Research on collaborative decision-making support with oncologists about treatment and medical care using applications

A Randomized Controlled Trial Evaluating the Efficacy of a Collaborative Decision-Making Support Program Using Mobile Devices for Treatment and Care of Patients with Advanced Cancer

Summary of this document

- This consent form explains the contents and the procedures of the research. Please read it carefully, and if you have any questions, please do not hesitate to ask the researcher.
- We know that patients' thinking about their bodies, treatment and life, and their future, and discussing and making decisions with their attending oncologists can positively impact their minds, body, and life. In this study, we planned to use a mobile application (app) to examine whether our intervention program improves communications with the attending oncologists when we support patients to ask questions and share their values with their oncologists.
- Eligible participants for this study must be diagnosed with advanced or recurrent cancer, be at least 20 years of age, and be able to understand Japanese.
- Participation in this study is based on your free will, and even if you do not agree to participate, you will not be disadvantaged in any way in your future treatment. If you wish to learn more about this study, you may view the research protocol and other materials to the extent that the rights of the researcher and those of other patients are not infringed.

1. About the clinical research and this Informed Consent Form

Much research is needed to develop methods of diagnosis and treatment for diseases. Current treatments have been studied and developed over a long period.

The National Cancer Center is also actively engaged in various studies to contribute to the development of cancer treatment. Among these studies, those conducted with the cooperation of patients are called clinical research. Clinical research is possible with your understanding and cooperation, and the treatments currently available are the result of the cooperation of many people who have participated in research to date.

In conducting this clinical research, consideration for the human rights and safety of patients was reviewed by the National Cancer Center Research Ethics Review Committee to determine whether the research will contribute to the development of medical science, and approval was obtained from the Director. At that time, the research was also reviewed to ensure that it was planned by the ethical guidelines established by the government.

This document explains the content of the clinical research and is intended to supplement the researcher's explanation to help potential research participants understand the content of this research and think about whether they want to participate. Please be sure to ask the researchers if you have any questions.

2. Freedom of Participation

Participation in this study is based on your free will, and if you do not agree to participate, you will not be disadvantaged in any way in your future treatment. Even if you do not participate in this study, you can consult with your oncologist and medical staff at any time during your regular visits. You may withdraw your consent to participate in this study at any time. You will not be disadvantaged in any way for withdrawing your consent to participate. If you wish to learn more about this study, you may review the research protocol and other materials, provided that the rights of the researcher and those of other patients are not infringed.

If you have read the detailed explanation of this clinical research, and if you understand the content of the clinical research and wish to participate after receiving an explanation from the researcher, please sign the consent form on the last page.

3. Who is Eligible for This Clinical Research?

This clinical research is open to individuals who have been diagnosed with advanced or recurrent-stage cancer, are at least 20 years of age, and can understand Japanese. Please inform the investigator if you are participating in other psychological or communication studies, as you may not be eligible.

4. The Significance and Purpose of This Clinical Research

For many patients diagnosed with advanced or recurrent stages of cancer, the goal of treatment is to live better with the disease. The type of treatment (or combination of treatments) that they choose to

continue to lead the life they cherish varies from patient to patient. For patients to choose a way of life that they are comfortable with, they need to think about their bodies, treatment and life, and daily plans and share and discuss them with their oncologists. Studies have shown that when patients discuss their treatment and recuperation with their oncologists, it has a positive impact on their minds, bodies, and lives.

We planned a study to see whether patients could improve their discussions with their oncologists by using the app and sharing with their oncologists at the consultation what they have thought about their bodies, treatment and life, and their future, and how they have organized their intentions.

5. Methods of This Clinical Research

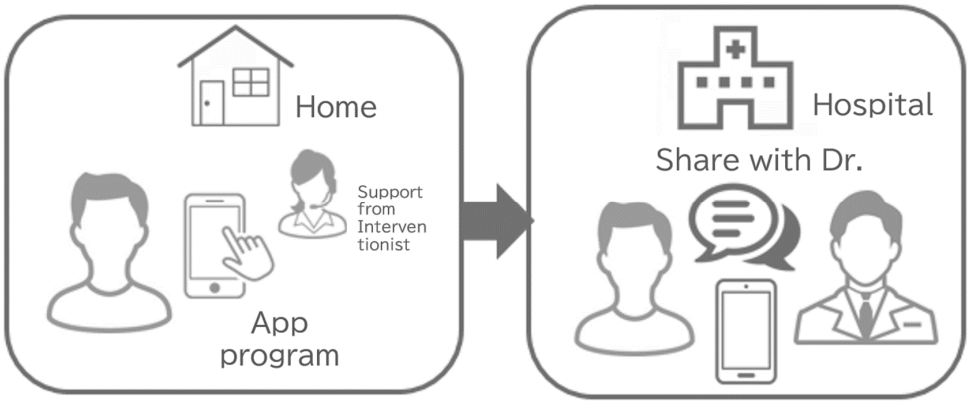

Figure 1: Image of application implementation (Group 1)

In this clinical research, patients will be placed in one of two groups (Group 1 and Group 2).

