Quality Assessment Criteria for Mobile Health Apps: A Systematic Review

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Abstract

Summative evidences on the criteria for user assessment of health apps are still limited. In order to determine an assessment method for mobile health apps, rigorous and appropriate criteria must be chosen. The aim of this study is to review the existing quality assessment criteria that are being used to assess the quality of mobile health apps focusing on users' perspectives. In addition, a procedure for the quality assessment of health apps is also presented.

A systematic review was conducted utilizing 5 databases; PubMed, ScienceDirect, Scopus, CENTRAL and IEEE Xplore from 2008 to 2017. Search terms were; "mHealth", "Applications", "iOS OR Android", "smartphones", "quality", etc. Papers that assessed the quality of health apps by users were selected. The PRISMA guideline was followed to complete the list of final studies. Likewise, a data extraction form was based on the PICO framework. From 6,514 studies, 69 studies met the eligibility criteria. Four hundred and forty-one quality assessment criteria for users were classified into 15 domains: Ease of use, Usability, Aesthetics, Connectivity, Functionality, Information, User satisfaction, Acceptability, Error occurrence, Motivation, Engagement, Data management, Undesirable events, Credentials and Security and privacy. An "ease of use" domain was found common in the included studies. The 15 domains were suggested as criteria for further study of the quality assessment and development of mHealth apps. Moreover, five recommended steps were presented for future research of quality of mobile health apps.

Keywords: Assessment, Systematic review, Mobile health apps, Quality, mHealth

Introduction

It is undeniable that smartphones increasingly become a crucial part of our lives. A significant number of people use smartphone apps for self-management of their health. There are 5 million apps available in two leading app stores Google Play Store (Android) and Apple App Store (iOS). In 2015, 3 billion mobile health apps were downloaded [1]. With such a large availability of apps, the possibility of launching low quality or harmful mobile health apps by some developers may lead to adverse effect for users. For instance, Acne App (iOS) and Acne Pwnder (Android) which falsely claimed that blue and red light therapy is an effective acne treatment were removed from the app marketplaces [2].

Mobile health apps are increasingly advanced with new technologies; however, they may not have been approved by health care providers or there may be no peer-review systems that exist before releasing these health apps through the app marketplaces. Although the users consider the quality of health apps from user ratings and reviews in the app marketplaces, there is no guarantee whether these reviews are reliable or not [3].

The United States Food and Drug Administration (US FDA) provides guidelines to regulate only mobile medical apps which are intended to be used as an accessory to a regular medical device or to transform a mobile platform into a medical device [4]. However, clinicians and patients are still concerned regarding other types of health apps that, without proper assessment systems, could pose a significant threat to users [5].

Currently, there is a lack of standardized assessment method for mobile health apps. Although there may be some systems, for instance, Psyberguide [6] and the American Psychiatric Association App Evaluation Model [7], that provide classification criteria of the apps, they only provide assessment guides for mental health apps. Moreover, summative evidences on the criteria for user assessment of health apps are still limited. In order to determine an assessment method for mobile health apps, rigorous and appropriate criteria must be chosen.

The objective of this systematic review is to review existing quality assessment criteria that are being used to assess the quality of mobile health apps focusing on users' perspectives. In addition, a procedure for the quality assessment of health apps is presented. In this study, we focus on mobile health apps in a broader sense, such as disease management, health and fitness, health information and other health-related apps to identify a wide variety of quality assessment criteria.

Materials and methods

Search strategy
With the research question: "What are the existing criteria used for assessing quality of mobile health apps?", 5 databases were searched: PubMed, ScienceDirect, Scopus, Cochrane Central Register of Controlled Trials (CENTRAL) and IEEE Xplore. Grey literature (literature that has not been formally published) [8] was searched from www.ntis.gov, www.mobileactive.org and www.opengrey.eu. The search time window was limited from July 2008 to December 2017 (the first app store launched in July, 2008). The search terms were divided into 5 groups and combined using the Boolean operator AND: 1. (health OR medical OR medication OR medications OR mHealth), 2. (app OR apps OR Application OR Applications), 3. (iOS OR Android), 4. (mobile OR mobiles OR smartphone OR smartphones OR "cell phone" OR "cell phones" OR "mobile device" OR "mobile devices"), 5. (quality OR criteria OR assess* OR evaluate* OR "rating scale" OR checklist OR "content analysis" OR framework).

