別添１

厚生労働科学研究費補助金

がん対策推進総合研究事業

進行がん患者に対する

効果的かつ効率的な意思決定支援に向けた研究

令和2～4年度　総合研究報告書

研究代表者　内富　庸介

令和5（2023）年　5月

別添２

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厚生労働科学研究費補助金（がん対策推進総合研究事業）
総合研究報告書

進行がん患者に対する効果的かつ効率的な意思決定支援に向けた研究
研究代表者　内富庸介　中央病院支持療法開発部門・部門長

研究要旨

本研究の目的は、進行がん患者に対する質問促進リスト（QPL）と、個別の価値観や意向の整理を含む協働意思決定支援プログラムを開発し、モバイル電子端末のアプリに実装し、患者 - 医師間のコミュニケーション改善に対する有効性を無作為化比較試験により検証することである。本プログラムにより、進行がん患者が自分自身の治療や症状、今後の経過を理解し、標準がん治療終了後の治療や療養について考え、自らの価値観に照らし合わせ、その意向や今後の目標を明確にし、これらのプロセスを家族や医療者と共有することで、納得した協働意思決定が可能となる。これは、我が国が推進しているアドバンス・ケア・プランニングを実現するものである。

本研究の介入プログラムは、モバイル電子端末に実装することで患者が自宅等で自身のタイミングで、標準がん治療終了後に希望する医療や、過ごしたい場所について考えることができ、患者自身の意向の明確化を支援することができる。さらに、モバイル端末上で医療者と情報共有することで遠隔での意思決定支援が可能になり、医療資源の乏しい施設においても実施可能となり医療アクセスの格差是正に貢献することが期待できる。

令和 2 年度に研究体制を構築し、標準がん治療終了後のケアに関する協働意思決定支援プログラムの開発と、アプリ仕様書作成を進めた。令和 3 年度は、開発した協働意思決定支援プログラムをプロトタイプとしてアプリ（デモ版）に実装し、予備試験の実施、予備試験を踏まえたプログラム改修、無作為化比較試験の症例登録管理システムの構築、介入手順書の作成と介入者の養成を行い、患者登録を開始した。介入プログラムの有効性検証と並行して、介入プログラムの普及・臨床実装について検討しており、具体的には臨床での協働意思決定支援の実施状況を関係者へのヒアリングと、アプリ使用状況のログ解析の検討を進めた。最終年度である令和 4 年度は解析計画書を作成し、必要症例数の登録を完了した。主要評価である協働意思決定の話合いに対する医師の態度のデータ取得を予定どおり完遂した。副次評価項目を含むフォローアップ調査は継続されているので、最終解析後、令和 5 年度中に結果を公表する予定である。無作為化比較試験のプロトコル論文は公表済である(Obama et al., BMJ Open, 2023)。また実装可能性について評価し、次相試験について検討を開始した。

研究代表者

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A．研究目的

進行・再発期のがんの多くは根治不能で、治療の目標は生存期間の延長や生活の質の向上・維持になる。医師は患者にこのような状況を事前に、しかも適切に説明し、理解を促し、患者の意向に即した治療選択を協働することが求められるが、時間の猶予がない切迫した状況のため、十分な終末期ケアが提供されていない（Mack et al., 2012）。我が国で 2019 年度に行われた人生の最終段階の療養生活の状況や受けた医療に関する全国調査により、患者が希望する最期の療養場所や蘇生処置について患者、医師間で話し合われた割合は約 3 割であることが報告されている。人生の最終段階をどのように迎えるか、自らの価値観、今後の目標や意向を明確にし、事前に家族や医療者と話し合うプロセス（アドバンス・ケア・プランニング）は国策として進められているが、標準的な介入手順は提示されていない。

患者が治療選択や今後の方針を医師と話し合う際、自らの考えや医師に聞きたいことを整理し、質

問や理解を促すための具体的質問集（Question asking Prompt List: QPL）を用いることで、話し合いが促進されることが示されている（Brandes et al., 2015）。我が国においても、難治がんの初診患者への治療選択に関するQPLの有用性が無作為化比較試験により示されているが（Shirai et al., 2012）、患者から医師への質問数は欧米（平均5-10問）と比べ少なく（平均1問）、より高強度の支援が必要であると考えられる。

我々は予備的無作為化比較試験により、進行・再発がん患者に対して抗がん剤治療中の早い段階から医療従事者がQPLによる質問支援を行うことで、質問数と、望ましいコミュニケーション行動（患者が望む情報提供、共感的対話）が増加し、心理的苦痛を改善することを示した。一方で経口抗がん剤を処方される患者が増え、点滴治療と違って病院内滞在時間が減少し、病院内でのプログラム介入が困難となってきた。そのため場所を問わない介入方法を改善する必要があると考えられた。

