

BMJ Open Do lifestyle measures to counter COVID-19 affect frailty rates in elderly community dwelling? Protocol for cross-sectional and cohort study

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ABSTRACT

Introduction Local activities that functioned to prevent frailty in the elderly have been suspended or reduced as a countermeasure against COVID-19. As a result, frailty rates are expected to increase, and frailty is expected to worsen as a secondary problem associated with COVID-19 countermeasures. Therefore, this study aims to determine the extent of frailty in the elderly associated with lifestyle changes implemented as COVID-19 countermeasures, to ascertain actual lifestyle changes and clarify the existence of Corona-Frailty. We will also conduct Corona-Frailty screening to verify the effect of support provided as feedback to supporters of the elderly.

Methods and analysis The survey target area is Takasaki City, Gunma Prefecture, Japan. Phase I aims to verify the short-term effects of COVID-19. A questionnaire will be distributed to 465 community-dwelling elderly people, and responses will be obtained by post. Frailty will be evaluated using the Frailty Screening Index. Respondents who are frail and have had many changes in their lifestyle will be screened as high-risk people, and feedback will be provided to local supporters. The aim of Phase II will be to verify the long-term effects of COVID-19 and the effect of screening. A similar survey will be distributed twice after the first survey, once after 6 months and again after 1 year and the frailty rate will be tested. Furthermore, out of the subjects identified with frailty in Phase I, the progress of those who were screened and those who were not screened will be compared between groups.

Ethics and dissemination This study has been approved by the Research Ethics Committee of the Takasaki University of Health and Welfare (approval number: 2009). The results of this study will be reported to the policymaker, presented at academic conferences and published in peer-reviewed journals.

Trial registration number UMIN000040335.

INTRODUCTION

Background

The novel COVID-19 first occurred in Wuhan, China, in November 2019. The Japanese government declared Japan's first state of emergency covering seven prefectures on 7 April,¹ which was extended to all 47 prefectures on 16 April.² The Japanese public were asked to avoid mass gatherings and to

Strengths and limitations of this study

- This study aims to clarify the increase in frailty rates among community-dwelling elderly as a secondary problem associated with COVID-19; that is, the aim is to clarify the existence of Corona-Frailty.
- This study will screen frail subjects whose lifestyle has been affected by COVID-19 measures and will clarify the effect of providing feedback to supporters of the elderly.
- There are almost no similar surveys at present because the pandemic is ongoing, and people's lives are yet to return to normal.
- For this study, the survey form will be distributed by local volunteers who will continue to provide support to the elderly, and the form will be collected by post.
- The subjects will be limited to community-dwelling elderly who receive support from local volunteers.

thoroughly implement social distancing as measures to prevent the spread of infection in Japan. As a result, activities involving elderly outings (*kayoinoba*) have been suspended, and support involving regular visits to the elderly has been reduced.

Kayoinoba is a setting where activities are available for people to participate in, which includes strength training and light exercises in groups, and is also a place where people can simply interact with each other. Regular visits to the elderly is a type of lifestyle support aimed at preventing anxiety and isolation among the elderly living alone. These are not public services; rather, they are activities run by local volunteers,³ and are important local activities that support the lives of elderly people. Japan is a super-ageing society, and a community-based integrated care system is being built to support elderly people who live in the community.^{4 5} Therefore, these local activities play a role in preventing frailty in the elderly.

Frailty is a condition where a person has increased vulnerability to stress due to a

decline in their physiological reserve, which then tends to result in poor health.⁶ Frailty has three elements: physical, cognitive and social. A systematic review reported that 9.9% of the 44 894 community-dwelling elderly experienced physical frailty.⁷ Cognitive frailty is a condition where a person displays a decline in both physical and cognitive functions,⁸ and in Japan, the rates of cognitive frailty have been reported as 4.4% in 594 community-dwelling elderly⁹ and 1.2% in 8864 people.¹⁰ Social frailty focuses on the social aspect of this condition and is defined by various elements, including a person's satisfaction with their social needs, social resources and social activities. The rate of social frailty in Japan was 10.2%.¹¹

