



**Franca Ruikes**

# **Integrated primary care for frail elderly**

*Implementation, effects, and costs  
of the CareWell primary care program*



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**Colofon**

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# Integrated primary care for frail elderly

## Implementation, effects, and costs of the CareWell primary care program

Proefschrift

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Houd een hart vol van warmte,  
En van liefde in je borst.  
Maar wees op je vierkante meter een vorst.  
Wat je zoekt kan geen ander je geven.  
Mens, durf te leven.

*Dirk Witte, 1917*



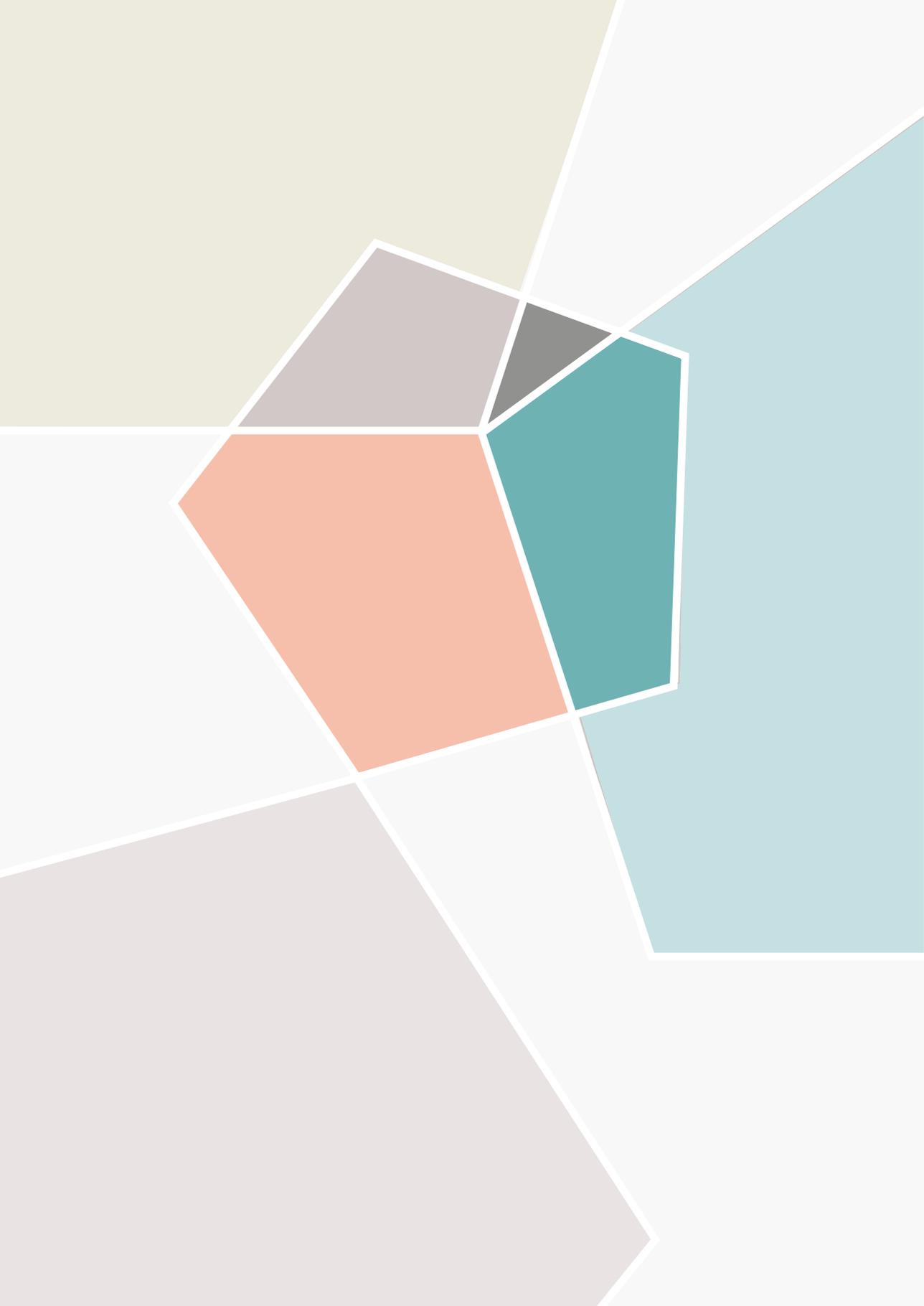
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## List of abbreviations

ADL	activities of daily living
CCM	Chronic Care Model
EasyCare-TOS	EasyCare Two-step Older persons Screening instrument
ECP	elderly care physician
EMR	electronic medical record
EQ-5D(-3L)	EuroQoL five-dimensional (three-level) instrument
GAS	goal attainment scaling
GP	general practitioner
ICER	incremental cost-effectiveness ratio
iNMB	incremental Net Monetary Benefit
LTC	long-term care
MDT	multidisciplinary team
NCEP	National Care for the Elderly Program
PROM	patient reported outcome measure
QALY	quality-adjusted life years
QoL	quality of life
SES	Socio Economic Status
TIS	total implementation score
VAS	visual analog scale
WTP	willingness to pay
ZWIP	Health and Welfare Information Portal



**General introduction**



In the Netherlands, the proportion of older people aged 65 years and over will raise from 16% of the total population in 2010 to over 25% of the total population in 2050. [1] With population ageing, the number of frail elderly with complex and interacting health and social care needs will increase. [2]

In 2008, the Dutch Ministry of Health, Welfare, and Sports initiated the National Care for the Elderly Program (NCEP) to improve the quality of care for this growing number of frail elderly (<http://www.beteroud.nl/ouderen/nationaal-programma-ouderenzorg-npo.html>).

This thesis is written as part of the NCEP program and aims to improve the quality of primary care for community-dwelling frail elderly. This General Introduction provides background information on the scope of this thesis and describes the objectives and outline of this thesis.

## The challenge of ageing and frailty to primary care

Advancing age often comes with multiple chronic diseases, i.e. multimorbidity, as well as psychosocial impairments, e.g. loss of social support and isolation, that lead to an increased vulnerability to adverse outcomes. [3,4] To characterize this vulnerability, that is heterogenic for different individuals, the concept of frailty was introduced by Vaupel et al. in 1979. [5]

Frailty refers to a condition in which losses in several domains of functioning lead to a decrease in reserve capacity and a subsequent increase in vulnerability to adverse health outcomes, such as functional decline, hospitalization, institutionalization, and death. [2] Frailty is considered to be dynamic over time, meaning that individuals can switch between more or less frail conditions [6-8], although transitions from frail to non-frail states occur rarely [6]. Although it partly overlaps with the concepts of disability and multimorbidity, frailty is viewed as a distinct clinical entity. [9,10] In 2001, Fried's Frailty phenotype was proposed to identify frailty in older adults. [9] It defines frailty as a clinical syndrome in which three or more of the following criteria are present: unintentional weight loss, self-reported exhaustion, impaired grip strength, slow walking speed, and low physical activity levels. [11] In the same year, Rockwood and Mitnitski introduced their Frailty Index that conceptualizes frailty as an accumulation of deficits (symptoms, signs, illnesses, disabilities) in the physical as well as psychological and social domains. [12] This multidimensional approach is most consistent with the views of primary care professionals on frailty. [13] In the ongoing discussion on the definition and conceptualization of frailty, many frailty identification instruments have been developed and tested since then, but many are too time-consuming, not accurate enough, and/or not validated specifically for use in primary care. [14,15] As a result of the heterogeneity

in the frailty definitions and identification instruments, frailty prevalence rates in community-dwelling older populations vary considerably with rates of 4% up to 59%. [16] Although prevalence rates are unclear, it is well established that frailty predicts adverse health outcomes, such as functional decline, institutionalization and hospitalization, and mortality. [17-20] As a result, frail elderly account for a disproportional large share of health care costs, mainly due to expensive hospital and long-term care. [21,22] In response to the increasing health care expenditure of frail elderly, significant health care reforms have become a prominent issue in many Western governments, including the Netherlands. [23,24] Most (frail) elderly themselves want to 'age in place', i.e. maintain their functional independence and remain living in the community. [25,26] Many governments support this trend and acknowledge the need for a transition from hospital and long-term care towards community-based formal and informal care, to prevent an unaffordable financial burden. [27,28] In the Netherlands in 2009, the Health Council declared in their report "Prevention in the elderly: Focus on functioning in daily life" that the prevention of functional decline is the most important aim in providing elderly care. [29] Thus, the impetus to develop (cost-) effective interventions in primary care that can prevent functional decline in timely identified community-dwelling frail elderly is clear.

## Community-based care for frail elderly

Current Western health care delivery systems often are insufficient in addressing the complex and interacting health care needs of community-dwelling frail elderly, due to their reactive, disease-oriented structure that leads to fragmentation, and a lack of coordination between cure, care and welfare professionals. [10,30] Frail elderly, especially those in a complex care-situation [13], are believed to benefit greatly from a coordinated health care system that is person-centred and, from a holistic approach, integrates health and social care in a continuum across providers and settings. [31-33] Care-complexity refers to the experienced problems with the organization and coordination of care, where multiple health care professionals and/or services are involved. [34]

A well-known person-centred and integrated health care delivery model is the Chronic Care Model (CCM), which was developed in the US. [35] The CCM incorporates patient empowerment and self-management support, care coordination, decision support with access to a multidisciplinary team, and clinical information systems such as a web-based geriatric assessment. [35] In the past two decades, several integrated care programs for community-dwelling frail elderly that are (partly) based on this CCM have been developed and evaluated. They show a large heterogeneity in the targeted population, the (mix of) intervention components, and the outcome measures used. [25,36,37] So far, no overall conclusion on the effectiveness of these integrated care programs can be drawn as their outcomes are small and conflicting. [38-41] This urges for process evaluations alongside the (cost-) effectiveness studies. A process evaluation helps to gain insight into the

level at which an intervention is delivered as planned, i.e. the intervention 'fidelity'. [42] By understanding and measuring the degree of implementation of an intervention, researchers gain a better understanding of how and why an intervention works. Moreover, it can be understood whether a lack of effectiveness should be explained by the program itself or by insufficiencies with regard to program delivery. It is widely recognized that complex interventions, which consist of multiple interrelated and/or interdependent components, are especially challenging to implement. [42,43] To date, little is known on the association between the effectiveness and the implementation of comprehensive care programs for frail community-dwelling elderly, which can be viewed as complex interventions. Moreover, few studies report on caregiver outcomes [44,45] and on the costs and/or cost-effectiveness of these programs [46-48]. More knowledge on the (cost-) effectiveness of comprehensive care programs on functional decline in community-dwelling frail elderly, on caregiver outcomes, and on the association between the degree of implementation and the effectiveness is needed to direct the redesign of current insufficient health care delivery systems.

## The CareWell primary care program

As stated above, the Dutch Government initiated the NCEP in 2008 in order to improve the quality of care for frail elderly. The program promotes research projects on frail elderly across different health care settings, carried out by all eight university medical centres in the Netherlands. For this purpose, the Radboud University Medical Centre in Nijmegen, in the east of the Netherlands, created a network of relevant stakeholders from cure, care and welfare domains and representatives of frail elderly and their caregivers ('Netwerk 100', [www.netwerk100.nl/](http://www.netwerk100.nl/)). This network conducted three primary-care research projects within the NCEP.

First, a method for the identification of community-dwelling frail elderly in primary care, called the EasyCare Two-step Older persons Screening instrument (EasyCare-TOS) was developed and validated, to meet the concerns and evidence gaps on frailty identification instruments for use in primary care. [49] This EasyCare-TOS fits the multidimensional approach on frailty that is most in line with the views of primary care professionals. Next, it makes optimal use of general practitioners' prior and tacit knowledge to increase its feasibility and efficiency. [50] The EasyCare-TOS can be found in additional file 1.

Second, a Health and Welfare Information Portal called 'ZWIP' was developed to reduce fragmentation and improve multidisciplinary collaboration and information exchange between professionals involved in the care for community-dwelling frail elderly. [51]

The third research project of 'Network 100', and the subject of this thesis, was the development, implementation and evaluation of the CareWell primary care program.

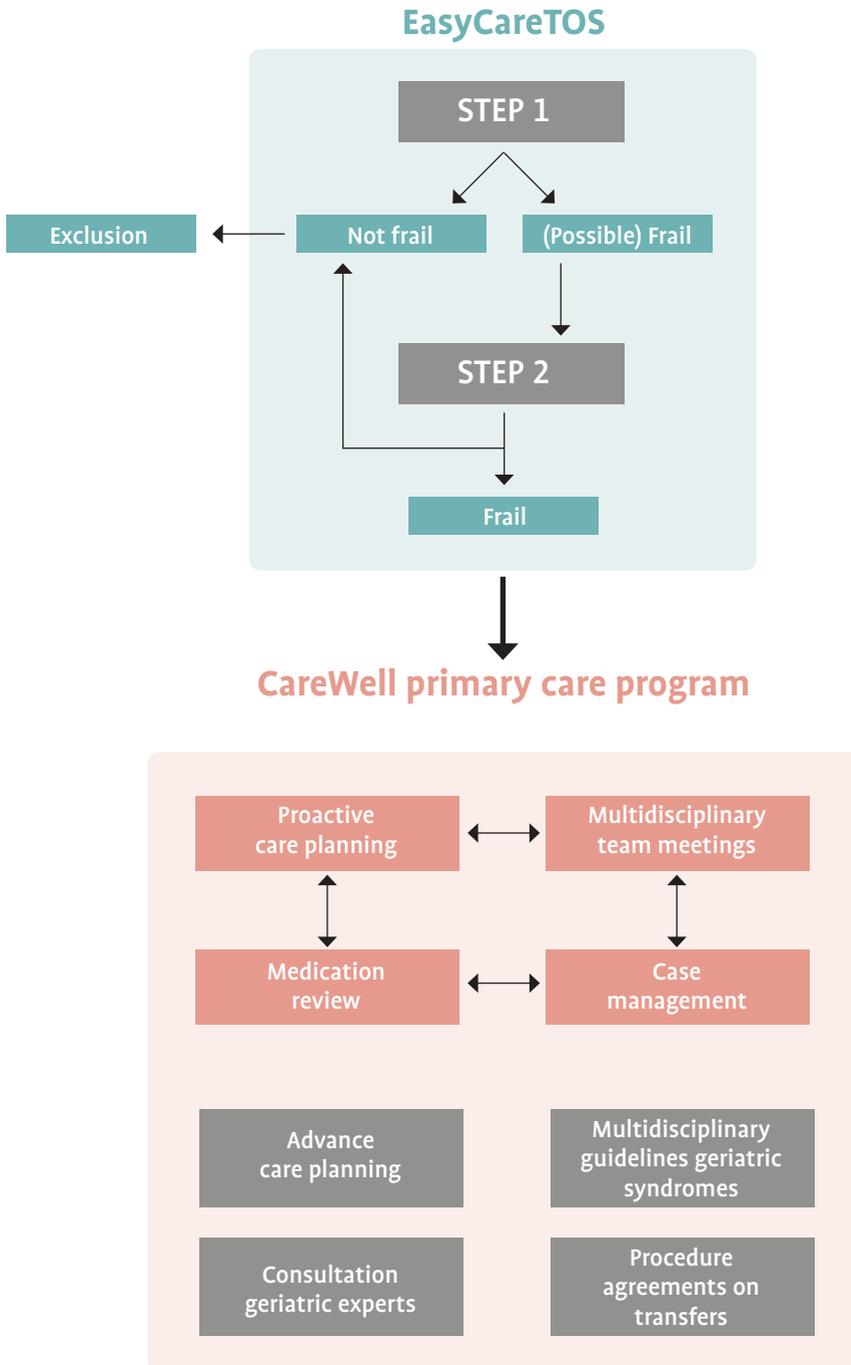


FIGURE 1 | Schematic representation of the EasyCare-TOS and the CareWell primary care program.

This program is a complex intervention that integrates cure, care and welfare and aims to prevent functional decline, hospitalization, and institutionalization in community-dwelling frail elderly. The program is based on existing chronic care models and is adapted to the Dutch health care system. The program consists of four key elements: (1) multidisciplinary team work, (2) proactive care planning, (3) case management, and (4) medication reviews. Four supporting elements facilitate the program's interventions: (1) multidisciplinary practice guidelines for eight common geriatric syndromes (depression, dementia, chronic pain, falls, urinary incontinence, malnutrition, and vision and hearing impairment), (2) an advance care planning practice guideline, (3) procedure agreements on consultation of geriatric experts, (4) procedure agreements on hospitalization and discharge. Moreover, ZWIP is used to facilitate multidisciplinary communication and information exchange through a combined multidisciplinary electronic health record.

In figure 1, a schematic representation of the EasyCare-TOS and the CareWell primary care program is shown.

## Objectives and outline of this thesis

In this thesis on the CareWell primary care program we provide answers and insights with regard to the (cost-) effectiveness of the program on community-dwelling frail elderly and their informal caregivers. First, in chapter 2 we describe the design of the CareWell primary care study. In Chapter 3 we report on the results of the CareWell primary care program on functional decline and secondary outcomes of community-dwelling frail elderly, as evaluated in a cluster controlled trial of twelve months follow-up. In Chapter 4, we present the results of the same cluster controlled trial on informal caregiver outcomes. In Chapter 5, we report on the process evaluation that focuses on the implementation fidelity of the program in the six general practitioner (GP) practices in the intervention group. In Chapter 6, we investigate the program's cost-effectiveness. Consecutively, the following research questions are answered:

- What is the effectiveness of the CareWell primary care program on functional decline (primary outcome), and on quality of life, mental health, health-related limitations in social functioning, hospitalization, and institutionalization of community dwelling-frail elderly, when compared to care as usual after a follow up of twelve months? (Chapter 3)
- What is the effectiveness of the program on care-related quality of life, caregiver burden, and time investment on caregiver tasks, when compared to usual care after a follow up of twelve months? (Chapter 4)
- To what extent is the program implemented as intended?  
What is the association between the degree of implementation of the program and

the program's primary outcome, i.e. functional decline of community-dwelling frail elderly? (Chapter 5)

- What are the differences in health care costs between frail elderly receiving care according to the program and those receiving care as usual?

Is the program cost-effective from a healthcare perspective after 12 months? (Chapter 6)

Finally, in Chapter 7, we provide a general discussion of this thesis in which we will summarise our main findings, reflect on these findings, discuss methodological and theoretical issues, elaborate on the implications of our findings, and propose recommendations for clinical practice, education, and future research.

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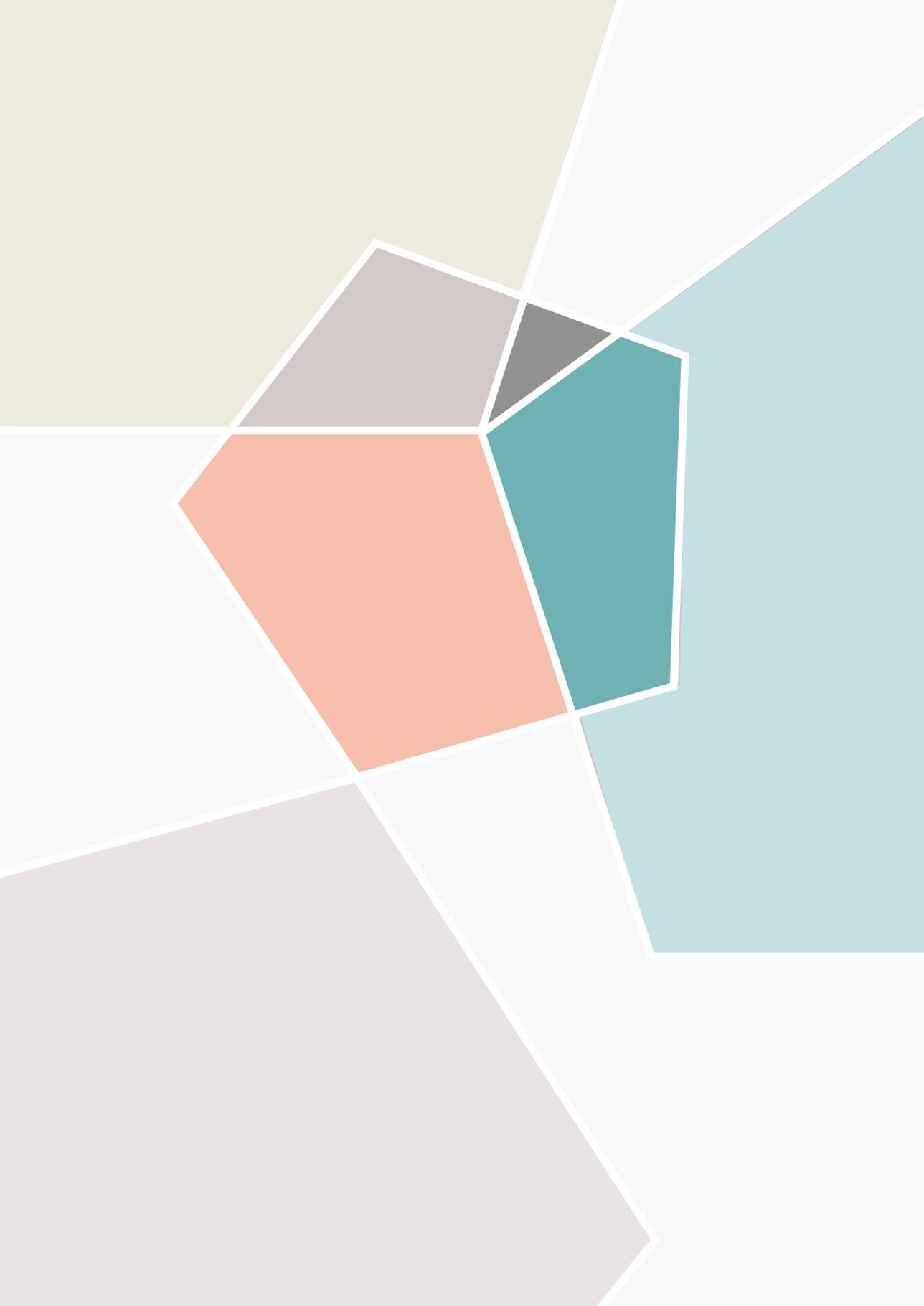
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**The CareWell primary care program:  
design of a cluster controlled trial  
and process evaluation of a complex  
intervention targeting community-  
dwelling frail elderly**

Ruikes FGH, Meys ARM, van de Wetering G, Akkermans RP, van Gaal BGI, Zuidema SU,  
Schers HJ, van Achterberg T, Koopmans RTCM.

*BMC Family Practice* 2012; 13:115.

## Abstract

### Background

With increasing age and longevity, the rising number of frail elders with complex and numerous health-related needs demands a coordinated health care delivery system integrating cure, care and welfare. Studies on the effectiveness of such comprehensive chronic care models targeting frail elders show inconclusive results. The CareWell primary care program is a complex intervention targeting community-dwelling frail elderly people that aims to prevent functional decline, improve quality of life, and reduce or postpone hospital and nursing home admissions of community dwelling frail elderly.

### Methods/Design

The CareWell primary care study includes a (cost-) effectiveness study and a comprehensive process evaluation. In a one-year pragmatic, cluster controlled trial, six general practices are non-randomly recruited to adopt the CareWell primary care program and six control practices will deliver 'care as usual'. Each practice includes a random sample of fifty frail elders aged 70 years or above in the cost-effectiveness study. A sample of patients and informal caregivers and all health care professionals participating in the CareWell primary care program are included in the process evaluation.

In the cost-effectiveness study, the primary outcome is the level of functional abilities as measured with the Katz-15 index. Hierarchical mixed-effects regression models / multilevel modelling approach will be used, since the study participants are nested within the general practices. Furthermore, incremental cost-effectiveness ratios will be calculated as costs per QALY gained and as costs weighed against functional abilities. In the process evaluation, mixed methods will be used to provide insight in the implementation degree of the program, patients' and professionals' approval of the program, and the barriers and facilitators to implementation.

### Discussion

The CareWell primary care study will provide new insights into the (cost-) effectiveness, feasibility, and barriers and facilitators for implementation of this complex intervention in primary care.

## Background

Worldwide, an increase in life-expectancy and ageing of the baby boom generation is leading to a vastly expanding population of elders. In the Netherlands, the number of people aged 65 years or above will increase from 2.4 million in 2010 to 4.6 million in 2040. Furthermore, life expectancy in the Netherlands will increase from 78.8 years to 84.5 years for males and 82.7 years to 87.4 years for females in the same time span [1].

Advancing age often implies an increase in the incidence of chronic diseases and multi morbidity with subsequent functional decline and social impairments, e.g. the loss of social support, financial limitations, and the lack of appropriate housing [2,3]. The current system of health care delivery for community-dwelling frail older people, with these numerous and complex health-related needs, is insufficient due to fragmentation and a lack of coordination and information exchange between health care professionals. Furthermore, sophisticated health information technologies that facilitate the essential processes of chronic care are not widely in use [4,5]. Moreover, less urgent needs to optimally manage chronic illness and care for health related social and welfare problems are overshadowed by acute symptoms and concerns [6,7]. Last, payment for and provision of medical and nursing care and social services are separated rather than integrated, and payment policies do not support supplemental services needed in providing chronic care [4,5].

Frail elderly people are believed to benefit greatly from a coordinated chronic health care delivery system that integrates health and social care [8]. A variety of models have been developed and tested over the last twenty-five years [9,10]. This gave rise to an emerging vision of an optimal chronic care model in which health care organizations give priority to chronic care, health care providers are linked to community resources, chronic care management is separated from the acute care, elders receive self-management support, and evidence-based guidelines and clinical information systems are available to facilitate chronic care management [6,7].

Few studies on such comprehensive chronic care models targeting frail older persons have been conducted. Positive effects on functional performance [11], on self-reported quality of health care [12], and on informal caregiver satisfaction [13] are suggested, although overall (review) findings are inconsistent [14,15]. Furthermore, previous studies have shown some cost-saving implications through a postponement or reduction in residential or nursing home admissions, hospital admissions and emergency department visits [11,13,16-18].

The CareWell primary care program is a complex intervention integrating cure, care and welfare that aims to prevent functional decline, improve quality of life and reduce or postpone hospital admissions and nursing home admissions in community-dwelling frail elderly. The program is based on existing chronic care models and is adapted to the Dutch health care system. It is designed as part of the National Care for the Elderly Program

(NCEP), which is launched in 2008 by the Netherlands Organization for Health Research and Development (ZonMW), in cooperation with the Nijmegen Network for the Care and Welfare of Elderly People [4]. In developing the program, both health care professionals and a panel representing frail elderly and their informal caregivers were closely involved.

Complex interventions comprise multiple components that are interrelated or interdependent and therefore can be difficult to develop, document, evaluate, and reproduce [19]. To create a better understanding of how and why a complex intervention works, and to gain insight into costs and benefits, the framework for development and evaluation of complex interventions as published by the UK Medical Research Council is widely used [20]. This framework emphasizes the value of including a process evaluation and an economic evaluation alongside the outcome evaluation. It provided the theoretical background for the design of our study. By gaining process information, we aim to detect gaps in implementation that might be responsible for the effectiveness of the program. Furthermore, we will explore why some general practices are more successful than others in improving the quality of care for their frail elderly patients [21].

This paper presents the elements of the CareWell primary care program as well as the design of both the CareWell primary care (cost-) effectiveness study and process evaluation.

## Methods/Design

### Study design and setting

The CareWell primary care study has a pragmatic, cluster controlled design [22]. It will be conducted in 12 general practices in (the municipality of) Nijmegen, the Eastern region of the Netherlands.

### Study population

#### *Recruitment of general practices*

General practitioners (GPs) are recruited to participate in the CareWell primary care program through an invitational letter and a subsequent telephone call from one of the principal investigators. They are fully informed on the EasyCare Two-step Older persons Screening instrument (EasyCare-TOS) [23], used to identify the frail elderly study participants, and on the elements of the program. GPs with a minimum of 300 patients aged 70 years or above in their practice population, a solid motivation to implement the program, and the organizational facilities required for implementation are eligible to participate in the intervention arm. After their informed consent, six GPs will be non-randomly assigned to the intervention arm.

A second group of GPs is similarly recruited to participate in the control group. These GPs receive information on the EasyCare-TOS, but no information on the CareWell primary care program in order to prevent contamination bias. Furthermore, they are explicitly instructed to deliver 'care as usual', and not to start new collaborations with community nurses, elderly care physicians or gerontological social workers. No restrictions on existing collaborations are imposed. However, no multidisciplinary team collaborations comparable to those in the CareWell primary care program are regularly available in usual care. Six GPs consenting to participation are non-randomly assigned to the control arm.

### ***Study participants in the cost-effectiveness study***

In each general practice, a random sample of fifty frail elders aged 70 years or above will be included in alphabetical order with the use of the EasyCare-TOS [23]. In step 1 of the EasyCare-TOS, the GP rapidly subdivides 'not-frail' from '(possibly-) frail' elders by using prior, tacit knowledge. (Possible) Frail elders proceed to step 2, in which a trained community nurse or research assistant conducts a comprehensive geriatric assessment during a home-visit. The EasyCare-TOS is shown in additional file 1. In both study arms 300 frail elders will be included. Excluded from participation are (1) elders living in a residential or nursing home, (2) critically or terminally ill elders, (3) elders who are already enrolled in a case-management program, comparable to the CareWell primary care program.

### ***Informed consent***

Eligible elders are asked for their willingness to participate in step 2 of the EasyCare-TOS and, in the intervention arm, in the CareWell primary care program. Interested elders subsequently receive a written letter containing information on the EasyCare-TOS and, in the intervention group, the CareWell primary care program. Finally, written informed consent is collected during the home-visits.

