Cultural Safety in Medical Education: transformative learning through co-designing serious games in Colombia

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ABSTRACT

Background: Cultural safety encourages health practitioners to examine how their own culture shapes their clinical practice; it proposes they should respect patient worldviews. Lack of cultural safety in health care is linked to stigma and discrimination towards patients from non-dominant cultures. Multicultural Colombia is a useful setting for cultural safety research, with potential lessons for Canada and other countries. The Colombian government supports health services firmly based on the Western biomedical model yet 40% of the population turn to traditional medicine for their health care. The resulting gap between communities' expectations and physicians' skills could be more effectively bridged if medical education included cultural safety training. A challenge facing cultural safety education is that health professionals are seldom motivated to interact with traditional medicine. *Game jams*, collaborative workshops to create and play games, have the potential to be engaging and effective in university-level education.

Objective: foster cultural safety in medical training through game jam education of medical students and interns in Colombia. In this project, game jam learning involves participating in a game jam to create educational games about cultural safety.

Methods: This was a multi-study program of participatory research. (1) A scoping review mapped current knowledge on cultural safety in health sciences education with a focus on game-based learning; (2) Two exploratory community-based transformative learning interventions explored the feasibility and acceptability of cultural safety training in Colombia. A sequential-consensual qualitative study informed by the community-based interventions developed a consensus about the key elements for a curriculum for cultural safety training: focus groups explored the opinions of traditional medicine users, medical students, and cultural safety experts about the content of the curriculum; deliberative dialogue between key cultural safety experts settled the academic content of the curriculum. (3) A pilot randomized controlled trial examined the feasibility and acceptability of conducting a trial of game jam learning for cultural safety training. (4) A parallel group randomized controlled trial measured the impact of game jam learning compared with a standard lecture plus workshop for cultural safety training of medical

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students on outcomes of self-reported intended patient-oriented behavior and transcultural self-efficacy. The narrative Most Significant Change technique explored the impact of the intervention on supervised clinical experience of the trainees.

Results: (1) The scoping review allowed me to document research designs and methods to inform the design of my trial, identify and address research gaps in the existing literature, and summarize and share examples of educational games with the participants of the trial to support the game design process. (2) The two community-based experiences showed that cultural safety training through community-based transformative learning is feasible and accepted by Colombian medical students. The co-designed curriculum included five learning objectives: to acknowledge intercultural tensions and their consequences; to examine students' own attitudes, beliefs, and values, and how they shape their professional practice; to listen and learn from patients about their traditional practices; to describe and compare current pedagogical approaches to intercultural tensions; and to discuss and agree treatment options with patients. The co-designed curriculum informed the lectures of both the intervention and control group in the full-scale trial. (3) Some 79 medical students participated in the pilot trial. The study allowed me to explore the acceptability and feasibility of cultural safety training through a game jam, pilot research methods, gain the support of the academic staff to conduct the full-scale trial, and acquire the skills needed to conduct a full-scale game jam trial. (4) In the full-scale trial, 531 students completed the baseline survey and were randomised. After the intervention, game jam participants did not report better intended culturally safe behaviour compared with participants in the control group who attended a lesson and interactive workshop (difference in means: 0.08; 95% Confidence Interval -0.05 to 0.23). Game jam learning was associated with higher transcultural self-efficacy immediately after the intervention (weighted OR 2.03; cluster adjusted 95% CI 1.25 - 3.30). Separately, both the game jam and the lesson plus workshop improved intended culturally safe behaviour (primary outcome) and transcultural self-efficacy (secondary outcome). The participants' narratives illustrated the impact of cultural safety training on a range of outcomes from conscious knowledge to action.

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Conclusion: The research developed participatory methods to design and conduct cultural safety training interventions for medical trainees. It applied the cultural safety approach outside the Indigenous experience and with a focus on traditional medicine. The project explored two different teaching vehicles based on transformative learning (community-based learning and game jam learning) and provided quantitative and qualitative evidence about the efficacy of cultural safety training. This innovative solution to a long-standing and neglected problem in medical education helped to meet the educational expectations and needs of Millennial medical students.

RÉSUMÉ

Contexte: La sécurité culturelle encourage les professionnels de la santé à examiner comment leur propre culture façonne leur pratique clinique, et à respecter le point de vue des patients. L'absence de sécurité culturelle dans les services de santé est liée à la stigmatisation et à la discrimination envers les patients de cultures non dominantes. La Colombie, un pays multiculturel, est un cadre utile pour la recherche sur la sécurité culturelle et peut donc offrir des leçons potentielles pour le Canada et d'autres pays. Le gouvernement colombien offre des services de santé foncièrement basés sur le modèle biomédical occidental, pourtant, près de 40% de la population utilisent la médecine traditionnelle pour leurs soins de santé. L'écart entre les besoins des communautés et les compétences des médecins pourrait être comblé en ajoutant la sécurité culturelle à l'éducation médicale. L'un des défis de l'éducation à la sécurité culturelle est le manque de motivation des professionnels de la santé à interagir avec la médecine traditionnelle. Les *game jams*, ateliers collaboratifs pour créer et jouer à des jeux, ont le potentiel d'être plus engageants et efficaces que l'éducation standard de l'enseignement universitaire.

Objectif: encourager la sécurité culturelle dans la formation médicale à l'aide d'une formation basé sur le *game jams* avec des étudiants en médecine et des stagiaires en médecine en Colombie. Dans ce projet, l'apprentissage basé sur le *game jams* consiste à participer à un *game jam* pour créer des jeux éducatifs sur la sécurité culturelle.

Méthodes: ce projet comportait plusieurs études participatives. (1) Un examen de la portée a permis de cartographier les connaissances actuelles sur les jeux éducatifs pour encourager la sécurité culturelle dans l'enseignement des sciences de la santé; (2) Deux interventions d'apprentissage transformateur communautaire ont exploré la faisabilité et l'acceptabilité de la formation sur la sécurité culturelle en Colombie. Une étude qualitative séquentielle-consensuelle basée sur les interventions communautaires a permis de dégager un consensus sur les éléments clés d'un programme de formation à la sécurité culturelle : les groupes de discussion ont permis de prendre en compte les opinions des utilisateurs de la médecine traditionnelle, des étudiants en médecine et des experts en sécurité culturelle sur le contenu du programme; ensuite, un dialogue délibératif entre les experts en sécurité

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culturelle a permis de définir le contenu académique du programme. (3) Un essai randomisé contrôlé pilote a examiné la faisabilité et l'acceptabilité de mener un essai d'apprentissage *de game jam* pour la formation à la sécurité culturelle. (4) Un essai contrôlé randomisé en groupe parallèle a mesuré l'impact de l'apprentissage du *game jam*, par rapport à un cours standard en plus d'un atelier de formation à la sécurité culturelle des étudiants en médecine, sur les résultats du comportement autodéclaré destiné au patient et de l'auto-efficacité transculturelle. La technique narrative du changement le plus significatif a exploré l'impact de l'intervention sur l'expérience clinique supervisée des étudiants et stagiaires en médicine.

Résultats: (1) L'examen de la portée m'a permis de documenter les conceptions et les méthodes de recherche pour éclairer la conception de mon essai randomisé contrôlé, identifier et combler les écarts de recherche dans la littérature existante, et résumer et partager des exemples de jeux éducatifs avec les participants de l'essai pour soutenir le processus de création de jeux. (2) Les deux expériences communautaires ont montré que la formation à la sécurité culturelle basé sur l'apprentissage transformateur communautaire est faisable et acceptée par les étudiants en médecine colombiens. Le programme co-concu comprenait cinq objectifs d'apprentissage: reconnaître les tensions interculturelles et leurs conséquences; examiner les attitudes, les crovances et les valeurs des apprenants et la manière dont ils façonnent leur pratique professionnelle; écouter et apprendre des patients sur leurs pratiques traditionnelles; décrire et comparer les approches pédagogiques actuelles des tensions interculturelles; et discuter et convenir des options de traitement avec les patients. Le programme co-conçu a informé les leçons pour les groupes d'intervention et de contrôle dans l'essai contrôlé randomisé. (3) 79 étudiants en médecine ont participé à l'essai pilote. L'étude m'a permis d'explorer l'acceptabilité et la faisabilité d'une formation à la sécurité culturelle à travers un *game jam*, de piloter les méthodes de recherche, obtenir le soutien du personnel académique pour mener l'essai et acquérir les compétences nécessaires pour mener un essai de *game jam* à grande échelle. (4) Dans l'essai contrôlé randomisé, 531 étudiants ont répondu à l'enquête de base et ont été randomisés. Après l'intervention, les participants au *game jam* n'ont pas rapporté un meilleur comportement culturellement sécuritaire comparativement aux participants du

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groupe témoin qui ont assisté à une cours et à un atelier interactif (différence de moyenne: 0,08; intervalle de confiance à 95% de -0,05 à 0,23). L'apprentissage du *game jam* était associé à une auto-efficacité transculturelle plus élevée immédiatement après l'intervention (OR pondéré 2,03; IC à 95% ajusté par conglomérats 1,25 - 3,30). Séparément, le *game jam* et le cours plus l'atelier ont amélioré le comportement culturellement sécuritaire (résultat principal) et l'auto-efficacité transculturelle (résultat secondaire). Les histoires des participants ont illustré l'impact de la formation sur la sécurité culturelle sur une gamme de résultats allant de la connaissance consciente à l'action.

Conclusion: Cette recherche a permis de développer des méthodes participatives pour concevoir et mener des interventions de formation à la sécurité culturelle pour les étudiants et stagiaires en médecine, tout en appliquant l'approche de la sécurité culturelle en dehors de l'expérience autochtone et en mettant l'accent sur la médecine traditionnelle. Le projet a exploré deux méthodes d'enseignement différents basés sur l'apprentissage transformateur (apprentissage communautaire et apprentissage de *game jam*) et a fourni des preuves quantitatives et qualitatives sur l'efficacité de la formation sur la sécurité culturelle. Cette solution innovante à un problème de longue date et négligé dans l'éducation médicale a aidé à répondre aux attentes et aux besoins éducatifs des étudiants en médecine appartenant à la génération millénaire.

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LIST OF ABBREVIATIONS

CASCADA	Conscious knowledge, Attitudes, positive deviation from negative Subjective norms,
	Change intention, sense of Agency, Discussion, and change in practice/Action
CEMI	Center of Intercultural Medical Studies
CONSORT	Consolidated Standards of Reporting Trials
GEE	Generalized estimating equation
GESTS	Traditional Health Systems Studies Group
NAPCRG	North American Primary Care Research Group
NGO	Non-governmental Organization
PICOT	Population, intervention, contrast, outcome, and timing
PRISMA-ScR	PRISMA extension for reporting scoping reviews
RCT	Randomised Controlled Trial
SCQS	Sequential-Consensual Qualitative Study
SD	Standard Deviation
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
STEAM	Science, technology, engineering, arts, and mathematics
TSET-MHP	Transcultural Self- Efficacy Tool—Multidisciplinary health care Provider
US	United States
WFME	World Federation of Medical Education

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DEDICATION

"The crown of feathers is a privilege earned after years of tests and arduous training that demand concentration, special diets, long vigils and days and nights of dances and ceremonies. It is gained through effort and dedication, and by showing a willingness to serve others. The crown is sacred because it enables communication with the world of the Spirit to be able to receive its knowledge and advice. As long as there are shamans and apprentices performing their duties during traditional ceremonies, the forest will remain healthy, and the gifts it provides will be available for the wellbeing of the community."¹

I dedicate this work to those who have earned the privilege of wearing the crown of feathers, a path that is way more difficult than getting a doctoral degree. I hope this research contributes to honouring and strengthening traditional knowledge and its bearers. Every day I feel privileged to have learned valuable lessons from the crown holders.

To my beloved wife, Cass Laurie, and our nascent family...

To my mom, Elizabeth, dad, Rodrigo, and brothers, Alejandro and Manuel ...

PREFACE

Contribution to original knowledge

This is a manuscript-based dissertation comprised of nine articles. My dissertation is an original contribution to the field of cultural safety in medical education. It uses a participatory research approach² and transformative learning theory³ to co-design a cultural safety training experience for Colombian medical students and interns. Manuscript 1 is the first published knowledge synthesis summarizing the evidence about game-based learning interventions to foster cross-cultural care training.* Manuscripts 2 and 3 are one of the first experiences applying the concept of cultural safety outside the Indigenous experience, with a focus on traditional medicine users from Cota, Colombia. These studies represent the first reported experiences of cultural safety training in Colombia. Manuscripts 4 and 5 describe the experience of Colombian traditional medicine users, medical students, and cultural safety experts co-designing a consensus of key elements for a cultural safety curriculum in medical education. These papers represent one of the first attempts to apply active participation⁴, inherent in cultural safety, to engage knowledge users in co-designing culturally safe interventions. Manuscripts 6 to 9 report the first randomised controlled trial of an intervention to promote cultural safety in medical education, and the first study to examine the role of game jam learning in medical education.

Contribution of authors

Manuscript 1: Game-based learning interventions to foster cross-cultural care training: a scoping review (published in *Games for Health Journal*)

Juan Pimentel, Alexandra Arias, David Ramírez, Adriana Molina, Anne-Marie Chomat, Anne Cockcroft, Neil Andersson

^{*} I use the term cross-cultural training as an umbrella term to include the large lexicon of terms aligned with cultural safety, including cultural competence, cultural sensitivity, cultural humility, cultural awareness, cross-cultural medicine, culturally congruent care, and culturally responsive care.

JP designed and conducted the scoping review, synthesized and interpreted the findings, and wrote the manuscript. AA, DR, and AM provided input on methodology, and participated in the screening of potential publications and data extraction. A-MC, AC, and NA provided input on methodology. All authors provided feedback and approved the final version of the manuscript.

Manuscript 2: What motivates medical students to learn about traditional medicine? a qualitative study of cultural safety in Colombia (published in the *International Journal* of Medical Education)

Juan Pimentel, Iván Sarmiento, Germán Zuluaga, Neil Andersson

JP designed this study, led the community-based intervention, synthesized and interpreted the findings, and wrote the manuscript. IS and GZ provided input on methodology, participated in the study activities, and supported the data analysis. NA provided input on methodology. All authors provided feedback and approved the final version of the manuscript.

Manuscript 3: The experience of Colombian medical students in a pilot cultural safety training program: a qualitative study using the most significant change technique (published in *Teaching and Learning in Medicine*)

Juan Pimentel, Camila Kairuz, Claudia Merchán, Daniel Vesga, Camilo Correal, Germán Zuluaga, Iván Sarmiento, Neil Andersson

All the authors designed the study, conducted the analysis, and wrote the manuscript. JP, CM, DV, CK, IS, and CC conducted the community-based intervention. JP, CM, DV, and CK collected the data of the study. All the authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Manuscript 4: Curriculum co-design for cultural safety training of medical students in Colombia: protocol for a qualitative study (published in *Advances in Intelligent Systems and Computing*)

Juan Pimentel, Germán Zuluaga, Andrés Isaza, Adriana Molina, Anne Cockcroft, Neil Andersson JP designed this study and wrote the manuscript. GZ, AI, AM, AC, and NA provided input on methodology. All authors provided feedback and approved the final version of the manuscript.

Manuscript 5: A co-designed curriculum for cultural safety training of Colombian health professionals: sequential-consensual qualitative study (under review in *Medical Science Educator*)

Juan Pimentel, Camila Kairuz, Lilia Suárez, Andrés Cañón, Andrés Isaza, Germán Zuluaga, Anne Cockcroft, Neil Andersson

JP designed this study, collected and analysed the data, synthesized and interpreted the findings, and wrote the manuscript. CK and LA supported the data collection and analysis, and the interpretation of the findings. AC, AI, GZ, AC, and NA provided input on methodology, and supported the interpretation of the findings. All authors provided feedback and approved the final version of the manuscript.

Manuscript 6: Game jams for cultural safety training in Colombian medical education: a pilot randomised controlled trial (under review in *BMJ Open*)

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NA and AC advised on the development of the study. JP led the study design and coordinated the fieldwork. JP drafted the manuscript and all authors adjusted it. All authors read and approved the final manuscript.

Manuscript 7: Impact of co-designed game learning on cultural safety in Colombian medical education: protocol for a randomised controlled trial (published in the *Journal* of Medical Internet Research)

Juan Pimentel, Anne Cockcroft, Neil Andersson

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Manuscript 8: Impact of game jam learning on cultural safety in Colombian medical education: a randomised controlled trial (under review in *BMC Medical Education*)

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NA and AC advised on the development of the study. JP led the study design and coordinated the fieldwork. JP drafted the paper and all authors contributed to it. All authors read and approved the final manuscript.

Manuscript 9: The most significant change described by Colombian medical trainees after cultural safety training through transformative learning: qualitative results from a randomised controlled trial (will be submitted to *Medical Education*)

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NA and AC advised on the development of the study. JP led the study design and coordinated the fieldwork. PL supported the data analysis and the interpretation of the findings. JP drafted this paper and all authors adjusted it. All authors read and approved the final manuscript.

CHAPTER 1 INTRODUCTION

Failing to consider the relationship between culture and health outcomes in medical education is linked to stigma and discrimination towards patients from non-dominant cultures.^{5,6} Several systematic reviews have looked at the effects of stereotypes, prejudices and/or discrimination against minority groups. Reported findings include lower levels of healthcare-related trust, patient satisfaction, adherence to treatment uptake, and delaying or not seeking healthcare.⁷ Effects on patient-related outcomes include poorer mental and general health, and poorer physical health.⁸ The 2002 Institute of Medicine⁵ report described sources of health disparities including cultural barriers, prejudice, and bias against patients from non-dominant cultures. Researchers and educators have called attention to the need to address adversarial intercultural interactions in health care.

In its review of Primary Health Care in 1978, the World Health Organization called for collaboration between Western and traditional medicine, recognizing the inextricable relationship between culture and health outcomes.⁹ Along with other countries,¹⁰ Colombia confirmed the government's commitment to primary health care and included the intercultural approach as a core element of health development (Article 13, law 1438 of 2011). These legal instruments, however, have not affected every-day medical practice. Lack of training opportunities to prepare health professionals to interact with patients from non-dominant cultures has largely forestalled culturally appropriate delivery of health services.^{11,6}

There is growing agreement about the need to train medical students to provide care that is congruent with the culture of patients.^{12,13} The 2021 Standards for Accreditation of Medical Education Programs in Canada,¹⁴ for example, calls for training to: (a) prepare medical students to recognize how people from non-dominant cultures perceive health and illness and respond to treatments; (b) acknowledge and address personal biases; (c) develop intercultural skills; and (d) identify and address health care disparities related to culture.

Cultural safety training encourages medical students and practitioners, in a culturally congruent way, to acknowledge the validity of their patients' worldviews and beliefs, including traditional medicine. This type of training has recently gained attention among researchers and educators. The Royal College of Physicians and Surgeons of Canada, for example, will soon require all residency programs to include cultural safety training in their curriculums.¹⁵ The College of Family Physicians of Canada proposed the Patient's Medical Home model¹⁶ as the vision for the future of primary care. In its 2019 version, one of the 10 pillars -community adaptiveness and social accountability- included the cultural safety training, few initiatives have been successfully implemented.^{15,17}

1.1 Cultural safety training in Colombia

Multicultural Colombia is an ideal setting for researching cultural contexts in medical training. The Colombian population comprises Afro-Colombians (including *Raizal* and *Palenqueros*, 11%), Amerindian (4%), *Mestizo* (Indigenous and Spanish mix, 64%), and White (21%).¹⁸ Some 65 Amerindian languages, two creole languages, and the Romani language are spoken in the country, which is home to 102 Indigenous groups.¹⁹ The government provides health services based on the Western biomedical model. In contrast, up to 40% of the population seek care in traditional medicine,²⁰ creating a care gap between the communities' expectations and needs, and the physicians' knowledge and skills. This gap is not harmless; it leads to a confrontation with, and discrimination against patients from non-dominant cultures, thus hindering their access to acceptable and effective health services.²¹ Negative attitudes towards traditional medicine users promote cultural destruction and increased dependence on Western health services.²²

Medical schools could help address adversarial interactions between health professionals and traditional medicine users by offering cultural safety training. Unfortunately, this type of education is not currently available in Colombia. My thesis is the first cultural safety medical education initiative in the country.

Cultural safety education of medical students is challenging and recent studies call for strategies to increase student engagement.²³ Educators might find cultural safety complicated to teach and medical students might perceive it to be dull.²⁴ Millennial students have novel ways of learning that include technology, creativity and amusement.^{25,26} Contemporary medical training is overloaded, with little space to include new subjects. Finally, cultural safety must promote a *transformative* experience if it is to impact student behavior in clinical practice.²⁷ To address these challenges, my thesis explored game-based cultural safety training for Millennial medical students and interns in Colombia.

CHAPTER 2 LITERATURE REVIEW

An early contributor to cross-cultural care training was Madeleine Leininger, a nurse theorist and anthropologist who noticed the missing relationship between culture and health outcomes in the nursing care practice and education.²⁸ In the 1960s, Leininger coined the term *culturally congruent care* to call attention to the need to reconsolidate Indigenous and outsider care phenomena²⁹ to increase the quality of Western nursing care.

Promoting medical training to meet the cultural characteristics of patients has been a concern since the 1980s. Medical educators have implemented educational programs under a wide variety of terms, such as cultural competence, cultural sensitivity, cultural awareness, and cultural humility.³⁰ A lack of agreement on the meaning of these terms has historically led to difficulties in their implementation and assessment.³¹

Cultural competence is the most popular approach to cultural diversity in healthcare around the world, especially in the US.³² The official recognition of the need to provide cultural competence training to medical students, however, is recent. In 2015 and 2017, the Committee on Accreditation of Canadian Medical Schools¹⁴ and the Liaison Committee on Medical Education,¹² called for cultural competence training, respectively.

2.1 Cultural competence

Cultural competence emerged in the US in the 1980s in recognition of the increasing health disparities of minorities,⁵ including Black, Hispanics, Asians, and Indigenous.³³ A widely cited definition of cultural competence is: "a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals and enable that system, agency, or those professionals to work effectively in cross-cultural situations."(p13)³⁴

There are different interpretations of how to implement cultural competence in practice. Kirmayer³⁰ described two levels: the practitioner level and the institutional level. The most common approach, "ethnic matching," seeks to pair physicians and patients by race, for example, a Black patient with a Black practitioner. Other examples of cultural

competence include the 'Do's and don'ts' lists to care for specific cultural groups of patients³⁵ and the use of translators in health encounters.³⁰

Many educators have implemented cultural competence training across the world. In the Netherlands, Harmsen³⁶ implemented a 2.5-day lecture-based program for general practitioners with a follow-up session after two weeks. The educational content addressed models of health and illness, cultural competence, and health disparities. In Southern Ontario, Majumdar³⁷ implemented a 36-hour program targeting nursing and home care providers. The training was on cultural awareness and cultural sensitivity. In Massachusetts, US, Sequist³⁸ led a two-day training program for primary care physicians, nurse practitioners, and physicians assistants. The program was based on a mix of lectures, group discussions, and community engagement activities and delivered content on cultural competence, health disparities, racism and prejudice, and models of health and disease.

Five systematic reviews have assessed the impact of cultural competence training programs for health professionals.^{31,39–42} The reviews reported positive results, including increased patient satisfaction, mutual understanding between patients and health professionals, adherence to treatment, and improved knowledge, attitudes, and skills of medical students. Despite these benefits, many have criticized the concept on the basis of stereotyping and oversimplification of culture.³⁰ For example, checklists to care for specific cultural blocks of patients may promote stereotyping, and ethnic matching and use of translators reduce culture to a skin color or language. Betancourt argued that the common element in cultural competence training is teaching about the attitudes, values, beliefs, and behaviour of non-dominant cultures, *the other*.⁴³ Pon writes about this with a clearly negative view, "cultural competence resembles new racism both by otherizing non-whites and by deploying modernist and absolutist views of culture while not using racialist language." (p60)⁴⁴

One practical implication of cultural competence, implemented in this way, is that it does not affect the asymmetrical power relation between patients and health professionals. Addressing the power dynamics in health care, however, requires a deeper understanding of the role that culture plays in health care. It requires recognizing the power imbalances

between practitioners and patients, and the epistemic racism (the positioning of the knowledge of one racialized group as superior to another)⁶ that non-dominant cultures have experienced through history. Similarly, it requires promoting dialogue between health care providers and patients from non-dominant cultures, where both parties are able to share and blend their knowledge systems so that the quality of the relationship, and consequently the quality of the health care, improves.

The relatively newly popularised concept of *cultural safety*⁴⁵ goes beyond cultural competence, insisting that patients from non-dominant cultures should have an opportunity to bring their cultural strengths and experiences to enhance the quality of health care.⁴⁶

2.2 Cultural safety

Irihapeti Ramsden developed the concept of cultural safety⁴⁷ in the 1980s in New Zealand in response to the increasing discontent of Māori Indigenous people with the imposition of Western worldviews in government health services. A central concern was that health services were disconnected from the cultural background and traditional practices of the Māori people. Although cultural safety is an evolving concept that lacks a formal definition,⁴⁸ it is commonly described as a space "that is spiritually, socially, emotionally and physically safe for people; where there is no assault, challenge or denial of their identity, of who they are, and what they need."(p272)⁴⁹

Cultural safety goes well beyond cultural competence, reflecting a deeper understanding and respect of culture *as an asset*.³² The concern is not only about how to increase the fit of Western service delivery/supply among "*those others*"; it requires inviting patients and their communities to bring their cultural strengths, their interpretations of health and disease, to co-construct better health systems to achieve improved health outcomes. Cultural safety embraces *dialogue* between patients and physicians to make joint decisions and especially provides a space for patients to judge whether the interaction is culturally safe or not.⁵⁰ Increasing awareness of cultural safety in medical education would yield the benefits of cultural competence, but also acknowledge the power relationships that occur in practice while accepting the legitimacy of diversity in

human societies.⁴⁶ Such a shift in practice would facilitate the transition to a more equitable and client-centred provision of health services, simultaneously reaffirming the communities' right to self-determination and providing respectful services free of colonized perspectives.

Bozorgzad⁵¹ clarified cultural safety by using the Rodgers' evolutionary concept analysis method.⁵² The first attribute described by the author was biculturalism. Cultural safety should be contextualized by interactions between two cultures. In New Zealand for example, biculturalism was rooted in postcolonial theory and was concerned with interactions between two groups: the colonizer and the colonized. In a broader view, Bozorgzad argues that biculturalism refers to cultural interactions between caregivers and the recipient of care and that "the lack of convergence between the two cultures shifts the power to the caregiver."(p35)⁵¹

The second attribute was critical self-reflection. As opposed to cultural competence, self-awareness of health professionals in cultural safety is more important than learning about the culture of patients. This entails caregivers who are aware of their "invisible baggage," or the attitudes, beliefs, and values that they bring to each clinical encounter and that shape their practice. ^{47,48}

Respecting rights, dignity, and recognition was the third attribute. Bozorgzad cited Smye⁵³ to explain that health care is culturally safe when health professionals are able to respect the wishes of patients, that are rooted in their beliefs. Cultural safety, however, goes beyond the beliefs of patients to include age, gender, race, social class, and economic and political status.

Attention to the recipient of care means that service users and their communities are the ones who define what cultural safety is and whether the service provided was culturally safe or not. Health providers can never claim that their care is culturally safe; it is the patient who has the last word.⁵⁴

Cultural safety is an emerging field and scientific evidence on its benefits for health professionals and service users is scarce.⁵⁰ Cultural safety education has featured mainly in nursing programs from New Zealand, Australia and, more recently, Canada, and its

implementation in medical education is still limited.¹⁷ At McGill University, Laurence Kirmayer leads regular workshops to train psychiatrists on the core values of cultural safety, to change the way they relate to patients from non-dominant cultures.⁵⁵ At the University of Otago in New Zealand, medical educators offer a cultural immersion program with Māori Indigenous people for third-year medical students.⁵⁶ The San'yas Indigenous Cultural Safety Training Program, an online course for health professionals, is offered in British Columbia.⁵⁷

Cultural safety training has mostly focused on the consequences of colonization and the resulting power dynamics on Indigenous populations.⁵⁰ Cultural safety initiatives outside the ethnic experience and the role of traditional medicine in assuring a culturally safe clinical practice have received little attention.

In summary, cultural competence was developed by researchers in the US in response to increasing health disparities between the White population and racial minorities, while cultural safety was developed by Māori Indigenous people in response to their increasing discontent with the imposition of Western worldviews in health services. Consequently, most interventions based on cultural competence are top-down, while cultural safety is defined by end-users. Cultural competence sees culture *as a way* to reach people from non-dominant cultures and cultural safety sees culture as an *asset* to address health problems. There is more evidence about cultural competence because it has been widely implemented, mostly in the US. Criticisms of cultural competence include its utilitarian and superficial understanding of culture, while cultural safety gets criticized for lacking quantitative evidence of benefits. While the first step in cultural competence is learning about the other culture -the do's and don'ts list-, cultural safety promotes self-reflection to confront ethnocentrism. Finally, cultural safety recognizes the colonial, historical, and sociopolitical context in which health disparities are produced and perpetuated.

2.3 Game-based learning in medical education

There are several challenges to promoting cultural safety in medical education. Cultural safety is not necessarily enjoyable for people who feel entitled, intelligent, motivated and

well-informed.^{24,58} To this perhaps timeless characterisation of Western medical students, the digital age has added a new twist. Many contemporary medical students have grown up with the generational challenges and opportunities of the Millennial generation²⁵ (one definition of Millennial refers to the birth cohort between 1979 and 2000).⁵⁹

The functional issue is that the exposure of this generation to massive informational input from digital media, and their unchallenged belief in their right and their ability to choose between information bytes, results in Millennials having special learning relationships with technology, creativity, and amusement.²⁵ Yet outside of medical and surgical simulations, modern medical education pays little attention to this opportunity for learning. Game learning may be effective in transmitting content where traditional methods have failed due to motivational problems.^{60,61}

Educational games in medical education

An educational or serious game is a teaching method requiring the student to participate in a competitive activity with predetermined rules.⁶² A recent report on emerging technologies for teaching and learning,⁶³ identified four categories of serious games: role-playing or simulations, which aim to replicate real-life situations in a fully interactive environment (e.g. surgery simulators); virtual environments, which are usually web-based applications (e.g. Second Life); social and cooperative games (e.g. board games); and alternative reality games, which blend gameplay and real life.

Examples of serious games in medical education include "The Phenytoin Game,"⁶⁴ a video game for teaching phenytoin dosage to medical students; "Pediatric jeopardy,"⁶⁵ a jeopardy-style game for pediatric residents designed to foster evidence-based clinical practice; "T- and B-Cell Ontogeny Game,"⁶⁶ a board game for teaching medical students about immunology; and "Lego® Activity,"⁶⁷ a game based on Lego® bricks for medical students to improve the doctor/patient relationship.

Serious games provide the players with an opportunity to immerse themselves in a risk-free, interactive, and engaging environment. In this context, the learner assimilates theoretic knowledge while simultaneously applying the concepts learned.⁶⁸ The interaction activates positive emotions that increase the engagement potential and learning

effectiveness for students.⁶⁹ Three systematic reviews confirm the beneficial effects of using serious games in medical education.^{70–72} No firm conclusions about the long-term impact of educational games on professional performance and/or patient outcomes were reported, and the authors strongly recommended further research on the topic.

2.4 Game jam learning

Game jams are participatory events that allow attendees to create games in a timeconstrained environment.⁷³ These complex interventions, typically aimed at creating video games, involve a mix of actions and opportunities for participatory learning. For example, Musil⁷⁴ defined eight key elements ordinarily present in game jams: new product development; participatory design; lightweight construction; product value-focused; rapid experience prototyping; aesthetics and technology; concurrent development; and multidisciplinarity.

Whatever they achieve for the game development, making games can help people learn collaboratively.⁷⁵ These events foster a culture of creativity and learning, play testing, idea sharing, and collaboration between "jammers",⁷³ thus helping the participant to approach the design of the game both as a student and as an author or game designer. Game jams support the process of learning-by-doing while enhancing creative thinking and innovation.⁷⁶

Evidence suggests that people perceive game jams as a fun and engaging method to assimilate new knowledge and skills.⁷³ This fun in collaborative learning, with ownership of the material and messages part of the process rather than the education outcome, offers a stark contrast to conventional lecture halls and multiple-choice questions.

Game jams are a relatively recent phenomenon with the earliest documented as recently as 2002.⁷⁷ These events have been used for other purposes beyond game design. Examples include the Health Games Challenge Game Jam, promoted by Michelle Obama in 2010; the Fukushima Game Jam, aimed at providing assistance after the 2011 earthquake and nuclear disaster;⁷⁵ and even the utilization of the game jam model as a research codesign method.⁷⁸ Furthermore, through their Sami Game Jam, Laiti and collaborators⁷⁹

suggested that game jams could promote self-discovery, reflections on identity, and support the cultural identity of minority groups, such as the Sami people from Finland.

2.5 Transformative learning

Medical educators face an additional challenge in training health professionals in cultural safety. This type of education must go beyond mere knowledge acquisition. Medical educators should promote a transformative experience to impact their learners' behavior in clinical practice. The theory of transformative learning provides a framework to address this challenge.

Mezirow described transformative learning as a process aimed at effecting change in frames of reference, which are "the structures of assumptions through which we understand our experiences."(p5)³ Frames of reference are in turn comprised of habits of mind, which are habitual ways of thinking and acting, and points of view, which are beliefs, values, and attitudes.

Mezirow argued that ethnocentrism, defined as "the predisposition to regard others outside one's own group as inferior,"(p6)³ is an example of a habit of mind. Irihapeti Ramsden, in turn, proposed that confronting ethnocentrism must be the first step in cultural safety training.⁸⁰ Transformative learning may, therefore, be suitable to provide cultural safety training to medical students.

Transformation of frames of reference requires reflection on the assumptions upon which trainees base their habits of mind and points of view.³ In transformative learning, people become critically reflective of their assumptions through education that is participatory and interactive, and through group problem-solving or communicative learning.⁸¹ This is the type of environment that game jams offer. Educators have implemented transformative learning through game-based learning. Odreman,⁸² for example, used Mezirow's theory of transformative learning to inform a videotaped role-play simulation for cultural competence training of nursing, personal support worker, dental hygiene, and retail pharmacy students. Podleschny⁸³ argued that educational games are learning frameworks for transformative learning in educational settings.

In summary, engaging medical students in cultural safety is challenging. We do not know the most effective way to provide cultural safety training for health professionals.³¹ Future teaching interventions should take into account the educational expectations and needs of contemporary medical students. Game jam learning might help address this issue while enhancing the engaging and transformative potential of teaching interventions.

CHAPTER 3 RESEARCH OBJECTIVES

3.1 Knowledge gap

A lack of agreement on methodological frameworks and lack of consensus on how to implement and assess cultural safety training hinder cultural safety research and education. My research is a step towards a practice-based framework for cultural safety training of undergraduate medical students, with a focus on the transformative learning approach. While most cultural safety training interventions have focused on Indigenous populations, my thesis applies the cultural safety concept outside the ethnic scope. I invited *mestizo* (person of combined European and Amerindian descent) traditional medicine users who do not identify themselves as Indigenous. Similarly, while most cultural safety initiatives do not stress the important role of traditional medicine, my thesis focuses on this widely used yet under investigated health system. There are no randomised controlled trials (RCT) assessing cultural safety in medical education and no medical education research has explored the role of game jam learning as a training intervention. My research includes the first RCT investigating cultural safety in medical education, and the first study exploring the role of game jam learning in medical education.

3.2 Action gap

Currently, no Colombian faculty of medicine provides cultural safety training. Yet Colombians from non-dominant cultures experience culturally unsafe actions (practices that demean the cultural identity of an individual),⁸⁴ thus hindering their access to acceptable and effective health services. Adversarial interactions between health professionals and patients from non-dominant cultures erode the cultural diversity of the country and increase the dependence on Western health services. My thesis is the first cultural safety training initiative for medical students and interns in the country, and to the best of my knowledge, in Latin America.

3.3 Objectives

The overall aim of my thesis was to foster cultural safety in medical training through game jam education of medical students and interns in Colombia.
My thesis comprised four specific objectives:

- 1. Review existing experience of game-based learning for cultural safety training.
- 2. Develop a consensus of key elements for a co-designed curriculum for cultural safety training in Colombian medical education.
- 3. Explore the feasibility and acceptability of conducting an RCT of game jam learning for cultural safety training.
- 4. Evaluate the impact of game jam learning compared with standard education for cultural safety training of Colombian medical students on the outcome of self-reported intended patient-oriented behavior.

CHAPTER 4 RESEARCH APPROACH & METHODS

4.1 Research approach: participatory research

Participatory research is "a systematic inquiry, with the participation of those affected by the issue being studied, for the purpose of education and taking action or effecting social change." (p2)⁸⁵ As a public health approach, participatory research combines research and action to address gaps in both knowledge and practice. It involves co-design and co-ownership of health solutions between researchers and end-users. Collaboration between stakeholders ensures that the solution to the issue being addressed is aligned with the needs and characteristics of the end-users, thus improving the reach, adoption, and effectiveness of the intervention.⁸⁶

Participatory research has taken root in the self-determination movements of the Māori people from New Zealand, Canada's First Nations, Inuit and Metis, Indigenous people from Australia, and American Indians.⁸⁷ Self-determination is considered to be one of three core values or drivers of participatory research, together with knowledge translation and social justice. Cargo defines self-determination as "the capacity of individuals and groups to chart their own courses."(p330)⁸⁷

There is a functional affinity between participatory research and cultural safety. Participatory research projects can overcome the separation of individuals from their culture and engage communities that have been marginalized based on their race, ethnicity, or class.⁸⁸ Participatory research generates research that is culturally appropriate to endusers⁸⁶ and "has the potential to 'bridge the cultural gaps that may exist' between the partners involved."(p181)⁸⁸

Andersson² defined three core components of authentic participatory research: engagement in governance and co-ownership of the research; the primacy of local evidence or experience; and innovation by participants. In cultural safety, local communities define the elements of a culturally safe intervention, thus engaging local stakeholders in the coproduction and co-ownership of knowledge. Moreover, culturally safe interventions are typically informed by local traditional knowledge, therefore promoting the use of local

evidence and experiences. Finally, cultural safety training is a challenging endeavour that requires innovation to engage students and ensure an effective learning experience.

Taylor highlights the compatibility between participatory research and transformative learning.⁸¹ The author argues that both approaches share comparable assumptions and outcomes about teaching with a transformative objective in mind, for example, the emphasis on dialogue and communication, the necessity of a critical-self reflection process of learners, the need for action or behaviour change, and the participatory approach. Taylor also calls attention to the need to conduct further research to better understand the relationship between participatory research and transformative learning. In light of these considerations, participatory research is an appropriate research paradigm for my project.

4.2 Methods

Overall study design

A multi-study research program addressed the specific research objectives in a participatory research framework. Table 4.2.1 summarizes the specific objectives, research designs, participants, and outcomes of my research program.

Table 4.2.1 Specific objectives, research designs, participants, and expected outcomes of the research program

Specific objective	Research design	Participants	Outcomes
1. Review existing experience of game-based learning for cultural safety training.	Scoping review	Not applicable	Understanding of: - the characteristics of game-based learning interventions to foster cross-cultural care training around the world - the knowledge gaps in the field
2.Develop a co-designed curriculum for cultural safety training in Colombian	Pilot teaching interventions: Qualitative descriptive study using an inductive thematic analysis and the Most Significant Change narrative technique ^a	17 last-year Colombian medical students	Understanding of: - the feasibility and acceptability of community- based transformative learning for cultural safety training in Colombian medical education
medical education.	Sequential-consensual qualitative research study	7 key traditional medicine users6 last-year medical students4 cultural safety experts	stakeholders to develop co-designed cultural safety curriculum
3. Explore the feasibility and acceptability of conducting an RCT of game jam learning for cultural safety training.	Pilot randomized controlled trial	79 last-year medical students(40 in the intervention group,39 in the control group)	Understanding of the feasibility and acceptability of conducting an RCT of game jam learning for cultural safety training
4. Evaluate the impact of game jam learning compared with standard education for cultural safety	Parallel group randomized controlled trial	531 medical students and interns (268 in the intervention group and 263 in the control group)	- Students and interns' self-reported intended patient-oriented behavior six months post- intervention.
training of Colombian medical students on the outcome of self-reported intended patient-oriented behavior.	Qualitative descriptive study based on the Most Significant Change narrative technique	27 medical students and interns	 skills Qualitative understanding of the impact of the intervention in the clinical practice of medical students and interns
Qualitative component participants		61	
Quantitative component participants		610	
Total pa	rticipants in the study	671 ^b	

^a Most Significant Change only for manuscript 3; ^b Some participants contribute to both the quantitative and qualitative components of the project

Scoping review

My scoping review followed the methods proposed by Arksey and O'Malley,⁸⁹ and Levac et al.:⁹⁰ identify the research question; identify relevant studies; extract the data; and collate, summarize, and report the results. The research question was: *what is the extent and nature of the literature on educational games to foster cross-cultural care training of health sciences students*?

I included theoretical and empirical publications in English, Spanish, Italian, Portuguese, or French. The publications examined a game-based learning intervention to promote cross-cultural care training. An experienced health sciences librarian supported the creation of the search strategy, which included PubMed, Eric, Embase, Lilacs, PsycINFO, and Google Scholar. Two independent reviewers used the web application Rayyan⁹¹ to perform the title and abstract screening. The reviewers completed the final selection of studies using an eligibility format based on the inclusion criteria.

I extracted the following data: basic study information; study design; discipline; type of game, and basic characteristics of each game. I invited three final-year medical students interested in cross-cultural care training along with four participatory research experts. The stakeholders participated by framing the research question, codesigning the study, collecting and analyzing data, and reporting the results of the study.

My scoping review allowed me to document research designs and methods to inform the design of my full-scale RCT, identify and address research gaps in the existing literature, and summarize and share examples of educational games with the participants of the RCT to support the game design process.

Community-based learning experiences

This involved two qualitative descriptive studies to explore the feasibility and acceptability of community-based transformative learning for cultural safety education of Colombian medical students in Cota, Colombia. Cota is a small town 15 kilometres from Bogota that has gone through rapid urbanization and cultural change.⁹² A consequence of this change

was the abandonment of traditional medicine practices and resources that the community had used for centuries.

I supervised two groups of final-year medical students attending a course on community health.⁹³ The first group comprised four medical students between July and November of 2015. The second group involved 13 medical students between January and May of 2016. Both learning experiences shared a similar structure. Prior to the fieldwork, the medical students received training on cultural safety, traditional medicine, primary health care, and participatory research. Next, the students co-created a participatory intervention with schoolteachers from a public elementary school and two kindergartens to promote traditional medicine. The teachers were also traditional medicine users. The activities of the interventions were tailored to the age groups of the school children, and included renovating medicinal plant orchards, visiting the local botanical garden, looking after and savouring medicinal plants, and investigating about traditional medicine, among others.

After completing the exercise with the schoolchildren, their communities, and teachers, I invited the students to write about their experience and to discuss their thoughts in discussion groups. I explored the factors that motivated the students to explore traditional medicine (manuscript 2) and the most significant change experienced by the students in the way they see traditional medicine (manuscript 3). To determine the themes and sub-themes reported by the students, I analyzed the transcriptions of the notes and discussion groups using an inductive thematic analysis technique.⁹⁴ I invited three final-year medical students to co-design and conduct the study reported in manuscript 3.

Both qualitative studies allowed me to explore the perceptions of medical students regarding traditional medicine after the pilot experiences. These experiences indicated the feasibility and acceptability of community-based cultural safety transformative learning. The studies informed the deliberative dialogue of the sequential-consensual qualitative study to co-design a curriculum for cultural safety training in Colombian medical education.

Co-designed curriculum for cultural safety training

A modified sequential-consensual qualitative study (SCQS) explored the question: *what academic content should we include in the co-designed cultural safety curriculum?* A SCQS is a sequence of qualitative research methods that produces data with adequate generalizability to shape public health planning and clinical practice.⁹⁵ In a purposive sample,⁹⁶ seven traditional medicine users from a community organization in Cota, six lastyear medical students from *La Sabana* University, and four intercultural health experts from the Center for Intercultural Medical Studies (CEMI) and the Traditional Health Systems Studies Group (GESTS) participated in the study.

Individual self-administered semi-structured questionnaires and focus groups explored the opinions of the participants. The stakeholders completed the questionnaires before participating in the focus groups, and their answers informed the focus group discussion. I invited a general physician to participate in the data analysis, which used an inductive thematic analysis approach.⁹⁴ In the second phase of the study, an intercultural health expert panel in Colombia decided on the learning goals of the co-designed curriculum. The panel followed a deliberative dialogue format.⁹⁷ Using a member-checking strategy⁹⁸ we shared the co-designed curriculum with the traditional medicine users, medical students, and experts, who modified and approved the final version.

Two medical students and three intercultural health experts from Colombia participated in the study and contributed to the manuscript as co-authors. The co-designed curriculum informed the content of the lectures to both the intervention and control group in the full-scale RCT. The game jam participants used the structure of the co-designed curriculum to design their educational games.

Pilot RCT

A parallel-group, two-arm, pilot RCT compared participation in a game jam on cultural safety with a standard lesson on cultural safety, with student self-reported behaviour as the primary outcome. A convenience sample of 79 final-year medical students taking a compulsory community health course⁹³ participated in the study. Stratified randomization

based on baseline cultural safety scores (lower and higher levels) allocated the participants to the intervention and control arms.

The intervention was a game jam⁷³ comprised of a preliminary lecture on cultural safety and game-design, followed by a practical session to create educational games about cultural safety. The control group received a conventional lecture on cultural safety, followed by a reading session based on cultural safety selected readings. The activity duration was the same (six hours) in the game jam and control groups. The students completed a baseline self-administered, multiple-choice, Likert-type questionnaire, a second questionnaire immediately following the teaching session, and a third questionnaire four months post-intervention.

