Dhr. en mevr. van Leijden (85 en 82)
“We zouden wel een tuinman willen! We zitten vaak in en bij het huis en hopen hier ook te kunnen blijven wonen.”
**GENERAL INTRODUCTION**

**The silver tsunami**

As a result of rising life expectancy and declining fertility, population ageing is taking place in nearly all the countries of the world.\(^1,2\) In the Netherlands, approximately 2.5 million persons are 65 years or older, corresponding to 16% of the population. This proportion is projected to increase to 26% in 2060.\(^3\) In Europe the proportion of very old people (i.e., those aged 80 years or older) is projected to triple between 2008 and 2060.\(^4\) Because of its associated rise in health care expenditures, this ‘silver tsunami’ raises concerns about the affordability of current health care systems.\(^1,2,5–8\) To limit costs associated with institutionalisation of older adults, many governments aim to support older adults to live independently at home as long as possible.\(^2,4\) Since admissions to hospitals, care homes and nursing homes are better predicted by frailty then by age,\(^9,10\) the growing interest in frail older adults as target group of health interventions and government policies is evident.\(^11,12\)

**Frailty, multimorbidity and disability**

Although frailty is related to both multimorbidity and disability, these are three different concepts.\(^9,13\) More than half of the population of older adults have several coexisting diseases or medical conditions (multimorbidity).\(^14–17\) Disorders that are common in older people are osteoarthritis, chronic obstructive pulmonary disease, cancer, diabetes mellitus type 2, heart disease, stroke and dementia.\(^4,18\) Such disorders, as well as the ‘four giants of geriatrics’ (memory loss, urinary incontinence, depression and immobility) often result in disability.\(^1\) Disability is an umbrella term covering impairments, activity limitations and participation restrictions.\(^19\) Around 20-30% of community-dwelling adults older than 70 years report disability in mobility, self-care and/or house-management tasks.\(^20\) The risk of disability is higher with multimorbidity than with individual diseases.\(^13\)

People with a high vulnerability for adverse health outcomes, including disability, dependency, falls, need for long-term care and mortality, due to age- or disease related decreased physiologic reserves, are considered frail.\(^12,13\) Common clinical presentations of frailty are extreme fatigue, unexplained weight loss, frequent infections, slow gait speed, balance problems and delirium.\(^12\) Although frailty often coexists with multimorbidity, the physiological changes that underlie frailty do not always result in disease.\(^21\) In this definition, frailty is considered as a (potentially reversible) pre-disability state\(^19\) and focuses on an underlying multisystem physiological change. Models that are used to identify frail older adults based on this characterisation include Fried and colleagues’ frailty phenotype\(^22\) and Rockwood and colleagues’ cumulative deficit model.\(^21\) The first model identifies frailty based on clinical presentations as mentioned above, while the second uses
a Frailty Index which sums the presence of numerous symptoms, signs, disabilities, diseases and abnormal laboratory values, collectively referred to as deficits. However, there are also broader operationalisations of frailty which include psychological and social deficits in functioning.\textsuperscript{10,11,23,24} The chapters 2, 3, 4, 6 and 7 in this thesis are based on a study in which such a broad definition was initially used for the selection of participants, whereas further eligibility for study entry was determined by a questionnaire containing risk factors for functional decline.\textsuperscript{25,26} The concept of frailty is primarily used to refer to risk groups and to organise care.\textsuperscript{11} Identification of frail older adults as a risk group for adverse outcomes offers opportunities for early detection and targeted prevention of the consequences of frailty.

Frailty occurs in a significant proportion of older adults in the community. The different definitions and operationalisations of frailty, however, make it difficult to give an estimate of the prevalence of frailty. Using a broad definition including psychological and social deficits, there were over 600,000 frail older adults in 2007 in the Netherlands, of whom 500,000 lived independently.\textsuperscript{11} International studies indicate that the prevalence of frailty varies from 4-59%, with a weighted average of about 10% and increasing prevalence rates with increasing age.\textsuperscript{27,28} The number of frail older adults in the Netherlands are expected to increase to more than one million in 2030.\textsuperscript{11}

**Frailty and quality of life**

Frail persons typically have a lower quality of life than older people who are not frail.\textsuperscript{29–34} Multimorbidity is associated with lower quality of life,\textsuperscript{4,16,35,36} but a significant proportion of older adults also experiences limitations in psychological and social domains, which negatively impact quality of life as well.\textsuperscript{11} Among frail older adults memory problems are common, just like a sad mood, depression and feelings of helplessness and loneliness\textsuperscript{11} This combination of physical, psychological and cognitive limitations generally result in a loss of social contacts and decreased participation in society. Moreover, older people have to cope with loss of loved ones, such as the partner, siblings and close friends. Together, this means that the social network becomes smaller and that especially frail older adults experience a lack of support.\textsuperscript{11,37} With increasing frailty the level of dependency on others increases as well.\textsuperscript{11} As a result, some older adults experience a loss of control over their daily life.\textsuperscript{38} Yet some frail older adults are able to actively balance these losses in life with some continuity, for example by creating daily routines and stronger connections with family and their physical environment.\textsuperscript{39}

**Frailty and care use**

Frail older adults are at increased risk of high utilisation of care. Especially very frail people aged 80 years and over are major users of informal care and health and social care services.\textsuperscript{19} Frailty is
commonly associated with long term, but fluctuating care needs due to the presence of chronic disorders and the vulnerability for sudden health changes. Such care needs require specialised services from multiple care providers and organisations. The presence of multimorbidity and disability simultaneously increases the complexity of care needs. Many frail older adults follow multiple treatment regimens for their chronic disorders and take various drugs that potentially interact. Besides that, many frail older adults have disability and need rehabilitation and assistance with activities of daily living. Moreover, formal care is often complemented by informal care which is most often provided by the partner and children. However, there are boundaries to both the amount and type of support that informal caregivers can give. Deterioration in function or acute episodes of illness or injury might result in admissions to hospitals and in the long term in a need for institutional care.

