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Geriatric assessment and management with question prompt list using a web-based application for elderly patients with cancer (MAPLE) to communicate ageing-related concerns: J-SUPPORT 2101 study protocol for a multicentre, parallel group, randomised controlled trial

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ABSTRACT

Introduction Elderly cancer patients often have ageing-related physical and psychosocial problems that should be fully shared with their oncologists. Geriatric assessment (GA) can assess these ageing-related problems and guide management. Communication support might also facilitate implementation of GA-guided management. We will conduct a multicentre, randomised controlled trial to examine the efficacy of a programme that combines a GA summary, management recommendations and communication support to facilitate ageing-related communications between elderly Japanese patients with cancer and their oncologists, and thus to implement programme-guided management.

Methods and analysis We plan to recruit a total of 210 patients aged ≥70 years, diagnosed with incurable cancers of gastrointestinal origin, and referred for first-line or second-line chemotherapy. In the intervention arm, a summary of management recommendations based on a GA and question prompt list (QPL) will be provided to patients and shared with their oncologists at the first outpatient visit after randomisation by trained intervention providers. For 5 months after the initial intervention, implementation of GA-guided management recommendations will be reviewed monthly with the patients and their oncologists to implement management as needed. The GA and QPL will be re-evaluated at 3 months, with a summary provided to patients and their oncologists. Those participants allocated to the usual care arm will receive usual oncology care. The primary endpoint is the number of conversations about ageing-related concerns at the first outpatient visit after randomisation.

Ethics and dissemination This study was approved by the institutional review board of the National Cancer Center Japan on 15 April 2021 (ID: 2020–592). Study findings will be disseminated through peer-reviewed journals and conference presentations.

Trial registration number UMIN000045428.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the protocol paper of a multicentrer, randomised controlled trial to examine the efficacy of a programme that combines a geriatric assessment (GA), GA-guided management and communication support using a question prompt list (QPL) for elderly Japanese patients with cancer.
⇒ With the aim of facilitating future implementation, this study will use a self-reported GA and QPL administered via a web-based application to generate a GA summary, tailored recommendations and patients' selected questions.
⇒ Due to the nature of the intervention, both patients and their oncologists would be aware of the allocated arm, which could potentially influence care during treatment.
⇒ The intervention programme is complex, consisting of a multifactorial component (GA summary, management recommendations and communication support using QPL), making it difficult to determine each component's contribution to the outcomes.
⇒ Because this study is limited to patients with gastrointestinal cancers, its generalisability to other cancers will not be clarified.

INTRODUCTION

Many cancers are ageing-related diseases.[1] Japan is a front runner of the super-aged societies, which is defined as greater than 21% of a population aged ≥65 years,[2] and its number of elderly patients with cancer is increasing. In Japan, more than 70% of cancer incidences and 80% of cancer mortality occur in patients aged ≥65 years.[3 4] However, elderly patients are often excluded from clinical

trials and they face difficulty due to lack of evidence for treatment decisions.[5] Elderly patients with cancer are physically, psychologically and socially heterogeneous; they differ from their younger counterparts in terms of physical function, psychological well-being, life circumstances and values and preferences.[6] Therefore, the treatment and care of elderly patients with cancer are complex and should be individualised. Subjective assessment by oncologists based on performance status and chronological age is inadequate to cope with these heterogeneous conditions, which can lead to overtreatment or undertreatment. The concept of geriatrics, which evaluates elderly patients in a multifaceted and comprehensive manner, is necessary in oncology.

Comprehensive geriatric assessment (CGA) is a multidimensional, interdisciplinary diagnostic process that focuses on determining the medical, psychosocial and functional capabilities of elderly adults in order to develop a coordinated and integrated plan for treatment and long-term follow-up.[7] In geriatrics, CGA has been shown to reduce mortality, decrease institutionalisation and readmission, and improve cognitive and physical functioning, mainly through interventions by a multidisciplinary team.[8 9] The term 'geriatric assessment' (GA) is commonly used in oncology instead of CGA because CGA research in oncology has studied mainly the diagnostic process for selecting appropriate treatment through assessment of ageing-related problems without a thorough focus on geriatric interventions for these problems.[10] Recently published randomised controlled trials (RCTs) in the USA have demonstrated that feedback in the form of a GA summary and GA-guided management recommendations to patients and their oncologists facilitates communication about ageing-related concerns (COACH study),[11] and reduces incidences of serious adverse events related to chemotherapy (GAP70+ study).[12]

Patient-centred communication is important to help patients prioritise their concerns, ensuring that decisions are in line with their values and preferences. Although studies have shown benefits of communication interventions to facilitate patient-centred communication,[13 14] these interventions were not tailored to address ageing-related concerns of elderly patients with cancer. In fact, many elderly patients with cancer have ageing-related symptoms that are not identified, communicated or addressed in daily oncology practice.[15] Communication interventions might help elderly patients with cancer and their oncologists share and manage ageing-related problems by recognising these conditions that are often overlooked in daily oncology practice.

