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Original Research Article

Perception of decentralized clinical trials and home nursing in oncology clinical research: insights from a survey of clinical research professionals across experimental sites

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ABSTRACT

Background: Post-COVID-19, rapid technological progress enabled remote healthcare interactions, fostering DCT activities. Sponsors and sites adapted by digitizing traditional model, utilizing wearables and home nursing. However, challenges like staff oversight and logistics demand careful evaluation for regulatory compliance.
Methods: Italian association of medical oncology's study coordinators working group, in collaboration with Italian group of data managers, conducted an anonymous online survey among Italian oncology professionals. Survey aimed to explore their perceptions of remote patient monitoring, trial activities, and home nursing in oncology clinical trials.
Results: Out of 111 professionals (42.3% coordinators, 27.0% physicians, 18.8% nurses), 29.7% lacked prior experience in remote patient data capture, while 61.3% had low or medium experience. On a 0-10 VAS scale, 58.6% found remote modalities very useful, with high scores (8-10) for various remote activities like quality of life data capture (71.2%), vital signs transmission (66.7%), and home nursing tasks (65.8%). Regarding home nursing in oncology clinical trials 73.0% of participants (n=81) have declared no previous experience. However this remote activity is considered highly useful for tasks such as biological samples collection (76.6%), vital signs collection (73.9%), quality of life evaluation (71.2%), and adverse events monitoring (65.8%).
Conclusions: Electronic devices for remote data capture are prevalent in oncology trials, positively perceived by a significant portion of staff. Remote data collection correlates with improved workload perception. Although home nursing is less common in Italy, healthcare professionals show a positive perception, indicating potential benefits for clinical trial efficiency and workload improvement.

Keywords: Decentralized clinical trials, Home nursing, Clinical research, Oncology

INTRODUCTION

Following the COVID-19 pandemic, there has been a notable surge in the integration of digital tools within clinical trials, enabling remote interactions between healthcare professionals and patients.[1-3] This trend towards decentralized activities in clinical trials has been documented.[1,2,4] In response to this trend, sponsors and experimental sites have actively pursued avenues to modernize the traditional clinical trial model. Their aim was to streamline patient enrolment, monitoring, and data capture through the implementation of digital instruments, increased flexibility, and optimized resource utilization.[4]

Additionally, clinical trials involving investigational medicinal products (IMPs) increasingly incorporate procedures conducted beyond the confines of the traditional 'clinical trial site,' a trend commonly referred to as decentralization.[3] This trend could pave the way for a new operational approach termed "decentralized clinical trials" (DCTs) or hybrid decentralized clinical trials (hDCTs).[5,6] In hDCTs some trial activities involve in-person visits by trial participants to traditional clinical trial sites, and other activities are conducted at locations other than traditional clinical trial sites, such as participants' homes.[6]

The acceptance of this evolving research model is poised to elevate the integration of technological advances.[3,4] However, the widespread adoption of these solutions hinges on various factors. These factors include the organizational structure of the healthcare system, investments in infrastructure, accessibility to technology, regulatory constraints, and internet connectivity in remote areas.[7,8] Importantly, these factors exhibit variations not only across countries with differing per capita income levels but also within individual countries.[7]

Digitalized tools, such as biometric sensors, have the potential to introduce more objective means of measuring pain, quality of life, functional status and cognitive function. This capability facilitates a better understanding of individual responses to treatment and enables the assessment of individualized patient toxicities.[4,9-11] Moreover, they streamline the process of remote and automatic data capture adding another layer of efficiency to the overall trial structure.[12]

Additionally, literature suggests that DCT and decentralized procedures could enhance trial efficiency while reducing costs. This is achieved by lowering screen failure rates, enhancing the convenience of consent and enrolment processes, and mitigating the burden of time and travel through the remote provision of study intervention or study procedures.[4,9,13]

Despite the decentralized approach appear feasible in fields such as dermatology, psychiatry and cardiology, to date implementation of DCTs in oncology appears rare probably due to recruitment mechanisms, protocol requirements, and characteristics of the anticancer drug that require a controlled environment, such as a hospital, for patient administration.[14-17]

In the scenario of decentralized procedures applied to clinical trials, home nursing also plays a significant role. The concept of homecare nursing emerges as a pivotal strategy, bringing the clinical trial directly to the patient's doorstep.[4,18] Conduct research in the home setting empowers nurses to monitor outcomes and execute study procedures within the patient's home environment. However, several challenges must be addressed, such as the inadequacy of nursing home medical records, logistical challenges in handling research samples or study drugs and administrative and logistical burdens relating to presence of outside research staff or principal investigator oversight.[6,18]

