Preferences and expectations of patients in clinical trial about laboratory exams at home and remote tests

Preferências e expectativas de pacientes de ensaio clínico sobre exames em domicílio e testes remotos

Preferencias y expectativas de los pacientes en ensayo clínico sobre exámenes domiciliarios y pruebas remotas

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RESUMO

Objetivo: Conhecer a aceitação de pacientes de ensaio clínico quanto a coleta de exames domiciliares, testes remotos e teleconsultas, compreendendo as suas preferências e expectativas. **Método:** Estudo qualitativo, exploratório, descritivo, com entrevistas em profundidade envolvendo profissionais de saúde (especialistas) e pacientes, com e sem experiência em ensaios clínicos, com posterior validação dos constructos por meio de workshop participativo**. Resultados:** Para os pacientes de ensaio clínico, a aceitação mostrou-se relativa. Diversos fatores influenciam suas preferências e expectativas, sendo as principais: a) O grau de confiabilidade nos processos e a acurácia dos resultados de exames domiciliares. b) Os testes remotos, apesar de bem aceitos, dependem da capacidade de entendimento no correto manuseio da tecnologia requerida. c) A teleconsulta, já bem utilizada e aceita, não substitui totalmente o encontro presencial com o médico em fases críticas. A preferência é pelo uso equilibrado do "presencial x remoto". **Conclusão:** A aceitação é influenciada por diversas variáveis. Devem ser definidas estratégias adequadas para cada caso, para garantir resultados seguros e confiáveis, com equilíbrio entre o presencial e remoto, através da participação ativa dos pacientes nas tomadas de decisão.

Descritores: Pacientes; Ensaio clínico; Domicílio; Coleta de amostras; Telemedicina.

ABSTRACT

Objective: To understand the acceptance of clinical trial patients regarding in-house exams, remote tests and teleconsultations, revealing their preferences and expectations **Method:** Qualitative, exploratory-descriptive study, with in-depth interviews involving health professionals (specialists) and patients, with and without experience in clinical trials, with subsequent validation of the constructs through a participatory workshop. **Results:** For clinical trial patients, acceptance was relative. Several factors influence their preferences and expectations, the main ones being: a) The degree of reliability in the processes and the accuracy of the results of home exams. b) Remote tests, although well accepted, depend on the ability of the patient to understand the correct handling of the required technology. c) Teleconsultation, already well used and accepted, does not completely replace the face-to-face meeting with the doctor in critical phases. The preference is for the balanced use of "in person versus remote". **Conclusion:** Acceptance is influenced by several variables. Adequate strategies must be defined for each case, to ensure safe and reliable results, with a balance between face-to-face and remote, through the active participation of patients in decision-making.

Descriptors: Patients; Clinical Trial; Residence; Specimen Handling; Telemedicine.

RESUMEN

Objetivo: Conocer la aceptación de los pacientes de ensayos clínicos en cuanto a la recogida de exámenes domiciliarios, pruebas a distancia y teleconsultas, entendiendo sus preferencias y expectativas. **Método:** Estudio cualitativo, exploratorio-descriptivo, con entrevistas en profundidad involucrando a profesionales de la salud (especialistas) y pacientes, con y sin experiencia en ensayos clínicos, con posterior validación de los constructos a través de un taller participativo. **Resultados:** Para pacientes de ensayos clínicos, la aceptación fue relativa. Varios factores influyen en sus preferencias y expectativas, siendo los principales: a) El grado de confiabilidad en los procesos y la precisión de los resultados de los exámenes domiciliarios. b) Las pruebas a distancia, aunque bien aceptadas, dependen de la capacidad de comprender el manejo correcto de la tecnología requerida. c) La teleconsulta, ya muy utilizada y aceptada, no sustituye por completo al encuentro presencial con el médico en fases críticas. La preferencia es por el uso equilibrado de "en persona versus remoto". **Conclusión:** La aceptación está influenciada por varias variables. Se deben definir estrategias adecuadas para cada caso, para garantizar resultados seguros y confiables, con equilibrio entre presencial y remoto, a través de la participación activa de los pacientes en la toma de decisiones.

