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Equitable digital medicine and home health care

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Equitable digital medicine and home health care

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Editorial: Equitable digital medicine and home health care

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Editorial on the Research Topic
Equitable digital medicine and home health care

Digital health technology (DHT) concerns the use of high-quality hardware and software to support medical practice, including diagnosis, treatment, disease prevention and health promotion for individuals and populations (1). DHT has made great progress in the last decade, radically transforming the way health care is delivered. Thanks to DHT, health can be monitored, diagnosed and treated in innovative and efficient ways (2, 3). Digital technologies are used to control asthma and COPD (4), to treat ADHD (5), to improve sleep quality (6), to treat low back pain (7), to manage type 2 diabetes (8), for improving executive function and emotional adjustment in the rehabilitation of traumatic brain injury (9) for monitoring substance use disorders (10) and for the early detection of acute kidney injury (AKI) (Shi et al.). This non-exhaustive list of digital therapies shows the wide, varied and hypothetically boundless spectrum in which the development and use of DHT can implement health.

Then, there was the COVID-19 pandemic that posed unprecedented challenges to the global health system, highlighting the importance of home care and the role that DHT can play in a context where "moving information" is much better than "moving people" (11).

During the pandemic emergency, there was a significant increase in investment in digital health technology solutions, with a record USD 24 billion investment in digital health in 2020, and a new monthly record in December 2020 of USD 3.4 billion (12).

Digital technologies have been crucial in the fight against coronavirus because they have enabled contact tracing (13), monitoring (14) and diagnosis (15) of citizens and patients during a global pandemic in which without social distancing there would have been a progressive and uncontrolled spread of the virus.

As the world adapts to the "new normal", home care has undergone a significant evolution from a complementary service to a primary form of care (16). DHT is joining home care to create a powerful combination, bringing innovation, efficiency and equitable access to healthcare into the homes of millions of people around the world. This synergy is revolutionizing the way healthcare is delivered, enabling people to receive appropriate and personalized treatment in their own homes.

Estebanez-Pérez et al. show how in rural areas of India, DHT makes it possible to overcome the shortage of physiotherapists and ensure the rehabilitation of children with ankle fractures by improving functional independence and quality of life.

However, access to these digital health solutions is not equally distributed throughout the world. DHT is more developed in urban areas than in rural areas, is used more by young, white, English-speaking individuals with higher education and higher economic status. Moreover, paradoxically, better access to DHT has been found in individuals without disabilities or complex health needs (17). In this scenario, in order to optimize potential and concrete improvements in health care, it is necessary to overcome certain limitations, well-highlighted by the study of Cingolani et al.: the shortcomings of health information systems and digital tools, the slow spread of electronic medical records, the problems of digital literacy, the high cost of devices, and the poor protection of data privacy. The danger of over-reliance on such systems must also be examined.

The political decision-makers of each country have the fundamental responsibility to establish and ensure a robust legal and regulatory framework that places the protection of patients at the center within the healthcare context. This legal framework should clearly outline patients' rights, including equitable access to care, privacy, and the security of medical data, as well as mechanisms for recourse in the event of medical errors or violations of patients' rights (Cingolani et al.). The clarity and robustness of the legal framework are essential to ensure patients' trust in the healthcare system and to guarantee that they are treated fairly, safely, and in a manner that respects their rights. Furthermore, a sturdy legal foundation promotes accountability among healthcare professionals and institutions involved in delivering care, thereby contributing to enhancing the overall quality and safety of healthcare services (18).

Home care based on equitable digital medicine aims to overcome this inequality and ensure that everyone, regardless of their geographical location or socio-economic background, can benefit from advances in DHT.

DHT must be a means through which all citizens have equal access to healthcare. Thanks to DHT, patients can be monitored, diagnosed and treated remotely, eliminating the need to physically travel to the hospital. This is especially relevant for people who live in remote areas or who have mobility difficulties, enabling them to receive appropriate care without having to make long and expensive journeys (19).

Among digital technologies applied to healthcare, telemedicine is a key pillar for equitable DHT in home care. Telemedicine can contribute to a reorganization of health services, enabling the shift of health care from the hospital to the local area, through innovative patient-centered care models and facilitating access to services for people who would otherwise have difficulty traveling to a traditional health facility, such as the older adult, the disabled or those living in rural areas (20–24). However, Bashir et al. showed that successful telemedicine requires the creation of specialized educational programs for healthcare workers (HWs) to ensure proper implementation.

Another key to equitable DHT in home care is remote monitoring and the use of wearable devices. Thanks to advanced sensors and devices such as smartwatches or smart bracelets, patients can measure their vital parameters, monitor physical activity, check glucose levels or track other important indicators of their health. This data is sent in real time to HWs who can carry out constant monitoring and intervene promptly in the event of anomalies (25–29). This allows personalized treatment and more accurate monitoring of the patient's health condition as well as increasing patient empowerment. Through the use of mobile applications, patients can access health information, educate themselves about medical conditions and manage their own wellbeing more independently. This increased awareness and responsibility for one's own health enables patients to make informed decisions and actively participate in the treatment of their illnesses (30). In addition, data analysis can allow the identification of potential risks, enabling early intervention to prevent the development of diseases. This proactive approach to health could help reduce the incidence of chronic diseases and improve people's quality of life.

In order for everyone to benefit from DHT-based home healthcare, it is necessary for policy-makers to take up and address important challenges.

a) Establish regulations, develop guidelines with methodological rigor, quality, transparency and accuracy while reducing the risk of bias (Silva et al.) and formulate guidelines to support decision-making in digital health (17). According to Petrini et al., special regulatory attention should also be paid with regard to decentralized clinical trials (DCTs) that rely on the use of digital tools such as electronic consent, apps, wearable devices, electronic patient reported outcomes (ePROs), telemedicine, as well as on moving trial activities to the patient's home.
b) Less than half of the population in developing countries has access to the internet. Advanced economies such as the US, France, Germany, the UK and Canada have the highest access rates. The large emerging economies show large disparities in the proportion of Internet users in their population, ranging from about two-thirds in Brazil and Mexico to about one-third in India (31). Without reliable connectivity and appropriate devices, it becomes difficult for people to fully benefit from digital health services. Therefore, efforts by governments and international organizations are needed to improve access to the technology infrastructure and promote global connectivity.
c) DHT "feeds" on personal information that is collected and shared. This is the essence of DHT. Therefore, it is crucial to ensure that patient data are properly protected and only used for legitimate purposes. Furthermore, it is mandatory to take appropriate and proportionate technical and organizational measures to manage risks and to prevent and minimize the impact of network and information system security incidents. Patient safety should be supported by governance activities that strengthen the information infrastructure (Verga et al.).
d) DHT must be designed considering the different cultural backgrounds and specific needs of local communities. This involves the translation of medical applications and content into local languages, as well as the adaptation of medical

practices to specific cultural contexts. In this respect, Kim's study is very interesting: it is undeniable that the use of ITC can be beneficial for the health care brought to the older adult. But this is not enough, because there is a need for consistency between national health policies and the choice to use technological devices to manage the health of the older adult (Kim).

e) The adoption of digital technologies in healthcare can depersonalize and negatively affect the care relationship leading to insufficient communication and limited data transmission that can expose the patient to clinical risk in multiple situations (32, 33). For this reason, home care supported by DHT cannot completely replace the need for traditional health care. DHT and home care should be integrated into a holistic approach to health care that considers the individual needs and circumstances of patients.

Equitable digital medicine has the "potential" to revolutionize access to health care worldwide. However, for it not to remain only a "potential" benefit for a large part of the world's population, geographic and economic barriers must be overcome and health services must be offered to everyone who needs them. New legislation, targeted investment in technology infrastructure, data protection policies and an inclusive approach can certainly help to create a future where everyone has access to high quality healthcare. Doing the right thing for the right patient at the right time requires that all interventions are based on a strong ethical framework. The patient's centrality, the medical act as a free and responsible human act with an intrinsic ethical value, interdisciplinary co-design, a realist knowledge, a management model based on motivational involvement, professional excellence as an instrument of service to society and the common good, and the capacity for radical procedural innovation are the pillars of the ethics of a job well-done (34) and could constitute the ethical guidelines on which to build an equitable DHT serving all citizens, especially the older adult, the disabled or those living in remote areas (35).

Author contributions

VT and FD wrote the first version of the manuscript. All authors made a significant contribution to this paper and have read and approved the final version of the manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Digital physiotherapy intervention in children in a low resource setting in Anantapur (India): Study protocol for a randomized controlled trial

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Introduction: In rural India the scarcity of physiotherapists and inequalities complicate the recovery of traumatized children. This study protocol will explore a digital physiotherapy intervention in children with ankle fracture in a low-resource setting to improve functional independence and quality of life.

Methods and analysis: A randomized clinical trial with a mixed quantitative-qualitative design will be carried out. It is a single-blind study, where the evaluator does not know the nature of the intervention. Sixty subjects will be enrolled and randomly divided into two groups: the experimental group (EG) will receive a 4-week digital physiotherapy intervention through an app in a recycled mobile device after hospital discharge; the control group (CG) will receive the physiotherapy standard care recommended for patients discharged from the hospital. Subjects will receive a baseline (T0-pre) assessment of Functional Independence and Quality of Life. At the end of the 4-week intervention (T1-post) a new assessment of the outcome will be performed adding data on adherence, satisfaction (*ad hoc* questionnaire and TSQ), and barriers of use. Qualitative outcomes will also be explored. The author's hypothesized that the implementation of a digital physiotherapy intervention is feasible and effective to improve functional independence and quality of life. This study protocol is the first to explore the effect of digital physiotherapy intervention in children's patients in a low resource setting (Anantapur).

Discussion: The successful delivery of the intervention, an optimal adherence records, the absence of significant adverse effects, user satisfaction level and the qualitative analysis of limitations, will demonstrate the effectiveness of these procedure. This study will add more evidence in support the use of digital physiotherapy practice as an effective tool. User particularities, provider's capacity, technological and cultural limitations, and considerations for vulnerable populations will be taken into account.

Clinical trial registration: NCT04946695 (https://clinicaltrials.gov/).

KEYWORDS

telerehabilitation, fracture, low resources, pediatrics, digital practice

Introduction

Trauma remains the most common cause of injuries in children over 1 year of age (1, 2). In India, the prevalence of trauma in child patients ranges from 5.5 to 19.23%, where orthopedic account for the largest proportion of injuries (1). A prospective study reported that majority of the pediatric trauma cases were seen in males (69.86%) where 11–15 years comprised the most common age group. Road traffic accidents (RTA) and falls was the most common mode of trauma followed by thermal injuries and assaults (3). The greatest risk occurs during the schooling years because they develop a sense of independence and freedom, which predisposes them to new risks (4). A 1-year prospective study observed that orthopedic injuries were the most frequent (37.8%) type of injuries (5). Another multicenter study collected from 9,496 children showed a high incidence at least one fracture with significantly ($p < 0.05$) greater in boys than in girls. Of the fractures, 26% were in the lower limbs (6), ankle fractures being the most frequent (7).

Anantapur, a region of the Republic of India, is one of the poorest and most needy areas in the country (8). Organizations such as the Vicente Ferrer Foundation have been working in the area for years in order to provide quality health care to the poorest people with two references hospitals in Bathalapali and Kaliandur (8). However, the scarcity of rehabilitation centers and inequalities in the provision of health services inherent in developing countries, complicate the recovery of traumatized children (9). In rural regions, there are also few physiotherapists compared to the potential need (10). There are only 12,245 members of the Indian Physiotherapist association to attend 1,380,004,385 population, whereas according to the World Health Organization (WHO) there should be one for every 10,000 citizens. Consequently, according to WHO norms there is a great shortage of physiotherapists in India (11).

Physiotherapy plays an important role for musculoskeletal health conditions (12, 13) over the past few decades, physiotherapist have emerged as key health care providers in emergency departments, especially for patients with musculoskeletal disorders (14). Therapeutic exercise programmes are interventions with a high degree of evidence for their use in the recovery of mobility, strength, endurance and function in children and adolescents (15, 16). In addition, systematic reviews on the effects of exercise in children include improvements in attention level, motor skills, well-being, balance, reduction of disability, pain and walking tolerance (17–19). Evidence shows that structured programmes (20), home exercise programmes (21) and different types of progressive resistance exercises are recommended treatments for orthopedic rehabilitation (22).

Therefore, innovative strategies are needed to improve access to more specialized physiotherapy care (23, 24). One of the growing innovative strategies is the use of communication technologies in their most varied forms and definitions as is the case of digital physiotherapy practice (10). The digital physiotherapy practice is the provision of physiotherapy services at a distance, using telecommunication technology when an in-person visit is not a feasible option (25). Research based on digital physiotherapy practice and telerehabilitation (TR) programmes have published results of effectiveness in some neurological, cognitive, musculoskeletal and respiratory disorders (26), and pediatric population (27). The digital physiotherapy practice is presented as a promising complementary treatment method to standard physiotherapy (28, 29). The digital physiotherapy practice improves patient accessibility and reduce healthcare costs (30). It has also been claimed that the high acceptability of this technology can be successful in improving patients' quality of life (31).

However, there appears to be a significant shortage of studies in developing or low-income countries or geographic areas (32). The participation of smaller health units in remote areas in clinical research processes is a fundamental requirement (33). However, a collaborative approach and open dialogue with the health-care workforce will be needed to facilitate their participation in the clinical research process (34).

Reviews of existing literature suggest that several barriers contribute to the low adoption of health technology including insufficient health literacy, lack of effectiveness, safety, privacy, awareness and poor integration with the traditional healthcare system (35).

Past and current studies regarding physiotherapy interventions in India and developing countries have suggested a lack of adherence to evidence-based interventions (36, 37). To avoid this issue, current clinical practice guidelines and protocols will be consulted in advance through scientific databases and information provided by the Indian Association of Physiotherapists (38). In this study the researchers in conjunction with local physiotherapists will offer exclusively evidence-based interventions.

Given the high rates of musculoskeletal injuries, the lack of an efficient physiotherapy system, and the opportunities that technology offers, research with digital physiotherapy intervention in low resources rural areas are highly justified.

The main objective of this research is to evaluate the effectiveness of a personalized digital physiotherapy intervention in children with ankle fracture in a low-resource setting. The author's hypothesized that the implementation of a digital physiotherapy service in children with ankle fractures in

Abbreviations: RTA, road traffic accidents; WHO, World Health Organization; SQUIRE, Standards for Quality Improvement and Excellence in Reporting; CONSORT, Consolidated Standards of Reporting Trials; app, application; FIM, Functional Independence Measure; SPPB, Short Physical Performance Battery; SF-12, Short Form Health Survey 12; TSQ, Telemedicine Satisfaction Questionnaire; RDT, Rural Development Trust.

a low-resource setting is feasible and effective to improve functional independence and quality of life. This research also explore participant's and caregivers' satisfaction, level of adherence and identified possible barriers in the development of the digital physiotherapy service in a mixed quantitative-qualitative research design.

Methods

Study design and participants

This research is carried out by means of a multicentre randomized clinical trial with mixed quantitative-qualitative research, in subjects residing in Anantapur with ankle fractures, who have been discharged from referential hospitals. This research uses the guidelines of the Standards for Quality Improvement and Reporting Excellence (SQUIRE) (39) and will be conducted according to the Consolidated Standards of Reporting Trials (CONSORT) criteria (40). The Standard Protocol Items Recommendations for Interventional Trial (SPIRIT) checklist has been added as Supplementary material (41). A flow chart of the study design is shown in Figure 1.

The collaborators will be informed about the characteristics of the study in personal interviews and presentation of the project.

Participants will be recruited from rural areas based at Bathalapali and Kaliandur referral hospitals. Based on the high incidence of fractures and the information provided by the medical teams, the following inclusion and exclusion criteria were selected:

Inclusion criteria

1. Child population (5–16 years) with a diagnosis of ankle fracture.
2. Child attended at one of the referral hospitals (Bathalapali or Kaliandur).
3. Participants or their relatives must have of reading and writing skills in English or Telugu (language of the Anantapur region).

Exclusion criteria

1. Participants will be excluded if there is presence of neurological disease.
2. Participants will be excluded if there is presence of mental or cognitive disorder.
3. Participants will be excluded if there are comorbidities to musculoskeletal involvement.

Sample size

To date, no studies have reported on the use of digital physiotherapy practice program in children in low resource setting; so that this randomized, blinded clinical trial will provide evidence for the effect size. However, an online sample size calculator was used (https://www.ai-therapy.com/psychology-statistics/sample-size-calculator) to determine minimal sample size (accessed on 10 May 2021). Included in the calculation was a one-tailed test, we assumed a medium effect size of 0.65 based on related study on a similar topic (42–44), a significance level of 0.05 and power of 0.8. As the first estimate of effect size, a sample size of 66 participants has been calculated, with an expected proportion of losses (10%), and a proportional distribution for each arm of the study (EG = 30 and CG = 30), this information is expanded in the Supplementary material.

For the development of this research a non-probabilistic purposive sampling will be used for the convenience of the study, due to the characteristics of the subjects. Patient recruitment will ensure socio-demographic diversity with regard to social background, gender, ethnicity and education adapted to the particularities of the reference population in India and prior information on compliance with data protection laws. The homogeneity of the sample data will be checked at baseline to ensure that there are no significant differences in demographic and medical variables.

Randomization

Before patient inclusion, the research team will generate the allocation sequence and randomly assign patients consecutively with opaque sealed numbered envelopes in the EG and the CG. A computerized random number generator will be used. Each participant will be treated separately to prevent any exchange of study information. The nature of the intervention in both groups does not allow blinding of patients and physiotherapists. It is therefore a single-blind study, where the evaluator does not know the nature of the intervention. Evaluator in the study were blinded during the entire process. The evaluator was unaware of the study objectives and the randomized distribution of patients to study groups, and he did not have access to the randomization sequence. Subjects receive an initial evaluation based on clinical parameters and follow-up discharge reports. Data will be collected by the principal investigator and integrated into research databases.

Intervention

The experimental group (EG) will receive a recycle mobile device with the Physiotec mobile application (app) installed. The app was selected as the one that best suits the characteristics

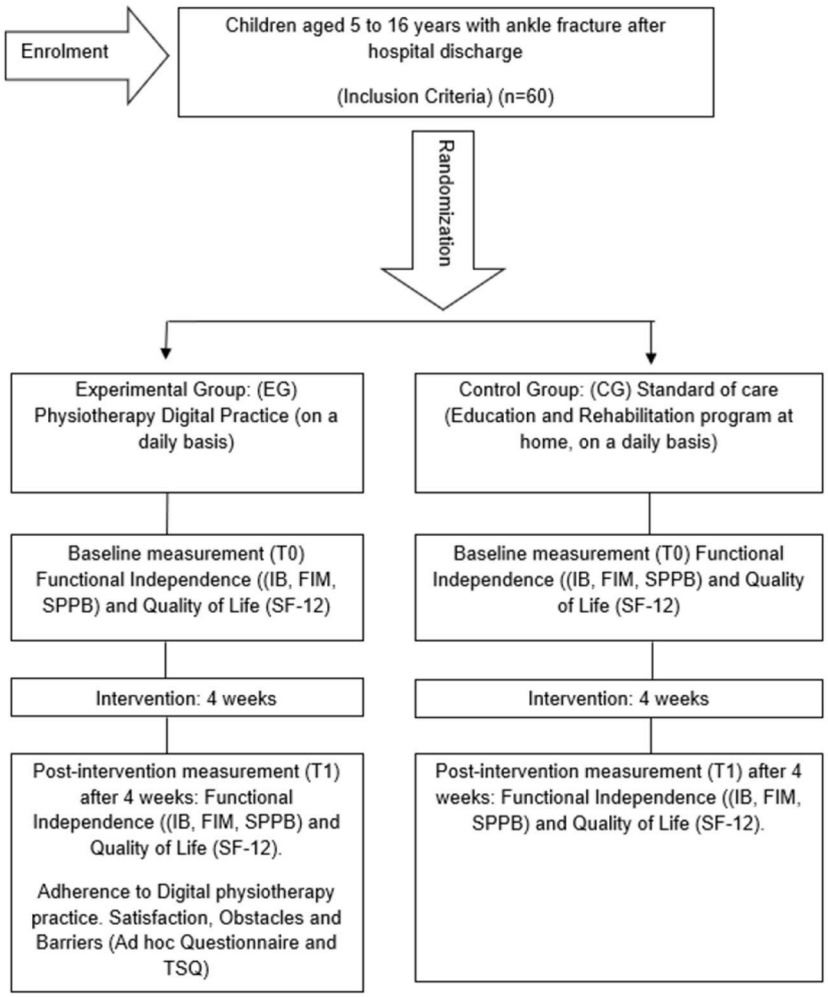

FIGURE 1
Flow chart.

of this research and the needs of the patients used in previous interventions (26, 28, 45, 46). Patients will receive a personalized digital physiotherapy programme during 4 weeks adapted to their injury using the app. The digital physiotherapy programme describes the exercises to be performed, the number of sets and repetitions and the progression criteria, which will be based on published clinical guidelines for patients with ankle fractures. Interventions include pain management, reinforce of realistic expectations for recovery time, mobilize as allow, crutches use, progressive strength training and functional training including daily live activities starting at a low intensity and duration and increasing gradually based on the progression of each patient. Exercise patterns such as walking, fast walking, jogging and swimming will be recommended (47).

The digital physiotherapy app allows health professionals to create personalized exercise programmes, generate videos, images and parameters for each exercise, as well as monitor adherence to treatment and possible incidents on its implementation (45). Patients perform the treatment by replicating the video exercise and physiotherapy recommendations in their own device in an easy and visual app that automatically register adherence and follow up. An example of the digital physiotherapy app and a demo programme is shown in Figure 2.

Patients will be initially supervised by the hospital's medical and physiotherapy team, who will conduct a training session to ensure correct use of the device, correct execution of the exercises and encourage patient adherence. Participants and their relatives will be instructed to perform the self-training at home on a daily basis. The device, and the digital physiotherapy programme will be updated weekly according to the patient's evolution.

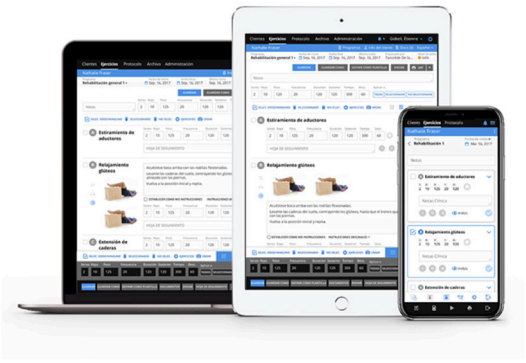

FIGURE 2
An example of the digital physiotherapy app and a demo programme.

Research team and referral hospital physiotherapist are responsible for updates following clinical guidelines in a weekly ass. Treatments would be designed and carried out in coordination with the healthcare professionals and their relatives. Any deviations from adherence and practice will be recorded daily, with any adverse incidents noted. The Physiotec app is provided and funded under exclusive license by the principal investigator and with the collaboration of the app owner. The recycled mobile devices were obtained through a collaborative and not profit campaign.

This research facilitate access to communication technology to support digital physiotherapy treatment by providing personalized video exercises that can be easily carried out at home.

The control group (CG) receives the physiotherapy standard care recommended for patients discharged from the hospital, during 4-week. Based on individual needs, standard physiotherapy care after hospital discharge includes an outpatient physical therapy program at home on a daily basis that will be updated weekly according to the patient's evolution.

Outcomes measures and tools

The investigators considered the following outcomes: affiliation Data and Socio-Demographic Questionnaire: including age, gender, location, and other socio-demographic outcomes.

Primary outcome measures

Functional independence

The assessment of functional independence, physical function and daily live activities is a routine task in rehabilitation centers and units. Functional assessments provide a measure of functional capacity and information on prognosis, disease severity and degree of disability. Obtained from the results of the following assessment instruments: Functional Independence Measure (FIM) and the Short Physical Performance Battery (SPPB).

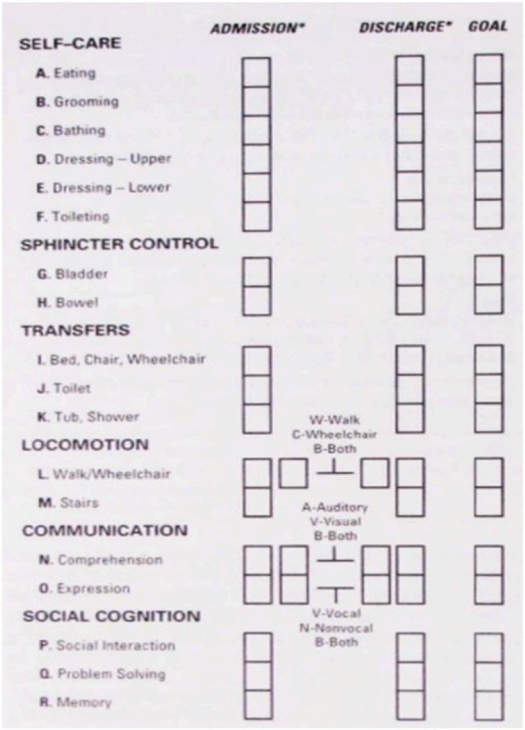

FIGURE 3
Functional independence measure (51).

The FIM is an instrument that was developed as a measure of disability for a variety of populations including children's fractures (48). An ordinal scale for functional assessment (mobility and self-care), is useful in making decisions about the effectiveness of therapy. Several studies have used the FIM to investigate treatment outcomes in self-care, transfers (mobility) and locomotion. The total FIM score is obtained by summing the ratings of the 18 items included in the different levels. High FIM scores are associated with high levels of function and low FIM scores indicate low function (37). The scale has good reliability and its comparison with other instruments yields correlations of 0.84 with the Barthel Index (49). WeeFIM is the pediatric version of FIM. It is very similar to the original FIM but differs in its scoring processes in order to take into account the child's developmental stages. WeeFIM is needed if the injured person has had a traumatic brain injury or burns, therefore, in our study protocol we will use the FIM for this outcome measure (50). A Functional Independence Measure is shown in Figure 3.

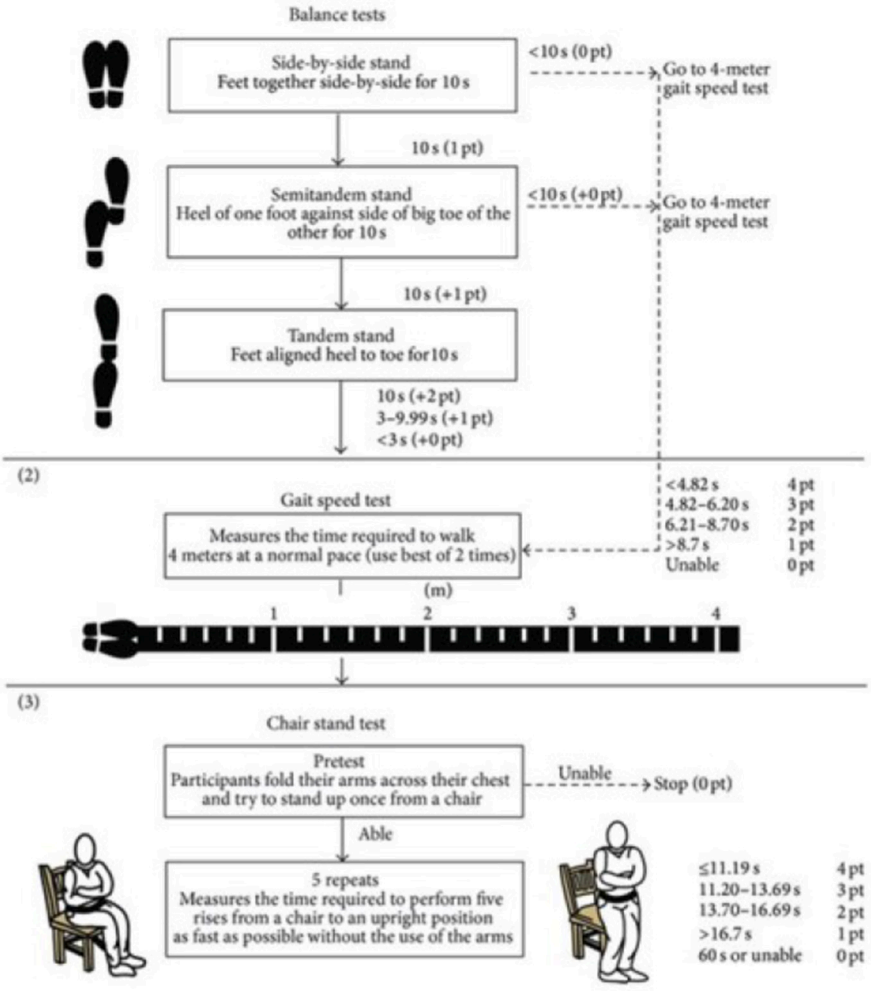

FIGURE 4
SPPB test (53).

The Short Physical Performance Battery (SPPB) is a widely used and validated test battery with high internal consistency, which evaluates three points: walking speed (the 4-m walk test); strength and resistance of the lower limbs (time required to perform 5 squats sit-to-stand test), and balance by standing with feet together, in tandem and semi-tandem. The SPPB proved to be a good tool for assessing functional mobility in the pediatric population, showing good reproducibility (52). A SPPB text is shown in Figure 4.

Quality of life

Health-Related Quality of Life refers to the subjective assessment of the influences of current health status, health care, and health promotion on the individual's ability to achieve and maintain an overall level of functioning that enables the pursuit of those activities that are important to the individual and that affect his or her general state of wellbeing (54).

The 12-Item Short Form Survey for Quality of life (SF-12) questionnaire was used for the assessment of health-related quality of life. The SF-12 is considered a suitable instrument of choice to measure the general health status of the population. The SF-12 questionnaire assesses eight dimensions of health-related quality of life: physical function, physical role, bodily pain, general health, vitality, social function, emotional role and mental health. High internal consistency indices are observed 0.83 and 0.9039, in several international studies (55). A SF-12 questionnaire is shown in Figure 5.

Secondary explanatory outcomes

Adherence

The concept of adherence to digital interventions is roughly defined as the degree to which the user followed the program

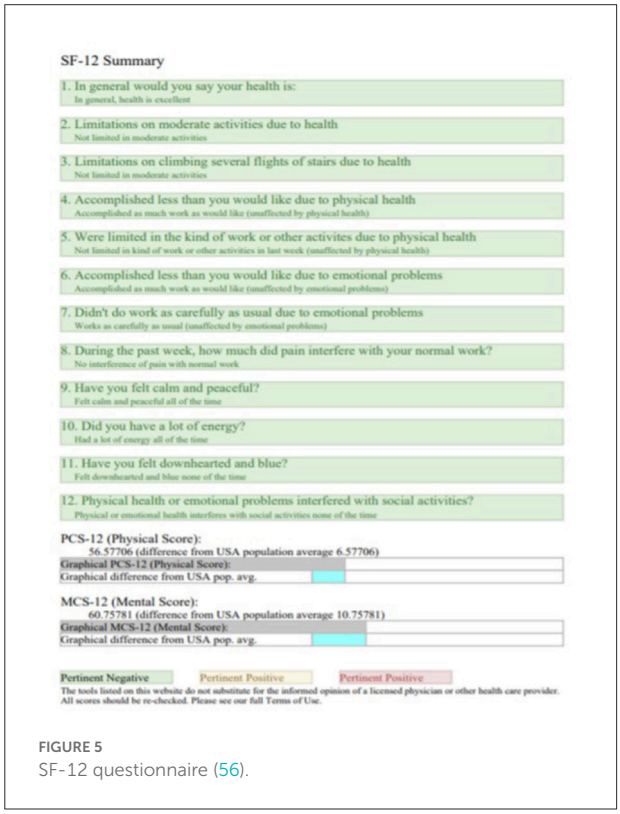

FIGURE 5
SF-12 questionnaire (56).

NO.	Item	Score (1-5)
1	I can easily talk to my physiotherapist or health provider.	
	I can easily listen to my physiotherapist or health care provider.	
	My physiotherapist or health care provider can easily understand my health condition.	
	I can see my Physiotherapist or health provider as if we were in person.	
5	I do not need assistance while using the system	
	I feel comfortable communicating with my physiotherapist or health care provider.	
	I feel that the telemedicine service offered to me is consistent.	
8	I get better service to my physiotherapist or healthcare provider through telemedicine.	
	Telemedicine allows me to save time travelling to the hospital or clinical speciality centre.	
	I have received adequate care	
	Telemedicine gives me what I need for my health	
	I find telemedicine an acceptable means of receiving my health services.	
	I will use telemedicine services again.	
	Overall I am satisfied with the services received through telemedicine.	

FIGURE 6
TSQ (59).

as it was designed, which can also be paraphrased as "intended use" or "use as it is designed" (57). Adherence to the digital physiotherapy intervention will be automatically recorded by the app, in compliance with the scheduled sessions.

Satisfaction, obstacles and barriers in the use of digital physiotherapy practice

The acceptance of telemedicine applications is a prerequisite for identifying the potential clinical benefits of this technology. It is therefore important to complement this research with tools that examine patient satisfaction and perception (58). The satisfaction will be obtained from the result of the Telemedicine Satisfaction Questionnaire (TSQ) and a qualitative questionnaire with *ad hoc* design.

The TSQ is the most widely used assessment test in telemedicine to explore patient satisfaction such as quality of care, quality of virtual visits, and interpersonal interactions (59). The internal consistency of the TSQ was 0.93, which is considered acceptable and indicates strong correlations between the items that make up the scale (60). A Telemedicine Satisfaction Questionnaire is shown in Figure 6.

A qualitative *ad hoc* questionnaire, (Annex I) informs which includes a Likert scale (1 Dissatisfied - 5 Very satisfied), and open questions for the patient and relatives to point out the limitations, obstacles and barriers in the use of the digital physiotherapy intervention. The qualitive *ad hoc* questionnaire has been added in the Supplementary material.

A summary of the research outcomes and measurement instruments is shown in Table 1.

Data collection procedure, monitoring, and management

Subjects of EG and CG will receive an initial assessment (T0-pre) by the medical team of the referral hospitals. The initial assessment will include a clinical interview for anamnesis. In this first assessment, score data from the FIM, SPPB and SF-12 scales would be collected and registered in the research database.