On the other side, digital monitoring technology provides a variety of opportunities for oncology nurses and study staff to efficiently extend and improve patient management in multiple settings at home, including cancer patients.[19]

However, it is essential to meticulously evaluate staff oversight, technological infrastructures and logistical challenges to guarantee compliance with the quality standards set forth by regulatory authorities and good clinical practice (ICH-GCP) Guidelines, also considering the concept of 'flexibility' in the conduct of clinical trials, which will be introduced by revision three of the GCP.[3,6,20,21]

Nevertheless, it is important to emphasize how regulations, both at the international and European levels, as well as in Italy, are still lacking in the field of DCTs, confirming that in this scenario, innovation often moves faster than legal framework that governs it.[8,22,23]

The study coordinators working group of the Italian association of medical oncology (AIOM), in collaboration with the Italian group of data managers and clinical research coordinators (GIDMcrc), have spread an online anonymous survey among the Italian oncology healthcare professionals aimed to investigate their perception on remote patients' monitoring and data capture applied to oncology clinical trials and their perception of home nursing applied to oncology clinical research.

METHODS

A web-based anonymous survey was distributed among Italian oncology healthcare professionals. The questionnaire, hosted on Google forms app, was composed of multiple-choice questions (multiple checkbox), single choice (radio button) or 0-10 score scale (visual analogue scale or VAS), for a total of 27 items.

The first part of the questionnaire was designed to profile the respondents' characteristics and professional experience. Subsequent sections explored respondents' perceptions of remote activities and home nursing.

After an initial design phase, the questionnaire underwent validation with a sample of 10 respondents, to ensure proper functioning and accurate data capture and extraction by the system.

After completing the validation phase, the questionnaire was published online on GIDMcrc and AIOM web channels, accessible from March 14th to April 16th 2023. Subsequently, it was disseminated through the network of associated organizations.

All data were collected anonymously and processed in aggregate form for purposes stated in the questionnaire.

The answers were considered valid only if they came from professionals operating in the field of oncology clinical research. Given the type of survey and the characteristics of the channels used for the dissemination, an a priori sample was not defined. However, considering possible future uses of the collected results, it was decided to proceed with the analysis only if the following criteria were met: at least 100 responses received; at least 3 different professional categories represented; questionnaires completed by clinical research coordinators and study nurses less than 80 percentages of the total.

Considering the nature of the project and in compliance with local legislation, the input of the ethics committee was deemed unnecessary. Nonetheless, the questionnaire includes a disclaimer outlining the purposes and methods of data processing.

RESULTS

The survey was completed by 111 professionals: 47 study coordinators (42.3%), 30 physicians (27.0%), 18 general nurses (16.2%), 14 research nurses (12.6%), and two others.

The majority of respondents, comprising 66 individuals (59.5%), are primarily engaged in the field of oncology. Following closely is onco-haematology, with 34 respondents (30.6%). Additionally, a smaller percentage, accounting for 9.9% (11 respondents), is involved in various other medical areas associated with oncology, such as palliative care, radiotherapy, and oncology nutrition.

General hospitals were the most represented experimental sites type (n=37, 33.3%) alongside Scientific Research Institutes (IRCCS) (n=37, 33.3%) and followed by university hospitals (n=28, 25.2%) (Table 1). Approximately 36.0% (n=40) of respondents participate in over 20 clinical trials annually, meanwhile 24.3% (n=27) are involved in 10 to 20 trials and 22.5% (n=25) take part in 5 to 10 trials. The remaining respondents (17.1%, n=19) engage in fewer than 5 trials per year.

Among the participants, 29.7% (n=33) reported having no prior experience in remote patient data capture using devices, a majority of 61.3% (n=68) indicated low or medium experience, while 9% (n=10) declared a strong level of experience.

Through a 0-10 VAS scale, the use of remote modalities and electronic devices to receive patients' data was considered very useful by 65 respondents (58.6% with 8-10 score) and medium-high useful by 35 (31.5% with 5-7 score), while only 11 has selected a 0-4 score (9.9%, not useful); the median score assigned by the pool of responders was 8 on the 0-10 scale, with the most frequently occurring score being 10 (assigned by 30 responders).

