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Qualitative analysis of clinical research coordinators' role in phase I cancer clinical trials

Noriko Fujiwara[a,b,*], Ryota Ochiai[a], Yuki Shirai[a], Yuko Saito[c], Fumitaka Nagamura[b], Satoru Iwase[b], Keiko Kazuma[a]

[a] School of Health Sciences and Nursing, Graduate School of Medicine, University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan
[b] IMSUT Hospital, The Institute of Medical Science, The University of Tokyo, 4-6-1 Shirokanedai, Minato-ku, Tokyo 108-8639, Japan
[c] Formerly of the Clinical Trial Coordination Office, Shizuoka Cancer Center, 1007 Shimonagakubo, Nagaizumi-cho, Sunto-gun, Shizuoka 411-8777, Japan

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ABSTRACT

Background: Clinical research coordinators play a pivotal role in phase I cancer clinical trials.
Purpose: We clarified the care coordination and practice for patients provided by clinical research coordinators in phase I cancer clinical trials in Japan and elucidated clinical research coordinators' perspective on patients' expectations and understanding of these trials.
Method: Fifteen clinical research coordinators participated in semi-structured interviews regarding clinical practices; perceptions of patients' expectations; and the challenges that occur before, during, and after phase I cancer clinical trials.
Discussion: Qualitative content analysis showed that most clinical research coordinators observed that patients have high expectations from the trials. Most listened to patients to confirm patients' understanding and reflected on responses to maintain hope, but to avoid excessive expectations; clinical research coordinators considered avoiding unplanned endings; and they aimed to establish good relationships between patients, medical staff, and among the professional team.
Conclusions: Clinical research coordinators were insightful about the needs of patients and took a meticulous approach to the phase I cancer clinical trial process, allowing time to connect with patients and to coordinate the inter-professional research team. Additionally, education in advanced oncology care was valuable for comforting participants in cancer clinical trials.

1. Introduction

Phase I clinical trials are designed primarily to evaluate the safety and toxicity of new agents, establish their pharmacokinetic properties, and determine appropriate doses for subsequent phase II and phase III studies. Recently, trials are being complicated by the promotion of "precision medicine." Additionally, as American Cancer Society said that this kind of trials have the highest risk compared with other phases of trials. Therefore, they require research teams to consider the risks and benefits carefully [1]. The impact makes clinical trials more time consuming to explain to terminally ill research participants [2]. Patients enrolled in phase I cancer trials are usually those with advanced cancers that are refractory to standard treatments [3] and 90-days mortality rate is over 15% [4]. .As the American society of clinical oncology (ASCO) pointed out in 2015, these kinds of trials have improved their response rate as a therapeutic option for patients as participants [5]. However, there are three conceptual problems. (1) Phase I cancer trials provided many different compounds and regimens, and are highly variable. (2) The trials do not have therapeutic intent. (3) The drugs provided in the specific way for conducting trials, and the participants are exposed to the new agents in testing conditions.

Patients with advanced cancers who are refractory to standard treatments tend to have high expectations for the clinical benefits that may come from participating in clinical trials [6,7]. This is despite tumor response rates being typically only 4–10% [8,9] and grade 4 adverse events occurring in 14–30% of patients [8,10].

To manage patients' expectations appropriately, it is essential to promote and maintain high levels of scientific and ethical integrity in

Abbreviations: CRC, Clinical Research Coordinators; CRN, Clinical Research Nurses; CTN, Clinical Trial Nurses; RNC, Research Nurse Coordinators

* Corresponding author. Department of Palliative Medicine, IMSUT Hospital, The Institute of Medical Science, The University of Tokyo, 4-6-1 Shirokanedai, Minato-ku, Tokyo 108-8639, Japan.
E-mail addresses: cam-osk@umin.ac.jp (N. Fujiwara), rochiai@yokohama-cu.ac.jp (R. Ochiai), yukishirai0904@gmail.com (Y. Shirai), yuko.saito@merck.com (Y. Saito), nagamura@ims.u-tokyo.ac.jp (F. Nagamura), iwase.evol@gmail.com (S. Iwase), kazuma-tky@umin.ac.jp (K. Kazuma).

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clinical research. Therefore, for early-phase clinical trials, multidisciplinary approaches including clinical research coordinators (CRCs) are needed. Worldwide, CRCs comprise clinical research nurses (CRNs), clinical trial nurses (CTNs), research nurse coordinators (RNCs), and study coordinators. The preferred term in Japan is CRCs, because Japanese CRCs have various healthcare professionals such as nurses, pharmacists, lab technicians and others. Regarding the role of CRCs, some studies have reported that they are responsible for numerous aspects of clinical trials including patient protection, study coordination, data management, participant recruitment, compliance with regulatory requirements, and reporting [11–14].

Especially in phase I cancer clinical trials, where patients typically have severe physical and mental burdens, the care coordination and practice are critical parts of the CRC role. Therefore, it should be clear. Elucidating this activity will enhance the CRCs performance and improve the quality of clinical research; therefore, this study qualitatively examined the care coordination and practice provided by CRCs, and the associated challenges that they face in phase I cancer trials to improve educational resources.

