

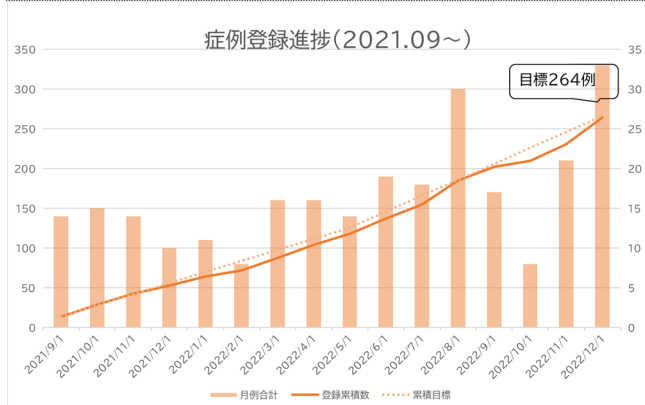
## J-SUPPORT - Japan Supportive, Palliative and Psychosocial Oncology Group

### 研究進捗報告書 (IRB/CRB 承認後)

下記のとおり、2023年1月J-SUPPORT執行委員会に報告します。

研究者名：藤森麻衣子、PI 内富庸介、研究事務局 小濱京子・岡村優子

所属：国立がん研究センターがん対策研究所

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**J-SUPPORT - Japan Supportive, Palliative and Psychosocial Oncology Group**

**研究進捗報告書 （IRB/CRB 承認後）**

これまでと今後のスケジュールについて記載して下さい。例：IRB 審査、WG 会議、症例登録開始など			
IRB/CRB 審査会	2021/4/15	次回 WG 会議	2023/1/31 (R4 年度第 4 回班会議)
各施設キックオフ MTG	2021/7/1 (腫瘍内科) 2021/7/30 (肝胆膵内科)	症例登録開始日	2021/9/6

\*本報告書を修正して 1 月 4 日(水)正午 12 時まで J-SUPPORT 運営事務局 (j-supportcore@ml.res.ncc.go.jp)までご提出ください。



— Advance Care Planningの社会実装に関する討議資料

- ACPについての患者さんへの説明や話し合いの実施に関する、医療現場での実態
  - 院内における、進行がん患者さんとの終末期の意思決定についての話し合いはどの様に行われているでしょうか
    - 実施者
      - ・ 主治医、看護師、その他
    - 実施内容
      - ・ 説明内容
      - ・ 資料、パンフレットの利用
      - ・ 事前面談・電話面談の実施
    - 頻度、タイミング
  - 話し合いが十分に出来ないこともあると考えられますが、こういった要因がありますでしょうか
    - 患者さんのご事情・希望
    - 標準的な実施方法の確立
    - 医療従事者の人的資源・時間
    - 診療報酬等の財務面の制限
    - 医療機関における設備・環境

- 前頁に記載の内容について、ICT(アプリやWeb)を活用した解決の可能性
  - ICTで解決したい、解決を期待出来ることはどのような課題でしょうか
    - 対面で聞くことが難しいことが、アプリ等であれば患者さんから聴取できる
    - 標準的な実施方法が広く提供できる
      - ・・ ACPに積極的な医療機関で更に取り組みを増やす
      - ・・ 人的リソース・専門知識との関係でACPへの対応が困難な医療機関でも実施できる
    - 医療従事者の人的資源・時間の不足を補える
      - ・・ 患者さんとの話し合い
      - ・・ 患者さんからの情報の聴取
      - ・・ 診察する医師への情報共有
  
- 患者さんにとってのICT化の意義と負担について
  - 患者さんにとって、スマートフォン等の機器を通じて考えを入力したり、整理したりすることについての意味合い
  - 身体的・それ以外でのご負担への留意点について

# 教科書的な意思決定に関する業務の流れ(外来治療)

前回受診時まで

外来受診前

診察時

外来受診後

次回受診時

患者

きっかけとなるような  
イベント  
(症状、検査結果)

主治医

話し合いの準備  
・治療方針  
・説明内容、資料  
・日時

看護師

患者様の情報整理  
・背景情報  
・大事なこと  
・望む医療  
・聞きたいこと

MSW

当日の打ち合わせ  
・説明内容、分担  
・資料  
・面談のゴール

面談  
・場所、時間  
・同席者、分担  
・面談内容

検討、相談

面談の記録  
・カルテ記載

意思決定、共有

# — これまでのヒアリングのまとめ

## リソース不足

通常診療では、 <u>Drが一人ひとり患者から詳細に話を聞く時間がない</u>	患者の希望聴取については <u>MSWに丸投げ</u> になってしまっている	<u>経口薬主体の外</u> 来では、Nsが個々の患者について詳細かつ継続的に情報を取得するリソースはない
<u>個々の患者のことを誰が一番よく知っているのか把握できない</u>	相談に来た患者の <u>背景、治療の段階、説明の状況がわからない</u>	
<u>カルテに患者の希望など治療内容以外のところまで書くかは医師次第。</u>	カルテからだけでは患者がどのような希望を持っているか <u>読み取れとれない</u>	カルテの情報の中には、 <u>患者に伝えられていない情報もある</u>

情報が集約されない

医師

看護師

MSW

患者

## 抵抗感

<u>医師からは今後の療養のことを患者に言い出せない</u>	病状や今後の療養について、 <u>誰に何を聞いたらいいかかわらない</u>	診察時には医師や看護師に <u>質問しにくい。</u>
療養の話をするきっかけが難しい	<u>いきなり死を意識させるようなことはやめてほしい。</u>	療養の話はMSWからではなく <u>医師から切り出してほしい。</u>
<u>介入する適切なタイミングが難しい、診療科によっても、個々の患者によっても異なる</u>	<u>介入する条件は現状定めておらず、個々のNsの主観に委ねられている状況。</u>	相談に来られない患者がどうしているが <u>カルテから患者をピックアップすることは難しい</u>

介入時期の判断が困難

## — 本日のディスカッションポイント(課題、ニーズの抽出)



■前頁のヒアリングのまとめの内容について、社会実装に向けた課題の観点で、以下について是非お話を伺えればと存じます。

- 貴院でも当てはまる課題
- 貴院では当てはまらない課題、その背景
- その他に、貴院特有の課題や取り組み



# BMJ Open Effectiveness of a facilitation programme using a mobile application for initiating advance care planning discussions between patients with advanced cancer and healthcare providers: protocol for a randomised controlled trial (J-SUPPORT 2104)

資料3

Kyoko Obama <sup>1</sup>, Maiko Fujimori <sup>1</sup>, Masako Okamura,<sup>1</sup> Midori Kadowaki,<sup>1</sup> Taro Ueno,<sup>2</sup> Narikazu Boku,<sup>3</sup> Masanori Mori,<sup>4</sup> Tatsuo Akechi,<sup>5</sup> Takuhiro Yamaguchi,<sup>6</sup> Shunsuke Oyamada,<sup>7</sup> Ayumi Okizaki,<sup>1</sup> Tempei Miyaji,<sup>1</sup> Naomi Sakurai,<sup>8</sup> Yosuke Uchitomi<sup>1,9</sup>

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## ABSTRACT

**Introduction** Timely implementation of the discussion process of advance care planning (ACP) is recommended. The communication attitude of healthcare providers is critical in ACP facilitation; thus, improving their communication attitudes may reduce patient distress and unnecessary aggressive treatment while enhancing care satisfaction. Digital mobile devices are being developed for behavioural interventions owing to their low space and time restrictions and ease of information sharing. This study aims to evaluate the effectiveness of an intervention programme using an application intended to facilitate patient questioning behaviour on improving communication related to ACP between patients with advanced cancer and healthcare providers.

