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Evaluating pain reduction interventions during blood donation: A randomised controlled trial

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Abstract

Background: Blood shortages for transfusions are often associated with potential donors' fear of pain from large-bore needles, which may deter them from donating.

Objective: This study evaluated the effectiveness and satisfaction of topical anaesthetics, cooling sprays, and audiovisual distractions in reducing needle-induced pain during blood donation.

Methods: This randomised controlled study (August 2023 – January 2024) investigated methods to alleviate pain during blood donation and was registered with the Thai Clinical Trials Registry (TCTR20230324007). Forty-eight eligible participants were recruited via convenience sampling and randomly assigned to one of four groups: control, topical anaesthetic, cooling spray, or audiovisual distraction. All procedures involved 16-gauge needle insertion. Pain was assessed immediately after needle insertion and blood collection using a 10-point numeric rating scale, while satisfaction was measured using a 4-point Likert scale. Participants met standard blood donation eligibility criteria. Data were analysed using descriptive statistics, one-way ANOVA, and multivariate linear regression to determine intervention effects on pain scores.

Results: The final analysis incorporated all 48 subjects, with 12 individuals in each of the four groups. The mean age of participants was 30.73 years (SD = 11.83), and females comprised the majority of the sample (54.16%). Mean pain scores during needle insertion were 3.25 (SD = 1.21), 2.83 (SD = 1.11), 2.67 (SD = 1.61), and 3.00 (SD = 2.22) (p = 0.960) for Groups A through D, respectively. Compared with the control, regression analyses of audiovisual distraction showed small differences that were not statistically significant (e.g., audiovisual distraction: β = 0.78, 95% CI 1.01 to 2.58). During blood withdrawal, mean pain scores were 1.67 (SD = 1.19), 1.67 (SD = 0.83), 1.58 (SD = 1.51), and 1.25 (SD = 0.62) (p = 0.892). Similarly, regression analyses showed no significant intervention effects (audiovisual distraction vs. control: β = 0.79, 95% CI 0.50 to 2.08). Multivariate analyses revealed no significant effects of the intervention methods, demographic factors, prior blood procedure experience, or body mass index on pain scores.

Conclusion: Although pain-reduction interventions showed a trend toward lowering pain, the differences were not statistically significant. Given the variability in pain perception, larger multicentre studies are needed to confirm these findings.

Keywords: Blood donation, pain assessment, blood transfusion, pre-venipuncture pain, needle-induced pain

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INTRODUCTION

Blood transfusions are essential medical procedures used to treat various conditions, including acute and chronic anaemia, thrombocytopenia, and coagulopathy [1]. However, these life-saving interventions rely on an initial blood donation procedure. In Thailand, the National Transfusion Medicine Services are organised by the Thai Red Cross Society, which oversees the National Blood Centre and provincial branches [2]. In 2022, individuals donated approximately 2.5 million units of blood, averaging 200,000 units monthly. However, blood shortages persist, as donations have remained below the target range of 40 to 50 units per 1,000 person-years in recent years. Factors accountable for this observation include inadequate donor recruitment and a low rate of repeat donors [2]. Barriers to blood donation include limited privacy during pre-donation screening, concerns about the potential sale of donated blood, fear of weakness

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after donation, inconvenient clinic locations, and anxiety related to pain [3-5]. To address these concerns, blood collection staff are required to provide clear information about the safety of blood donation and its life-saving impact, foster a welcoming environment, and implement pain-reduction strategies [6].

Pain perception can be understood by both physiological and psychological mechanisms. Pre-venipuncture pain management techniques include vapocoolants, active distraction, vibration, cough tricks, and local anaesthetic creams [7-11]. Specificity Theory explains that pain can be blocked or managed by blocking specific mechanistic pathways responsible for pain response, while Gate Control Theory suggests that competing sensory input or attention distraction can block pain signals to the brain or constrain pain perception. Both pain theories help to emphasise the need to manage physical and psychological components of pain [12,13]. Similarly, pain management strategies in blood donation that inform best practice should include techniques that address both nociceptive pathways and cognitive–emotion processes.

In a previous research, we assessed the impact of three pain management techniques—topical anaesthetics, cooling spray, and audiovisual distraction—on alleviating needle-induced pain during blood sampling with a 21-gauge needle [14]. We found statistically significant reductions in pain across all interventions, with the greatest reductions observed with topical anaesthetics. However, the majority of studies conducted by other investigators examined lower-gauge needles or different clinical populations (e.g., pediatric or hemodialysis patients), whereas blood donation specifically uses 16-gauge needles and usually involves longer procedures [7-11]. Furthermore, few trials have compared interventions that operate using different mechanisms (local anaesthesia, counter-irritation, cognitive distraction) within a single blood donation context [15,16]. Thus, the current study aimed to implement, evaluate, and compare the clinical efficacy and patient satisfaction with a topical anaesthetic, cooling spray, and audiovisual distraction to reduce needle pain during blood donation.

