The impact on pain of listening to natural sounds: a randomised controlled trial in patients receiving mechanical ventilation support

Abstract

Background: Non-pharmacological pain management in patients receiving mechanical ventilation support in critical care units is under-investigated. Natural sounds may help reduce the potentially harmful effects of anxiety and pain in hospitalized patients.

Aims: This article examines the effect of pleasant, natural sounds on self-reported pain in patients receiving mechanical ventilation support.

Design: A pragmatic parallel arm randomised controlled trial.

Settings: A general adult ICU of a high turnover teaching hospital, Tehran, Iran.

Participants/Subjects: Sixty patients receiving mechanical ventilation support

Methods: Between Oct 2011 and June 2012, we recruited sixty patients receiving mechanical ventilation support to intervention (n=30), and control arms (n=30) of a pragmatic parallel group randomized controlled trial. Participants in both arms wore headphones for 90 minutes. Those in the intervention arm heard pleasant natural sounds, while those in the control arm heard nothing. Outcome measures included the self-reported Visual Analog Scale (VAS) for pain at baseline, and 30, 60, 90 minutes into the intervention and 30 minutes after the intervention.

Results: All those approached agreed to participate. The trial arms were similar at baseline. In the intervention arm, pain scores fell and were significantly lower than in the control arm at each time point ($p < 0.05$).

Conclusions: Administration of pleasant natural sounds via headphones is a simple, safe, non-pharmacologic nursing intervention that may be used to allay pain for up to 120 minutes in patients receiving mechanical ventilation support.

Key words: mechanical ventilation, nurse, nursing, pain, randomised controlled trial, sounds.

Background

Pain is the fifth vital sign. Its management is central to the care of critically ill patients, but is sometimes misunderstood and poorly executed by nurses (Aslan *et al*. 2003, Summer & Puntillo *et al*. 2001, Shannon & Bucknall 2003, Higgins *et al.* 2004, Gélinas *et al*. 2004, Gélinas *et al*. 2006). Pain is frequently a barrier to caring, haemodynamic stability and healing (Cullen *et al*. 2001).

The need for mechanical ventilation, to maintain adequate oxygenation and protect the airway, is one of the principal reasons for admission to Intensive Care Units (ICUs). Many medical conditions, critical illnesses and critical care procedures, such as intubation, suction, immobilization, repositioning, and invasive monitoring evoke pain (Stanik-Hutt 2003, Kwekkeboom & Herr 2001). Respiratory distress, hypoxemia, and mechanical ventilation, particularly the presence of endotracheal tubes and airway suctioning, may also induce anxiety, in addition to pain and discomfort (Tracy & Chlan 2011, Nelson et al. 2004, Costa et al. 2006, Pun & Dunn 2007). Therefore, provision of adequate care to mechanically ventilated patients usually entails administration of opioids not only to decrease pain and discomfort, but also tominimize the anxiety, tachypnoea and hypertension associated with the unpleasant experiences of endotracheal intubation and mechanical ventilation (McAtamney et al 1998, Yagan *et al*. 2000, Hogarth & Hall 2004) and pre-empt adverse events such as self-extubation, and disconnection of oxygen supplies (Yagan *et al*. 2000).

Pain management in the ICU

Intubated patients are at high risk of poor pain management, due to their inability to communicate verbally (Stanik-Hutt 2003). While a few patients receiving mechanical ventilation experience little pain and may need minimal or no sedation (Patel & Kress 2012), optimal sedation improves patients' tolerance of and compliance with mechanical ventilation (McAtamney et al 1998,). The main goals of pain management in ICUs are to provide adequate analgesia during mechanical ventilation and minimize distress or discomfort, while preserving or improving oxygenation and hemodynamic and respiratory functions (Yagan, White, and Staab 2000, Beaulieu-Boire *et al*. 2013). If pain is not detected or is not relieved efficiently, patient recovery may be delayed or hemodynamic, psychological, and behavioural parameters disturbed

(Reimer-Kent 2003, Pardo *et al*. 2006). Pain also hinders mobilization or chest physiotherapy leading to complications that may lengthen hospital stay and increase costs (Kwekkebbom 2001, Jeitziner *et al*. 2006).

