Challenges and alternatives to evaluation methods and regulation approaches of medical apps as mobile medical devices: An international and multidisciplinary focus group discussion

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Abstract

Background: The rapid proliferation of medical apps has transformed the healthcare landscape by giving patients and providers unprecedented access to personalized health information and services. However, concerns regarding the effectiveness and safety of apps have raised questions regarding the efficacy of randomized controlled trials (RCTs) for their evaluation and as a requirement for their regulation as a mobile medical device.

Objective: This study addresses this issue by investigating alternative methods besides RCTs for evaluating and regulating medical apps.

Methods: Using a qualitative approach, a focus group study with 46 international and multidisciplinary public health experts, split into three groups, was conducted at the 17th World Congress on Public Health in May 2023 in Rome (Italy) to gather in-depth insights into alternative approaches to evaluation and regulation. We conducted a policy analysis of the current regulation of medical apps as mobile medical devices for the four most represented countries in the workshop: Italy, Germany, Canada, and Australia. We developed a logic model that combines the evaluation and regulation domains based on these findings.

Results: The focus group discussions explored the strengths and limitations of current evaluation and regulation methods and identified potential alternatives that could enhance the quality and safety of medical apps. Although RCTs were only explicitly mentioned in the German regulative system as one of many options, an analysis of chosen evaluation methods for the German apps on prescription pointed towards a “scientific reflex” where RCTs are always the chosen evaluation method. However, this method poses substantial limitations regarding digital interventions such as medical apps. Comparable results were observed during the focus group discussions, where participants expressed similar experiences for their own evaluation approaches. Additionally, the participants highlighted numerous alternatives to RCTs that can be used at different points during the life cycle of a digital intervention to assess its efficacy and potential harm to users.

Conclusions: It is crucial to recognize that digital interventions constantly evolve, unlike analog tools, posing challenges to inflexible evaluation methods, such as RCTs. Potential risks include high dropout rates, decreased adherence, and non-significant results. However, existing regulations do not explicitly advocate for other evaluation methodologies. Our research highlighted the necessity of overcoming the gap between regulatory demands to demonstrate safety and efficacy in medical apps and evolving scientific practices, ensuring that digital health innovation is evaluated and regulated in a way that considers the unique characteristics of mobile medical devices.

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Keywords

medical apps; mobile medical devices; evaluation methods; mobile medical device regulation; focus group study; alternative approaches; logic model

Introduction

Background

Medical applications (medical apps) have emerged as a subgroup of health apps as powerful tools with the potential to revolutionize healthcare by supporting, managing, and enhancing individual and population health [1]. These software programs can run on mobile devices and offer new possibilities for processing health-related data [2, 3]. According to the General Data Protection Regulation (GDPR), data processing includes any operation performed on personal (health) data, including collecting, organizing, storing, adapting, visualizing, retrieving, disseminating, restricting, or erasing the data [4, 5]. Unlike most health app types, medical apps do not primarily target healthy or health-conscious individuals but patients, health professionals, or family caregivers. This stems from their primary use as treatment supplements or medical devices in clinical contexts such as diagnostics, treatment, or rehabilitation. Figure 1 summarizes the distinction between medical apps as a subgroup and other areas of health apps (such as wellness) from a legal point of view [6].

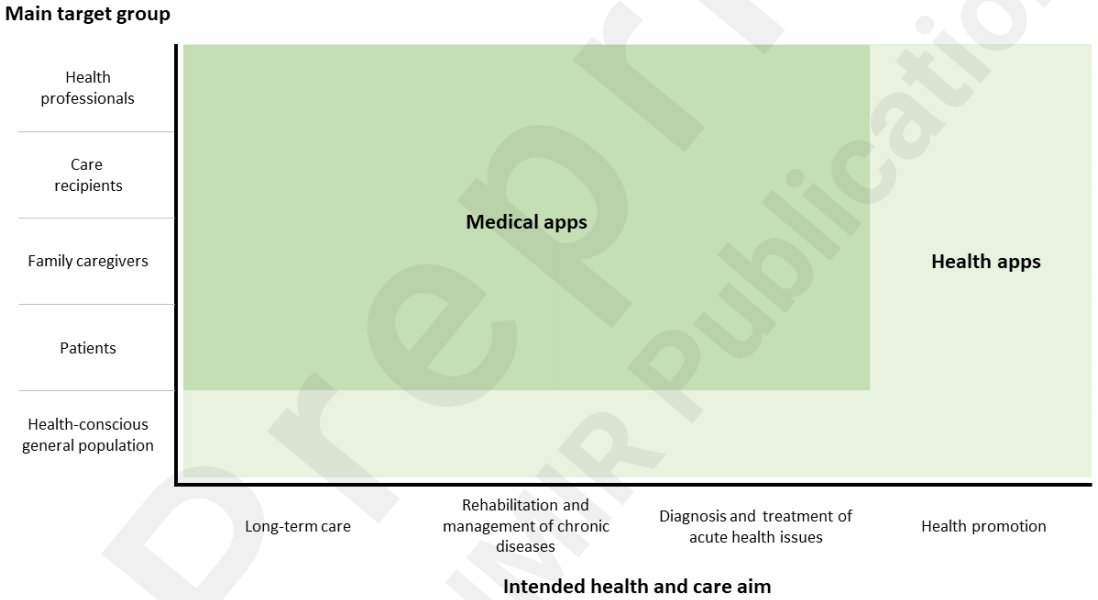

Figure 1. Medical apps as a sub-group of health apps. Adapted from Maaß et al. (2022) [6].

Medical apps promise personalized healthcare, improving access to medical resources and fostering active patient participation [7]. However, this thematic orientation of medical apps introduces a range of potential risks. Health and patient information may be inaccurate or flawed [8], sensitive data can be disclosed to the wrong recipients or lost [9], and applications frequently target broad user adoption via the internet, increasing the risk of rapid dissemination of any potential dangers. Due to the sensitive nature of health data, medical apps must adhere to rigorous data security standards. As many apps are used across borders, different jurisdictions and regulatory standards may need to be met [10, 11].

When considering covering the costs of these products through entities such as health insurance providers, demonstrating their clinical and medical benefits becomes essential to be regulated as mobile medical devices [12-15]. This advantage must be substantiated and evaluated to align costs adequately within the insurance community [16]. In addition, high data protection requirements, such as the GDPR, impact the possibilities of data collection,

analysis, and, therefore, the evaluation of medical apps [17-19]. Software is an increasingly critical area of healthcare product development, and there is a need to establish a standard and converged understanding of clinical evaluation globally [20].

Challenges in the evaluation of medical apps

With the increase in medical apps' usage in healthcare, it is crucial to validate their effectiveness. Randomized controlled trials (RCTs) are commonly considered the gold standard for establishing cause-and-effect relationships owing to their rigorous methodology [21-23]. However, there is an apparent disparity between the design of RCTs and the need to evaluate medical apps: RCTs are structured and rigid, whereas medical apps are versatile, updated frequently and depend on specific contexts [24]. A critical challenge arises from the discrepancy between the thoroughness of evaluations and the pace of generating evidence, as depicted in Figure 2 [25]. This misalignment underscores the need for developing more adaptable evaluation strategies in the rapidly evolving field of medical technology.

