The application of the Pre-operative Intrusive Thoughts Inventory (Crockett et al. 2007) in an elective hernia repair surgery population

& Clinical Research portfolio

Part One (Part Two bound separately)

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*Appendix 2.10 and 2.11 has been removed due to Copyright restrictions.

Chapter 1: Systematic Literature Review

Is there an association between social support and symptoms of anxiety or depression within a cardiac surgery population?

Running title – "*social support in cardiac surgery*"

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Prepared in accordance with guidelines for submission to Psychosomatic Medicine (See Appendix 1.1)

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Is there an association between social support and symptoms of anxiety or depression within a cardiac surgery population?

Running title – "*social support in cardiac surgery*"

Ms Salma Iqbal & Professor Keith Millar

Abstract

Objective: A review of evidence for the benefit of social support across a range of cardiac surgical populations was conducted. **Methods:** A computerised search of major health care databases between the years 1980-2008 was completed. Criteria assessing methodological quality were applied using a specifically designed checklist. Twelve studies met review inclusion criteria. **Results:** Evidence for an inverse relationship between social support, anxiety and depression was found in six papers. A further six studies found no relationship but the validity of their results was questioned due to conceptual and methodological failings. **Conclusions:** Prospective studies of good methodological quality provide evidence for a positive association between higher levels of social support and better psychological functioning pre- and post-surgery. There is scope for methodological improvement in this field given that the negative results of six studies can be ascribed to methodological short-comings. Further research is required to provide evidence that can be used to identify those at risk of developing pre-and post-surgical psychological distress. **Key words:** social, support, anxiety, depression, cardiac and surgery.

OHT = Orthotopic heart transplantation; RCT = Randomised, Controlled Trial; CABG = coronary bypass graft surgery; STAI = State Trait Anxiety Inventory; CES-D = Centre for Epidemiological Studies Depression Scale; ACE = Angiotensin Converting Enzyme; MOS = Medical Outcomes Study; DASS = Depression and Anxiety Stress Scales; PSSS = Perceived social support scale; ENRICHD = Enhancing Recovery in Coronary Heart Disease; BDI = Beck Depression Inventory; PRQ = Personal Resource Questionnaire; QLI = Quality of Life Index; PAIS = Psychosocial Adjustment to Illness Scale; WCCL = Ways of Coping Checklist; POMS = Profile of Mood States; GHQ = General Health Questionnaire; BSA = body surface area

Introduction

Definitions of social support

The purpose of the present review is to summarise evidence for the benefit of social support in reducing anxiety or depression within those undergoing cardiac surgery. An understanding of social support has generated debate across disciplines yet a sole definition has not been agreed.

Cohen and Wills (1) propose four functional categories of support, namely esteem (emotional) support, informational support, social companionship and instrumental support (provision of practical assistance). Social support is likely to involve multiple functions operating simultaneously (1). Social companionship may provide instrumental and emotional support. Each functional support category may have greater salience depending upon the situation. The effectiveness of functional support is increased when there is a match between the stressor and type of support required (1).

A review of social support and coronary heart disease commented upon the lack of consensus across definitions (2). Shumaker and Brownell (3) define social support as "an exchange of resources between at least two persons, aimed at increasing the well-being of the receiver" (pp.11). This makes reference to structural (exchange of resources) and functional aspects of support (e.g. emotional support leading to improvement of well being). This definition incorporates current conceptualisations

of social support; therefore it will be considered the operational definition of social support for the purposes of the present review.

Theoretical models of social support

Uchino (4) distinguishes between stress-related and direct effect models. Of the various stress-related models, the "buffering hypothesis" proposes that social support serves a protective function at a cognitive or physiological level. Upon actual or potential occurrence of a stressful event, an appraisal process is activated. Information generating a stress response is examined against coping mechanisms, such as availability of actual or perceived social support, leading to a reduction or prevention of stress responses (1,4).

Uchino (4) criticises the "buffering hypothesis" stating that measures of social support have not always supported the described effect. The buffering hypothesis refers to the positive effects of social support. However, social support can lead to an exacerbation of perceived or actual stress in the case of inappropriate support resources (lack of matching between stressor and support function).

The "direct or main effect" model suggests social support is of benefit regardless of whether a person is under stress. Roles and expectations within a social network membership have the potential to provide opportunities that are positive. Such affective experiences allow predictability to develop and enhance self concepts (1). By being embedded within a social network, individuals will be able to access

health-appropriate information relevant to the stressor in question (5). This could influence actions at a behavioural or cognitive level, leading to an effect upon health status. Despite evidence to suggest the benefits of membership of a social network, Hughes and Gove (6) propose the likelihood of social networks causing emotional distress. For example, Helgeson et al. (7) examined health behaviour among men with prostate cancer and found that social control exhibited by wives did not lead to health-related benefits and was associated with physiological distress.

Social support, surgery and psychological outcome

Krohne and Slangen (8) examined the influence of social support on adaptation to surgery. Both emotional and informational social support predicted pre-operative anxiety such that patients who reported high informational support had lower anxiety. Emotional support was found to be predictive of lower anxiety across all phases of the study for women only. Makabe and Nomizu (9) found higher scores in social reciprocity (perceived access to emotional resources) were correlated with better psychological states pre-surgery. Both studies provide evidence to suggest the benefits of social support on psychological adjustment to surgery.

Previous systematic reviews examining social support and physical or psychological outcomes

In a review on psychosocial factors and surgical outcomes, social support was found to be influential on long-term surgical outcome. Surgical outcome was determined by physical health status and post-operative psychological functioning was not

considered within the review. Furthermore, Rosenberger et al. (10) did not detail the strengths and limitations of the methodology of the selected studies.

Mookadam and Arthur (11) reviewed evidence regarding the role of social support in cardiovascular disease outcomes. Social isolation was associated with increased mortality and morbidity, independent of age, gender, past medical history and health behaviours. The review found that the presence and acquired benefit of a social support network is protective against depressive symptomology.

Duits et al. (12) reviewed studies predicting psychological outcome after coronary bypass graft surgery (CABG). High pre-operative anxiety or depression were predictive of poor functioning after CABG and there was benefit from hospital support in emotional and behavioural adjustment to CABG. Of most significance was that social support was predictive of a reduction in anxiety and depression post-surgery.

Rationale for present systematic review

Rosenberger et al. (10) report that there is a need to determine what factors may modify post-surgical adjustment. Whilst physical health factors are of importance, psychosocial factors (such as social support) may contribute to adaptation after surgery. A review which summarises evidence for the role of social support on anxiety or depression has not been previously conducted.

Whilst Duits and colleagues reviewed psychological outcome after CABG, it is intended that additional cardiac surgeries will be included. The present review will consider all papers published in the last 28 years, expanding the date parameters used in the review conducted by Duits et al. (12). Having considered the current literature and identified gaps in research to date, a systematic review of the literature from the years 1980-2008 examining evidence for the association of social support with symptoms of anxiety or depression within a cardiac population is warranted.

Method

Objective

The present systematic review will summarise the literature and aim to answer the following questions through exploration of the methodological rigour of the studies retrieved:

- What is the evidence for the association between social support and symptoms of anxiety or depression pre- and post-cardiac surgery?

Lett et al. (2) recommended that future research should consider what factors moderate social support. Supplementary questions to be addressed include:

- Does age moderate the effect of social support?
- Does gender moderate the effect of social support?
- Does socioeconomic status (defined by either employment status or years of education completed) moderate the effect of social support?
- Does marital status moderate the effect of social support?

Search strategy

The following electronic databases were searched using the identified search terms.

- All Evidence Based Medicine (EBM) reviews (ACP Journal club, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects).
- CINAHL (1980 to week 1 December 2007)
- EMBASE (1980 to week 04 2008)
- Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) (1980 to Present)
- PsycINFO (1980 to January Week 2 2008)

Search terms

The electronic search used six key terms to reflect the main aim of the review. Search terms were also combined to increase search sensitivity.

1. Social support
2. Social isolation
3. Social network
4. Anxiety
5. Depression
6. Surg* (truncation used to increase search sensitivity)
7. 1 and 4
8. 1 and 5
9. 2 and 4

10. 2 and 5

11. 3 and 4

12. 3 and 5

13. 7 and 6

14. 8 and 6

15. 9 and 6

16. 10 and 6

17. 11 and 6

18. 12 and 6

19. 13 or 14

20. 15 or 16

21. 17 or 18

22. 19 or 20 or 21

Experts in the field (Professor S Cohen, Carnegie Mellon University; Professor B Uchino, University of Utah and Ms M Oxlad, The Flinders University of South Australia) were contacted to obtain details of any other studies. No further articles were identified. Hand searching of key journals (British Journal of Health Psychology, Journal of Psychosomatic Research and Psychosomatic Medicine), did not yield any further results. Relevant articles were accessed by the NHS electronic library. Unavailable articles were obtained through the British Library Document Service.

Selection criteria

Inclusion Criteria

- Studies that investigate social support within a cardiac population.
- Design is prospective with a pre- and post-surgical or pre- and post-intervention comparison.
- The study samples an adult population (over 18 years of age).
- Study samples those undergoing non emergency cardiac procedures.
- Measure of social support detailed as predictor variable.
- Measures of anxiety or depression detailed as outcome variable.
- Standardised and reliable psychological assessments used to assess and quantify social support and anxiety or depression.
- Studies published in a peer-reviewed journal article.

Exclusion Criteria

- Studies that only focus on social support as a predictor of physical outcome variables.
- Study design is not prospective.
- Study is not published in English.
- Single case studies, dissertations or qualitative studies.
- Sample age is less than 18 years old.
- Surgical procedure is not cardiac, heart or coronary related.

Results

Outcome of Search Process

The electronic search returned a total of 510 articles of which 445 were immediately excluded. Table 1 illustrates reasons for exclusion of articles on the basis of examination of the title and abstract only.

[Insert Table 1. here]

The 65 remaining articles were then subjected to secondary searching specifically to identify articles that made reference to either "cardiac", "heart" or "coronary" surgery. A total of 24 studies were selected and retrieved.

Eleven articles fulfilled all of the review inclusion criteria. Hand searching of the reference lists of these articles, identified one further study that was not generated by the electronic search and met review inclusion criteria. Therefore, 12 studies were identified for review.

Characteristics of Excluded Papers

Upon retrieval of the full text article, a total of 13 studies were excluded. Five studies did not use standardised measures of social support (13-17) and four studies did not use social support as a predictor (18-21). Two studies did not examine anxiety or depression (22,23). One study did not use an exclusively surgical

population (24). One study used a prospective design but asked participants to recall their pre-surgical functioning when interviewed post-surgery (25).

Sample characteristics

The twelve studies included in the review ranged in sample size from 22 to 343 participants. Ten studies included male and female participants. Ten studies looked at CABG surgery only. Other procedures included valve replacement or repair and orthotopic heart transplantation (OHT). OHT is a standard method of heart transplantation surgery whereby removal of the recipient's failing heart and atria occurs and then the donor heart is attached. Two studies reported power calculations to determine sample size. All studies used sampling of convenience to recruit participants.

Assessment of methodological quality

A quality rating scale was developed based on checklists published for randomised, controlled trial (RCT) and non RCT studies (see appendix 1.2) (26-28). In a validation study, Cho and Bero (28) reported a mean quality score of 0.60 (SD = 0.13, range 0.36-0.74). Downs and Black (27) reported high scores on both inter-rater and test-retest reliability (r = 0.75 and r = 0.88 respectively). The quality rating scale checklist questions were answered using a "yes" (score 2), "partially addressed" (score 1), "no/not addressed" (score 0) and "not applicable" (question omitted from totals). Points were also allocated dependent upon the design of the study. One point was awarded for case reports, two points for time series or

uncontrolled designs, three points for cohort or case-control studies, four points for unrandomised controlled trials and five for randomised controlled trials (28).

All studies were scored on 28 factors of methodological quality. Study ratings were assigned by the total points awarded divided by the total possible points (sum of maximum points for each item, except for "not applicable" items) to generate a fraction between 0 and 1. A score of 1 represents a study of the highest quality. A score of 0.75 and above defined a study as "high quality" (rated A). Ratings of 0.60-0.74 were considered to be of "moderate quality" (rated B). Scores of 0.50 and 0.59 were "low quality" (rated C). Studies rated of less than or equal to 0.49 were "poor quality" (rated D).

Data extraction

Data were extracted in respect to the checklist and aims of the review. Table 2 summarises data extracted from reviewed studies.

[Insert Table 2. here]

Methodological quality varied from high to low quality studies (A-C). Four studies met criteria for an A quality rating (29-32). Six studies met criteria for a B quality rating (33-38) and two studies met criteria for a C quality rating (39,40).

Reliability of quality rating

Quality rating of studies was also conducted by an independent reviewer. Agreement between raters was >95%. Discrepancies in ratings were resolved by the author and independent rater meeting to discuss and review disagreements.

Review of Findings

Studies will be reviewed in order of quality rating and in reference to the main and supplementary review questions. Table 2 provides details of study design, methodology, sample size, outcome measures, analyses used and limitations.

Relationship between social support and anxiety

Three papers found a significant association between social support and anxiety.

Oxlad and Wade (31) [*high quality*] conducted a prospective study examining risk factors for poor psychological functioning pre- and post-CABG. Higher anxiety at six months post-surgery was predicted by lower social support pre- and up to three months post-surgery ($p<0.05$). The generalisability of the results is limited to those with relatively better physical health status. Attrition data revealed that those who dropped out had significantly poorer physical health status including diabetes and hypertension (both $p<0.05$).

Okkonen and Vanhanen (35) [*moderate quality*] evaluated the relationship between family support and subjective health pre- and six months post-CABG. Participants

with low family support reported significantly more symptoms of anxiety pre- and post-CABG ($P = 0.031$ and $P = 0.016$ respectively). Participants were grouped into low or high support, but cut offs were not specified. It cannot be determined whether groups are representative of differences in social support. The external validity of this study is compromised by the use of a measure of social support that has only been validated within a Finnish population.

Burker et al. (37) [*moderate quality*] assessed the prevalence of depression in patients awaiting CABG and/or heart valve repair. Within the pre-surgery phase, those who were above the clinical cut off for depression (score of ≥16 on Centre for Epidemiological Studies Depression Scale (CES-D)) had higher state and trait anxiety (both $p<0.0001$) and lower perceived social support ($p<0.01$). Anxiety decreased pre- to post-surgery whilst depression increased across time. The authors hypothesise that different psychological needs across time reflected variation in psychological status pre- and post-surgery. However, this assertion was not tested in the analysis.

Relationship between social support and depression

Five papers found a negative association between social support and depression.

Bishop et al. (30) [*high quality*] conducted a RCT in male CABG patients. Participants were allocated to either a psychosocial skills training group or an information-only session. Post-intervention analyses revealed significant reduction

in depression ($p<0.05$) and a significant increase in satisfaction with social support ($p<0.01$) compared to control. This suggests a benefit of psychosocial skills intervention albeit only in males. The authors do acknowledge limitation in their study, but explain insufficient female participants were available.

Oxlad and Wade (31) [*high quality*: see above for more detailed review], found that increased depression six months post-CABG was predicted by lower social support three months post-CABG ($p = 0.03$).

Oxman and Hull (33) [*moderate quality*] conducted a prospective study to assess the association between social support and emotional outcome in patients awaiting CABG and/or aortic valve replacement. Greater perceived adequacy of social support was associated with lower scores of depression pre- and post-surgery (both $p\leq0.01$). Contact with a greater number of close social network members was also related to lower scores of depression pre- and post-surgery (all $p<0.05$). Analysis of attrition data revealed that this sample had significantly more impairment of activities of daily living and lower perceived adequacy of social support when assessed pre-surgery.

Okkonen and Vanhanen (35) [*moderate quality*] found that pre- and post-surgery more symptoms of depression were reported in the low social support group ($P = 0.008$ and $p<0.01$). Participants living alone reported significantly higher depressive symptoms pre- and post-surgery ($P = 0.021$ and $P = 0.045$ respectively). Measures

of family support were only completed by those individuals who were living with someone; therefore comparability of social support with those living alone is problematic. This bias in measurement was not accounted for in the statistical analyses.

Burker et al. (37) [*moderate quality*] found that significant predictors of pre-surgery depression included gender, state and trait anxiety and social support (model R^2 = 0.51, p <0.0001). Less social support was found to be independently associated with higher levels of depression (p<0.001). At post-surgery, perception of low and high social support did not differentiate between depressed and non-depressed participants. Therefore, social support was found to be related to pre-surgery levels of social support, but this association was not found to be maintained post-surgery.

Moderating variables – age, gender, socioeconomic status and marital status

Five papers employed statistical analyses designed to investigate the influence of covariates (age, gender, socioeconomic and marital status). However, none of the five papers made all four comparisons. A sixth paper has been included within this section but it was unable to examine gender differences due to an unequal male and female distribution (85% male, 15% female).

Bute et al. (32) [*high quality*] examined gender differences at pre- and one year post-CABG. Female participants had lower scores in social support and higher anxiety and depression scores (both p<0.001). Covariates were identified at baseline

reflecting gender differences (see Table 2). When covariates were entered into analyses, gender differences were no longer evident for social support ($p = 0.69$) and depression ($p = 0.29$), but they did remain for anxiety ($p = 0.03$). This suggests that post-operative differences are not explained by baseline variation across gender for depression and social support.

Oxman and Hull (33) [*moderate quality*] found that age was significantly related to less depression at six months post surgery ($p<0.05$). When age was controlled for the association remained significant suggesting that age does not account for this relationship.

Okkonen and Vanhanen (35) [*moderate quality*] found the relationship between family support and pre-surgery depression remained significant despite controlling for gender, age (both $p<0.05$) and education ($p<0.001$). The same was found for the post-surgery phase (all $p<0.001$). Comparisons between living alone and pre-surgery depression also remained statistically significant when the same covariates were examined (all $p<0.05$). The relationship between living alone and post-surgery depression remained significant after controlling for age only ($P = 0.027$). This suggests that gender and education may moderate the relationship between living alone and post-surgery depression. Neither gender nor education was associated with family support and pre-surgery anxiety ($P<0.05$ and $P = 0.011$ respectively). The relationship between family support and pre-surgery anxiety was weakened when adjusted for age ($P = 0.052$). Analyses of family support and post-surgery

anxiety revealed comparable findings with pre-surgery results in that the relationship remained significant after adjusting for gender and education ($P = 0.014$ and $P = 0.002$).

Mitchell et al. (34) [*moderate quality*] examined gender differences in depression one month pre- and 6-12 weeks post-surgery. In the pre-surgery phase, more women than men met criteria for mild depression and major depressive disorder (both $p<0.01$). Social support, education and physical health risk status were entered as covariates and these did not explain the association between gender and depressive symptomology. This suggests that gender can explain differences between pre- and post-surgery depression status. This was the only study to examine the relationship between social support and marital status. Within the post-surgery phase, women reported higher levels of social support ($P = 0.04$) and yet were less likely to be married and of a lower socio-economic status. The authors postulate that marital status may be related to depressive symptomology although this relationship between marital status and depression was not explicitly examined.

Keresztes et al. (36) [*moderate quality*] employed a prospective design to assess gender differences across physical, social and psychological functioning pre- and post-CABG. Participants were matched on body surface area (BSA) (within $0.1m^2$) and age (within 5 years). No significant differences across gender and time on the Personal Resource Questionnaire (PRQ – emotional support measure) were found. No differences were found across gender for measures of anxiety as assessed by the

Profile of Mood States tension/anxiety subscale. Female participants were found to have higher pre-operative depression scores than men. Once pre-operative differences in depression were controlled for, no significant differences were found in the post-operative period across gender. Women reported lower levels of social support on the Quality of Life Index (QLI) ($p<0.01$). Unlike the QLI, the reliability of the PRQ has not been demonstrated within a cardiac population; therefore the sensitivity of this measure is questioned. The authors also state that since only one measure of social support showed significance, no conclusions can be drawn about the possible impact of social support on anxiety and depression levels across gender. In order to match participants, the mean BSA for women was greater than what would be expected in the population, therefore limiting the generalisability of the findings.

Langeluddecke et al. (38) [*moderate quality*] compared psychological and psychosocial impairment pre- and post-CABG. Significant improvements were found pre- to post-surgery (6 and 12 months, $p<0.01$) on the social functioning subscale of the Psychological Adjustment to Illness Scale (PAIS). Depression and anxiety were both significantly reduced at 6 and 12 months post-surgery (both $p<0.001$). No analyses were conducted to compare a possible association between social support and anxiety or depression. The measure of social functioning was not specifically designed to measure the construct of social support; therefore its specificity is questioned. Due to a low number of female participants, analyses by gender could not be conducted.

Lack of evidence for relationship between social support and anxiety or depression

Three papers found no evidence for, or did not investigate, the relationship between social support and anxiety or depression.

Arthur et al. (29) [*high quality*] conducted a RCT examining effects of an exercise training intervention versus a "usual care" group. Assessments were completed pre- and post- surgery across four time points (see table 2). The eight week intervention was conducted in the pre-operative phase. Following the end of the intervention program, no significant changes were found in state anxiety in both control or exercise groups when assessed pre-surgery. Pre-surgery scores of social support were relatively similar and within the normal limits for this measure of anxiety. Participants within the intervention group did report more support six months post-surgery ($P = 0.002$).

