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ORIGINAL RESEARCH

Implementation of a Fully Decentralized Clinical Trial Design in a Psycho-Oncology Trial

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Introduction/Objectives: We propose and conduct an infrastructure for a fully remote, decentralized psycho-oncology trial using smartphones. We also discuss the data collection flow and mechanism.
Methods: A multidisciplinary team of researchers, data center members, and vendors built a Decentralized Clinical Trial system. We facilitated virtual trials through web-based systems and zero site visit, Web-recruiting, eConsent, ePRO, Apps, and Google Analytics.
Results: Virtual Clinical Trials enabled by technological levers have increased the efficiency of clinical trials. Considering the characteristics of the research, the building part or all web-based systems dramatically reduced the burden on patients and researchers.
Conclusions: We emphasize the potential benefits of our novel strategy of conducting a fully decentralized clinical trial. However, it is always important to take all possible precautions to ensure that participants who are not proficient in digital technology are not disadvantaged.

Keywords: Decentralized clinical trial (DCT); electronic Informed Consent (eIC); electronic Patient Reported Outcome (ePRO)

Introduction

Digital transformation has been an important development in all industries, and IT technology has been adopted and developed rapidly in the healthcare industry. Digitalization in the medical field, including electronic medical records, plays a major role in improving the efficiency of healthcare delivery. In terms of digitalization, concern over the Decentralized Clinical Trial (DCT), which is defined as "a clinical trial in which some or all of the trial-related activities occur at locations other than traditional clinical trial sites,"[1] has emerged in recent years.[2]

The burden and problems of traveling to and from hospitals have been cited as obstacles to participating in traditional research, and the DCT has attracted attention as a solution. While clinical research has traditionally focused on face-to-face (F2F) visits throughout a study, advancements in IT technology and research methodology have enabled clinical trials to be conducted without a "site visit" by the participants. Additionally, owing to the COVID-19 pandemic, remote medical practices, such as online medical care, have advanced to provide medical care that does not require F2F contact. Research methods that do not require a visit to the hospital are called "virtual clinical trials" or "web-based clinical trials", in addition to the DCT. The use of various digital technologies in clinical research will not only reduce the burden on patients but also on medical professionals. For example, web-based clinical trials date back to the REMOTE trial,[3] which consists of the following elements: (1) web-based recruitment; (2) electronic Informed Consent (eConsent/eIC); (3) electronic data capture at the source (electronic Patient-Reported Outcome (ePRO); electronic Source (eSource); (4) remote drug adherence monitoring and telemedicine; and (5) a study call center available 24/7 by e-mail and phone. Additionally, previous studies have reported that compared with traditional trials, DCT improves the rate of patient progress to consent, and study completion.[4,5]

Background

No effective treatment exists for reducing the fear of breast cancer recurrence with drugs, and cognitive behavioral therapy (CBT) is expected to be used; however, CBT is rarely used for care and treatment, and medical personnel such as psychiatrists, psychosomatic physicians, and licensed psychologists who can provide specialized

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treatments are limited in number. Coupled with busy lives, including work and child rearing, most patients are forced to endure without receiving appropriate treatment. We therefore developed an application that allows patients to conduct CBT on their own, and conducted a clinical trial[6] to confirm its effectiveness. We developed a DCT platform that allows patients to participate in clinical research with their smartphones, and without having to visit the hospital. Consequently, we succeeded in reducing fear of recurrence in patients with breast cancer for the first time using an application for CBT. Our hope is that in the future, this will enable patients to use their own smartphones to receive medical care that alleviates their suffering at any place and time without needing to visit a hospital. We proposed and implemented an infrastructure for a fully remote DCT using smartphones. Below, we discuss the flow and mechanism of data collection.

Methods

Study Design

This DCT was implemented in a study in the Psycho-Oncology area called "SMILE project" (SMILE). It was investigator-initiated and randomized. The inclusion criteria for participants were as follows: (1) diagnosis of breast cancer and awareness of the cancer diagnosis; (2) ages 20–49 years; (3) 1 year following breast surgery; (4) currently disease-free; (5) ability to complete an electronic Patient-Reported Outcome (e-PRO) using an iPhone or iPad; and (6) being an iPhone or iPad user with an Apple ID to install applications using the App Store.

