

Multimodal e-Health Services for Smoking Cessation and Public Health: The SmokeFreeBrain Project Approach

Panagiotis D. Bamidis, Evangelos Paraskevopoulos,
Evdokimos Konstantinidis, Dimitris Spachos, Antonis Billis

Lab of Medical Physics, Medical School, Aristotle University of Thessaloniki, Greece

Abstract

Smoking is the largest avoidable cause of preventable morbidity worldwide. It causes most of the cases of lung cancer and chronic obstructive pulmonary disease (COPD) and contributes to the development of other lung diseases. SmokeFreeBrain aims to address the effectiveness of a multi-level variety of interventions aiming at smoking cessation in high risk target groups within High Middle Income Countries (HMIC) such as unemployed young adults, COPD and asthma patients, and within the general population in Low-Middle Income Countries (LMIC). The project addresses existing approaches aimed to prevent lung diseases caused by tobacco while developing new treatments and evaluating: (i) Public Service Announcement (PSA) against smoking, (ii) the use of electronic cigarettes, (iii) neurofeedback protocols against smoking addiction, (iv) a specifically developed intervention protocol based on behavioral therapy, social media/mobile apps and short text messages (sms) and (v) pharmacologic interventions. Emphasis in this paper, however, is placed on the e-health, m-health, open (big) data, mobile game and neuroscientific challenges and developments upon facilitating the aforementioned interventions.

Keywords:

Smoking Cessation, Telemedicine, Neuroscience

Introduction

Smoking is the largest avoidable cause of preventable morbidity and premature mortality worldwide [1]. The prevalence of smoking worldwide is estimated at about one billion smokers, half of whom will die prematurely as a consequence of their addiction, unless they quit [2]. Smoking causes approximately 85% of the cases of lung cancer and chronic obstructive pulmonary disease (COPD) and contributes to the development of many other lung diseases [3]. Therefore, the control of smoking and the active reduction of exposure to tobacco substances in the environment are considered highly important interventions for lung disease prevention [4].

According to World Health Organization (WHO) one third of the world adult population today, 1.1 billion people are smokers and 3.5 million deaths per year are attributed to smoking. It is estimated that in 2020 the number of deaths per year will be increased to 10 million. Smokers are 13 times more likely to die from COPD than nonsmokers.

Tobacco consumption is highly influenced by socioeconomic factors, affecting mostly low- and middle-income countries as well as vulnerable populations within high income countries. Additionally, smoking causes health inequality between

gender and age groups [4], while it significantly elevates the preventable morbidity and premature mortality rates worldwide.

In the past, our team has described an approach towards the development of an integrated system supporting the smoking cessation network initiatives in Greek public hospitals. The system combined the availability of an open source, web based EHR subsystems, with a Web 2.0 facilitated e-learning component for supporting continuing medical education and promoting public awareness [5].

With these in mind, the SmokeFreeBrain project (www.smokefreebrain.eu), funded by the H2020 programme of the European Commission, aims to address the effectiveness of a multi-level variety of intervention strategies for smoking cessation in high risk target groups within High Middle Income Countries (HMIC) such as unemployed young adults, chronic obstructive pulmonary disease (COPD) and asthma patients, and within the general population in Low Middle Income Countries (LMIC). As the main effect of the recent economic crisis in various European countries, is a significant increase of youth unemployment. The present project focuses on how this socioeconomic development affects the vulnerability of the young population. The project addresses existing approaches aimed to prevent and control lung diseases caused by tobacco consumption, while proposing the development of new treatments and analyzing their contextual adaptability to the local and global health care system as it is affected by the recent socioeconomic changes [6].

In this paper, the various SmokeFreeBrain interventions are first outlined. Emphasis is then placed on the facilitation of these interventions with various e-health, m-health, open (big) data, mobile game and neuroscientific developments where technical aspects such as the design and system architectures of the database registry, as well as, the mhealth systems, together with the informatics implications for pilot preparations are discussed.

