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Title: Preparatory education for cancer patients undergoing surgery: a systematic review of volume and quality of research output over time.

Running head: Preparing cancer patients for surgery

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ABSTRACT

Objective: To examine the volume and scope of research output examining preparation of patients for people undergoing cancer-related surgical treatment, and the impact of pre-operative education on patient outcomes and health care utilisation.

Methods: Medline, EMBASE, PsychINFO databases were systematically searched. Eligible papers were coded as data-based or non-data-based. Data-based papers were further classified as descriptive, measurement or intervention studies. Methodological quality and effectiveness of intervention studies were assessed using Cochrane Effective Practice and Organisation of Care (EPOC) criteria.

Results: We identified 121 eligible papers. The number of publications significantly increased over time. Most were data-based (n=99) and descriptive (n=83). Fourteen intervention studies met EPOC design criteria. Face-to-face interventions reported benefits for anxiety (5/7), satisfaction (1/1), knowledge (3/3) and health care costs (1/1). Audio-visual and multi-media interventions improved satisfaction (1/1) and knowledge (2/3), but not anxiety (0/3). Written interventions were mixed.

Conclusion: Descriptive studies dominate the literature examining preoperative education in oncology populations, with few rigorous intervention studies. Pre-operative education can improve satisfaction, knowledge and reduce anxiety.

Practice Implications: Further work should be directed at multi-modal interventions, and those that include the caregiver, given their role in assisting patients to prepare and recover from surgery.
INTRODUCTION

1.1 Inadequate preparation for surgery has negative consequences for patients and the healthcare system. Surgery can have a negative impact on a range of physical and psychological health outcomes. Patients report anxiety and fear about what will happen during the period of hospitalisation, and of the potential complications and outcomes of surgery.1,2 In extreme cases, high levels of anxiety may result in the postponement of procedures or the seeking of non-surgical alternatives.3 Adverse consequences of heightened pre-operative anxiety include missed appointments, poor physical preparation and a stress response that can impede recovery.2 Adverse consequences for the healthcare system include increased length of hospital stay, increased analgesic requirements and prolonged recovery time.4 In contrast, pre-operative psychological resilience may protect against severe acute as well as chronic post-operative pain.5 Unmet needs at discharge from hospital, including poor wound care, pain management and monitoring of complications, contribute to sub-optimal recovery and hospital readmissions.6

1.2 Providing information may help prepare patients for surgery, however, evidence is mixed. The potential benefits of providing patients with pre-operative education on physical and psychological outcomes has been explored in multiple medical conditions.7-16 However, the evidence for the effectiveness of pre-operative education is mixed. Meta-analysis of seminal studies in this field found beneficial effects of psychoeducational interventions on recovery, postoperative pain and psychological distress among adult surgical patients17. Other meta-analyses have reported that preparatory interventions for surgical patients which provide both sensory and procedural information,18 and address fears related to the procedure19 reduce anxiety and pain. However, a more recent review concluded that
preparatory interventions for major surgery only have a positive impact on patient knowledge, and not on anxiety, pain or length of stay.\textsuperscript{14} These mixed results reflect the heterogeneity of study populations and interventions, and suggest a need to consider the effectiveness of pre-operative education for specific patient groups.\textsuperscript{14}

1.3 Surgery is a common treatment for cancer which many patients find stressful.

Of oncology patients receiving surgery, data suggests that between 60% and 90% experience anxiety during the perioperative period.\textsuperscript{20-22} To date there have been no reviews focusing solely on preparing cancer patients undergoing surgery. This is an important gap given the increasing incidence of cancer worldwide.\textsuperscript{23} Evidence developed with other populations may not be generalizable to surgical cancer patients. Cancer patients face unique challenges due to a range of factors including the life threatening nature of the disease,\textsuperscript{24} the potential impact of surgery on body image,\textsuperscript{25} and the additional impact of non-surgical treatments such as chemotherapy or radiotherapy on wellbeing.\textsuperscript{26} Additionally, surgery to treat cancer is often performed soon after diagnosis\textsuperscript{27} when the patient may be in a state of emotional distress,\textsuperscript{28} resulting in information overload.\textsuperscript{11}

1.4 Research output as an indicator of gaps in knowledge.

Monitoring the volume and scope of research output can help identify gaps in knowledge and inform strategies to improve the quality and relevance of research to policy and practice.\textsuperscript{29-31} Descriptive research is needed to quantify the burden of outcomes, which can inform the development of methodologically rigorous interventions. Intervention studies are critical to produce evidence about the most effective strategies for preparing cancer patients for surgery. However, these studies must meet minimum standards of scientific quality to ensure adequate the validity of findings.
1.5 Aims.
This review aims to address an identified gap in the literature by examining the: 1) number of publications describing preparing cancer patients for a surgical procedure; 2) number of data-based publications examining preparation by research design (descriptive, measurement, intervention); and 3) methodological quality and effectiveness of pre-operative interventions aimed at improving patient outcomes and health care utilisation.