In the Netherlands, almost 40% of the health care budget in 2011 was spent on care for older adults. Particularly hospitalisations and institutionalisations are expensive. With the projected increase in number of frail older adults, health care expenditures are expected to rise as well. Public spending on long-term care is expected to increase from 1.2% to 2.3% of the gross domestic product (GDP) in the EU between 2007 and 2060. Because a declining share of the population might have to bear increasing costs of pensions and public health financing, the long term sustainability of health and welfare systems will come under heavy strain.

**Integrated care**

Meeting the complex, long-term and fluctuating care needs of community-dwelling frail older adults provides several challenges. Health systems are currently for the most part oriented at single diseases and acute problems. Therefore, the existing healthcare response to frailty is mainly reactive to the acute manifestations of frailty such as falls, delirium and immobility, whereas health risks and care needs are not always identified at a timely stage. Furthermore, when frail older adults have complex care needs, multiple care providers from different settings are involved in the care process. This can result in fragmented care and coordination problems, especially since health and social care services are often separately organised and funded. In addition, older adults experience a lack of involvement in their own care process.

Proactive, integrated care, including effective coordination of services across levels of care, is widely acknowledged as a solution for the challenges in care for older adults with complex care problems. Integrated care is defined by Kodner and Spreeuwenberg as "a coherent set of methods and models on the funding, administrative, organisational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors...[to] enhance quality of care and quality of life, consumer satisfaction and
system efficiency for patients with complex problems cutting across multiple services, providers and settings." 59 A key feature of integrated care is a patient-centred strategy designed to address complex and costly care needs. Integrated care models are expected to result in better patient outcomes and cost savings for society by prevention or postponement of acute care use and long-term institutionalisation.45,55,60–62

Integrated care models for older and/or multimorbid patients have increasingly been implemented.45,63–68 Integrated care models exist in all kinds of forms, but commonly include a mix of features such as multidisciplinary teams, care coordinators, self-management support, a single point of referral, comprehensive (geriatric) assessments, support of informal care, quality management, information systems and decision support tools.45,50,57,59 Most of the studies that have evaluated the effects of integrated care models are observational or non-randomised controlled studies, with mixed findings.45,63,67 Some randomised controlled trials also have been performed.69–75 The results of these trials vary as well, with the majority reporting no significant improvement in most of the outcomes: social support,74 depressive symptoms,74 functional limitations,72–74 health-related quality of life,72,73,75 use of home care,71 hospital70–73,75 and nursing home admissions,70–72 emergency department visits,70,71,75 primary care visits70 and mortality.69,71,72,75 However, some statistically significant improvements were found on the same outcomes: mental functioning,69,73 functional limitations,69,75 use of home care,70 hospital admissions,69 emergency department visits73 and primary care visits.69 It is impossible to draw conclusions about the effects of integrated care models on the basis of these contradicting results.

While it has been hypothesised that targeting integrated care models on frail older adults may be the most cost-effective strategy,46,64,76–78 there is a lack of convincing evidence from cost-effectiveness studies supporting this hypothesis. Descriptive cost studies suggest that integrated care for this specific group may result in either a reduction in costs or comparable costs to usual care.69,71,79–81 However, so far only three studies evaluated the short-term cost-effectiveness of integrated care models for community-dwelling frail older adults in comparison with usual care, and the results are inconclusive. Makai et al.82 showed that integrated care was not cost-effective in comparison with usual care after 3 months of follow-up. Two other studies suggest that integrated care may be cost-effective in comparison with usual care at high values for willingness to pay after 683 and 12 months84 of follow-up. However, long term effects of integrated care are still unknown.

The Chronic Care Model as basis for the Geriatric Care Model
One of the best-known frameworks aimed at improving chronic illness care is the Chronic Care Model.85,86 The Chronic Care Model adopts elements of the integrated care approach and aims to transform daily care for patients with chronic illnesses from reactive to proactive, planned, and
population-based. Reviews of mainly observational studies showed that the Chronic Care Model is positively associated with some care process and disease specific health outcomes, such as number of drug prescriptions and diagnostic tests, monitoring improvements, depressive symptoms and levels of haemoglobin A1C and LDL cholesterol. The effects on quality of life and costs were mixed. The Chronic Care Model is usually implemented around one single disease, and not yet targeted at frail older adults.

We have developed a Geriatric Care Model for community-dwelling frail older adults. Corresponding with the Chronic Care Model, the Geriatric Care Model aims to enable productive interactions between activated, informed patients and proactive, prepared health care professionals. The Geriatric Care Model included the following components: a regularly scheduled in-home comprehensive geriatric assessment by a practice nurse followed by a tailored care plan, management and training of practice nurses by a geriatric expert team, and coordination of care through community network meetings and multidisciplinary team consultations of patients with complex care needs. The model was designed to improve the quality of care of community-dwelling frail older adults, and subsequently improve their quality of life. We compared the Geriatric Care Model with usual care in the ‘Frail older Adults: Care in Transition (ACT)’ study. The ACT study is a 2-year stepped wedge cluster randomised controlled trial with 6-monthly measurements. The trial was carried out among 35 primary care practices in two regions in the Netherlands. The first part of this thesis describes the design of this study, the assessment of implementation fidelity (i.e. the degree to which the Geriatric Care Model is implemented as intended), and the cost-effectiveness of the Geriatric Care Model in comparison with usual care. Implementation fidelity was assessed to help understand the findings of the evaluation of cost-effectiveness, because the fidelity with which a program is implemented influences its level of success.

