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From Intervention Trial to Full-scale Implementation Research: Positive Tendencies for Frailty and Self-rated Health in Frail Older People

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Abstract

A continuum of care for frail older people was created to link the chain between the hospital, and discharge to the person's home. Despite earlier positive findings, it remains unclear if the benefits are sustainable in a real-life context. The present longitudinal study aimed at evaluate the effects of the implementation of a full-scale process program for frail older people in a real-life context regarding levels of frailty, self-rated health and activities of daily living up to one year later. The sample consisted of a total of 143 frail people aged 75 years and older, divided in the two groups: 77 participants from the full-scale process program and 66 historical controls. The findings showed that at the six months follow-up, the participants partaking in the full-scale process program had a significantly higher odds of displaying decreased frailty (p=0.015), and at twelve months, this sample had a significant lower likelihood of reporting decreased self-rated health (p=0.023). Thus, the findings showed positive results on frailty level and self-rated health when implementing the intervention in real life, indicating that a person-centred, multi-professional team with a case manager is beneficial for frail older people.

Clinical Trials Gov: NCT01260493.

Keywords: Activities of daily living; Frailty; Geriatric; Intervention; Multi-professional team

Introduction

Frail older people have varying levels of needs and may require treatment and care from multiple heath care professionals. Frailty, which is a geriatric syndrome related to a deterioration of multiple physiological systems in old age [1], are typically associated with restricted activity and morbidity. A frequently used definition of frailty includes weakness, fatigue, weight loss, low physical activity, poor balance, slow gait speed, and impaired cognition [2]. Despite clinical advances in the care and treatment of the frail older people, multiple discontinuities within the system can interfere, resulting in a fragmented care which is not always integrated in the best interest of the person receiving the services [3].

A well-functioned continuum of care can be achieved by involving the older people and their relatives in the planning, decision-making and in carrying out the care. The integration within the health care for this population could also be enhanced by using a geriatric screening and multidimensional assessment, entailing several of health care professionals working as a multi-professional team [4]. A central component of the integrated care program is the case manager, which refers to a person coordinating several components striving for a successful outcome [5]. Additional factors for a successful intervention included features such as individualized assessments and interventions, and long-term follow up [6].

Internationally, integrated care programs have been used to minimize fragmentation and to improve continuity and coordination of care [7]. In Sweden, health care chains are a significant part of the integrated health care. The randomised controlled, two-armed intervention study, the Continuum of Care for Frail Older People [8], was set up to evaluate a health care chain between the hospital emergency department, throughout the hospital stay, and upon discharge to the frail older people's own home. The intervention [8] involved collaboration between a nurse with geriatric competence at the hospital emergency department, the hospital wards, and a multi-professional team in the municipality with a case manager. The person-centred approach with shared decision-making was implemented throughout the health care chain. The central components of the intervention were as follows: geriatric assessment, coordination by a case manager in the municipality, multi-professional team, care-planning meetings in the older people's home, follow-up of personal needs and planned care, and support when needed for relatives.

Berglund et al. [9] showed that one of the central aspects of the intervention, to perform the care-planning meetings in the frail older people's home, had a positive effect on the older people's involvement in their planning of their future care. The intervention [8], also, had a positive effect on independence in activities of daily living up to one year, as well as decreasing dependency in activities of daily living up to six months [10]. Further, positive effects were also found with regards to experienced symptoms and self-rated health [11], as well as the continuation of exercising self-determination in daily life at three and six months follow-up [12]. Based on previous findings [9-12], the randomised controlled intervention study Continuum of care for frail older people [8] was implemented in a real-life context, which meant that the previously project was implemented in the ordinary daily care of frail older people living in a municipality in Sweden. Further, this implementation process entailed that the frail older people received a care approach founded on the person-centred approach and the central components from the previous research [8]. Despite earlier findings [9-12], it remains unclear if the benefits of the Continuum of care for frail older people [8] are sustainable in a short and longer term when implementing the full-scale process program in a real-life context.

