BMJ Open

COMPrehensive geriatric AsseSSment and multidisciplinary team intervention for hospitalised older adults (COMPASS): a protocol of pragmatic trials within a cohort

Jung-Yeon Choi ,[1] Ji Yeon Lee ,[2] Jaeyong Shin,[3] Chang Oh Kim ,[4] Kwang Joon Kim ,[4] In Gyu Hwang ,[5] Yun-Gyoo Lee ,[6] Su-Jin Koh ,[7] Soojung Hong,[8] Sol-Ji Yoon ,[9] Min-gu Kang ,[10] Jin Won Kim ,[1] Jee Hyun Kim,[1,11] Kwang-il Kim [1,11]

To cite: Choi J-Y, Lee JY, Shin J, *et al*. COMPrehensive geriatric AsseSSment and multidisciplinary team intervention for hospitalised older adults (COMPASS): a protocol of pragmatic trials within a cohort. *BMJ Open* 2022;**12**:e060913. doi:10.1136/bmjopen-2022-060913

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-060913).

Received 07 January 2022
Accepted 17 July 2022

For numbered affiliations see end of article.

Correspondence to
Kwang-il Kim;
kikim907@snu.ac.kr

ABSTRACT

Introduction There is an increased demand for services for hospitalised older patients with acute medical conditions due to rapidly ageing population. The COMPrehensive geriatric AsseSSment and multidisciplinary team intervention for hospitalised older adults (COMPASS) study will test the effectiveness of comprehensive geriatric assessment (CGA) and multidisciplinary intervention by comparing it with conventional care among acute hospitalised older adults in Korea.

Methods and analysis A multicentre trial within a cohort comprising three substudies (randomised controlled trials) will be conducted. The intervention includes CGA and CGA-based multidisciplinary interventions by physicians (geriatricians, oncologists), nurses, nutritionists and pharmacists. The multidisciplinary intervention includes nutritional support, medication review and adjustment, rehabilitation, early discharge planning and prevention of geriatric syndromes (falls, delirium, pressure sore and urinary retention). The analysis will be based on an intention-to-treat principle. The primary outcome is living at home 3 months after discharge. In addition to assessing the economic effects of the intervention, a cost-utility analysis will be conducted.

Ethics and dissemination The study protocol was reviewed and approved by the ethics committees of Seoul National University Bundang Hospital and each study site. The study findings will be published in peer-reviewed journals. Subgroup and further in-depth analyses will subsequently be published.

Trial registration number KCT0006270.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The multicentre trials within the cohort study will evaluate the clinical effectiveness and health outcomes of comprehensive geriatric assessment (CGA) and CGA-based multidisciplinary team intervention for acute hospitalised older patients in various clinical settings.
⇒ The study will compare clinical effectiveness of the CGA and CGA-based multidisciplinary interventions, including nutritional support, medication adjustment, rehabilitation, discharge care plan, geriatric syndrome prevention (falls, delirium, pressure sore and urinary incontinence), with conventional care.
⇒ This pragmatic study will compare multicomponent intervention by an interdisciplinary team with usual care in various clinical settings; thus, this study's result will confirm the clinical effectiveness of CGA-based multidisciplinary intervention in real-world clinical practice conditions.
⇒ This pragmatic trials within cohort design has inevitable limitation of heterogeneity between substudies and institutions despite we will adjust potential confounding prerandomisation variables.
⇒ This study will be conducted in Korea, and the findings may not be generalisable to other countries due to the different healthcare systems.

INTRODUCTION

Comprehensive geriatric assessment (CGA) is a multidimensional, interdisciplinary assessment for evaluating older patients' medical, psychological, physical functions and social status. It aims to detect unidentified and potentially reversible problems and develop a coordinated and integrated management plan for treatment and long-term follow-up care.[1] Previous studies have suggested that CGA-based multidisciplinary care is superior to conventional care in reducing the risk of mortality or institutionalisation and improving functional capacity.[2 3] However, there was a difference in the effect between wards and teams, and no randomised controlled trial has been completed in an acute care setting in Korea.

