studies the levels of psychological morbidity were also greater than those reported in patients with comparable primary diagnoses, but without a stoma, suggesting psychological morbidity may be exacerbated by factors associated with stoma presence which is supported by previous research (Bullen et al. 2012; Ross et al. 2007; Sharpe et al. 2011). It has been noted that stoma cognitions may account for 60% of the variance in psychological morbidity and therefore differences in cognitions across participants

may have influenced the measures of psychological morbidity analysed and why some patients may be more distressed than others (White & Unwin, 1998).

However, psychological morbidity was not the primary focus of any of the studies reviewed, and was measured indirectly in seven studies. Only four studies used a specific measure of psychological morbidity, in this case the HADS and the Brief Symptom Inventory (Bullen et al. 2012; Chambers et al. 2011; Sharma et al. 2007; Sharpe et al. 2011). However, there appears a lack of standardised ostomy-specific measures used by nine studies, with three studies actually citing a lack of ostomy-specific measures as the reason for creating novel ostomy-specific measures for use with their sample. This brings the results into question given that stoma cognitions have been demonstrated to be very specific and powerful in predicting psychological morbidity (White & Unwin, 1998). The remaining eight studies used indirect measures that have been standardised in other medical populations, however there was a lack of clarity as to whether they had been validated in patients with a stoma. This is a recurring difficulty that has previously been identified by White & Hunt (1997) and suggests a need for development of stoma-specific measures. The results also appear limited by a lack of reporting of power analyses, and reliability or validity analyses. This is demonstrated by the three studies using the HADS demonstrating differing levels of anxiety and depression in patients with a stoma, although the internal consistency was high for all three studies, suggesting differing findings may be more associated with a lack of power, perhaps due to small sample sizes, meaning effect size and significance levels were not reached.

It is also noted that there is considerable variation between samples. The studies were conducted across seven different countries and it has been documented that the diagnostic categories of anxiety and depression used in health settings are not clinically valid across all cultures (Patel, 2001). This brings into question the standardised measures used across the review studies and may offer an explanation into the variation seen across scores and the inconsistency when scores are compared to community norms and other long term conditions. It is also noted that the mean age groups of participants ranged from 44-72. It has been suggested that psychological morbidity remains common across these age groups, however the prevalence is suggested to decline with age and this may also serve to explain some of the variance in scores across studies (Byers, Yaffe, Covinsky, Friedman & Bruce, 2010). Psychological morbidity is also noted to be more common in women, regardless of age, and given the majority of participants were males, this may also explain score variability (Byers, Yaffe, Covinsky, Friedman & Bruce, 2010).

A further factor to consider that may have impacted variance across study scores was the length of time since stoma formation. The six studies utilising a longitudinal design did demonstrate strengths over the cross-sectional studies as they allowed assessment of change in variables over time. However four of the six longitudinal studies follow up data were collected within 3-5 months post-surgery which may be questionable given that it has been reported normal psychological adjustment to such an event may take a considerable length of time (Sharpe & Curran, 2005).

Nevertheless, all eleven studies reviewed are not without limitations. Alongside the lack of ostomy-specific measures, the measures used are subjective and retrospective,

meaning they rely on heavily on memory which is consistent with the methodological critique raised by White & Hunt (1997). This means bias may be introduced as memory may not always be an accurate account, and may be prone to further bias if questions are considered leading. As such, prospective measures should be considered for use in future studies which may be further supplemented and validated by clinical interview with a Clinical Psychologist. Additionally, only one study documented a power analysis meaning the statistical analyses documented should be interpreted with some caution as it is unclear whether ten of the studies have statistical power.

5.2 Predictors of psychological morbidity

The wider impact of stoma formation is noted in the evidence of biopsychosocial predictors of psychological morbidity, with some consistency across the eleven review studies and with the previous review this paper sought to replicate (White & Hunt, 1997). Biological predictors related to stoma formation, stoma care and physical complications/symptoms were identified, which may serve to explain the higher psychological morbidity scores documented in patients with a stoma compared to those without a stoma but with comparable underlying medical diagnoses. This is in line with suggestions by Turnbull (2007) that depression may arise due to fears around the physical management of the stoma and the suggestion by White & Hunt (1997) that physical symptoms or complications may lead to poorer psychological wellbeing.

Psychosocial predictors identified related to body image disturbance, embarrassment, and the presence of supportive spousal relationships with the latter being the most commonly noted predictor of psychological morbidity across the reviewed studies. This is in part supported by Bekkers et al. (1995) who asserted that social impact of

stoma formation was greater in those with impaired spousal relationships and builds upon the stoma-related and psychological factors raised within the White & Hunt (1997) review which mainly relate to the presence of past psychiatric history and level of preoperative education.

5.3 Clinical and research implications

The results of this review suggest that psychological morbidity is problematic in patients with a stoma. However limitations identified in the measures used and the lack of psychological morbidity as a primary outcome, indicate that further research is required in this field which has been previously suggested by White & Hunt (1997) who identified similar limitations in their review paper. There is a need to more clearly demonstrate psychological morbidity compared with other illness and community samples to clarify the specific extent of psychological morbidity, and assess reliability and validity of measures of used within this population. It would be recommended for this research to be longitudinal, and use prospective measures where possible to reduce memory bias from retrospective measures. It may also be pertinent to validate the measures with clinical interview to ascertain psychological morbidity.

Such research may help identify a reliable and valid measure that could be used to form part of a screening for patients undergoing stoma formation for psychological morbidity. Therefore the predictors identified could be used to identify patients 'at risk' of psychological morbidity and needing further assessment or monitoring regarding any difficulties present. If this were developed, Clinical Psychologists may play a role in training Clinical Nurse Specialists and other health professionals to recognise and assess patients regarding psychological morbidity, supporting more

appropriate referrals to psychological support services where necessary, to reduce the impact of psychological difficulties on self-care and treatment adherence and improve long-term outcomes. Education programmes may also be developed to provide early intervention and screening for patients undergoing stoma formation regarding the psychological impact of the procedure, given that education programmes were reported to infer improved mental health outcomes within this review (Altundas et al. 2012; Follick et al. 1984; White & Hunt, 1997). Results from further research could therefore be used in service provision planning to help determine the support offered to patients undergoing stoma formation.

5.4 Limitations of the review

This review demonstrated the presence of psychological morbidity and its predictors in patients with a stoma following a thorough, systematic search process, covering seven computerised databases.

It is however not without its limitations. The paucity of studies identified via searches, meant it was not possible to conduct a meta-synthesis to statistically analyse for significant findings, and narrative synthesis was therefore conducted. Notwithstanding, there is a possibility of publication bias in the available studies, as non-significant findings may not always be published. It is also noted that several studies were identified within the introduction which did not appear within the systematic search results, perhaps because those studies were not available via the databases searched, however this is a limitation as studies have not been included that may have been appropriate. This is further compounded by possible limitations in institutional access to databases.

The search terms appear to offer a further limitation as they yielded considerable number of initial search hits, suggesting they may have been too vague or too lengthy, resulting in a high number of irrelevant articles being identified. However it is noted the variables are all described differently in the research depending on the professional background of the author, leading to a number of search terms needing to be employed. The search terminology may be further refined in future replications of this review.

Despite the noted limitations, this study has considerable strengths in the systematic approach taken and has demonstrated psychological morbidity for patients with a stoma and the associated predictors which may be assessed and monitored to support recognition and management of difficulties in this population. The study has however demonstrated a need for more specific research into psychological morbidity in comparison with other illness and community populations to identify and validate a screening measure that can be administered to assess for psychological morbidity and offer interventions and referral onto psychological services where appropriate, a process which may benefit from the supervision of qualified Clinical Psychologists or mental health professionals.

6. References

**Denotes review study*

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Section Two

Research Report

Shame and disgust-sensitivity in adult dialysis patients: Are these variables predictive of psychological morbidity, body image disturbance and quality of life?

Target Journal: The British Journal of Health Psychology

Shame and disgust-sensitivity in adult dialysis patients:

Are these variables predictive of psychological morbidity, body image disturbance and quality of life?

Author: Claire Leonard

1. Abstract

1.1 Objectives

Renal replacement therapies such as dialysis are not without significant personal cost. Psychological morbidity, diminished quality of life and body image disturbance have been reported in dialysis patients, yet predictors of these constructs are relatively unknown. This study aimed to consider whether dialysis patients experienced feeling of shame and disgust, and whether this was associated with psychological difficulties.

1.2 Design and method

The study employed a quantitative, cross-sectional survey design. Questionnaire packs were sent to peritoneal- and haemo-dialysis patients via routine appointments and by post. Questionnaires were returned by 93 participants. Data were examined using correlation analysis and multiple regression.

1.3 Results

Participants demonstrated significantly higher levels of psychological difficulties when compared with the general population. Measures of general shame and disgust-sensitivity were not significantly elevated, however specific measures of body shame and body disgust accounted for 18-61% of the variance in psychological difficulties.

1.4 Conclusions

Findings suggest the presence of complex emotional phenomena specifically regarding body shame and body disgust, which is advanced as a marker of psychological difficulty in this population. Further research is necessary to develop the measure used, with a view to being able to use it as a clinical tool to support professionals in recognising and managing psychological distress.

2. Introduction

2.1 Renal failure and replacement therapy

Renal Replacement Therapies (RRT) are medical interventions offered to individuals living with end-stage renal failure (ESRF); a diagnosis describing diverse pathological processes commonly concluding with kidney function reduced to irreversibly low levels, inadequate to sustain life. In these circumstances those with ESRF are offered either dialysis or transplantation to maintain their life, the specific intervention depending on clinical indication (Castledine, Casula & Fogarty, 2011; Quan & Quigley, 2005; National Institute of Clinical Excellence [NICE], 2002).

Approximately 50,965 adult patients were receiving RRT for kidney failure in the UK in 2010, a 3% increase on the previous year, with RRT's accounting for approximately 2% of the total NHS budget (Castledine *et al*. 2011; NICE, 2008). Many patients may be ineligible for transplantation (often because of co-morbid physical health problems), and dialysis is often received as a long-term intervention (Ashley & Morlidge, 2008). In the UK, 26,226 out of 50,965 adult patients were receiving dialysis during 2010 (Castledine *et al*. 2011).

Central to ESRF is a compromised ability to filter waste products from the body via the kidneys. Dialysis, via which individuals with kidney failure can prolong their life using external machinery and procedures to adopt the role of the kidney, comprises two forms, peritoneal- and haemo- dialysis (Ashley & Morlidge, 2008). Peritoneal dialysis enables filtering of waste body products via the peritoneum (membrane lining the

abdomen). The procedure involves surgical insertion of a catheter into the abdomen. Through this tube, dialysis fluid enters the peritoneal cavity, and a process of osmosis occurs, transferring the waste products and excess fluids from the blood into the dialysis fluid. This fluid is then drained from the peritoneal cavity. For optimal filtration this process must be carried out three to four times daily, for 30-40 minutes a time, or alternately run overnight (Ashley & Morlidge, 2008; Quan & Quigley, 2005).

Haemodialysis enables blood filtration through an external device to eliminate waste products and excess fluid from the blood. It involves either the formation of an arteriovenous fistula (the connection of an artery and a vein), or the surgical insertion of a catheter, most commonly in the arm or neck. This site is then used to insert needles into the artery and vein, allowing the blood to be removed and returned to the body via a dialysing machine. This process is similarly burdensome requiring hospital attendance at least three times a week, for up to four hours a time (Ashley & Morlidge, 2008; Quan & Quigley, 2005).

2.2 Psychological morbidity in dialysis patients

RRT's are not without personal cost; the sustained nature of dialysis and complex regimen engenders significant burden, and a growing body of research has elucidated pervasive, negative psychosocial effects such as fatigue and decreased appetite (Bossola, Vulpio & Tazza, 2011; Zabel, Ash, King & Bauer, 2009). Indeed, given aversive consequences of the dialysis therapies, non-adherence appears highly

prevalent within this population, with implications for physical health and mortality, alongside considerable financial cost to the NHS (Cronk et al., 2011; NICE, 2008).

Significant psychological morbidity is evidenced in this population. Elevated levels of anxiety and depression are common in dialysis patients, which are not only symptom specific but suggested to evolve because of substantial lifestyle changes needed for dialysis treatment; potentially exacerbating patient concerns about reduced autonomy and control (Cotera & Alvarez, 2008; Hutchinson, 2005; Tsay & Hung, 2004). Depression appears to be particularly prevalent with up to 43% of dialysis patients attaining psychiatric case range on the General Health Questionnaire, yet it is often misdiagnosed or unrecognised by medical professionals (Chilcot, Wellsted, Da Silva-Gane & Farrington, 2008; Petrie, 1989). Suicide rates too exceed population norms and are a further indication of the psychological distress encountered (McGee & Bradley, 1994). Additional clarification is needed regarding the nature of psychological distress encountered to be able to consider how it impacts on treatment adherence (Christensen & Ehlers, 2002).

The psychological burden of dialysing when compared with other chronically ill populations appear particularly associated with diminished quality of life, notably more for those receiving haemodialysis than peritoneal dialysis (Ginieri-Coccossis, Theofilou, Synodinou, Tomaras & Soldatos, 2008). The nature of quality of life impairment appears related to a number of factors including dialysis type, lifestyle restrictions and co-morbid conditions, and also may be associated with increasing

hospitalisation and infection rates (de Jonge, Ruinemans, Huyse & ter Wee, 2003; Evans et al., 1985; Gokal, 1993; Lew & Piraino, 2005; Merkus et al., 1996).

2.3 Physical changes and body image

Although relatively under-examined, there is increasing evidence that dialysis engenders considerable physical change notably in fluid retention and alteration in skin and nail colour, alongside formation of a dialysis access, reducing patients' satisfaction with their body (Jamal, Subramanian & Hussain, 2000; Lai et al., 2006; Lew-Starowicz & Gellert, 2009; Nassir, 2009). Yet such changes in body image, although demonstrably associated with adverse effects on emotional well-being of patients within other clinical populations, have been little quantified for patients with renal disease (Joseph, 2010; Partridge & Robertson, 2011). Further quantitative studies are needed define the nature of body image disturbance and how this may affect psychological morbidity in dialysis patients (Price, 1996; Schwab & Harmeling, 1967).

