Assessing the reporting and design of mHealth interventions for health behavior change: A methodological review of randomized controlled trials.

Study protocol

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1. INTRODUCTION

Supporting patients through the modification of health-related behaviors is a significant function of health care services, one that is often neglected due to limited resources.[1] Mobile health (mHealth) holds promise in bridging this gap. Mobile technologies have attracted research interest because they are popular, portable, and can allow real time intervention delivery in real-life contexts.[1] They can offer interactivity, tailoring, and enable access to interventions at a low cost.[1] Reviews demonstrate that these interventions may be effective for a range of outcomes, including improved medication adherence, smoking cessation,[1] and cardiovascular health-related behaviors.[2]

In spite of the enthusiasm, the current literature has a number of limitations. The field is rife with short-term pilot trials with small samples.[2-4] There are knowledge gaps regarding the long-term effects on clinically significant outcomes, user acceptability, adverse events, and cost-effectiveness.[1-7] Moreover, tailoring potential, which has been trumpeted as a main advantage of mHealth, seems to be under-utilized.[8]

The long-term sustainability of the behavior change produced by these interventions has also been questioned.[9] Health-related behaviors need to be sustained for a prolonged period of time in order to lead to meaningful improvements in population health.[9] Unfortunately, relapse to the old, undesirable behavior is not uncommon. Even in the case of incentive-based programs, such as contingency management, that offer material rewards to reinforce healthy behavior (eg., vouchers), patients often return to the baseline behavior after the intervention ends and the reinforcement is discontinued.[10] To create enduring health habits, mHealth devices need to encourage internal motivation, seeing as relying on external motivation alone may be difficult to sustain in the long term.[9] Evaluations of behavior change interventions also frequently fail to make a satisfactory link to health outcomes that are important to the

patient and to clinicians.[11] Lastly, the existing evidence on mHealth interventions is heterogeneous in reporting quality and completeness.[12] Poor reporting is not uncommon in trials of non-pharmacological interventions, and it limits their reproducibility and wider implementation.[13]

These shortcomings limit our ability to capitalize on mHealth technologies.[6,14] In order to understand if the full potential of mobile technologies is utilized, there is a need to summarize the current state of mHealth behavior change interventions across several aspects. These include reporting quality, long-term potential of the produced behavior to affect health outcomes, use of tailoring, and use of behavioral theory and techniques.

1.1.Objectives

Our aim is to assess reports of randomized controlled trials evaluating behavior change interventions delivered by mHealth devices, regarding intervention reporting and intervention characteristics (behavior theories used, use of tailoring, and long-term potential of the produced behavior to affect health outcomes).

2. METHODS

We will perform a methodological review of randomized controlled trials that evaluate mHealth behavior change interventions.

2.1. Eligibility criteria

We will include studies fulfilling all of the following criteria:

- Studies reporting on interventions that include at least one mHealth component, as this has been defined by the Global Observatory for e-health of the World Health Organization (WHO): *medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*'.[15]

- Studies reporting on interventions aiming to produce behavior change, as this has been defined in the *Encyclopedia of Behavioral Medicine*: "*Behavior change is the process of modifying a behavior, often to produce a desired outcome. Behavior change involves the substitution of one pattern of behavior for another*."[16]

- Studies with randomized controlled trial design (including complex designs such as cluster, crossover, stepped wedge, etc).
- Studies published since January 1st 2014.
- Studies published in journals in the 1st and 2nd quartiles of the average Impact Factor across all categories the journal belongs to, according to the InCites ranking, in pre-defined relevant Categories.[17]

We will exclude the following studies:

- Papers reporting on the process of trials that are ongoing.
- Studies reporting on interventions that have no clear mobile component. For example, web-based interventions, or studies where the mobile component is optional (eg., participants could choose to receive complementary SMS or not).
- Behavioral interventions aiming to change behaviors not relevant to health outcomes.

2.2. Search Strategy

We will search PubMed for eligible studies. The search equation is built around Mesh terms and free text words, referring to mHealth, behavior, and study type. The search will be restricted to the last three years (from January 1st 2014 to the date of last search).

Table 1. Search equation for Pubmed

#5		#1 AND #2 AND #3 AND #4
#4	Publication date filter	"2014/01/01"[PDAT] : "3000/12/31"[PDAT]
#3	Study type[18]	(randomly[tiab] OR trial[ti] OR clinical trials as topic[mesh:noexp] OR placebo[tiab] OR randomized[tiab] OR randomised[tiab]) OR controlled clinical trial[pt] OR randomized controlled trial[pt]) NOT (animals[mh] NOT humans[mh])
#2	Behavior	"behavior"[MeSH Terms] OR behav*[Title/Abstract]
#1	mHealth	tablet[Title/Abstract] OR mobile[Title/Abstract] OR "cellular phone"[Title/Abstract] OR “cellular phones”[Title/Abstract OR "cell phone"[Title/Abstract] OR "cell phones"[Title/Abstract] OR ipad[Title/Abstract] OR smartphone*[Title/Abstract] OR PDA[Title/Abstract] OR "personal digital assistant"[Title/Abstract] OR telemedicine[Title/Abstract] OR "tele-medicine"[Title/Abstract] OR

		telemetry[Title/Abstract] OR "monitoring device"[Title/Abstract] OR "monitoring devices"[Title/Abstract] OR "wireless patient monitoring"[Title/Abstract] OR "remote patient monitoring"[Title/Abstract] OR "sensing technology"[Title/Abstract] OR "sensing technologies"[Title/Abstract] OR sensor[Title/Abstract] OR sensors[Title/Abstract] OR portable[Title/Abstract] OR wireless[Title/Abstract] OR "text messaging"[Title/Abstract]) OR "text message"[Title/Abstract]) OR "text messages"[Title/Abstract]) OR "short messaging service"[Title/Abstract] OR sms[Title/Abstract] OR "global positioning system"[Title/Abstract] OR gps[Title/Abstract] OR bluetooth[Title/Abstract] OR telecommunication[Title/Abstract] OR telemonitoring[Title/Abstract] OR "tele-monitoring"[Title/Abstract] OR cybermedicine[Title/Abstract] OR mhealth[Title/Abstract] OR "m-health"[Title/Abstract]) OR telemedicine[MeSH Terms] OR computers, handheld[MeSH Terms] OR cell phones[MeSH Terms] OR medical informatics[MeSH Terms] OR text messaging[MeSH Terms] OR wireless technology[MeSH Terms]