Elderly patients with cancer in Japan are less likely to communicate their values and preferences regarding treatment to their physicians; therefore, they need support to express their intentions and preferences based on their values.[16] A question prompt list (QPL) is a list of specific questions that helps patients express their intentions by facilitating communication with their healthcare providers and encouraging them to ask their healthcare providers questions.[17] A systematic review has shown that use of a QPL increases the number of questions that patients ask their physicians.[18] We previously conducted an RCT on the usefulness of QPL in Japanese patients with advanced cancer undergoing initial anticancer therapy and found that patients perceived the materials, including the QPL, to be useful for understanding their treatment plans.[19]

Although our study is based on the COACH study, we hypothesise that feedback in the form of only a GA summary and GA-guided management recommendations to patients and their oncologists would be insufficient for elderly patients with cancer in Japan to express their ageing-related concerns. We further hypothesise that they would need communication support to express their concerns about problems identified by GA as well as their interest in GA-guided management recommendations. Therefore, this study will examine the efficacy of a programme that combines a GA summary, GA-guided management recommendations as provided by a multidisciplinary team and communication support using QPL, with the aims of facilitating communications between elderly patients with cancer and their oncologists. The rationale for combining these two interventions is that, after GA identifies ageing-related concerns not captured in routine oncology practice, with communication support using QPL, patients will be able to express their ageing related-concerns to their oncologists, which will facilitate patient-centred communication, thereby leading to higher implementation of GA-guided management and improved patient outcomes (figure 1).

METHODS AND ANALYSIS

This protocol was written in accordance with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and SPIRIT PRO Extension Guidelines.[20 21]

Study design

This study is a single-blind (outcome assessor blind), parallel-group RCT conducted at the National Cancer Center Hospital and Kyorin University Hospital. The study period is from April 2021 to March 2026; the registration period is from September 2021 to March 2024.

Screening

Trained study staff will review a list of potentially eligible patients (table 1) and approach patients consecutively with permission from their oncologists.

All elderly patients with cancer who meet inclusion criteria (1) through (7) will be registered and screened for GA. Patients having any GA impairment other than polypharmacy will be randomly assigned to either the intervention arm or the usual care arm (figure 2).

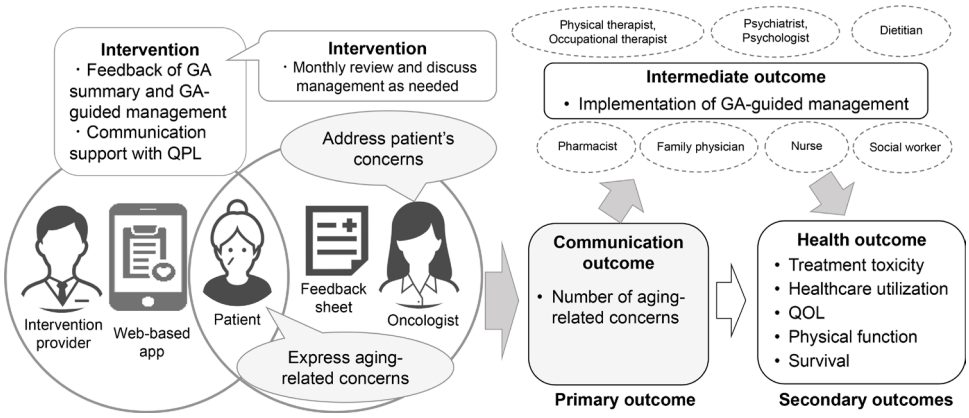

Figure 1 Conceptual model of this study. In our conceptual model, GA will identify ageing-related concerns not captured in routine oncology practice. Then, with communication support using QPL, patients will be able to express their ageing-related concerns to their oncologists, which will facilitate patient-centred communication, thereby leading to higher implementation of GA-guided management and improved patient health outcomes. GA, geriatric assessment; QOL, quality of life; QPL, question prompt list.

Geriatric assessment

All participants will undergo a GA that evaluates eight domains (falls, functional status, psychological status, nutrition, social support, cognition, polypharmacy and comorbidity) using electronic patient-reported measures at baseline (table 2).