### ***Study participants in the process evaluation***

Next to a sample of patients and informal caregivers, all health care professionals participating in the CareWell primary care program are included in the process evaluation; the GP's, community nurses, gerontological social workers and elderly care physicians.

## **Ethical considerations**

The study has been reviewed by the local accredited medical review ethics committee: CMO region Arnhem-Nijmegen, registration number 2010/403). They concluded that formal ethical approval is not required, since the study does not involve research as covered by the Medical Research Involving Human Subjects Act. The study is registered in the ClinicalTrials.gov Protocol Registration System: NCT01499797.

## The intervention: the CareWell primary care program

During a twelve-month intervention-period, the frail elders in the intervention group receive care according to the CareWell primary care program. Figure 1 (Chapter 1, page 16) shows a schematic representation of the EasyCare-TOS and the elements of the CareWell primary care program.

The program consists of four key elements: (1) multidisciplinary team work, (2) proactive care planning, (3) case management, and (4) medication reviews. Each general practice will assemble one or two multidisciplinary teams, consisting of the GP, the community nurse, an elderly care physician, and a gerontological social worker. These team members closely collaborate to ensure integration of cure, care, and welfare. Face-to-face multidisciplinary team meetings will be held at least twice a year for each frail elder, in which care plans will be reviewed and adapted. In addition, the team members will be able to virtually communicate at all times within a secured web based Health and Welfare Information Portal (ZWIP) [24]. This portal combines a shared electronic health record with a communication tool for primary care professionals, which is accessible to all involved caregivers through a secured login procedure.

A proactive integrated care plan is formulated for each participant on enrolment in the program. These care plans will be based on the individual patients' health-related goals and needs on the domains of cure, care and welfare as obtained with the EasyCare-TOS. The care plans will be stored in the ZWIP.

All elders will be assigned a case manager. This will be either the community nurse or the gerontological social worker, depending on the nature of the participants' health-related needs. The case manager will be responsible for the organization of the multidisciplinary team meetings and for the coordination and monitoring of the proactive care process according to the care plan, as directed by the primary care physician. Moreover, the case manager will provide participant-support in goal setting and self-management by means of home-visits and telephone contacts.

The GP, community nurse, and pharmacist will conduct a yearly medication review for those elders using five or more drugs for chronic use. Agreements on discontinuing inappropriate or unnecessary medications and starting medications in case of under-treatment will be incorporated in the care plan, thus ensuring appropriate drug treatment [25].

In addition to these four key elements, four supporting elements facilitate the care delivery according to the program. First, we developed multidisciplinary practice guidelines on the medical treatment and nursing and social care of eight common geriatric syndromes: depression, dementia, chronic pain, falls, urinary incontinence, malnutrition, and vision and hearing impairment. These guidelines are presented as a job aid in the ZWIP. Second,

a practice guideline concerning advance care planning is developed and presented in the ZWIP to promote a proactive dialog between frail elders and their GPs on wishes and expectations regarding medical treatment and end-of-life decisions. Third, procedure agreements regarding easy-access consultation of a geriatrician or a geriatric psychiatrist are constructed. Last, procedure agreements on hospitalization and discharge are made to facilitate the integration of primary- and in-hospital care, thus improving the interdisciplinary continuum of care.

## **Tailored implementation strategies**

At baseline, health care professionals in the intervention group are asked for their perceived barriers in the current practice of elderly care as well as for their expectations of the CareWell primary care program by means of a structured questionnaire. This questionnaire is based on the baseline questionnaire developed in the Dutch Easy Care study [26] and is pilot tested with peer group professionals. The information thus collected will be used to tailor the implementation strategies and activities, in order to facilitate optimal implementation of the CareWell primary care program. A combination of implementation strategies and activities targeting both health care professionals and organizations will be used, addressing a variety of barriers for change [27]: (1) different types of education (tailor-made meetings, coaching on the job, a helpdesk, and expert meetings) to overcome gaps in knowledge, attitude and skills needed to conduct the program, (2) persuasive communication and social influencing by means of large group meetings, in order to enhance both motivation and endurance for participation, (3) provision of additional information through a website, newsletters and written instructions, (4) providing feedback and advice to the participating professionals, and (5) financial reimbursement for all health care professionals and organizations to cover the extra efforts required by the program, to facilitate participation in the intervention. These implementation activities will start nine months before the actual start of the program and will be continued throughout the program.

## **Cost-effectiveness study**

### *Outcome measures and data collection*

The primary outcome is the change in the level of functional performance in ADL between baseline and follow-up at twelve months, as measured with the Katz-15 index [28].

Secondary outcomes are:

- 1 Quality of life, as measured with RAND-36 [29] and EQ-5D [30]
- 2 Psychological and social functioning, as measured with a subscale of the RAND-36 [29]
- 3 Number of residential home, nursing home and hospital admissions
- 4 Mortality

Participants' data are collected at baseline and at follow-up at twelve months with the EasyCare-TOS, in which baseline characteristics, the Katz-15 index, RAND-36, EQ-5D, and data on health service utilization and mortality are embedded.

Caregiver burden is measured with the Carer-QoL [31], which is embedded in a structured caregiver questionnaire, to be filled in by the main informal caregiver.

Last, regular health care costs and costs of the CareWell primary care program are collected with the EasyCare-TOS and through external sources, as shown in table 1.

### *Sample size calculation*

The change in functional status between baseline and follow-up will be measured as a change in the sum-score on the Katz-15 index between baseline and 12 months [28]. Although the Katz-15 index scores may be skewed, we expect these sum-score differences to have a normal distribution. For financial and logistic reasons, including 6 clusters in each study-arm is thought to be feasible. Each general practice is instructed to include 50 frail elderly. Based on the assumptions that 15% of eligible elders will decline informed consent and 20% will be lost to follow-up within the intervention-period of twelve months, the expected cluster size is 35. Using a two-sided alpha of 0,05, a power of 80%, an assumed between-clusters intra-class correlation of 0,01 [32], and a minimum cluster size of 35 with 2x6 clusters, we will be able to detect an effect size of  $> 0,32$ , which is sufficient to detect even small differences [33,34].

### *Statistical analysis*

The primary analysis will be performed adhering to the intention-to-treat principle.

Descriptive statistics will be used to summarize characteristics of both participants and practices.

Since the study has a hierarchical structure in which participants are nested within general practices, we will use hierarchical mixed-effects regression models / multilevel modelling approach to evaluate differences between the intervention and the control group in change in functional abilities between baseline and follow-up as measured with the Katz-15 index and all secondary outcomes. We will correct for the relevant covariates. Furthermore, the effect of the intervention on mortality and on the time to hospital and nursing home admissions will be analyzed using survival analysis (Kaplan-Meijer curves) and Cox proportional hazard regression models. An additional sensitivity analysis will be conducted on a per-protocol analysis set, and on a subset of general practices in which the intervention is optimally implemented. Interim analyses will not be conducted. Statistical analyses will be performed using SPSS version 20.

TABLE 1 | Overview of sources used to obtain regular health care costs and costs of the CareWell primary care program.

Costs	EasyCareTOS	External source
<b>Regular health care</b>		
regular GP contacts	X	electronic health record
out-of-office hours GP contacts	X	-
home care	X	home care organization
domestic care	X	municipality
medication	X	electronic health record
residential home admissions	X	-
nursing home admissions	X	-
day care in residential home	X	-
day care in nursing home	X	-
hospital admissions	X	-
physiotherapist	X	-
assistive devices	X	-
<b>CareWell primary care program</b>		
time needed for proactive care planning / case management / multidisciplinary deliberation / medication review	-	time registrations by health care professionals

### *Economic evaluation*

The economic evaluation will be conducted from a societal perspective. All relevant direct and indirect costs per participant will be determined by considering costs of the CareWell primary care program, for the intervention group, and regular health care costs, for both the intervention and the control group. The costs of the CareWell primary care program will be calculated from the registrations of health care professionals of the time spent on the elements of the program. Regular health care costs will be collected with EasyCare-TOS and external sources, as shown in table 1.

Unit resource prices are based on guideline prices according to the Dutch Insurance Board [35]. Real cost prices will be determined when unit resource prices are not available. Societal costs are quantified by calculating productivity losses for informal caregivers who perform paid labour during the study period using the friction cost method [36]. Data on productivity losses will be obtained using the structured caregiver questionnaires.

The incremental cost-effectiveness ratio (ICER) will be expressed as costs per quality-adjusted life years (QALYs) gained, as measured with the Euroqol-5D (EQ-5D) [30]. From these EQ-5D scores, utilities will be derived using the trapezium rule and the Dutch algorithm after which QALYs will be calculated [37].

Next to this, the ICER will be expressed as the difference in total mean costs weighed against the difference in the sum-scores between baseline and follow-up on functional performance, as measured with the Katz-15 index [28].

Both ICERs are subjected to bootstrap analysis and will be presented in cost-effectiveness planes. Deterministic uncertainty will be explored on a range of extremes of parameters potentially influencing the ICERs, i.e. sensitivity analyses. Furthermore, stochastic uncertainty surrounding the ICERs will be presented using a cost-effectiveness acceptability curve.

## Process evaluation

### *Outcome measures and data collection*

Our extensive process evaluation aims to answer the questions: To what extent is the CareWell primary care program implemented? How do patients, informal caregivers and professionals engage with and approve of the program? What are the barriers and facilitators to implementation?

The process evaluation is based on the steps for developing a process-evaluation plan provided by Saunders et al [38], adapted from Steckler and Linnan [39]. This framework describes the following components: context, recruitment, reach, dose delivered, dose received, and fidelity. In this process evaluation, we will use mixed methods, i.e. both qualitative and quantitative methods. Table 2 shows the methods and instruments used in the process evaluation (1-11). Implementation fidelity and dose delivered, referring to the completeness of the delivery of the program, will be measured by (1) file analysis, (2) structured observation, and (3) analysis of time registration. In the examination of patients' files in the ZWIP, the implementation rate of the four key elements of the program will be noted. Scores will be compared between general practices. In addition, two independent assessors will observe the practice teams during a multidisciplinary team meeting. A structured checklist that is based on the working instructions of the program will provide insights in elements concerning the organizational aspects of the meeting, the preparation of the participants, and the process of goal setting, action planning, monitoring and evaluation. Scores on the observed elements will be analyzed per general practice and per professional discipline. Inter-assessor reliability will be established by calculating Cohen's Kappa. Time registrations will be analyzed to evaluate variation in the course of time of the intervention period, variation between individual health

TABLE 2 | Methods and instruments used in the process evaluation.

Research question (outcome)	Components	Methods and instruments
1 Level of implementation	Fidelity Dose delivered (completeness)	<p>1 File analysis on web based patients files: presence of actual care plan per patient, domains concerned (somatic, functional, community participation, psychological, communication), planned and performed evaluations, team meeting reports, content of and professionals concerned in digital communication, registration of medication reviews</p> <p>2 Observation of team meetings by means of a structured checklist: attendance, preparation, goal setting, evaluation appointments, monitoring results</p> <p>3 Time registration form for professionals, collected by e-mail</p>
2 Engagement and approval of patients and informal caregivers	Dose received (exposure) Dose received (satisfaction)	<p>4 Structured questionnaire verbally collected from a sample of patients and informal caregivers. Items: engagement of patient in care plan, given choices and priorities, support, encouragement, cooperation between case manager and primary care physician</p> <p>5 Semi-structured interviews with a sample of patients and informal caregivers on the same items to deepen the outcomes of the structured questionnaires</p>
2 Engagement and approval of professionals	Dose delivered (completeness) Dose received (exposure)	<p>6 Registration of attendance of educational meetings</p> <p>7 Structured evaluation form for educational meetings</p>
3 Barriers and facilitators to Implementation	Dose received (satisfaction) Context	<p>8 Registration of site visits: frequency, duration and content</p> <p>9 File analysis on e-mail correspondence between program facilitator and teams</p> <p>10 Structured questionnaire electronically collected from all participating professionals. Items: relevance and feasibility of the program, extent to which the program was performed, interactions with staff and investigators, factors at individual, organizational and environmental levels that may have influenced the implementation of the program</p> <p>11 Focus groups with a sample of participating professionals to deepen the outcomes of the structured questionnaires</p>

care professionals within the same discipline, the distribution of spent time over the different categories of activities. Data on the approval of patients and informal caregivers concerning the program and its key elements will be gathered through (4-5) structured questionnaires and semi-structured interviews with patients and informal caregivers. These questionnaires will be based on both the Dutch translation of PACIC [40,41], and the CQ index [42], and adapted to our program. The results of the questionnaires will be compared to the key elements of the CareWell primary care program. Following this, semi-structured interviews with patients and informal caregivers will provide deeper insight in their experiences and relevant context factors. Furthermore, information on health care professionals' views on the completeness of, exposure to, and satisfaction with the implementation activities will be collected and related to context variables, through (6-7) the registration and evaluation of educational meetings, (8-9) the registration of site visits and e-mail contacts between investigators and general practices, and (10-11) both structured questionnaires, reflecting on the professionals' baseline expectations of the program, and focus group meetings. The interviews with patients and informal caregivers will be audio taped and reported by an independent observer. The focus group meetings will be audio taped, observed and reported.

### *Statistical analysis*

Descriptive statistics will be used in the analysis of the quantitative data coming from the patient's web based files, team meetings observations, time registration results, patient's questionnaires, attendance and approval of educational meetings, registration of site visits and e-mail correspondence, and structured questionnaires for health care professionals. Next, qualitative analysis will be performed on the interview data with patients and informal caregivers, and on the results of the focus group meetings for health care professionals, according to the method of open and axial coding [43], and with support of Atlas-TI software for qualitative analysis.

## **Discussion**

The CareWell primary care program is a unique program for community dwelling frail elderly for several reasons. First, it targets frail elderly aged 70 years and above with and without care-complexity. Second, it focuses on extensive collaboration between health care professionals in primary care for elders; not only GPs and community nurses are involved, but also elderly care physicians to contribute their specific geriatric expertise, and, to be stressed, gerontological social workers in order to achieve comprehensive integration of welfare issues in the care for the elderly, that commonly have a focus on medical aspects of care. Last, it uses a secured, easily accessible web-based health and information portal (ZWIP) [24], in which care plans and guidelines are stored in patients'

files, that facilitate interdisciplinary consultation and communication complementary to the 'live' multidisciplinary meetings.

The CareWell primary care program collects a minimum data set of baseline characteristics and outcome measures. Within the Dutch NCEP [4], these data will be openly shared in order to serve public interest, advance knowledge and, last but not least, to be able to compare outcomes of the different research projects [44,45].

## Strengths and limitations

Since the CareWell primary care program demands a thorough shift from reactive, acute-disease management to proactive, integrated, chronic care management that involves multiple health care professionals, the implementation of the program demands strongly motivated professionals working in adequately equipped practice settings. Interested GPs are therefore fully informed on the elements of the program to assure their motivation to participate, and their eligibility. Following their informed consent, they are non-randomly assigned to the intervention arm. Study participants are clustered within the general practices of these GPs. As a result of this recruitment strategy, the participating GPs may be atypically well motivated or resourced, influencing the external validity. Recognizing this, we will use the knowledge of facilitators and barriers to achieve further implementation of the CareWell primary care program to other regions in the Netherlands.

In recruiting both the intervention and the control practices, no restrictions are made in baseline characteristics of the GPs, such as working experience, nor in the practice settings, such as existing collaborations between professionals and caregivers in primary care. Moreover, the conduction of the CareWell primary care program is not subjected to standardization, other than the minimum requirements of twice-yearly multidisciplinary meetings, appointing a case manager to each participant and conducting yearly medication reviews. The subsequent heterogeneity in practice settings and in the delivery of the program will further enhance the generalizability of our study.

The control group in our study receives 'care as usual'. An important question to be answered is: "How usual is usual care in the control group?" [46]. Since the participants in the control arm are included with the EasyCare-TOS, it is very well possible this will change their health-seeking behaviour. Also, the professionals in the control group might enhance their usual care due to the surplus of information collected with the EasyCare-TOS. However, these possible effects will comparably occur in the participants and professionals of the intervention group. Since we intend to pragmatically study the effects of the CareWell primary care program in comparison to 'care as usual', these facts do not threaten our study as the focus will be on the additional value of our integrated care program in comparison to 'usual care', that is conducted following the EasyCare-TOS.

In combining the (cost-) effectiveness study with a thorough process evaluation, we will be able to draw conclusions not merely on the (cost-) effectiveness of the program, but, moreover, on the influence of the degree and process of implementation of the program on its efficacy. Moreover, we will be able to evaluate the feasibility of a nationwide implementation and structural financing of the program within the Dutch health care system.

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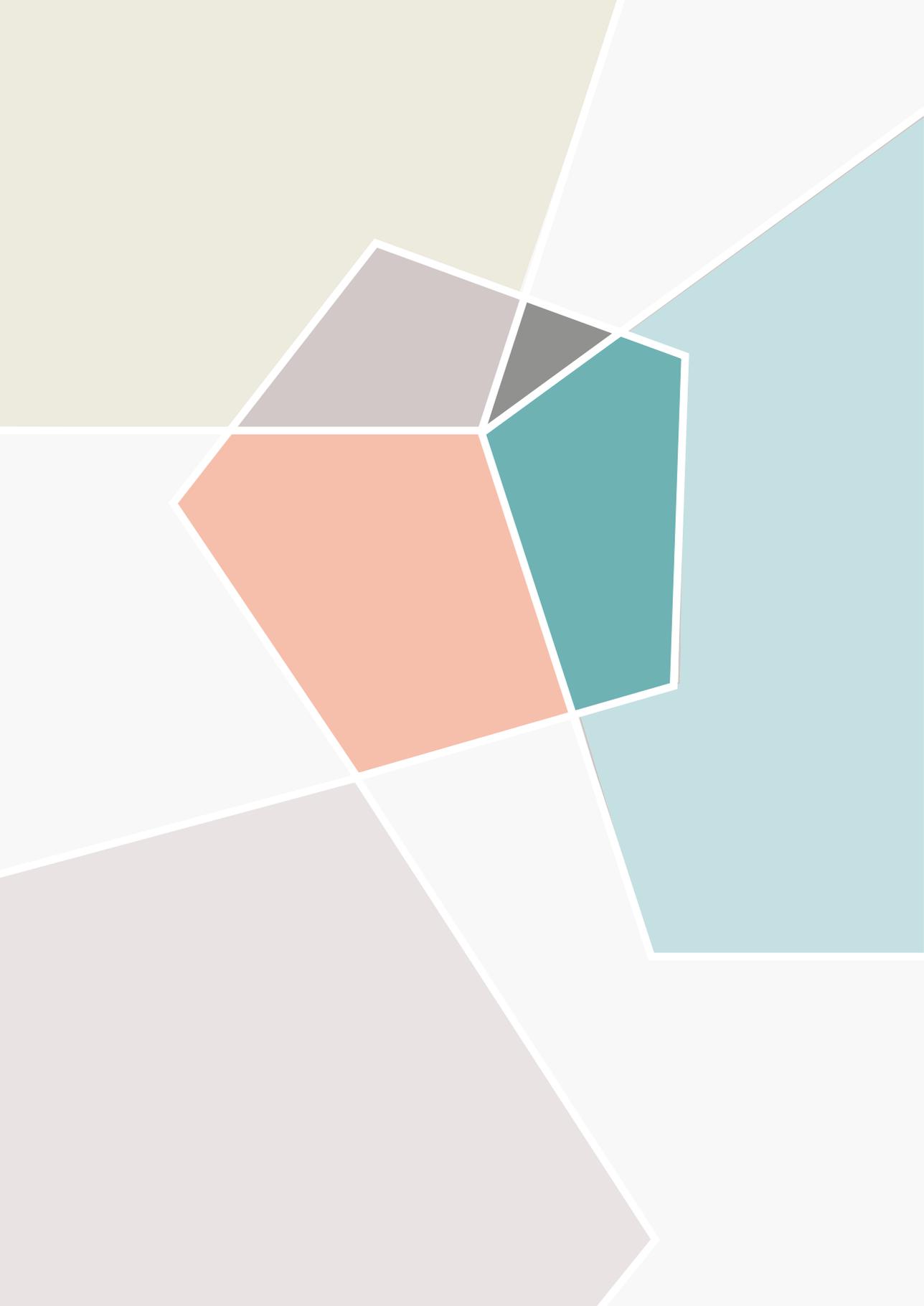
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**Multicomponent program to reduce functional decline in frail elderly people; a cluster controlled trial**

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## Abstract

### Background

The increasing number of community dwelling frail elderly people poses a challenge to general practice. We evaluated the effectiveness of a general practitioner led extensive multicomponent program integrating cure, care and welfare on the prevention of functional decline.

### Methods

We performed a cluster controlled trial in twelve general practices in Nijmegen, the Netherlands. Community-dwelling frail elderly people aged 70 years and up were identified with the EasyCare-TOS. In 6 general practices, 287 frail elderly received care according to the CareWell primary care program. This consisted of proactive care planning, case management, medication reviews and multidisciplinary team meetings with a general practitioner, practice and/or community nurse, elderly care physician, and social worker. In another 6 general practices, 249 participants received care as usual. Primary outcome was independence in functioning in (instrumental) activities of daily living (Katz-15 index). Secondary outcomes were quality of life (EQ5D+C), mental health and health-related social functioning (RAND-36), institutionalization, hospitalization, and mortality. Outcomes were assessed at baseline and at 12 months, and were analyzed with linear mixed model analyses.

### Results

204 (71.1%) participants in the intervention group and 165 (66.3%) participants in the control group completed the study. No differences between groups regarding independence in functioning and secondary outcomes were found.

### Conclusion

We found no evidence for the effectiveness of a multifaceted integrated care program in the prevention of adverse outcomes in community dwelling frail elderly people. Large-scale implementation of this program is not advocated.

## Introduction

Population aging has a profound effect on the number of frail elders and is a major challenge for health care systems. Frailty is a condition in which losses in several domains of functioning lead to a declining reserve capacity and a subsequent increased vulnerability to functional decline, dependence, hospitalization, institutionalization, and death. [1-3] It is thought to be present in up to a quarter of people aged 85 years or over. [4] The complex and interacting health care needs of these frail elders can be addressed only in a system that integrates health care and welfare services. This approach is supposed to delay the onset and progression of frailty and prevent its adverse outcomes including functional dependence and institutionalization. [5]

In countries with a strong primary care system, like the Netherlands, general practitioners (GPs) provide continuous, person-centred care to these community-dwelling frail elderly people. Care delivery is facilitated by the use of high-standard electronic medical records (EMRs) and patient panels, defining the population under care. [6,7] In the Netherlands, GPs often collaborate with practice nurses in the delivery of care (programs) according to the needs of the practice population. [7] Moreover, elderly care physicians (ECPs) increasingly operate (as consultants) in caring for frail older people in the community. [8] However, the coordination between GPs, other primary and specialist care providers, and home care and community services is often perceived to be insufficient, leading to a fragmented delivery of care. [9] Many opinion leaders therefore plea for a redesign of primary care services for frail elders.

Over the last decades, this perceived need led to the development of several integrated care programs targeting frail elderly people. Systematic reviews have shown these programs to vary considerably in content, disciplines involved, intensity, duration and setting. Disappointing to many, these studies have shown no or merely modest and inconsistent effects on clinical outcomes and health care utilization. [10-12] To date, therefore, there is no conclusive evidence for an efficient and effective approach to redesigning primary elderly care. In addition to the need for coordinated and integrated care, the need for medication intervention programs aiming at the management of polypharmacy, i.e. the (over)use of multiple medications, is widely recognized. [13-16]

In Dutch primary care, this has led to a well-supported belief that community based elderly care needs to be multifaceted, combining structured multidisciplinary collaboration between professionals from cure, care and welfare domains, proactive care planning, case management, and medication review. [17] Therefore we designed the CareWell primary care program that combines the above elements and aims at the prevention of functional decline, maintenance of well-being, and prevention of institutionalization and hospitalization in community-dwelling frail elders. This article reports on the results of the cluster controlled effectiveness trial.

## Methods

We conducted a two arm, non-randomized, cluster controlled trial in primary care in the municipality of Nijmegen, the Netherlands, between September 2011 and September 2012. To prevent contamination bias, we used a cluster controlled design with allocation by GP practice. [18,19] Details were published previously. [20] The study was reviewed by the Ethics Committee of the Radboud University Medical Centre Nijmegen (registration number 2010/403) and registered in the ClinicalTrials.gov Protocol Registration System (NCT01499797).

### Recruitment

Eligibility criteria for GP practices were: (1) a sufficient number of patients aged  $\geq 70$  years on their patient list, (2) adequate practice facilities enabling (future) implementation of the program, and – in the intervention group- (3) a solid motivation to adopt the program to reach optimal implementation. Six eligible GP practices were recruited for participation in the intervention arm and informed on the program. Then, six GP practices were recruited for the control group without being informed on the program. They were explicitly asked to deliver ‘care as usual’ and to decline new relevant inter professional collaborations during the intervention period. No restrictions on pre-existing collaborations between GPs and (practice) nurses were imposed.

GPs in both arms were trained to apply the concept of frailty and to identify the study participants with the EASY-Care Two-step Older persons Screening (EasyCare-TOS) instrument. [21] The EasyCare-TOS has shown good construct validity, interrater reliability and is well accepted by primary care professionals. [22,23] All practices were instructed to include 50 frail elders aged 70 years or above. Exclusion criteria were admission to a residential or nursing home, and/or critical or terminal illnesses. After the EasyCare-TOS assessment, the GP and practice nurse/ research assistant made a final decision on the presence of frailty, based on clinical reasoning using all explicit and tacit information. [21] In addition, the complexity of the care context, representing the organization and coordination of care, was judged. [24] Frail elders with and without care-complexity were then included. Details on the recruitment of practices and participants have been reported previously. [20]

### Intervention

The CareWell primary care program consisted of four key elements: multidisciplinary team meetings, proactive care planning, case management, and medication review.

Each practice assembled a core multidisciplinary team consisting of the GP, the practice nurse or, if not available, a community nurse, an ECP [8], added to the team to secure

geriatric expertise and knowledge on proactive care planning, and a social worker with expertise on social and welfare domains. No structural collaborations between GPs, ECPs, and social workers were readily available at the time of the intervention. Team meetings were held every 4-8 weeks. In addition, team members were able to communicate virtually through a secured web-based health and welfare information portal. [25]

Proactive, individually tailored care plans were formulated for each participant on enrolment in the program, based on individual health-related goals and needs as assessed with the EasyCare-TOS. Care plans were revised in the team meetings at least every six months and stored in the information portal.

A case manager, either a nurse or social worker, was assigned to each participant. Case managers were made responsible for the planning and logistics regarding the team meetings and for care coordination and monitoring. Furthermore, they were instructed to ensure participants' acknowledgment of the care plans, encourage their involvement in goal setting, and actively maintain treatment contact with the participants (and their informal caregivers) by telephone or home visits at least twice a year.

For each participant using five or more chronically prescribed drugs, a yearly medication review was held by the GP, the nurse, and a pharmacist.

Additionally, we developed multidisciplinary guidelines on eight common geriatric syndromes, a guideline on advance care planning, procedure agreements on easy-access consultation of geriatric experts, and procedure agreements between primary and specialized care providers on hospitalization and discharge. [20]

## Outcome measurements

Common baseline characteristics of the participants were expanded with a Socio Economic Status (SES) score, a cognition score, and a frailty index. The SES score was based on postal code areas and calculated on income, employment, and education. [26] A cognition score was based on a modified Mini-Mental State Examination. [22] The frailty index was defined as the proportion of accumulated deficits. [22,27] All baseline characteristics were included in the EasyCare-TOS step 2. Furthermore, the items constructing the primary and secondary outcomes were enclosed. Data were collected at baseline and after twelve months through a home-visit by either a trained nurse, in the intervention arm, or a research assistant, in the control arm. Outcome assessors were blinded for previous measurements, but not for the intervention arm for pragmatic reasons. Additional health care utilization data were extracted from the EMR at follow up.

Independence in functioning in (instrumental) activities of daily living, measured with the validated Katz-15 index [28], was used as the primary participants' outcome. Quality of life (measured with the EQ5D+C) [29], mental health (measured with the RAND-36) [30], health-related social functioning (measured with one question that was based on the social functioning subscale of the RAND-36) [30], institutionalization, hospitalization and mortality were chosen as secondary outcomes.

### Sample size calculation

Based on a power of 80%, a two-sided alpha of 0.05, an assumed ICC of 0.01 [31], and an expected loss to follow up of 35%, we calculated that we would be able to detect a clinically sufficient effect size of  $> 0.32$  on the Katz-15 index by including 50 participants in each of the 12 GP practices (total  $N=600$ , assuming equal cluster sizes). Extended information on the sample size calculation was published in the study protocol. [20]

### Statistical analysis

Outcomes at participants' level were analyzed with linear mixed model analyses to account for the clustering of participants within the GP practices. Outcome estimates were corrected for significant differences in baseline characteristics that correlated with the primary outcome, and for the baseline value of the outcome (in case of secondary outcomes) by including these variables as covariates. Subgroup analyses compared outcome estimates for participants in the lowest, middle and highest tertiles of age and Katz-15 index scores, and participants with and without care-complexity.

Residential and nursing home admissions, hospital admissions, and mortality were analyzed with binary logistic regression with correction for baseline values of the Katz-15 index. In evaluating admissions and mortality, no correction for baseline characteristics and covariates was done, since the number of events was too low to perform a multilevel analysis and the calculated intra-class coefficient was found to be negligibly low.

Baseline differences were analyzed using t-tests and chi-square tests.

All statistical analyses were performed using SPSS version 20. Tests were considered significant at  $P < 0.05$ .