The pilot explored acceptability and feasibility of conducting a full-scale RCT. Acceptability was students' interest and willingness to participate and to complete study activities, while feasibility was the methodological and logistical factors that could hinder the full-scale study. Jeffreys's⁹⁹ approach increased the validity and reliability of the instrument. To increase the content validity,¹⁰⁰ an open question at the end of the questionnaire explored student opinions of the instrument. To explore the construct validity, the contrasted group approach determined the difference between two separate groups.⁹⁹ Additionally, the test-retest method explored the reliability of the instrument,⁹⁹ and the score difference between two timepoints determined the predictive validity.¹⁰¹

A simple and paired t-test tested the significance of between-group and withingroup differences respectively. For the secondary analysis, probabilistic transitive closure explored the walks and blocks between the seven intermediate outcomes of the **C**onscious knowledge, **A**ttitudes, positive deviation from negative **S**ubjective norms, **C**hange intention, sense of **A**gency, **D**iscussion, and change in practice/**A**ction (CASCADA) model.¹⁰² The pilot RCT allowed me to explore the acceptability and feasibility of cultural safety training through a game jam, pilot research methods, gain the support of the academic staff at *La Sabana* University to conduct the full-scale RCT, and master the required skills to conduct a full-scale game jam.

Full-scale RCT

A parallel-group, two-arm, RCT¹⁰³ compared game jam participation with a standard lesson plus a workshop on cultural safety. The RCT addressed the question: *Among medical students and interns from University of La Sabana, does participating in a game jam for cultural safety training, in comparison to a standard lesson on cultural safety, result in increased change in students and interns': (a) self-reported intended behavior; (b) confidence in general transcultural skills; and (c) reported change in clinical practice?*

The intervention group joined an eight-hour game jam comprised of a preliminary lecture on cultural safety and game design, a game building session where groups of four students created educational games about cultural safety, and a play-test session in which students played and learned from each other's games. The control group received a more conventional lesson, including a two-hour lecture on cultural safety, followed by a six-hour interactive cultural safety workshop. I estimated that a group size of 199 participants in the game jam group and 199 participants in the control group (sample size = 398) could detect an effect size of 0.25, with a two-sided alpha = 0.05 and a power = 0.8.

I randomised after stratification by student intended patient-oriented behavior at baseline. Online self-administered 30-item Likert-type questionnaires assessed cultural safety self-reported behavior before, immediately after, and six months following the intervention. An intention-to-treat analysis used a t-test, including 95% confidence intervals, to determine the significance of the effect of the intervention, including within-and between-group comparisons. A supplementary analysis using transitive closure¹⁰² examined the primary outcome and intermediate outcomes in the CASCADA model of planned behavior.¹⁰⁴ The qualitative Most Significant Change technique explored the students' perceptions of the impact of the intervention on their clinical experience.

Ethical considerations

Research with students raises concerns regarding coercion, confidentiality of data, and anonymity of participants. On the other hand, participating in a study has educational value for students by training them in the study topic, exposing them to research methods, and engaging them in the analysis and communication of the research results.¹⁰⁵

According to the guidelines on conducting research in class from the University of Alberta¹⁰⁶ such research will generally be considered ethical, provided: the instructor and head of the unit approve the project, the instructor and head of the unit consider the study to have significant educational value to the students, voluntary participation is ensured, the study guarantees the confidentiality of student responses, an outline of the study and the research results are shared with the students, and the study complies with the Tri-Council Policy Statement.¹⁰⁷ The research in this thesis fulfills these criteria.

The project received ethical clearance from the Institutional Review Board of the Faculty of Medicine at McGill University (approval number A05-B37-17B), and from the Sub-committee for Research of the Faculty of Medicine at University of La Sabana (approval number 445).

Consent

All participants signed written informed consent before proceeding with any research activity. Since the risks and benefits were different for the different stakeholders participating in the study, the consent forms were tailored to each stakeholder group. Research assistants explained the purpose of the study, the confidentiality of responses, and the respondents' rights to not answer certain questions or to terminate their participation in the study.

Details on confidentiality

I treated all responses from participants as confidential. A password-protected computer held the encrypted data, and physical copies were secured in a locked cabinet at *La Sabana* University, inaccessible to anyone outside the study. Original paper records are securely transported, stored, retained, and will be destroyed in accordance with CIET guidelines for security, storage, and eventual destruction of paper records.¹⁰⁸

Minimizing potential risks to participants

The study posed minimal risk to participants. The probability and magnitude of possible harms stemming from their involvement in the study were no greater than those encountered by the participants in those aspects of their everyday life.¹⁰⁷ To avoid possible undue influence or coercion of students, the consent explained that no penalties (academic or otherwise) would result from not agreeing to participate in the study. Traditional medicine users from Cota do not belong to a vulnerable population and did not require special ethical considerations related to minorities.

Benefits to participants

I explained that taking part in the study entailed benefits; the students and interns learned about cultural safety and research methods. Direct benefits for traditional medicine users included the advancement of knowledge regarding cultural safety in medical education and providing the basis for an improvement in the quality of Colombian health care. I invited the cultural safety experts to co-author manuscripts, oral presentations, and posters in several academic conferences, thus advancing their research career.

CHAPTER 5 [Manuscript 1]: Game-Based Learning Interventions to Foster Cross-Cultural Care Training: A Scoping Review

PREFACE

Arksey and O'Malley⁸⁹ provided three common reasons for conducting a scoping review. The first reason is to describe the extent and nature of the research activity. My scoping review allowed me to document research designs and methods to inform the design of my RCT. Inspired by the results of the review, I: (a) used before-and-after timepoints and supplemented the quantitative analysis with the qualitative Most Significant Change technique; (b) adopted the Transcultural Self- Efficacy Tool—Multidisciplinary health care Provider (TSET-MHP) and developed Likert-type questions to assess secondary outcomes in my RCT; and (c) incorporated a complementary teaching method, such as theory lecture, to enhance the learning experience of trainees before my game jam. The second reason for conducting a scoping review is to identify research gaps in the existing literature. (a) All published research in this field comes from developed countries. My project was the first cultural safety training experience using game-based learning in Latin America. (b) None of the game-based interventions identified in my scoping review employed the cultural safety approach. My study was the first game-based intervention to train medical students in cultural safety. (c) Only one publication¹⁰⁹ used a participatory research approach. This confirmed a need to invite end-users to co-design the interventions, which is one of the key elements of my project. (d) The majority of the publications were theoretical, highlighting the need for more empirical research on the field. The third reason for conducting a scoping review is to summarize and share research findings with stakeholders and endusers. My scoping review identified examples of games related to cross-cultural care that I used to support the game design process of the game jam participants in my RCT.

I presented the protocol of this study at the 2018 North American Primary Care Research Group (NAPCRG) Annual Meeting in Chicago IL, USA, and the results of the review at the 2019 NAPCRG Annual Meeting in Toronto ON, Canada.

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ABSTRACT

Objective: Differences in cultural background between health providers and patients can reduce effective access to health services in multicultural settings. Health sciences educators have recently suggested that game-based learning may be effective for cross-cultural care training. This scoping review maps published knowledge on educational games intended to foster cross-cultural care training and highlights the research gaps for future research.

Materials and Methods: A scoping review searched PubMed, Eric, Embase, Lilacs, PsycINFO, and Google Scholar for theoretical and empirical research, using terms relevant to cross-cultural care and game-based learning. A participatory research framework engaged senior medical students and participatory research experts in conducting and evaluating the review.

Results: Forty-one documents met the inclusion criteria, all from developed countries. The most common source of publication was nursing and medicine (39%; 16/41) and used the cultural competence approach (44%; 18/41). Around one-half of the publications (51%; 21/41) were theoretical and 39% (16/41) were empirical. Empirical studies most commonly used mixed methods (44%; 7/16), followed by strictly quantitative (31%; 5/16) or qualitative (25%; 4/16) approaches. There were no randomized controlled trials and only one study engaged end-users in the design. Empirical studies most frequently assessed role-play-related games (44%; 7/16) and used game evaluation-related outcomes or learning-related outcomes. None used patient-oriented outcomes. Findings suggest that educational games are an effective and engaging educational intervention for cross-cultural care training.

Conclusions: The paucity of studies on educational games and cross-cultural care training precludes a systematic review. Future empirical studies should focus on randomized counterfactual designs and patient-related outcomes. We encourage involving end-users in developing content for educational games.

INTRODUCTION

Cultural diversity is an asset to societies that can also pose challenges to health care.¹ Without proper training, differences in cultural background between service providers and patients hinder access to health services in multicultural settings.² At worst, these differences can lead to confrontation with and discrimination against patients, accentuating racial/ethnic health disparities.³

The nursing sciences have advanced work on cultural diversity in health sciences education. In the 1960's, Madeleine Leininger, a nurse theorist and anthropologist, noticed the missing relationship between culture and health outcomes in nursing care practice and education.⁴ She coined the term *culturally congruent care* to call attention on the need to reconsolidate emic/indigenous and etic/outsider care phenomena.⁵

Later concepts and lexicon included cultural competence, cultural awareness, cultural sensitivity, cultural humility, and cultural safety.^{6,7} Some inconsistencies and debates continue about the exact meaning, boundaries, and application of each of these terms, and some authors use them interchangeably.⁸ There is growing agreement, however, about the need to train medical students to provide care that is congruent with the cultural needs of patients.^{9,10} The 2015 Standards for Accreditation of Medical Education Programs in Canada¹¹ calls for cultural competence training and the Royal College of Physicians and Surgeons of Canada will require all residency programs to include cultural safety training in their curricula.¹²

Many medical schools include cross-cultural care education, although with variation in the content and teaching approaches.¹³ There is no agreement about the most effective way to provide cross-cultural care training for health professionals.¹⁴ Health sciences educators have recently suggested that game-based learning may be effective for crosscultural care training.¹⁵

Early evidence of games for cross-cultural care education occurred out of the context of health sciences education. Since the 1970's, simulation games such as BaFá BaFá and Barnga¹⁶ allowed players to experience intercultural tensions and thus to foster cross-cultural skills. Yet contemporary use of educational games for cross-cultural training in health sciences education is not widespread.¹⁶

To the best of our knowledge, no previous literature reviews using systematic methods have explored the evidence on educational games to foster cross-cultural care training. This scoping review maps current knowledge on educational games intended to foster cross-cultural care training and to highlight the research gaps that should be addressed in future research. For the purposes of this review, the term *cross-cultural care* encompasses cultural competence, cultural awareness, cultural sensitivity, cultural safety, cultural humility, cross-cultural training, and other aligned concepts.

METHODS

Our scoping review followed methods proposed by Arksey and O'Malley,¹⁷ and Levac et al.¹⁸ to: (i) identify the research question; (ii) identify relevant studies; (iii) select the studies; (iv) chart the data; and (v) collate, summarize, and report the results. The review sought to answer the question: what is the extent and nature of the literature on educational games to foster cross-cultural care training of health sciences students? We developed a protocol for this scoping review in advance (available from the authors on request).

Inclusion/exclusion criteria

Our inclusion criteria were as follows: (i) publication theme was health sciences education; (ii) publication examined a game-based learning intervention; (iii) learning topic was cross-cultural care training (or related terms); and (iv) language of publication was English, Spanish, Italian, Portuguese, or French.

There is no standard definition for games;¹⁹ we followed the categories proposed by the 2006 Horizon Report²⁰ used in related systematic reviews:^{21,22} role-playing or

simulations (strategies to replicate real-life situations); virtual environments (interactive computer-based systems); social and cooperative games (based on social interaction such as board games); and alternative reality games, which blend gameplay and real life. We were especially interested in exploring role-playing and simulations since they often trigger conflictive emotions that favour cross-cultural training.^{15,23}

Search strategy

The search included PubMed, Eric (EBSCO), Embase (OVID), Lilacs, PsycINFO (OVID), and Google Scholar. An experienced health sciences librarian based at McGill University reviewed, modified, and approved the search strategy. Appendix 1 shows our search strategy.

The review included research in the fields of medicine, nursing, psychology, social work, occupational therapy, and physical therapy. We included terms of cultural safety, cultural competence, cultural sensitivity, cultural humility, cultural awareness, and cross-cultural medicine. We also included the aligned concepts proposed by Horvat,¹⁴ such as patient-centered care, person-centred care, family-centered care, patient engagement, equitable health care, and patient participation.

We included theoretical and empirical research, published or not, as well as different sources of data, including online databases, references lists, and conferences, as suggested by Arksey & O'Malley,¹⁷ and Levac.¹⁸

Study selection and data extraction

Using the open-source systematic review web application Rayyan,²⁴ two independent reviewers (AM and DR) performed the initial title and abstract screening. These research assistants solved discrepancies by discussion involving a third party (JP) in case of no resolution. Subsequently, we retrieved the full-text articles of all the selected references and removed the duplicates using Endnote X8.2.

Two independent reviewers (AA and JP) performed the final selection of studies using an eligibility format based on the inclusion criteria. We calibrated this format on 10% of the retrieved studies to ensure clarity of inclusion criteria.

The next step involved reviewing and charting the included studies. Charting is a "technique for synthesizing and interpreting qualitative data by sifting, categorizing, and sorting material according to key issues and themes." (p15)¹⁷ Using Google Sheets, the research team designed the data charting form based on the variables that would answer the research question. This step involved regular meetings to discuss and update the data charting form.

We followed the "descriptive-analytical method" which involves applying a common analytical framework and collecting standard information on each document.¹⁷ First, two independent reviewers (AM and DR) calibrated the data of 5% of the studies to determine whether our approach to data extraction was appropriate to answer the research question. Subsequently, the reviewers extracted all data and a third reviewer (JP) verified the accuracy of data extraction.

We extracted the following data when available: basic study information (title, year of publication, country, authors, and journal); type of document (journal article, book chapter, book, thesis, conference abstract, or technical report); study type (qualitative, quantitative, mixed-methods, or theoretical); reported study design (observational, experimental, systematic review, comment/reflection, case study, or qualitative descriptive); discipline (medicine, psychology, occupational therapy, physical therapy, nursing, or social work); type of game (e.g. board game, video game, simulation, and role play); and basic characteristics of each game.

Synthesis and presentation of results

We present the results of the scoping review following the categories proposed by Grudniewicz et al.²⁵ (i) a summary of the characteristics and distribution of included studies and (ii) a narrative synthesis and mapping of results. We generated tables to display an overview of the included studies and created a narrative synthesis describing the characteristics of game-based interventions to foster cross-cultural care training. In this article we followed the PRISMA extension for reporting scoping reviews (PRISMA-ScR).²⁶

Participatory research

Our participatory research framework²⁷ engaged knowledge users through all stages of the study. Our team included three senior medical students interested in cross-cultural care training (AA, DR, and AM) along with four participatory research experts (JP, AMC, AC, and NA). The stakeholders participated by framing the research question, codesigning the study, collecting and analyzing data, and reporting the results of the study. We held six 2-hour online meetings to discuss each stage of the study. Engaging end-users ensured the research design was aligned with their interests and needs.²⁸

RESULTS

Publication statistics

The final list of publications included 41 documents (Figure 5.1 and Appendix 2). The national affiliation of the first author included 24 from the United States, eight from Canada, two from Sweden, and one each from Australia, Finland, Germany, Greece, Israel, Saudi Arabia and the United Kingdom. 20 documents were published between 2013 and 2017, eight documents between 2007 and 2012, seven documents between 1998 and 2005, and six documents between 1988 and 1997. All the documents were in English.





Table 5.1 depicts the basic characteristics of included publications. Some 90% (37/41) of the documents were related to cross-cultural care training and the remainder to patient-centred care. Similarly, 44% (18/41) of the documents used the cultural competence approach, while 24% (10/41) used a non-specific cultural framework.

Most publications (73%; 30/41) were journal articles, followed by conference abstracts, thesis, book chapters, and technical reports. About half of included documents (51%; 21/41) were theoretical publications, and 39% (16/41) were empirical publications.

Empirical publications most commonly used mixed methods (44%; 7/16), followed by strictly quantitative (31%; 5/16) or qualitative (25%; 4/16) studies.

We analyzed theoretical and empirical publications separately. We included four additional publications, two literature reviews and two graduate theses, that we report in a separate study type category because they do not fit into either theoretical or empirical categories.

Regarding the discipline of the first author's affiliation, the majority of the documents came from nursing and medicine (39%; 16/41), followed by business and information technology, public health and health sciences, education, psychology, social work, and management.

Characteristic	Categories	n=41	%
m ·	Cross-cultural care training	37	90
Topic	Patient centred care	4	10
	Cultural competence	18	44
	Cultural awareness	3	7
	Cultural sensitivity	1	2
Conceptual	Acculturation	1	2
Iraniework	Cultural - non-specific	10	24
	More than one	4	10
	Patient-centred care	4	10
	Journal article	30	73
	Conference abstract	4	10
Type of document	Thesis	4	10
	Book chapter	2	5
	Technical report	1	2
	Theoretical	21	51
	Empirical		
	Quantitative	5	12
	Qualitative	4	10
Study type	Mixed methods	7	17
	Other		
	Literature review	2	5
	Theses	2	5
	Nursing	8	20
	Medicine	8	20
	Business and Information	Ę	12
	Technology	5	12
Discipline of first	Public health and health sciences	5	12
author's affiliation	Education	4	10
	Psychology	2	5
	Social work	2	5
	Management	1	2
	Not specified	6	15

Table 5.1 Characteristics of included publications

Empirical studies

Table 5.2 shows the characteristics of the 16 published empirical studies. About one third (31%; 5/16) reported before-and-after designs, while others reported experiments, mixed methods design, and qualitative descriptive studies (two studies each category). Five studies (31%) included a third time-point or follow-up measurement. None of the studies used a randomized controlled trial design and none of them used a multivariate approach to explore potentially confounding variables.

Four studies (25%) included students from more than one health profession and the others included students from a single health profession. More than one third of interventions involved nursing students (37; 6/16), followed by medical students or residents (31%; 5/16), social work students (12%; 2/16), and psychology students (12%; 2/16). Others included in the studies where paramedic, dental hygiene, community health, divinity, occupational therapy, and physical therapy students.

We found only one publication using a participatory research framework to develop content for a cross-cultural care training intervention. In Mathew's study,²⁹ a community advisory board comprised of cultural, clinical, and educational experts lead the development of the interventions' content.

The most common game type assessed by empirical studies was role-play related games (44%; 7/16), followed by simulation (five publications), video patient simulation (three publications), and board games (one publication). Six studies (37%) used a game-based learning intervention exclusively, while 10 mixed the game with other interventions, such as theory lectures, in-class discussions, field trips, reading assignments, workshops, and online modules.

Researchers reported a wide range of outcome types. We organized the studies' outcomes in two broad categories. Seven studies used course or game evaluation-related outcomes and seven studies used learning-related outcomes. No studies used patientoriented outcomes.

All mixed-methods or quantitative methods (12/12) studies used at least one Likert-type questionnaire, alone or combined with another method, to assess the impact of the intervention. One half of these studies (6/12) reported validation of their instrument.

Researchers used a variety of statistical tests to analyze their data: the most frequent was a paired t-test (three publications), followed by Mann-Whitney *U*, Kruskal-Wallis, multivariate analysis of variance, Wilcoxon signed-rank, f-adjusted, and Cohen's d tests. None used more complex modeling to account for potential confounding effects. Three studies used content analysis, and one study used thematic analysis. Of the studies using mixed or quantitative methods (n=12), the total number of participants was 1,300 (mean=118.2; median=71; SD=133.8; range= 9 - 415). Two-thirds (8/12) of these publications measured the effect before and after the intervention and the remaining measured the effect exclusively after the intervention. Only three empirical studies used a control group (without randomization).

Publications on theory

We identified 21 publications on conceptual or theoretical aspects of cross-cultural care. Ten of these (48%) used the cultural competence approach and seven (33%) used a nonspecific cultural approach. The publications discussed aspects of the games BaFá BaFá, Barnga, Fydlyty, HealthCare DIVERSOPHY, Take a risk?, Virtual patient system, Ecotonos, and Multi-player cultural competence serious game (CCSG), OWARE, MOSHI, Game-Based Cognitive Behavioral Group Therapy, and Breast Care Bingo. We describe the majority of these games in Table 5.3.

Other publications

We identified four additional publications. Two of these were literature reviews (one systematic and one scoping review) that included two of the studies that we included in this scoping review. The two remaining publications, a M.Sc. thesis and a Ph.D. thesis, described the development of content for a future game-based learning intervention.

Game-based interventions

Several review publications described as many as five games. Selected by reviewer consensus, we included four additional innovative games that might be of interest for researchers and educators. Table 5.3 describes the dynamics of each game.

Reference, game type, and game name (when available)	Study type/ reported design	Statistical test / qualitative method	Participants	Goal of the game	Main findings
Bai et al. (2016) ª Role-play	Qualitative	Not mentioned	Eight undergraduate and graduate students in social work and nursing	"engage students and demonstrate cultural difference."p76	"The pedagogical strategies were found to be effective in increasing cross-cultural learning, as reflected in the course evaluations."
Barber & Glanz (1989) Board game Trivia-Public Health and Medicine - USSR Edition	Quantitative	Not conducted	25 occupational health nurses	"increase participant sensitivity to sociocultural dimensions of lifestyle and health care."p129	Increased sensitivity to sociocultural dimensions of health care: mean= 6.1 SD 0.9 (Likert scale 7=highest level of attainment; 1=lowest level of attainment)
Brown et al. (1992) ª Role-play	Qualitative	Not mentioned	Five family physicians	"learn the patient-centered method of care which requires behavioral change and skill acquisition"p183	"The results of the course evaluation indicated that the teaching methods were generally viewed by the participants as acceptable and effective."
Ellman et al. (2012) Simulation	Mixed methods	Kruskal-Wallis test and Mann- Whitney U. Content analysis	205 medical, 65 nursing, 39 divinity students.	"identify spiritual and cultural needs of patients and understand how to meet these needs."p1241	Greater understanding of the role of culture in a patient's experience at the end of life: mean= 4.16 (divinity); 4.1 (med); 4.36 (nursing); <i>p</i> =.179 (Likert scale 5=strongly agree; 1 strongly disagree).
Harding & D`Eon (2001) ^a Simulation Lego-Based Communication Simulation	Mixed methods/ Before-and- after	Paired t-test and MANOVA. Qualitative analysis method not reported	Medical Undergraduates (number of students not mentioned)	"Introduce medical students to patient-centered interviewing."p1	Pieces of information recalled after seven months: mean= 2.74 (Lego Details) 1.03 (Details of Anecdotes) p=<.001; 1.5 (Lego Concepts) 0.33 (Concepts from Anecdotes) p =<.001.
Khan (2015) Virtual Patient Simulation ^c Fydlyty	Quantitative/ Experiment	Not conducted	Five volunteer health- care professionals and nine students (not-specified)	"low-fidelity, cultural competence web-based serious game intended to serve as a teaching tool for medical students, and practitioners."p24	Interaction with the system was easy (7.3), satisfying (6.5), and flexible (4.8) (scale 1=not at all; 10= to a great extent). 21% of the participants believed to be immersed into the game.
Kiosses (2017) ^{ab} Role-play Empathize with me, Doctor!	Quantitative/ Controlled before-and- after	Cohen's d	87 medical undergraduates	"empathy training for medical undergraduates, based on the principles of Person-Centered Approach."p20	Jefferson Scale of Physician Empathy mean score and SD before, after, and six months follow-up was 109.3 (12.7), 121.1 (9), and 121.1 (9.5), respectively. Before- after and before-follow-up difference was significant in both cases.

Table 5.2 Characteristics of empirical publications

Koskinen et al. (2008) Simulation ^c Barnga and BaFá BaFá	Mixed methods	Mann-Whitney U and Wilcoxon signed-rank test & Content analysis	23 nursing, 40 public health nursing, and 40 dental hygienist students	"provoke emotional confusion in learners, thus sensitising them to perceive the world from the perspective of a culturally different person."p55	Playing: gave me new insights into different cultures 1.83 (Barnga) 1.57 (BaFa BaFa) p =.000; changed my thinking about cultures 2.28 (Barnga) 2.07 (BaFa BaFa) p=.002; enabled me to become a member of another culture 1.89 (Barnga) 2.93 (BaFa BaFa) p =.000; Confirmed my own self-awareness 2.26 (Barnga) 2.35 (BaFa BaFa) p =.097; provided me with new personal insights 2.56 (Barnga) 2.54 (BaFa BaFa) p =.747. (Likert scale 1= strongly agree; 4 strongly disagree).
Kratzke & Bertolo (2013) Simulation BaFá BaFá	Qualitative/ Descriptive qualitative study	Content analysis	11 community health students	Not mentioned	"The results show that students may enhance their cultural competence in the classroom in academic preparation."
Mao et al. (1988) Role-play	Quantitative/ Before-and- after	Paired t-test	415 medical undergraduates	"improve the students' ability to provide medical care appropriate to the ethnic and sociocultural backgrounds of their patients"p625	68% of the students found the content useful in 1986 and 93% describe it as outstanding/very good in 1987. 49% found the role-playing exercises useful in 1986 and 94% rated interactions among group members outstanding/very good in 1987. In 1986, 94% approved the use of student discussion leaders and 85% enjoyed the use of video-taped scenarios. 70% felt that the workshop achieved its objectives in 1986 and 1987.
Odreman (2016) ^b Role-play ^c	Quantitative/ Quasi- experimental study	Paired t-test	196 healthcare students from nursing, paramedic, dental assisting, and occupational/physical therapy assisting	"allow observation of how a healthcare professional uses cultural knowledge to provide transculturally congruent care."p11	Learners' Transcultural Self-Efficacy: mean (SD): pretest 9.2 (61.2) posttest 33.6 (49.5). <i>p</i> < .05.
Ong et al. 2017 Simulation BaFá BaFá	Qualitative - Descriptive qualitative study	Thematic analysis	34 graduate nursing students and 11 doctoral clinical psychology students	"[Create] cultural awareness among graduate students in nursing and clinical psychology"p151	"Participants experienced heightened emotions, and with guided reflection, were able to empathize with others "different" from themselves, an indication of cultural humility."
Pantziaras et al. (2012) Virtual Patient Simulation c Virtual Mrs. K	Mixed methods/ Mixed methodological approach	Inductive content analysis & Statistical analysis not conducted	Eight residents in psychiatry and one general practitioner	"enhance clinical, interpersonal, social and cultural competence"133	Virtual Patient system's realistic nature score (median): 5; Virtual Patient's ability to mirror the course of a real clinical investigation score: 5. Likert scale (1=Highly disagree to 7=Highly agree)

Pantziaras et al. (2014) Virtual Patient Simulation ^c Virtual Mrs. K	Mixed methods/ Mixed methodology	Inductive content analysis and sign test	32 residents in psychiatry	"enhance clinical, interpersonal and intercultural competence"109	Experienced realism: 4 (median value); engagement 4.5 (median value); concentration 5 (median value). Likert scale: 1=Highly disagree; 5=Highly agree.
Pruegger & Rogers (1994) ^{ab} Simulation ^c BaFá BaFá	Mixed methods/ Controlled before-and- after	Adjusted F statistic & Content analysis of students' reflections	71 undergraduate psychology students	"promote cross-cultural sensitivity and to develop cross-cultural awareness"375	Cross-Cultural Sensitivity Scale mean and SD: pretest 43.61 (6.59); posttest 43.61 (6.06); follow-up 43.79 (6.52). <i>p</i> > .05
Zamboanga et al. (2016) Role-play	Mixed methods/ Before-and- after	Paired t-test & Thematic analysis	39 undergraduate psychology students	"simulate the process of acculturation and some of the cultural adjustment challenges associated with it"244	Mean and SD. Students' awareness that acculturation is a real-world phenomenon: pretest 6.79 (1.69) posttest 8.46 (1.45) p <.001; their understanding of how acculturation can impact people's lives: pretest 3.97 (0.78) postest 4.56 (0.55) p <.001 (Scale: 1= strongly disagree; 5=strongly agree); and their sensitivity (pretest 7.54 (1.86) postest 8.51 (1.47) p <.001) and empathy for people who face some of the challenges associated with acculturation: pretest 8.33 (1.53) posttest 9.08 (1.20) p <.001. Scale: 1= unaware, no empathy, no sensitivity; 10= extremely aware, high empathy, high sensitivity.

^a Included follow-up assessi SD= Standard Deviation

Game name / type	Game objective / number of players	Story/narrative	Game dynamics	Rewards/incentives	Penalties	Targeted group
BaFá BaFáª / Simulation	Stimulate self- reflection of personal responses to intercultural differences / >11	There are two different cultures: Alpha and Beta. Alpha values sharing and physical contact while Beta is individualistic and competitive.	Members of one culture visit the other one in pairs to try to male sense of it. They report back to their team after each interaction. The game elicits strong emotional reactions among participants.	Communication improves when cultural norms are respected.	Penalties are imposed when cultural norms are violated.	Originally targeted naval personal. Currently used in multiple professions.
Barngaª / Simulation	Reflect on communication problems in intercultural situations / >7	NA	Tournament-like card game. Participants are not allowed to speak. They switch tables at the end of each game. They do not know that the rules at each table are different, thus experiencing conflictive emotions.	Highest card wins a trick. The player who wins more tricks wins the game and moves to the next table (clockwise).	Losers move to the next table (counterclockwise).	Multiple professions.
Fydlytyª / Virtual Patient Simulation	Improve cultural competence skills through simulation / single player	The player, who takes the role of a physician, examines an 83-year- old retired nurse (a virtual patient), Li Chen. She complains of "toothache like" chest pain.	The objective of the player is to complete a dialogue script with the virtual patient, focusing on the cultural background and responsive mood of the patient. The system uses a set of predefined responses to the player, who must select the most appropriate options to conduct the medical interview successfully.	Selecting the appropriate response allows the player to earn points and move ahead in the conversation until the interaction ends.	The virtual patient exhibits upset and angry moods based on the player's wrong decisions.	Educators/ curriculum designers, and students/trainees. Mostly physicians.
HealthCare DIVERSOPHYª / Board Game	Develop cultural competence of health professionals who interact with major US ethnic groups / >2	Players go from ethnocentricity to wisdom about other cultures as they complete the game successfully.	Players roll dice and move around a board. They must overcome five challenges described on the cards: DiversiSMARTS cards develop players' knowledge of specific ethnic groups; DiversiCHOICE cards teach players how to handle intercultural tensions; DiversiSHARE cards promote self- reflection and cultural awareness of players; DiversiRISK cards allow players to experience the challenges of cross-cultural medicine; DiversiGUIDE cards offer advice to handle communication issues with	Successful players collect dividends (diversiCOINS).	Players can fall in four traps: ethnocentricity, stereotypes, bias, and assimilation.	Health professionals and health care administrators.

Table 5.3 Basic description of selected games

multicultural patients.

Virtual Mrs. Kª / Virtual Patient Simulation	Enhance clinical, interpersonal, and intercultural competence / single player	A female Bosnian refugee patient, "Mrs. K", comes to see the doctor (represented by the player) with severe mental trauma, post- traumatic stress disorder, and depression.	The system uses pre-recorded video clips and allows user interaction in five areas: medical interview, physical examination, screening instruments, and laboratory and imaging tests.	Automated feedback by the virtual patient and by a virtual advisor.	Patient's reactions such as leaving the examination room, crying, and coughing. Automated feedback by the virtual patient and by a virtual advisor.	Health professionals (residents in psychiatry).
Take a risk? / Simulation	Prepare students for cultural competence practice with members of oppressed populations / groups of five to seven students	Instructors can use scenarios related to gender, religious belief, physical ability, and race/ethnicity, and they can create other situations.	Groups of players are confronted with situations including (a) the background and setting; (b) the challenging situation; and (c) the question, "Do you take action by or would you remain silent?". Students use two index cards labelled "Take Action" and "Remain Silent." If players take action, they roll the dice.	A roll of one to four represents a positive outcome and the group earns four points. This rewards their decision to challenge oppression. Neutral outcomes (roll of three to six) receive two points.	A roll of two to five represents a negative outcome (players lose two points).	Social work students.
Virtual patient system / Virtual Patient Simulation	Allow medical students to develop interview skills when interacting with multicultural patients / single player	Students knock on the examination room door, enter, and start interacting with the virtual patient who is projected life-size on the room wall. The system uses virtual patients with diverse backgrounds.	Medical students interact with virtual patients in standard examination rooms. The system uses a projector, two cameras, a microphone, and speech recognition software. It tracks interaction differences such as empathy, body lean, interruptions, posture, and jargon use. Instructors can use this information to provide feedback to the students.	The system allows for assessing the effect of the patient's background on the interaction. Students can reflect on successful interactions.	Students can identify interaction biases based on the patients' background.	Medical students.
ECOTONOS / Simulation	Explore expectations, group processes, and contradictions that may arise in intercultural interactions / multiplayer	Using a set of cards, players create a myth that explains the origins of its culture, their values and beliefs, and the way their culture supports survival and harmony.	then are asked to solve a problem (case study or physical task). They are later blended into three different multicultural groups: majority/minority, balanced, and a complex mix of people from each culture. As participants bring their own way of addressing the issue, intercultural tensions arise.	Students reflect on the positive aspects of their way of dealing with intercultural tensions.	Students reflect on negative effects of their way to interact with other cultures.	Originally targeted corporations. Currently used in multiple professions.

Multi-player cultural competence serious game (CCSG) / Video Game	Cultural competence education and training / supports online multi-player	The game places the player in a hospital with several rooms. Each room/patient offers a specific cultural competence scenario. Educators can create or modify scenarios to simulate several culturally sensitive situations.	Players (taking the role of health professionals) interact with patients. The system uses pre-scripted dialogues. The player can choose from a list of responses/actions and must choose the correct answer at each step.	Correct answers will trigger a high- frequency sound effect and the player receives feedback.	An incorrect answer will anger, sadden, or make the patient upset. The player receives feedback.	Students in medical and nursing schools and health professionals.
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^a Games mentioned in at least two publications. The rest of the games are mentioned in only one publication.

DISCUSSION

This is the first review using systematic methods to collate evidence about educational games in cross-cultural care training. No impact assessment used a randomised controlled trial design and none reported patient-orient outcomes. Only one reported engagement of end-users in the design. All publications come from high-income developed countries, possibly prompted by immigration and the consequent increase in cultural diversity of these regions.¹⁰ In developing countries, game-based interventions and research to promote cross-cultural care are much less prominent, indicating a need to advance in this direction.

Educational games to foster cross-cultural care training

The majority of games in our review were role-playing and simulation, emulating cultural conflicts to make the players more aware of their own cultural backgrounds and prejudices.²³ Pyburn suggests that simulation provides learners with a safe environment for practicing cross-cultural situations that may be emotionally charged.¹⁵ Several games used virtual patient simulation systems (e.g. Fydlyty and Virtual Mrs K), an approach that is gaining attention due to its reported effectiveness, appropriateness, and the increasing use of technology in health care sciences education.³⁰ Our study highlights the advantages of using role-playing and simulation for cross-cultural care training.

Most studies reported a complementary teaching method such as theory lecture or in-class discussion in addition to game-learning to foster cross-cultural care training. This is in line with earlier recommendations that, to be most effective, educational games must be embedded in a multi-step program comprised of background knowledge on the topic, face-to-face training, and the game itself.³¹

Two games, BaFá BaFá and Barnga, accumulated most evidence in health sciences education research. BaFá BaFá was originally developed for creating cultural awareness in the US Navy while Barnga was developed to reflect on normative assumptions and crosscultural communication. The games have been used by sectors other than health care and its incorporation into health professional training is recent.³² Due to their reported effectiveness and availability, these games could be a good starting point for educators interested in exploring this type of training.

Cultural approaches: need for engaging end-users

Cultural competence – sensitizing students or health professionals about another culture – is the most frequent cultural focus of the publications reviewed. Some authors criticized the concept of cultural competence, widespread in the US, as it deals with beliefs and behaviours of heterogeneous *cultural blocks* such as African-American, Latino, and Indigenous patients. Betancourt argued that cultural competence "can lead to stereotyping and oversimplification of culture without respect for its complexity."(p145)²

The relatively newly popularized concept of cultural safety is an opportunity to approach complexity of culture in cross-cultural care training. Cultural safety starts with recognition that the patient's ways of knowing have validity; the patient is a partner in the health care decision-making process; and the patient determines whether the approach to care is culturally safe or not.³³ Cultural safety encourages co-design of culturally safe interventions by engaging end-users early in the research process.³⁴

End-users are better resources in matters of their own cultures and therefore better positioned to know what a cross-cultural care intervention should include. None of the game-based interventions identified in our scoping review used the cultural safety approach, and only one used a participatory framework.

Our participatory research approach helped the medical students involved to deepen their research interests and refine their research skills. The three students who contributed to this review (AA, DR, AM) participated in an international conference³⁵ to share the protocol of the scoping review, and they prepared and submitted the manuscript to a peer-reviewed journal. Earlier scoping reviews have used participatory research to include the perspectives of stakeholders throughout the study, to obtain additional sources of information, and to spearhead end-of-study knowledge *translation.²⁵*

Gaps in empirical research

Our review highlights the urgent need for more empirical research on the effectiveness of educational games in training for cross-cultural care, particularly for unbiased counterfactual studies. We found two broad types of outcomes in the studies included in our review: course evaluation outcomes and learning-related outcomes. Experts in cross-cultural care training, however, recommend use of patient-related outcomes to evaluate whether cross-cultural care interventions actually benefit patients.¹⁴

Several authors of the studies included in this review suggested that educational games are effective and engaging in cross-cultural care training. Empirical studies included in the review report only p-values exploring differences between the means of groups of participants, precluding meta-analysis.

Limitations

This study shares common limitations of scoping reviews. We did not assess the quality of empirical publications nor did we do a quantitative data synthesis, both of which are outside the objectives of scoping reviews.¹⁷ Future studies should appraise the quality of publications and perform a synthesis of quantitative data.

One limitation of using Google Scholar is that search results are not replicable.³⁶ The value of using this database is, however, that it collects grey literature.³⁷

The study generated a considerable quantity of data. Since we used a participatory research framework, our analysis focussed on the interests and needs of our stakeholders. This approach may have left out some information of interest for other groups of readers. Interested researchers can consult the list of included publications.

We dealt with a large range of study designs, methodologies, and concepts. Although our tables provide transparency in aggregated findings, others concerned with educational games or cross-cultural care training may have taken a different analytical approach. We hope that this study can pave the way for future scoping reviews, and eventually systematic reviews and meta-analyses, exploring the topic.

CONCLUSION

Educational games for cross-cultural care training are in their infancy. The current state of the literature underlines the need for research in developing countries that lack crosscultural care training despite traditional health care systems being prominent. Our review encourages exploration of methods that invite patients and end-users to co-design educational games, embracing a cultural safety approach. This will help to avoid oversimplification of culture and ensure that the interventions are better aligned with the patients' expectations and needs. Our review indicates a need for more empirical research to determine the effectiveness and acceptability of educational games for cross-cultural care training. Future studies should include a control group, randomization, and patient-related outcomes.

Our experience using a participatory research approach to conduct this scoping review was positive. Researchers conducting scoping reviews might consider a participatory research framework to improve the impact, appropriateness, and ownership of their research. **Acknowledgments:** Germán Zuluaga, Andrés Isaza, Carolina Amaya, Andrés Cañón, and Camilo Correal provided methodological advice on cultural safety and medical education. Genevieve Gore provided advice for conducting the systematic literature search. Cassandra Laurie helped proofread the final version of the manuscript and supported its write-up.

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CHAPTER 6 [Manuscripts 2 & 3]: Community-based learning interventions to explore motivators, feasibility, and acceptability of transformative learning for cultural safety training

PREFACE TO MANUSCRIPT 2

At the time of initiating my project, there were no published experiences of cultural safety training in Colombia or Latin America. I decided to conduct two community-based learning interventions to foster cultural safety in Colombian medical education.

The first intervention (manuscript 2) explored the motivation dynamics of medical students engaging with traditional medicine in Colombia. The experience allowed me to: (a) examine the range of outcomes of community-based transformative learning for cultural safety training; (b) create trust and credibility between the stakeholders (traditional medicine users, medical students, and cultural safety experts); and (c) inform the deliberative dialogue exercise of the sequential-consensual qualitative study (manuscript 5). Cultural safety experts used the motivators that medical students reported in manuscript 2 to co-design an engaging cultural safety curriculum for medical trainees. For example, the experts acknowledged the potential to increase engagement by leveraging past experiences of medical students with traditional medicine. The game jam protocol, described in manuscript 7, uses discussion and reflection about past experiences of the medical students to enhance their learning process.

I presented the results of manuscript 2 at the 2018 McGill Interprofessional Health Research Symposium. The published Manuscript 2 has 907 downloads (November 30th, 2020). 6.1 [Manuscript 2] What motivates medical students to learn about traditional medicine? A qualitative study of cultural safety in Colombia

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Keywords: transformative learning, traditional medicine, participatory research, cultural safety

ABSTRACT

Objectives: This study explored motivation dynamics of medical students engaging with traditional medicine in Colombia.

Methods: We conducted a qualitative descriptive study as part of a larger participatory research effort to develop a medical education curriculum on cultural safety. Four final-year medical students participated in a five-month program to strengthen knowledge of traditional medicinal plants with schoolchildren in Cota, a municipality outside Bogota with a high proportion of traditional medicine users. Students and schoolteachers co-designed the program aimed to promote involvement of school children with traditional medicine in their community. The medical students shared written narratives describing what facilitated their work and discussed experiences in a group session. Inductive thematic analysis of the narratives and discussion derived categories of motivation to learn about traditional medicine.

Results: Five key learning dynamics emerged from the analysis: (1) learning from/with communities as opposed to training them; (2) ownership of medical education as a result of co-designing the exercise; (3) rigorous academic contents of the program; (4) lack of cultural safety training in university; and (5) previous contacts with traditional knowledge.

Conclusions: We identified potential principles for engaged cultural safety training for medical students. We will use these in our larger training program. Our results may be relevant to other researchers and medical educators wanting to improve the interaction of medical health professionals in multicultural settings with people and communities who use traditional medicine. We expect these professionals will be better prepared to recognize and address intercultural challenges in their clinical practice.

INTRODUCTION

Since 1977,¹ the World Health Organization has called for engagement between Western and traditional medicine.^{2,3} The Alma Ata view of primary health care recognized that traditional practitioners and medicinal plants might have a role in health promotion.^{4,5} Culturally diverse Colombia is a suitable setting for medical education research, with potential lessons for other countries. The Colombian government supports official health services based exclusively on the Western biomedical model, yet a high proportion of the population uses traditional medicine.² The cultural gap between health professionals and communities, who include different cultures, hinders community access to acceptable and effective health services.⁶

Along with many other countries,⁷ Colombian legislation ratifies a commitment to primary health care and to include the intercultural approach as a core element of health development (Article 13, law 1438 of 2011). This legislation has not permeated everyday medical practice, however, and medical education still lacks training programs to address cultural differences between patients and practitioners. Uninformed intercultural interactions hinder the delivery of culturally safe health services.^{8,9}

As a partial response to this state of affairs, there have been several global calls for awareness in medical education of the cultural preferences of local communities.^{10,11} Cultural competence is currently a common intercultural approach in medical education.¹² Its utilitarian understanding of culture and centering on the dominant culture, however, has led educators to advocate for more comprehensive approaches to health care, such as cultural safety.¹³

Cultural safety training promotes professional practice "that is spiritually, socially, emotionally and physically safe for people; where there is no assault, challenge or denial of their identity, of who they are, and what they need."(p272)¹⁴ Recent evidence links this type of education to improved relationships between health professionals and their culturally different patients, with improved health outcomes.¹⁴

Inspired by the cultural safety approach, we are developing a medical curriculum in Colombia to promote respect for traditional medicine users.¹⁵ The important challenges, however, are that health professionals have no motivation to interact with traditional medicine,¹⁶ and they receive no cultural safety training. This small exploratory study looks for motivating dynamics that might inform the larger participatory development of a cultural safety curriculum, increasing medical student interaction with traditional medicine. By working with and learning from traditional medicine users, we expected the medical students to become more respectful of and more open to traditional medicine practices and users.

METHODS

Study design and participants

We conducted a qualitative descriptive study. Four final-year medical students (two women and two men, age range 22-24 years) attending a course on community health¹⁷ and two instructors conducted a community-based learning exercise in a public school and a private preschool in the municipality of Cota, Colombia between July and November 2015. The details of the community health course are described elsewhere.¹⁷

This community exercise embraced the bioethical principles proposed by the Council for International Organizations of Medical Sciences,¹⁸ the Declaration of Helsinki,¹⁹ the resolution 8430 of 1993 of the Republic of Colombia, and the principles for studies with indigenous communities in that country.²⁰ We made clear to participating medical students that the exercise was not to provide health services to the schools nor to train the medical students in the use of traditional medicine.

Medical students provided written informed consent. We obtained parental consent during a meeting at the beginning of the school year. In the meeting, two researchers presented the project to the parents and explained that it was co-designed and supervised by the teachers as part of the official curriculum. The Sub-committee for Research of the Faculty of Medicine at *La Sabana* University provided ethical approval of the project (approval number: 445).

Setting

Cota, a small municipality 15km from the capital of Colombia, includes a high proportion of traditional medicine users, many of them subsistence farmers who identify with both indigenous and European health traditions. A local committee, including traditional medicine users who were also schoolteachers, and a local NGO (Center for Intercultural Medical Studies – CEMI), supported the exercise.

Prior to the fieldwork, the medical students received training using standard medical school lecture formats on elements of cultural safety, traditional medicine, primary health care, and participatory research. A series of planning meetings increased the trust between the medical students and the Cota community. In parallel, to increase their knowledge of the educational content, the students conducted a literature review on interventions aimed at strengthening traditional knowledge, using PubMed, LILACS, and Google Scholar. Finally, the community and teachers at the local schools discussed the perceived needs of the community regarding the recovery of traditional medicine knowledge and resources.

School teachers helped the medical students develop a list of opportunities for accessing lost traditional knowledge among the children attending the schools. The medical students and school teachers prioritized the opportunities using the Hanlon method²¹ and used a problems and objectives tree to analyze the selected issue and to propose solutions.²² Finally, the students and teachers created a work plan that followed the logical framework approach,²³ and scheduled a time commitment for four hours per week over four months. The schoolteachers, medical students, and instructors developed 33 activities aligned with the ages of the children who participated in the project (Table 6.6.1).