METHODS
2.1 Search terms
Medline, EMBASE, PsycINFO and Cochrane databases were searched from the date of inception of each database (Medline 1946, Embase 1980, PsycINFO 1967, Cochrane 1992) to November 2014. Three search themes (neoplasm, patient education, surgery/surgical procedures) were combined using the Boolean operator AND. The complete list of MESH headings and search terms are listed in Appendix A: Search terms. The reference lists of reviews of relevant literature and of retrieved articles were also manually searched.

2.2 Inclusion and exclusion criteria
Papers were eligible for inclusion if they met the following criteria: 1) adults aged 18 years; 2) patients undergoing surgical procedures used to treat cancer; 3) examined patient pre- or post-operative outcomes including psychological wellbeing (e.g. anxiety, depression); physical symptoms (e.g. pain); knowledge; quality of life; or health care utilisation (e.g. cost, length of stay). Studies that tested preparatory education interventions were included if they were self-directed or delivered by a health care provider, face-to-face or technology-based (e.g. internet, telephone); or were written, video or audio materials. Studies were excluded if the intervention: 1) was delivered only after surgery; 2) focused solely on obtaining informed
consent or to help patients make a decision about having the procedure; or 3) did not focus on education regarding the specific procedure the patient was undergoing (e.g. provided general health education or stress management only). Editorials, letters, dissertations, protocol papers and conference proceedings were excluded.

2.3 Data coding

Paper titles were initially assessed against the eligibility criteria by KF following removal of duplicates and excluded if the study did not meet inclusion criteria based on the title screen. A random subsample (10%) of included studies were categorised by another author (AW), with any discrepancies resolved via discussion. Papers meeting eligibility criteria were categorised as follows:

**Data-based or non-data-based:** Data-based publications were those reporting new data or new analysis of existing data. Non-data-based publications included review, discussion or summary papers.

**Research design:** All data-based papers were further classified into one of the following categories: (i) Descriptive studies using cross-sectional study designs to document or describe the physical symptoms, psychosocial outcomes or health care utilisation of cancer patients undergoing surgery; (ii) measurement studies which describe the development and/or test the psychometric qualities of a measure of an outcome; or (iii) Intervention studies using experimental designs to test interventions to prepare cancer patients for surgery.

2.4 Assessment of risk of bias

Studies using an experimental design were also assessed as to whether the design was one of the four types allowed by the Effective Practice and Organisation of Care (EPOC) design criteria\textsuperscript{32} - randomized controlled trials, clinical controlled trials, controlled before and after
studies, or interrupted time series studies. For those studies meeting minimum design criteria, methodological quality was then assessed using EPOC risk of bias criteria independently by two reviewers (AW, KF). To assess intervention effectiveness, study data was extracted including: aim of study; study setting; sample characteristics; inclusion and exclusion criteria; intervention design; outcome measures; follow-up periods and study findings.

**RESULTS**

3.1 Search results

A flow diagram of the search strategy is provided in Figure 1. A total of 682 publications were identified using the search strategy and were assessed against the eligibility criteria. Overall, 121 publications met eligibility criteria and were included in the review.

![FIGURE 1 HERE]

3.2 Number of studies published over time by research design

A total of 99 data-based and 22 non-data-based publications met eligibility criteria. Non-data-based papers included summary or discussion papers (n=6); or reviews (n=16). The most common type of data-based publications were descriptive (n=83), followed by intervention (n=14) and measurement papers (n=2). Overall, the number of data-based publications increased over time (See Figure 2).

![FIGURE 2 HERE]

3.3 Methodological quality of intervention studies
A total of 14 intervention studies were identified and were assessed for methodological quality and effectiveness. Table 1 presents the assessment of risk of bias for each of the 14 included studies. No studies were assessed as low risk across all criteria. One study was scored as high risk on allocation concealment. Nine of the studies were scored as unclear on allocation sequence and/or concealment, while five had adequate scores. Five studies reported blinding of health care providers, outcome assessors and/or data analysts. Six studies were unclear in reporting of blinding and three studies were scored as high risk due to lack of blinding.