本研究の目的は、進行がん患者に対する、個別の価値観や意向に添った協働意思決定支援プログラムを開発し、モバイル端末のアプリに実装し、患者－医師間のコミュニケーション改善への有効性を検証することである。具体的な研究目標は開発したプログラムのアプリ化、予備試験の実施と評価、プログラムやアプリの見直し、無作為化比較試験の症例登録管理システムの構築、介入手順書作成と介入者の養成を行い、患者登録を開始することと並行して、介入プログラムの臨床実装の可能性について検討することであった。

B．研究方法

標準がん治療終了後の療養に関する患者と医師のコミュニケーションを促進するための協働意思決定支援プログラムを開発しアプリに搭載した。協働意思決定支援プログラムにはQPLを用いた医師への質問選択、患者の価値観の整理、標準がん治療後の療養の場や希望するケアの選択が含まれる。これらを介入資材として組み込んだアプリと、無作為化比較試験用の症例登録システムを開発するため、アプリ開発会社とともにアプリの仕様書を作成し、予備試験で使用するアプリ（デモ版）を構築した。

予備試験の結果を踏まえ、意思決定支援プログラムとアプリ内での表現方法を評価・改善した。改善された協働意思決定支援プログラムに基づき、アプリと症例管理システムを本番環境に移行し、患者登録を行った。

有効性検証試験の準備と並行して、介入手順書に基づき介入者を養成した。有効性検証試験の開始後、患者登録を継続しつつ、研究成果の活用をスムーズに進めるため、並行して実装可能性の評価のための関係者ヒアリングと、プログラムの評価について検討を開始した。必要症例数の登録を完了し、主要評価のデータ収集を完遂した。解析担当者を含めて検討事項を議論し、解析計画書を作成した。さらに実装可能性評価のための医療者インタビューを昨年度より継続して実施した。

具体的な研究方法は下記の通り：

1. 文献レビュー、専門家・患者参画によるプログラム開発

1）標準治療終了後のケア（アドバンスケアプランニング）の介入研究レビュー（研究方法、介入方法）

文献検索エンジンを用いて、関連する介入研究を系統的にレビューし、プログラムの内容を検討した（介入対象、時期、介入方法、評価指標、結果）。

2）標準治療終了後に関連するQuestion Prompt Listの作成

先行研究ならびに我々の研究チームが過去に開発したQPLの研究結果に基づき、本研究で使用するQPLを作成した。

3）アドバンスケアプランニングの介入資材の作成

上記1）の研究結果、並びに2）で作成したQPLを用いて、アドバンスケアプランニングのプログラムを開発するとともに、並行して、同プログラムの介入資材を作成した。

4）専門家、患者参画によるプログラム開発

上記1）～3）及び事前患者調査結果を基に研究者、患者、医師、看護師等で構成されるメンバーで協議し、協働意思決定支援プログラムを開発した。

2. 専門家の協議、患者参画によるアプリケーション開発

1）アプリ仕様書の作成

上記1.の結果に基づき、アプリケーション開発会社と共にアプリケーションの仕様を作成した。

2）プロトタイプの開発

仕様書に基づきアプリケーション開発会社と共にアプリケーションを構築した。

3）専門家の協議・患者参画による修正

上記1）2）のアプリケーションの使用感、表現内容を確認するため、アドバンスケアプランニングに臨床・研究で携わる専門家並びに患者会代表に依頼して、仕様書の修正を行った。

3.協働意思決定支援プログラムのアプリへの実装

1） 治療用アプリ開発会社と定例ミーティングを開催し、協働意思決定支援プログラムに沿って作成したアプリ仕様書に基づき、モバイル端末に搭載するアプリを構築した。アプリ開発会社とともに、プログラムに内容や意図した表現がアプリに十分反映されているか、想定通りの仕様で動作するかを確認した。

2） 研究協力者であるがん患者団体代表、研究協力

者である医師へヒアリングし、アプリに表現されているプログラムの文言や使用感について確認し、妥当性を評価した。

4.修正版アプリと症例登録管理システムをリリース

1) 研究分担者が実施する予備試験の結果を踏まえ、アプリの仕様書を改定し、アプリ開発会社とともに本番のシステム仕様を確定した。
2) 症例管理システムの割付ロジック、仕様書に沿って介入プログラムが動作するか確認し、本番環境のアプリと症例管理システムをリリースした。リリース後の症例登録状況、システム動作について確認した。

5.介入手順書の確定

予備試験結果に基づき、介入手順書を改訂・確定する。本研究の介入は対象者自身がモバイル電子端末を用いて進めるものであり、介入者は対象者自らの意思決定支援プログラムの実施を促すために、対象者にプログラムの意義と実施方法の説明、プログラムの導入支援を行う。また、介入者は診察前に電話や面談にて1回のみ対象者のプログラム実施状況を確認し、主治医との話し合いの準備を支援する。これらを含む介入者向けの介入手順書を作成した。

6.介入者の養成と介入手順書の評価

1) 予備試験結果に基づき、開発された介入者の養成プログラムに沿って介入者を養成した。
2) 介入手順書に基づき、介入者間でロールプレイを実施した。先行研究における患者への質問支援プログラムに携わった経験のある精神科医、公認心理師にフィードバックを得た。
3) 介入者間でピアレビューを行い、介入プログラムの内容に沿って介入が実施されているか、介入手順書に十分に介入プログラムの実施内容が表現されているかを評価した。

