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A Comparison of Mobile Health Evaluation Techniques

Full Paper

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Abstract

Mobile health (mHealth) has the potential to profoundly improve global healthcare delivery by enabling healthcare workers to make more accurate diagnoses, instantly access records and transmit data as well as allowing patients to take an active involvement in their own healthcare. However, this potential cannot be reached without the adequate evaluation of interventions to ensure that they are not only safe and beneficial, but that they are acceptable to end-users. A major challenge faced by emerging mHealth interventions is that of identifying an evaluation technique which is able to provide a thorough, rigorous evaluation, which incorporates the needs and requirements of all stakeholders. This investigation will compare four mHealth evaluation methodologies against the characteristics of mHealth across protocol-related and logistical factors to identify methodological "matches" and to highlight important "mismatches." These mismatches will require addressing in order to inform the design of the most rigorous and thorough mHealth evaluation protocol.

Keywords

mHealth (mobile health), evaluation, comparison.

Introduction

Mobile Health (mHealth) can be broadly defined as the use of mobile technologies like mobile phones, personal digital assistants, handheld and ultra-portable devices (tablets) and other mobile devices in healthcare to improve healthcare systems, support healthcare professionals and provide better health outcomes for patients (Burns, et al., 2016). In the past decade there has been an exponential increase in the number of mHealth applications available for use on mobile phones and tablets. There are currently 165,000 health applications publicly available for download across Apple's iOS and Google's Android platforms (IMS Institute for Health Informatics, 2015). At present, there is no evaluation method which is specific to mHealth and there is little or no existing quality control or regulations to ensure these health apps are user-friendly, accurate in content, evidence-based or efficacious (Boudreaux, et al., 2014).

There is very limited evidence on the effects of mHealth in low income countries and information on cost-effectiveness of mHealth interventions is largely unavailable (Stephani, et al., 2016). Further, current research into the assessment of mHealth from the perspective of developing countries particularly with community health workers as the primary users tends to be limited (Tariq & Akter, 2011 In a healthcare system already burdened with suboptimal outcomes and excessive costs, premature adoption of untested mHealth technologies may detract from, rather than contribute to, what is needed for true overall health improvement (Kumar, et al., 2013). A further challenge to the evaluation of mHealth interventions lies in the subjectivity of evaluation; one may see an initiative as a success if most stakeholders attain their major goals and do not experience significant undesirable outcomes (Heeks, 2002). However, the stakeholders who do not attain their major goals may brand the initiative as a failure. To remedy this issue requires the relatively sophisticated approach to evaluation that is absent in most mHealth cases (Heeks, 2002).

Science cannot move as fast as new innovations hit the market but it may be the case that science may not necessarily match the pace as the goals of science and the industry are different (Pagoto & Bennett, 2013). Hatt, et al., (2015) believe that a rigorous mixed-methods approach is essential to untangle the "why" and the "how" of the impact identified in a RCT and that global public health practitioners should use the most rigorous systematic approach available to answer questions and make decisions in the face of uncertainty. In recent years, alternative evaluation methods for mHealth have begun appearing across the literature but they are as yet, unsuccessful in changing the perception that a RCT is the best mechanism for mHealth evaluation. Pham, et al., (2016) observed during their study that not once in the registration of any mHealth clinical trial were alternative methodologies to RCTs mentioned as more suitable for mHealth evaluation.

This investigation will examine the classic RCT and newly emerging methods of mHealth evaluation; Continuous Evaluation of Evolving Behavioural Interventions Technologies (CEEBIT), Multiphase Optimisation Strategy (MOST) and Sequential Multiple Assignment Randomised Trial (SMART) outlining a comprehensive comparison between the characteristics of each trial design and the challenges posed by the unique field that is mHealth.

