

A mHealth Intervention to Prevent Smoking Relapse After Pregnancy (RESPREMO)

*Scientific Report
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I. Scientific Foundation

Tobacco cigarette smoking remains the leading global cause of preventable disease and death killing nearly 6 million people each year, with most of these deaths occurring in low- and middle-income countries such as Romania (1). Maternal smoking is one of the most modifiable factors clearly linked to adverse effects for the fetus and the baby (2). Preconception and pregnancy smoking are high in Romania and there is a need for local adaptations of tobacco interventions (3, 4, 5). Prior research estimated a smoking prevalence rate among Romanian women during preconception of up to 41% (3, 4), with approximately half quitting upon finding out about the pregnancy or early in the gestational period.

A significant problem, and the focus of this project, is that up to 70% of women who quit resume smoking after birth, with the majority relapsing in the first 3 months postpartum (6). Birth and infancy represent a window of opportunity to prevent smoking relapse among mothers who quit during or before pregnancy.

The theoretical relapse prevention model (7) and mobile technologies in recent years (110% penetration rate in Romania) (8) offer the possibility of low-cost, novel, innovative mobile phone based intervention approaches for smoking relapse prevention (mHealth) (9).

Mobile phones offer a virtually unused opportunity to deliver customizable tobacco cessation interventions, particularly relevant in low and middle income countries characterized by underfunded and understaffed health systems. mHealth intervention benefits include scalability to large populations, regardless of location; the ability to tailor content to key user characteristics (such as motivation, self-efficacy, demographics); the ability to send time-sensitive messages; the delivery of content that can distract the user from cravings. Mobile phone access, mainly to smart phones, is increasing exponentially across the world, surpassing fixed telephone lines, and fixed computers (10). Smoking cessation services in developed countries are increasingly using mobile phones to deliver smoking cessation support, mainly via text messaging integrated into routine clinical practice.

Factors which can negatively influence women's decision to remain smoke-free are their motivation and the existence of a life partner who smokes (7). In Romania, 80% of smoking pregnant women have life partners who are active smokers (1). Preliminary work suggests that couple-oriented interventions, with a particular focus on the dyadic efficacy for smoking cessation

(11) may be successful in preventing smoking relapse. The theoretical relapse prevention model suggests that effective programs for preventing postpartum smoking relapse need to combine 1) enhancing the motivation to maintain abstinence with 2) developing the self-efficacy to do so, as they capitalize on the quitters attempt to stay smoke free. However, most current interventions in the general population focus on only one of the two components. The only relapse intervention combining the two components, the Motivation and Problem Solving (MAPS) intervention approach, applied specifically to pregnant and postpartum women in the United States, showed promise among women who spontaneously quit during pregnancy (11).

Despite their increasing number (12), most mHealth smoking cessation applications do not follow clinical guidelines (13), do not draw on behavioral change theories, include only text messages (14), and extremely few have been implemented in low and middle income countries such as Romania where tobacco control policies may not be strong (15).

Thus, the long-term goal of my research program is to develop, implement, and disseminate effective and sustainable interventions to prevent and reduce smoking in families over their reproductive life span. The purpose of this application is to adapt, enhance, and test the implementation feasibility and efficacy of an evidence-based pregnancy and postnatal smoking relapse pilot mHealth intervention. The specific objectives of the project are:

- ✓ To develop an adapted and enhanced mHealth couple intervention to prevent postpartum smoking relapse based on the iCoach mobile application enhanced with SMS-delivered MAPS-based content.
- ✓ To conduct a pilot-test-scale randomized controlled trial (RCT) of the intervention.
- ✓ To examine in the pilot the implementation feasibility and initial efficacy in reducing maternal smoking relapse, with secondary hypotheses regarding spousal cessation and reduction.

II. Objectives of the project for July-December 2017

The objectives of the project for July-December 2017 were:

- ✓ The development and pretesting of the mHealth intervention
- ✓ The dissemination of the project and its results

All the objectives and activities of the project have been met, according to the contract. Their associated activities will be described below, as follows:

III. The activities of the project for 2017

1. Translating the iCoach application in Romanian

The initial version of the iCoach was received from the developers and it has been translated and adapted in Romanian by the research team. The application contained three main sections: "Daily tips" (around 630 items), containing information regarding the benefits of smoking cessation, "Panic tips" (around 100 items) that can be accessed when there a desire to smoke arises and "Library" (around 120 items), where users can find detailed information about the topics from the above two sections.

Thus, Activity 1.1. *Translating the iCoach application in Romanian* from the Project Implementation Plan was accomplished. The verifiable result of the activity is the *translated content of the iCoach application*.

2. Developing the text messages that will supplement the iCoach application, to be used in the clinical trial phase of the project

The process of developing the SMSs used in the RESPREMO SMS based intervention involved three steps. These three steps helped us develop the categories of SMSs, the objectives we want to reach with each SMS sent to participants and to inform the content of SMSs.

In *Step 1 – Tailoring SMS content* – based on previous literature and on the support received from MI specialist Dr. Ken Resnicow, we established six categories that tailored the SMSs participants receive: (1) Importance and confidence, (2) Fears of relapse, (3) Partner support, (4) Breastfeeding, (5) Urges/Withdrawal, and (6) Lapse/Relapse. Using these six categories, we will build a profile for each participant and send SMSs based on the participant's profile.