An 8-10 score (very useful) on a VAS scale was achieved for different remote activities applied to oncology clinical trials as quality-of-life outcomes data capture (n=79, 71.2%), vital signs transmission (n=74, 66.7%), therapies compliance monitoring (n=77, 67.4%), glycaemic control (n=77, 67.4%) and adverse events reporting (n=73, 65.8%) (Figure 1).

A score of 8-10, indicating a perception of being very useful on the VAS, was reported for various remote activities implemented in oncology clinical trials: these activities include quality of life outcomes data capture (n=79, 71.2%), transmission of vital signs (n=74, 66.7%), monitoring therapy compliance (n=77, 67.4%), glycaemic control (n=77, 67.4%), and reporting adverse events (n=73, 65.8%).

Professionals acknowledge a notable enhancement in workload efficiency due to the impact of remote patient monitoring and data transfer in clinical trials. Among the respondents, 46 individuals, constituting 41.4%, expressed a positive impact by assigning a score of 8-10. Additionally, 48 respondents, making up 43.2%, indicated a neutral or moderate impact with scores ranging from 4-7. Conversely, 17 participants, accounting for 15.3%, perceived a negative impact and assigned scores within the range of 0-3.

Regarding the home-nursing in oncology clinical trials the 73.0% of participants (n=81) has declared no previous experience, while the 26.1% (n=29) has a low or medium experience. One respondent (0,9%) has declared a high-level previous experience in the types of home-nursing activities described as following. The majority of respondents (n=80, 72.1%) would prefer home nursing to be conducted by internal staff within the experimental clinical center, while only 17.1% (n=19) would prefer outsourcing this activity to external personnel. A quote of 10.8% (n=12) of respondents abstain from expressing a preference on this matter.

The utility of home nursing was assessed through a 0-10 VAS across a range of healthcare activities. Participants considered home nursing highly useful (assigned a score of 8-10 on the VAS scale) for tasks such as biological samples collection (n=85, 76.6%), vital signs collection (n=82, 73.9%), quality of life evaluation (n=79, 71.2%), adverse events monitoring (n=73, 65.8%), and electrocardiograms execution (n=71, 64.0%) (Figure 2).

When it came to the administration of investigational medical products or drugs through home nursing, opinions varied. A total of 57 professionals (51.4%) perceived it as highly useful (assigned a VAS score of 8-10), 41 professionals (36.9%) considered it to be moderately useful (assigned a VAS score of 4-7), and 13 professionals (11.7%) deemed it not useful (assigned a VAS score of 0-3).

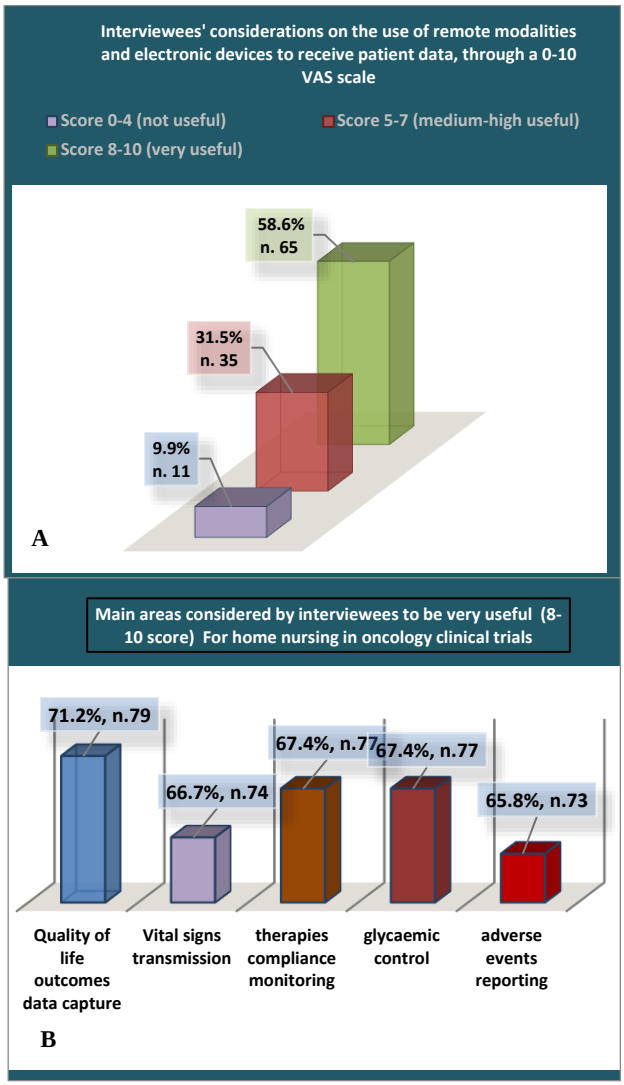

Figure 1 (A and B): Interviewees' considerations on the use of remote modalities and electronic devices to receive patient data, through a 0-10 VAS scale and main areas considered by interviewees to be very useful (8-10 score) for home nursing in oncology clinical trials.