Literature Review

The current evidence for the efficacy of mHealth interventions is sparse due to a lack of appropriate evaluation frameworks (Kumar, et al., 2013; Hall, et al., 2014; Déglise, et al., 2012). A comprehensive review of the scope of mHealth in 2014 found only a 5-year history, which may partly explain why, in low- and middle-income countries, there remains a strong focus on mHealth pilot studies which have rarely been followed up with more rigorous evaluation studies and have generally not been taken to scale (Hall, et al., 2014). Although problems like chronic health conditions are key targets of emerging mHealth research, the hypothesis that better monitoring with mobile technology will lead to better management, better outcomes and reduced disease burden has yet to be adequately tested (Nilsen, et al., 2012). The evaluations that have been carried out on mHealth interventions often do not follow rigorous scientific standards of randomised controlled trials and consequently, they carry a relatively high risk of bias (Stephani, et al., 2016) and the current evidence is not convincing enough for policy-makers (Chib, et al., 2014). Rigorous evaluation of mHealth apps is essential not only to estimate the magnitude of the outcomes but also to ensure that they do no harm (Pagoto & Bennett, 2013). Many health IT usability studies have been conducted to explore usability requirements, discover usability problems and design solutions, but few of these studies have evaluated the usability of mobile technologies (Brown III, et al., 2013). The lack of evaluation across the mHealth field as a whole is a major weakness and threatens the credibility of mHealth as a concept (Hall, et al., 2014). Premature scale-up of a mHealth initiative could, due to early selection and failure of the wrong initiative, by extension, harm the entire field (Chib, et al., 2014). The following sections descibe the different methods that are used to evaluate mHealth; RCT, CEEBIT, MOST and SMART methodologies.

Randomised Controlled Trials

The RCT is a trial in which subjects are randomly assigned to one of two groups: one (the experimental group) receiving the intervention that is being tested and the other (the comparison group or control) receiving an alternative (conventional or placebo) treatment (Kendall, 2003). All intervention groups are treated identically except for the experimental treatment (Sibbald & Roland, 1998). The two groups are then followed up to see if there are any differences between them in outcome. The results and subsequent analysis of the trial are used to assess the effectiveness of the intervention, which is the extent to which a treatment, procedure or service does more good than harm (Kendall, 2003).

RCTs are considered to be the "gold standard" for examining the effectiveness of a medical interventions in a clinical domain due to their ability to control for confounding factors and bias (Kendall, 2003). Calls for greater rigor in evaluation has increased the number of mHealth RCTs conducted in developed and developing countries (Burns, et al., 2016). The overwhelming majority of mHealth researchers are continuing to use the RCT as the trial design of choice for evaluating mHealth apps. This suggests that researchers view this design to be condition-agnostic and truly the gold-standard for any clinical trial evaluating app efficacy (Pham, et al., 2016).

Continuous Evaluation of Evolving Behavioural Intervention Technologies

Behavioural Intervention Technologies (BITs) are web-based and mobile interventions intended to support patients and consumers in changing behaviours related to health, mental health and well-being (Mohr, et al., 2013). CEEBIT is an evaluation method involving the deployment of substantively new versions of an intervention along with the previous version, with users randomised to available versions and the most efficacious version, based on a priori criteria, is retained (Kumar, et al., 2013). This framework was proposed by Mohr *et al.,* as an alternative to the gold-standard RCT.

This methodology addresses the current weak evidence base and lack of discussion addressing how to evaluate interventions, particularly BITs, effectively and efficiently and provides a solution to the challenge of rapid change, evolution and expanding expectations in the BIT market (Mohr, et al., 2013). This design may be well suited to ongoing evaluation of interventions as they go to scale, continuously improve over time and adapt to rapidly changing technologies (Kumar, et al., 2013). The method is statistically powered to continuously evaluate application efficacy throughout trial duration and accounts for changing application versions through a sophisticated elimination process (Pham, et al., 2016).

Multiphase Optimisation Strategy

MOST uses a principled method for identifying which components are active in an intervention and which levels of each component lead to the best outcomes. Its underlying principles are drawn from engineering and emphasize efficiency (Collins, et al., 2007). Promising components of an intervention are identified in a screening phase through either factorial or fractional factorial analysis of variance design (Kumar, et al., 2013). MOST uses three phases as a replacement for the cycle of confirmatory trial, exploratory analysis, revision and subsequent confirmatory trial (Collins, et al., 2005). The final, optimized intervention is then evaluated in a standard RCT in the confirming phase addressing whether the intervention is efficacious with a large enough effect to justify investment in a community implementation (Collins, et al., 2007).

MOST is a system aimed at creating optimal versions of multicomponent interventions (Clough, et al., 2015). The traditional approach to intervention development has involved constructing an intervention a priori and then evaluating it in a standard RCT, after which, post-hoc analyses are done and adjustments are made (Collins, et al., 2007).