These selected assessment tools are based on the American Society of Clinical Oncology guidelines, Japan Clinical Oncology Group geriatric research policy and previous clinical trials.[12 15 22–25] Once these GA measures are entered via a web-based application that was developed in a previous study[26] and customised for the present study, a GA summary and management recommendations tailored to each patient will be generated as a PDF. This summary will contain information on GA impairments and GA-guided management recommendations based on literature reviews, guidelines, previous clinical trials and expert consensus[12 15 22–25 27] (table 3). All assessments, other than cognitive and comorbidity measures performed by the study staff, will be self-administered on a touchscreen tablet. The study staff will assist patients who cannot independently complete the assessment.

Randomisation

Participants will be randomly allocated (1:1) to an intervention arm or a usual care arm (figure 2). Computer-generated random allocation sequences will be provided and centrally controlled by an independent data centre. A stratified block-randomisation method will be used to ensure balanced allocation by study site, cancer type (oesophageal, gastric, colorectal, hepatic, biliary tract or pancreatic) and line of treatment (first or second). Allocation results will be sent electronically to the study staff at each institution. Participants and their oncologists will remain unblinded due to the nature of the interventions.

Intervention

GA summary and management recommendations

In the intervention arm, a GA summary and management recommendations will be presented to the patients and

Table 1 Inclusion and exclusion criteria for patients and oncologists

Participant	Inclusion criteria	Exclusion criteria
Patient	1. Diagnosis of oesophageal, gastric, colorectal, hepatic, biliary tract or pancreatic cancer 2. Incurable disease (locally advanced stage III, IV or recurrent) 3. Age ≥70 years 4. ECOG Performance Status score of 0–2 5. Scheduled to receive first-line or second-line chemotherapy 6. Able to read, write and understand Japanese 7. Provide written informed consent for trial participation 8. Have at least one impairment of GA domains other than polypharmacy at the time of registration	1. Scheduled to undergo surgery within 3 months 2. Participating or planning to participate in other interventional studies for which intervention by this study would be undesirable (eg, other psychological or communication support studies, clinical trials, etc) 3. Judged to have difficulty participating in the study by attending oncologists
Oncologist	1. Currently in clinical practice at participating institutions 2. Oncologists that care for patients with oesophageal, gastric, colorectal, hepatic, biliary tract or pancreatic cancer 3. Not planning to leave the practice during the next 6 months	1. Non-physicians and physicians who are not oncologists

ECOG, Eastern Cooperative Oncology Group; GA, geriatric assessment.

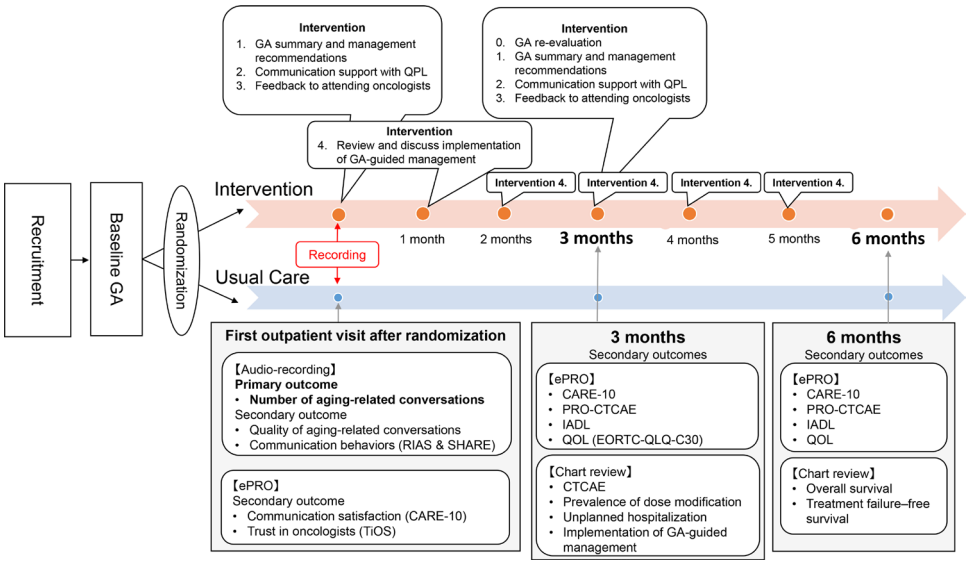

Figure 2 Flow diagram. CARE-10, Consultation and Relational Empathy measure-10; CTCAE, Common Terminology Criteria for Adverse Events; EORTC-QLQ-C-30; European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30-item version; ePRO, electronic-patient reported outcomes; GA, geriatric assessment; IADL, Instrumental Activities of Daily Living; PRO-CTCAE, Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events; QOL, quality of life; QPL, question prompt list; RIAS, Roter interaction analysis system; SHARE, setting, how to deliver bad news, additional information, reassurance and emotional support; TiOS, Trust in Oncologists Scale.