Frail people have an increased risk of falls, decline in activities of daily living ability, hospitalisation and death.⁶ This condition also affects mental function and is associated with an onset of depressive symptoms¹² and cognitive decline.¹³ Social frailty without activities involving interaction with the local community worsens life prognosis, similar to physical frailty.¹⁴ Living alone and not leaving the house and/or interacting with other people also leads to a decline in physical function.¹¹ The greater the availability of local activities such as *kayoinoba* and regular visits to the elderly, the lower the risk of the onset of frailty.¹⁵ It is said that social frailty leads to isolation and almost certainly results in physical frailty and sarcopenia too.¹⁶ Therefore, frailty is a major concern since it causes physical harm and results in psychological and/or social harm.

There is no doubt that the treatment and prevention of the spread of infection are the top priorities in the current situation with the pandemic still ongoing. However, it is easy to predict that the suspension of local activities will result in increased frailty rates and worsened frailty in the elderly. We hypothesise that frailty related to lifestyle changes implemented as COVID-19 countermeasures will develop as 'Corona-Frailty'¹⁷ and the frailty rate will be higher than before. There are also grave concerns about the elderly themselves and the supporters who provide support to the elderly. Preventive measures are needed to determine how the elderly can maintain their lifestyles without developing Corona-Frailty.

Purpose

Concerns have been raised regarding the increased mortality rate of COVID-19 in elderly people with respiratory disease and frailty,¹⁸ and the need for age-independent evaluation of frailty in emergency medical settings during pandemics has been proposed.¹⁹ However, we were unable to find any reports of the effects of COVID-19 on frailty in the elderly.

It has now been more than 2 months since the suspension of local activities that fulfilled a role in preventing frailty in community-dwelling elderly. Thus, we planned this study to achieve the following aims:

- ▶ Clarify the actual frailty condition of community-dwelling elderly people who are subject to lifestyle restrictions due to COVID-19 measures for determining the existence of Corona-Frailty.
- ▶ Clarify the longitudinal reality based on predicting the long-term effect of COVID-19.
- ▶ Screen frail elderly people whose lifestyle has been affected by COVID-19 measures, provide feedback on the associated risk of frailty to supporters of elderly people and clarify the effectiveness of this feedback.

TRIAL DESIGN AND METHODS

Study design

Phase I: A cross-sectional survey will be distributed to investigate the condition of frailty in community-dwelling elderly whose lives are affected by the COVID-19 measures (figure 1). This will be conducted to verify the short-term effects of COVID-19.

Phase II: A prospective cohort study will be conducted, investigating the subjects surveyed in Phase I (figure 1). This will be carried out to verify the long-term effects of COVID-19 and the effect of screening support provided to frail subjects whose lifestyles had changed.

Setting

This study will be conducted in Takasaki City, Gunma Prefecture. The proportion of the population over the age of 65 in Japan was 28.4% in 2019 (95% CI 29.2 to 30.9 among 47 prefectures in Japan),²⁰ and it is estimated to

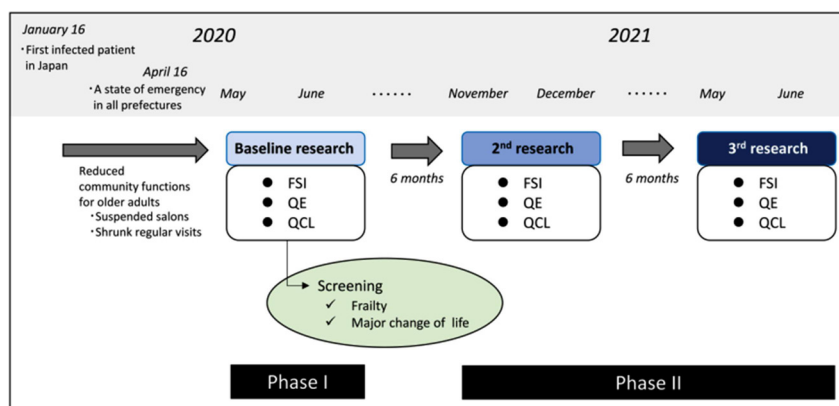


Figure 1 Overview of study design. FSI, Frailty Screening Index; QCL, Questionnaire for Change of Life; QE, Questionnaire for the Elderly.

