Does Expressive Writing Lead to Physical Health Benefits in Women who have undergone Surgery for Gynaecological Cancers?

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Overview

This thesis is presented in three parts. Part 1 is a review of the literature of psychological interventions which promote recovery from major surgery. The review covers 26 intervention studies. They divide into five main categories of intervention and for each, the theoretical rationale, features of the interventions, study designs and outcomes are considered.

Part 2 is the empirical paper which reports on a quantitative study investigating whether expressive writing leads to physical health benefits in women who have had surgery for gynaecological cancers. Running an expressive writing intervention was a joint project (see Saunders, 2008; Thomas, 2008). The challenges of conducting the study on a ward and suggestions for implementing future studies with surgical patients are discussed.

Part 3 is the critical appraisal which covers decisions which had to be made during the study. I give my personal reflections on carrying out this research and how the intervention was received by women on the ward.

Contents

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Part 1: Literature Review

Psychological Interventions which Promote Recovery from Major Surgery:

A review of the literature

Abstract

This paper examines the effectiveness of psychological interventions for patients undergoing major surgery. It reviews which of these help patients either in their psychological adaptation to or physical recovery from surgery. A total of 26 intervention studies were identified. These were divided into five categories of intervention: (1) psycho-education; (2) social support; (3) relaxation; (4) expressive writing; and (5) supportive and mixed interventions. Twenty two studies analysed measures of psychological outcomes; of these, eleven reported improvements. Twenty two studies reported on measures of physical recovery; of these, 10 studies reported improvements. Three further studies found better physical health outcomes in control than in intervention groups.

Overall, there is mixed evidence that psychological interventions improve physical and psychological outcomes after major surgery. More good quality studies are needed to explore how psychological interventions could be incorporated into surgical ward practises.

Introduction

There are significant threatening aspects to being hospitalised for major surgery. Patients may be anxious about anaesthetic procedures and pain and the possible outcomes of the surgery, including disfigurement, dependency, or even death (Contrada, Levanthal & Anderson, 1994; Horne, Vatmanidis & Careri, 1994; Swindale, 1989). The impact of surgery can be far reaching, although of course some kinds of surgery are less threatening than others. It might entail short or long term physical or functional restrictions and there may be economic implications (Contrada et al., 1994). In addition, in-patients face further difficulties in that during their time on the ward they have been removed from their home environments and routines which mean they have relinquished control and are dependent on medical staff (Sarafino, 2006). To some extent, the threats (or anxieties) of impending surgery may be counterbalanced by the prospect of some anticipated improvement in physical health or alleviation of symptoms (Vogele, 2004).

This paper reviews studies of the effectiveness of psychological interventions for surgical patients. Specifically, the review focuses on interventions aimed at improving recovery following surgery. Recovery from surgery covers both psychological aspects (e.g. reduction of depression or anxiety) and physical outcomes (e.g. shorter hospitalisations, better healing and fewer complications).

The first section of this paper sets out the background relating to psychological factors which are known to impact on recovery from surgery. It also provides an overview of two theoretical frameworks for understanding how psychological interventions might help in the process of adjustment. The second section describes the method of identifying relevant studies. The results section

examines the interventions and methodologies which have been used and weighs up the evidence for what kinds of interventions work in surgical settings. Finally, the discussion considers conclusions which can be drawn from the research to date as well as the practical considerations of carrying out further investigations in this area.

Background

Psychological Factors Associated with Recovery from Surgery

There is a vast literature on the psychological variables which influence surgical recovery. These include anxiety, stress, optimism and what are termed lifestyle factors or health behaviours.

Anxiety. Fifty years ago it was thought that some benefit could be derived from a moderate level of anxiety before surgery. Janis (1958, cited in Vogele, 2004), proposed that a moderate level of "distress" was related to the best recovery from surgery, while too much or too little distress was associated with poorer recovery. Janis' theory was that some useful active purpose is served by doing "the work of worry" and that coping strategies are activated.

Contrary to the early work of Janis, the subsequent literature has found that anxiety has a detrimental effect on surgical recovery. However, it is an oversimplification to regard anxiety as a single construct. Anxiety has been conceptualised as comprising two components: state anxiety (i.e. anxiety in a specific situation), which has been found to reduce when appropriate psychological interventions are used, and trait anxiety (i.e. a more enduring trait) which shows little change before and after surgery (Spielberger, Auerbach, Wadsworth, Dunn & Taulbee, 1973).

A recent meta-analysis by Munafo and Stevenson (2001) demonstrated the

relationship between lower anxiety and better psychological outcomes. This persuasive paper analysed studies which measured anxiety using the State Trait Anxiety Inventory (Spielberger, 1983) and found a moderate to large effect size for the association between pre-operative state anxiety and mood after surgery. Some associations were also found between higher self-reported anxiety and higher post operative pain (Munafo & Stevenson, 2001). There was also evidence of lower anxiety before surgery being related to clinical outcomes such as shorter length of stay in hospital and fewer complications (Contrada et al., 1994; Johnston & Vogele, 1993).

Stress. There is an extensive literature on how psychological stress affects the immune system and impedes wound healing (Kiecolt-Glaser, Marucha, Malarkey, Mercardo & Glaser, 1995; Kiecolt-Glaser, McGuire, Robles & Glaser, 2002), although space prohibits a full review of the literature. Stress and anxiety activate the hypothalamic pituitary adrenal axis (Miller & Cohen, 2001). Importantly, the physiological products derived from this stress response interfere with wound healing (Kiecolt-Glaser, Page, Marucha, MacCallum & Glaser, 1998). Therefore distressed individuals would be expected to recover more slowly from surgery, to have more post-surgical complications and longer periods in hospital. Few studies have examined the association between stress and wound healing in surgical populations. However, one study found that within surgical patients, less stress was associated with markers indicating the early phase of wound healing (Broadbent, Petrie, Alley & Booth, 2003).

Optimism. Optimism is the personality variable which has been studied most in the literature. There is some evidence within clinical populations that optimism is linked with better outcomes after surgery. Optimists are thought to

adjust to life events better than pessimists and there is some empirical evidence that they have enhanced immune functioning (Kiecolt-Glaser et al., 2002; Segerstrom, Taylor, Kemeny & Fahey, 1998).

A few studies have examined optimism in clinical populations. For example, positive expectations predicted better health in heart transplant patients and optimism predicted a lower rate of re-hospitalisation after coronary artery bypass graft (CABG) surgery (Leedham, Meyorwitz, Muirhead & Frist, 1998; Scheier et al., 1999).

Health behaviours. A number of health behaviours are associated with better healing and physical recovery from surgery. These include not exceeding recommended levels of alcohol consumption, not smoking, sleeping well and healthy eating. All of these behaviours have an effect on the immune system which is the key determinant of physical recovery.

Studies have demonstrated that post operative complications (mainly infections) were two to three times more common and protein levels in wounds were lower among alcohol abusers (Jorgensen, Tonnesen, Pedersen, Lavrsen, Tuxoe et al., 1998; Tonnesen & Kehlet, 1999). This is because ethanol suppresses processes which fight infection.

Smoking has been associated with reduced immune functioning (Broadbent et al., 2003; Kusaka, Kondou & Morimoto, 1992) and higher levels of complications after cosmetic surgery (Campanile, Hautmann & Lotti, 1998). Sleep benefits the immune system and healing processes as there is a reduction in the products of the stress response, such as adrenaline and glucocorticoids, which, when present, inhibit cell and skin regeneration (Adam & Oswald, 1984; Cole-King & Harding, 2001). Further, good nutrition (i.e. proteins, Vitamins A and C, zinc

and sufficient calories) is important in healing and recovery (Huckleberry, 2004; Singer 2002). Finally, a preliminary study indicated that taking regular exercise over three months predicted better healing of experimental wounds, although this association has yet to be substantiated within a surgical population (Emery, Kiecolt-Glaser, Glaser, Malarkey & Frid, 2005).

Summary. It is not clear whether the distress or worry mentioned by Janis translates either into stress or anxiety in the more recent literature but it is apparent that managing patients' anxiety and stress ought to lead to better clinical outcomes, whether these are psychological or physical. It is also important to note that other factors, such as personality variables and health behaviours, contribute to surgical recovery.

Psychological Adjustment to Surgery

Good management of patients' psychological needs and appropriate interventions should enable patients to make some cognitive adjustment to their circumstances. Two prominent models of adjustment to ill health or surgery assist in understanding how that process may come about.

The first is the model of coping proposed by Lazarus and Folkman (1984). It proposes two kinds of coping which, simultaneously, deal with objective and subjective aspects of an impending threat, respectively. Individuals adopt coping strategies and then evaluate their effectiveness and this is the crux of adaptation to the event. Problem-focused coping encompasses practical attempts or activities which are aimed to overcome objective difficulties. In the context of surgery, this might include carrying out exercises, behavioural modification, taking on activities of living and, ultimately, the resumption of pre-surgical roles. Emotion-focused coping refers to any attempts to deal with the subjective experience of a threatening

event (Lazarus & Folkman, 1984). In relation to surgery, emotion-focused coping might include attempts to deal with emotional distress and feelings related to pain, temporary disability and loss of social network. Importantly, it is the process whereby pain, symptoms, distress and unpleasant experiences are construed as necessary milestones of the recovery pathway. Problem-focused coping is used more appropriately in situations which are perceived as amenable to change whereas emotion-focused coping is more helpful in altering the meaning attached to situations which are not within a person's control.

Patients undergoing surgery are faced with both a threat and an event which may be perceived as unmanageable as it is outside their experience (Lazarus & Folkman, 1984). Well-planned psychological interventions ought, therefore, to assist in successful adaptation, provided they offer additional coping strategies for addressing practical difficulties or dealing with distress. It is also important to ensure that attempts to deal with both the objective and subjective aspects of the surgical experience do not conflict. Therefore effective interventions will enable patients to link their individual experience (e.g. of pain or anxiety) with more general statements about surgery (e.g. healing takes time).

The second model which explains why psychological interventions should help surgical patients is the self-regulatory model of illness (Levanthal et al., 1997). The construct of illness representations is central to this model. Patients form illness representations when they are diagnosed with an illness or medical condition. A patient's illness representations will incorporate highly individual beliefs about the identity of the illness, its cause, potential consequences, the likely duration and expectations about how it can be controlled.

Adjustment to surgery can be conceptualised as a process of self-

regulation. A patient will also have strategies for coping and will appraise how effective any coping patterns have been (Contrada et al., 1994). The process of reviewing the illness representation and attempts at coping is continuous. A patient achieves a high level of "coherence" (Contrada et al., 1994, p.244) when their coping attempts and reappraisals fit with the problem representation. The question is, therefore, what forms of psychological intervention can help with those processes. In particular, the model suggests that interventions which might be useful would help patients reappraise many aspects of their illness representation including the potential consequences, how controllable their condition is and how long any disability will last.

Method

Inclusion criteria

Studies had to satisfy four criteria in order to be included in this review. These concerned: (1) the nature of the psychological intervention; (2) sample characteristics; (3) outcome measures; and (4) research design.

Psychological Intervention

The objective was to consider as wide a range of psychological interventions as possible. These included providing psycho-education or psychosocial support and any other interventions aimed at promoting psychological or behavioural change. Interventions designed to create a more relaxing and pleasant environment (e.g. music interventions) were excluded. The interventions had to be delivered in hospital settings. For the purposes of inclusion in this review, no distinction was drawn between interventions which took place before or after surgery.

Sample Characteristics

Studies were included if the participants satisfied the following criteria: (a)

they were 18 years or older in age; and (b) they were undergoing major non-emergency surgery requiring an over-night stay with recovery on a ward and either general or epidural anaesthetic.

Outcome Measures

The review aimed to include a variety of outcomes, satisfying the following criteria: (a) The outcome was measured post surgery (which entailed elimination of any interventions only addressing pre-operative anxiety); and (b) outcomes included at least one measure of either physical recovery (e.g. physical activity, physiological functioning, length of stay in hospital and complications) or psychological adaptation to surgery (e.g. anxiety, depression, mood, self-efficacy, quality of life and pain). It is beyond the scope of this paper to include the extensive literature examining psychological or pharmacological methods of controlling pain. However, pain control is a key element in the care of in patients recovering from surgery and this is reflected in the inclusion of various measures of pain as outcomes.

Research Design

The original aim was to identify randomised controlled designs and quasi-experimental designs which assigned participants to an intervention or a control condition. However, given the limited number of studies identified and the objective of considering as broad a range of interventions as possible, a decision was taken to include uncontrolled single case studies.

Search Strategy

The PsychINFO and Medline databases for the period covering 1987-2007 were searched for articles published in peer-reviewed journals in the English language. A 20 year period was chosen as a sufficient time span which would

include the more recent literature.

Developing the search terms required some piloting as the potential choice of keyword terms is wide in this field and authors do not use a "clearly shared vocabulary" (Johnston & Vogele, 1993, p.246), particularly when the names of specific surgical procedures and medical conditions may be key words.

It was apparent that many studies of surgical outcomes had been carried out within coronary artery bypass graft patients. In order to include those studies as well as other surgical populations, the term "surg* (the asterisk indicating words with a similar stem such as surgery and surgical) or "coronary artery bypass graft" (CABG) were used to access the target population. A second search term, "intervention", ensured that intervention studies were included.

Finally, it was decided that, as interventions are sometimes described in very narrow terms, such as "using stress inoculation" or "the effects of discharge information", it was necessary to combine the above with a third search term which would cover the more specific kinds of intervention. This involved constructing five separate search terms, one for each of the five broad classes of interventions which had been identified at the piloting stage. These five search terms were: (1) "education", "psycho-education" or "information"; (2) "peer support" or "social support", (3) "relaxation", (4) "expressive writing" or "disclosure" and (5) "psychotherap*", "psycholog*", "behavio*", "cognitive" or "stress inoculation".

A hand search was also conducted of key journals in the area, including British Journal of Clinical Health Psychology, Clinical Psychology Review, Health Psychology and Journal of Consulting and Clinical Psychology, to identify relevant articles published between January 2000 to September 2007. In addition, a hand search of references of key papers was carried out.

This review places the findings in the context of some key meta-analyses, which examine the same constructs and which were also published from January 1987 to September 2007, inclusive.

Examples of Excluded Studies

A number of studies just fell short of the inclusion criteria. For example, studies reporting psychological interventions for patients undergoing more minor surgery, such as arthroscopy and day surgery were excluded (e.g. Allard, 2007; Ross & Berger; Stoddard, White, Covino & Strauss, 2005). Similarly interventions regarding invasive procedures rather than surgery were excluded (Ludwick-Rosenthal & Neufeld, 1993). Further, a study which examined a behaviour modification programme in a mixed group of myocardial infarction patients and cardiac surgery patients (Sebregts, Falger, Appels, Kester & Bar, 2005) was not included. The number of surgical participants was not reported and it was decided that any conclusions about the contribution of surgical participants to the results would be speculative.

Results

A total of 26 studies met the inclusion criteria and were included in the review (see Table 1, which has a key to abbreviations at the end). Three meta-analyses are also discussed. The studies fall into five clusters, in terms of the types of interventions evaluated: (1) psycho-educational approaches, (2) social support interventions, (3) relaxation, (4) expressive writing and (5) supportive and mixed psychological interventions (covering other supportive, cognitive, behavioural or psychotherapeutic approaches). The results are presented for each of these five clusters of interventions.