Table 6.1.1 Number of activities and their specific objective for each group oflearners, Cota (Colombia), 2015

Grade	Number of	Objective	Thomas	
	activities	Objective	i nemes	
Ninth	Five *	Improve the application of	Women's health care, self-care for common cold,	
		concepts and practices of	self-care for diarrhea, nutrition: basic concepts. †	
		traditional self-care for their		
		daily lives.		
Seventh	Eleven *	Deepen the knowledge about	Traditional knowledge, restoration of the orchard	
		medicinal plants and to	of medicinal plants, theatrical representation	
		introduce the concept of	about self-care, caring for medicinal plants,	
		traditional self-care of health.	visiting the medicinal botanical garden of Cota. †	
Sixth	Six *	Raise the interest of learners in	Sensorineural recognition of medicinal plants,	
		medicinal plants and traditional	restoration of the orchard of medicinal plants,	
		knowledge	caring for medicinal plants. †	
Transition	Eleven *	Raise the interest of learners in	Sensorineural recognition of medicinal plants,	
		medicinal plants	making and designing flowerpots, caring for	
			medicinal plants, making seals with medicinal	
			plants, visiting the medicinal botanical garden of	
			Cota	

* the designers set the number of activities before the exercise

† the teachers and students defined the themes together

The project promoted the intergenerational transmission of knowledge between groups of children and their parents through surveys with open-ended questions that the learners asked their parents at home. The intended effect was that, by asking the questions, children would recognize there was an issue and discuss it with their families, peers, and community. With the permission of school principals, the medical students also helped the children to restore school gardens of medicinal plants. The school gardens offered an opportunity for children to take care of the plants used for in-class discussions, thus promoting hands-on experience. The medical students conducted the 33 planned activities (for example, recognition and care of medicinal plants, and visiting the Cota's medicinal garden), accumulating 64 hours of direct work with the community. Some 482 people benefited from the project either directly or indirectly. The characteristics of the beneficiaries are shown in Table 6.1.2.

Table 6.1.2 The beneficiary population of the community exercise, Cota (Colombia),2015 (n=482)

Grade	Age range	Males	Females	Direct	Indirect	Total
	(years)			Beneficiaries*	Beneficiaries†	
Transition	4 to 5	7	6	13	44	57
Sixth	12 to 13	17	15	32	122	154
Seventh	13 to 14	14	17	31	122	153
Ninth	15 to 21	15	16	31	87	118
Total	4 to 21	53	54	107	375	482

* Students of the school and preschool in Cota

† People in the close family of the students in Cota

At the end of the exercise, the medical students organized an activity they called *Plant-art* to share the results with the school community; the participating children made infographics to communicate their experience and the results of their research (Table 6.1.3).

Table 6.1.3 Selected themes submitted for the infographics presented in Plant-art,Cota (Colombia), 2015

Grade	Infographic theme			
	Nutrition			
Ninth	Women's care Self-care for common cold			
INIII(II				
	Self-care for diarrhea			
	Manzanilla [Chamomile] (Matricaria chamomilla)			
	Diente de león [Dandelion] (Taraxacum officinale)			
	Sábila [Aloe vera] (<i>Aloe vera</i>)			
Coventh	Cidrón [Lemon verbena] (Aloysia citriodora)			
Seventin	Limonaria [Lemon grass] (<i>Cymbopogon citratus</i>)			
	Caléndula [Marigold] (Calendula officinalis)			
	Menta [Mint] (<i>Mentha sp.</i>)			
	Canelón [Radiator Plant] (Peperomia inaequalifolia)			
	Diente de león [Dandelion] (Taraxacum officinale)			
Civith	Manzanilla [Chamomile] (Matricaria chamomilla)			
Sixui	Ortiga [Stinging nettle] (Urtica dioica)			
	Limonaria [Lemon grass] (<i>Cymbopogon citratus</i>)			

Data collection

The medical students each wrote a brief narrative describing what facilitated their interaction with traditional medicine. They shared these texts with one another and participated in a group discussion of their reports, facilitated by educators from La Sabana University and CEMI.

Data analysis

We transcribed written information and audio files of the group discussion and submitted them to an inductive thematic analysis following the methods proposed by Braun and Clarke.²⁴ Two researchers (JP and IS) independently reviewed the transcripts and defined codes, involving a third party (GZ) in instances of disagreement. Consequently, they

compared their independent analysis and created themes and subthemes to offer a comprehensive explanation that would answer the research question.

RESULTS

The medical students described what motivated them to explore traditional medicine. They appreciated learning from or with people, as opposed to training them. The shared ownership of medical education motivated them as students co-designed the exercise with the community. They preferred a rigorous structure of the academic content of the program. They noted a lack of cultural safety training programs at university. And the exercise helped them recognize their previous experience with traditional knowledge.

Learning with the community

The students acknowledged gaps in their medical education as they became aware of the widespread traditional knowledge in the communities where they live and work:

"One feels a little bit uncomfortable because, this close to finishing our career, one realizes that there is some knowledge about health that we do not have." [male, 23 years, No. 1]

It was interesting for students that, in traditional medicine, the production of knowledge occurs outside of the academic context of Western universities:

"We realized that the source of knowledge was not us but the community." [female, 22 years, No.3]

"The surprise was that the majority of these children already knew these traditional concepts thanks to the intergenerational transmission of information in each family." [male, 24 years, No.2]

They expressed surprise that the direction of knowledge transfer, which they originally expected to be from the university to the community. As the project advanced, information began to move in the opposite direction:

"That moment was uncomfortable and disconcerting: we realized we came to the community to develop this project with very little knowledge about traditional medicine. However, the children taught us many things we did not know." [male, 24 years, No.2]

"Most of the traditional knowledge was imparted by the community [...] an atypical flow of knowledge, from which we learned." [male, 23 years, No.1]

This elicited student reflection about conventional research and health interventions in Western universities. The usual vertical approach to research was replaced by a more horizontal dialogue between the community and university students:

"They learned as much as we learned. That is not typical in research, where the researcher usually has way more knowledge and is therefore better able to intervene and teach. We experienced research-based on participation and dialogue, with the community and ourselves at the same level, both contributing knowledge to solve problems." [female, 22 years, No.3]

"We found other sources of knowledge. The hands-on experience became very important. It was like learning a different language." [female, 23 years, No.4]

The medical students gradually realized that their role as researchers in the project was mostly about respecting and thus strengthening knowledge and practices that had existed in the community for a long time:

"What we ended up doing was renovating interest in the knowledge they already had. It was like bringing that knowledge back to this century. We came here not to generate knowledge but to revitalize and to strengthen local knowledge, to foster the intergenerational flow of knowledge, and to encourage them to recover and promote their knowledge." [male, 24 years, No.2]

"For the teachers and schoolchildren, involvement of medical students boosted the process; they felt supported and encouraged to recover their traditions." [female, 23 years, No.4]

Ownership of medical education

Throughout their participation in the community-based experience, the students became more aware of the disconnect between medical education and the cultural context they work in:

"It is not that these communities live far from Western medicine, from the 'real medicine.' But many of us, health professionals and some citizens, live far from traditional medicine." [female, 23 years, No.4]

"There are a tradition and history behind this topic, the people have faith in that. One should be there to strengthen and not to change their culture." [male, 23 years, No 1]

The medical students also reflected on the gap between the conventional care available in official health services and culturally safe care that health professionals *could* offer based on local resources and traditional knowledge. "This training helps to reevaluate the field of health promotion because, at the hospital, health services are oriented towards disease. In this project, however, we learned there are many things that we can do in the community to promote health using local resources and traditional knowledge." [male, 24 years, No.2]

The medical students mentioned contributions of this community-based learning to their professional training. They saw traditional medicine as a key component of culturally safe health services in multicultural settings.

"I can now make recommendations [to patients] about self-care using traditional knowledge. It would be irresponsible to prescribe plants, but we can give some simple advice for health promotion based on traditional knowledge." [female, 23 years, No. 4]

A key experience was co-creation and co-ownership of elements of the training. By the end of the project, medical students began to implement some traditional care practices that they learned from the community:

"In nutrition, for example, traditional advice is to eat as a family. And when one does so, one realizes that there is much more behind eating as a family, such as strengthening ties. As a medical student, one eats very badly and following traditional advice could help to improve our nutrition. In the case of women's health, one can now give traditional advice to improve the health of women in our families." [male, 23 years, No.1]

"It made me reflect on my own self-care. I realized that I needed to eat healthier, to do exercise, and to improve my relationships with my family and friends. Moreover, when I got a common cold, I did some traditional care and I felt better, it was less severe." [female, 22 years, No.3]

Finally, the students identified risks associated with a reckless approach to traditional medicine. For example, the distortion of traditional knowledge that frequently occurs by unscrupulous persons:

"We are aware that in this world of traditional knowledge, we must be very careful of charlatans. For example, in the case of neo-shamanism." [male, 24 years, No.2]

"I believe this training is about health promotion, because learning to manage medicinal plants involves much more complex knowledge and training." [male, 24 years, No.2]

Rigorous program structure

At the beginning of the community-based experience, the students reported an attitude of skepticism or caution regarding traditional medicine:

"I have never believed in medicine that is not Western medicine. Perhaps this is because all my life I have followed a line of thought that I see as strictly logical and scientific, without ever opening myself to knowledge fields that are not based on the Western scientific method." [female, 23 years, No.4]

The students appreciated the lecture-based introduction because it gave them a recognizable format for organizing this new type of knowledge:

"I remember the first days of the training in which the professors gave us structured lectures on traditional medicine, participatory research, and intercultural dialogue. We realized that there are serious researchers from prestigious institutions who study and promote a respectful and rigorous approach to traditional knowledge." [male, 24 years, No.2]

Paucity of cultural safety training

Asked about the reasons for wanting to participate in the course, the students mentioned the lack of these experiences at the university level and their curiosity about exploring the ways traditional medicine users and their communities understand and approach health and disease:

"Most physicians do not have the chance to explore local understanding of the health-disease phenomenon during training. These are different from those of the Western biomedical model." [female, 22 years, No.3]

The content offered in the course proved to be novel for the students:

"It was something totally new for us." [male, 23 years, No.1]

"At the beginning, traditional knowledge was a totally unknown type of knowledge for me." [female, 23 years, No.4]

Prior traditional medicine experience

Some students recognized their previous contacts with traditional knowledge, either through their family or close friends:

"I have an olfactory memory, and I recognized the plant that my grandmother used to give me when I was little, and I was sick." [female, 23 years, No.4]

"Once when I was at my parent's farm in Caquetá [Colombian region], my brother got diarrhea, and a local lady who used to work in the farm gave him a traditional remedy, and it helped." [female, 22 years, No.2]

DISCUSSION

This study is part of a larger participatory research effort to develop a medical education curriculum on cultural safety.¹⁵ The idea is to encourage medical students to acknowledge and to respect patient ways of being and knowing. Training in cultural safety²⁵ can bridge the divide between traditional medicine users and health professionals in Colombian health services. This in turn can improve multicultural patient access to health services and increase the overall quality of healthcare delivery.¹⁴ As a first step along this path, we explored what motivates medical students as they interact with traditional medicine. We identified several actionable themes: learning with the community, ownership of medical education, a rigorous structure of the training program, paucity of cultural safety programs, and previous exposure to traditional medicine.

The community base of this training encouraged medical students to acknowledge traditional medicine users as a source of knowledge. Learning with the community promoted equitable inclusion of traditional medicine users. The participatory nature of the project contrasted in a positive way the conventional hierarchy of knowledge passed from teacher to student.

At the beginning of the project, students expressed caution or even skepticism about traditional medicine since it does not follow familiar logic and or what they recognize as scientific procedures. Parra and Pacheco suggested this attitude stems from the proposal of

conventional medical training that Western science is the only valid way to create and transfer knowledge.²⁶

In our study, the focus on community voices provoked a positive attitude of the medical students towards traditional medicine. Macaulay²⁷ highlights the value of community-based participatory initiatives that allow researchers and communities to contribute equally to co-creation of knowledge. Researchers and communities learn from each other. Participatory research combines education and action to "democratize the knowledge production process." (p327)²⁸

Several authors have described the role of community-based projects in intercultural training. Clark²⁹ reported that social work students increased their personal and professional awareness of diversity, recognized their own biases, and increased their level of comfort with cultural differences after participating in community-based transformative learning. Muñoz-Cano³⁰ and Arce-Antezana³¹ suggested that project-based learning allows development of the skills for intercultural education by promoting awareness and respect for other cultures, languages, and people; it allows medical students to empathize with people who are different from themselves. Our study confirms the value of community-based learning in cultural safety.

Engaging higher education students in the co-creation and co-ownership of academic content has recently gained attention,³² although it is still uncommon in medical education. Curriculum co-creation is additionally promoted by the World Federation of Medical Education (WFME) Global Standards for Quality Improvement.³³ Benefits from cocreated curriculum initiatives include a deeper understanding of the learning process, changing the way students relate to others, and enhanced student motivation, enjoyment, and enthusiasm for learning.³⁴

By co-designing the exercise with community members and schoolteachers, the students in our study explored traditional medicine based on both their own interests and the needs of the community. This helped them to address the disconnect between medical education and the sociocultural context they will work in. Our proposal was motivated by the idea that medical education should respond to the expectations and needs of patients

and their communities, and that medical training should address the relationships between local culture and health outcomes.³⁵

The medical students evaluated the structured introductory academic cycle in positive terms, mentioning that it gave them the confidence and motivation to approach the intercultural training. This suggests likely value in creating cultural safety training initiatives based on a structure that is familiar, logical, formal, easy-to-follow, and rigorous in the experience of medical students, allowing them more easily to internalise the content. It also highlights the need to refer to international guidelines and local legislation in cultural safety training.

Before the exposure to traditional medicine in this project, the medical students did not recognize the potential benefits of traditional practices. Medical students preferred the knowledge they received at university over the health practices they experienced at home. Students saw Western science as more advanced and civilized.^{31,36} Notwithstanding this, several students reported previous experience with traditional medicine, mostly through their families, as an enabling or motivating factor.

Importantly, the medical students near the end of their studies mentioned a complete lack of cultural safety training. According to Chitindingu,³⁷ the increasing demand for traditional medicine in multicultural settings makes medical students show more interest in and enthusiasm for participating in intercultural training. This confirms the need to foster and document experiences on learning about cultural safety in Colombia.

Limitations

A well-recognized limitation in medical education research is its risk of social desirability bias.³⁸ Medical students could respond with the most socially desirable answers rather than their own point of view. We encouraged students to be sincere when writing down their narratives and assured them that their answers would not have any impact on any grade in any course. We recognize, nonetheless, the narratives are unlikely to reflect a full 360-degree account of the experience.

Our study is qualitative and involves only a small number of participants. The relative uniformity of narratives encourages us to think a larger size would not generate very different results, given the abovementioned likely bias. We report here only the student perspective (and not the community, schoolchild or teachers' view), as the exercise set out to examine student motivation. The nature of the study means the results are likely to be influenced by our own values and beliefs, and our interpretation takes account of that limitation.

CONCLUSIONS

Cultural safety should be a standard component in medical education in Colombia, which is currently quite distant from the cultural preferences of large segments of the population. Educators in similar settings may find our results informative in design of training initiatives to improve professional interactions and to enhance respect for traditional medicine users.

We recommend anchoring cultural safety training in community voices, involving students and communities as co-authors of training content, providing formality and rigour to the content, and exploring prior student contact with traditional medicine. If time and resources are sufficient, the involvement of students in community-based programs offers a rich environment to encourage transformative learning.

Medical education about cultural safety is a necessary step in adapting health systems to the cultural expectations and preferences of the population. A transformative dynamic of these programs helps to generate attitudes of openness among medical students. We expect these students will be better prepared to recognize and address intercultural challenges in their future clinical practice.

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Teachers Astrid Romero, Marcela Balcero, Mélida Valbuena, Patricia Hómez, and Sara Romero opened their classrooms to advance the activities of the project. One primary school (*Institución Educativa Departamental Enrique Pardo Parra* [Enrique Pardo Parra Departmental Educational Institution]) and two preschools (*Sol Solecito* [Sun Little-Sun] and *Manitos Creativas* [Creative Little-Hands]) allowed the implementation of the program. Camilo Correal, Rosa Durán, Sandra Espitia, Erwin Hernández, and Francisco Lamus contributed ideas to the project. Cassandra Laurie and Brenda Atkinson proofread the final version of the manuscript and supported its write-up.

Conflict of Interest

The authors declare that they have no conflict of interests.

Authors' contributions

JP and IS designed the study and supported the fieldwork; they also analyzed the data and drafted the manuscript. GS and NA supported the study design and contributed to the manuscript. All authors read and approved the final manuscript.

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PREFACE TO MANUSCRIPT 3

The community-based learning intervention described in manuscript 3 allowed me to: (a) explore the acceptability and feasibility of using community-based transformative learning for cultural safety training; (b) pilot the Most Significant Change technique, which I used in the full-scale RCT (manuscripts 7 and 9); (c) examine the range of outcomes of transformative learning for cultural safety training; and (d) strengthen trust and credibility between the stakeholders (traditional medicine users, medical students, and cultural safety experts).

Acceptability and feasibility were confirmed by 17 senior medical students who successfully completed their cultural safety training using community-based transformative learning. The students reported positive perceptions of traditional medicine after the interventions. The faculty members at *La Sabana* University expressed interest in continuing to use this type of training.

I presented the protocol of manuscript 3 at the 2018 Annual Family Medicine Research Symposium, McGill University, and the results at the 2018 NAPCRG Annual Meeting in Chicago IL, USA. I supported co-author and medical student Camila Kairuz to win a travel award to present the results at NAPCRG together. The published Manuscript 3 has 200 views and 13 tweets (November 30th, 2020). 6.2 [Manuscript 3] The Experience of Colombian Medical Students in a Pilot Cultural Safety Training Program: A Qualitative Study using the Most Significant Change technique

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Keywords: cultural safety, transformative learning, participatory research, Colombia

ABSTRACT

Problem: The Colombian government provides health services grounded in the Western biomedical model, yet 40% of the population use cultural and traditional practices to maintain their health. Adversarial interactions between physicians and patients from other cultures hinder access to quality health services and reinforce health disparities. Cultural safety is an approach to medical training that encourages practitioners to examine how their own culture shapes their clinical practice and how to respect their patients' worldviews. This approach could help bridge the cultural divide in Colombian health services, improving multicultural access to health services and reducing health disparities.

Intervention: In 2016, we conducted a pilot cultural safety training program in Cota, Colombia. A five-month training program for medical students included: (a) theoretical training on cultural safety and participatory research, and (b) a community-based intervention, co-designed by community leaders, training supervisors, and the medical students, with the aim of strengthening cultural practices related to health. Evaluation used the Most Significant Change narrative approach, which allows participants to communicate the changes most meaningful to them. Using an inductive thematic analysis, the authors analysed the stories and discussed these findings in a debriefing session with the medical students.

Context: Cota is located only 15 km from Bogota, the national capital and biggest city of Colombia, so the small town has gone through rapid urbanization and cultural change. A few decades ago, inhabitants of Cota were mainly peasants with Indigenous and European traditions. Urbanization displaced agriculture with industrial and commercial occupations. One consequence of this change was loss of cultural health care practices and resources, for example, medicinal plants, that the community had used for centuries.

Impact: A group of 13 final-year medical students (ten female and three male, age range 20-24) participated in the study. The medical students listed four areas of change after their experience: increased respect for traditional health practices to provide better healthcare; increased recognition of traditional practices as part of their cultural heritage

and identity; a desire to deepen their knowledge about cultural practices; and openness to incorporate cultural practices in healthcare.

Lessons Learned: Medical students reported positive perceptions of their patients' cultural practices after participating in this community-based training program. The training preceded a positive shift in perceptions and was accepted by Colombian medical students. To the best of our knowledge, this was the first documented cultural safety training initiative with medical students in Colombia and an early attempt to apply the cultural safety approach outside the Indigenous experience.

INTRODUCTION

Training medical students to meet the cultural needs of their patients has been a concern in medical education since the 1980s. Related identifying labels for these concerns include cultural competence, cultural sensitivity, cultural awareness, and cultural humility. All share the objective of making health care services more accessible, acceptable, and effective for people from diverse ethnocultural communities.¹

Cultural competence

Cultural competence is currently the most common intercultural approach in medical education. Three systematic reviews²⁻⁴ identified benefits of cultural competence training including increased patient satisfaction, mutual understanding, and adherence to treatment. They also document positive changes in knowledge, attitudes, and skills of medical students.²⁻⁴ Cultural competence training addresses the beliefs and behaviors of *cultural minorities* such as Afro-American, Asian, Latinx, and Indigenous patients. Training programs often include simple "dos and don'ts" for care of these specific cultural groups of patients.⁵ They have introduced translators into clinical settings and sometimes involved *ethnic matching* of patients and physicians.^{1,4} Although cultural competence is a step towards understanding the role of culture in health care, some authors have recently criticized the concept and associated practices.⁶ Betancourt,⁵ for example, argues that cultural competence promotes stereotyping and simplification of culture, and therefore calls for more comprehensive cultural approaches.

Cultural safety training in Colombia

Cultural safety training promotes a deeper understanding of the complexity of culture than does cultural competence. Cultural safety encourages practitioners to examine how their own culture shapes their clinical practice and to respect their patients' worldviews and cultural practices.⁷ One key element of cultural safety is inviting end-users to co-construct culturally safe care,⁸ recognizing their authority to ensure interventions are aligned with the patients' local cultural expectations and needs. In their concept analysis, Blanchet & Pepin⁹ reported three elements of cultural safety: equal partnership, active participation of patients from different cultures, and protection of their cultural identity and well-being.

These elements, and especially the participation of patients in intervention co-design, make cultural safety a more comprehensive approach than cultural awareness, sensitivity, competence, and humility.

Around the world, there is growing agreement about the need to train medical students to provide culturally safe services.¹⁰ The Royal College of Physicians and Surgeons of Canada will soon require all residency programs to include cultural safety training in their curricula. Since there is little research in the field, however, "few programs are prepared or know what that training should include." ^{11(pE778)}

Multicultural Colombia is a rich setting for medical education research, with potential relevance in other multicultural settings. The Colombian government provides health services grounded in the Western biomedical model yet 40% of the population use cultural and traditional practices to maintain their health.¹² Adversarial interactions between physicians and patients with different cultural backgrounds hinder access to quality health services and reinforce health disparities.¹³⁻¹⁵

Cultural safety training could help bridge the cultural divide in Colombian health services, thus improving patients' access to health services and reducing health disparities.¹⁶ Co-designed with community leaders knowledgeable in traditional health practices, the objective of this qualitative evaluation was to explore the experiences of 13 medical students to determine the feasibility, acceptability, and impact potential of a community-based cultural safety training program.

METHOD

Study design

This qualitative, descriptive study used the Most Significant Change (MSC) technique.¹⁷ MSC is a narrative approach that allows participants to communicate changes most meaningful to them after participating in interventions.¹⁸ We used MSC because cultural safety training goes beyond simply knowledge acquisition; it promotes attitudinal and behavior change of participants.

Setting and participants

From January to May of 2016, a group of 13 final-year medical students participated in a pilot cultural safety training program in Cota, Colombia. Cota is a small town 15 kilometers from Bogota (the national capital and biggest city in the country), and has gone through rapid urbanization and cultural change.¹⁹ A few decades ago, people in Cota were mainly peasants with Indigenous and European traditions. The urbanization process replaced agricultural activities with industrial and commercial occupations. One of the consequences of this change was the abandonment of cultural health care practices and resources that the community had used for centuries, for example, medicinal plants. Community members from Cota, however, have initiated a process to recover local traditional knowledge and practices.²⁰

The pilot program was part of a mandatory theoretical-practical community health course at *La Sabana* University.²¹ In that larger course, 63 students received a one-week theoretical training based on the community health cycle. They learned about community engagement and assessment, intervention co-creation, results dissemination, and change sustainability. Subsequently, the class split into smaller groups of students to work with a range of communities, including homeless, elderly, children from financially challenged families, and traditional medicine users. The 13 students who participated in our study chose to work with the traditional medicine users. These 13 received an additional week of lecture-based training on cultural safety, participatory research, intercultural epidemiology, and local cultural practices. Eight university professors (including the authors JP, IS, GZ and CC) delivered the two-week training program that lasted 58 hours.

In the practical session, the medical students participated as research assistants in an intercultural epidemiology case-control study. The study explored the relationship between traditional health practices and asthma diagnosis in eight rural municipalities near Bogota. The students participated in the design of the research instrument, gathered the data through phone-calls, analyzed the data, and wrote a preliminary research report that they shared and discussed with their classmates.

In the last part of the study, the students participated in a community-based intervention involving a public elementary school and two kindergartens. The intervention aimed to recover and promote the traditional knowledge and resources traditionally used in Cota for promoting respiratory health. The medical students co-designed the intervention in collaboration with five schoolteachers who were knowledgeable about local traditional health practices and supported by three training supervisors (JP, CC, and IS). The program included in-class activities tailored to the age groups of the school children (see Table 6.2.1).

Grade	Objective	Activities
Kindergarten	To raise the interest of	- Recognition of medicinal plants through the senses
	children and their	- Discussion-based overview of medicinal plants
	families about	- Visit to the Cota's botanical garden
	traditional medicine	- Compilation of teachings and memories
Seventh grade	To deepen knowledge	- Lecture-based introduction to traditional medicine
	about traditional	- Lecture-based overview of traditional medicine for respiratory
	medicine with a focus	health
	on respiratory care	- Game-based learning: "who wants to be a millionaire" format
		tailored to traditional medicine
		- Hands-on learning on how to prepare traditional remedies
Eighth grade	To deepen knowledge	- Lecture-based introduction to traditional medicine
	about health traditions	- Lecture-based overview of traditional medicine for respiratory
	with emphasis on	health and women's health
	respiratory care and	- Lecture-based overview of agroecological techniques
	women's health	- Hands-on learning: rehabilitation of the orchard of medicinal
		plants
		- Game-based learning: role play based on the concepts learned

Table 6.2.1. Activities of the co-designed community-based intervention

Data collection

After completing the exercise with the schoolchildren, their communities, and teachers, we invited the 13 medical students to write about their experience using the MSC technique.

The inclusion criteria were participation in the training program and providing informed consent. We informed the students that the research exercise was not mandatory and had no influence on their performance in the course. Through their narratives, the medical students answered three questions: a) looking back over the last five months, what do you believe was the most significant change in your way of seeing traditional practices for health care after participating in the intervention? b) can you please share a real-life story depicting this change? c) why do you think this story is significant? The students had a week to write their narratives independently and were free to write as much as they wanted, although we suggested one to two pages, as we preferred concise stories.

We invited participants to tell stories of both positive or negative changes or to report that they experienced no change at all. Together with the research team, the medical students presented and discussed their MSC narratives with their medical school peers.

Data analysis

Three members of the research team (CM, DV, and CK) transcribed the narratives and the recordings of the group discussion and carried out an inductive thematic analysis using AtlasTi V8 for Windows. Analysis followed the phases of inductive thematic analysis proposed by Braun and Clarke.¹⁷ First, two independent team members reviewed the transcripts and created codes. They compared their analyses and decided on themes and subthemes, involving a third researcher (JP) in instances of disagreement. The researchers defined the meaning, name, and relationships of the agreed themes.

Rigor

We followed the strategies for increasing trustworthiness in qualitative research proposed by Shenton.²² We employed validated research methods to gather and to analyze the data. We enhanced confirmability by disclosing that the researchers' background influences the analysis of the data, as well as by recognizing the limitations of the study. The three researchers who conducted the thematic analysis (CM, DV, and CK) were sixth-year medical students at *La Sabana* University with no previous experience on cultural safety or community health when this article was written. JP, a general practitioner with an MSc in Epidemiology and a Doctoral Candidate in Family Medicine and Primary Care, guided CM,

DV, and CK during the analysis phase. Prior to the analysis, JP provided a one-day training on thematic analysis. CM, DV, CK, and JP are Colombian.

Ethical approval

The Sub-committee for Research of the Faculty of Medicine at La Sabana University provided ethical approval of the project (approval number: 445).

RESULTS

A group of 13 final-year medical students (ten female and three male, age range 20-24) participated in the study. They reported four areas of change: new respect for traditional health practices to provide better healthcare; recognition of traditional practices as part of their cultural heritage and identity; wanting to deepen their knowledge about cultural health practices; and openness to incorporate cultural practices in healthcare.

Increased respect for traditional health practices to provide better healthcare

The medical students reported that their clinician professors and professional role models do not encourage respect for local traditional and cultural health practices. Participating in the pilot training fostered a new sense of respect for the traditions of their patients.

"I have had experiences with specialists [physicians] in which, when the patient tries to say 'I am doing this thing, or I go to the bonesetter to be rubbed', the specialist immediately reacts aggressively to say 'do not tell me that, I only know that that does not work.'" (Student #8)

"It is like opening your mind a little bit, it allows you to be a bit more aware of the reality and avoid judging, because one does not know, and one cannot take a risk to say that [cultural practices] do or do not work. But the point is to respect our patients. I think it is a question of values to respect." (Student #8)

Some students highlighted their interest in learning from their patients' experiences.

"And now, each time that a patient comes to the office and tells me about a traditional remedy, instead of interrupting him abruptly to redirect the consultation, I am interested in what they say, and I even ask them more questions about the topic." (Student #10) The students regarded engaging patients in dialogue as a way to empower them and to increase their participation in the health decision-making process.

"I will make them [the patients] feel more understood and less stigmatized because of their health practices; I will be able to empower them and make them participants of their health-disease process." (Student #10)

The students acknowledged additional benefits of respecting their patients' cultural practices such as improving doctor-patient relationships and adherence to treatments. They recognized these positive effects could help them become better doctors.

"I think that simply the fact of being more empathetic with the patients, not judging them; the simple fact that the physician shows empathy with patients' practices and believes, helps to improve doctor-patient relationships, to improve adherence to treatment, to improve many things that can help us (...) to become better doctors." (Student #10)

Traditional health practices are part of their cultural heritage and identity

The students reported a feeling of disconnection between what they learn at the faculty of medicine and their own cultural context. After several years of medical school, they found themselves alienated from their own cultural traditions.

"The majority of our knowledge is based on a language that is not ours, from countries that of course are not ours (...) and we have become so used to apply and follow those standards that now we consider them our own. We tend to forget what is indigenous and our own, like our traditional knowledge." (Student #9)

Beyond their significance in the therapeutic process, students thought that cultural practices must be protected and preserved because they are an integral part of their culture and traditions.

"It is a knowledge that (...) should not disappear. The reason is not that I believe it works because I really do not know, but because it is an integral part of our culture, our knowledge, and our traditions. That is why it should be protected and must endure." (Student #4)

Finally, some students recognized that they have had personal experiences with traditional health practices.

"In my house, I have medicinal plants in the patio; there is *sábila* [aloe], there is *yerbabuena* [peppermint], there is *caléndula* [marigold]. Because my dad is from Boyacá, he has those traditions (...), I even had the opportunity to be nettled [getting brushed with stinging nettle is a traditional therapy]." (Student #2)

The need to deepen the knowledge about traditional health practices

The participants acknowledged that traditional health practices are worthy of being studied, recognized, and considered. Similarly, they acknowledged the need for further research on this topic.

"I am aware that it is a field of knowledge to be recognized and taken into account, that deserves further study, because it represents our cultural identity and the valuable heritage of our grandparents." (Student #12)

Some students recounted their interest in engaging in traditional health practices, identifying the potential benefits for their own personal health and well-being.

"After this experience, I have decided to apply some traditional practices of self-care in my personal life and see what happens." (Student #13)

Openness to incorporate traditional health practices in healthcare

The students recognized cultural health practices as a form of primary health care that can easily take place at home.

"I understood that there are different ways to help improve the quality of life of people, and many of these can be done as a way of primary health care at home, without having to go always to a health center." (Student #3)

Students identified several positive aspects of traditional health practices, including their inexpensive methods and accessible resources.

"[Traditional practices involve] methods that are more affordable, with fewer adverse effects, and are available any time they are needed." (Student #5)

In self-care of uncomplicated mild diseases, the students recognized traditional health practices as potential assets in community health promotion. The students saw the value of cultural practices in preventing disease and reducing the overall costs of health systems. "I see it as an important resource that could have a great impact on the health of populations and on health systems in terms of reducing costs of treatments and especially preventing diseases." (Student #1)

DISCUSSION

The medical students described four areas of change after our community-based learning: new respect for traditional health practices to provide better healthcare; recognition of traditional practices as part of their cultural heritage and identity; wanting to deepen their knowledge about cultural health practices; and openness to incorporate cultural practices in healthcare.

Recently, other researchers have described the value of community-based projects in developing intercultural skills.^{23,24} Muñoz-Cano argued that project-based learning provides medical students with a complex environment to build the required skills for intercultural interactions.²⁵ Clark reported that engaging students in community-based learning increases personal and professional awareness of cultural diversity and biases and increases their comfort and tolerance of ambiguity.²³ A literature review on cultural safety education demonstrated that university-community partnerships are a key element to ensuring an immersive and successful cultural safety experience for learners.²⁶ These results and our findings endorse the role of community-based learning in cultivating the intercultural skills of health professionals.

Throughout the experiential learning program, the medical students engaged with community experts in traditional health practices and in the co-design and execution of the community-based intervention. The theoretical content and practical experience provided a safe space for the students to familiarize themselves with local cultural practices and to acknowledge the importance of respecting patients who use traditional and cultural health practices. Protection of cultural identity is a key element of cultural safety training.^{9,27}

The students reported recognition of traditional practices as part of their cultural heritage and history. A key objective of cultural safety is to minimize any assault on the patients' cultural identity,^{24,28} and to legitimize local knowledge and traditions as genuine
sources of knowledge and expertise.²⁹ By acknowledging that traditional health practices are part of their identity, the medical students may be more open to understand their patients' cultural knowledge and practices.

Students expressed an interest in engaging in traditional health practices themselves and through their patients' experiences, in addition to an awareness of the need for more research on cultural safety and traditional practices. This goes beyond the demands of cultural safety, to involve re-enculturation, as students who have been separated from their culture of origin grow closer to their patients and communities. Participatory projects can "overcome the fragmentation and separation of the individual from his/her culture;" ³⁰ (p¹⁸¹) they generate research that is culturally appropriate to endusers³¹ and have "the potential to bridge the cultural gaps that may exist between the partners involved." ³⁰ (p¹⁸¹)

Adopting cultural safety can benefit patients, providers, and health care systems.^{7,26} In our study, participating medical students suggested potential benefits of cultural safety training in clinical practice. They proposed possible improvements in the patient-provider relationship, patient adherence to treatment, and transformations in their practice as physicians. Furthermore, they recognized that traditional health practices are accessible and inexpensive health resources with the potential to reduce dependence on an overburdened healthcare system.³²

Cultural safety acknowledges and addresses power imbalances between service users and healthcare providers.³³ This can be promoted by inviting patients to be partners in the health-decision making process.⁸ In our study, the medical students recognized that showing interest in traditional practices could engage patients in their health decisionmaking process, thus potentially addressing the power imbalances that are naturally present in clinical encounters.

Cultural safety also aims to promote self-awareness.³⁴ According to the National Aboriginal Health Organization,⁷ this requires healthcare providers to examine their own culture, history, experiences, beliefs, and attitudes. Ramsden³⁵ suggested that students should reflect on their own 'invisible baggage', which are values and attitudes that

influence their clinical practice. By understanding these elements, healthcare providers recognize the effect their own culture has on health care and their patients' responses. In our study, an example of this self-awareness was recognizing the disconnect between what the students learned at the faculty of medicine and their own cultural context, since they do not learn about Colombian cultural health practices in the MD program.

Another important concept in cultural safety is recognition of the colonial and sociopolitical context in which racial/ethnic disparities have been created, and the ongoing racism in which they were maintained.⁷ Some students mentioned experiences of clinical professors demeaning patients based on their traditional practices. Similarly, the students recognized that the current education that they receive is part of a global process that positions the Western view of health and health care as superior to local traditional health systems. Some have referred to this unfortunate view of local knowledge and practices as epistemic racism.³⁶

Perhaps the most important concept in cultural safety is authority, meaning that those receiving the service are the ones who define cultural safety.^{9,27} This can happen at two levels. First, patients and their communities might work together with clinicians, researchers, or educators to define the elements of culturally safe interventions. Second, end-users of health care might judge whether they participated in a culturally safe intervention or not. In our study, community members and medical students worked together in the co-design of a culturally safe community intervention. We did not measure the experience of authority for the school children, their community, and teachers, but we believe the exercise gave medical students a glimpse of what the authority means. This was an opportunity for the medical students to learn about the local cultural expectations and needs of communities, perhaps helping them to consider the cultural context of their patients in their future clinical practice.

There is a growing agreement on the need to integrate intercultural experiences in medical curricula.³⁷ Inspired by the cultural safety approach, our pilot community-based learning experience was a first step towards addressing the cultural gap between communities and medical students. To the best of our knowledge, this was the first

documented cultural safety training initiative with medical students in Colombia and an early application of the cultural safety approach outside the Indigenous experience.³⁴

Limitations

A significant limitation of the intervention was its length; certainly, the intervention was longer than most medical schools commit to cultural safety training in an already condensed undergraduate medical curriculum. However, this pilot was concerned not so much with a "model program", but rather with exploring *how* cultural safety training might be experienced by medical students and the training's potential effect. Since the results were broadly resonant with cultural safety, our next step will be to work out how similar results might be achieved in less time.

Because of the invariable power imbalances present in medical education, we recognize that participants in our study may have felt the need to report a positive effect after the intervention. We cannot rule out that the participants, like others in medical education research, may have been influenced by social desirability bias.³⁸ To mitigate this, we encouraged students to be sincere when writing down their stories. We let them know that they should not give responses they thought we wanted to hear, but those that best reflected their most significant change. Finally, we informed students that their answers would not have any impact on their academic record. We are aware these measures do not preclude social desirability bias and we interpret our results with caution, anticipating confirmation by future studies in other settings.

CONCLUSIONS

Colombian medical students reported positive perceptions of traditional health practices after participating in this training program. They showed that cultural safety training is feasible and accepted through community-based learning involving co-design of intervention with traditional medicine users. We hope that these students will be more respectful and open towards patients from non-dominant cultures - especially those involved in traditional health practices - to engage in collaborative health decision-making. As medical educators, we are concerned with reproducing cultural safety training in other settings, hopefully developing a less time-consuming modality. **Acknowledgments:** The authors wish to thank Sara Romero, Astrid Romero, Patricia Hómez, Mélida Valbuena, and Marcela Balcero, the community leaders who supported the study, Erwin Hernández, Sandra Espitia, Rosa Margarita, and Francisco Lamus who provided feedback to the project, and Hila Silver and Cassandra Laurie who helped proofread the final version of the manuscript.

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Contributors: All the authors designed the study, conducted the analysis, and wrote the article manuscript. JP, CM, DV, CK, IS, and CC conducted the community-based intervention. JP, CM, DV, and CK collected the data of the study. All the authors approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

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CHAPTER 7 [Manuscripts 4 & 5]: A Co-Designed Curriculum for Cultural Safety Training of Colombian Health Professionals: sequential-consensual qualitative study

PREFACE

Blanchet & Pepin⁴ present the key elements of cultural safety: equal partnership, protection of culture and active participation of patients from non-dominant cultures. Additional concept analyses⁵¹ and the National Aboriginal Health Organization⁵⁴ have also highlighted the need to engage patients and their communities in co-designing and evaluating cultural safety interventions. Active participation differentiates cultural safety from other cultural approaches, such as cultural competence. The participation of patients is aligned with the participatory research approach,² and contributes to addressing the power imbalance in official health services and to promote the self-determination of minorities.⁸⁷ Manuscript 4 describes the protocol of sequential-consensual qualitative study to co-design a curriculum of cultural safety training for health professionals. Manuscript 5 presents the results of co-designing a curriculum.

I invited traditional medicine users, final-year medical students, and cultural safety experts to co-design a curriculum for cultural safety training of Colombian health professionals. By doing so, I adhered to the active participation principle of cultural safety. The co-designed curriculum informed the lectures of both the intervention and control groups in the full-scale RCT (manuscripts 7, 8, and 9). Also, the game jam participants used the structure of the co-designed curriculum to design their educational games.

I presented the protocol of the qualitative study (manuscript 4) at the 2018 World Conference on Qualitative Research in Lisbon, Portugal. I did not originally plan to publish the protocol of the study; the paper was selected by the conference committee to be published as a book chapter in the Springer's series *Advances in Intelligent Systems and Computing*.¹¹⁰ The published document has 581 downloads (November 30th, 2020).

7.1 [Manuscript 4] Curriculum Co-design for Cultural Safety Training of Medical Students in Colombia: Protocol for a Qualitative Study

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Keywords: cultural safety, participatory research, medical education, Colombia, thematic analysis

ABSTRACT

Cultural safety in medical training encourages practitioners, in a culturally congruent way, to acknowledge the validity of their patients' worldviews. Lack of cultural safety is linked to ethnic health disparities and ineffective health services. Colombian medical schools currently provide no training in cultural safety. The aim of this qualitative study is to: (i) document the opinions of stakeholders on what a curriculum in cultural safety should teach to medical students; and (ii) use this understanding to co-design a curriculum for cultural safety training of Colombian medical students. Focus groups will explore opinions of traditional medicine users, medical students, and cultural safety experts regarding the content of the curriculum; deliberative dialogue between key cultural safety experts will settle the academic content of the curriculum. The research develops participatory methods in medical education that might be of relevance in other subjects.

INTRODUCTION

In 1977, the WHO called for collaboration of Western and traditional medicine,¹ in its view of Primary Health Care ² recognising an inextricable relationship between culture and health outcomes. Yet, this international recognition does not guarantee acknowledgment in everyday medical practice.³ Western physicians continue to receive medical education and to be presented with role models that do not emphasise culture as a positive resource in health outcomes.

Medical education curricula in most Western countries still focus on biomedical content and perspectives, reducing the chances that the next generation of physicians will acquire the skills and mindset to provide culturally congruent health services. This is compounded by differences in cultural background between physicians and their patients that accentuates the shortfalls of Western medical education, hindering accessibility, acceptability, and effectiveness of health services in the intercultural context.⁴ At worst, these differences lead to confrontation with, discrimination against, and even harm to patients, with racial/ethnic health disparities as the outcome.⁵ In terms of economic impact, the combined cost of these disparities was estimated at \$1.24 trillion between 2003 and 2006 in the US.⁶

There is growing agreement about the need to train medical students to provide culturally congruent services.^{7,8} For instance, the 2015 Standards for Accreditation of Medical Education Programs in Canada⁹ call for training on "the basic principles of culturally competent health care" (p.21) and "the manner in which people of diverse cultures perceive health and illness and respond to various symptoms, diseases, and treatments" (p.21). Some medical curricula have implemented "cultural competence" training with positive results including reduction of health care disparities,¹⁰ increased satisfaction, increased adherence to prescribed treatments,¹¹ a healthier doctor-patient relationship,¹² and even improved physiological and biochemical indices of disease.¹³

These improvements, notwithstanding, some authors criticize cultural competence as a concern that improves Western service delivery/supply without dialogue about demand, a new form of colonialism,¹⁴ leaving the *power* relations between the patient and

professional unaffected.¹⁵ The relatively newly popularised concept of "cultural safety"¹⁶ goes beyond cultural competence, insisting that the patients should have an opportunity to "comment on practices and contribute to the achievement of positive health outcomes and experiences".¹⁷ Cultural safety embraces *dialogue* between patients and physicians to make joint decisions and especially to judge whether the interaction is culturally safe or not.¹⁸

Increasing awareness of cultural safety in medical education would yield the benefits of cultural competence, but also acknowledge the power relationships that occur in practice while "accepting the legitimacy of difference and diversity in human behavior and social structure."¹⁷ Such a shift in practice would facilitate the transition to a more equitable and client-centred provision of health services, simultaneously reaffirming the communities' right to self-determination and providing respectful services free of colonized perspectives.

Multicultural Colombia is an ideal setting for implementing cultural safety in medical training. In the country, the government supports health services firmly based on the Western biomedical model. In contrast, up to 40% of the population seek care in traditional medicine,¹⁹ creating a care gap between the community expectations and needs, and the physician's knowledge and skills. Unfortunately, at present Colombian medical schools provide no cultural safety training.

In light of this, the purpose of our study is two-fold: (a) to examine the opinions of several stakeholders on what a curriculum in cultural safety should teach to medical students so they can provide a culturally safe practice when interacting with traditional medicine users in Colombia; and (b) to use this understanding to co-design a curriculum for cultural safety training of Colombian medical students.

Research Question

What are the opinions of stakeholders on what a co-designed cultural safety curriculum should teach to medical students so that they can provide culturally safe services in Colombia? In this study, the stakeholders include key-informant traditional medicine users and medical students from Colombia, as well as key cultural safety experts from Colombia and Canada.

METHODOLOGY

Research Design

We will use a qualitative research design that uses a sequence of qualitative research methods aimed at producing data "with adequate generalizability, (...) to influence public health programming and clinical work" (p.417).²⁰ The goal of this methodology is to produce relevant knowledge to generate social change of stakeholders, end-users, and their communities.

Participants

We will invite three different groups of stakeholders: a) traditional medicine users from the "Seed of life" (Semilla de vida) community organization at Cota, Colombia; b) senior medical students from *La Sabana* University (Colombia); and c) cultural safety experts from the Center for Intercultural Medical Studies (CEMI) and the Research Group on Traditional Health Systems (GESTS) in Colombia, as well as from the Participatory Research at McGill (PRAM) and the McGill Institute for Human Development and Wellbeing (IHDW) in Canada.

According to Israel, a participatory research expert, "building upon prior positive working relationships is a viable strategy for conducting participatory research" (p.187).²¹ This project is based on previous partnerships between CEMI, GESTS, McGill PRAM and the Seed of Life organization. Collaborating for more than 13 years in participatory initiatives to protect traditional cultures, ^{22,23} these stakeholders have developed reliable relationships that will facilitate the progress of the project.

Sampling Strategy

We will use a purposive sample of key informants.²⁴ The Seed of life organization is comprised of 10 key traditional medicine users and community leaders. They are key informants because they have been recognized by the community as knowledgeable about traditional medicine and also have 20 years of experience working in community-based projects to protect their culture. The 25 medical students that we will invite are former research assistants in community-based intercultural health interventions conducted by CEMI and GESTS. They are key informants because they have experience in communitybased interventions aimed at strengthening traditional medicine. Finally, CEMI, GESTS, and McGill PRAM bring together 20 cultural safety experts with nearly 30 years of experience in intercultural health projects in Latin America, Canada, and Africa. We will mail/email invitations to all these stakeholders to participate in the project.

Methods for Collecting and Analyzing Data

The qualitative study will have two phases:

Phase one. In this phase, individual self-administered structured qualitative questionnaires and focus group discussions will explore the opinions of the stakeholders on what a codesigned cultural safety curriculum should teach to medical students in order for them to provide culturally safe services in Colombia. The questionnaires will gather individual opinions, enabling us to capture and compare what has been said in public and in private, as is proposed by Green.²⁵ The stakeholders will complete the questionnaires before participating in the focus groups. The questionnaires will inform the focus group discussion.