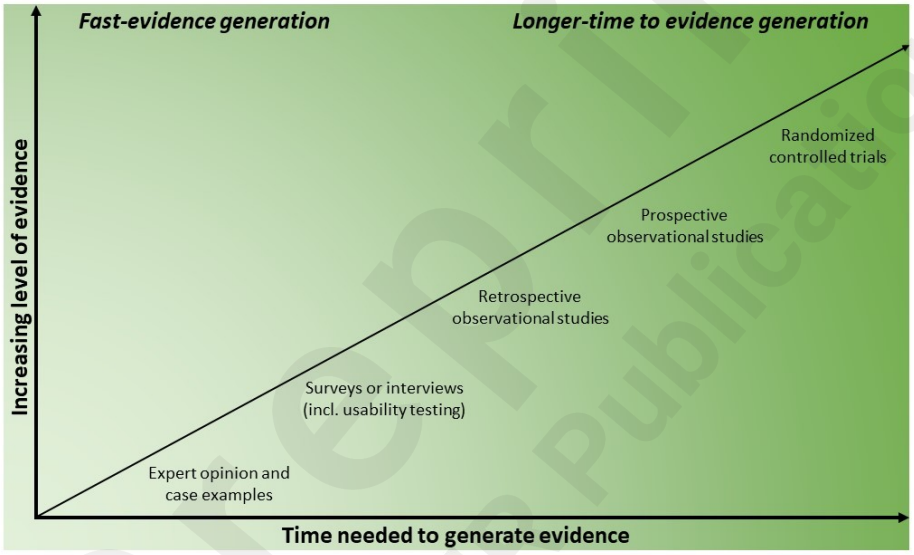

Figure 2. The balancing act between increasing evidence levels and the time needed to generate them. Adapted from Guo et al. (2020) [26]

Furthermore, traditional trials like RCTs do not necessarily align with the unique characteristics of medical apps [27, 28]. The evaluations of medical apps tend to be based on short-term studies [29-31], limited patient samples [32], feasibility trials, and user preference surveys [33]. While these methods can swiftly provide valuable insights during the development phase, they only offer a narrow view of the apps' true efficacy [34].

Another challenge is that medical apps are often customized to individual needs, in contrast to the between-group design of RCTs. Continuous updates and tweaks to medical apps to improve their performance can sometimes shift their fundamental functionality. It is essential to recognize that these updates might influence patient outcomes and call for continuous reassessment [24]. Given users' diverse health needs, preferences, and technological expertise, a universal evaluation method seems impractical. Moreover, blinding participants and researchers, a cornerstone of RCTs to reduce bias, can be difficult with medical apps since users are often aware they are using an app, and developers may struggle to create "placebo" apps with identical functionalities.

Additionally, app evaluation is multifaceted, demanding attention to factors beyond the mere health metrics typically assessed in RCTs [34]. Aspects such as user engagement and sustained use are vital for long-lasting behavioral shifts [35-37]. During the developmental

phase of a medical app, alternative study designs, including feasibility studies and user preference surveys, might be more suitable [33], even if they offer limited efficacy data [32]. They can promptly provide essential evidence regarding developmental and application areas. The multifaceted demands of medical app evaluation call for innovative evaluation methods to form the foundation of medical app regulations.

The complexity and struggles of overregulation

Regulatory and quality standards that are legally mandated and government-reviewed ensure medical apps' safety, efficacy, and data privacy [26]. Historically, pharmaceuticals and medical devices have faced increased regulation only after significant scandals and incidents have emerged. “Fueled” by these scandals, medical app regulation seeks to prevent scandals and incidents through rigorous guidelines [38-40]. However, there is a risk that anticipatory regulation may overemphasize securing against hypothetical risks [41]. It is crucial to weigh hypothetical risks against the effort required for regulatory compliance and the expected benefits of maintaining a balanced regulatory approach [42]. Relevant criteria for regulating medical apps are displayed in Textbox 1. Regulatory solutions should adopt the mildest measures possible to minimize resistance to technological advancement. Consequently, it is essential to incorporate the potential severity of harm into regulatory assessments and, if necessary, accept manageable errors as learning opportunities. Post-market surveillance is a critical component of quality control and assurance in the regulation of innovative medical developments.

Textbox 1. Relevant criteria for regulating mobile apps as mobile medical devices

Effectiveness and Safety: Regulatory frameworks should be adapted to the specific characteristics of digital health applications, necessitating clinical studies and testing procedures tailored to these applications.

Data Privacy and Security: Regulation must ensure applications implement appropriate data protection and security measures.

Interoperability: Digital health applications should be integrable into existing healthcare systems to ensure seamless care delivery.

Provider Qualifications: Regulations should mandate that qualified professionals develop and operate applications to ensure patient safety and quality.

Monitoring and Traceability: Regulatory mechanisms should enable digital health applications' ongoing monitoring and traceability to identify and address adverse events promptly.

Patient Involvement: Patients should be actively engaged in the development and evaluation of digital health applications to ensure that their needs and expectations are met

Adapted from Torous et al. (2022) [43]; Meskó & deBronkart (2022) [44]

Need for alternative evaluation approaches and regulation

Regulatory requirements homogenize research conditions, while the results are prone to reduction and distortion. At the same time, medical apps are, by nature, complex interventions due to their structure, a large number of interactions, and various intervention components. The efficacy of medical apps depends on context and leads to distinct effects on individuals. This requires a broader evaluation framework that does not focus solely on

specific intervention outcomes but combines different perspectives from feasibility testing to intervention, implementation, and impact evaluation [26, 45, 46]. Current regulatory approaches to evaluating medical apps do not appropriately reflect the complex nature of medical apps.

Regulation of medical apps in selected countries

To illustrate similarities and differences, four countries have been selected for case studies about the existing regulation methods for medical apps as mobile medical devices. The analysis for Germany, Italy, Australia, and Canada followed an adapted version of the policy benchmarking framework by Essén et al. 2022 [38] (see Table 1).

Table 1. Overview of medical app regulation for selected countries

Country	Germany	Italy	Australia	Canada
Actors developing national policy regulation	Health Innovation Hub, an external, interdisciplinary expert think tank to the Federal Ministry of Health and the Federal Institute for Drugs and Medical Devices	Ministry of Health overseeing conformity following the European Medical Device Regulation and classification of Software as a Medical Device (SaMD)	Therapeutic Goods Administration (TGA)	Health Canada (Federal Government Agency)
Intended use of the framework	Determine eligibility of an app for reimbursement through the public insurance scheme. Either permanently or on a preliminary basis.	No	National guidance and a helpful reference tool for app developers working on mobile health apps for release in Australia. It provides a solid basis for further research and analysis	To determine if the app meets the legal definition of a SaMD
Key regulations underpinning the policy framework	Digital care applications (DiGAs) under the Digital Care Act	No	The Privacy Act 1988, overseen by the Office of the Australian Information Commissioner, Competition and Consumer Act 2010 administered by the Australian Competition and Consumer Commission	Risk classification as a SaMD
Risk	European Medical	European	TGA (Medical	Health Canada

classification framework for medical apps	Device Regulation (Risk classes I, IIa, IIb, III)	Medical Device Regulation (Risk classes I, IIa, IIb, III)	Devices) Regulation 2002 (Risk classes I, IIa, IIb, III)	Medical Device Classification (Risk classes I, II, III, IV)
Reimbursement approval policy regulation developed?	Applications get approved through the DiGA fast-track procedure. Approved DiGA are reimbursed through health insurance	No	No	No
End-user interface to clinical practice and patients, which lists approved medical apps	DiGA directory	No	No	No, but Health Canada does engage with the Canadian Agency for Drugs and Technologies to provide evidence and publicly available Health Technology Assessments
Are RCTs explicitly mentioned in the regulation?	Mentioned as an example of a methodology designed to demonstrate a positive care effect	No	No	No