**Methods and analysis** This study uses a parallel-group, evaluator-blind, randomised controlled trial design. We plan to recruit 264 adult patients with incurable advanced cancer at the National Cancer Centre in Tokyo, Japan. Intervention group participants use a mobile application ACP programme and undergo a 30 min interview with a trained intervention provider for discussions with the oncologist at the next patient visit, while control group participants continue their usual treatment. The primary outcome is the oncologist's communication behaviour score assessed using audiorecordings of the consultation. Secondary outcomes include communication between patients and oncologists and the patients' distress, quality of life, care goals and preferences, and medical care utilisation. We will use a full analysis set including the registered participant population who receive at least a part of the intervention.

**Ethics and dissemination** The study protocol was reviewed and approved by the Scientific Advisory Board of the Japan Supportive, Palliative and Psychosocial Oncology Group (Registration No. 2104) and the Institutional Review

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study employs a randomised controlled trial design, patients with diverse cancer types and oncologists in a real-world setting where the intervention will be tested.
- ⇒ The intervention programme includes a mobile application (app), which can be used in environments that participants find relaxing and engaging, regardless of location or time.
- ⇒ There is currently no gold standard for evaluating advance care planning (ACP) discussions between patients and healthcare providers.
- ⇒ In real-world practice, the appropriate time to initiate ACP discussions should be carefully evaluated based on the patient's condition and psychological status, which may not be optimal in a controlled research setting that enrolls patients in the order of their referral.
- ⇒ Multiple intervention components make it difficult to determine how much each component contributes to the outcome.

Board of the National Cancer Centre Hospital (registration No. 2020-500). Written informed consent is obtained from the patients. The results of the trial will be published in peer-reviewed scientific journals and presented at scientific meetings.

**Trial registration numbers** UMIN000045305, NCT05045040.

## INTRODUCTION

Cancer is a leading cause of death in developed countries, with an estimated 10 million deaths worldwide in 2020,<sup>1</sup> accounting for a

one-in-six risk of dying from cancer. Although discussions help patients and their families prepare for the end of life, healthcare providers do not adequately discuss treatment preferences or how families may spend their final days with patients with incurable advanced cancer.<sup>2</sup> Delayed discussions, that is, after the patient's condition deteriorates, are associated with unprofitable treatment and delayed coordination with community health services.<sup>3</sup> Communicating with patients with incurable advanced cancer is challenging, especially regarding preferred end-of-life care appropriate to their condition.

This discussion, called advance care planning (ACP), is practised based on clinical guidelines worldwide.<sup>4 5</sup> In this study, we refer to the following definition of ACP reported by Sudore *et al*:<sup>6</sup> 'ACP is a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals and preferences regarding future medical care. The goal of ACP is to help ensure that people receive medical care that is consistent with their values, goals and preferences during serious and chronic illness.' The National Comprehensive Cancer Network guidelines recommend beginning the ACP discussion when a patient's estimated prognosis is 1 year or less.<sup>7</sup> ACP improves communication regarding end-of-life care between patients with cancer and healthcare providers<sup>8–11</sup> and increases accessibility to palliative care,<sup>12</sup> thus reducing patients' anxiety and depression and unnecessary aggressive treatment<sup>13 14</sup> while increasing satisfaction with care.<sup>13</sup> Moreover, patients receiving communication intervention tend to share their end-of-life care preferences with healthcare providers.<sup>15</sup>

Since barriers to ACP include a lack of supportive and empathetic attitudes and inadequate information delivery by healthcare providers,<sup>16</sup> healthcare providers' communication attitudes towards patients is an essential element of ACP evaluation. Additionally, patients in Asian countries, including Japan, are less likely to communicate their values and preferences to healthcare providers<sup>17–19</sup> because they tend to leave treatment decisions to their oncologists, which applies even to end-of-life care.<sup>20 21</sup> Therefore, healthcare providers are expected to help patients to share their values and preferences, and provide care in line with their needs. The ACP intervention components include communication support using question prompt lists (QPL) for patients,<sup>8 10 22</sup> communication skill training (CST) for healthcare providers,<sup>13 23</sup> a combination of CST for healthcare providers and patients,<sup>24</sup> and step-by-step in-depth counselling for patients by trained facilitators.<sup>12 25</sup> We previously developed a face-to-face behavioural intervention programme using QPL and CST to facilitate patient questioning behaviour to improve the introduction of ACP discussion between healthcare providers who deliver bad news and their patients with cancer.<sup>26</sup> A combined 2.5-hour individualised CST for healthcare providers with a 30 min coaching intervention for patients showed statistically significant improvements in empathetic communication and information sharing. Additionally, patients in the intervention group

were more satisfied with the consultation than those in the control group.<sup>26 27</sup> However, face-to-face programmes held in hospitals can create a significant time and space burden for patients and healthcare providers.

To overcome these problems, we developed an ACP programme mobile application (hereinafter, referred to as 'app'). We revised the intervention programme<sup>26</sup> to include an app with reference to previous QPL studies,<sup>28–30</sup> the goal concordant care framework,<sup>31</sup> the good death<sup>32 33</sup> and digital health-based intervention.<sup>34</sup> Owing to the advantages of digital health-based interventions, such as fewer space and time constraints and easier real-time information sharing compared with face-to-face interventions, several medical apps are being developed for behavioural interventions (eg, for physical activity<sup>32 33</sup> and psychoeducation<sup>35</sup>) among patients with cancer. Intervention via apps can reduce the chance of patient contact, which is useful during the COVID-19 pandemic. In light of this, the present study aims to evaluate the effectiveness of an app-based intervention programme intended to facilitate patient questioning behaviour on improving communication related to ACP between patients with advanced cancer and healthcare providers.

## METHODS AND ANALYSIS

### Study design

This study is a parallel-group, evaluator-blind, randomised controlled trial.

### Patient and public involvement

A cancer survivor from a patient advocacy group contributed to the study design and materials via a series of reviews. The study protocol was reviewed by researchers, healthcare providers, patients and the public through the Scientific Advisory Committee of the Japan Supportive, Palliative and Psychosocial Oncology Group (J-SUPPORT, the study ID: 2104). Five patients with cancer attending a study field hospital volunteered to participate in the pretest; their comments were used to refine the study procedures.

