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RANDOMISED CONTROLLED TRIALS AS A METHOD OF EVALUATING MOBILE HEALTH INTERVENTIONS

Research in Progress

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Abstract

With the momentum around the Millennium Development Goals (MDGs), more recently the Sustainable Development Goals (SDGs), there is a steady increase in the number of mobile health (mHealth) pilots, feasibility studies and randomised controlled trials (RCTs) used to evaluate the potential for mHealth in developing countries. Recent research indicates the need for more robust ways of evaluating and measuring mHealth in order to truly understand the tangible benefits, and to better plan for, wide scale mHealth roll-out and implementation. In a number of large funded mHealth projects in Africa, RCTs have been selected as a means of assessing mHealth. However, there remains a dearth of research to support the selection of RCTs as a means of evaluating mHealth. The objective of this research is to investigate RCTs as a method of evaluating mobile health interventions in developing countries. Using a qualitative analysis approach, this study aims to explore the challenges associated with pursuing an RCT for the evaluation of mHealth in Malawi, Africa. Following this, as part of the wider study a checklist of factors will be proposed as a means of determining the suitability (or lack thereof) of RCTs as a means of mHealth evaluation.

Keywords: mobile health (mHealth), randomised controlled trials (RCTs), evaluation, developing countries.

1 Introduction

mHealth (mobile health) is 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). Mobile phones are an ideal platform from which to deliver healthcare interventions due to their widespread infiltration into society. The adoption of mobile phones has soared from 4.6 million mobile subscriptions in 2009, to over 98 mobile subscriptions per 100 people globally. Mobile subscriptions now outnumber people in high income countries (The World Bank Group, 2016) and 95% of people are living in an area that is covered by a mobile cellular network (International Telecommunications Union, 2016). Developing countries in particular, have the fastest growing mobile phone subscriber market in the world (Stephani, et al., 2016), growing from just 7 subscriptions

per 100 people to almost 60 subscriptions per 100 people, in the last decade (The World Bank Group, 2016).

The particular driving force for the advancement of mHealth is a clinician's need for providing the right care to the right patient, at any time, in any place (Yu et al., 2006). Mobile phones provide the ideal platform to achieve this due to people's tendencies to keep their mobile phones switched on and on their person at all times. This allows millions of previously unconnected people to be within reach and has therefore produced millions of potential points of care. Mobile health provides the opportunity to advance research, strengthen prevention, enhance diagnostic abilities, improve treatment, increase access, improve quality of health care and reduce costs in ways previously unimaginable (Nilsen, et al., 2012; Davey & Davey, 2014). Short message service (SMS), the simplest form of mHealth delivery, is available on even the most basic of devices and does not require access to the internet. The one-to-many ability of SMS means that information can be delivered to a large number of recipients with minimal use of resources. SMS communication can be used to ease the administrational burden on healthcare workers by enabling them to send test results and may play a role in the reduction of missed appointments by providing a simple method of sending patient reminders and information (Lim, et al., 2008). mHealth is continually growing and evolving and although the simple SMS is still a very valuable tool, technologies with new and greater potential benefits are being designed and implemented continuously. These are not only beneficial to health care providers but allow the patient to take a more active, independent role in their healthcare (IMS Institute for Healthcare Informatics, 2015).

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) targetting two broad heathcare categories of Disease & Treatment Management and Wellness Management. Many of these apps are freely available and target broad areas such as fitness, diet and lifestyle as well as more disease-specific interventions and gender-specific apps targetting womens health and family planning. 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). To date, the majority of mHealth evaluation has been carried out using a randomised controlled trial (RCT) study design which has a rigid qualitative protocol. More recently, pilot trials are being designed which incorporate both a qualitative and quantitative aspect in their methodology but they are still in their infancy and have yet to produce any definitive results. There are also several theoretical evaluation methods which have been developed specifically for mHealth, but these have yet to be empirically tested.