3.4 Study characteristics

Table 2 presents the study characteristics of the 14 included studies which involved a total of 1507 patients. Only one study included cancer patients with heterogeneous types of cancer. The remaining 13 studies targeted patients with a particular type of cancer, including breast, oral, gynaecological, colorectal, prostate, lung, and bladder cancers. Study sample sizes ranged from 19 to 234.

3.5 Effectiveness of interventions to prepare patients for surgical procedures

3.5.1 Written information

Three studies examined the impact of providing written information over usual care in people diagnosed with lung, endometrial and rectal cancer. Lung cancer patients who received additional written information reported lower levels of satisfaction with staff than patients receiving oral information at the time of surgery and 3 months later; however there were no differences between the groups in satisfaction with information or psychological wellbeing. Endometrial cancer patients who received written information reported lower pain, length of stay and higher satisfaction compared to verbal only information group. Rectal cancer
patients who received an information pack reported lower post-operative anxiety and higher satisfaction than the control group.45

3.52 Audio-visual information

Three studies examined the benefits of audio-visual or multi-media interventions. Wysocki and colleagues found no significant difference in knowledge or in anxiety levels at 1, 7 and 30 days post-operatively between patients who watched a 12 minute video once in the clinic prior to their surgery and a control group.43 Huber and colleagues found improved satisfaction and knowledge, but no differences in anxiety between patients who received information in the multi-media format and patients receiving standard education (a consent form provided prior to the preoperative consultation).42 Finally, Kakinuma and colleagues found that in addition to increasing knowledge, watching a video shortened the pre-anesthetic interview time for cancer patients.38 However, there were not benefits of video for anxiety.

3.53 Individual or group face-to-face sessions

The most common intervention format examined was face-to-face education sessions. Patients who received a psycho-educational intervention 1-2 days prior to surgery reported lower levels of post-operative anxiety at 3 days and immediately prior to discharge (12 days post-surgery).34 Similarly, a pilot study found that patients who had a psycho-educational booklet delivered by a health educator resulted in significantly greater satisfaction and knowledge, and lower levels of anxiety at 3 month follow-up than control group patients.39 Pinar and colleagues reported that systematic pre-operative instruction was effective in reducing the anxiety levels of gynaecological oncology patients compared to patients receiving usual care.33 Belleau and colleagues reported that pre-operative levels of anxiety
decreased over time in patients receiving a psycho-cognitive education session compared to the control group. However, there were no differences in depression outcomes.\\n
Chaudri and colleagues reported that those who received an educational intervention involving home visits and audio-visual aids reported a shorter time to stoma proficiency, fewer unplanned stoma-related visits in the community after discharge, and subsequently lower cost.\\n
The incidence of anxiety and depression did not differ between the groups pre-operatively and 6 weeks after discharge in Chaudri and colleagues’ study, however these were secondary outcomes only and the study lacked adequate power. Lilja and colleagues’ study showed no statistically significant differences between intervention and control patients in pre-operative anxiety levels. Women who received the combined intervention of a Papilla Gown and education demonstrated greater activity, greater comfort level and decreased lymphedema. While the education intervention also increased knowledge.\\n
Among highly anxious patients, those interviewed by a psycho-oncologist prior to surgery reported a greater reduction in anxiety compared to those receiving standard care. However, no significant differences were found for retention of information between groups.

**DISCUSSION**

4.1 Discussion

This review examined the volume and scope of research output in relation to the preparation of patients for people undergoing cancer-related surgical treatment, and the impact of pre-operative education on patient outcomes and health care utilisation. Despite surgery being a common treatment for cancer, most of the 121 data-based studies have examined the preoperative education in oncology populations are cross-sectional, descriptive studies. Only 14 intervention studies were identified. Each of the 14 intervention studies were assessed as
unclear or high risk of bias on at least one of the EPOC criteria. While homogeneous in terms of diagnoses (mostly single cancer type), small sample sizes were used in many studies.\textsuperscript{47} Whilst four studies reported details of required sample sizes or power calculations, it is unclear whether these studies had sufficient statistical power to detect clinically important effects for both their primary and secondary outcomes.

