Care for older people in Dutch general practice: Results from the FIT study

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General discussion

This thesis focuses on nurse-led multifactorial care to prevent or postpone new disabilities in community-living older people. We developed an instrument to identify older persons at increased risk of functional decline, a multifactorial nurse-led intervention (Functiebehoor in Transitie (FIT) care model) for the most prevalent geriatric conditions based on all available evidence in primary care, and evaluated the (cost-)effectiveness of the intervention to prevent or postpone new disabilities. In this chapter the main findings will be placed in the perspective of recent developments and current knowledge, and methodological issues will be addressed. Finally, we provide recommendations for use in clinical practice and future research.

Identifying the target population

Prevention or postponement of new disabilities starts with identification of the target population: older people at increased risk of functional decline. We modified and validated the original ISAR screening questionnaire into an instrument to identify older people at increased risk of functional decline in primary care (Identification of Seniors at Risk - Primary Care) (Chapter 2). The modified version comprises three items: IADL dependence, self-reported memory complaints, and age. These three variables together predicted functional decline best above all other combinations of variables. The ISAR-PC appeared to have moderate discrimination and was well calibrated. The ISAR-PC is easily applicable, requires very little time to complete, and may serve as an efficient first step in a two-step approach targeting community-dwelling older people at risk of functional decline.

The variables IADL dependence, self-reported memory complaints and age also appeared to be strong predictors of functional decline in several other studies. This also supports the validity of the individual items included in the ISAR-PC. Based on the literature, we aimed to include a younger (70-75 years) and a less frail (“prefrail”) population to increase the yield of comprehensive geriatric assessments and tailored interventions. The median age of persons identified at increased risk with the ISAR-PC was 79.8 (SD 6.6) years in the development cohort (N=790) and 82.0 (SD 6.4) years in the validation cohort (N=2,573) (Chapter 2). The age of the persons identified at increased risk with the ISAR-PC was higher than the age we aimed to target, which was probably caused by the item ‘age’ in the prediction model. However, in the FIT trial the identified population had a median Katz-score of 2 (IQR 1-5) points, and a low overall
mortality rate (3.9%) after one year. This indicates that the persons identified with the ISAR-PC were predominantly pre-frail (Chapter 4).

The ISAR-PC demonstrated a moderate discrimination in both the developmental and the external validation cohorts. The discriminative ability of several screening instruments to distinguish a high risk from a low risk population ranges from 0.70 to 0.80.\textsuperscript{6-11} Considering the heterogeneous group of community-dwelling older persons, the relatively long time frame in which decline takes place, and the (partly) reversible character of functional decline, it may be difficult to further increase the AUC for a prediction of 12 months. As the differences between prediction models attenuate, more emphasis may be put on the feasibility of the screening instrument, their face validity, the aim of the subsequent proactive intervention strategy, but also on available alternatives (e.g. the GP’s judgement).\textsuperscript{12}

At the start of this study, there were no results available on the predictive accuracy of the GP’s identifying a pre-frail population at increased risk of functional decline. A recent study demonstrated that, based on a two-step tool (EASY-Care Two step Older persons Screening (EASY-Care TOS)), the GP’s predictive accuracy of functional decline was similar to identification instruments.\textsuperscript{11} However, without a specific definition of vulnerability, the GP’s personal assessment of individual vulnerability demonstrated substantial variation between GPs on the functional status.\textsuperscript{13} In view of these inconsistent results, screening questionnaires are preferred to identify a pre-frail population at increased risk of functional decline. Future research is needed to assess whether different identification strategies target different profiles of older people.