2.3. Study selection

The titles and abstracts of retrieved records will be screened independently by two reviewers according to pre-specified eligibility criteria. Disagreements will be resolved by consensus. Eligible studies will be included for full-text consideration. The number of excluded studies will be reported. The primary reason for exclusion will be reported for the studies excluded after full-text consideration only. We will use the Covidence online platform (https://www.covidence.org/) to manage this process.

In the case of exact duplicate records, we will keep only the most recent publication. If more than one retrieved records refer to the same trial (eg., same intervention and methodology, but reporting on different outcomes) we will retrieve information from both publications. If an included study cites another source where the intervention is described in detail (a

protocol, online supplementary materials, an application depository, or a previous publication), we will retrieve information from all cited sources.

2.4. Data extraction

We will use a pre-specified, piloted data collection form to extract data from study reports and supplementary files. Two reviewers will independently extract data for the intervention reporting (mERA checklist) and any disagreement will be resolved by consensus. One reviewer will extract data for the remaining items (intervention contents and study characteristics), and a second reviewer will duplicate 10% of the extraction to confirm accuracy. Data will be extracted on the following:

2.4.1.Study characteristics

We will extract the year of publication, study location (country classification by income level according to The World Bank), disease and behavior targeted, and type of comparator (eg., sham intervention or active comparator). We will note where recruitment occurred (i.e., primary, secondary, tertiary care, community). As primary care we define locally based practitioners that serve as a first point of consultation for patients (ie., family physician). As secondary care we define specialized practitioners, who usually do not have first contact with patients (ie., psychiatrist). As tertiary care we define specialized care for advanced treatment that is accessed upon referral, usually for inpatients.

2.4.2.Reporting of interventions

For the assessment of reporting quality we will focus on the arm assessing interventions where mHealth is a primary or secondary component. In case a trial includes more than one mHealth intervention, data will be extracted by all arms for each individual active mHealth behavior change intervention (excluding sham interventions used as control arms).

We will use the mERA checklist as a guide. The mERA is a 16 item list that has been developed specifically to aid authors in the reporting of mHealth interventions. It aims to aid the description of technical aspects (eg data handling) as well as content/ delivery aspects of interventions.[12] We will assess the reporting completeness of each item by marking it as YES (if the description is adequate) or NO (if the item is missing or unclear).

2.4.3. Intervention characteristics

We will note whether the mobile technology component is an add-on or a stand-alone. We will extract information on the timing, duration and frequency of the intervention, the device, and whether staff was involved in the delivery. We will note if the patients required training to use the intervention.

2.4.4. Intervention design: Use of theory

- We will note if one or more theories of behavior change have been cited for the intervention design. We will note if theories from other fields of knowledge have been cited (eg engineering, systems science).
- We will note if any behavior change techniques have been cited from the Taxonomy of Behavior Change Techniques (v1) by Michie et al.[19].
- We will note the presence or absence of commonly used techniques (eg., goal setting, active or passive monitoring, feedback in graphic or message form, education/information, etc.)

2.4.5. Intervention design: Use of tailoring

We aim to assess tailoring use (input, output, timing, automatization).

- Input and output: we will note what input and output data consist of. Input refers to the information entered in the device that the tailoring is built upon (ie., demographics, preferences, etc). Output refers to the way the input alters the intervention (ie., by changing the content or frequency of messages, or personalizing the intervention goal).
- Timing: we will note when tailoring occurs (i.e., only at initiation, at specific predefined time points, or continuously according to the principles of just-in-time adaptive technology).
- Automatization: we will note if the tailoring input and output is produced automatically (i.e., using algorithms), or manually (i.e., manual input by patient, manual tailored output by staff).

2.4.6. Long-term potential to impact health outcomes

We aim to assess the long-term potential of these interventions to impact significant health outcomes. We will therefore map the type of outcomes and the follow up intervals used in

trials, and the different types of behavior reinforcement used (ie., external rewards and reminders, creating cues, planning for behavior maintenance, etc.).

- Outcomes: we will extract which category the primary and secondary outcomes belong to:
    - Patient important health outcomes (including death, quality of life, major or minor morbid events, pain or functional status),[20]
    - Surrogate health outcomes (defined as intermediate end points that might indicate disease progression and increased risk for patient-important outcomes),[20]
    - Physiological/laboratory outcomes (defined as the assessed response to physiological or laboratory maneuvers that have no direct tangible effects on patients),[20]
    - Behavior (eg., daily fruit consumption),
    - Theoretical variables (eg., knowledge, attitudes, readiness to change).
- Follow up: we will note how long after intervention initiation the last follow up occurred (interval in months), and if the intervention was completed or ongoing at that time.
- We will note any effort by the interventionists to ensure the behavior change will be sustained after the intervention is over.

2.5. Data synthesis

We will use descriptive statistics to present the extracted data. All analyses will be performed using R version 3.3.0.[21]

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