7. 計画の承認と患者登録の準備

研究計画を日本がん支持療法試験グループJ-SUPPORT科学諮問委員会と、研究フィールドの倫理審査委員会へ提出し、承認を受けた。フィールドとの環境調整を行い、患者登録の準備を進めた。

8. 症例登録の遂行

研究分担者が事務局を担い、研究協力者とともに症例登録、介入、患者調査の手順書を確認しながら実施した。調査フィールドは国立がん研究センター腫瘍内科、肝胆膵内科、呼吸器内科に協力を仰ぎ昨年度に引き続き実施した。アプリ運用および症例登録システムの管理は、研究分担者が責任者として協力した。進捗管理はJ-SUPPORT（日本がん支持療法研究グループ）にも依頼した。

9. 発話評定者のトレーニングと信頼性確保

主要評価項目である患者と医師のコミュニケーション行動の発話評定を実施する評定者のトレーニングを実施した。過去に実施実績のある評定者1名を標準として、新規に評定を実施する評定者の一致率を確認した。 また評定者はRIAS研究会日本支部（RIAS Japan）が主催するRIASトレーニングワークショップに参加した。

10. 有効性検証のための統計解析計画書の作成

研究分担者に統計解析責任者を依頼し、統計解析のスケジュール、中止症例の取り扱い、欠測補完方法を含めた統計解析計画書を作成した。作成にあたり、主要評価解析の参考とした先行研究(Epstein et al., 2017)の著者及び解析責任者らに助言を仰いだ。

11.実装可能性の評価

有効性検証試験と並行し、下記1）2）により実装可能性評価を進めた。

1) 研究成果を臨床に実装するための阻害・促進要因を明らかにするため、実装科学の研究者の助言を受け、アプリ開発会社とともに研究協力者、関係者のヒアリングを行った。
2) 対象者のアプリプログラム実施や取り組み状況を確認するため、アプリの実施記録（ログ）の取得と評価方法について検討を開始した。毎月1回の打ち合わせを行い、詳細な分析方法を検討した。

（倫理面への配慮）

本研究は国立がん研究センター研究倫理審査委員会において承認された（課題番号 2020-500）。

調査において研究協力は個人の自由意思によるものとし、研究同意後もいつでも中止や随時撤回が可能であること、不参加や同意撤回による不利益は生じないこと、個人のプライバシーは厳重に守られることを文書で説明して同意を得た。現時点で特に検討が必要な事象は発生していない。

C．研究結果

プログラム開発は2020年中に実施し、2021年にアプリへの実装と症例登録管理システムのリリースが完了した。2021年4月にJ-SUPPORT科学諮問委員会の承認を受けて、国立がん研究センター中央病院外来でフィールドを調整し、6月よりパイロット試験を実施した。並行して、介入手順書の作成、介入者の養成を進めた。アプリ及び症例登録管理システムを改修し、2021年9月より症例登録が開始され、当初予定通り、2022年12月までに264症例の登録を完了した。進捗管理はJ-SUPPORT、毎月の進捗報告を行って適宜相談し、助言を受けた。研究分担者との

班会議を定期的に設け、進捗報告及び検討事項の確認を行った。

症例登録の進行状況は以下の通り：

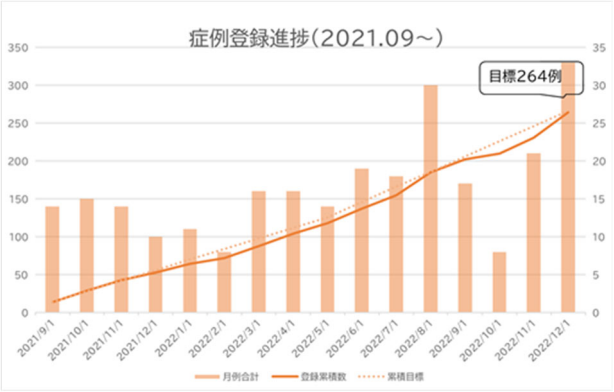

図 1. 月例登録数（2021 年 9 月-2022 年 12 月）

発話評定者2名は主要評価項目のSHAREスコアおよびRIASコーディングを実施するためそれぞれトレーニング期間を設けた。RIASコーディングはRIAS研究会日本支部が主催する研修会に参加し、課題の合格をもって評定者の認定を受けた。

過去にSHAREとRIASの評定経験を有する評定者１を基準として、評定者２の評定を確認した。症例登録264例のうちの10%をダブルコーディングし、SHARE、RIASともに評定者間信頼性の相関係数≧0.8を確認した。

統計解析当初計画で主要評価の解析に必要な症例数を250例、中止症例を5%と仮定して症例登録264例とする解析計画を作成した。

定期的な症例報告において、中止症例の検討を行った。両群で発生した中止の理由や患者の状況を比較した結果、介入群では具体的な終末期の過ごし方を扱ったプログラム内容によって、不安が増したような中止理由が含まれた。