Pharmacological pain management confers both benefits and harms. Although sedation and analgesia have improved significantly in recent years, nurses are often concerned that adverse drug reactions may compromise the patient (Tobias & Leder, 2011). Analgesics are not free of adverse effects, such as sedation, emesis, anxiety, agitation or delirium (Arbour 2000, Jordan 2008), prolongation of mechanical ventilation or hospital stay and increased healthcare costs (Bobek *et al*. 2001, Egerod 2002). In ICU patients, both inadequate and excessive sedation are potentially harmful (Hogarth &Hall 2004). Inadequate sedation may increase the risks of adverse events, such as accidental self-extubation, with subsequent acute respiratory insufficiency due to upper airway collapse, loss of venous catheters, and injury to self or others (Walder & Tramèr 2004, Hogarth &Hall 2004). However, excessive sedation can lead to respiratory depression, hypotension and bradycardia or prolonged duration of mechanical ventilation (Feeley & Gardner 2006).

Non-pharmacologic interventions for pain management should not be underestimated as they can help decrease patients' pain and subsequent anxiety and reduce the need for opioids or non-steroidal anti-inflammatories (Summer & Puntillo 2001, Stanik-Hutt 2003). Non-pharmacologic pain relief, such as music therapy, alleviates patients' pain and anxiety (Vaajoki *et al*. 2011). Listening to relaxing music: reduces biochemical markers of stress (Lai & Li, 2011), depression and disability (Siedliecki & Good 2006); promotes sleep and relaxation (Su, 2012), quality of life (Lee, 2011), comfort and analgesia (Li *et al*, 2013); reduces heart rate, blood pressure, body temperature, respiration rate and pain (Deng et al. 2005, Korczak *et al*. 2013); stimulates EEG alpha waves, which are related to endorphin release, relaxation, pain relief, and lowered blood pressure, heart rate (Demir, 2012).

Aims

The effect of listening to natural sounds on agitation, anxiety, and vital signs has been described in patients receiving mechanical ventilation (Saadatmand *et al*. 2012). However, to our knowledge, no previous studies have reported on changes in self-reported pain associated with listening to pleasant natural sounds in mechanically ventilated patients. The aim of this

study was to evaluate the effectiveness of a pleasant natural sounds listening intervention on self-reported pain in patients receiving mechanical ventilation in an ICU. It was hypothesised that the pleasant listening intervention in sedated, mechanically ventilated patients would lead to a modification in their level of pain, as measured on a Visual Analog Scale (VAS).

Methods

Design

This pragmatic parallel arm randomized placebo controlled trial was conducted in a single intensive care unit in Tehran between Oct 2011 and June 2012 (Fig. 1). To calculate the sample size needed in this context, a small pre-pilot study was undertaken (Thabane 2004). In this pre-pilot work, the mean changes in pain scores in the intervention and control arms were 0.6 [SD 0.55] and 0.00 [SD 0.71] at 30 and 60 minutes. A sample size of 60 participants (30 in each arm) was calculated to be sufficient to detect this difference with 90% power and 5% significance (Uitenbroek 1997).

When a decision to initiate mechanical ventilation had been taken, relatives of 60 patients were approached by the lead authors regarding participation. When signed consent had been given, the study was explained to patients. Patients' GCS was ≥ 9. Therefore, they were asked to indicate their assent, by non-verbal communication, to wearing headphones for 90 minutes and responding to researchers' questions over 120 minutes. Participants were free to indicate that they wished to remove the headphones at any time.

Participants were randomly assigned to the intervention (n=30), and control arms (n=30) by flipping a coin (Higgins *et al*. 2011). All those collecting data in the ICU, and the data analysts were blinded to the allocation. Participants in the intervention arm heard pleasant natural sounds through headphones. Those in the control group put on headphones, but heard nothing. Therefore, unavoidably, participants were aware of their allocation.

Participants and setting

The study was carried out in a general adult ICU of a high turnover teaching hospital, Tehran, Iran. The hospital had 120 beds including 10 beds in the ICU ward, admitting 6-7 patients each

week. Relatives of all patients meeting the inclusion criteria between October 2011 and June 2012 were approached.

Inclusion criteria were

- Mechanically ventilated adults hospitalized in the ICU;
- Age >17 years (no upper age limit)
- Being mechanically ventilated for ≥ 48 h;
- Being alert enough to participate;
- Glasgow Coma Scores (GCS) ≥ 9, and therefore able to communicate;
- Hemodynamically stable;
- Able to hear, understand and respond to Farsi;

Exclusion criteria were:

- Receiving continuous intravenous sedation and/or analgesia;
- Quadriplegia and skull injury that may affect listening to sounds and using headphones;
- Not mentally competent and unable to communicate by holding up fingers in response to researcher's questions during data collection;
- Receiving resuscitation;
- Psychiatric or neurological illnesses;
- Receiving inotropic agents, neuromuscular blockade, or anti-hypertensive drugs;
- Addiction to recreational drugs or alcohol;
- Facial signs of being scared or anxious.

