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Framework to assess the quality of mHealth apps: a mixed-method international case study protocol

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ABSTRACT

Introduction Healthcare professionals (HCPs) often recommend their patients to use a specific mHealth app as part of health promotion, disease prevention and patient self-management. There has been a significant growth in the number of HCPs downloading and using mobile health (mHealth) apps. Most mHealth apps that are available in app stores employ a 'star rating' system. This is based on user feedback on an app, but is highly subjective. Thus, the identification of quality mHealth apps which are deemed fit for purpose can be a difficult task for HCPs. Currently, there is no unified, validated standard guidelines for assessment of mHealth apps for patient safety, which can be used by HCPs. The Modified Enlight Suite (MES) is a quality assessment framework designed to provide a means for HCPs to evaluate mHealth apps before they are recommended to patients. MES was adapted from the original Enlight Suite for international use through a Delphi method, followed by preliminary validation process among a population predominantly consisting of medical students. This study aims to evaluate the applicability and validity of the MES, by HCPs, in low, middle and high income country settings.

Methods and analysis MES will be evaluated through a mixed-method study, consisting of qualitative (focus group) and quantitative (survey instruments) research, in three target countries: Malaŵi (low income), South Africa (middle income) and Ireland (high income). The focus groups will be conducted through Microsoft Teams (Microsoft, Redmond, Washington, USA) and surveys will be conducted online using Qualtrics (Qualtrics International, Seattle, Washington, USA). Participants will be recruited through the help of national representatives in Malawi (Mzuzu University), South Africa (University of Fort Hare) and Ireland (University College Cork) by email invitation. Data analysis for the focus group will be by the means of thematic analysis. Data analysis for the survey will use descriptive statistics and use Cronbach alpha as an indicator of internal consistency of the MES. The construct validity of the mHealth app will be assessed by computing the confirmatory factor analysis using Amos.

Ethics and dissemination The study has received ethical approval from the Social Research Ethics Committee (SREC) SREC/SOM/03092021/1 at University College Cork, Ireland, Malaŵi Research Ethics Committee (MREC), Malaŵi MZUNIREC/DOR/21/59 and Inter-Faculty Research Ethics Committee (IFREC) of University of Fort Hare (REC-2 70 710-028-RA). The results of the study will be disseminated through the internet, peer-reviewed journals and conference presentations.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The Modified Enlight Suite (MES) will be further modified to become a more inclusive framework considering national context across low, middle and high income country (LMHIC) settings.
⇒ The evaluation of the framework will be carried out in different settings across LMHICs.
⇒ The use of non-probability sampling may increase the risk of self-selection bias.

INTRODUCTION

Background

The WHO defines mobile health (mHealth) as 'medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices'.[1] Mobile health applications can be defined as 'software that are incorporated into smartphones to improve health outcome, health research, and healthcare services'.[2] Many of these mHealth apps are now available in different app stores such as AppStore (Apple, Cuppertino, California, USA) and Google Play Store (Google, Mountain View, California, USA). The use of mHealth apps in low, middle and high income countries (LMHICs) is increasing. More than 325 000 mHealth apps are available to download across the app stores.[3] Furthermore, there is an increasing number of mobile phone ownership and mobile internet subscription across low and middle income countries (LMICs).[4 5]

Healthcare professionals (HCPs) often recommend their patients to use a specific mHealth app as part of health promotion, disease prevention and patient

self-management. mHealth apps serve multiple purposes such as assisting HCPs in identifying the correct drug dosage, supporting communication among different HCPs across the globe and time management.[6] As the digitalisation of healthcare increases, HCPs are likely to increase their reliance on mobile phones to support patient management and healthcare delivery, both now and in the future.[7–9]

However, many HCPs are still cautious when adopting mHealth apps,[10] despite the added value such technology could bring to assist their workflow, at a lower overall cost, to care for their patients.[11] However, with the anticipated increase in the adoption of mHealth apps among HCPs, there will be associated risks with their usage, given that most of these mHealth apps do not undergo a strict quality assessment evaluation, using a unified or standardised guideline.[12] Until now, even though multiple evaluation frameworks exist, there has not been a standardised evaluation framework that can be used among HCPs to evaluate the quality of mHealth apps. Factors that could limit the adoption include the lack of legislative and regulatory frameworks, poor encryption of patient data and when mHealth app content is inappropriate or has poor software functionality.[11 13] Similarly, the five-star rating scale, which is available in the two most used app stores (Apple and Google) is subjective, providing a potentially unreliable indication of the quality of the mHealth app. Thus, it is a difficult task among HCPs to differentiate high-quality mHealth apps from low-quality ones.

