

# An interdisciplinary primary care approach for frail older people : feasibility, effects and costs

Citation for published version (APA):

Metzelthin, S. F. (2014). *An interdisciplinary primary care approach for frail older people : feasibility, effects and costs*. [Doctoral Thesis, Maastricht University]. Maastricht University.  
<https://doi.org/10.26481/dis.20140326sm>

## Document status and date:

Published: 01/01/2014

## DOI:

[10.26481/dis.20140326sm](https://doi.org/10.26481/dis.20140326sm)

## Document Version:

Publisher's PDF, also known as Version of record

## Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
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# An interdisciplinary primary care approach for frail older people

## FEASIBILITY, EFFECTS AND COSTS

The studies presented in this thesis were performed at the Department of Health Services Research, School for Public Health and Primary Care (CAPHRI), Maastricht University. CAPHRI is part of the Netherlands School of Primary Care Research (CaRe), which has been acknowledged since 1995 by the Royal Netherlands Academy of Arts and Sciences (KNAW).

The work described in this thesis was funded by The Dutch National Care for the Elderly Programme, coordinated and sponsored by The Netherlands Organisation for Health Research and Development (ZonMw). Printing of this thesis was financially supported by Centres of Research on Autonomy and Participation, and Technology in Health Care, Zuyd University of Applied Sciences, School for Public Health and Primary Care (CAPHRI), Maastricht University, Medical Coordination Centre Omnes, Meditta and ABN AMRO.

### Design and lay-out

Promotie In Zicht, Arnhem

### Print

Ipskamp Drukkers, Enschede

### ISBN

978-94-6191-982-3

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## Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Maastricht,  
op gezag van de Rector Magnificus, Prof dr. L.L.G. Soete  
volgens het besluit van het College van Decanen,  
in het openbaar te verdedigen  
op woensdag 26 maart 2014 om 16.00 uur

door

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# 1

## General introduction





## Introduction

In our ageing society, care for older people is one of the greatest challenges in healthcare. In the Netherlands, the proportion of older people ( $\geq 65$  years) will rise from 2.4 million (16% of the total population) in 2010 to 4.6 million (25% of the total population) in 2050.<sup>1</sup> In 2008, the Dutch Ministry of Health, Welfare and Sport launched the National Care for the Elderly Program, an initiative to improve the quality of care for frail older people. As part of the program, this thesis focuses on the evaluation of a pro-active primary care approach to reduce disability and to prevent (further) functional decline in community-dwelling frail older people.

## Frailty

Within an ageing population, the number of frail older people will increase.<sup>2</sup> Frailty appears when the reserve capacity of older people has decreased to a critically low point, at which even small disturbances can lead to a series of complications.<sup>3</sup> Frailty can be positioned on a continuum from pre-frail to frail. The level of frailty can change over time in either direction, meaning that individuals can become more or less frail.<sup>4</sup> In the on-going discussion about the conceptualisation of frailty two main streams can be distinguished: firstly, the frailty phenotype, which focuses on the physical domain of functioning taking into account slow walking speed, impaired grip strength, declining activity levels, exhaustion and unintended weight loss;<sup>3,5</sup> secondly, a multi-dimensional perspective that incorporates physical, psychological and social deficits.<sup>6,7</sup> Within each dimension various (risk) factors or determinants for frailty exist.<sup>7</sup> A well-known example is the Frailty Index, also acknowledged as the deficit accumulation model.<sup>8</sup> It conceptualises frailty as a multidimensional risk state that can be measured by the quantity of deficits. The more deficits an older person has, the higher his or her likelihood of being frail.<sup>8</sup> In the literature, the prevalence rates of frailty range considerably, as frailty is defined and measured in different ways and is assessed in different populations.<sup>9-12</sup> A recent systematic review by Collard and colleagues<sup>10</sup> identified prevalence rates in community-dwelling older people ranging from 4 to 59%. On average, 11% of community-dwelling older people ( $\geq 65$  years) were frail and 42% were pre-frail.<sup>10</sup> Despite the on-going discussion about the conceptualisation of frailty, there is consensus that frail older people have an increased risk of adverse health outcomes, such as acute and chronic diseases, falls, disability, institutionalisation and death.<sup>10,13</sup> The concept of frailty is important for clinicians to understand the heterogeneity and inequalities of ageing, as individuals with the same chronological age may vary widely in health, functional status and need for healthcare utilisation.<sup>10</sup>

## Identification of frail older people

To reduce disability and prevent (further) functional decline frail older people have to be identified in time. Consequently, appropriate screening methods are of increasing importance. One possible screening strategy is regular screening of all individuals of a certain age, which is also known as population screening.<sup>13</sup> For this purpose the age of 70 years seems to be reasonable, as rapid decline of physiological function occurs after this age.<sup>13</sup> In contrast, based on an opportunistic screening approach, older people are screened during regular contact with a healthcare provider (e.g. GP consultation, admission to hospital).<sup>13</sup> Irrespective of the screening strategy, there are numerous performance tests, questionnaires and indices available to measure frailty.<sup>4</sup> Some of them are based on a physiological definition of frailty, while others are developed from a multidimensional perspective. Instruments that focus on physical functioning provide lower and more consistent prevalence rates. However, a multidimensional approach provides information about deficits and care needs in different areas of functioning, which might be of clinical relevance.<sup>10</sup> Frailty instruments can also be distinguished in self-report versus performance-based measures. Self-report measures are believed to be an efficient method for reaching large populations and for providing high response rates and reliable and valid answers.<sup>14</sup> However, performance-based measures are less influenced by socio-demographic variables, personality and cognitive and affective factors.<sup>14-16</sup> Finally, the choice of a particular instrument depends on the setting, the aim of the measurement, the qualities of the person who administers the instrument and the time available.<sup>4</sup>

## Reduction of disability and prevention of (further) functional decline

The identification of frail older people is only useful if effective interventions are available to reverse frailty or to reduce or prevent its adverse health outcomes.<sup>13</sup> One major health outcome is disability, which is defined as difficulty or dependency in the execution of daily activities.<sup>5</sup> Disability can more specifically be related to self-care activities and meaningful activities that are essential for independent living and one's quality of life.<sup>5</sup> Functioning of older people may be influenced by their physiological or psychological state, however, interactions with the physical and social environment can also stimulate or hinder participation in daily activities.<sup>4</sup> In other words, disability reflects the gap between an individual's abilities and the environment in which that person functions.<sup>17</sup> Disability can be considered as a dynamic process, which means that older people can recover to a less or non-disabled state.<sup>18</sup> While disability itself is an adverse health outcome, it is also a risk factor for other adverse events. It increases the risk of diseases, further functional decline, injuries and falls, increased healthcare utilisation, including informal and formal care, and mortality.<sup>19</sup> Consequently, disability in older people affects their quality of life and has a major impact on their social network and the entire healthcare system.<sup>19</sup> Thus, effective interventions

with regard to disability and other adverse health outcomes have the potential to substantially diminish the burden caused by frailty.

## Community-based care in frail older people

Western countries with ageing populations, such as the Netherlands, have to deal with an increasing demand for care, while financial resources and manpower are shrinking.<sup>20</sup> The proportion of older people in Dutch nursing homes and homes for the elderly is decreasing and community-based care is becoming more important.<sup>21</sup> The majority of older people, even with fragile health and faced with challenging social situations, prefer to stay at home for as long as possible.<sup>18</sup> Active and independent participation in daily life is highly important to them.<sup>22</sup> In addition, evidence suggests that community-based care may achieve better outcomes at lower costs compared to institutionalisation.<sup>23</sup> Consequently, The Dutch Council for Public Health and Care emphasises the importance of structural healthcare reforms based on scientific evidence, to improve.<sup>24</sup> Innovative initiatives are needed to provide cost-effective community-based care.<sup>25,26</sup>

During the past decades much research on complex interventions targeting community-dwelling (frail) older people has been conducted, with a substantial amount of studies in the field of preventive home visiting programmes. Since 2000, several meta-analyses,<sup>27-29</sup> systematic reviews,<sup>30-32</sup> and literature reviews<sup>18,33</sup> have been published. The reviews evaluated a range of interventions (e.g. multidimensional geriatric assessment, care planning, organisation and monitoring, health promotion, self-management support, nursing services and referrals to other services) carried out by various professionals (e.g. general practitioners, nurses, allied professionals). The aim of these interventions is to proactively detect modifiable risk factors and worsening health conditions to reduce or prevent disability and other negative health outcomes, health care utilisation and related costs. However, the reviews produced inconsistent and conflicting results regarding their effectiveness and little is known about their cost-effectiveness. It is not yet clear whether such interventions have the potential to reduce disability or prevent (further) functional decline in frail older people or which components are most promising.

## Recent developments in the Dutch healthcare system

As stated in the beginning the National Care for the Elderly Program<sup>34</sup> aims to improve the quality of care for older people by developing coherent care that is better suited to their individual needs. First, the eight University Medical Centres in the Netherlands were asked to create networks in their region, consisting of relevant stakeholders in healthcare and welfare services and patient representatives, to increase the infrastructure for healthcare delivery. Second, each regional network has conducted a number of research projects to improve the quality and coherence of care for frail

older people.<sup>34</sup> In the south of the Netherlands the ACZIO (Academisch Centrum ZorgInnovatie Ouderenzorg) network was created. This thesis reports on one of their research projects evaluating the 'Prevention of Care' (PoC) approach. The PoC approach is an interdisciplinary primary care approach for community-dwelling frail older people. The development of the programme was based on the Intervention Mapping protocol<sup>35</sup> for developing health promotion programmes. In the beginning, two literature reviews were conducted to provide an extensive overview of existing interventions for community-dwelling frail older people, which report on disability as outcome measure. Various interventions were identified with most of them in the field of comprehensive geriatric assessment and physical exercise programmes.<sup>36,37</sup> Based on these reviews we suggested that community-based interventions for frail older people should be conducted by an interdisciplinary primary care team, involving (population) screening, individualised assessments and interventions (tailor-made care), self-management support, engagement in meaningful activities, case management and long-term follow-up. These elements were combined in the PoC approach. A multidisciplinary task group, consisting of researchers and healthcare professionals (general practitioner, practice nurse, geriatrician, nursing home physician, geriatric clinical nurse specialist, physiotherapist and occupational therapist, technology expert) developed the protocol and materials of the PoC approach. Finally, a pilot study (n=41) was conducted providing promising results with regard to its feasibility.<sup>38</sup> Older people appreciated the attention they got and felt supported in reaching their goals and in handling future disability. Healthcare professionals reported that the approach provided a useful structure for geriatric primary care; interdisciplinary collaboration, a focus on meaningful activities and self-management support were stimulated by the approach.<sup>38</sup> However, the effectiveness of the PoC approach with regard to disability and various related outcomes was not studied.

## Aims and outline

The main objective of this thesis is to evaluate the surplus value of the PoC approach. The underlying aims of this thesis are:

- To evaluate and compare the psychometric properties of three screening instruments to identify frail older people.
- To evaluate the feasibility of the PoC approach.
- To evaluate the PoC approach with regard to disability (primary outcome) and other secondary outcomes, including healthcare utilisation and costs.

Findings may lead to more insight into effective methods to identify community-dwelling frail older people. In addition, findings will contribute to the knowledge about

community-based interventions to reduce disability and prevent (further) functional decline and other adverse health outcomes.

Chapter 2 reports on the internal consistency and construct validity of three frailty instruments used for postal screening to identify community-dwelling frail older people: the Groningen Frailty Indicator,<sup>39</sup> the Tilburg Frailty Indicator<sup>40</sup> and the Sherbrook Postal Questionnaire.<sup>41</sup> Chapter 3 gives an overview of interventions that have been studied in randomised controlled and clinical controlled trials aimed at community-dwelling frail older people with disability as an outcome measure. The review was conducted to identify and summarise promising components for future intervention programmes. The design of the cluster randomised trial is described in Chapter 4. Information is provided on the recruitment of participants, the randomisation procedure, the intervention under study, data collection and data analyses. Chapter 5 is about the results of the process evaluation, which was conducted alongside the trial. Data was collected among older people and healthcare professionals to examine the extent of implementing the intervention protocol and to gain insight into healthcare professionals' and frail older people's experiences regarding benefits, burdens, stimulating factors and barriers. In Chapter 6 the effects of the PoC approach with regard to disability (primary outcome) and depressive symptomatology, social support interactions, fear of falling and social participation are presented. Data were collected after 6, 12 and 24 months among 346 community-dwelling frail older people. The outcomes of the cost-effectiveness (CEA) and cost-utility analysis (CUA) are reported in Chapter 7. The evaluation was performed from a societal perspective with a time horizon of 24 months. Finally, Chapter 8 provides a summary and a discussion of the main findings, followed by implications for practice and future research. The PoC approach is described in more detail in the Appendix.

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# 2

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## **The psychometric properties of three self-report screening instruments for identifying frail older people in the community**



**This chapter was published as:**

Metzelthin, SF, Daniëls, R, van Rossum, E, de Witte, LP, van den Heuvel, W, Kempen, GJM  
BMC Public Health 2010;10:51

## Abstract

**Background:** Frailty is highly prevalent in older people. Its serious adverse consequences, such as disability, are considered to be a public health problem. Therefore, disability prevention in community-dwelling frail older people is considered to be a priority for research and clinical practice in geriatric care. With regard to disability prevention, valid screening instruments are needed to identify frail older people in time. The aim of this study was to evaluate and compare the psychometric properties of three screening instruments: the Groningen Frailty Indicator (GFI), the Tilburg Frailty Indicator (TFI) and the Sherbrooke Postal Questionnaire (SPQ). For validation purposes the Groningen Activity Restriction Scale (GARS) was added.

**Methods:** A questionnaire was sent to 687 community-dwelling older people ( $\geq 70$  years). Agreement between instruments, internal consistency, and construct validity of instruments were evaluated and compared.

**Results:** The response rate was 77%. Prevalence estimates of frailty ranged from 40% to 59%. The highest agreement was found between the GFI and the TFI (Cohen's kappa=0.74). Cronbach's alpha for the GFI, the TFI and the SPQ was 0.73, 0.79 and 0.26, respectively. Scores on the three instruments correlated significantly with each other (GFI-TFI,  $r=0.87$ ; GFI-SPQ,  $r=0.47$ ; TFI-SPQ,  $r=0.42$ ) and with the GARS (GFI-GARS,  $r=0.57$ ; TFI-GARS,  $r=0.61$ ; SPQ-GARS,  $r=0.46$ ). The GFI and the TFI scores were, as expected, significantly related to age, sex, education and income.

**Conclusions:** The GFI and the TFI showed high internal consistency and construct validity in contrast to the SPQ. Based on these findings it is not yet possible to conclude whether the GFI or the TFI should be preferred; data on the predictive values of both instruments are needed. The SPQ seems less appropriate for postal screening of frailty among community-dwelling older people.

## Background

Frailty is highly prevalent in older people. Up to 40% of older people can be considered as frail and an increasing trend can be expected.<sup>1</sup> Next to its high prevalence, frailty is characterized by its seriousness as it is related to increased risk of adverse health outcomes such as disability.<sup>2-4</sup> Disability is defined as difficulty or dependency in the execution of activities of daily living and it is associated with increased health service utilisation and related costs. Frailty and disability are separate but overlapping concepts. On the one hand, frailty predicts disability. On the other hand, disability may well exacerbate frailty.<sup>5</sup> With regard to a growing frail population and limited health care expenditures, disability in community-dwelling frail older people is suggested to be a public health problem.<sup>3</sup> Therefore disability prevention in community-dwelling frail older people is considered to be a priority for research and clinical practice in geriatric care.<sup>6</sup>

Several authors emphasize a two-step approach in preventive interventions for community-dwelling frail older people, in which screening is followed by extensive assessment. With valid (screening) instruments to identify frail older people this approach may avoid costs and the unnecessary assessment of healthy people.<sup>7,8</sup> During the last few decades, various instruments, based on various definitions, have been developed to detect frailty. This has led to a diversity of prevalence estimates of frailty.<sup>4</sup> Little is yet known about the reliability and validity of these instruments and no gold standard exists. Therefore, more insight into the psychometric properties of frailty instruments is relevant for geriatric care and research in this area.<sup>4</sup>

Frailty instruments have been developed from the point of view of different perspectives on frailty.<sup>9</sup> From a physiological perspective physical frailty markers, such as unintentional weight loss or weakness (grip strength), are used to identify frail older people.<sup>5</sup> Next to physical factors, a multifactorial perspective on frailty also takes psychological, social and environmental factors into account.<sup>10</sup> An example of such an instrument is the Frailty Index,<sup>11,12</sup> which combines, for example, physical frailty markers such as weight loss and grip strength with other factors such as cognition, mood or limitations in (instrumental) activities of daily living. Frailty may be elaborated more sharply if it is described from a physiological perspective. However, the usefulness of this perspective in daily practice is questioned, as frailty cannot be separated from other factors such as cognition, mood or social support.<sup>9</sup>

Frailty instruments can be divided into self-report and performance-based instruments.<sup>9</sup> It is assumed that performance-based instruments provide more precise and valid answers.<sup>13,14</sup> Although they are less influenced by socio-demographic variables, personality and cognitive and affective factors, they are more sensitive to non-response, changes in time and differences in the execution of activities. Furthermore, they are less easy to conduct and time-consuming.<sup>13-15</sup> Self-report



measures are believed to be an efficient method for reaching large groups and for providing high response rates and reliable and valid answers.<sup>15</sup>

In this study, we present the psychometric properties of frailty instruments that define frailty from a multifactorial perspective and are applicable for postal screening of community-dwelling older people. Given this objective and the target population, the Groningen Frailty Indicator (GFI)<sup>16</sup>, the Tilburg Frailty Indicator (TFI)<sup>17</sup>, and the Sherbrooke Postal Questionnaire (SPQ)<sup>8</sup> were chosen. The GFI and the SPQ have been used in previous studies for the purpose of postal screening.<sup>18-22</sup> However, empirical evidence about the psychometric properties of the GFI, the TFI, and the SPQ is still scarce. The purpose of the present study was to evaluate and compare their psychometric properties.

## Methods

### Study design and participants

A cross-sectional study was conducted in a sample of 687 community-dwelling older people living in the areas of Limburg and Utrecht in the Netherlands. Older people were identified between November 2008 and April 2009 from the panels of three general practitioners (GPs). All persons aged 70 years or above from each of the panels were invited by these GPs to participate in the study and to fill in a short questionnaire. The questionnaire included the three frailty instruments (GFI, TFI, SPQ) and an instrument that measures disability with respect to (instrumental) activities of daily living: the Groningen Activity Restriction Scale (GARS).<sup>23</sup> After two weeks a reminder was sent to non-respondents. Participants of the study were well informed about the study in a patient information letter that accompanied the questionnaire. The information letter was formulated according to the guidelines of good clinical practice. Participants had to give written informed consent. The study did not require ethical approval. The postal procedure, including the questionnaire, has proven to be feasible for postal screening in a pilot study.<sup>24</sup>

### Data collection

The three frailty instruments and the disability measure are briefly described below.

### Measures

The Groningen Frailty Indicator (GFI), developed by Steverink and colleagues,<sup>16</sup> is a screening instrument for determining the level of frailty. It consists of fifteen items and focuses on the loss of functions and resources in four domains of functioning: physical (nine items), cognitive (one item), social (three items) and psychological (two items). Most items can be answered with 'yes' or 'no'. For the cognitive and

psychosocial items the option 'sometimes' is added. Scores on the GFI range from zero to fifteen. A total score of four or higher is considered as moderately to severely frail.<sup>16,21</sup> A study by Steverink and colleagues<sup>16</sup> suggested that the GFI is an internally consistent scale with positive indications for construct and clinical validity.

The Tilburg Frailty Indicator (TFI) has recently been described by Gobbens and colleagues<sup>17</sup> and consists of two subscales. The first subscale (ten items) comprises determinants of frailty, for example, socio-demographic data and data about life-events and chronic diseases. Socio-demographic data (age, sex, educational level and income) were used for validation purposes. The analyses of psychometric properties focus on the second subscale, which determines the level of frailty. This subscale consists of fifteen items that are about physical (eight items), social (three items) and psychological factors (four items), including one item which is about cognition. Most items can be answered with 'yes' or 'no'. For the psychological items the option 'sometimes' is added. Scores for the TFI range from zero to fifteen. A score of five or higher is considered to be associated with frailty.<sup>17</sup>

The Sherbrooke Postal Questionnaire (SPQ) was developed by Hébert and colleagues<sup>8</sup> and consists of six items aiming to identify frail older people in the community. The items focus on the physical (four items), social (one item) and cognitive (one item) domains of functioning. Items can be answered with 'yes' or 'no'. Scores range from zero to six. Those older persons scoring two or higher, or who do not respond to the questionnaire, are considered to have an increased risk for functional decline and therefore are assumed to be frail. It should be noted that in the present study non-respondents were excluded from the analyses. In a Canadian sample of community-dwelling older people, predictive validity with regard to functional decline has been found.<sup>8</sup> There are also indications for its predictive validity with regard to requirements for further assessment,<sup>20</sup> use of emergency services<sup>22</sup> and mortality.<sup>19</sup>

The Groningen Activity and Restriction Scale (GARS)<sup>23</sup> is a valid and reliable instrument and consists of two subscales. The first subscale is about activities of daily living (ADL) (eleven items). The second subscale relates to instrumental activities of daily living (IADL) (seven items). Items can be answered on a four point scale ranging from 'Yes, I can do it fully independently without any difficulty' to 'No, I cannot do it fully independently; I can only do it with someone's help'. Scores range from 18 to 72 (total scale), from 11 to 44 (ADL subscale) and from 7 to 28 (IADL subscale). Higher scores indicate greater disability in activities of daily living.

### Statistical analysis

Firstly, to provide an overview of respondents' background characteristics, descriptive statistics were used.

Secondly, the reliability was determined from agreement between instruments (Kappa statistic based on proposed cut-off points by original authors) and internal consistency. Cronbach's alpha coefficient was calculated to evaluate internal consistency of items. Cronbach's alpha produces the same result as the Kuder-Richardson Formula 20 (KR-20), which can be used to assess the internal consistency for dichotomous items.<sup>25</sup> Furthermore, corrected total-item-correlations were calculated.

Thirdly, to assess the validity, non-parametric tests were used as our data were not normally distributed. If less than 25% (GFI, TFI, SPQ) or 50% (GARS)<sup>23</sup> of the items were missing, these were imputed by means of case mean substitution.<sup>26</sup> If more items were missing, persons were excluded from the analysis for the particular scale. The construct validity was assessed using Spearman's rank correlation between the three frailty instruments, as the instruments were assumed to measure the same concept of frailty. Frailty and disability are strongly related concepts,<sup>5</sup> as frail older people have an increased risk of disability and disability exacerbates frailty.<sup>2,3,5</sup> Substantial associations between frailty and disability were expected. Therefore, construct validity was also assessed by examining associations between frailty and disability, measured by means of the GARS (Spearman's rank correlation). However, correlations should not be too high, otherwise frailty instruments and the GARS would measure the same concept. Furthermore, frail older people were more likely to be older, female, less educated, and had lower incomes compared to their non-frail counterparts.<sup>27</sup> Since the distribution of frailty scores was non-normally distributed, Mann-Whitney U and Kruskal-Wallis tests were performed to evaluate differences in the distribution of frailty scores among groups with different background characteristics.<sup>28</sup> For the dichotomous variable gender (female versus male) the Mann-Whitney U test was applied. For categorical variables with more than two groups (age, education and income), Kruskal-Wallis tests were used to compare the distribution of frailty scores among groups.

All statistical analyses were performed using SPSS for Windows, version 16.0. The level of statistical significance was set at  $p=0.05$  (two-tailed). For post-hoc pairwise comparisons a Bonferroni correction was applied, so all effects are reported at a  $p=0.02$  level of significance (two-tailed) in the case of three groups (age, education, income).

## Results

### Participants

Of the 687 community-dwelling older people ( $\geq 70$  years), 532 (77%) returned the questionnaire. The sample consisted of 311 women (59%) and 221 men (42%). In total, 64% of respondents lived in an urban area (Roermond, Amersfoort), while 36% lived in a rural area (Roggel). When using the proposed cut-off points, the GFI detected 245 frail

cases (46%). The TFI and the SPQ identified 211 (40%) and 305 (59%) frail older people, respectively. The mean age of respondents was 77.2 years with a range of 70–97 years ( $SD=5.5$ ). Nearly half of the sample (49%) had a secondary educational level. The largest proportion of people (42%) had a net income of more than €1500 (per month/ per household). An overview of background characteristics is presented in Table 1. The sample is representative for the Dutch population of older people. According to a report of the Netherlands Institute for Social Research<sup>29</sup> slightly more people aged 75 years and older are female. Older people, especially women, are often less educated and have an average income of about €1500 (per month/ per household).

The frailty instrument with the greatest number of excluded respondents due to missing values ( $>25\%$  missing values) was the SPQ ( $n=8$ ). For the GFI and the TFI, one and two persons, respectively, were excluded due to missing values. On an

**Table 1** Characteristics of the participants ( $n=532$ ).

		Men ( $n=221$ )	Women ( $n=311$ )	Total ( $n=532$ )
<i>Frail<sup>1</sup></i>	<i>n (%)</i>			
GFI		86 (39)	159 (51)	245 (46)
TFI		66 (30)	145 (47)	211 (40)
SPQ		148 (68)	157 (53)	305 (59)
<i>Age<sup>2</sup></i>	<i>n (%)</i>			
70-74 yrs		91 (41)	102 (33)	193 (36)
75-79 yrs		78 (35)	115 (37)	193 (36)
$\geq 80$ yrs		52 (24)	94 (30)	146 (27)
<i>Education</i>	<i>n (%)</i>			
No Education/ Primary Education		62 (29)	124 (41)	186 (36)
Secondary Education		102 (47)	151 (50)	253 (49)
Higher Education		53 (24)	29 (10)	82 (16)
<i>Income</i>	<i>n (%)</i>			
$\leq \text{€}900$		34 (16)	59 (21)	93 (19)
€901 to €1500		63 (30)	131 (46)	194 (39)
$\geq \text{€}1501$		114 (54)	97 (34)	211 (42)

<sup>1</sup> Based on proposed cut-off points by original authors: GFI $\geq 4$ , TFI $\geq 5$ , SPQ $\geq 2$ .

<sup>2</sup> Mean age men 76.6 years ( $SD$  5.4), mean age women 77.6 years ( $SD$  5.5).



item-level the number of missing values ranged from zero to eight (GFI), from zero to twelve (TFI) and from one to ten (SPQ). The average number of missing values per item was 2.4, 5.1 and 5.3 for the GFI, the TFI and the SPQ, respectively.

### Reliability

Cohen's Kappa coefficients between instruments were 0.74 (GFI-TFI), 0.28 (SPQ-GFI) and 0.25 (SPQ-TFI). According to Landis & Koch<sup>30</sup> the kappa values indicated good agreement between GFI and TFI and fair agreement between the between GFI and SPQ and TFI and SPQ (<0.20=poor, 0.21-0.40=fair, 0.41-0.60=moderate, 0.60-0.80=good, 0.81-1.00=very good agreement). Cronbach's alpha coefficients for the GFI, the TFI and the SPQ were  $\alpha=0.73$ ,  $\alpha=0.79$  and  $\alpha=0.26$ , respectively. The higher Cronbach's alpha, the more reliable the test is. Alpha values above 0.70 indicated a satisfactory internal consistency for a scale.<sup>31</sup> Corrected item-total correlations ranged from 0.14 to 0.55 with a mean of 0.30 (GFI), from 0.18 to 0.58 with a mean of 0.39 (TFI) and from 0.13 to 0.25 with a mean of 0.18 (SPQ).

### Validity

Frailty instruments correlated significantly ( $p < 0.05$ ) with each other and with disability measured by means of the GARS (convergent validity). The association between the GFI and the TFI scores was  $r=0.87$ . Correlations with the SPQ scores were  $r=0.47$  for the GFI and  $r=0.42$  for the TFI. The correlation coefficients between frailty instruments and disability (GARS) were  $r=0.57$  (GFI-GARS),  $r=0.61$  (TFI-GARS) and  $r=0.46$  (SPQ-GARS). An overview of all correlation coefficients is presented in Table 2.

**Table 2** Spearman correlation coefficients (99%-confidence interval) among frailty instruments and GARS.

	GFI	TFI	SPQ	GARS Total scale	GARS ADL scale
TFI	0.87 (0.84-0.89)				
SPQ	0.47 (0.1-0.55)	0.42 (0.32-0.51)			
GARS Total scale	0.57 (0.49-0.64)	0.61 (0.53-0.68)	0.46 (0.37-0.54)		
GARS ADL scale	0.54 (0.46-0.61)	0.58 (0.5-0.65)	0.41 (0.32-0.5)	0.94 (0.93-0.95)	
GARS IADL scale	0.55 (0.47-0.62)	0.57 (0.49-0.64)	0.46 (0.37-0.54)	0.96 (0.95-0.97)	0.79 (0.74-0.83)

Table 3 shows the mean total scores and standard deviations of the GFI, the TFI and the SPQ related to (a) age, (b) sex, (c) education and (d) income. Scores on the GFI and the TFI were significantly higher for females, for persons with a higher age and for persons with lower education and lower incomes as compared to males, persons with a lower age, and persons with higher education and higher incomes. In

**Table 3** Mean scores on frailty instruments<sup>1</sup> according to sex, age, educational level and income.

		GFI	TFI	SPQ
Total sample	Mean (sd)	3.6 (2.8)	4.2 (3.2)	1.9 (1.2)
Sex	Mean (sd)			
Male		3.2 (2.7)	3.4 (3.1)	2.1 (1.2)
Female		3.9 (2.8)	4.7 (3.2)	1.7 (1.2)
	Z statistic (P-value)	-3.31 (0.001)	-4.95 (0.000)	-3.28 (0.001)
Age	Mean (sd)			
≤74 yrs		3.0 (2.7)	3.3 (3.1)	1.7 (1.2)
75-79 yrs		3.6 (2.8)	4.2 (3.3)	1.9 (1.2)
≥80 yrs		4.4 (2.7)	5.3 (3.1)	2.2 (1.2)
	Chi-square <sup>2</sup> (P-value)	27.58 (0.000)	37.2 (0.000)	15.84 (0.000)
Education	Mean (sd)			
No Education/ Primary Education		4.1 (3.0)	4.7 (3.5)	2.0 (1.3)
Secondary Education		3.6 (2.7)	4.1 (3.1)	1.8 (1.2)
Higher Education		2.7 (2.2)	3.1 (2.8)	1.7 (1.0)
	Chi-square <sup>2</sup> (P-value)	12.13 (0.002)	13.47 (0.001)	2.47 (0.291)
Income	Mean (sd)			
≤€900		4.6 (3.0)	5.3 (3.6)	2.2 (1.4)
€901 to €1500		4.0 (2.9)	4.8 (3.4)	1.8 (1.3)
≥€1501		2.8 (2.3)	3.1 (2.6)	1.8 (1.0)
	Chi-square <sup>2</sup> (P-value)	29.42 (0.000)	37.16 (0.000)	5.05 (0.080)

<sup>1</sup> Higher scores indicate poorer functioning.

<sup>2</sup> Kruskal Wallis test

contrast, on the SPQ we found higher scores among males as compared to females. Scores on the SPQ increased with higher age, lower education and lower incomes, however, the differences with respect to education and income were not significant ( $p=0.29$  and  $p=0.08$  respectively).

## Discussion

The purpose of the present study was to evaluate and compare the psychometric properties of three screening instruments that define frailty from a multifactorial perspective and which are applicable for postal screening in community-dwelling older people. The chosen instruments were the Groningen Frailty Indicator (GFI), the Tilburg Frailty Indicator (TFI) and the Sherbrooke Postal Questionnaire (SPQ).

From the present study we may conclude that: (1) prevalence estimates of frailty ranged between 40% (TFI), 46% (GFI) and 59% (SPQ); (2) the agreement in identifying frailty between the GFI and the TFI was satisfactory ( $\kappa=0.74$ ) and the agreements between the SPQ and the GFI and the TFI, respectively, were much lower; (3) both the GFI and the TFI had high internal consistency in contrast to the SPQ; (4) the GFI and the TFI had better construct validity in comparison with the SPQ.

Prevalence estimates of 40% to 60% found in the present study can be considered as high. It is important to bear in mind that prevalence estimates strongly depend on the interpretation of the concept of frailty and the approach that is chosen to measure it.<sup>32</sup> In a recent study by Santos-Eggimann and colleagues,<sup>33</sup> a distinction was made between frail and pre-frail older people based on the frailty phenotype of Fried and colleagues.<sup>5,34</sup> In a Dutch sample of community-dwelling older people, Santos-Eggimann and colleagues<sup>33</sup> found a frailty prevalence of 11%, while 39% were identified as pre-frail. These results indicate that the instruments in our study, based on the proposed cut-off points, may identify pre-frail instead of frail older people. Further research is needed to provide a better view on relevant cut-off points for frailty instruments. Longitudinal studies are needed to investigate the predictive power of instruments to identify older people who are at risk for adverse health outcomes in the near future.

Steverink and colleagues<sup>16</sup> suggested that the GFI is an internally consistent scale with positive indications for construct and clinical validity. The present study supports these findings. Similar results for the TFI may be explained by seven out of fifteen items of the TFI being identical with the GFI. These items are about hearing and vision capacity, unintentional weight loss and psychosocial and cognitive functioning. Scores on the Sherbrooke Postal Questionnaire were higher for males compared with females. This finding is inconsistent with the literature.<sup>27</sup> However, other findings on the Sherbrooke Questionnaire (higher score with higher age, lower

educational level and lower incomes) are well in line with the literature.<sup>27</sup> Previous studies about the SPQ have reported regarding the predictive validity of the SPQ,<sup>8,19,20,22</sup> however, in the present study the SPQ showed less reliability and construct validity. Conclusions about predictive validity cannot be drawn for any of the three instruments.

The findings of the present study should be interpreted in the context of potential limitations. First, little is known about the test-retest reliability of the instruments. Second, there is no gold standard available as an external criterion of frailty. Future studies could analyse the predictive validity of the frailty instruments with respect to disability, health service utilisation and mortality. Last, the SPQ was not fully used according to the protocol, as non-respondents were excluded from analyses. According to the protocol of the SPQ<sup>8</sup>, non-respondents should also be considered at risk (which would have resulted in a prevalence estimate of 67% instead of 59%). The strengths of the present study are the comparisons of the psychometric properties of the frailty instruments, the proven feasibility of the postal procedure<sup>24</sup> and the response rate of 77%, which is as good as, or even better than, previous studies in which postal screening procedures were applied.<sup>24,35,36</sup>

Although most older people may visit their GP regularly, primary care often fails in the identification of the health care needs of older people.<sup>37</sup> Screening has the potential to identify older people at risk, followed by comprehensive assessment when needed.<sup>7,8</sup> Frailty instruments have to provide reliable and valid answers and have to be feasible.<sup>15</sup> The psychometric properties of the TFI were slightly better than those of the GFI. However, the number of missing values was lower for GFI items than for TFI items, indicating a higher feasibility of the GFI. Based on these findings it is not yet possible to conclude whether the GFI or the TFI should be preferred for postal screening. The SPQ is less appropriate with regard to its psychometric quality and missing values.

The Frailty Index<sup>8,11</sup> is a simple measure that is based on self-reports. However, less is known about its feasibility for postal screening. Investigating the feasibility and validity of the Frailty Index as a postal screening instrument may be a point of interest for future research. Future (longitudinal) research into the psychometric properties of the GFI and the TFI is urgently needed with regard to predictive validity and test-retest reliability of the GFI and the TFI. In addition, comparing the GFI and the TFI with other frailty-related constructs would lead to more insight into their construct validity.

## Conclusion

Valid screening instruments for identifying community-dwelling frail older people are needed for disability prevention. The GFI and the TFI have shown high internal consistency and construct validity, in contrast to the SPQ. Prevalence estimates of

frailty ranged from 40% to 59%. Most agreement was found between the GFI and the TFI. Based on these findings, it is not possible to conclude whether the GFI or the TFI should be preferred for screening. The SPQ seems less appropriate. Further research is needed.

### Acknowledgements

The authors are grateful to the patients for their willingness to participate in the present study. The Centre for Data and Information Management (MEMIC) at Maastricht University is acknowledged for their assistance in the data collection. This research has been funded by Zuyd University of Applied Sciences.

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## **Interventions to prevent disability in community-dwelling frail older people: an overview**



**This chapter was published as:**

Daniëls, R, Metzelthin, S, van Rossum, E, de Witte, LP, van den Heuvel, W  
European Journal of Ageing 2010;7:37-55

## Abstract

This narrative review was conducted to provide an overview of the variety of interventions aimed at disability prevention in community-dwelling frail older people and to summarise promising elements. The search strategy and selection process found 48 papers that met the inclusion criteria. The 49 interventions described in these 48 papers were categorised into 'comprehensive geriatric assessment', 'physical exercise', 'nutrition', 'technology' and 'other interventions'. There is a large diversity within and between the groups of interventions in terms of content, disciplines involved, duration, intensity and setting. For 18 of the 49 interventions, significant positive effects for disability were reported for the experimental group. Promising features of interventions seem to be: multidisciplinary and multifactorial, individualised assessment and intervention, case management, long-term follow-up, physical exercise component (for moderate physically frail older people) and the use of technology. Future intervention studies could combine these elements and consider the addition of new elements.

## Introduction

Frail older people are at much higher risk of disability, hospitalisation, institutionalisation, and death, compared with their age-matched non-frail counterparts.<sup>1-3</sup> In scenarios that predict future health service delivery in the Western world, the rapid increase in frail older people is seen as one of the major challenges to healthcare.<sup>4-6</sup> There has been an exponential rise in the use of the term 'frailty' in the literature.<sup>7</sup> Markle-Reid and Brown (2003) reported substantial disagreement in the literature how frailty is defined and measured.<sup>5</sup> The debate has focused on whether the frailty should be defined purely in terms of biomedical factors or whether psychosocial factors should be included as well.<sup>8</sup> From their literature reviews, Levers and colleagues (2006) as well as Aminzadeh and colleagues (2002) conclude that most definitions of frailty do include the idea of loss of age-related reserve capacity, though differences exist regarding other factors contributing to frailty.<sup>9,10</sup> Despite a lack of consensus about the definition of frailty, a growing number of intervention studies for frail older people are reported, implying that interventions can be targeted at frail older people independent of specific diseases. Disability, defined as experienced difficulty in performing activities in any domain of life,<sup>11</sup> is generally considered as one of the major adverse outcomes of frailty. Prevention of disability in frail older people is seen as a priority for research in geriatrics and can lead to the maintenance of quality of life and reduced healthcare costs.<sup>12,13</sup> Several systematic reviews are available, which focus on specific categories of interventions for frail older people, e.g. comprehensive geriatric assessment, after-care or respite care.<sup>14-16</sup> No overview is available, however, which provides an extensive overview of the content of the full range of existing programmes for community-living frail older people that are aimed at the prevention of disability. The present study is a narrative review covering a wide range of programmes for community-dwelling frail older people. The primary aim of this study is to provide an overview of the type of interventions studied in randomised or controlled clinical trials regardless of other aspects of their methodological quality. In order to develop future effective interventions aimed at disability prevention lessons can be learned from such studies. Therefore, the secondary aim of the review is to summarise promising components for future interventions from studies that reported significant effects.

## Methods

### Search strategy

On 3 March 2008, the databases PubMed, the Cochrane Central Register of Controlled Trials (CENTRAL) and CINAHL were searched for randomised controlled clinical trials by use of the words 'frail\*', 'vulnerable', 'at risk', 'high risk', 'low functioning',

and the MESH terms 'chronic disease' and 'disabled persons' in combination with the MESH term 'aged'. Search terms for outcomes focused on disability measures and included terms like 'disabil\*', 'functional decline', 'functional capabilit\*', 'functional performance', 'independen\*' and MESH terms 'activities of daily living', 'quality of life' and 'well-being'. In order to restrict the search to interventions that targeted community-dwelling older people, terms like 'home\*', 'in-home\*', 'communit\*', 'independent living' and MESH term 'primary care' were added. Additionally, studies were identified by a manual search of reference lists from relevant papers. The search was restricted to articles in English, Dutch and German. There was no restriction on type of intervention or year of publication.

### Selection criteria

Inclusion criteria were set for study population, outcome measure, and design. Randomised and controlled clinical trials specifically aimed at community-dwelling frail older people were included. No restrictions were set concerning the definition of frailty. As frailty points to an increased risk of adverse outcomes, only studies that specified the criteria used to operationalise the increased risk were included. Studies that used physical markers to include participants were included as well as studies that used a combination of factors (multifactorial perspective on frailty) as inclusion criteria. Exclusion criteria for the population concerned the selection of participants solely based on age, age and fall incident(s), and age and having one chronic disease.

Disability was used as the outcome measure (regardless of whether it was used as a primary or secondary outcome) and defined as difficulty experienced in performing activities.<sup>11</sup> Avlund (2004) found that most current studies of disability among older people focus on the ability to carry out activities of daily living.<sup>17</sup> In this review, studies reporting measurements of Activities of Daily Living (ADL) or Instrumental Activities of Daily Living (IADL) were included.

### Data extraction and analysis

A first selection of relevant studies was made by RD on title-level with a conservative approach, meaning that in case of doubt an article would always be screened on abstract-level. The second (abstract-level) and third selection phase (full-text level) were independently undertaken by two reviewers (RD and SM) scoring 'relevant', 'doubt' or 'irrelevant' on forms. In case of inconsistencies, the reviewers discussed their scores. Consensus on 'irrelevant' led to the exclusion of an article. On several occasions, the reviewers asked for the involvement of a third party (EvR) to reach consensus.

