Protocol

Effectiveness of digital interventions based on mobile phones for the prevention of sexually transmitted infections: A systematic review protocol

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Citation Duarte G, Vanegas J, Bravo G, Rada G, Pantoja T. Effectiveness of digital interventions based on mobile phones for the prevention of sexually transmitted infections: A systematic review protocol. *Medwave* 2019;19(2):e7605

Doi 10.5867/medwave.2019.02.7605

Submission date 30/8/2018
Acceptance date 11/3/2019
Publication date 28/3/2019

Origin not commissioned

Type of review reviewed by three external peer reviewers, double-blind

Key Words sexually transmitted infection, prevention, mobile phone, public health

Abstract

Introduction

Sexually transmitted infections, including HIV, are an important public health problem. Every day, over one million persons become infected with a sexually transmitted infection (STI). Health systems are searching for solutions to improve sex education and change the sexual behavior of people in order to prevent them. In public health, digital interventions based on mobile health technologies (M-health), especially those based on mobile phones, might be a crucial tool for the prevention of STIs and HIV. This systematic will review and summarize the evidence on the effectiveness of mobile phone-based interventions for the prevention of STIs and HIV.

Methods and analysis

The protocol was designed and will be reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P). The protocol will include randomized controlled trials that assess the effect of interventions based on mobile phones for the prevention of STIs/HIV. The interventions of interest will be those targeting mobile phone users and should consist of providing information by mobile phone through any function or application that can be used or sent to, and that has been designed to educate, promote or modify sexual behaviors and prevent STIs, including HIV. The data sources to identify these studies will be the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE and MEDLINE. The risk of bias will be assessed using the tool recommended by Cochrane. Finally, a meta-analysis will be done and data will be presented following the GRADE method.

Ethics and dissemination

This research was exempted by the Ethics Committee of Pontificia Universidad Católica de Chile (ID 171128002)

Trial registration number

CRD42018099008

Main messages

- Sexually transmitted infections, including HIV, are an important public health problem.
- Digital interventions based on mobile health technologies, especially those based on mobile phones, might be a crucial tool for public health.
- This protocol explores methods for the systematic review of the effectiveness of interventions based on mobile phones in the prevention of sexually transmitted diseases/HIV.

Introduction

Sexually transmitted infections, including human immunodeficiency virus (HIV), are a major public health problem. Every day more than 1 million people in the world become infected with a sexually transmitted infection (STI). The complications caused by these infections can produce injuries and consequences such as infertility, ectopic pregnancy and sometimes cancer associated with an infection by human papilloma virus[1].

Counselling and behavioral approach interventions based on safe sex represent the first prevention strategy for STIs/HIV. Nevertheless, the results achieved are insufficient and the global trend is a rise in STIs and HIV.

In Chile, according to the last reports of the Public Health Institute, confirmed cases of HIV have increased by 45% between 2010 and 2015[2]. In addition, data released by the 2016-1017 National Health Survey indicates that only 1 in 5 young people uses condoms[3].

The use of technology in health, as well as interventions based on mobile phones, have increased over the last years and could be a useful tool for disease prevention. The advantage of these interventions resides in their potential to enhance access at low cost, eliminating barriers such as poverty, adolescent population, rural zones and incompatibility with health care centers schedules, among others.

The World Bank estimates that 96% of the world population has access to a mobile phone, including the poorest 70%[4]. Out of the 7 billion people in the world, 2 billion have smartphones and approximately 50% of mobile phone users access the Internet with them. By 2019, it is expected that mobile phones will exceed 5 billion users[5]. Chile leads in the use of smartphones in Latin America, with 7.9 million users[6].

Digital interventions based on mobile phones were used for the first time to handle chronic non-communicable diseases. The current systematic reviews on this topic are centered on chronic diseases such as hypertension and diabetes, as well as addictions such as tobacco and alcohol, which are intervened through text messages[7]. With respect to M-Health-based interventions on sexually transmitted diseases/HIV, a study demonstrated the effectiveness of short messages service (SMS) over the adherence to antiretroviral therapy[8].