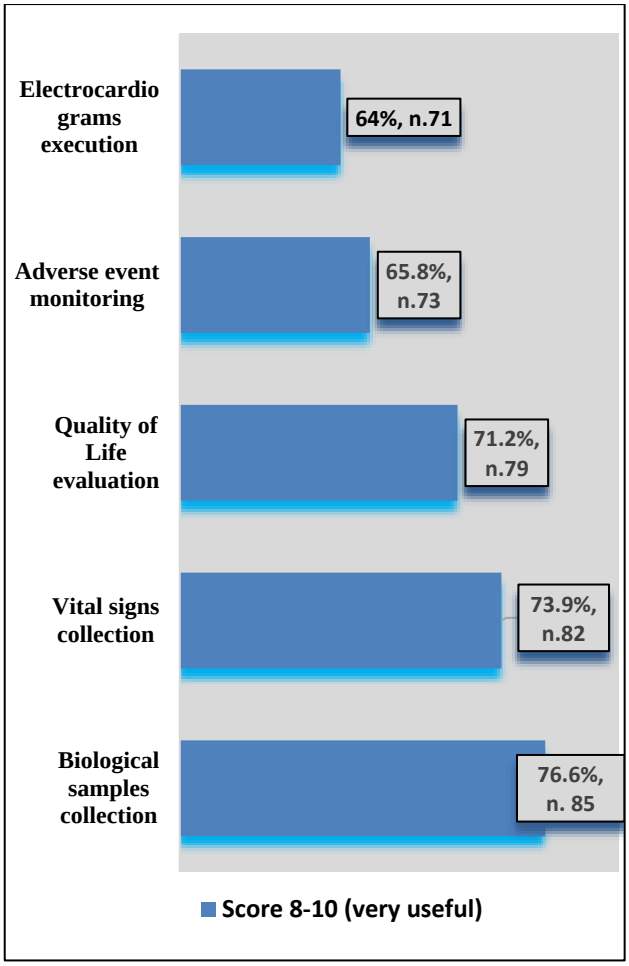

Figure 2: Utility of home nursing (score of 8-10 on the vas scale) according respondents.

Always on a VAS ranging from 0 to 10, where 0 indicates no impact and 10 signifies high impact, was employed to assess the perceived obstacles related to home nursing. In terms of insurance aspects, 48 respondents (43.2%) rated it as having a high impact (scoring 8-10), 44 respondents (39.6%) considered it to have a medium impact (scoring 4-7), and 19 respondents (17.1%) perceived no impact (scoring 0-3).

Similarly, concerning the distance exceeding forty kilometers between the patient's home and the experimental site, 68 respondents (61.3%) regarded it as a high-impact factor (scoring 8-10), 30 respondents (27.0%) saw it as having a medium impact (scoring 4-7), and thirteen respondents (11.7%) indicated the no impact (scoring 0-3) (Table 2).

There is also a general perception of a medium workload improvement due to home-nursing in clinical trials: on a 0-10 VAS scale (0 for worsening to 10 for improvement) a quote of 40 responders (36.0%) selected 8-10 score, 55 responders (49.6%) selected a medium-neutral 4-7 score, as well as the sixteen (14.4%) responders selected a 0-3 score.

Table 1: Characteristics of survey respondents.

Responders	N	%	Sums of %
A			
Clinical research coordinator	47	42.3	42.3
Physician/investigator	30	27.0	69.4
Nurse	18	16.2	85.6
Research nurse	14	12.6	98.2
Other	2	1.8	100.0
Total	111	100.0	-
B			
General hospitals	37	33.3	33.3
University hospitals	28	25.2	58.6
Private Scientific Institute for Research, Hospitalization, and Healthcare (private IRCCS)	21	18.9	77.5
Public Scientific Institute for Research, Hospitalization, and Healthcare (public IRCCS)	16	14.4	91.9
Local health center (ASL/AST)	3	2.7	94.6
Other organizations types	6	5.4	100.0
Total	111	100.0	-
C			
Oncology	66	59.5	59.5
Onco-hematology	34	30.6	90.1
Others oncology related areas	11	9.9	100.0
Total	111	100.0	-

Table 2: VAS scale assignments by respondents.

