University of Iceland
Faculty of Psychology

Smartphone based health behaviour intervention for adolescents
-Study Protocol-

Researchers:

Erlendur Egilsson, CandPsych

Ragnar Bjarnason, MD, PhD

Urður Njarðvík, PhD

June 9th 2023
Reykjavik
Iceland

Introduction

Throughout the past decade ownership and access to smartphones and mobile devices has grown profoundly among adolescents and youth worldwide [1, 2]. The growth has been such that smartphone ownership or access among US adolescents was 95% four years ago and had increased by 23% in the four years prior [1, 2]. Similar development was observed in the majority of developed economies where adolescent smartphone access and ownership is above the 90th percentile [2]. Smartphones are so widely distributed and used that approximately 45% of adolescents spend nearly all waking hours online [3]. However, modest projections of daily usage is that many spend way less time online each day though it is usually more than 4 hours [4-6].

Extreme smartphone usage in adolescent and youth populations has been extensively covered but a more positive side to mobile usage is that a significant proportion of adolescents seek health information and clinical help online through their mobile devices, providing ample opportunities to reach at risk adolescents with science based methods focusing on health improvement [7-9]. Health problems, i.e. mental health and lifestyle disease, disproportionally burden lower SES groups as well as diverse minority groups and smartphones could become a vital tool in eliminating such disparities since smartphone access and ownership is not related to SES status, gender or race in diverse economies [2, 10, 11]. The mHealth market is steadily becoming saturated with applications and yearly increase in number of applications available has skyrocketed in recent years, with estimated 350.000 mHealth applications currently on the market [12]. However, only 8% of adolescents seem to use health applications to improve their health, highlighting the apparent gap between easy access, extensive daily usage and lack of interest in mHealth applications among adolescents [13].

Lack of physical activity has been labelled a global pandemic and reported as the 4th leading global cause of death [14]. Physical inactivity increases risk of lifestyle diseases, such as heart disease, type 2 diabetes and cancer, resulting in over 5 million annual global deaths [15]. Further, the estimated annual financial burden of physical inactivity is nearly 54 billion USD in health care costs around the world [16]. There seems to be a drop in physical activity in adolescence and a large part of adolescents are under the recommended physical activity levels provided by the World Health Organization (WHO) [17-19]. Lack of sufficient physical activity tends to continue into adulthood and research suggests that the majority of adolescents in the EU do not even reach 30% of recommended daily physical activity [19-21]. Further, adolescents seem to have the unhealtiest diet of all age groups and adolescence is a particular susceptibility period to weight gain [22]. Research has repeatedly revealed a significant relationship between nutritional behavior and physical activity in terms of weight management [23]. A tremendous increase in global adolescent obesity has been witnessed in the past decades and prevalence for instance tripled since 1975 [24]. Cost-effective interventions to increase physical activity and improve nutritional behavior in adolescent populations are therefore direly needed.

Physical inactivity and inadequate nutritional habits are often interrelated to disabling emotional problems and integrated strategies should include all three pillars to improve physical as well as mental well-being in adolescent populations. Mobile health interventions targeting disabling emotional problems in adolescent populations have revealed encouraging outcome, despite the fact that attrition rates in these interventions are generally high [11, 25-30]. Varying definitions of attrition have complicated research on this topic but attrition is defined as leaving treatment before obtaining a required level of improvement or completing intervention goals [31-33]. Research on mental mHealth interventions among adolescents have frequently lacked detailed time related attrition data alongside accurate definitions and analysis of attrition reasons though recent studies show promise in that regard [11, 30, 34]. Attrition is regularly reported at two distinct points of time; intervention start and at end of intervention. A continuous measure of usage vs. non-usage in mHealth interventions for adolescents while simultaneously obtaining detailed usage data in order to prevent or delay exact times of attrition in future interventions would perhaps be an improved representation of attrition [35].

Increased knowledge on actual attrition factors and patterns in adolescent populations from mHealth interventions are direly needed. Obtaining a better understanding of how motivational support motivates adolescents to use mHealth applications and why they maintain or lose interest in using them to improve their health is of vital importance. Motivational support in mHealth interventions, defined as strategies to enhance motivation and counter attrition to overcome behavior change barriers, often include goal-setting, feedback, social support and rewards (36-37). Systematic reviews examining possible drivers behind usage point to group and task customization, localization, functional user support, gamification of health tasks and immediate visual but simplified feedback on user action while while gender-related motivational support features could be contributing factors [36-38]. Timing of tailored motivational support, through just-in-time adaptive interventions (JITAIs), should be considered as well when implementing adolescent mHealth interventions since time-based individualization could counter high attritions rates [35, 39]. Given the magnitude of reported health problems among adolescents and lack of cost-effective health behaviour interventions specifically developed for adolescent populations, the need for better understanding of attrition reasons in adolescent mHealth interventions is massive. The purpose of this study was firstly to seek richer understanding of continuous attrition rates from a mHealth intervention in an adolescent population and what effects motivational support has on attrition rates. Secondly, the aim was to examine effectiveness of the intervention with the aim to increase daily mental, nutritional and physical health behaviour.

