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Validation of an integrated service model, Health-RESPECT, for older patients in long-term care institution using information and communication technologies: protocol of a cluster randomised controlled trial

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ABSTRACT

Introduction There is an increased healthcare need to manage institutionalised older patients owing to the ageing population. To overcome substantial future challenges, the Health-RESPECT (caRE Systems for Patients/Elderly with Coordinated care using icT), a new information and communication technologies based integrated management service model, was developed to provide effective management, enable consultation with distant professionals and share medical information between acute care hospitals and long-term care institutions.

Methods and analysis A cluster randomised controlled trial will be conducted to examine the effectiveness of the Health-RESPECT in older patients with chronic diseases and their medical staff in charge. Intervention involves registration with simple comprehensive geriatric assessment, establishment of an individualised care plan for three chronic diseases (hypertension, diabetes and heart failure), medication and rehabilitation management, periodic video-conference and in-system assessment after intervention period. Primary outcomes are control levels of the three chronic diseases, adequacy of drug management and overall functional status. Patients will be assessed at before and after study period and 3 months after study ended. Analysis will be carried out with an intention-to-treat principle. In addition to evaluate intervention effects, clinical usability and economic evaluation will be assessed.

Ethics and dissemination The study protocol was reviewed and approved by the Seoul National University Bundang Hospital Institutional Review Board. Study findings will be published in peer-reviewed journals.

Trial registration number KCT0004360.

Strengths and limitations of this study

- This is a pioneering study for evaluating the information and communication technologies (ICT) based healthcare management programme (Health-caRE Systems for Patients/Elderly with Coordinated care using icT (RESPECT)) tailored for older patients in long-term care institutions, with the intention to incorporate the investigation of health outcomes using a clustered, randomised design.
- The study will compare ICT-based multi-component management of older patients in long-term care hospitals or nursing homes and the usual care provided.
- Health-RESPECT provides comprehensive geriatric assessment, an individualised care plan for hypertension, diabetes and heart failure, information for potentially inappropriate medication, a tailored rehabilitation programme, periodic videoconferencing and in-system follow-up assessment.
- Health-RESPECT supports medical staff decisions by remote consultation of distant professionals, but patient participation was limited.
- Further research in diverse countries will be necessary because this study will be conducted in only one Asian country, and the findings may not be generalisable to all locales.

INTRODUCTION

With the rapidly ageing population in Korea, the proportion of older adults has doubled in just 17 years from 7% (an ageing society) in 2000 to 14% (an aged society) in 2017 and is expected to increase up to 20% (a post-aged society) by 2026.[1] These elderly individuals have higher prevalence of chronic medical conditions, along with a higher rate of poor self-reported health status, functional decline and institutionalisation in long-term care hospitals (LTCH) or nursing homes (NHs).[2 3] Even though most older people prefer to reside in their homes with independent physical and functional capacity to maintain the integrity of their social network

and enjoy a higher quality of life, due to the increase in single-person households and women's participation in the labour force, older adults are admitted to long-term care institution (LTCH or NH) that provide both medical and care support.[4 5]

Thus, the cost of medical care for older adults is expected to increase exponentially, highlighting the necessity for alternative, sustainable healthcare systems to manage older patients.[6] Older patients usually have multiple, multidimensional problem lists, and it is difficult for one expert to decide the optimal care plan. However, fragmented medical services in Korea lead to challenges in providing integrated medical services to older patients with multiple chronic diseases, resulting in considerable unmet needs. Digital medicine using information and communication technologies (ICT), can be a better alternative for institutionalised older patients who have difficulty moving or transferring. It can also improve control of chronic medical conditions by monitoring or quick detection and communication with distant professionals.[7] In older patients with complex multiple disease and functional status combinations, the integrated services model using ICT, for example, 'suggestions of treatment targets which consider patient's frailty status', 'providing evaluation tools and automatically suggest rehabilitation program based on functional status' and 'selecting inappropriate medicine among automatically identified prescribed medicine and recommending the appropriate medication according to disease status' are needed.

For effective treatment and management of older patients, consultation with distant professionals and sharing medical information between acute care hospitals and LTCH or NH, which participate in patient care, we developed the Health-RESPECT (caRE Systems for Patients/Elderly with Coordinated care using icT), a new service model and systems using ICT.[8] Through qualitative literature review, focus group interviews and structured surveys, three chronic diseases (hypertension, diabetes and heart failure), which are common and problematic in LTCH or NH older patients, and services that can be provided by using ICT were selected. The developed Health-RESPECT includes comprehensive geriatric assessment, management of three chronic diseases, individualised rehabilitation, drug management and remote video and written consultation services.

