TITLE　Research on communication between patients and physicians in oncology

RESEARCH ORGANIZATION　Psycho-oncology Division, Research Center for Innovative Oncology, National Cancer Center Hospital East

CONTENTS

SUMMARY

Purpose: The aim of this study is to identify the effects of a communication skills training (CST) program for oncologists, developed based on patient preferences regarding oncologists' communication.

Design: Randomized control trial.

Subjective of Intervention: Oncologists in National Cancer Center (NCC) Hospital, Tokyo, and Hospital East, Chiba, Japan.

Subjective of Evaluation: Oncologists and patients in NCC Hospitals.

Eligibility Criteria: The inclusion criteria in this study are oncologists who are staff at NCC hospitals and outpatients who attend follow-up medical appointments with the oncologists who are participants in this study at NCC hospitals, who received a diagnosis of cancer, and who are 20 years old or older. The exclusion criteria in this study are patients who are judged incapable of completing the survey physically and cognitively, or who are incapable of understanding spoken and written Japanese.

Intervention: The intervention is a CST program for oncologists, developed based on patient preferences regarding how oncologists communicate when breaking bad news. The workshop involves a two-day participant-centered program and consists of an icebreaking discussion, a one-hour computer-aided didactic lecture with text and a video, eight hours of role-playing with simulated patients, and discussions on this role-playing.

Evaluation: Oncologists are assessed on their communication performances during simulated consultation and their confidence in communicating with patients before and after CST. In addition, the subsequent usefulness of the CST program is evaluated, along with the level of distress of the oncologists, using the Maslach Burnout Inventory (MBI) and the General Health Questionnaire (GHQ), before and three months after the CST.

The oncologists are also assessed in terms of their socio-demographic characteristics.

Patients who had consultations with the participating oncologists at baseline and/or follow-up are assessed regarding their level of distress, using the Hospital Anxiety and Depression Scale (HADS); their satisfaction with the consultation; their trust in their oncologist after the consultation; their symptoms, using the MD Anderson Symptom Inventory (MDASI); as well as their socio-demographic and medical characteristics.

Methods: After providing informed consent, the baseline survey required oncologists to undertake a simulated consultation, in which they relay a diagnosis of incurable advanced cancer to a simulated patient (SP), and to fill in a questionnaire requesting information about their demographic characteristics (age, sex, and marital status), medical experience (specialty, clinical experience, and clinical experience in oncology), and perceived confidence in communicating with a patient. On days when a participating oncologist have consultations in the outpatient clinic, all eligible outpatients are invited to participate in the study after their follow-up medical visit. Patients who provide written informed consent are asked to complete and return within a week a series of questionnaires on HADS, their satisfaction with their oncologist's communication during the consultation, their trust in oncologists, MDASI, and their demographic characteristics.

After the baseline survey, the oncologists are randomly assigned to an intervention (two-day CST workshop) group (CST group) or a control group (WLC group). Oncologists assigned to the CST group are required to attend the whole of a CST workshop.

After the CST workshop in the CST group or two weeks after baseline in the

WLC group, information on the same variables as at baseline is collected as follow-up data. Three months after the CST workshop, participants underwent a second follow-up survey. After this follow-up survey, the oncologists who have been assigned to the WLC group are allowed to participate in the workshop, if they desired.

Analysis: Total scores of performance and confidence of the oncologists are analyzed using repeated measures analysis of variance (ANOVA), including the CST and WLC groups as a between-subjects variable. In this study, primary endpoint is differences between the CST group and the WLC group in terms of the emotional support factor in the SHARE categories. For the CST group, data on the participants' evaluation of the CST workshop component that they attended are shown as the mean scores, standard deviation, and range.

Data on patients' distress are compared between groups using a t-test. Mixed-effects models are employed to investigate factors associated with the post-consultation rating of patients' psychological distress, satisfaction with communication, and trust in communication. Patients' demographic characteristics (age, sex, employment status: employed or not, marital status: married or not, household size, years of education, type of cancer: surgical/medical/diagnosis/radiation oncology, recurrence or metastasis: yes or no, current treatment status: under treatment or not, subject of consultation: good or bad news) are entered in a multivariate model.

