Personalised Guidance Services for Optimising Lifestyle in Teen-Agers Through Awareness, Motivation and Engagement – PEGASO: A Pilot Study Protocol

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Abstract. Adolescence is a vulnerable stage in which the development of certain unhealthy behaviours can occur. The prevalence of overweight and obesity among European teenagers is rapidly increasing and may lead to both short- and long-term health complications. The fast development of the ICT, and in particular mobile technologies, together with their increasing diffusion among the EU populations offers an important opportunity for facing these issues in an innovative manner introducing the possibility of a new technological framework to re-design the healthcare system model. The PEGASO project relies on a mobile-and cloud-based ICT platform to set up a system of new healthcare services targeted to teens for obesity prevention. The present paper describes the protocol of a six-month Pilot Study that will be carried out on 525 adolescents in four different European sites (Italy, Catalonia, England, Scotland), aiming to evaluate the PEGASO system usability and effectiveness in promoting healthy lifestyles.

Keywords: ICT · Lifestyles habits · Adolescents · Awareness · Motivation

1 Introduction

Adolescence is a vulnerable stage in which the development of certain unhealthy behaviours can occur, such as the adoption and maintenance of maladaptive lifestyles [1].

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P. Perego et al. (Eds.): MobiHealth 2016, LNICST 192, pp. 45–52, 2017.
DOI: 10.1007/978-3-319-58877-3_6

The adoption of and the adherence to healthy lifestyles amongst the young population is a crucial issue in order to: (a) improve the health, as well as physical and mental well-being of teenagers [2–5]; (b) maintain a healthy lifestyle during adulthood; and, (c) prevent sedentary behaviour, overweight and obesity and other chronic diseases related to a unhealthy lifestyle, like cardiovascular diseases or cancer [6].

In particular, healthy dietary habits [7], regular physical activity [8], and good sleeping behaviour [9] during adolescence play an important role as protective factors in the development of both short- and long-term chronic diseases, also including overweight and obesity during adulthood [10, 11]. According to the World Health Organization (WHO), more than 50% of the European adult population is overweight, more than 20% are obese, and the prevalence of overweight among European 13-year-olds is about 27% [12, 13]. Taking into account these data and the fact that overweight adolescents are at higher risk to be overweight in adulthood [12], the promotion of healthy lifestyles among adolescents is a major issue from a public health perspective.

Concurrently, the rapid development of the information and communication technologies (ICTs) – and in particular mobile technologies – together with their increasing diffusion among the EU populations (>60 millions of person only in EU-5), offers an important opportunity for facing overweight and obesity issues in an innovative manner, and also introduces the possibility to re-design the healthcare system model on the basis of a new technological framework.

Teenagers live in a highly technological world and are considered to be technology natives. In fact, ICTs – and especially those linked to mobile phones/smartphones, tablets, electronic bracelets, intelligent clothing and other devices – are being rapidly extended amongst adolescents. Digital platforms allow teenagers to go beyond mere face-to-face contact, to be connected online and to have access to information included in social media and networks, independently from the socioeconomic or familial strata [14]. In this context, public health authorities have a great opportunity to spread key messages for adolescents to promote habits of healthy life in a creative and innovative way [15].

2 Objectives

The PEGASO (Personalised Guidance Services for Optimising lifestyle in teen-agers through awareness, motivation and engagement) project aims to develop an ICT based system to motivate behavioural changes towards healthier lifestyles in adolescents. The specific objectives of the present Pilot Study are to test the PEGASO system in real life conditions in Lombardy, England, Scotland and Catalonia, as well as to assess changes in teenagers' awareness and lifestyles as a result of the use of PEGASO system. Specifically, we aim to:

(1) Test the usability of PEGASO platform.
(2) Test the effectiveness of the system to promote:
    (a) increase of knowledge/awareness about healthy habits
    (b) behavioural change in lifestyle, and specifically on target behaviours.

3 Subjects and Methods

3.1 Study Design

A multi-centre quasi-experimental controlled pilot study will be undertaken to evaluate the PEGASO System from October 2016 to March 2017.