Geriatric medical professionals and multidisciplinary teams for older inpatient management are rare in Korea (with less than 10 academic hospitals), and detailed protocols vary between institutions. Furthermore, a hospitalist system was introduced in 2016 to improve the quality of in-patient care in Korea.[4] Although CGA-based multidimensional intervention is the accepted gold standard in care for older hospitalised patients with frailty, CGA-based intervention needs to be verified in Korea due to differences in insurance and healthcare systems. The shortage of geriatric consultants or practitioners caring for hospitalised older patients is also one of the biggest problems in other countries. Therefore, it is necessary to validate the effect of CGA-based multidimensional intervention in the setting with or without geriatricians.[5]

Randomised controlled trials (RCTs) are considered the gold standard for generating high-quality evidence for the efficacy of an intervention. However, RCT design is sometimes criticised due to its limited external validity, resulting from difficulties and restricted environments in patient recruitment. Consequently, pragmatic trials, aiming to guide decision-making in clinical practice, were proposed.[6] As an implementation of both pragmatic trials and RCT concepts, trials within cohorts (TwiCs) enable researchers to conduct several randomised trials using conventional care comparators within a cohort.[6]

The COMPrehensive geriatric AsseSSment and multidisciplinary team intervention for hospitalised older adults (COMPASS) was set up according to the TwiCs design. COMPASS aims to compare the clinical efficacies of CGA-based multidisciplinary team intervention and conventional care for prefrail or frail older patients hospitalised in an acute care setting. COMPASS study targeted multiple domains; medical optimisation for multimorbidity, early mobilisation or physical rehabilitation to reduce functional decline, prevention of geriatric syndromes, medication management, nutritional intervention and discharge planning to prevent readmission.

We hypothesised that the CGA-based multidisciplinary team intervention increases the likelihood that patients will be living at home 3 months after discharge (primary outcome). Reduction in the total number of medications or inappropriate medications, length of hospital stay, readmission, all-cause mortality, quality of life, length of days living at home, geriatric syndrome incidence during hospitalisation, emergency department visits, functional status, cost-utility analysis tand other indicators will be assessed as secondary outcomes.

METHODS AND ANALYSIS

Trial design

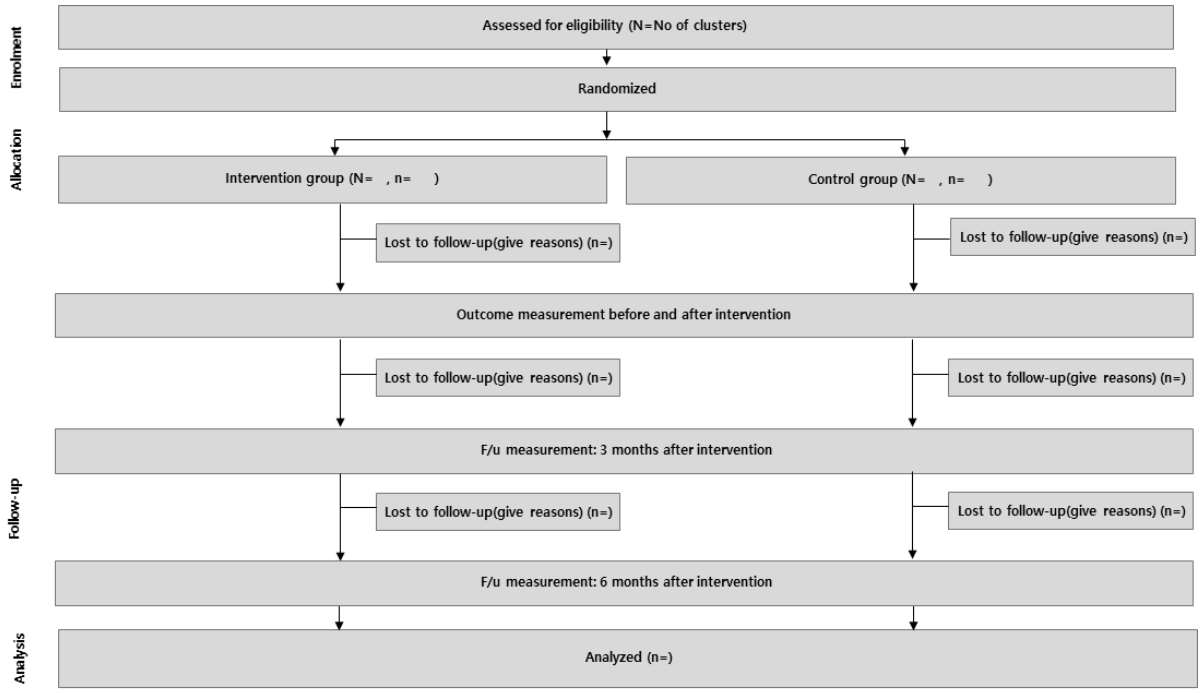
The COMPASS study will adopt the TwiCs design with three RCT substudies. Each substudy will recruit patients from institutions (COMPASS-ER: two hospitals, COMPASS-IN: two hospitals, COMPASS-ONCO: five hospitals). COMPASS-ER compares the effect of a proactive multidisciplinary team intervention model based on the CGA to that of conventional treatment for patients admitted through the emergency department. COMPASS-IN compares the geriatrician-led care (multidisciplinary team intervention model based on the CGA) to the hospitalist-led care (conventional treatment) for hospitalised older patients. COMPASS-ONCO compares the effect of an oncologist-led multidisciplinary team intervention based on the CGA to that of conventional treatment for older cancer patients without the involvement of geriatricians. The patients will be randomised into the intervention or control groups in a 1:1 ratio. Randomisation will be performed through a web-based system according to the pre-embedded, computer-generated, permuted blocks with stratification. Allocation concealment will be secured by preventing researchers from assigning groups using the central system. The recruitment of participants started on 2 November 2021. This study will follow the Consolidation Standards of Reporting Trials (figure 1).[7]

