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Pre-operative self-efficacy education versus usual care for patients undergoing joint replacement surgery (PoEt): A pilot randomized controlled trial.

Authors: Marie Cooke¹, Rachel Walker¹, Leanne M Aitken^{1,2}, Andrea Freeman³, Sharlene Pavey⁴, Ruth Cantrill¹

¹ NHMRC Centre for Research Excellence in Nursing Interventions, Griffith Health Institute, Centre for Health Practice Innovation

² Intensive Care Unit, Princess Alexandra Hospital

³ Acute Pain Service, The Queen Elizabeth II Jubilee Hospital

⁴ Acute Pain Service, Gold Coast Hospital and Health Service District

Corresponding author:

Marie Cooke

NHMRC Centre for Research Excellence in Nursing Interventions
Griffith Health Institute, Centre for Health Practice Innovation
Griffith University
170 Kessels Road
Nathan Qld 4111
m.cooke@griffith.edu.au

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Authors Contributions:

MC, RW, LMA, AF, SP all contributed to study conception/design

MC, RW, AF, SP, RC all contributed to various aspects of data collection/analysis

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Abstract

Background: Hip and knee replacement is a major surgical procedure performed worldwide. Despite 20 or so years of clinical research and care guidelines, the management of acute post-operative pain continues to be a concern. A growing number of self-efficacy strategies are being included in education programs for patients to enable them to have a central role in managing their illness and symptoms.

Aims and Objectives: The purpose of this pilot study was to evaluate the feasibility of testing an education intervention to improve self-efficacy in patients undergoing hip or knee replacement.

Methods: A single-blinded, parallel, pilot randomised control trial design was used. Ninety-one patients undergoing hip or knee replacement surgery were randomly assigned to an intervention or control group. Intervention group participants were given a DVD demonstrating self-efficacy activities to undertake four times before admission. Feasibility criteria related to recruitment, protocol adherence and missing data were assessed. Participants were assessed for pain, anxiety, self-efficacy, and health care utilisation.

Results: In relation to recruitment, 55% of screened patients were eligible and of these 81% enrolled (n=91). Exclusion following randomisation was 10% with missing data ranging from 0 – 20.7%. Nineteen percent of participants were lost to follow up in the control group and 20% lost to follow up in DVD group. Protocol adherence to components of the intervention varied. Both groups were generally satisfied with pain management during hospitalisation and there were no differences in groups on clinical outcome measures.

Conclusions: Preliminary evidence for the benefits of self-efficacy based education for patients undergoing hip or knee replacement was identified. Additional findings included a need to strengthen the intervention and reducing the number of data collection points to

improve the protocol, missing data and numbers lost to follow up before a larger trial is undertaken.

BACKGROUND

Hip or knee replacements are relatively common surgical procedures. Most often the need for such surgery results from osteoarthritis (1), and associated pain, stiffness and decreased mobility. These symptoms frequently cause psychological distress for the person living with the condition (2). Pain experienced post-operatively after joint replacement surgery has been linked to longer lengths of stay, delayed ambulation following surgery, and impaired mobility at six months (3). Anxiety also has numerous detrimental psychological and physiological effects (such as, increasing blood pressure, glucose and clotting speed, while simultaneously reducing immune function and peripheral perfusion) (4). As such, nursing interventions directed at decreasing pain and anxiety pre- and post-operatively may improve both care and outcomes for patients. A growing number of self-management strategies are being included in education programs for patients to enable them to have a central role in managing their illness and symptoms. Self-efficacy is the belief and confidence in one's own ability to perform well and achieve things (5). Self-efficacy determines how hard we try and persist. Self-efficacy has been found to be a modifiable mediator for improving pain (6,7) and anxiety (7) post-operatively. Including a self-efficacy component in pre-operative education could improve physical and psychological outcomes for patients undergoing surgery.

Hip and knee replacement is a major surgical procedure performed worldwide. According to the most recent data collated by the Australian Orthopaedic Association (1), a total of 547,607 hip or knee replacement procedures were performed on 421,527 individual patients in the 10-year period from August 1, 1999 to December 31, 2009. In the United States there were 1,051,000 hip/knee replacement procedures in 2010 (8) and in England/Wales there are around 160,000 performed annually (9). Pain is a predictable

outcome post joint replacement surgery. Results of a national study in the United States (10) found that more needs to be done to improve patients' post-operative pain experience with Swedish researchers finding 24% of patients identified more pain than expected post-operatively and reported less satisfaction with the quality of their care (11).