Table 1. Summary of studies included in the review

I Psycho-educational Interventions

Author and Date	Participants	Study Design and Intervention	Outcome Measures	Main Findings
Anderson (1987)	60 male coronary artery bypass graft patients Mean age 59.1	Experimental design with 3 groups:- *Information*: detailed information about procedures and sensations, video of recovered patients and focussing on the specific procedures plus researcher interview. *Information and coping*: info as above and slide show showing the exercises required after surgery and emphasising participants role in recovery. *Control*: routine hospital info and 30 mins with researcher discussing neutral topics.	**Post surgery** STAI Post operative affect scale Recovery inventory (physical recovery) Staff observation scale (nurse's rating of physical and psychological recovery).	Post surgery: experimental groups had lower negative affect, better nurse-rated recovery. No difference between the 2 groups. Nurse rating of physical recovery better on day 7 than controls and the experimental group had lower hypertensive ratings but no diff between groups.
Daltroy et al (1998)	222 hip and knee surgery patients (148 women and 74 men). Mean age 64	RCT with 2 groups: *Educational*: The day before surgery audiotape and slide presentation describing the hospital, procedure, sensations and rehabilitation. *Benson's Relaxation Response*: 18 minute audio tape, instructions how to practise and to use relaxation to lessen discomfort and anxiety.	**Pre surgery** STAI Wilson's 3-item scale of denial **Post surgery** STAI Length of stay Pain medication MMSE	No effect on Length of stay, pain or anxiety. Interaction between denial in the information group and length of stay and pain medication.
Moore & Dolansky (2001)	180 coronary artery bypass graft patients (96 male and 84 female). Mean age 62.6	RCT with 2 groups: Recruitment was 4-5 days post operation. *Intervention*: The Cardiac Home Information Programme: audio tape describing, procedures, sensations, equipment and normal recovery. *Control:* Usual cardiac discharge information i.e.	**Post surgery** POMS SIP Symptom Inventory (symptoms relevant to recovery from cardiac surgery)	At one month following discharge, a beneficial effect on physical functioning (effect size =.31) attributable to a difference in outcomes for women, who had worse physical functioning and more symptoms. There was a significant difference in the vigor subscale between groups (effect size = .33) which was attributable to the pre post difference in the male scores. 2 significant improvements for men on POMS (total

		risk factors, diet, activity and medication.		score and depression, anger, confusion subscale). Also less fatigue and more vigour.
Moore (1996)	82 coronary artery bypass graft patients (67 men and 15 women). Mean age 64	Experimental design with 2 groups: *Intervention*: The Cardiac Home Information Programme: audio tape describing procedures, sensations, equipment and normal recovery *Control*: Usual cardiac discharge information I.e. physiology, how to modify risk factors, diet, activity and medication.	**Post surgery** POMS SIPS (physiological functioning)	Patients who had listened to the intervention tape reported higher physical functioning compared with controls
Shelley & Pakenham (2007)	80 coronary artery bypass graft (64 male and 16 female) patients Mean age 65.5	RCT into 2 groups: *Experimental:* before surgery instruction and cognitive coping. 4 stages covered:- building rapport, patient concerns, prompting for questions and linking questions with concerns. Patient driven discussion but with reframing (i.e. cognitive elements).	**Pre surgery** External health locus of control Self-Efficacy **Post surgery** DASS Pain Cortisol Tumor necrosis factor alpha.	No significant difference between groups. Significant interaction: matching EHLC and SE in prepared patients meant they reported less distress and non-matched prepared patients reported more distress.
Shuldham et al. (2002)	329 coronary artery bypass graft patients. (288 men and 41 women).	RCT with 2 groups: *Intervention:* 4 hours in a group of 10-15 people before admission. Info comprised video, written info and discussion of any individual factors. *Control*: usual information - more informal, delivered by MDT. Also attendance at "pre and in hospital programmes" mentioned.	**Pre surgery** HADS SF-36 General Well-Being questionnaire VAS for pain, **Post surgery** Length of stay Repeated baseline measures, as above	Control patients had shorter stay No group differences re depression, anxiety, pain and wellbeing.
Sjoling et al. (2003)	60 patients (24 males, 36	Experimental design with 2 groups: *Intervention*: received (1) routine	**Post surgery** Satisfaction with nursing	No difference in pain report or oral analgesics, length of hospitalisation or anxiety.

	females) admitted for total knee arthroplasty. Mean age 71	information and (2) additional information, delivered in a supportive-educative model, which emphasised importance of patients' active role in surgery, reporting pain, the importance of physiotherapy and asking questions. *Control*: routine procedural information delivered in same time frame.	care. VAS re pain Daily pain index Overall pain index (worst experience) Morphine equivalent analgesics Length of hospitalisation	Experimental group were more satisfied with their pain management

II Social Support Interventions

Author and Date	Participants	Study Design and Intervention	Outcome Measures	Main Findings
Kulik & Mahler (1987)	27 male coronary artery bypass graft patients. Mean age 58.6 years	Experimental design with allocation into 4 groups:- 2 x 2 design of intervention groups With room mate having (1) similar or dissimilar operative status (pre or post) and (2) similar or non-similar surgery (cardiac or non-cardiac)	**Post operative** Pain medications, divided into "weak" and "strong . Reconstruction of distance walked 3-5 days post surgery using IMAM. Post surgical recovery Length of stay	Patients assigned to a post operative room mate had higher levels of ambulation, shorter lengths of stay and used fewer weak pain medications. The type of surgery had no effect.
Kulik et al. (1996)	84 male coronary artery bypass graft patients Mean age 58.3	Experimental design with allocation into 5 groups:- 2 x 2 design of intervention groups With room mate having (1) similar or dissimilar operative status (pre or post) and (2) similar or non-similar surgery (cardiac or non-cardiac) No room mate control group.	**Post surgery** Patient interaction questionnaire (to assess cognitive clarity and emotional affiliation) Time talking to room mate Total distance walked 3-5 days post surgery using IMAM. Post surgical recovery Length of stay	Better ambulation in patients with post operative room mate. Ambulation was better in patients with a cardiac surgery room mate than in the no room mate condition. Length of stay was shorter in patients reporting greater cognitive affiliation, implying info derived from the contact is important. Patients reported greater cognitive clarity if room mate was either post operative or cardiac, indicating this could be a mediator.

Parent & Fortin (2000)	56 male inpatients undergoing coronary artery bypass graft. Mean age 56.5 years	RCT with 2 groups: *Intervention*: Received 3 visits from former patient trained in a supportive approach. Visits 24 hours before surgery, 5 days and 4 weeks post surgery. *Control*: routine information on surgery and recovery.	**Pre surgery** STAI **Post surgery** STAI Jenkins self-efficacy expectation Self report of activity	Reduction in anxiety in the experimental group compared to controls at all 3 visits. At discharge greater self-efficacy expectations in experimental group with difference no longer apparent at 4 weeks. At discharge, experimental group reported more walking. At 4 weeks they also reported an increase in general activities and climbing stairs.
Thoits et al. (2000)	178 men undergoing coronary artery bypass graft. Mean age 58.8	Quasi Experimental Design: 1 month's participants assigned to intervention group with similar-other support (Former patient volunteers were trained to let patients talk, not to interrupt or advise but to offer own experiences). 30 mins daily totalling minimum of 4 hours. Followed by 8 day "washout" period to avoid contamination, Followed by allocation of 1 month's participants to control group with no support.	**Post surgery** Questionnaire to determine -level of natural similar-other support from former CABG patients. -satisfaction with social support -quality of interactions (in experimental group) 4 ratings of physical health CES-D SCL-90	No difference in outcomes relating to physical or mental health. In experimental group a reduction in activity at 12 months. Main discussion related to the confounding factor of the level of natural similar-other contacts on an open ward.
Weber et al. (2007)	72 men post surgery for prostate cancer Mean age 60	RCT with 2 groups: *Intervention:* 8 meetings to discuss thoughts and feelings related to diagnosis. Support partners had had similar treatment and training to listen actively and recognise depressive symptomatology. *Control:* usual care from the urologist.	**Post surgery** GDS SICPA (self-efficacy) UCLA Prostate Cancer Index (erectile dysfunction and incontinence)	The intervention group had lower depression and higher self-efficacy scores at 8 weeks.

III Relaxation Interventions

Author and Date	Participants	Study Design and Intervention	Outcome Measures	Main Findings
Cheung et al. (2003)	40 males and 19 females, after colorectal surgery for cancer involving stoma.	RCT with 2 groups: *Intervention*: Progressive muscle relaxation training which focussed on tensing and relaxing muscles and deep breathing. 2 teaching sessions and practise over 10 weeks using audiotape at home. *Control*: routine care	**Post surgery** STAI QOL-C WHOQOL-BREF-HK Log of how often they used the technique	The experimental group had significantly reduced state anxiety scores and significant increases on QOL-C scores. The experimental group had higher ratings on the WHO-QOL over 10 weeks, compared with the control group, although scores decreased over time.
Haase et al. (2005)	60 patients (37 male and 23 female) undergoing resection of colorectal cancer. Mean age 65.	RCT with 3 groups: *Guided imagery*: which taught participants to become calm and use inner resources and imagery to work through stress. *Progressive muscle relaxation*: focused on contraction and relaxation and feeling warmth and heaviness. *Control*: no intervention	**Post surgery** Patient controlled analgesia Pulmonary function 5 point scale to rate benefit and liking for the intervention.	No clinically relevant outcomes. Subjectively a positive patient response
Hattan et al. (2002)	20 males and 5 females undergoing coronary artery bypass graft surgery. Mean age 63.1	RCT with 3 groups: 2 days post surgery: *Guided relaxation*: 20 minute audiotape of guided relaxation *Foot massage*: 20 minute massage. *Control*: normal ward protocol.	**Pre and Post surgery** VAS of 6 variables: Pain Anxiety Tension Calm Rest relaxation	Significant difference between pre and post test scores on calm scores, with the foot massage producing more improvement. The effect of relaxation did not reach significance. No group differences in anxiety or other psychological measures.
Holden-Lund (1988)	24 adults (22 female and 2 male) undergoing cholecystecto my	RCT with 2 groups: *Intervention*: 4 x 20min Relaxation with Guided Imagery tapes, psychosocial support.1 session pre surgery and 3 post. *Control*: 20 minute quiet period in lieu of tapes	**Post surgery** STAI Cortisol levels Wound inflammation	Intervention group were significantly less anxious than controls 3 days following surgery. In control group no net reduction in anxiety by end of 5 day intervention. A difference at one day re cortisol levels (lower in intervention group) but differences not sustained.

	Mean age not reported.			3 days after surgery one measure of wound inflammation was lower in intervention group.
Miro & Raich (1999)	48 women and 42 men undergoing cholecystectomy. Mean age 44	RCT with 3 groups: *Relaxation training*: focus on tension and relaxation of muscles, use of imagery and instructions on how to continue. *Information*: sensations, procedures and emphasis on the importance of information. *Attention control*: focus on neutral facts about patient, directing specific questions to the surgeon.	**Pre surgery** MBSS (coping) Quiz about information or no times relaxation **Post surgery** Pain Return to activities Rating of satisfaction with intervention	No significant difference in outcomes between control group and interventions groups. Low monitoring patients trained in relaxation reported less pain at 24 hours, 72 hours and 3 weeks after surgery. This improvement was noted across 3 categories of activity (lying in bed, walking, standing up). No overall support for hypothesis that treatment is more effective if matched to coping style.

IV Expressive Writing

Author and Title	Participants	Study Design and Intervention	Outcome Measures	Main Findings
Solano et al. (2003)	40 inpatients undergoing papilloma resection of the bladder. Mean age 55.75; 32 men and 8 women.	Quasi experimental design with non random allocation to 2 groups: *Expressive writing group*: 3-4 days before surgery wrote for 20 minutes per day on 3 consecutive days about their deepest thoughts and feelings concerning the pending operation. *Control:* on the ward for at least 3 days before surgery.	**Pre surgery** TAS-20 **Post surgery** SCL-90 Record of post-operative course of overall recovery.	Experimental group had fewer days in hospital and lower scores on SCL-90. There was an interaction between writing and alexythymia, i.e. a reduction in number of days in hospital and lower SCL-90 scores only in the high alexithymia group.
Solano et al. (2007)	40 male inpatients undergoing endoscopic operation for benign prostatic hypertrophy. Mean age 60.60 years	Quasi experimental design with non random allocation to 2 groups: *Expressive writing group*: 3-4 days before surgery wrote for 20 minutes per day on 3 consecutive days about their deepest thoughts and feelings concerning the pending operation. *Control:* in hospital 4-5 days before surgery.	**Pre surgery** GPRI **Post surgery** SCL-90 Record of post-operative course of overall recovery.	There was an interaction with better post operative course evaluation, fewer days in hospital and lower SCL-90 scores in the low risk group. Writing had a small negative effect on outcomes in the high risk group.

V Supportive and Mixed Interventions

Author and Date	Participants	Study Design and Intervention	Outcome Measures	Main Findings
Blythe & Erdahl (1988)	1 56 year old woman prior to cardiac surgery	Single case study using stress inoculation, comprising 3 parts:- - education and cognitive preparation; - skill acquisition including relaxation techniques and self-statements; and - application, modelling and role-playing. 4 treatment sessions, total contact of between 4 and 6 hours.	**Post surgery** CES-Depression scale Behavioural checklist to record positive and negative behaviours.	Drop in depression score over time, with a marked reduction between the baseline measure and first day of the intervention, and from severe depressive episode to level just indicating need for intervention. Decrease in negative and increase in positive behaviours.
Larson et al. (2000)	41 women, newly diagnosed with breast cancer prior to surgery	RCT with 2 groups: *Intervention*: prior to surgery 2 x 90 min sessions with clinical psychologist; included psychoeducation about stress, instruction and rehearsal in active problem-solving, relaxation techniques and psychosocial support. *Control:* standard care	**Pre surgery** CES-D DES-IV IES LOT **Pre and post surgery** Blood assays, in particular NK activity and interferon (a cytokine)	Interferon levels in intervention group remained higher over time and decreased in control group, but this effect vanished when controlling for the baseline interferon levels. Optimism increased over time for both groups. On CES subscales interest and enjoyment increased and sadness decreased over time. Only group difference on psychological measures was decrease in disgust in experimental group.
Lie et al. (2007)	185 Patients (19 female and 166 male undergoing coronary artery bypass graft). Mean age 62 years	RCT with 2 groups: Intervention: Received 2 visits from nurse post surgery. Included individualised information, assessment of anxiety and depression and encouragement to set goals. Intervention manual documented coping strategies and second visit evaluated goals attained. Total time of contact 2 hours. *Control*: standard talk with a nurse or doctor, giving information and encouraging participants to ask questions.	**Pre surgery** HADS **Post surgery** HADS Post operative complications and re-hospitalisations	Anxiety and depression improved over time significantly for both intervention and control groups. There were more re-hospitalisations in the intervention group. In a predefined group of (N=65) of people who had anxiety and depression at baseline (it is not clear what cut off was used for those diagnoses) there were between group significant differences in terms of the intervention group improving more.

Mahler & Kulik (2002)	226 men and 70 women. coronary artery bypass graft patients. Mean age 63.2.	RCT of patients' spouses into 3 groups: All received sensory and procedural information from nurse specialist. Intervention groups viewed videos of CABG patients and their spouses. Editing for the 2 different experimental groups focussed on selecting examples of *Mastery* (calm, confident, without problems); *Coping* (concerns and efforts made to cope with any difficulties) and *Control*: no video	**Post surgery** Spouse outcomes: not discussed Patients: PANAS Post-operative problems	No between group differences. There was a trend towards significance for patients whose spouses were allocated to the Mastery group having fewer complications (compared with Coping or Control) Rehospitalisations were significantly higher among females whose spouse was in control condition compared with those whose spouse was in the mastery condition.
Ross et al. (2005)	249 patients undergoing colorectal surgery for cancer. (121 men and 128 women). Median age 68	RCT with 2 groups: *Intervention*: 10 home visits by project nurse or doctor over 2 years following discharge. Aim to give information and emotional support and to encourage participants to use own social network. *Control:* no visit	**Post surgery** HADS QLQ-C30 and C38 Data collected at 3,6,12 and 24 months.	At 3 months intervention produced a significant effect on symptoms of fatigue. No effect on well-being except for a trend towards significant improvement for intervention group at 3 months.
Schindler et al. (1989)	33 coronary artery bypass graft patients (26 men and 7 women). Mean age 59.5	RCT with 2 groups: *Intervention*: Structured Psychiatric interview, encouraging discussion of anxieties pre surgery. Post surgery supportive psychotherapy daily. *Control*: No detail	**Pre and post surgery** MMSE PAIS-SR **Post surgery** Clinical data, including length of stay and complications	Intervention group used more pain medication. Difference apparent on days 3-6 and not apparent after 8 days. Controls used more morphine sulphate and benzodiazepines, from days 4-6, differences not apparent after 8 days. In experimental group a reduction in length of stay. Post-operatively more complications in control group
Sorlie et al. (2007)	109 coronary artery bypass graft patients. (96 men and 13 women).	RCT with 2 groups: *Intervention*: viewed a 12 min video. Plus 2 x 40min individualised information sessions, encouraging expression of anxiety, responding to emotional and situational problems, encouraging patients to seek further information and to	**Post surgery** BAI Zung depression rating scale Subjective health ICD classification and cardiologic function.	Lower anxiety in intervention group from discharge up to 1 year. Less depression from 6 to 24 months. Better subjective health from discharge up to 2 years.

	use their support networks. *Control*: routine surgical information.

NOTES ON MEASURES

BAI- Beck Anxiety Inventory
CES-D – Center for Epidemiological Studies Depression Scale
DASS – Distress, Anxiety and Stress Scale
DES-IV – Differential Emotions Scale – IV
GDS – Geriatric Depression Scale
GPRI – Goldman Preoperative Risk Index – risk of cardiac complications
HADS – Hospital Anxiety and Depression Scale
IES – Impact of Events Scale
IMAM – Integrated Motor Activity Monitor
KHOS – Krantz Health Opinion survey – measures desire to ask about medical procedures.
LOT – Life Optimism Test
MBSS – Miller Behavioural Style Scale
MMSE – mini mental state examination
PAIS-SR – Psychological Adjustment to Illness Scale – Self-Report
PANAS – Positive and Negative Affect Scale
POMS – Profile of Mood States
QLQ – Quality of Life Core Questionnaire (C-30 relating to cancer and C-38 relating to colorectal cancer)
QOL-C – Quality of life Scale - Colostomy
SCL-90 – Symptom Checklist
SF-36 – Short form health survey
SICPS – Stanford Inventory of Patient Adjustment
SIP – Sickness Impact Profile
STAI – State Trait Anxiety Inventory
TAS-20 – Toronto Alexithymia Scale
VAS – Visual analogue scale
WHOQOL-BREF-HK – world health organisation quality of life scale Hong Kong version

Psycho-educational Interventions

Seven studies examined interventions providing surgical patients with education or information. Five studies were conducted with CABG patients and the two others with orthopaedic surgery populations. They are summarised in Part I of Table 1.

Theoretical rationale

There is a clear theoretical model which explains how providing patients with information about their impending surgery might help post-surgical psychological adjustment. The construct of external health locus of control (Wollaston, Wollaston & de Vellis, 1978) was based on Rotter's (1966) Locus of Control theory. Information helps individuals who are high in external health locus of control. This is because they appraise an event such as surgery as something over which they have no control and they regard powerful others, such as surgeons, as the people who will most influence the outcome. This leads to distress. However, providing information removes some of the uncertainty about the anticipated events and bolsters feelings of control over the approaching event. Individuals who are low in external health locus of control are less likely to be as distressed as they have a greater sense of being able to manage their medical conditions (Folkman, 1984).