Phase one will use inductive semantic thematic analysis following the six steps proposed by Braun and Clarke.²⁶ With the consent of all participants, we will audio-record, transcribe, de-identify and safely hold the data produced by questionnaires and focus groups. We will invite two end-users (medical students from Colombia) to analyze the transcripts. In participatory research, hiring staff from the community is a way of increasing the ownership of the research process and capacity building.²⁷

Using AtlasTi V8.0, two research assistants will code the transcripts separately using an inductive approach. Subsequently, they will meet, compare their individual analysis, and create themes and sub-themes. Here, the research assistants will implement two levels of analysis. Firstly, they will look at the quotations and codes within each theme, looking for consistency and internal coherence. Secondly, they will look at the validity of the theme in relation to the data set. Finally, we will generate a visual representation of the themes using a thematic map to display the relationships between themes.

Phase two. In phase two, two expert panels comprised of cultural safety experts, one in Colombia and one in Canada, will use the results of phase one to decide on the learning goals of the co-designed curriculum. The panels will follow a deliberative dialogue format.²⁸

Deliberative dialogue is a "a group process that emphasizes transformative discussion and may be informed by research evidence" (p.1939).²⁸ This process has recently received attention in health policy and systems research. Deliberative dialogue supports the use of evidence for decision making by: (i) using evidence as an input for discussions; (ii) providing an opportunity for stakeholders to discuss, contextualize, and determine the meaning of research evidence in light of their real-world experiences; and (iii) equipping decision-makers with decision-relevant knowledge in a format they can use.²⁸

The expert panels will use formal group facilitation techniques ²⁷ as a way of creating a safe environment to maximize the effectiveness of the meeting. Firstly, we will present the results of phase one, using short and easy to read visual representations of the data. Secondly, we will provide the experts with materials (boards, paper, post-its, etc.) to work together to decide on the learning goals and academic content of the co-designed curriculum. The objective is to reach a consensus among experts.

We will use Bloom's revised taxonomy of educational objectives ²⁹ as a framework for creating the learning goals. One research assistant will transcribe and organize the proposed learning goals and academic content. We will share the proposed curriculum via email with the experts who will suggest adjustments and give the final approval. Finally, we

will share the co-designed curriculum with the traditional medicine users and medical students, who will modify and approve the final version.

Rigor

We will follow the strategies for ensuring trustworthiness in qualitative research projects proposed by Shenton.³⁰ *Credibility* will be assured by adopting validated research methods to gather the data (semi-structured questionnaires, focus groups, deliberative dialogue) and analyze the data (inductive thematic analysis).

The inclusion of different methods to collect data (questionnaires, focus groups, expert panels), stakeholders (traditional medicine users, students, experts) and sites (Colombia and Canada) will ensure good triangulation. Our key informants' universe is comprised of 55 individuals, and we will invite all of them in order to ensure a maximum variation sample. Similarly, we plan to undertake at least two-member checks to ensure that we correctly report what stakeholders want to say. There will be ongoing debriefing sessions with the research team every two months as well as continuous feedback provided by an experts committee in the Department of Family Medicine at McGill University.

Secondly, we will ensure *transferability* by implementing qualitative methods sequentially. In qualitative designs, the combination of different qualitative methods used at various stages of the research project strengthens the external validity of the data, thus helping to shape the opinions of decision makers.²⁰ Although the specific results of this project will not be generalizable to other settings, as traditional medicine is context and culture specific, the research design and methods we will employ will be transferable to other settings in Latin America and beyond.

Thirdly, we will ensure *dependability* by providing an in-depth methodological description that will allow researchers to replicate the study in the future. Moreover, we will use "overlapping methods" such as individual qualitative questionnaires and focus groups.

Finally, we will ensure *confirmability* by disclosing the researchers' background and other predispositions that may influence the analysis of the data, as well as by recognizing the limitations of the study.

Expected Research Contributions for Theory and Practice

This participatory research project will produce the first co-designed curriculum on cultural safety in medical education in Colombia. This curriculum will integrate the perspectives of different stakeholders, such as traditional medicine users, medical students, and cultural safety experts. The curriculum will inform future cultural safety training in medical and health sciences education. Ultimately, the results of this project will yield evidence to develop participatory methods to co-design medical training programs.

Indirect outcomes include: 1) capacity building: involved stakeholders will learn about cultural safety in medical education, participatory research, and qualitative inquiry; 2) strengthened partnership between stakeholders that will facilitate future projects; 3) finally, given that cultural safety is a new concept to medical education in Colombia, this project will bring awareness of it to academia, thus facilitating its potential acceptance in the future.

Long-term potential benefits for stakeholders include enhanced quality of delivery of healthcare services (higher patient satisfaction, improved doctor-patient relationship, increased patient adherence) and reduced health disparities in communities of Colombia. The results of this study will be relevant to Canada and other multicultural settings.

CONCLUSION

The research supports cultural safety in medical education. It will develop participatory methods in medical education that might be of relevance in other subjects. The co-designed curriculum can be used to inform medical education interventions to foster cultural safety skills for medical students, improving quality of health services, and enhancing overall population health.

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7.2 [Manuscript 5] A Co-Designed Curriculum for Cultural Safety Training of Colombian Health Professionals: sequential-consensual qualitative study

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ABSTRACT

Although traditional and cultural health practices are widely used in Colombia, physicians are not trained to address intercultural tensions that often arise in clinical practice. Cultural safety encourages practitioners to examine how their own culture shapes their clinical practice to respect their patients' culture. It requires inviting patients of nondominant cultures to co-design culturally safe health care. We co-designed a curriculum for cultural safety training of Colombian health professionals. A sequential-consensual qualitative study considered academic content for the co-designed cultural safety curriculum. Semi-structured questionnaires and focus groups explored opinions of traditional medicine users, medical students, and intercultural health experts to inform the content of the curriculum. Deliberative dialogue between key intercultural health experts settled the academic content of the curriculum. A member-checking strategy shared the codesigned curriculum with the stakeholders, who modified and approved the final version. The curriculum has five learning objectives: (i) culturally unsafe practices: acknowledge the intercultural tensions and its consequences; (ii) cultural awareness: examine their own attitudes, beliefs, and values, and how they shape their professional practice; (iii) cultural humility: listen and learn from the patients' traditional practices; (iv) cultural competence: describe and compare current pedagogical approaches to address intercultural tensions; and (v) cultural safety: discuss with patients to reach an agreement on their treatment. This study integrated the perspectives of different stakeholders and proposed new applications of cultural safety that are relevant to other countries. Researchers and educators can use these results to inform future cultural safety initiatives.

INTRODUCTION

Background

In Colombia, government supported health services rely exclusively on the Western biomedical model. Yet some 40% of the population seek care in traditional and cultural health practices,¹ creating a gap between the community's expectations and needs, and the physicians' knowledge and skills. This gap leads to confrontation with and discrimination against patients, hindering their access to acceptable and effective health services.² There is growing agreement about the need to train medical students to provide health care that is responsive to the cultural characteristics of each setting.³ At present, Colombian medical schools provide no such training. Cultural safety training encourages medical students to examine their own culture, experiences, beliefs, and attitudes, to consider how these shape clinical practice, and to respect their patients' ways of being and knowing.⁴ Blanchet & Pepin⁵ reported three key elements of cultural safety: equal partnership, active participation of patients, and protection of cultural identity and well-being. These elements, and especially the participation of patients in co-design of interventions, make cultural safety a comprehensive approach to cultural diversity in health care.

Exploratory experience in Colombia

Between 2015 and 2016, an exploratory training of final-year medical students attempted to improve the cultural safety of work with traditional medicine users in Cota, Colombia.^{6,7} The students received theoretical training on cultural safety and participatory research. They then co-designed with traditional medicine users a five-month community-based intervention to strengthen traditional medicine. Students appreciated learning from or with the community; they enjoyed co-creation and ownership of the training program; and they felt confident when learning through a theoretical framework that was logical and rigorous to them.⁷ After participating in the pilot experience, they reported increased respect for traditional medicine users to provide better healthcare; recognition of traditional medicine as part of their cultural heritage and identity; wanting to deepen their knowledge about traditional medicine; and openness to incorporate traditional medicine in healthcare.⁶

The exploratory training suggested cultural safety training is feasible and acceptable for Colombian medical students. Without wider agreement of what cultural safety content we should offer medical students in the Colombian context, we co-designed a curriculum that included voices of the communities affected. ⁵ The purpose of our study was: (a) to collate opinions of stakeholders on what a curriculum in cultural safety should teach to health professionals to enable culturally safe practice; and (b) to use this understanding to co-design a curriculum for cultural safety training of Colombian health professionals.

METHODS

Research design

A modified sequential-consensual qualitative study set out to answer the question: what academic content should we include in the co-designed cultural safety curriculum? This sequence of qualitative research methods produces data with adequate generalizability to shape public health planning and clinical practice.⁸ We published a detailed protocol of the study,⁹ and adhered to the Standards for Reporting Qualitative Research in reporting (Appendix 1).¹⁰

Participants and setting

We invited three groups of stakeholders using a purposive sample in each group:¹¹ (a) 10 traditional medicine users from a community organization in Cota, Colombia; (b) 25 senior medical students from *La Sabana* University (Colombia); and (c) 20 intercultural health experts from the Center for Intercultural Medical Studies (CEMI) and the Traditional Health Systems Studies Group (GESTS) in Colombia.

Traditional medicine users all had community recognition as knowledgeable about traditional medicine and many years of experience working in community-based projects to protect their culture. The medical students we invited also participated in the exploratory cultural safety training experience in 2015 and 2016. The academic and nonprofit groups (CEMI and GESTS) bring together decades of experience in intercultural health projects in Latin America. These experts were also professors at the faculties of

medicine of three private universities in Colombia. We mailed/emailed invitations to all these stakeholders to participate in the project.

Methods for collecting and analyzing data

The first phase of the study used individual self-administered semi-structured questionnaires and focus groups to explore the opinions of the participants. Stakeholders completed the questionnaires before participating in the focus groups, and their answers informed the focus group discussion. With the consent of participants, we audio-recorded and transcribed the focus group discussions. To maintain confidentiality, we removed all individual identifiers from the transcripts. We invited a general physician (CK) to participate in the data analysis that used inductive thematic analysis following the six steps proposed by Braun and Clarke.¹² Using AtlasTi V8.0, two team members (CK and JP) coded the transcripts separately and made minor edits to the selected quotes for readability. The coders met to compare analyses. They created themes and sub-themes and thematic maps to communicate the results. We include the selected quotes as Appendix.

In the second phase of the study, an intercultural health expert panel in Colombia decided on the learning goals of the co-designed curriculum. The panel followed a deliberative dialogue format,¹³ which assists the use of evidence for decision making by: (i) using evidence as an input for discussions; (ii) fostering discussion and contextualization of the evidence; and (iii) equipping decision-makers with decision-relevant knowledge.¹³ Using easy to understand representations of the data, we shared the results of the two exploratory teaching interventions^{6,7} and the evidence from the focus groups in the first phase of this study. Then we provided the materials (boards, paper, post-its, pens and markers) for experts to work together on the learning goals and academic content. As the goal of cultural safety training is to change the behaviour of medical students, we used Bloom's revised taxonomy of educational objectives¹⁴ as a framework for creating the learning goals. We recorded the deliberation of the experts and took pictures of the boards with Post-its. The lead author transcribed and organized the proposed learning goals and academic content.

As a member-checking strategy, we shared the co-designed curriculum with the traditional medicine users, medical students, and experts, who modified and approved the final version. In member checking, results are returned to participants to ensure accuracy and resonance with their experience.¹⁵

Rigour

We followed the strategies for ensuring trustworthiness in qualitative research projects proposed by Shenton¹⁶ and Patton.¹⁷ We enhanced <u>credibility</u> by adopting validated research methods to gather the data (semi-structured questionnaires, focus groups, deliberative dialogue) and analyze the data (inductive thematic analysis). The inclusion of different methods to collect data (questionnaires, focus groups, expert panel) and stakeholders (traditional medicine users, students, experts) supported good triangulation. We ensured transferability by implementing a sequence of qualitative methods. In a sequential-consensual qualitative study, the combination of different qualitative methods used at various stages of the research project strengthens the external validity of the data.⁸ We increased <u>dependability</u> by adhering to the Standards for Reporting Qualitative Research, which will allow researchers to replicate the study in the future. Finally, we enhanced <u>confirmability</u> by disclosing the researchers' background, as well as by recognizing the limitations of the study. JP, a general physician with an MSc in Epidemiology and a Doctoral Candidate in Family Medicine, guided CK during the analysis phase. CK, a Colombian general physician, was a first year MPH student at Torrens University, Australia, with previous experience on cultural safety and community health, when this article was written. Prior to the analysis, JP provided a two-days training on thematic analysis to CK.

Ethical approval

This study received approval from the Sub-committee for Research of the Faculty of Medicine at *La Sabana* University (approval number: 445) and the Institutional Review Board of the McGill's Faculty of Medicine (approval number A05-B37-17B).

RESULTS

From those invited to take part in the study, seven traditional medicine users, six medical students, and four intercultural health experts agreed to participate. Table 7.2.1 shows the demographic information of the study participants.

Stakeholder	Number of participants	Range of age (years)	Sex (women)	Education level	Range of experience (years)	Number of focus groups
Traditional medicine users – older adults	4	48 - 52	4	University	21 – 30ª	1
Traditional medicine users – young adults	3	18 - 21	3	University students	18 - 21ª	1
Medical students	6	23 - 27	3	University	1 – 2 ^b	2
Intercultural health experts – Colombia	4	47 - 59	1	Postgraduate degree	13 - 33 ^b	1

^aYears of experience using traditional medicine

^b Years of intercultural health-related work experience

Traditional medicine users

Our analysis of the discussion with the traditional medicine users identified five themes and 21 subthemes (Appendix 2 and figure 7.2.1). The focus group participants suggested that health professionals should be familiar with basic principles of traditional medicine and self-care, be aware of the consequences of disrespecting traditional medicine users and the benefits of respecting them, and become aware of the reasons why people use traditional medicine.

Principles of traditional medicine: Health professionals should be aware of principles of Andean traditional medicine. Concepts of *frío* (cold) and *calor* (heat) are foundations of traditional medicine in Colombia. Imbalances of *frío* and *calor* can cause diseases, and warm and cold plants can prevent and treat diseases. Cultural nosology involves traditional

diseases, such as *susto*, *descuaje*, and *pujo*, and health professionals should be aware that they exist.

Principles of self-care: Traditional medicine practices promote health and well-being, including environmental, social, emotional, and spiritual aspects. In women's health, this includes menstruation, pregnancy, puerperium, and menopause. Menstruation care involves avoiding cold environments, cold food and drinks, and dairy produce, as well as consuming *warm* plant infusions during menstruation. Care of the common cold includes avoiding cold environments, drinking warm plant infusions, and "avoiding stopping the process". This means to avoid stopping fever abruptly, as they see it as necessary to improve health. The traditional medicine users described some practices and remedies to manage fever (Appendix 2). Traditional care of the digestive system includes uncomplicated diarrhea and taking acidic fruits (daily) or bitter plant infusions (once a week) on an empty stomach. It encompasses nutrition based on locally-produced food, and drinking infusions of fresh plants to keep the body "fresh and clean." Self-care also involves strengthening social relationships as well as respecting others, the environment, and the spiritual world. The benefits of traditional self-care comprise positive health effects on menstruation pain, pregnancies and births, menopause, and respiratory health, as well as positive effects for families and their communities.

Awareness of the consequences of disrespecting traditional medicine: These include patients hiding information from the physician, decreasing their adherence to treatments, feeling that health decisions are imposed on them, reinforcement of stereotypes, and loss of culture. The main consequence is the deterioration of the doctor-patient relationship. Box 1 depicts three stories that the traditional medicine users shared during the focus groups.

Box 1. Stories of intercultural tensions recounted by the traditional medicine users

First story

"Regarding the concept of cold, I have a story to tell. When my kid was born at the hospital, a nurse came and forced me to take a shower. I told her that I did not want to take a shower, and she said 'no mom, you must go inside and take a shower.' I decided to enter the bathroom and open the shower so she could hear the sound of the water. She thought I had taken a shower and let me rest. When I finally got home, I could do my traditional remedies.

With my young daughter it was even worse, because I tried to do the same, but the nurse noticed that I was not in the shower -I do not know if they have cameras or something like that-. She yelled at me and asked me to leave the door open. I entered the shower, but I was leaning towards the wall, trying to avoid touching the water, but some drops splashed out on my feet. When I got home, I did my traditional remedies, but on the second day, I got a terrible headache. It was very hard, and I think it was because of the water that splashed out on my feet in the shower. The traditional doctor gave me some plants to treat that."

Second story

"With one of my pregnancies, I went to see the doctor. I was talking about my diet habit, and I told him about a purge that I did in the second month of the pregnancy... He almost kicked me out of the room! He scolded me severely and told me that that was irresponsible, that it could damage the development of the child, and asked what my intention was, and if I wanted an abortion. He then made me sign a consent form so I would assume all the responsibility of everything. I was very scared."

Third story

"My child had ear pain once, so I put some drops of *ruda* [medicinal plant] in her ear and it helped. Some days after that, we went to see the doctor for a regular check-in. While doing the physical examination, the doctor noticed that my daughter had a green-coloured ear. He was very angry, he scolded me and called me irresponsible. Since then, I never say anything about traditional medicine. I try to avoid the health system as much as possible."

Acknowledge the benefits of respecting traditional medicine users: this involves

making medical students aware that respecting traditional medicine users improves the doctor-patient relationship and the quality of healthcare. The traditional medicine users also reported that they have found physicians who respect traditional medicine and even incorporate it into their treatment options.

Know why we use traditional medicine: the traditional medicine users want health professionals to know that they use traditional medicine not because they are ignorant or poor, but because it has helped them to solve health problems, and therefore, they have faith in it.

Medical students

The focus group discussion of medical students identified three themes and 12 subthemes (Appendix 3 and figure 7.2.2). They recommended five learning objectives, provided suggestions for the pedagogical strategy, and suggested that it should acknowledge and address barriers to cultural safety training.

Learning objectives: the curriculum should promote self-awareness among medical students. This involves becoming aware of the flaws and biases of the biomedical model, acknowledging that it is not the only medical system in Colombia, and recognizing themselves as part of an intercultural setting.

Health professionals should be aware of the benefits of cultural safety such as openness to dialogue with their patients and a better doctor-patient relationship. The students shared some stories to illustrate with examples the benefits of such type of training (see Box 2), and recommended that health professionals should be able to recognize the 'target population' of this type of training and the setting where it would be useful for them.

Box 2. Cultural safety stories described by the medical students

First story

"Now that we are doing home visits in *Tenjo* [rural municipality] as part of our family medicine rotation, we have noticed that people usually have orchards at home. When we visit them, patients offer *agüitas* [plant infusions], for example *agüita de poleo* [medicinal plant] and whatnot... And when that happens, I am reminded of what I have learned [cultural safety training], and I receive those *agüitas* with affection, and it is a way to bond with people, we ask them about that [traditional medicine]. One time, a patient even gave me some plants to bring to my home."

Second story

"I am doing my home visits rotation as an intern, and I went to a traditional medicine user household. I was talking about the plants, and a woman told me that *ruda* [medicinal plant] is not only medicinal, it is a plant that also protects you. She told me that I have to take five sprouts of *ruda* and keep them with me, like in my wallet. Later on, the woman picked up five sprouts, packed them, and gave them to me. I think that it [cultural safety] makes them more receptive, they say things such as 'I hope you come back soon to my house', I guess that it would make them more adherent to the treatment... like it would improve the doctor-patient relationship."

Third story

"It is clear that I won't give prescriptions of traditional medicine to patients, because I don't know how to do that. But there are small things that we can do, for example, I remember what traditional medicine users say about common cold care. I think it is five days. At the hospital, I could provide advice like 'keep your child warmly clothed, cover their nose and mouth and don't expose them to the cold.' A baby with bronchiolitis is a good example, I can advise the mom, if she is going to transport the baby, 'please cover them up, keep them warmly clothed.' Very basic things."

According to the medical students, health professionals should acknowledge traditional medicine; they should be aware that traditional medicine practices might be common among their families and friends. This also includes knowing the principles of traditional medicine, such as cold care, cultural nosology, the roots of traditional medicine in Colombia, and the differences between traditional and alternative medicine. The medical students suggested that, in practice, health professionals could approach traditional medicine as a type of primary healthcare, because it is focused on prevention. They think that it makes sense to explore basic principles of traditional medicine with their patients such as cold and menstruation care, as well as traditional practices for simple and common diseases. Similarly, they mentioned that health professionals should be equipped with tools to safely explore traditional medicine while being aware of quacks. They think that the intercultural interaction should go beyond solely respecting traditional medicine, but recognizing traditional medicine as a valid tool in the health-decision making process of their patients.

Pedagogical strategy: The learning strategy should adapt to each cultural context and to the specific needs of each student. The students felt cultural safety training should be mandatory in Colombian medical education. They discouraged standard education formats and rather suggested innovative strategies such as game-based learning, apps, videos, and an 'arsenal' of strategies that educators can use on a case-by-case basis. They commented on the value of community-based learning for cultural safety training and highlighted the transformative potential of interacting and learning directly from traditional medicine users and through experiencing traditional medicine themselves.

Acknowledge and address barriers: The pedagogical strategy should recognize and address the biomedical model factors that can hinder cultural safety training. Examples include the idea that Western medicine is the only valid health system, the curative focus of Western medicine, and the relationship between Western medicine and social status and technology. Barriers related to traditional medicine included not understanding how traditional medicine works, concerns regarding the effectiveness and safety of traditional medicine, and the idea that traditional medicine is outdated. Medical education barriers included lack of learning opportunities and professors trained to provide cultural safety training, the fact that the topic is not important for the faculties of medicine, and ethnocentrism of medical education. Sociocultural factors included deeper issues such as urbanization, colonialism, and their cultural identity as Colombians.

Intercultural health experts

Our analysis identified two themes and 12 subthemes (Appendix 4 and Figure 7.2.3). The experts provided suggestions for the educational strategy and recommended that it should acknowledge and address difficulties of cultural safety training.

Suggestions for the learning strategy: The strategy should highlight the benefits of cultural safety training through real life examples and by demonstrating how the training can help address intercultural tensions in clinical practice. It should promote self-awareness and real-life encounters with traditional medicine, not only for medical students

but also for general practitioners and specialists. The strategy should provide health professionals with tools to recognize the multiple ways in which intercultural tensions arise in daily medical practice, for example, by using real-life stories of traditional medicine users who had negative experiences in Western health services, or by using strategies such as fiction and autobiography. More importantly, the strategy should be based on a solid and convincing theoretical framework and a problem-solution structure. This involves making the students aware of the real-life problems that they face without cultural safety training, and encouraging them to find solutions. In their words, "it is seeking the solution where they will learn, that is the key".

Acknowledge and address difficulties: the pedagogical strategy should recognize and address factors that hinder cultural safety training such as the hegemony of the Western biomedical model. This involves ethnocentrism, the logic implicit in the evidence-based medicine culture prevents medical students from making sense of traditional medicine, and traditional medicine is perceived as unimportant and, at most, an anecdotic issue. The experts commented on the deficient pedagogical strategies on cultural training for medical students. There is a lack of 'movers and shakers' as cultural safety training is not offered in any faculty of medicine in Colombia. Also, they highlighted the negative influence of role models who mistreat traditional medicine users. Medical students learn from them through imitation; this is the so-called 'hidden curriculum.' Fostering self-awareness is a challenge. It entails recognizing the flaws and biases of the Western biomedical model, confronting the students with the idea that Western medicine is neither perfect nor the only medical system. Students and professors seldom acknowledge their inability to recognize intercultural tensions nor the need for a change in medical education or clinical practice to include cultural safety training.

Expert panel

The intercultural health experts examined the thematic maps (Figures 7.2.1, 7.2.2, and 7.2.3), and the results of the previous community-based experiences.^{6,7} They suggested five sequential learning objectives for the co-designed curriculum. In Figures 7.2.1, 7.2.2, and 7.2.3, the themes stem from the center of the graph and the subthemes stem from each of the themes. The subthemes were organized by the intercultural health experts into learning objectives described in colors.

Figure 7.2.1 Five themes and 21 subthemes described by the traditional medicine users


1) Health professionals acknowledge the intercultural tensions that occur in medical practice and its consequences: this involves making health professionals aware that they are not usually prepared to adequately recognize and handle the intercultural tensions that they face in their daily professional practice, thus disregarding and even confronting patients because of their cultural knowledge and practices. In other words, *surfacing* or *unearthing* the issue of culturally unsafe behaviour.

This objective also comprises making health professionals aware of the consequences of this situation, such as cultural loss, stereotypes, decreased adherence to treatment, poor communication, and an ineffective doctor-patient relationship. Health professionals should feel the need to address intercultural tensions adequately to ensure a sound clinical practice in intercultural settings. The experts termed this stage *culturally unsafe practices* (represented in red in the figures).



Figure 7.2.2 Three themes and 12 subthemes described by the medical students

2) Health professionals examine their own attitudes, beliefs, and values, and how they shape their professional practice: This self-reflection exercise acknowledges that, just as traditional medicine users have their own culture, so do Western-trained medical doctors. This increases awareness of cultural diversity and that Western medicine is not the only medical system in multicultural settings. Students are part of a multicultural setting and that each clinical encounter is also a cultural encounter. This objective also involves awareness of factors that prevent health professionals from embracing traditional medicine, such as sociocultural factors, biomedical factors, ethnocentrism, and the 'hidden curriculum.' This in turn requires learning about the limitations, flaws, and biases of the Western biomedical model. The experts called this stage *cultural awareness* (represented in yellow in the figures).

Figure 7.2.3 Two themes and 12 subthemes described by the intercultural health experts



3) Health professionals listen and learn from the patients' traditional practices: Health professionals need tools to listen to traditional medicine users explaining their traditional knowledge and health practices. Health professionals should learn basic concepts of Andean traditional medicine, such as traditional self-care, frío and calor, cultural nosology, and bitter and sweet plants. Professionals should acknowledge that they likely have traditional medicine users among their family members and that traditional medicines and their practitioners can help maintain the health of populations. Finally, health professionals should understand the relationship between traditional medicine and primary healthcare. The experts called this *cultural humility* (represented in green in the figures).

4) Health professionals describe and compare current pedagogical approaches to address intercultural tensions: this involves learning about the existing cultural approaches to solve intercultural tensions, such as cultural competence. Health professionals will learn that the common element of these cultural approaches is respect for the culture of their patients. Respect is an essential element for cultural safety, but cultural safety training goes beyond this. Health professionals will be able to describe the benefits and limitations of these cultural approaches. This objective also involves touching on the current situation of intercultural health programs in Colombia, including the medical education barriers to cultural safety training. The experts termed this stage **cultural competence** (represented in grey in the figures).

5) Health professionals discuss with patients to reach an agreement, taking into account their medical knowledge and the knowledge of their patients: this involves providing health professionals with tools to identify the setting and target population where cultural safety is more relevant. They should be able to dialogue respectfully with their patients and explore the knowledge, attitudes, and practice related to their cultural background. Through an iterative process, health professionals will gradually learn from their patients and adopt a positive attitude towards cultural differences in medical practice. Health professionals also acknowledge the benefits of cultural safety training, such as respect, openness to dialogue, and a better doctor-patient relationship. They will become agents of change and will promote a culturally safe clinical practice among their colleagues. The experts called this stage **cultural safety** (represented in blue in the figures).

Pedagogical strategy

The intercultural health experts highlighted the need to take into account three main recommendations of the stakeholders about teaching strategy. First, it should be based on a solid, logical, and straightforward framework. They suggested a process starting with culturally unsafe practices and finishing with cultural safety (Figure 7.2.4). Culturally unsafe practices emphasize cultural destruction as a result of culturally unsafe behaviors. Cultural awareness proposes a self-exploration exercise where health professionals reflect on their own culture. Cultural humility invites health professionals to listen to their

patients and to discover traditional medicine. In cultural competence, health professionals learn to respect their patients'culture. Finally, cultural safety emphisizes dialogue, exploration, and intervention co-creation. This structure will help health professionals to situate themselves within the learning process, thus providing a learning experience that is easier to follow and internalize.

Second, the co-designed curriculum should follow a problem-solution structure, starting by *surfacing* or *unearthing* the issue of intercultural tensions and its consequences (culturally unsafe practices), thus motivating health professionals to navigate all the phases of the cultural safety learning process to reach the cultural safety level. Finally, the teaching should ideally use innovative strategies such as community-based learning, game-based learning, technology, and humanities.



Figure 7.2.4 Pedagogical strategy suggested by the intercultural health experts

In three member-checking meetings to share the co-designed curriculum, the traditional medicine users, the medical students, and the Colombian intercultural health experts adjusted and approved the final version. For example, in the fifth learning objective, the stakeholders suggested replacing the word "negotiate" with "discuss" as they thought it was more appropriate.

DISCUSSION

The work with stakeholders led to five learning objectives for teaching health professionals to provide culturally safe services in Colombia: (i) acknowledge intercultural tensions and their consequences; (ii) examine their own attitudes, beliefs, and values, and how they shape their professional practice; (iii) listen and learn from their patients about traditional practices; (iv) describe and compare current pedagogical approaches to address intercultural tensions; and (v) be able to discuss with patients to reach an agreement on their treatment.

Other authors have suggested a multi-level or spectrum of standpoints leading up to cultural safety. Ramsden, for example, proposed a dynamic process moving from cultural awareness to cultural sensitivity to cultural safety.¹⁸ Wood and Schwass proposed a model linking culturally unsafe behaviors (cultural risk in their model) and cultural safety.¹⁹

Culturally unsafe practices

Learning to recognize culturally unsafe practices and its consequences as a first step in the cultural safety journey will help health professionals to make sense of the relevance and benefits of this type of training. Culturally unsafe practices have been defined as "any actions which diminish, demean or disempower the cultural identity and wellbeing of an individual."²⁰ Cooney²¹ describes that unsafe clinicians diminish, demean and/or disempower patients from non-dominant cultures, while safe clinicians acknowledge and respect the rights of others.

Although common in clinical practice, culturally unsafe practices have been poorly documented in Colombia and Latin America. In Guatemala, Bekker and collaborators

described a case study of the Mayan-Indigenous Populations in which traditional concepts of *frío* and *calor* were often overlooked in the perinatal period.² As in the first story presented in Box 1, the consequences of ignoring these intercultural tensions are negative for service users: "It is not uncommon to hear rural indigenous women say that they would rather die, and die at home, rather than go to the hospital, even if their *comadrona* (traditional birth attendant) recommended them to seek formal care."² (p 492) Several systematic reviews have looked at the effects of stereotypes, prejudices or discrimination against minority groups including lower levels of healthcare-related trust, patient satisfaction, adherence to treatment uptake, and delaying or not seeking healthcare. Patients' health outcomes include poor mental health (depression, anxiety, and stress), effects on physical health (hypertension), and poor general health.^{22,23} These outcomes can exacerbate health disparities.²⁴

Cultural awareness

The Nursing Council of New Zealand recommended including cultural awareness in cultural safety programs.⁴ Ramsden²⁵ suggested that students should reflect on their own 'invisible baggage', which are values and attitudes that influence their clinical practice. In our study, this involves reflecting on how their values, beliefs, and assumptions regarding traditional medicine influence the way they interact with traditional medicine users. Cultural awareness also requires reflecting on ethnocentrism and its attributes including cultural preference, purity, superiority, and exploitativeness.²⁶ Cultural awareness requires examining the flaws and biases of the Western biomedical model. As was mentioned by Anne Fadiman in his best-seller about intercultural tensions of a Hmong family in California, "If you can't see that your own culture has its own set of interests, emotions, and biases, how can you expect to deal successfully with someone else's culture?"²⁷ We suggest introducing health professionals to popular readings on the flaws of Western science, such as the reading by Ioannidis.²⁸ The problems of publication bias^{29,30} and external validity of randomized controlled trials, and the materials prepared by Ben Goldacre^{31,32}are useful resources.

Cultural humility

Once health professionals have reflected on their own cultural identity and the flaws and biases of their own medical system, they will be ready to learn about the cultural health practices of their patients. According to Tervalon "humility is a prerequisite in this process, as the physician abandons the role of expert to the patient, becoming the student of the patient, with a conviction of the patient's potential to be full partner in the therapeutic alliance."³³ (p121) In our study, this involves becoming familiar with basic principles of Andean traditional medicine. Zuluaga & Correal³⁴ suggested key characteristics of traditional medicine including: (i) historical roots (i.e. ancient intergenerational transmission of knowledge and practices); (ii) cultural roots (i.e. a particular way to explain health and disease that is different from that of Western science); (iii) and territorial roots (i.e. the knowledge, practices, and resources are connected to a geographical space).

A key issue is that health professionals must be able to describe the difference between traditional medicine and alternative medicine. The latter lacks at least one of the three requirements (i.e. homeopathy was first described only two centuries ago).³⁵ Zuluaga & Correal described four additional characteristics of traditional medicine in Colombia: (i) triple inheritance (i.e. traditional medicine stems from three types of knowledge systems: Indigenous, African, and ancient European); (ii) traditional medicine providers (i.e. authentic traditional doctors or shamans, bonesetters, and traditional midwives); (iii) traditional concepts of *calor* (hot), *frío* (cold), *limpieza* (cleanse), and *purga* (purge); (iv) cultural nosology, meaning traditional diseases such as *descuaje*, *mal de ojo* (evil eye), *frío de difunto* (cold of the deceased), *susto* (fright), among others.

Some of the concepts and practices described by the traditional medicine users in our study have been reported elsewhere. For example, traditional practices for menstruation care in Colombia,³⁶ Saudi Arabia,³⁷ and Laos.³⁸ Other studies have reported traditional concepts, such as heat and cold,^{39,40} and traditional diseases, such as *susto* (fright).⁴¹ Knowledge about these concepts, and the other concepts reported by the traditional medicine users in our study, can help health professionals to respectfully interact with patients users during their professional practice.

The medical students suggested that health professionals could approach traditional medicine practices of self-care as a form of primary care. The Alma-Ata declaration on Primary Care recommends that primary care systems should reflect the cultural characteristics of a country, include traditional practitioners as needed, and have a focus on health promotion and disease prevention.⁴²

Cultural competence

Although with many interprations, cultural competence mostly focuses on learning about the culture of the recipient of care *-the other-*. Three systematic reviews report benefits in patients' adherence to treatment, mutual understanding between caregiver and service users, patient satisfaction, and knowledge, attitudes, and skills of medical students.⁴³⁻⁴⁵ Despite the reported benefits, some suggest that cultural competence leads to stereotyping and oversimplification of culture.⁴⁶ According to Pon,⁴⁷ cultural competence promotes otherizing non-whites by using "modernist and absolutist" views of culture without using a racialist language. Betancourt argues that it "can lead to stereotyping and oversimplification of culture without respect for its complexity."⁴⁸(p145)

Health professionals should, therefore, understand that although cultural competence is a first step in recognizing the relationship between culture and health outcomes, there is a need to promote a more comprehensive approach to cultural differences in clinical practice. The key message at this stage, however, is that health professionals should, at least, respect the traditional medicine practices of their patients.

Cultural safety

Cultural safety comes after traversing all the previous stages. Our current understanding of cultural safety builds on contributions by Blanchet & Pepin,⁵ Bozorgzad,⁴⁹ and the Canadian National Aboriginal Health Organization.⁵⁰ It involves five concepts; three of them related to at least one of the stages that we described in our study: (i) *selfawareness*: health professionals examine their own culture and how it impacts service

users. Linked to cultural awareness; (ii) *sociopolitical context*: students to recognize the colonial context in which racial/ethnic disparities are created. Linked to culturally unsafe practices and cultural awareness; (iii) *respect*: the cultural and traditional health practice of patients are valid. Linked to cultural humility and cultural competence. In our study, cultural safety includes two additional elements: (iv) *dialogue*: the patient and provider work together as a team in the healthcare decision-making process; and finally (v) *authority*: those receiving the service define culturally safe care.

The elements provided in the *cultural humility* stage will help health professionals to explore safely basic traditional medicine concepts and practices. The goal of this exercise is twofold: to include their patients' knowledge and practices in the health decision-making process leading to improved doctor-patient relationship and quality of care, and gradually to learn about traditional medicine directly from their patients through an iterative process. As suggested by the medical students, health professionals should carry out this exercise within the scope of primary care (traditional self-care). Regardless of the way health professionals operationalize cultural safety in clinical practice, they must always be reminded that the most important element of cultural safety is that it should be defined and co-constructed by end-users,⁵ as in this study.

Limitations

In our study, the participants could have felt the need to report positive views of traditional medicine due to the strong power imbalances that are present in medical education. Experts in cross-cultural care training have pointed out that trainees often fall in the social desirability bias -choosing socially desirable answers rather than their own thoughts-.⁵¹ To reduce this bias, we let them know that we wanted them to state the answers they think best reflect their position regarding cultural safety, and stressed that their answers would not have any impact on any grade in any course.

The results of our study may not be generalizable to other settings, as traditional medicine is context/culture specific. In other settings, where traditional medicine is not as widely used, this approach will be less relevant, and it might be necessary to develop

cultural safety interventions through other stigmatizations. The research methods that we employed, however, could be transferable to other settings in Latin America and elsewhere.

We did not discuss how to assess the educational program. We are aware that this is a fundamental issue for curriculum development and, therefore, we are currently developing methods to assess the impact of cultural safety training using mixed-methods research.⁵²

CONCLUSION

This study produced the first co-designed curriculum on cultural safety in medical education in Latin America. It integrates the perspectives of different stakeholders, such as traditional medicine users, medical students, and intercultural health experts. Our curriculum explored how to apply cultural safety with non-Indigenous knowledge users and by focusing on traditional medicine practices. It starts by acknowledging cultural tensions and highlights the importance of listening to what patients have to say. The process we followed could be relevant for design and implementation of future cultural safety interventions, offering a participatory framework to co-design cultural safety programs with input provided by end-users.

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CHAPTER 8: [Manuscript 6]: Game jams for cultural safety training in Colombian medical education: a pilot randomised controlled trial

PREFACE

I conducted a pilot RCT before the full-scale RCT to: (1) master the required skills to successfully conduct a full-scale game jam; (2) explore the acceptability and feasibility of cultural safety training through a game jam; (3) pilot research methods; and (4) reveal local politics or potential logistical problems that might affect the full-scale RCT.

Game jam experts argue that game jams are complex and chaotic, and that the only way to learn how to run a game jam successfully is through hands on practice.¹¹¹ Moore¹¹² argued that pilot studies are necessary to investigate the feasibility (whether something can be done and how) of implementing a new intervention. Van Teijlingen¹¹³ suggested that pilot studies are important to assess the willingness of individuals to participate in the study, their likely response rates, and to identify potential practical problems in following the proposed research plan. For example, a pilot study on maternity care showed that the proposed procedure of distributing questionnaires would not work for the full-scale study.¹¹³

Pilot studies can also reveal local politics or interests that might affect the research process.¹¹⁴ Mudur¹¹⁵ described a strong opposition of Indian doctors when the Indian health ministry proposed introducing courses on traditional medicine for medical students as a response to the high demand of these practices by the population. Conducting a pilot study helped me to gain the support of the academic staff at *La Sabana* University for the full-scale study, to assess the proposed data analysis techniques, and to test the adequacy of research instruments.¹¹³

I presented the results of the pilot at the 2020 *Regards contemporains sur la santé au Québec et dans le monde: colloque étudiant conjoint RRSPQ/RISUQ*, in Montreal QC, Canada. A video of the pilot RCT is available.¹¹⁶

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ABSTRACT

Objectives: Explore the acceptability and feasibility of a randomised controlled trial to assess game jams - participatory events to co-create digital or board games in a time-constrained environment – in cultural safety training of medical students. The pilot will test methods and procedures, and explore the validity and reliability of our research instrument.

Design: Two arm parallel-group pilot randomised controlled trial.

Setting: Faculty of Medicine at a private university in Chia, Colombia.

Participants: 79 final-year medical students completed the baseline questionnaire. 64 completed the second timepoint assessment immediately after the intervention; 31 in the intervention group (20 female) and 33 in the control group (18 female). 35 completed the final assessment (18 control and 17 intervention) four months after the intervention.

Interventions: The intervention group joined a 5-hour game jam comprised of a one-hour lecture and a four-hour session to create and to play educational games about cultural safety. The control group received a one-hour conventional lesson, followed by a four-hour study session of selected readings on cultural safety.

Primary and secondary outcome measures: Online self-administered Likert-type questionnaires assessed a self-reported cultural safety results chain using a modified theory of planned behavior. Student recruitment, retention, and perception of the activity determined acceptability. The methodological and logistical factors for a full-scale study possible determined feasibility.

Results: After the intervention, students randomised to that arm reported a slightly higher cultural safety score (26.9) than those in the control group (25.9) (difference -1, 95% CI - 3.0 to 1). Students described game jam learning in favourable terms and considered cultural safety training relevant. The university authorized the conduct of the full-scale RCT.

Conclusions: Game jam learning is feasible and acceptable for cultural safety training of Colombian medical students. Researchers and educators may find our results informative in design of randomised controlled trials assessing educational interventions.

Full-scale trial registration: the full-scale study is registered on ISRCTN registry (ISRCTN14261595) <u>http://www.isrctn.com/ISRCTN14261595</u>

Strengths and limitations of this study

- This is the first randomised controlled trial exploring game jam learning in medical education and the first quantitative study exploring cultural safety training in Latin America.
- Innovative research methods included probabilistic transitive closure.
- We tested the validity and reliability of the instrument for use in the full RCT.
- This pilot study was underpowered to detect differences within and between study arms.

INTRODUCTION

Ignoring the role of culture in health and health care is an integral part of the stigma and discrimination towards culturally diverse patients.¹ International institutions have called for more attention to the relationship between culture and health outcomes in medical education. ² Contemporary cultural training programs for health professionals use a range of approaches including cultural competence, sensitivity, awareness, safety, cross-cultural and transcultural medicine, and culturally responsive care.³

Cultural competence is "a set of congruent behaviors, attitudes, and policies that come together in a system, agency, or among professionals and enable that system, agency, or those professionals to work effectively in cross-cultural situations" (p12)⁴. This is the most common cultural training approach. Examples of cultural competence include ethnic matching of physician and patient, and clinician training in generic cultural knowledge.³ Three systematic reviews published on the topic have reported positive effects of this training, including improved patient satisfaction, mutual understanding, and adherence to treatment.^{5–7} Some authors recently criticized cultural competence, however, based on its superficial and often utilitarian understanding of the patient culture⁸. Others advocate for more comprehensive approaches to cultural diversity in healthcare, such as cultural safety.⁹

Cultural safety is "a space that is spiritually, socially, emotionally and physically safe for people; where there is no assault, challenge or denial of their identity, of who they are, and what they need"¹⁰. This is an opportunity to overcome some of the limitations of cultural competence.¹¹ Adding considerable value to other cultural approaches in health care, cultural safety requires active participation of patients of non-dominant cultures in co-creating interventions that address their needs.¹² Recent evidence suggests this type of training is linked to improved relationships between patients in non-dominant cultures and their health professionals, and to improved health outcomes.¹³

Culturally diverse Colombia is an ideal setting for cultural safety education, with potential lessons for other countries. Some 14% of the population belongs to minority groups (mostly black and Indigenous)¹⁴, and some 40% of the population seek care in

traditional and cultural health practices.¹⁵ Yet modern health services and their training programs rely entirely on Western concepts of health and healing. As part of an effort to bridge the cultural divide between Western health services and the cultural preferences of the Colombian society, a recent initiative to introduce cultural safety in medical training engaged traditional medicine users, medical students, and cultural safety experts to develop a consensus of key elements for a co-designed curriculum for cultural safety training.¹⁶ A challenge facing cultural safety education, however, is that health professionals are seldom motivated to interact with traditional health practices¹⁷ or to receive intercultural education,¹⁸ thus requiring innovative teaching strategies to overcome these challenges.

Game jams are participatory events that allow attendants to co-create digital or board games in a time-restricted environment.¹⁹ These could provide a more engaging cultural safety learning experience for health professionals. Recent studies of game jam learning suggest likely effectiveness and engagement potential in university-level education.²⁰ We could find no published medical education research exploring the role of game jam learning. In preparation for a full-scale randomised controlled trial (RCT) to determine whether game jam learning is more effective than a standard lesson on cultural safety in terms of change in medical students' self-reported cultural safety behavior,²¹ this pilot study attempted to (1) explore the acceptability and feasibility of conducting a RCT to assess game jam learning for cultural safety training of medical students; (2) pilot research methods and procedures; and (3) explore the validity and reliability of our research instrument.

METHODS

Study design and public involvement

A parallel-group, two-arm, pilot RCT with a 1:1 allocation ratio compared participation in a game jam on cultural safety with a standard lesson on cultural safety, with student self-reported behaviour as outcomes. We followed the CONSORT 2010 extension for

randomised pilot and feasibility trials to report our results²² (see Additional file 1). The protocol of the full-scale study is available elsewhere.²³

The study received support from an advisory group comprised of cultural safety experts, medical students, and general physicians. The group helped to develop the research instrument and we invited them to co-design the dissemination plan, funded by the Quebec Population Health Research Network.

Setting and participants

The Faculty of Medicine at *La Sabana* University in Chia, is located 24 km from Bogota, the capital of Colombia. *La Sabana* University is a private institution with 9,000 undergraduate students.²⁴ In 2017, we invited a convenience sample of 79 final-year medical students taking a compulsory community health course,²⁵ expecting to allocate at least 30 students to each arm. Our sample size was restricted by the availability of students due to other commitments. Inclusion criteria were: (a) being a medical student taking the community health course and (b) giving informed consent. The single exclusion criterion was not wanting to participate in the study. Since 40% of Colombians seek care in cultural health practices,¹⁵ we anticipated that some students would be more open to the cultural safety approach than others. We stratified randomization to the intervention based on baseline cultural safety scores (lower and higher levels).

Procedure

The intervention was a game jam,¹⁹ a one-day collaborative activity to co-design low-tech prototypes of educational games about cultural safety. The game jam had three parts: (a) a one-hour preliminary lecture on cultural safety; (b) a 30-minute lecture about game-design principles; and (c) a three-and-a-half-hour practical session to create educational games about cultural safety. We used the preliminary version of a medical curriculum we had developed in parallel to this pilot study to inform the lecture on cultural safety.¹⁶ The students worked in groups of four or five to create game prototypes, including narratives, objectives, game dynamics, rewards, and penalties. We asked the students to bring game elements from their favourite board games and provided game materials such as game

boards, playing cards, game money, dice, markers, pencils, glue, and tokens. A video of the activity is available.²⁶

The control group received a one-hour PowerPoint-based conventional lesson on cultural safety in health care. This group also had four hours to study selected readings on cultural safety. We provided laptops with the readings for those students who did not have access to the class materials. The class for the control group included the same cultural safety concepts covered in the intervention group activities.