Germany

Since December 2019, digital care applications (DiGAs) have become eligible for reimbursement through statutory health insurance in Germany. This mechanism is included in the Digital Care Act (DVG) [47, 48]. Reimbursable DiGAs are listed in a directory administered by the Federal Institute for Drugs and Medical Devices (BfArM), DiGA directory. Applications can be added to the directory through a fast-track procedure [49]. Applications can either be permanently included in the list if evidence of a positive care effect is provided at the time of application or a provisional reimbursability is granted if apps meet a set of essential requirements but evidence of the positive care effect is still missing. Evidence of the positive care effect must be provided within 12 months for permanent inclusion. Otherwise, the app will be removed from the list. The term “positive care effect” introduced by the DVG can either be a “medical benefit” or "patient-relevant improvement of structure and processes". For instance, the application can help improve health literacy and improve coordination of treatment processes or can reduce therapy costs. Currently, most DiGAs provide evidence for the positive care effect using data from RCTs [50]. As of October 13, 2023, the DiGA directory included 55 applications, of which 23 were provisionally included, 26 were permanently included, and six were removed. All were assessed through an RCT, although the DVG does not explicitly call for an RCT [51]. A limitation of the DVG is the restriction on low-risk devices (risk classes I and IIa) under the Medical Devices Act. All applications outside the Medical Devices Act, such as preventive applications, and high-risk medical devices do not fall under the DVG. The fast-track procedure only applies to applications classified and certified as medical devices in risk classes I and IIa; therefore many potentially helpful applications do not fall within the scope

of the DVG [52].

Italy

In Italy, medical apps can be promptly marketed, provided they meet legal requirements, are classified as Software as a Medical Device (SaMD), and obtain a CE marking [53, 54]. On May 25, 2021, the Italian Ministry of Health issued a newsletter to offer interested stakeholders with recommendations for clinical investigations of medical devices in line with current regulations [55]. The Ministry is currently responsible for the approval process. However, there is no national framework for market access or reimbursement approval, and a law for the health technology assessment of medical apps is also lacking. While an application can be sold, it cannot be prescribed or reimbursed, hindering equitable healthcare access. Discussions are ongoing in legislative bodies to address this issue, and a Parliamentary Intergroup for Digital Health and Digital Therapies was established in May 2023 [56]. This initiative aims to develop regulations that align with those of other European countries, ideally during the current legislative term.

Australia

In Australia, medical devices, including software-based medical devices, are classified according to the medical device classification rules of the Therapeutic Goods (Medical Devices) Regulations 2002 [57]. This act oversees the quality, safety, efficacy, and availability of therapeutic goods in Australia. Medical devices are classified and regulated according to the level of harm they may pose to the users or patients. This includes medical device software and medical devices that incorporate software. A four-tiered classification system is used to determine the minimum conformity assessment procedures, or comparable overseas regulator evidence requirements, to be determined by the manufacturer before an application is made for the device's inclusion in the Australian Register of Therapeutic Goods (ARTG) [58]. The classification rules are applied according to the manufacturer’s intended purpose and the device’s functionality. Where more than one rule applies, the device must be classified at the highest applicable level [57, 59]. However, the Australian regulatory system lacks refinement regarding emerging technologies, such as AI in medical decision-making and wearable technology. This generates problems in deciding which tools and devices must be registered and to what classification standard [60].

Canada

Within Canada, mobile health apps are classified as SaMD and regulated according to a 4-tier risk-based classification system utilized for Medical Devices similar to Australia. The manufacturer’s intended use determines the classification of potential SaMD and corresponding regulation and whether the federal department Health Canada agrees with the use-case [61]. The clinical and evaluation evidence required to support the use-case varies depending on the tiered classification and intended use. However, the guidance on SaMD released by Health Canada in 2019 suggests broad exclusion criteria, eliminating many health apps from requiring SaMD status and thus leaving many apps unregulated and without evaluation [62].

Study aim

Due to the described challenges in regulating and evaluating medical apps, this study pursues two central objectives. Building on the previously described country examples for the current regulation and evaluation practices of medical apps, this study aims first to determine whether there are international challenges in regulation and evaluation and second to gather

the opinions and perspectives of digital (public) health researchers on current practices and future developments through a focus group approach. The results from both objectives are then utilized to develop a logic model proposing a differentiated approach to regulating and evaluating medical apps. Therefore, this study attempts to initiate a discussion about current regulation and evaluation practices of medical apps and accelerate the adoption of innovations in healthcare systems.

Methods

The reporting quality of this study is assessed through the consolidated criteria for reporting qualitative research checklist (COREQ) (see Multimedia Appendix 1).

Focus group discussion workshop at the 17th World Congress on Public Health

Participants for the focus groups were recruited through a convenient sampling method, where interested attendees of the 17th World Congress on Public Health (WCPH) attended the workshop in person. The study was advertised to participants through the conference program. Due to the nature of the context, information on non-participation was not recorded. 46 WCPH delegates from 14 countries joined the workshop. Besides the moderators and workshop participants, two conference technical-team members were in the room to oversee the technical equipment. They did not participate in the workshop. At the beginning of the session, participants were introduced to the general concepts of health and medical apps and the problems that RCTs pose for evaluating these types of digital health interventions.

We used a QR-Code leading to a LimeSurvey questionnaire (LimeSurvey GmbH, Hamburg, Germany) hosted by the University of Bremen (Germany) to collect demographic data and information regarding the participants' knowledge. All questions were optional. The 46 participants were equally distributed among three focus groups, each led and protocolled by one of the article's authors. One female and two male authors introduced themselves as researchers interested in evaluating digital apps and explained the scope of the workshop. They discussed the two questions presented in the study's aim section. The two questions were not pilot-tested. The three authors have a background in public health and medical informatics with previous research on the topic: One author conducts his PhD on alternative evaluation approaches [63], one author published a review on definitions for health and medical apps [6], and the third author conducted an assessment of evaluation methods for mobile health interventions [35]. The authors had the underlying assumption that the majority of participants will come from Italy and that the discussions will focus more on the first question due to the conference's target group of public health researchers and practitioners.

Focus groups are used in qualitative research to gain in-depth knowledge of specific issues; in our case, the evaluation and regulation of medical apps. Unlike in surveys or individual interviews, a strength of focus groups is that participants can interact with other participants and the moderator rather than merely sharing their views [64]. In our case, we followed the methodology proposed by Traynor [64] with a minor adaptation to avoid audio-recording the discussions due to the noise in the room. Instead, we asked one participant per group to assist the moderator in taking notes on a flip chart visible to the respective focus group. The discussion lasted forty minutes, with half the time focusing on question one and the second half on question two. The moderators asked the two guiding and follow-up collective questions, encouraged quieter participants to express their opinions, and quietened more dominant speakers if necessary. After the workshop, all participants were invited to contribute to the project as co-authors, which nine participants did. The workshop transcripts were only provided to the nine co-authoring participants (see Multimedia Appendix 2).

Ethical considerations

The study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the Joint Ethics Committee of the Universities of Applied Sciences of Bavaria (GEHBa-202304-V-105, dated April 28, 2023). After the introductory presentations described above, we handed out written participant information sheets to educate them on the study and which data would be collected, stored, and analyzed. All data were anonymized, as we did not collect information that would allow the identification of participants. All participants were informed that their study participation was voluntary and that they could withdraw from the study at any time without providing reasons. Participants were informed before data collection that they would not receive any financial compensation for participating in this study but were invited as co-authors if they expressed written interest. In this case, the participant's e-mail addresses were collected on a paper sheet and were not connected to the online survey where we collected their sociodemographic data. Lastly, all participants provided their written informed consent before data collection.