Dialysis is also associated with pronounced dietary change for individuals, and often limited fluid intake (Higgins, 2005). Physical complications such as uremic syndrome (high levels of urea in the bloodstream, a complication of kidney disease), are also common and have been linked to appetitive changes, malnutrition and disorders of eating behaviour (Aguilera et al. 2004). Evidence from analogous populations who are eating disordered reveal close association between psychological morbidity and body image; the former not dependant on weight status but a result of several different factors such as appearance concern and body shame (Gilbert & Miles, 2002). Perceived

body image changes may be closely associated with the psychological morbidity already documented in the dialysis population, given profound and unsettling adjustments to altered appearance and managing the reactions of others (Kent & Thompson, 2002, in Gilbert & Miles, 2002).

Indeed circumscribed research undertaken with dialysis patients concluded that levels of body image disturbance were significantly higher in dialysis patients than in community samples, and significantly associated with psychological distress (Partridge & Robertson, 2011). However, despite body image disturbance being identified as closely related to psychological morbidity, the exact nature of the body image disturbance itself as experienced by this population remains unclear and warrants further investigation.

2.4 Body image and shame

Greater scrutiny of body image disturbance has suggested close association with body shame in several clinical populations. Body shame is a multifaceted, complex emotion and due to its complexity and inherent self-focus it is also referred to as a self-conscious emotion (Gilbert & Miles, 2002). Level of experienced body shame has been identified as a significant factor within adjustment to living with a physical disfigurement, or notable change in appearance (Kent & Thompson, 2002, in Gilbert & Miles, 2002). Indeed, high levels of shame were found in patients adjusting to the rheumatoid skin condition Psoriasis, although the researchers did not distinguish between internal shame and external stigmatisation (Gilbert & Miles 2002). Further

studies suggest patients with visible conditions experienced greater levels of body shame than those with conditions they were able to conceal, and describe the complexity of body image reactions to a change in appearance (Kent & Keohane, 2001; Rumsey & Harcourt, 2004; Sharpe, Patel & Clarke, 2011).

Thematic analysis of semi-structured interviews with those undergoing dialysis also revealed emerging themes regarding body awareness, concern, shame and stigma associated with the appearance of the dialysis access (Curtin, Johnson & Schatell, 2004; Richardson & Engebretson, 2010). Shame and disgust regarding appearance were evidenced in narratives, as was a desire to conceal dialysis access sites, sensitivity to a self-described disfigurement. Such experiences of shame regarding altered appearance may affect psychological morbidity, social relationships and subsequent quality of life. Shame may also contribute to difficulties in treatment regimes given evidence that high levels of shame and distress predict information with-holding and avoidance of medical contact completely, compromising optimal care for dialysis patients (Lazare, 1987).

2.5 Body image, shame and disgust

Body image disturbance and body shame have also been related to disgust-sensitivity in clinical populations. Experience of 'disgust', finding something offensive or recoiling from loathsome stimuli, is arguably a manifestation of a survival instinct, to avoid danger and/or contamination (Dossey, 2005). Disgust-sensitivity has been related to psychological morbidity in a number of conditions, including eating disorders, phobias,

sexual dysfunctions and anxiety, and appears to have a strong positive correlation with health anxiety (Davey, 2011; Davey & Bond, 2006).

The concepts of disgust-sensitivity, appearance concern and body shame are hypothesised to be closely related with body image disturbance; with disgust-sensitivity and body shame are both described as having similar psychological and behavioural components (Gilbert & Miles, 2002). Indeed self-disgust and shame have been reported as closely linked but separate constructs, and self-disgust is advanced as a marker of low self esteem and depression (Power & Dalgleish, 2007; Simpson, Hillman, Crawford & Overton, 2010).

Disgust-sensitivity has been evidenced in patients who have undergone resections to the bowel, subsequently adjusting to life with a colostomy, and has been shown to negatively affect life satisfaction and quality of life (Brown & Randle, 2005; Smith, Loewenstein, Rozin, Sherriff & Ubel, 2007). There appear compelling similarities between those requiring fistulas and those undergoing colostomy. Patient discourse from qualitative studies reveals a prominence of 'disgust' in particular noting avoidance of other patient's access sites, and with patients describing the appearance of their fistula in detail, using emotive language suggestive of disgust (Curtin et al., 2004; Richard & Engebretson, 2010).

Given such similarities between stoma and dialysis access formation, that both involve bodily excretions, and dialysis patients are also encouraged to be vigilant to infection

risk to reduce contamination of their access site, patients undergoing dialysis may react similarly to those living with colostomies, and disgust-sensitivity may too be a significant predictor in adjustment to dialysis treatment and resulting quality of life warranting further research. Yet disgust and its putative effects on body image and psychological morbidity have not been evidenced in a renal population.

2.6 Summary and rationale

In summary, undergoing dialysis confers significant psychological burden which has only recently become the focus of increased psychological study. It further imposes a number of physical changes alongside an increased need to regulate health behaviour. Yet quantitative research examining impacts on body image and the putative contributory factors of shame and disgust has not been undertaken, despite qualitative data suggesting their influence and association with psychological distress and compromised adherence.

With this in mind, developing greater understanding of any psychological morbidity and its relationship to concerns around physical changes for dialysis patients may facilitate enhanced understanding of the evolution of psychological distress and offer strategies to mitigate distress and the potential impact on future treatment adherence.

2.7 Research aims

This research therefore aims to look at what psychological difficulties may be present in the dialysis sample population, more specifically:

a. Are significant levels of psychological morbidity, quality of life, body image disturbance, general and body shame and general and body disgust present in the sample population?

Furthermore it aims to consider any relationships between the variables, more specifically:

a. Are there significant relationships between psychological morbidity, quality of life and body image disturbance?
b. Are there significant relationships between general and body shame, and general and body disgust?
c. Are there significant relationships between general and body shame, general and body disgust and psychological morbidity, quality of life and body image disturbance?
d. If significant relationships are demonstrated, to further examine and explain the relationships using multiple regression analysis.

3 Method

The study utilised a quantitative, cross-sectional, survey design. Adult dialysis patients were approached to participate. Participants completed 5 standardised questionnaires and one questionnaire containing items taken from a standardised measure alongside novel items created for the purpose of this study. The dependent variables were psychological morbidity (anxiety and depression), quality of life and body image disturbance. The independent variables were general and body-specific shame and disgust. The quantitative data were subject to statistical analysis. Some qualitative data were collected via open-ended questions within the questionnaires and were subject to a thematic analysis.

3.1 Participants

Participants comprised volunteer adult patients undergoing dialysis, receiving treatment at a regional specialist centre and associated satellite sites in the Midlands, UK. To optimise sample homogeneity inclusion and exclusion criteria were applied.

Inclusion criteria comprised the following:

- Patients must have been undergoing dialysis (peritoneal or haemodialysis) for a considerable time to account for normal adjustment reactions therefore patients on dialysis for less than 6 months will be exlcuded (Sharpe & Curran, 2005).
- Patients must be adult, aged 18 years and above.
- Patients must have a good standard of written English to complete the measures used in the research given the proposed measures have not been validated in different languages.

Patients not meeting these criteria, or deemed by staff to be too ill at the time of the study's conduct were excluded from the study.

An *a priori* power analysis was conducted to investigate what sample size should be used in this study. Given that possible relationships between variables were investigated, Pearson correlations were planned for analysis. According to Cohen (1992) 0.80 is considered a suitable power value in order to demonstrate a large effect size, thus reducing the possibility of a Type II error occurring (Cohen, 1992). A significance level of 0.05 is the most commonly identified standard in order to be able to reduce the probability of a Type I error (Cohen, 1992). For correlation studies Cohen (1992) advances 0.10, 0.30, and 0.50 for a small, medium and large effect size respectively (Cohen, 1992). Therefore a 0.80 power value, medium effect size and 0.05 significance criterion were used which suggested the sample size for the present study to be 783 for a small effect size, 85 for a medium effect size and 28 for a large effect size (Cohen, 1992). Therefore the study aimed for a minimum sample size of 85 (medium effect).

3.2 Measures

Demographic data were collected using a questionnaire devised for the purpose of this study to include age, gender, ethnicity, dialysis type and duration, and co-morbid conditions (Appendix H).

Hospital Anxiety and Depression Scale (HADS; Snaith & Zigmond, 1983) (Appendix I). This is a 14-item screening measure of psychological morbidity widely used in chronic illness populations. Participants choose from four responses for each item

which correspond with scores between 0-3. Subsequently the items are totalled to give an anxiety score (up to 21), depression score (up to 21), and an overall total score (up to 42). Scores between 0-7 are considered within the normal range, 8-10 considered to be borderline and 11 or above in the clinical range (Snaith, 2003). It has been shown to have good test-retest reliability and face, concurrent and construct validity (Crawford, Henry, Crombie & Taylor, 2001; Snaith & Zigmond, 1994). Moreover, the HADS has been shown to be a valid measure of psychological morbidity in research with ESRF and dialysis patients (Martin & Thompson, 1999; Partridge & Robertson, 2011). For the purpose of this study this questionnaire was used to measure psychological morbidity.

Short Form 36 Health Survey (SF36; Ware, 1993) (Appendix J). This is a self-report health survey used to assess quality of life in the dialysis population. It contains 36 Likert-scale items on which participant's rate how much they agree or disagree with each statement. Items scores are totalled to produce eight subscale scores, and two overall component scores of physical and mental health. Normative data advances 50 with a standard deviation of 10 as non-clinical range, with any scores below this range considered indicative of reduced quality of life (Ware, Snow, Kosinski & Gandek, 1993). Strong reliability and validity has been demonstrated in numerous studies of renal patients (Wight et al., 1998; de Jonge, Ruinemans, Huyse, ter Wee, 2003). The SF36 has been described as the most suitable measure of quality of life for patients with end-stage renal failure following a comprehensive review (de Jonge, Ruinemans, Huyse, ter Wee, 2003). For the purpose of this study the physical and mental health component scores were used to measure psychological morbidity and quality of life.

Body Image Disturbance Questionnaire (BIDQ; Cash, Phillips, Santos & Hrabosky, 2004) (Appendix K). This is a self-report measure containing seven items measuring concerns about appearance of some body parts, preoccupation with such concerns, and effects on social functioning. Responses are rated on a Likert-scale of 1-5 with higher scores indicative of greater body image disorder. There are also open-ended responses for five items to allow participants to elaborate on and enrich the Likert-scale responses. Normative data states advances a mean score of 1.57, standard deviation of 0.60 for males, and a mean score of 1.81, standard deviation of 0.67 for females in the general population. Therefore scores greater than 2.17 and 2.48 for males and females respectively, are considered to indicate problematic levels of body image disturbance (Cash & Grasso, 2005). This measure has been shown to have strong test-retest reliability of 0.80 to 0.92 and has good internal consistency (Cash et al., 2004; Cash & Grasso, 2005; Partridge & Robertson, 2011). For the purpose of this study this questionnaire was used to measure body image disturbance.

Derriford Appearance Scale-Short Form (DAS-24; Carr, Moss & Harris, 2005) (Appendix L). This is a 24 item, self-report measure asking patients about appearance concern, fear, social anxiety, shame, negative affect, withdrawal and avoidance. Furthermore, on three items it prompts qualitative identification of specific aspects of appearance that are of concern. The 24 items are scored between 0 and 4, with a minimum total score of 11 and a maximum total score of 96. No clinical cut offs are provided to indicate 'caseness' however higher scores are considered indicative of greater appearance concerns. General population norms for the total score suggest a mean score of 29.54, standard deviation 12.39, whereas clinical population norms

suggest a mean score of 42.58, standard deviation 16.04 (Carr et al., 2005). Generally however, scores are assessed by age categories of 18-30, 31-60 and 61 and above to ensure homogeneity of sample. This measure has been well-validated in other physical health domains such as oncology, burns, disfigurement and cosmetic surgery, and the internal consistency .92, test-retest reliability .82, and criterion validity .88, show that the measure is psychometrically robust (Carr et al., 2005). Given the DAS-24 has been used with other chronically ill populations, it was felt appropriate to transfer to a renal population, and was therefore used in this research study to give a measure of body image disturbance and general shame.

Experience of Shame Scale/Body shame and disgust measure (ESS; Andrews, Qian & Valentine, 2002) (Appendix M). This is a 25 item self-report measure. Only four items of this scale were administered for the purpose of this research study, to focus on assessing body shame in the dialysis population more specifically. An additional four novel items were created for this study to focus on assessing body disgust in the dialysis population. These items followed the same format as the body shame items taken from the measure. All items used a Likert-scale rating from not at all to very much, with corresponding scores 1-4, giving a score between 4 and 16 for shame and for disgust, with higher scores indicating higher levels of experienced body shame or disgust. Previous studies of the ESS as a whole have shown good validity and reliability, with Cronbach's alpha of .94 (Sandquist, Grenyer & Caputi, 2009). Therefore these scores were used in this research study to measure body shame and body disgust.

Disgust Scale – Revised (DS-R; Haidt, McCauley & Rozin, 1994, modified by Olatunji et al. (2007)) (Appendix N). This scale was used to assess general disgust-sensitivity in the dialysis population. It is a self-report scale containing 27 disgust-provoking items to be rated between 0 and 4. Scores on this measure are summed to give a total score between 0-100 with higher scores indicative of higher sensitivity to disgust. General population norms advance a mean score of 51.06, standard deviation 18.09, therefore scores >69.15 may be considered problematic, and has been shown to have strong validity (Olatunji et al., 2008). It has also been used to assess adjustment to colostomy formation, another excretory process, and was shown to have strong internal consistency (.75) within a chronic illness population (Smith et al., 2007).

3.3 Procedure

The research was undertaken subsequent to gaining ethical approval from the local Research Ethics Committee, and the host NHS Trust Research and Development department (Appendix O). As a precautionary measure, participants were informed they could contact the Patient Information and Liaison Service at the host trust or request a referral to the psychology department at the hospital if they experienced distress associated with study participation.

As the study employed a quantitative, cross-sectional, survey design, participants were approached and issued self-report questionnaire packs by the lead researcher at a routine haemodialysis session. Peritoneal dialysis patients received a questionnaire pack through the post after the research had been outlined to them by a staff member at a routine appointment. Home haemodialysis patients received a questionnaire pack at one of their regular appointments with a member of the Community Renal Team.

