Personalized Primary Care for Older People:

An evaluation of a multicomponent nurse-led care program

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Zorg op maat voor ouderen in de eerstelijn:
Een evaluatie van een multicomponent verpleegkundig zorgprogramma
(met een samenvatting in het Nederlands)

Proefschrift

ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de rector manificus, prof.dr. G.J. van der Zwaan, ingevolge het besluit van het college voor promoties in het openbaar te verdedigen op donderdag 17 oktober 2013 des morgens 10.30 uur

door

Nienke Bleijenberg

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Co-promotor:	Dr. V.H. ten Dam

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Voor alle ouderen,
voor mijn beide opa's en oma's

Contents

Chapter 1

General introduction

Aging society

Population aging is accelerating rapidly worldwide, from 461 million older people (i.e., 65 years and over) in 2004 to an estimated one billion people by 2050.[1, 2] In Europe, the number of older people is expected to almost double in the next decade, whereas the number of the oldest old, i.e., 80 years and over) is expected to even triple by 2060. This increase in the proportion of older people is mainly caused by a combination of low fertility and longer life expectancy.[3] In 2011, the percentage of older people in the Netherlands was 15%, and this figure will increase to approximately 25% by 2040.[4] With this, the proportion of people with multiple chronic diseases, also referred to as multimorbidity, will rise as well.[5, 6] In the Netherlands, approximately two-thirds of the people between 65 and 70 years of age experience multiplediseases; whereas the percentage of people aged 85+ experiencing multimorbidity is approximately 85%.[7] This will inevitably result in high demands of health care and health care expenditures.[7]

Maintaining independence and preservation of physical functioning

Although the population of older people is largely heterogeneous in terms of health and self-sufficiency, the majority of older people want to maintain independence and a good quality of life and remain living at home for as long as possible.[8] However, the ability to perform activities of daily living (ADLs), such as bathing or dressing, or instrumental activities of daily living (IADLs), like shopping, is often threatened by various factors associated with aging, such as multimorbidity and loss in multiple domains of functioning.[9]
Older people as well as the Dutch Government are stressing the importance of maintaining independence in older persons. In 2009, the Dutch Health Council presented an advisory report "Prevention in the elderly: Focus on functioning in daily life" and noted that preservation of physical functioning and prevention of functional decline is the most important aim in providing care to older people.[10] Health care professionals should focus not only on the occurrence of diseases or postponing death but also on the prevention of functional disabilities and the promotion of independence. This will also increase the wellbeing and quality of life of older people.[11]

Preservation of physical functioning requires early identification of functional decline.[12] The onset of functional decline is a dynamic and progressive process that is mainly caused by multiple underlying factors, diseases, and physiological changes associated with age.[12, 13] To enhance our understanding of physical functioning and to provide a scientific basis for studying this concept, the International Classification of Functioning, Disability, and Health (ICF) model has been developed.[14] In the ICF model, functional decline is presented as a multifactorial problem influenced by several domains: health condition, body function, body structure, environmental factors, personal factors, and participation (Figure 1). This conceptual framework emphasizes the need for a multifactorial approach in the preservation of physical functioning in older patients.

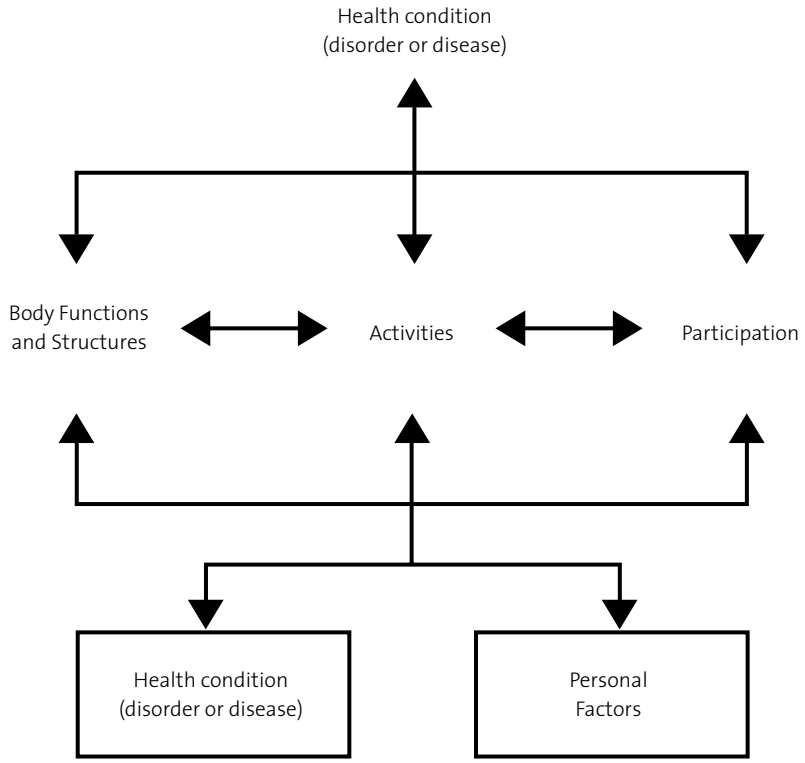

Figure 1 The International Classification of Functioning, Disability, and Health (ICF) model.

Current health care is suboptimal

Currently, care for older people with multiple diseases is suboptimal and does not meet people's individual care needs.[15] A lack of overview and care coordination when multiple health care providers are involved is one perceived problem indicated by older patients.[16] Consequently, older patients and their caregivers experience unnecessary loss in functioning and a higher disease burden, resulting in a lower quality of life.[17] Another barrier in care for older people with multiple diseases is the lack of an integrated care approach that includes all domains of physical, psychological, social, and cognitive functioning.[7] Furthermore, the current health care system is reactive, time consuming, and demand driven, with little attention paid to preventive care that focuses on the preservation of independence and wellbeing in older people.[10] Therefore, a transformation of our health care system is urgently needed in order to account for the growing number of older patients.

Transition toward proactive care

To prevent functional decline and preserve independence, a transition toward a proactive, preventive, and personalized health care system is required.[10, 18] This challenges all health care providers, but especially health care providers in primary care.[19, 20] General Practitioners (GPs) and nurses in primary care can play an important role in the early identification of older patients at risk who might benefit from personalized care.[21] However, a current deficiency in primary care is lack of time, personnel, and adequate methods to proactively and systematically detect older patients and provide optimal care. To make a transition, patient-centered medicine has been proposed as a model for restructure primary care by focusing on individual care needs before deterioration and loss on multiple domains occur. [22, 23] Key components of this transformation are the identification of at-risk patients, followed by longitudinal personalized care tailored to each patient's needs. Hence, it remains to be determined which methods are most successful in detecting the target population and which combination of elements should be included when defining the optimal primary care strategy for older patients.[24]

Selection of patients at risk

To identify older patients at risk, numerous instruments have been developed.[25] Evidence suggests that frail individuals who are not yet disabled and those with early disability who are at high risk of progression are the most likely to benefit from preventive interventions.[26] Despite some disagreement on the precise definition, frailty can be described as a loss of resources in multiple domains (i.e., physical, psychological, cognitive, social) resulting in a state of increased vulnerability for adverse health outcomes, including disability, dependency, need for long-term care, and mortality.[27, 28, 29] Furthermore, frailty is associated with reduced quality of life and satisfaction among older people.[12, 30] A multistage selection process that identifies the frail while excluding the "robust" has been recommended in order to include the most appropriate study population.[26]

Comprehensive care programs

The early identification of patients at risk combined with a comprehensive multicomponent care program is reported as a promising approach to prevent deterioration in functional status.[31] Although several complex interventions or comprehensive care programs for older people have been developed, the reported benefits from those interventions are controversial.[32-34] Comparison of care programs is difficult due to the extensive heterogeneity of the intervention components and inclusion criteria. There is little consensus regarding which programs and (combination of) components are most successful in improving the quality of care for frail older people in primary care.[24] A multidisciplinary approach including individual assessments and tailored care provided by integrated care teams is consistently reported to be a key element of such interventions.[31, 35] In some care models, specially trained nurses have a pivotal role as care managers and deliver and coordinate the care for older patients.[32, 33] In the Netherlands, registered practice nurses in primary care trained in care for older persons are educated to identify older patients at risk early using assessments and to deliver (evidence-based) care to the patient and his caregiver, provide ongoing care coordination, and evaluate the care.[36] Therefore, nurses in primary care can play an important role regarding the provision of proactive and personalized care.

To improve care for older people with complex care needs, the Dutch Government initiated the National Care for the Elderly Program in 2008.[37] A four-year research program was set up to investigate optimal strategies to provide proactive care. Within this research program, we designed the Utrecht Proactive Frailty Intervention Trial (U-PROFIT), in which we developed and evaluated a strategy for proactive patient-centered care of frail older people in primary care. The strategy consisted of the Utrecht Periodic Risk Identification and Monitoring (U-PRIM) system, a frailty-screening intervention based on risk selection in administrative patient data, and U-CARE, a nurse-led multicomponent personalized care program.

The U-CARE program can be defined as a multicomponent intervention, because it includes multiple, interacting components, a number of behaviors and levels of difficulty required by those delivering or receiving the intervention, and it is flexible and tailored.[38] To help researchers and research funders to make appropriate methodological and practical choices for the development and evaluation of complex interventions, the UK Medical Research Council (MRC) developed a framework consisting of four phases (development, feasibility/piloting, evaluation, and implementation) that will be used as a theoretical guide.[38] (Figure 2).

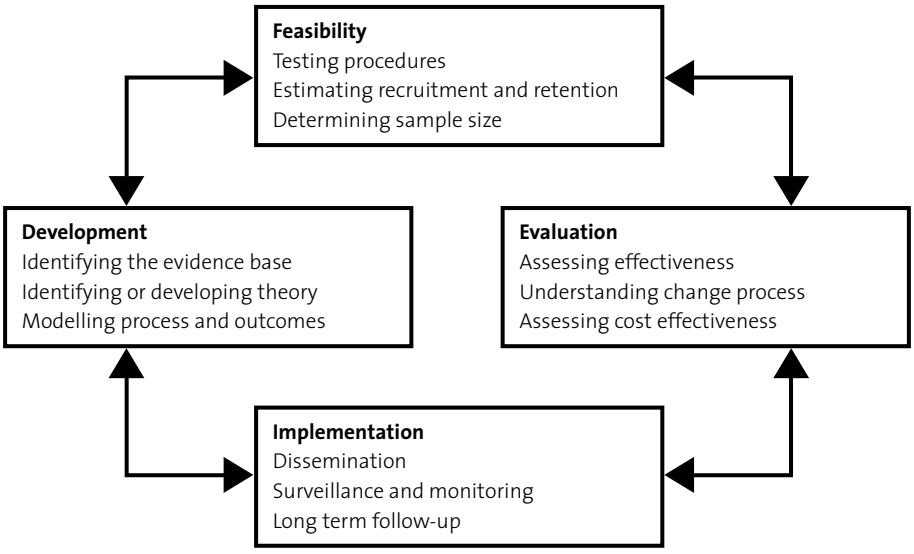

Figure 2 MRC framework for the development and evaluation of complex interventions.

Objectives of this thesis

The objective of this thesis is to develop and evaluate a multicomponent nurse-led personalized care program (U-CARE) to preserve physical functioning and improve quality of life for frail older people in primary care. Specially trained registered nurses will provide care that is structured and tailored to the individual needs of the patient. The guiding principles of this program are as follows: targeted at patients at risk for functional decline, biopsychosocial assessment, focus on patients' needs, evidence-based, and feasible in clinical practice.

Outline of this thesis

The outline of this thesis is visualized in Figure 3. To understand the different components of a complex intervention and to allow in-depth review and replication, a detailed description of an intervention and its development process is needed. Therefore, in Chapter 2, we provide a detailed description of the development of the U-CARE program. In Chapter 3, the design, methods, and methodological challenges of the U-PROFIT are reported in which the effectiveness of the U-CARE program will be evaluated. Next, we explore in a mixed-methods design the expectations, needs, and experiences of nurses and GPs toward the U-CARE program in Chapter 4. Chapter 5 describes the effectiveness of the U-CARE intervention that has been evaluated in a large single-blind three-armed cluster randomized controlled trial. In Chapter 6, we assess the actual nursing care delivered within the nurse-led care program and explore how the care delivery may have influenced our trial results. Chapter 7 contains a qualitative study that investigates patients' perception of the roles of the registered practice nurse and how they perceive proactive personalized nurse-led care. In Chapter 8, we identify patient characteristics who benefit most from proactive, personalized nurse-led care. We investigate the association between the concepts of frailty, complexity of care, and quality of life in a cross-sectional study in multi-morbid older persons in Chapter 9.

We discuss the main findings and reflect on choices and considerations regarding the development and content of the intervention and regarding the methodological aspects of our study in Chapter 10. In addition, specific emphasis will be put on the role of the nurse within proactive personalized care. Implications and recommendations for future research, education, and clinical practice will be given. This thesis closes with a summary of the findings presented.

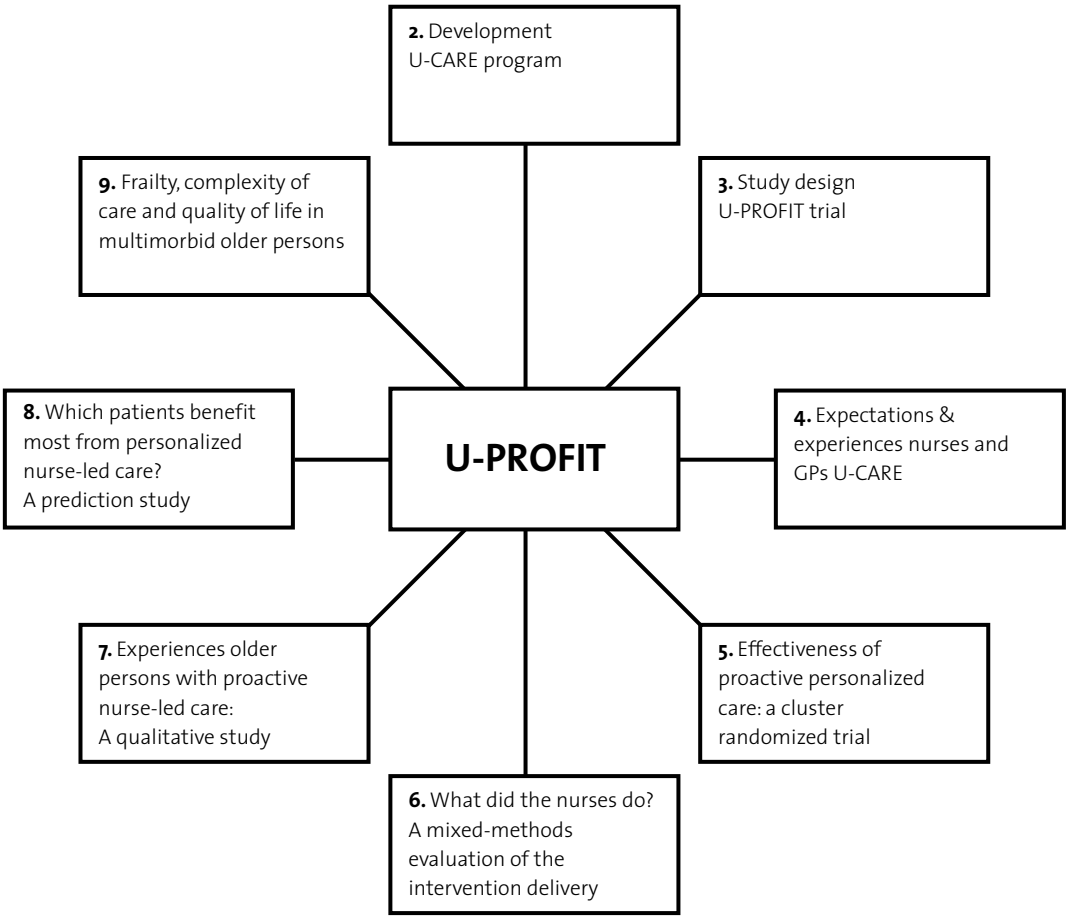

Figure 3 Outline of this thesis.

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Chapter 2

Development of a proactive care program (U-CARE) to preserve physical functioning of frail older people in primary care

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Journal of Nursing Scholarship. 2013 Mar 26. doi: 10.1111/jnu.12023.

Abstract

Purpose: Care for older patients in primary care is currently reactive, fragmented and time-consuming. An innovative structured and proactive primary care program (U-CARE) has been developed to preserve physical functioning and enhance quality of life of frail older people. This study describes in detail the development process of the U-CARE program to allow its replication.

Methods: The framework of The Medical Research Council (MRC) for the development and evaluation of complex interventions was used as a theoretical guide for the design of the U-CARE program. An extended stepwise multi-method procedure was used to develop U-CARE. A team of researchers, general practitioners, registered practice nurses, experts and an independent panel of older persons was involved in the development process to increase its feasibility in clinical practice. A systematic review of the literature and of relevant guidelines, combined with clinical practice experience and expert opinion was used for the development of the intervention.

Findings: Based on predefined potentially effective guiding components, the U-CARE program comprises three steps: a frailty assessment, a comprehensive geriatric assessment at home followed by a tailor-made care plan and multiple follow-up visits. Evidence-based care plans were developed for eleven geriatric conditions. The feasibility in clinical practice was tested and approved by experienced registered practice nurses.

Conclusion: An extended stepwise multi-method procedure was used to develop the U-CARE program. The MRC framework was instrumental in the development of this proactive and structured care program in primary care. A detailed description is provided, which is often lacking from complex intervention trials.

Clinical relevance: The U-CARE program consists of promising components and has the potential to improve the care of older patients.

Introduction

One of the major challenges in primary care is providing optimal care to a rapidly increasing population of frail older people.[1, 2] Currently, primary care of older people is reactive, fragmented and time consuming.[3, 4] Moreover, the health care system does not meet the individual needs of patients' and many patients and their caregivers experience a poor quality of life.[5, 6] Frailty can be defined as a progressive condition that is associated with adverse health outcomes including functional decline, long term care and mortality.[7, 8] Therefore, proactive strategies and interventions that prevent functional decline are urgently needed to enhance the care of frail older people.[9]
Several complex interventions that aimed to preserve physical functioning and independence of frail older people living in the community achieved inconsistent results.[1, 10] Beswick and colleagues (2008) reported in a systematic review and meta-analysis that complex interventions allowed older patients' to live safely and independently.[1] Huss and colleagues (2008) concluded in their systematic review and meta-analysis that multidimensional preventive home visits can potentially reduce disability among older patients, however, the effects on nursing home admissions varied.[10] Furthermore, there is little consensus regarding which models and what combination of components are most successful in improving the quality of care for frail older people, and it is unclear how primary care can best support older people who have complex care needs.[11] To understand the different components of a complex intervention and to allow in-depth review and replication, a detailed description of an intervention and its development process is needed.[12, 13] Descriptions of the details, considerations and choices are often missing from the reports of complex intervention trials.[14] The British Medical Research Council (MRC) has proposed a framework for the development and evaluation of complex interventions to help researchers and research funders to recognize and adopt appropriate methods.[13] This framework was used to develop the present innovative structured and proactive care program (U-CARE) to preserve physical functioning and quality of life of frail older persons aged 60 years or older who are living independently in the community.

Specially trained registered practice nurses will provide care to frail older patients with complex care needs in close collaboration with general practitioners (GPs) and other primary care providers. The aim of this study is to describe the development process of the U-CARE program in detail, to allow its thorough review and replication.

Methods

In 2008, the MRC published a revised and updated version of their "Framework for the Development and Evaluation of Complex Interventions" that included several non-linear phases: Development, Feasibility and Piloting and Evaluation and Implementation.[13] Therefore, a detailed description of the steps and choices made throughout the development and feasibility phase of U-CARE will first be elaborated in-depth, guided by the criteria proposed for reporting the development and evaluation of complex interventions in health care (CReDECI).[15] The content of the program will be described in the results section. Next, the considerations prior to the evaluation phase, as well as the choices made for the design and the sampling process of the evaluation phase will be described briefly. A team of researchers, GPs, registered practice nurses, experts and an independent panel of older people was involved in the development to increase its quality and feasibility for clinical practice. A stepwise approach of the literature and guidelines review, combined with clinical practice experiences and expert opinions was used for the development of the intervention. This project was supported by a grant from the Netherlands Organization for Health Research and Development, as part of the National Care for the Elderly Program that aims to improve the care of elderly people with complex care needs.

1. Development phase

During the development phase, the aim was to identify the existing relevant evidence as well to gain a theoretical understanding of the likely process of changes that would support the U-CARE intervention.[13] The reported evidence indicated that both a multidimensional geriatric assessment and multiple follow-up visits for patients at-risk are effective components of improving the quality and efficiency of the care of older people in primary care.[1, 5 10, 16-19]

Other important elements include a team-based approach that focuses on the patients' needs.[20, 21] After studying the existing evidence, we concluded that the most promising elements were based on those of the Chronic Care Model (CCM). This model provided a framework for redesigning practice to enhance the quality of care. The care delivery system is designed to be a more proactive and preventive system.[22,23] The elements of this model consist of an improved clinical information system, decision and self-management support, and better access to community resources. The CCM was therefore used as a theoretical foundation that may help to explain and predict the potential effects of the U-CARE intervention. Building on lessons learned from the literature, we combined all of the potentially successful components to develop our intervention. Predefined guiding components for our intervention program were formulated and discussed by a group of researchers and practitioners in primary care (Box 1).

- **Targeting older patiens at risk for functional decline**
- **Biopsychosocial assessment**
- **Focus on patient's needs**
- **Evidence-based**
- **Feasible in clinical practice**

1.1 Development frailty assessment

The U-CARE program was developed based on predefined guiding components comprised the three following steps: a frailty assessment to identify frail patients, a comprehensive geriatric assessment (CGA) of frail patients at home followed by a tailor-made care plan with evidence-based interventions.
The first step of the U-CARE program was developed based on the literature, clinical experiences and the discussions of a multidisciplinary team of researchers and practitioners to meet the predefined components of "targeting older patients at risk for functional decline", "biopsychosocial approach" and "focus on patients' needs". Various instruments have been developed to assess the frailty of community-dwelling older people.[24] In the U-CARE program, the Groningen Frailty Indicator questionnaire (GFI) was chosen for its comprehensiveness and its feasibility in clinical practice.[25, 26]

The GFI is a 15-item validated self-reported questionnaire covering four domains: physical (9 items), cognitive (1 item), social (3 items) and psychological (2 items). The score ranges from zero (non- frail) to 15 (severely frail) and a score of 4 or higher denotes frailty. The GFI has shown a high level of internal consistency and construct validity.[24,27] Additional instruments were studied to enable a patient needs approach. From the literature and experiences in other research projects in the Netherlands, two questionnaires were included: the INTERMED for the Elderly (IM-E) and the Groningen Well-being Indicator (GWI). The INTERMED is based on a bio-psychosocial model that assesses multiple health risks and needs of the patients on four dimensions: biological, psychological, social and experiences with the healthcare system.[28]
Several adjustments were made to adapt this instrument to the elderly population.[29] The scores range from zero to sixty, and a higher score indicates more complex care needs. A high internal consistency (Cronbach's alpha between 0.83 and 0.87) was found and the inter-rater reliability for the various domains of the IM-E ranged between 0.87 and 0.95.[29] The GWI explores patients' well-being according to the following eight items: 'enjoying food and drinks', 'sleeping', 'social relationships', 'being active', 'being yourself, 'being independent', 'feeling healthy in body and mind' and 'pleasant home situation'.
First, patients indicated items that are important to them and then they indicated whether they were satisfied with these item(s). Two additional questions about falls and urinary incontinence were included in the frailty assessment because both of these factors are known geriatric syndromes and are essential for geriatric screening.[30,31]

1.2 Development CGA and evidence-based care plans
To meet all of the predefined components, CGA and evidence-based care plans were developed in a highly structured approach that included a literature review, guidelines review, assessment of the face validity by registered practice nurses and the compilation of expert opinions. The CGA considers the biopsychosocial components of health and provides the basis for an overall plan for treatment and follow-up.[32] The CGA and evidence-based care plans concerned the following geriatric conditions: 1. Falls and mobility; 2. Physical functioning; 3. Nutrition and malnutrition; 4. Mood and depression; 5. Loneliness; 6. Cognition; 7. Urinary incontinence; 8. Polypharmacy; 9. Vision impairment; 10.

Hearing loss; and 11. Caregiver burden. For these conditions, evidence-based care plans were developed. This selection was chosen because most of the conditions are known risk factors that influence patients' physical functioning and independence[31] and highly prevalent in older patients.

Literature review

During the first step of the development of the CGA and the evidence-based care plans, a systematic literature search was performed. Searches were performed to discover assessments, nursing interventions and patient recommendations in meta-analyses and systematic reviews for each chosen geriatric condition. These searches were conducted in PubMed, PsycINFO, CINAHL and the Cochrane Library databases for literature published between January 2000 and January 2010. The methodological quality and level of evidence per intervention or recommendation was graded by the Dutch Institute for Healthcare Improvement (CBO). An average of eleven systematic reviews and meta-analyses for each geriatric condition were included. Adequate evidence was found for 'falls and mobility', 'cognitive decline', 'mood and depression' and 'polypharmacy'. Only two systematic reviews were found for the condition 'loneliness'. The results of the literature research are provided see Additional file 1.

Guidelines review

To incorporate additional assessments, interventions and recommendations into the CGA and evidence-based care plans, a review of a selection of guidelines was performed: National Institute of Clinical Excellence (NICE), Dutch Institute for Healthcare Improvement (CBO), Dutch General Practitioner Society (NHG), Dutch Nurses Association (V&VN) and The Netherlands Center of Excellence in Nursing (LEVV). The number of guidelines varied for each of the geriatric conditions. No guidelines were found for 'loneliness' and 'physical functioning'. Nursing guidelines were found for 'urinary incontinence' and 'cognition'. An average of three interventions and recommendations were added for each evidence-based care plan.

Assessment of the face validity by registered practice nurses
The face validity of the CGA and the provisional evidence-based care plans were assessed and tested in clinical practice by a panel of three experienced registered practice nurses. The included assessments, interventions and recommendations from the literature and guidelines review were discussed during ten meetings. The practical knowledge and best practices interventions recommended by the registered practice nurses were added to the care plans. Most of the interventions and recommendations obtained from the literature and guidelines were adopted by the practice nurses. An average of two interventions or recommendations was added to each care plan (see Additional file 2).

Gathering of expert opinion
Two or three experts (PhD-fellow or PhD) on each geriatric condition appraised the CGA and the provisional evidence-based care plans. Divergent or conflicting suggestions were resolved by consensus between the expert and researcher. Most experts agreed with the content of the evidence-based care plans. Minor adaptations were made, only for the conditions of nutrition/malnutrition and loneliness. Flowcharts for each geriatric condition containing the total set of assessments, evidence-based interventions and recommendations were developed as practical tools for the practice nurses. An example of the flowchart "falls" is included (see Additional file 3). The content of the U-CARE program was assessed and approved by a panel of five independent older people, who were not participants in the trial during two meetings. This panel suggested developing evidence-based plans for alcohol abuse, pain and sleeping disorders in the program. Unfortunately, for pragmatic reasons, it was not possible to develop evidence-based plans for those conditions. Instead, we instructed all of the practice nurses to give attention to and discuss these problems during each CGA. Overall, the panel of older people agreed on the content of the U-CARE program.

2. Feasibility study
To assess the barriers and facilitators for the implementation of this intervention in clinical practice, a questionnaire was sent to all participating GPs and registered practice nurses one month prior to the start of the intervention.[33]

We received permission to use the same questionnaires, with minor adaptations, as were employed in a study of Van Eijken et al. (2008) to assess the feasibility on a 5-point likert scale, with a range from 5 (strongly agree) to 1 (strongly disagree).[34] The questionnaire considered the characteristics of the care providers, the innovation, the characteristics of the patient and organizational and social factors; the content validity was tested by a group of experts.

Results

Content of the U-CARE program in clinical practice

For the trial, the frailty assessment questionnaire will be sent by mail to all eligible older patients aged ≥ 60 at risk for adverse health outcomes meeting any of the following three criteria: Multimorbidity (defined by a frailty index score); Polypharmacy (defined as chronic use of five or more different medications); Consultation gap in primary care (defined as not having consulted a GP in the past three years, except for the annual influenza vaccination).[35] If the patient is unable to complete the questionnaire, a proxy or a practice nurse will be asked to assist. The outcome of the frailty assessment for each patient will be available to all registered practice nurses on a specially developed innovative web-based computer program. Frail patients (indicated with a GFI score ≥ 4) will receive a CGA at home, conducted by the specially trained practice nurse. During the CGA, the registered practice nurse will focus on patients' perceived care needs and tailor the intervention to the patients' preferences.
Medical problems will be discussed with the GP. If a caregiver is involved, the nurse will discuss the outcome of the CGA with the caregiver and the caregiver burden will be evaluated. After the CGA has been performed, a tailor-made care plan of evidence-based interventions will be developed by the registered practice nurse in close collaboration with the GP, and if needed, with other disciplines. The evidence-based care plans that we have developed will guide the registered practice nurses to tailor and deliver the intervention based on patients' needs. Because the care approach is tailor-made, the actual intervention and the number of additional home visits are flexible and therefore not known in advance. The care plan, approved by the patient and/ or his caregiver, ensures that structured and coordinated care will be provided by a registered practice nurse.

2. Feasibility and pilot
A high response rate among the GPs (27/31; 87.5%) and registered practice nurses (20/21; 95.2%) was obtained during the first measurement prior to start of the intervention. Three barriers to providing structured and proactive care were reported by the registered practice nurses and GPs.

First, a majority of the nurses (85%) and the GPs (59%) indicated having a lack of time for coordination and geriatric assessments. Second, 74% of the GPs indicated the lack of financial compensation for developing proactive care. Third, nurses (60%) and GPs (62%) reported that providing care to older people with a different cultural background is difficult, and 63% of the GPs indicated that it is difficult to provide care to multimorbid older patients. A large majority of the registered practice nurses and GPs (85% of each) indicated that the U-CARE program would enable them to address geriatric problems with a structured approach and that it focuses on the major geriatric health problems (nurses: 90%; GPs: 74%). Over 80% of the GPs indicated that the U-CARE program would provide an additional benefit for the patients suffering from loneliness, whereas almost 90% of the registered practice nurses indicated that this phenomenon would be true for the patients with mood and depression disorders and urinary-incontinence.[36]

Pilot study
To assess the feasibility of the intervention and the acceptability among the care providers and patients, a small pilot study was performed. This pilot study was not a 'scale model' of the planned main evaluation: rather, it aimed to identify uncertainties in the U-CARE intervention in clinical practice. Three experienced registered practice nurses from different general practices, who were also involved during the development phase, tested the intervention. A total of 30 patients were included. During the six-week pilot period, the nurses reported their experiences and the barriers, strengths, limitations and time investment for each step and geriatric condition in a daily diary.
The registered practice nurses concluded that the U-CARE program was feasible in clinical practice. Based on the qualitative results, the registered practice nurses indicated that the program improved their knowledge, enhanced the structured care and provided a better understanding of patients' needs.

"...Due to the new evidence-based care plans, I think we can improve the care for older patients. The screening assessment provided a comprehensive overview of the patient's needs"

"...Patients perceived that I have more time to provide care compared with the GP. Care is more accessible"

Minor adaptations of the evidence-based care plans were made based on three evaluation meetings.

3. Preparations prior to the evaluation phase

Selection of registered practice nurses

Prior to the evaluation phase, 21 registered practice nurses were recruited and trained to perform the intervention in clinical practice. This number was calculated based on the number and size of the participating general practices involved in the evaluation phase. All nurses were employed by the project.
A profile of nursing skills and competencies was defined in collaboration with GPs, experienced registered practice nurses and researchers. Each nurse was required to have a minimum of two years of experience as a registered nurse working with older people in a primary care setting or in the community.
See Table 1 for a summary of the tasks and skills of the registered practice nurse.

Table 1: Tasks and skills of the registered practice nurses.

Tasks of the nurses	Skills of the nurses
Performing the frailty assessment and the CGA	At least two years of experience as a registered nurse working with older people in a primary care setting or in the community. Can provide innovative, proactive care based on patients' needs.
Focus on patients' problems and needs	Help the patient to identify and prioritize his care needs with the use of validated instruments.
Monitoring patients & conducting follow-up visits	Promote self-management. Be perseverant, flexible and able to cope with adversity.
Developing tailor-made care plans	Provide care with an evidence-based approach. Able to develop a tailor-made care plan derived from evidence-based care plans. Discuss preliminary care plan with GP, patient and his caregiver
Coordinating care and continuation of care	Good communication skills with staff in all health care disciplines. Access community resources.
Supporting caregivers	Assess caregiver burden.

Education of registered practice nurses and general practitioners

To increase the study fidelity and to facilitate role transition, all of the recruited registered practice nurses participated in an obligatory U-CARE training program prior to the implementation of the program in routine practice. The training program was funded by the project and consisted of six days of eight hours of lessons in a class plus four hours of self-study per day. The included assessments, the CGA and evidence-based care plans were extensively discussed. After completing the program, monthly meetings during the trial were held to provide ongoing learning, support, problem-solving, networking and feedback to prevent the dilution of knowledge.[37] Additionally, all of the GPs and registered practice nurses participated in a mandatory four-hour training session one month prior to the start of the trial. The content of the U-CARE program was demonstrated and a workshop regarding the collaboration between GP's and practice nurses was conducted. This training program was arranged in collaboration with the University of Applied Sciences Utrecht in the Netherlands.

4. Evaluation phase

To evaluate the effectiveness of the U-CARE program, a single-blind, three-armed, cluster-randomized controlled trial with one-year follow-up is currently being performed.[35] Recruitment for the trial was conducted in three primary care networks that consisted of 39 clusters of general practices including and included 122 GPs, 21 specially trained registered practice nurses and over 3.000 patients in and around Utrecht, the Netherlands. The primary outcomes of the trial are the preservation of physical functioning and the quality of life. If shown to be effective, an extended cost-effectiveness study will then be performed. This U-PROFIT trial has been approved by the Institutional Review Board of the University Medical Center Utrecht (UMCU), protocol ID 10-149/O and registered in the Netherlands Trial Register: NTR2288.

Discussion

In this study, a detailed description of the development process of the innovative U-CARE program is provided, which is often missing in reports of complex intervention trials.[38] The MRC framework was used as a theoretical guide for the development of the U-CARE program.[13] Combining this model with the guiding principles enabled collaborative decisions to improve the developmental process of this intervention. Reporting these details is essential to understanding the different components of the intervention and enhancing the understanding of the trial results in th e future[12], and will allow replication of this intervention.[39] A stepwise approach including literature and guideline review combined with practical experiences, expert opinions and a target group evaluation was used to develop this intervention. Although this approach was time-consuming and costly, it has improved the acceptability and quality of the intervention. Based on our feasibility /pilot study, the GPs and the registered practice nurses indicated that the U-CARE intervention is feasible in clinical practice. A proactive, structured and integrated approach in primary care is urgently needed to cope with the growing number of older people with increased risk factors for decline.[4, 9, 40]. Currently, there is no widely adopted care approach for frail older people in primary care in the Netherlands. If it is shown to be effective, the U-CARE program would represent an innovative care model for frail older patients in primary care.

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Additional file 1. Overview results development CGA and evidence-based care plans from phase 1-4 per geriatric condition.

Geriatric condition	**Phase 1: Literature search** *N studies included.* *N Interventions.* *N Recommendations.* *N Assessments/instruments.*	**Phase 2: Guidelines** *Title Guideline(s.)* *N additional included interventions.* *N additional recommendations*	**Phase 3: Knowledge registered practice nurses** *N additional interventions.* *N additional recommendations.*	**Phase 4: Expert opinion.** *N rejected/changes/accepted in previous phases.* *Number additional interventions.* *Number additional recommendations.*	**Total**
Falls & mobility	N = 15 (2 Cochrane reviews; 11 Meta-analyses; 2 Systematic reviews) - 10 generated interventions - 4 generated recommendations; - 3 Assessments	N= 2: CBO guideline and NICE guideline - 2 additional interventions - 2 additional recommendations	- 4 additional interventions	All interventions and recommendations of previous phases accepted. - 1 additional intervention - 2 additional recommendations	- 17 I's* - 8 R's**
Physical Functioning	N = 12 (3 Cochrane reviews; 9 systematic reviews) - 5 generated Interventions; - 2 generated recommendations - 3 Assessments	No official guidelines found	- 1 additional Intervention - 1 additional recommendation	All interventions and recommendations of previous phases accepted. - 3 interventions - 1 recommendation	- 9 I's - 4 R's
Nutrition & malnutrition	N = 10 (1 Cochrane review; 1 Meta-Analysis; 8 Systematic reviews) - 5 generated Interventions - 3 generated Recommendations - 3 Assessments	N = 1: Guideline: Screening and treatment malnutrition - 2 additional Interventions - 4 additional Recommendations	-3 additional Interventions -2 additional Recommendations	N = 1 recommendation of phase 3 adjusted by expert. - 1 additional Intervention - 2 additional Recommendations	- 11 I's - 11 R's
Cognition	N = 17 (2 Cochrane reviews; 15 Systematic reviews) - 7 generated Interventions - 6 generated Recommendations - 6 Assessments	N = 3 Guidelines: CBO Dementia NHG Dementia, V&VN - 1 additional intervention - 4 additional recommendations	- 3 additional interventions - 2 additional recommendations	All interventions and recommendations of previous phases accepted.	- 11 I´s - 12 R's
Mood & Depression	N = 18 (2 Cochrane reviews; 16 systematic reviews) - 7 generated Interventions - 4 generated Recommendations - 3 Assessments	N = 2: NHG Guideline Depression, CBO guideline Depression - 3 additional interventions - 4 additional recommendations	- 4 additional interventions - 4 additional recommendations	All interventions and recommendations of previous phases accepted. - 1 additional Intervention - 1 additional Recommendation	-15 I´s -13 R´s

Loneliness	N = 2 Systematic reviews - 8 generated-Interventions - 4 generated Recommendations - 2 Assessments	No official guidelines found	- 2 additional interventions - 1 additional recommendation	- 1 Intervention of phase 1 not accepted; - 1 intervention doubtful - 1 Additional intervention - 4 Recommendations	- 11 I´s - 6 R´s
Polypharmacy	N = 17 (2 Meta-analyses; 5 Systematic reviews) - 6 generated Interventions - 4 generated Recommendations - 4 Assessments	N = 1 Guideline: NHG Praktijkwijzer polypharmacy - 3 additional interventions - 1 additional recommendation	- 2 additional interventions - 1 additional recommendation	All interventions and recommendations of previous phases accepted. - 3 additional recommendations	- 11 I´s - 9 R´s
Urinary incontinence	N = 7 (2 Cochrane reviews; 5 Systematic reviews) - 8 generated Interventions - 2 generated Recommendation - 4 Assessments	N = 3: Guideline NHG / NICE Guideline/ V&VN guideline Urinary incontinence for frail older persons - 4 additional interventions - 5 additional recommendations	- 2 additional interventions - 2 additional recommendations	All interventions and recommendations of previous phases accepted. - 2 additional interventions - 2 additional recommendations	- 16 I´s - 11 R´s
Hearing loss	N = 4 Systematic reviews - 6 generated Interventions - 6 generated Recommendations - 1 Assessment	N = 1 Guideline NHG Hearing loss: - 3 additional interventions	- 0 additional interventions - 2 additional recommendations	All interventions and recommendations phases accepted. No additional interventions or recommendations	- 9 I´s - 8 R´s
Vision impairment	N = 6 (2 Cochrane reviews; 4 Systematic reviews) - 5 generated interventions - 4 generated recommendations - 0 assessments	N = 1 Guideline - 2 additional interventions	- 1 additional intervention - 4 additional recommendations	All interventions and recommendations of previous phases accepted. - 1 additional recommendation	- 8 I´s - 9 R´s
Caregiver burden	N = 12 (7 Meta-Analyses; 5 systematic reviews) - 5 generated interventions - 6 generated recommendations	No guidelines found	- 4 additional interventions - 3 additional recommendations		- 9 I´s - 9 R´s

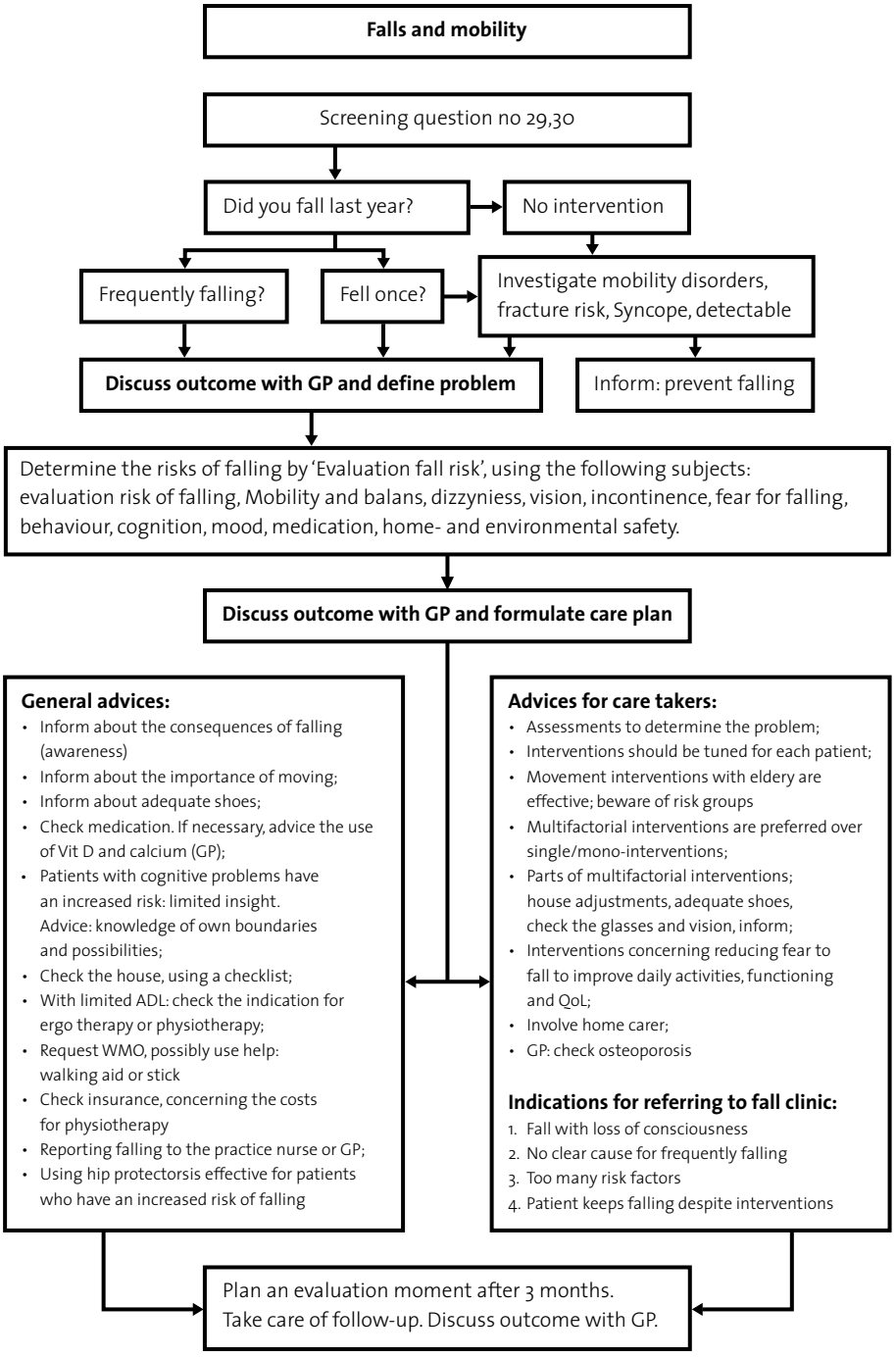
NHG: Dutch General Practitioner Society Guideline. NICE: National Institute of Health and Clinical Excellence. V&VN: Dutch Nurses Association *: I's: Interventions ** R's: Recommendations

Additional file 2. Overview of included assessments, summary of interventions and recommendations per evidence-based care plan.