Methods

Participants

Participants are adolescents, age 13 to 16 years old, attending one of three public schools for children and adolescents in the greater capital area of Iceland. All children attending the oldest 3 classes, called 8th to 10th classes, in three participating public elementary schools in

Iceland are eligible participants (n=661, m:f ratio=313:348). All children in public schools in the municipality are equipped with an iPad from 10 years of age. Exclusion criteria are diagnosis of severe disorder of intellectual development and/or physical-, developmental- and mental illness significantly restricting ability to use mobile apps. Research specifications and introduction to the application will be sent via email to parents and legal caretakers of all eligible participants through school officials along with confirmative survey link. If the link is answered, it yields confirmation for informed consent. Adolescents with informed consent from parents/legal caretakers will then invited to take part in the study through confirmative survey link. The study has been approved by the National Bioethics Committee (license number: VSNb2015060065/03-01).

Measurements

Original primary outcome measure will be app acceptability and functionality, measured with *Systematic Usability Scale* (SUS), a widely used and relatively well studied 10-item questionnaire on app usability where scores range from 0-100 and total score over 70 yielding satisfactory usability and user acceptance [40, 41]. Further primary measures were amount, frequency and time of daily physical activity measured through in-app activity, self-reported stress levels, quality of sleep and energy levels, measured through levels of the health app usage and completion of in-app health tasks.

Secondary outcome measures include standardized body mass index (*BMI-SDS)* based on BMI index reference values for Swedish children and adjusted for age and sex. Participants are weighed in kilograms in light clothing without shoes using a digital scale (Marel type C2; Marel, Reykjavik, Iceland). Height is measured in centimetres using a wall-mounted stadiometer (Seca stadiometer; Seca, Hamburg, Germany).

Anxiety and depressive symptoms will be assessed using the *Revised Children´s Anxiety and Depression Scale* (RCADS), a self-report assessment tool for children and youth. The scale is a four point Likert scale, spans 47 questions and is divided into 6 subscales; separation anxiety symptoms, general anxiety symptoms, obsessive-compulsion symptoms, social anxiety symptoms, panic symptoms, depression symptoms. A *T*-score over 65 marks a clinical cut-off point. The inventory's psychometrics have been studied with acceptable findings in both US and Icelandic paediatric populations [42, 43].

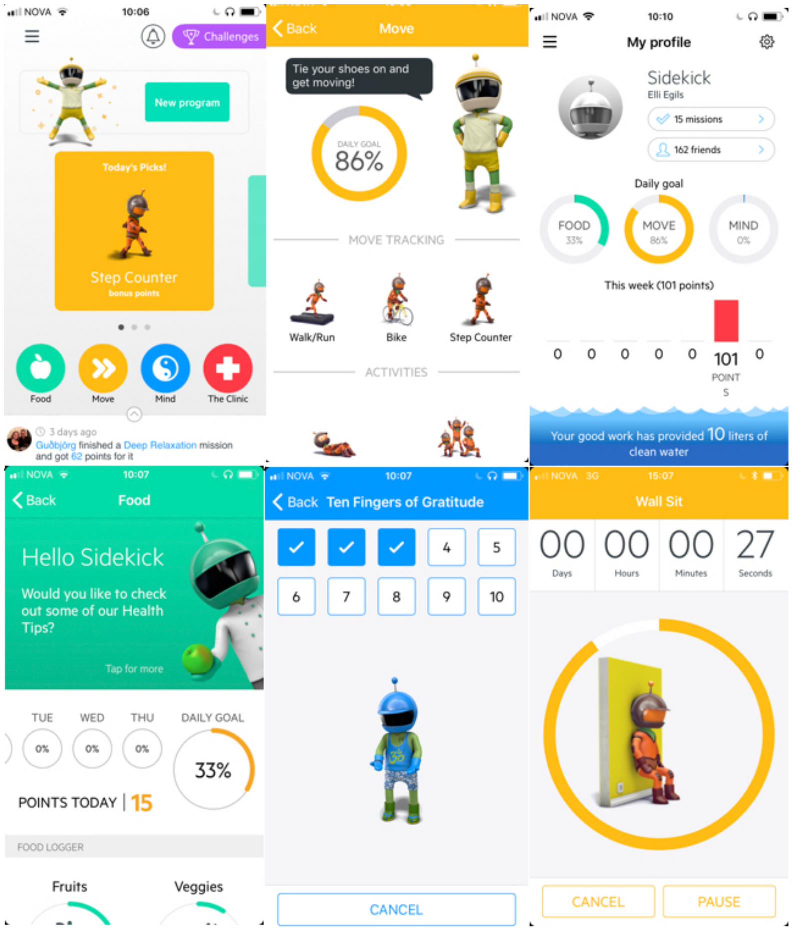
General Self Efficacy Scale (GSE), a 10 item self-report questionnaire with ranging total scores from 10 to 40, is used to measure self-efficacy levels where higher score yielding increases self-efficacy [44]. Acceptable psychometric properties for the questionnaire have been obtained and it is used globally in youth populations [45].