Given the promising findings, more evidence from well conducted experimental studies is needed to confirm the benefits of delivering information using written information supported by face-to-face discussions.\textsuperscript{34,36,37,39,41,42} Most interventions were delivered in a single session\textsuperscript{28,33-35,37,38,40,42-45}, often one day prior to or on the day of surgery.\textsuperscript{28,33,34,38-40,42,43} This may place additional stress on a patient who may already be highly anxious, reducing the likelihood that information is processed. Providing information earlier may assist patients to take an active role in managing their care, and enhance preparation for the post-operative period. Ensuring that information is delivered to patients with sufficient time to reflect on the information prior to attending pre-operative consultations may be more effective. Given that information about some aspects of the patient experience is presented to patients pre-operatively may only be relevant in the immediate and longer-term post-operative phase, the potential added benefit of incorporating post-operative follow-up sessions as a core component, or access to information and instructions about how to manage these concerns during this phase should be tested. Providing education that encompasses each of the phases of the surgical care pathway may better reflect the patient experience.

The content of interventions often included preparation instructions, a description of what to expect during the surgical procedure and hospital stay, as well common side-effects they may experience post-operatively. Practical information about strategies to manage side-effects and
symptoms was less often provided. Few interventions considered also a range of issues that patients may face across physical, psychological, practical and social dimensions. A major challenge facing clinicians in accurately identifying those experiencing significant pre-operative anxiety, as well as those at risk of poor post-operative outcomes, such as pain. Incorporating evidence-based tools, such as question prompt lists and screening tools which can be accessed by patients and shared with clinicians prior to or during the delivery of pre-operative education may facilitate the identification of these concerns. Accurate identification can facilitate early intervention, including the delivery of tailored education about what to expect and how to manage these concerns more effectively.

For preparatory education interventions to achieve their goals, they must be accessible and used as intended in routine practice. Face-to-face sessions appear more effective at improving patient outcomes. How these sessions can be sustained in routine practice is especially pertinent, given the variability of clinicians’ skills, the time and resources taken to deliver the education, and the short time frame in the peri-operative phase in which to do so. Multimedia formats may offer an alternative mode of delivery that could be used to augment standard face-to-face sessions. For example, prior to their pre-operative consultation patients could access a multi-media program that provides written and audio-visual information about the potential risks of surgery, preparation instructions, and what to expect post-operatively. This has the potential to direct discussions, minimising the need to discuss general topics during time-limited face-to-face sessions.

Such multimedia interventions offer a number of advantages. They can accessed at the patient’s own convenience at any time of the day. Features such as algorithms that tailor information to user needs and preferences can help overcome poor health literacy.
Information can be presented in a range of accessible formats such as video and audio clips. Such programs can be updated as the patient progresses through the surgical care pathway, their condition changes, or as new evidence becomes available. Despite these benefits, few studies have examined these interventions and the accessibility to sub-groups of patients has been questioned. Strategies to maximise engagement and uptake must therefore considered during development. For example, proactive, personal and detailed invitations from clinicians may improve uptake of interventions. Having surgeons emphasise the potential value of frequent use of programs and advising patients to follow recommendations is also likely to have an impact on utilisation and adherence.

Carers play an increasing role in assisting surgical patients to prepare for and recover from surgery. However, no studies examined interventions that would help equip them to assist the patient. Ensuring that carers are appropriately informed and supported is likely to enhance their ability to assist recovery. This may involve providing practical advice about pre-operative preparation and admission procedures, as well as post-operative concerns such as administering medications, wound care and recognising complications; and clarification about the patient’s functional capacity. Further work is needed to accurately characterise the impact that caring for poorly prepared patients has on carer wellbeing, and develop and test interventions that can support caregivers in assisting patients as well as managing their wellbeing.

The search strategy was limited to published literature. We did not consider non-published studies or grey literature. These restrictions may have resulted in some relevant publications being missed. The methodological quality of the descriptive studies was not assessed. The quality of descriptive studies informing intervention development is important given the
reliance of intervention on these studies, however is often more difficult to assess given the lack of well-established guidelines and criteria.

4.2 Conclusions

Delivering pre-operative education can increase cancer patients’ knowledge and satisfaction and, in some cases, reduce anxiety levels, especially when delivered via face-to-face format. Variability of clinicians’ skills to deliver education; lack of systems to support routine delivery, as well as time and resource pressures may all act as barriers to this care. Greater research effort is needed to examine strategies to enhance sustainability of these interventions, potential for alternative approaches to reduce burden on clinicians and ways to support carers in aiding patient preparation and recovery.