The same two reviewers performed the data extraction with respect to the aims, target population, design, care disciplines involved, and content of the interventions. Furthermore, follow-up and reported effectiveness on disability was retrieved from

the articles. Assessment of the methodological quality of studies was not performed, as the primary aim was to provide an overview of the type of interventions reported for community-dwelling frail older people. The research team (RD, SM, EvR, LdW, WvdH) discussed ways of categorising the studies based on descriptions common in geriatric literature. As this review intends to provide an overview of the content of interventions, it was decided to categorise the interventions according to their intervention characteristics. Interventions were classified into 'comprehensive geriatric assessment (CGA)', 'physical exercise', 'nutrition', 'assistive technology', and 'other interventions'. Studies that reported significant effects in favour of the experimental group on ADL or IADL measures were further explored (by RD and SM) to identify intervention elements that might explain successful outcomes.

## Results

Four thousand, six hundred and forty-five articles were identified in the literature search. After screening of the titles, 170 studies were considered relevant for further screening on abstract-level. Of these, another 63 studies were excluded, because they did not meet the inclusion criteria (Figure 1). In the next phase, the screening of 107 full-text articles resulted in the exclusion of 59 studies. Of these, 21 were excluded as they did not meet the criteria for population characteristics; Fourteen did not meet the criteria for the outcome measure (disability); and fourteen failed owing to study design. Forty-eight studies, describing 49 interventions, were included. Among these, 26 interventions were categorised as 'comprehensive geriatric assessment (CGA)', twelve as 'physical exercise', three as 'nutrition', two as 'assistive technology', and six were classified as 'other interventions'. All studies were published between 1986 and 2008. There is a large variation in the criteria that studies used to include frail older people (see Table 1). Physical frailty markers are more common as inclusion criteria in physical exercise programmes, while more complex interventions (CGA) generally use a combination of factors, taking a multifactorial perspective on frailty. All 48 studies met the inclusion criterion to measure disability by using measurements on ADL or IADL. However, disability was not the primary outcome measure for all studies. Eleven studies did perform a long-term follow-up measurement ( $\geq 6$  months after the end of the intervention). For nine studies information on follow-up was lacking.



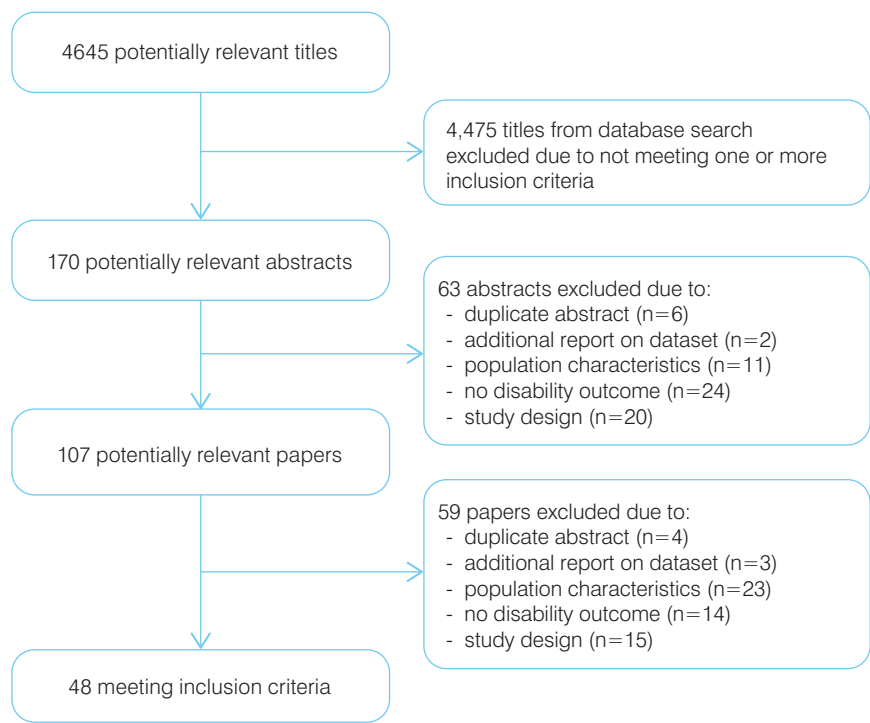


Figure 1 Progress of search for relevant trials.

Table 1 Intervention characteristics.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
CGA: Transmural care			
Burns et al. (1995) USA RCT (n=128)	Aged≥65; at least two of following criteria: ADL deficits, two or more chronic diseases, polypharmacy, two or more hospitalizations in the previous year	Initial assessment of functional limitations, gait, incontinence, polypharmacy, depression and cognitive impairment in outpatient geriatric clinic by interdisciplinary primary care team (physician, nurse practitioner, social worker, psychologist and pharmacist), followed by long-term management (2 years) with individualized goals, interventions, treatment and follow-up	Katz Activities of Daily Living Scale: Small differences (NS) in favour of IG at 12, 24 months. Lawton & Brody Instrumental Activities of Daily Living Scale: Small differences (NS) in favour of IG at 12 months. No differences between groups at 24 months
Hughes et al. (1990) USA RCT (n=233)	Two or more impairments based on the Katz Activities of Daily Living Scale	Hospital-based home care program directed by a physician. Approximately 6 home visits by primary care team (physician, nurse, social worker, physical therapist, occupational therapist, dietitian, health technician). Medications and supplies from the hospital pharmacy	Barthel ADL Index: No significant differences between groups at 1, 6 months (after discharge)
McCusker et al. (2001) Canada RCT (n=388)	Aged≥65; score of 2 or more on the Identification of Seniors at Risk Screening Tool	Evaluation by nurse (physical and mental function, medical status and social factors) followed by an interdisciplinary team meeting. After discharge referrals to primary physician, local community health centre, outpatient clinic and other community services. Follow-up visits by nurse to ensure execution of appointments and services	Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL and IADL scale): Differences (SS) in favour of IG at 4 months



Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
<i>CGA: Transmural care</i>			
Naylor et al. (1999) USA RCT (n=363)	Aged≥65; medical diagnose AND at least 1 of several criteria, e.g., inadequate support system, depression, impairments, hospitalization, poor self-rating of health	Comprehensive discharge planning and home follow-up (till 4 weeks after discharge). Advanced nurse practitioner did a physical and environmental assessment and targeted efforts at patient's and caregivers' management of health problems. Interventions (home visits and telephone follow-up) focused on medications, symptom management, diet, activity, sleep, medical follow-up and emotional status	Enforced Social Dependency Scale: No significant differences between groups at 2, 6, 12, 24 weeks (after discharge)
Oktaay and Volland (1990) USA CCT (n=191)	Aged≥65; chronic post-hospital care needs	Assessment by nurse and social worker. After discharge followed home visits (on average 4 home visits per month during 1 year). Nurse and social worker (supported by weekly staff meetings) provided a coordinated program including case management, counselling, referrals, respite, education, support group sessions, medical back-up and on-call help. Strong focus on caregiver/patient configuration	Katz Activities of Daily Living Scale/3 items of Lawton & Brody Instrumental Activities of Daily Living Scale: No significant differences between groups at 1, 3, 6, 9, 12 months (after discharge)
Rubin et al. (1993) USA RCT (n=194)	Aged≥70; at high risk of hospital readmission for inpatient treatment to stabilize acute episodes of chronic illness	Geriatric Assessment Team (internist, psychiatrist, nurse, social worker) did assessment, developed plan for long-term care and directed discharge planning (including referrals for home health services). In the outpatient period comprehensive interdisciplinary care was provided on an on-going base in the clinic	Katz Activities of Daily Living Scale: No significant differences between groups at 12 months (after discharge). Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL and IADL scale): Differences (SS) in favour of IG at 12 months (after discharge)
Siu et al. (1996) USA RCT (n=354)	Aged≥65; unstable medical problems OR recent functional limitations OR potentially reversible geriatric clinical problems	At hospital nurse practitioner (NP) carried out a physical examination focused on geriatric problems. Multidisciplinary team meeting was followed by recommendations to the primary care physician (strong focus on physician's adherence with these recommendations). A home visit was made by NP within 1–3 days after discharge. Three home visits followed by the NP and other team members	Medical Outcome Study Short Form: No significant differences between groups at 1, 2 months (after discharge)
<i>CGA: Assessment followed by referrals and recommendations</i>			
Hebert et al. (2001) Canada RCT (n=503)	Aged≥75; identified at risk by Sherbrooke postal questionnaire	Home visit by nurse to assess problems with medication, mood, cognition, vision, hearing, blood pressure, gait and balance, orthostatic hypotension, environmental risk of fall, malnutrition, incontinence and social support. Recommendations were sent to general practitioner and referrals were made to specialized resources. Nurse contacted monthly clients to check the implementation	Functional Autonomy Measurement System: No significant differences between groups at 12 months
Reuben et al. (1999) USA RCT (n=363)	Aged≥65; failed a screen for at least one condition: falls, incontinence, depressive symptoms, functional impairment	Assessment done by social worker, geriatric nurse practitioner/geriatrician team at community-based clinic, followed by team meeting resulting in written recommendations for the patient and the primary physician. Telephone contact with the primary physician. A booklet (how to talk to your doctor) was given to patient. Telephone contacts with a health educator were applied to enhance adherence	Medical Outcome Study Short Form (physical functioning scale): Differences (SS) in favour of IG at 15 months

Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
<i>CGA: Assessment followed by referrals and recommendations</i>			
Robichaud et al. (2000) Canada RCT (n=99)	Aged ≥75; identified at risk by Sherbrooke postal questionnaire	Home visit by nurse to assess problems with medication, mood, cognition, vision, hearing, blood pressure, gait and balance, orthostatic hypotension, environmental risk of fall, malnutrition, incontinence and social support. Results and information sheet (summarizing suggested interventions) were sent to general practitioner. Nurse conducted bimonthly telephone interviews for follow-up	Functional Autonomy Measurement System: Small differences (NS) in favour of IG at 10 months
Silverman et al. (1995) USA RCT (n=442)	Aged ≥65; instability in health status in previous 6 months (one or more specific risk indicators, e.g., difficulty walking, falls, incontinence, loss of vision or hearing)	Hospital geriatric team (internist, nurse, social worker) provided a comprehensive outpatient evaluation (medical, psychological and social health problems) and treatment plan. Findings and treatment plan were discussed with the patient and the family. Recommendations were communicated to referring physicians	Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL and IADL scale)/Barthel ADL Index: No significant differences between groups at 12 months
<i>CGA: Assessment followed by treatment and care</i>			
Bernabei et al. (1998) Italy RCT (n=200)	Aged ≥65; already receiving community care services or home assistant programs, mostly because of multiple geriatric conditions	Case-manager performed initial assessment and reported findings to geriatric evaluation unit that designed and implemented individualized care plan in agreement with general practitioner. Weekly team meetings to discuss problems emerging from home visits. Re-assessment every 2 months. Team is constantly available to deal with problems, to monitor the provision of services and to guarantee extra help as requested	6-item scale of daily living/7-item scale of instrumental activities of daily living (name not specified): Differences (SS) in favour of the IG at 12 months
Boult et al. (2001) USA RCT (n=568)	Aged ≥70; at risk for hospitalization and functional decline: ore likely to use hospitals, nursing homes, home care, emergency rooms and medication	4-steps assessment: General practitioner, home visit by social worker, 2 visits at GEM clinic (general nurse practitioner, geriatrician, nurse). Team meeting led to care plan, delivered by team (medication, regimes, counselling, health education, advance directives, referrals). Hospital care and 24-hours on-call service. Monthly meeting and phone calls (on average for 6 months) to monitor and coordinate care plan. Recommendation for period after discharge was given to general practitioner	Sickness Impact Profile (physical functioning dimension): Differences (SS) in favour of the IG at 6, 12, and 18 months
Cohen et al. (2002) USA RCT (n=1388)	Aged ≥65; hospitalization; ≥2 frailty criteria: e.g., falls, limitations in BADL or walking, dementia, depression, stroke, bed rest, incontinence, malnutrition	Inpatient and outpatient intervention teams (geriatrician, social worker, nurse) assessed functional, cognitive, affective and nutritional status, caregiver's capabilities and social situation; team meetings (twice a week) to evaluate and discuss treatment plan with regard to preventive and management services (dietetics, physical and occupational therapy, clinical pharmacy)	Physical Performance Test/Katz Activities of Daily Living Scale: Differences (SS) in favour of inpatient IG in comparison with CG at discharge. No significant differences between groups at 12 months. No significant differences at discharge and at 12 months for the outpatient IG in comparison with CG
Gagnon et al. (1999) Canada RCT (n=427)	Aged ≥70; discharge from hospital previous 12 months at risk for repeated admission (≥40%), assistance with ≥1 ADL OR ≥2 IADL	Nurse assessed health, physical, functional, social, environmental aspects, community services, needs and concerns of older people and caregivers, created and implemented care plan and coordinated professionals. Weekly interdisciplinary case conference. Collaboration with emergency department and community health centre (24-h available). Monthly call, home visits every 6 weeks (10-month period) follow-up by telephone	Older American Resources and Services Multidimensional Functional Assessment Questionnaire/Medical Outcome Study Short Form: No significant differences between groups at 10 months

Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
<i>CGA: Assessment followed by treatment and care</i>			
Gitlin et al. (2006) USA RCT (n=319)	Aged ≥70; functional vulnerable defined as needing help with ≥2 IADL OR ≥1 ADL OR ≥1 falls (last 1 year)	Interviews and observations to assess problem areas. During 6 months physiotherapist provided 1 visit (90 min) consisting of balance, muscle strength, safe fall, recovery training. Occupational therapist provided 4 visits (90 min) for problem solving, use of control-oriented strategies (environmental modifications, behavioural/cognitive strategies). Installation of home modifications. 3 phone contacts (20 min) to reinforce strategy use and to generalize strategies to new problems	ADL index, IADL index (name not specified): Differences (SS) in favour of IG at 6 months. Mobility/transfer index: Small differences (NS) in favour of IG at 6 months. ADL index, IADL index, mobility/transfer index: No significant differences between groups at 12 months
Landi et al. (2001) Italy RCT (n=187)	Eligible for home care services: older disabled persons	Case-manager assessed function, health, social support, and service use every 3 months (1 year period) by using Minimum Data Set for Home Care that provided guidelines for further assessment and care (client oriented assessment protocols). Collaboration with community geriatric evaluation unit and general practitioner led to individualized care plan. Case-manager coordinated and integrated care that is delivered by multidisciplinary team	Barthel ADL Index/Lawton & Brody Instrumental Activities of Daily Living Scale: Differences (SS) in favour of IG at 12 months
Markle-Reid et al. (2006) Canada RCT (n=288)	Aged ≥75; referral to personal support services; a model of vulnerability is used to define frailty	Nurse regularly assessed risk factors for functional decline and provided health education regarding lifestyle and management of chronic diseases (telephone calls and home visits during 6 months). A participatory approach, involving empowerment, was used to promote positive attitudes, knowledge and skills. Focus on environmental support, referral and coordination of community services (goals-led health plan)	Medical Outcome Study Short Form: Small differences (NS) in favour of IG at 6 months
Melin and Bygren (1992) Sweden RCT (n=249)	Discharge from hospital (internal medicine, orthopaedics); chronically ill and dependent in 1–5 functions of personal ADL according to Katz activities of Daily Living Scale	Assessment of medical and functional status by nurse/home service (phone calls) and physician (home visit) to develop treatment plan. Weekly interdisciplinary team meetings (nurse, home service assistant, geriatrician, psychiatrist). 24 h telephone service. Emergency and routine home visits whenever needed (by nurse, assistant nurse, home aids), also in the weekend (by physician, is always accessible for primary care staff by phone)	Katz Activities of Daily Living Scale: No significant differences between groups at 6 months. IADL modified Katz index: Differences (SS) in favour of IG at 6 months
Melis et al. (2008) Netherlands RCT (n=151)	Aged ≥70; living at home or in retirement home; limitations in cognition (Mini Mental State Examination) (I) ADL (Groningen Activity Restriction Scale), or mental health (Medical Outcome Study Short Form)	Home visits by nurse for evaluation and management (max. 6 visits during 3-month period). Multidimensional assessment (cognition, nutrition, behaviour, mood, mobility), coordination of care, therapeutic monitoring, case management (individualized and integrated treatment plan, including advices and psycho education). Collaboration with primary care physician, other health professionals and caregivers	Groningen Activity Restriction Scale-3: Differences (SS) in favour of IG at 3 months. Slightly smaller differences (NS) in favour of IG at 6 months
Phelan et al. (2004) USA RCT (n=201)	Aged ≥70 AND one more chronic condition; difficulties with ADL but no human help is needed, ability to walk, nonparticipation in senior centre	General nurse practitioner assessed health and risk factors (self-management of chronic diseases, psychoactive medication, physical activity, depression, social isolation) and developed in collaboration with general practitioner tailor-made health action plan. Senior centre-based, self-management class, peer support, and exercise class (or exercise program at home). Follow-up until 12 months (on average 3 visits and 9 telephone calls)	Health Assessment Questionnaire Disability Index: Incident disability: No significant differences between groups at 6 months. Small differences (NS) in favour of IG at 12 months; Disability improvement: Differences (SS) in favour of IG at 6, 12 months; Disability worsening: Small differences (NS) at 6 months, modest differences (NS) at 12 months in favour of IG

Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
<i>CGA: Assessment followed by treatment and care</i>			
Rockwood et al. (2000) Canada RCT (n=182)	At least one criteria, e.g., concern about community living, acute illness, frequent physician contact, multiple medical problems, functional decline	Geriatrician nurse assessed mental and emotional status, communication, mobility, balance, bowels, bladders, nutrition, daily activities, and social situation. Geriatrician used Goal Attainment Scaling to set goals, finalizing in multidisciplinary conference. Mobile Geriatric Assessment Team (nurse, geriatrician, physiotherapist, occupational therapist, social worker, dietitian, audiologist, speech-language pathologist) implemented recommendations. 3 interdisciplinary consults during 3 months period	Barthel ADL Index/Instrumental activities of daily living scale (name not specified): No significant differences between groups at 12 months
Rubenstein et al. (2007) USA RCT (n=792)	Aged ≥65; clinical visit previous 18 months; ≥4 positive responses on Geriatric Postal Screening Survey	Case-manager (physician assistant) assessed geriatric target conditions and other health problems. Additional assessment in geriatric clinic (in general 1 visit). Team meeting led to care plan given to primary care provider. Case-manager referred and gave recommendations (health promotion). Telephone follow-up by case-manager every 3 months during 3 years	Functional Status Questionnaire (ADL and IADL scale): No significant differences between groups at 1, 2, 3 years. Differences (NS) between subgroups at 12 months
Toseland et al./Engelhardt et al. 1997/1996, USA RCT (n=160)	Aged between 55–75 AND ≥1 ADL or ≥2 IADL impairments; > 75 AND any combination of 2 ADL or IADL impairments	Team (nurse practitioner, geriatrician, social worker) participated in assessment, development and implementation of care plan, follow-up and reassessment, monitoring and revision of care plan, referral to and coordination with health and social services. Advices for hospitalization, discharge planning. Weekly team meetings. Routine follow-up and walk-in care	Functional Independence Measure: No significant differences between groups at 8 and 16 months
Williams et al. (1987) USA RCT (n=117)	Aged ≥65; medical evaluation (last year), decline in functional ability and unmet needs, unstable medical problems; polypharmacy; dissatisfaction with care	Multidisciplinary team (internist, physician, psychiatrist, nurse, social worker, nutritionist) assessed physical, mental, social functioning and resulted in a problem list and team goals. Team provided counselling and family support. Follow-up visits were scheduled, among which home visits if requested	Interviews (name not specified)/Patient Assessment Forms: small non-significant differences in favour of the IG at 8 months. No information provided at 12 months
<i>Physical exercise</i>			
Binder et al. (2002) USA RCT (n=119)	Aged ≥78; 2 out of 3 criteria: score between 18–32 on Modified Physical Performance Test, peak oxygen uptake between 10 and 18 mL/kg/min, self-reported difficulty in max. 2 ADLs or 1 IADL	9 month program provided by physiology exercise technicians consisting of three phases of each 36 sessions. Phase 1: Group format: 22 exercises on flexibility, balance, coordination, speed of reaction and strength. Phase 2: Progressive resistance training and shortened version of phase 1 exercises. Phase 3: Endurance training and shortened version of phase 1 and phase 2 exercises	Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL and IADL scale): No differences between group at 3, 6 and 9 months. Functional Status Questionnaire (physical function subscale): Difference (SS) in favour of IG at 6 and 9 months
Boshuizen et al. (2005) Netherlands RCT (n=72)	Experiencing difficulty in rising from chair AND maximum knee-extensor torque ≤87.5 N·m	10 week exercise program, each week two group sessions (60 min) by physiotherapist and one unsupervised home session. Focus on exercises with a variation in concentric, isometric and eccentric knee extensor activity	Groningen Activity Restriction Scale: No differences between groups at 10–12 weeks
Chandler et al. (1998) USA RCT (n=100)	Aged ≥65; Inability to descend stairs step over step without holding the railing	10 week exercise program, each week three individual in-home sessions by physiotherapist. Focus: progressive resistive lower extremity exercises with theraband	Medical Outcome Study Short Form (physical functioning subscale): No significant differences between groups at 10 weeks
Chin A Paw et al. (2001) Netherlands RCT (n=157)	Aged ≥70; Physical inactivity and involuntary weight loss OR body mass index below 25 kg/m <sup>2</sup>	17 week exercise program, each week 2 group sessions (45 min) by experienced instructors. Focus: skills training focused on learning physiologic parameters to perform and sustain motor action	Self-rated disabilities (name not specified): No differences between groups at 17 weeks



Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
<i>Physical exercise</i>			
Gill et al. (2002) USA RCT (n=188)	Aged≥75; performance on rapid gait test > 10 s OR inability to stand up from seated position	12 month program with average of 16 visits (45–60 min) by physiotherapist and home exercising in the first 6 months, followed by 6 phone calls in the next 6 months to encourage further (daily) home exercising. Focus: instruction in safe techniques, proper use of devices, removal of environmental hazards and exercises for range of motion, balance, muscle conditioning and strengthening	Self-reported performance in activities of daily living (name not specified): Differences (SS) in favour of IG 7 and 12 months
Jette et al. (1999) USA RCT (n=215)	Aged≥60; limitations in at least 1 of 9 items of Medical Outcome Study Short Form (physical functioning subscale)	6 month program with 3-times a week a (videotaped) exercise program for 35 min with elastic bands varying in thickness to individualize resistance. Physiotherapist did two home visits and provided telephone follow-up and support. Several cognitive and behavioural techniques were used to increase adherence	Sickness Impact Profile 68: Differences (SS) in favour of IG at 3 and 6 months
King et al. (2002) USA RCT (n=155)	Aged≥70; Short Physical Performance Battery score ≤9 AND independence in at least 5 ADL's	18 month exercise program with 6 months of 3 group sessions (75 min) each week (by physiotherapist and/ or exercise leader), followed by 6 months of 1 group session a week and two home-exercise sessions, and 6 months of 3 home exercises a week with monthly call from exercise leader. Focus on endurance, strength, balance and flexibility	Medical Outcome Study Short Form (physical functioning subscale): Slight difference (NS) in favour of CG at 6 and 12 months. Slight difference (NS) in favour of IG 18 months
Latham et al. (2003) New Zealand/ Australia RCT (n=243)	Aged≥65; one or more health problems or functional limitations	10 weeks three times a week quadriceps exercise program by physiotherapist. Patients performed their first two sessions in the hospital and continued the rest of their sessions at home. Physiotherapist monitored progress weekly, alternating home visits with telephone calls	Medical Outcome Study Short Form (physical functioning subscale)/ Barthel Self-care index: No significant differences between groups at 3 and 6 months
Luukinen et al. (2006) Finland RCT (n=555)	Aged≥85; at least one risk factor for disability or mobility, e.g., falls, loneliness, depression, low cognitive status, impaired vision or hearing, impaired balance	Risk inventarisation and suggestions for interventions done by physiotherapist and occupational therapist were discussed by patient and family physician. Home exercises (recommended three times daily with 5–15 repetitions) focused on a number of physical exercises (standing, lying or sitting position) in combination with self-care exercises, walking exercises or/and physical exercises in groups	Postal questionnaire for physical disability (name not specified): No significant differences between groups at 5 months
Ota et al. (2007) Japan RCT (n=46)	Aged≥65; eligible for long-term care needs	12 week program with 24 sessions (twice a week) with training machines focused on leg press, leg extension/ flexion, torso extension/ flexion, rowing, chest press and hip adduction/ abduction	TMIG-IC instrumental self-maintenance: No significant differences between groups at 12 weeks
Timonen et al. (2004) Finland RCT (n=68)	Aged≥75; difficulty with balance AND mobility AND symptoms such as dizziness or reported falls or difficulty in walking independently	10 week exercise program, each week two group sessions (90 min) supervised by two physiotherapists. Core of program: progressive resistance training (lower extremity) and functional exercises. One home visit to instruct stretching program to be performed 2–3 times a week at home	Joensuu Classification Model: No significant differences between groups at 1 week, 3 and 9 months
Worm et al. (2001) Denmark RCT (n=46)	Aged≥74; inability to leave home unaided OR unattended OR without mobility aids	12 weeks exercise program with 2 group sessions per week (60 min); flexibility training, aerobics and rhythm, balance and reaction exercises, muscle training. Participants were also asked to perform a home-based exercise program (8–10 min) every morning	Medical Outcome Study Short Form (physical functioning subscale): Differences (SS) in favour of IG at 12 weeks
<i>Nutritional interventions</i>			
Chin A Paw et al. (2001) Netherlands RCT (n=157)	Aged≥70; physical inactivity and involuntary weight loss OR body mass index below 25 kg/m <sup>2</sup>	17 weeks nutrition program; several fruit and dairy products enriched with vitamins and minerals. One fruit and a dairy product in addition to daily diet or as a replacement	Self-rated disabilities (name not specified): No significant differences between groups at 17 weeks

Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
<i>Nutritional interventions</i>			
Kretser et al. (2003) USA RCT (n=203)	Aged ≥60; score <22.5 on Mini Nutritional Assessment	6 month nutrition program consisting of weekly 21 meals and 14 snacks meeting 100% of the Daily Reference Intake (DRI) needed for people over 50 and with a daily caloric level of 1,800 kcal	(Self-?) Reported performance of activities of daily living (name not specified): No significant differences between groups at 6 months
Payette et al. (2002) Canada RCT (n=83)	Aged >65; involuntary weight loss and Body Mass Index <27 OR Body Mass Index <24	16 weeks nutrition program; provision of 235-ml cans of nutrient-dense protein-energy liquid. Two cans a day in addition to usual diet. Each month 1 home visit and each two weeks a phone call was conducted by a dietitian	Medical Outcome Study Short Form (physical role functioning scale and emotional role functioning scale): No significant differences between groups at 16 weeks
<i>Assistive technology</i>			
Mann et al. (1999) USA RCT (n=104)	Receiving services or initial referral for in-home services or in-patient rehabilitation services in previous year	Assessment done by occupational therapists, followed by recommendations for assistive devices and/or home modifications. Participants were trained in the use of the devices and follow-up continued with assessment and provision of assistive technology as needs changed	Functional Independence Measure/ Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL scale). Differences (SS) in favour of IG at 18 months
Tomita et al. (2007) USA RCT (n=113)	Aged ≥60; difficulties in ADL or IADL	About 18 months computer and internet facilities were provided. Level of automatization fitted participants' desire and the capacity of the house. Computer engineer ensured a good fit between computer and users. Smart technology (door and window sensors, motion sensors and remote control for lamps and radio) was installed. Participants received instruction from a geriatric nurse	Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL score)/CHART mobility: Differences (SS) in favour of IG at 24 months
<i>Others</i>			
Beck et al. (1997) USA RCT (n=321)	Aged ≥65; high care utilization AND one of the following diseases: lung disease, heart disease, joint disease, diabetes	Monthly group meetings (12.9 h) with primary care physician and nurse (contributions of other professionals). Each session had a warming up period and specific health related topic (e.g., disease processes, medication, exercise, alternate care home safety) were presented. Medical assessment (e.g., blood pressure) took place by the nurse and a meeting with the physician was possible	Katz Activities of Daily Living Scale/ Older American Resources and Services Multidimensional Functional Assessment Questionnaire (ADL score): No significant differences between groups at 12 months
Giannini et al. (2006) Italy CCT (n=121)	Aged (not clear): necessity of help in two ADL or severely chronically ill with mental impairment (Mini Mental State Examination score 24/30)	Additional home care attendance (HCA) 24 months varying from 4 to 24 h daily. The primary caregiver got vouchers to buy the amount of hours of HCA from health providers who demonstrated to have professional training in the care of frail elderly	Katz Activities of Daily Living Scale/ Lawton & Brody Instrumental Activities of Daily Living Scale: Differences (SS) in favour of IG at 24 months
Latham et al. (2003) New Zealand/ Australia RCT (n=243)	Aged ≥65; one or more health problems or functional limitations	Vitamin D in a single oral dose. Patients received six 1.25-mg calciferol	Medical Outcome Study Short Form (physical functioning subscale)/ Barthel Self-care index: No significant differences between groups at 3 and 6 months
Liang et al. (1986) USA RCT (n=57)	Inability to perform self-care tasks OR ADL dysfunction AND potential for rehabilitation, judged by physician, home care and physiotherapist for ≥3 months	Two months treatment program provided by physician and physiotherapist with occasional consultation with hospital-based rehabilitation specialists. Interventions included equipment and assistive devices, supervised exercises to improve function and home modifications for safety and improved function	Functional Status Index: No significant differences between groups at 2, 4 and 6 months

Table 1 Continued.

Study	Participants inclusion criteria	Interventions	Disability outcomes*
Others			
Ollonqvist et al. (2008) Finland RCT (n= 708)	Aged≥65; eligibility criteria for SII allowance for pensioners with a medical disability as verified by a physician to be in need of assistance	3 separate inpatient treatment periods at a rehabilitation centre within 8 months provided by a team (e.g., physician, physiotherapist, social worker, occupational therapist) with focus on physical activation (group). Home visit for advice on personal hygiene and assistive devices. Activation days between rehabilitation periods with focus on discussing topics, e.g., as safety at home, health promotion and cognition	ADL and IADL items (name not specified). No significant differences between groups at 12 months
Scott et al. (2004) USA RCT (n=294)	Aged≥60; one or more chronic conditions AND at least 11 outpatient clinic visits in the past 18 months	Monthly group meetings (12.9 2 h) with primary care physician and nurse (contributions of other professionals). Each session had a warning up period and specific health related topic (e.g., disease processes, medication, exercise, alternate care home safety) were presented. Medical assessment (e.g., blood pressure) took place by the nurse and a meeting with the physician was possible	ADL and IADL items (name not specified). No significant differences between groups at 24 months

\*Instruments used to measure disability and reported differences (SS=statistically significant difference if p<0.05; NS=not statistically significant difference) between intervention group (IG) and control group (CG) at follow-up. Follow-up measurements are in weeks or months after randomisation, unless stated otherwise

Intervention characteristics

Comprehensive Geriatric Assessment (n=26)

Comprehensive geriatric assessment (CGA) has been defined as 'a multidimensional, often interdisciplinary, diagnostic process intended to determine a frail older persons' medical, psychosocial, and functional capabilities and problems, with the objective of developing an overall plan for treatment and long-term follow-up'.<sup>18</sup> For this review, the included CGA studies were further divided into transmural care and community-based care. In the latter, a distinction was made between studies in which assessment was followed by referrals or recommendations and studies where assessment was directly followed by treatment and care.

Transmural Care (n=7)

In this review, transmural care points to interventions in which clients were identified and assessed during admission to the hospital setting. After discharge, client referrals were made and interventions were delivered in the community. In the seven studies, assessment was performed by a nurse practitioner<sup>19-21</sup>, a physician<sup>22</sup> or an interdisciplinary team<sup>23-26</sup> focusing on a variety of physical, mental, medical and social factors. Usually, the assessment was followed by a team meeting leading to an individualised treatment plan and a variety of actions e.g. referrals<sup>19</sup> and recommendations to the general practitioner<sup>21</sup>, home visits by a nurse practitioner<sup>20</sup> or several disciplines<sup>20,22,25</sup> and long-term outpatient comprehensive care by a geriatric clinic<sup>23,24,26</sup>. Nursing interventions targeted, for example, medications, symptom management, diet, activity, sleep, medical follow-up and emotional status.<sup>20</sup> The interdisciplinary team in the studies by Burns and colleagues (1995, 2000) focused on functional limitations, gait impairment, incontinence, polypharmacy, depression, cognitive impairments and caregiver needs.<sup>23,24</sup> Out of the seven transmural care interventions, one study reports significant effects in favour of the experimental group.<sup>19</sup>

Pointing out effective elements is difficult. In the study by McCusker and colleagues (2001), a two-step screening approach including the ISAR screening tool was used.<sup>19</sup> This screening tool, specifically designed and evaluated for identifying seniors at high risk, might have increased the efficacy of the selection of participants. In the study by McCusker and colleagues (2001), treatment was individualised and clients were seen by a variety of disciplines.<sup>19</sup> Referrals were made to the physician, local community, health centre, geriatric outpatient clinic and other community services. Comparable features, however, are present in the other CGA 'transmural care' studies that did not report effectiveness on disability.

### Community-based care: assessment followed by referrals and recommendations (n=4)

Eligible participants for these four studies were identified by a self-administered postal questionnaire<sup>27,28</sup>, telephone interview<sup>29</sup> or an interviewer-assisted self-administered screening<sup>30</sup>. Extensive assessment was performed by a nurse during home visits<sup>27,28</sup> or by a team in community-based clinics<sup>29,30</sup>. Medication, mood, cognition, vision, hearing, blood pressure, gait and balance, orthostatic hypotension, environmental risk of fall, malnutrition, incontinence and social support were part of the assessment in the studies by Hebert and colleagues (2001) and Robichaud and colleagues (2000).<sup>27,28</sup> In all studies, the assessment was followed by recommendations to the general practitioner. In the study by Hebert and colleagues (2001) and Robichaud and colleagues (2000), recommendations to other health professionals were also made and bi-monthly or monthly phone follow-up interviews took place.<sup>27,28</sup> In the study by Silverman and colleagues (1995), the treatment plan was discussed with the patient and family.<sup>29</sup> Preparation of the patient and caregiver for the meeting with the general practitioner was part of the intervention in the study by Reuben and colleagues (1999).<sup>30</sup>

Out of these four community-based CGA studies, only the study by Reuben and colleagues (1990) found significant differences in disability in favour of the experimental group.<sup>30</sup> The near-significant effect that Robichaud (2000) and colleagues found did not reach significance in the study by Hebert and colleagues (2001) in the evaluation of the same intervention among a larger group of participants.<sup>27,28</sup> As all other three interventions have similar features to those of Reuben and colleagues<sup>30</sup>, elements that produce effectiveness in this type of CGA cannot be identified.

### Community-based care: assessment followed by treatment (n=15)

Two out of fifteen studies are about the same intervention.<sup>31,32</sup> All interventions were delivered by an interdisciplinary team consisting of at least two disciplines. Members of the interdisciplinary team were, for example, general practitioners, geriatricians, nurses, nurse practitioners, social workers, allied health professionals or medical specialists. The core of the intervention was mainly delivered by primary care professionals. Professionals working in institutions, for example, a geriatric clinic, were, however, often involved in the assessment and the development of the treatment plan, including referrals and recommendations. In addition, they could be consulted about the delivery of supplementary treatment if needed. In many interventions one person from the interdisciplinary team, often a nurse (practitioner), had the role of a case-manager.<sup>33-39</sup> The case manager was responsible for planning, coordination, monitoring, and evaluation of assessment and treatment. The assessment in the 15 studies focused on medical conditions and general status of the participants (functional, psychosocial, cognitive, affective and nutritional), personal resources and preferences, caregiver's capabilities and other environmental factors. The focus

of the interventions varied strongly across studies. Issues covered were falls, balance, urinary incontinence, functional impairment, depression, cognitive deficits, nutrition, mobility, medication, social support, service use, communication, environmental aspects and financial needs.

Nearly all interventions were delivered in an individual format, except for Phelan and colleagues (2004), who combined individual sessions with group sessions (exercise and self-management classes).<sup>38</sup> Home visits<sup>34,37,39-41</sup>, telephone calls<sup>39</sup> or a combination of both<sup>35,36,38,39,42</sup> are repeatedly used to address frail older people. In three studies assessment and treatment were done in a (geriatric) clinic.<sup>31,32,43</sup> Two studies combined clinic visits, home visits and telephone contacts.<sup>39,44</sup>

Out of fifteen CGA studies, nine report significant differences in disability in favour of the experimental group.<sup>34,36-38,40,42-45</sup> There are some features that promising interventions have in common. Out of the nine studies, seven studies report the use of an individualised treatment plan that is based on a multidimensional assessment.<sup>34,36,37,40,43,44,46</sup> A case manager had a key role during the intervention process in six out of nine effective studies.<sup>34-38,40</sup> Regular team meetings were applied in four studies.<sup>36,37,40,43</sup> In seven out of the nine studies, on-going assessment, evaluation and monitoring are described as a feature of the intervention.<sup>34,35,37,38,40,44,46</sup> Therefore a combination of home visits and telephone contacts is often used.<sup>35,36,38,39,42</sup> Out of nine studies, four interventions also intervene in factors in the social and physical environment of frail older people.<sup>35,37,44,46</sup> Health education is applied in four interventions.<sup>35,37,39,44</sup> A complication in drawing conclusions about elements that contributed to effectiveness is the presence of identical features in the six clinical trials that did not show any differences for disability. There is, however, some indication that case management, individualised treatment, multidimensional assessment and on-going evaluation and monitoring are relevant features in this type of CGA interventions. A combination of home visits and telephone contacts and regular team meetings seems to be promising. Health education may also be an important component for future interventions.

### Physical Exercise programmes (n=12)

Twelve studies describing physical exercise interventions were found. Physical exercise interventions for community-dwelling frail older people show a large variation in content, duration, intensity, balance between supervised and non-supervised sessions and level of individualisation. Five interventions were *single-component*, focusing mainly on lower extremity strength.<sup>47-51</sup> The other seven were *multi-component*, addressing a variety of physical parameters such as endurance, flexibility, balance and strength.<sup>52-58</sup> All interventions were offered by professionals in physical exercise, mostly physical therapists. In most studies, participants performed at least three exercise sessions a week.<sup>47-50,52,54-58</sup> Strength training was usually comprised of



a number of exercises for improvement of lower body strength using weights<sup>59</sup>, elastic bands<sup>47-49</sup> or training machines<sup>51</sup>. Among the multi-component exercise programmes, three addressed several parameters in all exercise sessions.<sup>56-58</sup> These also belong to the shortest multicomponent exercise programmes (10-12 weeks). The longest multi-component programmes lasted 9 months<sup>52</sup>, 12 months<sup>54</sup> and 18 months<sup>55</sup>. In two studies, different phases (respectively 3 or 6 months) were distinguished with a focus on specific physical parameters in each phase.<sup>52,55</sup> The content of the programme of Gill and colleagues<sup>54</sup> was more individualised, as the outcomes of an extensive assessment directed the programme. Among the physical exercise programmes, there is a large difference between the number of supervised and non-supervised sessions. For example, Binder and colleagues (2002) report a total of 108 supervised sessions, while Jette and colleagues (1999) report only two home visits by a physical therapist. The participants exercised non-supervised, supported by techniques to enhance adherence.<sup>49,52</sup>

Out of twelve physical exercise programmes, four report significant positive effects for disability. Of the *single-component* physical exercise programmes (n=5), one reports positive effects. Jette and colleagues (1999) found evidence for the effect of resistance training using elastic bands.<sup>49</sup> For three (out of seven) *multi-component* programmes, significant positive effects are reported on the disability outcome.<sup>52,54,58</sup> In these three studies, participants were included according to physical frailty indicators and programmes were relatively intensive with at least three exercise sessions per week. Binder and colleagues (2002) included only moderate physically frail older people.<sup>52</sup> Gill and colleagues (2002) found that only moderate physically frail older people benefited from their intervention.<sup>54</sup>

### Nutrition (n=3)

Studies that investigated the effect of single nutritional interventions focused on macronutrient status (nutrient-dense protein energy liquid)<sup>60</sup>, micronutrient status (fruits and dairy products enriched with vitamins and minerals)<sup>53</sup> or both (meals and snacks providing 100% of macro- and micronutrient requirements)<sup>61</sup>. In the study by Kretser and colleagues (2003) participants received 21 meals and 14 snacks every week for 6 months, accounting for most of the daily nutritional intake.<sup>61</sup> In Chin A Paw and colleagues' study (2001), participants were asked to eat the products in addition to their daily diet or as a replacement (for 17 weeks).<sup>53</sup> In Payette and colleagues study (2002), the liquid product was an addition to the usual daily dietary intake for 16 weeks.<sup>60</sup> Additional support included monthly home visits by dieticians and a phone call every 2 weeks with nutritional counselling and encouragement<sup>60</sup> or daily additional phone calls from older adult volunteers to provide a measure of safety and socialisation<sup>61</sup>.

Despite an observed effect on total energy intake<sup>60</sup> and weight gain<sup>60,61</sup>, none of the three nutritional intervention studies report evidence for the effect of nutritional interventions on disability.<sup>53,60,61</sup>

### Technological interventions (n=2)

Environmental adaptations are often part of the multifactorial and multidisciplinary programmes described under CGA. Two reports were found on the effect of single assistive devices and home modifications<sup>62</sup> and smart technology on disability<sup>63</sup>. In the study by Mann and colleagues (1999), an occupational therapist performed a comprehensive functional assessment of the person and the home followed by recommendations for assistive devices and/ or home modifications.<sup>62</sup> Participants were trained in the use of the devices and follow-up continued with assessment and provision of assistive technology as needs changed. Over about 18 months computer and internet facilities were provided to the participants in the study by Tomita and colleagues (2007).<sup>63</sup> A computer engineer adapted the computer to ensure a good fit with its users. Furthermore, smart technology, like door and window sensors, motion sensors and remote control for lamps and radio, was installed. The level of automatisation was determined by the participants' desire and the capacity of the house. Participants received instruction from a geriatric nurse who was a specialist in computer instruction.

Both studies report significant differences on disability in favour of the experimental group.<sup>62,63</sup> In both interventions there is an emphasis on the adaptation of technology towards the needs of the clients and on intensive instruction in the use of devices.

