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Title

A Protocol for a Systematic Review Investigating the Characteristics of Health-related Data Collection Tools used in Randomised Controlled Trials in Low- and Middle-income Countries

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Abstract

Introduction

Health-related data collection tools, including digital ones, have become more prevalent across clinical studies in the last number of years. However, using digital data collection tools in low- and middle-income countries presents unique challenges. In this review, we aim to provide an overview of the data collection tools currently being used in randomised controlled trials (RCTs) conducted in low resource settings and evaluate the tools based on the characteristics outlined in the Mobile Survey Tool (MST) evaluation framework. These include functionality, reliability, usability, efficiency, maintainability, portability, effectiveness, cost-benefit, satisfaction, freedom from risk, and context coverage. This evidence may provide a guide to selecting a suitable data collection tool for researchers planning to conduct research in low- and middle-income countries for future studies.

Methods and Analysis

Searches will be conducted in four electronic databases: Pubmed, CINAHL, Web of Science, and EMBASE. For inclusion, studies must be a randomised controlled trial, mention a health-related data collection tool, and conducted in a low- and middle-income country. Only studies with available full-text and written in English will be included. This systematic review will utilise the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) tool. Two review authors will screen the titles and abstracts of search results independently for inclusion eligibility based on the selection criteria. In the initial screening process, the full-text articles will be retrieved if the abstract contains limited information about the study.

Disagreements will be resolved through discussion. If the disagreement cannot be resolved, a third author (JD) will adjudicate. The study selection process will be outlined in a PRISMA flow-diagram. Data will be analysed using a narrative synthesis approach. The included studies and their outcomes will be presented in a table.

Ethics and Dissemination

Formal ethical approval is not required as primary data will not be collected in this study. The findings from this systematic review will be published in a peer-reviewed journal.

Trial registration number

PROSPERO CRD42023405738.

Strengths and Limitations of this Study

- This systematic review is the first to explore health-related data collection tools used in RCTs in low- and middle-income countries. Evidence generated from the review may be relevant for future research conducted in these settings.
- The formulation and development of comprehensive search terms which cover the various types of data collection is challenging. The terms selected are as inclusive and as generalisable as possible.
- Studies that are not published in English will be excluded. Since most LMICs are non-English speaking countries, relevant non-English articles could have been excluded due to the applied filters.

Introduction

Data collection tools are a key part of service delivery and medical research, as it is the means through which statistics on a micro and macro level are gathered in relation to healthcare of the patient and or at the population level via Public Health. Data collection tools are defined as any instrument used by researchers and healthcare professionals to collect data ranging from paper questionnaires to peak flow metres (1). The field of clinical medicine is unique in that countless specialised data collection tools exist. For instance, one specialised data collection tool is the blood glucometer, which was invented in the 1970s (2). While this was initially available to practitioners, over time, they became more portable and widely accessible to the general public. The data collection of blood glucose levels on a public scale has played a significant role in discovering new diabetes medications and in calibrating the management of diabetes (2). Similar patterns exist with other types of health-related data collection tools, as they have been instrumental in positively impacting public health.

Over the last number of years, the development of new digital technologies has enabled researchers to collect data in a more effective and efficient manner (3). Digital data collection tools such as mobile survey tools, apps, wearable devices, AI, video and audio analytical tools

and internet-of-things based products are becoming more prevalent in clinical research. One particular benefit of digital data collection tools is that it enables researchers to undertake these processes digitally and remotely, without requiring the physical presence of the patient (e.g. remote monitoring). Other benefits include their cost effectiveness and time efficiency (4), which is of particular importance in low resource settings. More recently, the application of wearable devices was highlighted during the COVID-19 pandemic (5). These tools collected data on a range of parameters such as "pulse, physical activity, and sleep" in order to calculate the regional probability of a COVID-19 outbreak (5). Hence, this review will also focus on the emerging digital aspect of health-related data collection tools used in low- and middle-income countries.

According to the World Health Organisation, developing research capacity in LMICs is one of the key ways to promote global health equality (7). More specifically, it is recommended that governments of LMICs must enact policies that incentivise health research, offer financial support for higher education research departments, and promote research partnerships between research bodies, academia, and health providers (6). One article highlighted the importance of identifying and improving preexisting data collection tools in LMICs can be instrumental in saving lives, particularly in emergency departments (7). LMICs, which include low-income and lower middle-income countries, are defined as those with a GNI per capita of below $4,255 (8).

The Country classification by GNI per capita for 2023 is presented in Table 1.

A Randomised Controlled Trial (RCT) is a research methodology in which participants are randomly assigned to one of two or more clinical interventions (9). RCTs are considered the most scientifically rigorous method of hypothesis testing available and is regarded as the gold standard study design for evaluating the effectiveness of interventions (9). The use of RCTs as a study design is becoming more prevalent in LMICs (10). Therefore, conducting research focused on RCTs could offer valuable guidance for researchers utilising RCTs in similar settings in the future.

In this review, the mobile survey tool (MST) framework will be used to assess the characteristics of the data collection tools (11). While there are various evaluation frameworks for certain subtypes of digital data collection tools such as wearables (12) and apps (13), an overarching framework for all data collection tools does not exist. It may be challenging to evaluate the wide variety of data collection tools available under one framework. While the MST is designed for evaluating mobile survey tools, the characteristics within this framework provide a comprehensive assessment that may be applicable for other data collection tools. It contains the key characteristics that practitioners may consider when choosing a data collection tool for their research. Fisher et al. defines the function of mobile survey tools by stating "MSTs allow users to gather and transmit field data in real time, standardise data storage and management, automate routine analyses, and visualise data" (11). This is broadly the function of all data collection tools. Therefore, a framework used to evaluate the functions of an MST can be applicable when evaluating the function of all data collection tools. Based on other frameworks reviewed (14,15), the MST has been modified to include the following additional criteria:

- Type of data collection tool

- Online or offline data storage
- Whether the tool is custom, off the shelf, or open source
- Details of the process of planning/development of the tool (e.g. requirements gathering)
- Data protection and privacy

The aim of this systematic review is to identify randomised controlled trials that have used health-related data collection tools in low- and middle-income countries and to evaluate the characteristics of the identified data collection tools according to the modified MST framework.

Similar reviews investigating data collection tools in LMICs have been conducted. A systematic review by Keating et al. investigated electronic data collection tools used for outbreak response in the context of the COVID-19 pandemic (16). The review identified 75 electronic data collection, analysis, and management tools that were used during the pandemic (16). It emphasised the importance of improving interoperability among different tools and software to effectively manage outbreaks in LMICs (16). The review also highlighted the need for additional training on these tools and software (16). Faruk et al. conducted a review examining the screening tools utilised in low- and middle-income countries (LMICs) to identify developmental delays encompassing a range from neurological to behavioral concerns in children (17). A total of 16 tools were identified for qualitative synthesis (17). The findings indicated a significant lack of culturally sensitive tools in LMICs (17). Furthermore, most of the tools failed to reach the expected specificity and sensitivity due to the lack of access to a gold standard assessment tool (17). However, there is yet to be a review conducted that examines data collection tools as a whole.