### Study population

Participants are recruited from the Departments of Oncology, Hepatobiliary Medicine, Respiratory Medicine and Gastroenterology at the National Cancer Centre Hospital (Tokyo), Japan. The inclusion criteria are as follows: patients 20 years or older with incurable advanced cancer, whose attending oncologist indicates that they meet the Surprise Question<sup>13 36</sup> (answering 'no' to the question 'Would you be surprised if this patient dies within a year?'); patients are required have an Eastern Cooperative Oncology Group performance status score of 0–2; provision of written consent prior to participation, and ability to read, write and understand Japanese. Exclusion criteria are patients who the attending oncologist judges to have serious cognitive decline, such as delirium

or dementia; an estimated prognosis of fewer than 3 months; who are judged by an attending oncologist to be unsuitable for this study; or those participating in other psychological or communication support interventions at the time of enrolment.

### Enrolment and randomisation

Participant management, including enrolment, randomisation and data collection via electronic patient-reported outcome (ePRO) and PRO, is conducted online using the central registration system; this system is linked to the app developed in collaboration with SUSMED (Tokyo, Japan), a medical app developer. Research assistants explain the research purpose and procedures to the candidates and obtain written consent (see online supplemental file). After obtaining baseline data, participants are randomly assigned using a minimising method to either the intervention or the control group, in a 1:1 ratio, with stratification factors of the clinical department (respiratory medicine, gastroenterology, hepatobiliary medicine and oncology), sex (male and female) and age (64 years or younger and 65 years or older). Allocation results are blinded to the primary outcome evaluators.

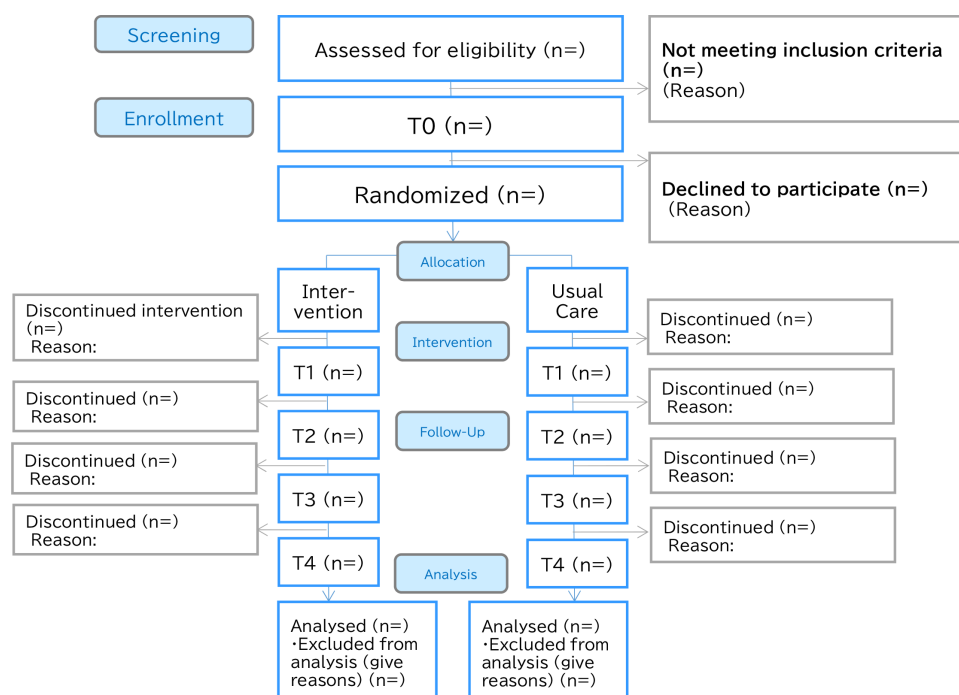
Detailed allocation procedures are not shared with researchers at participating sites, data centres or statistical analysts. Furthermore, they are defined in an internal document at the site of the person responsible for allocation. Participants instal the app on their mobile devices on enrolment. Participants allocated to the control group use an app that contains only ePRO, whereas those allocated to the intervention group use an app containing the intervention programme, in addition to ePRO. If the app cannot be installed on the participant's mobile device, an iPad with the app installed is available for loan.

### Procedures

Five visits are planned: baseline evaluation (T0), an outpatient visit at least 1 week later (T1) and follow-up surveys at 1 week (T2), 12 weeks (T3) and 24 weeks (T4) after the T1 visit, as shown in figure 1. Each visit mainly evaluates how the intervention programme impacts communication between participants and their oncologists during the consultation at T1, the psychological burden of the participants around 2 weeks after the consultation at T2, and the patients' preferred end-of-life care settings and care preferences and their actual healthcare utilisation at T3 and T4. Intervention group participants receive interventions before T1. Control group participants receive care as usual. The schedule for outcome measurement is shown in table 1. At the T1 visit, the consultation is audio-recorded. The research assistant reminds and asks participants to respond to ePRO according to the response schedule.

### Intervention programme

The intervention programme, completed between T0 and T1, includes two parts: QPL and identifying participants' values (table 2). Participants receive a brief explanation of the intervention programme and how to use the app from an intervention provider. Intervention providers are clinical psychologists, nurses or psychiatrists who have participated in intensive training using the intervention manual and have at least 2 years of clinical experience. Participants can review the intervention programme anywhere they like, including the comfort of their own homes, and are encouraged to complete all content on the app before an interview with an intervention provider. A sample of the app screen for the intervention



**Figure 1** CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

**Table 1** Schedule for outcome measurement

	T0	T1	T2	T3	T4
Outcomes	Baseline	Next oncologist visit scheduled after 1 week	Follow-up at 1 week	Follow-up at 12 weeks	Follow-up at 24 weeks
Primary outcome measure					
Oncologist's communication behaviours					
SHARE score (RE subscale)		○			
Secondary outcome measures					
Oncologist's communication behaviours					
SHARE score (S, H and A subscales)		○			
Communication behaviour between participant and oncologist					
No of communication behaviours evaluated by RIAS		○			
No of conversations about ACP		○			
Psychological distress					
HADS	○	○	○	○	○
Quality of life					
EORTC-QLQ-C30	○		○	○	○
Participant care goals and preferred place for spending their final days					
Care Goals and Preferred Place for Spending Their Final Days	○			○	○
Participant satisfaction with their oncologists' consultation					
PSQ		○			
Feasibility of the intervention					
Usefulness, helpfulness and comfort level of the intervention programme		⊙			
Application log records					⊙
Demographics and clinical characteristics					
Medical care utilisation					○
Medical and social background	○				

⊙Evaluated only in patients in the intervention group.  
A, additional information; ACP, advance care planning; EORTC-QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30; H, how to deliver bad news; HADS, Hospital Anxiety and Depression Scale; PSQ, Patient Satisfaction Questionnaire; RE, Reassurance and Emotional support; RIAS, roter interaction analysis system; S, supportive environment.

programme is available in the Appendix (see online supplemental figure A1). In the interview, an intervention provider reviews the items selected by a participant and assists them in considering priorities and verbalising crucial topics to discuss with the oncologist. The interview is individually provided once on the phone or face to face at the hospital and is designed to take 30–60 min. Before the outpatient visit following the interview, the intervention provider informs the oncologist what the participant would like to discuss. The intervention providers record and summarise the intervention interviews, review them at weekly conferences and ensure intervention fidelity by the intervention supervisor.