Participants and setting

The study participants are hospitalised older patients with acute medical problems. The inclusion criteria are as follows: (1) 65 years of age or older, (2) prefrail or frail status assessed by Korean version of the Fatigue, Resistance, Ambulation, Illnesses and Loss of Weight scale (K-FRAIL) questionnaire,[8] (3) having two or more of the following diseases; hypertension, diabetes, ischaemic heart disease, chronic lung disease, arthritis, stroke, depression, chronic kidney disease and dementia, (4) living at home for more than 3 months before hospitalisation, (5) (for COMPASS-ONCO only) subject to conventional primary chemotherapy because local treatment for curative purposes (such as surgery, concurrent chemoradiotherapy and radiation therapy) is ineligible (stage 3 or higher) and (6) (for COMPASS-ONCO only) histologically confirmed cancer (gastric adenocarcinoma, colorectal adenocarcinoma, non-small cell and small cell lung cancer, pancreatic adenocarcinoma or biliary adenocarcinoma).

The exclusion criteria are as follows: (1) planned hospitalisation in the specialised care unit, such as an intensive care unit and/or acute stroke ward, at the time of admission, (2) terminal status requiring hospice or palliative care, (3) life expectancy of 6 months or less, (4) other severe conditions that limit the participation in the research, (5) (for COMPASS-ONCO only) oral targeted therapy as a palliative first-line chemotherapy and (6) (for COMPASS-ONCO only) recurrence within 6 months after adjuvant chemotherapy.

Informed consent will be obtained from the patients. At the sponsor's request, consent for third party provision of research data and use of secondary ancillary research will be additionally obtained. Participants were recruited from 2 November 2021, and recruitment will continue until December 2024.



N: No of clusters; n: No of participants

Figure 1 Flow diagram of inclusion and randomisation of study participants. N, number of clusters; n, number of patients.

Interventions

The intervention comprises the CGA and CGA-based multidisciplinary interventions. A description of the adapted CGA and multicomponent intervention is shown in table 1.

Comprehensive geriatric assessment

The CGA includes the collection of information on sociodemographic characteristics, functional status (activities of daily living (ADL)[9] and instrumental activities of daily living[10]), comorbidities (the Charlson Comorbidity Index[11]), history of falls, delirium and pressure sores, a medication review, grip strength, timed up-and-go test (TUGT), nutritional status (Mini Nutritional Assessment (MNA) or MNA short form (MNA-SF)),[12] cognitive function (Korean-mini mental state examination 2 (K-MMSE 2))[13] and mood (Korean Version of Short Form Geriatric Depression Scale (SGDS-K)).[14] The CGA will be administered by geriatric advanced practice nurses (APN) or registered nurses (RN) at baseline. The CGA, in our experience, takes approximately 45–60 min based on the cooperation of the older patients.

CGA-based multidisciplinary intervention

The standardised geriatric management protocol will be delivered based on the CGA results; the predefined evidence-based intervention is described in table 1. The multidisciplinary intervention team will comprise a geriatrician, nurse, case manager, pharmacist and nutritionist. Physicians will request consultations with a healthcare professional if it is difficult to assemble a multidisciplinary team with all members. For the COMPASS-ONCO substudy, the oncologist will be the principal investigator instead of a geriatrician.

RN or APN will monitor whether the individualised intervention plan is properly applied based on the CGA results for the participant randomised to the intervention group. The recommended intervention strategy will be communicated to the multidisciplinary team. The intervention team will implement all recommendations as much as possible to facilitate adherence.

Comparison

Patients in the control group will receive conventional care provided by the study hospital. Since a structured CGA will not be implemented, consultations will be allowed without any restriction if physicians in charge determine that there is a specific problem.