A self-efficacy approach has been developed for painful osteoarthritis (12,13) and includes "(a) facilitation of achievable performance accomplishments of skills mastery; (b) exposure to, and sharing of, vicarious experiences; (c) use of social and verbal persuasion by others deemed knowledgeable about the activity; and (d) drawing attention to the individual's physiological and affective state prior to and following the desired activity" (14).

A Cochrane Systematic Review (15) of nine studies with a total of $N = 782$ participants, reported that there was insufficient evidence to conclude that pre-operative education improves patient post-operative outcomes, over and above routine care for patients undergoing hip or knee replacement surgery. However, the authors did find some evidence of beneficial effects in respect of anxiety levels. Specifically, pre-operative education appeared to have a modest effect on pre-operative anxiety and was most beneficial when tailored according to patient's individual anxiety or targeted at those most in need of support (such as the severely disabled). Further research was advocated to better elucidate the effects.

Benefits and usefulness of an education program that includes components on self-efficacy for improving physical and psychological outcomes for patients undergoing surgery have been demonstrated in multiple studies. These studies however typically employ a non-randomised design, small sample sizes with limited description of the intervention (7,16,17), which limits the findings and makes it difficult to conclude the true efficacy of pre-operative education for patients undergoing surgery. For example, in 125 patients with musculoskeletal trauma Wong and colleagues (7) compared the effectiveness of a 30-minute pre-operative pain management educational intervention (one day prior to surgery) to enhance patients'

self-efficacy with routine care. Results showed that pre-operative education significantly reduced levels of pain, anxiety, and improved self-efficacy during hospitalisation for those in the intervention group as opposed to those who received routine care only. There was no significant difference, however, between the intervention and control group in terms of length of stay. In another study (17), 66 patients undergoing total hip replacement received either routine care or a multimedia CD (video and audio) with printed resources that covered “introduction of joint, preparation for surgery, usage of assistance apparatus, and rehabilitation” (p. 218) with the functional ability to practice and review the material. The authors found that those participants given the multimedia CD had significantly higher levels of self-efficacy and activity functioning, and a reduced length of hospitalisation, than their control group counterparts. Similar findings were reported in an American study (16), which compared the effects of a 24-minute videotape showing a nurse demonstrating breathing techniques and movement skills (known as The Foster Pain Intervention), with routine care in a sample of 70 elective hysterectomy patients.

In summary, research on pre-operative education programs, including those involving a self-efficacy component for patients undergoing hip or knee replacements, have tested the effect of the immediate pre-operative education (within one–four days of surgery). No study reporting testing of a longer self-efficacy based intervention for those undergoing hip or knee replacement surgery was found. Wu and colleagues (18) found a four-week osteoarthritis self-management program based on Bandura’s self-efficacy theory however lead to significant improvements in participants self-efficacy, pain control beliefs and arthritis-related consultations, pain and disability days at four and eight weeks. An educational intervention that includes strategies to enhance patients’ self-efficacy started four to six weeks prior to surgery may offer greater benefits pre- and post-operatively. The overall aim of this study was to evaluate the feasibility of testing an education intervention to improve

self-efficacy in patients undergoing hip or knee replacement to inform decisions regarding launching a full-scale multi-site RCT. Specifically, this study intended to: (1) evaluate the feasibility of launching a full-scale multi-site efficacy trial, using pre-defined feasibility criteria for recruitment, retention and protocol fidelity; (2) use pilot data to refine the protocol and; (3) assess whether pre-operative self-efficacy based education intervention holds promise on pain, anxiety, self-efficacy and satisfaction with pain management in patients undergoing hip or knee replacement.

METHODS

The study used a single-blinded, parallel, pilot RCT design. Advantages of pilot trials are that the findings provide information for the planning of and justification for a larger scale trial of an intervention through supporting or refining of study components including the methods, procedures, and protocols to be used (19). Ethical approval to conduct this study was granted by the Queensland Health Human Research Ethics Committee (Metro South Region) and Griffith University Human Research Ethics Committee. The trial was registered with the Australian New Zealand Clinical Trials Registry - ACTRN 12612001156875

Participants

Eligible participants were patients who: (i) were aged over 18 years of age; (ii) were medically assessed and booked for an admission for hip or knee replacement surgery in South East Queensland, Australia; (iii) provided informed consent and; (iv) were able to watch a DVD. Two exclusion criteria were: (i) could not read or write English; and (ii) cognitive or mental impairment which prevented completion of self-report surveys.

