

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

<b>TITLE (PROVISIONAL)</b>	An integrated communication support program for oncologists, caregivers, and patients with rapidly progressing advanced cancer to promote patient-centered communication: J-SUPPORT 1904 study protocol for a randomized controlled trial
<b>AUTHORS</b>	Fujimori, Maiko; Sato, Ayako; Jinno, Sayaka; Okusaka, Takuji; Yamaguchi, Takuhiro; Ikeda, Masafumi; Ueno, Makoto; Ozaka, Masato; Takayama, Yukiko; Miyaji, Tempei; Majima, Yoshiyuki; Uchitomi, Yosuke

### VERSION 1 – REVIEW

<b>REVIEWER</b>	Laura Porter Duke University, USA
<b>REVIEW RETURNED</b>	10-Mar-2020

<b>GENERAL COMMENTS</b>	<p>This manuscript describes the protocol for an ongoing RCT testing an integrated communication program for patients with advanced cancer and oncologists. Overall, this is an impressive study that is clearly outlined in the paper. The introduction provides a strong rationale for the importance of patient-provider communication, and the potential value of combining oncologist-focused communication training with patient coaching in the use of question prompt lists. There are a number of areas that would benefit from further clarification:</p> <ol style="list-style-type: none"><li>1. Given that 20 oncologists and 200 patients are currently enrolled in the trial, it would seem appropriate to provide information about enrollment rates (e.g., number of oncologists, patients, and caregivers who were approached, number accepted, reasons for refusal) as well as the characteristics of the enrolled participants.</li><li>2. How does the SHARE-CST intervention compare to other widely used communication interventions such as OncoTalk?</li><li>3. In what population was the previous RCT of the SHARE-CST intervention conducted? Did this trial provide evidence of changes in observed oncologist communication behavior?</li><li>4. In the second paragraph on p. 15, the phrase “after standard chemotherapy during first-line chemotherapy” is unclear. This should be clarified in the eligibility criteria as well. Were patients enrolled after they completed the first line chemotherapy and before they started a second course? What was the rationale for this criteria, and what was the typical time since diagnosis of enrolled patients?</li><li>5. There is a lack of clarity regarding the aims and measures. In the Introduction (p. 15), the authors state that they hypothesize the intervention will increase patients’ question-asking behaviors, however the primary outcome measure appears to assess oncologist communication behaviors only. The authors should be sure to clarify when they are referring to oncologist communication behaviors vs. patient behaviors. For example, “patient-centered</li></ol>
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	<p>communication behaviors” seems to refer to oncologist behaviors but this is not clear.</p> <p>6. “SP” should be spelled out in the text (p. 17)</p> <p>7. Please discuss the potential implications of shortening the SHARE-CST intervention from 2 days to 2.5 hours. What was included in the 2 day training that was not included in the shorter intervention? It seems likely that the reduced dose would impact the expected effect size of the intervention.</p> <p>8. On p. 19 (second paragraph), should “QPS” be “QPL”?</p> <p>9. Please clarify the role of the caregiver in the intervention. Is enrollment of a caregiver a requirement for patient enrollment?</p> <p>10. There is a discrepancy in the statements regarding the number of patients enrolled per oncologist (3-5 in some places, 10 in others).</p> <p>11. What was the rationale for the timing of the long-term follow ups? Given the low one-year survival rate for this population, one would assume attrition would be very high after 6 months.</p> <p>12. The difference between the primary outcome measure and secondary outcome measure is not clear – it appears to be 8 categories of SHARE vs the total score of 27 SHARE categories – but it’s not clear what specifically is captured in the latter that is not in the former.</p> <p>13. The manuscript should be carefully edited for grammar (see e.g., p. 13 first sentence of second paragraph, last sentence of p. 16).</p>
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<b>REVIEWER</b>	Katherine Treiman RTI International U.S.
<b>REVIEW RETURNED</b>	26-Apr-2020