研究分担者らと協議し、主要評価を欠測とする場合と、欠測とせず最悪値による補完する方法を検討した。また先行研究の著者および統計解析責任者らに状況を報告して助言を仰いだ。最終的に、主要評価の解析時の取り扱いについて、解析者を含めて以下のように検討した：

1) 主要な解析は当初の予定通り、Intention-to-treatで実施する
2) 欠測はMissing at randamを加味して一次解析を実施する
3) 感度解析では欠測に基づく値を複数検討して補完する

D．考察

当初の予定通りに研究が進捗し、必要な資材の開発を完了し、必要症例数の登録を完了した。発話評定者のトレーニングも完了し、有効性検証に必要な作業を進捗している。データ管理センターや統計解析者らの協力も得ながら、主要評価項目の解析準備が進められている。

E．結論

予定通り研究が進捗した。今後の解析を待って、成果の公表および社会実装を進めていく。

F．健康危険情報

特記すべきことなし

G．研究発表

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（発表誌名巻号・頁・発行年等も記入）

H. 知的財産権の出願・登録状況
なし

1. 特許取得
なし

2. 実用新案登録
なし

3.その他
なし

別添４

研究成果の刊行に関する一覧表

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Assessing the need for a question prompt list that encourages end-of-life discussions between patients with advanced cancer and their physicians: A focus group interview study

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Abstract

Objective. Early integration of palliative and cancer care improves the quality of life and is facilitated by discussions about the end of life after cessation of active cancer treatment between patients with advanced cancer and their physicians. However, both patients and physicians find end-of-life discussions challenging. The aim of this study was to assess the need for a question prompt list (QPL) that encourages end-of-life discussions between patients with advanced cancer and their physicians.

Methods. Focus group interviews (FGIs) were conducted with 18 participants comprising 5 pancreatic cancer patients, 3 family caregivers, 4 bereaved family members, and 6 physicians. Three themes were discussed: question items that should be included in the QPL that encourages end-of-life discussions with patients, family caregivers, and physicians after cessation of active cancer treatment; when the QPL should be provided; and who should provide the QPL. Each interview was audio-recorded, and content analysis was performed.

Results. The following 9 categories, with 57 question items, emerged from the FGIs: (1) preparing for the end of life, (2) treatment decision-making, (3) current and future quality of life, (4) current and future symptom management, (5) information on the transition to palliative care services, (6) coping with cancer, (7) caregivers' role, (8) psychological care, and (9) continuity of cancer care. Participants felt that the physician in charge of the patient's care and other medical staff should provide the QPL early during active cancer treatment.

Significance of results. Data were collected to develop a QPL that encourages end-of-life discussions between patients with advanced cancer and their physicians.

Introduction

In cancer care, physicians often have to give bad news to patients and caregivers, such as when cancer treatment has failed and cessation of active cancer treatment is advisable. Optimal communication between patients, caregivers, and physicians has been addressed as a core component of cancer care (Steinhauser et al., 2000). Even for patients with newly diagnosed advanced cancer, early integration of palliative care has been shown to improve the quality of life (Temel et al., 2017). The American Society of Clinical Oncology clinical practice guidelines recommend that inpatients and outpatients with advanced cancer should receive dedicated palliative care services early in the disease course, concurrent with active treatment (Ferrell et al., 2017). However, both patients and physicians find discussions about prognosis and end-of-life issues to be challenging (Kaplan et al., 1996). Our previous interview study at an outpatient clinic found that, when receiving bad news, patients preferred physicians to give them opportunities to ask questions and wanted to be told about frequently asked questions from other patients in advance (Fujimori et al., 2005).

Butow et al. developed a question prompt list (QPL) containing frequently asked questions from cancer patients (Butow et al., 1994). Patients refer to the QPL beforehand and then ask the physician questions at the consultation. In subsequent work, various types of QPLs have been developed and reported to be useful and effective in increasing patients' question-asking behaviors (Bruera et al., 2003; Clayton et al., 2003). We also conducted a randomized controlled trial and reported the usefulness of a QPL for patients with advanced cancer when making an initial treatment decision (Shirai et al., 2012). In systematic reviews, QPLs have been shown to have a significant effect on facilitating discussions on specific topics, such as prognosis (Brandes et al., 2015; Sansoni et al., 2015). Brandes et al. (2014) suggested that consultations in the setting of advanced cancer could be tailored to the specific information needs of patients and caregivers. Rodenbach et al. (2017) suggested that a combined QPL and coaching intervention was effective in helping patients and caregivers discuss topics of concern, including prognosis.