In *Step 2 - Theoretical framework* – we review the theoretical underpinnings of the proposed intervention. This first step contributed in establishing the objectives we want to reach with the SMS content. Four main objectives were established, based on previous literature: (1) support motivation, (2) support self-efficacy, (3) support dyadic efficacy and (4) develop problem solving skills.

In *Step 3 - Reviewing the PRISM counselor's registry* – we used the counselor registries developed in the PRISM study. Based on counselors' notes we informed to content of SMSs by using participants' reported information for the above established objectives, as follows:

<i>Concepts based on the MAPS theoretical framework</i>	<i>Information from PRISM counselor's registry</i>
Motivation	Triggers women report increased their motivation
Self-efficacy	Aspects helping women increase their self-efficacy
Dyadic efficacy	Mechanisms for partners' support
Problem solving	Situations women report having a high risk for smoking relapse Coping behaviors reported by women to help them resist smoking temptation

Thus, *Activity 1.2. Developing the text messages that will supplement the iCoach application, to be used in the clinical trial phase of the project* from the Project Implementation Plan was accomplished. The verifiable result of the activity is the text messages repository.

3. Pretesting of the iCoach application and text messages and their adaptation

For pretesting the two components of our research project, the mobile application and the text messages, we first developed the necessary documents: the standard operating procedures manual, the informed consents, the eligibility register and the semi-structured interview guide.

The interview guide was divided into three sections: the first section of questions was about women and their experience with smoking cessation, the second one was based on the mobile application, and the third section contained specific questions regarding the text messages developed within the project.

The data needed for the pre-testing was collected from mothers who recently gave birth and quit smoking before or during pregnancy, after we signed collaboration agreements/contracts with two obstetrics- gynecology clinics in Cluj - Obstetrics- Gynecology 1 Clinic (5 interviews) and Obstetrics-Gynecology 2 “Dominic Stanca” Clinic (7 interviews).

The results of the pre-testing phase helped the research team to develop the mHealth intervention according to the data that the women offered during the face-to-face interviews (10 interviews) and the phone interviews (2 interviews)

Thus, Activity 1.3. - *Pretesting the iCoach application and text messages and their adaptation* – from the Project Implementation Plan was accomplished. The verifiable results of this activity are the semi-structured interview guide, the database with qualitative information (BD_mHealth Intervention Testing_2017) and the activity report associated with this activity.

4. Dissemination of the project

The second objective for this year was to disseminate the RESPREMO project by developing, updating and maintaining the project’s web site online, as well as by having three oral presentations within three scientific manifestations. These three oral presentations in the three scientific manifestations were not included in the project implementation plan and were not funded from the financial resources of the project (e.g. travel costs, participation fee, etc.).

During this reporting period, the team developed the project website (both in Romanian and in English), hosted on the website of the Department of Public Health, Faculty of Political, Administrative and Communication Sciences, Babes-Bolyai University. This page contains the project title and logo, a brief description of the project and its implementation methodology, the list of materials and tools developed as part of the project implementation process, and details of the implementation period and the name of the funding institution. The web page also contains a description of the project team and a specific section dedicated to Publications. This section will be updated periodically by the project team with the scientific reports developed within the project, the presentations at the scientific conferences that the team members are going to have, as well as the articles published based on the data gathered during the project.

The Romanian page can be accessed [here](#) or by clicking the http://publichealth.ro/index.php/respremo_ro/ link, and the English page can be accessed [here](#) or by clicking the http://publichealth.ro/index.php/respremo_en/ link.

Moreover, the preliminary results and the experience of implementing the RESPREMO research project have been described within three oral presentations held at three scientific manifestations, as follows:

- ✓ A rapid review on the development and pre-testing of mHealth interventions. Transylvanian International Conference in Public Administration Conference (Cluj-Napoca, November 2-4 2017)
- ✓ Good practices in developing mHealth interventions: A case study on a mHealth intervention to prevent smoking uptake after birth. Nutrition – Medicine of the Future Conference 2017 (Cluj-Napoca, November 23-24 2017)
- ✓ A couple mHealth intervention for prevention of smoking relapse after pregnancy: The RESPREMO study design. Meeting the Future in Healthcare Innovation Conference (Cluj-Napoca, December 15-16 2017)

As a result of the activities described above, *Activity 1.4. Dissemination of the project* from the Project Implementation Plan has been successfully accomplished. The verifiable results of the activity are the *project's web page and the three oral presentations of the project, held at scientific conferences.*

III. Conclusions

During July-December 2017, the research team carried out the project's Phase I, namely the development and pretesting of the mHealth intervention. More specifically, the research team members have signed collaboration agreements with the two partner clinics of the project, translated the content of the iCoach application into Romanian, developed the text messages repository and the necessary tools for pretesting the application and text messages (the project's standard operating procedures manual, semi-structured interview guides, eligibility register). The research team also conducted the pre-testing of the mHealth intervention to prevent post-pregnancy smoking resumption. In terms of dissemination of the project, this was realized through

the development and publication of the project's webpage in Romanian and English, as well as by having three oral presentations within three scientific manifestations.

In conclusion, all the activities included in the Project Implementation Plan for the year 2017 were successfully completed, according to the contract and in the established timeframes.

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