### Other interventions (n=6)

In this group, six interventions are described. Latham and colleagues (2003) studied the effect of Vitamin D. Participants in the experimental group received 1.25 mg calciferol.<sup>50</sup> Giannini and colleagues (2007) focused on the effect of home care attendance (between 4 and 24 hours) by professionals with training in the care of frail older people.<sup>64</sup> In two studies<sup>65,66</sup> the intervention consisted of monthly group meetings (over 12 months) with a physician and a nurse.<sup>65,66</sup> The meetings focused on health promotion and control. One intervention contains three inpatient rehab periods with individual and group sessions plus home activation days and home visits for personal hygiene and assistive devices.<sup>67</sup> Liang and colleagues (1986) used a stepped-up treatment (on top of nursing and social services) provided by a physician and physical therapist focusing on assistive devices and home modification and supervised exercises.<sup>68</sup>

Out of the six interventions, Giannini and colleagues (2007) report significant positive effects on disability in favour of the experimental group.<sup>64</sup> They describe how the home care attendance, provided by a nurse trained in the care of frail older people, was delivered according to a programme established by a Geriatric Evaluation Unit. Specific features of this programme are lacking.

## Discussion

This review offers a comprehensive overview of the content of interventions targeted at disability prevention in community-dwelling frail older people. In total, 48 clinical trials evaluating 49 interventions aimed at disability prevention were identified. The majority of trials in 46 RCTs and two CCTs were conducted in the field of comprehensive geriatric assessment (CGA) (n=26). Studies of physical exercise programmes are the second largest group of interventions (n=12). There is a small number of studies that specifically focus on the effect of technology (n=2) or nutrition (n=3) on disability in community-living frail older people. Both environmental adaptations and nutrition, however, are frequently mentioned as part of the CGA studies. The results show a large diversity within and between the groups of interventions in terms of content, disciplines involved, duration, intensity and setting.

The reported effectiveness of interventions is not consistent. Eighteen of the 49 interventions reported significant positive effects for disability for the experimental group. As most studies did not include long-term follow-up measurement, the preventive potential of interventions remains unclear for the time period after the completion of the intervention. The most promising findings were found for *technology* (but only two studies), *CGA 'assessment followed by treatment'* (nine out of fifteen studies) and, to a lesser extent, *physical exercise programmes* (four out of twelve). Technology, adapted to the needs of the frail older people and well-taught, may be very effective in preventing disability in community-dwelling frail older people, though more research is needed in this area. Most trials were conducted in CGA, but the reported effectiveness of CGA for community-dwelling frail older people is inconsistent. Comparable findings are reported in previous reviews on CGA.<sup>16,69,70</sup> Individualised, multifactorial and multidisciplinary assessments and interventions, case management and on-going monitoring (long-term management) seem to be essential elements for effective CGA. The mixed results of physical exercise programmes hamper the identification of effective elements. There is, however, some indication that *multi-component* high intensive physical exercise programmes may be promising, especially for *moderate physically frail* community-dwelling older people.

This overview has some limitations. The use of the term frailty in the literature is relatively new. Although reference lists were checked, a limitation of this overview is that older studies might not have been identified as we searched with terms for frailty and its synonyms. Another risk in terms of publication bias is the selection of 4602 studies on title-level that may have resulted in the exclusion of relevant articles. Only randomised controlled trials were selected as we considered these as a (minimal) standard for quality. Some caution in interpretation of results is warranted as the methodological quality of the studies was not assessed. Furthermore, we analysed

the results in a qualitative way. As a consequence effect sizes of interventions were not calculated or taken into account. And last, owing to small sample sizes, trials may have been underpowered to detect differences in the self-reported measures for disability.

Recent literature on disability development suggests that disability is multifactorial in nature. Stuck and colleagues (1999) reported that risk factors for developing disability in community-dwelling older people are cognitive impairment, depression, comorbidity, increased and decreased body mass index, lower extremity functional limitation, low frequency of social contacts, and low level of physical activity.<sup>71</sup> Femia and colleagues (2003) suggest that although disease conditions and physical impairments are as risk factors strongly related to an individual's ability to carry out activities of daily living, other factors like the beliefs about one's health (e.g., subjective health), motivation and self-efficacy are potentially as important as the ability to perform them. Therefore, it seems that a combination of risk factors and other factors plays a role in the development of disability implying that disability prevention in frail older people is complex. In view of this complexity, the Dutch National Health Council recently pointed out the need for research on 'function-oriented prevention'. The Health Council stated that knowledge of the effectiveness of preventive interventions on disability is fragmented, heterogenic, and still lacking in a variety of areas.<sup>72</sup> How might the findings of this overview influence future interventions for community-dwelling frail older people?

In the light of this overview, future interventions may be directed toward tailor-made, multidisciplinary and multifactorial interventions, with individualised assessment and interventions conducted by a (primary) care team, involving case management, and long-term follow-up. These tailor-made programmes may include a physical exercise component for moderate physically frail older people and a technology component tailored to the needs of older people. Several new elements might be added to future interventions. For example, technology for monitoring health conditions and enhancing compliance and communication between health professionals and clients is available and can be incorporated in interventions for frail older people.<sup>73</sup> Techniques for enhancing self-management abilities in older people have been described in several studies<sup>74,75</sup> and seem applicable to, and promising for, community-dwelling frail older people.<sup>74,75</sup> A systematic approach toward enabling community-dwelling frail older people to be engaged in meaningful social and productive activities might also be effective to prevent disability, as it fosters natural motivation and self-efficacy in older people. Recent studies show the potential of meaningful activities as a core of preventive programmes.<sup>76,77</sup> It is likely that the development of interventions for community-living frail older people has still some way to go. Further research with a focus on interventions that can prevent or delay disability in community-dwelling frail older people is necessary.

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## **The reduction of disability in community-dwelling frail older people: design of a two-arm cluster randomised controlled trial**

**This chapter was published as:**

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BMC Public Health 2010;10:511



## Abstract

**Background:** Frailty among older people is related to an increased risk of adverse health outcomes such as acute and chronic diseases, disability and mortality. Although many intervention studies for frail older people have been reported, only a few have shown positive effects regarding disability prevention. This article presents the design of a two-arm cluster randomised controlled trial on the effectiveness, cost-effectiveness and feasibility of a primary care intervention that combines the most promising elements of disability prevention in community-dwelling frail older people.

**Methods/ design:** In this study twelve general practitioner practices were randomly allocated to the intervention group (6 practices) or to the control group (6 practices). Three thousand four hundred ninety-eight screening questionnaires including the Groningen Frailty Indicator (GFI) were sent out to identify frail older people. Based on their GFI score ( $\geq 5$ ), 360 participants will be included in the study. The intervention group will receive an interdisciplinary primary care intervention. After a comprehensive assessment by a practice nurse and additional assessments by other professionals, if needed, an individual action plan will be defined. The action plan is related to a flexible toolbox of interventions, which will be conducted by an interdisciplinary team. Effects of the intervention, both for frail older people and their informal caregivers, will be measured after 6, 12 and 24 months using postal questionnaires and telephone interviews. Data for the process evaluation and economic evaluation will be gathered continuously over a 24-month period.

**Discussion:** The proposed study will provide information about the usefulness of an interdisciplinary primary care intervention. The postal screening procedure was conducted in two cycles between December 2009 and April 2010 and turned out to be a feasible method. The response rate was 80%. According to GFI scores 29% of the respondents can be considered as frail (GFI  $\geq 5$ ). Nearly half of them (48%) were willing to participate. The baseline measurements started in January 2010. In February 2010 the first older people were approached by the practice nurse for a comprehensive assessment. Data on the effect, process, and economic evaluation will be available in 2012.

**Trial Registration:** ISRCTN31954692

## Background

Frailty is highly prevalent in older people; up to 40% of this population is estimated to be frail and an increasing trend is expected.<sup>1</sup> Frailty is related to an increased risk of adverse health outcomes such as acute and chronic diseases, disability and mortality.<sup>2-4</sup> Disability is defined as difficulty or dependency in the execution of the activities of daily living and is associated with increased healthcare utilisation and related costs.<sup>5</sup> Next to professional healthcare services, informal caregivers are a source of long-term care for frail older people. However, demographic and social changes such as fewer children, high divorce rates and other caregiving responsibilities reduce the ability of informal caregivers to provide this care.<sup>6</sup> In view of a growing frail older population and restraints in healthcare expenditure and availability of informal care, disability in frail older people is a public health problem and its prevention is considered to be a priority for research and clinical practice in geriatric care.<sup>3,7</sup>

During the last few decades various interventions have been developed targeting frail older people. These show a large diversity in terms of content, disciplines involved, duration, intensity and setting. Most studies have been conducted in the field of comprehensive geriatric assessment (CGA) or physical exercise.<sup>8</sup> Comprehensive geriatric assessment has been defined as 'a multidimensional, often interdisciplinary, diagnostic process intended to determine a frail older person's medical, psychosocial, and functional capabilities and problems, with the objective of developing an overall plan for treatment and long-term follow-up'.<sup>9</sup> Reviews have shown that the reported effectiveness of CGA studies is inconsistent.<sup>8,10-12</sup> Physical exercise programs for frail older people are mostly effective on frailty components such as physical fitness and balance, but they are less effective on disability outcomes.<sup>13</sup> The use of technology may be effective but more research is needed in this area.<sup>14,15</sup> In conclusion, only a small number of intervention studies have shown beneficial effects with regard to disability prevention and most studies did not report on the long-term effects.<sup>13</sup>

A narrative review by Daniëls and colleagues (2010) suggested that future community care interventions for frail older people should be directed towards tailor-made, multidisciplinary and multifactorial interventions, with individualised assessment and interventions conducted by a (primary) care team, involving case management and long-term follow-up.<sup>8</sup> These programmes may include a physical exercise component for moderately physically frail older people and a technology component tailored to the needs of older people.<sup>8</sup> Other promising elements are techniques for enhancing self-management abilities<sup>16-19</sup> and engagement in meaningful social and productive activities, as these foster natural motivation and self-efficacy in older people<sup>20,21</sup>.

The present study focuses on a primary care intervention that combines the most promising elements suggested above. This two-arm cluster randomised controlled trial aims to investigate (1) the effectiveness of the intervention with regard to disability (primary outcome) and several secondary functional outcomes, (2) the impact of the intervention on the central informal caregiver with respect to perceived burden on health-related quality of life and (3) the impact of the intervention on healthcare utilisation and related costs. In addition, (4) the feasibility of the intervention, including the adherence, will be studied. This article presents the study design and reports on the results of the screening procedure.

## Methods/ design

### Study Design

All general practitioner (GP) practices in the region of Sittard (the Netherlands) and its surroundings were invited to take part in the study, with the restriction that they had no current active and systematic policy for the detection and follow-up of frail older people. In total, 24 GP practices were interested, of which 12 were randomly selected for the study. Cluster randomisation was applied to allocate the selected practices to the intervention group (six practices) or the care as usual group (six practices). A flow diagram of the study design is shown in Figure 1.

Effects of the intervention, both for frail older people and their informal caregivers, will be measured after 6, 12 and 24 months using postal questionnaires and telephone interviews. Data on healthcare utilisation and related costs will be gathered continuously over a 24-month period from health insurance registries and registries of GPs and regional hospitals (economic evaluation). A process evaluation will be conducted by means of diaries, questionnaires and semi-structured interviews.

The study obtained approval by the Medical Ethical Committee of the Maastricht University/Academic Hospital Maastricht in the Netherlands in 2009 (MEC 09-3-067).

### Participants and recruitment

The study focuses on community-dwelling frail older people ( $\geq 70$  years). Those who were terminally ill, were confined to bed, had severe cognitive or psychological impairments or were unable to communicate in Dutch were excluded based on the advice of their GP. Consequently, frail older people were screened for frailty. On average, 300 screening questionnaires per practice were sent out depending on the number of older people registered (range 200-350). Where practices had more older people who fulfilled the inclusion criteria, a random selection was drawn. On behalf of their GP, the selected older people received the Groningen Frailty Indicator (GFI) to screen for frailty.<sup>22</sup> In the literature, a score of four or higher (range 0-15) is proposed

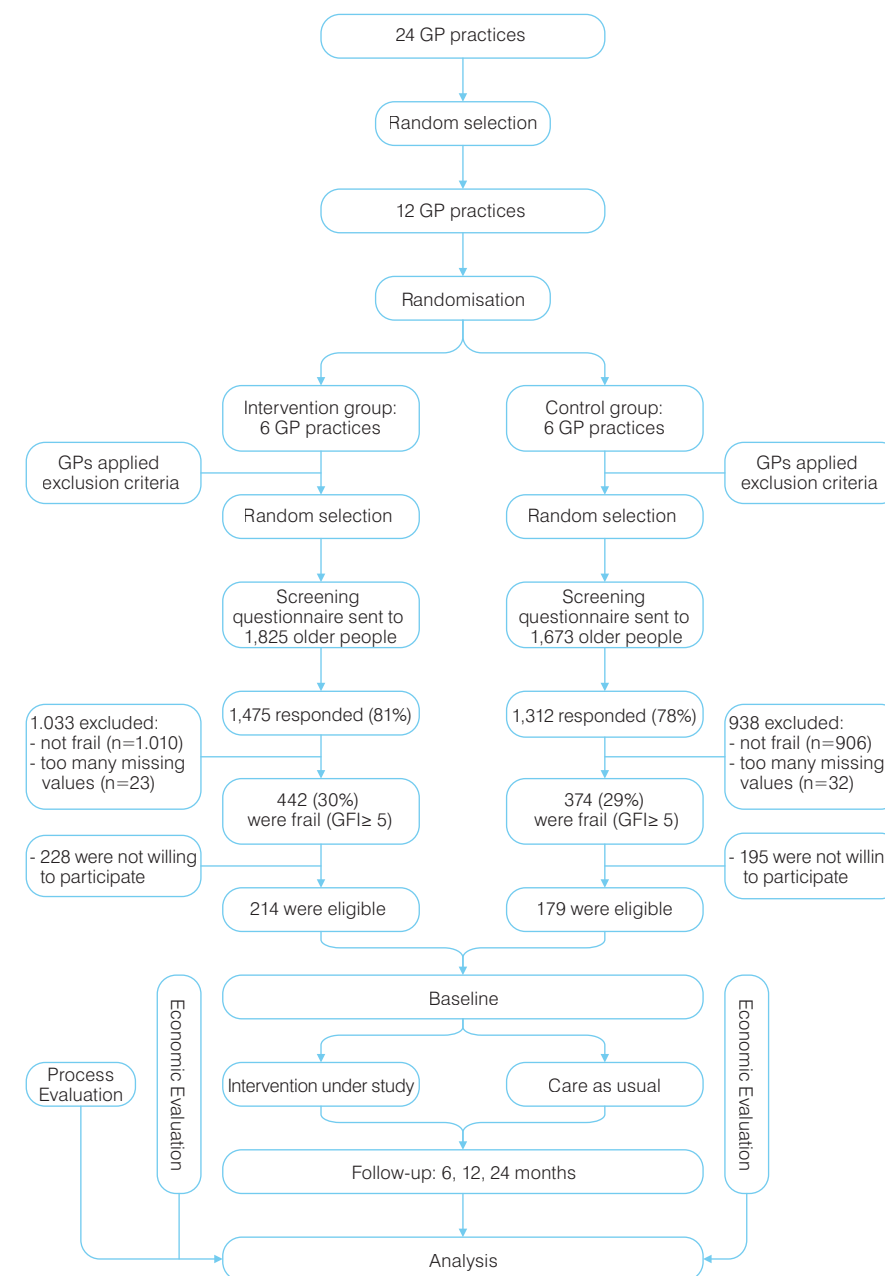


Figure 1 Study design.

as cut-off point for moderately to severely frail older people.<sup>22,23</sup> However, this study focuses on people who are considerably frail. Therefore a cut-off score of five was chosen. A letter from the GP, an information leaflet, an informed consent form and a postage free return envelope were included with the screening questionnaire. In total, a sample size of 3,498 older people was addressed (see Figure 1). Reminders were sent to non-responders after three weeks. The selection of participants is performed in two cycles for practical reasons. The first cycle started in December 2009 and the second in February 2010. The undertaking of the intervention and the collection of data will be performed in two cycles as well.

### Randomisation

Cluster randomisation was applied to avoid contamination bias.<sup>24-26</sup> Before the screening procedure started, six practices were randomly allocated to the new intervention and six practices continued care as usual. Before randomisation, the GP practices were pre-stratified into four strata on the basis of practice characteristics, which may influence the results of the study:

1. number of older patients in the practice (<350 patients versus ≥350 patients);
2. urban versus rural area.

It is assumed that GPs working in a practice with a large number of older patients have more experience with geriatric care. Furthermore, it is expected that older people living in a rural area have more support from the informal care system than people living in an urban area.

The practices were stratified in pairs and randomised into either intervention or control group using a computer generated randomisation list. To promote extrapolation of the results, practices settled in an urban area with a large number of older people had twice the chance of being included in the study than practices in the other three strata.

### Intervention and control group

#### Intervention group

Based on literature studies and an expert meeting a first draft of the intervention protocol was developed by a multidisciplinary task group. This group consisted of a GP, a nursing home physician, a geriatrician, a practice nurse, a home nurse staff member, a nurse specialist, a physical therapist, an occupational therapist, an expert in technology and a researcher as the coordinator. Studies on the screening procedure<sup>27</sup> and on the validity of screening instruments<sup>28</sup> were followed by a pre-pilot study (one GP practice, 10 frail older people) and a pilot study (two GP practices, 50 frail older people)<sup>29</sup> to test the feasibility of the intervention programme. The results were used to develop the final version of the intervention protocol under study.

The GP and the practice nurse are the core team of the intervention with the practice nurse as the case manager. This core team can be extended to include an occupational therapist and a physiotherapist, or other inpatient and outpatient specialists. The intervention puts emphasis on supporting frail older people to restore or continue the activities they need or enjoy, assuming that participation in social and productive activities is protective against adverse outcomes.<sup>29</sup> The intervention has two main features:

- Identifying risk factors<sup>30</sup> for developing disability and targeting risk factors using professional standards (i.e. Standards of Dutch College of GPs) and the 5A Behavioural Change Model.<sup>31</sup>
- Identifying problems in performing activities and enhancing meaningful activities based on the Model of Human Occupation.<sup>32</sup>

The intervention takes an individual approach to self-management. The 5A Behavioural Change Model combines a client-centred approach, a model for behavioural change (Stages of Change) and motivational interviewing techniques to provide concrete tools for professionals to support self-management. The 5As refer to the assessment of levels of behaviour, beliefs and motivation, advice adapted to the need for information, the agreement with frail older people on a realistic set of goals, the assistance provided to help them to anticipate barriers and the development of a specific action plan and arrangement of follow-up support.<sup>31</sup> In terms of performing activities, the Model of Human Occupation<sup>32</sup> is considered to be a good tool for analysis and problem-solving. With its base in occupational therapy, the model illuminates how factors of capacity, motivation, lifestyle and environment inter-relate in human occupation. This model has been used in previous successful effect studies.<sup>33,34</sup>

The intervention consists of six steps (see Figure 2). After an initial postal screening (step 1) frail older people (GFI score ≥5) will receive a comprehensive multidimensional assessment (step 2) by a practice nurse in collaboration with the GP. This assessment phase will focus on the identification of existing problems in performing daily activities and on risk factors for developing disability (i.e. poly-pharmacy, mobility, lack of social and productive activities, cognitive impairments). The practice nurse and GP will determine if additional assessment is needed by the GP, physiotherapist, occupational therapist or other inpatient or outpatient specialists. At the end of the assessment phase the practice nurse and GP will develop an intermediate action plan (step 3). Alternatively in cases of complex problems, the interdisciplinary team (i.e. practice nurse, GP, physiotherapist and occupational therapist) will meet to formulate a shared action plan. Consequently, a meeting between the practice nurse and the frail older person (and informal caregiver) will take place to define a final action plan, including goals, strategies and actions (step 4). The action plan will be tailored to the specific needs and wishes of the frail older person and will be related to a flexible toolbox of interventions which will be conducted



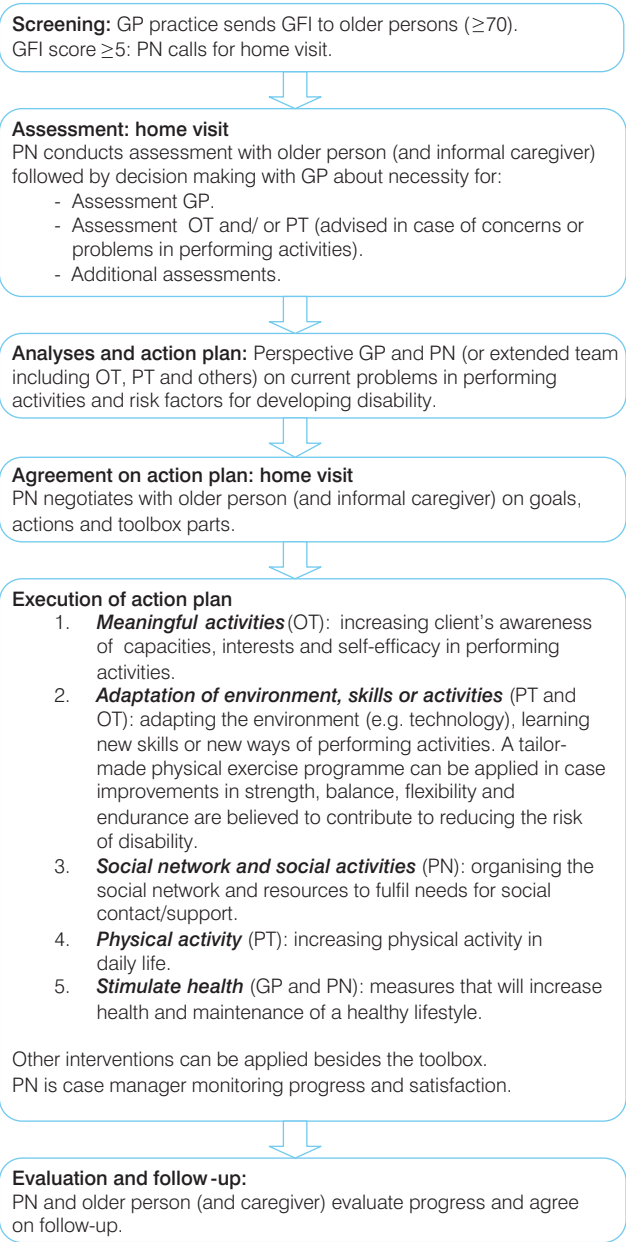


Figure 2 Steps of the programme.

PN=practice nurse, GP=general practitioner, OT=occupational therapist, PT=physiotherapist

by the interdisciplinary team (step 5). The toolbox can be supplemented with other interventions delivered by inpatient and outpatient specialists. The intervention protocol provides guidelines for referral to other disciplines. During execution and after finishing the components of the toolbox, the practice nurse will evaluate, with the frail older person (and the informal caregiver), the achievement of goals, the implementation of strategies into daily life and the need for further support (step 6).<sup>29</sup>

Training of healthcare professionals

In the 3-month period before the start of the intervention, healthcare professionals (practice nurses, GPs, physiotherapists and occupational therapists) received relevant training sessions with regard to the intervention protocol. Several meetings about the aspects and basic principles of the intervention protocol took place (i.e. the screening procedure, self-management principles, client centeredness, motivational interviewing, interdisciplinary collaboration, assessment tools, parts of the toolbox and referrals). Before the start of the study, health professionals had the opportunity to gain experience with the intervention protocol under supervision by the project team in small samples of frail older people who were not included in the study.

Control group

Frail older people in the control group were also selected by means of the screening questionnaire (GFI score≥5). They will receive care as usual, and will be able to use or apply for all available services for older people as before.

Outcome

Primary outcome measure

The primary outcome measure is disability. The Groningen Activity Restriction Scale (GARS) is an easy-to-administer, comprehensive, reliable, hierarchical and valid measure for assessing disability in the domains of activities of daily living (ADL) and instrumental activities of daily living (IADL) in older people.<sup>35</sup>

Secondary outcome measures

Secondary outcomes are depressive symptomatology (depression subscale Hospital Anxiety and Depression Scale)<sup>36</sup>, social support interactions (Social Support List - Interaction version)<sup>37</sup>, fear of falling (Short Falls Efficacy Scale - International)<sup>38</sup> and social participation (Maastricht Social Participation Profile)<sup>39</sup>. Feelings of loneliness will be assessed by the question: "During the past 4 weeks, how often did you feel lonely?".<sup>19</sup> The frequency of falls will be assessed by the question: "How often did you fall during the past 6 months/ 12 months".<sup>19</sup> Mortality, healthcare utilisation and related costs will be continuously registered during 24 months.

Additional variables

Several additional variables will be assessed to provide insight into population characteristics and to interpret the outcomes of the study. Mental, physical, social, economic and behavioural factors may affect our primary outcome of disability.<sup>40</sup> Socio-demographic data (i.e. age, gender, marital status, living situation, educational level) will be gathered at baseline from the GFI and a standardised data set: the Minimal DataSet (MDS). Other variables to be assessed at baseline and at 6, 12 and 24 month follow-up are cognitive impairment<sup>41</sup> and vision and hearing capacity<sup>42</sup>.

We assume two variables to be potential effect modifiers. First, the frailty status at baseline (GFI score) as it predicts disability.<sup>5</sup> Second, feelings of competence and control, as they are crucial for self-management and coping<sup>43</sup>, which are important underlying mechanisms of the proposed intervention. Feelings of competence and control will be assessed at baseline and at 6, 12 and 24 month follow-up using the Mastery scale.<sup>44</sup> The impact of potential effect modifiers on disability will be studied in subgroup analyses. Table 1 provides an overview of the instruments used to measure primary and secondary outcomes, and the additional variables.

The proposed study will be embedded in the Dutch National Care for the Elderly Programme. This implies that the MDS has to be applied. The MDS for the care receiver provides global data on: age, gender, marital status, ethnicity, living arrangements, socio-economic status, level of education, health perception, multi-morbidity, daily functioning in ADL, mental well-being, cognitive functioning, social functioning, quality of life and use of healthcare services. Data about the impact of the intervention on informal caregivers (perceived burden and health-related quality of life) will be gathered by the MDS for informal caregivers.

Data will be collected by a combination of two methods, telephone interviews (TI) and postal questionnaires (PQ), which have been proven to be feasible and efficient in previous research.<sup>18,19</sup> First, a second postal questionnaire after the screening questionnaire will be sent to frail older people to gather baseline data. Two weeks later a telephone interview will take place in order to gather additional information. These interviews will be conducted by independent interviewers of the Centre for Data and Information Management of Maastricht University (MEMIC), who will be blinded to the treatment assignment. The same procedure (postal questionnaire and telephone interview) will be repeated after 6, 12 and 24 months after baseline to gather follow-up data. In addition, data on healthcare utilisation and related costs will be continuously gathered from health insurance registries and registries of the GPs and hospitals in the region. The central informal caregivers of the frail older people will receive a questionnaire at baseline and after 6, 12 and 24 months.

Table 1 Primary, secondary and additional outcome measures.

Variables	Instrument	No. of items	Range*	B	FU1	FU2	FU3
Primary outcome measure							
Disability	GARS <sup>35</sup>	18	<u>18-72</u>	TI	TI	TI	TI
Secondary outcome measures							
Cognitive impairment	TICS <sup>41</sup>	11	<u>0-41</u>	TI	TI	TI	TI
Symptoms of depression	HADS <sup>36</sup>	7	<u>0-21</u>	TI	TI	TI	TI
Social participation	MSPP <sup>39</sup>	10	<u>0-90</u>	TI	TI	TI	TI
Social support interactions	SSL12-I <sup>37</sup>	12	<u>12-48</u>	PQ	PQ	PQ	PQ
Fear of falling	Short FES-I <sup>38</sup>	7	<u>7-28</u>	TI	TI	TI	TI
No. of falls in the previous 6 months <sup>19</sup>	N/A	1	N/A	TI	TI	TI	TI
Consultation with physician due to fall	N/A	1	N/A	TI	TI	TI	TI
Feelings of loneliness <sup>19</sup>	N/A	1	N/A	PQ	PQ	PQ	PQ
Mortality	N/A	N/A	N/A	R	R	R	R
Additional measures							
Vision/hearing capacity	OECD-long-term disability indicator <sup>42</sup>	4	<u>4-16</u>	TI	TI	TI	TI
Mastery	Mastery scale <sup>44</sup>	7	<u>7-35</u>	TI	TI	TI	TI
Healthcare utilisation	N/A	N/A	N/A	R	R	R	R

\* The underlined scores indicate the most favourable scores; N/A=not applicable  
B=baseline; FU1=6-month follow-up; FU2=12-month follow-up; FU3=24-month follow-up;  
TI=telephone interview, PQ=postal questionnaire; R=registries of health insurance/ GP/ hospital

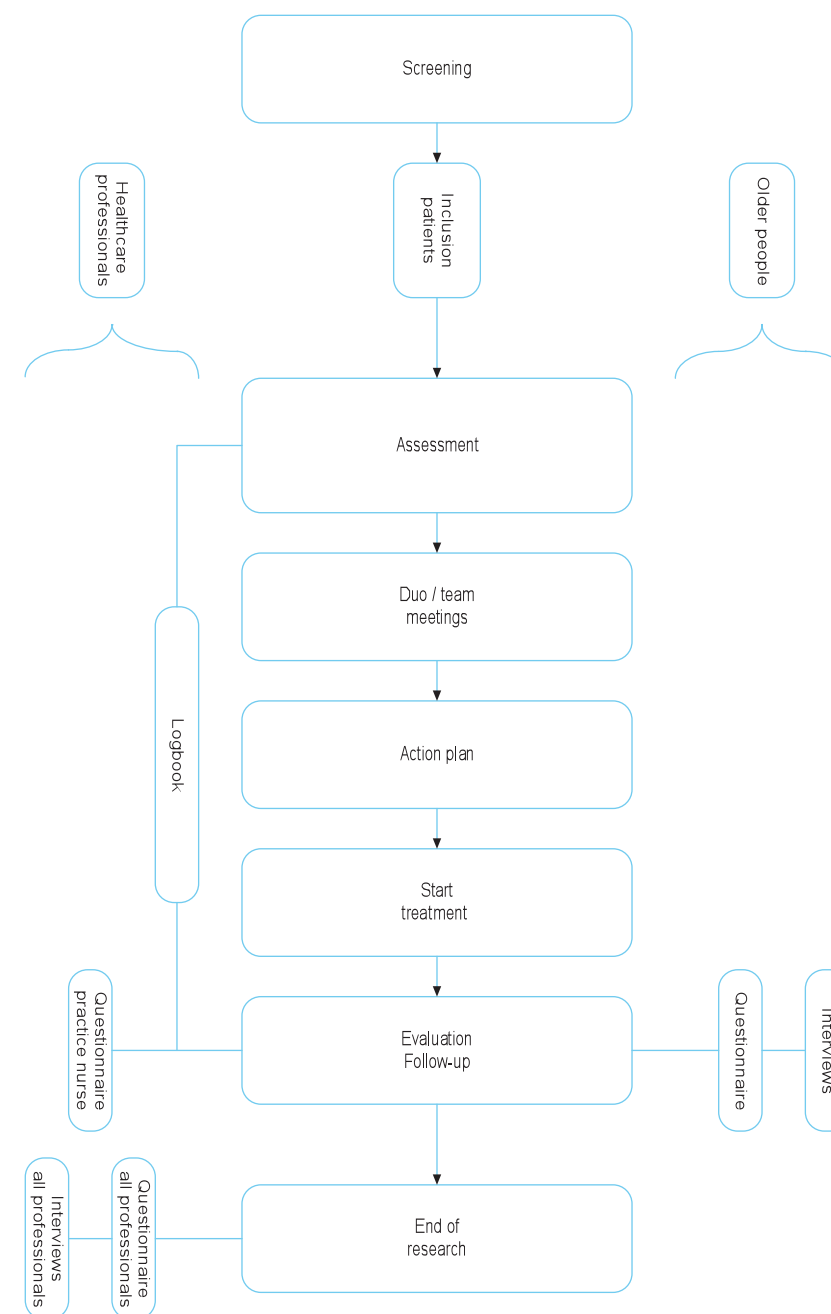
Process evaluation

The process evaluation aims to improve further implementation of the intervention and to validate the results of the study. A systematic approach will be used for this evaluation, involving key elements such as reach, dose delivered, dose received (exposure and satisfaction) and barriers.<sup>45-47</sup> Table 2 gives a description of these elements.

**Table 2** Elements of the process evaluation and data collection methods

Component and definition	Outcome variables	Measurement
<i>Reach</i>		
Proportion of the intended target population that participated in the intervention	<ul style="list-style-type: none"> <li>- Number of older people that refused, dropped-out or completed the intervention</li> <li>- Reasons for refusal/drop-out (before start and during the intervention)</li> </ul>	- Logbook
<i>Dose delivered (completeness)</i>		
Amount of delivered intervention	<ul style="list-style-type: none"> <li>- Assessments</li> <li>- Referrals to other disciplines</li> <li>- Interventions / toolbox parts</li> <li>- Evaluation / follow-up</li> </ul>	- Logbook
<i>Dose received (exposure)</i>		
Extent of active engagement in and receptiveness to the intervention by older people	<ul style="list-style-type: none"> <li>- Opinion about older peoples' ability to understand and implement principles of the intervention</li> <li>- Adherence to commitments made by older people</li> <li>- Intention of patients to implement the intervention</li> </ul>	<ul style="list-style-type: none"> <li>- Questionnaire/ interviews older people</li> <li>- Questionnaire/ interviews healthcare professionals</li> </ul>
<i>Dose received (satisfaction)</i>		
Satisfaction of older people and healthcare professionals with the intervention	<ul style="list-style-type: none"> <li>- Overall opinion of older people</li> <li>- Experienced benefits, burden, usefulness by older people</li> <li>- Overall opinion of healthcare professionals</li> </ul>	<ul style="list-style-type: none"> <li>- Questionnaire/ interviews older people</li> <li>- Questionnaire/ interviews healthcare professionals</li> </ul>
<i>Barriers</i>		
The extent to which problems were encountered while applying the intervention	- Barriers in applying the intervention	- Questionnaire/ interviews healthcare professionals

Both quantitative and qualitative information will be collected from participants and healthcare professionals. Participants will evaluate the intervention by means of a self-administered questionnaire, directly after their last intervention contact. In addition, semi-structured interviews will be conducted among a random sample of participants to evaluate their experiences with the intervention. Questionnaires and semi-structured

**Figure 3** Process evaluation plan.

interviews will also be used among healthcare professionals to evaluate the intervention. In addition, they will be asked to register the treatments delivered (including the time spent on them) and reasons given for refusal and dropout throughout the intervention period. Figure 3 shows the data to be collected for the process evaluation during the study period.

### Economic evaluation

A cost-effectiveness analysis will be carried out in which costs will be considered from a societal perspective, which implies that all costs and effects are taken into account. The economic evaluation will be a combination of a cost-effectiveness and cost-utility analysis. The primary clinical outcome for the cost-effectiveness analysis is disability, which will be measured at baseline and at 6, 12 and 24 months follow-up by means of the GARS.<sup>35</sup> Within the cost-utility analysis, the primary outcome is generic health-related quality of life (QALY). Therefore utilities will be measured by means of the standard Dutch version of the EuroQol (EQ-6D)<sup>48,49</sup> at baseline and at 6, 12 and 24 months follow-up. Subsequently, a direct value for every state of health will be generated using the Dolan tariff, which involves an algorithm for interpolating EuroQol results to population utilities.<sup>50,51</sup>

This study will assess intervention costs, healthcare costs and patient/ family costs. Intervention costs relate to the delivery of the intervention, for example costs related to the screening procedure, time spent on intervention by healthcare professionals, travel expenses of professionals and costs for training activities. Data will be registered prospectively by the researchers. Healthcare costs relate to hospital visits (inpatient and outpatient treatment), GP consultations, visits to allied professionals, prescribed medication and (nursing) home care. Data of healthcare utilisation will be assessed by means of registries of health insurance agencies, GP practices and hospitals. In addition, questions about healthcare utilisation are included in the postal questionnaire and the telephone interview. Patient and family costs relate to costs that are made by the patients or informal caregivers themselves and include, for example, travel expenses (based on the mean distance to and from healthcare professionals) and informal care (based on hours delivered). These data would preferably be assessed by means of a cost diary.<sup>52</sup> However, in the present study a diary was considered to be too burdensome for frail older people (and their informal caregivers).

In order to calculate costs, volumes of resource utilisation will be multiplied by the cost price of that unit. Cost prices will be obtained from the Dutch guidelines for cost analysis in health care research.<sup>53,54</sup> Where such guidelines are not available for a specific category, real costs or tariffs will be used to estimate costs.

Differences in costs and effects will be presented in incremental cost-effectiveness ratios (ICERs). The ICERs represent the differences in mean costs between the intervention and usual care group in the numerator and the difference in mean effects

in the denominator.<sup>55</sup> Sensitivity analysis will be done to assess the robustness of the assumptions we made.

### Sample size

The population sample size is based on the primary outcome measure of disability. Based on a previous study<sup>19</sup>, we expect to demonstrate a difference in disability between the mean change score of the intervention and the control group of at least 2.0 points on the Groningen Activity Restriction Scale (GARS)<sup>35</sup> (which is equivalent to an effect size of 0.44 with SD 4.5). Based on a power of 80% and an alpha of 0.05 (two-sided testing), this leads to a minimal sample size of  $n=80$  per group (160 in total). Based on an expected drop-out rate of 30%, the required sample size would be  $n=104$  per group ( $n=208$  in total). However, the cluster randomised design of this study has consequences for the sample size and power. Scores of individuals within a cluster are assumed to be correlated in contrast to those of individuals between clusters. A within-cluster correlation leads to a greater homogeneity of individuals within a cluster, which increases the standard error of the estimate of the treatment effect. This may result in a loss of power for detecting differences between the intervention and control group. Therefore, an Intra Cluster Correlation (ICC) coefficient is needed to determine a corrected sample size.<sup>56</sup> In earlier intervention trials among GPs, ICC values between 0.03 and 0.06 were used.<sup>57-59</sup> In the present study an ICC value of 0.05 was estimated, resulting in a design effect of 1.7273. Based on the expected drop-out rate of 30%, the required sample size is  $n=180$  per group ( $n=360$  in total, an average of  $n=30$  per GP practice).

According to Puts and colleagues (2005), the prevalence of frailty in Dutch older people aged 55 to 85 years old varies from 12% to 21%.<sup>60</sup> We have conservatively estimated that 15% of the screened population will fulfil all criteria. A response rate on the postal screening of at least 65% was expected among older people.<sup>19,61</sup> On average, 300 screening questionnaires per GP practice (3,498 in total) were sent to older people to obtain a sufficient number of frail older people for the trial ( $n=360$ ). In addition, (central) informal caregivers will be included as well. It is expected that a central informal caregiver will be identified for 80% of frail older people.

### Statistical analysis

Descriptive techniques will be used to describe the study groups. Baseline variables will be compared to detect differences between the intervention and control group at the start of the study. Data of the effect evaluation will be analysed according to the intention-to-treat principle. Analysis of primary and secondary endpoints will be performed using relevant univariate, multivariate and multilevel techniques including mixed-effects regression models. A subgroup analysis will be performed for frailty status and feelings of competence and control (mastery), as these variables are

assumed to be potential effect modifiers. The software package SPSS for Windows, version 17.0., will be used for all statistical analyses. The level of statistical significance will be set at 0.05 (two-tailed).

Data on the process and economic evaluation will be analysed and presented using descriptive techniques and appropriate statistical testing. Data gathered from interviews (process evaluation) will be analysed using descriptive techniques.

## Discussion

Out of 52 GP practices, 24 practices have applied for taking part in the proposed study. This indicates a substantial interest of GPs in innovations regarding care for frail older people. Twelve of them were randomly selected to take part in the current study. A random selection of their community-dwelling older patients ( $\geq 70$  years) was screened for frailty. For practical reasons the screening procedure was distributed across two cycles between December 2009 and April 2010. A total of 3,498 older people received the screening questionnaire. The response rate was 80%. According to the GFI scores 29% of the respondents can be considered as frail (GFI score  $\geq 5$ ). Nearly half of them (48%) were willing to participate. Sending out a postal questionnaire including the GFI<sup>22</sup> turned out to be a feasible and inexpensive method of identifying frail older people. Adding a letter from their general practitioners to the information leaflet may have contributed to the high response rate.

The proposed study has some potential limitations. First, the participating GPs are very interested in innovations in the care of older people otherwise they would not have applied to take part in the study. Consequently, the GPs allocated to the control group may take initiatives to improve the care for the older people in this group during the study period. The researchers will carefully monitor the activities of GPs regarding the potential improvement of care of these older people. Second, implementation of the intervention protocol is a point of concern. Based on a combination of elements such as interdisciplinary decision-making and collaboration (i.e. team meetings), self-management (taking principles of client-centeredness, behavioural change and motivational interviewing into account), and an extensive toolbox of interventions, the intervention is very complex. Educating and guiding teams in implementing the programme are therefore important.

## Progress of study

The baseline measurements started in January 2010. In February 2010 the first frail older people were approached by the PN for a comprehensive assessment. Data on the effect evaluation will be available in 2012. Data for the process evaluation and economic evaluation will be gathered between 2010 and 2012.

## Acknowledgements

- Participants of the study;
- Participating GPs and other healthcare professionals, who are involved in the research;
- Health Insurance companies;
- Centre for Data and Information Management (MEMIC): Anita Legtenberg, Alfons Schroten, Marlène Ronner;
- Members of the research group: Sjoerd Hobma (GP), Lilo Crasborn (MCC Omnes), Simone Denis (MCC Omnes), Marlou Wolters (MCC Omnes), Herbert Habets (Orbis Medical Centre), Walther Sipers (Orbis Medical Centre), Ramon Daniels (Zuyd University of Applied Sciences, Heerlen);
- Research assistance: Floor Koomen, Ine Hesdahl;
- Sponsor: Dutch National Care for the Elderly Programme by The Netherlands Organisation for Health Research and Development (ZonMw 311070301), the Hague, the Netherlands.