Packs comprised a covering letter explaining the study, patient information sheets, the seven measures, a prize draw entry and a debrief sheet (Appendix G). Stamped-addressed envelopes were provided for completed packs to be returned direct to the lead researcher. After information was given, consent was considered assumed by the participant's completion of the questionnaires. A prize draw was offered to promote participation, with two prizes of £25 High Street Spending vouchers available. Each questionnaire pack had a unique reference number which participants were able to use should they wish to retract their data. Data were collected over a four month period from November to February 2013.

3.4 Data Analyses

Quantitative data were numerically coded and subject to analysis using the computer programmes Statistical Package for the Social Sciences (SPSS) v20 and the Health Outcomes Scoring Software 4.0 (for the SF-36) (IBM Corporation 2011, Quality Metric Incorporated, 2004). After management of missing data processes were completed, descriptive analysis was undertaken. Furthermore the data were subjected to inferential statistical analysis to assess statistical significance. A minimum significance level $p<0.05$ was used to identify results that were statistically significant for all following analyses, however where appropriate the significance level 0.01 was reported when met. Qualitative data were subject to a thematic analysis to identify any themes within responses.

4 Results

4.1 Managing missing data

Datasets with missing values can be misleading, and may mean calculated statistics are less precise. Many statistical procedures assume a complete dataset, and therefore difficulties can arise with incomplete data in the procedure (IBM Corporation, 2011, Raghunathan, 2004). In SPSS, multiple imputation approaches can be used to analyse data for missing cases, and predict missing values based on observed data (Raghunathan, 2004). Missing data analyses demonstrated that multiple imputation would be appropriate, and may reduce possible bias in the results due to missing data.

4.2 Quality of data

Analyses of normality were undertaken for each of the measures to ascertain whether the data were normally distributed and parametric tests could be applied to the data (see Appendix P).

The scores for each questionnaire were assessed as to their internal reliability using Cronbach's alpha and the results are presented in Table 1.

Table 1: Summary of reliability analyses.

Measure	Cronbach's alpha
Hospital Anxiety and Depression Scale (HADS)	0.93
Short Form 36 Health Survey (SF36)	0.57
Body Image Disturbance Questionnaire (BIDQ)	0.91
Derriford Appearance Scale 24 (DAS24)	0.94
Experience of Shame Scale items (ESS)	0.96
Disgust Scale-Revised (DS-R)	0.88

The HADS, BIDQ, DAS24, ESS and DS-R all demonstrated high internal reliability, above the recommended .7 cut-off (Pallant, 2001). However the SF36 Cronbach's alpha was somewhat below the recommended reliability cut-off, suggesting the questionnaire has poor internal consistency and should therefore be interpreted with caution.

4.3 Sample characteristics

Ninety-four of 287 questionnaire packs originally distributed were returned. One questionnaire pack was removed from the analyses as it was largely incomplete, giving a return rate of 32.75%.

Information regarding gender, age, ethnicity, dialysis type and duration, access site location, and co-morbid conditions was examined to compare how representative the sample is with regional and national information from UK Renal Registry (Castledine et al. 2011). This information is summarised in Table 2.

Table 2: Demographic characteristics of participants and comparison with local and national data

Variable	Total Sample (n=93)	Regional data	National UK data
Gender (%)			
Male	63.4	-	62.6
Female	36.6	-	37.4
Age			
Mean	58.61	-	57.9
SD	16.39	-	-
Range	20-90 (70)	-	-
Ethnicity (%)			
White	64.5	74.6	69.7
Black	2.2	3.3	6.5
Asian	28.0	16.6	9.3
Chinese	1.1	0.3	0.6
Other	2.2	1.0	1.3
Would prefer not to say	2.2	2.0	12.6
Dialysis Type (%)			
Haemodialysis (HD)	66.7	82.47	85.27
Peritoneal Dialysis (PD)	33.4	17.53	14.73
Dialysis Access Site (%)			
Neck	7.5	-	-
Arm	57.0	-	-
Leg	3.2	-	-
Lower Torso	32.3	-	-
Duration (years)			
Mean	3.33	-	3.2
SD	2.95	-	-
Range	0.5-15 (14.5)	-	-
Co-morbid conditions (%)			
Yes	61.3	-	55.4
No	38.7	-	44.6

The sample was predominantly male (63.4%), with a mean age of 58 years. This was consistent with gender percentages for the national UK profile. A z-test was used to compare age representations to national UK profiles and no significant differences were found ($z= -0.42$, $p=0.68$).

Regarding ethnicity, the sample population data follow the same pattern as the regional data, suggesting that the sample is representative of the area, despite there being some differences with the national UK data.

By dialysis type, the sample differs from the regional and national UK figures, suggesting the sample population are less representative, although this difference was not significant. The dialysis access site data does support the dialysis type figures, with the highest percentage of access sites located in the arm, and the second highest percentage being located in the lower torso. This would be indicative of Haemodialysis and Peritoneal Dialysis access sites respectively.

Mean duration of dialysing appeared no different than that for national UK profiles ($z= -0.43$, $p=0.67$), and the sample population reported similar extent of co-morbid conditions.

4.4 Psychological difficulties

Extent of psychological morbidity derived from the measures is tabulated below (Table 3).

Table 3: Psychological morbidity of current sample and comparison with other renal, chronic illness and community norms.

	Sample			Renal[1]		Chronic Illness[2]			Community[3]		
HADS Anxiety											
Mean (SD)	6.52 (4.68)			7.06 (5.18)		8.1 (3.7)			6.14 (3.76)		
Clinical range (%)	36.6			71.1		63.0			33.2		
HADS Depression											
Mean (SD)	6.38 (4.81)			6.50 (4.09)		8.5 (3.6)			3.68 (3.07)		
Clinical range (%)	38.8			58.8		78.0			11.4		
SF36 Mental Component											
Mean (SD)	46.05(11.43)			38.71 (10.08)		-			50.00(10.03)		
Median	46.58			-		-			52.82		
SF36 Physical Component											
Mean (SD)	36.04(10.42)			51.12 (7.14)		-			50.00 (9.95)		
Median	35.48			-					53.16		
BIDQ (by gender)	Male		Female	Male	Female				Male		Female
Mean	2.02		2.33	2.17	2.22	-			1.57		1.81
SD	0.93		0.96	1.01	1.12	-			0.60		0.67
DAS24 (by age)	*18-30*	*31-60*	*61+*			*18-30*	*31-60*	*61+*	*18-30*	*31-60*	*61+*
Mean	42.8	43.8	31.8	-		47.9	47.2	32.6	33.6	31.3	23.8
SD	18.9	18.8	12	-		17.6	17.9	12.7	13.8	12.9	10.5

[1] Martin, Tweed & Metcalfe, 2004; Martin & Thompson, 1999; Cleary & Drennan, 2005; Partridge & Robertson, 2011

[2] Banbauer, Locke, Aupont, Mullan & McLaughlin, 2005; Carr, Moss & Harris, 2005

[3] Crawford, Henry, Crombie & Taylor, 2001; Ware, Snow, Kosinski & Gandek., 1993; Cash & Grasso, 2005; Carr, Moss & Harris, 2005

N.B. Comparison studies were identified using systematic scoping searches of the following electronic databases: PsycINFO, Web of Science, National Library for Health and ScienceDirect. Search strings included the target population (renal, chronic illness or community) and the measure (HADS, SF36, BIDQ and DAS24).

4.4.1 Psychological morbidity

Hospital Anxiety and Depression Scale data were examined to assess the extent of clinical caseness in the current sample and scores were compared with other renal, chronic illness and community data.

Participants within the research sample reported lower mean and clinical range scores than other renal populations for HADS Anxiety scores, although this was not significant (z=1.11, p=0.27). However, the research sample scored significantly lower than other chronic illness populations (z= 3.26, p=0.01). Scores were higher than community samples however this was not significant (z= -0.78, p=0.43).

HADS Depression scores were not significantly different to other renal populations (z=0.24, p=0.81), however were significantly lower than other chronic illness populations (z= 4.25, p=0.01) although significantly higher than other community populations (z= -5.41, p=0.01).

Further analysis of psychological morbidity was undertaken using the SF36 Mental Component Score. The current sample demonstrated significantly lower scores (z=3.33, p=0.01) than the general population which may be indicative of greater levels of psychological morbidity. However, when compared with other renal samples, the current sample demonstrated better emotional quality of life than other renal populations (z= -6.19, p=0.01).

It was therefore demonstrated that levels of depression are significantly higher when compared with community samples. Compared with cardiac patients, scores for anxiety and depression are significantly lower. The levels of psychological morbidity as measured by the SF36 are significantly greater than community samples, significantly different to those measured in other renal populations.

4.4.2 Quality of life

Quality of life was assessed using the Short-Form Health Survey 36 (SF36), and the dialysis sample scores were compared with normative data using z-tests to ascertain if the sample experienced significant impairment in quality of life. Quality of life Physical Component scores ($z=12.92$, $p=0.01$) and Mental Component scores ($z=3.333$, $p=0.01$) were significantly lower than normative sample scores, suggesting impaired quality of life in the dialysis sample compared with the general population.

Scores were also compared with other renal population and the Physical Component score ($z=13.96$, $p=0.01$) and Mental Component score ($z= -6.19$, $p=0.01$) demonstrated the study sample had greater impairment in physical quality of life and less impairment in mental quality of life than other renal samples.

4.4.3 Body image disturbance

Scores on the Body Image Disturbance Questionnaire (BIDQ) and Derriford Appearance Scale 24 (DAS24) were examined to assess the extent of body image disturbance compared with community samples. Initially BIDQ scores were compared

with normative data and with another renal sample. Derriford Appearance Scale 24 (DAS24) scores were compared with normative data and with another clinical sample.

In the current sample, body image disturbance measured by the BIDQ was not significantly different to other renal populations for males (z=1.56, p=0.12) or females (z= -1.11, p=0.27), however was significantly greater than normative sample data for males (z= -4.67, p=0.01) and for females (z= -5.22, p=0.01), indicating body image disturbance above what would be expected in a general population.

Sample scores on the DAS24 were significantly lower than other chronic illness populations for the 18-30 age category (z=2.60, p=0.01). However no significant differences were found between samples for the 31-60 age category (z=1.74, p=0.08), or the 61+ age category (z=0.64, p=0.52). When compared with the general population, scores were significantly higher for all age categories; 18-30 (z= -4.69, p=0.01), 31-60 (z= -6.41, p=0.01), and 61+ (z= -6.43, p=0.01), indicating notable elevated appearance concerns compared with the general population.

4.4.4 Shame

An exploratory aspect of the study was to measure shame within the dialysis population and this is demonstrated within the DAS24 scores.

To measure 'body shame' four items were taken from the Experience of Shame Scale which related to 'body shame'. These four items were summed to a total 'body shame' score, with a minimum score of 4, and a maximum of 16. For the complete dialysis

sample, scores were towards the mid-point, suggesting median levels of body shame are present within the population (mean=7.78, median=7.00, standard deviation=4.11).

4.4.5 Disgust

Data was also collected regarding disgust-sensitivity using the Disgust Scale-Revised (DS-R), to ascertain if disgust-sensitivity is problematic as a general trait within the dialysis population. Total DS-R scores for the current sample are not significantly different to the general population norms (z= -0.33, p=0.75), demonstrating the current sample did not disclose increased disgust-sensitivity. However, it is interesting to note that there is a significant difference in Contamination Disgust sub-scale score (z=-7.24, p=0.01), with the current sample demonstrating higher levels compared with the general population.

To measure 'body disgust' four novel items were created in line with the Experience of Shame Scale items. These four items were summed to a total 'body disgust' score, with a minimum score of 4, and a maximum of 16. For the complete dialysis sample, scores were towards the lower end, suggesting low levels of body disgust are present within the population (mean=6.56, median=5.00, standard deviation=3.71).

4.5 Relationships between variables

A further aim of the research was to assess for any relationships between variables.

Table 4: Correlation analysis of psychological morbidity, quality of life and body image disturbance

	HADS Total	HADS Anxiety	HADS Depression	SF36 Physical Component Score	SF36 Mental Component Score	BIDQ Total
HADS Total	-	-	-	-	-	-
HADS Anxiety	.71**	-	-	-	-	-
HADS Depression	.70**	-.71**	-	-	-	-
SF36 Physical Component Score	-.64**	-.42**	-.44**	-	-	-
SF36 Mental Component Score	-.74**	-.66**	-.64**	.37**	-	-
BIDQ Total	.70**	.73**	.54**	-.54**	-.61**	-

**Correlation significant at the 0.01 level (two-tailed)

*Correlation significant at the 0.05 level (two tailed)

4.5.1 Psychological morbidity, quality of life and body image disturbance

As demonstrated in Table 4, correlation analyses demonstrated strong relationships between psychological morbidity (HADS total, anxiety and depression), quality of life (SF36 physical and mental components) and body image disturbance (BIDQ and DAS24 total). Those scales measuring similar variables are highly correlated as would be expected (e.g. anxiety, depression and mental health impairment). However strong

relationships are also noted between body image disturbance and anxiety (r=.73), and total anxiety and depression, and physical quality of life impairment (r=.64).

4.5.2 Shame and disgust

The relationships between general and body shame and general and body disgust were assessed with results outlined in Table 5.

Table 5: Correlation analysis summary of relationships between shame and disgust

	DAS24 Total	Body Shame	DS-R Total	Body Disgust
DAS24 Total	-	-	-	-
Body Shame	.80**	-	-	-
DS-R Total	.37**	.37**	-	-
Body Disgust	.77**	.90**	.35**	-

**Correlation significant at the 0.01 level (two-tailed)

*Correlation significant at the 0.05 level (two tailed)

When considering general and body shame and general and body disgust, body shame and body disgust demonstrated the strongest relationship (r=.90). Body shame and general shame also demonstrated a strong relationship (r=.80), however general disgust demonstrated a very weak relationship with both general and body shame (r=.37), and body disgust (r=.35).

4.5.3 Shame and disgust correlated with psychological difficulties

The relationships between general and body shame and general and body disgust and the measures of psychological morbidity were assessed and the results are outlined in Table 6.