Therefore, we aimed to examine the effectiveness of intervention using Health-RESPECT on the outcomes for institutionalised older adults using clustered randomisation design. We hypothesised that intervention group would show a significant difference in adequacy of chronic disease management, adequacy of drug management and assessment of overall functional status compared with the control group. Additionally, clinical usability and economic evaluation will be assessed.

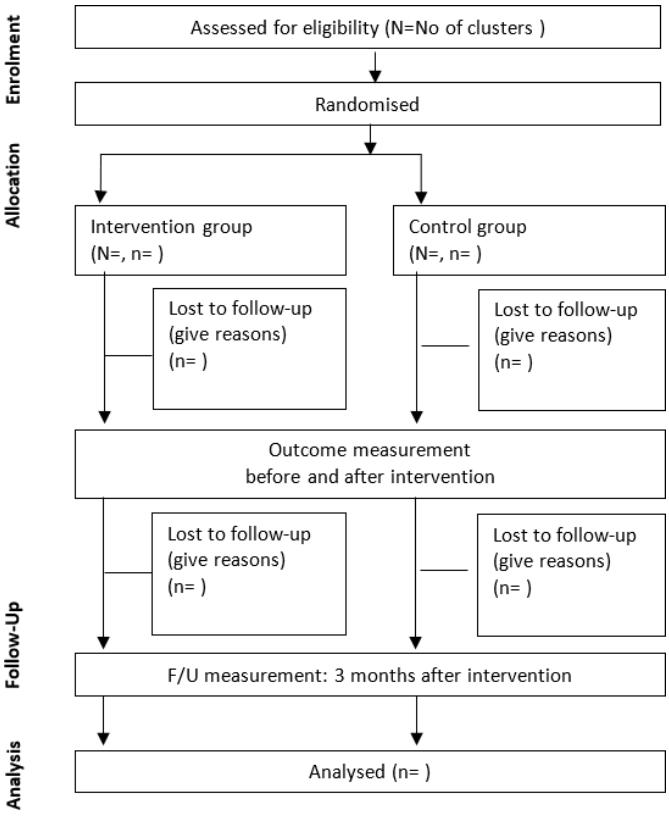

Figure 1 Flow diagram of cluster trial. N, No. of clusters; n, No. of elderly patients

METHODS AND ANALYSIS

Trial design

The Health-RESPECT study will adopt cluster randomised controlled trial (RCT) design with parallel equal arms performed in South Korea. The long-term care institution will be assigned into the cluster by the same category (LTCH or NH), and the same number of clusters will be allocated to the intervention and control groups through randomisation. Thereafter, the patients and medical staff recruited from the clusters will be assigned to the intervention or control groups. Inclusion of participants started on 6 September 2019 with a 3-month intervention period and a 3-month follow-up. This study will follow the CONsolidation Standards Of Reporting Trials flow chart to show the flow of participants through each stage of the RCT (figure 1).[9]

Participants and setting

The study is carried out in 12 long-term care institutions, and one additional institution is used as a reserve in case some withdraw early from the study. All long-term care institutions are administrated under the public health insurance or long-term care insurance system in 2019.

There are two groups of study participants. The first group includes older patients who (1) are over 65 years old, (2) are expected to stay in the facilities for at least 2 weeks at the point of observation/intervention and (3) have at least one or more chronic disease (hypertension, diabetes, heart failure and so on). Patients who are

Table 1 Participant inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Patients	► Over 65 years old. ► Expected to have length of stay over 2 weeks at point of observation/intervention. ► Have at least one or more chronic disease (hypertension, diabetes, chronic heart failure and so on).	► Expect to pass away or discharge within the 3-month intervention period. ► If in coma. ► Disagree with the study. ► Serious reason that limits the participation and progress of the research, depending on the researcher's judgement.
Healthcare professionals	► Works or contracts with a participating institution. ► Participated in the treatment or management of the patients.	► If the work is changed during the intervention period or the contract is terminated, the work cannot be performed. ► If the relevant work experience is less than 1 month.

expected to die or be discharged within the 3-month or who disagree with study were excluded. The second group includes healthcare professionals who (1) are working at the participating institutions and (2) have participated in the treatment or management of the patients. Study participants will provide informed consent to participate in the study (online supplemental data). For those participants with impaired ability to consent, caregivers can act as a proxy to provide agreement to participate in the study. Patients may withdraw from the study on request or in the case of transfer to a different hospital, discharge or death (table 1).