3.2 Study Population

Approximately a total of 525 voluntary adolescents aged 13–16 years old (gender balanced) will be enrolled in selected high schools belonging to the four different sites, including Lombardy (Italy), Catalonia (Spain), England and Scotland (UK). Participants will be allocated to the intervention or comparative group in a 2:1 ratio. Therefore, about 350 participants will test the PEGASO platform, whilst 175 will be included in the comparative group. Sample selection will be carried out in two stages: in the first phase, schools with medium-low socioeconomic level will be selected by convenience sampling; in the second phase classes will be selected for participation in each school in agreement with schools principals/head teachers. Classes of students at each school considered suitable to take part in the study will be identified. Study information will then be disseminated to parents and students so that individuals can voluntarily 'opt in' and take part in the study.

The approval from the research Ethics Committee (EC) of the participant pilot sites will be asked. Students and their parents will be required to sign the informed consent prior to inclusion in the study, in accordance with the Declaration of Helsinki. The confidentiality of the recruited subjects will be ensured at all times in accordance with the provisions of current legislation on personal data protection.

3.3 PEGASO Ecosystem

The development of the PEGASO system is guided by the comprehensive Behaviour Change Wheel (BCW) framework [16] and in particular by the Capability-Opportunity-Motivation-Behaviour (COM-B) system. The highly innovative key component of the PEGASO system is the behaviour recognition system that allows detection and evaluation of participants' real-time behaviour (collected through other components of the PEGASO system. The lifestyle behaviours targeted (Table 1) by the PEGASO system include known potential modifiable risk factors for obesity development in adolescents.

PEGASO comprises seven different components (Fig. 1). The Companion is the main application of the platform that integrates all the apps developed in the PEGASO system and provides a seamless and unique experience to the participant. Companion is a Personal Digital "Friend" acting as a daily-life guide for coaching, caring for, and empowering the participants in their activities toward healthy habits. The Companion includes:

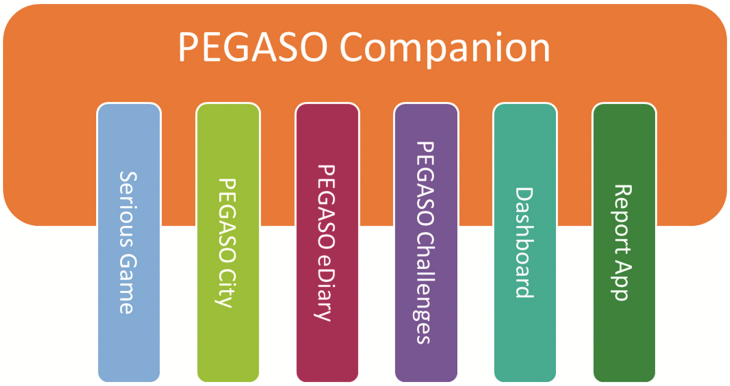

Fig. 1. PEGASO ecosystem

Table 1. Target behaviours definitions

Target behaviours	Cut-off definition
Diet	Fruit consumption of ≥2 servings (250–375 g)/day of at least two different types
	Vegetable consumption of ≥2 servings (300–450 g)/day of at least two different types
	Reduced intake of sugar-sweetened beverages
	Breakfast consumption including intake of food from more than two food groups
	Reduced intake of fast food
	Reduced sweet and salty high-energy snack intake
Physical activity and Sedentariness	60 min of daily physical activity in moderate-to-vigorous intensity
	12.000 steps/day
	Daily active transport to and from school (walking, cycling, skateboarding)
	<45% of after-school time daily spent in sedentary activities (<1.5 MET)
Sleep	Daily sleep duration of at least 8 h
	≥95% of bed time spent sleeping (i.e. sleep quality/ efficiency)

(i) The *eDiary* app is an application that collects dietary habits entered by the users and provides feedback about the healthy eating habits and suggestions for improving their dietary behaviours;
(ii) The *Challenge* app allows users to challenge themselves and other users in a competitive or collaborative way.
(iii) The *City* app is a bridge between the digital world of the PEGASO system with the physical world: helps teenagers to find places that are part of the PEGASO

Stakeholder Ecosystem and provides the teenagers a set of possible interactions and actions that contribute to the gamification process and the rewarding system.

(iv) The *Dashboard* app allows visualizing all the data acquired (steps and minutes of activities, sleep time, type of activities) by the PEGASO system. The smart garments measure heart rate (ECG) and physical activities (accelerometer) whereas the bracelet monitors physical activities and sleep.

(v) The *Serious Game* serves a central role as the motivational component of PEGASO. As such, it needs to entertain and engage the player, whilst using the PEGASO ecosystem to capture information about lifestyles and encourage positive health behaviour changes.

