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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/01/2020	**Overall study status** Completed	
Last Edited 18/06/2024	**Condition category** Other	

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
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
1

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 01 478 60 01; gp.mz@gov.si), ref: 0120-67/2020/7

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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

ROR
https://ror.org/04fx4vz25

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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