Cessation of cancer treatment and end-of-life issues mark a major turning point and necessitate communication that is difficult for both patients and physicians because of the complex decision-making required (Buckman, 1984). Previous studies showed that patients with advanced cancer, who need to discuss anticancer treatment cessation and transition to palliative care, preferred to have end-of-life discussions (Clayton et al., 2003; Walczak et al., 2013; Umezawa et al., 2015). Their preferences included discussing both their current condition and the future disease course. Furthermore, patients with rapidly progressing cancer, such as pancreatic cancer, were more likely to prefer that their physician carefully tell them to prepare mentally and to maintain hope in addition to providing the prognosis. It is likely that pancreatic cancer patients, family caregivers, bereaved family members, and physicians have extensive experience with end-of-life discussions after the cessation of active cancer treatment. Therefore, the aim of this study was to assess the need for a QPL that encourages end-of-life discussions between patients with advanced cancer and their physicians.

Methods

Participants and procedure

We recruited pancreatic cancer patients, family caregivers, and bereaved family members who participate in a pancreatic cancer patient support group (NPO PanCAN Japan) and physicians working in the Department of Hepatobiliary and Pancreatic Oncology at the National Cancer Center (NCC) Hospital. Written informed consent was obtained from all participants. Eligibility criteria were as follows: patients with rapidly progressing pancreatic cancer who received active cancer treatment; family caregivers who provided care to a family member with rapidly progressing cancer; bereaved family members who experienced the death of a family member with rapidly progressing cancer; and physicians who regularly treating patients with cancer. Participants were excluded if they were not able to understand Japanese or if they were too ill.

Study design

Focus group interviews (FGIs) and content analysis were performed.

Procedure

This study was approved by the National Cancer Center Institutional Review Board, Japan. We conducted four FGIs and one individual interview. Each interview took about 180 min. One FGI with patients who had pancreatic cancer and two FGIs with family caregivers and bereaved family members were conducted at the office of NPO PanCAN Japan. One FGI with physicians and one individual interview with a physician were conducted at the NCC Hospital. All FGIs were conducted by a clinical psychologist with experience conducting interviews (M.F.). At the start of each interview, the interviewer (M.F.) introduced herself and explained the purpose, background, methods, and schedule of the FGI. Based on an interview guide (Supplementary material), participants were asked to discuss three themes: the question items that should be included in the QPL that encourages the end-of-life discussions with patients, family caregivers, and physicians after cessation of active cancer treatment; when the QPL should be provided; and who should provide the QPL booklet. The participants engaged in an open discussion guided by the interviewer. When necessary, the interviewer asked further questions to clarify replies. All interviews were recorded using digital voice recorders.

Analysis

All recorded dialogue was transcribed, and the transcribed dialogue was independently divided into basic blocks, each of which was a single utterance that did not include multiple different meanings in the sentence. Utterances of similar content were organized and summarized into categories, and the number of utterances was counted for each. If a person mentioned the same thing multiple times, it was counted once. Not all participants commented on all the questions. Three cancer specialists (Y.S., S.U., and M.M.) independently coded the basic blocks so that the same meaning was assigned to one attribute. When opinions about the coding differed, discussions were held until consensus was reached. The attributes of coding integrity were checked throughout the coding process (Pope and Mays, 1999; Colorafi and Evans, 2016).

Results

Participant characteristics

We recruited 21 people who participated in NPO PanCAN Japan, 10 members of NPO PanCAN Japan living in the suburbs of Tokyo, and 6 physicians who treated patients with cancer. Eighteen of these 37 agreed to participate (response rate 48.6%). The 18 participants comprised 5 patients with pancreatic cancer (including 1 who had just stopped active cancer treatment; 3 in their 50s, 1 in their 60s, and 1 in their 70s), 3 family caregivers (1 spouse and 2 daughters) of patients (2 with biliary tract cancer and 1 with pancreatic cancer), 4 bereaved family members (2 spouses, 1 son, and 1 brother) of patients (1 with biliary tract cancer and 3 with pancreatic cancer), and 6 physicians. Five patients, 1 family caregiver, 2 bereaved family members, and 1 physician were over the age of 50 years. There were 13 men (3 patients, 1 family caregiver, 3 bereaved family members, and 6 physicians) and 5 women (2 patients, 2 family caregivers, and 1 bereaved family member). Two patients had recurrence/metastasis.

Questions for the QPL

In total, 57 question items in 9 categories emerged from 150 utterances regarding question items required for the QPL. The nine categories were (1) preparing for the end of life, (2) treatment decision-making, (3) current and future quality of life, (4) current and future symptom management, (5) information on the transition to palliative care services, (6) coping with cancer, (7) caregivers' role, (8) psychological care, and (9) continuity of cancer care. The 57 question items in these 9 categories are shown in Table 1.