their oncologists at the first outpatient visit after randomisation (figure 2). An intervention provider will explain the GA summary to the patient and then discuss the patient's perceptions of the GA impairments, need for recommended management, resources available at each institution and other specific issues. An intervention provider will prepare a feedback sheet based on information obtained from the patients, including ageing-related concerns and their interest in the recommendations, to reduce oncologists' burden. An intervention provider will present QPL on ageing-related concerns as needed, and the patients can select ageing-related questions from QPL to ask their oncologists. Oncologists will have autonomy to incorporate into their practice whatever recommendations are deemed necessary. The multidisciplinary team at each institution will implement management recommendations with referrals from an oncologist based on clinical judgement. An intervention provider may help implement management recommendations with an oncologist's approval.

Table 2 GA tools

GA domain	Assessment tools	Cut-off points
Falls	History of falls in the past 6 months	Any history of falls
Functional status	The IADL subscale of the Multidimensional Functional Assessment Questionnaire; OARS[30]	Any IADL deficit
Psychological status	Patient Health Questionnaire-9[47]	≥5 points
Nutrition	Mini Nutritional Assessment[48 49]	≤11 points
Social support	Living status and assistance	Living alone and/or without any assistance
Cognition	Mini-Cog[50]	≤2 points
Polypharmacy	Number of medications	≥5 regularly scheduled prescriptions
Comorbidity	Charlson Comorbidity Index[51]	≥3 points

GA, geriatric assessment; IADL, Instrumental Activities of Daily Living; OARS, Older American Resources and Services.

For 5 months after the initial intervention, an intervention provider will review and discuss implementation of GA-guided management recommendations monthly with the patients and their oncologists to implement management as needed. Three months after the initial intervention, the GA will undergo reevaluation, and an intervention provider will provide a GA summary, management recommendations and a feedback sheet to the patients and their oncologists so that GA-guided recommendations can be modified and implemented as needed.

Oncologists will receive a 20-minute lecture on how to most effectively use GA information in their clinical practice for elderly patients with cancer. An in-person group lecture will be provided and include an overview of the usefulness of GA and GA-guided management in oncology.

Communication support using QPL

In this study, a QPL that was developed based on our previous studies[19 28 29] to support shared decision-making

Table 3 GA-guided management recommendations

GA impairments	Recommendations
Any history of falls Any IADL deficit	1.Referral to physical therapy and/or occupational therapy 1–1. Strength and balance training; introduce home exercise programme 1–2. Assist according to IADL disability 1–3. Provide support according to falling risk 2.Referral to medical social workers and/or nurses 2–1. Provide support according to IADL disability 2–2. Evaluate home safety, adjust environmental factors (fall prevention) and use nursing care services 3.Review falling risk due to polypharmacy and adjust medications as needed (referral to pharmacist)
Patient Health Questionnaire-9 ≥5	1.Referral to a psychologist and/or psychiatrist 1–1. Cognitive-behavioural therapy and pharmacotherapy 2.Referral to medical social workers and/or nurses 2–1. Referral to hospital-based psychological support services 2–2. Referral to local social activities (eg, community comprehensive support centre)
Mini Nutritional Assessment ≦11	1.Referral to a dietician 1–1. Assess nutritional status and provide nutritional guidance 1–2. Provide information materials and brochures 1–3. Provide information on nutritional supplements and prescribe nutritional supplements 2. Referral to social workers as needed (assistance with shopping and meal preparation)
Living alone and/or without any assistance	1.Referral to medical social workers and/or nurses 1–1. Apply for long-term care insurance and referral to community comprehensive support centre 1–2. Referral to transportation services, home care/nursing care and support group 1–3. Identify and establish key persons in case of anyone's absence
Mini-Cog ≦2	1. Referral to a cognitive specialist or memory clinic (psychiatrist or neurologist) 1–1. Evaluate decision-making ability and capacity to consent as needed 1–2. Counsel on risk of delirium and reduce medications at risk of delirium 2. Encourage family/caregivers to participate in consultation and treatment decisions 3. Reduce the number of medications or adjust dosage and administration (referral to a pharmacist)
≧5 medications Charlson Comorbidity Index ≧3	1.Referral to a pharmacist 1–1. Reduce the number of medications or adjust dosage and/or administration 1–2. Discontinue PIMs 2.Consult with nurses and/or a pharmacist to confirm adherence 2–1. Determine patient's understanding of medication, missed doses and patient's ability to manage medications and decipher text on a medication bag 3. Involve family and caregiver in treatment decisions and management of comorbidities 4. Review prescriptions and management of comorbidities by family physicians, geriatricians and other specialists