### Assessment measures

Table 1 shows the schedule for outcome measurement.

#### Primary outcome measure:

Score of oncologists' communication behaviours—RE subscale (reassurance and emotional support) from the SHARE scoring manual.

The conversation between the participants and oncologists at visit T1 is audiorecorded, and the oncologist's communication behaviour is scored using the SHARE scoring manual (table 3). SHARE is a conceptual communication skills model comprising 26 items and four subscales: S (supportive environment; 2 items), H (how to deliver bad news; 7 items), A (additional information; 8 items), and RE (reassurance and emotional support; 9 items). We focus on RE, which assesses oncologists' behaviour in providing reassurance and their empathetic responses to participants' emotions.<sup>37</sup> Scores range from 0 (not applicable at all) to 4 (strongly applicable). Scoring

**Table 2** Intervention programme (question prompt list and identifying participants' values)

Contents	Component descriptions
Question prompt list with 45 questions categorised into eight topics	Eight topics (no of items for each topic): <ol style="list-style-type: none"> <li>1. Diagnosis and stage of disease (4)</li> <li>2. Current treatment (7)</li> <li>3. Symptom management and palliative care (4)</li> <li>4. Future treatment (6)</li> <li>5. Future living arrangements (9)</li> <li>6. When standard treatment is no longer available (7)</li> <li>7. Prognosis for the future (5)</li> <li>8. Family support (3).</li> </ol>
Identifying participants' values	Three questions: <ol style="list-style-type: none"> <li>1. Things you value in terms of treatment and spending your days.                Question-1: This is a list of common examples of things people value in terms of treatment and spending the last days. Please select the one (or more) that you feel you would value.                Options: 18 domains of the Good Death Inventory (eg, 'physical and psychological comfort', 'not being a burden to others', 'good relationship with family')</li> <li>2. Goals in terms of treatment and spending the last days developed based on the Goal Concordant Care framework.                Question-2: Please think about if you were to become ill or have difficulty continuing anticancer treatment as recommended by your doctor, then think about your further treatment goals and how you would like to spend your days. The following are some general examples of treatment goals and spending time. Please choose one that most closely matches your idea.                Options: (1) I would like to receive treatment to relieve symptoms so that I can live a peaceful life, but I do not want to receive any cancer treatment that has side effects or burden, (2) I would like to receive cancer treatment that has few side effects and low burden so that I can continue my life as prior to the cancer diagnosis, (3) I have important things I need to do, so I would like to receive cancer treatment even if there are side effects or burden, so that I can accomplish them and (4) I would like to receive all cancer treatments, regardless of their side effects or burden, so that I can live as long as possible.</li> <li>3. Places to spend the last days:                Question-3: choose where they would like to spend their days                Options: home, hospital near their home, palliative care unit/hospice, hospital they are visiting or other.</li> </ol>

is conducted by multiple evaluators blinded to the assignment. Evaluators are trained in conversation analysis with a manual, and interevaluator and intraevaluator agreements are checked in advance. To achieve a coding agreement rate of 80%, a series of discussions among raters is conducted before the evaluation. An agreement rate of 80% or higher ensures that the reliability of coding is maintained through discussions with a third party, especially for items with few codings, because the possibility that the agreement rate will not reach 80% increases.

### Secondary outcome measures

Score of oncologists' communication behaviours—S, H and A subscales from the SHARE scoring manual.

Oncologists' communication behaviours at visit T1 are evaluated using the S, H and A subscales of the SHARE manual. The scoring method is the same as for the RE subscale used in the primary outcome.

### Communication behaviours between participants and oncologists

The audiorecorded conversations between the participant and oncologists are coded, and the communication behaviours are counted using a computer version of the RIAS (the Roter interaction process analysis system).<sup>38</sup> The system is widely used in the USA, the UK and

Japan.<sup>39 40</sup> Manuals have been translated into Japanese and validated for examining patients with cancer.<sup>41</sup>

RIAS has 42 categories for coding in-consultation communication behaviours. Two blinded, trained coders assign one of the 42 codes to each utterance of the participants and oncologists. To facilitate data interpretation, 21 categories related to the communication behaviours of interest in this study are grouped into 4 clusters based on the conceptual communication skills model used in previous studies.<sup>37 42</sup> Table 4 shows the categories constituting each cluster, and all RIAS categories are demonstrated in online supplemental table A1. The number of utterances in each cluster is also evaluated. Coders are trained and certified at the official training site, the RIAS Study Group Japan Chapter. Ten per cent of the total consultations (25 consultations) are double-coded, and intercoder reliability is examined regarding the degree of agreement for the identification of utterances and coding of each utterance. The reliability is high (0.7–0.8) in previous studies.<sup>39 43</sup> During the training period, it should be verified that the correlation coefficient meets 0.8.

**Table 3** Oncologists' communication behaviours: the SHARE coding manual

Categories	Definitions	Subscores (range: 0–4 for each item)
S: Supportive environment	Setting up the supporting environment of the consultation	<ol style="list-style-type: none"> <li>1. Greeting a patient cordially</li> <li>2. Taking sufficient time</li> </ol>
H: How to deliver bad news	Make consideration for how to deliver the bad news	<ol style="list-style-type: none"> <li>1. Encouraging patients to ask questions</li> <li>2. Not beginning bad news without preamble</li> <li>3. Asking how much the patients know about their illness before breaking bad news</li> <li>4. Not using technical words (using actual images and test data, writing on a paper to explain)</li> <li>5. Checking patients' comprehension</li> <li>6. Checking to see whether talk is fast-paced</li> <li>7. Clearly communicating the main points of bad news</li> </ol>
A: Additional information	Discuss about additional information	<ol style="list-style-type: none"> <li>1. Answering patients' questions completely</li> <li>2. Explaining patients' illness status</li> <li>3. Explaining the prospects of cancer cure</li> <li>4. Providing information on support services</li> <li>5. Discussing patients' daily activities and future work</li> <li>6. Explaining the need for a second opinion</li> <li>7. Asking if the patients have any questions</li> <li>8. Discussing patients' future treatment and care</li> </ol>
RE: Reassurance and Emotional support	Provision reassurance and addressing the patient's emotions with empathetic responses	<ol style="list-style-type: none"> <li>1. Asking about patients' worries and concerns</li> <li>2. Saying words to prepare patients mentally</li> <li>3. Remaining silent for concern for patients' feelings</li> <li>4. Accepting patients' expressing emotions</li> <li>5. Saying words to soothe patients' feelings</li> <li>6. Explaining with hope</li> <li>7. Telling what patients can hope for</li> <li>8. Assuming responsibility for patients' care until the end</li> <li>9. Discussing patients' values</li> </ol>

#### *Number of ACP-related topics in the consultation*

Conversations between patients and oncologists are coded and counted based on a conversation analysis manual.<sup>24</sup> The coders, blinded to assignment, extract the patients' questions and the cues that the patient is trying to initiate or control the conversation. Next, the coders identify and categorise the patients' questions and cues into ACP topics along with the QPL questions. The patients' questions are listed on the intervention feedback sheet given to the oncologist before the visit; therefore, the oncologist may begin to discuss the patients' questions. The following ACP-related topics are included in the QPL (table 2): future treatment, future living arrangements, when standard treatment is no longer available, prognosis for the future and family support.