This study found differences in social support only within the post-surgery phase and did not report any significant changes in anxiety scores across the duration of the study in either the control or intervention groups. The authors hypothesise that mean scores of anxiety in both groups did not indicate clinically significant distress in relation to published norms of the STAI. This study scored the highest number of points within the present review for its quality, demonstrating its methodological rigour, with adequate attention paid to methods of randomisation, use of power calculations and the inclusion of a valid control group. The predicted effect of the intervention was not found in the immediate post-intervention stage (pre-surgery

phase). Exercise may have been perceived to be a source of support after surgery only for participants who maintained their exercise regimens post-surgery. This may explain the significant differences across intervention and control groups found only in the post-surgery phase.

Triffaux et al. (39) [*low quality*] used a prospective design to examine psychological functioning in patients undergoing OHT. Across the duration of the study, there was a 41% attrition rate. Significant decreases in depression (p = 0.008), state (p = 0.0007) and trait (p = 0.01) anxiety scores were found between pre- and 1 month post-OHT, however no significant differences were found between 1 to 6-months post-OHT. No analyses were conducted on attrition data to determine whether their sample characteristics significantly differed. The sample size was small and was further reduced by the moderate attrition rate, thereby greatly reducing the statistical power of the study. Triffaux et al. (39) provide evidence of improvements in psychological functioning pre- and post-OHT, however no significant changes were found in long-term social support functioning.

Crumlish (40) [*low quality*] examined changes in coping and emotional functioning in women undergoing cardiac surgery. No significant changes across time were found on the "seeks support" subscale of the revised Ways of Coping Checklist (WCCL). Significant decreases from pre- to post-surgery were found on the tension/anxiety subscale of the Profile of Mood States (POMS) (p<0.01). Furthermore, pre-operative depression was found to be significantly correlated with

post-operative depression (r = 1.00, p<0.001). Crumlish (40) does question the specificity of this measure, and generalisability of study findings are limited by both sample size and the use of only female participants.

Discussion

The present review aimed to evaluate evidence for the benefit of social support in association with levels of anxiety or depression amongst those undergoing cardiac surgery. Five studies found evidence for an association between higher levels of social support and lower levels of anxiety or depression. A further study by Bute et al. (32) also found an association between social support, anxiety and depression once gender differences were controlled for. All six studies were of either high or moderate methodological quality, with adequate attention given to aspects of study design, methodology, analysis and consideration of implications of research findings. All of these studies were able to employ statistical analyses to examine associations of social support and psychological functioning over time from pre- to post-surgery.

Six papers did not report an association between social support and anxiety or depression. Keresztes et al. (36) considered the relationship between social support and psychological functioning but were unable to conduct such analyses due to the reliability and validity of the measure of social support used. The use of the Personal Resource Questionnaire used within the study the study by Keresztes and colleagues has not previously been validated within a cardiac population. Mitchell

et al. (34) did examine the relationship between social support, gender and depression but found no evidence that social support influenced the relationship between gender and depression.

A further four papers, despite meeting review inclusion criteria did not explicitly examine the relationship between social support, anxiety or depression (29, 38, 39 and 40). Reasons for the lack of such analyses varied. In studies by Langeluddecke et al. (38), Crumlish (40), the specificity of social support measures were questioned in relation to use within a cardiac population. Triffaux et al. (39) reported no changes in social support functioning across time but their analysis was limited by low statistical power. Furthermore, the non-significant results found across measures of social support precluded further analysis of predictors of psychological functioning that could otherwise have been conducted with the prospective design employed by Triffaux and colleagues. Similarly, Arthur et al. (29) did not conduct analyses of the association between social support and anxiety, because of the lack of clinically significant anxiety and minimal differences in social support pre-surgery.

Lack of association between measures of social support and levels of anxiety or depression may be related to the distribution of scores on measures of psychological functioning. Studies that did not find associations across these variables often reported scores within the lower range of the distribution, with many reporting mean scores below levels of clinical significance. Table 2a presents psychological

outcome data for the six papers that did not report an association between social support and measures of psychological functioning.

[Insert Table 2a. here]

As the table shows, the majority of the studies had particularly low scores on depression and anxiety, therefore reducing the likelihood of finding clinically significant associations with social support.

Lett and colleagues (2) stated the importance of moderating factors to determine under what circumstances social support is of benefit. Evidence for the role of moderating variables is questionable. Associations between gender, social support and pre-surgery depression were found. Within the post-surgery phase, gender and education level were associated with the factor of living alone and depression. Age was related to low family support within the pre-surgery phase with younger participants reporting increased symptoms. There was a lack of studies that examined the role of marital status and social support.

Variability in social support assessment tools was found as noted by Lett et al. (2). All of the studies used self-report measures with the most common assessment tools considering perceived social support. The lack of consensus in definitions of social support is well documented and variable measures of social support (actual versus perceived) seem to reflect this inconsistency. Uchino (4) discusses the need for

dominant theoretical models of social support to be integrated. Research evidence at present suggests that social support is largely considered in relation to the protective or "buffering" effects. This is consistent with previous research that suggests that perceived support has been shown to be more closely related to psychological symptoms than actual support (47). Oxman and Hull (33) considered multiple measures of social support and did find evidence for the benefit of actual and perceived support measures. Future studies should consider the use of multiple measures of social support as this will integrate diverse theoretical approaches.

Implications for future research

Studies included in the present review have identified that variations in levels of social support do relate to psychological functioning both pre- and post-surgery. The ability of social support to be associated with psychological functioning suggests that identification of at-risk categories of individuals may be of merit, particularly within the pre-operative phase.

Many of the studies included within the present review used measures of perceived social support. In a review examining the efficacy of social support interventions, Hogan et al. (48) suggest that the concept of perceived social support relates to appraisal of potential and actual support mechanisms. Such appraisal may be modified by a person's current depressive or anxious mood state. Perceived social support may be at risk of being affected by biases in cognitive processing. This provides a viable rationale to utilise social support interventions that take a cognitive

approach. Whilst cognitive strategies are most routinely conducted in an individual setting, Hogan et al. (48) suggest that working at a cognitive and systemic level may help to enhance the efficacy of such approaches. Attention should be paid to modifying cognitions and providing skills training to help supplement and enhance social relationships and networks.

Identification of those in need of support could be conducted in a number of ways, both using self-report inventories and through clinicians being aware of which individuals are more susceptible to problems with post-operative psychological adjustment. Patient demographic variables (age, gender, socio-economic and marital status) may be a useful approach although evidence for their relative influence is, at present, equivocal.

Limitations of present review

There are a number of limitations of the present review. The methodological quality of studies was assessed using a structured rating scale designed especially for this review. No previously published checklist was found to meet the requirements of the review. Whilst quality ratings were also completed by an independent rater and a high level of agreement was reached, there may be limitations in the design of the checklist which could have introduced bias into the ratings. Higher weightings were given to studies that had used a RCT design and this resulted in the two studies which used this design being awarded the highest points in the review. This may be seen to be inequitable compared to other prospective studies that were unable to use

RCT designs but had a study methodology that was appropriate to their research question. It was intended that additional questions within the methodology section of the checklist accounted for this bias by providing adequate attention to sampling, randomisation and measurement bias, characteristics that were of importance to all studies, regardless of their overall design.

Socio-economic status was one of four moderating variables chosen to consider its relative influence on social support and psychological functioning. However, an agreed definition of socio-economic status could not be determined, reflecting the heterogeneity in the literature (2). Inconsistency in definitions of socio-economic status were found across all of the studies included in the review, making it problematic to reach an agreed consensus of how best to measure this construct.

The present review intended to consider a range of cardiac surgeries; however the majority of studies reviewed considered CABG only. This distribution may reflect the nature of the present evidence base. Whilst research into other cardiac procedures has occurred, conceptual and methodological problems limit the validity of these findings.

Conclusion

The aim of the present review was to summarise the evidence for the benefit of social support in reducing anxiety or depression within a cardiac surgery population. Tentative evidence has been found for the association between enhanced social

support and better psychological functioning (as measured by anxiety and depression) across pre- and post-surgical phases. A number of studies did not report an association between social support and anxiety or depression. All of these studies reported particularly low levels of distress amongst participants which, it is suggested, may have led to the reduced likelihood detecting of relationships between variables. Further research is required to confirm the influence of moderating variables such as patient demographics as evidence is inconclusive. Such findings will allow clinicians to identify those at psychological and psychosocial risk at various stages during their surgical journey.

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Table One: Summary of studies meeting review exclusion criteria

Review Exclusion Criteria	Number of articles meeting review exclusion criteria
Study not published in English	40
Non cardiac population	232
Narrative study	51
Non adult population	15
Non human population (rats)	1
Dissertation publications	86
Non prospective design	20
Subtotal	445
Studies potentially fulfilling eligibility criteria	65
Total	**510**

Table Two: Summary table of studies considering the role of social support in reducing anxiety or depression in cardiac surgery patients including design, methodology, sample characteristics, outcome measures, findings and limitations

Author & Year	Study quality Overview **1. Design/intro** **2. Method** **3. Results** **4. Discussion** **5. Total** *(questions answered N/A omitted when scoring)*	Design **If intervention was used:** **1. Evidence of randomisation?** **2. Was randomisation robust?** **3. Blinding (of investigators, participants or not possible).**	Methodology **1. Type(s) of cardiac surgery** **2. Type of sample** **3. Sample size** **4. Power calculation specified?**	Sample **1. Mean age (SD)** **2. Gender** **3. Socioeconomic status** **4. Marital status**	Outcome measures **1. Social Support** **2. Anxiety (if applicable)** **3. Depression (if applicable)** **4. Reliability and validity data**	Analyses/Findings **Participant numbers across study.** **Drop out rate (attrition numbers included in final analyses)**	Limitations
Arthur et al. (29)	A (0.83) 1. 9/9 2. 23/30 3. 11/14 4. 6/6 5. **49/59**	RCT Pre-operative intervention (exercise training, education and telephone contact from nurse clinician) versus a "usual care" group. 1. Yes 2. Inadequate (selected from papers sealed in envelopes) 3. Not possible due to nature of intervention. Participants assessed at four time points (baseline, pre-surgery (post-intervention), 6-8 weeks and 6 months post-surgery).	1. CABG 2. Waiting list (sample of convenience). 3. 249 randomly assigned. 4. Original power calculation N = 250.	Baseline characteristics reported. 1.61.8 (8.4) – intervention. 63.8 (7.8) – control. 2. 107 men, 16 women (intervention). 102 men, 21 women (control). 3. Years of education: 12.2 years (intervention). 11.1 years (control).	1. Interpersonal Support Evaluation List. 2. STAI. 3. N/A 4. $\alpha = 0.88$-0.90, $r = 0.87$ (Interpersonal Support Evaluation List). Reliability and validity data not provided for STAI.	246 at baseline 220 at time two (1 week pre-surgery) 208 at time three (6 to 8 weeks post-surgery) 168 at time four (6 months after surgery) Drop outs not included in analysis. <u>Outcome data – waiting period (baseline to time two)</u> Intervention and control group's scores on state subscale of STAI remained unchanged from baseline to time two. <u>Outcome data – entire study period</u>	Analysis by gender unable to be completed. Sampled only those participants that had lower physical health risks.

				4. Asked whether living alone or not. 12.2% living alone (intervention). 14.5 % living alone (control).		Intervention group reported more support at time four (t = 3.18; *P* = 0.002). Moderating effects of age, gender, socioeconomic and marital status not examined. No data on the role of social support on reducing anxiety provided.	
Bishop et al. (30)	A (0.81) 1. 9/9 2. 21/24 3. 7/14 4. 6/6 5. **43/53**	RCT Psychosocial skills training workshop for reducing physiological and psychological risk in CABG patients versus an "information only" group. Psychosocial risk factors defined as depression, trait anger, trait anxiety, stress, social support and life satisfaction. Physiological risk assessed by anger reactivity scores as measured by heart rate and blood pressure. Measures taken at rest and during an anger induction task. Study conducted pre-CABG. Six weekly 2 hour sessions. Information only was 1x2 hour session.	1. CABG 2. Clinic attendees (sample of convenience). 3. 68 randomised (29 intervention and 29 information only). 4. Original power calculation N = 30 participants in each condition.	1. 54.7 (1.4) – intervention. 53.6 (1.4) – information only. 2. All male participants. 3. Employment status: 15/29 (51%) employed (intervention). 22/29 (76%) employed (information only). 4. 25/29 (86%) married (intervention) 24/29 (82%) (information only).	1. Short-Form Social Support Questionnaire. 2. Trait subscale of the STAI . 3. CES-D. 4. None.	A total of 10 participants lost across duration of study. Drop outs not included in analyses. Outcome data: Perceived stress and use of Angiotensin Converting Enzyme (ACE) inhibitors entered as covariates in analyses. <u>Psychosocial measures (intervention group)</u> Significant reductions from baseline to post-intervention in depression (*d* = 0.38, *P*<0.05). Significant increases from baseline to follow up for satisfaction with social support (*d* = 0.56, *P*<0.01). <u>Psychosocial measures (information only group)</u> Significant increases in	Generalisability of study is limited as a male-only sample was used. Unclear whether study measures (physiological and psychosocial) were administered by group facilitators, therefore leading to unblinding of assessors.

		Participants assessed at baseline (pre-intervention/information session), post-intervention and at three month follow up. 1. Yes. 2. Inadequate (slips of paper placed in a container). 3. Not possible due to nature of intervention.				depression from baseline to post-intervention (d = -0.48, P<0.001) and three month follow up (d = -0.48, P<0.001). Significant decreases in satisfaction with social support from baseline to 3 month follow up (d = -0.39, P<0.001). No significant changes in trait anxiety across study for either intervention or information only group. Moderating effects of age, gender, socioeconomic and marital status not examined. No data on the role of social support on reducing anxiety or depression provided.	
Oxlad & Wade (35)	A (0.81) 1. 7/9 2. 15/18 3. 10/14 4. 6/6 5. **38/47**	Prospective (pre- and post-CABG surgery). Investigated modifiable risk factors (optimism, illness representations, self rated health, multiple measures of social support and coping) for poor psychological functioning (depression, anxiety and post traumatic stress disorder) six months post-CABG. Participants were assessed	1. CABG 2. Waiting list (sample of convenience). 3. 119 agreed to participate. 4. No power calculation specified.	1. 63.26 (10.16). 2. 100 men and 19 women. 3. Mean years of education = 10.22 (SD = 3.41). 4. 63.9% (married) 19.3% (living alone).	1. Medical Outcomes Study (MOS) social support survey. 2. & 3. DASS 4. α = 0.95-0.98 (MOS). α = 0.90-0.97 (DASS depression). α = 0.76-0.82 (DASS anxiety).	Attrition rates reported for each stage of study. 102 participants (85.7%) completed assessments at all four time points. Drop outs were not included in analyses. Demographic variables, cardiac factors and medical co-morbidities were entered as covariates in analyses.	Analysis of attrition data revealed that these participants had a statistically significant increased likelihood of diabetes and hypertension. Psychological risk factors identified may only be applicable to CABG patients who are less physically ill.

		on four occasions: Time 1: Face to face pre-operatively (outpatient appointment). Time 2: Face to face prior to hospital discharge. Time 3: Telephone interview at three months post-operatively. Time 4: Telephone interview at six months post-operatively.				<u>Prospective prediction of psychological functioning at six months post-operatively</u> Higher level of depression was predicted by lower social support at three months post-operatively ($P = 0.03$). Higher level of anxiety was predicted by lower social support in the pre-operative period, at discharge and three months post-operatively ($p<0.05$).	
Bute et al. (32)	A (0.76) 1. 7/9 2. 16/20 3. 9/14 4. 5/6 5. **37/49**	Prospective (pre- and post-CABG). Study examined gender differences in quality of life and cognitive outcomes after CABG. Participants were assessed on the day before surgery and one year after CABG. Quality of life was defined by measurements of functional status, activities of daily living, general health status, social activity/interaction, presence or absence of physical ill health symptoms, depression, anxiety and perceived social support.	1. CABG 2. Waiting list (sample of convenience). 3. 343 participants recruited and provided baseline data. 280 participants followed up at one year post-CABG. 4. No power calculation specified.	Baseline patient demographics reported: 1. Male: 61.69 (10.13). Female: 63.68 (10.5). 2. Male and Female numbers not reported for baseline characteristics. At follow up, of the 280 participants remaining, 96 were women and 184 were men.	1. PSSS. 2. STAI. 3. CES-D. 4. $\alpha = 0.97$ (PSSS) $\alpha = 0.93$ (STAI) $\alpha = 0.88$ (CES-D)	Attrition rate reported from baseline to follow up. Reasons for drop out were partially recorded. Drop outs not included in analyses. Baseline differences across gender entered as covariates in analyses. These were age, years of education, marital status, index of physical comorbidity, hypertension, diabetes and race. Significant gender differences found for all quality of life and cognitive outcomes. Effect of gender examined across outcome variables. <u>Quality of life outcomes</u> At follow up, female patients	Study does not explore the relationship between social support and anxiety or depression.

		Cognitive outcomes were assessed objectively (auditory/visual immediate and delayed memory, working memory and speed of processing) and subjectively (Cognitive Difficulties Scale). Participants assessed day before surgery and one year post-operatively.		3. Male mean years of education: 13.15 (3.29). Female mean years of education: 11.47 (2.75). (p<0.0001) 4. Married: Male: 83.9% Female: 51.2% (p<0.0001)		had lower scores in social support and higher scores in depression and anxiety (both p<0.001) indicating worse functioning. When covariates were included in analyses, gender differences were still evident for anxiety (p = 0.03) but not for depression (p = 0.29) or social support (p = 0.69).	
Oxman & Hull (33)	B (0.74) 1. 7/9 2. 15/18 3. 8/14 4. 5/6 5. **35/47**	Prospective (pre- and post-CABG and/or aortic valve replacement). Study examined relationship of social support to physical (activities of daily living) and emotional outcome (social support) in patients undergoing heart surgery. Participants were assessed at three time points (pre-surgery, 1 month post-surgery and 6 months post-surgery) on measures of functional impairment, depression and social networks.	1. CABG and/or aortic valve replacement. 2. Waiting list (sample of convenience). 3. 200 participants agreed to participate, data complete for 147 participants across duration of entire study. 4. No power calculation specified.	1. Mean age of sample: 69 years (7). 2. 30% female and 70% male. 3. Educational history: 29% (less than high school education). 29% (high school education). 42% (1+ years of college education). 4. 79% of sample was married.	1. Social Network Questionnaire. Inventory of Socially Supportive Behaviours. Multidimensional Scale of Perceived Social Support. 2. N/A 3. Hamilton Rating Scale for Depression. 4. None.	200 participants were entered into study; complete data was collected for only 147 participants. Drop out numbers and reasons were provided. Moderating effect of age examined. <u>Social support and emotional outcome</u> Greater perceived adequacy of social support related to lower scores of depression pre-surgery and six months post-surgery (both p≤0.001). Number of close network members seen in one month related to lower scores of depression pre- and 1 month post-surgery (p≤0.0001).	Statistically significant differences were found between data for those who did complete the study versus those who did not. Authors state that results may only apply to older cardiac patients.

						Same relationship found for pre- and 6 months post-surgery ($p \leq 0.05$) as well as 1 month and 6 months post-surgery ($p \leq 0.01$). <u>A priori hypotheses – social support and/or depression</u> Lower number of emotionally close network members seen 1 month post-surgery was significantly related to higher depression scores six months post-surgery ($p < 0.05$). <u>Age effects</u> Being older was related to less depression within the six month post-surgery phase ($p < 0.05$).	
Mitchell et al. (34)	B (0.74) 1. 7/9 2. 15/18 3. 8/14 4. 5/6 5. **35/47**	Prospective (pre- and post-CABG surgery). Study examined gender differences in depression during recovery from CABG. Measures of health status, symptom severity, depression (using semi structured and self report measures) and self report measure of social support. Participants were assessed during the month before surgery and then 6-12 weeks	1. First time CABG patients. 2. Sample of convenience. 3. 137 participants enrolled. Final sample post-surgery was 130. 4. No power calculation specified.	Pre-surgery characteristics reported for only those who completed the study (N = 130). 1. Mean age (sample): 63.3 (10.2). 2. 69 men and 61 women. 3. Greater than high school education: 44% (N = 54) from a	1. Enhancing Recovery in Coronary Heart Disease (ENRICHD) social support inventory. 2. N/A 3a. Mini International Neuropsychiatric Interview. 3b. BDI. 4. None.	Attrition rates and reasons for drop out reported. Drop outs were not included in analyses. Moderating effects of gender, socioeconomic and marital status examined. <u>Post-surgery gender differences – social support</u> Women reported higher levels of social support post-surgery ($P = 0.04$). They were also found to be less likely to be married and of lower socioeconomic status.	No control group to consider whether results were due to Type I error.

		post-surgery.		data set of 123 participants. 4. Married 68% (N = 86 of which 54 were men). Women found to be statistically less likely to be married (p = 0.002).		<u>Interaction effects between gender and depression across time (pre- and post-CABG)</u> Both men and women showed an improvement in depressive symptomology post-surgery. This relationship was statistically significant for women only (P<0.01). Relationship was not accountable by covariates (education, social support and health risk status).	
Okkonen & Vanhanen (35)	B (0.72) 1. 7/9 2. 14/18 3. 7/14 4. 6/6 5. **34/47**	Prospective (Pre- and Post-CABG surgery) Study examined role of family support on subjective health status in patients undergoing CABG surgery. Information collected included chest pain, symptoms of depression, anxiety, hopelessness and family support. Participants were assessed four days before surgery (face to face) and then sent a questionnaire six months.	1. CABG patients. 2. Sample of convenience. 3. N = 279. At pre-surgery, number of non-respondents was 7.2%, with data from 15 questionnaires unable to be used. At follow up, number of non-respondents was 4.8% 4. No power calculation specified.	1. Mean age: 60.2 (no SD reported). 2. Male 81%, female 19%. 3. No vocational education 41% (N = 111), vocational education 30% (N = 84), college/university education 29% (N = 80). Data missing for 4 participants. 4. Married 78% (N = 217)	1. Family support measure. 2. Endler Multidimensional Anxiety Scale. 3. 14 item BDI. 4. α = 0.80 (Family Support Measure) α = 0.95-0.96 (Multidimensional Anxiety Scale) α = 0.85-0.88 (BDI).	Attrition rate reported but reasons for drop out not stated. Participants with low family support reported significantly more symptoms of anxiety pre- and post-CABG (P = 0.031 and P = 0.016). Moderating effects of age, gender, and socioeconomic status examined. <u>Low/high family support and depression (pre- and post-surgery)</u> Relationship between low family support and pre-surgery depression remained significant despite controlling for gender, age (both p<0.05) and education (p<0.001). The same was found for the post-surgery phase (all p<0.001).	Authors state response bias may be present due to use of self report measures only. Participants that were recruited into the study may have had a better health status, therefore authors are unsure of whether sample is representative of CABG population as a whole. Validity of Family Support measure is limited to a Finnish population only.