The purpose of this study is to investigate RCTs as a method of evaluating mHealth interventions. RCTs are considered to be the "gold standard" for examining the effectiveness of medical interventions in a clinical domain due to their ability to control for confounding factors and bias (Kendall, 2003). However, this title has been earned mainly in a pharmaceutical context and there are now suggestions that this may not be the case for other health and medical interventions (Bothwell, et al., 2016). In spite of this, RCTs still appear to be the study design of choice for researchers evaluating mHealth interventions. This investigation will examine the effectiveness of RCTs in a mHealth context. This paper is laid out as follows; Section 2 considers the literature in the area of mHealth in developing countries, challenges and risks to mHealth and the lack of evaluation in the area; Section 3 outlines the proposed methodology including the data collection strategy and a brief overview of a large European-funded mHealth project, within the context of which this study will be carried out. Section 4 summarises the expected contributions that this study will make to the field of mHealth.

2 Rationale

2.1 Mobile Health in Developing Countries

Mobile phones can offer health systems in developing countries the opportunity of handling health information in a digital format at the grass-roots level (Ezenwa & Brooks, 2014) and mHealth is transforming healthcare in developing countries by improving the quality of care (Tariq & Akter, 2011). It has significantly facilitated information access, enhanced workflow, and promoted the evidence based practice to make informed and effective decisions directly at the point of care (Tariq & Akter, 2011). Current mHealth applications and technologies available include applications for emergency, ambulatory and hospital care, clinical nursing, pre-hospital emergency, medical calculation, homecare and personal healthcare (Yu, et al., 2006).

Although the scope of mHealth across developing countries is similar to that across developed countries, there are some different trends due to the major differences in leading causes of mortality across developing regions (World Health Organisation, 2012). In high-income counties, the leading causes of mortality are mainly non-communicable diseases whereas in low-income countries, infectious diseases, maternal and infant mortality are the dominating health challenges faced (World Health Organisation, 2012). In countries where there is a non-universal coverage of good quality infrastructure, such as roads and people living in very rural, hard to reach areas, mobiles can contribute to development efforts in terms of bringing efficiency to the process of communicating and handling information (Ezenwa & Brooks, 2014). Further, mobile phones enable patients to seek healthcare information while retaining their anonimity and this is of particular importance in low income countries where highly stigmatized diseases such as HIV/AIDS are prevalent and individuals may be unwilling to seek information surrounding prevention and treatment. The ability of mHealth to deliver care beyond the traditional clinical setting may be of particular benefit to vulnerable populations who may be unable to access the care they require. For men who have sex with men (MSM), who are perhaps the most vulnerable population in terms of contraction of HIV, stigmatisation and inability to access care due to the fact that homosexual acts are illegal in many African and Middle-Eastern countries (Cameron & Berkowitz, 2016), mHealth may provide a vehicle to reach this population to provide confidential information and advice, test results, appointment scheduling and medication reminders (Catalani, et al., 2013). The potential for mHealth to make a considerable impact to the provision of healthcare in low-income countries is huge and emphasises the importance of robust evaluation methods to ensure that only the most efficacious applications and technologies are being adopted (Déglise, et al., 2012; Chib, et al., 2014).

2.2 Challenges and Risks to mHealth

In general, mHealth is subject to several logistical challenges, but these issues may be more problematic in low-income countries. Poor battery life, while mildly inconvenient in the western world can be crippling to any mHealth intervention due to lack of electricity and subsequent charging points, particularly in rural areas or in countries which suffer frequent power-outages (Eberhard, et al., 2008). In low-income countries, mobile phones are still seen as a luxury and may be a target for theft which introduces challenges into the confidentiality of data stored on them (Ezenwa & Brooks, 2014). A lack of internet access is also problematic for interventions that require information transfer and upload on a scale larger than can be dealt with via SMS (Patel, et al., 2015). Other external challenges to mHealth lie with the users of the interventions because an individual's usage and engagement with technology is complex and sophisticated (White et al., 2016). A lack of health informatics experts who can bridge the gap between health and technology significantly hinder the advancement of mHealth so strong training and education programmes are critical (Yu, et al., 2006). Widely held beliefs and traditional cultures are challenging to the advancement of mHealth as the end users may show significant resistance to any changes or advancements in their society (Tariq & Akter, 2011). Howev-

er, it could be argued that the greatest risk to any mHealth intervention is the lack of evaluation in the field as a whole (Hall, et al., 2014; Chib, et al., 2014).