Whether you are placed in Group 1 or Group 2 is not determined by your wishes or your oncologist's decision but by "randomization," which uses a computer to determine a 50-50 chance of being in either group.

If you are in Group 1, you will use an application on a mobile electronic device to organize your questions using a question prompt list (QPL) and your intentions regarding treatment and recuperation. A nurse, psychologist, or psychiatrist will assist you in this process by phone or in person (30–60 minutes). Additionally, you will be asked to complete questionnaires at the time of study enrollment, at the medical examination after one week from study enrollment (date of medical recording), between one and four weeks from the date of medical recording, three months later, and six months later (the questionnaires will be administered at the medical examination closest to the scheduled date but may be requested by phone or mail depending on your visit schedule).

If you are in Group 2, the application on your mobile electronic device will only be used to answer the questionnaire. The survey will be administered at the time of study enrollment, at the office visit 1 week after study enrollment (date of office visit recording), between 1 and 4 weeks after the date of

office visit recording, 3 months later, and 6 months later. Each survey takes approximately 5–15 minutes to complete (the survey will be administered on the date closest to the scheduled survey date but may be requested by phone or mail depending on the schedule of visits.)

Additionally, we will record your consultation with your attending oncologist only once during the routine visit, using an IC recorder. This is to evaluate the communication with the attending oncologist and the type of interaction during the consultation. The recorded data will be strictly managed by a communication analysis team and processed into information that does not contain personal details before analysis.

Research assistants will review your medical histories related to cancer treatment from the electric medical record. The information from the medical record includes diagnosis, treatment details, and treatment status. If the patient has been transferred to a different hospital, we will inquire about this information with the respective hospital.

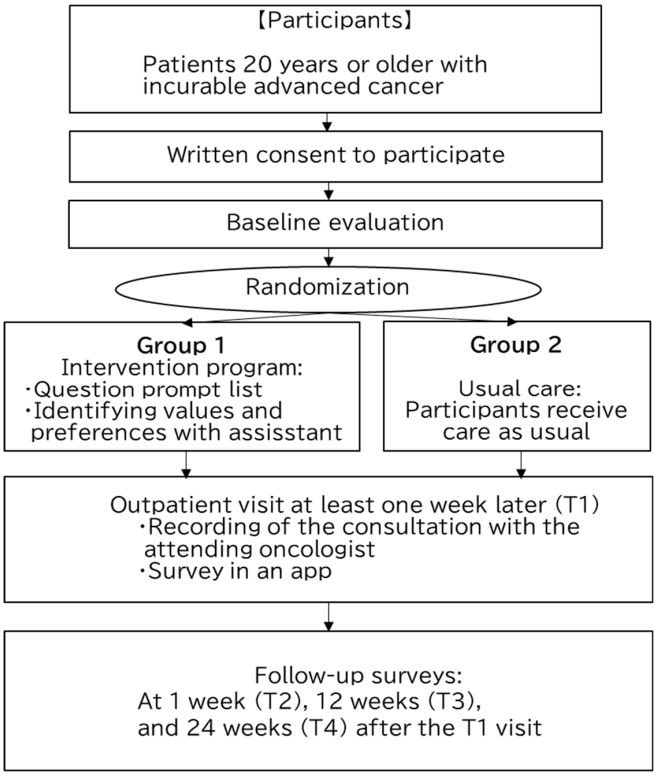

Figure 2: Overview of the study

6. Anticipated Benefits and Disadvantages of Participation in the Study

Patients (Group 1) who participate in the study and receive the app-based intervention program may benefit from an increased understanding of their diagnosis and treatment and reduced anxiety but may not experience any particular benefit. One disadvantage of participating in the study will be the potential time commitment. There will be a 5–15 minute commitment per session for downloading the

application or answering the questionnaires. You will be charged a cost of communication associated with the use of your device.

Patients in usual care (Group 2) will not benefit from participating in this study. However, they can contribute to the establishment of new support methods. Additionally, materials such as applications and pamphlets used in the intervention program in this study can be used upon request after the study period. However, it will take approximately 5–15 minutes per session to answer the questionnaire.