Assignment

Following informed consent, participants were randomly allocated to the intervention or control group using a computer-generated random assignment on a 1:1 ratio with random variation in block sizes using a web-based independent automated service at a university Clinical Trials Randomisation Service. This process ensured adequate concealment, limiting likelihood of selection bias (20).

The intervention

The intervention involved pre-operative self-efficacy based education sessions of around 20–30 minutes delivered via a DVD. The self-efficacy component was based on the work of Marks and Allegrante (14). The self-efficacy principles and the components of the DVD are outlined in Table 1. Participants in the intervention group received the DVD at the booked pre-operative session to take home with them. Participants were asked to review this DVD within 72 hours and work through the activities at home 4 times before admission for surgery. A research assistant (registered nurse) called the participants 72 hours after the pre-operative session and then again in two to three weeks to support participation. Participants in both groups received routine in-hospital pre- and post-operative care. Post-operatively this included all care provided by healthcare professionals in terms of nursing, wound care, physiotherapy and pain management.

Table 1 around here

Masking

Although care providers and outcome assessors were blinded to group allocation, patients were not.

Outcome Measures

The primary outcomes related to the assessment of feasibility and included measures of recruitment, retention and protocol fidelity. Secondary outcomes of pain, anxiety, self-efficacy were assessed through self-report questionnaires to identify whether the intervention held promise for patients undergoing hip or knee replacement and to provide data for effect sizes for a larger study. Self-reported assessment of pain management during hospitalisation and utilisation of post-discharge health service/resource utilisation and self-efficacy and relaxation utilisation post-discharge were also collected.

- Pain: Numeric Rating Scale (NRS) for pain enables the participant to rate the intensity of the pain currently experienced on an 11-point scale, ranging from 0 (no pain) to 10 (worst pain possible). The popularity of the NRS as a standard measure for pain has led to its widespread use in clinical research (21).
- Anxiety: The State-Trait Anxiety Inventory (STAI) – Form Y (22) measures participants' anxiety levels. The State anxiety section of the STAI measures how a person feels at the time and comprises 20 items using a four-point Likert-type response scale to obtain an overall score of anxiety from 20 to 80, with higher scores indicating higher levels of anxiety. The internal consistency alpha coefficients of the State anxiety section range from 0.86 to 0.92 (22) and the validity of this section has also been well established (22,23).
- Self-Efficacy: The 10-item General Self-Efficacy Scale (GSE) (24) assesses perceived ability to cope with daily hassles and adapt after experiencing a stressful life, using a four-point Likert-type response with overall self-efficacy score from 10 to 40. Strong reliability, stability and construct validity of the scale have been demonstrated (24-27)
- Pain management: The Total Quality Pain Management (TQPM) measures participants' satisfaction with pain management post-operatively. Satisfaction with pain

management uses a 5 point scale from 1 = very dissatisfied to 5 = very satisfied. The TQPM survey has been used and tested in a number of studies (28,29)

- Health service and resource utilisation: This survey was developed for this research and asked how often participants used health care services such as general practitioners, physiotherapists, and support from family/others for assistance with activities of daily living.
- Self-efficacy and relaxation method utilisation: This survey was developed for this research and asked how frequently participants engaged in these activities.

Assessments occurred at 6 time-points and the schedule is outlined in Table 2. Additional data consisted of a range of demographic information of patient's age, gender, marital status, current living arrangements, employment status, Body Mass Index (BMI), current medications (regular and as required), existing co-morbidities, surgical history (i.e. previous hip or knee replacement), current therapies employed for pain management (e.g. herbal medicine, glucosamine and chondroitin) and current practitioners used for pain management (e.g. acupuncture, physiotherapy).

Table 2 around here.

Sample Size

As the aim of this pilot was to test the feasibility and the acceptability of the protocol and interventions, and not to test a hypothesis, power calculations were not a valid consideration for sample size. Several authors provide alternative recommendations for sample sizes appropriate for pilot studies (30-32). Given these recommendations, based on feasibility alone, groups of up to approximately 40 are required to effectively compare groups and to provide initial insights into the performance of the intervention tested, as well as to the suitability of the RCT protocol.