Whilst providing evidence-based comparisons of varied theoretical pain modulation approaches in a prospective randomised controlled trial, this study also provides valuable insights on how to best prioritise among different theoretical approaches to enhance donor comfort and retention in transfusion services.

MATERIALS AND METHODS

Participants

Participants were recruited through announcements posted in the blood donation room at Walailak University Hospital, inviting volunteers to join the study. The study employed a randomised controlled trial design, conducted from August 2023 to January 2024. Participants had to fulfil the standard blood donation eligibility criteria, including being aged ≥18 years, weighing >45 kg, and meeting the Thai Red Cross health requirements for blood donation. Health screening included assessment of vital signs (temperature, pulse, and blood pressure) and haemoglobin levels (≥13 g/dL in men and ≥12.5 g/dL in women), and participants with any acute illness at screening were excluded. Participants were excluded if they were taking antibiotics, nonsteroidal anti-inflammatory drugs, or hormonal therapy, as well as those who consumed alcohol, were pregnant or breastfeeding, or practised unsafe sex. Individuals aged 18 to 40 years were eligible to participate in the study if they were able to provide informed consent and were proficient in reading, writing, and understanding Thai and English. Individuals were excluded if they had cognitive impairments, difficulty rating pain scores, required more than two needle insertion attempts, had a body mass index (BMI) greater than 30 kg/m², faced difficulties with blood collection, experienced adverse reactions to topical anesthesia, had significant audiovisual impairments affecting their quality of life, or were diagnosed with mental health disorders, peripheral arterial disease, peripheral neuropathy, or cold sensitivity. This study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines to ensure comprehensive and transparent reporting of the randomised controlled trial. The participant flowchart is presented in Figure 1.

Study design and randomisation

Baseline information on the participants, including age, sex, height, weight, and vital signs, was collected through structured questionnaires and medical records. Participants were assigned to one of four groups by simple randomisation, generated using Excel 2019 (Microsoft, USA), consistent with the approach used in our previous study [14]. The groups included a control group and three intervention groups, which received either a topical anaesthetic, a cooling spray, or audiovisual distraction.

Intervention procedures

With the exception of the control group, the assigned intervention was administered before needle insertion. Participants in the topical anaesthetic group received a 5% emulsion containing equal parts of 2.5% lidocaine and 2.5% prilocaine applied to a 10-square-centimetre area at the injection site 1 hour before venipuncture. The cooling spray group received a 5-second application of a 0.5% menthol spray, administered at a perpendicular angle to the needle insertion site from a distance of 15 centimetres away. Following a 10-second evaporation period and skin disinfection, vascular access was initiated. During venipuncture, subjects in the audiovisual distraction group viewed a video clip (https://youtu.be/vJG698U2Mvo) featuring a selective attention test in which they were instructed to count the passes made by white-shirted players among six individuals passing two basketballs. As participants reclined on the blood donor couch, an elastic tourniquet was positioned 5 cm above the antecubital fossa. Before the procedure, all participants were informed that needle insertion using a 16-gauge needle could cause

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moderate to severe pain [15-18]. To maintain consistency during the study, a single medical professional was responsible for sterilising the needle insertion sites with 70% alcohol pads, ensuring they dried before performing venipuncture with a 16-gauge needle. Blood collection involved withdrawing 350 - 450 mL from the antecubital vein. For donors with a body weight of 45 – 50 kg, 350 mL of blood was collected, while those weighing over 50 kg provided 450 mL.

Outcome measures

Pain was assessed using the 10-point Numeric Rating Scale (NRS)- a validated and reliable tool widely used to measure acute procedural pain. Scores ranged from 0 (no pain) to 10 (worst imaginable pain), with higher scores indicating greater pain intensity [19]. The NRS has demonstrated strong psychometric properties, including high test-retest reliability and responsiveness to changes in clinical pain. Participant satisfaction was assessed using a 4-point Likert scale ranging from 0 (extremely dissatisfied) to 3 (highly satisfied). This scale captured the subjective experience of the blood donation process.