The use of mobile phones could improve the knowledge about health, behavior and results in groups that experience obstacles in health care, such as stigma and embarrassment when searching for information in clinical environments. These interventions offer more privacy than face-to-face counselling and can provide information anonymously. Furthermore, young people feel motivated with the use of these new technologies[9].

The potential benefits of these interventions are ease of use, cost-effective delivery and scaling to large populations, the capacity to adapt messages to the characteristics of the user (such as sex and age) and send information everywhere at any time if the device is always turned on, which translates into counselling and behavioral changes.

Behavioral changes can be achieved if interventions are based on theories. This was demonstrated through a randomized clinical trial in which mobile ads were used to promote safe sex and sun care for young people through text messages[10]. The intervention was based mainly on Weinstein's precaution adoption process model[11] and incorporated elements from Ajzen's theory of planned behavior[12] and Bandura's self-efficacy concept[13].

The use of new technologies like mobile phones and the Internet is widespread. Text messages offer a new method for promoting sexual health in young people, who are the most recurrent users of these new technologies and also have a high risk of STIs. Studies show that mobile phones will be the top tool for connecting to the Internet in 2020 and that it will be feasible to include them in health care[14]. In connection, health care systems have been looking for solutions to improve awareness and generate changes in people's behavior to prevent sexually transmitted infections[15].

The relevance of this systematic review is related to the approximately 44.6% increase in the cases of HIV in 2015 compared to 2010[2] and to the lack of effective interventions that reach the population and reduce this risk.

The current national health strategy for 2011-2020 has the goal of increasing the prevalence of safe sexual behaviors in adolescents and young adults[16]. However, prevention still plays a secondary role in many health systems, including the Chilean one, since health care providers often do not take the interaction with patients as an opportunity to inform them about the strategies for patient advocacy and preventing diseases[17].

Interventions are needed to change behaviors and conducts in such a way that this helps health care users and personnel to adopt preventive measures for STIs/HIV. Interventions based on mobile phones might be an important tool for preventing STIs/HIV in public health.

Although some publications examine mobile phone-based interventions, evidence needs to be updated. This review seeks to summarize the findings of all interventions for the prevention of STIs that are based on mobile phones in order to contribute to the planning, research and implementation of programs with innovative solutions to improve the indicators in public health[18].

Objectives

To assess the impact of mobile phone-based interventions on the prevention of sexually transmitted infections, including the infection caused by the human immunodeficiency virus (STIs/HIV).

Secondary objectives

- To determine what type of mobile phone-based intervention is more effective in preventing STIs/HIV.
- To explore what components of the design of these interventions contribute to a positive behavioral change.
- To explore the behavioral change techniques and theoretical models that sustain these interventions.

Methods

This protocol presents the objectives and methods that will be used for the systematic review. We expect that the methods for final review proposed by this protocol will allow us to conduct the process in a transparent way, restricting biased interpretations by the reviewers.

Protocol and register

Our protocol was enrolled in PROSPERO (CRD42018099008) and is structured according to the recommendations provided by Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P)[19] (Annex 1).

Study selection criteria for this review

Type of studies This review will include only randomized controlled trials [individual or by clusters] that assess the effect of mobile phone-based interventions on the prevention of sexually transmitted infections/HIV. The reason to include only trials lies in the possibility of obtaining higher reliability in the estimations of the effects.

Type of population We will include trials that assess the effect of digital interventions conducted through mobile phones on any type of population, and that have been designed to educate, promote or modify behaviors for the prevention of sexually transmitted infections including HIV in all contexts and at all levels of health care (i.e., primary, secondary and tertiary health care).

Interventions that are not aimed at preventing the transmission of STIs will be excluded. For example, studies to improve adherence to treatment of chronic conditions, such as antiretroviral therapy in HIV-positive patients or vaccine therapies.