In this study, the aim was to evaluate the effects of the implementation of a full-scale process program for frail older people in a real-life context regarding levels of frailty, self-rated health and activities of daily living up to one year later.

Materials and Methods

Study Design

In this longitudinal study with three-, six- and 12 months follow-up, data from a controlled study, from intervention trial (RCT) to full-scale implementation research, was evaluated in relation to a sample with historical controls gathered from the randomized non-blinded controlled trial, the Continuum of care for frail older people [8]. The Regional Ethical Review Board in Gothenburg approved the study (ref.nr. 413-08), and the additional ethical approval for the implementation phase application (T140-12). A written informed consent was obtained from all participants, and information was given both verbal and in writing regarding the purpose of the respective study, and that it was voluntary to participate in the interviews.

Participants

The study population comprised a sample of people who had their 75th birthday during the study period or were older. The participants were eligible if they sought care at an emergency department, and thereafter were discharged to their own homes in the municipality of Mölndal, Sweden. People requiring acute medical services, those clinically observed as having severe cognitive impairment or dementia, and or requiring palliative care as assessed by a nurse with geriatric competence were excluded.

Implementing a Full-scale Process Program Intervention

The same central components as described previous in the Continuum of care for frail older people [8], was used when implementing of the full-scale process program intervention in a real-life context. It comprised collaboration between a nurse with geriatric competence at the emergency department, the hospital wards, and a multi-professional team working in the municipality. Together, these parts resulted in a continuum of care, starting from the emergency department, through the hospital ward, and in to the older people's homes.

A case manager in the municipality was the primary contact for the frail older people with complex needs, and worked closely in cooperation with a multi-professional team (occupational therapist, physical therapist, and social worker). The case manager was responsible for new and/or changing needs, whether they were formal (e.g. primary health care, municipality, hospital wards) or informal (e.g. the family caregivers). Responding to the altered needs, a care planning meeting was immediately offered in the older people's home after the participant had been discharged to their own homes. The case manager and the multi-professional team shared responsibilities for care planning. The individualized care plan was based on a comprehensive geriatric assessment made by the multi-professional team, and was followed up after one week by the case manager and subsequently as deemed necessary. The historical controls received ordinary care, where rehabilitation and other care services were delivered by the municipality when needed.

Data Collection

The data from the Continuum of care for frail older people (historical controls) [8] were collected during the period of October 2008 until October 2011, and the data from the intervention trial (RCT) to full-scale implementation research were collected during the period of November 2012 until June 2016. Both studies collected data at baseline, three-, six- and 12 months follow-ups in the older people's own homes by research assistants trained in interviewing.

The interviewers in both studies had experience in care of older people, and the interviews were performed in accordance with guidelines for the different outcome measurements. The same measurements were used in both studies when collecting the data.

In this study, the outcome measures of frailty, self-rated health, and activities of daily living were evaluated.

Outcome Measures

- **Frailty:** Eight frailty indicators were used when capturing levels of frailty: weakness, fatigue, weight loss, physical activity, poor balance, slow gait speed, visual impairments, and cognition. Weakness (grip strength) was measured with the North Coast dynamometer [13]. Frailty was defined as a grip strength of less than 13 kg (dominant hand), and 10 kg (non-dominant hand) for women, and less than 21 kg (dominate hand) and 18 kg (non-dominant hand) for men. Fatigue and weight loss was measured using the Göteborg Quality of Life instrument (GQL) [14] where the answer of "yes" to the two questions: "Have you suffered any general fatigue/tiredness over the last three months?" and "Have you suffered from any weight loss over the last three months?". Frailty was also indicated by low physical activity (outdoor walking two times or less each weak) measured with a six-point scale. Poor balance, indicated as a score of 47 or lower (maximum is 56 points), was measured with the Bergs Balance Scale (BBS) [15]. Gait speed of 6.7 seconds or slower over four meters [16] was considered an indicator of frailty. Visual acuity of ≤0.5 (both eyes) measured with the KM chart [17,18], and reduced cognition below 25 points measured with the Mini Mental State Examination (MMSE) [19] indicated frailty. The sum of the frailty indicators was then categorized into non-frail (0 indicators), pre-frail (1-2 indicators), and frail (≥3 indicators).
- **Self-rated Health (SRH):** The participant's self-rated health was measured using the following question: "In general, would you say your health is excellent, very good, good, fair or poor?" The response alternatives were dichotomized into good (excellent, very good, or good), and poor (fair or poor).
- **Activities of Daily Living (ADL):** The ADL staircase is a cumulative scale that indicates a person's independence or degree of dependence on another person in personal activities of daily living (P-ADL), which refers to activities related to a person's own body (bathing, dressing, going to the toilet, transfer, and feeding). It also captures a person's independence or degree of dependence on another person in instrumental activities of daily living (I-ADL), which refers to activities in the persons own home (cleaning, shopping, transportation and, cooking). Participants living with another person were assessed as independent if they were able to perform an activity by themselves while alone. Degree of dependence in activities of daily living was dichotomized to either independent, or dependent [20,21].