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## **A nurse-led interdisciplinary primary care approach to prevent disability among community-dwelling frail older people: a large-scale process evaluation**

**This chapter was published as:**

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International Journal of Nursing Studies 2011;50(9):1184-96

## Abstract

**Background:** The complex healthcare needs of frail older people and their increased risk of disability require an integrated and proactive approach. In the Netherlands, an interdisciplinary primary care approach has recently been developed, involving individualised assessment and interventions (tailor-made care), case management and long-term follow-up. The practice nurse as part of a general practice is case manager and plans, organises and monitors the care process and facilitates cooperation between professionals. The approach has shown positive indications regarding its feasibility in a small pilot, but its implementation on a large scale had not hitherto been investigated.

**Objectives:** To examine the extent to which the interdisciplinary care approach is implemented as planned and to gain insight into healthcare professionals' and frail older people's experiences regarding the benefits, burden, stimulating factors and barriers.

**Design:** A process evaluation was conducted using a mixed methods design.

**Settings:** Six GP practices in the south of the Netherlands.

**Participants:** Practice nurses (n=7), GPs (n=12), occupational therapists (n=6) and physical therapists (n=20) participated in the process evaluation. Furthermore, 194 community-dwelling frail older people (≥70 years) were included using the Groningen Frailty Indicator. People who were terminally ill, were confined to bed, had severe cognitive or psychological impairments or were unable to communicate in Dutch were excluded.

**Methods:** Quantitative data (logbooks and evaluation forms) were collected from all the participating frail older people and thirteen semi-structured interviews with a selection of them were conducted. In addition, data from healthcare professionals were collected through twelve semi-structured interviews and four focus group discussions.

**Results:** Although some parts of the protocol were insufficiently executed, healthcare professionals and frail older people were satisfied with the care approach, as it provided a useful structure for the delivery of geriatric primary care and increased the attention to preventive treatment. Frail older people felt acknowledged by healthcare professionals and experienced support in handling their problems and fulfilling their wishes.

**Conclusions:** The findings of the study revealed several positive aspects of the interdisciplinary primary care approach. Given its complexity, the implementation of the nurse-led interdisciplinary care approach is challenging and some parts of the protocol need special attention.

## Background

Frail older people often suffer from a combination of acute and chronic diseases (multimorbidity) and functional impairments leading towards disability and dependency on long-term care.<sup>1</sup> In general, older people prefer to stay at home for as long as possible.<sup>2</sup> However, community-based care is challenging, due to the complex healthcare needs of frail older people, which have to be addressed by various healthcare professionals.<sup>3</sup>

Beswick and colleagues (2008) have shown in their meta-analysis that complex interventions like community-based geriatric assessment and follow-up programs have the potential to support older people to live independently, although there is no clear evidence yet that one specific format is better than another.<sup>4</sup> In the Netherlands, several recent studies on proactive home visits for vulnerable older people showed conflicting results. These visits did not turn out to be effective<sup>5,6</sup>, or showed only modest short-term effects<sup>7</sup>. Despite the strong emphasis on primary care in the Dutch healthcare system, it may be assumed that the implementation of complex interventions is hampered by a fragmented and reactive approach and a lack of intense collaboration between healthcare professionals.<sup>8</sup> Fragmented care is also a problem in other western countries. For example in the US the PACE programs have been introduced in many states to unite the fragmented healthcare financing and delivery system. PACE programs are comprehensive community-based care models for frail older people, who are eligible for nursing home admission. All needed preventive, primary, acute and long-term care services are delivered by an interdisciplinary team in the community care setting focusing on the individual needs of community-dwelling frail older people and their families.<sup>9,10</sup> There is consensus in the Netherlands that a shift has to be made towards a more integrated and proactive approach to prevent disability in community-dwelling frail older people successfully.<sup>11</sup>

A narrative review by Daniëls and colleagues (2010) offers a comprehensive overview of interventions studies focusing on disability prevention in community-dwelling frail older people.<sup>12</sup> There is a large diversity in content, disciplines involved, duration, intensity, and setting. The reported effectiveness of interventions is not consistent, but elements such as interdisciplinary cooperation, individualised assessment and interventions (tailor-made care), case management and long-term follow-up seem to be promising with regard to disability prevention. In addition, self-management support and stimulating engagement in meaningful activities were recommended by the authors.<sup>12</sup> Consequently, these elements were combined in an interdisciplinary primary care approach for community-dwelling frail older people, called 'Prevention of Care' (PoC).

The PoC approach starts with a postal screening for frailty followed by an extended multifactorial assessment conducted by a practice nurse (and, if needed,

other professionals). Based on the assessment phase the team of involved professionals formulate a preliminary treatment plan. Consequently, the practice nurse discusses this plan with the frail older person and his/ her informal caregiver resulting in a final treatment plan. A flexible toolbox of interventions, organised around five topics such as ‘enhancing meaningful activities’ or ‘stimulating health’ is available to guide the treatment. The toolbox is described in more detail elsewhere.<sup>8</sup> Finally, the treatment plan is coordinated, monitored and evaluated by the practice nurse, who acts as case manager.<sup>13</sup> The strength of the PoC protocol is that all elements mentioned above were combined in one comprehensive and interdisciplinary approach. The protocol offers healthcare professionals a useful structure for healthcare delivery (consisting of six steps) and practical tools for interdisciplinary, client-centered care, case management, behavioral change and self-management support.

The implementation of the PoC approach in daily practice is challenging due to the combination of a number of elements, which are based on literature<sup>12</sup>, but are relatively new in geriatric primary care practice. A pilot study among 41 frail older people and 10 healthcare professionals has shown positive indications regarding its feasibility, but implementation on a large scale has not been investigated yet.<sup>13</sup> This article presents a comprehensive process evaluation of the PoC approach on a larger scale, among 194 frail older people and 45 healthcare professionals. The aim of the process evaluation was to provide insight into the extent to which the interdisciplinary PoC approach is implemented as intended.<sup>14</sup> Furthermore, healthcare professionals’ and frail older people’s experiences regarding benefits, burden, stimulating factors and barriers were evaluated. More insight into these factors may increase the understanding of its implementation and may lead towards an improved interdisciplinary care approach for frail older people in daily practice.<sup>15</sup>

Methods

Study design

Between February 2010 and December 2011 the PoC approach was evaluated in a large-scale process evaluation among six GP practices in the south of the Netherlands. Several process evaluation components from Baranowski and Stables (i.e. reach, dose delivered, fidelity, dose received (exposure and satisfaction), and barriers) were chosen as theoretical base for the process evaluation.<sup>15-17</sup> Table 1 shows an overview of these components, their definition and the related research questions.

Table 1 Components of the process evaluation and related research questions

Theoretical element	Research question(s)
<i>Reach</i>	
Proportion of the intended target population that participated in the care approach	- Does PoC reach the target group (frail older people)? - What were the numbers of and reasons for refusals and drop-outs?
<i>Dose delivered</i>	
'Amount' of delivered care approach	- To what extent was PoC performed according to protocol?
<i>Fidelity</i>	
Extent to which care approach was delivered in intended manner and spirit	- To what extent was PoC implemented consistently with its core principles?
<i>Exposure (dose received)</i>	
Extent of active engagement in and receptiveness to the care approach	- What was the frail older people's and informal caregivers' ability to understand and implement the principles of PoC?
<i>Satisfaction (dose received)</i>	
Satisfaction of older people and health care professionals with the care approach	- What were the experiences of healthcare professionals and frail older people regarding PoC in terms of benefits, satisfaction and stimulating factors?
<i>Barriers</i>	
The extent to which problems were encountered while applying the care approach	- What were the experiences of healthcare professionals and frail older people regarding PoC in terms of barriers?

Setting and participants

Professionals

Six GP practices in the region of Sittard and its surroundings (in the south of the Netherlands), involving twelve GPs and seven practice nurses implemented the PoC approach and were invited to participate in the process evaluation. The GP practices had no current active and systematic policy for the detection and follow-up of frail older people. Furthermore, six occupational therapists and twenty physical therapists, working in the same region, participated.

### Frail older people

Frail older people have an increased risk of adverse health outcomes, such as falls, hospitalisation, disability, and death.<sup>18</sup> The reserve capacity of frail older people is reduced to a critically low point. Consequently, even small disturbances can lead to a series of complications.<sup>19</sup> Despite the growing interest for frailty, there is an on-going debate of its definition. In general, there are two perspectives on frailty. On the one hand, a physical perspective describing frailty as a clinical syndrome characterised by multiple physical characteristics such as weight loss, fatigue or slow motor performance.<sup>18</sup> On the other hand, from a multifactorial perspective frailty is explained by an accumulation of physical, psychological and social characteristics (e.g. physical problems, mood, and cognition).<sup>20,21</sup> With regard to disability prevention a multifactorial approach to frailty seems to be more suitable.<sup>8</sup> As a consequence, the PoC approach takes a multifactorial perspective on screening, assessment and treatment. The Groningen Frailty Indicator (GFI), a self-report instrument that measures frailty from a multifactorial perspective, is used to identify community-dwelling frail older people ( $\geq 70$  years).<sup>22</sup> Those older people scoring five or higher (range 0-15) were assumed to be frail and were included for the study ( $n=194$ ).<sup>23</sup> People who were terminally ill, were confined to bed, had severe cognitive or psychological impairments or were unable to communicate in Dutch were excluded in advance, based on the advice of their GP.

### Ethical Approval

The study protocol and procedures were approved by the Medical Ethics Committee of the University Hospital Maastricht/ Maastricht University (#09-3-067). Written informed consent from all participating frail older people was obtained.

### The interdisciplinary care approach 'Prevention of Care' (PoC)

The core team of the interdisciplinary care approach PoC consists of a practice nurse and a GP. In the Netherlands, GPs have the role of a gatekeeper, who coordinates access to specialised and hospital care. The profession of practice nurses was introduced in 2001 to reduce the workload of Dutch GPs.<sup>24</sup> They often work, under supervision of the GP, on disease prevention, chronic care management, mental health services, frail elderly assessments, and care of families with young children.<sup>25</sup> To fulfill the role of case manager adequately, practice nurses need at least a bachelor degree, sufficient clinical expertise, effective communication and problem-solving skills, and a broad knowledge of the healthcare system, including financing, regulations, and resources.<sup>26</sup> Nurses are well suited to provide this role of case manager, as the nursing process is similar to the process of case management including tasks such assessment of client needs, planning of care, and on-going coordination, monitoring, and evaluation of delivered care. However, principally other

professionals, for example a physiotherapist, an occupational therapist or a social worker may fulfill this role as well.<sup>27</sup> However, nurses in primary care are often the linking pin between patient and specific healthcare professionals.<sup>28</sup>

Within the PoC approach the practice nurse and the GP cooperate closely with occupational and physical therapists. If needed, other inpatient and outpatient healthcare professionals, for example, a pharmacist or a geriatrician can be involved as well. The PoC approach focuses on existing problems in performing daily activities and on risk factors for developing disability, and consists of six steps (see Table 2). The core principles of the approach are interdisciplinary cooperation, tailor-made care, self-management support, and a focus on meaningful activities. The interdisciplinary care approach has been described in more detail elsewhere.<sup>8</sup> An adapted version of the PoC approach has been developed for hospitals to increase the cooperation between primary and hospital care. However, its evaluation is not a part of the current study.

### Interdisciplinary cooperation

Frail older people often have complex healthcare needs, which have to be addressed by various healthcare professionals.<sup>3</sup> To ensure integrated care, the PoC protocol encompasses tasks, decision criteria, and working procedures for the healthcare professionals involved. A common care philosophy, defined roles, open and clear communication, regular structural communication, shared decision-making and goal setting are important determinants to enhance team cooperation.<sup>29,30</sup>

### Tailor-made care and self-management support

Self-management support is based on the 5A's Behaviour Change Model<sup>31</sup>, which combines a client-centred approach, a model of behavioural change (Stages of Change model<sup>32</sup>) and motivational interviewing techniques<sup>33</sup>. Motivational interviewing provides practical tools for professionals to support self-management, which has been shown to be effective in improving clinical outcomes.<sup>34,35</sup> Use of the 5A's Behavioural Model implies that goals and strategies are individually determined and will depend strongly on the frail older people's (self-perceived) problems, motivation and capabilities. The self-management skills of older people will influence whether goals are focused on the client or more on (support of) the social and physical environment.<sup>8</sup>

### Meaningful activities

As the PoC approach aims to support frail older people in continuing to do those activities they enjoy or need to do, meaningful activities have to be at the core of the approach. Healthcare professionals need to explore the concerns or problems of older people regarding the performance of meaningful activities, need to understand the older people's priorities, and need to use meaningful activities, where possible.

**Table 2** Steps of the interdisciplinary care approach 'Prevention of Care' (PoC)

Steps	Content
<b>Step 1:</b> <i>Frailty Screening</i>	A postal questionnaire, including the 15-item Groningen Frailty Indicator (GFI) <sup>22</sup> is used to identify frail older people based on a GFI score $\geq$ 5.
<b>Step 2:</b> <i>Assessment</i>	The practice nurse of the GP visits frail older people for a multidimensional assessment in the presence of the main informal caregiver (if available). The focus is on existing problems in performing daily activities and on risk factors for developing disability. After the home visit, the practice nurse and the GP discuss whether additional assessment by other inpatient or outpatient healthcare professionals is needed.
<b>Step 3:</b> <i>Analysis and preliminary treatment plan</i>	Based on the assessment phase, a preliminary treatment plan is formulated, whether in a bilateral meeting (practice nurse and GP) or in an extended team meeting consisting of practice nurse, GP, occupational and physiotherapist and, if necessary, other healthcare professionals. The treatment plan includes goals, strategies and responsibilities.
<b>Step 4:</b> <i>Agreement on treatment plan</i>	During a second home visit, conducted by the practice nurse, a final treatment plan is formulated together with the frail older person and, if available, the informal caregiver. The plan involves goals, strategies and responsibilities that fit their needs. The practice nurse involves them in decision-making and establishes a cooperation, in which a learning process begins, leading to new insights and possibly to new goals and actions.
<b>Step 5:</b> <i>Executing the treatment plan</i>	The intervention protocol offers recommendations and guidelines for the execution of the treatment plan. For example, a flexible toolbox of interventions is available which focuses on five topics: <ul style="list-style-type: none"><li>• Meaningful activities</li><li>• Adapting the environment, activities or skills</li><li>• Social network and social activities</li><li>• Daily physical activity</li><li>• Stimulating health</li></ul>
<b>Step 6:</b> <i>Evaluation and follow-up</i>	During and after the treatment the practice nurse evaluates with the frail older person (and, if available, the informal caregiver) the achievement of goals, the implementation of strategies in daily life and the need for support in the following period. The professionals involved will be updated about the agreements.

Examples of meaningful activities are gardening, visiting family/ friends, reading a book, taking a walk, playing games or joining religious activities. The experience of 'doing' may increase insight and beliefs in one's own capabilities (self-efficacy)<sup>36</sup>, which is central to self-management. Graff and colleagues (2006) showed the

effectiveness of a focus on meaningful activities in a program for older people with dementia.<sup>37</sup>

**Training healthcare professionals**

The healthcare professionals involved (practice nurses, GPs, occupational therapists and physical therapists) were trained for a 3-month period before the implementation of the PoC approach. They attended several meetings about the steps and core principles of the intervention, such as interdisciplinary cooperation (e.g. team meetings), tailor-made care, self-management support, meaningful activities and toolbox parts. These meetings were more general and were held for all healthcare professionals. Discipline-specific meetings were also organised regarding the conduct of assessments and treatment by the different healthcare professionals. In addition, a meeting about geriatric syndromes (e.g. incontinence, malnutrition, falls) was organised.

During the implementation period, healthcare professionals had the opportunity to ask for supervision by the project group members (training on the job), if they experienced difficulties in implementing the PoC protocol. If healthcare professionals took little initiative towards support, members of the project group approached them more directly offering supervision. Project staff gave feedback and advice with regard to the new working methods and procedures and how to implement them in their daily routines. One issue, for example, was how to organise a team meeting. In addition, ten lunch meetings for practice nurses and two evaluation meetings with all the healthcare professionals involved took place to exchange information and experiences.

**Data collection**

Quantitative and qualitative data collection methods were applied in a mixed methods design. The focus of the quantitative data collection (logbooks and evaluation forms) was on reach, dose delivered and frail older people's exposure to the PoC approach. Qualitative data methods (semi-structured and focus group interviews) were used to investigate the fidelity of the PoC approach and healthcare professionals' and frail older people's experiences with the PoC approach. Insight into their experiences is useful to explain the extent of reach, exposure and delivery of the care approach (dose delivered and fidelity). A combination of methods is useful to broaden the scope of the data (triangulation).<sup>38</sup>

**Logbooks and evaluation forms**

During the evaluation period, practice nurses were asked to fill in logbooks and evaluation forms for all the participating frail older people. The logbooks contained information about the 'amount' of care delivery (dose delivered), for example, the number of team meetings or referrals to other disciplines. The numbers of and



reasons for refusals and drop-outs were registered here as well (reach). In the evaluation forms, practice nurses were asked to judge on an individual level the frailty status of the participating older people (reach) and their ability to understand the goal and the working method of the care approach and their adherence to commitments (exposure).<sup>15-17</sup>

### Semi-structured and focus group interviews

Semi-structured and focus group interviews were used to assess the fidelity of the interdisciplinary care approach. Fidelity refers to whether the care approach was carried out in the intended manner and spirit (interdisciplinary cooperation, tailor-made care, self-management support, and meaningful activities). Furthermore, the experiences of healthcare professionals and frail older people in terms of benefits, burden, stimulating factors and barriers were investigated and recommendations regarding future implementation of the approach were collected.<sup>15-17</sup>

The semi-structured interviews with the practice nurses and the GPs were conducted at practice-level at two moments, half-way through the evaluation period (December 2010) and near the end (September 2011). A list of quality indicators, including the steps and key elements of the intervention, was used as a guideline for these interviews. At the end of the evaluation period (from October until December 2011), four focus group interviews with healthcare professionals were conducted. They were organized separately for GPs, practice nurses, and allied healthcare professionals (occupational therapists and physical therapists). The semi-structured interviews with frail older people (n=13) were conducted half-way through the evaluation period (May and June 2011). Each practice nurse was asked to select several older people based on the following criteria: ability to do an interview (e.g. sufficient cognition and hearing capacity), recent contact with the practice nurse (< two months ago), received at least one part of the toolbox (see Table 2), seen by at least one other discipline than the practice nurse. A self-developed and pre-tested topic list was used as a guideline for the interviews. Table 3 shows an overview of how the components of the process evaluation were operationalised and measured.

### Data analysis

For the analysis of quantitative data, descriptive statistics (frequencies, means, and percentages) were calculated using software package SPSS for Windows, version 17.0. Qualitative methods were used for research questions that quantitative research cannot deal with. The focus group interviews and semi-structured interviews with older people were audio-taped and transcribed verbatim. To analyse qualitative data an integrated approach developed by Bradley and colleagues (1964) was applied.<sup>39</sup> This approach combines the principles of inductive reasoning using predetermined code types. A coding list, based on the theoretical components derived from

**Table 3** Summary of evaluation aspects and data collection methods

Theoretical element	Operationalisation	Measurement				
		PN	PN	PN, GP	PN, GP, OT, PT	Older people
		Logbook	Evaluation form	Interview	Focus group	Interview
Reach target group	<ul style="list-style-type: none"><li>- Extent of reaching frail older people</li><li>- # and reasons for refusals and drop-outs</li></ul>		X			
Dose delivered	<ul style="list-style-type: none"><li>- Extent of following steps of PoC</li><li>- # Contacts with practice nurse</li><li>- # Referrals to other professionals</li><li>- # Team meetings</li><li>- # Toolbox parts used</li><li>- # Evaluation/ follow-up meetings</li></ul>	X				
Fidelity	<ul style="list-style-type: none"><li>- Extent of applying core principles of PoC</li><li>- Interdisciplinary cooperation</li><li>- Tailor-made care and self-management support</li><li>- Meaningful activities</li></ul>			X	X	
Exposure (dose received)	<ul style="list-style-type: none"><li>- Ability to understand and implement principles of the intervention</li><li>- Adherence to commitments</li></ul>		X			
Satisfaction (dose received)	<ul style="list-style-type: none"><li>- Experiences in terms of benefits, burden, stimulating factors; recommendations</li></ul>			X	X	X
Barriers	<ul style="list-style-type: none"><li>- Barriers</li></ul>			X	X	X

PN=practice nurses, GP=general practitioner, OT=occupational therapist, PT=physiotherapist

PN=practice nurses, GP=general practitioner, OT=occupational therapist, PT=physiotherapist

Baranowski and Stables (2000), was used to code the collected data.<sup>16</sup> While all participating GPs and practice nurses were visited for a semi-structured interview, the amount of interviews with frail older people was established by applying the principal of theoretical saturation. This means that data saturation is reached, when no new insights are obtained, no new themes are identified, and no issues arise regarding a category of data.<sup>40</sup> Saturation of all categories signifies the point at which to end the research.<sup>41</sup> Through the coding process and constant comparison, theoretical saturation occurred after thirteen interviews. This choice can be considered as legitimate as there is some evidence in the literature that saturation often occurs within the first twelve interviews.<sup>42</sup> The use of both, semi-structured and focus group interviews, increased the richness and trustworthiness of qualitative data. Researcher triangulation was used to increase the credibility and validity of the results.<sup>43</sup> First, data were analysed independently by three members of the research group followed by a collaborative discussion about the data. Secondly, quantitative and qualitative data was integrated to confirm and cross-validate findings and resulted in an overall interpretation of the results (methods triangulation). The model of Baranowski and Stables (2000) was used as a structure to present the results.<sup>16</sup>

Results

Reach

On behalf of the six GP practices, 1,825 screening lists were sent to community-dwelling frail older people (≥70 years) (see Figure 1). The response rate was 81% (n=1,477). According to the (GFI score ≥5) the prevalence of frailty was 33% (n=444). Nearly half of the frail older people identified (44%, n=194) were interested in participation and being included in the study. Of these, 45% (n=87) were male and 46% (n=90) lived alone (versus living together, n=104). Most people (60%, n=117) had no or lower than average education (29%, n=56) or higher education (11%, n=21). The mean age of the sample was 77.7 years (sd=5.2) and the mean GFI score was 7.1 (sd=1.9).

After a multifactorial assessment, conducted by the practice nurse during a home visit, practice nurses and GPs concluded that 36 older people (19%) had no indication for/ no interest in care. These older people stopped with the PoC approach and received only the usual care if needed. They were significantly younger (p=0.02) than the rest of the sample (on average 75.9 vs. 78.2, respectively) and scored significantly better (p=0.00) on the GFI (on average 6.3 vs. 7.3, respectively). Furthermore, 29 out of 194 older people (15%) stopped earlier with the PoC approach, due to health-related problems such as a decline in health or long-term admission (n=13), a change-over to another GP practice (n=12) or for other reasons (n=4). They received usual care as well. These people were slightly older (p=0.56)

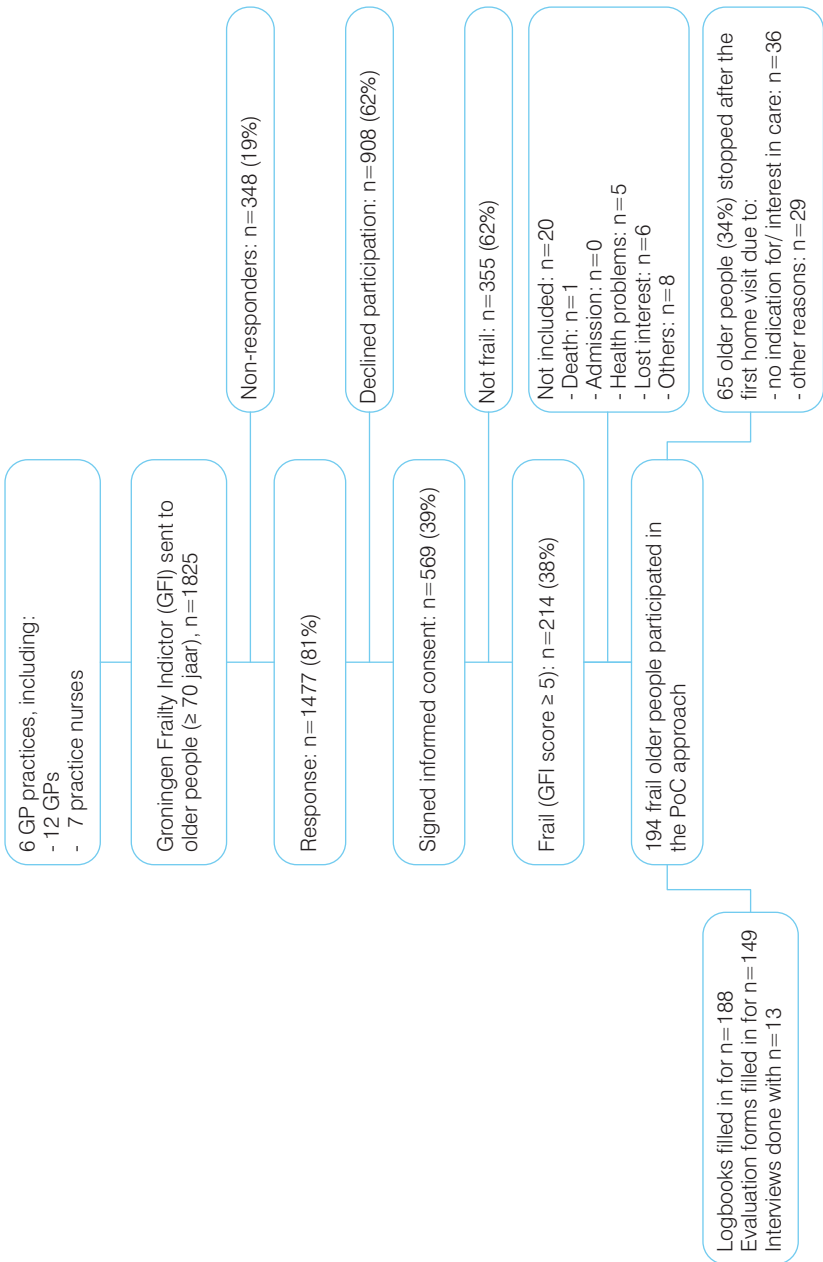


Figure 1 Flowchart process evaluation.

(on average 78.6 vs. 77.6, respectively) and significantly frailer ( $p=0.05$ ) (on average 7.7 vs. 7.0, respectively) than the rest of the sample.

The practice nurses filled in evaluation forms for 166 older people. For the analysis only complete evaluation forms were taken into account ( $n=149$ ). According to the practice nurses, 108 out of 149 older people (73%) were frail and the PoC approach was appropriate for 69% of the older people identified ( $n=102$ ).

### Dose delivered

Practice nurses filled in the logbook for 188 frail older people (six logbooks were missing). All frail older people received an extended assessment conducted by the practice nurse during a home visit, except for two individuals who died before the assessment could be arranged. Out of the 188 people, 82 (44%) were seen by their GP during the assessment phase. Referrals to an occupational therapist ( $n=36$ ), a physiotherapist ( $n=28$ ) or other disciplines ( $n=17$ ) such as nutritionist, pharmacist, speech therapist or geriatrician were less frequent. The amount of referrals ranged from zero ( $n=88$ ) to four ( $n=3$ ). Most of the older people ( $n=64$ ) were referred to one other discipline. The preliminary treatment plan was formulated by the practice nurse and GP ( $n=121$ ) in an extended team meeting ( $n=42$ ) or by the practice nurse alone ( $n=23$ ). Some frail older people were discussed in a later phase in a bilateral meeting between the practice nurse and GP ( $n=9$ ) and/ or in an extended team meeting in which other disciplines were involved as well ( $n=23$ ). In 52% of the cases, the practice nurse formulated a plan together with the frail older person (and if available the informal caregiver) during a second home visit. The use of the toolbox parts ranged from 14% (Social network & social activities) to 26% (Adapting environment, activities and skills). The number of toolbox parts received ranged from zero ( $n=89$ ) to four ( $n=5$ ). Some older people received one ( $n=38$ ) or two ( $n=39$ ) toolbox parts. Appointments for evaluation and follow-up were often (50%) made between practice nurses and frail older people. In addition, in some cases evaluation and follow-up was discussed between healthcare professionals (in a bilateral or team meeting), but this occurred less often. Some older people were seen for evaluation and follow-up by the practice nurse, but were also discussed in a bilateral and/ or in an extended team meeting. Table 4 presents the extent to which the PoC protocol was delivered (dose delivered).

### Fidelity

#### Interdisciplinary cooperation

One dominant topic during the semi-structured and focus group interviews was the substantial improvement of interdisciplinary cooperation. Before the implementation of the PoC approach, there was only occasionally contact between disciplines, mainly by telephone. According to all the healthcare professionals interviewed the

**Table 4** Dose delivered of interdisciplinary care approach 'Prevention of Care' ( $n=188$ )

Steps of Prevention of Care	n (%)	
Screening		
Send questionnaires	1,825	
Response	1,477	81%
Signed informed consent	569	39%
Frail according to GFI (≥5)	214	38%
Participated in PoC approach	194	91%
Assessment		
Practice nurse	186	99%
Additional assessment		
GP	82	44%
Occupational therapist	36	19%
Physiotherapist	28	15%
Other disciplines	17	9%
Analysis and preliminary treatment plan		
Practice nurse	23	12%
Bilateral meeting (practice nurse, GP)	121	64%
Extended team meeting (practice nurse, GP and others)	42	22%
Agreement on treatment plan		
Practice nurse	97	52%
Executing the treatment plan		
Use of toolbox parts		
- Meaningful activities	32	17%
- Adapting the environment, activities or skills	48	26%
- Social network & social activities	27	14%
- Daily physical activity	36	19%
- Stimulate health	41	22%
Other interventions	27	14%
Evaluation and follow-up		
Practice nurse and frail older person	94	50%
Bilateral meeting (practice nurse, GP)	35	19%
Extended team meeting (practice nurse, GP and others)	54	29%

frequency of contacts, by telephone, email and in person, increased substantially by applying the principles of the PoC approach. Furthermore, interdisciplinary team meetings took place to discuss the (preliminary) treatment plan. Whether meetings were executed according to protocol depended strongly on the chair of the meeting (usually the practice nurse, otherwise the GP). Due to the open communication in the team, all the healthcare professionals interviewed felt free to share their own expertise. Practice nurses and GPs reported that they learned particularly more about the expertise of occupational therapists resulting in a rise in referrals. In contrast, the physiotherapists involved seemed disappointed as they experienced less increase in referrals as expected.

The roles in the team were clearly defined according to the healthcare professionals interviewed. Overlapping tasks were minimised by formulating an integrated treatment plan, involving collaborative goals and specified tasks for each discipline. Sometimes, other healthcare professionals, such as a social worker, homecare provider or pharmacist, were also invited to the team meetings. The role of the practice nurse was considered important by all the healthcare professionals interviewed. The practice nurse was case manager and responsible for the coordination and organisation of care. Also, monitoring and follow-up of frail older people and their informal caregivers was one of the tasks of the practice nurse. Evaluation and follow-up occurred via home visits or telephone contacts.

### *Tailor-made care and self-management support*

All healthcare professionals interviewed reported that the PoC approach encouraged frail older people to think about their concerns and problems, their motivation and capabilities and their wishes for the future. The information was used to develop a preliminary treatment plan, including individual goals, strategies and responsibilities. The preliminary treatment plan was supposed to be discussed by the practice nurse with the frail older person (and informal caregivers if available) during a second home visit. The aim was to involve them in decision-making and to establish a cooperation, in which a learning process begins, leading to new insights and possibly to new goals and actions. However, some of the practice nurses interviewed reported that the treatment plan was often not discussed with the frail older person and some of these home visits were replaced by telephone contacts, which does not conform to the protocol.

Some of the healthcare professionals interviewed mentioned that they were not aware of applying the 5A's Behaviour Change Model<sup>31</sup>, but the semi-structured and focus group interviews indicated that healthcare professionals considered the frail older peoples' readiness to change in their counselling style, adapted information and advice to their individual needs and respected their decisions. Furthermore, the principles of Motivational Interviewing were applied, which is also part of the 5A's Behaviour Change Model.

### *Meaningful activities*

During the semi-structured and focus group interviews all the practice nurses interviewed reported that the concerns or problems of frail older people regarding the performance of meaningful activities were assessed during the assessment phase. According to the healthcare professionals interviewed, an integrated treatment plan was developed to fit the individual needs and preferences of older people.

### *Exposure*

Based on the complete evaluation forms (n=149) filled in by practice nurses, 76% (n=113) of the older people included understood the goal and the procedure of the PoC approach. Their adherence regarding the commitments made with the practice nurse was assessed as (very) good for 72 older people (48%), sufficient for 46 people (31%) and poor for 20 people (13%). For 11 people (7%) this question was not applicable, as no commitments were made.

### *Satisfaction and barriers experienced by healthcare professionals*

#### *Benefits*

According to all the healthcare professionals interviewed, the PoC approach provided a useful structure for the delivery of geriatric primary care and increased the attention to preventive treatment of frail older people. One of the greatest benefits of the approach was the improvement of interdisciplinary cooperation. Sharing information during the team meetings led towards a better understanding of concerns, problems and wishes of frail older people. The information acquired was relevant for the delivery of tailor-made care. Healthcare professionals also learned much about each other's expertise, which led to more consultations of involved healthcare professionals and more frequent referrals (occupational therapy). The clearly defined roles and tasks led to more efficient healthcare delivery. The possibility of expanding the team with other healthcare professionals was also appreciated by those interviewed.

#### *Burden*

Despite their usefulness, team meetings were experienced as time-consuming and sometimes difficult to organise and required good organisation. Before the PoC approach, healthcare professionals were used to act immediately after identifying a problem. According to the PoC protocol, healthcare professionals had to finish the assessment phase first, resulting in a collaborative treatment plan. Before they could start the treatment, the frail older person had to agree on this plan. This change in the culture of healthcare delivery was initially difficult for healthcare professionals, but after a while they recognised the added value of formulating a collaborative treatment plan.

### *Stimulating factors*

In general, the PoC protocol provided a useful structure and tools for integrated community-based care of frail older people. According to all the healthcare professionals, the implementation of the protocol depended strongly on the professional skills of the practice nurse. GPs and allied professionals mentioned that an empathic capacity of the practice nurse and good organisation and communication skills had positive effects on the implementation of the PoC approach, while a lack of education, experience and capacities was considered as a barrier. Practice nurses reported that frail older people expressed much gratitude for the attention they received, which gave them a feeling of work fulfilment.

### *Barriers and recommendations*

During the semi-structured and focus group interviews, doubts about the screening method were expressed by all practice nurses and GPs interviewed. In their opinion, the screening method worked insufficiently in identifying the appropriate target group for the PoC approach. On the one hand, the health status of some older people was too poor to participate. On the other hand, some older people were considered to be not (yet) frail. Practice nurses and GPs recommended a higher cut-off score on the Groningen Frailty Indicator<sup>22</sup> or at least a cut-off score that is less sensitive to psychosocial problems. In their opinion, frail older people with a low score on the Groningen Frailty Indicator (GFI=5) often suffer from psychosocial problems, but have no indication for care. Practice nurses and GPs also indicated during the interviews that some frail older people might have been missed by the chosen screenings approach due to non-response or the exclusion criteria. They thought that case-finding based on the judgement of the practice nurse and GP would enable the identification of a more appropriate target group.

Some parts of the PoC protocol were time-consuming (e.g. assessment, team meetings) or difficult to apply (e.g. toolbox). The toolbox provided healthcare professionals with guidelines for assessment and treatment organised by different topics, but they did not know how to put these guidelines into practice. Also, how to use the theoretical models such as the 5A's Behaviour Change Model<sup>31</sup> remained unclear to them. According to the healthcare professionals interviewed, barriers to implementing the protocol were due to an overload of information during the training activities and a lack of training on the job. They recommended more supervision and opportunities to exchange experiences with other healthcare professionals. Furthermore, a digitalisation of forms was recommended by practice nurses and GPs to avoid double registration and to facilitate an exchange of data with other disciplines.

### *Satisfaction and barriers experienced by frail older people*

#### *Benefits*

Frail older people reported in the interviews that they greatly appreciate their independence. They prefer to take their own decisions and to find solutions by themselves. These norms and values fit the self-management character of the PoC approach. Frail older people saw one of the greatest benefits of the PoC approach in becoming aware of their needs and (potential) problems. Healthcare professionals listened carefully and spent much attention to the topics introduced by the frail older person. Frail older people felt acknowledged by healthcare professionals and experienced support in fulfilling their needs and handling their problems. A good relationship with the healthcare professionals involved was perceived as a safety net with regard to future problems.

#### *Burden*

There were hardly any burden mentioned by frail older people, except for the intensity and complexity of the PoC approach. For a few older people, participation was too time-consuming. Others experienced difficulties in distinguishing the disciplines involved.

#### *Stimulating factors*

In general, frail older people did not have many expectations regarding participation, but felt that there was no harm in trying it. Some frail older people expected to find a solution for their problems. The fact that the invitation to participate was sent by their GP enhanced their willingness to participate. For most of them, the GP is still an important and respected person and his or her advice was followed most of the time. A few older people mentioned that they were no longer used to get so much attention from their GP and they appreciated their initiative very much.

#### *Barriers and recommendations*

Frail older people did not experience specific barriers to the PoC approach. However, they made the general recommendation that older people want to be taken seriously by healthcare professionals. Furthermore, healthcare professionals should consider that older people often struggle with irreversible losses such as the death of a dear person, which may result in frustration, loss of motivation and neglect of advice regarding care in general.



## Discussion

The aim of the process evaluation was to provide insight into the extent to which the interdisciplinary care approach PoC is implemented as planned. Furthermore, healthcare professionals' and frail older people's experiences regarding its feasibility were evaluated. From the perspective of the healthcare professionals, the PoC approach provided a useful structure for the delivery of geriatric primary care and increased the attention to preventive treatment. Frail older people were satisfied, as they felt acknowledged by healthcare professionals and experienced support in handling their problems and fulfilling their needs. While frail older people experienced hardly any burden or barriers regarding the PoC approach, healthcare professionals made several recommendations for its improvement.

Firstly, they experienced barriers regarding the screening approach and recommended either a higher cut-off score on the Groningen Frailty Indicator or a case-finding approach based on the clinical judgement of the practice nurse and the GP. According to the literature, clinical judgement in itself seems insufficient to identify frail older people.<sup>44</sup> Frailty can be easily overlooked by GPs, who are used to focus on specific medical diseases, whereas frailty is multidimensional in nature and results from a complex interplay of physical, psychological, social, and environmental factors. In addition, it is not feasible given the large populations, which have to be screened. Therefore a two-step approach consisting of a short screening integrated in the daily practice of the GP as the first step, and a more complex assessment as the second is assumed to be most promising.<sup>44</sup> Such a two-step approach is included in the PoC approach, but the screening method for frailty (step 1) needs some improvement regarding its specificity.<sup>45</sup> Secondly, some parts of the PoC protocol were (initially) time-consuming or difficult to apply (e.g. interdisciplinary team meetings, toolbox, 5A's Behaviour Change Model). Healthcare professionals recommended more training on the job and opportunities to exchange experiences with each other. How to improve the training with regard to the implementation of the PoC approach in daily practice needs special attention.