						<u>Living alone/living with someone and depression (pre- and post-surgery)</u> Comparisons between living alone and pre-surgery depression also remained statistically significant when covariates were examined (age, gender and education all $p<0.05$). The relationship between living alone and post-surgery depression remained significant after controlling for age only ($P = 0.027$). <u>Low/high family support and anxiety (pre-surgery)</u> Gender and education were not found to be associated with low family support and pre-surgery anxiety ($P<0.05$ and $P = 0.011$ respectively). However, the relationship between family support and pre-surgery anxiety was weakened when age was entered into analyses ($P = 0.052$). <u>Low/high family support and anxiety (post-surgery)</u> Gender and education were not found to be associated with family support and anxiety ($P = 0.014$ and $P = 0.002$). Age was not found to be related to	

						the low family support group who reported more symptoms of anxiety (P = 0.018).	
Burker et al. (37)	B (0.72) 1. 7/9 2. 14/18 3. 7/14 4. 6/6 5. **34/47**	Prospective (pre- and post-CABG, valve repair or both). Study aimed to assess the prevalence of depression across gender and identify factors associated with mood related difficulties. Participants were assessed one day prior to surgery and one day prior to hospital discharge. Assessed levels of depression, anxiety and scale of perceived social support.	1. CABG and/or valve repair patients. 2. Sample of convenience. 3. N = 141, with 114 participants completing pre and post measures. 4. No power calculation specified.	1. Mean age: 61.4 (10.86)*. 2. Of the 114 who completed the study, 81 were male and 33 female. 3. Mean years of education: 12.06 (3.86)*. 4. Married: 82%*. *Reviewer unable to determine whether these figures are based on total sample or after attrition occurred.	1. PSSS. 2. STAI. 3. CES-D. 4. None.	Attrition rates reported, but reasons for drop out not stated. <u>Pre-surgery</u> Those who were depressed (using a score of ≥16 on CES-D), had higher levels of state and trait anxiety (both p<0.0001) and lower levels of social support (p<0.01). Age, marital status, or years of education were not significantly associated with depression. Regression analyses revealed that gender, state anxiety, trait anxiety and social support were significant predictors of depression pre-surgery ($F(4,127) = 44.6$, p<0.0001, R^2 = 0.51). <u>Post-surgery</u> Perception of social support did not differentiate between depressed and non depressed participants post surgery. Regression analyses revealed that pre-surgery depression, post-surgery state anxiety and being diabetic were significant	No control group.

						predictors of depression post-surgery (F (3,110) = 41.39, p<0.0001, R^2 = 0.53).	
Keresztes et al. (36)	B (0.69) 1. 7/9 2. 15/20 3. 7/14 4. 5/6 5. **34/49**	Prospective (pre- and post-CABG surgery). Study examined the gender differences across physical, social and psychological domains of health Quality of Life. Participants were assessed using a range of measures (Quality of Life index, social support index, Profile of mood states, physical health symptom scale, health rating and level of physical activity) pre-operatively (time frame not specified), one and three months after surgery.	1. CABG patients. 2. Sample of convenience. 3. N = 80 (40 pairs of men and women, matched Body Surface Area (BSA) (within 0.1m²) and age (within 5 years). 4. No power calculation specified.	1. Mean age – male: 63.8 (10.8). Female: 62.7(12.1). 2. 40 male and 40 female. 3. Years of school attended – male: 12.2 (3.0). Female: 11.6 (2.2). 4. Married – male: 85% (N = 34). Female: 75% (N = 30).	1. PRQ. Measures provision for intimacy, social integration, reassurance, provision of informational and emotional support. Socioeconomic subscale of the QLI. 2. POMS – Tension/anxiety subscale. 3. POMS – depression/ dejection subscale. 4. None.	Attrition rate not reported. <u>Social domain of health QoL (gender effects)</u> Women reported lower levels of social support on the socioeconomic subscale of the QLI three months after surgery (p <0.01). No significant differences found across gender and time on the measure of social support used (PRQ). <u>POMS (gender effects)</u> No differences were found across gender for measures of anxiety as assessed by the Profile of Mood States tension subscale. Female participants were found to have higher pre-operative depression scores than men. Once pre-operative differences in depression were controlled for, no significant differences were found in the post-operative period between gender.	Study aimed to have matched pairs of participants on the basis of BSA. Authors state that as men generally have higher BSA's, the mean BSA for women in this study was greater than what is usually found, therefore limiting generalisability of findings to all female CABG candidates. Additional constraints on generalisability of study findings include ethnicity (no ethnic minorities included in sample). Participants who required emergency CABG were eliminated due to pre-operative data being unable to be collected. Authors state that findings may not fully represent the

							physical and psychological health status of CABG population. Only one measure of social support showed significance (socioeconomic subscale of the QLI), no conclusions can be drawn about the possible impact of social support on anxiety and depression levels across gender.
Langeluddecke et al. (38)	B (0.64) 1. 6/9 2. 15/18 3. 5/14 4. 4/6 5. **30/47**	Prospective design (pre- and post-first time CABG). Study aimed to determine psychological and psychosocial impairment pre- and post-CABG. Assessment measures included coronary angiography data, indexes of psychosocial impairment in areas of health care, work, activities of daily living, sexual functioning, family relationships, social functioning and psychological distress. Measure of involvement in social and family pursuits	1. First time CABG. 2. Sample of convenience. 3. N = 107 participated, however pre- and post-surgery data available for 89 participants (17% attrition rate). 4. No power calculation specified.	1. Mean age: 56 years (no SD specified). 2. Male: 85%, female: 15%. 3. 55% full/part time employment. 23% retired. 11% domestic duties noted as occupation. 11% unemployed due to illness. 4. 87% married. 7% widowed. 2% single. 3% divorced. 1% separated.	1. Social functioning subscale of the PAIS. 2. State subscale of STAI. 3. CES-D. 4. None.	Attrition rates reported and reasons for drop out stated. Drop outs not included in analyses. Moderating effects of age, gender, socioeconomic and marital status not examined. <u>Social functioning</u> On the social functioning subscale of the PAIS, modest yet significant improvements from pre- to post-surgery (both 6 and 12 months) were found (p<0.01). <u>Psychological functioning (depression)</u> Depression was found to be	Low number of female participants within sample did not allow analyses by gender to be conducted. No analyses by age were conducted. No comparison of levels of psychological distress in relation to social functioning.

		over a period of one month. Additional separate measures of depression and state anxiety were also conducted. Participants were assessed pre-surgery (time frame not specified), 6 and 12 months post-surgery.				significantly reduced at six months and this was maintained at 12 months (both $p<0.001$). <u>Psychological functioning (state anxiety)</u> State anxiety was found to be significantly reduced between pre-surgery and 6 months post-surgery and this was maintained at 12 months (both $p<0.001$).	
Triffaux et al. (39)	C (0.55) 1. 7/9 2. 7/20 3. 8/14 4. 5/6 5. **27/49**	Prospective study (pre- and post-OHT). Participants were provided psychological assistance or treatment pre- and post-OHT. Participants were assessed using semi-structured interviews to allocate DSM-IV categories. Self report measures of depression, anxiety, minor psychiatric morbidity, perceived social support, alexithymia were conducted as well an assessment of social desirability responses. Measures were completed pre-OHT, 1 and 6 month post-OHT.	1. OHT 2. Sample of convenience. 3. N = 22 assessed pre-OHT, 15 assessed 1 month post-OHT and 13 assessed 6 months post-OHT. 4. No power calculation specified.	Baseline demographics reported. 1. Mean age: 53.3 years (9.6). 2. 18 men and 4 women. 3. Not reported. 4. Not reported.	1. PSSS. 2. STAI and GHQ anxiety subscale. 3. 13-item BDI and GHQ depression subscale. 4. None.	Seven participants excluded from study due to emergency surgery, leaving 15 participants who completed pre- and one post-surgery measures. At six months, two participants were lost to follow up. <u>Pre- and 1 month post-OHT</u> Significant decrease in depression ($p = 0.008$), state ($p = 0.0007$) and trait anxiety ($p = 0.01$) scores. No significant differences reported across measure of social support. <u>One and six months post-OHT</u> No significant differences found across this time period for STAI, GHQ, BDI and PSSS measures. No data on the role of social support on reducing anxiety or	Limited participant demographics reported. No control group. Low sample size.

						depression provided.	
Crumlish (40)	C (0.55) 1. 7/9 2. 8/18 3. 6/14 4. 5/6 5. **26/47**	Prospective (pre- and post-cardiac surgery – type not specified). Study aimed to examine changes in coping and emotional change pre- and post-cardiac surgery. Participants were assessed day before surgery and five days after. Measures of coping and emotion were completed.	1. Cardiac surgery – type not specified. 2. Sample of convenience. 3. N = 28 recruited with 24 participants completing pre- and post-surgery measures. 4. No power calculation specified.	Demographics reported on those that completed the study. 1. Mean age: 59.5 years (11). 2. All female sample. 3. 50% high school graduates. No further educational or employment information provided. 4. 64% married.	1. Revised WCCL seeks social support subscale. 2. POMS – tension/anxiety subscale. 3. POMS – depression/ dejection subscale. 4. $\alpha = 0.62\text{-}0.87$ (WCCL) $\alpha = 0.75\text{-}0.95$ (POMS).	Attrition rates reported and reasons for drop out not stated. Drop outs not included in analyses. <u>WCCL – measure of coping</u> No significant changes in any coping subscale across pre- and post-surgery. <u>POMS – tension/anxiety subscale</u> Significant decrease in tension and anxiety subscale from pre- to post-surgery ($p<0.01$). <u>POMS – depression/dejection subscale</u> Correlations revealed that pre-operative depression is significantly associated with post-operative depression ($r = 1.00$, $p<0.001$).	No gender comparisons made due to female only sample, although authors do state that this was beyond the scope of the present study. Low sample size. Specificity of measures used to capture construct of coping and emotional change is questioned by authors. No data on the role of social support on reducing anxiety or depression provided.

OUTCOME MEASURES – KEY
STAI = State Trait Anxiety Inventory; CES-D = Centre for Epidemiological Studies Depression Scale; DASS = Depression and Anxiety Stress Scales; PSSS = Perceived social support scale; BDI = Beck Depression Inventory; PRQ = Personal Resource Questionnaire; QLI = Quality of Life Index; POMS = Profile of Mood States; PAIS = Psychosocial Adjustment to Illness Scale; GHQ = General Health Questionnaire; WCCL = Ways of Coping Checklist

Table 2a: Comparison of mean scores of measures of anxiety or depression reported by six studies reporting no association with social support, anxiety or depression

Study	Measure of anxiety or depression Assessment time points	Reported mean (SD) across study duration	Comparison with published norms
Arthur et al. (29)	STAI Baseline: Pre-surgery 6-8 weeks post-surgery 6 months post-surgery	*Baseline data reported only Intervention group – 37.2 (state anxiety). Control group – 39.0 (state anxiety). Intervention group – 37.0 (trait anxiety). Control group – 39.5 (trait anxiety).	All mean scores within normal range (20-39) Reference: Spielberger, Gorsuch and Lushene (41).
Mitchell et al. (34)	BDI 1 month pre-surgery 6-12 weeks post-surgery	Pre-CABG (men): 8.0 (7.0). Pre-CABG (women): 12.2 (8.1). Post-CABG (men): 7.2 (6.4). Post-CABG (women): 7.9 (6.1).	Mean scores within no (0-9) or mild depression range (10-19). Reference: Beck, Steer and Garbin (42).
Keresztes et al. (36)	POMS anxiety and depression subscales Pre-operative (time frame not specified) 1 month post-surgery 3 months post-surgery	<u>POMS – anxiety/depression (men)</u> Pre-operative: 14.5(6.2)/10.9(8.4). 1 month post-surgery: 9.8 (4.5)/4.6(5.7). 3 months post-surgery: 9.1(4.7)/5.6 (6.4). <u>POMS – anxiety/depression (women)</u> Pre-operative: 15.7 (6.1)/15.4 (11.5). 1 month post-surgery: 9.9 (5.3)/8 (9.3). 3 months post-surgery: 9.1 (4.9)/8.4 (10).	Scores above mean reported for anxiety (12.9 (6.8) men, 13.9 (7.4) women) in pre-operative phase only. Scores for depression lower than published normative data (13.1 (10.5) men, 14.8 (11.4) women) expect for pre-operative depression score for women. Reference: McNair, Loor and Droppleman (43)
Langeluddecke et al. (38)	STAI (state) and CES-D Pre-operative (time frame not specified). 6 months post-surgery 12 months post-surgery	*No standard deviations reported <u>STAI (state)</u> Pre-operative: 39.4. 6 months post-surgery: 36.8. 12 months post-surgery: 34.7. <u>CES-D</u> Pre-operative: 13.2. 6 months post-surgery: 11.2. 12 months post-surgery: 9.8.	<u>STAI (state)</u> All mean scores within normal range (20-39). <u>CES-D</u> All scores below clinical significance (≥15). References: Spielberger, Gorsuch and Lushene

			(41) Radloff (44)
Triffaux et al. (39)	STAI, GHQ (anxiety and depression subscales) and 13-item BDI Pre-OHT 1 month post-OHT 6 months post-OHT	<u>STAI – state/trait</u> Pre-OHT: 36.4 (11.3)/36.7 (8.8) 1 month post-OHT: 28.4 (9.9)/31.9 (9.1) 6 months post-OHT: 28.2 (9.9)/31.9 (9.3) <u>GHQ – anxiety/depression</u> Pre-OHT: 6.7 (5.7)/0.5 (1.1) 1 month post-OHT: 4.3 (5.2)/0.4 (0.7) 6 months post-OHT: 3.5 (4.0)/1.0 (2.3) <u>13-item BDI</u> Pre-OHT: 4.0 (2.8) 1 month post-OHT: 2.1 (2.9) 6 months post-OHT: 2.5 (2.8)	<u>STAI – state/trait</u> All mean scores within normal range (20-39). <u>GHQ – anxiety/depression</u> Clinical cut off of 4/5 normally used to define caseness. All scores below this apart from pre-OHT anxiety. <u>13-item BDI</u> Mean scores within no depression range (0-4). References: Spielberger, Gorsuch and Lushene (41). Goldberg and Hillier (45) Beck, Rials and Rickels (46)
Crumlish (40)	POMS anxiety and depression subscales 1 day pre-surgery 5 days post-surgery	<u>POMS – anxiety/depression (female only sample)</u> 1 day pre-surgery: 2.12 (0.92)/0.92(0.63) 5 days post-surgery: 1.30(1.01)/0.92(0.63)	Scores below mean reported for anxiety (13.9 (7.4) women) Scores for depression lower than published normative data (14.8 (11.4) women). Reference: McNair, Loor and Droppleman (43)

Chapter 2: Major Research Project

The application of the Pre-operative Intrusive Thoughts Inventory (Crockett et al. 2007) in an elective hernia repair surgery population

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(See Appendix 2.2 for notes for contributors)

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Summary

Researchers have indicated the need for consideration of emotional distress prior to surgery. Measures of pre-operative anxiety have been developed and include the Pre-operative Intrusive Thoughts Inventory (PITI). The aim of the present study is to evaluate the application of the PITI in a mid- to older-adult population awaiting elective hernia repair. A cross-sectional design was employed to examine whether anxiety, depression, previous surgical history and personality characteristics modified intrusive thoughts. Twenty-one participants were recruited and assessed in hospital before surgery. Measures of state anxiety, neuroticism, psychoticism and negative surgical history correlated with the PITI or its subscales. However, lower levels of pre-operative distress as assessed by the PITI were found in the present sample when compared to mean scores in the original study and reasons for these findings are proposed. Results indicate the importance of assessment of pre-operative functioning and the association of psychological and personality characteristics in responses to surgery.

Theoretical understanding of worry and intrusive thoughts

Worry is a feature of many anxiety disorders and is related to negative perceptions of future events [1]. Worry may be of reference to both past and future events, with cognitions being related to depressive and anxious mood states. Borkovec et al. [2] states that worry may impair emotional processing and problem solving. Such strategies are counterproductive and lead to an increase in intrusive cognitions [3].

Clark and Rhyno [4] (pp.4) define intrusive thoughts as "any distinct, identifiable cognitive event that is unwanted, unintended and recurrent. It interrupts the flow of thought interferes in task performance, is associated with negative affect and is difficult to control". Experimental research has shown that those who worry after exposure to a stressful event do experience a higher level of intrusive thoughts for up to three days after the event [3,5]. Intrusive thoughts are disruptive leading to decreased emotional and cognitive processing of the event. Furthermore, the occurrence of worry or intrusive thoughts pre- and post-stressful events leads to the increased presence of anxious or depressive cognitions.

Psychological consequences of surgery

Surgery is considered to be a stressful experience that requires physical and emotional adjustment [6]. Patients with higher levels of pre-operative anxiety have poorer psychological outcome, increased pain, less symptom relief and a higher rate of readmission [7,8]. In a review considering anxiety and surgical

recovery, Munafò and Stevenson [9] found evidence for an association between pre- and post-surgery state anxiety or depression.

Several studies have considered previous surgical experience in relation to pre-operative anxiety. Domar et al. [10] state that previous surgical experience may lead to lower levels of anxiety due to a familiarity with subsequent procedures. Enduring characteristics such as personality will predispose individuals to a more problematic post-operative adjustment. Neuroticism has been associated with difficulties in recovery from coronary artery bypass graft surgery [11]. In addition those with high neuroticism scores have an increased likelihood of suffering from emotional difficulties [12].

Development of pre-operative anxiety assessment tools

Researchers have begun to develop pre-operative measures of surgical-related thinking but findings are in the preliminary stages. The Amsterdam Pre-operative Anxiety and Information Scale (APAIS) [13] is a six-item questionnaire examining anxiety and fear in relation to anaesthesia and surgery. The questionnaire is divided into two subscales; anxiety-related thoughts and need for information. The APAIS had good psychometric properties and correlated well with the State-Trait Anxiety Inventory [14]. Higher scores on the need for information subscale were related to an increased score on the anxiety subscale. An increased need for information may trigger more distress-related reactions, resulting in an increased level of anxiety experienced.

Crockett et al. [15] have developed the PITI which is a 20-item questionnaire designed to assess pre-operative anxiety. The PITI is divided into six subscales which examine preoccupation with the surgical procedure, concerns with outcome, anxieties regarding being unconscious, loss of control, dependence on others and pain/discomfort. In a validation study of the PITI, 128 participants were assessed across a range of surgical subspecialties. Crockett et al. [15] found the scale to have good internal consistency ($\alpha = 0.91$) and good sensitivity and specificity to detect clinically-significant anxiety levels. Furthermore, the PITI showed that investigative surgical procedures generated higher scores than did non-investigative procedures.

Rationale for study

There is a growth of assessment tools being developed specifically to assess level of pre-operative anxiety [13,15]. However, measures are in preliminary stages of development and require generalisability to other surgical populations and age groups. In the studies by Moerman et al. [13] and Crockett et al. [15], the mean age of participants was 38 and 42 years respectively. Despite inclusion of middle aged adults in both of these studies, there was not particular emphasis placed upon the nature of pre-operative anxiety within this population. Older surgical patients form a significant group in view of the increasing proportion of the elderly in the population [16]. In particular, the stress of impending hospitalisation and surgery has been shown to have greater adverse effects upon elderly patients [17].