4.3 Practice Implications

Despite their limitations, the reviewed studies provide some insight into intervention components that may enhance the benefits of preoperative education interventions for cancer patients. Patients report a preference for contact with clinicians to discuss aspects of their care. However, resource constraints means that not all patients are able to have their pre-operative education needs met. Further, not all clinicians have the skills and knowledge to provide high quality education. Strategies to supplement face-to-face education are an important avenue for further research. Given the severity and type of information needs may vary over time, providing access to credible information sources from the point of informed consent through to the post-operative phase may also maximise benefits for patients. Despite recommendations by the Institute of Medicine that family members/carers be involved in important health care discussions, their involvement in pre-operative education interventions was overlooked in all studies. Carers offer and important source of help to patients, and the
impact of preparing carers for what to expect on patient recovery should be explored.
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Conflicts of interest: none

Authorship contribution:

Conception: AW, KF, RSF

Data acquisition and/or analysis: AW, KF, JB

Data interpretation: All authors

Drafting and revising manuscript: All authors

Final approval: All authors
REFERENCES


32. Cochrane Effective Practice and Organisation of Care Review Group: Suggested risk of bias criteria for EPOC review 2012


Figure 1: Inclusion and exclusion of studies
Figure 2: Number of data-based and non-data-based studies by year of publication
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Table I: Quality of intervention studies meeting EPOC methodological criteria (Low, High, Unclear)
Table II: Interventions used to prepare patients for surgical procedures to treat cancer.