The evaluation of the logbooks showed that some parts of the PoC protocol were insufficiently executed. Firstly, the problem analysis and the development of a preliminary treatment plan was often not done in a bilateral or an extended team meeting (step 3) and only half of the treatment plans were discussed with the frail older person (step 4). Secondly, the toolbox parts were not frequently used in the treatment of frail older people (step 5). Thirdly, the extent of evaluation and follow-up, especially among the healthcare professionals, was limited (step 6). With regard to behavioural change, discussion of the treatment plan in the interdisciplinary team and between healthcare professionals and frail older people (step 3 and 4) is essential to reach collaborative agreement about treatment goals. Furthermore, regular follow-up

and feedback is important for behavioural change.<sup>46</sup> Continuous collaboration, from the assessment (step 2) until evaluation and follow-up (step 6), is also an important element in patient-centred interdisciplinary care. It recognises and values the expertise and perspectives of a variety of different healthcare professionals and enables a partnership between the healthcare professionals involved and the patient in decision-making.<sup>29</sup>

It is well-known that a gap exists between research and the translation of findings into practice, especially in the field of preventive and behavioral change interventions. Glasgow and Emmons (2007) focus on four categories of barriers.<sup>47</sup> These include characteristics of (a) the intervention, (b) the target settings, (c) the research or evaluation design, and (d) interactions among the first three categories. With regard to intervention characteristics (a) it may be assumed that PoC particularly required too much time and expertise from healthcare professionals. Furthermore, some parts of the protocol may be not packaged or 'manualised' enough to provide the care according to the protocol principals. The primary care setting (b) may also have had an impact on the extent of implementing the PoC approach. For example the structures of a predominantly reactive healthcare system in the Netherlands<sup>48</sup> may work against a proactive approach in community-dwelling frail older people. Barriers regarding the research design (c) may be that the target group was not adequately identified. As we discussed earlier, some older people were not (yet) frail. More research should be done into the complexity and context of an intervention to increase the success of implementation into daily practice.<sup>47</sup>

Interdisciplinary collaboration is one of the core principles of the PoC approach and the healthcare professionals reported improved collaboration, but the limited extent of discussing and evaluating the treatment plan and using the toolbox parts is not in line with this finding. This may be explained by the structure of the healthcare system, in which most decisions regarding care are taken by the GP or practice nurse.<sup>29</sup> It seems questionable, whether always the right decisions were made with regard to the involvement of other healthcare professionals. When implementing interdisciplinary care, the cultural change of professionals' attitudes and organisational structures need to be considered further.<sup>29</sup> Furthermore, factors related to team structure (e.g. team size and composition, organisational support) or team processes (e.g. goal setting, regular team meetings) may work as barriers or facilitators. More attention should be paid to these factors to reach effective and efficient interdisciplinary collaboration.<sup>49</sup>

The semi-structured and focus group interviews with healthcare professionals and frail older people gave some indication that engagement in meaningful activities, another core principle of the PoC approach, is insufficiently applied in healthcare delivery. They reported that meaningful activities were part of the assessment and treatment, but most of the time they talked about existing problems in performing



daily activities and risk factors for developing disability instead of enhancing meaningful activities. Although frail older people suffer from a combination of physical, social and psychological losses the focus of care should be on their capacity to maintain quality of life instead of eliminating specific diseases or complaints.<sup>50</sup> Maybe healthcare professionals undervalue the importance of meaningful activities, because of their 'everyday' nature, and the assumption that the desire to engage in activity is an in-built physiological mechanism that drives and satisfies people to meet basic needs and develop potential.<sup>51</sup> Furthermore, the term 'meaningful activities' is an inherently difficult construct to define and assess, although it is rather important for healthcare professionals for the development of interventions.<sup>52</sup> In future, more attention has to be paid to the identification of and participation in meaningful activities, as they contribute strongly to the sense of purpose and fulfilment in life, with significant implications for health, well-being and aging successfully.<sup>53</sup>

This process evaluation has some limitations. Firstly, previous studies have shown that healthcare professionals have difficulties in reflecting adequately on their functioning, as they perceive themselves as performing better than they actually do, maybe due to a lack of awareness of their own behaviour or socially desirable answers.<sup>54,55</sup> The current study also shows some conflicting results. Healthcare professionals involved were very positive about the implementation of the PoC approach during the semi-structured and focus group interviews. However, the logbooks showed that not all the steps of the PoC approach were applied. Video- or audiotaping would have been useful to add to the data collection methods to provide more valid information about the actual performance of healthcare professionals. Secondly, frail older people participating in the semi-structured interviews were selected by practice nurses. These frail older people may not be representative, as there is a risk that only 'success cases' were selected for the interviews. Selection bias may also have played a role in the focus groups with the healthcare professionals, as their participation was not mandatory and possibly only the most motivated and satisfied professionals joined the group. However, this study has some strengths as well. One of these is the use of a theoretical framework<sup>15-17</sup> for the design of the process evaluation and the data collection and analysis. Thirdly, the use of a mixed methods approach, combining quantitative and qualitative data collection methods, improves the quality of the study. Both methods have their strengths and limitations; consequently an integration of different methods provides better findings than either a quantitative or qualitative approach alone.<sup>43</sup>

The PoC approach is very complex in nature, as it combines a number of relatively new elements in geriatric primary care. The more complex an intervention is, the more difficult its implementation in clinical practice may be. Even if healthcare professionals are aware of the need to change and willing to do so, it is difficult to

modify well-established patterns of care, especially if the clinical environment is not conducive to change. Barriers can arise at the level of the patient, the individual professional, the healthcare team, the healthcare organisation, or the wider environment.<sup>56</sup> Consequently, more research into the implementation of the PoC approach is needed, especially with regard to client-centred interdisciplinary care, behavioural change and engagement in meaningful activities.

## Conclusion

To prevent disability in community-dwelling frail older people, complex interventions conducted by an interdisciplinary primary care team are needed, involving individualised assessment, tailor-made interventions and long-term follow-up. With regard to integrated care, nurses are recommended as case managers to plan, organise and monitor the care process and to facilitate cooperation between professionals. The PoC approach is appreciated by healthcare professionals and frail older people and provides a useful structure for the delivery of geriatric primary care. However, given its complexity, the implementation of the protocol needs special attention, especially with regard to client-centred interdisciplinary care, behavioural change and engagement in meaningful activities.

## Acknowledgements

The authors would like to thank participating older people and healthcare professionals, the members of the research group: Walther Sipers (Orbis Medical Centre) Lilo Crasborn (MCC Omnes), Simone Denis (MCC Omnes), Marlou Wolters (MCC Omnes), Jill Bindels (Maastricht University) and their research assistants: Floor Koomen, Ine Hesdahl and Astrid Dello. This research is funded by the Dutch National Care for the Elderly Programme by The Netherlands Organisation for Health Research and Development (ZonMw 311070301), The Hague, the Netherlands.

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## **Effectiveness of an interdisciplinary primary care approach to reduce disability in community-dwelling frail older people: a cluster randomised controlled trial**

**This chapter was published as:**

Metzelthin, SF, van Rossum, E, de Witte, LP, Ambergen, AW, Hobma, SO,  
Sipers, W, Kempen, GIJM  
British Medical Journal 2013;347:f5264

## Abstract

**Objective:** To evaluate whether an interdisciplinary primary care approach for community-dwelling frail older people is more effective than usual care in reducing disability and preventing (further) functional decline.

**Design:** Cluster randomised controlled trial.

**Setting:** Twelve general practices in the south of the Netherlands

**Participants:** 346 frail older people (score  $\geq 5$  on Groningen Frailty Indicator) were included; 270 (78%) completed the study.

**Interventions:** General practices were randomised to the intervention or control group. Practices in the control group delivered care as usual. Practices in the intervention group implemented the 'Prevention of Care' (PoC) approach, in which frail older people received a multidimensional assessment and interdisciplinary care based on a tailor-made treatment plan and regular evaluation and follow-up.

**Main outcome measures:** The primary outcome was disability, assessed at 24 months by means of the Groningen Activity Restriction Scale. Secondary outcomes were depressive symptomatology, social support interactions, fear of falling, and social participation. Outcomes were measured at baseline and at 6, 12, and 24 months' follow-up.

**Results:** 193 older people in the intervention group (six practices) received the PoC approach; 153 older people in the control group (six practices) received care as usual. Follow-up rates for patients were 91% (n=316) at six months, 86% (n=298) at 12 months, and 78% (n=270) at 24 months. Mixed model multilevel analyses showed no significant differences between the two groups with regard to disability (primary outcome) and secondary outcomes. Pre-planned subgroup analyses confirmed these results.

**Conclusions:** This study found no evidence for the effectiveness of the PoC approach. The study contributes to the emerging body of evidence that community-based care in frail older people is a challenging task. More research in this field is needed.

**Trial registration:** Current Controlled Trials ISRCTN31954692.

## Introduction

In our ageing society the care for older people is one of the greatest challenges in healthcare.<sup>1,2</sup> Evidence suggests that community-based care in comparison with institutionalisation may achieve better outcomes at lower costs and is also preferred by older people themselves.<sup>3,4</sup> Consequently, an increasing demand exists for innovative initiatives to provide cost-effective community-based care.<sup>5,6</sup> In most Western countries, such as the United Kingdom (UK) and the Netherlands, general practitioners (GPs) have a central position in the provision of community care, as they are gatekeepers to specialised and hospital care.<sup>7</sup> In the UK, GPs are required since 1990 to offer an annual multidimensional assessment to their patients aged 75 years and over.<sup>8</sup> In addition, GPs geographical proximity to older people and their intense and long-lasting relationship with their patients may contribute to effective care in older people.<sup>7</sup> However, community-based care in frail older people is challenging. Frail older people have multiple and complex health care needs, which often lead to disability.<sup>9-11</sup> Disability is defined as difficulty or dependency in the execution of daily activities that are essential for independent living.<sup>9</sup> As disability is considered a dynamic process, older people can recover to a less or non-disabled state.<sup>12</sup> Regardless, preventive actions have to be taken to improve the abilities of frail older people to remain at home as long as possible.<sup>13</sup>

Daniëls and colleagues<sup>14</sup> did a narrative review to provide an extensive overview of existing interventions for prevention of disability in community-dwelling frail older people. The identified interventions, most of which were in the field of comprehensive geriatric assessment and physical exercise programmes, showed a large diversity in terms of content, disciplines involved, duration, intensity and setting. Only a small number have shown beneficial effects with regard to disability, and most studies did not report on any long-term effects.<sup>14</sup> On the basis of this review, the authors suggested that community-based care interventions for frail older people should be conducted by an interdisciplinary primary care team involving individualised assessments and interventions (tailor-made care), self-management support, engagement in meaningful activities, case management and long-term follow-up. In an effort to reduce disability and preventing (further) functional decline in community-dwelling frail older people, in the present study these elements were combined into one approach: the 'Prevention of Care' (PoC) approach. This approach focuses on both older people with an increased risk for developing disability and older people who are already disabled.<sup>15</sup> A previous pilot study (n=41) using the PoC approach has shown promising results.<sup>15</sup> Older people appreciated the attention they got and felt supported in reaching their goals and in handling future disability. Healthcare professionals reported that the approach provided a useful structure for geriatric primary care. In addition, the approach stimulated interdisciplinary collaboration, a

focus on meaningful activities and self-management support.<sup>15</sup> However, the effectiveness with regard to disability and various related outcomes has not yet been studied. Consequently, we conducted this trial to investigate the effectiveness of the PoC approach on various patient level outcomes compared with usual care.<sup>16</sup> We chose a cluster randomised design for practical reasons and to avoid contamination bias.<sup>17</sup>

## Methods

### Study design

We did a two-arm cluster randomised controlled trial among twelve GP practices in the south of the Netherlands. Before the screening procedure for identifying frail older people started, we randomly allocated six practices to the PoC approach and six practices continued care as usual. Before randomisation, the GP practices were pre-stratified into four strata based on the number of older patients (<350 patients versus  $\geq 350$  patients) and location (urban versus rural area). We assumed that GPs working in a practice with a large number of older patients have more experience with geriatric care and that older people living in a rural area receive more support from the informal care system than do those living in an urban area. We stratified the practices in pairs and used a computer generated randomisation list to randomise them into either intervention or control group. To promote extrapolation of the results, practices in an urban area with a large number of older people had twice the chance of being included in the study than practices in the other three strata. The cluster randomised controlled trial was performed as planned. More details of the study design have been published elsewhere.<sup>16</sup>

### Participants

We invited all GP practices in the region of Sittard (the Netherlands) and its surrounding area that had no current active and systematic policy for the detection and follow-up of frail older people to take part in the study. In total, 24 GP practices were interested, of which we randomly selected twelve for the study on the basis of a computer generated list of numbers. The study focused on their community-dwelling frail older patients ( $\geq 70$  years). Those who were terminally ill, were confined to bed, had severe cognitive or psychological impairments or were unable to communicate in Dutch were excluded based on the advice of the GP. The remaining other older people ( $n=3,498$ ) in the twelve practices received a postal questionnaire, including the Groningen Frailty Indicator (GFI).<sup>18</sup> In the literature, a score of four or higher (range 0-15) is proposed as the cut-off point for moderately to severely frail older people.<sup>18</sup> However, this study focused on people who were considerably frail, ranging from

people who have an increased risk for developing disability to disabled older people. Therefore, older people who signed the informed consent form and had a GFI score of five or higher were included in the study. For practical reasons, the recruitment of frail older people took place in three cycles. The first cycle started in December 2009, the second in February 2010 and the third in March 2010. The intervention and the collection of data also took place in three cycles. All included older people gave written informed consent prior to collection of the baseline measure. This study was approved by the Medical Ethical Committee of the Maastricht University/ Academic Hospital Maastricht in the Netherlands in 2009 (MEC 09-3-067).

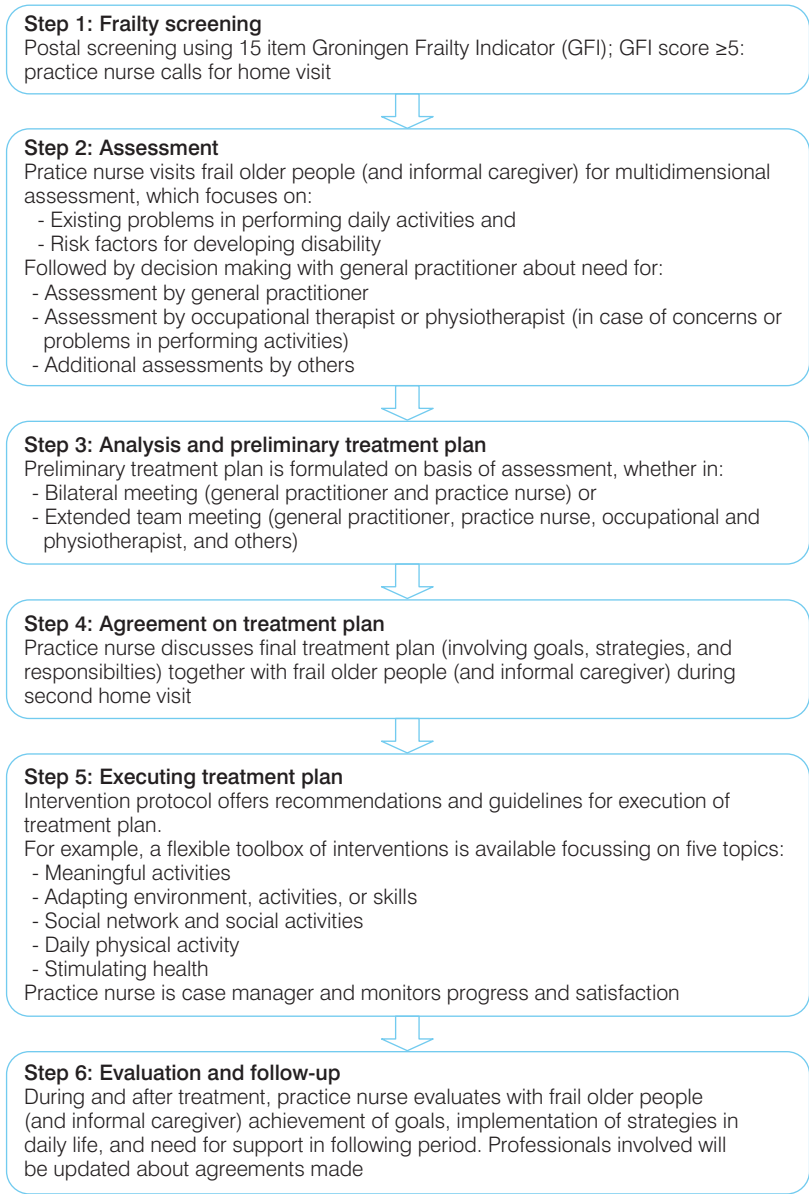
### Intervention

In the intervention group (six GP practices) frail older people received the PoC approach. The GP and practice nurse built the core team of the interdisciplinary care approach. In 2001 the profession of practice nurses was introduced in the Netherlands to reduce the workload of Dutch GPs who are the gatekeeper to specialised and hospital care.<sup>19</sup> Practice nurses often work, under supervision of the GP, on disease prevention, chronic care management, mental health services, assessments among frail older people, and care of families with young children.<sup>20</sup> Within the PoC approach the GP and his practice nurse cooperate closely with occupational and physiotherapists. If needed, other inpatient and outpatient healthcare professionals, for example, a pharmacist or a geriatrician are involved as well.

The PoC approach aims to reduce disability and prevent (further) functional decline using a six step approach (Figure 1).<sup>21</sup> After the postal screening for frailty using the GFI (step 1), frail older people and their informal caregiver, if available, receive a home visit by the practice nurse who does a multidimensional assessment focusing on existing problems in performing daily activities and on risk factors for disability (step 2). The focus is on activities, which are meaningful to the older person. Examples of meaningful activities are gardening, visiting family/ friends, reading a book, taking a walk, playing games or joining religious activities. After the home visit, the GP and practice nurse discuss whether additional assessments by other inpatient or outpatient healthcare professionals are needed. On the basis of the assessment phase, a preliminary treatment plan is formulated (step 3), either in a bilateral meeting (GP and practice nurse) or in an extended team meeting consisting of a GP, practice nurse, occupational and physiotherapist and, if necessary, other healthcare professionals.

During a second home visit by the practice nurse (step 4), a final treatment plan is formulated, including a list of goals, strategies and actions that meet the older person's needs. Depending on the self-management skills and preferences of the older person, strategies and actions are either focused on the older person or more on (support of) the social and physical environment. On the basis of the 5A's





**Figure 1** Six steps of the 'Prevention of Care' (PoC) approach.

Behavioural Change Model<sup>22</sup> and motivational interviewing techniques<sup>23</sup> the practice nurse encourages active involvement in decision-making and establishes cooperative working relationship with the frail older person and the informal caregiver. Subsequently, the treatment starts (step 5). The intervention protocol offers recommendations and guidelines for the execution of the treatment plan. For example, a toolbox of interventions is available that focuses on five topics: 'enhancing meaningful activities', 'daily physical activity', 'social network and social activities', 'adapting the environment, activities or skills' and 'stimulating health'. The practice nurse is also the case manager and, along with the frail older person and the informal caregiver, regularly evaluates the achievement of goals, the implementation of strategies in daily life and the need for support in the following period (step 6). The professionals involved are updated about the progress and the agreements made. The remaining six practices (control

**Case summary**

AK is a 75 year old woman living independently in a small flat. She has four children, who live in the same city. Her husband has been living in a nursing home for two years.

AK received a letter from her general practitioner, who asked her to fill in the Groningen Frailty Indicator (step 1). She had a total frailty score of 7, and the practice nurse called her to offer a home visit for a multidimensional assessment (step 2). The assessment focused on existing problems in performing daily activities and risk factors for developing disability. The practice nurse also discussed with AK her individual needs and goals and her motivation to make changes in her life. AK's most important goal was to stay independently in her home. She experienced problems with cooking, shopping, and visiting her husband in the nursing home. The last of these was particularly meaningful to her. She often felt exhausted and suffered from fear of falling. In addition, memory deficits affected her participation in daily life. Her chronic diseases (diabetes and heart failure) were under control.

After the home visit, the practice nurse discussed the results of the assessment with the general practitioner and decided to refer AK to a geriatrician for further cognitive assessment. In addition, they agreed that involving an occupational therapist and physiotherapist would also be useful, as AK had problems with daily activities. An interdisciplinary team meeting, consisting of the general practitioner, practice nurse, occupational therapist, and physiotherapist took place to formulate a preliminary treatment plan based on the results of the assessment (step 3). The assessment of the geriatrician showed no signs of dementia. Regarding her fear of falling, the team assumed that AK needed

to change her attitudes and self-efficacy beliefs with regard to falling, leading towards improved participation in daily activities such as shopping and visiting her husband. An increase in physical activity was supposed to positively affect her fear of falling as well. In addition, simple strategies and a few helping aids were discussed to help AK with cooking and handling her memory deficits.

After the team meeting, the practice nurse visited AK again to finalise the treatment plan (step 4). Which toolbox parts could be used was also discussed. For the treatment of AK the toolboxes “adapting the environment, activities, or skills” and “daily physical activity” were chosen (step 5). During the treatment, the practice nurse visited AK four times to evaluate the achievement of goals and the implementation of strategies in daily life (step 6). Four months later, during the last visit, AK reported that she had fewer problems with cooking and visiting her husband. She had increased her physical activity in daily life and had less fear of falling. However, the strategies learnt for handling her memory deficits were still difficult to apply in daily life. A few helping aids and a stool placed in the kitchen helped her to cook more efficiently. The practice nurse will visit AK every six months to follow-up with her.

group) continued to deliver care as usual. The box illustrates how the approach works.

### Measurements

We measured data for the effectiveness analysis at the level of the patient at baseline and after 6, 12 and 24 months by using postal questionnaires and telephone interviews. Whereas older people and healthcare professionals were aware of the allocated arm (intervention or control), outcome assessors were kept blinded to the allocation.

### Outcome measures

We measured the primary outcome, disability, at 24 months by means of the Groningen Activity Restriction Scale (GARS).<sup>24</sup> This is an easy to administer, comprehensive, reliable, hierarchical and valid measure for assessing disability in older people. It consists of two subscales. The first subscale is about activities of daily living (ADL) (eleven items), and the second subscale relates to instrumental activities of daily living (IADL) (seven items). The scores for the total scale range from 18 to 72 with higher scores indicating more disability.<sup>24</sup> As disability is strongly related to psychological and social functioning,<sup>25</sup> we chose depressive symptomatology (depression subscale Hospital Anxiety and Depression Scale),<sup>26</sup> social support

interactions (Social Support List-Interaction version),<sup>27</sup> fear of falling (Short Falls Efficacy Scale-International)<sup>28</sup> and social participation (Maastricht Social Participation Profile, subscale A)<sup>29</sup> as secondary outcomes. In addition, we used the Pearlin Mastery Scale to determine the feelings of competence and control in older people,<sup>30</sup> feelings crucial for self-management and coping,<sup>31</sup> which belong to the important underlying mechanisms of the PoC approach.

### Statistical analysis

We used descriptive techniques to describe the study groups. We compared baseline variables to detect differences between the intervention and control group at the start of the study. Because of the cluster randomised design of the study including three levels (GP practices, participants and repeated measurements), we applied a mixed model multi-level analysis. We analysed the primary and secondary outcomes, measured on the level of the patient, according to the intention to treat principle. We imputed missing values on the level of the scale by means of multiple imputations. We based the maximum number of missing values within a scale on the guidelines given by the developers. If no guidelines were available, we accepted a limit of 25% missing values. Multi-level analyses are quite robust against missing values on measurement level. Therefore, we needed at least the baseline measurement and one out of three follow-up measurements to include older people in the analyses. For all analyses, we used a standard model including six independent variables. We corrected outcome estimates of the multilevel analyses for age, sex, educational level, significant differences at baseline (frailty and disability) and the baseline status of the outcome variable (in case of secondary outcomes) by including these variables as covariates in each model. We obtained insight into the effectiveness of the PoC approach in comparison with usual care at various follow-up times by examining fixed effects for group by time interaction. We evaluated the trend in time by removing the interaction term (group by time) from the model and testing only fixed effects for group and time. In a few imputed data sets, variance of GP practice iterated to zero. Consequently, we have examined in a basic model of disability, including only baseline status of disability as a covariate, whether GP practices had an impact on outcomes. The analyses of the basic model with and without GP practice as random effect have shown that results were highly similar for the two analyses. Therefore, we decided to exclude GP practice as an extra level.

We did several subgroup analyses. Firstly, we divided older people in the intervention group into two subgroups on the basis of their exposure to the PoC approach. We compared older people who received only assessment(s) (exposure group low) with those who received interventions, follow-up visits, or both (exposure group high). We tested fixed effects for exposure group by time interactions for significance. In addition, we did pre-planned subgroup analyses for the potential

effect modifiers baseline status of frailty and mastery.<sup>16</sup> We created two groups for each effect modifier based on the median scores: low frailty (GFI score 5-6) versus high frailty (score 7-14) and low mastery (PMS score 23-32) versus high mastery (score 10-22). Again we tested fixed effects for effect modifier by group interactions for significance.

The sample size calculation was based on our primary outcome (disability). On the basis of a power of 80% and an alpha of 0.05 (two-tailed testing), and an expected treatment difference of at least 2.0 points on the GARS,<sup>24</sup> the required sample size was n=80 per group (N=160 in total). Accounting for a drop-out rate of 30% and a cluster effect of 1.73 (ICC=0.05),<sup>16</sup> assuming equal cluster sizes, the final sample size had to be 180 per group (360 in total).<sup>16</sup> We used software package SPSS for Windows, version 20.0, for all statistical analyses.

Results

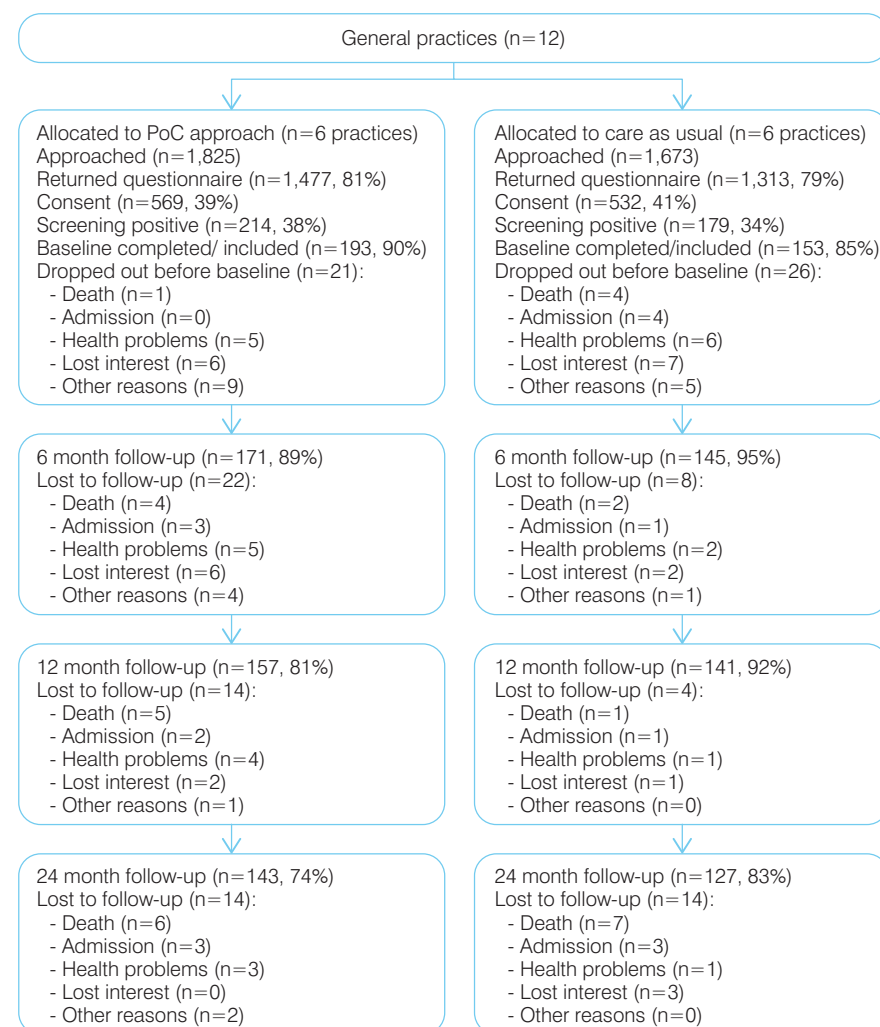
We allocated twelve GP practices at random to the control (six practices) or intervention group (six practices). Half of the practices had less than 350 patients and half of them had at least 350 patients. In addition, six practices were located in an urban area and six in a rural area. These cluster characteristics were equally distributed among the groups. As shown in Figure 2, 3,498 community-dwelling older patients (≥70years) of the twelve practices received the screening questionnaire. The response rate was 80% (n=2,790). Non-responders were significantly younger than responders (mean age 76.75 years vs. 77.62 years, p<0.05) and slightly non-responders were male (42.9% vs. 39.1%, p=0.07). Older people who completed the questionnaire and were willing to participate in the study (n=1,101) were significantly frailer than respondents who completed the questionnaire but declined participation (n=1,634) (mean score on GFI 3.64 vs. 2.96, p<0.05). Several participants declined participation and the questionnaire was not (completely) filled in (n=55), thus, we were not able to obtain GFI scores and have no information about the level of frailty. Of the older people who were willing to participate, 34% (n=179) in the control group and 38% (n=214) in the intervention group were frail according to their frailty score (GFI≥5). Of the 393 older people who were eligible for the study (frail and written informed consent) 47 older people were not included in the study, as they had not completed the baseline measurement (Figure 2). Finally, 346 older people were included in the study; 193 (56%) of whom received the PoC approach. The mean age of participants was 77.2 years (SD=5.1), 58% (n=199) were female, 49% (n=170) were living alone and 58% (n=202) had a low level of education.

**Table 1** Baseline characteristics of participants in control group and intervention group. Values are numbers (percentages) unless stated otherwise

Characteristics	Control (n=153)	Intervention (n=193)
Mean (SD) age (years)	76.80 (4.92)	77.49 (5.28)
Female sex	93 (61)	106 (55)
Living alone	80 (52)	90 (47)
Low education	94 (61)	108 (56)
<i>Mean (SD) scores:</i>		
GARS total	30.58* (10.62)	33.09* (11.52)
GARS ADL scale	16.54* (5.35)	17.97* (6.14)
GARS IADL scale	14.03 (5.86)	15.12 (5.96)
MSPP-CP-D	1.90 (1.63)	1.63 (1.48)
MSPP-CP-F	0.46 (0.44)	0.36 (0.35)
MSPP-FSP-D	0.73 (0.88)	0.61 0.84
MSPP-FSP-F	0.45 (0.63)	0.38 (0.55)
Short FES-I	12.38 (4.72)	13.24 (5.39)
HADS-D	6.69 (4.35)	6.54 (3.77)
SSL-I12	27.46 (6.06)	27.17 (6.30)
GFI	6.72* (1.71)	7.13* (1.89)
PMS	21.41 (4.25)	21.97 (4.01)

GARS=Groningen Activity Restriction Scale (range total scale 18-72, range activities of daily living (ADL) scale 11-44, range instrumental ADL (IADL) scale 7-28; higher scores indicate more disability); MSPP=Maastricht Social Participation Profile; MSPP-CP-D=MSPP consumptive participation, diversity score (range 0-7; higher score indicates more diverse consumptive participation); MSPP-CP-F=MSPP consumptive participation, frequency score (range 0-3; higher score indicates more frequent consumptive participation); MSPP-FSP-D=MSPP formal social participation, diversity score (range 0-7; higher score indicates more diverse formal social participation); MSPP-FSP-F=MSPP formal social participation, frequency score (range 0-3; higher score indicates more frequent formal social participation); Short FES-I=Short Falls Efficacy Scale-International (range 7-28; higher score indicates more fear of falling); HADS-D=Hospital Anxiety and Depression Scale-depression subscale (range 0-21, higher score indicates more depressive); SSL-I12=Social Support List-Interaction version (range 12-48; higher score indicates more social support); GFI=Groningen Frailty Indicator (range 0-15; higher score indicates more severe frailty); PMS=Pearlin Mastery Scale (higher score indicates less own control).

\*Significant differences: P<0.05.



**Figure 2** Flow of participants through trial.

PoC=Prevention of Care approach.

We found significant differences between intervention and control group participants with regard to frailty (GFI) and disability (GARS) scores. The intervention group participants were significantly frailer (GFI score 7.13 vs. 6.72,  $p<0.05$ ) and more disabled (GARS score 33.09 vs. 30.58,  $p<0.05$ ). All other characteristics were similar between the groups at baseline (Table 1). In total, 76 older people were lost to follow-up during the trial, significantly more people in the intervention group (26% vs. 17%,  $p<0.05$ ).

### Primary outcome

All twelve clusters, consisting of 310 frail older people with a baseline disability score and at least one out of three follow-up measurements, were included in the mixed model multilevel analyses. With regard to disability, we identified no significant difference between control and intervention group at 24 months follow-up. We found no significant group by time interaction effects for the total GARS scores and for the ADL and IADL subscale scores. After removing the interaction term from the model, we tested the trend for time. Both groups increased significantly ( $p<0.05$ ) in disability over a period of 24 months, but no significant differences between the groups with respect to their increase existed. Table 2 gives a summary of these results.

### Secondary outcomes

Table 3 shows the results on the secondary outcomes. Again, we found no significant group by time interaction effects of the intervention group on any of these outcomes.

### Subgroup analyses

The fixed effects for exposure groups (low versus high) by time interactions were not significant ( $p<0.05$ ). We found no significant ( $p<0.05$ ) mediating effects for a higher level of mastery or a lower level of frailty (data not presented).

**Table 2** Multilevel analyses for differences between control group (CG) and intervention group (IG) for primary outcome measures at 6, 12, and 24 months' follow-up (n=310)

Outcome	6 months' follow-up			12 months' follow-up			24 months' follow-up		
	Mean (SD)		Mean difference* (95% CI); P value	Mean (SD)		Mean difference* (95% CI); P value	Mean (SD)		Mean difference* (95% CI); P value
	CG	IG		CG	IG		CG	IG	
GARS	30.16 (10.07)	32.83 (10.98)	0.41 (-0.80 to 1.62); 0.51	30.81 (10.29)	33.08 (11.34)	0.47 (-0.81 to 1.76); 0.47	31.50 (10.92)	34.39 (11.58)	1.18 (-0.35 to 2.71); 0.35
GARS ADL	16.17 (5.13)	17.54 (5.82)	0.25 (-0.44 to 0.94); 0.48	16.30 (5.31)	17.81 (5.90)	0.59 (-0.14 to 1.33); 0.11	16.73 (5.73)	18.31 (5.82)	0.77 (-0.05 to 1.59); 0.07
GARS IADL	14.00 (5.51)	15.29 (5.92)	0.17 (-0.63 to 0.97); 0.67	14.51 (5.69)	15.28 (6.03)	-0.12 (-0.93 to 0.68); 0.76	14.77 (5.86)	16.08 (6.35)	0.40 (-0.54 to 1.34); 0.41

GARS=Groningen Activity Restriction Scale (range ADL 18-72; higher scores indicate more disability); GARS ADL=Groningen Activity Restriction Scale-activities of daily living (ADL) subscale (range ADL scale 11-44; higher scores indicate more disability); GARS IADL=Groningen Activity Restriction Scale-instrumental ADL subscale (range IADL scale 7-28; higher scores indicate more disability).

\*Adjusted for age, sex, education, and significant differences at baseline (frailty and disability).

**Table 3** Multilevel analyses for differences between control group (CG) and intervention group (IG) for secondary outcome measures at 6, 12, and 24 months' follow-up

Outcome	6 months' follow-up			12 months' follow-up			24 months' follow-up		
	Mean (SD)		Mean difference* (95% CI); P value	Mean (SD)		Mean difference* (95% CI); P value	Mean (SD)		Mean difference* (95% CI); P value
	CG	IG		CG	IG		CG	IG	
MSPP-CP-D (n=310)	2.10 (1.63)	1.92 (1.57)	-0.06 (-0.21 to 0.09); 0.71	2.10 (1.64)	1.73 (1.45)	-0.22 (-0.48 to 0.03); 0.09	1.94 (1.70)	1.61 (1.33)	-0.13 (-0.43 to 0.16); 0.38
MSPP-CP-F (n=310)	0.46 (0.40)	0.40 (0.36)	0.00 (-0.04 to 0.03); 0.96	0.45 (0.40)	0.35 (0.32)	-0.05 (-0.11 to 0.01); 0.12	0.44 (0.45)	0.33 (0.31)	-0.04 (-0.11 to 0.04); 0.32
MSPP-FSP-D (n=310)	0.69 (0.88)	0.64 (0.79)	0.03 (-0.05 to 0.10); 0.73	0.73 (0.91)	0.60 (0.81)	-0.06 (-0.14 to 0.02); 0.43	0.71 (0.87)	0.58 (0.77)	-0.04 (-0.12 to 0.04); 0.57
MSPP-FSP-F (n=310)	0.41 (0.59)	0.39 (0.55)	0.03 (-0.02 to 0.08); 0.52	0.43 (0.62)	0.35 (0.51)	-0.03 (-0.08 to 0.01); 0.47	0.45 (0.64)	0.34 (0.51)	-0.05 (-0.11 to 0.00); 0.31
HADS-D (n=305)	5.82 (3.88)	5.72 (3.49)	-0.11 (-0.80 to 0.58); 0.76	5.68 (3.92)	6.36 (4.13)	0.78 (0.04 to 1.53); 0.04	6.10 (3.78)	5.97 (4.18)	-0.07 (-0.90 to 0.77); 0.87
SSL-I12 (n=312)	26.94 (5.53)	27.03 (6.36)	0.18 (-0.79 to 1.15); 0.71	27.27 (6.54)	27.10 (6.09)	-0.12 (-1.22 to 0.99); 0.84	27.35 (6.27)	26.76 (5.98)	-0.29 (-1.37 to 0.79); 0.60
Short FES-I (n=306)	12.37 (4.90)	12.66 (5.25)	-0.67 (-1.48 to 0.14); 0.11	12.15 (5.24)	13.42 (5.43)	0.34 (-0.54 to 1.22); 0.44	12.95 (5.29)	13.73 (5.75)	-0.04 (-1.01 to 0.93); 0.94

MSPP=Maastricht Social Participation Profile, MSPP-CP-D=MSPP consumptive participation diversity score (range 0-7; higher score indicates more diverse consumptive participation); MSPP-CP-F=MSPP consumptive participation, frequency score (range 0-3; higher score indicates more frequent consumptive participation); MSPP-FSP-D=MSPP formal social participation, diversity score (range 0-7; higher score indicates more diverse formal social participation); MSPP-FSP-F=MSPP formal social participation, frequency score (range 0-3; higher score indicates more frequent formal social participation); HADS-D=Hospital Anxiety and Depression Scale-depression subscale (range 0-21, higher score indicates more depressive); SSL-I12=Social Support List-Interaction version (range 12-48; higher score indicates more social support); Short FES-I=Short Falls Efficacy Scale-International (range 7-28; higher score indicates more fear of falling).

\*Adjusted for age, sex, education, significant differences at baseline (frailty and disability), and baseline status outcome measure.



## Discussion

Our study has provided no evidence for the effectiveness of a pro-active primary care approach, consisting of a multidimensional assessment with interdisciplinary care based on a tailor-made treatment plan and regular evaluation and follow-up, among frail older people. We found no significant differences between the intervention and control group (care as usual) with regard to disability (primary outcome) and our secondary outcomes: depressive symptomatology, social support interactions, fear of falling and social participation. Pre-planned subgroup analyses confirmed these results.

### Strengths and weaknesses of study

The strengths of this cluster randomised trial include a long follow-up period with relatively few missing data and high follow-up rates. In addition, outcome measures with good psychometric properties were used, which were assessed by blinded data collectors. This study also has some weaknesses. Firstly, significant baseline differences existed between the intervention and control group with regard to frailty and disability and the sample size distribution was skewed. These differences were result of the cluster randomised design of the study, which is a common approach with this kind of intervention to avoid contamination bias.<sup>17</sup> Although, we adjusted for baseline differences in our analyses, this still may have affected our findings to some extent. Secondly, significantly more participants were lost to follow-up in the intervention than in the control group (26% vs. 17%). We cannot fully explain this finding, but older people in the intervention group were significantly more frail and disabled than those in the control group, which might have had affect the completion rate. Third, the PoC approach is evaluated in a real life setting among twelve GP practices. Although we did a comprehensive process evaluation alongside the trial,<sup>32</sup> we have limited insight into what has happened in practice for several reasons. Participating older people were patients of their GP irrespective of their study participation. Consequently, making a distinction between usual care activities and contacts related to the PoC approach was difficult, resulting in an overlap in time spent in delivering usual care versus the new approach. Also, practice nurses had trouble in determining a clear endpoint of the PoC approach, because older people remained a patient of their GP after the PoC approach had been delivered, resulting in continuous monitoring of older people. In addition, older people were referred to other healthcare professionals as well. As a result, we do not know exactly how much time was spent in delivering the PoC approach and for how long these activities were continued. However, the process evaluation showed that slightly more than one third of the participants in the intervention group (34%) had only the multidimensional assessment conducted by the practice nurse during an initial home visit. The remaining older people received a tailor-made treatment followed by up to five follow-up visits by the practice nurse.<sup>32</sup>

### Comparison with other studies

During the past decades, much research targeting community-dwelling (frail) older people has been done, with many studies in the field of preventive home visiting programs. Since 2000, several meta-analyses,<sup>33,34</sup> systematic reviews,<sup>35-37</sup> and literature reviews<sup>12,13</sup> were published. The studies evaluated a range of interventions (such as multidimensional geriatric assessment, care planning, organisation and monitoring, health promotion, self-management support, nursing services and referrals to other services) carried out by various professionals (GPs, nurses, allied professionals). The aim of these interventions is to proactively detect modifiable risk factors and worsening health conditions to reduce or prevent disability, health care use and related costs. Results regarding the effectiveness of these interventions have been inconsistent and conflicting. A few studies have shown favourable effects with regard to disability. For example, Bernabei and colleagues (1998) did a randomised controlled trial showing that a model of integrated care and case management had favourable effects with regard to disability in community-dwelling older people.<sup>38</sup> Services were provided by the GP and a community geriatric evaluation unit, consisting of a geriatrician, a social worker, and several nurses. Gill and colleagues (2002) have reported a successful randomised controlled trial evaluating an intense exercise programme for physically frail older people living in the community.<sup>39</sup> The programme is based on the outcomes of an extensive assessment and focus on the individual needs of older people, but also takes their environmental conditions into account. Most studies however, reported no or only modest effects of their interventions. Also, the largest trial in this field, by Fletcher and colleagues (2004), comparing different strategies for assessment (targeted versus universal) and evaluation and management (primary care versus multidisciplinary geriatric team) in more than 40,000 older people, did not result in convincing effects or adequate evidence that one strategy is better than another.<sup>40</sup>

### Meaning of the study: explanations and clinical implications

Besides the methodological drawbacks, some other explanations for the lacking effects are possible. These relate to the target group, insufficient implementation of the PoC approach, and current healthcare delivery in the Netherlands.

Firstly, the PoC approach focuses on frail older people (GFI $\geq$ 5). The baseline disability score in our frail sample (mean 32.0, SD=11.2) was substantially higher than in a comparable sample ( $\geq$ 70 years) of the Dutch general population (mean 24.9, SD=9.3).<sup>41</sup> Some participants in our study may have been too frail, as some previous reviews in the field of preventive home visiting programmes suggest that interventions may be more effective in low-risk, non-disabled older people.<sup>25,34</sup> This is in line with a more recent review reporting that frail older people have to be identified in relatively early stage when negative health outcomes can still be avoided.<sup>42</sup> In contrast, practice nurses and GPs interviewed during the process evaluation mentioned that a large



number of participants were in their view not eligible for the PoC approach, as they had hardly any disability in terms of ADL and IADL.<sup>32</sup> In efforts to reduce disability and prevent (further) functional decline, which older people would benefit the most from interventions such as the PoC approach is still not clear.