#### *Psychological distress*

This is obtained at all five scheduled visits. The Hospital Anxiety and Depression Scale (HADS) is a 14-item self-report questionnaire developed for patients with medical illnesses.<sup>44</sup> It comprises anxiety and depression subscales (0–21 points each) with a 4-point scale, with higher scores indicating greater anxiety and depression. The Japanese version of the HADS has been validated in a cancer patient population.<sup>45</sup>

#### *Quality of life*

Quality of life is obtained at T0, T2, T3 and T4. The European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 is a 4-domain, 30-item questionnaire comprising functional scales, global health and quality of life scales, symptom scales/items and financial impact.<sup>46</sup> Scores for all scales range from 0 to 100. A high score on the functional scales indicates high functioning, and on the global health and quality of life scales, it indicates high health status; a high score on the symptom scales and financial impact indicates severe symptoms or problems. The reliability and validity of the Japanese version have been confirmed.<sup>47</sup>

#### *Participants' care goals and preferred places for spending their final days*

Participants are questioned about their goals and the places where they would prefer to spend their final days at T0, T3 and T4. We develop two original scales based on the conceptual diagram of care consistent with incurable cancer patients' goals presented by Halpern<sup>31</sup> to assess (1) participants' preferred treatment options after the completion of standard care (care goal) and (2) participants' preferred place where they would spend their final days. The treatment options are as follows: (1) I would like to receive treatment to relieve symptoms so that I can

**Table 4** Communication behaviours of both participants and oncologists: the Roter interaction process analysis system

RIAS clusters (N of categories)	Definitions	Categories
Setting up the interview (1)	Social behaviour	Personal remarks and social conversation
Reassurance and empathetic response (9)	Emotional responses,	Empathy Legitimising Asks for reassurance Showing partnership Agreement Encourages or shows optimism Concern and worry Approval Asks psychosocial feelings
Medical and other information giving (4)	Providing information related to medical care	Information giving: ▶ Medical condition ▶ Therapeutic regimen ▶ Psychosocial feelings Counselling (oncologist only): ▶ Medical condition/therapeutic regimen
How to deliver the bad news (7)	Attitudes when communicating bad news	Question asking (open-ended): ▶ Medical condition ▶ Lifestyle information Orientations and instruction Asks for opinion Asks for permission Asks for understanding Paraphrasing or checking

RIAS, Roter interaction analysis system.

live a peaceful life, but I do not want to receive any cancer treatment that has side effects or burden, (2) I would like to receive cancer treatment that has few side effects and low burden so that I can continue my life as prior to the cancer diagnosis, (3) I have important things I need to do, so I would like to receive cancer treatment even if there are side effects or burden, so that I can accomplish them, and (4) I would like to receive all cancer treatments, regardless of their side effects or burden, so that I can live as long as possible. The options for participants' preferred place where they would spend their final days are as follows: (1) home, (2) a nearby hospital, (3) a palliative care hospital or ward, (4) the hospital where they are receiving treatment and (5) others. These questions are asked to observe the proportion of patients who choose unnecessarily aggressive treatment goals or unrealistic treatment decisions over time.

#### *Participant satisfaction with their oncologists' consultation*

The Patient Satisfaction Survey<sup>43 48 49</sup> is conducted at T1. The 11-point scale (0, not satisfied at all, to 10, very satisfied) measures five categories of satisfaction with their oncology consultations: (1) needs addressed, (2) active involvement in the interaction, (3) adequacy of information, (4) emotional support received and (5) the overall interaction.

#### *Feasibility of the intervention*

The timing of each data collection is shown in [table 1](#). The intervention's feasibility is evaluated according

to the participants' assessments of the app's usability, the time taken for interventions and app log records. The app's usability is determined by the following five questions: (1) Were the questions you wanted to ask identified during the visit to your oncologist? (2) Did you understand and use the app? (3) Was the app programme helpful? (4) Were you comfortable with the app programme? and (5) Was the telephone or in-person assistance helpful?

Participants rate each item on an 11-point scale (0, not satisfied at all, to 10, very satisfied). The intervention provider records the time taken for the intervention on the intervention report form. App log records, including the time spent browsing and the operation status of the intervention programme, are provided by the app developer.

#### *Demographics and clinical characteristics*

##### *Medical care utilisation*

This is obtained from the electrical medical record of each participant at the 6-month follow-up. If the participant is not alive at 6 months, a medical record survey will be conducted based on information at the time of death. We obtain the presence or absence of anticancer treatment and a reason for treatment termination if it is discontinued or if there are unscheduled outpatient visits, hospitalisation, intensive care unit admission or use of end-of-life care consultations and palliative care services.

### Medical and social background

This information includes cancer type, length of time since diagnosis, age, sex, educational background, employment history, financial status, marital status, household status (lives with others, such as children or those requiring nursing care), methods and times of hospital visits, and whether there is a family member or other person who can accompany them.

### Harms

No particularly serious physical adverse events are anticipated for the participants. However, using the app may cause a psychological burden as participants think about preparing for when they will have difficulty continuing cancer treatments. Hence, newly diagnosed anxiety disorders or depression resulting from a psychological burden caused by the intervention are considered adverse events. If a participant reports that the intervention is causing a psychological burden or requests discontinuation of the intervention, it is stopped and reported promptly to their attending oncologists. Participants in the intervention group are scheduled to see an oncologist within 1 week after the intervention. Researchers regularly check for updates to their medical records, if necessary, and case reports are provided at regular team meetings to ensure that researchers can review the course of psychological distress, discuss changes in participants' conditions caused by the intervention and determine what should be reported to their attending oncologists.

### Compensation

Any unexpected health problems participants may experience from study participation are adequately treated based on standard medical care covered by public health insurance programmes, such as National Health Insurance. Participants receive a gift card worth ¥500 at T1.