<b>GENERAL COMMENTS</b>	<p>The planned study will address important questions about a multi-component intervention to improve patient-centered communication in the context of advanced cancer. The multi-center study has many strengths. The manuscript presents both the strengths and limitations of the study design in a balanced manner.</p> <p>Clarification questions and comments</p> <p>Introduction:</p> <ul style="list-style-type: none"> <li>• Please discuss cultural expectations and norms related to patient-provider communication. Most of the references are from western countries and raises questions about relevance.</li> <li>• Is SHARE-CST focused on communication in advanced care or more general?</li> <li>• What was the approach for condensing the 2-day workshop into the 2.5 hour short training? Discuss how you determined what elements were most beneficial and impactful?</li> <li>• You state the previous RCT found that QPL did not promote patient question-asking behavior. Did you revise this intervention component based on these findings?</li> <li>• Discuss the role of family members/other caregivers in communication with providers. Does the intervention address communication between caregivers as well?</li> </ul> <p>Methods and Analysis:</p> <ul style="list-style-type: none"> <li>• Clarify whether the previous RCT trial also involved patient with pancreatic cancer or other cancers as well?</li> </ul> <p>Intervention:</p> <ul style="list-style-type: none"> <li>• Clarify whether all of the patients had caregivers involved in the study?</li> <li>• Is the individual training for patients only? Or ever for patients and caregivers together? Or caregivers only?</li> <li>• You state that “all intervention sessions are noted, summarized, and reported to each oncologist before patient’s visits.” Please</li> </ul>
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	<p>clarify exactly what is shared with the oncologist. Is it a summary of the QPL answers. (p. 17)</p> <ul style="list-style-type: none"> <li>• Baseline phase – please clarify how the audio-recording is used. What are patients asked to give feedback about? (p. 19) Is this the same as “evaluation on consultation” in Table 2?</li> <li>• Overall, I found it difficult to connect the measures discussed in the text with Table 2. Please make sure to cross-reference and use consistent terminology.</li> <li>• Table 2: spell out all acronyms in a footnote.</li> </ul>
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## VERSION 1 – AUTHOR RESPONSE

### Reviewer 1

#### Comment #1:

**Given that 20 oncologists and 200 patients are currently enrolled in the trial, it would seem appropriate to provide information about enrollment rates (e.g., number of oncologists, patients, and caregivers who were approached, number accepted, reasons for refusal) as well as the characteristics of the enrolled participants.**

#### Response

We thank the reviewer for this helpful comment. In Figure 1, we added columns for the number of registrations, registration rate, and reasons for refusal for oncologists, patients, and caregivers (Figure 1).

#### Comment #2:

**How does the SHARE-CST intervention compare to other widely used communication interventions such as OncoTalk?**

#### Response

Thank you for this comment. The SHARE-CST intervention consists of a lecture, role-plays and immediate feedback as main components, like OncoTalk (Tang et al., *Psychooncology*, 2014), to learn the conceptual communication skills model—SHARE, based on patients’ preferences as shown in our previous study (Fujimori et al., *Psychooncology*, 2007)—when discussing serious news with cancer patients and caregivers. The SHARE-CST emphasizes that physicians respect the values of each patient and provide reassurance and emotional support in Asian culture (Tang et al., *Psychooncology*, 2014).

We described these points in the introduction section as follows (Page 10, line 17; page 11, line 5):

“Learning tools (e.g., [www.vitaltalk.org](http://www.vitaltalk.org)) are available to medical practitioners to support this learning.”

“The program is a small-group workshop including the above-mentioned modules; it employs role-play with simulated patients and immediate feedback[15] to allow learners to practice discussing serious news with cancer patients and caregivers, such as transition to palliative care when chemotherapy is failing. The program emphasizes that physicians respect the values of each patient and provide reassurance and emotional support in Asian culture.[20]”

### Comment #3:

**In what population was the previous RCT of the SHARE-CST intervention conducted? Did this trial provide evidence of changes in observed oncologist communication behavior?**

#### Response

Thank you for this comment. In our previous RCT study, the SHARE-CST intervention was provided to physicians, including oncologists mainly treating pancreatic cancer, and revealed positive changes in their communication behavior, which was the main outcome in this study. We revised the introduction section of our manuscript to reflect this (Page 11, line 11).