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<th>Study</th>
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<th>Outcome measures; Follow-up time points</th>
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| **Ali et al., 1989[36]**     | Urinary bladder cancer and planned urinary diversion surgical intervention | Routine physical preoperative care      | Psycho-educational preparation: semi-structured teaching program (30-60 min session) provided to patient and a significant other 1-2 days pre-operatively; visit from a patient with a functioning stoma; encouragement of expression of fears and anxieties | *Primary:* State anxiety (STAI)  
*Secondary:* qualitative aspect: worries before surgery  
Data points: Baseline (after recruitment); 3rd day post op; and before discharge (approx. 12 days) | - Patients who received the intervention exhibited significantly less state anxiety on the 3rd day post op and before discharge than the control group (p<0.001).  
- Significant correlation between anxiety on 3rd day post-op and anxiety before discharge. |
| **Country:** Egypt           | N= 30 (control n=15, intervention n=15)    |                                          |                                                                              |                                         |                                                                                                                                         |
| **Design:** 2 arm RCT        | Age (mean): control: 45.86 years; intervention: 45.33 years  
Gender: Control: 80% male; intervention: 73% male |                                          |                                                                              |                                         |                                                                                                                                         |
| **Angioli et al., 2013[42]** | Endometrial cancer patients undergoing surgery |                                          | Group V: Verbal information provided the day before surgery about type of surgery, hospitalisation, stay, pain and postoperative management | Satisfaction (EORTC QLQ-C30 and EORTC QLQ-INFO25); pain (VAS); hospitalisation days; pain medication usage.  
Data points:  
Satisfaction: Within 6 weeks of discharge  
Pain: Day 1 and 3 post-op  
Pain medication usage: reported daily | - Group W (written information) patients reported statistically significant better information satisfaction (p=0.0008); lower mean pain VAS value (p=0.02); lower number of hospitalisation days (p=0.0265); and lower daily usage of pain medication (p=0.0120) than Group V (verbal information). |
| **Country:** Italy           | N=190 (control: Group V n=98, intervention: Group W n=92)  
Age (median): control:64.2 years; intervention: 64.7 years  
Gender: Female |                                          | Group W: Written information covering same topics as Group W                  |                                         |                                                                                                                                         |
<p>| <strong>Design:</strong> Randomised study |                                                                                                          |                                                                              |                                         |                                                                                                                                         |</p>
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| Barlesi et al., 2008[37] | Non-small cell lung cancer patients undergoing standard thoracic surgery | Oral only information about disease and treatment                      | Oral plus written information: same information as control group plus a 5 page document of information provided at the end of clinic appointment | *Primary:* Psychological wellbeing (6 mood states) (PGWBI)  
*Secondary:* Satisfaction (QSH)  
*Data points:* QoL: Baseline (pre-op at first clinic with surgeon); 1 month (post-op period); and 3 months post-op.  
Satisfaction: At discharge only | - No significant difference in psychological wellbeing or satisfaction with information between control and intervention groups at any of the analysis time points.  
- Intervention patients reported a statistically significant lower level of satisfaction with staff at time of discharge (p=0.04). |
| Country: France  | N=75 (control n=34, intervention n=41)  
*Age (mean):* Control: 63.7 years; intervention: 63.4 years  
*Gender:* Control: 27 (79%) male; intervention: 32 (78%) male |                                                                                       |                                                                                    |                                          |                                                                         |
| Design: 2 arm RCT |                                                                       |                                                                                        |                                                                                    |                                          |                                                                         |
| Belleau et al., 2001[39] | Breast cancer patients scheduled for mastectomy                      | Standard educational information – a more direct cognitive approach       | Individualised education intervention combining both psychotherapeutic and cognitive approaches, delivered 14-19 days prior to surgery. Exploring and supporting feelings, emotions and coping strategies. Teaching tools included charts, an information brochure about the surgery and a video on operating room stay. | *Data points:* Pre-educational (14-19 days before surgery at time of recruitment), post-educational (immediately after the education, about 14-19 days before surgery), and pre-surgery (the day before surgery) | - Both groups reported a significant reduction in anxiety (p<0.01) immediately following education.  
- Intervention group had additional reduction of 4.83 (p=0.05) compared to control group.  
- Day before surgery intervention group only had significant reduction in anxiety (p=0.03), but difference between groups not significant. |
| Country: Canada  | N=60 (control n=30, intervention n=30)  
*Age (mean):* Control: 51.50 years; intervention: 52.17 years  
*Gender:* Female |                                                                                       |                                                                                    |                                          |                                                                         |
<p>| Design: 2 arm RCT |                                                                       |                                                                                        |                                                                                    |                                          |                                                                         |</p>
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<tr>
<th>Study</th>
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<th>Outcome measures; Follow-up time points</th>
<th>Results</th>
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<tbody>
<tr>
<td>Chaudhri et al., 2005[43]</td>
<td>Elective colorectal resection requiring a stoma</td>
<td>Usual care: Post-operative stoma education</td>
<td>Usual care plus intensive preoperative teaching: 2 pre-op education home visits by colorectal nurse specialist (approximately. 45 mins in duration) with audio-visual aids teaching use and change of stoma pouch system</td>
<td>Primary: Time to stoma proficiency; postoperative hospital stay; unplanned stoma-related visits Secondary: -Anxiety and depression (HADS) -Satisfaction with stoma support service. Economic assessment Data points: Baseline (pre-op) and 6 weeks post-op</td>