Participants were randomized to the smartphone-based intervention or waitlist control group. The intervention group used the two apps for eight weeks. The waitlist control group was allowed to use the same apps after the observation period. The primary endpoint is the Concerns About Recurrence Scale (CARS) score after eight weeks.

Since no DCT system has been developed in Japan, this was built by a multidisciplinary team of researchers, data center members, and vendors. When the study began, regulations for the DCT and eConsent were not established in Japan. The system for this study was therefore constructed with reference to US Food and Drug Administration (FDA) guidance.[7] The specifications of the system were discussed and decided so that the same data flow could be reproduced as much as possible in traditional F2F, paper-based research, and digitalized DCT. **Figure 1** outlines the study flow. **Figure 2** presents the system configurations and individual procedure.

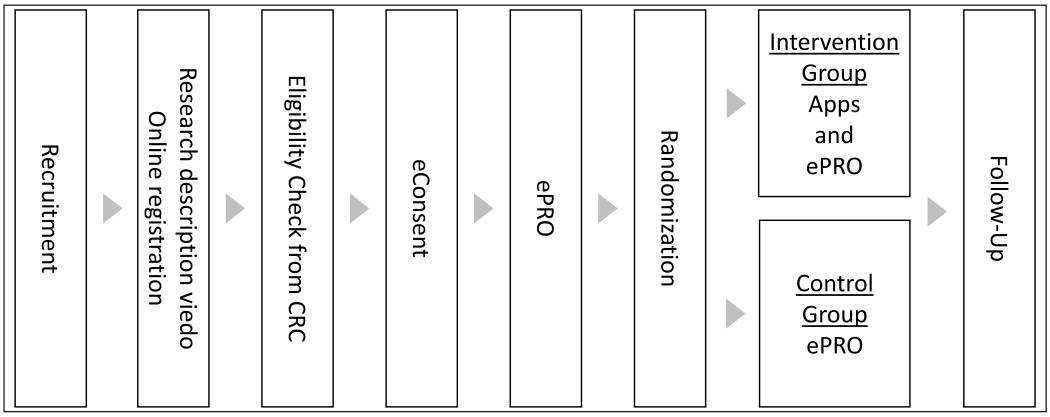

Figure 1: Study Flow.

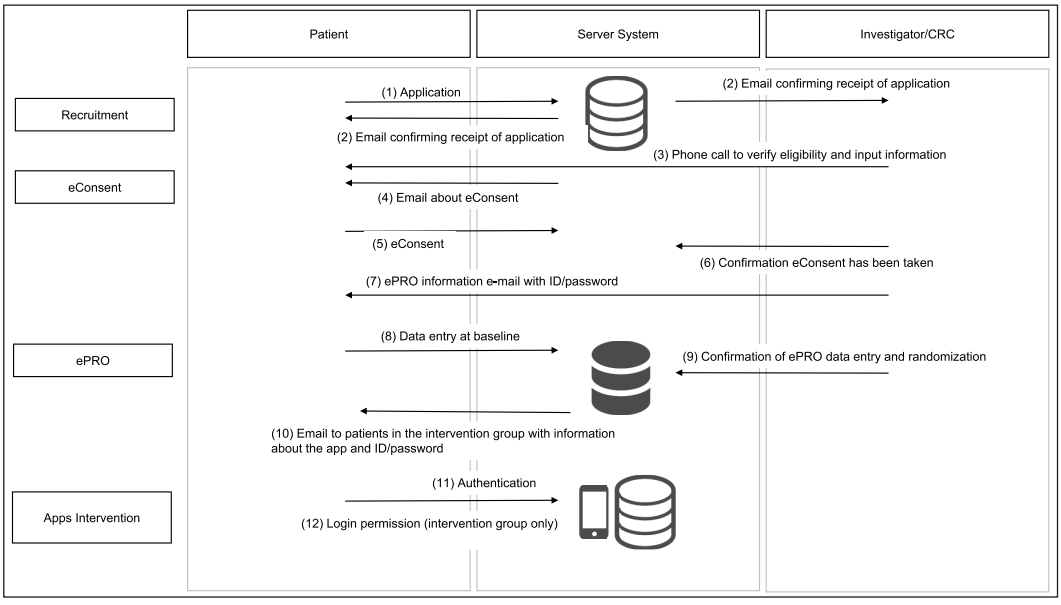

Figure 2: System Configurations and Individual Procedure.