SmokeFreeBrain Objectives and Concept

The objectives of the project are outlined below:

- Examine the effects of the use of electronic cigarettes during the initial phase of smoking cessation along with the possible formation of carcinogenic nitrosocompounds via the exposure to nicotine through electronic cigarette vaping.
- Examine the global DNA methylation status under two different situations, tobacco smoking and inhaling e-cigarette vapor.

- Development and evaluation of a novel neurofeedback protocol for smoking cessation.
- Develop a smoking cessation intervention based on adherence to physical activity with ICT support (App Gamification, Facebook and SMS).
- Generate and validate a set of software tools that can be used to inform EU policymakers and local governments as to how to produce optimal Public Service Announcements (PSA) regarding smoking.
- Develop a best practice guide for promoting smoking cessation and how these can be applied in large scale
- Evaluate and report on the effectiveness of the proposed interventions in terms of cost, socioeconomic and health demographics terms and report to policy making bodies.

SmokeFreeBrain follows an interdisciplinary approach in various relevant fields in order to generate new knowledge. State of the art techniques in toxicology, pulmonary medicine, neuroscience and behavior are utilized to evaluate the effectiveness of: (i) Public Service Announcement (PSA) against smoking, (ii) the use of electronic cigarettes with and without nicotine as a harm reduction approach and/or cessation aid, (iii) a specifically developed neurofeedback intervention protocol against smoking addiction, (iv) a specifically developed intervention protocol based on behavioral therapy, social media/mobile apps and short text messages (sms) and (v) pharmacologic interventions.

In attempting to set a summarised outline of the project in a nutshell, one may say that it will use samples of the populations showing high vulnerability to smoking in order to study the effects of five distinct interventions for smoking cessation to measure their cost-effectiveness and allow conclusions regarding the outcomes scalability in terms of health economics. Figure 1 illustrates this concept.

SmokeFreeBrain Interventions

e-Cigarette Intervention

Electronic cigarettes (EC) are a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges. ECs or electronic nicotine delivery systems (ENDS) are also defined as devices whose function is to vaporize and deliver to the lungs of the user a chemical mixture typically composed of nicotine, propylene glycol and other chemicals, although some products claim to contain no nicotine. These products are not currently regulated or monitored. As such, contents may vary and may not be known to the consumer. The safety of ECs has not yet been scientifically demonstrated. Additionally the products vary widely in the amount of nicotine and other chemicals they deliver and there is no way for consumers to find out what is actually delivered by the product they have purchased. Consumers often believe that the use of ECs is safer than smoking tobacco. The chemicals used in ECs have not been fully disclosed, and there are no adequate data on their emissions [7].

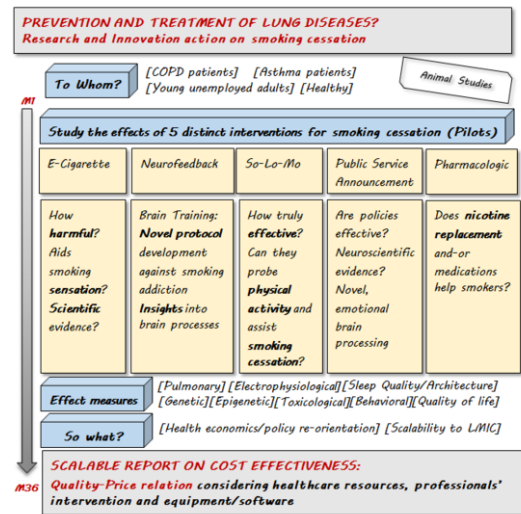


Figure 1 – A conceptual outline of the SmokeFreeBrain project Neurofeedback Intervention

As a non-pharmacological, non-invasive and painless brainwave technique, Neurofeedback (NF) trains individuals to take control of their mind through operant conditioning [8]. As nicotine consumption acts on the brain through specific receptors causing changes in neurological function, the goal of NF interventions is for an individual to learn to control his or her brain function without the need of relevant psychoactive substances. Therefore, NF can eliminate addictive behaviors and lead to better results for smoking cessation than other mainstream approaches, as recent studies indicate. Although a universally accepted neurofeedback protocol for smoking cessation therapy is not yet established, several studies employing real time fMRI (rtfMRI) revealed that reductions in activity of specific brain regions and craving have been observed [9].

