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

Scientific Report

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Contents

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, are not adapted for the pregnancy period, 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 xSmoker 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 January-December 2018

The objectives of the project for the January-December 2018 were:

- ✓ Delivering the mHealth intervention top prevent smocking relapse in the postpartum period, through a randomized controlled study
- ✓ 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 2018

A2.1. Developing study instruments and RCT standard operating procedure manual

Regarding the implementation of the study, two questionnaires containing validated tools were developed and applied in the pre-intervention phase (baseline questionnaires), one for the women enrolled and one for the men enrolled. The questionnaire developed for the women has five main sections: (a) socio-demographic questions - 10 general questions about the age, level of education, ethnicity, residence and monthly net income; (b) the medical and reproductive history - 9 questions regarding the number of previous pregnancies, possible complications during previous pregnancies and questions about injuries or accidents suffered during the pregnancy; (c) information about smoking and alcohol consumption - 18 questions regarding the smoking behaviour, exposure to passive smoking, previous quit attempts, alcohol consumption and drug use; (d) information regarding the relationship with the husband/partner - 4 questions regarding the relationship with the partner and his smoking status; (e) emotional health - 2 questions about the recent emotional experiences.

The baseline questionnaire for men consists of four main sections: (a) socio-demographic questions - 2 questions about the age, ethnicity and level of education; (b) information about smoking - 4 questions about smoking and previous quit attempts; (c) information about the

relationship with their partner - 5 questions regarding the relationship with his partner and her smoking behaviour; (d) emotional health - includes a question about his recent emotional health.

The research team also developed an informative brochure containing information on the strategies used by the women who quit smoking and recently gave birth, about the ways in which they can remain smoke free after the birth, and information regarding how their partners can support them during this process. This brochure is distributed to all the participants enrolled in the project.

For ensuring a systematic process of data collection, the research team developed a standard operating procedures manual for data collection (SOP). This document has 42 pages and it describes the aim, objective and study design, the materials used for the randomized controlled trial, the data collection instruments used and how they are administrated, the standard procedures for enrolling and evaluating the participants, the process of randomization of the participants in the three study groups, and the process of delivering the intervention.

Thus, the activity *A2.1. Developing study instruments and RCT standard operating procedure manual* from the Project Implementation Plan was accomplished. The verifiable results of the activity are: the standard operating procedure manual; the questionnaire used to collect data from women who just gave birth and their partners, in the pre-intervention period; informational brochure.

A2.2. Enrollment of study participants, their randomization in intervention and control groups, and data management and analysis

The enrollment of the participants in the randomized controlled trial started on June 26, 2018 and is currently being carried out in the post-partum wards of the two state-owned obstetrics-gynecology clinics from Cluj-Napoca: The Obsetric-Gynecology Clinic 1 and the Obsetric-Gynecology Clinic 2 'Dominic Stanca' which belong to the County Emergency Clinical Hospital Cluj-Napoca.

After verifying that the eligibility criteria is met and the informed consent form is signed, each woman enrolled in the study is assigned a 4-digit identification code. These codes were pre-

randomized in the three groups of the study (the group in which the woman benefits of the xSmoker app, the group in which the woman benefits of the xSmoker app and short text messages sent on the mobile phone, and the control group), before starting the data collection in the two clinics.

The randomization of the participants in the study groups is made by the data collector in the clinic after enrolling the participants, by using the pre-randomization list with the identification codes. After women are enrolled in the study, their partners are contacted by phone and invited to participate in the project, being assigned to the same study groups as their spouse/partner.

All the data collected during the study is recorded, via electronic forms, directly into the Qualtrics platform, a data collection and management of the data collection platform that ensures their safety to the highest standards in the domain. The data collected is periodically verified by the research team for accuracy.

In order to facilitate the management, the quality control and analysis of the data collected, the research team developed a set of specific procedures, preparing the database with the information already collected in the pre-intervention phase (BD_RCT_baseline_2018) for analysis and documenting it with the help of a codebook. The preliminary analysis performed until the development of this report includes univariate analysis (such as frequencies, measures of central tendency, data variability and the distribution), and bivariate analysis (such as frequency tables, correlations or associations).

Thus, the activity *A2.2. Enrollment of study participants, their randomization in intervention and control groups, and data management and analysis* from the Project Implementation Plan was accomplished. The verifiable result of the activity is the *Database with collected information (BD_RCT_baseline_2018).*

A2.3. Delivering the mHealth intervention

The delivery of the mHealth intervention for the couples included in the study began on July 2, 2018. It starts right after birth and it continues for 6 weeks post-partum, both for women and their partners, depending on the study group they were randomly assigned to : (a) Group 1 - the

mHealth intervention which consisted in using the xSmoker app; (b) Group 2 - the intervention consisted in using the xSmoker app and text messages with content based on the Motivation and Problem Solving tehnique; (c) Group 3 - represented by the control group based on which the results of the intervention will be evaluated. All the women enrolled in the study, irrespective of the group they were assigned to, receive the informative brochure descibed in the Activity A2.1 section.