On a weekly basis, EG and EC patients return to visit the physiotherapist at hospital to monitor the recovery and in the case of EG, update the digital physiotherapy programme in their device.

At the end of the 4 weeks intervention a new assessment (T1-post) will be carried out including FIM, SPPB and SF-12 to both groups. TSQ and qualitative *ad hoc* questionnaire will also be performed. Data collected will be registered in the research database. It is therefore a single-blind study, where the evaluator, the medical team of the referral hospitals, does not know the nature of the intervention.

A schedule of enrolment and randomization, interventions, and assessments is shown in Table 2.

Quantitative variables should be expressed as mean and standard deviation, while qualitative variables would be expressed as absolute value and percentage in a descriptive analysis of the results. This study protocol is designed to use the triangulation technique by combining qualitative and quantitative method (61). The results of the research shall be

TABLE 1 Outcomes and measurement instruments.

	Definition and instrument	Type of outcomes
Functional Independence	Numerical. FIM and SPPB	Main. Performed by the assessor to the patient and/or relatives
Quality of life	Numerical. SF-12 questionnaire	Main. Performed by assessor to patient and/or relatives
Adherence	Numeric. Obtained by automatic recorded of the app	Secondary. Automatic recorded of the app
Satisfaction, obstacles and barriers of use	Qualitative. Description of the satisfaction category and identification of barriers in *ad hoc* questionnaire and TSQ	Secondary. Self-reported

presented as a summary of the outcome measures, together with the estimated effect size and its precision. Statistical analysis will be performed according to the intention-to-treat principle. The results will be evaluated by comparing the differences between EG and CG with mixed linear model and *T*-test statistics to test the hypothesis that the means of two groups are or are not significantly different from each other. The outcome measures will be compared before and after the completion of the 4-week intervention. All statistical analyses will be carried out using SPSS software. Statistical significance will set at $p < 0.05$.

Discussion and implications

There is scarce research published about physiotherapy services for musculoskeletal conditions in Indian rural areas (62–64). Hence, it is difficult to gauge the existing strategies for musculoskeletal rehabilitation of communities in the country. While a few suggestions have been highlighted, there is ample scope for further research to assess the effectiveness of these strategies in the Indian context (35). Actually, children with ankle fractures have poor chances to be treated correctly in their recovery process after a fracture, especially in rural areas like Anantapur. A study conducted at a high-volume level I trauma center in India declare that children's patients are managed using Advanced Trauma Life Support (ATLS) protocol (48). Children with fractures may require surgical or conservative management according to the type of lesion. The hospitalization periods, the delay in the rehabilitation treatment, and the social and personal conditioning factors are highly heterogeneous and this situation is even more complex in rural areas due to the lack of health services and the long distances to them.

Currently, health systems are immersed in a continuous process of innovation to improve the effectiveness of health services (65, 66). This study protocol and a successfully research development, will provide knowledge about the possibility of implementing digital physiotherapy services in low resources areas allowing to define new intervention policies. This study will add more evidence in support of the use of digital physiotherapy practice as an effective tool in orthopedic rehabilitation programs.

The objective of this study is to evaluate the effectiveness of implementing the intervention in such a poor area that at present they basically only receive emergency medical care with occasional physiotherapy care.

The digital physiotherapy practice, offers a number of advantages for service users, service providers, and society (67, 68). To realize these benefits, certain conditions need to be established with both the service user and provider in mind.

Service users must be confident that they are receiving high quality, safe, and evidenced-based care; the anticipated outcomes must be equivalent to in person care; there must be a clear and easy pathway to communicate with the provider or receive a face-to-face consultation as needed; must be able to easily understand the provided information and navigate the technology; their personal health care data must store in compliance with the law and regulations; health care providers must fulfilled all required regulatory and professional requirements; and cultural preferences should be considered and respected during the digital interaction (69).

Although there are many documented advantages with digital practice models, it is important to consider the current limitations inherent with this health care delivery. Technical problems may include lack of electricity supply, poor or absent internet connectivity, and device failures. In some circumstances, may impact the ability to deploy the service. Alternative communication pathways may be required where internet connectivity is inadequate. In our digital physiotherapy service, the delivery of free mobile devices with fully charged batteries allow their use in the absence of electricity and internet connection in their homes. In addition, devices are recharged and updated during weekly visits to the referral hospital. Research members will be available to provide technical support by remote connection.

Important limitations to be taken into account are related to service users, especially with vulnerable individuals or groups, such as children and low-income areas inhabitants. Moreover, culturally specific considerations may need to be observed and limitations in reading and writing, mainly when completing the psychometric variables SF-12 and TSQ that will require the help of the local physiotherapist to complete. A further limitation like the lack of improvement in patient's condition, a low level of adherence or excessive workload during rehabilitation programs will be considered.

TABLE 2 Schedule of enrolment and randomization, interventions, and assessments statistical analysis.

Time point	Enrolment	Initial assessment	Week updates			Final assessment	Close out
	-T 1	T 0 (Baseline)	(Week 1)	(Week 2)	(Week 3)	T1 (Final evaluation)	
Enrolment and randomization							
Eligibility screen	X						
Informed consent	X						
Advance info	X						
Customized programme design	X						
Delivery of recycle devices	X						
Intervention							
Customized programme update		X	X	X	X		
Assesment							
Baseline outcomes	X						
FIM		X				X	
SPPB		X				X	
SF-12		X				X	
Qualitative *ad hoc* questionnaire						X	
TSQ						X	
Data collection		X				X	
Statistical analysis							X

Actually, in rural areas, children with ankle fracture, have poor chances to be treated correctly in their recovery process after a fracture. The development of this research is a challenge to engage health professionals in remote and low-resource areas, including of careers from Anantapur Hospitals. This research will demonstrate that cohesive relationships could be developed using communication technology through a collaborative, non-commercial process, to help one of the neediest areas of the world.

In our digital physiotherapy service, a solid relationship with local healthcare providers is essential for proper operation and would be unfeasible without the collaboration of local people. Principal investigator has been in contact with local professionals since 2017 due to previous collaborations with the Rural Development Trust (RDT) foundation. Referral hospitals physiotherapist will be in permanent contact with research team to ensure proper development.

In the author's knowledge, this research protocol is the first to examine the effect of the digital physiotherapy intervention in child patients in a low-resource area in Anantapur.

Communication technology provides the ability to create and deliver innovative services. The digital physiotherapy practice will allow us to engage health professionals in remote and low-resource areas to design an intervention with children. The inclusion of carers from Anantapur Hospitals strengthens the program's appropriateness across the area. The digital physiotherapy programme is personalized to individual needed and updated on a weekly visit to the local physiotherapist during the course of the research. This research will demonstrate that cohesive relationships could be developed using communication technology. Through a collaborative, non-commercial process, support networks could be created to help one of the neediest areas of the world.

Future research could be of longer duration and a larger sample would be necessary. It is also essential to add qualitative approach with professionals and health managements and collect sufficient data to allow comparisons with routine physical therapy care and extrapolate to other populations and health conditions.

Author's note

The research team declares that it follows the protocols on the publication of data in accordance with the provisions of Organic Law 3/2018, 5 of December on the Protection of Personal Data (LOPD), and that the data will be incorporated into a file for the purpose of carrying out this research project.

Patients EG and CG and their relatives would be informed of the rationale and procedure of the study and of the research prior to the start of the study. Each patient will sign an informed consent form and confidentiality will be guaranteed based on data protection laws and the research ethics committee. The informed consent and prior patient information has been added to the Supplementary material.

Participants has the possibility of exercising their rights of access, rectification, cancellation and opposition of their data at any time. Patients were not involved in the design, or conduct, or reporting, or dissemination parts of our research. When the study is completed the research team will send results, *via* e-mail and by meetings, of the study to all participants and also to the organizations involved.

The fundamental ethical precepts according to the Declaration of Helsinki (42) and Law 14/2007 of 3 July on Biomedical Research (43) will be respected, guaranteeing the protection and confidentiality of the data. Only researchers will have access to the data. The information collected will be associated with a numerical identification code and is the only identification of the patient for the purposes of data processing and analysis.

Ethics statement

Ethical approval was granted from the Ethics Committee for Biomedical Research of the Andalusian Regional Government (Study code: Telefisio-India, 1141-N-21). Written informed consent to participate in this study was provided by the participants' legal guardian/next of kin.

Author contributions

All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.1012369/full#supplementary-material

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The rate of acute kidney injury (AKI) alert detection by the attending physicians was associated with the prognosis of patients with AKI

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Introduction: Early identification of AKI was always considered to improve patients' prognosis. Some studies found that AKI early warning tools didn't affect patients' prognosis. Therefore, additional studies were necessary to explore the reasons.

Methods: This study was a secondary analysis of a multicenter randomized controlled trial that found electronic health record warnings for AKI did not influence patients' prognoses. Univariate, multivariate, subgroup, curve fitting, and threshold effect analysis were used to explore the association between AKI warnings detected by attending physicians and the patient's prognosis.

Results: A total of 6,030 AKI patients were included in the study. The patients were classified into two groups based on the rate of AKI alerts detected by attending physicians: the partial group (n = 5,377), and the complete group (n = 653). In comparison to the partial group, the complete group significantly decreased 14-day AKI progression, 14-day dialysis, and 14-day mortality, with adjusted ORs of 0.48 (0.33, 0.70), 0.26 (0.09, 0.77), and 0.53 (0.33, 0.84) respectively, and the complete group significantly improve the discharge to home, with an OR value of 1.50 (1.21, 1.87). When the rate of AKI alerts detected by the attending physicians as a continuity variable, we found that the rate of alerts seen by attending physicians was associated with 14-day mortality and the discharge to home, with adjusted ORs of 1.76 (1.11, 2.81) and 1.42 (1.13, 1.80). The sensitivity analysis, curve-fitting analysis, and threshold effect analysis also showed that the rate of alert seen by the attending physician was correlated with the patient's prognosis.

Conclusion: The rate of AKI alert detection by attending physician were related to the patient's prognosis. The higher the rate of AKI alert detection by attending physicians, the better the prognosis of patients with AKI.

KEYWORDS

acute kidney injury, electronic alert, AKI alert, attending physicians, prognosis

Introduction

AKI is a prevalent clinical syndrome with a significant incidence and significant mortality risk (1–4). Patients' outcomes might be vastly improved with early detection and treatment of AKI, which had been widely believed for a very long time (5–7). The clinical practice used to often be accompanied by a delayed diagnosis of AKI since there were no techniques available to warn of AKI from time to time (8). According to reports, more than 25% of hospitalized patients with a doubled creatinine level documented AKI without a symptom record, and unrecorded AKI was independently associated with a higher mortality rate (9). Excitedly, automated early warnings based on electronic medical data may effectively counter the false reports or alarms of AKI (10, 11). Unfortunately, related research showed that the automatic early warning model of AKI did not seem to improve the prognosis of patients. A study of 1,201 individuals with AKI randomly assigned them to the early warning group or the usual treatment group in a ratio of 1:1. The research discovered that an electronic alarm system for acute kidney damage did not improve hospital patients' clinical outcomes (12). A randomized controlled trial with 6,030 AKI patients, similarly demonstrated that the automated early warning model based on electronic medical data could not enhance the prognosis of AKI patients (13). Early detection of AKI might improve the patient's prognosis by changing the dosage of medication properties, avoiding nephrotoxicity, and paying attention to fluid balance, which needed the attending physician to develop a systematic and comprehensive treatment strategy for the patient (14). Therefore, the impact of AKI early warning on the patient's prognosis might be related to the rate of AKI early warning identification by the attending physicians. However, there is no relevant research to explore the relationship between the rate of AKI alert detection by attending physicians and the patient's prognosis. Therefore, this study assumed that the identification rate of AKI early alerts by the attending physician might be one of the main reasons, which influenced the effect of early warning of AKI on the prognosis of patients.

Objective

To investigate the association between the rate of AKI alerts detected by the attending physicians and the prognosis of patients with AKI including 14-day AKI progression, 14-day dialysis, 14-day mortality, and the discharge to home.

Abbreviations: NSAIDs, non-steroidal anti-inflammatory drugs; MAP, mean arterial pressure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; BUN, Blood urea nitrogen; SOFA, sequential organ failure assessment; AKI, acute kidney injury; ACEi, angiotensin-converting enzyme inhibitors; ARB, angiotensin receptor blocker; KDIGO, Kidney Disease: Improving Global Outcomes.

Methods

Study design

An exploratory study of a multicenter, randomized clinical trial on AKI early warning system.

Data source

The data was taken from the digital repository at dryad. The database is a public repository of data that authors had added to, so that their research data can be found, used for free, and cited. This URL may be used to obtain further information: https://datadryad.org/stash/dataset/doi:10.5061/dryad.4f4qrfj95 (13).

Setting

Six hospitals in the Yale New Health System in Connecticut and Rhode Island, US.

Inclusion criteria

(1) The age of the inpatient was equal to or more than 18 years old. (2) Inpatient diagnosed with AKI according to the KDIGO (Kidney Disease: Improving Global Outcomes) AKI criteria; (3) For patients admitted for multiple times, only the data of the first admission were included in the analysis.

Exclusion criteria

(1) patients who had previously been on dialysis; (2) patients who have end-stage renal disease; (3) patients who had an initial serum creatinine level of <4.0 mg/L; (4) patients who are currently receiving hospice care; and (5) patients who are scheduled to undergo kidney transplantation within the next 6 months.

The definition of AKI in electronic early warning system

A creatinine rise of 0.3 mg/dL (26.5 mol/L) within 48 h, or 1.5 times the lowest measured creatinine during the preceding seven days of hospitalization.

The electronic alert system for AKI

The AKI diagnostic algorithm (KDIGO AKI criteria) was built into the medical system, along with automated collection of key indications and generation of alerts. When medical staff open the medical system, an AKI "pop-up" warning displays and the indications for AKI diagnosis will also be shown to let the them to check the accuracy of the warning. If different medical staff access the same patient's medical system, they will be warned individually (13). Before the study, all medical staff obtained AKI and alert system education to guarantee appropriate and reliable application. Interns, residents, fellows, attending physicians, nurse practitioners, and physician's assistants, together referred to as "providers," were the only ones to see alerts. Alerts were shown when the chart was opened as long as the patient still met the criteria for AKI. Whether the provider agreed or disagreed that AKI was present, the alert was turned off for that provider for 48 h. If more than one provider used the same patient's electronic health record, the alert would show up for all of them (13).

The AKI alert detected by attending physicians

An attending physician detected an AKI warning, indicating that the AKI alert was recognized independently of individual doctors or the treatment team.

Grouping

The patients were classified into two groups based on the rate of AKI alerts detected by attending physicians: the partial group ($n = 5{,}377$) in which only partial AKI alert was detected by attending physicians, and the complete group ($n = 653$) in which 100% of AKI alert was detected by attending physicians. The partial group was used as an control to calculate the risk ratios.

The outcome indicators

14-day AKI progression (defined as an increase in AKI stage), 14-day dialysis, 14-day mortality and discharge to home.

Statistical analysis

The mean and standard ± deviation were used to describe data for continuous variables, whereas numbers and percentages were used to describe data for counting variables. Two groups were compared using the one-way analysis of variance (ANOVA) or the Kruskal-Wallis test (K-W test) based on the continuous variables' distributions and variances. We employed the chi-square test since it was appropriate for counting variables. The association between the rate of AKI alerts detected by attending physicians and the progression and prognosis of patients with AKI was identified using univariate analysis, multi-factor regression analysis, smooth curve fitting, and threshold effect analysis. EmpowerStats (http://www.empowerstats.com, X&Y Solutions, Inc, Boston, MA) and the R (http://www.R-project.org, The R Foundation) statistical software packages were used for the analysis. We judged a statistical difference between groups at $P < 0.05$ to be significant.

Results

Baseline characteristics of included patients

The clinical characteristics and laboratory findings of all patients were shown in Table 1. A total of 6,030 AKI patients were included in the study. The mean age of the partial group, and the complete group were 66.69 ± 15.35 years and 69.73 ± 15.32 years, respectively. The ratio of men to women, respectively was 2,818/2,559 and 330/323 in the two groups. The complete group was with less 14-day AKI progression, 14-day dialysis and 14-day mortality, and higher discharge to home than the complete group (Table 1).

The results of univariate analysis and multi-factor regression analysis

Univariate analysis revealed that the complete group was associated with lower 14-day AKI progression and 14-day dialysis, with the OR values of 0.35 (95% CI: 0.25 to 0.48, $P < 0.001$) and 0.16 (95% CI: 0.06 to 0.44, $P < 0.001$), and that it was not associated with 14-day mortality and discharge to home, the OR values were separately 0.75 (95% CI: 0.55 to 1.03, $P = 0.078$) and 1.17 (95% CI: 0.99 to 1.37, $P = 0.063$). In the multivariate logistic regression analysis, the following variables were adjusted: age, sex, race, Na^+, K^+, anion gap, HB, aminoglycoside, NSAIDs treatment, ACE/ARB/ACEI treatment, contrast examination, Elixhauser comorbidity score, SOFA score, loop diuretic within 24 h of AKI, alert, hospital, and duration of AKI. The multivariate logistic regression analysis revealed that the complete group could decrease the 14-day AKI progression, 14-day dialysis, and 14-day mortality, with the adjusted OR values of 0.48 (95% CI: 0.33 to 0.70, $P < 0.001$), 0.26 (95% CI: 0.09 to 0.77, $P = 0.015$), and 0.53 (95% CI: 0.33 to 0.84, $P = 0.006$), respectively; and that the complete group could increase the discharge to home, the OR value was 1.50 (95% CI: 1.20 to 1.86, $P < 0.001$) (Table 2).

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TABLE 1 The clinical characteristic of patients.

Variables	Partial group ($n = 5,377$)	Complete group ($n = 653$)	*P*-value
Age	66.69 ± 15.35	69.73 ± 15.32	<0.001
Sex (M/F)	2,818/2,559	330/323	0.366
MAP	84.72 ± 14.68	85.63 ± 14.33	0.107
Race			<0.001
African American	891 (16.57%)	55 (8.42%)	
Hispanic	575 (10.69%)	45 (6.89%)	
Other	3,911 (72.74%)	553 (84.69%)	
Diabetes	2,213 (41.16%)	271 (41.50%)	0.866
Malignancy	864 (16.07%)	67 (10.26%)	<0.001
Liver disease	789 (14.67%)	66 (10.11%)	<0.002
Congestive heart failure	2,342 (43.56%)	316 (48.39%)	0.019
CKD	2,007 (37.33%)	283 (43.34%)	0.003
COPD	1,790 (33.29%)	274 (41.96%)	<0.001
Alert	2,734 (50.85%)	325 (49.77%)	0.604
Bicarbonate	23.50 ± 5.18	25.58 ± 5.31	<0.001
BUN	31.88 ± 19.11	33.46 ± 18.01	<0.001
HB	10.68 ± 2.34	11.27 ± 2.21	<0.001
Anion gap	12.69 ± 4.30	9.95 ± 3.85	<0.001
K^+	4.25 ± 0.64	4.18 ± 0.66	0.005
Na+	138.12 ± 5.29	138.45 ± 5.09	0.012
eGFR	61.59 ± 31.76	54.93 ± 29.39	<0.001
Elixhauser comorbidity score	6.34 ± 2.87	6.13 ± 2.62	0.216
SOFA score	2.50 ± 2.13	2.06 ± 1.82	<0.001
Any diuretic treatment	1,496 (27.82%)	178 (27.26%)	0.761
Nephrology consult	1,317 (24.49%)	120 (18.38%)	<0.001
Aminoglycoside treatment	38 (0.71%)	2 (0.31%)	0.234
ACEI/ARB treatment	923 (17.17%)	170 (26.03%)	<0.001
NSAIDs treatment	547 (10.17%)	53 (8.12%)	<0.001
Contrast examination	205 (3.81%)	12 (1.84%)	0.011
Duration of alert	3,790 (70.49%)	557 (85.30%)	<0.001
≤48 h	3,790 (70.49%)	557 (85.30%)	
48 h ∼7 days	1,334 (24.81%)	88 (13.48%)	
>7 days	253 (4.71%)	8 (1.23%)	
14-day AKI progression	905 (16.83%)	43 (6.58%)	<0.001
14-day dialysis	195 (3.63%)	4 (0.61%)	<0.001
14-day mortality	491 (9.13%)	46 (7.04%)	0.077
Discharge to home	2,650 (49.28%)	347 (53.14%)	0.063

CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; MAP, mean arterial pressure; SOFA, sequential organ failure assessment; NSAIDs, non-steroidal anti-inflammatory drugs.

The results of subgroup analysis of multi-factor regression analysis

In this study, subgroup analysis was conducted based on whether the duration of the alert was more than 2 days and whether the patients received alert care or usual care. Alerts care was displayed each time the chart was opened, provided the patient continued to meet the criteria for AKI. Therefore, the longer duration of the alert might reflect the period of AKI. In comparison to usual care, the alert care featured an option to add AKI to the patient's issue list and a link to an AKI order set, which included choices for blood and urine testing as well as renal imaging but was restricted to minimal-risk tests and operations (that is, intravenous fluid administration was not included). When the rate of AKI alert seen by the attending physician as a continuous variable, it was found that the duration

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TABLE 2 Univariate and multivariate logistic regression analysis.

Exposure	Unadjusted OR, (95% CI), *P* Value	Adjusted OR, (95% CI), *P* Value
14-day AKI progression		
Alert seen by attending physician	0.85 (0.68, 1.08), 0.183	1.34 (0.97, 1.85), 0.077
Alert seen by attending physician		
Partially	Reference	Reference
Completely	0.35 (0.25, 0.48), <0.001	0.48 (0.33, 0.70), <0.001
14-day dialysis		
Alert seen by attending physician	0.99 (0.62, 1.58), 0.967	1.99 (0.96, 4.12), 0.065
Alert seen by attending physician		
Partially	Reference	Reference
Completely	0.16 (0.06, 0.44), <0.001	0.26 (0.09, 0.77), 0.015
14 day-mortality		
Alert seen by an attending physician	1.77 (1.33, 2.35), <0.001	1.76 (1.11, 2.81), 0.017
Alert seen by an attending physician		
Partially	Reference	Reference
Completely	0.75 (0.55, 1.03), 0.078	0.53 (0.33, 0.84), 0.006
Discharge to home		
Alert seen by attending physician	0.81 (0.68, 0.96), 0.013	1.42 (1.13, 1.80), 0.003
Alert seen by attending physician		
Partially	Reference	Reference
Completely	1.17 (0.99, 1.37), 0.063	1.50 (1.21, 1.87), <0.001

Adjusted variables: Age, sex, race, Na+, K+, anion gap, HB, aminoglycoside, NSAIDs treatment, ACE/ARB/ACEI treatment, contrast examination, Elixhauser comorbidity score, SOFA score, any diuretic post 24 h after AKI, alert, hospital, and duration of alert.

of the alert >2 days, the higher the alert seen by the attending physician, the higher the patient's 14-day mortality, with an OR value 2.67 (95% CI: 1.10 to 6.46, $P = 0.029$); While when the duration of alert ≤2 days, the higher the alert seen by attending physician, the higher the patient's discharge to home, with an OR value of 1.53 (95% CI: 1.18 to 1.99, $P = 0.001$); When the patients received usual care, the higher the alert seen by attending physician, the higher the patient's 14-day AKI progress and 14-day mortality, with OR values of 1.78 (95% CI: 1.05 to 3.00, $P = 0.031$) and 2.81 (95% CI: 1.46 to 5.44, $P = 0.002$), respectively. And when the patient received an alert, the higher the alert was seen by the attending physician, the higher the discharge to the home of the patient. When the rate of AKI alert seen by attending physical as a classified variable, it was found that when the duration of alert ≤2 days, the complete group significantly reduced 14-day AKI progress and 14-day mortality, with ORs 0.50 (95% CI: 0.28 to 0.89, $P = 0.018$) and 0.58 (95% CI: 0.34 to 0.99, $p = 0.047$), respectively. No matter the duration of alert ≤2 days or >2 days, the complete group significantly improved the discharge to home, with ORs of 1.54 (1.54 (95% CI: 1.21 to 1.95, $P < 0.001$) and 1.82 (1.82 (95% CI: 1.03 to 3.21, $P = 0.038$), respectively. When the patient received an alert, the complete group significantly reduced the 14-day mortality of the patient, with an OR value of 0.44 (95% CI: 0.22 to 0.87, $P = 0.018$). Regardless of whether the patient was with usual care or alert, the complete group significantly improved discharge to home, with ORs of 1.55 (1.55 (95% CI: 1.14 to 2.11, $P = 0.005$) and 1.59 (95% CI: 1.17 to 2.17, $P = 0.003$), respectively (Table 3).

The results of curve fitting and threshold effect analysis

Using curve fitting and threshold effect analysis, it was shown that when the alert seen by the attending physician <10%, the 14-day AKI Progression increased dramatically. However, when the alert seen by an attending physician ≥10%, the 14-day AKI Progression did not rise significantly. 14-day dialysis rose when the alert was seen by the attending physician <45%; conversely, 14-day dialysis reduced dramatically when seen by the attending physician ≥45%. When the alert was seen by the attending physician <30%, the 14-day mortality rose considerably; however, the 14-day mortality did not increase when the alert was seen by the attending physician ≥30%. When an alert was seen by the attending physician <29%, discharge to home dropped dramatically; While the proportion of alerts seen

TABLE 3 Subgroup analysis of multivariate logistic regression analysis.

Exposure	Alert seen by attending physician[a] Adjusted OR(95% CI)	*P*-value	Alert seen by attending physician[b] Adjusted OR(95% CI)	*P*-value
14-day AKI progression				
Duration of alert				
≤2 days	1.19 (0.71, 2.01)	0.504	0.50 (0.28, 0.89)	0.018
>2 days	1.47 (0.88, 2.45)	0.146	0.68 (0.38, 1.21)	0.186
Alert				
Usual care	1.78 (1.05, 3.00)	0.031	0.58 (0.32, 1.03)	0.062
Alert	1.05 (0.63, 1.75)	0.845	0.61 (0.35, 1.06)	0.082
14-day dialysis				
Duration of alert				
≤2 days	2.05 (0.49, 8.54)	0.324	0.63 (0.07, 5.38)	0.676
>2 days	2.53 (0.95, 6.77)	0.065	0.33 (0.08, 1.27)	0.106
Alert				
Usual care	2.72 (0.84, 8.78)	0.094	0.32 (0.06, 1.68)	0.180
Alert	2.07 (0.69, 6.23)	0.197	0.29 (0.06, 1.51)	0.142
14-day mortality				
Duration of alert				
≤2 days	1.61 (0.91, 2.84)	0.102	0.58 (0.34, 0.99)	0.047
>2 days	2.67 (1.10, 6.46)	0.029	0.54 (0.20, 1.45)	0.222
Alert				
Usual care	2.81 (1.46, 5.44)	0.002	0.69 (0.37, 1.28)	0.239
Alert	1.28 (0.65, 2.49)	0.472	0.44 (0.22, 0.87)	0.018
Discharge to home				
Duration of alert				
≤2 days	1.53 (1.18, 1.99)	0.001	1.54 (1.21, 1.95)	< 0.001
>2 days	1.25 (0.74, 2.09)	0.405	1.82 (1.03, 3.21)	0.038
Alert				
Usual care	1.25 (0.89, 1.74)	0.196	1.55 (1.14, 2.11)	0.005
Alert	1.65 (1.20, 2.28)	0.002	1.59 (1.17, 2.17)	0.003

[a]Alert seen by attending physician as a continuity variable. [b]Alert seen by attending physician as a classification variable (the completely group vs. partially group, the partially group as a reference), the partial group was used as an control to calculate the risk ratios. Adjusted variables (without the subgroup analysis variables themselves): Age, sex, race, Na+, K+, anion gap, HB, aminoglycoside, NSAIDs treatment, ACE/ARB/ACEI treatment, contrast examination, Elixhauser comorbidity score, SOFA score, any diuretic post 24 h after AKI, alert, hospital, and duration of alert.

by the attending physician ≥29%, the proportion of patients discharged to their homes increased (Table 4 and Figure 1).

Discussion

This study discovered that the rate of alert seen by attending physicians is closely related to the prognosis of AKI patients. The higher the rate of alert seen by the attending physician, the lower the 14-day AKI progress, 14-day dialysis, and 14-day mortality of AKI patients, and the higher the discharge to home. Especially in the early stage of AKI, the higher the rate of alert seen by the attending physician, the better the prognosis of patients.

Currently, there were numerous research on AKI-related early warning models, but most of them had limited clinical importance due to their small sample size and lack of efficient external validation (15–17). The early warning model based on electronic medical data was capable of constantly validating and enhancing the model's prediction capacity as additional patients are added. Secondly, electronic medical records contained a wealth of clinical data, including demographic characteristics, disease characteristics, and related laboratory test results of patients, which made the alert model more reliable. More importantly, the electronic medical record-based prediction model was implanted into the electronic medical record system, allowing it to predict AKI automatically, and it was beneficial to guiding clinical practice (18). Unfortunately, two substantial studies on AKI early warning based on electronic medical records had shown that they cannot improve patients' prognoses (12, 13). We believed the probable explanations are as follows:

TABLE 4 The results of threshold effect analysis.

Exposure	Unadjusted OR, (95% CI), *P*-value	Adjusted OR, (95% CI), *P*-value
14-day AKI progression		
<0%	Inf. (50426.53, inf.), < 0.001	Inf. (2908.74, inf.), <0.001
≥10%	0.43 (0.32, 0.56), < 0.001	0.75 (0.51, 1.09), 0.131
14-day dialysis		
<45%	56.38 (12.66, 251.04), <0.001	43.38 (6.56, 286.89), <0.001
≥45%	0.06 (0.02, 0.23), <0.001	0.11 (0.02, 0.64), 0.014
14-day mortality		
<30%	557.22 (85.60, 3627.33), < 0.001	183.23 (17.39, 1930.64) <0.001
≥30%	0.69 (0.44, 1.09), 0.110	0.51 (0.24, 1.08), 0.078
Discharge to home		
<29%	0.06 (0.03, 0.15), <0.001	0.30 (0.11, 0.85), 0.023
≥29%	1.61 (1.23, 2.11), <0.001	2.22 (1.51, 3.27), <0.001

Alert seen by attending physician as a continuity variable in the threshold effect analysis.

The primary distinction between the alert group and the usual care group was that the alert group merely provided an AKI warning to on-duty physicians, but it did not mandate action based on an AKI warning, which might lead to the delay of AKI consultation and deterioration of patient prognosis (19). Unfortunately, this was not enough for the management of AKI. To effectively prevent or halt the course of AKI, a variety of systematic measures must be taken, such as modifying the dosage of a medication, avoiding addiction, and monitoring fluid balance, etc., (14). However, on-duty doctors were unable to complete a continuous and systematic AKI treatment, which might be the fundamental reason why electronic medical record alerts couldn't considerably improve the prognosis of AKI patients.

In the existing healthcare system, only the attending physician provided a systematic approach to AKI treatment. The only way to avoid the development of AKI and improve the prognosis of patients with AKI was to send AKI alerts continuously and effectively to attending doctors, who then constructed or changed the AKI treatment strategy dynamically based on the AKI alert (20).

In this study, we found that the higher the duration of alert ≤2 days, the higher the rate of alert seen by the attending physician, and the better the prognosis of patients. attending doctors could get an early warning of AKI and implement relevant therapies as soon as feasible, which might dramatically improve patients' prognoses. In the early phase of AKI (21), particularly within the first 48 h of AKI, by actively taking relevant treatment measures, such as maintaining hemodynamic stability, avoiding the continued use of nephrotoxic drug properties, and providing relevant renal protection, further deterioration of renal function and the worsening of patients' prognoses can be prevented.

In addition, this research identified a threshold relationship between the rate of alerts seen by the attending physician and the prognosis of patients. The thresholds for 14-day AKI progress, 14-day dialysis, 14-day mortality, and discharge to home are 10, 45, 30, and 29% respectively. Therefore, the rate of AKI alert by the attending physician should be improved as much as possible. It was unrealistic to let the attending doctor get all the alerts. The rate of AKI alert seen by the attending physician should be one of the characteristics included in the future early warning model, and our research may provide some reference for it.

Monique conducted a comprehensive analysis of articles related to clinical decision support systems and found that 57% of clinical decision support systems could affect the behavior of doctors, which in turn affected the prognosis of patients (22). At the same time, the rate of AKI alert seen by the attending physician would affect the treatment time of doctors after the occurrence of AKI to a certain extent. A prospective observational study by Kristen found that 28.7% of patients in the alert group received interventions, such as fluid therapy, diuretic, or vasopressors, and the interventions were significantly more effective than the control (17). Within 8 h= of the AKI notice, patients in the alert group had substantially higher rates of renal function recovery to baseline than patients in the control group (23). This showed that if the attending physician can receive and deal with the alert records in time, it will have a favorable impact on the prognosis of patients with AKI. Therefore, improving the awareness rate of AKI alerts by attending physicians was the primary key to ensuring the prognosis of patients with AKI.