**Economic evaluations**

In economic evaluations, interventions are compared with alternatives (including usual care) in terms of both their costs and consequences. Economic evaluations aim to support policy makers in decisions about which interventions to fund or reimburse and which not by providing information about the value for money that competing interventions provide. This value can be measured in terms of money, disease specific outcomes or more generic outcomes. The latter are preferred by health care decision makers who seek to maximise the benefits of health care spending through the most efficient use of limited resources, as generic outcomes enable the comparison...
of consequences across different programs and conditions.\textsuperscript{93,94}

An example of such a generic outcome is the quality adjusted life year (QALY).\textsuperscript{95,96} Economic evaluations incorporating QALYs as the unit of effect are often referred to as cost-utility analyses. The QALY combines length and health-related quality of life. One QALY reflects one year in perfect health. QALYs are commonly calculated by multiplying the time spent in a certain health state by the utility associated with this health state. Utilities reflect the desirability of health states relative to other health states. Health-related quality of life instruments such as the EQ-5D or the SF-6D are most often used to measure and value the health state of participants.\textsuperscript{97} Health states are subsequently valued using pre-existing fixed utility weights obtained from the general populations. The weights are available from a scoring function (or tariff) that accompanies the measure.\textsuperscript{93}

Interventions are considered cost-effective compared to the alternative, i.e. providing good value for money, when the additional costs per QALY (or other outcome units) do not exceed a specified monetary threshold. This threshold represents the maximum amount that society is willing to pay to obtain an additional unit of effect (e.g. a QALY).\textsuperscript{98} However, there is no consensus about the value of this willingness to pay (WTP) in the Netherlands. Therefore, results of cost-effectiveness analyses are interpreted using a range of hypothetical WTP values.

**Quality of life: not limited to health**

Frail older adults commonly use a mix of curative and long term care. Long term care is the system of activities undertaken by professionals and/or informal caregivers to ensure that a person who is not fully capable of self-care can maintain the highest possible quality of life, according to his or her individual preferences, with the greatest possible degree of independence, autonomy, participation, personal fulfilment, and human dignity.\textsuperscript{53} Long term care consists of both healthcare and social care services.\textsuperscript{99} While curative care focuses on treating symptoms and conditions and returning individuals to health and function, in long term care (and some other sectors such as public health) improving health or function is not the sole or main objective.\textsuperscript{5} Therefore, using health-related quality of life measures in economic evaluations will likely lead to an underestimation of the benefits of long term care.\textsuperscript{100,101} The benefits that result in quality of life improvements beyond health are not taken into account in these measures, while such improvements can be very valuable for older adults. Therefore, more comprehensive measures are needed that encompass broad aspects of quality of life and are not restricted to health.

In economic evaluations of care services for older adults, there are at least three reasons why quality of life should not be limited to health. First, curative treatments may not exist for older adults, or may be too invasive or causing severe adverse reactions. Therefore, improvements in the health of older adults are often out of reach. In these situations, the objective of
care services changes from cure to symptom management and to helping older adults to adjust to an altered daily life. \textsuperscript{102,103} As mentioned above, the long term care activities involved in these situations aim to ensure that a person can maintain the highest possible quality of life. Second, especially in vulnerable older adults with limited reserve capacities, changes in one area may induce effects in other areas, and such ‘side effects’, either positive or negative, should be measured as well. Thirdly, older adults see their lives as coming toward a conclusion, which influences what is considered important in one’s life. \textsuperscript{39,104} With a limited time-horizon, the contribution of health to quality of life remains important, but other aspects of life are relatively more important for older adults compared to younger adults. \textsuperscript{105–107} A substantial number of studies have been undertaken on aspects of quality of life that older people consider important. \textsuperscript{11,29,105,107–111} According to older adults, quality of life encompasses health, feeling good, feeling secure, being connected to family, having social relationships and a role in society, being independent, being active, being positive and able to adapt to change, helping other people and living in a nice home and neighbourhood.

Since different types of care are involved in integrated care models, measuring quality of life beyond health is even more relevant for the evaluation of integrated care, particularly when integrated care models are targeted at older adults and aim to integrate health and social care services.

**ASCOT and ICECAP-O**

Recently, there have been several initiatives to develop instruments that can be used to measure outcomes of care services that not directly aim to improve health. \textsuperscript{112,113} The Adult Social Care Outcomes Toolkit (ASCOT)\textsuperscript{114} and the ICEpop CAPability measure (ICECAP)\textsuperscript{111,115} are the most well-known of these initiatives.

The ASCOT is designed for social care settings and captures information about an individual’s social care-related quality of life in eight domains: *control over daily life, personal cleanliness and comfort, food and drink, personal safety, social participation and involvement, occupation, accommodation cleanliness and comfort and dignity*.\textsuperscript{114} The toolkit includes the ASCOT SCT-4, a four-level self-report version that can be used for economic evaluations in community settings.

The ICECAP measure for Older people (ICECAP-O) is a measure specifically developed for use in economic evaluations of health and social care interventions for older adults. The ICECAP-O covers the domains attachment (love and friendship), security (thinking about the future without concern), role (doing things that make you valued), enjoyment (enjoyment and pleasure), and control (independence). For the ICECAP-O, as well as for the ASCOT SCT-4, is preference weighted tariff is available that was estimated based on values from the general population in England.\textsuperscript{114,115}

Both the ASCOT and the ICECAP are conceptually based on the capability approach.\textsuperscript{111,115–119}
Chapter 1

The capability approach defines wellbeing in terms of an individual’s ability to ‘do’ and ‘be’ the things that are important in life. Following this approach; rather than evaluating how persons function, we should evaluate ‘capabilities’, i.e.; the extent to which a person is able to function in a particular way, whether or not he or she chooses to do so. Older adults and service users were involved in the selection of relevant capabilities for both the ASCOT and ICECAP-O.

Because of the inclusion of quality of life aspects beyond health and the involvement of older adults in the development of the measures, it is likely that the ASCOT and ICECAP-O more adequately reflect the objectives of care services for older adults and the perspective of older adults than health-oriented quality of measures such as the EQ-5D and the SF-6D. Studies have shown that both the ASCOT and ICECAP-O are moderately to strongly associated with general quality of life scales, but also with health-oriented measures such as the EQ-5D, ADL limitations, illness and depressive symptoms. There is some evidence that, compared to the EQ-5D, the ASCOT and ICECAP-O are equally or stronger associated with the quality of care services and the intensity of care, as measured by hours delivered. Two other studies showed improvements in ICECAP-O after hip or knee surgery. This suggests that the ASCOT and ICECAP-O may be responsive to the impact of care services. Not much is known yet about how the measurement properties of the EQ-5D, ASCOT and ICECAP-O compare to each other. Therefore, the second part of this thesis describes the translation of the ASCOT into Dutch, and the comparison of the test-retest reliability, construct validity, responsiveness, content validity and feasibility of these three instruments when used in frail older adults. These are all measurement properties that are important for the use of instruments in evaluative studies such as economic evaluations. The last chapter in the second part of this thesis describes the use of the ASCOT for identifying factors that local authorities can use as policy targets for improving the quality of life for older adults in the community.

