

Title Page

Title Project: Development and Dissemination of an Online Tobacco Cessation Training Program for Healthcare Professionals in three Spanish-speaking Latin American countries: the Protocol of the Fruitful study

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Inclusive Dates: 10/1/2014 to 10/1/2016

Grant Number: Request ID: 13520139

Abstract:

Background: Tobacco cessation training programs to treat tobacco dependence have measurable effects on patients' smoking. Tobacco consumption in low and middle income countries is increasing, but these countries usually lack measures to face the epidemic, including tobacco cessation training programs addressed to their health professionals and organizations. Based on a previous online smoking cessation training program for hospital workers in Spain, the Fruitful Study aims are twofold: 1) to adapt the course to the reality of three Spanish-speaking low and middle income countries (Bolivia, Guatemala, and Paraguay) and; 2) to evaluate the effectiveness of the program among the participant hospitals and workers.

Objective: Evaluate the implementation process and the effectiveness of an online evidence-based tobacco cessation training program aimed to increase smoking cessation knowledge, attitudes, self-confidence, and performance interventions among health care professionals of three Spanish-speaking low and middle income Latin American and Caribbean countries.

Methods/design: Mixed methods design with a pre-post evaluation (quantitative approach) and in-depth interviews and focus groups (qualitative approach). The main outcomes will be 1) participants' attitudes, knowledge and behaviors before and after the training and 2) the level of implementation of tobacco control policies within the hospitals before and after the training.

Results: The study is currently underway. The study started in November 2014, and evaluations will finish in November 2016. Results are expected by the beginning of 2017 and will be reported in two follow-up papers (one about the implementation process and the other about the outcome evaluation).

Conclusions: This study will show whether it is possible to adapt an online smoking cessation training program to the reality of developing countries. In addition, we will measure whether the training program will increase knowledge, attitudes and perception in tobacco cessation among participants and will produce changes in tobacco control policies at the organizational level. The methods and results of Fruitful study may offer a new approach to adapting programs to LMICs countries in order to offer education solutions with the use of the emerging and growing communication technologies.

Keywords: tobacco cessation; on-line; training; low and middle-income countries; policies

Ethical approval was obtained from the ethics committee of the ICO-IDIBELL PR 338/15 (Comité Ètic d'Investigació Clínica de l'Hospital Universitari de Bellvitge) and the study protocol has been registered under Clinicaltrials.gov (NCT02718872 approved the 19th of March 2016).

Introduction

Purpose and Scope

Tobacco use remains a global public health concern; annually it causes 6 million deaths that could be preventable [1]. The tobacco consumption epidemic is shifting to low and medium income countries such as the ones in the Latin American and Caribbean (LAC) region [2]. Currently, more than 120 million smokers live in these countries [3]; half of them will develop a tobacco-related disease, and consequently, they will require medical care.

In the LAC region, smoking rates vary by country, sex and socio-economic status [4, 5]. In some low income countries, such as Bolivia, Guatemala, and Paraguay, smoking rates are 10 percentage points higher than the rest of LAC countries [6]. Thus, among men, smoking prevalence ranges from 42% (in Bolivia) to 22.9% (in Paraguay) [7]. Among women, the prevalence is lower, but it is rapidly increasing, confirming the alarming feminization of the epidemic in LAC countries [7]. In the overall region, smoking-related mortality accounts for 16% [7], and according to WHO, smoking-related deaths will increase by 700% by 2030 [8].

Despite the magnitude of the epidemic, smoking can be tackled by applying the tobacco control measures embraced by the WHO Framework Convention on Tobacco Control (WHO-FCTC) [9]. These measures have demonstrated the reduction of tobacco use and the increase of awareness of its hazards [9]. Guatemala, Paraguay, and Bolivia signed the WHO-FCTC early on, and have implemented some tobacco control measures, including smoke-free legislation (according to the WHO-FCTC Article 8) in workplaces and public places, including health care services. However, smoking cessation services (Article 14) have not received the same recognition and attention [5]. In consequence, smoking cessation interventions are not well spread among health care services within these countries. Smokers are frequent users of health care services, and their contact with the health system might be an adequate “teachable moment” for quitting [10]. In fact, between 60% and 70% of patients make an attempt to quit while they are hospitalized [11]. However, in spite of these favorable conditions, evidence-based cessation programs are hardly available in LAC countries [12]. The most common barriers to incorporating tobacco cessation interventions into hospitals involve lack of training, expertise, and time. In addition, organizational and financial constraints threaten the suitability of smoking cessation interventions [6].