GA, geriatric assessment; IADL, Instrumental Activities of Daily Living; PIMs, potentially inappropriate medications.

for treatment of elderly patients with cancer will be used to facilitate communications with attending oncologists. The QPL consists of 75 questions categorised into 8 topics and a free-writing section for other ageing-related questions based on the opinions of elderly patients with cancer, oncologists and geriatricians (table 4).

Patient communication coaching using the QPL consists of three parts: (1) reading a list and selecting questions that the patient prefers to discuss with their oncologists and prioritising selected questions via a web-based application; (2) discussing the reasons for and background behind selecting the questions and identifying difficult questions to ask and (3) practicing asking their oncologists these questions. Patients are given a 14-page A4 size QPL brochure for reference after the intervention. An intervention provider will prepare a feedback sheet, including a list of selected questions rephrased in the patients' own words, if necessary, for patients to present to their oncologists before the first outpatient visit after randomisation (figure 2).

Three months after the initial intervention, an intervention provider will provide communication support

Table 4 Domains of QPL and sample questions

Domains	Sample questions
1. Diagnosis and disease stage	► May I ask again what the diagnosis is ?
2. Current and future treatment	► Do comorbidities affect treatment or are they made worse by treatment? ► What treatment options do other patients in my situation have?
3. Management of current and possible future symptoms	► Why do the symptoms I am experiencing now occur? How long will they last? ► What are the symptoms or side effects of treatment that may occur in the future?
4. Daily life activities	► Can I discuss long-term care insurance? ► I am concerned about meal preparation and shopping. Are there any services available in my community? ► Do I need to reduce the number of medications I usually take ? ► Can I discuss my lack of appetite, difficulty eating and weight loss? ► I am concerned about future visits to the hospital. Can I discuss transportation service? ► I want to exercise to keep my fitness level up. Can you introduce me to an exercise programme that I can do at home?
5. Care and expected prognosis after standard treatment	► Can I discuss home care and long-term care for the future? ► Can I ask what my future prospects might be?
6. Needs of caregivers	► Can someone listen to my family's concerns and worries?
7. Psychological distress and management	► Can I discuss my concerns and worries? ► I am having trouble enjoying or maintaining interest in things I used to enjoy. Can I discuss this with someone?
8. Values	► Can I tell you what is important to me in choosing treatment and what I really want to prioritise or continue in my life?

QPL, question prompt list.

using QPL and a feedback sheet for patients to present to their oncologists along with their GA results.

Intervention providers will be clinical psychologists, nurses, physicians or hospital staff who have participated in intensive training using an intervention manual. They will hold weekly meetings to review all intervention sessions with supervision by the primary investigator to maintain quality. Intervention providers do not need to have prior experience or training for patient-centred communication. Through our training programme and periodic feedback, even lay hospital staff with little clinical experience will be able to provide the intervention with fidelity.

In the usual care arm, participants will receive usual oncology care. Participants and their oncologists will not receive GA results at the time of registration unless severe cognitive or psychological problems are revealed.

Concomitant treatments will not be restricted.

Stopping rules for participants

The protocol intervention will be discontinued under the following conditions: (1) the attending oncologists deem it necessary to discontinue the intervention, (2) the patient requests discontinuation of the intervention, (3) the patient dies during the intervention period, (4) the patient's condition suddenly deteriorates after registration, (5) a protocol violation or ineligibility is discovered or (6) the patient withdraws consent to participate. The investigator will report the reasons for the discontinuation of the intervention to the data centre. Follow-up assessments, including questionnaires, will continue unless consent is withdrawn.

Assessment measures

Table 5 shows the schedule of outcome measurements.

Primary outcome measure

The primary outcome is the number of conversations about ageing-related concerns during consultation, which is used to evaluate whether the intervention facilitates discussions between patients and their oncologists. At the first outpatient visit within 4 weeks from the baseline GA, the conversation between patients and their oncologist will be audio-recorded and transcribed verbatim. Based on the COACH study,[22] a content analysis framework will be used to assess how to identify ageing-related concerns and whether stated concerns are acknowledged and considered further by the oncologist (quality of discussion) and to determine whether acknowledged concerns motivate implementation of management recommendations. For each transcript, coding will be performed directly by two coders who have received extensive training and supervision by the principal investigator, are blind to the study hypotheses and the allocation and are not involved in any other aspect of the study.