The objectives of this review are:

- Categorise the types of health-related data collection tools currently being used in LMICs. This may include digital/manual, custom/Off the shelf, wearable/non-wearable among others.
- Identify the primary differences in the attributes between the various health-related data collection tools used in randomised controlled trials in low middle-income countries.
- Establish a robust framework (e.g. modified MST) for researchers to assess the characteristics of health-related data collection tools.

Review Questions

This systematic review aims to address the following questions:

- What are the health-related data collection tools that are used in randomised controlled trials in low- and middle-income countries?
- What are the key differences in the attributes of health-related data collection tools that are used in RCTs in low- and middle-income countries with the modified Mobile Survey Tool (MST) framework as a reference point?
- How suitable is the modified MST framework for healthcare researchers to evaluate the characteristics of health-related data collection tools in LMICs?

Methods

Design

This protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: CRD42023405738). It has been developed using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- The review will include only randomised controlled trials (RCTs) as this study design is regarded as the gold standard for evaluating the effectiveness of interventions.
- The RCT must be conducted in a low- and middle-income country and mentions a health-related data collection tool.
- Participants are adults aged 19+.
- Recruitment of participants exclusively from the local population.
- Published, peer-reviewed, randomised controlled trials that utilise a health-related data collection tool in a low- and middle-income country will be eligible for inclusion in the initial stage of the systematic review.
- Publication dates between 2005 and 2023. The year 2005 is set as the publication year limit as mobile devices such as smartphones became available along with the rollout of the internet to facilitate the transmission of data.
- English language only articles.
- Published in full-text.

Exclusion criteria:

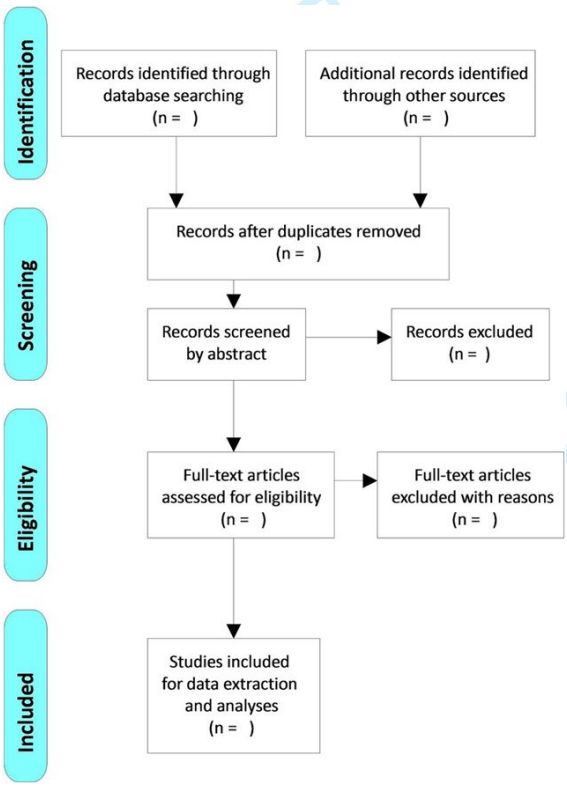
- The RCT does not utilise a health-related data collection tool.
- Studies where participants are under 19 years of age. Including younger participants in studies that utilise complex data collection tools may skew the results as they may not possess the skills to interpret the instructions or results of the tools accurately.
- The study will be excluded if there is insufficient information in the RCT regarding the characteristics within the modified MST framework.

Search Strategy

A search of the literature will be conducted in four electronic databases: PubMed, CINAHL, Web of Science, and Embase. The primary search strategy was designed for PubMed and adapted as appropriate for each of the databases. The full search strategy is presented in the online supplementary appendix. The terms will be slightly adapted to the search particulars (eg. truncations, wildcards (*)) and filters available for each database. The search will be conducted in July 2023.

Selection Process

Two review authors (RK and NA) will screen the titles and abstracts of search results independently based on the eligibility criteria. The full-text articles will be retrieved if the abstract contains limited information about the study. Duplicate articles will be removed. Study authors will be contacted for clarification if eligibility is unclear. Disagreements will be resolved through discussion. If the disagreement cannot be resolved, a third author (JOD) will adjudicate. The list of the excluded studies and the reasons for their exclusion will be presented in a 'Characteristics of excluded studies' table. The study selection process will be outlined in a PRISMA flow-diagram. Mendeley referencing software will be used to screen and determine the eligibility of all the references from the initial search.



Data Collection

Data from the included studies will be extracted by RK and NA independently into a data extraction table in Microsoft Excel. This includes the following:

- Descriptive information about the study: DOI, author and year of publication, objective of the study, where the RCT was conducted, language, and age of the study participants.

- Descriptive information about the data collection tool: type of data collection tool, online or offline data storage, whether the tool is custom, off the shelf or open source, planning and development, and data protection and privacy.

- Information relating to the characteristics of the MST framework: functionality, reliability, usability, efficiency, maintainability, portability, effectiveness, cost-benefit, satisfaction, freedom from risk, and context coverage.

Assessment of Risk of Bias

Risk of bias will not be conducted for the selected RCTs, as this systematic review is focused on the data collection tools being used, not the outcome of the RCTs themselves. However, quasi experimental studies that do not involve randomisation will be excluded.

Data Synthesis

Data will be analysed using a narrative synthesis approach. The included studies and their outcomes will be presented in a table format and categorised based on relevant parameters. Qualitative analysis will be used to assess the tools identified within each study against the criteria of the modified MST framework. There are 11 characteristics within the framework. These include functionality, reliability, usability, efficiency, maintainability, portability, effectiveness, cost-benefit, satisfaction, freedom from risk, and context coverage. These characteristics are broken down into 32 sub-characteristics. For example, functionality involves assessing the suitability, accuracy, interoperability, and security of a data collection tool. These characteristics and the sub-characteristics will be used to conduct a descriptive analysis of each selected data collection tool. Moreover, in future studies, researchers can use the same characteristics, in addition to the added ones, to evaluate the attributes of any tools they are investigating. Finally, the modified MST framework will be evaluated based on its efficacy of assessing the characteristics of a data collection tool used in an RCT.

Discussion

This systematic review is the first to focus on health-related data collection tools in randomised controlled trials (RCTs) conducted in low- and middle-income countries (LMICs). The review aims to provide a comprehensive and up-to-date assessment of the various data collection tools currently being used in RCTs in LMICs, categorise the type of data collection tools, and assess their characteristics and the challenges associated with deploying them in these settings.