Eligibility criteria
The inclusion criteria were 1. The studies that related to the evaluation or assessment of mobile health apps (any apps that intend to provide disease management, health and fitness, health information and other health-related apps), 2. The target groups of the apps were patients or general users, 3. The full texts of the studies were published in English. On the other hand, the exclusion criteria were 1.The studies that focused on the effectiveness or development of the apps without quality assessment by users, 2. The studies that allowed only the developers to assess the apps, 3.The studies that adopted the quality assessment tools from previously published studies without adaptation.

Selection process
This review followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines to complete a list of final studies [9]. The studies were identified, screened, and selected based on specific inclusion and exclusion criteria by two independent reviewers (SI and WH).

First, all studies were screened based on titles and abstracts. The abstracts that met the inclusion criteria (focusing on types of apps and target groups) were included. If the abstracts did not provide sufficient information, the full texts of articles were assessed according to the eligibility criteria by both reviewers. Disagreement was resolved by discussion. Reference lists and citations of included studies were screened to identify additional relevant studies. The data from included studies were extracted and analyzed to generate the quality assessment criteria.

Data extraction

The data extraction forms were developed based on the PICO framework [10]. The extracted data included: general characteristics of the studies, characteristics of mobile health apps, the procedure for quality assessment and the quality assessment criteria of mobile health apps. Data entered was automatically stored in an online spreadsheet and assessed for agreement by two reviewers. In the case of disagreement, consensus was established based on face to face discussion or on acquiring feedback from an external reviewer.

Classification of the quality assessment criteria

The quality assessment criteria of mobile health apps extracted from the studies were classified by two reviewers. Disease specific quality assessment criteria were excluded. The criteria were then independently classified from identified sources using two steps: 1. The quality assessment criteria used in each study were grouped based on the similarity of the area or duplicated meaning of assessment. This provided the themes of assessment criteria. 2. All the themes of assessment criteria were grouped into the same quality domain. All discrepancies were resolved by discussion.

Risk of bias of included studies

The included studies were evaluated for their quality and risk of bias using a checklist. The checklist consisted of 8 questions with 8 as the maximum score where higher score represents lower risk of bias and higher quality of the study. The quality of each study was rated according to the corresponding items on the checklist [11]. The 8 questions were: consideration of the data collection time frame, the apps were fully downloaded for consideration based on its content , the clarity method of appraisal the app's quality, the clarity describe the methodology taken to search for appropriate apps, the clarity of the inclusion and exclusion criteria for app selection, the clarity identify the country where the search was conducted, definition of the targeted groups of users and provision of a list of the apps [11].

Results

Studies identified

Initially 6,514 studies were identified after excluding the duplicates. After screening the titles and abstracts, 205 full text articles were reviewed and 66 studies met the eligibility criteria. Three studies were included through screening the reference lists and citations. Thus, 69 studies were identified as relevant and were included in this review, as shown in **Table 1**. **Figure 1** is a PRISMA flow diagram showing the number of studies identified in each database and the number of studies excluded [9,12].