Type of interventions The interventions included will be those targeting mobile phones and based on communicating information through any function or application in order to prevent STIs and/or reduce sexual risk behaviors. The interventions of interest should be digital, based on mobile phones and conducted through:

- Text messages (SMS)
- Voice messages
- Phone calls
- Mobile applications
- Sending videos

Type of comparison Our main interest will be to assess the channel through which the STI prevention messages are delivered to the control group (face-to-face and group counselling). However, all interventions will be compared as follows:

- Digital intervention based on mobile phone vs. passive control (no intervention)
- Digital intervention based on mobile phone vs. active control (individual counselling (face-to-face))
- Digital intervention based on mobile phone vs. active control (group intervention)

Types of outcomes

Primary outcomes:

- Change in specific behaviors that reduce the risk of STIs (for example, sexual abstinence, reduction in the number of sexual partners, reduction in unprotected intercourse).

Secondary outcomes:

- Change in awareness (i.e., knowledge and perception of risk in sexual life).
- Attitude and intention to change.
- Self-efficacy (the belief that a person has the capacities to perform a specific action, for example, to use condoms more frequently).
- Improve STI/HIV test participation.

Search method for identifying studies

Electronic Searches The search for primary studies will be conducted in the Cochrane Central Register of Control Trials (CENTRAL), EMBASE and PubMed/MEDLINE. There will not be restrictions related to date, language or publication status in order to make the search comprehensive and rigorous, the matrix will be created by an expert librarian. The detailed search strategy is described in Appendix 2. Additionally, an extended search will be conducted using other sources.

Other sources An extended search will be conducted to identify articles from the "gray literature" as well as studies to be published. The search comprises the following types of articles:

1. Review of conferences and congresses.
2. Search in other relevant systematic reviews. Both the articles included and excluded from all systematic reviews will be analyzed. Studies and systematic reviews from multiple sources, including MEDLINE/PubMed, EMBASE, and Cochrane, among others, will be identified to create an evidence matrix that allows us to identify the key words and terms for phase II or definite search. The detailed search strategy is described in Appendix 3.
3. Manual review of references. A manual search will be conducted in the reference lists of all studies included as well as in the narrative reviews and clinical practice guidelines that are more relevant to the study.
4. Contact with experts via e-mail. The authors of the studies included, as well as local and foreign experts in the field, will be reached via e-mail and invited to provide published or non-published additional information.
5. Search for related articles. Using the references of each study included, the *related articles* tool from PubMed, the databases from Scopus and Google Scholar will be used to find possibly related articles.
6. Search in the World Health Organization (WHO) International Clinical Trials Registry Platform to identify studies still unpublished or in progress.

Selection of studies

The results of the literature search will be uploaded to the CollaboratronTM software [http//collaboratron.epistemonikos.org]. References will be duplicated through an algorithm for the comparison of unique identifiers, that is, names of authors, journal, years of publication, volume, issue, page, title of the article and excerpt of the article.

Two authors will separately contrast the titles and abstracts of the references identified in the search against the inclusion criteria. The full version of all articles that comply with the inclusion criteria will be obtained. When necessary, the authors of the articles will be consulted to clarify doubts about the eligibility of the article. Disagreements will be resolved through discussion. The study selection process will be presented in the PRISMA flowchart.

Data extraction and handling

Using standardized forms, two reviewers (GD, JV) will separately extract data from each study included [general information, population, methods, measures of effect and risk of bias]. To ensure consistency, calibration exercises will be carried out prior to data extraction. Disagreements will be resolved through discussion and, if necessary, with the participation of a referee (third reviewer).

Evaluation of the risk of bias of the studies

Two reviewers (GD and TP) will separately assess the risk of bias by means of Cochrane's collaboration tool[20] which performs the following steps: generation of a randomized sequence; allocation concealment; blinding of participants, personnel and outcome reviewers; incomplete results data; selective report of outcomes and other sources of bias. Decisions will be made regarding each of these aspects, classifying them as high, low or uncertain risk of bias. Disagreements will be resolved through discussion between both reviewers and, if necessary, consulting a third author. The risk of bias of each dimension from each study will be graphed using RevMan 5.1[20,21]

Measurement of the effect of the intervention To analyze the effect of the intervention, results will be classified into dichotomous and continuous outcomes. For dichotomous results, relative risk with 95% confidence intervals will be used as the effect measure. For continuous outcomes we will use mean difference with 95% confidence intervals as the effect measure. When the latter are measured using different scales, standardized mean difference (SMD) with 95% confidence intervals will be used instead.