Qualitative analysis and data synthesis

Data analysis and synthesis followed the conceptual and design thinking for the thematic analysis (TA) methodology of Braun and Clarke [65, 66]. TA aims to indicate and analyze patterns (so-called themes) in minimally organized datasets. TA was deemed the most suitable framework as it can be applied without pre-existing theoretical frameworks, which makes it an ideal methodology for multi- and interdisciplinary research questions, such as the current ones/topic [65, 66]. In our case, two authors individually clustered the workshop results inductively, without predefined themes, in two separate Microsoft Excel sheets. Both authors were provided with transcripts of all the flip charts for the focus groups. They then merged individual statements based on the same typology and meaning, for example, when two groups mentioned the same evaluation designs or barriers. The results were then grouped according to a shared umbrella theme. This was performed separately for the evaluation and regulation of medical apps. The final themes were approved during a discourse among three authors with one of these having the ultimate decision-making power.

Based on the workshop findings and policy analysis, we developed a logic model to capture the complexity of medical app evaluation and regulation. Logic models can be helpful to display the life cycle of a medical app based on overarching themes, for instance problem, target, intervention and content, moderating and mediating factors, outcomes, and impact [67] and have been used to evaluate digital health interventions [68, 69]. The model can be adapted to the specific context. It enables the display of interaction and feedback loops and distinguishes between outcomes and impacts in different domains [67]. Furthermore, adjusted logic models can provide a framework to display how complex interventions work across multiple domains in a single setting, with interlinking actions producing a range of outputs and outcomes. In our logic model, we used a generic medical app example to display significant findings and assign them to specific phases of the medical app lifecycle, such as development, implementation, and impact.

Results

46 experts participated in the one-hour international workshop at the 17th WCPH [70]. The participants were divided into three focus groups of 15-16 people each. The participant demographics are displayed in Table 2.

Table 2. Workshop participant demographics

Criteria	Number of participants

	(n=46; 100%)
Highest qualification	
Bachelor	2 (4.3%)
Master	13 (28.3%)
Diploma	2 (4.3%)
Medical Doctor	18 (39.1%)
PhD	11 (23.9%)
Primary discipline	
Computer Science	5 (10.9%)
Medicine	3 (6.5%)
Psychology	3 (6.5%)
Public Health	34 (73.9%)
Sociology	1 (2.2%)
Gender	
Women	26 (56.5%)
Men	20 (43.5%)
Country of residence	
Australia	5 (10.9%)
Austria	1 (2.2%)
Canada	4 (8.7%)
Finland	1 (2.2%)
Germany	8 (17.4%)
Hungary	1 (2.2%)
Indonesia	1 (2.2%)
Italy	17 (37.0%)
Netherlands	1 (2.2%)
New Zealand	2 (4.3%)
Philippines	1 (2.2%)
Portugal	1 (2.2%)
Switzerland	1 (2.2%)
Taiwan	1 (2.2%)
United States of America	1 (2.2%)
Age	
Average (Range, SD)	35.1 (25-73, 9.6)
Median	31.5
Years of general work experience in the primary field	
Average (Range, SD)	8.3 (1-40, 8.5)
Median	5
Years of experience in developing, implementing, regulating, or evaluating health or medical apps	
Average (Range, SD)	1.8 (0-15, 2.7)
Median	1

We asked the participants about their experiences and opinions regarding evaluating and regulating medical mobile apps. The thematic analysis of the contributions in the three groups resulted in four clusters for the evaluation and three for the regulation of medical mobile apps, which are presented in more detail later (Textboxes 2 and 3).

Alternative evaluation methods

The following general question was presented to the participants at the beginning of the focus group discussions: “What could be alternative evaluation methods for assessing the effectiveness of medical applications?” Four overarching themes crystallized as pivotal

according to the participants (see Textbox 2):

1. **Traditional evaluation practice:** Participants emphasized the advantages of RCTs in evaluating medical apps, acknowledging their ability to reduce bias and establish causal relationships. However, concerns were raised about participant dissatisfaction and high attrition rates due to random assignment, questioning sustainable implementation, and user centricity. Incongruence between RCT temporal requirements and the rapid evolution of medical apps necessitated frequent updates, prompting the consideration of alternative evaluation methods.
2. **Universal considerations for all evaluation types:** The importance of engagement and user data in app evaluations was highlighted, and participants advocated qualitative assessment in pre-study designs to reduce dropouts. Additionally, the participants stated that standard outcome parameters were essential for effectiveness evaluation and could be supplemented by output data to demonstrate efficacy. The participants further suggested segmental app evaluations and various comparative interventions. The importance of enhancing power and data quality through a priori sample calculations and suitable study designs was highlighted, regardless of the study design.
3. **Alternative approaches for participant recruitment & grouping in an RCT:** Alternative recruitment and grouping methods were explored to address dissatisfaction and attrition in RCTs. These included preference clinical trials, pragmatic RCTs, partially randomized patient-preference trials, and best-choice experiments. By increasing flexibility and allowing participants to choose their interventions, these approaches might reduce withdrawal, shorten study duration, reduce bias, and facilitate participant recruitment.
4. **Alternative research designs to RCTs:** Other research designs, such as qualitative and participatory approaches, can help to understand engagement barriers and enhance user experience. Prototype checklists were proposed for researchers unfamiliar with alternative evaluation designs. Alternative data sources, including real-world evidence, smartphone sensors, and commercially available user analytics, can complement traditional evaluation methods.

Textbox 2. Results of thematic data analysis about alternative evaluation methods.

Traditional RCTs:

- Strength of RCTs (e.g., internal validity, the strength of causal relationships)
- Weakness of RCTs to represent reality, resource consumption, and low generalizability
- Randomization might cause dissatisfaction and increase dropout
- Effectiveness trials tend to produce too little engagement
- The speed of app development does not align with RCT duration

General evaluation aspects:

- Different types of outcomes need to be acknowledged by evaluation goals and methods.
- Power (a priori sample size, bias) and data validity (level of causality, purity of data)
- Differentiation of traditional (e.g., effectiveness, satisfaction) and implementation outcomes (e.g., acceptability, costs, feasibility)
- Qualitative pre-study generates fast evidence
- Level of engagement and interaction (user frequency, duration of use, etc.)

- Level of engagement and interaction (user frequency, duration of use, etc.)
- Importance of multiple and standardized outcomes
- Find a suitable comparison group (new, existing, or non-treatment intervention)
- Consider intervention effects (e.g., Hawthorne)
- Outcomes for stakeholder and target groups differ and need to be considered
- Relevance of component's effectiveness
- Relevance of output evaluation

Alternatives for recruiting and grouping in RCTs:

- Preference-based controlled trials
- Evaluation of specific implementation stages rather than implementation as one
- Pragmatic RCTs / Real-world RCTs
- Ensure data quality through volunteer participation
- Quasi-controlled trial
- Best choice experiment after randomization
- Stepped wedge trials
- Waitlist-control-group design
- Evaluation as treated

Alternatives to RCTs:

- Qualitative empirical data (e.g., user interviews) to understand engagement
- Improving user experience to promote engagement
- Create a prototype evaluation checklist for researchers with less experience in app development.
- Use of real-world evidence (e.g., hospital data, cohort data set)
- Shortcut evaluation if a known aspect works (McCarthy Evaluation)
- Evaluate the practice/roll-out phase
- Model app usage through existing, similar datasets
- Apply user analytics (e.g., Google Analytics)
- Use of additional data through smartphone sensors

A glossary explaining the alternative evaluation methods in more detail is available in Multimedia Appendix 3.