Characteristics of included studies

General characteristics of the 69 included studies are presented in **Table 2**. Fifty studies (73 %) used non-app development study design (cross sectional, experimental or RCT). Both Android and iOS platforms were evaluated in 26 studies (38 %). It was notable that 36 studies (50 %) involved disease specific or disease management apps. The target groups of the apps were both lay person users and healthcare providers in 46 studies (67 %). Moreover, the numbers of app assessors were varied, ranging from 2 to 3,977 (Mean 99.1 ± SD 509.6).
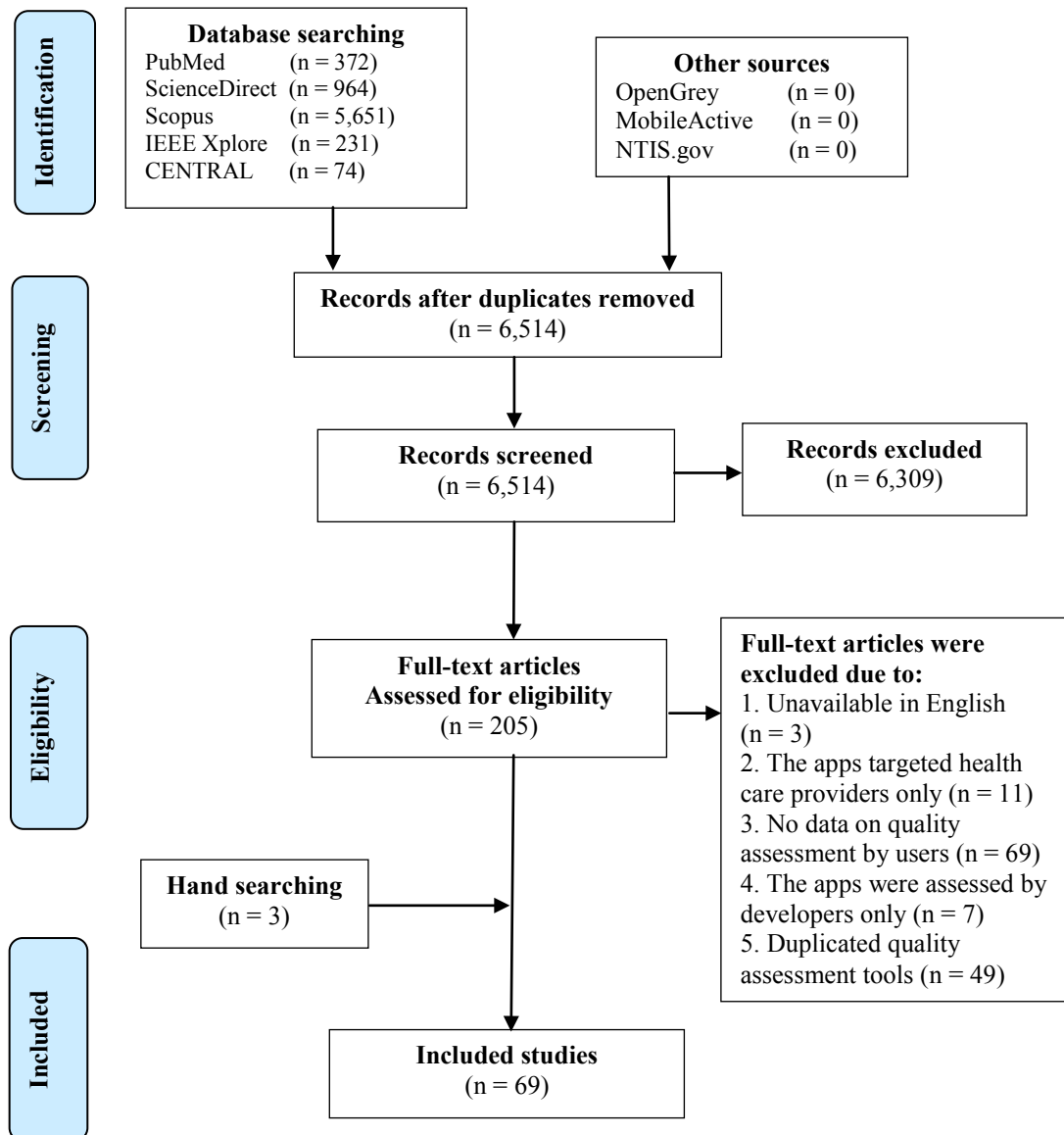
Figure 1 PRISMA flow diagram.

Table 1 Included studies.