Social Media: So-Lo-Mo (Social-Local-Mobile) Intervention

There is some evidence both on the usefulness of exercise for smoking cessation and the motivating effect of Social Networks with successful people trying to quit smoking using the same process. Therefore, an intervention based on adherence to physical activity with ICT support (App Gamification, Facebook and SMS) may provide a valuable aid for smoking cessation [10]. In addition, craving is one key component that has been shown to vary over time during a smoking-cessation attempt and to be highly related to treatment efficacy and cessation success [10]. The objective of the So-Lo-Mo intervention would be twofold. First, the So-Lo-Mo intervention will focus on distracting the user by delivering several tasks through a mobile app. By taking into consideration the understanding of craving during smoking cessation attempts and based on the user's profile, So-Lo-Mo asks the user to undertake some short-term or long-term tasks. The short-term tasks rely on specific physical exercise activities (utilizing the smartphone's accelerometer), gamification, socialization, goal assignment and achievements list, etcetera. The long-term tasks are represented by physical exercise.

Public Service Announcements (PSAs)

Governments across the world are required to disseminate information concerning risks to public health and to promote messages that encourage healthier life style options to improve public health and reduce the huge burden placed on state spending from state subsidized health care in countries with social security systems such as Germany, the UK and France. In this context, PSAs are non-commercial advertisements intended to achieve attitudinal and behavioural changes in the public. PSAs are at the core of many public health campaigns against smoking, and other possible public health problems.

When effective, PSAs are of substantial benefit to public welfare. However, the lack of reliable, quantitative and objective means of evaluating advertising effectiveness is one of the key impediments to better PSA outcomes. In addition, poorly designed PSAs can often have effects that are contrary to their desired goals [11]. Over the past few years, considerable developments in methodologies to record brain activity (e.g. functional Magnetic Resonance Imaging (fMRI), Electro-Encephalography (EEG)) and psychophysics have allowed novel paradigm designs and analyses providing key insight into both the explicit (conscious) and implicit (subconscious) cerebral responses to PSAs. This intervention uses modern neuroscientific tools with the latest thinking and methodological approaches available in the fields of marketing and social science and the interaction of experts from academia, private companies and governmental organizations to derive a new device that can measure and predict the efficacy of PSAs related to smoking abuse.

Pharmacologic interventions

This intervention will investigate the effects of current pharmacological treatments on sleep quality and physiology of COPD and asthma patients as well as in young unemployed adults focusing on two well-known drugs: Varenicline and bupropion. Varenicline is a chemical substance that it used as medication for smoking cessation and affects the nervous system by making nicotine less effective in two different ways: by acting like nicotine as a partial agonist to reduce craving for cigarettes or by replacing nicotine (agonist) and decreases the pleasurable effect of cigarettes. However, there are studies that report an adverse drug reaction of "abnormal sleep related events" associated with varenicline. To allow for such inferences, SmokeFreeBrain will conduct a sleep study, which will be performed using overnight polysomnographic (PSG) recordings consisting of electroencephalography (EEG), electrooculography (EOG), electrocardiography (ECG) and electromyography (EMG) sensors.

The insights gained from the pharmacological studies will generate new knowledge regarding the toxicity of these interventions according to their effectiveness. These effects will then be compared with the toxicity of e-cigarettes via that intervention, allowing inferences regarding the safety of the relevant, corresponding use.