Measures

Acceptability

We used a standard definition of "whether the research is likely to be acceptable to potential participants"²⁷ to inform our understanding of acceptability. We assessed student interest and willingness to participate and to complete study activities, and we evaluated this with participant recruitment, retention, and survey response rates. Our instrument also included an open-ended question at the end of the questionnaire to assess student perception of the activity. We analysed these responses using an inductive thematic analysis.²⁸

Feasibility

We used Eldridge's²⁹ definition of feasibility to ask: "whether something can be done, should we proceed with it, and if so, how". In the pilot RCT context, we explored the methodological and logistical factors that would make the full-scale study possible or not. For example, we asked whether using self-administered online questionnaires was feasible. We were also concerned if the academic staff at *La Sabana* University would allow cultural safety training, given the reported reluctance of health professionals to support teaching of traditional and cultural health practices.¹⁷

Surveys

Given that cultural safety is always context specific, we developed a survey instrument based on the characteristics of our cultural context in Colombia. The research team developed a preliminary version of the instrument that a group of five cultural safety experts (four from Colombia and one from Canada) later reviewed and refined.

An online self-administered multiple-choice Likert-type questionnaire assessed the efficacy of the two teaching methods. A modified theory of planned behavior³⁰ provided a framework for our primary outcome. Seven statements explored the results chain (acronym CASCADA: *C*onscious knowledge, *A*ttitudes, positive deviation from negative *S*ubjective norms, *C*hange intention, sense of *A*gency, *D*iscussion, and change in practice/*A*ction) in response to real-life clinical cases depicting intercultural tensions. For example, the statement "You know what the cultural safety approach is" indicated *c*onscious knowledge. Each question had five response options ranging from "strongly agree=5" to "strongly disagree=1". We added the scores of each of the seven questions to determine a cultural safety score. The students completed a baseline questionnaire, a second questionnaire immediately following the teaching session, and a third questionnaire four months after the intervention.

Validity of the instrument

Jeffreys³¹ described an approach to improve the validity and reliability of the Transcultural Self-Efficacy Tool (TSET), an instrument to assess cultural competence education of health professionals. We followed this approach to increase the validity and reliability of our instrument. We followed a two-phase procedure to increase the content validity.³² First, an open question at the end of the questionnaire *(how can we improve this instrument?)* explored student opinions of the instrument. An inductive thematic analysis²⁸ of responses generated suggestions to adjust our survey. Second, we shared the adjusted version of the instrument by email with two general medical practitioners, one medical intern, six medical students, and four cultural safety experts, all from Colombia. We asked the question: *does our instrument assess cultural safety training?* We adjusted the instrument according to their comments and reached consensus on the content validity of the instrument.

To increase the construct validity of our instrument, we used the contrasted group approach, which explores the difference between two separate groups.³¹ Our stratified randomisation facilitated this. We tested the assumption that the greatest change in cultural safety score will be detected in individuals with a low score initially who have then been exposed to formalized cultural safety training. To increase the predictive validity of our instrument, we looked at the score difference between two timepoints.³³ We compared the first timepoint with the last timepoint. We assumed that cultural safety is a dynamic construct that changes over time, and it is influenced by formalized exposure to cultural safety training.

Reliability of the instrument

Reliability explores the degree of accuracy and consistency in measurement. We explored the reliability of our instrument using the test-retest method,³¹ the most common approach to measure the stability of an assessment over time.³⁴ Our assumption was that the students' scores would be stable across the second and third timepoints.

Analysis

A simple and paired t-test explored between-group and within-group differences respectively. For the secondary analysis, we used probabilistic transitive closure of each CASCADA result chain.³⁵ This allowed us to explore walks and blocks between the seven intermediate outcomes of the CASCADA model, and to determine the cumulative net influence. In this way, we evaluated the CASCADA construct as a network of interrelated elements rather than an isolated outcome.

We used R Studio to convert each intermediate Likert-type outcome of the CASCADA results chain into binomial variables. We compared students who reported the greater effect against the remaining students (cut-off point [1, 2, 3, 4] vs [5]) with one as "strongly disagree" and five "strongly agree." We used the TABMAT command on CIETmap 2.0 v17³⁶ – open-source software that uses the statistical programming language R – to generate a matrix of crude odds ratios between each pair of intermediate outcomes in the CASCADA

model. Subsequently, we calculated the probabilistic transitive closure and uploaded the resulting adjacency matrix to yED v3.19.1 to create cognitive maps representing the walks and blocks between the CASCADA elements.

To identify potential patterns of missing data that could hinder retention in the fullscale RCT, we stratified missing data by participant age, socioeconomic level, sex, place of birth, and presence of family in rural areas for each timepoint. Finally, we conducted an inductive thematic analysis²⁸ of the open-ended questions at the end of the questionnaire to identify themes describing (a) the students' perception of the activity (acceptability) and (b) the content validity of our instrument.

Ethics

The Institutional Review Board of the McGill's Faculty of Medicine (approval number A05-B37-17B) and the Sub-committee for Research of the Faculty of Medicine at *La Sabana* University (approval number 445) provided ethical clearance for this pilot study. All participants signed written informed consent before proceeding with any research activity.

RESULTS

A total of 79 students completed the baseline questionnaire and we randomised these centrally to two arms. Only 64 students completed the second timepoint and 35 the third. Table 8.1 shows the sociodemographic characteristics of the participants and Figure 8.1 shows the schedule of enrolment, interventions, and assessments of the pilot RCT.

	Standard lesson (n= 33)	Game jam (n= 31)	
Sex	n (%)	n (%)	
Female	20 (61)	18 (58)	
Male	13 (39)	13 (42)	
Place of birth			
Bogotá	18 (54.6)	20 (64.5)	
Colombia, another city	13 (39.4)	9 (29)	
Venezuela	2 (6)	2 (6.5)	
Family in rural settings			
Yes	12 (36.6)	15 (48.4)	
No	21 (63.4)	14 (45.2)	
Do not know	0	2 (6.4)	
Socioeconomic level			
One – lowest	0	0	
Two	2 (6)	0	
Three	4 (12.1)	5 (16.1)	
Four	22 (66.8)	9 (29)	
Five	4 (12.1)	13 (42)	
Six – highest	1 (3)	4 (12.9)	
Family uses traditional			
medicine			
Yes	26 (78.8)	23 (74.2)	
No	7 (21.2)	8 (25.8)	
Do not know	0	0	
home			
Yes	9 (27.3)	13 (42)	
No	24 (72.7)	18 (58)	
Do not know	0	0	
Student self-identifies as minority			
Rural population/ peasant	1 (3)	3 (9.6)	
No	32 (97)	28 (90.4)	
Do not know	0	0	
Age in years			
Min	21	21	
Max	30	30	
Mean (sd)	22.7 ± 1.6	23.3 ± 1.8	

Table 8.1 Sociodemographic characteristics of the participants of the study



Figure 8.1 Schematic diagram of the pilot RCT

Students randomised to the intervention arm reported a slightly higher cultural safety score after the intervention, not significant at the 5% level. Both intervention and control arms reported a higher cultural safety score after participating in the training sessions, with statistically significant pre-post differences. Tables 8.2 and 8.3 show the difference in cultural safety score between and within intervention groups by timepoint.

Table 8.2 Difference of cultural safety score between intervention groups

	Standard lesson	Game jam	Difference	95% CI	n=
Pre-intervention	23.3	23	0.3	-1.4 to 2	64
Post-intervention 1	25.9	26.9	-1	-3.0 to 1	64
Post-intervention 2	26.8	26.5	0.3	-2.4 to 3	35

Table 8.3 Difference of cultural safety score within intervention groups
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	Pre-intervention	Post-intervention 1	Difference*	95% CI	n=
Total	23.1	26.3	-3.2	-4.3 to -2	64
Standard lesson	23.3	25.9	-2.6	-4. To -1.1	33
Game jam	23	26.9	-3.9	-5.6 to -2.1	31
	Pre-intervention	Post-intervention 2	Difference	95% CI	n=
Total	23.1	26.7	-3.6	-4.7 to -1.6	35
Standard lesson	23.9	26.8	-2.9	-5.3 to -0.4	18
Game jam	23	26.6	-3.6	-5.4 to -0.9	17
	Post-intervention 1	Post-intervention 2	Difference	95% CI	n=
Total	26.3	26.7	-0.4	-1.7 to 1	35
Standard lesson	25.7	26.8	-1.1	-3.1 to 0.9	18
Game jam	26.9	26.6	0.3	-1.6 to 2.4	17

* Significant differences are shown in bold font.

The net probabilistic transitive closure showed a good progression of the CASCADA intermediate outcomes for both the intervention and control groups after the intervention (Figure 8.2). The intervention group showed a higher cumulative net influence (5.99) than the control group (5.86), and all arcs where positive.

Figure 8.2 Net probabilistic transitive closure of the CASCADA results chain of medical students' responses in control and intervention groups in the pilot RCT



Perception of the activity

Students in the intervention arm described the game jam experience in favourable terms. They highlighted the importance of a topic that is not offered in standard medical training, and described game jam learning as an innovative strategy to learn through hands-on experience:

"It was great learning about such an important and neglected topic [cultural safety], and it was even better learning through innovative approaches such as the game jam" [student 11, female]

"The experiential learning approach is the best way to learn. I learned a lot: cultural safety, game jam, innovation, and creativity!" [student 14, female]

"We learned through creating the games because we used the knowledge that we acquired in the lecture. In this self-learning activity, we could apply what we learned through hands-on experience and playing." [student 3, male]

Additionally, some medical students considered cultural safety training relevant to the multicultural context of Colombia and commented about potential benefits of cultural safety training:

"It is worth having this training to educate integral physicians who are adapted to the cultural characteristics of the communities in Colombia." [student 5, male]

"The lecture was fascinating, and I think that [cultural safety training] invites us to become more curious about our own culture, to be more inclusive towards our patients, and to accept cultural differences in our professional practice." [student 18, female]

"I think it is a topic that all medical students should learn because our country is extremely rich in terms of cultural diversity. It is very common to see patients with different cultural healing practices." [student 28, female]

The students suggested an increase in the game building period since the three-anda-half-hour block was not enough to fully create and test an educational game. Similarly, the students recommended having facilitators to ensure better progress of the game jam.

Content validity of the instrument

The medical students, general practitioners, and medical intern recommended changes in the instrument for the full-scale study. They suggested better wording of questions and shorter statements (some questions had two statements), as well as adding the definition of some traditional concepts in the questionnaire, for example, *atole* -traditional hot cornbased beverage of Mesoamerican origin-³⁷. The cultural safety experts suggested using the term *yerbas medicinales* (medicinal herbs) instead of *plantas medicinales* (medicinal plants) throughout the questionnaire. According to these experts, *yerbas medicinales* may better reflect the traditional use of medicinal plants.

Construct and predictive validity

For both the second and third timepoint, the greatest change in cultural safety score was among students with low cultural safety score initially who were then exposed to cultural safety training (Figure 8.3). This fits with the contrasted group assumption. Since we observed a significant increase in the cultural safety score comparing the baseline and last timepoint, our findings support the assumption that the cultural safety score is a dynamic construct that changes over time, and it is influenced by exposure to cultural safety training (Figure 8.3). Figure 8.3 Differences in cultural safety score between intervention groups by timepoints. The figure compares the scores of cultural safety between the study intervention and control groups. For each timepoint, we show: the total score; the score for students with a low score pre-intervention; and the score for students with a high score pre-intervention. Low pre-intervention scores are those below the median, and high pre-intervention scores are those above the median. The horizontal lines in the figure are the median value for the group at that time point.



Reliability of the instrument

The difference between the second and the third timepoint revealed stability of the instrument (Figure 8.3). We did not detect a significant difference in student scores between the second and third timepoint, which corroborated the test-retest reliability assumption (Table 8.3). Finally, we did not identify patterns of missing data that could hinder retention in the full-scale RCT along timepoints.

DISCUSSION

Compared with the control group, students allocated to the intervention arm reported a slightly higher cultural safety score after the intervention, althought this difference was not significant. Pilot RCT studies, however, are not appropriate to support statistical inferences and should be rather focused on acceptability and feasibility of interventions and data collection/analysis methods.³⁸ Our pilot study supported the acceptability and feasibility of cultural safety training through game jam learning. It allowed us to gain skills required to conduct a full-scale game jam and RCT, to test research methods and procedures, and to explore the validity and reliability of our instrument. It was also a valuable opportunity to garner the support of the academic staff of the university for the full-scale study.

Acceptability and feasibility of cultural safety training and game jam learning

Participating medical students reported that cultural safety education is relevant to the multicultural context of Colombia and they commented about the potential benefits of this training. An earlier small-scale community-based learning intervention³⁹ helped Colombian medical students become aware of the relevance of this type of training in the multicultural setting such as Colombia. The full-scale trial will help to explore the transformative potential of cultural safety training. While medical students reported that the cultural safety training was important, attrition of students throughout the pilot indicated the need for recruiting facilitators to support retention in the full-scale study.

Moore argued that pilot studies are necessary to establish feasibility.⁴⁰ The idea of game jams to improve learning is recent⁴¹ and, to the best of our knowledge, this is the first experience using a game jam to train medical students. In the open-ended questions, the medical students described the game jam as an innovative strategy to learn through handson experience. Some authors recently reported that game jam participation could improve performance of computing students,^{19,20} promoting learning through self-discovery and reflections on identity.⁴² The full-scale RCT will shed further light on the learning potential of game jams in medical education.

Pilot studies can also reveal local attitudes or interests that might affect the research process.⁴³ Mudur¹⁷ described opposition from Western trained physicians when the Indian Ministry of Health proposed introducing courses on traditional medicine for medical students. Prior to study initiation, we presented the project to the Academic Commission, the Sub-committee for Research, and the Department of Epidemiology in three separate meetings at the Faculty of Medicine at *La Sabana* University. The academic staff requested us to explore the validity and reliability of the instrument before the full-scale study and to ensure that the intervention and control arms were exposed to the same cultural safety concepts. The meetings gained the support of the faculty at the university, which authorized the conduct of the full-scale RCT.

Research methods and procedures

Game jams are complex and chaotic, often lacking identifiable structure or form, and this makes them unpredictable.⁴⁴ Experts highlight the role of hands-on practice to master game jam facilitation skills. Macklin et al., for example, mentioned that "game jams are best mastered through practice.[...] With each one, you'll add ideas, style, and specifics that will make the next one you do even better."⁴⁵(p209) Our pilot RCT allowed us to develop the skills to conduct a successful full-scale RCT with a game jam intervention.

Van Teijlingen³⁸ found a pilot study identified potential problems in a research plan on maternity care. It showed the proposed procedure of distributing questionnaires would not work for a full-scale study.³⁸ Our pilot helped us to test mobile devices for the selfadministered questionnaires. Since all students had access to a personal device (smartphone, tablet, or computer) we confirmed this method would be feasible and convenient in the full-scale study. We also determined the time, materials, and staff we would require. Students requested, for example, the game jam last longer than five hours.

Pilot studies also allow researchers, including those in training, to gain experience with research methods, procedures, and data analysis techniques.^{38,40} We practiced stratified randomization by level of training on cultural safety at baseline. Similarly, we explored data analysis using probabilistic transitive closure. Andersson and collaborators used fuzzy transitive closure to explore gender-specific CASCADA intermediate outcomes

underlying dengue prevention in the *Camino Verde* trial.³⁵ They illustrated gender differences in the overall influence of the intervention potentially due to higher participation and engagement of women. In transitive closure, every relationship in the map contributes to the summary weight of a walk through a multiplicative function. The approach is appropriate when the number of factors of the model is pre-set – for example in the fixed length CASCADA results chain – and when the weights of relationships between concepts can be interpreted as probabilities.⁴⁶ To our knowledge, the present study is only the second application of transitive closure to examine group-specific intermediate outcomes in behaviour change interventions, and the first to do so with probabilistic transitive closure.

Validity and reliability of our research instrument

Our recent scoping review could identify no validated instruments to assess cultural safety interventions.⁴⁷ Since cultural safety responds to the specific cultural needs of each cultural setting,¹² research instruments should also reflect the specific characteristics of each context. In piloting a preliminary version of our instrument, we used stakeholder opinions on how to improve the questions of the survey to enhance the content validity of our instrument. We explored the construct and predictive validity, as well as the reliability of our instrument in preparation for the full-scale study.

Limitations

A pilot focussed entirely on the validity and reliability of the instrument might have achieved more in those domains. The objectives of our study, however, went beyond exploring the performance of our instrument and we had to balance our time and resources to cover the complex elements and skills to conduct the innovative full-scale study. We did not include a qualitative evaluation of the impact of the intervention in the clinical practice of the medical students as will the full-scale study. We propose to examine the most significant change⁴⁸ in the clinical practice of the medical students and interns after participating in cultural safety training. This will help us to identify unintended effects of the intervention and help to understand the experience of the intervention in health care education.
Our pilot study detected considerable interaction between students, with resulting contamination between the intervention and control groups. This could affect estimation of impact in our future full-scale RCT. We adjusted the protocol of the full-scale study to include facilitators, who will help to minimize communication and subsequent contamination between the two study arms. The facilitators will also help to address participant attrition in the full-scale study.

CONCLUSION

Cultural safety is an appropriate approach to medical education in Colombia, where training of physicians is disconnected from the cultural preferences of the population. Our pilot study confirmed cultural safety training is feasible and acceptable to Colombian medical students when delivered through game jam learning. We improved the skills required to conduct a full-scale study, piloted research methods and data analysis techniques, improved both our instrument and intervention, identified logistical problems that may hinder our research endeavour, and garnered the support of the academic staff of the university for the full-scale study. Researchers and educators may find our results informative in design of RCTs assessing educational interventions. We are using the lessons learned in our study to conduct an ongoing full-scale study with 400 medical students in Colombia.^{21,23}

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Author Contributors

This study is part of the PhD work of JP. NA is the supervisor and AC is the co-supervisor of JP. NA and AC advised on the development of the study. JP lead the study design and coordinated the fieldwork. JP drafted this paper and all authors adjusted it. All authors read and approved the final manuscript.

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Competing interests

None declared.

Ethics approval

This study was approved by the Institutional Review Board of the McGill's Faculty of Medicine (approval number A05-B37-17B) and by the Sub-committee for Research of the Faculty of Medicine at La Sabana University (approval number 445).

Data sharing statement

The data sets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

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CHAPTER 9 [Manuscripts 7, 8 & 9]: Impact of Game Jam Learning on Cultural Safety in Colombian Medical Education: a Randomised Controlled Trial

PREFACE

The three specific objectives that preceded the full-scale randomised controlled trial contributed to the design of the trial. The scoping review (objective one, manuscript 1) identified research gaps that shaped my project, informed my research design, and facilitated the game design process of the participants in the game jam. The co-designed curriculum (objective two, manuscripts 4 and 5), informed by the community-based learning interventions (objective two, manuscripts 2, 3), informed the lectures of both the game jam and standard lesson groups and inspired the game creation process of the game jam. I used the results of the pilot RCT (objective three, manuscript 6) to inform the design of the full-scale trial: (a) I identified the need to include facilitators in the activities of both the game jam and control groups; (b) I used the results of the pilot to calculate the sample size of the full-study, and piloted research methods and procedures; (c) I improved the content and construct validity, and explored the internal consistency and stability of my instrument; and (d) I gained visibility and support to conduct the full-scale study, and determined the materials and time needed for the game jam. Manuscript 7 describes the protocol of the full-scale RCT, manuscript 8 present the quantitative results of the trial, and manuscript 9 describes the qualitative results of the trial.

I presented the quantitative results of the RCT at McGill University's 2020 Global Health Night (Digital Poster Fair), and mentored medical student Paula López to present the qualitative results at the Research Day of the Colombian *Fundación Cardioinfantil* (Digital Poster Fair). If my abstract is accepted, I will present the full results of the RCT at the 2021 Canadian Conference on Medical Education. 9.1 [Manuscript 7] Impact of Co-Designed Game Learning on Cultural Safety in Colombian Medical Education: Protocol for a Randomised Controlled Trial

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Keywords: transformative learning, medical education, cultural safety, participatory research, game jam

ABSTRACT

Background: Cultural safety encourages practitioners to examine how their own culture shapes their clinical practice, and to respect their patients' worldviews. Lack of cultural safety in health care is linked to stigma and discrimination toward culturally diverse patients. Training in cultural safety poses considerable challenges. It is an unappealing subject for medical students and requires behavioral changes in their clinical practice. Game jams, collaborative workshops to create and play games, have recently shown effectiveness and engaging potential in university-level education.

Objective: The trial aims to determine if medical student participation in a game jam to design an educational game on cultural safety is more effective than a standard lesson on cultural safety in terms of change in students' self-reported intended patient-oriented behavior.

Methods: A parallel group, two arm, randomised controlled trial with a 1:1 allocation ratio will randomize 340 medical students and 60 medical interns (n=400) at the Faculty of Medicine at *La Sabana* University, Colombia (170 students and 30 medical interns to each arm). The intervention group will participate in an 8-hour game jam comprised of: (1) a preliminary lecture on cultural safety and game design; (2) a game building session where groups of students will create educational games about cultural safety; and (3) a play-test session in which students will play and learn from each other's games. The control group will receive a standard lesson, including a 2-hour lecture on cultural safety, followed by a 6-hour workshop to create posters about cultural safety. Web-based self-administered 30-item Likert-type questionnaires will assess cultural safety self-reported intended behavior before, immediately after, and six months after the intervention. An intention-to-treat approach will use a *t*-test with 95% CIs to determine the significance of the effect of the intervention, including within- and between-group comparisons. The qualitative Most Significant Change technique will explore the impact of the intervention on the clinical experience of the students.

Results: Study enrollment began in July 2019. A total of 531 students completed the baseline survey and were randomized. Data collection is expected to be complete by July

2020, and results are expected in October 2020. The study was approved by the institutional review board of the Faculty of Medicine at McGill University (May 31, 2017) and by the Subcommittee for Research of the Faculty of Medicine at La Sabana University (approval number 445).

Conclusions: The research will develop participatory methods in game-based learning codesign that might be relevant to other subjects. Ultimately, it should foster improved cultural safety skills for medical students, improve the quality of health services for diverse cultural groups, and contribute to enhanced population health. Game learning may provide an innovative solution to a long-standing and neglected problem in medical education, helping to meet the educational expectations and needs of Millennial medical students.

Trial registration: ISRCTN registry ISRCTN14261595;

http://www.isrctn.com/ISRCTN14261595

INTRODUCTION

Cultural safety training

Although cultural safety is an evolving term and lacks a formal definition,¹ it is often described as a space "that is spiritually, socially, emotionally and physically safe for people; where there is no assault, challenge or denial of their identity, of who they are, and what they need."² The concept originated in New Zealand to address the disconnect between the type of health care that Indigenous Māori people were receiving and the culturally-congruent care that they were advocating for.³

Cultural safety has gradually gained attention because it offers a more comprehensive and respectful way to approach culture, in many settings replacing the current standard, which is cultural competence.⁴ Cultural safety is distinct from cultural competence, in that it invites culturally diverse patients and their communities to co-design and evaluate culturally safe health care.¹⁵ The notion of participation in health care design also differentiates cultural safety from cultural humility,⁶ another well-known approach to cultural diversity in health care.

The Royal College of Physicians and Surgeons of Canada will soon require all medical residency programs to provide mandatory cultural safety training.^{7,8} There is, however, little research on how to implement this approach in medical education,⁹ and how health professionals acquire cultural safety skills is poorly understood.¹⁰

There are additional challenges to promoting cultural safety in medical education. Educators might find cultural safety complicated to teach and medical students might perceive it as dull or, given the altruistic tone of their chosen profession, unnecessary for them.^{11,} Contemporary medical training is overloaded almost everywhere, with little space to include an entirely new if very important subject. Millennial medical students – the birth cohort between 1979 and 2000 ¹² – have new learning relationships with technology, creativity, and amusement that modern teaching strategies cannot overlook.¹³ Finally, cultural safety training goes beyond merely knowledge acquisition; it must promote a *transformative* experience to impact students' behavior in clinical practice. The theory of transformative learning provides a framework to address these challenges. ¹⁴

Transformative learning and game co-design

Mezirow describes transformative learning as a process that changes frames of reference, "the structures of assumptions through which we understand our experiences."¹⁴ Frames of reference comprise habits of mind, which are habitual ways of thinking and acting, and points of view, which are beliefs, values, and attitudes.

Mezirow argues that ethnocentrism, defined as "the predisposition to regard others outside one's own group as inferior,"¹⁴ is an example of a habit of mind. Ramsden, the Māori nurse who developed the concept of cultural safety, proposes that confronting ethnocentrism must be the first step in cultural safety training.³ Transformative learning may, therefore, be suitable for providing cultural safety training to medical students.

Transforming frames of reference requires reflection on the assumptions upon which learners base their habits of mind and points of view.¹⁴ In transformative learning, people become critically reflective of their assumptions through education that is participatory and interactive and through group problem-solving or communicative learning.¹⁵

Game jams provide an environment to foster learning through interacting and communicating with others,¹⁶ an essential aspect of transformative learning. These participatory events allow attendees to create games (digital or board games) in a timeconstrained environment.¹⁷ Unlike other educational approaches, game jams could offer a solution to the challenges of cultural safety in medical education by (1) engaging Millennial students through a culture of creativity and learning, play testing, and idea sharing; (2) supporting a transformative process of learning-by-doing while enhancing creative thinking, problem-solving, communication, and innovation; and (3) promoting transformative learning in less time, thus offering an alternative to overloaded medical curricula.

Fowler et al¹⁶ recently found that game jam participation could improve the performance of computing students. However, we are not aware of any reported experience using game jams to train medical students. Our primary objective is to determine if medical student participation in a game jam to design an educational game on

cultural safety is more effective than a standard lesson on cultural safety in terms of change in students' self-reported intended patient-oriented behavior. Our secondary objectives are to: (1) determine the impact of the intervention (game jam) compared with the control (standard lesson on cultural safety) on students' confidence in their general transcultural skills; and (2) assess the impact of participation in the game jam through a narrative approach that identifies in their own words the effect of the learning on cultural safety in their clinical practice.

METHODS

Trial design

A parallel-group, 2-arm randomized controlled trial (RCT) with 1:1 allocation will compare participation in a game jam with a standard lesson on cultural safety. The RCT will answer the following question:

Among medical students and interns from *La Sabana* University, does participating in a game jam for cultural safety training, in comparison to a standard lesson on cultural safety, result in increased change in students and interns': (a) self-reported intended behavior; (b) confidence in general transcultural skills; and (c) reported change in clinical practice?

Table 9.1.1 presents the population, intervention, contrast, outcomes, and time points components of the research question. This protocol description follows the standard protocol items: recommendations for interventional trials 2013 statement¹⁸ (Multimedia Appendix 1).

Table 9.1.1 Population, intervention, contrast, outcome, and timing (PICOT) of theRCT

Components	Description
Population	Undergraduate medical students and medical interns at La Sabana University in
	Colombia
Intervention	Game jam aimed at fostering cultural safety in clinical practice
Contrast	Standard lecture and workshop on cultural safety
Outcome	(1) Cultural safety intended patient-oriented behavior change outcomes from
	knowledge to action; (2) Students' confidence in general transcultural skills; and
	(3) Qualitative understanding of the change experienced by participants in their
	clinical practice
Timing	Before the intervention, immediately following the teaching session, and six
	months post-intervention

Study setting

We will conduct the RCT at the Faculty of Medicine at *La Sabana* University in the municipality of Chía, Colombia. Chía is a small town located 15 km from Bogotá, the capital of Colombia. *La Sabana* University is a private higher education institution that has 8,926 undergraduate students; 22% of these students come from a low socioeconomic level, 52% belong to the middle class, and the remaining 26% come from higher socioeconomic backgrounds.¹⁹ Presently, there are 956 students enrolled in the medical school and 256 medical interns (n=1,212).¹⁹ At *La Sabana*, the duration of the doctor in medicine program is 7 years. As part of that training, all medical students must undergo a one-and-a-half-year medical internship before graduating.

Eligibility criteria

The inclusion criteria are as follows: (1) being a medical student or medical intern at any level of training and (2) providing informed consent. The exclusion criterion is not wanting to participate in the study.

Interventions

Game jam

The intervention will consist of a game jam aimed at creating a low-tech prototype of an educational game to foster cultural safety in medical education. Groups of five or six students or medical interns will create an educational game prototype from scratch. We will follow a six-step game jam protocol based on Macklin's *Planning your game jam* guidelines²⁰ (Figure 9.1.1).





(1) Preliminary lecture session (1 hour): this comprises a 30 min lecture on cultural safety, based on a cultural safety curriculum co-designed with local community members knowledgeable about cultural and traditional health practices²¹, and a 30 minute lecture on game design.

(2) Opening ceremony: game jams usually start with opening comments from the host. We will welcome the participants and share the agenda and rules of the game jam.

(3) Game building (4 hours): this includes 6 steps:

- We will invite participants to write a brief narrative of when they witnessed (or heard of) discrimination or disrespect against a patient because of their traditional health practices, and the consequences of this discrimination.
- Participants will share their brief stories within their game jam group to discuss and select the story (based on consensus) that best describes discrimination or disrespect against a patient. A key component of this step is to imagine and brainstorm the fullest range of possible consequences – from trivial to life-threatening.
- Participants will anonymize the selected story as that of a fictional medical student who has to undergo a primary care clinical rotation in a local community where she or he faces intercultural tensions in clinical practice. The participants will then convert this narrative into a game, and define a set of rules, rewards, and penalties.
- Participants will discuss the factors that hypothetically led the medical student to be discriminatory or disrespectful towards his or her patient in the story. After the discussion, each group will select and integrate 5 to 10 factors into the game. The *challenge* here is that players have to become aware gradually that these factors can lead to disrespect or discrimination against culturally diverse patients as they play the game. Concretely, the jammers will be expected to add factors such as the hegemony of evidence-based medicine, colonization and ethnocentrism, and other factors defined in the co-designed cultural safety curriculum.
- Participants will discuss what can be done to address each of the selected factors that contributed to the disrespect or discrimination experienced by the patient in the narrative. Each group will select and integrate 5 to 10 actions to promote dialogue and respect towards culturally diverse patients in clinical encounters into their game. The *challenge* is that players learn to respect patients who use traditional health practices in clinical encounters as they play the game.

The students will discuss and identify ideas to start working with the patient as a team in the health care decision-making process. This involves engaging in dialogue with the patient to invite them to bring their cultural and traditional practices to inform the health care decision-making process. Traditional practices will be pre-defined by our co-designed curriculum.²¹ The *challenge* is that players of the game have to learn how to work with traditional medicine users to make health decisions that are culturally safe jointly.

(4) Game testing (one hour): groups will learn from each other's solutions, ideas, and resources, thus strengthening the cultural safety learning process. At least one member of each group will stay at their workplace to present their game. The remaining students of the group will rotate to play the games created by other groups, thus ensuring that participants from all groups will play at least two additional games. Before the end of the session and using Google Forms (Google LCC), we will ask the students to evaluate other groups' games in different categories aligned with each of the challenges.

(5) Game refining (30 min): after playing and testing other teams' games, each group will have new ideas for refining their own game. Groups will then return to their workplace and apply lessons to improve their own game. Each group will fill a form to register their game on Google Forms.

(6) Closing (1 hour 30 min): we will bring the full group together for final presentation of the games. Each group will have to provide a brief description of their game and discuss how they solved each of the game building challenges. We will facilitate this session to highlight the underlying concepts of cultural safety. Finally, we will award prizes in three different categories aligned with each of the challenges.

Control

The control group will receive a 1 hour 30 min lecture on cultural safety in medical education by an expert in cultural safety. The lecture will be a standard lesson using PowerPoint slides and will cover the same key concepts used in the game jam, including (1) definition of cultural safety; (2) consequences of cultural tensions in health care; (3) self-

awareness; (4) Colombian cultural health practices; and (5) respect for culturally diverse patients. The lecture will be based on our co-designed curriculum.²¹ The session will be followed by a 15-min period to make comments and to ask questions and a 15-min break.

After the break, the students will participate in a 6-hour workshop based on cultural safety selected readings. Groups of 5 or 6 students or medical interns will answer 10 openended questions based on the lecture and the readings. They will create a poster to graphically display their responses to other students. Similar to the game jam session, we will split each group and encourage a rotation process where participants from all groups will learn from at least two additional posters. Before the end of the session and using Google Forms, we will ask the students to evaluate other groups' posters in different four categories: creativity, coverage of the topic, graphics and pictures, and layout and design.

In the closing session, the best groups will present their posters to the group at large. In this session, we will unpack and highlight the key concepts of cultural safety. Similar to the game jam session, we will award prizes in the 4 evaluated categories. Similar to that in the intervention group, the duration of participation in the control group will be 8 hours.

Criteria for discontinuing or modifying allocated interventions

Participants are free to withdraw from the trial at any point. We will collect reasons for withdrawal from subjects who drop out of the trial.

Participants will not be able to switch groups once they have been randomized to the intervention or control arms, even if they request to do so. Using participants' lists, the facilitators will ensure that participants remain in their designated groups.

Strategies to improve adherence to intervention

We will recruit 10 to 20 game jam facilitators to support participants and to ensure that all groups are able to meet the challenge of each step of the game jam protocol. The facilitators will be final-year medical students or medical interns interested in cultural safety research or game-based learning. We will train the facilitators for 1 month before the game jam to

ensure that they will have the skills to support the game jam participants in their learning process successfully.

We will record the attendance to the intervention and control arms activities. Along with the names of the participants, we will record the date, hour, and their signatures.

Relevant concomitant care and interventions that are permitted or prohibited during the trial

Contamination is a concern of parallel-group RCTs in education. This occurs when individuals who are receiving the intervention *leak information*, which influences results in the control group. This usually reduces the measured intervention impact, making it more difficult to find a significant difference between groups.²²

In this study, we cannot guarantee that contamination will not occur. We will minimize this risk by asking students to avoid real-time communication with their peers (for example using their cell phones) and we will conduct intervention and control activities simultaneously in different buildings. The groups will have different lunch breaks.

Outcomes

Primary outcome

The primary outcome is the self-reported intended patient-oriented behavior of students. This derives from response to the statement: I will never be open to include my patients' cultural beliefs and practices in the health-decision making process. We are assessing students' *intended* behavior instead of actual practice/action. Our primary concern is sustained intention 6 months post-intervention.

A supplementary analysis will examine the primary outcome in the context of a results chain using the conscious knowledge, attitudes, subjective norms, change intention, sense of agency, discussion, and behavior/action (CASCADA) model of planned behavior.²³ The model includes the following variables:

• Conscious knowledge was the response to the statement: "I consider the cultural beliefs of my patients are not important for health decision-making."

- Attitude to cultural safety was derived from the statement: "It is not worth considering the cultural beliefs of my patients to improve their health."
- Subjective norm used the statement: "Although many physicians disapprove of cultural beliefs, I think that these beliefs could improve my patients' health."
- Intention to Change was derived from the statement: "I will never be open to include my patients' cultural beliefs and practices in the health-decision making process."
- Agency was the response to the statement: "I feel prepared with the knowledge and skills to prudently incorporate my patients' cultural practices in the health-decision making process."
- Discussion derived from the response to the statement: "I will discuss cultural safety with other students and physicians so they can prudently incorporate their patients' cultural practices in the health-decision making process."

Agency and Discussion replace perceived behavior in a conventional theory of planned behavior.²⁴ Agency involves both self-efficacy and collective efficacy. The CASCADA model includes Discussion as an additional element in the results chain toward behavior change.²⁵ Action as a clinician, of course, cannot be known while the student is still studying. We will extrapolate this in a supplementary analysis following the successful use the CASCADA model to explore dengue prevention behavior.²⁵

Secondary outcomes

Secondary outcomes comprise (1) students' confidence (transcultural self-efficacy) in their general transcultural skills; and (2) qualitative understanding of the impact of the intervention in the clinical practice of medical students and medical interns through the Most Significant Change Technique. We will assess transcultural self-efficacy at baseline, immediately following the teaching session, and 6 months post-intervention, and we will conduct the qualitative assessment in both groups 6 months after the intervention.

Output

Each student group of the intervention arm will create a co-designed low-technology prototype of a serious game to foster cultural safety in medical students. Some of these

prototypes may serve as blueprints for future fully developed games, or as input for future educational videogames.

In addition to the quantitative outcomes of the RCT, we will use the qualitative Most Significant Change narrative technique²⁶ to collect and analyze stories of change from the medical students 6 months after the intervention. This technique will allow us to capture meaningful changes in the students' clinical practice, which may not be apparent from the quantitative evaluation.

Participant timeline

Figure 9.1.2 shows the consolidated standards of reporting trials flow diagram of the RCT.²⁷



Figure 9.1.2 Consolidated standards of reporting trials flow diagram of the RCT

Sample size

Our pilot RCT found an effect size (Cohen *d*) of 0.25 between the intervention and control arms after the teaching session (mean in game jam group 26.9 SD 4; mean in control group 25.9 SD 4). Using the *pwr* package in R, ²⁸ a group size of 199 participants in the game jam group and 199 participants in the control group (sample size = 398) will allow detection of an effect size of 0.25, with a 2-sided alpha = .05 and a power = 0.8 (see Figure 9.1.3). Since we observed considerable contamination in the pilot RCT, 0.25 is a conservative estimate of effect size.



Figure 9.1.3 One-arm power curve for sample size calculation

Recruitment

We will contact the medical students and medical interns using *La Sabana* University's mailing lists and will e-mail invitations for voluntary participation in the project. For those willing to participate, we will send further information about the project and the date and

place of the intervention. We will ask interested students to complete the web-based informed consent and baseline questionnaire 1 week before the RCT.

Allocation

A potential source of bias in our study is a possible imbalance in the level of cultural safety training between the intervention and control groups before the intervention. The reason for this issue is that in Colombia around 40% of the population uses cultural and traditional practices to maintain their health.²⁹ Therefore, some students will be familiar with traditional health practices, probably making them more likely to embrace the cultural safety approach compared with students not familiar with these practices.

To address this potential bias, we will use stratified randomization based on the cultural safety score at baseline. On the basis of the preliminary results of the baseline survey, we will split the group of medical students into two groups: low and high level of cultural safety knowledge. Computerized randomization will allocate the students either to the intervention or control arm and we will use equal allocation between treatment arms. The study coordinator will be responsible for generating the allocation sequence, enrol participants, and assign participants to interventions.

Data collection methods

Data collection

We will collect quantitative data at 3 time-points: baseline, immediately after the intervention, and 6 months after the intervention, and will collect the narratives of change only 6 months after the intervention. Participants will enter quantitative data using mobile devices and SurveyMonkey self-administered questionnaires. Similarly, they will upload their stories of change using a pre-designed format on Google forms. We report our webbased instruments in accordance with the Checklist for Reporting Results of Internet E-Surveys --³⁰ (Multimedia Appendix 2).

Instrument and quantitative data to be collected

To the best of our knowledge, there are no validated research instruments to measure cultural safety outcomes in healthcare providers. A recent systematic review³¹ exploring

instruments to assess cultural competence (and aligned concepts) identified ten instruments. All of them were self-administered and based on respondent perceptions. Half of these instruments (5/10) measured cultural competence; none were designed to measure cultural safety.

Our recently published scoping review identified that the transcultural self–efficacy tool — multidisciplinary healthcare provider version (TSET–MHP) has been used to assess the effectiveness of game-based learning interventions to promote cultural competence.³² Researchers report a growing body of evidence supporting validity and reliability of the instrument.³³ The instrument assesses cognitive, practical, and affective learning dimensions that can be categorized within the classic knowledge, attitudes, and skills behavior change outcomes.

Brascoupé points out that cultural competence provides a foundation for cultural safety.³⁴ Ramsden sees cultural safety training as a dynamic process moving from cultural awareness to cultural sensitivity to cultural safety.³ Following this rationale, we will use a 30-item instrument comprised of 3 parts. The first part (5 items) will explore sociodemographic characteristics of the students. These include sex, age, level of training, place of birth, socioeconomic status, and traditional health practices used in the family. The second part (15 items) will be based on the Likert-type TSET-MHP and will explore transcultural self-efficacy.

For the third part of the instrument (cultural safety), we developed a Likert-type preliminary version based on our CASCADA variables (Primary Outcomes section) and tested it for validity and reliability in our pilot RCT.

Validity and reliability

Using data from our pilot RCT, we followed the process proposed by Jeffreys³⁵ to improve the validity and reliability of the third part of our instrument. In the pilot study, the questionnaire included the following open question: How can we improve this instrument? An inductive thematic analysis³⁶ of responses identified suggestions to adjust our survey. We shared the adjusted version of the instrument by email with two general practitioners, one medical intern, six medical students, and four cultural safety experts. We adjusted the

instrument according to their comments and agreed on the content validity of the instrument by consensus.

To increase the construct validity of our instrument, we used the contrasted group approach, which explores the difference between two separate groups.³⁵ To increase the predictive validity of our instrument, we looked at the score difference between two time points.³⁷ Reliability explores the degree of accuracy and consistency in measurement. Using R Studio v1.1.419, we calculated Cronbach α^{38} to determine the internal consistency of our instrument. As our instrument was short (<10 items), we expected a value of >0.5.³⁹ We complemented the reliability exploration using the test-retest method to explore the stability of the instrument.³⁵ We report the validity and reliability results of our instrument in the pilot RCT, which is not yet published.

Qualitative data to be collected

To explore students' stories of change after cultural safety training, we will use the Most Significant Change approach, which is a narrative technique that allows participants to communicate changes that are most meaningful to them.⁴⁰ Using a pre-defined format in Google forms, we will ask participants to write down and enter their stories based on the following instruction: "Please, tell me a story describing what you think is the most significant change in your clinical practice as a result of your participation in the activity [game jam and standard lesson] 6 months ago."

The instructions will clarify that participants should feel free to write down stories of negative changes or to say that they did not experience any change at all. Only medical students involved in clinical practice and medical interns (third to seventh year of medical school) will be invited to participate in this part of the RCT.

Methods to maximise completeness and quality of data

The study coordinator and facilitators will be physically present while collecting the data at each time point to ensure the completeness of data. In addition, we will use several validation options to increase the quality of the data: specific number range, specific character range, date validation, email address format, and prompts that alert participants when they enter incomplete or invalid answers.

In this study, the familiarity of Millennial and Generation Z medical students with technology and computer-based education supports using web-based questionnaires should decrease social desirability bias.⁴¹ Assured of anonymity, respondents should be less concerned about what others may think about their responses, including peers and professors.⁴² Data reliability in Web-based questionnaires is reportedly equal to or better than traditional paper-based approaches.⁴³ Examples include data on self-reported perceived health status, oral contraceptive use, and smoking and alcohol use. Web-based questionnaires are also faster to complete and typically cheaper than traditional approaches, making them ideal for our research.

Methods for ensuring secure storage of data

SurveyMonkey and Google Forms responses are stored in a worksheet that can only be accessed through an account login. Data transmission uses Secure Sockets Layer to encrypt information during transport. After downloading the data, we will delete it from SurveyMonkey and Google Forms. We will store the data securely for seven years and then destroy them in accordance with Centro de Investigación de Enfermedades Tropicales (Tropical Disease Research Centre) guidelines for security, storage, and eventual destruction of data records.⁴⁴

Methods for analyzing data

Primary analysis

Using an intention-to-treat approach, we will perform a *t*-test with 95% CIs to determine the effect of the intervention on Change Intention between parallel intervention and control groups, six months after the intervention. We will assess the influence of this primary outcome in the results chain using the CASCADA approach developed by Andersson et al.²⁵ Transitive closure estimates the net influence of each element of the results chain on each other, and on the final outcome – behavior change in practice.⁴⁵

Secondary analysis

We will examine the residual impact of key baseline and socio-demographic baseline characteristics, including clustering (work group during the intervention or control activities), on the primary outcome. We will examine the residuals for model assumptions and goodness of fit. This will rely on the Mantel-Haenszel approach adjusted for cluster, and unconditional linear regression.

Supplementary analysis

We will explore other parameters of impact, including within-group comparisons (baseline and post-intervention I and II) and between-group comparisons (treated versus control immediately post-intervention). We will consider possible interactions with prior cultural safety training, family use of traditional medicines and social class of participants. Planned subgroup analyses include gender, age and social class, also using generalised linear mixed modelling (GLMM) with cluster as a random effect. All statistical tests will be two-sided at the 0.05 level of significance. The Bonferroni method will adjust the level of significance for testing for secondary outcomes to keep the overall level at alpha = 0.05. We will express results as odds ratio/relative risk reduction for binary outcomes, standard errors, corresponding 2-sided 95% Cis, and associated *P* values.

Missing data

There is no reason to expect differential missing data between game jam and standard lesson groups. We will document missingness and analyze missing data using Amelia II⁴⁶ to impute values for missing data with an expectation-maximization algorithm for the primary outcome. Estimates will reconcile data from ten imputed data sets using Rubin's approach⁴⁷ in the R package Zelig.⁴⁸ In addition, we will provide an attrition diagram⁴⁹ (e.g., proportion of participants completing the surveys in each group plotted over time) demonstrating the engagement of participants over time.

Non-statistical methods

Students will enter their narratives of change on the web. Using AtlasTi 8, 2 research assistants will individually analyze the transcripts following a deductive thematic analysis approach. In a deductive analysis, a theory aligned with the researchers' interest drives the

data analysis;³⁶ we will use the steps described by the CASCADA model to identify themes of change in the stories.

Ethics

This RCT applies the ethical principles in the Tri-Council Policy Statement⁵⁰ and was approved by Institutional Review Board of the Faculty of Medicine at McGill University (approval number A05-B37-17B) and by the Sub-committee for Research of the Faculty of Medicine at *La Sabana* University (approval number 445). We will explain the confidentiality and anonymity mechanisms and the voluntary nature of participation, and obtain informed consent from participants prior to the study.

The facilitators will ensure that each participant has signed the online informed consent before proceeding with any research activity. They will be available to explain the purpose of the study, potential risks and benefits, the confidentiality of responses, and the respondents' rights to not answer certain questions or to end their participation in the study.

RESULTS

Study enrollment began in July 2019. A total of 531 students completed the baseline survey and were randomized. Data collection is expected to be complete by July 2020, and results are expected in October 2020. The study was approved by the institutional review board of the Faculty of Medicine at McGill University (May 31, 2017).