Geriatric condition	Assessment	Interventions and recommendations (summary)	Level of evidence*
1. Falls & Mobility	Get-up and Go-test Falls Efficacy Scale (FES-NL)	- Multidisciplinary, multifactorial, health/environmental risk factor; Screening/intervention programs in the community; - A program of muscle strengthening and balance retraining, individually prescribed at home by a trained health professional; - Medication control and, if possible, withdrawal of psychotropic medication.	- A1 - A1 - A1
2. Physical functioning	Instrumental Activities of Daily Living (IADL scale Lawton & Brody	- Exercise programs that consist of muscle strengthening, balance retraining, endurance and flexibility; - Motivation, feedback, patient education; - Practice should reflect the opportunities that are available in the community.	- A1 - A1 - B
3. Nutrition & Malnutrition	Short Nutritional Assessment Questionnaire (SNAQ-65) Mini Nutritional Assessment (MNA)	- Screening the nutritional status - Systematic identification of nutrition problem - Educating health care workers on the consequences of malnutrition	- A1 - A1 - A1
4. Cognitive decline	Mini Mental State Examination (MMSE) Clock Drawing	- Support, motivating activities on social interaction, cognitive and physical activities - Individual programs focus on IADL problems - Cognitive stimulation and training	- B - B - A1
5. Polypharmacy	Medication review assessment	- Multifactorial interventions are more effective that mono-interventions - Tailored patient education, instruction, support, feedback and follow-up - Tools and reminders for adherence	- A1 - A1 - A1

6. Mood & depression	Mini Mental State Examination (MMSE) Geriatric Depression Scale (GDS) Observation List early symptoms Dementia (OLD) Clock Drawing test	- Screening instruments as part of the intervention strategy - Exercise interventions - Collaboration with other disciplines is essential	- A1 - C - A1
7. Loneliness	De Jong-Gierveld loneliness scale	- Adapted interventions to target patients - Patient education, instruction, referral - Knowledge of health care workers about referral possibilities	- A1 - A1 - C
8. Vision impairment & hearing loss	Hearing Handicap Inventory for the Elderly-Screening (HHIE-S)	- Determine the cause of reduced vision - General practitioners have important role in screening (vision) - Knowledge about referral possibilities and environmental adaptations	- A1 - A1 - D
9. Urinary incontinence	Protection Amount Frequency, Adjustment, Body image (PRAFAB)	- Bladder training - Pelvic floor muscles training - Planned bladder	- A1 - A1 - A1
10. Caregiver burden	Experienced burden informal care (EDIZ) Caregiver Strain Index (CSI)	- Ask for use of support. If rejected, ask for underlying reason - Nurses can play an important role in case finding - Multidimensional programs on physical and mental support	- D - C - A2

*Level of evidence:
A1: Systematic review of at least two independently conducted studies of A2 levelA2: Well-designed, double blind, randomized controlled trial.
B: Comparative studies not randomized but well-designed cohort or case/control analytic studies (preferably from more than one center or research group).
C: Observational studies, case series studies.
D: Expert opinion.



Additional file 3. Example evidence-based care plan.

Chapter 3

Proactive and integrated primary care for frail older people: design and methodological challenges of the Utrecht Primary care PROactive Frailty Intervention Trial (U-PROFIT)

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Abstract

Background: Currently, primary care for frail older people is reactive, time consuming and does not meet patients' needs. A transition is needed towards proactive and integrated care, so that daily functioning and a good quality of life can be preserved. To work towards these goals, two interventions were developed to enhance the care of frail older patients in general practice: a screening and monitoring intervention using routine healthcare data (U-PRIM) and a nurse-led multidisciplinary intervention program (U-CARE). The U-PROFIT trial was designed to evaluate the effectiveness of these interventions. The aim of this paper is to describe the U-PROFIT trial design and to discuss methodological issues and challenges.
Methods/Design: The effectiveness of U-PRIM and U-CARE is being tested in a three-armed, cluster randomized trial in 58 general practices in the Netherlands, with approximately 5000 elderly individuals expected to participate. The primary outcome is the effect on activities of daily living as measured with the Katz ADL index. Secondary outcomes are quality of life, mortality, nursing home admission, emergency department and out-of-hours General Practice (GP), surgery visits, and caregiver burden.
Discussion: In a large, pragmatic trial conducted in daily clinical practice with frail older patients, several challenges and methodological issues will occur. Recruitment and retention of patients and feasibility of the interventions are important issues. To enable broad generalizability of results, careful choices of the design and outcome measures are required. Taking this into account, the U-PROFIT trial aims to provide robust evidence for a structured and integrated approach to provide care for frail older people in primary care.

Trial registration: NTR2288

Background

With an increasing number of older people in society, the number of frail older people with complex care needs will rise.[1] Frailty is a term often used among health care professionals to characterize older people who have a functional loss of resources in different domains. Frail older people have an increased risk for adverse health outcomes, such as mortality, morbidity and institutionalization.[2,5] The increasing number of frail older people will seriously challenge the health care system because primary care for these patients is currently fragmented, time consuming and reactive.[6] Because the care system does not address their needs, many older patients and their caregivers have a poor quality of life.[7,8] To preserve functional performance and maintain independent living in this vulnerable population, a transition is needed towards more proactive, integrated and structured health care for older people.
Until today, scientific evidence on how primary care providers can provide optimal care for frail older people with complex care needs is inconsistent. Previous intervention studies often used a selection of patients at risk combined with an additional geriatric assessment and follow-up visits.[9,10] However, evidence for these complex interventions is not clear. Moreover, it is unclear what the independent effectiveness of these interventions is.
One widely studied approach to select patients at risk is panel management. Panel management involves periodic reporting of clustered electronic medical record data from a certain 'patient panel' as an overview of the most important health parameters.[11,12] Missed patient encounters and care gaps can then easily be identified, which enables proactive, integrated and timesaving care.
Panel management programs have been set up for various chronic diseases; however, integrated panel management approaches for frail older patients are lacking.[13] Other solutions to prevent functional decline are complex interventions, such as preventive home visiting programs with comprehensive geriatric assessments.[9,14,16] Little is known about the effectiveness of the different interacting components of these complex interventions. Elements that were demonstrated to be promising in different intervention studies are a multidisciplinary, multifactorial approach with tailor-made interventions and an individual assessment for frail older people provided by a (primary) care team with long-term follow-up.[17-19]

To understand the effectiveness of these different approaches, we developed two interventions: a screening and monitoring intervention using routine healthcare data with the Utrecht Periodic Risk Identification and Monitoring system (U-PRIM) and a nurse-led multidisciplinary intervention program, U-CARE. In the Utrecht Primary care PROactive Frailty Intervention Trial (U-PROFIT), the effectiveness of the U-PRIM intervention, alone and in combination with U-CARE, will be assessed in comparison to usual care. The aim is to preserve physical functioning and improve quality of life for frail older people and their caregivers. The trial will be conducted from October 2010 to spring 2012. The aim of this paper is to describe the design of the U-PROFIT trial, the content of the two interventions and its methodological challenges.

Methods

Design and setting

A single-blind, three-armed, cluster-randomized controlled trial with a one-year follow-up is being conducted (see Figure 1). Recruitment was performed in three primary care networks with almost 70 practices in Utrecht, the Netherlands.

Participants - Inclusion criteria

Selection of patients is performed by the U-PRIM system, a software application that is installed in all participating general practices. Exploring the electronic medical records (EMRs) in each general practice, U-PRIM will screen for three inclusion criteria in patients aged 60 years or older:

- Multimorbidity (defined as a frailty index score of ≥ 0.20; see the 'U-PRIM intervention' section) AND / OR
- Polypharmacy (defined as the chronic use of five or more different medications)[20] AND / OR
- Care gap in primary care of three or more years (defined as not having consulted the GP in the past three years, except for the yearly influenza vaccination).

Exclusion criteria

Terminally ill patients or patients living in an elderly home or nursing home are excluded. Reasons for exclusion are registered on the general practice level.

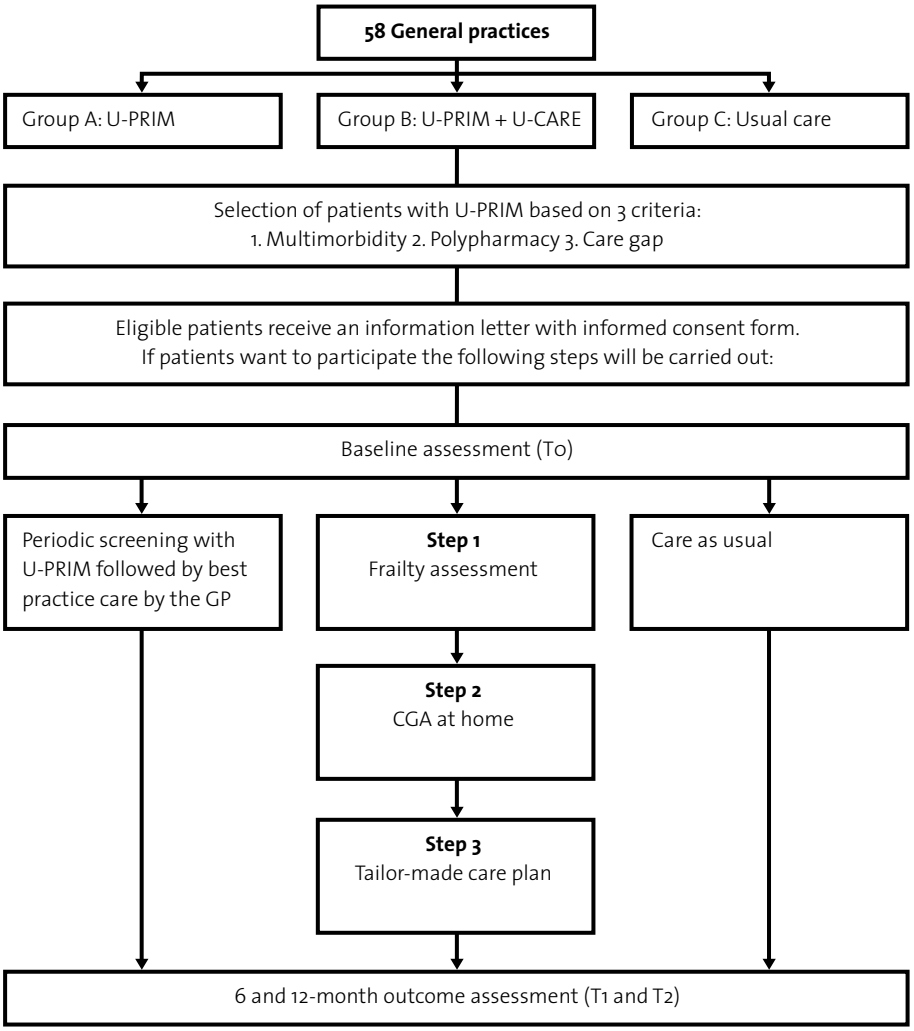

Figure 1. Flowchart U-PROFIT

Procedure
At the start of the inclusion period, U-PRIM automatically generates a list of frail patients of 60 years and older in every participating practice. Using the U-PRIM software, data extractions from the electronic medical records (EMRs) in the practices are uploaded to an external server area. Here, reports on frail patients are generated and delivered back to the general practice. To guarantee patient privacy, U-PRIM software encodes the personal data by means of a third trusted party procedure, so personal data are only disclosed to the general practice personnel.

Eligible patients are listed in the first U-PRIM report. These patients are approached by their GP with a patient information letter and informed consent form for participation in the U-PROFIT trial. In addition, patients are asked if they have an informal caregiver. If so, the caregiver is also invited to participate in the study to investigate caregiver burden. In the practices in the control group, a similar U-PRIM report with potentially frail patients is generated, but this report is not visible to the GP.

Ethical considerations
The U-PROFIT trial is approved by the Institutional Review Board of the University Medical Center Utrecht (UMCU) with protocol ID 10-149/O and registered in the Netherlands Trial Register: NTR2288.

Randomization and blinding
The participating general practices are randomly allocated to one of the two intervention groups (A or B) or the control group (C) by cluster randomization on the general practice level (see flowchart Figure 1). Practices in group A are allocated to the U-PRIM intervention, those in group B to the U-PRIM plus U-CARE intervention and the practices in group C formed the control group. Within the 58 participating general practices, clusters are created because some general practices are working closely together at the same location. Before randomization, clusters are stratified according to the expected number of frail older people in the general practice. The cluster size is estimated based on the number of invitations for the yearly influenza vaccination per practice.

Informed consent
A modified informed consent procedure is used to maintain a single-blind design; the so- called "consent to postponed information".[21, 22] With this procedure, a valid assessment of subjective outcomes can be obtained in a trial even if the patients cannot be blinded to the intervention. Additionally, selection bias and dropout in the control group can be reduced. In the U-PROFIT trial, patients were not informed as to which intervention group their general practice was allocated until the end of the follow-up period.

Blinding of the GPs and practice nurses
Blinding the GPs and their practice nurses is not possible in this study because they are part of the intervention.

Blinding the investigators
Because the investigators need to directly communicate with the general practices about the study, it is not possible to blind the investigators. However, during data analysis, investigators will be blinded to the data. When the data analysis is completed, this information will be disclosed to the investigators.

The interventions

Two interventions are being tested in the U-PROFIT trial: 1. Screening and Monitoring of frailty (U-PRIM) and 2. Nurse-led multidisciplinary intervention program (U-CARE).

Intervention 1: U-PRIM

The U-PRIM software application is an electronic monitoring system aiming at identification of older patients at increased risk of frailty in routine health care data. The software is based on periodic screening for relevant risk factors in the EMRs of the general practice. U-PRIM screens for three core risk factors in patients aged 60 years or older. These are also the eligibility criteria of the U-PROFIT trial as described earlier (multimorbidity, polypharmacy and a care gap).

Multimorbidity

The frailty index concept is used as an indicator of multimorbidity.[23] The frailty index uses 50 so-called 'health deficits': symptoms, signs, diseases, social problems and functional impairments, all routinely encoded in the EMR using International Classification of Primary Care (ICPC) codes (see Additional file 1). In the choice of the deficits, we followed previously published guidelines for the construction of a frailty index.[24] U-PRIM assesses the number of deficits in each individual. The frailty index score expresses the number of deficits present as a proportion of the total number of deficits.[25] Thus, a patent with 15 deficits has a frailty index score of 0.30 (15/50). For this study, multimorbidity based on the frailty index alone is defined as a frailty index score of ≥ 0.20.[26]

Polypharmacy

The U-PRIM software screens the medication list for chronic drug use, using anatomical therapeutic chemical (ATC) codes. Chronic use is present when the medication was prescribed at least three times in the past year, with at least one prescription in the last six months. Polypharmacy is in this study is defined as 5 or more different drugs in chronic use in the past year.[20]

Care gap

The period that patients are out of sight of their GP is assessed to include possible care avoiders prone to self-neglect, for example patients with dementia, psychiatric conditions or alcohol abuse.[27] For this study, a "care gap" is defined as a period of at least 3 years without GP consultation, excluding the annual influenza vaccination.

The U-PRIM procedure

In the U-PROFIT trial, the periodic U-PRIM frailty screening of the trial population takes place every three months in intervention groups A and B. This results in a U-PRIM report for each general practice with a selection of older patients at high risk of adverse health outcomes.

Patients are prioritized by means of the frailty index score, with possibilities to prioritize according to polypharmacy or care gap. For an example of a U-PRIM report, see Additional file 2. The report will be passed on to the GP in intervention groups A and B. In group A, GPs are asked to act upon the U-PRIM report in accordance with current available guidelines and best practices and to carry out interventions among the frail elderly patients if needed. In group B, all patients selected by U-PRIM will receive the additional steps of the U-CARE program (see Intervention 2). In every participating practice in group A and B, a staff member is responsible for generating the reports with the U-PRIM computer program and for distributing the report among the care providers involved. These contact persons received protocolized, one-on-one guidance with the first U-PRIM report, with an explanation of the software application and suggestions on how to implement the report in daily clinical practice.

Intervention 2: U-CARE program

U-CARE is a nurse-led, multidisciplinary intervention program to be used in frail patients selected by U-PRIM. Specially trained, registered practice nurses provide structured and integrated care based on a patients' needs approach. U-CARE is developed by a multidisciplinary team consisting of researchers and practitioners in nursing and primary care medicine. Three experienced practice nurses, a panel of experts and a panel of older people are involved to validate the content. The program consists of three steps. The first step is a frailty assessment for patients at risk. The second step is a comprehensive geriatric assessment (CGA) at home of frail patients. The third step is a tailor-made care plan with evidence-based interventions developed by the practice nurse. Details of the development and the content of the program are described elsewhere.[28]

Step 1. Frailty assessment
The level of frailty in patients at risk selected by U-PRIM will be further explored with the Groningen Frailty Indicator questionnaire (GFI). The GFI is a 15-item validated questionnaire that assesses frailty from a functional ADL/IADL perspective on four domains: physical, cognitive, social and psychological.[29]

Scores on each item are zero or one, and the total score ranges from 0 (not frail) to 15 (severely frail). We chose a score of 4 or higher as the relevant cut-off for the selection of patients that should be visited for a comprehensive geriatric assessment.[30] The GFI has shown high internal consistency and construct validity.[31] This questionnaire will be sent to all patients selected by U-PRIM. The INTERMED for the Elderly (IM-E)[32] and the Groningen Wellbeing Indicator (GWI) are additional assessments included in U-CARE to enable a multidimensional approach and to measure patients' needs and complexity of care among frail patients on the GFI.

Step 2. Comprehensive Geriatric Assessment at home (CGA)
For those patients identified as being frail, a CGA at home is conducted by a registered practice nurse. During this home visit, the practice nurse focuses on patients' health problems and needs in a structured manner based on the outcome of the frailty assessment. Based on the literature and their prevalence[33, 35], ten health problems in older patients with additional assessments are included in the CGA (see Additional file 3).

Step 3. Tailor-made care plan
In collaboration with the GP, the practice nurse will prepare a tailor-made care plan based on the outcome of step 2. This tailor-made care plan consists of interventions derived from evidence-based care plans developed by the research team, practice nurses and experts. For all ten health problems assessed in the CGA, separate evidence-based care plans are developed. The use of the care plan ensures uniformity among practice nurses in tailoring and delivering interventions per health problem. Flowcharts with suggested (nursing) interventions per health problem are developed as a practical tool and will help to guide the practice nurses through a structured process of decision making.

Training program
All practice nurses will receive an extended U-CARE training program that consists of 5 weeks of 4 hours of lessons in class and 4 hours of self-study. During this training program, the included frailty assessments, the content of the CGA and the evidence-based care plans will be discussed. The U-CARE training program is set up in collaboration with the University of Applied Science Utrecht in the Netherlands.

One month prior to the start of the trial, all GPs and registered practice nurses from intervention group are participating in a training session of 4 hours in which the content of U-CARE program is explained and discussed. Additionally, a workshop about collaboration between GP's and practice nurses is set up.

Outcomes and measurements

Primary outcome

The primary outcome of the U-PROFIT trial is the level of Activities of Daily Living (ADL) as measured with the Katz ADL index score.[36] The Katz index measures independence of ADL on six items (bathing, dressing, toileting, transferring, eating and the use of incontinence materials). The score ranges from 0 (total independence) to 6 (total dependence), and it is widely used to assess activities of daily living.[37] Baseline ADL functioning (T0) will be compared with ADL functioning after six months (T1) and one year of follow-up (T2). The questionnaire will be filled in by the patient or a proxy relative.

Secondary outcomes

Secondary outcome parameters will be measured at the same time as the primary outcome parameter (T0-T1-T2). Quality of life will be measured with RAND-36 and EuroQol (EQ-5D) [38,39] mortality, number of nursing home admissions, number of emergency department and out-of-hours GP surgery visits, caregiver burden measured with Self-Rated Burden (VAS) and Carer-QoL.[40]

Additional data collection

Routine health care data will be extracted from the EMRs of the participating practices. Socio-demographic data, such as age, gender, educational level, ethnicity, marital status and living situation, will be gathered at baseline. General practice characteristics, such as size, percentage of older people, working experiences and geographical location of the general practice, will also be gathered.

Process evaluation
To understand the different components, their interaction and the applicability of the U-CARE program, a feasibility study will be conducted among doctors and practice nurses of intervention group B. Furthermore, interventions delivered by the practice nurse or other health care providers will be registered to gain insight into targeted interventions that are performed by the practice nurses. The U-PRIM system will be evaluated on psychometric properties, prognostic value for adverse health outcomes and in concordance with the GFI, and the system will be refined following a user demands study. In addition, qualitative data on patients' satisfaction with the U-CARE program will be qualitatively assessed. In the end, various data will be collected to perform a cost-effectiveness analysis, e.g., data on workload of the GP and practice nurses and time registration.

Sample size calculation

At present, a valid estimation of the variance in the Katz ADL results within and between general practices cannot be given because these data are not available for Dutch populations. For that reason, a formal power analysis for the cluster-randomized trial is not possible. Therefore, it is also not feasible in this study to take into account a potential cluster effect. In line with Faber et al., [41] we assume that any randomization effect per practice will be absent. Furthermore, we assume that with an expected number of at least 5000 frail older people included, relevant effects can be found on the outcome between the clusters because the power of a trial increases if the number of clusters, subjects, or repeated measures within a subject increases.

Data analysis

The data will be analyzed using SPSS version 17.0. An 'intention to treat' analysis will be carried out to assess the differences between the intervention groups and the control group regarding ADL functional status. The variations in outcome between the groups will be calculated using mixed linear model analysis. Regression analyses and (co)variation analyses will be carried out when relevant to correct for baseline differences between older people in the three groups.

Survival analysis using a Cox regression model with Kaplan-Meier survival curves will be used on mortality and admission into nursing homes. As social economic status (SES), gender, age and education are assumed to be potential effect modifiers, subgroup analysis will be applied where relevant. We will also take the working experience of the participating GPs and practice nurses into account in separate analyses.

Discussion

In this paper, we present the research design and methodology of the U-PROFIT trial. This trial assesses the effectiveness of two interventions: a proactive screening and monitoring system and a nurse-led intervention program. U-PROFIT is unique because of the robust and pragmatic study design directly embedded in primary care practice, which maximizes the generalizability of the results. The integration of the U-PRIM proactive screening tool with the U-CARE nurse-led multidisciplinary intervention program, once proven effective, will provide an innovative, practical panel management approach for frail older people that can be broadly implemented in daily clinical practice. We met several challenges during the design and implementation of the U-PROFIT trial.

Design

As mentioned, the two interventions are tested and embedded in routine clinical practice. Therefore, it is hard to create controlled experimental circumstances. We randomized on a practice level, and some practices may have already use screening lists or structured plans to provide care for older people, while others have not. In addition, in some practices, a practice nurse may have already been part of the practice team. Because all practices can be randomized in one of the intervention groups or in the control group, we consider these differences in elderly care at baseline as normal variations in clinical practice. In this way, both interventions are compared to the broad range of routine clinical care, enabling generalizability. We chose a three-armed design for several reasons. First, our baseline assumption is that the U-PRIM screening followed by usual care and the combination of U-PRIM and U-CARE will both give better results than current usual care. Additionally, we hypothesize that both interventions are synergistic and that the effect of U-PRIM and U-CARE is more effective than the U-PRIM intervention alone.[42]

Outcome

The effectiveness of the interventions should be assessed on outcomes that are directly relevant for patients and their caregivers. We decided to take ADL functioning as measured with the Katz ADL index as the primary outcome. ADL functioning is generally reported as the most important parameter in the lives of older people.[43] The Katz ADL index is widely used in studies of prognosis and effects of treatments.[37, 44] Additionally, a broad array of relevant secondary outcomes will be assessed to evaluate both interventions. These will be measured based on a combination of self-report, proxy report and data extraction out of routine healthcare data.

Recruitment and compliance

Proper recruitment of older people for a clinical trial is often considered as complex.[45, 46] To improve generalizability, it is important that not only healthy people are included but also less fit older people.[43] For logistical reasons, we opted for a postal approach of eligible patients by the participating GPs. In this approach, we tried to find the optimal balance between extensive information provision, which is strongly advised by the Institutional Medical Ethic Committee, and the need for short and simple information letters in this population. Although patients can contact their GP or the researchers for extra clarification, this postal approach might lead to some response bias with fewer cognitively impaired or frailer patients included than with a personal approach. To limit this problem, patients who do not give consent are approached by telephone two weeks after the information letter is sent, and home visits by a research assistant are offered. Limiting informative censoring is a second challenge in elderly research. Informative censoring occurs when drop-outs happen for reasons directly related to the primary outcome. [47] In U-PROFIT, this can occur because frailer patients are more likely to die before we can evaluate functional status at the end of follow-up. To limit this problem and assess the extent of it, reasons for withdrawal will be collected, and an intention-to-treat analysis will be performed. Additionally, various retention strategies will be applied, e.g., home visits, interviews by phone when a postal questionnaire is difficult, small incentives, such as a U-PROFIT pen, and a newsletter to keep patients informed about the project.

Development of the U-PRIM system

The U-PRIM system uses criteria that are known from literature to be linked to frailty, disability and morbidity and that have been selected by a local GP focus group as relevant in daily clinical practice.[2,48,49] Small pilot studies have shown that the current U-PRIM criteria identify a significant number of patients at high risk for frailty. However, the psychometric properties of U-PRIM and exact cut-off values for clinically relevant risk groups still have to be further assessed. The influence of EMR data quality on the U-PRIM output should also be examined.[50] While preparing for the U-PROFIT trial, major effort was put into building the software, implementing the U-PRIM system and testing it. However, during the trial, technical aspects of the U-PRIM system may need to be adjusted. This might influence the current system of use and acceptance during the trial. We will assist participating centers by means of manuals, ICT assistance, and proactive contact after report generation to check for any content related questions or user feedback. With updates on the practical implications of ongoing U-PRIM research, we hope to keep all participating primary care providers on board. In this way, the U-PRIM system can be further developed into an easy-to-use frailty screening instrument that contributes to efficient and proactive panel management care. Requiring only sound EMR registration habits and periodic data upload, the U-PRIM system is an ideal candidate for efficient risk stratification of older people in primary care.

Feasibility and adherence

The U-CARE program is a complex, multifactorial intervention with multiple components. In the trial, U-CARE will be provided by over 20 practice nurses and over 100 doctors, and optimal implementation is vital. By means of an extended training program and ongoing education during the trial, we aim for a uniform baseline level of knowledge and skills among the practice nurses. However, motivation for proactive care provision and professional experience with older patients can be different within the group of GPs and practice nurses. These differences reflect daily clinical practice, so general conclusions about the effectiveness can be drawn. However, the effectiveness may differ in relation to characteristics of health care professionals. For that reason, we will perform subgroup analyses.

Finally, this program is based on a proactive care approach. Some patients will appreciate the active interference of care providers, but other patients might not and consider it as patronizing. Possible benefits of a proactive outreach should therefore clearly outweigh the unwanted burden it may put on others.

Strengths

Despite many challenges, we think that U-PROFIT offers many opportunities. First, the design of a three-armed, cluster randomized trial enables us to investigate the effectiveness of both interventions separately as well as in combination. Secondly, current literature recommends that trials on frailty should target persons aged 70 and older, because in younger age groups, frailty prevalence is thought to be too low.[3] However, during the development of U-PROFIT, general practitioners suggested to lower the age threshold for inclusion to 60. A substantial part of the ageing population in the practices consists of first generation immigrants of non-Dutch origin. In these elderly individuals, who often came to Holland for physical labor, frailty is reported to appear at a relatively young age.[7] With the inclusion of patients aged 60 years and older in our study, we include the group most relevant in current clinical practice.The frailty index score is demonstrated to be a valuable indicator of the 'frailty state' of an individual. Frailty indices constructed differently, with different deficit content and considering different numbers of deficits, yield closely related results.[25]
In this trial, we aim to demonstrate that the frailty index can be used for structured risk assessment in primary care practice, using routine care data.
For optimal implementation of the U-CARE intervention, we will maintain a training and supervision process of the practice nurses during the trial. In monthly meetings, special attention will be paid to collaboration between nurses and GPs to achieve optimal functioning of this important team.
In addition, lectures and education about geriatric health problems will be performed. During regular project meetings, research updates will be provided to inform nurses and GPs. While the intervention in non-pharmacological intervention studies is often poorly described, the interventions in the U-PROFIT trial consist of well-defined and thoroughly designed components.
This will safeguard the reproducibility of the intervention program once the effectiveness is established.

Although various challenges have to be addressed, the U-PROFIT trial offers excellent opportunities for a valid scientific evaluation of a structured and integrated approach to improve physical functioning in frail older people in primary care. Once proven effective, it can be broadly implemented in daily clinical practice.

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Additional file 1. ICPC encoded frailty index deficits

Deficit	ICPC*	ICPC-Label	Days**
1	K78	Atrial fibrillation/flutter	365
2	P74	Anxiety disorder/anxiety state	365
3	R96	Asthma	-
4	K77	Heart failure	-
5	T90	Diabetes mellitus	-
6	N88	Epilepsy	-
7	S70	Herpes zoster	365
8	S97	Chronic ulcer skin	365
9	D94	Chronic enteritis/ulcerative colitis	-
10	N89	Migraine	365
11	U99	Urinary disease, other	-
12	K88	Postural hypotension	365
13	L95	Osteoporosis	-
14	R81	Pneumonia	365
15	S91	Psoriasis	-
16	L88	Rheumatoid arthritis / related condition	-
17	P17	Tobacco abuse	-
18	P06	Sleep disturbance	365
19	N87	Parkinsonism, Parkinson's disease	-
20	P15	Chronic alcohol abuse	-
20	P16	Acute alcohol abuse	365
21	A01	Pain general/multiple sites	365
21	A04	Weakness/tiredness general	365
21	A05	General deterioration	365
21	P78	Neuraesthenia/surmenage	365
22	B80	Iron deficiency anaemia	365
22	B81	Anaemia, Vitamin B12/folate def.	365
22	B82	Anaemia other/unspecified	365
23	L89	Osteoarthrosis of hip	-
23	L90	Osteoarthrosis of knee	-
23	L91	Osteoarthrosis other / related condition	-
24	P20	Memory / concentration / orientation disturbance	365
24	P70	Dementia / Alzheimer's disease	-
24	P85	Mental retardation	-
25	R91	Chronic bronchitis / bronchiectasis	-
25	R95	Chronic obstructive pulmonary disease	-
26	K89	Transient cerebral ischaemia	365
26	K90	Stroke/cerebrovascular accident	-

27	P03	Feeling depressed	365
27	P76	Depressive disorder	365
28	K02	Pressure/tightness of heart	365
28	R02	Shortness of breath/dyspnoea w/o K02	365
29	N17	Vertigo/dizziness	365
29	H82	Vertiginous syndrome / labyrinthitis	365
30	L72	Fracture: radius/ulna	365
30	L73	Fracture: tibia/fibula	365
30	L74	Fracture: hand/foot bone	365
30	L75	Fracture: femur	365
30	L76	Fracture: other	365
31	H84	Presbyacusis	-
31	H85	Acoustic trauma	-
31	H86	Deafness	-
32	T05	Feeding problem of adult	365
32	T07	Weight gain	365
32	T08	Weight loss	365
32	T82	Obesity	-
32	T83	Overweight	-
33	K86	Hypertension uncomplicated	365
33	K87	Hypertension complicated	-
34	K74	Angina pectoris	365
34	K75	Acute myocardial infarction	365
34	K76	Other / chronic ischaemic heart disease	-
35	D17	Incontinence of bowel	-
35	U04	Incontinence urine	-
36	D72	Viral hepatitis	-
36	D97	Cirrhosis / liver disease NOS	-
37	A79	Malignancy NOS	
37	B72	Hodgkin's disease	-
37	B73	Leukaemia	-
37	B74	Malignant neoplasm blood other	-
37	D74	Malignant neoplasm stomach	-
37	D75	Malignant neoplasm colon/rectum	-
37	D76	Malignant neoplasm pancreas	-
37	D77	Malig. neoplasm digest other/NOS	-
37	F74	Neoplasm of eye/adnexa	-
37	H75	Neoplasm of ear	-
37	K72	Neoplasm cardiovascular	-
37	L71	Malignant neoplasm musculoskeletal	-
37	N74	Malignant neoplasm nervous system	-
37	R84	Malignant neoplasm bronchus/lung	-

37	S77	Malignant neoplasm of skin	-
37	T71	Malignant neoplasm thyroid	-
37	U75	Malignant neoplasm of kidney	-
37	U76	Malignant neoplasm of bladder	-
37	U77	Malignant neoplasm urinary other	-
37	X75	Malignant neoplasm cervix	-
37	X76	Malignant neoplasm breast female	-
37	X77	Malignant neoplasm genital other (f)	-
37	Y77	Malignant neoplasm prostate	-
37	Y78	Malignant neoplasm male genital / mammae	-
38	P18	Medication abuse	365
38	P19	Drug abuse	365
39	N86	Multiple sclerosis	-
39	N94	Peripheral neuritis/neuropathy	-
39	N99	Neurological disease, other	-
40	F83	Retinopathy	-
40	F84	Macular degeneration	-
40	F92	Cataract	-
40	F93	Glaucoma	-
40	F94	Blindness	-
41	P71	Organic psychosis other	365
41	P72	Schizophrenia	-
41	P73	Affective psychosis	365
42	K91	Atherosclerosis	-
42	K92	other PVD	-
42	K99	Cardiovascular disease other	-
43	T85	Hyperthyroidism/thyrotoxicosis	365
43	T86	Hypothyroidism/myxoedema	365
44	X87	Uterovaginal prolapse	-
44	Y85	Benign prostatic hypertrophy	-
45	K93	Pulmonary embolism	365
45	K94	Phlebitis/thrombophlebitis	365
46	D84	Oesophagus disease	365
46	D85	Duodenal ulcer	365
46	D86	Peptic ulcer other	365
47	A06	Fainting/syncope	365
47	A80	Trauma/injury NOS	365
48	A28	Limited function/disability NOS	-
48	B28	Limited function/disability	-
48	D28	Limited function/disability (d)	-
48	F28	Limited function/disability (f)	-
48	H28	Limited function/disability ear	-

48	K28	Limited function/disability (k)	-
48	L28	Limited function/disability (l)	-
48	N28	Limited function/disability (n)	-
48	P28	Limited function/disability (p)	-
48	R28	Limited function/disability (r)	-
48	S28	Limited function/disability (s)	-
48	T28	Limited function/disability (t)	-
48	U28	Limited function/disability urinary	-
48	X28	Limited function/disability (x)	-
48	Y28	Limited function/disability (y)	-
48	Z28	Limited function/disability (z)	-
49	Z12	Relationship problem with partner	365
49	Z14	Partner illness problem	365
49	Z15	Loss/death of partner problem	-
50	Z01	Poverty/financial problem	365
50	Z03	Housing/neighbourhood problem	365
50	Z04	Social cultural problem	365
50	Z29	Social problem NOS	365

* Dutch ICPC-1 version as currently in use in general practices
** '365 days' indicates that the belonging ICPC code is only considered present when registered at least once in the past year. For ICPC codes without the '365 days' indication, all time presence is considered.

Additional file 2. Lay-out of UPRIM report

Patient	Sex	Age	FI-score	Multimorbidity	Polypharmacy	Care Gap
Smith	F	87	0,26	13	12	5
Jones	M	63	0,22	11	16	18
Taylor	F	70	0,20	11	8	3
Brown	F	75	0,20	10	10	77
Smith	M	81	0,16	8	5	330
Johnson	F	72	0,14	7	6	32
White	F	94	0,08	5	4	1503

Additional file 3. Overview of health problems, assessments and summary of interventions.

Health Problem	Assessment	Interventions and recommendations (summary)	Level of evidence*
1. Falls & Mobility	Get-up and Go-test Falls Efficacy Scale (FES-NL)	- Multidisciplinary, multifactorial, health/environmental risk factor; Screening/intervention programs in the community; - A program of muscle strengthening and balance retraining, individually prescribed at home by a trained health professional; - Medication control and, if possible, withdrawal of psychotropic medication.	- A1 - A1 - A1
2. Physical functioning	Instrumental Activities of Daily Living (IADL scale Lawton & Brody	- Exercise programs that consist of muscle strengthening, balance retraining, endurance and flexibility; - Motivation, feedback, patient education; - Practice should reflect the opportunities that are available in the community.	- A1 - A1 - B
3. Nutrition & Malnutrition	Short Nutritional Assessment Questionnaire (SNAQ-65) Mini Nutritional Assessment (MNA)	- Screening the nutritional status - Systematic identification of nutrition problem - Educating health care workers on the consequences of malnutrition	- A1 - A1 - A1
4. Cognitive decline	Mini Mental State Examination (MMSE) Clock Drawing	- Support, motivating activities on social interaction, cognitive and physical activities - Individual programs focus on IADL problems - Cognitive stimulation and training	- B - B - A1
5. Polypharmacy	Medication review assessment	- Multifactorial interventions are more effective that mono-interventions - Tailored patient education, instruction, support, feedback and follow-up - Tools and reminders for adherence	- A1 - A1 - A1
6. Mood & depression	Mini Mental State Examination (MMSE) Geriatric Depression Scale (GDS) Observation List early symptoms Dementia (OLD) Clock Drawing test	- Screening instruments as part of the intervention strategy - Exercise interventions - Collaboration with other disciplines is essential	- A1 - C - A1
7. Loneliness	De Jong-Gierveld loneliness scale	- Adapted interventions to target patients - Patient education, instruction, referral - Knowledge of health care workers about referral possibilities	- A1 - A1 - C

8. Vision problems & hearing loss	Hearing Handicap Inventory for the Elderly-Screening (HHIE-S)	- Determine the cause of reduced vision - General practitioners have important role in screening (vision) - Knowledge about referral possibilities and environmental adaptations	- A1 - A1 - D
9. Urinary incontinence	Protection Amount Frequency, Adjustment, Body image (PRAFAB)	- Bladder training - Pelvic floor muscles training - Planned bladder	- A1 - A1 - A1
10. Caregiver burden	Experienced burden informal care (EDIZ) Caregiver Strain Index (CSI)	- Ask for use of support. If rejected, ask for underlying reason - Nurses can play an important role in case finding - Multidimensional programs on physical and mental support	- D - C - A2

Legend: *Level of evidence:
A1: Systematic review of at least two independently conducted studies of A2 level. A2: Well-designed, double blind, randomized controlled trial.
B: Comparative studies not randomized but well-designed cohort or case/control analytic studies (preferably from more than one center or research group).
C: Observational studies, case series studies.

D: Expert opinion.

Chapter 4

Exploring the expectations, needs and experiences of general practitioners and nurses towards a proactive and structured care program for frail older patients: a mixed-methods study

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Abstract

Aim: To report the expectations and experiences of general practitioners and practice nurses regarding the U-CARE program, to gain a better understanding of the barriers and facilitators in providing proactive, structured care to frail older people and to determine whether implementation is feasible.
Background: Care for older patients with complex care needs in primary care is fragmented, reactive and time consuming. A structured, proactive care program was developed to improve physical functioning and quality of life in frail older patients.
Design: An explanatory mixed-methods study nested in a clustered randomized trial.
Methods: The barriers to and needs for the provision of structured, proactive care and expectations regarding the U-CARE program were assessed with pre-questionnaires sent to all participating general practitioners (n= 32) and practice nurses (n= 21) in October 2010. Post-questionnaires measured experiences with the program after five months. Twelve months later, focus group meetings were conducted.
Results: Practice nurses and general practitioners reported that it was difficult to provide proactive and structured care to older patients with multi-morbidity, different cultural backgrounds and low socioeconomic status. Barriers were a lack of time and financial compensation. Most general practitioners and practice nurses indicated that the program added value for the coordination of care and allowed them to provide structured care.
Conclusion: This explanatory mixed-methods study showed that general practitioners and practice nurses perceived the U-CARE program as feasible in general practice. A transition was made from reactive, ad hoc care towards a proactive and preventive care approach.