Statistical Analysis

All the analyses were made on the basis of the intention-to-treat principle. The imputation of the data was based on the assumption that older people are expected to deteriorate over time as this is a natural course of the ageing process. Thus, an imputation method was selected to replace the missing values of the sum of levels of frailty, self-rated health, and activities of daily living managed independently, between baseline data, and follow-up of all participants with a value based on the Median Change of Deterioration (MCD), in accordance as in the Continuum of care for frail older people [8] study. Worst-case scenario was used for participants who died [22].

Baseline and dropouts characteristics of participants in both groups were compared using Chi-square or Fishers exact test (p-value ≤ 0.05). The number of participants that had improved, maintained or decreased in frailty, self-rated health, and activities of daily living compared to baseline was analyzed using Chi-square, and Odds Ratio (OR). A p-value ≤ 0.05 was considered statistically significant, and a 95% confidence interval (CI) is provided. The statistical analyzed was made using IBM SPSS Statistics for Windows, Version 24.0, 2016, Armonk, NY: IBM Corp. In addition, analyses adjusted for baseline differences with regards to frailty, self-rated health, and activities of daily living were also made using logistic regression, with the SAS-procedure logistic, SAS version 9.3 (SAS Institute Inc., N.C.; USA).

Results

The whole sample consisted of 143 frail older participants, 77 participants from intervention trial (RCT) to full-scale implementation research, and 66 historical controls from Continuum of care for frail older people [8]. The drop-outs for the full-scale process program from baseline to three months were 16% (n=12), from baseline to six months were 24% (n=18), and from baseline to 12 months were 30% (n=23). The drop-outs for the controls from baseline to three months were 11% (n=8), from baseline to six months were 16% (n=12), and from baseline to 12 months were 22% (n=17). To match the inclusion criteria of the present study, participants that did not have their 75th birthday during the study period were excluded from the control group. The flow of participation is shown in CONSORT diagram, Figure 1 of both studies used.