Study design	Target groups of the apps	Platforms	Mobile Health apps for
Non App-development [13]	Health care providers/Smokers	iOS	Smoking cessation
App development [14]	Patients /General users	Android	Weight control
Non App-development [15]	Health care providers/Patients	iOS, Android, Blackberry ,Nokia/Symbian , and Windows Mobile	Pain management
Non App-development [3]	Health care providers/Diabetes patients	Android	Diabetes
Non App-development [16]	Menopausal women	Symbian	Recording symptoms and physical activity
Non App-development [17]	Health care providers/Patients	iOS, Android, Blackberry and Windows phone	Asthma
Non App-development [18]	Health care providers/Patients	iOS, BlackBerry, and Android	Personal health records
App Development [19]	General users (Arab)	Android	Diet Assisting
Non App-development [20]	Health care providers /Colorectal diseases patients	iOS, Android, Blackberry, Nokia and Windows sites	Colorectal cancer
Non App-development [21]	General users (Adolescents)	iOS, Android	Daily diet app and exercise activities app
Non App-development [22]	Health care providers/Patients / General users	iOS, Android	HIV
Non App-development [23]	Health care providers/Patients	Android	Treatment of diseases/ Health awareness/ Content diffusion/ Aid for professionals
Non App-development [24]	Health care providers/Patients/ General users	iOS, Android	HIV/ STD
Non App-development [25]	Health care providers/Patients / General users	iOS	Cancer
App development [26]	Patients (adolescents with cancer)	iOS	Pain Assessment
App development [27]	Patients with age-related macular degeneration and diabetic retinopathy	iOS	Monitoring of Visual Function
Non App-development [28]	Health care providers/Diabetes patients aged 50 or older	iOS, Android	Diabetes
App development [29]	Health care providers/Patients	Android	Knee rehabilitation
Non App-development [30]	Health care providers/Patients	iOS, Android	Hepatitis
App development [31]	Coronary artery disease patients	iOS, Android	Coronary artery disease
Non App-development [32]	Health care providers/Patients	iOS, Android, Nokia, Blackberry, Samsung and Windows	Hernia
Non App-development [33]	Patients /General users	iOS, Android	Mobile Personal Health Records (PHRs)
App development [34]	Health care providers/Patients	iOS, Android	Assessment pain intensity
Non App-development [35]	Health care providers/Patients	iOS, Android	Stroke
App development [36]	Patients (the low-income women)	iOS	A counseling app to promote interest in and awareness of long-acting reversible contraceptive
Non App-development [37]	Health care providers/Patients	iOS	Obesity management
Non App-development [38]	Health care providers/Patients	iOS	Mental health
Non App-development [39]	Health care providers/Patients	iOS, Android	General health apps
App development [40]	Patients (children with DM)	Android	Games for diabetes education
Non App-development [41]	Health care providers/Patients	Android	General medical apps
Non App-development [42]	Health care providers/Patients	iOS	Stress management

Study design	Target groups of the apps	Platforms	Mobile Health apps for
Non App-development [43]	Health care providers /Patients (older adult)	Android	Management of headache
Non App-development [44]	Health care providers/Patients	iOS, Android, Blackberry	Adherence apps
Non App-development [45]	Adult bipolar disorder patients	Android	Self-management of bipolar disorder
App development [46]	GDM patients	Android	Gestational diabetes mellitus management
Non App-development [47]	Health care providers/Patients	iOS, Android	Medication-related problems (MRPs)
Non App-development [48]	Health care providers/General users	iOS, Android	Prevention of unintended pregnancy
Non App-development [49]	Health care providers/Patients	iOS	Menstrual cycle
Non App-development [50]	Health care providers/Patients	iOS, Android, Blackberry	Management of childhood enuresis
Non App-development [51]	Health care providers/Patients	iOS	Depression apps, Smoking cessation apps
Non App-development [52]	Patients/General users	iOS, Android	Diabetes, Depression, and Caring for the elderly
Non App-development [53]	General users	iOS	Knowledge and awareness
Non App-development [54]	Health care providers/Smokers	iOS	Smoking cessations
Non App-development [55]	Health care providers/Patients / General users	Android	Health related behaviors apps and Mental health apps
App development [56]	Patients/ General users	iOS, Android	Monitoring and awareness of healthy eating
Non App-development [57]	Health care providers/Patients / General users	iOS, Android	Breast cancer
Non App-development [58]	Health care providers/Patients / General users	iOS, Android	Medication management
Non App-development [59]	Health care providers/General users	iOS	Fitness and exercise apps
Non App-development [60]	Health care providers/Patients	iOS, Android	Chronic pain
Non App-development [61]	Health care providers/Patients	iOS, Android	Chronic Insomnia Disorder
App development [62]	General users	Android	Mindfulness training and practice
Non App-development [63]	Health care providers/Patients	Android	Physiotherapy for frozen shoulder
App development [64]	Patients /General users	iOS	Drug information
App development [65]	Patients	Android	Colonoscopy Preparation
Non App-development [66]	Health care providers/Patients / General users	iOS	Cancer

Table 2 Study characteristics.

General characteristics	Number of Studies (n = 69)
Study design	
App Development	19
Non-App Development	50
Target groups of the apps	
Lay person users only	23
Lay person users and healthcare providers	46

General characteristics	Number of Studies (n = 69)
Platforms	
Symbian only	1
iOS only	15
Android only	17
iOS and Android	26
iOS, Android and others	10
Mobile Health apps for[a]	
Mental health and addiction behaviors	10
Disease specific or disease management	36
General health behaviors	24
Not specified	2

[a]More than one types of the apps were evaluated in some studies.