Score	VAS scale assignments by respondents																						Total
	0		1		2		3		4		5		6		7		8		9		10		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
In which areas do you consider home nursing to be most beneficial in oncological clinical trials? (0 low-10 high)																							
Collection and management of blood/ biological samples at home	2	1.8	0	0	1	0.9	2	1.8	1	0.9	2	1.8	9	8.1	9	8.1	35	31.5	9	8.1	41	36.9	111
Administration of medications at home	5	4.5	1	0.9	1	0.9	6	5.4	7	6.3	8	7.2	11	9.9	15	13.5	28	25.2	5	4.5	24	21.6	111
Monitoring vital signs at home	2	1.8	0	0	0	0	2	1.8	2	1.8	9	8.1	6	5.4	8	7.2	27	24.3	16	14.4	39	35.1	111
Administration of questions (e.g, QoL)	2	1.8	1	0.9	2	1.8	0	0	4	3.6	6	5.4	10	9.0	7	6.3	21	18.9	12	10.8	46	41.4	111
Collection of clinical data	2	1.8	0	0	1	0.9	3	2.7	5	4.5	10	9.0	12	10.8	14	12.6	17	15.3	14	12.6	33	29.7	111
Execution of ECG at home	1	0.9	1	0.9	1	0.9	5	4.5	2	1.8	9	8.1	14	12.6	7	6.3	29	26.1	9	8.1	33	29.7	111
Monitoring adverse events	1	0.9	0	0	2	1.8	2	1.8	2	1.8	10	9.0	9	8.1	12	10.8	18	16.2	17	15.3	38	34.2	111

Continued.

Score	VAS scale assignments by respondents																						Total
	0		1		2		3		4		5		6		7		8		9		10		
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	
How much do you consider the following aspects related to home nursing in a clinical trial to be hindrances? (0 low-10 high)																							
Insurance aspects	5	4.5	1	0.9	8	7.2	5	4.5	4	3.6	15	13.5	13	11.7	12	10.8	21	18.9	10	9.0	17	15.3	111
Logistical considerations for patients >40 km away from clinical center	6	5.4	1	0.9	4	3.6	2	1.8	2	1.8	11	9.9	7	6.3	10	9.0	18	16.2	21	18.9	29	26.1	111
Ensuring PI supervision on study and staff	3	2.7	2	1.8	6	5.4	3	2.7	7	6.3	19	17.1	10	9.0	13	11.7	26	23.4	11	9.9	11	9.9	111
Workload of study staff	1	0.9	2	1.8	4	3.6	6	5.4	3	2.7	16	14.4	16	14.4	11	9.9	23	20.7	10	9.0	19	17.1	111
Management of staff scheduling	4	3.6	1	0.9	1	0.9	5	4.5	4	3.6	14	12.6	11	9.9	12	10.8	23	20.7	16	14.4	20	18.0	111
What perception do you have of impact of home nursing on workload of clinical center? (0 negative-10 positive)	6	5.4	1	0.9	2	1.8	7	6.3	9	8.1	19	17.1	14	12.6	13	11.7	22	19.8	9	8.1	9	8.1	111
In which areas do you consider the remote transmission of patient data to be most beneficial in the context of oncological clinical trials? (0 low-10 high)																							
Transmission of QoL data (e.g. QoL question)	1	0.9	1	0.9	0	0.0	3	2.7	3	2.7	6	5.4	12	10.8	6	5.4	16	14.4	18	16.2	45	40.5	111
Monitoring and transmission of vital parameters (e.g., SpO_2, heart rate, etc.)	2	1.8	1	0.9	1	0.9	2	1.8	5	4.5	4	3.6	13	11.7	9	8.1	29	26.1	11	9.9	34	30.6	111
Remote verification of therapy/medication compliance (e.g., medication intake diary)	3	2.7	0	0.0	2	1.8	3	2.7	3	2.7	5	4.5	8	7.2	10	9.0	21	18.9	16	14.4	40	36.0	111
Remote blood glucose assessment	3	2.7	0	0.0	3	2.7	1	0.9	2	1.8	4	3.6	12	10.8	9	8.1	27	24.3	10	9.0	40	36.0	111
Assessment and communication of adverse events/toxicity	1	0.9	0	0.0	2	1.8	4	3.6	3	2.7	9	8.1	11	9.9	8	7.2	24	21.6	15	13.5	34	30.6	111
What perception do you have of impact of such technology/ device on workload of clinical center? (0 negative-10 positive)	4	3.6	1	0.9	5	4.5	7	6.3	2	1.8	15	13.5	17	15.3	14	12.6	19	17.1	9	8.1	18	16.2	111
How useful do you consider use of devices for remote transmission of patient data to home? (0 low-10 high)	3	2.7	2	1.8	1	0.9	1	0.9	4	3.6	10	9.0	11	9.9	14	12.6	18	16.2	17	15.3	30	27.0	111