ICT positioning of the project

SmokeFreeBrain will develop and deploy both cutting edge and stable, well-understood, technologies (from previous EU projects and commercial partners) within the new field of smoking cessation support, including neurofeedback intervention, gamification platform, mobile app for delivering challenges and interaction information, serious games promoting physical exercise, neurometric approaches, and decision support for challenging and motivational tasks and

smoking related profile databases to maximise value from research and to optimise commercial opportunities. Technical partners have assessed technology readiness levels of existing components to be used in SmokeFreeBrain. Figure 2 illustrates the current technology readiness levels (TRLs) in line with the corresponding estimated readiness level at the end of the project (TRLs vary from 1 to 9).

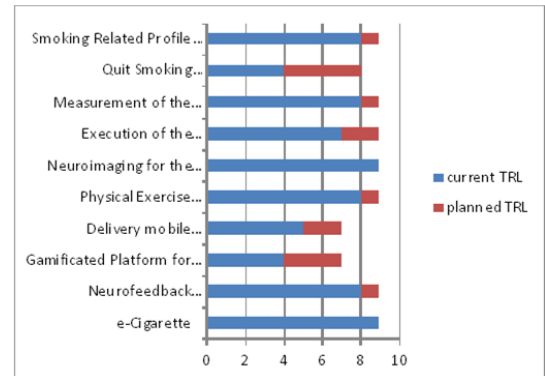


Figure 2 – TRLs of SmokeFreeBrain technologies at project start and estimates envisioned at the end of the 3 year run.

Data Management Plan

The data management plan will guide all activities regarding the anonymization, exchange and release of data gathered in the pilot sites as required for participation in the Open Research Data Pilot in H2020. Datasets that are produced within the SmokeFreeBrain project span from smokers' demographic and clinical data to outcome measures of several clinical interventions and their cost-effectiveness results. These data will allow for the benchmarking of the different approaches when dealing with smoking cessation, providing a common basis for further policy decision making. Since SmokeFreeBrain pilots involve human participants, data collected will contain sensitive personal information. Focus is also given to possible ethical issues and access restrictions regarding personal data so that regulations on sensitive information are not violated.

The data management portal will be based on the popular open source software CKAN and it will be accessible through a portal (endpoint) at the following address: ckan.smokefreebrain.org

CKAN is a powerful data management system that makes data accessible by providing tools to streamline publishing, sharing, finding and using data. CKAN is aimed at data publishers (national and regional governments, companies and organizations) wanting to make their data open and available. The software supports strong integration with third-party CMS's, such as Drupal and WordPress.

Among the portal's features will be:

- Complete catalog system with an easy to use web interface and a powerful API
- Integration with the profile database system
- Data visualization and analytics
- Fine access controls
- Raw data and metadata storage

- Search by keyword or filter by tags. See dataset information at a glance.
- Rich application programming interface (API), and over 60 extensions including link checking, comments, and analytics and many more.

The SmokeFreeBrain Profile database

The profile database will be a clinical trial database. It will be a general data hub for the needs of the project and will hold data from all interventions. Partners can use the profile database with 2 ways:

- As a database for their intervention
- As a hub for storing data from interventions for processing purposes

In the first case, partners will be able to insert their data into the database. In the second case, they have to send the data via web services, which will follow the ISO EN 13606 standard. A general overview of the system architecture can be shown in Figure 3. The profile database will produce reports and statistics based on the stored data. The reports will be used to evaluate the results of the interventions of the project.

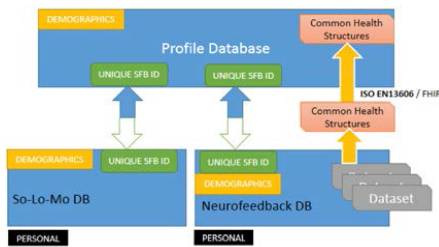


Figure 3 – A general overview of the SmokeFreeBrain system.

The SmokeFreeBrain API

This API is used to Post, Read and Update data in the Profile Database using the CEN/ISO EN13606, a European norm from the European Committee for Standardization (CEN) which is also approved as an international ISO standard [12].