Outline of this thesis

As described above, this thesis consists of two parts. The first part focuses on the design and evaluation of the Geriatric Care Model in the ACT study, and the second part focuses on the evaluation of the ASCOT and the ICECAP-O.

In Chapter 2 the study protocol of the ACT study is presented. This protocol includes a detailed description of the Geriatric Care Model and the selection procedure of community-dwelling frail older adults. In Chapter 3, we assess the implementation fidelity of the Geriatric Care Model in the ACT study. Implementation fidelity is a measure for the degree to which an intervention is implemented as intended. This study gives insight in the implementation process of the Geriatric
General introduction

Care Model, which is important for the interpretation of the results of the study. The study presented in Chapter 4 evaluates the cost-effectiveness of the Geriatric Care Model in comparison with usual care.

In Chapter 5, 6, and 7 data from the ACT study is used to evaluate the ASCOT and ICECAP-O. Chapter 5 describes the translation process of the ASCOT into Dutch. Part of the translation procedure was an assessment of the cross-cultural validity using think-aloud interviews, test-retest reliability and a comparison of the response distributions and construct validity in the UK and the Netherlands. In Chapter 6, we compared the test-retest reliability, construct validity and responsiveness of the ASCOT, ICECAP-O and EQ-5D. Chapter 7 reports the content validity and feasibility of the ASCOT, ICECAP-O and EQ-5D from the perspective of older adults, by identifying response issues and participants’ opinions about the comprehensibility of items and coverage of quality of life domains. In Chapter 8, we use data from the English national Adult Social Care Survey to examine associations between the ASCOT and three potential policy targets for local authorities: (1) accessibility of information and advice, (2) design of the home and (3) accessibility of the local area.

Finally, in Chapter 9 we discuss the findings of the studies presented in this thesis and methodological considerations when interpreting these studies, followed by recommendations for clinical practice, policy and further research.
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Part 1

‘Frail older adults: Care in Transition’ study

Mevr. den Dubbelden (83) “Dat weet ik niet hoor, ik geef het aan mijn kinderen. En hoop dat de hulp in huis zo blijft zoals het nu is, en dat ik net zo goed verzorgd word.”
IMPLEMENTING THE CHRONIC CARE MODEL FOR FRAIL OLDER ADULTS IN THE NETHERLANDS:
STUDY PROTOCOL OF ACT
(FLAIL OLDER ADULTS: CARE IN TRANSITION)

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ABSTRACT

BACKGROUND Care for older adults is facing a number of challenges: health problems are not consistently identified at a timely stage, older adults report a lack of autonomy in their care process, and care systems are often confronted with the need for better coordination between health care professionals. We aim to address these challenges by introducing the geriatric care model, based on the chronic care model, and to evaluate its effects on the quality of life of community-dwelling frail older adults.

METHODS Design: In a 2-year stepped-wedge cluster randomised clinical trial with 6-monthly measurements, the chronic care model will be compared with usual care. The trial will be carried out among 35 primary care practices in two regions in the Netherlands. Per region, practices will be randomly allocated to four allocation arms designating the starting point of the intervention. Participants: 1200 community-dwelling older adults aged 65 or over and their primary informal caregivers. Primary care physicians will identify frail individuals based on a composite definition of frailty and a polypharmacy criterion. Final inclusion criterion: scoring 3 or more on a disability case-finding tool. Intervention: Every 6 months patients will receive a geriatric in-home assessment by a practice nurse, followed by a tailored care plan. Expert teams will manage and train practice nurses. Patients with complex care needs will be reviewed in interdisciplinary consultations. Evaluation: We will perform an effect evaluation, an economic evaluation, and a process evaluation. Primary outcome is quality of life as measured with the Short Form-12 questionnaire. Effect analyses will be based on the “intention-to-treat” principle, using multilevel regression analysis. Cost measurements will be administered continually during the study period. A cost-effectiveness analysis and cost-utility analysis will be conducted comparing mean total costs to functional status, care needs and QALYs. We will investigate the level of implementation, barriers and facilitators to successful implementation and the extent to which the intervention manages to achieve the transition necessary to overcome challenges in elderly care.

DISCUSSION This is one of the first studies assessing the effectiveness, cost-effectiveness and implementation process of the chronic care model for frail community-dwelling older adults.
BACKGROUND

As a result of aging of the population of industrialized countries, the group of community-dwelling older adults with multiple chronic conditions is vastly expanding. The subsequent accumulation of complex and long-term health needs causes the demand for care services to increase rapidly, accounting for a considerable share of health care utilization. Globally, usual care is attempting to uphold the standards necessary to deliver high-quality chronic disease care. Pressure on the sustainability of health care systems is likely to further increase in the near future, demanding the identification and targeting of the main bottlenecks in care for frail older adults.

In Europe, three major barriers to high-quality care for frail community-dwelling older adults have repeatedly been identified over the past few years. First, our predominantly reactive care systems fail to identify many older adults’ health risks and care needs at a timely stage, impeding the successful prevention of adverse outcomes. In addition, older adults experience a lack of autonomy in their own care process. Finally, care for frail older adults living at home is often fragmented, resulting in a lack of coordination and information exchange between health care professionals.

Offering integrated chronic care services may be the appropriate approach to overcome the challenges observed in elderly care: Evidence suggests that integrated care models have the potential to successfully improve quality of elderly care and may have a positive effect on health-related outcomes. In addition, qualitative studies evaluating the environmental impact of such models report perceived benefits by informal caregivers. However, overall review findings present a mixed picture, with studies showing inconsistent evaluation outcomes regarding the efficiency and effectiveness of the care models investigated.