In LAC countries smoking consumption among healthcare professionals is still similar to that of the general population [13, 14]. And most doctors and nurses acknowledge that they have not received formal training in smoking cessation during undergraduate nor graduate education [14]. Generally, they state little confidence in its effectiveness to help their patients to stop smoking. In consequence, given that about 70% of smokers visit health services over the course of a year, the lost opportunities to intervene remain significant. Frequently, providers believe that smoking cessation is extremely important, but also extremely difficult due to a serious communication gap between doctors and patients, that jeopardizes the opportunities to support smokers to quit [15].

Smoking cessation interventions to help smokers quit are effective [16]. A Cochrane review points out that training health professionals to treat tobacco dependence has measureable effects on patients' smoking, continuous abstinence, and professional performance [17]. Therefore, evidence-based programs have the potential of increasing delivery of tobacco cessation treatments to smokers. Implementation research recommends to address the organizational constraints in order to overcome the executive barriers when the cessation messages are delivered [18-20]. So, training programs obtain higher impact and sustainability when they are fostered by organizations that allocate time, promote key champions, and provide implementation materials and resources [20]. In brief, tobacco cessation training programs supported by health organizations provide a unique arena for impacting professional norms and increasing access to tobacco cessation in healthcare services.

In the literature, there are several conceptual training models that exhibit a significant heterogeneity [21]. Among them, online courses allow distance-learning, are more cost-efficient, and provide modes to teach and reinforce counseling skills that often can be difficult to convey in the traditional classroom setting [22, 23]. Previous online tobacco cessation training courses have demonstrated an increase in the health providers' skills to counsel patients on tobacco cessation [17, 24, 25]. Although there are several distant learning tobacco cessation training programs the majority have been developed and evaluated in Anglo-Saxon countries. A recent review on online tobacco dependence treatment training programs – all in English- found that 17 out of 24 courses evaluated failed to meet minimal quality standards. Authors suggested improving institutional design elements, such as teaching effectiveness, learning strategies, instructor's role and assessment and evaluation [26].

Using previously established programs can save time and money while increasing the likelihood of achieving successful outcomes [27]. In addition, research training initiatives

have been suggested to increase capacity-building efforts, in particular within developing countries [21]. However, the evidence of distant learning training from high income countries (HICs) may not be directly applicable to low and middle income countries (LMICs) and need cultural and content adaptation. Research is needed to develop and understand how best implement effective smoking cessation strategies in LMICs, especially in resource-poor environments where access to health care providers are limited.

Theory

Adaptation implies not only the replication or translation of a program. It is the process of adjusting a program to reduce mismatches between its characteristics and the new context in which it is to be implemented. Adapting a tobacco cessation education program should take into account the treatment regulation of each country, the existence guidance and proceedings, and the dynamics of the health organizations [3]. Card et.al propose science-based pragmatic steps to adapt an existing program to new contexts [27], based on the following steps: 1) select a suitable effective program; (2) gather the original program materials; (3) develop a program model; (4) identify the program core components and best-practice characteristics; (5) identify and categorize mismatches between the original program model or materials and the new context; (6) adapt the original program model, if warranted; and (7) adapt the original program materials. To fill the gap of the lack of tobacco cessation training programs in Spanish speaking LAC countries, we designed the “Fruitful project”.

Prior work

We selected the ongoing “Brief Intervention for Smoking Cessation Training Program” from the Catalan Institute of Oncology (ICO) as the beginning point. So, we created a partnership between ICO and three hospitals from Bolivia, Paraguay and Guatemala to first adapt and later disseminate the course. We intend to increase the capacity building of the implicated organizations that ultimately will initiate a cascade of change within their countries [29]. Our training is intended to a vehicle for systematic dissemination of the clinical practice guidelines for treating tobacco dependence in hospitalized and ambulatory smoker patients.

The aim of this paper is to describe the “Fruitful Project” (Desarrollo y Difusión de Formación para Dejar de Fumar en Latino América) a project to adapt, disseminate and evaluate an online evidence-based tobacco cessation training program.

Research objectives of the project

The primary research goal of the “Fruitful Study” is to evaluate the impact of an online evidence-based tobacco cessation training program aimed to increase smoking cessation knowledge, attitudes, self-confidence, and performance interventions among health care professionals of three Spanish-speaking LMIC LAC countries (Bolivia, Guatemala, and Paraguay).