2.3 A Lack of Evaluation

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). The current evidence is not convincing enough for policy-makers (Chib, et al., 2014) since another crucial role that evaluation plays is communicating information to a variety of stakeholders via the provision of some form of data on their impact to measure their success (Yang & Varshney, 2016). Table 1 presents an overview of the proposed and completed mHealth evaluation techniques reported in the literature.

Method of Evaluation	**Author**
Theoretical	Mohr, et al., 2013; Forsythe & Buchanan, 1991; Collins, et al., 2005; Brown III, et al., 2013.
Mixed-Method	Chang, et al, 2011; Whittaker, et al., 2012; Ybarra, et al., 2014.
Randomised Controlled Trial	Lester, et al., 2010; Arora, et al., 2014; Holmen, et al., 2014; Gamito, et al., 2014; Delisle, et al., 2015; Partridge, et al., 2015; Martin, et al., 2015.

Table 1 Overview of the mHealth Evaluation Techniques.

As outlined in Table 1, there are several authors who have proposed theoretical study designs for the evaluation of mHealth but most of these have yet to be empirically tested in the area of mHealth specifically. Several authors have chosen to use a mixed methodology in their mHealth evaluation but the majority of evaluations that are carried out in the mHealth space use a RCT study design (Lester, et al., 2010).

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). 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). 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). Further, the absence of a standardised evaluation for mHealth means that there is little or no quality control or regulation to ensure that interventions are efficacious or indeed, safe and secure for patient use (Boudreaux, et al., 2014). In context of patient safety and security, the absent evaluation has the potential to damage the field by the risk of allowing sub-standard technologies and applications into the public domain which may cause substantial harm and conclude in future litigation, damaging the public confidence in the field (Rahman, 2015). 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). One evaluation approach that is widely used in the area of mHealth and eHealth are

Randomised Controlled Trials (RCTs). The next section considers RCTs as a means of evaluating mHealth at present.

2.4 Randomised Controlled Trials (RCTs)

Calls for greater rigor in evaluation has increased the number of mHealth RCTs conducted in developed and developing countries (Burns et al., 2016). While the RCT is classed as the "gold standard" for quantifying the effects of a clinical intervention, their study design may not be ideally suited for the evaluation of mHealth interventions (Ben-Zeev, et al., 2015). Table 2 outlines the characteristics of RCTs and how these pose a challenge to mHealth evaluation.

	RCT Characteristics	mHealth Challenges
Data Collection and Analysis	Quantitative analysis - The analysis is focused on estimating the size of differences in predefined outcomes (Sibbald & Roland, 1998).	mHealth literature suggests the need for mixed-method evaluation to accurately capture the sociotechnical reasons for using an initiative (Chib, et al., 2014).
Standard execution protocol	Blinding - Double blinding (usually investigator and participants) is the usual standard and will eliminate any confounding factors occurring after randomisation (Kendall, 2003).	It is difficult to blind participants receiving a mHealth intervention (Stroux, 2012; Eysenbach, 2002).
Sample Size	The sample size must be large enough to eliminate chance (Kendall, 2003).	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).	In low-income countries where there may not be the resources to carry out RCTs (Rosen, et al., 2006; World Health Organisation, 2012) and also in high-income countries where the sheer volume of mHealth interventions available, as mentioned in Section 1, may mean it is not feasible to carry out RCTs.
Protocol	Rigid protocol, designed for the elimination of bias and confounding factors (Pham, et al., 2016).	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).	This extensive process is incompatible with a mHealth intervention due to the fast pace at which the technology field evolves. In the times 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).

