Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effect of Touch Therapy and Virtual Reality on Pain Intensity, Anxiety Level, and Satisfaction in Patients Requiring Sutures Referred to the Emergency Department

Protocol summary

Study aim
Determining and comparing the effects of touch therapy and virtual reality on pain intensity, anxiety level, and satisfaction in patients requiring suturing presenting to the emergency department

Design
This is a randomized controlled clinical trial, single-blinded with three parallel groups: therapeutic touch, virtual reality, and control group. Sampling was done by convenience method and by assigning individuals to groups based on random blocks of 9 generated by an online system, on 81 patients.

Settings and conduct
Statistical blinding. Sampling is by convenience method and 81 patients are randomly assigned based on blocks of 9 into three equal groups. The first group receives a therapeutic touch intervention by a trained companion, which includes standard hand massage techniques during the suturing process. The second group uses a virtual reality headset with naturalistic content and relaxing music. The control group receives only routine emergency care. Data are collected using standard questionnaires including the Visual Analogue Scale of Pain, the Spielberger State-Trait Anxiety Inventory , and the Satisfaction Scale before and after the intervention.

Participants/Inclusion and exclusion criteria
Inclusion: Age over 18, consciousness, tear greater than 2 cm, no pain medication, no tendon rupture or mental disorder, specific suture. Exclusion: Disability, self-harm, multiple tears, addiction, dementia, seizures, head/face laceration, hand deformity.

Intervention groups
Control Group: This group receives routine emergency care. Touch Therapy Group: Touch therapy is taught to the patient's companion to be performed during suturing. Virtual Reality Group: Patients use VR headset. Relaxing content is played 5 minutes before anesthesia and during suturing.

Main outcome variables
Pain intensity, anxiety level, and patient satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260627069963N1**
Registration date: **2026-07-04, 1405/04/13**
Registration timing: **retrospective**

Last update: **2026-07-04, 1405/04/13**
Update count: **0**

Registration date
2026-07-04, 1405/04/13

Registrant information

Name
Tooba Khajehhasani Rabori

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-29, 1405/04/08

Expected recruitment end date
2026-07-03, 1405/04/12

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Touch Therapy and Virtual Reality on Pain Intensity, Anxiety Level, and Satisfaction in Patients Requiring Sutures Referred to the Emergency Department

Public title
The effect of therapeutic touch and virtual reality on pain intensity, anxiety level, and satisfaction in patients requiring sutures.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
At least 18 years of age Alert and oriented to time, place, and person Patients with lacerations at least 2 cm in length that require suturing for wound closure No use of anxiolytics or analgesics within 12 hours prior to the study No tendon or ligament rupture No severe psychiatric disorders (e.g., psychotic disorders, schizophrenia, post-traumatic stress disorder, major depressive disorder, etc.) Patients whose suturing is performed using 4-0 nylon suture with a reverse-cutting needle. The suturing technique used is either simple interrupted or vertical mattress
Exclusion criteria:
Visual, hearing, speech, or physical disability and paralysis Having a rheumatologic disease and undergoing medical treatment Lacerations resulting from self-harm Multiple lacerations and concurrent injury to other organs Opioid addiction Patients with a history of senile dementia, seizure disorder, motion sickness, or any condition that affects tactile perception. Patients with lacerations on the head or face that would interfere with placement of the virtual reality headset. Patients who had injury or infection above the neck Erythema, edema, fracture, pain, or abnormality in the hands, as well as other conditions affecting the hands (e.g., phlebitis, diabetes mellitus, neurological disorders) Patients who have received massage or other relaxation interventions (e.g., music therapy) within the past week
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **81**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, blinding of participants is not feasible due to the nature of the interventions (touch therapy and virtual reality). Touch therapy requires the patient's awareness of physical contact, and virtual reality is clearly distinguishable; moreover, the use of a sham intervention (e.g., neutral content) would not completely mislead the patient. To mitigate assessment bias, statistical blinding will be employed, whereby the data analyst remains unaware of group allocation, allowing the results to be examined without prejudice.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Aria Building, 7th Alley, Imam Hassan Boulevard, Kerman, Iran
City
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Province
Kerman
Postal code
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Approval date
2026-01-11, 1404/10/21
Ethics committee reference number
IR.KMU.REC.1404.545

Health conditions studied

1

Description of health condition studied
Patients Requiring Sutures
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity
Timepoint
The questionnaires are administered by the researcher via direct questioning of the patient, five minutes before local anesthesia and suturing, and are completed once

more after the suturing procedure.