Table 6: Correlation analysis summary of relationships between shame and disgust and measures of psychological difficulty

	HADS Total	HADS Anxiety	HADS Depression	SF36 Physical Component Score	SF36 Mental Component Score	BIDQ Total
DAS24 Total	.65**	.67**	.56**	-.44**	-.70**	.78**
Body Shame	.65**	.71**	.57**	-.46**	-.64**	.70**
DS-R Total	.35**	.31**	.23*	n.s.	-.32**	.31**
Body Disgust	.60**	.71**	.55**	-.37**	-.59**	.67**

**Correlation significant at the 0.01 level (two-tailed)

*Correlation significant at the 0.05 level (two tailed)

The strongest relationships were demonstrated between general shame and body image disturbance (r=.78), body disgust and body shame with anxiety (r=.71 and r=.71), body shame and body image disturbance (r=.70), and general shame and mental health impairment in quality of life (r=-.70). The weakest relationships were demonstrated between disgust-sensitivity and depression (r=.23).

4.5.4 Linear multiple regressions

As aforementioned, correlation analyses were used to assess the results in line with the aims of the research. However, given that significant correlations were demonstrated between shame and disgust and the dependent variables, exploratory post hoc regression analyses were considered to further examine the relationships in addition to the research aims. Following evaluation of the data it was noted that the assumptions for a multiple regression were met and therefore post hoc linear multiple regressions were carried out to examine how each of the independent variables may predict the variance in the dependent variables. These results are summarised in Table 7.

Table 7: Summary of linear multiple regression outcomes

	Dependent Variables														
	HADS Anxiety			**HADS Depression**			**SF36 Physical Component Score**			**SF36 Mental Component Score**			**BIDQ Total**		
Independent Variables	**β**	**Adj. R^2**	***p***	**β**	**Adj. R^2**	***p***	**B**	**Adj. R^2**	***P***	**β**	**Adj. R^2**	***p***	**β**	**Adj. R^2**	***p***
DAS24 Total	0.22	0.53	n.s.	0.27	0.33	n.s.	0.12	0.18	n.s.	0.03	0.47	n.s.	0.60	0.61	0.00*
Body Shame	0.24		n.s.	0.25		n.s.	-0.24		n.s.	0.10		n.s.	0.20		n.s.
DS-R Total	0.03		n.s.	-0.01		n.s.	0.11		n.s.	-0.01		n.s.	0.01		n.s.
Body Disgust	0.33		0.05*	0.13		n.s.	0.06		n.s.	0.03		n.s.	0.02		n.s.

*Correlation significant at the 0.05 level

As demonstrated in Table 7, using standardised and adjusted scores, the independent variables accounted for 53% of the variance in HADS anxiety scores, with body disgust scores significantly predicting HADS anxiety scores at the .05 level. For HADS depression scores, 33% of the variance was explained by the independent variables, however no one significant predictor was identified. A previous regression analysis suggested that between 30 and 45% of the variance in psychological morbidity is explained by psychosocial constructs, whereas 33-53% of variance in psychological morbidity was accounted for in this study (Chan et al. 2011).

Similarly SF36 physical and mental component scores had 18% and 47% of the variance explained by the independent variables, although no one significant predictor was identified. A previous regression analysis suggested between 31 and 78% of variance in quality of life is explained by psychosocial constructs, suggesting less of the variance in quality of life was accounted for in this study (Chan et al. 2012).

The independent variables did however account for 61% of the variance in body image disturbance scores, with DAS24 scores significantly predicting body image disturbance scores at the .01 level. Previous studies have suggested 20% of variance in body image disturbance is predicted by psychosocial factors, whereas 61% of the variance was explained in this study (Menon & Harter, 2012).

4.6 Qualitative Information

The Body Image Disturbance Questionnaire (BIDQ) and the Derriford Appearance Scale 24 (DAS24) included open-ended questions to facilitate collection of qualitative information.

The five questions contained in the BIDQ related to identifying concerns about appearance, preoccupation with these concerns, interference with social and work roles, and what was avoided due to the concerns.

The three questions in the DAS24 related to identifying sensitivity or concerns about appearance, what specifically was disliked about their appearance and any other appearance related concerns. Given that all qualitative questions were addressing similar issues, the dataset was analysed as a whole using thematic analysis to identify themes within the responses. There were seven overarching themes identified within the responses and these are summarised in Table 8.

Table 8: Themes identified from qualitative responses to the Body Image Disturbance Questionnaire and the Derriford Appearance Scale 24.

Theme Identified	Example
Physical changes	"I have gained quite a lot of weight during my treatments" "My face often appears puffy" "My hair is going thin, and my nails are crumbling" "Scars on my body" "The appearance of large mounds where needles are inserted"
Dialysis access	"Fistula is ugly" "Fistula arm fatter than other arm [sic]" "The look of my catheter"
Disguise	"I wear long sleeves all the time as I do not want people to see it" "Try to cover up with clothing to prevent questions and stares from others" "I have to choose the clothes I wear carefully" "Summertime is hard as you can't cover up"
Emotional changes	"Just feel upset at times" "Spend too much time worrying about it" "It makes me depressed" "Feel ashamed" "Not confident going out"
Activity avoidance	"I can't go to events on dialysis days" "Used to go to a swimming club, can't now" "Unable to continue ballroom dancing" "The constraint of having to be connected to dialysing station for approx. 9hr each night"
Others	"It can be awkward when faced with people I don't know and they notice" "Don't like people seeing it" "I always think other people can see it under my clothes" "Affected my relationship with family members and work colleagues"
Physical limitations	"Dialysis days don't really exist due to recovery time" "Sometimes too tired to go out" "3 weekly dyalisis [sic] limits social life" "Had to take a little time off to attend hosp [sic] appointments" "I have to be careful when lifting heavy objects or working with sharp metal not to damage my fistula"

The qualitative responses are largely supportive of the phenomena demonstrated by statistical analyses. There were many comments related to physical aspects of dialysis, including physical changes to the body over the course of treatment, physical limitations due to dialysis, and opinions regarding dialysis access itself. Many comments were related to disguising the dialysis access, usually by adapting clothing choices to keep it covered.

Further comments related to emotional changes during treatment, and these were notably concerning more negative emotions. Alongside this, responses also mention the impact on relationship with others, and the perceived reaction of others regarding their appearance. Responses identified a number of activities that were avoided, often pertaining to specific activities such as swimming, but also related to activities being avoided on treatment days due to tiredness.

5 Discussion

5.1 Study overview

This purpose of this research study was to investigate areas of psychological difficulty in adult dialysis patients; specifically regarding psychological morbidity, quality of life, and body image disturbance. The study also sought to investigate associations and predictors of variance between the constructs measured.

Overall the demographic data collected from the sample were largely in line with regional and national profiles, suggesting the sample is representative of the wider dialysis population.

5.2 Psychological morbidity, quality of life and body image disturbance

As reported in previous research, the findings in this study demonstrate elevated HADS anxiety and depression scores that were above community norms, however were significantly lower than other chronic illness populations (Martin et al. 2004; Martin & Thompson, 1999). HADS Anxiety and Depression scores are lower than reported in previous research within renal populations, although this difference was not significant (Partridge & Robertson, 2011). Quality of life results followed a similar pattern however when findings were compared with other research with a renal sample, the findings demonstrated mental-health quality of life to be less adversely affected than other renal samples, but physical quality of life was more diminished (Cleary & Drennan, 2005). Body image disturbance exceeded what would be expected in the

general population, yet was consonant with other renal populations (Cash & Grasso, 2005; Partridge & Robertson, 2011).

Such elevated levels of psychological difficulties are perhaps not surprising given the significant burden that the complex dialysis regimen places on the individual, and the negative psychosocial effects noted and the substantial lifestyle changes needed to adhere to dialysis treatment, impacting on a patients' autonomy and control as previously identified (Cotera & Alvarez, 2008; Bossola et al., 2011; Hutchinson, 2005; Tsay & Hung, 2004; Zabel et al., 2009). This is compounded by the extensive time demands of treatment decreasing life satisfaction, the physical and psychosocial impact of the regimen, and impact of the regimen on relationships with others (Ashley & Morlidge, 2008; Quan & Quigley, 2005; Curtis et al., 2004; Richardson & Engebretson, 2010).

However the results regarding body image disturbance are novel as they have received very little focus in previous literature. Qualitative studies advance increased body awareness, and concerns around perceived negative evaluation suggestive of a body image disturbance which are now validated by quantitative investigation (Curtis et al., 2004; Richardson & Engebretson, 2010). Alongside considerable physical changes, the formation of a dialysis access site itself, either a surgically formed fistula or catheter can give rise to concern for patients due to a change in appearance and may give rise to body image disturbance (Ashley & Morlidge, 2008). This assertion is supported by the qualitative responses gathered from participants.

5.3 Shame and disgust

The measures of shame and disgust demonstrated interesting results. DAS24 scores gave an indication of general shame, with a similar magnitude to other chronic illness populations but significantly greater than would be expected in the general population (Carr et al., 2005). The more specific, novel measure of body shame demonstrated median levels of body shame in this dialysing population. Whilst comparative data is unavailable, qualitative findings suggest patients feeling a need to disguise their dialysis access, and perceiving negative evaluation by others are related factors in body shame.

Previous research in body shame infers explanations for the scores demonstrated in this study. High levels of shame have been demonstrated in other chronic conditions, with a mediating factor of being able to conceal the condition (Kent & Keohane, 2001; Rumsey & Harcourt, 2004; Sharpe et al., 2011). Given many dialysis access sites can be concealed by long sleeved and loose-fit clothing, it may be that this has mediated the body shame scores in the sample to some extent. Further investigation examining the nature of body shame in the dialysis population would be warranted to provide greater explanation of the nature of this construct and comparison with other samples.

However, trait disgust-sensitivity scores were not significantly different from what would be expected in the general population, demonstrating no increase in disgust-sensitivity, in contrast to previous research (Smith et al., 2007). It is interesting to note that an elevated Contamination Disgust sub-scale score is present in the sample compared with a general population sample. A possible explanation is that hyper-vigilance for possible infection is encouraged to ensure the dialysis access is free from

infection, and the individual's health may not be compromised through infection. In contrast, the more specific measure of body disgust demonstrated low levels of body disgust. However given the novel nature of this measure, comparative data is unavailable, although qualitative findings do make reference to body disgust findings in terms of physical changes, and the emotive language used in quotations regarding the dialysis access.

There may be several explanations for the disgust findings. It may be possible that prolonged hyper-vigilance of infection has led to a to an increased disgust-sensitivity threshold, however further research would be needed to support this assertion. However, given that the mean length of time patients had been receiving dialysis for was 3.3 years, a normal process of adjustment may have occurred which may have impacted on disgust scores particularly given higher scores have previously been linked to poorer adjustment and vice versa (Sharpe & Curran, 2005; Smith et al., 2007).

5.4 Relationships between variables

The measures of psychological morbidity, quality of life, and body image disturbance all demonstrated strong relationships, particularly between body image disturbance and anxiety, and psychological morbidity and physical quality of life.

The measures of body shame and body disgust also demonstrated a strong correlation, meaning higher levels of body shame would indicate higher levels of body disgust. Interestingly, despite strong correlations demonstrated between general and body

shame and body disgust, general disgust demonstrated a very weak relationship with any of these variables.

When correlating shame and disgust scores with measures of psychological difficulty, general shame and body image disturbance demonstrated the strongest relationship which may be explained by the DAS24 and BIDQ measuring overlapping constructs. However, the measure of body shame and body disgust did demonstrate significantly strong correlations with anxiety, body image disturbance and mental-health quality of life.

The most interesting findings relate to the linear multiple regression analysis. It was demonstrated that body shame, body disgust, general shame and general disgust accounted for over half of the variance in HADS Anxiety scores, with body disgust being the greatest predictor. For body image disturbance, two-thirds of the variance was accounted for by the independent variables, with general shame being the greatest predictor. These are greater predictors of variance than have previously been reported (Chan et al. 2011; Chan et al. 2012; Menon & Harter, 2012). However this finding should be interpreted with caution as the measures of general shame and body image disturbance measure overlapping constructs which may in part account for the strength of the relationship.

The relationships demonstrated between variables may be explained with reference to previous research. The relationship between psychological morbidity and quality of life in dialysis patients has received considerable focus in the literature (Ginieri-

Coccossis et al., 2008). Likewise, physical changes associated with dialysis have been associated with body image disturbance and psychological morbidity (Jamal et al., 2000; Lai et al., 2006; Lew-Starowicz & Gellert, 2009; Nassir, 2009; Partridge & Robertson, 2011). The constructs of shame and disgust remain an interesting addition, and research does assert these constructs have similar psychological and behavioural components, and demonstrate a link with psychological morbidity which has been demonstrated to be the case in this sample (Gilbert & Miles, 2002; Power & Dalgleish, 2007; Simpson et al., 2010).

In summary, strong relationships have been demonstrated between all of the variables. Notably between 18 and 61% of the variance in psychological difficulty scores were explained by shame and disgust, despite not all of these measures being elevated above general population scores.

5.5 Clinical Implications

As such the results offer increased insight into the management of psychological difficulties in dialysis patients than previous literature has advanced. The sample was representative when compared with the national profile, hence the results may tentatively be generalised to the national profile of patients, whilst giving consideration to the limitations of this research. Therefore, the levels of psychological difficulties reported in this study emphasise a need for health professionals to be vigilant of the psychological effects associated with dialysis as a treatment regime. This is especially important in the light of a growing recognition of psychological needs of patients, following a previous emphasis on biomedical care of which many health professionals are familiar.

The research has suggested a complex relationship between shame, disgust and psychological difficulties. Despite general measures of shame and disgust not identifying significant findings, the more specific constructs of body shame and body disgust appear to predict a significant amount of variance in psychological difficulties, suggesting a complex emotional response. As such it may be prudent to further develop and evaluate the novel measure used in this study, as to whether elevated levels of body shame and body disgust are indeed present in the dialysis population, and the relationship with psychological difficulties. Over time this may allow development of a measure which health professionals may be supported to use in recognising and supporting patients who may be struggling psychologically.