Secondary outcome measures

We will evaluate several health outcomes as secondary outcome measures. Our hypothesis is that the

Table 5 Schedule of outcome measurements

	Baseline	Primary registration	Secondary registration	1st outpatient visit after GA	3 months	6 months	12 months
GA	○				•		
Patient characteristics*		○					
Oncologist characteristics†				△			
Number of ageing-related conversations				◎			
Quality of ageing-related conversations				◎			
RIAS[37] and SHARE[36]				◎			
CARE-10[38 39]				◎	◎	◎	
TiOS[40 41]				◎			
CTCAE					◎		
Prevalence of dose modifications					◎		
Implementation of GA-guided management					◎	◎	
GA evaluation		○					
QPL evaluation				•			
GA+QPL evaluation				△		△	
PRO-CTCAE[33–35]			◎		◎	◎	
IADL[30]			◎		◎	◎	
QOL[31 32]			◎		◎	◎	
Overall survival rate						◎	◎

○ will be evaluated among all participants at the primary registration. ◎ will be evaluated among all participants after the secondary registration. • will be evaluated among participants in the intervention arm. △ will be evaluated among attending oncologists in the intervention arm.
*Patient characteristics include age, gender, highest level of education, employment status, marital status, financial concerns and self-rated health.
†Oncologist characteristics include age, gender, years in practice and years in oncology practice.
CARE-10, Consultation and Relational Empathy measure-10; CTCAE, Common Terminology Criteria for Adverse Events; GA,geriatric assessment; IADL, Instrumental Activities of Daily Living; PRO-CTCAE, Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events; QOL, quality of life; QPL, question prompt list; RIAS, Roter interaction analysis system; SHARE, setting, how to deliver bad news, additional information, reassurance and emotional support; TiOS, Trust in Oncologists Scale.

intervention will facilitate ageing-related communication between patients and their oncologists (primary outcome and proximal outcome), thereby leading to higher implementation of GA-guided management (intermediate outcome), which in turn will lead to improved patient health outcomes (figure 1). We will also evaluate communication outcomes as proximal outcome measures.

Health outcomes

1. Overall survival rate at 6 months and 12 months. Overall survival is defined as the time from randomisation to death from any cause or last contact, whichever is earlier.
2. Treatment failure-free survival, which is defined as the time from randomisation to treatment discontinuation for any cause or last contact, whichever is earlier.
3. Grade 3–5 chemotherapy-related treatment toxicity within 3 months evaluated according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events V.5.0 by physicians and/or nurses.
4. Prevalence of dose modification within 3 months (treatment modification, dose reduction and/or discontinuation).
5. Unscheduled hospitalisation and emergency department visits within 3 months.
6. Functional status using the OARS-IADL questionnaire[30] (electronic-patient reported outcomes (ePRO)) consisting of seven questions rated on a three-point Likert scale; the Japanese version was translated and validated by Ogawa *et al* (unpublished data).
7. Quality of life measured by the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30-item version[31] (ePRO) consisting of 30 items, including functional scales (physical, role, cognitive, emotional and social), global health and Quality of Life (QOL) scale, symptoms scale and/or items (fatigue, nausea and vomiting, pain, dyspnoea, sleep disturbance, appetite loss, constipation and diarrhoea) and financial impact; the Japanese version was validated by Kobayashi *et al*.[32]
8. Core items (12 symptoms) of the NCI's Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events system; the Japanese version[33–35] (ePRO) was linguistically and psychometrically validated by Kawaguchi *et al* and Miyaji *et al*.[34 35]

Communication outcomes

1. Patient-centred communication behaviours will be analysed based on impression ratings by two blinded coders. The analysis will use audio-recorded oncology visits for all participants and assess the total score of the 27 SHARE categories: setting, how to deliver the bad news, additional information, reassurance and emotional support.[36] In addition, patient-preferred communication behaviours will be analysed using the 40 categories of the Roter interaction analysis system (RIAS).[37]
2. Communication satisfaction using the Consultation and Relational Empathy measure[38 39] (ePRO) consisting of 10 items rated on a 5-point Likert scale; the Japanese version was translated and validated by Aomatsu *et al*.[38]
3. Trust in Oncologists Scale[40 41] (ePRO) consisting of five items rated on a five-point Likert scale; the Japanese version was translated and validated by the authors (unpublished data).