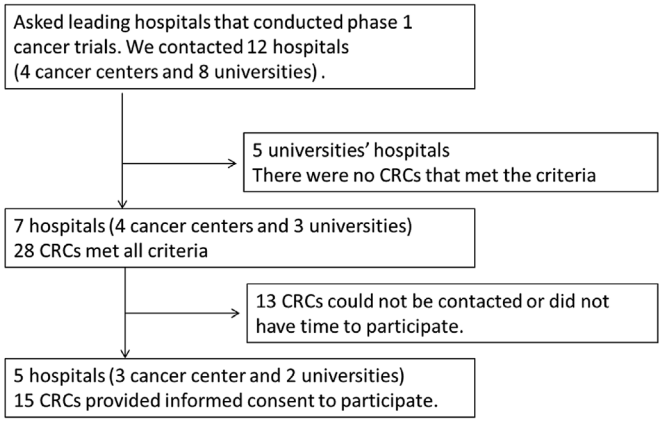
2. Materials and methods

We conducted semi-structured interviews with Japanese CRCs who were conducting phase I cancer trials and analyzed interview data using the qualitative content analysis method.

2.1. Participant recruitment

Inclusion criteria for this study participants included the following: (1) working at facilities conducting phase I cancer trials, (2) more than 2 years' experience as a CRC (based on the certification requirement of clinical research professionals), and (3) involved in at least three phase I cancer protocols (including being currently involved in one). We adopted the third inclusion criterion because we considered that formation of empirical knowledge requires being involved in phase I cancer protocols multiple times. There is no exclusion criteria.

For participant recruitment, we contacted twelve hospitals that conducted phase I cancer clinical trials and who met the inclusion criteria. The twelve hospitals comprised four cancer centers and eight university hospitals. Eight hospitals were designated as “Translational Research Centers” or “Clinical Research Centers” by the Japanese government. Then, seven hospitals reported having 28 CRCs who met the study criteria. There were no eligible CRCs in five hospitals. After contacting the 28 CRCs by mail or e-mail, 15 CRCs at 3 cancer centers and 2 university hospitals showed their intention to participate in the study. We obtained written informed consent from all participants (Fig. 1).



Note. CRCs = clinical research coordinators.

Fig. 1. Participants' recruitment. *Note.* CRCs = clinical research coordinators.

2.2. Data collection

This study was approved by the Ethics Committee of the Graduate School of Medicine, University of Tokyo. Semi-structured interviews were conducted by one researcher (N.F.), who considered the interview content among the authors including one CRC (N.F.), two cancer nursing researchers (Y.Shi. and K.K.), and one nursing researcher who specialized in qualitative research (R.O.) before meeting the CRCs. This study was conducted in accordance with the Declaration of Helsinki.

The researcher met each CRC in a private room so that participants' privacy would be protected, explained the study purpose, informed them that their identities would be kept anonymous, and allowed them to ask questions for clarification. Then, written informed consent was obtained from each participant. There were no time constraints affecting interview length.

Interviews were audio recorded and then transcribed verbatim. Three sets of interviews were conducted: before, during, and after the trial. This method was devised based on the existing literature [6], a general trial timeline, and our clinical experience. Each set contained the following three topics: Patients: “What needs and expectations do patients and their families have?” (For example, physical conditions, mental conditions, and the participants' expectations); Clinical Practice: “How do you care for the patients and their families?” (For example, the collaboration with other team members); and Challenges: “What challenges do you face?” Participants were encouraged to provide detailed descriptions of their experiences (Fig. 2).

2.3. Data analysis

Qualitative content analysis was performed to divide the transcribed data [15] into content units; each had a specific meaning, and codes were created based on these. Codes were grouped based on similarities into “categories.” The units, codes, and categories were decided through deliberation among the researchers. Then, the data were classified based on the three topics of Patients, Clinical Practices, and Challenges (See Data Collection section and Fig. 2). Then, one coder with experience in hospital-based nursing (a practice nurse with advanced experience in oncology), conducting phase I cancer clinical trials, and conducting qualitative studies as a principal investigator validated the coding. We also calculated intercoder reliability regarding choices of code and unit, and the resulting level of agreement between coders was tentatively acceptable (77%). Therefore, the coder and the interviewer discussed the units that they disagreed until they reached consensus. Finally, the authors including two CRCs (N.F. and Y. Sa.), two cancer nursing researchers (Y.Shi. and K.K.), one nursing

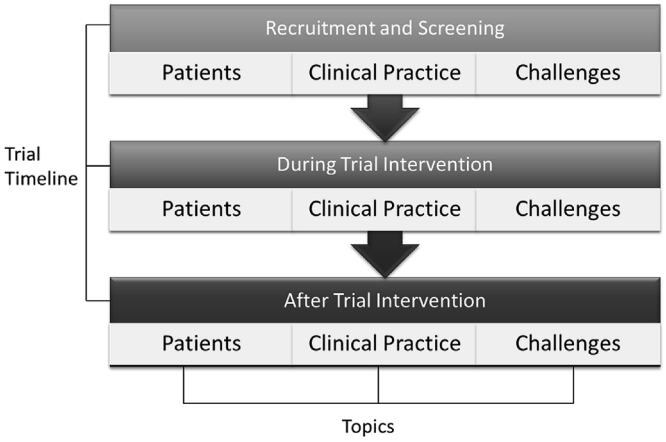


Fig. 2. Structure of interview guide.