Data analysis

The sample size was determined using effect sizes reported in a prior study [20]. Initial calculations suggested that nine participants per group would provide 90% power to identify an effect size of 2.1 when comparing intervention groups to the control group, using a two-sample t-test with a two-tailed significance level of 0.01. To account for an anticipated 25% dropout rate, the target enrollment per group was increased to 12, resulting in a planned total sample size of 48.

The data were analysed using descriptive statistics, including counts, percentages, means, medians, standard deviations (SD), and interquartile ranges (IQR), depending on the distribution of the data. Normality was assessed for all continuous variables (see Supplementary Table 1). Categorical variables were compared using Fisher's exact test, while continuous variables were analysed using the Kruskal–Wallis test, one-way ANOVA, or independent t-tests, depending on their distribution. A p-value of less than 0.05 was considered statistically significant. In addition to p-values, effect sizes and 95% confidence intervals were calculated to provide estimates of the magnitude and precision of intervention effects.

To evaluate the effects of the interventions on pain scores while adjusting for potential confounders, multivariate linear regression models were employed. Two separate models were constructed: Model A, which assessed pain scores during needle insertion, and Model B, which evaluated pain scores during blood withdrawal. These models included key covariates such as procedural methods (intervention groups), demographic factors (age, sex, BMI), educational level, type of punctured vessel, presence of a same-sex environment, and history of prior blood sampling or donation. The regression coefficients and their 95% confidence intervals (CI) were reported to quantify the impact of each predictor variable. All statistical analyses were performed using SPSS version 17 (IBM Corp., Armonk, NY, USA).

RESULTS

Demographic characteristics

A total of 50 participants were recruited; however, 2 were excluded for failing to meet the required weight criteria, leaving 48 participants who completed the study and were included in the final analysis. The participants had a mean age of 30.73 years (SD 11.83), with 54.16% of the participants being females. The baseline characteristics of the participants in the four groups are shown in Table 1. There were no significant differences across the groups in terms of sex ($p = 0.254$), age ($p = 0.073$), educational level ($p = 0.547$), or dominant hand ($p = 0.307$). However, a significant difference in BMI was observed, with participants in Group B having a higher average BMI (27.2 kg/m², SD = 4) than those in the other groups ($p = 0.014$). Additionally, significant differences were found in the type of punctured vessel ($p = 0.016$). In Group A, all participants underwent median vein puncture (100%), whereas Group D had a higher proportion of basilic vein punctures (8.3%). Furthermore, the history of blood donation varied significantly among the groups ($p = 0.010$), with Group D having the highest proportion of participants who had donated blood more than 10 times (50.0%).

Pain and satisfaction

As shown in Table 2, mean pain scores at 95% confidence intervals during needle insertion and blood withdrawal were generally mild across all groups, with slightly lower scores observed during blood withdrawal. Satisfaction levels were uniformly high, with all participants reporting the highest satisfaction rating. There were no significant differences in pain scores during needle insertion, blood withdrawal, and satisfaction levels among the groups (Table 3). Regression analyses confirmed the absence of statistically significant effects; the audiovisual distraction group compared with the control showed $\beta = 0.78$ (95% CI 1.01 to 2.58) for needle insertion pain and $\beta = 0.79$ (95% CI 0.50 to 2.08) for blood withdrawal pain. No severe adverse events were observed during the blood donation process or the intervention throughout the study.

Predictive models of pain scores during needle insertion and blood withdrawal

Multivariate linear regression analyses were performed to evaluate factors associated with pain scores during needle insertion (Model A) and blood withdrawal (Model B), as summarised in Tables 4 and 5. None of the intervention groups (Groups B – D) demonstrated statistically significant differences in pain scores compared with the control group in either model (Model A: $p = 0.39 – 0.72$; Model B: $p = 0.23 – 0.62$). Age and sex were not significantly associated with pain scores in either model (Model A: age, $p = 0.224$; sex, $p = 0.71$; Model B: age, $p = 0.79$; sex, $p = 0.92$). Body

