

# Game-based learning for cultural safety training of Colombian medical students: a randomized controlled trial

<b>Submission date</b> 09/07/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/08/2024	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

In Colombia, the government primarily provides health services based on the Western biomedical model. However, 40% of the country's diverse population uses traditional medicine to maintain their health. The resulting gap between communities' expectations and physicians' skills could be bridged if medical training included cultural safety. Training in cultural safety encourages medical students to examine their own culture, how it shapes clinical practice, and to respect their patients' understanding of health and disease. Lack of cultural safety in health care is linked to health disparities, while the training itself provides challenges. It is an unappealing subject for medical students and requires behavioral changes in their clinical practice. Recent studies of game-based medical education suggest it could be effective and engaging for medical students and residents. The researchers aim to foster cultural safety in medical education through game-based training of medical students and family medicine residents in Colombia. In this study, game-based learning involves participating in a game jam, an 8-hour collaborative workshop to co-design and play educational games. In 2017, the researchers travelled to Colombia to co-design a curriculum for cultural safety training with input from traditional medicine users, medical students, and cultural safety experts, and to explore the feasibility and acceptability of using a game jam for cultural safety training. The aim of this study is to assess the impact of medical students' participation in a game jam, compared with a standard lesson on cultural safety.

### Who can participate?

Medical student or family medicine resident at any level of training at La Sabana University

### What does the study involve?

Medical students are randomly allocated to the intervention group or the control group. The intervention group participate in an 8-hour game jam comprised of: a preliminary lecture on cultural safety and game design; a game building session where groups of students create educational games based on the co-designed curriculum; and a play-test session in which

students play and learn from each others' games. The control group receive a 2-hour lecture on cultural safety, followed by a 6-hour reading session. Self-reported cultural safety behavior change is measured immediately following the teaching session and 6 months later.

What are the possible benefits and risks of participating?

Participation has educational value since students will learn about cultural safety and research methods. Furthermore, the results of this project will yield evidence to support cultural safety in medical education, as well as to develop research methods related to educational games co-design. End-outcomes include medical students with cultural safety skills, improved quality of health services, and enhanced overall population health. There are no anticipated risks to students by taking part in this study. However, the researchers are aware that research with students raises concerns regarding coercion and undue influence. In other words, students may feel influenced to participate in the study. Potential participants will be reminded that their participation in this study is entirely voluntary. Participating or refusing to participate in this study will not in any way affect the grades of participants in any course at La Sabana University.

Where is the study run from?

La Sabana University (Canada)

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

September 2016 to June 2020

Who is funding the study?

1. Fonds de Recherche du Québec – Santé
2. Ceiba Foundation

Who is the main contact?

Dr Juan Pimentel

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## Contact information

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## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

A05-B37-17B

## **Study information**

**Scientific Title**

Impact of co-designed game learning on cultural safety in Colombian medical education: a randomized controlled trial

**Acronym**

IGACSAT

**Study objectives**

In terms of self-reported behavior change, participating in a game jam for cultural safety training is more effective to train medical students and family medicine residents compared with a standard lesson on cultural safety.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Original approval on 31/05/2017; re-approval on 13/05/2019, Institutional Review Board of the McGill's Faculty of Medicine (McIntyre Medical Building, 3655 Promenade Sir William Osler, Montreal, Quebec, Canada H3G 1Y6; Tel: +1(0) 514 398 8302; Email: [ilde.lepore@mcgill.ca](mailto:ilde.lepore@mcgill.ca)), approval number A05-B37-17B

2. Approved 21/09/2018, Subcommittee for Research of the Faculty of Medicine at La Sabana University (Campus del Puente del Común, Km. 7, Autopista Norte de Bogotá. Chía, Cundinamarca, Colombia; Tel: +57 (0)861 5555; Email: pedro.sarmiento@unisabana.edu.co), approval number: 445

### **Study design**

Parallel-group two-arm randomized controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised parallel trial

### **Study setting(s)**

School

### **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**

Cultural safety training of undergraduate medical students and family medicine residents at La Sabana University

### **Interventions**

The intervention will consist of an 8-hour long game jam aimed at building a low-tech prototype of a serious game to foster cultural safety in medical education. The control will be an 8-hour long standard lesson on cultural safety. The researchers will use stratified randomization by level of training on cultural safety at baseline.