Recently published research in 2020 discussed that safety concerns within apps related to the quality of their content came up top on the list. The quality of the content presented on apps identified either that they were inappropriate, incorrect, inconsistent or incomplete.[11] For example, mHealth apps that were available on the Apple Appstore and Android Google Play Store used to estimate blood alcohol concentration levels were shown to be highly unreliable. This underscores the need for health authorities to endorse mHealth apps that are accurate and scientifically evidence-based, thus providing credibility in an ever-expanding market of unregulated mHealth apps.[14]

Existing frameworks for assessing mobile health apps

Various approaches have been used throughout the world to help HCPs identify high-quality mHealth apps. One example is the NHS Apps Library in the UK (https://digital.nhs.uk/services/nhs-apps-library), which provides a collection of approved mHealth apps.[15] The mHealth apps in the NHS Apps Library are evaluated based on clinical safety, accessibility, usability and technical stability, ensuring apps are of high standards before publishing them for patients and HCPs to use. While awaiting national approaches, such as the NHS app library, mHealth frameworks such as the Mobile App Rating Scale (MARS)[16] or Enlight Suite[17] could be used in the interim. Woulfe and colleagues[18] conducted a rapid literature review and identified the Enlight Suite as the most comprehensive framework to evaluate mobile health apps among the existing evaluation frameworks. While the Enlight Suite provides a comprehensive measure for mHealth app assessment (table 1), the suite fails to consider key factors known to hinder the uptake and use of mHealth apps in poor resource settings such as cultural appropriateness, readability and ongoing access to an app.[13 18] The Enlight Suite was modified through a Delphi study among digital health experts from Ireland, UK and Malaŵi to adapt it for international use, leading to the development of the Modified Enlight Suite (MES). The MES was then validated through a survey of medical students and HCPs in Ireland.[19] The MES contains five additional questions relating to (1)

Table 1 Comparison of Enlight Suite and Modified Enlight Suite

Concepts	Enlight Suite	Modified Enlight Suite
Quality assessment section		
Usability	Assesses the ease of learning how to use the eHealth intervention programme (EHP) and the ease of using it properly.	Questions added: Question 9: Timeliness Question 10: Errors Question 11: Understandability Question 12: Access
Visual design	Assesses the look and feel of the programme, the visual quality of the graphical user interface (GUI).	No changes
User engagement	Assesses the extent to which the EHP's design attracts users to use it.	No changes
Content	Assesses the content provided or learnt while using the EHP.	Question 25: Cultural appropriateness
Therapeutic persuasiveness	Assesses the extent to which the EHP is designed to encourage users to make positive behaviour changes OR to maintain positive aspects of their life.	No changes
Therapeutic alliance	Assesses the ability of the programme to create an alliance with the user to effect a beneficial change.	No changes
General subjective evaluation of programme's potential	Examines the programme's general potential to benefit its target audience based on the rater's subjective evaluation.	No changes

Table 2 Phases of MES development

Phases	Description	Process	Version	Status
1	Identification of existing methodology (Enlight Suite)	Rapid systematic review	ES	Completed
2	Development of Modified Enlight Suite (Delphi study)	Delphi study followed by a survey in Ireland	MES version 1	Completed
3	Initial validation of Modified Enlight Suite (survey)			Completed
4	International modification of the Modified Enlight Suite (focus group)	Focus group followed by a survey in Malawi, South Africa and Ireland	MES version 2	In progress
5	International validation of Modified Enlight Suite (survey)			In progress

ES, Enlight Suite; MES, Modified Enlight Suite.

cultural appropriateness, (2) understandability, (3) access, (4) timeliness and (5) errors. Questions relating to cultural appropriateness, understandability and access were included based on the Delphi study to make the MES more applicable internationally across LMHIC. Questions relating to timeliness and errors are important for the ongoing use of mHealth apps. The results of the Delphi study and subsequent survey for validation of MES have been submitted for publication.[19] The key modifications to the Enlight Suite based on the previous Delphi study are provided in table 1.

Thus, the MES was developed using a systematic and rigorous approach involving a Delphi study and a validation survey. However, the Delphi study was conducted among digital health researchers and the validation survey was conducted among a population consisting mainly of medical students in a high income country (Ireland). This current study aims to evaluate the applicability and validity of the MES in low, middle and high income countries among HCPs who will be the prospective users of the MES. The study seeks to obtain feedback on what the prospective users perceive as key components to enhance MES and make it more applicable in their various settings.

METHODS AND ANALYSIS

This study is a follow-up to previous studies on MES. Table 2 summarises the five phases of the development of MES with the current study representing Phases 4 and 5.

Study design

This study will employ a mixed-method approach which will involve the collection of qualitative and quantitative data. The first stage will involve the collection of qualitative data through six focus group discussions (two focus groups per country) over Microsoft Teams with HCPs in Malawi, South Africa and Ireland. The second stage of the study will involve the collection of quantitative data in an online survey among HCPs in the three countries to validate the updated MES.

Sampling and eligibility criteria

The study will use non-probability (purposive) sampling to achieve representative cases and comparability for the focus groups. A total of 16 HCPs (8 per focus group) will be recruited per country for the focus group discussions, making a total of 48 HCPs across the three countries. The participant's inclusion criteria for the focus groups will be as follows:

1. Access to a stable internet connection for the duration of the study.
2. Experience in using any mHealth app.
3. Over 1 year of clinical experience.
4. Ability to understand and communicate in English.