Application value of the research

Electronic medical records contained a wealth of clinical data. This study discovered that the electronic medical record-based prediction model was implanted into the electronic medical record system, allowing it to predict AKI automatically,

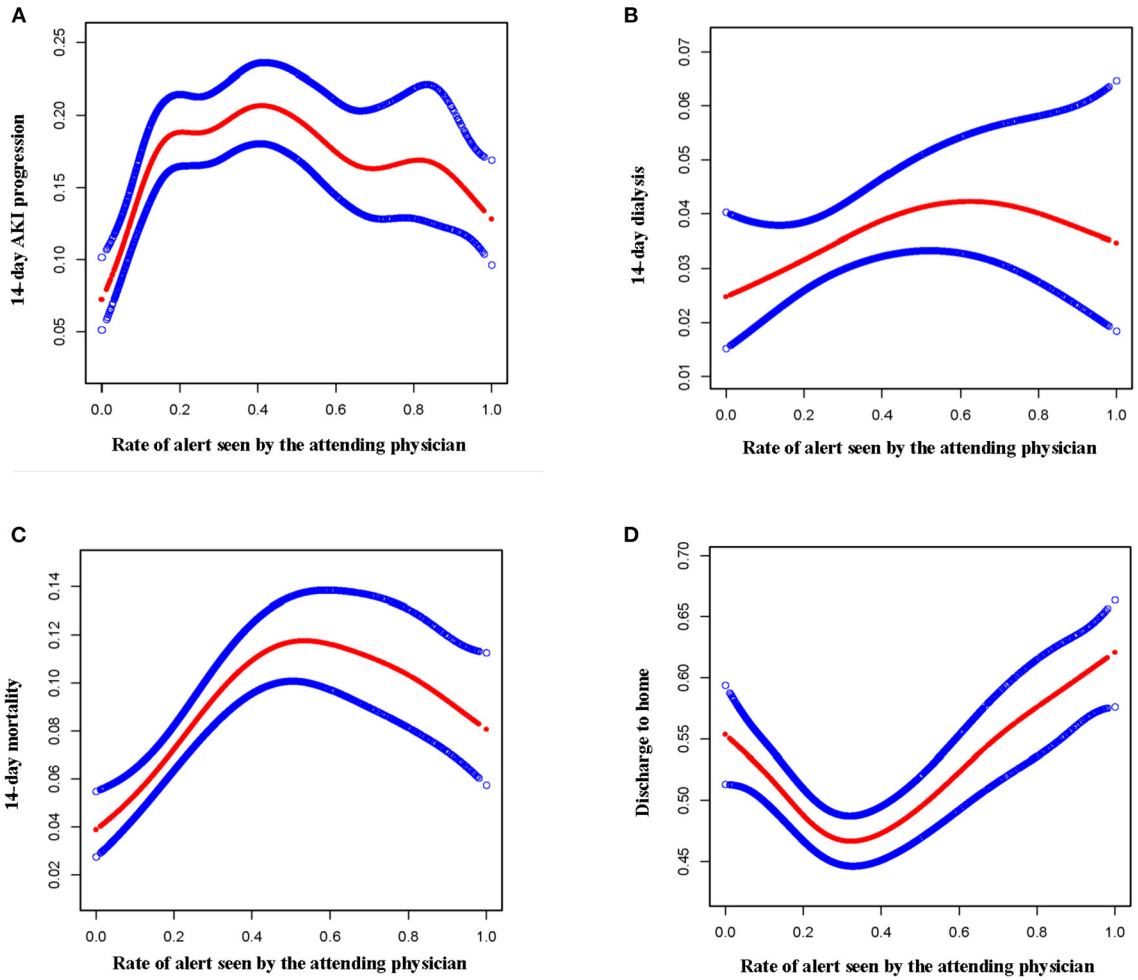

FIGURE 1
The results of curve fitting analysis. **(A)** The relationship between alert seen by attending physician and 14-day AKI progression. **(B)** The relationship between alert seen by attending physician and 14-day dialysis. **(C)** The relationship between alert seen by attending physician and 14-day mortality. **(D)** The relationship between alert seen by attending physician and the discharge to home.

and it was beneficial to guiding clinical practice. The rate of alert seen by the attending physicians was closely related to the prognosis of AKI patients. Attending doctors could construct or change the AKI treatment strategy dynamically based on the AKI alert. Especially in the early stage of AKI, they could get an early warning of AKI and take actively relevant treatment measures to provide relevant renal protection. In addition, this research identified a threshold relationship between the rate of alerts seen by the attending physician and the prognosis of patients. These results could provide some references for future research on related early warning models.

Limitations of the study

This research belongs to the second retrospective analysis of data; hence the result of this study should be validated by subsequent prospective investigations. Due to the fact that creatinine was used as the only indicator of AKI definition in this electronic early warning system and urine volume was ignored, the population of people with AKI in this study might be underestimated, and the research could not rule out the impact of different clinical departments, such as critical care or surgery, as well as the type of AKI (prerenal, renal, or posterior) on the progression or prognosis of AKI patients, introducing the possibility of bias into the findings of this study. The influence of the rate of AKI alert detection by attending physicians on the alteration of medical behavior and the choice of treatment method needs to be further validated, and the causal link between them is required to be further proven. The role of a clinical nephrologist in AKI alert was not investigated in this research. If an AKI alert was sent to a clinical nephrologist, the patient's clinical prognosis might be improved.

Conclusion

In conclusion, the study revealed a correlation between the rate of AKI alert detection by the attending physician and the prognosis of the patient. The prognosis of patients with AKI improves with a greater probability of AKI alarm identification by the attending physician. The better the prognosis of patients, particularly in the early stages of AKI, the greater the rate of alertness seen by the attending physician. They may get an early warning of AKI and adopt actively appropriate therapeutic steps to successfully prevent or arrest the progression of AKI, particularly in the early stages of AKI. In clinical practice, we must thus increase the proportion of AKI alert detection by the attending physician. Whether it is the nursing team or the doctor team, if an AKI alert is detected, they should immediately notify the attending physician so that the attending physician can grasp the progression of the patient's condition, which makes the electronic alarm system a vital tool for assisting doctors with diagnosis and treatment.

Data availability statement

The datasets presented in this study can be found in online repositories. The names of the repository/repositories and accession number(s) can be found below: https://datadryad.org/stash/dataset/doi:10.5061/dryad.4f4qrfj95.

Ethics statement

Ethical review and approval was not required for the study on human participants in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Author contributions

YS and HW participated in the research design, the writing of the manuscript, and data analysis. LB, YW, and LZ participated in data analysis. XZ and J-hL participated in the improving and revising of the paper. H-hP and Z-hB provided substantial advice in designing the study and assisting in the division of labor, writing, and revising the paper. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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Decentralized clinical trials (DCTs): A few ethical considerations

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Decentralized clinical trials (DCTs) are studies in which the need for patients to physically access hospital-based trial sites is reduced or eliminated. The CoViD-19 pandemic has caused a significant increase in DCT: a survey shows that 76% of pharmaceutical companies, device manufacturers, and Contract Research Organizations adopted decentralized techniques during the early phase of the pandemic. The implementation of DCTs relies on the use of digital tools such as e-consent, apps, wearable devices, Electronic Patient-Reported Outcomes (ePRO), telemedicine, as well as on moving trial activities to the patient's home (e.g., drug delivery) or to local healthcare settings (i.e., community-based diagnosis and care facilities). DCTs adapt to patients' routines, allow patients to participate regardless of where they live by removing logistical barriers, offer better access to the study and the investigational product, and permit the inclusion of more diverse and more representative populations. The feasibility and quality of DCTs depends on several requirements including dedicated infrastructures and staff, an adequate regulatory framework, and partnerships between research sites, patients and sponsors. The evaluation of Ethics Committees (ECs) is crucial to the process of innovating and digitalizing clinical trials: adequate assessment tools and a suitable regulatory framework are needed for evaluation by ECs. DCTs also raise issues, many of which are of considerable ethical significance. These include the implications for the relationship between patients and healthcare staff, for the social dimension of the patient, for data integrity (at the source, during transmission, in the analysis phase), for personal data protection, and for the possible risks to health and safety. Despite their considerable growth, DCTs have only received little attention from bioethicists. This paper offers a review on some ethical implications and requirements of DCTs in order to encourage further ethical reflection on this rapidly emerging field.

KEYWORDS

DCTs, Research Ethics, Bioethics, healthcare, digitalization

Introduction

Decentralized clinical trials[1] (DCTs) make use of digital technologies and other methods to enable access of patients to clinical research, remote data collection and monitoring, and communication between the investigators and participating subjects.

In a DCT, enrolled patients are no longer required to frequently travel to a healthcare facility in order to participate in the trial, as they are able to take part from their normal living environment. The center of gravity of the trial therefore shifts from the study site (i.e., the hospital) to the patient's home. Thus, DCTs can adapt to patients' routines and allow them to participate regardless of their geographical position.

DCTs can include the direct delivery of investigational medicinal products (IMP) to participating subjects, laboratory examinations and/or instrumental tests carried out in centers other than the trial site and close to the patient's home, and home visits by healthcare professionals. This study model typically involves use of Internet, smartphones and their applications, telemedicine platforms, social media and similar technologies at different stages of the trial (patients' enrolment and consent, clinical checks, remote data collection, monitoring and source data verification).

In DCTs, remote data collection can be active or passive. When it is active, the patient is required to enter data using one or more devices, whereas when it is passive the data are logged by the device/s used in the study (e.g., wearables or sensors) without active intervention by the patient. In both cases, patient involvement in data collection may actually be more active than with conventional participation at a healthcare facility. Furthermore, by means of electronic instruments, DCTs allow constant contact between the patient and research staff.

DCTs are not an all-or-nothing method, as the decentralization can be of varying degrees. The use of technology does not exclude personal interaction or the possibility of the patient traveling to a healthcare facility and participating in the trial under certain circumstances. More specifically, a DCT may include procedures that cannot be carried out in a home environment. Many DCTs are therefore in hybrid form, combining home-based, traditional on-site visits, and study procedures.

DCTs are especially useful in cases that make travel difficult for the patient, either for clinical conditions (e.g., neuromuscular diseases), or logistical barriers, when research sites are far from patient's home (as often occurs in case of rare diseases). Decentralized studies are particularly suitable for low- to medium-complexity conditions, and for studies that are not excessively long.

In light of the above, it should be noted that currently, in many cases, DCTs do not replace conventional trials. Rather, they are supplementary to them.

The therapeutic areas for which DCTs are most readily applicable are those in which telemedicine is most advanced like diabetes, neurorehabilitation, cardiovascular diseases, pulmonary diseases and, more recently, COVID-19.

One of the main challenges in the implementation of DCTs (in Europe and worldwide) at the current time regards the fact that the existing regulatory frameworks were devised with conventional clinical trials in mind. Besides, there are still very few documents and guidelines on the planning, design and evaluation of DCTs and decentralized methods (1), and this is in some ways surprising since DCTs are not absolutely a novel mode.

Indeed, the earliest studies on the feasibility of "Internet trials" date back to 2003. Since then, there has been a continuous crescendo, for example the first "Trial over the Internet" was patented in the USA in 2007. In 2011, Pfizer conducted the first fully-decentralized randomized study titled "Research on Electronic Monitoring of Overactive Bladder Treatment Experience, REMOTE" (2, 3), the results of which were published in 2014. In this trial, the Internet was used for subject enrolment, the administration of online screening questionnaires and provision of electronic outcomes diaries, and the investigational medicinal product was delivered to the patients' homes.

Over the last decade, all major pharmaceutical companies have conducted DCTs. According to a survey carried out by the consulting company McKinsey in December 2019, immediately before the pandemic, 38% of representatives of the pharmaceutical industry and contract research organizations (CROs) anticipated that the majority of their activities would be comprised of "virtual" studies and 48% anticipated conducting trials in which most of the activities would be carried out at patients' homes. When McKinsey asked the same questions 1 year later, the answers were 100 and 89%, respectively (4).

It should therefore be pointed out that the COVID-19 pandemic has stimulated a considerable increase in DCTs: a survey conducted by Oracle (5) showed that, already in the 1st year of the pandemic, 76% of pharmaceutical companies, device manufacturers and CROs had adopted decentralized techniques. Of these, 7% used fully decentralized methods. Actually, COVID-19 has provided a significant proof of concept (PoC) regarding clinical trials in a context of emergency and, in particular, on the integration of decentralized approaches.

In order to support the on-going process, in March 2020 the FDA issued in the United States specific operational guidelines covering many of the challenges posed by the decentralization of activities in clinical studies, with its "Guidance for Industry, Investigators, and Institutional Review Boards" (6).

On 4 February 2021, the European Commission published the fourth version of its guidelines on the management of

1 This paper only refers to DCTs on medicinal products.

clinical studies during the COVID-19 pandemic, i.e. "Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) Pandemic." Despite the temporary nature of these guidelines, which were designed for the management of clinical trials during the health emergency, they contain key information for the implementation of DCTs. Moreover, they include the authorization of procedures such as the delivery of investigational products at patient's home, home-based visits, use of community-based diagnostic facilities, and remote monitoring of collected data / source data verification (7). Now the question is whether, which and how those methods authorized by the central European and local authorities during the emergency will pass from derogation to rule. In certain European countries, in recent years, the competent institutions have started to deal with the matter starting from the local regulatory framework, in order to provide guidance to investigators and sponsors (8, 9).

It is crucial to carry out feasibility studies in order to identify the opportunities and the challenges from a regulatory standpoint and to favor the authorization and implementation of DCTs (10).

The opportunities appear to be numerous. It has been suggested that DCT approaches can be justified and particularly suitable for trials with chronic diseases, rare diseases, immobile participants, self-administrable IMP, lower safety risk profile, and confirmatory clinical trials. Particularly in rare disease studies, the changes necessitated by the COVID-19 pandemic have provided an opportunity to become a standard approach. Although some DCT projects were developed even earlier in this area, during COVID-19 they forcibly entered clinical practice offering advantages in terms of patient burden, practicality, inclusion and data quality (11).

However, not all clinical trials are suitable for decentralization and hybrid solutions appear as the more reasonable scenario in the very majority of cases. Future research will be needed to demonstrate, for example, whether studies on DCTs or hybrid DTCs are particularly suitable for carrying out prevention or screening studies compared to treatment clinical studies.

The risks and benefits of DCTs

The possibility of decentralizing studies affords a number of opportunities, with ethical and clinical implications (12–16). The potential advantages of DCTs include:

- The possibility of enrolling subjects who are unlikely to be able to take part in conventional trials, because their home is a long way from a healthcare facility, or because of physical difficulties in reaching the facility. Facilitated access allows a higher number of patients to be eligible for participation. This aspect is particularly important, especially in research on rare diseases, because it favors inclusion, and improves the representativeness and generalisability of the results.
- More convenient conditions for subjects, with less avoidable discomfort and suffering, in particular for frail subjects. DCTs do away with waiting times, contact with the suffering of other patients, in some cases hospitalization, possible exposure to pathogens in hospital settings that can cause complications.
- Greater autonomy for the participating subject, who can remain at home at least for part of the study procedures.
- Greater convenience for families and caregivers.
- The possibility of collecting "real-time" and "real-world data," in the subjects' usual living environment and therefore avoiding potential bias resulting from assessments performed in *ad hoc* facilities.
- The possibility of evaluating endpoints difficult to measure with conventional studies, thanks to the ways in which the data can be collected.
- Time-saving.
- Cost-saving.

Although some studies show an increase in patient retention rates in DCTs and better compliance with procedures than in conventional trials (due to the home setting, use of electronic reminders, an overall less burdensome participation etc.), there is no full consensus regarding these aspects in the literature (17, 18).

Nevertheless, despite considering the significant benefits decentralized trials can offer, it is also necessary to mention disadvantages (some of them may occur in CTs as well). Potential barriers, limitations and risks associated with the implementation of DCTs (19–24), include:

- Potential amplification of inequalities. Groups with reduced access to technologies could be penalized. This aspect should be considered both in relation to the ability to use devices and the availability of the equipment required for connection, i.e., access to a stable connection (which may depend on both economic and geographical factors) and of supporting devices.
- Partial application (DCTs are not suitable for all medical conditions).
- Remote data collection can favor quality, thanks to automation of the processes involved. However, the quality of collection can be jeopardized as it takes place in a less "protected" setting than a research facility. This may lead to the risk of technical failures when digital devices are used. Therefore, deterioration in data quality at the source and during transmission are possible.
- Risks regarding the validity and reliability of the data collected. One example is the "6-min walk test" used to assess the effects of treatments aimed at improving walking

capacity in patients with peripheral artery disease. In order for the data to be reliable, the test must be performed by making the patient walk on a rigid and flat surface, and of accurately documented length. However, when the test is carried out by a patient at home, it may be troublesome to ensure that the surface meets the requirements, is obstacle-free and precisely measured (25). This inconsistency could have an impact on the reliability of the data. Although mistakes and inaccuracy may occur in conventional trials as well, factors that may jeopardize validity and reliability in DCTs should be properly identified and addressed.

- A methodological bias may arise from the combined use of clinical measurements performed in a hospital or home setting. A typical example is that of arterial blood pressure measurement.
- Some clinical checks may be less accurate if conducted remotely. This can lead to potential issues for the wellbeing and safety of patients.
- Risks regarding the protection of personal data, also due to the increased number of actors involved (e.g., couriers for delivery of the investigational product, providers for home assistance and digital services, etc).
- Data breach risks.
- Risk of weakening the physician-patient relationship.
- Potential isolation of the trial subject, who does not have opportunities to meet and share experiences with other patients taking part in the same study.

Some requirements

Information and consent

Given their nature, DCTs often involve the use of e-consent of various forms.

E-consent has advantages over the conventional paper form, for example it can be filed easily, retrieved rapidly, updated readily and promptly shared amongst the staff involved. Among relevant aspects, it is important to ensure that the systems used for e-consent have proportionate security levels, and safeguards regarding confidentiality are in place.

Special care must be dedicated to the clarity and completeness of the information provided to the patient. In the case of fully-digital consent, the validity of the signature must be guaranteed from a legal perspective as well. It must be borne in mind that electronic signatures, particularly Advanced Electronic Signatures (AdESs) require identification and registration procedures that could be complicated for some subjects: this could hamper, or even preclude, the access of certain population groups.

If the personal relationship with the healthcare professionals is important in the information and conventional consent procedure, it is even more so in DCTs. Indeed, as DCTs are conducted remotely, personal contacts are infrequent (or completely absent): it is therefore important to provide chances for direct exchange and communication during the initial stage and whenever the need arises. In this perspective, face-to-face communication should take place between the investigator and the potential trial participant. If this discussion takes place in a digital / virtual mode, this should be generally performed in real time where the parties are able to see and communicate with each other *via* audio and video, and to ask questions.

Access

DCTs can increase the number of individuals eligible for a trial by removing the logistical and geographical barriers but, at the same time, they can increase inequalities in access, penalizing individuals who do not possess the technologies or the skills required. The availability of technologies should not constitute an exclusion criterion and the necessary equipment should be provided by the sponsor.

Participants and, if necessary, also their caregivers, should be provided not only with initial training on using the devices, but also with on-going support throughout the progress/evolution/unrolling of the DCT.

Data collected, transmitted, and analyzed

In general, special care must be taken when applying the basic criteria that pertain to all data processing:

- Lawfulness, fairness, and transparency. Data must be processed lawfully, fairly, and in a transparent manner in relation to the data subject.
- Restriction of the purpose: data must be processed for specified, explicit, and legitimate purposes. They must also be processed in a manner that is compatible with such purposes.
- Minimization: personal data must be adequate, relevant and restricted to the purposes for which they were collected.
- Accuracy and updating: data must be accurate and up-to-date. There must be procedures in place for the timely correction or erasure of inaccurate data.
- Restriction of storage: data must be stored in a form that permits the identification of the data subjects only for as long as is strictly necessary to fulfill the purposes for which they were processed, unless that patient has explicitly consented to reuse the data for future research.
- Integrity and confidentiality: personal data must be guaranteed adequate security.
- Accountability: the controller must ensure that the data are processed in an appropriate manner.

Data must be: Attributable, Legible, Contemporaneous (i.e., recorded at the time the activities are carried out), Original (or true to the original), Accurate (ALCOA) (26).

In order to allow the reuse of existing data and avoid useless duplications, data should also be made Findable, Accessible, Interoperable and Reusable (FAIR) (27).

The accuracy of data recording is particularly important in the case of active data collection by the patient. Therefore, the subjects taking part in trials must be given adequate instructions on this matter.

There must be commensurate procedures in place to ensure the integrity of the data during their transmission and management. Special attention must be given to the fact that the data stored on personal devices can be easily linked to other personal data (contacts, location, microphone, video camera, purchases, etc.). Therefore, there must be adequate procedures in place to guarantee the effective protection of all personal data. The risks of unintentional data disclosure or deliberate breach of privacy go well beyond the scope of the DCTs. For example, health-related information can result in discrimination in the workplace. In order to reduce this kind of risk, it may be useful to use distributed ledgers, decentralized databases and blockchain technology (28, 29).

The final use of the data must also be strictly governed: DCTs favor the collection of a multitude of real-world data, which in some cases go beyond the scope of the study. Therefore, it is necessary to prevent their use in contexts other than those envisaged by the study. It is also necessary to clearly establish which data may be used after the end of the DCT. Patients must be adequately informed of this possibility and given the chance to grant or refuse their consent to such use.

Study protocol flexibility

Preferences vary from one person to another. For example, some may prefer direct personal interactions, without the mediation of technology.

Flexible research programmes can make it possible to not overlook differences in personal preferences. To this end, it would be useful to give patients the possibility to provide regular feedback on their experience regarding the trial. However, flexibility may also introduce the risk of methodological biases (see what previously reported on arterial blood pressure).

Provision of the IMP

In planning a clinical trial, the sponsor and investigator may consider whether the IMP is suitable for administration at home, and if the appropriate storage conditions of the IMP can be met. In DCTs, the medicinal product can be delivered to the subject's home, usually by courier, under supervision and responsibility of the pharmacy of the healthcare facility and the investigator. In addition to rigorous protection of privacy, the distribution system must guarantee quality and efficiency, particularly for medicinal products requiring special storage and transportation conditions (for instance: maintenance of the cold chain).

Return of result

Patients generally wish to know the results of the clinical investigations in which they are involved as soon as possible. In DCTs, given the way the studies are conducted, patients may be even more eager to find out the results quickly.

Among other aspects, special attention must be paid to the occurring of any incidental findings, in other words, unexpected results that are not related to the study and are not intentionally sought. In the case of incidental findings that are clinically relevant (for prevention and therapy) and actionable, it is the physician's duty not to overlook them: therefore, precise procedures must be adopted for the management of any incidental findings (30–32).

Discussion

The DCT approval process deserves special attention, making the role of Ethics Committees (ECs) crucial.

The procedures for conducting DCTs are such that the current regulatory framework may be only partially adequate. There are no detailed documents or reference standards concerning the role of ECs in the oversight and evaluation of DCTs (33). These bodies may encounter difficulties when reviewing studies that involve significant complexities due to the innovative approaches employed. Information on the decentralized activities should therefore be clear and justified on a case-by-case basis in the clinical trial protocol (34). In a simulated survey on members of European ECs called on to review a DCT protocol, it was observed that the quality, safety, and organization of the DCT were perceived as being more problematic than those of conventional clinical studies. For instance, the members expressed concerns regarding the validity and accuracy of the data, in case the participating subjects were responsible for measuring and inputting them (1). Although the criteria used by ECs when analyzing a decentralized clinical study are the same as those for conventional studies, the application of such criteria to the specific cases can be more complex. Moreover, EC members may require supplementary information in order to consider, for example, whether the procedures for implementing the electronic informed consent process are suited to guaranteeing a true personal data communication, comprehension, and protection process.

Aspects examined by ECs when reviewing new studies must be considered in the light of the DCTs as well. This scenario may be troublesome because of the numerous peculiarities DCTs show. One example regards the assessment of site suitability.

DCTs are coordinated by trial sites, whose suitability can be assessed using the conventional criteria. However, DCTs are conducted at the subjects' home, which makes it difficult, if not impossible, to guarantee *a priori* that each home is fully suited to the conduct of the DCT in question.

Another example regards the way in which devices are used. Most (but not necessarily all) the devices used in DCTs are classified as medical devices. The medical devices must be marked pursuant to regulations and used in compliance with their intended use. If this were not the case, the DCT would qualify as a clinical investigation on a medical device. This actually creates a intertwining between the regulations governing clinical trials on medicinal products and those on medical devices that is often difficult to manage, especially for ECs.

More generally, adequate guidelines, recommendations and regulations must be adopted in order to favor harmonization of both DCT review and authorization procedures and foster virtuous implementation of these trials.

At European level, an in-depth review of the ethical and legal framework is essential for establishing how the existing definitions and conceptual rules for clinical trials are applicable to the decentralized activities of DCTs. As digital technologies gradually become more extensively incorporated into clinical trials, the EU regulatory framework for DCTs/hybrid trials will have to evolve and the Good Clinical Practice (GCP) protocols will have to be modernized. Modernizing GCP regulatory supervision in order to enable decentralized clinical study models is currently an objective for the European institutions (35).

The need for homogeneous safety standards that guarantee patients a level of protection not lower than that adopted for conventional trials, is particularly important: the fact that DCTs can allow real-time continuous monitoring is not, in itself, a guarantee of adequate protection. It is also necessary to adopt procedures that lead to timely intervention and, preferably, provide a remedy in the case of unforeseen circumstances, incidents and adverse events. This calls for effective e-health systems that are suited to the purpose, and above all a health organization that guarantees 24/7 surveillance and possible assistance.

E-health systems must, in any case, offer patients the possibility of direct contact with the healthcare facility and with the doctors and researchers conducting the trial. With a view to this, in many cases, hybrid DCTs are appropriate as they alternate procedures at the subject's home with procedures at the trial site.

Considering the growing number of DCTs and their challenging implementation, adequate training - both on the technical aspects, including digital skills, and on the ethical implications resulting from the decentralized methods - should be provided to stakeholders, namely:

- the healthcare personnel that design and conduct DCTs: all of them (including those that carry out home visits) must be technically and ethically skilled;
- the patients and their caregivers, who must be not only informed, but also trained;
- the EC members, so that they can play their responsibility for authorizing DCTs with competence and awareness.

The planning and conduct of DCTs involve particularly complex matters: partnerships between sponsors, study sites and patient advocacy groups must be favored to promote the best individual involvement of the patients themselves. General practitioners should also be involved.

DCTs must be planned and conducted maintaining the standards for the production of evidence commonly adopted by the scientific community: although for DCTs changes in the organizational, administrative, regulatory and operational conditions for the conduct are permitted, shortcuts and exceptions in the scientific method and rigor are not acceptable.

Groups that are unlikely to participate in DCTs because of digital divide (for example many elderly people) must be offered alternative options for trial participation, so that anyone who meets the eligibility criteria has the chance to take part. This is a major challenge for clinical research in the near future: combining and harmonizing the need for equity of access, the procedural flexibility offered by the availability of different methods of conducting studies, and the methodological rigor in the production of reliable scientific evidence.

Therefore, any decision to switch from a traditional trial to DCTs must be decided on a case-by-case basis: the elements of decentralization must be justified in relation to the characteristics of the study, and balancing improved access for patients, their safety, rights and dignity, with the quality of collected data. Respect for the person, his/her wellbeing and his/her central role must always come first, taking precedence over any procedural consideration regarding organization, quality, efficiency, effectiveness, and the progress of knowledge.

Author contributions

CP wrote the initial draft of the manuscript with the contribution of CM. LR and SG contributed with insightful feedback and integrations. GG provided critical revision. All authors approved the final manuscript.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Artificial intelligence and digital medicine for integrated home care services in Italy: Opportunities and limits

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Home healthcare in the Italian health system has proven to be an essential factor in adequately responding to the health needs of an increasingly aging population. The opportunities offered by digitization and new technologies, such as artificial intelligence (AI) and robotics, are a lever for making home care services more effective and efficient on the one hand, and on the other for improving remote patient monitoring. Telemedicine devices have enormous potential for telemonitoring and telerehabilitation of patients suffering from chronic disabling diseases; in particular, AI systems can now provide very useful managerial and decision-making support in numerous clinical areas. AI combined with digitalization, could also allow for the remote monitoring of patients' health conditions. In this paper authors describe some digital and healthcare tools or system of AI, such as the Connected Care model, the Home Care Premium (HCP) project, The Resilia App and some professional service robotics. In this context, to optimize potential and concrete healthcare improvements, some limits need to be overcome: gaps in health information systems and digital tools at all levels of the Italian National Health Service, the slow dissemination of the computerized medical record, issues of digital literacy, the high cost of devices, the poor protection of data privacy. The danger of over-reliance on such systems should also be examined. Therefore the legal systems of the various countries, including Italy, should indicate clear decision-making paths for the patient.

KEYWORDS

artificial intelligence, home care service, telemedicine, telerehabilitation, limits

Introduction

Integrated Home Care (IHC) is a service available throughout Italy (1), structured to guarantee health and social assistance to elderly or sick citizens of all ages and social conditions, who are placed in family contexts suitable for providing the care they need at home.

Home care for elderly and/or non-self-sufficient patients is a priority for the Italian National Health Service (NHS), mainly for two reasons. On the one hand, it responds

to the need to cope with the growing demands for health services related to the aging of the population, by providing patients with medical, rehabilitation and nursing services at home, thus significantly improving their quality of life in their family environment (13). On the other hand, it relieves the burden on hospitals, reducing emergency room admissions and inappropriate hospitalizations, which cuts costs for the National Health System (14).

Healthcare administered by IHC services at the patient's home is multidisciplinary. After a multi-professional team (Multidimensional Evaluation Unit) has completed an assessment, an Individual Care Plan (ICP) is drafted, and these steps call for the assistance of:

- Doctors (GPs or specialists)
- Nurses
- Physiotherapists or other rehabilitation professionals
- Psychologists
- Healthcare assistants.

Indeed, responding to the complex health and social needs of a typical multipathological patient requires the involvement of multiple medical professionals. The most frequently expressed need is to have a home nurse where necessary.

Although health policies in Italy have provided for home care for decades, IHC continues to play a marginal role and to be greatly insufficient compared to the real needs of the population. In fact, in 2021 only about 3% of Italians aged 65 and over were assisted at home, in view of a total of 3 million people suffering from multiple chronic conditions (MCC) and disabilities required continuous care (2). This is a very small percentage compared with other European countries, especially those of Northern Europe. Implementing the diffusion of new IHC systems remains a fundamental goal of the Italian NHS. The interest in the technological frontier of AI is consolidating more and more internationally and public health is an area that arouses great interest, especially where it is decided to intervene to improve the duration and quality of life (15). In addition, the importance of telemonitoring the patient both in healthcare facilities and at home is an even more pressing priority during the last years of the pandemic (16).

Digital healthcare tools

The aging of the population (on 31 December 2021 Italian inhabitants aged 65 and over represented 23.2% of the total population, those up to 14 years of age 13% and those in the 15–64 age group 63.8%, while the average age approached 46 years) (3), an increase in chronic diseases and limited economic and human resources have put pressure on the health system, necessitating change

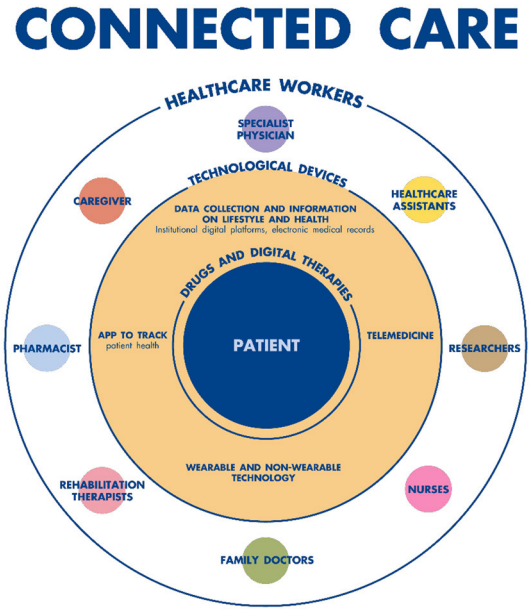

FIGURE 1
Connected care operating model.

in the form of better health services for patients, more efficient assistance from professionals and rationalization of economic resources.

Digitization is one of the major drivers of innovation and may be the solution to meeting the challenge of sustainability in the healthcare sector (17). Connected Care (4) (Figure 1) is gradually acquiring a strategic role in Italian digital healthcare, which puts the citizen-patient at the center of the system by creating organizational models that favor integrated care, between hospital and territory, to foster patient empowerment (18). This system includes new organizational models and technological solutions, in order to enable the sharing of patients' clinical information among all the actors involved in the treatment process (hospital doctors and nurses, local and home health workers, patients, insurers, institutional representatives, etc.); it is intended to be an operating system on which almost all institutions converge at central (Ministry of Health, MEF, Agid, etc.) and local (Regions and Health Authorities) levels to meet new health needs and maintain the balance of the health system.

The objective of Connected Care is to put the citizen-patient at the center of the system and to create organizational models that favor integrated care between hospital and territory, to enable patients to become more empowered. New technologies are fundamental in that they offer the means to enhance services and relationships between patients and health workers, from accessing health data and using services, to monitoring the clinical course and the overall evolving (or stabilized) state of

health. Furthermore, based on the analysis of statistical models, such technologies can help to identify preventive behaviors.

The Italian NHS is therefore moving toward a new model of integrated and connected healthcare, with a clear path mapped out for its implementation and dissemination. To achieve this, it is necessary to combine different care models, intrinsically integrating the support of technology to ensure continuity of care for all patients, especially those who are chronically ill.

In this era of digitization, there are many ways to organize home healthcare. A valuable tool that has been introduced in Italy is the Resilia app (5), a mobile phone application which allows users to quickly find nursing care or other health professionals, such as social health workers and physiotherapists.

The Resilia app is very easy to download from the Google Store or Apple Store, depending on the operating system. It is simple to use and guarantees absolute security and privacy for all users. Once a person has registered as a user, they can use either their Google or Facebook account to complete the activation with a few pieces of information, and the service will be immediately active. Navigating through the menu, it is possible to select a geographical area and type of homecare support (e.g., nursing) to find out which services are available and how much they cost. The idea of developing an app that would connect patients to healthcare professionals and to all psycho-physical wellness operators stemmed from the difficulties encountered in accessing the services of a trusted professional (19, 20).

Potentiality and future perspectives of AI in the healthcare system

Evolving technologies, such as AI, have the potential to help healthcare systems around the world respond to the major challenges they face, such as an aging population and the rise of chronic diseases, while increasing their sustainability. Systems equipped with automation mechanisms can help doctors improve diagnoses, perform surgical procedures, predict the spread of diseases and personalize treatments, thereby making a significant contribution to precision medicine–an emerging approach to the treatment and prevention of diseases that takes into account the individual variability in genes, environment and lifestyle to develop "tailor-made" treatments. Thanks to cognitive "supercomputers" capable of analyzing huge amounts of data, it is possible to make early diagnoses, as well as identify life-saving therapies much faster than traditional methods (21). Artificial intelligence, combined with digitalization, could also allow for the remote monitoring of patients' health conditions, thus potentially expanding the home care system (22). Similarly, the implementation of digital technologies in patients' homes could concretely and increasingly transform and improve healthcare in general and the home care system in particular. Intelligent machines are being developed to monitor correct adherence to medication and, more generally, the state of health of the elderly. Not only that, they could assist the patient in rehabilitation or in simple daily movements, such as getting out of bed, or alerting medical and nursing staff in case of need (23). From this point of view, AI and robotics truly have the potential to significantly improve the lives of millions of elderly and non-self-sufficient patients (24).

