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A Guideline for Reporting and Assessment of Health Interventions Using Mobile Phones

Nimet Karataş, Ayşegül İşler Dalgıç

Department of Pediatric Nursing, Nursing Faculty, Akdeniz University, Antalya, Turkey

Abstract

Background: In recent years, especially considering today's conditions, the use of mobile health applications that offer the remote health education, management, and monitoring has been increasing.

Aim: The aim of this study is to present the Turkish form of the mobile health evidence reporting and assessment mobile health checklist, which is a guide for the full and accurate reporting of mobile health applications provided via mobile phones, to the national literature.

Methods: In the first stage of the mobile health evidence reporting and assessment checklist consisting of 16 items, a Turkish translation text was created by 2 authors, and in the second stage, the views of 10 academicians from different disciplines were examined with Kendall's *W* coefficient.

Results: It was determined that there was agreement among the observers on intelligibility and clarity of items (W = 0.556, P = .000). The minimum set of information required to describe the content, context, and how the mobile health application was implemented was provided with 16 items and explanatory examples regarding how the technological elements are reported, how the content is tested, how participants are involved, and so on were provided on Turkish form of the mERA checklist.

Conclusion: It is thought that mobile health Evidence Reporting and Assessment will ensure the active use of standards that can increase the quality of future publications and bring them to an acceptable level by eliminating the possible evidence gaps in the reporting of research on mobile health applications. With this article, it is envisaged, as first nurses, that all researchers working in the field of health informatics will contribute to the reporting of study evidence.

Keywords: Checklist, health informatics, mHealth evidence reporting, mobile health, nurse

Introduction

Technological developments have influenced the world today. Mobile technologies, one of these developments, have the potential to improve access to health resources and the correct and adequate use of resources. According to the International Telecommunication Union, it is estimated that approximately 5.3 billion people, or 66% of the world's population, use the internet in 2022. This rate represents an increase of 24 percent since 2019.[1] In addition, 90% of the world's population is covered by a mobile network and 47% of them has a mobile phone of their own.[2] In the report prepared by World Health Organization (WHO) in 2015, 463 565 people from 11 countries were reached with 17 comprehensive mobile health (mHealth) projects.[3] The Global Observatory for eHealth (GOe) group consisting of more than 800 eHealth experts was established by WHO to support the development of mHealth policy and strategy. Global Observatory for eHealth defines mHealth as "medical and public health applications powered by mobile devices such as mobile phones, patient monitors, personal digital assistants and other wireless devices."[4] The Global Observatory for eHealth (GOe) group consisting of more than 800 eHealth experts was established by WHO to support the development of mHealth policy and strategy. GOe defines mHealth as "medical and public health applications powered by mobile devices such as mobile phones, patient monitors, personal digital assistants (PDAs) and other wireless devices.[4]

It is seen that the interest in mHealth projects has increased globally. This situation raises the need for reporting guides that increase the quality of the studies to be carried

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Corresponding author: Nimet Karataş
E-mail: nimetkaratas@akdeniz.edu.tr

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out with the increase in the quantity. Checklists guide from the quality structuring of studies to the presentation of reporting. Checklists are tools that provide convenience with the standardization they offer to the researcher, the reader, and the academic journal editor/referee team.[5]

In the literature, CONSORT (The Consolidated Standards of Reporting Trials) for randomized controlled studies,[6,7] TREND (Transparent Reporting of Evaluations With Non-Randomized Designs) for non-randomized controlled studies,[8] STROBE (Strengthening the Reporting of Observational Studies in Epidemiology)[9,10] for systematic reviews, PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analysis)[11,12] for study protocols, SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials)[13] and PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols)[14] are among the commonly used checklists for CARE (Consensus-based Clinical Case Reporting Guideline Development)[15] for case studies.[16] CONSORT-EHEALTH, which is used in reporting studies covering web-based applications and mHealth applications, targets a general area that can be used from all devices such as tablets and phones. On the other hand, he CONSORT-EHEALTH checklist does not make recommendations for technical details of intervention strategies, reporting feasibility, and sustainability.[17] The absence of any reporting guidelines that define the priorities needed to adequately understand and potentially improve the quality of mHealth practices has prompted WHO's mHealth Technical Evidence Review Group (WHO mHealth Technical Evidence Review Group). Under the leadership of this group, an mHealth evidence reporting and evaluation (Mobile Health–mHealth–Evidence Reporting and Assessment–mERA) checklist was developed by Agarwal et al.[18] The quality of reporting on evidence on mHealth practices is thought to have fallen below the expected level due to 2 factors. The first factor is the multidisciplinary nature of mHealth, which combines different approaches from the fields of health and technology. The second factor is technological progress. The development of technology is so rapid that often outpaces the ability of researchers to produce and convey quality evidence.[19] Starting from this point the aim is to present the Turkish version of the mERA checklist, which will guide full and accurate reporting, to the literature in order to increase the level of evidence.