### **Intervention Type**

Behavioural

### **Primary outcome measure**

Students' self-reported behavior change, measured by responses to clinical scenarios indicating change in practice/action at baseline, immediately following the teaching session, and 6 months post-intervention. This uses a results chain of cultural safety, including conscious knowledge, attitudes, subjective norms, change intention, sense of agency, socialization/discussion, and behavior change/action. Primary outcomes are based on the CASCADA model of planned behavior.

### **Secondary outcome measures**

1. Students' confidence (transcultural self-efficacy) in their general transcultural skills is measured using the Transcultural Self- Efficacy Tool—Multidisciplinary Healthcare Provider (TSET-MHP) at baseline, immediately following the teaching session, and 6 months post-intervention
2. A qualitative understanding of the impact of the intervention in the clinical practice of medical

students and family medicine residents is measured using the qualitative Most Significant Change narrative technique to collect and analyze stories of change from the medical students and family medicine residents 6 months after the intervention

**Overall study start date**

05/09/2016

**Completion date**

30/06/2020

## **Eligibility**

**Key inclusion criteria**

1. Medical student or family medicine resident at any level of training at La Sabana University
2. Giving informed consent

**Participant type(s)**

Health professional

**Age group**

Adult

**Sex**

Both

**Target number of participants**

330

**Total final enrolment**

531

**Key exclusion criteria**

Not wanting to participate in the study

**Date of first enrolment**

15/07/2019

**Date of final enrolment**

24/07/2019

## **Locations**

**Countries of recruitment**

Colombia

**Study participating centre**

**La Sabana University**

Campus del Puente del Común, Km. 7, Autopista Norte de Bogotá

Chia  
Colombia  
53753

## Sponsor information

### Organisation

Ceiba Foundation

### Sponsor details

Carrera 13A # 29-24 Torre Empresarial Allianz  
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### Sponsor type

University/education

### Website

<https://www.ceiba.org.co>

### Organisation

La Sabana University

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### Sponsor type

University/education

### Website

<https://www.unisabana.edu.co/programas/carreras/facultad-de-medicina/medicina/>

## Funder(s)

Funder type

Government

**Funder Name**

Fonds de Recherche du Québec - Santé

**Alternative Name(s)**

Fonds de la recherche en sante du Quebec, FRQS

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

Canada

**Funder Name**

Ceiba Foundation

## Results and Publications

**Publication and dissemination plan**

Diffusion plan: targeting medical students, family medicine residents, and cultural safety experts: The researchers will invite stakeholders to be co-authors of at least one peer-reviewed manuscript in an open access journal. They plan to publish the study protocol, the quantitative findings and the qualitative findings. Similarly, they will invite stakeholders to submit their work and to attend at least two relevant national or international conferences on topics related to the study. The deadline for publishing these articles and attending conferences is September 2021.

Dissemination plan: intended for traditional medicine users: The researchers will invite end-users (medical students) to develop and circulate a lay report to share findings, reaching all stakeholders. Moreover, they will visit Cota to share the results in a tailored format that will include input from the intercultural health experts.

**Intention to publish date**

31/12/2021

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of agreement with the participants of the study.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		31/08/2020	25/05/2020	Yes	No
<a href="#">Results article</a>	Quantitative results	25/02/2021	01/03/2021	Yes	No
<a href="#">Results article</a>	Qualitative results	10/09/2022	12/09/2022	Yes	No
<a href="#">Results article</a>		13/05/2021	05/08/2024	Yes	No