Introduction

Care for older people with complex needs is often fragmented, reactive and time consuming.[1,3] The increasing numbers of older people with multi-morbidity, functional disabilities and complex care needs challenge health care providers, particularly primary care providers, to provide coordinated and structured car.[2,4,7] To reduce health care costs and improve care, a transition towards a proactive, structured approach is needed.[6,8]
Various 'complex' interventions in primary care have been developed to enhance care for older patients by supporting physical functioning and maintaining independent living.[9,11] Complex interventions include multiple interacting components that act both independently and interdependently and are flexible and tailored to the population.[12,13] Unfortunately, randomized controlled trials of complex interventions often focus only on pre-specified health outcomes and not on the process of implementation.[14] An evaluation of the intervention alongside a trial of other outcomes such as on the provider level is recommended to understand the different components and the barriers to and facilitators of new interventions from this perspective.[12,14]
New care models and programs require new roles and work processes for health care providers[15], therefore, the barriers to and facilitators of an intervention should be identified to improve the intervention and its implementation in clinical practice.[14,16] A multi-faceted and integrated approach using both quantitative and qualitative research techniques is particularly useful in the evaluation of complex interventions that involve social or behavioral processes that are difficult to explore using quantitative methods alone.[12,17] This approach will provide a more in-depth understanding of how providers experience the new intervention and what difficulties might occur when implementing the intervention in clinical practice. Therefore, this study evaluates a complex intervention program at the level of the providers.

Background

There has been little consensus on how primary care providers can address the needs of older patients.[1,18] However, elements that were demonstrated to be promising are preventive home visiting programs with a comprehensive geriatric assessment, a multi-disciplinary and multi-factorial approach with tailor-made interventions and long-term follow-up.[9,19,20]

Based on previous evidence, we combined all potentially successful components and developed an innovative structured and proactive care program (U-CARE) to preserve physical functioning and to improve quality of life in frail older patients. The U-CARE program is currently being tested and implemented in a large, three-armed cluster randomized trial, the Utrecht Primary care Proactive Frailty Intervention Trial (U-PROFIT), which includes 57 participating primary care practices, 122 general practitioners (GPs), 21 specially trained registered practice nurses (PNs) and 3235 patients.[21]

The U-CARE program

The U-CARE program involves three steps: a frailty screening, a home-based comprehensive geriatric assessment (CGA) based on a patient needs approach and a tailor-made care plan with evidence-based and best practice interventions developed by the PN in collaboration with the GP. The U-CARE program was developed by a multi-disciplinary team of researchers and practitioners in nursing and primary care to enhance its quality and feasibility in clinical practice. For ten highly prevalent geriatric conditions in older patients, evidence-based care plans were developed to guide PNs and ensure structured care. The CGA and care plans were developed by the research team, PNs and experts. Patients included in the program were aged 60 years or older and were selected using a software application that explores the electronic medical records (EMR) for patients meeting any of the following three criteria: polypharmacy; defined as the chronic use of five or more different medications; multi-morbidity (defined by a Frailty Index score); or a care gap; defined as not having consulted a GP in the past three years, except for the yearly influenza vaccination.[21] In clinical practice, the PN will send the frailty assessment to eligible patients. If necessary, the nurse will help the patient complete the questionnaire. In addition to conducting a CGA and developing an evidence-based care plan, the PN will coordinate and proactively monitor the care of the patient and will focus on the needs of the patient in close collaboration with the GP and other disciplines. Furthermore, the PN will provide caregiver support and facilitates access to community resources, such as home-delivered meals, medication delivery at home and transport services. In the Netherlands, no structured and proactive program has been widely adopted and nurses visit patients at home on a reactive, ad hoc approach. Moreover, not all GPs collaborate with practice nurses.

In practices where nurses visit frail patients at home, the work process is reactive and takes an ad hoc approach. In the U-CARE program, the nurse, have a pro-active, structured way of working that emphasizes case management. A detailed description of the development of the U-CARE program has been described elsewhere.[22]

All GPs and PNs in the U-CARE intervention group received an obligatory three-hour training session one month prior to the start of the program. All PNs participated in an extended education program of eight hours per week for a period of five weeks. During this training program, the frailty assessments, CGA and evidence-based care plans were discussed. The training program was developed by a multi-disciplinary faculty team in collaboration with the Utrecht University of Applied Sciences in the Netherlands. In addition, monthly education and supervision meetings with the PNs were scheduled during the trial, which provided ongoing learning, support, role clarification, problem solving, feedback and networking. GPs and PNs providing the U-CARE intervention have to make the transition from reactive and ad hoc care to a structured and proactive care approach. Therefore, an in-depth understanding of the barriers to and facilitators of the intervention at the provider level is needed to optimize the intervention and its implementation.

The study

Aim

The aim of this study was to explore the expectations, needs and experiences of GPs and PNs with respect to the U-CARE program, to gain a better understanding of the barriers and facilitators in providing proactive and structured care to frail older people in primary care and to determine whether implementation is feasible.

Design

An explanatory, sequential, mixed-methods design was used.[23-25] Quantitative data were collected at two moments in time using a questionnaire. Qualitative data were collected during two focus group meetings.

Participants and setting

Thirteen primary care practices participated in this study, including 32 GPs and 21 PNs, randomized into the U-CARE intervention group in the U-PROFIT trial. All primary care practices were located in and around Utrecht, the Netherlands.

Data collection

Barriers, limitations, needs, expectations and experiences related to the U-CARE program were measured using pre- and post-questionnaires. Pre-questionnaires were sent in October 2010 and post-questionnaires were sent five months after the intervention began in the primary care practice. Focus group meetings were conducted to explore the views of the GPs and PNs twelve months later.

Questionnaires

Limitations, barriers and needs with respect to the provision of structured and integrated care for older patients in general practice and expectations of the U-CARE program were identified using pre-questionnaires adapted with minor revisions from van Eijken and colleagues.[26] The pre-questionnaires were sent after the first training session, one month prior to the start of the U-CARE program. The post-questionnaire identified perceived limitations and barriers to the proper execution of the program and investigated participants' experiences with the program. The questionnaires were derived from a structured list of barriers and facilitators and were tested for content validity by a group of experts.[26, 27] The questionnaires included background variables, limitations in current care for older patients, needs in current care for older patients, expectations and experiences of the U-CARE program and expectations of the added value of the included geriatric conditions in the CGA. All questions were measured on a 5-point Likert scale, ranging from 5 (strongly agree) to 1 (strongly disagree).

Focus group meetings

Twelve months after the program started, focus group meetings were conducted to explore the opinions and experiences of the GPs and PNs. Separate groups were held to create a safe and homogeneous group for both disciplines.[28] A subgroup of GPs and PNs were invited to participate.

This subgroup was a representative sample of the total group of both types of practitioners with respect to general practice characteristics. Therefore, we selected a heterogeneous group of GPs and PNs that differed in years of experience in primary care, the practice size where they worked and the social geographic area of the general practice because the socioeconomic status (SES) of a patient may be a potential effect modifier. GPs and PNs were contacted by email by the researcher. The first author (NB) wrote the protocol, selected topics from the most interesting results of the questionnaire for discussion, observed, took notes and handled the technical equipment. The moderator (BS) performed the consent process for the protocol, introduced the groups and led the discussion. A member of the research team (VHD) observed the discussions. Two focus group meetings were conducted. At the beginning of each focus group meeting, the results from the questionnaires were presented to stimulate the discussion. The GPs and PNs chose the items to be discussed. If needed, the moderator suggested topics from the protocol to ensure that all predefined topics were discussed.

Ethical considerations

This study is nested in a three-armed cluster-randomized trial approved by the Institutional Review Board of the University Medical Center Utrecht (UMCU) with protocol ID 10-149/O. The questionnaires were analysed anonymously and audio-recorded verbal consent was acquired at the beginning of each focus group

Data analysis

Descriptive analyses of quantitative data were performed with the Statistical Package for the Social Sciences (SPSS version 17.0). Continuous data were represented as means with corresponding standard deviations and as medians and interquartile ranges for data with a non-normal distribution. Categorical data were represented as numbers with the corresponding percentages of GPs and PNs who agreed and strongly agreed with an item on the questionnaire. The focus group interviews were audio taped and transcribed verbatim to allow for systematic analysis.[29]

Rigour

To increase the validity and reliability of the qualitative data, content validity was ensured by member checking, obtaining agreement from the participating GPs and PNs by sending session summaries after the conclusion of the groups. The transcripts were studied by two independent researchers (NB & VHD) repeatedly and themes were identified from open coding of the data. Differences in themes were resolved through discussions with BS, VHD and NB. Subsequently, the main issues for each topic were identified. The data were studied in a transparent and systematic way using triangulation, segmenting and reassembling.[30] The quantitative and qualitative results were used in the interpretation of the results to increase validity.

Results

Questionnaires

A high response rate was demonstrated among GPs and PNs: 20 out of 21 PNs (95.2%) and 27 out of 32 GPs (87.5%) participated (Table 1).

Table 1. Characteristics GPs and PNs

Characteristics questionnaires	**GPs (N=27)**	**PNs (N=20)**
Age, median (IQR)	55 (49-57)	46.5 (37-52)
Female, n (%)	15 (55.5)	19 (95.2)
Work experience in years, median (IQR)	25 (18-30)	17 (7-30)
Working in general practice size (>2400 patients), n (%)	20 (74.1)	11 (55)
Characteristics focus group	**GPs (N= 5)**	**PNs (N= 6)**
Female, n (%)	2 (40)	6 (100)
Work experience, median (range)	28 (25-35)	17 (4-40)
General practice size (>2400 patients), n (%)	3 (60)	4 (67)

Focus groups

Six PNs and five GPs participated in the focus groups, which lasted approximately two hours (Table 1). One invited GP canceled the meeting for personal reasons. All GPs and PNs knew each other, facilitating a lively discussion. During the focus group meetings, the following discussion themes were identified: program characteristics; patient care; quality of life; time (GPs) and work satisfaction (PNs). Quotes are presented to illustrate the various perspectives.

Limitations, barriers and needs in the provision of structured care to older patients- GPs

In the pre-questionnaire, a majority of the GPs indicated that a barrier to providing structured care was a lack of well-educated practice nurses and financial compensation to develop this care. The results of the post-questionnaire showed that GPs experienced more barriers and difficulties in providing structured care to older patients with multi-morbidity, patients with a different cultural background and patients with low SES than reported prior to the start of the intervention (Table 2). The GPs explained during the focus group:

> '...It is just simple with all these items: because of the U-CARE pro gram, we see these patients more often now. They are visible now. Before the program we were not confronted with these patients. However, I am more aware of this type of patients now.'

Table 2. Limitations and barriers to the provision of structured and integrated care

Limitations *Current limitations are caused by:*	**GPs pre (N=27)**	**GPs post (N=27)**	**PNs pre (N=20)**	**PNs post (N=18)**
...the lack of health care staff, n (%)	10 (37)*	9 (33.3)*	15 (75)*	11 (61.1)*
...the lack of time for coordination and geriatric assessment, n (%)	16 (59)	17 (63)	17 (85)	9 (50)
...nurses or doctors who are not educated to perform specific geriatric function and care research, n (%)	6 (22.2)	5 (18.5)	12 (60)	10 (55.6)
...nurses or doctors who have inadequate knowledge to perform and interpret a geriatric screening and assessment, n (%)	6 (22.2)	5 (18.5)	13 (65)	9 (50)
...nurses or doctors who are not aware enough of the possibilities of care coordination, n (%)	9 (33.3)	7 (25.9)	4 (20)	4 (22.2)
...older patients who are not motivated for treatment, n (%)	2 (7.4)	5 (18.5)	1 (5)	3 (16.7)
GPs perspective				
...older patients have less treatment adherence, n (%)	1 (3.7)	2 (7.4)		
...lack of a well-educated practice nurse, n (%)	7 (25.9)	1 (3.7)		
...no financial compensation to develop this care, n (%)	20 (74.1)	12 (44.4)		
PNs perspective				
...nurses have fewer tools and time to guide older patients in treatment adherence, n (%)	-		11 (55)	7 (38.9)
...nurses are not sufficiently educated to investigate the care needs of older patients, n (%)	-		7 (35)	4 (22.2)
...collaboration with the GP is poor, n (%)	-		1 (5)	3 (16.7)
Barriers *To Provide care to older patients is difficult when patients...*	**GPs pre (N=27)**	**GPs post (N =27)**	**PNs pre (N =20)**	**PNs post (N =18)**
...have a different cultural background, n (%)	17 (62.9)	21 (80.8)	12 (60)	12 (66.7)
...are predominantly healthy, n (%)	6 (22.2)	13 (48.1)	4 (20)	5 (27.8)
...have a low socioeconomic status, n (%)	12 (44.4)	17 (63)	8 (40)	2 (12.5)
...have multimorbidity, n (%)	17 (63)	18 (66.7)	5 (25)	4 (22.2)
...are male, n (%)	1 (3.7)	3 (11.1)		
...are male, n (%)	1 (3.7)	1 (3.7)		
...are female, n (%)	1 (3.7)	0		
...visit the general practice often, n (%)	4 (14.8)	3 (11.1)		
...visit the general practice infrequently, n (%)	13 (48.1)	12 (44.4)		
Needs of GP's & PNs *To execute the U-CARE program properly, I think I need...*				
...more knowledge about geriatric problems, n (%)	12 (44.4)	13 (48.1)	9 (45)	8 (44.5)
...more transparency about referral possibilities, n (%)	18 (66.7)	15 (55.6)	10 (50)	7 (38.9)
...more knowledge about specific diagnostic tests for older people, n (%)	19 (70.4)	16 (59.3)	7 (35)	9 (50)
...regular contact with other practice nurses, n (%)	11 (40.7)	11 (40.7)	11 (55)	13 (72.3)
...regular contact with community nurses, n (%)	-	-	14 (70)	8 (44.5)
...regular contact with GPs, n (%)	-	-	11 (55)	12 (66.7)

** Percentage presented reflects both agreed and strongly agreed. - Indicates that the item was not asked*

Limitations, barriers and needs in the provision of structured care to older patients- Nurses

One of the limitations in the provision of structured care that was quantitatively reported by the PNs is a dearth of health care staff (Table 2). On the post-questionnaire, approximately 70% of the PNs reported that they needed more regular contact with other PNs and the GP to perform the U-CARE program properly:

> '...Since the U-CARE program, the role of the GP has changed. Currently, the GP is more involved. We discuss the outcomes of the frailty screening. More things are visible for the GP.'

> '...The role of the GP is very important in how I can deliver and organize the care for older patients. The vision of the GP regarding proactive and structured care is essential here.'

Expectations and experiences of the U-CARE program – GPs

Program characteristics

A majority of the GPs indicated on the questionnaires that the U-CARE program 'enables them to address geriatric conditions in a structured manner', 'is an added value for the coordination of care' and 'focuses on the major geriatric problems' (Table 3).

> '...Because of the U-CARE program, care for older patients is more structured, people are more visible and there is more continuity now.

> ' ...Since U-CARE, I find that I conduct fewer home visits than before, partly due to the home visits of the practice nurse. I think we can prevent things now and we are detecting more. The practice nurse is accessible; it's about care and not cure. People talk easier to her and I really make use of it.'

Patient care

GPs indicated the following on the questionnaires: the program will improve patients' satisfaction with care and leaves enough space for the opinion and wishes of the patient (Table 3). During the focus group, the GPs highlighted the added value of the U-CARE program.

'...Due to the U-CARE program and the home visit by the practice nurse, the focus is on patients' needs and the problems that they experience because there is more time.'

'...It gives people the feeling that someone really cares for them- a warm feeling.'

'...Our patients who participate in the study are very satisfied with the U-CARE program.'

Quality of life

Half of the GPs questioned whether the U-CARE program would improve patients' quality of life and whether the positive experiences of patients in the program were measurable (Table 3).

'...Sometimes there are some questions that need some time for consideration, for example, a hospitalization procedure, that type of thing. I am wondering if that is really measurable on the patient's quality of life.'

'...The whole part of care in this program looks past today; it is a long process that will continue.'

Time

Prior to the start of the program, 70% of the GPs expected that the U-CARE program would be time consuming; after five months, this percentage had decreased to 56%. Time gain was discussed during the focus group:

'...In my opinion, I think the time benefit is equal because sometimes the nurses prevent some home visits, but on the other hand, sometimes they arrange for additional home visits because they detected deviations for which we are responsible.'
'...It is not a decrease in tasks but a shifting in tasks. I am more of a manager now. Direct patient care has decreased.'

Expectations and experiences of the U-CARE program – Nurses
Patient care
A majority of the PNs had high expectations and positive experiences regarding the following questionnaire items: the program considers enough space for the opinions and wishes of the patient, the program focuses on the major geriatric health problems and the program will improve patient satisfaction with care.

'...Due to the new evidence-based care plans, I think we can improve care - for example, on the conditions of incontinence, depression and loneliness. The care plans provide new insights.'

'...Patients find that they get more time and attention. Care is more accessible. Patients are surprised when I take my jacket off.'

Quality of life
Some PNs became less positive on the following questionnaire items: the program will improve patients' quality of life and the program is an added value for the quality of patient care.

'...Quality of life is hard to improve. Perhaps we think it is easy; however, older patients experience difficulties in accepting their decline.'

'...I am wondering whether the nursing interventions are measurable on a patient quality of life questionnaire. Do we see a change after one year?'

Work satisfaction

After five months of working with the U-CARE program, fewer PNs reported on the questionnaire that the program would improve their work-satisfaction in contrast to their expectations prior to the start. During the focus group, all PNs highlighted that the program had increased their work satisfaction. PNs emphasized that due to the new proactive and preventive approach, their role had changed.

> '...The decrease in work satisfaction occurred because when I received the second questionnaire (which measured the experiences), the proactive ap proach of visiting patients based on the frailty screening was new for me.'

> '...Well, that (a decrease in work satisfaction) was just in the beginning. It was difficult to get a place in the general practice because care for older patients was already well arranged. It made me insecure; however, that feeling has changed completely. My work satisfaction is very positive now.'

Additionally, the PNs mentioned that it took some time to visit all patients with complex care needs and structure their care. The PNs argued that the outcome of the geriatric screening differed at times from the actual situation at home. Sometimes they visited healthy older patients who were considered frail by the frailty assessment, whereas some frail patients did not need help because all possible care was already arranged. Some nurses emphasized that they felt helpless at times when those patients rejected highly needed care.

> '...Sometimes it was very difficult because I knew that other types of care were needed, but the patient did not accept any care. On one hand, I feel responsible for the patient, but on the other hand, I know that I do not have enough knowledge and 'know how' to do something about the situation.'

Table 3. Expectations of and experiences with the U-CARE program for GPs and PNs.

Domains	GPs		PNs	
Knowledge and Organizational *The U-CARE program…*	**GPs pre (N=27)**	**GPs post (N=27)**	**PNs pre (N=20)**	**PNs post (N=18)**
…enables me to address geriatric problems in a structured manner, n (%)	23 (85.2)	24 (88.9)	17 (85)	14 (77.8)
…is clear about the professional responsibilities towards patient care for the GP and nurse, n (%)	16 (59.3)	17 (63)	10 (50)	10 (55.6)
…creates care that was not available before, n (%)	17 (63)	15 (55.5)	9 (45)	9 (50)
…is too complex, n (%)	2 (7.4)	6 (22.2)	0	4 (22.2)
…provides enough freedom to make my own decisions, n (%)	16 (59.3)	23 (85.2)	16 (80)	15 (83.3)
…looks similar to my current job/as my job before, n (%)	9 (33.3)	10 (37)	10 (50)	7 (38.9)
Patient care *The U-CARE program…*				
…considers the individual characteristics of patients, n (%)	17 (63)	20 (74.1)	17 (85)	11 (61.2)
…focuses on the major geriatric problems of older patients, n (%)	20 (74.1)	22 (81.5)	18 (90)	16 (88.9)
…acknowledges the opinions and wishes of the patients, n (%)	17 (63)	21 (77.8)	16 (80)	16 (88.9)
…is an added value for quality patient care, n (%)	19 (70.4)	19 (70.4)	15 (75)	11 (61.2)
…will improve patient compliance, n (%)	13 (48.1)	14 (51.9)	10 (50)	5 (27.8)
…will improve patient satisfaction with care, n (%)	16 (59.2)	19 (70.4)	16 (80)	14 (77.8)
…will improve patients' quality of life, n (%)	13 (48.1)	15 (55.6)	14 (70)	9 (50)
PNs perspective *The U-CARE program…*				
…provides the opportunity to extend the profession of the nurse, n (%)			16 (80)	15 (83.3)
…requires the support of the GP in planning and performing nursing care, n (%)			3 (15)	7 (38.9)
…requires the support of the nurse in planning and performing nursing care, n (%)			19 (95)	16 (88.9)
…the GP is too uninvolved in the program			0	4 (22.2)
…would be more easily performed if there was more time for re-education (nurse), n (%)			1 (5)	1 (5.6)
…will improve my work satisfaction, n (%)			12 (60)	7 (38.9)
..makes it difficult to perform goal-setting together with the patient, n (%)			0	1 (5.6)
GPs perspective *The U-CARE program…*				
…lacks an understanding of important geriatric problems, n (%)	1 (3.7)	3 (11.1)		
…will not be supported by patients, n (%)	2 (7.4)	3 (11.1)		
…will yield a positive experience for patients, but this positivity is most likely not measurable, n (%)	17 (63)	12 (44.4)		
…provides a decrease in task burden, n (%)	17 (63)	14 (51.8)		
…is time-consuming, n (%)	19 (70.4)	15 (55.5)		
….is an added value by offering re-education (GP), n (%)	15 (55.5)	9 (33.3)		
… is an added value for the coordination of care, n (%)	21 (77.8)	24 (88.9)		
…is an added value by offering possibilities for additional diagnostic assessments for older people, n (%)	17 (63)	13 (48.1)		

Discussion

In this study, we examined the expectations and experiences of GPs and PNs with respect to the U-CARE program to gain a better understanding of the barriers and facilitators related to providing proactive and structured care to frail older people in primary care and to determine whether implementation is feasible in general practice. Primary care practitioners are facing a growing number of frail older people with multi-morbidity and complex care needs.[4,6] One of the many challenges in primary care is the provision of structured and well-coordinated care.[4, 6, 8, 31] The GPs in our study reported difficulties in providing coordinated care to frail older patients due to a lack of time. This finding is in line with a recent qualitative study that has shown that primary care professionals identify the same challenges in care for multi-morbid patients.[31] Furthermore, prior to the start of the intervention in general practice GPs indicated that another limitation was a lack of a well-educated practice nurse and no financial compensation to provide this care. After five months, this limitation was no longer an issue because the nurses were employed by the research project and not by the GP. Before the start of the project, the nurses were well trained. To enhance and stimulate good collaboration between the nurses and GPs, a training session was set up prior to the implementation of the intervention. During the development of the intervention and the trial period, a prominent health insurance company in our region was involved to ensure reimbursement of the U-CARE intervention if the results are convincing.
Van Eijken and colleagues (2008) described barriers to and facilitators of a community-based geriatric intervention program (Dutch Geriatric Intervention Program, DGIP) reported by GPs, nurses, geriatricians, patients and caregivers with respect to implementation.[26] In our study we used the same questionnaires as van Eijken and colleagues. Therefore, a comparison at the level of the GPs and nurses was possible. The GPs in our study experienced the same limitations in the provision of structured care as the physicians from van Eijken's study on the topics of 'time' and 'lack of knowledge'. However, both groups of GPs mentioned that the program required less time than expected.[26] The PNs of our study indicated the same positive experiences as the nurses in the study by Van Eijken et al. (2008). Both groups of nurses felt that the programs enabled them to address geriatric problems in a structured manner and that the program will improve patient satisfaction with care.

Half of the PNs in this study questioned whether the program was beneficial for all patients. An evaluation study of a Dutch home visiting program for older people investigated the compliance and experiences of patients and nurses showed the same results. The nurses were uncertain about the program's effectiveness for patients who were not motivated, were less open to change or had little knowledge of relevant problems.[32] The same barrier was found in a qualitative study of the experiences of doctors and nurses towards implementing a nurse-delivered cardiovascular prevention program in primary care.[33]

After five months, the PNs were less positive about whether this program would improve their work satisfaction. They mentioned that they initially had feelings of uncertainty. PNs were not used to providing care on a proactive approach and to focusing on patients' needs based on the outcome of a structured frailty assessment. As expected, this feeling was replaced by feelings of self-confidence after twelve months. The PNs in our study had to make a transition from a reactive approach to a proactive care approach as well as a transition from an ad hoc to a highly structured care approach. The findings from the literature regarding role transition in nursing have shown similar results.[34] Furthermore, the adaptation of the intervention by PNs requires time.

Implications

In this process evaluation, we focused on gaining a better understanding of the barriers and facilitators to providing proactive and structured care to frail older people in primary care using a mixed-methods procedure, which is often lacking in complex, multi-component intervention studies.[13, 14, 16] These findings may help GPs or primary care practices decide whether to adopt the U-CARE program.[15, 35] A mixed-methods procedure was used to gain an in-depth understanding of how providers experience the U-CARE intervention and what difficulties might occur when implementing the intervention in clinical practice. Surprisingly, it remains relatively uncommon in trials of complex interventions to include qualitative data.[17] Exploring the expectations, experiences and barriers and facilitators of an intervention may contribute to an optimal implementation strategy[36], which may enhance the implementation once the effectiveness has been established.

The results of this study show that implementation of proactive care programs in clinical practice is complex by nature. To improve implementation, we have defined five preconditions that must to be fulfilled based on our results. First, the providers of the new intervention must be well educated and trained. Second, to enhance the quality and feasibility of a new care program in clinical practice, the providers of the intervention must be involved during the development phase of the intervention. Third, financial compensation for the proactive preventive care is required. Fourth, good collaboration between GPs and PNs is needed to improve care for older people. Fifth, it is important for researchers and innovators to acknowledge that it takes time for new care programs or models to be adapted by providers and to ensure that the intervention works in the most efficient and effective way.[14]

Study limitations

To appreciate these results, a few limitations need to be considered. Although we had a high response rate, the low number of GPs and PNs participating in this study makes the generalizability of the results difficult. Only one focus group meeting was conducted for both disciplines. It can be questioned whether more focus group meetings might have been more appropriate. However, the researchers assessed that saturation was reached after the first meeting. Another limitation of the study is the short follow-up period of five months between the pre- and post-questionnaire. During the focus group meetings, the PNs mentioned that they initially some difficulties and problems with their new role; therefore, their work satisfaction had decreased. However, the focus group meetings after twelve months led to an explanation for this decrease after five months. The effectiveness of the U-CARE program with regard to physical functioning and quality of life is being tested in the U-PROFIT trial. The results of the trial are expected in spring 2013. It can then be determined whether a study of expectations and experiences is needed in this phase. However, to prevent bias in interpreting the results[14]; we believe that the current study is appropriate at this stage. If the GPs and PNs were already aware of the outcome of the trial, the results of the focus group meetings would have been biased. Furthermore, the results clarify what is needed to adopt the intervention in clinical practice.[35]

Conclusion

Prior to the start of the U-CARE program in general practice, the GPs had neutral expectations regarding the U-CARE program. These expectations became more positive after five months and became highly positive after twelve months. The PNs had very high expectations prior to the beginning of the program, were somewhat less positive after five months and then became positive again after twelve months. Although the intervention requires time before it will be adopted, a transition was made in both disciplines from reactive and ad hoc care to a proactive and more preventive care approach.
A majority of the GPs and PNs believed that the U-CARE program provide added value for the coordination of care; it focuses on the major geriatric health problems and it enables them to address these problems in a structured manner. Based on these results, the GPs and PNs perceived the U-CARE program as feasible in general practice. A mixed-methods procedure contributes to a more in-depth understanding of the barriers and facilitators of a proactive structured care program. This study has increased our knowledge regarding the needs and experiences of GPs and PNs in providing proactive and structured care to frail older people in primary care.

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Chapter 5

The effectiveness of a proactive patient-centered primary care program on physical functioning of frail older patients: a cluster randomised controlled trial

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In revision

Abstract

Background: Primary care for frail older people is reported to be suboptimal. A transition toward proactive patient-centered care is needed. We investigated the effectiveness of U-PRIM, a frailty screening intervention based on routine care data, and of U-PRIM followed by U-CARE, a nurse-led personalised care intervention, on physical functioning of frail older people in primary care.
Methods: A single-blind, three-armed, cluster-randomized controlled trial including 3092 older patients recruited in 39 general practices was conducted between October 2010 and March 2012, including one-year follow-up.
The general practices were randomly assigned to the U-PRIM, U-PRIM+U-CARE, or control groups. The primary outcome of the study was physical functioning measured on the Katz-15 ADL/IADL scale. The secondary outcomes were quality of life (Short Form 36), EQ5D, primary care consultations, hospital admissions, emergency department visits, nursing home admissions, and mortality. Analysis was by intention to treat. This trial is registered as NTR2288.
Findings: Patients in both intervention groups demonstrated better preservation of physical functioning compared to the control group at 12 months (mean Katz-15 (95% confidence interval): U-PRIM 1·87 (1·77-1·97), U-PRIM+ U-CARE 1·88 (1·80-1·96), and control group 2·03 (1·92-2·13); p = 0·03). In prespecified subgroup analyses, a significant interaction between educational level and intervention was observed, indicating stronger favorable differences for more highly educated patients in the U-PRIM+U-CARE intervention group. No overall differences in quality of life were observed. The patients in the U-PRIM+U-CARE intervention group consulted their general practice more often by telephone compared to patients in the other groups.
Interpretation: A frailty screening intervention (U-PRIM) and U-PRIM followed by a nurse-led personalised care intervention (U-CARE) led to better preservation of physical functioning compared to the control group. More highly educated older people had additional benefits from U-CARE, indicating that the effect is dependent on individual patient characteristics. Further refinement is necessary to optimize the U-CARE intervention to a heterogeneous group of frail older people.

Introduction

Providing optimal care for the increasing number of frail older people with complex care needs is a major challenge in primary care.[1,2] The current approach is reactive, resulting in unnecessary disease burden, increased after-hours consultations and emergency department (ED) visits, and high health care expenditures. Current care does not adequately meet the needs of older patients, resulting in an unnecessary loss of physical functioning and a suboptimal quality of life.[3,5] Patient-centered medicine has been proposed as a model for transforming primary care by focusing on the needs and concerns of individual patients before deterioration and health problems occur.[6,7]

The key components of this transformation are the identification of at-risk patients, followed by longitudinal personalised care tailored to each patient's needs.[6,7] There is no consensus regarding how to operationalize these key components in daily practice, while their effectiveness, both integrated and in isolation, remains to be determined.[8]

To identify older patients at risk, numerous instruments have been developed.[9] The Frailty Index (FI), a screening instrument based on health deficits[10], adequately predicts adverse health outcomes in community-dwelling older people and correlates well with other frailty measures.[11,12] With other health indicators related to frailty such as polypharmacy[13], the FI may be easily implemented in primary care with extraction and analysis of routine administrative healthcare data.[8]

Although several complex interventions or comprehensive care models for older people have been developed, the reported benefits for frail older people are controversial.[14,15] Comparison of care models is difficult due to the extensive heterogeneity of the intervention components and inclusion criteria.

A multidisciplinary approach including individual assessments and tailored care provided by integrated care teams is consistently reported to be a key element of such interventions.[16,17]

In the Utrecht Proactive Frailty Intervention Trial (U-PROFIT), we designed and evaluated a strategy for proactive patient-centered care of frail older people in primary care.[18]

The strategy consists of the Utrecht Periodic Risk Identification and Monitoring (U-PRIM) system, a frailty screening intervention based on risk selection in administrative patient data, and U-CARE, a nurse-led personalised care intervention comprising frailty screening, a comprehensive geriatric assessment, evidence-based tailor-made care planning, and follow-up visits. In a three-arm cluster-randomized trial, we evaluated the effectiveness of U-PRIM and U-PRIM followed by U-CARE on the preservation of physical functioning of frail older people in primary care compared with usual care.

Methods

Study design

We conducted a single blind, three-armed, cluster-randomized controlled trial with one-year follow-up. A detailed study protocol has been described elsewhere.[18] We invited 44 general practices in the urban region of Utrecht, the Netherlands. A total of 39 general practice centres with 124 general practitioners (GPs) agreed to participate. Together, these practices provide primary health care for 44·000 patients aged over 60 years. From October 2010 to March 2011, patients aged 60 years and older were identified by screening their Electronic Medical Record (EMR) for frailty as defined by the U-PRIM criteria (see U-PRIM intervention). Terminally ill patients and patients living in an assisted living facility or nursing home were excluded. Eligible patients were approached by their GP for participation. Written informed consent was obtained from all the patients. The U-PROFIT trial was approved by the Institutional Review Board of the University Medical Centre Utrecht (protocol ID 10-149/O).

Randomisation and masking

The participating general practices were stratified according to practice size (small: <1·000; average: 1·000-3·000; large: >3·000 patients). Using a computer-generated simple random allocation sequence, the practices were allocated to one of the two intervention groups or the control group (Figure 1, flowchart). We used a modified informed consent procedure, i.e., the patients were not aware of the intervention arm they were allocated to and were only fully informed at the end of the follow-up period.[19] This plan enabled us to maintain a single-blind design while minimizing selective inclusion and loss to follow-up and obtaining a valid assessment of the subjective outcomes.[19]

Members of all participating general practices were instructed not to inform the patients concerning the full study aim. The GPs and nurses could not be blinded because they were part of the intervention. The investigators were not blinded for pragmatic and logistic reasons.

Intervention 1: Frailty screening and monitoring intervention using U-PRIM
The U-PRIM software application aimed to identify potentially frail older patients using readily available routine care data in the EMRs kept in the general practice. Patients 60 years of age and older were considered potentially frail if they fulfilled one or more of the following three criteria: multimorbidity, polypharmacy, or a 'consultation gap'. To measure multimorbidity, we constructed a FI consisting of 50 potential health deficits, each defined as the presence of one or more ICPC coded symptoms or diseases in the patient's EMR.[12] A patient's FI score was defined as the proportion of deficits present and theoretically ranged from zero (fit) to one (extremely frail). Multimorbidity was considered present if the FI score was ≥ 0·20.[20]
Polypharmacy was defined as the chronic use of five or more different pharmacotherapeutics listed according to the Anatomic Therapeutic Chemical (ATC) coding.[21, 22] A 'consultation gap', defined as not having consulted the general practice in the past three years with the exception of the annual influenza vaccination[23], was included to detect possible 'care avoiders'. Every three months, a U-PRIM report was generated (Appendix A) and reported to the practice. GPs in the U-PRIM intervention were advised to use these U-PRIM reports to support proactive care according to current standards and guidelines with their existing personnel.

Intervention 2: U-PRIM followed by a nurse-led personalised care intervention (U-CARE)
In the second arm, U-PRIM selection was followed by U-CARE, a multicomponent intervention delivered by specially trained registered nurses working in the general practice. The details of the development and content of the U-CARE intervention were described elsewhere.[24] Briefly, the U-CARE intervention starts with a detailed individual frailty assessment using the Groningen Frailty Indicator (GFI) questionnaire[25] and the Intermed Self-Assessment scale, an instrument that assesses the bio-psychosocial care needs of older patients.[26]

For patients who were frail according to the GFI questionnaire, nurses conducted a Comprehensive Geriatric Assessment (CGA). Based on the outcome of the CGA and the individual needs of the patient, the nurse provided evidence-based tailored care, care coordination, and multiple follow-up visits. A total of 21 registered nurses were recruited and extensively trained during a six-week training programme (total of 48 hours). All intervention components were pretested in a pilot study for feasibility and acceptability.[27]

Control group

In the general practices in the control group, the U-PRIM frailty screening was conducted every three months, but the results were not visible to the general practices. The GPs in the control group were instructed to provide care as usual.

Outcome measurements

Patient and practice data were collected at baseline and at six and 12 months after inclusion. We collected demographic data and data on the primary and secondary outcomes using questionnaires. The primary study outcome was the self-reported level of Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) on a modified Katz-15 index score (scale 0-15).[28, 29] A higher score indicates a higher ADL/IADL dependency. The secondary outcomes were quality of life, as measured by the physical, mental, social, and vitality domains of the Short-Form 36 (SF-36)[30], by the EuroQol (EQ-5D)[31], and by perceived QoL score (0-10); satisfaction with primary care (0-10); the number of hospital admissions; admissions to a nursing home or assisted living facility; and primary care out-of-hours consultations during follow-up. The following secondary outcomes were collected from the EMR data in the participating practices over 12 months of follow-up: the number of emergency department (ED) visits; primary care consultations (telephone, consultations in the centre or visits at home) during office hours; and mortality. Quality control checks were performed for the questionnaires and the EMR data.

Statistical analysis

An intention to treat analysis was performed to detect the differences between the intervention groups and the control group. The patient characteristics were reported as the means (SD), medians (IQR), or n (%) where applicable. The primary and secondary outcomes after 6 and 12 months follow-up were analysed with generalized linear mixed models. A random intercept was included in all models to account for cluster randomisation. A residual (i.e., GEE type) covariance matrix was included to correct for the associations between the 6- and 12-month outcomes.[32, 33] Linear mixed models for the continuous outcomes were applied for the Katz-15 and all dimensions of the SF-36, the EQ5D, the quality of care received from the general practice, and perceived QoL. Because all outcomes displayed skewed distributions, we estimated the effects with robust standard errors.[34] For each group, the means with 95% CIs were estimated from the analysis. The number of nursing home admissions, hospital admissions, general practice consultations within office hours, general practice after-hours consultations, and emergency department visits were analysed as counts with robust standard errors to correct for deviations from the Poisson distribution. For these outcomes, the rates with 95% CIs were estimated. The mortality was analyzed with logistic mixed models. The adjusted probabilities with 95% CIs were estimated.
The analyses were performed in three steps. First, a crude model with treatment and time of measurement was estimated. In the second model, we adjusted for baseline values. Third, we adjusted for known confounders including age, gender, socioeconomic status (SES), educational level[35], and indications for inclusion: FI score, polypharmacy, and consultation gap. Because the effects of treatment on a patient's physical functioning may be delayed, we tested the interaction between the interventions and the time of measurement. We tested the interactions between the outcome measurements and the predefined parameters of age, gender, SES (low, moderate, high), and educational level (low, moderate, high). When this interaction was significant after correction for confounders and indication, subgroup analyses were performed. A p-value of 0·05 or less was considered statistically significant. We corrected for multiple testing with the Holm method.[36] Statistical analyses were performed using SAS version 9·2 (SAS Institute Inc., Cary, North Carolina) and SPSS (IBM, Chicago, IL, USA) version 20·0.

A valid estimation of the variance of the Katz-15 results within and between the general practices is not available for the elderly populations, and a state-of-the-art power analysis for the cluster-randomised trial was not possible. We initially assumed that with an inclusion of 5000 frail older people, significant effects could be observed in the primary outcome between the three groups. The trial is registered as NTR2288.

Role of the funding source

The sponsors approved the study design but had no role in the data collection, analysis, and interpretation or in the writing of the report. The authors had full access to all data as well as final responsibility for the submission of the manuscript.

Results

The 39 participating general practices were randomised to one of three groups. Four practices withdrew shortly after the randomisation because of technical EMR problems (Figure 1). In the remaining practices, of 44·000 patients older than 60 years, 8156 patients were identified as potentially frail by the U-PRIM programme. Of these patients, 518 were excluded because of terminal illness, not living independently, or because the GP thought approaching an eligible patient was inappropriate for other reasons, resulting in 7638 eligible patients. In total, 3092 (40·5%) gave informed consent to participate. The responders did not differ from the non-responders with respect to age, sex, FI score, medication use, or the length of the consultation gap. The patients in the three groups did not differ, except in educational level and SES (Table 1).

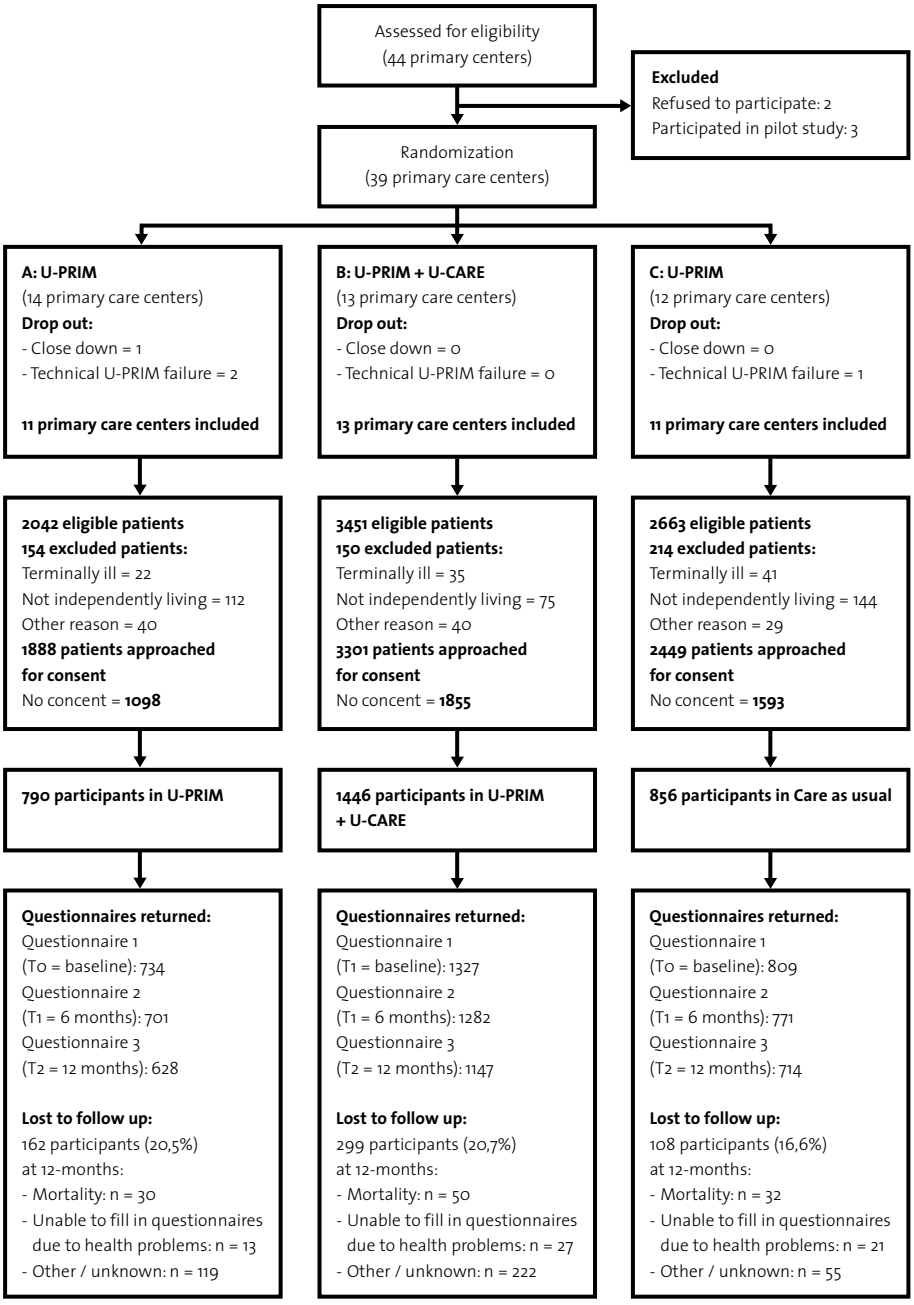

Figure 1. Flowchart of general practices and patients assigned to the interventions and control group.