Table 2 Characteristics of RCTs and Challenges to mHealth Evaluation

As outlined in Table 2, there is a quite a considerable mismatch between the classic characteristics of a RCT and those of a mHealth evaluation. In many of the RCTs carried out on mHealth solutions, some of the fundamental principles of the RCT have been compromised in order to "fit" the study design to the intervention (Pham, et al., 2016). The first issue that arises lies with the methodology of a classic RCT, which is quantitative (Stolberg, et al., 2004). This is problematic in the mHealth field since the success of a technology depends not only on the technical components but also on the end-users and the context within which the technology is being used. These sociotechnical factors include the social, religious, cultural and behavioural interactions of the end-users as well as the technological aspect of the intervention (Chib, et al., 2014). Recent literature is suggesting the use of alternative, mixed-

methods of evaluation of mHealth interventions to not only quantify the size of the effect of the intervention but to collect rich, qualitative data surrounding the reasons for use and barriers to use in order to implement the optimum version of an intervention to allow the greatest chance for success. This is particularly important in low-income countries where resources are scarce and persuading policy-makers to prioritise an intervention is futile without comprehensive evidence. In addition, RCTs carry a high financial burden, costing much more than the development and design of the intervention itself (Comstock, 2012) and it may be difficult to justify these high costs in low-income regions where many other issues may take priority. McDonald *et al.,* (2006) identified a "good" level of funding as £1000 per planned participant in a RCT with recruitment targets ranging anywhere from 60 to 60,000 participants. Because published estimates of RCT costs and empirical evidence on cost-drivers of RCTs in different disciplines and settings are sparse (Von Niederhausern, et al., 2016), it is difficult to ascertain the average cost of a RCT. It could be speculated that this may be due to a reluctance by researchers to fully disclose trial costs and since most research funding is granted in the short term and typically determines the existence, or not, of a project (Sanson-Fisher, et al., 2007), this could create problems for the longitudinal follow-up which is required to assess how mHealth interventions are utilised in developing countries to ensure long-term implementation. This lack of transparency concerning the financial burden that a RCT carries highlights the potential for the costs to be beyond the reach of low-income countries that often rely on external funding.

RCTs are characterised by a rigid protocol which demands adequate sample sizes and lengthy follow up, both of which contribute to the high cost of the study and the long process may be entirely incompatible with the mHealth field. Whereas 17 years for the development and evaluation of a pharmaceutical product is acceptable, the field of mHealth moves much faster, as highlighted in Section 1; a decade brings exponential growth and change to the field. This time gap is critical and may render RCTs entirely unsuitable for mHealth interventions and without an appropriate alternative, developers may decide to move quickly from pilot to dissemination or skip outcome evaluations altogether to avoid a full-scale RCT, threatening understanding of the long-term value of mHealth (Kumar, et al., 2013). The inability to blind study participants is a further incompatibility between RCTs and mHealth evaluation. Blinding, which is the concealment of group allocation, is a critical aspect of a RCT as it reduces the risk of biases which may occur due to behavioural differences in members of the study being aware of the group allocation (Karanicolas, et al., 2010). Obviously, neither patient nor clinician can be blinded in many mHealth evaluations due to the physical presence of a mobile device. This 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. Despite the perceived mismatch across these characteristics, the overwhelming majority of mHealth researchers continue to use the RCT as the trial design of choice for evaluating mHealth apps (Pham, et al., 2016).

3 Proposed Methodology

The purpose of this investigation is to understand RCTs as a method of evaluating mHealth interventions. The research approach will involve gathering qualitative data from members of a large European-funded mHealth project to determine whether randomised controlled trials are the most suitable method of evaluation for mHealth interventions.

3.1 Data Collection

The data collection for this investigation will take place in Malawi in January 2017, toward the end of the mHealth project. Approximately fifteen semi-structured interviews will be carried out with members of the project consortium. Participants will be selected using reputational and positional methods (Knoke, 1994) and will include clinical and managerial members of the consortium, the system devel-

opers and those responsible for trial implementation. The interview guide will include a number of questions eliciting the participant's personal views and opinions on the suitability of RCTs for evaluating the project's application. Following Ägerfalk and Fitzgerald (2008), qualitative data analysis will be used to decipher the "*thick transcripts"* (Miles and Huberman, 1994) derived from the interview process.

The Supporting LIFE consortium has designed a mobile application for use by Health Surveillance Assistants (HSAs) in Malawi. The application has been designed to be used as an adjunct to standard practice to assess acutely unwell children aged between 2 months and 5 years, to record socio-demographic and symptomatic data and direct treatment during the trial, which is outlined in the next section. The HSAs will use the application, to complete relevant assessments after which a treatment recommendation will be given.