Table 1. Participant demographics

Parameters		Group A	Group B	Group C	Group D	p-value
Sex, n (%)	Men	8 (66.7)	6 (50.0)	3 (25.0)	5 (41.7)	0.254
	Women	4 (33.3)	6 (50.0)	9 (25.0)	7 (58.3)	
Age, years (SD)		32.2 (13.6)	29 (13.4)	25.5 (8.9)	36.3(9.3)	0.073
BMI, kg/m^2 (SD)		22.7 (2.8)	27.2 (4.0)	23.8 (4.9)	26.6 (4.5)	0.014
Education, n (%)	Primary education	0 (0)	1 (8.3)	0 (0)	0 (0)	0.547
	Secondary education	1 (8.3)	3 (25.0)	1 (8.3)	2 (16.7)	
	Higher education	11 (91.7)	8 (66.7)	11 (91.7)	10 (83.3)	
Dominant hand, n (%)	Right	10 (83.3)	12 (100.0)	12 (100.0)	10 (83.3)	0.307
	Left	2 (16.7)	0 (0.0)	0 (0.0)	2 (16.7)	
Association between punctured hand and dominant hand, n (%)	Same side	4 (33.3)	6 (50.0)	6 (50.0)	3 (25.0)	0.562
	Different side	8 (66.7)	6 (50.0)	6 (50.0)	9 (75.0)	
Punctured vessel, n (%)	Median vein	12 (100.0)	10 (83.3)	11 (91.7)	7 (58.3)	0.016
	Cephalic vein	0 (0.0)	0 (0.0)	1 (8.3)	4 (33.3)	
	Basilic vein	0 (0.0)	2 (16.7)	0 (0.0)	1 (8.3)	
Number of previous blood samplings, n (%)	0	2 (16.7)	5 (41.7)	7 (58.3)	4 (33.3)	0.241
	1–3	6 (50.0)	4 (33.3)	1 (8.3)	1 (8.3)	
	4–6	2 (16.7)	1 (8.3)	1 (8.3)	4 (33.3)	
	7–10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	
	> 10	2 (16.7)	2 (16.7)	3 (25.0)	3 (25.0)	
Number of previous blood donations, n (%)	0	2 (16.7)	5 (41.7)	3 (25.0)	1 (8.3)	0.010
	1–3	6 (50.0)	0 (0.0)	4 (33.3)	1 (8.3)	
	4–6	0 (0.0)	3 (25.0)	0 (0.0)	4 (33.3)	
	7–10	0 (0.0)	0 (0.0)	2 (16.7)	0 (0.0)	
	> 10	4 (33.3)	4 (33.3)	3 (25.0)	6 (50.0)	

Notes: Group A, control group; Group B, topical anesthetic group; Grwaszoup C, cooling spray group; Group D, audiovisual distraction group; BMI, body mass index; SD, standard deviation.

Table 2. Pain ratings and satisfaction levels among the four participant groups (n = 48).

Group	Number	Pain scores during needle insertion		Pain scores during blood withdrawal		Satisfaction Level	
		Mean (SD)	95% CI	Mean	95% CI	Median	IQR
A	12	3.25 (1.21)	2.48-4.02	1.67 (1.19)	0.91-2.43	3.00	0.00
B	12	2.83 (1.11)	2.12-3.54	1.67 (0.83)	1.14-2.20	3.00	0.00
C	12	2.67 (1.61)	1.65-3.69	1.58 (1.51)	0.62-2.54	3.00	0.00
D	12	3.00 (2.22)	1.59-4.41	1.25 (0.62)	0.86-1.64	3.00	0.00
All	48	2.94 (1.56)	2.49-3.39	1.54 (1.07)	1.24-1.85	3.00	0.00

Notes: Group A, control group; Group B, topical anesthetic group; Group C, cooling spray group; Group D, audiovisual distraction group; CI, confidence interval; IQR, interquartile range; SD, standard deviation.

Table 3. Comparison of pain scores and satisfaction levels among the four participant groups (n = 48).

Variables	Test value and p-value	Test name
Pain scores during needle insertion	F (3, 44) = 0.100, p = 0.960	One-way ANOVA
Pain scores during blood withdrawal	H (3) = 0.620, p = 0.892	Kruskal–Wallis test
Satisfaction level	H (3) = 0.180, p = 0.980	Kruskal–Wallis test

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Table 4. Multivariable linear regression analysis of pain scores during needle insertion across the four participant groups (n = 48)

Variables	Coefficient	Standard error	t-statistic	p-value	95% CI
Group					
Group A	reference				
Group B	0.60	0.97	0.62	0.54	[-1.30, 2.51]
Group C	-0.30	0.84	-0.36	0.72	[-1.33, 1.94]
Group D	0.78	0.92	0.86	0.39	[-1.01, 2.58]
Age	0.04	0.03	1.24	0.22	[-0.02, 0.09]
Women	-0.21	0.56	-0.37	0.71	[-1.31, 0.90]
BMI	-0.10	0.07	-1.50	0.13	[-0.23, 0.03]
Education					
Secondary education	-2.12	1.94	-1.09	0.28	[-5.92, 1.68]
Higher education	-1.35	1.77	-0.76	0.45	[-4.81, 2.11]
Punctured vessel					
Cephalic vein	-0.76	0.94	-0.81	0.42	[-2.60, 1.08]
Basilic vein	1.90	1.13	1.68	0.09	[-0.32, 4.13]
Number of previous blood sampling					
1–3	1.00	0.69	1.44	0.15	[-0.36, 2.35]
4–6	1.08	0.75	1.44	0.15	[-0.39, 2.56]
7–10	NA	NA	NA	NA	NA
>10	0.28	0.75	0.37	0.71	[-1.20, 1.75]
Number of previous blood donation					
1–3	0.99	0.83	1.20	0.23	[-0.62, 2.61]
4–6	1.20	0.94	0.13	0.90	[-1.73, 1.97]
7–10	1.58	1.44	1.10	0.27	[-1.24, 4.41]
>10	-0.03	0.84	-0.04	0.97	[-1.67, 1.61]