Table 1. Baseline characteristics of general practices and patients.

General practice characteristics at baseline		U-PRIM (N = 11)	U-PRIM + U-CARE (N = 13)	Control group (N = 11)
General practice size Small (< 1000) Average (1000-3000) Large (>3000)		5 2 4	7 3 3	5 3 3
FTE per practice, mean (SD)		1·9 (1·1)	2·7 (1·7)	2·9 (1·3)
Patient characteristics at baseline	**No· of patients with non-missing data**	**U-PRIM N = 790**	**U-PRIM + U-CARE N = 1446**	**Control group N = 856**
Age, mean (SD)	2870	73·5 (8·2)	74 (8·2)	74·6 (8·8)
Female gender, n (%)	2870	406 (55·3)	772 (58·2)	453 (56·0)
Living independently alone, n (%)	2794	226 (31·7)	379 (29·3)	229 (29·1)
Married / living together, n (%)	2847	411 (56·4)	766 (58·2)	465 (58·0)
Having children, n (%)	2731	595 (85·0)	1079 (85·5)	627 (81·5)
Native Dutch, n (%)	2846	669 (91·8)	1223 (93·1)	757 (94·3)
Education Low Moderate High		 288 (39.5) 335 (46.0) 106 (14.5)	 529 (40.2) 589 (44.8) 198 (14.3)	 210 (26.2) 364 (45.4) 228 (28.4)
SES score Low Moderate High		 403 (55) 224 (30.6) 106 (14.5)	 535 (40.4) 536 (42) 234 (17.7)	 139 (17.2) 295 (36.5) 374 (46.3)

Katz-15 score, mean (SD)	2858	1·60 (2·29)	1·73 (2·22)	1·74 (2·36)
EQ-5D-NL score, mean (SD)	2870	0·75 (0·23)	0·73 (0·24)	0·75 (0·22)
Self-reported QoL (0-10), mean (SD)	2988	7·2 (1·3)	7·1 (1·3)	7·2 (1·3)
SF-36 Physical Domain, mean (SD)	2867	58·9 (29·6)	56·8 (29·4)	59·8 (30·0)
SF-36 Mental Domain, mean (SD)	2869	68·5 (19·5)	69·2 (19·1)	71·6 (17·9)
SF-36 Social Domain, mean (SD)	2823	43·8 (10·8)	42·8 (11·5)	43·5 (10·2)
SF-36 Vitality Domain, mean (SD)	2868	55·7 (20·6)	55·6 (20·2)	57·5 (19·3)
Number of diseases in year prior to inclusion, median (IQR)	2870	2 (1-3)	2 (1-3)	2 (1-3)
Hearing problems, n (%)	2870	226 (30·8)	449 (33·8)	259 (32·0)
Vision problems, n (%)	2870	172 (23·4)	361 (27·2)	232 (28·7)
FI-score, median (IQR)	2687	0·06 (0·02-0·10)	0·08 (0·04-0·10)	0·08 (0·06-0·12)
Number of chronically used medication during last year, median (IQR)	2687	6 (5-8)	7 (5-8)	6 (5-8)
Consultation gap, days, median (IQR)	2687	29 (13-64)	35 (21-64)	23 (10-50)
Patients with hospital admissions in previous year, n (%)	2827	168 (23·2)	338 (25·9)	193 (24·2)
Patients with temporary nursing home admissions in previous year, n(%)	2840	6 (0·8)	16 (1·2)	6 (0·7)
Patients with home care, n (%)	2832	184 (25·4)	376 (28·8)	194 (24·2)

Note: EQ5D-NL = EuroQol-5D questionnaire, Dutch version, FI = frailty index, FTE = full-time equivalent, IQR = interquartile range, QoL = quality of life, SD = standard deviation, Education level low: primary school or less, moderate: secondary school, high: more than secondary school. SES = socioeconomic status based on ZIP code. SF-36: Short Form 36 questionnaire. Percentages represent valid percentages.

Primary outcome

After 6 months, the mean physical functioning scores of the patients among the three groups did not differ significantly (mean Katz score (95% CI): UPRIM = 1.69 (1.61- 1.77), U-PRIM+U-CARE = 1·70 (1·60- 1·79), control group: 1·74 (1·67- 1·82). After twelve months, the patients of both intervention groups demonstrated better preservation of physical functioning compared to the patients in the control group (mean Katz score (95%CI): U-PRIM = 1·87 (1·77-1·97), U-PRIM+ U-CARE = 1·88 (1·80- 1·96), control group = 2·03 (1·92-2·13), p = 0·03 time*treatment (Table 2).

The ICC value for the Katz 15 was 0·031. No significant interactions between age and gender and the interventions were observed. We observed a significant interaction between the intervention and educational level and SES. The more highly educated patients in the U-PRIM+U-CARE group displayed better preservation of physical functioning on the Katz-15 compared to the more highly educated patients in the U-PRIM and control groups. The patients in the U-PRIM intervention group with a high SES level reported better preservation of functioning compared to the patients in the other groups with a high SES level.

Secondary outcomes

After six and at 12 months, no differences were observed between the patients in the three intervention groups with respect to the physical, mental, social, and vitality domains of the SF-36 or the EQ-5D (Table 3). The patients in both intervention groups reported a better-perceived QoL at 12 months compared with the control group. The patients in the U-PRIM+U-CARE intervention group were more satisfied with the care they received, although this difference was not significant. The patients in the U-PRIM+U-CARE group consulted their general practice more frequently by telephone during the one-year follow-up than the patients in the other two groups (Table 4). A trend of more in-practice consultations and home visits was observed in this intervention group. No overall differences in hospital admissions and ED visits were observed. When adjusted for age, the mortality rates at 12 months did not differ between the three groups. We were unable to perform a multivariate analysis for nursing home admissions (n = 32) and admissions to an assisted living facility (n = 62) because of the relatively low number of events.

Table 2. Estimated means (95% CI) of physical functioning on the Katz-15 and pre-specified subgroups at 6 and 12 months.

	6-Months follow-up			12-Months follow-up			
	U-PRIM Mean (95%CI)	**U-PRIM + U-CARE Mean (95%CI)**	**Control group Mean (95%CI)**	**U-PRIM Mean (95%CI)**	**U-PRIM + U-CARE Mean (95%CI)**	**Control group Mean (95%CI)**	**P-value**
Katz-15*	1·69 (1·61- 1·77)	1·70 (1·60- 1·79)	1·74 (1·67- 1·82)	1·87 (1·77- 1·97)	1·88 (1·80- 1·96)	2·03 (1·92- 2·13)	0·03¥
Katz-15							0·13
Male	1·05 (0·79-1·31)	1·07 (0·87-1·26)	0·97 (0·81-1·14)	1·17 (0·86-1·48)	1·26 (1·05-1·48)	1·31 (1·09-1·53)	0·06¥
Female	2·14 (1·77-2·51)	2·18 (1·94-2·41)	2·40 (2·10-2·70)	2·33 (1·98-2·67)	2·33 (2·11-2·55)	2·61 (2·33-2·88)	0·36fb
Katz-15							0·76
Age 60-74	1·16 (1·06-1·26)	1·09 (0·99-1·20)	1·18 (1·11-1·25)	1·26 (1.15-1.37)	1·22 (1·13-1·31)	1·38 (1·29-1·48)	0·12fb
Age 75+	2·28 (2·14-2·42)	2·35 (2·22-2·49)	2·38 (2·24-2·52)	2·56 (2.38-2.74)	2·61 (2·50-2·73)	2·77 (2·55-2·99)	0·36¥
Katz-15							0·04
SES – low	1·94 (1·82-2·06)	1·92 (1·81-2·04)	1·81 (1·62-1·99)	2·19 (2·05- 2·33)	2·13 (2·03- 2·24)	1·99 (1·66- 2·31)	0·47fb
SES– moderate	1·62 (1·53-1·71)	1·66 (1·51-1·80)	1·78 (1·65-1·90)	1·74 (1·57- 1·92)	1·77 (1·64- 1·90)	2·18 (1·94- 2·41)	0·008¥
SES – high	1·48 (1·27-1·70)	1·41 (1·28-1·54)	1·50 (1·39-1·61)	1·45 (1·19- 1·72)	1·72 (1·56- 1·89)	1·71 (1·56- 1·86)	0·003¥
Katz-15							0·005
Education level – low	2·25 (2·11-2·39)	2·22 (2·11-2·33)	2·46 (2·28-2·64)	2·50 (2·31-2·69)	2·46 (2·34- 2·57)	2·71 (2·51- 2·91)	0·03fb
Education level– moderate	1·53 (1·44-1·63)	1·65 (1·51-1·79)	1·61 (1·49-1·73)	1·67 (1·54-1·81)	1·81 (1·70- 1·93)	1·78 (1·65- 1·93	0·20fb
Education level – high	1·13 (0·96- 1·30	0·90 (0·76-1·04)	0·88 (0·77- 0·99)	1·24 (1·03- 1·47)	1·00 (0·82- 1·18)	1·39 (1·17- 1·62)	<·001¥

Notes: *Adjusted for baseline, age, sex, social economic status (SES), education, frailty-index, polypharmacy and consultation gap.
The highest significant level of p-values is reported: ¥ p-value for interaction of intervention with time; fb p-value for intervention.

Table 3. Estimated means (95% CI) of Quality of life and satisfaction of care, 6 and 12 months*.

	6-Months follow-up			12-Months follow-up				
	U-PRIM Mean (95%CI)	**U-PRIM + U-CARE Mean (95%CI)**	**Control group Mean (95%CI)**	**U-PRIM Mean (95%CI)**	**U-PRIM + U-CARE Mean (95%CI)**	**Control group Mean (95%CI)**	**P-value**	**Corrected P-value^**
SF-36 physical**	59·28 (58·20- 60·36)	59·24 (58·40- 60·08)	58·22 (57·05- 59·38)	56·93 (55·22- 58·65)	58·11 (57·09- 59·13)	56·46 (54·94- 57·98)	0·18fb	0.54
SF 36 social**	42·66 (41·92-43·40)	43·19 (42·45- 43·94)	42·71 (41·82- 43·60)	42·63 (41·72- 43·55)	42·82 (42·18- 43·45)	42·41 (41·77- 43·05)	0·53fb	1.0
SF 36 mental**	70·44 (69·51- 71·38)	70·00 (69·30- 70·70)	69·74 (69·07- 70·41)	68·61 (67·46- 69·77)	69·47 (68·83- 70·11)	68·18 (67·32- 69·04)	0·12¥	0.5
SF 36 vitality**	56·59 (55·39- 57·78)	56·58 (55·59- 57·57)	56·48 (55·44- 57·53)	56·19 (55·27- 57·10)	56·85 (54·93- 56·77)	54·89 (53·65- 56·14)	0·10¥	0.5
EQ-5D***	0·75 (0·74- 0·76)	0·75 (0·74- 0·75)	0·75 (0·74- 0·76)	0·73 (0·72- 0·75)	0·74 (0·73- 0·75)	0·73 (0·72- 0·75)	0·54¥	1.0
QoL mark 0-10∞	7·21 (7·12- 7·30)	7·20 (7·15- 7·25)	7·16 (7·12- 7·21	7·18 (7·08- 7·28)	7·18 (7·12- 7·24)	7·08 (7·00- 7·17)	0·0486fb	0.34
Satisfaction care °	7·88 (7·76- 8·00)	8·05 (7·98- 8·11)	8·02 (7·95- 8·10	7·84 (7·72- 7·97)	7·98 (7·90- 8·05)	7·91 (7·80- 8·03)	0·051fb	0.34

*Adjusted for baseline, age, sex, social economic status (SES), education, frailty-index, polypharmacy and consultation gap. **SF-36 all domains score range from 0-100.
***EQ-5D score range from -1 to 1. ∞ QoL mark between 0-10, higher score indicates higher QoL. °Satisfaction with care received from general practice, score 0-10, higher score, more satisfied.
The highest significant level of p-values is reported: ¥ p-value for interaction of intervention with time; fb p-value for intervention. ^Corrected p-value for multiple testing using Holm correction.

Table 4. Health care consumption mean rates and prevalence (95%CI) after 12-months follow-up and mortality.

	After 12-Months Follow-up				
	U-PRIM	**U-PRIM + U-CARE**	**Control group**	**P-value**	**Corrected P-value^**
	Mean rate (95%CI)	**Mean rate** (95%CI)	**Mean rate** (95%CI)		
Consultations in general practice and home visits*	6·43 (5·61-7·37)	8·24 (7·09-9·58)	7·53 (6·41-8·85)	0·045	0.23
Telephone consultations with general practice*	2·50 (1·84-3·40)	3·92 (3·25-4·74)	2·57 (1·99-3·29)	0·005	0.03
General practice out-of-hours consultation*	0·81 (0·65- 1·01)	1·01 (0·83- 1·22)	0·98 (0·84- 1·15)	0·29	0.87
Number hospital admission *	0·29 (0·25-0·35)	0·27 (0·24-0·31)	0·33 (0·29-0·39)	0·17	0.68
Emergency department visits**	0·10 (0·06-0·15)	0·09 (0·07-0·13)	0·13 (0·08-0·20)	0·51	1.0
Mortality, adjusted for age	0·002 (0- 0·01)	0·003 (0-0·01)	0·004 (0·001- 0·2)	0·70	1.0

* Adjusted for baseline, age, sex, education, SES, frailty index, polypharmacy, consultation gap. ** Adjusted for age, sex, education, SES, frailty index, polypharmacy, consultation gap.
^Corrected p-value for multiple testing using Holm correction.

Discussion

In this large-scale cluster-randomised trial, screening for frailty in routine primary care data of older patients (U-PRIM) and screening followed by nurse-led personalised care (U-PRIM + U-CARE) resulted in better preservation of physical functioning compared with usual care after one-year follow-up. The additional benefits of nurse-led personalised care (U-PRIM + U-CARE) were observed in the preservation of physical functioning of more highly educated patients but not in older patients with a low or intermediate educational level. Although the patients in both intervention groups reported a modest increase in overall perceived quality of life compared to the control group, no significant differences on the SF-36 domains and EQ-5D were observed. The patients in the U-PRIM+U-CARE intervention group consulted their general practice more often than patients of the other two groups.

Although consistently present in both intervention arms, the benefits of the U-PRIM on the Katz-15 were small (0·16 and 0·15 points, respectively), indicating a limited effect of screening only. In the subgroup of more highly educated patients, the benefit of U-PRIM screening remained in the same range (0·15 points), whereas the benefits of the combined U-PRIM + U-CARE intervention nearly tripled, to 0·.39 points. This difference indicates that the provision of nurse-led personalised care to frail older patients is vital in preserving their physical functioning. These results suggest that the effectiveness and impact of the U-CARE intervention component is related to individual patient characteristics. Socio-demographic factors such as educational level are associated with health-related[37] and psychosocial factors in older people.[38,39] Multimorbid older persons report that a sense of acknowledgement by their healthcare providers and a good relationship are important prerequisites for patient-centered care.[40] Clear communication and an understanding of the individual needs of the patient is crucial.[38,40] Similar preferences were identified in a subsample of the U-PROFIT study population that participated in a qualitative study (submitted, data available on request). This finding suggests that the U-CARE intervention requires refinement to optimally meet the diverse needs of frail older persons. The effects on the Katz-15 scale in SES subgroups are less clear, which might be due to the measurement of the SES on the community level with postal codes instead of on the individual patient level. No differences in quality of life measured on the SF-36 were observed. Although there is some evidence to support an association between health status and quality of life, others

have recognized that even persons with substantial health problems may still report a good quality of life.[41] An assessment of the SF-36 in older adults with chronic conditions demonstrated measurement bias for the social domain, suggesting a potential underestimation of any underlying effect.[42]

The fact that the patients in the U-PRIM+U-CARE group consulted their general practice more often compared to the patients in the other two groups is not surprising, given the timely detection of undiscovered health problems by the nurse. As all consultations with the nurse and the GP were documented in the EMR system, the reported differences in consultation rates are most likely an expression of the increased efforts of the nurses in the U-CARE group. This finding is most obvious for the number of consultations by telephone. The alternative explanation, i.e., that the GPs in the UPRIM group tend to follow a 'wait and see' approach after the UPRIM report, is less likely. No significant differences in hospital admission and ED visits were observed, which is in line with the results of other studies.[14, 43] A longer follow-up period is needed to identify whether U-CARE contributes to a reduction in unexpected GP consultations and ED visits.

Our study has several limitations. First, we did not monitor the detailed actions of the GPs in the U-PRIM group during follow-up. Although the U-CARE intervention consisted of three consecutive steps, the individual intervention components were not standardised. As a result, application and adherence were difficult to observe in all practices. Second, the effect size may have been relatively small due to the short follow-up period. The fact that we detected significant differences in preservation of physical functioning for both intervention groups after 12 months follow-up but not after 6 months suggests that the beneficial effect of the intervention increases over time. Full and adequate implementation of a complex multicomponent intervention takes time and may require more than one year follow-up to achieve sufficient benefits.[44] Third, the effectiveness of both interventions was evaluated on multiple secondary outcomes, which increases the risk of false-positive findings (type 1 error). To overcome this effect, we applied the Holm correction, a modification of the Bonferroni method, thus obtaining adjusted p-values with limited reduction of statistical power.[36] Fourth, only 41% of the eligible older patients participated. Although the responders did not differ from the non-responders in most aspects, selective inclusion cannot be ruled out. Finally, the FI screening may not have selected all frail older patients.

Some general practitioners reported that patients with known cognitive disorders were not explicitly detected by the U-PRIM, suggesting that cognitive disorders might have been underestimated by the screening tool or underregistered by the GPs.

The current study is unique in its robust design and magnitude. The U-PROFIT trial is, to our knowledge, the largest cluster-randomised trial evaluating a complex multicomponent intervention in frail older people in primary care. This study was embedded in routine primary care practice. A single-blind design was used with a modified informed consent procedure to reduce selection bias and dropout in the control group. In the design, recruitment, and evaluation, we followed the recommendations for studies on preventing disability in older persons.[45] Mixed models analyses were performed, not only to correct for cluster effects but also to evaluate potential time effects during follow-up. We decided to use an age threshold of 60, given the high number of elderly of non-Dutch origin, in whom frailty is reported to start at earlier age. We hypothesised that the intervention might have a different effect on the 'oldest old'; we did not observe any interaction effects with age, indicating that this age threshold was justified. We used a frailty instrument that is based on existing EMR patient data from primary care. This appealing and efficient approach can be easily implemented in routine care. The U-PRIM included an FI that has been associated with the risk of adverse health outcomes.[12] In the U-PRIM+U-CARE group, a two-step screening approach that included frailty screening based on existing patient data and on the validated GFI questionnaire was employed. We have demonstrated that the FI and GFI highlight different aspects of frailty. By using both measures, two complementary, easy-to-use frailty instruments were employed that provide valuable starting points for patient-centered care.[46]

We demonstrated that screening of older patients for frailty using routine primary care data (U-PRIM) and U-PRIM followed by nurse-led care intervention (U-CARE) lead to better preservation of physical functioning compared to care as usual. Although the additional benefit of the U-CARE intervention on the primary outcome could not be demonstrated for the total study population, the subgroup analysis revealed that more highly educated older patients perceived additional benefits from this nurse-led intervention.

This result indicates that the U-CARE intervention has potential but that its effectiveness depends on individual patient characteristics. Further refinement of the U-CARE programme is needed to optimally address the individual expectations and care needs of frail older people.

Panel: Research in context

Systematic review

In a systematic review and meta-analysis, Beswick and colleagues (2008) summarised the evidence from randomised trials of multifactorial interventions for frail older people and concluded that complex interventions are able to help older persons safely live independently, although the most frail patients seem to benefit the least.[16] The interventions should be tailored to the individual needs and preferences, but no evidence was found concerning whether the intensity is important and which combination of intervention components is most successful. Beswick and colleagues did not include studies that evaluated the effectiveness of the screening instrument for the patients at-risk and a screening instrument followed by a comprehensive geriatric assessment.[16] To assess whether the combined and independent effectiveness of both intervention components has been established since 2008, we searched PubMed for relevant cluster-randomized trials with the terms "frailty", "screening and monitoring", and "comprehensive geriatric assessment" in combination with the terms "personalised care" or "patient-centered care" and "primary care" and their synonyms in any heading for the period 2008-March 2013.

Interpretation

Our search revealed 100 hits. No three-armed cluster randomised trials were found that evaluated the effectiveness of both interventions separately and combined, and none of the studies identified the patients based on the existing patient record data of the GP. Four two-armed trials were published that met our criteria. An advanced-practice nurse in-home health consultation programme for community-dwelling older persons aged 80 years and older did not demonstrate improvement in quality of life.[47] The programme showed a reduction in adverse health outcomes such as falls, acute events, and hospitalizations.[47]

Boyd and colleagues determined the effectiveness of 'Guided-Care', an intervention to enhance the quality of health care for multimorbid older people by integrating a registered nurse into a primary care practice.[48] The authors concluded that Guided-Care improved the self-reported quality of chronic health care. The Guided Care program reduced the use of home care but had little effect on the use of other health services.[14] Van Hout et al. reported that a preventive home visiting programme did not demonstrate any beneficial effects on physical functioning and health care utilization.[43]
In conclusion, the current study is the first that investigated the effectiveness of the frailty identification instrument based on existing patient data and this instrument followed by a multicomponent nurse-led personalised care intervention. This study adds support to the use of existing patient data to detect frail older persons in primary care. The results of this study indicate that the beneficial effects increase with time and that the effect is dependent on individual patient characteristics. An increase in telephone consultations with the general practice was observed in the U-PRIM+U-CARE group. We hypothesize that in cases in which health problems are detected in an earlier phase, a reduction of ED visits and hospital admissions will be achieved after a longer follow-up period. Future studies should consider this finding in the design of research in this area. Researchers and clinicians must be aware that implementing a multicomponent care programme in clinical practice is complex and requires time for maximum effectiveness.

Contributors
MJS, MEN, and NJW developed the design of the study and obtained the funding. MEN, ID, and NJW developed the U-PRIM intervention, and MJS, NB, and VHD developed the U-CARE intervention. NB, ID, VHD, MJS, MEN, and NJW implemented the programme in clinical practice. NB and ID collected the data and cleaned the data. NB, NPZ, and ID conducted the analysis. All authors contributed to the interpretation of the findings and preparation of the report and approved the final version.

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Appendix A. Lay-out of U-PRIM report.

Patient	Sex	Age	FI-score	Multimorbidity	Polypharmacy	Care Gap
Smith	F	87	0,26	13	12	5
Jones	M	63	0,22	11	16	18
Taylor	F	70	0,20	11	8	3
Brown	F	75	0,20	10	10	77
Smith	M	81	0,16	8	5	330
Johnson	F	72	0,14	7	6	32
White	F	94	0,08	5	4	1503

Appendix B-1: Estimated means (95% CI) of physical functioning, Quality of life and satisfaction of care 6 and 12 months, crude analyses, adjusted for baseline, adjusted for more confounders*.

	6-Months follow-up			**12-Months follow-up**				
	U-PRIM Mean (95%CI)	U-PRIM+ U-CARE Mean (95%CI)	Control group Mean (95%CI)	U-PRIM Mean (95%CI)	U-PRIM + U-CARE Mean (95%CI)	Control group Mean (95%CI)	P-value	Adjusted P-value^
Katz-15 crude	1·65 (1·37- 1·91)	1·91 (1·73- 2·09)	1·73 (1·48- 1·98)	1·81 (1·49- 2·12)	2·12 (1·93- 2·31)	1·97 (1·71- 2·23)	0·22fb 0·46¥	-
Adjusted for baseline	1·71 (1·62- 1·81)	1·74 (1·65- 1·83)	1·73 (1·65- 1·79)	1·87 (1·66- 1·80)	1·92 (1·86- 1·99)	1·98 (1·87- 2·08)	0·60fb 0·25¥	-
Adjusted for confounders**	1·69 (1·61- 1·77)	1·70 (1·60- 1·79)	1·74 (1·67- 1·82)	1·87 (1·77- 1·97)	1·88 (1·80- 1·96)	2·03 (1·92- 2·13)	0·18fb 0·03¥	-
SF 36 physical** Crude*	59·55 (56·04- 63·06)	56·28 (53·79- 58·77)	59·99 (56·34- 63·64)	57·42 (53·63- 61·20)	55·12 (52·73- 57·52)	58·85 (55·13- 62·57)	0·18fb 0·33¥	1.00
Adjusted for baseline	59·25 (58·09- 60·41)	58·90 (58·30- 59·51)	58·49 (57·34- 59·64)	57·01 (55·48- 58·54)	57·76 (56·902 58·60)	57·23 (55·53- 58·94)	0·81fb 0·25¥	1.00
Adjusted for confounders**	59·28 (58·20- 60·36)	59·24 (58·40- 60·08)	58·22 (57·05- 59·38)	56·93 (55·22- 58·65)	58·11 (57·09- 59·13)	56·46 (54·94- 57·98)	0·18fb 0·19¥	1.00
SF 36 social** Crude	42·83 (42·01- 43·64)	42·79 (42·10- 43·49)	43·11 (42·13- 44·10)	43·10 (42·12- 44·09)	42·29 (41·42- 43·17)	42·83 (42·07-43·59)	0·63fb 0·49¥	1.00
Adjusted for baseline	42·69 (41·89- 43·49)	43·00 (42·32- 43·68)	43·14 (42·19- 44·08)	42·82 (41·87- 43·78)	42·53 (41·80- 43·25)	42·87 (42·12- 43·62)	0·86fb 0·65¥	1.00
Adjusted for confounders	42·66 (41·92 43·40)	43·19 (42·45- 43·94)	42·71 (41·82- 43·60)	42·63 (41·72- 43·55)	42·82 (42·18- 43·45)	42·41 (41·77- 43·05)	0·53fb 0·87¥	1.00
SF 36 mental** Crude	69·64 (67·63- 71·64)	68·73 (67·72- 69·74)	71·56 (69·55- 73·56)	67·96 (65·88- 70·05)	68·33 (66·82- 69·84)	70·50 (68·52- 72·48)	0·10fb 0·15¥	1.00
Adjusted for baseline	70·47 (69·28- 71·65)	69·76 (69·09- 70·44)	70·27 (69·46- 71·07)	68·82 (67·48- 70·15)	69·38 (68·67- 70·09)	69·04 (68·04- 70·04)	0·99fb 0·12¥	1.00
Adjusted for confounders*	70·44 (69·51- 71·38)	70·00 (69·30- 70·70)	69·74 (69·07- 70·41)	68·61 (67·46- 69·77)	69·47 (68·83- 70·11)	68·18 (67·32- 69·04)	0·17fb 0·12¥	1.00

SF 36 vitality** Crude	56·19 (54·04- 58·34)	55·21 (53·78- 56·63)	57·79 (55·29- 60·30)	55·87 (53·89- 57·86)	54·73 (52·91- 56·56)	56·63 (54·22- 59·04)	0·30fb 0·24¥	1.00
Adjusted for baseline	56·61 (55·24- 57·97)	56·29 (55·54- 57·05)	56·84 (55·70- 57·97)	56·36 (55·16- 57·56)	55·79 (54·95- 56·64)	55·57 (54·46- 56·67)	0·83fb 0·11¥	1.00
Adjusted for confounders*	56·59 (55·39- 57·78)	56·58 (55·59- 57·57)	56·48 (55·44- 57·53)	56·19 (55·27- 57·10)	56·85 (54·93- 56·77)	54·89 (53·65- 56·14)	0·62fb 0·10¥	1.00
EQ5D crude***	0·75 (0·73- 0·77)	0·72 (0·70- 0·75)	0·76 (0·74- 0·79)	0·74 (0·71- 0·76)	0·72 (0·70- 0·74)	0·75 (0·73- 0·77)	0·10fb 0·59¥	1.00
Adjusted for baseline	0·75 (0·73- 0·76)	0·74 (0·74- 0·75)	0·75 (0·74- 0·76)	0·73 (0·72- 0·75)	0·74 (0·73- 0·75)	0·74 (0·73- 0·75)	0·54fb 0·61¥	1.00
Adjusted for confounders**	0·75 (0·74- 0·76)	0·75 (0·74- 0·75)	0·75 (0·74- 0·76)	0·73 (0·72- 0·75)	0·74 (0·73- 0·75)	0·73 (0·72- 0·75)	0·95fb 0·54¥	1.00
QoL mark 0-10∞ crude	7·20 (7·07- 7·34)	7·13 (7·05- 7·22)	7·23 (7·10- 7·36)	7·21 (7·07- 7·34)	7·11 (7·03- 7·20)	7·16 (7·02- 7·29)	0·44fb 0·38¥	1.00
Adjusted for baseline	7·22 (7·11- 7·32)	7·21 (7·15- 7·26)	7·20 (7·14- 7·26)	7·21 (7·10- 7·33)	7·18 (7·12- 7·20)	7·12 (7·04- 7·21)	0·64fb 0·39¥	1.00
Adjusted for confounders**	7·21 (7·12- 7·30)	7·20 (7·15- 7·25)	7·16 (7·12- 7·21)	7·18 (7·08- 7·28)	7·18 (7·12- 7·24)	7·08 (7·00- 7·17)	0·0486fb 0·54¥	1.00
Satisfaction care crude°	7·86 (7·64- 8·07)	8·07 (7·93- 8·20)	7·95 (7·80- 8·01)	7·83 (7·79- 8·04)	8·01 (7·88- 8·15)	7·87 (7·69- 8·05)	0·22fb 0·80¥	1.00
Adjusted for baseline	7·90 (7·77- 8·01)	8·02 (7·96- 8·09)	7·98 (7·89- 8·07)	7·87 (7·75- 7·99)	7·98 (7·90- 8·06)	7·90 (7·79- 8·01)	0·15fb 0·69¥	1.00
Adjusted for confounders**	7·88 (7·76- 8·00)	8·05 (7·98- 8·11)	8·02 (7·95- 8·10)	7·84 (7·72- 7·97)	7·98 (7·90- 8·05)	7·91 (7·80- 8·03)	0·051fb 0·62¥	1.00

*Adjusted for baseline, age, gender, social economic status (SES), education, frailty-index, polypharmacy and consultation gap. **SF-36 all domains score range from 0-100. °Satisfaction care general practice, score 0-10, higher score, more satisfied. ∞ QoL mark between 0-10, higher score indicates higher QoL. ***EQ5D score range from -1 to 1. The highest significant level of p-values is reported: ¥ p-value for interaction of intervention with time; fb p-value for intervention. ^Corrected p-value for multiple testing using Holm correction.

Appendix B-2. Health care consumption mean rates and prevalence (95%CI) after 12-months follow-up, crude and adjusted for more confounders

After 12-Months Follow-up					
	U-PRIM	**U-PRIM + U-CARE**	**Control group**	**P-value**	**Corrected P-value^**
	Mean rate (95%CI)	**Mean rate (95%CI)**	**Mean rate (95%CI)**		
Consultations and home visits in general practice, crude Adjusted more confounders*	5·86 (4·51-7·60) 6·43 (5·61-7·37)	8·30 (7·05-9·77) 8·24 (7·09-9·58)	7·72 (6·25-9·54) 7·53 (6·41-8·85)	0·07 0·0453	0.70 0.23
Telephone consultations, practice nurse or doctor's assistant, crude Adjusted more confounders*	2·27 (1·69-3·04) 2·50 (1·84-3·40)	4·17 (3·39-5·13) 3·92 (3·25-4·74)	2·81 (2·12-3·71) 2·57 (1·99-3·29)	0·002 0·005	0.024 0.03
General practice out-of-hours consultation, crude Adjusted more confounders*	0·89 (0·72- 1·10) 0·81 (0·65- 1·01)	1·03 (0·86- 1·23) 1·01 (0·83- 1·22)	1·02 (0·84- 1·23) 0·98 (0·84- 1·15)	0·55 0·29	1.00 0.87
Number hospital admission, crude (score 0-5) Adjusted more confounders*	0·26 (0·23-0·31) 0·29 (0·25-0·35)	0·25 (0·22-0·29) 0·27 (0·24-0·31)	0·30 (0·26-0·36) 0·33 (0·29-0·39)	0·21 0·17	1.00 0.68
Emergency department visits, crude Adjusted more confounders**	0·13 (0·09- 0·18) 0·10 (0·06-0·15)	0·13 (0·10- 0·18) 0·09 (0·07-0·13)	0·16 (0·11- 0·23) 0·13 (0·08-0·20)	0·72 0·51	1.00 1.00
Mortality Crude Adjusted***	 0·008 (0- 0·02) 0·002 (0- 0·01)	 0·007 (0- 0·02) 0·003 (0-0·01)	 0·02 (0·01- 0·04) 0·004 (0·001- 0·2)	 0·04 0·70	 0.44 1.0

* Adjusted for baseline, age, sexe, education, SES, frailty index, polypharmacy, consultation gap. ** Adjusted for age, sexe, education, SES, frailty index, polypharmacy, consultation gap.
^Corrected p-value for multiple testing using Holm correction. *** Adjusted for age.

Appendix B-3. Subgroup analyses, estimated means and rates (95%CI) at 12 months.

	U-PRIM	U-PRIM + U-CARE	Control group		
	Mean (95% CI)	**Mean (95% CI)**	**Mean (95% CI)**	**P-value**	**Corrected P-value ^**
EQ5D*				0·0497∞	1.00
Age 60-74	0·77 (0·75- 0·78)	0·77 (0·75- 0·78)	0·76 (0·75- 0·78)	0·53fb	
Age 75+	0·70 (0·67- 0·72)	0·71 (0·70- 0·73)	0·71 (0·69- 0·73)	0·38¥	
SF-36 physical*				0·004∞	0.164
Education level – low	47·11 (44·69- 49·52)	48·43(46·62- 50·25)	47·89 (46·31- 49·46)	0·93¥	
Education level – moderate	59·27 (57·30- 61·25)	58·92 (57·42- 60·43)	57·29 (55·42- 560·42)	0·39¥	
Education level – high	68·49 (65·40- 71·57)	73·33 (71·62- 75·03)	70·84 (66·49- 74·74)	0·01¥	
Self-reported QoL (0-10)*				0·03∞	1.0
Male	7·32 (7·17- 7·47)	7·32 (7·19- 7·46)	7·17 (7·01- 7·33)	0·02¥	
Female	7·10 (6·92- 7·29)	7·08 (6·96- 7·20)	7·02 (6·87- 7·18)	0·61fb	
	Mean rate (95% CI)	**Mean rate (95% CI)**	**Mean rate (95% CI)**		
General practice out-of-hours consultations **				0·002∞	0.084
Education level – low	1·04 (0·72- 1·50)	1·11 (0·87- 1·41)	0·75 (0·43- 1·31)	0·43fb	
Education level– moderate	0·73 (0·57- 0·93)	0·85 (0·71- 1·02)	1·12 (0·88- 1·42)	0·05fb	
Education level – high	0·57 (0·34- 0·95)	0·96 (0·66 1·45)	0·52 (0·31- 0·87)	0·11fb	
General practice out-of-hours consultations**				0·001∞	0.044
SES – low	0·74 (0·52- 1·05)	1·05 (0·67- 1·64)	0·92 (0·61- 1·39)	0·28fb	
SES – moderate	0·72 (0·40- 1·29)	0·56 (0·29- 1·08)	0·78 (0·52- 1·16)	0·62fb	
SES – high	0·75 (0·48- 1·18)	0·83 (0·61- 1·13)	0·74 (0·52- 1·05)	0·86fb	
Emergency department visits**				0·01∞	0.40
Education level – low	0·14 (0·08-0·23)	0·08 (0·05- 0·13)	0·13 (0·07- 0·22)	0·29fb	
Education level – moderate	0·05 (0·03- 0·11)	0·10 (0·07- 0·15)	0·14 (0·07- 0·27)	0·15fb	
Education level – high	0·10 (0·04- 0·21)	0·05 (0·02- 0·12)	0·06 (0·03- 0·14)	0·51fb	

Telephone consultations with general practice**				0·001∞	0.044
Education level – low	2·80 (2·03-3·86)	4·65 (3·91-5·52)	2·87 (2·27-3·63)	0·002fb	
Education level – moderate	1·90 (1·42-2·55)	4·21 (3·44-5·17)	2·40 (1·86-3·09)	<0·0001fb	
Education level – high	2·31 (1·63-3·27)	2·88 (2·15-3·86)	1·53 (1·15-2·05)	0·01fb	
Consultation and visits with general practice**				0·01∞	0.40
Education level – low	7·94 (6·88- 9·16)	10·04 (9·06- 11·14)	7·71 (6·36- 9·35)	0·01fb	
Education level – moderate	5·97 (5·17- 6·88)	8·73 (7·59- 10·05)	7·39 (6·23- 8·76)	0·001fb	
Education level – high	4·85 (3·60- 6·54)	6·52 (4·97- 8·56)	4·38 (2·99- 6·40)	0·15fb	

* Adjusted for baseline, age, sex, education, SES, frailty index, polypharmacy, consultation gap. ** Adjusted for age, sex, education, SES, frailty index, polypharmacy, consultation gap.
∞ p-value for interaction test of variable with intervention in overall model. Within the subgroup analyses, the highest significant level of p-values is reported: ¥ p-value for interaction of intervention with time; fb p-value for intervention. ^Corrected p-value for multiple testing using Holm correction

Chapter 6

Opening the black-box of intervention delivery by nurses during a complex intervention trial: Did the nurses influence the trial results?

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Submitted

Abstract

Background: We performed a clinical trial on proactive elderly care and demonstrated that both early identification of frailty (U-PRIM) and U-PRIM followed by a multicomponent nurse-led care program (U-CARE) better preserve physical functioning in older people. To better understand the results of the trial, we assessed the actual nursing care delivered within the nurse-led care program and explored how the care delivery may have influenced our trial results.
Design: A mixed-methods study was conducted, using both the original trial data as well as additional qualitative information.
Methods: This study was nested in a large three-armed cluster randomized controlled trial.
Data of practices and patients in the U-PRIM plus U-CARE group were used for this study. Quantitative data of the nursing care delivered during the one-year intervention period were collected using website registration. A focus group session with a sub-sample of nurses was conducted to explore reasons for the identified differences in the delivery of nursing care for certain geriatric problems.
Results: Out of the 1327 patients that participated in the U-PRIM plus U-CARE group, 835 (62.9%) older persons were identified as frail and received a comprehensive assessment by the nurses at home. The most frequent self-reported geriatric conditions were polypharmacy (95.6%), loneliness (60.8%), and cognitive problems (59.4%). The most nursing care was delivered to patients at risk of falling and urinary incontinence, and least to patients with nutrition or malnutrition problems. The nurses applied at least one problem assessment to approximately one-third of the patients with a geriatric condition (range 21.9- 48.1%). The vast majority of the patients who received an assessment also received at least one specific nursing action (range 85-96%). The nurses explained that these differences were caused by the preference of the patient, the type of problem, and the time required to apply a specific nursing action.
Conclusions: This comprehensive mixed-methods study shows that the nurses in the U-CARE program tailored the interventions to the individual needs of the frail older people. However, not all components were delivered as planned. The findings of this study support the trial results and suggest that the actual care delivery by the nurses did influence the trial results.

Introduction

The increasing number of frail older persons with complex care needs challenges health care providers in primary care.[1,2] Care for frail older persons does not meet the needs of older persons resulting in unnecessary loss of physical functioning and quality of life and high health expenditures.[3,4] To maintain independent living and preserve physical functioning in older people a transition toward proactive, personalized care is urgently needed.[5] We recently developed a multicomponent personalized nurse-led care program for frail older people in primary care called U-CARE.[6] The effectiveness of U-CARE in combination with a screening intervention on frailty (U-PRIM) was evaluated in a three-armed ((1) U-PRIM, (2) U-PRIM and U-CARE, and (3) control) cluster randomized trial with over 3,000 older people in the Netherlands. The trial results showed favorable effects of both intervention arms on the preservation of physical functioning, with better results for well-educated older people. No effects on quality of life or health care consumption rates were observed.[7]

According to Craig and colleagues, the nurse-led U-CARE program can be defined as a complex intervention, as it consists of multiple components and it has a flexible, tailored approach.[8] The program includes a frailty assessment, a comprehensive geriatric assessment at home for frail patients and evidence-based care planning, coordination and follow-up visits conducted by specially trained registered practice nurses. A detailed description of the development process of the U-CARE program has been described previously.[6]

An important limitation of many trials with complex multicomponent non-pharmacological interventions is that the results cannot be fully understood, implemented, and replicated due to inadequate description of the intervention in research reports.[9] Furthermore, trial reports often fail to describe the extent to which the intervention was delivered as planned (i.e. study fidelity). Detailed description of the intended and actual intervention delivery allows readers to determine if implementation during the trial may have affected outcomes.[8,10] Five elements of an intervention should be described in research reports: theory, intervention recipient, interventionist, intervention content, and intervention delivery.[11] These elements address the why, who, what, how where, and how much questions concerning the intervention.[8,11] We addressed the first four elements previously.[6,12]

The objectives of this study were to determine the delivery of the U-CARE program by the nurses and to assess how and how much of the nursing care was delivered in response to identified problems. In addition, we explored how the care delivery may have influenced our trial results.

