

BMJ Open Implementation and use of mHealth home telemonitoring in adults with acute COVID-19 infection: a scoping review protocol

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ABSTRACT

Introduction mHealth refers to digital technologies that, via smartphones, mobile apps and specialised digital sensors, yield real-time assessments of patient's health status. In the context of the COVID-19 pandemic, these technologies enable remote patient monitoring, with the benefit of timely recognition of disease progression to convalescence, deterioration or postacute sequelae. This should enable appropriate medical interventions and facilitate recovery. Various barriers, both at patient and technology levels, have been reported, hindering implementation and use of mHealth telemonitoring. As systematised and synthesised evidence in this area is lacking, we developed this protocol for a scoping review on mHealth home telemonitoring of acute COVID-19.

Methods and analysis We compiled a search strategy following the PICO (Population, Intervention, Comparator, Outcome) and PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses recommendation for Scoping Reviews) guidelines. MEDLINE, Embase and Web of Science will be searched from 1 March 2020 to 31 August 2021. Following the title and abstract screening, we will identify, systematise and synthesise the available knowledge. Based on pilot searches, we preview three themes for descriptive evidence synthesis. The first theme relates to implementation and use of mHealth telemonitoring, including reported barriers. The second theme covers the interactions of the telemonitoring team within and between different levels of the healthcare system. The third theme addresses how this telemonitoring warrants the continuity of care, also during disease transition into deterioration or postacute sequelae.

Ethics and dissemination The studied evidence is in the public domain, therefore, no specific ethics approval is required. Evidence dissemination will be via peer-reviewed publications, conference presentations and reports to the policy makers.

INTRODUCTION

The pandemic of COVID-19 is still ongoing and continues to impact various aspects of our lives. Until sufficient collective immunity will be achieved by mass vaccination, acute COVID-19 cases are expected to flourish.

Strength and limitations of this study

- The strength of this scoping review is in its comprehensive approach, designed to cover three major electronic databases in three languages over a period of 18 months.
- Another strength lies in rigorous implementation of the newest methodological guidelines for scoping reviews, as well as in utilisation of innovative approaches, such as automated text mining.
- Stakeholders representing different levels of the healthcare system and a range of medical subspecialties contributed to conceptualising of this scoping review.
- Due to a rapidly growing body of publications on COVID-19, our scoping review may inadvertently miss some publications that have not been assigned the used search tags and/or keywords.
- This scoping review focuses on the evidence synthesis related to acute COVID-19 and transition into postacute sequelae, whereas long COVID-19 will not be addressed in depth.

Addressing this challenge, many medical innovations are being implemented.¹ They often rely on utilisation of information and communication technologies, thereby falling under the definition of eHealth technologies.² A particular subtype of eHealth is called mHealth.^{2,3} The latter concept enables assessments of health data, typically via a smartphone or tablet, and in conjunction with dedicated mobile apps. In addition, mHealth telemonitoring can employ specialised digital sensors capable of remote transmission of patient's data.

During the pandemic, the eHealth/mHealth technologies emerged as popular tools for remote consultations of non-COVID-19 conditions.^{4–10} mHealth technologies are also suitable for procuring the COVID-19 related health data.^{11–14} In this

regard, mHealth technologies exhibit excellent scalability, which ranges from gathering population-level data^{15 16} to following, in real time, the symptoms of an individual patient.

The latter feature of mHealth telemonitoring is attractive, as it enables remote patient monitoring and remote patient stratification.¹⁷ Moreover, patient monitoring can be individualised to respect the patient's demographic and medical profile. Thereby, individual risks for severe COVID-19 and associated mortality, which both can be high in certain patient groups,^{18–21} can be given appropriate attention. Conversely, monitoring of acute COVID-19 could reveal signs of delayed convalescence and potential transition into postacute sequelae. The latter phenomenon has been attracting attention recently.²²

While seemingly straightforward, implementation of mHealth technologies for monitoring of acute COVID-19 can be hindered by various issues. These issues include reluctant embrace by the end users, insufficient local expertise and resources for implementation, lacking qualifications by physicians and other healthcare professionals, and cybersafety concerns. Furthermore, this implementation could exhibit varying successes when applied to patients with differing affinity to digital media. Another difficulty could evolve when different levels of the healthcare system need to be integrated into one mHealth telemonitoring concept. For instance, deterioration of acute COVID-19 can occur very rapidly, necessitating prompt medical interventions. In contrast to a hospital setting, with its established standard operating procedures and proximity of a multidisciplinary response team, prompt responsiveness to deterioration of outpatient COVID-19 may not be trivial. This could partially negate the benefit of real-time monitoring.