Outcome measures

This study aims to assess the clinical effectiveness and cost-effectiveness of the CGA-based multidisciplinary intervention. The primary outcome is living at home 3 months after discharge. Living at home at 3 months is the odds of participants being alive and in their own home 3 months after discharge. The secondary outcomes are living at home 6 months after discharge, the total number of medications reduced or inappropriate medications at discharge, length of hospital stay, unplanned readmission, all-cause mortality and quality of life. In addition, length of days living at home, the incidence of geriatric syndromes during hospitalisation, emergency department visits after discharge, functional status at 3 months after discharge and cost-utility will be assessed

Table 1 Overview of comprehensive geriatric assessment and multidisciplinary team intervention

Domain	Assessment tool and risk criteria	Assessor/provider	Intervention
Nutrition	MNA≤ 23	Nutritionist	Dietary change and education (patient/caregiver)
	MNA-SF≤ 11	APN	Oral nutritional supplements
		RN	Protein/amino acid replacement
			Dysphagia assessment and rehabilitation if needed
			Tube feeding
			Dental care
Medication	Potentially inappropriate medication list	Pharmacist	Education (institution/patient/caregiver)
	Polypharmacy (≥10)	APN	Medication reconciliation
		RN	
		Physician	Deprescription
Rehabilitation	TUGT≥ 10 s	APN	Early ambulation/rehabilitation
	Grip strength (<28 kg in male, <18 kg in female)	RN	Transfer to rehabilitation medicine
	ADL/IADL dependency	Physician	
Discharge care plan		APN	Identify decision-makers among family members and preferred discharge location
		RN	Check financial and social situation
		Physician	Discharge care planning and consultation
			Consult with hospital transfer centre or home health nursing centre
Geriatric syndrome (falls, delirium, sore, urinary incontinency)	(Falls) Hendrich II fall risk model≥5, John's Hopkins fall risk assessment tool≥14, history of falls, TUGT≥ 10s	Nutritionist	(Falls)
		Pharmacist	Fall prevention education handouts for patient and caregiver
		APN	Early ambulation/exercise
		RN	Consultation to rehabilitation medicine
	(Delirium) history of delirium, K-MMSE 2≤ 26, age≥80	Physician	(Delirium)
			Non-pharmacological delirium prevention (medical optimisation, pain control, sleep hygiene)
			Deprescribing for medications that potentially cause delirium
	(Sore) Braden scale≤18		(Sore)
			Nutritional support
			Frequent positioning and application of pressure relief aids
			Consultation to pressure sore management team or plastic surgery
	(Urinary incontinence) indwelling urinary catheter		(Urinary retention)
			Identification of urinary retention (infection)
			Residual urine volume check after catheter removal
			Education for clean intermittent catheterisation
			Medication treatment if needed

ADL, activities of daily living; APN, advanced practice nurse; IADL, instrumental activities of daily living; MMSE, Mini-Mental State Examination; MNA, Mini Nutritional Assessment; MNA-SF, Mini Nutritional Assessment Short Form; RN, registered nurse; TUGT, timed up-and-go test.

for secondary outcomes. Quality of life will be assessed by Korean version of EuroQol- 5 Dimension and functional status will be measured by ADL.[15]

In addition to the outcomes measured in the entire COMPASS study, additional outcomes will be measured in the substudies. In the COMPASS-IN study, the readiness for hospital discharge,[16] family interaction,[17] a therapeutic alliance between patient and provider[18] and empowerment[19] will be investigated, and frailty status will be followed-up at 3 and 6 months.[8] In the COMPASS-ONCO study, overall treatment utility, recognition of advance directives, changes in body composition and validity of anticancer drug toxicity prediction model will also be assessed.[20] Overall treatment utility is a clinical outcome incorporating objective and subjective measures of anticancer efficacy, tolerability and acceptability.[21]

A cost-utility analysis will be conducted. For cost analysis, medical costs and programme operating costs will

be assessed. From insurer's perspective, the medical cost is primarily defined that official or direct medical cost, including out-of-pocket expenditures, copayment from insurance. In addition, we also perform sensitivity analysis considering the perspective of limited healthcare system including long-term care costs and nursing expenses based on the indirect data from the nationally representative data, the Korea Health Panel Survey and the Korean Longitudinal Study of Ageing.[22 23] Finally, medical costs will be evaluated based on the difference in the healthcare expenses between the intervention and control groups. Based on the fee for service reimbursement system, the medical cost can be calculated by adding the costs of all medical treatments, examinations and other input resources microscopically. The programme's cost will be determined using the data of the participating institutions. The duration of participation of the healthcare professionals in the intervention team will be assessed by medical staff by asking for the additional time used for the intervention. The minute-wise cost of the programme will be determined by the wages of the healthcare professionals and the duration of participation in the intervention team. The index of clinical effectiveness will be used as the reference in the cost-utility analysis. The results will be analysed as incremental cost-utility ratios.