Use of Mobile Health Applications

The number of studies examining mHealth practices in various health fields from childhood to adulthood has been increasing exponentially in recent years.[19,20] mHealth practices, which have become a new focus of care today, make it possible to develop 2-way communication between individuals and health professionals and to ensure the continuity of care.[19] It also supports the self-efficacy of individuals, their active role in treatment processes, and cooperation with health professionals.[20]

The integration of biological sensors, artificial intelligence, and wearable technologies into mHealth applications brings many conveniences to healthcare. In this way, the course of the disease can be followed, a preliminary estimation can be made, the individual can provide self-control, information can be sent to the relevant center in emergencies, and a more effective treatment process can be made possible by accessing statistical data. mHealth applications, which are predicted to bring radical changes in the provision of health services in the future, is a system that eliminates time and space.[21] With mHealth applications, which is a highly accepted product of today's technology, it is possible to reach healthcare easily and quickly.[22] Interventions used in the studies are carried out in line with different groups and targets such as family-based behavioral, nutritional and physical,[23] social groups,[24] video, laboratory and demographic data storage,[25] and simultaneous pain assessment.[26] Using a standard guideline in reporting studies using mHealth input can enable a highly valuable product to reach the expected quality and value with an accurate and complete presentation.

Mobile Health Evidence Reporting and Assessment Checklist and Purpose

Mobile health evidence reporting and assessment aims to provide guidance to make assessment and reporting on the viability and effectiveness of mHealth practices complete and understandable. It cannot be assessed the design or the quality of research methods used of the studies reviewed, via the checklist. Mobile health evidence reporting and assessment aims to identify minimum priorities needed to increase transparency in reporting, provide a critical assessment of mHealth research evidence, and potentially improve the quality of reports of findings from planned research.[18]

Development of the Mobile Health Evidence Reporting and Assessment Checklist

The development of the reporting guide was based on the strategies put forward by Moher et al.[27] The development process of the mERA checklist consists of 3 stages: developing an approach for mERA, refining and finalising the mERA tool, and pilot testing the mERA checklist.[18]

Scope of the Mobile Health Evidence Reporting and Assessment Checklist

To highlight the importance of reporting evidence in evaluating both the technical platform and the core application, mERA includes the required technical specification criteria. The mERA checklist is appropriate for the maturation of mHealth practice, from prototyping (defined as feasibility and acceptability) to final product evaluation (the stage where impact and applicability assessment is highly valuable).[18] The mERA checklist items are explained in detail and made available to readers as appendix (See Appendix).

Components of Mobile Health Evidence Reporting and Assessment and Use with the Other Guides

The mERA checklist is a 16-item checklist focused on reporting the studies related to mHealth apps. Turkish and English forms of the checklist are provided in appendix (See Appendix Table 1 and Table 2). As much as possible, the mERA checklist should be used in conjunction with appropriate checklists for study design, such as CONSORT in randomized trials and STROBE for observational studies. The mERA identifies key aspects of research that should be minimally reported to allow synthesis and meta-analysis.[18]

Mobile Health Evidence Reporting and Assessment Checklist in Literature

Standardized checklists are tools to help ensure data presentation and publication consistency across studies.[28] The mERA checklist includes 16 items covering infrastructure facilities, technology platform, integration with Health Information Systems, implementation and content, applicability testing, limitations, application context,