The intention of the present study is to apply the PITI in a sample of patients awaiting elective hernia repair. This selection avoids confounding caused by anxiety associated with investigative surgical procedures. Crockett et al. [15] hypothesise that an investigative procedure may generate greater uncertainty and lead to a higher incidence of pre-operative intrusive thoughts.

Aims and hypotheses

Aims

1. To evaluate the application of the PITI [15] in a middle aged to older adult population having the same surgical procedure.
2. To determine what other factors modify pre-operative intrusive thoughts in a middle aged to older adult population. Factors to be investigated are anxiety, depression, previous surgical history, neuroticism and extroversion.

Hypotheses

Previous surgical history

1. Participants with previous negative surgical history will score higher on measures of anxiety Hospital Anxiety Depression Inventory (HADS) and State-Trait Anxiety Inventory (STAI) and will show an increased presence of intrusive thoughts as assessed by the PITI.

Anxiety

2. Participants with increased levels of pre-operative anxiety as measured by the HADS and the STAI will show an increased presence of intrusive thoughts as assessed by the PITI.

Depression

3. Participants with increased levels of pre-operative depression as measured by the HADS will show an increased presence of intrusive thoughts as assessed by the PITI.

Personality characteristics

4. Participants with high scores on the neuroticism subscale of the Eysenck Personality Questionnaire Revised – Short Form (EPQR-S) will show an increased presence of intrusive thoughts as assessed by the PITI.

Methods

Participants

Inclusion and Exclusion Criteria

Inclusion criteria: aged 50 years old and over awaiting elective hernia repair at Gartnavel General Hospital and Western Infirmary, NHS Greater Glasgow and Clyde.

Exclusion criteria: other significant physical co−morbid condition (e.g. malignant or cardiovascular disease) that might affect the emotional state; current psychiatric condition; intellectual impairment that would affect comprehension of the psychological assessment.

Sample size and power

The sample size was determined on the basis of a cross-sectional design and the intended data analysis. The intention in the analysis was to conduct a regression analysis to determine which of the independent variables predicts outcome on the

PITI. Initial correlation analysis would establish the association between the PITI and the independent variables and inter−correlations between the independent variables. Due to the certain occurrence of collinearity between some of the predictor variables (e.g. between neuroticism and anxiety), the number of predictor variables that would be entered in any one regression analysis would not exceed four.

Sample size was determined by the formula specified by Green [18]. There were no data to estimate effect size within such a study. Therefore by conservatively estimating a medium effect size ($f^2 = 0.15$), the formula takes the form of:

$N \geq (8/f^2) + (m-1)$, where f^2 = the assumed effect size; m = the number of independent variables in the regression. For a power of 0.80 and an alpha of 0.05 and assumed medium effect size of 0.15, the estimated sample size required is: $(8/0.15) + (4 - 1) = 56$ participants.

Procedure

Recruitment – methods of identification, approach and consent

Approval was obtained from NHS Greater Glasgow and Clyde Primary Care, Community and Mental Health Research Ethics Committee (see Appendix 2.3 and 2.4). Following approval, eight Consultant Vascular surgeons were identified at locations in the West of Glasgow. Letters introducing the study and consent forms requesting access to patients were sent (see Appendix 2.5) across January to February 2008. There was an 87.5% response rate (seven replies) and six surgeons (75%) granted access. Identification and recruitment of participants was conducted from March to June 2008. Fifty nine potential

participants were identified and sent a study introduction letter (see Appendix 2.6) describing an overview of the research. Individuals interested in meeting the investigator were required to identify themselves by signing and completing a "consent to be approach" form (see Appendix 2.7). There was a 61% (n = 36) response rate with 46% agreeing (n = 27) to be approached. Figure 1 illustrates the recruitment process from identification, consent to be approached to participation in the study.

[Insert Figure 1. here]

Twenty seven participants were met in hospital and were informed of the study rationale and procedure. An opportunity to answer questions was provided and informed consent was then obtained (see Appendix 2.8). Six participants declined to participate at this stage, leaving a final sample of 21. A brief semi-structured clinical interview was conducted to collect demographic information (age, gender, socio-economic status, marital status, employment and educational history). Socio-economic status was defined using the participant's "deprivation category" (DEPCAT) [19] based on postal codes. Postal codes have been allocated to DEPCAT categories 1 (high affluence) to 7 (severe deprivation). A copy of the semi-structured interview is presented in appendix 2.9.

Following the semi-structured interview, participants were asked to complete screening measures to assess study inclusion/exclusion criteria.

Measures – screening for inclusion/exclusion criteria

(investigator administrated)

National Adult Reading Test Revised (NART-R) [20].

The NART-R is a 50-item reading list which participants read out aloud. Words are scored as correct or incorrect dependent upon pronunciation. The NART-R is intended to be an estimate of pre-morbid ability based on the assumption that oral reading is closely related to general intellectual ability and that this skill is relatively well preserved until late in dementia [21]. The NART-R error score was used in the present study as an assessment of reading error [20]. The NART-R error score equals 50 minus the number of words read correctly. Poor readers are defined as those with fewer than 10 NART-R words read correctly [20].

Mini-Mental State Examination (MMSE) [22].

The MMSE is a screening measure designed for suspected cognitive impairment. It is acknowledged that this measure is brief in its examination of cognitive functioning as only memory, language and visuoperceptual functions are assessed [23]. MMSE is recommended as an initial cognitive screen by the Scottish Intercollegiate Guidelines Network (SIGN) guidelines on the management of patients with dementia [23]. Despite its limitations, the MMSE fulfils the remit of the need for a brief cognitive screen for the purposes of the study exclusion criteria. The use of the MMSE was purely for research purposes and not used as a basis on which to make a judgement regarding a person's competence to give informed consent.

All of the participants were assessed to meet study inclusion criteria and then completed the five self-report measures while the investigator was present.

Measures – self-report

Surgery-related intrusive thoughts

Pre-operative Intrusive Thoughts Inventory (PITI) [15].

The PITI is a 20-item scale that was developed to measure the nature of pre-operative thoughts and incidence of anxiety. Scores are rated on a 4-point scale ranging from 0 (not at all) to 3 (most of the time). Cronbach's alpha coefficient (measure of internal consistency) was calculated. Alpha coefficients were as follows; PITI (total) $\alpha = 0.96$, being unconscious $\alpha = 0.86$, pre-occupation $\alpha = 0.86$, outcome concerns $\alpha = 0.80$, pain/discomfort $\alpha = 0.85$, dependence on others $\alpha = 0.71$, and loss of control $\alpha = 0.67$. A copy of the PITI is presented in Appendix 2.10*. Appendix 2.11 presents an overview of the PITI questions organised under each of its six subscales*.

Depression and anxiety

Hospital Depression and Anxiety Scale (HADS) [24].

The HADS is a 14-item scale that is designed to detect the presence and severity of anxiety and depression with scores ranging from 0-14. Internal consistency has previously been reported to be between 0.80 and 0.90 for both anxiety and depression subscales [25]. Cronbach's alpha for the present study was 0.87 (anxiety) and 0.75 (depression).[2]

*Appendix 2.10 and 2.11 has been removed due to Copyright restrictions.

State-Trait Anxiety Inventory (STAI) [26].

The STAI presents 40 statements assessing state anxiety (transitory changes in arousal) and trait anxiety (a predisposition to respond in an anxious manner to trigger situations). The STAI shows good reliability with coefficients of between 0.85-0.94 and 0.75-0.88 reported for state and trait subscales respectively [27]. Cronbach's alpha for the present study was 0.89 (state anxiety) and 0.88 (trait anxiety).

Personality characteristics

Eysenck Personality Questionnaire Revised – Short Form (EPQR-S) [28].

The EPQR-S is a 48-item scale that assesses the personality traits of extroversion, neuroticism and psychoticism. It also includes a so-called "lie scale" to detect tendencies to answer in a socially-acceptable way. Scores range between 0-12 for each subscale. Eysenck et al. [29] found all subscales had moderate to high internal consistency. Cronbach's alpha for the present study was 0.70 (psychoticism), 0.90 (extraversion), 0.90 (neuroticism) and 0.77 (social desirability).

Previous surgical history – Visual Analogue Scale (VAS) (devised for present study).

Participants' previous surgical experience was determined by asking them to rate their experience on a visual analogue scale measuring positive, negative or neutral experiences. The visual analogue scale was anchored with the words "very poorly" and "very well" at 0 and 100mm respectively. Visual analogue

scales have been found to correlate well with measures of depression and anxiety [30]. A copy of the visual analogue scale used is presented in Appendix 2.12.

Once study measures were complete, participants were informed that the study was concluded and no further input was required.

Statistical analysis

All analyses were performed using the Statistical Package for Social Sciences [31]. All outcome and predictor variables were checked for accuracy of data entry. Preliminary analysis of the distribution of PITI item scores, HADS (depression) and EPQR-S (psychoticism), EPQR-S (neuroticism) indicated a non-normal distribution (Kolmogorov-Smirnov test of normality – all $p<0.05$). Data were found to be positively skewed and were transformed by a log10 calculation. Analysis revealed that only PITI (total) and EPQR-S (neuroticism) could be transformed to a normal distribution. Non-parametric tests were therefore used in further analyses to examine study hypotheses. One-tailed tests were appropriate due to the use of directional hypotheses in the study. Bivariate non-parametric analyses (Spearman's Rho) were then conducted to examine associations between study predictor and outcome variables. The small sample size of the study limited analyses to correlations as assumptions of multivariate analyses were not met, the intended regression analyses could not therefore be conducted.

Results

Table 1a presents participant demographic characteristics. Of the 21 participants, 18 were male (86%) and 3 female (14%). The mean age of the sample was 67.7 years (SD = 9.67). The majority of the sample was married (52%) and retired (81%). Seventy-three percent (n = 15) had DEPCAT scores of 4 to 7 indicating the prevalence of socio-economic deprivation within the sample. Table 1b presents summary data for clinically relevant information. Physical comorbidities were gathered by self-report and grouped across five categories defined by the investigator. Cardiovascular and respiratory problems were reported by 32% of the sample. Anxiety or affective-related problems were reported by 20% (n = 4) participants, although clinically relevant diagnoses were not confirmed by medical records. No participants reported problems with drug or alcohol misuse, although this information was gathered by self report data only and not corroborated by medical records. Four participants (19%) reported previous history of a head injury; however, upon further investigation all were found to be of mild severity that had not required any neurological follow up.

[Insert Table 1a. here]

[Insert Table 1b. here]

The mean error score on the NART-R was 9.62 (SD = 4.39, range 3-15) was found for the sample. Mean score on the MMSE was 28.9 (SD = 1.04, range 27-30). The sample had scores above the clinical cut-off of 24 specified by the original MMSE validation study [22]. Scores found in the present sample are

consistent with recommendations of Kukull et al. [32] who suggest that a cut-off of 27 increases the MMSE's sensitivity in symptomatic individuals.

Table 2a presents psychological outcome data for all study measures. Mean score on the PITI (total scale) was 11.23 (SD = 11.55, range 0-49). This score is lower than data from the original study by Crockett et al. [15] who reported a mean score of 17.83 (SD = 11.63, n = 54) for investigative and 13.84 (SD = 9.97 n = 66) for non-investigative procedures. The present mean PITI total score is significantly lower than the mean score for investigative procedures reported in the study by Crockett et al. (t = 2.21, df = 73, p<0.05), but not significantly different from that of the non-investigative mean from the same study (t = 1.01, df = 85, p>0.1). The latter comparisons were computed using pooled variance estimates.

[Insert Table 2a. here]

Table 2b shows frequency of scores across clinical cut offs for the HADS and STAI based on published data. As table 2b shows, the majority of the sample scored within the "normal" range for both the anxiety and depression subscales of the HADS and state subscale of the STAI (72%, 95% and 57% respectively). The majority of the sample (96%) had scores across the normal and mild range on the trait subscale of the STAI.

[Insert Table 2b. here]

Table 3 summarises Spearman's correlations between PITI total, subscales and study predictor variables. In order to adjust for multiple comparisons and Type I error, $p<0.01$ was used as the critical level of significance as opposed to the conventional $p<0.05$. While additional methods of adjusting p-value include the Bonferroni method, this was deemed to be too conservative for the purposes of the present study [33]. A summary of inter-correlations across all study measures is presented in Appendix 2.13.

[Insert Table 3. here]

Hypothesis one – previous surgical history

Correlations between measure of previous surgical history and anxiety were non-significant (see Appendix 2.13): HADS (anxiety) $r_{rho} = 0.038$, $P = 0.877$ [95% CI = -0.371-0.435]; STAI (state) $r_{rho} = 0.001$, $P = 0.996$ [95% CI = -0.403-0.404] and STAI (trait) $r_{rho} = -0.071$, $P = 0.772$ [95% CI = -0.461-0.342]. A significant negative correlation between measure of previous surgical history and the pre-occupation subscale of the PITI was found ($r_{rho} = -0.565$, $P = 0.006$) [95% CI = -0.797-0.188] (see table 3). A negative surgical history (as indicated by lower scores on the visual analogue scale) was associated with increased pre-occupation as assessed by the PITI. Poorer surgical history was found to explain approximately 32% of the variance between surgical history and pre-occupation with surgery.

Hypothesis two – anxiety

As table 3 shows, the total score of the PITI was found to correlate with the state anxiety subscale of the STAI (r_{rho} = 0.513, *P* = 0.009) [95% CI = 0.138-0.759]. State anxiety accounted for 26% of the variance between this variable and PITI total score. Trait anxiety also correlated with the PITI total score (r_{rho} = 0.486, *P* = 0.013) [95% CI = 0.103-0.744], a finding that was significant at the $p<0.05$ level. Other significant correlations that were found at the $p<0.05$ level included the anxiety subscale of the HADS and dependence on others subscale of the PITI (r_{rho} = 0.408, *P* = 0.033) [95% CI = 0.006-0.697]. State and trait anxiety were correlated with control and unconscious subscales of the PITI (see table 3). Pre-occupation was found to be significantly correlated at $p<0.05$ level with trait anxiety (r_{rho} = 0.438) [95% CI = 0.042-0.715]. These results suggest that intrusive thoughts not only correlate with measures of anxiety, but that differences in types of intrusive thoughts and their association with anxiety are also evident. Both state and trait anxiety correlate with fear of being unconscious and loss of control, yet trait anxiety is also associated with preoccupation with the surgical procedure. Furthermore, the anxiety subscale of the HADS showed an association with dependence on others.

Hypothesis three – depression

Hypothesis three proposed that participants with increased levels of pre-operative depression will show an increased presence of intrusive thoughts. No significant correlations were found between HADS depression and any subscales on the PITI.

Hypothesis four – personality characteristics (neuroticism and psychoticism)

A strong association was found between neuroticism subscale of the EPQR-S and PITI total (r_{rho} = 0.570) [95% CI = 0.216-0.791] and dependence on others subscale (r_{rho} = 0.607) [95% CI = 0.270-0.812] both at p<0.01. Both of these correlations were of moderate magnitude, accounting for 32% and 37% of the variance across the variables respectively. This suggests the association of measures of neuroticism with levels of pre-operative anxiety. A negative correlation was found between the outcome subscale of the PITI and psychoticism subscale of the EPQR-S (r_{rho} = -0.710, *p*<0.001) [95% CI = -0.866 to -0.430] indicating that higher scores on psychoticism are associated with lower concerns with outcome of surgery. The magnitude of this correlation was moderate with 50% of the variance explained by the association between these two variables.

Discussion

This study has demonstrated the application of a brief assessment tool designed to assess anxiety and has considered the relationship of pre-operative intrusive thoughts to other psychological and personality variables.

Significant correlations were found between measures of anxiety and pre-operative intrusive thoughts. State anxiety correlated with the PITI total score, indicating that surgical patients do experience higher arousal related to their present situation. Those with enduring higher levels of anxiety (trait) also experience more pre-operative intrusive thoughts, although this relationship was significant at the p<0.05 level only. All other significant relationships were

found at the $p<0.05$ indicating a general trend for measures of state and trait anxiety to be related to fears regarding being unconscious, pre-occupation with the surgical procedure and loss of control. Interestingly, a significant correlation was found between the HADS anxiety subscale and dependence on others, a relationship that was only significant at the $p<0.05$ level and not detected by measures of state or trait anxiety. This provides preliminary evidence to suggest that differing measures of anxiety are able to detect varying types of intrusive thoughts. However, further research is required to validate such findings. Berth et al. [34] validated the APAIS [13] in a German population and despite finding significant correlations with this measure they have questioned the specificity and relevance of the HADS within the pre-operative situation.

Negative previous surgical experience (lower scores on the visual analogue scale) correlated with higher measures of pre-occupation on the PITI. This study has established an association between measures of intrusive thoughts and judgements about past surgeries. It could be hypothesised that past negative surgical experience, results in an individual engaging in increased periods of time thinking about their impending surgery. Given the nature of questions included under the pre-occupation subscale of the PITI (thoughts about the surgical procedure, feeling nervous while waiting for surgery) this seems a valid assertion. Caumo et al. [35] found that previous surgery reduced the risk of pre-operative anxiety. However, unlike the present study, the nature of surgical experience was not assessed and present findings may indicate the importance of the nature of such experience in moderating levels of psychological distress.

Contrary to expectations, levels of depression were not found to correlate significantly with the PITI. This finding is inconsistent with those published by Crockett et al. [15] who found significant associations with the HADS depression subscale and all six subscales of the PITI. This finding is also contrary to the results of Whitaker et al. [36] who found that the presence of intrusive cognitions was significantly associated with sadness, anxiety and helplessness. Examination of the score range of the present HADS depression subscale revealed that no scores were above the clinical "caseness" threshold (≥11), furthermore the mean score was within normal limits (3.86, SD = 2.63). This finding indicates that it was unlikely that the present sample had scores that indicated prevalence of depression and hence that an association with the PITI or its subscales would be unlikely.

Measures of neuroticism were found to correlate positively with the PITI total and dependence-on-others subscale. Harvey et al. [37] suggest that dependent upon the nature of the intrusive thought (indicative of danger or self referent) this may trigger rumination [37]. It has also been proposed that neuroticism may be related to rumination [38]. Taken together, this could suggest that intrusive thoughts are a precipitating factor for rumination and that personality traits such as neuroticism increase the likelihood of this style of thinking occurring. This would explain the associations between neuroticism and depression and anxiety documented within literature [39].

Psychoticism scores correlated negatively with scores on the outcome subscale of the PITI. This finding was unexpected but may be explained by the relationship

of psychoticism to indifference about personal safety and emotional coldness. Heath and Martin [40] report that high scorers on Psychoticism scale are described as impersonal, lacking in sympathy and insight. The negative correlation found between psychoticism and outcome of surgery may be related to a decreased lack of insight into the consequences of surgery or indeed decreased attendance to such information. Further research is required to evaluate these assertions.

Within the present study, the mean score for the PITI was significantly lower than that reported by Crockett et al. [15] for investigative procedures, but not for non-investigative procedures. The comparison with investigative is most apt given that the present participants were having an elective surgical procedure. It appears that the scores of the present sample represent lower levels of distress than the original study by Crockett et al. [15]. Low levels of distress within the present sample are also further supported by fact that the majority of the scores on the psychological outcome measures are positively skewed. Furthermore, as described above, there was no association between measures of intrusive thoughts and depression, largely because no participants met the clinical "caseness" threshold for depression as defined by the HADS.

Reasons for lower levels of distress within the present sample may be due to the nature of recruitment (participants consented to be approached and were self-selected into the study) which favoured participants who were functioning better psychologically and therefore more willing to volunteer their time. Participants with greater concerns about their impending surgery may have been more

reluctant to engage in research focused upon surgical anxieties. Furthermore, lower levels of distress may reflect the feelings participants had about this particular type of surgery. It may be the case that the prospect of hernia surgery, which is routine and with low morbidity and very low mortality did not evoke similar levels of distress to those classified as investigative by Crockett et al. [15]. An example of a non-investigative procedure in the latter study was laparoscopic tubal ligation (closure of fallopian tubes in order to prevent fertilisation). Further research is required to consider whether such variation within types of non-investigative surgical procedures may lead to different levels of distress exhibited.

Applications for Clinical Psychology

Clinical practice demands the need for measures of pre-operative distress to be brief but sensitive [13,15]. Such measures should allow clinicians to identify those experiencing levels of distress that warrant further attention and intervention. Research has consistently shown the relationship between pre- and post-operative anxiety states, with Gallagher and McKinley [41] reporting that those who are anxious pre-surgery are more likely to continue to be anxious post-surgery. This necessitates the use of an assessment tool designed to detect pre-operative distress. The PITI is a viable candidate for use in a surgical environment. Gallagher and McKinley [41] state the importance of detecting particular personality profiles that lead to increased difficulties in adjustment. The present research has found preliminary evidence for the association of enduring characteristics such as trait anxiety, neuroticism and psychoticism which may predispose individuals to greater problems. Such information would

be of crucial importance in designing and tailoring interventions appropriately. Interestingly, within the present study, psychoticism was found to be associated with decreased concerns with surgical outcome; hence, prospective research may be required to determine the impact of such characteristics to short and long term recovery.