Sequential Multiple Assignment Randomised Trial

The SMART approach is a randomised experimental design that has been developed especially for building time-varying adaptive interventions (Collins, et al., 2007). It allows investigators to evaluate the timing, sequencing, and adaptive selection of treatments in a principled fashion by use of randomised data (Almirall, et al., 2012). All questions within the SMART trial are addressed by means of randomised experiments and the end goal of the SMART approach is the development of evidence-based adaptive intervention strategies which are then evaluated in a subsequent RCT (Collins, et al., 2007).

The SMART approach enables the intervention scientist to address questions about the intervention in a holistic yet rigorous manner, taking into account the order in which components are presented rather than considering each component in isolation (Collins, et al., 2007). Researchers decide which aspects of treatment require investigation and then individuals are randomly assigned to various intervention choices over time (Kumar, et al., 2013). With this approach, a number of important treatment questions can be answered; the optimal length of the intervention, the best approach to take for treatment of non-responders and the level of support required for individuals (Clough, et al., 2015). It may be most advantageous to integrate a SMART trial into the MOST procedure during the refining phase, but SMART may also be used as a stand-alone technique (Collins, et al., 2007).

Comparison of Evaluation Techniques

The following table outlines the main characteristics of each evaluation technique in a comparison of their suitability to mHealth evaluation. These criteria have been determined as important in terms of choosing an evaluation technique as they examine both protocol-related factors, including standard execution and data collection techniques as well as logistical, resource requirement factors such as time and cost.

	RCT Characteristics	CEEBIT Characteristics	MOST Characteristics	SMART Characteristics	**mHealth Challenges**
Data Collection & Analysis	Quantitative analysis - The analysis is focused on estimating the size of difference in predefined outcomes (Sibbald & Roland, 1998).	Collects outcome and use data in real time. CEEBIT capitalizes on data generates by BITs to continuously evaluate efficacy in a manner consistent with the current socio-technologic environment (Mohr, et al., 2013).	A key feature of MOST is that each new intervention produced will have been engineered, and empirically demonstrated, to be an improvement over the previous version (Collins, et al., 2011).	SMART designs provide a framework to empirically determine the most powerful version of an intervention (Clough, et al., 2015). However, the SMART design does not compare the intervention to a control or comparative treatment condition (Clough, et al., 2015).	mHealth literature suggests the need for mixed-method evaluation to accurately capture the socio-technical reasons for using an inititative (Chib, et al., 2014).
Standard Execution Protocol	Blinding - Double blinding (usually investigator and participants) is the usual standard and will eliminiate any confounding factors occuring after randomisation (Kendall, 2003).	In instances when non-randomised assignment methods are warranted, statistical methods can mitigate overt bias when all confounding factors are observed (Mohr, et al., 2013).	Based on randomised experimentation, meaning that a high degree of confidence can be placed on the results (Collins, et al., 2007).	Based on randomised experimentation, placing a high degree of confidence on the results (Collins, et al., 2007). To avoid information bias, the use of a blinded, independent evaluator is suggested (Almirall, et al., 2014).	It is difficult to blind participants receiving an mHealth intervention due to the physical presence of the device (Stroux, 2012; Eysenbach, 2002).
Sample Size	The sample size must be large enough to eliminate chance (Kendall, 2003).	The sample size required in a CEEBIT methodology is considerably reduced due to a more liberal Type I error rate of 50% (Mohr, et al., 2013).	Interaction effect sizes tend to be small, making it important to ensure that there is sufficient statistical power to test any interactions that are of particular interest (Collins, et al., 2007).	The sample size required will depend on the primary aim for the trial and the level of analyses. In a longitudinal comparison of two groups, the sample size requirement is identical to that of a two-group, longitudinal RCT (Almirall, et al., 2014).	Recruiting adequate numbers may be challenging in developing countries where cultural and religious barriers may resist technological change (Tariq & Akter, 2011).
Cost	RCTs are expensive to carry out (Comstock, 2012) often due to the large sample size and length of follow-up time required (Rosen, et al., 2006).	The reduced sample size and rapid, real-time evaluation may contribute to lower financial costs than other methodologies.	MOST does not directly assess the overall effectiveness of the intervention to a comparative treatment or control condition but the process does ensure that the most efficacious version of the intervention goes forward to the final testing stage, thereby making for a more efficient use of time and resources (Clough, et al., 2015).	It would be more cost-effective both in terms of dollars spent, and in terms of the value of scientific information gained to use the SMART methodology, than to use a RCT to evaluate each question in the SMART stages (Almirall, et al., 2014).	In low-income countries where there may not be the resources to carry out expensive trials (Rosen, et al., 2006; World Health Organisation, 2012) and also in high-income countries where the sheer volume of mHealth interventions available, may mean it is not feasable to carry out resource-intensive evaluations.
Protocol	Rigid protocol, designed for the elimination of bias and confounding factors (Pham, et al., 2016).	Protocol is fluid, allowing for consumer choice to be incorporated into the evaluation as a fully observed pre-randomisation factor (Mohr, et al., 2013).	Protocol is fluid, exact details about its implementation depend on the application (Collins, et al., 2007). It is a "general approach," rather than an off-the-shelf procedure (Collins, et al., 2011).	SMART designs are not, as per common misconceptions, "adaptive trial designs," they are a fixed study design. (Almirall, et al., 2014, Almirall, et al., 2012).	Software is meant to evolve, change and progress over time at a rapid pace (Ben-Zeev, et al., 2015).
Time	RCTs are notoriously long (Pham, et al., 2016), with the entire process, including funding proposals and publication, taking upto 17 years (Pagoto & Bennett, 2013; Mohr, et al., 2013).	CEEBIT can support the rapid evaluation of BITs in near-real time through deployment sites located in care-providing organisations or commercial market places with the aim of protecting consumers from ineffective or inferior BITs (Mohr, et al., 2013).	A challenge is whether a full cycle of MOST can be completed within the five-year duration of the typical National Institutes of Health (NIH) funding cycle (Collins, et al., 2011).	The overarching aim of a SMART is to construct a high quality adaptive intervention based on data (Almirall, et al., 2014). This may save resources in the long run as the end intervention will be already optimised.	In the mHealth field, the fast pace at which technology evolves, may make lengthy study designs unsuitable for evaluation as in the time it takes to design and evaluate an intervention, the mHealth space may move so fast that the intervention is obsolete before it has even been implemented (Kumar, et al., 2013).