Notes: BMI, body mass index; CI, confidence interval; Group A, control group; Group B, topical anesthetic group; Group C, cooling spray group; Group D, audiovisual distraction group; NA, not applicable

Table 5. Multivariable linear regression analysis of pain scores during blood withdrawal across the four participant groups (n = 48).

Variables	Coefficient	Standard error	t-statistic	p-value	95% CI
Group					
Group A			reference		
Group B	0.82	0.70	1.18	0.24	[-0.55, 2.20]
Group C	0.29	0.60	0.49	0.62	[-0.88, 1.47]
Group D	0.79	0.66	1.20	0.23	[-0.50, 2.08]
Age	0.01	0.02	0.27	0.79	[-0.04, 0.05]
Female	-0.04	0.40	-0.10	0.92	[-0.83, 0.75]
BMI	-0.09	0.05	-1.94	0.05	[-0.18, 0.00]
Education					
Secondary education	0.51	1.40	0.37	0.71	[-2.22, 3.25]
Higher education	0.59	1.28	0.47	0.64	[-1.90, 3.09]
Punctured vessel					
Cephalic vein	0.22	0.68	0.33	0.74	[-1.10, 1.55]
Basilic vein	-0.34	0.82	-0.41	0.68	[-1.94, 1.26]
Number of previous blood sampling					
1–3	-0.21	0.50	-0.43	0.67	[-1.19, 0.76]
4–6	-0.41	0.54	-0.75	0.45	[-1.46, 0.65]
7–10	NA	NA	NA	NA	NA
>10	-0.49	0.54	-0.90	0.37	[-1.55, 0.58]
Number of previous blood donation					
1–3	0.43	0.59	0.73	0.47	[-0.73, 1.60]
4–6	-0.47	0.68	-0.69	0.49	[-1.80, 0.86]
7–10	1.39	1.31	1.33	0.18	[-0.65, 3.42]
>10	-0.29	0.60	-0.48	0.63	[-1.47, 0.89]

Notes: BMI, body mass index; CI, confidence interval; Group A, control group; Group B, topical anesthetic group; Group C, cooling spray group; Group D, audiovisual distraction group; NA, not applicable

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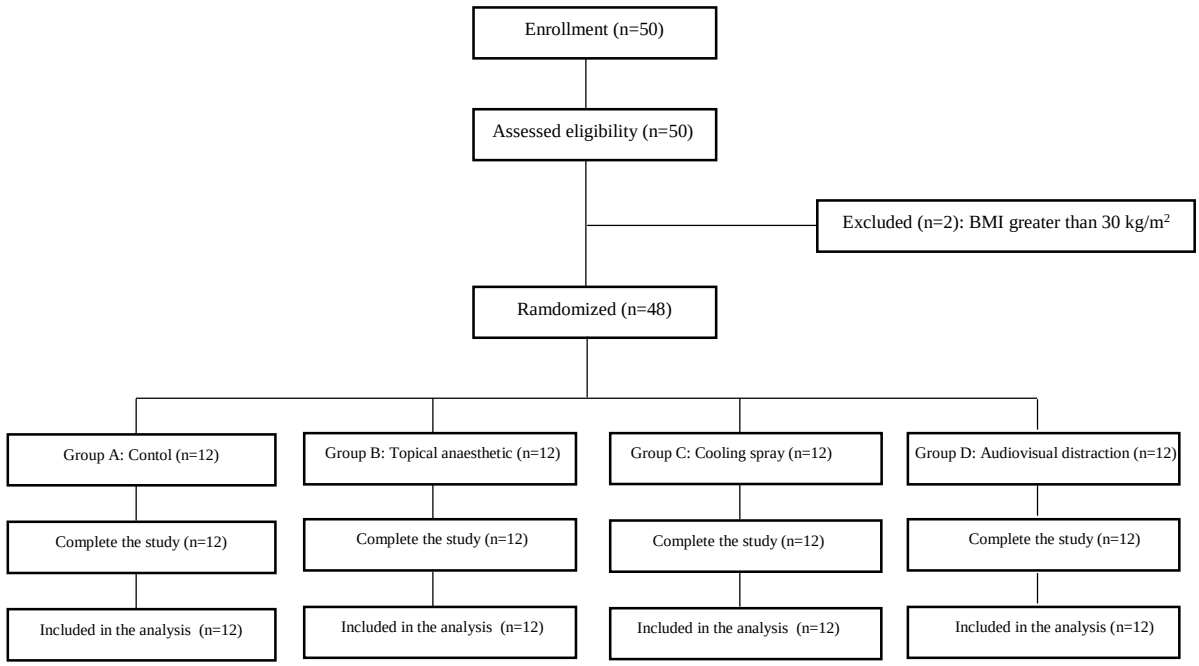