In this field, professional service robotics has been developed with very sophisticated humanoid machines, capable of providing direct assistance to people with dementia, thus replacing or complementing the assistance provided by caregivers. Fraunhofer IPA's Care-O-bot (now in its fourth generation, Care-O-bot 4) is a cross-platform interactive mobile robot, successfully tested to help with memory deficits and to support seniors in carrying out daily tasks (25). Another humanoid robot, Abel, resembles a young boy and is able to understand human emotions, make decisions and converse (26). A Japanese-designed humanoid robot, known as Pepper, has similar functions; it is capable of recognizing human faces and basic emotions thanks to emotion engine software (27). With machine learning programming, Pepper interacts and learns to become a social robot-caregiver that continuously improves its empathic skills and bidirectional interactions, learning to read and interpret emotions and then to react appropriately, thanks to the system of emotion classification.

AI tools represent an emerging field of application in healthcare, especially with regard to frail people, the elderly and those with chronic diseases who may benefit from remote patient monitoring, the prevention of critical situations and assistance with daily activities (28–30). Below is a list of what can be considered operational proposals, planned or partly prepared by the Italian health system:

- AI tools should be promoted in combination with telemedicine, to make it possible to expand the home care system (6, 7, 31);
- A digital hospital-doctor-territory network should be activated to monitor patients suffering from chronic diseases and to promote prevention through digital medicine systems;
- Guidelines should be given for the correct treatment of complicated situations (e.g., bladder catheters, ostomies, PEGs, difficult wounds) through all means available to the scientific community, such as newsletters, scientific journals, meetings and face-to-face and online events;
- Training courses should be planned for caregivers, including tutorial videos, with the aim of managing and empowering the patient at home as much as possible;
- Big data in healthcare systems and deep learning techniques should be used for the purpose of effective predictive and preventive medicine, thus acting long before the onset of symptoms for chronic and worsening diseases. In fact, instant access to the entire set of data would make it

possible to predict the evolution of the clinical picture through decision support algorithms that could make the entire diagnostic-therapeutic-care process more efficient;
- A diagnostic-assistance model should be developed, based on the creation of a personalized electronic health record, capable of responding to requests for increasingly effective, efficient and quality diagnostic, prognostic and treatment services for the patient. Two ministerial decrees (8) were recently published to give a certain basis to the application of the Electronic Health Record (EHR), a tool of fundamental importance for digital healthcare. All of this can be achieved by emphasizing the constructivist nature of the process, aimed at bringing significant advantages to all stakeholders interested in the individual's care and assistance pathway. This would also lead to savings and better management of individual cases (32).

An interesting attempt to organize assistance for the non-self-sufficient person at home is the Home Care Premium (HCP) project, managed by the National Social Security Institute (INPS) and aimed at public employees and their family members who have a disability or are non-self-sufficient (33); the so-called "prevailing services" consist of monthly financial contributions to help reimburse expenses incurred for the remuneration of caregivers who support daily life activities. Then there are the "supplementary services" to support the daily care pathway: they consist of professional services at home and out of the home to enhance abilities, prevent or slow down the degeneration of the level of non-self-sufficiency and support ancillary assistance services, adapted to the level of non-self-sufficiency and socio-assistance needs (9). The healthcare worker is entrusted with the task of defining the potentially usable resources for each activity of daily life (ADL), in relation to the care that the person needs. In addition to a family assistant, home services of a medical or non-medical nature can be provided, as well as the possible installation of equipment at home (various aids) or home automation technological tools for mobility and autonomy to better manage the home environment and communications.

The Italian state is moving in this direction, and the welfare reform envisaged by the National Recovery and Resilience Plan (PNRR) has become law (10). Mission 6 of the PNRR (11), which stemmed from the need to bridge territorial disparities and offer greater integration between health services in different care settings, is dedicated to health and divided into two components:

- Component 1: Proximity networks, intermediate structures and telemedicine for territorial healthcare;
- Component 2: Innovation, research and digitalization of the national health service.

The possibility of accessing (freely and without discrimination) the new options offered by the extraordinary developments of intelligent assisted technologies (IAT) is an extremely important issue for the protection and promotion of human rights (34). As set out in the delegated law, it is necessary to precisely define the concept of disability. The Italian Society of Forensic Medicine, in a recent position paper, stated: "*A person with a disability is anyone who has a stabilized or progressive impairment of the integrated physical, psychic, intellectual and sensorial functions, or who suffers from a morbid process, even of a short duration, which seriously affects the integrity and efficiency of the person, causing the loss of personal autonomy. The impairment, interacting with barriers of a different nature, may hinder the full and effective social-relational-working participation of the person by inducing inequality and/or direct or indirect discrimination*" (12).

What further opportunities can we find in these new AI systems? (35).

a) The introduction of AI-enabled technologies, will allow family members and the care team to increase the level of communication with each other regarding better care for their loved ones aged.
b) Some robots can also remind seniors if social events occur in the neighborhood, encouraging them to go out and socialize.
c) Installing AI-powered sensors at home can also identify if a senior has fallen or has encountered an accident.
d) Many of the AI apps available on smartphones today could monitor health data, such as the elderly's daily activities, diet, and even lifestyle, in a less intrusive way.

Limits and criticalities

The question arises as to whether the extraordinary options offered by AI open up avenues for those in real need, or whether the ways in which the technological tools are distributed are affected by prejudice that differentiates and hierarchies people, without agreed rules–not bound by any scruples. Intelligent assistive technologies (IAT) have made great strides; until recently, the areas of rehabilitation/inclusive intervention were usually limited to incontinence aids, active mobilization systems (wheelchairs and lifts), positioning aids (self-elevating armchairs) and aids for the prevention of pressure sores (water mattresses and pillows or the more innovative air mattresses with interchangeable elements). However, this does not rule out the possibility of new critical issues related to: the safety and reproducibility of the software; ethical-legal problems linked to the protection of the privacy of the data subject; and, above all, civil liability for any damage caused by the manufacturer and/or programmer (36, 37): if an AI system fails to deliver a rehabilitation treatment, or worse still, harms the patient, who is liable? The developer? The producer? The distributor? The programmer? The healthcare professional who made the decision to use it? The patient who uses it? The family

member who puts it into operation? These issues are known in other fields of application of AI and have motivated legal positions on both national and international levels (38). In this regard, the legal systems of various countries, including Italy, should probably outline clear decision-making paths that are guaranteed for the patient.

The danger of over-reliance and excessive dependence on such systems should also be highlighted and investigated, for this could lead to serious effects such as the deskilling and desensitization of healthcare personnel. In other words, some decision-making processes could be influenced by new technologies, undermining the essential doctor-patient relationship (39).

Another matter of concern is the protection of privacy and security (40). In this context, there is unanimous agreement that the implementation of AI must be accompanied by careful reflection on the part of the legislator to ensure that the rights of citizens and patients are truly protected. For example, there is the question of consent to the processing of personal health data by artificial intelligence systems.

Finally, there are further limitations and criticalities to point out (41):

- While AI technologies can allow a lengthening of the patient's life, on the other hand it should avoid compromising the quality of health and social care that people who get older and older receive;
- The big data used may be unrepresentative of older people or distorted by past age stereotypes, prejudices or discrimination;
- There may be a risk of a reduction in intergenerational contact.

Conclusions

The massive deployment of intelligent tools for physical, cognitive and behavioral assistance, as well as for the monitoring and provision of subsidized healthcare, will necessarily respond to social needs by allowing the elderly to continue living at home, while maintaining a residual degree of independence even when they live in sheltered care accommodation. There is a triple-win effect because these technologies are able to:

- Delay or obviate the need for institutional care, thus reducing the healthcare costs associated with long-term care and institutionalization;
- Mitigate the burden of care that often weighs on the family or other informal assistants;
- Improve the quality of life of the elderly who are not longer self-sufficient by supporting their independence, autonomy, social interaction and their right to age without being institutionalized (42).

Researchers, politicians and health professionals around the world have high hopes that assistive technologies can support the elderly, even in the face of questions that remain unanswered (43). Many devices are available for free on the market and are used widely even if research is ongoing to improve their effectiveness. However, the use of new enabling technologies and the consequent need for a reorganization of health services impose the urgency of applying systematic frameworks to increase the quality and safety of health services (44).

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

MC and RS drafted the document (both as first authors) and acquired the information. PF made a substantial contribution to the conception of the work. FC analyzed the regulatory information and reviewed it critically. All authors contributed to revising the manuscript and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Digital health interventions and quality of home-based primary care for older adults: A scoping review protocol

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Introduction: The use of digital health interventions has expanded, particularly in home-based primary care (HBPC), following the increase in the older adult population and the need to respond to the higher demand of chronic conditions, weakness and loss of autonomy of this population. There was an even greater demand with COVID-19 and subsequent isolation/social distancing measures for this risk group. The objective of this study is to map and identify the uses and types of digital health interventions and their reported impacts on the quality of HBPC for older adults worldwide.

Methods and analysis: This is a scoping review protocol which will enable a rigorous, transparent and reliable synthesis of knowledge. The review will be developed from the theoretical perspective of Arksey and O'malley, with updates by Levac and Peters and respective collaborators based on the Joanna Briggs Institute manual, and guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR). Data from white literature will be extracted from multidisciplinary health databases such as: the Virtual Health Library, LILACS, MEDLINE/PubMed, Scopus, Web of Science, Cinahl and Embase; while Google Scholar will be used for gray literature. No date limit or language restrictions will be determined. The quantitative data will be analyzed through descriptive statistics and qualitative data through thematic analysis. The results will be submitted to stakeholder consultation for preliminary sharing of the study and will later be disseminated through publication in open access scientific journals, scientific events and academic and community journals. The full scoping review report will present the main impacts, challenges, opportunities and gaps found in publications related to the use of digital technologies in primary home care.

Discussion: The organization of this protocol will increase the methodological rigor, quality, transparency and accuracy of scoping reviews, reducing the risk of bias.

KEYWORDS

digital health, telemedicine, home-based primary care, older adults, geriatric care, quality in healthcare, scoping review, digital health interventions

1. Introduction

The increase in the older adult population and the subsequent need for health systems to respond to issues of chronic diseases, weaknesses, and loss of autonomy has increased the demand for home-based primary care (HBPC) around the world. HBPC includes care that seeks to adequately meet the social and health needs of people in the residential environment. Actions are offered for promotion, prevention, minimization of disease sequelae, situations of weakness and loss of autonomy, monitoring of chronic diseases, palliative care, and support in activities of daily living. These actions can be technical, offered by health professionals or laypeople, the result of intuition, and support in daily life activities care for older adults and self-care guided by professionals (1–4).

The World Health Organization has been evaluating the challenges of home-based care on the European continent, and the analysis presents several issues, among which include the need for governments to regulate the private sector, and to have policies focused on quality, accessibility, efficiency and equity. In this direction, the analysis warns that the aging population requires appreciation of public funding which is specific to home care within health financing, highlighting the relevance of Primary Health Care (5).

Home care is one of the PHC priorities, especially for those who cannot easily commute to health services (6). Studies about PHC and home care articulation present advantages such as providing users with mechanisms to access longitudinal care and promoting improved quality of care with lower costs due to a stronger relationship between the person and their caregiver (7, 8). Expanding coverage and quality of services are of paramount importance for PHC (9) as a strategy to reorganize health systems in order to guarantee longitudinal and comprehensive care for chronic patients in the territories covered, especially in cases where HBPC is the timeliest form of care (5, 9).

An important additional challenge for the quality of HBPC is the need for complex coordination due to the interdependence of health services, as this coordination can be performed by Primary Healthcare (PHC), hospitals or nursing services (5), with advantages for coordination by PHC (5).

HBPC demand has significantly increased during the COVID-19 pandemic, considering that older adults, carriers of chronic diseases and affected by immunosenescence, are more susceptible to infectious diseases (7). HBPC was used to reduce attendance at emergency services and ensure that chronic medical problems were treated within the home environment to prevent their worsening (10, 11). Faced with the challenges in PHC from COVID-19, the use of Information and Communication Technologies (ICT). Moreover, digital health gained even more prominence due to the operability and versatility of generating information at an opportune time (12–14).

Digital health can be defined as a safe and cost-effective way of using information and communication technologies in health and related areas (15, 16). Its scope includes several informational areas such as artificial intelligence, big data, blockchain, health data, health information systems, infodemics, internet of things, teleconsultations, telemonitoring, e-learning and mHealth (16, 17). Digital health assists healthcare workers in diagnosing, monitoring, and communicating with older adult patients around the world, especially during the COVID-19 pandemic (18). Its use can contribute to strengthen health systems by quickly making reliable and up-to-date health information available (16).

Digital health can be used to accelerate the achievement of global health and wellbeing and to expand older people's access to quality PHC (12–15). Some studies emphasize the possibilities of using digital health in home care among the older adults. A study conducted in Indonesia identified needs and opportunities for enabling the use of cell phones and mobile applications for the health of older adults (18).

On the other hand, there are barriers to the use of digital health, such as the digital divide, the fact that half of the world's population is still offline, and the contrast between developed and developing countries is enormous (19). In addition, older adults with lower socioeconomic status have reduced access to digital resources and may not be able to afford the technology or internet needed to use digital tools (20).

In a preliminary search conducted in November 2022 on MEDLINE/PubMed and Google Scholar using the keywords: Aged; Telemedicine; Digital health; and Primary Health Care, review articles were found that explored the uses and experiences of digital health technologies used in care for older adults (21–25). However, no review studies were found that established an

association between digital health, home care for older adults and health quality.

Thus, the objective of this study is identify and map the uses and types of digital health interventions and their impacts on the quality of primary home care for older adults worldwide. The Donabedian model approach will be used for the concept of quality applied to healthcare, as it presents a set of desirable attributes which are called (the seven) pillars of quality: efficacy, effectiveness, efficiency, optimization, acceptability, legitimacy and equity (26, 27). These seven pillars are defined in three dimensions: technical (accuracy in the choice of actions and the way in which they are produced), interpersonal (social and psychological relationships between care providers and users) and organizational (conditions in which services are offered comprehensively and with continuity of care, coverage, coordination of actions, access and accessibility to services).

2. Materials and methods

This study is a scoping review protocol which seeks to answer broader research questions. The study will identify and map emerging evidence on the topic addressed, synthesizing knowledge with rigor, transparency and reliability. It is based on Joanna Briggs Institute (JBI) criteria guided by the theoretical framework of Arksey and O'malley (28), with updates from Levac et al. (29) and Peters et al. (30), as well as by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) (31). The protocol was registered in the Open Science Framework (OSF) (https://osf.io/vgkhy). As shown in Figure 1, the nine steps of the Scoping Review include: (1) Defining and aligning the objective/s and question/s; (2) Developing and aligning the inclusion criteria with the objective and questions; (3) Describing the planned approach to evidence searching, selection, data extraction, and presentation of the evidence; (4) Searching for the evidence; (5) Selecting the evidence; (6) Extracting the evidence; (7) Analysis of the evidence; (8) Presentation of the results; (9) Summarizing the evidence in relation to the purpose of the review, making conclusions and noting any implications of the findings (32).

2.1. Step 1: Defining and aligning the objective and questions

Objective: Identify and map the uses and types of digital health interventions and their impacts on the quality of primary home care for older people worldwide.

The research questions were formulated through the PCC mnemonic conceptual model—(Population, Concept, Context) (31), as:

P: Older adults;

C: Digital health interventions;

C: Home-based primary care.

The following research questions were prepared by the authors according to the PCC:

1. Which countries use digital health interventions in home-based primary care for older adults?
2. What sort of digital health interventions are used in home-based primary care for older adults?
3. What is the measured impact of digital health interventions on the quality of home-based primary care for older adults?

The key concepts for elaborating the research questions are described in Table 1.

2.2. Step 2: Developing and aligning the inclusion criteria with the objective and questions

Publications that address the use of digital health interventions in HBPC for older adults will be included, available in full, which answer the study questions.

The following will be included:

a) Primary studies, theoretical and brief communications.
b) Gray literature, including government manuals, expert opinions and brief communications as well as dissertations and theses.

Time filters will not be applied to the searches, as the search strategies will contain descriptors and terms referring to digital health. The search will not be limited by date or language. Duplicate publications, literature reviews, editorials, will be excluded.

2.3. Step 3: Describing the planned approach to evidence searching, selection, data extraction, and presentation of the evidence

The following steps will be taken to enhance the identification of documents in white literature and gray literature:

The initial search was conducted in MEDLINE/PubMed using Medical Subject Headings (MeSH) in English to identify main descriptors, synonyms, and keywords included in titles, abstracts, and indexed terms of publications regarding the theme. A similar search was conducted in Portuguese using the Virtual Health Library (VHL) and *Descritores em Ciências da Saúde* (*DeCS*).

Moreover, a librarian improved the search strategy using four controlled vocabularies (DeCS, MeSH terms, Emtree terms;

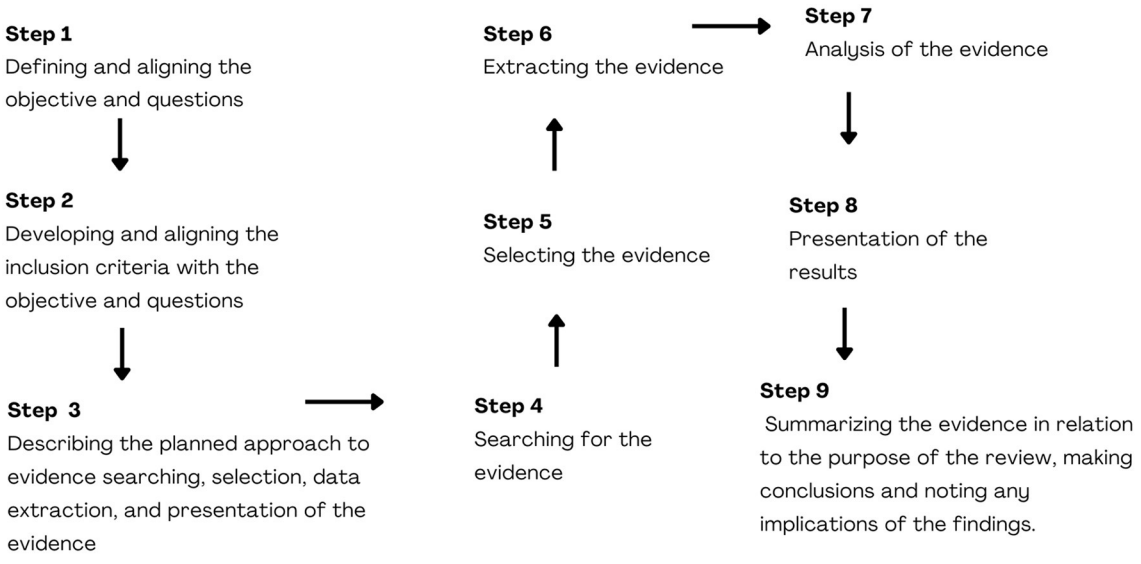

FIGURE 1
Steps of the scoping review (32). Source: prepared by the authors, 2022.

Cinahl headings) to obtain a wide range of multidisciplinary results in different databases. Natural language (non-controlled vocabulary) was also used to increase the sensitivity of the strategy (37).

The search strategy was constructed using the Extraction, Conversion, Combination, Construction, and Use model, which enables developing highly sensitive search strategies by following a set of complementary steps (37).

2.4. Step 4: Searching for the evidence

English was used to structure the research strategy, considering that it is the main language used in the scientific environment (38). Table 2 organizes the main descriptors available in the DeCS that started the search strategy carried out by the authors based on the PCC, the standard search strategy is available in Appendix I. The detailed search strategy for all data sources (i.e., white and gray literature) will be attached to the final scoping review.

2.4.1. Data sources

The data collection will be conducted in the following indicated portals and databases: LILACS; MEDLINE/PubMed; Scopus; Web of Science; Cinahl and Embase. Gray literature will be searched through Google Scholar, Open gray, "Gray Matters: a practical tool for searching health-related gray literature", ProQuest Dissertations and Theses Global and Preprints for Health Sciences [medRXiv]. The appropriate strategy will be applied to each of them, and the title and abstract of all identified studies will be evaluated and the duplicates removed.

The search strategy was pre-tested on MEDLINE/PubMed for white literature (Appendix II) and Google Scholar for gray literature (Appendix III) to check for the possibility of data collection limitations related to the search strategy.

2.4.2. Additional sources

Reference lists of included studies will be consulted for verification of additional publications. If needed, corresponding authors will be contacted *via* e-mail for additional information.

2.4.3. Pilot test

A pilot test will be carried out with two reviewers (IdSS and AJA) before starting data collection in order to reduce bias, ensure alignment in the selection process and testing the form among some team members to refine it and ensure that all relevant data were captured. The two reviewers will be to evaluate the same random sample of 25 papers, evaluating titles and abstracts in a data source and then select them using eligibility criteria. Afterwards, the team will meet to discuss and to resolution the discrepancies, and make necessary changes to the criteria and definitions. Screening will only begin when 75% or more similarity is achieved (32).

TABLE 1 Key concepts for the study questions.

Concept	Definition
Older adult	For the World Health Organization (33), the concept of "old age" is multidimensional, and includes the terms chronological (based on the date of birth), biological (related to the capacity of the human body), psychological (related to the psycho-emotional functioning) and social age (related to social roles). For the United Nations (34), the definition of an older adult is related to those who are 60 years old or more, but at the same time they affirm that there is a diversity of older people with different needs, abilities, lifestyles, experiences and preferences which are influenced by age, gender, health, income, education, ethnicity and other factors.
Digital health interventions	The classification of digital health interventions (DHIs) categorizes the different ways in which digital technologies are being used to support health system needs. This classification framework is primarily targeted at public health audiences, and aims to promote an accessible and bridging language for health program planners to articulate functionalities of digital health implementations (16).
HBPC (home-based primary care	This is a model of providing long-term primary care at home, ranging from palliative care, rehabilitation, and disease management to care coordination. The multidisciplinary team has older adults with chronic diseases and physical and cognitive disabilities as its main clientele (35, 36).
Care quality	The quality of care can be defined in three dimensions: technical (accuracy in the choice of actions and the way in which they are produced), interpersonal (social and psychological relationships between care providers and users) and organizational (conditions in which services are offered comprehensively and with continuity of care, coverage, coordination of actions, access and accessibility to services (26).

Source: prepared by the authors, 2022.

TABLE 2 Descriptors used according to the PCC Mnemonic.

Mnemonic	Descriptor	Synonyms/keywords
P	aged/elderly/frail elderly	Older adults; Aging; older persons; elderly care; aged people; Older Adult
C	Digital health	eHealth; e-Health; telehealth; Telecare; mHealth; Telerehabilitation; Telehomecare; home telehealth; Home telecare; telemonitoring; telecare monitoring system; telenursing; Digital Health; Digital Health Strategies; Digital Health Strategy; Digital Health Interventions; eHealth Strategies and Policies; Telemedicine
C	Home-based care services	home health services; home monitoring; home health care; home care; home-based primary care; Hospitalization at home; Home-based care; Home healthcare; Home-based primary care

Source: Prepared by the authors, 2022.

2.5. Step 5: Selecting the evidence

The study selection process will be guided by the steps proposed in the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA-ScR) (31) for both white and gray literature, which are: (1) identification; (2) screening; (3) eligibility; and (4) inclusion, which will be presented in detail in the review selection diagram.

The selection process of publications belonging to the gray literature will follow the guidelines recommended by Godin et al. (39), with specific strategies for searches on Google Scholar and Preprints repositories. Combinations of the following groups of search terms will be used: Aged OR elderly OR "middle age" OR "old people" OR "very elderly" AND Digital Health OR Telemedicine OR teleconsultation OR "electronic consultation" OR "remote consultation" OR telehealth "home health care" OR "home care". The search terms and the number of results retrieved for each gray literature search strategy will be recorded and will follow the other proposed selection steps. The results from Google Scholar will be sorted by relevance and the first hundred will be included in the screening (39).

Identified studies will be grouped in the Endnote reference manager and duplicates removed. The Rayyan software program will be used in the evaluation of studies by titles and abstracts to assist in blinding the reviewers (40) and any differences between the two reviewers (IdSS and AJA) will be discussed with a third reviewer (SACU). Studies selected by title and abstract will be retrieved in full and exported to a database in the Microsoft Excel® program. After reading the full text and building the final review sample, data will be extracted by the two independent reviewers, highlighting all reasons for exclusion when necessary and the entire selection process, eligibility, inclusion and reasons for exclusions will be presented in a specific flowchart (31).

2.6. Step 6: Extracting the evidence

Data will be extracted according to Appendix IV and included if they align with the objectives and research questions of the scoping review. Data related to the included studies will be extracted by two independent reviewers to reduce the chance of errors and biases using a data extraction form elaborated by authors.

The following items will be extracted from the studies: Type of literature, Publication title, authors, Year of publication, Country, Language. To white literature it will be identified Study design, Study population, Study objective, Research question, Participants, Main results. For both white and gray literature will be extracted type and health situation of digital health interventions used, care actions and its agent and coordination ability to use digital tools, Availability of Digital health interventions and other impacts of using digital health interventions on the quality of home-based primary care.

The instrument can receive updates during the research to obtain a deeper understanding of the theme, as, according to Peters et al. (30).

2.7. Step 7: Analysis of the evidence

Descriptive statistics (absolute and percentage frequencies) will be used to analyze quantitative data with the help of the Microsoft Excel® program. Qualitative data analysis will be guided by thematic analysis (41).

This step will be divided into three others, according to Levac (29), namely: (1) data analysis; (2) exposure of results linked to research questions; and (3) interpreting the implications of the results for other research and services.

A map of identified countries that use digital health interventions in HBPC for older adults will be developed using the GeoDa version 1.20 software program (Center for Spatial Data Science, Chicago, IL, USA).

All results will be discussed with the relevant literature. The evidence synthesis will be presented in a descriptive format through tables, diagrams, and thematic maps to better visualize the results found. A narrative summary will follow the mapped data, and report how the results relate to the review objective and questions.

2.8. Step 8: Presentation of the results

The final report guided by the PRISMA-ScR (31) will include the results in flowcharts, charts, or figures, and will be presented to a group of stakeholders with experience in digital health. The stakeholder analyses are used throughout the entire planning process of health innovations, more frequently for policies and services and delivery methods (42), and it will be useful for preliminary sharing and suggestion of dissemination of results. The objectives of this strategy, recommended by Levac et al., will be the preliminary sharing of study findings, being considered a mechanism for knowledge transfer and exchange, as well as to develop effective dissemination strategies and ideas for future studies and encourage the search for new evidence or field of research not present in the review (29). In this step, the identification of interested parties will be carried out; the differentiation or categorization of stakeholders based on some attributes, such as power, position, level of interest, possible contributions; and investigating stakeholder relationships with the topic of study (42, 43).

In this protocol, the sample of stakeholders will be intentionally listed through the snowball technique with 9 (nine) stakeholders: researcher (3), health professional (3) and digital professional (3) all with experience in digital health aimed at home-based care. The first included will be identified by the study researchers, who will successively indicate the others.

The procedure will include sending an individual invitation to candidates for research participants, explaining the purpose of their participation and, if they accept, they will sign the Free and Informed Consent Form. Preliminary results and informed consent will be included in an electronic form and sent to stakeholders *via* e-mail. Stakeholders will not be identified, and authors will request the appreciation of dissemination, sharing of results of the review and of the database of publications as well as about possible new fields or evidence for researchers, managers, caregivers and older adults.

2.9. Step 9: Summary of evidence, conclusions, implications of findings

The main results will be summarized (including an overview of the concepts, themes and types of evidence available), the research questions and the objective should be answered based on the results found. Expectations about the implications of the findings on digital health interventions and their relevance to the home-based care of older adults will be presented.

3. Ethics and dissemination of the results

The study does not directly involve patients, but the stakeholder consultation was approved by the Research Ethics Committee of the Onofre Lopes University Hospital/Federal University of Rio Grande do Norte CAEE 54853921.0.0000.5292. The results will be presented at scientific conferences, events

with stakeholders and submitted for open-access publication in a peer-reviewed journal.

4. Discussion

This protocol was developed by researchers trained in this type of research and following the methodological criteria suggested by Arksey and O'Malley (28), Levac et al. (29), and JBI (32) guided by the PRISMA-ScR (31). The organization of this protocol will increase the methodological rigor, quality, transparency and accuracy of scoping reviews, reducing the risk of bias. Scoping review protocols contribute to an increasing need to synthesize and summarize research following a reproducible design, implementation and reporting method (44).

The scoping review will be able to present the convergence of two emerging themes, namely, digital health, which offers an opportunity to address health system challenges, improve coverage and maintain the quality of service (45) and home primary care for older adults who demand continuous and sustainable long-term care (7).

5. Strengths and limitations

Thus, the main contribution of this study is the elaboration of a protocol with methodological rigor, which will be guide the development of a scope review in the future. The methodological rigor adopted in this protocol, as well as the training and experience of the researchers, will ensure quality and transparency for the development of the scoping review. In addition, this is the first study to propose mapping the use and type of digital health interventions used, and their impacts on the quality of care for older adults. One of the most relevant aspects of the methodology is the inclusion of stakeholder consultation as a way of indicating future strategies for dissemination and applicability of the review results so that they can be more accessible to other researchers, managers, caregivers from different countries.

However, two limitations in the search strategy can be highlighted. The first is that the definition of Digital Health is recent (2020) and evolving. If there are changes in WHO definitions of digital health by the study selection stage, the terms will be updated. The second is the structuring of the search strategy in English which may not include publications from the gray literature in the native language of some countries. Thus, the search strategy may be adapted to Portuguese, Spanish, and French to extend the reach and software will be used to translate these publications into the aforementioned languages. Therefore, we constructed the search in a manner that increased comprehensiveness to minimize the effect of these limitations.

6. Conclusion

The present protocol has methodological rigor and is proposed to guide a scoping review that will map and identify the uses and types of health interventions and their impacts on the digital quality of HBPC for older adults worldwide.

The future Scoping Review will provide a reliable source of evidence for managers, digital tool developers and future research to guide the use of digital health interventions in the practice of HBPC for older people, and its results may guide discussions for the elaboration of upcoming healthcare policies and guidelines. Older adults, families, society, caregivers and health professionals will be able to consult the results, identify and decide which digital health intervention best suits their reality, and respond to the demands of care for the elderly, in addition to knowing the impacts of digital health in the HBPC, guided by a scientific study developed with rigor and seriousness.

Results of this review will create socialization with stakeholders and be published in peer-reviewed open-access journals, favoring dissemination of knowledge with the scientific community. Changes in this protocol will be appropriately reported in the final publication, including dates and justifications.

Author contributions

SU proposed the study and coordinated the elaboration of the protocol. ÍS developed the protocol. ÍS, CS, RL, OB, AA, RF, LL, and SU participated in the discussion of the theoretical and methodological aspects of the study. CS, ÍS, and RL conducted the pilot searches to substantiate the search strategy. PX was in charge of implementing the reviewers' considerations and updating the article and critically reviewed the content. All authors reviewed the protocol and approved its final version for publication. All authors contributed to the article and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships

that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fpubh.2022.1022587/full#supplementary-material

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The digitization process and the evolution of Clinical Risk Management concept: The role of Clinical Engineering in the operational management of biomedical technologies

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Introduction: Digital transformation and technological innovation which have influenced several areas of social and productive life in recent years, are now also a tangible and concrete reality in the vast and strategic sector of public healthcare. The progressive introduction of digital technologies and their widespread diffusion in many segments of the population undoubtedly represent a driving force both for the evolution of care delivery methods and for the introduction of new organizational and management methods within clinical structures.

Methods: The CS Clinical Engineering of the "Spedali Civili Hospital in Brescia" decided to design a path that would lead to the development of a software for the management of biomedical technologies within its competence inside the hospital. The ultimate aim of this path stems from the need of Clinical Engineering Department to have up-to-date, realistic, and systematic control of all biomedical technologies present in the company. "Spedali Civili Hospital in Brescia" is not just one of the most important corporate realities in the city, but it is also the largest hospital in Lombardy and one of the largest in Italy. System development has followed the well-established phases: requirement analysis phase, development phase, release phase and evaluating and updating phase.

Results: Finally, cooperation between the various figures involved in the multidisciplinary working group led to the development of an innovative management software called "*SIC Brescia*".

Discussion: The contribution of the present paper is to illustrate the development of a complex implementation model for the digitization of processes, information relating to biomedical technologies and their management throughout the entire life cycle. The purpose of sharing this path is to highlight the methodologies followed for its realization, the results obtained and possible future developments. This may enable other realities in the healthcare context to undertake the same type of pathway inspired by an accomplished model. Furthermore, future implementation and data collection related to the proposed Key Performance Indicators, as well as the consequent development of new operational management models for biomedical technologies and maintenance processes will be possible. In this way, the Clinical Risk Management concept will also be able to evolve into a more controlled, safe, and efficient system for the patient and the user.