Classification of quality assessment criteria of mobile health apps

Four hundred and forty-one criteria from the 69 studies were grouped based on the similarity of the area of assessment. These were narrowed to 77 themes of quality assessment criteria after similar or duplicated meaning criteria were grouped together. Then, all 77 themes of criteria were clustered into 15 quality domains. **Table 3** shows the list of the 15 domains: Ease of use, Credential, Usability, Aesthetics, Connectivity, Functionality, Information, Acceptability, User satisfaction, Error occurrence, Motivation, Engagement, Security and Privacy, Data management and Undesirable events. The "Ease of use" domain was the most common domain found in quality assessment of mobile health apps. Moreover, 9 out of 77 themes criteria were not classified into any domains: App size (n = 1) [42], Social influence (n = 1) [67], GPS (n = 2) [17,48], Reduce health care cost (n = 1) [60], HIPAA (the Health Insurance Portability and Accountability Act) compliance (n = 1) [44], Printing (n = 1) [50], Software support (n = 1) [51], Voluntariness (n = 1) [67] and ICE (In case of emergency) feature (n = 2) [17,18].

Table 3 Domains of quality assessment criteria.

Name of domains	Quality assessment criteria of mobile health apps	Number of studies
Ease of use	Ease of use, Navigation, Gestural design, Learnability / Learning, Adherence to literate principles of design plain language, Technical support throughout the application	62
Credentials	Contact details, Authoritative, Medical professional involvement, Endorsement of the app, Funding, Advertising policy, A credible source of information	51
Usability	Usability, Purpose of the app, Usage intention, Effectiveness, Effectiveness tested (claimed by app), Efficiency	50
Aesthetics	User interface design, Aesthetics	34
Connectivity	Availability, Available in other languages, Inter-platform availability, Support interoperability, Data entry, Interactivity and connectivity	26
Functionality	Functionality, Technology-enhanced features, Specificity of intervention, Flexibility, Other data tracking	26

Name of domains	Quality assessment criteria of mobile health apps	Number of studies
Information	Information, Content, Information provided in a clear and appropriate way for the target audience, Complete and Concise information, Claims, Currency, Perceived risk	26
Acceptability	Acceptability, Worth recommending, Stimulate repeat use	26
User satisfaction	User ratings	25
Error occurrence	Error, Navigational links were broken, Precision/ Accuracy, Unreliable performance	22
Motivation	Game and rewards aspects of the app, Intrinsic motivation, Peer support, Reminder, Calendar, Appointment scheduling	20
Engagement	Engagement, Video / Audio, Feedback and Response time	20
Security and Privacy	Security and privacy	18
Data management	Data sharing, Data export, Data backup, History, Data graphing, Daily reports	15
Undesirable events	How bothersome the daily prompts were, Undesirable events, Commercial links, In-app purchases	9

Characteristics of assessors and procedures

Table 4 shows the procedures and assessors' characteristics. For the purposes of this review, the assessors were defined as the person who evaluated or assessed the quality of mobile health apps. The majority of studies (38 studies, 55 %) used experts (health professionals or researchers) as assessors only. The numbers of expert assessors ranged from 2 - 28 (Mean 4.0±SD 5.2) and the most common number was 2 (24 studies). The numbers of lay person assessors ranged from 5 - 3,977 (Mean 202.3±SD 731.5), the most common number were 14, 22, 30 and 52 (2 studies each)

Furthermore, in 59 studies (85 %), the app contents were downloaded for quality assessment while in 10 studies (15%), only the contents on the description page of the app were assessed.

Additionally, most of the studies did not report duration of time to use the apps before assessment (47 studies, 68 %).The maximum duration was 6 months in the study which assessed a healthy diet app [56], while the minimum duration was 5-10 min in the study of a drug information app [64]. Three studies (4 %) did not specify the duration of usage (e.g. for some time, several weeks or a few days).

In addition, questionnaires were the only most commonly used methods to collect data in the process of quality assessment (65 studies, 94 %). Fifty four studies (78 %) did not report psychometric properties of the questionnaires or assessment tools.