Participants were not receiving continuous infusions of sedative medicines, but bolus doses were available to all patients, as needed: fentanyl 0.5 μg/kg IV prn midazolam 2-5mg prn. Administration of a bolus dose during the two hours of the trial would necessitate exclusion from the trial.

Measures

The demographic and clinical characteristics of the participants were obtained from participants' medical files. Age, sex, primary diagnoses, previous ICU-admissions, type of admission, type of room, severity of illness, number of days receiving mechanical ventilation, affecting mental state in the past 24 hours, length of stay in the ICU, and GCS were recorded.

The effect of listening to pleasant natural sounds on self-reported pain was measured using a Visual Analog Scale (VAS). The VAS is valid in critically ill patients, even when delirious, as long as patients can communicate by speaking or pointing (Nelson *et al*. 2004, Costa *et al*. 2006). This scale uses ten equal divisions marked 0 to 10, anchored by the descriptors “no pain” and “pain as bad as it could be” (Pun & Dunn 2007). A change of 9 mm (95% CI 6-13) is usually considered significant (Kelly 1998).

Intubated and ventilator-dependent patients, who are awake and oriented but unable to speak, can point to a number to rate the level of their pain (McCaffrey & Pasero 1999). More ICU patients are able to respond to this scale than to a 6-item pain scale or a numeric analogue pain scale. The VAS may be considered a continuous measurement scale (van Dijk *et al*. 2012). Accurate administration requires: a clearly readable scale with descriptors, the participant’s understanding and co-operation, and adequate response time (van Dijk *et al*. 2012, Ahlers *et al*. 2008). The VAS is suitable for obtaining self-reports on the status of pain from ventilator-dependent patients for both routine clinical and research purposes (Ahlers *et al*. 2008, Aissaoui *et al*. 2005, Hamill-Ruth & Marohn 1999).

Intervention

The intervention took place during the afternoon or early evening, because these times interfered minimally with patients' routine care and visiting hours. The intervention entailed wearing foam-lined disposable headphones for 90 min. Participants in the intervention arm heard natural sounds; those in the control arm heard nothing. Headphones minimized extraneous environmental noises and stimuli.

After allocation, participants in the intervention arm selected their preferred sounds from the investigator's CD collection: birds’ song, soothing rain, flowing rivers or streams, waterfalls, or walking through a forest. The researcher helped patients to wear the headphones correctly, if required. Participants’ hearing thresholds were tested. The mean sound pressure level was set to 25–50 dB. Participants were asked to follow the flow of sounds during the intervention. The volume of the sounds was adjusted according to the participants’ preferences; when the participant was not able to express a preference, the volume was set by the attending nurse, based on the volume of sound required to communicate with the patients. .

Unless contraindicated, the lights in the participants' rooms were dimmed, curtains closed, and the door partially shut to minimize any unnecessary disturbance.

Pain scores were recorded by the investigator at baseline and 30 minute intervals during the intervention and for 30 minutes afterwards. The investigator was unaware of the trial allocation, to minimise bias in data collection. Each participant completed five sets of measurements.

Ethical approval

The Shahed university ethics committee approved the study protocol. The researchers gained permission to access participants' records and to implement the intervention. Participants were assured of confidentiality and anonymity. Names and study identification numbers were known only to the lead investigator. Participants were told that they could withdraw at any time throughout the study and that not participating would have no detrimental effects on treatments and services received. Ability to communicate and consent was assessed by the GCS. Each participant was provided with a personal set of disposable headphones for sole use to eliminate any risks of transmission of infection. Measurement of level of pain was an integral aspect of routine ICU care; consequently no additional respondent burden was placed on participants. Even so, the research team was instructed to stop the intervention, if the participant's condition deteriorated during the intervention. Deterioration was defined as an increase of heart rate (> 140 beats/minute) or respiratory rate (>35 breathings/minute), blood pressure (systolic blood pressure >180 mmHg or <90 mmHg).

Data analysis

Data were entered into the IBM Statistical Package for the Social Sciences (SPSS) data analysis program (version 16.0 for Windows). The Kolmogorov–Smirnov test was used to test the distribution of variables.