Secondly, the process evaluation showed that some parts of the intervention protocol were not implemented as planned.<sup>32</sup> The problem analysis and the development of a preliminary treatment plan (step 3) was often not done in a bilateral or an extended team meeting and only half of the treatment plans were discussed with the frail older person (step 4). Also, the toolbox parts were not frequently used in the treatment phase (step 5), and the extent of evaluation and follow-up, especially among the healthcare professionals, was limited (step 6).<sup>32</sup> Insufficient implementation is a well-known problem, especially in the field of preventive and behavioural change interventions.<sup>43</sup> During the process evaluation, professionals mentioned that some parts of the intervention protocol were (too) time-consuming or difficult to apply;<sup>32</sup> this may have been a reason for insufficient implementation.<sup>43</sup> In addition, professionals expressed a need for more training on the job and more opportunities to exchange experiences with each other. Education and experience of professionals and the intensity of provided training activities are strongly related to beneficial outcomes.<sup>12</sup> Despite an extensive development period and a comprehensive training program with regard to the intervention protocol, we probably failed in providing professionals with the needed competencies and feasible tools to apply rather complex concepts, such as interdisciplinary collaboration, tailor-made care and self-management support, into daily practice.<sup>32</sup> For example, the development of individualised goals, a prerequisite for tailor-made care and self-management support, is a challenging task, as patients tend to adopt a passive role in goal setting.<sup>44</sup> Encouragement of active involvement is even more difficult in older people owing to highly prevalent cognitive impairments, communication difficulties and comorbidities and as such requires a unique set of competencies.<sup>45</sup> Goal identification tools, such as the Canadian Occupational Performance Measure<sup>46</sup> or Goal Attainment Scaling<sup>47</sup>, may be useful in the process of goal setting. In addition, more attention has to be paid to the implementation of evaluation and follow-up activities, as a minimum intensity and length of follow-up is needed to reach favourable effects.<sup>25,34</sup>

Third, standard healthcare delivery in the Netherlands is already at a relatively high level. Nearly all people are covered by healthcare insurance, healthcare is easily accessible and its quality is often considered to be good.<sup>48</sup> Moreover, the contrast between the PoC approach and care as usual was probably too small to detect substantial effects. The non-effective results of this study and the complexity of effective interventions (or elements) described in the literature mean that drawing conclusions about which specific strategies would result in a surplus effect in which target group is difficult.

## Future research

Although this study has not shown any beneficial effects of a pro-active primary care approach, including a multidimensional assessment and interdisciplinary care based on a tailor-made treatment plan and regular evaluation and follow-up, it adds to the evidence base for clinical decision-making and future research regarding community-based care for frail older people. The publication of non-effective studies is highly relevant to prevent an overestimation of the benefits of interventions and a waste of healthcare resources. This study contributes to the emerging body of evidence that more research is needed to improve the effectiveness of interventions for frail older people.

## Acknowledgements

The authors would like to thank the participants in the study; participating healthcare professionals; Centre for Data and Information Management (MEMIC): Anita Legtenberg, Alfons Schroten, Marlène Ronner; the members of the research group: Lilo Crasborn (MCC Omnes), Simone Denis (MCC Omnes), Marlou Wolters (MCC Omnes), Herbert Habets (Orbis Medical Centre), Ramon Daniels (Zuyd University of Applied Sciences, Heerlen); their research assistants: Floor Koomen, Ine Hesdahl and Astrid Dello; and their sponsor: Dutch National Care for the Elderly Programme by The Netherlands Organisation for Health Research and Development (ZonMw 311070301), the Hague, the Netherlands.

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# 7

## **Cost-effectiveness of an interdisciplinary primary care approach to reduce disability in community-dwelling frail older people: a cluster randomised controlled trial**

**Under review**

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## Abstract

**Background:** There is increasing interest in cost-effective interventions for community-dwelling frail older people. However, there are only few economic evaluations conducted. The aim of this study was to evaluate the cost-effectiveness of an interdisciplinary primary care approach.

**Methods:** Embedded in a cluster randomised trial among 12 general practitioner practices (registered with Current Controlled Trials, ISRCTN31954692), an economic evaluation was performed from a societal perspective with a time horizon of 24 months. Frail older people in the intervention group received a multidimensional comprehensive geriatric assessment and interdisciplinary care based on a tailor made treatment plan and regular evaluation and follow-up. Practices in the control group delivered usual care. The primary outcome for the cost-effectiveness (CEA) and cost-utility analysis (CUA) was disability and quality of life, respectively.

**Results:** Multilevel analyses among 346 frail older people showed no significant differences between the groups regarding disability and quality of life at 24 months. People in the intervention group used, as expected, more primary care services, but there was no decline in more expensive hospital and long-term care. Total costs over 24 months tended to be higher in the intervention group than in the control group (€26,503 versus €20,550,  $p=0.08$ ).

**Conclusion:** This study does not support the surplus value of the interdisciplinary primary care approach for frail older people and its implementation in the current form is not recommended, at least in the Netherlands or other countries with similar healthcare systems.

## Background

Frail older people have an increased risk for adverse outcomes such as disability.<sup>1,2</sup> In most Western countries, including the Netherlands and the US, disability prevention in community-dwelling frail older people is considered to be a priority in geriatric care and research.<sup>3,4</sup> In several countries, for example the UK, proactive approaches, including early detection and treatment of frail older people, have even become part of the national healthcare policy.<sup>5</sup> However, results regarding their effectiveness are inconsistent and little is known about their cost-effectiveness.<sup>6-9</sup> The review of Markle-Reid and colleagues<sup>9</sup> identified six studies between 1966 and 2003 that included an economic evaluation; three studies provided some evidence that healthcare costs can be reduced (in particular by hospital and nursing home savings). However, the usefulness of this evidence is limited as only one study<sup>10</sup> conducted a cost-effectiveness analysis, meaning that relative costs and outcomes (effects) were compared. During the last decade (2003-2013) a few more economic evaluations were conducted,<sup>11-14</sup> but only one study<sup>14</sup> showed some beneficial effects regarding functional decline and improved well-being at 6 months, while costs were comparable between both groups. Long-term effects are not known.<sup>14</sup>

Between 2008 and 2010 Daniëls and colleagues<sup>15</sup> developed an interdisciplinary primary care approach for frail older people: the 'Prevention of Care' (PoC) approach.<sup>16</sup> It was expected that PoC leads to reduced disability and improved quality of life in frail older people. Furthermore, we assumed an increase in the use of primary care services and a decline in the use of more expensive hospital and long-term care, leading to a reduction in overall healthcare costs, and consequently a cost-effective intervention. This paper reports about shifts in healthcare utilisation and the cost-effectiveness of the PoC approach compared to usual care.

## Methods

### Design

Embedded in a cluster randomised controlled trial a cost-effectiveness (CEA) and cost-utility analysis (CUA) were performed from a societal perspective with a time horizon of 24 months. The design, methods, feasibility, and clinical outcomes of this trial have been described in detail elsewhere.<sup>17-19</sup> The Medical Ethical Committee of Maastricht University/ Academic Hospital Maastricht approved the study (MEC 09-3-067).

## Setting and participants

The trial was conducted among 12 Dutch general practitioner (GP) practices. Community-dwelling frail older people ( $\geq 70$  years) were recruited from these practices by means of postal screening, including the Groningen Frailty Indicator (GFI).<sup>20</sup> People with a GFI score of five or higher (range 0-15) who signed the informed consent prior to the baseline measurement were eligible for the study.

## Randomisation and blinding

Before randomisation, GP practices were pre-stratified into four strata based on two characteristics: number of older patients ( $< 350$  patients versus  $\geq 350$  patients) and location (urban versus rural area). A computer generated randomisation list was used to allocate stratified pairs to either the intervention or control group.<sup>17</sup> Whereas participants and healthcare professionals were aware of the allocated arm, outcome assessors were kept blinded to the allocation.

## Intervention

Older people in the intervention group received the PoC approach, which was delivered by an interdisciplinary team (e.g. GP, practice nurse, occupational therapist, and physiotherapist). The six-step approach aims to reduce disability and to prevent (further) functional decline.<sup>16</sup> After the frailty screening (step 1), people receive a comprehensive in-home assessment by the practice nurse and additional assessments by other professionals if indicated (step 2). In a bilateral meeting (i.e. GP and practice nurse) or in an extended team meeting (e.g. GP, practice nurse, occupational therapist and physiotherapist) a preliminary treatment plan is formulated (step 3). During a second home visit a final treatment plan is made together with the frail older person (step 4). A specific toolbox offers recommendations and guidelines for the execution of the treatment plan (step 5). The achievement of goals and implementation of strategies in daily life are regularly evaluated and the need for follow-up is determined (step 6). The intervention is described in more detail elsewhere.<sup>16</sup> Older people in the control group received usual care. In the Netherlands, GPs have a central position in community-based care, as they are gatekeepers to secondary care. In 2001, the profession of practice nurses was introduced to reduce the workload of GPs.<sup>21</sup> However, no standard approach for the care for frail older people is available.

## Healthcare utilisation and costs

We assessed intervention costs, other healthcare costs and patient and family costs. Intervention costs (i.e. screening, training activities and intervention delivery) were not assessed individually, but mean volumes were estimated based on the feasibility study that was conducted alongside this trial (see Appendix 1).<sup>19</sup> Other healthcare

costs related to: primary care, including services from GP, practice nurse, allied professionals (i.e., occupational therapist, physiotherapist, speech therapist and dietician), hospital care (i.e., admission days, outpatient medical services and day care), long-term care (i.e., home for the elderly/ nursing home admission, professional homecare), and prescribed medication. In addition, patient and family costs (i.e., informal care and helping aids/ in-home modifications) were assessed. During 24 months, volumes of healthcare utilisation as well as medication costs were collected from registries of health insurance agencies, as nearly all people in the Netherlands are covered by healthcare insurance.<sup>22</sup> Volumes that could not be obtained from these registries were assessed from the local hospital or directly from the participants by means of telephone interviews and postal questionnaires at baseline, 6, 12 and 24 months follow-up (see Appendix 2).

Cost valuation was conducted according to Dutch guidelines for costing research.<sup>23</sup> Costs were calculated by multiplying the volumes with cost prices of that unit (see Appendix 2). Where no standardised cost prices were available (i.e., helping aids and assistive devices), costs were obtained from the internet. Costs are presented in Euros (€) for the year 2010, and if needed, prices were indexed to the reference year using a consumer price index.<sup>23</sup>

## Cost-effectiveness

The primary outcome of our CEA is disability, which was assessed by the Groningen Activity Restriction Scale (GARS)<sup>24</sup> at baseline, 6, 12, and 24 months. For the CUA, outcomes are expressed in terms of generic quality adjusted life years (QALYs), measured by means of the EuroQol-5D (EQ-5D).<sup>25</sup> A direct value for every state of health was generated using the UK Dolan tariff,<sup>26</sup> which involves an algorithm for interpolating EuroQol results to population utilities. Utilities refer to preferences that individuals or society may have for a particular set of health outcomes.<sup>25</sup> The utilities at the four measurement points were used to compute QALYs using the area under the curve method.<sup>25</sup> Data for CEA and CUA were collected at 6, 12, and 24 months.

## Statistical analysis

Clinical outcomes were analysed according to the intention-to-treat principle using mixed model multilevel analyses. Volumes of healthcare utilisation and related costs are presented as arithmetic means and were tested for their significance by using *t*-tests, which is considered the most appropriate method to analyse cost data.<sup>27</sup> Incremental cost-effectiveness ratios (ICERs) were calculated, representing the differences in mean costs between the intervention and control group in the numerator and the difference in mean clinical effects in the denominator.<sup>25</sup> Sampling uncertainty around the ICER was assessed by means of (1,000 times) non-parametric bootstrapping (percentile method).<sup>25</sup> To assess the robustness of the assumptions



made, we performed one-way sensitivity analyses. First, the intervention costs were not assessed individually, but mean volumes were estimated based on the feasibility study that was conducted alongside this trial.<sup>19</sup> If interventions aspects are reimbursed as usual care this may have resulted in double counting of intervention costs. Therefore, we compared the base-case with the analyses without intervention costs. Second, as the study was performed in a Dutch setting, the base-case (UK tariff)<sup>26</sup> was compared with the Dutch tariff<sup>28</sup>. Statistical analyses were conducted with SPSS for Windows version 20.0, bootstrapping was done in Excel 2010.

## Results

### Participants

In total, 346 frail older people were included in the study, 193 (56%) received the PoC approach. The mean age of participants was 77.2 years. At baseline, participants in the intervention group were on average significantly more frail (GFI: 7.13 versus 6.72,  $p=0.03$ ) and more disabled (GARS: 33.09 versus 30.58,  $p=0.03$ ). Other characteristics and the amount of healthcare utilisation were comparable between both groups (Table 1). Details of the progress of participants through the trial are reported elsewhere.<sup>18</sup>

### Healthcare utilisation and costs

Volumes of hospital care (including outpatient medical services), long-term care, informal care and helping aids/ in-home modifications were comparable between the groups over a period of 24 months. However, people in the intervention group had more primary care use compared to the control group (Table 2).

Additional analyses of annual volumes showed that this group difference was strongest in the first 12 months: the intervention group showed significantly more contacts with the occupational therapist (4.6 to 0.4,  $p<0.001$ ), practice nurse (5.2 to 1.0,  $p<0.001$ ) and GP (15.0 to 12.4,  $p=0.05$ ). From month 12 to 24 only the amount of occupational therapy sessions was significantly higher in the intervention group (2.6 to 0.7,  $p=0.01$ ). Annual volumes are not tabulated, but available on request.

Table 3 shows the mean costs for participants with a complete dataset over a period of two years ( $n=194$ , 56%). The mean total costs in 24 months were €26,503 per participant in the intervention group compared to €20,550 in the control group. The costs for the PoC approach were €728. Mean healthcare costs were significantly higher in the intervention group than in the control group (€17,664 versus €12,963,  $p=0.03$ ). Participants in the intervention group showed significantly higher mean costs for GP care (€1,072 versus €729,  $p<0.001$ ), hospital care (€2,905 versus €1,488,  $p=0.05$ ), and helping aids/ in-home modifications (€552 versus €278,  $p=0.03$ ) than

**Table 1** Baseline characteristics of frail older people ( $n=346$ )

	Intervention ( $n=193$ )	Control ( $n=153$ )
Age mean	77.5 (5.3)	76.8 (4.9)
Female	106 (55)	93 (60)
Living alone	90 (47)	80 (52)
Low education	108 (56)	94 (61)
Frailty		
GFI 0-15**	7.1 (1.9)	6.7 (1.7)
Disability		
GARS 18-72**	33.1 (11.5)	30.6 (10.6)
Utilities		
EuroQol-5D based on UK tariff (0-1)†	0.6 (0.2)	0.7 (0.2)
EuroQol-5D based on NL tariff (0-1)†	0.7 (0.2)	0.7 (0.2)
Contacts GP last year‡	6.5 (5.2)	4.5 (3.8)
Contacts allied professionals last year‡	24.9 (47.3)	19.3 (30.3)
Hospital admission last year (days)‡	3.4 (10.1)	3.3 (16.1)
Nursing home admission last year (days)	0.2 (3.0)	2.0 (14.2)
Professional homecare (hours/week)	2.4 (3.4)	2.2 (3.2)
Informal care (hours/week)	7.0 (20.9)	5.1 (10.0)
Aids/ in-home modifications available	3.2 (2.6)	2.9 (2.7)

Notes: Data are n (%), or mean (SD); GFI=Groningen Frailty Indicator; GARS=Groningen Activity Restriction Scale.

\*Significant differences at baseline  $p<0.05$ .

† Underlined scores=most favourable scores.

‡Baseline: self-report, follow-up measurements: continuous registration.

participants in the control group. The remaining categories of healthcare utilisation were comparable between the groups.

Table 2 Mean (SD) volumes of healthcare utilisation 0-24 months

	Intervention			Comparison				
Variable	Subjects†	Mean	SD	Subjects‡	Mean	SD	Mean difference (95% CI)	p
Primary care†								
- GP (contacts)	131/132	31.4	23.4	115/115	27.2	20.7	4.2 (-1.35-9.79)	0.14
- Practice nurse (contacts)	128/132	5.2	3.4	33/115	1.1	2.7	4.1 (3.29-4.82)	0.00*
- Occupational therapist (contacts)	41/132	7.1	13.4	8/115	1.2	4.7	5.9 (3.44-8.35)	0.00*
- Physiotherapist (contacts)	85/132	33.5	53.0	68/115	32.8	50.9	0.7 (-12.39-13.74)	0.92
Hospital care‡								
- Admission (days)	39/148	5.3	17.6	33/131	3.1	9.8	2.2 (-1.07-5.57)	0.18
- Outpatient medical services (contacts)	138/148	11.5	11.4	113/131	10.0	8.7	1.5 (-0.85-3.88)	0.21
Long-term care§								
- Admission (days)	5/134	2.1	12.0	6/119	2.1	10.8	0.1 (-2.74-2.94)	0.95
- Professional homecare (hours)	77/134	228.2	288.5	67/119	220.2	319.9	8.0 (-67.30-83.36)	0.83
Others§								
- Informal care (hours)	44/154	479.0	1,238.4	38/135	503.2	1,152.4	-24.1 (-302.37-254.12)	0.87
- Aids/ in-home modifications (number)	85/137	1.5	1.8	74/122	1.2	1.4	0.3 (-0.11-0.67)	0.16

Data are mean (SD) by group allocation. GP and practice nurse contacts: (telephone) consults, home visits. \*Statistically significant. Data were collected by † health insurance registries, ‡ registry of the local hospital or § gathered via self-reported measures. † Proportion of subjects who received services.

Table 3 Mean (SD) costs of healthcare utilisation after 24 months complete cases

Variable	Intervention (n=103)		Control (n=91)		Mean difference (95% CI)	p	Bootstrap 95% Uncertainty Interval	
	Mean	SD	Mean	SD			2.5th percentile	97.5th percentile
Healthcare costs	17,664	18,277	12,963	10,439	4,701 (540.38-8,861.51)	0.03*	767	8,928
Intervention costs†	728	0	0	0	788			
Other healthcare costs	16,936	18,277	12,963	10,439	3,973 (-188-8,134)	0.06	-7	8,069
- GP care	1072	732	729	545	343 (158-528)	0.00*	166	524
- Allied professionals	1,189	1,918	1,322	1,937	-134 (-681-413)	0.63	-680	416
- Hospital care	2,905	6,882	1,488	2,235	1,417 (-3-2,837)	0.05*	172	2,862
- Long-term admission	531	2,787	221	1,554	310 (-341-961)	0.35	-283	947
- Professional homecare	8,031	10,462	7,020	7,473	1,011 (-1,595-3,617)	0.45	-1,514	3,957
- Medication	3,208	6,306	2,182	2,211	1,026 (-286-2,338)	0.12	-101	2,632
Patient and family costs	8,839	18,459	7,587	14,521	1,252 (-3,496-5,999)	0.60	-2,758	6,158
Informal care	8,287	18,352	7,309	14,490	978 (-3,747-5,704)	0.68	-3,303	6,205
Aids/ in-home modifications	552	1,067	278	643	273 (27-520)	0.03*	34	541
Total costs	26,503	27,273	20,550	18,891	5,953 (-633.84-12,538.80)	0.08	-785	12,741

Data are mean (SD) by group allocation. \*Statistically significant. † Intervention costs are estimated based on the process evaluation.

Table 4 Results regarding disability and quality of life

	Intervention		Control		Mean difference* (95% CI)	p-value
	Mean	SD	Mean	SD		
Disability	(n=310)					
GARS (18-72, 18=best)	Baseline	33.09	11.52	30.58	2.50 (0.14-4.87)	0.04*
	6 months	32.83	10.98	30.16	0.41 (-0.80-1.62)	0.51
	12 months	33.08	11.34	30.81	0.47 (-0.81-1.76)	0.47
	24 months	34.39	11.58	31.50	1.18 (-0.35-2.71)	0.35
Self-rated quality of life	(n=312)					
EQ-5D (0-1, 1=best) based on UK tariff	Baseline	0.62	0.23	0.66	-0.04 (-0.09-0.01)	0.10
	6 months	0.63	0.22	0.69	-0.02 (-0.05-0.01)	0.20
	12 months	0.64	0.21	0.68	-0.01 (-0.04-0.03)	0.69
	24 months	0.63	0.19	0.65	0.00 (-0.04-0.04)	0.98
QALY based on UK tariff (0-2, 2=best)	Baseline	1.30	0.32	1.36	-0.06 (-0.14-0.02)	0.15
	6 months	0.67	0.20	0.70	-0.03 (-0.07-0.01)	0.16
	12 months	0.68	0.19	0.73	-0.01 (-0.04-0.01)	0.34
	24 months	0.69	0.18	0.72	0.00 (-0.04-0.03)	0.81
EQ-5D (0-1, 1=best) based on NL tariff	Baseline	0.68	0.17	0.69	0.00 (-0.04-0.04)	0.97
	24 months	1.40	0.28	1.44	-0.04 (-0.11-0.03)	0.26
QALY based on NL tariff (0-2, 2=best)						

Data are mean (SD) by group allocation; GARS= Groningen Activity Restriction Scale, EQ-5D=EuroQol-5D, QALY= quality adjusted life years; \*Statistically significant; †Multilevel analyses: adjusted for age, sex, education, significant differences at baseline (frailty and disability).

Clinical outcomes

No significant effects were found for disability (GARS) and quality of life (EuroQol-5D). Table 4 summarises scores at baseline, 6, 12 and 24 months follow-up. In addition 2 year QALYs are presented.<sup>29</sup>

Base-Case cost-effectiveness analysis and sensitivity analyses

Since we did not detect differences in clinical effects, it is not useful to present ICERs. The cost-effectiveness plane of the CUA base-case bootstrap analysis for QALYs (Figure 1) shows that 2% of the ICERs lies in the dominant ('south east') quadrant (representing the probability of the PoC approach having more effect and lower costs compared to usual care). Sensitivity analyses did not reveal other results (see Appendix 3).

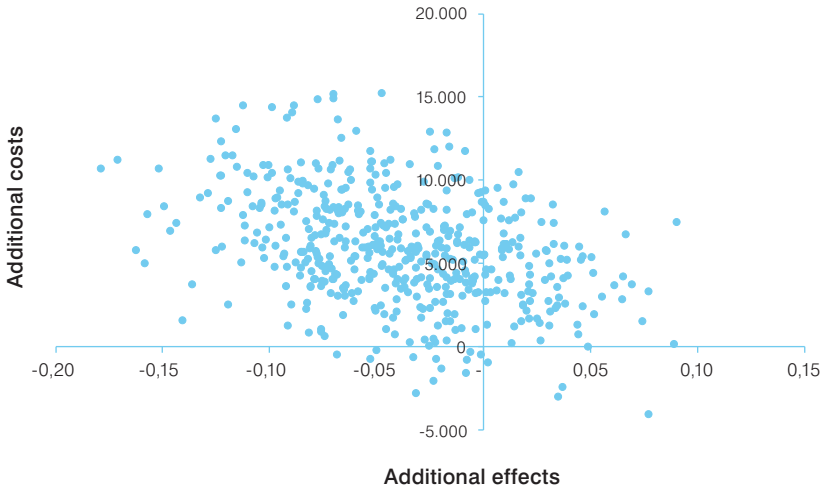


Figure 1 Cost-effectiveness plane for costs (euros) versus adjusted life years (QALYs) based on UK tariff

Discussion

As expected frail older people in the intervention group used more primary care services compared to the control group, especially in the first 12 months, but against our hypothesis we found no effects on disability or quality of life and no decline in more expensive hospital and long-term care. Subsequently, total healthcare costs

over 24 months tended to be higher in the intervention group than in the control group (€26,503 versus €20,550,  $p=0.08$ ). The probability of the PoC approach being cost-effective compared to usual care is negligible (2%).

The findings of this economic evaluation are in line with the effect evaluation.<sup>18</sup> There are some possible explanations why the PoC approach has shown no beneficial effects. First, there is still a lively debate about the conceptualisation and measurement of frailty.<sup>30</sup> Possibly the wrong target group was recruited for the PoC approach. Second, according to the process evaluation some steps of the intervention protocol were not sufficient implemented.<sup>19</sup> The problem analysis and development of a preliminary treatment plan (step 3) was often not done in a bilateral or an extended team meeting and only half of the treatment plans were discussed with the frail older person (step 4). Also toolbox parts were not frequently used in the treatment phase (step 5) and the extent of evaluation and follow-up, especially among the healthcare professionals, was limited (step 6).<sup>19</sup> Finally, standard healthcare in the Netherlands is at a relatively high level. Nearly all people are covered by healthcare insurance and care is easily accessible.<sup>22</sup> This is supported by the volumes of healthcare utilisation in the control group. Over a period of 24 months, people in this latter group had, on average, 27 contacts with their GP, 33 physiotherapy sessions and 10 contacts with outpatient medical services. The contrast between the PoC approach and usual care was possibly too small to demonstrate convincing effects. This is in line with other studies assuming that the increasing awareness of the needs and problems of older people might have reduced the potential benefit of recent interventions compared to studies in earlier decades.<sup>31</sup>

Comparing our results with previous studies is complex for several reasons. First, interventions differ in terms of content, disciplines involved, duration, intensity and setting. Second, the measurement and data analysis of volumes of healthcare utilisation and related costs vary across studies. Third, results of economic evaluations have to be interpreted in the light of national contexts, as cost-effectiveness strongly depends on the characteristics of the healthcare system in which the intervention is evaluated.<sup>25</sup> Finally, economic evaluations in this field are scarce. To our knowledge the present study is the first cost-effectiveness analysis of an interdisciplinary primary care approach for frail older people, including postal screening, a multidimensional assessment and interdisciplinary care based on a tailor made treatment plan and regular evaluation and follow-up, which was conducted from a societal perspective with a time horizon of 24 months.

The present study has some limitations that may have influenced our results. First, although healthcare registries were used as primary data sources, some data were collected via self-reports, which were assessed at 6, 12 and 24 months follow-up. The relatively long period between the measurements may have led to recall bias. However, there is no reason to assume that possible recall bias is unevenly distributed

between the groups. Second, the intervention costs were not assessed individually, but mean costs were based on the process evaluation.<sup>19</sup> When interventions aspects are reimbursed as usual care this may have resulted in double counting. However, sensitivity analyses without intervention costs did not reveal other results though.

Against our hypothesis, the PoC approach is not cost-effective. Consequently, its implementation in its current form is not recommended, at least not in the Netherlands or other countries with similar healthcare systems. Anyway, it is questionable to some extent whether it is justified yet to integrate early detection and treatment of frail older people in national healthcare policies. According to the screening literature, the 'screening condition' has to be fully understood and suitable screening tools and accepted interventions are needed.<sup>32</sup> Furthermore, the costs of screening, including subsequent assessment and treatment should be economically balanced in relation to potential healthcare costs.<sup>32</sup> With regard to frailty there is, as mentioned earlier, still a lively debate about its conceptualisation and measurement.<sup>30</sup> In addition, available interventions have produced inconsistent and conflicting results regarding their effectiveness and little is known about cost-effectiveness.<sup>6-9</sup> At least our study has shown that such a proactive approach may lead to increased healthcare costs without providing any beneficial effects. Consequently, more research into the conceptualisation and measurement of frailty is needed and more studies, including economic evaluations, have to be conducted to optimise services for community-dwelling frail older people.

### Acknowledgements

We thank older people and professionals for their participation. We are grateful to the insurance agencies (ZilverenKruis/ Achmea, VGZ and CZ in the Netherlands) and the local hospital (Orbis Medical Centre Sittard-Geleen, the Netherlands) for providing healthcare utilisation data.

### Funding

This work was supported by The Netherlands Organisation for Health Research and Development (ZonMw 311070301), the Hague, the Netherlands.

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**Appendix 1** Estimated intervention costs for a sample of n=200 (based on process evaluation)

				Total costs (€) n=200	Costs (€) per patient
Intervention materials				1,200.00	6.00
Training activities				16,500.00	82.50
Postal screening				8,100.00	40.50

	Price (per hour)	Minutes	Number of patients	Total costs (€) n=200	Costs (€) per patient
<b>Assessment practice nurse</b>					
- Home visit practice nurse	50.00	90	200	15,000.00	75.00
- Home visit GP	50.00	45	80	3,000.00	15.00
- Home visit occupational therapist	50.00	45	40	1,500.00	7.50
- Home visit physiotherapist	50.00	45	30	1,125.00	5.63
- Home visit other professionals	50.00	45	20	750.00	3.75
<b>Total</b>				<b>21,375.00</b>	<b>106.88</b>
<b>Preliminary treatment plan</b>					
- Practice nurse	50.00	10	25	208.33	1.04
- Duo meeting (practice nurse and GP)	100.00	15	120	3,000.00	15.00
- Team meeting (all professionals)	200.00	20	40	2,666.67	13.33
<b>Total</b>				<b>5,875.00</b>	<b>29.37</b>
<b>Definitive treatment plan</b>					
- Home visit (preparation included)	50.00	90	100	7,500.00	37.50
<b>Toolbox</b>					
- Meaningful activities	50.00	600	30	15,000.00	75.00
- Adapting the environment, activities or skills	50.00	600	50	25,000.00	125.00
- Social network and social activities	50.00	300	30	7,500.00	37.50
- Daily physical activity	50.00	600	35	17,500.00	87.50
- Stimulating health	50.00	300	40	10,000.00	50.00
<b>Total</b>				<b>75,000.00</b>	<b>375.00</b>

**Appendix 1** Continued

	Price (per hour)	Minutes	Number of patients	Total costs (€) n=200	Costs (€) per patient
<b>Other interventions</b>	50.00	120	30	<b>3,000.00</b>	<b>15.00</b>
<b>Evaluation and follow-up</b>					
- Practice nurse	50.00	30	100	2,500.00	12.50
- Duo meeting (practice nurse and GP)	100.00	15	35	875.00	4.38
- Team meeting (all professionals)	200.00	20	55	3,666.67	18.33
<b>Total</b>				<b>7,041.67</b>	<b>35.21</b>
<b>TOTAL</b>				<b>145,591.67</b>	<b>727.96</b>



Appendix 2 Health care utilisation: costs prices used

Category	Volume	Costs	Source of data
<b>Healthcare costs</b>			
Intervention costs	N/A	728.00	Process evaluation
Other healthcare costs			
- GP and practice nurse	Consultation	28.00	Health insurance agency
	Telephone consultation	14.00	Health insurance agency
	Home visit	43.00	Health insurance agency
- Occupational therapist	Session	22.00	Health insurance agency
- Physiotherapist	Session	36.00	Health insurance agency
- Dietician	Session	27.00	Health insurance agency
- Speech therapist	Session	33.00	Health insurance agency
- Hospital admission	Admission day	435.00	Local hospital
- Outpatient medical services	Consultation	64.00	Local hospital
- Day care	Day	251.00	Local hospital
- Nursing home	Admission day	238.00	Postal questionnaire
- Home for the elderly	Admission day	90.00	Postal questionnaire
- Professional homecare	Hour	35.00	Postal questionnaire
- Prescribed medication	N/A	total	Health insurance agency
<b>Patient and family costs</b>			
- Informal care	Hour	12.50	Postal questionnaire
- Helping aids/ in-home modifications	Number	total	Telephone interview

Most prices are obtained from the Dutch manual for cost-analysis in healthcare research (2009), except for medication (health insurance agency) and helping aids/ in home modifications (internet, 2013). Subsequently, costs per categories were indexed to the reference year (2010) using a consumer price index

Appendix 3 Results of base-case and sensitivity analysis over 24 months (n=194)

	ICER	Distribution of cost-effectiveness plane			
		NE%	NW% (inferior)	SW%	SE% (superior)
Base-case analysis					
QALYs UK	150,616	0.19	0.77	0.02	0.02
GARS	1,920	0.02	0.95	0.03	0.01
Sensitivity analyses					
Without intervention costs	132,195	0.18	0.76	0.03	0.04
QALYs NL	285,428	0.29	0.68	0.02	0.02

NE=north east quadrant (higher costs, more effects), NW=north west quadrant (higher costs, less effect), SW-south west quadrant (less costs, less effects), SE=south east quadrant (less costs, more effects); QALY=quality adjusted life years

# 8

## General Discussion



## Introduction

The main objective of this thesis was to evaluate an interdisciplinary primary care approach for community-dwelling frail older people: the 'Prevention of Care' (PoC) approach. The aim of this approach is to reduce disability and prevent (further) functional decline. The PoC approach consists of a postal frailty screening, a multi-dimensional in-home assessment, interdisciplinary care based on a tailor-made treatment plan and regular evaluation and follow-up.

A cluster randomised trial was conducted to investigate the effectiveness and cost-effectiveness of the PoC approach. Alongside the trial, a comprehensive process evaluation was done. In addition, a validation study was conducted evaluating and comparing three screening instruments for identifying frail older people in the community.

This final chapter summarises the main findings of this thesis. Furthermore, it discusses some methodological issues and reflects on theoretical considerations regarding the interpretation of the results. The chapter ends with implications for practice and future research.

## Main findings

First, a *validation study* was conducted to evaluate and compare three frailty screening instruments: the Groningen Frailty Indicator (GFI),<sup>1</sup> the Tilburg Frailty Indicator (TFI)<sup>2</sup> and the Sherbrook Postal Questionnaire (SPQ).<sup>3</sup> The GFI and the TFI showed high internal consistency and construct validity in contrast to the SPQ. Based on our findings it is not yet possible to conclude whether the GFI or the TFI should be preferred, but the SPQ seems less appropriate.

Second, a comprehensive *process evaluation* was conducted in the intervention group to provide insight into the extent to which the PoC approach was implemented as intended and to evaluate experiences of healthcare professionals and frail older people regarding benefits, burden, stimulating factors and barriers. Data was collected from 193 older people and 45 healthcare professionals. Although some parts of the protocol were insufficiently executed, healthcare professionals and frail older people were satisfied with the PoC approach; it provided a useful structure for the delivery of geriatric primary care and increased the attention to preventive treatment. Frail older people felt acknowledged by healthcare professionals and experienced support in handling their problems and fulfilling their wishes. Given its complexity, the implementation of the PoC approach was challenging and some parts of the protocol need further attention.

Third, to test the *effectiveness* of the PoC approach a *cluster randomised controlled trial* was conducted among twelve general practitioner practices, which

were randomly allocated to the intervention (six practices – PoC approach) or control group (six practices – usual care). Based on a postal questionnaire, including the GFI, 346 frail older people were included in the study. Their mean age was 77.2 years and 58% were female. Patient follow-up rates were 91% at 6 months, 86% at 12 months and 78% at 24 months with significantly more loss to follow-up in the intervention group. Mixed-model multi-level analyses showed no significant differences between the two groups with regard to all primary (disability) and secondary outcomes (i.e., depressive symptomatology, social support interactions, fear of falling and social participation, quality of life) at 6, 12 and 24 months follow-up. Pre-planned subgroup analyses confirmed these results.

Finally, embedded in the trial a *cost-effectiveness* (CEA) and *cost-utility analysis* (CUA) was performed from a societal perspective with a time horizon of 24 months. People in the intervention group had significantly more contacts with the practice nurse (5.2 versus 1.1,  $p < 0.001$ ) and occupational therapy sessions (7.1 versus 1.2,  $p < 0.001$ ) over a period of two years than people in the control group. Remaining categories of healthcare utilisation were comparable between the groups. Total healthcare costs in the sample of complete cases (56%) were €6,503 in the intervention group compared to €0,550 in the control group. Despite higher healthcare costs in the intervention group we found no significant differences between the groups with regard to disability and quality of life.

## Methodological considerations

Regarding the methodological strengths and limitations of our trial the following issues will be discussed: 1) study design, 2) recruitment of participants, 3) outcome measures, and 4) treatment fidelity.

### Study design

Randomised controlled trials are considered to be a gold standard for evaluating interventions, as they estimate the impact of an intervention through direct comparison with a randomly allocated control group. Randomisation is the best way to ensure that factors, which may affect the outcome of an intervention, are evenly distributed among study groups.<sup>4</sup> In the current study individual randomisation was inappropriate; it was assumed that organisational circumstances and professional behaviour affect the treatment. Consequently, a cluster design was chosen to avoid contamination bias between the groups. Unfortunately, this choice led to significant baseline differences between the groups with regard to frailty and disability and a skewed sample size distribution. These are common risks in a cluster approach.<sup>4</sup> Another problem in cluster randomised designs is within-cluster correlation leading to a

greater homogeneity of individuals within a cluster, which results in a loss of power for detecting differences between the groups.<sup>5</sup> In order to correct for the disadvantages of a cluster approach, an Intra Cluster Correlation (ICC) coefficient was taken into account in the sample size calculation and outcome estimates of the multilevel analyses were adjusted for significant differences at baseline by including these two variables as covariates in each model. Despite all efforts taken, the methodological drawbacks of a cluster randomised design may have affected our findings to some extent.

### Recruitment of participants

One of the biggest challenges in this study was the recruitment of appropriate participants. During the last decades, the concept of frailty has been established to describe older people with an increased risk for adverse outcomes. However, there is still a lively debate about the definition and measurement of frailty.<sup>6</sup> In the current study, postal screening (GFI) followed by a comprehensive assessment, has shown to be a feasible method to identify community-dwelling frail older people. However, there are still some doubts about the psychometric properties of the chosen screening instrument. The GFI showed high internal consistency and construct validity in a cross-sectional validation study, which is part of this thesis (*Chapter 2*), but information about the predictive validity was lacking when the trial started. Two recent validation studies<sup>7,8</sup> have shown that the GFI needs further improvement regarding its accuracy. There are numerous other self-report instruments available, but all of them are in the early stage of development and their psychometric properties are still insufficient or unclear.<sup>7,9</sup>

An alternative for self-report instruments are performance-based measures. It is assumed that performance-based measures provide more precise and valid answers as they are less influenced by socio-demographic variables, personality and cognitive and affective factors. However, they are more sensitive to non-response, changes in time and differences in the execution of activities. Furthermore, they are less easy to conduct and time-consuming.<sup>10-12</sup> When considering performance-based measures, modern technologies have the potential to monitor frailty markers efficiently. For example, a modified bathroom scale, a grip ball, or a mobile phone with built-in accelerometer are relatively inexpensive technologies to measure balance, grip strength and physical activity, which are known as relevant predictors for adverse health outcomes in older people.<sup>13,14</sup> In a recent validation study, the modified bathroom scale was compared with clinical balance tests and provided promising results. However, more research into their validity, feasibility and clinical relevance is needed.<sup>15</sup>

## Outcome measures

This study, like many intervention studies in this domain, is based primarily on self-report measures. To increase the validity of the outcome measurements several strategies were applied. First, assessed by blinded data collectors, outcome measures with good psychometric properties were used. Second, missing values were minimised by using telephone interviews for most outcome measures. To complete missing data gathered via postal questionnaires, participants were contacted by telephone. This method led to relatively few missing data and high follow-up rates. Third, during the economic evaluation, registries from health insurance agencies and the local hospital were used as primary sources for data collection. Only data that could not be obtained from the registries were collected via self-report.

Despite a thoughtful selection of outcome measures and data collection methods, we failed to include some measures of relevant intermediate outcomes that are strongly related to the PoC approach, for example, the achievement of individual goals. Older people interviewed during the process evaluation (*Chapter 5*) felt acknowledged by healthcare professionals and experienced support in handling their problems and fulfilling their wishes. However, our outcome measures, which were focussed on frail older peoples' health status rather than on the achievement of their goals, did not detect any effects. A study by Rockwood and colleagues evaluating a comprehensive geriatric assessment and management approach has shown that Goal Attainment Scaling<sup>16</sup> is more responsive to clinical relevant changes than for example (I)ADL measures.<sup>17</sup> We probably missed clinically important changes due to our choice of outcome measures. Furthermore, additional information about intermediate outcomes would have been useful to explain the lack of effects.

## Treatment fidelity

Being aware of the complexity of the PoC approach, much effort was put into a comprehensive process evaluation (*Chapter 5*). A mixed methods design was applied, integrating quantitative and qualitative data from different sources. Nevertheless, to some extent it remains unclear what has happened in daily practice. While healthcare professionals involved were very positive about the implementation of the PoC approach during the semi-structured and focus group interviews, the logbooks showed that not all the steps of the PoC approach were applied. This finding is in line with previous studies in this field,<sup>18,19</sup> which have shown that healthcare professionals have difficulties in reflecting adequately on their functioning, perhaps due to a lack of awareness of their own behaviour. These researchers suggest more objective measures like video- or audio-taping to increase treatment fidelity. It is also insufficiently known what happened in the control group, as no fidelity data were collected in this group. Based on the economic evaluation (*Chapter 7*) it is known that

older people in the control group had comparable volumes of healthcare utilisation apart from contacts with practice nurses and occupational therapists, which were more frequent in the intervention group. Older people in the control group probably received active ingredients of the PoC approach as well resulting in insufficient contrast between the groups and consequently a reduced effect size. Detailed treatment fidelity data measured in both groups would have been useful to provide more insight into the differences between the groups.

## Theoretical considerations

This section provides some theoretical considerations regarding the interpretation of the results. The following issues will be discussed: 1) target group, 2) ingredients of the PoC approach, and 3) the implementation of the PoC approach.

### Target group

Earlier in this chapter we reflected on some psychometric issues regarding the recruitment of frail older people. However, there are also some theoretical considerations regarding the target group of the PoC approach. The PoC approach is based on a multifactorial perspective on frailty.<sup>20,21</sup> Compared to the frailty phenotype<sup>22,23</sup> this perspective leads to a more heterogeneous target group with a great diversity in deficits (i.e., physical, psychological and social). Also the severity of health problems varied, as the PoC approach focuses on both older people in a relatively early stage of frailty with no disability and older people who are already disabled. Obviously, the heterogeneity of the target group has consequences for healthcare delivery. Frail older people who are already disabled may benefit from a rehabilitative approach that attempts to improve functional status. In contrast, older people with no disability may profit, to a larger extent, from a health promotion and prevention approach that attempts to reduce risk factors for functional decline. Furthermore, physically frail older people may need another approach than older people with psychological or social problems. Consequently, the PoC approach is designed in a tailor-made way and the guidelines for assessment and treatment cover the full range of deficits irrespective of their severity. However, the process evaluation has shown that practice nurses and GPs in our study were used to focus particularly on specific diseases and existing disability; they paid less attention to psycho-social problems and the enhancement of meaningful activities. Older people with hardly any disability in terms of activities of daily living were in their view not (yet) frail and consequently not eligible for the PoC approach. A preventive approach and a multifactorial perspective on frailty may therefore not fit very well with their (current) philosophy of healthcare delivery.