Table 1. mSağlık Kanıt Raporlama ve Değerlendirme (mERA) Rehberi

Kriter	Madde No	Notlar
Altyapı (yoğunluk seviyesi)	1	Çalışma alanındaki teknoloji faaliyetlerini destekleyecek altyapının kullanılabilirliğini açıkça sunar. Bu, yerel bağlamda elektrik, güce erişim, bağlantı, ağ kapsamı vb. fiziksel altyapı anlamına gelir. Çalışma ülke düzeyinde yürütülmüyorsa, ülkedeki fiziksel altyapının %X ağ kapsama oranının raporlanması yetersizdir.
Teknoloji platformu	2	Teknoloji mimarisini gerekçelendirir ve tanımlar. Bu, yazılım ve donanımın bir açıklamasını ve genel kullanıma açık yazılımda yapılan değişikliklerin ayrıntılarını içerir.
Uyumlanabilme/Sağlık bilgi sistemleri (SBS) bağlamı	3	mSağlık uygulamasının mevcut Sağlık Bilgi Sistemlerine (SBS) nasıl entegre edilebileceğini açıklar. Mevcut SBS ya da programa teknik ve yapısal entegrasyon potansiyelinin olup olmadığı ya da entegrasyonun mevcut sistem tarafından gerçekleştirilip gerçekleştirilmediğine bakılmaksızın tanımlanmış olan yazılımı belirtir.
Uygulamanın sağlanması	4	mSağlık uygulamasının nasıl sağlandığı açık bir şekilde tanımlanır. Bu, mobil iletişimin sıklığını, uygulamanın sunum şeklini (örneğin; SMS, yüz yüze, etkileşimli sesli yanıt), hizmetin sağlandığı zaman ve süreyi içermelidir.
Uygulama içeriği	5	Uygulamanın içeriğinin ayrıntıları tanımlanır. Uygulama içeriğindeki kaynak ve her bir değişiklik tanımlanır.
Kullanılabilirlik/İçeriğin test edilmesi	6	Araştırmanın biçimlendirilmesine yönelik, hedef grup(lar) ile birlikte yapılan içerik ya da uygulanabilirlik testi uygun şekilde açıklanır.
Kullanıcı geri bildirimi	7	Uygulama ile ilgili ya da uygulamaya ilişkin kullanıcı memnuniyeti üzerine kullanıcı geri bildirimi tanımlanır. Kullanıcı geri bildirimi, içerik ya da kullanıcı ara yüzü hakkındaki kullanıcı görüşlerini, kullanılabilirlik, erişim, bağlantı vb. hakkındaki algılarını içerebilir.
Bireysel katılımcıların erişimi	8	Çalışma katılımcıları arasında uygulamanın kabulü için engelleri ya da kolaylaştırıcıları belirtir. Bireysel düzeydeki yapısal, ekonomik ve sosyal engeller ya da etkin maliyet gibi erişimi kolaylaştırıcı ve kullanıcının uygulamayı kabul yeteneğini sınırlayabilecek diğer faktörler ile ilgilidir.
Maliyet değerlendirmesi	9	mSağlık uygulamasının temel maliyet değerlendirmesini farklı perspektiflerden sunar. Bu kriter genel olarak, tam bir ekonomik analiz yerine mSağlık uygulaması için bazı maliyet unsurlarının rapor edilmesine atıfta bulunmaktadır. Resmi bir ekonomik değerlendirme yapılmışsa, uygun referanslarla belirtilmelidir. Ekonomik raporlamaya rehberlik etmek için ayrı raporlama kriteri kullanılabilir.
Program girişi	10	İlgili olması durumunda, kişilerin, eğitim de dahil olmak üzere, program hakkında nasıl bilgilendi rildiklerini açıklar. İlgili kullanıcı nüfus arasında mSağlık uygulamasının gerçekleştirmek için gereken tanıtım faaliyetlerinin ve/veya eğitimin açıklamasını içerir.
Uygulamanın yaygın hale getirilmesi için sınırlılıklar	11	Girişimin genelleştirilebilmesi için mSağlık uygulamasının sınırlılıklarını, öngörülen zorlukları açıkça sunar.
Bağlamsal uyarlanabilirlik	12	mSağlık uygulaması farklı bir dile, farklı nüfusa ya da içeriğe uyarlanıp uyarlanmama durumunu açıklar. Pilot test/kullanılabilirlik değerlendirmesinin sonucu olarak uygulamada yapılan herhangi bir uyarlama ya da düzenleme açıklanır
Tekrarlanabilirlik	13	Tekrarlanabilirliği desteklemek için uygulamanın detaylandırılmasıdır. Farklı bir alanda mSağlık uygulaması tekrarlanabilirliğini desteklemek için algoritmaların kaynak kodu/ekran görüntüleri/ akış şemaları ya da mesaj örneklerini açıkça sunar.
Veri güvenliği	14	Veri güvenliği prosedürlerini/gizlilik protokolünü açıklar.
Ulusal yönergelere ya da yasal düzenlemelere uygunluk	15	Kapsamın ya da uygulama tarafından sağlanan diğer rehber/bilgi içeriğinin, mevcut ulusal/ düzenleyici yönergelere uygun olduğunu garanti etmek için kullanılan yöntem açıklanır.
Uygulamaya bağlılık	16	Uygulama planlandığı gibi sağlandı mı? Uygulamaya bağlılığı değerlendirmek için kullanılan stratejiler açıklanır. Bu, katılımcı bağlılığının değerlendirilmesini, mesaj iletimini izlemek için arka sunucu verilerinin kullanımını ve uygulamanın sağlanmasındaki diğer teknolojik zorlukları kapsayabilir.