increase to 30.0% in 2025.²¹ The proportion of the population over the age of 65 in the study area was 28.3% in 2019 (95% CI 32.3 to 38.8 among 35 municipalities in Gunma Prefecture),²² and is estimated to be 30.8% in 2025.²³ The target area of this study is an area that roughly follows the national average of Japan, and can therefore be regarded as an average area in Japan in terms of the population ratio of the elderly.

Participants

Inclusion criteria

The study will target elderly people aged 65 and over who live in local housing rather than in hospitals or aged care facilities. Subjects will not be excluded due to the presence of specific types of comorbidities and/or disorders, to enable a broad investigation of the actual condition of community-dwelling elderly.

Exclusion criteria

The subjects will have the choice to withdraw consent. If they wish to withdraw consent, they need to contact the consent withdrawal contact person. The fact that consent can be withdrawn and the contact details for withdrawing consent will be specified during the distribution of the survey form. The instructions will also state that consent cannot be withdrawn after the study results have been presented at academic conferences and/or published in journals.

Outcome measures

Primary outcome measures

Frailty and prefrailty will be evaluated using the Frailty Screening Index (FSI) (table 1) developed by Yamada and Arai²⁴ based on the frailty evaluation criteria proposed by Freid *et al.*⁶ The FSI was used to assess physical/psychological frailty and had predictive validity for disability²⁴ and concurrent validity for social frailty²⁵ among Japanese elderly. The FSI is a questionnaire that comprises five items answered with simple Yes/No responses, and scoring ranging from 0 to 5. It does not require an actual measurement of grip strength or walking speed. The frailty status was based on the participant's score, where a

score of 3 or more was defined as frailty, 1–2 as prefrailty and 0 as robust.²⁴

Secondary outcome measures

The questionnaire for the elderly (QE, table 2),²⁶ prepared by the Japanese Ministry of Health, Labour and Welfare, will be used to comprehensively evaluate the health status of the subjects based on the characteristics of the elderly. In Japan, the use of QE has been required to ascertain the condition of elderly people aged 75 and over during medical examinations, since April 2020. The questionnaire comprises 10 different areas: (1) health condition, (2) mental health condition, (3) eating habits, (4) oral function, (5) weight change, (6) exercise/falls, (7) cognitive function, (8) smoking, (9) social participation, and (10) social support. In consideration of the burden on the elderly, only 15 questions were included in the questionnaire. We will indicate social isolation, which became a critical factor as a result of the lifestyle restrictions due to the COVID-19 measures using the questionnaire items (9) social participation and (10) social support.

The Questionnaire for Change of Life (QCL) will be used to evaluate the impact of COVID-19 measures on daily life (table 3). The QCL was created referencing the Impact of Event Scale-Revised (IES-R),²⁷ which has been translated into many languages. The reliability and validity of the IES-R has been verified as an Impact of Event Scale²⁸ for evaluating psychological reactions caused by stressors such as pandemics and disasters. The QCL comprises five items related to frailty^{6 11 12 15}: physical activity, muscle strength, meal size, anxiety and communication opportunities, using 5-point Likert scale response options based on the IES-R. The participants will be asked about subjective changes in the past month to evaluate the changes in the person's lifestyle due to the measures implemented to prevent the spread of infection. Because we do not have the subject's condition prior to the study period, we will use the QCL to assess the current situation.

Procedure

Phase I: The survey method will involve the distribution of the questionnaire by local volunteers who run the *kayo-inoba* and provide support with regular visits to elderly residents. The people who distribute the survey form will be defined as research collaborators. In addition to the survey form, we will also distribute the instructions for this study, a return envelope and a pamphlet to raise awareness of frailty prevention during lifestyle restrictions associated with COVID-19 measures. To maintain social distance as an infection control measure, the research collaborator's role is to distribute a set of survey forms. Once the person has received the survey form from the research collaborator, they will be candidates for this study. If the person agrees to participate in this study, they will write their name on the survey form and return the form by post. Any person who completes these procedures will be a subject in this study. Researchers will be responsible for the cost of the postage and envelopes.