(vi) The *Web Portal* allows participants to socially interact and learn via training module; two (technological): aggregate data and services across the whole PEGASO platform (images, video, blog materials, activities data, n° of steps, n° of km).

(vii) The *Report App* represents a connection between the PEGASO ecosystem and the personal health folder. The BRIDGE allows extracting health data collected and elaborated into the PEGASO ecosystem and to create a report to be shared with physicians into the personal health folder (PHF). This functionality will only be available in Lombardy and Catalonia.

3.4 Procedures

Schools and participants of both intervention and comparative group will be given information about the purpose of the study at a single face-to-face session held by the field researchers. The students allocated to the intervention group will be provided with a smart phone (android, version 5.0), two smart garments, a smart garment sensor and an activity bracelet (Fig. 2) for the duration of the Pilot Study (6 months). The smart phones will have all apps of the PEGASO ecosystem installed.

Fig. 2. Smart garments and bracelets sensors

In addition, participants will be asked to join the PEGASO community by signing in to the PEGASO Portal (https://portal.pegasof4f.eu/web/others/sign-in).

Those students assigned to the comparative group will be asked to continue their routine daily physical and educational activities related to leading a healthy lifestyle.

PEGASO framework will provide the tools to evaluate the groups in three time points during the pilot study (Fig. 3):

- *Baseline evaluation*: assessment of users' profile regarding the pre-specified indicators before the use of the platform (i.e., socio-demographic characteristics, anthropometric measurements, lifestyle behaviours, motivation, knowledge);
- *Mid-pilot evaluation (month 3)*: mid-term evaluation will be focused on teenagers' feelings and perceptions of the platform (i.e., usability, satisfaction, emotional response, motivation);
- *Final evaluation (month 6)*: at the end of the intervention we will compare teenagers' progresses against the identified targets and both the initial and the mid-pilot evaluation (i.e., usability, satisfaction, emotional response, trusting technology, anthropometric measurements, lifestyle behaviours, motivation, knowledge).

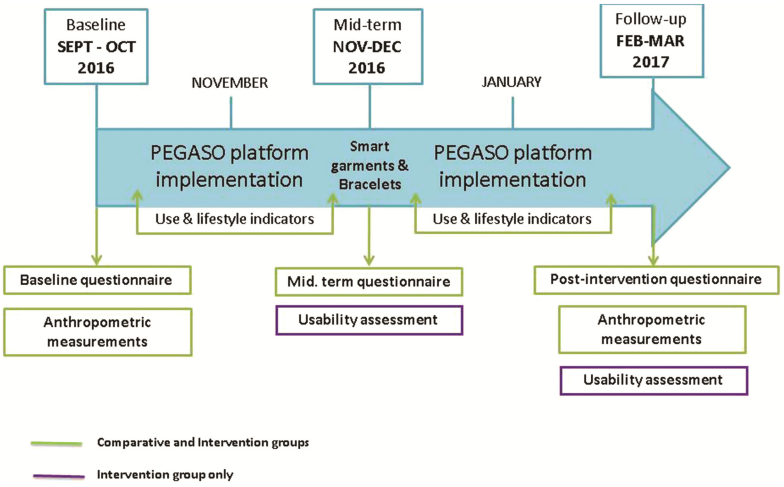

Fig. 3. Pilot study timeline

Participants will be asked to fill in validated and/or 'ad *hoc*' on-line questionnaires in order to assess the main objectives of the project.

4 Discussion

The vast development of smartphone applications in health care and lifestyles fields is lacking of sufficient scientific evidence on how applications can improve the health of the population in general, and in adolescents in particular. It is necessary to pilot and

conduct experimental studies to obtain sufficient scientific evidence of the possible usefulness of these tools.

With the present Pilot Study we expect to test the effectiveness that regular use of the PEGASO platform will have on the improvement of lifestyles (in terms of dietary behaviour, physical activity and sedentary and sleeping behaviours) among adolescents, over a period of six month. Hence, the results of this study could lead to a strategy based on the incorporation of mHealth solutions among teenagers, would result in healthier lifestyles.

Acknowledgements. The European Commission under the 7th Framework Programme funds the PEGASO project. The authors of the paper wish to thank all the partners of the PEGASO Consortium for their contribution to the work.

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