In addition, the study will include a process evaluation approach by measuring the curriculum adoption, delivery, and maintenance.

Hypothesis

The participants in the online tobacco cessation training program will increase their tobacco-related knowledge, attitudes, and behaviors by the six-month follow-up, as compared to baseline conditions prior to the training.

Our secondary hypothesis poses that participant hospitals in the project will exhibit greater tobacco control progression, commitment, and implementation of tobacco cessation services.

Methods

Study Design

The Fruitful project is a two-year mixed methods (qualitative and quantitative) study conducted in one hospital in each of the three participant countries (Bolivia, Guatemala, and Paraguay).

Quantitative methods: pre-post design.

- To assess participants’ attitudes, knowledge and behaviors before and after the training using a questionnaire (Tool 1).
- To measure level of implementation of tobacco control policies within the participant hospitals before and after the training by using the Selfaudit questionnaire (Tool 2).

Qualitative methods: by using a focus group and in depth interviews of participants and key person.

- To explore the experience of adapting the training program in each of the participant hospitals.
- To ascertain participants' experience undertaking the training program.
- To understand the opportunities and barriers of undertaking online smoking cessation training programs in the participant countries.

Participants

Participants will all be health professionals and paraprofessional staff from the three participant hospitals. All health providers in the selected hospitals, including nurses, doctors and other health professionals, will be trained. Therefore, there are two units of participation, hospitals and health professionals from each organization. Each local coordinator will recruit participants from a variety of units and departments over 6 months through informative sessions, leaflets and posters (designed to inform about the training program).

Procedure and timeline

a) Select a suitable effective training program

The selected original training program has been chosen because it has been shaped using evidence-based guides, it was originally designed for Spanish hospitals - culturally and organizationally similar to LAC hospitals-, and is addressed to hospital workers. Furthermore, offering the course through an online platform network will reduce the cost but increase the training coverage within participant hospitals in less time.

The original course had been developed in the online platform e-oncologia (<http://www.e-oncologia.org/en/>) based on the in-person courses offered during the last 10 years by the Tobacco Control Unit of the Catalan Institute of Oncology. The theoretical framework underpinning the training program is the Stages of Change Model [30] and the curriculum was developed with the content of numerous meta-analysis and clinical practice guidelines [17, 31-34] (Figure 2). We created a fully referenced curriculum online, with feedback from an expert advisory group that oriented in the instructional design to ensure the course content

was palatable for an online format and aligned with the learning objectives. The goals and program components (strategies, activities, services, etc) are depicted in Figure 1. The final curriculum content of the “Brief Intervention for Smoking Cessation Training Program” is composed of 4 modules:

- Module 1 describes the tobacco epidemic, tobacco-related morbidity and mortality, second hand smoke, and measures included in the MPOWER strategy to tackle smoking.
- Module 2 provides orientation on how to assess the smoker, how to assess tobacco dependence, willingness to quit, evaluate smoker self-efficacy, previous quit attempts, previous relapses, and so on.
- Module 3 introduces the efficacy of the different levels of attention and treatment orientations (e.g, cognitive behavioral, psychodynamic, medication management) and presents the clinical settings where the intervention is possible (e.g, inpatient, outpatient, ambulatory treatments). It explains in detail the 5As intervention model.
- Module 4 explains in detail the different tobacco cessation treatments available (nicotine replacement, bupropion, varenicline, and other treatments). It also provides orientation about the follow-up, strategies to improve the adherence of the treatment, how to identify withdrawal symptoms, how to deal with relapses, and so on.

This online training includes: a) slides, b) review exercises, c) cases of 4 patients differing in demographics, diagnostic, stages of change, setting, and d) problem solving exercises. The training provides several materials including slides, online tutorials with an expert tutor, recommended readings, patient cessation brochures, and a therapeutic pocket guideline, and an organizational recommendation model to facilitate the implementation of tobacco cessation services in the hospital setting.