### Sample size calculation

In a previous preliminary study, the effect size of the primary endpoint was 3.1.<sup>27</sup> In this study, the principal investigators agree that an effect size of 2.5 would be considered clinically meaningful, given that this is an app-based intervention. Based on a significance level of 5% with a two-tailed test and a power of 80%, 250 participants are required. Previous studies on palliative care had high drop-out rates. This is mainly owing to changes in patients' physical condition over the study period. This study, however, has a short time frame of 1–4 weeks to obtain a primary outcome. In a previous study conducted in the same time frame, the drop-out rate before obtaining the primary outcome was 5%.<sup>50</sup> Additionally, in a study that adopted surprise questions in the eligibility criteria, the drop-out rate was 6%.<sup>24</sup> Therefore, the planned enrolment is 264 patients, assuming a realistic and minimal drop-out rate of 5%.

### Statistical analysis

We estimate the point estimates and 95% CIs of the mean for each group and between-group differences for

the primary endpoint. Two-tailed tests determine significance at 5%. We conduct the analysis using a general linear model with the clinical department, sex and age as adjustment factors for allocation. If the number of cases in each stratum is small, we consider whether to adopt all adjustment factors. We use a full analysis set comprising the registered participant population who received at least part of the protocol treatment; however, participants deemed ineligible for the study after registration are excluded from the analysis set. All statistical procedures, including the secondary endpoint and handling of missing data, are detailed in the statistical analysis plan before data evaluation. The occurrence of discontinued cases after randomisation is assessed in both groups. Owing to the nature of the intervention, the programme may cause psychological burdens for some intervention group patients experiencing deteriorating physical conditions. Thus, patients' reasons for discontinuation must be obtained (to the extent possible) to examine potential bias.

### Data monitoring and management

An independent data monitoring team reports monitoring results semiannually. The PRO data obtained are not reported to individual participants or their oncologists to improve clinical care. Weekly meetings are held between the research office and the monitoring team to discuss case enrolment progress and report on cases. Data monitoring is conducted using the entry data in EDC, Viedoc V.4 (Viedoc Technologies, Sweden) and the central registration system by SUSMED (Tokyo, Japan). All study-related paper data, including research assistant notes, intervention case reports, patient-reported questionnaires and consent forms, are stored securely in a lockable cabinet in the principal investigator's office, as audiorecorded data are stored on an encrypted external hard drive. Only authorised researchers directly involved in the study have data access. All data supporting the study results are stored for at least 5 years and are available on request to the corresponding author. A data monitoring plan is developed and kept by the data management team. No audit is required, and no data monitoring committee is established. No interim analysis is planned.

### ETHICS AND DISSEMINATION

The study protocol was reviewed and approved by the Scientific Advisory Board of J-SUPPORT (registration No. 2104) and by the Institutional Review Board of the National Cancer Centre Hospital (registration No. 2020-500). If significant protocol modifications are necessary, the investigators discuss and report them to the committee for approval. The study is conducted according to the ethical guidelines for clinical studies published by the Japanese Ministry of Education, Science and Technology and the Ministry of Health, Labour and Welfare, the modified Act on the Protection of Personal Information, and the principles of the Declaration of Helsinki. Written



informed consent is obtained from patients. The results of the study will be published in peer-reviewed scientific journals and presented at scientific meetings. After completing this trial, our team will explore possibilities to expand the app's availability.

### Trial status

The study is currently recruiting participants; enrolment is scheduled for March 2023, with a follow-up in September 2023.

## DISCUSSION

We believe that maintaining good communication helps facilitate ACP and ensures that patients with cancer receive care consistent with their values and preferences.<sup>51</sup> Communication attitudes, such as lack of empathy and inadequate information delivery by oncologists, are barriers to ACP.<sup>16</sup> We hypothesise that providing the oncologists with the feedback sheets will encourage them to communicate supportively with patients, promote patient questioning behaviour and continue the discussion process related to ACP.<sup>26 50</sup> Japanese patients with cancer approve of their oncologist's empathetic behaviour in communicating bad news, which indicates better communication.<sup>52</sup>

To evaluate ACP discussions, there is currently no gold standard for assessing the success of discussions between patients and healthcare providers. We agree that goal concordance is a crucial patient-centred outcome that we would like to achieve by implementing ACP. However, we do not adopt it as the primary outcome in this study. One reason is that more directly related factors, such as treatments, physical conditions and social situations, affect the outcome related to the concordance between patient preferences and the medical care they received, making it difficult to assess the effectiveness of intervention. Another reason is that patients' values and preferences might change over time; therefore, it is difficult to show an association between the two at the time of intervention and end of life outcomes. Most previous studies have failed to evaluate the effectiveness of interventions using the outcome.<sup>4</sup> Previous studies have used bereaved family assessments for patient goal concordance after patients' death,<sup>13 25</sup> but it is not a direct patient assessment. Additionally, for this study's eligibility criteria, obtaining enough patients for long-term follow-up survey would be difficult. In this study, we analyse the patients' healthcare utilisation, care goals and preferences after 6 months resulting from discussions with the oncologist, and only as an exploratory evaluation.

Although the eligibility criteria are based on ACP guidelines, depending on the participant's readiness, some participants may feel it is too early to consider future treatment and end-of-life while undergoing cancer treatment. There has been much discussion about the appropriate timing of ACP, which is likely to be triggered by a patient's deteriorating health or reduced treatment options.<sup>53</sup>

However, there is no evidence regarding the appropriate timing for introducing ACP discussions,<sup>53</sup> and it is assumed that some participants may find this intervention burdensome. Moreover, healthcare providers might hesitate to initiate the discussion for fear of causing patient anxiety; thus, more careful ACP referrals and a qualitative exploration of study drop-outs are required.

This study uses the mobile app to improve communication between patients and healthcare providers regarding ACP. Although the apps for behaviour change and psychological intervention are increasing, this study is unique in its focus on facilitating communication related to ACP. The advantage of the app programme is that participants can find an environment and time where they can relax and actively engage in ACP. This is significant for patients with cancer in the ACP programme who have to consider their future treatment and life and express their values and priorities. The scoping review by McMahan *et al* reported a lack of studies on healthcare systems and policies in the context of ACP.<sup>4</sup> A healthcare system should be constructed to ensure that ACP can reach the overall population in need.<sup>54</sup> The strength of ACP implemented with apps is the ease of adaptation to the healthcare system, which is promising in a world where COVID-19 brings about uncertain situations.

We recognise the importance of exploring the barriers and facilitators of implementation based on the information gained from this study. When implementing this programme in routine care, it is necessary to consider how multidisciplinary professionals, such as oncologists, nurses and psychologists, can play the role that the intervention providers take on in this study or how existing medical systems, such as electronic medical records can be used. In the Japanese healthcare system, public health insurers pay medical fees for medical consultations conducted by doctors and nurses to alleviate patients' psychological burden. In 2022, certified psychologists were added as consultation providers, expanding the possibility of implementing ACP for patients in need. Future work should include cost and quality assessment from this study and discussion with study participants and healthcare providers to explore this programme's feasibility.

The study has several methodological limitations. Although not all eligible patients may own a mobile device compatible with the app, we determined that device access would not limit eligibility. Hence, to allow for a diverse group of participants, iPads able to run the programme app are on loan as alternative means of participation. While patients unfamiliar with the use of the app could participate in this study, patients unable to use the app when adapting to the real world should be considered.