## Results

### Sample characteristics

We included 536 participants: 287 in the intervention group and 249 in the control group. Baseline characteristics are shown in table 1. Participants in the intervention group more often lived alone, had more health-related limitations in social functioning, more cognitive deficits, more social disadvantage, and showed less care-complexity. These five characteristics correlated to the Katz-15 index score and were therefore used as covariates in our analyses. Furthermore, participants in the intervention group were higher educated.

TABLE 1 | Baseline characteristics of participants in the intervention group and control group.\*

Characteristics	CareWell- primary care (n=287)	Usual care (n=249)	P value for difference
Age, mean (SD), y	83.1 (5.6)	80.5 (6.0)	.42
Female sex	192 (66.9)	160 (64.3)	.52
Living alone	182 (63.4)	136 (54.6)	.039
Socioeconomic status score <sup>a</sup> , mean (SD)	0.5 (1.1)	0.2 (0.5)	<.001
Low level of education	69 (24.1)	100 (41.0)	<.001
Cognition score <sup>b</sup> , mean (SD)	7.5 (7.0)	5.3 (4.8)	<.001
Katz 15 index <sup>c</sup> , mean (SD)	5.4 (2.9)	4.6 (2.7)	.33
EQ5D+C <sup>d</sup> , mean (SD)	0.6 (0.3)	0.6 (0.3)	.08
RAND-36 Mental health <sup>e</sup>	61.1 (13.1)	62.4 (13.7)	.38
Presence of health-related limitations in social functioning <sup>f</sup>	178 (64.3)	88 (37.1)	<.001
Frailty index <sup>g</sup> , mean (SD)	0.4 (0.2)	0.4 (0.2)	.90
Presence of care-complexity	60 (21.1)	75 (30.1)	.017

\* Values are expressed as numbers (percentage) unless otherwise indicated.

<sup>a</sup> Socioeconomic status score was based on postal code areas (income, employment, and education); higher score indicates more social disadvantage.

<sup>b</sup> Based on a modified Mini-Mental State Examination (MMSE; range 0 to 28); higher score indicates more cognitive problems.

<sup>c</sup> Katz-15 (range 0 to 15); higher score indicates more dependence in (instrumental) activities of daily living.

<sup>d</sup> EQ5D+C scores (range -0.33 to 1.00); higher score indicates a higher health-related quality of life.

<sup>e</sup> RAND-36 Mental Health (range from 0 to 100; higher score indicates better mental health).

<sup>f</sup> Based on the social functioning subscale of the RAND-36. Answers dichotomized in 'absence of limitations' vs. the other categories indicating 'presence of limitations'.

<sup>g</sup> The frailty index measures (scale 0 to 1); a higher index suggests of a more frail status.

SD, Standard Deviation

We had a loss to follow-up of 83 (28.9%) in the intervention and 84 (33.7%) in the control group, respectively (figure 1). The follow up measurements therefore included 204 (71.1%) in the intervention group and 165 (66.3%) in the control group. Participants lost to follow-up in the intervention group were significantly older, more dependent in daily life, had more health-related limitations in social functioning, more cognitive deficits, more social disadvantage, a more frail status, and were higher educated in comparison to participants that were lost in the control group.

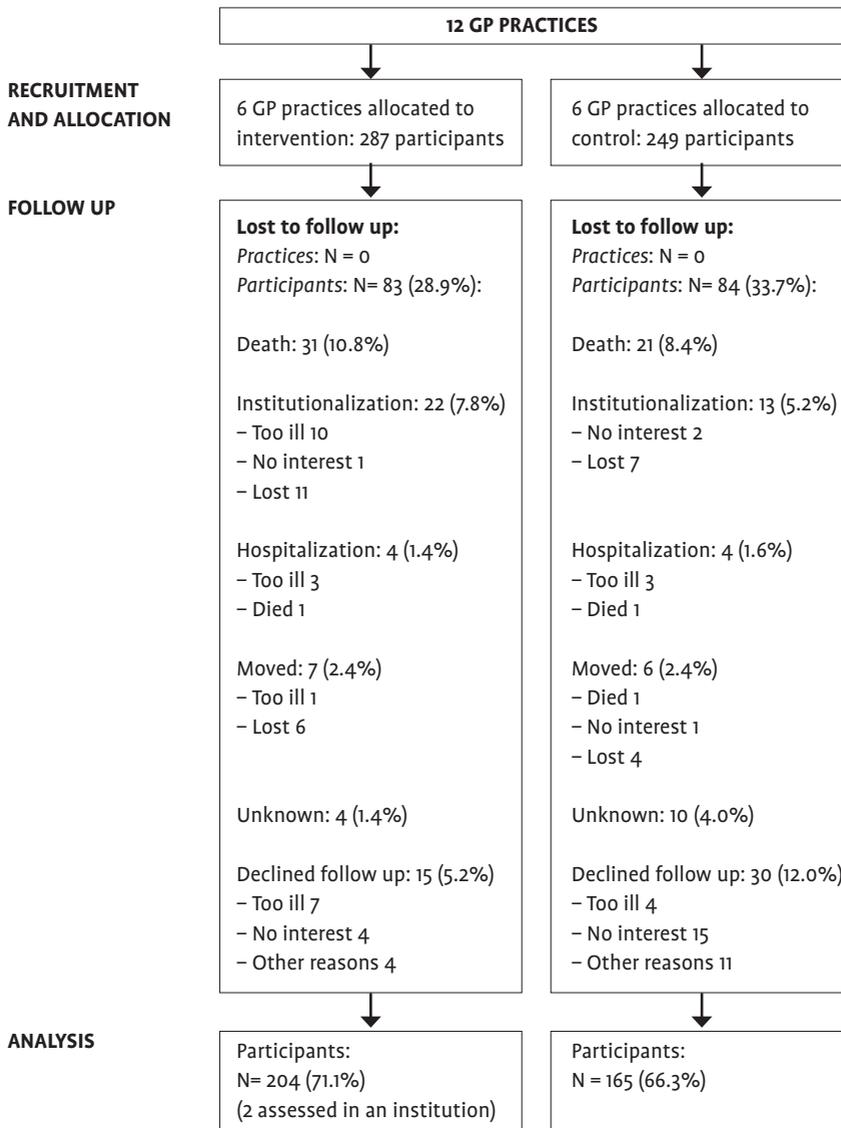


FIGURE 1 | Flow diagram of practices and participants.

## Patient outcomes

The Katz-15 index score showed a greater increase, indicating more decline in functioning, in the intervention group as compared to the control group. After correction for clustering (with a calculated ICC of 0.05), relevant covariates, and the Katz-15 index score at baseline, no significant effects on functioning were found (table 2). Moreover, we found no significant effects on quality of life, mental health, and health related limitations in social functioning (table 2). Subgroup analyses showed no mediating effects of age (divided in tertiles; <80 yrs, 80-85 yrs, >85 yrs), baseline Katz-15 index scores (divided in tertiles; <3, 3-6, >6), and the absence or presence of care-complexity, with the exception of small effects on quality of life (-0.18 (95% CI -0.36 to -0.00; P = 0.048) and on social functioning (0.29 (95% CI 0.10 to 0.48; P = 0.003) in the 80-85 year-olds in favour of the control group (data not shown in tables). No differences in residential and nursing home admissions, hospital admissions and mortality were found (table 3).

TABLE 2 | Effects of the CareWell primary care program on primary and secondary outcomes.

Outcome	CareWell primary care* (n=204)		Usual care* (n=165)		Estimated intervention effect* (95% CI)	P value
	Baseline mean (SD)	Change at follow-up mean (SD)	Baseline (SD)	Change at follow-up mean (SD)		
Katz-15 index <sup>a</sup>	5.4 (2.9)	0.8 (1.9)	4.6 (2.7)	0.5 (2.1)	0.37 (-0.1 to 0.8)	.10
EQ5D+C <sup>b</sup>	0.6 (0.3)	0.0 (0.3)	0.6 (0.3)	0.0 (0.3)	-0.031 (-0.1 to 0.0)	.37
RAND-36 Mental health <sup>c</sup>	61.1(13.1)	-0.28 (13.6)	62.4 (13.7)	-0.8 (13.7)	0.86 (-2.3 to 4.0)	.56
Health-related limitations in social functioning <sup>d</sup>	1.5 (1.4)	-0.1 (1.6)	0.9 (1.3)	0.3 (1.7)	0.037 (0.2 to 0.2)	.76

\* Adjusted for clustering, baseline values of relevant covariates (living situation, health-related limitations in social functioning, cognition score, socio-economic status score, and care-complexity), baseline value of the Katz-15 index and, in case of secondary outcomes, baseline value of the outcome parameter.

<sup>a</sup> Katz-15 (range 0 to 15); higher score indicates more dependence in (instrumental) activities of daily living.

<sup>b</sup> EQ5D+C scores (range -0.33 to 1.00); higher score indicates a higher health-related quality of life.

<sup>c</sup> RAND-36 Mental Health (range from 0 to 100; higher score indicates better mental health).

<sup>d</sup> Based on the social functioning subscale of the RAND-36. Answers dichotomized in 'absence of limitations' vs. the other categories indicating 'presence of limitations'.

SD Standard Deviation

95% CI 95% Confidence Interval

TABLE 3 | Admissions and mortality during follow up.

Outcome	CareWell primary care* (n=204)	Usual care* (n=165)	Odds ratio (95% CI)	P value
Residential and nursing home admissions	24 (8.3)	13 (5.2)	1.32 (0.64 to 2.71)	.46
Hospital admissions	52 (18.1)	57 (22.9)	0.74 (0.48 to 1.14)	.17
Mortality	31 (10.8)	21 (8.4)	1.13 (0.61 to 2.08)	.70

\* Values are expressed as numbers (percentage).

## Discussion

We found no effects of the CareWell primary care program on functioning, quality of life, mental health, health-related social functioning, institutionalization, hospitalization, and mortality in community-dwelling frail elderly people in Dutch primary care.

Strength of this study is the inclusion of a large sample of well-defined frail elderly people by professionals who were trained in the concept of frailty. Next, the inclusion of motivated primary care professionals in the intervention group and the use of several tailored implementation strategies supported optimal implementation and benefit of the program. The implementation of the program in everyday practice contributed to its external validity.

We also consider some weaknesses. First, significant baseline differences existed between the study groups. These may have resulted from the cluster design that was used to prevent spill over of intervention effects.<sup>[19]</sup> Moreover, differences in the appraisal of participants' frailty by the GPs in both groups may have contributed. However, all professionals were trained in the concept of frailty and the use of the EasyCare-TOS to minimize these kinds of imbalances. Although we corrected for baseline differences, this may still have affected our results. Second, the allocation of motivated professionals to the intervention group might have led to differences in the quality of care delivery between groups in favour of the intervention group. However, since we found no between group differences in effects on functioning and secondary outcomes, it is unlikely that the allocation procedure led to bias in favour of the intervention. Professionals in both groups used the EasyCare-TOS instrument, which may have led to "enhanced" usual care in the control group.<sup>[32]</sup> We tried to minimize this effect by instructing the control practices not to start new activities related to the intervention, such as improved collaboration, making care plans, and starting medication reviews in the study period. Third, outcome assessors were not

blinded for the intervention since this was not feasible. Last, participants with the least degree in functioning (i.e. higher Katz-15 index scores) were more often lost to follow up in the intervention group. However, since we assume that these participants would have the least potential to benefit, an effect in favour of the intervention group without this loss to follow up is unlikely.

In the past decades, several studies have been conducted with programs targeting at improving functioning and preventing institutionalization and hospitalization in community dwelling frail elderly people. These studies show heterogeneous designs and settings, and have yielded inconsistent results. [10-12] For example, Bernabei et al. showed that an integrated community care program with standardized multidisciplinary meetings between the GP, nurse, geriatrician, and social worker reduced functional decline, institutionalization, and hospitalization. [33] However, a home-based care management program delivered by a nurse and social worker in collaboration with a geriatric multidisciplinary team, complementary to care delivered by the GP, showed no effects on functioning. [34] More recently, Metzselthin et al. found no effect on disability after introducing a program based on meetings between the GP and practice nurse, care planning, and regular monitoring and follow-up. [35] Despite our efforts to optimally implement a fully integrated care and welfare program, we found no evidence for the effectiveness of this program in the prevention of functional decline, institutionalization and hospitalization either.

In addition to the methodological drawbacks, there are some other potential explanations for the absence of effects of the CareWell primary care program. First, the used outcome measures might not be specific and responsive enough in our targeted population. Although the Katz-15 index is applied in the vast majority of studies on functional decline and reliably predicts adverse health outcomes in community dwelling frail elderly people [36,37], it might not be responsive to change in individual elders within a limited time span. Moreover, the EasyCare-TOS identifies health risks relating to functioning but also to psychosocial and environmental domains that are negatively influenced by frailty. Subsequently, the programs' interventions and goals are highly individualized and heterogeneous. Outcome measures that are more person- and goal-centred might better measure the effectiveness of our intervention, e.g. goal-attainment scaling. [38] Second, it is widely recognized that complex interventions are often not delivered or adhered to as intended [39-41], which we accept as part of the outcome given the pragmatic nature of our study. Moreover, the follow-up period of twelve months may be too short to establish effective multidisciplinary collaborations, a true transition towards integrated care [41], and to achieve measurable effects on patient outcomes. A third explanation may be that the targeted population was too frail for the interventions to be effective in the prevention of adverse health outcomes. On the other hand, frail elderly people may appraise the boundaries of functional decline differently, leading to a willingness to adhere to preventive interventions at too late a stage, leading to a low adherence at participants'

level. A last explanation relates to the Dutch health care system, in which the GP already has a strong position and a central role in delivering elderly care, often in collaboration with practice nurses, and facilitated by high quality EMRs. [7] This suggests that limited room for improvement existed in comparison to health care settings in which primary care is less well organized. On the other hand, our results may hold external validity to health care settings in which collaboration can be set up between health care and welfare, and primary and geriatric care.

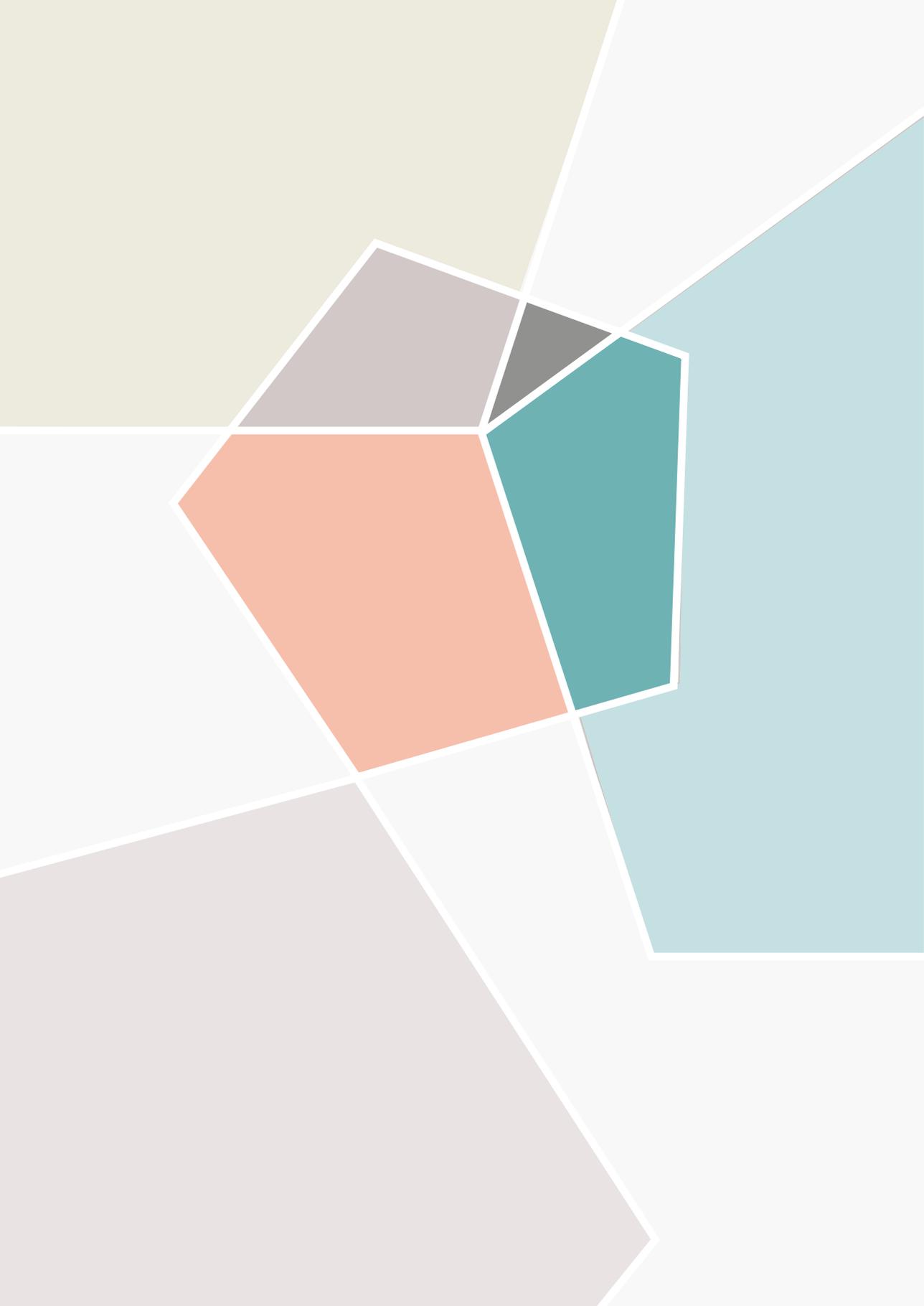
In conclusion, we found no beneficial effects of our CareWell primary care program in community dwelling frail elderly people in Dutch primary care. Current evidence is insufficient to advocate large-scale implementation of this multicomponent integrated primary care program. Further (longitudinal) studies are needed on the different trajectories of frailty and the most efficient timing of interventions. Moreover, research is needed on the validity and applicability of goal-oriented outcome measures in the field of elderly research.

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**Effects of an integrated care program  
on caregivers of community-dwelling  
frail elderly; lessons learned from a  
cluster controlled trial**

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## Abstract

### Background

The CareWell primary care program aims to improve the care for community-dwelling frail elderly and their caregivers by organizing multidisciplinary team meetings, proactive care planning, case management, and medication reviews. This paper reports on the impact on caregiver outcomes.

### Methods

Pragmatic, cluster controlled trial in 12 general practices in the Netherlands, with a follow-up of 12 months. Six general practices implemented the CareWell primary care program; six control practices continued 'care as usual'. Frail elderly care recipients were identified with the EasyCare-TOS; their caregivers were recruited by the care recipients. We measured care-related quality of life of caregivers with the CarerQoL-7D questionnaire and caregiver burden with the CarerQoL-VAS. Caregivers estimated the time they invested in caregiver tasks.

### Results

Three hundred sixty-four of 536 care recipients (68%) indicated to have an informal caregiver; 73 caregivers (21%) completed both baseline and follow-up questionnaires and were included in the final analyses. No differences were found in care-related quality of life (mean difference 5.0, 95% CI -0.4 to 10.7), burden (mean difference -0.5, 95% CI -2.1 to 1.2), and time invested in caregiver tasks (mean difference -5.0, 95% CI -11.9 to 1.8).

### Conclusion

We could not draw solid conclusions on the effect of the program on caregiver outcomes, due to challenges both in recruitment and follow-up of caregivers. Lessons learned include the insight that studies on integrated care programs need a specific focus on the care recipient/caregiver dyad, incorporating effective dyad-focused recruitment strategies, separate power calculations on both entities, and dyad-focused outcome measures.

## Background

Population aging has a profound effect on the number of frail elderly and is a major challenge for health care systems. In the Netherlands, the number of frail elderly, aged 65 years and above is expected to increase from 16% in 2010 to over 25% of the population in 2030. [1] Frailty is a condition in which losses in several domains of functioning lead to an increased vulnerability to functional decline, hospitalization, institutionalization, and death. [2,3] While the ageing population puts an increasing demand on health care, many Western countries are confronted with cutbacks in formal care spending. [4] To reduce the pressure on the healthcare budget, expensive institution-based care for elderly is increasingly substituted with community-based care services and informal care. [5] Informal care refers to the unprofessional and unpaid assistance provided by partners, family or friends. [6] Whilst informal caregivers already contribute largely in the health care delivery to community-dwelling frail elderly, even in countries that traditionally have a strong, publicly funded health care system, the pressure on informal caregivers is increasing.

Given the substantial morbidity associated with frailty, caregivers of frail elderly are prone to physical, psychosocial and financial burden. [7] Evidence suggests that caregivers of frail elderly have increased risk of depression, anxiety, and other negative effects, while they can also feel rewarded by their caregiving role. [8] A balanced view on the positive and negative aspects of caregiving for frail elderly is needed.

While the prevention of caregiver burden is essential for caregivers themselves as well as to ensure a sufficient supply of informal care within the health care system, most of the intervention programs targeting frail elderly to date have paid little attention to caregivers' outcomes. The scarce available evidence shows limited and inconsistent effectiveness of case management and support services such as respite services, psychosocial interventions, and information and communication technology interventions. [9,10] Moreover, most studies that primarily focused on caregivers' outcomes emphasized on relatively homogeneous care recipient populations, such as care recipients with dementia or cancer [11-14], limiting their generalizability to frail elderly populations in general.

There is an increasing consensus that care delivery for community-dwelling frail elderly, with complex and interacting health care needs, and their caregivers needs to be proactive and integrated, based on structured, multidisciplinary collaboration between professionals from cure, care and welfare domains. [15-17] We designed the CareWell primary care program that consists of four key elements: multidisciplinary team meetings, proactive care planning, case management, and medication reviews. [18] Earlier we published papers on the program's effectiveness on care recipient outcomes and implementation fidelity. [19,20] The aim of this study is to report on the impact on caregiver outcomes.

## Methods

### Setting and participants

We set up a cluster controlled trial of twelve months between September 2011 and September 2012. The study protocol was reviewed by the local accredited medical review ethics committee: CMO region Arnhem-Nijmegen (registration number 2010/403). They waived further examination as the Medical Research Involving Subjects Act did not apply. The trial was registered in the ClinicalTrials.gov Protocol Registration System (NCT01499797).

The CareWell primary care program was implemented in six general practices in (the region of) Nijmegen, the Netherlands; six control practices delivered usual care. Frail elderly care recipients were identified and assessed with the EasyCare Two-step Older persons Screening instrument (EasyCare-TOS) during a home-visit by a nurse. [21,22] Details on the recruitment and informed consent procedures of care recipients were reported previously. [19] The informal caregivers were recruited via the care recipients; the nurses asked them to identify their primary caregiver that is ‘the person that voluntarily helps you the most with domestic tasks, personal care tasks, and/or practical care tasks, e.g. transfers’. Caregivers were then invited by their care recipients to attend the home visit by a nurse, where they received study information and were asked for their informed consent. When the caregivers were absent during the home visit, they received the study information and informed consent forms by mail.

### Intervention

The CareWell primary care program consists of four key components: 1) multidisciplinary team (MDT) meetings, 2) proactive care planning, 3) case management, and 4) medication reviews.

Earlier, we published an extensive description of the intervention. [18,19] In brief, regular MDT meetings were planned with the involved professionals, in which all care recipients and their care plans were discussed at least twice a year and more often if needed. Caregivers’ needs regarding assistance and support were included in the care planning. Case managers were installed for each patient, and they were instructed to engage caregivers in goal setting and care planning, and to evaluate the care process with both the care recipients and the caregivers at least twice a year through home visits or by telephone, and more often if needed. Next, caregivers were encouraged to communicate with the healthcare professionals of the MDT through a secured web-based Health and Welfare Information Portal (ZWIP). [23]

## Usual care

In the Netherlands, general practitioners (GPs) provide continuous, person-centred care to community-dwelling frail elderly, facilitated by the use of 'patient panels', defining the patient population under care of a GP, and high-standard electronic medical records. [24,25] GPs often collaborate with practice and/or community nurses. However, structured multidisciplinary collaboration between the cure, care and welfare domains hardly exists in current usual care. [26] At the start of the study, usual care was mostly reactive, with the patient or caregiver initiating consultation with the GP. Moreover, structured, proactive identification of caregiver needs and proactive engagement of caregivers as partners in care delivery was uncommon, leading to a substantial variation in the current (quality of) care delivery to frail elderly and their caregivers.

## Outcome measurements

Caregiver data were collected at baseline and at follow up after 12 months through a structured questionnaire, i.e. the TOPICS-MDS caregiver questionnaire. [27]

When the caregivers were present at the home visit during which the care recipients were assessed, they were asked to fill out the questionnaire during this visit. When absent, they received the questionnaire with fill-in instructions per mail, together with a prepaid answer envelop. When necessary, the nurse sent one reminder after 4 weeks.

Care-related quality of life was measured with the well-validated Care-Related Quality of Life (QoL) instrument (CarerQol-7D). [28-30] This instrument contains two positive dimensions of caregiving (care-related fulfilment, perceived social support) and 5 negative dimensions of caregiving (relational problems with the care recipient, mental health problems, problems combining daily activities, financial problems, physical health problems) [29], that are calculated into a single summary score ranging 0 to 100, with a higher score indicating a more favourable QoL. [31] Caregiver burden was measured with the validated CarerQol-visual analog scale (VAS), by asking caregivers to indicate how burdened they feel by their caregiver tasks on a visual analog scale ranging from 0 (no burden) to 10 (highest burden). [28] Last, caregivers were asked to estimate their time investment in three categories of informal caregiver tasks, i.e. domestic care tasks, personal care tasks, and instrumental care tasks, e.g. transfers, financial/administrative duties.

We published details on data collection and outcome measures regarding care recipients elsewhere. [19]

### Statistical analysis

We compared baseline characteristics of caregivers and care recipients of both the intervention and the control group using t-tests and chi-square tests. Differences in outcomes at caregivers' level were analyzed with linear mixed model analyses, in order to account for clustering of the frail elderly participants within GP practices. We used a random intercept model. Outcomes estimates were corrected for the baseline value of the outcomes, and for those dyad characteristics that correlated to the CarerQoL-7D and differed significantly and/or relevantly (i.e. a difference >10%) at baseline between the intervention and the control group. All statistical analyses were performed using SPSS version 22. Tests were considered significant at  $p < .05$ .

The power calculation was based on the cluster controlled effectiveness trial in which independence in functioning in (instrumental) activities of daily living (measured with the validated Katz-15 index) [32] was used as the primary care recipient outcome. No additional power calculation was done on caregiver outcomes.

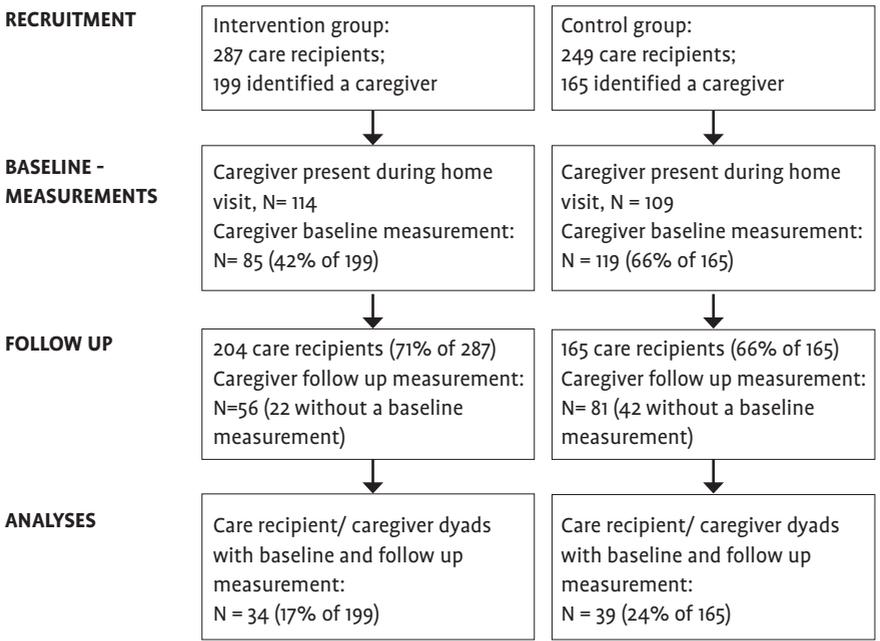


FIGURE 1 | Flow diagram of caregivers (CG) and care recipients (CR).

## Results

Five hundred thirty-six frail elderly care recipients were included in the study: 287 in the intervention group and 249 in the control group. Three hundred sixty-four frail elderly care recipients (68%) indicated to have an informal caregiver; 199 in the intervention group and 165 in the control group. We collected 204 (56% of 364) caregiver questionnaires at baseline (85 resp. 119) and 137 (38% of 364) at follow-up (56 resp. 81). Seventy-three caregivers (20%) completed both questionnaires and were analyzed; 34 (17%) in the intervention group and 39 (24%) in the control group (figure 1).

TABLE 1 | Baseline characteristics of caregivers and care recipients in the intervention group and control group.

Characteristics	CareWell primary care (N=34)	Control (N=39)	P value for the difference
<b>Caregivers</b>			
Living together with care recipient, N (%)	11 (32.4)	20 (51.3)	.10
Relationship with care recipient, N (%):			.55
Spouse/ partner			
Daughter/Son (- in law)	11 (32.4)	16 (41.0)	
Other	18 (52.9)	19 (48.7)	
	5 (14.7)	4 (10.3)	
CarerQoL-7D, mean (SD)	86.8 (7.3)	84.5 (10.8)	.28
CareQoL-VAS, mean (SD)	3.29 (2.4)	3.38 (2.2)	.88
Time investment, mean (SD), (hrs/wk)	11.6 (20.9)	11.9 (12.8)	.94
<b>Care recipients</b>			
Age, mean (SD), yrs	81.8 (5.9)	80.1 (5.4)	.20
Living alone, %	15 (44.1)	17 (43.6)	.96
Socioeconomic status score*, mean (SD)	0.69 (1.1)	0.32 (0.4)	.06
Cognition score <sup>a</sup> , mean (SD)	6.1 (7.3)	4.8 (4.4)	.38
Katz 15 index <sup>b</sup> , mean (SD)	6.3 (2.4)	5.3 (2.4)	.08
Frailty index <sup>c</sup>	0.4	0.4	.62

\* Socioeconomic status score was based on postal code areas (income, employment, and education); higher score indicates more social disadvantage.