Each video is coded in terms of categories of performance in a random order by two blinded coders, who have been trained, independently, on two occasions with a rating manual.

Sample Size: We decide that 32 oncologists should be enrolled in this study. We judged that this would be possible because eight doctors can participate in one workshop at a

time, and this number would correspond to a rate of participation of approximately 20% among the total of about 190 doctors in NCC hospitals.

We decide that 32 patients would be enrolled in this study (10 per oncologist).

Study Period: 10 months (June 1st , 2006 to March 31st, 2007)

BACKGROUND

Bad news consists of any information likely to alter drastically a patient's view of his/her future[1] and includes information regarding diagnosis, recurrence, and treatment failure in clinical oncology settings. The communication skills of physicians delivering bad news about cancer can affect the degree of a patient's distress.[2-4]

There are a various guidelines and principles designed to enhance physicians' communication skills when delivering bad news.[5-7] For example, Girgis et al. proposed 15 principles and 12 steps of communication regarding breaking bad news.[6] In Japan, a set of guidelines named the Manual of Cancer Notification was posted on the homepage of NCC (http://www.ncc.go.jp/jp/ncc-cis/pro/index/ic.htm1) by Okamura et al.[7]

However, many physicians do not have a standard strategy for delivering bad news to patients and find it difficult to communicate such news to cancer patients and their relatives. Therefore, CST has been designed to enhance physicians' communication skills when delivering bad news[8,9] and has been shown to improve both the objective performance of physicians and subjective ratings of their own confidence in communicating with patients.[10-12] However, no research has shown that such training for oncologists have a positive effect on patient distress and satisfaction.[13] One possible reason for this has been suggested to be that such training is based only on experts' opinions and does not have a strong theoretical basis.[14] In other words, the approaches taught in such training do not necessarily reflect the preferences of patients,[2] despite patients' preferred communication behavior having been linked to lower psychological distress and higher satisfaction levels.[15] Therefore, interventions that enhance physicians' communication skills and that take into account patients' preferences are needed. Against this background, the aim of this study was to identify the effects of a

CST program for oncologists.

Our previous quantitative and qualitative surveys showed that patient preferences regarding the communication of bad news consist of four factors: setting, considering how to deliver the news, provision of various types of information, and emotional support.

On the basis of such patient preferences, we developed a two-day CST program. This program stresses empathic communication, effective behaviors for oncologists, and their confidence in their own ability to communicate with patients. The content validity of the conceptual model had been confirmed by two psychiatrists, a psychologist, and two oncologists who were attending staff with experience in clinical oncology and with extensive knowledge about preferred communication between patients and oncologists.

This study might be able to show that communication skills that comply with patient preferences can be taught to oncologists and that their utilization decreases patient distress.

PURPOSE

The aim of this study is to identify the effects of a CST program for oncologists, developed based on patient preferences regarding oncologists' communication.

DESIGN: Randomized control trial.

ELIGIBILITY CLITERIA

Inclusion criteria:

Oncologists who are staff at NCC hospitals.

Outpatients who attend follow-up medical appointments with the oncologists who are participants in this study at NCC hospitals, who received a diagnosis of cancer, and who are 20 years old or older.

Exclusion criteria:

Patients who are judged incapable of completing the survey physically and cognitively, or who are incapable of understanding spoken and written Japanese.

INFORMED CONSENT

Candidate oncologists and patients are given information about the purpose and the method of this study, as well as the protection of their human rights and of their privacy, along with an informed consent form. However, the patients are not given information about whether their oncologists have been assigned to the CST group or the WLC group. Agreement to participate in this study is given by signing the consent form.

CLINICAL IMPLICATION

If this study could show that communication skills that comply with patient preferences can be taught to oncologists and that their utilization decreases patient distress, the CST program for oncologists could provide the opportunity for more advanced learning of communication skills and could increase patients' QOL in an oncology setting.

INTERVENTION

The intervention is a CST program for oncologists, developed based on patient preferences regarding how oncologists communicate when breaking bad news. The

workshop involves a two-day participant-centered program and consists of an icebreaking discussion, a one-hour computer-aided didactic lecture with text and a video, eight hours of role-playing with simulated patients, and discussions on this role-playing.