In an effort to prevent (further) functional decline, it is still not clear which older people would benefit the most from interventions like the PoC approach. Several previous reviews in the field of preventive home visiting programmes suggested that interventions may be more effective in low-risk, non-disabled older people.<sup>24,25</sup> This is in line with a more recent review reporting that frail older people have to be identified in a relatively early phase when negative health outcomes can still be avoided.<sup>26</sup> Participants in our study were probably, at least in part, too frail. The baseline disability score in our sample was substantially higher compared to the Dutch general population of those 70 years of age and older.<sup>8</sup> Still, subgroup analyses based on the baseline scores of frailty (pre-planned) and disability (post-hoc) did not reveal other results.

### Ingredients of the PoC approach

With regard to community-based care for frail older people, Dutch policy makers recommend pro-active, client-centred care.<sup>27</sup> Due to the complex healthcare needs of frail older people, care should be delivered by an interdisciplinary team coordinated by a case-manager to ensure integrated care.<sup>27</sup> The importance of these components is supported by the review in this thesis (*Chapter 3*). In addition, we suggested self-management support and engagement in meaningful activities as promising elements for the reduction of disability and prevention of (further) functional decline. It was expected that combining these ingredients would lead to an intervention that is more (cost-) effective than usual care. However, no significant results were found. Due to the complexity of the PoC approach it is difficult to interpret these unexpected results. According to the Medical Research Council (MRC)<sup>28,29</sup> complex interventions 1) have a high number of interacting components, 2) affect behaviour of those delivering and receiving care, 3) target a variety of groups, 4) affect variable outcomes, and 5) need a degree of flexibility and tailoring during implementation. Consequently, active ingredients of the PoC approach could have been limited in their effectiveness by other components. Perhaps the right ingredients were chosen, but the combination led to an approach that was too complex to apply in daily practice resulting in insufficient delivery or receipt by professionals and older people. In addition, it is unclear whether the components of the PoC approach are sufficiently tailored to the needs and preferences of the heterogeneous target group of frail older people. In conclusion, it is not possible to determine whether or not the right ingredients were chosen for the PoC approach and which (combination of) ingredients work better than others.

### Implementation of the PoC approach

Although healthcare professionals in this study appreciated the PoC approach, the process evaluation (*Chapter 5*) has shown that some parts of the protocol were

insufficiently executed. For example, 1) fewer older people than expected were referred to other disciplines; 2) the problem analysis and the development of a treatment plan was often not done within the team of professionals involved; 3) half of the frail older people did not receive a second home visit to discuss their treatment plan or follow-up activities; 4) the toolbox, including guidelines for assessment and treatment and the theoretical models to stimulate behavioural change and self-management, were not frequently applied; 5) the extent of evaluation and follow-up was limited; and 6) healthcare professionals focussed too much on risk factors for disability or existing problems in performing daily activities instead of enhancing meaningful activities. The interviews of the process evaluation provided some reasons for the insufficient implementation of the PoC approach. Professionals mentioned that some parts of the intervention protocol were (too) time-consuming or difficult to apply. They expressed a need for more on the job training and more opportunities to exchange experiences with each other. Despite an extensive development period and a comprehensive training program, we probably failed in providing professionals with the needed competencies, feasible tools or environmental circumstances to apply the PoC approach in daily practice. For example, the development of individualised goals, a prerequisite for tailor-made care and self-management support, is a challenging task, as patients tend to adopt a passive role in goal setting.<sup>30</sup> Tools to facilitate goal-setting might have been useful to add. Furthermore, healthcare professionals are used to focusing their treatment on a single diagnosis.<sup>6</sup> Maybe professionals lack the competencies to deal with multiple, interacting medical and social problems, which characterise frail older people. In addition, the structure of a predominantly reactive healthcare system in the Netherlands<sup>31</sup> may have worked against a proactive approach and the philosophy of healthcare delivery has to be changed first.

## Implications

This thesis results in several implications for practice and future research.

### Practice

First, frail older people are a heterogeneous target group with a great diversity in deficits (i.e., physical, social and psychological), risks and severity of health problems. Interdisciplinary collaboration, client-centeredness, self-management support, engagement in meaningful activities and case management are suggested as relevant ingredients in the scientific literature and recent policy reports to increase the quality of care for frail older people. These recommendations have led to the development of highly complex interventions. However, we have to critically consider



how much complexity healthcare professionals can handle and how to design interventions that are as simple and straightforward as possible.

Second, although an intensive training program was offered, additional time and efforts seem to be necessary to change well-established patterns of care. An initial educational program, review of specific competencies needed and on-going supervision and encouragement to implement new activities are recommended to facilitate the implementation of complex interventions. In addition, changing behaviour requires a comprehensive approach at different levels such as patient, professionals, and environment.<sup>32</sup> Taking into account a socio-ecological model may contribute to the understanding of intrapersonal, interpersonal, environmental and policy factors and may facilitate changes in health behaviour, current care philosophies and care practices.<sup>33</sup> Consequently, successful interventions have to focus on both patients and professionals, while taking into account their environmental circumstances.

Lastly, although no difference in effects between the intervention and control group was found, implementation of the PoC approach results in higher healthcare costs compared to usual care. Consequently, the implementation of the PoC approach, in its current form, is not recommended, at least not in the Netherlands or in other countries with a similar healthcare system. In the Netherlands, standard healthcare is already at a relatively high level. Nearly all people are covered by healthcare insurance, care is easily accessible and its quality is often considered to be good.<sup>34</sup> Consequently, it is difficult to add something to increase the (cost-) effectiveness of current healthcare delivery. Within the Dutch National Care for the Elderly Program, several other projects have focused on community-based care in frail older people as well.<sup>35-38</sup> Despite some variances, the projects have several features in common like screening and assessment, tailor-made treatment, integrated healthcare delivery, and regular monitoring and follow-up. It is not yet clear, whether these projects will provide significant results, but it seems obvious that findings have to be combined in a next step to make final recommendations on how to reduce disability and prevent (further) functional decline in community-dwelling frail older people.

## Research

First, this thesis has shown that more research into the conceptualisation and measurement of frailty is needed. On the one hand it is not known which older people have to be considered as frail and would benefit the most from which intervention. On the other hand, the validity of available screening methods to measure frailty has to be improved. Given the large population which were screened, a two-step approach consisting of a short postal screening followed by a comprehensive in-home assessment has shown to be feasible. However, it is not yet clear which screening instruments (first step) are preferred in identifying frail older people for the second

step. Available screening instruments that could be used for the postal screening have shown not to be sensitive enough for the purpose of screening and diagnosis.<sup>7,8,26</sup> They can be used for the exclusion of non-frail older people rather than for case-findings.<sup>26</sup> An alternative for postal screenings are performance-based measures. For example, modern technologies can be used to measure the performance of older people on a regular basis; this fits the dynamic nature of frailty.<sup>39</sup> Moreover, the combination of self-reported and performance-based measures is also promising, but research in this area is just in the initial stage.

Second, despite a comprehensive process evaluation, which was conducted alongside the trial, it remains questionable whether or not the lack of effects in this study is due to an ineffective intervention or insufficient implementation of the PoC approach. Furthermore, it is not known whether older people in the control group received active ingredients of the PoC approach resulting in insufficient contrasts between the groups and consequently a reduced effect size. It is recommended that in the future more time and efforts is focused on the measurement of treatment fidelity (e.g., by using audio-/ videotaping), in both the intervention and control group to draw accurate conclusions about treatment effectiveness.<sup>40</sup>

Finally, it has to be considered whether or not randomised controlled trials are the most appropriate design to evaluate complex interventions like the PoC approach, in which individual randomisation is inappropriate. One variant of the cluster trial design is the stepped wedge trial design, which is in essence a one-way crossover cluster trial. The stepped wedge trial design requires fewer clusters and maximises statistical power compared with a parallel-group cluster randomised trial design; the intervention effect is estimated not only by between-cluster comparisons but also by within-cluster comparisons. Also, the phased implementation allows for improvement of the intervention or its delivery where necessary before the next implementation phase.<sup>41</sup> It is recommended that in the future when planning a study on complex interventions, these innovative design techniques are considered.

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**Summary**  
**Nederlandse samenvatting**  
**Deutsche Zusammenfassung**  
**Dankwoord | Dankwort**  
**About the author**  
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## Summary

### *Evaluation of the Prevention of Care Approach*

This thesis reports on the evaluation of an interdisciplinary primary care approach for community-dwelling frail older people: the 'Prevention of Care' (PoC) approach. The aim of this approach is to reduce disability and prevent (further) functional decline. The PoC approach consists of six steps: (1) first a *postal screening* for frailty takes place using the Groningen Frailty Indicator (GFI); (2) identified frail older people receive a *comprehensive geriatric assessment* during a home visit by the practice nurse and if indicated additional assessments by other professionals (e.g., occupational therapist or a geriatrician); (3) after the assessment a *preliminary treatment plan* is formulated, either in a bilateral meeting (general practitioner and practice nurse) or in an extended team meeting consisting of a general practitioner, practice nurse, occupational and physiotherapist and, if indicated, other healthcare professionals; (4) during a second home visit by the practice nurse a *final treatment plan* is formulated, including a list of goals, strategies and actions that meet the older person's needs; (5) subsequently, the treatment starts (step 5). The intervention protocol offers a *toolbox* with recommendations and guidelines for the execution of the treatment plan; (6) finally, the achievement of goals and the implementation of strategies in daily life is *evaluated* and appointments for *follow-up* are made (see *Appendix* for a more detailed description of the approach).

*Chapter 1* provides information about the concept of 'frailty' and 'disability' in older people. Furthermore, the relevance of community-based care for frail older people is introduced and recent developments in the Dutch healthcare system are described. The chapter ends with the main objectives of this thesis.

To reduce disability and prevent (further) functional decline frail older people have to be identified in time. Consequently, valid screening instruments are needed. However, the empirical evidence with regard to the psychometric properties of available instruments is scarce. A validation study (*Chapter 2*) was conducted to evaluate and compare three self-report screening instruments: the 'Groningen Frailty Indicator' (GFI), the 'Tilburg Frailty Indicator' (TFI) and the 'Sherbrook Postal Questionnaire' (SPQ). The GFI and the TFI showed high internal consistency and construct validity in contrast to the SPQ. Based on our findings it is not yet possible to conclude whether the GFI or the TFI should be preferred, but the SPQ seems less appropriate.

During the last decades many intervention studies targeting community-dwelling frail older people have been conducted. Although several meta-analyses and systematic

reviews were conducted focusing on specific categories of interventions, mostly in the field of preventive home visiting programmes and physical exercises, no review was available that provides an overview of the full range of existing interventions aimed at community-dwelling frail older people with 'disability' as an outcome measure. Consequently, a narrative review (*Chapter 3*) was conducted to identify and summarise promising components for future intervention programmes that aim to reduce disability and prevent (further) functional decline. Based on the review it is suggested that community-based interventions for frail older people should be conducted by an interdisciplinary primary care team, involving (population) screening, individualised assessments and interventions (tailor-made care), self-management support, engagement in meaningful activities, case management and long-term follow-up. Promising elements identified in the narrative review were combined in the PoC approach.

To evaluate its feasibility, effectiveness and cost-effectiveness a cluster randomised controlled trial was conducted among twelve general practitioner practices, which were randomly allocated to the intervention group (six practices – PoC approach) or control group (six practices – usual care) (*Chapter 4*). A postal questionnaire, including the GFI, was sent to 3,498 of their patients ( $\geq 70$  years) to identify frail older people. The response rate was 80%. Of the older people who were willing to participate, 36% was frail according to the GFI scores ( $GFI \geq 5$ ). Finally, 346 frail older people were included in the trial, which consists of three interrelated sub-studies: a process evaluation, an effect evaluation and an economic evaluation.

First, a comprehensive process evaluation (*Chapter 5*) was conducted using a mixed methods design to provide insight into the extent to which the PoC approach was implemented as intended and to evaluate experiences of healthcare professionals and frail older people regarding benefits, burden, stimulating factors and barriers. Data were collected from participating older people and healthcare professionals. Professionals were satisfied with the PoC approach, as it provided a useful structure for the delivery of geriatric primary care and increased the attention to interdisciplinary cooperation and preventive treatment. Frail older people felt acknowledged by healthcare professionals and experienced support in handling their problems and fulfilling their wishes. Given its complexity, some parts of the intervention protocol were not implemented as planned. The problem analysis and the development of a preliminary treatment plan (step 3) was often not done in a bilateral or an extended team meeting and only half of the treatment plans were discussed with the frail older person (step 4). Also, the toolbox parts were not frequently used in the treatment phase (step 5), and the extent of evaluation and follow-up was limited (step 6).

Second, with regard to disability (primary outcome) and several secondary outcomes, the effectiveness of the PoC approach was evaluated (*Chapter 6*). In the intervention group (6 practices), 193 frail older people received the PoC approach compared to 153 in the control group (6 practices) who received care as usual. The mean age of the total sample was 77.2 years; 58% of the sample was female, 49% was living alone and 58% had a low level of education. At baseline, participants in the intervention group were significantly frailer and more disabled than those in the control group. Patient follow-up rates were 91% at 6 months, 86% at 12 months and 78% at 24 months, with significantly more loss to follow-up in the intervention group. Data on our primary and secondary outcomes were collected after 6, 12 and 24 months. Mixed-model multi-level analyses showed no significant differences between the two groups with regard to all primary (disability) and secondary outcomes (i.e., depressive symptomatology, social support interactions, fear of falling, social participation and quality of life). Pre-planned subgroup analyses confirmed these results. Consequently, no evidence for the effectiveness of the PoC approach was found.

Third, an economic evaluation was conducted to evaluate the cost-effectiveness of the PoC approach (*Chapter 7*). We hypothesised that the programme should lead to reduced disability, improved quality of life and reduced healthcare use and related costs. A cost-effectiveness (CEA) and cost-utility analysis (CUA) were performed from a societal perspective with a time horizon of 24 months. Healthcare utilisation was measured continuously during 24 months. Daily functioning and quality of life were measured at baseline and after 6, 12 and 24 months follow-up. Bootstrap analyses were performed to estimate uncertainty of the findings, and sensitivity analyses were conducted to assess the generalisability of assumptions made. People in the intervention group had significantly more contacts with the practice nurse (5.2 versus 1.1,  $p < 0.001$ ) and had more occupational therapy sessions (7.1 versus 1.2,  $p < 0.001$ ) than older people in the control group. Remaining categories of healthcare utilisation were similar between the groups. Complete cases (56%) were included in the CEA and CUA analyses. Total healthcare costs in the intervention group were €6,503 compared to €0,550 in the control group. Despite these higher costs in the intervention group we found no significant differences between the groups with regard to disability and quality of life.

*Chapter 8* provides a summary and discussion of the main findings, followed by implications for practice and future research.

There is no evidence for the effectiveness and cost-effectiveness of the PoC approach. Possibly the wrong target group was recruited for this study. There is still a lot of discussion in the literature about the concept of frailty and frailty instruments with sufficient psychometric properties are lacking. Another reason might be the



inadequate implementation of the intervention protocol during the study period. Although participating older people and professionals were satisfied with the approach, some parts were not implemented as planned, as professionals experienced difficulties in applying them into daily practice. Multiple and complex healthcare needs of frail older people have to be addressed by complex interventions. However, we have to critically consider how much complexity healthcare professionals can handle and how to design interventions that are as simple and straightforward as possible. Intense training programme are needed to change well-established patterns of care. Consequently, successful interventions have to focus on both patients and professionals, while taking into account their environmental circumstances. Due to a lack of effects and higher costs compared to usual care, the implementation of the PoC approach in its current form is not recommended, at least not in the Netherlands or in other countries with similar healthcare systems. Future research should focus on the conceptualisation and measurement of frailty and (cost-) effective interventions for the target group of community-dwelling frail older people.

In conclusion, the aim of this thesis was to provide evidence for the feasibility, effectiveness and cost-effectiveness of the PoC approach. Although, no positive results were found this thesis provided valuable knowledge with regard to the complexity of interdisciplinary primary care for frail older people and describes methodological challenges in this field of research.

## Samenvatting

### *Evaluatie van Zorg uit Voorzorg*

Dit proefschrift beschrijft de evaluatie van een interdisciplinair eerstelijnsprogramma voor thuiswonende ouderen in een kwetsbare positie: “Zorg uit Voorzorg”. Het doel van dit programma is het reduceren van beperkingen in activiteiten van het dagelijkse leven en het voorkomen van (verdere) functionele achteruitgang. Zorg uit Voorzorg bestaat uit een zestal stappen: (1) eerst vindt een *schriftelijke screening* met behulp van de “Groningen Frailty Indicator” plaats om ouderen in een kwetsbare positie op te sporen; (2) vervolgens krijgen de opgespoorde ouderen tijdens een huisbezoek een *uitgebreid onderzoek* door een praktijkondersteuner en eventueel aanvullende onderzoek door andere disciplines zoals ergotherapeut of geriater; (3) daarna stellen praktijkondersteuner en huisarts samen een *voorlopig plan van aanpak* op. Bij complexe problematiek wordt het team uitgebreid met andere disciplines (bijvoorbeeld fysiotherapeut of ergotherapeut); in dat geval vindt multidisciplinair overleg plaats; (4) de praktijkondersteuner stelt samen met de oudere tijdens een tweede huisbezoek een *definitief plan van aanpak* vast. Dit plan bevat doelen, strategieën en acties die gerelateerd zijn aan een toolbox van interventies. De toolbox bestaat uit een combinatie van medische en meer sociaal (participatie/activiteiten) gerichte interventies. (5) De praktijkondersteuner, huisarts, fysiotherapeut en ergotherapeut zijn bij de *uitvoering* van de *toolbox* onderdelen betrokken. Daarnaast kan een beroep gedaan worden op andere hulpverleners en voorzieningen in de eerste of tweede lijn; (6) het bereiken van doelen en de implementatie van strategieën in het dagelijkse leven worden regelmatig *geëvalueerd* en er worden afspraken gemaakt voor *follow-up* (zie *Appendix* voor een gedetailleerde beschrijving van het programma).

*Hoofdstuk 1* gaat in op de concepten “kwetsbaarheid” en “beperkingen in activiteiten van het dagelijkse leven” bij ouderen. Bovendien wordt het belang van eerstelijnszorg voor ouderen in een kwetsbare positie aangegeven en recente ontwikkelingen in de Nederlandse gezondheidszorg beschreven. Het hoofdstuk eindigt met de hoofddoelstellingen van dit proefschrift.

Om beperkingen in activiteiten van het dagelijkse leven te verminderen en (verdere) functionele achteruitgang te voorkomen, is het van belang om ouderen in een kwetsbare positie tijdig op te sporen. Hiervoor zijn valide screeningsinstrumenten nodig. Tot op heden is er echter weinig wetenschappelijke ondersteuning voor de psychometrische kwaliteit van bestaande instrumenten. Een valideringstudie (*Hoofdstuk 2*) is uitgevoerd om de kwaliteit van drie vragenlijsten te evalueren en te vergelijken: de “Groningen Frailty Indicator” (GFI), de “Tilburg Frailty Indicator” (TFI) en de “Sherbrook Postal

Questionnaire" (SPQ). De GFI en de TFI hebben in vergelijking met de SPQ een hoge interne consistentie en construct validiteit laten zien. De resultaten laten het echter niet toe om eenduidige conclusies te trekken of de GFI of de TFI de voorkeur verdient. Wel kan worden geconcludeerd dat de SPQ minder geschikt is.

In de laatste decennia is er veel onderzoek gedaan naar interventies voor thuiswonende ouderen in een kwetsbare positie. Er zijn diverse meta-analyses en systematische reviews uitgevoerd die zich richten op specifieke categorieën van interventies; het betreft vooral preventieve huisbezoeken en fysieke oefenprogramma's. Echter, er bleek geen studie te zijn die een volledig beeld geeft van bestaande interventies met "beperkingen in activiteiten van het dagelijkse leven" als uitkomstmaat. Daarom is een narratieve review (*Hoofdstuk 3*) uitgevoerd om veelbelovende componenten voor toekomstige interventies te achterhalen, gericht op het verminderen van beperkingen in dagelijkse activiteiten en het voorkomen van (verdere) achteruitgang in functioneren bij ouderen. Gebaseerd op deze review wordt aanbevolen dat toekomstige interventies voor thuiswonende ouderen in een kwetsbare positie uitgevoerd moeten worden door een interdisciplinair eerstelijnssteam. Het programma zou de volgende elementen moeten bevatten: een screening, individueel onderzoek met bijbehorende specifieke interventies (zorg op maat), zelfmanagement ondersteuning, het identificeren en werken aan betekenisvolle activiteiten, casemanagement en lange termijn follow-up. Deze veelbelovende elementen zijn gecombineerd in het programma Zorg uit Voorzorg.

Om de praktische uitvoerbaarheid, effectiviteit en kosteneffectiviteit van Zorg uit Voorzorg te evalueren is er een cluster gerandomiseerd onderzoek uitgevoerd in twaalf huisartspraktijken in de Westelijke Mijnstreek. Deze praktijken zijn at random toegewezen aan de interventiegroep (zes praktijken, Zorg uit Voorzorg) of controlegroep (zes praktijken, reguliere zorg) (*Hoofdstuk 4*). Een schriftelijke screeningslijst, bestaande uit de GFI, is naar 3.498 ouderen ( $\geq 70$  jaar) gestuurd. Het responspercentage was 80%. Van de ouderen die bereid waren om deel te nemen aan het onderzoek, bevonden zich volgens de GFI (GFI $\geq 5$ ) 36% in een kwetsbare positie. Uiteindelijk zijn er 346 ouderen geïncludeerd in het onderzoek dat uit drie samenhangende deelstudies bestaat: een procesevaluatie, een effectevaluatie en een economische evaluatie.

Ten eerste is er een uitgebreide procesevaluatie uitgevoerd (*Hoofdstuk 5*). Een mixed methods design is toegepast om inzicht te verkrijgen in hoeverre Zorg uit Voorzorg volgens protocol is uitgevoerd. Bovendien zijn de ervaringen van hulpverleners en ouderen met het programma geëvalueerd en zijn belemmerende en bevorderende factoren geïnventariseerd. Gegevens voor de procesevaluatie zijn verzameld bij ouderen in de interventiegroep en betrokken hulpverleners. Hulpverleners waren over

het algemeen tevreden over Zorg uit Voorzorg, omdat het een goede structuur geeft aan de invulling van de geriatrische zorg in de eerste lijn en de aandacht verhoogt voor interdisciplinair samenwerken en preventieve zorg. Ouderen in een kwetsbare positie voelden zich begrepen door de hulpverleners en hebben steun ervaren bij het omgaan met hun problemen en het bereiken van betekenisvolle doelen die binnen het programma werden geformuleerd. Door de complexiteit van het interventieprotocol zijn sommige onderdelen echter niet goed gevolgd: (1) de voorlopig plan van aanpak is vaak niet tijdens een bilateraal overleg of een teambijeenkomst besproken (stap 3); (2) slechts de helft van de deelnemende ouderen heeft een tweede huisbezoek ontvangen om het plan van aanpak te bespreken (stap 4); (3) de zogenaamde toolbox onderdelen zijn niet vaak gebruikt (stap 5); en (4) er was sprake van een beperkt aantal evaluatie- en follow-up momenten (stap 6).

Ten tweede zijn de effecten van het programma Zorg uit Voorzorg op beperkingen in activiteiten van het dagelijkse leven (primaire uitkomstmaat) en diverse secundaire uitkomstmaten onderzocht (*Hoofdstuk 6*). In de interventiegroep (zes praktijken) hebben 193 ouderen het programma Zorg uit Voorzorg ontvangen. Deze zijn vergeleken met 153 ouderen in de controlegroep die reguliere zorg ontvingen. De gemiddelde leeftijd van de gehele onderzoeksgroep was 77,2 jaar; 58% was vrouw, 49% was alleenstaand en 58% had een lage opleiding. Bij de start van het onderzoek waren ouderen in de interventiegroep gemiddeld meer kwetsbaar en beperkt dan ouderen in de controlegroep. Na 6 maanden nam 91% van de ouderen nog deel aan het onderzoek, na 12 maanden was het percentage 86% en na 24 maanden 78%, met significant meer uitval in de interventiegroep. Gegevens betreffende de primaire en secundaire uitkomstmaten zijn verzameld na 6, 12 en 24 maanden. Uit de resultaten blijkt dat er geen significante verschillen zijn tussen de groepen met betrekking tot alle primaire (beperkingen in activiteiten van het dagelijkse activiteiten) en secundaire uitkomstmaten (depressieve symptomen, sociale steun interacties, bezorgdheid om te vallen, sociale participatie en kwaliteit van leven). De vooraf geplande subgroep analyses laten geen andere bevindingen zien. Er kan worden geconcludeerd dat er voor deze uitkomsten geen empirisch bewijs is voor de effectiviteit van Zorg uit Voorzorg.

Ten derde is een economische evaluatie uitgevoerd om de kosteneffectiviteit van Zorg uit Voorzorg te evalueren (*Hoofdstuk 7*). De aanname vooraf was dat het programma zou leiden tot minder beperkingen in activiteiten van het dagelijkse leven, een hogere kwaliteit van leven en over het geheel genomen minder gebruik van zorg en gerelateerde kosten. Vanuit een maatschappelijk perspectief met een tijdshorizon van 24 maanden zijn er kosten-effectiviteitsanalyses (KEA) en kosten-utiliteitsanalyses (KUA) uitgevoerd. Zorggebruik is gedurende een periode van 24 maanden

geregistreerd. Beperkingen in activiteiten van het dagelijkse leven en kwaliteit van leven zijn gemeten aan het begin van de studie en na 6, 12 en 24 maanden. Bootstrap analyses zijn uitgevoerd om de onzekerheid rondom de resultaten te schatten. Bovendien zijn er sensitiviteitsanalyses gedaan om de generaliseerbaarheid van de gemaakte aannames te onderzoeken. Ouderen in de interventiegroep hadden significant meer contacten met de praktijkondersteuner (5,2 contacten versus 1,1 contacten,  $p < 0,001$ ) en gebruikten ook significant meer ergotherapie (7,1 sessies versus 1,2 sessies,  $p < 0,001$ ) dan ouderen in de controlegroep. Het gebruik van andere typen zorg was vergelijkbaar tussen de twee groepen. Alleen de ouderen voor wie alle gegevens gedurende de 24 maanden beschikbaar waren (56%) zijn geïnccludeerd in de KEA en KUA analyses. De totale kosten voor het gebruik van zorg bedroegen per persoon €6.503 in de interventiegroep en €0.550 in de controlegroep. Er zijn geen significant verschillen tussen de groepen gevonden met betrekking tot beperkingen in activiteiten van het dagelijkse leven en kwaliteit van leven.

*Hoofdstuk 8* bevat de conclusies van het onderzoek, evenals een discussie van de bevindingen. Tevens worden aanbevelingen voor de praktijk en toekomstig onderzoek geformuleerd.

Er is geen empirisch bewijs voor de effectiviteit en kosteneffectiviteit van Zorg uit Voorzorg. Een verklaring zou kunnen zijn dat niet de goede doelgroep voor het onderzoek gerekruteerd is. Er is nog steeds veel onduidelijkheid rondom het begrip kwetsbaarheid en meetinstrumenten op dit terrein met goede psychometrische eigenschappen zijn nog onvoldoende voorhanden. Maar het ontbreken van effecten zou ook te maken kunnen hebben met onvoldoende implementatie van Zorg uit Voorzorg tijdens de onderzoeksperiode. Ofschoon de deelnemende ouderen en hulpverleners over het algemeen tevreden waren over het programma, zijn sommige onderdelen van het protocol niet goed uitgevoerd, omdat ze als moeilijk toepasbaar ervaren zijn. De meervoudige en complexe zorgbehoeftes van ouderen in een kwetsbare positie vragen om complexe interventies. Echter, een punt van aandacht blijft de vraag hoeveel complexiteit hulpverleners aan kunnen en hoe interventies op een zo eenvoudig mogelijke wijze kunnen worden aangeboden. Er is een behoefte aan intensieve scholingsprogramma's om gevestigde patronen van zorgverlening te veranderen. Als gevolg zouden succesvolle interventies zich moeten richten op zowel ouderen als hulpverleners rekening houdend met de fysieke en sociale omgeving waar ouderen in verblijven en hulpverleners in werken. Gezien er geen effecten op de primaire en secundaire uitkomstmaten gevonden zijn en Zorg uit Voorzorg geleid heeft tot meer (zorg-) kosten, wordt aanbevolen om het programma in de huidige vorm niet te implementeren. Dit geldt in ieder geval voor Nederland of andere landen met een vergelijkbaar gezondheidszorgsysteem. Toekomstig onderzoek zou zich eerst moeten richten op het conceptualiseren en het meten van kwetsbaarheid en

(kosten-) effectieve interventies voor de doelgroep of thuiswonende kwetsbare ouderen.

Concluderend: het doel van dit proefschrift was het genereren van empirisch bewijs voor de praktische toepasbaarheid, effectiviteit en kosteneffectiviteit van het programma Zorg uit Voorzorg. Ofschoon er met betrekking tot (kosten-) effectiviteit geen positief bewijs is gevonden, heeft het onderzoek waardevolle inzichten opgeleverd waar het gaat om de complexiteit van interdisciplinaire eerstelijnszorg voor ouderen in een kwetsbare positie. Tevens zijn verschillende methodologische uitdagingen geformuleerd.

## Zusammenfassung

### *Evaluation des „Prevention of Care“ Ansatzes*

Die vorliegende Dissertation beschreibt eine cluster-randomisierte Interventionsstudie in der ein interdisziplinärer ambulanter Versorgungsansatz für gebrechliche ältere Menschen evaluiert wird: der „Prevention of Care“ (PoC) Ansatz. Zielsetzung dieses Versorgungsansatzes ist zum einen, bestehende funktionelle Einschränkungen, die mit der Gebrechlichkeit einhergehen, zu reduzieren und zum anderen, (weiteren) Einschränkungen vorzubeugen, sodass ältere Menschen trotz ihrer Gebrechlichkeit die Anforderungen des alltäglichen Lebens meistern und länger in ihrem gewohnten Lebensumfeld verbleiben können.

Der PoC-Ansatz besteht aus sechs Schritten: (1) im ersten Schritt findet ein *Gebrechlichkeits-Screening* statt. Ältere Menschen ( $\geq 70$  Jahre) erhalten per Post einen schriftlichen Fragebogen, den „Groningen Frailty Indicator“; (2) Personen, die als gebrechlich identifiziert wurden, werden während eines Hausbesuches einer *ausführlichen Diagnostik* unterzogen, die durch die medizinische Fachangestellte des Hausarztes („practice nurse“) ausgeführt wird. Bei Bedarf können diagnostische Verfahren durch andere medizinische Fachkräfte erfolgen (z.B. Ergotherapeuten oder Geriater); (3) danach erstellen der Hausarzt und die medizinische Fachangestellte gemeinsam einen *vorläufigen Behandlungsplan*. Bei komplexen Problemen werden andere medizinische Fachkräfte hinzugezogen (z.B. Physiotherapeuten, Ergotherapeuten oder Apotheker). In diesem Fall findet eine interdisziplinäre Teambesprechung statt; (4) im vierten Schritt besucht die medizinische Fachangestellte den Patienten ein zweites Mal, um einen *definitiven Behandlungsplan* zu erstellen. Der Behandlungsplan beinhaltet Ziele, Strategien und Handlungsempfehlungen. Für die Behandlung steht eine Toolbox mit Interventionen zur Verfügung. (5) Die *Toolbox*-Interventionen werden im nächsten Schritt je nach Bedarf durch die Medizinische Fachangestellte, den Physiotherapeuten, den Ergotherapeuten oder den Hausarzt ausgeführt. Zudem können andere medizinische Fachangestellte und Institutionen konsultiert werden; (6) abschließend wird das Erreichen der Behandlungsziele und die Umsetzung der Strategien ins alltägliche Leben *evaluiert*. Außerdem werden Absprachen hinsichtlich der *Nachsorge* getroffen (siehe *Appendix* für eine detaillierte Beschreibung des PoC-Ansatzes).

In *Kapitel 1* werden die Konzepte der „Gebrechlichkeit“ und der „funktionellen Beeinträchtigungen“ erläutert. Des Weiteren wird die Bedeutung der ambulanten Versorgung gebrechlicher älterer Menschen thematisiert, die es ihnen ermöglichen soll, trotz ihrer Gebrechlichkeit die Anforderungen des alltäglichen Lebens zu meistern

und in ihrem gewohnten Lebensumfeld zu verbleiben. Zudem werden gegenwärtige Entwicklungen im Niederländischen Gesundheitswesen beschrieben. Das Kapitel endet mit einer Beschreibung der Hauptzielsetzungen dieser Dissertation.

Um bestehende funktionelle Einschränkungen, die mit der Gebrechlichkeit einhergehen, zu reduzieren und (weiteren) Einschränkungen vorzubeugen, müssen gebrechliche ältere Menschen frühzeitig identifiziert werden. Hierfür werden valide Screenings Instrumente benötigt. Es gibt jedoch kaum empirische Grundlage hinsichtlich der psychometrischen Eigenschaften bestehender Instrumente. In einer Validationsstudie (*Kapitel 2*) wurden die Eigenschaften dreier Fragebögen evaluiert und miteinander verglichen: der „Groningen Frailty Indicator“ (GFI), der „Tilburg Frailty Indicator“ (TFI) und der „Sherbrook Postal Questionnaire“ (SPQ). Dem GFI- und TFI-Fragebogen sind im Vergleich zum SPQ-Fragebogen eine hohe interne Konsistenz- und Konstruktvalidität zu zuschreiben. Es bleibt jedoch unklar, ob GFI oder TFI bevorzugt werden sollten. Lediglich der SPQ-Fragebogen scheint weniger angemessen zu sein.

In den letzten Jahrzehnten wurden zahlreiche Interventionsstudien bei gebrechlichen älteren Menschen durchgeführt. Obschon einige Meta-Analysen und systematische Reviews erschienen sind, richten sich diese zumeist auf spezifische Interventionskategorien, meistens im Bereich von physischen Trainingsprogrammen oder präventiven Hausbesuchen. Es gab keine Literaturstudie, welche die gesamte Bandbreite an ambulanten Interventionen zur Behandlung von funktionellen Einschränkungen widerspiegelt. Demzufolge wurde ein narrativer Review ausgeführt (*Kapitel 3*) um vielversprechende Komponenten für zukünftige Interventionen herauszufiltern. Basierend auf diesem Review sollte ein ambulanter Versorgungsansatz für gebrechliche ältere Menschen der durch ein interdisziplinäres Team angeboten wird, entwickelt werden. Des Weiteren scheinen ein Gebrechlichkeits-Screening, individuelle Diagnostik und Interventionen, Unterstützung bei Selbstmanagement, Betätigung in bedeutungsvollen Aktivitäten, Case Management und Langzeitnachsorge vielversprechende Komponenten zu sein. Diese Komponenten wurden im PoC Ansatz vereinigt.

Um die praktische Ausführbarkeit, Effektivität und Kosteneffektivität des PoC Ansatzes zu evaluieren wurde eine cluster-randomisierte Interventionsstudie in zwölf Hausarztpraxen in Sittard (NL) und Umgebung ausgeführt. Die Praxen wurden per Zufall der Interventionsgruppe (sechs Praxen, PoC Ansatz) oder Kontrollgruppe (sechs Praxen, reguläre Versorgung) (*Kapitel 4*) zugeteilt. Ein schriftlicher Fragenbogen (GFI) wurden an 3.498 ältere Menschen ( $\geq 70$  Jahre) verschickt. Die Antwortrate des schriftlichen Screenings war 80%. Von den Personen, die bereit waren an der Studie teilzunehmen, waren laut des GFI-Fragebogens (GFI $\geq 5$ ) 36% gebrechlich. Letztendlich haben 346

gebrechliche ältere Menschen an der Studie teilgenommen, die aus drei Teilstudien besteht: einer Prozessevaluation, einer Effektivitätsstudie und einer ökonomischen Evaluation.

Als erstes, wurde mit Hilfe eines Mixed Methods Design eine umfassende Prozessevaluation ausgeführt (*Chapter 5*) um zu beurteilen, ob bei der Anwendung des PoC-Ansatz gemäß Protokoll ausgeführt wurde. Des Weiteren wurden die Erfahrungen der gebrechlichen älteren Menschen und des interdisziplinären Teams (Hausärzte, medizinischen Fachangestellten, Physiotherapeuten und Ergotherapeuten) im Hinblick auf unterstützende und hinderliche Faktoren evaluiert. Das interdisziplinäre Team war im Allgemeinen zufrieden mit dem PoC-Ansatz, da er eine gute Struktur für die ambulante geriatrische Versorgung bot und zudem die Aufmerksamkeit bezüglich interdisziplinärer Zusammenarbeit und Prävention erhöhte. Teilnehmende gebrechliche ältere Menschen fühlten sich verstanden und haben Unterstützung bei dem Erreichen ihrer Ziele erfahren, die im Rahmen des PoC-Ansatzes erstellt wurden. Durch die Komplexität des Interventionsprotokolls wurden manche Aspekte der Intervention nicht wie gewünscht ausgeführt: (1) der vorläufige Behandlungsplan wurde oftmals nicht während eines Teammeetings besprochen (Schritt 3); (2) nur die Hälfte der gebrechlichen älteren Menschen haben einen zweiten Hausbesuch erhalten um den definitiven Behandlungsplan zu besprechen (Schritt 4); (3) die sogenannte Toolbox wurde nicht oft angewendet (Schritt 5); und (4) es gab nur wenige Evaluations- und Nachsorgemomente (Schritt 6).

Als Zweites, wurden die Effekte des PoC Ansatzes im Hinblick auf funktionelle Beeinträchtigungen (primärer Endpunkt) und diverse sekundäre Endpunkte untersucht (depressive Symptome, soziale Unterstützung, Angst vor dem Fallen, soziale Partizipation und Lebensqualität) (*Kapitel 6*). In der Interventionsgruppe (sechs Praxen) wurden 193 gebrechliche ältere Menschen nach dem PoC-Ansatz behandelt. Diese wurden verglichen mit 153 gebrechlichen älteren Menschen in der Kontrollgruppe, die die reguläre Versorgung erhielten. Das durchschnittliche Alter der gesamten Stichprobe war 77,2 Jahre, 58% waren weiblich, 49% waren alleinstehend und 58% hatten eine niedrige Schulbildung. Zu Beginn der Studie waren die gebrechlichen älteren Menschen in der Interventionsgruppe im Durchschnitt gebrechlicher und funktionell mehr beeinträchtigt als die Personen in der Kontrollgruppe. Nach 6 Monaten nahmen noch 91% der gebrechlichen älteren Menschen an der Studie teil, nach 12 Monate war der Prozentsatz auf 86% und nach 24 Monaten auf 78% gesunken, wobei in der Interventionsgruppe signifikant mehr Menschen die Studie frühzeitig beendet haben als in der Kontrollgruppe. Daten im Hinblick auf die primären und sekundären Endpunkte sind zu Beginn und nach 6, 12 und 24 Monaten erhoben worden. Basierend auf den Ergebnissen dieser Studie gab es keine signifikanten



Unterschiede zwischen den Gruppen bezüglich aller primären und sekundären Endpunkte. Die vorab geplanten Subgruppenanalysen verifizieren diese Ergebnisse. Auf Grund dessen ist die Schlussfolgerung, dass es keinen empirischen Beweis für die Effektivität des PoC-Ansatzes gibt.

Als drittes wurde eine ökonomische Evaluation durchgeführt um die Kosteneffektivität des PoC-Ansatzes zu beurteilen (*Kapitel 7*). Es wurde angenommen, dass der PoC-Ansatz funktionelle Beeinträchtigung reduziert und die Lebensqualität erhöht. Zudem sollte er im Allgemeinen die Inanspruchnahme von Versorgungsleistungen reduzieren und folglich geringere Kosten verursachen. Es wurde eine Kosten-Wirksamkeits-Analyse und Kosten-Nutzwert-Analyse ausgeführt, für diese Analyse wurde eine gesellschaftliche Perspektive und ein Zeitrahmen von 24 Monaten gewählt. Hierfür wurde in beiden Gruppen die Inanspruchnahme der Versorgungsleistungen in der 24-monatigen Studienperiode registriert. Daten bezüglich der funktionellen Beeinträchtigungen und Lebensqualität wurden zu Beginn der Studie, nach 6, 12 und 24 Monaten erhoben. Zur Validierung der Ergebnisse wurde eine Bootstrap Analyse angewendet. Mit Hilfe von Sensitivitätsanalysen wurde die Generalisierbarkeit der gemachten Annahmen evaluiert. Die ökonomische Evaluation zeigte, dass gebrechliche ältere Menschen in der Interventionsgruppe signifikant mehr Kontakte mit medizinischen Fachangestellten (5,2 Kontakte versus 1,1 Kontakte,  $p < 0,001$ ) und Ergotherapeuten (7,1 Einheiten versus 1,2 Einheiten,  $p < 0,001$ ) hatten als die Personen aus der Kontrollgruppe. Die Inanspruchnahme anderer Versorgungsformen war vergleichbar zwischen den Gruppen. Die gebrechlichen älteren Menschen, bei denen ein vollständiger Datensatz vorlag (56%), wurden in die Kosten-Wirksamkeits- und Kosten-Nutzwert-Analysen inkludiert. Die totalen Versorgungskosten in 24 Monaten waren pro Kopf 26.503 in der Interventionsgruppe und 20.550 in der Kontrollgruppe. Es gab keine signifikanten Unterschiede hinsichtlich funktioneller Beeinträchtigung und Lebensqualität.