The presence of shame and psychological distress has been reported to lead to difficulties in treatment adherence, as information-withholding and avoidance of medical contact is predicted; justifying a need for the development of routine psychological screening for such difficulties at an early stage in treatment (Lazare, 1987). Dialysis patients are routinely offered education programmes and provision of information prior to commencing their treatment. It therefore may also be prudent to screen patients at this stage to provide a baseline measure of psychological wellbeing. It may then be prudent to monitor psychological wellbeing regularly over time to allow for normal adjustment reactions (Sharpe & Curran, 2005). The baseline score would then provide a comparison figure when psychological wellbeing is monitored during later stages in the treatment regime. It would be recommended to monitor patients at least yearly, as psychological wellbeing is known to fluctuate over time. Such a psychological screening programme would require subsequent training for staff in identifying, monitoring and managing distress in patients, referring onto appropriate

psychological services where necessary, and to facilitate patient disclosure of distress before it comes to impact on treatment regimes. Clinical Psychologists may be involved in developing appropriate screening measures that can be used in a ward environment or at routine follow-up appointments, and in training and supervising staff in identifying and managing distress encountered. Given the limited service provision of psychology services for those on dialysis, interventions for psychological distress may be limited. Staff may be able to offer amount of psychological support in the form of support groups, which may help normalise some of the patient's difficulties. This may not however be appropriate for all patients, especially those with greater levels of distress. Therefore these report findings would also provide the basis of a case for improved psychological support for dialysis patients.

5.6 Limitations and recommendations for future research

This research has demonstrated psychological difficulties within a dialysis population, and their complex inter-relationships with shame and disgust using standardised measures.

Notwithstanding, this research is not without limitations. This research purports from a model that cognitive evaluation of health difficulties is key to understanding difficulties arising in this patient group, thereby eliminating and potentially missing other possible explanations for the phenomena recorded. The cross-sectional nature of the study also arises difficulties, as changes in psychological wellbeing over time cannot be assessed and causality cannot be inferred. A longitudinal study may provide greater knowledge

regarding how psychological difficulties change over time, and would be important in planning assessment and early interventions strategies.

Although efforts were made to ensure the robustness of the sample, such as sampling from satellite units across the region, inherent bias were introduced through using a volunteer sample. It may be possible there were responses bias, however the sample were representative at a regional and national level, despite a response rate of 33% tempering this somewhat. The only method for rectifying this would be to perform a full analysis of non-respondents, although study procedures put in place to ensure confidentiality of patients may hinder this somewhat. A further limitation is that patients without a good standard of written English did face exclusion from the study as the majority of the measures had not been validated in different languages. This arises a problem in a regional area where Black and Minority Ethnic (BME) profiles are at high levels, as in the area this research was undertaken. This may mean a number of groups were excluded, however without fuller analysis of non-respondents it is difficult to draw such assertions. The study did however recruit enough participants to be able to purport a medium effect size, which does increase its statistical power.

A further limitation of the study is the levels of missing data displayed. As such, reliability analyses were comprised, particularly for the quality of life measure. Cronbach's alpha score for the SF36 was below the recommended cut-off for reliability meaning the results must be interpreted with caution. When undertaking missing data analyses, it was noted that 15% of participants missed at least one item when completing this measure, which may have impacted on total scores, although multiple

imputation datasets should have accounted for this. Conversely a specific renal quality of life measure may have provided better estimates of quality of life difficulties for renal patients. It is also important to note that the chronic illness norms came from a variety of other health populations including burns, plastic surgery and oncology, all of which may be considered acute care, and it may be possible that these are traumatised patients groups given the acute nature of their illnesses, therefore meaning comparisons with these populations may not be accurate. For this research, a pilot study with the dialysis population would have been appropriate to examine methods by which to improve completion rates, and this would have also provided opportunity to further evaluate the reliability and validity of the novel measure of body disgust.

A number of recommendations for future research are noted. As previously outlined, a longitudinal study may afford monitoring of psychological wellbeing over time, therefore gaining greater explanatory power. Also, given the difference in age-related scores on the DAS24 and gender scores on the BIDQ, it may be useful to control for gender and age in future research. Further validation and development of the measure of body shame and disgust would be recommended. This would allow the development of a tool than could be used to screen patients in a clinical setting.

Given the exploratory nature of this study in purporting shame and disgust to explain variance in psychological difficulties, a significant amount of variance still remains unexplained. It may therefore be appropriate to consider alternative measures that more fully encapsulate and explain these constructs, and advance further variables that may identify the unexplained variance in dialysis patients. All the measures used in this

study may be brought into question in terms of their validity with a dialysis population, therefore renal specific measures may be more appropriate in future research.

This research does however provide further evidence of psychological difficulties in dialysis patients. As such, future research may focus on the development and trialling of support interventions for dialysis patients, and such research may be able to utilise a randomised controlled trial approach, which may add greater integrity to the findings.

In conclusion, whilst there are acknowledged limitations to this study, this research demonstrates increased levels of psychological difficulties in the dialysis population, especially when compared with the general population. It has advanced the constructs of body shame and body disgust as markers that may be assessed for and intervened with to increase psychological wellbeing in this population. This enhances previous research in the area as it draws together areas previously identified constructs, and further explains relationships between the variables. This also draws upon clinical evidence of distress in dialysis patients, and the themes identified in previous qualitative research. It is therefore hoped that this study will be the first in a succession of research into understanding more about the nature of distress, body shame and body disgust as experienced by dialysis patients, alongside management of their biomedical needs.

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Section Three

Critical Appraisal

During completion of this research, I have been afforded many learning opportunities in terms of understanding the research process and the competencies required in a researcher. This appraisal therefore aims to summarise my evaluation of the process and skills developed during the completion of my Doctoral research.

1. Literature review

During the first year of my clinical training I undertook a literature review which was submitted as a marked assignment. As my interest in health psychology had begun to develop over the course of my first year placement and because of the clinical presentation of many renal patients referred to Health Psychology, I undertook my review with a focus on the psychological impact of dialysis and whether dialysis patients experience disturbance in body image. This review identified five qualitative studies addressing body image in dialysis patients from which I was able to analyse and consider the qualitative themes presented across the studies. These themes broadly fell into the following categories; caring for self, social support, need for normality despite reliance on medical equipment, restrictions and body awareness and stigma. All of the identified themes were also considered to allude to complex feelings of shame and disgust regarding dialysis and the physical changes as a result.

This review led to the idea for my research study as later discussed, however as I had previously submitted this review for the same academic award I could not present this review in my thesis. I looked to replicate and update the review, however there was no further research published in the area that would make the review substantially different

in replication, leading me to consider other options. Thus began a frustrating process as I considered many ideas for example disgust-sensitivity in physical illness and psychological morbidity and quality of life in dialysis patients. Considerable scoping searches conducted however, proved these ideas to be untenable either because they were too limited, too variable, or a review had recently been published in the area.

During this time my research was progressing based on my first year literature review, identified previous research, discussion with supervisors and other clinicians working in the area, and the results of scoping searches. After discussion of my literature review with my supervisors it was decided that a complimentary literature review may be more appropriate, leading me to conduct scoping searches into related conditions and treatments. It was at this point I identified the growing body of literature regarding stoma surgery. Given that a stoma is often created due to illness affecting the digestive system and thus involves bodily secretions, it was felt that this topic would be complimentary to the difficulties dialysis patients may experience. Also as this was a growing body of evidence, a review encompassing and drawing together research in this area was particularly pertinent. This led to me conducting review looking at psychological morbidity in this population and the critical evaluation of how psychological morbidity is measured. This difference in focus did raise some concerns for me in presenting my thesis given the research was not directly based on the review presented within the thesis, but rather a review at an earlier date, however I was able to use supervision to discuss and alleviate these concerns.

2. Origins of the research study

The first placement year of my Clinical Psychology training was in a Clinical Health Psychology service. Within the service there was specific funding from the renal department for a Clinical Psychologist to work with renal patients. This provoked interesting discussions with my placement supervisors as to why this was and the psychological consequences of dialysis for some patients; considering the impact on psychological wellbeing and physical health in terms of adherence to the dialysis regime itself and its associated limitations (dietary influence, restricted fluid intake etc.). This reminded me of personal experiences of people undergoing dialysis, and how I had noticed how they had tended to become more introverted after beginning their treatment, and very self-conscious of their dialysis access, wanting to keep it covered. Further discussion with my placement supervisors centred on how, anecdotally, they had too found this to be the case for many of their renal patients. On undertaking scoping searches, the psychological consequences of the life changing process of receiving dialysis treatment have received little focus, with a dominance of research into medical factors and consequences of the treatment. With the subsequent closure of the service I completed my placement in, and discussions with my supervisors around this, I realised how there is a dearth of research evidence regarding psychological services within the health field, and how this can lead to difficulties when attempting to put forward a case for a service to continue to be funded in the face of lessening NHS budgets.

Staff at the University organised a research fair during my first year of Clinical Psychology training. At this fair several local clinicians presented research ideas, for

areas they had noticed as prevalent clinically, with issues around dialysis being raised as an area with little research. At this fair, several ideas for research within the renal field were outlined, and I was able to have brief discussions with those clinicians about their experience with renal patients and about my experience. Further meetings with a Clinical Psychologist working in the field allowed greater discussion of the issues often raised in therapy for dialysis patients, and the need to understand the prevalence of psychological consequences of a treatment in order to be able to intervene early and offer appropriate psychological support for the patient group.

As previously discussed, a first year literature review assignment raised the opportunity to focus on psychological phenomena within renal patients, and after several scoping searches I decided to focus on the idea of being 'self-conscious' regarding the dialysis access, and subsequently completed a review on the psychological impact of dialysis and if dialysis patients experience disturbance of body image. This process helped to develop ideas about the clinically-noticed phenomena that appeared to be 'missing' from the research field and helped form ideas about how such phenomena might be investigated. On discussion with my research supervisor about my ideas, she identified a study (in press) that she had worked on with a previous trainee, looking at body image disturbance in dialysis patients. This was both disappointing and interesting, as it had quantitatively identified that body image disturbance was present within a dialysis population. However, this gave greater opportunity to consider the question as to why dialysis patients may be experiencing such body image difficulties. On reflecting on research with an eating disordered population where body image disturbance is paramount, I was able to consider possible explanatory variables of shame and disgust, which also appeared present within qualitative literature with dialysis patients that I had

previously reviewed. I was therefore interested in whether shame and disgust sensitivity might be present in a renal population, and whether they may have some explanatory power in why body image disturbances appear to arise.

3. Choice of research methodology

Initially I felt a qualitative methodology would be most appropriate given that this is an understudied area, and qualitative methods might identify themes of phenomena that are pertinent to renal patients. I also felt that a qualitative design would afford a richer source of information, hopefully going into depth of experience for renal patients. However, given that qualitative studies had been completed previously, and that the literature review I had undertaken had identified several of these studies, my thoughts regarding the research methodology changed somewhat.

Given that the qualitative studies reviewed identified some themes around body image difficulties, and feeling of shame and disgust at the changed appearance, I wondered how prevalent a difficulty this is across the renal population, rather than in the smaller subset used within the qualitative studies. Bearing this in mind, a quantitative methodology was therefore considered for my research study. This took a positivist empirical standpoint, assuming that the phenomena are measurable, moreover allowing a greater number of patients to be investigated, and allowing an idea of whether there is a trend towards psychological morbidity and body image difficulties across the population.

In discussions with my research supervisor, it was debated whether to include an qualitative element in the research design so as to be able to give some meaning to whatever quantitative results came from the study. The possibility of conducting focus groups with some of the research participants regarding their psychological wellbeing and body image was considered. However by researching and understanding the demands of both quantitative and qualitative research methodologies, the focus group idea was dismissed for this study, as a thorough analysis would be sizeable and time-consuming in order to do it justice. Interviewing patients or conducting focus groups with the patients from this study would be appropriate as a follow up study to this research, in order to bring meaning and facilitate possible explanation for the quantitative results.

4. Peer and ethical review

There were several structured processes to be negotiated for my research study to commence and having never conducted research within the NHS previously, these were unfamiliar and somewhat daunting.

A research proposal was developed with the support of my research supervisors and submitted to the Clinical Psychology Department at the University for peer review. The feedback provided was helpful in considering how data collection might be approached (through a 'gate-keeper' or directly) and considering how shame and disgust are difficult emotions to identify yet the positivist empirical approach consider them measurable. This is an important consideration in the limitations to this research

as the assumption is that these emotions are recognisable and measurable, despite being very difficult for patients to identify themselves, and therefore this discrepancy may impact on the quantitative results. Indeed it may be that these emotions are present in the renal population, however admitting to them may be considered shaming in itself and therefore the questionnaires may not be completed as honestly. This is why it was considered so important that participants were in no way identifiable from their results, so as to give them complete anonymity to allow them to feel they could be open and honest in the completion of the questionnaires. The difficulties in measuring shame and disgust was a point I had not previously considered, however forms a vital confounding variable within the research, and had the research proposal not been peer reviewed, would have formed a unconsidered confounding variable and weakness in the research.

Submission to NHS ethics was reported to be a new, simplified process compared to how it had been previously. However, as I had not experienced applying for NHS ethical approval before this was a long and daunting process through the Integrated Research Application System. A lengthy and somewhat repetitive form is completed, which has to be electronically authorised by various people (including supervisors, representatives of the host trust, and Research and Development (R&D) representatives). As I was undertaking research in a host trust different to the trust I was employed by, this meant another level of authorisation was required by both trusts involved.

The process did appear geared towards clinical trials rather than psychological research, and therefore many of the questions were not appropriate. However I was reassured at how protected patients are, as all NHS research applications have to go through such a rigorous process before they are allowed to approach patients. This thought was compounded by my experience of the Research Ethics Committee (REC). At the REC I attended there were several professionals (not related to Psychology), alongside many lay members. The points raised at the committee were very psychologically minded, and were related to how patients would experience completing the form and being asked how 'disgust-sensitive' they were. When I explained that the wording of the questionnaires could not be changed as they are standardised, the committee appeared reassured, and there were only minor changes amendments required regarding the wording in the patient information sheets.

The R&D process appeared more stringent in comparison to my experience of the REC. There were additional authorisation signatures required, however difficulties arose as there was a changeover in the staff member who was required to authorise it during the time I needed them to sign the research off. This led to delays as I needed to follow up different staff members and/or people who might be able to authorise it in the interim period. This was a learning point in conducting research in the 'real world', in that people change positions, leave the trust, and sometimes positions are vacant for a period. This can lead to difficulties when the people in those positions are required to authorise research studies, and now I understand that it is helpful to overestimate the time required to allow for the process to be completed than to underestimate it!