The aforementioned issues provide a rationale for synthesis and dissemination of the evidence on successful mHealth telemonitoring of COVID-19. This is especially true for concepts involving horizontal and vertical integration across the healthcare system. It has been a year and a half since the COVID-19 pandemic had officially been announced,²³ and a vast body of literature has been accumulated. Yet, based on our pilot literature sample, such systematic evidence synthesis is still lacking. In particular, the existing review articles either focus on remote medical services for non COVID-19 conditions (eg, refs 24–32) or do not sufficiently elaborate on the implementation concepts.^{15 33–35} Moreover, to the best of our knowledge, structured literature synthesis has not been done with respect to the composition of the telemonitoring team. Similarly, the evidence synthesis is scarce on integration of different levels of the healthcare system implicated in the telemonitoring process. In addition, the data on postacute COVID-19 sequelae have only recently started to be compiled. Therefore, knowledge synthesis on the role of mHealth technologies in recognition of these sequelae is still lacking.

This rationale prompted us to plan a scoping review on the aforementioned subject. Our research question

was conceptualised broad: 'What are the determinants of successful implementation and use of mHealth telemonitoring in acute outpatient COVID-19?'. The following text presents the scoping review protocol that will address this research question.

METHODS AND ANALYSIS

Aims, objectives and methodological framework

This scoping review aims to identify, systematise and synthesise the available knowledge on the implementation and use of mHealth telemonitoring in acute outpatient COVID-19. This overarching aim will entail three specific objectives. The first objective will be to provide a qualitative and categorised overview of implementation and execution of this telemonitoring. Our second objective will be to aggregate the published evidence on the composition of the telemonitoring team. By the third objective, we will describe the use of mHealth technology to warrant the continuity of care of outpatient COVID-19 in the context of recognition of acute deterioration or postacute sequelae.

This scoping review will follow the essential stages of the methodological framework for scoping reviews, based on the previously published guidelines, including the Preferred Reporting Items for Systematic Reviews and Meta-Analyses recommendation for Scoping Reviews (PRISMA-ScR; online supplemental file 1 for PRISMA-ScR Checklist and refs 36–41). In particular, this scoping review corresponds to the type 3 (summary and dissemination of research findings) and type 4 (identification of knowledge gaps) of the scoping reviews.³⁶

Search strategy and knowledge databases

The search strategy aims for high coverage and sensitivity (recall). It was developed and test-run by the lead author (ND) and the chief librarian of the Central Medical Library of Philipps University of Marburg (SW) (online supplemental file 2) in discussions with team members.

The search strategy followed the PICO (Population, Intervention, Comparator, Outcome) criterion,⁴² with 'population' being acute COVID-19 (online supplemental file 2). In particular, we will consider publications on outpatients comprising: (A) asymptomatic adults (age >18 years old), typically identified via a PCR test and positive for SARS-CoV-2 and (B) symptomatic adults (age >18 years old) with clinical manifestations of COVID-19 (with or without positive PCR test). The 'intervention' will be mHealth home telemonitoring (online supplemental file 2). The latter was spelled out as different definitions of mHealth technology and the associated digital sensors (online supplemental file 2). The 'comparator' could be any (eg, standard practices of patient monitoring (such as by a phone call), monitoring without the use of portable digital devices) or none, and thus was not defined specifically in the search strategy.

With regard to the planned 'outcome', the following can be stated. Our pilot search identified a relative scarcity

of publications on telemonitoring of acute COVID-19 as opposed to reports on telemedicine for non COVID-19 conditions. Furthermore, the identified pertinent reports present evidence on heterogeneous topics. Addressing these two points, we formulated the ‘outcome’ as a combination of several potential end products of published studies.

The *outcome no. 1* will concern the reports on implementation and use of mHealth telemonitoring (online supplemental file 2). These reports could present a general concept (eg, telemonitoring implemented in primary care only, or with integration with secondary and/or tertiary healthcare facilities), description of barriers to implementation or lists of the employed mHealth technology, evaluated endpoints and achieved successes.