Recruitment

Patients applied for the study themselves rather than being recruited by doctors. At the hospital, a study poster with a QR code for the application was attached and information sheets were distributed. Newspaper advertisements and social networking sites (SNS) were used for recruitment.

When participants scanned this QR code, they were directed to the SMILE project website,[8] which comprises a research explanation document and video, Q&A section, and research application page.

In the research explanation video, a breast oncologist explained the study using an easy-to-understand animation. Specifically, difficult terms such as "randomization" were explained in a question-and-answer session, thereby creating a scenario that was easy for patients to follow. Patients were also invited to participate in creating a scenario and their opinions were considered in the dialogue and illustrations.

The participants completed the application form on the website by entering their names, e-mail addresses, cell phone numbers, and eligibility checks. The phone number field was set up with an edit check so that it could not be used to register again.

After completing the questionnaire, an e-mail was sent to the researcher. The researcher reviewed the application and called the participants to answer any questions they had about the study, and to ensure that they met the inclusion criteria. Although the entire flow could be systematically automated, a direct discussion between the Clinical Research Coordinator (CRC), and the participants over the phone was arranged to build trust between the participants and the researcher.

eConsent

eConsent was implemented according to the following steps.

> Step 1: Online registration was completed after reviewing the written and video explanations of the purpose, subject, and methods on the website.
> Step 2: CRC called the patient to confirm eligibility.
> Step 3: After confirmation, CRC informed the patient of the eConsent site.
> Step 4: To verify the participant's identity, they uploaded a photo of the medical ticket at the hospital they attend.
> Step 5: The researcher received a copy of their Informed Consent.
> Step 6: Participants answered comprehension questions to confirm their understanding of the study explanation.

After the patient's eligibility was verified, the system sent them an invitation e-mail to acquire eConsent. The eConsent page contains the same information as a paper consent form; it also includes a consent button, fields for names and e-mail addresses, and a button for uploading identification documents. This upload procedure requires the patient to upload a picture of their medical card of the hospital they visit for breast cancer using their smartphone. To prevent double or false registration, this procedure was performed in accordance with FDA guidelines.

The uploaded photographs were then reviewed by the researcher, and if they were unclear or inappropriate, the participant was asked to upload them again. After confirmation, the patient's card was printed by the researcher, stored with the consent form, and deleted from the server so that no personal information remained on the server. Thereafter, a PDF copy of the consent form with the date of consent printed was sent to the patient.

ePRO

Data were collected from the patients' smartphones during a 24-week study using PRO; it included understanding of eConsent and its characteristics, endpoint data, satisfaction with interventions, and qualitative assessment of the apps.

After completing the eConsent procedure, the researcher sent an e-mail containing the ePRO information to the patient. The ID/initial password for the ePRO was included in the e-mail, and the patients accessed the ePRO website using their smartphones. The patient logged into the ePRO and completed a week 0 (baseline) questionnaire. Once the responses were submitted, the EDC server performed the randomization. The control group was notified of their allocation and periodic questionnaires. Only the intervention group had access to the intervention apps. Servers that contain personal information for the application, where the ePRO data are stored and that contain the application, were constructed separately so that they could not be linked easily, thereby strengthening security.

Apps

The protocol intervention for this study required participants to install two apps on their smartphones and to use them at their own pace. The first is a "Kaiketsu" app, which means "problem-solving" in English. It provides participants with a structured problem-solving strategy and consists of dialogue learning and a practical part for inputting their own problems. The other is a "Genki" app, which means energy or power in English. It includes an introduction, training session, and activity schedule planning assistance. The researcher sent regular announcement messages reminding the participants to use the apps.

Data Management/Monitoring

Central monitoring was conducted instead of onsite visit monitoring, because all data were input directly from the subjects. As people from all over the country could participate using a web-based recruiting system, Google Analytics was used to analyze website access.