Data analysis

Data analysis was conducted using International Business Machines (IBM) SPSS version 22 (33). An Alpha level of .05 was used for all statistical tests and a 95% confidence interval was used for all estimated values. Prior to analysis, all missing data and improbable values were checked against source data. Multiple imputation (MI) was used to manage data that was missing at random. This is the best known method to obtain accurate estimates of standard errors and p values and to deal with issues of uncertainty for missing data (34). The Intention To Treat (ITT) principle was used for analyses of participants in treatment groups meeting *a priori* inclusion criteria. Whilst ITT is, in its true sense, the analysis of all randomized patients, Fergusson et al. (35) and Chan et al. (36) support removal of participants from the study post randomization if they do not have the disorder or when it is later determined that patients are ineligible for participation, thus it is typically acceptable to remove patients post randomization due to ineligibility factors that are stated *a priori*.

Descriptive statistical analyses were conducted using appropriate measures of spread and locations to answer the feasibility hypotheses. Independent groups t test was used to compare difference in mean scores for pain, anxiety and self-efficacy between the control and the intervention groups (34,37).

RESULTS

Ninety-one patients consented to participate in this study and were randomised. Nine participants were excluded after randomisation as they did not meet *a priori* inclusion criteria ($n = 8$) or revoked consent for participation and data use ($n = 1$) (see Figure 1). Of the remaining 82 participants meeting *a priori* inclusion criteria half were randomized to routine care ($n = 42$; 51.2%) and half to the intervention group of watching a DVD ($n = 40$; 48.8%).

The average age of participants was 67 years (range 36 years to 86 years). More females (n = 52; 63.4%) than males (n = 30; 36.6%) participated in the study. Around two thirds lived with their spouse or partner (67%) while 20 (24.4%) lived alone and 7 (8.5%) shared accommodation. Most were retired (n = 61; 76.3%) while eleven (14%) worked full time, five (6.3%) part-time and two (2.5%) worked on a casual basis. The profile for both groups was similar in terms of age, gender, living arrangements, type of surgery and previous history of surgery. Length of stay in hospital ranged from 3 to 27 days, the median was 5 days (IQR 4-6). Mean BMI was 32.3 (SD 6.46) (which is obese) lowest 22 highest 51. The BMI of participants having knee surgery (n=53) were slightly higher (Mean 34.22; SD 6.46 kg/m²) than those having hip surgery (n = 29; Mean 28.8; SD 4.9 kg/m²).

Figure 1 around here

Feasibility

In relation to recruitment, 55% of screened patients were eligible and of these 81% enrolled (n=91). Exclusions following randomisation was 10% with missing data ranging from 0 – 20.7%. Nineteen percent of participants were lost to follow up in the control group and 20% lost to follow up in DVD group. Protocol adherence was assessed at the completion of the study (see Table 3) and indicated that participation in components of the intervention varied with 6.3% - 78.1% engaged in aspects of goal setting and 12.5% - 68.8% with practising relaxation strategies.

Table 3 around here

Pain, Anxiety, Self-efficacy and Satisfaction with pain management

Both groups reported highest levels of pain prior to surgery. Measures of pain diminished at each subsequent time point to beyond discharge. No significant differences between groups

were noted in pain or anxiety scores reported at any of the time points (see Table 4). Self-efficacy increased for both groups from pre-hospital (T0) to six weeks post discharge (T5) with no significant differences between groups at any time point (see Table 4). Almost all participants (91%) expressed satisfaction with post-operative pain management. Although, five (6.2%) in the routine care group were dissatisfied, no significant difference was found between the two groups ($p = .203$). Levels of health service and resource utilisation at 6 weeks post-discharge were also similar for both groups (Table 5).