The SmokeFreeBrain SoLoMo App

The main features of the SoLo-Mo app are:

- Personal profile
- Achievements: Cigarettes not smoked, money savings, hours of live regained, time smoke free
- Total fitness time (Google Fit integration): Daily average, monthly average, days above the average
- Self-help contents
- Motivational tools: Readings, relaxation tool and mini-games
- Relapse tracker
- Encouraging messages: Both from the system, and from/to other users

The SmokeFreeBrain SoLoMo App mini-games

An interesting feature of the SoLo-Mo app is the concept of mini-games. The relevant contribution of mini-games in

smoking cessation has already been recognized in recent studies [13]:

- Playing Tetris decreases craving strength for drugs
- Puzzle-solving games reduce craving for nicotine
- Breath-control App emulating the physiological responses smokers get from smoking
- Crushing virtual cigarettes contributes to smoking cessation

We focused on 3 mini games:

- Crushing cigarettes [14]
- Breathing control by blowing up balloons
- Physical Exercise Coach/Instructor (based on the webFitForAll exer-gaming platform protocol) [15, 16]

For example, in the *Blowing up Balloons* mini-game, emphasis is placed on breathing control. The user is asked to blow close to the microphone when the balloon is green. If the user blows when the balloon is red, the balloon may pop. If the user does not blow when the balloon is green, the balloon deflates quickly. The number of totally blown balloons in 1 min reflects the total score, while the pop balloons are counted too. This is based on the Jamalian et al. conceptual study:

- Phone app that emulates the physiological responses smokers get from smoking
- Innovative breath-control element, which mimics the physiological and perceived effects of nicotine as well as the relaxant effects of smoking.
- The goal is to give players a cigarette-free, non-invasive way to satisfy their nicotine cravings

Figure 4 provides a rough screenshot of the game interfaces.

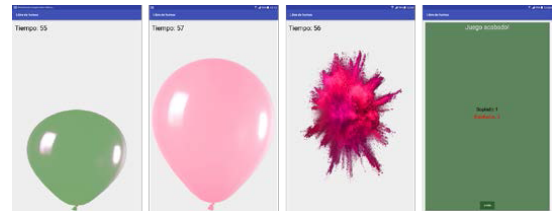


Figure 4 – A sense of the Blowing up Balloons SmokeFreeBrain and SoLo-Mo app minigame.

Envisioning the SmokeFreeBrain stakeholder ecosystem

The contribution of SmokeFreeBrain towards the creation of a social ecological model relies on understanding the multiple stakeholders and their needs. SmokeFreeBrain will develop and support a collaborative health-ecosystem by bringing together the relevant key stakeholders who will testify on their changing interactions and endorse the implemented interventions to ensure maximum health benefits. At the policy level, alliance with national healthcare policy makers will capitalize efforts and scale up interventions in a global context. The organisational stakeholders are hospitals, health service providers and national authorities who monitor existing approaches to prevention or develop treatments. The community stakeholders include the scientific community (e.g. researchers, academics), commercial actors

(pharmaceutical industry, insurers) and cross-sectoral experts (e.g. researchers on environmental effects). The interpersonal level includes the So-Lo-Mo community, existing smoking cessation networks, family and friends. The patient/smoker is central to the entire ecosystem. SmokeFreeBrain will inform all levels of the framework by providing access to real and valuable information on the establishment of effective interventions for the prevention and treatment of lung diseases. Figure 5 illustrates the above described ecosystem.



Figure 5– SmokeFreeBrain stakeholder ecosystem.

Conclusion

The SmokeFreeBrain project kicked off in November 2016 and is expected to have a three year duration. At the point of writing this paper, numerous multi-centric trials are underway. These are expected to shape the way forward by providing innovative systems, interventions and new, original, knowledge derived as statistical analysis and economic evaluation will soon kick-off. This paper has attempted to provide some overall, but technically oriented glimpses on the project concept. Given space limitations and the early stages of the trials, more details and results were thought improper for the purposes of this paper. Nevertheless, the technical frontiers which have been outlined in this paper can not be understated.