Figure 1. Study enrollment and randomization flowchart

mass index (BMI) was not a significant predictor of pain during needle insertion ($p = 0.139$), but showed a borderline association with reduced pain during blood withdrawal ($p = 0.050$). Educational level was not significantly associated with pain scores in either model (Model A: $p > 0.28$; Model B: $p > 0.64$). Similarly, the type of punctured vessel (cephalic or basilic) showed no statistically significant association (Model A: $p = 0.42$ and 0.09; Model B: $p = 0.74$ and 0.68, respectively). A previous history of blood sampling and donation was not significantly associated with pain scores (Model A and B: all p-values > 0.10). Both models yielded positive intercepts, which were not statistically significant (Model A: $p = 0.069$; Model B: $p = 0.095$).

DISCUSSION

One potential barrier to blood donation is the fear of the pain associated with the process [3]. This present study aimed to assess the efficacy of three interventions - topical anaesthesia, cooling spray, and audiovisual distraction - in alleviating needle-related pain during blood donation, specifically focusing on the use of a 16-gauge needle. Interestingly, in contrast to our previous study, our findings showed a trend toward pain reduction across the intervention groups. However, the differences were not statistically significant compared with the control group. The relatively mild pain scores may reflect cultural views of pain. Pain is not simply a biological process but is shaped in part by cultural beliefs, values, and practices which influence perception, expression and coping adaptations associated with pain [21,22]. Pain sensitivity, expression, and coping strategies have been documented to vary across cultural groups, firmly establishing the relevance of contextualisation of pain results [21]. In the Thai context, acceptance and tolerance of discomfort, especially when it serves a socially valued purpose, carry considerable meaning. Studies among Thai patients receiving hemodialysis, a setting in which large-bore needles are used almost routinely, have revealed that Buddhist and Muslim participants often view their discomfort as a result of past actions and cope by praying, making merit, and ultimately accepting the discomfort [23,24]. Cultural beliefs, such as those held by the individuals in our study, may have contributed to underreporting of pain intensity or severity. Combined with the generally mild pain scores reflected in our study, cultural beliefs will provide some context when considering our results in relation to other studies in other populations.

Pain during blood donation arises from mechanical trauma and neurophysiological activation, particularly at the site of needle insertion. Larger needles, such as the 16-gauge used in this study, are associated with increased tissue disruption and pain intensity [25-27]. Pain signalling involves both nociceptor activation and modulation by inflammatory mediators and neurotransmitters. However, perception of pain is also influenced by psychological factors such as fear

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and anxiety, which are particularly relevant in first-time donors [28,29]. The interventions examined in this study are grounded in established theories of pain modulation. Topical anaesthetics aim to block nociceptor activation by inhibiting sodium channels in peripheral nerves. Cooling sprays act via counter-irritation and may reduce local nerve conduction velocity, producing transient analgesia. Audiovisual distraction targets the psychological dimension of pain by shifting attention away from the procedure, in line with the Gate Control Theory. Despite their theoretical underpinnings, the present study found no statistically significant differences in pain scores between intervention and control groups.