Methods

Study design

We conducted a mixed-methods design using the original data of one intervention arm of the Utrecht Primary care PROactive Frailty Intervention Trial (U-PROFIT)[13] , collected between October 2010 and March 2012. For the qualitative questions, we conducted a focus group study among participating nurses in 2013.

Setting and participants

The general practices and frail patients randomized into the U-PRIM + U-CARE intervention participated in this study. The general practices were enrolled from 13 primary care practices in and around Utrecht, the Netherlands. The design and inclusion criteria of the U-PROFIT trial have been described previously.[13] In short, patients were selected using a software application installed on electronic medical records (EMRs). Eligible patients aged 60 years or older were screened for the following criteria: multimorbidity (based on ICPC registration of the EMR system, a frailty index was constructed)[14] ,polypharmacy (defined as chronic use of five or more different medications), and a consultation gap (defined as not having consulted the GP in the past three years, except for the yearly influenza vaccination). Patients falling into any of these three categories were then invited to participate.

Description of the U-CARE intervention components

The U-CARE intervention is a personalized multicomponent nurse-led care intervention. Prior to the start of the U-CARE intervention, an initial selection of older people at risk for adverse health outcomes was performed by a screening and monitoring intervention (U-PRIM). The U-CARE intervention included a frailty assessment to assess the level of frailty, complexity of care, and wellbeing;

a home comprehensive geriatric assessment (CGA) for those patients who were indicated as frail on the Groningen Frailty Indicator (GFI) (GFI score of ≥ 4);[15,16] evidence-based and tailor-made care planning; coordination of care; and multiple follow-up visits. A multidisciplinary team of researchers, GPs, registered practice nurses, experts, and an independent panel of older persons were involved during the development to increase the quality and feasibility in clinical practice.[6] All intervention components were tested in a pilot study for feasibility and acceptability.[12]

Recruitment and training of nurses

Prior to the start of the trial, 21 registered practice nurses were recruited and employed for the study. All nurses were embedded in the general practice and were extensively trained during a six-week training period of eight hours per week. During the training, the content of the program as well as its core components and delivery were discussed. Prior to the start of the intervention, all nurses and GPs participated jointly in a mandatory four-hour training session regarding collaboration skills in primary care. During the trial, monthly meetings were scheduled for the nurses to enhance ongoing learning and support in delivering the U-CARE intervention, led by an experienced coach. Patient cases were discussed in small groups to enhance problem-solving and feedback skills. In addition, experts in various geriatric topics were invited to support ongoing learning.

Evidence-based care plans and nursing care

For the following 11 common geriatric conditions, evidence-based care plans were developed to enhance and encourage continuity of care delivery by nurses: falls, physical functioning, loneliness, mood and depression, vision impairment, hearing impairment, nutrition and malnutrition, cognitive problems, urinary incontinence, polypharmacy and caregiver burden. The evidence-based care plans were developed using a stepwise approach consisting of literature and guidelines review, combined with clinical practice experiences and expert opinions. The care plans included assessments, evidence-based interventions, and recommendations for each geriatric problem. These were summarized on flowcharts to be used as a practical tool for the nurses. Nursing care was defined as the composite of assessments, interventions, and recommendations.

Interventions and recommendations can be categorized into specific nursing actions, primary care referrals, and specialized care and coordination referrals (Figure 1). As an example, an assessment for mood and depression is the Geriatric Depression 15 Scale (GDS)[17], a specific nursing action is "helping the patient with day structure," and coordination is "discussing treatment and care plan with GP or other health care professionals."

Data collection on nursing care delivery

To determine the actual nursing care delivered within the U-CARE program during the trial, we asked the nurses to report the executed problem assessments, specific nursing actions, primary care and specialized care referrals and coordination tasks for each frail patient on a website that was specially developed for study purposes.

Qualitative data

A focus group was conducted to explore the differences in the total volume of nursing care delivered as well as the differences in the number of applied specific nursing actions, referrals and coordination for each geriatric condition. A subgroup of nurses was invited to participate in the focus group. A protocol for the focus group meetings was set up and included the following topics: introduction, presentation of the quantitative results, discussion, and explanation of the differences in the delivery of nursing care within the U-CARE program. The first author (NB) wrote the protocol, presented the quantitative results, observed, took notes, and handled the technical equipment. The moderator (BS) performed the consent process for the protocol, introduced the groups, and led the discussion. Saturation was reached after one focus group meeting.

Analysis

Quantitative data were analyzed using descriptive statistics to describe the characteristics of the patients who participated in the U-CARE program, including means (SD), medians (IQR), or n (%) where applicable. Frequencies of applied interventions were reported for each geriatric condition. SPSS version 20 (IBM, Chicago, IL, USA) was used. The focus group was audiotaped, and the tape was then transcribed verbatim to allow for systematic analysis.[18]

The transcripts were studied by three independent researchers (NB, BS, and VHD) repeatedly, and themes were identified first from open coding of the data. Differences in themes were resolved through discussions with BS, VHD, and NB. Content validity was ensured by member checking, obtaining agreement from the participating nurses by sending a summary of the results obtained after the focus group meeting.
The data were studied in a transparent and systematic way using triangulation, segmenting, and reassembling.[19]

Ethical considerations
The U-PROFIT trial was approved by the Institutional Review Board of the University Medical Center Utrecht (UMCU) with protocol ID 10-149/O and it was registered in the Netherlands Trial Register: NTR2288. All participants signed an informed consent form.

Results

Out of the 1327 patients that participated in the U-PRIM plus U-CARE group, 835 (62.9%) older patients were identified as frail according to the GFI outcome, and received a comprehensive assessment at home by the nurse.
The mean age was 75.4 years (SD: 8.4), most patients were female (64.4%), and approximately half of the patients lived alone (46.5%) (Table 1).

The most frequent self-reported geriatric conditions identified among older patients were polypharmacy (95.6%), loneliness (60.8%) and cognition (59.4%) (Table 2). Overall, most nursing care was delivered to patients at risk for falls and urinary incontinence. The least nursing care was delivered to patients with nutritional problems (Figure 1). The nurses applied at least one problem assessment to approximately one-third of the patients with a geriatric condition (range 21.9-48.1%) (Table 2). Most assessments were conducted for polypharmacy (48.1%) and physical functioning (44.1%). In patients with self-reported risk for caregiver burden, mood and depression problems, or nutrition problems only 20.4 %, 21.9% and 22.8% received a problem assessment respectively (Table 2).

Table 1. Characteristics frail participants (N=835).

	All patients N = 835
Age, mean (SD)	75.4 (8.4)
Female, n (%)	538 (64.4)
Marital status, married, n (%) Widowed, n (%)	429 (51.4) 240 (28.7)
Having children, n (%)	685 (87.0)
Education level primary school or less, n (%)	203 (24.3)
Socioeconomic status, n (%) Low Average High	 363 (44.5) 325 (39.9) 128 (15.7)
Living situation, n (%) Alone Together with others,	 388 (46.5) 447 (53.5)
Number of medications in chronic use, median (IQR)	7.0 (5-9)
GFI score*, mean (SD)	6.6 (2.0)
Intermed score**, mean (SD) Intermed score ≥ 20, n (%)	14.57 (5.6) 105 (8.2)
Self-rated health, excellent or good, n (%)	192 (23)
Quality of life, mark between 0-10, mean (SD)	7.02 (1.2)

Notes: * GFI score ranges from 0-15. A score of ≥ 4 is indicated as frail.
** Intermedscore ranges from 0-60. A high score indicates high complexity of care.

Table 2. Number of self-reported geriatric problems, and overview of the type and number of nursing care (n and %) delivered to 835 frail older people*.

		Nursing care				
Patients with the condition, n (%)	**Number (%) patients**	**Problem assessment**	**Specific nursing action***	**Referral Primary care***	**Referral Specialized care***	**Coordination ***
Falls	315 (37.7)	106 (33.7)	92 (86.8)	31 (29.2)	42 (39.6)	60 (56.6)
Urinary incontinence	421 (50.3)	145 (34.4)	139 (95.9)	13 (9)	NA	97 (66.9)
Nutrition and malnutrition	386 (46.2)	88 (22.8)	61 (69.3)	25 (28.4)	NA	58 (65.9)
Cognition	496 (59.4)	161 (32.5)	78 (48.4)	29 (18)	17 (10.6)	87 (54)
Vision problems	350 (41.9)	109 (31.1)	104 (95.4)	35 (32.1)	NA	58 (53.2)
Hearing loss	432 (51.7)	145 (33.6)	126 (86.9)	46 (31.7)	9 (6.2)	60 (41.4)
Polypharmacy	798 (95.6)	384 (48.1)	324 (84.4)	29 (7.6)	NA	279 (72.7)
Physical functioning	270 (32.2)	119 (44.1)	101 (84.9)	25 (21)	NA	70 (58.8)
Loneliness	508 (60.8)	163 (32.1)	149 (91.4)	30 (18.4)	NA	106 (65)
Mood and depression	456 (54.6)	100 (21.9)	96 (96)	16 (16)	7 (7)	82 (82)
Caregiver burden	108 (12.9)	22 (20.4)	21 (95.5)	16 (72.7)	2 (9.1)	18 (81.8)

Notes: *The number and percentage of specific nursing actions, referrals and coordination is based on the number of patients who received at least one problem assessment.
NA: not applicable, referral to specialized care was not included in the evidence-based care plan and therefore not registered.

Except for patients with cognitive problems and nutrition or malnutrition, the vast majority of the patients who received an assessment also received at least one specific nursing action (range 85-96%). The nurses applied the most specific nursing actions to patients at risk of falls (mean: 12.8), and urinary incontinence .[8,9]

Few patients were referred to health care professionals within the primary care setting or to specialized care (Table 2). Most frequently referred to health care professionals within the primary care setting were patients, after further assessment targeting risk of caregiver burden (72.7%), vision problems (32.1%), hearing impairment (31.7%), falls (29.2%) and nutrition or malnutrition problems (28.4) (Table 2). These referrals included elderly care advisor, low vision specialist, hearing specialist, occupational therapist or dietician (the type of referrals are tabulated in Appendix A). Patients assessed at risk of fall problems were mostly referred to specialized care (39.6% were referred to a fall risk clinic in the hospital) and 10.6% of the patients with cognition problems were referred to a specialist in the hospital (Appendix A).

After assessment, the nurses applied coordination interventions to the majority of the patients, which ranged from 41.4% (hearing impairment) to 82% (mood and depression problems) (Table 2). The vast majority of patients with mood and depression problems and patients at risk for caregiver burden and polypharmacy received care coordination (Table 2).

Qualitative findings

During the focus group, three themes emerged that probably explained the differences in the volume of nursing care delivered: the type of problem and specific nursing action, the preferences of the patient, and the selected group of patients who participated.

"The occurrence of frequent falls is often an acute problem, and the evidence-based care plans included relatively 'quick and easy-to-apply' actions, such as removing some mats and tables and giving advice. Also, it is not a taboo topic to discuss in contrast to, for example, mood and depression."

"Nutrition was often not perceived as a problem. Most patients had multiple health problems, and nutrition had no priority. Also, sometimes, I did not want to disturb common habits when the situation was not hazardous."

"Patients that participated in the trial were relatively healthy. During the home visit, cognitive problems were often minor or even not an issue, because only one item assessed whether the patient perceived 'memory loss'; this item did not discriminate well."

Nurses perceived that mood or depression issues are more time-consuming problems, because it is essential to build trust and a good relationship before specific nursing actions can be applied. During the focus group, the number of referrals was discussed, and the nurses acknowledged that they deliver a high volume of care themselves. The nurses noted that the number of referrals to specialized care has reduced.
"Together with the GP, we can deliver a lot of care by ourselves, so referrals are less needed."
"Most patients were referred to specialized care by the GP, so it is possible that I did not report these referrals on the website."
"Currently, I refer patients with low vision or hearing loss to an optician or hearing care professional within the primary care setting, while some years ago, I referred these patients to a specialist."

The nurses emphasized the importance of care coordination, but the intensity of coordination was dependent on the type of problem and patient.
"Most frail patients suffer from multiple diseases, and multiple health care providers are involved. Good coordination and collaboration with the GP and other health care professionals is crucial."
"Problems such as mood and depression require more coordination time before I can apply interventions because I have to build up a confidence relationship with the patient first."

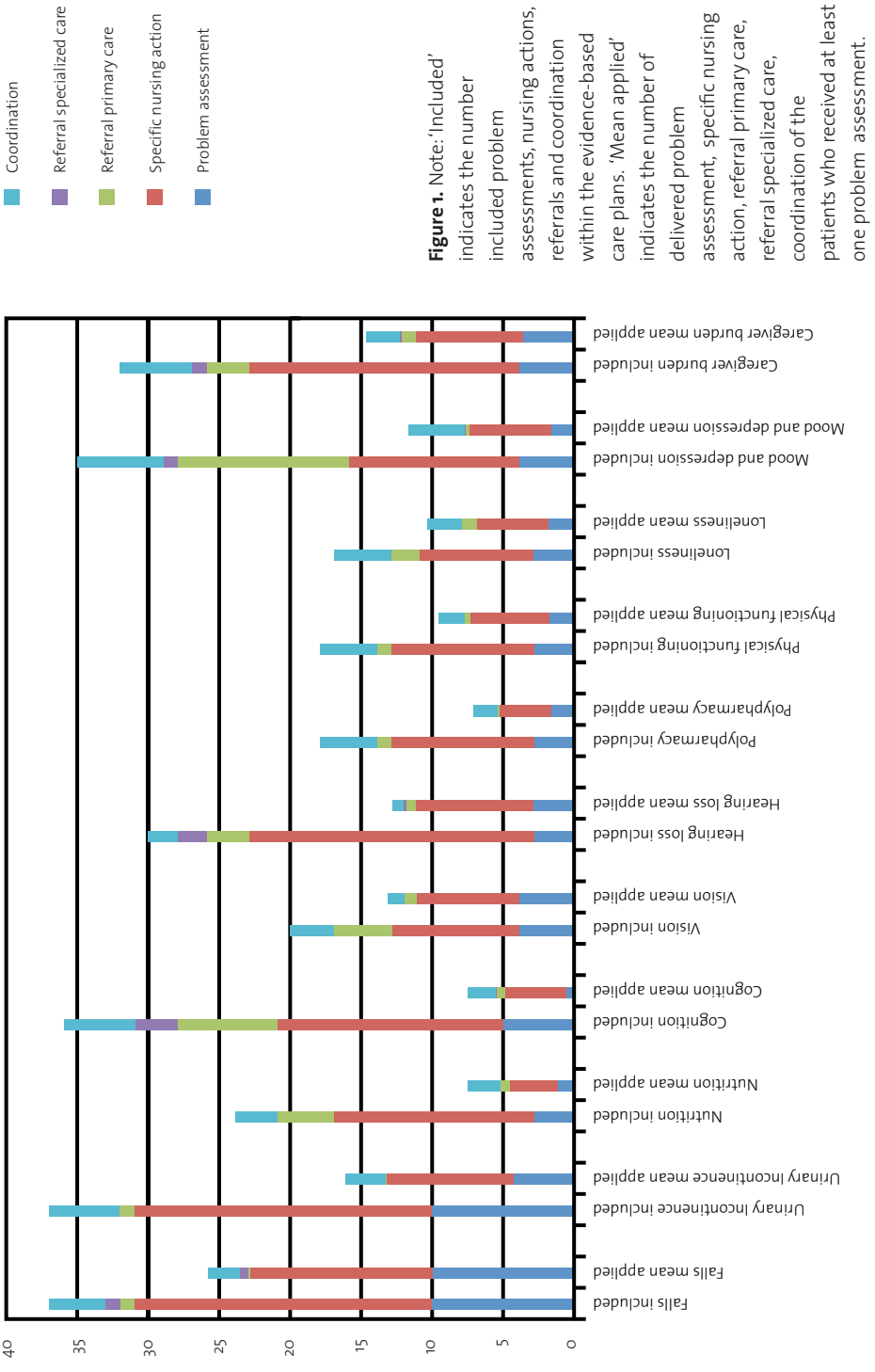

Figure 1. Note: 'Included' indicates the number included problem assessments, nursing actions, referrals and coordination within the evidence-based care plans. 'Mean applied' indicates the number of delivered problem assessment, specific nursing action, referral primary care, referral specialized care, coordination of the patients who received at least one problem assessment.

Discussion

This comprehensive mixed-method study shows that the actual nursing care delivered by nurses during the trial differed from the intended care delivery in the U-CARE program.
Overall, most nursing care was delivered to patients with an increased risk of falls and urinary incontinence. All U-CARE components (e.g. the CGA, the evidence-based care plans, care coordination, and follow-up visits) were delivered, but not all components were delivered as intended. Differences were most noticeable for cognition, nutrition and malnutrition and mood and depression problems. The nurses explained the differences between the intended and actual performed actions by individual patient factors: the preference of the patient, type of problem and type of specific nursing action (easy and quick-to-apply versus more time-consuming nursing actions). The results show that there is room for improvement in the delivery, especially in taking disease-specific problem assessments for identified conditions.

Strengths & limitations
Some limitations of this study need to be addressed. First, in our study, nursing care was the composite of assessments and interventions and recommendations. Interventions and recommendations were categorized into specific nursing actions, referral to primary care and specialized care, and coordination. In the literature, there is no consensus for the classification of different types of interventions.[20, 22] The absence of standardization results in various classifications making comparison between studies difficult. Second, it is possible that our findings are an underestimation of the actual care delivered by nurses during the trial. An explanation could be that not all actions and interventions were reported on the website due to a lack of time or other reasons.
In addition, we did not collect the number of frail patients who refused nursing care on specific geriatric conditions. Nonetheless, we do not assume that the registrations by nurses differ among the geriatric conditions and we believe that the results represent a valuable overview of the intervention delivery during the trial. Third, a selected group of older people participated in this study. The vast majority of the patients were included based on the polypharmacy criterion, which may explain the high proportion of older people with multiple medications in chronic use.

Additionally, it is plausible that most frail older people with for example mild or moderate cognitive problems or low literacy were not included. This was confirmed by the nurses during the focus group, and including frail older people has been reported as a common challenge in the literature.
A strength is that this mixed-methods study evaluates the actual delivered nursing care in response to identified problems within a multicomponent non-pharmacological intervention. Detailed registration of interventions and a focus group enables us to determine the actual nursing care and provides more insights into the "black-box" of multicomponent interventions.[9,11] This remains scarce in non-pharmacological trials, but it is highly recommended since it provides important information concerning why a successful intervention works and how it can be optimized.[8,9] A focus group improved our understanding of the quantitative findings obtained. Furthermore, we included an extended appendix with the details of all applied assessments, specific nursing actions, referrals and coordination to allow replication and to stimulate comparison.[11]

Comparison literature
In the literature, three studies of comparable interventions reported some information regarding the intervention delivery. Bouman and colleagues evaluated a home-visiting program for older people conducted by home care nurses in which patients received on average 11 interventions: 40% of these were related to referrals (housing, home care, day care, and optician), while others were related to "advice" and "information".[23] Comparison with our study was difficult, since details regarding the actual content of "advice" and "information" were not described for specific geriatric conditions. Metzelthin and colleagues evaluated whether an interdisciplinary primary care approach for frail older people in primary care was implemented as planned.[24] Practice nurses embedded in the general practice were case managers. Frail older patients were mostly referred to an occupational therapist or a physiotherapist. Referrals to other professionals—such as nutritionists, pharmacists, and geriatric speech therapists—were less frequent.[24] These referrals are comparable with our study, but patients in our study were also referred to social workers or elderly care workers in the community. Melis and colleagues reported on the content of and adherence to a nurse-led home-visiting program for vulnerable older people and concluded that the program was highly tailored to the heterogeneous group

of individuals.[25] In the current study, we observed a comparable pattern among the heterogeneous population. Caregivers who provide care to a chronically ill family member at home are potentially at risk for caregiver burden and declining physical and mental health.[26] Therefore we included in the Frailty Assessment one question to assess whether the patient was also a caregiver. In this step, we did not assess caregiver burden, because in the U-CARE program, we intended that for caregiver burden to be assessed during the comprehensive geriatric assessment at home. However, only 20.4% of the patients received an assessment. A possible explanation could be that there was no participants experienced caregiver burden; however, this information was not collected.

The nurses delivered a high volume of care to patients with falls and urinary incontinence, since these interventions were often "simple" and "quick to apply." Comparable findings were reported in a feasibility study of a fall-prevention program.[27] The literature describes an intervention as successful when it is "simple to use," "easy to find," and "within reach".[28] This may explain why time-consuming interventions, such as nursing interventions for depression, were less often applied compared to more ad hoc and acute interventions. Nurses emphasized that coordination of care is highly important in the care for frail older patients. Ensuring individual and ongoing care coordination is an important aspect of care desired by older patients[29] and acknowledged as an important role of the registered practice nurse.[30]

Interpretation of the findings in relation to the trial results obtained.
The trial results showed that a screening intervention (U-PRIM) and U-PRIM followed by U-CARE both preserved physical functioning in older people. No effects were observed for quality of life or health care consumption rates.[7] Our hypothesis that the combined intervention would result in advantageous effects was not confirmed. The findings of the current study support the obtained trial results suggesting that the effectiveness of the U-CARE intervention is an underestimation of the true effect. Based on the results of the current study, two explanations are discussed.

First, in the current study, the number of applied interventions differed among the geriatric conditions due to the preference of the patient, type of problem, and type of intervention. This implies that the U-CARE intervention was tailored to the patients' needs and preferences, which was one of our predefined aims of the intervention.[6] However, the number and percentage of people who received at least one problem assessment were much lower in all geriatric conditions than expected, since the nurses were trained to take an additional assessment when a problem was identified in the first step of the U-CARE intervention. Despite the fact that some patients indicated that problems such as nutrition were not burdensome or that no care was needed, it can be questioned whether all patients received the optimal intervention. The nurses noted that it is important to build trust and a good relationship before interventions are applied, especially for patients with mood and depression complaints. On the contrary, older people may not wish to bother medical professionals with their depression[31], or may not want to receive treatment, because they do not feel depressed or because they think that they are too old to learn new things.[32] Although building a good relationship is an important condition of person-centered care[33, 34], it is open to discussion whether nurses should be more proactive and intervene earlier in some situations. Since no effect on quality of life was observed in the trial, the results of this study may suggest that postponing interventions probably results in delayed or low intervention effects.

Second, it is important to note that the effectiveness of the U-CARE intervention and the intervention delivery by nurses was evaluated in a large cluster randomized trial. Despite the many advantages of this design, it is limited, in that creating "real-life" circumstances in non-pharmacological trials is difficult.[35] This has important consequences for the results obtained, since the U-CARE intervention was evaluated during only a one-year follow-up. In a short period of time, the nurses were exposed to a large number of frail patients in (urgent) need of tailored care, because all frailty assessments were sent at once, whereas this process will occur more gradually in a typical care situation. In addition, the nurses explained that providing proactive, personalized care was difficult in the beginning, but a transition toward proactive, personalized care was achieved.[12]

The findings from this study add to the evidence showing that the impact of actual delivery of nursing care plays an important independent role in the effectiveness of non-pharmacological intervention trials.[36]
Although the association between the applied assessments and specific nursing actions and the results of the trial on patient outcomes is complicated, the findings of the current study support the trial results obtained. The results of the current study underscore the need for improvement in the delivery of the U-CARE program, particularly in assessing the type and severity of the problem with disease-specific assessments. Nonetheless, even when some patients may have received a "suboptimal" intervention, U-CARE contributes to preserving physical functioning in frail older people after a short follow-up period of one year. More advantageous effects will be achieved when the U-CARE program is delivered as planned to frail older people in primary care. The findings of this study contribute to a better understanding of the trail results obtained and provide valuable starting points for refinement of the U-CARE program.

Conclusion
This study shows that the U-CARE program was highly tailored to the individual needs of older people. The nursing care delivered in response to identified problems was dependent on the preference of the patient, the type of problem, and the type of specific nursing action. All intervention components were delivered, however, not all components were delivered as planned. The findings of this study support the trial results and suggest that the actual care delivery by the nurses did influence the trial results.

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Appendix A All geriatric conditions and applied assessments and interventions

Loneliness (n=508)	**N**	**%**	**Category**
Assess type and severity of loneliness	103	20.3	P
Use the loneliness scale of de Jong-Gierveld	22	4.3	P
Check causes of loneliness	110	22	P
Tailor the intervention to the needs	106	21	A
Recommend patient to maintain contacts	144	28	A
Conduct reactivation home visits	88	17	A
Help patient to increase contact with others	96	19	A
Support patient in bereavement	38	8	A
Help the patient to reactivate	73	14.4	A
Recommend the use of internet for contact with friends/family	25	5	A
Suggest computer workshop	13	2.6	A
Suggest diner groups	15	3	A
Apply for group interventions	70	14	RP
Referral. employment social worker. elderly care advisor	49	10	RP
Discuss outcomes with GP	69	14	C
Discuss outcomes and treatment with GP	67	13.2	C
Check social map	74	15	C
Plan evaluation visit and follow-up visits	78	15.4	C

P: Problem assessment
A: Specific nursing action
RP: Referral primary care
RS: Referral specialized care
C: Coordination

Cognition (n=496)	N	%	Category
GDS scale	21	4	P
OLD scale	10	2	P
MMSE assessment	38	8	P
Clock Drawing test	31	6	P
Assess caregiver burden with EDIZ assessment	75	15	P
Prepare care plan	40	8	A
Patient education	49	10	A
Planning follow-up visits for patient and caregiver	47	10	A
Recommend patient on Alzheimer association	13	3	A
Recommendation for nurse: helping with financials	12	2.4	A
Check safety in and around the house	24	5	A
Remove care resistance	17	3.4	A
Discuss behavior problems and depression with caregiver	17	3.4	A
Prescribe Exelon by GP	2	0.4	A
Physical examination by GP	15	3	A
Blood examination by GP	25	5	A
Discuss with caregivers courses with caregiver	12	2.4	A
Check medication	39	8	A
Discuss emergency plan	8	2	A
Ask experienced problems	160	32	A
Discuss possibilities respite care	8	2	RP
Referral home care	6	1.2	RP
Referral / deployment volunteers	10	2	RP
Referral older people advisor	7	1.4	RP
Referral case manager dementia	10	2	RP
Referral professional help caregiver	11	2.2	RP
Referral day and night care	11	2.2	RP
Referral admission nursing home or hospital	3	0.6	RS
Referral for diagnostic assessment	6	1.2	RS
Referral hospital. specialists	10	2	RS
Prepare emergency plan	11	2.2	C
Check social map	30	6	C
Discuss outcomes screening with GP and other professionals	57	12	C
Discuss outcomes with GP	48	10	C
Prepare evaluation visit and follow-up visits	69	14	C

Nutrition. malnutrition (n=386)	N	%	Category
Check if the patient is treated by other professionals	85	22	P
MNA to assess nutrition status	16	4	P
SNAQ65 screening	16	4	P
Ask intake additional supplements. vitamin D. calcium. obstipation	53	14	P
Recommendation sodium lose flavor enhancers	4	1	A
Check if high energy meals are needed	13	3.4	A
Consider lab checks when malnutrition patient	6	2	A
Check policy and prepare care plan	37	10	A
Recommend good oral hygiene	11	3	A
Discuss case with dietician	7	2	A
Add energy supplements	19	5	A
Recommend to eat more often smaller meals	29	8	A
Recommend high energy nutrition meals	16	4	A
Recommend to avoid gas producing products	7	2	A
Recommend variety diet	17	4	A
Recommend a food diary	4	1	A
Recommendations regarding preparing meals	13	3	A
Recommendations regarding devices and home care shop	18	5	A
Recommend having meals in groups or in company	16	4	RP
Meals on wheels or elderly care advisor	4	1	RP
Recommend home care or day care	6	2	RP
Recommend consultation ergo. speech Therapists dietician	14	4	RP
Discuss outcome assessments with the GP	56	15	C
Problem definition defined by the GP	42	11	C
Plan evaluation visit and follow-up	39	10	C

Polypharmacy (n=798)	N	%	Category
Assess medication use. using EMR system and pharmacy	384	48	P
If non-compliance or adherence. check cause	64	8	A
Ask medication list of pharmacist	64	8	P
Check medication intake using medication list Dutch College General practitioners	81	10	P
Return expired medication to pharmacists	40	5	A
Check kidney functions and register and inform pharmacists	211	26	A
Ask patients to bring their medication list when visiting GP	69	9	A
Deployment of baxter role, medication kit, reminders	100	13	A
Medication use interview by nurse or GP	94	13.9	A
Discuss with pharmacist / GP other dosage or usage of the drug	60	8	A
Education and counseling	164	21	A

Register results and conclusions on medication review form	242	30	A
Support and enhance medication intake patient	182	23	A
Deployment of home care when problems with medication occur	29	3.6	RP
Problem definition defined by GP	127	16	C
Discuss with pharmacists / GP delivery possibilities	79	10	C
Discuss results with GP	267	34	C
Prepare and plan evaluation visit	117	15	C

Urinary incontinence (n=421)	**N**	**%**	**Category**
Ask if patient is receiving any treatment or care or examined	138	33	P
Investigate problems experienced by patient using PREFAB	24	6	P
Ask if current care is sufficient	117	28	P
Investigate type of urinary-incontinence	80	19	P
Conduct Urinary control	52	12	P
Ask if the patient use materials and is the patient is satisfied with it	135	32	A
Discuss overweight	16	4	A
Advice restrictions / limitations urinary incontinence	37	9	A
Suggest that patient can call or ask for information	65	15	A
Recommendation stress incontinence. counseling and education	24	6	A
Recommendation stress-incontinence: bladder training	1	0.2	A
Recommendation stress-incontinence start pelvic floor therapy	9	2	A
Recommendation urge-incontinence: education	23	5.5	A
Recommendation urge-incontinence: bladder training	6	1.4	A
Recommendation urge-Incontinence: start medication	2	0.5	A
Recommendation urge – incontinence: reduce caffeine drinks	3	0.7	A
Recommendation mixed incontinence: education. counseling	22	5	A
Recommendation mixed incontinence start with the most burden type	4	1	A
Recommendation mixed incontinence: bladder training	2	0.5	A
Recommendation mixed incontinence: pelvic floor muscle training	4	1	A
Recommendation mixed incontinence: check medication	3	0.7	A
Discuss feelings of humiliation/ discomfort	65	15	A
Discuss fluid hydration and secretion	66	16	A
Recommend planned toileting / toileting schedules	57	14	A
Recommend patient to take time and avoid compression presses	53	13	A
Recommendations mobility, vision, cognition, alcohol, caffeine, overweight, obstipation	29	7	A
Discuss using absorption materials and education	64	15	A
Prevent surrounding skin	40	10	A
Discuss problems and solution with clothes	36	9	A

Discuss personal hygiene	29	7	A
Information and advices in practical devices	34	8	A
Referral /consultation urinary incontinence nurse	13	3.1	RP
Discuss outcome home visit with the GP	53	13	C
Define problem definition in collaboration with the GP	61	15	C
Discuss the use of diuretics	44	11	C
Discuss diagnose and treatment with the GP	42	10	C
Plan evaluation moment with patient	66	16	C

Physical functioning (n=270)	**N**	**%**	**Category**
Assess how much the patient exercise	119	44	P
Check IADL score with Lawton and Brody scale	51	19	P
Check medication intake.	24	9	A
Travel problems: arrangement of travel aids	6	2	A
Recommend a phone with large buttons	5	2	A
Recommendation to exercise moderate to intensive	87	32	A
Recommendation for exercise programs and improve exercising	62	23	A
Recommendations strength, balance, flexible and endurance exercises	44	16	A
Recommendation: ask for support and report in daily diary	14	5	A
Recommendation for the nurse: Education and counseling	87	32	A
Recommendation for the nurse: Motivate and stimulate the patient	85	32	A
Recommendation for the nurse: give feedback and follow-up	36	13	A
Recommendation for the nurse: Ask possibilities and check hygiene	30	11	A
Recommend an alarm system for the patient	30	11	A
Administration problems: deployment of social welfare elderly assistance	7	2.6	RP
Referral home care assistance	23	9	RP
Service prepared meals, home care, meals on wheels	9	3	RP
Shopping service. delivery at home	7	3	RP
Recommendation for the nurse: Check social map	36	13	C
Discuss with GP regarding physiotherapist or ergo	45	17	C
Problem definition defined by GP	41	15	C
Follow-up and screening after three months	46	17	C

Mood and depression (n=456)	**N**	**%**	**Category**
Clock drawing	13	3	P
Assess care needs	82	18	P
MMSE	15	3	P

GDS	31	7	P
Observation by nurse	161	35	A
Check medication	66	15	A
Assessment of pleasant activity list	29	6	A
Discuss alcohol intake and psycho pharmacy	48	11	A
Check nutrition intake	70	15	A
Cognitive and behavioral therapy	18	4	A
Medication check and education	34	8	A
Help patient with day structure	53	12	A
Involvement of the patient with treatment decisions	59	13	A
Patient education	31	7	A
Caregiver support	51	11	A
Physical activities interventions	34	8	A
Referral group therapy	2	0.4	RP
Case manager employment	7	1.5	RP
Referral specialist elderly care. psychologist	4	0.9	RP
Referral spiritual caregiver	4	0.9	RP
Referral gerontologist, social worker	9	2	RS
Discuss diagnose and therapy/ treatment with GP	80	18	C
Discuss responsibilities with GP. if needed case manager	35	8	C
Collaboration with other disciplines	28	6	C
Discuss outcomes home visit with GP	65	14	C
Conduct an evaluation visit after three months	59	13	C
Plan evaluation visit	61	13	C

Hearing impairment (n=432)	**N**	**%**	**Category**
Assess if one or both ears have hearing loss	144	33	P
Assess if patient had previous examinations	140	51.6	P
Assess experienced problems using the HHIE-S assessment	30	7	P
Ask for social activities disabilities	120	28	A
Determine if patient has hearing aid	111	26	A
Recommend patient associations	1	0.2	A
Check is patient can recalculate the information	37	9	A
Prepare a care plan	12	3	A
Aid for telephone, alarm, doorbell	14	3	A
Check ears cerumen prop	34	8	A
Clear ears / cerumen	19	4	A
Determine hearing aid on hygiene	10	2	A
Asses knowledge patient in batteries hearing aid	46	11	A
Recommend to reduce background noise	60	14	A

Recommendation communication skills: increasing assertiveness	30	7	A
Recommend patient to take time for conversation	55	13	A
Recommend patient to have eye contact during communication	59	14	A
Recommend patient to talk on normal volume	50	12	A
Recommend patient to use short sentences	49	11	A
Recommend patient to use signs / gestures	33	8	A
Recommend communication note book	23	5	A
Recommend aid for doorbell with more tones	10	2	A
Recommend patient to use the manual of hearing aid	19	4	A
Recommend hearing care professional at home	9	2	RP
Recommend a training in word recognition	28	7	RP
Recommend to see a specialist	3	0.7	RS
Referral to specialist	8	2	RS
Referral to hearing specialist shop	37	9	RP
Check social map	18	4	C
Discuss outcomes with GP	59	14	C

Vision problems (n=350)	**N**	**%**	**Category**
Assess vision problems	160	45.6	P
Ask specific vision limitations	92	26	P
Ask if ADL/IADL tasks can be performed	82	23	P
Ask day and night vision. driving	60	17	P
Observe unusual color combinations	60	17	A
Check if patient fell lately	52	15	A
Check fall risk and lighting in the house	43	12	A
Check glasses of the patient	81	23	A
Check walking speed and movements	67	19	A
Observe spots in clothing	57	16	A
Check vision aids	30	9	A
Discuss mobility transfer possibilities	12	3	A
Check if patient can read	78	22	A
Prepare care plan	40	11	C
Check usage of eye drops and if help is needed	26	7	C
Discuss treatment with GP	55	16	C
Referral activities day care	21	6	RP
Recommend low vision assessment occupational therapist, financial help	12	3	RP
Referral home care assistance	22	6	RP
Deployment volunteers	8	2.3	RP

Falls (n=315)	N	%	Category
Use CBO guideline	58	18	P
Using the fall risk instrument U-CARE toolkit	91	29	P
Check vision problems using items of the fall risk instrument toolkit	68	22	P
Check mobility problems, fracture risk, syncope	83	26	P
Check mobility and balance using items of the fall risk instrument toolkit	95	30	P
Check dizziness using items of the fall risk instrument toolkit	80	25	P
Check urinary incontinence of the fall risk instrument toolkit	63	20	P
Check fear of falling using the FES-NL scale	68	22	P
Check cognition problems using items of the fall risk instrument toolkit	54	17	P
Check mood and depression using items of the fall risk instrument toolkit	54	17	P
Reduce fear of falling interventions	33	11	A
Involve caregiver when situation is burdensome	21	7	A
Check medication prescription and intake	75	24	A
Check house and environment	73	23	A
Education and counseling consequences of falling	73	23	A
Education and information regarding importance of exercise	78	25	A
Information: advice regarding good footwear	66	21	A
Check medication and recommend vitamin D and calcium	66	21	A
Discuss with cognitive impaired patients their limits and possibilities	27	9	A
Education: fall safety folder	32	10	A
Recommendations house safety using a checklist	35	11	A
Check indication physiotherapist, occupational therapist when patient has ADL disabilities	28	9	A
WMO insurance for using devices	20	6	A
Check osteoporosis by GP	13	4	A
Hip protectors	6	2	A
Tailoring the interventions	50	16	A
Exercise interventions	42	13	A
Multifactorial interventions	26	8	A
Check house, glasses, food gear, vision impairment	34	11	A
Assess patients' insurance for physiotherapy	15	5	RP
Referral fall risk department	43	14	RS
Problem definition defined by GP	46	15	C
Register new falls in routine patient data system	30	10	C
Discuss outcomes and referral with GP	55	17.5	C
Plan evaluation and follow-up	42	13	C

Caregiver burden (n=108)	N	%	Category
Discuss problems with caregiver without patient	19	17.6	P
Assess positive feelings	21	19.4	P
Assess negative feelings	21	19.4	P
Assess mental complaints	21	19.4	P
Determine general health	21	19.4	A
Discuss medication use	17	15.7	A
Education and counseling psychological health	16	14.8	A
Education and counseling physical activities	16	14.8	A
Discuss depression or burnout	12	11.1	A
Inform the caregiver about courses	10	9.3	A
Provide information regarding respite care	3	2.8	A
Ask for social support caregiver	11	10.2	A
Discuss activity possibilities caregiver	7	6.5	A
Inform the caregiver that he/she can contact you	13	12	A
Pay attention to the caregiver and give compliments	5	4.6	A
Recommendation to reduce care avoiding and resistance	5	4.6	A
Recommendation regarding safety	6	5.6	A
Assess personal financial possibilities insurance	0	0	A
Ask for financial problems	5	4.6	A
Provide information regarding the disease and prognosis of the patient	8	7.4	A
Information regarding patient associations	2	1.9	A
Ask caregiver to pay attention to the quality of care delivered	10	9.3	A
Referral volunteers, elderly advisors, case manager	6	5.6	R1
Referral to other health care professional primary care	12	11.1	R1
Referral to day or night care	4	3.7	R1
Referral to specialized care	2	1.9	R2
Assess social map for referral possibilities	9	8.3	C
Plan an evaluation	13	12	C
Discuss outcome home-visit with the GP	13	12	C
Plan follow-up visits	11	10.2	C
Discuss emergency plan	4	3.7	C
Planning a meeting with the family	2	1.9	C

Chapter 7

Frail older people's experience with proactive nurse-led primary care: a qualitative study.

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In revision

Abstract

The aim of this study was to examine frail older persons' perceptions of the roles of the registered practice nurse and how they perceive proactive personalized nurse-led care. A qualitative study nested within a randomized trial in primary care was conducted. In total, 18 semi-structured interviews were performed in a subsample of the intervention and control group. The intervention group received proactive nurse-led care, and the control group usual care. Computer-assisted qualitative data analysis was performed. Participants in the intervention group identified four roles provided by the nurses: monitor, director, coach and visitor. The monitor role – observing and assessing potential risks – was the most important role. Proactive care was appreciated when the relationship, timing and the nurse's role were tailored to the individual needs. In the control group, needs were expressed that could be translated into the nursing roles described. The results highlight preconditions for nurse-led care for older persons.

Introduction

One of the major challenges in primary care is to provide optimal care to an increasing population of frail older people.[1,3] Frail older people face continuous challenges in the physical, cognitive and psychosocial domains of functioning and in their interactions. When the different domains of functioning are unbalanced, frail older people living at home are at risk for a high burden of disease, disability and health care costs.[3] As increasing attention is given to the scarce resources in the health and social sectors, the care provided to this group should be tailored to the needs of the recipients, focused on preserving function and cost-effective.[4,5]

Several studies acknowledge the need for more proactive and comprehensive primary care for frail older people; however, the evidence about the effects is inconsistent.[5-7] A proactive and personalized nurse-led care program (U-CARE) has been developed and is currently being evaluated in the Utrecht Proactive Frailty Intervention Trial (U-PROFIT). A detailed description of the development and the content of the U-CARE intervention has been reported elsewhere.[8] Specially trained registered practice nurses provide a comprehensive geriatric assessment at home (including an assessment of the level of frailty), conduct follow-up visits and coordinate the care of frail older persons. The practice nurses generate individually tailored care plans in close collaboration with the general practitioner (GP) and other health care practitioners. The care plan is approved by older people and/or their caregivers. The nurses synchronize different types of care and adjust them to the recipients' needs. The primary outcomes are the preservation of physical functioning and improvement in the quality of life for frail older people and their caregivers.[9]

In addition to the quantitative evaluation, a qualitative study was performed alongside the trial because qualitative research can improve the usefulness and relevance of the findings of a trial.[10]

The objectives of this study are to examine the frail older persons' perceptions of the roles that registered practice nurses perform and how the proactive nurse-led care is received compared with older persons receiving care as usual. The aim of the study is to inform policymakers and health care professionals about the value of proactive, nurse-led primary care from the perspective of the target group.