Please do not hesitate to inform the researcher or researcher-in-charge of any inconvenience or difficulty you may experience during your participation in the study.

7. Options if You Do Not Participate in This Clinical Research

If you choose not to participate in this clinical research, you will still receive the treatment that we believe is most appropriate for you. Your participation or non-participation in this clinical research will not affect your cancer treatment decisions in any way. Even if you do not participate in this study, you may consult with your healthcare providers at any time during your regular visits.

8. Planned Duration of the Entire Clinical Research

The study enrollment period for patients participating in this clinical research is planned to be two years from the date the study is approved, and the follow-up period for participating patients will be six months after enrollment is completed.

The entire study is expected to last four years from the date the study is approved.

9. Cost and Payment for Cost

By participating in this clinical research, you will receive a QUO card worth 500 yen to cover communication fees and time.

10. Response and Compensation in the Event of Health Problems

No unanticipated serious side effects or other adverse health effects will occur as a result of this clinical research.

11. Protection of Personal Information

If you participate in this clinical research, part of your personal information and records related to your medical information will be stored in the National Cancer Center Cancer Control Research Institute and the Supportive Care Division of the Central Hospital, which is the data center. The principal investigator will manage this information. Information collected for data management for use in clinical research will include medical record number, name, telephone number, date of birth, and address.

In all communication between the research office and the hospital, we will use the unique study number assigned to you in the study, not your name. This unique study number will be very important to properly manage your information as a participant in the clinical research, even if your attending

oncologist is transferred during subsequent investigations.

Information may be provided to researchers involved in the research who is in charge of data analysis, under appropriate management, with data that does not contain personal information. The information to be provided includes information on diagnosis and treatment and the results of questionnaires.

The National Cancer Center Research Ethics Review Board has approved the method of protection and management of personal information in this clinical research. The research office and research sites will make every effort to ensure that this information is not disclosed to outside parties or used for purposes other than those of the clinical research. If you are interested in participating in this clinical research, we ask that you consent to the use of your personal information.

To verify from a third party's perspective that this research is being conducted properly, the person or persons in charge of auditing clinical research at our center may review your medical records and other medical records. In such cases, these parties are bound by confidentiality agreements, and your personal information will be protected.

12. Handling of Samples and Information

Information obtained in this clinical research will be kept following the rules of the institution where the researcher is affiliated until five years from the date of submission of the study completion report or three years from the date of publication of any article related to this study, whichever is later. This is currently considered a necessary step to ensure that the results of the research can be later verified by someone else. After the specified period has elapsed, if the data need to be destroyed, we will process them such that it will not be immediately apparent to whom they belong.

13. Publication and Return of the Results of This Clinical Research

Results obtained from this clinical research will be published in medical societies and medical journals. Your name and other personally identifiable information will not be used in the publication.

Please note that the analysis results of this clinical research are in the research phase and, as a rule, will not be shared with you. However, if they become more likely to be useful for your health condition, your oncologist may contact you again after careful consultation with specialists and your oncologist. Furthermore, information about this clinical trial will be registered in the clinical trial registration system (UMIN-CTR, ClinicalTrials.gov, etc.) and made public according to established regulations. Additionally, data obtained from this study may be used secondarily in literature reviews and other studies such that does not identify individuals.

14. Funding and Conflicts of Interest for This Clinical Research

(1) Explanation of "Conflict of Interest"

Conflict of interest in clinical research refers to a situation in which a researcher receives financial benefits (e.g., honoraria, research expenses, and stock) from a company or other entity, and the existence of such benefits may affect the outcome of the clinical research.

(2) Statement Regarding Existence and Description of Conflicts of Interest

This research will be funded by the Health and Labor Sciences Research Grant-in-Aid for Cancer Policy Research Project (20EA1010). Other than this, we have not received any funding or free provision of drugs from any specific organization; therefore, there are no potential conflicts of interest regarding the research organization as a whole. Additionally, there are no conflicts of interest between the study and the company developing the app (SusMed, Inc.) that should be disclosed. SusMed Inc. is a pioneering company in the development of medical applications and has a wealth of experience in conducting research using high-quality applications from a security perspective, and we are collaborating with them in the development of the application.

(3) Description of How Conflicts of Interest are Managed

The management of researchers' conflicts of interest is handled by each participating institution concerning researchers affiliated with the institution. The National Cancer Center Conflict of Interest Committee manages conflicts of interest for researchers at our center. If you would like more information, please contact your primary oncologist.

15. Research Organization and Contact

If you have any questions or concerns about this clinical research or its results, please do not hesitate to contact the Research Office below.

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