Discussion

As outlined in the table above, a number of factors must be taken into account when selecting an evaluation method for a mHealth intervention. The mHealth literature widely suggests that a mixed-methods approach should be used when evaluating a mHealth intervention. Quantitative data is important to determine if, and to what extent an intervention is functional and beneficial, but because of the many socio-technical aspects of mHealth, failing to include a qualitative evaluation may mean that the intervention will fail to be implemented. These sociotechnical factors include the social, cultural, religious and behavioural interactions of the end user, as well as other technological issues (Chib, et al., 2014), such as adequate cellular service and charging points, an issue which is particularly important in low- and middle- income countries. A RCT in its pure state immediately highlights an issue as its data collection and analysis is purely quantitative, meaning a standard RCT is unable to isolate the socio-technical aspects of mHealth which are so important for their successful implementation. The inclusion/exclusion criteria employed in RCTs can at times lead to high levels of internal validity but poor external validity when programs are eventually deployed in community settings (Clough, et al., 2015). The CEEBIT method has the potential to include a qualitative aspect but the selection of outcome measures will depend on whether the research question primarily pertains to the efficacy or the effectiveness of the app (Clough, et al., 2015). However, if a researcher is primarily concerned with the efficacy of an app, it could be possible that a qualitative evaluation will be absent and compromise the implementation of the intervention. Similarly, the MOST method consists of three phases, each of which addresses a different set of questions about the intervention by means of randomised, quantitative experiment and ending with the optimised intervention being evaluated in a RCT. Although the SMART trial follows a quantitative methodology, the pilot SMART trial can include qualitative aspects such as focus groups or structured exit interviews to help uncover new and potentially important tailoring variables (Almirall, et al., 2012).

All methodologies outlined in the table above include randomisation to eliminate certain biases and confounding factors, as well as allowing confidence to be placed on the results. The randomisations in SMART are aimed at permitting unbiased comparisons between treatment components (or their levels) at each decision stage in the development of adaptive interventions (Almirall, et al., 2014). As outlined, there is a difficulty in blinding recipients of a mHealth intervention due to the physical presence of the device but the SMART trial suggests the use of an independent evaluator who is blind to treatment assignment to eliminate any information bias which may result (Almirall, et al., 2014). This is important because a lack of blinding in a study design could lead to an over-estimation of the effects of an intervention, as was illustrated by Colditz, et al., (1989) who found that medical interventions evaluated within randomised trials that did not use a double-blind design reported a significantly greater likelihood of success on average than the studies that used double blinding.