Achieving sustained growth in health policy and systems research in developing countries is a systemic issue that requires significant reform to existing research law and policy in high-income countries (18). The implementation of facility-building measures, such as the adoption of advanced digital data collection methods, can play a crucial role in mitigating research capacity issues in low- and middle-income countries (18).

The findings of this review may have significant implications for researchers seeking to utilise data collection tools in LMICs. Researchers may be unaware of the available range of data collection tools leading them to develop a customised tool, which can be costly and time-consuming. By identifying and assessing the characteristics of the various data collection tools,

this review will assist researchers in selecting an existing tool that will meet their research objectives.

It is important to note that most LMICs are non-english speaking countries. Therefore, a limitation of this systematic review is the exclusion of potentially relevant non-English articles, as a result of the applied filters. The anticipated impact on the results is minimal, given the relatively small number of non-English articles available. Another limitation is that individual countries identified as low- and middle-income countries were not included in the search string due to the massive volume of results generated. However, the search string has been modified to include different variations of the term "LMICs" and the income classification of each country will be evaluated based on the World Atlas Bank's definition.

References

1. Kabir SM. METHODS OF DATA COLLECTION. 2016. p. 201-75.
2. Tonyushkina K, Nichols JH. Glucose meters: a review of technical challenges to obtaining accurate results. J Diabetes Sci Technol [Internet]. 2009 Jul [cited 2023 May 31];3(4):971–80. Available from: http://journals.sagepub.com/doi/10.1177/193229680900300446
3. Alghamdi NS, Alghamdi SM. The role of digital technology in curbing covid-19. IJERPH [Internet]. 2022 Jul 7 [cited 2023 May 31];19(14):8287. Available from: https://www.mdpi.com/1660-4601/19/14/8287
4. Will DJ, Campbell KJ, Holmes ND. Using digital data collection tools to improve overall cost-efficiency and provide timely analysis for decision making during invasive species eradication campaigns. Wildlife Research. 2015;41(6):499-509.
5. Channa A, Popescu N, Skibinska J, Burget R. The rise of wearable devices during the covid-19 pandemic: a systematic review. Sensors [Internet]. 2021 Aug 28 [cited 2023 May 31];21(17):5787. Available from: https://www.mdpi.com/1424-8220/21/17/5787
6. Pratt B, Loff B. Health research systems: promoting health equity or economic competitiveness? Bull World Health Organ [Internet]. 2012 Jan 1 [cited 2023 May 31];90(1):55–62. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3260576/pdf/BLT.11.092007.pdf/
7. Katyal A, Kumar A. Strengthening emergency care by developing data collection systems in low- and middle-income countries [Internet]. Elsevier; 2020 [cited 2023 Jun 6]. Available from: https://www.sciencedirect.com/science/article/pii/S2211419X20301002#s0025
8. World bank country and lending groups – world bank data help desk [Internet]. [cited 2023 May 31]. Available from: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups
9. Akobeng AK. Understanding randomised controlled trials. Archives of Disease in Childhood [Internet]. 2005 Aug 1 [cited 2023 May 31];90(8):840–4. Available from: https://adc.bmj.com/lookup/doi/10.1136/adc.2004.058222
10. Rubagumya F, Hopman WM, Gyawali B, Mukherji D, Hammad N, Pramesh CS, et al. Participation of lower and upper middle–income countries in clinical trials led by high-

income countries. JAMA Netw Open [Internet]. 2022 Aug 18 [cited 2023 Jun 4];5(8):e2227252. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9389348/

11. Fisher M, Mann B, Cronk R, Shields K, Klug T, Ramaswamy R. Evaluating mobile survey tools (Msts) for field-level monitoring and data collection: development of a novel evaluation framework, and application to msts for rural water and sanitation monitoring. IJERPH [Internet]. 2016 Aug 23 [cited 2023 May 31];13(9):840. Available from: http://www.mdpi.com/1660-4601/13/9/840

12. Connelly K, Molchan H, Bidanta R, Siddh S, Lowens B, Caine K, et al. Evaluation framework for selecting wearable activity monitors for research. mHealth [Internet]. 2021 Jan [cited 2023 May 31];7:6–6. Available from: https://mhealth.amegroups.com/article/view/45621/html

13. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR mHealth uHealth [Internet]. 2015 Mar 11 [cited 2023 May 31];3(1):e27. Available from: http://mhealth.jmir.org/2015/1/e27/

14. McMillan B, Hickey E, Patel MG, Mitchell C. Quality assessment of a sample of mobile app-based health behavior change interventions using a tool based on the National Institute of Health and Care Excellence behavior change guidance. Patient Education and Counseling [Internet]. 2016 Mar [cited 2023 May 31];99(3):429–35. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0738399115301014

15. Zelmer J, Van Hoof K, Notarianni M, Van Mierlo T, Schellenberg M, Tannenbaum C. An assessment framework for e-mental health apps in canada: results of a modified delphi process. JMIR Mhealth Uhealth [Internet]. 2018 Jul 9 [cited 2023 May 31];6(7):e10016. Available from: http://mhealth.jmir.org/2018/7/e10016/

16. Keating P, Murray J, Schenkel K, Merson L, Seale A. Electronic data collection, management and analysis tools used for outbreak response in low- and middle-income countries: a systematic review and stakeholder survey. BMC Public Health. 2021 Sep 25;21(1):1741.

17. Faruk T, King C, Muhit M, Islam MK, Jahan I, Baset K ul, et al. Screening tools for early identification of children with developmental delay in low- and middle-income countries: a systematic review. BMJ Open [Internet]. 2020 Nov 23 [cited 2023 Jun 4];10(11):e038182. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7684835/

18. The role of Europe and of international science and technology cooperation. [Internet]. Council on Health Research for Development - COHRED. [cited 2023 Jun 4]. Available from: https://www.cohred.org/publications/open-archive/the-role-of-europe-and-of-international-science-and-technology-cooperation-specific-needs-for-health-research-in-low-and-middle-income-countries/

Table 1 Country classification by GNI per capita for the year 2023 according to the World Bank Atlas method (8).