The *outcome no. 2* will aggregate the evidence on the composition and competencies of the telemonitoring team. The latter may comprise general practitioners, nurse practitioners, physician assistants, respirologists, intensive care specialists, information technology specialists or other experts. In the MEDLINE (online supplemental file 2) and other database searches, this ‘Outcome’ will not be specified separately, as the evidence on the team composition may be embedded in the description of the implementation process (eg, refs 16 17).

The *outcome no. 3* will comprise all medical decisions related to changes of COVID-19 progression, either towards acute deterioration or postacute sequelae (online supplemental file 2). These decisions may comprise triage, hospitalisation, intensive care or other urgent measures, or may be those addressing the burgeoning postacute sequelae (online supplemental file 2).

Finally, the *outcome no. 4* will be related to patients’ adherence to medical procedures (online supplemental file 2).

The search strategy was developed principally using MEDLINE terms (Medical Subject Headings and Supplementary Concepts), enhanced by custom keywords (online supplemental file 2). The custom keywords were derived from the titles, abstracts or author-tagged keywords of the publications identified in the pilot run of the test strategy. These keywords were compiled manually, as well as by text mining algorithms. Text mining was conducted using the packages ‘revtools’⁴³ and ‘litsearchr’⁴⁴ for R statistical environment.⁴⁵ Addition of custom keywords to the search strategy aimed to increase the sensitivity of the latter.

To warrant sufficient coverage, we will search the following electronic databases: Ovid/MEDLINE, Ovid/Embase and Web of Science. The combination of these three databases is expected to yield the median sensitivity of the literature search of over 97%.⁴⁶ The search terminology for the latter two databases will be adapted from the one developed for MEDLINE (online supplemental file 2). The search languages will be English (American and British spelling), German and French. The publication timeframe is set from 1 March 2020 to 31 August 2021. The start date was selected as to include the first

date of the month when the COVID-19 pandemic had been announced.²³ The end date marks the date of compilation of the final version of the study protocol. The actual study (evidence screening and synthesis) is planned between the start date of 1 October 2021 and the end date of 15 November 2021.

To further increase the coverage, we will use Cochrane Library and ClinicalTrial.gov. The latter two databases will inform the secondary searches, as described further.

Eligibility criteria for publications on mHealth telemonitoring

As a general inclusion criterion, we will consider original publications that describe mHealth home telemonitoring of patients with acute COVID-19. This telemonitoring is supposed to generate a stream of real-time electronic signals from one or several digital sensor(s), with or without integration by a mobile app. The primary use of these signals should be for the objective and repeated remote assessment of patient’s COVID-19 condition by a telemonitoring team. All types of original publications (observational and experimental; cross-sectional or longitudinal; RCT or non-randomised or non-controlled trial, case series or case reports) will be included for screening.

Excluded from the screening will be original publications on mHealth home telemonitoring if such telemonitoring was used as a substitute for personal visits to the clinic of patients with non COVID-19 conditions (eg, diabetes, Chronic Obstructive Pulmonary Disease (COPD), cardiovascular disease, etc). Conference abstracts and proceedings will also be excluded, as will the editorials, commentaries, letters to editor, essays, book chapters, books and contents of internet websites.

Protocols for clinical trials (ClinicalTrial.gov and clinical trial protocols in MEDLINE) will not be included per se but will inform the secondary literature search in MEDLINE for publications that present the results of these clinical trials. Similarly, relevant review publications (such as those identified in the Cochrane Library) will not be included but will inform the secondary search in MEDLINE. Specifically, the references of review publications will be screened for potential suitability in this scoping study (‘forward snowballing’). We will also identify original publications which cite these review publications (‘reverse snowballing’).

Before screening for inclusion in the final reference sample, the references will first undergo deduplication. To this end, the references identified through all searches will be subjected to automated deduplication (the aforementioned package ‘revtools’⁴³) and comprehensive manual deduplication in Endnote, as per published optimised protocol.⁴⁷

Screening for suitable publications

Following deduplication, the publications will undergo manual screening. The latter will be conducted as follows. First, the titles and abstracts will be screened by the reviewers’ team comprising the lead author and two other reviewers (SH and LN). We will use the online

software Rayyan⁴⁸ to enable independent and collaborative screening. The Cohen's kappa coefficient will be used to quantitatively assess the inter-reviewer reproducibility of title and abstract screening. The expectation is that this coefficient will be at least 0.8. Potential disagreements between these reviewers will be solved on consultation with the fourth member of reviewers' team (SK).