Google Analytics was also used for app adherence, and to obtain various data for free, such as users' usage time, access pages, and so on. We reviewed these data and provided central monitoring reports to discuss the problems and solutions.

Table 1 presents a comparison of the traditional and SMILE study designs.

Table 1: Traditional and SMILE Study Design.

	Traditional Study	SMILE project (DCT)
Recruitment	Direct approach from researchers	eRecruitment using SNS, etc. Online registration
Informed Consent	Face-to-face Paper-based	Explanation by video eConsent
Intervention	Direct intervention such as medication, surgery, etc.	Smart Phone Apps
Data collection Data entry	Assessment by in-hospital tests and paper-based questionnaire	ePRO App usage log data
Data Monitoring	On-site monitoring	Central monitoring

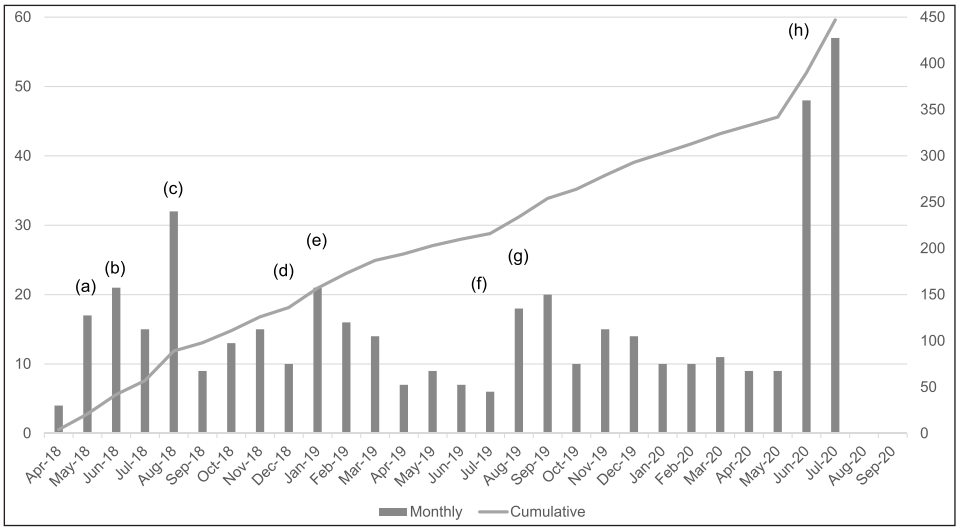

Figure 3: Patient Enrollment.

Results

Recruitment

The recruitment was conducted between April 2018 and July 2020. **Figure 3** illustrates the pace of participant enrollment. Initially, recruitment was performed only by placing posters in the hospital; however, due to lower enrollment than expected, in May 2018, the primary investigator (PI) started distributing information about the study on SNS (**Figure 3**). In June of the same year, after the PI submitted an article about the trial to a newspaper, approximately ten people registered per day. This article was published in a newspaper in August and September 2018. In late November and early December 2018, the study was advertised on SNS, but it was not effective. Recruiting for the study required obtaining information from people who needed it rather than from the public at large. Beginning in January 2019, study referral cards were placed in breast specialty clinics. This information was published in newspapers in June and July of 2019. An e-newsletter was published on a well-known patient community website between August and September 2019. From June to July 2020, the program featured a peer-supported social networking site, which resulted in a significant increase in enrollment. Enrollment was closed on July 13, 2020, when the target caseload was reached. During the recruitment period, 24,257 people accessed the website and 510 subjects applied. Of these, 63 cases discontinued before group allocation, 447 cases were allocated, and protocol intervention was initiated.

eConsent

In accordance with the FDA guidelines, patients were given the option of paper consent in addition to web-based consent; however, all patients provided the latter. None of the patients refused to upload their identification documents, uploaded irrelevant photos or photos of others, or engaged in other deceptive behaviors. All eConsent comprehension questionnaires indicated high levels of comprehension.

The following comments were received from participants.