<td>Intervention group reported significantly shorter time to achieve stoma proficiency (P=0.0005); shorter hospital stay (P=0.029) and fewer unplanned stoma-related visits (P=0.0309). No significant difference in anxiety or depression between the groups. High level of satisfaction with both groups. Mean cost lower for intervention group (average saving per patient £1,119)</td>
</tr>
<tr>
<td>Country: United Kingdom (UK) Design: 2 arm RCT</td>
<td>N=42 (control n=21 and intervention n=21) Age (mean): Control: 62 years; Intervention: 69 years Gender: Control: 62% male; Intervention: 52% male</td>
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<td>Cho et al., 2013[38]</td>
<td>Stages 2 and 3 breast cancer with axillary lymph node dissection; planned total, modified radical or radical mastectomy with the use of a drain</td>
<td>Usual care and hospital gown</td>
<td>Group 1: papilla gown + education Group 2: education Group 3: papilla gown. The education sessions (40 mins of personal teaching) were provided 1 week prior and 1 week after surgery, and included the provision of a pictorial handbook on care after surgery.</td>
<td>-Activity (PAS), body image (BIS) and comfort (PMGCI) -knowledge -lymphoedema (tape measurement of arm) Data points: Activity, body image and comfort: 1 week (T1) and 6 months post-surgery (T2) Knowledge: Baseline, T1 &amp; T2 - Lymphoedema: Baseline &amp; T2</td>
<td>Combined intervention of papilla gown and education led to positive outcomes. All 3 intervention groups had significant association with knowledge at T1 (p&lt;0.05). Papilla gown and education group demonstrated greater activity (p=0.039). Gown only group had greater increase in comfort (p=0.0004) and decreased lymphoedema (p=0.0097).</td>
</tr>
<tr>
<td>Country: United States of America (USA) Design: 4 arm RCT</td>
<td>N= 145 (papilla gown + education n=45; education n=45, papilla gown n=45; control=45) Age (mean): 55 years Gender: female</td>
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| **Granziera et al., 2013** | Breast cancer surgery patients N=234 (control: SAI arm n=110, intervention: IPA arm n=124) | Structured anaesthesiology interview (SAI): Anaesthesiology interview only | Integrated multidisciplinary psycho-oncological approach (IPA): Interview with a psycho-oncologist. Prior to the pre-op anaesthesia evaluation, the psycho-oncologist then informed the anaesthesiologist of details of the patient’s emotional reaction, cognitive coping style. Illness awareness and level of compliance; and the type of communicative strategy to adopt for each patient. | **Primary**: Anxiety (STAI), retention of information.  
**Secondary**: Subjective perception of anaesthesia information.  
**Data points**: Anxiety: Before randomisation (baseline) and after anaesthesiology interview. | Mean anxiety scores significantly lower after the anaesthesiology interview in both groups (both P<0.0001).  
- However, no significant difference between groups in mean anxiety scores.  
- Anxiety score for highly anxious patients decreased significantly more (P=0.024) in IPA group than SAI group.  
- Information correctly understood by more than 80%, with no significant difference between groups. |
| **Country**                 | Italy                                       |                                                  |                                                                               |                                           |                                                                         |
| **Design**                  | 2 arm RCT                                   |                                                  |                                                                               |                                           |                                                                         |
| **Age (median)**            | Control: 53.6 years; Intervention: 53.4 years |                                                  |                                                                               |                                           |                                                                         |
| **Gender**                  | Female                                      |                                                  |                                                                               |                                           |                                                                         |
| **Huber et al., 2013**     | Radical prostatectomy with curative intent N=203 (control n=101, intervention n=102) | Standard preoperative education                   | Multi-media supported education covering anatomy, the surgery, side effects and treatment course, involved into the preoperative talk provided the day before surgery. Physician navigated the tool to illustrate the talk with pictures, short videos and written information | **Primary**: Satisfaction  
**Secondary**: Consultation duration, knowledge, anxiety (STAI), decision-making (COMRADE),  
**Data points**: 6-10 hours after preoperative education | Complete satisfaction with preoperative education significantly more frequent in intervention group (P=0.016).  
- No differences in consultation duration, anxiety or decision making  
- Perceived knowledge higher after intervention (P=0.037) |
<p>| <strong>Country</strong>                 | Germany                                     |                                                  |                                                                               |                                           |                                                                         |
| <strong>Design</strong>                  | 2 arm RCT                                   |                                                  |                                                                               |                                           |                                                                         |</p>
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| Kakinuma et al., 2011[40]| Cancer surgery (including diagnostic biopsy) under general or combined general and epidural anaesthesia; patients admitted at least 1 day prior to surgery  | No-video. Pre-anaesthetic interview and risk assessment performed by an Anaesthesiologist | Short interactive animation video (risks, benefits and alternative of anaesthetic procedures) provided for 30 mins in the ward the day before surgery. Pre-anaesthetic interview and risk assessment performed by an Anaesthesiologist | - Anxiety (STAI)  
- Anaesthesia knowledge  
- Interview time with anaesthesiologist | - No difference in pre-anaesthetic anxiety between the 2 groups.  
- Knowledge of anaesthesia on the day of surgery was 11.6% better in the video group  
- Interview time 34.4% shorter in the video group |
| Country: Japan  
Design: 2 arm RCT | N= 211 (control n=105, intervention n=106)  
Age (median): Control: 60.0 years; Intervention: 60.1 years  
Gender: Control: 65% male; Intervention: 54% male | | | |
| Katz et al., 2004[41]    | Oral cavity cancer and proposed curative surgery                       | Usual care: meeting with surgeon at time of surgery consent, brief orientation to ward, seen by ENT staff for focused history and examination | Educational booklet (95 pages) covering information about the cancer, treatment and effective coping strategies, disseminated in 2 parts (pre-op and pre-discharge) incl. a session with a nurse (60-90 mins) to discuss content. Pre-op: Prior to hospital admission with telephone contact session. Pre-discharge: Several days prior to discharge. | Anxiety (STAI); depression (CESD); wellbeing (ABS); quality of life (ALHRS, IIRS, EORTC); social support (MOS); knowledge; self-efficacy (SICPA); body-image; satisfaction | - Intervention reported significantly lower trait anxiety (P=0.020), higher knowledge (P=0.020) and satisfaction with appearance (P=0.021) at T3.  
- Post-hoc analyses found significant improvement in anxiety in intervention group from T1 to T3 (P=0.018), and significant difference to control group at T3 (P=0.049). |