Vaughn et al. [42] highlight the importance of psychological aspects of pre-operative preparation and suggest the role of nurse-led assessment and intervention programs to reduce anxiety. Interventions may take the form of behavioural (controlled breathing) and cognitive (restructuring of thoughts) approaches. The efficacy of such approaches is uncertain at present [42]. Despite the suggested implementation of programs by nursing staff, since methods would be informed by psychological principles, it necessitates the role of Clinical Psychologists in the design and evaluation of interventions for pre-operative anxiety.

Methodological issues

There are a number of methodological issues to consider. Estimated sample size could not be met resulting in a reduction in the statistical power of the study, thus precluding the intended regression analyses. Due to limitations of sample size, only correlation analysis could be conducted, hence limiting the conclusions that could be drawn regarding the independent variables. Additional methods of data analysis were considered. A conventional method is the "median split", whereby scores are divided at the middle point to create groups scoring "high" and "low" on the variable of interest. Such a method could have been employed in the

present study in order to compare "group" differences. Based on recommendations of published literature, such dichotomisation was not conducted. Irwin and McClelland [43] question the use of such methods stating that consequences of dichotomisation include loss of effect size and power and, importantly, loss of measurement reliability as psychometric properties of scales are developed on measures that are continuous. Additional methods of defining thresholds in continuous data include the use of clinical cut-points defined by pre-existing normative data. However, examination of the range of scores revealed an inequitable distribution of participants across the pre-defined cut-points that made this approach non viable.

Nelson and Willison [20] report that the NART-R should be used with caution in participants aged 70 years and above as no participants of this age were included in the standardisation sample. In the present study, 29% of the sample was aged 70 and above, making interpretation of results in elderly subjects problematic although other studies have reported that the NART-R is resistant to ageing effects up to 84 years of age [44]. Despite attempting to exclude participants with physical co-morbidities, 32% of the sample reported a history of cardiovascular problems, introducing a potential confound into the study sample.

Analysis by gender could not be completed due to the unequal gender distribution reflecting the greater prevalence of hernia operations in men [45]. Previous studies that have examined gender differences did find that women were more anxious than men pre-operatively [46,47], suggesting the importance of gender differences in measure of pre-operative distress.

Munafò and Stevenson [9] highlight the importance of assessing distress both subjectively and objectively. The majority of evidence is based on self-report data as was the case in the present study. Vaughn et al. [42] suggest the use of objective or physical indicators of anxiety such as cortisol levels to increase the validity of self-report data.

A visual analogue scale was devised for the purpose of the study to assess experience of previous surgeries. Miller and Ferris [48] state the importance of psychometric properties of reliability and validity in determining the use of such measures. The present study could not conduct any assessment of internal consistency as only one data point per scale was collected. By virtue of using a cross-sectional design, participants were only assessed on one occasion; therefore repeat assessments could not be conducted in order to assess reliability of responses. Nor could measures of validity be conducted as the nature of previous surgical experience was only assessed by the visual analogue scale. Miller and Ferris [48] propose the benefits of the visual analogue scale in allowing individuals to represent feelings and perceptions that are then amenable to numerical quantification. However, research has also identified sources of error affecting validity of the visual analogue scale. In particular, the scale calls into question whether variation in responses is related to relative or absolute differences. It could be argued that a positive or negative assessment of previous surgery may not be equivalent to others within the sample and only relevant to that individual's subjective perception. These conceptual matters are of importance when using visual measures of such phenomena.

The use of a cross-sectional design limits the conclusions about causality that can be drawn. It is important to consider evidence from prospective studies that have considered the relationship between pre- and post-measures of psychological functioning [9]. Furthermore, a recent systematic review conducted by Iqbal and Millar [49] found evidence for the benefit of psychosocial variables such as social support as implicated in pre- and post-operative psychological distress. This suggests the importance not only of individual differences, but also the value of considering psychosocial factors implicated in adjustment to surgery.

Conclusion

This study has demonstrated evidence for a significant association between pre-operative intrusive thoughts and state anxiety, neuroticism and previous surgical history. A negative association between the personality trait of psychoticism and intrusive thoughts may suggest a personality factor that predisposes individuals to emotional indifference to surgical events. Due to limitations of sample size and methodology, analysis to determine predictors of intrusive thoughts and causality could not be determined. Furthermore, this study found that scores of pre-operative intrusive thoughts were significantly lower than mean scores for investigative procedures as previously demonstrated by Crockett et al. [15] reflecting the low levels of distress within the present sample. This was further corroborated by low mean scores on other psychological outcome measures used within the study. Assessment of pre-operative functioning will help to detect those requiring intervention to facilitate adjustment to surgery both pre- and post-operatively.

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Figure 1: Participant identification and recruitment flow chart

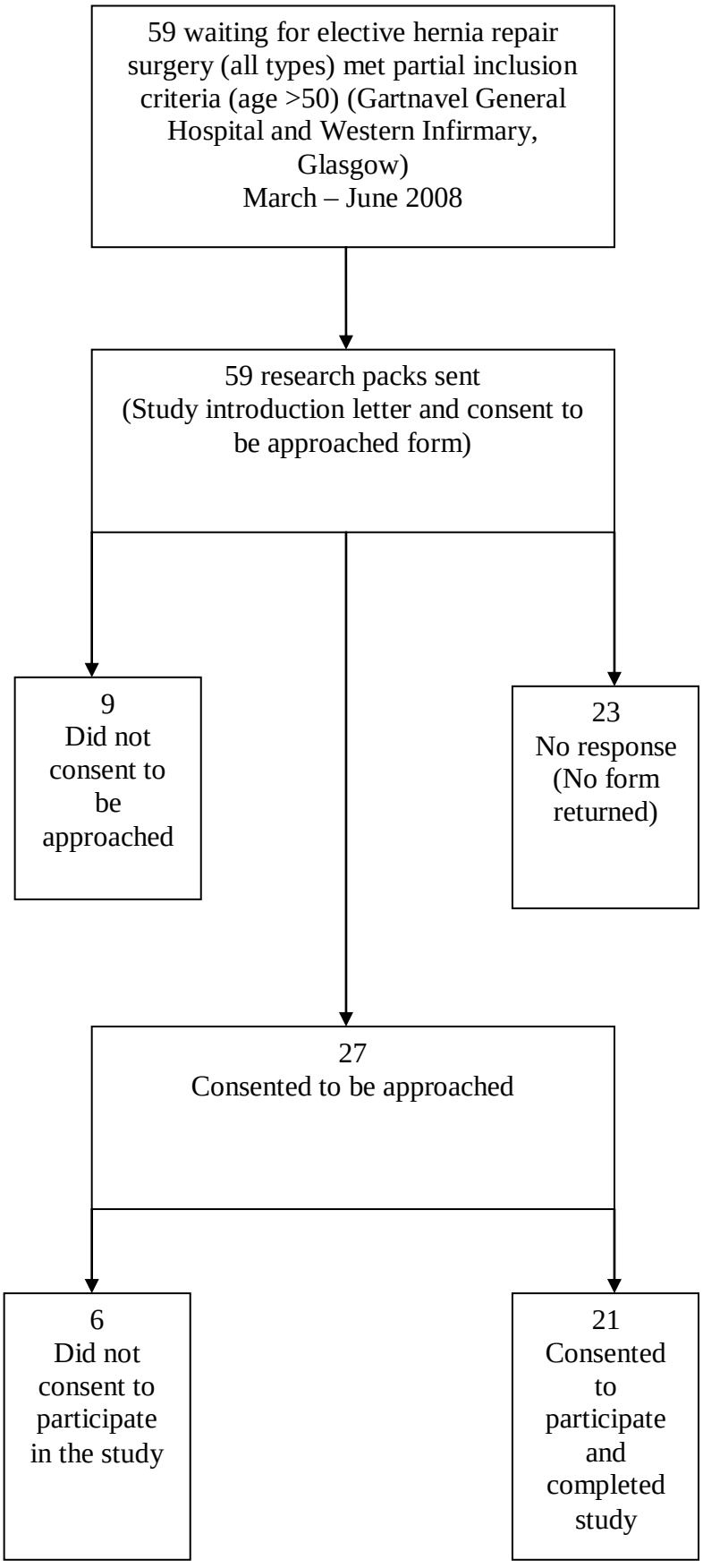

Table 1a: Participant Characteristics

Gender (%) N = 21	
Male	86 (n = 18)
Female	14 (n = 3)
Mean age (SD) N = 21	
Male	67.61 (9.41) (n = 18) 55-88 years
Female	68.33 (13.5) (n = 3) 55-82 years
Total sample	67.71 (9.67) (N = 21) 55-88 years
Marital status (%) N = 21	
Married	52 (n = 11)
Widowed	24 (n = 5)
Divorced	10 (n = 2)
Single	10 (n = 2)
Living with partner	5 (n = 1)
Employment Status (%) N = 21	
Employed	19 (n = 4)
Retired	81 (n = 17)
Mean years of education (SD)	10.12 (1.3). Range: 7-13 years
Socioeconomic Status – DEPCAT score (%) N = 21	
DEPCAT 1	19 (n = 4)
DEPCAT 2	5 (n = 1)
DEPCAT 3	5 (n = 1)
DEPCAT 4	29 (n = 6)
DEPCAT 5	10 (n = 2)
DEPCAT 6	29 (n = 6)
DEPCAT 7	5 (n = 1)

Table 1b: Participant Characteristics – Clinically relevant data

Previous Surgical History (%) N = 21	
Yes	(91) (n = 19)
No	(10) (n = 2)
Screening measures	
Mean NART error (SD)	9.62 (4.39) 3-15
Mean MMSE score (SD)	28.9 (1.04) 27-30
Comorbidities	
Physical health (%) (N ≠ 21 multiple conditions reported by sample) – self report	
Cardiovascular conditions	(32) (n = 6)
Respiratory conditions	(32) (n = 6)
Arthritis	(16) (n = 3)
Digestive system problems	(16) (n = 3)
Cancer (previous history)	(5) (n = 1)
Anxiety or mood related difficulties (%) (n = 4) – self report	
Anxiety disorder	(10) (n = 2)
Affective disorder	(10) (n = 2)
Drug and alcohol misuse (%) (N = 21) – self report	
Yes	(0) (n = 0)
No	(100) (n = 21)
Past history of head injury (%) (N = 21) – self report	
Yes	(19) (n = 4)
No	(81) (n = 17)

Table 2a: Psychological outcome data (including range, mean, SD, median, IQR, confidence interval and tests of normality)

Measure	Range	Range (present study)	Mean (SD)	Median (IQR)	Confidence Interval (95%)	Skewness (Standard Error)	Kurtosis (Standard Error)	Kolmogorov-Smirnov test of normality (p<0.05)
PITI (total)	0-60	0-49	11.23(11.55)	8 (4.5-12)	5.98-16.49	2.10 (0.50)	5.00 (0.97)	P = 0.000
PITI (unconscious)	0-12	0-10	2.05 (2.46)	1 (0-4)	0.93-3.17	1.86 (0.50)	4.34 (0.97)	P = 0.000
PITI (pre-occupation)	0-12	0-10	2.43 (2.88)	1 (0.5-3)	1.12-3.74	1.62 (0.50)	1.86 (0.97)	P = 0.005
PITI (outcome)	0-9	0-6	1.62 (1.81)	1 (0-2.5)	0.80-2.44	1.32 (0.50)	0.84 (0.97)	P = 0.000
PITI (pain/discomfort)	0-9	0-8	2.05 (2.22)	1 (0.5-3)	1.04-3.06	1.56 (0.50)	2.09 (0.97)	P = 0.008
PITI (dependence on others)	0-9	0-8	1.95 (1.96)	1 (0.5-3)	1.06-2.85	1.52 (0.50)	3.21 (0.97)	P = 0.016
PITI (control)	0-9	0-7	1.14 (1.62)	1 (0-2)	0.40-1.88	2.55 (0.50)	8.28 (0.97)	P = 0.001
HADS (anxiety)	0-21	0-15	6.29 (4.35)	7 (3-9)	4.31-8.27	0.37 (0.50)	-0.49 (0.97)	P = 0.200
HADS (depression)	0-21	0-8	3.86 (2.63)	5 (1-6)	2.66-5.06	-0.19 (0.50)	-1.36 (0.97)	P = 0.042
STAI (state)	20-80	22-60	37.29 (10.19)	37 (30-43)	32.65-41.93	0.45 (0.50)	-0.10 (0.97)	P = 0.200
STAI (trait)	20-80	25-60	39.14 (8.71)	40 (33-43)	35.18-43.11	0.44 (0.50)	0.55 (0.97)	P = 0.200
EPQR (psychoticism)	0-12	0-7	2.10 (2.10)	1 (0-4)	1.14-3.05	0.87 (0.50)	-0.05 (0.97)	P = 0.008
EPQR (extraversion)	0-12	0-12	6.53 (4.08)	6 (2.5-10.5)	4.67-8.38	-0.04 (0.50)	-1.52 (0.97)	P = 0.200
EPQR (neuroticism)	0-12	0-11	4.52 (3.96)	4 (1-8)	2.72-6.33	0.36 (0.50)	-1.32 (0.97)	P = 0.037
EPQR (social desirability)	0-12	0-11	5.86 (2.94)	6 (3.5-8)	4.52-7.19	0.36 (0.50)	-0.52 (0.97)	P = 0.200
Previous surgical history n=19	0-100	12-100	73.63 (26.40)	78 (64-100)	60.91-86.36	-0.99 (0.52)	0.41 (1.01)	P = 0.200

MEASURES – KEY
PITI = Pre-operative Intrusive Thoughts Inventory; HADS = Hospital Anxiety and Depression Scale; STAI = State Trait Anxiety Inventory; EPQR = Eysenck Personality Questionnaire Revised

Table 2b: Frequency of scores across clinical cut off data – Hospital Anxiety and Depression Scale (HADS) and State Trait Anxiety Inventory (STAI)

Hospital Anxiety and Depression Scale (%) (N = 21)				
	Normal (0-7)	**Borderline (8-10)**	**Clinical "caseness" (11+)**	
HADS (anxiety)	(72) (n =15)	(14) (n = 3)	(14) (n = 3)	
HADS (depression)	(95) (n= 20)	(5) (n =1)	(n = 0) (0)	
State Trait Anxiety Inventory (%) (N = 21)				
	Normal (20-39)	**Mild (40-55)**	**Moderate (56-65)**	**Severe (65+)**
STAI (state)	(57) (n = 12)	(38) (n = 8)	(5) (n =1)	(n = 0) (0)
STAI (trait)	(48) (n = 10)	(48) (n = 10)	(5) (n =1)	(n = 0) (0)

Table 3: Spearman's rho correlations between study predictor and outcome variables

Measure	HADS A	HADS D	STAI S	STAI T	EPQR P	EPQR E	EPQR N	EPQR S	PSH
PITI (total)									
Correlation co-efficient	0.357	0.284	0.513**	0.486*	-0.433*	0.198	0.570**	0.038	-0.066
Significance 1-tailed	0.056	0.106	0.009	0.013	0.025	0.195	0.003	0.436	0.394
PITI (unconscious)									
Correlation co-efficient	0.338	0.252	0.495*	0.402*	-0.471*	0.153	0.492*	0.035	-0.124
Significance 1-tailed	0.067	0.135	0.011	0.035	0.016	0.254	0.012	0.440	0.306
PITI (pre-occupation)									
Correlation co-efficient	0.256	0.326	0.364	0.438*	-0.447*	-0.018	0.410	0.061	-0.565**
Significance 1-tailed	0.131	0.074	0.053	0.023	0.021	0.469	0.032	0.396	0.006
PITI (outcome)									
Correlation co-efficient	0.134	0.091	0.300	0.341	-0.710**	0.184	0.202	-0.200	-0.059
Significance 1-tailed	0.281	0.347	0.093	0.065	0.000	0.212	0.189	0.192	0.406
PITI (pain/discomfort)									
Correlation co-efficient	0.217	0.205	0.232	0.205	-0.470*	0.156	0.190	-0.277	0.029
Significance 1-tailed	0.172	0.186	0.156	0.186	0.016	0.250	0.204	0.112	0.453
PITI (dependence on others)									
Correlation co-efficient	0.408*	0.203	0.336	0.306	-0.186	0.359	0.607**	0.102	-0.095
Significance 1-tailed	0.033	0.189	0.068	0.089	0.209	0.055	0.002	0.330	0.350
PITI (control)									
Correlation co-efficient	0.313	0.350	0.400*	0.474*	-0.167	0.120	0.497*	0.038	-0.257
Significance 1-tailed	0.084	0.060	0.036	0.015	0.235	0.303	0.011	0.434	0.144

PITI = Pre-operative Intrusive Thoughts Inventory; HADS A = Hospital Anxiety and Depression Scale (anxiety); HADS D = Hospital Anxiety and Depression Scale (depression); STAI S = State Trait Anxiety Inventory (State); STAI T = State Trait Anxiety Inventory (Trait); EPQR P = Eysenck Personality Questionnaire Revised (Psychoticism); EPQR E = Eysenck Personality Questionnaire Revised (Extraversion); EPQR N = Eysenck Personality Questionnaire Revised (Neuroticism); EPQR S = Eysenck Personality Questionnaire Revised (Social desirability); PSH = Previous surgical history

**Correlation is significant at the 0.01 level (1-tailed)
*Correlation is significant at the 0.05 level (1-tailed)
r, correlation co-efficient; N = 21 for all correlations except PSH (N = 19)

Chapter 3: Advanced Clinical Practice I Reflective Account

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"TheraPet"

Submitted in partial fulfilment for the requirements of the degree of Doctorate in Clinical Psychology

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Abstract

Clinical Psychology is beginning to embrace the role of reflection and how such theoretical approaches can inform our practice. The work of Schön (1983) has been influential in generating models of reflection that can be applied to a range of experiences encountered. Within Clinical Psychology, practitioners have considered the importance of reflection as an aid to understanding the process of therapy and professional issues.

The present account, describes a therapeutic session which generated emotions within myself that were amenable to reflection. The work of Schön (1983) was chosen to help structure my reflective account. This model provided a structure to conceptualise my thoughts, yet provided the flexibility to question my practice and the consequences of having experienced such a situation.

Extending beyond the review, I reflect on questions that require me to consider my training experience to date as well as my expectations of future practice. Such reflections have assisted in developing an understanding of my identity as a therapist in the early stages of my career.

Chapter 4: Advanced Clinical Practice II Reflective Account

Salma Iqbal[1]

There is no "I" in team

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Abstract

There is a growing emphasis on the role of Clinical Psychology within multidisciplinary working. At my present stage of training, the emphasis on working in close collaboration with colleagues is of paramount importance to achieving advanced clinical competencies.

The present account details my experience of working in an older adult multidisciplinary team. I reflect upon the process of learning using Kolb's model of experiential learning (1984) and consider my journey across the stages of concrete experience, reflective observation, abstract conceptualisation and active experimentation. This model allowed me to accurately chart my experience on placement and to objectively quantify the change in not only my knowledge and skills but the effect this had on my multidisciplinary colleagues.

I consider the impact of my work on not only my current learning but the implications it has on my future practice as I begin to embrace the roles that I hold both clinically and professionally within the National Health Service.

Appendix 1.1 Notes for contributors to: Psychosomatic Medicine

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Manuscripts are reviewed with the understanding that they are original, have not been published other than in an abstract form, and are not under simultaneous review elsewhere. All authors must approve of the submission, and before publication, the corresponding author should secure permission to name anyone listed under acknowledgments. Most manuscripts are sent to outside peer reviewers, but a small percentage are evaluated only in-house and may be rejected if they are not suitable for the journal or up to the journal's quality standards. *Psychosomatic Medicine* requests authors to adhere to the journal's statistical guidelines, available on the Web at: http://www.psychosomaticmedicine.org/misc/stat.shtml. The journal endorses several statements developed to improve the quality of medical research reports. Authors are encouraged to consult the CONSORT, MOOSE, and QUOROM statements, available on the World Wide Web at: http://www.consort-statement.org.

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Journals: Irvine J, Baker B, Smith J, Jandciu S, Paquette M, Cairns J, Connolly S, Roberts R, Gent M, Dorian P. Poor adherence to placebo or amiodarone therapy

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Appendix 1.2 Methodological quality criteria checklist

Study design	**Study design selected** (mark with an X)	**Points awarded** 1 point: Case report 2 points: Time series/uncontrolled design 3 points: Cohort/case-control 4 points: Unrandomised controlled trial 5 points: Randomised controlled trial
Experimental, randomised		
Placebo-controlled trial		
Comparative trial, no placebo		
Time series trial		
Crossover trial		
Experimental, unrandomised		
Placebo-controlled trial		
Comparative trial, no placebo		
Time series trial		
Crossover trial		
Nonexperimental		
Cohort, prospective		
Cohort retrospective		
Cross-sectional		
Case-control		
Case reports or case series		

Definition of methodological quality criteria

Criterion	Definition
Yes	Question answered, clear reference to methodology/procedure used, would allow procedure to be replicated. No ambiguity in information/conclusions presented.
Partially addressed	Question answered, partial reference to methodology/procedure used. Degree of ambiguity present in procedure or information presented.
No/not addressed	Question not answered, indicating that this aspect of study design was ignored or not completed.
Not applicable	Question not relevant to study.