The original online course was firstly tested by 10 voluntary participants in Spain. Evaluation of the tobacco cessation program was thereafter tested in a Spanish hospital by 150 health professionals. This pilot test proved the acceptability of this training model, the adequacy of its contents, and obtained a high level of satisfaction in the trainees. Training initiatives have proven to increase the level of implementation of tobacco control in hospitals (according to the Selfaudit questionnaire) [35, 36] and the engagement of health professionals [37, 38], making them part of the epidemic solution. Since its launch in November 2012 to June 2014 more than 1000 Catalan health professionals had undertaken this course.

b) Adaptation of the material:

The adaptation has been done with local partners and other stakeholders. First, a group of professionals with extensive experience in tobacco control in their country were selected for identifying and categorizing mismatches between the original materials and the new context. Experts expressed that the goal and objectives were aligned with the original program model (Figure 2). However, we detected mismatches that included:

- Language background and literacy level in some of the terms used: the course was in Spanish from Spain, and the Spanish spoken in Bolivia, Guatemala and Paraguay differs somewhat with respect to vocabulary, some expressions, and in some cases even in grammar structures;
- Description of the epidemiology smoking in Model 1: the original version included the situation in Spain, whereas the adapted version included the most updated data in Bolivia, Guatemala and Paraguay;
- Tobacco cessation pharmacological treatment in Module 4 (NRT, bupropion, varenicline) and settings where tobacco prevention and cessation services are performed in Spain (primary care, hospitals, quitlines, etc), were adapted to the current resources in each country;
- In case studies, clinical simulations and demonstrations the cultural characteristics of each country;
- Questions and answers of the assessment and evaluation were also changed according to the adapted contents;

Once the mismatches were detected by the group of experts, they were modified in a version that was pilot-tested by 8 to 10 volunteers in each country.

c) Implementation

This project will be undertaken in 24-months (from November 2014 to November 2016). Information of the activities is depicted in the event planning timeline (Figure 3).

Each participant has one month to fill in the baseline evaluation, complete the online training, and take the exam. Participants are monitored by local coordinators that act as champions. They offer their assistance to log into the online platform, fill out the questionnaires, complete the evaluation, including other technical support. Participants' progress is monitored in real

time onto the web platform. The project coordinator at ICO sends a report of the participants progress every other week to coordinators, and if necessary personal emails to motivate students to finish the course and complete the evaluations.

Participants can access the course by using their electronic devices (cell phone, tablet or computer) or the ones provided by their hospitals during and after working shifts.

d) Evaluation Design: Process and Outcome evaluation are planned

Process Evaluation

The process evaluation will assess the adoption, implementation and maintenance of the training program. We will measure the program coverage, the compliance, the fidelity with the training program, the usage of the materials and the satisfaction with the training. We will use qualitative and quantitative methods to gather this information.

Indicators linked to the performance of the program:

- Number of participants.
- Characteristics of the participants (profession, units, sex, age).
- Number of hours dedicated to the training program.
- Program performance/Fidelity to the curriculum plan (whether the students completed all the modules, the exercises as planned).
- Service utilization or dosage use of the training (time applied for undertaking the course, number of downloads of the materials, etc).
- Opinions, experience, perceptions, satisfaction with the training course.

Outcome evaluation

The quantitative evaluation will measure short and intermediate outcomes measuring the impact of the “Smoking cessation training program” within the participant hospitals.

- Level of implementation of tobacco control policies within the participant hospitals before and after the training by using the Selfaudit questionnaire (Q1).
- Participants’ attitudes, knowledge and behaviors before and after the training using a questionnaire (Q2).

Instruments:

Tool 1: To assess differences in tobacco control policies implemented within hospitals we will use the ENSH Selfaudit Questionnaire (SAQ) [35]. This tool was developed for the ENSH-Global Network for Tobacco Healthcare Services. The questionnaire is composed of 10 policy standards and each standard contains a number of items for its definition: commitment (6 items), communication (4 items), education and training (4 items), identification and cessation support (8 items), tobacco control (5 items), environment (6 items), healthy workplace (5 items), health promotion (1 item), compliance monitoring (2 item), and policy implementation (1 item). Each item is scored as follows: 1=not implemented, 2=less than half of the aspects are implemented, 3= more than half are implemented, 4= fully implemented. The maximum score of the ENSH-SAQ is 168 points, as the sum of its 10 standards [35]. At baseline, the SAQ provides information on the tobacco control policies undertaken within the organization. Once it is used to monitor the project, the instrument detects the fulfilled standards and the areas for improvement.