Second, the intervention package comprises multiple components, including the introductory session with the app and patients' choice of questions to ask and share with their oncologists. We cannot indicate which components improve communication most effectively. Individualised

evaluation of app usage, intervention adherence and patient satisfaction should be conducted to understand the challenges ahead for the next step.

Finally, we hypothesise that the intervention programme improves communication between patients and oncologists, leading to ongoing discussions and improving the quality of end-of-life care; however, it is a partial and indirect evaluation of ACP. Although the primary outcome is selected after careful consideration, there is no established method for evaluating ACP, and standardised measurement is still challenging.

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スコアリング 0:まったくあてはまらない-4:とてもよくあてはまる

Setting		チェック項目			採点申合せ・採点例	
item		1	2	3		
1	礼儀正しく患者に接する(あいさつをする、敬語を使う)。 患者の目や顔を見て接する。	Greeting a patient cordially Looking at patient's eyes and face	【始まり方】 こんにちは、よろしくおねがいします、どうぞお入りくださいなどの声掛けから始まっているか	【診察中の敬語】 敬語をどのくらいの頻度で使っているか、失礼な態度をとっていないか	【終わり方】 ありがとうございます、お大事になさってください、失礼しますなどの声掛けで終わっているか	2 ぬるっと始まった感じがあったので
2	十分な時間を確保する。	Taking sufficient time	【時間の長さ】 10分以下 10分以上	【医者がせかすように終わらせていないか】	【患者が診察に満足しているかどうか】	3 患者が満足していたが、時間が短い
How to						
3	患者の質問や相談を聞く。	Lidtening patient's questions and concerns	【質問に対して、傾聴ができていますかどうか】 ※質問に答えることや促すことは別	【相談(不安や心配など)に対して傾聴ができていますかどうか】 ※相談に答えることや促すことは別		4 どちらかが出てこなかったら、減点。
4	大切な話の前に、患者が心の準備を促す。	Not beginning serious talking without preamble	【話の前置きがあるか:ネガティブなことを伝えるとき】 (例)これから話す内容には、良いことと悪いことがあります等の声掛けしてから本題に入る	【話の前置きがあるか:結果を伝える際に、最初におおまかに伝えてから詳細を説明する】 (例)今回の結果はおおむね良好です。～の数値は…		2 この項目は、深刻な話重視なので、前者が出てこなかった場合には減点-2。後者のみ出てこなかった場合は-1。両方できていれば4
5	患者の病気に対する認識を確認する。	Asking how much you know about your illness	【病気:患者の過去・現在・未来の状態について患者の理解を得ながら話をする】 医者が伝えたことに対して、患者が理解をしているか 医者が一方的に話していないか 患者のペースで話しているか	【医者が言ったことについて、患者が理解できているか言葉で確認する】 わかりますか?いいですか?		3
6	専門用語を用いない。 実際の写真や検査データを用いて情報を伝える。紙に書いて説明する。	Not using technical words Using actual images and test data Writing on paper to explain	【患者がわからなさそうな専門用語を使う際にはそれに対する説明をしている】			3 ALPという用語でできたが、おそらく、患者に何かを見せながら話していた。(こなんですけど、と言って)
7	患者の理解度を確認する。	Checking to see that patient's understand	【治療計画や薬のことなど理解を確認しなければならない話】について患者の理解を得ながら話をする】 医者が伝えたことに対して、患者が理解をしているか 医者が一方的に話していないか 患者のペースで話しているか	【医者が言ったこと[治療計画や薬のことなど理解を確認しなければならない話]について、患者が理解できているか言葉で確認する】 (例)わかりますか?いいですか?		3
8	話の進み具合を調整する(医師のペースで一方的に話すのではなく、患者が自由に発言できる)。	Pacing	【患者が自発的に発言をしているか】	【医者が沈黙をつくる】		4
9	話の要点をまとめる。	Communicating clearly the main points of bad news	【話を整理する】 (例)過去～現在に至るまでの経過を説明する、その他	【大事なポイントを強調して伝える、確認しながら話す】		3 6月7月に～して、なので～(整理している)
Additional infomration						
10	患者の質問や相談に十分答える。	Answering patient's questions fully	【質問に対して十分に答える】 ※質問を促すとは別	【相談(不安や心配など)に対して十分にこたえる】 ※質問を促すとは別		4
11	病状(例えば、進行度、症状、症状の原因、転移の場所など)について話し合う。	Explaining the status of patient's illness	【病状(検査結果も含む症状など)について十分に説明している】			2 いずれかについて話し合っていれば4点(程度で減点)。でてこなければ0点。

SHAREチェック項目

スコアリング 0:まったくあてはまらない-4:とてもよくあてはまる

Setting item	チェック項目			採点申告せ・採点例
	1	2	3	
12 がんの治る見込みを話し合う。	Telling the prospects of cancer cure	【余命(生存率)について話す】		0 なければ0
13 利用できるサービスやサポート(医療相談、高額医療負担、訪問看護、ソーシャル・ワーカー、カウンセラー)に関する情報を提供する。	Providing information on services and support	【サポートいずれかについて説明している】 ※ サポート:医療相談、高額医療負担、訪問看護、ソーシャル・ワーカー、カウンセラー		0 なければ0
14 日常生活や仕事についても話し合う。	Discussing patient's everyday life and work	【仕事、日常生活(治療以外のこと)いずれかについての話題がでている】	【仕事、日常生活(治療以外のこと)いずれかについて話し合っている】 ※話し合う:了解するだけでなく、患者も思いや意見を伝える	4
15 患者が他のがん専門医にも相談できること(セカンド・オピニオン)について説明をする。	Explaining a second opinion	左記の質問通り		0
16 患者に質問を促す。	Encouraging a patient to ask questions	【なにか聞きたいことありますか?などの医者からの促し】	【なにか聞きたいことありますか?などの医者からの促しが、複数回であったか】	4
17 患者の今後の治療や療養について話し合う。	Discussing the patient's future treatment and care	【治療や療養いずれかにつて話題にでているか】	【治療や療養いずれかについて話し合っている】	2
<b>Emotional support</b>				
18 患者の心配や懸念について尋ねる。	Asking patient's worry and concern	【心配事や懸念について、なにか聞きたいことありますか?などの医者からの促し】	【心配事や懸念について、なにか聞きたいことありますか?などの医者からの促しが、複数回であったか】	1
19 患者の気持ちを支える言葉をかける。	Saying words to prepare mentally	やわらげるとの違い 支える+ない意味 やわらげる-を0インする	【ポジティブな言葉がけをする(一緒に頑張っていきましょうなど)】	2
20 患者が感情を表出している間は共感的に沈黙する。	Remaining silent for concern for patient feelings	【患者が感情を表出している間に、話を遮らない】	【患者が感情を表出している場面があるかどうか】	0
21 患者の感情を受け止める。	Accepting patient's expressing emotions	【共感的な言葉がけをする】 患者が表出した感情をそのまま受け止める (例)おうむ返しなど	【患者が感情を表出している場面があるかどうか】	0
22 患者の気持ちをやわらげる言葉をかける。	Saying words that soothe patient feelings	【ショックを緩和するような言葉がけをする】 (例)大丈夫ですよ、心配ないですよ	【情緒的に言葉がけをしているか】	0
23 患者が「できないこと」だけでなく「できること」を伝える。	Telling in a way with hope	【食事や旅行など(日常生活)に制限がないことを伝える】	【食事や旅行など(日常生活)の話題があるか】	3
24 患者が希望を持てる情報も伝える。	Telling what patient can hope for	【ポジティブな情報(現在)も伝える】 (例)治療の良い結果などについて話す	【ポジティブな情報(未来)も伝える】 (例)治療の良い結果などについて話す	4
25 最後まで責任を持って診療にあたることを伝える。	Assuming responsibility for patient's care until the end	【医師が患者を援助したり支えたりする言葉があるか】 (例)一緒に頑張りましょう		0
26 患者の価値観や大切にしていることを話し合う。	Discussing patient values	【患者の価値観や大切にしていることが話題に出ているか】	【患者の価値観や大切にしていることについて話し合っているか】	0