Descriptores: Pacientes; Ensayo Clínico; Residencia; Manejo de Especímenes; Telemedicina.

ORIGINAL

Introduction

Increasingly, health professionals must consider the patient's voice in order to provide opportunities for actions that truly add value to their health outcomes and experience.

We live in the age of experience, with the patient at the center of care having more voice than in the past, a phenomenon resulting from changes in technology and social media.[1]

In the case of clinical research patients, listening to them is an even more relevant issue, because their health conditions are often life-threatening and participation in a clinical trial is a final alternative.

Corroborating this statement, a publication revealed that most patients who agreed to participate in a clinical trial were motivated by the "medical treatment" offered, with the profile and content of their discourses being indicators of vulnerability and social inequality.[2] Thus, it is essential to know their preferences and expectations arising from their experience in this situation.

This concern does not occur only in the Brazilian scenario, but at the international level, which led to the realization of a study with the patients of clinical trials from Spain and Brazil as interlocutors, focusing on the performance of remote, home and teleconsultation exams. The results of this research showed that these tests are well accepted by patients, but they are not priorities and determinants for their participation, as is the search for drugs to improve their health or for a better treatment for the disease.[3] It is up to this present publication to disseminate in a more in-depth way the Brazilian findings given the importance of the data emerged for the context of clinical research.

Currently, there is a growing trend in remote and home services and teleconsultation. This expansion was accelerated and influenced by the COVID-19 pandemic, which determined the rapid reorganization of health systems, including home care[4], which undeniably enables the patient to play a leading role in self-care and the convenience of providing/performing a service in his home.

The researchers considered remote tests as all tests in which the patient himself performs the collection of biological material in his home (collection of urine, feces, saliva, among others), the use of clinical monitoring applications and the measurement of vital signs at a distance. Home examinations, such as those in which a health professional goes to the patient to perform the collection of biological material or the measurement of vital signs and other measures.

And finally, teleconsultation is revealed in the literature as an innovative mediation tool in the communication between physician-patient geographically distant, which has numerous benefits and peculiar needs of planning and clinical indication.[5]

It is known that performing remote monitoring is an innovative technology with the following benefits: helping people with chronic diseases to feel more empowered and better manage their health condition and adherence to treatment[6], in addition to being fast, economical and allowing an attitude on the part of the patient towards the result they present because they are an early screening.[7]

Therefore, understanding the perspectives of patients in clinical trials, on home examinations, remote tests and teleconsultation, can add valuable

qualitative information regarding the preferences of these actors and their decision-making, as well as help to design better solutions from the clinical and social point of view, adding value to the care experienced by them, since there is still scarce evidence in the literature on the object of this study.

This study adopted the assumption that patients may prefer to collect biological samples in the hospital/laboratory instead of at home. With this, the guiding question to be unveiled was: "What are the preferences and expectations of patients regarding the collection of laboratory tests and remote tests, at home, within the scope of the clinical trial?"

In this sense, this research aimed to: to know the acceptance of clinical trial patients regarding the collection of home examinations, remote tests and teleconsultations, understanding their preferences and expectations.

Method

This is a qualitative, exploratory and descriptive study carried out in two stages, the first through in-depth individual interviews with health professionals (specialists) and patients and the second through a workshop for the validation of the findings of the first stage.

We chose to add the participation of specialists because they are professionals who are directly involved in the patient's experience and whose perspective would contribute to the understanding of the patient's preferences and expectations.

Data collection took place between the months of September and November 2021, initiated by the specialists, since the findings were used in order to validate the guiding script applied to patients. Both the specialists' and the patients' scripts were semi-structured with open guiding questions.