Quality Criteria	Yes 2 points	Partially addressed 1 point	No/not addressed 0 points	Not applicable Omit from scoring
Introduction				
1. Is the hypothesis/aim/objective of the study clearly described?				
2. Are the main outcomes to be measured clearly described in the introduction or method section?				
Methodology/sample characteristics				
3. Are the characteristics of the participants included in the study clearly described? *Are study inclusion/exclusion criteria specified?*				
4. Are participant demographics (age, gender, socioeconomic				

and marital status) adequately described? *Socioeconomic status defined by either employment status or years of education*.				
5. Was the study design appropriate to answer the study question?				
6. Were study participants appropriate to the study question? *Evidence that distribution of main confounding variables is the same in the study sample and source population*. *Proportion of those asked who agreed, must be stated*. *Study must identify source population and describe how patients were selected*. *Representative if:* - *Entire population used in study*. - *Unselected sample of consecutive patients*. - *Random sample*.				
7. Were control subjects appropriate? *If no controls were used, check not applicable*.				
8. What was the method of selection from the target population? *0 = Highly selective sample (volunteers)*. *1 = Sample of convenience/not random selection (clinic attendees)*. *2 = Probability or random sampling used*.				
9. If participants were selected at random, was the method of random selection sufficiently well described?				

Not applicable = if participants were not randomly selected or sample of convenience. *If participants were randomly selected:* *1 = unclear or vague description.* *2 = adequate (process of probability or random sampling is clearly documented and replicable).*				
10. If participants were randomly allocated to treatment/intervention groups, was the method of random allocation sufficiently described? *If participants were not randomly allocated check not applicable.*				
11. Was the process of randomisation robust? *0 = Inadequate if use of alternation, case record numbers, birth dates or week days.* *1 = unclear or not stated.* *2 = Adequate (computer generated random numbers or random number tables).* *If participants were not randomly allocated check not applicable.*				
12. If blinding of investigators to intervention was possible, was it reported? *If not possible, check not applicable.*				
13. If blinding of participants to intervention was possible, was it reported? *If not possible, check not applicable.*				
14. Was measurement bias accounted for by methods other				

than blinding? *Has the measurement tool (i.e. questionnaire) been piloted?* *Have the administrators been trained?* *Evidence of statistical procedures to adjust for bias (if applicable)* *Best practice: Multiple measures of the same construct?*				
15. Were known confounders accounted for by study design? *If no known confounders, check not applicable.*				
16. Were known confounders accounted for by analysis? *If no known confounders, check not applicable.*				
17. Was there a sample size justification before the study?				
Results/statistical analysis				
18. Were outcome measures supported by evidence of validity and reliability statistics.				
19. Were post hoc power calculations or confidence intervals reported for statistically non-significant results?				
20. Were statistical analyses appropriate?				
21. Were the statistical tests stated?				
22. Were exact P values or confidence intervals reported for each test? *2 points for exact p value stated.* *1 point for P<0.05 or P<0.01.*				
23. Were attrition of participants and reason for attrition recorded?				
24. For those participants who completed the study, were results completely recorded? i.e. were drop outs included in the analysis?				

Discussion/implications of results				
25. Do the findings support the conclusions?				
26. Are the main findings of the study clearly described?				
27. Does the study make recommendations for clinical practice based on findings?				

Total points awarded: _____
Total points awarded divided by total possible points (sum of maximum points, except for non applicable ratings): _____

Quality criteria assessment decimal rating: _____

Quality assessment decimal rating	Quality assessment decimal rating selected (select appropriate box)
0.75 and above (A – high quality)	
0.60-0.74 (B – moderate quality)	
0.50 and 0.59 (C – low quality)	
≤0.49 (D – poor quality)	

Appendix 2.1 Major Research Project Proposal

MAJOR RESEARCH PROJECT PROPOSAL

The application of the Pre-operative Intrusive Thoughts Inventory (Crockett et al. 2007) in an elective hernia repair surgery population

Ms Salma Iqbal[1]

Submitted in partial fulfilment for the requirements of the degree of Doctorate in Clinical Psychology

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Abstract

Background

It has been found that individuals who exhibited levels of pre-operative anxiety were more likely to be anxious in the post-surgery and post-discharge phase. Researchers are beginning to develop measures of pre-operative anxiety, an example of which is the Pre-operative Intrusive Thoughts Inventory (PITI) (Crockett et al., 2007). Its development and validation was conducted with a relatively young patient sample (mean age 42 years).

Aims

The aim of the proposed study is to evaluate the application of the PITI (Crockett et al., 2007) in a middle aged to older adult population. The proposed study aims to consider what factors modify levels of pre-operative intrusive thoughts within a population awaiting elective hernia repair.

Methods

A cross-sectional design will be used to consider anxiety, depression, nature of previous surgical experience and personality characteristics in relation to levels of pre-operative intrusive thoughts within a population of patients awaiting elective hernia surgery.

Applications

Research considering what psychological variables are of importance in the pre-operative period is importance to Clinical Psychology, as it may help to elucidate factors that are amenable to psychological intervention.

Introduction

The experience of surgery and hospitalisation in mid to later life

The experience of surgery and hospitalisation is well documented as stressful and the manner by which an individual adapts to such a life event is of inherent importance to post-surgery recovery (O'Hara et al., 1989). Blacher (1987) states that psychological reactions to surgery are more common than have been previously realised. Zambricki (2000) notes that particular stresses caused by surgery and hospitalisation can be found to affect elderly patients to a greater extent than other populations. Such concerns may be related to their particular stage of life. However, this finding is contradicted by Plach et al., (2003). In a study examining incidence of post-operative depression in individuals recovering from heart surgery, it was found that that older women (aged 66 years and above) had lower mean scores on a measure of depression compared to women aged between 40-55 years. Plach et al., (2003) attribute such a result to the incidence of cardiac events as being more expected later in life and therefore the psychological resources that are required to deal with such an event are not as disruptive to an individual's psychological well being. Findings described by Plach et al., (2003) have limited generalisability as only females were sampled and a high percentage was from a white ethnic background. It is recommended that future research should consider age as a significant factor in relation to post-surgical emotional functioning.

There is evidence to suggest that with increasing age, individuals become more vulnerable to the effects of anaesthesia (Rohan et al., 2005). Findings from Rohan et al., (2005) state that additional factors as opposed to the specific

anaesthetic drug may be implicated in post-operative complications. These include the stress response to surgery, anxiety and other changes required pre- and post-surgery may have an impact upon memory and concentration. The majority of studies published have considered whether there is cognitive impairment post-surgery but have not examined psychosocial variables across the entire duration of hospitalisation. This has led to a difficulty in being able to attribute findings to post-operative adjustment or the prevalence of pre-existing risk factors such as economic or social support that may have predisposed difficulties in adjustment (Di Monaco et al., 2003). If identification of predisposing and precipitating factors to poor post-operative adjustment is possible, then such information is amenable to interventions designed to target such factors (Plach et al., 2003).

Applications of models of anxiety and worry to psychological functioning in surgical patients

The presence of worry is recognised in anxiety disorders and most notably in Generalised Anxiety Disorder (GAD) (Wells, 1997). Worry is defined as a "chain of thoughts and images, negatively affect-laden and relatively uncontrollable" (Borkovec et al., 1983, p.10).

Wells (1997) states that worry may assume two different forms. Type 1 worry is in relation to events such as concern with regards to external events (e.g. health of a partner) or internal states such as bodily sensations. Behavioural consequences of Type 1 worry include avoidance of external dangers. At an emotional level, Type 1 worry can lead to increases in anxiety or tension. Type 2

worry is related to the nature and occurrence of worry related thoughts. Common thoughts include a fear that worry will produce physical or psychological ill health (Laidlaw et al., 2003). Worry is noted to impair emotional processing as well as adaptive problem solving capabilities (Wells, 1997). Borkovec et al., (1998) suggests that many individuals hold the belief that worry helps prepare for the worst and at a maladaptive level, leads to a cognitive avoidance of perceived dangers.

Research evidence has suggested that worry suppresses physiological responses to threatening stimuli. This results in negative reinforcement of the use of worry as a technique by which the experience of physiological symptoms of anxiety can be reduced (Borkovec et al., 1998). It is hypothesised that this may be an explanation as to why individuals may hold the belief that worry is useful. However, such experiences are only beneficial in the short term reduction of physiological correlates of anxiety. Such theoretical models and empirical findings can facilitate understanding of the role of pre-surgery-related worry. The use of worry as an avoidant coping strategy provides short term benefits (less physiological correlates of anxiety). However in the long term, it results in a reduction of emotional processing of the event. Furthermore, there is evidence to suggest that worry has been noted to increase intrusive thoughts after exposure to a stressor. This has implications for adjustment to a significant event such as impending surgery.

Status of psychological functioning pre- and post-surgery

With research having focused upon post-operative psychological impairment (Lewis et al., 2005) there is now a greater need to identify the origin of such difficulties and the relationship to pre-operative psychological functioning. Researchers have found that higher levels of pre-operative anxiety relate to the need to use higher doses of anaesthetics (Goldmann et al., 1988). Incidence rates of pre-operative anxiety in patients scheduled for cardiac surgery has been noted to vary from 25% to 80% (Koivula et al., 2001). Variation in reports of incidence can be attributed to differences in measurement tools as well as what stage of treatment measurements were taken.

The impact of hospitalisation necessitates those involved in post-operative care to consider factors that are of specific relevance to an individual's stage of life. Specific surgery-related stressors include a decrease in independence and functioning inhibiting factors such as fatigue or chronic pain (Zambricki, 2000; Robinson, 1999). The need for adequate psychological assessment both pre- and post-surgery is now being advocated. Oxlad and Wade (2006) indicate the importance of psychological variables as crucial in further explaining the health status of individuals who have had cardiac surgery. Numerous studies have reported a relationship between pre-operative depression and anxiety in individuals undergoing Coronary Artery Bypass Surgery and their post-operative psychological functioning (Pignay-Demaria et al., 2003). Of the studies that have examined pre- and post-operative psychological states, levels of depression and anxiety are at their highest pre-surgery and then reduce post-surgery (Pirraglia et al., 1999; Vingerhoets, 1998). This fluctuation in emotional state

has been examined further by a study of fear and anxiety in pre-Coronary Artery Bypass Surgery patients (Koivula et al., 2001). Variations in levels of anxiety were crucial in how patients prepared for and adjusted to life, post-operation. It was found that higher levels of pre-operative anxiety were associated with the presence of post-operative depression. Furthermore, a moderate level of anxiety has been reported to increase motivation to adapt to life changes and develop effective coping skills.

Studies have documented that patients with higher levels of pre-operative anxiety had poorer psychological outcome including a greater experience of pain, less symptom relief and a higher rate of readmission (Nelson et al., 1998; Duits et al., 1997). In a study examining stress and anxiety in patients undergoing coronary artery bypass surgery, Gallagher and McKinley (2007) found that certain patient-related factors were predictive of higher levels of anxiety in the pre-surgery phase. Predictors included being female, level of pain or discomfort and concerns with regards to resuming social roles. In the post-discharge phase, older age was associated with higher anxiety levels.

Several studies have considered previous surgical experience in relation to pre-operative anxiety. Domar et al., (1989) state that previous surgical experience may lead to lower levels of anxiety due to a familiarity with subsequent procedures. In a study examining risk factors for pre-operative anxiety in adults, Caumo et al., (2001) also found that previous surgery reduced the risk for pre-operative anxiety. However, such findings should be interpreted with caution as the nature of previous surgical history was not examined. Caumo et al., (2001)

asked participants if they had previously experienced surgery without considering the emotional consequences of such an event. An understanding of the manner in which individuals emotionally conceptualised their previous surgical experience is warranted to determine whether this would moderate levels of anxiety in the pre-operative phase.

Coping and adjustment is subject to the status of psychological and psychosocial functioning as well as other more enduring characteristics such as personality. Certain personality constructs will predispose individuals to a more problematic post-operative adjustment. Timberlake et al., (1997) provide evidence to suggest that stable factors such as trait anxiety were found to significantly predict incidence of depression post-surgery. Aspects of personality such as neuroticism have been associated with difficulties in recovery from Coronary Artery Bypass Graft Surgery (Jerram and Coleman, 1999). Furthermore, it has been found that individuals with high scores on measures of neuroticism have an increased likelihood of suffering from emotional difficulties (Caruso et al., 2001).

Gallagher and McKinley (2007) state that intervention for pre-operative anxiety is warranted as results have shown that individuals who exhibited levels of pre-operative anxiety were more likely to be anxious in the post-surgery and post-discharge phase. Such findings provide support for the need for routine assessment of pre-operative anxiety in order to determine groups of individuals appropriate for psychological or pharmacological intervention (Gallagher and McKinley, 2007; Koivula et al., 2001).

Development of instruments for measurement of pre-operative anxiety

Researchers have begun to develop pre-operative measures of surgical-related thinking but findings are in the preliminary stages. The Amsterdam Pre-operative Anxiety and Information Scale (APAIS) (Moerman et al., 1996) is a six-item questionnaire examining anxiety and fear in relation to anaesthesia and surgery. The questionnaire is divided into two subscales; anxiety-related thoughts and need for information. The APAIS had good psychometric properties and correlated well with the State-Trait Anxiety Inventory (Spielberger et al., 1970). Higher scores on the need for information subscale were related to an increased score on the anxiety subscale. An increased need for information may trigger more distress-related reactions, resulting in an increased level of anxiety experienced.

Crockett et al., (2007) have developed the PITI which is a 20-item questionnaire designed to assess pre-operative anxiety. The PITI is divided into six subscales which examine preoccupation with the surgical procedure, concerns with outcome, anxieties regarding being unconscious, loss of control, dependence on others and pain/discomfort. In a validation study of the PITI, 128 participants were assessed across a range of surgical subspecialties. Crockett et al. (2007) found the scale to have good internal consistency ($\alpha = 0.91$) and good sensitivity and specificity to detect clinically-significant anxiety levels. Furthermore, the PITI showed that investigative surgical procedures generated higher scores than did non-investigative procedures.

Rationale for proposed study

There is a growth of assessment tools being developed specifically to assess level of pre-operative anxiety (Moerman et al., 1996; Crockett et al., 2007). However, measures are in preliminary stages of development and require generalisability to other surgical populations and age groups. In the studies by Moerman et al., (1996) and Crockett et al., (2007), the mean age of participants was 38 and 42 years respectively. Despite inclusion of middle aged adults in both of these studies, there was not particular emphasis placed upon the nature of pre-operative anxiety within this population. Older surgical patients form a significant group in view of the increasing proportion of the elderly in the population (Seshamani and Grey, 2002). In particular, the stress of impending hospitalisation and surgery has been shown to have greater adverse effects upon elderly patients (Zambricki, 2000).

The intention of the proposed study is to apply the PITI in a sample of patients awaiting elective hernia repair. This selection avoids confounding caused by anxiety associated with investigative surgical procedures. Crockett et al., (2007) hypothesise that an investigative procedure may generate greater uncertainty and lead to a higher incidence of pre-operative intrusive thoughts.

Aims and hypotheses

Aims

1. To evaluate the application of the PITI (Crockett et al., 2007) in a middle aged to older adult population having the same surgical procedure.

2. To determine what other factors modify pre-operative intrusive thoughts in a middle aged to older adult population. Factors to be investigated are anxiety, depression, previous surgical history, neuroticism and extroversion.

Hypotheses

Previous surgical history

1. Participants with previous negative surgical history will score higher on measures of anxiety (Hospital Anxiety Depression Inventory (HADS) and State-Trait Anxiety Inventory (STAI) and will show an increased presence of intrusive thoughts as assessed by the PITI.

Anxiety

2. Participants with increased levels of pre-operative anxiety as measured by the HADS and the STAI will show an increased presence of intrusive thoughts as assessed by the PITI.

Depression

3. Participants with increased levels of pre-operative depression as measured by the HADS will show an increased presence of intrusive thoughts as assessed by the PITI.

Personality characteristics

4. Participants with high scores on the neuroticism subscale of the Eysenck Personality Questionnaire Revised – Short Form (EPQR-S) will show an increased presence of intrusive thoughts as assessed by the PITI.

Plan of investigation

Participants

Middle aged to older adult patients awaiting elective hernia surgery will be invited to participate. The study aims to sample participants from one type of surgery (elective hernia repair) in order to reduce confounding variables such as type of surgery as impacting upon post-operative variables. Previous studies have used heterogeneous surgical populations (O'Hara et al., 1989; Crockett et al., 2007) and it is acknowledged that use of only hernia patients may limit the generalisabilty of study findings.

Inclusion and Exclusion Criteria

Inclusion criteria: aged 50 years old and over awaiting elective hernia repair at Gartnavel General Hospital and Western Infirmary, NHS Greater Glasgow and Clyde.

Exclusion criteria: other significant physical co−morbid condition (e.g. malignant or cardiovascular disease) that might affect the emotional state; current psychiatric condition; intellectual impairment that would affect comprehension of the psychological assessment.

Recruitment Procedures

Participant surgical locations are Gartnavel General Hospital and Western Infirmary, Glasgow, NHS Greater Glasgow and Clyde.

Participant information form (devised by the researcher for the purposes of the study).

A brief semi-structured clinical interview will be conducted to collect demographic information (age, gender, socio-economic status, marital status, employment and educational history). Socio-economic status will be defined using the participant's "deprivation category" (DEPCAT) (Carstairs and Morris, 1991) based on postal codes. Postal codes have been allocated to DEPCAT categories 1 (high affluence) to 7 (severe deprivation). A copy of the semi-structured interview is presented in appendix 2.9.

Following the semi-structured interview, participants will be asked to complete screening measures to assess study inclusion/exclusion criteria.

Measures – screening for inclusion and exclusion criteria (researcher administrated)

National Adult Reading Test Revised (NART-R) (Nelson and Willison, 1991).

The NART-R is a 50-item reading list which participants read out aloud. Words are scored as correct or incorrect dependent upon pronunciation. The NART-R is intended to be an estimate of pre-morbid ability based on the assumption that oral reading is closely related to general intellectual ability and that this skill is relatively well preserved until late in dementia (Crawford et al., 2001). The NART-R error score was used in the present study as an assessment of reading error (Nelson and Willison, 1991). The NART-R error score equals 50 minus the number of words read correctly. Poor readers are defined as those with fewer than 10 NART-R words read correctly (Nelson and Willison, 1991).

Mini-Mental State Examination (MMSE) (Folstein et al., 1975).

The MMSE is a screening measure designed for suspected cognitive impairment. It is acknowledged that this measure is brief in its examination of cognitive functioning as only memory, language and visuoperceptual functions are assessed (Scottish Intercollegiate Guidelines Network, 2006). MMSE is recommended as an initial cognitive screen by the Scottish Intercollegiate Guidelines Network (SIGN) guidelines on the management of patients with dementia (SIGN, 2006). Despite its limitations, the MMSE fulfils the remit of the need for a brief cognitive screen for the purposes of the study exclusion criteria. The use of the MMSE was purely for research purposes and not used as a basis on which to make a judgement regarding a person's competence to give informed consent.

Measures – self-report

Surgery-related intrusive thoughts

Pre-operative Intrusive Thoughts Inventory (PITI) (Crockett et al., 2007).

The PITI is a 20-item scale that was developed to measure the nature of pre-operative thoughts and incidence of anxiety. Scores are rated on a 4-point scale ranging from 0 (not at all) to 3 (most of the time). The PITI is divided into six subscales which examine preoccupation with the surgical procedure, concerns with outcome, anxieties regarding being unconscious, loss of control, dependence on others and pain/discomfort. Good internal consistency of the PITI was demonstrated in the validation study by Crockett et al., (2007): being unconscious ($\alpha = 0.85$), pre-occupation ($\alpha = 0.84$), outcome concerns ($\alpha = 0.74$),

pain/discomfort (α = 0.85), dependence (α = 0.84) and loss of control (α = 0.75). A copy of the PITI is presented in Appendix 2.10*[3].

Depression and anxiety

Hospital Depression and Anxiety Scale (HADS) (Zigmond and Snaith, 1983).

The HADS is a 14-item scale that is designed to detect the presence and severity of anxiety and depression with scores ranging from 0-14. Internal consistency has previously been reported to be between 0.80 and 0.90 for both anxiety and depression subscales (Herrmann, 1997).

State-Trait Anxiety Inventory (STAI) (Spielberger, 1983).

The STAI presents 40 statements assessing state anxiety (transitory changes in arousal) and trait anxiety (a predisposition to respond in an anxious manner to trigger situations). The STAI shows good reliability with coefficients of between 0.85-0.94 and 0.75-0.88 reported for state and trait subscales respectively (Stanley et al., 1996).

Personality characteristics

Eysenck Personality Questionnaire Revised – Short Form (EPQR-S) (Eysenck and Eysenck, 1991).

The EPQR-S is a 48-item scale that assesses the personality traits of extroversion, neuroticism and psychoticism. It also includes a so-called "lie scale" to detect tendencies to answer in a socially-acceptable way. Scores range

* Appendix 2.10 has been removed due to Copyright restrictions.

between 0-12 for each subscale. Eysenck et al., (1985) found all subscales had moderate to high internal consistency.

Previous surgical history – Visual Analogue Scale (VAS) (devised for present study).