5. Data collection and analysis

Whilst designing the study it was difficult to balance the number of measures, with the data I needed to collect to investigate the research questions fully. I was very aware that the research was being conducted with an 'ill-population' and wanted to keep participant burden to a minimum where possible. I found choosing measures and the research design to be a balancing act; reasoning through strengths and weaknesses of each measure and, where possible putting measures in place to validate other measures used. This unfortunately leads to unavoidable limitations in the research, and made me more aware of how all research studies are prone to such limitations however hard a researcher works to reduce them.

Given that one previous study had identified body image disturbance in a renal population, and identified a relationship with psychological morbidity it felt appropriate to replicate the measures used in an attempt to validate the previous findings, which may in turn add weight to the findings of my research study, providing they found similar outcomes. As such this led to certain measures being selected namely the Hospital Anxiety and Depression Scale (HADS), and the Body Image Disturbance Questionnaire (BIDQ). Whilst being aware of the limitations of the HADS, it was felt appropriate as it is designed for use in a medically unwell population, whereas other psychological morbidity measures do not generally take ill-health and subsequent difficulties in mood into account. However I felt a way to validate the HADS score was needed. Therefore the quality of life measure was recommended by a Clinical Psychologist in the renal field. The Short-Form 36 (SF-36) gives a score of physical health and mental health, and I felt the mental health score might be appropriate to

validate the HADS score. It is also helpful to measure quality of life given the anecdotal interplay noticed clinically between psychological morbidity and perceived quality of life.

Despite using the BIDQ to attempt to both validate previous findings and possibly add weight to my own findings, I felt that it was quite limited in terms of a measure. especially as the total score is a mean score which is susceptible to becoming skewed due to outliers. It was therefore felt that relying on this measure to give a total score might be nebulous at best. As such, the Derriford Appearance Scale 24 (DAS24) was included to verify the BIDQ score, and also measure shame. I chose the shortened version of this measure, again to attempt to reduce participant burden. This scale also added to the qualitative information collected in that it has some open ended questions, asking participants to identify what in particular about their appearance they dislike.

Measuring body shame and disgust also brought about difficulties. These are powerful, multifaceted emotions and given the exploratory aspect of measuring shame and disgust in a renal population, I felt it was appropriate to measure an indication of these two emotions, rather than an in depth analysis of each. This again was to attempt to reduce participant burden, but also to reduce the emotional impact of completing questions regarding powerful emotions. This led to the decision to use items related to body shame from the Experience of Shame Scale, with four novel items created by my research supervisor looking more specifically at body disgust. However, when researching how these emotions had been measured in previous research, I came across the Disgust Scale-Revised. This scale measures trait disgust, not only looking at core

trait disgust, but more interestingly giving a sub-scale for contamination disgust. I felt this was important to measure as dialysis patients are taught how to care for their access site, in terms of keeping it free from contaminates, but also working within its limitations (e.g. not doing heavy lifting with the arm their fistula is in). I felt that if this were not measured, this may introduce a confounding variable, as body disgust may possibly be influenced by sensitivity to trait disgust. Also if hyper-sensitivity to contaminates is somewhat encouraged by hospital staff to ensure the dialysis access site is kept healthy, then this may be indicated in the contamination disgust score.

The data collection method also proved to be a steep learning curve. I had numerous discussions with colleagues, supervisors, staff and dialysis patients regarding the number of questionnaires to be used. This greatly influenced the decision to use the short-form of measures to attempt to keep participant burden to a minimum. Patients did however report that those approached would probably just not participate if they did not feel well enough. I did however work to alleviate this responsibility for patients as much as possible by ensuring staff were consulted as to patients who could and could not be approached with a consideration of the individual's health status. It is however noted that the Short-Form 36 (SF36) questionnaire had questionable reliability which was thought to be because of the high levels of missing data. I did consider whether this was missed due to overload on the participant, however when looking at the pattern of missing data I noticed there were specific questions missed more than others, all of which were on the same page. This led me to question whether this data was overlooked due to the layout of the questionnaire pack meaning this page was easily missed by turning too many pages at once. In future the layout of the questionnaire packs should be given further consideration as to methods to reduce pages being missed

(e.g. by using page numbers) and asking participants to check at the end that they have completed all the pages.

During discussions with hospital staff, it was agreed that staff could give out the questionnaire packs to patients on arrival for their dialysis appointment. Initially this seemed like a good idea given that staff would be seeing each patient upon arrival, and therefore no-one would be missed. However in reality, the hospital staff are so busy with undertaking their daily duties, that questionnaire packs were being forgotten and not handed out, despite their offer and best intentions. This was resolved when I attended each dialysis session at all of the dialysis clinics, and spoke to each patient individually, explaining the study to them and giving them a questionnaire pack. In hindsight, although the most time-consuming, this was the best method for data collection as it allowed me to talk about the study, explaining its relevance, and also allowed patients to put a 'face to the name' in the questionnaire pack. I feel that this was the reason for the good return rates on questionnaires issued, and provided a valuable learning experience in data collection for the future.

6. Engaging other professionals

The research study relied upon engaging other professionals and I was overwhelmed with the support I received from the professionals approached. Although I was somewhat daunted with approaching those is positions of power (head of departments, consultants etc.), once I explained the study to them, they showed great psychological mindedness, and real interest in the results. This was a lesson in the importance of

selling a study well to the professional audience in order for it to be undertaken and supported effectively. During the time I was approaching hospital staff, there were a number of ideas they came up with for the study. Sometimes these were more straightforward to manage, for example when a consultant was interested in whether scarring had an effect on how patients felt about themselves. In this case, I explained that the qualitative questions would give opportunity for patients to raise scarring if this was an issue for them. Another professional raised the idea of assessing pre-dialysis patients due to there being little research evidence with this population. After some discussion, it was decided that this would not be appropriate in this case, as pre-dialysis patients may be experiencing normal adjustment processes and therefore psychological morbidity scores may be more variable in this population. However, I do agree that the pre-dialysis population has received little focus in the research literature, and it may be useful to undertake a longitudinal study following change over time in this population.

Within the research process I became aware of the importance of establishing good working links with other professionals. This allowed for the research processes to run more smoothly, for example when the R&D department required research CV's for the local collaborators, these were returned promptly by the hospital staff, despite this being in addition to their daily role. I have found good working relationships and mutual support to be invaluable in helping aid the research process to run as well as possible.

7. Learning Outcomes

Overall, by conducting this research study I have developed a number of competencies, and learnt an invaluable amount about governing a research process.

On reflection the process has allowed me to access some specific training, e.g. Good Clinical Practice training. This has allowed me to learn about the specific guidance in place to protect participants in research, and has given me an appreciation of how much the NHS protects its patients from unsound research. This was further evidenced in my experience of the NHS Integrated Research Application System, Research Ethics Committee and Research and Development process for the host trust.

It was an interesting experience in accessing participants from a host trust different to that which I was employed by. I chose to access patients within that particular trust due to the contacts made, and the number of dialysis clinics contained within the trust. However I had underestimated that this may lead to additional paperwork in registering the research both with the host trust and my employer trust.

Another steep learning curve for me was that of balancing the research opportunity with keeping the research to a manageable size for me to undertake as part of my thesis. This became more difficult when selling the research to professionals within the host trust, as understandably they have helpful ideas about phenomena to measure within their patient population. Attempting to balance helpful ideas, with what was

manageable for me was difficult, especially in the context of maintaining a good working relationship, was paramount in ensuring the research progressed well.

As is the case in most research studies, I found it to be a balancing act to choose measures that measured variables in the most appropriate way, but yet kept participant burden to a minimum, especially in the context of an ill-population. I now appreciate more how difficult this is within research, and how this process in itself introduces unavoidable strengths and weaknesses into the research.

Finally, there were some general pragmatics to negotiate and develop during the course of the research. I found that being organised, and good timekeeping were paramount as when these were not managed well, difficulties arose. However I do feel that when difficulties do arise in research, it again teaches us something about the process, and how we might work to improve this in future research studies undertaken. The most difficult aspect of the research was maintaining the motivation for the study, especially as a single principal investigator. There are times when difficulties arise within the process which can be frustrating and disheartening, and maintaining motivation at these times were key. This was achieved by reminding myself that results would be disseminated both to professionals, and the patients themselves, and this process may then effect future policy and most importantly, the psychology services offered to dialysis patients.

Appendices

Appendix A: Guideline for authors for literature review and research report target journal.

British Journal of Health Psychology

Downloaded from http://onlinelibrary.wiley.com/journal/10.1111/(ISSN)2044-8287/homepage/ForAuthors.html on 11th June 2013.

The aim of the British Journal of Health Psychology is to provide a forum for high quality research relating to health and illness. The scope of the journal includes all areas of health psychology across the life span, ranging from experimental and clinical research on aetiology and the management of acute and chronic illness, responses to ill-health, screening and medical procedures, to research on health behaviour and psychological aspects of prevention. Research carried out at the individual, group and community levels is welcome, and submissions concerning clinical applications and interventions are particularly encouraged.

The types of paper invited are:

• papers reporting original empirical investigations;

• theoretical papers which may be analyses or commentaries on established theories in health psychology, or presentations of theoretical innovations;

• review papers, which should aim to provide systematic overviews, evaluations and interpretations of research in a given field of health psychology; and

• methodological papers dealing with methodological issues of particular relevance to health psychology.

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

Papers should normally be no more than 5000 words (excluding the abstract, reference list, tables and figures), although the Editor retains discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length.

3. Editorial policy

The Journal receives a large volume of papers to review each year, and in order to make the process as efficient as possible for authors and editors alike, all papers are initially examined by the Editors to ascertain whether the article is suitable for full peer review. In order to qualify for full review, papers must meet the following criteria:

• the content of the paper falls within the scope of the Journal

• the methods and/or sample size are appropriate for the questions being addressed

• research with student populations is appropriately justified

• the word count is within the stated limit for the Journal (i.e. 5000 words)

4. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. You may like to use the Submission Checklist to help you prepare your manuscript. The Journal operates a policy of anonymous peer review. Authors must suggest three reviewers when submitting their manuscript, who may or may not be approached by the Associate Editor dealing with the paper. Before submitting, please read the terms and conditions of submission and the declaration of competing interests.

5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded from here.

• Statement of Contribution: All authors are required to provide a clear summary of ‘what is already known on this subject?’ and ‘what does this study add?’. The 2-3 (maximum) sentences for each point should identify existing research knowledge relating to the specific research question/topic and a summary of the new knowledge added by your study. Under each of these headings, please provide 2-3 clear outcome statements (not process statements of what the paper does); the statements for 'what does this study add?' should be presented as bullet points of no more than 100 characters each. The Statement of Contribution should be a separate file.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript with their approximate locations indicated in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi.

• For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results,

Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide doi numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright. For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.

• Manuscripts describing clinical trials are encouraged to submit in accordance with the CONSORT statement on reporting randomised controlled trials.

6. Supporting information

Supporting Information can be a useful way for an author to include important but ancillary information with the online version of an article. Examples of Supporting Information include appendices, additional tables, data sets, figures, movie files, audio clips, and other related nonessential multimedia files. Supporting Information should be cited within the article text, and a descriptive legend should be included. Please indicate clearly on submission which material is for online only publication. It is published as supplied by the author, and a proof is not made available prior to publication; for these reasons, authors should provide any Supporting Information in the desired final format.

For further information on recommended file types and requirements for submission, please visit the Supporting Information page on Author Services.

7. OnlineOpen

OnlineOpen is available to authors of primary research articles who wish to make their article available to non-subscribers on publication, or whose funding agency requires grantees to archive the final version of their article. With OnlineOpen, the author, the author's funding agency, or the author's institution pays a fee to ensure that the article is made available to non-subscribers upon publication via Wiley Online Library, as well as deposited in the funding agency's preferred archive. A full list of terms and conditions is available on Wiley Online Library.

Any authors wishing to send their paper OnlineOpen will be required to complete the payment form.

Prior to acceptance there is no requirement to inform an Editorial Office that you intend to publish your paper OnlineOpen if you do not wish to. All OnlineOpen articles are treated in the same way as any other article. They go through the journal's standard peer-review process and will be accepted or rejected based on their own merit.

8. Author Services

Author Services enables authors to track their article – once it has been accepted – through the production process to publication online and in print. Authors can check the status of their articles online and choose to receive automated e-mails at key stages of production. The author will receive an e-mail with a unique link that enables them to register and have their article automatically added to the system. Please ensure that a complete e-mail address is provided when submitting the manuscript. Visit Author Services for more details on online production tracking and for a wealth of resources including FAQs and tips on article preparation, submission and more.

9. Copyright and licences

If your paper is accepted, the author identified as the formal corresponding author for the paper will receive an email prompting them to login into Author Services, where via the Wiley Author Licensing Service (WALS) they will be able to complete the licence agreement on behalf of all authors on the paper.

For authors signing the copyright transfer agreement

If the OnlineOpen option is not selected the corresponding author will be presented with the copyright transfer agreement (CTA) to sign. The terms and conditions of the CTA can be previewed in the samples associated with the Copyright FAQs .

For authors choosing OnlineOpen

If the OnlineOpen option is selected the corresponding author will have a choice of the following Creative Commons Licence Open Access Agreements (OAA):

- Creative Commons Attribution Non-Commercial Licence (CC-BY-NC)
- Creative Commons Attribution Non-Commercial -NoDerivs Licence (CC-BY-NC-ND)

To preview the terms and conditions of these open access agreements please visit the Copyright FAQs and you may also like to visit the Wiley Open Access Copyright and Licence page.

If you select the OnlineOpen option and your research is funded by The Wellcome Trust and members of the Research Councils UK (RCUK) you will be given the opportunity to publish your article under a CC-BY licence supporting you in complying with Wellcome Trust and Research Councils UK requirements. For more information

on this policy and the Journal's compliant self-archiving policy please visit our Funder Policy page.

10. Colour illustrations

Colour illustrations can be accepted for publication online. These would be reproduced in greyscale in the print version. If authors would like these figures to be reproduced in colour in print at their expense they should request this by completing a Colour Work Agreement form upon acceptance of the paper.

11. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found in Author Services. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

12. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. A working e-mail address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from Adobe's web site. This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be supplied by hard copy if preferred. Further instructions will be sent with the proof. Hard copy proofs will be posted if no e-mail address is available. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

13. Early View

British Journal of Health Psychology is covered by the Early View service on Wiley Online Library. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Articles are therefore available as soon as they are ready, rather than having to wait for the next scheduled print issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. Eg Jones, A.B. (2010). Human rights Issues. *Journal of Human Rights.* Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x Further information about the process of peer review and production can be found in this document. What happens to my paper?