Descriptive analyses were used to summarize the data. Paired t-tests were used to compare means between baseline and sequential intervals. Repeated measures ANOVA (with Mauchly's test of sphericity) was used to examine mean pain scores across the intervention periods, measured at 30-min intervals, within and between arms.

Results

Sample characteristics

All 60 patients approached consented to participate. Nurses needed to adjust the volume of sound for 2 intervention patients and 3 control patients. All participants completed the trial, and no sedation or analgesia was administered during the trial (Figure 1). Interval data were normally distributed. Participants had received mechanical ventilation support for between two and thirteen days (mean 8.67; SD 3.25). All participants were intubated with oral endotracheal tubes and were undergoing Continuous Positive Airways Pressure or Synchronised Intermittent Mandatory Ventilation. The oxygen concentration administered ranged from 30% to 60%. Primary diagnoses of the participants included: chronic obstructive pulmonary disease (COPD), pneumonia, chest trauma, pancreatitis, poisoning, and sepsis. (Table 1)

Intensity of pain

Pain scores in the intervention arm participants fell during the intervention (Figure 2), but no significant difference from baseline was seen 30 minutes after discontinuation of the intervention (Table 2). The pain scores of the two arms were similar at baseline, but not in subsequent measurements (Table 3).

Using repeated measures ANOVA, a significant time trend was found in the intervention arm, and for the interaction between time and intervention on pain scores. The interaction between time and intervention was statistically significant (Wilk's lambda 0.849, F (4.0, 55.0) = 2.45, p = 0. 06, partial eta squared 0.15).

No risks associated with listening to pleasant natural sounds as a nursing intervention were identified.

Discussion

Our natural sounds listening intervention relieved self-reported pain in sedated, mechanically ventilated patients receiving intensive care. The changes of 7.7 to 13 mm in the VAS are likely to be clinically significant (Kelly 1998). This finding is pertinent to the ultimate goals of nursing interventions - to enhance patients' comfort and safety (Kolcaba, 2003) and reduce pain.

In critical care, the subjective sensations of pain and anxiety are often interrelated, and both are alleviated by opiates, implying a shared physiological aetiology (Frazier *et al*. 2002, 2003). Analgesia relieves pain, agitation, restlessness and further work is needed to optimize pain-induced agitation (Ocañez et al. 2010, Husebo et al. 2013, Barr et al. 2013). Pain, anxiety and agitation are potential stressors for critically ill patients (Jones et al. 2001), and the similarity between pain scores and agitation scores reported elsewhere (Saadatmand et al 2012) may reflect responses to common stressors. Similarly, pain and discomfort are closely correlated (Aslan et al. 2003, Puntillo et al. 2010), and alleviation of pain promotes comfort (McKinley et al. 2004).

Findings from this study reflect those of others, suggesting that pleasurable natural environments can facilitate recovery from surgery, and increase perceptions of quality of life (Ogunseitan 2005). Patients who have undergone abdominal surgery report that mean pain scores significantly decrease following music therapy on the first and second postoperative days (Vaajoki *et al*. 2011). In music therapy, patients may need time to accustom themselves to music (Lee et al. 2005). However, our participants experienced benefit within 30 minutes.

In recent years, the application of pleasant natural sounds as complementary therapy has increased and this may reflect the growing interest in complementary therapies. Natural sounds listening interventions have several health benefits, including: reduced sleep disturbance in older adults (Morita et al. 2001), enhanced well-being in patients with mental health disorders (Pryor et al. 2006), improved attention and mental fatigue in US women diagnosed with breast cancer (Cimprich and Ronis 2003), reduced agitation and anxiety (Saadatmand et al 2012), and enhanced mental activity (Hansen-Ketchum & Halpenny, 2011).

In contrast to music therapy provided by specially trained and board certified music therapists, the pleasant natural sounds listening intervention as a non-pharmacologic, self-administered (or minimal assistance) intervention may serve as a means of distraction. This type of intervention is designed to be an easy, simple, and safe method of empowering patients to relieve pain and anxiety as and when needed.

Complementary, adjunct and patient-directed approaches, such as ours, allow patients to manage their symptoms even when a healthcare worker is not available. This intervention appears ideal for patients receiving mechanical ventilation in ICUs, because it requires limited effort, and is simple and self-administered. Our trial indicates that our cheap listening intervention is safe and

can be applied by clinical nurses without special training to allay pain without risking unwanted adverse effects. . The element of choice allowed patients to maintain a sense of control.