reproducibility, data security, cost assessment, compliance with guidelines/instruction, participation/commitment, and feedback.[18]

In a recent systematic review, it is noted that only 2 of the 16 items of the checklist were frequently reported in the articles of mHealth interventions (item 4: ensuring implementation and item 5: content of implementation).[29] In another analysis, the fact that no study reported the items containing barriers or facilitators (item 8) for integration into Health Information Systems (item 3) and acceptance of practice among its participants reveals the need for standardization in the reporting of study evidence.[30] The mERA checklist can be useful as a tool for examining the reporting of clinical studies for smartphone applications in a standard way, with respect to provide a comprehensive methodological framework in the systematic analysis.[31,32]

As suggested in the literature,[18] the mERA checklist appears to be used in conjunction with CONSORT[33] for randomized controlled trial and PRISMA[29] for systematic review, in accordance with the study's methodological design. Reporting of the cost assessment is usually an unmet criterion in studies that are reviewed based on the mERA

Table 2. Mobile Health Evidence Reporting and Assessment Guidelines

Criteria	Item No	Notes
Infrastructure (population level)	1	Clearly presents the availability of infrastructure to support technology operations in the study location. This refers to physical infrastructure such as electricity, access to power, connectivity, etc. in the local context. Reporting X% network coverage rate in the country is insufficient if the study is not being conducted at the country level.
Technology platform	2	Describes and provides justification for the technology architecture. This includes a description of software and hardware and details of any modifications made to publicly available software.
Interoperability/health information systems (HIS) context	3	Describes how mHealth intervention can integrate into existing health information systems. Refers to whether the potential of technical and structural integration into existing HIS or program has been described irrespective of whether such integration has been achieved by the existing system.
Intervention delivery	4	The delivery of the mHealth intervention is clearly described. This should include frequency of mobile communication, mode of delivery of intervention (that is, SMS, face to face, interactive voice response), timing and duration over which delivery occurred.
Intervention content	5	Details of the content of the intervention are described. Source and any modifications of the intervention content are described.
Usability/content testing	6	Describes formative research and/or content and/or usability testing with target group(s) clearly identified, as appropriate.
User feedback	7	Describes user feedback about the intervention or user satisfaction with the intervention. User feedback could include user opinions about content or user interface, their perceptions about usability, access, connectivity, etc.
Access of individual participants	8	Mentions barriers or facilitators to the adoption of the intervention among study participants. Relates to individual-level structural, economic, and social barriers or facilitators to access such as affordability, and other factors that may limit a user's ability to adopt the intervention.
Cost assessment	9	Presents basic cost assessment of the mHealth intervention from varying perspectives. This criterion broadly refers to the reporting of some cost considerations for the mHealth intervention in lieu of a full economic analysis. If a formal economic evaluation has been undertaken, it should be mentioned with appropriate references. Separate reporting criteria are available to guide economic reporting.
Adoption inputs/program entry	10	Describes how people are informed about the program including training, if relevant. Includes description of promotional activities and/or training required to implement the mHealth solution among the user population of interest.
Limitations for delivery at scale	11	Clearly presents mHealth solution limitations for delivery at scale.
Contextual adaptability	12	Describes the adaptation, or not, of the solution to a different language, different population or context. Any tailoring or modification of the intervention that resulted from pilot testing/usability assessment is described.
Replicability	13	Detailed intervention to support replicability. Clearly presents the source code/ screenshots/ flowcharts of the algorithms or examples of messages to support replicability of the mHealth solution in another setting.
Data security	14	Describes the data security procedures/ confidentiality protocol.
Compliance with national guidelines or regulatory statutes	15	Mechanism used to assure that content or other guidance/information provided by the intervention is in alignment with existing national/regulatory guidelines and is described.
Fidelity of the intervention	16	Was the intervention delivered as planned? Describe the strategies employed to assess the fidelity of the intervention. This may include assessment of participant engagement, use of backend data to track message delivery, and other technological challenges in the delivery of the intervention.