<sup>a</sup> Based on a modified Mini-Mental State Examination (MMSE; range 0 to 28); higher score indicates more cognitive problems.

<sup>b</sup> Katz-15 (range 0 to 15); higher score indicates more dependence in (instrumental) activities of daily living.

<sup>c</sup> The frailty index was defined as the proportion of accumulated deficits (range 0 to 1); a higher score indicates more frail status.

SD Standard Deviation

We found baseline differences between caregiver/care recipient dyads that were analyzed and those that were lost to follow-up. Caregivers that were analyzed had a higher care-related quality of life ( $p = .007$ ), and experienced less burden ( $p = .04$ ) at baseline than caregivers that were lost to follow-up. Moreover, at baseline, the care recipients of the caregivers that had a follow-up lived alone less often ( $p = .005$ ), were frailer ( $p = .01$ ), and more dependent in (instrumental) activities of daily living ( $p = .02$ ) (data not shown).

At baseline, we found no significant differences in dyad characteristics between the intervention and the control group, as shown in table 1.

After correction for clustering, relevant covariates, and the baseline values of the outcome measure, no significant effects of the intervention on care-related QoL, burden and time investment were found (table 2). Uncorrected (not shown) and corrected outcome estimates did not differ, with the exception of an uncorrected significant effect on time investment in favour of the intervention group.

TABLE 2 | Effects of the CareWell primary care program on caregiver outcomes

Outcome	CareWell primary care* (n=34)		Usual care* (n=39)		Mean difference* (95% CI)	P value
	Baseline mean (SD)	Follow-up mean (SD)	Baseline (SD)	Follow-up mean (SD)		
CarerQoL-7D <sup>a</sup>	86.8 (7.3)	87.4 (7.7)	84.5 (10.8)	81.3 (15.1)	5.1 (-0.4 to 10.7)	.07
CarerQoL-VAS <sup>b</sup>	3.3 (2.4)	3.6 (2.2)	3.4 (2.2)	4.3 (2.5)	-0.5 (-2.1 to 1.2)	.52
Total time (hrs/wk) <sup>c</sup>	11.6 (20.9)	9.7 (9.7)	11.9 (12.8)	17.9 (20.0)	- 5.0 (-11.9 to 1.8)	.15

\* Adjusted for clustering, baseline values of the outcome parameter, and relevant covariates, i.e. co-residence, caregiver/care recipient relationship, and care recipients' cognition score.

<sup>a</sup> CarerQoL-7D measures care-related quality of life; a higher score indicates a more favourable quality of life (range 0-100)

<sup>b</sup> CareQoL-VAS measures caregiver burden on a visual analog scale; a higher score indicates more burden (rang 0-10)

<sup>c</sup> Time invested on caregiver tasks, as estimated by the caregivers (hrs/wk).

SD Standard Deviation

95% CI, 95% Confidence Interval

## Discussion

This study explored the effects of the CareWell primary care program on caregiver outcomes of caregivers of community-dwelling frail elderly people. After twelve months, we found no statistically significant effects on care-related quality of life, caregiver burden, and time investment in caregiver tasks.

These study results match a study of Melis et al. who did not find significant effects of a nurse-led comprehensive case management program for community-dwelling frail older people on caregiver burden and time investment on caregiver tasks. [33] In contrast, Janse et al. found significant improvements in caregiver QoL in the intervention group and not in the control group. They also found that burden significantly decreased in the control group, but not in the intervention group, without effects on time investment in either group.[34] Overall, evidence on caregiver outcomes of integrated care programs aimed at community-dwelling frail elderly is inconsistent, and the mechanisms by which their effectiveness might be exerted remains largely unresolved. [34]

We intended to examine the impact of our CareWell program on caregiver outcomes from a balanced caregiving perspective, by including both objective and subjective, and positive and negative dimensions of caregiving in our measurements. This is a strength of our study, as it acknowledges the complexity of caregiving in which positive experiences such as satisfaction, pleasure, and enjoyment protect caregivers against burden and other negative outcomes. [35-38] However, we also acknowledge some study limitations. First, we did not power the study on caregiver outcomes. Perhaps in a larger study sample we might have been able to demonstrate statistical significance of the trends we found, i.e. an increase in care-related QoL, less increase in caregiver burden, and a decrease in time investment in caregivers in the intervention group compared to the control group. Moreover, in a full-scale study we would have been able to perform sensible subgroup analyses, aiming at subpopulations of caregivers, e.g. co-residing and/or spousal caregivers [39-41] or male/female caregivers [36], or subpopulations of care recipients, e.g. more/less frail status. [42] Next, we encountered problems with the recruitment and attrition of caregivers. Only 68% of the care recipients were able to identify an informal caregiver, and we could include only 20% of these dyads in the analyses. We did not foresee these problems, as a comparable study reported a follow up rate of caregivers of 63%. [43] A possible explanation is that the identified caregivers, who were indicated by the care recipients, did not recognize themselves sufficiently as a caregiver ('a person that voluntarily helps you the most with domestic tasks, personal care tasks, and/or practical care tasks, e.g. transfers'). This may have led to non-response. It is known that caregivers rarely self-identify [7], and that spousal caregivers only start identifying themselves as caregivers at the time they need to perform personal care tasks. [44] An even more plausible factor may relate to the fact that our intervention did not primarily focus on the caregivers. This may have resulted in less commitment of

caregivers to participate and consent to follow up. Unfortunately, we could not evaluate these assumptions.

Some possible explanations for the absence of effects of our program on caregiver outcomes can be given. First, we did not find significant effects of the program on care recipient outcomes, i.e. functional decline, institutionalization, and hospitalization. We even found a (not significant) increase in functional decline in the intervention group as compared to the control group. [19] The absence of effects of our intervention on care recipients may have impeded the effectiveness on caregivers, as it is generally assumed that the health state of community-dwelling frail elderly influences the quality of life and burden of their caregivers. [37,42,45,46] Second, in retrospect, we think that our follow-up of twelve months may have been too short to fully implement the CareWell program and simultaneously exert measurable effects on care recipients and caregivers. For example, in our process evaluation we found significant between-practices differences in the degree of implementation of our program, with a large variation in the implementation of case management. [20] Although we did not record which case management interventions were specifically aimed at the caregiver or the dyad relationship, it is possible that caregivers needed more ‘time to benefit’ from the positive effects of our program. [47-49] This may have led to an underestimation of our study effects. Last, caregivers with a lower care-related QoL and a higher caregiver burden at baseline showed higher attrition rates. This also may have led to an underestimation of effects. However, the caregivers that were analyzed more often co-resided with the care recipients, and cared for more frail and more dependent care recipients. Literature suggests that these caregivers would benefit most from the intervention. [8,41] Due to insufficient power, we could not perform subgroup analyses and therefore we cannot state the overall effect of this attrition problem on our results.

## Lessons learned

Our study reveals important lessons for future research. First, we conclude that more specific attention to the recruitment and follow up of informal caregivers is needed, in order to prevent recruitment and attrition problems. For this aim, we propose:

- The involvement of caregivers in the design of the study. In doing so, a definition of caregiving that is clear to both health care professionals and the dyad can be formulated, preventing non-response due to non-compelling definitions of caregiving. Next, by engaging caregivers in the study design, they may feel more appreciated in their caregiver role and subsequently more willing to participate in the study.
- The use of specific recruitment and follow up strategies for caregivers, e.g. involve GPs and/or nurses in identifying and engaging caregivers. [50]

Second, we learned that more insight is needed into the factors that influence caregiver outcomes. It is generally assumed that the health state of community-dwelling frail elderly influences the quality of life and burden of their caregivers [37,42,45,46], but the association over time is unclear. [51] Also, evidence exists on the influence of caregiver information and support interventions on caregiver outcomes, e.g. intervention to strengthen coping abilities, to improve the dyad relationship, or formal care support such as home care. [37,52,53] Unfortunately, we were not able to collect qualitative data to examine the mechanisms by which our intervention influenced caregiver outcomes. We make the following recommendations for future studies:

- The development of dyad-focused outcome measures.
- The use of mixed-method analyses to examine which effects on caregivers are the results of dyad interactions, and which are resulting from interventions that target caregiver information and support.

A third and last lesson learned is that the implementation of a complex intervention like our CareWell primary care program is challenging and time-consuming. Whilst to date there is no consensus on the dose-response relationship between case management interventions and caregiver outcomes [10], combining qualitative with quantitative analyses might have provided more insight in the association between implementation and dyad outcomes. This leads to the following recommendations:

- The use of a longer follow up period to prevent lag-time bias in implementation and effectiveness.
- The use of mixed method analyses to provide insight in the association between implementation and dyad outcomes.

## Conclusion

We are not able to draw robust conclusions on the effectiveness on caregiver outcomes of our integrated care program for community-dwelling frail elderly. For future studies, it is crucial to think about separate strategies for effective recruitment and follow up of caregivers. This includes engagement of caregivers in the design and planning of intervention studies, incorporation of dyad-focused outcome measures, and separate power calculations for this purpose. Only then, comparable studies will be able to answer questions about preferable health services reforms that meet the needs and priorities of frail elderly and their informal caregivers.

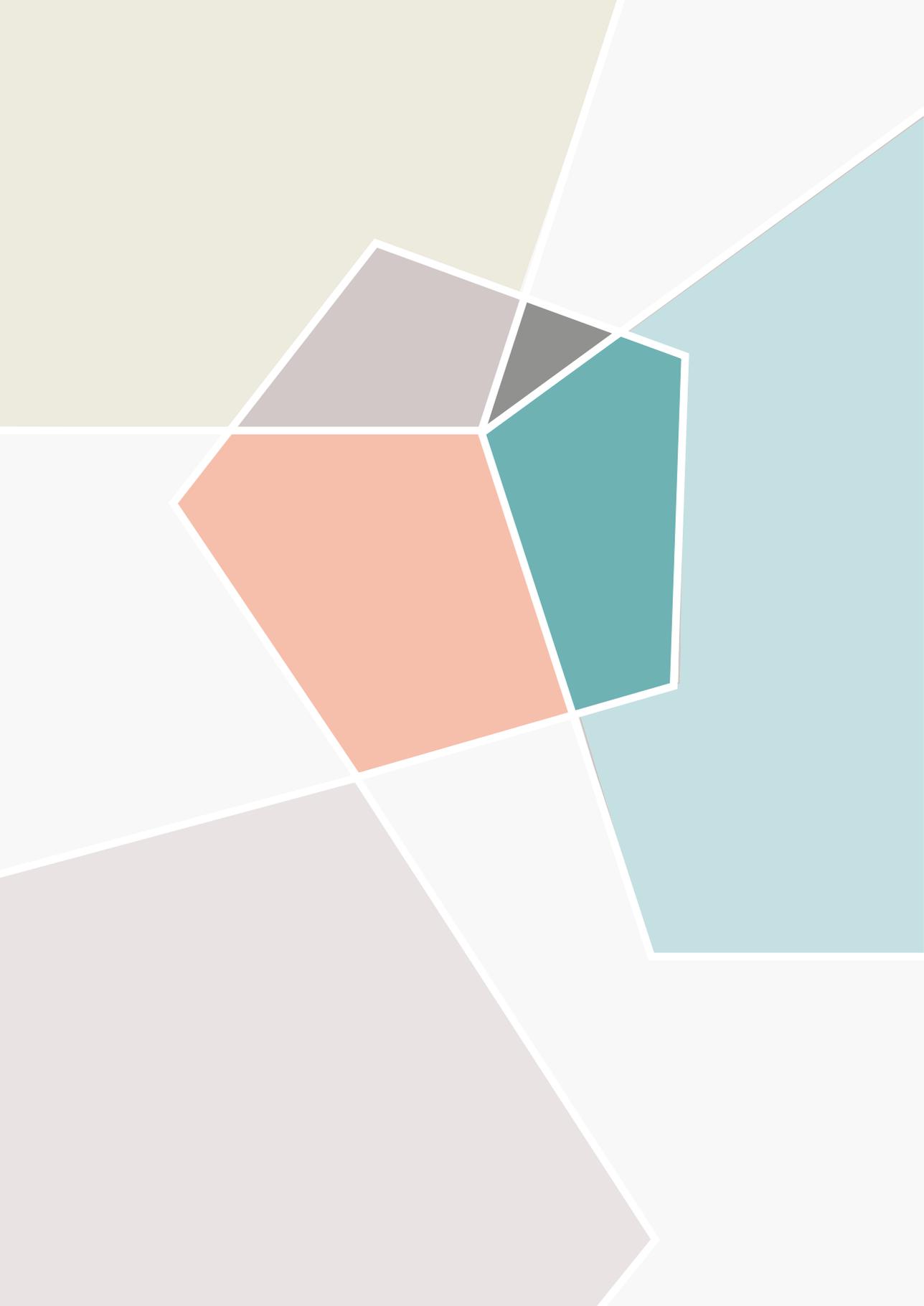
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**The association between  
implementation and outcome of a  
complex care program for frail elderly  
people**

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# Abstract

## Background

Over the last 20 years, the effectiveness of complex care programs aiming to prevent adverse outcomes in frail elderly people has been disappointing. Recently, we found no effectiveness of the CareWell primary care program. It is largely unknown to what extent incomplete implementation of these complex interventions influences their outcomes.

## Objective

To examine the association between the degree of implementation of the CareWell program and the prevention of functional decline in frail elderly people.

## Methods

Quantitative process evaluation conducted alongside a cluster controlled trial. Two hundred and four frail elderly participants from six general practitioner practices in the Netherlands received care according to the CareWell program, consisting of four key components: multidisciplinary team meetings, proactive care planning, case management, and medication reviews. We measured time registrations of team meetings, case management and medication reviews, and care plan data as stored in a digital information portal. These data were aggregated into a total implementation score (TIS) representing the program's overall implementation. We measured functional decline with the Katz-15 change score (follow-up score at twelve months minus the baseline score). The association between TIS and functional decline was analyzed with linear mixed model analyses.

## Results

We found no statistically significant differences in functional decline between TIS groups ( $F = 1.350$ ,  $p = .245$ ). In the groups with the highest TISs we found more functional decline.

## Conclusion

A higher degree of implementation of the CareWell program did not lead to the prevention of functional decline in frail elderly people.

## Background

In the past 20 years, studies on complex care programs for frail elderly people have shown inconsistent and disappointing results on the prevention of functional decline. [1,2] These have been attributed to the heterogeneity in care formats, professionals involved, outcome measures used, and the setting and intensity of the interventions. [1,2] Moreover, it is increasingly recognized that implementation fidelity, i.e. the degree to which the intervention was carried out as intended, can affect the intervention's outcomes. [3]

Complex care programs comprise of multiple interacting components and require professionals and patients to change their behaviour. [4] Moreover, they target several organizational levels, and necessitate flexibility and tailoring. [4] These features cause complex programs to show great variation in their implementation. [5] Therefore, it is important to interpret the outcome results of these programs in the light of their degree of implementation. [6] Nowadays, process evaluations of complex interventions are common, especially in health promotion and public health domains. [5] However, integrating implementation and outcome data in statistical analyses still is uncommon. [6]

Recently, we published the negative results of the multicomponent CareWell primary care program that aimed to prevent functional decline in community-dwelling frail elderly people. [7] To interpret the lack of effectiveness, we performed this study to gain insight into the degree of implementation of the program. We hypothesized that a higher degree of implementation would be associated with less functional decline. The following research questions were addressed:

- To what extent was the CareWell primary care program implemented as intended?
- What is the association between the degree of implementation of the program and its primary outcome, i.e. (the prevention of) functional decline?

## Methods

### Study design and setting

In the Netherlands, general practitioners (GPs) provide continuous, person-centred care within a strong primary care setting. GPs often collaborate with practice nurses in the delivery of chronic care for the elderly. [8] Moreover, elderly care physicians (ECPs), i.e. medical practitioners that have specialized as primary care experts in geriatric medicine, increasingly operate (as consultants) in primary geriatric care. [9] However, coordination between GPs, other primary and specialist care providers, and home care and community services often is insufficient and fragmented. [10]

Therefore, we developed the CareWell primary care program. It was implemented in six GP practices in Nijmegen, the Netherlands in a cluster controlled trial of twelve months between September 2011 and September 2012; six control practices delivered usual care. [7] The process evaluation was conducted alongside this trial.

The power calculation was based on the cluster controlled effectiveness trial: we calculated that we would be able to detect an effect size of  $> 0.32$  by including 50 participants in each cluster (total  $n=600$ , assuming equal clusters), using a power of 80%, a two-sided alpha of 0.05, an assumed ICC of 0.01, and an expected loss to follow up of 35%. [7]

## Target population

All practices were instructed to include 50 frail participants  $\geq 70$  years within a limited two month inclusion period prior to the start of the intervention period, with the use of the EasyCare Two-step Older persons Screening instrument (EasyCare-TOS). First, GPs use prior knowledge to subdivide 'not frail' from '(possibly) frail' elders. The second step involves trained nurses to perform a comprehensive geriatric assessment of (possible) frail elders during a home-visit. Then, GPs and nurses weigh all signs into a final frailty judgment.<sup>11</sup> Exclusion criteria were institutionalization and/or critical or terminal illnesses. Details on recruitment were reported previously. [7]

## The intervention

The CareWell primary care program consisted of four key components: 1) multidisciplinary team (MDT) meetings, 2) proactive care planning, 3) case management, and 4) medication reviews.

Each practice assembled a MDT consisting of a GP(s), practice nurse(s) and/or community nurse(s), an ECP, and a social worker with elderly care expertise. MDT meetings were supposed to be held every 4-8 weeks, and at least half-yearly per participant- more often if indicated. In addition, team members were able to communicate virtually through a secured web-based health and welfare information portal. [12]

Tailor-made proactive care plans, based on the individual health-related problems and goals as assessed with the EasyCare-TOS, were formulated for each participant at the start of the intervention. A structured format including somatic, functional, psychological, social and communicative domains was used. Professionals were instructed to revise participants' care plans after discussion in a MDT meeting at least every six months, and to store the revised care plans, even when unchanged, in the information portal.

A case manager (nurse or social worker) was assigned to each participant. Case managers were responsible for coordinating, monitoring and evaluating proactive care planning and

for the MDT planning. They were instructed to support participants' goal setting and self-management, and to actively maintain contact with participants (and informal caregivers) by telephone or home visits at least half-yearly.

Last, the GP and nurse were instructed to conduct a yearly medication review for each participant, in collaboration with a pharmacist.

All professionals attended two preparatory educational meetings and received written instructions, coaching on the job, and help-desk support when needed. Professionals received financial reimbursement for time-investment and overhead costs.

### **Assessment of implementation fidelity**

We developed a total implementation score (TIS) composed of the four components: 1) MDT meetings, 2) proactive care planning, 3) case management, and 4) medication reviews.

#### ***Data collection***

All professionals were asked to fill in monthly time registration forms for individual patients. To stimulate uniformity in and compliance with time registrations, structured timesheets with written instructions were sent each month. Community nurses were already familiar with these time registrations, as they were required by their employer.

In scoring the delivery of MDT meetings and medication reviews, time registrations were used as a proxy, i.e. registered time for that component on a particular date was accounted for as 'delivery' on that date. In scoring proactive care planning, two investigators (FR and LO) independently assessed the care plan data as stored in the information portal. A care plan needed to contain a minimum of two health care problems with associated treatment goals and actions in order to count as a sufficient care plan. To be defined as a new version of a care plan, additional problems needed to be included or pre-existing problems needed to be adjusted. Also, care plan revisions (independent of whether changes to the plan were made) six months after the last revision were counted as new care plans, assuming the revision was done in the half-yearly MDT. In scoring the delivery of case management, case managers were instructed to daily register their time spent per participant, in minutes.

#### ***Measurement of implementation fidelity of the key components***

The TIS construction was based on consensus in the research group, consisting of experts in the field and a statistician, after extensive discussion prior to the availability of the study data, and without an available theoretical framework: TIS was calculated by summing the implementation scores of the individual components, i.e. '1' indicating that the component was 'implemented as intended', '0' if not (table 1).

TABLE 1 | Data collection and measurement of implementation scores of key components and total implementation score.

Key component	Measure	Source	Score
Multidisciplinary team work	Frequency	Time registrations	<2 meetings = 0 =/> 2 meetings = 1
Proactive care planning	Number of care plan versions	Information portal	<2 care plan versions = 0 =/> 2 care plan versions = 1
Case management	Time invested (minutes)	Time registrations	No time = 0 < Median time = 1 =/> Median time = 2
Medication reviews	Frequency	Time registrations	Polypharmacy-, review- = 1 Polypharmacy+, review- = 0 Polypharmacy-, review+ = 1 Polypharmacy+, review+ = 1
<b>Total implementation score</b>	-	-	= Sum of above scores

For each participant, MDT meetings scored '1' when two or more meetings were held; '0' when less than two meetings were held. Proactive care planning scored '1' when two or more care plans versions were stored; '0' when less than two care plan versions were available. Case management activities were intended to be tailored to individual participants' needs; limits were thus not set beforehand. After finding a large spread in the overall minutes registered for case management activities, and acknowledging the importance of this component in the delivery of integrated care [13], we revised our theoretical construct and decided to add additional weight to this component. Case management activities were then scored as follows: '2' if median time or more was spent, '1' if less than median time was spent, and '0' if no time was spent. According to the Dutch guideline 'Polypharmacy in the elderly', a medication review is indicated for patients with polypharmacy, i.e. the use of 5 or more chronically prescribed drugs. [14] Therefore, the first step in medication review was the identification of the participants with polypharmacy. For participants without polypharmacy, the medication review was then complete; these participants scored '1'. For participants with polypharmacy, a thorough review needed to follow, after which score '1' was appointed. Without this formal review, participants with polypharmacy scored '0'.

#### *Measurement of the total implementation score (TIS)*

TIS, reflecting the degree to which the intervention was implemented as intended, was calculated by summing the scores of the four components into a sum score ranging from zero to five; a higher score reflecting a higher degree of implementation (table 1).

TABLE 2 | Baseline characteristics of participants.\*

Characteristics	GP practice						p value	Overall (N=204)
	1 (N=29)	2 (N=28)	3 (N=38)	4 (N=30)	5 (N=38)	6 (N=41)		
Age, mean (yrs)	81.8	80.8	81.4	83.7	82.7	83.6	.17	82.4
Female sex, %	75.9	60.7	73.7	73.3	76.3	68.3	.75	71.6
Living alone, %	62.1	46.4	86.8	76.7	57.9	68.3	.01	67.2
Socioeconomic status score <sup>a</sup> , mean	0.3	1.4	1.5	0.8	-0.6	-0.6	< .001	0.4
Low level of education, %	31.0	11.1	36.8	36.7	5.3	24.4	< .001	24.1
Cognition score <sup>b</sup> , mean	5.6	7.5	5.6	9.4	5.0	4.9	.018	6.2
Baseline Katz 15 score <sup>c</sup> , mean	5.3	6.0	4.5	5.2	4.6	4.1	.053	4.9
EQ-5D+C <sup>d</sup> , mean	0.59	0.51	0.59	0.57	0.68	0.72	.034	0.62
RAND-36 Mental health <sup>e</sup>	60.6	63.3	64.7	57.6	60.3	62.7	.22	61.7
Presence of health-related limitations in social functioning <sup>f</sup>	42.9	53.8	52.6	82.8	62.2	75.6	.010	124
Frailty index <sup>g</sup> , mean	0.39	0.43	0.37	0.40	0.36	0.32	.041	0.37
Presence of care-complexity	27.6	7.1	13.2	6.7	32.4	19.5	.030	18.2

GP = general practitioner

\* Values are expressed as numbers (percentage) unless otherwise indicated.

<sup>a</sup> Socioeconomic status score was based on postal code areas (income, employment, and education); higher score indicates more social disadvantage.

<sup>b</sup> Based on a modified Mini-Mental State Examination (MMSE; range 0 to 28); higher score indicates more cognitive problems.

<sup>c</sup> Katz 15 score (range 0 to 15); higher score indicates more dependence in (instrumental) activities of daily living.

<sup>d</sup> EuroQol-5D+C (EQ-5D+C) scores (range -0.33 to 1.00); higher score indicates a higher health-related quality of life.

<sup>e</sup> RAND-36 Mental Health (range from 0 to 100); higher score indicates better mental health.

<sup>f</sup> Based on the social functioning subscale of the RAND-36. Answers dichotomized in 'absence of limitations' vs. the other categories indicating 'presence of limitations'.

<sup>g</sup> The frailty index measures accumulation of deficits (scale 0 to 1); a higher index suggests a more frail status.

## Baseline characteristics of the target population

Participant's baseline characteristics were measured at baseline and at follow up after twelve months.

## Data analysis

We calculated frequencies and means of participants' baseline characteristics, implementation of the key components, and the TISs at practice and participant level. Between-practices differences in means were analyzed with ANOVA.

The association between participants' Katz-15 change scores (i.e. follow up score minus baseline score) and TIS were analyzed with linear mixed model analyses. We performed a model with a random intercept, representing the clustering of participants in GP practices, and all other variables fixed. Depending on the linearity of the relationship between the Katz-15 change scores and TISs, the TIS would be taken as a continuous or categorical variable in the model.

All statistical analyses were performed using SPSS version 20. Tests were considered significant at  $p < .05$ .

## Results

### Baseline characteristics of the target population

We included 287 participants in the intervention group and had a loss to follow up of 83 out of the 287 participants in the program due to death (10.8%), institutionalization/hospitalization (9.1%), and unknown other reasons/ lost to follow up (9.1%).<sup>7</sup> This study included 204 (71.1%) participants, ranging from 28-41 participants per setting. Baseline characteristics are shown in table 2.

### Implementation fidelity of key components

#### *MDT meetings*

Overall, complete MDT meetings were organized at least twice for 47.5% of the participants, with a mean of 1.5 team meetings per participant (SD 1.2, range 0-6). The degree of implementation of MDT meetings in GP practices ranged from 24.4%-67.9%,  $p = .002$ .

#### *Proactive care planning*

Of the 204 participants, 51.0% had at least two proactive care plans formulated. The mean number of care plans per participant was 1.7 (SD 1.3, range 0-6). The implementation degree of proactive care planning in GP practices ranged from 3.4%-94.7%,  $p < .001$ .

#### *Case management*

Overall, 153 participants (75.0%) received case management; at practice level, this ranged from 46.3%-97.4%. A mean of 155.8 minutes (SD 264, range 0-1625 minutes) was spent per participant, with a median of 62.5 minutes. The mean time spent per participant differed between practices with a range of 66.6-310.4 minutes,  $p < .001$ .

### Medication reviews

149 (73.0%) of participants had polypharmacy; 116 (77.9%) of them received a thorough medication review. 147 (72.1%) participants scored 1 point, of which 92 (62.6%) had polypharmacy. The degree of implementation of medication reviews differed between practices with a range of 47.4%-85.7%,  $p = .001$ .

### Implementation of the complete program: TIS

The mean TIS at participant level was 3.0 (SD 1.2, range 0-5), with a between-practices range of 2.3-4.0,  $p < .001$ . This variation was mainly caused by differences in the implementation of proactive care planning and case management.

The implementation of the program's key components and the TISs are presented in table 3.

TABLE 3 | Delivery of key components, total implementation scores, and primary outcome scores at practice and participant level.\*

	GP practice						Overall N=204	
	1 N=29	2 N=28	3 N=38	4 N=30	5 N=38	6 N=41		
<b>Practice characteristics</b>								
No. of professionals involved	7	5	9	8	10	6		
							<b>p value<sup>#</sup></b>	
<b>Key components</b>								
Multidisciplinary team work*	51.7	67.9	65.8	56.7	55.3	24.4	.002	47.5
Proactive care planning*	3.4	64.3	94.7	60.0	10.5	65.9	< .001	51.0
CM score, %:	< .001							
0 (no time)	17.2	14.3	2.6	23.3	31.6	53.4		25.0
1 (less than median)	55.2	3.6	7.9	23.3	47.4	14.6		25.0
2 (median or more)	27.6	82.1	89.5	53.3	21.1	31.7		50.0
CM minutes, mean	66.6	310.4	287.5	92.4	105.5	84.3		155.8
Medication Reviews*	65.5	85.7	47.4	66.7	84.2	82.9	.001	72.1
<b>Complete intervention</b>								
TIS, mean	2.3	3.5	4.0	3.1	2.4	2.5	< .001	3.0
<b>Primary outcome</b>								
Katz 15 change score, mean**	0.55	0.79	0.92	0.83	0.66	1.15	0.83	0.83

GP = general practitioner

TIS = total implementation score

\* values are expressed as percentage 'delivered as intended' (i.e. a score of 1 point)

<sup>#</sup> p value of the difference in means between practices (ANOVA)

\*\* A higher Katz 15 change score indicates more functional decline regarding (instrumental) activities of daily living

## Association between TIS and primary outcome

No linear association between the TISs and the Katz-15 change scores was found; the difference between TIS groups was analysed with TIS included as a categorical variable. We found no significant difference in Katz-15 change scores between TIS groups ( $F = 1.350$ ,  $p = .245$ ), as shown in table 4. However, the effect sizes of the Katz-15 change scores in the groups with a TIS score of 3, 4 or 5 exceed the a priori calculated effect size of  $>0.32$ . Sensitivity analysis with TISs dichotomised in low (0-1-2) and high (3-4-5) scores underlined these results (data not shown).