Quality and risk of bias

Based on the quality and risk of bias checklist by BinDhim *et al.* (2015) [11], the scores ranged from 4/8 to 8/8 (Mean 5.9±SD1.2). The most common score was 5 (24 studies, 35 %), the maximum score was 8 (9 studies, 13 %) and the minimum score was 4 (7 studies, 10 %). Most of the studies clearly described the method of appraisal of an app's quality (68 studies, 99 %) and clearly identified the target groups of users (69 studies, 100 %). A higher score represented lower risk of bias and higher quality of the studies [11].

Table 4 Characteristics of Procedures and Assessors.

Characteristics	Number of studies (n = 69)
Assessors	
Lay person users only	24
Experts only	38
Lay person users and experts	5
Experts and developers	1
Experts, developers, and lay person users	1
Tools for collecting data	
Interview guide only	3
Questionnaires only	65
Interview and questionnaires	1
Duration of the apps usage before assessment	
6 months (maximum)	1
3 months (most common)	3
7 days (most common)	3
4 days	1
5 - 10 min (minimum)	1
Others	10
Not specified	3
Not reported	47
Downloading apps' contents	
Downloaded	59
Not downloaded	10
Psychometric properties of questionnaires or assessment tools	
No reported	54
Reliability tests only	10
Validity and reliability tests	5

Discussion

Quality assessment criteria of mobile health apps

We grouped 441 quality assessment criteria into 15 domains. Nine criteria could not be classified into any domain as these criteria were used to evaluate specific features of the apps. In 2017, Baumel *et al*. reviewed key criteria related to the evaluation of user-facing eHealth programs. Using information from all types of eHealth programs, Baumel's 454 criteria were grouped into 11 domains [68]. Despite the difference in the included studies, our study focused on mHealth apps and found almost similar in the number and contents of the assessment criteria.

The 15 domains for quality assessment criteria of health apps were presented. However, the classification of criteria into each domain might overlap. For instance, the concept of "Usability" is not straightforward [69]. In our findings we believe that "Usability" means more than just "Ease of use". Usability includes efficient, effective, engaging, error tolerant, and easy to learn [70]. Some health apps might be easy to use but the users cannot achieve specified goals of their health from using the apps. On the other hand, users might believe that a health app has potential to deliver some health benefits, at the same time find the app too difficult to use. Hence, the performance benefits of usage are outweighed by the effort of using the app. Unlike Baumel *et al*. [68] that grouped "Ease of use" into "Usability" domain, we have decided to separate these 2 domains in this study. "Ease of use" in this study is defined as "users might want only little guidance through any procedures". Likewise, the definition "Usability" is based on the ISO 9241 standard which means "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" [70].

In addition, the "Undesirable events" domain considers interfering events that might occur during the use of mHealth apps. However, Baumel *et al.* [68] did not report an "Undesirable events" domain to evaluate eHealth programs. We believe that the "Undesirable events" domain should be targeted for mobile health apps quality assessment because interfering events may interrupt users with biased or misleading information. For instance, when an advertisement pops-up to sell some health care products, users might believe that the products are trustworthy as they were recommended to use by the apps.

Five recommended steps for research on quality assessment of mobile health apps

Our review suggests that researchers who are interested in the quality assessment of mobile health apps should follow these 5 key steps in order to conduct a concrete apps assessment (**Figure 2**). All recommendations are based on the data gathered from included studies.

Step 1: Select appropriate category and the number of assessors to assess the quality of the apps. The exact target groups of the apps should be defined whether the apps were developed for patients/lay person users, health care providers, or both because the quality assessment criteria will be specific to their use. In addition, the number of assessors might differ in each assessor category. The number of expert assessors should be 2 - 4 persons. The number of lay person assessors in the pilot or early stage of app development should be between 15 - 50 persons and in the later stage of app development should be 200 persons.

Step 2: Determine appropriate usage duration of the apps prior to performing quality assessment. The assessors need time to use the apps before an assessment can be made. The duration of usage depends on the functions, and goals of the apps. We recommend 7 days for general health apps and 3 months for the apps. In other words, apps require long term use to see their results.

Step 3: The app's contents must be downloaded into the device for quality assessment. Descriptive information shown in the apps marketplaces are insufficient for assessing the quality of the apps [11].