Participants recruitment

Long-term care institutions that are near the study institute (acute care hospital) and maintain a continuous relationship for patient transfer and re-transfer were chosen as candidates and were recruited through e-mail, phone calls and in-person meetings by the research team. Information on the research contents and purpose was delivered to physicians and nursing staff currently working in the long-term care institutions. Posters and handouts describing the research were also provided to the long-term care institutions for the patients. Those medical staff and patients were enrolled with written informed consent after providing enough information.

Interventions

The interventions are comprised of (1) registration, (2) establishment of care plan, (3) management and (4) assessment. Patients were recruited and registered by entering basic demographic information in both the intervention and control groups. After Comprehensive Geriatric Assessment (CGA), with the established interdisciplinary care plan, the Health-RESPECT platform provides an individualised management strategy, according to frailty, for patients with three chronic diseases (hypertension, diabetes and heart failure) to medical staff. Data on patients' vital signs, laboratory findings, diagnosis and prescribed medication will be collected from the electronic medical records (EMRs) of the long-term care institutions and accumulated in Health-RESPECT. The users of Health-RESPECT are medical staffs of LTCH, NHs and study institute. Health-RESPECT automatically provides recommendations for treatment goals, additional evaluation or tests needed, recommended medications for the target diseases (hypertension, diabetes and heart failure) based on recent guidelines and potentially inappropriate medication (PIM) for older patients. Health-RESPECT also includes a function for screening for adverse events and generating warning alarms by message or consultation with the attending physician at the LTCHs, NHs and acute care hospitals. Health-RESPECT contains cognitive, physical and swallowing rehabilitation services tailored to each patient's level of function, assessed in CGA. Access to medical information within Health-RESPECT will be granted only to medical staffs. Additionally, tools for written consultation or video-conference will be provided monthly or as needed. The drug management service screens the medications currently being prescribed and provides the number and specified drugs corresponding to the absolute or potentially inappropriate drug list. After the 3-month intervention period, a simple assessment of the disease and functional status will be performed through Health-RESPECT[8] (table 2). If there is a request to stop the intervention or observation of the patient or family member after recruiting, or even during the study period, we drop the participant.

Outcome measures

To collect the outcome indicators, data transmission from the EMR of the LTCH or NH to Health-RESPECT occurs on average once a month, in both the intervention and control group, from the start of the study to 3 months after the end of the study. Primary outcomes of this study

Table 2 Schedule of enrolment, interventions and assessments

	Study period					
	Enrolment (I)	Allocation (I)	Enrolment (P)	Postallocation		Close-out
Timepoint	$-t_2$	$-t_1$	0	t_1	t_2	t_3
Enrolment						
Eligibility screen (I)	X					
Informed consent (I)	X					
Allocation (I)		X				
Eligibility screen (P)			X			
Informed consent (P)			X			
Interventions						
Health-RESPECT				⟷		
Assessments						
(Clinical effectiveness) primary outcomes				X^a	X^a	
(Clinical effectiveness) secondary outcomes				X^b	X^b	$X^{b'}$
(Clinical usability)					X^c	
(Economic effect)				X^d	$X^{d'}$	X^d

I, institutions; P, patients; RESPECT, caRE Systems for Patients/Elderly with Coordinated care using icT; t1, before intervention measurement (baseline); t2, after intervention measurement; t3, follow-up measurement (3 months after intervention); X^a, chronic disease management, inappropriate medications and overall functional status with a composite indicator; $X^{b'}$, acute healthcare utilisations; X^b, functional rehabilitation management, functional status with individual indicators, quality of life and acute healthcare utilisations; X^c, patient experiences, technology acceptability and healthcare professionals' experiences; $X^{d'}$, cost-effectiveness and willingness to pay; X^d, cost-effectiveness.