KEYWORDS

digitization process, digital transformation, thematic evolution, clinical engineering, operational management, clinical risk management, biomedical technologies, management software

1. Introduction

1.1. Contest of reference

We live in an era in which we have witnessed and continue to witness birth, development and progressive spread of digital infrastructures and tools. The magnitude of this change makes it possible to assert that what we are facing today is a true digital revolution that influences and changes the paradigms in which we live, operate, and conduct our daily work (1). Digital transformation and technological innovation which have influenced several areas of social and productive life in recent years, are now also a tangible and concrete reality in the vast and strategic sector of public healthcare (2, 3). The progressive introduction of digital technologies and their widespread diffusion in many segments of the population undoubtedly represent a driving force both for the evolution of care delivery methods—which are increasingly precise and personalized—and for the introduction of new organizational and management methods within clinical structures (4, 5). Indeed, it can be asserted that the reformative thrust of digital health has a strong impact not only in the evolution of the delivery of clinical therapies in support of the patient, but it can also find significant applications in the context of the activities related to the management of biomedical technologies and the development of the models of what is nowadays defined as "Operational Management (OM)" (6, 7). So, a real transformation in a digital key consequently requires a not easy changing in the technological, structural, and organizational assets that its implementation imposes; thus, producing a new managerial structure that contemplates new aspects or new opportunities to deepen (8). Among the new aspects related to this renewed management, it is necessary and proper to emphasize how a biomedical technology today can no longer be seen as a stand-alone and independent element—even where it was—but rather, it becomes an element active part of a larger system. In this increasingly articulated system, within which it is placed, its role becomes fundamental to the functioning of the embedded process. A context that wants to evolve its organization and that aims to improve quality and efficiency of health services, must therefore be able to obtain structured and multi-parametric information; not easy way because this aspiration implies in having to face new challenges (9). The most important one is represented by the establishment of new information flows that require a logic of compatibility, interoperability and strong integration between technologies and the rest of—local, regional and national—information systems. This aggregate overview suggests the need for increasingly structured data collection and its subsequent processing for construction of dashboards with summary data and Key Performance Indicators (KPIs) (10, 11). This approach allows the optimization of resources according to economic (management costs) and organizational (resources) requirements, quality, regulatory and safety reference standards (12, 13). Against this backdrop, the challenge for today's Clinical Engineering Departments (CED) is to embark on a digitization path of technologies and processes (14–16). The latter is represented by defining a new way of mapping and managing medical equipment and medical devices distributed at a territorial level, even more so at home (in the logic of proximity medicine), throughout their entire life cycle, considering all the possible needs that can be encountered, ranging from simple periodic maintenance to extraordinary maintenance to technological and/or software upgrades, to the renewal of any necessary consumables. Last but not least, the safe use of medical device according to its specific destination. Thus, in this articulated scenario, a new range of action and supervision is established for the Clinical Engineer, a professional figure which is able to move from a hospital-centric logic to a digitized territorial logic. The role of CED, within healthcare facilities, is to participate in health care and to ensure the safe, appropriate, and economical use of biomedical technology. They are therefore specialized in optimizing the management of healthcare equipment for hospital use. One of their main tasks is to balance the need for optimization of healthcare expenditure and the quality of service rendered to the end-patient. For this reason, they carry out very cross-disciplinary studies, touching on the traditional worlds of engineering but also the worlds of healthcare and even management economics. The development of CED within healthcare facilities in a structured manner is of recent occurrence and it has been expanding significantly in recent years. However, it is still present a significant variety in methods and in application's areas. For this reason, in order to facilitate greater contextualization with respect to the digitization pathway that will be illustrated, the reference context and the activities in charge of Clinical Engineering Department of the "Spedali Civili Hospital in Brescia" will be described.

The Complex Structure (CS) Clinical Engineering of the "Spedali Civili Hospital in Brescia" is responsible of the management—at company level—of medical and technical-economic equipment throughout their entire life cycle (technical specifications, evaluations, purchase, management, maintenance, end-of-life), of drawing up the investment plan, of the implementation of new projects, of innovative technologies in the biomedical field and of supporting the management for all strategic activities and issues related to medical technologies, medical devices and technical-economic equipment of all the facilities under its jurisdiction. The primary objective is to ensure the safe, appropriate, and efficient use of biomedical technologies and to draw up programs aimed at their best possible management. The main activities consist of:

- Planning purchasing of technological equipment, in cooperation with the company's biomedical technology committee.
- Definition of the technical specifications of biomedical and technical-economic technologies, verifying with departmental referents the specific needs to be met.
- Direct (preventive and corrective) maintenance or maintenance control for the technologies provided.
- Installation, testing, inventory of new equipment.
- Management of work related to the installation of technologies, in collaboration with the technical department of the company; management and distribution of medical, technical, and cryogenic gases and their cylinders in support of the company pharmacy department; management of medical IT in cooperation with the company information systems department (ICT).
- Development of HTA studies, in connection with regional organization.
- Studies on the implementation of innovative technologies and their Operational Management in current healthcare facilities and in the structures/hospitals of the future.

The CS Clinical Engineering operates according to a quality management system certified according to ISO 9001:2015.

Furthermore, it is part of the "Facility Management and Safety" (FMS) team, which follows accreditation according to Joint Commission International standards.

Lastly it should be pointed out that, in the manner and under the terms of an existing contract, the CS cooperates with an external company to perform maintenance activities and electrical safety checks inside the hospital.

1.2. The fundamental role of an effective management program

Medical equipment is one of the key components contributing to the effectiveness of health services (17). The procedures involved in health services, ranging from diagnosis to treatment, rehabilitation to screening, prevention to monitoring, depend on the efficiency of medical equipment (18). Therefore, the provision of health services is almost impossible without proper maintenance of medical equipment (19). In addition, devices must be monitored to maintain performance in terms of calibration, maintenance, restoration, training, and decommissioning (20). As mentioned above, clinical engineers in a healthcare facility are responsible for regulating and introducing an effective management program for the reliability and safety of medical equipment (21). Therefore, maintenance management of medical equipment is critical to ensure that medical equipment operates according to the manufacturer's specifications and ensures the safety of patients and users (22). Proper implementation of maintenance can prevent failures or breakdowns that affect healthcare operations and can cause serious injuries to patients. Kutor et al. (23) reported that equipment failures are commonly due to inadequate transportation and storage, preliminary failures, mismanagement, lack of maintenance, environmental stress, random failures, improper repair methods, and wear and tear failures. Also important is the fact that 50-80% of equipment failures are due to poor maintenance and lack of highly trained technicians. In addition, the four main causes of these failures are: avoidable incidence, insufficient technical personnel, lack of data, and lack of predictive maintenance. Therefore, the maintenance and management of medical equipment can be progressively improved by identifying the influencing factors. Bahreini et al. (24) stated that unprofessional execution of maintenance affects health care performance, safety, and overall expenses of health care institutions, while Wu et al. (25) showed that effective maintenance management can reduce operating costs by more than one million dollars and improve equipment availability. Key factors in these rates are the increasing motivation for preventive maintenance, demand for equipment, implementation of advanced financing mechanisms, purchase of refurbished equipment, and implementation of a strict regulatory framework. These data show that the substantial budget for the purchase and maintenance of medical equipment is imposed to provide effective health services. In conclusion, it can be said that the current availability of medical equipment data in terms of equipment details, purchasing information, operational performance, and maintenance activities is critical to improving equipment life cycle management. However, the appropriate technique is critical to manage big data that provide meaningful indicators for maintenance management planning (26).

As cited by Zamzam et al. (27) four gaps have been highlighted by literature review which are:

- Lack of studies concentrated on comprehensive maintenance management, including preventive maintenance, corrective maintenance, and replacement program (28–30).
- Inconsistency of mathematical approaches that require manual intervention in identifying the criteria weightages in reliability assessment.
- Inefficiency of the previous predictive models, which can be applied to the several types of medical equipment (31–34).
- None of the studies combines assessment and predictive models using the same unlabeled dataset of medical equipment.

In the light of these evidence and in spite of the evident correlation with the provision of better healthcare services, it is noticeable that this area of study is still underdeveloped (35–38).

It is therefore clear that the proper management and maintenance of biomedical equipment is closely related to the delivery of more efficient healthcare services but also to a better utilization of company resources (39). So, in order to manage new technologies efficiently the numerous technical, economic and usability factors associated with clinical equipment must be taken into account. Consequently, it is of utmost importance that technical decision makers—this means Clinical Engineers—acquire the appropriate method and information for equipment planning and acquisition (40).

1.3. Purpose of the article

With all these considerations kept in mind, the CS Clinical Engineering of the "Spedali Civili Hospital in Brescia" decided to take up the challenge and to design a path that would lead to the development of a software for the management of biomedical technologies within its competence inside the hospital. The ultimate aim of this path stems from the need of Clinical Engineering Department to have up-to-date, realistic, and systematic control of all biomedical technologies present in the company. This path stems from the necessity to respond to the needs illustrated in the previous paragraphs and it finds in the digitization of processes an adequate response to these demands. The aim is to share the followed path and, on the basis of this, to develop a series of reasoning and considerations on how a good digitization process could take place and be successful. In this sense, there is evident transversality with recently discussed topics such as telemedicine and proximity medicine which, although articulated on the basis of different needs, find points of convergence with this digitalization process. With respect to the latter consideration, however, it should be considered that telemedicine involves medical practice and information and communications technology. It has been proven to be very effective for remote health care, especially in areas with poor provision of health facilities. However, implementation of these technologies is often hampered by various issues. In particular technical, ethical, medico-legal, and legal aspects must be considered (41–43). The project illustrated in this article considers these issues but it deals with minor limitations due to the fact that it does not handle with sensitive patient data but only with technical and managerial specifications of the biomedical equipment used to produce them. In light of this,

anyway, the software platform must still comply with the provisions of the General Data Protection Regulation (GDPR) No. 2016/679.

This case study is articulated on the basis of a very complex logistical structure, and this can therefore make it scalable to other realities of equal or lesser complexity. In fact, the "Spedali Civili Hospital in Brescia" is not just one of the most important corporate realities in the city, but it is also the largest hospital in Lombardy and one of the largest in Italy. In addition to the central referral center, it has three other hospital presidia and several outpatient clinics and afferent facilities in the territory. The "Spedali Civili Hospital in Brescia" has been recognized as the second-best hospital in Italy in 2013 and it is characterized by the presence of a machine park of about 30.000 units that, despite its high volume, requires operational management and organized monitoring.

2. Materials and methods

Appropriate and efficient use of this integrated software is inevitably related to the proper functionality and differentiation of each specific function and to the subcomponents' synchronized work. System development has followed the well-established phases (Figure 1):

2.1. Requirement analysis phase

The identification of both the currently existing management criticalities and the consequent project requirements, has represented only the first step of this path. The main objective of such an integrated software system is to assist the Clinical Engineering in performing tasks concerning safety, effectiveness, and efficiency in use of medical equipment. Requirement analysis indicated that the system should provide the following features:

- Management of files for medical devices, manufacturers, and suppliers.
- Follow up of purchasing procedures, from the request of the departments through acceptance tests of the devices.
- Implementation and management of quality and safety protocols and procedures—including the necessary documentation and data—presented in an appropriate and comprehensible format.
- Scheduling of all routine procedures such as acceptance testing, preventive maintenance, and quality and safety inspections.
- Follow up of corrective maintenance tasks.
- Monitoring of the overall performance of the department, using quality and cost indicators.
- Easy access to and exchange of vigilance-related information.
- Data analysis and report generation, either predefined or customized by the users.

Also, the main general technical specifications of the architecture related to hardware and software structure are explained next. Their identification, which took place through brainstorming techniques, is based on the technical, theoretical, and logistical needs of CS Clinical Engineering:

- Ability to use the core functionality of the platform without the need for installation/setup on end-users' computers. For this reason, it is preferable for the application to have a "web application" type user interface so that it can be enjoyed through common web browsers. Exceptions are allowed related to specific features that have the unavoidable need for interfacing with dedicated hardware and/or that cannot be achieved *via* web browsers. A simplified software upgrade process that does not require desktop client installation and upgrades is also required.
- User authentication: the software platform must have functionality for user authentication and secure access, as well as a log-in mechanism for user authentications.
- User profiling: the software platform must have dedicated functionality for user management and user profiling. It must be possible for System Administrators users to manage through an interface the configuration of users, their profiling, and the definition of user roles.
- User management and user licensing: the number of users that can be configured within the software platform must be unlimited, and it must be possible to provide for a simultaneity of at least 150 users.
- Handheld software management: for easier direct on-site management, handhelds or mobile devices must be provided that allow for the reading of any barcode, QR or RFID codes in order to be able to make on-the-spot changes to the last detection of the equipment, as well as to be able to use all software functions in synchronous and asynchronous modes. Device synchronizations must be able to be simultaneous, scheduled (at least once a day) and with the possibility of performing them on demand.
- Integration with monitoring portals of external companies: the possibility is required, for high technologies and where available, to link directly to the monitoring portal link of the Company responsible for the maintenance contract in place.
- Possibility of massive uploading of data and/or documents related to equipment management by the supplier.
- The software platform must comply with the provisions of the General Data Protection Regulation (GDPR) No. 2016/679.
- Integrated authentication with enterprise Active Directory on Premise. Two-way integration with Archiflow, Siaweb, EUSIS/DigitGO, Coswin software and enterprise folders. Data interchange between systems must allow for "one-time" import of data sets, two-way live integration to obtain data from the above systems or to be able to enter/update information entered on the new software platform, two-way live integration for document retrieval archiving with Archiflow software.
- User friendly and customizable interface.
- Cloud hosting that ensures data security and scalability.

The above specifications as well as the contemporary trends in the clinical engineering sector worldwide, were taken into consideration throughout the Development Phase of the system.

2.2. Development phase

Firstly, a technological partner—for the development of Information Technology (IT) section related to the software—has

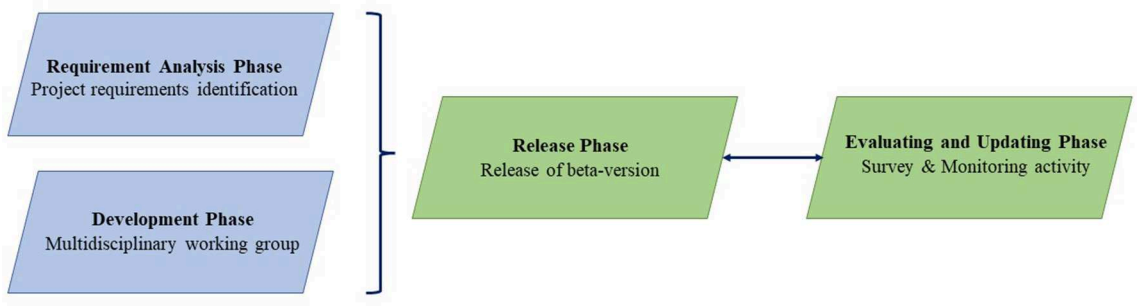

FIGURE 1
The four distinct phases followed in order to develop the software.

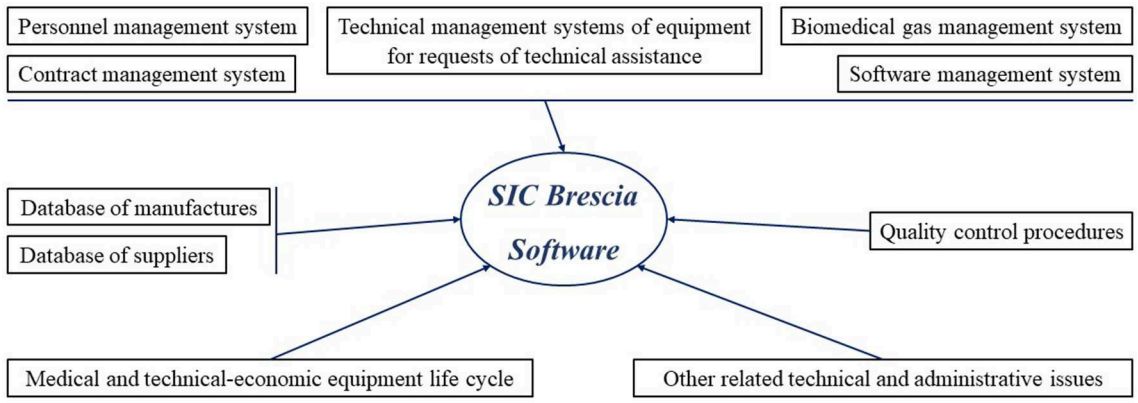

FIGURE 2
All aspects related with Clinical Engineering Management that has been implemented in software's architecture.

been identified through an open procedure. Subsequently, it was deemed appropriate to form a multidisciplinary group composed by the Clinical Engineering staff and ICT department—for IT security issues—of the "Spedali Civili Hospital in Brescia" and a research university group from the Department of Electronics, Information and Bioengineering (DEIB) of "Polytechnic of Milan". All of them in collaboration with the technological partner identified in "E.L.L.F. S.r.l."; a series of meetings were then held for one year to design and develop the digital system. Steps of this process, specifically, were the following: *definition of software technical specifications*, *flow analysis and optimization*, and *software design*. Meetings were characterized by a detailed analysis of Clinical Engineering's processes: management of the registry of equipment present in the facility, orders and contracts, pre-testing phase and subsequent testing of new equipment that has been taken over, management during the entire life cycle and end-of-life. The flows, in addition to being studied in the form in which they are currently carried out, have been optimized in order to lend themselves better to the digitization process. Finally, the work was focused on the design of the portal. Starting with an analysis of the graphical user interface of the management software previously in use and how the processes were previously managed, it was discussed how the same—after being revised and optimized—could be made available in digital form in a way that was as intuitive and user-friendly as possible.

Various techniques and methodologies were used during the meetings to carry out the characteristics and the requirements that the software had to satisfy. Solutions were discussed and selected through common brainstorming techniques. Regarding the process analysis, Clinical Engineering reviewed in detail all phases and steps of the current internal procedures. Subsequently, the data involved within a given process and their flow within the processes themselves were highlighted: data used as input and the corresponding data produced as output were identified for each process. In order to conduct these process analyses, *User Stories* and *Use Cases Diagrams* were developed. The latter made it possible to capture the functional requirements that the software must fulfill within a given process.

2.3. Release phase

Release Phase consisted of two different stages. Initially, the release of a beta-version of the software—including the main functionalities—was launched. The beta-version was for the exclusive use of Clinical Engineers and Clinical Engineering Technicians (CET) and the purpose of this preliminary release was exclusively to test the correct implementation of the first functionalities and to verify that they met the previously identified needs. Subsequently the definitive version of the software, called *Asset Manager*, was released for the use of all end-users.

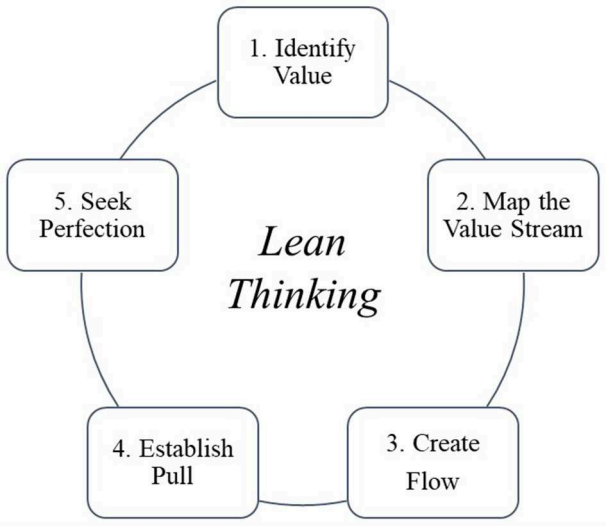

FIGURE 3
The five steps of lean thinking implementation.

In view of the remarkable structural and logistical complexity of the "Spedali Civili Hospital in Brescia", the software Release Phase followed a very precise logic. The release of the software took place at first at the territorial hospital presidia and only later at the referral center. This choice is due to the fact that most of the overall volume of biomedical equipment and coordination and management flows of Clinical Engineering are concentrated at the central presidium. For this reason, it was deemed appropriate to release the new software in a progressive manner and according to an increasing gradient of complexity. This approach is indicated in bibliography as a gold standard for the delivery and implementation of new services.

2.4. Evaluating and updating phase

Evaluation, an integral part of the system development to ensure system functionality, was performed in three distinct phases which included testing, verification and validation. Testing procedures were performed by internal evaluators of the technological partner as well as software professionals with significant knowledge related to the system structure. Testing goal was to determine the proper functioning of the system, to monitor problems related to database management, and to identify weak points in the software packages. The integrated system also was distributed for verification to a set of end-users; here it should be emphasized that before the final release of *Asset Manager* platform, functional (i.e., simulation of activities and procedures) tests were conducted to simulate all functionalities and their enforceability by the entire CS.

End-users were instructed through appropriate training programs. The objective of gathering their feedback was achieved through the development and distribution of a survey. The macro-areas of the survey are those relating to the management section of the software, and for this reason the questionnaire was only addressed to the Clinical Engineering personnel, even though they are not the only users of the software.

Bottom line, the path could not disregard from a constant monitoring activity of the progressive implementation status of the software in order to supervise the functional integration of the new system into the operational reality.

3. Results

3.1. Clinical engineering management software (SIC Brescia)

First of all, the name that has been chosen for this new management software is "*SIC Brescia*".

Discussion about needs and requirements of Clinical Engineering led to the identification of the desired characteristics which were then summarized in a list of technical specification required for the software. Cooperation between the various figures involved in the multidisciplinary group led to the development of an innovative software realized through the application of the latest available web technologies, characterized by user friendly and customizable interface, single page application usable through all modern browsers, cloud hosting for data security and scalability, integrated authentication with corporate Active Directory on Premise and simplified software update process that does not require installation and upgrade of desktop clients.

The input provided by the multidisciplinary group was crucial in highlighting, by virtue of their areas of expertise, a number of needs and design specifications to be taken into close consideration during the software *Development Phase*. It is emphasized that multidisciplinary can only be seen as an added value in the implementation of complex projects, such as those involving health care facilities nowadays. In particular, the technical-operational section of CS Clinical Engineering as well as the medical/clinical personnel that will interface with the use of the software consider the following aspects to be fundamental: simplicity in searching for a specific piece of equipment through the use of search filters, immediacy in finding information related to it, detail in compiling the technical-file of each device, facilitation of workflows, ease in attaching and subsequently consulting documents related to a piece of equipment, intuitiveness of software's graphical interface, and efficiency and comprehensiveness of processes. The management component of CS Clinical Engineering needs the possibility to retrieve overall and final data about all the equipment under its purview with a specific degree of detail about maintenance operations and equipment testing processes. The ICT department mediated the integration of the new software with the company's IT architecture, ensuring the functionality of the systems already in place and the security of the data processed. The technology partner mediated all the requirements presented to make possible their effective fulfillment in the software implementation. Finally, the research group was involved, and it is actually involved in the development of indicators for the creation of new OM tools and indicators.

From a technical point of view this system was designed to manage all aspects related with Clinical Engineering technical management, as summarize in Figure 2, inclusive of:

1. Contract management system, both for the acquisition of new equipment and maintenance of the same.
2. Personnel management system.

3. Medical and technical-economic equipment life cycle from acquisition to dismission and this includes the following aspects: inventory, classification, technical specification, warranty period follow-up, equipment service support including preventive and corrective maintenance, analysis of performance, equipment dismission and out of service, electrical safety check, testing of an equipment.
4. Software management system.
5. Biomedical gas management system.
6. Database of suppliers and related contacts.
7. Database of manufactures and related contacts.
8. Technical management systems of equipment for requests of technical assistance.
9. Quality control procedures.
10. Other related technical and administrative issues.

The system also includes an efficient reporting scheme that can produce immediate reports on all aspects concerning medical equipment such as list of equipment in any location, equipment list of certain type or manufacturer, list of equipment failures, all information (severity, duration, current state etc.,) related to technical intervention and preventive and corrective maintenance reports. From a systemic point of view the release of beta-version allowed an initial analysis of preliminary evidence and it revealed how the new digitization path led to:

- *Speeding up procedural flows* by computerizing the company's administrative and technical processes currently managed entirely on paper.
- *Development of operational management activity* by monitoring the effectiveness and efficiency indicators of biomedical technologies in charge through the creation of a *Management Dashboard* within the software.
- *Development of indicators to support Health Technology Assessment (HTA)* by monitoring maintenance activities performed and the degree of equipment utilization.
- *Development of a prioritization algorithm* for the optimized handling of requests for assistance made by hospital operating units.
- *Increased traceability of* actions taken through the completion by suppliers of a dedicated form to collect input data of all tested equipment.
- *Integration of the system* with software already in use and with company IT tools in accordance with the ICT department.

3.2. Survey's results

Results of the survey revealed that, with regard to the comparison with the previously used—not company property—management software, all respondents agreed that *SIC Brescia* was more intuitive and efficient. Furthermore, with regard to the overall assessment, all users felt that the new software was intuitive, user-friendly, and easily comprehensive Also, it has been highlighted that a large number of steps were not required to perform the desired tasks. Finally, on the basis of a scale of one to five, all users were more than satisfied with the overall use of the new digital software.

4. Discussion

4.1. Contest of reference analysis

This article deals with all distinct phases of design and implementation of a fully automated clinical engineering technical and operational management software called "*SIC Brescia*" at "Spedali Civili Hospital in Brescia". The conception of an innovative digitization process stems from the need to coordinate and manage the number of new technologies that has increased exponentially in recent years. Digital innovation is nowadays affecting many aspects of healthcare processes: from the management of appointments to the administration of pharmacological therapies, from the organization of territorial care and the new way of delivering services remotely to the management of biomedical technologies, with a consequent impact also on the various professions that are involved. Modern technologies require more dedicated professionals, not only health professionals but also technical professionals, who must ensure the safe delivery of services (17–20, 44, 45). Clinical engineers find themselves among the main players in this transformation, and it can be stated that all of this necessarily implies the adoption of new management logics that allow a true integration of the most diversified needs connected to the broader and more complex healthcare context (46). In fact, a real transformation in digital terms requires more than a simple change in the technological, structural and organizational assets that its implementation imposes, thus producing a new management that contemplates new aspects or new opportunities. A context that wants to evolve and aims at quality and performance efficiency must dispose of structured and multi-parametric information; this implies facing new challenges such as the establishment of new information flows that require a logic of compatibility, interoperability and integration between technologies and the rest of the corporate and regional information systems. The collection of structured data can also be used to build dashboards with summary data and KPIs. Furthermore, it enables the optimization of resources according to economic (management costs) and organizational (resources, spaces) requirements, quality, regulatory and security reference standards. Hence the need for a systemic vision and dialogue between the various professionals: in order for the digitization process to be conducted effectively, internal processes and procedures must be rethought and recoded to ensure the true applicability and application of the new digital technologies. In this context, the concept that led to the realization of the new management software "*SIC Brescia*" was developed. The authors emphasized that they could state with significant certainty that the general technical specifications in the *Requirement Analysis Phase* section are predominantly scalable and contextualizable with so many other CED realities. The entire process of realizing the platform was not born with the exclusive intention of digitalizing the data and information relating to the activities carried out by Clinical Engineering. On the contrary, it should be taken as an opportunity to rethink processes by making them simpler and more streamlined. It is therefore clear that the aim must not only be to create a "paper-less" system, but to obtain software that integrates itself into the operational and technical reality, facilitating the completion of activities and the carrying out of processes. Only in this way technological innovation, and specifically this digitization path will be able to realize the much desired "added value" to be gained from innovative processes. As a corollary to this reflection, it is especially

important not to lose sight of the principle by which technological innovation must be flexible and capable of modulating itself to the needs of the realities in which it is structured, and not vice-versa. Only in this way a constructive integration capable of creating value, not only for the company but also for the citizen, could be finally observed.

4.2. "Value added" theme & change management process

Another important aspect to be considered when major changes are introduced into processes—all the more so in the healthcare context—is a careful study of the processes being innovated. Lean Thinking [Figure 3, (47–50)] provides a number of tools, including the fundamental "*value stream map*" (51). It starts with an analytical "*as is*" snapshot of the current situation, followed by a prospective "*to be*" view of how the process will change in relation to the findings and the technologies introduced. First of all, the concept of "*value*" must be defined. Value for a process of this type can only be the response to adequate management of equipment and operational processes. In order to do this, many activities have been carried out: of these, all those activities in an operational process that are actively carried out on the life cycle of a technology are considered "*value added*". Surrounding these activities—from which the entire organization benefits—there are many others. Some of which are necessary for the processes and acts of healthcare to be carried out, the so-called "*business value added*," and others which could and should be done without, the so-called "*non-value added*". The objective of the *Requirement Analysis Phase* was precisely a lean review of the operational processes of biomedical technology management, which aimed to eliminate non-value-added activities and increase and optimize value added ones. The correct description in a flow chart (*value stream map*) (52), according to the concepts just outlined, of all the activities, human and instrumental resources employed, and the time required to provide the services themselves, has provided a snapshot of the current state of the processes and the possibilities to improve them. Given this premise it seems clear that in general the best innovative digital technologies are those that, inserted in a process, in addition to improving the qualitative performance of health-technological management, are aimed at reducing the previously cited non-value-added activities. In all this context, what is known as "change management" should by no means be underestimated. The more innovative digital processes are, the more they change the way in which they are delivered by the practitioner and also the way in which the practitioner can use them. The risk is to create feelings of discomfort that—if the change is not properly managed—may lead to their rejection. Reference is also made to those technologies that are currently defined as "disruptive innovation" due to their strong innovative nature and for which process mining and change management activities are necessary. Change management should help professionals to achieve optimal everyday use of new methodologies by supporting each one of them, in an almost personalized way, during each phase of the new process. Change management is a process structured in precise steps. These steps have been followed in the realization of this project and they have been summarized in the following cornerstones: the change that new technologies introduce must be part of a clear project design (*vision*), be able to count on adequate professional competences (*skills*), with adequate incentives (*incentives*), the right resources (*resources*) and a clear action plan (*clear action plan*). The lack of only one of these elements, or the poor definition and/or incomplete implementation of one of the steps described above will certainly lead to the failure and breakdown of the innovation that was intended to be introduced. Change management helps professionals to value change, to accept it, and to correctly identify areas of improvement for their business (53). This procedural approach can be declined to a broader and more generalized character with respect to contemporary reality: we are faced with increasingly innovative technological development and there is an urgent need to discern which innovations are most useful and applicable. We need to be able to discern among all the technologies which really allow us to change healthcare processes by making them leaner, more efficient, and more useful to the patient which is the end user of the process but who should actually be considered the trigger for any improvement action. There is therefore a responsibility to optimize the resources made available to us and allocate them correctly in the knowledge that they will never be enough and that it is therefore up to us to discern useful innovations from those without added value for the patient. This last consideration leads to the possibility of conducting a constructive reasoning about the contextualization of technological development in hospital context. If, on the one hand, the innovation brought about by the "*SIC Brescia*" software brings about a change in working mentality, revolutionizing the current parceled out working method, reorganizing and facilitating the ordinary activities of Clinical Engineering in a single digitized working solution, it is also true that the latter cannot fail to be accompanied by the development of an adequate digital culture in the system in which it is integrated. In this sense, the effort of company management, and even before that of institutions, in training and orientation toward adequate digital training plays a fundamental role. It follows therefore that continuous training and skills development—both technical and digital—for all the professionals working in the system are essential, in order to ensure full compliance and real implementation of new processes under way for the renewal of the care settings of the "Spedali Civili Hospital in Brescia". Lastly, this discussion cannot end without considering the delicate issue of technology acceptance: a topic that is neither trivial nor inessential. In fact, the quality of the final use of the software passes through the mediation of the technology in the relationship with the user, not forgetting that the motivation of the need or usefulness of the technology passes through concepts such as usability, perception of benefit and comprehensibility. It is precisely for this reason that the multi-disciplinary character held during the realization and design of the software and the drafting of a questionnaire to assess the usability of the software itself were important aspects to take into consideration concerning to the topic of technological acceptance.

4.3. Transversality with digital healthcare

The potentialities of this digitization pathway also find transversal points of contact with other tremendously contemporary themes inherent in the innovative digital processes currently taking place in the healthcare sector. Although the peculiarities associated with other themes have a different functional character and application context,

the considerations mentioned above also find a contextualization in them. In particular, a direct connection can thus be drawn with the topic of telemedicine. Here too, only a careful and objective assessment of the processes and the benefits that the technologies bring to them and to the patients can provide the measure—both in terms of the priority of intervention and in terms of the need—to intervene and improve the healthcare process. In the absence of such careful study, the risk is that of following the trends of the moment and under- or over-estimating innovative technologies compared to the value they would bring to healthcare processes. In this context, in addition to complying with the current rules and regulations governing their marketing and use, the new challenge for the Clinical Engineer is therefore how to map and manage remotely distributed medical equipment and devices, even more so in a home-based regime (in a logic of proximity medicine), throughout their entire life cycle considering all the possible needs that may arise, ranging from simple periodic maintenance to extraordinary maintenance to technological and/or software upgrades, to the renewal of any necessary consumables and the safe use of the medical device according to its specific destination. A new range of action and supervision, therefore, asserts itself in this scenario for the Clinical Engineer who advances from a hospital-centric logic to a digitized territorial logic.

The development of the new "*SIC Brescia*" software was created to meet these requirements as well. It also considered the current implementation of the new Regulation on Medical Devices (MDR)—Regulation (EU) No. 2017/745—thanks to the presence of a section for reporting the UDI (Unique Device Identification) code in the master data section of each piece of new equipment. This made it possible to comply with the strict traceability requirements in accordance with the new regulation.

4.4. Toward a new concept of Clinical Risk Management

Effective operational management cannot disregard, among other aspects, from the concept of Clinical Risk Management (54, 55), which aims to improve the quality and safe delivery of healthcare services through procedures designed to identify and prevent circumstances that could expose a patient to the risk of an adverse event. Throughout its history, clinical engineering was focused on medical devices and how they are used in the healthcare environment. However, during time, clinical engineers have become deeply involved in quality improvement and risk management activity. The healthcare technology management aims to optimize the acquisition and utilization of medical technology to achieve maximum beneficial impact on health outcomes (56, 57). In particular, proper maintenance implementation can prevent failure or breakdown that affects the healthcare operations and may cause severe injury to the patients (44). Development of a new software is fundamental in order to acquire a list of new information and to organize these ones with a set of new KPIs (58, 59). The development of these indexes allows an evolution of the Clinical Risk Management concept that tends toward an integrated model with increasingly organized and complete data. The digitalization process allows the systemic organization of a series of information that, in an organization without this type of software, could not be developed. Hence, we are moving from a "static" Clinical Risk Management model to an increasingly "dynamic" model that finds its consistency in a series of progressively more articulated data. However, it must be remembered that a large amount of data needs to be organized in order to produce valid information. Consequently, it is of absolute importance that Clinical Engineers acquire the appropriate methods and information regarding equipment planning, acquisition, and evaluation. According with the recent literature some examples of KPIs that could be implemented in next future are: Global Failure Rate (GFR), Age Failure Rate (AFR) and Acquisition Trend (AT). The GFR is calculated using the total number of failures by the total number of completed repair work-calls divided by the total number of devices (45, 59). This measures the reliability of medical equipment, a fundamental aspect in guaranteeing hospital medical services (33, 60). The AFR represents the total number of failures divided by the total number of devices according to the number of years used and provides us with more information than the GFR as it takes into consideration user experience and learning ease. The AT of medical devices provides further information for long term equipment replacement by providing a periodical purchasing trend which can be applied toward economic resource planning. In addition, the presence of a management dashboard makes it possible to monitor the progress of ordinary maintenance and the integration of this data with the aforementioned KPIs will make it possible to evaluate optimization of the maintenance process (12–15, 17). The maintenance process and program can be improved through the development of models that test changes in the periodicity and in the methodologies of maintenance activities with the final aim of increase the lifecycle length and management of biomedical technologies (19–24). So, this new methodology will provide some useful information for maintenance and technology replacement phases and KPIs for decision-makers in technical analysis within technology management. Further improvements are connected to technical dashboard development for sustainable technology management by including usability and economic indicators. This would assist decision makers in technology replacement and management phases, allowing for an efficient view of technological information in health structures and for a better realization of the concept of Clinical Risk Management.

