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# How does practising simulated emergency medical situations physically and mentally affect medical students?

**Submission date**
25/12/2019

**Recruitment status**
No longer recruiting

**Registration date**
03/01/2020

**Overall study status**
Completed

**Last Edited**
24/03/2025

**Condition category**
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
The world of teaching of Health Sciences is experiencing a revolution. Virtual reality and other simulation technologies are a powerful tool teaching and training of future healthcare professionals in techniques, procedures and skills. Current and future generations of students have integrated the use of mobile devices and computer technologies into their daily lives, and are very used to interacting with a virtual environment. Advanced clinical simulations provide two substantial advantages. The first is patient safety, since the student can repeat the techniques that they did not fully master. The second advantage is that their performance can be recorded, which enables detailed feedback from instructors.
This study aims to investigate the physical responses and perceptions of medical students participating in an Advanced Clinical Simulation Subject.

Who can participate?
Students in the final year of a Medicine degree

What does the study involve?
Students who have agreed to participate will fill out questionnaires to assess their anxiety level, level of physical activity and lifestyle habits. They will also have their heart rate, blood pressure and temperature measured and will provide a saliva sample and a have a finger-prick to collect a drop of blood. They will then be randomly allocated to perform one of four simulated medical situations as either the leader or assistant in a team of two students. After the simulation, they will repeat the tests from before the simulation.

What are the possible benefits and risks of participating?
There are no direct benefits to participants, but this research should benefit future students in helping to identify those who might develop anxiety during the simulation. The study has no risks apart from the pain potentially involved in the finger prick.

Where is the study run from?
University of Valladolid (Spain)

When is the study starting and how long is it expected to run for?
September 2019 to June 2021

Who is funding the study?
The study is funded by the researchers themselves.

Who is the main contact?
Dr Francisco Martín-Rodríguez, fmartin@saludcastillayleon.es

# Contact information

### Type(s)
Scientific

### Contact name
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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
PI-033/18

# Study information

### Scientific Title
Randomized controlled clinical trial on the influence of physiological, metabolic and anxiety parameters on high fidelity clinical simulation

### Acronym
ACSC-ax

## Study objectives
The anxiety that students endure when carrying out a case of advanced clinical simulation can influence the physiological and metabolic sphere.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 10/04/2018, Comité de Ética de la Investigación con medicamentos (CEIm) Area de Salud de Valladolid Oeste [Drug Research Ethics Committee of West Valladolid Health Region] (Río Hortega University Hospital, Dulzaina 2, 47012 Valladolid, Spain; +34 983 420 400; rconvi@saludcastillayleon.es), ref: PI033-18

## Study design
Double-blind randomized controlled clinical trial

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Metabolic and physiological fatigue

## Interventions
There are 4 simulation scenarios. Each case will be solved by two students, one will act as a team leader and the other as an assistant, solving the situation according to the pre-established protocols and procedures for the management of each pathology. The cases are of similar difficulty, and all have a maximum duration of 10 min.

Before starting any of the cases, it will be explained to the students that they must perform the techniques and procedures in the simulator as correctly as possible.

Once the students are in the debriefing classroom and have signed the informed consent, they must fill out a form to describe their basal level of anxiety (STAI questionnaire), and proceed to the baseline taking of heart rate, systolic and diastolic blood pressure, tympanic temperature, saliva pH, capillary lactic acid, and to fill in a brief epidemiological survey, asking about lifestyle habits (alcohol, tobacco, coffee, etc.). In addition, weight and height are measured and they perform the International IPAQ Physical Activity Questionnaire.

Through the XLAT BIOMED program a randomization of the clinical case that should be performed and the role (leader or assistant) was performed.

The clinical simulation scenarios proposed and that will be randomized are:
1. Young woman, with a poorly tolerated supraventricular tachycardia
2. Elderly woman, with a drug poisoning by benzodiazepines
3. Elderly male, in a coma due to a hypoglycemia situation
4. Young male, with arm and leg burns and smoke inhalation

At the end of the simulation and just before debriefing the two students who have done the case (team leader and assistant) perform a new STAI questionnaire and have heart rate, systolic and diastolic blood pressure, tympanic temperature, pH in saliva and capillary lactic acid measured again.

### Intervention Type
Behavioural

### Primary outcome(s)
1. Heart rate, assessed using a Physio LifePAK® 15 monitor, immediately before and after the simulation
2. Blood pressure, assessed using a Physio LifePAK® 15 monitor, immediately before and after the simulation
3. Tympanic temperature, assessed using a Braun model ThermoScan® PRO 6000, immediately before and after the simulation
4. Lactic acid levels, assessed using an Accutrend® Plus meter, immediately before and after the simulation
5. Saliva pH, assessed using saliva strips, immediately before and after the simulation
6. Level of anxiety, assessed using using the State-Trait Anxiety Inventory (STAI) questionnaire, immediately before and after the simulation
7. Level of physical activity, assessed using the International Physical Activity Questionnaire (IPAQ), immediately before and after the simulation

### Key secondary outcome(s))
The following are assessed before and after the simulation:
1. Anthropometric study, carried out with the Tanita BC541-N smart scale
2. Demographic data and lifestyle habits, assessed through a direct response questionnaire.

### Completion date
10/06/2021

## Eligibility

### Key inclusion criteria
1. Aged 18-65 years
2. Students of the Faculty of Medicine in the 4th, 5th or 6th year of the course

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
65 years

### Sex
All

### Key exclusion criteria
1. Basal heart rate greater than 120 or less than 35 beats per min
2. Systolic or diastolic blood pressure greater than 160 or 95 mmHg respectively
3. Systolic blood pressure less than 80 mmHg
4. Body mass index greater than 40 kg/m2
5. Severe visual or hearing impairment
6. Disability or injury that prevents the participant from physically conducting the simulation
7. Capillary hemoglobin less than 8 g/dl
8. Temperature greater than 38º C
9. Major surgery up to 30 days before
10. Cutaneous diseases in acute phase
11. Epilepsy
12. Anticoagulation
13. Infections in progress
14. Systemic immunological diseases

### Date of first enrolment
10/10/2019

### Date of final enrolment
23/12/2019

## Locations

### Countries of recruitment
Spain

### Study participating centre
**Valladolid University**
Faculty of Medicine
Advanced Clinical Simulation Center
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## Sponsor information

### Organisation

Universidad de Valladolid

**ROR**
https://ror.org/01fvbaw18

# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated and/or analysed during this study will be included in the subsequent results publication.

**IPD sharing plan summary**
Other

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 23/03/2025 | 24/03/2025 | Yes | No |