- It was good to be able to register on smartphones.
- I think it was easy to understand, with explanations provided via both videos and writing.
- I feel that the hurdle to participate in research has been lowered.
- I think the system is very innovative in that the procedures are easy to follow and no time lag exists from the time I want to cooperate with the research.
- I can check what I need to know as many times as I need, and I think it was good that I could answer the questions according to my time.

On the other hand, the following comments were also received as points for future improvement.

- I have the impression that research explanations are difficult to understand in written form. Therefore, I thought that the explanation provided in advance via the video was easy to understand. I also thought that the emails were easily missed, which was a problem.
- I understand that a photo is necessary for identification, but I also feel uncomfortable about providing it.
- I thought that since the procedures were easy and the app was hassle-free to operate, I might have participated with a light heart. I also felt that the content did not stick to my mind.

This was the first attempt to conduct a study using eIC; therefore, all participants were asked to complete a questionnaire. The results showed that the participants' understanding of the study content was better than that of conventional written informed consent (**Table 2**).

ePRO

The ePRO response rate was very high: at week 8, it was 99.3% (the primary endpoint). Even after 24 weeks, the percentage remained high at 98.8%. The dropout rate was also low, with only three discontinuations throughout the study.

Data Management/Monitoring

While central monitoring using EDC/ePRO data is usually conducted in clinical studies, we adopted monitoring through metric analysis using Google Analytics (**Figure 4**), in addition to the input data. Specifically, the number of visits to the website and page transitions were monitored to examine recruitment strategies. Regarding the intervention status, access to and time spent using the application were monitored. For example, the mean, median, and range of completed sessions of each problem-solving therapy (total of nine sessions) and behavioral activation (total of six sessions) apps were 6.7 (standard deviation [SD] = 3.3), 9, 0–9/4.7 (SD = 1.9), 6, and 0–6, respectively.[5]

The application/ePRO and intervention applications were separate systems, and because monitoring was conducted using Google Analytics, three different systems were required, which is not good with regard to coordination. In addition, collecting log data in the form required for the study was difficult, and obtaining data that could be analyzed was labor-intensive. Utilizing tools already in use in other fields can reduce costs, but this needs to be considered beforehand, as they may lack applicability and require labor when combining data after collection.

Safety concerns

No serious adverse events were reported for this trial, including infrastructure systems.

Table 2: Results of Questionnaire on Electronic Informed Consent.

Question item	Total	Did not understand		Rather did not understand		Rather understood		Understood well	
The purpose of this study	447	8	(2%)	4	(1%)	139	(31%)	296	(66%)
Randomization	446	5	(1%)	10	(2%)	110	(25%)	321	(72%)
The risks (disadvantages) and benefits (advantages) associated with participation in this clinical trial	446	4	(1%)	14	(3%)	122	(27%)	306	(69%)
Impression About the method of identity verification		Couldn't understand, had to get help from someone else		Was a little confused by the operation, but was able to complete it by myself		It was easy			
For the purpose of this study, we have adopted the method of attaching a photo of the clinic visit card from a medical institution. Please share your impressions about the operation method.	447	1	(0%)	33	(7%)	413	(92%)		
General opinions on eConsent (video-based research explanations and consent acquisition on the web)		Understood better with the video.		Understood both about the same.		Understood better with the paper document			
Regarding the 'video-based research explanation' and the 'document-based research explanation' available on our website, which one did you find more helpful in understanding the content of the research?"	446	175	(39%)	229	(51%)	42	(9%)		