Psychological factors also significantly impact pain perception and outcomes. Emotional states such as anxiety and depression, dysfunctional coping styles such as catastrophising, low self-efficacy, kinesiophobia, perceived injustice, and sleep-related impairments have been linked to variability in pain intensity reporting and treatment response [30]. Anxiety and depression are powerful predictors of chronic pain and reduced analgesic response: additionally, positive state affect is associated with positive responses, while negative affect correlates with worse outcomes [31]. Anticipatory anxiety may diminish the brain's accuracy when updating expectations concerning pain and aid in sustaining or re-experiencing negative pain [31,32]. Pain catastrophising or an exaggerated negative mental set towards pain is among the most robust and clinically impactful risk factors [33-35]. Moreover, there is neurobiological evidence that pain catastrophising is associated with increased nociceptive signalling, central sensitisation, and pain-modulating networks in the brain [33]. Other psychological traits (for example, kinesiophobia and perceived injustice) are also related to worse outcomes and can be elicited from negative experiences in early life [36]. Sleep disturbances interact bi-directionally with pain, reinforcing its severity and chronicity. Screening instruments such as the Pittsburgh Sleep Quality Index (PSQI) are useful for the clinical assessment of sleep disturbances in patients with chronic pain [30]. These findings suggest that psychological phenotyping is not merely descriptive but can also inform risk stratification, perioperative planning, and multimodal, opioid-sparing pain management strategies in both blood donation and other medical settings.

Studies evaluating pain reduction interventions using large-bore needles for blood donation are limited. Previous studies on 16-gauge needles, which are the same size as those used in blood donation, primarily focused on haemodialysis patients with arteriovenous fistulas [37]. Our findings are consistent with those of previous studies. Pour et al. [38] performed an open-label, randomised crossover clinical trial with three periods and three treatment sequences to evaluate the effects of cooling and lidocaine sprays on needle insertion pain using a 16-gauge needle in hemodialysis patients. The cooling spray notably reduced pain compared with placebo ($p = 0.002$), whereas the lidocaine spray group did not reach statistical significance ($p = 0.052$). Babamohamadi and coworkers conducted a randomised controlled trial to evaluate the effectiveness of topical lidocaine-prilocaine cream (Eutectic Mixture of Local Anaesthetics, EMLA) compared to the Valsalva manoeuvre (VM) in alleviating pain during vascular needle insertion in patients undergoing haemodialysis [15]. The mean pain intensity during cannulation was 2.06 (SD = 2.19) in the EMLA group, 3.2 (SD = 3.42) in the VM group, and 6.20 (SD = 1.49) in the control group.

Statistical analysis revealed significant differences in pain intensity between the EMLA and control groups, as well as between the VM and control groups, with p-values < 0.001 for each comparison. Mirzaei et al. conducted a quasi-experimental study to investigate the effects of EMLA cream, lidocaine spray, and ice packs on pain intensity during arteriovenous cannulation in patients undergoing hemodialysis [16]. The mean pain scores (on a 0 – 10 scale) across the four stages were as follows: no intervention (7.45, SD = 0.88), ice pack (5.38, SD = 0.83), lidocaine spray (4.22, SD = 1.13), and EMLA cream (2.8, SD = 0.7). All three interventions — EMLA cream, lidocaine spray, and ice pack — effectively reduced pain during arteriovenous fistula cannulation. EMLA cream was found to be the most effective, significantly reducing pain compared to lidocaine spray and ice pack ($p < 0.001$). Additionally, the lidocaine spray was more effective than the ice pack, with a significantly greater mean reduction in pain ($p < 0.001$). Shafii et al. [18] conducted a randomised, double-blinded, controlled trial to investigate the effectiveness of a cooling spray in reducing the pain associated with needle insertion in haemodialysis patients. Patients in the intervention group experienced significantly milder pain during cannulation than those in the control group (mean = 3.28, SD = 1.13 vs. mean = 5.30, SD = 1.76, $p < 0.001$). Ghadimi et al. conducted a quasi-experimental study to examine the effects of audio distraction techniques on pain levels in older patients undergoing haemodialysis for arteriovenous fistulas. The mean pain intensity in the experimental group was 5.50 (SD = 0.50), compared to 6.70 (SD = 0.03) in the control group, showing a statistically significant difference ($p < 0.001$) [17].

High satisfaction observed across groups is likely due to a ceiling effect, in which the measure failed to distinguish among the subtleties of the interventions. The ceiling effect occurs when a large percentage of participants score at the highest level of a measurement scale, limiting an investigator's ability to detect meaningful differences or improvements [39,40]. Ceiling effects may conceal the actual impact of an intervention because the measurement tool lacks nearly as much sensitivity at the top end of the scale. These effects can be easily encountered in clinical and survey research, particularly with patient-reported outcomes, such as satisfaction or quality of life scales [41]. Ceiling effects can be reduced through the use of a more sensitive instrument that allows for additional measures or by adopting a multidimensional approach to measurement.