The chronic care model is a multidimensional framework for chronic illness management, designed to guide and enhance the comprehensive and interdisciplinary delivery of care. Previous research has demonstrated its potential to improve health outcomes of patients with a chronic condition, and to improve quality of care. Despite the fact that the chronic care model approach is widely used to implement integrated and long-term care services, to our knowledge only one study so far reported using the model to deliver care to community-dwelling frail older persons in a primary care setting.

To overcome the aforementioned barriers to high-quality care for older adults, the frail older Adults: Care in Transition (ACT) study introduces the geriatric care model, a multifaceted intervention based on the chronic care model. Corresponding with the chronic care model, the geriatric care model aims to enable productive interactions between activated, informed patients and proactive, prepared health care professionals by combining in-home geriatric assessments.
with strong management by expert geriatric teams. To our knowledge, we are the only European study so far to investigate the impact of a chronic care model approach on frail older adults, and to evaluate the effectiveness as well as the cost-effectiveness and implementation process of such an intervention in a stepped wedge cluster randomised clinical trial.

Through implementation of the geriatric care model in a pragmatic trial, we seek to target the untimely recognition of health problems, the lack of autonomy perceived by older adults and the lack of coordination between health care professionals. In doing so, we hope to improve the quality of care for community-dwelling frail older adults, and subsequently improve their quality of life.

**METHODS**

**Study design and setting**

We will implement the geriatric care model using a stepped-wedge cluster randomised clinical trial design. A stepped wedge design is a type of cluster randomized trial design involving sequential roll-out of an intervention to primary care practices (clusters) over a number of time periods.20 Primary care practices in the control group offer usual care, whereas practices in the intervention group deliver care according to the geriatric care model. By the end of the study, all practices will have started with the intervention. The trial will run over a 24-month period, and will be conducted among a total of 35 primary care practices in the Netherlands, with practices distributed among the regions Amsterdam (18 practices) and West-Friesland (17 practices). The Amsterdam region is of an urban nature, whilst the West-Friesland area can be characterized as an urbanised rural setting. Following participant inclusion, effect measurements will be administered at baseline and at 6, 12, 18, and 24 months (Figure 1). The study received approval by the medical ethics committee of the VU University medical centre. Participants will enrol only after a signed declaration of informed consent.

**Randomisation**

Per region, primary care practices will be randomised using the computer-based ‘Random Allocation Software’ program. In both regions, primary care practices will be allocated to one of a total of four allocation arms by randomization. The allocation arm number designates the starting moment of the intervention with the geriatric care model at practice level (at 0, 6, 12 and 18 months after baseline). Figure 1 shows the number of primary care practices per region, as well as the starting moment of the geriatric care model on cluster level.
Study participants and recruitment methods

We will include community-dwelling frail older adults aged 65 years and over, recruited in participating primary care practices involved in the project, and their primary informal caregivers.

Frail older adults will be recruited in three steps.

1. Primary care physicians of participating primary care practices will identify frail individuals based on a composite definition of frailty (experiencing one or more limitations in either
physical, psychological and/or social areas) in their population of patients age 65 years and over meeting a polypharmacy criterion: 5 or more drugs prescribed in the last 3 months.\textsuperscript{21} Additionally, primary care physicians will include all other older patients meeting the composite description of frailty. Patients are excluded based on the following criteria: Residence outside area of practice registration; residence in a nursing home or in a home for the elderly; cognitive impairment or impaired mental status; critical or terminal illness.

2. Subsequently, all patients included by their primary care physician will receive an information letter and an informed consent form. Within two weeks, individuals selected during step one will be contacted by telephone by a project interviewer and asked to consider study participation.

3. In case of verbal consent, eligibility for trial entry will be established with the Program on Research for Integrating Services for the Maintenance of Autonomy case-finding tool for disability (PRISMA-7).\textsuperscript{22} Eligible patients (score $\geq 3$) will be invited to participate in the study, whereupon an appointment will be made for administration of baseline measurements and the collection of the signed informed consent form by a project interviewer.

Primary informal caregivers will be recruited by inquiring with participating older adults. We define a primary informal caregiver as the caregiver carrying most of the care burden for the family member, relative or friend requiring care. If a primary informal caregiver is present, and the participating older adult does not oppose to their involvement in the study, eligible persons will be contacted by telephone and asked to enrol. Informal caregivers interested in participating will receive an information letter and an informed consent form.

\textbf{Intervention: Geriatric care model}

\textit{Rationale}

The geriatric care model aims to target three main challenges care for older adults is currently facing (i.e. untimely detection of older adults’ health risks and care needs, older adults’ lack of autonomy in their care process and inadequate coordination of care). We expect the geriatric care model to improve the quality of the organisation and delivery of care on structure, process and outcome levels. We expect the total impact of this process to improve patient outcomes, resulting in improved self-reported quality of life (Figure 2).

\textit{Geriatric care model}

The geriatric care model aims to enable productive interactions between activated, informed patients and proactive, prepared health care professionals by combining tailored in-home geriatric
assessments with strong management. In both the Amsterdam and West-Friesland region, the geriatric care model is integrated into routine practice by an expert geriatric team consisting of an experienced geriatric nurse and an elderly care physician.

**Figure 2.** Schematic representation of the geriatric care model

*Geriatric assessments by practice nurses*

Every six months, a frail older adult will receive an assessment of health and care needs by a practice nurse, followed by a tailored care plan. This procedure will involve two home visits. During the first visit, a multidimensional assessment will be conducted using the web-based Community Health Assessment version 9.1 of the Resident Assessment Instrument (RAI-CHA). RAI facilitates the identification of existing care needs, helps nurses standardize their routines, and works as a reminder system for follow-up. After each RAI-assessment, the practice nurse will review the outcomes with the primary care physician and write a tailored care plan. Two weeks after the first visit a second home visit will take place, in which the nurse explores the older adult’s wishes regarding the outcomes of the assessment, provides them with information on appropriate management and/or treatment options, and stimulates their active involvement in the decision making process. According to their nature and content, actions listed in the final care plan will be evaluated by the older adult in consultation with the nurse. At all time, the older adult’s own care wishes will remain at the center of the decision making process.
Management by expert geriatric teams

During the intervention the geriatric expert teams will carry out the following three main tasks: (1) (quality) management, (2) expert knowledge transfer and (3) building and maintaining local networks of care organisations (Figure 2).