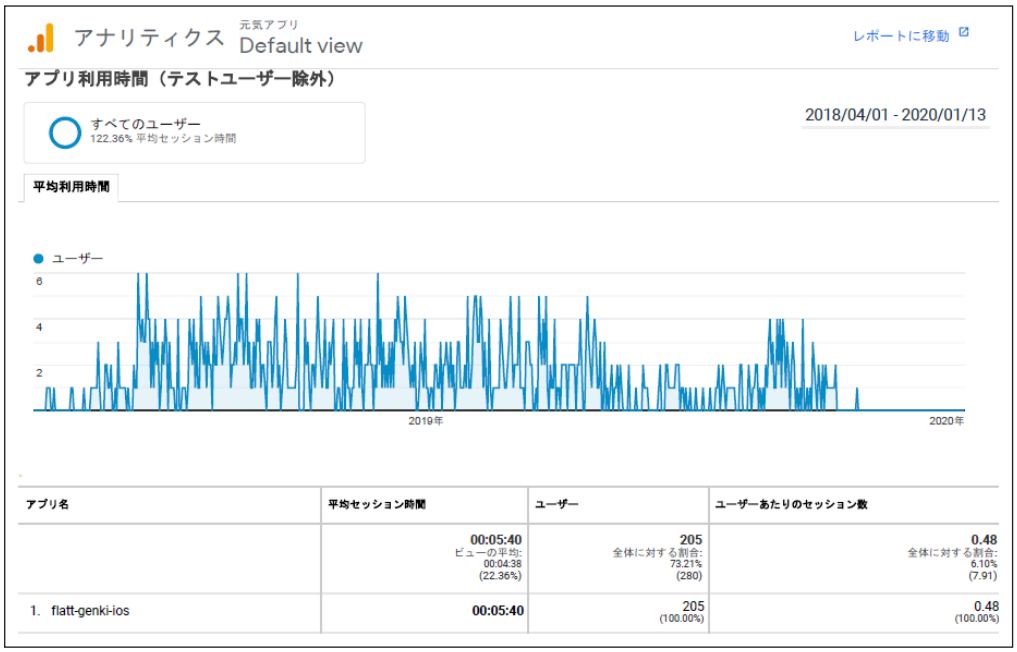

Figure 4: Output Image of Google Analytics (in Japanese).

Discussion

This study developed a full DCT system and examined its feasibility for implementation in breast cancer survivors with infrequent hospital visits. The successful implementation of the DCT in this study can be attributed to several factors. First, the participants had completed their primary treatment and did not require regular hospital visits, thereby facilitating their participation without requiring site visits. Second, since the intervention employed app-based CBT, F2F interaction was not required, thus allowing the intervention to be delivered remotely. Third, the primary outcome measure, the CARS, along with other assessment tools, consisted of PRO measures. The use of an ePRO system enables remote assessment and minimizes logistical constraints. These three design elements—target population, intervention modality, and outcome assessment—were well aligned with the principles of DCTs, making full decentralization feasible.

In a previous study using REMOTE trial,[3] delays in subject enrollment were an issue. However, this study achieved the target number of cases through various efforts, including the use of SNS and patient-community sites. This suggests that the advantage of the DCT in today's world, where smartphones are more widespread than ever, is the possibility to reach a large number of patients without geographical restrictions if the recruitment strategy is optimized. The ePRO response rate in this study was extremely high, at 99.3% at 8 weeks and 98.8% at 24 weeks. These results indicate that DCTs have the potential to encourage patient participation in research and maintain high-quality data without requiring hospital visits. This result is consistent with that of the REMOTE trial,[3] which reported that DCT resulted in a high response rate. As noted in a previous study that conducted a systematic review,[9] there is a lack of data on subject retention, and further studies are warranted. Furthermore, all the participants opted for web-based consent, and the results of the questionnaire indicated the usefulness of eConsent. These results strongly suggest that eConsent is an effective alternative to traditional paper-based consent, as in previous studies.[10]

The advantages and disadvantages of the DCT are summarized in **Table 3**. The advantages include the following: (1) reducing the number of onsite visits and site burden, (2) reducing patient burden and increasing willingness to participate and be compliant, (3) increasing opportunities for contextually relevant data capture, (4) narrowing the gap between clinical trials and real-world experience, (5) expanding access to eligible participants, and (6) reducing the cost of site setup and management. One advantage is that the burden on researchers and patients is reduced because it is a zero-site visit trial, and some procedures are automated. Researchers and CRCs indicated that reducing the time required for informed consent was very effective owing to the video explanation. As participants do not have to go through the process of receiving an explanation from a researcher or research assistant and signing a document in front of them, this eliminates the possibility of invisible coercion, which may also be considered an advantage that contributes to the assurance of their autonomy. However, they should check the patients' understanding of the study and prepare a help desk call center. Another advantage is the reduction in barriers to participation.