We will design model of natural history of discharge outcomes in geriatric patients. Then, we will observe type of complications, its duration of state and its related quality of life. Also, transition probability to each pathway will be calculated with cost. After developing the analytic model, we will set virtual cohort of the aged 65 with 100 000 populations. It is planned to perform 35 annual cycles, to reach 100-years old, with half-cycle correction with equal weight. Discount rate will be 3% annually. To consolidate the results, we will consider different discount rates including 0%, and 5% as sensitivity analyses (table 2)

Data collection and management

Research assessors registered in this study will collect data according to the standardised protocol. A 4-hour educational programme consisting of the study overview, measurement tools and practice sessions with scenarios will be provided for the assessors before data collection. All patients in the intervention and control groups will be evaluated with baseline tests before intervention or observation (T_1). At discharge, the second assessment (T_2) will

Table 2 Outcome variables

Domain	Variable	Source (target population)	Outcome Type	Timeline t_1	t_2	t_3	t_4
Clinical effectiveness							
	Living at home	Survey and EMR	Primary and secondary			X	X
	Inappropriate medications	Survey and EMR	Secondary	X	X		
	Total number of medications	Survey and EMR	Secondary	X	X		
	Length of hospital stay	Survey and EMR	Secondary		X		
Healthcare utilisation							
	Readmission and visit to emergency department	Survey and EMR	Secondary			X	X
	Mortality	Survey and EMR	Secondary				X
	Quality of Life	Survey using EQ-5D	Secondary	X		X	
	Length of days living at home	EMR	Secondary				X
	Geriatric syndrome during hospitalisation	Survey and EMR	Secondary		X		
	Activities of daily living	Survey and EMR	Secondary	X		X	
	Readiness for hospital discharge (only in COMPASS-IN)	Survey	Secondary		X		
	Family interaction (only in COMPASS-IN)	Survey	Secondary		X		
	Therapeutic alliance (only in COMPASS-IN)	Survey	Secondary		X		
	Empowerment (only in COMPASS-IN)	Survey	Secondary		X	X	
	Frailty (only in COMPASS-IN)	Survey and EMR	Secondary			X	X
	Overall treatment utility (only in COMPASS-ON)	Survey and EMR	Secondary			X	
	Recognition of advance directive (only in COMPASS-ON)	Survey	Secondary		X		
	Changes in body composition (only in COMPASS-ON)	Survey and EMR	Secondary	X		X	X
Economic effectiveness	Economic evaluation	Survey using EQ-5D, ADL	Secondary	X		X	

t_1, before intervention measurement (baseline); t_2, after intervention measurement (at discharge); t_3, follow-up measurement (3 months after discharge); t_4, follow-up measurement (6 months after discharge).
ADL, activities of daily living; COMPASS, COMPrehensive geriatric AsseSSment and multidisciplinary team intervention for hospitalised older adults; EMR, electronic medical record.

Table 3 Schedule of enrolment, interventions and assessments

	Study period					
	Enrolment	Allocation	Post-allocation			Close-out
Timepoint	$-t_2$	$-t_1$	t_1	t_2	t_3	t_4
Enrolment						
Eligibility screen	X					
Informed consent	X					
Allocation		X				
Interventions						
CGA-based multicomponent intervention			⟷			
Assessments						
Primary outcomes (clinical effectiveness)					X^a	
Secondary outcomes	X^{b-1}		X^{b-2}	X^{b-3}	X^{b-4}	X^a, X^{b-5}
Economic evaluation				X^c	X^c	

t_1, baseline (before intervention measurement); t_2, discharge (after intervention measurement); t_3, follow-up measurement (3 months after discharge); t_4, follow-up measurement (6 months after discharge); X^a, living at home; X^{b-1}: frailty; X^{b-2}, quality of life, recognition of advance directive and changes in sarcopenic obesity, activity of daily living; X^{b-3}, medication management, length of hospital stay, geriatric syndrome during hospitalisation, readiness for hospital discharge, family interaction, connectedness, empowerment; X^{b-4}, quality of life, activity of daily living, overall treatment utility, recognition of advance directive and changes in sarcopenic obesity, healthcare utilisation, empowerment, frailty; X^{b-5}, overall treatment utility, recognition of advance directive and changes in sarcopenic obesity, healthcare utilisation, frailty; X^c, cost-effectiveness analysis.
CGA, comprehensive geriatric assessment.

be conducted. Follow-up assessments will be conducted for 3 months±4 weeks (T_3) and 6 months±4 weeks (T_4) after discharge. A research assessor will conduct T_1 and T_2 measurements at hospital before the participants' discharge. After discharge, T_3 and T_4 measurements will be conducted by face-to-face personal interview at an outpatient clinic. However, a telephone interview will be used if the participants cannot visit the clinic. A summary of the main measures at the patient level and the corresponding timetable is shown in table 3.

