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

Submission date	Recruitment status	Prospectively registered		
09/07/2019	No longer recruiting	[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
18/07/2019	Completed	[X] Results		
Last Edited 05/08/2024	Condition category	[] 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 codesign. 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
juan.pimentel@mail.mcgill.ca

Contact information

Type(s)

Scientific

Contact name

Dr Juan Pimentel

ORCID ID

https://orcid.org/0000-0002-6842-3064

Contact details

5858 Chemin de la Côte-des-Neiges Montreal Canada H3S 1Z1 +1 (0)5146052590 juan.pimentel@mail.mcgill.ca

Type(s)

Public

Contact name

Dr Juan Pimentel

ORCID ID

https://orcid.org/0000-0002-6842-3064

Contact details

5858 Chemin de la Côte-des-Neiges Montreal Canada H3S 1Z1 +1 (0)5146052590 juan.pimentel@mail.mcgill.ca

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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), 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

Study type(s)

Other

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(s)

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.

Key secondary outcome(s))

- 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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Organisation

La Sabana University

Funder(s)

Funder type

Government

Funder Name

Fonds de Recherche du Québec - Santé

Alternative Name(s)

Fonds de Recherche du Québec - Sante, Fonds de la recherche en sante du Quebec, Fonds de Recherche du Québec - Santé, Fonds de Recherche du Québec - Santé (FRQS), SciChefQC, FRQS

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Canada

Funder Name

Ceiba Foundation

Results and Publications

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	l Date added	Peer reviewed?	Patient-facing?
Results article	Quantitative results	25/02/2021	01/03/2021	Yes	No
Results article	Qualitative results	10/09/2022	12/09/2022	Yes	No

Results article	13/05/2021	05/08/2024 Yes	No
Protocol article	31/08/2020	25/05/2020 Yes	No
Participant information sheet	11/11/2025	11/11/2025 No	Yes