5. Conclusions

The contribution of the present paper is to illustrate the development of a complex implementation model for the digitization of processes, information relating to biomedical technologies and their management throughout the entire life cycle. This process was made possible by the implementation of management software and was carried out by a multidisciplinary working group at the CS Clinical Engineering of the "Spedali Civili Hospital in Brescia". The purpose of sharing this path is to highlight the methodologies followed for its realization, the results obtained and possible future developments. This may enable other realities in the healthcare context to undertake the same type of pathway inspired by an accomplished model. The theme of "added value" associated with digitization processes can thus be realized and find final fulfillment. In fact, the realization of the model, from conceptual idea to the practical implementation, has been designed

with the terminal aim of making it scalable and extendable to other hospital facilities. Scalability will be the subject of future deeper analysis, after the steady-state phase of the software will be fully operational and fully integrated at the "Spedali Civili Hospital in Brescia". Furthermore, the implementation and data collection related to the previously proposed KPIs, as well as the consequent development of new operational management models for biomedical technologies and maintenance processes will be studied. In this way, the Clinical Risk Management concept will also be able to evolve into a more controlled, safe, and efficient system for the patient. Finally, the impact of this process finds fulfillment at the systemic level by promoting the transition from a working method historically set up with the "silo concept" (a vertical approach separated by competence in which people tend to think independently) toward a new more linear and integrated logic between the various professionals involved in the operational processes. The latter finds realization in the optimization of the overall functioning within the entire organization and in the common interest.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Author contributions

MV, GV, MC, CD, LI, and PP participated in research design and in developing the entire project. MV wrote the manuscript. GV, MC, CD, LI, and PP participated in process analysis. VC and GV participated in the improving and revising of the paper. GV provided substantial advice in designing the study and VC assisting in the division of labor, writing, and revising of the paper. All authors listed have made a substantial, direct, and intellectual contribution to the work and approved it for publication.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Health care professionals' knowledge and attitudes toward telemedicine

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Background: The utilization of modern communication technology in the healthcare field is known as telemedicine, and it represents an advancement in the healthcare industry. For effective implementation of these technologies, healthcare professionals must possess the appropriate knowledge and hold a positive perspective toward the implementation of telemedicine. The current study aims to evaluate the knowledge and perspective of healthcare professionals in King Fahad Medical City, Saudi Arabia toward telemedicine.

Methods: This study was carried out in a diverse hospital, King Fahad Medical City, Saudi Arabia and it was a cross-sectional study. The study took place from June 2019 until February 2020, during which 370 healthcare professionals, including physicians, nurses, and other healthcare professionals participated. The data was gathered by using a structured self-administered questionnaire.

Results: The analysis of the data revealed that the majority of the healthcare professionals who participated in the study, 237 (63.7%), had limited knowledge of telemedicine. About 41 (11%) participants had a good understanding of the technology, and 94 participants (25.3%) had extensive knowledge. The overall attitude of the participants toward telemedicine was positive, with a mean score of 3.26. The mean attitude scores varied significantly ($P < 0.001$) among the different professions, with physicians scoring 3.69, allied healthcare professionals scoring 3.31, and nurses scoring 3.07. The coefficient of determination (R2) was used to evaluate the variation in attitude toward telemedicine and it was found that education (12.4%) and nationality (4.7%) had the least impact on the attitude toward telemedicine.

Conclusion: Healthcare professionals are crucial to the successful implementation and continuity of telemedicine. However, despite their positive attitude toward telemedicine, most of the healthcare professionals who participated in the study had limited knowledge of it. There were differences in attitude among different groups of healthcare professionals. As a result, it is necessary to create specialized educational programs for healthcare professionals to guarantee the proper implementation and continuation of telemedicine.

KEYWORDS

E-health, telemedicine, knowledge, attitude, health care professionals

1. Introduction

Telemedicine is a technology that enables the delivery of healthcare and the exchange of healthcare information over long distances. As technology and the world evolve, telemedicine has become more prevalent, particularly due to advances in telecommunications and healthcare. Despite high demand for telemedicine services, there are still challenges that need to be addressed such as clinician availability and service delivery. Additionally, factors such as internet

availability, security, and workflow can have an impact on telemedicine. Despite these challenges, it is expected that telemedicine will have a positive impact on healthcare, similar to how the personal computer revolutionized office work. Telemedicine can improve access to healthcare, healthcare standards and the efficiency of healthcare delivery with only a little improvement.

Telemedicine is a powerful technology that uses telecommunication and information systems to deliver health care services. It is widely accepted across the globe because of its extensive applications and benefits. At present, the utilization of E-health applications has significantly increased throughout the healthcare delivery system of many countries (1). Several programs have been introduced in developed countries and reported rapidly for 10–15 years e.g., UK, Finland, Europe, Taiwan, and worldwide. Some recent programs are also dedicated to medical education, such as Western Australia. The healthcare industry and medical organizations worldwide have predominantly engaged in utilizing telemedicine technology to improve and expand the existing medical services and patient care system. Thus, the contemporary approach is to improve the efficiency of telemedicine applications in terms of speed, ease to use, and affordability (2). Currently the traditional health care system strives to enhance the efficiency, equity, and contribution to cost-effectiveness in healthcare, which can potentially be achieved through the implementation of specific telemedicine applications, such as remote patient monitoring and remote healthcare delivery (3).

The usage of telemedicine took a surge after the outbreak of COVID-19 pandemic when both patients and healthcare professionals were figuring out ways to access and deliver medical services safely (4). The increased development of digital technologies further boosted the importance of implementing telemedicine. At the present time there are numerous issues in the healthcare system of Saudi Arabia including a shortage of healthcare professionals, limited financial resources, and an increased demand for healthcare services. Moreover, the changing pattern of disease from infectious to non-infectious pathologies and poor access to healthcare services has casted an additional burden on the health care system in Saudi Arabia (5). The main health problems of the country include non-communicable diseases like diabetes, hypertension, cardiovascular diseases, and obesity (6). Furthermore, there are future challenges that must be overcome, such as ensuring a sustainable financial system and workforce planning issues, including the provision of high-quality training and the realignment of health services to adapt and respond to changing demographics and disease patterns (7). Thus, telemedicine is a solution to curb most of the present and future challenges facing the healthcare system of Saudi Arabia by offering new solutions for rural healthcare services and bridge the disparity in quality and accessibility of health care between urban and rural regions (8). Recently, the Ministry of Health Saudi Arabia has launched a project to build a centralized national electronic health record database and create a national electronic medical system (9). The Kingdom of Saudi Arabia is also marching toward establishing a research center for E-health service implementation (10). These projects clearly illustrate the potential of telemedicine in the medical industry and its ability to improve the overall healthcare system of Saudi Arabia. The current large government health care system in Saudi Arabia has an extensive geographical coverage and aims to provide E-health services to target population. It is also significant to provide free healthcare services for individuals, families, and communities in remote areas. Therefore, the implementation of telemedicine technology in such settings will offer many benefits, including the ability to cater the needs of communities in remote areas and provide improved health care services to larger population (11).

The success of a new technology, such as telemedicine, depends on various factors including the understanding and skills of professionals, their attitudes, and the work environment. In order for telemedicine to be adopted, it is crucial to train professionals and assess their readiness to provide these services. Telemedicine is a new technology in the healthcare sector, and understanding the knowledge and attitudes of healthcare professionals toward it is important for facilitating its adoption. The researcher aims to evaluate the knowledge and attitudes of healthcare professionals toward telemedicine. Healthcare professionals play a vital role in the success of telemedicine by ensuring proper implementation of information technology, facilitating a smooth transition and encouraging the use of this technology in the future. Given the need for telemedicine services in Saudi Arabia, this study aims to examine the knowledge and attitudes of healthcare professionals toward telemedicine and assess their readiness to provide such services. The goal of this study is to aid in the successful implementation of telemedicine technology and ensure its long-term viability in the medical industry. As the field of e-health services and telemedicine continues to grow globally, the findings of this study will contribute to both theoretical knowledge and practical applications.

2. Materials and methods

2.1. Study design

This study is a cross-sectional study conducted at King Fahad Medical City (KFMC), Riyadh, Saudi Arabia between June 2019 and February 2020 (Figure 1). KFMC has a total of 5,000 employees, among whom 68% are women while 32% are men. The estimation of the sample was determined by PASS ® software version 11.0.10

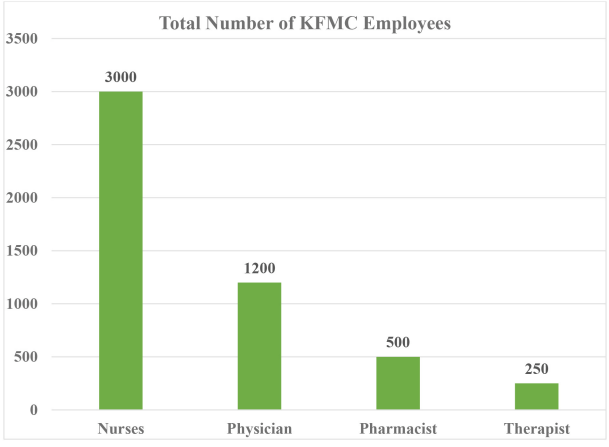

FIGURE 1
Total population of KFMC employee.

[1983-2011.NCSS, LLC]. A total of 385 eligible participants recruited from nursing, pharmacy, clinics and rehabilitation department. By considering the total population of KFMC and using population portion sampling technique with 80% power of test to detect significant difference among groups followed by 95% C.I and 5% margin of error.

The size of a sample varies depending on the requirements of each study, in case of this research groups of employees from KFMC answered a survey questionnaire to provide a comprehensive insight on the concept of telecommunication. A survey questionnaire was distributed among a sample of 385 health care professionals, and the response rate obtained was 96.10%. Therefore, a total of 370 participants enrolled in the study that provided sufficient information by adopting the approach of meaning saturation i.e., it was assumed that majority of the healthcare providers in the same hospital had a homogeneous viewpoint with reference to their knowledge and attitude toward telemedicine technology. The saturation approach will hence validate the data preciseness for a purposive sample. The purpose and design of the study were explained to these potential participants initially, and a written consent was obtained from each. Once the researcher had the consent of these participants, a survey was distributed and the responses were gathered to interpret the study results (12).

2.2. Recruitment of participants

The readings of the study are specific to the population of Saudi Arabia. A structured self-administered questionnaire was used to record the responses of 370 healthcare providers from KFMC. The participants included in the study were physicians, nurses, physical therapists, and occupational therapists. All other health care professionals absent during the study, and not willing to participate were excluded from the study. The purpose and problem statement of the study were explained to the potential participants, and after getting their signed consent the questionnaire was distributed in their respective department according to population proportion sampling technique. Therefore, step by step every questionnaire was filled by participants and was double-checked by the researcher to identify any question missed or a non-responsive participant.

In order to control the parasitic variables of the study, the researcher will match participants in the telemedicine and control groups on key demographic or clinical characteristics which will help control for variables that might influence the results of the study. Besides this, establishing standardized protocols for the implementation of telemedicine services will further help control for parasitic variables that might influence the results of the study.

2.3. Data collection instrument

Data was collected using a structured self-administered questionnaire as a data acquisition tool that was adapted from previous studies and existing literature on telemedicine (13). The data collection tool, i.e., a survey questionnaire, comprised of three parts; demographic data, assessing the knowledge of healthcare professionals on telemedicine and evaluating the attitude of healthcare professionals toward telemedicine.

The first part included the demographic data related to the participants (7 items), such as gender, age, nationality, education, profession, work experience, and monthly income. The second part (9 items) was designed to assess healthcare professionals' knowledge of telemedicine by determining the participant's awareness and training on telemedicine, telemedicine technology, healthcare quality, effects of telemedicine, and benefits of telemedicine. The level of participants' knowledge regarding telemedicine was determined by their responses "Yes" or "No," each "Yes" response was awarded a score of "1" while each "No" was given a score of "0." In this section a participant could achieve a maximum score of 9 for the knowledge component and a minimum score of 0. The total scores were classified as poor (<50%), good (50–70%), and excellent (>70%). The third part investigated the healthcare professionals' attitudes toward telemedicine. This section consisted of 24 items rated on a 5-point scale ranging from 1 (strongly agree) to 5 (strongly disagree). These 24 items referred to the following perceived telemedicine attributes: relative advantage, compatibility, complexity, trial ability and observability. The scores for each of the statement in the third section were averaged to evaluate a specific mean value. A mean score of 2.5 (50%) was considered as poor attitude, 2.6 (51%)—3.0 (59%) as moderate attitude, and above 3.0 (60%) was marked as good attitude of healthcare professionals toward telemedicine technology.

2.4. Defining study domains

The perceived attributes of telemedicine technology examined in this study to assess the attitudes of healthcare professionals toward the new advancement include the following:

- Relative advantage:
  Relative advantage is defined as a degree to which a new product, technology, innovation or service is perceived as superior to the already existing idea. Relative advantage basically determines the rate of adoption of a new technology or service.
- Compatibility:
  Compatibility is referred as the ability to work or perform together due to well-matched and homogeneous characteristics or approach. Compatibility also verifies the consistency of an idea and the fact of being in agreement to it.
- Complexity:
  Complexity is defined as the quality of a phenomenon or idea to be complicated, confusing or intricate. Complexity is also referred as a condition where a phenomenon is difficult to understand or adopt.
- Trial ability:
  Trial ability defines that how easy and convenient it is for potential users to adopt and investigate a new product or technology. It facilitates the successful adoption of new innovations by enabling users to test run a technology or product before its implementation.
- Observability:
  Observability is referred as the ability to deduce and infer the internal states and operations of a system by analyzing its output and consequences. It is a process of management strategy that allows adopters of an innovation to focus on the most critical and relevant issues in a system.

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2.5. Statistical analysis procedure

Data gathered in the study was presented as numbers, percentages, and Mean ± S.D. Parametric tests were used to compare groups on normally distributed variables and the normality of data was confirmed by the Kolmogorov-Smirnov test. Chi-square and Fisher's exact test were also incorporated according to whether or not the cell expected frequency was smaller than 5 and applied to determine the significant association between categorical variables. ANOVA *t*-test was applied to determine the mean significant differences between the dimension score (attitude of telemedicine) and profession. A stepwise regression test was used to determine the significant factors and predictors impacting the attitude toward telemedicine. A two-tailed ($P < 0.05$) was considered statistically significant. All data was entered and analyzed through the Statistical Package for the Social Sciences (SPSS 25), (SPSS Inc., Chicago, IL, USA).

2.6. Ethical considerations

The study was approved by the Institutional Review Board of the King Fahad Medical City Hospital. Consent was obtained from all subjects after explaining them the purpose of the study. Data was only collected from participants who gave a signed consent. Participation in the study was purely voluntary. Confidentiality and anonymity were maintained throughout the study as the participant's identity was not revealed in any stage of the research.

3. Results

Out of 385 distributed questionnaires, 370 participants were enrolled in the study, provided that the response rate was 96.10%. Of all participants, 112 (30.3%) were male and the remaining 258 respondents (69.7%) were female. Regarding the age group, more than half of the participants, i.e., 194 (52.2%), belonged to the age group of 30–40 years. The majority of participants i.e., 283 (76.7%) had a bachelor's degree. The distribution of the health care professionals was as follows: 90 (24.6%) were physicians, 230 (62.8%) were nurses and 46 (12.6%) were other allied health care professionals. The average score of telemedicine's knowledge was 11.12 among all participants. The demographic characteristics of the participants are represented clearly in Table 1.

TABLE 1 Basic demographic characteristics of participants ($n = 370$).

Characteristics	Description	*n* (*n*%)
Gender	Male	112 (30.3%)
	Female	258 (69.7%)
Age group	<30	99 (26.6%)
	30–40	194 (52.2%)
	>40	79 (21.2%)
Nationality	Saudi	134 (36.1%)
	Non-Saudi	237 (63.9%)
Education	Diploma	38 (10.3%)
	Bachelors	283 (76.7%)
	Masters	44 (11.9%)
	PhD	4 (1.1%)
Type of profession	Physician	90 (24.6%)
	Nurse	230 (62.8%)
	Allied health care	46 (12.6%)
Working experience (years)	<5	98 (26.3%)
	5–10	141 (37.9%)
	>10	133 (35.8%)
Monthly income (SAR)	<5,000	61 (16.4%)
	5,000–10,000	181 (48.7%)
	>10,000	130 (34.9%)
Knowledge score of telemedicine	Median [IQR]	11.12 [77.78–1.12]

IQR, Interquartile Range; PhD, Doctor of Philosophy; SAR, Saudi Arabian Riyal.

The knowledge scoring of telemedicine was classified as poor (<50%), good (50–70%) and excellent (>70%). Two hundred and thirty-seven (63.7%) participants showed poor knowledge of telemedicine, 41 (11%) participants showed good knowledge, and only 94 (25.3%) participants exhibited excellent knowledge. There was a statistically significant ($P < 0.001$) association observed between the age, gender, education, nationality, profession, and the knowledge score of telemedicine (Table 2).

The total mean score of the overall attitudes of health care professionals was (3.26 ± 0.51), which reflects a good attitude toward telemedicine among the healthcare professionals. The mean scores of attitudes dimensions toward telemedicine among the different types of professions were also computed independently. The overall mean score of the attitudes of physicians was (3.69 ± 0.54, good), which was higher than other health care professionals. The overall mean score of the attitudes of nurses was also good except for the following two dimensions; complexity (2.99 ± 0.47) and observability (2.79 ± 0.81), which showed a moderate attitude toward telemedicine.

As a result, the health care professionals depicted a good attitude in all dimensions toward telemedicine. This can be interpreted from the Mean ± SD values of the study domains; relative advantage (3.47 ± 0.76), compatibility (3.30 ± 0.80), complexity (3.14 ± 0.63), trial ability (3.43 ± 0.78) and observability (3.15 ± 1.08). Table 3 is a visual representation of these results.

Table 4 represents the regression model, where attitudes scores were the dependent variables. The model's R^2 represents the variance in the attitudes toward telemedicine i.e., the impact of education explained 12.4% of the variance in the attitude toward telemedicine. Also, the impact of nationality explained 4.7% of the variance in the attitude toward telemedicine (for model 2). Furthermore, in models 3 and 4, the impact of age groups and work experience explained 1.6 and 1.00% of the variance in the attitude toward telemedicine, respectively. In model 5, the impact of gender explained 6.8% of the variance in the attitude toward telemedicine.

4. Discussion

The successful implementation of any technology is predominantly influenced by a number of factors. Human-related factors are of great significance, especially when implementing any technology in the healthcare system. This proposed study

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TABLE 2 Impact and association between knowledge score of telemedicine and study factors.

		Knowledge score of telemedicine			*P*-value
		Poor	Good	Excellent	
Gender	Male	48 (20.3%)	15 (38.5%)	49 (52.1%)	<0.001
	Female	189 (79.7%)	24 (61.5%)	45 (47.9%)	
Age group	<30	71 (30.0%)	15 (36.6%)	13 (13.8%)	0.001
	30–40	128 (54.0%)	17 (41.5%)	49 (52.1%)	
	>40	38 (16.0%)	9 (22.0%)	32 (34.0%)	
Nationality	Saudi	71 (30.1%)	17 (41.5%)	46 (48.9%)	0.004
	Non-Saudi	165 (69.9%)	24 (58.5%)	48 (51.1%)	
Education	Diploma	31 (13.2%)	5 (12.2%)	2 (2.1%)	<0.001
	Bachelors	194 (82.9%)	33 (80.5%)	56 (59.6%)	
	Masters	8 (3.4%)	3 (7.3%)	33 (35.1%)	
	PhD	1 (0.4%)	0 (0.0%)	3 (3.2%)	
Type of profession	Physician	30 (12.8%)	12 (30.8%)	48 (52.2%)	<0.001
	Nurse	175 (74.5%)	21 (53.8%)	34 (37.0%)	
	Allied health care	30 (12.8%)	6 (15.4%)	10 (10.9%)	
Work experience (years)	<5	74 (31.2%)	13 (31.7%)	11 (11.7%)	0.007
	5–10	85 (35.9%)	14 (34.1%)	42 (44.7%)	
	>10	78 (32.9%)	14 (34.1%)	41 (43.6%)	

PhD, Doctor of Philosophy.

TABLE 3 Comparative analysis of dimension scores among health care professionals.

	Total	Physician	Nurse	Allied health care	*P*-value
Relative advantage	3.47 ± 0.76	4.07 ± 0.78	3.22 ± 0.61	3.58 ± 0.79	<0.001
Compatibility	3.30 ± 0.80	3.87 ± 0.91	3.06 ± 0.62	3.46 ± 0.8	<0.001
Complexity	3.14 ± 0.63	3.55 ± 0.8	2.99 ± 0.47	3.13 ± 0.64	<0.001
Trial ability	3.43 ± 0.78	4.07 ± 0.83	3.18 ± 0.62	3.46 ± 0.73	<0.001
Observability	3.15 ± 1.08	4.07 ± 1.09	2.79 ± 0.81	3.15 ± 1.17	<0.001
Overall attitude score	3.26 ± 0.51	3.69 ± 0.54	3.07 ± 0.37	3.31 ± 0.50	<0.001

basically explored the knowledge and attitude of healthcare professionals toward telemedicine by conducting a survey among healthcare professionals at KFMC. The results show that healthcare professionals play a vital role in the practical implementation of telemedicine and the sustainability of health care technology. Therefore, adequate knowledge of the new innovation and a good attitude of medical specialists toward such a technology are mandatory so that telemedicine can be implemented extensively (13).

Literature includes many relevant studies on the role and significance of telemedicine in the medical industry. Telemedicine approach helps to reduce the costs and minimize the traveling of patients's from remote areas to metropolitan cities (14, 15). According to a recent Chinese research, <5% of research respondents were of the viewpoint that telemedicine doesn't play a helpful role in improving the healthcare system and mitigating the medical cost and burden on patients whereas the majority were in favor of the new medical advancement (16). Moreover, the literature also reveals that using teleconsultation and by receiving distant medical education, the new and grassroots doctors can learn and gain guidance on the treatment plans by communicating with senior medical experts in larger cities which will eventually enhance their medical skill (17). A group of Chinese researchers claimed that majority of the medical staff and professionals were willing to adopt and promote the telemedicine technology in China (16). Similar results were generated by a survey study conducted in Australia where around 61.9% of participants revealed that they had a "better" experience with adopting telemedicine rather than using the traditional appointment scheduling medical system (18).

Adding further, a study of Saudi Arabia propounded that majority of the medical professionals readily accepted the implementation of telemedicine in hospitals (15). A German survey demonstrated that maximum number of postgraduate medical officers are satisfied by the implementation of telemedicine and are willing to get more training (19). According to a US study, international oncologists revealed that 73.8% of them were satisfied by the adoption of telemedicine and after the outbreak of COVID-19

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TABLE 4 Identification of factors affecting the attitude of telemedicine by regression analysis.

Attitude scores		Unstandardized coefficients		Standardized coefficients	t	R^2	*P*-value
Model		B	Std. error	β			
Step 1	Education	0.256	0.051	0.256	4.986	0.124	<0.001
Step 2	Nationality	−0.271	0.065	−0.254	−4.183	0.047	<0.001
Step 3	Age group	0.101	0.052	0.136	1.931	0.016	0.054
Step 4	Work experience (years)	0.068	0.048	0.105	1.423	0.005	0.156
Step 5	Gender	−0.099	0.06	−0.089	−1.649	0.068	0.100

this percentage escalated to 81.5% (20). Moreover, the ESAIC (European Society of Anaesthesiology and Intensive Care) and ASA (American society of Anaesthesiology) collaborated to conduct a survey which claimed that anaesthesiologists are highly satisfied by the use of telemedicine technology and around 86.3% of them are willing to pursue the use of telemedicine in their clinical practices (21).

Additionally, the survey conducted by Michigan State University in the US and other relevant studies manifest that the attitude of healthcare professionals and their viewpoint regarding telemedicine usage are key components to figure out the successful implementation of this technology (22, 23). To deal with human-related constraints in the development of a new technology like telemedicine, countries and medical industries need to frame targeted strategies. The purpose of this study is to assess the knowledge level and attitude of healthcare professionals at KFMC regarding the implementation of telemedicine in Saudi Arabia. The study results interpreted that 63.7% of the total 370 respondents had poor knowledge regarding telemedicine, which is still less than the percentage of European healthcare professionals, i.e., 84%, who have little awareness on telemedicine (24). However, the mean score of the participants was >3.0 which shows that on a whole the medical professionals at KFMC have a good attitude toward the implementation of telemedicine technology. Besides this, the study model suggested that education had a 12.4% impact on the variance in the attitude toward telemedicine which suggests that efforts need to be put forward in order to educate healthcare professionals and increase their awareness and training on telemedicine for the sustainable adoption of this advancement in Saudi Arabia.

In comparison to the findings of this study, a research was conducted in the teaching hospitals in Mashhad, Iran which showed that although most of the research participants had a positive attitude toward telemedicine (65%) but their knowledge on telemedicine was signified to be at a lower level with a mean score of 13 ± 5.5 (23). These results are hence similar to the findings of this proposed research as both indicate poor knowledge of healthcare professionals on telemedicine and a positive attitude toward the adoption of this new technology. Another study conducted in Isfahan, Iran reveals that 63.3% of its participants have a good attitude toward telemedicine's implementation hence complying with the findings of this research (25). Therefore, the findings of this research clearly indicate that the knowledge level of most healthcare professionals is poor but their attitude toward the adoption of telemedicine is positive which acknowledges other literature findings from similar studies.

As telemedicine is a new development in the field of medical services, its implementation has still not been satisfactory and far-reaching. However, the favorable attitude of healthcare professionals in Saudi Arabia ensures their ability to offer Continuing Medical Education (CME) for ground roots doctorsin rural and remote areas in addition to providing remote consultations to patients from expert medical specialists (26). The research findings also signify the need to enhance the knowledge and skills of health care professionals by introducing targeted interventions and training programs before the complete implementation of telemedicine. Thus, these interpretations provide a great opportunity for implementing telemedicine fully in the medical system of Saudi Arabia, provided that adequate training and education sessions are provided to the healthcare professionals. Hence before the extensive implementation of this technology, it is crucial to increase the user knowledge level of telemedicine and make them aware of the competencies and advantages of this advancement. This will validate the successful use of telemedicine technology in the coming future and promote sustainability in the medical infrastructure.

5. Challenges and future recommendations

The challenges that impede the wide-scale adoption of telemedicine include inadequate medical infrastructure, such as a lack of necessary equipment, hardware, and software, as well as unreliable internet connections. Additionally, there are costs associated with updating to telemedicine technology. One of the biggest challenges is raising concerns regarding training, awareness and acceptance of telemedicine among healthcare professionals and the general public. Furthermore, a lack of education is a significant obstacle to the implementation of telemedicine in many developing countries (27).

Thus, there is a need to adapt policies that increase the awareness regarding telemedicine applications and its benefits among the laymen, makes telemedicine knowledge and training more accessible to medical staff at hospitals and universalize telemedicine in all remote and under developed areas through media coverage and training programs. Providing incentives to medical staff on adopting telemedicine in their system will enhance their satisfaction, utilization and willingness to continue the usage of this advancement in clinical practices. The increased convenience and cost reduction following telemedicine adoption will further raise the satisfaction level of healthcare professionals. Cost subsidy incentives, expense strategies and professional title promotions must also be offered in

hospitals to promote the successful implementation and popularity of telemedicine.

To overcome the challenges associated with implementing telemedicine in Saudi Arabia, a number of different types of awareness and training sessions will likely be needed. Some key areas that will likely need to be addressed include:

- Technical training: Medical staff will need to be trained on the technical aspects of telemedicine, including how to use the necessary equipment, hardware, and software.
- Clinical training: Medical staff will also need to be trained on the clinical aspects of telemedicine, including how to conduct virtual consultations, remote monitoring, and other telemedicine-related procedures.
- Legal and regulatory training: Medical staff will need to be aware of the legal and regulatory requirements related to telemedicine in Saudi Arabia, including issues related to data privacy and security, patient consent, and reimbursement.
- Communication training: Medical staff will also need to be trained on how to effectively communicate with patients during virtual consultations, as the physical presence of the doctor is not there, which can be a barrier in trust factor between the doctor and the patient.
- Public awareness campaigns: The general public will need to be educated about the benefits of telemedicine and how to access telemedicine services.
- Incentives for adoption: To encourage healthcare professionals to adopt telemedicine, various incentives such as cost subsidies, expense strategies, and professional title promotions should be offered.

6. Strengths and limitations

Telemedicine has both advantages and disadvantages. One limitation is that it can't provide the same level of detail as an in-person examination. Additionally, the use of a screen can make some patients feel less comfortable, which can make it harder to build trust with their doctor. Some patients may also have difficulty communicating their health concerns through online consultations. However, telemedicine also has several strengths that should not be overlooked. For example, it can be very effective in controlling the spread of infectious diseases such as COVID-19. It is also more convenient and can reduce the need for unnecessary emergency room visits. Additionally, it can be more cost-effective by saving on travel expenses for routine check-ups. Telemedicine can also provide access to healthcare in rural areas with limited medical facilities. Additionally, online therapy-led support groups can provide peer-to-peer support for people dealing with similar challenges. Overall, telemedicine has its pros and cons when applied on a larger scale.

The major limitation of this study was that the participants were recruited from a single hospital (KFMC) due to the limited resources of the researchers. As a result, the study findings were confined to a smaller medical population affecting the credibility of the results. The study should have been conducted using a larger sample of healthcare professionals from all across the country to evaluate the knowledge level and attitude of healthcare professionals more precisely. This would have also increased the generalizability of the research findings. Moreover, this study analyses the telemedicine approach from the perspective of Saudi healthcare professionals only, neglecting the viewpoint of patients. The scope of this study can be expanded further by combing and comparing the perspectives of both patients and medical professionals simultaneously in a single research. Analyzing the impact of COVID-19 on the usage of telemedicine technology and the attitude of healthcare professionals can also be studied in future research to provide an in-depth perspicacity on the topic of telemedicine. Lastly, this study was based on a self-administered survey questionnaire which can increase the chances of researcher bias and impact the output of the study.

Considering the strengths, this study provides a multi-level understanding of telemedicine technology by discussing the experience, knowledge level and attitude of healthcare professionals, and the challenges and expectations from the development and implementation of this advanced technology. It is also one of the few studies using regression models to analyse the factors that impact healthcare professional's attitude and satisfaction level toward telemedicine.

7. Conclusion

This study declares that healthcare professionals are the key users of telemedicine technology and their perceptions and knowledge on telemedicine plays a crucial role in the sustainable development of health industry. The use of telemedicine in Saudi Arabia is insufficient and limited which is why many healthcare professionals have low-grade knowledge about the new medical concept, only 25.3% of participants were having good knowledge of telemedicine. However, the positive attitude of majority participants toward implementing telemedicine increases the scope of this technology in achieving a sustainable medical system. Variations in attitude exist among the different groups of healthcare professionals. Therefore, there is a need to establish tailored educational interventions for healthcare professionals to ensure the proper implementation and sustainability of telemedicine. To conclude, as the knowledge deficit can have an impact on the success of the implementation of telemedicine, it is vital to build targeted interventions to train the health care professionals in telemedicine, which would aid in ensuring the proper implementation and sustainability of this technology. Telemedicine technology is thus a salvation to the medical industry and healthcare systems, opening a gateway to improved medical services for patients all across the globe.

Telemedicine technology is on the verge of revolutionizing healthcare, and it's not too far in the future when most of our healthcare-related issues will be addressed virtually. With only a little further development and improvement, telemedicine technology has the potential to benefit the entire world. Some of its research is already showing promising long-term results. As more people will be cared for without having to crowd hospitals or institutions, the technology will also make it possible for patients who require urgent physical encounters with their clinicians to receive treatment immediately. Introducing new technologies is never easy, and telemedicine has and will continue to face criticism and resistance, but over time it will become widely accepted and successfully used throughout the world.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

Ethics review and approval/written informed consent was not required as per local legislation and institutional requirements.

Author contributions

MB and DL contributed to the conception and design of the study. DL organized the database. MB performed the statistical analysis and wrote the first draft of the manuscript. SA and AA-S wrote sections of the manuscript. All authors contributed to manuscript's revision, read, and approved the submitted version.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Can healthcare apps and smart speakers improve the health behavior and depression of older adults? A quasi-experimental study

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Purpose: This study identified the effects of applying information and communication technologies (ICT) to the health management of older adults aged 65 or older.
Methods: Older adults registered at public health centers were provided with the health management app "Health Today" and a smart speaker for 6 months to perform assigned healthcare missions. The program was conducted for 6 months by dividing participants into two groups: one that received both the health management app and the smart speaker, and another that used only the health management app. Depression, self-efficacy, number of days of moderate-intensity exercise, relative grip strength, balance tests, and five-times-sit-to-stand tests were measured during the pre- and post-evaluation.
Results: Both groups showed a positive health status and behavioral changes at post-evaluation. However, no reduced depression was observed due to communication and music listening functions in the group that was additionally provided smart speakers.
Conclusion: ICT use in healthcare can be beneficial for older adults. However, whether these devices meet the purpose of the national health project must be determined, and an effect evaluation must be undertaken prior to providing these ICT devices for the health management of older adults in the public domain.