This means that patients can participate in research anytime and anywhere, and not only in a limited number of hospitals. Even if one wants to participate in a clinical trial, one will not be able to do so if there is no participation site. Virtual trials make this possible. Real-world data can therefore be collected more easily than in traditional clinical trials. A virtual clinical trial will facilitate an understanding of whether medicines and medical devices are effective and safe for daily life. Finally, there are benefits related to cost-effectiveness. Previous research has reported cost reductions; however, we have not yet confirmed this in our study. One disadvantage is that researchers must

Table 3: Pros and Cons of DCT.

	Pros	Cons
Subjects	· Reduce burden (Reduces the number of onsite visits and waiting time) · Reduce barriers to participation · Patient-Centric Clinical Trials	· Lack of communication with researchers · Poor understanding of the research
Researchers CRC	· Reduce burden (Time spent on data entry and explaining the study) · Faster recruitment(Can recruit from outside of the target facility)	· Setting up the data capturing platform · Operational procedure training Dealing with system glitches and people with low IT literacy)
DM	· Reduce burden (data entry time) · Real-time data collection · Centralized data management	· Setting up the web-based system in the preparation phase · Data monitoring on many pieces of information is possible
Other	· Small gap between clinical trial and real-world data · Reduce cost (Reduction of time and cost)	· Explaining the eIC to the IRB committee · Consider in advance what type of research is appropriate for the study. · Potential for participant bias · System failures

make considerable efforts to ensure the correct setup and implementation of the study. In the preparation phase, researchers and data managers establish a platform and explain the system to an Institutional Review Board (IRB) committee. Considerable time was spent preparing the platform based on requests from patients, researchers, CRCs, and data centers. If a problem arises in a device or a web network, it was necessary to consider how to deal with it in advance. Furthermore, managing people with low IT literacy should be considered. A flexible system to support the targeted groups should be in place, such as a CRC or call center. From the patients' perspective, they may experience anxiety because they do not have F2F meetings with medical professionals, including attending physicians and a CRC. In addition, the participants were geographically distant from the investigators. Studies that allow patients to participate without any such concerns must be conducted.

Limitations

This study has some limitations. First, the study population was limited to women with breast cancer, limiting the generalizability of the results. Further verification is necessary when applying this system to patients of different sexes, age groups, and with other diseases.

Second, the devices used in this study were limited to iOS-enabled iPhones. While this ensured the standardization of the research procedures, it also limited the applicability of the results. To implement this strategy for a larger number of patients, it is essential to target a variety of devices and to establish a flexible support system that can accommodate participants with low IT literacy.

Finally, the efficiency gains achieved by introducing this system may reduce the opportunities for face-to-face communication between medical staff and patients. This could cause anxiety among patients, which was an important consideration in this study. Although no serious problems were reported in the questionnaire used in this study, the possibility of anxiety could not be completely ruled out. Maintaining trust among patients and reducing anxiety are important issues requiring ongoing consideration.

Future Directions

Despite the relative lack of DCTs in Japan, recent advances in information technology have made it possible to perform DCTs without hospital visits. A DCT is only one of the possible research methods, and the optimal method for patients and researchers should be considered within the regulatory framework, taking into account the purpose, subject, and design of the research, and which parts should be systematized. DCTs are likely to spread in the future with the further development of Internet of Things technology, regulatory requirements, and the introduction of online medical services. Although considerable effort is required for preparation prior to the start of a study, it is expected to be less burdensome than normal clinical research. The development of the DCT will enable 24-hour study application and participation, thus allowing patients to choose when and where they participate in research in their daily lives.

Conclusion

We introduced an infrastructure for a fully remote DCT using smartphones from the perspective of data collection flow and mechanism. We emphasized the potential benefits of our novel strategy for fully performing DCT.

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Competing Interests

Tatsuo Akechi has the patents (7313617) (Institute). The remaining authors have no competing interests to declare.

Author Contributions

Tomoe Mashiko led study design, study conduct and contributed to the manuscript draft. Tempei Miyaji and Tatsuo Akechi led study design and study conduct. Takuhiro Yamaguchi led study design and contributed to the manuscript draft.

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