“Our previous randomized controlled trial (RCT) [of physicians, including oncologists treating pancreatic cancer, showed that oncologists who participated in SHARE-CST improved their behavior in terms of patient-preferred communication](#) as well as their self-confidence in communication with patients and that their patients experienced a relatively low level of psychological distress and a high level of trust in the oncologist.[12]”

### Comment #4:

**In the second paragraph on p. 15, the phrase “after standard chemotherapy during first-line chemotherapy” is unclear. This should be clarified in the eligibility criteria as well. Were patients enrolled after they completed the first line chemotherapy and before they started a second course? What was the rationale for this criteria, and what was the typical time since diagnosis of enrolled patients?**

#### Response

We appreciate your important comment. In this study, we recruit patients who have received first-line chemotherapy and are scheduled for a second course—basically, 15–28 days after the start date of first-line chemotherapy, depending on the regimen. Please see patient’s eligibility criteria (3) receive a first-line chemotherapy and be scheduled for a second course (Page 17, line 17). This is done because patients are doing their best to receive treatment during the first course of first-line chemotherapy, and we are concerned that participating in any study would be a physical and mental burden for the patients. However the relevant part was deleted as follows in consideration of Comment #5 (Page 13, line 3). Regarding the timing of each evaluation after registration, the number of days after the start of the first-line chemotherapy is added in Table 2.

“Based on the results of previous trials, [this study aims to evaluate the efficacy of a new, integrated communication support program, consisting of a CST for oncologists and communication coaching with QPL for patients with rapidly progressing advanced cancer and their caregivers, promoting oncologists’ patient-centered communication behaviors.](#)”

### Comment #5:

**There is a lack of clarity regarding the aims and measures. In the Introduction (p. 15), the authors’ state that they hypothesize the intervention will increase patients’ question-asking behaviors, however the primary outcome measure appears to assess oncologist communication behaviors only. The authors should be sure to clarify when they are referring to oncologist communication behaviors vs. patient behaviors. For example, “patient-centered communication behaviors” seems to refer to oncologist behaviors but this is not clear.**

## Response

We appreciate your important comment. Indeed, “patient-centered communication behaviors” meant “oncologist behaviors.” We clarified the aim and measurement sections of the manuscript as follows (Page 13, line 3; page 22, line 9):

“Based on the results of previous trials, [this study aims to evaluate the efficacy of a new, integrated communication support program, consisting of a CST for oncologists and communication coaching with QPL for patients with rapidly progressing advanced cancer and their caregivers, promoting oncologists’ patient-centered communication behaviors.](#)”

[“Oncologist’s patient-centered communication behaviors”](#)

## **Comment #6:**

**“SP” should be spelled out in the text (p. 17)**

## Response

Thank you for your careful review. We spelled “SP” out as “simulated patient (SP),” as follows (Page 16, line 1):

“We modified the original SHARE-CST design,[12] adopting a 2.5-hour individual program with a facilitator and [a simulated patient \(SP\)](#), consisting of lecture with a textbook (30 min) and 2 role-plays with immediate feedback (see Table 1).”

## **Comment #7:**

**Please discuss the potential implications of shortening the SHARE-CST intervention from 2 days to 2.5 hours. What was included in the 2 day training that was not included in the shorter intervention? It seems likely that the reduced dose would impact the expected effect size of the intervention.**

## Response

We appreciate your important comment. SHARE-CST is basically group work by 4 oncologists, 2 facilitators, and 1 or 2 simulated patient(s). The main content of the SHARE-CST program is about 30 minutes of lecture and (2 times per person x 4 people =) 8 role-plays with feedback. In this study, the intervention program for oncologists adopts an individual SHARE-CST program for 2.5 hours, consisting of 30 minutes of lecture and 2 role-plays. Lectures and role-plays given to the individual SHARE-CST will be provided for the same amount of time as the group SHARE-CST; however, their time spent on observational learning about the role-plays of others is reduced, which may in turn reduce their effectiveness. On the other hand, since there is an intervention with QPL for the patient, it may be offset. We described this point in the intervention and the sample size estimation/sections as follows (Page 15, line 1; page 27, line 17):

“We modified the original SHARE-CST design,[12] adopting a 2.5-hour individual program with a facilitator and a simulated patient (SP), [consisting of lecture with a textbook \(30 min\) and 2 role-plays with immediate feedback](#) (see Table 1). [The original SHARE-CST is a small group consisting of 4 oncologists, 2 facilitators and 2 SPs, and included a lecture and 8 role-plays \(twice per oncologist\) with immediate feedback.](#)”