KEYWORDS
aged, internet of things, information technology, depression, health behavior

1. Introduction

Information and communication technology (ICT) has recently come to refer to all fields of collecting, processing, and consuming information, rather than merely communication-related technology that transmits information. Mobile health (mHealth) and Internet of Things (IoT) are emerging keywords in various industries, including healthcare, and are being applied to multiple fields.

Aging is an unavoidable demographic trend worldwide, with the main health problem being frailty. The increase in weakness and chronic diseases of older adults consumes socioeconomic resources in the community, and the increase in medical expenses is a serious problem. Care for vulnerable older adults has often been undertaken in medical and nursing facilities, but many recent studies have shown that providing healthcare in a familiar home environment has the same or more effective clinical outcomes compared to care in medical facilities (1–3). In particular, the perceived quality of life increases when older adults live in their own homes. The fact that they can continue to be in an

environment they are familiar with gives them psychological stability, which can have a positive effect on their mental and social health.

From the service receiver's perspective, there is no need for older adults to wait until formal care services become available. This reduces waiting time and increases the participant's ability to self-manage, which can have great long-term health effects. Ultimately, the goal of the healthcare service using ICTs is to serve as a self-management mechanism that can be intuitively used by participants without requiring special effort by health professionals (1, 2). In the past, to evaluate the physical activity of older adults, one had to use a pedometer and write evaluation notes in a notebook. However, when ICT is used, the number of steps taken and calories consumed are automatically measured by the smartphones that are linked to the database, so that health experts can check and manage it in real time. The purpose of using ICT for health management is to incorporate technology into the life of the user, thus helping them efficiently manage their health with minimal effort.

ICT provides an advantage for service providers in that one health professional can manage more people simultaneously, thereby increasing work efficiency and reducing costs. The time for providing indirect services such as data collection and preparation for patient visits is greatly reduced, which allows health professionals to focus more on direct healthcare services. In terms of efficiency and effectiveness, ICT healthcare services targeted towards older adults are an approach with great potential (1).

Representative projects that aimed to prevent the frailty of older adults using ICT are PERSSILAA (Personalized ICT Supported Service for Independent Living and Active Aging), SPRINTT, and My-AHA (4, 5). They were implemented to prevent weakness in older adults in the community and to achieve independent and successful aging. Cognitive, nutrition, and exercise programs were conducted after primary screening and secondary detailed evaluation in groups and individually. Technologies such as video calls, messages, remote monitoring, and health measurement through smartphone apps were grafted. These projects yielded positive results in improving activities of daily living, quality of life, and frailty. A previous study confirmed that healthcare services using ICT had a positive effect on exercise ability, cognitive function, and depression (4, 6). Smart speakers have different effects depending on the participants' attitudes toward smart devices and gender. They are also easy to use because they operate as a voice interface and can have a positive effect on emotion through a conversation function (6, 7).

Home care services are implemented at 254 public health centers across South Korea as part of a community-wide health promotion project, in which a nurse visits the homes of those aged 65 or older, periodically checking health status and counselling. However, from 2020 to 2022, it was difficult to manage health through direct home visits due to the spread of COVID-19 in the community. To solve this problem, a pilot project, known as the "AI-IoT Healthcare Service for Older Adults," has been implemented since 2020 by the Ministry of Health and Welfare, the Korea Health Promotion and Development Institute, and Korea Social Security Information Services to convert healthcare visits for the vulnerable from face-to-face to virtual visits.

This study statistically verifies the effect of the local health center's newly attempted "AI-IoT healthcare service for older adults" in Seoul, South Korea. The pilot project consisted of providing wearable devices to older adults living in the local area, along with a smartphone app that can check healthcare missions and monitor this information to offer non-face-to-face professional counseling with exercise experts, nutritionists, and home care nurses.

According to the theory of planned behavior, attitudes, subjective norms, and perceived behavioral control influence intentions. Further, behavioral intentions are strongly correlated with behaviors. Attitudes toward health behaviors are determined by beliefs about health outcomes and evaluations of the values associated with those outcomes (8). Health interventions using ICT can increase value and a perceived sense of control over health outcomes. Positive health results were expected in the group that was additionally provided the smart speaker, due to higher adherence to health behaviors than the group that used the App alone. Previous studies found that the communication function of smart speakers, music, and ASMR functions had a positive effect on relieving depression (7, 9). Previous research has also shown that healthcare services using ICTs are an effective approach for the successful aging of community-dwelling older adults, but it is necessary to accumulate more knowledge about the acceptability and effectiveness of the various types of interventions. Therefore, this study discerns the effect of ICT healthcare services for older adults on depression and health behaviors (10).

The purpose of this study is (1) to identify the effect of health management services using healthcare apps and smart speakers with older adults in the community on health behavior, health status, and depression, and (2) to compare the effects on health status, health behavior, and depression between the group that was provided both the healthcare app and the smart speaker and the group that was only provided the healthcare app.

2. Methods

2.1. Study design

This study consisted of a nonequivalent control group pretest-posttest design. The participants were either assigned to the experimental group [i.e., the smart speaker group (SS)], who were provided with a smartphone app ("Health Today"), wearable devices, and smart speakers, or to the control group, that only received a smartphone app and wearable devices [i.e., the healthcare app group (HA)].

Older adults registered with the health center home care service who agreed to participate in the study but did not agree to the provision of smart speakers were assigned to the control (HA) group. Those who agreed to use the smart speaker were assigned

to the SS group, in accordance with the Korean national project guidelines for those who live alone, have low social contact, or experience depression. The recruitment of study participants started in July 2021 after the IRB approval date, and the preliminary evaluation was completed by August 2021. The post evaluation was conducted between December 2021 and January 2022.

2.2. Participants

Our participant sample consisted of older adults aged 65 or older registered for the home care services provided by a public health center in Seoul. The criteria for the selection of study participants were the ability to maintain cognitive function to use IoT devices and to understand the survey or follow the instructions of the visiting nurse. Chronic diseases such as hypertension, diabetes, cancer, hyperlipidemia, cerebrovascular disease, and cardiovascular disease may be present in the participants. The exclusion criteria for participation in the study were those diagnosed with dementia or significantly reduced cognitive function who were unable to complete questionnaires and follow the visiting nurse's instructions. People who had taken drugs or been diagnosed by a doctor for alcoholism, depression, schizophrenia, or any other type of psychosis were also excluded. If it was determined that it was impossible for a participant to continue participating in the study due to a deterioration of health during the study or if they passed away, they were excluded. Further, if voluntary participation was difficult to guarantee, or if participants wanted to withdraw their participation, these individuals were removed from the study.

2.3. Ethical consideration

The entire process of this study was planned after deliberation by the Public Institutional Review Board of the Korea National Institute for Bioethics Policy, and the study termination report was completed in compliance with the ethical guidelines (Public IRB No. 2021-0808-004). Recruitment and pre- and post-evaluation of the control and intervention groups were conducted at public health centers. Participants provided consent after the lead researcher explained the research at the time of registration and pre-evaluation. The participants also received a separate explanation through written consent forms.

2.4. Interventions

Following a booking for a visit to the public health center, the participants underwent a multicomponent intervention which included a consent form, pre-evaluation, 6 months of non-face-to-face health counseling, and health management information for using ICT devices. At the end of the 6-month service, the same items were subject to a post-evaluation. All the participants received non-face-to-face health counseling at least once a month. The healthcare missions consisted of the following: eating 3 meals per day, walking 5,000 steps or 30 min per day, taking prescribed medication on time, going outside at least once a day, measuring blood pressure once a day if participants had hypertension, measuring glucose level regularly if participants had hyperglycemia and drinking 8 cups of water per day (see **Supplementary Figure S1**). The participants connected their health data (step count, blood pressure, blood glucose, healthcare mission) to the smartphone app through wearable devices in real-time. This information was remotely monitored by visiting nurses, exercise experts, nutritionists, and other experts from the health center. Non-face-to-face consultations were conducted more than once based on this information. Health education materials were also provided in a non-face-to-face manner, and pictures or video links related to healthcare were sent to the participants' mobile phones at least once a month. Using the app's push notifications, we sent a text message encouraging the participants to perform a healthcare mission at least once a week. The home care nurses monitored blood pressure, blood glucose levels, and step count levels at least once a week and provided consultations if there were any abnormalities. **Table 1** presents the functions of smart speakers, smartphone apps, and wearable devices provided for each group.

2.5. Instruments

2.5.1. General characteristics

The factors reported to potentially influence depression and health behavior, such as sex, age, family type (living alone, couple of older adults, multicultural families, etc.) were investigated.

2.5.2. Physical measurements and health status

- Body mass index (BMI): BMI is calculated as weight (kg)/height (m^2). The participants were classified as normal ($18.5 \leq$ BMI < 25 kg/m^2), underweight (<18.5 kg/m^2), or obese (≥ 25 kg/m^2).
- Relative hand grip strength [Absolute grip strength (kg)/weight (kg)*100, %]: grip strength was measured using a hand dynamometer by trained nurses. The arm is naturally lowered to the research participant, and both hands are measured alternately twice. The participants were asked to hold the grip dynamometer, contract it with maximum force for 5–10 s, and then record the maximum value out of measurements. Relative grip strength was judged according to "normal," "risk," and "weak" stages by referring to the standard value according to the age and gender of the participant (11, 12).
- One leg balance test: After having the elderly stand on one foot, the number of seconds they can stand is measured with a stopwatch. If it is less than 5 s, it is evaluated as abnormal, and if it is more than 5 s, it is evaluated as normal (13).
- Five-time-seat-to-stand test (FTSTS): The FTSTS score measures the time it takes the participants to transfer from a sitting position to a standing position and back to a sitting position 5 times. The age matched norms scores are 11.4 s for

TABLE 1 Functions of healthcare devices by intervention groups.

Provided devices		Healthcare app + smart speaker user group (SS group)	Healthcare app user group (HA group)
Smart speaker	Emotional support	Tactile or voice recognition type conversation	None
	Disease management	Chronic disease related medication notification	
	Safety management	Sending voice rescue messages: 24/7 monitoring in conjunction with security companies	
	Cognitive function	Cognitive Enhancement Quiz Program	
	Life information	–Various information necessary for senior life (living information, health information provided) –Wakeup call	
	Exercise	Provide gymnastics program according to voice guidance	
	Sound contents	News, music, radio, religious content, ASMR (sound of waves, wind, etc.)	
Smartphone app ("Health Today"[a])	–Monthly healthcare mission assignment (e.g., "Eat three meals a day," "Walk more than 5,000 steps every day," etc.) –Remote consultations with exercise therapists, nutritionists, and visiting nurses –Send health-related text messages and push notifications on the smartphone		
Wearable devices	Wrist-worn activity monitor, Bluetooth blood pressure monitor, Bluetooth blood glucose monitor, Bluetooth scale (Health condition monitored in conjunction with the smartphone app)		

ASMR, autonomous sensory meridian response; SS, App + smart speaker; HA, healthcare app.
[a]Smartphone healthcare app, which is developed by the Korean Health Promotion Institute.

the 60–69 years age group and 12.6 and 14.8 s for the 70–79 and 80–89 years age group, respectively (14).

- Diagnosis of chronic disease (high blood pressure, diabetes, stroke, cancer, arthritis, other diseases).

2.5.3. Health behavior

- Dietary diversity scores (DDS): The daily intake of cereals, proteins, vegetables, fruits, milk, and dairy products is given as 1 point for each group and 0 points for non-intake, ranging from 0 to 5 points. The higher the score, the more balanced the food consumption.
- Physical activity: Average exercise frequency per week. The number of days of moderate-intensity exercise was investigated through a self-response, ranging from 0 to 7 days.

2.5.4. Exercise self-efficacy

The exercise self-efficacy tool, developed by Marcus et al. (15) and translated by Lee and Jang (16), was used with a total of 5 items. This tool uses a 5-point scale that assesses confidence in one's ability to consistently perform exercise in any situation. The higher the value, the higher the self-efficacy, with 1 point for "not at all confident" and 5 points for "very confident," and a higher score indicating a higher sense of self-efficacy. Total scores range from 5 to 25.

2.5.5. Depression

The Geriatric Depression Scale (GDS) was developed with 30 items. Sheikh and Yesavage (17) developed a short form version consisting of 15 items based on the diagnostic validity study on GDS. In Cho et al.'s study (18), the validity of the Korean version of the GDS in short form was verified and the reliability was 0.88. It consists of a total of 15 items and measures "yes" and "no" on a binary scale for each symptom. A higher score indicates a higher level of depression. If the cut-off point is 8 or higher, it reveals a risk of depression.

2.5.6. Data analysis

Of the total of 356 participants, those who lived alone, had low social contact, or were depressed were assigned to the SS group, according to the health center project guidelines. 74 out of 356 people refused to participate in the study. 85 people were assigned to the SS group and 197 people to the HA group. Two people in the SS group and four people in the HA group dropped out due to an accident or because they withdrew from the study. A propensity score matching (PSM) method using depression scores was used to accurately analyze the effects of the SS group and the HA group. The propensity score was calculated by performing logistic regression analysis, with age and depression as the independent variables, and the provision of a smart speaker as the dependent variable. Participants with similar scores were matched 1:1 between the two groups; 83 people who used the healthcare app, and 83 people who used both the app and the smart speaker were matched and included in the final analysis (**Figure 1**).

The Shapiro-Wilk normality test was performed on the data; a *t*-test and the Wilcoxon rank sum test were performed on the continuous variables; the Chi-squared test and Fisher's exact test were performed on the categorical variables as appropriate methods, according to the normality results. The homogeneity of the pre-screening by group was verified for the analysis of the intervention effect. For continuous variables, the Wilcoxon rank sum test or *t*-test for differences in pre-post values was used, and for qualitative variables, Fisher's exact test or χ^2 test was used. Statistical analysis was performed using Stata 17.0 (19). Statistical significance was based on an alpha value of 0.05.

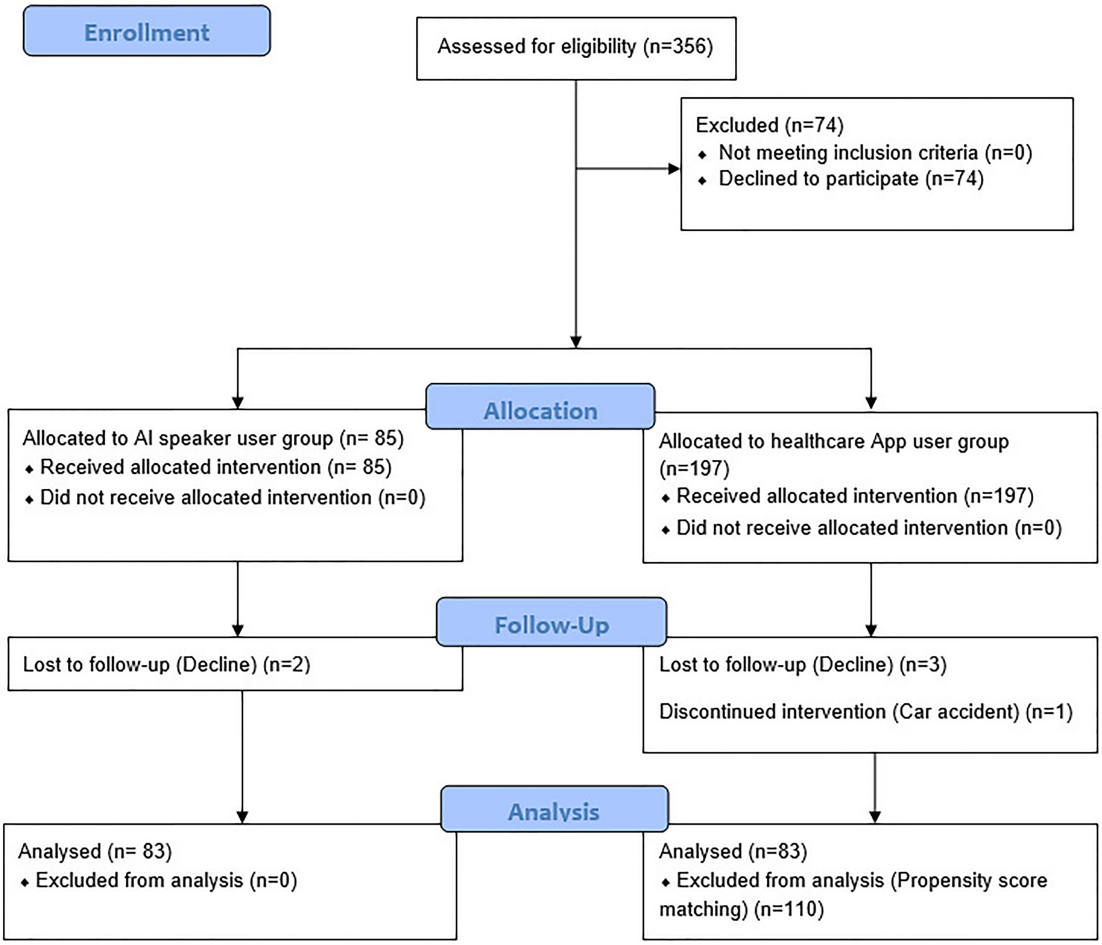

FIGURE 1
CONSORT flow diagram of the study.

3. Results

3.1. Participants' general characteristics

Table 2 presents the general characteristics of the study participants: 24.1% were male and 75.9% were female, and both groups showed no statistical difference. The mean age was 71.05 ± 4.65 years, and there was no statistical difference between the two groups. Among those living alone, 55 were from the SS group (66.27%), and 36 (43.37%) were from the HA group. This study was conducted as part of a public health center project; these results were produced according to the standard for distributing smart speakers to people living alone, and it is therefore necessary to pay attention to the interpretation of the results.

A total of 94 (56.63%) out of the 166 participants had hypertension, 43 (25.9%) had diabetes, 9 (5.42%) had a stroke, 14 (8.43%) had cancer, 46 (27.71%) had arthritis, and 53 (31.93%) had dyslipidemia. Those without chronic disease accounted for 18.67% of the total participants, compared to those with one or more disease at 81.33%.

A BMI of 25 kg/m^2 or more was considered as obese and less than 18.5 kg/m^2 as underweight; hence, 63 (37.95%) of participants were obese and 8 (4.82%) were underweight. For the relative grip strength, 32 (19.28%) of the participants were at the risk level and 53 (31.93%) were rated as weak, with no significant difference between the two groups. Ten (10.84%) participants were evaluated as weak in the one leg balance test, and 45 (25.45%) were assessed as weak in the five-times-sit-to-stand test, with no significant difference between the two groups.

3.2. Effects of smart speaker and healthcare app on health behavior and depression

Table 3 presents the results of comparison between pre- and post-values of the participants. The level of depression increased in both groups in the post-test compared to the pre-test, and there was no difference in the degree of increase in the post-test between the two groups (HA: 0.83 ± 3.77 and SS: 1.73 ± 3.38, $p > 0.05$).

The average value of exercise on self-efficacy in the pre-test was 18.55 ± 4.56 in the HA group and 18.39 ± 4.2 in the SS group. There was no difference between the posttest and pretest (d) between the two groups (HA: 0.92 ± 3.61 and SS: 0.25 ± 3.73,

TABLE 2 General characteristics and health status of participants.

Category		Total	HA	SS	t or χ^2	p
		($N = 166$)	($N = 83$)	($N = 83$)		
		n (%) or mean ± SD				
Sex	Male	40 (24.1)	20 (24.1)	20 (24.1)	0.00	>0.99
	Female	126 (75.9)	63 (75.9)	63 (75.9)		
Age		71.05 ± 4.65	70.37 ± 4.83	71.73 ± 4.4	1.90	0.059
Characteristics of family	Multicultural family	1 (0.6)	0 (0)	1 (1.2)	12.686	0.027*
	Living with grandchildren	1 (0.6)	1 (1.2)	0 (0)		
	Living alone	91 (54.82)	36 (43.37)	55 (66.27)		
	Living with spouse	46 (27.71)	31 (37.35)	15 (18.07)		
	Living with children	27 (15.72)	15 (18.07)	12 (14.46)		
Hypertension	No	72 (43.37)	39 (46.99)	33 (39.76)	0.88	0.347
	Yes	94 (56.63)	44 (53.01)	50 (60.24)		
Diabetes	No	123 (74.1)	65 (78.31)	58 (69.88)	1.53	0.215
	Yes	43 (25.9)	18 (21.69)	25 (30.12)		
Stroke	No	157 (94.58)	79 (95.18)	78 (93.98)	0.12	0.732
	Yes	9 (5.42)	4 (4.82)	5 (6.02)		
Cancer	No	152 (91.57)	80 (96.39)	72 (86.75)	4.99	0.026*
	Yes	14 (8.43)	3 (3.61)	11 (13.25)		
Arthritis	No	120 (72.29)	64 (77.11)	56 (67.47)	1.91	0.167
	Yes	46 (27.71)	19 (22.89)	27 (32.53)		
Hyperlipidemia	No	113 (68.07)	62 (74.7)	51 (61.45)	3.353	0.067
	Yes	53 (31.93)	21 (25.3)	32 (38.55)		
Number of chronic diseases	0	31 (18.67)	21 (25.3)	10 (12.05)	8.575	0.0726
	1	57 (34.34)	31 (37.35)	26 (31.33)		
	2	40 (24.1)	18 (21.69)	22 (26.51)		
	3	30 (18.07)	10 (12.05)	20 (24.1)		
	4	8 (4.82)	3 (3.61)	5 (6.02)		

HA, healthcare app user group; SS, app + smart speaker user group.
*$p < 0.05$.
**$p < 0.01$.
***$p < 0.001$.

$p > 0.05$). The proportion of those who did not exercise at all was 45.78% (76 out of 166 participants) and decreased to 57 (34.34%) after 6 months of intervention. However, there was no difference between the HA and SS groups ($\chi^2 = 3.893$, $p > 0.05$).

26 people (15.66%) had a dietary diversity score between 0 and 2. After 6 months, the number decreased to 23 (13.86%). In addition, the proportion of those who ate from all five food groups evenly increased from 48 (28.92%) to 56 (33.73%). Although the pre-test values were the same, there was a statistically significant difference between the two groups in the post-test. In the HA group, the number increased from 31.33% to 42.17%, but in the SS group, it decreased from 26.51% to 25.3%. However, in the SS group, those who consumed 0–2 food groups decreased from 18.07% to 13.25%, and those who consumed 3 or 4 food groups increased from 55.42% to 61.45%, thus indicating a positive change.

In the case of BMI, 95 people (57.23%) were evaluated as normal at the pre-evaluation, and 99 (59.64%) at the post-evaluation, a similar level. The obese group also remained at a similar level: 63 (37.95%) at the pre-evaluation compared to 58 (34.94%) at the post-evaluation. There was no statistically significant difference between the HA group and the SS group for both pre and post values.

In terms of relative handgrip strength, the number of those evaluated as normal increased from 80 (48.19%) to 94 (56.63%), and the pre- and post-evaluation were the same for those evaluated as at-risk at 32 (19.28%). The number of those evaluated as weak decreased from 53 (31.93%) in the pre-

TABLE 3 Pre-post effects evaluation between the Smart Speaker group and healthcare app user group.

Category		Pre-test			t or χ^2	p	Post-test n (%) or d (Post-pre)			t or χ^2	p
		Total	HA	SS			Total	HA	SS		
		($N = 166$)	($N = 83$)	($N = 83$)			($N = 166$)	($N = 83$)	($N = 83$)		
GDS		3.5 ± 3.19	3.18 ± 3.05	3.82 ± 3.32	1.276	0.204	1.27 ± 3.6	0.83 ± 3.77	1.73 ± 3.38	1.589	0.114
Exercise self-efficacy		18.47 ± 4.37	18.55 ± 4.56	18.39 ± 4.2	−0.248	0.805	0.58 ± 3.68	0.92 ± 3.61	0.25 ± 3.73	−1.162	0.247
Moderate exercise frequency/week	0	76 (45.78%)	34 (40.96%)	42 (50.6%)	3.893	0.143	57 (34.34%)	29 (34.94%)	28 (33.73%)	0.361	0.835
	1–2	12 (7.23%)	9 (10.84%)	3 (3.61%)			12 (7.23%)	5 (6.02%)	7 (8.43%)		
	Over 3 times	78 (46.99%)	40 (48.19%)	38 (45.78%)			97 (58.43%)	49 (59.04%)	48 (57.83%)		
DDS	0–2	26 (15.66%)	11 (13.25%)	15 (18.07%)	0.949	0.622	23 (13.86%)	12 (14.46%)	11 (13.25%)	6.130	0.047*
	3–4	92 (55.42%)	46 (55.42%)	46 (55.42%)			87 (52.41%)	36 (43.37%)	51 (61.45%)		
	5	48 (28.92%)	26 (31.33%)	22 (26.51%)			56 (33.73%)	35 (42.17%)	21 (25.3%)		
BMI	Normal	95 (57.23%)	51 (61.45%)	44 (53.01%)	1.294	0.524	99 (59.64%)	53 (63.86%)	46 (55.42%)	1.227	0.542
	Underweight	8 (4.82%)	4 (4.82%)	4 (4.82%)			9 (5.42%)	4 (4.82%)	5 (6.02%)		
	Obesity	63 (37.95%)	28 (33.73%)	35 (42.17%)			58 (34.94%)	26 (31.33%)	32 (38.55%)		
Relative hand grip strength	Normal	80 (48.19%)	40 (48.19%)	40 (48.19%)	1.138	0.767	94 (56.63%)	48 (57.83%)	46 (55.42%)	0.568	0.753
	Risk	32 (19.28%)	15 (18.07%)	17 (20.48%)			32 (19.28%)	17 (20.48%)	15 (18.07%)		
	Weak	53 (31.93%)	27 (32.53%)	26 (31.33%)			40 (24.1%)	18 (21.69%)	22 (26.51%)		
	Missing	1 (0.6%)	1 (1.2%)	0 (0%)			0 (0)	0 (0)	0 (0)		
One leg balance test	Normal	148 (89.16%)	76 (91.57%)	72 (86.75%)	0.997	0.318	150 (90.36%)	77 (92.77%)	73 (87.95%)	1.107	0.293
	Weak	18 (10.84%)	7 (8.43%)	11 (13.25%)			16 (9.64%)	6 (7.23%)	10 (12.05%)		
FTSTS	Normal	123 (74.55%)	63 (76.83%)	60 (72.29%)	0.448	0.503	137 (82.53%)	70 (84.34%)	67 (80.72%)	1.510	0.219
	Weak	42 (25.45%)	19 (23.17%)	23 (27.71%)			24 (14.46%)	9 (10.84%)	15 (18.07%)		
	Missing	0 (0)	0 (0)	0 (0)			5 (3.01%)	4 (4.82%)	1 (1.2%)		

HA, healthcare app user group; SS, app + smart speaker user group; BMI, body mass index; FTSTS, five-times-sit-to-stand test; GDS, geriatric depression scale; DDS, dietary diversity scale.
*$p < 0.05$.
**$p < 0.01$.
***$p < 0.001$.

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evaluation to 40 (24.1%) in the post-evaluation. There was no statistically significant difference between the HA and SS groups ($\chi^2 = 0.568$, $p > 0.05$).

As a result of the one leg balance test, the normal group increased slightly from 148 (89.16%) to 150 (90.36%), but no significant difference was found between the HA and SS groups ($\chi^2 = 1.107$, $p > 0.05$).

Those who were evaluated as normal during the FTSTS test increased from 123 (74.55%) in the pre-evaluation to 137 (82.53%) in the post-evaluation. However, there was no significant difference between the two groups ($\chi^2 = 1.510$, $p > 0.05$).

4. Discussion

Owing to the recent COVID-19 pandemic, the introduction of non-face-to-face healthcare has accelerated. In South Korea, the introduction of ICT healthcare services is progressing rapidly with the full support of the government, not only in private medicine but also in the public health field. To integrate digital technology as one of the health management methods, significant economic, time, and human resources are being mobilized. However, rather than the indiscriminate introduction of the digital method, it is time to determine what specific function of digital devices to provide to the target population and to accurately verify its effectiveness.

The first important finding of this study is that both the HA and SS group showed positive health status and behavior changes at the time of post-evaluation. Though older adults with low digital literacy should first be educated on these technologies, our study demonstrated that there were significant improvements in health behaviors after adaptation to digital devices. As **Table 3** reveals, perceived self-efficacy in exercise, moderate exercise frequency per week, the diet diversity scale, relative grip strength, and FTSTS were positively changed during post-evaluation compared to the pre-evaluation. On the contrary, depression increased, and BMI and balance test scores were maintained at similar levels in both groups after 6 months.

According to a systematic review, studies have found that IoT-enabled health care services can lead to improved outcomes in health and wellbeing for older adults, such as improved medication adherence, better management of chronic conditions, and improved quality of life (20). Similar to this study, previous studies also showed a statistically significant increase in exercise frequency and improved eating habits (21–24). Recording eating habits and exercise frequency with mobile apps and wearable devices can raise the level of awareness of health behaviors, making it easier for older people to change their behavior, rather than just counseling them to change. In the study of Barnason andZimmerman (21), 36 telephone counseling sessions were conducted intensively over 3 months, during which self-efficacy improved as in the results of this study. However, Fukuoka and Gay (23) reported no improvement in self-efficacy after providing a multicomponent intervention using a mobile app and wearable device for 5 months. Unlike many previous studies that showed significant improvements in BMI and weight loss, this study showed similar levels after 6 months (21, 23, 25). In addition, among objective indicators such as BMI, relative grip strength, balance test, and FTSTS test levels were classified according to risk level, so there may not have been a significant difference across categories during the 6-month study period. There were no previous studies using FTSTS, relative grip strength, balance test, etc., which are important indicators for predicting frailty.

Second, unlike previous studies, our hypothesis that listening to songs, Autonomous Sensory Meridian Response (ASMR), and conversation functions (which are the main functions of smart speakers) will have a positive effect on reducing depression has not been supported (26). Rather, the feeling of depression increased further in the post-test, which may be due to the influence of the Corona-blue due to COVID-19, an external environmental factor, or the test-retest bias. In addition, as there was no statistically significant difference in the degree of increase in depression between the two groups, it was not possible to reveal any additional benefits of the smart speakers on depression in older adults living alone or those who were socially frail. According to the results of a recent study, depression and loneliness were significantly reduced in older adults after 2 months of using the same smart speaker used in our study. However, no statistically significant difference was found between those who frequently used smart speakers and those who used them intermittently. Therefore, it is difficult to infer that depression decreased due to the direct influence of smart speakers (9).

There are studies that show a statistically significant reduction in depression when a smart speaker in the form of a child doll is provided to an elderly person with type 2 diabetes and cognitive decline who lives alone (7, 27, 28). In addition, in a path analysis of the effects of smart speakers on health behavior and depression, it was found that health behavior mediates attitudes toward smart speakers, leading to an alleviation of depression (29). Only older adults who had a positive attitude toward a smart speaker showed a significant effect.

A limitation of this study is that it was not possible to control attitudes and usage patterns toward smart speakers. Follow-up studies should aim to identify and control usage patterns for digital devices. Since most previous studies applying eHealth or mHealth were for middle-aged people, more research on mHealth-related effects in older adults seems necessary (20). Variables such as relative grip strength, balance test, and FTSTS, which are mentioned as reliable tools to predict frailty, should be considered.

The importance of chronic disease management for older adults is further emphasized when considering the threat of infectious diseases and mortality statistics (30, 31). Another problem is that vulnerable older adults, who are the main target group of public health, may have difficulty managing their diseases due to fear of visiting public health centers, hospitals, and clinics, and due to concerns regarding social distancing. For public health centers to achieve chronic disease management and health promotion in addition to their role in quarantine, it is

necessary to expand non-face-to-face healthcare and attempt to effectively integrate it with existing services.

Despite the advantages of international trends and previous research results, the reason that ICT has not been widely used as a health promotion intervention for older adults is that there are doubts about its acceptability and effectiveness from health professionals and older adults (32). Since qualitative research still dominates the research field of ICT healthcare services, many experimental studies need to be conducted (33).

Health management results may differ depending on the ability to use smartphones and the IoT, and the ability to acquire, understand, and utilize health information. Therefore, if the device or application used by older adults is not developed so that the user can intuitively use it, it can become a barrier to health management. Although the acceptance of ICT by older adults is still lower than that of adults, it is gradually gaining acceptance among the former (34). Hence, active intervention by health experts is important, which is why accessible technology for older adults needs to be further developed (35).

5. Conclusion and recommendations

ICT can be sufficiently attempted even for older adults as it is an efficient healthcare approach that can be used more actively as the older adult population becomes increasingly accustomed to digital devices. In addition, as older adults in the community cannot be managed by medical staff near them, such as in hospitals, ICT is a useful method to monitor symptoms of chronic diseases, detect abnormalities, and manage health behaviors remotely, and it will be an important leap forward for the healthcare industry. However, to provide an ICT device for the health management of socially and economically vulnerable older adults in the public domain, such devices should be introduced after verifying the older adult-friendly interface and functions of the healthcare device and ascertaining whether it meets the purpose and goal set by the national health project.

Data availability statement

The datasets presented in this article are not readily available because this study was conducted at a public health center in South Korea, and disclosure of data other than for research purposes is not permitted. Requests to access the datasets should be directed to Dasom Kim, dudurdaram@naver.com.

Ethics statement

The studies involving human participants were reviewed and approved by the Korea National Institute for Bioethics Policy. The patients/participants provided their written informed consent to participate in this study.

Author contributions

DK contributed to conception and design of the study; DK organized the database; DK performed the statistical analysis; DK wrote the first draft of the manuscript; DK wrote sections of the manuscript; DK contributed to manuscript revision, read, and approved the submitted version.

Conflict of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fdgth.2023.1117280/full#supplementary-material.

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Effects of a nurse-led structured home visiting program on quality of life and adherence to treatment in hemodialysis patients

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Purpose: This study aimed to determine the effects of a nurse-led structured home visit program on quality of life and adherence to treatment in patients undergoing hemodialysis.

Methods: The study was quasi-experimental research in which 62 hemodialysis patients referred to Bu Ali hospital in Ardabil participated in two groups: Intervention ($n = 31$) and control ($n = 31$). The intervention included a structured and planned home visit program that was performed in five stages over 3 months. Data collection tools were a demographic information form, Kidney Disease Quality of Life Short Form (KDQOL–SF^{TM}) and End Stage Renal Disease Adherence Questionnaire (ESRD_AQ) which were completed by patients before, at the end of the first, second, and third month of intervention. SPSS v20 software and descriptive and analytical tests (Chi-square, *t*-test, ANOVA and repeated measure) were used for data analysis.