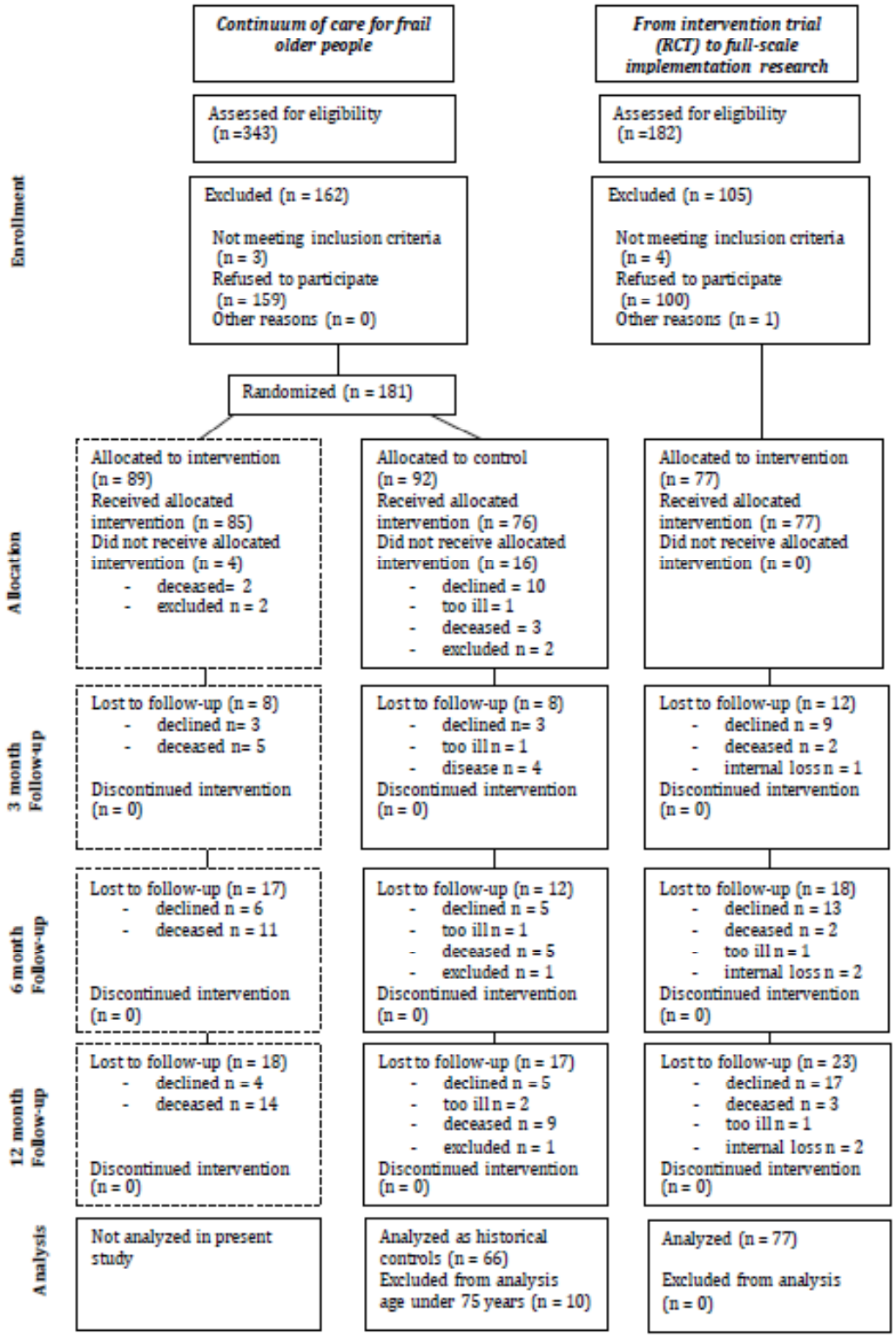

Figure 1: CONSORT 2010 The flow of participants.

Baseline Characteristics

A statistically significant larger amount of the participants, from intervention trial (RCT) to full-scale implementation research were female (p=0.004), and had cognitive impairment (p=0.021) when comparing with the historical controls. The historical controls were statistically significant more independent in instrumental activities of daily living (p=0.023). No statistically significant differences were observed between the groups with regards to living status, educational level, self-rated health, levels of frailty, fatigue/tiredness, and weight loss (Table 1).

Characteristics	Historical controls n=66	From intervention trial (RCT) to full-scale n=77	p-value
Female	36 (55%)	60 (78%)	**0.004**
Living alone	39 (59%)	51 (66%)	0.391
Tertiary education[1]	11 (17%)	18 (23%)	0.404
Independent in I-ADL[2]	19 (29%)	10 (13%)	**0.023**
Self-rated health[3]	21 (32%)	24 (31%)	1.000
Non-frail[4]	0 (0%)	2 (3%)	0.499
Pre-frail[4]	18 (27%)	15 (19%)	0.321
Frail[4]	48 (73%)	60 (78%)	0.559
General Fatigue/tiredness	45 (68%)	54 (70%)	0.857
Weight Loss	27 (41%)	26 (34%)	0.391
MMSE, <25[5]	2 (3%)	12 (16%)	**0.021**