Table 1 Frailty Screening Index

No	Item	Score	
		Yes	No
(1)	Have you lost 2 kg or more in the past 6 months?	1	0
(2)	Do you think you walk slower than before?	1	0
(3)	Do you go for a walk for your health at least once a week?	0	1
(4)	Can you recall what happened 5 min ago?	0	1
(5)	In the past 2 weeks, have you felt tired without a reason?	1	0

A subject with total scores of 3 or more was defined as frail, 1–2 as prefrailty and 0 as robust.

Table 2 Questionnaire for the Elderly

No	Type	Item	Response	
(1)	Health condition	How is your health?	1. Good 2. Fairly good 3. Normal 4. Not very good 5. Bad	
(2)	Mental health condition	Are you satisfied with your daily life?	1. Satisfied 2. Somewhat satisfied 3. Somewhat dissatisfied 4. Dissatisfied	
(3)	Eating habits	Do you consistently eat three meals a day?	Yes	No
(4)	Oral function	Has it become more difficult to eat hard food than it was 6 months ago?	Yes	No
(5)		Do you sometimes choke on tea or soup?	Yes	No
(6)		Weight change	Have you lost 2–3 kg or more in the past 6 months?	Yes
(7)	Exercise/falls	Do you think you walk slower than before?	Yes	No
(8)		Have you fallen in the past year?	Yes	No
(9)		Do you take a walk to exercise at least once a week?	Yes	No
(10)	Cognitive function	Are you told that you are forgetful, with comments such as 'you are always telling me the same thing'?	Yes	No
(11)		Do you sometimes forget what day and month it is that day?	Yes	No
(12)	Smoking	Do you smoke cigarettes?	1. Yes, I smoke. 2. No, I do not smoke. 3. I quit smoking.	
(13)	Social participation	Do you go out at least once a week?	Yes	No
(14)		Are you normally in close contact with family and friends?	Yes	No
(15)	Social support	Do you have anyone to talk to if you feel unwell?	Yes	No

Using the returned survey form, any respondent who was defined as frail based on FSI and who responded with 'decreased' for QCL questions on physical activity, muscle strength, meal size and communication opportunities or 'increased' for anxiety, for a total of 2 or more items, will be screened as high risk (figure 1) and that

Table 3 Questionnaire for change of life

No.	Item	Response
(1)	Amount of daily movement	Decreased / Slightly decreased / Unchanged / Slightly increased / Increased
(2)	Leg muscle strength	Weaker / Slightly weaker / Unchanged / Slightly stronger / Stronger
(3)	Meal size	Decreased / Slightly decreased / Unchanged / Slightly increased / Increased
(4)	Worry or anxiety	Decreased / Slightly decreased / Unchanged / Slightly increased / Increased
(5)	Opportunities of talking to people	Decreased / Slightly decreased / Unchanged / Slightly increased / Increased

result will be provided as feedback to the research collaborators. It is expected that understanding these risks will enable research collaborators, namely, the supporters, to enhance their support for regular visits to the elderly and provide lifestyle support, increase family support and assist in the introduction and deployment of public services.

Phase II: The subjects in Phase I were surveyed again with a similar survey in Phase II, which will be distributed and collected at intervals of 6 months and 1 year after Phase I (figure 1). If the Japanese government's request to avoid mass gatherings and to thoroughly implement social distancing as an infection control measure is protracted, we might consider shortening the 6 months to 3 or 4 months due to the negative impact on frailty.

Patient and public involvement

Participants were not involved in the development of the research question nor study design. However, the research collaborators at a Public Interest Incorporated and Social Welfare Corporations were involved in coordinating with local volunteers. The local volunteers who were going to distribute the survey form were involved in study design.