Exclusion criteria for the focus groups:

1. Willingness to be recorded in a Teams Meeting.
2. Conflict of interests.

There is no consensus in the literature on the adequate sample size required for the validation of a questionnaire.[20] However, we will not limit the sample size for each country because larger sample sizes are always more representative of the population. The inclusion criteria for the survey will be as follows:

1. Access to a working smartphone for the duration of the study that supports the target app (MySugr).
2. Willingness to install MySugr app on their smartphone for the purpose of the study.
3. Fluent in reading and writing in English.

Exclusion criteria for the survey:

1. Unable to install or use the target app.
2. Conflict of interest.

Recruitment and study procedures

During the first stage, the participants for the focus group discussions will be recruited with the help of university representatives from Malawi (Mzuzu University), South Africa (University of Fort Hare) and Ireland (University College Cork). Participants will be required to provide their written consent before participating in the focus group discussion with the help of clinical leads from their respective countries. The focus group discussions will be conducted using a list of standardised questions as a guide (online supplemental appendix A). Six focus group discussions (two per country) will be held with participants from Malawi, South Africa and Ireland using the Microsoft Teams. The focus group discussions will be recorded after obtaining the consent of the participants. The focus group discussions will serve to obtain feedback on the MES (version 1) (online supplemental appendix B) from HCPs in the three target countries. The findings of the focus group discussions will be used to further update the MES and improve its international applicability.

The updated MES (version 2) from the focus group discussion will be validated in the second stage. During the second stage, HCPs in Malawi, South Africa and Ireland will be recruited for the survey by an email invitation containing an instruction about how to install MySugr app and a link to the survey including participant information leaflet and electronic consent. The updated MES (version 2) will be distributed to the participants through the online survey platform, Qualtrics. Study participants will be asked to use the online version of the updated MES to evaluate the quality of MySugr mHealth app, which is a freely available mHealth app in all the three countries with sufficient features to test all the components of the MES.

Data analysis

The recording of the Microsoft Teams focus group discussions will be transcribed verbatim and analysed using the thematic analysis approach.[21] The transcribed data will be closely examined to identify codes (eg, ideas, topics and patterns). The codes will be further examined to identify common recurring themes by integrating similar codes. The MES (version 1) will be updated based on the themes to improve its international applicability across LMHIC leading to the development of an updated MES (version 2).

The updated MES (version 2) will be validated in the survey. The survey data from Qualtrics will be exported into SPSS (V.28) for statistical analysis. The reliability of the MES will be assessed by using the SPSS to compute the Cronbach alpha as an indication of the internal consistency for the updated MES. The construct validity of the updated MES will be evaluated by computing the confirmatory factor analysis using Amos V.26 (IBM Statistics).

Ethics and dissemination

The study has been approved by three ethics committees: (1) Social Research Ethics Committee (SREC) SREC/SOM/03092021/1 at University College Cork, Ireland; (2) Malawi Research Ethics Committee (MREC), Malawi MZUNIREC/DOR/21/59; and (3) Inter-Faculty Research Ethics Committee (IFREC) of University of Fort Hare (REC-270710-028-RA). Participation in this research is voluntary. Potential participants will be invited through email to the focus group and survey with the support of local contacts in Malawi, South Africa and Ireland. Data collected from the study will be stored securely and password protected by the researchers. Data protection will be in line with UCC requirements. Should a participant like to withdraw from the study, they can do so up to 2 weeks after the data collection until the data have been analysed. The results of the study will be disseminated through the internet, journals and conference presentations.

Patient and public involvement

The design and conduct of this study will not involve patients. However, the participants will be HCPs who look after patients and are likely to need to evaluate mHealth apps before recommending them to their patients.

DISCUSSION

When it comes to assessing the quality of mHealth apps, it can prove to be a challenging task. As such, it is not uncommon for certain apps to not have been thoroughly assessed before their release into the market. While guidelines do exist, such as the Enlight Suite and MARS, past research has highlighted potential weaknesses associated with their use when applied in resource poor settings.[18] The MES is a tool that addresses many factors known to hinder the uptake and use of mHealth apps in LMICs. Future work of this research completed in 2021 indicated a need to obtain feedback on the modifications from prospective end-users. Furthermore, the reliability of the modifications has yet to be obtained in an LMIC setting. This study serves not only as a continuation of the aforementioned work, but also allows for additional modifications to the tool to enhance its efficacy.

The strength of this research is that the MES will be further modified to become a more inclusive framework considering the national context across LMHIC settings. Similarly, the validation of the framework across different settings is another strength as this will result in wider applicability of the framework. However, the use of purposive sampling may introduce a risk of selection bias. The choice of purposive sampling is informed by the need to achieve representative cases and comparability across the three countries.

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terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

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