“Although the total time devoted to CST for the oncologists in this study is reduced from the original SHARE-CST program, the role-plays for individual participants are performed the same time, and communication coaching with QPL for the patients is added. Therefore the effect size from the previous study was adopted for sample size calculation, and 20 oncologists, 3 patients per oncologist, a total of 60 patients in the baseline phase, and 10 patients per oncologist, for a total of 200 patients, are enrolled in the follow-up phase (Figure 1).”

**Comment #8:**

**On p. 19 (second paragraph), should “QPS” be “QPL”?**

Response

Thank you for your careful review. This is a typo. We corrected “QPS” to “QPL” (Page 16, line 10).

“Communication coaching for patients was developed to facilitate communication with physicians using a 63-question QPL based on in-depth focus-group interviews with 18 participants (5 pancreatic cancer patients, 3 caregivers patients with pancreatic cancer, 4 bereaved people who had lost a family with pancreatic cancer, and 6 pancreatic oncologists), and previous QPL studies.[23,24,29]”

**Comment #9:**

**Please clarify the role of the caregiver in the intervention. Is enrollment of a caregiver a requirement for patient enrollment?**

Response

Thank you for your comment. If an enrolled patient is accompanied by a caregiver, the caregiver is also approached. We described this point in the participants section as follows (Page 18, line 12);

“If an enrolled patient is accompanied by a caregiver, the caregiver is also approached.”

**Comment #10:**

**There is a discrepancy in the statements regarding the number of patients enrolled per oncologist (3-5 in some places, 10 in others).**

Response

Thank you for your comment. The number of patients enrolled is 3–5 in the baseline phase and 10 in the follow-up phase. We mentioned this point in the sample size estimation section, as follows (Page 28, line 3):

“Therefore the effect size from the previous study was adopted for sample size calculation, and 20 oncologists, 3 patients per oncologist, a total of 60 patients in the baseline phase, and 10 patients per oncologist, for a total of 200 patients, are enrolled in the follow-up phase (Figure 1).”

**Comment #11:**

**What was the rationale for the timing of the long-term follow ups? Given the low one-year survival rate for this population, one would assume attrition would be very high after 6 months.**

Response

We agree with your comment and understand that long-term follow-up is very difficult. In this study, we would like to evaluate how the consideration of treatment and care after standard chemotherapy by and between patients, caregivers, and oncologists earlier affects patients' physical and psychological condition and medical utilization at the end-of-life. We described this point in the long-term follow-up phase section (Page 20, line 11).

“Patients and their caregivers will be encouraged to provide long-term follow-up assessments at 3, 6, 12, 24, and 36 months after the first follow-up assessment to evaluate effects on patient's physical and psychological condition and medical utilization at end of life.”

**Comment #12:**

**The difference between the primary outcome measure and secondary outcome measure is not clear – it appears to be 8 categories of SHARE vs the total score of 27 SHARE categories – but it's not clear what specifically is captured in the latter that is not in the former.**

Response

Thank you for your comment. As the primary outcome measure, the SHARE-RE factor (sum of 8 items) score on SHARE (total of 27 items) is assessed for analysis. We revised the primary outcome measure and secondary outcome measure sections of the manuscript as follows (Page 22, line 17; page 23, line 7):

“Following previous study methods,[19] impressions of conversations from consultations will be assessed using the SHARE-RE factor score, consisting of 8 categories for analysis, in a random order, by two blinded coders who have been trained for 30 hours or more on two occasions with a rating manual.”

“The analysis will include the audio-recorded oncology visits for all participants using the total SHARE score, for all 27 categories.[18,19]”

**Comment #13:**

**The manuscript should be carefully edited for grammar (see e.g., p. 13 first sentence of second paragraph, last sentence of p. 16).**

Response

Thank you for your careful review. We corrected grammatical errors as follows and had a native speaker of English proofread our revised manuscript again (Page 10, line 3; page 14, line 10);

“Hence, oncologists need to provide adequate information regarding cancer treatment decisions for patients and their caregivers approaching the end of life, confirm patients' and

caregivers' understanding, and achieve shared decision making about treatment and care based on patients' personal values, life goals, and treatment preferences.”