Handling of missing data

If possible, we will try to reach the authors to obtain missing data. In case it is not possible to obtain such data, the study will include them in the review but not in the quantitative synthesis.

Heterogeneity evaluation

The degree of heterogeneity between studies will be evaluated qualitatively in terms of , technology used, subjects' characteristics, context of the population in the study, follow-up period and results of the intervention

When relevant, heterogeneity will be analyzed statistically using the I2 statistics. The I2 value interpretation established in the Cochrane Handbook will be used as a reference. This indicates that 0 – 40% could be non-significant, 30 – 60% could represent moderate heterogeneity, 50-90% substantial heterogeneity and 75 – 100% great heterogeneity.

All possible sources of heterogeneity will be assessed by means of subgroup case analysis in the case of having enough studies.

Data synthesis

Metanalysis will be conducted only if there are studies homogeneous enough in terms of design, population, interventions and comparators reporting the same result measures. This analysis will be carried out through the inverse variance method using a random effects model. Separate analysis will be presented for populations and/or specific interventions according to the process explained in the section subgroup analysis. Analyses will be computed in the software Review Manager (RevMan) from Cochrane Collaboration. If conducting metanalyses is not possible, a structures synthesis of results will be presented instead.

Subgroup analysis and heterogeneity research

If relevant heterogeneity is detected in the qualitative or quantitative analysis, we will explore whether one of the following factors can explain it by using the standard subgroup analysis methods, comprising type of population (adults versus adolescents), intensity of the intervention (text messages vs. mobile apps vs. videos) and types of outcomes (knowledge, self-efficacy/intention, behavior).

Assessment of publishing bias

We will assess publishing bias visually using funnel charts (funnel plot). Reporting bias will be measured through discrepancies between the registered protocol and the final publication. If the registry of a study is not found in the International Clinical Trials Registry Platform, the authors will be contacted for more information.

Sensitivity analysis

Sensitivity analysis will be used to assess the impact of including studies with high risk of bias or of imputation of missing data on the effect estimators for the main comparison.

Degree of evidence certainty

The certainty (also called quality) of evidence for each outcome will be assessed using the GRADE (*Grading of Recommendations Assessment, Development and Evaluation)* methodology[22]. A judgment will be made about the certainty of evidence in terms of risk of bias, consistency, precision, direct or indirect evidence and publication bias. Adding the judgments about each domain, we will estimate if certainty is high, moderate, low or very low.

Results presentation

Results are presented based on the GRADE methodology through the table Summary of Findings/SoF table, which includes all data on population, intervention and comparison. Each outcome is presented with its related and absolute effect estimator (if possible), evidence certainty and the structured key message.

Notes

Annexes
Annex 1

Annex 2

Annex 3

Contributions and acknowledgments

GD,JV, TP, GB and GR started and designed the protocol. All the authors contributed to the article. All of them read, provided feedback and approved the final article.

Funding statement

The authors declare that no third parties provided funding for this study.

Competing interests

Authors filled in ICMJE's conflict of interest statement and declare not having received funding for this report nor having any links with organizations that might have been interested in the article published three years, as well as other relationships or activities that might influence the article published. The forms can be requested by contacting the corresponding author or the editorial board of this journal.

Acknowledgements

To Macarena Morel, librarian from Centro de Evidencia of Universidad Católica de Chile, who was in charge of the searching strategy in MEDLINE/PubMed.

Author's note

This protocol was created and designed for the thesis to qualify for a Master's in Public Health.

From the editor

This article was originally submitted in Spanish. The journal has not copyedited the English translation of the article.

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