Features of the interventions

There was considerable variability in the interventions used. Some interventions in this cluster, although using predominantly psycho-educational methods, also used elements of other approaches such as using a supportive-educative nursing model for provision of information (Sjoling, Nordahl, Olofsson & Asplund, 2003), encouraging discussion of individual factors (Shuldham, Fleming

& Goodman, 2002), cognitive coping (Shelley & Packenham, 2007) or a steer towards coping and taking control of recovery (Anderson, 1987).

What the interventions had in common was provision of information. Six out of the seven studies gave information about procedures and sensations which patients would experience, and five out of the seven studies provided information about rehabilitation or recovery. Shelley and Packenham's (2007) intervention did not follow this format, focusing instead on what was described as "information instruction", structured interview and linking concerns to key questions. The total time of the interventions varied from short taped material, the shortest being 12 minutes (Daltroy at al., 1998), usually combined with written information, discussion or presentation, and extended to a four hour group intervention (Shuldham et al., 2002).

Study designs

All the studies used experimental designs with a control group. Four were randomised controlled trials and three were non-randomised experimental designs with either one or two intervention groups and one control group.

There was considerable variability in the control conditions. One group was instructed in relaxation (Daltroy et al., 1998), one received discharge information from a multidisciplinary team (Shuldham et al., 2002), three provided the same face-to-face interaction time but focused on neutral topics (Anderson et al, 1987; Moore, 1996; Sjoling et al., 2003) and one did not describe the control group intervention (Shelley & Packenham, 2007). One group received the same cardiac information on discharge as the information group but did not see the video (Moore & Dolansky, 2001).

Outcomes

The post-operative outcomes for these interventions were varied and none of the studies used identical outcome measures. The variation makes it difficult to compare studies and to draw firm conclusions.

All seven studies examined psychological outcomes. Only two studies found a significant result. Anderson (1987) found a reduction in negative affect, while Moore and Dolansky (2001) reported improved vigor scores on the Profile of Mood States (POMS). The remaining five studies found no between-group differences. In particular, none of the three studies examining post-operative anxiety demonstrated a reduction in anxiety, nor did any of the four examining pain show any improvement.

All the studies measured physical recovery outcomes. Three found improvements within the intervention groups and one study reported a better outcome within a control group. Providing information led to higher nurse ratings of recovery seven days after surgery (although whether they were blind to condition is not reported), compared with the control group, in the only study which examined that outcome (Anderson, 1987) and better levels of physical functioning in two other studies (Moore, 1996; Moore & Dolansky, 2001). Of the three studies which reported length of stay as an outcome, two demonstrated no group differences (Daltroy et al., 1998; Sjoling et al., 2003) and one showed that the control group had shorter stays on the ward than the intervention group (Shuldham et al., 2002).

One striking aspect of the methodologies raises the question whether control groups were, in fact, receiving perfectly adequate information or a beneficial intervention, even if they did not receive additional material or instruction. In particular, Daltroy et al. (1998) had originally intended to use a relaxation tape,

aimed at lessening discomfort and anxiety, as a second condition. However, when the results were reported this was, confusingly, referred to as the control condition. Another example of what might be a non-neutral control was informal provision of education on a one-to-one basis, in which "nurse, doctor, physiotherapist, occupational therapist, pharmacist and dietician all participated" (Shuldham et al., 2002, p.668). While there is no way of describing the exact content of this education, it seems that these participants received a fairly good spread of information. It also might, methodologically, have been difficult to ensure that those natural contacts with a range of professionals did not cover information of the kind specifically offered in the experimental condition. This may be a particular concern in cardiac settings as on discharge, patients will, necessarily, be given information on diet, exercise, managing risk factors and so on.

However, there were examples of careful consideration being given to the nature of the control group. Anderson (1987) and Moore (1996) ensured that participants in the control conditions had a similar length of time spent face-to-face with researchers, in the course of receiving more routine information.

Some studies examined individual differences that may moderate the effect of psycho-education on surgical outcome. Daltroy et al. (1998) found a reduction in pain medication and length of stay only among those in the information condition who were high on a measure of denial. Moore and Dolansky (2001) identified an improvement on two of the POMS scales only for men following the intervention. Finally, Shelley and Packenham (2007) measured two individual difference variables: external locus of control and self efficacy. The results showed there was reduced distress at discharge (i.e. greater benefit) if patients receiving preparation

were matched on these measures, i.e. were either high on both external locus of control and self-efficacy or low on both.

Meta-analyses of psycho-educational interventions

Three meta-analyses have also been carried out on studies using psycho-education with surgical populations. They review studies published in the period of publication 1963 to 1989 and, therefore, represent little overlap with the intervention studies described above.

Suls and Wan (1989) analysed 21 studies (published between 1967 and 1984) in which the interventions comprised providing sensory and procedural information. Sixteen of the studies included were of adult surgical patients, two were studies of child surgical patients and five were studies of laboratory processes which induce pain. They identified that sensory information, which details what will be felt, seen and so on, was more effective in reducing self-reported pain than procedural information, which describes what the operation involves (effect size = .47). There was a medium effect size for reduction in pain and reduced negative affect among groups who received either sensory or procedural information. There were large effect sizes for reduction in pain where groups received both kinds of information and for reduction in distress in groups receiving only sensory information.

Devine's (1992) larger meta-analysis examined the effectiveness of psycho-educational interventions, including provision of health care information, teaching skills and psychosocial support. This meta-analysis included studies published between 1967 and 1989 and was more inclusive in its scope as it identified 191 studies (including dissertations). Overall there was considerable evidence to conclude that patient preparation is an effective intervention. Medium effect sizes

were reported for outcomes relating to pain, psychological distress and physical recovery.

Johnston and Vogele (1993) analysed 38 studies (published between 1980 and 1989) in which the intervention was some form of psychological preparation for surgery. Seventeen of the studies examined providing procedural or sensory information or both to patients. There was greater variability in the kind of interventions included, which, as well as looking at the effect of providing information before surgery, examined relaxation, giving behavioural instructions as well as some cognitive strategies. Despite considerable heterogeneity in the method of providing information before surgery, prepared patients did better than controls on all categories of outcome with medium effect sizes for outcomes such as pain and pain medication, negative affect, length of stay and behavioural and clinical measures. Behavioural instructions had a universal beneficial effect as part of preparation for surgery and this effect was found in all their outcome categories.

Summary

In summary, there is mixed evidence that preparing patients before surgery, with a combination of procedural and sensory information, provides psychological and physical benefits, in terms of recovery. There is a discrepancy between the inconclusive evidence from the studies identified and the strong conclusions in meta-analyses. Good studies are hard to design because of the difficulties over deciding what intervention, if any, control participants should receive. This is a particular concern since much of the literature reviewed comes from post cardiac surgery settings, in which the usual discharge care must cover aspects of health behaviour which might prevent a recurrence.

Social Support Interventions

Five studies were identified which used predominantly social support interventions. Four came from populations of CABG patients, while the other was a study of patients undergoing prostate surgery (See part II of Table 1).

Theoretical rationale

Epidemiological studies have established that there is a link between levels of social integration and mortality (e.g. Berkman, 1995). Further, research in the field of psychoneuroimmunology concludes that high quality social support has a beneficial effect on the immune system, while abrasive or stressful close relationships have a detrimental effect on regulating the immune system, (Kiecolt-Glaser et al., 2002). Social support has been defined in many ways but the term covers a combination of emotional support and tangible assistance provided by an individual's social network. In terms of measuring social support, Wills (1998) draws an important distinction between structural social support (which is the existence and number of social relationships) and functional social support (which refers to the practical benefits received and perceptions of the quality of social support).

The beneficial effect of a good supportive social network is thought to work in two ways. First, good social support promotes health and well being at all times. Secondly, at times of stress, the support network will have a buffering effect (Cohen & Wills, 1985). The level of social support which an individual can rely on is an important aspect in terms of addressing the potential impact of a distressing event, such as surgery.

Features of the interventions

The interventions focussed on support provided by other patients. Two of the

studies (Kulik & Mahler, 1987; Kulik, Mahler & Moore, 1996) involved allocating CABG patients to different types of room mates. The room mates were similar or dissimilar in terms of type of surgery and operative status. Three studies involved contact with a former patient prior to surgery to enable discussion about surgery and what to expect (Parent & Fortin, 2000; Thoits, Hohmann, Harvey & Fletcher, 2000; Weber, Roberts, Yarandi, Mills, Chumbler et al., 2007). One further study which focussed on the support provided by patient's partners, rather than other patients, is discussed later in the supportive and mixed interventions section.

Study designs

The studies comprised two randomised controlled trials and three experimental designs which compared intervention and control groups.

Outcomes

The different outcome measures used make it hard to draw overall conclusions about the effectiveness of the interventions although they can be divided into psychological and physical health measures. Three studies examined measures of psychological adjustment and greater improvements in the intervention group were found in two (Parent & Fortin, 2000; Weber et al., 2007). Both studies reported greater self-efficacy expectations. Parent and Fortin (2000) also found a reduction in anxiety, and Weber et al. (2007) found a reduction in depression. Thoits et al. (2000) did not find any significant differences in psychological outcomes.

All five studies used measures of physical improvement. The intervention groups improved in three studies (Kulik & Mahler, 1987; Kulik et al., 1996; Parent & Fortin, 2000), in terms of greater activity levels and shorter stays in hospital. In contrast, one study found a significant reduction in activity levels in the intervention

group (Thoits et al., 2000) and another found that intervention produced no differences in physical outcomes (Weber et al., 2007).

Some studies attempted to analyse what might be helpful about receiving social support from other patients. In a well-designed study, Kulik and Mahler (1987) found that participants assigned pre-operatively to room mates who had had surgery recovered better than patients assigned to room mates who were waiting for surgery. Kulik et al. (1996) looked for potential moderators between social support and outcomes. Their allocation of CABG patients to room mates who were either similar or dissimilar, in terms of operative status (pre or post) or in terms of the kind of surgery (cardiac or non-cardiac) found that post operative ambulation was better in patients who either had a cardiac room mate or a post operative one, while having no room mate led to significantly worse ambulation. A post surgery questionnaire captured how much cognitive clarity and emotional affiliation had been gained by the room mate interactions. From this it was evident that length of stay was shorter in patients who reported greater cognitive clarity. This suggests that some assimilation of information from the room mates was a key part of the contact.

A critical look at two other conclusions raises another issue about support provided by other patients. Parent and Fortin (2000) found better psychological and physical adjustment within an experimental group who received three visits from a former patient. The authors proposed that the potent part of the intervention was gaining "vicarious experience" (Parent & Fortin, 2000, p.394) and facing "living proof" that the procedure had been effective.

By contrast, using a careful methodology, Thoits et al. (2000) did not find that patients who were visited by surviving patients recovered better than controls.

Interestingly, the data captured how much both groups had talked to others recuperating on a semi-open ward. Analysis showed that it was the level of that "natural" contact with other patients, rather than the intervention visits, which was associated with improved physical and psychological recovery.

Summary

Taken as a whole, there is some evidence for the effectiveness of pre-surgical patients meeting post-surgical patients, whether this is through natural contact on an open ward, prescribed visits from volunteers or room mate allocation. The findings are not restricted to cardiac surgery patients and it will be interesting to see if they are generalised further in future research.

Relaxation Interventions

Five studies using primarily relaxation techniques were identified. (See Part III of Table 1). These comprised one study of CABG patients, two studies of patients undergoing cholecystectomy and two of patients having colorectal surgery for cancer.

Theoretical rationale

Relaxation has been defined as a state in which a relief from tension or strain is felt (Sweeney, 1978, cited in Hattan, King & Griffiths, 2002). Like other stress-relieving approaches its effectiveness is due to the reduction in the activation of the autonomic nervous system. A longitudinal study demonstrated the effectiveness of relaxation training in lowering blood pressure and reducing the incidence of further coronary incidents in post myocardial infarct patients (Patel et al., 1985). There has also been some support for the approach in a meta-analysis of 48 studies using relaxation interventions in various patient populations (Hyman,

Feldman, Harris, Levin & Malloy, 1989). Reductions in hypertension, insomnia, headaches, anxiety and pain levels were reported.

Features of the interventions

A number of slight variations on relaxation training were used, including guided relaxation (Hattan, King & Griffiths, 2002), progressive muscle training (Cheung, Molassiotis & Chang, 2003) and relaxation with guided imagery (Haase, Schwenk, Hermann & Muller, 2005; Holden-Lund, 1988; Miro & Raich, 1999).

Study designs

All the studies were randomised controlled trials.

Outcomes

Four studies measured psychological outcomes and two of them found a significant improvement following the intervention. Three studies measured anxiety levels and two found reduced scores compared with control groups (Cheung et al., 2003; Holden-Lund, 1988). By contrast, Hattan et al. (2002) did not report a significant difference in anxiety levels although greater calm scores were reported in the foot massage (not relaxation) condition. Further, Cheung et al. (2003) reported better quality of life in the group who received relaxation training.

Three studies measured physical recovery outcomes. Holden-Lund (1988) reported reductions in cortisol one day after surgery and lower concentrations of one measure of wound inflammation three days post-operatively. However, no differences in post-surgery activity levels (Miro & Raich, 1999) or pulmonary function (Haase et al., 2005) were found.

One study examined individual differences which may moderate the effect of relaxation interventions. Miro and Raich (1999) divided participants who

received relaxation training into those who had a low or high tendency to seek out information (as measured by the Miller Behavioural Style Scale). Those who were low on the trait reported less pain and improved activity levels from 24 hours to 3 weeks after surgery.

Summary

There is some evidence for the effectiveness of relaxation training in improving psychological adjustment and less evidence that it promotes physical recovery.

Expressive Writing

Two studies were identified which used an expressive writing intervention (Solano, Donati, Persichetti & Colaci, 2003: Solano, Pepe, Donati, Persichetti, Laudano et al., 2007, see Part IV of Table 1). The surgical populations were patients undergoing papilloma resection of the bladder and endoscopic surgery for benign prostatic hypertrophy.

Theoretical rationale

There is a growing body of literature which indicates that expressive writing enhances immune functioning and confers physical health benefits. A lot of evidence has been gathered from studies using healthy populations while there has been more limited research into its effects in medical populations. A meta-analysis of the effectiveness of expressive writing in 146 randomised controlled trials encompassing a variety of clinical and non-clinical populations, reported an overall small effect size across a range of outcomes, including psychological health and physiological functioning (Frattaroli, 2006). An earlier meta-analysis, which focussed on health outcomes in nine studies of clinical populations, concluded that there was a small effect size for psychological health outcomes and a medium effect size for physical health outcomes (Frisina, Borod & Lepore, 2004). The overall

picture is, therefore, at slight variance with the conclusions in some of the better known studies reporting improvements in physiological outcomes (e.g. Esterling, Antoni, Fletcher, Pennebaker, Kiecolt-Glaser & Glaser, 1988; Petrie, Fontanilla, Thomas, Booth & Pennebaker, 2004).

There are three main theories which offer explanations of how expressive writing may work which are: inhibition theory, cognitive-processing theory and self-regulation theory. Inhibition theory draws on the Freudian proposition that inhibition of thoughts and feelings is harmful. Expressing those feelings through writing is thought to reduce stress. The benefits have been attributed to processes similar to catharsis or the release of previously inhibited emotions (Freud, 1904/1954, Lepore & Smyth, 2002). Cognitive-processing theory bases the benefits of expressive writing on making sense of distressing events and gaining insight (Pennebaker, 1993). Finally, self-regulation theory likens expressive writing to gaining mastery, a process which allows participants both to observe themselves and to gain control of their emotions. This, in turn, bolsters their feelings of self-efficacy in relation to regulating emotions (Lepore & Smyth, 2002).

In all of these explanations, there is a common link between reducing stress and sympathetic nervous system activity, (Miller and Cohen 2001). This should promote better physical recovery from surgery.

Features of the interventions

Both studies, conducted by the same first author, followed the experimental paradigm of Pennebaker and Beall (1986). Participants were told to write for 20 minutes about their deepest thoughts and feelings regarding the impending operation. The expressive writing took place on three consecutive days before surgery.

Study design

The studies were randomised controlled trials. Both studies used a control group who were admitted onto the ward for a similar period of time before surgery and who were not asked to write. That departed from the usual paradigm in which the control group are asked to write for a comparable length of time about neutral topics.

Outcomes

Both studies examined physical recovery and psychological outcomes. Solano et al. (2003) found two significant group differences, with the experimental group staying fewer days in hospital and reporting fewer symptoms on the Symptom Check List-90 (Derogatis, 1977). The intervention in the second study (Solano et al., 2007) did not replicate that result.

Both studies examined individual differences that may moderate the effect of expressive writing. Solano et al. (2003) found that participants who were high on alexithymia generally reported more symptoms, stayed on the ward longer and received a lower rating of overall healing. However, the benefits of expressive writing were apparent in this group rather than in the low alexithymia group. Solano et al. (2007) found an interaction which demonstrated that that the benefits of expressive writing were only evident in participants who were low on the Goldman Preoperative Risk Index (a measure of the risk of cardiac complications in non-cardiac patients; Goldman et al., 1978). The low risk expressive writing group spent fewer days in hospital and reported fewer symptoms.