Country Classification	GNI per capita
Low-income	$1,085 or less
Lower middle-income	$1,086 and $4,255
Upper middle-income	$4,256 and $13,205
Upper high-income	$13,205 or more

Extraction Sheet

- DOI
- Author
- Year of Publication
- Where the RCT was conducted
- Language
- Purpose of study
- Age of participants
- Type of data collection tool
- Online or offline data storage
- Custom or off the shelf
- Planning and development
- Data protection/privacy
- Functionality
- Reliability
- Usability
- Efficiency
- Maintainability
- Portability
- Effectiveness
- Cost-benefit
- Satisfaction
- Freedom from risk
- Context coverage

Modified MST Framework		
Functionality	Suitability	Degree to which an MST meets stated and implied user needs when used under specified conditions
	Accuracy	Degree to which an MST provides accurate results with the needed degree of precision
	Interoperability (Only Digital)	Degree to which MSTs can exchange information with other systems and use information that has been exchanged
	Security	Degree to which an MST protects data from unauthorized access by other persons or systems
Reliability	Maturity	Degree to which an MST has overcome initial bugs and defects, and meets needs for reliability under normal operation
	Fault Tolerance (Digital)	Degree to which an MST operates as intended despite the presence of hardware or software faults
	Recoverability	Degree to which, in the event of an interruption or a failure, an MST can recover the data directly affected and re-establish the desired state of the system
Usability	Understandability	Degree to which the features and functions of an MST can be understood by users with a wide range of backgrounds and levels of expertise
	Learnability	Degree to which users with a wide range of backgrounds and levels of expertise can efficiently learn to use an MST to achieve specified goals
	Operability	Degree to which an MST is easy to operate and control

Modified MST Framework		
	Attractiveness	Degree to which users perceive an MST's user interface to be attractive and satisfying to use
Efficiency	Time Behaviour	Degree to which MST response times, processing times, and throughput rates meet or exceed user requirements
	Resource Utilisation	Degree to which the amounts and types of resources used by an MST, when performing its functions, meet requirements
Maintainability	Analyzability	Degree of effectiveness and efficiency with which it is possible to assess the impact on an MST of an intended change to one or more of its parts, or to diagnose an MST for deficiencies or causes of failures, or to identify parts to be modified
	Changeability	Degree to which an MST can be effectively and efficiently modified by users without introducing defects or degrading existing product quality
	Stability	Degree to which an MST performs free from failures, interruptions, and unexpected effects
	Testability	Degree of effectiveness and efficiency with which test criteria can be established for an MST and tests can be performed to determine whether those criteria have been met
Portability	Adaptability	Degree to which an MST can effectively and efficiently be adapted for different or evolving hardware, software or other operational or usage environments

Modified MST Framework		
	Ease of Installation	Degree of effectiveness and efficiency with which an MST can be successfully installed and/or uninstalled in a specified environment
	Co-Existance	The capability of an MST to exist and operate on systems on which other software simultaneously exists and operates
	Replacability	The capability of an MST to be used in place of another specified MST for the same purpose in the same environment
Effectiveness	User accomplishment	Accuracy and completeness with which users achieve specified goals
Efficiency	Cost-Benefit	Resources expended in relation to the accuracy and completeness with which users achieve goals
Satisfaction	Usefulness	Degree to which a user is satisfied with their perceived achievement of pragmatic goals, including the results of use and the consequences of use
	Trust	Degree to which a user or other stakeholder has confidence that an MST will behave as intended
	Pleasure	Degree to which a user obtains pleasure from fulfilling their personal needs when using an MST
	Comfort	Degree to which the user is satisfied with his or her physical comfort when using an MST
Freedom from Risk	Economic Risk Mitigation	Degree to which an MST mitigates potential risks to financial status, efficient operation, commercial property, reputation or other resources in the intended contexts of use

Modified MST Framework		
	Health and Safety Risk Mitigation	Degree to which an MST mitigates potential risks to people in the intended contexts of use
	Environmental Risk Mitigation	Degree to which an MST mitigates potential risks to property or the environment in the intended contexts of use
Context Coverage	Context Completeness	Degree to which an MST can be used with effectiveness, efficiency, freedom from risk and satisfaction in all the specified contexts of use
	Flexibility	Degree to which an MST can be used with effectiveness, efficiency, freedom from risk and satisfaction in contexts beyond those initially specified in the requirements
DOI		
Author and Year of Publication		
Where the RCT was conducted		
Language		
Purpose of the Study		
Age of Participants		
Type of Data Collection Tool		
Online or Offline Data Storage		
Custom or Off the Shelf		
Planning and Development		
Data Protection/Privacy		

Search Strategy

#1

"Digital form*" OR "Digital Data Collection Tool*" OR "Mobile Data Collection Tool*" OR "Mobile Survey Tool*" OR "Mobile Data Collection" OR "Electronic Data Collection" OR "mHealth" OR "Wearable Technology" OR "Wearable Sensor*" OR "Biosensor*" OR "Smart medical device*" OR “electronic data capture” OR “patient monitoring device*” OR “electronic medical device*” OR “digital self monitoring” OR “survey*” OR "data collection" OR "data collection tool*" OR "data entry" OR "data logging" OR "self report*" OR "self-reporting" OR "self-monitor*" OR "self test*"

#2

"Low middle income countr*" OR "low and middle income countr*" OR "low income countr*" OR "developing countr*" OR "LMIC"

#3

"Randomised controlled trial*" OR "RCT" OR "RCTs" OR "randomized controlled trial*"

#4

#1 AND #2 AND #3

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
DISCUSSION			

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
Limitations	20	Discuss the limitations of the scoping review process.	
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	

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A Protocol for a Systematic Review Investigating the Characteristics of Health-related Data Collection Tools used in Randomised Controlled Trials in Low- and Middle-income Countries

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Title

A Protocol for a Systematic Review Investigating the Characteristics of Health-related Data Collection Tools Used in Randomised Controlled Trials in Low- and Middle-income Countries

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Abstract

Introduction

Health-related data collection tools, including digital ones, have become more prevalent across clinical studies in the last number of years. However, using digital data collection tools in low- and middle-income countries presents unique challenges. In this review, we aim to provide an overview of the data collection tools currently being used in randomised controlled trials (RCTs) conducted in low resource settings and evaluate the tools based on the characteristics outlined in the modified Mobile Survey Tool (MST) framework. These include functionality, reliability, usability, efficiency, maintainability, portability, effectiveness, cost-benefit, satisfaction, freedom from risk, and context coverage. This evidence may provide a guide to selecting a suitable data collection tool for researchers planning to conduct research in low- and middle-income countries for future studies.

Methods and Analysis

Searches will be conducted in four electronic databases: Pubmed, CINAHL, Web of Science, and EMBASE. For inclusion, studies must be a randomised controlled trial, mention a health-related data collection tool, and conducted in a low- and middle-income country. Only studies with available full-text and written in English will be included. The search was restricted to studies published between January 2005 and June 2023. This systematic review will utilise the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) tool. Two review authors will screen the titles and abstracts of search results independently for inclusion. In the initial screening process, the full-text articles will be retrieved if the abstract contains limited information about the study. Disagreements will be resolved through discussion. If the disagreement cannot be resolved, a third author (JOD) will adjudicate. The study selection process will be outlined in a PRISMA flow-diagram. Data will be analysed using a narrative synthesis approach. The included studies and their outcomes will be presented in a table.

Ethics and Dissemination

Formal ethical approval is not required as primary data will not be collected in this study. The findings from this systematic review will be published in a peer-reviewed journal.

Registration Number

PROSPERO CRD42023405738.

Strengths and Limitations of this Study

- The review will utilise four well-established databases, which cover the primary area of interest.