Findings: Examining demographic characteristics showed that there is a negative and significant relationship between age and quality of life scores ($P = 0.004$), that is, with increasing age, the quality of life score decreases, but other demographic characteristics did not have a significant relationship with quality of life scores and adherence to treatment ($P > 0.05$).
Also, the results showed that in the intervention and control groups, during the study, the scores of quality of life and adherence to treatment increased significantly, and this increase was significantly higher in the intervention group than in the control group ($P < 0.001$).
The scores of quality of life and adherence to treatment increased significantly both during the study in each group separately and between groups during the study ($P < 0.001$).

Conclusions: According to the significant improvement in quality of life and adherence to treatment in patients following a home-visiting program during 3 months, these interventions can be utilized to improve quality of life and adherence to treatment of patients undergoing hemodialysis.

Practice implications: Home visiting programs significantly improve the level of knowledge of patients undergoing hemodialysis and their family members, through their involvement in the care process. Having said that, it seems plausible to implement home visits in the standard care plans of hemodialysis patients.

KEYWORDS

home visit, quality of life, adherence to treatment, hemodialysis, nurse

Introduction

End-Stage Renal Disease (ESRD) is characterized by a glomerular filtration rate of <15 ml/min. At this stage, various clinical manifestations such as hypertension, anemia, edema, metabolic disorders, and endocrine disorders may occur that require renal replacement therapy such as hemodialysis (HD) (1).

The life of these patients changes due to changes in diet, frequent use of nutritional supplements, fluid restriction and multiple dialysis sessions. Due to the lifestyle changes and treatment, these patients often experience Physical and mental problems (2), all of which can lead to a lower quality of life (QOL) (3). Quality of life (QOL) is considered an important issue in evaluating the outcomes of patients receiving health care. Although there is no consensus on the definition of quality of life, it has been found that in patients with kidney failure, especially in patients undergoing dialysis, QOL affects more physical aspects and less mental functioning (4). It is important to pay attention to the quality of life of these patients because, according to some evidence, it is related to medical outcomes, including the reduction of hospitalization and mortality due to hospitalization (5, 6).

Non-adherence to treatment is also one of the main clinical concerns in patients undergoing hemodialysis (7). Adherence to treatment which is defined as the degree to which individuals' behavior conforms to health or treatment recommendations, is a complex behavioral process and is influenced by several factors, such as patients' personal characteristics, physician-patient interactions, and the quality of the health care system (8).

Poor adherence or non-adherence of patients to treatment is one of the main reasons for failure in a treatment plan, increased complications, prolongation of treatment, and increased healthcare costs (9). According to reports, ∼25–86% of hemodialysis patients do not follow their treatment regimen (10, 11). The study conducted by Gerogianni et al. showed that rejection of treatment and treatment limitations were among the most important problems of hemodialysis patients (12). Furthermore, polypharmacy and the inability to purchase all the required drugs are among the notable problems (13).

Moreover, many patients report feelings of anger, guilt, and fear about their illness, and most of them have no motivation to take care of themselves and adhere strictly to treatment (14). Therefore, due to the rising trend of chronic renal failure and the prevalence of physical and mental problems in hemodialysis patients and the resulting complications and consequences, the existence of effective interventions as a crucial element in the treatment of these patients is essential (15).

One way to provide care is home visits. During home visit, the patients and their family members are educated on the healthcare needs of their patient in the home environment in order to allow them to meet these needs independently. Home is an intimate environment for the patient and their family members to interact with the nurse, and in some cases a home visit is the only way to access information or to educate, reduce health risks, promote health, and provide services to families (16). Home visits allow the health professionals to identify the health problems of the patients, and when necessary, set treatment plans in order to improve their quality of life (17). In addition, the home environment allows for a more realistic assessment, an efficient identification of the risk factors and problems, and the initiation of the interventions in the early stages (18).

There only a small number of studies that have investigated the effect of home visiting programs and their effect on quality of life in particular including the study of Liimatta et al. titled "The effect of home visit on the quality of life of the elderly" (19). Ahangarzadeh Rezaei et al. (20) also investigated the effect of home visiting programs on improving the physical condition of hemodialysis patients and considered it as a basic yet important method in the healthcare (20).

In addition, home visits may provide unique opportunities to identify and address issues that may exacerbate the illness. In the home visiting program, a caregiver may collect vital information about following up on patients' medical visits and how to take medication. Educating patients and their families about medical treatment events, managing acute or chronic conditions, and detecting warning signs of illness are among the other advantages of a home visit program (21).

Despite the rising number of patients requiring hemodialysis and the importance of their education by nurse practitioners, the effect of home visiting programs on quality of life and treatment adherence has not been widely studies in these patients. To that end, the present study aims to determine the effect of a nurse-led structured home visiting program on quality of life and treatment adherence in patients undergoing hemodialysis in Ardabil, Iran.

Methods

Study design

The present study was a quasi-experimental research with a control group.

Participants

The study population was patients undergoing hemodialysis referred to Bu Ali Hospital and the Red Crescent Center of Ardabil in 2021. Inclusion criteria included patients aged 18–65 years undergoing hemodialysis, with a history of dialysis for more than 6 months and at least twice a week, no history of known mental disorders, no hearing problems, no history of formal education in the last year, and willingness to participate in the study. Change of residence during the study, having a kidney transplant surgery, and cessation of hemodialysis were regarded as exclusion criteria. Sample size was calculated based on the statistical formula

$$n = \frac{\left(z_{1-\alpha} + z_{1-\beta}\right)^{2*}\left(\int_1{}^2 + \int_2{}^2\right)}{\left(\overline{X}_1 - \overline{X}_2\right)^2}$$

- α: Probability of first type error; If α = 0.05, Z1-α/2 is equal to 1.96.
- β: Probability of second type error; If β = 0.02, Z1-β is equal to 1.96.
- σ_1: The standard deviation of the trait in the first community

Abbreviations: ESRD, End-Stage of Renal Disease; CKD, Chronic Kidney Disease; HD, hemodialysis.

- σ_2: Standard deviation of the attribute in the second society
- X_1: Average trait in the first community

and the results of (22) and considering $\alpha = 0.05$ and $\beta = 0.02$, the test power of 80, and the possible fall of 72 patients (36 people in the intervention group and 36 people in the control group). The patients were initially sampled randomly (through a lottery system) and were assigned to the intervention and control groups using the permuted block randomization method (Figure 1).

In this study, 6 blocks of 4 were used to randomly assign patients to two intervention and control groups. The intervention group was named A and the control group was named B, and the following 4 conditions were created in each block:

Next, having six hypothetical blocks, six numbers (1 to 6) were used for random selection. Seventy two patients were coded after 18 random selections of blocks of 4. Based on the initial estimate of the required number of samples ($n = 72$) and the two required groups, 72 codes were prepared, 36 codes of the control group and 36 codes of the intervention group were written.

After receiving the code of ethics from the Ethics Committee of Ardabil University of Medical Sciences, obtaining written consent from the patients, and assuring them that their information was not disclosed, the intervention began. The intervention was the home visit of hemodialysis patients based on home visit model (23). This intervention consisted of several steps as follows:

Initial stage: In this stage, after selecting the samples based on the entry criteria and randomization, informed consent was obtained from the samples and then the objectives of the research were explained.

Pre-visit stage: In this stage, the duration of hemodialysis, the time of hemodialysis during the day, the drugs received by the patients during dialysis and at home, the amount of ultrafiltration that is reduced on average from the patient during dialysis, the weight of the patients, the settings that are given to the dialysis machine such as sodium, temperature, etc..., the type of vascular access of the patient and how it works, the medical orders in the file, the history of the patient's previous hospitalizations in other medical centers, the problems that arise for the patient during dialysis under the dialysis machine, and finally, the patient's intolerance or non-cooperation during dialysis It was obtained from the clinical records of patients in hemodialysis centers. At this stage, an appointment was also made with the opinion of the clients.

At-home stage: First, the researcher introduced himself to the patient and family members. Again, about the home visit, the objectives of the study were discussed with the patients and their families. Then, in the first visit, all the questionnaires were filled before the start of the intervention. After filling the questionnaires, the training of the patients started. Our training included all aspects of the quality of life and adherence to the treatment Also, about the physiology of the disease, the process of hemodialysis, access to dialysis and related care, education about diet and fluid intake, important points about drugs, activity level, problems of hemodialysis patients such as itching, muscle cramps, depression, disorders Sleep and etc. The educational needs of the patients were discussed for 45–60 min and the questions of the patient and the family were answered.

Quality of life and Adherence to treatment questionnaires are always filled before communicating with patients at this stage.

Final stage: At this stage, the educational materials were summarized and the evaluation of the learned items was summarized. Also, an educational booklet was given to the patients. The samples were followed up by phone for 1 month.

Post-visit stage: A report of the activities performed during the visit was made and a planning was made for the next visit. Finally, the questionnaires were scored and entered into the software SPSS.

A monthly home visit was conducted for three consecutive months for the intervention group, and the necessary explanations were provided based on the educational needs of each patient. The patients could also call the researchers with their inquiries before the time of the visit.

In the control group, after obtaining written and informed consent, the purpose of the study was shared with the patient and family members. Afterward, the patients' medical records were studied, and the patient or their main caregiver was contacted every month. Additionally, based on the patients' educational needs, the required explanations were provided. In case of any inquiries, the patients could contact the researchers.

Data collection

Evaluations were conducted for each patient in the 4 stages including before the intervention, at the end of first, second and third month based on demographic information form (age, sex, marital status, occupation, level of education, medical history, duration of dialysis, and occupational status), Kidney Disease Quality of Life- Short Form (KDQOL–SF^{TM} 1.3), and End Stage Renal Disease- Adherence to Treatment Questionnaire (ESRD_AQ). The demographic information questionnaire was completed only once in the first session, and the next two questionnaires were completed in each of the four sessions. The KDQOL-SF instrument is a standardized self-report instrument that includes 8 health-related quality of life subscales and 11 kidney disease-specific quality of life subscales. The tool of health-related quality of life, which is the general core of KDQOL-SF, is the same 36-question questionnaire (SF-36). This tool has 8 dimensions of physical performance (10 questions), role limitation caused by physical problems (4 questions), role limitation caused by emotional problems (3 questions), social function (2 questions), emotional well-being (5 questions), examines pain (2 questions), fatigue and energy (4 questions), understanding of general health (5 questions) and a general question about personal health. The second part of the KDQOL-SF instrument focuses on health-related items of people with kidney disease and undergoing hemodialysis, which is divided under the title of Kidney Disease Component Summary (KDCS) and includes subscales: symptoms (signs/problems); 12 questions), the effect of kidney disease on life (8 questions), burden of responsibility for kidney disease (4 questions), job status (2 questions), cognitive function (3 questions), quality of social interaction (3 questions), sexual function (2 question), sleep (4 questions), social support (2 questions), encouragement by dialysis department staff (2 questions) and patient satisfaction (1 question). To answer this questionnaire, multiple-choice Likert is used, which is assigned a score from zero to 100 for each dimension. Higher scores indicate

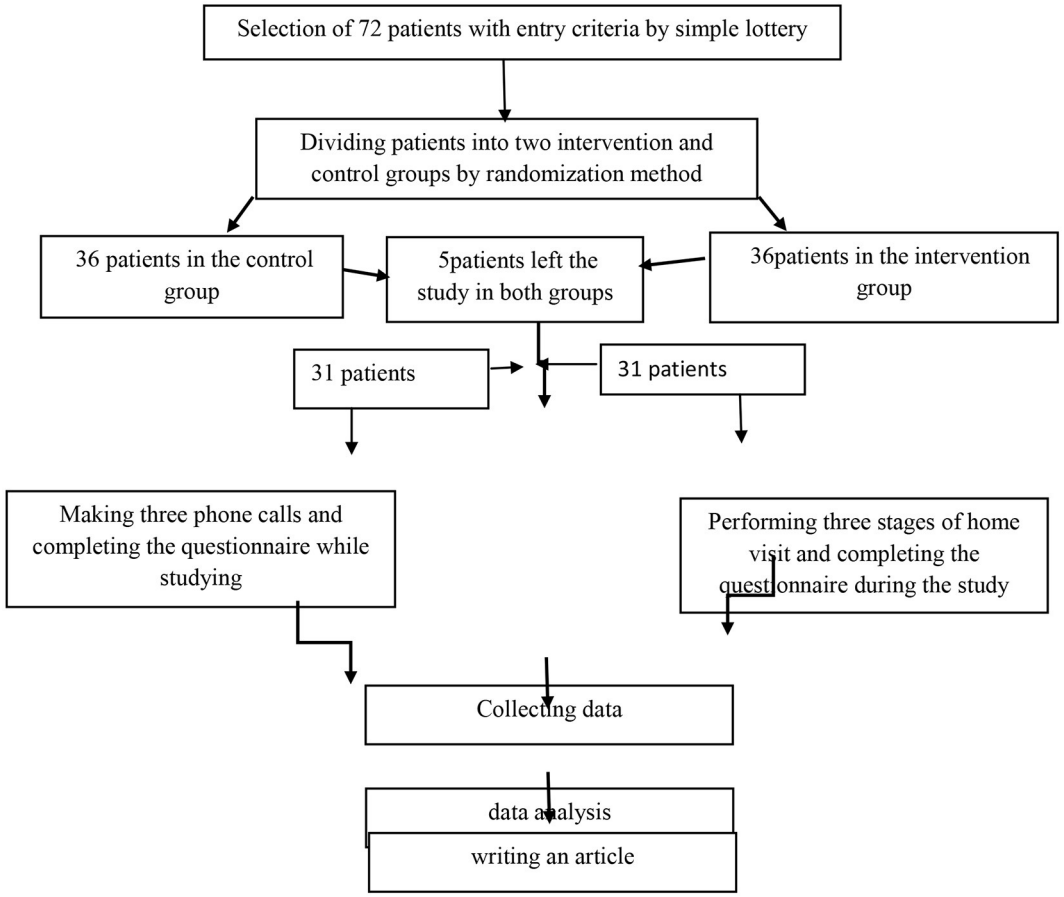

FIGURE 1
Study flowchart.

a better quality of life. The results of the study conducted by Yekaninejad et al. (24) indicated high internal consistency on all scales (range of alpha-Cronbach coefficients from 0.73 to 0.93) (24).

A self-report questionnaire of treatment adherence behaviors among patients with end-stage renal disease (ESRD-AQ) was developed by Kim (25). This 46-item questionnaire is designed for patients needing dialysis treatment and has five sections. The first section examines general information about the patients with end-stage renal disease (5 items), and the remaining four sections, namely attendance at sessions (14 items), medication adherence (9 items), fluid restriction (10 items), and diet (eight items), evaluates treatment adherence in hemodialysis patients. The total score of treatment adherence is the sum of the scores of these five sections. The lowest score of the questionnaire is zero, and the highest score is 1,200. Khalili et al. (26) first psychometrically assessed this tool in Iran and the questionnaire was found to be valid. The reliability of the instrument was also confirmed by the Cronbach's alpha coefficient of 0.75 (26).

Statistical analysis

Data analysis was conducted using SPSS version 25. Descriptive statistics were used to evaluate the samples' demographic characteristics The relationship between demographic characteristics and quality of life scores and adherence to treatment in the intervention and control groups was investigated with linear regression tests, *t*-test and analysis of variance. The Kolmogorov-Smirnov test was performed to evaluate data normality. To achieve the research objectives, descriptive statistics methods (mean, standard deviation, frequency, and percentage), *t*-test, Chi-squared test, and repeated measures analysis of variance (ANOVA) were performed. The significance level was considered <0.05.

Results

Participants' demographic characteristics

Owing to the exclusion of 10 participants from the study (7 patients reluctant to continue cooperation, 1 patient due to change of residence, and 2 patients due to death), this study was conducted on 62 patients undergoing hemodialysis (31 patients in the intervention group and 31 patients in the control group). Table 1 presents the demographic information of the studied patients. As the table shows, the patients' mean age and standard deviation in the intervention and control groups were 48.70 ± 13.98 and 54.38 ± 8.57 respectively. The minimum age of the participant was 22 and

TABLE 1 Demographic characteristics of patients in the intervention and control groups.

Group variable		Intervention		Control		Chi-square test results
		N	%	*N*	%	
Gender	Male	12	38.7	17	54.8	0.15 = P
	Female	19	61.3	14	45.2	
Marital status	Married	24	77.4	24	77.4	0.29 = P
	Single	6	19.4	1	3.2	
	Widow	1	3.2	5	16.1	
	Divorced	0	0	1	3.2	
Job	Unemployed	10	32.3	7	22.6	0.32 = P
	Worker	0	0	1	3.2	
	Employee	1	3.2	1	3.2	
	Housework	16	51.6	13	41.9	
	Freelance worker	4	12.9	9	29	
Level of Education	High school	17	54.8	24	77.4	0.09 = P
	Diploma	11	35.5	6	19.4	
	Associate Degree	1	3.2	0	0	
	Bachelor's degree and higher	2	6.5	1	3.2	
Disease background	Yes	27	87.1	25	80.6	0.36 = P
	No	4	12.9	6	19.4	
Age (mean ± SD)		48.70 ± 13.98		54.38 ± 8.57		$P = 0.34$*

*Independent sample T-test.

the maximum was 64. There was no significant difference between intervention and control group regarding the demographic characteristics ($P > 0.05$).

The effect of home visiting program on the subscales and two main dimensions of quality of life

The mean and standard deviation were calculated in all the subscales of the quality of life questionnaire. In most cases, with the progress of the study, a statistically significant difference was observed in the intervention and control groups ($P < 0.05$), except for the subscales Work status ($P = 0.43$), Cognitive function ($P = 0.70$) and Physical functioning ($P = 0.41$) where the relationship between the intervention and control groups was not significant (Table 2).

Quality of life scores were calculated in two main dimensions (general and specific). To analyze the data, ANOVA was used. The studies showed that the scores of the quality of life in the intervention and control groups in both general and specific dimensions increased significantly during the intervention, and this increase was more in the intervention group than in the control group (Table 3).

The effect of home visiting program on quality of life

The results of the ANOVA indicated a statistically significant difference between the experimental and control groups in terms of changes in the mean score of quality of life in the previous 4 stages until the end of the third month of the intervention ($P < 0.05$). The mean scores of quality of life in the intervention group in the pre-intervention stage, the end of the first, second, and third month were 35.29 ± 2.18, 45.47 ± 2.60, 49.43 ± 2.69, and 52.64 ± 2.77, respectively; this upward trend was significant ($p<0.05$). Also, the change in the mean scores in 4 stages, before the intervention (37.83 ± 2.73), the end of the first (37.85 ± 2.39), the second (40.04 ± 2.90), and the third month (41.08 ± 3.60), was significant in the control group (Table 3).

Figure 2A shows the changes in total quality of life scores during the study in both groups.

The effect of home visiting program on treatment adherence

According to Table 3 and the results of the ANOVA, the average score of adherence to treatment in patients of the intervention group in the time intervals before the intervention (767.74 ± 155.88), in the first month (900.80 ± 112.45) in the end of the

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TABLE 2 Quality of life (subscales) in the intervention and control groups during the intervention.

Dedicated dimension (SF-36)		Before intervention Mean ± SD	The first month Mean ± SD	The second month Mean ± SD	The third month Mean ± SD	*F*	P-value
Symptom/problem list	Intervention group	65.79 ± 5.55	71.23 ± 5.22	76.07 ± 5.15	76.41 ± 5.33	57.25	<0.001
	Control group	58.53 ± 5.44	61.76 ± 5.60	64.58 ± 6.01	65.67 ± 6.45		
Effects of kidney disease	Intervention group	49.97 ± 10.77	56.55 ± 10.02	60.28 ± 9.95	63.20 ± 10.26	17.91	<0.001
	Control group	44.55 ± 10.04	46.67 ± 9.94	48.28 ± 8.41	50.30 ± 9.28		
Burden of kidney disease	Intervention group	39.91 ± 8.64	64.91 ± 11.02	72.58 ± 9.50	77.82 ± 10.56	185.95	<0.001
	Control group	36.29 ± 7.64	39.51 ± 7.28	42.54 ± 7.29	44.75 ± 6.27		
Work status	Intervention group	12.90 ± 28.77	32.25 ± 35.46	32.25 ± 35.46	32.25 ± 35.46	0.623	0.433
	Control group	12.90 ± 25.71	17.74 ± 30.40	24.19 ± 33.84	30.64 ± 35.77		
Cognitive function	Intervention group	32.25 ± 9.28	29.24 ± 9.05	29.24 ± 9.05	29.24 ± 9.05	0.140	0.709
	Control group	27.52 ± 8.90	29.89 ± 10.16	32.68 ± 9.94	33.33 ± 10.32		
Quality of social	Intervention group	49.24 ± 8.37	46.45 ± 7.97	46.45 ± 7.97	46.45 ± 7.97	5.66	0.002
	Control group	42.58 ± 9.98	46.23 ± 10.31	47.95 ± 8.50	47.95 ± 8.50		
Sexual function	Intervention group	60.88 ± 23.21	68.14 ± 20.37	68.54 ± 20.37	72.17 ± 18.17	3.44	0.06
	Control group	54.83 ± 17.28	58.46 ± 15.93	60.88 ± 15.72	62.50 ± 14.43		
Sleep	Intervention group	65.00 ± 6.48	70.56 ± 6.44	75.08 ± 7.65	81.20 ± 7.32	44.97	<0.001
	Control group	59.19 ± 8.59	60.00 ± 9.21	61.45 ± 8.48	62.09 ± 8.44		
Social support	Intervention group	81.71 ± 13.16	89.24 ± 11.82	93.00 ± 9.40	95.69 ± 8.57	8.210	0.006
	Control group	76.34 ± 17.62	79.02 ± 16.65	82.25 ± 17.18	86.01 ± 14.33		
Dialysis staff encouragement	Intervention group	88.30 ± 30.00	91.53 ± 8.15	93.54 ± 7.82	96.77 ± 5.56	7.35	0.009
	Control group	85.48 ± 9.18	87.09 ± 9.40	88.30 ± 8.49	89.91 ± 8.79		
Patient satisfaction	Intervention group	94.62 ± 7.92	95.69 ± 7.41	98.38 ± 5.01	98.92 ± 4.16	8.412	<0.001
	Control group	92.47 ± 8.43	94.08 ± 8.10	95.16 ± 7.69	95.69 ± 4.16		
General dimension (KDCS)							
Physical functioning	Intervention group	53.06 ± 10.05	56.81 ± 9.03	59.03 ± 8.60	61.12 ± 7.71	0.672	0.416
	Control group	51.29 ± 7.74	57.34 ± 7.77	59.35 ± 6.79	55.64 ± 11.08		
Role physical	Intervention group	4.83 ± 10.04	28.22 ± 23.04	70.56 ± 23.36	48.38 ± 29.53	8.103	0.006
	Control group	12.90 ± 16.92	12.90 ± 16.92	19.35 ± 21.12	21.77 ± 27.78		
Pain	Intervention group	38.30 ± 12.04	60.48 ± 17.99	70.56 ± 15.99	81.04 ± 12.44	86.53	<0.001
	Control group	30.64 ± 15.75	33.06 ± 14.98	35.48 ± 13.34	37.09 ± 12.70		
General health	Intervention group	31.29 ± 6.32	52.74 ± 8.54	62.25 ± 8.54	70.48 ± 10.25	136.947	<0.001
	Control group	29.51 ± 6.37	34.51 ± 6.99	39.03 ± 7.89	42.90 ± 7.72		
Emotional well-being	Intervention group	50.58 ± 6.97	59.87 ± 6.65	67.22 ± 6.31	74.58 ± 6.24	78.89	<0.001
	Control group	43.09 ± 7.56	46.19 ± 8.38	49.03 ± 10.01	51.74 ± 10.11		
Role emotional	Intervention group	12.90 ± 26.77	20.10v29.00	33.33v28.54	36.55 ± 27.69	56.83	<0.001
	Control group	22.58 ± 21.75	25.80 ± 23.89	29.03 ± 28.20	30.10 ± 27.69		
Social function	Intervention group	38.30 ± 9.64	54.43 ± 14.98	64.51 ± 16.48	69.75 ± 16.38	33.00	<0.001
	Control group	35.08 ± 13.07	38.70 ± 13.44	40.72 ± 14.05	42.33 ± 12.36		
Energy/fatigue	Intervention group	34.83 ± 6.89	45.80 ± 8.27	55.80 ± 7.75	68.06 ± 8.13	30.22	<0.001
	Control group	36.45 ± 9.59	38.87 ± 9.37	42.74 ± 8.44	47.09 ± 9.01		

TABLE 3 Quality of life (Dimensions) and adherence to the treatment in the intervention and control groups during the intervention.

Time / Variable		Before intervention	The first month	The second month	The third month	F (*P*-value*) Intergroup comparison	F (*P*-value*) Interactive effect (group and time)
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD		
Quality of life	Intervention group	35.29 ± 2.18	45.47 ± 2.60	49.43 ± 2.69	52.64 ± 2.77	147.761 (<0.001)	131.729 (<0.001)
	Control group	37.83 ± 2.73	37.85 ± 2.39	40.04 ± 2.90	41.08 ± 3.60		
Specific dimension of quality of life	Intervention group	56.65 ± 4.14	63.56 ± 4.18	67.56 ± 4.08	66.00 ± 4.74	94.377 (<0.001)	26.150 (<0.001)
	Control group	51.30 ± 2.62	54.00 ± 3.23	56.42 ± 3.51	56.52 ± 4.05		
General dimension of quality of life	Intervention group	36.87 ± 4.37	50.00 ± 4.25	56.92 ± 5.11	63.24 ± 5.51	83.312 (<0.001)	105.210 (<0.001)
	Control group	36.34 ± 4.471	4.25 ± 4.17	43.47 ± 5.61	44.41 ± 7.43		
Adherence to treatment	Intervention group	767.74 ± 155.88	900.80 ± 112.45	1,026 ± 104.66	1,076.61 ± 99.14	13.732 (<0.001)	3.305 (0.02)
	Control group	694.18 ± 118.23	897.58 ± 101.03	975.00 ± 84.90	1,018.54 ± 61.90		

*ANOVA.

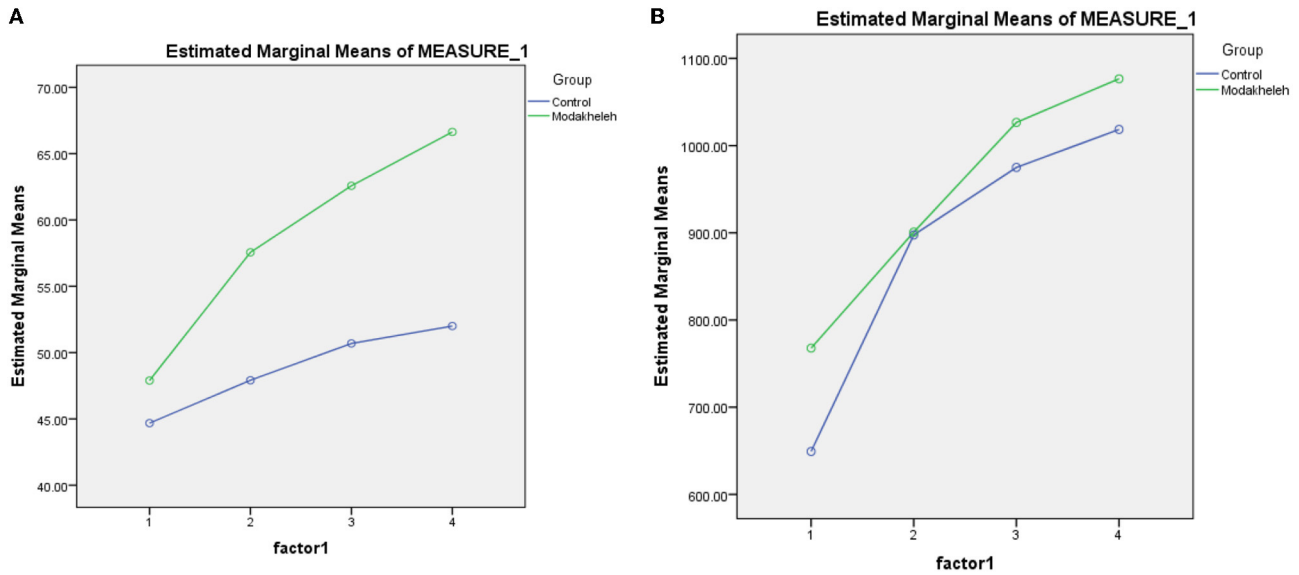

FIGURE 2
(A) Changes in the quality of life during the intervention process in both groups. **(B)** Changes in the adherence to treatment during the intervention process in both groups.

second month (1026 ± 104.66) and in the end the third month of the intervention (1,076.61 ± 99.14) had a significant increase ($P < 0.05$), in the control group, the score between before and 3 month after the intervention showed a significant change ($P < 0.05$). These results were the result of ANOVA showing that the upward trend of treatment adherence scores in the intervention group was significant compared to the control group ($p < 0.05$).

Figure 2B shows the changes in total treatment adherence scores during the study in both groups.

Table 3 also shows that the scores of quality of life and adherence to treatment increased significantly both during the study in each group separately and between groups during the study.

Statistical analysis showed that there is a significant relationship between age and quality of life in both the intervention and control groups ($p < 0.05$), In a way that the quality of life decreases with increasing age. There was no significant relationship between other demographic characteristics in the intervention and control groups with quality of life and adherence to treatment ($p > 0.05$).

Discussion

The findings of this study showed a significant improvement in the quality of life of patients from an unfavorable level in the pre-intervention period to a high level at the end of the third month

of the intervention. Therefore, it appears that the use of a well-codified and planned home visiting program can be effective in improving the quality of life of patients undergoing hemodialysis. In this regard, studies conducted on patients with schizophrenia (27), type II diabetes (28–30), burns (31), hypertension (30) and on couples with stress and anxiety (32) reported similar findings. This suggests that home visiting programs can motivate patients to take responsibility for their treatment by actively involving them in the treatment process. Additionally, an effective, one-on-one, and dynamic relationship can be established between the patient and the nurse practitioner which allows for a better understanding of the patients' needs and problems and the nurses' expectations. This improves patient adaptation through the development of self-care and problem-solving skills, thereby playing a crucial role in the individuals' quality of life.

Furthermore, the results of the present study on the effect of home visiting intervention on treatment adherence of hemodialysis patients showed a significant increase in the mean score of treatment adherence of patients in the intervention group at the end of the second and third months of the intervention. This finding is in line with the results of the studies conducted by Lockwood et al. (33) on patients with hospital-acquired discharge pelvic fractures, Comulada et al. (34) on patients with acquired immunodeficiency infection, Justvig et al. (35) on elderly patients with hypertension, and Chow et al. (36) on patients with diabetes (33–37). One of the important factors influencing the treatment adherence of patients with chronic diseases is to raise their level of awareness to increase the acceptance of treatment and its continuation (38). It appears that a home visiting program, such as the one implemented in this study, can successfully improve treatment adherence by raising the level of awareness of the patients. Moreover, considering the relationship between quality of life and treatment adherence, the improved treatment adherence of the patients during the 3 months of home visit intervention can be related to the patients' increased quality of life.

Limitations

The present study was conducted only on hemodialysis patients in Ardabil, Iran; therefore, its results cannot be generalized to all patients undergoing hemodialysis. Accordingly, it is suggested that the effect of this care model needs to be examined on the abovementioned variables and evaluated with a larger sample size.

Another limitation of our study was the failure to calculate the cost of the intervention and its cost-effectiveness, so it is suggested to calculate the cost of the intervention for future studies.

Conclusions

The results of this study demonstrate that a nurse-led structured home visiting program significantly improved the quality of life and treatment adherence in hemodialysis patients during the 3 months after the intervention. Although, the cost of the home visit in the intervention group has not been investigated in the study, in several studies conducted on the benefits of home visit plans, the issue of reducing costs has been significantly mentioned (39–41), It is therefore recommended to implement this program in the standard care plan of hemodialysis patients by informing them about their disease and reinforcing self-care according to the facilities and conditions of the home environment.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving human participants were reviewed and approved by the Ethics Committee in Biomedical Research at Ardabil University of Medical Sciences (ARUMS) (ethicIR.ARUMS.REC.1400.065). The patients/participants provided their written informed consent to participate in this study.

Author contributions

MP and MA designed the study and had a role in preparing the manuscript. MP held home visit sessions and collected the data. MP and SI analyzed the data. All authors approved the final manuscript.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Publisher's note

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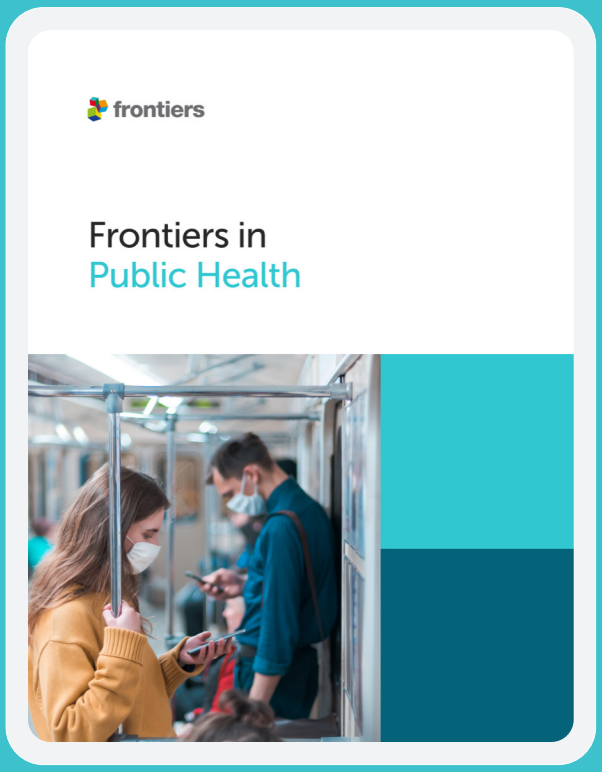

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