Participants' previous surgical experience was determined by asking them to rate their experience on a visual analogue scale measuring positive, negative or neutral experiences. The visual analogue scale was anchored with the words "very poorly" and "very well" at 0 and 100mm respectively. Visual analogue scales have been found to correlate well with measures of depression and anxiety (Cella and Perry, 1986). A copy of the visual analogue scale used is presented in Appendix 2.12.

Design

A cross-sectional design will be utilised that will consider levels of anxiety, depression, nature of previous surgical experience and personality characteristics in relation to levels of pre-operative intrusive thoughts within an elective hernia surgical population.

Research Procedures

Recruitment – methods of identification, approach and consent

The study aims to sample patients who are undergoing elective hernia repair surgery. A letter requesting access to patients for participation in the study will be sent to relevant surgeons to inform them of the study rationale, study procedure, inclusion and exclusion criteria. The surgeons will be asked to

consent to having patients under their care to be considered for the study. Initially, patients will be asked to consent to be approached by the researcher on the day of their pre-operative assessment clinic appointment. This will be detailed in a study introduction letter and consent to be approached form being sent at the same time as their pre-operative assessment clinic appointment letter by the clinic administrator. The "consent to approach" form will be sent back to the researcher in a stamped addressed envelope. Therefore on the day of the pre-operative assessment clinic, the researcher will only approach individuals who have consented to be approached with regards to the study. Identified participants will be asked if they wish to discuss the study in further detail with the researcher.

Assessment (screening for inclusion/exclusion criteria and study measures)

Potential participants will be informed of the rationale and procedure of the study, and will have an opportunity to ask questions. Informed consent will then be obtained. As described above, there are various study inclusion and exclusion criteria to ensure that participants are competent to give consent. However, should the researcher has any doubt regarding the participant's competence to give informed consent, then the supervisor would be consulted. If during the process of participation in the study, any matters of concern relating to participant's physical or psychological health status arose, then it is the duty of the researcher to inform those responsible for the participant's medical care. This would occur in accordance with NHS patient duty of care procedures. Individuals will be informed that their decision to participate or not, will not affect their health care. It is intended that the study will be conducted on the

same day as the pre-surgery consultation to minimise number of meetings required. After obtaining informed consent, a general clinical interview will take place (part of screening process), additional screening measures will be conducted (NART-R and MMSE) and finally study measures will be completed (HADS, STAI, EPQR-S and PITI). It is expected that this process will take approximately forty minutes. Participants who wish to take part, but who do not have sufficient time at the assessment clinic, will be permitted to complete the study measures at home and return them in a stamped addressed envelope. The questionnaires will show only the participant's study code for the study so that they could not be identified if the forms should go astray in the post. Completion of the questionnaires concludes the patients' participation in the study: nothing further will be asked of them.

Confidentiality and anonymity of study data

All participant-related data will have any identifiers removed and each participant will be given a study number. Information will be stored in a locked filing cabinet and any electronic data will be stored on a password protected computer.

Justification of sample size

A quantitative approach will be used to examine the above variables. Correlations will be conducted to examine relationships between predictor variables. If significant relationships are found then regression analysis would be conducted. Due to the probable presence of collinearity between some of the

predictor variables, the number of predictors in the regression analysis is unlikely to exceed four in any one analysis.

Sample size was determined by the formula specified by Green (1991). There were no data to estimate effect size within such a study. Therefore by conservatively estimating a medium effect size ($f^2 = 0.15$), the formula takes the form of: $N \geq (8/f^2) + (m-1)$, where f^2 = the assumed effect size; m = the number of independent variables in the regression. For a power of 0.80 and an alpha of 0.05 and assumed medium effect size of 0.15, the estimated sample size required is: $(8/0.15) + (4 - 1) = 56$ participants.

Setting and equipment

The setting for data collection will be within Gartnavel General Hospital and Western Infirmary, Glasgow, NHS Greater Glasgow and Clyde. Equipment required will include study measures of psychological functioning that are appropriate to the setting and individuals concerned.

Data analysis

Data analysis will be conducted using the Statistical Package for Social Sciences (SPSS, 2007). Initially, descriptive statistics on participant demographic data will be calculated. A table of overall outcome of psychological assessment data for all study measures will be presented (means, standard deviations and range of scores). Further analysis would then involve correlations between the dependent variable (PITI) and the scores on the other psychological assessments. Correlations will specify which predictor values have the strongest association

with the dependent variable and also indicate collinearity between predictor variables. Following correlation analysis, regression analysis will be conducted as appropriate to correlations found.

Health and safety issues

Researcher safety issues

It will be ensured that any meetings with participants are conducted within the hospital setting. This will eliminate the need for home-visit risk assessments to be conducted and ensure that researcher safety is at a high a level as possible. Local or field supervisors are not available for the proposed study. Organisation of access to participants, nursing and administrative staff will be conducted under the guidance of Professor O' Dwyer (Professor of Gastrointestinal Surgery, University of Glasgow).

Participant safety issues

It will be important to ensure that data collection is not disruptive to the participant or hospital ward/department concerned.

Ethical Issues

There are a number of ethical issues to be considered. The impact of a researcher attending a clinic where individuals are preparing for elective hernia repair surgery will need to be assessed to ensure a minimal level of disruption. It will be important to liaise with department and/or nursing staff with regards to this matter.

The explanation of the rationale and procedure of the study will be of crucial importance to prepare participants for what is required for the purposes of the study. The proposed study measures are routinely used by Clinical Psychologists working with such a population and the procedures are not reported to cause significant levels of distress. However assessment of emotional variables is not part of routine pre-operative hernia care; therefore such measures may be a novel experience for participants. If a participant does become distressed, the researcher will assess the situation and respond in a professionally and sensitively to address that distress. In the event of severe distress, the Consultant in charge will be informed as well as the Research Supervisor. If required, further referral to the appropriate service will be discussed with the participant.

Financial Issues

Equipment cost

Costs of questionnaires, research travel and administrative costs are being met by the Section of Psychological Medicine and NHS Ayrshire and Arran.

Travel

The researcher will be required to travel to Gartnavel General Hospital and Western Infirmary, Glasgow, NHS Greater Glasgow and Clyde. It is intended that participants will be seen in hospital and not expected to travel to any additional areas in order to participate in the study. This will minimise additional travel expenses and other costs.

Timetable

8th December 2006 – submit outline 2 page major research project proposal to supervisor

12th January 2007 – submit draft major research proposal

30th March 2007 – submit major research proposal

30th March 2007 – Research agreement and research logbook initiation

August 2007 – November 2007 – Preparation for submission to local research ethics committee

December 2007 (approx) – Preparation for materials for research

January 2008 – March 2008 (approx) – Data collection

April 2008 until June 2008 (approx) – Data analysis and write up

June 2008 (approx) – Final draft to supervisor

Practical Applications

Research considering what psychological variables are of importance in the pre-operative period is required and of inherent importance to Clinical Psychology, particularly as it may help to elucidate factors that are amenable to psychological intervention (Gin and Chung, 2001).

Ethical and Management approval submissions

Approval from ethics and relevant management committees will be sought following University approval of the present proposal.

It will be essential to meet with relevant surgical departments to inform staff of the purpose of the research and allow them to gain an understanding of the

relevance of such work as well as raise any concerns that they may have. This may require various meetings or presentations to be conducted. If required, adequate time for this part of the study will be included within the research timetable. Preliminary meetings with Professor O'Dwyer (Professor of Gastrointestinal surgery, University of Glasgow) have occurred to provide an overview of the research area and discuss practicalities of participant recruitment.

Other relevant issues to consider

Co-sponsorship agreement

As an NHS Ayrshire and Arran locality trainee, a co-sponsorship agreement has been arranged. NHS Ayrshire and Arran will sponsor clinical matters of the research project (contact person: Dr Karen Bell) and the University of Glasgow, Section of Psychological Medicine will act as sponsor for academic matters (contact person: Professor Tom McMillan).

Time out of third year placements

This study will be primarily conducted within NHS Greater Glasgow and Clyde health board. Time allocated to research will be negotiated with third year placement supervisors to ensure that clinical work is unaffected.

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Appendix 2.2 Notes for contributors to: Anaesthesia

Anaesthesia – Notice to contributors

Anaesthesia is the official journal of the Association of Anaesthetists of Great Britain and Ireland and is published monthly. It is international in scope and comprehensive in coverage. It publishes original, peer-reviewed articles on all aspects of general and regional anaesthesia, intensive care and pain therapy, including research on equipment. The Editorial Board of *Anaesthesia* supports the statement on Geopolitical Intrusion on Editorial Decisions, by the World Association of Medical Editors (http://www.wame.org/wamestmt.htm#geopolitical) and is a member of the Committee on Publication Ethics (www.publicationethics.org.uk/). The editors regret that failure to comply with the following requirements may result in a delay in publication of accepted papers.

Submission of correspondence, manuscripts and covering letter
Manuscripts should have page numbers at the bottom of each page. Use Times New Roman in 11 or 12 point. Submission should be via email to the address below with the manuscript as an attachment (Word for Windows or rich text format - see below for information regarding Figures), and the Author's declaration form sent as an attached scanned document, by fax (44 (0) 115 823 1908), or in the post. Submission in any other format may slow down the review/publication process but is possible for those authors who do not have access to the appropriate technology - please contact the Editor-in-Chief in advance if this applies.

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NB Online ('rapid') correspondence may also be submitted via the following website www.anaesthesiacorrespondence.com - a selection will be published in the printed journal several times a year.

Covering letter
All manuscripts must be accompanied by an Authors' declaration form, which may be downloaded. Failure to do so will significantly delay the reviewing process.

Types of manuscript
Anaesthesia has the following regular sections: Editorials, Original Articles, Apparatus, Case Reports, Correspondence and Book Reviews. Reviews, Historical Articles or Special Articles may also be included. Although Editorials and Reviews are usually commissioned, authors may contact the Editor-in-Chief if they wish to discuss potential topics.

Content and style of manuscripts
A typical manuscript will have the following sections in the following order, each section starting on a new page:

Title page
The name and address of the corresponding author should appear in the top left-hand corner. The rest of the page should be as follows:

Title of paper: as short as possible but capturing the essence of the paper (a subtitle may be appropriate) without stating the conclusion or posing a question*

A. B. Author[1] and C. D. Author[2]

1 Position/designation of 1st author, primary institution, city, country.
2 Position/designation of 2nd author, primary institution, city, country.
Correspondence to: Dr Corresponding Author (incl. e-mail address and full postal address)
**footnote if presented in part at any national or international meetings, with details including location and date.*

For three or more authors, place the superscript number *after* the commas.

Summary
A Summary of fewer than 150 words should state the purpose of the study or investigation, basic procedures, main findings and their statistical significance, and principal conclusions. The Summary should not be structured nor in note or abbreviated form. It should not state that 'the results are discussed' or that 'work is presented'. Abbreviations should not be used except for units of measurement. Use the same order when discussing the methods and results as in the main body of the text, and always mention the groups in the same order.

Introduction
No heading is required for this section. The Introduction should give a concise account of the subject's background. Previously published work should only be quoted if it has a direct bearing on the present study. The Introduction should clearly and explicitly state the aims of the project.

Methods
A statement confirming Local Research Ethics Committee approval and written informed consent should be at the beginning of this section (see Ethical Considerations, below).
The Methods section must describe in sufficient detail the techniques and processes used so that the investigation can be interpreted and repeated by the reader. Any modification of previously published methods should be described and the appropriate reference given. If the methods are commonly used, only a reference to the original source is required. If special equipment is used, then the manufacturer's details (including town and country) should be given in parentheses. Drugs should be identified by their international non-proprietary name. Label groups in a way that is easy to follow; thus 'propofol group' and 'thiopental group' instead of 'Group 1' and 'Group 2'. Occassionally, abbreviated group titles may be better, e.g. 'Group BLEB' instead of 'bupivacaine-lidocaine-

epinephrine-bicarbonate group'. Remember to include inclusion/exclusion criteria, a justification of sample size (see Statistics, below) and the method of randomisation and blinding. The statistical methods used to investigate data should be given at the end of the Methods section (see below).

Results
Express results as mean (SD), median (IQR [range]) - i.e. use parentheses then square brackets - or number (proportion) as appropriate.
Results (including actual p values) must be presented for all measurements detailed in the Methods section, and in the same order. Data should not be repeated unnecessarily in the text, Tables and Figures - for example if a graph is used, do not present the same information elsewhere, e.g. in a Table as well. Results should not be given to an unwarranted number of decimal places and 95% confidence intervals should be used where possible.

Discussion
The Discussion should not merely recapitulate the results but should present their interpretation against a background of existing knowledge. Any conclusions must be warranted by the results. In general, avoid a paragraph headed 'Conclusions' which merely repeats a summary of the results. Also avoid ending with 'further work is needed' (it almost always is) unless you have specific areas of research to suggest.

Acknowledgments
The authors should acknowledge those who have made substantial contributions to the study or preparation of the manuscript but whose contributions do not fulfill the requirements for authorship. Sources of funding and potential conflicts of interest should be given here.

Appendices
Information or data not directly a result of the study but necessary for the reader to understand the manuscript should be included as an Appendix. Examples might include copies of questionnaires used; recognised mathematical processes used to generate results or previously published and validated classification systems. All should be appropriately referenced and the authors must obtain permission from the copyright holders if the contents have been previously published.

References
Number references consecutively in the order they appear in the text, using Arabic numerals enclosed in square brackets on the line (not superscript). Use [1-4] instead of [1,2,3,4]. References cited for the first time in Tables or Figures should be numbered in the sequence established by the first mention of the particular Table/Figure in the text.
All references (including those in press) should be listed at the end of the text in the order they are quoted; when submitting your manuscript please submit copies of any articles accepted for publication but not yet published. Abstracts may be quoted as references so long as they have been published in peer-reviewed journals. Unpublished observations, personal communications and abstracts published only in proceedings of meetings should be quoted within the text of the manuscript, in parentheses. Information from manuscripts submitted but not yet

accepted should be cited in the text as unpublished observations.
Internet sites may be quoted as references by listing them in the normal way in the text (using Arabic numerals) and in the References section. Please include the date accessed in parentheses.
List all authors unless there are seven or more, in which case give the first three followed by 'et al.'. Spell out the names of all journals in full, and give the first and last page number, not just the first.
Examples:

1. Author AB, Author CD. Title of paper. *Journal Title Written Out in Full in Italics* 1999; **12:** 123-4.
2. Author AB, Author CD, Author EF, et al. Seven or more authors - what's the point? (chapter title). In: Editor GH, Editor IJ, eds. *Title of Book.* Place: Publisher, 1998: 345-67.
3. Author AB. *Book Title*, 5th edn. Place: Publisher, 2000.
4. Author(s) of website. www.URL.co.uk (accessed 01/01/2004).

Tables
Include the Tables in the same file as the text, but after the References not in the middle of the text. Each Table should be on a separate page and 1.5-spaced. Number the Tables consecutively with Arabic numerals. Each Table should have a brief legend immediately above it; the legend should provide enough information for readers to follow it without having to look through the text. The legend should explain whether the values refer to mean (SD), number (proportion), etc. Abbreviations should not be mentioned in the legend without explanation. Abbreviations used in the body of the Table should be explained as footnotes in the order in which they are first mentioned, using the following symbols (nb not superscript) in the following order: *, , , §, ¶, **, , etc. The study groups should form the columns rather than the rows. If statistical comparisons are being made, a separate column with exact p values should appear. Each Legend should include an explanation of the symbols used to provide enough information for readers to follow it without having to look through the text. Thus 'Changes in arterial blood pressure and heart rate in patients given thiopental (-O-)' instead of 'Cardiovascular changes'.

Figures
Please supply each Figure as a separate file, rather than embed them within the body of the Word document, and preferably in TIFF or high-resolution JPEG format.
Please ensure related graphs have the same format (fonts, use of symbols, etc). The same requirements for abbreviations and units apply as for those in the text. Plot frames, gridlines and legends within the graph itself should be removed. Avoid colour and the use of 3-D unless absolutely necessary (a charge will apply for colour Figures).

Style
In general, we prefer a clear, precise style to jargon. Please avoid long, complicated sentences and the passive voice when the active is more appropriate (e.g. 'We chose epidural anesthesia because.' instead of 'Epidural anaesthesia was chosen by the authors because .'). Remove unnecessary clutter and focus on the

actual message of each sentence; thus 'Hypotension is important because...' instead of 'It would be remiss of us not to mention hypotension because...'). Remember that lungs are ventilated, not patients (nor are they intubated - their tracheas are). Similarly, patients are not induced - anaesthesia is - or put on ventilators. Correct terms are tracheal (not **endo**tracheal) tube and neuromuscular blocking drugs (not muscle relaxants).

Abbreviations
In general, the Journal does not encourage the use of abbreviations, since their frequent use makes papers difficult to read. However, it will accept abbreviations in the following circumstances:
Universal abbreviations that do not need to be written out in full when first mentioned in the text. These include abbreviations that appear in a large proportion of the articles published in the Journal. Acceptable abbreviations that do not need to be written out in full when first mentioned but whose use should be restricted to situations where space is limited, such as in formulae or in Tables and Figures.

Numbers and units
Numbers should be spelled out in full when they start a sentence, and when they are less than 10 (unless they are followed by units of measurement). Thus 'Thirteen days later, five patients each received 7 ml solution...' Commas are not used to indicate thousands; thus 2000 and 20 000 instead of 2,000 and 20,000.

Ethical Considerations
Whatever their other merits, manuscripts will only be considered for publication in *Anaesthesia* if they adhere to the highest ethical standards. These are detailed in two editorials (Investigators, *Anaesthesia* and ethics. *Anaesthesia* 2000; **55:** 521-2 and Ethics again - hoops, loops and principles. *Anaesthesia* 2004; **59:** 316-17) which potential authors are strongly advised to consult.

Statistics
The following guidelines have been prepared by the Editorial Board of *Anaesthesia* to help authors avoid the common statistical errors that frequently lead to rejection of work submitted for publication. This should not be regarded as an exhaustive list and, of course, the Editorial Board and their reviewers may ask authors for revisions that are not detailed here. However, adherence to these guidelines in a paper that is otherwise acceptable will give researchers a good chance of publication and help ensure that their work is statistically valid. A good overview of the subject can be found in Pocock SJ, Hughes MD, Lee RJ. Statistical problems in the reporting of clinical trials. *New England Journal of Medicine* 1987; **317:** 426-32.

Review process
All papers are reviewed by the Editor-in-Chief and at least one Editor. External review is used as deemed appropriate. The Editor-in-Chief's verdict on acceptance or rejection is final. Papers submitted with one of the Editorial Board members as an author are automatically sent out for an additional external review.

Papers accepted for publication require an Exclusive Licence Form to be signed and returned to the Publishers before they can be published. Once accepted for publication, the manuscript will be subedited by an Editor; this usually involves some alterations to clarify points and maintain house style. Rather than be excessively prescriptive, the Editorial team tries to be as helpful as possible at this stage - with the aim of improving your paper and its readability. The article is then sent to the publishers who will send a set of proofs to the author, Editor and finally the Editor-in-Chief. Changes by the authors at proof stage should be kept to a minimum - authors may be charged for excessive alterations.
Time from acceptance to publication is usually under two to three months.

Material storage policy
Please note that unless specifically requested, Blackwell Publishing will dispose of all hardcopy or electronic material submitted two months after publication. If you require the return of any material submitted, please inform the editorial office or production editor as soon as possible if you have not yet done so.

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Appendix 2.3 Approval letter from NHS Greater Glasgow and Clyde Primary Care, Community and Mental Health Research Ethics Committee

Primary Care Division

NHS
Greater Glasgow and Clyde

Research Ethics
R&D Directorate
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH
www.nhsggc.org.uk

Ms Salma Iqbal
Trainee Clinical Psychologist
University of Glasgow
Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH

Date 12 December 2007
Your Ref
Our Ref
Direct line 0141 211 3824
Fax 0141 211 3814
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Ms Iqbal

Full title of study: **The application of the Pre-operative Intrusive Thoughts Inventory (Crockett et al., 2007) in individuals awaiting elective hernia repair surgery.**

REC reference number: **07/S0701/153**

The Research Ethics Committee reviewed the above application at the meeting held on 06 December 2007. Thank you for attending to discuss the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation. This favourable opinion is given subject to the researcher submitting the information and revised documentation to the Committee Co-ordinator as soon as possible.

1) A sentence around the duty of care must be included in the protocol and participant information sheet.

2) If in doubt about the participant's ability to give informed consent then the researcher should consult the supervisor for guidance.

3) It must be made clear in the protocol that the use of the MMSE is purely for research only and not a judgement of the person's ability to give informed consent.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Application	Version 1	08 November 2007
Investigator CV		08 November 2007
Protocol	Version 1	08 November 2007
Covering Letter		08 November 2007
Summary/Synopsis	Version 1	08 November 2007
Letter from Sponsor	Professor McMillan	
Letter from Sponsor	NHS Ayrshire & Arran R&D	
Interview Schedules/Topic Guides	Version 1	08 November 2007
Questionnaire: Validated - 6		
Letter of invitation to participant	Version 1	08 November 2007
GP/Consultant Information Sheets	Version 1	08 November 2007
Participant Information Sheet	Version 1	08 November 2007
Participant Consent Form	Version 1	08 November 2007
Consultant Information Sheets - Request for access	Version 1	08 November 2007
Supervisor's CV		08 November 2007

R&D approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final approval from the R&D office for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics 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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

Here you will find links to the following

a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.
b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nationalres.org.uk .