TABLE 4 | Association between total implementation score and primary outcome (Katz-15 change score).

TIS	No. of participants	Katz 15 change score*, estimated effect	SE	95% CI
0	4	0.50	0.92	-1.32 to 2.32
1	28	0.54	0.35	-0.15 to 1.23
2	41	0.46	0.29	-0.11 to 1.03
3	53	0.70	0.25	0.20 to 1.20
4	56	1.20	0.25	0.71 to 1.68
5	22	1.36	0.39	0.59 to 2.14

TIS = total implementation score

\* A higher Katz-15 change score indicates more functional dependence in (instrumental) activities of daily living.

## Discussion

To our best knowledge this is the first study that developed a quantitative implementation score to measure the degree of implementation and study the association between implementation and outcome of a complex care program for frail elderly people. We found no statistically significant differences in functional decline between TIS groups. The degree of implementation differed significantly between practices, mainly due to variation in the implementation of proactive care planning and case management. In contrast to our hypothesis, a higher degree of implementation tended to be associated with an increase in functional decline.

Our results show that implementation of the (key components of the) CareWell program in everyday GP practices is feasible, but leaves room for improvement. The practice with the highest degree of implementation showed the (second) best implementation scores for all key components, with the exception of medication reviews. The practice with the lowest degree of implementation had an exceptionally low score for proactive care planning.

Although most participants in this practice did have one or more care plan versions stored in the information portal, these were either not updated or did not meet the requirements to be counted as a sufficient care plan. On the contrary, the practice with the highest degree of implementation had an exceptionally high score for proactive care planning. The influence of time and organizational constraints might be substantial. Prior experience with the concept and assessment of frailty, as observed in the practice with the highest score for care planning, might facilitate implementation. Between practices, we found a large variation in minutes spent on case management. This is suggestive of intentional and purposeful tailoring to individual participants' needs. [15] Although multidisciplinary guidelines for follow up care were available, difficulties in their use, as well as time constraints might have hindered the implementation of case management activities. [15] Moreover, individual professionals' skills and learning curves might have contributed to inconsistencies in the delivery and quality of case management activities, despite antecedent training and coaching on the job. [15] The implementation of MDT meetings showed a large variation between practices, possibly due to time and organizational constraints. Moreover, lacking knowledge on each others' roles and expertise, as well as time needed to build trusting working relationships might hinder truly integrated team work. [13] Our twelve month follow-up period might be too short to achieve this. On the other hand, it is possible that 'delayed delivery' in MDT meetings and care planning was interpreted as non-adherence, while these were in fact intentional, tailored deviations.

We need to consider some study limitations. First, the power calculation of this study was derived from the effectiveness trial. [7] The absence of significant differences in Katz-15 change scores between TIS groups might therefore be due to a type-II error. Although not statistically significant, the observed effects in the three highest TIS groups might have clinical relevance as they exceeded the a priori calculated effect size. [16]

Second, our theoretical framework underlying the construction of the TIS was based on research team consensus after deliberate discussion prior to data analysis. No existing literature on the conceptualization of an implementation score of complex interventions was readily available. Although the validity of our construct cannot be validated into detail, we believe it has face validity. Third, time registrations were used as a proxy for the delivery of two of the four key components. Although community nurses are used to fill in time registrations as endorsements of their hours worked, the time registrations of the practice nurses and social workers might have been incomplete or inaccurate due to time constraints, as is known from literature. [15,17] However, it is unlikely that this selectively influenced these professionals and caused bias. A fourth limitation is that we were not able to include qualitative implementation data, e.g. the quality of the delivery of the components, in the analysis. [5] This would have further strengthened our findings.

In a recently published primary elderly care trial in the BMJ, implementation data were linked to outcome by using a dichotomy variable. [18] We aimed to take these analyses

a step further by constructing a more refined implementation variable. In contrast to our hypothesis, we found that a higher degree of implementation tended to be counter intuitively associated with increased functional decline. We speculate that the program led to an increased, timelier awareness of participants' health and care risks, resulting in an increase of purposefully tailored interventions directed at those participants that were most prone of functional decline. However, the fact that these tailored interventions did not prevent functional decline raises some concerns. First, we used the validated EasyCare-TOS to identify the frail participants. However, during the intervention period, professionals deliberately targeted their interventions to those participants at highest risk of functional dependence, i.e. confounding by severity. It is possible that the targeted participants were already too frail for the program to show measurable effects on daily functioning. Conversely, the participants that were identified to be less prone of functional decline might have been more susceptible to respond to the program. Second, it is possible that more person- or goal-oriented outcomes, e.g. goal-attainment scaling, better capture the effectiveness of the heterogeneous and tailored interventions, that were aimed at a diversity of risk factors for functional dependence. [19] Third, the follow-up period might have been too short for this complex program to be optimally implemented and thus achieve its optimal effectiveness. Our fourth concern refers to the evaluation of the degree of implementation of our complex CareWell program, with its four interacting adaptive components. As we standardized the minimum implementation requirements of the components, it is possible that the dynamics of our complex intervention were not fully captured. [20] Moreover, the program was implemented in GP practices that are on their own turn complex settings, in which change in input often is disproportionally correlated to change in outcome. The validity of our TIS construct in the light of the complexity of our program and its setting remains unclear.

## Conclusion

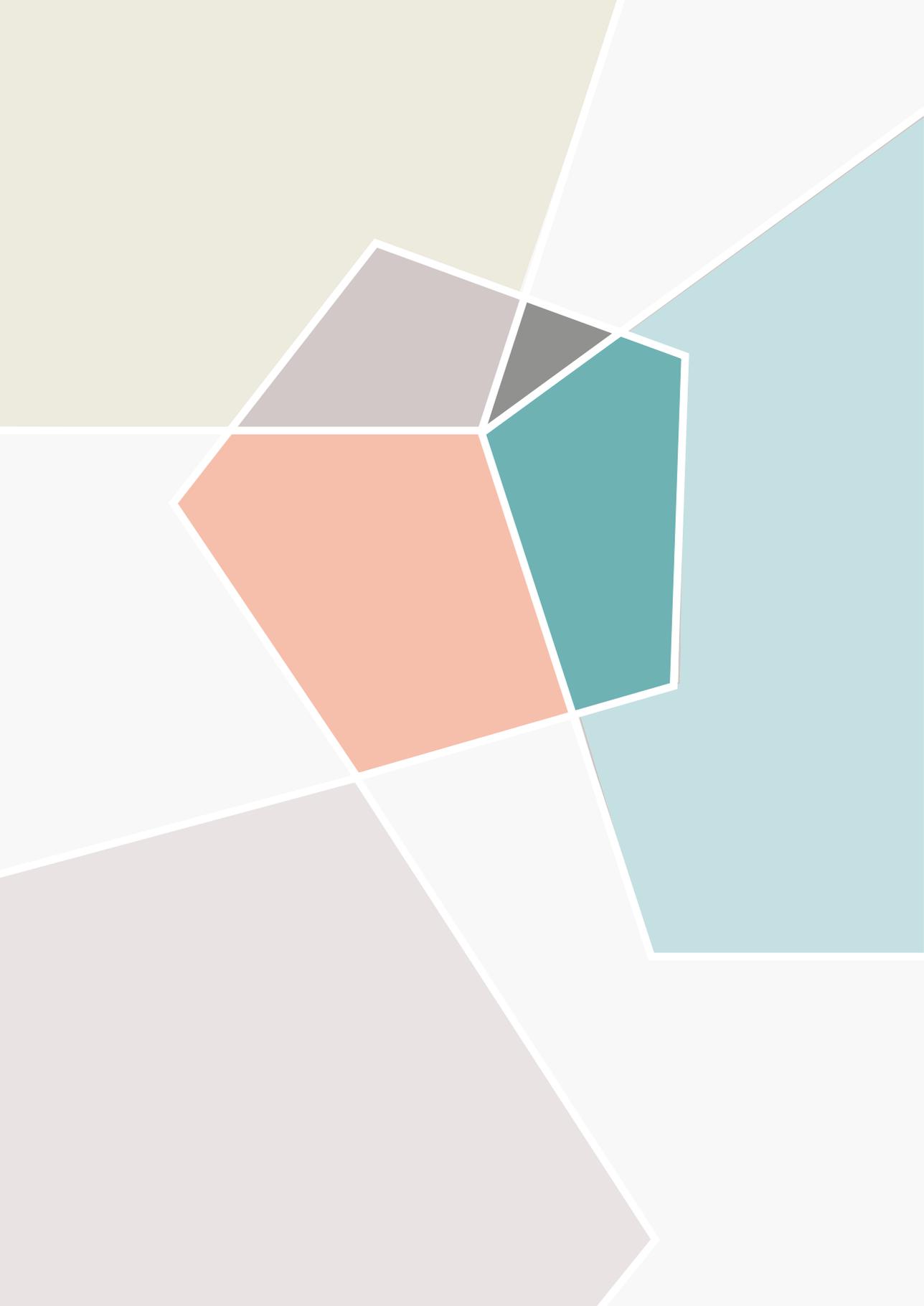
A higher degree of implementation of the CareWell program did not lead to the prevention of functional decline in frail elderly people.

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**Cost-effectiveness of a  
multicomponent primary care  
program targeting frail  
elderly people**

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## Abstract

### Background

Over the last 20 years, integrated care programs for frail elderly people aimed to prevent functional dependence and reduce hospitalization and institutionalization. However, results have been inconsistent and merely modest. To date, evidence on the cost-effectiveness of these programs is scarce. We evaluated the cost-effectiveness of the CareWell program, a multicomponent integrated care program for frail elderly people.

### Methods

Economic evaluation from a healthcare perspective embedded in a cluster controlled trial of 12 months in 12 general practices in (the region of) Nijmegen. Two hundred and four frail elderly from 6 general practices in the intervention group received care according to the CareWell program, consisting of multidisciplinary team meetings, proactive care planning, case management, and medication reviews; 165 frail elderly from 6 general practices in the control group received usual care. In cost-effectiveness analyses, we related costs to daily functioning (Katz-15 change score i.e. follow up score minus baseline score) and quality adjusted life years (EQ-5D-3L).

### Results

Adjusted mean costs directly related to the intervention were €456 per person. Adjusted mean total costs, i.e. intervention costs plus healthcare utilization costs, were €1583 (95% CI -4647 to 1481) higher in the intervention group than in the control group. Incremental Net Monetary Benefits did not show significant differences between groups, but on average tended to favour usual care.

### Conclusions

The CareWell primary program was not cost-effective after 12 months. From a cost-effectiveness perspective, widespread implementation of the program in its current form cannot be recommended.

### Trial registration

The study was registered in the ClinicalTrials.gov Protocol Registration System (NCT01499797; December 26, 2011).

### Keywords

Cost-Benefit Analysis, Frail Elderly, Delivery of Health Care, integrated, Activities of Daily Living, Primary Health Care

## Background

Frail elderly account for a disproportionately large share of healthcare costs, spending over \$70,000/year in 2011 in the United States, with particularly high expenditure on inpatient and post-acute care. [1,2] In the Western world, the prevalence of frailty – a state of increased vulnerability to adverse outcomes through a complex interplay of physical, psychological, social and environmental factors [3] – will even increase due to population ageing, since frailty is thought to be present in 10% of people aged  $\geq 65$  years up to 25%-50% of people aged  $\geq 85$  years. [4,5] Western countries are forced to adapt their healthcare policies addressing frail elderly in order to achieve cost reductions in health and social services and maintain financial sustainability.

Proactive integrated care programs, addressing the complex and interacting healthcare and welfare needs, are thought to have the potential to prevent adverse outcomes and lower healthcare costs. [6,7] However, results so far have shown merely modest, inconsistent results regarding their effectiveness and efficiency. [8-12] Some studies pointed out the potential to prevent hospitalization and nursing home admissions [10,11,13], but accompanying increases in home care and social services use might impede overall cost savings. [8,10,14] Formal economic evaluations of integrated programs targeting frail elderly are scarce. [15,16] Moreover, heterogeneity between studies regarding target population (age, low or high risk of functional decline), context (home-, primary care- or institution based), and intervention components hinder comparability and generalizability. Moreover, results of economic evaluations need to be interpreted in the light of national contexts. [17]

In the Netherlands, the Dutch Ministry of Health, Welfare and Sports initiated the National Care for the Elderly Program (NCEP) in 2008, in which over 650 organizations in health, welfare and housing work together in eight regional networks led by academic medical centres to improve care for elderly people with complex care needs. As part of this program, we developed the CareWell primary care program that aimed to reduce functional decline, institutionalization, and hospitalization of community-dwelling frail elderly. Although effectiveness of the program could not be demonstrated [18], the program might theoretically save overall costs and, depending on the trade-off between costs and effects, might be cost-effective. Therefore, we conducted a separate economic evaluation to answer the following research questions:

- What are the differences in health care costs between participants receiving care according to the CareWell primary care program and those receiving care as usual?
- Is the CareWell primary care program cost-effective from a healthcare perspective after 12 months?

## Methods

### Design

This economic evaluation from a healthcare perspective was performed alongside a cluster controlled effectiveness study with a follow-up of twelve months. Design, methods and outcomes of the effectiveness study have been reported elsewhere. [18]

### *Setting and participants*

The study was conducted between September 2011 and September 2012 in 12 general practitioner (GP) practices in the region of Nijmegen, the Netherlands. After informed consent, frail elderly aged  $\geq 70$  years were included with the use of the EasyCare-TOS instrument [19]: First, GPs use prior knowledge to subdivide 'not frail' from '(possibly) frail' elders. Then, trained nurses perform a comprehensive geriatric assessment of (possible) frail elders during a home visit. Last, GPs and nurses weigh all signs into a final frailty judgment. Exclusion criteria were institutionalization, and/or critical or terminal illnesses. Details on the recruitment and informed consent procedures have been reported previously. [18,20]

### *Intervention*

In brief, the CareWell primary care program consisted of four key components: 1) multidisciplinary team (MDT) meetings, 2) proactive care planning, 3) case management, and 4) medication reviews.

Each practice assembled a MDT consisting of a general practitioner (GP), practice nurse(s) and/or community nurse(s), an elderly care physician (ECP) [21], and a social worker with elderly care expertise. Each participant was discussed in a MDT meeting at least half-yearly, more often if needed. Meetings were planned every 4-8 weeks. Tailor-made proactive care plans, based on the individual health-related problems and goals as assessed with the EasyCare-TOS [19], were formulated for each participant on enrolment in the program and revised after discussion in a MDT meeting at least every six months. A case manager, either a nurse or social worker, was assigned to each participant. They were responsible for care planning and coordination, patient-support in goal setting and self-management, and caregivers support. Last, the GP and nurse conducted a yearly medication review in collaboration with a pharmacist for each participant with polypharmacy (use of  $\geq 5$  chronically prescribed drugs).

Professionals received financial reimbursement to cover time-investment and overhead costs.

### *Usual care*

In the Netherlands, GPs provide continuous, person-centred care to community-dwelling frail elderly, facilitated by the use of high-standard electronic medical records and patient panels, defining the population under care. [22,23] GPs often collaborate with practice and/or community nurses. Moreover, elderly care physicians, i.e. medical practitioners that are specialized as primary care experts in geriatric medicine, increasingly operate (as consultants) in the care for community-dwelling frail elderly. [21] However, the coordination between GPs, other primary and specialist care providers, and home care and community services is often perceived to be insufficient, leading to a fragmented delivery of care. [24]

GPs in the usual care group were explicitly asked to decline new relevant inter professional collaborations during the intervention period. No restrictions on pre-existing collaborations between GPs and (practice) nurses were imposed.

### *Outcome measures*

Dependence in functioning in (instrumental) activities of daily living (measured with the Katz-15 [25] change score, i.e. follow-up score minus baseline score) and health-related quality of life (measured with the EuroQol five-dimensional three-level instrument (EQ-5D-3L) [26]) were collected at baseline and at follow-up after twelve months by structured interviews by trained nurses. The Katz-15 score ranges from 0 to 15 points with higher scores indicating more dependence in (instrumental) activities of daily living. The EQ-5D-3L instrument is a 'preference-based' measure of health status [27], that defines health-related quality of life according to five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) at three levels (no problems, some problems, severe problems). [26] In line with the guidelines of the National Care for the Elderly Program, we used the modified EQ-5D+C-3L instrument that includes cognitive functioning as an additional dimension, with a similar operationalization at three levels. [28] To date, to the best of our knowledge, there is no validated weighting formula for the EQ-5D+C-3L. Utilities, reflecting the relative desirability of each health state, were thus calculated for the EQ-5D-3L, without the cognitive dimension, using the Dutch tariff. [29] EQ-5D-3L scores range from -0.33 to 1.00, with a higher score indicating a higher health status. Quality Adjusted Life Years (QALYs) were then calculated by multiplying the utilities by the amount of time spent in a particular health state. 1 QALY represents 1 year in perfect health. [29]

### *Healthcare utilization costs and intervention costs*

We assessed intervention costs and healthcare utilization during the follow up period. [17] An overview of the healthcare cost variables, prices per unit and sources are presented in table 1.

TABLE 1 | Overview of the cost variables, sources, and cost prices per unit.

Cost variable	Source of variable	Cost price per unit (in Euros)
<b>Healthcare utilization costs:</b>		
GP care <sup>a</sup> (per contact):		
Consultation	Structured interview	28
Consult >20 min		56
Home visit		43
Home visit >20 min		72
Consultation by phone		14
Prescription refill		14
GP care, out of office hours <sup>b</sup> (per contact)	Structured interview	101
Home care (per hour)	Structured interview	35
Domestic care (per hour)	Municipality registries	12,5
Hospital care, inpatient (per day)	Structured interview	457
Hospital care, outpatient (per contact)	Structured interview	72
Nursing home (per day)	Structured interview	238
Care home (per day)	Structured interview	90
Day care (per day)	Welfare organization registries	45
Physiotherapy (per contact)	Structured interview	36
Medication <sup>c</sup>	Electronic medical record	n/a
Intervention costs (per hour):		
General Practitioner <sup>b</sup>	Time registrations	103
Practice nurse <sup>d</sup>		30
Community nurse <sup>d</sup>		27
Social worker <sup>d</sup>		32
Elderly care physician <sup>b</sup>		103
Pharmacist <sup>b</sup>		85

Sources of cost prices per unit:

<sup>a</sup> Dutch guideline for costing research. [30]

<sup>b</sup> Dutch Healthcare Authority.

<sup>c</sup> Royal Dutch Society for Pharmacy. [31]

<sup>d</sup> Collective Agreements.

Intervention costs regarding time spent on team meetings, care planning, case management, and medication reviews were assessed by instructing practice and/or community nurses and social workers to fill in monthly time registration forms at participant level. To stimulate uniformity in and compliance with time registrations, structured timesheets with written instructions were sent each month as reminders. GPs and ECPs estimated their mean time spent on the intervention per GP practice, from which invested time per participant was calculated. Pharmacists estimated a time investment of 30 minutes per participant per medication review.

Healthcare utilization variables, i.e. GP care, hospital care, institutionalization (i.e. nursing home admission, care home admission), home care, and physiotherapy were individually assessed at baseline and follow up through a structured interview by the nurse. Data on domestic care and day care were individually extracted from registries from the municipality of Nijmegen and welfare organizations. Last, data on medication costs (both reimbursed and non-reimbursed) were individually extracted from the electronic medical record (EMR).

Costs were calculated by multiplying volumes of care with their corresponding unit prices. In calculating costs of time invested by practice and/or community nurses and social workers we used their Collective Agreements. The thus generated hourly wages were raised with an estimated 45% for employers and overhead expenses and thus set on € 30, € 27, and € 32 respectively. [30] We used hourly wages of € 103, € 103, and € 85 in calculating costs of time invested by the GPs, ECPs, and pharmacists respectively, according to the fixed rates of the Dutch Healthcare Authority. Costs of healthcare utilization were valued according to the Dutch manual for costing research. [30] When no standardized unit cost prices were available, costs were derived from the Dutch Healthcare Authority. Medication costs were valued using prices of the Royal Dutch Society for Pharmacy [31], using minimum cost prices. All costs were presented in Euros, and indexed to the year 2011 using the consumer price index.

## Statistical analysis

Katz-15 change scores and EQ-5D-3L scores were analyzed using mixed model multilevel analyses, accounting for clustering of participants within GP practices and correcting for those variables that differed between groups at baseline and correlated to the primary outcome, as well as for baseline Katz-15 and EQ-5D-3L scores to account for regression to the mean. [18] Quality adjusted life years (QALYs) were derived from the EQ-5D-3L using the trapezium rule (i.e. an approximation of the area under the QALY curve). Mean healthcare utilization costs were analyzed with descriptive statistics and compared between groups using multilevel mixed model analyses, adjusting for clustering of participants within GP practices and for relevant covariates. The incremental Net Monetary Benefit (iNMB) statistic was used to evaluate cost-effectiveness [32] and consequently used as the dependent variable in the mixed model. The iNMB prevents several statistical drawbacks

of an incremental cost-effectiveness ratio and enables the use of multilevel regression techniques including covariates in a convenient way. [17] It indicates the monetary gains or costs of an intervention at explicit Willingness to Pay (WTP) thresholds per gained unit of effect. In formula:  $iNMB = (WTP * \Delta \text{ effects}) - \Delta \text{ costs}$ . An  $iNMB$  (and 95% lower-level confidence interval) greater than zero indicates significant cost-effectiveness of the intervention. We used five WTP thresholds per point improvement on the Katz-15 change score, i.e. €0, €5000, €10000, €15000, and €20000, where no reference values were readily available. Six commonly used WTP thresholds per QALY were used: €0, € 20000, € 40000, € 60000, € 80000, and € 100000. [33]

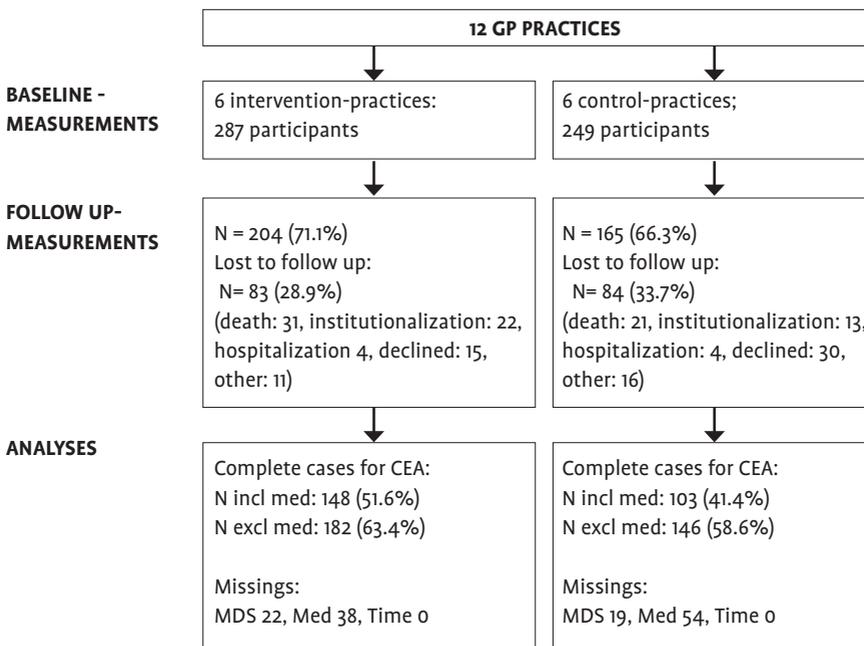


FIGURE 1 | Flow diagram of participants.

## Results

### Participants

In total, 536 participants (287 in the intervention group resp. 249 in the control group) were included in the effectiveness study. [18] At baseline, participants in the intervention group significantly more often lived alone, had more health-related limitations in social functioning, more cognitive deficits, and more social disadvantage, but showed less

complex care.[18] No significant between-group differences in baseline Katz-15 scores and EQ-5D-3L scores were found. We had a loss to follow up of 28.9% participants in the intervention group and 33.7% in the control group, mainly due to death, institutionalization and declined consent for follow-up (figure 1). Additionally, we encountered a considerable number of missing cost variables, mainly medication cost data due to declined consent for use of EPF medication data and limited coverage of medication data in the EPFs. We adhered a complete case analysis with regard to missing values. [34] We analyzed costs and iNMB both with and without medication cost data, including 148 (51.6%) resp. 182 (63.4%) participants in the intervention group and 103 (41.3%) resp. 146 (58.6%) participants in the control group (figure 1), and considered the analyses including medication costs as the primary analysis. Participants included in the economic evaluation had a lower frailty index. This frailty index was calculated based on the accumulation of deficits in health (symptoms, morbidities, and/or functional abilities), and was used as an extra indicator of frailty next to the EasyCare-TOS. [28] It theoretically ranges from 0 (no indication of frailty) to 1 (extreme frailty), though frailty index scores in similar studies typically culminate at 0.7. Therefore, in addition to the covariates included in the effectiveness analysis, the frailty index was included as a covariate in this economic evaluation.

## Outcome measures

At 12 months, we found no significant differences in functional dependence (adjusted mean difference of 0.37, 95% CI -0.1 to 0.8) nor QALYs (adjusted mean difference of -0.031, 95% CI -0.1 to 0.0) between the intervention and control group, but the control group did show less functional decline (table 2). [18]

## Healthcare utilization costs and intervention costs

Mean intervention costs, adjusted for clustering and relevant covariates, were €456 (95% CI -512 to -398). In the intervention group, mean total costs, i.e. intervention costs plus healthcare utilization costs, adjusted for clustering and relevant covariates, were €1583 (95% CI -4647 to 1481) higher than in the control group. Mean adjusted healthcare utilization costs, i.e. without the intervention costs, were €1143 (95% CI -4198 to 1912) higher in the intervention group. Of the healthcare utilization variables, only medication costs differed significantly, although mean costs of hospitalization, institutionalization, home care and physiotherapy in the intervention group exceeded those in the control group (table 2).

## Economic analysis

Figure 2 shows the iNMBs. It can be noticed that generally these iNMBs are negative, meaning that the intervention does not provide value for money compared to usual care, although the results are not significant. Sensitivity analysis, excluding medication costs, underlined these results.

TABLE 2 | Costs of care in intervention and control groups 0-12 months (in Euros).

	Intervention group		Control group		Adjusted mean difference <sup>b</sup> (95% CI)	P value
	Unadjusted mean <sup>a</sup>	SE**	Unadjusted mean <sup>a</sup>	SE**		
<b>Outcome:</b>						
Katz-15 change score <sup>1</sup>	0.80	0.13	0.50	0.16	0.37 (-0.10 to 0.80)	.10
QALY <sup>2</sup>	0.60	0.02	0.60	0.02	-0.03 (-0.10 to 0.00)	.37
<b>Intervention costs:</b>	456	14	0	0	-455 (-512 to -398)	<.001
<b>Healthcare utilization costs, total:</b>	10125	983	8114	845	-1143 (-4198 to 1912)	.46
GP care	163	13	169	18		
GP care, out of office hours	40	11	36	7		
Hospital care, inpatient	1557	510	1225	248		
Hospital care, outpatient	239	24	304	40		
Nursing home	943	399	198	118		
Care home	416	218	161	76		
Day care	422	102	342	101		
Home care	3712	423	2787	412		
Domestic care	1472	91	1417	113		
Physiotherapy	988	309	485	87		
Medication	1617	296	978	126		
<b>Total costs<sup>c</sup></b>	10576	983	8114	845	-1583 (-4647 to 1481)	.31

\*\* SE = standard error

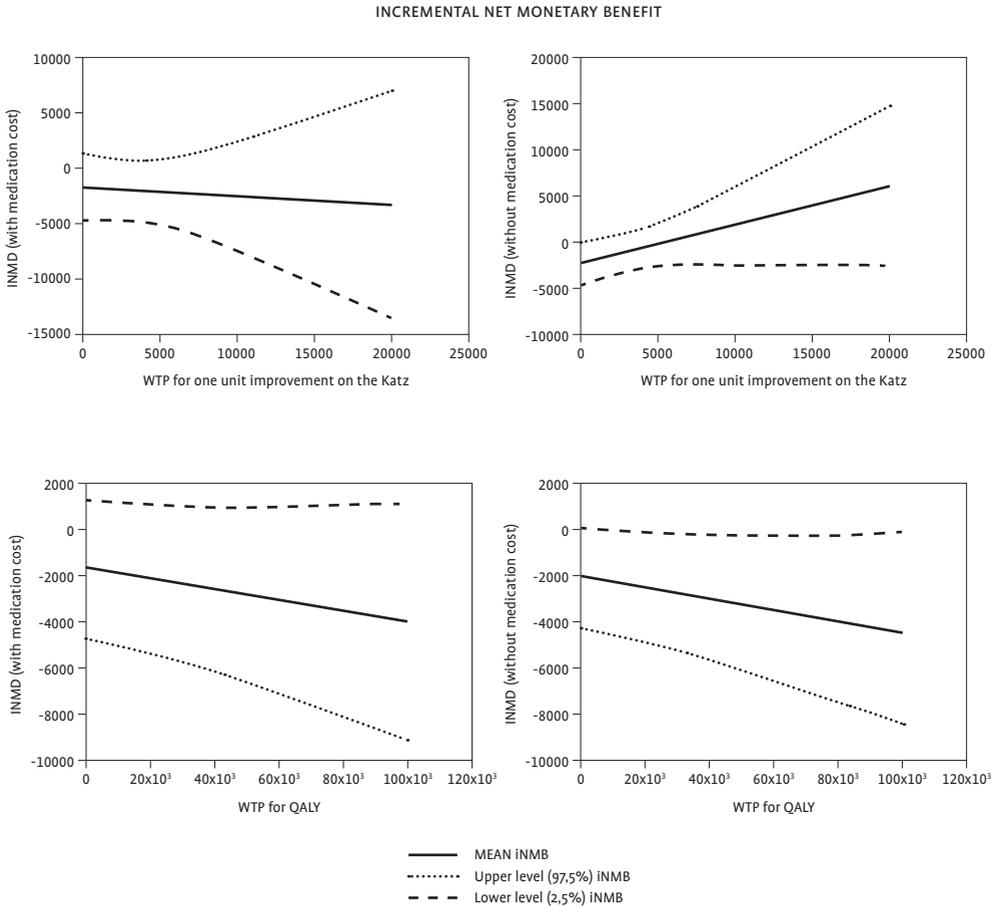
<sup>1</sup> Katz-15 index (range 0 to 15); higher score indicates more functional dependence in (instrumental) activities of daily living.