EVALUATION

Main outcome:

Oncologists' objective performance of communication skills: We videotape the oncologists in terms of their performances during simulated consultation at baseline and follow-up. These performances are assessed in random order by two trained, blinded coders independently based on rating manuals, using two assessment tools: the 31 SHARE categories for analyzing the impressions of participants' performances and the 40 RIAS categories for objective analysis of utterances during medical consultation.[18,19]

Secondary outcome:

Oncologists' confidence in communication with patients: Confidence in communication with patients was assessed using two questionnaires consisting of 32 items related to SHARE[18] and 21 items by Baile in the U.S.[8] These questionnaires measure the self-efficacy of communication skills in breaking bad news. All items were rated on a 10-point Likert scale from 1 to 10, ranging from "not at all" to "extremely." Total scores (ranges of 32 to 320 in SHARE and 21 to 210 in the confidence questionnaire) were used to rate oncologists' confidence in communication with patients.

Oncologists' evaluation of the workshop: Nine components of the workshop (lecture on communication skills, giving feedback to others, getting feedback from others, using role-play, facilitators' general approach, facilitators' suggestions, simulated patients, scenarios, and clinical relevance of the workshop to their own clinical practice)

are evaluated. Each item is measured on an 11-point Likert scale from 0 to 10, with higher scores indicating that the participants felt that the workshop is useful.

Oncologists' burnout: The Japanese version of MBI is used to measure the oncologists' occupational distress. The MBI is a well-validated, self-administered, and standardized instrument for evaluating distress. It consists of 22 items grouped into three subscales: depersonalization (five items), personal accomplishment (eight items), and emotional-exhaustion (nine items). Each item is rated on a seven-point (0–6) Likert scale.[21]

Oncologists' general health: The Japanese 12 items version of GHQ was used to measure oncologists' psychological status. The GHQ is a well-validated, self-administered, and standardized instrument for evaluating psychological status.[22]

Oncologists' demographic factors: Data on socio-demographic factors (age, sex, and marital status) and medical experience (specialty, clinical experience, and clinical experience in oncology) are obtained by questionnaire.

Patient satisfaction with the consultation and patient trust in the oncologist: Patient satisfaction with the performance of their oncologist during consultation and patient trust in their oncologist were assessed using an 11-point (0–10) Likert scale.[24]

Patients' distress: The Japanese version of HADS is used to measure patients' distress. The HADS is a well-validated, self-administered, and standardized instrument for evaluating patients' distress. It consists of 14 items grouped into 2 factors: anxiety (7 items) and depression (7 items). Each item is rated on a 4-point (0- 3) Likert scale.[25,26]

Patients' symptoms: The Japanese version of MDASI is used to measure patients' symptoms. The MDASI is a well-validated, self-administered, and standardized instrument for evaluating patients' symptoms. It consists of 19 items. Each item is rated

on a VAS scale (0–10).[27,28]

Patients' demographic factors: Data on the socio-demographic factors (age, sex, household size, education year, marital status, employment status) and medical factors (type of cancer, recurrence or metastasis, current treatment status, subject of consultation) of the patients are obtained by questionnaire and from medical charts.

METHODS

After providing informed consent, the baseline survey required oncologists to undertake a simulated consultation, in which they relay a diagnosis of incurable advanced cancer to an SP, and to fill in a questionnaire requesting information about their demographic characteristics (age, sex, and marital status), medical experience (specialty, clinical experience, and clinical experience in oncology), and perceived confidence in communicating with a patient. On days when a participating oncologist have consultations in the outpatient clinic, all eligible outpatients are invited to participate in the study after their follow-up medical visit. Patients who provide written informed consent are asked to complete and return within a week a series of questionnaires on HADS, their satisfaction with their oncologist's communication during the consultation, their trust in oncologists, MDASI, and their demographic characteristics.

After the baseline survey, the oncologists are randomly assigned to the CST group or the WLC group. Oncologists assigned to the CST group are required to attend the whole of a CST workshop.

After the CST workshop in the CST group or two weeks after baseline in the WLC group, information on the same variables as at baseline is collected as follow-up

data. Three months after the CST workshop, participants underwent a second follow-up survey. After this follow-up survey, the oncologists who have been assigned to the WLC group are allowed to participate in the workshop, if they desired.