The participants were attracted through a Research Coordinating Center – SMO (Site Management Organization).

The opinion of chronic patients, due to the high use of services and exams throughout their treatment and follow-up journeys, even if they are not included in a clinical trial, may also be useful in this scenario, as they allow comparisons between the perspectives and contexts of these patients.

Therefore, the following inclusion criteria were established: chronic patients (six cancer patients, six patients with rare diseases and six patients with inflammatory diseases); preferably with experience in home examinations, remote tests and clinical trial participants; independent of the public or private health system and with its own autonomy. And as exclusion criteria: patients with cognitive difficulties and under 18 years.

All interviews were conducted by videoconference on the Google Meet® or Zoom® platform, recorded with the consent of the interviewees and lasted an average of 45 to 50 minutes.

Once transcribed, the 22 interviews (four with specialists and 18 with patients) were submitted to thematic content analysis[8]: performing the stage of pre-analysis (floating reading), exploration of the material (identification of categories) and treatment of the obtained results /interpretation.

The validation workshop took place through the Zoom® platform, had 15 participants (six health professionals, six patients and three family members),

through virtual discussion rooms coordinated by the researchers, it was possible to produce a dialogue between the participants and thus obtain the planned validation.

The study respected all the recommendations of ethics in research involving human beings, and began only after the approval of the Ethics Committee of the University of Passo Fundo with the opinion number: 5,056,469 and CAAE 49172921.9.0000.534, according to the specifications of Resolution 466, of December 12, 2012 that approves the guidelines and regulatory standards for research involving human beings.

Because this is a research involving patients in a clinical trial, the researchers remotely conducted a training on pharmacovigilance and later, a content validation test. There was no need to report cases, because no patient verbalized any type of adverse event regarding the use of medications.

Results

Of the four professionals, three were specialized in clinical trials (one physician, one nurse and one biomedical) and one specialized in home collection (biomedical).

Of the 18 patients, aged between 31 and 72 years, three males and 15 females, six had rare diseases (two with Sjogren's disease, three with Fabry disease and one with Diffuse Scleroderma), six with inflammatory diseases (four with Systemic Lupus Erythematosus and two with Crohn's disease) and six with oncological diseases (in various organs). Most were served by the private health system and those in clinical trials were sponsored by research centers.

Of the patients, 12 had experience with remote tests (type I and 24-hour urine collections), two with clinical monitoring through the use of applications via smartphone and one with monitoring via telephone. Two patients had experience with collecting blood samples at home. Six patients reported experience with remote medical consultation. Five patients had experience in clinical trials (three in Oncology and two in Crohn's Disease).

The following are the three thematic categories that emerged and with their respective contents already validated in the workshop.

Sociocultural and Access Factors

The patients, without experience in clinical trials, who accept the performance of home examinations, report that the care is personalized, private, more comfortable and less stressful because they are in their own environment.

The most emphasized factor, regardless of whether or not it was a clinical trial, was the non-need for travel and, consequently, the confrontation of traffic and transportation/parking costs.

> *"[...] It's quieter. You're at home, you don't have to move... take traffic, pay parking. So, for the sake of my convenience even, it is quieter you have this service at home. I have this right by my covenant." (General context patient with rare disease)*

Patients in the general context also report that this type of service is restricted to some health plans. It was mentioned that if there is such availability in the public service they do not know.

In the case of patients in clinical trials, the interviews revealed that home examinations seem to be secondary to the priority in ensuring their access and participation in the study group. So, if this modality is offered it will be accepted by many patients participating in clinical trials. If not offered, they will continue to travel to the research centers to ensure their treatment.

These patients also indicated that access to home examinations and remote tests can be directly influenced by the investigating physician, who offers or does not offer this possibility to the patient, according to the verification of their degree of confidence about the accuracy of remote measurements and laboratory results of tests collected at home (possibility of failures in the collection or transport of the sample), that you will get to make clinical decisions.