Summary

It is not possible to conclude from the results of two studies that expressive writing interventions improve physical recovery and psychological adjustment

following surgery. Improvements might be moderated by individual differences, with greater benefits being found in individuals who might not, otherwise, be inclined to explore their emotions. More studies using both physical and psychological outcome measures are needed to explore whether expressive writing assists recovery from surgery.

Supportive and Mixed Interventions

This section covers fairly diverse interventions and includes psychological, psychotherapeutic, cognitive and behavioural methods not covered in the previous sections. Many were characterised by a combination of elements but the majority gave participants the opportunity to talk to and gain support from professionals about their anxieties. Seven such studies were identified (See Part V of Table 1). Five of these investigated interventions for CABG patients, one for patients undergoing colorectal surgery for cancer and one for patients undergoing surgery for breast cancer.

Features of the interventions

Several of the studies used a mixture of more than one psychological approach. Four studies used, in part, a psychiatric interview or patient-centred supportive intervention (Larson, Duberstein, Talbot, Caldwell & Moynihan, 2000; Ross, Thomsen, Karlsen, Boesen & Johansen, 2005; Schindler, Shook & Schwartz, 1989; Sorlie, Busund, Sexton, Sexton & Sorlie, 2007). Three studies used strategies very similar to cognitive behavioural therapy. One intervention included elements of active problem solving (Larson et al., 2000) and one used a manualised approach to goal setting and using coping strategies (Lie, Arnesen, Sandvik, Hamilton & Bunch, 2007). A further study (Blythe & Erdahl, 1988) used stress inoculation which is a cognitive behavioural approach. The intervention was conducted in three

phases: (1) education and cognitive preparation; (2) skill acquisition; and (3) training and role play. The common factors in all of these interventions was promoting emotional adjustment by giving patients a broad range of strategies to cope with aversive events and moving away from the negative connotations of surgery.

Finally, one study randomly allocated participants' spouses into three conditions to view a video in order to investigate how preparation of spouses might impact on patients' post operative recovery (Mahler & Kulik, 2002). Three different videos were made by the editing of patient and spouse interviews into statements which demonstrated mastery, coping or neutrality (for the control group). Although support from spouses is social support, the study relied on a sufficiently different concept from the social support interventions (which drew on interactions with former patients) to merit it being put in a different category from those studies.

Study designs

Six randomised controlled trials and one single case study were identified.

Outcomes

Overall nine different psychological and eight different physical health outcome measures were reported. Six studies examined psychological outcomes. Four found improvements within the intervention group and two found no difference between groups. In the three studies which looked at post-operative anxiety, the intervention reduced scores significantly in two. One study found that a reduction in anxiety was sustained for one year post-surgery (Sorlie et al., 2007). In a further study, Lie et al. (2007) demonstrated significant reductions in anxiety following the intervention, within a predefined group who had been identified with

a diagnosis of anxiety before surgery. Four studies measured depression scores as outcomes. Two of these reported reductions following the intervention (Blythe& Erdahl, 1988; Sorlie et al., 2007) and, similarly, Lie et al. (2007) demonstrated significantly reduced depression scores within a predefined population who had depression prior to surgery. One study found no between-group differences in depression scores (Ross et al., 2005). The other improved psychological outcomes were less fatigue (Ross et al., 2005), a decrease in disgust (Larson et al., 2000) and more positive and fewer negative behaviours (measured by a behavioural checklist, Blythe & Erdahl, 1988).

Five studies analysed physical recovery outcomes. Two found a physical benefit following the intervention, two found no between-group differences (Larson et al., 2000; Mahler & Kulik, 2002) and in one study the intervention resulted in worse outcomes for the intervention group (Lie et al., 2007). The outcomes which were improved by the interventions were improved report of physical health (sustained for two years following surgery, Sorlie et al., 2007) and shorter length of stay and fewer complications in the intervention group (Schindler et al., 1989). In contrast, Lie et al. (2007) reported a greater number of re-hospitalisations in the intervention group. Finally, Schindler et al. (1989) analysed use of pain medication and found that the intervention group required lower quantities of morphine sulphate and benzodiazepines but greater levels of weaker pain medications.

One study examined individual differences which may moderate the effect of interventions. Mahler and Kulik (2002) looked at whether preparing the spouses of cardiac patients may affect the patients' own adjustment to surgery. The results examined gender differences and found that the intervention was effective for female patients: there were fewer re-hospitalisations among women whose spouses

viewed a video, which emphasised mastery of the effects of cardiac surgery, compared with women whose spouses had seen a neutral video.

Summary

There is some evidence for the effectiveness of supportive and mixed psychological interventions. The effectiveness of these interventions in reducing depression and anxiety was supported by the most evidence. In contrast, there was mixed evidence that these interventions enhance physical recovery.

Finally, this review failed to identify any studies where the outcomes for patients receiving stress inoculation interventions were compared with a control group. Only well-designed future research can confirm if this form of intervention should be developed further.

Discussion

It is difficult to draw firm conclusions from the studies which were reviewed. The 26 studies which were identified clustered into five broad types of intervention and mixed evidence was found regarding their effectiveness. Twenty two studies examined psychological outcomes and 11 of these demonstrated a statistically significant improvement for the intervention group. Twenty two studies also examined physical recovery outcomes; 10 of these found significant improvements following the intervention and, surprisingly, three studies reported worse physical outcomes. Nineteen studies examined both physical and psychological outcomes.

This discussion will address the nature of the interventions, methodological issues, practical considerations in providing interventions and recommendations for future research.

Nature of the Interventions

A fairly broad range of interventions was included in this review. There is more evidence for the effectiveness of some interventions than others. There were some trends suggesting that certain interventions are more effective for particular outcomes. Regarding psychological outcomes, there is some limited evidence that the interventions which showed the most consistent trend in improving psychological wellbeing were the provision of social support, relaxation training and supportive and mixed approaches. There was little evidence of the efficacy of psycho-educational approaches in psychological adaptation to surgery, although meta-analyses of earlier studies have reported good evidence for such interventions. One possible explanation for not finding evidence from individual studies in predominantly cardiac settings is that "treatment as usual" control groups may be receiving sufficient information.

Regarding physical recovery, social support interventions provided evidence of a trend towards improved physical outcomes. Studies of psycho-educational interventions, relaxation and supportive and mixed interventions showed some evidence of improving physical recovery although the findings were mixed. It is difficult to draw firm conclusions about the effectiveness of expressive writing interventions as only two studies have been conducted using this intervention with surgical populations.

Many of the studies were not clear on what the exact content of the interaction was. In addition, there was only one example of an intervention being manualised (Lie et al., 2007). In that study the manual outlined coping strategies. The lack of a manual means many of the interventions may not be easily replicable.

More manualised approaches would also have ensured that interventions can be delivered efficiently and effectively.

Finally, one point arises from the nature of the interventions. First, given the emergence of evidence-based Cognitive Behavioural Therapy (CBT) to treat some chronically ill populations, such as chronic fatigue sufferers (e.g. Deale, Chalder Marks & Wessely, 1997), it was surprising not to find more interventions which draw on the principles of CBT, within the studies identified.

Methodological Issues

The studies identified in this review have several strengths. Seventeen were randomised controlled trials, the gold-standard in study design. A further eight studies used experimental designs, comparing experimental groups with controls. Therefore, overall, the conclusions are supported by good evidence. However, one limitation of the studies was that only one of the studies reported effect size (Moore & Dolansky, 2001), which would have allowed a more direct comparison of change across studies.

The majority of studies (14) were conducted in cardiac surgery settings. Other populations were only represented in a small number of studies, which means it is not possible to draw firm conclusions about the effectiveness of specific interventions across populations, or whether particular interventions might be more effective for particular populations. It is also worth considering what effect the exclusion criteria of the review may have had on the conclusions drawn. Interventions for non-surgical medical populations were excluded and yet there is no reason to suppose that such interventions are not attempting to achieve similar aims, namely improving psychological and physical adjustment to a major physical health problem. In addition, the exclusion of studies of day case surgery (e.g.

Allard, 2007) raises a question regarding the surgical populations. Day cases tend to be carried out using straightforward procedures with fewer post-surgical complications. Therefore studies with the most homogenous samples, in which it might be easier to detect the impact of interventions, may have been excluded.

Another methodological strength was the use of standardised psychological outcome measures. In addition, a broad and appropriate range of physical outcome measures were used in the studies, including physiological measures (such as blood samples), objective measures (e.g. length of stay), subjective measures (e.g. clinician ratings) and self-report. This breadth, however, meant that it was hard to weigh up the evidence overall regarding which interventions worked in improving physical health outcomes. Only a few studies looked at personality variables (e.g. alexithymia) which makes it hard to gain any overall understanding of individual differences which moderate the effect of psychological interventions on recovery.

Further the focus of the current review was on post-operative outcome. However, many of the studies measured the effect of the various interventions on pre-operative anxiety and those results have not been reported. Interestingly, none of the studies analysed any of the psychological factors which are known to predict good recovery from surgery and so it is not known whether interventions confer any additional benefit.

Practical Considerations in Providing Interventions

Fast track surgery has been introduced in many surgical settings in order to enhance early recovery. Wilmore and Kehlet (2001) advocate "fast track" practices, which include early mobilisation and minimal access technologies in order to minimise the physical insult of surgery and to reduce the number of days spent in hospital. Advances in medical treatment have made it possible to minimise

the incisions made during surgery, for example using laparoscopic techniques. This less invasive surgery accounts for an increasingly large percentage of high volume surgery performed (Contrada et al., 1994). These approaches are aiming for the same improved outcomes as the psychological interventions which have been reviewed, which mean there is possibly less role for psychological interventions in settings where surgery is minimally invasive. However, there is still a role for psychological interventions to deal with the impact of the illness as well as in more invasive surgery.

The literature does not adequately address how psychological interventions could be incorporated into the practices of a busy health service. Swindale (1989) describes the nurse's role as the key emotional supporter of surgical patients but it is hard to see how this role fits in with the pressures of nursing on busy wards with a high changeover of staff. In planning interventions, some thought must be given to the gradations of intensity in the additional staff input which will be required.

Recommendations for Future Research

More well-designed studies are needed in this area. In particular, it would be beneficial to gather more evidence of the efficacy of interventions which do not rely on a great deal of input from health professionals, such as using group approaches. Training in relaxation techniques could also be developed for use on wards. Future studies could also usefully follow an intervention manual so that any interventions which produce improved outcomes can be replicated.

In many ways surgery provides a natural setting for studies (Vogele, 2004) and because non-emergency surgery is planned, there is clinical data which serves as objective pre-surgery and outcome data. It is also possible to collect psychological measures at baseline and follow-up. Further, the main opportunity

for psychological intervention is likely to be before surgery because of competing demands in patient care, mainly medical ones, afterwards (Contrada et al., 1994).

In planning future intervention studies, it will be important to continue obtaining good evidence from randomised controlled trials which use follow-up data (Miller & Cohen, 2001). Good studies would also combine more objective measures (e.g. clinical data) with more subjective ones (ratings and self-report). This might establish whether these mixed findings regarding physical health outcomes are due to measurement issues.

Finally, while pre-operative anxiety has not been discussed, it would be interesting to bridge the gap in the literature between interventions which have addressed pre- and post-operative psychological outcomes.

Conclusion

This review covered a fairly diverse literature examining five broad clusters of intervention. It is hard to draw conclusions about the kind of interventions which most benefit patients having major surgery, although some trends have been identified. There remains a continuing need to carry out good quality research in this field to evaluate whether there are interventions which could be incorporated into hospital care to assist recovery from major surgery.

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Part 2: Empirical Paper

Does Expressive Writing Lead to Physical Health Benefits in Women who have undergone Surgery for Gynaecological Cancers?

Abstract

This study investigates whether a group of women undergoing surgery for various kinds of gynaecological cancer had better physical health outcomes when they took part in an expressive writing intervention compared with a control group who wrote about neutral topics. Twenty women completed the writing while on a ward recovering from surgery. The outcome measures were length of stay in hospital, nursed rated recovery, pain medication and health care utilisation. No between group differences were found, although the lack of findings may be attributable to the small sample size and low statistical power. A number of issues are considered regarding the feasibility of running an expressive writing intervention on a surgical ward, the timing of the intervention and the complexities of measuring outcomes.

Introduction

Major surgery is a threatening event and surgical patients typically experience psychological distress as they anticipate going to hospital, the surgery itself and the risk of not achieving the expected result. Not only do surgical patients face undergoing anaesthetic, invasive procedures and what might be a painful recovery period but a good outcome is not guaranteed. This means that loss of function, dependency, or even death might be contemplated (Contrada, Levanthal & Anderson, 1994; Horne, Vatmanidis & Careri, 1994; Swindale, 1989).

There is a large literature which describes the psychological influences on surgical recovery. Given the links which exist between psychological factors and recovery, a number of psychological interventions have been investigated in surgical populations, aiming to improve post-surgical recovery. Recovery in this context encompasses reduced levels of psychological distress (e.g. anxiety and pain) as well as enhanced physical outcomes (e.g. shorter hospitalisations and fewer complications).

Psychological predictors of post-operative recovery

Most of the focus in the literature is on anxiety and its association with poor psychological adjustment after surgery. For example, a meta-analysis of 27 studies linked pre-operative anxiety with worse post-operative mood and higher report of pain (Munafo & Stevenson, 2001). A number of studies have also examined stress and, in particular, its effect on physical recovery: greater levels of stress have been associated with delayed healing in non-clinical experimental settings (Glaser et al., 1999; Kiecolt-Glaser, McGuire, Robles & Glaser, 2002; Marucha, Kiecolt-Glaser & Faveghi, 1998) and also in surgical healing (Broadbent, Petrie, Alley & Booth, 2003). The physiological explanation for this is that stress activates the

hypothalamic pituitary adrenal axis and this impairs the immune system which is important in efficient healing (Sapolsky, 1998).

A number of other psychological variables may also have some influence on recovery from surgery. For example, dispositional optimism has been found to correlate with better immune functioning and physical health (Kiecolt-Glaser, J.M., Page, G.G., Marucha, P.T., MacCallum, R.C. & Glaser, R., 1998; Kiecolt-Glaser et al., 2002; Segerstrom, Taylor, Kemeny & Fahey, 1998) and to predict a lower rate of re-hospitalisation after coronary artery bypass graft surgery (Scheier et al., 1999). Health behaviours also seem to play a role in surgical outcomes. Smoking and alcohol consumption are associated with post-surgical complications and slower wound healing (Campanile, Hautmann & Lotti, 1998; Kusaka, Kondou & Morimoto, 1992; Jorgensen et al., 1998; Tonnesen & Kehlet, 1999). There is also evidence from a non-clinical experimental study that taking regular exercise improves the rate of wound healing (Emery, Kiecolt-Glaser, Glaser, Malarkey & Frid, 2005).

Psychological interventions in surgical populations

The nature of the interventions which have been used to alleviate distress in surgical patients is diverse. The majority of studies have investigated the benefits of providing patients with psycho-education about their planned surgical procedures and the sensations they can expect. The benefits of preparing patients for surgery, in providing them with information, is highlighted in several meta-analyses (Devine, 1992; Johnston & Vogele, 1993; Suls & Wan, 1989). However, an examination of individual studies of psycho-educational interventions published in the last 20 years presents more of a mixed picture, with only a few psycho-educational interventions providing improved outcomes (e.g. Anderson, 1987;

Moore & Dolansky, 2001). One difficulty in analysing the effect of providing psycho-education is that control groups in the studies tend to receive "routine information", which may be adequate preparation.

A meta-analysis of 38 randomised controlled trials (Johnston & Vogele, 1993) examined a broader range of interventions which have been used in preparing patients for surgery. These included psycho-educational approaches, relaxation, behavioural instruction, hypnosis, cognitive techniques and emotion-focused interventions. Johnston and Vogele analysed eight categories of outcome and identified that all intervention groups recovered better than control groups on these measures of recovery. There were medium effect sizes for reduction in reported pain and pain medication, negative affect, length of stay in hospital, as well as improvements in other behavioural and clinical indices of recovery.

Other types of interventions have also been reported to have beneficial effects. For example, in cardiac surgery settings, patients who were given additional social support from former patients improved on a number of outcomes, including reduced anxiety and depression, greater self-efficacy and shorter hospitalisations (e.g. Kulik & Mahler, 1987; Parent & Fortin, 2000; Weber, Roberts, Yarandi, Mills, Chumbler et al., 2007). Supportive approaches which encourage emotional expression have also been found beneficial (e.g. Larson, Duberstein, Talbot, Caldwell & Moynihan, 2000; Ross, Thomsen, Karlsen, Boesen & Johansen, 2005; Schindler, Shook & Schwartz, 1989; Sorlie, Busund, Sexton, Sexton & Sorlie, 2007) as has relaxation training (e.g. Cheung et al., 2003; Holden-Lund, 1988). However, for all these kinds of intervention the evidence is mixed and a number of studies do not describe the intervention in sufficient detail to enable methodologies to be repeated. Further, the majority of studies have come

from cardiac settings and it is not known if positive findings generalise to other surgical populations.

Expressive writing

One interesting intervention which has shown positive results in a number of medical settings, but has rarely been investigated in surgical populations, is expressive writing. This follows the paradigm of Pennebaker and Beall (1986). It asks participants to write down their deepest thoughts and feelings, usually related to a traumatic event or, in the case of medical populations, to their medical condition. Participants in the experimental condition write over three or four consecutive days for approximately 20 minutes each day. Most expressive writing study designs include a control group who write for the same amount of time about neutral topics.