are adequacy of management for three chronic diseases (hypertension, diabetes and heart failure), adequacy of drug management and assessment of overall functional status. First, to assess disease management status, the control rate of the treatment targets for each chronic disease (above) will be evaluated. Treatment targets for hypertension and diabetes are determined differently according to frailty status. The target blood pressure for hypertension is 140/90 mm Hg in the robust and prefrail groups and 150/90 mm Hg in frail groups. The target Hemoglobin A1c (HbA1c) for diabetes is <7.5% in robust groups, <8.0% in prefrail groups and <8.5% in frail groups, or for random glucose level the target is ≤190 mg/dL in robust groups, ≤210 mg/dL in prefrail groups and ≤230 mg/dL in frail groups. Failure of proper heart failure management is defined as an emergency room visit or unintended hospitalisation due to acute deterioration of heart failure symptoms. Frailty status was evaluated with the Korean version of the FRAIL (Fatigue, Resistance, Ambulation, Illness, and Loss of weight, K-FRAIL) scale. Scores of 3 and more, 1–2 and 0 were classified as frail, prefrail and robust, respectively.

Second, to assess the adequacy of drug management among older patients with multiple chronic diseases, PIMs and number of drugs (polypharmacy) prescribed by physicians will be measured. List of PIMs is defined by referring to the Beers Criteria and considering the medical environment of the long-term care institutions in Korea.[10] The polypharmacy is defined as the case where the patient-specific prescription drug type exceeds the standard (eg, 5, 9).[11]

Third, for the assessment of overall functional status, a series of care quality indicators based on functional status in the interRAI Long-term Care Facilities (LTCF) Tool will be measured and integrated.[12 13] The interRAI LTCF is a reliable assessment tool for institutionalised people with long-term care needs, and it is possible to examine the effects of interventions by identifying changes in functional status.[12] In this study, a set of functional indicators in mental and physical health conditions, and treatment domains were measured and computed as a composite measure at the individual level in a similar way to the ones previously conducted in the Netherlands[14] and Korea.[15]

Secondary outcomes will be measured with the following: rehabilitation service management indicators, an individual functional measures, quality of life and acute care hospital utilisation. Rehabilitation service management will be assessed using the Korean Mini-Mental State Examination for participants' cognitive function, Functional Ambulation Category for evaluation of motor function and pneumonia incidence due to swallowing problem. Multidimensional functional status will be measured by the set of individual measures we used to compute the composite functional measure explained above.[15] We will use the EuroQol- 5 Dimension Korean version, developed by the EuroQol, to assess patients' quality of life.[16] Acute care hospital utilisation will be measured by the checklists of hospitalisations through the emergency room and

emergency room visits. Even with medical optimisation through Health-RESPECT, functional status may change slowly over a period longer than 3 months. However, we included the functional outcome whether it sharply deteriorate during study period because it is important in older patients living in long-term care facility.

For clinical usability assessment, a focus group discussion (FGD) and survey will examine the patient and healthcare professional experience. An FGD session, held separately by each institution, proceeds to the healthcare provider with the following semi-structured questions: frequency of use, changed work methods, satisfaction and usefulness of system components, patient reactions, differences from existing systems and changes in the method of consultation. Based on the answers to these questions, additional questions are presented to identify participants' responses and identify the mechanisms of effectiveness and results of the unexpected assistance. As in this study, changes due to the introduction of an ICT-based system can be expected from the medical work perspective as an effect on workflow, general merits, communication and information processing work. We intend to observe this using Brooke's System Usability Scale (SUS).[17 18] SUS consists of 10 simple questions, and each item is designated from 0 to 100 points by converting it to a weight. The higher the score, the higher the usability. In addition, the Telehealth Usability Questionnaire tool, which measures satisfaction with the intervention system, is used to understand the patient's experience as the ultimate beneficiary of this system.[19]

The economic evaluation will be conducted by cost-effectiveness analysis and cost–benefit analysis. For cost analysis, medical costs, non-medical costs and programme costs will be assessed. Medical cost will be measured by the change of healthcare use after the implementation of intervention. To analyse the change, the number of healthcare use in inpatient setting will be recorded, and the average cost of each case will be multiplied to sum up the medical cost. Also non-medical cost, such as the transfer cost, will be measured by data from the Korea Health Panel.[20] Cost of programme will be measured by a bottom-up approach from the data of the participating institutions. The time to conduct the intervention of healthcare personnel will be surveyed in medical staff who will participate in intervention by asking for the additional time used for the intervention. The wage of healthcare personnel will be used to value the time of intervention conducted. The index of clinical effectiveness will be used as the reference in cost-effectiveness analysis. The results will be assessed as incremental cost-effectiveness ratio.[15] For the cost–benefit analysis, benefit will be measured by willingness to pay. To measure subjective utility of healthcare, willingness to pay will be measured for healthcare personnel. Starting bids will be presented as 10 000, 20 000, 40 000 and 60 000 Korean won. Net benefits will be calculated by deducting total cost from the willingness to pay values (table 3).