Appendix B: Databases searched for literature review and number identified

Database	Dates searched	Search terms used	Limits applied	Initial number of hits
PsycINFO	15/04/2013 – 29/04/2013	*bio** OR *psycho** OR *social* OR *biopsychosocial* AND *predict**AND *psychological distress* OR *depression* OR *anxiety* OR *psychological morbidity* AND *stoma* OR **ostomy* OR **ostomies* OR *colostomy* OR *urostomy* OR *ileostomy*	All years Full text Peer-reviewed English	4
Web of Science	15/04/2013 – 29/04/2013		All years Title search Journal article English	522
Medline	15/04/2013 – 29/04/2013		All years Full text	778
The Cochrane Library	15/04/2013 – 29/04/2013		All years Methods studies	2004
National Library for Health (using CINAHL and AMED	15/04/2013 – 29/04/2013		All years Search title & abstract	2
Science Direct	15/04/2013 – 29/04/2013		All years Journals only Exclude child	125

Appendix C: Quality assessment tool for review studies

Taken from http://www.strobe-statement.org/index.php?id=available-checklists, March 2013.

	Criteria
1. Title and abstract	(*a*) Indicate the study's design with a commonly used term in the title or the abstract (*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction	
2. Background & rationale	Explain the scientific background and rationale for the investigation being reported
3. Objectives	State specific objectives, including any prespecified hypotheses
Method	
4. Study design	Present key elements of study design early in the paper
5. Setting	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
6. Participants	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants (*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
7. Variables	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable

8. Data sources & measurement	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
9. Bias	Describe any efforts to address potential sources of bias
10. Study size	Explain how the study size was arrived at
11. Quantitative variables	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
12. Statistical methods	(*a*) Describe all statistical methods, including those used to control for confounding (*b*) Describe any methods used to examine subgroups and interactions (*c*) Explain how missing data were addressed (*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy (*e*) Describe any sensitivity analyses
Results	
13. Participants	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
14. Descriptive data	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) *Cohort study*—Summarise follow-up time (eg, average and

	total amount)
15. Outcome data	*Cohort study*—Report numbers of outcome events or summary measures over time *Case-control study*—Report numbers in each exposure category, or summary measures of exposure *Cross-sectional study*—Report numbers of outcome events or summary measures
16. Main results	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (*b*) Report category boundaries when continuous variables were categorized (*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
17. Other analyses	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion	
18. Key results	Summarise key results with reference to study objectives
19. Limitations	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
20. Interpretations	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
21. Generalisability	Discuss the generalisability (external validity) of the study results
Other Information	
22. Funding	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

Appendix D: Data extraction categories used

Data were extracted under the following categories, taken from http://www.york.ac.uk/inst/crd/pdf/Systematic_Reviews.pdf, 15th March 2013

General information

Date of extraction

Record number (to uniquely identify study)

Author

Article title

Country of origin

Source of funding

Participant characteristics

Age

Gender

Ethnicity

Socio-economic status

Disease characteristics

Co-morbidities

Number of participants in each characteristic category for intervention and control group(s) or mean/median characteristic values

Outcome data/Results

Statistical techniques used

For each pre-specified outcome:

Whether reported

Definition used in study

Measurement tool or method used

Study characteristics

Aim/objectives of the study

Study design

Study inclusion and exclusion criteria

Recruitment procedures used (e.g. details of randomisation, blinding)

Intervention and setting

Setting in which the intervention is delivered

Description of the intervention(s) and control(s)

Theoretical basis

Description of co-interventions

Length of follow-up, number and/or times of follow-up measurements

For all intervention group(s) and control group(s):

Number of participants enrolled

Number of participants included in analysis

Number of withdrawals, exclusions, lost to follow-up

Summary outcome data e.g.

Dichotomous: number of events, number of participants

Continuous: mean and standard deviation

Type of analysis used in study (e.g. intention to treat, per protocol)

Results of study analysis e.g.

Dichotomous: odds ratio, risk ratio and confidence intervals, p-value

Continuous: mean difference, confidence intervals

Additional outcomes

Appendix E: Statement of epistemological position

This research was designed from a positivist epistemological standpoint. This assumed that psychological morbidity, body image disturbance, quality of life, shame and disgust-sensitivity are both quantifiable and measurable constructs that may be problematic within a sample of patients undergoing dialysis. There is an assumption that these constructs may be measured using reliable and valid quantitative measures. The research methodology was driven by these assumptions, and therefore was designed to be primarily quantitative in nature.

Appendix F: Chronology of research process

January 2011	Research ideas and supervisor preferences put forward
May 2011	Research proposal peer reviewed
February 2012	Integrated Research Application System (IRAS) forms submitted to ethics
March 2012	Attended Research Ethics Committee panel meeting
July 2012	Ethical approval received
November 2012 – February 2013	Research & Development approval received, data collection
March 2013	Data analysis
April 2013	Literature review completed
June 2013	Thesis submission
July 2013 - September 2013	Preparation for publication
September 2013	Presentation at research conference

Appendix G: Patient recruitment letter and information sheets

University of Leicester

<Trust Logo> NHS

Renal, and Urology Directorate
Hospital
Address
Address
Postcode

24th July 2012

Dear Sir/Madam,

Re: An investigation into body shame and disgust-sensitivity in adult dialysis patients.

By receiving this pack, you are invited to take part in a research study looking at the effects of dialysis on body image, disgust-sensitivity and wellbeing. This study is being undertaken by Claire Leonard, Trainee Clinical Psychologist, training at the University of Leicester. It has been approved by the NHS Research Ethics Committee and the [redacted] Research and Development Department.

If you are interested in being a participant in this study, please read all of the following information carefully as it will outline the study in detail, and answer any questions you may have.

If you do decide to take part, please make sure you have completed all sections of the pack and return it directly to the researcher, Claire Leonard, using the stamped-addressed-envelope provided. If you decide to participate in the study, there is a prize draw form you can complete to be entered into a prize draw to win one of two £25 High Street spending vouchers.

Please take your time to decide if you would like to take part or not. You are not under any obligation to take part, and your care will not be affected in any way whether you decide to participate or not.

If you have any questions about participating, please contact the researcher, Claire Leonard using the contact details on the information sheet.

Thank you for your time and interest in this research study.

Yours sincerely,

Dr [redacted]

Consultant Nephrologist
Renal and Urology Directorate

University of Leicester

<Trust Logo> NHS

Renal, and Urology Directorate
Hospital
Address
Address
Postcode

PATIENT INFORMATION SHEET

An investigation into body shame and disgust-sensitivity in adult dialysis patients.

You are invited to take part in a research study looking at the effects of dialysis on body image, disgust-sensitivity and wellbeing. This sheet will take you through some information on what the research is about and why you are being asked to take part. Please read this information sheet carefully before you decide to take part or not. You may talk to others about the study if you wish.

What is the purpose of the study?

This study is looking at how dialysis might effect the way you feel about your body and how you might feel about things that you consider 'loathsome'. There is very little known about whether dialysis might change the way you think and feel about your body and what these changes might be. We hope that this will help our understanding of body image changes for dialysis patients, and will improve our care of dialysis patients in the future.

Why have I been invited?

You have been invited to take part in this study because you are over the age of 18 and have been on a form of dialysis for longer than 6 months. If you have been on dialysis for less than 6 months, you cannot take part. A member of your direct care team may have reviewed your medical record to ensure that you have been appropriately approached about this study. No member of staff who would not usually have access to your medical records will have reviewed your record.

Do I have to take part?

No. It is your decision whether you would like to take part or not. You are asked to read through all of the information and then make a decision on whether to take part or not. Your normal care will not be affected in any way whether you decide to participate or not.

What will happen to me if I take part?

This study will involve completing a number of questionnaires that are all enclosed in this pack. This may take approximately 40 minutes of your time. The questionnaires are anonymous, meaning you cannot be identified personally. Please do not put your name on the questionnaires. The questionnaires are about:

- Basic information about you (age, gender, ethnicity etc)
- Levels of stress and anxiety

- Your quality of life
- Your thoughts and feelings about your physical appearance
- Any possible areas of concern regarding your physical appearance
- Any possible feelings of self-consciousness
- Any situations that might make you feel disgusted.

Please try to complete all items on all of the questionnaires. If you feel particularly uncomfortable answering any of the questions, please leave the item blank and go onto the next item, or consider if you want to continue with the study. Once all of this paperwork has been completed, this will end your participation in the study. You will not be contacted again by the researcher, unless you have won a prize in the prize draw.

Prize Draw

Everyone who completes the questionnaires and enters their name and address on the prize draw slip will be entered into a prize draw to **win one of two £25 High Street spending vouchers.** Please do not return the slip with your personal details if you do not want to take part in the prize draw.
Your information will be kept in a locked cabinet at the University of Leicester Clinical Psychology Department. Once the draw has been completed, all slips containing name and addresses will be destroyed by the researcher (this will be completed by the end of January 2013). You will not be contacted again, other than to tell you if you have won the prize draw.

What if there is a problem?

If you feel distressed following reading or completing the questionnaires, a referral to Medical Psychology can be arranged. If you would like to be referred to Medical Psychology for emotional support, please ask your consultant or a member of the Renal team who will be able to arrange this for you.

If you wish to obtain independent advice about any aspect of this study or your treatment, you can contact the Patient Information and Liaison Service (PILS) by telephone [redacted], or by writing to the PILS Office Patient Information and Liaison Service, [redacted].

What if I don't want to continue with the study?

If you have read this information and decide that you do not wish to take part, there are no implications for the treatment you receive. If you do take part and then change your mind, you are free to withdraw your data from the study at any time and do not have to give a reason as to why.

Are there any benefits to taking part?

There is no benefit to your treatment at the Hospital. By taking part you will help to inform our knowledge of the effects of dialysis treatment to be able to provide better care to all dialysis patients in the future.

Will my taking part in the study be kept confidential?

Yes. All information that you complete in this pack will be kept confidential by the researcher. You will not be able to be personally identified by the information collected from you. The prize draw information will be kept separately to the questionnaires and will be destroyed once the draw has been made. Your GP will not be informed about your involvement. The completed questionnaires will be kept in locked cabinet at the University of Leicester Clinical Psychology Department and destroyed 5 years following the researchers graduation (due to be destroyed in 2018).

What will happen to the results of the research study?

Your responses will be analysed with all the data collected from other participants. The overall results will be written up as part of a research thesis due to be submitted as part fulfilment of a Clinical Psychology Doctorate, and later in a research journal. You will not be personally identified from the results, however written comments made on the questionnaires may be referred to within the research report.
A summary of the results will be provided to all departments where patients participated from and information will be provided to patients in the Kidney Management Handbook you collect during your time at the Hospital.

Who is funding and organising the study?

The research is being carried out by Claire Leonard, as part of a Clinical Psychology Doctorate being completed at the University of Leicester. The researcher is not being paid to complete the research, however administration costs are covered by the University.

Who has reviewed the study?

All research carried out with NHS patients has to be reviewed by an independent group of individuals known as a Research Ethics Committee to ensure that patients are not a risk, and will be treated fairly and with dignity. The NRES Committee [redacted] – [redacted] Committee have reviewed this study. The study has been given a favourable opinion by this committee before being allowed to approach patients.

What do I do now?

If you have any further queries, please contact the researcher as below. If you have decided that you would like to take part, please complete the following information pack. A copy of the debrief form has been provided for you to keep.

Further Information and Contact Details

Please contact the researcher if you have any other queries.

Claire Leonard
Trainee Clinical Psychologist

Department of Clinical Psychology
University of Leicester

104 Regent Road
Leicester, LE1 7LT
Tel: [redacted]
Email: cll25@le.ac.uk

Thank you for taking the time to read this information.

Appendix H: Demographic collection questionnaire

N.B. For copyright reasons copies of questionnaires are not included

Appendix I: Hospital Anxiety and Depression Scale

N.B. For copyright reasons copies of questionnaires are not included

Appendix J: Short Form 36 Health Survey

N.B. For copyright reasons copies of questionnaires are not included

Appendix K: Body Image Disturbance Questionnaire

N.B. For copyright reasons copies of questionnaires are not included

Appendix L: Derriford Appearance Scale 24

N.B. For copyright reasons copies of questionnaires are not included

Appendix M: Body Shame and Disgust Measure

N.B. For copyright reasons copies of questionnaires are not included

Appendix N: Disgust Scale-Revised

N.B. For copyright reasons copies of questionnaires are not included

Appendix O: Research ethics committee correspondence

NHS
Health Research Authority

NRES Committee East Midlands - Northampton
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839425
Facsimile: 0115 8839294

[redacted]

Dear Miss Leonard,

Study Title:	**An investigation into body shame and disgust-sensitivity in adult dialysis patients; Are these variables predictive of psychological morbidity, body image disturbance and quality of life?**
REC reference:	**12/EM/0094**
Protocol number:	**N/A**

The Research Ethics Committee reviewed the above application at the meeting held on 15 March 2012. Thank you for attending to discuss the study.