Intermediate outcomes

1. The number of geriatric problems successfully addressed for participants in the intervention arm.

Other outcomes

1. Patients' assessment surveys on the burden and usefulness of the intervention, including 'Was it difficult to answer the (GA) questions?', 'Did you feel burdened by the (GA) questions?', 'Did you feel burdened by the intervention (GA+QPL)?', 'Did you find the intervention (GA+QPL) helpful in organising your thoughts?' and 'Did the intervention (GA+QPL) help you talk with your doctor?'.
2. Oncologists' assessment surveys on the burden and usefulness of the intervention, including 'Was the intervention (GA+QPL) useful to you?' and 'Did you feel burdened by the intervention (GA+QPL)?'.

Secondary outcome measures 1–5, and intermediate outcome measure 1 will be collected through medical charts, consulting the oncologists if needed. Secondary outcome measures 6–8, communication outcome measures 2 and 3 and other outcome measure 1 will be collected through ePRO using a touchscreen tablet. Secondary other outcomes measure 2 will be collected using a paper form for the convenience of attending oncologists.

Harms

No specific serious adverse events are anticipated for participants in this study. Patients will be subjected to time burdens of 30–40 min for the study intervention and 10–20 min for the GA as well as baseline and follow-up questionnaires. There is no direct financial cost associated with study participation, but we recognise that patients are donating their time to participate. Patients will not be compensated for their participation.

Compensation

If patients develop any unforeseen health issues due to study participation, they will be adequately treated according to standard medical care as covered by National Health Insurance.

Sample size estimation

Sample size and power considerations are based on the primary outcome of the number of conversations about ageing-related concerns. In our preliminary study (unpublished data) of 40 Japanese elderly patients with cancer, the number of ageing-related concerns discussed during their consultations was 1.4

in the usual care arm and 2.3 in the intervention arm (SD 1.3). Along with the results of a previous study on communication in Japanese patients with cancer,[19] we defined the clinically minimally important difference in the number of ageing-related conversations as 1.0. The design has 80% power with a significance level of 0.05 (two-sided) to detect a difference of 1.0 in the number of conversations about ageing-related concerns with an SD of 2.5. Assuming a 5% withdrawal rate, 210 is the targeted accrual.

Statistical analysis

In accordance with intention-to-treat principles, the primary outcome will be analysed to examine the intervention effect parameters for all randomly assigned subjects. To compare categorical variables, Fisher's exact tests will be used. Continuous measures will be compared using the Wilcoxon rank-sum test. Overall survival and treatment failure-free survival will be estimated using the Kaplan-Meier method and compared using log-rank test. No interim analysis is planned.

Missing data

Every effort will be made to facilitate participants' completion of questionnaires, but missing data will inevitably occur due to dropout. We will evaluate the patterns of missing data and associations of missingness with other available variables. Based on the missing at random assumption, the parameter estimates from the mixed-model analyses should be unbiased. However, if the data are suspected of being missing not at random, a sensitivity analysis using selection and/or pattern-mixture models will be performed to determine the impact on the results. If the estimates are similar to the ones obtained from the simpler analysis of only complete cases, we will report the complete-case analysis results.

Patient and public involvement statement

This study protocol was co-designed by a patient with cancer and family member of a patient with pancreatic cancer, and was reviewed by patient and public involvement (PPI) representatives. PPI representatives will help our team disseminate the results of this study. The QPL was reviewed and revised based on comments from elderly patients with cancer who were treated at the National Cancer Center in Tokyo.

Data management, central monitoring, data monitoring and auditing

Except for audio-recorded data, all data will be collected through electronic data capture (EDC) and ePRO systems. Paper questionnaires will be used for patients with physical or cognitive limitations. Data management and central monitoring will be performed by the J-SUPPORT Data Science Team using EDC Viedoc (Viedoc Technologies AB, Uppsala, Sweden). No auditing is planned for this study.

Publication policy

The protocol and study results will be submitted to peer-reviewed journals. The first author of the main paper should be a member of the steering committee. The list of coauthors will be determined prior to submission of each paper.

Ethics and dissemination

This study protocol was reviewed and approved by the protocol review committee of Japan Supportive, Palliative and Psychosocial Oncology Group as a J-SUPPORT 2101 study and the institutional review boards at each participating institution. This study will be conducted in accordance with 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 ethical principles for research on human subjects stipulated in the Declaration of Helsinki and its amendments. If important protocol modifications are necessary, the investigators will discuss and report them to the review committee for approval. With regard to dissemination, the results obtained will be submitted to peer-reviewed journals. The main and relevant findings will be presented at conferences.