Methods

A qualitative study nested within a large cluster-randomized trial was conducted to examine the experiences of older people participating in an intervention group and a control group.

Sample
The participants were recruited from a sub-sample of the participants in the U-PROFIT trial, which includes six general practices in Utrecht, the Netherlands. The patients were screened for eligibility based upon four inclusion criteria: being 60 years or older; having multimorbidity (defined as a frailty index score) and / or having polypharmacy (defined as the chronic use of five or more different medications) and / or having a gap of three or more years in GP care (defined as not having consulted a GP in the past three years except for a yearly influenza vaccination). Terminally ill patients and patients living in an assisted living home or a nursing home were excluded. The inclusion criteria have been described in detail elsewhere.[9]

Community-dwelling older people who were living independently were approached by their GP with a patient information letter and an informed consent form for the trial between October 2010 and March 2011. A questionnaire that screened for frailty was mailed to all of the eligible patients in the intervention group with the specially trained registered practice nurses.
For this qualitative study, a purposive sample was selected from both the experimental group (N=12) and the control group (N=6) to capture the variation that was considered relevant to the topic (see Table 1).

The following criteria were considered in selecting the participants: gender, area of residents (urban or rural), socioeconomic status (SES; based on area of residence), family members providing informal care, and the degree of care needed and received at baseline. Individuals who were not able to speak the Dutch language and those who had serious mental or cognitive disorders were not included.

Twenty older people who fulfilled these criteria were contacted for consent by telephone by the second author [NB]. After they provided consent, the third author [AO] made an appointment for an interview. Two individuals refused to participate; one lacked the time, and one did not want to participate. Eighteen individuals (ten males, eight females) participated in the study.

Interviews

Qualitative interviews were conducted using a semi-structured interview guide in the participants' homes between June and September 2011. In seven instances, the participant's partner joined the interview, and the couple was interviewed together. The interview guide topics related to the participants' current health situation and any changes they had experienced, their living situation, capacity and frailty, social contacts, the care they received, and their satisfaction with their care. The interviewer addressed the participants' experiences with the home visits in the intervention group and explored potentially unfulfilled needs in the control group. An experienced, independent interviewer [AO] with a background in social psychology conducted the interviews. The interviews lasted an average of 1.5 hours and were recorded and transcribed verbatim. Personal identifiers were removed to guarantee the anonymity of the participants.

Medical ethics committee

The U-PROFIT trial, including this qualitative study, was approved by the Institutional Review Board of the University Medical Center Utrecht (UMCU) with the protocol ID 10-149/O and registered in the Netherlands Trial Register (NTR2288).

Analysis

The analysis was performed continuously as the interviews progressed using MAXqda2007 software for qualitative data analysis.[11] First, a thematic analysis was conducted. The analysis began by open coding the interviews to discover important themes that were discussed.[12] The researchers, who came from different backgrounds (nursing, psychology and sociology), discussed the codes. The coding system that resulted from these discussions is shown as subthemes in the left column of Figure 1.

Subsequently, axial coding was conducted; the concepts that turned out to be important were further analyzed and described. They are displayed in the middle column of Figure 1 as superordinate themes. Finally, selective coding was performed: we focused on the relationships between the relevant concepts and developed the master themes (right column of Figure 1).
In addition to the thematic analysis, a case-wise analysis was conducted[13], keeping the context of each separate case intact. For this purpose, summaries were written of each case, enabling us to compare the cases in the intervention group to the cases in the control group.

Results

Aging and support
Eleven participants from both the experimental group and the control group reported that their situation was not quite stable (e.g., they had experienced medication problems, a decline in mobility, a hip operation, loss of sight or COPD; they became forgetful and anxious; their caregivers or therapists had left; they had lost friends and family members). For six participants, their situation had remained the same for the last six months. Several interviewees received a substantial amount of support from family members, mainly their children, who helped them regularly with cooking, shopping for groceries, administration or housekeeping. (Grand-)children and neighbors often looked out for them. Although the participants very much appreciated this help, they did not want to burden the caregivers any more with their worries or with more requests for help.
As shown in Table 1, all of the frail older persons received professional help. They only wished to receive care that was strictly necessary to enable them to remain self-reliant as long as possible and dreaded being admitted to a nursing home. All of the participants except one thought their GPs were technically well skilled, but most of the participants only posed medical questions because the GPs lacked the time to address other issues. The discontinuity in GPs was the biggest problem for the participants, although electronic medical records or scheduling an appointment on the day their GP was present sometimes resolved the problem. Some of the participants had little contact with their GPs. Fifteen participants received help from medical specialists as well.

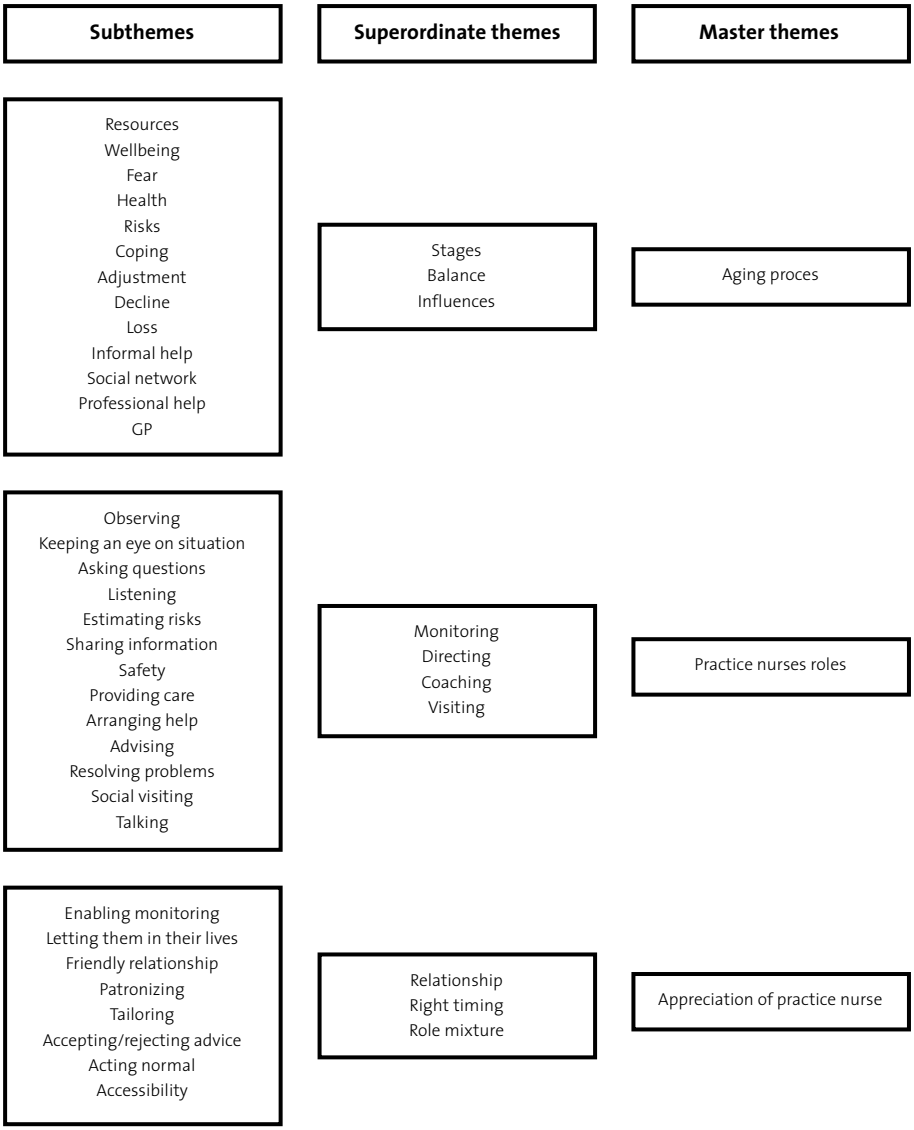

Figure 1. Subthemes, superordinate and master themes that emerged from open coding, axial coding and selective coding.

Table 1. Characteristics of interviewees in the intervention and control group

	Intervention group (n = 12)	**Control group** (n = 6)	**Total** (n = 18)
Age in years			
Mean (SD) Range	79 (78,6) (62 – 93)	78 (77,8) (63 – 93)	78 (62 – 93)
Gender			
Female	6	2	8
Male	6	4	10
Social economic status (SES)			
Low	4	2	6
Middle	4	2	6
High	4	2	6
Living situation			
Alone	5	4	9
Together	7	2	9
Physical limitations and need of help			
Low	-	1	1
Medium	5	3	8
High	7	2	9
Informal caregivers			
Present	3	2	5
Partner	7	2	9
Absent	2	2	4
Professional help			
None/Low	4	3	7
Moderate	-	2	2
High	8	1	9

The roles of the registered practice nurse

Eight participants in the intervention group welcomed the registered practice nurse visits, two participants were neutral and one was negative. Generally, the participants noted that the nurse was a valuable addition to the assistance offered by the GP. Based on the interviews, four different roles of the registered practice nurse could be identified: 1) monitoring, 2) directing, 3) coaching and 4) visiting.

Monitoring role

All of the participants reported that the nurse monitored the frail older person's situation by observing their living situation during the home visit and by asking questions to assess possible health risks and needs:

> 'She is a nurse, so she can easily sense my current mood and whether she is needed here, and if she is not, she quickly disappears. Because she has more clients to visit.' (P02, 83-year-old women living alone)

Generally, the participants' physical and mental health deteriorated slowly and their health complaints accumulated, making it harder to perform daily activities. ('I can't say that I declined rapidly, not at all. It is vicious, sneaky, it gradually deteriorates.' P07, 87-year-old man living alone). In addition to the instability of their situation, the older people experienced fear of falling, deteriorating health, dying and being robbery. Some were anxious that the partners or relatives who lived with them could not handle their share of the responsibilities anymore. The nurse asked probing questions about their worries, including the subtleties, and was aware that if balance in their daily lives was disturbed, more or different help would be needed. The registered practice nurse shared this information with other professionals, including the GP. This service was much appreciated by participants because it partially resolved their problems with discontinuity with their GP and because they did not have to repeat their stories. A participant with a history of psychiatric disease reported:

> 'What I really like is that things I discuss with her don't linger. You notice that she discusses it with the physician. I do not need to tell my whole story again because the doctor is already informed of what I discussed with her earlier.' (P04, 86-year-old woman living with her husband)

The interviewees reported an increased feeling of security because their changing situations were closely monitored by the registered practice nurse. In one case, a son also closely monitored his mother's situation, but the nurse was perceived differently because she can act upon her observations; she knows 'where to be'.

Directing role

The registered practice nurse sometimes provided care or arranged for the assistance that was deemed necessary, according to nine participants. For one couple, she arranged for someone from an elderly home to come over to discuss a possible move. For others, she arranged for a nurse specialist or home visits by thrombosis services. She also initiated extra help, offered help with medication, helped with elastic stockings and demonstrated their use, contacted other professionals (e.g., a medical specialist) when the participant could not remember what was said on the telephone, and arranged for medical equipment, such as a stair lift, a bed and a walker:

> 'My husband needed a walker, and she [the practice nurse] called us asking if we needed anything. Then she said, 'I will take care of getting it sent to you.' And she took care of the bed as well. So, I mean, these are things, and I don't know whether it is part of her job, but I really benefit from it.' (P10, 57-year-old wife of a 62-year-old husband)

In one case, the registered practice nurse informed the participants' children about their father's illness (Parkinson's disease), aiming to help them better understand his disease and to enable them to help support their parents.

Coaching role

Some of the participants put their trust in the registered practice nurse. Five of them discussed various issues with her, including non-medical issues (e.g., divorce in their children's families, grief, disturbed relationships with their children, or concerns about brothers or sisters who widowed). In her coaching role, the nurse offered a listening ear or gave advice and eventually resolved problems. One participant told the practice nurse that she was restless during the day, and the practice nurse recommended that she visit a day care center. The older person took this advice and frequently visits the day care center. Given that many participants lose family members and friends in their social networks (sometimes because of declining mobility but mostly because of death), they also lose persons in whom they can confide. Talking, asking for and receiving advice, and thinking issues through with someone else resulted in calmness among the participants.

> 'Let's see, I think she has visited me seven or eight times (...). Yes, now it is once every three months that she visits me officially. But if I need her, sometimes when I felt anxious and tense, then I called her, and then she would propose to stop by and talk. And then she visits me and makes an appointment. (P11, 81-year-old woman living alone)

Visiting role

According to three participants, the registered practice nurse sometimes came over simply to visit them. Several interviewees noted that their social contacts kept them going, particularly with their children and grandchildren, who sometimes visited or called them every day. Most of them wanted to see their family members more often. Some participants still had several activities and hobbies and thus many social contacts. Six participants, including three couples, were often on their own. Some of the participants were quite comfortable with being alone, but others would have liked more visitors because their contacts had diminished. For them, the registered practice nurse was received as a welcome visitor:

Interviewer: Does she bring you anything when she comes over? Is it helpful in any way?
Participant: No, nothing special. I like it when she stops by to talk, of course, but otherwise, I do not care.
Interviewer: Is the situation different now compared to before she came here?
Participant: Well, you meet someone. (P2, 83-year-old female who lives with her son)

Factors related to the appreciation of the registered practice nurse
The participants' appreciation of the care offered by the registered practice nurse and optimal outcomes depended on the extent to which the care matched the older person's own ideas and situation. We found three factors that affected the participants' opinions about whether the care was appropriately tailored:

1 the relationship between the registered practice nurse and the frail older person;
2 the timing of the visits and the care advised or offered by the registered practice nurse;
3 the mixture of roles that the registered practice nurse performed in a specific situation.

Relationship

Most of the participants appreciated the home visits by the registered practice nurse and described her as a friendly person. They appreciated that the practice nurse acted 'normally' (i.e., her visits had an informal character that made it easier to talk freely with her). Several participants mentioned that they could ask her many types of questions and share their concerns with her. When there was a good relationship, it increased the older person's feeling of well-being, and the care provided by the practice nurse was viewed more positively.
Three participants were not clear about who had sent the registered practice nurse, what her role was, and when and if she would return.

For two participants, this uncertainty produced a neutral feeling about her visits; for one participant, it led to dissatisfaction. When the relationship was poor, there were more arguments about the advice and care offered. A positive, open relationship between the older person and the registered practice nurse helped the participants to accept her presence and proactive activities.
A receptive attitude enabled the practice nurses to function as a monitor and to take the needs and wishes of the older people into account when giving advice or arranging for assistance. For example, when the husband in a couple was admitted to the hospital, the practice nurse arranged for his wife to receive a medication carousel to prevent her from experiencing medication problems.

Appropriate timing
It was highly important that the home visits by the registered practice nurse and the advice given were well-timed. A few frail older persons gave examples of the practice nurse's coaching role in which she gave them just-in-time assistance that met their needs, such as a stair lift and meals on wheels. If the ti-ming was appropriate, the nurse could also be valuable in her directing role. For example, the nurse arranged for a wheelchair for a male participant who was initially skeptical about using one. When advice and care were badly timed, they were sometimes experienced as overwhelming and patronizing, potentially resulting in rejection. Even if they were well-timed, they were not always welcomed immediately because the participants wanted to maintain their situation and preserve their regular routine. One participant influenced the timing of care by initiating contact herself and informing the practice nurse about a new development in her situation (i.e., the results of a consultation with a lung specialist).

Mixture of roles
In the examples given by the frail older persons, the registered practice nurse often performed several different roles at once. For the participants to appreciate the tasks performed by the practice nurse, the mixture of roles had to match the older individuals' situations. The majority of the interviewees were satisfied with the way the practice nurse carried out the home visits. In most cases, she primarily played the monitoring role combined with the directing role and/or the coaching role.

The older persons appreciated that the nurse knew when and how to interfere and when to withdraw. One couple was pleased with the practice nurse who monitored them but also knew when to withdraw:

> 'She really tries to find out what kind of people we are. That is how it should be. You need to try to have a nice conversation. We are very satisfied. (...) She is a kind person. Of course, it is nice that they try to prevent chaotic situations here. They want to stay in touch. But they do understand that there is really nothing going on here. I got her card, and if there were ever an emergency, we could call her. But it is not necessary. (P05, 87-year-old woman living with her 93-year-old husband)

Some of the participants liked having her as a visitor; others thought that visiting was not a task that should be performed by a professional nurse.

Control group: could the practice nurse have made a difference?
There were no differences between the six participants in the intervention group and the individuals in the control group with regard to the GP relationship and the accessibility of their GPs. They received a substantial amount of help from family caregivers; two participants had family members who monitored their overall situation daily. Although the participants in the control group had difficulty speculating about the benefits of a practice nurse, they could imagine the advantages of having a registered practice nurse and presumed that she would complement the GP. However, during the interviews, they denied that they needed a practice nurse because they were doing fine, they had good contact with the GP, and they did not need extra medical help. During the interviews, they described aspects of aging and support that were similar to the descriptions given by their counterparts in the intervention group. For some of the participants, a registered practice nurse might have been valuable. She could have acted as a monitor and provided the GP with insights about the actual frailty of the older adults. For the interviewees in the control group who had few contacts with the GP and/or the pharmacist, the practice nurse could have tried to increase the amount of contact between them while acting as a coach or director. Some participants suggested that they needed someone to accompany them to the hospital.

A few older persons who lived alone mentioned that they would appreciate talking to other people more often to share their thoughts. In these cases, a practice nurse could have fulfilled the role of a coach or visitor. This role might also have benefitted some spouses who supported their partners. A few frail older persons reported that a practice nurse would be welcome (or even a "God-send"): someone to talk to, to rely on and to help brainstorm solutions:

> 'It would be nice if I had someone behind the scenes as a kind of in-between for ordinary issues, someone who comes to discuss them with you. I do not mean directly for medical issues, but just for difficulties; for instance, I need to go to the hospital and do you think someone could accompany me? (...) Someone who will come talk to you on a reasonably intellectual level, to discuss things with, ordinary things. (...) In fact, a friendly person to whom you feel comfortable saying, "This really stinks" or "Listen to this fun story!"' (P15 control group, 76-year-old man living alone)

Several participants in the control group noted that it would be important for the care offered by the registered practice nurse to meet their individual needs. They indicated that it would be crucial for the practice nurse to build a professional and friendly relationship with them and to take on different roles at the right time, echoing the voices of the participants in the intervention group.

Discussion

In this qualitative study, the experiences of frail older people in an intervention group that received proactive home visits from a registered practice nurse were compared with the experiences of a control group who received the usual standard of care. Generally, the frail older persons in the intervention group welcomed the initiative demonstrated by the practice nurse in the general practice. The participants' perceived that the registered practice nurse performed four roles: monitoring, directing, coaching, and visiting. The monitoring role was performed in tandem with the other roles, and if the monitoring role was performed adequately, the other roles could be played depending on the specific situation.

Tailoring the care to match the individual needs of the older persons with respect to the relationship, the timing and the mixture of roles performed strongly influenced the extent to which the participants appreciated the care provided by the registered practice nurse. If the care was well regarded, the older persons were more likely to accept it, which helped them to anticipate changes or handle the consequences of aging more easily. Some older persons in the control group had difficulty imagining what the practice nurse could do for them. Nonetheless, they expressed needs that could be met by a practice nurse performing the roles that the intervention group described.

The results of this study showed that older persons with multiple problems are open to receiving proactive, nurse-led primary care, and overall, they had more opportunities to address non-medical concerns and issues that affect 'old people'. This finding is in line with the study by Fortin et al. (2010), in which the patients welcomed the contributions of nurses in primary care but noted that the professional roles and fields of doctors and nurses should be clear to them.[14] The participants in our study considered the practice nurse to be part of the GP's practice, but they were sometimes in doubt about her position (i.e., whether she was sent by their GP, what her purpose was, and whether she would visit them again). In addition, van Kempen et al. (2012) reported that most older persons had positive opinions about receiving home visits, and they recommended that well-being, psychosocial issues and relationships with health professionals should be addressed during these home visits.[15]

The roles of monitor, director, coach and visitor align with the professional terms used by Frazier (2006)[16]. According to these authors, anticipatory guidance should target expected changes, potential changes, and situational changes; accomplishing these tasks requires assessing, monitoring, coordinating, and managing the health status of patients over time.

The visitor role was also described in an integrated research review of preventive home visits by McGarry (2008).[17] The authors described the visitor role as a 'professional friendship', emphasizing the need to maintain professional distance and clear boundaries.[18] In an environment such as the home, it might be difficult to define or manage boundaries. If the relationship between nurses and frail older persons is central to the patient experience and the perceptions of the quality of care overall[18], then the implicit qualities that are valued in nurse–patient relationships in this context (e.g., listening skills, attention, and trustworthiness) must be recognized and made more explicit.

Many of the frail older persons received a substantial amount of care from their family members. Family caregivers are important monitors, but they do not always take action and act more as 'good listeners'.[19] The registered practice nurse, in a more professional role, not only acts as a good listener but also has the ability to act upon her observations and to coordinate health and social services, to prioritize care needs, and to communicate with other primary care providers as well as family caregivers. Previous research has shown that older patients with multimorbidity desired someone to perform these tasks; they described an ideal process of care that was patient-centered and tailored to their needs.[20] With regard to the need for services, the main concerns and needs were related to maximizing independence and living a full life.[19]

Strengths and limitations

Some limitations and strengths of the study must be considered when interpreting the findings. Frail older persons experience a delicate balance between their health status and their resources (e.g., support or equipment). As a consequence, their situation can change from day to day, and it is possible that we might have missed important changes by performing a one-time observation. Furthermore, the participants can refrain from addressing serious or complex individual problems during one session with an interviewer. However, the interviews were conducted by a trained interviewer who, in our opinion, gained the trust of the participants and succeeded in prompting them to discuss their concerns. In the intervention group, the participants gave examples of the benefits of the practice nurses' home visits. However, we do not know how their situations would have developed without the proactive care of a practice nurse. In a similar vein, we do not know how the participants in the control group would have regarded the practice nurse's care. A strength of our qualitative study is that it was conducted alongside a large cluster randomized trial that evaluated the effectiveness of a complex multicomponent intervention. This practice remains uncommon in complex intervention trials, but it enhances our understanding of the participants' experiences with the intervention.10 To our knowledge, this is the first study that used qualitative methods to examine how frail older persons experience proactive, nurse-led primary care and to determine the roles that the registered practice nurse plays for them.

The results of this study suggest that providing proactive nurse-led care for frail older persons is inherently complex because of the substantial heterogeneity of this population. Although registered practice nurses should play several roles, the monitor role seems crucial for providing the appropriate type and amount of care at the right time to meet the recipient's needs. A 'one-size-fits-all' approach is unlikely to be effective in this population.[21] To play all required roles adequately, practice nurses for frail older persons act as case managers; at the least, they should have good communication skills, sufficient clinical expertise, knowledge of the health care system and problem solving skills.[22] The results of this study are valuable for other registered practice nurses who provide care to frail older persons. Moreover, educators can use the results to educate nursing students about the acceptance of proactive care by older persons.

Conclusion

In conclusion, proactive nurse-led care is appreciated by frail older persons when the care is tailored to their current situation and the dynamics of their circumstances. Generally, the initiative of the registered practice nurse in the general practice was welcomed. The value of the monitor role, which underlies the roles of director, coach and visitor, is that practice nurses can act upon their observations and anticipate possible changes to prevent the need for more complex and expensive health care services. The relationship with the nurse and the timing of the care provided are important for ensuring the acceptability of care, which in turn promotes shared understanding and adherence to preventive advice and care. Exploring how proactive nurse-led care is regarded and whether it is appreciated may encourage adequate and acceptable care for frail older persons in the future.

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Chapter 8

Which older patients benefit most from a multicomponent nurse-led primary care program? Individualized prediction for preservation of physical functioning based on trial data

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Submitted

Abstract

Purpose: In a large trial, a multicomponent nurse-led care program has shown to preserve physical functioning in frail older people in primary care. Our objective is to identify individual characteristics of older people who are most likely to benefit from this personalized care.
Methods: We used data of one intervention arm of the U-PROFIT trial, which included 1,293 independent-living older people. Successful treatment was defined as preservation or improvement of physical functioning measured with the Katz-15 Activities of Daily Living (ADL)/Instrumental Activities of Daily Living (IADL) scale. Candidate predictors were collected using self-report questionnaires and electronic patient data from the general practice. A multivariate logistic regression model was fitted. A backward selection process resulted in a reduced final model. The performance of the model was expressed by discrimination.
Results: The final model showed that older patients were most likely to perceive benefits from personalized care if they had fewer medications in chronic use, higher education level, and higher self-reported quality of life (QoL) and were not using a walking aid. The strongest predictor was using a walking aid (OR 0.52 [0.36-0.75]). The model showed a moderate to good ability to discriminate between older patients who will or will not benefit from the treatment (AUC 0.65 [0.61-0.70]). The majority of the patients with successful treatment had preserved physical functioning and 27.2% showed an improvement on the Katz 15 or one point or more.
Conclusion: This re-analysis provides insights into which people are most likely to benefit from a multicomponent nurse-led care program and provides valuable starting points for further refinement of the intervention. Future trials are needed to determine if benefits can be achieved in more vulnerable older people.

Introduction

As the population ages, a new model for elderly care is needed to better maintain independence and to promote quality of life (QoL) in older people.[1,2]
Despite the fact that several comprehensive multicomponent care models have been evaluated, the results are inconclusive, and it remains unclear which older people benefit most.[3,5]
Randomized trials are the most appropriate method to evaluate an intervention; however, trials report their treatment effects on mean group level, suggesting that all patients have the same likelihood responding to treatment. This assumption is incorrect; as treatment effects for individual patients vary[6,7], especially in the heterogeneous group of older people.[3,5]
Subgroup analyses make it possible to identify characteristics of patients at different levels of treatment response. This is limited by the fact that the study sample is often divided according to the presence or absence of one single patient characteristic and it reduces power.[8] To identify individual patient characteristics associated with optimal intervention effect, trial data can be used to develop prediction models estimating treatment effect for individual patients.[9]
Recently, in a cluster randomized trial (U-PROFIT), we evaluated a screening and monitoring intervention (U-PRIM) and U-PRIM followed by a multicomponent nurse-led care intervention (U-CARE) aiming at preserving physical functioning and improving QoL in older persons in primary care. We demonstrated that both interventions significantly preserved physical functioning in frail older people at a one-year follow-up.[10] Subgroup analyses for socioeconomic status and education level showed significant interaction effects favoring the U-PRIM plus U-CARE intervention. We concluded that the effectiveness and impact of the multicomponent U-PRIM plus U-CARE intervention are dependent on individual patient characteristics.[10]
In this reanalysis of the U-PROFIT trial data, we aimed to identify the individual characteristics of the older people who benefited most from this multicomponent nurse-led care based on the U-PROFIT data.

Methods

The U-PROFIT trial data

In this study, we constructed a prediction model from individual patients' characteristics using the data from the U-PRIM plus U-CARE intervention arm from the U-PROFIT trial. Only the patients who were indicated as frail on the Groningen Frailty Indicator and received personalized nurse-led care were included in this study. Details and outcomes of the U-PROFIT trial are described elsewhere.[11] In short, the single-blind three-armed cluster randomized trial evaluated the effectiveness of a frailty screening and monitoring intervention (U-PRIM), and U-PRIM followed by a multicomponent nurse-led care program (U-PRIM+U-CARE) on the preservation of physical functioning in older persons at a one- year follow-up. Eligible patients were enrolled in the U-PROFIT trial between October 2010 and March 2011.The U-CARE program included the following components: a frailty assessment, a comprehensive geriatric assessment at home for those patients who were found to be frail on the Groningen Frailty Indicator (GFI)[12], a tailor-made care plan, care coordination and multiple follow-up visits. Specially trained registered nurses were employed and embedded within the primary care center, and they delivered the program in close collaboration with the GP and other health care professionals in primary care. A detailed description has been published.[13]

Prediction of intervention effect for individual patients - outcome

Preservation of physical functioning was measured with the Katz-15 scale, which includes Activities of Daily Living (ADL) and Instrumental Activities of Daily Living (IADL) items.[14] All items of the Katz 15 were scored as zero or one, with a higher score indicating a higher ADL/IADL dependency. A successful treatment was defined as having the same or a lower Katz score (indicating a better level of physical functioning) at a one-year follow-up when compared to baseline and without any admission to an assisted living facility or nursing home. Unsuccessful treatment was defined as having a score of one or more on the Katz-15 scale at a one-year follow-up (lower level of physical functioning), being admitted to an assisted living facility or nursing home, or death.

Candidate predictors

We selected candidate predictors for functional decline based on the literature and clinical reasoning. Since limitations in physical functioning are often influenced by multiple health conditions, a prediction model that includes predictors of multiple domains is recommended.[15] To enhance our understanding of which domains contribute most to successful treatment the International Classification of Functioning and Disability was used as a conceptual model in this study.[16] The predictors were categorized in the domains of the ICF model of health condition, body structure & body function, environmental factors, personal factors and participation (Figure 1).

Health condition

The presence of the following chronic diseases was identified using self-report questionnaires: diabetes, heart failure and COPD/Asthma. Furthermore, a frailty index score based on routine care data was included.[17] The frailty index included 50 deficits and was defined as the proportion of deficits present, theoretically ranging from zero (fit) to one (extremely frail).[17] The number of medications in chronic use was included as a continuous variable.[18, 19] The frailty index and number of medications were extracted from the electronic medical record data from the general practice.

Body structure & body function

Using self-report questionnaires the following functions were assessed: vision problems[20, 21], hearing problems[21], weight loss[18, 20], falls ('have fallen once or more within the pasts six months?')[22], urinary incontinence[23], and cognition problems.[20] Cognition was assessed with one item from the GFI questionnaire ('Do you have any complaints about your memory?').[24]

Environmental factors

Satisfaction with care, assessed on a scale from 0–10, and history of hospitalization in the past year, and using a walking aid were assessed using a self-report questionnaire.[25]

For study purposes we assessed whether the nurse was already embedded in general practice prior to the trial, and whether the general practice was a single or group practice.

Personal factors

Information about age, gender, educational level (categorized as low, moderate, or high) and living situation (alone or with others) was obtained. Self-rated health[25, 27] was assessed on a scale from 0–10 (a higher score indicates that the respondent feels healthy). Depressive feelings 20 were assessed with one item of the GFI questionnaire ("In the past four weeks, did you feel downhearted or sad?"). All candidate predictors were assessed using self-report questionnaires.

Participation

Loneliness[28] was assessed with one item of the GFI questionnaire ("Do you sometimes miss people being around").

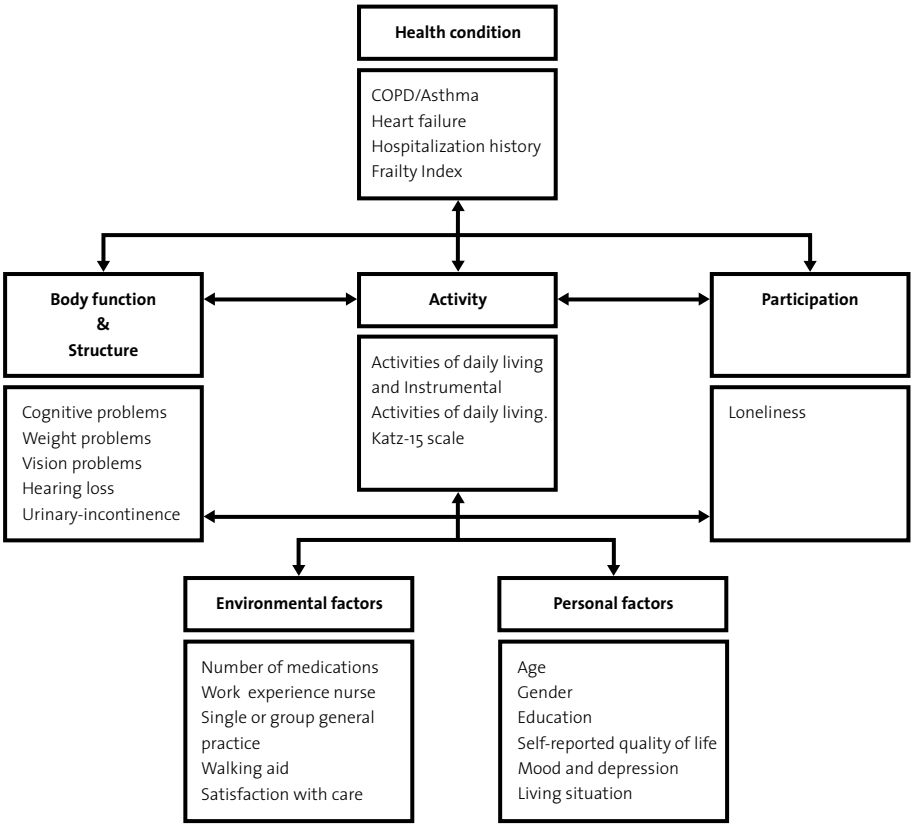

Figure 1. Categorization of the domains of functional decline (ADL/ IADL) measured in the present study based on the ICF-model.

Data analysis

Univariable associations between the candidate predictors and successful treatment were estimated with logistic regression analysis. The overall percentage of missing data was 3.1%. Missing data rarely occur at random, and a complete case analysis (deletion of all patients with one or more missing values) may result in a loss of statistical power and biased results. We therefore applied multiple imputation to address missing values in the candidate predictors. Missing data was imputed 10 times, and subsequent results in each of the 10 imputations were pooled with Rubin's rule.[29, 30]

Age, the frailty index score, number of medications in chronic use, self-reported health, and satisfaction with care were analyzed as continuous variables. Linearity of their association with the outcome was assessed using restricted cubic spline analyses.[31] All other variables were included as dichotomous or categorical variables. No selection was made based on these estimations, since selection of predictors based on univariable statistics may result in unstable prediction models.[31]

The predictors in the final model were identified using a backward stepwise selection procedure using Akaike's information criterion, which corresponds to selection based on a p-value of 0.157.[31, 32, 33] The regression coefficients and standard errors of the final predictors were combined from the ten datasets using Rubin's rule to come to the final prediction model.[29]

The results are reported as odds ratios (ORs) with 95% confidence intervals (CIs). The ability of the model to discriminate between older persons with and without functional decline was studied with the area under the Receiver Operating Characteristics (ROC) curve (c-statistics). All analyses were performed in SPSS Statistics version 20.0 (IBM, New York, NY, USA) and with the rms package in R version 2.15.0 (The R Foundation for Statistical Computation, www.r-project.org).

Results

The total number of frail older people based on the GFI in the U-PRIM plus U-CARE intervention group was 835. At the one-year follow-up, 478 (57.3%) of the patients in the U-PRIM plus U-CARE intervention arm had a successful treatment (Table 1). Two patients had been admitted to a nursing home, two had been admitted to an assisted living facility, and 39 (3%) patients had died by the one-year follow-up. Characteristics of the participants with successful and unsuccessful treatment are presented in Table 1.

Persons with successful treatment were somewhat younger, reported a higher QoL, and had a higher educational level. The patients with successful treatment 72.8% preserved physical functioning and had the same Katz-15 score after twelve months, 19.7% of the patients had an improvement of one point, and 7.5% of the patients had an improvement of more than one point on the Katz-15. Patients with more than one point improvement on the Katz were somewhat older (Table 2).

The cubic spline analyses showed that age, frailty index and number of medication were linearly related to the outcome, i.e. preservation or improvement on physical functioning.

In the multivariable analysis, age, gender, number of medications in chronic use, frailty index score, education level, self-reported QoL, and the use of a walking aid were identified as predictors of successful treatment (Table 3). The most significant predictors were the use of a walking aid (OR [95% CI], 0.52 [0.36-0.75]) and high education level (2.08 [1.11-3.91]) whereas the weakest predictor was gender (1.02 [0.74-1.40]) (Table 3). The c-statistic of the model was 0.65 (95%CI [0.61-0.70]), which indicates a moderate discriminative ability between persons who will have a successful treatment and persons who will have an unsuccessful treatment (Figure 2).

Table 1. Baseline characteristics of the study population and the univariable associations between potential predictors in functional decline (n=835).

	Unsuccessful treatment* N = 357	**Successful treatment§ N = 478**	**OR**	**95% CI**
Health condition				
Diabetes	117 (32.8)	153 (32.0)	0.97	0.72-1.29
Heart failure	90 (25.2)	115 (24.1)	0.94	0.68-1.30
COPD / Asthma	106 (29.7)	112 (23.4)	0.73	0.53-0.99
Hospitalized last year, yes	96 (26.9)	120 (25.1)	0.91	0.67-1.25
Frailty Index score^, median (IQR)	0.08 (0.06-0.12)	0.06 (0.04-0.10)	0.86	0.82- 0.91
Body function & Body structure				
Weight loss	57 (16.0)	71 (14.9)	0.92	0.63- 1.34
Vision	162 (45.4)	188 (39.3)	0.78	0.59-1.03
Hearing loss	189 (52.9)	243 (50.8)	0.92	0.69-1.21
Urinary incontinence	182 (51)	239 (50)	0.96	0.73-1.27
Memory loss	221 (61.9)	275 (57.5)	0.83	0.63-1.10
Falls	122 (34.2)	193 (40.4)	1.30	0.98-1.74
Personal factors				
Age^, mean (SD)	76.14 (8.4)	74.85 (8.4)	0.98	0.97-1.00
Female	232 (65.0)	306 (64.0)	0.96	0.72-1.28
Educational level -Low	174 (48.7)	187 (39.1)	1 (ref)	-
Educational level Average	155 (43.4)	210 (43.9)	1.26	0.94- 1.69
Educational level High	28 (7.8)	81 (16.9)	2.69	1.67- 4.34
Self-reported QoL, mean (SD)	6.85 (1.2)	7.14 (1.2)	1.21	1.08-1.35
Mood, depression	239 (66.9)	298 (57.2)	0.82	0.61-1.09
Environmental factors				
Number of medications in chronic use^, mean (SD)	7.8 (2.7)	7.1 (2.8)	0.91	0.87- 0.96
Satisfaction with care, mean (SD)	8.06 (1.2)	8.0 (1.7)	0.96	0.85- 1.08
Living situation, alone	192 (53.8)	255 (53.3)	1.02	0.77-1.34
Together with others	165 (46.2)	223 (46.7)		
Using a walking aid	170 (47.6)	142 (29.7)	0.47	0.35-0.62
Group practice	296 (82.9)	373 (78.0)	0.73	0.52-1.04
Nurse in practice prior to the study	183 (51.3)	266 (55.6)	1.19	0.91-1.57
Participation				
Loneliness	238 (67.0)	321 (67.3)	1.01	0.76-1.36

*§Successful treatment was defined as having the same or a lower Katz score (indicating a better level of physical functioning) after one-year follow-up. * Unsuccessful treatment was defined as a score of 1 or more on the Katz-15 scale after one year-follow-up (lower level of physical functioning), or when admitted to assisted living facility, nursing home, or death. ^ Effects are depicted per year increase in age, deficit increase in the Frailty Index score, per adjacent medicine in chronic use. QoL score: Quality of life score between 0-10*

Table 2. Characteristics of patients with successful treatment (N=478)

	Patients with preserved physical functioning, N= 348 (72.8%)	**Patients with an improvement in physical functioning of one point, N= 94 (19.7%)**	**Patients with an improvement in physical functioning of ≥ one point, = 36 (7.5%)**
Age, mean (SD)	74.9 (8.4)	73.5 (8.2)	78.3 (7.9)
Female, %	212 (60.9)	64 (68.1)	30 (83.3)
Living situation, alone	181 (52)	59 (62.8)	15 (41.7)
Number of medications of chronic use, mean (SD)	6.7 (2.6)	8.2 (2.9)	8.4 (3.1)

Table 3. Multivariable associations of selected predictors for successful treatment*.

Predictors	**Model 1**		
	B	**OR (95% CI)**	**P**
Intercept	1.38		
Age^	-0.18	0.98 (0.97-1.00)	0.04
Gender, female	0.15	1.02 (0.74-1.40)	0.93
Number of medications in chronic use^	-0.54	0.95 (0.89-1.01)	0.07
Education –low (ref.***) Education – moderate Education – high	0 0.18 0.73	1 1.20 (0.86-1.68) 2.08 (1.11-3.91)	 0.28 0.02
Self-reported QoL**	0.10	1.11 (0.97-1.26)	0.12
Walking aid, yes	-0.66	0.52 (0.36-0.75)	0.001
Falls	0.31	1.36 (0.98-1.89)	0.11

*Notes: *Results based on 10 Imputed dataset, see text for details. ^ Effects are depicted per year increase in age, deficit increase in the Frailty Index score, per adjacent medicine in chronic use. **QoL score: Quality of life score between 0-10. *** Reference category*

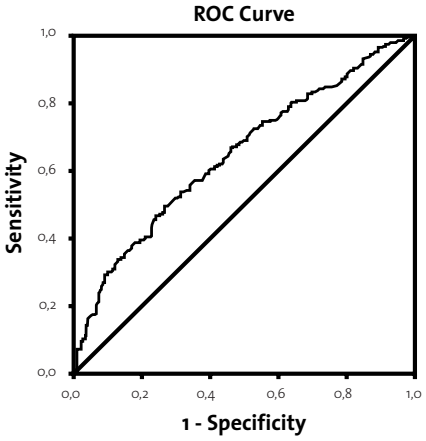

Figure 2. ROC curve.