Method of measurement

Visual analog scale

2

Description

Anxiety level

Timepoint

The questionnaires are administered by the researcher via direct questioning of the patient, five minutes before local anesthesia and suturing, and are completed once more after the suturing procedure.

Method of measurement

Spielberg State-Trait Anxiety Inventory

3

Description

Satisfaction

Timepoint

After the suturing is completed

Method of measurement

Visual Analog Scale for Satisfaction

Secondary outcomes

empty

Intervention groups

1

Description

Control group: This group receives routine emergency care. In standard care, the emergency physician, after local anesthesia with 2% lidocaine (based on wound size and patient weight) and wound examination, performs wound closure in a minor procedure room. Patients have the opportunity to request additional local anesthesia during the procedure. All simple laceration suturing will be performed by the emergency physician. A simple laceration refers to a skin tear that does not involve nerves, tendons, arteries, veins, or bones. Before suturing and intervention, patients are placed in an appropriate position. To ensure maximum consistency of conditions, all patients will be placed in a supine position under suitable conditions before and after the intervention. Routine care provided to all patients includes the following: initially, the wound and the area to be sutured are irrigated with 0.9% normal saline by an experienced emergency operating room nurse. The emergency physician's hands are washed using the proper technique and sterile gloves are worn. All required equipment, including syringes, local anesthetic, suture needles and threads, and suture sets, are prepared and placed sterilely on the tray. Lidocaine 2% without epinephrine (based on wound size and patient weight, with a maximum dose of 4.5 cc/kg) is used for anesthesia of the suture site. The syringe is filled using a sterile technique, and a 25G or 27G needle is selected according to the injection site. For anesthetic injection, the emergency physician first disinfects the skin of the target area again with Hexaspet or alcohol antiseptic solution, then the pre-filled syringe is gently inserted into the dermal area at a 10-15 degree angle, and lidocaine is injected gradually. Injection is performed in a parallel manner around the wound and its edges to ensure complete anesthesia of the entire area. After injection, 3-5 minutes are allowed for the anesthetic to take full effect, then the wound is examined, and if suturing is required, it is performed by an experienced emergency physician. For simple interrupted sutures, a sterile reverse-cutting curved needle with 4-0 nylon suture material is selected. The needle is inserted into the skin at an appropriate depth and angle according to the suture site, maintaining a distance of approximately 3-5 mm from the wound edge. The needle is passed in a curved manner from one side of the wound and exits from the other side at the same distance from the wound edge (ensuring equal depth of entry and exit). The suture is then pulled to approximate the wound edges. Finally, simple knots are tied (5-6 simple knots) and the suture ends are cut to an appropriate length. This process is repeated for each suture individually. For vertical mattress sutures, the needle is inserted approximately 4-6 mm from the wound edge and exits from the opposite side at the same distance from the wound edge. The needle is then reinserted approximately 1-2 mm from the wound edge and exits from the opposite side at the same distance. The suture is pulled to approximate the wound edges, and then 4-6 simple knots are tied and secured. Finally, the suture ends are cut to an appropriate length. This process is repeated for each suture individually. Throughout the study, every effort will be made to ensure that all procedures are performed by the same physician and the same nurse.