DISCUSSION

Our intervention programme is unique in combining a GA summary and management recommendations with communication support using a QPL. Several RCTs in the USA have demonstrated the efficacy of GA and GA-guided management for elderly patients with cancer.[12 22 23] There seems to be two core components of GA-guided management among these trials: (1) stratifying elderly patients with cancer based on GA results in order to select appropriate treatment and (2) intervening in impaired GA domains with a multidisciplinary team.[27] This study focuses on GA-guided management by a multidisciplinary team. In prior studies, limited implementation of GA management recommendations did not improve patient outcomes, even when GA results and management recommendations were presented to attending oncologists.[42 43] To improve patient outcomes, it is necessary to successfully implement GA-guided management.

This study is expected to provide new evidence building on the COACH study, which demonstrated that feedback in the form of a GA summary and GA-guided management recommendations to patients and their oncologists facilitates communication about ageing-related concerns.[22] Our study differs from the COACH study in the following ways: (1) an intervention provider will review and discuss GA results and GA-guided management recommendations with patients and then provide a feedback sheet based on information derived from the patients in order to reduce the oncologists' burden, (2) an intervention provider will provide communication support using QPL and help patients communicate ageing-related concerns

to their oncologists and (3) an intervention provider will meet with the patients and oncologists monthly to review and facilitate implementation of GA-guided management as needed. We hypothesise that our intervention combining a GA summary and management recommendations with communication support using QPL will facilitate patient-centred communication about ageing-related concerns, even among Japanese elderly patients with cancer who are less likely to express their values and preferences to their oncologists, thereby leading to successful implementation of GA-guided management. Previous studies in the USA have shown that older, non-White, lower-income or less-educated patients tend to ask their physicians fewer questions, resulting in less effective communication.[44–46] Therefore, we believe that our intervention, if proven effective, would benefit not only Japanese elderly patients with cancer but also other vulnerable populations who may be less likely to express their concerns to their oncologists, thereby contributing to reducing healthcare disparities.

No data exist on whether an increased number of ageing-related conversations will improve QOL, maintain physical function, decrease treatment-related toxicities and prolong patient survival. However, we chose the number of ageing-related conversations as the primary outcome for this study because GA-guided management will not be implemented in daily oncology practice, and thus not lead to the improvement of patient outcomes, unless these problems are well recognised and shared between patients and their oncologists.

In this study, trained intervention providers will perform the GA+QPL intervention in an interview format over 30–40 min. For future implementation of the intervention programme, in addition to the study's web-based system on a touch-panel screen, electronic media such as AI-navigated self-administered GA and communication support might be more applicable to reducing burdens of time and human resources.

Study strengths and limitations

The main strength of our study is that communication support using QPL is combined with GA. This approach is expected to facilitate patient-centred communication regarding ageing-related concerns, even among vulnerable populations who are generally less likely to express their values and preferences to their oncologists. This study has three methodological limitations. First, due to the nature of the intervention, both patients and their oncologists would be aware of the allocated arm, which could potentially influence care during treatment. We have not chosen a cluster-randomised study design, so there might be a risk of contamination in that oncologists could learn from the intervention model and apply that knowledge to other patients, given that they will be exposed to both arms. However, we consider this risk to be low because it is unlikely for oncologists to identify ageing-related problems unless GA is performed; ageing-related concerns are not captured by routine oncology assessments.[15 22] Actually, GA is not performed in routine oncology practice at the participating institutions. Second, because the intervention programme is complex and consists of multifactorial components, each component's contribution to the outcomes would be hard to ascertain. Third, because this study is limited to patients with gastrointestinal cancers, its generalisability to other cancers will not be clarified.

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Contributors MF is the principal investigator. AM is the project manager. MF, AM, BN, AT, TO, YM, FN and YU developed the intervention programme, including the question prompt list, the geriatric assessment summary and management recommendations. MF, AM, BN, AT, KM, AT, TS, AO, TM, YM, FN and YU participated in the study design. KM played a chief role in developing the statistical parts. AO and TM played roles in the data management. MF and AM drafted the manuscript. All authors prepared the protocol, agree with the final protocol and revisions and participated in, read and approved the final manuscript.

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Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval The protocol was reviewed and approved by the Institutional Review Board of the National Cancer Center on April 15, 2021 (ID: 2020-592) as well as by the J-SUPPORT Scientific Advisory Board. The patient consent form is attached to this submission as Appendix A, B.

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