BEARS sleep screening algorithm will be used to evaluate participant´s sleep problems. It is a sleep screening instrument for children from 2 to 18 years old, divided into 5 sleep domains; bedtime problems, excessive daytime sleepiness, awakenings during night, regularity and duration of sleep and snoring [46]. The algorithm's psychometrics have been studied with acceptable findings in paediatric populations [47].

mHealth application

SidekickHealth was initially developed through multiple focus group studies amongst both Icelandic elementary school students and adolescents in the obesity clinic at the Landspitali University Hospital in Iceland to incorporate the target groups' needs and opinions. Based on results from focus-group studies and design advisors, the app took the form of a social health game (see Figure 1). Functionality of the app evolves around motivational support to help the user set goals and complete health tasks (gamification of tasks), in three main categories: food and drink (e.g. vegetable and water intake, consumption of fruits, avoiding sugary soda or energy drinks), physical activity (e.g. body-weight exercises, logged minutes of sports activity, gps-based biking, walking or running), and mental health exercises (e.g. reducing stress, exercising gratitude and improving sleep habits). By completing health tasks that are labelled missions and participating in friendly competitions with peers, users earn points (called "kicks") and badges providing altruistic rewards (e.g. litres of water for children in need or polio vaccinations that are sent in their name to children in need through UNICEF). A visual representation of the user's performance is provided in different categories. Keeping the app fun, entertaining, and easy-to-use is of integral importance and was a strong focus point throughout all developmental phases. The smartphone application operates on Android and iOS platforms. The app's function focuses on education and simple health behaviour changes through the benefits of increased physical activity and mental health exercises as well as a healthy diet, portion sizes, and appetite awareness training (AAT). AAT is a behaviour modification tool that has for instance been used in obesity treatment and encourages overweight/obese children and youth to consume food and drink in response to internal appetite cues. It has shown promise for the treatment of overweight and obese children and teenagers and has been visually developed as an individual mission in the app's nutrition category [48, 49]. Participants in the intervention realm will be randomly assigned to groups consisting of 8 individuals which collectively and individually competed in point collection through completion of in-app health tasks. In the beginning of each of the trial's 6 weeks, the intervention group receives in-app messages where a new weekly competition (both individual and on group level) with altruistic rewards is introduced. In weeks 2 to 6, altruistic rewards for past week's efforts will also be handed out. Winners of competitions receive confirmation that UNICEF had sent Polio vaccinations to children in need. Further, through completion of in-app health exercises participants collect litres of water that will be sent in their name to children in need through UNICEF. The total cost for the altruistic rewards for all in-app rewards throughout the treatment period was roughly is estimated to be between 50 to 100 US dollars or roughly 50 US cents per participant.