Table 4 and 5 around here

DISCUSSION

The lessons learned from this pilot are useful in conceiving and planning a larger trial. Assessment against feasibility objectives suggests that a high proportion of the eligible potential participants were enrolled in the study suggesting the patients had no concerns with participating however there were a significant number of participants excluded after randomization, which is not ideal. Most of these were excluded as their surgery was cancelled or changed. We are not sure how this might be resolved in future enquiries, as research targeting elective surgical patients in this way is dependent on processes used by public hospitals and this is currently not predictable or controlled given current economic imperatives. No studies could be found that address how other researchers have managed this and little information about what a reasonable rate might be for post-randomisation exclusion for not meeting specific a priori inclusion criteria reported in intervention studies on orthopaedic surgical populations. Cancellation of elective orthopaedic surgery however is common with Caesar et al. (38) finding in a retrospective observational single centre study in

Sweden that 39% of 17,625 patients scheduled for surgery over 4 years had their procedure cancelled. The biggest proportion of cancellations (41%) was joint replacement surgeries.

There were too many data collection time points and this impacted negatively on missing data and those lost to follow-up. Many of the patients contacted at the two time points following discharge identified that they felt that they had been assessed too many times. In light of this, we would recommend removing the post-operative day two and the 10 – 14 days post-discharge assessments. To enable participants to be blinded in a larger trial we would recommend giving all participants a DVD. The DVD given to those in the control group could have general pre- and post-operative advice rather than the relaxation and self-efficacy activities provided to participants in the intervention. Although there is debate around placebo effect, it is argued (39) that when a credible placebo exists its use is effective in controlling several risks to internal validity and as such placebos should sensibly be used and these authors provide six questions to consider to guide decisions around placebo versus usual care.

Although this pilot study was not powered to detect a significant change, absence of any trend separating groups in terms of pain, anxiety, and self-efficacy suggest the intervention that was delivered may not be strong enough. However participants allocated to the intervention group were not provided with any strategies to help them develop skills of self-monitoring, and self-appraisal that may have improved adherence and confidence to use relaxation and self-efficacy activities outlined in the DVD. The intervention could therefore be strengthened with the inclusion of strategies to promote a sense of personal efficacy (40) Although we contacted participants by telephone after receiving the DVD regarding any questions they may have had, a more supportive and structured process involving feedback, discussion of problem-solving strategies and action plans may have assisted in promoting

motivation and self-management. This could be achieved through an on-line discussion group to augment DVD activities (although this may limit some participation based on access to and usability of the on-line environment), or a workbook to trigger daily engagement with aspects of the DVD with more structured follow-up telephone calls.

CONCLUSIONS

Hip and knee replacement surgery is a major procedure performed routinely in both public and private Australian hospitals, which can cause considerable pain, anxiety and stress for patients pre- and post-operatively ultimately reducing their levels of satisfaction with nursing care pain management and prolonging their recovery. The results have provided preliminary evidence for the physical and psychological benefits that pre-operative education can provide to patients undergoing hip or knee replacement. Importantly, pre-operative education encourages patients to take on a central role in their recovery promoting sustainable, long-term positive outcomes. While limitations of a feasibility study restrict generalisability of results, lessons learned can guide the decisions informing the development of a larger multi-site trial, which will better elucidate the effects of pre-operative education in hip and knee replacement patients. Such evidence could enable clinical guidelines to be developed regarding the implementation of a specific pre-operative educational intervention for patients undergoing hip or knee replacement surgery that could promote high quality nursing care and improve patient outcomes.

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Figure 1. Flow of Participants