“An independent data center provides computer-generated random allocation sequences. The assignment sequence is centrally managed; assignment results are automatically sent to a clinical research coordinator (CRC), electronically. The oncologist participants are randomly assigned to an intervention group (IG) or control group (CG) after the baseline phase; patient/caregiver participants are assigned to the same group as their oncologists. A stratified block-randomization scheme is used to assure balanced assignment by site. Within each site, oncologists are randomly assigned approximately evenly across IG and CG. Participants in IG provide intervention in addition to TAU, and are unblinded.”

## Reviewer 2

### Introduction:

### Comment #1:

**Please discuss cultural expectations and norms related to patient-provider communication. Most of the references are from western countries and raises questions about relevance.**

### Response

We appreciate your valuable comment. We discussed cultural expectations and norms around patient-provider communication in the introduction section, as follows (Page 11, line 8; page 12, line 13):

“The program emphasizes that physicians respect the values of each patient and provide reassurance and emotional support in Asian culture.[20]”

“The number of patients asking their physician questions was median 1, compared to mean/median 8.5 to 14 in studies in Western countries.[22,24] In Japan, it has been reported that cancer patients have preference of not being burden to others and of “omakase” (leaving the decision-making to a medical expert), and it is difficult to elicit the patient's preference.[25] Thus, in Japan, integrated interventions combining CST for oncologists and communication coaching with QPL for patients might increase patient questioning behavior and improve patient-centered communication in consultations.[26,27]”

### Comment #2:

**Is SHARE-CST focused on communication in advanced care or more general?**

### Response



Thank you for your comment. The SHARE-CST adopts scenarios on communication in advanced care and also includes fundamental communication skills in the conceptual communication skills model: SHARE. We added this point in Table 1, line 4 and line 11.

“Setting up supportive environment for interview, [including fundamental communication skills](#) (eg, greeting patient cordially, looking at patient’s eyes and face)”

“Scenarios [on communication in advanced care](#)”

### Comment #3:

**What was the approach for condensing the 2-day workshop into the 2.5 hour short training? Discuss how you determined what elements were most beneficial and impactful?**

#### Response

We appreciate for your important comment. As we responded in Comment #7 of Reviewer 1, SHARE-CST is basically a group work of 4 oncologists, 2 facilitators and one or 2 simulated patient(s). The main contents of the SHARE-CST program are about 30 minutes of lecture and 2 times per person x 4 people= 8 role plays. In this study, the intervention program for oncologists is adopted an individual SHARE-CST program for 2.5 hours, which is consisted of 30 minutes of lecture and 2 role plays. Lectures and role plays given to the individual SHARE-CST will be provided for the same amount of time as the group SHARE-CST, however the time spent observational learning about the role plays of others is reduced, which may reduce their effectiveness. On the other hand, since there is an intervention with QPL for the patient, it may be offset. We described this point in the intervention section and the sample size estimation section (Page 15, line 1; page 27, line 17).

“We modified the original SHARE-CST design,[12] adopting a 2.5-hour individual program with a facilitator and a simulated patient (SP), [consisting of lecture with a textbook \(30 min\) and 2 role-plays with immediate feedback](#) (see Table 1). [The original SHARE-CST is a small group consisting of 4 oncologists, 2 facilitators and 2 SPs, and included a lecture and 8 role-plays \(twice per oncologist\) with immediate feedback.](#)”

[“Although the total time devoted to CST for the oncologists in this study is reduced from the original SHARE-CST program, the role-plays for individual participants are performed the same time, and communication coaching with QPL for the patients is added.”](#)

### Comment #4:

**You state the previous RCT found that QPL did not promote patient question-asking behavior. Did you revise this intervention component based on these findings?**

#### Response

Thank you for your important comment. In addition to provide a QPL to a patient, we have added components in which a psychologist or a nurse discuss to a patient about the questions he/she want to ask his/her oncologist and how to ask the oncologist using the QPL. We described this point in the introduction section as follows (Page 12, line 9):