Source: Agarwal et al (2016).[18]

checklist, which is not yet widely used in the reporting of studies.[31] It is seen as a limitation that the mERA checklist developed by GOe team on WHO's behalf does not refer to the negative aspects of mHealth intervention, possible adverse events,[34] and the reproducibility of data analysis and statistical methods.[31] In addition, it is recommended to include the items regarding evaluation of technical and transmission characteristics of the mobile device and interoperability with other applications or systems.[30]

Mobile Health Applications in Nursing and Mobile Health Evidence Reporting and Assessment Checklist

In parallel with the increasing interest in mHealth applications nowadays, it is observed that there is a rapid increase in scientific studies on the subject[35] and it is known that nurses follow this issue closely. Studies on mHealth interventions conducted by nurses were examined. These studies included many different areas such as follow-up after outpatient surgical treatment,[36] supporting mothers in the postpartum period,[37-39] improving maternal, newborn, and child health,[40] symptom self-management of patients with cancer,[41] post-stroke care,[42] heart failure self-management,[43] asthma management,[44] type-2 diabetes management,[45] gestational diabetes,[46] and stress management.[47]

mHealth applications are preferred as an effective tool to ensure the sustainability of health-related education and management behaviors. Although mHealth applications are frequently preferred by the researchers, the use of reporting guides is quite limited. It is extremely important that the mERA checklist, which was developed to improve the quality of mHealth evidence reporting for all disciplines, is used to improve the reporting quality of studies in this field.

Methods

First, the authors who developed the mERA checklist were contacted via e-mail and permission was obtained from the responsible author to prepare the Turkish version of the mERA checklist. In order to ensure the language equivalence of the mERA checklist, 2 drafts independently translated into Turkish by the 2 authors were unanimously turned into a single translated text. In the second stage, the mERA checklist was evaluated by 10 faculty members in total. The experts were from the School of Foreign Languages (1), the Faculty of Nursing (8)—Pediatric Nursing, Public Health Nursing, Internal Medicine Nursing, and the Open Education Faculty (1). Expert opinions on the mERA checklist items were statistically analyzed. According to the Kendall's *W* coefficient of agreement correlation test, it was determined that the interobserver agreement was high and significant ($W = 0.556$, $P = .000$). In the third stage, the Turkish version of the checklist was revised by both authors with a consensus on all items, and the Turkish version of the mERA checklist was created (See Appendix-Table 1).

Results

The mERA consists of a total of 16 items as shown in Table 1 (See Appendix). Item 1 refers to physical infrastructure, including electricity, access to power, and connectivity in a local context. Item 2 means that the software and hardware used are detailed enough to allow the reapplication of the study. Item 3 expresses the details of how the mHealth strategy is adapted to the content of Health Information Systems and how it interacts. Item 4 specifies the details of how mHealth app is delivered. Item 5 covers details of how the content was developed/completed. Item 6 describes the details of the work done to involve end users in the development of the system. Item 7 refers to the user's views on the content, user interface, usability, access, and applicability of the mHealth app. Item 8 proposes to explain potential limitations related to the mHealth app. Item 9 refers to explaining factors such as cost-effectiveness and cost outcome. Item 10 refers to how people are informed about the program, its acceptance to the system, and the steps taken to support them to use the system. Item 11 expresses the limiting factors that are effective for delivering the app, taking into account the difficulties encountered. Item 12 expresses the extent to which the mHealth app can be adapted to healthcare, user groups, and health requirements. Item 13 suggests to provide details such as software code, workflow or screenshots, and flowcharts of algorithms to support replicability. Item 14 refers to a brief description of the hardware, software, and procedural steps for data security. Item 15 refers to information on whether the information is in line with evidence-based practices and is in line with the recommendations of existing national or regulatory agencies. Item 16 recommends determining fidelity to the plan on how the mHealth app will be delivered to individuals, based on system-generated or follow-up data.

Conclusion

In this study, Turkish language translation and expert opinion evaluation of the mERA checklist were performed. The mERA checklist has the potential to guide researchers in all processes, from planning to reporting studies on mHealth applications. In addition, it is foreseen that it will provide a contribution to referees, editors, and all researchers interested in the subject in the journals' review process. Using standard checklists is recommended from the planning stage of studies as regard reporting mHealth app. The use of checklists accepted internationally for reporting the studies will provide an opportunity to increase the quality of studies related mHealth apps.

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