

# The operating room (OR) utility

<b>Submission date</b> 28/06/2014	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/08/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

First experiences in the operating room (OR) with real patients are always stressful and intimidating for health sciences students. We thought that a game-like simulation could improve how the students felt about, and how they performed, in the OR. An interactive videogame has been developed, with pictures and short videos, showing the students how to act when in the OR. The game also includes detailed descriptive information helpful to the students. After playing, students are given feedback on their performance. For this study, we want to see how this educational tool performs when tested with medical and nursing students with no previous OR experience.

### Who can participate?

Medical and nursing students, from 3rd and 2nd year respectively at the Complutense University of Madrid with no previous experience in the OR.

### What does the study involve?

Half of the students are randomly allocated to a control group (CG) and the other half to a study group (SG). Those in the SG play the game on the day before their first experience in the OR. Students in CG do not play the game. On the day after their OR experience, all students fill in a questionnaire about their experience in the OR. Students in the CG get to play the game after their first visit.

### What are the possible benefits and risks of participating?

Participants gain knowledge on how to move and behave, plus some descriptive information, about the OR. Both groups of students do play the game; SG before their first visit to the operating theatre, and CG after. There are no risks of participating.

### Where is the study run from?

The school of Medicine and Nursing of the Complutense University of Madrid (Spain)

### When is the study starting and how long is it expected to run for?

October 2012 to May 2014

### Who is funding the study?

1. Complutense University of Madrid (PIMCDs 2013-101 and 2014-161) (Madrid, Spain)

2. The Department of Surgery, School of Medicine, Complutense University of Madrid (Madrid, Spain)

Who is the main contact?

Dr Manuel Giner

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

### Scientific Title

Using a videogame to facilitate students first visit to the operating room: a randomized controlled trial

### Study objectives

A videogame may help to overcome the difficulties experienced by students at their first visit to the operating room

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics approval not required.

Students participation is entirely voluntary and performed with the informed consent of the participants. Students are orally informed about the nature of the study in which a new instructional method is investigated to the benefit of the students prior to its routine deployment. The intervention of the study (game playing and filling in a questionnaire) is not part of any examination, so that a participation or non-participation has no consequences on their grades. The ethics committee at our Medical School reviewed the project and concluded that a full formal ethics committee statement was not required, due to the educational nature of the study. Data analysis is anonymous. With the participation in the study, the students' agree on the anonymously analysis of their data. Students who do not like to participate can chose to deny participation without further consequences. Anonymous participation is document of the oral agreement of the students. This type of orally agreement employed in our study was discussed with the ethics committee which agreed on it. Due to practical reasons, a formal written consent prior to the study was not feasible.

**Study design**

Randomized controlled trial.

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Increasing students' confidence at their first visit to the OR with real patients

**Interventions**

Students were randomly allocated to one of two groups.

1. Study group: Played an interactive videogame one day before first experience in an operating room.
2. Control group: No access to the interactive video game before first experience in an operating room.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Fear at making mistakes
2. Perceived knowledge on how to behave
3. Perceived errors committed
4. Attitude/behavior towards patients and staff

### **Secondary outcome measures**

General opinion of the tool (videogame)

All outcome measures (primary and secondary) are measured via answers to a questionnaire in a 7-point Likert format a day after the students OR experience.

### **Overall study start date**

01/10/2012

### **Completion date**

30/05/2014

## **Eligibility**

### **Key inclusion criteria**

Medical and nursing students with no previous experience in the OR

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

130

### **Total final enrolment**

132

### **Key exclusion criteria**

Previous experience in the operating room.

### **Date of first enrolment**

01/10/2012

### **Date of final enrolment**

30/05/2014

## **Locations**

### **Countries of recruitment**

Spain

**Study participating centre**  
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## Sponsor information

**Organisation**  
Complutense University of Madrid (Spain)

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**Sponsor type**  
University/education

**Website**  
<http://www.ucm.es/cirugia>

**ROR**  
<https://ror.org/02p0gd045>

## Funder(s)

**Funder type**  
University/education

**Funder Name**  
Complutense University of Madrid (PIMCDs 2013-101 and 2014-161) (Madrid, Spain)

**Alternative Name(s)**

Complutense University of Madrid, UCM

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

Spain

**Funder Name**

The Department of Surgery, School of Medicine, Complutense University of Madrid (Madrid, Spain)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>		10/04/2013		Yes	No
<a href="#">Results article</a>		09/05/2017	08/11/2022	Yes	No