Management of the quality of care delivery by practice nurses and knowledge transfer will constitute of team meetings, training sessions and multidisciplinary patient reviews. First, team meetings will be held on a regular basis, and if required additional coaching and support will be provided to nurses individually. Additionally, as described in the paragraph below, geriatric team members will organize training sessions conform nurses’ educational needs. The sessions provide a platform for peer supervision and encourage knowledge exchange between nurses. Finally, in the event of a practice nurse reporting a complex patient, a multidisciplinary consultation will be organised by the geriatric team for an interdisciplinary review of the client’s situation. The consultation will be attended by a core group, consisting of the practice nurse, the primary care physician, the pharmacists and the geriatric team members. Depending on the situation demanding the consultation, other health care professionals central to the patient’s treatment (e.g. a physiotherapist) will be invited to join.

Throughout the intervention, the two geriatric teams will set up and maintain regional networks of local organisations. In order to facilitate the coordination between providers of care services for older adults in the region, primary care professionals and representatives of various community-based care organisations will meet on a regular basis, with the aim to subsequently enhance the coordination of care on a patient level.

Education of professionals

Practice nurses carrying out the intervention will take part in a tailored training program. Prior to the start of the intervention, nurses will participate in a 3-day motivational interviewing course. Further, both the practice nurses and the geriatric team members will participate in a one day RAI workshop before carrying out the intervention. In order to prevent contamination bias between the allocation arms, nurses will start their training program shortly before they start working with the geriatric care model. Alongside the intervention a second training program will run, consisting of a ‘training on the job’ motivational interviewing session as well as clinical education on geriatric topics provided by the expert team staff. Expert team members will identify each session’s topic(s) by means of field observations and RAI-output reviews. Several months into the intervention, practice nurses and the geriatric team members will be offered a refresher course RAI.
Strategies for implementation

Implementation of the geriatric care model is predicated upon the idea of the professional self-regulation of expert teams and practice nurses. Before the intervention is carried out its main theoretical and practical content is outlined by the research team, where after the development of work routines and protocols is informed by the professionals’ experiences in the field without research staff interference.

To avoid contamination, nurses working with the geriatric care model will not be employed in primary care practices in the control groups that have yet to start delivering the intervention.

Control group: usual care

Aimed at providing integral care services, primary care in the Netherlands plays an important role in the organisation of community elderly care. Of people over 75, almost hundred percent initiate contact with a primary care physician at least once a year. Offering both (sub)acute and chronic care to older adults living at home, primary care physicians work in close collaboration with local health care services. A primary care physician may refer an older adult to a variety of local care organisations, whose services range from specialised in-home care to mental health support.

Evaluating the geriatric care model

We will perform an effect evaluation, an economic evaluation, and a process evaluation. Throughout the 2-year data collection period older adults will advice researchers on the appropriateness and quality of the content of qualitative and quantitative research material, and will assist researchers with the interpretation of qualitative data derived from interviews with older adults.

Effect evaluation

The primary outcome of the study is quality of life as measured by the 12-item Short Form questionnaire (SF-12). The SF-12 measures quality of life in two domains: a mental health component score (MCS) and a physical health component score (PCS). All outcome measures are presented in Table 1.

Sample size calculations

Sample size calculations are based on the expected effects of the intervention on the primary outcome, quality of life, measured by the SF-12. Calculations are done using the equation for a longitudinal design and adjusted for the effect of clustering of primary care practices; SF-12 coefficients used in the calculations are derived from previous studies with a study population similar to ours. The number of follow up measurements is 4; Mean cluster size is based on the
Table 1. Overview of outcomes, baseline measurements and follow-up measurements

<table>
<thead>
<tr>
<th>Patient outcomes</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Quality of Life</td>
<td>SF-12 25</td>
</tr>
<tr>
<td>2. Health-related Quality of Life</td>
<td>EuroQol (EQ-5D) 26</td>
</tr>
<tr>
<td>3. Independence in ADL</td>
<td>Katz ADL index 27</td>
</tr>
<tr>
<td>4. Psychological Wellbeing</td>
<td>RAND-36 subscale 28</td>
</tr>
<tr>
<td>5. Social Functioning</td>
<td>1 item on RAND-36 scale</td>
</tr>
<tr>
<td>6. Self-reported Health</td>
<td>2 items on RAND-36 scale</td>
</tr>
<tr>
<td>7. Acute Hospital Admissions</td>
<td>1 item of our data set and Cost diaries</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality of Care</th>
<th>8. Care Needs</th>
<th>CANE 29</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Process Outcomes: Achieved transition</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Patient-reported Client-centred Care</td>
<td>CCCQ 30</td>
</tr>
<tr>
<td>10. Coordination of Care from the patient’s perspective</td>
<td>2 items on QUOTE 31</td>
</tr>
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<table>
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<tr>
<th>Informal Caregivers</th>
<th>Instrument</th>
</tr>
</thead>
<tbody>
<tr>
<td>12. Quality of life</td>
<td>SF-12</td>
</tr>
<tr>
<td>13. Self-rated Burden of Care</td>
<td>CarerQol 31</td>
</tr>
</tbody>
</table>

| Costs | Direct and Indirect Costs | Cost diaries |

SF-12=Short Form-12 questionnaire; EuroQol (EQ-5D)=measures of 5 dimensions of health-related quality of life; Katz ADL=Katz Activities of Daily Living; RAND-36=measure of health-related quality of life; CANE=Camberwell assessment of needs in the elderly; Arm 1-4=allocation arm number 1-4; CCCQ=Client-centred Care Questionnaire; QUOTE= QUality Of care Through the patient’s Eyes; CarerQol=care-related quality of life of informal caregivers.

expected number of participants per cluster at baseline (N=33). We assume the following: a standard deviation of 7.1 (PCS) and 6.6 (MCS), a correlation coefficient of repeated measurements of 0.66 (PCS) and 0.5 (MCS), an intra-cluster correlation coefficient of 0.02 for both PCS and MCS, an alpha of 0.05 and a power of 90%. To detect a clinical difference of 3 points on the SF-12 scale between intervention and control groups and assuming an attrition rate of 20%, the study would require 180 (PCS) and 131 (MCS) eligible patients per arm.

