The use of augmented reality to teach management of severe allergic reaction to health care professionals

Submission date 17/12/2019	Recruitment status No longer recruiting	[X] Prospectively registered	
		[X] Protocol	
Registration date	Overall study status Completed	[] Statistical analysis plan	
16/01/2020		[_] Results	
Last Edited 18/06/2024	Condition category Other	Individual participant data	
		[] Record updated in last year	

Plain English summary of protocol

Background and study aims

Anaphylactic shock is a severe and potentially life-threatening reaction to a trigger such as an allergy. It is a rare medical situation and primary care doctors do not encounter it often. It needs to be recognised and managed quickly and appropriately, so it is essential that the doctor knows what to do and is confident in their knowledge. The aim of this study is to investigate whether using augmented reality simulation in training doctors how to recognize and manage a patient with anaphylactic shock will improve their confidence in managing these situations.

Who can participate? Family medicine doctors

What does the study involve?

Participants will be randomly allocated to the test and control group. Both groups will receive one day of training on management of patients with anaphylactic shock. The test group will also receive additional training using augmented reality.

What are the possible benefits and risks of participating?

The benefits are learning in a safe environment to manage a patient with anaphylactic shock, allowing the doctors to recognise their own lack of knowledge, skills and competencies and being able to overcome them, recognise safety risks when managing such patients, learn to work in a team, learning to cope with the stress and perform well also under stress. The risks include exposing their knowledge, skills and competencies before other people. Also the training is potentially time-consuming.

Where is the study run from? Community Health Centre Ljubljana (Slovenia)

When is the study starting and how long is it expected to run for? September 2019 to June 2025 Who is funding the study? The researchers are funding the study.

Who is the main contact? Prof. Zalika Klemenc-Ketis, zalika.klemenc@um.si

Contact information

Type(s) Scientific

Contact name Prof Zalika Klemenc-Ketis

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers

Study information

Scientific Title

The effect of the use of augmented reality in teaching anaphylactic shock management at the primary health care level: a randomised controlled trial

Study objectives

Learning of the management of anaphylactic shock with the use of augmented reality is more effective than learning without this method.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 27/02/2020, Slovenian Ethical Committee (Štefanova 5, Ljubljana, 1000, Slovenia; +386 01; gp.mz@gov.si), ref: 0120-67/2020/7

Study design Randomized controlled trial

Primary study design Interventional

Secondary study design Randomised controlled trial

Study setting(s) GP practice

Study type(s) Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Learning the management of anaphylactic shock at the primary health care level

Interventions

The participants (family medicine physicians) will be classified into two groups on the basis of a random selection: test and control. Each participant will receive a consecutive number upon enrolling to the study. These numbers will then be used in a randomisation process using random numbers selection by the computer program.

Both groups will complete a questionnaire on demographic characteristics and coping with stress and manage a patient with anaphylactic shock (drug allergy shock) using a high-fidelity simulator. Thereafter, both groups will receive one-day training following a pre-prepared protocol.

The test team will have additional augmented reality education included in the training.

Immediately after completion of the training, both groups will complete a questionnaire on coping with stress and provide care to the patient with anaphylactic shock using a high-fidelity simulator. 6 and 12 months after the education, both groups will complete a stress response questionnaire and manage a patient with anaphylactic shock using a standardised patient, but this care will be provided in a clinical setting.

Intervention Type

Behavioural

Primary outcome measure

The management of a patient with anaphylactic shock. The evaluation will be done using the high-fidelity simulators with a pre-prepared scenario and with the use of a standardised patient with a pre-prepared scenario. The evaluation will be done before the education process, immediately after it, 6 months afterwards and 1 year afterwards.

Secondary outcome measures

Coping with stress assessed using the Ways of Coping Questionnaire (WCQ) before the education process, immediately after it, 6 months afterwards and 1 year afterwards

Overall study start date 01/09/2019

Completion date 30/06/2025

Eligibility

Key inclusion criteria 1. Family medicine physician 2. Willing to participate in the study

Participant type(s) Health professional

Age group Adult

Sex Both

Target number of participants 150

Total final enrolment 109

Key exclusion criteria 1. Students 2. Not willing to participate in the study

Date of first enrolment 01/10/2020

Date of final enrolment 30/06/2024

Locations

Countries of recruitment Slovenia **Study participating centre Community Health Centre Ljubljana** Metelkova 9 Ljubljana Slovenia 1000

Sponsor information

Organisation Community Health Centre Ljubljana

Sponsor details Metelkova 9 Ljubljana Slovenia 1000 +38613003928 taj.irroz@zd-lj.si

Sponsor type Hospital/treatment centre

Website https://www.zd-lj.si/

ROR https://ror.org/04fx4vz25

Funder(s)

Funder type Other

Funder Name Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publications:

1. A protocol of the study (JMIR Research Protocols)

- 2. A doctoral thesis
- 3. The effect of using the augmented reality
- 4. Coping with stress

Intention to publish date

31/12/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/01/2021	05/01/2021	Yes	No