3.2 The Supporting LIFE Trial

The Supporting LIFE trial is a pragmatic, stepped-wedge, cluster randomised trial assessing the added value of the Supporting LIFE application compared to standard care on referral rates of acutely unwell children aged >2 months to <5 years at the index visit; re-consultation and; hospitalisation rates within 7-days of the index visit. The Supporting LIFE application is an android smartphone application which replicates the WHO and UNICEF validated paper-based Community Case Management (CCM) decision aid routinely used by community health workers in Malawi, Africa (Supporting LIFE, 2016). The trial aims to recruit 100 HSAs and 8000 children from village clinics across Malawi. The primary objective of the trial is to evaluate the added value of the application compared with standard practice alone on HSA referral practices at the index consultation and parent/caregiver health-seeking behaviour in the following seven days.

4 Expected Contributions

Currently, there is no universally agreed-upon method for evaluating mHealth interventions and consequently, resources are being spent on carrying out trials which may not be the most suitable study design. Table 2 characterises RCTs and mHealth across a range of factors emphasising the challenges associated with conducting a RCT in a developing country. As outlined in Table 2, RCTs are the traditionally used method of evaluation, due to their high quality protocol and ability to control for bias and confounding factors (Kendall, 2003). However, RCTs are long and expensive with a rigid protocol originally designed for the area of pharmaceuticals, to quantify a biological effect between one drug and another (or a placebo) (Bothwell, et al., 2016). Table 2 highlights the fundamental mismatch between RCTs as a means of evaluating mHealth. Fundamental to the success of a mHealth intervention is the mix of sociotechnical factors (Chib et al., 2014). To identify these requires the use of more in-depth evaluation methods to understand the reasons behind an individual's ability, desire to use (or not use) and attitudes towards a mobile intervention (Kaplan, 2001) and this is something that will be overlooked in a quantitative evaluation. Further, time is a crucial element of a mHealth evaluation given the fast paced nature at which the technology field evolves and it is evident that from this aspect, a lengthy RCT is essentially incompatible with mHealth evaluation.

This study will help us to better understand the nature of RCTs specifically within the context of mHealth. As we have previously highlighted, there are several systematic challenges with the use of RCTs for mHealth, such as the quantitative design and the rigid protocol which, to be ignored or overlooked, would seriously affect the integrity of the results. This is because the hallmark of a RCT is its ability to control for contextual variables in order to only measure causal impact between independent and dependent variables, but mHealth evaluations that implement a RCT methodology are often forced to engage in trade-offs that breach RCT protocol (Pham, et al., 2016). This study will result in contributions to both theory and practice. Firstly, this study will provide an indication of whether a RCT is

the most suitable method for evaluating mHealth interventions by eliciting the opinions and perceptions of a multi-disciplinary group involved in a mHealth project. It is anticipated that the differing backgrounds of the team will provide a strong insight into the drivers behind the selection of a RCT for mHealth and the limitations of this methodology in the evaluation of a mHealth intervention. We anticipate that future research extending from this study will allow for an in-depth exploration of RCTs versus non-RCTs for mHealth evaluation. This study will contribute to the mHealth evaluation design literature and strengthen the argument for the design of evaluation methods better suited to mHealth. Since this is among the first studies in the field to investigate RCTs for mHealth evaluation (to the best of our knowledge), it is anticipated that this study will demonstrate the importance of an evaluation model for mHealth that is fit for purpose. Data analysis on this study is currently in the early stages; the lengthy process of transcription has been completed and early coding of the transcripts has begun. At this point of analysis, it is too soon to make any recommendations around the suitability of the methodology used in the Supporting LIFE trial. Finally, this research will inform the future evaluation of mHealth by producing a comprehensive checklist that a RCT, or other potential evaluation method, can be compared against when considering its potential use for assessing a mHealth intervention. We anticipate that this will enable the identification and utilisation of the most efficacious, effective and resource-efficient evaluations in order to harvest the full potential of this rapidly expanding, important field of healthcare delivery.

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