Category

Other

2

Description

Intervention group: First Intervention Group – Touch Therapy by Patient's Companion Among the patient's companions, the one who has the closest relationship and attachment to the patient and has no mental health issues will be selected if willing to participate in the intervention. A 3-minute instructional video is shown to the companion, followed by in-person practical training. The training content includes: 1) introduction to the basic principles of touch therapy and its benefits in reducing pain and anxiety; 2) training in standard touch therapy techniques; 3) emphasis on avoiding direct pressure on the wound or painful areas; and 4) observance of ethical principles (respecting the patient's privacy and obtaining verbal consent during performance).After training completion, the companion sits beside the patient's bed and a calm environment is established (reducing light and ambient noise when possible). The patient is asked to close their eyes and practice deep breathing. Then, the companion gently takes the patient's hands and performs touch therapy during suturing with gentle, rhythmic movements (such as stroking the back of the hand or massaging the palm) according to the following steps: Hand Massage Steps: First Touch (Gentle

Rhythmic Pressure): Using the fingertips, gentle rhythmic pressure is applied to the thenar eminence, the base of the index finger, the webbing between fingers, and the fleshy part of the palm (palmar surface). Second Touch (Compressive-Rotatory Touch): Using the thumb and index finger eminences, compressive touch with a twisting motion (similar to gentle squeezing and kneading) is applied from the base to the tip of each of the patient's fingers. Third Touch (Circular Massage): While the patient's palm is supported by the companion's palm, the back of the patient's hand and fingers are massaged in a circular motion with the other palm. The researcher indirectly monitors the correct execution of the touch from an appropriate distance, and in case of errors, the intervention is corrected or stopped

Category

Other

3

Description

Intervention group: Second Intervention Group – Virtual Reality VRG (virtual reality glasses) are devices that work with compatible smartphones. They can be used to watch videos taken at a 360-degree angle, and any type of wired headphones can be connected to the audio output. Observing relaxing images along with soothing music through VRG during invasive procedures such as suturing allows patients to embark on an imaginary journey that distances them from the clinic where they are surrounded by medical equipment and leads them to a calmer environment. It is believed that the use of VRG increases the secretion of endorphins and oxytocin while reducing adrenaline levels, thus inducing physical relaxation. This technology can be used as a non-invasive and effective method for pain relief. This approach was selected because studies using VRG have demonstrated that it is an efficient method for pain management. A video depicting a natural environment along with music featuring nature sounds is shown to patients in the VRG intervention group for 5 minutes prior to anesthetic injection and during wound repair by suturing. Headphones are used to listen to recorded music that plays nature sounds. The glasses are placed on the patient's eyes before suturing begins and are not removed during wound repair. The aim is for patients to observe nature more effectively and listen to its sounds, allowing them to focus on the images and sounds and distract themselves from the stress of the current environment. The same video was shown to each patient, and the glasses were disinfected after each use. Regarding the equipment used, a VR headset with high resolution and a wide field of view (at least 100 degrees) was used, and the designed content includes relaxing environments such as seashore, forest, and green spaces with nature sound effects. The patient will be positioned in a semi-recumbent or supine position on the emergency bed. Ambient lighting will be adjusted and distracting noises minimized. The use of the headset will be explained to the patient, and the patient will also be assured that if they experience dizziness or discomfort, they may remove the device. Regarding the intervention protocol, five minutes before suturing begins, the headset is placed on the patient's head and the necessary adjustments are made for comfort. The patient is immersed in the virtual environment for the duration of the suturing, noting that the VR content is 10 minutes long and is replayed if needed. During the intervention, the researcher remains beside the patient to assist if necessary. After the intervention is completed, the headset is removed from the patient's head, and the patient is then given 2-3 minutes to re-adapt to the real environment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Bahonar hospital

Full name of responsible person
Shahab Ilka

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Kerman University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No further information is available.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Individual participant data, including pain scores (VAS), anxiety scores (STAI), and satisfaction scores (VAS-sat), along with baseline demographic characteristics, will be made available upon reasonable request and with the

approval of the Research Ethics Committee of Kerman University of Medical Sciences. Data will be shared in a secure, anonymized format (SPSS or Excel file) for non-commercial research purposes only, and recipients will be required to sign a confidentiality agreement.