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Moreover, the 4-point Likert scale, although simple, may have been insensitive to detecting this difference, given that participants were concentrated at the higher scores [42]. Future research might consider using more sensitive, multidimensional measurements, such as more detailed scales that include satisfaction with individual aspects of the donor experience (e.g comfort, anxiety, willingness to return, perceived support from staff), to assess variability with respect to the context of donors' perceptions across contexts.

Our study limitations included participants' predispositions toward pain intensity, which may have accounted for the low overall scores, highlighting the importance of operator skill and mental preparedness in terms of the reported pain experience. Second, the lack of statistical significance in pain reduction during the blood donation procedure, despite its potential clinical relevance, may be due to the relatively low-intensity pain observed at our study site. Although the sample size was calculated based on previous research and provided sufficient power for the expected effect, the actual effect in this population may have been smaller than anticipated, thereby reducing the study's ability to detect statistically significant differences.

Psychological preparedness or prior experience may have a greater influence on pain perception than of physical characteristics. Nonetheless, variations in BMI and vessel type may still influence vascular procedures or donor comfort [44,45] and should be considered in future studies with larger and more diverse samples. Further, pain expectations play a significant role in determining how individuals perceive discomfort during medical procedures [46]. Individuals intending to donate blood often anticipate moderate-to-severe pain [15-18]; hence, we intentionally informed them of this potential pain intensity as part of comprehensive informed consent. The absence of notable variations in pain scores across the four groups might be attributed to this methodology. When the actual pain experienced was less intense than expected, the participants tended to report only mild pain across all interventions. This study was conducted at a single centre with a relatively homogeneous population, which may limit the generalizability of the findings to other settings or more diverse populations. Cultural perceptions of pain, donor motivation, and operator variability may differ across regions and institutions. As such, the external validity of our results may be limited.

Further multicenter studies involving more heterogeneous populations are needed to evaluate the efficacy of these pain-reduction interventions. These trials should also incorporate economic and clinical outcome measures, including cost-effectiveness analyses, donor-reported comfort during and after blood donation, and subsequent donor return rates. Psychological factors such as anticipatory anxiety or fear were also not evaluated in this study. These factors may influence individual pain perception and could have contributed to variability in reported pain scores. The absence of a psychometric assessment limits our ability to control for these confounders. Future research should include validated instruments to evaluate psychological states both prior to and during the intervention, such as the State-Trait Anxiety Inventory (STAI) or the Pain Catastrophizing Scale (PCS), to clarify their effects on pain reporting [47,48].

In addition, this study was not blinded. Although participants could not actively manipulate the intervention they received, they were aware of what they had received, which may have affected pain ratings accordingly. Despite the practical challenges of blinding participants in this type of study design, future studies may reduce this bias by using placebo or sham interventions and blinding the outcome assessment when applicable. Another potential consideration is the Hawthorne effect, which suggests that a participant's awareness of being observed in a research study may alter their perception of pain or reporting of pain even if the amount of pain remains unchanged [49]. In future studies, several strategies may help minimise the Hawthorne effect. First, objective pain biomarkers, such as heart rate variability and skin conductance, can yield data less biased by participants' knowledge of being observed, thereby reducing dependence on self-report measures [50]. Second, using blinded raters who are unaware of group assignments [by the observers] minimises bias, ensuring that the outcome reflects actual behaviour rather than behaviour that has been altered by being observed [50]. Lastly, by standardising procedures across study arms, variability in the outcome from differential attention would be reduced in this aspect of human interaction, and supporting consistency between experimental groups [51].

Conclusion

Blood donation is a crucial step in the transfusion process and a vital medical intervention used to treat various conditions in clinical practice. A common barrier to donation is the fear of pain associated with the procedure. Our study reports that the process generally resulted in mild pain when gentle needle insertion techniques were used. Moreover, pain-reduction techniques, including topical anaesthetics, cooling spray, and audiovisual distraction, showed a tendency to decrease pain; however, the observed differences did not reach statistical significance. Multicentre studies are required to further compare and validate the consistency of these findings.

DECLARATIONS

Ethical consideration

This study received ethics approval from the Walailak University Ethics Committee (WUEC-23-070-01).

Consent to publish

All authors agreed on the content of the final paper.

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Competing Interest
The authors declare no conflict of interest

Author contribution
SP participated in the research conceptualisation, design, data analysis, interpretation, writing, and final approval of the article. AM contributed to the research concept, design, and final approval of the article. WT was involved in the research conceptualisation, design, data analysis, drafting, critical revision, and final approval of the article. All authors reviewed and approved the final version for publication, consented to the journal submission, and accepted accountability for all aspects of the study.

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Availability of data
Data is available upon request to the corresponding author.

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