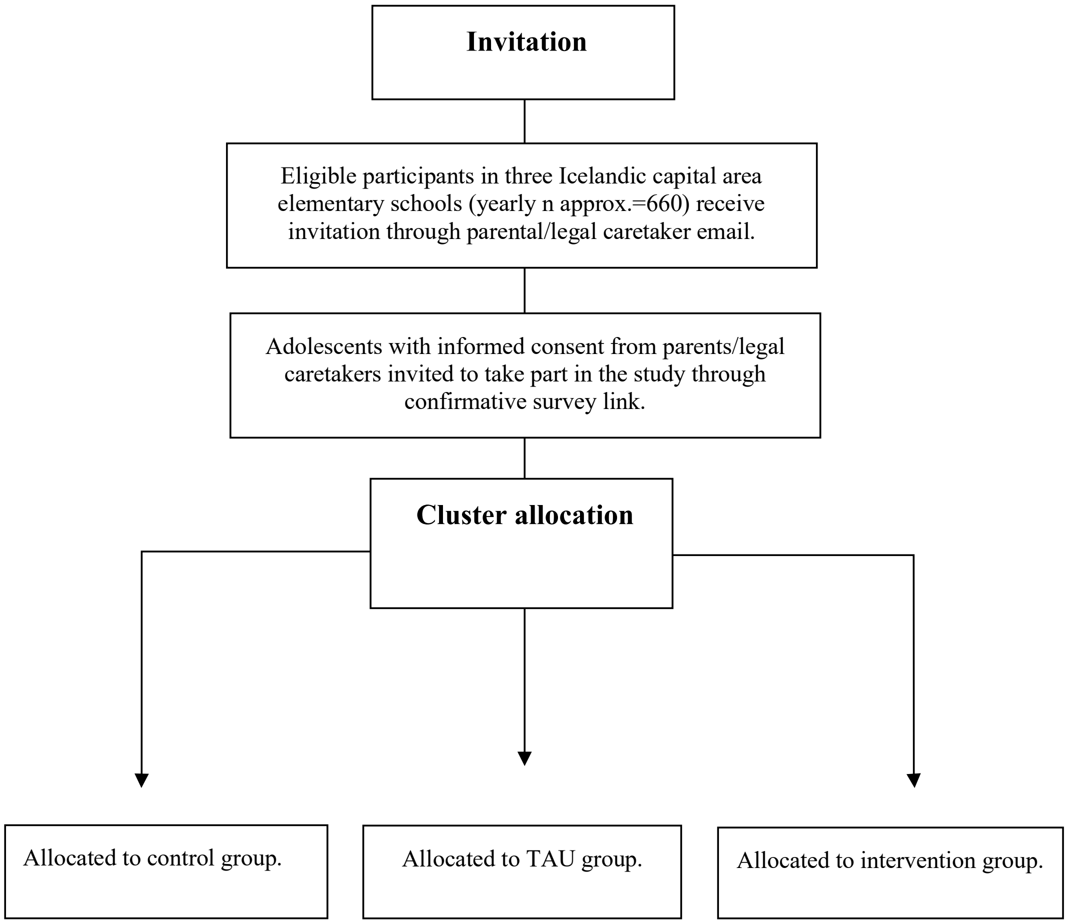
Figure 1. Overview of app functions & categories



Procedure

The study is a randomized controlled study. Cluster randomization is used to distinguish three participating schools into control, treatment-as-usual (TAU) and intervention groups. Measures will be obtained at baseline and 42 days later. Participants in both the TAU group and the intervention group receive an approximately 10 minutes long introduction regarding the study specifications and the application. The control group receives no further contact, access to the application or information until study-end questionnaire measures. Participants in the intervention group are randomly assigned to teams consisting of 8 individuals that collectively and individually compete in point collection through completion of in-app health tasks. Participation in the TAU group and intervention group is defined as downloading the Sidekick app and completing at least 3 health exercises within it. Time of exercise is defined as the timestamp on completion of exercise within any of the three types of exercise categories (physical activity, nutrition and mental health) of the app. Exercise frequency refers to how often a given exercise was completed by a participant. Time of attrition was defined as the time stamp of last completing health exercise within the Sidekick throughout intervention period. The procedural difference between TAU group and intervention group evolves around motivational support. The intervention group receives weekly motivational support in form of individual and group feedback on usage, participation in friendly health task competitions and weekly altruistic rewards for usage. Participants in TAU group use the application individually throughout trial period without any motivational support. A flow chart of participation is displayed in figure 2.

Figure 2. Participant flow chart



Statistical analysis

Descriptive characteristics of participants along with attrition reason are reported. Pearson's correlation coefficient, independent samples *t*-tests, repeated measures ANOVAs with adjusted alpha levels, and $\chi 2$ tests will be used to measure mean differences from baseline to trial's end within and between research groups on primary and secondary outcome measures. Kaplan-Meier survival analysis plots and logrank tests are deployed to assess time of attrition and possible significant differences between and within research groups [50, 51]. Trial beginning is defined as time of first in-app health exercise completion and the trial period was six weeks, or 42 days, from that moment. Attrition, or the event, is defined as the time of participants' last completed health exercise in SidekickHealth. Participants' cases will be evaluated as censored when the application was still being used 42 days after study start. Cox proportional hazard regression models with interacting covariables using research groups as clusters was used to examine attrition prediction based on usage of in-app health exercises between time, type and frequency of exercises as well as sociodemographic variables (age, gender) [52]. Significance will be defined at $p<.05$. Data was analysed using IBM SPSS Statistics, Release Version 29 (SPSS, Inc., 2009, Chicago, IL, USA, http://www.spss.com).

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