07/S0701/153	Please quote this number on all correspondence

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

Yours sincerely

Liz Jamieson

Liz Jamieson
Research Ethics Committee Co-ordinator on behalf of Dr Paul Fleming, Chair

Enclosures:	List of names and professions of members who were present at the meeting and those who submitted written comments Standard approval conditions Site approval form (SF1)
Copy to:	Dr Karen Bell R&D office for NHS care organisation at lead site

Glasgow & Clyde Primary Care, Community & Mental Health

LIST OF SITES WITH A FAVOURABLE ETHICAL OPINION

For all studies requiring site-specific assessment, this form is issued by the main REC to the Chief Investigator and sponsor with the favourable opinion letter and following subsequent notifications from site assessors. For issue 2 onwards, all sites with a favourable opinion are listed, adding the new sites approved.

REC reference number:	07/S0701/153	**Issue number:**	0	**Date of issue:**	12 December 2007
Chief Investigator:	Ms Salma Iqbal				
Full title of study:	The application of the Pre-operative Intrusive Thoughts Inventory (Crockett et al., 2007) in individuals awaiting elective hernia repair surgery				

This study was given a favourable ethical opinion by Glasgow & Clyde Primary Care, Community & Mental Health on 06 December 2007. The favourable opinion is extended to each of the sites listed below. The research may commence at each NHS site when management approval from the relevant NHS care organisation has been confirmed.

Principal Investigator	*Post*	*Research site*	*Site assessor*	*Date of favourable opinion for this site*	*Notes* [1]
Ms Salma Iqbal	Trainee Clinical Psychologist	NHS Greater Glasgow and Clyde	Glasgow & Clyde Primary Care, Community & Mental Health	12/12/2007	

Approved by the Chair on behalf of the REC

Liz Jamieson ..... (Signature of ~~Chair~~/Co-ordinator)

(delete as applicable)

Liz Jamieson ..... (Name)

Appendix 2.4 Approval letter from NHS Greater Glasgow and Clyde Research and Development Directorate

Acute Services Division

Research & Development Directorate
NHS Greater Glasgow and Clyde
The Tennent Institute
WIG, 38 Church Street
Glasgow
G11 6NT

NHS Greater Glasgow and Clyde

Ms Salma Iqbal,
Trainee Clinical Psychologist,
University of Glasgow,
Department of Psychological Medicine,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow G12 0XH

Direct Line 0141 211 8548
Fax 0141 232 9516
Email mary.fraser@ggc.scot.nhs.uk

Date 08 January 2008

Dear Salma Iqbal,

Project Title: The application of the Pre-operative Intrusive Thoughts Inventory (Crockett, et al, 2007) in individuals awaiting elective hernia repair surgery

I am pleased to inform you that R&D management approval has been granted by NHS Greater Glasgow & Clyde Community and Mental Health Partnership, subject to the following requirements:

- You should notify me of any changes to the original submission, including copies of notification to ethics committee(s) and send regular, brief interim reports including recruitment numbers where applicable. You must also notify me of any changes to the original research staff and send CVs of any new researchers.
- Researchers covered in this approval are:- **yourself; and Professor Keith Millar.**
- Your research must be conducted in accordance with the Scottish Executive Health Department, *Research Governance Framework for Health and Community Care* (Second Edition, 2006) see Chief Scientist Website http://www.sehd.scot.nhs.uk/cso Local research governance monitoring requirements are presently being developed. This may involve audit of your research at some time in the future.
- You must comply with any requirements regarding data handling (Data Protection Act). Advice may be obtained from the Scottish Executive Confidentiality and Security Advisory Group for Scotland website http://www.csags.scot.nhs.uk/
- A final report, with an abstract which can be disseminated widely within the NHS, should be submitted when the project has been completed.

Do not hesitate to contact the R&D Office if we can be of any assistance.

We wish you every success with your project.

Yours sincerely

Mary Fraser

Dr Mary Fraser

Delivering better health

www.nhsggc.org.uk

40389

Appendix 2.5 Request for access to patients and Consultant Consent Form

Request for access to patients for participation in a research study

Dear <Name>,

Following discussion and advice from Professor O'Dwyer, we are writing to enquire whether you would be agreeable to some of your patients being approached to consider giving their consent to recruitment to a research project.

The research is being conducted by Ms Salma Iqbal who is a final-year trainee clinical psychologist studying for the Doctorate in Clinical Psychology through University of Glasgow Medical School. The study has been approved by the Greater Glasgow and Clyde Primary Care, Community and Mental Health Research Ethics Committee. Ms Iqbal is supervised by Professor Keith Millar of the University Section of Psychological Medicine.

The research will use a brief validated "Pre-operative Intrusive Thoughts Inventory" (PITI) to investigate pre-operative intrusive thoughts in individuals awaiting hernia repair. The questionnaire was developed in the Section of Psychological Medicine of Glasgow University Medical School and published in the journal *Anaesthesia* (Crockett et al., 2007). In addition to the PITI, the research will include brief assessments of anxiety and depression (the "Hospital Anxiety and Depression Scale" and the "State-Trait Anxiety Scale"), and personality characteristics (the "Eysenck Personality Scale"), in order to assess other variables which are known to influence pre-operative anxiety. Copies of the questionnaires are enclosed. The study aims to restrict sampling to hernia patients in order to achieve a relatively homogeneous group. Inclusion criteria will be: aged 50 years or older and a score of 25+ on the Mini Mental State Screening Examination.

With your permission, patients who are to attend your out-patient assessment clinic would be sent the enclosed study information sheet with their appointment letter. The information sheet describes the study and invites patients to consider whether they would be willing to be approached by Ms Iqbal at their out-patient visit with a view to recruitment to the study.

Patients who consent to participate and who meet the inclusion criteria, will be asked to complete the questionnaires described above whilst at the assessment clinic. The procedure will take a maximum of forty minutes per participant and nothing further will be asked of them. If participants do not wish to complete the questionnaires in the assessment clinic, they will be given a stamped addressed envelope in which to return the completed questionnaires to Ms Iqbal.

We realise that such requests are a considerable imposition and will fully understand if you would prefer that your patients are not involved. If, however, you would be agreeable to your patients being approached in this way, we should be most grateful if you could take a moment to return the attached form so that Ms Iqbal can then arrange to liaise with your administrative staff with regards to patient contact via the out-patient appointment clinic. We should be delighted to answer any questions regarding the research or provide further information, and can be contacted as shown below.

Ms Salma Iqbal
Trainee Clinical Psychologist

Professor Keith Millar
Research Supervisor

Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Telephone Number: 0141 211 0607/3939 (Secretary)

E-mail: 0511378i@student.gla.ac.uk

E-mail: k.millar@clinmed.gla.ac.uk

Consultant Consent Form

Study Title:
The application of the Pre-operative Intrusive Thoughts Inventory (Crockett et al., 2007) in an elective hernia repair surgery population.

Researcher: **Ms Salma Iqbal**
Trainee Clinical Psychologist

Contact details:
Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Telephone Number: 0141 211 0607 (Secretary)
Email: 0511378i@student.gla.ac.uk

Please tick to confirm

1. I confirm that I have read and understood the letter entitled "request for access to patients for participation in a research study" dated November 2007 and have had the opportunity to ask questions. ☐

2. I confirm that I am willing for any patients under my care, who meet inclusion criteria and who are able to provide written consent, attending the pre-operative assessment clinics at Gartnavel General Hospital or Western Infirmary to participate in the above-named research. ☐

3. I agree to the researcher to access information about the consenting participant either from nursing staff, medical records or the participant themselves. ☐

_____	_____	_____
Name of Doctor (please print)	Date	Signature
_____	_____	_____
Name of researcher	Date	Signature

Appendix 2.6 Introductory letter to potential participants

Information about a Research Study
"Assessing thoughts and feelings before surgery"

Dear sir/madam,

I am writing to you regarding the appointment that you are due to attend at the Pre-operative Assessment Clinic at Gartnavel General Hospital/Western Infirmary (delete as appropriate). My name is Salma Iqbal and I am a Trainee Clinical Psychologist who is conducting a research study at the Assessment clinic as part of my qualification as a Doctor of Clinical Psychology through the Medical School of the University of Glasgow. My study is entitled "Assessing thoughts and feelings before surgery" and the intention is to understand more about any worrying or anxious thoughts that people might have before surgery. My research is being supervised by Professor Millar who is Professor of Medical Psychology at the University of Glasgow. I have permission from your consultant to contact you in order to introduce you to my research study and to ask if you would consider taking part.

The study involves taking part in a short confidential interview with me when you attend the Assessment Clinic. I will ask for some basic information about you (for example, your age, where you live, any previous surgery that you have had) and then ask you to complete a set of short questionnaires. The questionnaires ask about your thoughts about your planned surgery, any other emotions that you are experiencing, and some questions about the ways in which you think and behave in various situations. In total, the interview and questionnaires would require about 40 minutes of your time. However, if it is more convenient, you will have the option to take the questionnaires home to complete and return at your convenience.

The purpose of this letter is to enquire whether you would consider taking part in the study and, if so, whether you would agree to being approached when you attend the Assessment Clinic appointment. It would be most helpful if you would complete the enclosed form indicating whether you agree to being approached, and then post it to me in the stamped envelope enclosed. Please note that if you do not wish to take part in the study it will not affect your NHS treatment in any way. Similarly, if you do agree to being approached, and then agree to take part in the study, you will still be absolutely free to change your mind and withdraw at any time. Deciding to withdraw from the study will not affect your NHS treatment. I have enclosed an information sheet which provides further information about the study. If you have any additional questions, you can contact me directly via the telephone number below, or in person at the Assessment Clinic. I am most grateful to you for taking the time to read this letter and give consideration to the study.

Ms Salma Iqbal
Trainee Clinical Psychologist

Professor Keith Millar
Research Supervisor

Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Telephone Number: 0141 211 0607/3939 (Secretary)
E-mail: 0511378i@student.gla.ac.uk
E-mail: k.millar@clinmed.gla.ac.uk

Appendix 2.7 Consent to approach form

"Assessing thoughts and feelings before surgery"

Consent to approach form

	Please tick to confirm
I have read and understood the above information and have had an opportunity to ask any questions that I may have.	☐
I **agree** to be approached by Ms Salma Iqbal (Trainee Clinical Psychologist) with regards to participating in the study entitled "Assessing thoughts and feelings before surgery" on the day of my pre-operative assessment appointment.	☐
I **do not agree** to be approached by Ms Salma Iqbal (Trainee Clinical Psychologist) with regards to participating in the study entitled "Assessing thoughts and feelings before surgery" on the day of my pre-operative assessment appointment.	☐

_____	_____	_____
Name (please print)	Date	Signature

Please return this form in the self addressed envelope provided.

Thank you very much for your time.

Ms Salma Iqbal
Trainee Clinical Psychologist
Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Telephone Number: 0141 211 0607 (Secretary)
Email: 0511378i@student.gla.ac.uk

Appendix 2.8 Participant Information Sheet and Consent Form

Participant Information Sheet

Study Title
Assessing thoughts and feelings before surgery.

Invitation to participate
You are being invited to take part in a research study. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it would involve. Please take the time to read the following information sheet. If there is anything that is not clear, or if you would like further information, please contact the researcher, Salma Iqbal.

What is the purpose of the study?
The research will look at what types of thoughts and feelings individuals have before surgery. It will also look at whether certain psychological factors can have an effect on the types of thoughts and feelings individuals have before surgery. These will include feelings about your mood or other thoughts about yourself and your past experiences of surgery.

Why have I been chosen?
This study will include people over the age of fifty, who are planned to undergo a non-explorative hernia surgery, who are able to provide informed and written consent to be involved. It is hoped that a total of approximately 56 patients will take part.

Do I have to take part?
The study is entirely voluntary. It is completely up to you whether or not you decide to take part. If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you do decide to take part you are still free to withdraw at any time and without giving a reason. Please note that your NHS treatment will not be affected in any way.

What will I be asked to do if I take part?
If you decide to take part you will be interviewed by the researcher on the day of your pre-operative assessment clinic appointment. The researcher will ask you for some basic information about you as well as questions about any past surgeries. This should not take any more than 25 minutes. You will then also be asked to complete to complete a series of questionnaires whilst you are at your pre-operative assessment clinic. The questions ask about your thoughts about your planned surgery, any symptoms of anxiety or depression you are experiencing as well as some questions about the type of person that you are. There are five questionnaires in total, and these should take an additional 15 minutes to complete. If you decide that you do not wish to complete these questionnaires on the day of the pre-operative assessment clinic, then please indicate this to the researcher and you will be given a self addressed envelope and asked to complete and return the questionnaires at your convenience. At this point your participation in the study will be complete and nothing more will be asked of you.

Are there any disadvantages or risks associated with taking part?
Whether or not you choose to take part your current and future treatment will not be affected. If you do choose to take part you will be asked about your feelings about

having your planned procedure. By thinking about your surgery you may become more or less anxious or worried. The researcher will be available for you to talk to about any concerns that may have been raised by participating in the study and you will also be encouraged to speak with the medical team. However the researcher will not discuss the content of your interview with any of the medical team without your permission. If during the process of participation in the study, any matters of concern relating to your physical or psychological health status arose, then it is the duty of the researcher (Ms Salma Iqbal) to inform those responsible for your medical care. This would occur in accordance with NHS patient duty of care procedures.

What are the benefits of taking part?
The information we get from this study may help us to support future patients undergoing surgical procedures better.

Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research, will be kept strictly confidential. Any information which leaves the hospital will have your name removed and will be stored in a locked cabinet or password protected computer file to which only the research team will have access. All data will be destroyed after five years. Relevant members of staff of NHS Greater Glasgow and Clyde may require access to study data as part of routine monitoring of research required by all NHS trusts.

What will happen to the results of the research study?
The results of this study will be available in Autumn 2008. If you would like a summarised copy of the finished research please inform the researcher who will keep a record of your name and address on a password protected computer file and post the results out to you.

Who is organising the research?
The research is being conducted by a final year Doctorate in Clinical Psychology trainee who is based at the University of Glasgow and employed by NHS Ayrshire and Arran.

Who has reviewed the research?
This study has been reviewed by the Department of Psychological Medicine to ensure that it meets important standards of scientific conduct and has been reviewed by NHS Greater Glasgow and Clyde Research Ethics Committee to ensure that it meets important standards of ethical conduct.

Who can I contact for independent information on the study?
You may contact Dr Mary Fraser – Research and Development Directorate, NHS Greater Glasgow and Clyde (Telephone Number: 0141 232 9524).

Contact for further information?
If you have any further questions about the study, please contact the researcher either whilst at your pre-operative assessment clinic or at the below address and telephone number. Thank you for your time and consideration of the study.

Ms Salma Iqbal
Trainee Clinical Psychologist

Professor Keith Millar
Research Supervisor

Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Telephone Number: 0141 211 0607/3939 (Secretary)

E-mail: 0511378i@student.gla.ac.uk

E-mail: k.millar@clinmed.gla.ac.uk

Participant Consent Form

Study Title

Assessing thoughts and feelings before surgery.

Researcher: **Ms Salma Iqbal**
Trainee Clinical Psychologist

Contact details:
Section of Psychological Medicine
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
G12 0XH
Telephone Number: 0141 211 0607 (Secretary)
Email: 0511378i@student.gla.ac.uk

Please tick to confirm

1. I confirm that I have read and understood the information sheet dated November 2007 for the above study and have had the opportunity to ask questions. ☐
2. I understand that all data will be securely stored by the researcher in a locked cabinet or password protected file for five years before being destroyed and that relevant Trust staff can access the data as part of routine monitoring of research. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, without my NHS treatment or legal rights being affected. ☐
4. I agree to the researcher accessing study relevant information from either the nursing staff or my medical notes. ☐
5. I agree to take part in the above study. ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Name of researcher	Date	Signature

3 copies, 1 for the participant, 1 for the researcher, 1 to be kept with the hospital notes.

Appendix 2.9 Participant semi-structured interview

Participant information form

1. **What is your date of birth_____(DD/MM/YYYY)**

2. **What is your marital status**

Single □
Married □
Living with partner □
Divorced □
Separated □
Widowed □
Other □

3. **Are you currently**

Employed □
Unemployed □
Retired □

If unemployed or retired please state your previous occupation:
_____

4. **Educational History**

What age did you start school? _____ Years
What age did you leave school? _____ Years

5. **Do you have any physical health problems other than your hernia?**

Yes□
No□

If yes, please describe:
_____

6. **Do you have any problems with anxiety or mood related disorder?**

Yes□
No□

If yes, please describe:

_____

7. **Do you have any problems with alcohol or drug misuse?**

Yes□
No□

8. **Have you ever had a head injury?**

Yes□
No□

If yes, please describe:

_____

Appendix 2.10 Pre-operative Intrusive Thoughts Inventory (PITI)

Appendix 2.10 has been removed due to Copyright restrictions.

Appendix 2.11 PITI questions and subscales

Appendix 2.11 has been removed due to Copyright restrictions.

Appendix 2.12 Previous Surgical History – Visual Analogue Scale

NATURE OF PREVIOUS SURGICAL EXPERIENCE

Have you been admitted for a surgical procedure before?

Yes□
No□

If you answered yes to this question, please make a mark on the following line that represents how well you believe that your previous surgeries have gone:

Very Poorly **Very Well**

Appendix 2.13 PITI and Inter-correlations matrix

Measure	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1. PITI (total)	...															
Correlation co-efficient		0.888**	0.706**	0.767**	0.733**	0.785**	0.721**									
Significance 2-tailed		0.000	0.000	0.000	0.000	0.000	0.000									
2. PITI (unconscious)		...														
Correlation co-efficient			0.511*	0.587**	0.567**	0.708**	0.825**									
Significance 2-tailed			0.018	0.005	0.007	0.000	0.000									
3. PITI (pre-occupation)			...													
Correlation co-efficient				0.711**	0.483*	0.439*	0.491*									
Significance 2-tailed				0.000	0.027	0.047	0.024					**See table 3**				
4. PITI (outcome)				...												
Correlation co-efficient					0.812**	0.500*	0.315									
Significance 2-tailed					0.000	0.021	0.164									
5. PITI (pain/discomfort)					...											
Correlation co-efficient						0.488*	0.255									
Significance 2-tailed						0.025	0.265									
6. PITI (dependence on others)						...										
Correlation co-efficient							0.592**									
Significance 2-tailed							0.005									
7. PITI (control)							...									
Correlation co-efficient																
Significance 2-tailed																
8. HADS (anxiety)								...								
Correlation co-efficient									0.829**	0.564**†	0.615**†	-0.021	-.116†	0.736**†	0.324†	0.038†
Significance 2-tailed									0.000	0.008	0.003	0.929	0.617	0.000	0.152	0.877
9. HADS (depression)									...							
Correlation co-efficient										0.471*	0.578**	-0.005	-0.080	0.566**	0.410	-0.208
Significance 2-tailed										0.031	0.006	0.982	0.731	0.007	0.065	0.393
10. STAI (state)										...						
Correlation co-efficient											0.791**†	-0.210	0.089†	0.550**	0.310†	0.001†
Significance 2-tailed											0.000	0.360	0.702	0.010	0.171	0.996
11. STAI (trait)				**See table 3**							...					
Correlation co-efficient												-0.166	-.119†	0.578**	0.208	-.071†
Significance 2-tailed												0.472	0.608	0.006	0.366	0.772
12. EPQR (psychoticism)												...				
Correlation co-efficient													-0.156	-0.020	0.188	0.148
Significance 2-tailed													0.499	0.932	0.413	0.547
13. EPQR (extraversion)													...			
Correlation co-efficient														-0.103	0.069†	0.234†
Significance 2-tailed														0.656	0.766	0.335

14. EPQR (neuroticism)	...		
Correlation co-efficient		0.391	0.018
Significance 2-tailed		0.079	0.942
15. EPQR (social desirability)			
Correlation co-efficient		...	-.051†
Significance 2-tailed			0.837
16. Previous surgical history			...
N=19			
Correlation co-efficient			
Significance 2-tailed			

MEASURES – KEY

PITI = Pre-operative Intrusive Thoughts Inventory; HADS A = Hospital Anxiety and Depression Scale (anxiety); HADS D = Hospital Anxiety and Depression Scale (depression); STAI S = State Trait Anxiety Inventory (State); STAI T = State Trait Anxiety Inventory (Trait); EPQR P = Eysenck Personality Questionnaire Revised (Psychoticism); EPQR E = Eysenck Personality Questionnaire Revised (Extraversion); EPQR N = Eysenck Personality Questionnaire Revised (Neuroticism); EPQR S = Eysenck Personality Questionnaire Revised (Social desirability); PSH = Previous surgical history

**Correlation is significant at the 0.01 level (2-tailed)

*Correlation is significant at the 0.05 level (2-tailed)

r, correlation co-efficient; N = 21 for all correlations except previous surgical history (N = 19)

†normally distributed data – Pearson's product-moment correlation used