Alternative regulation approaches

Participants worked on the regulative part during the second half of the focus group discussions. The guiding question was: “What could be alternative approaches to regulating medical applications as mobile medical devices?”. Three themes emerged from these discussions (see Textbox 3):

1. **Minimal standards for medical apps:** Participants emphasized essential minimum standards that medical apps should adhere to ensure safety and harmlessness, including data privacy, user accountability, informed consent, and prevention of biases or discrimination. Experts acknowledged that regulatory requirements should be proportional to the app's function and data processing. Central to the regulation process is prioritizing the efficacy of the medical app, established through rigorous evaluation procedures.
2. **Tools for regulation:** Labels are commonly used in public health and can offer a concise way to communicate information and evaluate app content and user-friendliness. Participants stressed the need for standardized guidelines across geographic regions,

exemplified by the Device Regulation in Europe, to establish a foundational standard for further country-specific development.

3. **Barriers to regulation:** The primary concern regarding the law was potential overregulation. Complex approval processes could stifle app innovations. Overregulation might lead to an abundance of specialized "silo apps," where patients managing multiple health conditions require numerous apps, hindering efficiency and user friendliness. Additionally, participants recognized that the app's usability is contingent on the device, a factor beyond the scope of app regulation.

Textbox 3. Results of thematic data analysis about alternative regulation approaches.

Functionality of medical apps:
- Regulation should be proportional to app functionality
- No discrimination and not doing any harm as the minimum requirements
- Privacy of data needs to be ensured
- Accountability and informed consent as a developer's responsibility
- Efficacy should be measured

Tools for regulation:
- Using labels that rate various aspects of the app (e.g., accessibility, health benefits)
- Standardize regulation across geographical areas, e.g., in Europe: create minimal requirements

Barriers to regulation:
- There should be no overregulation
- Silo Apps: if a chronically ill person needs 20 apps to manage their symptoms, this is unfeasible and expensive
- It is equally important to consider the device as the app

Logic model for the evaluation and regulation of medical apps

Based on the country assessment and the focus-group discussions, we developed a logic model highlighting the complexity of medical app evaluation and regulation. A logic model depicts the relationship between a program’s activities and its intended effects [71]. In our case, the logic model illustrates different stages of app development (read from left to right) along with the various types of evidence and regulation required at these stages [72, 73]. The logic model consists of three independent horizontal blocks (see Figure 3). The first horizontal block provides an example of a generic medical app. The second horizontal block focuses on evaluation designs for the effectiveness and usability of such apps, and the third contains regulatory aspects. Each block is divided into ‘columns’ defined as the general phases of logic models (Problem, Target, Intervention and Content, Moderating and Mediating Factors, Outcomes, Impact). The boxes on evaluation and regulation are additionally influenced by the conceptual, implementation, and evaluation quality. It is essential for evaluation and regulation approaches for medical apps to also consider these additionally to the mere analysis of outcomes (e.g., as measured through RCTs).

Feasibility studies can be applied to evaluate the medical apps’ target and its content. They can include multidisciplinary and participatory designs or theoretical models based on evidence-based frameworks. Machine learning algorithms and app usage modeling from similar datasets can provide additional feasibility analyses [74]. Clinical simulations can be run to test digital interventions in a safe, cost-effective, and efficient manner [26]. Alternative trial and study designs that integrate qualitative studies, and user analytics (to evaluate the

outcomes of the medical app) allow for integrating multiple perspectives and offer efficient approaches to evidence generation. Regulation of medical apps should incorporate the app's life cycle similarly. An a priori regulatory concept should be applied already during the target and content phase of the app development based on the purpose (e.g., disease-related) and functionality (e.g., documenting, storing, monitoring, data analyzing, or transferring data) of the app. Its potential harm concerning data protection and safety of use (e.g., informed consent, appropriateness of data processing) should be best regulated even earlier during the problem-identification phase. Relevant regulation is needed for adverse events, patient benefits, and clinical evidence during the outcome-phase. The quality and risk management as well as the technical documentation should be regulated continuously. Together with the market surveillance after the implementation of the medical app, these procedures will ensure that the application adheres to regulations and fulfills its intended benefits.

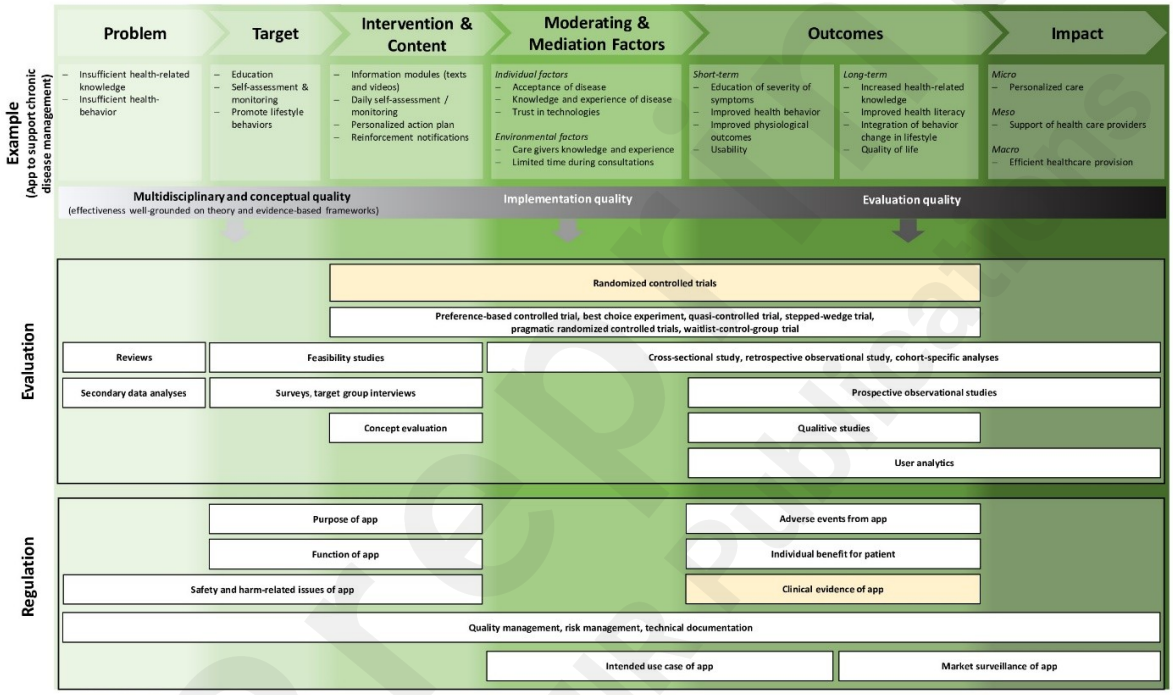

Figure 3. Logic model for evaluating and regulating medical apps through the intervention's life-cycle phases.

'Randomized controlled trials' and 'clinical evidence of apps' are highlighted in yellow, as most medical apps focus on these methods and outcomes [51], as confirmed in our country analysis. This is despite the fact that the relevant regulatory framework requires a sufficient evaluation, which does not necessarily have to be an RCT [12]. In addition, our logic model underlines that RCTs start too late in medical app development and are unsuitable for all development stages.