“Our previous RCT [of patients with advanced gastric, colorectal, esophageal, and lung cancer](#) showed that QPL was useful in making initial treatment decisions for them but failed to promote patient question-asking behavior,[24] in part because Japanese patients tend to wait for physicians to encourage them to ask questions.[25] [The number of patients asking their physician](#)

questions was median 1, compared to mean/median 8.5 to 14 in studies in Western countries.[23,24] In Japan, it has been reported that cancer patients have preference of not being burden to others and of "omakase" (leaving the decision-making to a medical expert), and it is difficult to elicit the patient's preference.[26] Thus, in Japan, integrated interventions combining CST for oncologists and communication coaching with QPL for patients might increase patient questioning behavior and improve patient-centered communication in consultations.[27,28]

Based on the results of previous trials, this study aims to evaluate the efficacy of a new, integrated communication support program, consisting of a CST for oncologists and communication coaching with QPL for patients with rapidly progressing advanced cancer and their caregivers, promoting oncologists' patient-centered communication behaviors."

#### **Comment #5:**

**Discuss the role of family members/other caregivers in communication with providers. Does the intervention address communication between caregivers as well?**

#### Response

Thank you for the comment. The CST interventions for oncologists deal primarily with communication with patients and also with caregivers. The communication coaching intervention with QPL for patients and caregivers deal with communication with oncologists. The caregivers' communication behaviors will be also analyzed using RIAS. We described this point in the secondary outcome measure section as follows (Page 23, line 12):

"Patient's and caregiver's communication behavior

Following previous study methods,[19] the 40 categories of the Roter Intention Analysis System (RIAS) will also be used in assessing patient's and caregiver's communications behavior, for example question-asking.[30]"

#### **Methods and Analysis:**

#### **Comment #6:**

**Clarify whether the previous RCT trial also involved patient with pancreatic cancer or other cancers as well?**

#### Response

We thank the reviewer for this helpful comment. As you commented, the previous RCT trial involved patients with pancreatic cancer and oncologists who treat pancreatic cancer. We described this point in the introduction section (Page 11, line 11; page 12, lines 9).

"Our previous randomized controlled trial (RCT) of physicians, including oncologists treating pancreatic cancer, showed that oncologists who participated in SHARE-CST improved their behavior in terms of patient-preferred communication as well as their self-confidence in communication with patients and that their patients experienced a relatively low level of psychological distress and a high level of trust in the oncologist.[12]"

"Our previous RCT of patients with advanced gastric, colorectal, esophageal, and lung cancer showed that QPS was useful in making initial treatment decisions for them but failed to

promote patient question-asking behavior,[23] in part because Japanese patients tend to wait for physicians to encourage them to ask questions.[24]”

**Intervention:**

**Comment #7:**

**Clarify whether all of the patients had caregivers involved in the study?**

Response

Thank you for your comment. If the recruited patient agrees to participate in this study, and if there is a caregiver present there and he/she meet criteria, the family will be recruited, as we responded in Comment #9 of Reviewer 1. We described this point in the participants section as follows (Page 18, line 12):

“Caregivers

If an enrolled patient is accompanied by a caregiver, the caregiver is also approached. Enrolled caregivers must (1) be aged 20 years or older; (2) regularly accompany an enrolled patient as primary caregiver; (3) provide written informed consent to trial participation; (4) be able to read, write, understand, and speak Japanese.”

**Comment #8:**

**Is the individual training for patients only? Or ever for patients and caregivers together? Or caregivers only?**

Response

Thank you for careful review. If any caregiver are not present, the patient who participate of this study is provided an intervention individually and if the caregiver who participate of this study are present, the patient is provided an intervention with the caregiver. We described this point in the intervention section (Page 17, line 1):

“The intervention is to be provided to patients individually or with caregivers by clinical psychologists and nurses who have participated in a 10-hour intensive training workshop using an intervention manual.”

**Comment #9:**

**You state that “all intervention sessions are noted, summarized, and reported to each oncologist before patient’s visits.” Please clarify exactly what is shared with the oncologist. Is it a summary of the QPL answers? (p. 17)**

Response

We thank the reviewer for this useful comment. The oncologist will be provided with a summary of the patient's QPL answers and a conversation summary during the patient intervention. We clarified this point in the intervention section (Page 17, line 3):

“All intervention sessions are noted and summarized. Before patients' visits, the oncologist is told which the questions the patient chose to ask from the QPL and the summary of the intervention.”