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Table 1. Participants' preferences on question items for the QPL

Factors	Question items	*n*	Cancer patients	Family caregivers	Bereaved family members	Physicians
(1) Preparing for the end of life		48	1	3	6	38
	What can I expect in my last days of life?	11		1	1	9
	Are there any services or resources that would be useful for me or my caregivers (such as financial, social, and healthcare services)?	10			1	9
	What is likely to happen at the very end?	7			1	6
	Is it possible to know my life expectancy?	5			1	4
	Is it possible to give a time frame for when treatment will fail?	4			2	2
	What will happen when treatment fails?	3	1			2
	What should I do if I cannot go to the hospital?	3				3
	Can I get information about the place for care at the end of life?	1				1
	Can I be contacted if a new treatment is developed?	1				1
	What should I do if I am too unwell?	1		1		
	Can I get information about cardiopulmonary resuscitation?	1				1
	Can I ask how to use my medicine?	1		1		
(2) Treatment decision-making		29	5	2	7	15
	Can I talk about my concerns about treatment?	8	1			7
	What can I expect when treatment fails?	6	3			3
	What is the purpose of treatment?	4			2	2
	Can I take folk medicine or complementary and alternative medicine during treatment?	4		1	3	
	What treatment options are available for me when my current treatment fails?	2	1	1		
	What are the pros and cons of treatment?	2			1	1
	Can you tell me about the newly developed treatment?	1				1
	Can you tell me about cancer immunotherapy?	1			1	
	What will happen if I decide not to have treatment?	1				1
(3) Current and future quality of life		28	6	2	1	19
	Can I talk about my lifestyle?	4	1			3
	Is it OK for me to travel?	4				4
	What kind of food should I eat?	3		1	1	1
	Should I consider preparing my will?	3	2	1		
	How long can I work?	2				2
	Can I talk about my needs for living?	2				2
	Is it better to put my affairs in order?	2				2
	Can I talk about a farewell note?	2	2			
	Is it OK for me to smoke?	1				1
	Is it OK for me to drink?	1				1
	Can I talk about financial matters?	1				1
	Can I talk about my sense of values?	1				1
	Can you give me tips on how to take medicine?	1	1			
	Can I talk about nursing care insurance?	1				1
(4) Current and future symptom management		20	1	2	3	14
	What treatments can help manage my symptoms, such as pain, nausea, fatigue, depression, insomnia, and anxiety?	9	1		1	7

(*Continued*)

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Table 1. (*Continued.*)

Factors	Question items	*n*	Cancer patients	Family caregivers	Bereaved family members	Physicians
	What is currently happening with my cancer?	4			2	2
	What will happen in the future with my cancer?	3		1		2
	What can I do if my symptoms worsen?	2				2
	Will my caregiver know what to do for worsening symptoms?	1		1		
	What are the common side effects of treatment?	1				1
(5) Information on the transition to palliative care services		7			4	3
	What information is available about palliative care?	4			2	2
	Can you tell me about the difference between hospice and palliative care in a hospital?	2			2	
	Can I talk about my concerns about the transition to the palliative care?	1				1
(6) Coping with cancer		6		1		5
	Was there a way to detect my cancer earlier?	2				2
	Do my family members have a higher risk of getting cancer?	2				2
	Why did I have a recurrence of cancer?	1		1		
	What caused my cancer?	1				1
(7) Caregivers' role		5			2	3
	What kind of support can my caregivers provide?	1				1
	Can my caregivers talk about their preferences for care?	1			1	
	Who can my caregivers talk to if they have worries or concerns?	1				1
	Can you tell me about end-of-life care?	1			1	
	Can you tell me about home medical care skills?	1				1
(8) Psychological care		5			3	2
	Who can take care of my mental health?	3			2	1
	Can I talk about my anxiety?	1			1	
	Can you tell me about mental care that I can receive?	1				1
(9) Continuity of cancer care		2	2			
	Which physician will treat me after cessation of active treatment?	2	2			
Total		150	15	10	26	99

When the QPL should be provided?

Five opinions on when the QPL should be provided were compiled from 14 utterances: (1) during first-line treatment, (2) during second-line treatment, (3) between first-line and second-line treatments, (4) before first-line treatment, and (5) during the transition from second-line treatment to palliative care services (Table 2).

Who should provide the QPL?

Seven opinions on who should provide the QPL were compiled from 17 utterances: (1) the physician in charge of the patient's care, (2) a nurse (certified nurse specialist), (3) medical staff who is not a physician, (4) medical staff who is not a nurse, (5) medical staff (not specified), (6) a nurse after a physician briefly explains the QPL, and (7) a psychologist (Table 3).

Discussion

In this study, we conducted FGIs with patients, family caregivers, bereaved family members, and physicians and collected basic data in order to assess the need for a QPL that encourages end-of-life discussions between patients with advanced cancer and their physicians. From the results, 57 question items emerged in 9 categories related to physical and psychological symptoms, treatment and care for symptoms, preparations for the end of life, and continuity of cancer care. These results were generally consistent with those of previous studies (Walczak et al., 2013; Umezawa et al., 2015). Participants responded that a QPL would help patients remember the questions they wished to ask and would prompt them to consider issues of which they were previously unaware.