Table 3 Outcome variables

Domain/variable	Source (target population)	Outcome type	Timeline		
			t_1	t_2	t_3
Clinical effectiveness					
Chronic disease management	Survey (P) and EMR (P)	Primary	×	×	
Inappropriate medications	EMR (P)	Primary	×	×	
Overall functional status with a composite indicator	Assessment using interRAI LTCF (P)	Primary	×	×	
Functional rehabilitation management	Assessment using FAC, MMSE (P)	Secondary	×	×	
Functional status with individual indicators	Assessment using interRAI LTCF (P)	Secondary	×	×	
Quality of life	Survey using EQ-5D (P)	Secondary	×	×	
Acute healthcare utilisation	Survey (P) and EMR (P)	Secondary	×	×	×
Clinical usability					
Patient experience	Survey (P)	Secondary		×	
Technology acceptability	Survey (HCP)	Secondary		×	
Healthcare professional experience	FGD (HCP)	Secondary		×	
Economic effectiveness					
Cost-effectiveness	Survey (P)	Secondary	×	×	×
Willingness to pay	Survey (P and HCP)	Secondary		×	

EMR, electronic medical record; EQ-5D, EuroQol-5 dimension; FAC, functional ambulation category; FGD, focus group discussion; HCP, healthcare professional; LTCF, Long-term Care Facilities; MMSE, mini-mental state examination; P, patient; t_1, before intervention measurement (baseline); t_2, after intervention measurement; t_3, follow-up measurement (3 months after intervention).

Data collection and management

Research nurses (assessors) who are registered in the study will conduct all data collection according to the standard guidelines. Research nurses will be trained through an 8-hour educational programme that consists of an overview of the study, measurement tools and practice sessions with scenarios prior to data collection and review for errors. Additional training and practice will be provided if needed. All patients in the intervention and control groups will be asked to complete an assessor-administered survey before (T1) and after completion of intervention or observation (T2, follow-up). Qualitative (FGD) and quantitative (usability survey and willingness-to-pay survey) data for medical staff will be collected after completion of the intervention (T2).

To improve the reliability of data quality, some cases will be evaluated by two independent assessors. Throughout the whole data collection period, real-time support using instant message or phone call for assessors will be provided. Assessors will enter the data collected during the survey period in a web-based data collection programme and Microsoft Excel, and research team members will review according to defined monitoring strategies and double-check for missing data and unusual responses. If any errors are found in the data, the data managers will ask the assessors for correction or clarification, and all the corrections will be made after the Data Monitoring Committee's (DMC) confirmation. Furthermore, to promote follow-up and retention, assessors will report any issues with the patients. If any discontinuation of research participation occurs, a brief short form report will be generated and reported immediately. All of the completed survey data will be checked and collected by research team members. 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 in a password-protected computer. DMC consists of the investigators of the evaluation team as well as data managers and a statistician who manage data quality in the data collection, analysis, auditing and reporting intervention process. DMC is held regularly once a month and is independent from the sponsor and has no competing interests. The interventions which will be provided in this study is unlikely affect the safety of participants because the interventions are mainly non-invasive ICT-based professional collaboration. However, if any problem is reported during the monitoring process, it will be immediately reviewed by the DMC and reported to the Seoul National University Hospital (SNUBH) Institutional Review Board (IRB). The datasets generated and/or analysed during the current study do not allow opening or sharing with any third party due to the policy of the SNBH IRB but are available from the corresponding author on reasonable request.

Sample size

The sample size calculation was performed based on the primary clinical outcome of adequacy of drug management, defined as reduction of prescription of PIM. According to a literature review and a previous study conducted by the research team, we expect that the intervention will reduce PIM by a further 20% compared with the control group.[21] Assuming a 5% significance, 80% power and an intracluster correlation coefficient of 0.01,[14 15] we calculated that we needed 480 participants—for RCT with two different arms. Allowing for an attrition rate of 25%, a total of 640 participants (320 participants per group) will be recruited. Additionally, we will recruit all healthcare professionals (5–15 medical doctors and nurses per institution for a maximum of 100) who will participate in the study.