[1]Tertiary education (partial or completed university or college)

[2]I-ADL=Instrumental Activities of Daily Living

[3]Excellent/very good/good

[4]Frailty measured with the following frailty indicators: weakness, fatigue, weight loss, physical activity, poor balance, slow gait speed, visual impairments, and cognition categorized into non-frail (0 indicators), pre-frail (1-2 indicators), and frail (≥3 indicators)

[5]MMSE=Mini Mental State Examination

Table 1: Baseline characteristics of participants.

Frailty

At the six months follow up, from intervention trial (RCT) to full-scale implementation research had a statistically significant higher OR of 2.36 (p=0.015) in decreased levels of frailty when comparing with the historical controls. In general, this sample had a tendency towards lower levels of frailty, while the historical controls had higher levels of frailty at the follow-ups (Table 2).

	Historical controls n=66		From intervention trial (RCT) to full-scale n=77		p-value
		OR		OR	
Higher levels of frailty					
three months	25 (38%)	1	23 (30%)	0.70 (CI 0.35-1.40)	0.313
six months	27 (41%)	1	24 (31%)	0.62 (CI 0.33-1.30)	0.227
twelve months	29 (44%)	1	24 (31%)	0.58 (CI 0.29-1.15)	0.116
Maintained levels of frailty					
three months	18 (27%)	1	15 (20%)	0.65 (CI 0.30-1.41)	0.272
six months	19 (29%)	1	14 (18%)	0.55 (CI 0.25-1.21)	0.136
twelve months	10 (15%)	1	11 (14%)	0.93 (CI 0.37-2.36)	0.884
Decreased levels of frailty					
three months	23 (35%)	1	39 (51%)	1.92 (CI 0.98-3.77)	0.059
six months	20 (30%)	1	39 (51%)	2.36 (CI 1.18-4.70)	**0.015**
twelve months	27 (41%)	1	42 (55%)	1.73 (CI 0.89-3.37)	0.105

Table 2: Odds ratio (OR) with 95% confidence interval (CI) for changes in levels of frailty at follow-ups.

Self-rated Health

At the twelve months follow up, from intervention trial (RCT) to full-scale implementation research had a statistically significant lower likelihood of reporting decreased levels of self-rated health with an OR of 0.38 (p=0.023) in comparison with the historical controls. This sample had a tendency towards reporting higher levels of self-rated health, whereas the historical controls reported lower levels of self-rated health, at the follow-ups (Table 3).

	Historical controls n=66		From intervention trial (RCT) to full-scale n=77		p-value
		OR		OR	
Higher levels of SRH					
three months	20 (30%)	1	27 (35%)	1.24 (CI 0.61-2.51)	0.546
six months	20 (30%)	1	30 (39%)	1.47 (CI 0.73-2.95)	0.280
twelve months	18 (27%)	1	29 (38%)	1.61 (CI 0.79-3.28)	0.189
Maintained levels of SRH					
three months	31 (47%)	1	40 (52%)	1.22 (CI 0.63-2.36)	0.553
six months	29 (44%)	1	31 (40%)	0.86 (CI 0.44-1.67)	0.657
twelve months	28 (42%)	1	37 (48%)	1.26 (CI 0.65-2.43)	0.501
Decreased levels of SRH					
three months	15 (23%)	1	10 (13%)	0.51 (CI 0.21-1.22)	0.130
six months	17 (26%)	1	16 (21%)	0.76 (CI 0.35-1.65)	0.482
twelve months	20 (30%)	1	11 (14%)	0.38 (CI 0.17-0.88)	**0.023**

Table 3: Odds ratio (OR) with 95% confidence interval (CI) in changes in levels of self-rated heath (SRH) at follow-ups.