- The formulation and development of comprehensive search terms that cover the various types of data collection is challenging.
- Studies that are not published in English will be excluded.

Introduction

Data collection tools are a key part of service delivery and medical research, as it is the means through which statistics on a micro and macro level are gathered in relation to the healthcare of the patient and or at the population level via public health. Data collection tools are defined as any instrument used by researchers and healthcare professionals to collect data ranging from paper questionnaires to peak flow metres (1). The field of clinical medicine is unique in that countless specialised data collection tools exist. For instance, one specialised data collection tool is the blood glucometer, which was invented in the 1970s (2). While this was initially only available to practitioners, over time, it became more portable and widely accessible to the general public. The data collection of blood glucose levels on a public scale has played a significant role in discovering new diabetes medications and in calibrating the management of diabetes (2). Similar patterns exist with other types of health-related data collection tools, as they have been instrumental in positively impacting public health.

Over the last number of years, the development of new digital technologies has enabled researchers to collect data in a more effective and efficient manner (3). Digital data collection tools such as mobile survey tools, apps, wearable devices, AI, video and audio analytical tools, and internet-of-things-based products are becoming more prevalent in clinical research. One particular benefit of digital data collection tools is that they enable researchers to undertake these processes digitally and remotely, without requiring the physical presence of the patient (e.g. remote monitoring). Other benefits include their cost effectiveness and time efficiency (4), which is of particular importance in low-resource settings. More recently, the application of wearable devices was highlighted during the COVID-19 pandemic (5). These tools collected data on a range of parameters such as “pulse, physical activity, and sleep” in order to calculate the regional probability of a COVID-19 outbreak (5). Hence, this review will also focus on the emerging digital aspect of health-related data collection tools used in low- and middle-income countries.

As the years progress, data collection in healthcare will keep increasing. An editorial from 2023 by Md Aanisur Rahman claims machine learning and deep learning techniques will greatly increase the volume of medical data collected in the future. The editorial cites the PATINA decision support tool as an example of an intelligent monitoring system that can prevent the hospitalisation rates of frail older adults (6). Social media can also be used to harness data on patients to improve their management. This can occur on an individual and population level (7).

According to the World Health Organisation, developing research capacity in LMICs is one of the key ways to promote global health equality (8). More specifically, it is recommended that governments of LMICs enact policies that incentivise health research, offer financial support for higher education research departments, and promote research partnerships between research bodies, academia, and health providers (8). One article highlighted that identifying and improving pre-existing data collection tools in LMICs can be instrumental in saving lives, particularly in emergency departments (9). LMICs, which include low-income and lower-middle-income countries, are defined as those with a GNI per capita of below $4,255 (10).

The Country classification by GNI per capita for 2023 is presented in Table 1.

Table 1 Country classification by GNI per capita for the year 2023 according to the World Bank Atlas method (10).

Country Classification	GNI per capita
Low-income	$1,085 or less
Lower middle-income	$1,086 and $4,255
Upper middle-income	$4,256 and $13,205
High-income	$13,205 or more

A Randomised Controlled Trial (RCT) is a research methodology in which participants are randomly assigned to one of two or more clinical interventions (11). RCTs are considered the most scientifically rigorous method of hypothesis testing available and are regarded as the gold standard study design for evaluating the effectiveness of interventions (11). The use of RCTs as a study design is becoming more prevalent in LMICs (12). Therefore, conducting research focused on RCTs could offer valuable guidance for researchers utilising RCTs in similar settings in the future.

In this review, the mobile survey tool (MST) framework will be used to assess the characteristics of the data collection tools (13). While there are various evaluation frameworks for certain subtypes of digital data collection tools such as wearables (14) and apps (15), an overarching framework for all data collection tools does not exist. It may be challenging to evaluate the wide variety of data collection tools available under one framework. While the MST is designed for evaluating mobile survey tools, the characteristics within this framework provide a comprehensive assessment that may be applicable to other data collection tools. It contains the key characteristics that practitioners may consider when choosing a data collection tool for their research. Fisher et al. define the function of mobile survey tools, stating, "MSTs allow users to gather and transmit field data in real-time, standardise data storage and management, automate routine analyses, and visualise data" (13). This is broadly the function of all data collection tools. Therefore, a framework used to evaluate the functions of an MST can be applicable when evaluating the function of all data collection tools. Based on other frameworks reviewed (16,17), the MST has been modified to include the following additional criteria:

- Type of data collection tool
- Online or offline data storage
- Whether the tool is custom, off-the-shelf, or open source
- Data protection and privacy

The aim of this systematic review is to identify randomised controlled trials that have used health-related data collection tools in low- and middle-income countries and to evaluate the characteristics of the identified data collection tools according to the modified MST framework.

Similar reviews investigating data collection tools in LMICs have been conducted. A systematic review by Keating et al. investigated electronic data collection tools used for outbreak response in the context of the COVID-19 pandemic (18). The review identified 75 electronic data collection, analysis, and management tools that were used during the pandemic (18). It emphasised the importance of improving interoperability among different tools and software to effectively manage outbreaks in LMICs (18). The review also highlighted the need for additional training on these tools and software (18). Faruk et al. conducted a review examining the screening tools utilised in LMICs to identify developmental delays encompassing a range from neurological to behavioural concerns in children (19). A total of 16 tools were identified for qualitative synthesis (19). The findings indicated a significant lack of culturally sensitive tools in LMICs (19). Furthermore, most of the tools failed to reach the expected specificity and sensitivity due to the lack of access to a gold-standard assessment tool (19). However, there is yet to be a review conducted that examines data collection tools as a whole.

The objectives of this review are:

- Categorise the types of health-related data collection tools currently being used in LMICs. This may include digital/manual, custom/Off-the-shelf, and wearable/non-wearable among others.
- Identify the primary differences in the attributes between the various health-related data collection tools used in randomised controlled trials in low-middle-income countries.
- Establish a robust framework (e.g. modified MST) for researchers to assess the characteristics of health-related data collection tools.

Review Questions

This systematic review aims to address the following questions:

- What are the health-related data collection tools that are used in randomised controlled trials in low- and middle-income countries?
- What are the key differences in the attributes of health-related data collection tools that are used in RCTs in low- and middle-income countries with the modified Mobile Survey Tool (MST) framework as a reference point?
- How suitable is the modified MST framework for healthcare researchers to evaluate the characteristics of health-related data collection tools in LMICs?

Methods

Design

This protocol has been registered with the International Prospective Register of Systematic Reviews (PROSPERO) (registration number: CRD42023405738). It has been developed using the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) checklist.