DISCUSSION

The survey, involving the participation of 111 responders, was conducted anonymously and on a voluntary basis. Despite the involvement of various types of professionals, it may not provide a comprehensive representation of Italian professionals across different oncological experimental sites in Italy due to the possibility of selection bias among the responders.

The majority of respondents (59.5%) were primarily engaged in the field of oncology with onco-hematology closely following (30.6%). The survey encompassed professionals from various experimental sites, with general hospitals and scientific research institutes (IRCCS) being the most represented (33.3% each), followed by university hospitals (25.2%).

Around 29.7% reported having no prior experience in remote patient data capture in oncology clinical trials, while the majority (61.3%) indicated low or medium experience. In this context the significant shift towards remote activities and digitalization prompted by the COVID-19 pandemic could have played a crucial role.[1,2]

Respondents generally considered the use of remote modalities and electronic devices for data capture to be very useful (58.6% with 8-10 score), with a median score of 8 on a 0-10 VAS scale. The perceived usefulness extended to various remote activities applied to oncology clinical trials, such as quality of life outcomes data capture, vital signs transmission, therapy compliance monitoring, glycaemic control, and adverse events reporting. Very similar data with a positive perception of these remote activities in oncology clinical trials have also been reported by De Las Heras et al thanks to a survey addressed to a sample of oncologists in the US and UK.[7] Data confirm also that the use of wearables devices and remote data capture in clinical trials appear to be already in use and quite diffuse for oncology clinical trials, and can be useful if applied in this setting as confirmed by Cox et al and Gresham et al.[10,11]

Professionals acknowledged a notable enhancement in workload efficiency due to the impact of remote patient monitoring and data transfer in clinical trials. A substantial portion (41.4%) expressed a positive impact, while 43.2% indicated a neutral or moderate impact, and 15.3% perceived a negative impact.

The majority (73.0%) of respondents had no previous experience with home nursing in oncology clinical trials, indicating that this practice is uncommon in Italy within the oncology clinical research field. This could be attributed, in part, to the absence of specific guidelines by regulatory authorities.[22,23] While home nursing in oncology clinical trials appears to be not common, the majority of professionals (72.1%) prefer home nursing to be carried out by internal staff within the experimental sites. On the other side, insurance aspects and distance exceeding 40 km between the patient's home and the experimental site were noted as high-impact factors for home nursing by a significant portion of respondents. These results align with the data reported by De Las Heras et al and by Mahoney et al and Hanley Jr et al confirming that the distance from the experimental sites can be a limitation for the conduct of such activity and for the patient's participation in the trial.[2,7,13]

However, participants considered home nursing highly useful for various healthcare activities, including biological samples collection, vital signs collection, quality of life evaluation, adverse events monitoring, and electrocardiograms execution. Opinions varied when it came to the administration of investigational medical products or drugs through home nursing. Overall, there was a general perception of a medium workload improvement due to home nursing in clinical trials.

CONCLUSION

The survey results provide valuable insights into the perspectives and experiences of professionals in the field of clinical trials, particularly in oncology. Remote data capture through electronic devices seems to be quite employed in oncology clinical trials. A significant portion of staff at experimental sites and healthcare professionals specializing in oncology already possesses some level of experience in these activities, and their perception is generally positive. The positive reception of remote patient data capture and acknowledgment of its impact on workload efficiency indicate a growing acceptance of technological advancements. The varying opinions on home nursing highlight the need for careful consideration of factors such as distance between sites and patient's home and insurance aspects when implementing such practices in clinical trials. These findings contribute to the ongoing discussions surrounding the integration of technology and novel approaches in the evolving landscape of clinical research.

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