In this study, anxiety and concern about cancer progression and future treatment, knowledge for when treatment fails, symptom management, and life expectancy emerged as question items to be included in the QPL. Most of the utterances about

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Table 2. When the QPL should be provided to patients with advanced cancer?

	n	Cancer patients	Family caregivers	Bereaved family members	Physicians
(1) During first-line treatment	5		2		3
(2) During second-line treatment	3				3
(3) Between first-line and second-line treatments	3			3	
(4) Before first-line treatment	2	1			1
(5) During the transition from second-line treatment to palliative care services	1	1			
Total	14	2	2	3	7

Table 3. Who should provide the QPL to patients with advanced cancer?

	n	Cancer patients	Family caregivers	Bereaved family members	Physicians
(1) Physician in charge of the patient's care	8	2		2	4
(2) Nurse (certified nurse specialist)	2		2		
(3) Medical staff who is not a physician	2	1			1
(4) Medical staff who is not a nurse	2				2
(5) Medical staff (not specified)	1			1	
(6) Nurse after a physician briefly explains the QPL	1				1
(7) Psychologist	1		1		
Total	17	3	3	3	8

end-of-life preparations were from physicians, followed by bereaved family members; only one utterance was from a patient. Patients experience high levels of anxiety and thus may be more reluctant to have end-of-life discussions than their physician and family members (El-Jawahri et al., 2014). Death-related topics can elicit psychologically strong emotions in patients and physicians, and may be unconsciously avoided (Stiefel et al., 2019). Since all of the patient study participants were pancreatic cancer patients with poor prognoses, they may have been more resistant to the topic of end-of life due to their imminent death. In contrast, previous studies have found that patients with advanced cancer prefer to have discussions with their physician about their physical and psychological status, their symptoms and symptom management, and the transition to palliative care (Clayton et al., 2003; Walczak et al., 2013; Yeh et al., 2014; Umezawa et al., 2015; Bouleuc et al., 2021). Furthermore, our previous study found that patient preferences regarding the communication of bad news by physicians vary according to demographic and psychological variables but not according to disease variables, whereas preferences for discussing life expectancy differed according to the individual (Fujimori and Uchitomi, 2009; Umezawa et al., 2015). The small number of patients with pancreatic cancer who participated in these studies did not allow us to conclude that there are no disease differences in patient preferences regarding the communication of bad news by physicians; however, it suggests that patients' individual preferences need to be taken into account when engaging in end-of life discussions. Therefore, it might be necessary to consider patients' individual preferences when engaging in end-of life discussions.

By using the QPL, healthcare providers could easily understand these individual differences.

Consistent with a previous study by Walczak et al. (2013), participants preferred end-of-life discussions that included advance care planning (ACP). The QPL for end-of-life discussions developed by Walczak et al. (2013) listed questions about ACP, preferences for future care, and helping patients and their caregivers to maintain autonomy and authority in treatment decisions once the patients have become incapacitated. In 2007, the Japanese Ministry of Health, Labour and Welfare (2007) developed guidelines for the decision-making process in end-of-life medical care to promote patient's self-determination at the end of life. And in 2018, the ministry issued revised guidelines that advocated ACP (Ministry of Health, Labour and Welfare, 2018). ACP is a process involving discussions between a patient, caregivers, and health providers about future medical and long-term care. In practice, ACP requires sufficient discussion among patients, caregivers, and health providers.

The participants preferred that the physician in charge of a patient's care and other healthcare professionals provide the QPL. In terms of when to provide the QPL, "during first-line treatment" and "during second-line treatment" were preferred. Chemotherapy treatment options for pancreatic cancer are currently limited, so it is necessary for patients, family caregivers, and physicians to hold discussions in the context of early integration of cancer treatment and palliative care. The American Society of Clinical Oncology recommends discussing prognosis and treatment options from the start of treatment and clarifying patients' wishes for the end of life (Peppercorn et al., 2011).

This study has three main limitations. First, the sample size was small, with only 18 participants comprising patients with pancreatic cancer, caregivers, bereaved family members, and hepatobiliary-pancreatic oncologists. However, various interviews were carried out until saturation was reached and both the quality and quantity of the interviews were sufficient. Second, all of the patients in this study had pancreatic cancer and were relatively young, so caution should be exercised when generalizing the results. Third, the physicians provided more utterances compared with the patients. Individual differences in preferences for end-of-life discussions were observed between patients and physicians.

Using the group interview data, in future work we will develop a QPL and assess each item. In addition, we are planning a study to evaluate the efficacy of an integrated communication support program including QPL for patients with rapidly progressing advanced cancer and their caregivers. In conclusion, data were collected to develop a QPL that encourages end-of-life discussions between patients with advanced cancer and their physicians.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1478951521001796.

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Conflict of interest. The authors declare that there is no conflict of interest in this study.

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資料2

Open access Protocol

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)

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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 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.

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 enrols patients in the order of their refferal.
⇒ Multiple intervention components make it difficult to determine how much each component contributes to the outcome.