A number of theories have been put forward to explain the possible mechanism by which expressive writing leads to change (Frattaroli, 2006). For example, inhibition theory proposes that inhibiting emotions is a process which causes physiological stress and therefore letting go of feelings rather than repressing them should reduce that stress (Pennebaker, 1997). Cognitive processing theory (Pennebaker, 1993) proposes that the writing process allows participants to gain insight into their experiences. This has been supported by a linguistic analysis of written scripts, which demonstrated that participants whose health improved had used, progressively, an increasing number of cognitive words over the sessions (Pennebaker, 1993). Self-regulation theory explains the benefit of expressive writing in terms of participants gaining mastery over their emotions (Lepore, Greenberg, Bruno & Smyth, 2002). The theory proposes that through writing, participants are able to observe, reveal and control their emotions more effectively.

Whatever the exact mechanism for change, it is the reduction in the stress response through expressive writing which would promote better immune functioning and healing (Miller & Cohen, 2001).

Expressive writing in non-clinical populations

The majority of expressive writing studies have focused on non-clinical populations and have produced improvements in a variety of health outcomes (Smyth, 1998; Frattaroli, 2006; Frisina, Borod & Lepore, 2004). This positive effect has been found across a wide range of measures including objectively assessed outcomes (such as blood assays of immune markers and health centre visits) and self-report, both of physical and psychological health.

The studies have highlighted physical health improvements such as a reduced number of health centre visits and fewer reported physical complaints (Pennebaker & Beall, 1986). A number of improved social and behavioural outcomes have also been documented, including fewer absentee days (Francis & Pennebaker, 1992) and faster re-employment following job loss (Spera, Buhrfeind & Pennebaker, 1994). Expressive writing has also been found to be associated with enhanced immunological competence, as demonstrated by the presence of increased levels of T helper cells, T lymphocytes, Epstein-Barr antibody titers and hepatitis B antibodies (Esterling, Antoni, Fletcher, Marguilies & Schneiderman, 1994; Pennebaker, Kiecolt-Glaser & Glaser, 1988; Petrie, Booth & Pennebaker, 1998; Petrie, Booth, Pennebaker, Davison & Thomas, 1995).

Expressive writing in clinical populations

A small number of studies have investigated whether expressive writing can produce positive effects in medical populations. Although the results are somewhat mixed, a tentative conclusion can be drawn that there are potential benefits for

clinical populations as well. A meta-analysis by Frattaroli (2006) outlines the diverse clinical populations, including both physical and mental health problems, in which expressive writing studies have been carried out. Studies have used expressive writing in psychiatric populations, including severely depressed and bipolar patients, and with prison inmates and people suffering from post traumatic stress disorder. Research has also taken place in a broad range of physical health settings including patients with cancer, asthma, rheumatoid arthritis, Type I diabetes and fibromyalgia. Frisina et al. (2004) evaluated nine studies from a variety of such clinical populations and found only very small improvements on psychological measures but more substantial improvements on physical outcomes.

Expressive writing in cancer patients

Several studies have investigated whether cancer patients derive benefits from expressive writing. In a study of breast cancer patients, Stanton et al. (2002) found that the expressive writing groups had significantly fewer medical appointments for cancer-related morbidities and fewer self-reported symptoms at a three month follow-up. In contrast, Walker, Nail and Croyle (1999) found no improvement in psychological or psychosocial adjustment in breast cancer patients undergoing radiotherapy. Rosenberg et al. (2002) found improvements in physical symptoms and a trend towards reduced health care utilisation among prostate cancer patients and De Moor et al. (2002) found that expressive writing led to better quality sleep and more Vigor (measured by the Profile of Mood States) in patients with metastatic renal cell carcinoma.

Expressive writing in surgical populations

Only two studies have investigated whether expressive writing benefits surgical populations (Solano, Donati, Persichetti & Colaci, 2003; Solano, Pepe,

Donati, Persichetti, Laudano et al., 2007). One study involved patients undergoing bladder papilloma resection, and the other transurethral resection of the prostate. Both populations were selected for their homogeneity in that those procedures are relatively straightforward and result in comparatively few complications. The authors' stated interest in using expressive writing in surgical populations centred on the existence of one very distressing event (surgery). This required participants to undergo physical intervention and to process it psychologically in a short time period. They identified this as a rather different course from that followed by people with chronic illnesses. Interestingly, both studies departed from the format of constructing a neutral writing task for the control group, who did not write at all.

Solano et al. (2003) found that the expressive writing group had significantly shorter periods of hospitalisation and fewer reported symptoms than the control group. They also investigated whether individual differences moderated the effect of expressive writing by dividing participants into groups who were high and low on the trait alexithymia (a tendency not to identify, process and express emotions). High alexithymic participants did much better if they were allocated to the expressive writing condition compared with those who did not write and their outcomes were comparable to the progress of low alexithymic participants.

In contrast, Solano et al. (2007) found no group differences between the expressive writing and non-writing control group. However, they also measured an individual difference factor: participants were assessed according to the Goldman Preoperative Risk Index, a measure of the risk of cardiac complications in non-cardiac patients. Those high on surgical risk in the writing condition showed a non-significant trend towards worse physical and psychological outcomes, while the low risk group who wrote improved significantly compared with those who did not

write. These findings, as well as those by Solano et al. (2003) suggest that expressive writing may not benefit all individuals.

Rationale and Aims of the Current Study

In summary, there is a paucity of literature documenting the effect of expressive writing in surgical populations. However, one study which used such a population found that both length of stay in hospital and reported symptoms were lower in the expressive writing condition. Expressive writing has also produced promising results in studies of patients with cancer, with participants reporting fewer symptoms, less healthcare utilisation, better sleep quality and more vigour. The studies which have demonstrated enhanced immune functioning after expressive writing in non-clinical experimental settings also suggest that it may benefit women who are healing after major surgery.

The current study aimed to extend the literature by investigating the use of expressive writing for women undergoing surgery for gynaecological cancers. It is common for women with gynaecological cancer to experience difficulties, such as depression, anxiety and relationship problems (Booth, Beaver, Kitchener, O'Neill & Farrell, 2005; Ferrell, Smith, Ervin, Itano & Melancon, 2003). There are additional fears concerning the effects of exhausting and unpleasant adjuvant treatment and survival prospects (Steginga & Dunn, 1997). To compound this, women with gynaecological cancer may undergo surgical procedures which severely affect the body and which raise issues of sexuality and femininity. In many cases, depending on the extent of planned surgery, they must contemplate sexual dysfunction, menopause or infertility (Steginga & Dunn, 1997). This host of distressing possibilities makes some kind of intervention desirable. There is some evidence that giving cancer patients a supportive context in which they can express emotions

is beneficial (Stanton & Danoff-Burg, 2002), although little intervention research has been carried out with gynaecological-cancer patients.

Given that previous studies of expressive writing have found stronger evidence for its beneficial effects on physical rather than psychological health, the current study focused on a number of physical health outcomes: pain medication, clinician-rated recovery/healing, length of stay in hospital and health care utilisation. The original aim of the research was to investigate whether expressive writing has incremental health benefits over and above psychological variables known to improve healing, namely pre-operative stress, dispositional optimism, and health behaviours (smoking, drinking and exercise). However, because of recruitment difficulties and a small sample size, a more exploratory approach was taken.

Method

Surgical Setting

Participants were recruited from the gynaecological oncology ward at a major London teaching hospital.

Design

The study used a randomised design. The two conditions were an expressive writing condition, in which participants wrote about their thoughts and feelings related to having surgery for gynaecological cancer, and a neutral condition, in which participants wrote a factual account of life on the ward. Participants were asked to write for 20 minutes for three or four days, consecutively, after surgery. The study was a joint project (see Appendix I; Saunders, 2008; Thomas, 2008).

Participants

Inclusion and exclusion criteria

The study involved women who satisfied the following criteria: (1) over 18 years old, (2) admitted for surgery for gynaecological cancers (either diagnosed or suspected), including endometrial, cervical, ovarian cancer and cancer of the vulva, and (3) scheduled to undergo major surgery with an overall estimated stay on the ward of between seven to ten days.

Women were excluded if their post-surgical care plan involved recovery in intensive care. They were also excluded if they did not read or write English fluently, or if they had learning or writing difficulties. Initially women with diabetes were excluded but this exclusion criterion was changed during the study when recruitment became problematic.

Recruitment

Recruitment took place between June 2007 and April 2008. A total of 112 women met the study criteria. Of these, 39 agreed to participate and completed the baseline measures, and 20 of these completed either the expressive writing or neutral writing intervention. Details of the flow of patients and characteristics of participants are presented in the Results.

Procedure

Explanation of the study and informed consent

Once patients agreed to proceed with surgery at an outpatients' clinic with their surgeon, they met a clinical nurse specialist and were given an information pack about gynaecological surgery in which a leaflet about the study, entitled "Hospital Diary Study" was included. The majority of patients, following the standard referral pathway, received this approximately one week before being

admitted to the ward. Each week the researchers obtained surgical lists from the ward sister and potential participants who appeared to fulfil the inclusion criteria were approached on the day they were admitted to the ward (the day before surgery). The researcher discussed the study with potential participants, giving them an opportunity to read the Patient Information Sheet (Appendix II) and to ask questions, before obtaining informed consent (Appendix III). Participants then completed the pre-surgery (baseline) measures.

Randomisation

Randomisation was carried out once women confirmed that they were happy to proceed with the study after their surgery. On the day that they felt well enough to start writing they were randomly allocated to either the expressive writing or neutral writing group.

Writing Procedure

Provided women felt well enough, they started writing the second or third day after surgery (although some started writing a bit later). Participants were asked to write for 20 minutes over three to four consecutive days.

Since the paradigm's inception, instructions have varied from asking participants to write about their most traumatic experience to asking them to write their deepest thoughts and feelings associated with their medical condition. For reasons of face validity and following the recommendations of Pennebaker (1994), it was decided to ask participants to write about their surgery or illness without prescribing this in more detail or preventing them from taking the writing in any related direction they chose. The instructions for the two writing conditions followed the format used by Stanton et al. (2002). The following written instructions were given to the expressive writing condition:

"What we would like you to write about for these four sessions are your deepest thoughts and feelings about your surgery or illness. You might think about all the various feelings and changes that you have experienced before being diagnosed, after diagnosis, before surgery and now. Whatever you choose to write, we want you to really let go and explore your very deepest emotions and thoughts. Ideally, we would like you to focus on feelings, thoughts or changes that you have not discussed in great detail with others. You might also tie these thoughts and feelings to other parts of your life i.e. your childhood, people you love, who you are, who you want to be etc. Again, the most important part is that you really focus on your deepest emotions and thoughts. The only rule we have is that you write continuously for the entire time. If you run out of things to say, just repeat what you have already written. Don't worry about grammar, spelling, sentence structure or crossing things out. Just write."

The type of task given to the neutral writing group has varied in the published studies from writing about how participants use their time, a recent social event or their plans for the remainder of the day (Pennebaker, 1994; Pennebaker, Kiecolt-Glaser & Glaser, 1988), describing a health behaviour (de Moor et al., 2002) or giving facts about their cancer (Stanton et al., 2002). As participants were restricted in their activities on the ward, the wording of the neutral task was modified to encourage them to write a factual account in the spirit of previous studies. However, it was decided that no reference should be made to participants' cancer and the focus would be events on the ward. The following written instructions were given to the neutral writing condition:

"What we would like you to write during these four sessions is a factual account of life on the ward during the last 24 hours. For instance, you may choose to describe the daily routine or timetables of activities, the different people on the ward and what they have been doing, the hospital food, the physical surroundings etc. The most important part is that you describe what is happening as a 'detached observer', rather than write about your own personal thoughts and feelings. The only rule we have is that you write continuously for the entire time. If you run out of things to say, just repeat what you have already written. Don't worry about grammar, spelling, sentence structure or crossing things out. Just write."

Participants were left alone with their curtains drawn while they wrote. After each writing session, participants completed a brief "manipulation check" measure. This asked participants to rate how personal their writing was and how

much they revealed their emotions in it, using a 7-point rating scale (1 = not at all; 7 = a great deal/extremely). These questions were taken from Stanton et al. (2002). The researchers referred to this in order to gauge whether participants were following the writing instructions. When the manipulation check showed that participants had not followed instructions, researchers reiterated the instructions either to focus on factual or emotional topics before subsequent writing sessions.

The aim was for participants to complete three or four writing sessions, depending on their planned date of discharge from the ward. When participants had completed their last writing session they were given a form (with a return envelope) on which they were asked to record their ongoing health utilisation and continuing medication use for the next five weeks.

Measures

Baseline data were gathered by questionnaire on admission to the ward the day before surgery. On discharge from the ward a senior nurse rated participants on their overall recovery. The researcher also collected information about pain medication and total days on the ward from patients' files.

Participants attended an outpatient clinic with their consultant surgeon two to three weeks after surgery. At this appointment surgeons rated participants on their overall recovery and healing.

Finally, participants were telephoned five weeks after they completed writing to prompt them to return a form on which they had completed details of their health utilisation and continuing need for medication over the five week follow-up period.

Baseline questionnaires

The baseline questionnaires (see Appendix IV) included demographic information and a number of standardised self-report measures. Some of these were used for another doctoral thesis (Saunders, 2008) and are not reported here.

Demographic Information. This included age, occupation, education, ethnicity, marital status and whether the participant had any other medical conditions.

Perceived Stress. The Perceived Stress Scale (PSS: Cohen, Kamarck & Mermelstein, 1983) was included to measure participants' stress levels pre-surgery. It is a 14 item self-report questionnaire designed to capture non-specific stresses over the previous month. However, the instructions were modified to "the last week" in order to be consistent with other measures in the study. An example is "How often have you found that you could not cope with all the things you had to do?" The possible responses range from 0 ("Never") to 4 ("Very often"). The final score is in the range 0 – 56, with a higher score representing greater perceived stress. The measure has good internal consistency (Cronbach's alpha = 0.84-0.86) and possesses good test-retest reliability.

Optimism. The Life Orientation Test (LOT: Scheier & Carver, 1985; Scheier, Carver & Bridges, 1994) measures dispositional optimism. Respondents rate ten statements such as "I rarely count on good things happening to me" on a 5 point Likert scale from 0 ("Strongly agree") to 4 ("Strongly disagree"). There are four filler items designed to disguise the underlying purpose of the test (Scheier and Carver, 1985). This gives a range of 0 to 24 with higher scores indicating greater optimism. The LOT has been shown to have good internal consistency (Cronbach's alpha = 0.76) and test-retest reliability.

Health behaviours. Participants were asked to indicate if they drank alcohol or smoked and to estimate their average weekly consumption, using the questions, "How many units of alcohol do you drink each week? (N.B. a unit of alcohol is half a pint of cider or beer, a small (125ml) glass of wine or a pub measure of spirits)" and "On average how many cigarettes do you smoke each week?" Participants were also asked to estimate the average number of hours per week spent exercising over the previous four weeks, including aerobics, walking, running, weight training, squash etc. (Emery et al., 2005).

Clinical Outcomes Data

Pain medication. Totals of pain medications received on the ward were taken from the medical notes. These included patient controlled analgesia (morphine sulphate or fentanyl) and a number of opiate based medications, taken orally, including tramadol and dihydrocodeine. These were all converted into one morphine-equivalent dose for the purpose of analysis (Twycross, Wilcock & Thorp, 1998), by the researcher. As the pain data was only identified by a participant number, the researcher was blind to the participant's writing condition. This approach was recommended by a consultant anaesthetist (Brown, J., personal communication on 14 March 2008), who suggested it was the best way to compare the various combinations of stronger analgesics used. The researcher also computed participants' total use of opiate medication in the five weeks after writing from their health utilisation and medication log (see below).

Length of hospitalisation. This was routinely recorded within participants' clinical records.

Health care Utilisation. A log was given to participants on completion of the writing task (Appendix V). They were asked to record on it the number of

hospital and other medical appointments and any medication taken over the five week follow-up period. The approach was informed by Stanton et al. (2002), who asked participants to record prospectively all medical visits from the end of the writing until the follow-up. The researcher, who was blind to the writing condition, computed totals of face-to-face and telephone contacts with health professionals in relation to (1) cancer or surgery; (2) other medical conditions; and (3) counselling or psychological sessions. The researcher also calculated the number of different prescriptions participants had continued to take over five weeks after the writing task finished in relation to (1) having cancer or recovering from surgery; (2) other physical conditions; and (3) mental health conditions.

Nurse rated recovery/healing. When participants were discharged from the ward the ward sister or ward coordinator (i.e. a senior nurse with personal knowledge of the participant and who was blind to the writing condition) rated their overall healing. The rating was on a four-point scale (poor, mediocre, fair, good) and was adapted from Solano et al. (2003). It was intended to be an overall rating of healing taking into account all the relevant clinical information including wound healing, general mobility and independent activity, bowel and bladder function and appetite (Appendix VI).

Surgeon rated recovery/healing. The consultant surgeon, who was blind to the writing condition, rated each participant's overall healing on the same four-point scale described above (Appendix VII). This was done at the outpatient follow-up clinic which was two to three weeks after surgery.

Information from surgical lists. Information about diagnosis, the type of surgery (i.e. laparoscopic or open) and the nature of any planned adjuvant treatments were collected from computerised patient records.