Discussion

Discussion of results

This study explored alternative methods of evaluating and regulating medical apps in an international focus group of public health professionals. The focus group debate highlighted that medical app development could benefit from flexible study designs that can evaluate multiple components simultaneously and independently. While acknowledging the value of RCTs in establishing causal relationships, participants were dissatisfied with RCTs as the

"go-to" evaluation method. Instead, they perceived them as a barrier to medical app development. Although participants were aware of various alternative evaluation methods, they found that their practice application is lacking because the default method remains RCTs.

According to participants, medical app regulation should align with the rapid technological development of medical apps through an agile and iterative evaluation process, which could more appropriately capture the breadth of efficacy and safety outcomes associated with medical apps and potentially reduce the time-to-evidence and time-to-market.

The focus group enabled a difficult discussion to challenge the medical dogma of RCTs. Following the global thalidomide tragedy in 1962, RCTs became established as best practice and are a requirement to demonstrate safety and efficacy for drugs entering the drug market [75]. The scientific community successfully lobbied for stricter evaluation and regulation at the time. In the context of medical apps, regulation is in its infancy. The launch of a diagnostic radiology app at Apple's World Wide Developers Conference in 2008 caused a regulatory headache and is arguably the catalyst for medical app regulation worldwide [76]. As scientists, we know the benefits of evaluation. Still, we now see that RCTs are not apt to the agile nature of digital interventions and that viewing them as the status quo stifles innovation in the digital health sector.

The focus group provided an opportunity to share our collective desire for change and collate alternative methods of evaluation and regulation, which are presented in the logic model. This model offers a more dynamic approach to medical app evaluation and regulation. Its structure considers medical apps' decomposed evaluation and regulation process and encourages researchers to combine alternative study designs to meet their research goals. Alternative study designs mentioned in the focus group include pragmatic RCTs [77, 78], such as cohort multiple control randomized studies [79], regression discontinuity designs [80], and registry-based randomized trials [81], which were incorporated into our logic model. To enable sustainable evidence generation, a paradigm shift in the approach to evaluation is needed: from RCTs as the gold standard to a multi-method, flexible approach that reflects the agility of the medical app market [28]. Selected methods should aim to reduce time-to-market access, provide robust evidence on the desired (health) outcomes, and be compatible with the rapid technological development of medical apps.

Finally, it is essential to recognize that digital products constantly evolve, necessitating ongoing efforts to optimize them retrospectively. Undertaking resource-intensive RCTs for updates to, for instance, the German DiGA, may pose significant problems in adherence, increase dropout rates, and may lead to statistically non-significant results when analyses are conducted for the whole study population. The high costs and risks of re-evaluating apps using RCTs increase development costs and, thus, risks for app developers. This, in turn, increases the probability that apps will not be launched onto the market as medical apps at all but as health and well-being apps, circumventing regulatory approaches. Overregulation then becomes dysregulation.

Strengths and limitations

Focus groups have become a frequently used method in healthcare research due to their usefulness in identifying and analyzing collective opinions and experiences [82, 83]. Our study included multinational and multidisciplinary experts, allowing us to collect global perspectives from practitioners and researchers. The participants provided valuable insights on the challenges of using RCTs for medical app evaluation and how alternatives could be applied and integrated into current regulations. Real-world examples were shared as the group included participants who had used RCTs in medical app evaluation or refrained from developing medical apps due to the challenges discussed in this paper. Lastly, our analysis of

the four most prominently represented countries (Germany, Italy, Canada, and Australia) followed a predefined framework to guarantee comparability between countries [38]. This analysis highlights the lack of a legal obligation to use RCTs to evaluate and regulate medical apps. It suggests that there may be a reflex to use RCTs for evaluation.

Our study comes with certain limitations. Conducting the workshop at an international conference meant we had no control over recruitment and participant demographics. Despite the global attendance at the conference, this workshop was primarily attended by people living in European and Western countries, with an underrepresentation of participants from the global South and low- and middle-income countries. Given the international nature of digital health interventions and in particular its potential in low- and middle-income countries [84, 85], the focus group likely did not adequately capture the full spectrum of experiences and viewpoints. This limits the generalizability of findings, particularly given the general underrepresentation of researchers from low-and middle-income countries in the discussion around evaluation criteria in medical apps [86]. With a more diverse participant pool, future research could provide a more comprehensive understanding of challenges and opportunities in medical app regulation. Furthermore, participants differed in their age, academic background, and previous knowledge of this topic. Selection bias, defined as participants choosing to participate based on personal interest, limits the study's external validity.

Large focus groups, such as our study with 15 participants per group, tend to be challenging to moderate and may not achieve in-depth discussions [82, 83]. This was addressed by having experienced focus group moderators who were able to facilitate an open discussion atmosphere. Although approximately eight participants per focus group are recommended [82, 83], larger groups allow for capturing more views in a shorter period. As the goal of the focus group was to gain a broad overview of current views on app evaluation and regulation, large focus groups seemed appropriate.

Additionally, the feedback quality was mixed, potentially originating from the self-reported low average experiences with medical app development, evaluation, or regulation (average 1.8 years, range 0-15 years). Another reason might be a differing understanding of medical apps compared to health apps due to varying definitions [6] and regulation practices globally. This might have led to an inaccurate participant understanding of medical apps. A 20-minute introductory workshop on RCTs, medical apps, and their regulation as mobile devices hopefully cleared up some of the misconceptions.

Further research and a first look at the desired future

Medical apps do not necessarily have borders, making this a topic of global interest, with the same challenges occurring in various countries. A focus group discussion with researchers can only be the first step in assessing this topic's relevance and diverse aspects. Further research needs to develop an evaluation framework that allows different methodological approaches for specific stages during the evaluation of the medical app life span from development over implementation to broader impact among all stakeholders, like developers, patients, or app prescribers. Simultaneously, this evaluation framework should include regulatory aspects beyond the clinical evidence generated by RCTs.

Establishing the use of evaluation frameworks like the proposed logic model can provide developers and regulators with a scientifically sound set of evaluation criteria that can address the agile and time-efficient development of medical apps while gradually generating evidence. In turn, this will help overcome the misconception of using RCTs as the cultural gold standard for evaluating digital health applications. Furthermore, future research should also focus on other regulatory aspects, such as patient safety and effectiveness, which are vital for the market approval of medical apps but are not necessarily covered by RCTs. Therefore, future evaluation frameworks must enhance the acceptability of alternative

evaluation methods for stakeholders despite the traditional research evidence provided by RCTs.
Medical apps developed by professionals without medical backgrounds can lead to several challenges, including ineffective, unsafe, and difficult-to-use interventions. Therefore, the development of medical applications should be conducted in multi-professional teams to balance the priority of health outcomes over profitable motives.
Establishing clear regulatory criteria centered on safety, efficacy, and data protection is essential to minimize errors and harm while fully harnessing the potential of medical applications to improve healthcare delivery. By carefully evaluating hypothetical risks, avoiding unnecessary regulatory burdens (overregulation), and incorporating the potential for learning from manageable errors, innovation, and safety can be balanced in regulating digital health applications. This approach ensures that digital medical apps continue to evolve and improve the quality of healthcare services while safeguarding the well-being of users.