Thus, the activity *A2.3. Delivering the mHealth intervention* from the Project Implementation Plan was accomplished. The verifiable result of the activity is the *Activity report* generated through the process of delivering the intervention.

A2.4. Preparing the evaluation of the intervention at 6 months postpartum for the subjects enrolled in the study

In order to prepare the evaluation of the intervention at 6 months post-partum, the research team developed two evaluation questionnaires (one for the women and one for their partners) and a set of standard procedures to guide the evaluation process. The research team developed an electronic form on the Qualtrics platform (as did before for the baseline questionnaires), and this platform will also be used for the collection and management of the data in the post-intervention phase. Moreover, the Qualtrics platform will also be used to build the structure of the database for the information collected in the evaluation phase of the project (BD_RCT_evaluare_2018).

According to the standard procedures of the study, the evaluation of the intervention takes place 6 months after the couple is enrolled in the study. The evaluation consists of filling in the questionnaire via telephone with the data collector and applying a saliva test. The test measures the level of cotinine in the saliva and is an indicator for tobacco consumption. This saliva test is only applied to women who declare themselves as being non-smokers 6 months after they gave birth.

Thus, the activity *A2.4. Preparing the evaluation of the intervention at 6 months postpartum for the subjects enrolled in the study* from the Project Implementation Plan was accomplished. The verifiable result of the activity is the *Structure of the database for information to be collected during the evaluation (BD_RCT_evaluare_2018).*

A2.5. Dissemination of the project

The second objective for this year was to disseminate the RESPREMO project through: (1) updating and maintaining the project's website; (2) delivering three poster presentation in two scientific conferences; (3) developing and submitting for publishing a scientific manuscript in a scientific journal (Nicotine and Tobacco Research IF: 4.609); as well as (4) by publishing a conference proceeding paper in the volume of an ISI-indexed conference. These dissemination results will be detailed below.

During this reporting period, the project team maintained online and periodically updated the project's website (both in Romanian and in English). The webpage is 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 is updated periodically by the project team with the scientific reports developed within the project, the presentations at the scientific conferences held by team members, 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 through three poster presentation held within two scientific conferences:

- ✓ Risk factors for postnatal smoking relapse among Romanian women, 3rd International Conference of the European Network for Smoking and Tobacco Prevention (14-16 June 2018, Madrid, Spain)
- ✓ Pre-testing mHealth interventions: a case report, 3rd International Conference of the European Network for Smoking and Tobacco Prevention (14-16 June 2018, Madrid, Spain)
- ✓ Use of a visually-built platform to deliver mHealth interventions: A case study on the use of the Textit platform to deliver SMSs to prevent smoking relapse after birth, SRNT Europe 18th Annual Conference (6-8 September 2018, Munich, Germany)

We must mention that these three scientific presentations were not included in the Project's Implementation Plan and did not benefit from any financial resources from the project (i.e. travel costs, registration fee, etc.).

Nonetheless, the results of the project were disseminated by developing a manuscript and sending it for publication in the Nicotine and Tobacco Research Journal (IF: 4.609). The title of the manuscript is "Pre-testing Stay Quit Together: A mHealth intervention to prevent smoking relapse after birth". It aims to report on the results of the pre-testing phase of the intervention developed within the RESPREMO project, which consisted in a qualitative research.

The last dissemination results of the project consists in the conference proceeding titled „The use of mHealth technology in smoking cessation interventions for pregnant women: The emerging field of eHealth and mHealth in Romania" and published in the volume of the Transylvanian International Conference in Public Administration conference (ISI indexed conference, ISBN 978-606-561-184-9). The publication details the emerging status of the use of mHealth and eHealth in Romania, especially for the benefit of members from special populations, such as women who just gave birth.

All the above-mentioned dissemination outcomes of the project, resulted as part of the implementation of the activities funded through the current research project, listed the name of the funder and the number of the contract.

As a results of the dissemination results described above, the Activity 2.4. The dissemination of the project from the Project Implementation Plan was accomplished. The verifiable results of the

activity are: *the project's website, three poster presentation, one manuscript submitted for publication, and one conference proceeding published in the volume of an ISI-indexed conference.*

III. Conclusions

During January-December 2018, the research team has finalized Phase II of the project, namely the implementation and evaluation of the mHealth intervention for the prevention of smoking relapse in the postpartum period, through a randomized controlled study.

Specifically, the research team developed the research instruments used for the randomized clinical trial (the questionnaires, the standard operating procedures manual and the informative brochure), started the enrollment of the participants in the randomized clinical trial and initiated the delivery of the intervention. Moreover, the research team developed two databases, one that started to be filled in with the data collected from the participants before the delivery of the intervention and one that is going to be filled in with the data collected from the participants six months after the delivery of the intervention.

The project dissemination was completed through the maintenance and periodical update of the project website in Romanian and in English, through three presentations held at two scientific manifestations, through one scientific manuscript that was sent for publication to a ISI indexed scientific journal and through a conference proceedings paper that was published in the proceedings of an ISI-indexed conference.

In conclusion, all the activities included in the Project Implementation Plan for the year 2018 were successfully completed, according to the contract and in the established timeframes.

IV. References

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