Inclusion and Exclusion Criteria

Inclusion Criteria:

- Published, peer-reviewed, randomised controlled trials that utilise a health-related data collection tool in a low- and middle-income country will be eligible for inclusion in the initial stage of the systematic review.
- Participants are adults aged 18+.
- Recruitment of participants exclusively from the local population.
- Publication dates between January 2005 and June 2023. The year 2005 is set as the publication year limit as mobile devices such as smartphones became available along with the rollout of the internet to facilitate the transmission of data.
- English language-only articles.
- Published in full-text.

Exclusion Criteria:

- Quasi-randomised trials and randomised clinical trials will be excluded.
- The RCT does not utilise a health-related data collection tool.
- Studies where participants are under 18 years of age.
- The study will be excluded if there are less than 5 MST characteristics addressed in the RCT.

Patient and Public Involvement

None

Search Strategy

A search of the literature will be conducted in four electronic databases: PubMed, CINAHL, Web of Science, and Embase. The primary search strategy was designed for PubMed and adapted as appropriate for each of the databases. The full search strategy for all databases is presented in the online supplementary appendix. The terms were slightly adapted to the search particulars (eg. truncations, wildcards (*)) and filters available for each database. The search was conducted in June 2023.

Selection Process

Two review authors (RK and NA) will independently screen the titles and abstracts of search results based on the eligibility criteria. The full-text articles will be retrieved if the abstract contains limited information about the study. In the case where a relevant conference abstract is identified, RK and NA will contact the authors for the full-text article. Duplicate articles will be removed. Study authors will be contacted for clarification if eligibility is unclear. Disagreements will be resolved through discussion. A third author (JOD) will adjudicate if the disagreement cannot be resolved. The list of the excluded studies and the reasons for their exclusion will be presented in a 'Characteristics of excluded studies' table. The study selection process will be outlined in a PRISMA flow diagram. Mendeley referencing software will be used to screen and determine the eligibility of all the references from the initial search.

Data Collection

Data from the included studies will be extracted by RK and NA independently into a data extraction table in Microsoft Excel. This includes the following (supplementary file):

- Descriptive information about the study: DOI, author and year of publication, objective of the study, where the RCT was conducted, language, and age of the study participants.

- Descriptive information about the data collection tool: type of data collection tool, online or offline data storage, whether the tool is custom, off the shelf or open source, and data protection and privacy.

- Information relating to the characteristics of the MST framework: functionality, reliability, usability, efficiency, maintainability, portability, effectiveness, cost-benefit, satisfaction, freedom from risk, and context coverage.

Assessment of Risk of Bias

Risk of bias will not be conducted for the selected RCTs, as this systematic review is focused on the data collection tools being used, not the outcome of the RCTs themselves. However, quasi experimental studies that do not involve randomisation will be excluded.

Data Synthesis

Data will be analysed using a narrative synthesis approach. The included studies and their outcomes will be presented in a table format and categorised based on the relevant parameters. Qualitative analysis will be used to assess the tools identified within each study against the criteria of the modified MST framework. There are 11 characteristics within the framework. These include functionality, reliability, usability, efficiency, maintainability, portability, effectiveness, cost-benefit, satisfaction, freedom from risk, and context coverage. These characteristics are broken down into 32 sub-characteristics. For example, functionality involves assessing the suitability, accuracy, interoperability, and security of a data collection tool. These characteristics and the sub-characteristics will be used to conduct a descriptive analysis of each selected data collection tool. Moreover, in future studies, researchers can use the same characteristics, in addition to the added ones, to evaluate the attributes of any tools they are investigating. Finally, the modified MST framework will be evaluated based on its efficacy of assessing the characteristics of a data collection tool used in an RCT.

Ethics and Dissemination

Formal ethical approval is not required as primary data will not be collected in this study. The findings from this systematic review will be published in a peer-reviewed journal.

Discussion

This systematic review is the first to focus on health-related data collection tools in randomised controlled trials (RCTs) conducted in low- and middle-income countries (LMICs). The review aims to provide a comprehensive and up-to-date assessment of the various data collection tools currently being used in RCTs in LMICs, categorise the type of data collection tools, and assess their characteristics and the challenges associated with deploying them in these settings.

Achieving sustained growth in health policy and systems research in developing countries is a systemic issue that requires significant reform to existing research laws and policies in high-income countries (20). The implementation of facility-building measures, such as the adoption of advanced digital data collection methods can play a crucial role in mitigating research capacity issues in low- and middle-income countries (20).

The findings of this review may have significant implications for researchers seeking to utilise data collection tools in LMICs. Researchers may be unaware of the available range of data collection tools leading them to develop a customised tool, which can be costly and time-consuming. By identifying and assessing the characteristics of the various data collection tools, this review will assist researchers in selecting an existing tool that will meet their research objectives.

It is important to note that most LMICs are non-English speaking countries. Therefore, a limitation of this systematic review is the exclusion of potentially relevant non-English articles, as a result of the applied filters. The anticipated impact on the results is minimal, given the relatively small number of non-English articles available. Another limitation is that individual countries identified as low- and middle-income countries were not included in the search string due to the massive volume of results generated. However, the search string has been modified to include different variations of the term “LMICs” and the income classification of each country will be evaluated based on the World Atlas Bank's definition.

Contributors

RK, NA, JOD, KPF, and EJK designed the protocol. RK and NA wrote the first draft of the protocol. JOD and KPF provided critical appraisal regarding the design of the systematic review and revised the protocol. RK and NA performed the search and designed the extraction sheet. All authors approved the final draft of the protocol.