<sup>2</sup> Quality Adjusted Life Years (QALY), as derived from the EQ-5D-3L.

<sup>a</sup> Unadjusted means, analyzed with descriptive techniques.

<sup>b</sup> Multilevel mixed model analyses, accounting for clustering and covariates.

<sup>c</sup> Total costs = intervention costs plus healthcare utilization costs.



**FIGURE 2** | Incremental net monetary benefits (in Euros) against WTP for Katz-15 change score\* and QALY.

Upper panels show the incremental net monetary benefits (in formula:  $iNMB = (WTP * \Delta \text{ effects}) - \Delta \text{ costs}$ ) against WTP for Katz-15 change scores; lower panels show iNMBs against WTP for QALY. All iNMBs are negative, i.e. the intervention does not provide value for money compared to usual care (not significant). Sensitivity analyses, excluding medication costs, underline the results (right panels). WTP = Willingness to Pay.

QALY = Quality Adjusted Life Year, derived from the EQ-5D-3L, based on the Dutch tariff [29] using the trapezium rule.

\* Improvement on the Katz-15 change score is indicated by a lower score, meaning less functional decline regarding (instrumental) activities of daily living.

## Discussion

In this cluster controlled study with a follow up of 12 months, healthcare utilization costs and cost-effectiveness of the CareWell primary care program was compared to usual care. Earlier, effectiveness of the CareWell program on daily functioning and quality of life could not be demonstrated. [18] In this study, we found no statistically significant differences between groups in total costs and healthcare utilization costs, with the exception of higher medication costs in the intervention group. Moreover, cost-effectiveness analyses showed no significant differences between groups, but tended to favour usual care.

There are some possible explanations for the absence of cost-effectiveness. First, there is still a lively debate on the concept of frailty and the right timing of interventions. [35,36] Possibly, the targeted population was too heterogeneous or, in part, too frail to respond to the intervention. Second, the Katz-15 index, measuring daily functioning, might be too restricted to capture the effects of our heterogeneous intervention. Possibly, more person- or goal centred outcomes, e.g. goal-attainment scaling, might suit better. [37] Moreover, the sensitivity to change of the EQ-5D-3L in frail elders might have been (too) low. [38] The concept of 'capability wellbeing' has recently been suggested as an alternative, more sensitive measure. [33] However, further work on the validity and value of these capability indices in economic evaluations is needed. [33,39] Third, it is likely that more profound effects of the intervention only become apparent after a longer follow up period that exceeds the time needed for implementation, individual and organizational learning effects, and efficient multidisciplinary collaboration. [40,41] This lag-time in effectiveness is presumed to be even more important in complex interventions like our program. [40] Awareness to these short-run inefficiencies that might have resulted from the time limits set by the NCEP is needed. Last, the selection of motivated professionals in the intervention group might have limited the room for improvement in the delivered care and possibly led to higher costs due to more proactive care, irrespective of the CareWell program. The overall increased awareness to the health care needs of frail elderly in Western countries in the last two decades together with the Dutch high-quality primary care might have further reduced the contrasts between the CareWell program and usual care. Possibly, our program would show clearer effectiveness in less well managed healthcare settings. [12]

Our results are in line with comparable integrated care programs aimed at frail elderly, performed in other contexts. [14,42] More recently, three cost-effectiveness studies of integrated care programs from the NCEP demonstrated no effects on functioning nor quality of life, at unchanged or higher total costs mainly due to increased GP care and intervention costs without (expected) decreases in hospital and long-term care costs, after 12-24 months. [43-45] However, Van Leeuwen et al. did find increasing effects at lower costs compared to usual care in the last 18-24 months of follow up. [45] Previously, Counsell et al. demonstrated similar decreased costs in their third year of follow up, mainly through a shift away from emergency and hospital services towards more-desirable

chronic and preventive care expenditures. [14] This supports our assumption of a lag-time in effectiveness. The results of the cost-utility analyses of the recent other Dutch studies, finding low probabilities of the intervention increasing QALYs at lower costs, correspond with our results. [43-45] However, only Van Leeuwen et al. performed a formal cost-effectiveness analysis. [45] Like us, they found low probabilities of the intervention being cost-effective.

This study has several strengths. First, we used a comprehensive approach to costing, including a wide variety of cost variables that were assessed at participant level, thus enhancing internal validity. Next, robust multilevel techniques were used in analyzing both differences in costs and net monetary benefits. Last, since we used only a limited number of exclusion criteria and included participants from heterogeneous GP practices, our results should be generalizable to the population of frail elders in the Netherlands and comparable high-quality primary care settings.

We also should consider some limitations. First, we were unable to include informal care costs, since informal caregivers' willingness to participate was low and differed between groups. We were therefore not able to adhere to the societal perspective, as announced in our study protocol [20], but had to switch to a healthcare perspective. Since prior studies show contrasting results on the impact of informal care on total costs, the impact of this switch on our results is unclear. [42,45] Next, since the extraction of data on healthcare use from external sources like healthcare insurance companies, as originally planned in the study design, was not possible, we had to collect these data through participants' retrospective self-report. This could have led to recall bias. Different studies showed self-report after 12 months to be an appropriate, reasonably accurate method for obtaining a wide range of healthcare utilization data in elderly people. [46,47] More salient events in general suffer less from memory decay and thus recall bias. [48] Seidl et al. for example found the recall bias of hospital admissions of elderly people not to be influenced by applying various recall periods, although the probability of correctly self-reporting a single event was higher using a shorter recall period. [47] However, less salient events such as GP contacts could lead to both under- and over-reporting, and show less accuracy in self-report. [48,49] Also, time registrations used to calculate intervention costs might be biased due to inaccuracies. However, we have no reason to assume unequal distributions of these potential biases between the groups. Last, we had to deal with a considerable number of missing medication cost data that had to be considered missing not at random. However, our additional sensitivity analysis without medication costs did not reveal other results.

## Conclusions

After 12 months follow-up, no net monetary benefit of the CareWell program over usual care could be demonstrated.

This study adds to the currently scarce body of evidence regarding cost-effectiveness of integrated care programs targeting frail elderly. Future economic evaluations should account for pitfalls in their design with respect to the target population, outcome measures used, and adequate follow-up period. From a cost-effectiveness perspective, the CareWell primary program in its current form is not suited for widespread implementation.

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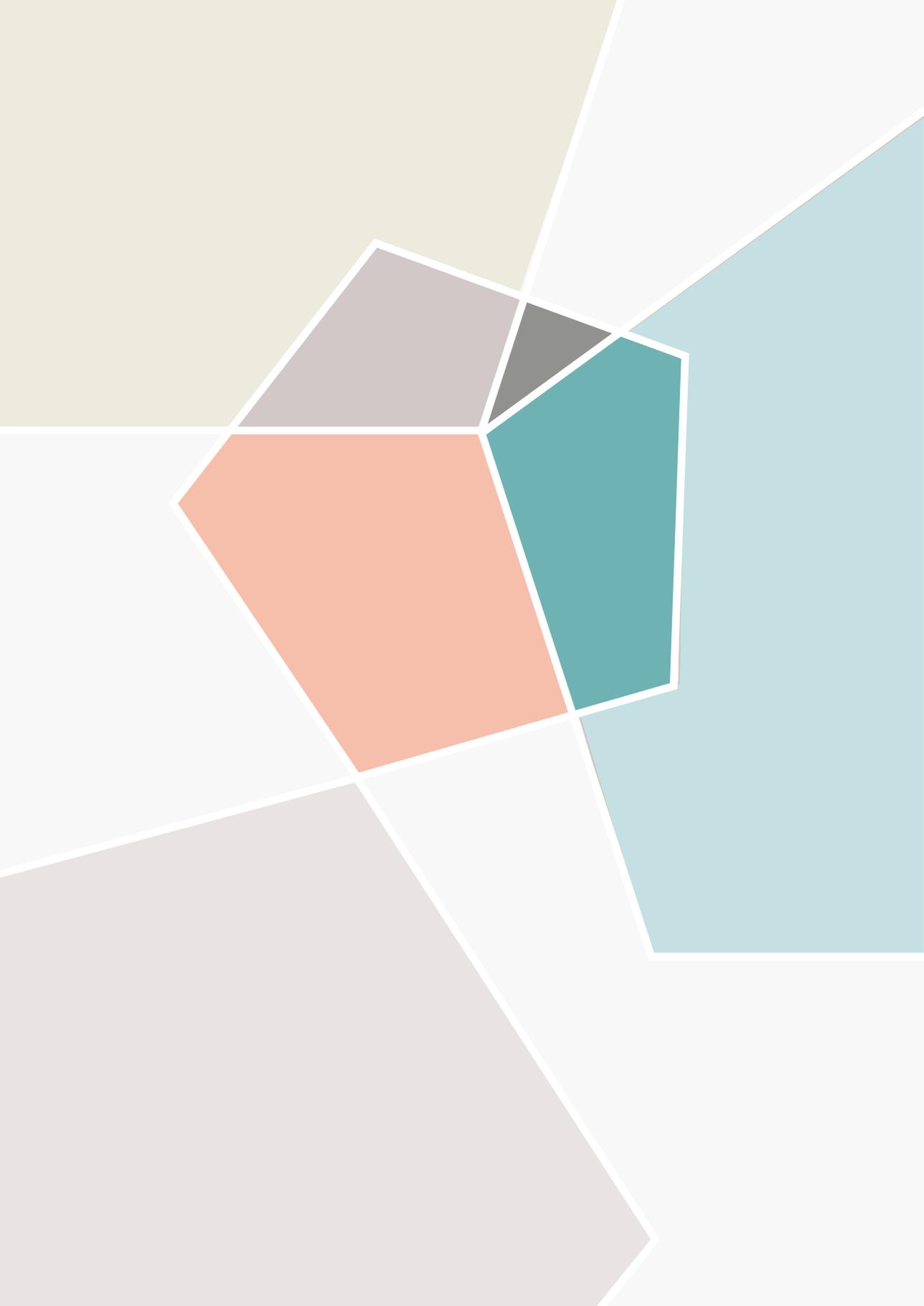
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**General discussion and conclusion**



In this thesis, we evaluated the implementation and (cost-) effectiveness of an integrated care program for community-dwelling frail elderly, the CareWell primary care program that consists of 4 key elements: (1) multidisciplinary team work (MDT), (2) proactive care planning, (3) case management, and (4) medication reviews. The main aim of the program was to prevent (further) functional decline in community-dwelling frail elderly.

In this chapter, we first give an overview of the main findings of this thesis and relate these findings to the current evidence. Next, we discuss some methodological and theoretical issues. Finally, we provide implications and recommendations for clinical practice, education, and future research.

## Main findings

We found:

- No statistically significant differences in functional decline between frail elderly receiving care according to the CareWell primary care program and those receiving care as usual after a follow up of twelve months, and no statistically significant effects on quality of life, mental health, health-related limitations in social functioning, hospitalization, institutionalization and mortality.
- No statistically significant effects of the program on caregiver's care related quality of life (QoL), caregiver burden, nor on time investment in caregiver tasks after a follow up of twelve months.
- Statistically significant differences in the degree of implementation between the intervention practices, mainly due to the large variation in proactive care planning and case management, but no statistically significant differences in functional decline between the groups of frail elderly as classified according to the degree of implementation of the program.
- That mean total health care costs (intervention costs plus healthcare utilization costs) were € 1583 (95% CI -4647 to 1481) higher in the intervention group in comparison to the control group, although the difference was not significant, and that incremental net monetary benefits did not show significant differences between groups, but on average tended to favour usual care.

## Discussion of main findings

### Effects on frail elderly

During the 1990s, evidence on the effectiveness of case management programs on the prevention of functional decline of frail elderly began to emerge. [1,2] However, while it

became generally accepted that primary care for community-dwelling frail elderly needed to shift to person-centred, integrated care, several reviews since then showed inconsistent evidence of the effectiveness of integrated care programs on functional improvement. [3-7]

The lack in effectiveness of our CareWell program on functional decline of frail elderly is in line with that of comparable integrated care programs, as conducted within the National Care for the Elderly Program (NCEP) in the Netherlands (table 1&2). Most studies found no differences in functional decline between the intervention group and the usual care group. [8-11] Only Bleijenberg et al. found a statistically significant, though small effect, on functioning at 12 months follow up in the U-PROFIT trial. In the intervention group (i.e. nurse-led care plus interventions) they found a mean baseline score of 1.73 and mean change score (follow up score minus baseline score) of 0.15 on the Katz-15 index; in the control group they found a mean baseline score of 1.74 and a mean change score of 0.29. [12] In our study, we included participants that were older and more dependent in functioning (i.e. higher baseline Katz-15 scores of 5.4 resp. 4.6 in our intervention resp. control group) and found higher mean Katz-15 change scores of 0.8 in the intervention group resp. 0.5 in the control group. The reliability and validity of the Katz-15 score in predicting unfavourable health outcomes in community-dwelling frail elderly has been established. [13] However, to our knowledge, there are no studies on the clinical relevant change of the Katz-15 score in this population available. Suijker et al. suggested a minimal important change of the Katz-6 ADL index score (ranging 0-6) in frail elderly of approximately 0.5 points [14], which, although it is unclear how to extrapolate this to the Katz-15 score, suggests that the minimal important change on the Katz-15 score should at least exceed these 0.5 points. The clinical relevance of the mean changes as found in the U-PROFIT trial thus seems to be limited.

Next to differences in the study populations, there is heterogeneity in the combination of elements and health care disciplines involved in the different NCEP programs (table 1). This hinders comparison of the results. Nonetheless, we conclude that our results are in line with most NCEP programs that show no convincing evidence of the effectiveness on functioning of community-dwelling frail elderly (table 2). This conclusion is in line with that of a recent review of 29 interventions from European countries, the USA, Canada, Australia, Japan and Hong Kong, that also shows unconvincing evidence of integrated care programs on functioning of community-dwelling frail elderly. [15]

Although no convincing effects on functioning were found in the NCEP studies, qualitative process evaluations of some of the other NCEP programs indicated satisfaction of the frail elderly with the programs. For example, frail elderly in the Embrace program felt safe (“*I find it a great reassurance that she [case manager] says ‘We’re here if you need us.’*”), and encouraged (“*She [the case manager] brought me a leaflet. Because there are computer lessons for seniors here in Stadskanaal, ‘And that’s just what you need,’ she said.*”). [16], whilst the programs’ effectiveness on the domains of health, wellbeing and self-management

could not be demonstrated. [17] Also, professionals indicated that the program provided a useful structure for care, and that one of the greatest benefits of the approach was the improvement in interdisciplinary cooperation (18), although this coincided with increased time investments and unchanged job satisfaction. [18, 19]

## Effects on informal caregivers

We were one of the 3 out of 8 NCEP studies that examined the effects on caregiver outcomes of an integrated care program for frail elderly (table 2). In line with our results, the ISCOPE study demonstrated no effects on care-related quality of life (QoL), burden, and time investment on caregiving tasks. [20] In contrast, in the WICM study Janse et al. found significant differences in care-related QoL between the intervention and the control group, with an increase in caregiver QoL in the intervention group and a decrease in the control group, whilst no significant differences between groups in burden nor time investment were found. [21] Moreover, caregivers showed a decreased satisfaction with the perceived support by professionals. [22] Last, Janse et al. demonstrated an inverse relationship between formal caregivers delivering personal care, e.g. bathing, (un)dressing, and caregivers' time investment in instrumental assistance, e.g. transfers and financial tasks, without affecting total time investment by caregivers. [23] The above mentioned review of 29 integrated care programs for community-dwelling frail elderly showed that only 9 programs studied caregiver outcomes, with some evidence on caregiver satisfaction but inconsistent evidence of the effects on caregiver burden and time investment. [15]

The dynamics between caregivers' quality of life, burden, and time investment, and their association with formal and informal care tasks and caregivers' preferences and needs with regard to coping and support remain unclear.

## Implementation fidelity and the association with outcome

To our knowledge, we were the first to conduct an explorative study on the association between the degree of implementation and the effectiveness of an integrated care program on functional decline of community-dwelling frail elderly. We found that the highest degree of implementation was found in frail elderly with the most functional decline. We hypothesize that healthcare professionals purposefully tailored the program to the needs and preferences of the care recipients, and, even more likely, foremost addressed those care recipients that were suspected to be at highest risk of functional decline, and who further declined despite the intervention. However, in the absence of qualitative data we cannot substantiate these assumptions.

TABLE 1 | Overview of NCEP programs.

Study	Design	Follow up period (months)	Age of population (yrs)	Identification method	Intervention	Healthcare disciplines involved
<b>U-PROFIT</b> (Bleijenberg, Drubbel)	Cluster randomized trial	12	≥60	Participants with: - Multimorbidity (defined as a frailty index score of $\geq 0.20$ computed from EPR data); AND/OR - Polypharmacy ( $\geq 5$ chronic prescription medications) AND/OR - $\geq 3$ years without consultation by GP	Personalized nurse-led care: First, further frailty assessment using the Groningen Frailty Indicator, and Intermed Self-Assessment (IM-E-SA). Frail elderly received a comprehensive geriatric assessment at home, follow-up visits, and care coordination. Evidence-based care plans were developed for 11 common geriatric conditions.	GP and nurse
<b>Frail older Adults: Care in Transition (ACT)</b> (Hoogendijk, Muntinga, van Leeuwen)	Stepped-wedge cluster randomized trial	24	≥65	2 consecutive steps: 1) GPs identify frail persons i.e. $\geq 1$ limitation in physical, psychological and/or social areas; 2) PRISMA-7 questionnaire score $> 3$ (i.e. considered as frail)	Home visits by nurse (every 6 months) for CGA, tailored care plan, MDT consultation and meetings. Geriatric expert team to expert knowledge transfer (to PNs, GPs, other professionals involved), build networks for care coordination	Nurses, GPs and expert geriatric team. Expert geriatric team= experienced geriatric nurse and ECP for management and training.
<b>Prevention of Care (POC)</b> (Metzelthin)	Cluster randomized trial	24	≥70	Groningen Frailty Index (GFI) score $\geq 5$	Comprehensive geriatric assessment followed by interdisciplinary care (based on a tailor-made treatment plan) and regular evaluation and follow-up.	GP, nurse, occupational therapist, physiotherapist
<b>Frailty in Transition (FIT)</b> (Suijker)	Cluster randomized trial	12	≥70	Identification of Seniors at Risk-Primary Care (ISAR-PC) score $\geq 2$	Comprehensive geriatric assessment and individually tailored care treatment plan consisting of multifactorial interventions based on standardized evidence-based protocols, and nurse-led care coordination with multiple follow-up visits	GP and nurse

<b>ISCOPE</b> (Blom)	Cluster randomized trial	12	≥75	ISCOPE-screening questionnaire: ≥3 problems on functional, somatic, mental, social health domains	Multidisciplinary integrated care plan using a functional approach delivered by the GP and PN.	GP and nurse
<b>Walcheren Integrated Care Model (WICM)</b> (Janse, Looman)	Quasi-experimental cluster controlled trial	12	≥75	Groningen Frailty Index (GFI) score ≥4	Single entry point, comprehensive need assessment tool (Easycare), multidisciplinary individualized treatment plan, case management, multidisciplinary team consultation and meetings, protocol-led assignment, a steering group, task specialization and delegation, and a chain computerization system.	Core team: GP, geriatric nurse practitioner, geriatric nursing specialist. Other health professionals if needed.
<b>Embrace</b> (Uittenbroek, Spooenenberg)	Stratified randomized controlled trial	12	≥75	INTERMED-Elderly Self-Assessment plus Groningen Frailty Index: stratified into (A) robust; (B) frail; (C) complex care needs	1) self-management support and prevention program 2) individual care plan; case management; monthly evaluations by Elderly Care Team of participants' health status and social situation.	Elderly Care Team: GP, ECP, nurse and social worker
<b>CareWell</b> (Ruikes)	Cluster controlled trial	12	≥70	EasyCare-TOS instrument	4 key components: 1) MDT meetings with a GP, PN and/or CN, ECP and social worker, at least twice per year per participant; 2) proactive care planning 3) case management, by either a nurse or social worker 4) medication review, by the GP, nurse and a pharmacist	GP, nurse, ECP and social worker

GP = general practitioner  
ECP = elderly care physician

TABLE 2 | Overview of outcomes of the NCEP programs.

Study	Participant outcomes	Caregiver outcomes	Costs of intervention per participant	Total health care costs	Cost-effectiveness
<b>U-PROFIT</b>	Less functional decline in intervention (Katz-15) at 12 months; Mean Katz-15 score 1.88 (95% CI 1.80 to 1.96) vs. 2.03 (95% CI 1.92 to 2.13) in control group	/	€ 131	Lower total costs (including informal care) in intervention, i.e. €6.825 (SD11.452), vs. €7.601 (SD)15.717	Probability of cost-effectiveness at a WTP of €20.000 per QALY gained 87% for screening and 55% for screening plus nurse-led care, versus 91% for usual care.
<b>Frail older Adults: Care in Transition (ACT)</b>	Small significant improvement in IADL limitations (Katz-15 score) after 18 months in intervention; mean difference -0.25, (95% CI 0.43 to -0.06), not significant after correction for multiple comparisons.	/(recruitment problems)	€ 258	Higher total costs (including informal care) in intervention group, i.e. €11.659 (SD329) vs. €10.207 (SD408)	Probability of cost-effective at a WTP of was €30.000 per point improvement on the Kat-ADL resp. Kat-IADL scores was 0.35 resp. 0.42; The cost per QALY gained in the intervention over usual care €133.611.
<b>Prevention of Care (POC)</b>	No effect on disability (Groningen Activity Restriction Scale); mean difference 0.47 (-0.8 to 1.76)	/	€ 728	Higher total costs (including informal care) in intervention, mean difference of €5.953 (95% CI -633 to 12,538)	/
<b>Frailty in Transition (FIT)</b>	No effect on disability (Katz 15 score); -0.07 (95% CI -0.22 to 0.07), p = 0.33).	/	€ 158	Higher total costs (excluding informal care costs) in intervention, mean difference €1.457 (95% CI 572 to 2537)	Probability of cost-effectiveness at WTP of €50.000 per point improvement on Katz- score was 0.14, At WTP of €50.000 per QALY gained was 0.04; not cost-effective
<b>ISCOPE</b>	No effects on functioning (GARS); mean difference of -0.6 (-1.7 to 0.5)	No effects on caregiver QoL (RAND, Cantril's Ladder, CarerQoL-7D), burden, and time investment	€ 236	Lower total costs (including informal care costs) in the intervention, mean difference of -€1,305 (95% CI -16.349 to 13.744)	/

<b>WICM</b>	No effect on functioning (Katz-15); mean difference of 0.22 (-0.13 to 0.56)	Improvement in QoL (CarerQoL-7D) in intervention group (+3.88), not in control group (-0.55). Significant decrease in burden in control group (-0.49), not intervention group (-0.07). No effects on time.	€ 340	Higher total costs (including informal care) in intervention vs. usual care; 17,089 vs. €15,189	Incremental costs €1.970; ICER €412.450
<b>Embrace</b>	Significantly more functional decline in intervention group (Katz-15); mean difference 0.10, p 0.047	/	€684	Higher total costs (including informal care) for intervention, mean difference €2.397 (95% CI 547 to 427) Higher informal care costs of intervention, mean difference €331 (95% CI 61 to 600)	Probability of cost-effectiveness at WTP of €20.000 per QALY gained was 1%, at WTP of €250 per “day able to age in place” (i.e. €91.250/yr)<80%
<b>CareWell</b>	No effects on functioning (Katz 15 score); mean difference of 0.37 (-0.1 to 0.8)	No effects on care-related QoL (CarerQoL-7D), burden (CarerQoL-VAS) and time investment	€456 (95% CI -512 to -398)	Higher total costs (excluding informal care) in intervention, mean difference of €1.583 (95% CI -4647 to 1481)	No

In their NCEP study, Metzeltin et al. linked implementation data to their outcomes by using a simple dichotomized variable. They found no differences in effect by comparing 'low exposure' (assessment only) versus 'high exposure' (assessment plus follow up interventions). [8] We took these analyses a step further by constructing a more refined implementation variable. Since no other (inter-)national studies performed a comparable exploration of the association between implementation and outcome, we are unable to compare our results to others.

Other NCEP process evaluations demonstrated comparable differences in the degree of implementation of the program elements, but did not relate these to their outcomes. With regard to care planning for example, the ISCOPE study found that 15% of participants lacked a care plan due to time constraints or logistic problems. [20] The ACT study demonstrated that, although adherence to care planning was high with a range of 75-99%, care plans were not always carried out as intended, e.g. some care plans did not include the intended information (i.e. they were incomplete), or did not get written at all. [24] With regard to case management, Bleijenberg et al. demonstrated that the type and dose of interventions were tailored to patients' preferences and type of problems [25], which supports our assumption of purposeful tailoring. Next, problems in organizing and performing MDT meetings were found in the ACT and POC studies [18,26], due to time constraints and/or difficulties in network processes, e.g. identification of the right partners, knowing each other's role and expertise. However, differences between the NCEP studies in the operationalization and methods used to study the implementation of the (different elements of the) programs hinders true comparison.

## Cost-effectiveness

In line with our results, most other NCEP studies demonstrated that total health care costs tended to increase in the intervention group (table 2). [27-31] Most studies found increased expenditures on home care, long-term care and hospital care costs, but results were inconsistent. Moreover, most studies that included informal care costs in their analyses tended to find increased informal care costs. [27-30] The results of the ISCOPE and U-PROFIT studies partly conflict with the other NCEP studies, as they demonstrated lower total health care costs in the intervention group. Both studies found lower costs of home care and hospital care costs, and unchanged respectively decreased informal care costs. [20,32] In the ACT study, lower health care costs in the intervention group compared to usual care were demonstrated only in the last 18-24 months of follow up. [33] This might indicate that a lag-time in reaching cost-reduction exists. [33] All formal cost-effectiveness analyses within the NCEP showed low probabilities of the programs being cost-effective, in line with our results. [27,30-32,34]

A cost-effectiveness study performed in Australia demonstrated that an interdisciplinary intervention was effective in reducing frailty in community-dwelling elderly at a cost of

\$A15,955 (i.e. € 10,016) for one extra person transitioning out of frailty. [35] In this study, frailty was defined according to Fried's frailty phenotype [36] and addressed by interventions by a physiotherapist directed at lower limb balance and strength and/or a dietician directed at weight loss. Comparison with the results of the NCEP studies is difficult, as most NCEP studies used a multidimensional definition of frailty, more in line with Rockwood's frailty index [37], and performed multidisciplinary interventions that had heterogeneous aims.

We conclude that the absence of cost-effectiveness in our program is in line with the results of the other programs that targeted functional decline in community-dwelling frail elderly, as conducted within the NCEP. The degree of impact of the inclusion of informal care on cost-effectiveness outcomes in these integrated care programs needs further examination. [38]

## Methodological and theoretical considerations

In this thesis we evaluated the CareWell primary care program from different research perspectives that demonstrate the full width of the impact of the program, which is a major strength of this thesis.

However, some general methodological and theoretical issues concerning our research on integrated care programs for frail elderly and their informal caregivers need consideration.

### Identification of the target population

Frailty is generally considered to be a geriatric condition in which losses in several domains of functioning lead to an increased vulnerability to adverse health outcomes [39], but consensus on its definition is lacking. As a result, there is a plethora of frailty measurements. Some focus on a physical phenotype, while others assess a more heterogeneous accumulation of deficits in physical, psychological and social domains of health, in line with a more holistic view of frailty. To date, evidence is insufficient to determine which measurement is best used in primary care research and clinical practice to identify those elderly that are at risk of adverse health outcomes and are responsive to potential interventions and outcome measures. [40] The EasyCare Two-step Older persons Screening (EasyCare-TOS) questionnaire that we used meets the emerging criteria of a feasible two-step approach, i.e. a simple pre-selection by the (general practitioner (GP) followed by an extensive assessment by a nurse (or research assistant) [41-43], and includes a weighing of psychological and social deficits and assets, e.g. coping ability and resources such as a social network, that are deemed important in the measurement of frailty from a person-centred, holistic approach. [44,45] Also, we think that by filling in the questionnaire by a nurse (or research assistant) through a structured interview in a home visit, we met the criteria that are thought to be needed to discuss issues related to psychosocial needs, i.e. time, interest and an open conversation [46], but we did not test these assumptions.

Although the EasyCare-TOS instrument thus seems feasible for the identification of community-dwelling frail elderly from a holistic approach, in retrospect we question the alignment with the subsequent interventions and the primary outcome measure that was chosen within the NCEP framework. We think that the Katz-15 instrument was perhaps not responsive to the heterogeneous interventions that were performed in the heterogeneous population of elderly with widely differing frailty 'profiles' [45], as identified with the EasyCare-TOS. For example, frail elderly might indicate problems in pursuing leisure or hobbies that are important to them. A subsequent intervention might then be that the case manager helps the frail elderly to find suitable activities in a day care centre. Although this improves psychosocial functioning, it does not improve independence in functioning, which is the focus of the Katz-15 instrument. A frailty instrument that is based on a mainly physical phenotype, thus guiding specific physical exercise and training interventions that have proven their effectiveness [47-49], might better identify those frail elderly that are at risk of functional decline and consequently might be more responsive on the Katz 15 instrument. Thus, we think that the alignment between our frailty measurement (the EasyCare-TOS instrument), the broad range of possible interventions, and the outcome measure that was chosen (the Katz-15 instrument) was suboptimal.