| Country: Canada  
Design: 2 arm RCT | N=19 (control n=9, intervention n=10)  
Age (mean): Control: 53.4 years; Intervention: 60 years  
Gender: Control: 70% male; Intervention: 56% male | | | |
| Lilja et al., 1998[30]   | Breast cancer and total hip replacement patients.                      | Usual care: standard preoperative information from ward nurse             | Usual care and extended preoperative information about what was going to happen from the anaesthetic nurse. Provided in a 30 min session on day before surgery | Anxiety (HADS) (T1, T2); stress hormones (S-Cortisol) (T1, T2, T3, T4); pain (VAS) (T3, Day 2 post-op and T4) | No statistically significant differences in anxiety, stress or pain between the groups. |
| Country: Sweden  
Design: 2 arm RCT | Breast cancer patients only:  
N= 44 (control n=22, intervention n=22)  
Age (median): 53 years  
Gender: Female | | | |
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| O’Connor et al., 2014[47]    | Rectal cancer patients undergoing surgery   | Usual care: current information package (generic colorectal cancer and stoma information leaflets) | Information pack tailored to their treatment plan and preferred information. Patients received ‘guided tour’ of the 14 leaflets in the information pack and were guided in choosing the leaflets relevant to their treatment plan. | *Primary*: Satisfaction with information (PSCaTE), a *Secondary*: Anxiety and depression (HADS), readjustment (Reintegration to Normal Living Index) Data points: Pre intervention (time 1); post-op prior to hospital discharge (time 2); and 6 months after time 2 (time 3) | - Intervention group reported a statistically significant higher level of satisfaction with information at times 2 and 3 (p=0.00) and significantly lower anxiety score at time 3 (p=0.03) than the control group.  
- No statistically significant differences in depression or readjustment scores between the groups. |
| Country: Ireland             | N=76 (control n=33, intervention n=43)     | Age (mean): Control: 68.29 years; intervention: 63.12 years |                                                                             |                                                                                         |                                                                                                                                                                                                       |
| Design: Parallel design with equal (1:1) allocation | Gender: 64.5% male, 35.5% female            |                                                                             |                                                                             |                                                                                         |                                                                                                                                                                                                       |
| Pinar et al., 2011[35]      | Gynaecological oncology surgery             | Routine nursing care and information                          | Systematic preoperative instruction provided in clinic (approx. 1hr duration) at least one day prior to surgery: including written and visual information with a booklet on: pre-operative preparation; relaxation skills; post-operative self-practices | Anxiety (STAI) Data points: Baseline (pre-surgery, at least one day prior to surgery) and before discharge | Intervention patients reported lower trait anxiety post-operatively than control patients (P=<0.05).                                                                                                                                                           |
| Country: Turkey              | N= 120 (control n=60, intervention n=60)   |                                                                             |                                                                             |                                                                                         |                                                                                                                                                                                                       |
| Design: Quasi-experimental case control | Age (mean): Control: 49.87 years; Intervention: 48.52 years |                                                                             |                                                                             |                                                                                         |                                                                                                                                                                                                       |
| Wysocki et al., 2012[45]    | Breast cancer patients undergoing mastectomy | Routine information plus structured information (short 12 min video about practical aspects of hospital stay, surgical and adjuvant treatment), delivered pre-operatively, usually on day before surgery. | Routine information | Anxiety (VAS), subjective knowledge (VAS and questionnaire) Data points: 12-18hrs pre-operatively, post-op: 24-36hrs, 7 days and 30 days | - No significant effect of the intervention on anxiety or knowledge.  
- However, significantly more patients in intervention group listed all treatment options, both preoperatively (P=0.0101) and postoperatively (P=0.0367).                                                                 |
| Country: Poland              | N=58 (control n=29, intervention n=29)     |                                                                             |                                                                             |                                                                                         |                                                                                                                                                                                                       |
| Design: 2 arm RCT            | Age (mean): Control: 55 years; Intervention: 60 years |                                                                             |                                                                             |                                                                                         |                                                                                                                                                                                                       |
| Gender: Female               |                                                                             |                                                                             |                                                                             |                                                                                         |                                                                                                                                                                                                       |

ALHRS= Atkinson Life Happiness Rating Scale; ABS= Affect Balance Scale; BCKQ= Breast Cancer Knowledge Questionnaire; BIS= Body Image Scale; CESD= Center for Epidemiologic Studies – Depression Scale; COMRADE=Combined outcome measure for risk communication and treatment decision-making effectiveness; EORTC= European Organisation for Research and Treatment for Cancer Quality of Life Questionnaire; IAS=Situalional Anxiety Inventory; IIRS=Illness Intrusiveness Rating Scale; MOS= MOS Social Support Survey; PAG= Post mastectomy Activity Scale; PGWBI= Psychologic Global Well-Being Index; PMGCI=Post Mastectomy Gown Comfort Instrument; PSCaTE= Patient Satisfaction with Cancer Treatment Education; QoL = Quality of Life; QSH= Satisfaction of Hospitalised Patients; SICPA= Stanford Inventory of Cancer Patient Adjustment; STAI=State-Trait Anxiety Inventory; VAS=Visual Analogue Scale
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