AUC 0.65 (95% CI: 0.61-0.70)
**Note: The figure was constructed on the mean of the 10 imputations.*

Discussion

In this study, we identified individual patient characteristics associated with successful preservation of physical functioning in older people who participated in a structured proactive elderly care program consisting of frailty screening and personalized nurse-led care. Older people with fewer medications in chronic use, higher self-reported QoL, and higher educational level and those not using a walking aid were most likely to perceive benefits from the personalized care program. In the group of patients with a successful treatment, 27% showed an improvement on the Katz-15 of one point or more and 72.8% preserved physical functioning.

Interpretation & comparison literature

In the WHO ICF model, multiple domains of health condition, body function, body structure, environmental factors, personal factors, and participation contribute to a deterioration of physical functioning.[16] The results of the current study show that the majority of the predictors for successful treatment were related to the domain of personal factors (age, gender, education, and self-reported QoL) from the ICF model. Only one predictor related to the environmental domain (number of medications) was included in the final prediction model. The results of this study support the assertion of the WHO ICF model and of other studies[16, 34] that multiple domains contribute to predicting functional decline.[15, 16]

Our results are mainly in line with the findings in the literature concerning the prediction of functional decline in older people. Poor walking ability and gait speed have been reported as strong predictors of functional decline and mortality in other studies.[20, 25, 27]

Negative self-rated health has been reported in several studies as a predictor of functional decline in older people[20, 25, 27] and positive self-rated health as a predictor of IADL improvement.[27] Cognitive status has been consistently reported as a predictor of functional decline.[27, 35] We could not confirm this in our study, which could be explained by the way in which cognitive status was assessed. Most studies do this using the Mini Mental State Examination (MMSE), whereas we included only one cognitive question.[36]

It may have been that our cognition item was not sensitive enough to discriminate between patients with and without cognitive complaints.
An increasing number of chronic diseases have been frequently reported as important predictors of functional decline in older people.[25] We included diabetes, heart failure, and asthma/COPD as single predictors rather than as a sum score for chronic disease. The predictive ability of these individual chronic diseases is probably incorporated in other candidate predictors, such as the number of medications in chronic use and the frailty index, as the performance of the model was comparable when this predictor was excluded.
The effectiveness of multicomponent care programs to preserve physical functioning in older people is inconsistent due to the large heterogeneity of studies and intervention components.[3, 5] Few trials have examined which subgroup of older people benefits most from intervention, since many of these trials had limited power to detect treatment subgroup interactions.[8] In line with the trial results, education level was identified as a strong predictor and showed that older people with a higher education are most likely to benefit from personalized care.10 It is important to note that a predictive relation does not equal a causal relation.[37] We do not assume that educational level contributes to a successful treatment but that educational level is an indicator of socioeconomic status, which is a well-known predictor for health status and a predictor of functional decline.[38, 39] Although the association between socioeconomic status, health status, and functional decline in older people has been widely established[40, 41], to our knowledge, no other trials have reported a subgroup effect on educational level or socioeconomic status.
Our results show that age was not the strongest predictor of successful treatment (0.98 [0.97-1.00]). This finding conflicts with the results of a systematic review.[5] The authors reported that younger people had more favorable outcomes in terms of physical functioning, living at home, and nursing home admission.[5] Although people in our study with successful treatment were somewhat younger compared to the unsuccessful treatment group, a subgroup analysis on age did not showed a significant interaction effect.[10] There is a lack of consensus among studies regarding the effectiveness of care models in patients at high or low risk of functional decline.[3, 5]
Some studies have reported that proactive care models are most effective in patients at high risk of functional decline.[42]

Conversely, others have reported benefits among people at low risk at baseline.[43] The findings of our study suggest that older persons with a relatively good physical health status are more likely to receive benefits from comprehensive nurse-led care. The results of the current study may therefore support the hypothesis that preventive interventions are most successful at early reversible stages in the process from health to physical decline.[44]

Strengths and limitations

Some limitations need to be addressed when appreciating the results.
The U-PROFIT trial had a relatively short follow-up period of one year.
The duration of follow-up, however, should preferably be long enough to provide meaningful treatment effects.[45] Since favorable intervention effects of the U-PROFIT strategy were observed most clearly after twelve months, but not after six, we assume that more benefits may be observed after longer follow-up.[10] This, in turn, may influence the results in the present study. We used a subsample of the U-PROFIT dataset, resulting in a selected group of patients, which is inherent to trial designs. Patients were included when they met the eligibility criteria, but, as expected, frail patients or patients with substantial cognitive problems or low literacy were probably not included. This is known from other trials in this population and may hamper the generalizability of the results.[46] However, the number of frail older patients that participated in this study was substantial.

This is, to our knowledge, the first study to identify characteristics of older people who are likely to benefit most from a multicomponent nurse-led care program using individualized prediction. A prediction model for estimating the effect of preservation of physical functioning was developed based on a subsample of the U-PROFIT trial data. The major advantage of this method is that we were able to identify multiple characteristics that are associated with successful treatment whereas subgroup analyses are often limited by a reduced power.[8]

Although we attempted to identify predictors of successful treatment, our objective was not to develop a clinical prediction rule for nurses or doctors in the general practice. This re-analyses enhances our understanding of the characteristics of the individual patients who are likely to respond positively to a proactive personalized nurse-led care program.

The findings of this study add to the accumulating evidence of multicomponent interventions and shows that multiple characteristics contribute to successful treatment. The identification of patient characteristics who benefit most provide valuable starting points for further refinement and of the multicomponent nurse-led U-CARE intervention such as targeting older patients at risk. The results of this study show that beneficial effects of the nurse-led intervention were obtained in a study population who have a relatively good health status, with relatively less conditions and medications, suggesting that intervening at an early age is promising. Future trials are needed to determine if substantial improvements can be achieved in more vulnerable older people, especially those who are less educated and are living in socioeconomically deprived areas.

In conclusion, older people with a relatively low number of medications in chronic use, a higher education level, and a higher self-reported QoL and those not using a walking aid are most likely to benefit from personalized nurse-led care in terms of preservation or improvement of physical functioning. Our findings support the notion that multiple domains contribute to the preservation of physical functioning. We have shown that with a limited number of predictors, we were able to provide more insight into which people are most likely to benefit from a personalized nurse-led care program.

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Chapter 9

Associations between Frailty, Complex Care Needs and Quality of Life in multi-morbid older people

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Submitted

Abstract

Objectives: The objective of this study was to determine the relationship between frailty, complexity of care and quality of life in multi-morbid older people.
Study design: A total of 1150 multi-morbid older people living in the community were included in this cross-sectional study. Using questionnaires the level of frailty was assessed with the Groningen Frailty Indicator, complexity of care needs was measured with the Intermed Self-Assessment. Quality of life was measured with the Short Form 36. The relationships between frailty, complexity of care and quality of life were examined with Pearson's correlation. Associations between frailty, complexity of care, quality of life and its individual determinants were examined by multivariable linear regression.
Results: In total, 758 out of 1150 (65.9%) patients were frail, 8.3% had complex care needs, and the mean quality of life score was 7.1. Correlations between frailty and complexity, frailty and quality of life, and complexity of care and quality of life were 0.67, -0.51 and -0.52 respectively. All patients with complex care needs were frail, but, only 12.5% of the frail patients had complex care needs. Low education, problems with walking on stairs, falls, urinary incontinence and decreased appetite were associated with higher levels of frailty and complexity of care but with a lower quality of life.
Conclusions: Three groups were identified: multi-morbid patients, multi-morbid and frail patients and multi-morbid, frail patients with complex care needs. Lower levels of QoL were observed when the number of geriatric conditions, frailty status and level of complex care needs increased.

Introduction

The concepts complexity of care and frailty are frequently used synonymously to identify vulnerable older adults, although both should be recognized as distinct concepts that are causally related.[1,2] Frailty can be defined as a progressive condition that is associated with adverse health outcomes, including functional decline, long-term care and mortality.[3,4] Although several methods are used to identify patients with increased health care needs, no definition of complexity of care has been widely established.[5,6] Multi-morbid older persons experience problems in diverse domains, and therefore, there is a growing consensus that an assessment of bio-psychosocial health care needs is required.[7,8]
In the literature, various instruments have been described to measure frailty, resulting in a broad range of prevalence in community-dwelling older people. [9,11] However, less attention has been paid to studying both concepts together combined with quality of life in multi-morbid older people in primary care. Understanding these concepts and their interactions are essential to improve the quality of care of older people with multiple problems. The early detection of complex care needs combined with the level of frailty enables the design of a proactive process of care, meeting the needs of older people.[12] Moreover, understanding their inter-relationships will encourage the development of tailored interventions to prevent onset and adverse outcomes of multi-morbid older persons in the future.[4,13]
Therefore, the aim of this study was to determine the relationship between frailty, complexity of care, and quality of life (QoL) and to examine their inter-related associations in multi-morbid older patients living in the community.

Methods

Design

A cross-sectional study nested in a cluster randomized trial was conducted in a primary care setting. The patients were enrolled from 13 primary care practices in and around Utrecht, the Netherlands, who participated in the Utrecht Primary Care Proactive Intervention Trial (U-PROFIT trial). [14]

Participants

Multi-morbid older people aged 60 years or older who lived independently in the community were eligible for inclusion in the study. The criterion 'polypharmacy' was used as a proxy for multimorbidity[15] and defined as chronically using 5 or more different medications that were prescribed at least three times in the past year, with at least one prescription in the last six months. Eligible patients were selected by a software program, which was applied to the electronic medical record system of the GP. Patients were enrolled between October 2010 and March 2011. Terminally ill patients or patients living in an elderly home or nursing home were excluded. A patient information letter and informed consent form were sent to all eligible patients. Patients who gave informed consent received a questionnaire. If the patient was not able to fill out the questionnaire, a proxy or assistance by a nurse was initiated. The study was approved by the Institutional Review Board of the University Medical Center Utrecht (UMCU) with protocol ID 10-149/O.

Measurements

Frailty - The Groningen Frailty Indicator (GFI)

The GFI is a validated 15-item self-reported questionnaire that measures the loss of functions and resources in 4 domains: physical (9 items; shopping, walking around outside, dressing, toileting, physical fitness, vision, hearing, weight loss, and medication), cognitive (1 item; cognitive dysfunction), social (3 items; emotional isolation) and psychological (2 items; depressed mood and feelings of anxiety). [3, 16] The frailty score ranges from 0 (not frail) to 15 (severely frail), and a score of 4 or greater is considered the cut-off point for frailty.[16] The GFI has shown high internal consistency and construct validity.[9] Recently, a comprehensive psychometric evaluation of this self-reported questionnaire was conducted. The authors concluded that the instrument was feasible and valid for home-dwelling and institutionalized older persons.[17]

Complexity of care - Intermed Self-Assessment for the Elderly (IM-E-SA)

The Intermed is a valid and reliable instrument that assesses case complexity and health care needs of patients using a biopsychosocial model and developed to foster better coordinated and integrated health care.[18] The patients' complexity of care is characterized by 4 domains: biological, psychological,

social and health domains.
Several adjustments were made to adapt this instrument to a self-reported questionnaire for the elderly population (IM-E-SA).[19] The instrument consists of 20 items, and the score ranges between 0 and 60. A score of 21 or higher indicates high complexity. Recently the reliability and validity has been assessed. The internal consistency was good (Cronbach's alpha 0.78) and correlations for convergent validity were moderate to strong (0.50-0.70).[19]

Quality of life and perceived health status
Two items of the domain general health of the Short Form 36 (SF-36) were used to measure QoL and perceived health status.[20] QOL was measured with the following question: *"What mark would you give your quality of life at this moment (mark between 0-10)?"* A higher score indicates a higher QoL.
A subjective evaluation of perceived health status was measured with the following question: *"In general, how would you say your health is; very good, good, fair, poor or very poor?"* The reliability of this sub-scale of the SF-36 ranges between 0.74 and 0.81.[21]

Socio-demographic determinants and geriatric conditions
The following additional socio-demographic variables were included: age, gender, living situation, marital status, social economic status and education level. Geriatric conditions that were not part of the GFI questionnaire, such as urinary incontinence, problems with walking on stairs, decreased appetite and falls, were included, as these are known risk factors for functional decline and a lower state of frailty.[22, 23] Furthermore, these conditions are related to the phenotype concept of frailty proposed by Fried, in which frailty is defined by the presence of three or more elements of weakness, poor endurance, weight loss, low physical activity and slow gait speed.[2] The following questions were asked: "Do you have urinary incontinence problems", "Do you have problems with walking on stairs", "Did you have a loss of appetite last week" and "Did you fall or have multiple falls during the last six months".

Statistical analysis

Descriptive statistics were used to provide an overview of the study population. Total scores, means and standard deviations of the GFI, IM, and QoL were calculated. Pearson's Chi-square test and Student's t-test were used for dichotomous and continuous variables to test differences between frail and non-frail patients in age, gender and QoL. Pearson's correlation coefficient was used to assess the relationship between frailty, complexity of care and QoL. Linear regression analysis was used to estimate the association between potential determinants and frailty, complexity of care and QoL. Three models were constructed. In the first model, crude betas and 95% confidence intervals (CIs) were calculated; the second model was adjusted for age and gender; and the third model was adjusted for more potential confounders, including age, gender and education.[24] Significance levels were set at $\alpha = 0.05$ for all tests. Analyses were performed with SPSS version 20 (IBM, New York, NY, USA).

Results

In total, 3257 patients of the 13,000 were selected based on the polypharmacy criterion, of which 1150 patients (35.3%) participated in the study. The mean age was 75 years (SD: 8.2), most patients were female (58.5%), and 22.2% had an educational level of primary school or less.

Frail and non-frail patients

The prevalence of frailty (GFI ≥ 4) in this multi-morbid population was 65.9% (758 out of 1150). Table 1 shows the differences between frail and non-frail patients. Frail patients were older, more often female and more often alone lived compared to non-frail patients. Only 12.5% of the frail patients had complex care needs. All frail patients had significantly higher care needs on all biopsychological domains compared to non-frail patients. Almost half of the non-frail patients (54.1%) reported their health as 'good' or 'excellent' compared to 16.1% of the frail patients (Table 1).

Complexity of care

In total, 95 out of 1150 patients (8.3%) had complex care needs. The care needs of older patients were most frequent in the biological domain.

Females had more complex care needs than males (p 0.04). The oldest people (> 75 years) had more complex care needs on the biological, social and health care domains compared to respondents between 60 and 74 years of age. Except for one, all patients with complex care needs were frail (Table 1). Frail patients with complex care needs were significantly less educated, suffered from significantly more geriatric problems, and perceived a lower health state and lower QoL compared to frail patients without complex care needs (Table 1).

Quality of life

The mean score of health-related QoL in the total population was 7.1 (SD: 1.2). Frail patients reported a significantly lower QoL score compared to non-frail patients. Frail patients with complex care needs reported a significantly lower QoL compared to frail patients without complex care needs. In total, 16.4% of the frail patients without complex care needs reported their health status as 'excellent' or 'good', whereas only 4.2% of the frail patients with complex problems labeled their health status as such (Table 1).

Table 1. Characteristics of patients, non-frail and frail patients

	All patients N = 1150 (100%)	**Multimorbid N= 392 (34%)**	**Multimorbid and Frail patients N = 663 (57.7%)**	**Multimorbid and Frail and Complex N= 95 (8.3%)**
Age, mean (SD) - 60-74 years, n (%) - >75 years, n (%)	75 (8.2) 556 (48.4) 593 (51.6)	74.2 (7.7) 206 (52.6) 186 (47.4)	75.4 (8.4) 350 (46.2) 407 (53.7)	74.6 (.0) 48 (50.5) 47 (49.5)
Gender, female, n (%)	673 (58.5)	181 (46.2)	492 (64.9)	65 (68.4)
Marital status, Married Widowed	595 (51.7) 304 (26.4)	260 (66.3) 66 (16.8)	335 (44.2) 238 (31.4)	39 (41.1) 26 (27.4)
Education level primary school or less, n (%)	255 (22.2)	51 (13)	204 (26.9)	35 (36.8)
Living situation, Alone, n (%) Together with others, n (%)	457 (39.7) 693 (60.3)	97 (24.7) 295 (75.3)	360 (47.5) 398 (52.5)	46 (48.4) 40 (42.1)
Geriatric conditions Urinary incontinence problems	491 (42.7)	106 (27)	385 (50.8)	61 (64.2)
Problems with walking the stairs	651 (56.6)	132 (33.7)	519 (68.5)	80 (84.2)
Decreased appetite	433 (37.7)	83 (21.2)	350 (46.2)	53 (55.8)
Fall problems	358 (31.7)	73 (18.6)	285 (37.6)	55 (57.9)
Medications in chronic use, median (IQR)	7 (5-9)	6 (5-7)	7 (6-9)	8 (6-11)
GFI score †, mean (SD) GFI score ≥ 4, n (%)	5.1 (2.7) 758 (65.9)	2.1 (0.8) -	6.6 (2) 758 (65.9)	8.51 (2.2) 95 (100)
Intermed score ‡, mean (SD) Intermed score ≥ 21, n (%) Biological domain (score 0-20, mean, SD) Psych domain (score 0-20, mean, SD) Social domain∞ (score 0-20, mean, SD) Health care domain (score 0-20, mean, SD)	12.5 (5.7) 95 (8.3) 10.8 (3.7) 4 (3.4) 3.3 (3.0) 5.9 (3.1)	8.6 (3.4) 1 (0.3) 8.7 (3.5) 2 (2.5) 2 (2.3) 4.9 (2.8)	14.5 (5.6) 95 (12.5) 11.8 (3.4) 5 (3.4) 4.1 (3.1) 6.4 (3.1)	24.75 (4.4) 95 (100) 14.73 (2.5) 8.69 (3.4) 7.29 (3.1) 8.23 (3.1)
Self-rated health, excellent or good, n (%)	353 (27.4)	230 (54.1)	123 (16.1)	4 (4.2)
Quality of life, mark between 0-10, mean (SD)	7.1 (1.2)	7.83 (0.9)	6.8 (1.2)	6 (1.3)

† GFI score ranges from 0-15. A score of ≥ 4 indicates frail. Number of questions and score range per domain: Physical domain: 9 questions, score range 0-9; Cognitive domain 1 question, score range 0-1; Social domain: 3 questions, score range 0-3, Psychological domain: 2 questions, score range 0-2.
‡ Intermed score ranges from 0-60. A score of ≥ 21 score indicates high complexity of care. ∞ All domains have a score range between 0-20.

Interrelationships and associations

A moderate-strong positive correlation was observed between frailty and complex care needs ($r = 0.67$, $p < 0.01$). With an increase in the level of frailty, the complexity of care also increased. A moderate negative correlation was observed between frailty and QoL ($r = -0.51$, $p < 0.001$) and complex care needs and QoL ($r = -0.52$, $p < 0.01$). Table 2, 3, and 4 shows the factors associated with frailty, complexity of care and QoL, respectively. In the multivariate model adjusted for age, gender and education, decreased appetite, problems with walking on stairs, urinary incontinence, low education and falls were significantly ($p =< 0.001$) associated with a higher level of frailty and complexity of care and a lower level of QoL (Figure 1).

Based on our results, three groups of patients were identified: 1. multi-morbid patients (n=392; 2. multi-morbid, frail patients (n=663); and 3. multi-morbid, frail patients with complex care needs (n=95) (Figure 2). QoL declined over the groups, while the number of geriatric conditions increased.

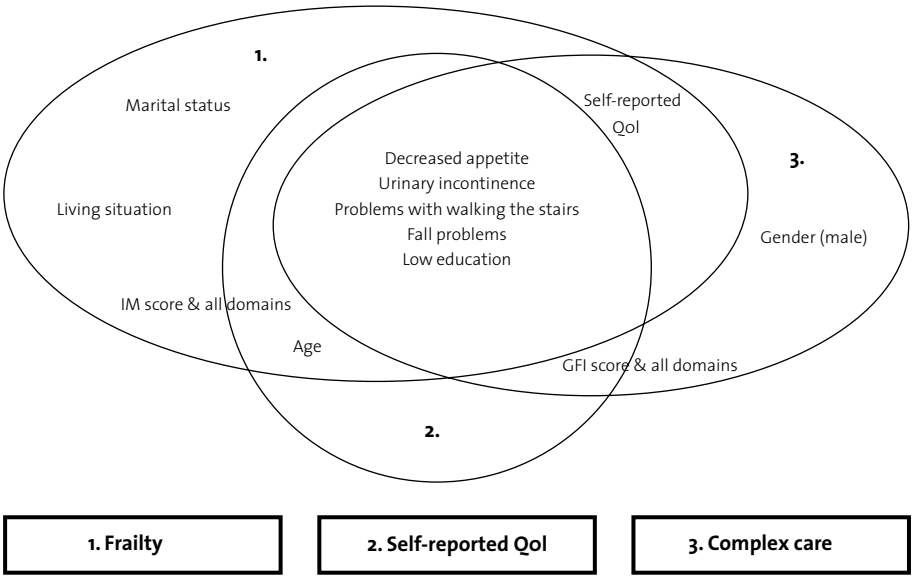

Figure 1. Factors associated with Frailty, Complex care needs, Quality of life*

*Result from three linear regression model (frailty, self-reported QoL, Complex care), adjusted for age and gender (n=1150). All significant factors are reported. IM score: Intermed Assesment for the elderly score. Domains: biological, social, psychosocial and health care associated with frailty and self-reported QoL. GFI score and domains associated with self-reported QoL and Complex care.

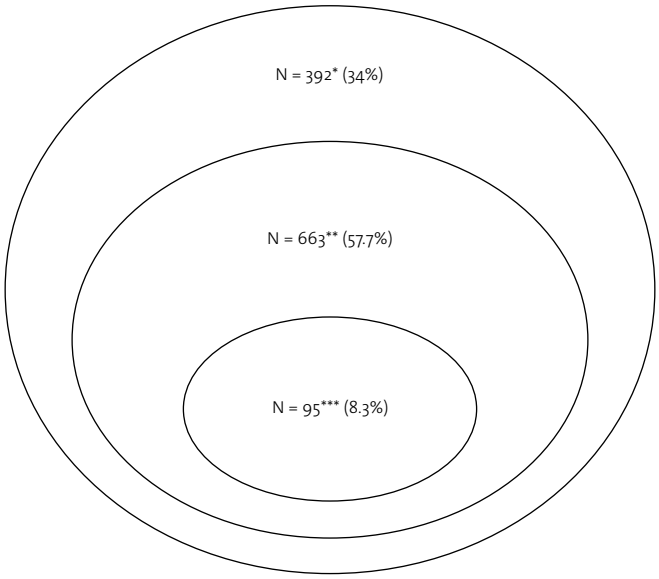

Figure 2. Overview and overlaps of multimorbidity, frailty, complexity of care.
Three groups of multi-morbid older patients (N=1150).

* N= 392 multi-morbid patients. ** N = 663 Frail multi-morbid patients. *** N= 95 Frail multi-morbid patients with complex care needs.

Discussion

In this study, we explored the relationships between the concepts of frailty, complex care needs and QoL in independently living older people with multimorbidity. The prevalence of frailty was 65.9%. Correlations between frailty and complexity, frailty and QoL, and complexity of care and QoL were 0.67, -0.51 and -0.52 respectively. Notably, almost all persons with complex care needs were frail; in contrast, only a small number of frail patients had complex care needs. Determinants associated with the concepts frailty, complexity of care and QoL were 'decreased appetite', 'urinary incontinence', 'problems with walking the stairs', 'fall problems' and 'low education'. Three groups of patients could be defined: multi-morbid patients who were frail and had complex problems reported more health problems and perceived a lower level of QoL compared to frail patients who did not reported complex care needs.

Some limitations of this study must be considered when interpreting these findings. First, due to the cross-sectional design, we cannot infer causality. Second, it is likely that the frailest people or people who suffer from cognitive problems were most likely not included in this study, which is known from other studies in older people[25]. Third, in the current study, we used the Groningen Frailty Indicator to measure frailty. Despite its validity and feasibility in clinical practice, there is currently no agreement on the best method to measure frailty in clinical practice. We considered age, gender and education to be potential confounders. Although associations remained significant after adjustment, residual confounding by known and unknown factors cannot be ruled out. Finally, the cut-off score of complexity of care needs was set at 21. However, it has been shown that older patients indicated themselves as less case complex compared with the assessment conducted by a research nurse and optimal cut-off values may vary between study populations.[19]

Our study has several strengths. To our knowledge, this is the first study that explores the interrelationships between frailty, complex care needs and QoL in a large population of multi-morbid older people in the community. The findings of this study provide an in-depth understanding of these concepts, which may help clinicians in primary care to prioritize care for multi-morbid older people. Our selection of multi-morbid older people was based on the polypharmacy criterion. Selection of polypharmacy patients can easily be conducted in existing EMR data in clinical practice. This enables general practitioners and nurses in primary care to easily select this group of patient supporting the generalizability of the results. Moreover, based on our results, this criterion appear to be a potentially good screenings method for frailty and it can be used to estimate medication-related adverse effects in older adults.[26] Furthermore, our results are important for the development of tailored interventions for multi-morbid older people in primary care in the future.[27]

Consistent with the literature, frail people are more often older, female, widowed, less educated and have a lower state of QoL compared to non-frail people.[28, 29] The prevalence of frailty in community-dwelling older people varies among different studies. In this study, we found a prevalence of frailty of 65.9%, which is much higher than comparable studies that measured frailty in older patients with the GFI.

Peters et al reported a prevalence of 46%, as measured with the GFI, in a population of people aged 65 years or older living independently at home.[17] Another study in the Netherlands found comparable results of 46.3%.[9] Furthermore, a moderate-strong correlation was observed between complexity of care and frailty, which is in line with the results of a previous study.[19] The high prevalence of frailty in our study may be explained by our selection criterion of multi-morbid older patients that resulted in probably frailer people compared to other studies. Despite a strong correlation between frailty and complexity was observed, the concepts frailty and complexity cannot be used interchangeably. This finding is comparable with a qualitative study and concluded that the dynamic nature of frailty and complexity has implications for clinical nursing care that require further investigation.
A negative correlation between frailty and QoL was observed, which is consistent with the literature, although different instruments were used.[30] Our findings showed that decreased appetite, urinary incontinence, problems with walking on stairs and fall problems were strongly associated with a higher probability of frailty, measured with the GFI. These conditions are comparable and related to the core 'frail' elements of the proposed phenotype frailty concept by Fried.[2]

Implications for clinical practice

Meeting the health care needs of multi-morbid older people in primary care is an ultimate challenge for general practitioners and nurses in primary care.[31] Understanding and identifying the concepts of frailty and complexity of care is an important first step in meeting the health care needs of older people.[12] Moreover, it allows clinicians, nurses and health care workers in primary care to prioritize and organize care. A comprehensive multidimensional approach including biological, psychological, social and cognitive domains will provide valuable knowledge of the individual patient and may enhance the development of tailor-made interventions in the future.[4,12] Although we observed some overlap between frailty, complexity of care and QoL, this does notindicate a homogeneous care approach in primary care. Older people with multimorbidity are heterogeneous in terms of functional status, prognosis and preferences, even when they experience the same pattern of medical conditions.[32]

Therefore, the screening and comprehensive assessments of frailty and care needs are highly recommended, enables to focus on the preferences and goals of the patient and not only on the disease. Preventive proactive and cost-saving strategies aimed at maximizing patient independence and functioning are urgently needed to improve the care for multi-morbid older patients in primary care.[31, 32]

In conclusion, we observed some overlap between frailty, complexity of care and QoL and three groups of multi-morbid older patients were identified: multi-morbid patients, multi-morbid, frail patients and multi-morbid, frail patients with complex care needs. Lower levels of QoL were observed when the number of geriatric conditions and the level of frailty and complex care needs increased. Future longitudinal research should focus on how the transitions between the three groups of multi-morbidity occur over a longer period of time.

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Table 2. Factors associated with frailty, measured with the GFI. Linear regression coefficients B and 95% CI (N = 1150)

	Crude model		Adjusted model[2]		Adjusted model[3]	
	B	**95% CI for B**	**B**	**95% CI for B**	**B**	**95% CI for B**
Age (in years)	0.03**	0.01; 0.05	0.02***	0.01; 0.05	0.02**	0.003; 0.04
Gender (male)	1.00***	0.70; 1.30	0.98***	0.68; 1.28	0.88***	0.57; 1.19
Marital status, married	-1.06***	-1.35; -0.75	-0.78***	-1.10; -0.46	-0.69 ***	-1.01; -0.37
Education level, primary school or less	1.41***	1.04; 1.77	1.26***	0.90; 1.62	1.26 ***	0.90; 1.62
Living independent alone	1.06***	0.76; 1.36	0.77***	0.46; 1.09	0.80 ***	0.47; 1.12
Decreased appetite	1.94***	1.64; 2.23	1.82***	1.52; 2.11	1.70***	1.39; 1.48
Problems with walking the stairs	2.21***	1.93; 2.49	2.07***	1.79; 2.36	2.0***	1.66; 2.25
Urinary incontinence	1.55***	1.26; 1.85	1.40***	1.10; 1.71	1.29***	0.98; 1.60
Fall problems	1.65***	1.34; 1.97	1.56***	1.25; 1.87	1.45***	1.13; 1.77
Intermed (IM-E) score total	0.32***	0.30; 0.34	0.31***	0.29 ; 0.33	0.31***	0.29; 0.33
- Biological domain	0.36***	0.33; 0.40	0.35***	0.32; 0.38	0.33***	0.30; 0.37
- Psychological domain	0.44***	0.40; 0.47	0.42***	0.39; 0.46	0.41***	0.37; 0.45
- Social domain	0.40***	0.35; 0.45	0.38***	0.34; 0.47	0.37***	0.32; 0.42
- Health care domain	0.27***	0.25; 0.34	0.27***	0.23; 0.32	0.24***	0.19; 0.28
QoL mark	-1.15***	-1.26; -1.04	-1.11***	-1.22; -1.00	-1.06***	-1.18; -0.95

Model[2]: Adjusted for age and gender. Model[3]. Adjusted for age, gender and education level. * <0.05. ** <0.01 *** <0.001

Table 3. Factors associated with complexity of care. Linear regression coefficients B and 95% CI (N= 1150)

	Crude model		Adjusted model[2]		Adjusted model[3]	
	B	**95% CI for B**	**B**	**95% CI for B**	**B**	**95% CI for B**
Age (in years)	.015	-0.02; 0.05	0.01	-0.03; 0.05	0.001	-0.04; 0.04
Gender (male)	1.56***	0.93; 2.20	1.58***	-0.03; 0.05	1.38***	0.74; 2.03
Marital status, married	-0.94**	-1.59; -0.28	-0.43	-1.12; 0.25	-0.24	-0.91; 0.44
Education level, primary school or less	2.51***	-1.76; 3.26	2.30***	1.54; 3.05	2.30***	1.54; 3.05
Living independent alone	.948**	0.30 ; 1.60	0.51	-0.17; 1.18	0.55*	-0.13; 1.24
Decreased appetite	1.94***	1.64; 2.23	3.26***	2.63; 3.89	2.90***	2.25; 3.54
Problems with walking the stairs	2.21***	1.93; 2.49	4.43***	3.83; 5.04	4.1***	3.48; 4.72
Urinary incontinence	1.55***	1.26; 1.85	2.41***	1.76; 3.05	2.10***	1.45; 2.75
Fall problems	1.65***	1.34; 1.97	3.28***	2.62; 3.94	3.06***	2.39; 3.74
GFI score (total) - Physical domain - Psychological domain - Social domain - Cognitive domain	1.39*** 1.93*** 3.74*** 2.05*** 2.41***	1.30; 1.47 1.74; 2.12 3.44; 4.04 1.81; 2.29 1.80; 3.02	1.39*** 1.91*** 3.70*** 2.00*** 2.41***	1.30; 1.48 1.73; 2.10 3.39; 4.00 1.76; 2.24 1.81; 3.02	1.34*** 1.85*** 3.53*** 1.89*** 2.16***	1.25; 1.43 1.65; 2.05 3.22; 3.84 1.65; 2.14 1.54; 2.79
QoL mark	-1.15***	-1.26; -1.04	-2.39***	-2.62; -2.16	-2.28***	-2.51; -2.05

Model[2]: Adjusted for age and gender. Model[3]. Adjusted for age, gender and education level. * <0.05. ** <0.01 *** <0.001

Table 4. Factors associated with self-reported Quality of life. Linear regression coefficients B and 95% CI (N= 1150)

	Crude model		Adjusted model[2]		Adjusted model[3]	
	B	**95% CI for B**	**B**	**95% CI for B**	**B**	**95% CI for B**
Age (in years)	-0.00***	-0.01; 0.01	0.00	-0.01; 0.01	0.001	-0.01; 0.01
Gender (male)	-0.31	-0.45; -0.17	-0.31	-0.45; -0.18	-0.25	-0.39; -0.11
Marital status, married	0.18	0.04; 0.32	0.10	-0.05; 0.25	0.07	-0.08; 0.22
Education level, primary school or less	-0.42	-0.58; -0.25	-0.38***	-0.54; -0.21	-0.38***	-0.54; -0.21
Living independent alone	-0.19***	-0.33; -0.04	-0.11	-0.26; 0.04	-0.09	-0.24; 0.06
Decreased appetite	-0.59***	-0.73; -0.45	-0.55***	-0.69; -0.41	-0.52***	-0.66; -0.38
Problems with walking the stairs	-0.82***	-0.95; -0.68	-0.79***	-0.93; -065	-0.75***	-0.89; -0.61
Urinary incontinence	-0.34***	-0.48; -0.20	-0.28***	-043; -0.14	-0.25***	-0.39; -0.10
Fall problems	-0.48***	-0.63; -0.33	-0.46***	-0.61; -0.31	-0.42***	-0.57; -0.27
GFI score (total)	0.23***	-0.25; -0.21	-0.23***	-0.25; -0.20	-0.22***	-0.24; -0.20
- Physical domain	-0.33***	-0.37; -0.29	-0.33***	-0.37; -0.28	-0.31***	-0.36; -0.26
- Psychological domain	-0.60***	-0.68; -0.53	-0.37***	-0.50; -0.23	-0.57***	-0.65; -0.50
- Social domain	-0.34***	-0.39; -0.28	-0.33***	-0.38; -0.27	-0.32***	-0.37; -0.26
- Cognitive domain	-0.37***	-0.51; -0.23	-0.59***	-0.67; -0.52	-0.33***	-0.47; -0.19
Intermed (IM-E) total score	-0.11***	-0.12; -0.10	-0.11***	-0.12; -0.10	-0.11***	-0.12; -0.10
- Biological domain	-0.12***	-0.14; -0.10	-0.12***	-0.13; -0.10	-0.11***	-0.13; -0.09
- Psychological domain	-0.15***	-0.17; -0.13	-0.15***	-0.16; -0.13	-0.14***	-0.16; -0.12
- Social domain	-0.15***	-0.17; -0.13	-0.15***	-0.17; -0.13	-0.14***	-0.16; -0.12
- Health care domain	-0.10***	-0.13; -0.08	-0.10***	-0.12; -0.08	-0.09***	-0.11; -0.07

Model[2]: Adjusted for age and gender. Model[3]. Adjusted for age, gender and education level. * <0.05. ** <0.01 *** <0.001

Chapter 10

General discussion

General discussion

The aim of this thesis was to develop and evaluate a multicomponent nurse-led care program to preserve physical functioning and enhance quality of life of frail older people in primary care. The work of this thesis adds to the accumulating evidence of interventions to maintain independence and wellbeing of older people. We successfully developed and evaluated a multicomponent nurse-led care program to preserve physical functioning and enhance quality of life of frail older people in primary care. Key elements of the intervention were the multidisciplinary, structured, and personalized care approach.

In this chapter, we discuss the main findings and reflect on choices and considerations regarding the development and content of the intervention and the methodological aspects of our study. Specific emphasis will be put on the role of the nurse within proactive personalized care. Implications and recommendations for future research, education, and clinical practice will be given.

Main findings

- The multicomponent nurse-led U-CARE program was developed using an extended multi-method procedure and in close collaboration with a multidisciplinary team of GPs, registered nurses, experts and an independent panel of older people.

- Our study showed that a frailty screening intervention (U-PRIM) and U-PRIM followed by U-CARE both preserved physical functioning in frail older people in primary care better than routine primary care at one-year follow-up.

- Stronger favorable effects were observed for more highly educated patients. No significant differences were observed for quality of life measured with four domains of the Short-Form-36 (physical, mental, vitality, social), EQ5D or health care consumption rates.

- The U-CARE program was highly appreciated by the nurses and GPs and considered the program valuable for the implementation and coordination of personalized proactive care. They perceived the program as feasible in general practice.

- A comprehensive evaluation of the actual nursing care delivered within the U-CARE program showed that the intervention was tailored to the individual needs of the patients, but not all intervention components were delivered as planned. The trial results may have underestimated the true effects.

- Interviews with a subsample of older persons showed that personalized nurse-led care was well appreciated when the relationship, the timing, and nurses' roles were tailored to the patient needs.

- Secondary analysis of our trial data, we showed that older people who have a relatively low number of chronic medications, a higher education level, a higher self-reported quality of life and who are not using a walking aid are most likely to benefit from personalized nurse-led care.

Reflections on the intervention development and content of the U-CARE intervention

The U-CARE intervention is a multicomponent intervention that consists of three steps: a frailty assessment, a comprehensive geriatric assessment at home, and a tailor-made care plan. During the trial, a total of 21 specially trained registered practice nurses were embedded in the participating general practices to execute the program. In the next paragraph, we reflect on the choices made in the development and content of the U-CARE intervention.

Developing a multicomponent intervention
To develop U-CARE we used the UK Medical Research Council framework for the development and evaluation of multicomponent complex interventions.[1] This framework consists of the following four non-linear phases: development, feasibility / pilot phase, evaluation, and implementation.[1]

We used this framework to make practical and methodological choices in the process of the U-CARE intervention development, and we perceived this as a useful theoretical guide.[2] In this thesis, the first three phases of the framework are described (Chapter 2-6).[2,3] The studies conducted in each phase did built up accumulating evidence and provided highly valuable information regarding the content and the effectiveness of the different components of the intervention.

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Proper reporting of a multicomponent intervention

There has been much criticism regarding the inadequate reporting of non-pharmacological interventions making replication almost impossible.[4] Details regarding the why, when, and how much, are often lacking in reports on multicomponent non-pharmacological interventions.[4,5] To allow replication, we described the development process of the U-CARE intervention in detail (Chapter 2).[2] This detailed description is highly valuable for other researchers and practitioners, stimulates effective implementation and is essential to further improving multicomponent interventions aiming at preserving functional decline in older people.

Components of the U-CARE intervention

Multiple factors and disorders are associated with ADL and IADL disabilities in older people.[6,7] The WHO International Classification of Functioning (ICF) presented ADL and IADL as a multifactorial concept that emphasizes the need for a multifactorial approach in the preservation of physical functioning in older patients.[8] Therefore, we developed a comprehensive program that focused on a broad spectrum of diseases in older people. Components such as a multidimensional comprehensive geriatric assessment and evidence-based care planning were described as potentially effective to preserve physical functioning in older people. We built on existing evidence and defined guiding components in collaboration with researchers and practitioners in primary care and older people (Box 1). The guiding components are discussed below.

Box 1. The guiding components are discussed below.

- **Targeting older patiens at risk for functional decline**
- **Biopsychosocial assessment**
- **Focus on patient's needs**
- **Evidence-based**
- **Feasible in clinical practice**

Targeting older patients at risk of functional decline

The identification of older patients at risk of functional decline and who are likely to benefit from proactive care is not easy.[9] In the literature, there is no consensus regarding the optimal instruments and strategies for frailty screening in primary care, but a multi-stage selection process has been recommended.[10,11] In our U-PROFIT trial, we used a two-step selection process.[12] First, the U-PRIM instrument identified potentially frail older patients based on available routine patient data in the participating practices. The U-PRIM criteria included polypharmacy, a care gap (the number of days that a patient did not visit the GP) and a frailty index. The frailty index was based on the concept of accumulated deficits collected from routine care data[13,14] which has been put forward as an attractive approach in primary care.[15]

In a second step, the Groningen Frailty Indicator (GFI)[16] was used to assess frailty in more detail, but, only in the U-PRIM plus U-CARE intervention group. This self-report questionnaire covers the physical, mental, social, and cognitive domains of frailty.[17] The advantage of this second step is that it selected patients with increased care needs, and it excluded the patients without additional care needs. We showed that this stepwise strategy, consisting of selection in routine patient data followed by a frailty questionnaire is a feasible and efficient approach to identify frail older people in the general practice.[18] Moreover, the nurses and GPs perceived that this strategy target frail patients at risk and in need for additional care (Chapter 4).[3]

Bio-psychosocial assessment and focus on patients' needs

The majority of older persons experience problems in multiple domains and an assessment of bio-psychosocial health care needs is generally recommended.[19, 20] To address all domains, we also included the Intermed for the Elderly Self-Assessment instrument (IM-E-SA) in our frailty assessment.[21] This instrument is specially developed to identify the care needs and case complexity in older people.[21] In addition, the Groningen Wellbeing Indicator (GWI) and three separate questions regarding the risk of falling, urinary incontinence, and nutritional deficits were included in the frailty assessment of the U-CARE program (Chapter 2).[2] Two recently published studies support the feasibility reliability and validity of the IM-E-SA and the GFI.[17, 21] In a subsample of our participants, we observed some moderate overlap between the concepts frailty and complexity of care (correlation: 0.67) and that all patients with complex care needs were frail, but, only 12.5% of the frail patients had complex care needs (Chapter 9). In our trial, the self-reported questionnaires were returned to the practice nurse who entered the answers on a website that was specially developed for study purposes. The outcomes of the GFI, IM-E-SA, and GWI were directly visualized for the nurses, with the geriatric conditions in need for further assessment colored in red. The nurses emphasized that in some cases, the results of the frailty assessment did not match with the actual situation that they saw in the patients' home (i.e. more or less frail compared to the outcome of the frailty assessment) (Chapter 4).[3] This mismatch was observed in situations where a caregiver or partner was involved.