Some clinical trial patients reported that they feel unsure about the reliability of test results collected at home.

> *"[...] with myself a laboratory error has already happened, when I was in the phase of diagnosis of Cancer. [...] So, as this mistake happened to me, it can happen to several people and because it is a research center I think they are afraid that these mistakes will happen [either in the traditional method or at home]. So, the thing is much more careful in clinical research. That's why I never want to leave clinical research." (Clinical trial patient with oncological disease)*

As for remote tests, such as the measurement of vital signs, patients in the general context verbalized fear of performing them inappropriately.

Emotional and Symbolic Factors

Clinical trial patients who used apps on mobile devices for remote clinical monitoring, and other patients in the general context, see themselves as modern, independent people.

> *"[...] When I went to learn, they even asked if I had anyone from the family to hear the explanation as well... I said, no need, I do fine. Quiet, I do it alone. [...] We end up using technology more today. It was easy for me..." (Clinical trial patient with inflammatory disease)*

Regarding home examinations, some patients in the general context reported that when they were cared for at home they felt special and privileged, even mentioning that being cared for at home is a "luxury".

In the general context and also in the clinical trial, the patients interviewed considered that home examinations are very important, but for elderly, debilitated, bedridden or with difficulty in locomotion.

> *"[...] Getting exam at home is for when I have to take care of my old age... But I new today, that I can do, walk, see people, I have my mobility, I go here, I go there, it's different. I prefer to go to the Center in person." (Clinical trial patient with inflammatory disease)*

> *"I think a home exam, in my view, only if I was in a lot of pain in a way that I couldn't walk, get around, any immobility (General context patient with rare disease)*

For the interviewees, teleconsultation is already well accepted in our environment, in general, driven by the pandemic, becoming something "normal" and commonplace in our lives. However, they reported that teleconsultation should not totally replace the face-to-face meeting, because they like the human and affective contact, the "face-to-face" with health professionals, an aspect well valued by patients. They believe that in person the exams and consultations will be more complete and reliable, because they find the most specialized professionals.

> *"[...] He won't be able to see you [completely] and I haven't even been able to examine you. It goes from the degree that you're sick, if you're very sick, I think you need a physical consultation, but you're not too 'attacked', you can do one online without problem." (General context patient with inflammatory disease)*

As for remote tests, there are reports of feelings of insecurity and fatigue on the part of some patients, due to the greater responsibility for measuring the results. Some report that they could feel stressed about being monitored continuously.

Factors related to logistics and technology

For both groups of patients, home collection, remote testing and teleconsultation were considered positive alternatives to prevent them from circulating in public places, reducing the risk of contagion during the SARS CoV-2 pandemic.

The patients also mentioned that they are very comfortable, practical and economical, because they do not require displacement, in addition to allowing access to tests that would not otherwise be available in their region.

Patients who use applications for remote monitoring reported that they allow them to continue working and/or studying while participating in the clinical trial.

Kits for remote sample collection are also cited as advances in logistics and security that favor some patients, especially those who live far from large centers.

It was also reported that, generally, elderly patients have difficulty in remote monitoring by application and families are not always able to assist them continuously. The interviewees also report the importance of training for the patient regarding the handling of equipment and technology.

> *"I think it has to give a training, an orientation for the person, for the patient who is going to use, in this case ... because you have to be careful also with the material.... it's taking a pressure, you have to take away fever, the temperature... that finger oximeter... So I think good training would make it a lot easier too, because that person would be in your residence... Except I don't know how the person's availability is for this there.... or help the patient to do it, because there are people and people, right? You have the age, if you can do it or not.... And that's one of the problems, I think." (General context patient with oncological disease)*

Discussion

A clinical trial because it allows the identification of new therapeutic responses to diseases and thus discover or confirm the use and repercussions of a drug in order to determine its efficacy and safety, in order to later be marketed or not, requires a rigor and systematization in its execution, being necessary to strictly follow the guidelines of a scientific method[9]. For the reasons described, the reliability for the results of the collected tests becomes essential, being necessary, therefore, trained professionals, a fact signaled by the participants when they are approached about collecting samples at home or performing remote tests.