DISCUSSION

This will be the first medical education RCT using a game jam as an educational intervention. The focus of game jams to date has been on their products, which are generally video games. Our proposal is to explore the transformative engagement occurring as a result of participating in a game jam.

Answering our research question will advance the current knowledge on game jam research and participatory design in game learning. More importantly, implementing this project will contribute to the exploration of new strategies to solve the challenges of cultural safety training in medical education, taking into consideration the time pressure in medical studies and the expectations and needs of Millennial medical students.

Some have recently advocated for the need to promote cultural safety rather than cultural competence.⁵¹ To the best of our knowledge, this will be the first initiative using the cultural safety approach in South America. Similarly, cultural safety has been traditionally restricted to the Indigenous context,³⁴ and this will be one of the first experiences to apply cultural safety in a non-Indigenous setting.

Benefits from this project include medical students gaining broader tools for their future work, including openness and dialogue about cultural and traditional health practices. This aspect will be especially relevant for them as most Colombian medical students must work at least one year in a rural area as part of their compulsory 1-year return service.

Long-term potential benefits derived from the project include enhanced quality in Colombian health services, improved reputation of health institutions (higher patient satisfaction, better physician-patient relationship, and better patient adherence), and reduced health disparities among culturally diverse patients in Colombia. Assessing these outcomes is, however, outside the scope of our study.

We recognise several challenges. The participatory design of serious games is an emerging field, and evidence of its impact is scarce.⁵² There are no agreed methodological frameworks, or consensus on operational definitions. This could lead to unexpected challenges, hindering the research process. To address this issue, we conducted a pilot RCT with 79 final-year medical students to explore the acceptability and feasibility of cultural safety training through co-designed game learning, master the skills required to conduct a full-scale co-designed game learning session, pilot research methods and procedures, explore the validity and reliability of our research instrument, and identify logistical problems that might hinder the full-scale study. This helped us to understand and to solve, in advance, some of the challenges. We will publish the results of the pilot RCT soon.

It is likely that only students interested in cultural safety, game learning, or research will agree to participate in the study. We will implement measures suggested by Kahan⁵³ to prevent self-selection bias in our study. We will use computerized randomization and all students will have equal probability to be randomized to the intervention or control arm. Although blinding is nearly impossible in RCTs applied to education research, the students will not be aware of the allocation sequence or what group they were allocated to. They will only have knowledge about the auditorium that each of them should attend on the day of the intervention. Our facilitators will prevent students from deliberately switching their allocation status. Finally, five facilitators in each study arm site will ensure that participants remain in their designated groups (game jam or standard lecture).

Some argue that the reproducibility of educational interventions is hard to ensure due to the "specific teacher effect" where the results of an intervention stem from the skills of a particular teacher.⁵⁴ To maximize the reproducibility and generalisability of our intervention, we will follow the recommendations provided by the British Medical Journal.⁵⁵ This involves describing the intervention rigorously enough to allow its reproducibility and scrutiny in the future. We will report details about the teachers (background, years of experience, and fields of expertise) and the teaching interventions (duration, education content, and pedagogical approach).

In this project, we will assess education-related outcomes based on a theory of planned behavior. Experts in cultural safety training recommend, however, the use of patient-related outcomes such as evaluations of care, health outcomes, involvement in care, and health behaviors, to assess cultural safety interventions.⁵⁶ Assessing patient-related outcomes would require a more complex approach that goes beyond our logistical and economic capacity. The impact assessment, however, will include a qualitative understanding through the Most Significant Change evaluation. This will document narratives of change in the clinical practice of medical students.

The findings of this project will be specific to the Colombian cultural context. In Colombia, exploring ethnocentrism and cultural safety is simplified by the widespread use of traditional health practices.²⁹ In other settings, where cultural and traditional health

practices are not widespread, this approach will be less relevant, and it might be necessary to confront ethnocentrism in a more abstract way or through other stigmatizations.

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Authors' contributions

This study is part of the PhD work of JP. NA is the supervisor and AC is the co-supervisor of JP. NA is the principal investigator and JP is the study coordinator. NA and JP conceived the study. AC provided feedback to drafts of the paper. JP drafted this paper and all authors adjusted it. All authors read and approved the final manuscript.

Conflicts of Interest

None declared.

Multimedia Appendix

Multimedia Appendix 1. Standard protocol items: recommendations for interventional trials checklist of the study protocol.

Multimedia Appendix 2. Checklist for reporting results of internet e-surveys.

Abbreviations

CASCADA: conscious knowledge, attitudes, subjective norms, change intention, sense of agency, socialization/discussion, and behavior change/action RCT: randomized controlled trial TSET-MHP: transcultural self- efficacy tool—multidisciplinary healthcare provider

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9.2 [Manuscript 8] Impact of Game Jam Learning about Cultural Safety in Colombian Medical Education: a Randomised Controlled Trial

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ABSTRACT

Background: Cultural safety training of Colombian medical students could reduce intercultural tensions that hinder patient access to effective health services. Introducing this training requires innovative strategies to engage Millennial medical students in an already overloaded medical curriculum. Game jams are participatory events to create educational games, a potentially engaging learning environment for Millennial medical students. We set out to determine whether medical student participation in a game jam on cultural safety is more effective than more conventional education in changing selfreported intended patient-oriented behavior and confidence in transcultural skills.

Methods: A parallel-group, two-arm RCT with 1:1 allocation. Colombian medical students or medical interns participated, with signed informed consent, in the trial at University of *La Sabana*. The intervention was a game jam to create an educational game on cultural safety and the reference was a standard lesson plus an interactive workshop on cultural safety. Both sessions lasted eight hours. Stratified randomisation allocated the participants to the intervention and control groups, with masked allocation until commencement.

Results: 531 students completed the baseline survey and were randomised. 347 students completed the second timepoint, and 336 students completed the third timepoint. Game jam participants did not have better intentions of culturally safe behaviour than did participants in the lesson and interactive workshop (difference in means: 0.08 95% CI - 0.05 to 0.23). The Mantel-Haenszel approach adjusted by clusters confirmed that game jam learning was associated with higher transcultural self-efficacy immediately after the intervention (wt OR 2.03 cl adj 95% CI 1.25 - 3.30). Separately, both game jam and the lesson plus interactive workshop showed effectiveness in terms of the primary and secondary outcomes.

Conclusions: Game jam learning improved cultural safety intentions of Colombian medical students to a similar degree as did a carefully designed lecture and interactive workshop. The game jam was also associated with positive change in participant transcultural self-efficacy. Our research yielded key lessons applicable to other multicultural countries

requiring cultural safety training. We encourage further research to explore the impact of cultural safety training on population health, ideally using patient-related outcomes.

Trial registration: retrospectively registered on ISRCTN registry (ISRCTN14261595) https://doi.org/10.1186/ISRCTN14261595

BACKGROUND

In Colombia, more than 40% of the population turns to traditional and cultural health practices,¹ but public and private institutions promote health services grounded in the Western biomedical model. Medical students do not receive training to acknowledge and address intercultural tensions that arise in clinical practice. These tensions hinder patient access to effective health services,^{2,3} especially for those who use traditional health practices.⁴ Cultural safety training of health professionals could address intercultural tensions the access of patients from non dominant cultures to health services.

Cultural safety is "a space that is spiritually, socially, emotionally and physically safe for people; where there is no assault, challenge or denial of their identity, of who they are, and what they need." (p213)⁵ Irihapeti Ramsden, a Māori nurse, named the concept to bridge the cultural divide between the Māori people and official health services in New Zealand.⁶ A more recent concept analysis of cultural safety⁷ identified three foundations: equal partnership, active participation of patients from non-dominant cultures, and protection of cultural identity and well-being.

Observational studies suggest that cultural safety training enhances respect for and acceptance of traditional and cultural health practices. It is associated with improved relationships between health professionals and patients from non-dominant cultures, changes in knowledge, attitudes, self-confidence and behavior of health professionals, and healthier outcomes.⁸ There is recognition of a lack of rigour in cultural safety assessment, however, and a need for formal randomised controlled trials (RCT) to evaluate cultural safety education.⁹

Cultural safety is a well established discourse in New Zealand and Australia, but Canadian researchers and educators have only recently called for implementing the concept in healthcare practice.¹⁰ There is little research on how best to apply this approach in medical education,¹¹ and on how health professionals acquire cultural safety skills.¹² There is also a pressing need to expand cultural safety initiatives to other culturally rich settings, such as Latin American countries, and in non-Indigenous populations.⁷

Cultural safety education of medical students is challenging. Contemporary medical training is overloaded, with little space to introduce new subjects. Educators might find cultural safety complicated to teach and medical students might perceive it to be dull or even unnecessary.¹³ Going beyond simple knowledge acquisition, the educational experience of cultural safety must be *transformative* if it is to impact behavior in professional practice.⁹ On the positive side, Millennial students have novel ways of learning that include technology, creativity, and amusement.^{14,15} Game jams offer an engaging learning environment for this generation. Game jams are participatory events for attendees to create games in a time-constrained environment, typically 48 hours.¹⁶ The experience fosters learning through interacting with others,¹⁷ an essential aspect of transformative learning.¹⁸ Game jams have a positive impact in the performance of computing students,^{16,17} personal, interpersonal, and STEAM (science, technology, engineering, arts, and mathematics) skills, and game development skills.¹⁹

The educational dimension of game jams is promising, but this research is still in its infancy.¹⁹ To the best of our knowledge, the current literature reflects no game jam learning initiative with medical students and no RCT has explored cultural safety in medical education. Our primary objective was thus to determine whether medical student participation in a game jam on cultural safety is more effective than a standard lesson in changing self-reported intended patient-oriented behavior. The secondary objective was to determine the impact of game jam learning on student confidence in their general transcultural skills.

METHODS

Trial design

A parallel-group, two-arm RCT with 1:1 allocation compared game jam participation with a standard lesson plus an interactive workshop on cultural safety. The RCT addressed the question: *Among medical students and interns from University of La Sabana, compared with a standard lesson plus a workshop on cultural safety, does game jam participation result in*

improved student and intern self-reported intended behavior, and confidence in transcultural skills?

We followed the CONSORT 2010 updated guidelines for reporting parallel group randomised trials.²⁰ (Additional file 1: CONSORT 2010 checklist of the study). We published the protocol of our study prior to completion of recruitment.²¹

Study setting and participants

La Sabana, in Chia municipality near Bogota in Colombia, is a private university with 8,926 undergraduate students. In July of 2019, there were 956 medical students and 256 medical interns (N=1,212) enrolled in the Faculty of Medicine.²² The inclusion criteria for this trial were being a medical student or medical intern at any level of training and giving written informed consent. The exclusion criteria were being underage or not wanting to participate in the study.

Interventions

The trial intervention was a game jam to create a low-tech prototype of an educational game promoting cultural safety in medical education. Groups of five or six students or medical interns participated in a six-step game jam comprised of: (a) preliminary lecture session (one hour); (b) opening ceremony; (c) game building (four hours); (d) game testing (one hour); (e) game refining (30 minutes); and (f) closing (one-and-a-half-hour).

Shortly before the intervention began, our academic partners at the University of *La Sabana* requested an interactive workshop, to foster problem-based and communicative learning for the control group, rather than just a standard lesson. The reference group thus received a different intervention, beginning with a one-and-a-half-hour lecture on cultural safety. After the PowerPoint-based lesson, a six-hour interactive workshop focussed on cultural safety selected readings. Groups of five or six students or medical interns answered a study guide based on the lecture and the readings. Participants created a poster to display their responses to other students. The activity duration was the same (eight hours) in the game jam and reference groups.

The lecture given to both the intervention and control groups reflected a cultural safety curriculum previously co-designed with traditional medicine users, medical students, and cultural safety experts.²³ It covered: (a) overview of cultural safety; (b) consequences of cultural tensions in health care; (c) self-awareness; (d) Colombian cultural health practices; and (e) respect for patients from non-dominant cultures.

A Colombian MD with a Master of Science in Epidemiology, six years of teaching experience, and nine years of intercultural research experience led the intervention group activities. A Colombian MD halfway through his Master of Public Health, with 18 years of teaching experience and 20 years of intercultural research experience, led the reference group activities on July 25th, 2019.

Outcomes

The primary outcome was student self-reported intention of patient-oriented behavior, which corresponded to the Intention to Change intermediate outcome of the CASCADA model of planned behavior.²⁴ This was the response to the statement: *I will never be open to include my patients' cultural beliefs and practices in the health-decision making process*. We assessed student intended behavior instead of actual practice/action, which would have required follow-up into clinical practice over several years. Our primary concern was the sustained intention six months post-intervention.

A supplementary analysis using transitive closure²⁵ examined the primary outcome in the context of a results chain using the CASCADA model.²⁴ The model included: Conscious knowledge, Attitude, Subjective norm, Intention to Change, Agency, and Discussion related to cultural safety. The questions used to assess each component of the CASCADA model are available (Additional file 2). We assessed our primary outcomes in the baseline, immediately following the teaching session, and six months post-intervention.

Our secondary outcome was students' confidence in their general transcultural skills (transcultural self-efficacy). We assessed transcultural self-efficacy at the same timepoints as the primary outcome and used a quantitative questionnaire with all participants. The 37-item instrument had three parts. The first (11 items) explored sociodemographic factors. The second part (19 items) used the validated Likert-type

Transcultural Self–Efficacy Tool — Multidisciplinary Healthcare Provider version (TSET– MHP).²⁶ The third part (cultural safety), was a seven-item Likert-type local questionnaire based on our CASCADA variables and tested for validity and reliability in our pilot RCT. Participants responded to questions using mobile devices and SurveyMonkey.

Sample size

Using the *pwr* package in R,²⁷ we estimated that a group size of 199 participants in the game jam group and 199 participants in the control group (sample size = 398) could detect an effect size of 0.25, with a two-sided alpha = 0.05 and a power = 0.8. Our pilot RCT found an effect size (Cohen's *d*) of 0.25 between intervention and control arms after the teaching session. Since we observed considerable contamination in the pilot, 0.25 was a conservative estimate of effect size.

Recruitment and randomisation

We contacted medical students and medical interns using mailing lists from the University of *La Sabana*, e-mailing invitations for voluntary participation in the project. We used stratified randomisation by student intended patient-oriented behavior at baseline, to address a possible imbalance in cultural safety awareness between the intervention and control groups before the intervention. The results of the baseline survey split medical students into two groups: low and high scores of cultural safety. Computerized randomisation allocated the students equally (1:1) to intervention or control arms. The first author generated the allocation sequence, enrolled participants, and assigned them to intervention/control.

Blinding is nearly impossible in education research RCTs, but participants were not aware of the allocation sequence nor the group they were allocated to until the start of the intervention. They only knew the auditorium they had to attend on the day of the intervention. Twenty facilitators prevented students from switching allocation status.

Data analysis

We used an intention-to-treat approach. For the primary analysis, a *t*-test with 95% confidence intervals assessed the effect of the intervention on the primary outcome six months after the intervention. Supplementary analysis of the influence of the CASCADA results chain assessed on the primary outcome used an approach developed by Andersson and colleagues.²⁵ Probabilistic transitive closure estimated the net influence of each element of the results chain on each other, and the penultimate outcome, which was **D**iscussion.²⁸

In the secondary analysis, a paired *t*-test assessed within-group comparisons (baseline and post-intervention I and II) and a simple *t*-test explored between-group comparisons (treated versus control post-intervention) of the student confidence (transcultural self-efficacy) in their general transcultural skills. Additionally, a simple *t*-test compared the mean difference in the mean between the baseline and the third timepoint between the intervention and control groups.

For those results that were statistically significant in the primary or secondary between-group comparisons, we conducted a multivariate analysis to adjust for baseline variables. These included sex, place of birth and residence, subsistence farmers in the family, socioeconomic level, traditional medicine use by the family or the participant, medicinal plants planted at home, level of training, age, and clustering (work group during the intervention or control activities).

The multivariate analysis relied on the Mantel-Haenszel approach adjusted for cluster, with analysis repeated using generalized estimating equations (GEE). The Lamothe cluster-adjusted Mantel-Haenszel is a non-parametric approach that is simple to compute and does not require any assumptions for binomial data. ^{29,30} GEE is not intended to model between-cluster variation but focuses on the within cluster similarity of the residuals.^{30,31}

The different characteristics of the two methods provided an opportunity for crosschecking our results.

Using the Lamothe cluster-adjusted Mantel-Haenszel procedure, sensitivity and subgroup analyses explored the effect of game jam learning on transcultural self-efficacy within different groups. All statistical tests were two-sided at the 0.05 level of significance. The Bonferroni method³² adjusted the level of significance for testing for the primary and secondary outcomes. To determine the number of tests used, we considered the type of test (simple or paired) and outcome (primary or secondary).

Ethics

The Institutional Review Board of the McGill's Faculty of Medicine (approval number A05-B37-17B) and the Sub-committee for Research of the Faculty of Medicine at University of *La Sabana* (approval number 445) provided ethical clearance for this study. All participants signed written informed consent before proceeding with any research activity.

RESULTS

Some 531 students completed the baseline survey and were randomised; 347 students completed the second timepoint assessment, and 336 students completed the third timepoint assessment (Figure 9.2.1). 195 were lost to follow-up, most of whom were in classes that completed the baseline survey and were randomised, but at the last minute were unable to attend the study activities, due to scheduling clashes. Additional file 3 is an attrition diagram³³ demonstrating the engagement of participants over time.



Figure 9.2.1 CONSORT flow diagram of the RCT

The intervention and control groups were similar for all baseline sociodemographic characteristics (Table 9.2.1). Some 85.4% (229/268) and 78.7% (207/263) of the students' families had used traditional medicine in the intervention and control group respectively; this difference was marginally statistically significant. 61.2% (164/268) and 54.4% (143/263) of the participants had used traditional medicine in the intervention and control group (Table 9.2.1).

Table 9.2.1 Baseline sociodemographic characteristics of the participants of thestudy

	Lesson and interactive workshop (n= 263)	Game jam (n= 268)	p-value
Sex	n (%)	n (%)	
Female	184 (70)	182 (67.9)	0.67
Male	78 (29.6)	85 (31.7)	0.67
Prefer not to say it	1 (0.4)	1 (0.4)	1
Place of birth			
Bogota	141 (53.6)	146 (54.5)	0.91
Colombia, another city	85 (32.3)	96 (35.8)	0.44
Venezuela	28 (10.6)	19 (7.1)	0.19
Another country	9 (3.5)	7 (2.6)	0.77
Place of residency			
Bogotá	176 (66.9)	169 (63.1)	0.4
Colombia, another city	87 (33.1)	99 (36.9)	0.4
Family in rural settings			
Yes	103 (39.1)	97 (36.2)	0.53
No	138 (52.4)	153 (57.1)	0.32
Do not know	22 (8.4)	18 (6.7)	0.57
Socioeconomic level			
One – lowest	3 (1.1)	5 (1.9)	0.74
Two	12 (4.6)	12 (4.5)	1
Three	44 (16.8)	55 (20.5)	0.31
Four	88 (33.5)	85 (31.7)	0.73
Five	65 (24.7)	67 (25)	1
Six – highest	40 (15.2)	34 (12.7)	0.47
Prefer not to say	3 (1.1)	2 (0.7)	0.98
Don't know	8 (3)	8 (3)	1
Family uses traditional medicine			
Yes	207 (78.7)	229 (85.4)	0.055
No	34 (12.9)	24 (9)	0.18
Do not know	22 (8.4)	15 (5.6)	0.27
Student uses traditional medicine			
Yes	143 (54.4)	164 (61.2)	0.13
No	114 (43.3)	101 (37.7)	0.21
Do not know	6 (2.3)	3 (1.1)	0.48
Medicinal plants planted at			
home	00 (22.4)	00 (00 ()	0.40
Yes	80 (30.4)	90 (33.6)	0.49
NO	167 (63.5)	151 (56.3)	0.11

Do not know	16 (6.1)	27 (10.1)	0.12
Education level			
II and III semester (preclinical)	58 (22.1)	62 (23.1)	0.84
VI to XI (Clinical)	190 (72.2)	191 (71.3)	0.87
Medical intern	15 (5.7)	15 (5.6)	1
Age in years			
Min	18	18	1
Max	31	31	1
Mean (SD)	20.96 (1.9)	20.98 (1.9)	0.91

SD= Standard Deviation

In the intention to treat t-test, game jam participants did not have better intended culturally safe behaviour than did participants in the lesson and interactive workshop (difference in means: 0.08 95% CI -0.05 to 0.23). Game jam learning was superior to the more conventional learning in terms of transcultural self-efficacy immediately after the intervention (difference in means: 0.12 95% CI 0.02 to 0.2), but not 6 months after the intervention (difference in means: 0.6 95% CI -0.06 to 0.11) (Table 9.2.2). We did not detect a statistically significant difference in the mean change between the baseline and the third timepoint between the intervention and control groups.

Table 9.2.2 Difference in the means of primary and secondary outcomes betweenintervention groups

Students' self-reported intended patient-oriented behavior					
	Lesson+workshop	Game jam	Difference	95% CI	n=
Pre-intervention	4.39	4.39	0	-0.1 to 0.1	531
Post-intervention 2	4.54 4.62 0.08 -0.0		-0.05 to 0.23	336	
Transcultural self-efficacy					
	Lesson+workshop	Game jam	Difference	95% CI	n=
Pre-intervention	4	3.96	-0.04	-1 to 0.02	531
Post-intervention 1	4.18	4.3	0.12	0.02 to 0.2	347
Post-intervention 2	4.13	4.15	0.02	-0.06 to 0.11	331

* Significant differences are shown in bold font.

Probabilistic transitive closure of the CASCADA results chain showed good progression to the final outcome (**D**iscussion) with no blocks in both game jam and control groups (net influence of 13.75 and 13.34 respectively). The baseline values favoured the control group (net influence of 5.12 in the intervention arm and 9.7 in the control arm); the change (from baseline to the six months assessment) was larger in the intervention group.

The game jam and lesson plus workshop separately both had positive and similar effects on the primary and secondary outcomes (Table 9.2.3). We used the Bonferroni correction to adjust the alpha level of the simple and paired t-test exploring differences in the primary and secondary outcomes. All non-adjusted significant associations remained significant.

Table 9.2.3 Difference in primary and secondary outcomes within interventiongroups

Students' self-reported intended patient-oriented behavior					
	Pre-intervention	Post-intervention 2	Difference	95% CI	n=
Total	4.37	4.58	0.25	0.11 to 0.29	336
Lesson+workshop	4.33	4.54	0.21	0.07 to 0.33	174
Game jam	4.41	4.62	0.21	0.09 to 0.32	162
Transcultural self-efficacy					
	Pre-intervention	Post-intervention 1	Difference	95% CI	n=
Total	3.97	4.24	0.27	0.22 to 0.30	347
Lesson+workshop	3.99	4.18	0.19	0.13 to 0.24	167
Game jam	3.96	4.3	0.34	0.28 to 0.4	180
	Pre-intervention	Post-intervention 2	Difference	95% CI	n=
Total	3.99	4.14	0.15	0.1 to 0.19	328
Lesson+workshop	3.99	4.13	0.14	0.07 to 0.19	170
Game jam	3.99	4.15	0.16	0.08 to 0.23	158
	Post-intervention 1	Post-intervention 2	Difference	95% CI	<i>n=</i>
Total	4.24	4.17	- 0.007	-0.02 to -0.13	259
Lesson+workshop	4.16	4.16	0	-0.05 to 0.06	128
Game jam	4.34	4.18	- 0.16	-0.07 to -0.23	131

* Significant differences are shown in bold font.

The multivariate analysis using the Mantel-Haenszel approach adjusted by clusters confirmed that game jam learning and traditional medicine use reported by students was associated with higher transcultural self-efficacy immediately after the intervention (wt OR 2.03 cl adj 95% CI 1.25 - 3.30 and wt OR 1.98 cl adj 95% CI 1.11 - 2.84, respectively). GEE

confirmed that game jam learning is associated with higher transcultural self-efficacy immediately after the intervention (adj OR=2.09 95% CI 1.22 - 3.60).

Although not statistically significant at the 5% level, sensitivity analysis suggested a stronger effect of game jam learning on transcultural self-efficacy among students who are male, born and living in Bogota, with no subsistence farmers in the family, and from higher socioeconomic level. The effect of game jam learning was slightly stronger (not statistically significant at the 5% level) among students who reported family traditional medicine use but who themselves had not used traditional medicine, who had medicinal plants planted at home, and among younger students (<22 years old) in preclinical training (Figure 9.2.2).



Figure 9.2.2 Game jam learning effect on transcultural self-efficacy according to subgroup

DISCUSSION

Separately, both the game jam (intervention) and the lesson plus interactive workshop (control/reference) had positive impacts on the primary and secondary outcomes and through the probabilistic transitive closure of the CASCADA results chain. Both the groups received training in the same key elements of cultural safety based on a rigorous curriculum that Colombian stakeholders co-created through a sequential-consensual qualitative study.²³ Notwithstanding the original hypothesis, our study provides evidence on the effectiveness of cultural safety training based on our co-designed curriculum. The difference between the intervention and control/reference group is reduced because the control group received many elements of transformative learning through the interactive workshop they engaged in after their standard lesson.

In this trial, game jam learning changed cultural safety intention, but it was not superior to more conventional learning approaches in doing so. We are aware of three possible explanations for this. First, contamination is a well-known concern of parallel-group RCTs in education and could have influenced the primary outcome results. Individuals who received the intervention could have *leaked information* about their experience during the six months before the third timepoint, which influenced results in the control group. This would have reduced the measured intervention impact, making it more difficult to find a significant difference between groups.³⁴ Second, a Hawthorne effect, triggered by self-awareness of observation and assessment,³⁵ could have influenced both the intervention and control group participants, thus decreasing the opportunity to detect a significant difference between the groups.

Third, and probably most important, the academic partners at the University of *La Sabana* requested an interactive complementary activity for the control group in the form of a workshop, to foster problem-based and communicative learning, two of the main elements of transformative learning.³⁶ This turned the "control" into an intervention in its own right. A professor with substantial intercultural experience led the control group activities, resulting in an unusually strong learning experience in the control group. We believe the game jam learning would show a bigger impact in settings where fewer

students came from families that use traditional medicine, and if contrasted with a standard lesson on the subject, without components of transformative learning. The direction of the effect favoured game jam learning. This suggests that the impact of the game jam should be further explored in future studies with bigger sample size. Medical education studies often use no control group and, when they do use one, control participants receive no training on the subject of interest.³⁷ Cook summarized four metaanalyses³⁸⁻⁴¹ with more than 750 studies comparing various forms of education against no intervention. Almost all these studies favoured the training group for outcomes of knowledge, skills, and behaviours,³⁷ confirming that an "educational placebo-controlled trial has very limited value."42 Similar to clinical research, where placebo-controlled research is often unethical, recent trends in medical education research advocate for comparative effectiveness, where control groups receive active interventions.⁴³ Despite such a study being harder to design and conduct, in our trial we opted to assess comparative effectiveness. Comparative effectiveness studies, however, require much larger sample sizes than placebo-controlled trials since the expected effect size is reduced.³⁷ The effective sample size for our analysis of the primary outcome was smaller than the calculated sample size.

Our multivariate analysis confirmed that game jam learning was associated with higher transcultural self-efficacy immediately after the intervention. A recent game jam promoted self-discovery, reflections on identity, and support of the cultural identity of the Sami people in Finland.⁴⁴ Ramsden suggested that cultural safety is a continuum rather than a fixed state, with prior steps such as cultural awareness and cultural sensitivity.⁴⁵ Our co-designed curriculum, which informed the intervention and control learning activities, also included prior steps before cultural safety, such as culturally unsafe practices, and cultural awareness, humility, and competence. These prior steps might be more easily identified by the TSET, which detects changes in knowledge, attitudes, and skills of cultural competence.⁴⁶ Moreover, as opposed to the section of the questionnaire that explored changes in the primary outcome of cultural safety intention, the TSET is a widely validated and used research instrument,⁴⁷ which could have facilitated detecting a significant effect on the secondary outcome of transcultural self-efficacy.

Although not statistically significant, the sensitivity analysis suggested that the effect of game jam learning might be stronger among male than among female participants. This is compatible with a study assessing the attitudes of medical students towards games and media technology reported that, compared with males, females are less likely to be willing to design an educational game and to believe in the educational potential of games.⁴⁸

A systematic review⁴⁹ to explore changes in trainee empathy found a significant decrease in empathy during medical school and medical residency, potentially compromising professionalism and health care quality. Our study also suggested game jam learning might work better among younger participants who were also in preclinical training. Initial openness to intercultural training could be later eroded as the students advance in their training and are exposed to role models engaged in culturally unsafe actions. If the game jam also influences student empathy, this would be an additional benefit of cultural safety education. Morrissey and Ball,⁵⁰ for example, reported improved empathy of pharmacy students toward Australian Indigenous people after cultural safety education.

Limitations

Reproducibility of educational interventions is hard to ensure due to the well known "teacher effect", with results of teaching interventions depending on the individual instructor's abilities and skills.⁵¹ We followed recommendations to maximize the reproducibility and generalisability of our intervention,⁵² like describing the intervention in detail to allow reproducibility and scrutiny in the future and providing the background of the instructors involved in the study activities. We recognize the experience of the reference group instructors influenced results in a positive direction, effectively reducing the difference between this group and the game jam group.

Our subgroup analysis should be interpreted with caution.⁵³ On the positive side, we assessed the subgroup variables before randomisation, explored the comparisons within the study rather than between studies, and supported biological rationale (having evidence

to support our findings). We did not describe the subgroup hypothesis nor the effect direction a priori, and our results were not statistically significant.

There is considerable merit in using patient-related outcomes such as evaluations of care received, health outcomes, and health behaviors to assess the effect of cultural safety interventions.⁵⁴ Given the time available for the study and the complexity of assessing patient-related outcomes in medical student education, we used education-related outcomes based on a theory of planned behavior. We included a qualitative understanding through the Most Significant Change evaluation (reported separately).

Finally, our findings are specific to the Colombian cultural context. In other settings, where traditional and cultural health practices are not widespread, it might be necessary to provide cultural safety training based on other stigmas.

CONCLUSION

Game jam learning improved cultural safety intentions of Colombian medical students to a similar degree as did a carefully designed lecture and workshop. The game jam was also associated with positive change in participant transcultural self-efficacy. Potential contamination and a strong control learning activity with an experienced instructor and elements of transformative learning likely precluded detecting a significant difference in terms of the primary outcome.

This is the first published RCT of cultural safety in medical education and one of few attempts to apply cultural safety to non-Indigenous yet culturally rich settings. Our research yielded key lessons applicable to other multicultural countries requiring cultural safety training in medical education. We encourage further research to explore the impact of cultural safety training on population health, ideally using patient-related outcomes and designs that are less prone to contamination, such as clustered RCTs. **Protocol:** The protocol of this RCT was accepted for publication before completion of recruitment.²¹

List of abbreviations

STEAM: science, technology, engineering, arts, and mathematics

RCT: Randomised Controlled Trial

CONSORT: Consolidated Standards of Reporting Trials

CASCADA: **C**onscious knowledge, **A**ttitudes, **S**ubjective norms, **C**hange intention, sense of **A**gency, socialization/**D**iscussion, and behavior change/**A**ction

TSET–MHP: Transcultural Self–Efficacy Tool — Multidisciplinary Healthcare Provider version

SD: Standard Deviation

GEE: generalized estimating equation

Ethics approval and consent to participate

This study was approved by the Institutional Review Board of the McGill's Faculty of Medicine (approval number A05-B37-17B) and by the Sub-committee for Research of the Faculty of Medicine at University of La Sabana (approval number 445).

Consent for publication

Not applicable

Availability of data and materials

The datasets used and/or analysed during the current study will be available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

This study is part of the PhD work of JP. NA is the supervisor and AC is the co-supervisor of JP. NA and AC advised on the development of the study. JP led the study design and coordinated the fieldwork. JP drafted this paper and all authors contributed to it. All authors read and approved the final manuscript.

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Additional file 1. CONSORT checklist of information to include when reporting an RCT (.docx) – filled CONSORT checklist

Additional file 2. Questions used to assess each component of the CASCADA model

Additional file 3. Attrition diagram of the study

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9.3 [Manuscript 9] The Most Significant Change Described by Colombian Medical Trainees After Cultural Safety Training Through Transformative Learning: Qualitative Results from a Randomised Controlled Trial

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Keywords: cultural safety, medical education, Colombia, transformative learning, most significant change

ABSTRACT

Introduction: Cultural safety training is largely absent from Colombian medical education. If incorporated, it could address adversarial interactions between health professionals and the 40% of the population who use traditional medicine practices. In 2019, a randomised controlled trial evaluated cultural safety training for medical students through transformative learning using serious game design. The quantitative evaluation showed improved cultural safety intentions of Colombian medical trainees. We report here a qualitative evaluation of the most significant change perceived in the clinical practice of trial participants.

Methods: This qualitative descriptive study used the most significant change technique. We invited the trial participants engaged in clinical settings to describe stories of change in their supervised clinical practice that they attributed to the learning intervention. Using a deductive thematic analysis based on a modified theory of planned behaviour, two independent reviewers coded the stories and, by consensus, created themes and subthemes.

Results: From 27 stories of change, we identified seven themes and 15 subthemes: (a) Conscious knowledge: benefits of cultural safety training, consequences of culturally unsafe behaviour, cultural diversity and cultural practices; (b) Attitudes: respect and appreciation for cultural diversity, openness, and self-awareness; (c) Subjective norms: positive perception of cultural practices and less ethnocentrism; (d) Intention to Change; (e) Agency to accept cultural diversity and to prevent culturally unsafe actions; (f) Discussion; and (g) Action: better communication and relationship with patients and peers, improved outcomes for patients, physicians, and society, investigation about cultural health practices, and efforts to integrate modern medicine and cultural health practices.

Conclusion: The narratives illustrated the impact of cultural safety training through transformative learning on outcomes from conscious knowledge to action. We encourage Latin American medical educators to conduct and report other cultural safety training experiences, ideally using patient-related outcomes or direct observation of medical trainees in clinical practice.

Trial registration: ISRCTN registry (ISRCTN14261595) https://doi.org/10.1186/ISRCTN14261595

INTRODUCTION

The Colombian government and private institutions provide health services based on the Western biomedical model. Some 40% of the population seek care in traditional and cultural health practices,¹ however, creating a gap between the population's expectations and the skills of health professionals. Intercultural tensions in clinical practice hinder full access to effective health services, especially for those who use traditional and cultural health practices,² exacerbating health disparities in an already inequitable country.³

There is ample evidence that respecting culture in medical education leads to benefits in future patient satisfaction and adherence to treatment, mutual understanding between health professionals and patients from non-dominant cultures, improved knowledge, attitudes, and skills of trainees, and enhanced respect for and acceptance of traditional and cultural health practices.^{4–7} This type of medical education, however, has not spread beyond high-income countries like Australia, New Zealand, Canada, and United States.⁷ In culturally diverse Latin America, there is a pressing need to train health professionals to provide care that is congruent with the cultural characteristics of the region.

Cultural safety training in Colombia

Cultural safety is "a space that is spiritually, socially, emotionally and physically safe for people; where there is no assault, challenge or denial of their identity, of who they are, and what they need." (p213)⁸ The foundation of cultural safety is that it depends on people, including patients, from non-dominant cultures engaging in equal partnerships in clinical practice, to protect their cultural identity and well-being.⁹

In 2015 and 2016, we pioneered a new approach to cultural safety training in Latin America.^{10,11} In preparing the curriculum, we reported medical students' positive perception of traditional and cultural health practices after participating in a five-month community-based cultural safety training intervention. In 2019, a randomised controlled trial (RCT) tested the training with Colombian medical students and medical interns at *La Sabana* University in Chia, Colombia.¹² The trial examined the impact of an intervention

based on transformative learning,¹³ using a format that was less time- and resourceconsuming than five-month community-based learning.

Due to the complexity of assessing patient-related outcomes⁴ in the case of medical students, the quantitative assessment relied on education-related outcomes, such as self-reported intended behaviour and self-confidence in transcultural skills. We complemented our quantitative evaluation with a narrative exploration of the impact of cultural safety training on the clinical practice of the Colombian trainees. In this article, we present the self-reported most significant change in clinical practice attributed to the participation in the trial by Colombian medical students and medical interns.

METHODS

Study design

Our parallel-group, two-arm RCT evaluated whether medical student participation in a game jam on cultural safety is more effective than a standard lesson plus interactive workshop in changing self-reported intended patient-oriented behavior. Six months after the intervention and control activities, we conducted this narrative assessment of the impact of the trial. The complete protocol of the trial is available.¹² We used the Most Significant Change technique (MSC)¹⁴ because the goal of cultural safety training is a behavioural change of participants rather than merely knowledge acquisition.¹⁵ MSC is a narrative-based method that allows people to report changes meaningful to them after participating in study activities.¹⁴ Our report adheres to the Standards for Reporting Qualitative Research (Additional file 1).¹⁶

Setting and participants

We conducted the RCT at *La Sabana* University in Chia, Colombia, which is located 20 minutes from Bogota, the capital of the country. *La Sabana* is a private university providing education to close to 9,000 undergraduate students, including 956 medical students and 256 medical interns.¹⁷ Our anticipated sample size was 199 students in each trial arm (n=398).¹² The inclusion criteria for the trial were giving informed consent and being a

medical intern or medical student at any level of training. We did not include trainees who did not agree to participate in the study.

Interventions

Transformative learning requires education that is participatory and interactive, through group problem-solving or communicative learning,¹⁸ all of which are present in *game jams*. Game jams are participatory events that allow attendees to create games in a time-restricted environment.¹⁹ The intervention was a game jam to create a prototype of an educational game on cultural safety. The activity included: (a) preliminary lecture on cultural safety and game design; (b) game building session where groups of participants created educational games about cultural safety; and (c) play-test session in which participants played and learned from each other's games. The lecture was based on our co-designed curriculum²⁰ and provided key elements of cultural safety, including (a) the definition of cultural safety; (b) consequences of cultural tensions in health care; (c) self-awareness; (d) Colombian cultural health practices; and (e) respect for patients who use traditional and cultural health practices.

The control group received a PowerPoint-based standard lecture on cultural safety plus an interactive workshop over several hours in which groups of participants created infographics to communicate selected readings on cultural safety. The control group received the same key concepts of cultural safety as the intervention group. The duration of both the intervention and control group activities was the same (eight hours). A detailed description of these activities is available.¹²

Data collection

For the narrative assessment, we used a pre-defined format in Google forms and asked participants to write and upload their stories of change. We used three questions: (*a*) what do you believe was the most significant change in your clinical practice as a result of your participation in the activity [game jam or standard lesson] 6 months ago? (*b*) can you please share a real-life story depicting this change? (*c*) why do you think this story is significant? We submitted an email with the link to the online form and collected the narratives of change

in both the intervention and control groups six months after the intervention, from January to May of 2020.

The instructions made clear that participants were free to write stories of negative changes or to say that they did not experience any change at all, and stressed that the stories would not have any influence in the evaluation of their performance in the faculty of medicine. The format was completely anonymous; it did not collect any personal information from the participants. We invited only medical students involved in supervised clinical practice and medical interns (third to seventh year of medical school) to participate in this part of the RCT (n=412).

Data processing and analysis

We used AtlasTi 8 to support our analysis of the stories. Two researchers (JP and PL) individually coded the transcripts of the anonymized stories following a deductive thematic analysis approach. They later compared their analysis and, by consensus, decided on themes and subthemes. In deductive analysis, a theory aligned with the researchers' interest drives the data analysis;²¹ we used the intermediate outcomes of the CASCADA model²² to identify themes of change in the stories. The model includes the elements of a modified theory of planned behaviour:^{23,24} Conscious knowledge, Attitudes, Subjective norms, Intention to Change, Agency, Discussion, and Action or behaviour change. The two researchers held ten two-hour meetings to carry out the qualitative analysis.

Rigour

We adhered to the strategies for ensuring trustworthiness in qualitative research suggested by Patton²⁵ and Shenton.²⁶ We increased credibility by using validated research methods to collect (MSC) and standard deductive thematic analysis to process the data. We enhanced dependability by adhering to the Standards for Reporting Qualitative Research and by publishing the protocol of our study in advance,¹² which will allow researchers to replicate the study in the future. We increased confirmability by disclosing the background of the researchers directly involved in the data analysis, as well as by recognizing the limitations of the study. JP, an MD with an MSc in Epidemiology and a Doctoral Candidate in Family Medicine, guided PL during the analysis phase. PL was a fourth-year medical
student with no previous experience in qualitative research or cultural safety when this article was written. Before the analysis, JP provided PL a two-day training on qualitative research and thematic analysis.

Ethical approval

The Institutional Review Board of the McGill's Faculty of Medicine (approval number A05-B37-17B) and the Sub-committee for Research of the Faculty of Medicine at *La Sabana* University (approval number 445) provided ethical clearance for this study. All participants signed informed consent before proceeding with any research activity.

RESULTS

A description of the sociodemographic characteristics of the RCT participants is available. For the qualitative assessment, we received 27 stories of change from the 412 invited participants. A deductive thematic analysis identified themes aligned with the seven elements of the CASCADA model and 15 subthemes (Table 9.3.1 and Additional file 2).

Theme	Subtheme
C onscious knowledge	 Benefits of cultural safety training and consequences of culturally unsafe practices Acknowledging cultural diversity and traditional medicine use among family, setting, and students Characteristics of traditional medicine and confusion of concepts
Attitudes	 Respect and appreciation for cultural diversity, and avoidance of cultural destruction and ethnocentrism Openness Self-awareness, cultural awareness, and awareness of benefits
S ubjective norms	 Positive perception of traditional medicine, respect for patients, and avoidance of culturally unsafe behaviours Biomedical model and evidence-based medicine Acknowledge benefits of cultural safety and less ethnocentrism
C hange intention	No subthemes
Agency	 Able to accept cultural diversity in health care Able to prevent culturally unsafe actions and improve the doctor-patient relationship
Discussion	No subthemes
Action	 Better communication and relationship with patients and with other health professionals Better outcomes for patients, physicians, and society Dialogue and integration/balance/consensus between traditional medicine and modern medicine Explore and investigate traditional medicine, and listen and learn from patients

Table 9.3.1 Themes and subthemes of the deductive thematic analysis

Conscious knowledge

Study participants told stories about learning the benefits of cultural safety training, such as increasing adherence of patients to treatment, generating a positive environment for health care, acquiring new knowledge and skills, and improving the doctor-patient relationship: "[cultural safety] helps to reach consensus between patients and me, it makes patients feel involved in their treatment without feeling diminished, therefore strengthening their adherence to medical treatment." (Participant 7)

"Taking the time to investigate the traditional practices of patients allows you to gain important knowledge and to develop a better relationship with patients." (Participant 16)

Learned consequences of culturally unsafe behaviour included discriminating against or diminishing someone for their beliefs, assaulting the patient identity and culture, and barriers to approaching patients:

"Diminishing or discriminating against someone for their beliefs or for using traditional medicine is like attacking that person's identity and culture." (Participant 4)

Participants learned to recognize cultural diversity and the use of cultural practices in their setting, family, and even in themselves. They acknowledged traditional health practices as part of their cultural identity:

"In the lecture, we learned about remote tribes and communities, but I don't have to go that far to experience what I learned from the talk. Not only does my dad use traditional medicine, but most of my family, even me. For example, I drink a cinnamon infusion when I have a colic." (Participant 19)

Participants learned to differentiate between traditional health practices and alternative medicine, although the confusion remained for some students:

"I can now differentiate the concept of alternative medicine from that of traditional medicine. I understood that traditional medicine has a way of being and that it is part of someone else's culture." (Participant 4)

Attitudes

This included respect and appreciation for cultural diversity and for their own culture:

"The most important thing is to recognize and respect cultural differences and protect them. Above all, preserve cultural practices and transmit them on from generation to generation, as this is part of the history of our region." (Participant 25) Participants described an attitude of openness to recognize and accept the cultural differences that patients may have, thus preventing judgements and fostering learning from patients:

"[Cultural safety] training allows me to have an open mind to the beliefs and cultural practices that patients have; [It allows me to] take these aspects into account to prevent judgments and even to learn from them, from their experience" (Participant 7)

Participants reported awareness of their culture and biases, and acknowledged the ways their culture shapes clinical practice, often imposing their point of view:

"Now I understand that all of us, including the patients, grow with different customs, needs, and beliefs, and that all of us belong to a culture and therefore to a different way of seeing diseases and their treatment" (Participant 21)

Subjective norms

Study participants reported a shift to a positive perception of traditional medicine, respect for patients, and willingness to address intercultural tensions:

"Now I see the impact that cultural practices have on patients' perception of health. I consider what people say about their beliefs, before I didn't even pay attention to it" (Participant 9)

"[Cultural safety] taught me that we should not belittle traditional medicine or believe that Western medicine is the truth and the solution to everything." (Participant 23)

Study participants acknowledged the impact that cultural practices have on patients' perception of health and reported less ethnocentrism:

"Because when we find a patient who has a culture with different beliefs from ours, we tend to ignore them; we believe that our culture is correct and that we are right, but [cultural safety training] makes us wonder if it is really like that."

They reported that while intercultural tensions were unpleasant before, they now see these tensions as opportunities to learn from the patient to provide better care:

"Before it was an unpleasant experience. There were many occasions in which the grandmothers talked about home remedies whose names were difficult for me to understand (I am not from this

region); I doubted their effectiveness. Today, those experiences are not unpleasant anymore. I can now learn from the context of my patient, therefore providing better healthcare. " (Participant 17)

Change intention

A study participant reported that cultural safety is what they want to do in their professional practice:

"I feel that this is what I want to do in my professional practice, to be able to help my patients, understand that traditional medicine is not wrong, and that [cultural safety] can enhance the doctorpatient relationship." (Participant 5)

Agency

Some study participants feel that they can now accept cultural diversity in clinical practice and prevent culturally unsafe actions to improve the doctor-patient relationship.

"I am able to accept that there are diversity of beliefs and that each one has its cultural and scientific basis. It is a great contribution to our clinical practice." (Participant 26)

"I am able to improve the doctor-patient relationship. I can now create a relationship with patients from different cultures without imposing my thoughts, making judgments, or demeaning my patients and their families." (Participant 7)

Discussion

Participants discussed traditional and modern practices with patients, facilitating a space where both parties shared knowledge to inform decision-making. Additionally, they discussed the experience with nursing students who supported the cultural safety approach:

"I listened to the patients more; we discussed ways to take care of children, comparing things that they believed and had done with things that we knew from our medical knowledge; it helped to improve the connection with patients to ensure proper growth and development of babies. This was quite special because the nursing students who rotated with us also supported our approach, and we learned from each other." (Participant 1)

Action

The students reported better communication and relationship with patients and with other health professionals, and better outcomes for patients, physicians, and society. This included patients feeling more understood, safe, and cared for, and increased knowledge of health professionals.