Randomisation

This study employs a stratified cluster randomised design. The unit of randomisation is the institution, as we randomised each institution and all of its participating patients into the intervention and control group. Since Health-RESPECT was developed for this study and applied for the first time, medical staff and patients who participate in this study have never been exposed to Health-RESPECT. We conducted systematic random sampling by listing the institutions in order of largest proportion of older adults aged over 75 in LTCH and NH, respectively. Patients were allocated into the intervention and control group with 1:1 ratio, and we checked that imbalance rate between the groups did not exceed 20%. The final data set is blind coded for randomisation. To maintain blindness during the assessment and analysis process, assessors and a statistician, who are separate external personnel managed by the DMC, are not disclosed to whether they are subject to the intervention arm by randomisation. External assessors and the statistician remain blind until their role is complete.

Statistical analysis

The main analysis will be conducted based on intention-to-treat principle. As a preliminary analysis, we will detect any significant difference in basic characteristics between clusters during the baseline period via χ^2 test and analysis of variance. To account for the clustered data structure, we will apply a multilevel regression analysis and use a generalised linear mixed effects model, including both fixed factors (time and intervention) and random factors. Two random effects will be introduced, one at the institution (cluster) level and the other at the patient (individual) level. To evaluate any significant benefit of the intervention, we will present the test statistics. We will use two-sided p values with α=0.05 for level of significance. As a secondary analysis, we will include the potential confounding prerandomisation variables as additional fixed effects in the regression model to derive the confounder-adjusted intervention effect. Also, we will explore the duration effect of the intervention by comparing the intervention period and follow-up period by appending an interaction term between time and intervention in the regression model. For each of the aforementioned analyses, we will implement imputation or inverse probability weighting methods to adjust for any kind of missing data. Sensitivity analyses to assess the effect of

attrition and inclusion of patients and subgroup analyses to examine the difference in LTCH and NH settings will also be conducted.

Patients and public involvement

When developing the Health-RESPECT, patients were participated with focus group interviews (one patient and two family member, one caregiver) and structured survey (3 patients, 38 family members or 9 caregivers) to identify patients' priorities, experience and preference. During the study, patients were assessed before and after 3 months of study period. Although patients in the intervention group will not be able to access medical recommendation provided through Health-RESPECT, but will be able to watch videos of physical or cognitive rehabilitation tailored to each individual. There are no plans to disseminate the results to study participants.

ETHICS AND DISSEMINATION

This study is sponsored by the Ministry of Health & Welfare, Republic of Korea, and centrally managed by staff at Seoul National University Bundang Hospital and registered with the Clinical Research Information Service Registry. The trial sponsor has no role in the design or conduct of the trial. The protocol was first reviewed by the SNUBH IRB on 19 July 2019 and lastly revised on 19 May 2020 for clarification of specific number of study participant group (patients and medical staff), detailed cluster randomisation process, method for data transfer and non-face-to-face evaluation as an alternative method when face-to-face evaluation is not possible due to pandemic of COVID-19 (IRB No. B-1904/534–304). The current protocol version is version 1.3, and there is no plan to change the current protocol.

The risk of negative effects on patient outcomes is thus minimal. The potential of not having a positive effect from the intervention on Health-RESPECT competence is present in control group. Health-RESPECT provides recommendations based on published clinical guidelines for hypertension, diabetes and heart failure or PIM for older patients. Despite the potential risk which might caused by Health-RESPECT is very low, additional consultation between medical staff in long-term care facilities and regional acute care hospital (study institute) will be provided if the patient's problem list is not resolved with the information provided by Health-RESPECT, or at whenever health-care professional wants. All of the participants will signed informed consent and will be recruited on a voluntary basis. If the patient lose their ability to make decisions, the information for this study will be provided their guardians and the guardians will signed informed consen. At the completion of the trial, the data will be analysed, and the study findings will be published in major peer-reviewed journals.

DISCUSSION

A cluster randomised controlled trial will be conducted to examine the feasibility, effectiveness and safety of the Health-RESPECT in older patients with chronic diseases and their medical staff in charge. Intervention involves registration with simple comprehensive geriatric assessment, establishment of a personalised treatment strategies for three chronic diseases (hypertension, diabetes and heart failure), medication and rehabilitation management, periodic video-conference and in-system assessment after intervention period. Although the Health-RESPECT platform has not been commercialised, we think an ICT service that provides medical information about specific diseases or medications and a consultation function to distant professionals, for older patients in long-term care facilities, will become more useful for management without contact in the pandemic infectious disease period.

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Competing interests None declared.

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 Not required.

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