Implications for nursing practice

While mechanical ventilation in itself is a life-saving treatment, it is physiologically and psychologically stressful for patients. Nurses usually administer pharmacological sedatives and analgesics to relieve pain and promote comfort for patients undergoing mechanical ventilation. Pleasant natural sounds offer a feasible adjunct to pharmacological analgesia during mechanical ventilation. Application of these findings has the potential to improve pain management for sedated patients receiving mechanical ventilation support. Music-therapy can be considered to be complementary to medication-therapy for reliving patient's pain and reducing the frequency of their applications in the ICU ward. Nurses are encouraged to ensure that non-pharmacological strategies for pain management, including listening interventions, are available to sedated patients receiving mechanical ventilation.

Conclusion

Listening to natural sounds is an effective, feasible, safe, and inexpensive intervention to reduce pain for patients undergoing mechanical ventilation when administered over 90 minutes. The changes on the pain scores were small, but of clinical significance (Kelly 1998) and warrant further investigation.

Limitations and suggestions for future studies

Conducting this study in only one ICU and with participants aged ≥ 18 years old detracts from the generalization of our findings. Our trial needs to be replicated in other settings and age groups. It is suggested that this intervention is repeated with four trial arms: the extra arms would be 1) the intervention without wearing headphones and 2) neither intervention nor headphones. This would explore any calming effect of the pleasant natural sounds despite background noises. Pain ratings slightly increased in participants wearing headphones and hearing nothing; the four arm trial would examine the possible negative effect of excluding background noise. Although

we collected data during the most convenient times for the participant and staff, this did not necessarily eliminate distractions from the clinical staff. It is important to allow healthcare providers to perform care as necessary; therefore distractions will never be completely avoided. Other variables, such as underlying medical conditions, that may have influenced self-reported pain should also be considered. These extraneous variables may influence pain ratings, and a larger sample is needed to explore such confounding. The intervention was ineffective after discontinuation, and we have no information on longer-term interventions, which may reduce the need for administration of analgesia. Opioids and sedatives have potential adverse effects, and may prolong hospitalisation and mechanical ventilation (Bobek et al 2001, Egerod 2002, Feeley & Gardner 2006). Therefore, we should like to examine the impact of longer-term listening interventions, and their potential to reduce administration of sedatives and duration of ICU and hospital stay.

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Table 1. Participants' Demographic Characteristics

Characteristics	Total (n = 60)	Intervention arm (n = 30)	Control arm (n = 30)	**Statistical tests**
	Mean ± SD		Mean ± SD	
Age				
Mean ± SD	43.91 ± 16.14	41.23 ± 15.31	46.60 ± 16.76	*t*=1.30 *df* =58 *P*=0.23
Gender n (%)				
Male	34(56.67%)	14(%46.66)	20(%66.67)	x^2 =0.19 *df* =1 *P*=0.12
Female	26(43.33%)	16(%53.34)	10(%33.33)	

Educational level, n (%)				
Illiterate	16(%26.66)	9(%56.20)	7(%43.80)	x^2 =2.55 *df* =2 *P*=0.28
Primary	24(%40)	9(%37.50)	15(%62.50)	
Secondary	10(%16.67)	6(%30.00)	4(%20.00)	
High/undergraduate school	10(%16.67)	6(%30.00)	4(%20.00)	
Marital status n (%)				
Single	18(%30)	11(%61.10)	7(%38.90)	x^2 =1.27 *df* =1 *P*=0.26
Married	42(%70)	19(%45.20)	23(%54.80)	
Underlying Medical Condition				
Trauma	5(%8.33)	4(%13.4)	1(%3.3)	
Pancreatitis	8(%13.33)	2(%6.7)	6(%20)	
Poisoning	12(%20.0)	6(%20)	6(%20)	x^2 =1.14 *df* =5 *P*=0.96
Asthma	14(%23.34)	8(%26.6)	6(%20)	
Pneumonia	18(%30.0)	8(%26.6)	10(%33.4)	
Sepsis	3(%5.0)	2(%6.7)	1(%3.3)	

Table 2. Changes in pain scores from baseline at 30, 60, 90 and 120 minutes in the intervention arm (n=30)

Pain		Mean Difference in visual analogue pain score from baseline	Std. Error	95% Confidence interval for difference in means		*P*
				Lower bound	Upper bound	
Baseline compared with:	Time 30 minutes	0.23*	0.10	0.04	0.42	0.02
	Time 60 minutes	0.23*	0.10	0.03	0.43	0.02
	Time 90 minutes	0.30*	0.10	0.09	0.51	0.01
	Time 120 minutes	0.13	0.09	-0.04	0.31	0.13

*. The mean difference is significant at the .05 level.