スコアリング 0:まったくあてはまらない-4:とてもよくあてはまる基本的な考え方:各チェック項目を考慮して採点。基本的

サスモID	Group Total score Setting	How to	Additional Information	Emotional Support
<b>評定者1</b>				
001-228	7	21	16	0
001-229	6	19	8	0
001-231	6	24	11	8
001-052	8	26	20	28
001-053	8	28	24	20
001-054	8	24	10	14
001-055	8	24	20	26
001-200	8	23	19	25
001-201	7	18	16	6
001-202	8	26	23	29
001-203	3	6	2	0
001-204	7	21	9	6
001-205	8	26	28	25
001-206	6	24	25	18
001-207	4	17	8	4
001-224	7	21	22	18
001-225	7	21	14	4
001-226	6	16	9	3
001-227	5	21	11	10
001-223	7	17	10	4
001-222	5	8	7	3
001-220	7	23	21	14
<b>評定者2</b>				
228	6	24	26	6
229	8	20	8	2
231	6	18	6	2
52	8	28	24	30
53	8	28	26	28
54	6	18	8	4
55	8	24	20	26
200	7	22	20	28
201	8	12	7	1
202	8	24	26	28
203	3	0	0	0
204	8	26	16	16
205	8	24	28	28
206	7	28	26	26
207	4	16	11	0
224	8	28	32	28
225	6	28	16	6
226	6	7	5	2
227	5	10	3	2
223	6	10	8	2
222	4	9	5	0
220	6	24	20	10
<b>Pearson</b>	<b>0.807</b>	<b>0.802</b>	<b>0.878</b>	<b>0.895</b>

szMediaID	nSpeaker 1	Setting up the interview	Reassuara nce and empathic response	Medical and the other giving	How to deliver the bad news
001_216_221118_1054(1).mp3	1+2 KO	6	23	55	16
001-200_221018_1040(1).mp3	1+2 KO	13	27	57	20
001-202_221102_1106(1).mp3	1+2 KO	5	35	48	9
001-203_221101_1137(1).mp3	1+2 KO	4	3	9	3
001-204_221028_1058(1).mp3	1+2 KO	2	15	55	10
001-205_221110_1237(1).mp3	1+2 KO	5	57	103	15
001-206_221024_0959(1).wav	1+2 KO	2	13	29	5
001-207_221115_1103(1).mp3	1+2 KO	6	9	22	1
001-208_221114_1410(1).mp3	1+2 KO	4	26	76	10
001-215_221221_1115(1).mp3	1+2 KO	5	44	41	29
001-218_221115_1201(1).mp3	1+2 KO	5	14	50	5
001-220_221130_1323(1).mp3	1+2 KO	8	5	47	6
001-222_221125_0927(1).mp3	1+2 KO	9	33	62	6
001-223_221125_1621(1).mp3	1+2 KO	4	20	43	5
001-224_221122_1434(1).mp3	1+2 KO	7	42	70	17
001-225_221125_1535(1).mp3	1+2 KO	7	27	55	10
001-226_221128_1034(1).mp3	1+2 KO	5	11	27	8
001-228_221219_1005(1).mp3	1+2 KO	8	18	45	12
001-229_221212_0937(1).mp3	1+2 KO	4	18	58	11
001-231_221228_1446(1).mp3	1+2 KO	6	10	45	6
001-045_211208_0848(1).mp3	1+2 KO	3	25	41	10
001-051_220112_1524(1).mp3	1+2 KO	4	17	38	9
001-052_220114_1015(1).mp3	1+2 KO	7	19	92	11
001-054_220207_1029(1).mp3	1+2 KO	8	19	49	11
001-055_220113_1445(1).mp3	1+2 KO	4	19	57	11
001_216_221118_1054(1).mp3	1+2 SG	9	25	70	14
001-200_221018_1040(1).mp3	1+2 SG	16	26	67	20
001-202_221102_1106(1).mp3	1+2 SG	4	39	56	10
001-203_221101_1137(1).mp3	1+2 SG	4	4	9	3
001-204_221028_1058(1).mp3	1+2 SG	4	18	82	15
001-205_221110_1237(1).mp3	1+2 SG	10	54	155	10
001-206_221024_0959(2).wav	1+2 SG	0	10	33	5
001-207_221115_1103(1).mp3	1+2 SG	6	10	28	1
001-208_221114_1410(1).mp3	1+2 SG	6	25	80	7
001-215_221221_1115(1).mp3	1+2 SG	5	16	65	12
001-218_221115_1201(1).mp3	1+2 SG	3	16	70	4
001-220_221130_1323(1).mp3	1+2 SG	8	5	52	7
001-222_221125_0927(1).mp3	1+2 SG	8	17	67	2
001-223_221125_1621(1).mp3	1+2 SG	4	12	48	6
001-224_221122_1434(1).mp3	1+2 SG	6	37	83	16
001-225_221125_1535(1).mp3	1+2 SG	8	14	71	7
001-226_221128_1034(1).mp3	1+2 SG	6	3	30	5
001-228_221219_1005(1).mp3	1+2 SG	7	17	56	9
001-229_221212_0937(1).mp3	1+2 SG	4	14	72	7
001-231_221228_1446(1).mp3	1+2 SG	4	8	42	6
001-045_211208_0848(1).mp3	1+2 SG	3	26	54	9
001-051_220112_1524(1).mp3	1+2 SG	5	19	51	11
001-052_220114_1015(1).mp3	1+2 SG	9	20	115	12
001-054_220207_1029(1).mp3	1+2 SG	10	24	62	10
001-055_220113_1445(1).mp3	1+2 SG	6	24	70	11
相関係数全42カテゴリ(PearsonI)		0.84	0.82	0.96	0.75