### **Aligning needs and preferences of elderly, interventions and outcome measures**

The Grant Committee of the NCEP preselected the Katz-15 score as the instrument of choice to measure functional decline in activities of daily living, which is the primary outcome of community-dwelling frail elderly in the NCEP integrated care programs.

Our study as well as the other NCEP studies, with the exception of the U-PROFIT trial, demonstrated only small changes in the Katz-15 scores (with mean differences between groups ranging from -0.25 to 0.37) that were insignificant. Although the Katz-15 index reliably predicts adverse health outcomes in community dwelling frail elderly people [13], it might not be responsive enough to detect change in the targeted populations in these studies. Another explanation might be that 'physical frailty', as measured with functional outcome measures such as the Katz-15 score, is perhaps not malleable or reversible any more after a certain point. This thought is increasingly adopted by stakeholders (frail and healthy elderly, informal caregivers, and health and social care professionals from research centres across Europe with expertise in frailty, elderly care, and mental health disability) [50], and supported by our process evaluation that showed more functional decline in frail elderly with higher implementation scores, i.e. in whom the program was better 'delivered as intended'. It might also explain why in the U-PROFIT trial, that targeted frail elderly that were younger and less dependent in functioning at baseline in comparison to our study, significant (though small) improvements in functioning were found. [51] Last, the negative results of our study and most other NCEP studies might indicate that current primary care in the Netherlands already embodies high-quality care in the prevention of

functional decline in frail elderly [52], reducing the potential superiority of a proactive, integrated care intervention compared to usual care.

The aim of our program was to deliver person-centred, integrated care from a holistic approach, including the psychological and social domains of frailty in addition to the physical functioning domain. In retrospect, we think that an outcome measure that more explicitly focuses on the needs and preferences of frail elderly and includes this full range of frailty domains might better align with the heterogeneous frail elderly population and concordant interventions in our program. An upcoming field of interest in this regard is that of the Patient Reported Outcome Measures (PROMs). PROMs measure perceived health outcomes, such as functional status or health related quality of life, as well as healthcare quality, from a care recipients' perspective [53,54], and might be used to focus on the person-centeredness of interventions and on care recipients' enablement and empowerment. [54,55] PROMs might do more justice to the emphasis frail elderly themselves put on the psychosocial domains of frailty, such as on coping, acceptance, remaining in control, and social participation, despite possible dependence in functioning. [45] A recent study on frailty 'profiles' demonstrated that a large group of frail elderly solely deals with these psychosocial domain problems, without limitations in the physical functioning. [16,17,45] At the start of our study, PROMs were not yet widely available for use in community-dwelling frail elderly. Most existing PROMs for use in primary care, e.g. the Primary Care Assessment Survey, the European Task Force on Patient Evaluations of General Practice, and the Patient Assessment of Chronic Illness Care, focus on primary care performance instead of care outcomes. [54] Recently, first experiences with PROMs in Dutch geriatric hospital care showed feasibility of the TOPICS-SF [56,57], which is a short-form of the validated TOPICS-MDS, i.e. the national database on the health and wellbeing of frail elderly and caregivers who participated in NCEP programs. [58] More research is needed to demonstrate its feasibility and validation in primary care. In addition to PROMs, the use of goal-attainment scaling (GAS), a tool for setting quantifiable person-centred goals and measuring improvement towards these goals [59], is promising in guiding person-centred interventions and empowering and engaging frail elderly in goal-setting and decision-making throughout the care delivery process. [60,61] GAS has shown good responsiveness in measuring clinically important change in frail elderly [60], and seems feasible for use in geriatric primary care. [59] Thus, PROMs and GAS are promising in targeting and evaluating person-centred interventions.

## Implementing the CareWell primary care program

The implementation of complex interventions, like our CareWell program, is known to be challenging. [62] Some issues regarding these challenges need consideration here.

First, successful implementation of the CareWell program requires its adaptation to the context of the intervention practices in which it is implemented as well as tailoring to

the needs and preferences of the targeted elderly. [26] For example, our process evaluation demonstrated that the time spent on case management showed a large variation, with a mean of 156 minutes per frail elderly per year (range 0-1625 minutes), suggestive for intentional and purposeful tailoring to the perceived needs of frail elderly. These presumably deliberate adaptations, however, might also have reduced the program's effectiveness, especially when effective or successful intervention components were adapted. [63] This paradox complicates the use of implementation outcomes to explain the program's effectiveness. We associated implementation data to the effectiveness of our program on functional decline, by constructing a (refined) implementation score. No literature on the conceptualization of such an implementation score of complex interventions was readily available at the start of our study. Therefore, our conceptual framework was based on research team consensus and thought to have face validity, although it could not be validated into detail. Moreover, we cannot determine the influence of purposeful adaptations on the validity of our implementation score used to study the association between implementation and outcome. For example, it is possible that 'delayed delivery' of MDT meetings and care planning was interpreted as 'not implemented as intended', while these were in fact intentional, tailored deviations to improve care recipients' outcomes. The use of qualitative data in the assessment of implementation fidelity would have strengthened our method.

Second, we cannot unravel the full extent of the processes of integration that were intended to occur between the professionals, as we did not use a generic framework for this evaluation nor qualitative data. Operational activities such as multidisciplinary collaborations beyond disciplinary responsibilities and boundaries, knowledge exchange and communication consequently remained in the so-called 'black box'. [64-66] The process evaluation of the "Prevention of Care" study, that was part of the NCEP, showed that the discussion of care plans occurred mainly between the GP and nurse, and only to a limited extent in multidisciplinary meetings. [18] Time constraints and, probably even more important, a lacking knowledge of or trust in each others' roles and expertise, and hindering attitudes due to an ongoing physician dominance and reluctance of both medical and social care professionals to relinquish respectively accept responsibilities are known barriers for effective multidisciplinary management of frailty. [50,64,67-69] The fact that our study, together with the Embrace study, were the only two out of eight studies in the NCEP program in which social workers structurally were part of the multidisciplinary team might be illustrative of these barriers. Next, although social workers structurally took part in the multidisciplinary meetings in our program, it might be that their contributions to the team discussions and care planning were overshadowed by the already established and/or medically dominated working relationships between the GPs, nurses, and elderly care physicians (ECPs), although we lack qualitative data to endorse these assumptions. Also, it remains unclear whether professionals were sufficiently able to deliver proactive care. It has been suggested that professionals are inclined to (return to) reactive care delivery when faced with time constraints, or a presumed lack of benefit in terms of proactively

detected problems. [70] For professionals to be able to deliver pro-active, integrated care, effective training to provide sufficient knowledge on frailty and its adverse outcomes from a holistic view and to secure ongoing behavioural changes with regard to sharing ownership of frailty between medical and community professionals is necessary. [50,71] We cannot determine whether the different types of antecedent training that was provided to increase knowledge and necessary attitudes and skills needed to implement our program enabled the professionals sufficiently, as we did not test their knowledge after the training nor measured behaviour changes after the training.

Last but not least, it is possible that the follow up period of twelve months was too short to fully implement the CareWell program, e.g. to build trusting working relationships and achieve true multidisciplinary collaboration. [64] Unfortunately, this short implementation and follow-up period was mainly due to the funding requirements. In retrospect, we think more time is needed for our program to reach implementation as intended, and also the subsequent follow-up period to study the effectiveness of the program needs to be sufficiently long.

## Study design and methods used

In addition to the outlined drawbacks of the primary outcome measure, the Katz-15 score, we need to consider methodological drawbacks of our study design and methods as well.

We chose to recruit eligible GP practices with a solid motivation to adopt the program, in order to reach optimal implementation and effectiveness of our complex intervention. Therefore, we did not randomize. This choice might have influenced the quality of care delivery between groups. However, as no differences between groups in favour of the intervention group were found it is unlikely that this allocation procedure has led to biased results. This choice also led to significant baseline differences between the groups, for which we corrected sufficiently in our analyses. Next, we chose to use a cluster-controlled design, and not an individual randomization, to avoid contamination bias between the frail elderly and their caregivers as clustered within GP practices, as we assumed that organizational circumstances and professional learning curves during implementation would definitely affect the effects of our program within these practices. [72] From a statistical perspective, however, the correction that is required for these practice-related effects results in a lower power for detecting differences between the groups compared to an individual randomization. [73] Thus, although we used multi-level analyses to account for the clustering of participants, these methodological drawbacks of our design might still have affected our outcomes. Third, the use of the EasyCare-TOS instrument to identify and assess frail elderly in both groups may have led to “enhanced” usual care in the control group [74], diluting the change to detect an effect of our intervention. These methodological drawbacks are exemplary for the challenges of implementing and evaluating complex interventions in routine daily practice. The

Medical Research Council framework for complex interventions that was first published in 2000 has been widely adopted by researchers. However, it can be questioned whether an experimental design as recommended in this framework is the most appropriate method through which to engage with the complexity of integrated care programs targeting frail elderly in primary care. [75] Other evaluative frameworks to guide the implementation and evaluation of complex interventions are therefore needed. Perhaps we even need to consider study designs outside the scope of experimental and quasi-experimental designs, such as longitudinal mixed-method case studies, to provide the needed insights into the implementation, stakeholders' experiences, and effectiveness on care recipients and (informal) caregiver outcomes. [76] Last, the methods that we used in this thesis were purely quantitative in nature. Additional qualitative data would have helped in studying the extent and quality of the implementation of our program, as well as the association between implementation and outcome. Also, it might have added insights to explain the ineffectiveness of our program on frail elderly and their caregivers.

## Implications and Recommendations

### Clinical practice and policy makers

After the start of the NCEP, several primary health care reforms started in the Netherlands as described in Box 1, leading to more community-based care for frail elderly.

#### **Box 1 Recent primary health care reforms in the Netherlands.**

- Since 2011, health insurers in the Netherlands provided funding to GPs to incorporate case finding of frail elderly and proactive care planning into daily practice routines.
- Starting in 2015, long-term care (LTC) in the Netherlands reformed comprehensively, to reign in health care expenditure growth and improve the quality of LTC. [67] A shift from residential to non-residential care was made, based on the assumption that elderly with 'mild' problems prefer to 'age in place' and are better cared for in the community at lower costs:
  - Residential care, financed by the 2015 Long-term Care Act (Wet Langdurige Zorg, WLZ), remained available only for patients in need of permanent supervision or 24-hour care.
  - Elderly Care Physicians, formerly called Nursing Home Physicians, increasingly started to work as consultants in primary care. [77]
  - The provision of all non-residential care was decentralized and faced expenditure cuts: Community nursing and body-related personal care came under the responsibility of insurers, financed by the Health Insurance Act (Zorgverzekeringswet, ZVW). All other non-residential care, e.g. housing, welfare programs, and transport, was assigned to the municipalities and financed by the Social Support Act (Wet Maatschappelijke Ondersteuning, WMO). Informal caregiver activities and local community networks replaced various social care services.

Facing the health care reforms and an ageing population, GPs felt urged to anticipate on the burden of an increasing number of community-dwelling frail elderly with complex health and social care needs in primary care. [78] At the same time, several Dutch position papers emphasized the need for proactive, integrated care to deal with the increasing workload for primary care professionals on the one hand and the need for more tailored, person-centred care to deal with the complex needs of community-dwelling (frail) elderly on the other hand. [78,79] As a result, the implementation of proactive, integrated care programs into current clinical practice is ongoing, despite a lack of evidence on their effectiveness in the prevention of (further) functional decline, as can be read earlier in this Discussion. Qualitative results of some of the NCEP studies indicated that health care professionals appreciated the coordinated care delivery structure of these programs as well as the multidisciplinary cooperation [18,19], whilst frail elderly felt safe and encouraged. [16]

We endorse that the embedding of proactive, integrated primary care programs for community-dwelling frail elderly in primary care is needed to reach shared responsibilities and partnership between the cure, care and welfare domains in order to cope with the increasing number of community-dwelling frail elderly with complex health and social care needs that need to be addressed from a holistic view. However, an important implication of our study is that the alignment between the needs of frail elderly and the content, aims, and outcome measures of these proactive integrated care programs needs to be improved. Moreover, our results, as well as those of the other NCEP studies, seem to support the idea that 'physical frailty' after a certain point is not malleable or reversible anymore, as discussed above.

We therefore argue that more notion of the heterogeneity of the frail elderly population in primary care is needed. Frailty instruments that use a broad multidimensional perspective on frailty and are able to identify and differentiate different frailty 'profiles' of frail elderly and their underlying problems, such as the EasyCare-TOS [80], are needed. Next, this frailty taxonomy needs to be applied to tailor person-centred interventions that accurately respond to the differing needs, preferences and goals of these elderly. This implies that for frail elderly as targeted in our study, i.e. those at risk of functional decline with already existing (severe) functional impairments, attention and efforts perhaps need to be re-focused primarily towards the psychosocial aspects of frailty in order to enable these elderly to cope with their limitations and remain in control and socially active despite being dependent, in order to enable 'ageing in place' in adequate housing. [81] 'Physically frail' elderly themselves indicated that functional impairments are of less importance provided that psychosocial wellbeing is retained. [50,82] Moreover, professionals need to realize that a large group of frail elderly exists that deals solely with psychosocial problems, such as anxiety, depressive feelings, loneliness, in the absence of physical impairments. [45] It might be that this group also benefits most from proactive interventions with a focus on psychosocial wellbeing and housing. On the other hand, frail elderly with milder functional impairments might benefit most from timely proactive interventions that aim

to reverse or prevent functional decline, such as exercise and training programs [47-49] and/or nutritional interventions [83], while these impairments are still malleable. This urges for shared responsibilities and integration between health and social care professionals and housing associations beyond the current boundaries, to overcome fragmentation in the delivery of person-centred integrated care to frail community-dwelling elderly.

The Dutch long-term health care reforms of 2015 urged for an upgraded role of the municipalities in the delivery of non-residential care to frail elderly, and the delivery of various social care services by local community based networks, the so-called neighbourhood teams ('sociale wijkteams') and informal caregivers. [67] To date, however, integrated primary care programs, as predominantly executed by GPs and practice and/or community nurses, mostly coexist with integrated neighbourhood approaches that have started to arise as a result of the health care reforms, without integrated collaboration between these two systems. As the Health Insurance Act finances GP and home care services whilst the Social Support Act finances social services, there are insufficient financial incentives towards collaboration between these sectors. For example, municipalities may refer elderly to community nursing in order to save money, and vice versa. Therefore, new initiatives to reach integration throughout organizational and financial levels and to develop an umbrella financing for elderly care are needed.

## Education

To reach true integration between health and social care, more familiarity between these sectors is needed to reinvent each other's roles and responsibilities and improve mutual receptiveness and commitment to share partnership and responsibilities in the care delivery to frail elderly. Within the NCEP programs, the diverse educational programs that have been developed only paid limited attention to the coordination and collaboration of health care professionals with professionals from the welfare and housing sectors. [83] Moreover, these educational programs paid too little attention to engaging, supporting and collaborating with informal caregivers. New educational programs thus need to be developed.

## Research

Future research needs to focus on the development, implementation, and evaluation of integrated care programs with an explicit focus on collaboration between health care, welfare, housing, and informal care. Frail elderly and their informal caregivers need to be involved in the design and implementation of these programs, to ensure that their needs and preferences are reflected. [84]

Person-centred outcome measures such as PROMs and GAS need to be developed and tested to align the outcomes of integrated care programs with the needs, preferences and goals of frail elderly. Next, new mixed-method frameworks for the evaluation of these

programs are needed, that allow for the adaptation and tailoring of the interventions to real-life settings. An important lesson learned from the NCEP program is that the period needed to reach sufficient implementation and the subsequent follow-up period to study the effectiveness of these transitional integrated care programs need to be sufficiently long. Last, cost-effectiveness evaluations with a societal perspective, thus including informal care costs, need to be performed alongside these studies.

## Conclusion

Our study, as conducted within the NCEP framework, showed that the CareWell primary care program, an integrated care program that consists of four key elements: (1) multidisciplinary team work, (2) proactive care planning, (3) case management, and (4) medication reviews, was not (cost-) effective in the prevention of (further) functional decline in community-dwelling frail elderly after a follow up of twelve months. Our results are in line with those of most other NCEP integrated care programs. Much is still unknown about the study designs and outcome measures that best fit the complexity of person-centred, integrated care for community-dwelling frail elderly. Valuable lessons are learned, and much more development has to be done to take account of the highly heterogeneous frailty profiles and subsequent health and social care needs and preferences of community-dwelling elderly people. Also, more emphasis is needed to reach further integration between the cure, care, and welfare domains and to engage informal caregivers in order to adequately respond to these needs. Thus, the challenge of ageing and frailty in community-dwelling elderly people to primary care is still ongoing.

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# Summary

This thesis provides answers and insights with regard to the implementation and (cost-) effectiveness of the CareWell primary care program, a comprehensive care program that aims to prevent functional decline in community-dwelling frail elderly. It is written as part of the National Care for the Elderly Program (NCEP), which was launched in 2008 by the Dutch Ministry of Health, Welfare, and Sports to improve the quality of care for a growing number of frail elderly in the Netherlands. The information in this thesis helps to direct the needed redesign of the Dutch primary care system to sufficiently address the complex and interacting health care needs of community-dwelling frail elderly.

In **Chapter 1** we introduce the background and main objectives of this thesis. Worldwide, the number of frail elderly with complex and interacting health and social care needs increases as a result of population ageing. Frailty refers to a geriatric condition in which losses in several domains of functioning lead to a decrease in reserve capacity and a subsequent increased vulnerability to adverse health outcomes, such as functional decline, hospitalization, institutionalization, and death. Consequently, frailty accounts for a disproportional large share of health care costs. Current Western health care delivery systems often are insufficient in addressing the complex and interacting health care needs of community-dwelling frail elderly, due to their reactive, disease-oriented structure and a lack of coordination between cure, care and welfare professionals. As significant health care reforms become a prominent issue in many Western governments, including the Netherlands, and most (frail) elderly wish to 'age in place', the impetus to develop (cost-) effective interventions in primary care that can prevent functional decline in timely identified community-dwelling frail elderly is clear. For this aim, we developed the CareWell program.

This thesis addresses the following questions:

- What is the effectiveness of the CareWell program on functional decline of community-dwelling frail elderly, when compared to care as usual after a follow up of twelve months? (Chapter 3)
- What is the effectiveness of the program on care-related quality of life, caregiver burden, and time investment on caregiver tasks, when compared to usual care after a follow up of twelve months? (Chapter 4)
- To what extent is the program implemented as intended? What is the association between the degree of implementation of the program and the degree of functional decline of community-dwelling frail elderly? (Chapter 5)
- What are the differences in health care costs between frail elderly receiving care according to the program and those receiving care as usual? Is the program cost-effective from a healthcare perspective after 12 months? (Chapter 6)

In **Chapter 2** we first describe the design of the CareWell program. It is a complex intervention that integrates cure, care and welfare and aims to prevent functional decline, improve quality of life and reduce or postpone institutionalization and hospitalization in community-dwelling frail elderly. The program is based on existing chronic care models and adapted to the Dutch health care system. It consists of four key elements: (1) multidisciplinary team work, (2) proactive care planning, (3) case management, and (4) medication reviews. Four supporting elements facilitate the care delivery according to the program: multidisciplinary guidelines for eight common geriatric syndromes, an advance care planning guideline, procedure agreements regarding consultation of geriatric experts, and procedure agreements on hospitalization and discharge.

Next, we describe the design of the process evaluation of the program and the design of the 12-month cluster controlled (cost-) effectiveness trial, in which we implemented the program in six general practices in (the region of) Nijmegen, the Netherlands, and compared it to usual care in six other general practices in the same area.

In **Chapter 3** we report on the effectiveness of the CareWell program on functional decline and secondary outcomes of community-dwelling frail elderly, as evaluated in our cluster controlled trial. 287 Frail elderly in 6 general practices received care according to the CareWell program, and 249 participants in another 6 practices received care as usual; 204 (71.1%) respectively 165 (66.3%) participants completed the study. Functional decline in (instrumental) activities of daily living, i.e. the primary outcome, was measured with the Katz-15 change score (i.e. the follow up score minus the baseline score). Secondary outcomes were quality of life (EQ5D+C), mental health (RAND-36), health-related social functioning (RAND-36), institutionalization, hospitalization, and mortality. We found no differences between the intervention and the control group regarding functional decline and the secondary outcomes. We discuss some potential explanations for the absence of effects of the program. We conclude that we found no evidence for the effectiveness of the CareWell program in the prevention of adverse outcomes in community dwelling frail elderly people, and that large-scale implementation of the program in its current form is not advocated.

**Chapter 4** reports on the effectiveness of the CareWell program on informal caregiver outcomes as investigated in the same cluster controlled trial. Out of the 536 frail elderly that were included in the trial, 364 (68%) indicated to have an informal caregiver; 73 caregivers (21%) completed both baseline and follow-up questionnaires after 12 months and were included in the final analyses. We found no effectiveness on care-related quality of life of caregivers (CarerQol-7D questionnaire), in caregiver burden (CarerQol-VAS), and in time invested in caregiver tasks. Due to challenges in both the recruitment and follow-up of caregivers, however, we were not able to draw solid conclusions. We discuss the lessons learned and provide recommendations with regard to the insight that a specific focus on the care recipient/caregiver dyad is needed in integrated care programs.

In **Chapter 5** the results of the quantitative process evaluation that was conducted alongside the cluster controlled trial are presented. 204 Frail elderly from six general practices that received care according to the CareWell program and completed the study were included in the process evaluation. Time registrations of multidisciplinary team meetings, case management activities and medication reviews were used as a proxy for the implementation of these components. Next, care plan data as stored in a digital information portal were assessed. These data were aggregated into a total implementation score (TIS) representing the program's overall implementation. We measured functional decline with the Katz-15 change score (follow-up score at twelve months minus the baseline score). We found no statistically significant differences in functional decline between TIS groups. The degree of implementation differed significantly between practices, mainly due to variation in the implementation of proactive care planning and case management. We discuss some factors that might have contributed to this large variation. In contrast to our hypothesis, a higher degree of implementation tended to be associated with an increase in functional decline. We speculate on this, and discuss some factors that might have hampered the program's effectiveness. We conclude that a higher degree of implementation of the CareWell program did not lead to the prevention of functional decline in frail elderly people.

**Chapter 6** reports on the results of the economic evaluation from a healthcare perspective, that was embedded in the 12-month cluster controlled trial. The 204 frail elderly that received care according to the CareWell program and 165 frail elderly that received usual care and completed the trial were included in this evaluation. We assessed intervention costs regarding time spent on team meetings, care planning, case management, and medication reviews during the twelve months follow up period. Healthcare utilization data were assessed at baseline and at follow up at twelve months with the EasyCare-TOS questionnaire, from extractions from registries of the municipality of Nijmegen and welfare organizations, and from electronic patient files. In cost-effectiveness analyses, we related costs to functioning in (instrumental) activities of daily life (measured with the Katz-15 change score) and quality adjusted life years (calculated from the EQ-5D). Adjusted mean costs directly related to the intervention were €456 per person. Adjusted mean total costs, i.e. intervention costs plus healthcare utilization costs, were €1583 (95% CI -4647 to 1481) higher in the intervention group than in the control group. Incremental Net Monetary Benefits did not show significant differences between groups, but on average tended to favour usual care. We discuss some possible explanations for the absence of cost-effectiveness of the program, and conclude that the CareWell primary program in its current form was not cost-effective after 12 months.

Finally, in **Chapter 7** we provide an overview of our main findings and reflect on these findings in the light of the current evidence base, with a focus on the results of comparable Dutch integrated care programs as conducted within the NCEP. We discuss some general methodological and theoretical issues concerning our research with

regard to the targeted population, the alignment between needs and preferences of frail elderly, subsequent interventions and outcome measures used, and the implementation of complex interventions into everyday clinical practice. Last, we elaborate on the implications of our findings, and propose some recommendations for clinical practice, policy makers, education, and future research. We conclude that much more development has to be done to take account of the highly heterogeneous frailty profiles and subsequent health and social care needs and preferences of community-dwelling elderly people. Also, more emphasis is needed to reach further integration between the cure, care, and welfare domains and to engage informal caregivers in the integrated care delivery to frail elderly.

# Samenvatting

Dit proefschrift behandelt antwoorden en inzichten met betrekking tot de implementatie en (kosten-) effectiviteit van het *CareWell primary care* programma, een complexe interventie gericht op het voorkomen van functionele achteruitgang bij thuiswonende kwetsbare ouderen. Dit proefschrift is geschreven als onderdeel van het Nationaal Programma Ouderenzorg, dat in 2008 in opdracht van het Ministerie van Volksgezondheid, Welzijn en Sport werd gestart met als doel de kwaliteit van zorg voor een toenemend aantal kwetsbare ouderen in Nederland te verbeteren. De informatie in dit proefschrift helpt ons bij het aanpassen van de Nederlandse eerstelijnszorg om adequaat tegemoet te komen aan de complexe gezondheidsgerelateerde behoeften van thuiswonende kwetsbare ouderen.

In **hoofdstuk 1** introduceren we de achtergrond en doelstellingen van dit proefschrift. Wereldwijd neemt het aantal kwetsbare ouderen met complexe, samenhangende gezondheidsvraagstukken toe als gevolg van de dubbele vergrijzing. 'Kwetsbaarheid (in internationale literatuur: frailty) verwijst naar een conditie waarin door het verlies van fysieke reserves een verhoogde kans ontstaat op ongewenste gezondheidsuitkomsten, zoals functionele achteruitgang, ziekenhuis- en verpleeghuisopname, en overlijden. Hierdoor leidt kwetsbaarheid tot hoge gezondheidszorgkosten. De huidige Westerse gezondheidszorgsystemen zijn vaak ontoereikend om de complexe zorgbehoeften van thuiswonende kwetsbare ouderen aan te pakken, vanwege hun reactieve, ziektegerichte structuur en een gebrek aan coördinatie tussen zorgverleners vanuit zorg- en welzijnsdomeinen. Nu veel Westerse regeringen, waaronder het Nederlandse, geconfronteerd worden met aanzienlijke bezuinigingen, en de meeste (kwetsbare) ouderen in hun eigen woonomgeving willen blijven wonen, is de noodzaak om (kosten-) effectieve interventies te ontwikkelen die functionele achteruitgang bij thuiswonende kwetsbare ouderen voorkomen duidelijk. Met dit doel ontwikkelden wij het *CareWell* programma.

Dit proefschrift behandelt de volgende vragen:

- Wat is de effectiviteit van het *CareWell* programma in het voorkomen van functionele achteruitgang bij thuiswonende kwetsbare ouderen, in vergelijking met gebruikelijke zorg na een follow-up periode van 12 maanden? (Hoofdstuk 3)
- Wat is de effectiviteit van het programma op de kwaliteit van leven van mantelzorgers, hun draaglast, en de tijd besteed aan mantelzorgerstaken, in vergelijking met gebruikelijke zorg na een follow-up periode van 12 maanden? (Hoofdstuk 4)
- In welke mate is het programma geïmplementeerd zoals beoogd? Wat is de associatie tussen de mate van implementatie van het programma en de mate van functionele achteruitgang van thuiswonende kwetsbare ouderen? (Hoofdstuk 5)

- Wat zijn de verschillen in gezondheidszorguitgaven tussen ouderen die zorg volgens het programma ontvangen en zij die gebruikelijke zorg ontvangen? Is het programma kosteneffectief vanuit een gezondheidszorgperspectief na 12 maanden? (Hoofdstuk 6)

In **hoofdstuk 2** beschrijven we eerst de design van het *CareWell* programma. Het is een complexe interventie gericht op thuiswonende kwetsbare ouderen, waarbinnen verschillende zorgverleners uit zorg- en welzijnsdomeinen geïntegreerd samenwerken om functionele achteruitgang te voorkomen, kwaliteit van leven te verbeteren, en ziekenhuis- en verpleeghuisopnames uit te stellen of te voorkomen. Het programma is gebaseerd op bestaande chronische zorgmodellen en aangepast aan het Nederlandse gezondheidszorgsysteem. Het programma bestaat uit 4 kerncomponenten: 1/ multidisciplinaire samenwerking, 2/ proactieve zorg, 3/ case management, en 4/ medicatie reviews. Vier ondersteunende elementen faciliteren het leveren van geïntegreerde zorg: multidisciplinaire richtlijnen voor de behandeling van veelvoorkomende geriatrische aandoeningen, een richtlijn voor anticiperende zorg, samenwerkingsafspraken m.b.t. de consultatie van geriatrische experts, en procedureafspraken rondom ziekenhuisopname en -ontslag.

Vervolgens beschrijven wij de design van de procesevaluatie van het programma en de design van de clustergecontroleerde (kosten-) effectiviteitsstudie met een looptijd van 12 maanden, waarin we het *CareWell* programma implementeerden in 6 huisartsenpraktijken in (de regio) Nijmegen en vergeleken met de gebruikelijke zorg in 6 andere huisartsenpraktijken in dezelfde regio.

In **hoofdstuk 3** rapporteren we over de effectiviteit van het *CareWell* programma op het voorkomen van (verdere) functionele achteruitgang en secundaire gezondheidsuitkomsten van thuiswonende kwetsbare ouderen, zoals onderzocht in onze clustergecontroleerde studie van 12 maanden.