Following the previous screening step, full-text publications will be procured using publications' digital object identifiers (doi's) or manually.

Charting the data

The full-text screening will be done by the lead author, supported by other members of the reviewers' team (SH, LN and SK) and will yield a final reference sample for descriptive synthetic analysis. If needed, consultations will be held with other coauthors.

The information from the final reference sample will be compiled in the data extraction table, which was developed and tested during the pilot searches. This table includes the publication ID (authors, title, journal and doi), country of study's origin, research question/hypothesis/objectives of the study, type of the study (RCT, non-randomised or non-controlled trial, observational study, case series or case report), study design (cross-sectional or longitudinal), population (patients' age, race and ethnicity, sex and gender, comorbidities, stage of the disease (asymptomatic SARS-CoV-2 carriage/oligosymptomatic or acute COVID-19), detailed description of telemonitoring (ie, which mHealth device(s) was/were used, particularities of the use), duration of digital telemonitoring, availability and characteristics of the comparator. Publications' outcomes and conclusions will also be documented.

In addition to demographic and clinical information, we will compile the details of processing of the incoming status feeds, such as the thresholds on which the monitoring medical team was alerted, the protocols of subsequent responses by the medical team and the reported medical interventions (eg, phone call, text message with referral to emergency department, etc). If available, we will gather information on the composition and competencies of the telemonitoring team. We will also record the information on whether and how the included studies addressed patients' adherence to telemonitoring. Processing of potential measurement errors (either patient-associated errors or due to intrinsic variability of mHealth devices) will also be noted.

Evidence synthesis

Descriptive synthesis of the retrieved evidence will be conducted, provided that there will be at least two identified relevant publications in the final reference sample. On finding of only one pertinent publication, we will use it in the scoping review as an example of the mHealth telemonitoring concept. To ensure the bias-free evidence synthesis, 10% of publications in the final reference sample will be randomly selected and subjected to

independent review by the second reviewer (SH). If the number of publications will be low, and allocation of 10% not feasible, a different proportion of the publications in the reference sample (eg, half of the publications in case of the reference sample comprising <10 publications) will be selected for the independent review by the second reviewer. Finally, the retrieved data and descriptive synthesis will jointly be discussed within the reviewers' team, as well as with other coauthors. The joint authors' team include the end users of mHealth technologies at primary, secondary and tertiary levels of the healthcare system.

The evidence from retrieved and selected publications will be presented in a structured form as a table, with rows presenting individual publications and columns presenting the key publication variables (eg, study's research question, country of origin, study design and population, type of mHealth technology used and other pertinent details). We will also describe the synthesised evidence in the text form. The text description will permit logical organisation of the evidence based on the three specific objectives of this scoping review.

As per these objectives, we preview three themes by which we will carry out the evidence synthesis. First, we will describe the process of implementation and use of mHealth home telemonitoring. In particular, we are interested to learn, aggregate and disseminate the knowledge about potential common barriers to implementation of mHealth technology (eg, remuneration issues, cybersafety aspects, costs of pertinent technology and lack of local expertise) that had been encountered and overcome by the authors of previous publications. Second, we will aggregate the published knowledge on the composition of the telemonitoring team. In many instances, this telemonitoring may invoke interactions within and between different levels of the healthcare system. Thereby, it is essential to synthesise the knowledge as to whether the telemonitoring team, from the onset on, should be multidisciplinary, with affiliations with the secondary/tertiary levels of the healthcare system. Alternatively, such team could represent only primary care experts but be backed up by a support (outreach) team comprising the secondary/tertiary level specialists. Third, we will aggregate the knowledge on the standard operating procedures that warrant the continuity of care in the home-telemonitored patients, such as by addressing changes in progression of COVID-19, either towards acute deterioration or postacute sequelae.

This review does not plan to critically appraise the available published evidence. Such appraisal (eg, of the reported successes of digital home telemonitoring in comparison to standard care) will be resorted to a subsequent systematic review. The decision as to whether to carry out a systematic review will be made depending on the number and quality of the identified references.