"Things that may seem so simple, but that for someone like the patient in the story, are important things. [Cultural safety] makes people feel safer, understood, and cared for, and they feel the desire to come back to see a doctor who also cares for them; in my opinion, it touches the most human part of medical practice." (Participant 15)

"Taking the time to investigate [traditional medicine] allows me to gain important knowledge and developing a better relationship with the patient." (Participant 16)

Participants reported efforts to find a balance or consensus between modern medicine and traditional health practices, based on dialogue with patients:

"I listened to the patients more; we discussed ways to take care of children, comparing things that they believed and had done with things that we knew from our medical knowledge. " (Participant 27)

"We were able to reach a consensus in which she understood that it is okay to go to the hospital in certain situations and I did not prevent her from continuing to use her traditional practices. Moreover, I learned about a home-made way of managing acute diarrhea" (Participant 7)

Both patients and study participants were able to share and learn from each other's knowledge and practices to inform the health-decision making process. Some participants investigated traditional practices that they heard in clinical settings. This helped them to learn things that they do not learn at the faculty of medicine:

"During my gynecology and obstetrics rotation at Kennedy's Hospital, it was common in prenatal check-ups to hear from several expectant mothers, talking about the use of *brevo* [medicinal plant] leaf baths. That was totally unknown to me at the time. I knew that *brevo* was the tree where the *brevas* grow [fruits that are traditionally eaten with *dulce de leche*]. I generally told the moms that the *brevo* baths were not necessary, that they were useless. However, while I was learning about cultural safety, I asked a patient the reason for these baths, to which she replied, 'it is that they serve to be able to start contractions.' After the consultation, I investigated the remedy and found that indeed the *brevo* leaf is used to start labor. Of course, I only knew of oxytocin and misoprostol, I had never heard

of this practice, which as I read has been used since many years ago here in Colombia." (Participant 20)

"when we asked the patients about traditional remedies, many told us about how drinking *hinojo* [fennel] infusion increase milk production." (Participant 9)

DISCUSSION

Our narrative assessment identified themes aligned with all seven elements of the CASCADA partial order of intermediate outcomes in behaviour change. The stories highlighted changes in knowledge, attitudes, subjective norms, and action.

Our findings fit with a review of cultural safety training changing student knowledge, attitude, self-confidence, and behaviour when interacting with Indigenous populations.⁷ The review suggested that cultural safety training in medical education enhances respect for and acceptance of traditional and cultural health practices, it improves relationships between health professionals and patients from non-dominant cultures, and promotes healthier outcomes.⁷ Another review reported changes in knowledge, attitudes, confidence, perceptions, collaboration, empathy, communication, behaviour, and practice. ¹⁵ A recent scoping review identified culturally safe strategies to improve rural Indigenous palliative care.²⁷ The authors described involvement of patients in decision making, self-reflection of care providers, and recognition of how culture shapes health care. A rapid review of diabetes care in Indigenous populations of Canada, Australia, New Zealand and the United States²⁸ identified positive effects of culturally safe interventions on clinical outcomes of patients, enhanced patient satisfaction and access to health care, and increased care provider confidence in providing care.

Our findings suggest that our training could encourage changes in practice of medical students and interns. While the literature reviews are entirely focused on Indigenous health, we provided evidence of the usefulness and relevance of cultural safety training among non-Indigenous populations that use traditional medicine, a widespread phenomenon in Latin American countries. Our results are relevant for medical educators interested in enhancing intercultural skills of medical trainees.

Our RCT explored the effectiveness of an innovative teaching strategy based the transformative learning approach, which uses education that is interactive, participatory, and based on challenges.²⁹ Although we provided transformative learning through our game jam, the control group also received elements of transformative learning as this was requested by the directives at *La Sabana* University. Mezirow proposed transformative learning as a way to confront ethnocentrism.¹³ Learners change beliefs about themselves, about others, and about practices, to make them more inclusive, open, and emotionally able to behavioural change.³⁰ Health-related students involved in transformative learning reported more confidence in caring for patients from non-dominant cultures.³¹⁻³³ Similarly, a recent game jam promoted self-discovery, reflections on identity, and support of the cultural identity of the Sami people in Finland.³⁴ Our results support the effectiveness of transformative learning for cultural safety training.

The reported areas of change in the stories reflected the content of our co-designed curriculum²⁰ and included acknowledging culturally unsafe actions and their consequences, examining the students' own attitudes, beliefs, and values, and how they shape their professional practice, willingness to listen and learn from their patients about traditional practices, and skills to discuss with patients to reach an agreement on their treatment, thus improving the doctor-patient relationship. Our results provide some evidence that cultural safety training based on our co-designed curriculum may promote positive outcomes for both health professionals and patients.

We previously reported a positive perception of traditional and cultural health practices among Colombian medical students who participated in a five-month communitybased cultural safety training program.^{10,11} The present study had a very substantial nonresponse rate, suggests positive outcomes for medical trainees after a much briefer (8 hours) intervention. With the content overload in contemporary medical training and little time to include new subjects, our findings will be relevant to medical educators interested in cultural safety training.

Limitations

A common limitation of medical education research based on self-reported data is social desirability bias,³⁵ where participants feel pressured to report what they think the researcher wants to hear. We minimized this bias by collecting anonymous data, making clear for the participants that their stories would not have any influence on their academic performance, and by suggesting that stories of negative changes or no change at all were also welcomed. There are reports of reduced desirability bias in web-based surveys, which we used in our study.³⁶ Despite this, we are cautious in interpreting our results. Only a self-selected minority of the students submitted a story, so this report emphasises stories from students interested in cultural safety.

To enhance trustworthiness of the data, the MSC stories were completely anonymized and we did not collect any additional information other than the responses to the MSC questions. A drawback of this approach, however, was that we did not know if the students who reported their stories participated in the intervention or control groups. Additionally, we did not know the sociodemographic characteristics of the small subsample who completed the stories of change. Future research could compare changes reported by, for example, younger students with changes experienced by senior students.

We described only an indirect assessment of the change self-reported by the participants in their clinical practice. Future cultural safety research should use more objective measures, like direct observation of trainees in clinical settings. Additionally, future studies should use patient-related outcomes, ideally measured on or reported directly by patients.

CONCLUSION

The stories of change provided insights into the likely nature of impact of cultural safety education on a range of outcomes from conscious knowledge to action after an eight-hour transformative learning training session. Our results support the idea that cultural safety training based on our co-designed curriculum can produce positive outcomes for both health professionals and patients. We encourage Latin American medical educators to conduct and report other cultural safety training experiences, ideally using patient-related outcomes or direct observation of medical trainees in clinical practice. **Acknowledgements:** Cassandra Laurie proofread the final version of the manuscript and supported its write-up.

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CHAPTER 10 DISCUSSION AND CONCLUSION

My experience using mixed-methods participatory research for cultural safety training via transformative learning makes several original contributions. Manuscript 1¹¹⁷ was the first review using systematic methods to map the evidence of game-based learning interventions for cross-cultural care education. Manuscripts 2¹¹⁸ and 3¹¹⁹ were the first experiences applying the cultural safety approach with the participation of *mestizo* traditional medicine users, and the first reported experiences of cultural safety training in Colombia. The five-month community-based transformative learning interventions confirmed a positive perception of traditional medicine among medical students.^{118,119} Using a rigorous research approach, manuscripts 4¹²⁰ and 5 applied the active participation⁴ principle of cultural safety, which requires engaging knowledge users in codesigning culturally safe interventions.

I sought a means of supporting transformative learning using a less time-consuming modality than the community-based experiences, to allow the training to fit into the standard medical curriculum. My pilot randomised controlled trial confirmed the feasibility and acceptability of game jam learning for cultural safety training (manuscript 6). Manuscripts 7 to 9 describe the first randomised controlled trial investigating cultural safety training in medical education, and the first study exploring the role of game jam learning in medical education.

I provided qualitative and quantitative evidence that cultural safety education promotes changes in knowledge, attitudes, self-confidence, and behavior of Colombian medical students and interns, whether the education is over five months (manuscripts 2 and 3), or over eight hours (manuscripts 8 and 9). Despite the reported benefits of cultural safety, the field of cultural safety still faces a fundamental challenge. There are no agreed methodological frameworks or consensus regarding cultural safety practice, which has historically led to difficulties in their implementation and assessment.^{32,121,122} I do not pretend to provide a fixed framework or set of instructions for how to conduct cultural safety training initiatives, but my experience and lessons learned in this thesis may offer some insights useful for future cultural safety training initiatives around the world. The

following section summarizes the key lessons learned, framed as 12 practical tips, as a step towards a practice-based framework for cultural safety training of undergraduate medical students.

10.1 RECOMMENDATIONS

1. Define the interacting cultural groups

My starting point of view in cultural safety was biculturalism.⁵¹ This relates to interactions between two groups: the colonizer and the colonized. Without diminishing the plurality within each group or the validity of experience of other groups, like immigrants, I found it useful to juxtapose two worldviews as these interact in health care services. Cultural safety juxtaposition goes beyond race- or ethnic-based differences to include gender, age, socioeconomic level, religious or spiritual beliefs, disability, and traditional practices.^{48,123} Blanchet and colleagues, for example, reported their experience exploring cultural safety with Amish and Low German Mennonites.¹²⁴ I juxtaposed Colombian medical students and traditional medicine users, initially from Cota, a small municipality 15 km from Bogota that has gone through rapid urbanization and cultural change.⁹² A few decades ago, inhabitants of Cota were mainly subsistence farmers with Indigenous and European traditions. One cultural change was the abandonment of traditional medicine practices and resources that the community had relied on for centuries. Recently, a series of initiatives set out to recover local traditional knowledge and practices,¹²⁵ and my community-based cultural safety experiences (manuscripts 2 and 3) were an opportunity to support this process. In the pilot RCT (manuscript 6), I juxtaposed medical students and traditional medicine users more generally.

2. Differentiate from cultural competence

Researchers and educators sometimes conflate cultural competence and cultural safety.^{32,121} Cultural competence is the better known approach to cultural diversity in health care.³² Researchers from the US developed this in response to increasing health disparities between the Caucasian population and racial minorities.⁵ Most interventions

based on cultural competence are top-down. A common cultural competence approach, 'ethnic matching,' seeks to pair physicians and patients by race, for example, a Black patient with a Black practitioner. Other examples of cultural competence include the 'Do's and don'ts' lists to care for specific cultural groups of patients³⁵ and the use of translators in health encounters.³⁰ In contrast, Māori Indigenous people proposed the cultural safety approach as their response to the increasing discontent with the imposition of Western worldviews in health services.³⁰ Safety is defined by knowledge-users, thus requiring participatory methodologies to co-design initiatives.⁴ Cultural competence sees culture as a way to reach people from non-dominant cultures and cultural safety sees culture as an asset to solve health problems. Criticisms of cultural competence include its utilitarian and superficial understanding of culture,⁴⁴ while cultural safety gets criticized for lacking quantitative evidence.³² And while the first step in cultural competence is learning about the other culture, cultural safety promotes self-reflection to confront ethnocentrism.¹²⁶ Finally, cultural safety recognizes the colonial, historical, and sociopolitical context in which health disparities are produced and perpetuated,¹²¹ a viewpoint that is neither necessary nor common in cultural competence initiatives. Keeping these distinctions between cultural competence and cultural safety in mind helped me to design communitybased cultural safety training (manuscripts 2 and 3), and to co-create a curriculum for cultural safety training of Colombian medical students (manuscripts 4 and 5).

3. Ensure co-design with those affected by culturally unsafe actions

Cultural safety is highly contextual and specific to a given interface in health care. Blanchet & Pepin⁴ and other scholars¹²¹ have called for engaging knowledge-users in co-creating culturally safe interventions. This involves several steps, including defining or naming culturally unsafe actions, and contributing to development and evaluation of the interventions. I found participatory research philosophy and methods key to co-creating cultural safety training interventions.² Manuscripts 4 and 5 implemented a sequential consensual qualitative study but alternative research approaches, such as fuzzy cognitive mapping,¹²⁷ are valuable tools as well. Stakeholder groups contextualising cultural safety in our context included traditional medicine users, cultural safety experts, faculty and the

trainees themselves. My co-creation of the five-step curriculum of cultural safety training (manuscript 5) drew in all these groups, leveraging prior working relationships.

4. Adjust to the time constraints within medical education

Contemporary medical curricula everywhere are already overloaded, with little space to introduce new subjects. I initially explored community-based learning,^{118,128} a five-month program (manuscripts 2 and 3), and then moved on to game jam learning and a standard lecture with an interactive workshop (manuscripts 8 and 9) (each of which took only eight hours.)¹²⁹ A key part of the adjustment was the qualitative evidence regarding community-based learning, and mixed-methods evidence regarding game jam learning. Future research might need to examine the effectiveness of still shorter training sessions, to ensure at least some effective coverage of cultural safety in a packed undergraduate medical curriculum.

5. Pilot for acceptability and feasibility

Cultural safety depends on the interacting cultural groups, the type of learners (medical students, nursing students, physical therapy students, social service students, decision-makers, graduate students, or established researchers) and the nature of the community (Indigenous groups, Black patients, traditional medicine users, Amish or Mennonites, among others). I piloted my particular brand of transformative learning to consider its feasibility and acceptability to Colombian medical students and faculty (manuscripts 2 and 3).^{118,128} My pilot RCT (manuscript 6) explored this counterfactual format for assessing game jam learning in cultural safety training. These small-scale experiences allowed me to test research methods and procedures, gain research experience, identify potential logistical factors, and gain visibility and support.^{112,114}

6. Search for transformative learning experiences

My application of transformative collaborative learning³ supported medical students' rewiring of their frames of reference (manuscripts 2, 3, 8, and 9). Additional learning theories such as critical systems thinking¹³⁰ and constructivism¹³¹ also informed my work, although the central thrust was to put learners together to reflect on each other's assumptions, and to build on common ground. This seems to have been effective through both community-based learning (manuscripts 2 and 3) and game jam learning

(manuscripts 8 and 9). The strong focus on transformative learning in both the intervention and control groups in the RCT probably also limited the impact it demonstrated for game jam learning (manuscripts 7 to 9). The quantitative evaluation showed that both the game jam and the "control" interactive workshop probably achieved a degree of transformative learning, decreasing the impact signal of the game jam (manuscript 8). Instructors in both intervention and control groups had strong intercultural health care backgrounds. They probably portrayed positive role models in both groups. My constructivist¹³¹ framework allowed students with prior knowledge to assimilate new information. It also fostered communicative learning, which is a key element of transformative learning³ and critical systems thinking.¹³⁰

7. Adapt to learners and their opportunities

Medical students are practical learners. They like to see the utility of what they learn. My co-designed curriculum (manuscripts 4 and 5)¹²⁰ started by surfacing the issue of culturally unsafe actions, defined as "any actions which diminish, demean or disempower the cultural identity and wellbeing of an individual."¹³² The students acknowledged the issue, which logically led them to wonder how to prevent or address culturally unsafe actions. I also found that medical students feel comfortable with a rigorous approach to learning (manuscript 2),¹¹⁸ in many cases using practical schemes or flow diagrams. My co-designed curriculum (manuscript 5) provided an easy-to-follow five-step curriculum of cultural safety training. I also used real-life stories and prior experiences of trainees, for example, related to culturally unsafe actions in clinical practice, to enhance the learning experience of medical students.

8. Measure the impact and understand limitations of the measurement

A common criticism of cultural safety training is the lack of evidence, especially from quantitative studies, of its impact on behaviour.³² I conducted the first randomised controlled trial of cultural safety training in medical education (manuscript 7),¹²⁹ and found that game jam learning improved cultural safety intentions of Colombian medical students to a similar degree as did a carefully designed lecture and workshop (manuscript 8). My first lesson here came from the fact that both the game jam and the reference intervention

– it could not really be called a control group as it was not the standard lesson – had similar impacts. Using a standard lesson as the control would probably have provided different information on impact. Another issue was the baseline status of the two groups of medical students. Before initiating the project, I understood that 40% of Colombians seek care in traditional medicine.²⁰ In my subpopulation, however, it turned out that 70-80% of the students were exposed to traditional medicine through their families (manuscript 8).
Participating medical students reported their high level of familiarity with local practices helped their engagement in cultural safety education. This left only a small segment of the population "available" for transformation.¹¹⁸ It is useful to complement the quantitative measurement of impact with a qualitative evaluation. I provided qualitative evidence of a positive shift in the perception of medical students regarding traditional medicine after cultural safety training (manuscript 9).^{118,119}

9. Use patient-related outcomes

Ideally, I would like to see the impact of cultural safety training on patient-oriented outcomes assessed in a trial of an educative intervention to increase the cultural responsiveness of health professionals.³¹ Patient-related outcomes include perceptions of care received, health outcomes, and health behaviors. Medical students while studying do not really affect patient outcomes, so one must wait several years to see the impact of a student training intervention on patient outcomes. Given the time available for my initiative and the complexity of assessing patient-related outcomes in medical student education, I used as indicators of patient-related outcomes the intermediate outcomes in the CASCADA results chain (manuscript 8).¹⁰² Narrative evaluation allowed an indirect exploration of the impact of the intervention in the supervised clinical practice of medical students and interns (manuscript 9). Based on the Most Significant Change technique,¹³³ my assessment showed a positive impact of cultural safety training in the behavior of trainees and, potentially, on patient perceptions of care.

10. Surface the hidden curriculum

Some medical students who participated in my project commented on the negative influence of role models who demonstrate, perhaps unwittingly, culturally unsafe attitudes

and actions (manuscript 5). These hidden aspects of the standard curriculum have an important and seldom acknowledged role in the education of medical students and what it means to become "a professional". It instills in students the values, norms, and behaviors of their instructors:¹³⁴ medical students learn through imitation. My experience confirmed a pressing need to extend cultural safety training to faculty members and established health professionals to address the negative influence of the hidden curriculum on the progress of learners.

11. A two-way compromise

Culturally unsafe actions could stem from the patients or communities towards health professionals as well. There are examples of racism on the part of patients against health professionals of Black,¹³⁵ Indian,¹³⁶ and Muslim¹³⁷ origins. My approach to cultural safety supports the idea of ongoing dialogue between patients and medical students, with both parties sharing their knowledge and experiences. Qualitative evidence from my community-based studies (manuscripts 2 and 3) and from the qualitative evaluation of the RCT (manuscript 9) showed students were indeed able to foster dialogue with their patients; both parties shared their knowledge and were able to find common ground based on respect.

12. An incremental and iterative process

My experience convinced me that cultural safety training of medical students is not a single shot exercise. In my project, medical students and interns unlocked skills that allowed them to acquire new knowledge from their patients – for example, the use of *hinojo* (fennel) infusion to promote breastfeeding and the use of *brevo* leaves (medicinal plant) for promoting birth (manuscript 9). An increasing curiosity and respect for traditional practices improved the relationship between students and community (manuscripts 2, 3 and 9). If they remain open to learning from their patients, each new clinical encounter will bring new knowledge and experiences for the students and later doctors. Cultural safety training is, therefore, only a component of an overall effort that requires changes from the medical students, their patients and communities, and the health systems. Researchers,

educators, and practitioners should review and adjust cultural safety initiatives based on their ongoing professional practice.

10.2 LIMITATIONS

Generalizability of findings

My mixed-methods approach generated multi-faceted evidence on the impact of cultural safety training in Colombian medical education. It also yielded several practical lessons in cultural safety training of undergraduate medical students. The results and recommendations might not be immediately relevant to all faculties of medicine, given the variations in the local cultural profile, time, and other resources. Not all countries have significant proportions of Indigenous peoples or traditional medicine users. The approach might well be relevant, however, for countries with marginalised minorities and immigrants.

Superiority and non-inferiority trials

My full scale RCT failed to show a statistically significant difference in the primary outcome between the intervention and control groups. Since I designed my RCT as a superiority trial, I did not conduct a post-hoc non-inferiority analysis, mostly because the noninferiority margin (or delta) was not specified in the protocol.¹³⁸ There are additional design issues that make superiority and noninferiority trials different, such as the sample size.¹³⁹ Future RCTs exploring transformative learning for cultural safety training (or related approaches) could either follow a non-inferiority approach, or ensure that the control group receives an intervention without strong elements of transformative learning.

Patient-reported outcomes

Trialists have called for research based on patient-reported outcomes to maximise the utility of RCT data for patients and society.¹⁴⁰ A limitation of my RCT was that I did not include patient-reported outcomes. Assessing patient-reported outcomes would have required a longer and more complex study, beyond my logistical and economic capacity. In the field of empathy research, however, some authors have reported a correlation between

physician self-reported outcomes and patient reported outcomes.¹⁴¹ My results are encouraging in light of these findings and support the need to use patient-reported outcomes in future cultural safety training trials.

Randomised controlled trials in medical education

There is still controversy surrounding the implementation of quantitative research in medical education. Some have argued that qualitative methods and observational studies should supplant RCTs and meta-analysis in medical education.¹⁴² Concerns include blinding (it is often impossible to blind both teacher and students), performance bias (the behavior of the teacher applying a novel technique may be different than a colleague giving the routine class),¹⁴³ the Hawthorne effect¹⁴⁴ (students pay more attention because they know they are taking part in a study), and social desirability bias¹⁴⁵ (students may report what is socially acceptable). Although I conducted a rigorous RCT and tried to guard against these biases, I cannot be sure that I excluded them entirely.

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APPENDIX

MANUSCRIPT 1

Appendix 1. Databases and Search Terms Used

Database	MESH/search terms
Pubmed	("Cultural Competency"[Mesh] OR "Cross-Cultural Comparison"[Mesh] OR "Culturally Competent Care"[Mesh] OR "Transcultural Nursing"[Mesh] OR "Ethnopsychology"[Mesh] OR "Cultural Competenc*"[Text Word] OR "Cultural Safety"[Text Word] OR "Culturally Safe Care"[Text Word] "Culturally unsafe"[Text Word] OR "Cultural Awareness"[Text Word] OR "Cultural sensitivity"[Text Word] OR "Cultural humility"[Text Word] OR "Cultural risk"[Text Word] OR "Cultural Awareness"[Text Word] OR "Cultural sensitivity"[Text Word] OR "Cultural humility"[Text Word] OR "Cultural risk"[Text Word] OR "Cultural Awareness"[Text Word] OR "Cross-Cultural Care"[Text Word] OR "Culturally Competent Health Care"[Text Word] OR "Cultural Care"[Text Word] OR "Cultural training"[Text Word] OR "Culture"[ti] OR "Cultural"[ti] OR "Transcultural Psychology"[Text Word] OR "Transcultural Psychiatry"[Text Word] OR "Ethnopsychiatry"[Text Word] OR "Cultural Psychiatry"[Text Word] OR "Cross-Cultural Medicine"[Text Word] OR "Intercultural dialogue"[Text Word] OR "Patient-Centered Care"[Mesh] OR "Community Participation"[Mesh] "Patient Participation"[Mesh] OR "Patient- Centered Nursing"[Text Word] OR "Patient Activation"[Text Word] OR "Medical Home*"[Text Word] OR "Patient Empowerment"[Text Word] "Patient Involvement"[Text Word] OR "Patient Activation"[Text Word] OR "Patient Participation Rate*"[Text Word] OR "Patient Engagement"[Text Word] OR "Patient centred"[Text Word] OR "Patient Participation Rate*"[Text Word] OR "Patient Experimental"[Mesh] OR "Play and Playthings"[Mesh] OR game*[Text Word] OR gaming[Text Word] Games, Experimental"[Mesh] OR "Play and Playthings"[Mesh] OR game*[Text Word] OR gaming[Text Word] OR "Games, Experimental"[Mesh] OR "Play and Playthings"[Mesh] OR game*[Text Word] OR gaming[Text Word] Gamification[Text Word] OR gamificing[Text Word] OR "Patient Word] OR game*[Text Word] OR gamification[Text Word] OR gamif
Embase (OVID)	("exp cultural competence/" OR "Cross-Cultural Comparison.mp." OR "Culturally Competent Care.mp." OR "Transcultural Nursing.mp." OR "Ethnopsychology.mp." OR "Cultural Competenc*.mp." OR "cultural safety/" OR "Culturally Safe Care.mp." OR "Culturally congruent Care.mp" OR "Cultural Awareness.mp." OR "cultural sensitivity/" OR "Cultural humility.mp." OR "Cultural risk.mp." OR "Culturally Congruent Care.mp" OR "Cross-Cultural Care.mp." OR "Culturally Competent Health Care.mp." OR "Cultural Care.mp." OR "Cultural training.mp." OR "Cultural Psychology.mp." OR "Cultural Psychiatry.mp." OR "Ethnopsychiatry.mp." OR "exp cultural psychiatry/" OR "Cross-Cultural Medicine.mp." OR "Intercultural dialogue.mp." "exp cultural diversity/" OR "exp cultural factor/" OR "exp transcultural care/" OR "exp cultural psychology/" OR "exp cultural diversity/" OR "exp cultural factor/" OR "exp transcultural care/" OR "exp cultural nursing/" OR "exp cultural psychology/" OR "exp patient participation/" OR "Patient-Centered Nursing.mp." OR "Patient-Centered Care.mp." OR "Patient Empowerment.mp." OR "Patient Involvement.mp." OR "Patient Activation.mp." OR "Patient Participation ARate*.mp." OR "Patient Engagement.mp." OR "Patient centred.mp." OR "exp patient advocacy/") AND ("exp video game/" OR "Games, Recreational.mp." OR "gamified.mp." OR "exp recreational game/" OR "exp game/" OR "exp recreational game/" OR "exp game/" OR "exp recreational game/" OR "exp game/" OR "exp game/" OR "exp recreational game/")

PsycINFO (OVID)	(cultural competence.mp. OR Cross-Cultural Comparison.mp. OR Culturally Competent Care.mp. OR Transcultural Nursing.mp. OR Ethnopsychology.mp. OR Cultural Competenc*.mp. OR cultural safety.mp. OR Culturally Safe Care.mp. OR Culturally unsafe.mp. OR cultural awareness.mp. OR exp Cultural Sensitivity/ OR Cultural humility.mp. OR cultural risk.mp. OR Culturally Congruent Care.mp OR exp Cross Cultural Treatment/ OR Culturally Competent Health Care.mp. OR Cultural Care.mp. OR Cultural training.mp. OR culture.ti. OR cultural.ti. OR transcultural psychology.mp. OR exp Transcultural Psychiatry/ OR Ethnopsychiatry.mp. OR cultural psychiatry.mp. OR Cross-Cultural Medicine.mp. OR Intercultural Medicine.mp. OR Intercultural dialogue.mp. OR cultural diversity.mp. OR exp Cross Cultural Differences/ OR exp Cross Cultural Differences/ OR Multiculturalism/ OR exp Cross Cultural Communication/ OR exp "Racial and Ethnic Differences"/ OR exp Cross Cultural Psychology OR Patient-Centered Care.mp. OR exp Client Participation/ OR Patient-Centered Nursing.mp. OR exp Client Centered Therapy/) AND ("video game.mp." OR game.mp. OR exp GAMES/ OR gaming.mp. OR gamification.mp. OR gamifying.mp. OR gamified.mp. OR play.mp. OR exp SIMULATION GAMES/ OR exp COMPUTER GAMES/)
Eric (EBSCO)	(Culturally Relevant Education OR Cultural Awareness OR Cultural Background OR Cultural Differences OR Cultural Education OR Cross Cultural Training OR Multicultural Education OR cultural competenc* OR cultural diversity OR cultural sensitivity OR culturally competent OR culturally sensitive OR culturally responsive OR intercultural OR cross cultural OR transcultural OR cultural safety OR patient engagement OR patient centered OR patient participation OR patient OR involvement OR patient focused OR patient empowerment OR patient activation OR patient centred) AND (Game* OR Game Theory OR gamification OR gamifying OR gamified OR play OR playing OR videogames) AND (Medical Education OR Medical Schools OR Medical Students OR Health Sciences OR Health Personnel OR Nursing Education OR Nursing Students OR Psychology OR Health Occupations OR Social Work OR Occupational Therapy OR Physical Therapy OR Medicine)
Lilacs	("Competencia Cultural" OR "Comparación Transcultural" OR "Asistencia Sanitaria Culturalmente Competente" OR "Enfermería Transcultural" OR Etnopsicología OR "seguridad cultural" OR "Asistencia Sanitaria Culturalmente Segura" OR Aculturación OR "Conciencia Cultural" OR "Sensibilidad Cultural" OR "Humildad cultural" OR "Riesgo Cultural" OR "Asistencia Sanitaria Culturalmente Congruente" OR "Asistencia Sanitaria Transcultural" OR "Entrenamiento Cultural" OR "Psicología Transcultural" OR "Psiquiatría Transcultural" OR "Etnopsiquiatría" OR "Psiquiatría Cultural" OR "Medicina Transcultural" OR "Medicina intercultural" OR "Diálogo Intercultural" OR "Atención Dirigida al Paciente" OR "Participación de la Comunidad" OR "Participación del Paciente") AND ("Juegos de Video" OR "Juegos Recreacionales" OR "Juegos Experimentales" OR "Juego e Implementos de Juego" OR Juego OR juegos OR Gamificación OR Gamificando OR Gamificado)
Google Scholar	("Cultural Competence" OR "Cultural Competency" OR "Cultural Safety") AND ("Video Games" OR "Game-based learning" OR Gaming OR Gamification OR Gamified OR Gamifying) AND "medical education"
Appendix 2. Publications included in this scoping review

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MANUSCRIPT 5

Appendix 1. Standards for Reporting Qualitative Research (SRQR)^a

No.	Торіс	Item	Page	
	Title and abstract			
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1	
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	2	
		Introduction		
S 3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	3 to 5	
S4	Purpose or research question	Purpose of the study and specific objectives or questions	5	
		Methods	-	
\$5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale ^b	Research design - 5 and 6	
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Rigour - 9	
S 7	Context	Setting/site and salient contextual factors; rationale ^b	Participants and setting - 6	
S 8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale ^b	Participants and setting - 6	
S 9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Ethical approval - 9	
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale ^b	Methods for collecting and analyzing data – 6 to 8	
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Methods for collecting and	

			analyzing data – 6 to 8
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Results – Table 1
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Methods for collecting and analyzing data – 6 to 8
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale ^b	Methods for collecting and analyzing data – 6 to 8
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale ^b	Rigour - 8
		Results/findings	
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Results - 9 to 23
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Appendix
		Discussion	
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/ generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Discussion 23 to 30
S19	Limitations	Trustworthiness and limitations of findings	Limitations - 31
		Other	-
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	Conflicts of interest - 32
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	Funding - 32

^a The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

^b The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Appendix 2. Traditional medicine users themes and subthemes

1. Traditional self-care

1.1. What is self-care

<u>Traditions -</u> "It is the traditions that we have. It involves me becoming aware that I am responsible for my own health. It is not waiting to be sick to go to see the doctor, but becoming aware that I should take care of myself to prevent disease."

<u>Complex</u> - "It involves environmental aspects, social aspects, emotional aspects, spiritual aspects... that is self-care. It does not involve only the physical part, how my organs are, but something more complex."

1.2. Women's health

Moments - "It involves taking care of menstruation, pregnancy, puerperium, and menopause."

Menstruation care - "menstruation care involves three days of care. It involves avoiding getting wet, getting cold, dairy, walking bare feet, acidic fruits, cold food and drinks, and exercise"

Hot plants - "there are specific plants that can help... hot plants like *gearanio aromático*, cinnamon, *altamisa*, among others. There is a remedy that you can prepare with *aguardiente* and hot plants."

1.3. Common cold

Care - "it involves five days. But you have to do it for five days, it is very important. You have to avoid getting cold or wet, cold drinks and food, the sereno."

<u>Remedies</u> - "you have to drink hot plant infusions, for example, *sauco* and *poleo*. There are remedies for each symptom. For example, nasal congestion, cough, stomach pain, among others."

<u>Avoid stopping -</u> "avoiding stopping the process is a key element. Because if you stop the process, the next cold will be harder. It has an influence on other respiratory illnesses".

1.4. Fever

Beneficial - "it is important to see the fever as a friend, fever is beneficial. But people generally attack the fever."

<u>Bitter plants -</u> "you can manage the fever with plants, especially bitter plants like *verbena* and *sauco* leaves. You can wet a small towel with *sauco* infusion and rub your child. When the children grow up, they can drink *verbena* juice every 15 minutes, or each half an hour, that way you can keep the temperature of the child low, but it does not stop the fever, as drugs do."

1.5. Digestive

<u>Not complicated</u> - "you have to be sure that it is not complicated diarrhea, that is not a bacterium nor that it does not last more than three days for example. When it is not complicated you can use plants, for example, the *yervabuena*. You can prepare a remedy to rehydrate yourself."

Rehydration - "the rehydration remedy is comprised of water, salt, sugar, toasted rice, cinnamon, and other plants."

Orange juice - "We usually have orange juice on an empty stomach. You can also have pineapple, papaya, or carrot juice."

Bitter infusion - "We usually have an infusion of a bitter plant, for example, verbena or ajenjo, once a week on an empty stomach."

1.6. Nutrition

Local - "Healthy nutrition based on our own food is important, based on what our soil produces, not based on industry."

Avoid junk food - "you have to avoid eating junk and processed food, sodas, food too sweet, fried and canned food, food with colourants or preservatives, all that."

Infusions - "and you can also keep drinking infusions of medicinal plants to keep your body fresh and clean."

1.7. Relationships

<u>Respect -</u> "Plants are living beings; my mom has plants planted at home and she loves them, they are like her pets. Sometimes she asks me to go and bring some plants and she tells us not to do it angrily, you have to sing to them while cutting them. That way you learn to respect other living beings."

Environment - "For me, health has a close relationship with the environment. We have done what we have wanted with the environment and now it is going crazy, now we have started talking about planting trees. So, it is broadening your understanding of health, to include the environment.

<u>Planting plants -</u> "medical students should take into account and value planting medicinal plants."

<u>Spiritual -</u> "self-care also involves the spiritual part, which is not usually taken into account by health providers"

1.8. Benefits

<u>Women -</u> "if you keep the womb warm, you can prevent menstrual pain, prepare your womb for future pregnancies, and also prepare your organs for menopause, to prevent harsh menopause. Also, it helps prevent myomas and cysts; it seems that it is caused by the cold that women who don't take care of their menstruation pick up along their lives".

Respiratory - "if we did this with all children, we would have fewer hospitalizations for pneumonia, bronchitis, bronchiolitis..."

<u>At home -</u> "knowing about self-care prevents people from going to see the doctor over and over again. If I know how to manage an episode of common cold at home, I know what I have to do and I can teach other people about it."

<u>Families</u> - "in our culture, women are important to maintain the health of the families. Therefore, if women take care of their health, they will be strong to help other members of the family if they are sick."

2. Traditional medicine principles

2.1. Hot and cold

Diseases & remedies - "The principal thing is the concept of hot and cold because they are the basis of many diseases. Moreover, plants play a role there, there are hot plants and cold plants."

Examples - "For example, in common cold care, you have to be careful with the cold. Another example, I was told to leave water with chopped limes outside in the *sereno*, to control the heat in my head. If I do not control that I get a migraine. Therefore, it is something fundamental."

2.2. Cultural nosology

<u>Traditional diseases -</u> "Another thing that has to be respected is when people go to see the doctor and they comment that they have diseases that... I don't know how to describe here... like traditional diseases, like *pujo, descuaje, susto*. I don't know how to describe that."

Example - "The descuaje, for example, doctors never accept when a child is descuajado. But if the child is rubbered by a bonesetter, he gets well. It does exist."

<u>Example -</u> "Or for example with the *frío de difunto*. I did not know that I was pregnant, and I went to sing in a mass at the cemetery. After that, I started feeling cold. I had to take traditional remedies for nine months so my daughter could be born well, because yes, I could feel the cold."

2.3. Bitter and sweet plants

"Medical students have to learn what bitter and sweet plants are. Therefore, if they understand this concept, they will be able to understand why it is necessary to have an infusion of a bitter plant once a week."

3. Be aware of the consequences of disrespecting traditional medicine

3.1. Patients hide information

"the problem is that a barrier is generated, or also, you don't tell the truth. You have to deceive them. Like, I am going to take the drugs, yes, but then you don't do it." 3.2. Imposition

"they (physicians) have this thought always in mind, they impose their way of thinking. It is as if an alternative doesn't exist. What they believe is correct, is what it has to be done for everybody."

3.3. Stereotypes

Third-class "they (physicians) say that medicine is a third-class thing, it just does not work'"

Poor people - "they (physicians) think that our medicine is what poor people use, because poor people do not have money to buy drugs. So that is why they use plants."

3.4. Culture loss

"(feeling rejected) ends up generating a feeling of protection. Protection for me as a person, because I don't want to clash against them. But also, protection of our medicine, because we know that it really works, but if I start talking about it with the physician, I feel like I am putting traditional medicine at stake, not the medicine itself but my confidence in it."

3.5. Adherence

<u>Option -</u> "I go to the hospital only when there is not another option, for example, to give birth".

<u>Certificate -</u> "I go to the hospital for matters related to my work. Because I need a certificate. Otherwise, I avoid going there."

3.6. Doctor-patient relationship

"I didn't go back; my experience generated a distance between doctors and patients. You lose your confidence in them."

4. Acknowledge the benefits of respecting traditional medicine users

4.1. It improves the doctor-patient relationship

"If physicians can generate a bond with traditional medicine users, they will generate confidence, reconciliation, it will make you want to go to see the doctor and not only when you are sick."

4.2. Some physicians respect traditional medicine

<u>Prudent -</u> "some doctors accept traditional medicine, but they are still just a few. Moreover, they are very careful, very prudent. I think that is because of the health system here in Colombia. They always say, you have to take the drug, and there is also this remedy you could take... they are afraid of labor repercussions."

Inherited - "I think that doctors in Colombia, after all, they do know something about traditional medicine, they have traditional knowledge inherited from their grandparents, but they do not say it."

Example - "once, I got an eye infection and the specialist suggested that I could do calendula baths, and I was like 'really'?"

5. Know why we use traditional medicine

5.1. Learning throughout experience

"I have been using traditional medicine for 20 years, and I can say that it has always helped me."

5.2. Faith

"I think that plants work because I believe in them. If I didn't believe in them, they wouldn't work. It has a relationship with faith (...) But plants are not only about faith. Even if I don't have faith in them, plants have chemical properties."

Appendix 3. Medical students themes and subthemes

1. Learning objectives

1.1. Self-reflection

<u>Biases</u> - "My daily clinical practice is a jump of faith. I base my practice on guidelines from people that I do not know, I learn those guidelines because I trust those people, I trust that they are doing things well, and they tell me that what they do works. So, I prescribe a drug to a patient, and I expect that drug to work. All my clinical practice is a jump of faith. The reality is that some of those studies are not well done. So, we have to bring all this to intercultural practice because Western medicine is an arrogant system and believes that it is always right, but in practice, it has the same problem that we impose to traditional medicine, the problem of validity."

<u>Something out there</u> "For me, one important lesson is to be self-aware that what has been taught to us is not the only thing that exists. That there is something else out there. I don't know whether it works or not, but it could work. They would feel better if they are using things from their own culture."

Intercultural setting - "(medical students) have to learn to identify an intercultural setting, and to recognize themselves as part of that environment".

1.2. Benefits of cultural safety

Benefits - "Understanding that there could be a benefit. Understand the benefits of cultural safety training."

<u>Openness</u> - "If the physician knows about traditional medicine, they will open up to dialogue, while a doctor who rejects traditional medicine will set up a barrier against the patient. It will make it harder to know some things from the patient, while in the other case both parties speak the same language".

<u>Relationship</u> - "The most important thing that a medical student must learn is that their clinical practice will be enriched with cultural safety training. If a patient who is also a traditional medicine user come to us, the relationship would be better if the doctor has knowledge of traditional medicine. If they can respect those practices and not put them aside."

1.3. Setting of practice

<u>Target population -</u> "The first thing is that medical students must learn to identify the target population of this type of training."

<u>Particular setting</u>. "If the students have the skills to recognize an intercultural setting, they can also be prepared to learn about the traditional knowledge specific to that particular setting."

1.4. Acknowledge traditional medicine

<u>Their families</u> - "to make the student able to acknowledge that traditional medicine is practiced not only by minorities, rather, even in their families, they will find traditional medicine users, and that should be preserved over time."

Roots - "First, what traditional medicine is. Also, what the roots of traditional medicine are."

<u>Different models -</u> "learning what the difference is between traditional medicine and other models, for example, alternative medicine. We believe that all the models are the same, but they do have differences."

<u>Cultural nosology</u> - "For example, if somebody tells me 'my head is hot,' 'I have *fiebre interna*', 'I am *descuajado'*, then I am prepared for people to tell me that."

<u>Tradition -</u> "Understanding where these concepts come from. When we hear those concepts we always think like, 'that person is talking nonsense". But after learning that those concepts come from an ancient cultural tradition, it changes your perception of it."

<u>Principles</u> - "I learned that the concept of cold care is essential, especially when it comes to women and their menstrual cycle. Therefore, I think it is important that students learn the principles of traditional medicine and how to recognize them."

1.5. Traditional medicine as a type of primary healthcare

Simple diseases - "The meeting point should not be very complex. It is better to have something basic, and start from there... Very simple and prevalent diseases, so people could manage them at home."

<u>Prevention -</u> "I believe that traditional medicine is focused on prevention. Our Western biomedical model is different because it is, sadly, a model based on diagnosis and treatment, and that mindset shapes our education."

Safety - "There is a fundamental issue: safety. It is important to find settings where the students could safely explore traditional medicine... to prevent being irresponsible."

<u>Quacks -</u> "One important aspect is acknowledging that quacks exist, not only for traditional medicine but also for Western medicine, for example, fake plastic surgeons, placebo pills, etc."

<u>More than respect -</u> "for me, the most important thing to learn is respect and tolerance towards intercultural differences. But not only to respect them, rather... I don't know how to say it... like, open our minds to the idea that those concepts that traditional medicine users propose, can be equally valid as those concepts that we know. In other words, not only to respect traditional medicine but to recognize it as valid."

<u>Example</u> - "It is common to find booklets about health promotion and disease prevention in the hospitals, so why can't we include those when, for example, one is about to discharge a patient with bronchiolitis, and we are providing advice? we can provide a booklet with basic advice on cold care. Or, in the case of a woman, advice on menstruation care."

2. Pedagogical strategy

2.1. Characteristics of strategy

<u>Adapted to context -</u> "Culture is very delicate and heterogeneous, the learning strategy must be adapted to each specific population. Traditional medicine is very different in Haiti and in Colombia, for example. Therefore, the model has to be flexible and adaptable to different community settings."

Adapted to needs - "Not all medical students learn the same way. Therefore, the teaching strategy must be adapted to the needs and interests of each student."

<u>Mandatory</u> - "there is a need to include cultural safety as a mandatory course in all medical schools. Not an elective course. It could open the students' mind to a whole new world."

2.2. Innovation

<u>Games</u> - "I love games and I know the potential that they have. Especially for my generation. All my friends play videogames for example. When I am not at the hospital, studying, or with friends, I am playing games. Therefore, I think it is a great opportunity and should be explored."

App - "I am thinking about an app where traditional medicine users and health professionals could exchange information."

<u>Videos</u> - "I liked the videos; I remember that the professors showed videos of traditional medicine users and providers to us. It is not a direct approach, but is good to have sort of an experiential learning."

<u>Arsenal -</u> "If we take into account that cultural safety is not an appealing topic for medical students, it is good to have a good arsenal of different methods and strategies to fit the learning ways of each person."

Not standard - "I don't like, I have never liked, and I will never like to get shut in a classroom to stuff information in us. It has never caught my attention. Never."

2.3. Community-based learning

Exchange - "I think that other medical students should have the same opportunity that we had. Going to Cota, and interacting with the families of traditional medicine users. It opened our eyes. If I had not had that opportunity, perhaps I would not be thinking the same, and perhaps I would discriminate against traditional medicine users."

<u>Interactive-</u> "the lectures were very boring. Like many figures and prevalence of traditional medicine use and that stuff. But when we went to the communities, it was different. You go there, you see the people, talk to traditional medicine users, they show you the plants, you even drink yoco... Of course, it was more interesting, more interactive, and then you get attracted to it. You realize that many people use traditional medicine, it could be effective. For me, it is the best way."

Teachers - "I loved the fact that it was the patients themselves who were the ones who taught us about traditional medicine."

<u>Transformative -</u> "When you go there and you live it yourself, you get to know the people, you bond with them, one becomes more empathetic and open, more receptive. In other words, you change a lot when you get to know the people."

3. Acknowledge and address barriers

3.1. Biomedical model factors

The only one - "Because physicians think the Western biomedical model is the only valid one to treat diseases. Therefore, it disqualifies traditional medicine."

<u>Curative focus -</u> "Because traditional medicine has a preventive focus, while Western medicine is focused on diagnosis and treatment. Therefore, our educational mindset is based on diagnosis and treatment and little on prevention and promotion."

<u>Status -</u> "Of course, a physician who has done many degrees would say to the traditional medicine user... 'how are you going to teach me about medicine? I have studied, I have done so many degrees, what are you going to teach me now?'

<u>Technology</u> - "Western medicine goes hand-in-hand with technology, like electronic tools and the use of different machines... while traditional medicine does not go hand-in-hand with technology."

3.2. Traditional medicine factors

<u>Black box -</u> "It can be that traditional medicine works, but it is like a 'black box.' We do not understand how it works. Therefore, we disqualify it. The thing is that we have been studying concepts for around seven years, concepts that are widely described even at the molecular level, and that have something that supports them, therefore, if traditional medicine is described like that, then we reject it."

Effectiveness - "If I said, for example, you can take this sauco remedy for respiratory disease, because it has been validated, and has been proven to work... I would accept it, but otherwise, I would not."

<u>Safety</u> - "For one it is hard to try to recommend traditional medicine because we really don't know if it is going to cause harm or benefit, or if it is going to do anything at all, compared to something that has all the scientific evidence (Western medicine)."

Outdated - "We think that (traditional medicine) is what our ancestors used... but it is not valid anymore."

3.3. Medical education factors

<u>Opportunities</u> - "We are privileged in that way because if we compare ourselves with students from other universities, they do not have the opportunity to learn about cultural safety."