Tool 2: Trainers' attitudes, knowledge and behaviors will be assessed by using a questionnaire composed of 63-items. The web-site delivered questionnaire is e-mailed to the participants at baseline and 3 months after finishing the training. The questionnaire takes 30-40 minutes to complete. It has been designed according to Sheffer work [39]. The questionnaire gathers information about the provider sex, tobacco use history, previous tobacco cessation education, level of proactivity addressing tobacco use, and perceived success in helping patients stop using tobacco [39]. Perceived knowledge and attitudes about treatment of tobacco use assessed including levels of: 1) motivation, 2) knowledge about tobacco cessation, 3) self-efficacy, 4) importance of providing tobacco use interventions, 5) effectiveness of interventions, 6) importance of barriers, 7) readiness, and 8) level of tobacco cessation intervention provided (assessed by the 5A's model). All items are assessed on a discrete scale of 0-10 with 0 being "none or not at all" and 10 being "the most possible". The pre-test will be administered immediately prior to the training. Post-training assessment is composed of a 37-item questionnaire assessing providers' knowledge, attitudes and behaviors as assessed in the pre-test.

Statistical analysis

For quantitative indicators we will use descriptive statistics. Quantitative variables will be summarized by using means and other central tendency measurements and qualitative data will be summarized by computing their frequencies and percentages. The qualitative indicators gathered by qualitative methods (focus groups and interviews) will be summarized by using the classical content analysis approach (creating codes and chunks of information and the researcher complements the codes with description of this code. Analysis of the data will be validated by informants to increase the reliability of the data [40].

Analysis plan: Usual statistics will be used to describe the sample and non-parametric test will be used for pre -post comparisons for tobacco control policies (measured by T1) and the trainees' knowledge, attitudes and behaviors (measure by the T2).

Sample size

As we expect an increase of 40% difference in health professionals' level of knowledge, attitudes and perception in tobacco cessation at 6-months, we will need a minimum of 43 subjects per hospital (overall 129) (criteria: alfa error=0.05 beta=0.1, 15% dropouts) . However, we expect at least an overall enrollment of 300 professionals (100 for each hospital).

Results

At the time of submission of this paper, data collection was underway. Evaluations will finish in November 2016. Results are expected by the beginning of 2017 and will be reported in two follow-up papers (one about the implementation process and the other about the outcome evaluation).

Discussion

Expected principal results

We will consider a good level of coverage of the training program if at least 50% of the enrolled health professionals in each hospital conclude the training program. We will measure the engagement of the training program with the focus groups and key informants interviews.

Besides this, we anticipate that hospitals will increase their tobacco control policies by between 20-30% according the SAQ. In addition, we anticipate that health professionals' level of knowledge, attitudes and perception in tobacco cessation will increase between 30-40%.

Expected Limitations and Strengths

Health professionals and paraprofessional staff from the three countries will be invited to voluntarily participate in the project and it can be discussed whether the recruitment process applied by each coordinator can affect both the number of participants recruited and the commitment to start and finish on time. We hypothesize that as they agree to join, they are highly motivated to pursue the course and we expect many of them to succeed on their own. However, participants might have a different level of computer skills and Internet usage that could affect their course enrollment and progression. Online training programs also require devices for its use- for instance computers, tablets or smart-phones, etc- and high speed Internet connection. Although the Internet service and technologic devices are rapidly growing in low-income countries [41] it may not be the same than in HICs. Nevertheless, the course could be followed by all these kinds of platforms facilitating the connectivity among users (tablets, smart-phones) being able to complete the training program at their homes or in their working hospitals. We foresee that many of our students will be using cell phones as primary access to the course, because of the high accessibility to mobile phones in these countries in comparison to computers [41]. Furthermore, the participants could have different knowledge in smoking cessation interventions within participant hospitals and among the different countries. This could make comparison among participant countries very stimulating. The fact that we included baseline and post intervention evaluations will permit evaluation of these differences.

Comparison with Prior Work

Tobacco use is rapidly increasing in low-income LAC region such as Bolivia, Guatemala and Paraguay. Tobacco cessation services have been poorly implemented so far in these countries [5] mainly because the lack of knowledge and skills of health providers, difficulty to ground tobacco cessation interventions in healthcare organizations, and lack of working groups and leaders on this topic [6]. Online education in tobacco cessation might be the solution to provide evidence-based treatment for tobacco dependence in these countries because it is cost

efficient, and can reach remote locations. Most of the existing smoking cessation training programs have been designed in HICs [26]. Nevertheless, the process of spreading new learning approaches requires cultural and content adaptation that implies reviewing whether the material, the examples, etc are applicable to the new target group [42]. To our knowledge this is the first study that tests the feasibility and effectiveness of implementing online smoking cessation training program addressed to health care providers in Bolivia, Guatemala and Paraguay. The methods and results of Fruitful study may offer a new approach to adapting programs to LMICs countries in order to offer education solutions with the use of the emerging and growing communication technologies.