Data will be recorded in hardcopy at the time of the measurement and subsequently entered electronically in iCReaT (http://icreat.nih.go.kr), a web-based clinical research management system developed by the Korea National Institute of Health. Automatic checks will be applied when entering the data based on predetermined ranges. Missing data will also be automatically detected, and data query reports will be sent to the local data manager. The data managers will ask the assessors for correction or clarification if any errors are found in the data. Furthermore, to promote follow-up and retention, assessors will report any issues with the patients. A brief short-form report will be generated and submitted if there is a discontinuation of research participation. All patients will be assigned a unique research ID, and the research team will train the assessors to secure the research data to maintain its safety. The data collection forms will not contain any identifiable personal information. An electronic password-protected file will be saved on a password-protected computer. The final data set will be retrieved by the iCReaT.

The data monitoring committee comprises investigators independent of the clinical investigation team and includes a team member who manages the data quality. This committee will meet once when 50% of the planned recruitment has occurred. The data sets that will be generated and/or analysed during the current study are not publicly available but are available from the sponsor on reasonable request.

The data centre of the Korean Cancer Study Group, which is independent of the investigators and sponsor, will design an electronic case report form (CRF) based on the paper CRF, invented by the clinical investigator. Data monitoring will also be conducted through site initiation, routine monitoring and site close-out visits. The principal investigator will review and report any serious adverse event to the Seoul National University Bundang Hospital (SNUBH) Institutional Review Board (IRB). A serious adverse event refers to an intensive care unit admission, death or other consequences of permanent or significant disability or impairment.

Patient and public involvement

There was no patient or public involvement in the design and conduct of this study.

Sample size

The sample size is calculated as follows: statistical power is calculated based on the primary clinical outcome (being alive and residing at home 3 months after discharge). We assume the clinical effectiveness of the CGA-based multidisciplinary intervention based on the results of a previous study.[24] A total sample of 882 participants will be

required. Approximately 1040 patients will be required for this study, anticipating a 15% dropout rate. The test statistic used is the two-sided Fisher's Exact Test, with an alpha of 0.05 and a probability of 0.01 for beta error (90% power). The power analysis and sample size calculations are performed using PASS 14.0 (NCSS LLC, Kaysville, UT).

Randomisation

This study uses a trial within cohorts with an un-blinded stratified randomised design. The unit of randomisation is the patient. We will conduct systematic randomisation using a random table generated by one of the researchers not involved in collecting the data from participants. The random table is embedded in iCReaT (http://icreat.nih.go.kr). Random tables have been generated for (1) substudies 1 and 2 and (2) substudy 3. Randomisation will be stratified with (1) substudy (in substudies 1 and 2), (2) institutions and (3) cancer type (in substudy 3). Patients will be allocated into the intervention and control groups with a 1:1 ratio. The final data set is coded for blinding for randomisation, and the analysis will be done with blinded until the end of the effectiveness evaluation.

Statistical analysis

Both descriptive and inferential statistics will be used. The baseline patient characteristics will be summarised for each group using descriptive statistics. Baseline differences will be evaluated using the independent t-test for continuous variables, and the χ^2 test or Fisher's exact test will be used for dichotomous or categorical variables. Two-sided p-values of <0.05 will be considered statistically significant. Any potential confounding factors of the groups will be considered for inclusion in the multivariable analysis. The main analysis is conducted based on an intention-to-treat principle. We will include the potential confounding prerandomisation variables as confounders in the regression model for the secondary analysis to derive the confounder-adjusted intervention effect. We will apply a multilevel regression analysis and a generalised linear mixed-effects model, including fixed factors (time, intervention) and random factors to account for the cluster data structure. Two random effects will be included, one at the institutional (cluster) and the other at the patient (individual) level. We will implement imputation or conduct sensitivity analysis to adjust for missing data for each analysis. Sensitivity analyses will also be conducted on the effect of attrition and the inclusion of patients and subgroup analyses to examine the difference in sub-study or institution.