**Comment #10:**

**Baseline phase – please clarify how the audio-recording is used. What are patients asked to give feedback about? (p. 19) Is this the same as “evaluation on consultation” in Table 2?**

Response

Thank you for your kind comment. The audio-recording is used to evaluate communication behavior by a third person. We revised the sentence in the procedure section as follows to more clearly show this (Page 19, line 11), as well as Table 2:

“Participants will be asked to allow themselves to be audio-recorded at one oncology visit for primary and secondary communication behavior outcomes and to provide some evaluation on consultation as to study measures for potential use as covariates in the RCT analyses (Table 2).”

**Comment #11:**

**Overall, I found it difficult to connect the measures discussed in the text with Table 2. Please make sure to cross-reference and use consistent terminology.**

Response

Thank you for your careful review. We revised terminology in Table 2 to make it consistent with our manuscript.

**Comment #12:**

**Table 2: spell out all acronyms in a footnote.**

Response

Thank you for your kind comment. We spelled out all acronyms in a footnote on Table 2.

**Instructions from the editor**

We greatly appreciate the careful comments from the editor on our manuscript. We have revised our manuscript in accordance with these comments.

<b>REVIEWER</b>	Laura Porter Duke University, USA
<b>REVIEW RETURNED</b>	30-Jun-2020

<b>GENERAL COMMENTS</b>	<p>The authors have responded thoroughly to the reviewers' comments and questions. However, the information presented in Figure 1 seems incomplete. For example, no information is presented about patients who were approached and declined (I assume the participation rate was not 100%). Given that the study is still in progress, it would also be helpful to indicate which study activities are yet to be completed.</p> <p>From my reading of the original version of the manuscript I did not realize that the sample of patients/caregivers differed from the baseline to intervention phase. This raises the question of whether patients who participate in the baseline phase also eligible to participate in the intervention phase?</p>
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<b>REVIEWER</b>	Katherine Treiman RTI International
<b>REVIEW RETURNED</b>	05-Jul-2020

<b>GENERAL COMMENTS</b>	<p>The revised manuscript largely addressed my prior comments. Please see a few additional comments and points for clarification on the attached document – please contact publisher for this file.</p> <p>I recommend editing for English-language clarity.</p>
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## VERSION 2 – AUTHOR RESPONSE

### Reviewer 1

The authors have responded thoroughly to the reviewers' comments and questions. However, the information presented in Figure 1 seems incomplete. For example, no information is presented about patients who were approached and declined (I assume the participation rate was not 100%). Given that the study is still in progress, it would also be helpful to indicate which study activities are yet to be completed.

From my reading of the original version of the manuscript I did not realize that the sample of patients/caregivers differed from the baseline to intervention phase. This raises the question of whether patients who participate in the baseline phase also eligible to participate in the intervention phase?

### Response

We thank the reviewer for this helpful comment. In Figure 1, we have deleted the number 100 from four places. As you pointed out, since research is currently in progress, we cannot enter specific numbers such as the number of participants and participation rate, therefore we left them blank. Patients and caregiver participants use the same inclusion and exclusion criteria. In accordance with your suggestions, the relevant section was modified from "patient" to "patient in baseline phase and intervention, long-term follow-up phase" and "caregiver" to "caregiver in baseline phase and intervention, long-term follow-up phase". (Page 18, line 3 and 14)

### Reviewer 2

The revised manuscript largely addressed my prior comments. Please see a few additional comments and points for clarification on the attached document.

I recommend editing for English-language clarity.

#### Response

We appreciate for valuable comments. In accordance with your recommendation, we revised our manuscript. The responses for each comment are described below.

#### Comment 1:

I don't understand this logic. Pls. explain why the fact that pancreatic cancer is rapidly progressing meant the findings are generalizable?

#### Response

We revised the sentence as follows (Page 8, line 4; page 32, line 13).

#### Before

However, as pancreatic cancer is one of the most rapidly progressing cancers, the intervention may also be effective for patients with other cancers.