Independence in Activities of Daily Living

There were no significant differences between the groups with regards to independence in activities of daily living at the three, six and twelve-month follow-ups (Table 4).

	Historical controls n=66		From intervention trial (RCT) to full-scale n=77		p-value
		OR		OR	
Improved ADL					
three months	21 (32%)	1	17 (22%)	0.61 (CI 0.29-1.28)	0.191
six months	17 (26%)	1	19 (25%)	0.94 (CI 0.44-2.01)	0.882
twelve months	15 (23%)	1	19 (25%)	1.11 (CI 0.51-2.42)	0.785
Maintained ADL					
three months	31 (47%)	1	34 (44%)	0.89 (CI 0.46-1.73)	0.736
six months	19 (29%)	1	29 (38%)	1.49 (CI 0.74-3.02)	0.264
twelve months	20 (30%)	1	23 (30%)	0.98 (CI 0.48-2.01)	0.955
Decreased ADL					
three months	14 (21%)	1	26 (34%)	1.89 (CI 0.89-4.03)	0.098
six months	31 (47%)	1	29 (38%)	0.68 (CI 0.35-1.33)	0.262
twelve months	31 (47%)	1	35 (45%)	0.94 (CI 0.49-1.82)	0.856

Table 4: Odds ratio (OR) with 95% confidence interval (CI) for changes in degree of independence in Activities of Daily Living (ADL) at follow-ups.

Frailty, Self-rated Health, and Independence in Activities of Daily Living

At the three, six, and twelve-month follow-ups, from intervention trial (RCT) to full-scale implementation research had a tendency towards decreased frailty and higher levels of self-rated health. This sample also had a tendency towards increased activities of daily living independence when comparing with the historical controls (analyses adjusted for baseline differences) (Table 5).

	Historical controls n=66	From intervention trial (RCT) to full-scale n=77	
	OR	OR	p-value
Decreased frailty			
three months	1	1.68 (CI 0.87-3.27)	0.124
six months	1	1.80 (CI 0.92-3.49)	0.085
twelve months	1	1.52 (CI 0.77-2.99)	0.226
Decreased self-rated health			
three months	1	0.73 (CI 0.37-1.46)	0.373
six months	1	0.76 (CI 0.39-1.47)	0.412
twelve months	1	0.59 (CI 0.30-1.15)	0.119
ADL independence			
three months	1	1.48 (CI 0.76-2.89)	0.249
six months	1	0.69 (CI 0.36-1.35)	0.283
twelve months	1	0.91 (CI 0.47-1.76)	0.777
*Analyses adjusted for baseline differences			

Table 5: Ordinal Logistic Regression with 95% confidence interval (CI) for decreased frailty, decreased self-rated health, and ADL independence at follow-ups*.

Discussion

This longitudinal study evaluated the effects of the implementation of the Continuum of care for frail older people in a real-life context regarding levels of frailty, self-rated health and activities of daily living. The evaluation showed that executing the program had succeeded for the full-scale process program concerning decreased levels of frailty after six months. Furthermore, a less likelihood amongst participants from the intervention trial (RCT) to full-scale implementation research reported decreased levels of self-rated health after one year. From the basis of the adjusted analysis data, tendencies were also positive in favor throughout the entire study with regards to both levels of frailty and self-rated health.