Ethical Considerations

The study was granted approval by the local Research Ethics Committee (See Appendix VIII). An amendment was also granted to expand the inclusion criteria from women with "ovarian and endometrial" cancers to women with "gynaecological" cancers.

Previous expressive writing studies have identified that participants sometimes become distressed immediately after the writing session, although no long term harm is typically caused (Hockemeyer et al., 1999; Pennebaker, 1994). Through liaison with the ward team, an action plan was prepared for participants' allocated clinical nurse specialist to support any distressed participants. In addition, instructions to participants stated that they could stop writing at any time. Finally, participants were assured that their writing would be kept confidential in a sealed envelope and analysed after they had left the ward.

Statistical Analysis

Previous studies of expressive writing in clinical populations using physical health outcomes have reported mostly medium effect sizes for physical health measures, although some meta-analyses demonstrate considerable variability and two studies demonstrated a large effect sizes for reported pain and physiological functioning, respectively (Frisina at al., 2004; Smyth, 1998). Given the practical limitations of recruiting large numbers of participants, the choice of physical health outcome measures and therefore assuming a large effect size, with power set at 0.80 and alpha at 0.05, the aim was to have 26 participants in each condition.

Because the sample size fell short of our target of 52 women completing the intervention, the approach to statistical analysis had to be reviewed. In the main the analysis was exploratory and a small number of total comparisons were conducted.

Had there been sufficient participants a multiple regression would have identified the extent to which any group differences were attributable to expressive writing rather than psychological factors which are known to predict healing.

Results

Participants

Recruitment

Figure 1 demonstrates the flow of patients in the study from recruitment to five weeks after they finished writing. There were 112 women who were potentially eligible, and of these 39 consented to take part. Women declined to take part for a variety of reasons: eight said they were put off by writing, one did not want to think about her emotions, 20 thought the intervention was "too much" in terms of its requirements and 44 said they were not interested.

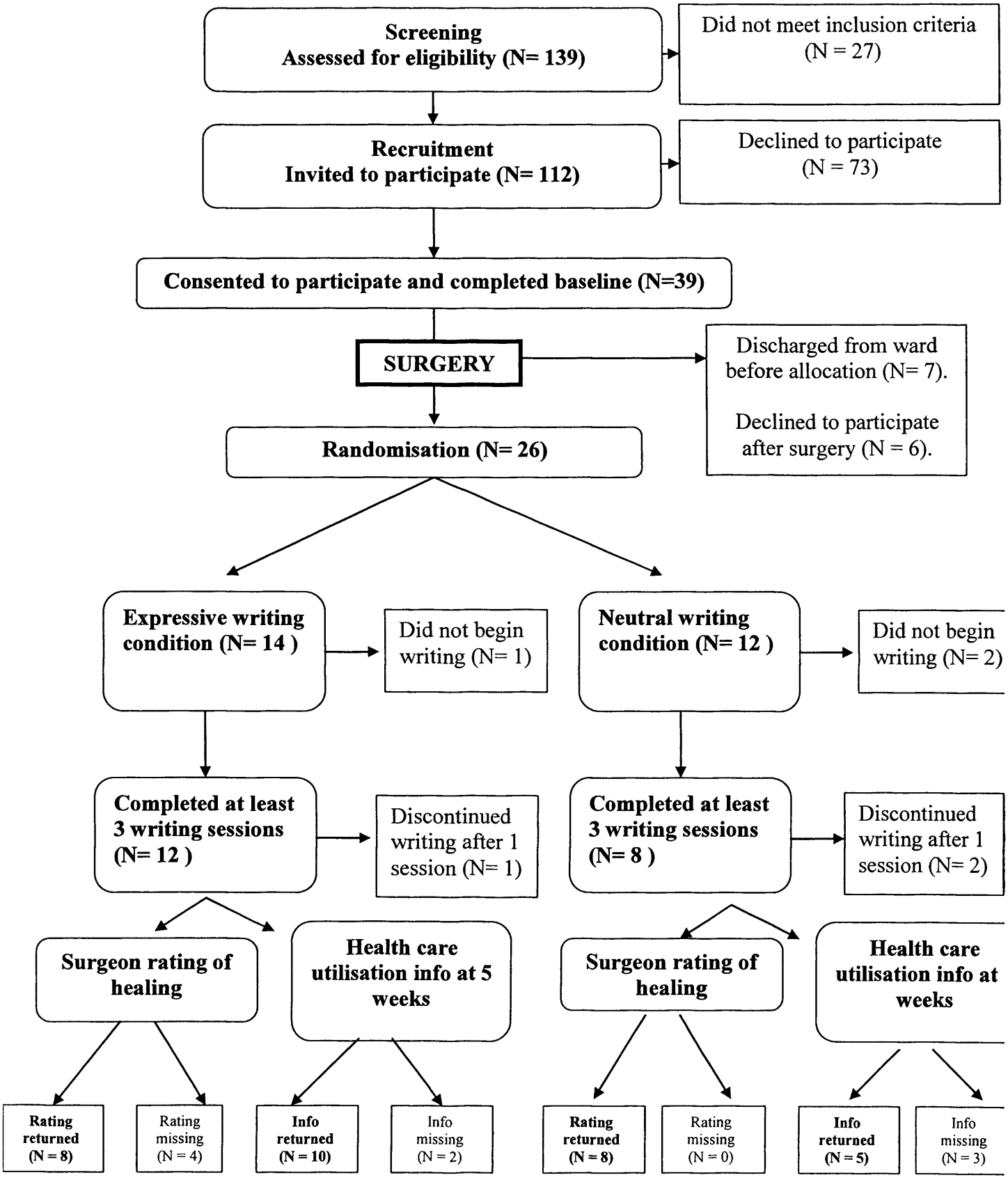
Attrition

After recruitment, seven participants were discharged quickly from the ward which meant it was not possible for them to start the intervention. A further six declined to continue in the study because of feeling unwell or "not up to" writing. Twenty six participants proceeded to being randomised, with 14 in the expressive writing condition and 12 in the neutral writing condition. On being randomised, three participants declined to take part as they were not interested in continuing in the allocated writing condition (two of them were in the neutral condition). This left 23 women who started the writing task.

Three participants declined to continue with the intervention after the first writing session which meant that 12 participants in the expressive writing condition and eight in the neutral writing condition completed at least three writing sessions.

Figure 1 CONSORT trial participation flow diagram

Adapted from The Consort E-Flowchart August. 2005, downloaded from http://www.consort-statement.org



Characteristics of participants who completed baseline measures

The full sample of 39 women who completed baseline measures had an average age of 52.9 (range 19 to 78) and were predominantly white (N = 31, 79%). They underwent a range of procedures, including hysterectomy (removal of the womb by either normal surgical or laparoscopic methods), oophorectomy (removal of the ovary), salpingo-oophorectomy (removal of the fallopian tube), cystectomy (removal of a cyst from an ovary) and vulvectomy (removal of the vulva). Insofar as information was available from participants' notes, it was apparent that 13 women would be receiving no further treatment following surgery, 14 were scheduled to commence chemotherapy and one woman was due to start radiotherapy. The sample comprised 24 women living with a partner, six single women, three who were separated or divorced and 5 widows. In addition 12 women indicated that they had other medical conditions, for example, thyroid problems, osteoporosis and high blood pressure.

Table 1 compares the characteristics of those women who completed at least three writing sessions and those who completed only baseline measures or dropped out prior to or during writing (referred to as "baseline only"). There were no significant differences between the groups on any variables. However, there was a trend for a difference in pre-surgical stress: the group who wrote reported higher stress levels than the baseline only group.

Table 1 Characteristics of all participants: (baseline only vs. writing)

	Baseline only	**Writing**	**Statistic**	**p**
	N=19	**N=20**		
Age	Mean 55.74 (s.d.15.67)	Mean 50.20 (s.d. 14.45)	t(37) = -1.148	0.258
Ethnicity	14 (74%) white British, 4 (21%) other	17 (85%) white British, 3 (15%) other	$\chi^2(1) = 0.329$	0.566
Education	12 (63%) A level or lower, 6 (32%) above A level	10 (50%) A level or lower, 9 (45%) above A level	$\chi^2(1) = 0.755$	0.385
Type of Surgery	6 (32%) open 8 (42%) laparoscopic	12 (60%) open 5 (25%) laparoscopic	$\chi^2(1) = 2.425$	0.119
Diagnosis	8 ovarian 2 endometrial 1 vulval 2 cervical 2 benign 1 other cancer	10 ovarian 2 endometrial 2 vulval 1 cervical 1 benign 4 other cancer		
LOT[a]	Mean 14.58 (s.d. 3.11)	Mean 13.50 (s.d. 4.33)	t (37) = -0.888	0.380
PSS[b]	Mean 20.68 (s.d. 6.72)	Mean 25.50 (s.d. 8.59)	t (37) = 1.944	0.060

[a] Life Orientation Test (higher score indicates greater dispositional optimism)
[b] Perceived Stress Scale (higher score indicates greater pre-surgery stress)
Note: Percentages do not always add up to 100% because of missing data

Characteristics of expressive and neutral writing participants

An exploratory analysis was carried out to identify any differences in the characteristics of the women in the expressive versus neutral writing conditions. As can be seen in Table 2, no significant differences were found.

Table 2 Characteristics of expressive and neutral writing participants

	Expressive writing N=12	**Neutral writing N=8**	**Statistic**	**p**
Age	Mean 50.25 (s.d.15.20)	Mean 50.12 (s.d. 14.28)	t(18) = 0.018	0.985
Ethnicity	9 (75%) white British, 3 (25%) other	8 (100%) white British	$\chi^2(1) = 2.353$	0.125
Education	7 (58%) A level or lower, 5 (42%) above A level	3 (37.5%) A level or lower, 4 (50%) above A level	$\chi^2(1) = 0.425$	0.515
Type of Surgery	6 (50%) open 3 (25%) laparoscopic	6 (75%) open 2 (25%) laparoscopic	$\chi^2(1) = 0.142$	0.707
Diagnosis	4 ovarian 1 endometrial 2 vulval 1 cervical 1 benign 3 other cancer	6 ovarian 1 endometrial 0 vulval 0 cervical 0 benign 1 other cancer		
LOT[a]	Mean 13.58 (s.d. 4.72)	Mean 13.37 (s.d. 4.00)	t(18) = 0.103	0.540
PSS[b]	Mean 23.92 (s.d. 8.94)	Mean 27.88 (s.d. 7.99)	t(18) = -1.010	0.326

[a] Life Orientation Test (higher score indicates greater dispositional optimism)
[b] Perceived Stress Scale (higher score indicates greater pre-surgery stress)
Note: Percentages do not always add up to 100 because of missing data

Effects of the writing intervention

Manipulation Check

Average manipulation check ratings were calculated in order to analyse whether the instructions for the two conditions did produce different kinds of writing. Participants in the expressive writing condition reported revealing significantly more emotions in their writing ($t(18) = 6.954$, $p = 0.000$). They also rated their writing as significantly more personal than participants in the neutral writing condition ($t(18) = 5.807$, $p = 0.000$). These self-report ratings suggest that the participants did adhere to the writing instructions.

Physical health outcomes

Before analysing the physical health outcomes, some decisions had to be made, given the small sample size and in order to avoid Type I errors. First the length of stay in hospital data showed an outlier of 25 days which was removed from the analysis. A decision was taken only to analyse the senior nurse's rating of healing as this correlated with the rating given by surgeons ($r = 0.536$, $p = 0.032$) and a full set of these ratings was available for analysis (whereas four surgeons' ratings were missing). Further, a decision was taken to combine the healthcare utilisation information so that a total of all the healthcare contacts, both face-to-face and telephone and for any reason, were analysed. Finally, the continuing use of opiate medications from the date the writing finished until five weeks later was not evaluated as it was apparent that a number of participants had not seen or completed the medication record (as it was attached to the health care utilisation log).

The distribution of each outcome was plotted. The nurse rating of recovery was normally distributed. In contrast, the distributions for number of days in hospital, medication on the ward and health care utilisation contacts were all

positively skewed and therefore non-parametric statistical tests (Mann-Whitney U) were used. Table 3 compares the outcomes for the expressive and neutral writing groups. None of the between group differences are significant.

Table 3 Outcomes of expressive and neutral writing groups

Outcome Measure	N	Expressive writing	Neutral writing	Statistic	p
Days in hospital	19	Median = 8.00 Interquartile range = 1.00	Median = 8.00 Interquartile range = 1.75	U = 37.00	0.539
Nurse rating of healing[a]	20	Mean = 3.00 (s.d. = 1.04)	Mean = 2.75 (s.d. = 0.89)	t(18) = 0.555	0.585
Medication on ward[b]	17	Median = 71.75 Interquartile range = 82.40	Median = 65.00 Interquartile range = 63.40	U = 32.00	0.539
Total health Utilisation contacts	15	Median = 7.00 Interquartile range = 8.75	Median = 5.00 Interquartile range = 4.50	U = 20.00	0.538

[a] The range was 1 to 4 (1 = poor and 4 = good)
[b] Medication on ward is the sum of the stronger medications, converted into morphine-equivalent dose

In terms of all the women who completed writing, the median number of days in hospital was 8 (range 6 to 16 days). The distribution of data was positively skewed with very few women (N = 2) staying over ten days, which was the upper bracket of the estimated length of stay for the population. The median level of opiate medication was 71.5 mg (ranging 4 to 351mg). The distribution was clustered to the lower end of the range with only five values above 100mg. Finally the median number of health care contacts for any reason after leaving the ward was 6 (range from 1 to 34). There was little variability with most participants having 10 or fewer contacts. One woman from the expressive writing group who had 34 contacts had required dressing changes for an infected wound.

The mean nurse rating was 2.90 indicating "fair" healing overall. Although the full range of the scale (from 1 to 4) was used, the bulk of participants were rated as having had a fair or good recovery (combined N = 16). Overall the ratings in this study (3.00 and 2.75 for expressive and neutral writing respectively) were similar to ratings reported in one other study which used the same measure (means of 3.45 and 2.95 for expressive and neutral writing respectively; Solano et al., 2003).

Psychological variables associated with surgical recovery

Correlation analyses, based on the sample of 20 women who wrote, were carried out to identify whether psychological variables known from the literature to predict surgical recovery were associated with outcomes. These included three health behaviours - alcohol consumption, smoking, exercise – as well as dispositional optimism and pre-surgical stress. Table 4 shows the inter-correlations between all the predictor and outcome variables.

Perceived stress and dispositional optimism were negatively correlated; that is, participants who reported greater stress tended to be lower on the trait of optimism. Two health behaviours, consumption of alcohol and cigarettes, were positively correlated. However, a further correlation was in an unexpected direction: number of cigarettes was positively correlated with physical exercise; that is, participants who smoked more cigarettes tended to have taken more physical exercise in the four weeks before coming onto the ward.

Table 4 Correlations between predictors of healing and outcomes

		1	2	3	4	5	6	7	8	9
1 Alcohol	r	_								
	p									
2 Cigarettes	r	.558*	_							
	p	.011								
3 Exercise	r	.325	.462*	_						
	p	.162	.041							
4 Dispositional	r	-.071	.065	-.146	_					
Optimism	p	.765	.784	.540						
5 Perceived	r	-.170	-.165	-.670	-.571**	_				
Stress	p	.473	.487	.778	.009					
6 Total health	r	-.217	-.071	-.046	-.257	.282	_			
contacts	p	.436	.800	.872	.355	.309				
7 Length of	r	-.206	.013	-.180	.375	-.335	-.283	_		
stay	p	.398	.957	.462	.113	.161	.307			
8 Total opiate	r	-.139	-.222	.598*	.065	.102	-.292	.151	_	
medication	p	.595	.392	.011	.805	.697	.357	.575		
9 Rating of	r	-.278	-.355	-.160	-.188	.418	.423	-.479*	.028	_
healing	p	.236	.125	.500	.427	.067	.116	.038	.914	

** Significant at the 0.05 level (2-tailed)
* Significant at the 0.01 level (2-tailed)

N ranged from 15-20 because of missing data

Only two correlations were found relating to outcome measures. First there was an inverse association between the number of days in hospital and the nurse rating of healing; that is, women who spent fewer days in hospital were judged to have healed better. Secondly, there was another correlation in an unexpected direction: participants who reported exercising more before surgery tended to require a higher total of opiate medication on the ward.

Discussion

The aim of the study was to examine whether expressing emotions in writing affects physical recovery among women with gynaecological cancers. Because of recruitment difficulties, which resulted in there being a small sample size, an exploratory approach was taken regarding data analysis.

No differences were found between the expressive and neutral writing groups on any of the physical health outcome measures. Dispositional optimism, pre-surgical stress and health behaviours were also not found to predict surgical recovery, with the exception of an unexpected correlation between taking exercise and higher post-surgical opiate medication.

The study's lack of findings will be discussed in relation to several methodological issues. Recruitment and attrition, and the acceptability of the intervention will also be discussed.

Methodological Issues

The main limitation was the small sample size which meant there was insufficient power to detect between group differences even if differences existed. In addition to this, features of the sample, procedure and outcome measures need to be considered.