287 Kwetsbare ouderen in 6 huisartsenpraktijken ontvingen zorg volgens het programma, en 249 ouderen in 6 andere huisartsenpraktijken ontvingen gebruikelijke zorg; 204 (71.1%) respectievelijk 165 (66.3%) ouderen completeerden de studie. Functionele achteruitgang in (instrumentale) activiteiten van het dagelijkse leven, de primaire uitkomstmaat, werd gemeten door middel van verandering op de Katz-15 score. Secundaire uitkomstmaten waren kwaliteit van leven (EQ-5D), geestelijke gezondheid (RAND-36), gezondheidsgerelateerde beperking in het sociale functioneren (RAND-36), ziekenhuis- en verpleeghuisopnames, en sterfte. We vonden geen statistisch significante verschillen tussen de interventiegroep en de controlegroep in functionele achteruitgang en de secundaire uitkomsten. We concluderen dat we geen bewijs vonden voor de effectiviteit van het *CareWell* programma in het voorkomen van negatieve gezondheidsuitkomsten in thuiswonende kwetsbare ouderen, en dat verdere uitrol van het programma in zijn huidige vorm niet aan te bevelen is.

In **hoofdstuk 4** rapporteren we over de effectiviteit van het CareWell programma op mantelzorgersuitkomsten, zoals onderzocht in dezelfde clustergecontroleerde studie van 12 maanden. Van de 536 geïnccludeerde kwetsbare ouderen gaven 364 (68%) ouderen aan een mantelzorger te hebben; 73 (21%) mantelzorgers vulden zowel de vragenlijst bij de start van het onderzoek als ook na 12 maanden in. Wij vonden geen statistisch significante effecten van het programma op zorggerelateerde kwaliteit van leven (CarerQoL-7D), draaglast (CarerQoL-VAS), en tijdsbesteding aan mantelzorgertaken (tijdsregistratie door mantelzorgers). Vanwege problemen in de inclusie en follow-up van mantelzorgers konden we echter geen solide conclusies trekken. We bediscussieren de geleerde lessen en doen enkele aanbevelingen met betrekking tot het inzicht dat binnen geïntegreerde zorgprogramma's specifieke aandacht voor kwetsbare ouderen en hun mantelzorgers, als eenheid, nodig is.

In **hoofdstuk 5** presenteren wij de resultaten van de kwantitatieve procesevaluatie, die naast de cluster gecontroleerde studie werd uitgevoerd. 204 Kwetsbare ouderen vanuit 6 huisartspraktijken die zorg volgens het CareWell programma ontvingen en de studie afmaakten werden geïnccludeerd in deze procesevaluatie. Tijdsregistraties van de multidisciplinaire teambesprekingen, case management activiteiten, en medicatie reviews werden gebruikt als maat voor implementatie van deze kernelementen. Daarnaast werden de zorgplannen, zoals opgeslagen in het digitale informatieportaal, bestudeerd op volledigheid. Deze data werden geaggregeerd tot een Totale Implementatie Score (TIS), als maat voor de implementatie van het programma 'volgens protocol'. We maten functionele achteruitgang met de verandering op de Katz-15 score. Wij vonden geen statistisch significante verschillen in functionele achteruitgang tussen de verschillende TIS groepen. De mate van implementatie van het programma verschilde significant tussen praktijken, vooral door grote verschillen in de implementatie van proactieve zorgplannen en casemanagement. We bediscussieren enkele factoren die mogelijk hebben bijgedragen aan deze grote variatie. In tegenstelling tot onze hypothese, vonden wij dat een hogere mate van implementatie geassocieerd leek te zijn met meer functionele achteruitgang. We speculeren hierover, en bediscussieren enkele mogelijke belemmerde factoren met betrekking tot de effectiviteit van het programma. We concluderen dat een hogere mate van implementatie van het CareWell programma niet leidt tot de preventie van functionele achteruitgang in thuiswonende kwetsbare ouderen.

**Hoofdstuk 6** rapporteert over de resultaten van de kosteneffectiviteitsstudie vanuit een gezondheidszorgperspectief, zoals uitgevoerd in de cluster gecontroleerde studie van 12 maanden. De 204 kwetsbare ouderen die zorg volgens het CareWell programma ontvingen en de 165 ouderen in de controlegroep die de studie afmaakten werden in deze studie meegenomen. Wij maten de kosten van het CareWell programma aan de hand van tijdsregistraties met betrekking tot de multidisciplinaire teambesprekingen, proactieve zorgplanning, case management, en medicatie reviews. Reguliere zorggebruikskosten werden bij de start van de interventie en na 12 maanden gemeten vanuit de

EasyCare-TOS, gemeentelijke administraties, en elektronische patiëntendossiers. In kosteneffectiviteitanalyses relateerden wij kosten aan functionele achteruitgang (gemeten met de verandering in de Katz-15 score) en 'quality adjusted life years' (berekend aan de hand van de EQ-5D scores). De kosten van het programma waren gemiddeld €456 per oudere in de interventiegroep. De kosten van het totale zorggebruik waren gemiddeld €1583 (95% CI -4647 to 1481) hoger in de interventiegroep dan in de controlegroep. De kosteneffectiviteitanalyse toonde geen statistisch significant verschil tussen de interventie- en de controlegroep, maar leek ten gunste van reguliere zorg uit te vallen. We bediscussiëren enkele mogelijke verklaringen voor de afwezigheid van kosteneffectiviteit van het programma, en concluderen dat het *CareWell* programma in zijn huidige vorm niet kosteneffectief is na 12 maanden.

Tot slot geven we in **hoofdstuk 7** een overzicht van de belangrijkste bevindingen van onze studies en relateren we deze aan recente literatuur, met een focus op de resultaten van vergelijkbare zorgprogramma's binnen het Nationaal Programma Ouderenzorg. We bediscussiëren enkele algemene methodologische en theoretische beperkingen met betrekking tot de doelpopulatie, het afstemmen tussen de behoeften van kwetsbare ouderen en de ingezette interventies en uitkomstmaten, en het implementeren van complexe interventies in de gangbare dagelijkse huisartspraktijk. Als laatste bespreken we de implicaties van onze bevindingen voor de klinische praktijk, voor onderwijs, en voor toekomstig onderzoek. We concluderen dat meer aandacht nodig is voor de grote verschillen tussen kwetsbare ouderen en hun gezondheidsgerelateerde zorgbehoeften. Daarnaast benadrukken we dat verdergaande integratie tussen de verschillende zorgverleners vanuit zorg- en welzijnsdomeinen nodig is, en dat mantelzorgers meer betrokken moeten worden in het leveren van geïntegreerde zorg aan kwetsbare ouderen.

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**Mijn boek is klaar! Laten we het vieren!**



# Publications

- 1 Blom JW, Van den Hout WB, Den Elzen, WPJ, Drewes YM, Bleijenberg, Fabricotti IN, Jansen APD, Kempen GIJM, Koopmans RTCM, Looman WM, Melis RJF, Metzelthin SF, Moll van Charante EP, Muntinga ME, Numans ME, **Ruikes FGH**, Spoorenberg SLW, Stijnen T, Suijker JJ, De Wit NJ, Wynia K, Wind AW, Gussekloo J, on behalf of the TOPICS-MDS Research Consortium.  
Effectiveness and cost-effectiveness of proactive and multidisciplinary integrated care for older people with complex problems in general practice: an individual participant data meta-analysis.  
Age and Ageing 2018; 47: 705–714.
  
- 2 **Ruikes FGH**, Adang EM, Assendelft WJJ, Schers HJ, Koopmans RTCM, Zuidema SU.  
Cost-effectiveness of a multicomponent primary care program targeting frail elderly people.  
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- 3 Smit LC, Schuurmans MJ, Blom JW, Fabbriotti IN, Jansen APD, Kempen GIJM, Koopmans R, Looman WM, Melis RJF, Metzelthin SF, Moll van Charante EP, Muntinga ME, **Ruikes FGH**, Spoorenberg SLW, Suijker JJ, Wynia K, Gussekloo J, De Wit NJ, Bleijenberg N.  
Unravelling complex primary-care programs to maintain independent living in older people: a systematic overview.  
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- 4 **Ruikes FGH**, van Gaal BGI, Oudshoorn L, Zuidema SU, Akkermans RP, Assendelft WJJ, Schers HJ, Koopmans RTCM.  
The association between implementation and outcome of a complex care program for frail elderly people.  
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- 5 **Ruikes FGH**, Zuidema SU, Akkermans RP, Assendelft WJJ, Schers HJ, Koopmans RTCM.  
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- 6 van Kempen JA, Schers HJ, Jacobs A, Zuidema SU, **Ruikes FGH**, Robben SH, Melis RJ, Olde Rikkert MG.  
Development of an instrument for the identification of frail older people as a target population for integrated care.  
Br J Gen Pract. 2013;63(608):e225-31.

- 7 **Ruikes FGH**, Meys ARM, van de Wetering G, Akkermans RP, van Gaal BG, Zuidema SU, Schers HJ, van Achterberg T, Koopmans RTCM.  
The CareWell-primary care program: design of a cluster controlled trial and process evaluation of a complex intervention targeting community-dwelling frail elderly.  
BMC Fam Pract. 2012;13:115.
- 8 [An outbreak of Q fever in The Netherlands--possible link to goats].  
Van Steenberghe JE, Morroy G, Groot CA, **Ruikes FGH**, Marcelis JH, Speelman P.  
Ned Tijdschr Geneesk. 2007;151(36):1998-2003. Dutch.

### Publications for clinical practice

- 1 **Franca Ruikes**, Mieke Postma. Een alledaagse hoofdpijn, of toch niet?  
Huisarts en Wetenschap, 2009 (10).
- 2 **Ruikes FGH**, Bruinsma RA, Broker FHL. Chronische recurrenente multifocale osteomyelitis;  
een relatief zeldzame entiteit.  
Tijdschrift voor Kindergeneeskunde, 2006 (3).

## About the author

Franca Ruikes was born on the 17<sup>th</sup> of December 1977 in Groenlo, the Netherlands. After graduating from secondary school (VWO) in 1996, she obtained her propaedeutic diploma in Health Sciences at Maastricht University in 1997. She then started to study Medicine at the Radboud University in Nijmegen, and graduated as a medical doctor in 2002. During this period she conducted a scientific internship in Kashikishi, Zambia, as well as a medical internship in Techiman, Ghana. After this, she first worked at the departments of Paediatrics of the Gelre hospital in Zutphen and Apeldoorn, and the department of Neonatology of the Radboud University Medical Centre in Nijmegen. During these years, she realized that her heart is in primary care, close to patients in their own living environments. In 2006, she started her general practice (GP) residency training at the Radboud University Nijmegen Medical Centre. She worked as a GP resident in the practices of Rob Besselink and Alfons Olde Loohuis (Herpen) and Vincent de Jong and Mieke Postma (Nijmegen). During this period, she was the chairman of the Regional Organization of GP residents (ROVAH), and board member of the National Organization of GP residents (LOVAH). In her last year as a GP resident, she conducted a research elective on the development of an instrument for the identification of frail older people as a target population for integrated care, at the department of primary and community care at the Radboud University Nijmegen Medical Centre, supervised by dr. Henk Schers. During this elective, her enthusiasm for scientific research increased. In 2009, she finished her GP training and started to work as a GP in different GP practices in (the surroundings of) Nijmegen. In 2010 she started her PhD study on the 'CareWell primary care program', an integrated care program for community-dwelling frail elderly. From 2013 onwards, she is working at the University Health Centre Heyendaal in Nijmegen. Besides this, she works as a GP trainer and teacher for the master in Medicine at the Radboud University Medical Centre Nijmegen.

Franca Ruikes lives together with Pieter de Mol and their daughters Sam (2008) and Nina (2011).

## Over de auteur

Franca Ruikes werd op 17 december 1977 in Groenlo geboren. Na het behalen van haar Vwo-diploma in 1996 en haar propedeutisch examen Gezondheidswetenschappen aan de Universiteit Maastricht in 1997, startte ze haar studie Geneeskunde aan de Radboud Universiteit Nijmegen in 1997. Gedurende deze studie deed ze haar wetenschappelijke stage in Kashikishi, Zambia, en volgde ze haar afsluitende coschappen in Techiman, Ghana. In 2002 behaalde ze haar artsendiploma. Hierna begon ze als arts-assistent te werken op de afdeling kindergeneeskunde van de Gelre ziekenhuis in Zutphen en Apeldoorn, en als arts-assistent neonatologie in het Radboudumc. Ze merkte als snel dat haar hart in de huisartsgeneeskunde ligt, dichtbij patiënten in hun eigen woonomgeving. In 2006 startte ze haar huisartsenopleiding aan de VOHA binnen het Radboudumc en werkte ze bij huisartsenpraktijk Herpen (Rob Besselink en Alfons Olde Loohuis) en de Hatertse Hoed in Nijmegen (Vincent de Jong and Mieke Postma). Tijdens haar huisartsenopleiding was ze voorzitter van de Regionale Vereniging van Aspirant Huisartsen (ROVAH) en algemeen bestuurslid van de Landelijke Vereniging van Aspirant Huisartsen. In het laatste jaar van haar huisartsenopleiding deed ze onderzoek naar de ontwikkeling van een screeningsinstrument voor thuiswonende kwetsbare ouderen als doelpopulatie voor geïntegreerde eerstelijnszorg, onder supervisie van dr. Henk Schers. In 2009 rondde ze haar huisartsenopleiding af waarna ze werkte als waarnemend huisarts in diverse huisartspraktijken. In 2010 begon ze aan haar promotietraject naar het *'CareWell primary care programma'*, een geïntegreerd zorgprogramma voor thuiswonende kwetsbare ouderen. Sinds 2013 werkt ze als huisarts in Universitair Gezondheidscentrum Heyendaal. Daarnaast werkt ze als huisartsopleider en docent binnen de masterfase van de geneeskundeopleiding van het Radboudumc.

Franca Ruikes woont samen met Pieter de Mol en hun dochters Sam (2008) and Nina (2011).

**Additional file 1: EasyCare-TOS**



# Step 1

Name patient:

---

Postal code patient:

Date of birth patient:

Assessment date:

GENDER:

Male  Female

1 **Multimorbidity**, patient has:

- 0 or 1 important chronic diseases
- 2 important chronic diseases
- 3 or more important chronic diseases
- unknown

2 **Polypharmacy**, patient has:

- less than 4 chronic medications
- 4 or more chronic medications
- unknown

3 **Cognitive problems**, patient has:

- no cognitive problems
- mild cognitive problems
- dementia (diagnosed)
- unknown

**4 Hearing and Vision**, patient has:

- no problems with hearing and vision
- mild problems with hearing and vision
- obvious problems with hearing and vision
- unknown

**5 Activities of daily living**, patient is:

- not dependent on professional or informal care
- to some extent dependent on professional or informal care
- highly dependent on professional or informal care
- unknown

**6 Mobility**, patient is:

- able to move independently
- able to move with some help
- unable to move
- unknown

**7 Falls**, patient has:

- not fallen the past 12 months
- fallen 1 time in the past 12 months
- fallen 2 times or more in the past 12 months
- unknown

**8 Informal care**, patient has:

- sufficient amount of informal care
- insufficient amount of informal care
- no informal care
- unknown

**9 Loneliness**, patient has:

- no loneliness
- had complaints of loneliness in the past 12 months
- unknown

10 **Social network**, patient has:

- sufficient and strong social network
- large but weak social network
- small but strong social network
- small and weak or no social network
- unknown

11 **Depressive complaints**, patient has:

- no depressive complaints
- depressive complaints
- unknown

12 **Anxiety complaints**, patient has:

- no anxiety complaints
- anxiety complaints
- unknown

13 **Somatoform complaints**, patient has:

- no somatoform complaints
- somatoform complaints
- unknown

14 **Other psychiatric complaints**, patient has:

- no other psychiatric complaints
- other psychiatric complaints,  
namely \_\_\_\_\_
- unknown

---

You went through all the domains that may have influence on the frailty status of the patient.

Based on your prior knowledge of the patient, do you think this patient is frail?

- The patient is not frail
- The patient is frail
- The frailty status of the patient is unclear

## Step 2

Name patient:

---

Postal code patient:

--	--	--	--	--	--

Date of birth patient:

--	--	--	--	--	--

Assessment date:

--	--	--	--	--	--

Caregiver present at assessment:

No  Yes

Name: \_\_\_\_\_

Relationship with patient: \_\_\_\_\_

Age:

--

GENDER:

Male  Female

COUNTRY OF BIRTH:

In which country were you born:

The Netherlands

Another country: \_\_\_\_\_

In which country was your father born:

The Netherlands

Another country: \_\_\_\_\_

In which country was your mother born:

- The Netherlands
- Another country: \_\_\_\_\_

EDUCATION:

- What is the highest level of education that you have completed?
- Fewer than 6 years of primary school 6 years of primary school
- More than primary school/primary school without further completed education
- Vocational school
- Secondary professional education University entrance level
- University / tertiary education

MARITAL STATUS:

- Married Divorced
- Widow / widower / partner deceased Unmarried
- Long-term cohabitation, unmarried

LIVING SITUATION:

In what kind of accommodation do you live:

- |   |  |
|---|--|
| <input type="checkbox"/> Single-family dwelling | <input type="checkbox"/> Senior apartment        |
| <input type="checkbox"/> Flat without elevator  | <input type="checkbox"/> Flat with elevator      |
| <input type="checkbox"/> Upstairs apartment     | <input type="checkbox"/> First-floor apartment   |
| <input type="checkbox"/> Serviced apartment     | <input type="checkbox"/> Sheltered accommodation |
| <input type="checkbox"/> Detached house         | <input type="checkbox"/> Care home               |

You are living:

- Independent, alone
- Independent, with others (partner, children, etc) Care home / residential care centre

CARE USE

Have you been admitted to a hospital in the past 12 months?

- No
- Yes, namely \_\_\_\_\_ days in total

Admission 1:

Hospital \_\_\_\_\_

City \_\_\_\_\_

Admission 2:

Hospital \_\_\_\_\_

City \_\_\_\_\_

Admission 3:

Hospital \_\_\_\_\_

City \_\_\_\_\_

Have you visited an out of ours GP service or had a visit from a general practitioner in the evening, night or on the weekend for yourself in the past 12 months?

- No
- Yes, namely \_\_\_\_\_ times in total

Do you receive home care? For example a community nurse, family care or home help.

- No
- Yes, namely \_\_\_\_\_ hours per week

Have you been admitted to a care home or nursing home temporarily in the past 12 months? For example because you were unable to go home immediately after a hospital admission.

- No
- Yes, namely \_\_\_\_\_ weeks in total

Do you go to a day care centre?

- No
- Yes, namely \_\_\_\_\_ days per week

Do you go for day treatment?

- No
- Yes, namely \_\_\_\_\_ days per week

Do you have an informal caregiver?

- No
- Yes, namely \_\_\_\_\_

**YOUR HEALTH**

How is your health in general?

- Excellent
- Very good
- Good
- Reasonable
- Poor

How is your health in general, in comparison to one year ago?

- Much better
  - Slightly better
  - About the same
  - Slightly worse
  - Much worse
- 

**1 Multimorbidity**

1.1 Current medical conditions of the patient Condition:

- 1 \_\_\_\_\_
- 2 \_\_\_\_\_
- 3 \_\_\_\_\_
- 4 \_\_\_\_\_
- 5 \_\_\_\_\_
- 6 \_\_\_\_\_
- 7 \_\_\_\_\_
- 8 \_\_\_\_\_
- 9 \_\_\_\_\_
- 10 \_\_\_\_\_

## 2 Medication

2.1 Do you use 4 or more different types of medicine?

- No
- Yes

2.2 Do you take your medicine as prescribed by the doctor?

- No
- Yes

## 3 Cognitive problems

3.1 Do you have any concerns about memory loss or forgetfulness?

- No
- Some
- Yes

3.2 Do you have problems with brain functions as memory, attention and thinking?

- No problems
- Some problems
- Severe problems

3.3 Memory test: see appendix 1

## 4 Mobility and falling

4.1 Can you rise from a chair?

- Without help
- With some help
- Unable to rise from a chair

4.2 Can you move yourself from bed to chair, if they are next to each other?

- Without help
- With some help
- Unable to move from bed to chair

4.3 Do you have problems with your feet?

- No
- Yes, namely \_\_\_\_\_

4.4 Can you get around indoors?

- Without help (including carrying any walking aid)
- With some help
- Confined to bed

4.5 Can you manage stairs?

- Without help (including carrying any walking aid)
- With some help
- Unable to manage stairs

4.6 Have you had any falls in the last 12 months?

- No
- One
- Two or more

4.7 Can you walk outside?

- Without help (including carrying any walking aid)
- With some help
- Unable to walk outside

4.8 Do you need help with travelling?

- Without help
- With some help
- Unable to travel without help

4.9 Observation mobility: see appendix 2 4.10. Chairtest: see appendix 2

## 5 Looking after yourself

5.1 Can you keep up your personal appearance? (e.g. brush hair, shave, put make-up on, etc.)

- Without help
- Need some help

5.2 Can you dress yourself?

- Without help (including buttons, zips, laces, etc.)
- With some help (can do half unaided)
- Unable to dress yourself

5.3 Can you wash your hands and face?

- Without help
- Need some help

5.4 Can you use the bath or shower?

- Without help
- Need some help

5.5 Can you do your housework?

- Without help (clean floors etc.)
- With some help (can do light housework, but need help with heavy work)
- Unable to do any housework

5.6 Can you prepare your own meal?

- Without help (plan and cook full meals yourself)
- With some help (can prepare some things but unable to cook full meals yourself)
- Unable to prepare meals

5.7 Can you feed yourself?

- Without help
- With some help (cutting food up, spreading butter, etc.)
- Unable to feed yourself

5.8 Can you take your own medicine?

- Without help (in right doses and at the right time)
- With some help (if someone prepares it for you or reminds you to take it)
- Unable to take own medicine

5.9 Can you use the toilet?

- Without help (can reach toilet, undress sufficiently, clean self and leave)
- With some help (can do some things, including wiping self)
- Unable to use the toilet

5.10 Do you have accidents with your bladder (incontinence of urine)?

- No accidents
- Occasional accident (less than once a day)
- Frequent accidents (once a day or more) or need help with urinary catheter

5.11 Do you have accidents with your bowels (incontinence of faeces)?

- No accidents
- Occasional accident (less than once a week)
- Frequent accidents or need to be given an enema

5.12 Do you use incontinence products?

- No
- Yes

5.13 Can you go shopping?

- Without help (taking care of all shopping needs yourself)
- With some help (need someone to go with you on all shopping trips)
- Unable to do any shopping

5.14 Do you need help in dealing with finances?

- No
- Yes

5.15 Do you have problems with daily activities (for example work, education, household, family and leisure activities)

- No problems
- Some problems
- Unable to perform my daily activities

## 6 Seeing, hearing and communicating

6.1 Can you see (with glasses if worn)?

- Yes
- With difficulty
- Cannot see at all

6.2 Can you hear (with hearing aid if worn)?

- Yes
- With difficulty
- Cannot hear at all

6.3 Do you have difficulty in making yourself understood because of problems with your speech?

- No difficulty
- Difficulty with some people
- Considerable difficulty with everybody

6.4 Can you use the telephone?

- Without help including looking up numbers and dialing
- With some help
- Unable to use the telephone

## 7 Staying healthy

7.1 Do you take regular exercise?

- No
- Yes

7.2 Do you get out of breath during normal activities?

- No
- Yes

7.3 Do you smoke any tobacco (e.g. cigarettes, cigars, pipe)?

- No
- Yes

7.4 How many glasses of alcohol do you drink per week?

- Less than 15 glasses per week
- 15 or more glasses per week, nl. \_\_\_\_\_

7.5 Do you have any concerns about your weight?

- No concerns
- Yes, being overweight
- Yes, weight loss

## 8 Nourishment

8.1 Do you have any problems with your mouth or teeth?

- No
- Yes, namely \_\_\_\_\_

8.2 Do you have difficulties with chewing food?

- No difficulties
- Some difficulties
- Unable to chew food

8.3 How is your appetite?

- Poor
- Good

8.4 Do you eat enough?

- No
- Yes

8.5 Did you lose weight?

No

Yes

## 9 Safety

9.1 Do you feel safe inside your home?

No

Yes

9.2 Do you feel safe outside your home?

No

Yes

## 10 Loneliness / Social network

10.1 Do you live alone?

No

Yes

10.2 Is there anyone who would be able to help you in case of illness or emergency?

No

Yes

10.3 Do you have contact with people in your neighborhood?

With few people, little contact

With few people, but sufficient contact

With many people, little contact

With enough people sufficient contact

10.4 Do you feel lonely?

Never

Sometimes

Often

## 11 Psychosocial problems

11.1 Are you able to pursue leisure, interests, hobbies, work and learning activities which are important to you?

No

Yes

11.2 How often in the past 4 weeks have your physical health or emotional problems hampered your social activities (such as visits to friends or close family members)?

Continuously

Mostly

Sometimes

Rarely

Never

11.3 Have you suffered from any recent loss or bereavement?

No

Yes

11.4 Have you had any trouble sleeping in the past month?

No

Yes

11.5 Have you had bodily pain in the past month?

No

Yes

If 'yes':

Very mild

Moderate

Mild

Severe

11.6 How often in the past month have you been very nervous?

- Always
- Very often
- Quite often
- Sometimes
- Almost never
- Never

11.7 How often in the past month have you felt calm and tranquil?

- Always
- Very often
- Quite often
- Sometimes
- Almost never
- Never

11.8 How often in the past month have you felt despondent and sombre?

- Always
- Very often
- Quite often
- Sometimes
- Almost never
- Never

11.9 During the last month, have you often been bothered by having little interest or pleasure in doing things?

- No
- yes

11.10 How often in the past month have you felt happy?

- Always
- Very often
- Quite often
- Sometimes
- Almost never
- Never

11.11 How often in the past month have you felt so somber that nothing could cheer you up?

- Always
- Very often
- Quite often
- Sometimes
- Almost never
- Never

11.12 How is your quality of life in general?

- Excellent
- Very good
- Good
- Reasonable
- Poor

11.13 Which report mark (between 0 and 10) would you give your life at this moment?

11.14 How is your quality of life in general, in comparison to one year ago?

- Much better
- Slightly better
- About the same
- Slightly worse
- Much worse

**13 Additional comments**

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## Appendix 1

### 3.3 Memory test (6-CIT):

Score 1 for every wrong answer

a What year is it? \_\_\_\_\_ (max 1) x 4 = \_\_\_\_\_

b What month is it? \_\_\_\_\_ (max 1) x 3 = \_\_\_\_\_

Memory question:

Repeat after me: John Smith, 42 High Street, Bedford

c. About what time is it (within 1 hour)? \_\_\_\_\_ (max 1) x 3 = \_\_\_\_\_

d. Count backwards from 20-1 \_\_\_\_\_ (max 2) x 2 = \_\_\_\_\_

e. Say the months of the year in reverse \_\_\_\_\_ (max 2) x 2 = \_\_\_\_\_

f. Repeat memory question

John \_\_\_\_\_

Smith \_\_\_\_\_

42 \_\_\_\_\_

High \_\_\_\_\_

Street \_\_\_\_\_

Bedford \_\_\_\_\_

\_\_\_\_\_ (max 5) x 2 = \_\_\_\_\_

Total = \_\_\_\_\_

*A total score of > 10 is indicative for memory problems*

## Appendix 2

### 4.9 Observation mobility:

- Patient is wheelchair-dependent

Does the patient use a walking aid?

- Yes  
 No

Does the patient walk safely?

- Yes  
 No

How would you the falling risk of the patient?

- High  
 Moderate  
 No

### 4.10 Rise from a stair without using your arms?

- Patient rises quickly  
 Patient rises with any difficulties  
 Patient rises from seat, but falls back into the chair  
 Patient cannot rise

**Summary of EASYcare-TOS step 2**

Physical functioning

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---

Medication

---

---

Cognition

---

---

ADL / IADL

---

---

Seeing/hearing

---

---

Mobility / falling

---

---

Mental wellbeing

---

---

Social network

---

---

Loneliness

---

---

Demographic information

---

---

Care use

---

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**14 Complexity of the care context (questions for GP)**

14.1 Were other care professionals involved in the care of the patient in the past 12 months? (e.g., medical specialist, physical therapist, home care, social worker, etc.)

- No other care professionals involved
- 1-3 other care professionals involved
- > 3 other care professionals involved
- unknown

14.2 How do you rate the amount of agreement between the several care professionals involved in the care of the patient, on a rating scale of 1 to 10? (1 is absolutely no agreement and 10 is complete agreement)

1 \_\_\_\_\_ 10

Additional information:

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14.3 How certain are you about the treatment of the patient, on a rating scale of 1 to 10? (1 is absolutely uncertain and 10 is completely certain)

1 \_\_\_\_\_ 10

Additional information:

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14.4 Did other professionals involved in the care of the patient have doubts about the delivered or required care?

- No
- Yes
- Unclear

Additional information:

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14.5 Do you think the patient will benefit from more coordinated and integrated care?

- No  
 Yes  
 Unclear

Additional information:

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### Judgment of patient

How do you evaluate the following domains in this patient?

Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Physical functioning	Good	Fair	Poor
Medication*	Good	Fair	Poor
Cognition	Good	Fair	Poor
Vision and hearing	Good	Fair	Poor
ADL/IADL	Good	Fair	Poor
Mobility	Good	Fair	Poor
Mental wellbeing	Good	Fair	Poor
Social context**	Good	Fair	Poor

\* *this covers: polypharmacy, high-risk medication and adherence*

\*\* *this covers: safety, environment, social network, social activities*

How would you judge the patient?

- Not frail  
 Frail but no complex care context  
 Frail and no complex care context