#### After

However, as pancreatic cancer is one of the most rapidly progressing cancers, if the intervention is effective for patients with pancreatic cancer who have severe physical and psychological conditions, it may be applied to patients with other cancers as well.

#### Comment 2:

Does this mean show emotional support in a manner that is appropriate for Asian culture?

#### Response

We revised the sentence as follows (Page 11, line 10).

#### Before

The program emphasizes that physicians respect the values of each patient and provide reassurance and emotional support in Asian culture.[20]

#### After

The program emphasizes that physicians respect the values of each patient and provide reassurance and emotional support and has been implemented in several Asian countries.[20]

#### Comment 3:

Did you revise the QPL so that would be more effective in terms of promoting patient question asking?

#### Response

In this study, a communication coaching have been added in addition to provide the QPL as a patient intervention to facilitate patient question asking and a brief communication skills training have been provided to oncologists in this study. This is described a few lines down as follows (Page 12, line 18). "Thus, in Japan, integrated interventions combining CST for oncologists and communication coaching with QPL for patients might increase patient questioning behavior and improve patient-centered communication in consultations.[27,28]."

#### Comment 4:

Please clarify what "noted and summarized" means.

#### Response

We added the description to the sentence as follows (Page 17, line 4).

#### Before

All intervention sessions are noted and summarized.

#### After

The intervention providers note and summarize the content of all intervention sessions, that is, the information that the patient want to know and their preferences of treatment and care.

#### Comment 5:

If oncologist knows what question the patient wants to ask, the oncologist may provide the information without the patient having to ask the question.

Couldn't this skew your results?

Response

Communication outcomes are assessed by both the oncologist and the patient conversation. Therefore even if the oncologist provides the information the patient wants to know before asking the question, we believe they could facilitate to communicate with each other and the evaluation of communication outcomes by a third person will be high. We revised the sentence related communication outcomes in the assessment measures section as follows (Page 23, line 1).

Before

Following previous study methods,[19] impressions of conversations from consultations will be assessed using the SHARE-RE factor score, consisting of 8 categories for analysis ...

After

Following previous study methods,[19] impressions of conversations between patient/caregiver and oncologist from consultations will be assessed using the SHARE-RE factor score, consisting of 8 categories for analysis ...

Comment 6:

I'm not clear what this means?

Response

We revised the sentence in the introduction section as follows (Page 19, line 15).

Before

Participants will be asked to allow themselves to be audio-recorded at one oncology visit for primary and secondary communication behavior outcomes and to provide some evaluation on consultation as to study measures for potential use as covariates in the RCT analyses (Table 2).

After

Participants will be asked to allow themselves to be audio-recorded at one oncology visit and to provide the evaluation of consultation for primary and secondary outcomes as covariates in the analyses (Table 2).

Comment 7:

Is end of life expected for all study participants during the study period?

Response

Based on the 2013 National Cancer Registry data, the National Cancer Center in Japan reported the 3-year survival rate for stage III and IV of pancreatic cancer is 11.9% and 2.5%, respectively. We think that most participants are likely to reach the end of life during the study period. We added the sentence in the introduction section as follows (Page 9, line 5).

Before

Over 40% of patients with pancreatic cancer are stage IV at diagnosis, and the 5-year survival rate is 7%.[2]

After

Over 40% of patients with pancreatic cancer are stage IV at diagnosis, and the 3-year survival rate for stage III and IV is 11.9% and 2.5%, respectively.[2]

Comment 8:

During the visit (vs. after)?

Response

We modified the word, "visit" to "consultaion" as follows (Page 20, line 8; 25, line 7).

Before

After the visit

After

After the consultation

Comment 9:

This in itself isn't a limitation. I think your point is that the intervention is complex because involves both groups. Pls clarify

Response

We revised the sentences as follows (Page 32, line 8).

Before

First, we involve both oncologists and patients/caregivers. The intervention program for both is complex, consisting of multiple factorial components.

After

First, the intervention program for both oncologists and patients/caregivers is complex, consisting of multiple factorial components.

Comment 10:

Table is poorly formatted and difficult to review

Response

We reformatted the table 2 in the text (Page 47).