Patient and public involvement

As mentioned previously, the joint authors' team includes the medical end users of mHealth telemonitoring at different levels of the healthcare system. Thereby, the development of this protocol benefited from regular discussions within the team. No patient or public involvement took place in the development of this scoping review protocol. This scoping review may identify the need for a subsequent systematic review. At that stage, medical end users of these technologies will again be involved. We will also seek the patients' reflection and perspective on mHealth home monitoring. To this end, we, at the stage of drafting a subsequent systematic review, will consult former patients with COVID-19, especially those representing vulnerable groups (eg, refugees, those with a handicap, patients in advanced age or residents of long-term care facilities).

DISCUSSION

Home telemonitoring is an attractive solution in the context of the still ongoing pandemic and its extensive burden on the tertiary healthcare system. The majority of patients with COVID-19 can and do endure the acute disease in an outpatient setting.^{49–53} Addressing this fact, various solutions have been proposed for monitoring of non-hospitalised patients with acute COVID-19. These solutions range from online questionnaires¹⁶ to teleconsultations or videoconsultations.⁵⁴ Disease deterioration can, however, develop rapidly in COVID-19. Digital sensors, especially pulse oximetry, are helpful as harbingers of such deterioration.^{18 52 53 55 56} In this regard, mHealth-based home telemonitoring, comprising pulse oximetry and other pertinent wearables, represents a crucial bridge between COVID-19 deterioration and a subsequent medical response.

In a similar manner, the use of mHealth wearables (eg, fitness trackers, portable spirometers and monitors for cardiovascular function) may be helpful for early recognition and subsequent monitoring of postacute COVID-19 sequelae. As of the past few months, there is a growing attention to those sequelae (also known as 'long COVID-19' or 'chronic COVID-19').^{22 57–59} The mHealth technologies that monitor functional status of the cardiopulmonary system are particularly well suited for timely recognition of troubled physical recovery. This is especially important, given the current lack of individual predictors of these sequelae.⁶⁰

As mentioned previously, this attractive concept may be hindered by various factors, including insufficient embrace by the end users, unresolved issues with fees and remuneration, as well as by technological and legal problems. For example, pulse oximetry can generate substantial measurement artefacts.⁵⁶ This necessitates appropriate guidance and counselling of the patient, especially to warrant the conformity with the measurement standards.⁶¹ In addition, implementation of mHealth technology can be viewed as disruptive by

the medical personnel⁶² who are already overworked during the pandemic and may lack sufficient expertise in this area. At present, the majority of practising health professionals are not adequately trained in utilisation of mHealth and telemedicine. Thereby, additional efforts are needed to integrate these concepts into daily clinical practice.

On the patient level, too, there could exist certain barriers. In particular, proficiency with digital devices, affinity to digital media and acceptability of digital healthcare may differ substantially among patients, depending on their age,^{63 64} education level⁶⁵ or minority representation (eg, recent immigrants,⁶⁴ refugees⁶⁶ or religious minority communities).⁶⁶ On top of this, adherence to telemonitoring routines may vary, depending on the severity and duration of the disease,⁶⁷ or duration⁶⁸ and frequency⁶⁹ of telemonitoring events.

Therefore, identification and dissemination of successful concepts on digital home telemonitoring of COVID-19 using mHealth technology is crucial. The present scoping review will focus on this goal. In particular, this review will structure and synthesise the available evidence on implementation and use of mHealth home telemonitoring in acute COVID-19. Furthermore, this review will aggregate the knowledge on prerequisites, both in personnel and technology, that are essential for continuity of care and seamless integration of this telemonitoring with different levels of the healthcare system.

In conclusion, prompt aggregation and synthesis of the evidence on implementation and use of mHealth technology in acute outpatient COVID-19 is an exigency. This scoping review is the necessary step towards future critical evidence appraisal in this area.

ETHICS AND DISSEMINATION

For proper dissemination of the evidence synthesis, we plan to publish this scoping review in a peer-reviewed journal, as well as share the findings at medical conferences, both on primary care (eg, German Society of General Practice and Family Medicine; North American Primary Research Group) and respiratory medicine (American Thoracic Society, European Respiratory Society and German Society of Pulmonary Medicine). In addition, we will prepare a concept document that will be submitted to policy makers in Germany. Our group works as part of the national consortium of university hospitals (egePAN Unimed). This consortium developed a website (www.egepan.de) that could be used for podcasts and other tools for dissemination of the synthesised evidence.

As mentioned previously, this scoping review may inform the authors' team about the feasibility of a systematic review in this area. Such systematic review could be done in direct collaboration with the national and European institutes specialising in advancing evidence-based digital medicine.

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