A large sample size may be problematic in the area of mHealth, particularly in low- and middle-income countries where there may be cultural and religious barriers to technology, resisting change and creating challenges with recruitment (Tariq, et al., 2011) as well as technological barriers which may prevent usage such as intermittent reception and unreliable electricity for charging of devices. RCTs require a relatively large sample size in order to eliminate chance (Kendall, 2003), MOST requires a large enough sample size to detect small variations in interaction effects with sufficient statistical power (Collins, et al., 2007) and SMART claims to require a sample size similar to that of a RCT (Almirall, et al., 2014). However, CEEBIT claims to require a much smaller sample size due to it's much more liberal Type 1 error rate of 50%, compared to the standard Type 1 error rate of 5%.

RCTs are notoriously expensive (Comstock, 2012), rendering them potentially unsuitable for a low- and middle-income countries where financial resources are scarce (Rosen, et al., 2006; World Health Organisation, 2012), or even in a developed country, given the sheer volume of mHealth tools and applications currently requiring evaluation, as outlined earlier. The MOST and SMART methodologies both suggest greater cost-effectiveness than RCTs in that they are ensuring that the most efficient, fully optimised version of the app is going forward to be tested in a RCT (Almirall, et al., 2012, Clough, et al., 2015). The use of MOST does not require more resources than the classical approach, just a realignment of resources (Kugler, et al., 2016). Although it could be argued that because these methodologies still require RCT evaluation, they are equally as expensive, the proponents of these methodologies argue that the typical cycle of intervention-RCT-post hoc analyses-revision of intervention-RCT is likely to lead very slowly, if at all to an optimised intervention (Collins, et al., 2007). By presenting an already-optimised

intervention for RCT, both financial and time resources can be saved because the traditional RCT evaluates the intervention only as a whole, using the RCT alone does not enable isolation of the effects of individual program or delivery components (Collins, et al., 2007). The SMART design differs considerably from standard RCTs in terms of their overarching aim. Whereas the overarching aim of a SMART is to construct a high quality adaptive intervention based on data, the overarching aim of a RCT is to evaluate an already developed interventions versus a suitable control (Almirall, et al., 2014).

Timing is critical in the evaluation of mHealth interventions, given how fast technology evolves and develops, with a mere decade bringing exponential growth and change to the field. In the typically lengthy process of a RCT, a mHealth intervention may become obsolete in the time it takes to evaluate it. The CEEBIT methodology deals with this issue well, evaluating interventions in near real-time through deployment sites located in care providing organisations (Mohr, et al., 2013). The MOST methodology faces challenges as to whether a full cycle can be completed within the typical National Institute of Health (NIH) funding cycle (Collins, et al., 2011). Although, as Collins, et al., (2011) argue, this five-year funding cycle is merely an administrative necessity with no intrinsic scientific meaning or merit, it may still be incompatible with the speed at which the field of mHealth develops, as mentioned previously, a relatively short period of time in the context of drug development and trialing equates to a very long period of time in the mHealth field and the MOST methodology may be, similarly to the RCT, regarded as too long for mHealth.

Conclusion

As outlined by White, et al., (2016), to determine the success of a mHealth intervention, evaluation should examine user feedback and outcome measures, as well as the robustness of the technology, the intervention principles, engagement strategies and the interaction of the user with the technology. The comparison of the RCT, CEEBIT, MOST and SMART methodologies shows that each is capable of examining a number of these factors. However, it is apparent that the methodologies discussed are unable to examine all elements simultaneously and within the strict time constraints imposed by the rapidly evolving field of mHealth. There is a need for further research into the area of mHealth evaluation to build upon the methodologies currently available for mHealth interventions. The mis-matches between the mHealth criteria and the evaluation methodologies must be addressed to allow for the development of a holistic evaluation approach that will allow evaluations of mHealth interventions to provide the most robust and thorough results and contribute to timely, successful and long-term mHealth implementations. This investigation has limitations; the evaluation methodologies have been described in their simplest, pure state and the observations made apply only to those. Evaluation methodologies are adapted to suit the context in which they are being carried out and these context-dependent adaptations have not been taken into account in the above comparison; due to time constraints, it was possible to examine only the most common evaluation methodologies and it is possible that this comparison of evaluation methodologies against mHealth criteria is not exhaustive. Further investigation should examine the contextual adaptations applied to the RCT, CEEBIT, MOST and SMART methodologies and the potential of these adaptations to produce a better “fit” for mHealth evaluation.

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