Tables 3. Pain scores baseline to 120 minutes in both trial arms

Groups / Variable	**Experiment group (n = 30)**	**Control group (n = 30)**	**Mean Difference**	**t**
	Mean ± SD	**Mean ± SD**		***p* Value**
Baseline pain	4.60 ± 1.13	4.43 ± 1.13	-017±0.29	t= - 0.57 *p* =0. 57 *df* =58
Pain 30 minutes into the intervention	3.90 ± 1.02	4.66 ± 0.95	0.77±0.26	t=2.99 *p* =0.004 *df* =58
Pain 60 minutes into the intervention	3.63 ± 0.99	4.93 ± 0.94	1.30±0.25	t=5.18 *p* =0.001 *df* =58
Pain 90 minutes into the intervention	3.60 ± 0.89	4.83 ± 0.74	1.23±0.21	t=5.80 *p* =0.001 *df* =58
Pain 30 minutes after the intervention stopped	3.93 ± 0.94	4.83 ± 0.91	0.90±0.24	t=3.75 *p* =0.001 *df* =58

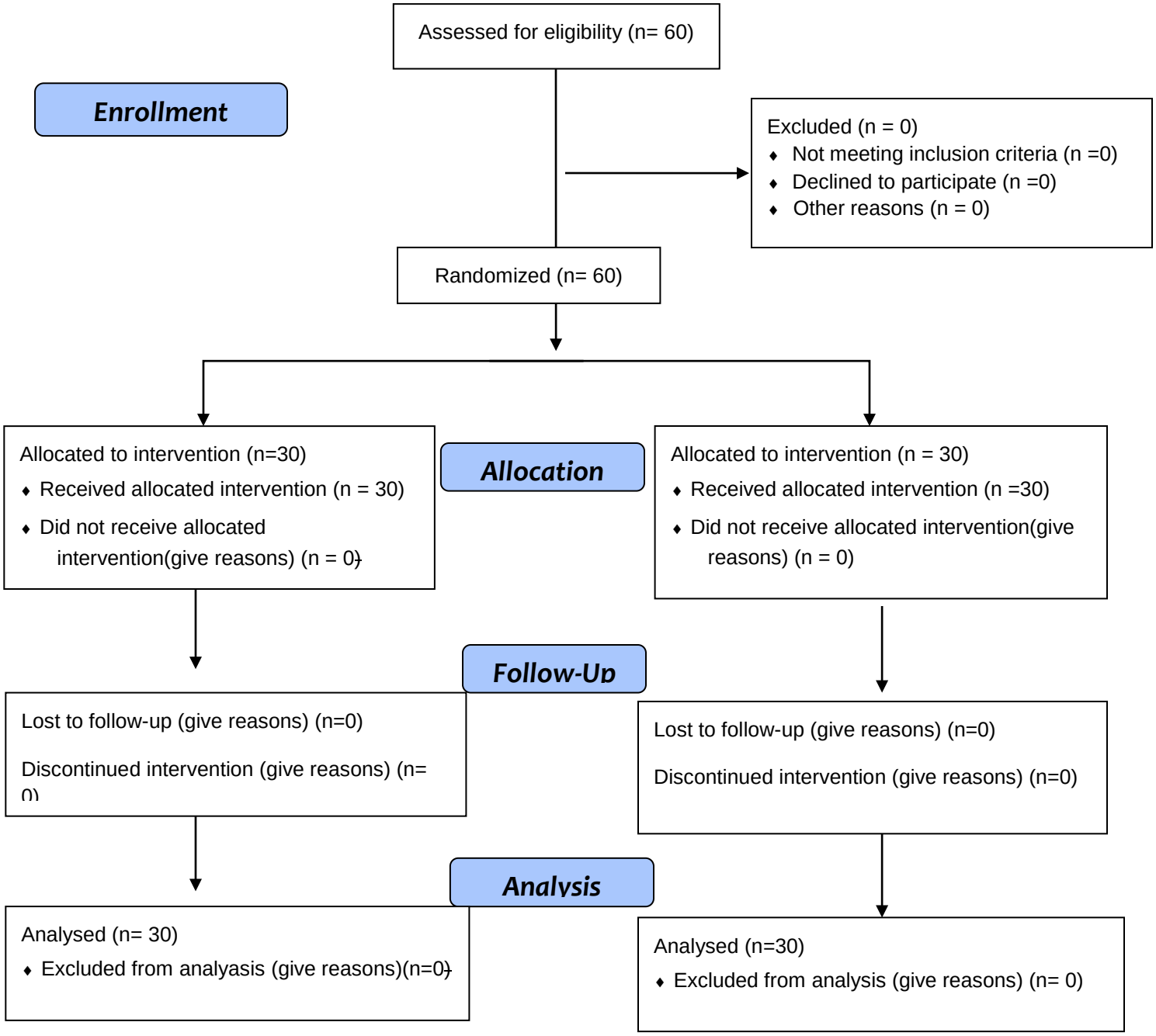

Figure 1. Trial Flow Diagram

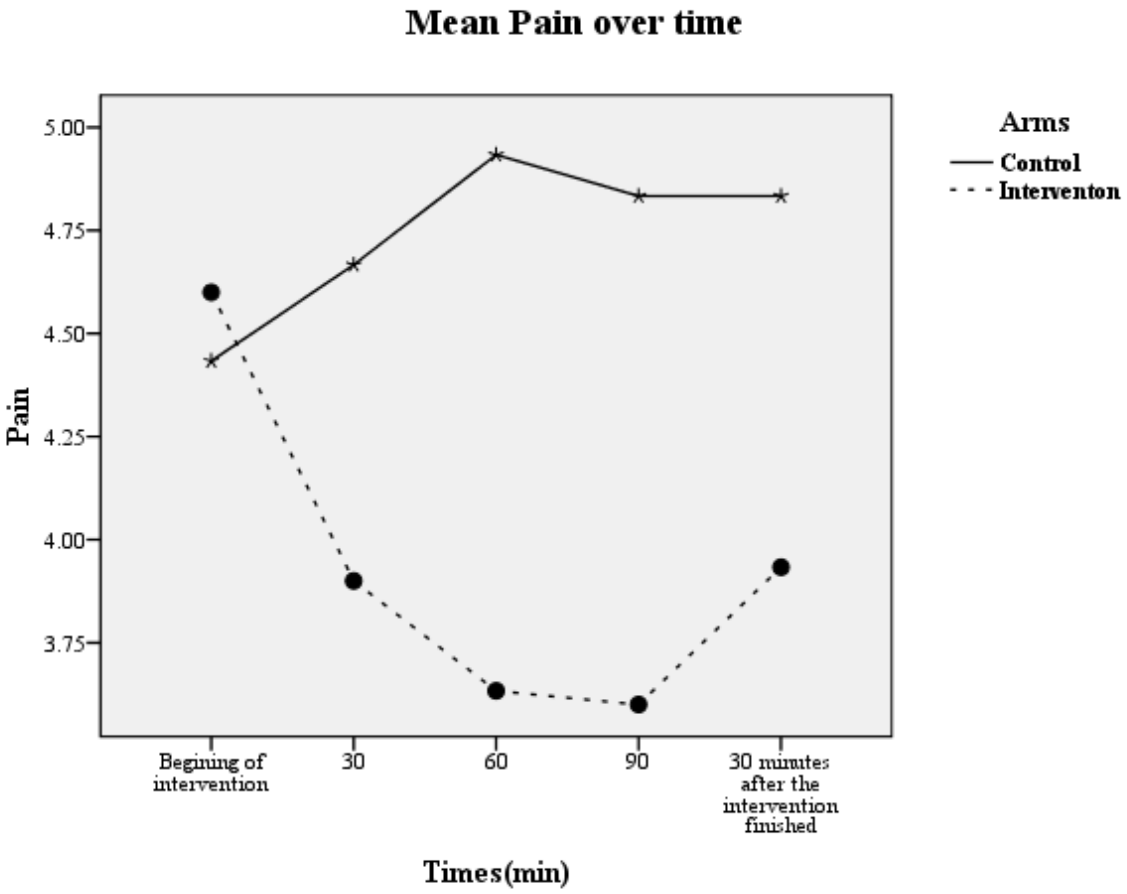

Fig 2. Mean Pain VAS scores at each time point