Competing Interests

None declared

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References

1. 1.Kabir SMS. Methods of Data Collection [Internet]. ResearchGate. 2018. Available from: https://www.researchgate.net/publication/325846997_METHODS_OF_DATA_COLLECTION
2. Tonyushkina K, Nichols JH. Glucose meters: a review of technical challenges to obtaining accurate results. J Diabetes Sci Technol [Internet]. 2009 Jul [cited 2023 May 31];3(4):971–80. Available from: http://journals.sagepub.com/doi/10.1177/193229680900300446
3. Alghamdi NS, Alghamdi SM. The role of digital technology in curbing covid-19. IJERPH [Internet]. 2022 Jul 7 [cited 2023 May 31];19(14):8287. Available from: https://www.mdpi.com/1660-4601/19/14/8287
4. Will DJ, Campbell KJ, Holmes ND. Using digital data collection tools to improve overall cost-efficiency and provide timely analysis for decision making during invasive species eradication campaigns. Wildlife Research. 2015;41(6):499-509.
5. Channa A, Popescu N, Skibinska J, Burget R. The rise of wearable devices during the covid-19 pandemic: a systematic review. Sensors [Internet]. 2021 Aug 28 [cited 2023 May 31];21(17):5787. Available from: https://www.mdpi.com/1424-8220/21/17/5787
6. 1.Rahman MA, Moayedikia A, Wiil UK. Editorial: Data-driven technologies for future healthcare systems. Frontiers in Medical Technology [Internet]. 2023 May 24 [cited 2023 Sep 14];5:1183687. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10244758/
7. 1.Alshaikh F, Ramzan F, Rawaf S, Majeed A. Social Network Sites as a Mode to Collect Health Data: A Systematic Review. Journal of Medical Internet Research. 2014 Jul 14;16(7):e171. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4397388/
8. Pratt B, Loff B. Health research systems: promoting health equity or economic competitiveness? Bull World Health Organ [Internet]. 2012 Jan 1 [cited 2023 May 31];90(1):55–62. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3260576/pdf/BLT.11.092007.pdf/
9. Katyal A, Kumar A. Strengthening emergency care by developing data collection systems in low- and middle-income countries [Internet]. Elsevier; 2020 [cited 2023 Jun 6]. Available from: https://www.sciencedirect.com/science/article/pii/S2211419X20301002#s0025
10. World bank country and lending groups – world bank data help desk [Internet]. [cited 2023 May 31]. Available from: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups
11. Akobeng AK. Understanding randomised controlled trials. Archives of Disease in Childhood [Internet]. 2005 Aug 1 [cited 2023 May 31];90(8):840–4. Available from: https://adc.bmj.com/lookup/doi/10.1136/adc.2004.058222
12. Rubagumya F, Hopman WM, Gyawali B, Mukherji D, Hammad N, Pramesh CS, et al. Participation of lower and upper middle–income countries in clinical trials led by high-income countries. JAMA Netw Open [Internet]. 2022 Aug 18 [cited 2023 Jun 4];5(8):e2227252. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9389348/
13. Fisher M, Mann B, Cronk R, Shields K, Klug T, Ramaswamy R. Evaluating mobile survey tools (Msts) for field-level monitoring and data collection: development of a novel evaluation

framework, and application to msts for rural water and sanitation monitoring. IJERPH [Internet]. 2016 Aug 23 [cited 2023 May 31];13(9):840. Available from: http://www.mdpi.com/1660-4601/13/9/840

14. Connelly K, Molchan H, Bidanta R, Siddh S, Lowens B, Caine K, et al. Evaluation framework for selecting wearable activity monitors for research. mHealth [Internet]. 2021 Jan [cited 2023 May 31];7:6–6. Available from: https://mhealth.amegroups.com/article/view/45621/html

15. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR mHealth uHealth [Internet]. 2015 Mar 11 [cited 2023 May 31];3(1):e27. Available from: http://mhealth.jmir.org/2015/1/e27/

16. McMillan B, Hickey E, Patel MG, Mitchell C. Quality assessment of a sample of mobile app-based health behavior change interventions using a tool based on the National Institute of Health and Care Excellence behavior change guidance. Patient Education and Counseling [Internet]. 2016 Mar [cited 2023 May 31];99(3):429–35. Available from: https://linkinghub.elsevier.com/retrieve/pii/S0738399115301014

17. Zelmer J, Van Hoof K, Notarianni M, Van Mierlo T, Schellenberg M, Tannenbaum C. An assessment framework for e-mental health apps in canada: results of a modified delphi process. JMIR Mhealth Uhealth [Internet]. 2018 Jul 9 [cited 2023 May 31];6(7):e10016. Available from: http://mhealth.jmir.org/2018/7/e10016/

18. Keating P, Murray J, Schenkel K, Merson L, Seale A. Electronic data collection, management and analysis tools used for outbreak response in low- and middle-income countries: a systematic review and stakeholder survey. BMC Public Health. 2021 Sep 25;21(1):1741.

19. Faruk T, King C, Muhit M, Islam MK, Jahan I, Baset K ul, et al. Screening tools for early identification of children with developmental delay in low- and middle-income countries: a systematic review. BMJ Open [Internet]. 2020 Nov 23 [cited 2023 Jun 4];10(11):e038182. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7684835/

20. The role of Europe and of international science and technology cooperation. [Internet]. Council on Health Research for Development - COHRED. [cited 2023 Jun 4]. Available from: https://www.cohred.org/publications/open-archive/the-role-of-europe-and-of-international-science-and-technology-cooperation-specific-needs-for-health-research-in-low-and-middle-income-countries/

Extraction Sheet

- DOI
- Author
- Year of Publication
- Where the RCT was conducted
- Language
- Purpose of study
- Age of participants
- Type of data collection tool
- Online or offline data storage
- Custom or off the shelf
- Data protection/privacy
- Functionality
- Reliability
- Usability
- Efficiency
- Maintainability
- Portability
- Effectiveness
- Cost-benefit
- Satisfaction
- Freedom from risk
- Context coverage

Modified MST Framework		
Functionality	Suitability	Degree to which an MST meets stated and implied user needs when used under specified conditions
	Accuracy	Degree to which an MST provides accurate results with the needed degree of precision
	Interoperability (Only Digital)	Degree to which MSTs can exchange information with other systems and use information that has been exchanged
	Security	Degree to which an MST protects data from unauthorized access by other persons or systems
Reliability	Maturity	Degree to which an MST has overcome initial bugs and defects, and meets needs for reliability under normal operation
	Fault Tolerance (Digital)	Degree to which an MST operates as intended despite the presence of hardware or software faults
	Recoverability	Degree to which, in the event of an interruption or a failure, an MST can recover the data directly affected and re-establish the desired state of the system
Usability	Understandability	Degree to which the features and functions of an MST can be understood by users with a wide range of backgrounds and levels of expertise
	Learnability	Degree to which users with a wide range of backgrounds and levels of expertise can efficiently learn to use an MST to achieve specified goals
	Operability	Degree to which an MST is easy to operate and control

Modified MST Framework		
	Attractiveness	Degree to which users perceive an MST's user interface to be attractive and satisfying to use
Efficiency	Time Behaviour	Degree to which MST response times, processing times, and throughput rates meet or exceed user requirements
	Resource Utilisation	Degree to which the amounts and types of resources used by an MST, when performing its functions, meet requirements
Maintainability	Analyzability	Degree of effectiveness and efficiency with which it is possible to assess the impact on an MST of an intended change to one or more of its parts, or to diagnose an MST for deficiencies or causes of failures, or to identify parts to be modified
	Changeability	Degree to which an MST can be effectively and efficiently modified by users without introducing defects or degrading existing product quality
	Stability	Degree to which an MST performs free from failures, interruptions, and unexpected effects
	Testability	Degree of effectiveness and efficiency with which test criteria can be established for an MST and tests can be performed to determine whether those criteria have been met
Portability	Adaptability	Degree to which an MST can effectively and efficiently be adapted for different or evolving hardware, software or other operational or usage environments