ETHICS AND DISSEMINATION

This study is registered with the Clinical Research Information Service Registry. The study is sponsored by a grant of Patient-Centered Clinical Research Coordinating Center (PACEN) funded by the Ministry of Health and Welfare, Republic of Korea (grant number: HC20C0086) and centrally managed by staff at SNUBH. The sponsors had no role in the design, methods, participant recruitment, data collection and analysis or preparation of the article. The protocol was first reviewed and approved by the SNUBH IRB on 26 April 2021. Further protocol revision was followed by final approval on 30 November 2021 for the informed consent form, correction of typographical errors, addition of assessment items and clarification of inclusion criteria (IRB No. B-2104/676-001). The current protocol version is version 1.4. The corresponding author and the researchers of this study will have access to the data set. Further dissemination of the data set can be decided by the corresponding author.

The CGA-based multicomponent intervention may not have positive effects, but the risk of negative effects on patient outcomes is limited. All participants and their guardians (only if the participants lose their ability to make decisions) will sign an informed consent form. After the trial, the data will be analysed, and the study findings will be published in major peer-reviewed journals.

DISCUSSION

To the best of our knowledge, this is the first pragmatic multicentre trial focusing on CGA and multidisciplinary intervention for hospitalised older patients in various healthcare settings of Korea. This individualised geriatric intervention seems to be a promising approach for maintaining functional status and staying in their home instead of institutionalisation. Our study design is similar to that of real clinical settings, considering the difference in the availability of medical resources between medical centres. This type of trial design could provide more meaningful information on which healthcare decision-making could be based.

Despite the strength of our study, the pragmatic TwiC design present some inherent limitations. First, heterogeneity between substudy and institutions is inevitable because multicentre three substudy will be conducted. Even though we will adjust potential confounding prerandomisation variables as confounders in the regression model to derive the confounder-adjusted intervention effect, there may be confounding factors that could not been measured. Second, a pragmatic trial design designed to show the real-world effectiveness of the intervention in broad patient groups may improve external validity. However, internal validity is less likely to be guaranteed than traditional RCT design.

Author affiliations
[1]Internal Medicine, Seoul National University Bundang Hospital, Seongnam, Korea
[2]Yonsei University College of Nursing, Seoul, Korea
[3]Preventive Medicine and Institute of Health Service Research, Yonsei University College of Medicine, Seodaemun-gu, Seoul, Korea
[4]Internal Medicine, Yonsei University College of Medicine, Seodaemun-gu, Korea
[5]Internal Medicine, Chung-Ang University College of Medicine, Dongjak-gu, Seoul, Korea
[6]Internal Medicine, Kangbuk Samsung Hospital, Sungkyunkwan University School of Medicine, Seoul, Korea

[7]Hematology and Oncology, Ulsan University Hospital, Ulsan University College of Medicine, Ulsan, Korea
[8]Internal Medicine, National Health Insurance Service, Ilsan Hospital, Goyang, Korea
[9]Internal Medicine, Kangwon National University Hospital, Chuncheon, Kangwon, Korea
[10]Internal Medicine, Chonnam National University Bitgoeul Hospital, Gwang-ju, Korea
[11]Internal Medicine, Seoul National University College of Medicine, Seoul, Korea

Contributors J-YC, K-iK, JYL, IGH, JS and Y-GL drafted the manuscript. J-YC, JYL, JS, COK, KJK, IGH, Y-GL, S-JK, S-JY, M-gK, JWK, SH, JHK and K-iK contributed to the study design, data collection and critical revision of the manuscript. J-YC, K-iK, JYL, IGH, COK, KJK, JWK, S-JY, SH and M-gK contributed to the study design and critical revision of the manuscript. K-iK, JYL, IGH and J-YC contributed to the study concept. All authors reviewed and approved the manuscript and agreed to be accountable for all aspects of the work.

Funding The study is sponsored by a grant of Patient-Centered Clinical Research Coordinating Center (PACEN) funded by the Ministry of Health & Welfare, Republic of Korea (Grant number: HC20C0086).

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting or dissemination plans of this research.