Data collection

Data will be collected among older adults at home by means of computer assisted personal interviewing. For each observation, interviewers will receive training and will be supervised by research
staff. A random sample of the interviews will be tape recorded; in order to enhance the quality of the data, researchers will evaluate the quality of the recordings and report back their findings to the interviewers. We will use postal questionnaires to collect data among the primary informal caregivers.

**Analyses**

First, characteristics of the participants at baseline will be described and differences between the 4 allocation arms are tested using chi-square tests and ANOVA or non-parametric tests. Second, effect analyses will be done based on the “intention-to-treat” principle. For both older adults and their primary caregivers, all outcome measures will be compared between the group receiving the geriatric care model and the group receiving usual care using multilevel regression analysis. Multilevel regression analysis takes into account the non-independent nature of hierarchical data and does not require data for a fixed number of observations for all respondents. In the present study, three levels can be distinguished. Repeated observations are clustered within the patient and the patients are clustered within the primary care practices. Potential confounding (due to baseline differences) and effect-modifying will be accounted for during the analysis. If necessary an adjustment will be made for baseline differences between the groups.

In addition to the investigation of the overall effect of the intervention, the stepped-wedge design allows us to study the effects of the duration of the intervention on outcome measures. Therefore, in additional analysis, the interaction between time and intervention will be added to the analyses.

**Blinding**

We will aim to maintain a blind status for as many people involved in the study as possible. Professionals carrying out the intervention will not be informed about a patient’s enrolment in the study until the start of the intervention. During data analysis, researchers will be blinded to the group assignment. Due to ethical considerations, it will not be feasible for interviewers collecting the data and participants to be blinded to group assignment. All participants will be informed about the starting time of the intervention, and will at all times be aware of their group status.

**Economic evaluation**

The economic evaluation will be performed from a societal perspective. We will consider all relevant direct and indirect costs, such as costs of the care model, consultations with primary care physicians, medical specialists, home care, medication use, hospital and nursing home admissions, informal care time and cost of lost labour days of the informal caregiver. Care utilization data
of both the client and the caregiver will be prospectively collected alongside the trial using six monthly cost diaries. Medication data of clients will be obtained from the centralized pharmacy files in the research regions. Dutch standard costs are used to value resource use. Medication costs will be valued using prices of the Royal Dutch Society for Pharmacy. Lost productivity costs will be calculated according to the friction cost approach (friction period 154 days) using the mean age and sex specific income of the Dutch population. We will calculate a cost price for the care model using a bottom-up approach. The EuroQol (EQ-5D) will be used to measure health-related quality of life. We will estimate utilities with the Dutch tariff developed by Lamers et al. and then calculate Quality Adjusted Life Years (QALYs).

Missing data on costs and outcomes will be imputed using multiple imputation according to the Multivariate Imputation by Chained Equations (MICE) algorithm. A cost-effectiveness (CE) analysis will be performed comparing the difference in total mean costs to the difference in quality of life, functional status and care needs; a cost-utility (CU) analysis will be used to estimate the incremental costs per QALY. Uncertainty around the incremental CE and CU ratios will be estimated using the bias-corrected percentile bootstrapping method (5000 replications) and will be plotted in cost-effectiveness planes. In addition, cost-effectiveness acceptability curves and net monetary benefits will be estimated to show the probability that the geriatric care model is cost-effective in comparison with usual care using different ceiling ratios. Sensitivity analysis will be done to assess the robustness of the results and will include the most important cost drivers.

Process evaluation

Alongside the intervention, we will conduct a mixed methods process evaluation. The process evaluation data will be used for summative purposes: Information will be used investigate the extent to which the intervention was implemented as planned. By exploring the ‘black box’ of the intervention, we aim to both gain an insight in (cost)effectiveness results and facilitate future implementation.

Process outcomes are level of implementation of the geriatric care model, barriers and facilitators to successful implementation, and the extent to which the intervention manages to achieve the transition necessary to target the three challenges in care for older adults, i.e. the untimely identification of health problems and care needs, the lack of client autonomy and the inadequate coordination between care professionals.

First, we will aim to assess the level of implementation using process constructs fidelity, dose delivered and dose received. Further, we will seek to identify barriers and facilitators to successful implementation of the geriatric care model on cultural, operational and structural levels. To investigate whether the geriatric care model accomplishes the transition we intended, we will
explore how older adults experience autonomy, how older adults and health care professionals experience the way care is coordinated during the intervention, and the extent to which the geriatric care model manages to be proactive in identifying previously undetected health problems and care needs. Finally, in order to facilitate future implementation of the geriatric care model, we will investigate health care professionals’ learning experiences with the intervention. Table 2 offers an overview of process outcomes, used constructs and methods of data collection.

Per process outcome, results of the qualitative and quantitative data collection will be analysed conform the requirements of a convergent parallel design. In a convergent parallel design, quantitative and qualitative data are concurrently collected in the same phase of the research process, and outcomes of both qualitative and quantitative analysis are combined during the overall interpretation.46

**DISCUSSION**

The ACT-study aims to investigate the extent to which the geriatric care model has an effect on frail older adults’ quality of life. To our knowledge, it is one of the first European studies adopting a chronic care model approach to not only assess the effectiveness, but also the cost-effectiveness and the implementation process of an intervention for frail older adults living at home.