Conclusion

This study will show whether it is possible to adapt an online course to the reality of developing countries. In addition, we will measure whether the training program will increase knowledge, attitudes and perception in tobacco cessation among participants and will produce changes in tobacco control policies at the organizational level.

List of Publications and Products:

- Online course adapted into the reality of 3 countries (online platform and pdf material)
- Leaflets and Posters designed to enroll students into the course
- Publication of the research protocol in the Journal of Medical Internet Research
- We have gathered baseline and post training surveys of student participants
- We have gathered baseline and post evaluations on tobacco control policies in the participant hospitals
- We have conducted 5 focus groups in each participant organization (total of 15 groups)
- Pending of publishing 2 papers (one qualitative and one quantitative)
- Publication of 4 post on the Global Bridges Blog (www.globalbridges.org) and the Tobacco Control Unit Blog (<https://tobaccorelated.org/>) in Spanish and English
- Participation and dissemination of the project in 3 conferences (Mayo Clinic in May 2016, ENSP Conference in October 2016, ECToH Conference in March 2017)

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Abbreviations

WHO-FCTC: WHO Framework Convention on Tobacco Control

LAC: Latin American and Caribbean

HIC(s): High income country/(ies)

LMIC(s): Low and middle income country/(ies)

Acknowledgements

We thank the group of hospital coordinators for their assistance in the implementation of this training project (Liz Soraya Pérez, Julio Poiqui, Maria del Camen Guzman, Noelia Cañete, Eduardo Gharzouzi, Joaquin Barnoya, Wendy Yantuche, and Victor Samayoa). Finally, we want to thank Cris Rajo for her help during the design process of this research protocol.

Declaration Section

Ethics approval and consent to participate

Ethical approval was obtained from the ethics committee of the ICO-IDIBELL PR 338/15 (Comité Ètic d'Investigació Clínica de l'Hospital Universitari de Bellvitge) and the study protocol has been registered under Clinicaltrials.gov (NCT02718872 approved the 19th of March 2016). The Catalan Institute of Oncology, as main partner of the research consortium requested to its partners the signature of a research collaboration agreement to assure their commitment with the activities and plans. In the agreement was detailed that "each of the parties will use all reasonable endeavors to obtain ethical licenses, consents and approvals necessary to allow it to carry out the tasks allotted to it". The three participant hospitals: (1) Instituto de Oncología de Bolivia del Este (Bolivia), (2) Hospital del Cáncer Dr. Bernardo del Valle (Guatemala) y (3) del Instituto Nacional de Enfermedades Respiratorias y Medio Ambiente (INERAM) (Paraguay) obtained the approval of their organizations and signed the agreement. All the above bodies represent no conflict of interest with the project. Participants are volunteers and are informed that they are testing an online course pioneered in their country. All data will be stored anonymously with only the ID-code and the analysis will be made only at group level.

Consent for publication

“Not applicable”

Availability of data and material

The datasets analyzed during the current study available from the corresponding author on reasonable request.

Competing interest

The authors declare no other competing interests. The project is funded by a grant from Global Bridges (Pfizer Medical Group; GB-13520139, see funding). The study protocol has undergone peer-reviewed by the funding body.

Funding

This study has been funded by Global Bridges Mayo Clinic (Pfizer Medical Group; GB-13520139: Development and Dissemination of a Tobacco Cessation Training Program for Healthcare Professionals in Spanish-speaking Countries). Moreover, CM and EF are also funded by the Spanish Government (Instituto de Salud Carlos III, grant PI15-00875) and the Catalan Government (Xarxa Catalana d'Hospitals sense fum, Agència de Salut Pública de Catalunya, contracte N° 2015VAR171)

Authors' contributions

Dr. Martinez and Dr. Fernández conceived the project. Dr. Martínez coordinated the contents of the program. Dr. Fernández and Dr. Company have co-designed the study, overseen the training content, and will supervise the day to day activities. O Guillen and M Margalef will manage technical support with the online platform. Dr. Arrien, Dr. Sánchez, Dr. Cáceres are the project leaders in their hospitals and responsible for advancement in the project activities as scheduled.

Authors' information

We declare that the manuscript is original and it is not submitted anywhere other than the JMIR- Journal of Medical Internet Research. The last version of this manuscript has been approved by all authors and by the responsible authorities where the work is being carried out.