When the data will become available and for how long

Access to individual participant data will begin 6 months after the publication of the main study results and will remain available for a period of 5 years. The publication date will subsequently be announced through reputable scientific databases.

To whom data/document is available

Access to the data and study documents will be granted solely to researchers affiliated with academic institutions, research centers, and recognized scientific organizations that have obtained approval from the Research Ethics Committee of Kerman University of Medical Sciences. Requests submitted by individuals working in industry or commercial sectors will not be accepted unless they are collaborating with an academic institution. All applicants will be required to submit a valid research proposal and sign a confidentiality and non-commercial use agreement prior to receiving any data.

Under which criteria data/document could be used

The data provided may only be used for analyses specifically approved by the Research Ethics Committee of Kerman University of Medical Sciences, and any analysis beyond the approved framework is strictly prohibited. Use of the data is permitted solely for non-commercial research purposes, and any commercial exploitation of the data or documents is expressly forbidden. All analyses conducted on the data must cite the source (this study) in any scientific publications resulting from the work. The data and documents provided may not be redistributed to third parties and will be made available only to the requesting researcher. Applicants are required to share the results of their analyses with the principal investigator's team. Any publication of results based on these data requires written approval from the principal investigator's team.

From where data/document is obtainable

Applicants may submit their written request for access to the data and documents of this study through one of the following channels: First Priority (Email): Email Address: r_Mhdipour@kmu.ac.ir (Responses will be provided as soon as possible, within a maximum of 72 hours) Second Priority (Postal Correspondence): Address: Department of Nursing, Razi Faculty of Nursing and Midwifery, Kerman University of Medical Sciences Campus, Haft Bagh-e Alavi, Kerman, Iran Postal Code: 7616913555 Telephone: +98 34 3132 5194 Third Priority (Telephone Contact): Telephone Number: +98 34 3132 5194 (Office hours: 8:00 AM to 2:00 PM) Contact Person: Dr. Roghayeh Mehdipour Raberi (Associate Professor, Department of Nursing, Razi Faculty of Nursing and Midwifery, Kerman University of Medical Sciences) Email: r_Mhdipour@kmu.ac.ir All requests must include the applicant's full name, institutional affiliation, a brief description of the purpose of the data request, and the proposed research plan. Requests will be reviewed within a maximum of 2 working weeks, and the outcome will be communicated to the applicant via email.

What processes are involved for a request to access data/document

Applicants requesting access to the data and documents of this study are required to follow the steps outlined below: Step 1: Submission of Written Request The applicant must submit a written request via email (r_Mhdipour@kmu.ac.ir). The request must include the following: Full name, institutional affiliation, and valid identification documents Comprehensive description of the purpose of the data request and research objectives Proposed research plan including research questions, analysis methods, and timeline Commitment to maintain confidentiality and non-commercial use of the data Step 2: Initial Review by the Principal Investigator's Team The received request is reviewed by the principal investigator's team. This review includes scientific evaluation of the proposed plan, alignment with the study objectives, and verification of the applicant's academic qualifications. If necessary, the principal investigator may contact the applicant for further clarification. Step 3: Referral to the Research Ethics Committee Following initial approval by the principal investigator's team, the request is referred to the Research Ethics Committee of Kerman University of Medical Sciences. The Ethics Committee reviews the ethical aspects of the request, including data confidentiality and protection of participant rights. Step 4: Signing the Data Access Agreement After receiving Ethics Committee approval, the applicant is required to review and sign a Data Access Agreement. This agreement includes commitments to non-commercial use, non-redistribution of data to third parties, proper citation of the source in publications, and provision of results to the principal investigator's team. Step 5: Data Delivery Upon signing the agreement, the requested data will be provided to the applicant in a secure, anonymized format (SPSS or Excel file) via email or a secure download link. Timeline: The entire process from request receipt to data delivery will take a maximum of 4 working weeks. Applicants can expect to receive the initial review outcome within 2 working weeks of submission, and, if approved, the data will be delivered within a further 2 working weeks after signing the agreement.

Comments