Sample

There was a high degree of heterogeneity in the sample as participants had diverse procedures and subsequent care paths and there were variations in the number of days post-surgery before participants felt ready to start the intervention. One previous expressive writing study with breast cancer patients (Stanton et al., 2002) had a more homogeneous sample, having excluded women who had metastatic spread of cancer or previous cancer morbidities. Because of recruitment problems, the criteria in this study were more inclusive. There were women with diverse medical histories, including metastases, previous cancers and other medical conditions. In addition, two women had been referred to the ward psychologist for psychological support. To some extent, the heterogeneity could be addressed in subsequent studies by excluding women with complex medical histories although that would not reflect the normal clinical population.

Procedure

In terms of the writing intervention, one positive finding was that the manipulation check ratings showed that participants understood and followed the writing instructions. Participants in the two groups reported that they had produced significantly different kinds of writing in terms of emotional content and expression of feelings.

Implementing an expressive writing intervention post-surgery was a challenge as many participants felt unwell. Regarding the timing of the intervention, there are no previous post-surgical expressive writing studies. Instead, previous studies used the intervention pre-surgery (Solano et al., 2003; Solano et al., 2007). In this setting, it would have been hard to implement, given that most women arrived on the ward as urgent referrals. Two other studies investigated

cancer patients after they had finished treatment. Stanton et al.'s (2002) study involved women who had finished treatment (including surgery) within 20 weeks and Rosenberg et al. (2002) used the intervention within four years of treatment for prostate cancer. Some adaptation of those methodologies could be used in carrying out an expressive writing study with surgical patients. It would avoid the complications of providing an intervention while participants are recovering on the ward. Post-surgical healing and psychological adjustment may be more advanced at that stage but the intervention could be used to focus on aspects of having a cancer diagnosis rather than surgical recovery.

Outcome measures

Several measures of surgical recovery were used, including number of days in hospital, a senior nurse's rating of healing at the end of the participant's hospital stay, and a surgeon's rating of healing at two weeks post-discharge. Not all surgeon's ratings were returned in spite of attaching the form (with a return envelope) to patient's files in outpatient clinics; this meant that only the nurse's ratings were used, the two sets of ratings showed a moderately high correlation. The nurse rating of healing also correlated with number of days in hospital (i.e., patients who had longer stays were judged to have poorer healing), lending some support to the validity of the measures.

The choice of morphine-equivalent pain medications as an additional outcome in this study was informed by the literature relating to psychological interventions with surgical patients (Schindler et al, 1989). One obvious limitation is that it does not capture all the forms of analgesic used on the ward, e.g. participants who had post-surgical epidural pain relief were not included in the analysis. In addition, the amounts of paracetamol and diclofenac (a non-steroidal

anti-inflammatory), which, in many cases, were used consistently throughout participants' stay on the ward, were not analysed. Schindler et al.'s (1989) approach of analysing both strong and weak pain medications should be considered in future studies.

There was a low return rate of health care utilisation logs at the five-week follow-up point. There was also some concern about the accuracy with which they were completed. In particular, the medication log (on the second page) was returned blank by some participants, which gave it the appearance of having been overlooked. The return rate could be explained by some participants having started adjuvant treatment in the follow-up period. Future studies should consider a method of collecting health care utilisation data that is not dependent on participant self-report. One way of doing this might be to restrict data to healthcare utilisation for cancer-related morbidities (Stanton et al., 2002), which could be obtained from hospital computer records and GP records.

Recruitment and Attrition

The recruitment rate in this study was low (35% of women who met the study criteria consented and completed the baseline measures). This is lower than the rates for other expressive writing studies among cancer patients which ranged from 56% to 92% (de Moor et al., 2002; Rosenberg et al, 2002; Stanton et al., 2002). It also differs from the recruitment rate reported by the two previous expressive writing studies with surgical populations, which were 87% (Solano et al., 2003) and 91% (Solano et al., 2007).

Solano et al. (2003) and Solano et al. (2007), carried out studies in Italy and screened participants to ensure they held the lower secondary certificate of education (equivalent to eight years of education) and set this as a study inclusion

criterion, specifically to ensure that participants had adequate writing capabilities. Unlike those studies, the present one did not set any education level as a criterion. This means that a proportion of women who were approached regarding participation excluded themselves if they did not like the sound of writing or sensed they might be judged on their standard of writing. Even referring to the study as a "Diary Study" did not get away from anxieties in this population about needing to write well.

The aim had been to take an inclusive approach to recruitment, although these findings suggest that screening potential participants for educational level would have improved the recruitment rate. This is also borne out by the fairly high proportion of women (38%) in the sample of 39 participants who were educated above A-level. However, Pennebaker (1997), in a review of ten years of the expressive writing paradigm, reported benefits which were comparable in "senior professionals with advanced degrees" and "maximum security prisoners with sixth-grade educations" (Pennebaker, 1997, p. 164). While the idea of writing may not be acceptable to whole populations, selecting a sample by their level of education would be a hard decision to justify from an ethical position and would not be an appropriate future direction.

Admission rates also fell well short of the annual rates which were predicted for women with gynaecological cancers. Finally, an important consideration, which may explain the recruitment level, was the emotive atmosphere on the ward where recruitment took place. Many of the women had been referred urgently, due to their cancer or possible cancer diagnosis, and many were uncertain about the extent of the planned surgery, which in some cases had to be left to the clinical judgment of the surgeons. This meant that a number of women had too much on their minds or

felt that the study (including baseline and follow-up questionnaires) was "too much".

Attrition from the study was also high: 19 of the 39 women (49%) who completed baseline measures did not go on to complete the writing tasks. This figure represents seven women who were discharged quickly from the ward and six who were too ill to contemplate writing or sitting up. Both are unavoidable characteristics of this specific sample. In addition, three women did not proceed with writing after randomisation and three women ceased participation after attempting one writing session. The two studies carried out using surgical patients (Solano et al., 2003; Solano et al., 2007) avoided any attrition by carrying out the writing intervention over several days prior to surgery. Rosenberg et al. (2002) also had a high rate of adherence by comparison with this study and did not report that any of their participants with prostate cancer (who had concluded treatment, including surgery in some instances) failed to complete the writing intervention.

There were no significant differences in demographics or type of surgery between the group of women who completed the writing intervention and those who did not. There was one trend towards a difference in psychological characteristics showing that women who completed the writing intervention had higher pre-surgical stress than the baseline only group. One explanation might be that women choosing to complete the intervention were more motivated to write because they were more stressed.

Acceptability of the writing intervention

Aside from the issue of attrition from the study as a whole, once women started writing, a large proportion (87%) completed it. At the end of the five week follow-up period, informal debrief interviews conducted with a majority of

participants highlighted some positive experiences from the expressive writing group.

Some typical examples of comments from the expressive writing group were:

"It made me think about what was going on. I processed the ups and downs. At times the writing made me upset. It was a chance to release things rather than bottle them up or bury them." and *"I enjoyed doing the part in hospital. It took the time up and you are very limited in whatever else you can do. I found it therapeutic. While writing, all these thoughts came from nowhere."* These comments demonstrate that some participants found it helpful to let go of their emotions. However, not all the women gave positive comments. For example, one woman said, *"It was a bit of a chore as I wasn't feeling well on the ward. I didn't mind the questionnaires, though."* This shows that one woman struggled to complete the intervention due to the after-effects of surgery.

It was also apparent that some participants found being allocated to the neutral writing condition a disappointment and were reluctant to continue with the intervention. The opportunity to explore emotions may have been something of an enticement for participants, as they were waiting for surgery for cancer-related morbidities. This is exemplified by the participant who gave this feedback: *"I found it was no help. I had no connection with something written as I am a people person."* In contrast, one woman was positive about the value of having a distraction on the ward. Her comment was: *"I enjoyed the writing. It was something concrete to focus on that was not related to my health."*

On the whole, the comments were encouraging and indicate that expressive writing was experienced as therapeutic by some participants. The more negative

reactions illustrate the challenges of using an intervention in this sample; that is, participants feeling ill and not engaging with the task, particularly in the neutral writing group.

Conclusion

This study has highlighted that recruitment and the high attrition rate are significant challenges to implementing a post-surgery expressive writing study on a hospital ward. Although there were no differences in outcomes between women in the expressive and neutral writing conditions, this was not surprising given the study's low statistical power. In spite of that, the study raises some important practical considerations in planning future interventions. In particular, some difficulties might be overcome if future studies focussed on using expressive writing either with surgical participants or people with a cancer diagnosis, rather than both. Writing before planned surgery might avoid problems with recruitment and attrition. The alternative would be to examine the effects of expressive writing in populations with a cancer diagnosis some months after their initial period of treatment. This would avoid trying to recruit participants at a time of distress.

Finally, many women found that expressing their deepest thoughts and feelings in writing was an acceptable way of managing their psychological distress in a ward setting.

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Part 3: Critical Appraisal

This paper is a reflection on the process of carrying out the study reported in Part 2 of this thesis. In particular, it focuses on decisions and challenges that arose in planning the study, deciding how and when to change the research protocol in adapting it to a ward setting, and issues concerning the feasibility of carrying out the expressive writing intervention. The paper covers five specific areas: (1) choosing an expressive writing intervention, (2) issues related to the sample and recruitment, (3) carrying out the intervention, (4) outcome measures and (5) clinical implications and future directions.

Many of the decisions relating to the project were jointly made with two other thesis students, with whom I collected data (See Saunders, 2008; Thomas, 2008). This paper uses the first person singular to express my own reflections and the first person plural to reflect team decisions.

Choosing an Expressive Writing Intervention

I became interested in James Pennebaker's expressive writing paradigm when I was studying for an MSc in Health Psychology. One of the aspects that appealed to me was its emphasis on the emotional expression of and processing of feelings related to either trauma or having medical conditions. I asked to be sent on a summer placement to work with Pennebaker in Austin, Texas, but for practical reasons this option was not taken up. I therefore welcomed the opportunity to devise this expressive writing intervention for patients on a surgical ward.

Sample, recruitment and attrition

Characteristics of the population

As well as being a population who have a high degree of psychosocial difficulties, our potential participants were contemplating surgical procedures

which might affect physical or sexual functioning or involve processes which raised issues of femininity or fertility (Booth, Beaver, Kitchener, O'Neill & Farrell, 2005; Steginga & Dunn, 1997). Most of them had been referred urgently due to the suspected cancer and therefore they carried with them the anxieties of uncertain diagnosis and prognosis. I underestimated the challenges faced in evaluating a psychological intervention in a setting characterised by such intense anxiety. Paradoxically, the emotive setting also convinced me that this was a population who would benefit from intervention.

Inclusion criteria

On discovering that recruitment was proving to be much slower than we had planned, a number of continuing choices had to be made, particularly in terms of inclusion and exclusion criteria.

Our first decision concerned the identification of potential participants who might stay on the ward long enough to complete a writing intervention of 3-4 days after surgery. It was originally suggested that an appropriate sample would be patients with ovarian and endometrial cancers since, typically, surgical removal of the affected areas would involve a stay of 7-10 days on the ward. After some debate we decided to include women with suspected cancers and non-life threatening conditions such as carcinoids. It was estimated that approximately 250 potential participants would be admitted in one year. However, several months into the study, the number of potential participants on surgical lists was lower than anticipated. A contributing factor may have been one of the three surgeons taking maternity leave during our period of recruitment. To address this, and with ethics approval, we reviewed our

inclusion criteria and decided to include women with cancer and suspected cancers of the vulva and other gynaecological cancers.

A further issue related to the different kinds of medical procedures carried out in the sample and the variation in the level of invasiveness. We had originally thought that our sample would only include women having open surgery but it became clear that women having laparoscopic procedures fulfilled our inclusion criteria.

Exclusion criteria

We originally decided to exclude women with a major health problem, such as diabetes, which affects healing (Kiecolt-Glaser, Marucha, Malarkey, Mercardo & Glaser, 1995) or with a major mental illness. A few months into the study, we relaxed the criterion related to physical health problems as we had excluded four participants with diabetes and wanted to boost recruitment levels.

Some judgment had to be exercised regarding the exclusion criteria. In one example, a woman's notes referred to taking antidepressant medication, although the nature of her mental health problems was not explicit. In her case, an assumption was made that she need not be excluded. Later in the study, when we had identified that recruitment was falling short of our target, we leaned towards including not excluding women who were on the borderline of our criteria. However, these decisions were always made with caution as we did not want to include participants if their history indicated that they would find it hard to contain their emotions in what was, essentially, a research not a therapeutic setting.

Decisions regarding the criterion of being able to read and write English fluently were fairly straightforward. However, the sample included a high

proportion of older adults. We had not set an upper age limit as an exclusion criterion and therefore some clinical judgment was used in not recruiting people who had age onset problems (such as sight or motor coordination difficulties or confusion) which would affect the writing task.

Heterogeneity of the sample

The different cancer sites, surgical procedures and techniques meant there was not much homogeneity in the sample and this will have made it harder for the effects of the intervention to be measured. This heterogeneity was caused, in part, by having to expand our inclusion criteria, when it became clear that recruitment levels were low.

Recruitment

In terms of recruitment, the women on the ward were characterised by a very high and understandable level of anxiety on the day they were admitted to the ward. In my view this hindered recruitment. When I discussed the study with potential participants they frequently said that they had been referred in a rush or could not commit to it, which, I think, implied a need to rally their resources primarily to get through the first stage of treatment for cancer. In many cases, they had already been recruited on the same day to take part in a large multi-centre study requiring them to give a blood test. While many participants recognised that conducting research is part of the business of a teaching hospital, my sense is that asking patients to participate in another study was one request too many.

There were also physical and practical barriers to carrying out an expressive writing study in the way we planned it. For example, most of the women underwent a bowel preparation before surgery. The consequence of this

was that many were experiencing the effects of a strong laxative at a time when we had hoped they would want to use up some waiting time by completing baseline questionnaires.

My experience of recruitment was that women who wanted to take part were self-selecting. They usually demonstrated an interest or preparedness to write about their emotions. Many others were put off by the concept of writing and my understanding of that was that they felt as though they would be judged on their written competence. Further, while some were drawn to the idea of exploring their emotions others were daunted by that and, as a consequence, not motivated to take part.

The preparedness of participants to explore their emotions led to problems at the randomisation stage as many of them had some preconception about which of the two writing conditions they would prefer. Indeed some of them had read the promotional leaflet "Hospital Diary Study" and were committed to exploring their feelings about their diagnosis. They were, subsequently, disappointed by being allocated to the neutral writing condition. Similarly, if participants wanted to write as a distraction from their situation, but did not want to face their emotions, they were less engaged in the expressive writing condition. Participants' preferences for one of the writing conditions led to three of them not starting the writing intervention and probably contributed to two others (in the neutral condition) dropping out. In addition, some women were put off by the idea of any continuing involvement (i.e. completing follow-up questionnaires) after leaving the ward.

Attrition

A major factor which accounted for attrition from the sample was ill health. Many women were too uncomfortable to sit up and some were in great pain or appeared to struggle to recover from having a general anaesthetic. Most of these bravely kept writing but in some respects it is surprising that more women did not drop out of the study when this was their experience.

Other practicalities accounted for the large level of attrition from the study. We had allowed women two days to recover, cognitively, from the effects of a general anaesthetic (Dale, Naik, Williams, Lloyd & Thompson, 2005) but writing required participants to sit up. Frequently, abdominal pain or other discomfort (such as from a canula in the back of the hand) ruled out our task. In addition, there were women who were too weak or nauseous to participate further.

Carrying out the Intervention

Ward procedures and patient records

One aspect of the study which was demanding was the need to become familiar with ward practises. We relied a great deal on other staff, in terms of gaining a thorough induction and in implementing certain parts of the research procedure. One example was the process of identifying potential participants from surgery lists, which was done in consultation with the ward sister. I also had some concerns about my competence in accurately reading clinical charts and understanding the way pain medication was recorded. I relied on the ward sister to explain how they were completed and how I should calculate totals.

When patients were discharged the ward administrator kept files on the ward for a short time, usually a day or so, before sending them to the central

records department. Sometimes, when I went through the files, in order to collect pain medication data, the charts had not been filed. This led to dedicating extra time to tracking down the complete file at a later date, so I did not miss this data.

The writing intervention

In terms of the writing intervention, Pennebaker offers good advice when he states, "Running these studies is extremely wearing on me and my other experimenters. You will be shocked and depressed by the horrors that your subjects will reveal." (Pennebaker, 1994, p.6) First, sticking to a rota which included weekend cover on the ward was demanding. I relied heavily on my co-researchers for support, encouragement and help with making on the spot decisions. It is also difficult to describe the highly emotive atmosphere on the particular surgical ward where the study took place. At every stage of the project, I met women on the ward who wanted reassurance or expressed very deeply felt emotions, including sadness, fear and anger. These feelings needed to be contained and I found myself listening and giving support, while at the same time I was aware of the importance of not departing from what was, primarily, a research objective into providing therapy. The project demanded clinical skills and the details or stories I listened to were moving.

Adherence to writing condition

It became clear that some participants wanted to explore emotional topics, whether or not they were assigned to the expressive writing condition. Some participants in the neutral writing condition told us that they had not been able to avoid writing a very personal account. However, while this may have been a temptation for some women in some sessions, on the whole, the writing

instructions did effectively encourage two different kinds of writing. The manipulation check was also a very useful tool in helping us to identify participants who had struggled to keep to their writing instructions in any given session. This allowed us to reiterate the importance of giving a personal or factual account before the next session.

Practicalities on the ward

We had wanted to ensure that participants had peace and quiet for 20 minutes when they were writing. However, the reality was that visitors turned up and staff interrupted, which meant there was a stop-start element to completing some sessions. I also found that nurses sometimes ignored drawn curtains with our "do not disturb" sign on them, when we did this to try and create a setting conducive to writing.