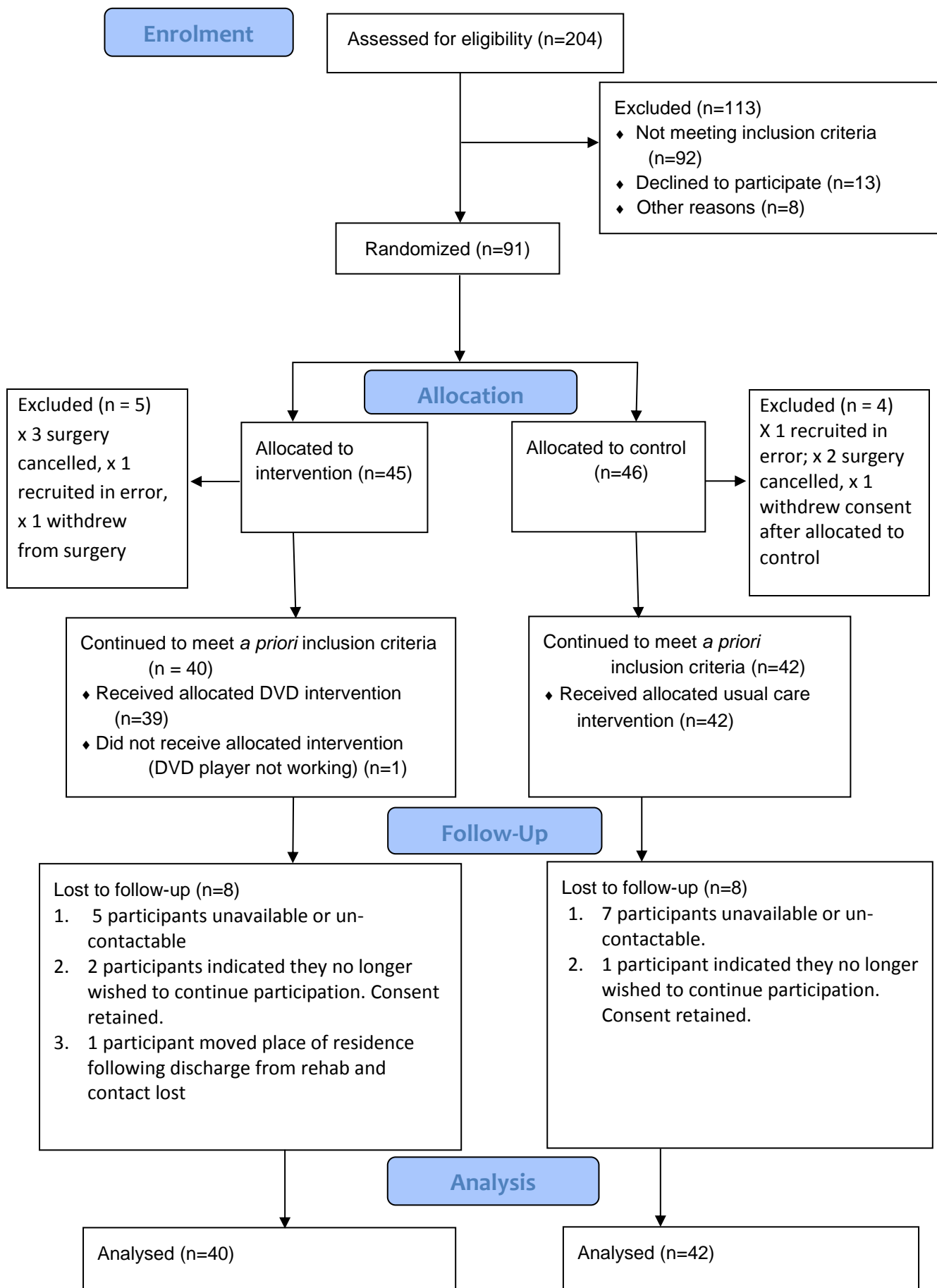


Table 1: Self-efficacy principles and components of the pre-operative education

Self-efficacy based principles	Content of DVD
<ul style="list-style-type: none"> • Behaviour modification. Behavioural contracting used to promote willingness and commitment to behavioural changes and weekly action planning around their relaxation, breathing and imagery exercises. • Improve self confidence. Self-modeling to be used to encourage achievement of goals/activities, foster monitoring and controlling and managing emotions, realign beliefs and evaluate and interpret internal physical states. • Foster problem solving. Strategies to assist in dealing with illness related issues 	<ol style="list-style-type: none"> 1. What is self-efficacy 2. How can I improve my self-efficacy 3. Setting goals 4. Obstacles to achieving goals 5. Strategies for achieving goals 6. Sharing your goals 7. Visualise achieving goals 8. Relaxation techniques <ul style="list-style-type: none"> - mindfulness exercises - deep breathing - prayer - listening to music - guided imagery

Table 2. Schedule of data collection time points and outcomes assessed

T0: Two to six weeks pre-operative	NRS, STAI – Form Y, GSS, and demographics including the Use and Frequency of Pain Medication.
T1: Day of surgery or day prior to surgery (dependant on booked surgery time and participant availability)	NRS, STAI – Form Y, and GSS
T2: Two days after surgery	NRS, STAI – Form Y, and GSS, and use of pain medication from the end-of-bed medication sheets
T3: Morning of discharge/day 4 post-operatively (whichever comes first)	TQPM, and use of pain medication from the end-of-bed medication sheets
T4: 10 – 14 days after discharge	NRS, STAI – Form Y, and GSS, Health Service and Resource Utilisation Survey I, Use and Frequency of Pain Medication
T5: 6 weeks after discharge	NRS, STAI – Form Y, Health Service and Resource Utilisation Survey II, Use and Frequency of Pain Medication, Self-Efficacy and Relaxation Method Utilisation Survey