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

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iDs
Jung-Yeon Choi http://orcid.org/0000-0001-5139-5346
Ji Yeon Lee http://orcid.org/0000-0003-1159-6068
Chang Oh Kim http://orcid.org/0000-0002-0773-5443
Kwang Joon Kim http://orcid.org/0000-0002-5554-8255
In Gyu Hwang http://orcid.org/0000-0002-7461-0333
Yun-Gyoo Lee http://orcid.org/0000-0002-2156-5081
Su-Jin Koh http://orcid.org/0000-0002-1545-8036
Sol-Ji Yoon http://orcid.org/0000-0002-1334-326X
Min-gu Kang http://orcid.org/0000-0001-6840-4931
Jin Won Kim http://orcid.org/0000-0002-1357-7015
Kwang-il Kim http://orcid.org/0000-0002-6658-047X

REFERENCES

1 Parker SG, McCue P, Phelps K, *et al*. What is comprehensive geriatric assessment (CgA)? an umbrella review. *Age Ageing* 2018;47:149–55.
2 Stuck AE, Siu AL, Wieland GD, *et al*. Comprehensive geriatric assessment: a meta-analysis of controlled trials. *Lancet* 1993;342:1032–6.
3 Ellis G, Gardner M, Tsiachristas A, *et al*. Comprehensive geriatric assessment for older adults admitted to hospital. *Cochrane Database Syst Rev* 2017;9:CD006211.
4 Kim J. Current status and future of internal medicine hospitalist in Korea. *J Korean Med Assoc* 2019;62:564–8. Korean.
5 Pitkälä KH, Martin FC, Maggi S, *et al*. Status of geriatrics in 22 countries. *J Nutr Health Aging* 2018;22:627–31.
6 Relton C, Torgerson D, O'Cathain A, *et al*. Rethinking pragmatic randomised controlled trials: introducing the "cohort multiple randomised controlled trial" design. *BMJ* 2010;340:c1066.
7 Schulz KF, Altman DG, Moher D, *et al*. Consort 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 2010;340:c332.
8 Jung H-W, Yoo H-J, Park S-Y, *et al*. The Korean version of the frail scale: clinical feasibility and validity of assessing the frailty status of Korean elderly. *Korean J Intern Med* 2016;31:594–600.
9 Mahoney FI, Barthel DW. Functional evaluation: the BARTHEL index. *Md State Med J* 1965;14:61–5.
10 Lawton MP, Brody EM. Assessment of older people: self-maintaining and instrumental activities of daily living. *Gerontologist* 1969;9:179–86.
11 Charlson ME, Pompei P, Ales KL, *et al*. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373–83.
12 Vellas B, Guigoz Y, Garry PJ, *et al*. The mini nutritional assessment (MNA) and its use in grading the nutritional state of elderly patients. *Nutrition* 1999;15:116–22.
13 Baek MJ, Kim K, Park YH, *et al*. The validity and reliability of the Mini-Mental state Examination-2 for detecting mild cognitive impairment and Alzheimer's disease in a Korean population. *PLoS One* 2016;11:e0163792.
14 Bae JN, Cho MJ. Development of the Korean version of the geriatric depression scale and its short form among elderly psychiatric patients. *J Psychosom Res* 2004;57:297–305.
15 Kim S-H, Ahn J, Ock M, *et al*. The EQ-5D-5L valuation study in Korea. *Qual Life Res* 2016;25:1845–52.
16 Weiss ME, Costa LL, Yakusheva O, *et al*. Validation of patient and nurse short forms of the readiness for hospital discharge scale and their relationship to return to the hospital. *Health Serv Res* 2014;49:304–17.
17 Smilkstein G. The family Apgar: a proposal for a family function test and its use by physicians. *J Fam Pract* 1978;6:1231–9.
18 Kim SC, Boren D, Solem SL. The Kim alliance scale: development and preliminary testing. *Clin Nurs Res* 2001;10:314–31.
19 Park C, Park Y-H. Validity and reliability of Korean version of health empowerment scale (K-HES) for older adults. *Asian Nurs Res* 2013;7:142–8.
20 Kim JW, Lee Y-G, Hwang IG, *et al*. Predicting cumulative incidence of adverse events in older patients with cancer undergoing first-line palliative chemotherapy: Korean cancer Study Group (KCSG) multicentre prospective study. *Br J Cancer* 2018;118:1169–75.
21 Seymour MT, Thompson LC, Wasan HS, *et al*. Chemotherapy options in elderly and frail patients with metastatic colorectal cancer (MRC FOCUS2): an open-label, randomised factorial trial. *Lancet* 2011;377:1749–59.
22 Kang YJ, Kang M-Y. Chronic diseases, health behaviors, and demographic characteristics as predictors of ill health retirement: findings from the Korea health panel survey (2008-2012). *PLoS One* 2016;11:e0166921.
23 Lee J. KLoSA-Korean longitudinal study of aging. *Korean J Fam Med* 2020;41:1–2.
24 Ekdahl AW, Sjöstrand F, Ehrenberg A, *et al*. Frailty and comprehensive geriatric assessment organized as CGA-ward or CGA-consult for older adult patients in the acute care setting: a systematic review and meta-analysis. *Eur Geriatr Med* 2015;6:523–40.