Modified MST Framework		
	Ease of Installation	Degree of effectiveness and efficiency with which an MST can be successfully installed and/or uninstalled in a specified environment
	Co-Existance	The capability of an MST to exist and operate on systems on which other software simultaneously exists and operates
	Replacability	The capability of an MST to be used in place of another specified MST for the same purpose in the same environment
Effectiveness	User accomplishment	Accuracy and completeness with which users achieve specified goals
Efficiency	Cost-Benefit	Resources expended in relation to the accuracy and completeness with which users achieve goals
Satisfaction	Usefulness	Degree to which a user is satisfied with their perceived achievement of pragmatic goals, including the results of use and the consequences of use
	Trust	Degree to which a user or other stakeholder has confidence that an MST will behave as intended
	Pleasure	Degree to which a user obtains pleasure from fulfilling their personal needs when using an MST
	Comfort	Degree to which the user is satisfied with his or her physical comfort when using an MST
Freedom from Risk	Economic Risk Mitigation	Degree to which an MST mitigates potential risks to financial status, efficient operation, commercial property, reputation or other resources in the intended contexts of use

Modified MST Framework		
	Health and Safety Risk Mitigation	Degree to which an MST mitigates potential risks to people in the intended contexts of use
	Environmental Risk Mitigation	Degree to which an MST mitigates potential risks to property or the environment in the intended contexts of use
Context Coverage	Context Completeness	Degree to which an MST can be used with effectiveness, efficiency, freedom from risk and satisfaction in all the specified contexts of use
	Flexibility	Degree to which an MST can be used with effectiveness, efficiency, freedom from risk and satisfaction in contexts beyond those initially specified in the requirements
DOI		
Author and Year of Publication		
Where the RCT was conducted		
Language		
Purpose of the Study		
Age of Participants		
Type of Data Collection Tool		
Online or Offline Data Storage		
Custom or Off the Shelf		
Data Protection/Privacy		

Search Strategy

Database	Search String	Filters
PubMed	**#1** "Digital form*" OR "Digital Data Collection Tool*" OR "Mobile Data Collection Tool*" OR "Mobile Survey Tool*" OR "Mobile Data Collection" OR "Electronic Data Collection" OR "mHealth" OR "Wearable Technology" OR "Wearable Sensor*" OR "Biosensor*" OR "Smart medical device*" OR “electronic data capture” OR “patient monitoring device*” OR “electronic medical device*” OR “digital self monitoring” OR “survey*” OR "data collection" OR "data collection tool*" OR "data entry" OR "data logging" OR "self report*" OR "self-reporting" OR "self monitor*" OR "self test*" **#2** "Low middle income countr*" OR "low and middle income countr*" OR "low income countr*" OR "developing countr*" OR "LMIC" **#3** "Randomised controlled trial*" OR "RCT" OR "RCTs" OR "randomized controlled trial*" **#4** #1 AND #2 AND #3	-RCT -Full text -Adult: 19+ -English articles only -Humans -Publication years: 2005-2023
CINAHL	**#1** "Digital form*" OR "Digital Data Collection Tool*" OR "Mobile Data Collection Tool*" OR "Mobile Survey Tool*" OR "Mobile Data Collection" OR "Electronic Data Collection" OR "mHealth" OR "Wearable Technology" OR "Wearable Sensor*" OR "Biosensor*" OR "Smart medical device*" OR “electronic data capture” OR “patient monitoring device*” OR “electronic medical device*” OR “digital self monitoring” OR “survey*” OR "data collection" OR "data	-Exclude medline -Publication years: Jan 2005-June 2023 -Adult (19-44) Middle aged (45-64) Aged (65+) -English articles only

	collection tool*" OR "data entry" OR "data logging" OR "self report*" OR "self-reporting" OR "self monitor*" OR "self test*" **#2** "Low middle income countr*" OR "low and middle income countr*" OR "low income countr*" OR "developing countr*" OR "LMIC" **#3** "Randomised controlled trial*" OR "RCT" OR "RCTs" OR "randomized controlled trial*" **#4** #1 AND #2 AND #3	-Full-text -RCT
Web of Science	**#1** ALL=("Digital form*" OR "Digital Data Collection Tool*" OR "Mobile Data Collection Tool*" OR "Mobile Survey Tool*" OR "Mobile Data Collection" OR "Electronic Data Collection" OR "mHealth" OR "Wearable Technology" OR "Wearable Sensor*" OR "Biosensor*" OR "Smart medical device*" OR “electronic data capture” OR “patient monitoring device*” OR “electronic medical device*” OR “digital self monitoring” OR “survey*” OR "data collection" OR "data collection tool*" OR "data entry" OR "data logging" OR "self report*" OR "self-reporting" OR "self monitor*" OR "self test*") **#2** ALL=("Low middle income countr*" OR "low and middle income countr*" OR "low income countr*" OR "developing countr*" OR "LMIC") **#3** ALL=("Randomised controlled trial*" OR "RCT" OR "RCTs" OR "randomized controlled trial*") **#4** #1 AND #2 AND #3	-Jan 2005- June 2023 -English articles only

Embase	**#1** "Digital form*" OR "Digital Data Collection Tool*" OR "Mobile Data Collection Tool*" OR "Mobile Survey Tool*" OR "Mobile Data Collection" OR "Electronic Data Collection" OR "mHealth" OR "Wearable Technology" OR "Wearable Sensor*" OR "Biosensor*" OR "Smart medical device*" OR “electronic data capture” OR “patient monitoring device*” OR “electronic medical device*” OR “digital self monitoring” OR “survey*” OR "data collection" OR "data collection tool*" OR "data entry" OR "data logging" OR "self report*" OR "self-reporting" OR "monitor*" OR "self test*" **#2** "Low middle income countr*" OR "low and middle income countr*" OR "low income countr*" "developing countr*" OR "LMIC" **#3** "Randomised controlled trial*" OR "RCT" OR "RCTs" OR "randomized controlled trial*" **#4** #1 AND #2 AND #3	- Randomized controlled trial - Publication years: 2005-2023 -Adult (18-64) Aged (65+) -Exclude Medline - English articles only

PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol*

Section and topic	Item No	Checklist item	Reported on page/line #
ADMINISTRATIVE INFORMATION			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1/8
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	N/A
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	2/51
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1/13
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	9/11
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	N/A
Support:			
Sources	5a	Indicate sources of financial or other support for the review	9/24
Sponsor	5b	Provide name for the review funder and/or sponsor	N/A
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	N/A
INTRODUCTION			
Rationale	6	Describe the rationale for the review in the context of what is already known	5/3
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	5/21
METHODS			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting,	6/3

		time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review		
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage		2/25 and 6/35
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	6/35 a	Search Strategy document
Study records:				
Data management	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review		7/34
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)		6/47
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators		6/47
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications		7/36 and extraction sheet
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale		5/21
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis		7/54
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised		N/A
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I^2, Kendall's τ)		N/A
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)		N/A
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned		8/6
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication		N/A

		bias across studies, selective reporting within studies)	
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	N/A

From: Shamseer L, Moher D, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart L, PRISMA-P Group. Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation. BMJ. 2015 Jan 2;349(jan02 1):g7647.