Conclusion

While regulations such as the German DVG or the regulations in Canada and Australia emphasize the need for comprehensive clinical data, their lack of strict RCT mandates allows for flexibility in evaluating digital health interventions, such as medical apps. This flexibility, reinforced by consensus in focus groups, highlights the need for integrating adaptable evaluation techniques into regulatory frameworks. Policy recommendations should include specific guidance regarding the unique considerations of mobile medical devices to bridge the gap between regulatory requirements and evolving scientific methods. Focusing on ongoing assessment, adaptation of evaluation strategies, and balancing patient safety and innovation will create a robust evaluation system for medical apps. This will ultimately empower patients and healthcare providers while ensuring digital health technology's safe and effective advancement. Regulatory frameworks should be updated to include guidelines for incorporating real-world data analysis, user engagement studies, and other adaptable evaluation techniques alongside traditional clinical trials.

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Author contributions

LM: Initiated the project, led the workshop with RH and FH, structured the manuscript, conducted the qualitative content analysis of workshop results, modified the logic

model, wrote sections in the manuscript, and edited the manuscript.
RH: Led the workshop with LM and FH, structured the manuscript, conducted the qualitative content analysis of workshop results, wrote sections in the manuscript, and edited the manuscript.
ML: Participated in the workshop, wrote sections in the manuscript, developed and modified the logic model, and edited the manuscript.
AL: Participated in the workshop, conducted the qualitative content analysis of workshop results, modified the logic model, and wrote sections in the manuscript.
KBur: Participated in the workshop, modified the logic model, and wrote sections in the manuscript.
KBut: Participated in the workshop, wrote sections in the manuscript, and edited the manuscript.
SV: Wrote sections in the manuscript, modified the logic model, and conducted the qualitative content analysis of workshop results.
MH: Participated in the workshop, wrote sections in the manuscript, and edited the manuscript.
AG: Participated in the workshop, wrote sections in the manuscript, and edited the manuscript.
VG: Participated in the workshop, conducted the qualitative content analysis of workshop results, and wrote sections in the manuscript.
VR: Participated in the workshop and wrote sections in the manuscript.
GV: Participated in the workshop and wrote sections in the manuscript.
MV: Wrote sections in the manuscript.
FH: Led the workshop with LM and RH, obtained IRB approval, structured the manuscript, modified the logic model, wrote sections in the manuscript, and edited the manuscript.

Multimedia Appendix

Multimedia Appendix 1: Coreq-Checklist
Multimedia Appendix 2: Transcribed flipcharts of the focus group discussions
Multimedia Appendix 3: Glossary of technical terms given during the focus group discussions

Abbreviations

Medical apps	Medical applications
ARTG	Australian Register of Therapeutic Goods
BfArM	Federal Institute for Drugs and Medical Devices
COREQ	Consolidated criteria for reporting qualitative research checklist
DiGA	Digital health applications
DVG	Digital Care Act
EU MDR	European Medical Device Regulation
GDPR	General Data Protection Regulation
RCT	Randomized controlled trial
SaMD	Software as a Medical Device
TA	Thematic analysis
WCPH	17th World Congress on Public Health

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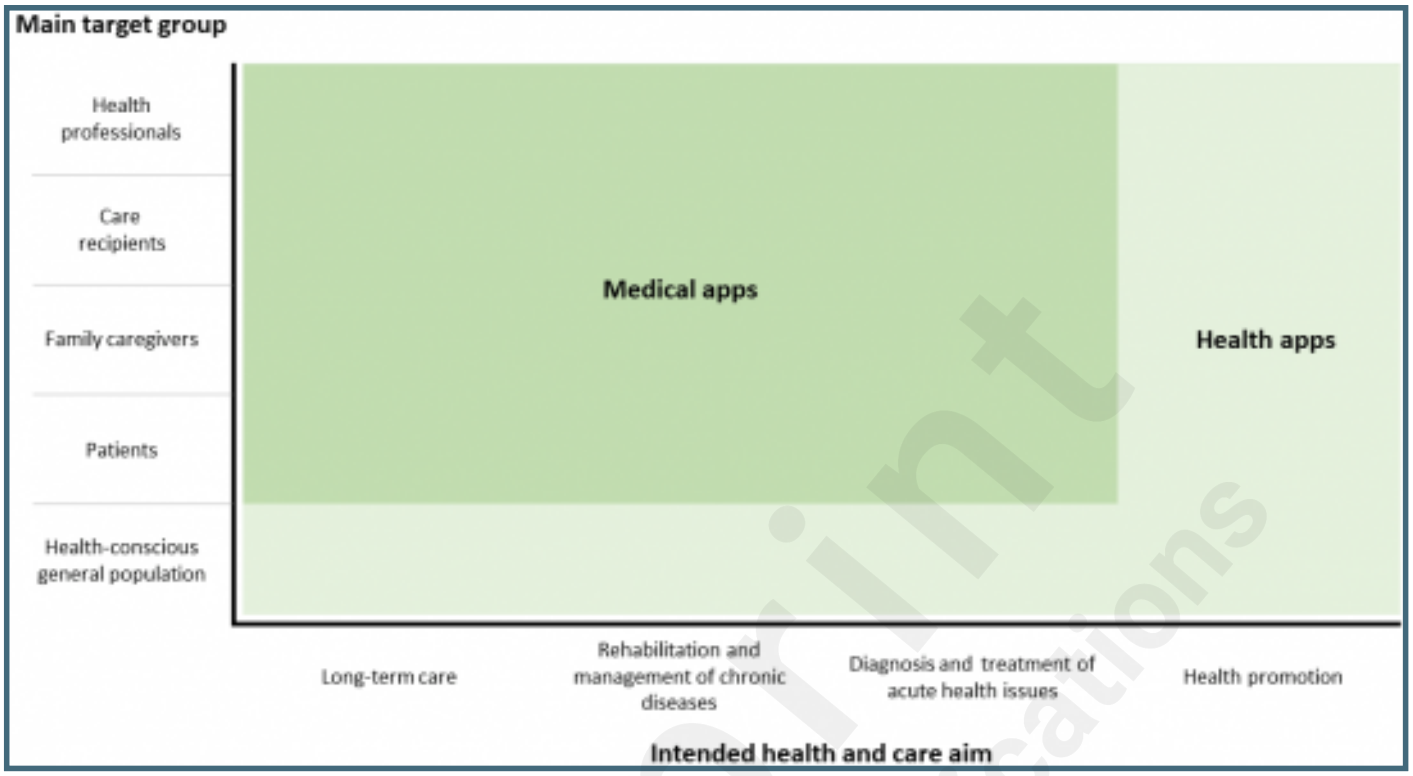
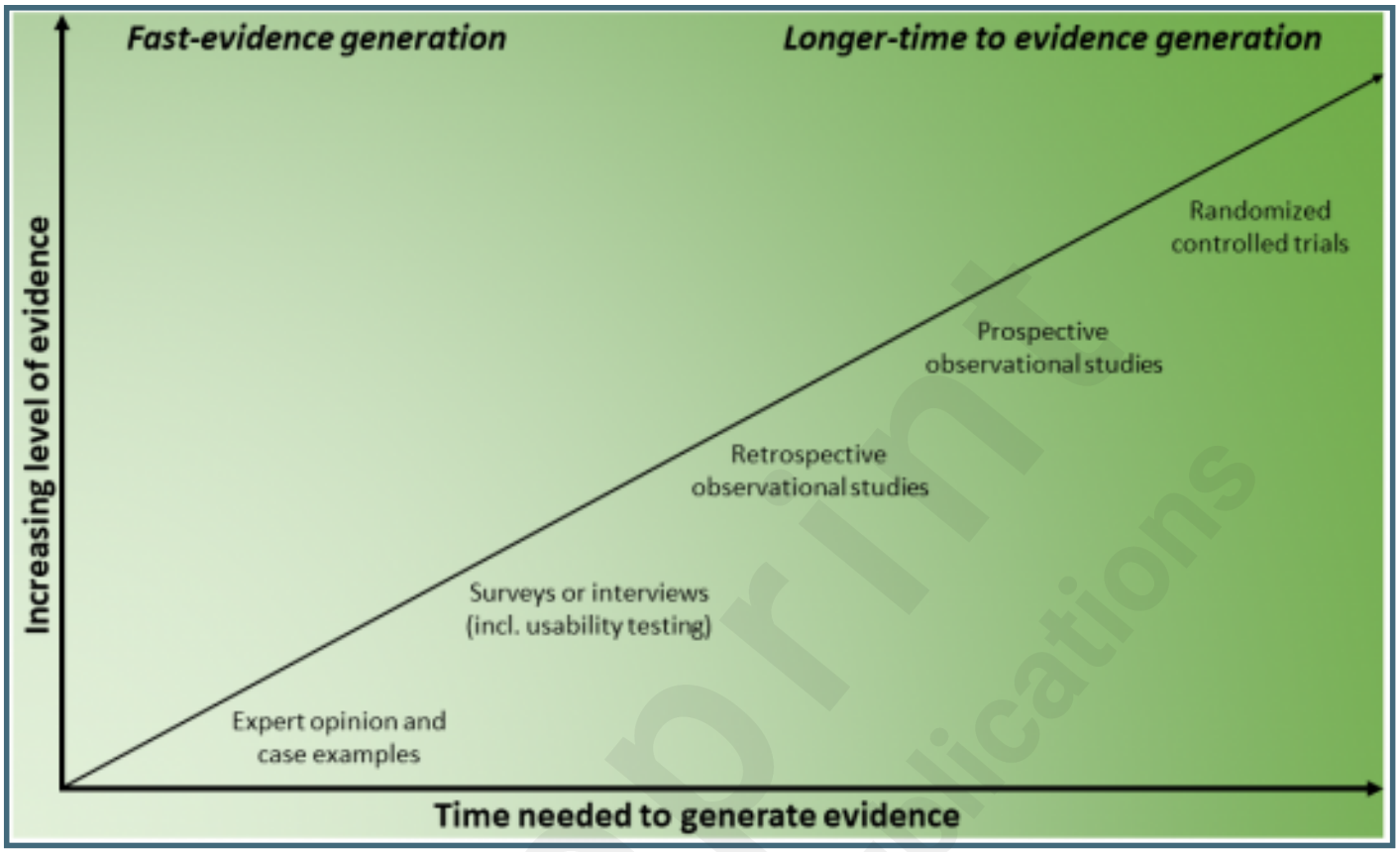
Supplementary Files