Acknowledgements

The SmokeFreeBrain project (www.smokefreebrain.eu) has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 681120.

References

- [1] WHO, Priority Medicine for Europe and the World 2013 Update (http://www.who.int/medicines/areas/priority_medicines/MasterDocJun_e28_FINAL_Web.pdf)
- [2] World Health Organization. Tobacco- Fact Sheet No339, July 2013. Available from: <http://www.who.int/mediacentre/factsheets/fs339/en/> (accessed 21 September 2013).
- [3] Lung cancer- Cancer Research UK. Available from: <http://www.cancerresearchuk.org/cancer-help/type/lung-cancer/>
- [4] The World Health Report 2002—Reducing Risks, Promoting Healthy Life (<http://www.who.int/whr/2002/en/>)
- [5] Konstantinidis ST, Konstantinidis E, Nikolaidou MM, Boutou AK, Havouzis N, Argyropoulou P, Bamidis PD. The use of open source and Web2.0 in developing an integrated EHR and e-learning system for the Greek Smoking Cessation Network. *Stud Health Technol Inform.* 2009;150:354-8.
- [6] T. McAfee and Others Helping Smokers Quit — Opportunities Created by the Affordable Care Act *N Engl J Med* 372:5, 2015
- [7] Position Statement on Electronic Cigarettes [ECs] / Electronic Nicotine Delivery Systems (ENDS)
- [8] Hammond, D. C. (2011). What is neurofeedback: An update. *Journal of Neurotherapy*, 15(4), 305-336.
- [9] Hanlon, C. A., Hartwell, K. J., Canterberry, M., Li, X., Owens, M., LeMatty, T., & George, M. S. (2013). Reduction of cue-induced craving through realtime neurofeedback in nicotine users: the role of region of interest selection and multiple visits. *Psychiatry Research: Neuroimaging*, 213(1), 79-81.
- [10] King, D., Greaves, F., Exeter, C., & Darzi, A. (2013). 'Gamification': Influencing health behaviours with games. *Journal of the Royal Society of Medicine*, 106(3), 76-78.
- [11] Biener, L., & Siegel, M. (2000). Tobacco marketing and adolescent smoking: more support for a causal inference. *American journal of public health*, 90(3), 407.
- [12] SmokeFreeBrainproject deliverable D2.5 App for Patient, Medical Station and So-Lo-Mo Administration Console, available through www.smokefreebrain.eu
- [13] Skorka-Brown J, Andrade J, Whalley B, May J, Playing Tetris decreases drug and other cravings in real world settings. *Addictive Behaviors* 51 (2015) 165–170.
- [14] Girard B, Turcotte V, Bouchard S, Girard B. Crushing virtual cigarettes reduces tobacco addiction and treatment discontinuation. *Cyberpsychol Behav.* 2009 Oct;12(5):477-83. doi: 10.1089/cpb.2009.0118.
- [15] Konstantinidis EI, Billis AS, Mouzakidis CA, Zilidou VI, Antoniou PE, Bamidis PD. *IEEE J Biomed Health Inform.* 2016 Jan;20(1):189-200. doi: 10.1109/JBHI.2014.2378814.
- [16] Bamparopoulos, G., Konstantinidis, E., Bratsas, C., & Bamidis, P. D. (2016). Towards exergaming commons: composing the exergame ontology for publishing open game data. *Journal of biomedical semantics*, 7(1), 1.

Address for correspondence

Panagiotis D. Bamidis,
Lab of Medical Physics, Medical School,
Aristotle University of Thessaloniki,
PO Box 376, 54124,
Thessaloniki, Greece,
tel: +30-2310-999310,
email: pdbamidis@gmail.com