INTRODUCTION

Cancer is a leading cause of death in developed countries, with an estimated 10 million deaths worldwide in 2020,[1] 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.[2] Delayed discussions, that is, after the patient's condition deteriorates, are associated with unprofitable treatment and delayed coordination with community health services.[3] 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.[4 5] In this study, we refer to the following definition of ACP reported by Sudore *et al*[6]: '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.[7] ACP improves communication regarding end-of-life care between patients with cancer and healthcare providers[8–11] and increases accessibility to palliative care,[12] thus reducing patients' anxiety and depression and unnecessary aggressive treatment[13 14] while increasing satisfaction with care.[13] Moreover, patients receiving communication intervention tend to share their end-of-life care preferences with healthcare providers.[15]

Since barriers to ACP include a lack of supportive and empathetic attitudes and inadequate information delivery by healthcare providers,[16] 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[17–19] because they tend to leave treatment decisions to their oncologists, which applies even to end-of-life care.[20 21] 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,[8 10 22] communication skill training (CST) for healthcare providers,[13 23] a combination of CST for healthcare providers and patients,[24] and step-by-step in-depth counselling for patients by trained facilitators.[12 25] 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.[26] 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.[26 27] 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[26] to include an app with reference to previous QPL studies,[28–30] the goal concordant care framework,[31] the good death[32 33] and digital health-based intervention.[34] 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[32 33] and psychoeducation[35]) 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[13 36] (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

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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

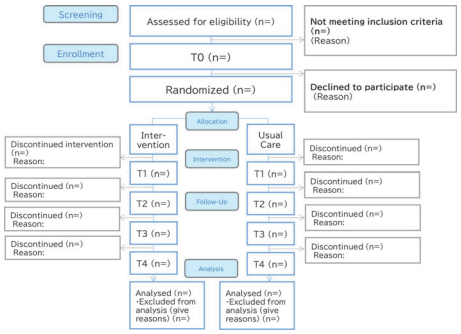

Figure 1 CONSORT diagram. CONSORT, Consolidated Standards of Reporting Trials.

Table 1 Schedule for outcome measurement

Outcomes	T0 Baseline	T1 Next oncologist visit scheduled after 1 week	T2 Follow-up at 1 week	T3 Follow-up at 12 weeks	T4 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.[37] 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): 1. Diagnosis and stage of disease (4) 2. Current treatment (7) 3. Symptom management and palliative care (4) 4. Future treatment (6) 5. Future living arrangements (9) 6. When standard treatment is no longer available (7) 7. Prognosis for the future (5) 8. Family support (3).
Identifying participants' values	Three questions: 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') 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. 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.

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).[38] The system is widely used in the USA, the UK and Japan.[39 40] Manuals have been translated into Japanese and validated for examining patients with cancer.[41]

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.[37 42] 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.[39 43] 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	1. Greeting a patient cordially 2. Taking sufficient time
H: How to deliver bad news	Make consideration for how to deliver the bad news	1. Encouraging patients to ask questions 2. Not beginning bad news without preamble 3. Asking how much the patients know about their illness before breaking bad news 4. Not using technical words (using actual images and test data, writing on a paper to explain) 5. Checking patients' comprehension 6. Checking to see whether talk is fast-paced 7. Clearly communicating the main points of bad news
A: Additional information	Discuss about additional information	1. Answering patients' questions completely 2. Explaining patients' illness status 3. Explaining the prospects of cancer cure 4. Providing information on support services 5. Discussing patients' daily activities and future work 6. Explaining the need for a second opinion 7. Asking if the patients have any questions 8. Discussing patients' future treatment and care
RE: Reassurance and Emotional support	Provision reassurance and addressing the patient's emotions with empathetic responses	1. Asking about patients' worries and concerns 2. Saying words to prepare patients mentally 3. Remaining silent for concern for patients' feelings 4. Accepting patients' expressing emotions 5. Saying words to soothe patients' feelings 6. Explaining with hope 7. Telling what patients can hope for 8. Assuming responsibility for patients' care until the end 9. Discussing patients' values

Number of ACP-related topics in the consultation

Conversations between patients and oncologists are coded and counted based on a conversation analysis manual.[24] 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.[44] 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.[45]

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.[46] 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.[47]

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[31] 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[43 48 49] 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.[27] 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%.[50] Additionally, in a study that adopted surprise questions in the eligibility criteria, the drop-out rate was 6%.[24] 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.[51] Communication attitudes, such as lack of empathy and inadequate information delivery by oncologists, are barriers to ACP.[16] 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.[26 50] Japanese patients with cancer approve of their oncologist's empathetic behaviour in communicating bad news, which indicates better communication.[52]

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.[4] Previous studies have used bereaved family assessments for patient goal concordance after patients' death,[13 25] 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.[53] However, there is no evidence regarding the appropriate timing for introducing ACP discussions,[33] 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.[4] A healthcare system should be constructed to ensure that ACP can reach the overall population in need.[54] 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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Contributors YU is the principal investigator. YU and MF conceived the concept of the study. YU, MF, BN, TA, MM, NS, TU, AO, TM and MK were involved in the study design. TY and SO developed the statistical analysis plan. AO and TM played roles in data management. KO, MK, MO and MF contributed to data collection. YU, MF and MO supervised the conduct of this study. KO, MO and MF drafted the manuscript. YU, BN, TA, MM and the other authors contributed substantially to the revision of the manuscript. All authors have approved the manuscript as submitted and agreed to accept responsibility for any part of the work.

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