Figures

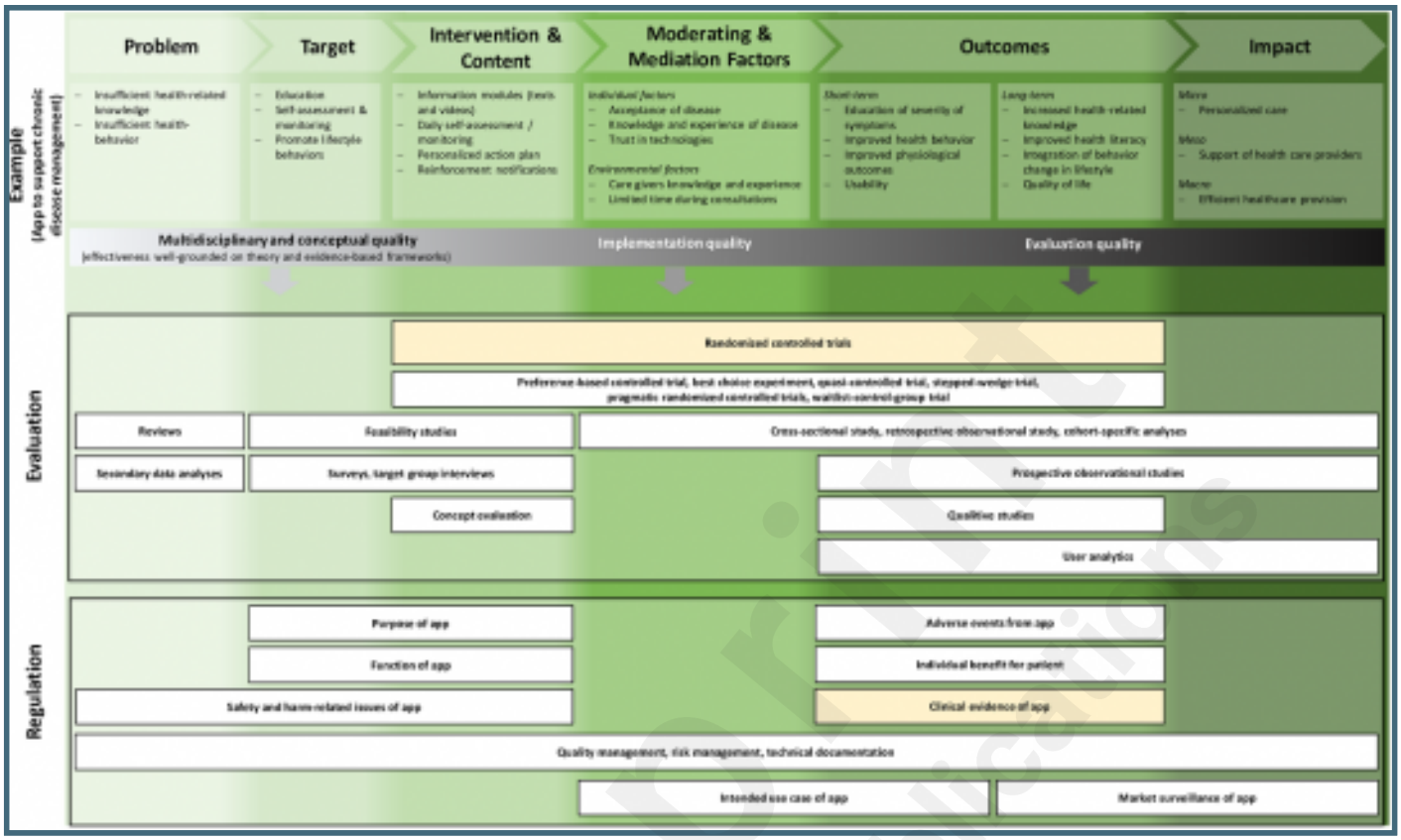
Medical apps as a sub-group of health apps. Adapted from Maaß et al. (2022).



The balancing act between increasing evidence levels and the time needed to generate them. Adapted from Guo et al. (2020).



Logic model for evaluating and regulating medical apps through the intervention's life-cycle phases.



Multimedia Appendixes

Coreq-Checklist.
URL: http://asset.jmir.pub/assets/46c77831a29164fb16dce2eb31fe9ee6.pdf

Transcribed flipcharts of the focus group discussions.
URL: http://asset.jmir.pub/assets/3db125bf2fa0ce2ad14e84f729e0a872.pdf

Glossary of technical terms given during the focus group discussions.
URL: http://asset.jmir.pub/assets/50d23cbd3a63448af796cb37a578d7ca.pdf

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