Table 3: Self-report of protocol adherence - Intervention Group (n = 40)

	n (%)
Goals^a	
Did you set any goals before your surgery?	25 (78.1)
Did you visualise yourself achieving your goals?	25 (78.1)
Did you achieve some or all of your goals	24 (75.0)
Did you talk about your goals with friends or family?	18 (56.3)
Did you identify any obstacles for achieving your goals?	17 (53.1)
Did you use strategies to overcome these obstacles?	17 (53.1)
Did you write your goals down?	2 (6.3)
Relaxation^a	
Did you practice mindfulness (meditation) exercises? ^b	3 (9.7)
Did you practice deep breathing exercises?	14 (43.8)
Did you pray?	8 (25.0)
Did you listen to music?	22 (68.8)
Did you practice guided imagery activities?	4 (12.5)
Did you practice a combination of relaxation activities?	15 (46.9)

^amissing data (n = 8) valid % reported for (n=32 out of 40)

^bmissing data (n = 9) valid % reported for (n=31 out of 40)

Table 4: Pain, STAI & Self-Efficacy measures at time points 0, 1, 2, 4 & 5

Pain		Routine care (n = 42)	DVD Intervention (n = 40)	<i>t</i> (df)	<i>p</i>	95% CI
T0				1.55 (80)	.121	-.25 - 2.13
	Mean	4.62	3.68			
	SD	2.8	2.5			
T1				.509 (80)	.611	-.97- 1.65
	Mean	4.66	4.32			
	SD	3.1	2.8			
T2				-1.258 (80)	.208	-1.9 - .42
	Mean	3.46	4.2			
	SD	2.3	3			
T4				1.667 (80)	.096	-.14 – 1.73
	Mean	2.84	2.05			
	SD	2.2	2			
T5				-.495 (80)	.621	-1.12 - .67
	Mean	1.43	1.66			
	SD	1.9	2.8			
STAI						
T0				1.389 (80)	.165	-1.59 - 9.28
	Mean	40.54	36.69			
	SD	12.40	11.97			
T1				.062 (80)	.950	-4.75 – 5.06
	Mean	38.10	37.95			
	SD	10.79	11.40			
T2				-.393 (80)	.695	-6.08 – 4.05
	Mean	36.68	37.70			
	SD	9.89	12.84			
T4				.562 (80)	.574	-3.38 - 6.09
	Mean	38.26	36.90			
	SD	10.73	10.19			
T5				.438 (80)	.662	-3.89 - 6.12
	Mean	32.67	31.56			
	SD	10.71	11.26			
Self Efficacy						
T0				.129 (80)	.897	-2.14 – 2.44
	Mean	31.98	31.83			
	SD	4.25	6.21			
T1				.038 (80)	.969	-1.94 – 2.02
	Mean	32.57	32.53			
	SD	3.9	4.4			
T2				.157 (80)	.875	-2.01 – 2.59
	Mean	32.34	32.14			
	SD	5.18	5.57			
T4				.647(80)	.517	-1.65 – 3.31
	Mean	33.20	32.38			
	SD	6.6	4.9			

Table 5: Health utilization 6 weeks after hospital discharge

	Routine care ^a (n = 42) n (%)	Frequency range	DVD Intervention ^b (n = 40) n (%)	Frequency range
Seen GP for replaced joint	19 (51.4)	1-6	21 (56.8)	1-5
Seen orthopaedic surgeon	31 (83.8)	1-2	29 (78.4)	1-5
Seen physiotherapist	33 (89.2)	1-15	35 (94.6)	1-9
Visited other health-care practitioner	4 (10.8)	1-6	4 (10.8)	1
Had x-rays of your replaced joint	10 (27)	1	12 (32.4)	1
Had a blood test or other pathology	6 (16.2)	1	6 (16.2)	1-2
Rely on others for help with ADL	19 (51.4)		20(54.1)	
Independent	25(67.6)		22(59.5)	

^aMissing 5 (11.9%)^bMissing 3 (7.5%)