Carrying out the study in a real life primary care setting will provide insight into the generalizability of the geriatric care model, and may facilitate future implementation into routine practice. Moreover, the stepped-wedge design used in this study will allow us to introduce the intervention to all primary care practices participating in the study, so all frail older adults in the four allocation arms will eventually receive the geriatric care model. This has a number of advantages. First, the phased rolling out of the intervention will give us an opportunity to avoid having to withhold the geriatric care model from people who might benefit from it. Not only is this ethical argument compelling in itself, it has also played an important role in motivating primary care physicians to participate in the study. In addition, introducing the intervention to all four allocation arms offers methodological advantages. As mentioned in the effect evaluation paragraph, it will present us with the opportunity to take into account the effects of the duration of the intervention on outcome measures, thusly allowing us to differentiate between changes in outcomes due to time and due to the intervention.

In the years to come, the aging of the population will increasingly impose a strain on health care systems worldwide. It has become apparent that tackling emerging obstacles is essential in the securing of high-quality elderly care. By introducing the geriatric care model, we hope to
contribute to the existing evidence on quality improvement and the effectiveness of integrated care models, and to present a solution for the many challenges facing care for older adults today.

**Table 2. Process outcomes, constructs and methods of data collection**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Concept</th>
<th>Methods</th>
</tr>
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</table>
| Level of implementation                      | Fidelity           | • Semi-structured interviews* with geriatric team members, nurses, primary care physicians  
• Focus groups* with practice nurses  
• Tailored care plans, time registration by practice nurses, registrations by expert geriatric teams, minutes of team meetings and training sessions  
• Time registrations by practice nurses  
- Average amount of nurse’s working hours spent delivering intervention components (e.g. In-home assessments and care plan evaluation with clients, consultations with primary care physician, multidisciplinary consultations)  
• Registrations by expert geriatric teams  
- Number of multidisciplinary consultations organized  
• Tailored care plans (sample)  
- Average number of observations (RAI outcomes, nurses’ own observations) per care plan  
- Average number of actions formulated per care plan  
- Average number of care professionals involved in actions listed  
• Minutes of team meetings, registrations by expert geriatric teams  
- Number of training and coaching sessions and frequency of nurse’s attendance at these sessions  
- Number of team meetings and frequency of nurse’s attendance at these meetings  
• Semi-structured interviews* with geriatric team members, nurses, primary care physicians  
• Focus groups* with practice nurses, local stakeholders  |
| Dose delivered (completeness)                |                    | • Tailored care plans  
- Total number of care plans delivered to clients during the intervention  
• Tailored care plans (sample)  
- Average number of observations (RAI outcomes, nurses’ own observations) per care plan  
- Average number of actions formulated per care plan  
- Average number of care professionals involved in actions listed  
• Time registrations by practice nurses  
- Average amount of nurse’s working hours spent delivering intervention components (e.g. In-home assessments and care plan evaluation with clients, consultations with primary care physician, multidisciplinary consultations)  
• Registrations by expert geriatric teams  
- Number of multidisciplinary consultations organized  
• Tailored care plans (sample)  
- Average number of observations (RAI outcomes, nurses’ own observations) per care plan  
- Average number of actions formulated per care plan  
- Average number of care professionals involved in actions listed  
• Minutes of team meetings, registrations by expert geriatric teams  
- Number of training and coaching sessions and frequency of nurse’s attendance at these sessions  
- Number of team meetings and frequency of nurse’s attendance at these meetings  
• Semi-structured interviews* with geriatric team members, nurses, primary care physicians  
• Focus groups* with practice nurses, local stakeholders  |
| Dose received (exposure, satisfaction)       |                    | • Tailored care plans (sample)  
- Average number of observations (RAI outcomes, nurses’ own observations) per care plan  
- Average number of actions formulated per care plan  
- Average number of care professionals involved in actions listed  
• Time registrations by practice nurses  
- Average amount of nurse’s working hours spent delivering intervention components (e.g. In-home assessments and care plan evaluation with clients, consultations with primary care physician, multidisciplinary consultations)  
• Registrations by expert geriatric teams  
- Number of multidisciplinary consultations organized  
• Tailored care plans (sample)  
- Average number of observations (RAI outcomes, nurses’ own observations) per care plan  
- Average number of actions formulated per care plan  
- Average number of care professionals involved in actions listed  
• Minutes of team meetings, registrations by expert geriatric teams  
- Number of training and coaching sessions and frequency of nurse’s attendance at these sessions  
- Number of team meetings and frequency of nurse’s attendance at these meetings  
• Semi-structured interviews* with geriatric team members, nurses, primary care physicians  
• Focus groups* with practice nurses, local stakeholders  |
| Barriers and facilitators to implementa tion | Barriers on cultural, operational and structural levels | • Semi-structured interviews* with older adults, geriatric team members, nurses, primary care physicians  
• Focus groups * with practice nurses, local stakeholders  |
| Extent to which transition is achieved       | Client autonomy    | • Semi-structured interviews * with older adults  
• CCCQ questionnaire **  |
| Coordination of care from the perspective of health professionals and patients |                     | • Semi-structured interviews * with geriatric team members, nurses, primary care physicians, older adults  
• Focus groups * with practice nurses  
• 2 Items on QUOTE questionnaire **  |
| Timely identification of health problems and care needs |                    | • Tailored care plans  
- Percentage of total number of RAI outcomes and nurses’ own registrations previously unknown to health care professionals  |
| Learning experiences of professionals       |                    | • Semi-structured interviews * with geriatric team members, nurses, primary care physicians  
• Focus groups * with practice nurses, stakeholders  |

* The qualitative study sample will include all older adults and health care professionals participating in the project, i.e. practice nurses, geriatric team members and primary care physicians and will be selected by means of a purposive (maximum variation) sampling procedure.** The quantitative study sample will include all older adults participating in the study; CCCQ=Client-centred Care Questionnaire; QUOTE=QUality Of care Through the patient’s Eyes.
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