Data management

We will collect data manually from the survey form, which is returned with the participant's consent signature. To avoid generating several errors, we will run a double check on the input data for 10% of the total reported data. The data will be deidentified and a master linking list with identities will be kept and stored separately from the data. Data will be stored on an external storage medium in a locked cabinet in a secure location. Access to the returned survey form and data will be limited to the study personnel.

Statistical methods

Sample size

The sample size required for this study was estimated based on the n:p rule of thumb.²⁹ The n:p is the minimum recommended ratio, (n) is the sample size and (p) is the number of variables being analysed. The n:p ratio recommended is at least 10.³⁰ The FSI has 5 items, the QE has 15 items and the QCL has 5 items. The total number of variables is 25. If n:p is set at 10, the minimum sample size is 250. We plan for the forms to be returned by post in this study, and the review results on the recovery rate for similar studies in Japan illustrated that the recovery rate for studies on elderly frailty, health and lifestyle using the postal method over the past 3 years was 67.8%–76.9%.^{31–34} Based on these findings, we estimated the recovery rate of the survey form in this study to be 60%, and incomplete survey forms to be 10%. Therefore, we ultimately plan to distribute 465 survey forms.

Analysis

In Phase I, we will clarify the actual effect of the COVID-19 countermeasures in daily life. The frailty and prefrailty rates will be calculated using FSI. The reference prevalence rates of frailty, prefrailty and robust status, based on a meta-analysis in Japan, were 7.5%, 48.1% and 44.4%, respectively.³⁵ These will be used as a reference value and the difference in the proportion of the frailty rate in this study will be verified using the Z test, to clarify whether frailty has increased due to the impact of COVID-19, that is, whether Corona-Frailty occurred. Descriptive statistics for gender and age will be performed to test the association with frailty status. We will also collate the answers to 10 types of QE and five QCL items to ascertain the health condition of the subjects. We will cross-tabulate each of the QCL results for frailty status and verify the findings using the χ^2 test or Fisher's exact test to determine the relationship between the change in daily life due to COVID-19 measures and frailty status.

Phase II will clarify the long-term effects of COVID-19 using Phase I as a baseline. The difference in the ratio of the frailty rate and the prefrailty rate at intervals of 6 months and 1 year after the baseline will be verified using the Z test. Ten types of QE and five QCL items will be collated, and the difference at each time point will be verified using the χ^2 test or Fisher's exact test. To indicate the factors that contribute to the transition to frailty,

multiple logistic regression analysis based on forced entry methods will be used. The transition to frailty or the non-transition to frailty is the dependent variable, and each item of QE and QCL are the independent variables. Of the subjects who were frail during Phase I, the frailty rates of the screened group and the non-screened group in 6 months and 1 year after the baseline will be examined to clarify the effect of Corona-Frailty screening support. The comparison will be verified using the Z test. Furthermore, we will apply two types of analysis: screening support and intention-to-treat analysis based on the screened group and the non-screened group.

ETHICS AND DISSEMINATION

Ethics

This study will commence once it has been approved by the Research Ethics Committee of the Takasaki University of Health and Welfare (approval number 2009). The study will be conducted in accordance with the tenets of the Declaration of Helsinki. The purpose of this study and the handling of information will be explained to all subjects, and a signed written consent will be obtained.

Dissemination

This study aims to clarify the effect of the unprecedented COVID-19 on frailty in community-dwelling elderly. It is expected to have both short-term and long-term effects. The policymaker has started to implement measures in view of the impact of COVID-19 on the elderly. The results of this study will be reported to the policymaker so that they can be used as materials for future measures. In particular, the results of Phase I, which will evaluate the short-term effects of COVID-19, including the existence of Corona-Frailty, will be communicated in the preliminary findings report. In addition, the activity details and study results will be presented at academic conferences and published in peer-reviewed journals.

DISCUSSION

We assume that the frailty rate of the study participants in Phase I will be higher than the reference rate. This is because Phase I research was conducted during the 2 months after the introduction of preventive measures against COVID-19 that resulted in the suspension or reduction of the local activities that functioned to prevent frailty in the elderly. If the frailty rate increases, it may be regarded as Corona-Frailty. We suggest that this study's target area is regarded as a representative sample area in Japan in terms of the population ratio of the elderly, as there were no contradictions in our comparison with the historical data in Japan.