However, both nurses and GPs reported the fact that frail older people are "more visible" in the general practice as major advantage of this strategy is that (Chapter 4).[3] Thus, although the outcome of the frailty assessment was not always representative, it contributed to a complete overview of the actual and individual care needs of the patient. In addition, the frailty assessment provided valuable starting points for the provision of personalized care (Chapter 4).[3]

Evidence-based interventions and feasible in routine clinical practice
Evidence-based care planning, followed by multiple interventions and follow-up and care coordination by one single care provider have been proposed as key elements to include in multicomponent care programs.[22, 24] In our study, we developed unique evidence-based care plans for eleven common geriatric conditions (Chapter 2). These care plans were developed using a well-structured approach consisting of literature and guideline review combined with practical experiences from the nurses', expert opinion and target group evaluations. Although this multi-method approach was costly and time-consuming, we showed that this approach resulted in an intervention that was acceptable and feasible in clinical practice.[2] Each evidence-based care plan started with one or more additional assessments to assess the specific type and severity of the problem. These assessments guided the choice of interventions. Earlier, it was noted that a panel of older people was involved during the development of the U-CARE program. Their opinion and suggestions were highly valuable during the development process. We asked their opinion regarding the 11 conditions included in the program. The panel was very positive however, the panel commented that "pain" and "sleeping" were perceived as common problems in older persons and recommended developing evidence-based care plans for these conditions (Chapter 2). We agreed that these are important problems that should be addressed during the CGA, but we choose to include conditions which are described in the literature as common risk factors for functional decline.[25] However, including these problems should be reconsidered since these a common in older people.[26, 27]

The evidence-based care plans were highly appreciated by the nurses.[3] The nurses perceived that the care plans provide a comprehensive overview of evidence-based interventions, more focus, and new insights and improve the care for older people in primary care.[3] Prior to the start of the trial, the process of frailty assessment and delivery of the evidence-based care plans were tested in clinical practice (Chapter 2). We consider the multidisciplinary collaboration with nurses and GPs, and the input of a panel of older people as essential for the development of a multicomponent intervention, and for the acceptance and successful implementation of the program in clinical practice.[2]

Experiences of patients, nurses, and GPs

Evaluation of a multicomponent non-pharmacological intervention is challenging. Not only patient outcomes should be considered but also process outcomes (i.e., experiences, barriers, and facilitators of successful implementation).[28, 29] Qualitative methods can provide valuable information on how the intervention works and how it can be optimized.[30] In this thesis, we used multiple methods to improve our understanding of the intervention. An extended multi-method evaluation was conducted to assess the expectations and experiences of the nurses and the GPs with the intervention (Chapter 4)[3], and a qualitative study was conducted on the level of patients (Chapter 7). In the qualitative study, we demonstrated that the U-CARE intervention was highly appreciated by patients when the nursing care was tailored to their individual care needs, and when the timing and relationship with the nurse was optimal (Chapter 7). If the care was well appreciated, the older persons were more likely to accept it, which helped them to handle the consequences of aging more easily. Although the importance of the nurse-patient relationship has been extensively reported in the literature[31, 32], the impact of this relationship on the results of our study was difficult to assess. We showed that both nurses and GPs perceived the U-CARE program as highly valuable for the implementation of structured care for frail older people. We showed that active involvement of older persons and of nurses and GPs during the development process was feasible and resulted in a program that matched the needs of its users.

Methodological reflections

The U-PROFIT trial is the first trial in which the U-PRIM combined with the U-CARE intervention was evaluated on a large scale in daily routine clinical practice. Out study showed that the combined intervention preserved physical functioning in frail older people after one-year follow-up. In the U-PROFIT trial, several choices were made regarding the design, setting, patients, and outcome measurement. We will discuss in more detail if and how these choices may have influenced the results.

Design

A single-blind three armed cluster randomized controlled trial was chosen to evaluate the effectiveness of the U-PRIM, and of the combined U-PRIM and U-CARE intervention.[12] The use of three arms allows for a valid comparison of both interventions with usual care. We chose for randomization at cluster level, since randomization at the individual level would have resulted in contamination (the unintentional spillover of the intervention effects from one treatment group to another).[33,34] In addition, the nurses and GPs could not be blinded because they were part of the intervention, making randomization on individual level not feasible. Alternative designs (e.g., a pre-post design) were less appropriate as they lack a valid control group comparison. To maintain a single-blind design, we used a modified informed consent procedure and the patients were not aware of the intervention arm they were allocated to and were only fully informed at the end of the follow-up period.[35] This enabled us to minimize selective inclusion and obtain a valid assessment of subjective outcome measures.[36]

Prior to the start of the trial, we hypothesized that the combined strategy of U-PRIM followed by U-CARE would result in more beneficial effects than the U-PRIM intervention alone. However, this was not the case. We choose an intention-to-treat analysis to compare the effectiveness of both interventions with usual care. This technique may have reduced the magnitude of the effectiveness of the interventions because only in the U-PRIM plus U-CARE group, an additional frailty assessment, (the GFI) was used. Personalized nurse-led care was only initiated when patients were identified as frail on the GFI.

Although 835 (62.9%) patients in the U-PRIM and U-CARE intervention were frail, the effectiveness of the intervention was evaluated on the total number of participants in the U-PRIM plus U-CARE group (N= 1,327). Despite the advantage of an additional assessment in the U-PRIM plus U-CARE intervention group, we were limited by this analysis, since we did not collect GFI data in the other two groups. Finally, our trial had a short follow-up of one year to achieve maximum benefits of both interventions. We could only demonstrate intervention effects after twelve months but not after six months, suggesting that full and adequate implementation of a personalized multicomponent nurse-led care program requires time before it works in its optimal way (Chapter 5).

Setting

The U-PROFIT trial was embedded in routine clinical practice where creating optimally controlled experimental circumstances is difficult.[37] Prior to the randomization, various levels of care provision for older people were observed and in some practices, nurses were already conducting home visits to older patients. Although some of these practices were randomized into the control group, we considered this as part of the heterogeneity of the "care a usual", and hypothesized that our proactive personalized care strategy would be more beneficial. However, this contamination may have contributed to an underestimation of the true effects of both interventions. In addition, while we were conducting the trial improving the care for older people in primary care became a nationwide "trending topic" since the launch of the National Care for the Elderly Program in 2008. Halfway the follow-up, a large health care insurance company in our region introduced a module for frail older people and offered practices a financial compensation for delivering proactive structured care to older people. To minimize contamination, we offered the practice in our control group a financial compensation to postpone the implementation of this module until the end of the follow-up period of the trial. Despite these challenges, conducting this trial in routine clinical practice had major advantages for the generalizability of the results and the demonstration of feasibility of implementation of a personalized strategy in routine care.

Patients

In the U-PROFIT trial, an age threshold of 60 years for inclusion was chosen instead of the frequently used cut-off of 65 years or even 70 years. Experts suggested a lower age threshold, since a substantial part of the ageing population in participating practices consisted of first-generation immigrants of non-Dutch origin. It has been reported that the physical functioning of these older people declines faster and at an earlier age resulting in a higher level of frailty starting at an earlier age.[38] The number of immigrants that participated was, however, very low (non-Dutch: 8.2%). Despite a maximum effort was made during the inclusion period, such as the employment of multicultural health consultants, the inclusion rate from this population remained low. This limits the generalizability of the results of our study for the immigrant population. We also hypothesized that the U-CARE intervention might have a different effect on the "oldest- old". However, in the subgroup analysis we did not observe an interaction effect with age, indicating that the intervention effect was comparable among the old and oldest-old (Chapter 5). In addition, in the multivariate analyses to predict successful treatment of patients that received the U-PRIM plus U-CARE intervention, age was not a very strong predictor (Chapter 8). Based on these findings, we think that the present age threshold was justified and can be used in future studies to prevent functional decline, especially at an early stage of aging.

Given the size of the elderly population in the participating practices, we expected to include 5000 frail older people. Although the response rate in the trials was comparable with that of other studies 10, we included a total of 3,092 older people. Two possible explanations are discussed. First, when designing the U-PRIM and U-CARE interventions, the research team considered the interventions as innovative organizational changes in elderly care, originating from routine clinical practice. However, the Medical Ethical Committee considered both interventions as experimental changes in care organization, liable to legislation resulting in a formal informed consent procedure. This procedure may have resulted in a lower number of older people than we expected. Second, we aimed to include frail older people with polypharmacy and or multimorbidity (defined with a frailty index) and or a care gap (i.e. patients that did not visits the GP in the last three year with the exception of the yearly influenza vaccination).

Patients were selected by the U-PRIM instrument which was based on the routine patient data from the general practice.[13] However, due to the influence of the routine patient data quality, we probably missed some subgroups of frail patients, such as those with (severe) cognitive decline (not consulting or inadequately coded by the GP), mobility problems or at increased risk of falling (not coded). Despite these limitations we were still able to include a sufficient number of frail older people in our trial.

Outcome measurement

Self-reported ADL/ IADL outcome measures are recommended in randomized trials aiming at preventing or delaying functional decline in older people.[10] Although widely used, the limitations of self-reported questionnaires on physical functioning concerning their validity, lack of sensitivity to detect changes and ceiling and floor effects remain.[39] The grant committee from the National Care for the Elderly Program preselected the Katz-15 ADL/ IADL scale as the primary outcome, since ADL and IADL independency is the outcome of choice for the majority of frail older people.[40] In addition, a uniform outcome assessment would enable direct comparison with other ongoing research projects within this program. However, a drawback of this instrument is that all items are dichotomized, which limits its potential to detect small changes over time. This limitation, combined with a 'floor-effect', would have been even bigger if we had used the Katz-6 ADL outcome.[41] In addition, even though approximately 60% of our study population reported to be almost (fully) independent on the Katz-15 at baseline, we could still demonstrate that the interventions preserved physical functioning better in older people at one-year follow-up. Prevent or even slowing down the loss of physical functioning in frail older people is of immense importance to facilitate independent living. Especially in the population of older people, even modest changes can lead to larger improvements in health.[42]

In conclusion, the U-PROFIT trial is, to our knowledge, the largest randomized controlled trial, embedded in routine clinical practice. It demonstrated that a frailty screening intervention based on routine care data, and the screening intervention plus a multicomponent nurse-led care intervention better preserve physical functioning in frail older people. The combined strategy is an efficient and effective approach that can be easily implemented in daily routine care.

Given the abovementioned methodological arguments regarding the choice of design, age threshold, participation rate and outcome, we think that the results of the trial actually underestimate the true effect of the intervention. When applied in frailer patients and with a longer follow-up, the "real life" effectiveness will probably even be more beneficial.

Role of nurses

Several care programs for frail older people have been evaluated in which nurses play an important role as care manager.[28, 43] Although the results of these programs on patient outcomes have been extensively reported[44, 45], little is known about the performance of nurses within these care programs. This information is essential to improve the content of the program and, more importantly, the care for older people. Therefore, in our study maximum effort was made to collect specific data regarding the actual nursing care delivered during the trial (Chapter 6). We asked the nurses to report all assessments conducted and interventions delivered to each individual patient on the study website. Although the nurses perceived this as a time-consuming approach, this mixed-method study provided valuable information. We showed that the nursing care delivered in response to identified problems was dependent on the preference of the patient, the type of problem and the type of specific nursing action (Chapter 6). This finding is important since we observed that "easy" and "simple" nursing actions for relatively acute conditions such as falls and urinary incontinence were much more often applied compared to more time-consuming interventions for mood problems (Chapter 6). Although the direct association between the actual nursing care delivered and the results of our trial is complicated, we showed that the impact of the delivery of nursing care plays an important role in the effectiveness of the intervention (Chapter 6). The results of our study suggest that there is room for improvement, because the number of detailed problem assessments conducted after identification on the frailty assessment was much lower than expected. It can be questioned whether the importance of using assessments was sufficiently emphasized during the training of the nurses. Nonetheless, this mixed-methods study improved our understanding of the actual nursing care delivered in relation to the trial results.

The nurses in our study played a key role and were extensively trained to deliver the multicomponent care program. The nurses noted that providing proactive and preventive care was new and difficult in the beginning, but during the trial, a transition from reactive to proactive care was achieved after five months (Chapter 4). In addition, the nurses argued that they found it difficult when frail older patients rejected, what they considered, highly needed care. Nonetheless, the U-CARE intervention was perceived as highly valuable in providing proactive, structured care, and it provided an opportunity to extend the professional role of the nurse in the general practice setting (Chapter 4). The patients in our study highlighted that a good relationship with the nurse is one of the most important conditions for appreciation of personalized nurse-led care (Chapter 7). In addition, a sustained relationship can only be built up when the care is coordinated by one single care provider. In our opinion, registered practice nurses specialized in care to older people are adequately equipped and trained to deliver personalized care in close collaboration with the GP, and are able to fulfill the complex care needs of this population.

Recommendations for research, education, and practice

Research

The results of our study suggest that a proactive personalized nurse-led care is most successful at early reversible stages of health and in a relatively vital older people. Because the intervention did not show a different effect on the oldest-old population, we recommend that personalized multicomponent nurse-led care should be targeted to younger patients (60+) as well as to the oldest-old (75+). A longer follow-up period is needed to determine whether the benefits of personalized nurse-led care will be higher after a longer period. To improve our understanding of the complex mechanisms in multicomponent interventions, the first priority for future research is to investigate the complex interrelation between the actual nursing care delivered and patient outcomes. These studies should include quantitative measures of adherence to ensure that effective components of the intervention can be identified. Second, more research is needed to determine the optimal treatment intensity for specific groups of older people to achieve maximum benefits of this nurse-led care.

Specific attention should be given to preventing deterioration in functional status in subgroups of older people with a low socioeconomic status such as non-Dutch immigrants who are at risk of functional decline earlier. More sensitive ADL and IADL outcome measures are recommended to observe small changes over time. Third, qualitative studies are needed to improve our understanding of the individual care needs of the heterogeneous group of older people. This will contribute to our ability to deliver optimal personalized care.

Education

Due to the growing number of older people and frail older people with complex care needs who will remain living independently, a transition in health care organization and in medical and nursing education is required.[46] A Canadian study reported that with the predicted increase of age, approximately 75% of nurses' time will be spent with older adults by 2020.[47] This stresses the importance of adequate preparation of registered nurses for the provision of care to older people during their training. In the bachelor education of nurses, special attention should be given to delivering proactive and preventive care in the primary care setting instead of reactive and ad hoc care. More importantly, this care should be tailored to the individual care needs and be focused on maintaining independence and well-being in older people. In our study, the nurses and GPs noted that providing personalized care to older people was difficult when patients had multiple diseases, a low socioeconomic status, and a different cultural background (Chapter 4). This emphasizes the urgency of paying more attention to these topics in the education of nurses and GPs. Last but not least, in order to deliver personalized care to the rapidly increasing population, more professionals specialized in elderly care are needed. However, it is known that only a minority of nursing and medical students are interested in working with older people after their basic education.[48,49] Therefore, trainers and tutors should put more effort in making this specialization attractive for students. There is an urgent need for role models that stimulate students working with older people.

Clinical practice

Our research has important consequences for clinical practice. Two conditions need to be addressed to implement personalized nurse-led care with maximum, prolonged effects. First, structural reimbursement of the registered practice nurse specialized in care for older people in the general practice is needed. Optimal care to older people requires a proactive complex coordination by a single care provider. Registered practice nurses with a bachelor degree specialized in care for older people are required to deliver and coordinate this care. The nurses should be embedded in the general practice to ensure continuity and efficiency. Adequate reimbursement is required for sufficient consultation time with the GP and other health care professionals, as well as for the care coordination, and continuous learning and support. Second, close collaboration between health care professionals in primary care and secondary care is crucial to enhance consistency and continuity in care for older patients.

The world is rapidly aging, and the current care approach is reactive and insufficient to deliver care to the fast-growing number of older people. For the majority of older people, maintaining independence and living in their own home is of outmost importance. Patients, as well as the Government and policymakers emphasize the need to focus on the preservation of functioning and well-being in older people. So far, examples of how proactive care can be adequately delivered were lacking. In our study we showed that a proactive strategy of identification of older people at risk followed by a multicomponent personalized nurse-led care program can successfully preserve physical functioning in frail older people. This approach is highly appreciated by older patients as well as by primary care professionals and can directly be implemented in clinical practice. The training for the registered nurses is embedded in the curriculum of the University of Applied Sciences. In addition, a ready-to-use U-CARE toolkit, which includes the evidence-based care plans and the implementation steps of the program, has been developed and is sent to over 200 nurses, GPs and other health care professionals in primary care. Right now, it is up to the health care insurance companies as well as the health care professionals in primary care to create sustainable collaborations to implement this approach in their daily work in the primary care setting. The time for change in primary care for older people is now.

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Chapter 11

Summary

The aging of the population is accelerating rapidly worldwide, from 461 million older people (i.e., 65 years and over) in 2004 to an estimated one billion people by 2050. In the Netherlands, the percentage of older people was 15% in 2011, and will increase to approximately 25% by 2040. Although the population of older people is largely heterogeneous in terms of health and self-sufficiency, the majority of older people desire to maintain independence with a good quality of life and to remain living at home as long as possible. However, the ability to perform activities of daily living (ADLs), such as bathing or dressing, or instrumental activities of daily living (IADLs), like shopping, is often threatened by health related factors associated with aging, such as multimorbidity, and functional decline.

Currently, care for older people is suboptimal and does not adequately address their individual care needs. Older people often perceive a lack of overview and care coordination when multiple health care providers are involved. Moreover, current health care system is reactive, time consuming and little attention is paid to preventive care to preserve independence and wellbeing of older people. Consequently, this results in unnecessary loss in physical functioning and a lower quality of life. To preserve physical functioning, a transition toward a proactive and personalized care approach is required. This challenges all health care professionals, but especially in primary care.

Early identification of patients at risk combined with a comprehensive multicomponent care program are considered as key components to prevent deterioration in functional status in older people, however, their effectiveness in daily practice needs to be established. It has been proposed that frail individuals who are not yet disabled and those with early disability are the most likely to benefit from preventive interventions. Frailty can be described as a loss of resources in multiple domains resulting in a state of increased vulnerability for adverse events (e.g. functional decline, hospitalization, and death). A multistage selection process that identifies the frail while excluding the 'robust' has been recommended to include the most appropriate study population.

Within the National Care for the Elderly Program, we designed the Utrecht Proactive Frailty Intervention Trial (U-PROFIT), in which we developed and evaluated a strategy for proactive patient-centered care of frail older people in primary care. The strategy consisted of the Utrecht Periodic Risk Identification and Monitoring (U-PRIM) system, a frailty-screening intervention based on risk

selection in routine care registration data, and U-CARE, a nurse-led multicomponent personalized care program. The objective of this thesis is to develop and evaluate a multicomponent nurse-led personalized care program (U-CARE) to preserve physical functioning and improve quality of life for frail older people in primary care. Furthermore, we evaluated the experiences of patients, nurses and general practitioners (GPs) with this program.

Chapter 2 describes the development process of a multicomponent nurse-led care program (U-CARE) in detail to allow replication. The U-CARE intervention was developed in collaboration with a team of researchers, general practitioners, registered practice nurses, experts, and an independent panel of older persons. Although it was time-consuming, this approach increased its feasibility in clinical practice. The U-CARE program includes three steps: a frailty assessment, a comprehensive geriatric assessment at home for frail patients and tailor-made care plan followed by care coordination and follow-up visits. We developed for the following conditions evidence-based care plans to guide the nurses to deliver tailored care: physical functioning, falls, nutrition and malnutrition, urinary incontinence, mood and depression, loneliness, cognitive disorders, hearing impairment, vision impairment, polypharmacy, and caregiver burden.

Chapter 3 describes the design and the methodological challenges of the U-PROFIT trial. In a three-armed single-blind cluster randomized controlled trial, the effectiveness of the U-PROFIT intervention for proactive care for older people, consisting of a frailty screening intervention (U-PRIM) and a multicomponent nurse-led care program (U-CARE), was evaluated in a large population of older people recruited from 39 general practices. Critical methodological issues were recruitment, retention of participants and the feasibility of the interventions.

Chapter 4 presents the results of a mixed-methods study regarding the expectations and experiences of nurses and GPs toward the U-CARE intervention. Most nurses and GPs indicated that the program improved the coordination of care and supported them to provide structured care. Both nurses and GPs perceived the implementation of the U-CARE program in the general practice as feasible.

At the start, the nurses noted that providing proactive care was difficult because previously, they were used to deliver ad hoc care. However, after five months, a transition was achieved toward a proactive and preventive care approach.

In chapter 5, we report the results of the U-PROFIT trial, in which we investigated the effectiveness of U-PRIM, and U-PRIM followed by U-CARE among 3092 older patients during one year follow-up. Both interventions led to better preservation of physical functioning compared to the control group. No differences on quality of life were observed between the three groups. Patients in the U-PRIM plus U-CARE group consulted their general practice more often by telephone compared to patients in the other groups No differences in hospital admission, emergency department visits and mortality rates were observed. More highly educated older people perceived additional benefits from U-PRIM plus U-CARE, indicating that the effectiveness of the intervention is dependent on individual patient characteristics.
To better understand the results of the trial, *in Chapter 6*, we aimed to identify the actual nursing care delivered within the U-CARE program and explored how the care delivery may have influenced the trial results. Most nursing care was delivered to patients at risk of falls and urinary incontinence, and the least to patients with nutrition or malnutrition problems. The intensity and volume of nursing care delivered was dependent on the preferences of the patient, type of problem and type of specific nursing action (i.e. simple versus more time-consuming). We concluded that the U-CARE program was tailored to the individual needs of older people, but that not all components were delivered as planned. The findings suggest that the actual nursing care delivered did influence the outcome of the U-PROFIT trial suggesting that an underestimation of the true effectiveness was observed.

In *Chapter 7* we report the perception of frail older persons regarding the roles of the nurse and how older persons perceived proactive personalized care. Interviews were conducted in a subsample of the intervention and control group. Participants identified four roles of the registered practice nurse: monitoring, directing, coaching and visiting. The monitor role, with observing and assessing potential risks, was considered the most important role. Proactive care was appreciated if the relationship, timing and the nurse's role were tailored to the individual needs.

Although some of the participants in the control group had difficulty speculating about the benefits of a practice nurse, others could imagine the advantages of having a nurse and presumed that she would complement the GP.

In *chapter 8*, we aimed to identify individual characteristics of older people who are most likely to benefit from proactive personalized nurse-led care. Key determinants in predicting a positive outcome from personalized proactive care were: a relatively low number of medications in chronic use, a higher education level, higher self-reported quality of life and not using a walking aid. The final model showed a moderate to good discriminative ability (c-statistic: 0.65). This re-analysis provides valuable starting points for refinement of the intervention.

In *chapter 9* we examined the interrelationship between the frailty, complexity of care and quality of life in a subsample of older people with multimorbidity that participated in one intervention arm of the U-PROFIT trial. Patients were selected using routine care data based on the polypharmacy criterion (five or more medications in chronic use) which was used as a proxy for multimorbidity. In total, 758 out of 1150 (65.9%) older patients were frail, 8.3% had complex care needs, and the mean quality of life score was 7.1 (SD 1.2), based on a scale between 0-10. All patients with complex care needs were frail, but, only 12.5% of the frail patients had complex care needs. Low education, problems with walking on stairs, falls, urinary incontinence and decreased appetite were associated with higher levels of frailty and complexity of care, and with a lower quality of life. Three groups of older patients with multimorbidity were identified: patients with multimorbidity, frail patients with multimorbidity, and frail patients with multimorbidity and complex care needs. Frail patients with multimorbidity and complex problems reported more health problems and a lower QoL compared to frail patients with multimorbidity but without complex care needs.

In the general discussion in *chapter 10* the main findings of the study are put in perspective, reflections are given on the methodological choices of the development and evaluation of the U-CARE intervention, and implications for future research, clinical practice and education are described. The U-PROFIT trial demonstrated that a strategy for proactive patient-centered care, consisting of frailty screening plus a multicomponent nurse-led care intervention better preserve physical functioning in frail older people. The strategy can be easily implemented in daily routine care, and is well appreciated by patients, nurses and GPs in primary care.

Our research has important consequences for clinical practice. In our opinion, proactive care for older people, such as the U-PROFIT strategy, need to be implemented in daily primary care practice. Three conditions need to be addressed for successful large scale implementation with maximum, prolonged effects. First, structural employment and reimbursement of the registered practice nurse specialized in care for older people is needed. In our opinion, registered practice nurses specialized in care to older people are adequately equipped and trained to deliver personalized care in close collaboration with the GP, and are able to fulfill the complex care needs of older people. Nurses did play a key role in the delivery of the intervention. Second, close collaboration between health care professionals in primary care and secondary care is crucial to enhance consistency and continuity in care for older patients. Third, more professionals specialized in elderly care are needed due to the rapidly increasing population. However, only a minority of nursing and medical students is interested in working with older people. Therefore, trainers and tutors should put more effort in making this specialization attractive for students. Further research is needed to determine the optimal treatment intensity for specific groups of older patients to achieve maximum benefits of proactive personalized care. Additionally, the complex interaction between the actual nursing care delivered and patient outcomes should be investigated. Qualitative studies are needed to improve our understanding of the individual care needs of the heterogeneous group of older people.

The time for change in primary care for older people is now.

Chapter 11

Samenvatting

De vergijzing neemt wereldwijd snel toe, van 461 miljoen ouderen (i.e. 65 jaar of ouder) in 2004, tot naar schatting één biljoen ouderen in 2050. In Nederland bedroeg het percentage ouderen in 2011 15%, dit zal naar verwachting toenemen tot ongeveer 25% in 2040. Ondanks dat de populatie ouderen zeer heterogeen is in termen van gezondheid en zelfredzaamheid willen de meeste ouderen graag zo lang mogelijk zelfstandig thuis blijven wonen, met een goede kwaliteit van leven. Echter, de mogelijkheid om dagelijkse activiteiten (ADL) uit te voeren zoals wassen en aankleden, of instrumentele activiteiten (IADL) zoals boodschappen doen, worden vaak bedreigd door met veroudering samenhangende gezondheidsfactoren, zoals multimorbiditeit en verlies van verschillende domeinen van het functioneren. Op dit moment is de zorg voor ouderen met meerdere aandoeningen suboptimaal en sluit niet aan op de behoeften van ouderen. Ouderen ervaren bijvoorbeeld een gebrek aan overzicht en continuïteit tussen verschillende zorgverleners. Daarnaast is het huidige gezondheidzorgsysteem reactief en tijdrovend en is er weinig aandacht voor functionele preventie en welbevinden. Dit resulteert in onnodig verlies van fysiek functioneren en een verminderde kwaliteit van leven. Een transitie naar proactieve zorg in de eerstelijnszorg is nodig om het fysiek functioneren van ouderen zo goed mogelijk te behouden. Dit is een uitdaging voor zorgverleners, met name in de eerstelijn.

In de literatuur wordt vroegtijdige identificatie van ouderen met een verhoogd risico op functionele achteruitgang, gevolgd door een verpleegkundig zorgprogramma, beschreven als een veelbelovende aanpak om functieverlies bij ouderen te voorkomen. Helaas zijn de resultaten van deze aanpak niet eenduidig. Uit de literatuur blijkt dat kwetsbare ouderen die nog niet ernstig beperkt zijn, of slechts een beginnende mate van functieverlies ervaren, waarschijnlijk de meeste voordelen ervaren van preventieve interventies. Kwetsbaarheid bij ouderen is een proces van opeenstapeling van lichamelijke, psychische en/of sociale beperkingen in het functioneren, met als gevolg een grotere kans op negatieve gezondheidsuitkomsten zoals functiebeperkingen, ziekenhuisopname en overlijden. Een systematische selectieprocedure op kwetsbaarheid, wordt aanbevolen om de meest kwetsbaren in de populatiepopulatie op te sporen.

In het kader van het Nationaal Programma Ouderenzorg is het Ouderenzorg-project Midden Utrecht (Om U) opgezet waarin een proactieve en gestructureerde strategie is ontwikkeld voor het opsporen en zorgverlenen aan kwetsbare ouderen in de huisartsenpraktijk. De strategie bestaat uit de Utrechtse Periodieke Risico Identificatie en Monitoring systeem (U-PRIM), een instrument voor screening op kwetsbaarheid in routine zorg data, en U-CARE, een verpleegkundig multicomponent zorgprogramma. Het doel van dit proefschrift is het ontwikkelen en evalueren van U-CARE op het behoud van fysiek functioneren van kwetsbare ouderen in de eerstelijn. Daarnaast zijn de ervaringen van patiënten, praktijkverpleegkundigen en huisartsen met deze proactieve strategie onderzocht.

Hoofdstuk 2 beschrijft de ontwikkeling van het verpleegkundig zorgprogramma U-CARE, met als doel om herhaling mogelijk te maken en implementatie te bevorderen. Het U-CARE programma is ontwikkeld in samenwerking met een team van onderzoekers, huisartsen, ervaren praktijkverpleegkundigen, experts en een groep ouderen. Deze ouderen participeerden in 'de adviesraad' van Om U. De methode was tijdrovend en kostbaar, maar heeft er toe geleid dat het optimaal afgestemd is op de klinische praktijk. Het U-CARE programma bestaat uit drie stappen: screening op kwetsbaarheid, uitgebreide geriatrisch assessment bij de kwetsbare patiënt thuis en het opstellen van een zorgplan op maat gevolgd door zorgcoördinatie en vervolgbezoeken. Voor de volgende veel voorkomende probleemgebieden zijn evidence-based zorgplannen ontwikkeld als hulpmiddel voor de praktijkverpleegkundigen: fysiek functioneren, vallen, voeding, urine incontinentie, stemming en depressie, eenzaamheid, cognitie, gehoor, visus, polyfarmacie en mantelzorgbelasting.

In *hoofdstuk 3* is het design en de methodologische uitdagingen van de Om U trial beschreven. In een driearmige single-blind cluster gerandomiseerde trial is het effect van de Om U strategie, bestaande uit een interventie die gericht is op het screenen van kwetsbaarheid (U-PRIM), en een multicomponent verpleegkundig zorgprogramma U-CARE, onderzocht in een grote populatie ouderen die gerekruteerd waren uit 39 huisartsenpraktijken. Methodologische uitdagingen waren de werving, het behoud van voldoende patiënten en de haalbaarheid van beide interventies in de klinische praktijk.

Hoofdstuk 4 beschrijft de resultaten van een mixed-methods studie waarin de verwachtingen en ervaringen van praktijkverpleegkundigen en huisartsen ten aanzien van het U-CARE programma zijn onderzocht. De meeste verpleegkundigen en huisartsen gaven aan dat het U-CARE programma de coördinatie van zorg verbeterde en dat het programma hielp om gestructureerde zorg te verlenen aan ouderen. Zowel de verpleegkundigen als de huisartsen vonden het U-CARE programma bruikbaar in de huisartsenpraktijk. In het begin vonden de praktijkverpleegkundigen het uitvoeren van proactieve lastig omdat zij gewend waren om 'ad-hoc' zorg te verlenen. Desalniettemin had er na vijf maanden een omslag plaatsgevonden naar proactieve, preventieve zorg.

Hoofdstuk 5 laat de resultaten van de Om U trial zien. Beide interventies (U-PRIM en U-PRIM plus U-CARE) leiden tot meer behoud van het fysiek functioneren in vergelijking met patiënten uit de controle groep. Er werd geen verschil in kwaliteit van leven aangetoond. Patiënten in de U-PRIM plus U-CARE groep hadden meer telefonische consulten met de huisartsenpraktijk vergeleken met de twee andere groepen. Bij hogeropgeleide ouderen in de U-PRIM plus U-CARE groep waren de effecten op het behoud van fysiek functioneren sterker. Dit suggereert dat de effectiviteit van de interventie afhankelijk is van individuele patiëntkenmerken.

Hoofdstuk 6 beschrijft welke verpleegkundige zorg daadwerkelijk is verleend binnen het U-CARE programma om zo de resultaten van de trial te kunnen verklaren. De meeste verpleegkundige interventies waren verleend aan ouderen die een risico hadden om te vallen of met urine incontinentie de minste aan ouderen met voedingsproblemen. De intensiteit en hoeveelheid ingezette verpleegkundige interventies waren afhankelijk van de voorkeur van de patiënt, het type probleem en het type (vervolg) actie van de verpleegkundige (i.e. snel en simpel versus meer tijdrovende acties). We concludeerden dat het U-CARE programma was uitgevoerd op basis van de behoeften van de patiënt, maar dat niet alle onderdelen van het programma waren uitgevoerd zoals verwacht. De bevindingen in deze studie laten zien dat er door een slechts gedeeltelijk uitvoeren van de verpleegkundige zorg waarschijnlijk een onderschatting van het daadwerkelijke effect van het Om U programma is gevonden.

In Hoofdstuk 7 onderzochten we de ervaringen van ouderen met het Om U programma en gingen we na welke rollen de verpleegkundige volgens de ouderen vervulde. De interviews werden afgenomen bij een subgroep van ouderen in de interventiegroep en in de controle groep. Vier verpleegkundige rollen werden beschreven door ouderen in de interventiegroep: de monitor, director, coach en visitor rol. De monitor rol, waarin de verpleegkundige de situatie observeert en mogelijke risico's in kaart brengt, werd als de meest belangrijke rol ervaren. Proactieve zorg werd gewaardeerd door ouderen wanneer de relatie, timing en de rollen van de verpleegkundige waren afgestemd op de individuele behoefte van de patiënt. Ouderen in de controle groep vonden het lastig om de voordelen van de praktijkverpleegkundigen in te schatten, maar velen verwachten dat deze verpleegkundige een mooie aanvulling op het zorgaanbod van de huisarts zou kunnen zijn.

Hoofdstuk 8 beschrijft welke ouderen mogelijk de meeste voordelen ervaren van de proactieve verpleegkundige zorg in het Om U project. Belangrijke kenmerken van ouderen die een verhoogde kans hebben op een positieve uitkomst waren: een relatief laag aantal medicijnen in chronisch gebruik, een hogere opleiding, hogere kwaliteit van leven en geen hulpmiddel (zoals een wandelstok) gebruiken bij het lopen. Het uiteindelijke model toonde een matig tot goed onderscheidend vermogen (c-statistiek: 0.65). Deze vervolganalyse geeft belangrijke aanknopingspunten voor verdere verfijning van de interventie.

Hoofdstuk 9 beschrijft de onderlinge relatie tussen de concepten kwetsbaarheid, complexiteit van zorg en kwaliteit van leven in een subgroep van ouderen met multimorbiditeit die deelnamen in één interventiearm van de Om U trial. Ouderen waren geselecteerd met behulp van routine zorg data op basis van polyfarmacie (vijf of meer medicijnen in chronisch gebruik), dat sterk geassocieerd is met multimorbiditeit. In totaal waren 758 van de 1150 (65.9%) ouderen kwetsbaar, 8.3% had complexe zorgbehoeften en de gemiddelde score op kwaliteit van leven was 7.1 (SD: 1.2) gebaseerd op een schaal van 0-10. Alle ouderen met complexe zorgbehoeften waren kwetsbaar, maar slechts 12.5% van de kwetsbare patiënten had complexe zorgbehoeften. Een lagere opleiding, problemen met traplopen, vallen, urine incontinentie en verminderde eetlust waren geassocieerd met een hogere mate van kwetsbaarheid en complexiteit van zorg en een lagere kwaliteit van leven.

Drie groepen ouderen konden worden onderscheiden: ouderen met multimorbiditeit, kwetsbare ouderen met multimorbiditeit en kwetsbare ouderen met multimorbiditeit en complexe zorgbehoeften.

Hoofdstuk 10 vat de resultaten samen en beschrijft implicaties voor verder onderzoek, klinische praktijk en onderwijs.
Het Om U project laat zien dat een strategie voor proactieve zorg, bestaande uit een kwetsbaarheid screening op basis van routinezorgdata plus een multicomponent verpleegkundig zorgprogramma, leidt tot beter behoud van het fysiek functioneren bij ouderen. De Om U strategie kan eenvoudig worden geïmplementeerd in de huidige zorg en wordt zeer gewaardeerd door ouderen, verpleegkundigen en huisartsen.
Ons onderzoek heeft belangrijke consequenties voor de klinische praktijk. Wij zijn van mening dat proactieve zorg, zoals de Om U strategie, grootschalig ingevoerd moet worden in de dagelijkse praktijk. Drie voorwaarden zijn van belang voor succesvolle implementatie met langdurige effecten.
Ten eerste, structurele financiering van de praktijkverpleegkundige ouderenzorg is noodzakelijk. Wij vinden dat praktijkverpleegkundigen ouderenzorg goed zijn toegerust om samen met de huisarts proactieve zorg te verlenen aan kwetsbare ouderen. De verpleegkundigen speelden een belangrijke rol in de uitvoering van de interventie. Ten tweede, nauwe samenwerking tussen zorgverleners in de eerste- en tweedelijn is cruciaal om de continuïteit in de zorg voor ouderen te bevorderen. Ten derde, er zijn meer gespecialiseerde zorgverleners voor ouderen nodig om voor de snel groeiende populatie ouderen te zorgen. Toch zijn slechts weinig verpleegkunde en geneeskunde studenten geïnteresseerd om met ouderen te werken. Opleiders en mentoren moeten daarom meer hun best doen om deze specialisatie aantrekkelijk te maken voor de studenten.
Meer onderzoek is nodig om de optimale samenstelling van het zorgaanbod voor specifieke groepen ouderen vast te stellen. Daarnaast zal vervolgonderzoek zich moeten richten op de complexe relatie tussen de uitgevoerde verpleegkundige zorg en de uitkomsten op patiëntniveau. Tevens is meer kwalitatief onderzoek is nodig om de zorgbehoeften van de heterogene groep ouderen in kaart te brengen.
Het is tijd voor een andere aanpak in de zorg voor ouderen in de eerstelijn.

Chapter 11

Dankwoord

Op een dag lees ik op mijn To-do lijstje: Dankwoord schrijven. Op dat moment realiseer ik mij dat er een einde lijkt te komen aan mijn promotieonderzoek. Een moment van reflectie. Het waren vier ontzettend leuke en bijzonder leerzame jaren waarin ik heb genoten van het opzetten, uitvoeren en afronden van het Om U project. Om U was een groot project waar veel mensen aan hebben meegewerkt en aan hebben bijgedragen. Zonder hen was dit proefschrift er niet gekomen. Graag wil ik deze mensen en alle anderen die hebben meegeleefd op deze plek bedanken.

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Let's have a drink! ☺

Chapter 11

Curriculum Vitae

Curriculum Vitae

Nienke Bleijenberg was born on the 7th of February 1985 in Doorn, the Netherlands. After graduating from secondary school at the Revius Lyceum, she obtained her Bachelor degree in Nursing at the University of Applied Sciences in Utrecht in 2007. During her final year of her Bachelor she started with the pre-master Nursing Science at the Utrecht University. She obtained her Master of Science degree in Nursing Science in 2009. Meanwhile, Nienke worked as a registered nurse in the home care setting. After graduation, she started her PhD studies at the University Medical Center Utrecht, department Julius Center for Health Sciences and Primary Care under supervision of Prof. dr. Marieke Schuurmans, Prof. dr. Niek de Wit and Dr. Hester ten Dam. During her PhD study, Nienke followed the Postgraduate Master of Clinical Epidemiology at the Utrecht University where she obtained a Master of Science degree in 2013.

Since 2012, Nienke is working as a lecturer in the pre-master and master program of Clinical Health Sciences / Nursing Science in Utrecht. Currently she is continuing her research at the department of Rehabilitation, Nursing Science and Sport and the Julius Center of Health Sciences and Primary Care, department General Practice, University Medical Center Utrecht. Nienke has the ambition to combine research, education and nursing practice in the near future.

Chapter 11

List of publications

List of publications

1 **Bleijenberg N**, Drubbel I, Schuurmans MJ, ten Dam VH, Zuithoff NPA, Numans ME, de Wit NJ. The effectiveness of a proactive patient-centered primary care programme on physical functioning of frail older patients; a cluster randomised controlled trial. In revision.

2 Boeije HR, **Bleijenberg N**, Onderwater AT, Schuurmans MJ. (2013). Frail older people's experiences with proactive nurse-led primary care: A qualitative study. In revision.

3 Laan W, **Bleijenberg N,** Drubbel I, Numans ME, de Wit NJ, Schuurmans MJ. Factors associated with increasing functional decline in multimorbid independently living older people. Maturitas, 2013, volume 75, Issue 3, Pages 276–281.

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9 **Bleijenberg N**, Drubbel I, ten Dam VH, Numans ME, Schuurmans MJ, de Wit NJ. Proactive and integrated primary care for frail older people: Design and methodological challenges of the Utrecht Primary care PROactive Frailty Intervention Trial (U-PROFIT). BMC Geriatrics. 2012;12:16.

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Abstract presentations (oral)

- The Gerontological Society of America's 65th (GSA's) annual Scientific Meeting, San Diego November, 2012. Symposium. Title: 'Care for the Older Persons: Focus on Preservation of Independency and Autonomy'.

- WONCA Europe conference July, 2012. Vienna, Austria. The Art and Science of General Practice. Symposium in collaboration with colleagues from Heidelberg University Germany. Title: 'Improving care for frail elderly patients in primary care: towards a proactive and structured care approach'.

- WONCA Europe conference July, 2012. Vienna, Austria. The Art and Science of General Practice. Oral presentation. Title: Does a proactive and structured care program for frail older patients meet the needs and expectations of general practitioners and practice nurses?
  A mixed-method study.

- NHG Wetenschapsdag 2012, Maastricht. Titel: Kwetsbaarheid, complexiteit van zorg en welbevinden bij ouderen met polyfarmacie in de huisartsenpraktijk.

- Sigma Theta Tau International Leadership Summit, Amsterdam. April 2011. Poster presentation. Title: A Nurse-led intervention program for frail older persons.

- Fourth European Nursing Congress, Older People, the Future of Care, Rotterdam, 4-October 2010. Title: Feasibility of a new intervention program for vulnerable older people in primary care.

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Bleijenberg N, Bosch-van den Berg LHM. Om U: proactieve en gestructureerde ouderenzorg in de praktijk. V&VN, de Praktijk 2013 (3).

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