Outcome measures

Follow-up questionnaires and health utilisation logs

Originally we had intended to obtain follow-up questionnaires at one and six weeks (for analysis in the thesis of Saunders, 2008). At six weeks we also planned to ask participants to return their log of health care utilisation since they left the ward. A balance had to be struck between ensuring a meaningful gap between the one and six week follow-ups, as some standardised measures were repeated. However, when the first participant in the study told us she was due to start chemotherapy, we decided to reduce the timescale to a five week follow-up period, in an attempt not to lose participants. In spite of some appreciation at the outset of the challenge of obtaining follow-up data, there was still a deficit in the number of logs returned at five weeks (75% being returned).

Nurse rating of healing

I experienced a set back when the ward sister left six months into the project. Until her departure, she had been fully conversant with every patient's recovery and had taken on the task of providing me with a rating of their healing overall. When she left I had to ask the ward coordinator for that rating. The ward coordinator was allocated from a group of 4-5 senior nurses and the increased number of clinicians providing that rating raises concerns about its reliability.

Pain medication

My original intention had been to ask a senior clinician to give an overall rating of the totals of pain medications which participants received on the ward. However, both the ward sister (Jones, J., personal communication, January 2008) and a consultant anaesthetist (Brown, J., personal communication, March 2008) explained that, even with their experience, it was difficult to give one overall rating. In doing so, it would be hard to compare a participant who had a lot of weaker pain medications with one who had a small amount of stronger pain medications. The differing strengths of pain medication ranged upwards from (1) paracetamol, which when given regularly can provide good pain relief, (2) diclofenac, an anti-inflammatory, to (3) medications containing morphine or its derivatives. I had not anticipated that my planned method of analysing pain data would not be feasible. This led to my decision to use only the stronger pain medications and to convert them all into a morphine-equivalent dose. These discussions also led to my decision not to include women who had received epidural analgesia on the ward in the analysis. One previous study (Schindler, Shook & Schwartz, 1989) looked at

between group differences for different medications (Percocet, morphine sulphate and benzodiapines) but I did not have sufficient participants to run three analyses using all the data I had collected. It was disappointing that a lot of work, in collecting the data, did not lead to a completely satisfactory outcome measure.

Clinical Implications and Future Directions

Acceptability

When I returned to participants in the expressive writing condition at the end of their 20 minutes, many of them started to cry or appeared pensive or seemed flat in affect. Even if they did not appear to be visibly distressed, my distinct impression was that they had been in "a distant place". It was not possible to collect feedback from all participants on a systematic basis. However, it became clear from the comments that we obtained, that these strong reactions did not put the women off completing the task and seemed to be symptoms of exactly the kind of processes which the intervention is designed to trigger. Although one woman reported that it had been a "chore", because she felt unwell, some positive comments about the expressive writing condition included:

"You hide it and then let it out"

"I felt calmer"

"It really helped my attitude towards my recovery. I saw someone's husband really distressed about her and realised that with my (name of husband) being dead, I don't have to worry about his reaction and recovery is up to me."

"I found it really helpful. I was hoping to get (the expressive writing condition). I found writing about my feelings therapeutic. It was good to have time and space with curtains closed to think about what was going on for me. Allowed me time to think and cry. Up until that point I'd been so focussed on worrying about how my family was going to cope with me in hospital. I found it easy to write. Good to tell a story. On 3rd writing session I was thinking what have I got left to write now, but actually wrote more on that day than any other."

"...I found it difficult to open up to my parents and found it therapeutic to put everything down on paper."

In contrast, some comments from women in the neutral writing condition included:

"I found it no help. Had no connection with something written as I am more of a people person. I think it would be better if participants could choose the kind of writing they prefer – factual or emotional. I am not a factual person. What helped me was a psychologist coming at a given time and getting to know me rather than different researchers breezing in"

"It was hard not to make it personal"

"It was nice not focussing on the illness"

The first comment demonstrates the importance of providing some psychosocial support in this population. While the comment is quite critical about the neutral writing condition and the involvement of different researchers, I have included it to illustrate that this woman clearly wanted to talk to someone about her situation and did not want to keep to a factual account.

Future directions

I believe the effectiveness of expressive writing, as a way of processing emotions, may have a significant part to play in the adaptation of women to a diagnosis of gynaecological cancer. The population have a clear need to express their feelings, as evidenced by the informal comments we obtained. It was, on the whole, an acceptable intervention and viewed as helpful. However, one major obstacle to its general acceptance as a therapeutic intervention, is that it is very difficult to carry out a randomised controlled trial of its efficacy, as this study has demonstrated. While a randomised controlled trial (using a control group who write about neutral topics) is the most robust way of evaluating this intervention, the other studies of expressive writing in surgical populations have been creative in using randomised controlled trials in which the control groups have not written at all (Solano et al., 2003; Solano et al., 2007). In my view, that could be the key to implementing further expressive writing studies in surgical settings as, not surprisingly, the majority of women did not find that writing factual accounts was helpful.

The feedback from women in the expressive writing group is encouraging. Although the study did not find any between group differences, there is anecdotal evidence that expressive writing was experienced as a way of processing emotions and, in particular, played a useful role if women had feelings which might have been hard to share. It will be interesting to see if quantitative studies examining physical health outcomes in the future support that view.

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Appendix I

Responsibilities within a Joint Project

Joint Responsibilities

All three researchers were jointly responsible for planning the intervention, recruitment, administration of the intervention, obtaining nurse ratings of healing and reminder telephone calls regarding the return of one and five week follow-up questionnaires (not analysed in this study) and healthcare utilisation forms. Setting up the database, coding and data entry were joint enterprises between Henny Saunders and Rebecca Delmar-Morgan.

Individual Responsibilities

Lois Thomas collected surgeon ratings from out patient clinics (in the first few months of the project), designed and printed the leaflets entitled "Hospital Diary Study", and analysed the recruitment and attrition data which was included in the consort diagram (Figure 1).

Henny Saunders spoke to clinical nurse specialists about providing patients with the "Hospital Diary Study" leaflet and contacted one of the surgeons before the study to discuss the feasibility of providing their rating of participants' healing.

Rebecca Delmar-Morgan collected pain medication data from clinical charts and attended out patient clinics to obtain (the bulk of) surgeon ratings in person.

Appendix II

Patient information sheet

University College London Hospitals NHS
NHS Foundation Trust

UCLH Gynaecological Cancer Centre

Version: 2
Date: 07.11.07
REC reference number: 07/Q0511/17

Hospital Diary Study

Patient Information Sheet

We are inviting you to take part in a research study looking at whether writing a daily diary while in hospital can help with recovery after surgery. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve.

Part 1 of this information sheet tells you the purpose of this study and what you will have to do if you take part. **Part 2** gives you more detailed information about the conduct of the study.

Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Part 1 of the information sheet

What is the purpose of the study?

Research has found that a daily writing task – similar to keeping a diary – may be helpful for people with medical conditions such as breast cancer, asthma and rheumatoid arthritis. However, little is known about whether writing might be useful just after surgery. This study aims to find out whether and how keeping a brief diary for 4 days might benefit women who are recovering from surgery for gynaecological cancer.

Why have I been chosen?

We are inviting all women undergoing major surgery at UCLH for gynaecological cancer to participate. Approximately 60 women will be taking part in the study.

Do I have to take part?

It is up to you to decide. If you do decide to take part you will be asked to sign a consent form and you will be given this information sheet and the signed consent form to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason either to the researchers or other staff. A decision not to take part or a decision to withdraw will not affect the standard of care you receive.

What will I have to do?

If you agree to take part, you will be asked to write for 20 minutes on four days while you are in hospital, starting on the third day after surgery. To find out about whether writing is helpful, we will be comparing two different ways of keeping a diary. You will be asked to either:

(1) write about your feelings and thoughts about your surgery and illness

or

(2) write about daily activities on the ward.

Which type of diary you are asked to keep will be decided by chance (randomly). You will have an equal chance of doing either one.

To make sure that your diary is anonymous, it will be identified by a code number only and it will be put in a sealed envelope each day. It will then be transcribed into electronic form, with any identifying information removed, and the hand-written sheets will be destroyed.

We will also ask you to complete some questionnaires on the day before surgery (when you are on the hospital ward) and then one week and six weeks after finishing the diary (when you are at home). These questionnaires ask about a range of things, including how you are sleeping, the amount of pain you are in, your mood, and your feelings about yourself and others. They should take about 40 minutes to complete. In addition, on each day you do the diary, we will ask you to complete some brief questionnaires, taking about 5 minutes. A member of the research team will also look in your medical records so that we can obtain some details of your medical care.

Expenses

There will be no expenses involved in taking part. We will provide you with pre-paid envelopes for sending us the questionnaires that you complete at home.

What are the possible disadvantages or risks of taking part?

Sometimes people feel upset or distressed immediately after writing in a diary, especially if they are writing about personal thoughts and feelings. Previous studies have found that such distress does not last long – it usually goes away within an hour or so after writing. Should you feel at all upset after any of the writing sessions, a member of the project team will be available to talk to you and will make sure that you are given support if it is needed. You will also be free to stop participating in the study if you wish to.

What are the possible benefits of taking part?

We hope that you will find participating in this study interesting, but we cannot promise that you will benefit directly from it. The findings of the study should be of benefit to future patients. By learning about the ways in which keeping a diary might be helpful, we hope to improve the treatment of women recovering from surgery for gynaecological cancer.

What happens when the research study stops?

At the end of your participation in the study (6 weeks after keeping the diary), we will give you more information about it if you are interested. We will also send you a summary of our findings when the study is completed.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

This completes Part 1 of the information sheet. If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before making any decision.

Part 2 of the information sheet

What will happen if I don't want to carry on with the study?

You are free to withdraw from the study at any time without giving any reason. If you withdraw from the study, we will use the data collected up to your withdrawal, unless you ask us to destroy it. If you decide not to carry on with keeping the 4-day diary, we will ask if you would still be willing to complete the questionnaires.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see contact details below). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal National Health Service complaints mechanisms should be available to you.

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 confidential. A code number, rather than your name, will be used to label all data, so that you cannot be identified. Transcriptions of the anonymous diaries will be made, with any identifying information removed, and then the hand-written scripts will be destroyed. Dr Nancy Pistrang will be responsible for the safety and security of all data, which will be stored at UCL. Only the research team will have access to the data. Participants have the right to check the accuracy of data held about them and correct any errors.

Your consultant at UCLH will be informed that you are taking part in the study, and a copy of the signed consent form will be put in your medical notes. The specific information you provide will not be passed on to the consultant without your permission. The only exception to this would be if any information gives us cause for concern about your health or safety or that of others.

What will happen to the results of the study?

The project is due to be completed in October 2008, after which we can send you a written summary of the results. We intend to publish the results of the study in doctoral theses and in a scientific or medical journal. You will not be identified in any report or publication.

Who is organising and funding the research?

This study is a collaboration between researchers at University College London and clinicians at University College London Hospitals NHS Trust. It is being conducted as part of the doctoral research of three post-graduate students in clinical psychology at UCL, with a small amount of funding from UCL.

Who has reviewed the study?

All research in the NHS is reviewed by a Research Ethics Committee (an independent group of people) before it can proceed. This study has been reviewed and given favourable opinion by the Camden and Islington Community Local Research Ethics Committee.

Further information and contact details

Please do not hesitate to contact one of the project team members for further information or if you have any questions about the study.

Dr Nancy Pistrang
Senior Lecturer in Clinical Psychology

Dr Sue Gessler
Consultant Clinical Psychologist

Rebecca Delmar-Morgan
Trainee Clinical Psychologist

Henrietta Saunders
Trainee Clinical Psychologist

Lois Thomas
Trainee Clinical Psychologist

Thank you for taking the time to read this information sheet. Please keep it for future reference.

Appendix III

Consent Form

University College London Hospitals NHS
NHS Foundation Trust

UCLH Gynaecological Cancer Centre

Version: 2
Date: 07.11.07
REC reference number: 07/Q0511/17
Patient Identification Number for this study:

CONSENT FORM

Title of Project: Hospital Diary Study

Name of Principal Investigator: Dr Nancy Pistrang

		Please initial box
1.	I confirm that I have read and understand the information sheet dated.....(version.....) for the above study and have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	☐
3.	I agree to my hospital consultant being informed of my participation in the study.	☐
4.	I understand that the daily diary that I write will be analysed by computer in an anonymous form, together with writing from other patients. I give permission for quotations from my writing to be used in reports or scientific publications, with all names and other identifying information removed.	☐
5.	I agree to take part in the above study.	☐

Name of Patient	Date	Signature
Name of Person taking consent	Date	Signature

When completed: 1 for patient, 1 for researcher site file, 1 to be kept in medical notes.

Appendix IV

Baseline questionnaire

ID Number: _____

Date: _____

Background Information

The following questions ask for some background information about yourself. Please answer each one by writing in the space provided or by circling one of the options.

1. Your age: _____

2. Your occupation: _____

3. Your highest educational qualification, if any: _____

4. How would you describe your ethnic background? _____

5. Do you have a partner? Please circle the number(s) that apply:

1 Married or living with partner
2 Single
3 Separated or divorced
4 Widowed

6. Do you have any current medical problems, in addition to those for which you are having surgery? If so, please describe:

7. Do you drink alcohol? Yes / No

If Yes, on average how many units of alcohol do you drink each week? _____

(NB. An alcohol unit is half a pint of cider or beer, a small (125ml) glass of wine or a pub measure of spirits.)

8. Do you smoke? Yes / No

If Yes, on average how many cigarettes do you smoke each week? _____

9. Please think about how much you have exercised over the past 4 weeks. Consider exercise as any behaviour which raises your pulse level – for example, aerobics, walking, running, weight lifting, squash. On average, how many hours per week have you spent exercising?

I have exercised for _____hours on average per week.

Appendix V

Clinical Outcomes data (Including clinician rating of healing)

Participant number……..

Date……

Clinical Outcomes Data

1. **Pain Medication post surgery**

(Orally: Tramadol, paracetamol, diclofenac, dihydrocodeine and morphine. Also IV/SC PCA morphine or epidural infusion)

NAME OF MEDICATION					
DOSAGE (mg)					
NUMBER OF TIMES					
TOTAL TAKEN					

2. **Length of stay in hospital**

Total days, counting day of admission and discharge = ……

3. **Health care Utilisation (taken from participants' completed record)**

Number of GP visits ……..

Number of other medical visits ……

Specialism of other medical professionals consulted ……

Name of medication ……

Dosage ……

Number of times pain medication given ……

Total dose (mg) taken ……

4. **Clinican Rating of Healing**

Poor Mediocre Fair Good

Appendix VI

Health care utilisation log

ID Number: _____

Date: _____

Record of Health Care and Medication

Date of discharge from ward:_____/_____/2008
Please keep this record for the next 5 weeks and post back on: _____/_____/2008

1. Contact with Health Care Professionals

Please complete this record with details of <u>all</u> contacts (appointments or phone calls) with medical or health professionals that you have after leaving hospital (following your surgery). This includes all GP, hospital and other health professional appointments, visits or phone calls, whether or not it is connected with your surgery. If possible, please write down each visit or phone call as it occurs, rather than trying to think back over several weeks.

Date	Please state who you saw or spoke to (e.g., GP, consultant, nurse specialist, etc.)	Please state briefly the reason	Was it face-to-face or over the telephone?

Continued on next page

ID Number: _____

Date: _____

2. Medication

Please complete this record with details of any medication you take after leaving hospital (following your surgery). This includes all medication, whether it is on a "one-off", occasional or regular basis. If possible, please write down the information as it occurs, rather than trying to think back over several weeks.

Date taken (or range of dates if taken regularly)	Purpose or name of medication (if known)	How many times a day	Dose (if known)

Appendix VII

Surgeon rating of recovery

ID Number: _____

Date: _____

Expressive Writing Study

Surgeon rating of recovery

Please complete at end of consultation

Make an overall assessment of the patient's recovery from surgery based on wound healing, general mobility and independent activity, bowel and bladder function and appetite (relative to pre-surgical state).

Please circle the option that best describes the patient's recovery:

Poor **Mediocre** **Fair** **Good**

Once completed, please detach from notes and return to Henrietta Saunders (Trainee Clinical Psychologist) or Sue Gessler. Thank you.

Appendix VIII

Local Research Ethics Committee Approval

NHS

Camden & Islington Community Local Research Ethics Committee

Telephone:
Facsimile:

02 May 2007

Dr Nancy Pistrang
Senior Lecturer in Clinical Psychology
Sub-Department of Clinical Health Psychology

Dear Dr Pistrang

Full title of study: **Expressive writing and recovery from surgery for ovarian and endometrial cancer: A hospital diary study**

REC reference number: **07/Q0511/17**

The REC gave a favourable ethical opinion to this study on 26 March 2007.

Further notification has been received from local site assessor following site-specific assessment. On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site. I attach an updated version of the site approval form, listing all sites with a favourable ethical opinion to conduct the research.

R&D approval

The Chief Investigator or sponsor should inform the local Principal Investigator at each site of the favourable opinion by sending a copy of this letter and the attached form. The research should not commence at any NHS site until approval from the R&D office for the relevant NHS care organisation has been confirmed.

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.

07/Q0511/17	Please quote this number on all correspondence

Yours sincerely

Committee Co-ordinator

Email:

Enclosure: *Site approval form*

Copy to: *Sponsor and Research Governance contact:*