Currently, there are few studies on secondary problems associated with COVID-19 because the focus is on the treatment and prevention of the spread of infection. Social distancing measures are required as a countermeasure against infectious diseases,³⁶ and it is necessary to pay



attention to research methods. Zhang and Ma³⁷ reported the impact of COVID-19 on mental health and quality of life, evaluated using the Impact of Event Scale.³⁸ This survey was conducted via the internet, and the mean age of the subjects was young at 38 years; therefore, it does not indicate the reaction of the elderly. The internet usage rate of the elderly in Japan is 45.8% in households with only elderly occupants.³⁹ In recent years, the share of smartphones has become larger than that of personal computers. The smartphone usage rate was reported to be 39% for people aged between 65 and 74 years, and 15% for those aged 75 and above,⁴⁰ and intervention studies on elderly people using smartphones as assistive devices have been conducted.⁴¹ However, when internet and smartphone usage rates are less than half, it is not suitable to use these methods to survey the actual situation in an area. Wolf *et al*⁴² have conducted a telephone survey of the awareness and attitude towards COVID-19 in young and old people. In a pandemic situation, it is essential to consider how best to access the target population. In this study, we were able to plan the distribution of the survey form by using the limited available access because local volunteers continue to check in on the elderly. We believe that this can provide a feasible method for conducting a survey in a pandemic situation.

One of the aims of this study is to verify the effect of support using Corona-Frailty screening. Kuwahara *et al*⁴³ stated the need for practical information to properly implement local activities based on the cancellation of local activities, and argued that isolation in the local area is a particularly major issue. Armitage and Nellums⁴⁴ also stated that although isolation is essential and effective in preventing infection, secondary problems do develop due to isolation. However, the WHO response to various problems such as exacerbation of symptoms and depression in the elderly is not sufficient.⁴⁵ Yang *et al*⁴⁶ proposed the need for adequate mental support for depressive symptoms during the period of isolation and restricted movement associated with COVID-19 infection control. Frailty has three elements: physical, cognitive and social, all of which are affected by COVID-19. We hope that effective support will be deployed by performing Corona-Frailty screening at an early stage and providing information to supporters.

This study has several limitations. First, the FSI has insufficient validity for other frailty criteria. However, to maintain the implementation of social distancing as a preventive measure against infection, we had to use an easy questionnaire that the elderly could answer without the support of others at home. Second, we could not research the health and frailty status of the participants as a reference condition before the pandemic. Third, we have set a wide inclusion to enable a broad investigation of the actual condition and do not collect the names of the diseases. This study has been conducted under limited conditions while taking infection control measures.

Frailty increases the risk of hospitalisation and admission to aged care facilities,⁴⁷ as there is a large degree of

functional deterioration, even if it is transient, and frailty diminishes a person's ability to recover to their original condition.⁴⁸ Gill *et al*⁴⁹ reported that physical frailty increases the risk of decline in life function, persistent decline in life function and decline in life function associated with admission to aged care facilities. On the other hand, appropriate intervention for individuals with frailty can be expected to improve their physical function and enable them to break away from frailty.⁵⁰ It is necessary to establish a system that is able to provide prompt support by properly evaluating the increase in frailty rates and deterioration of frailty due to the impact of COVID-19. COVID-19 continues to spread, and there is an urgent need to adopt measures for the elderly who are particularly susceptible. Research to resolve secondary problems such as Corona-Frailty and prompt disclosure of information are expected.

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Contributors The research question was proposed by TS and KS, and planning was performed by TS, KS, ST and AM. The protocol manuscript was prepared by TS, KS and ST. TS and KS coordinated with research collaborators, and TS, KS, ST and AM collated and analysed the study data and presented the research results. All authors contributed to the writing and critical revision of the manuscript and approved the final manuscript.

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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 Obtained.

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