A German study demonstrated that when given the choice for home fecal collection, most participants made this choice when compared to the study center. It was concluded that home collection is a viable method for studies that do not require newly collected feces[10], thus demonstrating that many tests require rigor to have their results considered valid.

Another study, conducted in a low-income community in the USA, regarding the collection of blood by digital puncture at home, demonstrated that the participants felt comfortable with this procedure in their home, but it was mentioned that the training of the researchers, the organization of the supplies and the communication with the participants were fundamental factors for their acceptance.[11]

Another aspect revealed in this study corroborated with a Brazilian literature review. She reported that elderly people perceive themselves as incapable of using different technologies due to the stereotype that being elderly is related to unproductivity. Even with all the technological diversity available, which can make the lives of the elderly more autonomous, the one they use the most is still the computer.[12]

The lack of support from family and friends to help the elderly to use the technology revealed in this study was also a concern of a public service of care for the elderly. When they realized the difficulty of the elderly in the handling of cell phones and perceiving the complaints of family and friends in not having the patience to teach them, they created a specific program to insert them in this social reality.[13]

In addition to the questions mentioned, teleconsultation was seen as an interesting possibility in this research, as long as it is not the choice in all situations. This finding converged with those in the literature, which mention that teleconsultation is performed to diagnose, monitor, and follow up patients with acute or chronic diseases. Among the benefits it is possible to mention: not having geographical barriers, being more flexible, convenient, contributing to the patient's autonomy and avoiding the lack of face-to-face consultations. However, it also has disadvantages, such as the accuracy and precision of the diagnosis, which makes it essential to evaluate the most beneficial and safe situation for each patient.[14]

One publication addressed some guidelines for conducting remote tests, among them, it recommended that there be patient education and training and the effective participation of professionals and manufacturers for this practice.[7]

Given the context exposed, the personalization of care should contemplate the scenario in which the patient is inserted, his clinical picture and his social, cultural, emotional, symbolic, access and infrastructure/technology context, which are essential factors to determine the balance between the home/remote and face-to-face environments.

Finally, even if patients prefer home examinations in specific contexts, access to this type of service will depend on the offer of this possibility. In Brazil, the economic aspects and access to information seem to negatively influence this alternative, mainly due to the collection of extra fees by laboratories and little dissemination and availability of this service in the public sphere.

Conclusion

The assumption of the study was partially confirmed, because in general, both patients with and without experience in clinical trials are receptive to the possibility of home examinations, remote tests and teleconsultations. However, several dynamic factors influence this degree of acceptance.

As contributions, this research highlights that the decentralization of services can be an alternative in order to facilitate the proximity to the patient's residence and thus enhance their insertion and adherence to the clinical study, provided that the professionals responsible for collecting the samples are trained and specialized and the laboratories have some way to certify the quality of their processes and accuracy of their results to the sponsor of the study or research center, Thus, it can influence the patient's perception.

One can consider the shortage of specialized professionals in the market as an additional challenge. Generally, managers assign home collections to the most experienced and qualified professionals, a fact aggravated when it comes to a patient who participates in a clinical trial protocol, which requires even greater rigor regarding the quality and reliability of the collection and transportation process to the processing laboratory unit. This phenomenon seems to be already occurring, given the dynamism and growing appreciation of clinical research.

This study had as a limitation the difficulty in recruiting patients who perform home examinations in the scope of clinical trials, a practice still little adopted in Brazil.

Because it is a relevant theme for the advancement of the experience of patients/families participating in clinical trials, it is suggested that further research be carried out in order to deepen the object of this study, since there is a trend of remote health care mediated by technology and the convenience of the home.

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