ISRCTN17740832 https://doi.org/10.1186/ISRCTN17740832

Can mobile application-augmented reality improve better skills and knowledge in interventional pain management of lumbar facet joint with fluoroscopic guidance? Comparison with traditional method

Submission date	**Recruitment status**	[X] Prospectively registered
21/01/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/01/2024	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
07/05/2024	Other	[X] Record updated in last year

Plain English Summary

Background and study aims

Pain is an unpleasant sensory and emotional experience associated with or resembling that associated with actual or potential tissue damage. Various types of therapy, both pharmacological and non-pharmacological, are given, intervention is one option in pain management. However, it is often found that there are limitations between the knowledge provided and the clinical skills obtained during education as well as inadequate supporting infrastructure. This causes practitioners to feel less confident in taking action. Learning innovations using mobile applications and augmented reality through the M-eDU PAIN application can overcome these problems. M-eDU PAIN is a new mobile application focused on learning interventional pain management. This study aims to find out about increasing skills and knowledge in the lumbar facet joint using the mobile application with Augmented Reality as a learning method.

Who can participate?

Residents of anesthesiology and intensive care department at Dr Sardjito General Hospital Yogyakarta who met the inclusion and exclusion criteria

What does the study involve?

Residents will receive one of two learning methods of lumbar facet joint intervention, traditional methods or digital methods by using the mobile application M-eDU PAIN and augmented reality. All participants will be examined using knowledge tests and skill improvement will be measured.

What are the possible benefits and risks of participating?
Possible benefits of digital methods are faster and better improvement of knowledge and skill of lumbar facet joint intervention, while the potential risks are possible exposure to fluoroscopy radiation and time-consuming.

Where is the study run from?
Universitas Gadjah Mada (Indonesia)

When is the study starting and how long is it expected to run for?
November 2023 to April 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Mahmud Mahmud, mahmudanestesi@ugm.ac.id

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Comparison of learning methods: mobile application-augmented reality with traditional learning for interventional pain management skills of lumbar facet joint with fluoroscopic guidance

Study hypothesis
Learning methods using mobile application with augmented reality can improve residents' skills and knowledge better than traditional learning for interventional pain management of lumbar facet joint with fluoroscopic guidance

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/12/2023, Medical and Health Research Ethics Committee of Universitas Gadjah Mada (Jl Kesehatan no 1, Sekip, Yogyakarta, 55284, Indonesia; +62 274 588688; mhrec_fmugm@ugm.ac.id), ref: KE/EK/1904/EC/2023

Study design
Single-center single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See study outputs table

Condition
Residents of anesthesiology and intensive care department

Interventions
Current interventions as of 07/05/2024:

The study will use a single-blind randomization controlled trial design to investigate the improvement of skill and knowledge of anesthesiology and intensive care residents after using the mobile application M-eDU PAIN and augmented reality in lumbar facet joint intervention. All participants will be given informed consent before joining the research and randomization to get details of the learning methods and the intervention. The randomization will be done with computerized permutation block randomization. Instructors and examiners will be blinded to the learning methods assigned to each participant.

There are two groups in this study. The intervention group is anesthesiology and intensive care residents who will be given digital learning methods which is access to download and use the M-eDU PAIN mobile application to get courses on pain intervention and management in 2 weeks. The control group is anesthesia and intensive care residents who will be given traditional learning methods by getting pain intervention and management lectures in class (face-to-face) two times from experts. After 2 weeks of courses, both groups will be given a simulation class, and the instructor will explain how to do selected pain interventions using phantoms that have been validated. Both groups will do a pre-test before the course and a post-test after the course to measure the improvement of knowledge. OSCE will be done to measure residents' skills after taking the courses and simulation classes. The total duration of the intervention is 5 weeks.

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Previous interventions:

The study will use a single-blind randomization controlled trial design to investigate the improvement of skill and knowledge of anesthesia residents after using the mobile application M-eDU PAIN and augmented reality in lumbar facet joint intervention. All participants will be given informed consent before joining the research and randomization to get details of the learning methods and the intervention. The randomization will be done with computerized permutation block randomization. Instructors and examiners will be blinded to the learning methods assigned to each participant.

There are two groups in this study. The intervention group is anesthesiology residents who will be given digital learning methods which is access to download and use the M-eDU PAIN mobile application to get courses on pain intervention and management in 2 weeks. The control group is anesthesiology residents who will be given traditional learning methods by getting pain intervention and management lectures in class (face-to-face) two times from experts. After 2 weeks of courses, both groups will be given a simulation class, and the instructor will explain how to do selected pain interventions using phantoms that have been validated. Both groups will do a pre-test before the course and a post-test after the course to measure the improvement of knowledge. OSCE will be done to measure residents' skills after taking the courses and simulation classes. The total duration of the intervention is 5 weeks.

Intervention Type
Other

Primary outcome measure
Skills measured using Objective Structured Clinical Examination (OSCE), participants will be examined by given cases and asked to do a simulation of pain intervention or management. The examiner will have a checklist for OSCE scoring (the checklist was made by the investigator and validated by the anesthesiologist and pain management expert). Participants will be given 20 minutes for each case/station.

Secondary outcome measures
Knowledge measured using questions formulated by the investigators and validated by an anesthesiologist or pain management specialist/expert. The pre-test will be done before all participants are exposed to the learning method (lecture or application). The post-test will be given after all participants finish all the courses.

Overall study start date

06/11/2023

Overall study end date
07/04/2024

Eligibility

Participant inclusion criteria
Current inclusion criteria as of 07/05/2024:

1. Resident of anesthesiology and intensive care department that had passed pain module
2. Willing to take part in research by signing informed consent

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Previous inclusion criteria:

1. Resident of anesthesia that had passed pain module
2. Willing to take part in research by signing informed consent

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
82

Total final enrolment
110

Participant exclusion criteria
1. Has previously done intervention for lumbar facet joint pain using fluoroscopic guidance
2. Can't speak Indonesian

Recruitment start date
05/02/2024

Recruitment end date
11/02/2024

Locations

Countries of recruitment
Indonesia

Study participating centre
Dr Sardjito General Hospital
Jl. Kesehatan No.1
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Sponsor information

Organisation
Universitas Gadjah Mada

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Sponsor type
University/education

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ROR
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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from the Department of Anesthesiology and Intensive Care, Faculty of Medicine, Nursing, and Public Health, Universitas Gadjah Mada.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			30/01/2024	No	Yes