Documents reviewed

The documents reviewed at the meeting were:

Document	*Version*	*Date*
Covering Letter		13 February 2012
Interview Schedules/Topic Guides	1	10 February 2012
Investigator CV		10 February 2012
Letter from Sponsor		10 February 2012
Letter from Statistician		10 January 2012
Letter of invitation to participant	1	10 February 2012
Other: Debrief Form for Participants	1	10 February 2012
Other: CV Academic Supervisor- Dr Noelle Robertson		01 June 2011
Other: Letter from Funder		06 February 2012
Participant Information Sheet	1	10 February 2012
Questionnaire: Hospital Anxiety and Depression Scale (HADs)		
Questionnaire: Short Form 36 Health Survey (SF36)		
Questionnaire: Body Image Disturbance Questionnaire (BIDQ)		
Questionnaire: Derriford Appearance Scale 24 (DAS24)		
Questionnaire: Experience of Shame Scale (ESS)		
Questionnaire: Disgust Scale Revised (DS-R)		

Questionnaire: Demographic Questionnaire	1	10 February 2012
REC application	3.4	13 February 2012
Referees or other scientific critique report		31 January 2012
Summary/Synopsis		05 January 2012

Provisional opinion

- The committee felt that the wording in the Participant Information Sheet could potentially trigger negative thoughts as to how participants portray dialysis. You confirmed that this would be amended.
- The committee felt that the prize draw was an incentive and therefore you should consider retracting this as it may create problems with regards to keeping participants personal data. You stated that they would consider this.
- The committee asked the researcher whether the term 'disgust sensitivity' could be changed to be less direct towards participants. You confirmed that they had considered changing the terminology but could not come up with anything less direct.
- The committee stated that under the heading 'Do I have to take part?' in the Participant Information Sheet it should be made explicit that their participation in the study will not affect their normal care.
- The committee agreed that there are several points that need amending in the Participant Information Sheet, e.g. the inclusion of the complaints procedure, the committee recommend PALS, it was made clear that these would be clarified in the decision letter.
- The committee asked you whether all the questionnaires where validated, the Americanisms would need translating to be UK specific. You confirmed that the questionnaires are validated apart from the Demographic Questionnaire, and that a list of translations will be provided.
- The committee pointed out that there are inconsistencies between the information given in the Participant Information Sheet and the Application Form as to how long data will be kept. You confirmed that this would be clarified.

The Committee is unable to give an ethical opinion on the basis of the information and documentation received so far. Before confirming its opinion, the Committee requests that you provide the further information set out below.

The Committee delegated authority to confirm its final opinion on the application to the Chair.

Further information or clarification required

1. The following changes/amendments are required to the Participant Information Sheet:
   a) It should include 'NRES Committee East Midlands – Northampton Committee' has reviewed the study'
   b) The process of completing the questionnaire should be made more explicit
   c) Under the heading 'Do I have to take part?' it should be included that participant's normal care will not be affected
   d) It should be made explicit how long participant's data will be kept for

e) Under the heading 'Why have I been invited?' the sentence 'you do not need to take part' should be 'you cannot take part'

f) An independent contact should be included such as PALS

2. The prize draw should be considered to not be given as this would require retaining participant's personal data.

3. A list of translations to be UK specific should be provided.

If you would find it helpful to discuss any of the matters raised above or seek further clarification from the Committee Co-ordinator, you are welcome to contact Miss Jessica Parfrement on 0115 8839425 .

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 24 July 2012.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

12/EM/0094	**Please quote this number on all correspondence**

Yours sincerely

pp [redacted]

Mr Ken Willis
Chair

Email: jessica.parfrement@nottspct.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments.*

Copy to: *Sponsor – LPT*

R&D Contact – UHL

NRES Committee East Midlands - Northampton

Attendance at Committee meeting on 15 March 2012

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr [redacted]	Senior Lecturer in Nursing	Yes	
Dr [redacted]	Consultant Anaesthetist	Yes	
Ms [redacted]	Clinical Trial Manager	Yes	
Mr [redacted]	Industrial Pharmacy Consultant and Locum Pharmacist	Yes	
Mr [redacted]	Lay Member	Yes	
Mrs [redacted]	Research Technician	Yes	
Mrs [redacted]	Lay Member	Yes	
Mr [redacted]	Lay Member	Yes	
Mr [redacted]	Medical Devices Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mis [redacted]	Assistant Committee Co-ordinator
Mis [redacted]	Co-ordinator

University of Leicester

12th July 2012

School of Psychology
Doctorate in Clinical Psychology
104 Regent Road
Leicester LE1 7LT
UK

T +44 (0)116 223 1639
F +44 (0)116 223 1650

FAO Mr Ken Willis
REC Chair
NRES Committee East Midlands - Northampton
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Dear Mr Willis,

Study Title: **An investigation into body shame and disgust-sensitivity in adult dialysis patients; Are these variables predictive of psychological morbidity, body image disturbance and quality of life?**

REC Reference: **12/EM/0094**

Re: **Response to your letter dated 26th March 2012**

Please find enclosed hard copies of revised documentation regarding the above named application to the Research Ethics Committee.

Amendments are as follows:

- Patient Information Sheet (PIS)
  The PIS now includes that NRES Committee East Midlands – Northampton Committee has reviewed the study.
  The process of completing the questionnaires has been made more explicit with the addition of separate instructions for completing questionnaires.
  The heading "Do I have to take part?" now more explicitly explains that normal care will not be affected in any way.
  The PIS now includes how long patient data will be stored for and where.
  Information under the heading "Why have I been invited" has been updated from 'you do not need to take part' to 'you cannot take part' as requested.
  An independent contact (PALS) is now included.
- Prize draw
  This has been retained following advice from medical professionals in the renal field. There is a concern that if an incentive is not offered, the uptake of the

study may be lower, and therefore may result in too small a sample size to make meaningful conclusions, in effect reducing the power of the study to make a sufficient impact in the renal field. Patients are asked only to provide their contact details if they wish to take part in the study and it is felt that patients are able to make a free choice about whether to provide that information or not. The details supplied by patients are confidential, and stored according to Information Governance guidelines as per University Hospitals of Leicester NHS Trust.

- A list of UK translations is provided for the "Americanisms" in the questionnaires.

I have highlighted the specific changes made to the Patient information sheet for your information.

The details of the enclosures are as follows:

Document Name	Copies
Patient Information Sheet (v2)	1
Guidance for completing questionnaires (v1)	1
List of UK translations (v1)	1

Please do not hesitate to contact me with any other queries.

Yours sincerely,

Claire Leonard
Trainee Clinical Psychologist/Chief Investigator
Email: c[redacted]
Mobile:[redacted]

Re issue letter including protocol 22.11.2012

NHS
Health Research Authority

NRES Committee East Midlands - Northampton
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839435
Facsimile: 0115 8839294

[redacted]

Dear Miss Leonard

Study title:	**An investigation into body shame and disgust-sensitivity in adult dialysis patients; Are these variables predictive of psychological morbidity, body image disturbance and quality of life?**
REC reference:	**12/EM/0094**
Protocol number:	**N/A**

Thank you for your letter of 12 July 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		13 February 2012
Interview Schedules/Topic Guides	1	10 February 2012
Investigator CV		10 February 2012
Letter from Sponsor		10 February 2012
Letter from Statistician		10 January 2012
Letter of invitation to participant	1	10 February 2012
Other: Debrief Form for Participants	1	10 February 2012
Other: CV Academic Supervisor- Dr Noelle Robertson		01 June 2011
Other: Letter from Funder		06 February 2012
Other: Guidance for completing questionnaires	1	12 July 2012
Other: List of UK Translations	1	12 July 2012
Participant Information Sheet	2	12 July 2012
Questionnaire: Hospital Anxiety and Depression Scale (HADs)		
Questionnaire: Short Form 36 Health Survey (SF36)		
Questionnaire: Body Image Disturbance Questionnaire (BIDQ)		
Questionnaire: Derriford Appearance Scale 24 (DAS24)		
Questionnaire: Experience of Shame Scale (ESS)		
Questionnaire: Disgust Scale Revised (DS-R)		
Questionnaire: Demographic Questionnaire	1	10 February 2012
REC application	3.4	13 February 2012
Referees or other scientific critique report		31 January 2012
Response to Request for Further Information		12 July 2012
Summary/Synopsis		05 January 2012
Protocol	4	21 December 2011

Re issue letter including protocol 22.11.2012

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

12/EM/0094	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Mr Ken Willis
Chair

Email: georgia.copeland@nottspct.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mr David Clarke*

Ms Carolyn Maloney, University Hospitals Leicester NHS Trust

Appendix P: Results of tests of normality for each measure

Descriptives					
				Statistic	Std. Error
	HADSOverallTotal	Mean		14.84	1.23
		95% Confidence Interval for Mean	Lower Bound	12.36	
			Upper Bound	17.31	
		5% Trimmed Mean		14.74	
		Median		15.00	
		Variance		83.62	
		Std. Deviation		9.14	
		Minimum		0.00	
		Maximum		32.00	
		Range		32.00	
		Interquartile Range		17.00	
		Skewness		0.01	0.32
		Kurtosis		-1.10	0.63
	HADSAnxietyOriginal	Mean		7.69	0.67
		95% Confidence Interval for Mean	Lower Bound	6.35	
			Upper Bound	9.03	
		5% Trimmed Mean		7.67	
		Median		8.00	
		Variance		24.48	
		Std. Deviation		4.95	
		Minimum		0.00	
		Maximum		17.00	
		Range		17.00	
		Interquartile Range		9.00	
		Skewness		-0.11	0.32
		Kurtosis		-1.20	0.63
	HADSDepressionOriginal	Mean		7.15	0.65
		95% Confidence Interval for Mean	Lower Bound	5.84	
			Upper Bound	8.45	
		5% Trimmed Mean		7.05	
		Median		7.00	
		Variance		23.39	
		Std. Deviation		4.84	

		Minimum	0.00	
		Maximum	17.00	
		Range	17.00	
		Interquartile Range	9.00	
		Skewness	0.25	0.32
		Kurtosis	-1.05	0.63
	DAS24Total	Mean	42.84	2.45
		95% Confidence Interval for Mean — Lower Bound	37.92	
		95% Confidence Interval for Mean — Upper Bound	47.75	
		5% Trimmed Mean	42.17	
		Median	40.00	
		Variance	330.40	
		Std. Deviation	18.18	
		Minimum	15.00	
		Maximum	82.00	
		Range	67.00	
		Interquartile Range	33.00	
		Skewness	0.43	0.32
		Kurtosis	-0.86	0.63
	ESSBodyShame	Mean	9.00	0.58
		95% Confidence Interval for Mean — Lower Bound	7.84	
		95% Confidence Interval for Mean — Upper Bound	10.16	
		5% Trimmed Mean	8.89	
		Median	8.00	
		Variance	18.33	
		Std. Deviation	4.28	
		Minimum	4.00	
		Maximum	16.00	
		Range	12.00	
		Interquartile Range	9.00	
		Skewness	0.38	0.32
		Kurtosis	-1.33	0.63
	ESSBodyDisgust	Mean	7.44	0.54
		95% Confidence Interval for Mean — Lower Bound	6.35	
		95% Confidence Interval for Mean — Upper Bound	8.53	
		5% Trimmed Mean	7.15	
		Median	6.00	

		Variance	16.29	
		Std. Deviation	4.04	
		Minimum	4.00	
		Maximum	16.00	
		Range	12.00	
		Interquartile Range	7.00	
		Skewness	0.91	0.32
		Kurtosis	-0.63	0.63
	ESSTotal	Mean	16.44	1.09
		95% Confidence Interval for Mean — Lower Bound	14.26	
		95% Confidence Interval for Mean — Upper Bound	18.61	
		5% Trimmed Mean	16.07	
		Median	13.00	
		Variance	64.92	
		Std. Deviation	8.06	
		Minimum	8.00	
		Maximum	32.00	
		Range	24.00	
		Interquartile Range	13.00	
		Skewness	0.63	0.32
		Kurtosis	-1.08	0.63
	Physical Component Score	Mean	35.23	1.33
		95% Confidence Interval for Mean — Lower Bound	32.58	
		95% Confidence Interval for Mean — Upper Bound	37.89	
		5% Trimmed Mean	34.87	
		Median	34.09	
		Variance	96.63	
		Std. Deviation	9.83	
		Minimum	18.00	
		Maximum	56.86	
		Range	38.86	
		Interquartile Range	14.09	
		Skewness	0.62	0.32
		Kurtosis	-0.35	0.63
	Mental Component Score	Mean	44.11	1.52
		95% Confidence Interval for Mean — Lower Bound	41.07	
		95% Confidence Interval for Mean — Upper Bound	47.15	

		5% Trimmed Mean	44.18	
		Median	43.07	
		Variance	126.31	
		Std. Deviation	11.24	
		Minimum	21.99	
		Maximum	64.61	
		Range	42.62	
		Interquartile Range	17.91	
		Skewness	-0.05	0.32
		Kurtosis	-0.97	0.63
	DSRSumTotal	Mean	54.96	2.46
		95% Confidence Interval for Mean — Lower Bound	50.03	
		95% Confidence Interval for Mean — Upper Bound	59.90	
		5% Trimmed Mean	55.42	
		Median	56.00	
		Variance	332.96	
		Std. Deviation	18.25	
		Minimum	5.00	
		Maximum	86.00	
		Range	81.00	
		Interquartile Range	25.00	
		Skewness	-0.43	0.32
		Kurtosis	-0.21	0.63
	DSRSumCore	Mean	29.31	1.25
		95% Confidence Interval for Mean — Lower Bound	26.79	
		95% Confidence Interval for Mean — Upper Bound	31.82	
		5% Trimmed Mean	29.80	
		Median	31.00	
		Variance	86.59	
		Std. Deviation	9.31	
		Minimum	2.00	
		Maximum	43.00	
		Range	41.00	
		Interquartile Range	13.00	
		Skewness	-0.75	0.32
		Kurtosis	0.17	0.63
	DSRSumAnimalRemainder	Mean	16.29	1.02
		95% Confidence Interval for Mean — Lower Bound	14.24	

		Interval for Mean	Upper Bound	18.34	
		5% Trimmed Mean		16.39	
		Median		17.00	
		Variance		57.28	
		Std. Deviation		7.57	
		Minimum		0.00	
		Maximum		30.00	
		Range		30.00	
		Interquartile Range		12.00	
		Skewness		-0.24	0.32
		Kurtosis		-0.92	0.63
	DSRSumContamination	Mean		9.36	0.61
		95% Confidence Interval for Mean	Lower Bound	8.14	
			Upper Bound	10.59	
		5% Trimmed Mean		9.33	
		Median		9.00	
		Variance		20.61	
		Std. Deviation		4.54	
		Minimum		0.00	
		Maximum		19.00	
		Range		19.00	
		Interquartile Range		6.00	
		Skewness		0.12	0.32
		Kurtosis		-0.21	0.63
	BIDQTotal	Mean		2.32	0.13
		95% Confidence Interval for Mean	Lower Bound	2.05	
			Upper Bound	2.58	
		5% Trimmed Mean		2.29	
		Median		2.14	
		Variance		0.96	
		Std. Deviation		0.98	
		Minimum		1.00	
		Maximum		4.29	
		Range		3.29	
		Interquartile Range		1.71	
		Skewness		0.25	0.32
		Kurtosis		-1.12	0.63