*Kapitel 8* beinhaltet die Schlussfolgerungen dieser Studie und eine Diskussion der Ergebnisse. Außerdem werden Handlungsempfehlungen für die Praxis und zukünftige Studien ausgesprochen.

Es gibt keine empirischen Beweise für die Effektivität und Kosteneffektivität des PoC-Ansatzes. Möglicherweise wurde in der vorliegenden Studie nicht die richtige Zielgruppe für den gewählten Ansatz rekrutiert. Dies kann unter anderem damit zusammenhängen, dass in der Fachliteratur noch nicht klar definiert ist was unter dem Begriff der Gebrechlichkeit verstanden wird. Des Weiteren sind Gebrechlichkeits-Instrumente mit guten psychometrischen Eigenschaften nur unzureichend vorhanden. Jedoch kann das Fehlen von Effekten auch mit der mangelhaften Umsetzung des PoC-Ansatzes während der Studienperiode zusammenhängen. Obwohl die

teilnehmenden gebrechlichen älteren Menschen und das interdisziplinäre Team im Allgemeinen mit dem PoC-Ansatz zufrieden waren, wurden einige Aspekte des Protokolls nicht wie gewünscht ausgeführt, da sie in ihrer praktischen Handhabung als schwierig empfunden wurden. Die Anzahl und Komplexität der Versorgungsbedarfe gebrechlicher älterer Menschen erfordert komplexe Interventionen. Jedoch bleibt es fraglich, wie viel Komplexität durch medizinische Fachkräfte umgesetzt werden kann und wie Interventionen so einfach wie möglich gestaltet werden können. Es gibt einen Bedarf an intensiven Fortbildungsprogrammen um gefestigte Routinen in der Versorgung zu verändern.

Da hinsichtlich der primären und sekundären Endpunkte keine Effekte gefunden werden konnten wird empfohlen, den PoC-Ansatz in der heutigen Form nicht in der Praxis einzuführen. Diese Empfehlung gilt zumindest für die Niederlande und andere Länder mit vergleichbaren Gesundheitssystemen. Zukünftige Studien sollten sich mit dem Konzept der Gebrechlichkeit und der Validierung von Gebrechlichkeits-Instrumenten beschäftigen. Zudem werden (kosten-) effektive ambulante Versorgungsansätze für gebrechliche ältere Menschen benötigt, um ihnen zu ermöglichen, dass sie die Anforderungen des alltäglichen Lebens meistern und länger in ihrem gewohnten Lebensumfeld verbleiben können.

Zusammenfassend: Das Ziel dieser Dissertation war es, empirische Beweise für die Ausführbarkeit, Effektivität und Kosteneffektivität des PoC-Ansatzes zu erbringen. Obschon hinsichtlich der (Kosten-) Effektivität keine positiven Resultate gefunden wurden, ergeben sich aus dieser Studie wertvolle Einblicke in die Komplexität der interdisziplinären ambulanten Versorgung gebrechlicher älterer Menschen. Des Weiteren werden verschiedene methodologische Herausforderungen beschrieben.

## Dankwoord | Dankwort

De laatste loodjes wegen het zwaarst ... volgens mij geldt dit in het bijzonder voor het schrijven van een dankwoord. De afgelopen jaren ben ik veel mensen tegen gekomen, die interesse in mijn onderzoek getoond hebben, me gemotiveerd en gesteund hebben en die tijd en energie in dit onderzoek gestoken hebben. Iedereen heeft op zijn of haar eigen manier, een steentje bijgedragen aan de totstandkoming van dit proefschrift. Mijn dank hiervoor!

Graag wil ik een aantal mensen persoonlijk bedanken.

Allereerst de deelnemers aan dit onderzoek: ouderen, mantelzorgers, huisartsen, praktijkondersteuners, ergotherapeuten en fysiotherapeuten. Zonder jullie bereidheid om mee te werken aan dit onderzoek was dit proefschrift er nooit gekomen.

Vervolgens zou ik graag mijn promotoren Ruud Kempen en Luc de Witte, en co-promotor Erik van Rossum willen danken. Voor mij waren jullie het perfecte promotieteam. Iedereen heeft vanuit zijn expertise input geleverd aan dit proefschrift. Hierbij hebben jullie elkaar uitstekend aangevuld. Vanaf het begin waren jullie een bron van inspiratie voor mij en gedurende het heel traject heb ik veel van jullie mogen leren. Ook hebben we vaak gelachen tijdens onze driewekelijkse overleggen, wat heb ik hiervan genoten! Beste Ruud, het is ongeveer 6 jaar geleden dat ik als fris afgestudeerde HBO student voor het eerst bij je binnenliep, maar met je hartelijke karakter en je aanmoedigende woorden wist je snel mijn onzekerheid weg te nemen. Je wetenschappelijke deskundigheid, je persoonlijke gedrevenheid, en je oog voor detail zijn eigenschappen die ik heel erg waardeer. Bovendien staat je deur altijd open wat niet vanzelfsprekend is bij zulke drukbezette mensen. Dankjewel voor je grote inzet, je vertrouwen in mij en dat je me de mogelijkheden biedt om me steeds verder te ontwikkelen. Beste Luc, als tweede promotor heb je de grote lijnen bewaakt en met je frisse en kritische blik wist je vaak een draai aan onze discussies te geven en de puntjes op de "i" te zetten. Mijn dank hiervoor. Beste Erik, vanaf het eerste uur heb je me – toen nog masterstudente en later promovendi – ontzettend goed begeleid. Jouw feedback was altijd helder en constructief en je wiste het zo te brengen dat ik nooit met een slecht gevoel naar buiten ging. Ik waardeer je pragmatische aanpak die gepaard gaat, met belangstelling voor wetenschap en praktijk en een grote portie humor. Erik en Ruud, ik ben heel erg blij dat we ook in komende jaren ons werk kunnen voortzetten. Luc, we zullen ons beslist blijven zien en wie weet misschien staat ooit weer een gemeenschappelijk project op ons te wachten.

Mijn dank gaat ook uit naar de leden van mijn projectgroep/ co-auteurs, die een belangrijke bijdrage hebben geleverd aan dit proefschrift: Sjoerd Hobma, Walther Sipers, Herbert Habets, Lilo Crasborn, Simone Denis, Marlou Wolters, Ton Ambergen, Karen Cox, Marike Hendriks en Ramon Daniëls. Beste Ramon, na de opleiding ergotherapie heb je me de weg naar de Universiteit Maastricht gewezen. Vervolgens gaf je me tijdens mijn masteropleiding de kans om als studentassistent een kijkje in de 'onderzoekskeuken' te nemen. Je was niet alleen nauw betrokken bij mijn masteronderzoek, maar ook later heb je als lid van de projectgroep altijd enthousiasme en betrokkenheid getoond. Beste Marike, jouw inzet bij de economische evaluatie was buitengewoon. Het artikel over zorggebruik en kosten was een beetje mijn zorgen-kindje, maar dankzij jouw voortdurende inzet en motivatie is er uiteindelijk een mooi artikel tot stand gekomen. Je stond me altijd met raad en daad terzijde en dat waardeer ik zeer! Beste Sjoerd, Walther, Herbert, Lilo, Simone en Marlou, geen veldonderzoek zonder mensen die dicht bij de praktijk staan. Jullie hebben ontzettend veel inspanningen verricht om dit project van de grond te krijgen en de boel draaiende te houden. Ton, bedankt voor hulp en adviezen bij de statistische analyses. Karen, mijn dank voor je steun bij de kwalitatieve data verzameling en analyse.

Beste collega's van de vakgroep Health Services Research, bedankt voor jullie belangstelling in mijn proefschrift, jullie constructieve feedback op mijn werk tijdens diverse refereerbijeenkomsten, de leuke gesprekken op de wandelgangen en de gezellige momenten tijdens uitstapjes en congresbezoeken. Beste Bart, beste Jill, sinds 2009 deelden we niet alleen een werkkamer, maar ook lief en leed. Jullie hadden altijd een luisterend oor en stonden me met goede adviezen ter zijde. Met een lach en een traan kijk ik uit naar onze promoties. Ik ben blij dat we het voor elkaar gekregen hebben om allemaal binnenkort te promoveren, maar ik ga jullie ook ontzettend missen op Dub30! Een belangrijke bron van steun was ook ons team van onderzoeksassistenten: Ine Hesdahl, Astrid Dello en Floor Komen. Samen met Bart en Jill vormden we het 'Tp1 team'. De dataverzameling stelde ons voor veel logistieke uitdagingen, maar met zijn vijven wisten we alles tot een goed einde te brengen. Bovendien was het in ons team ontzettend gezellig – ook buiten het werk. Ik kijk terug op diverse leuke avonden in Maastricht, Aken of Mönchengladbach. Beste Bart, Jill, Ine, Astrid en Floor, bedankt voor deze mooie momenten en de prettige samenwerking in de afgelopen jaren.

Bij de dataverzameling waren ook enige 'externe partners' betrokken, die belangrijk werk hebben verricht. Wilma Krämer, bedankt dat je in de registratie van Orbis Medisch Centrum bent gedoken om voor de deelnemers van onze studie de gegevens met betrekking tot ziekenhuisopnames en poliklinische bezoeken op te zoeken. Dank gaat ook uit naar Rob Doktor en Daniëlle Baenen van CZ, Herm Jan Mateboer en

Gerard Timmermans van Achmea en Marc Korzilius van VGZ. Jullie hebben de gegevens met betrekking tot het eerstelijns zorggebruik voor jullie rekening genomen. Beste medewerkers van MEMIC, in het bijzonder Marlène Ronner, Alfons Schroten en Anita Legtenberg, bedankt voor jullie hulp bij de logistiek rondom de dataverzameling en het afnemen respectievelijk invoeren van talrijke telefonische interviews en vragenlijsten.

Ook wil ik de leden van de beoordelingscommissie van dit proefschrift hartelijk danken voor het lezen en beoordelen van dit proefschrift: prof. dr. T. van der Weijden, prof. dr. med. A. Stuck, prof. dr. M. Schuurmans, prof. dr. C. Dirksen, onder voorzitterschap van prof. dr. J. Metsemakers.

Mijn dank gaat ook uit naar ZonMw, NWO, the School for Public Health and Primary Care (CAPHRI) en Zuyd Hogeschool voor het financieren van deze studie, diverse open-access publicaties en een verblijf in het buitenland gedurende mijn promotietraject.

Liebe Nicole, Eva, Rosalie, Sabrina D., Frauke, Jessica, Sabrina Z., Steffi, Moni und Ania, vielen Dank für Eure langjährige Freundschaft. Die meisten von Euch kenne ich schon fast mein ganzes Leben und ich weiß es unheimlich zu schätzen, dass unsere Freundschaft über all die Jahre hinweg Bestand hat. Ich möchte Euch von Herzen danken für das Interesse in meine Arbeit, die aufmunternden Worte und Eure langjährige Freundschaft. Ich kann es kaum erwarten mit Euch anzustoßen und diesen Meilenstein in meinem Leben zu feiern!

Liebe Mama, lieber Papa, mit Stolz schaue ich auf Euer Leben. Seit nunmehr 40 Jahre geht ihr durch dick und dünn und meistert alle Lebenslagen. Euer Lebensziel war es immer, Christina und mir einen guten Start in ein eigenständiges Leben zu ermöglichen. Hierfür habt ihr hart gearbeitet und auf vieles verzichtet und dies sollte sich letztendlich auszahlen. Sowohl Christina als auch ich haben unseren Weg gefunden und unser Erfolg ist Euer Erfolg, denn ohne Euch wäre das niemals möglich gewesen. Ich danke Euch, für Eure Liebe, Euren Zuspruch und Eure Unterstützung! Liebe Christina, auch wenn wir uns manchmal streiten wie die Kesselflicker weiß ich, dass ich mich zu 100% auf Dich verlassen kann. Es ist schön solche Menschen um sich zu wissen. Du wirst immer meine kleine-große Schwester bleiben! Ich hab Dich ganz doll lieb und bin froh, dass es Dich gibt! Lieber Arif, danke für Deine Hilfsbereitschaft in allen Lebenslagen.

Liebe Marlies, lieber Laurenz, liebe Sandra, vielen Dank für Euer Interesse in meine Arbeit. Mit Eurer herzlichen Art habt ihr mich immer willkommen geheißen im Hasenwald und ich fühle mich sehr, sehr wohl bei Euch!

Lieber Swen, dir sollen die letzten Worte meines Dankwortes zuteil werden. Ich möchte Dir für die letzten sechs Jahre danken in denen Du immer für mich da warst und mich unterstützt hast. Nie zuvor habe ich einen Menschen kennengelernt, der so bescheiden, ehrlich, hilfsbereit und liebenswürdig ist wie Du. Kurzum du hast das Herz am rechten Fleck und dafür liebe ich Dich. Ich bin froh Dich an meiner Seite habe. In Liebe, Silke!

## About the author

Silke Friederike Metzelthin was born on 5th May 1983 in Würselen (Germany). She attended the secondary school (Gymnasium) in Herzogenrath (Germany). After her graduation she studied Occupational Therapy at Zuyd University of Applied Sciences in Heerlen (the Netherlands). Her bachelor thesis was about the development of a self-management program for community-dwelling older people. After obtaining her bachelor's degree in June 2009, she followed the Health Sciences Research Master at Maastricht University (the Netherlands). At the same time she worked as student assistant at the Department of Health Services Research at Maastricht University. Her master thesis was about the validation of three frailty instruments. During the master she also developed a research proposal for a randomised controlled trial studying the feasibility, effectiveness and cost-effectiveness of an interdisciplinary primary care approach for community-dwelling frail older people. The proposal was approved by the Dutch Organisation for Health Research and Development (ZonMw) (grant number #60-61900-98-213). Consequently, in August 2009 she has started as a PhD student on this research project under supervision of prof. dr. Ruud Kempen, prof. dr. Luc de Witte and dr. Erik van Rossum.

In December 2012, Silke has received a travel grant awarded by Maastricht University, CAPHRI School for Public Health and Primary Care. Consequently, she visited Johns Hopkins University in Baltimore for nine weeks to work together with dr. Sarah Szanton and prof. dr. Laura Gitlin.

In April 2013, Silke has applied successfully for the 12 months Kootstra Talent Fellowship for future postdocs, awarded by Maastricht University. Her aim was to develop a community-based care approach for frail older people based on a philosophy of Function-Focused Care, a care philosophy developed by prof. dr. Barbara Resnick and colleagues from the University of Maryland. Within this philosophy caregivers learn to actively help older adults to achieve and maintain their highest level of function based on the theory of self-efficacy, while taking into account environmental and policy issues. At the same time Silke worked successfully with Dutch colleagues from Maastricht University, UMC St Radboud, and UMC Utrecht on a proposal for a research line to improve basic nursing care. Part of this ZonMw funded research line (grant number #80-80705-98-025) is an exploratory trial investigating the feasibility and effectiveness of a Function-Focused Care approach. Consequently, Silke has started in January 2014 as a postdoctoral researcher at the Department of Health Services Research at Maastricht University. During the upcoming four years she will focus on the development and evaluation of a community-based care approach for frail older people, which is based on the philosophy of Function-Focused Care.

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# Appendix

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## **A disability prevention programme for community-dwelling frail older people**

### **This chapter was published as:**

Daniëls, R, van Rossum, E, Metzelthin, S, Sipers, W, Habets, H, Hobma, S,  
van den Heuvel, W, de Witte, L  
Clinical Rehabilitation;25(11):963-974

## Abstract

**Objective:** To describe and justify a interdisciplinary primary care programme for community-dwelling frail older people aimed to prevent disability.

**Background:** Disability is a negative outcome of frailty among older people. Policy reports and research studies emphasise the need for programmes to reduce disability progression. Between 2008 and 2010 we developed such a programme.

**Development:** Following the Intervention Mapping protocol, a research team and a multidisciplinary task group developed the programme. Literature reviews and an expert meeting led to identification of basic elements, theory based methods and practical tools.

**The programme:** The general practitioner and the practice nurse comprise the core team that can be extended by other professionals such as the occupational and physiotherapist. The programme includes six steps: (1) screening, (2) assessment, (3) analysis and preliminary action plan, (4) agreement on action plan, (5) execution of the action plan (toolbox parts), and (6) evaluation and follow-up. The main features are: identifying risks for developing disability and targeting risk factors using professional standards and the 5A Behavioural Change Model to support self-management, and identifying problems in performing activities and enhancing meaningful activities based on the Model of Human Occupation. Screening and individual assessment, tailor-made and client-centred care, self-management support, case management and interdisciplinary cooperation are important principles in delivering the programme.

**Discussion:** The disability prevention programme seems promising for addressing the needs of frail older people for independent living and for targeting risk factors. Its feasibility and effects are being tested in an on-going randomised controlled trial.

## Introduction

The rising number of frail older people poses various challenges for the public healthcare system.<sup>1</sup> Frail older people are recognised as being at risk of adverse outcomes such as death, falls, hospitalisation and institutionalisation.<sup>2</sup> Disability, defined as experiencing difficulty in performing activities in any domain of life<sup>3</sup> is another negative outcome of frailty. Being independent and participating in society have great value for older people.<sup>4</sup>

Supporting older people to live independently and participate in society are key policy targets for the Dutch government.<sup>5</sup> Disability prevention for older people, in contrast to disease prevention, has recently been addressed by the Dutch Health Council<sup>6</sup> as function-oriented prevention. The Council emphasises the necessity for development and evaluation of tailor-made interventions that focus on promoting independent functioning in daily life for (vulnerable) older people with an important role for primary care, screening of vulnerable groups, and multidisciplinary cooperation.

Beswick and colleagues<sup>7</sup> found that complex interventions like community-based care can support older people to live independently, though there is no clear evidence yet that one specific format is better than another. Various recent studies on proactive home visits for vulnerable groups of older people in the Netherlands, for example, showed conflicting results. These home visits by nurses did not turn out to be effective<sup>8,9</sup> or only modest positive effects were reported in the short term.<sup>10</sup>

A more powerful intervention in primary care is needed to address the needs of frail older people and prevent or postpone further functional decline. Although the Dutch healthcare system is characterised by its strong emphasis on primary care,<sup>11</sup> it still seems insufficiently equipped to address the needs of frail older people and to prevent disability.<sup>6</sup> The overall reactive approach and lack of collaboration between disciplines<sup>12,6</sup> poses challenges in implementing complex interventions.

Between 2008 and 2010, we developed an interdisciplinary primary care disability prevention programme for frail older people. Between May 2009 and January 2010, a feasibility study was conducted.<sup>13</sup> Further, we studied the validity of the postal screening instrument used in the programme to identify frail older people.<sup>14,15</sup> In March 2010, sponsored by the Dutch National Care for the Elderly Programme, a full evaluation of the effectiveness of the programme started.<sup>16</sup> This article aims to describe and justify the programme based on our development work.

## Justification of the program – the theory

The development of the programme was based on the Intervention Mapping protocol<sup>17</sup> for developing health promotion programmes. Two teams cooperated during the development: a research team conducted (literature) studies and pilots to support decision making, and a multidisciplinary task group developed practical

tools. The latter group consisted of professional experts such as a general practitioner, a nursing home physician, a geriatrician, a practice nurse, a geriatric clinical nurse specialist, a physiotherapist, an occupational therapist, an expert in technology and a researcher (RD) as the coordinator.

Defining frailty

Although there is still debate on the definition of frailty, agreement exists on the core feature of frailty: an increased vulnerability to stressors due to impairments in multiple, interrelated systems that lead to decline in homeostatic reserve and resiliency.<sup>18</sup> Some authors describe frailty from a physiological perspective,<sup>19-24</sup> also referred to as physical frailty, while others consider frailty as multifactorial in nature, taking physical, psychological, social and environmental factors into account.<sup>25</sup>

Literature on disability development in older people suggests that disability is multifactorial in nature. Stuck et al.<sup>26</sup> identified in their review the following risk factors for developing disability in the community-dwelling older people: cognitive impairment, depression, comorbidity, increased and decreased body mass index, lower extremity functional limitation, falls, low frequency of social contact and low level of physical activity. Femia et al.<sup>27</sup> suggest that although disease conditions and physical impairments are as risk factors strongly related to an individual's functional abilities, other factors like the beliefs about one's health (e.g., subjective health), motivation and self-efficacy are potentially as important.

With disability prevention as the aim, a multifactorial approach to frailty was in our opinion a more promising approach in identifying and supporting community-dwelling frail older people dealing with multiple diseases, problems and risks. As a consequence, the programme takes a multifactorial perspective on screening, assessment and treatment. As we consider frailty and disability as overlapping but distinct concepts, the programme needs to address the needs of frail older people in different stages from mildly frail (without disabilities) to severely frail.

Programme outcome and goals

The overall desired outcome of the programme is that frail older people can do those activities they need to do or enjoy doing. As the programme intends to be preventive in nature, two ways of supporting performance of activities were formulated:

- Identifying risks (as described by Stuck et al.<sup>26</sup>) for developing disability and targeting risk factors. Targets could be focused on cognitive impairment, depression, comorbidity, increased and decreased body mass index, lower extremity functional limitation, falls, low frequency of social contact or low level of physical activity.
- Identifying problems in performing activities and enhancing meaningful activities. The Model of Human Occupation<sup>28</sup> describes determinants influencing performance

of activities. The model was successfully used in previous effect studies.<sup>29,30</sup> Goals could be focused on determinants such as personal causation (including self-efficacy), values, interests, roles, habits, performance capacity (mental and physical functions), skills (motor, cognitive, communicative) and the physical and social environment.

Delivery of the programme

Our literature review<sup>31</sup> on interventions aimed at disability prevention in community-dwelling frail older people concluded that a tailor-made, multidisciplinary and multifactorial approach, individualised assessment and intervention, physical activity, assistive technology, case management and long-term follow-up are promising elements for a disability prevention programme. During an expert meeting (with sixteen researchers in geriatric care), experts recognised similar factors as self-management, a tailor-made and client-centred approach, involvement of the client system and case management as relevant. Our programme elements are presented in Table 1.

Table 1 Elements of the disability-prevention programme

General	Process	Intervention
<ul style="list-style-type: none"><li>• Disease and function-oriented prevention</li><li>• Tailor-made</li><li>• Client-centred</li><li>• Supporting self-management</li><li>• Multifactorial approach to frailty</li><li>• Multidisciplinary cooperation</li></ul>	<ul style="list-style-type: none"><li>• Screening</li><li>• Assessment</li><li>• Case management</li><li>• Involvement of the client system</li><li>• Multifactorial and flexible toolbox of interventions</li><li>• Long-term follow-up</li></ul>	<p><b>Determinants:</b> Risk factor for developing disabilities, e.g.</p> <ul style="list-style-type: none"><li>• Falls</li><li>• Mood problems</li><li>• Lack of physical activity</li></ul> <p><b>Determinants</b> Enhancing performance of meaningful activities</p> <ul style="list-style-type: none"><li>• Performance components (physical and mental functions)</li><li>• Personal causation</li><li>• Values</li><li>• Interests</li><li>• Roles</li><li>• Habits</li><li>• Skills</li><li>• Social environment</li><li>• Physical environment (e.g., assistive technology)</li></ul>

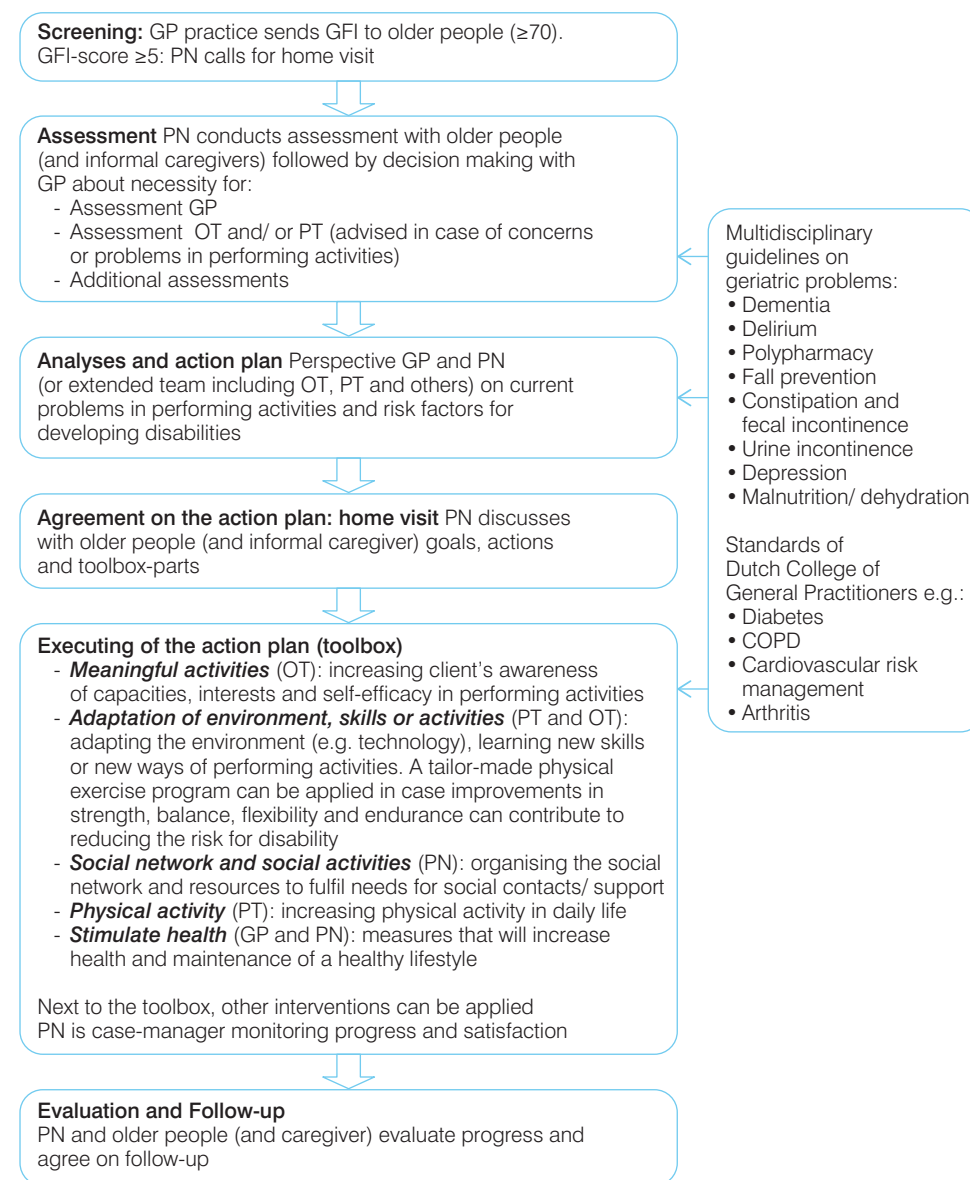
**Tailor-made care and self-management support** There is a strong body of evidence that self-management support, using a mixture of components is effective in improving clinical outcomes.<sup>32</sup> The 5A Behavioural Change Model<sup>32,33</sup> combines a client-centred approach, a model for behavioural change (Stages of Change model<sup>34</sup>) and motivational interviewing techniques<sup>35</sup> to provide practical tools for professionals to support self-management. Rubak and colleagues<sup>36</sup> reported that motivational interviewing outperforms traditional advice. The '5 As' refer to assessing the older person's level of behaviour, beliefs and motivation for change; advice adapted to the need for information; agreeing with the older person on a realistic set of goals and actions (goal setting and action planning); assisting to anticipate barriers and to increase skills; and arranging follow-up support.<sup>32</sup> Use of the 5A Behavioural Model implies that goals and strategies to achieve the goals are individually determined and will depend strongly on the older person's (self-perceived) problems, motivation and capabilities. Self-management skills of the older person will influence whether goals are focused on the client or more on (support of) the social and physical environment.

**Meaningful activities** As the programme aims to support older people in continuing to do those activities they enjoy or need to do, meaningful activities had to be at the core of the programme. The Occupational Performance Process Model<sup>37</sup> was helpful in understanding that professionals need to explore concerns or problems of older people with performance of activities, understand the older person's priorities and use meaningful activities, where possible, as outcomes and means. The experience of doing can increase insight and beliefs in one's own capabilities (self-efficacy)<sup>28</sup> which is central to self-management. Graff et al.<sup>30</sup> showed the effectiveness of a focus on meaningful activities in a programme for older people with dementia.

**Interdisciplinary cooperation** Besides having relevant clinical components, care programmes should also be seen as multidisciplinary protocols that encompass tasks, decision criteria and work procedures for the care professionals involved.<sup>38</sup> Studies into team collaboration in rehabilitation<sup>39,40</sup> show that a common care philosophy, defined roles, open and clear communication, regular structural communication, shared decision making and goal setting enhance team cooperation.

### Delivering the programme – the practice

The GP and the practice nurse comprised the core team of the programme with the practice nurse in the role of case manager. This team can be extended to include the occupational therapist and physiotherapist, other community care professionals or hospital professionals. The programme consists of six steps (Figure 1<sup>16</sup>).



**Figure 1** Steps of the programme.

PN=practice nurse, OT=occupational therapist, PT=physiotherapist.

### Step 1: Screening for frailty

The Groningen Frailty Indicator<sup>41</sup> accompanied by a covering letter from the general practice is sent to their population aged 70 or older. The Groningen Frailty Indicator<sup>41</sup> is a 15-item screening instrument for determining the level of frailty. It focuses on the loss of functions and resources in four domains of functioning: physical (nine items), cognitive (one item), social (three items) and psychological (two items). Scores on the Groningen Frailty Indicator range from 0 to 15. The instrument has shown high internal consistency and construct validity.<sup>15,41</sup> In our feasibility study<sup>13</sup> among 41 frail older people, nearly all older people were willing to return the Groningen Frailty Indicator by post (90% response), and the number of missing items was low. The study into predictive values of three postal questionnaires<sup>14</sup> showed that all three instruments, including the Groningen Frailty Indicator, do have potential to identify older people at risk, but their predictive power is not yet sufficient. A substantial proportion of older people identified as frail by the Groningen Frailty Indicator did not develop adverse outcomes at one-year follow-up. In practice, this implies that additional information is needed to lower the number of false positives.

### Step 2: Assessment

In the programme older people with scores  $\geq 5$  on the Groningen Frailty Indicator are considered as frail and are contacted by phone by the practice nurse to plan a home visit. During this visit a multidimensional assessment is conducted by the practice nurse in the presence of the main informal caregiver (if available). This assessment focuses on:

- concerns and wishes expressed by the older person and informal caregiver
- risk factors for disability (based on Stuck et al.<sup>26</sup>), such as polypharmacy, mobility problems, falls, lack of physical activity, cognitive impairments or mood problems
- problems or concerns experienced in performing activities
- readiness to change

A structured assessment format is used, based on various tools derived from instruments that have proven their use in previous research (e.g., the 'Easy-Care assessment'<sup>42</sup>). To optimise multidisciplinary communication, the format matches the structure of the electronic patient records of the geriatric department of the regional hospital.

Throughout the assessment the practice nurse uses motivational interviewing techniques<sup>35</sup> to enhance collaborative partnership. Motivational interviewing focuses on providing opportunities to help patients assess for themselves what might be important or possible and how change might be achieved.<sup>35</sup> Reflective listening (accurately understanding a patient's story through open questions, reflections, gentle probing for more details, and use of summaries) is a key element for the

practice nurse in conducting the multidimensional assessment. The Stages of Change model<sup>34</sup> is used in monitoring the readiness to change.

The stages of change are:

- *Precontemplation*: not yet acknowledging that there is a problem that needs to be changed
- *Contemplation*: acknowledging that there is a problem but not yet ready or sure of wanting to make a change
- *Preparation*: getting ready to change
- *Action*: changing behaviour
- *Maintenance*: maintaining the behaviour change
- *Relapse*: returning to older behaviours and abandoning the new changes

#### An example

In answering the practice nurse's question about fall incidents, an older person tells that she fell three times, expresses her concern with these incidents, but does not seem to know what to change to improve the situation. The practice nurse concludes that, concerning fall incidents, the older person is in a contemplation phase ready to move to a preparation phase to receive information about possible actions to prevent falling.

In the end of the meeting, the practice nurse summarises the answers of the older person (and informal caregiver) and validates outcomes by asking:

- 'Could you tell me once more what are important activities for you to keep doing?'
- 'What would you say could support you in keep doing those activities as long as you wish?'
- 'How motivated are you to take measures that will help you to keep doing those activities?'

Practice nurses were told to use the assessment in a flexible manner and to focus on understanding the story of the older person and not on problem-solving. The pilot study<sup>13</sup> showed that the assessment takes approximately one hour followed by half an hour of administration. Older people were very positive about the opportunity to share their story and regarded the questions in the assessment as relevant. Although professionals considered the assessment to contain sufficient items about activities, doubt was expressed about whether older people were sufficiently challenged to reflect on their patterns of activities in the context of well-being and health. It is not usual for older people to express their problems and concerns in terms of activities,



and more tools for professionals to discuss these kinds of issues with older people might be necessary.

Following assessment, the practice nurse and the GP discuss whether additional assessments are needed. In the case of problems or concerns about performing activities, a referral to the occupational therapist and physiotherapist for an assessment is recommended to gain a better understanding of the underlying causes of problems experienced. Additional assessments by other specialized professionals follow if needed (and if agreed on by the older person).

### Step 3: Analysis and preliminary action plan

As complex care needs may arise, thorough analyses of data available from assessments is necessary before action takes place. The GP and practice nurse discuss whether they can do the analysis and formulate a preliminary action plan together or whether the team has to be extended to include the occupational therapist and/or physiotherapist and, other disciplines. In the case of an extended team, the professionals will hold a team meeting using a format based on the Model of Human Occupation.<sup>28</sup> The older person and the informal caregiver can be invited to the team meeting.

The meeting takes a top-down approach towards analyses. After summarising the older person's background and context, the team identifies the activities meaningful to this person, the problems or concerns the older person expressed in performing activities, and the risk factors for developing disabilities. This is followed by analyses in which concepts as personal causation (including self-efficacy), values, interests, roles, habits, performance capacity (mental and physical functions), skills (motor, cognitive, communicative) and the physical and social environment are taken into account.

After analyses, the team focuses on two questions:

- How can we support the older person to keep doing those activities that are meaningful?
- How can we support the older person to reduce the risk of developing disability in the near future?

The protocol offers specific information on a number of geriatric problems (e.g., dementia, falls, depression, incontinence) based on recent standards and guidelines that professionals can use in their deliberations (see also figure 1<sup>16</sup>). The best course of action is discussed in perspective of the older person's needs, readiness for change and burden.

### An example

A team meeting could result in several goals and actions:

- Lowering the risk of developing disability using measures such as:
  - o polypharmacy: takes measures to increase safe use of medication toolbox 'stimulate health'.
  - o physical activity: increases physical activity in daily life toolbox 'physical activity'.
  - o falls: takes measures to reduce fall risks toolbox 'adapting the environment, skills or activities'.
- Enhancing performance of (meaningful) activities such as:
  - o older person wishes to continue working in the garden: physical environment: uses aids and adaptations to facilitate performance of activities toolbox 'adapting the environment, skills or activities'
  - o older person wishes to do meaningful activities in the weekend: interests: is able to explore interests and to choose for and perform meaningful activities toolbox 'meaningful activities'

During development of the programme, some professionals, especially GPs, were reluctant towards these team meetings. The pilot study showed some constraints in organising the meetings in one GP. The twelve practices in the randomised controlled trial, however, did not report problems with organisation so far. Interdisciplinary meetings usually took one hour in which three or four older people were discussed. Professionals experienced several advantages of this team collaboration, such as a more extensive picture of older people, sharing a mutual view on treatment, and a better understanding of the expertise of other disciplines. The feasibility study showed that education and guidance of teams may be important factors in achieving effective team collaboration.

### Step 4: Agreement on action plan

The next phase relates to goal setting and action planning together with the older person (and informal caregiver). During a second home visit, the practice nurse explains that she would like to talk about measures to support the older person to keep doing meaningful activities. The practice nurse uses the motivational interviewing tool 'agenda setting' to raise issues considered important by the older person, the informal caregiver and the team. In agenda setting, rather than impose the professionals' priority on patients, one conducts an overview by inviting patients to select an issue or behaviour that they are most ready and able to tackle, feeling free also to express one's own views.<sup>35</sup>

**An example**

Using the tool 'Agenda setting' the practice nurse asks: 'Is there some other topic that you would prefer to talk about? I'd like to talk at some point about your fear of falling and your wish to keep doing gardening. But what makes sense to you right now?'

After an agenda has been set, the older person's topics are discussed, followed by the topics of the practice nurse. Information and advice adapted to the needs of the older person (e.g. about possible treatment options) is given after permission has been asked. Further, the practice nurse can use motivational interviewing techniques such as 'reflecting on pros and cons of change' and 'assessing importance and confidence in change'.

The outcome of this meeting is a list of goals, actions and responsibilities that should meet the older person's and informal caregiver's needs. It is not important for practice nurses to make time for this meeting, and do this as a face-to-face interaction and not over the phone. The practice nurse needs to involve the older person in decision making, and goals of treatment should be specific so that they motivate and direct a person's attention toward goal relevant activities. It is not important that all issues seen as important by the team are negotiated. The setting of goals and actions is a part of a process in which professionals and clients establish a cooperation, in which a learning process begins, leading to new insights and possibly to new goals and actions. Practice nurses in the pilot study experienced that goal setting in this programme differs from goal setting with clients with chronic obstructive pulmonary disease (COPD) or diabetes. They reported that client goals in our programme range further in scope and are less pre-described.

**Step 5: Executing the action plan**

A flexible toolbox of interventions is available to execute the action plan. For each toolbox part, a rationale and method are described to guide professionals. The toolbox exists of five parts:

**Meaningful activities (occupational therapist).** This part of the toolbox is meant for older people who lack confidence in capabilities or experience a lack in activities that they enjoy to do or that give meaning to life. The objective is to explore capacities, interests and satisfaction with meaningful activities and ability to choose and perform meaningful activities. The method is based on occupational therapy literature<sup>28</sup>, motivational interviewing<sup>35</sup> and the Stages of Change model.<sup>34</sup>

**Adapting the environment, activities or skills (occupational and physiotherapist).** This module is for older people who experience problems in performance of activities. The objective is to adapt the environment, activities or skills to enhance performance of activities. The method is based on standards and guidelines in occupational and physiotherapy for advising assistive technology and strategy training. A functional exercise program (based on Gill et al.<sup>43</sup>) focusing on physical parameters as strength, balance, endurance and flexibility is also part of this module.

**Social network and social activities (practice nurse).** This part of the toolbox is for older people with a small or instable network, without sufficient support from their network, experiencing tension in their social network or loneliness. The objective is to strengthen the social network and/or increasing social activities. The method is based on the Dutch 'strengthening your network' programme, as described by Hofman et al.<sup>44</sup> and the 'friendship course' by Stevens et al.<sup>45</sup>. Increased insight in one's network and wishes in relation to the social network are translated into goals and an action plan.

**Daily physical activity (physiotherapist).** This part is meant for older people aiming to increase daily physical activity. The method is based on motivational interviewing, the Stages of Change model and the seven-step approach as described by Resnick et al.<sup>46</sup>

**Stimulate health (GP and practice nurse).** This module is for older people with chronic diseases or other risk factors for developing disability related to lifestyle. The objective is to take measures that stimulate health and a healthy lifestyle based on standards of the Dutch College of General Practitioners. In case of behavioural change, the GP and practice nurse use motivational interviewing and the Stages of Change model to guide the older person.

During execution of the toolbox parts the case manager (practice nurse) keeps in touch with the older person and the informal caregiver to monitor progress and satisfaction.

The pilot study<sup>13</sup> showed that professionals considered this toolbox appropriate for targeting frail older people. The methods in the toolbox required the professionals to adapt. They had to change their focus from problem-solving to support the client's self-management and increase their own coaching skills.

**Step 6: Evaluation and follow-up**

After finishing parts of the toolbox, the practice nurse evaluates, as case manager, with the older person the achievement of goals, the implementation of strategies in daily life and the need for support in the following period. This support could be arranged, for example, through regular visits, telephone, email or community-based

facilities. The professionals involved will be informed about the agreements. It is possible, for example, that an older person who was involved in the toolbox part 'physical activity' still has a monthly telephone contact with the physiotherapist to support the maintenance of new habits.

From the perspective of behavioural change, follow-up is a relevant phase. As a result of events and transitions, frail older people can have difficulty in maintaining self-management strategies. In the pilot study<sup>13</sup>, arranging the follow-up was one of the elements that was often not applied. Arranging a follow-up is a rather new element in primary care; it is not in the process of usual care and usually there is no reimbursement for it. A good system is needed to organise who is responsible, for what, in which period. This needs more attention in the programme.

## Discussion

This paper describes the content of a disability-prevention programme for community-dwelling frail older people. The programme was designed to promote self-management in a tailor-made way using motivational interviewing and meaningful activities as a vehicle to guide behavioural change. Literature studies provided relevant elements in delivering the programme. To shape the programme, the research team and the multidisciplinary task group used theories, models and tools that have proven their usefulness in other contexts. How this combination works out in the context of community-based care targeted at frail older people is still unclear. Bodenheimer<sup>32</sup>, for instance, emphasises that although there is a strong body of evidence that self-management support is effective in achieving clinical outcomes, much work is still needed on precisely which activities are the most effective for which patients. Jonker and colleagues<sup>47</sup> found in their review that a group based Chronic Disease Self-Management Programme for vulnerable older people (containing goal setting and action planning) was consistently beneficial for health behaviour, especially with regard to the variables of exercise and self-care. How effective self-management support is in an individual format in community-dwelling frail older people is a question for further studies.

The combination of elements, theories, models and tools has led to a complex intervention. New elements such as screening, motivational interviewing, meaningful activities in the core, team meetings and a toolbox of interventions might be too ambitious for the average GP practice. The pilot study<sup>13</sup> showed that the screening procedures needs reconsideration and that additional tools for professionals to support self-management are necessary.

## Acknowledgements

For their contribution to developing the disability prevention programme many thanks go to Inge Systemans, Margot van Melick, Frederique Prompers, Frank Vlaskamp, Henk Jochems, Rob de Ruijter and Michel Oostdam.

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