The operating room (OR) utility

Submission date 28/06/2014	Recruitment status No longer recruiting	<pre>[] Prospe [] Protoce</pre>
Registration date 01/08/2014	Overall study status Completed	[_] Statisti [X] Result
Last Edited 08/11/2022	Condition category Other	[] Individ

ectively registered

- ol
- ical analysis plan
- ะร
- lual 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 manginer@med.ucm.es

Contact information

Type(s) Scientific

Contact name Prof Manuel Giner

Contact details C/ Fernando Garrido, 11, bjo. A Madrid Spain 28015 +34 (0) 914450637 manginer@med.ucm.es

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 C/ Fernando Garrido, 11, bjo. A Madrid Spain 28015

Sponsor information

Organisation Complutense University of Madrid (Spain)

Sponsor details c/o Manuel Giner Department of Surgery School of Medicine Complutense University of Madrid Pza/ Ramón y Cajal s/n Madrid Spain 28040 +34 (0) 913941217 dp085@ucm.es

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?
Other publications		10/04/2013		Yes	No
Results article		09/05/2017	08/11/2022	Yes	No