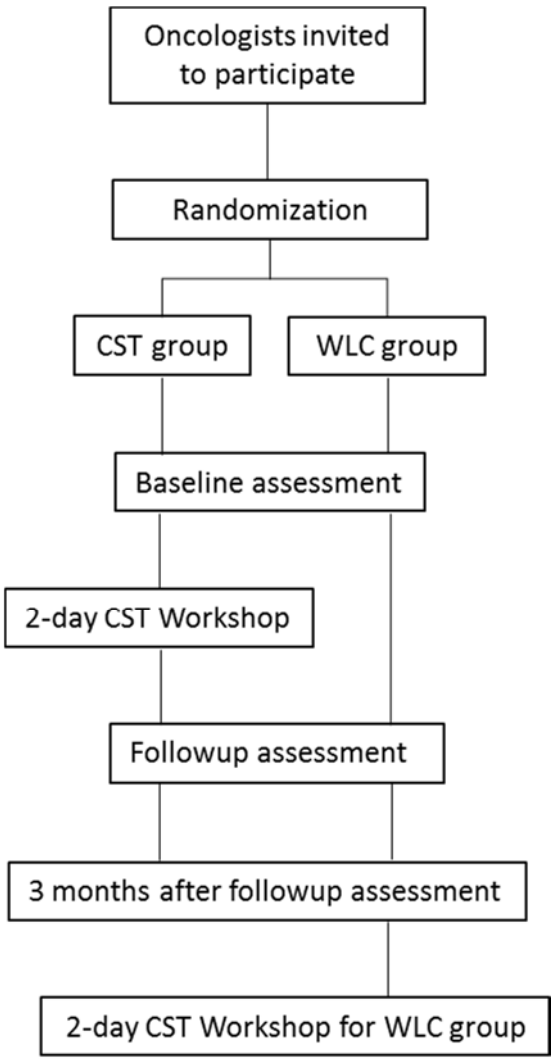

Figure. Study flow diagram

ANALYSIS

Total scores of performance and confidence of the oncologists are analyzed using repeated measures analysis of variance (ANOVA), including the CST and WLC groups as a between-subjects variable. In this study, the primary endpoint is differences between the CST group and the WLC group in terms of the emotional support factor in the SHARE categories. For the CST group, data on the participants' evaluation of the CST workshop component that they attended are shown as the mean scores, standard deviation, and range.

Data on patients' distress are compared between groups using a t-test. Mixed-effects models are employed to investigate factors associated with the post-consultation rating of patients' psychological distress, satisfaction with communication, and trust in communication. Patients' demographic characteristics (age, sex, employment status: employed or not, marital status: married or not, household size, years of education, type of cancer: surgical/medical/diagnosis/radiation oncology, recurrence or metastasis: yes or no, current treatment status: under treatment or not, subject of consultation: good or bad news) are entered in a multivariate model.

Each video is coded in terms of categories of performance in a random order by two blinded coders, who have been trained, independently, on two occasions with a rating manual.

ADVERSE EVENTS ASSOCIATED WITH PARTICIPATION IN THIS STUDY AND RULE ON EARLY CESSATION

There is no risk of adverse events related to participation in this study, apart from it taking some time. Sufficient consideration is given to the possibility that the

subjects might feel uncomfortable participating in this study.

If fewer than 16 oncologists choose to participate, this study will be stopped.

SAMPLE SIZE

We decide that 32 oncologists should be enrolled in this study. We judged that this would be possible because eight doctors can participate in one workshop at a time, and this number would correspond to a rate of participation of approximately 20% among the total of about 190 doctors in NCC hospitals.

We decide that 32 patients would be enrolled in this study (10 per oncologist).

STUDY PERIOD Ten months (June 1st, 2006, to March 31st, 2007)

ETHICAL CONSIDERATION

After the participants have been given a full oral explanation, provided with an information form, and been required to give written informed consent, after which, they could participate in this study. Even after giving consent, they could withdraw from the study at any time.

All of the obtained data are stored in a locked room and are only available to a data input worker and an analyst.

RESEARCH PUBLICATION

It is decided that the results of this study would be presented at a conference and in a scientific journal.

RESEARCH ORGANIZATION

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