Step 4: An appropriate quality assessment tool must be chosen. In order to assess the quality of mobile health apps, it is important to evaluate its psychometric properties. Questionnaires are the most commonly tools used to assess the quality of the apps. Several included studies did not report psychometrics properties for questionnaires or assessment tools. The questionnaires or assessment tools used in these studies might be lacking in reliability (consistency of the measurement process) and validity (measurement of what it is supposed to be measured) which could lead to poor quality data and misleading conclusions [51,71]. The questionnaires with acceptable levels of validity and reliability can present what they claim to measure with consistent results from repeated samples and different researchers over time [72].

There are two possible alternatives for this step: First, the researchers can create a set of their own quality assessment criteria in a new questionnaire with acceptable levels of validity and reliability. The quality assessment criteria should cover 15 quality domains presented in this review. The second alternative is to use valid, reliable, existing questionnaires. However, these questionnaires should be available in the same language and culture that are used by the assessors [73].

Step 5: Assess the app using a well-designed questionnaire then interpret the quality of the app and consider the scores from the questionnaires.
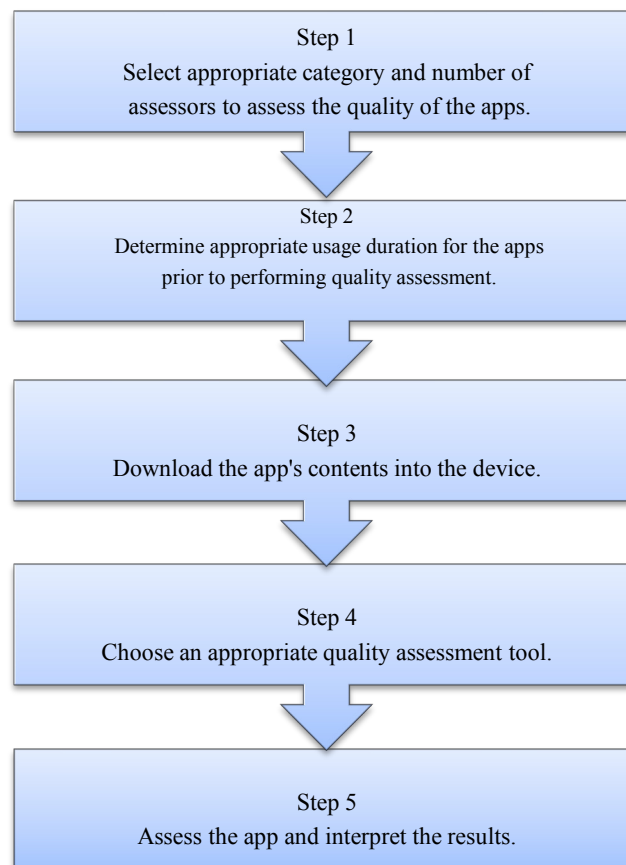
Step 1
Select appropriate category and number of assessors to assess the quality of the apps.

Step 2
Determine appropriate usage duration for the apps prior to performing quality assessment.

Step 3
Download the app's contents into the device.

Step 4
Choose an appropriate quality assessment tool.

Step 5
Assess the app and interpret the results.

Figure 2 Five recommended steps for a research on quality assessment of mobile health apps.

Limitations

One of the limitations of this study is the lack of details in reported information from the included studies such as the duration of usage before assessment, method to select the apps for assessment and method used to assess the apps. Such details can contribute to the improvement of assessment methods for mHealth apps in the future. Furthermore, this systematic review included only studies published in English and did not focus on language and cultural differences among the studies. Most mHealth apps aim for changing the user's quality of life to improve their health behavior. Language used in the questionnaire and cultural differences may contribute to the value that may be of concern to the app users. Future work is needed to further explore some important assessment criteria that might be different among languages and cultures.

Conclusions

The 15 domains of quality assessment criteria for mobile health apps were identified. Our review suggests that the researches and developers should apply these 15 domains in their mobile health apps development process or develop new assessment criteria based on the 15 domains for users to assess quality of mobile health apps themselves. However, the 15 domains are suitable for the general assessment criteria of mobile health apps. Many types of apps aim to benefit the health and wellness of users with a wide variety of features and functions. Further research should be focusing on identifying

specific criteria for a specific type of apps. Furthermore, the 5 recommended steps for the research on quality assessment of mobile health app are presented.

Acknowledgements

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