In the present study, the participants from the implementation group had over two times higher odds of displaying decreased levels of frailty than the historical controls at the six-months follow up even though not statistically significant. This finding was supported by the results from the adjusted analyses showing that during the course of the study, a positive trend with regards to decreased levels of frailty among participants from implementation group was found. A previous study [10], which evaluated the Continuum of care for frail older people before being implemented in a real-life context, showed no significant differences with regards to improved, maintained, or decreased levels of frailty at either three, six and twelve-mounts follow-up. On the other hand, the previous study [10] showed an increased independence in activities of daily living when observing the OR, which was not the case in the present study. There are different possible reasons for this difference in results between the two studies. One sign of weakness in the present study using historical controls is that the baseline comparison showed significant differences with regards to gender, independence in activities of daily living and cognition, as was not the case in the previous study [10]. The participants from intervention trial (RCT) to full-scale implementation research were more dependent in activities of daily living (29%) in comparison with the historical control (13%). The difference in results can also be explained by the day-to-day fluctuations of health outcomes that frailty is connected to as indicated in a study by Mulasso et al. [23], and that the result may indicate that physical frailty increases the variability contributing to dependence in activities of daily living. However, when comparing the results, the same pattern of OR from all the analyses were found concerning decreased frailty, as were shown in the previous evaluation [10] of the Continuum of care for frail older people, with a decrease in frailty that peaks at 6 months follow up and levels out at 12 months. In the case of activities of daily living, the participants from intervention trial (RCT) to full-scale implementation research retrieved a worse starting position, and by 12 months they have a lower share that deteriorates and a higher proportion is improved in activities of daily living.

From intervention trial (RCT) to full-scale implementation research displayed positive tendencies for the frail older people regarding self-rated health. The participants succeeded in displaying better self-rated health as compared with the historical control, when looking at the non-adjusted results after twelve months. This finding is in aligned with the positive effects the Continuum of care study had on self-rated health and number of experienced symptoms [11]. It has earlier been shown that how

frail older people manage their everyday life influences their experience of health despite frailty [24,25], and the frail older people describes health as being in harmony and balance in their everyday life [25]. In addition, social relations, functional ability and activities influence older people's quality of life as much as health status [26]. Thus, facilitating for the frail older people to continue with their activities is beneficial for their experiences of health and quality of life. It is important to have a multi-disciplinary approach with focus to provide supportive services to frail older people - as in the Continuum of care intervention [8] - in order to maintain their independence and experiences of good health despite frailty [27]. A multi-professional team including a case manager, occupational therapist, physical therapist and a social worker performing geriatric screening, and multidimensional assessment were one of the core components of the Continuum of care intervention [8]. The team was grounded in a person-centred approach to care, meaning that the caregiver and the caretaker created a partnership in all their meetings. Due to the findings from the present study, a multi-professional, person-centred team seems to be favorable with regards to frailty and self-rated health in frail older people. The results of this study could be implemented and evaluated universally regardless of country or cultural contexts, as a program which provides a case manager working together with a multidisciplinary team when providing care services for frail older people living at home. It is suggests that despite having reduced functional capacity, the experiences of personal satisfaction, and optimal aging can still be achieved [28]. If a certain activity's limitation is highly meaningful to a person, it may lead to reporting poor self-rated health. Thus, exploring the specific factors influencing frail older people's self-rated health may help to better comprehend and appreciate the clinical implications that self-rated health has. In turn, this may lead towards new methods of shaping and influencing frail older people's health [29].

The design in present study, using historical controls instead of performing a randomized control study, has its pros and cons. Above all; it means that fewer frail older people needed to be included in strenuous research. An obvious risk is that the time lap between the data gathering affects the results. In present study, the time lap was 12 months, which we consider a fairly short period and should not affect the results, arguing that changes in concomitant care were small. Throughout the study, caution was taken that all eligibility assessments and endpoint assessments were done in the same procedure, with the same follow-up periods and with the same instruments to lessen the risk of differences between the groups. In spite of this, the baseline data differed between the groups. Kennedy-Martin [30] points out that RCT samples are highly selected and have a lower risk profile than real-world populations. But we argue that this difference is mainly caused by phenotype variability as frail older people are a heterogenic group. According to de Boer [31], researchers should present findings from the fully adjusted analyses, as well as the crude analyses. Therefore, to ensure that the reader would get a result as truth as possible, both non-adjusted analysis, and analyses adjusted for baseline differences were presented in the present study, presenting similar trends.

Conclusions

The findings from the implementation study, from intervention trial (RCT) to full-scale process program, showed positive results on frailty level and self-rated health when implementing the intervention in real life, indicating that a person-centred, multi-professional team with a case manager is beneficial for frail older people.

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Conflict of Interest

The authors declare that there are no conflicts of interests.

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