Lack of professors - "(cultural safety) is not taught because you cannot teach what you don't know... Therefore, if knowledgeable professors on cultural issues are missing, the students will end up embracing only Western medicine because that is what they learned."

<u>Secondary courses -</u> "when the topic is approached by medical schools, it is only given in secondary courses (*tapahuecos*), and therefore, it is not perceived as a serious topic in medical training."

<u>Ethnocentrism</u> - "Our career is ethnocentric, that is what is sought, that students think that there is no another way to do things, but in practice this is clearly done, for example taking the *sauco*, extracting salicylic acid to make aspirin."

3.4. Sociocultural factors

<u>Identity</u> - "We do not appreciate what we have, we do not love what we have as Colombians. We are privileged to have traditional medicine, and almost all of us have had contact with traditional medicine at least once in life, but we do not know how to appreciate our roots and the history of that knowledge".

<u>Urbanization -</u> "Many students have to go to the big cities to study medicine. People think that they will get a better education in Bogota or Medellin, but in those urbanized settings traditional medicine does not have a place."

<u>Colonialism -</u> "There is a popular phrase that is 'everything in English sounds nicer.' Therefore, everything in English sounds better. We pay more attention to things if they are written in English."

Appendix 4. Intercultural health experts themes and subthemes

1. Strategy
1.1. Benefits of cultural safety
Example - "Finding real examples, not theoretical, about how this training can be beneficial for both their clinical practice and their patients and communities. It has to be an example of an intercultural conflict in medical practice and how to address it successfully and not only overlook it."
Benefits - "That they have the opportunity of observing and recognizing how the training to deal with intercultural tensions can turn out to be useful and benefit both the patient and themselves and the society."
1.2. Has to promote self-awareness
"The strategy has to promote self-awareness. For example, asking the students to write down diaries, writing about themselves. When they see themselves, they are ready to see the other."
1.3. Facilitating encounters with traditional medicine
Patient - "Another thing that has helped people to assimilate these contents is having personal experience as a patient of traditional medicine, I think that has been fundamental."
GP's and specialists - "This training should not be only for medical students. General practitioners and specialist require also training in cultural safety."
Encounters - "It is essential to facilitate encounters between the students and traditional medicine. Without this experience, what students learn stays within the theoretical field. I think that it is the ideal pedagogical strategy to teach about this."
1.4. Effective pedagogical strategies
Effectiveness - "Also, there is a need to find pedagogical strategies that have been proven effective. I don't have them right now."
Tensions - "they should be able to recognize all the multiple ways in which intercultural tensions can occur in medical practice; they have to learn to recognize that the tension is always there."
Mistreated - "the strategy has to take into account experiences of people who have been mistreated, who have had encounters with doctors who are not receptive at all, who do not understand their cultural understanding of health and disease."
<u>Framework -</u> "One thing that has helped me is offering a solid and convincing theoretical framework. A big problem linked to talking about traditional medicine is the chaos and confusion that is usually present in the area. Everybody thinks about something different, like homeopathic drugs, flower essences, witchcraft, naturism etc. Therefore, offering a clear and solid theoretical framework has helped me over my 30 years of experience."
1.5. Problem-solution structure
<u>Practice and theory -</u> "From my point of view, from my way to understand pedagogy, practice is before theory. I believe that there is something more practical, more empirical, that make the students interested in the theoretical framework And the theoretical framework strengthens the learning experience. I experienced it during my masters in education, I used to like the topic, I had my own reflections, I had seen some things in practice, and then I found a theoretical framework that allowed me to understand and interpret all those problems and interests that I had."
<u>Fix problems -</u> "The discourse of science is like, 'we understand everything, we can explain everything, everything is perfect, and the world is like that.' It is the hegemonic discourse. For me, it was motivating when I met a professor who told me that the world has problems, and therefore we have to work, to fix them. As we recognize the problems, think about them, try to address them and solve them, it becomes a motivation. In this case, recognizing the limitations and difficulties of medical science, that is what allows us to investigate and think of new options."
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<u>Identified -</u> "For me, there has to be a problem the student identifies with and feels motivated to find the solution. For me, this is what leads the student to learning everything (...) If having the problem is the starting point, the student goes to find the solution, it is in seeking the solution where they will learn, that is the key."

1.6. Humanities

<u>Fiction -</u> "It is about making something that actually happened as it was fiction. It allows the student to connect with that is fiction, making them want it to be true. When they internalize the message that way, after that, it is easier to show them, 'well it is actually true.' And that is how they link the concepts learned through fiction with real-life problems."

Environment - "Students connect well and easily also with the environmental education that they already have."

Stories - "I use something that I learned from Indigenous people. When I am talking about intercultural health, I am always doing an autobiography. I tell my own story, and I play with it all the time. Of course, it is a magical story, absolutely fascinating, but I use that a lot, for them to believe."

2. Acknowledge and address difficulties

2.1. The hegemony of the Western biomedical model

One way - "We are convinced that there is only one way to see reality, only one culture, only one epistemology."

<u>Neutral -</u> "Western science pretends to be THE science, and the science looks from nowhere. It is neutral."

<u>Ethnocentrism</u> - "We are all taught in some way and we all learn things; we learn them intuitively without criticizing. We learn them as our own, and this is related to ethnocentrism. Therefore, I have a particular way to see the world, and for me, it is the normal way, the right way. This is a barrier for me, it is hard to make the students realize that, that those things that we learn as normal or correct, are not necessarily correct or normal, it is just particular way to see things, but for us, it becomes the normal way to see things."

Evidence-based - "they (the students) have been trained under the evidence-based medicine approach, meaning that this is the only right way to see the world. Therefore, talking to them about worldviews different than EBM is hard."

<u>Anecdotic -</u> "another difficulty that I confront is that they don't see the value of respecting traditional medicine. For them it is more like a folk thing, anecdotic, but they don't necessarily see it as something important."

<u>Deeper issue-</u> "There is a deeper issue. It is stuck in our mind and colonization process that a cultured person is the one that who seems somebody from a 'first-world country.' And being a cultured person means having first-world education, and the Western worldview is within the first-world. In that context, the *maloka* is the pigsty of the uncultured. (...) Traditional medicine is automatically classified as uncultured. For example, an Indian does not usually know how to appreciate modern art or a concert of Mozart, but we don't know how to participate in a *Yuripari*. However, one is cultured, and the other one is uncultured. That makes cultural safety training hard."

2.2. Deficient current pedagogical strategies

Deficient - "current strategies, when they occur, are deficient. At best, what they try to teach is how to trick the patients into doing what they want them to do."

Interest - "no one promotes interest in the real dimensions of the problem."

<u>Processes</u> - "on a more technical level, medical education is more about teaching the names of the muscles, the molecules, or processes, and a big part of the pedagogical strategies are designed for that purpose. But when things have to do with these types of categories (cultural safety), there is a need to resort to other types of strategies."

<u>Hidden curriculum -</u> "There are things that medical students learn by the 'hidden curriculum.' Because if I go to the hospital, and I see the pediatrician scolding a woman for this thing or the other, what I learn as a medical student is simply to disregard the knowledge, beliefs, and culture of the other, and impose mine."

<u>Imitation</u> - "the way they (medical students) learn how to treat traditional medicine users is through imitation. That authority that the pulmonologist has, the admired clinician, and then he receives a woman using a *franela roja* (traditional practice), and then he scolds the woman and says to her 'stop using this nonsense,' then their students will learn that."

2.3. Is hard to foster self-awareness

<u>Failures -</u> "Cultural safety implies that there is something good in non-Western understandings of the world, and that also requires showing the potential biases and failures of Western medicine, showing them that it is not the only truth. That exercise is very uncomfortable for the students, it makes them uncomfortable."

<u>Confronting -</u> "When I aim to recognize the other, the first step is to recognize myself. But that exercise is not always easy or nice, because the students end up confronting themselves, which can generate strong reactions. They can be harsh because the students feel that their ideas and convictions are being attacked, there is a risk to confuse that with a personal attack."

Worldview - "Of course, if I don't understand that mine is just a worldview, everything that it is not my worldview can easily be rejected."

2.4. Western medicine is not the only one.

"(cultural safety) entails calling attention to the fact that Western medicine is not the only medical system, is not the best, maybe it has biases, it has defects."

2.5. Inability to recognize intercultural tensions.

<u>Thingy</u> - "What happens is that a physician like this, trained within the hegemony of the Western biomedical model, when they see patients wearing amulets against the evil eye, against *descuaje*, what happens is that the physician will scold the patient because the *thingy* will break and the patient will choke and whatnot... So, there is a lack of tools for them to recognize those tensions and how to address them."

Ignorance - "There is a lot of ignorance despite these situations happening all the time. There is an incapacity to acknowledge that... and what they (physicians) do is letting things pass and imposing their prescription, and that is it."

2.6. Not acknowledging the need for a change

"Another barrier is lack of acknowledgement for the need to propose changes to the biomedical model. We all know that the biomedical model is currently in crisis. There are problems. But all we want is to change the system or how the same biomedical model is delivered. Nobody proposes to change the biomedical model."

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Appendix 1. CONSORT checklist of information to include when reporting a pilot trial

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page no where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	Title page
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	See Abstract page and Appendix
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	Introduction
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	Introduction – last paragraph
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	Methods - Design
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	Methods - Design
Participants:			
4a	Eligibility criteria for participants		
4b	Settings and locations where the data were collected		
4c		How participants were identified and consented	Methods – Participants
Interventions:			

5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		
Outcomes:			
6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Completely defined pre-specified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	Methods – Outcome measures
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	Methods - Design
6c		If applicable, pre-specified criteria used to judge whether, or how, to proceed with future definitive trial	N/A
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	Method- Participants
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	Method- Participants
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		
Implementation:			

10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions		
Blinding:			
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		
11b	If relevant, description of the similarity of interventions		
Analytical methods:			
12a	Statistical methods used to compare group for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	Method- Outcome measures and Data analysis
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	N/A
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	Figure 1. Schematic diagram of the pilot RCT
13b	For each group, losses and exclusions after randomisation, together with reasons		
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	N/A
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		

Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these analyses should be by randomised group	Tables 2 and 3
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	Tables 2 and 3
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	Results - probabilistic transitive closure, students' perception of the game jam experience, validity, and reliability of the instrument.
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		
19a		If relevant, other important unintended consequences	N/A
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	Discussion - Limitations
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	Conclusion
Interpretation:			

22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	Conclusion
22a		Implications for progression from pilot to future definitive trial including any proposed amendments	Conclusion
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	Abstract
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	Methods –Design
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		
26		Ethical approval/research review committee approval confirmed with reference number	Methods - Ethics

Appendix 2. Revised version of example abstract for report of pilot trial

Item	Standard Checklist item	Extension for pilot trials	Reported
Title	Identification of study as randomised	Identification of study as randomised pilot trial	√
Trial design	Description of the trial design (e.g. parallel, cluster, non- inferiority)	Description of pilot trial design (e.g. parallel, cluster)	V
METHODS			
Participants	Eligibility criteria for participants and the settings where the data were collected	Eligibility criteria for participants and the settings where the pilot trial was conducted	√
Interventions	Interventions intended for each group	same	✓
Objective	Specific objective or hypothesis	Specific objectives of the pilot trial	✓
Outcome	Clearly defined primary outcome for this report	Pre-specified assessment or measurement to address the pilot trial objective(s)	✓
Randomisation	How participants were allocated to interventions	same	✓
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	same	V
RESULTS			
Numbers randomised	Number of participants randomised to each group	Number of participants screened and randomised to each group for the pilot trial objective(s) 1	~
Recruitment	Trial status (for conference abstracts)	same	N/A
Numbers analysed	Number of participants analysed in each group	Number of participants analysed in each group for the pilot objective(s) ¹	~
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Results for the pilot objective(s), including any expressions of uncertainty	~
Harms	Important adverse events or side-effects	same	N/A
Conclusions	General interpretation of the results	General interpretation of the results of pilot trial and their implications for the future definitive trial	~

Trial registration	Registration number and name of trial register	Registration number for pilot trial and name of trial register	✓
Funding	Source of funding	Source of funding for pilot trial	\checkmark

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Appendix 1 SPIRIT 2013 Checklist

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number on which item is reported	
Administrative informati	Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1	
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3	
	2b	All items from the World Health Organization Trial Registration Data Set	Appendix	
Protocol version	3	Date and version identifier	Appendix	
Funding	4	Sources and types of financial, material, and other support	8 and Appendix	
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	8 and Appendix	
	5b	Name and contact information for the trial sponsor	8 and Appendix	
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	8	
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A	
Introduction				
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3 to 6	

	6b	Explanation for choice of comparators	6
Objectives	7	Specific objectives or hypotheses	
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7 and 8
Methods: Participants, in	tervention	is, and outcomes	
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	8
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	8
Interventions 11a		Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9 to 13
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	13
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	13
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	14
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	14 and 15
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	16

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	17
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	18
Methods: Assignment of	interventio	ons (for controlled trials)	
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	18
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	19
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	18
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	19
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection	, managem	ent, and analysis	
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	19 to 21
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	22

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	22 and 23
Statistical methods	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol		23
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	23 and 24
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	24
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	Appendix
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	Appendix
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	Appendix
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will beAindependent from investigators and the sponsorA	
Ethics and dissemination	l		
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	24 and 25

Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	Appendix	
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	25	
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A	
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22 and 23	
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	28	
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators		
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	N/A	
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	ants, healthcare Appendix porting in results restrictions	
	31b	Authorship eligibility guidelines and any intended use of professional writers	Appendix	
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	28	
Appendices				
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Available upon request	

Biological specimens	22	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or	N/A
		molecular analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "<u>Attribution-NonCommercial-NoDerivs 3.0 Unported</u>" license.

Appendix

2b. World Health Organization Trial Registration Data Set information

1. Primary Registry and Trial Identifying Number: ISRCTN14261595 (<u>http://www.isrctn.com</u>) <u>https://doi.org/10.1186/ISRCTN14261595</u>

- 2. Date of Registration in Primary Registry: July 18^{th} , 2019
- 3. Secondary Identifying Numbers: N/A
- 4. Source(s) of Monetary or Material Support: McGill University
- 5. Primary Sponsor: McGill University
- 6. Secondary Sponsor(s): CEIBA Foundation (Colombia) and Fonds de recherche du Québec Santé (Canada)
- 7. Contact for Public Queries: Juan Pimentel (see page 1)
- 8. Contact for Scientific Queries: Juan Pimentel (see page 1)

9. Public Title: "Game-based learning for improving communication between doctors and communities who use traditional health practices in Colombia"

10. Scientific Title: "Impact of co-designed game learning on cultural safety in Colombian medical education: a randomized controlled trial"

- 11. Countries of Recruitment: Colombia
- 12. Health Condition(s) or Problem(s) Studied: see Background section
- 13. Intervention(s): see Interventions section of Methods
- 14. Key Inclusion and Exclusion Criteria: see eligibility criteria section of Methods
- 15. Study Type: Parallel group, two-arm, superiority RCT with 1:1 allocation ratio
- 16. Date of First Enrollment: July 15th, 2019
- 17. Target Sample Size: 330
- 18. Recruitment Status: No longer recruiting
- 19. Primary Outcome(s): see Outcomes section of Methods
- 20. Key Secondary Outcomes: see Outcomes section of Methods

Other items from SPIRIT Checklist

3. Protocol version: 3; last modified July 10th, 2019.

21a, 21b, 22. A full Data Safety Monitoring Board is not necessary for our study. We do not expect our methods to cause any safety concerns to the participants of the trial. However, if there is some distress related to the intervention or control activities, or any other aspect of our methods, the study coordinator will be available to support the participants. We will not conduct interim analyses.

23, 25. The Institutional Review Board of the McGill's Faculty of Medicine conducts annual reviews of the study procedures and progress. We will communicate any important protocol modification to the Review Board through the Continuing Review Form, which is a mandatory document that we submit each year. This mechanism allows monitoring of changes of financial support, status of the study (enrolment, data analysis, inactive), new risks or benefits for the participants, adverse events, and modifications of the consent form.

31a. We will invite stakeholders (facilitators or medical students) to be co-authors of at least one peer-reviewed manuscript in an openaccess journal, such as Games for Health Journal or BMC Medical Education. Similarly, we will invite stakeholders to submit their work and to attend at least two relevant national or international conferences on topics related to the study. Relevant conferences include The North American Primary Care Research Group (NAPCRG) Annual Meeting, The Annual Consortium of Universities for Global Health (CUGH) Global Health Conference, The Unite for Sight Global Health and Innovation Conference, The Cross-Cultural Health Care Conference, and The Society for Intercultural Education, Training and Research (SIETAR) Annual Congress. We will invite end-users (medical students) to develop and circulate a lay report to share findings, reaching all stakeholders.

31b. To define the authorship of the resulting articles of our study, we will follow the Role of Authors and Contributors criteria specified in the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals of the International Committee of Medical Journal Editors.

Appendix 2. Checklist for reporting results of internet e-surveys

Multimedia Appendix 2. Data reporting guidelines, checklist for reporting results of internet E-Surveys (CHERRIES)

Item category	Checklist item	This study
Design	Describe survey design	Target population: Undergraduate medical students and medical interns at La Sabana
		University in Colombia.
		Purposive sample. We will contact the medical students and medical interns using <i>La</i>
		Sabana University's mailing lists and will e-mail invitations for voluntary participation
		in the project. For those willing to participate, we will send further information about
		the project as well as the date and place of the intervention. We will ask interested
		students to complete the online informed consent and baseline questionnaire one week
		before the RCT.
IRB approval and informed	IRB approval	This RCT was approved by Institutional Review Board of the McGill's Faculty of
consent process		Medicine (approval number A05-B37-17B) and by the Sub-committee for Research of
		the Faculty of Medicine at La Sabana University (approval number 445).
	Informed consent	Informed consent was provided by completing the e-survey.
	Data protection	SurveyMonkey and Google responses are stored in a worksneet that can only be
		accessed through an account login. Data transmission uses Secure Sockets Layer to
		encrypt information during transport. The data storage is as secure as most other systems that store survey information. After downloading the data we will delete it
		from Survey Monkey and Coords Forma. We will be reasonable for ensuring the date are
		socurely stored for seven years and then destroyed in accordance with CIET guidelines
		for security storage and eventual destruction of data records
Development and pre-testing	Development and testing	We will use a 30-item instrument comprised of three parts. The first part (five items)
bevelopment und pre testing	bevelopment and testing	will explore sociodemographic factors of the students. The second part (15 items) will
		be based on the Transcultural Self-Efficacy Tool and will explore knowledge, attitudes.
		skills, and behaviors of cultural competence. For the third part of the instrument
		(cultural safety), we developed a Likert-type preliminary version based on our
		CASCADA variables (see primary outcome) and piloted it for validity and reliability in
		our pilot RCT.
		Regarding the qualitative data, using a pre-defined format in Google forms, we will ask
		participants to write down and enter their stories.
Recruitment process and	Open survey versus closed survey	Closed survey sent by institutional email from <i>La Sabana</i> University.
description of the sample		
having access to the		
questionnaire		
	Contact mode	Contact with participants online through e-mail and face-to-face.
	Advertising the survey	Not applicable.
Survey administration	Web/E-mail	E-mail survey using SurveyMonkey and Google Forms. There was an automatic method
	Contout	for capturing responses.
	Context	we will contact the medical students and medical interns using La Sabana University's
		maning ists and will e-mail invitations for voluntary participation in the project.

	Mandatory/voluntary Incentives	Voluntary survey. Participants of the qualitative component of the study will enter a raffle after submitting their story. We will offer one gift card of CAD 20 for every ten stories collected
	Time/date Randomization of items or questionnaires	July 2019 to July 2020. Stratified randomization by cultural safety score at baseline.
	Adaptive questioning	Not applicable.
	Number of items	30 items in total.
	Number of screens (pages)	Three Webpage per survey.
	Completeness check	We will use several validation options to increase the quality of the data: specific number range, specific character range, date validation, email address format, and prompts that alert participants when they enter incomplete or invalid answers.
	Review step	Respondents were not able to review and change their answers.
Response rates	Unique site visitor	Repeat visitors will not be excluded. Some students will share their devices with students who do not have access to an electronic device.
	View rate (ratio of unique survey visitors/unique site visitors)	Not available.
	Participation rate (ratio of unique visitors who agreed to participate/unique first	Not available.
	Completion rate (ratio of users who finished the survey/users who agreed to participate)	Not available.
Preventing multiple entries from the same individual	Cookies used	Repeat visitors will not be excluded.
	IP check	Repeat visitors will not be excluded.
	Log file analysis	Repeat visitors will not be excluded.
	Log file analysis	Repeat visitors will not be excluded.
	Registration	Repeat visitors will not be excluded.
Analysis	Handling of incomplete questionnaires	Only completed questionnaires will be analyzed.
	Questionnaires submitted with an atypical timestamp	Not applicable
	Statistical correction	Not applicable

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Appendix 1. CONSORT checklist of information to include when reporting an RCT

Reporting checklist for randomised trial.

Based on the CONSORT guidelines. *Instructions to authors*

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORTreporting guidelines, and cite them as:

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

		Reporting Item	Page Number
Title and Abstract			
Title	<u>#1a</u>	Identification as a randomized trial in the title.	1
Abstract	<u>#1b</u>	Structured summary of trial design, methods, results, and conclusions	2 & 3 (see our completed CONSORT for Abstracts checklist)
Introduction			
Background and objectives	<u>#2a</u>	Scientific background and explanation of rationale	4 & 5

Background and objectives	<u>#2b</u>	Specific objectives or hypothesis	5&6
Methods			
Trial design	<u>#3a</u>	Description of trial design (such as parallel, factorial) including allocation ratio.	6 - Trial design
Trial design	<u>#3b</u>	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	7 - Interventions
Participants	<u>#4a</u>	Eligibility criteria for participants	6 - Study setting and participants
Participants	<u>#4b</u>	Settings and locations where the data were collected	6 - Study setting and participants
Interventions	<u>#5</u>	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7 - Interventions
Outcomes	<u>#6a</u>	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	8 - Outcomes
Sample size	<u>#7a</u>	How sample size was determined.	9 - Sample size
Sample size	<u>#7b</u>	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization - Sequence generation	<u>#8a</u>	Method used to generate the random allocation sequence.	

9 - Recruitment and randomisation

#8b Type of randomization; details of any restriction (such as Randomization -Sequence generation blocking and block size) 9 - Recruitment and randomisation #9 Mechanism used to implement the random allocation sequence 9 - Recruitment and randomisation Randomization -Allocation concealment (such as sequentially numbered containers), describing any mechanism steps taken to conceal the sequence until interventions were assigned Randomization -Who generated the allocation sequence, who enrolled 9 - Recruitment and randomisation #10 Implementation participants, and who assigned participants to interventions 9 - Recruitment and randomisation Blinding #11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how. Blinding <u>#11b</u> If relevant, description of the similarity of interventions N/A <u>#12a</u> Statistical methods used to compare groups for primary and Statistical methods 9 & 10 - Data analysis secondary outcomes Statistical methods Methods for additional analyses, such as subgroup analyses and 9 & 10 - Data analysis #12b adjusted analyses Outcomes Any changes to trial outcomes after the trial commenced, with N/A #6b

reasons

Results

Participant flow diagram (strongly recommended)	<u>#13a</u>	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1 CONSORT flow diagram of the RCT
Participant flow	<u>#13b</u>	For each group, losses and exclusions after randomization, together with reason	Figure 1 CONSORT flow diagram of the RCT and Additional file 2 is an attrition diagram
Recruitment	<u>#14a</u>	Dates defining the periods of recruitment and follow-up	Figure 1 CONSORT flow diagram of the RCT
Recruitment	<u>#14b</u>	Why the trial ended or was stopped	Figure 1 CONSORT flow diagram of the RCT
Baseline data	<u>#15</u>	A table showing baseline demographic and clinical characteristics for each group	Table 1. Baseline sociodemographic characteristics of the participants of the study
Numbers analysed	<u>#16</u>	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Tables 2 & 3
Outcomes and estimation	<u>#17a</u>	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Tables 2 & 3
Outcomes and estimation	<u>#17b</u>	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	<u>#18</u>	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	16 & 17
--------------------------	------------	---	----------------------------
Harms	<u>#19</u>	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	N/A - not a clinical trial
Discussion			
Limitations	<u>#20</u>	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20 & 21 - Limitations
Interpretation	<u>#22</u>	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18 to 20
Registration	<u>#23</u>	Registration number and name of trial registry	3 - Trial registration
Other Information			
Protocol	<u>#24</u>	Where the full trial protocol can be accessed, if available	6 - Trial design
Funding	<u>#25</u>	Sources of funding and other support (such as supply of drugs), role of funders	23 - Funding
Notes:			
• 1b: 2 & 3 (see our com	pleted (CONSORT for Abstracts checklist)	

- 3a: 6 Trial design
- 3b: 7 Interventions
- 4a: 6 Study setting and participants

- 4b: 6 Study setting and participants
- 5: 7 Interventions
- 6a: 8 Outcomes
- 7a: 9 Sample size
- 8a: 9 Recruitment and randomisation
- 8b: 9 Recruitment and randomisation
- 9:9 Recruitment and randomisation
- 10: 9 Recruitment and randomisation
- 11a: 9 Recruitment and randomisation
- 12a: 9 & 10 Data analysis
- 12b: 9 & 10 Data analysis
- 13a: Figure 1 CONSORT flow diagram of the RCT
- 13b: Figure 1 CONSORT flow diagram of the RCT and Additional file 2 is an attrition diagram
- 14a: Figure 1 CONSORT flow diagram of the RCT
- 14b: Figure 1 CONSORT flow diagram of the RCT
- 15: Table 1. Baseline sociodemographic characteristics of the participants of the study
- 16: Tables 2 & 3
- 17a: Tables 2 & 3

- 19: N/A not a clinical trial
- 20: 20 & 21 Limitations
- 23: 3 Trial registration
- 24: 6 Trial design
- 25: 23 Funding The CONSORT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist was completed on 26. August 2020 using <u>https://www.goodreports.org/</u>, a tool made by the <u>EQUATOR Network</u> in collaboration with <u>Penelope.ai</u>

Reporting checklist for randomised trial abstract.

Based on the CONSORT for Abstracts guidelines. *Instructions to authors*

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORT for Abstractsreporting guidelines, and cite them as:

Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF and the CONSORT Group (2008) CONSORT for reporting randomised trials in journal and conference abstracts. Lancet: 371:281-283. PMID: 18221781

Reporting Item

Page Number

Title and study details

Title	<u>#1</u>	Identification of the study as randomized	1
Authors	<u>#2</u>	Contact details for the corresponding author.	1
Trial Design	<u>#3</u>	Description of the trial design.	2 - Methods
Abstract subsection: Methods			
Participants	<u>#4a</u>	Eligibility criteria for participants and the settings where the data were collected.	2 - Methods
Participants	<u>#4</u>	Eligibility criteria for participants and the settings where the data were collected	2 - Methods
Interventions	<u>#5</u>	Interventions intended for each group.	2 - Methods
Objective	<u>#6</u>	Specific objective or hypothesis.	2 - Background
Outcome	<u>#7</u>	Clearly defined primary outcome for this report.	2 - Background
Randomization	<u>#8</u>	How participants were allocated to interventions.	2 - Methods
Blinding (Masking)	<u>#9</u>	Whether or not participants, caregivers, and those assessing the outcomes were blinded to group assignment.	2 - Methods
Abstract subsection: Results			
Numbers Randomized	<u>#10</u>	Number of participants randomized to each group.	2 - Results
Recruitment	<u>#11</u>	Trial status	2 - Results

Numbers Analysed	<u>#12</u>	Number of participants analysed in each group.	2 - Results
Outcome	<u>#13</u>	For the primary outcome, a result for each group and the estimated effect size and its precision.	2 - Results
Harms	<u>#14</u>	Important adverse events or side effects.	N/A - not a clinical trial
Abstract subsection: Conclusions			
Conclusions	<u>#15</u>	General interpretation of the results.	3 - Conclusions
Trial Registration			
Trial Registration	<u>#16</u>	Registration number and name of trial register.	3 - Trial registration
Funding			
Funding	<u>#17</u>	Source of funding.	23 - Funding
Notes:			
• 4a: 2 - Methods			
• 3: 2 - Methods			
• 4: 2 - Methods			
• 5: 2 - Methods			
• 6: 2 - Background			

- 7: 2 Background
- 8: 2 Methods
- 9: 2 Methods
- 10: 2 Results
- 11: 2 Results
- 12: 2 Results
- 13: 2 Results
- 14: N/A not a clinical trial
- 15: 3 Conclusions
- 16: 3 Trial registration
- 17: 23 Funding This checklist was completed on 26. August 2020 using <u>https://www.goodreports.org/</u>, a tool made by the <u>EQUATOR</u> <u>Network</u> in collaboration with <u>Penelope.ai</u>

Appendix 2. Questions used to assess each component of the CASCADA model

The CASCADA (conscious knowledge, attitudes, subjective norms, change intention, sense of agency, discussion, and behavior/action) model of planned behavior[23] included the following variables:

Component	Statement
C onscious knowledge	"I consider the cultural beliefs of my patients is not important for health decision-making"
A ttitude	"It is not worth considering the cultural beliefs of my patients to improve their health."
S ubjective norms	"Although many physicians disapprove cultural beliefs, I think that these beliefs could improve my patients' health."
Intention to c hange	"I will never be open to include my patients" cultural beliefs and practices in the health decision- making process."
A gency	"I feel prepared with the knowledge and skills to prudently incorporate my patients' cultural practices in the health decision-making process."
D iscussion	"I will discuss cultural safety with other students and physicians so they can prudently

incorporate their patients' cultural practices in the
health decision-making process."

Appendix 3. Attrition diagram of the study



	Intervention	Control	Total
Baseline	268	263	531
Second timepoint	180	169	349
Third timepoint	162	174	336

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Appendix 1. Standards for Reporting Qualitative Research checklist²

Standards for Reporting Qualitative Research (SRQR)^a

No.	Торіс	Item	Page			
Title and abstract						
S1	Title	Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	1			
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	2			
		Introduction				
S 3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	3 & 4			
S4	Purpose or research question	Purpose of the study and specific objectives or questions	4			
		Methods				
\$5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale ^b	Study design - 4			
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	Rigour - 6			
S 7	Context	Setting/site and salient contextual factors; rationale ^b	Setting and participants – 4 & 5			
S 8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale ^b	Setting and participants – 4 & 5, and Data			

² O'Brien, B. C., Harris, I. B., Beckman, T. J., Reed, D. A., & Cook, D. A. (2014). Standards for Reporting Qualitative Research. Academic Medicine, 89(9), 1245–1251. https://doi.org/10.1097/ACM.00000000000388

			collection – 5 & 6	
S 9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	Ethical approval - 7	
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale ^b	Data collection – 5 & 6	
\$11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	Data collection – 5 & 6	
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	Data processing and analysis - 6	
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts	Data processing and analysis - 6	
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale ^b	Data processing and analysis - 6	
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale ^b	Rigour - 6	
		Results/findings		
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	Results - 7 to 12	
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	Additional file 2. Deductive thematic analysis results - complete list of quotes	
Discussion				
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/ generalizability; identification of unique contribution(s) to scholarship in a discipline or field	Discussion 12 and 13	
S19	Limitations	Trustworthiness and limitations of findings	Limitations - 13	
Other				

S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	14 & 15
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting	14 & 15

^a The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

^b The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Appendix 2. Deductive thematic analysis results - complete list of quotes

1. CONSCIOUS KNOWLEDGE

1.1. Benefits of cultural safety training and consequences of culturally unsafe practices

Benefits – adherence "[cultural safety] helps to reach consensus between patients and me, it makes patients feel involved in their treatment without feeling diminished, therefore strengthening their adherence to medical treatment." (Participant 7)

Benefits – positive environment "generating a pleasant and happy environment in which the patient feels that I take his culture into account and that, together, we can achieve positive health outcomes." (Participant 10)

Benefits - doctor-patient relationship "Taking the time to investigate about the traditional practices of patients allows you to gain important knowledge and to develop a better relationship with patients." (Participant 16)

Consequences of culturally unsafe practices "Diminishing or discriminating against someone for their beliefs or for using traditional medicine is like attacking that person's identity and culture." (Participant 4)

*Issues approaching patients "*We were doing surveys about breastfeeding practices, and one of the questions was literally about 'breastfeeding myths'. Shortly after starting the survey, we realized that it was a very poorly formulated question, mothers did not understand about 'myths', simply because for them they were not myths." (Participant 9)

1.2. Acknowledging cultural diversity and traditional medicine use among family, student setting, and the student themselves

Traditional medicine use among family and students "In the lecture, we learned about remote tribes and communities, but I don't have to go that far to experience what I learned from the talk. Not only my dad uses traditional medicine, but most of my family, even me. For example, I drink cinnamon infusion when I have a colic." (Participant 19)

Traditional medicine use in my setting "Being able to accept that there is a diversity of knowledge [...] is a great contribution to our clinical practice throughout the semester. We have the opportunity to work in Cundinamarca [Colombian province] where the rural population tends to have a rich oral tradition to manage their health" (Participant 26)

Cultural diversity "The most significant change I had was facing a 'new country' and realizing that there are many ways to practice medicine that are not taken into account in our medical education" (Participant 2)

"I identify more different cultures and I appreciate much more the importance that this has on my medical practice" (Participant 11)

Traditional medicine is part of our culture "The most important thing is to recognize and respect cultural differences and protect them. Above all, preserve cultural practices and transmit them on from generation to generation, as this is part of the history of our region." (Participant 25)

1.3. Characteristics of traditional medicine and confusion of concepts

"I can now differentiate the concept of alternative medicine as from traditional medicine. I understood that traditional medicine has a way of being and that it is part of someone else's culture." (Participant 4)

Confusion with homeopathy "Because the temptation when seeing a patient is to deny that homeopathic medicine will have any beneficial effect on our patients." (Participant 18)

2. ATTITUDES

2.1. Respect and appreciation for cultural diversity, and avoid cultural destruction and ethnocentrism

Acceptance of traditional medicine "Cultural safety training has allowed me to accept the traditional ways that do not correspond to western medicine" (Participant 16)

Respect and cultural preservation "The most important thing is to recognize and respect cultural differences and protect them. Above all, preserve cultural practices and transmit them on from generation to generation, as this is part of the history of our region." (Participant 25)

Avoid discrimination "[Cultural safety] taught me that we should not belittle traditional medicine or believe that Western medicine is the truth and the solution to everything." (Participant 23)

Appreciate cultural diversity "Now I can identify different cultures and I appreciate much more the importance that cultural diversity has on my medical practice" (Participant 24)

Less ethnocentrism "Because when we find a patient who has a culture with different beliefs from ours, we tend to ignore them; we believe that our culture is correct and we that are right, but [cultural safety training] make us wonder if it really like that." (Participant 21)

2.2. Openness

"As doctors in training, we often think that only our knowledge is objective and reasonable, but we must open our minds to accept the cultural practices and beliefs of other people and other communities" (Participant 25)

" I am now much more open to recognize and accept the cultural differences that my patients may have" (Participant 13)

"[Cultural safety] training allows me to have an open mind to the beliefs and cultural practices that patients have; [It allows me to] take these aspects into account to prevent judgments and even to learn from them, from their experience" (Participant 7)

2.3. Self-awareness, cultural awareness, and awareness of benefits

Cultural awareness "Now I understand that all of us, including the patients, grow with different customs, needs, and beliefs, and that all of us belong to a culture and therefore to a different way of seeing diseases and their treatment" (Participant 21)

"[Cultural safety] allowed me to understand that traditional medicine and culture is a lifestyle that has endured in the history of humanity for centuries... Long before the arrival of Western medicine. As a medical student I am biased and on various occasions I have confronted the culture of my patients." (Participant 23)

Self-awareness "I am aware of the paradigms and prior knowledge that I have from my training that can influence my clinical practice; it allowed me to be more empathetic and assertive when interacting with my patients" (Participant 1)

"Participating in this activity gives us a broader perspective; it allows us to realize that often we want to impose our will on the patient" (Participant 3)

3. SUBJECTIVE NORMS

3.1. Positive perception of traditional medicine, respect for patients, and eluding culturally unsafe practices

I respected traditional practices "Now I see the impact that cultural practices have on patients' perception of health. I consider what people say about their beliefs, before I didn't even pay attention to it" (Participant 9)

Avoid culturally unsafe practices "Often we want to impose our will on the patient; they might refuse to follow a treatment because they consider that physicians despise their ideas and culture. On the other hand, understanding and trying to include the patients' culture in the treatment of any pathology could lead to better health outcomes for the patient." (Participant 21)

Classic training "It showed me that one should not reject cultural practices just because they are not part of classic medical education" (Participant 16)

3.2. Biomedical model and evidence-based medicine

"[Cultural safety] taught me that we should not belittle traditional medicine or believe that Western medicine is the truth and the solution to everything." (Participant 23)

"In retrospect, the patient felt that traditional medicine worked for him, even more than the medication he was taking, and I had no right to tell him that traditional practices had no evidence and therefore, he had to stop doing them." (Participant 8)

3.3. Acknowledge benefits of cultural safety training and less ethnocentrism

Ethnocentrism "Because when we find a patient who has a culture with different beliefs from ours, we tend to ignore them; we believe that our culture is correct and we that are right, but [cultural safety training] make us wonder if it really like that." (Participant 21)

"As doctors in training, we often think that only our knowledge is objective and reasonable, but we must open our minds to accept the cultural practices and beliefs of other people and other communities" (Participant 25)

Other physicians don't have time "I think that at another time, I could say that [traditional practices] are absurd. Many doctors only think about imposing their opinion either because they are not interested or because the office time is short; they don't take the time to listen to their patients and much less to discuss with the patient in order to improve their health." (Participant 6)

Overcoming challenges "A situation that previously could have represented an obstacle and a reason for not carrying out treatment is now an opportunity to make the patient feel safe and to prevent judging or discriminating against them." (Participant 13)

"Before it was an unpleasant experience. There were many occasions in which the grandmothers talked about home remedies whose names were difficult for me to understand (I am not from this region); I doubted their effectiveness. Today, those experiences are not unpleasant anymore. I can now learn from the context of my patient, therefore providing better healthcare." (Participant 17)

4. CHANGE INTENTION

"We were overwhelmed by the situation: we had a minor patient who was a member of a community that was different from ours, accompanied by his father who did not allow us to touch his son, did not speak or understand our language. For a moment all that seemed like a barrier, but I remembered what I had learned and decided to try to make the change that I would like to see if I were that patient" (Participant 13)

" I feel that this is what I want to do in my professional practice, to be able to help my patients, understand that traditional medicine is not wrong, and that [cultural safety] can enhance the doctor-patient relationship." (Participant 5)

5. Agency

5.1. Able to accept cultural diversity in health care

"I am able to accept that there are diversity of beliefs and that each one has its cultural and scientific basis. It is a great contribution to our clinical practice." (Participant 26)

5.2. Able to prevent culturally unsafe actions and improve the doctor-patient relationship

"I am able to improve the doctor-patient relationship. I can now create a relationship with patients from different cultures without imposing my thoughts, making judgments, or demeaning my patients and their families." (Participant 7)

"Currently, I am open to recognize and accept the cultural differences that my patients may have. I am always trying not to make them feel judged or discriminated against because of their beliefs or their culture" (Participant 25)

6. DISCUSSION

"I listened to the patients more; we discussed ways to take care of children, comparing things that they believed and had done with things that we knew from our medical knowledge; it helped to improve the connection with patients to ensure proper growth and development of babies. This was quite special because the nursing students who rotated with us also supported our approach, and we learned from each other." (Participant 1)

7. ACTION

7.1. Better communication and relationship with patients and with other health professionals

Better communication, assertiveness, and empathy "I am aware of the paradigms and prior knowledge that I have from my training that can influence my clinical practice; it allowed me to be more empathetic and assertive when interacting with my patients" (Participant 1)

Doctor-patient relationship and between health professionals "I listened to the patients more; we discussed ways to take care of children, comparing things that they believed and had done with things that we knew from our medical knowledge; it helped to improve the connection with patients to ensure proper growth and development of babies. This was quite special because the nursing students who rotated with us also supported our approach, and we learned from each other." (Participant 1)

7.2. Better outcomes for patients, physicians, and society

Patients feel more understood, safe, and cared for, and it humanizes medicine "Things that may seem so simple, but that for someone like the patient in the story, are important things. [Cultural safety] makes people feel safer, understood, and cared for, and they feel the desire to come back to see a doctor who also cares for them; in my opinion, it touches the most human part of medical practice." (Participant 15)

Cultural preservation "The patient was very frustrated by her family situation, but fortunately I was able to calm her down and say that her mother did all this because she loved her and her grandson. I told her that, although all this seemed very strange to her, her mother had years of experience in these subjects [traditional medicine] and that, although we could take care of her using modern medicine, everything that her mother gave her was care that we could not offer. I asked her to please be patient with her mother because she knows her daughter and her culture more than ourselves." (Participant 20)

More knowledge "Because it showed me that one should not reject [traditional medicine] just because it is not part of classic medical education. Taking the time to investigate [traditional medicine] allows gaining important knowledge and developing a better relationship with the patient." (Participant 16)

7.3. Dialogue and integration/balance/consensus between traditional medicine and modern medicine

Balance and integration between traditional medicine and modern medicine "I listened to the patients more; we discussed ways to take care of children, comparing things that they believed and had done with things that we knew from our medical knowledge." (Participant 1)

Dialogue and consensus "The grandmother understood that there are times where they should go to the hospital while I did not prohibit her practices for handling these situations at home. We were able to reach a consensus in which she understands that it is okay to go to the hospital in certain situations and I did not prevent her from continuing to use her traditional practices. Moreover, I learned about a home-made way of managing acute diarrhea" (Participant 7)

"I told her that, although all this seemed very strange to her, her mother had years of experience in these subjects [traditional medicine] and that, although we could take care of her using modern medicine, everything that her mother gave her was care that we could not offer." (Participant 17)

Health care decision-making process "After several minutes explaining what the treatment was, the father accepted and asked us if he could continue giving his son the herbal tea and applying the cream that his wife had prepared with medicinal plants. We asked him what plants they were using. We investigated and discovered that several plants had anti-inflammatory properties. In the end, the agreement was that they had to come to the change of plasters every 8 days, and he could use the remedies. The father felt calmer knowing that he could continue using his own medicines" (Participant 13)

I shared my knowledge and point of view "I was also able to share what was best for the child from my point of view, and when to go to the emergency services to avoid complications in the future, without attacking, scolding or diminishing the traditional practices of the grandmother" (Participant 7)

"They told us that since they arrived in Colombia it had been very difficult for them to find their medicinal plants. They have different names in Venezuela. Therefore, when they had a health issue they had to agree to the use of drugs, which they do not like. The doctor explained the importance of the drugs; however, we also suggest some plants that could be similar to those that they used in his country. She was very pleased with what the medical team had done." (Participant 14)

7.4. I explored and investigated about traditional medicine, and listened and learned from patients

Curiosity about traditional practices "During my Gynecology and Obstetrics rotation at Kennedy's Hospital, it was common in prenatal check-ups to hear from several expectant mothers, talking about the use of *brevo* [medicinal plant] leaf baths. That was totally unknown to me at the time. I knew that *brevo* was the tree where the *brevas* grow [fruits that are traditionally eaten with *arequipe*]. I generally told the moms that the *brevo* baths were not necessary, that they were useless. However, while I was learning about cultural safety, I asked a patient the reason for these baths, to which she replied, 'it is that they serve to be able to start contractions.' After the consultation, I investigated about the remedy and found that indeed the *brevo* leaf is used to start labor. Of course, I only knew of oxytocin and misoprostol, I had never heard of this practice, which as I read has been used since many, many years ago here in Colombia." (Participant 20)

"when we asked the patients about traditional remedies, many told us about how drinking *hinojo* [fennel] tea increase milk production." (Participant 9)

I learned about traditional medicine "I was able to learn something that is not found in the so-called "evidence " upon which medicine is based so much today. I learned about a traditional practice passed down through generations" (Participant 7)

"I am now more willing to listen to the patients regarding the way they understand disease, what they have, and what they believe help them and does them good. In this way, I have also been able to learn from them and their traditions." (Participant 15)

"We were able to reach a consensus in which she understands that it is okay to go to the hospital in certain situations and I did not prevent her from continuing to use her traditional practices. Moreover, I learned about a home-made way of managing acute diarrhea" (Participant 7)

I investigated about the cultural context "A month ago, while rotating in the children's orthopedic department at the Roosevelt Institute, a 13-year-old patient from an Indigenous community came to us. They are the *Piapocos* and their community is located between the *Meta* and *Guaviare* rivers [...] The first thing I did was investigate a little bit about that community, about their beliefs, traditions, how was their organization. I wanted to know how to best approach them." (Participant 13)

I investigated about traditional medicine "Six months ago, when I was rotating in the general surgery department at the University of La Sabana Clinic, a patient came with an ulcer that was being treated with honey. At first, I thought it was not the ideal management, however reading about cures I found that honey has many properties that help wound healing" (Participant 16)

Subcomité de investigación, Facultad de Medicina, Universidad de La Sabana



Departamento de Bioética Facultad de Medicina

> Subcomisión de investigaciones Evaluación de proyectos

	2019
TITULO DEL PROYECTO	Seguridad Cultural en la Educación Médica: Impacto del co-diseño de juegos educativos en Colombia / Protocolo de Tesis doctoral
INVESTIGADOR	Dr. Juan Pablo Pimentel
PRINCIPAL y Co-	
investigadores	

Sobre el proyecto presentado, como responsable del examen bioético del mismo, me permito hacer los siguientes comentarios:

- Se trata de un proyecto sobre seguridad cultural que se propone 1. Revisar la experiencia existente de juegos educativos para el entrenamiento en seguridad cultural, 2. Desarrollar un currículum co-diseñado para el entrenamiento en seguridad cultural, 3. Explorar la factibilidad y aceptabilidad de educación basada en juegos para el entrenamiento en seguridad cultural y 4. Evaluar la efectividad del co-diseño de juegos educativos para el entrenamiento en seguridad cultural.
- Con relación a la metodología propuesta y atendiendo a la Resolución 8430/93 vigente, se determina que el proyecto se clasifica como una investigación sin riesgo.
- Se ha evaluado el Consentimiento informado y se encuentra redactado de forma satisfactoria, acorde con los lineamientos del protocolo y las exigencias éticas mínimas para la investigación en seres humanos.
- 4. El protocolo y sus anexos tienen Visto bueno.

Atentamente,

Pedro J. Sarmiento M.MD Ph.D Departamento de Bioética.



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