\textit{Nurse-led multifactorial care to prevent or postpone new disabilities in community-living older people}

We designed a cluster randomized trial consisting of comprehensive geriatric assessment, an individually tailored care and treatment plan based on multifactorial interventions and nurse-led care coordination to prevent or postpone new disabilities in community-living older persons at increased risk of functional decline (Chapter 3). We found no evidence that one-year nurse-led multifactorial care was better than current primary care to prevent or postpone new disabilities in older persons at increased risk of functional decline. Additionally, the intervention was not more effective than current primary care in the Netherlands on health-related quality of life,
A major strength of this study was that it robustly excluded clinically relevant effects of the intervention on the primary outcome (Chapter 4). Specifically, the 95% confidence interval around the mean difference between the two treatment groups (-0.07; 95% CI, −0.22 to 0.07) excluded the predefined functional decline of -0.5 points by a wide margin. Thus, although the study was not designed as a non-inferiority trial, we found evidence of no effect. The sensitivity analyses accounting for missing data confirmed the robustness of the main analyses.

There are several possible explanations why we did not find an effect of one-year nurse-led multifactorial care. First, insufficient contrast between the study groups regarding to available care and access to care could explain the lack of effect that was observed. Usual GP care in The Netherlands is available for every inhabitant and the quality of usual GP care is considered of high standard. The majority of the participants in the control group contacted their GP on a regular basis and received home care nursing. In these GP practices, evidence-based guidelines for the management of chronic conditions were available, and the adherence to these guidelines was good. Problem-based, goal-oriented approaches may already have been incorporated in usual care and additional improvement is perhaps more difficult than anticipated. Second, the intervention lasted one year, which may have been too short to find an effect. Targeting a pre-frail population, with emphasis on the prevention of the onset of new disabilities, several years of intervention and follow-up are likely required to demonstrate beneficial effects. Furthermore, although experienced CCRNs were trained before and during the intervention, we learned from the process evaluation that nurses needed time to incorporate the pro-active mindset, the new way of working with the GP, and to focus on geriatric conditions. A transition from reactive to pro-active care required a change in culture for GPs, nurses and participants. Until now, older people generally visited a GP with advanced symptoms, and GPs acted accordingly upon them. With pro-active care provision, older people had to learn about risk factors, that some geriatric conditions could be treated and were not necessarily part of normal aging, and how they could apply self-management. The nurses had to learn new skills and attitude how to enhance patient-centered care by coaching including self-management instead of solving the problems themselves. Such a profound change may take longer than one year. Third, although the modified Katz-ADL index was able to validly and reliably measure unfavorable health outcomes, its
summary scores from different residential settings should not be directly compared/combined in individuals. The modified Katz-ADL index exhibited different patterns of difficulty in community-dwelling and residential care facility settings.\textsuperscript{22} Besides, the modified Katz-ADL index poorly discriminated between people with relatively few disabilities in a community-dwelling setting.\textsuperscript{22} However, at the start of the study, this was still unknown. In addition, more insight is needed in its responsiveness to change.\textsuperscript{22,23} Using both standardized measures and patient-centered outcomes, such as goal attainment scaling (GAS), we might have been able to measure outcomes of the intervention for individual patients better.\textsuperscript{24} GAS, is a clinimetric tool that describes achievement of goals that are important for individual patients.\textsuperscript{25} It outlines the process of setting goals so that the achievement of each goal can be measured on a 5-point scale ranging from -2 to +2, and then explains a method for quantifying the outcome in a single aggregated goal attainment score.\textsuperscript{24} GAS has demonstrated ability to detect clinically important change in the evaluation of complex interventions in frail elderly patients.\textsuperscript{25} Fourth, there was insufficient alignment between the target population, initiated interventions and the outcome measures used. Participants received interventions for different geriatric conditions, such as pain, incontinence, mobility, depressive symptoms, and loneliness, but these interventions may not have direct effects on new disability and health-related quality of life. To enhance the effect of the intervention, more emphasis should be put on interventions that can directly postpone new disabilities, such as physical activity.\textsuperscript{16,26} Fifth, although in the comprehensive geriatric assessment (CGA) a mean number of 6.4 (SD 2.8) problems was identified, the median number of problems treated by the care and treatment plan (CTP) was 1 (IQR 0-2). This can be explained by the intervention starting with screening, with the participants having no active complaints or care needs. This is consistent with previous findings.\textsuperscript{27} Finally, although we found a small and transient effect of the intervention for after-hours GP care use, we think that this should be interpreted with caution because of the small numbers of observations and relatively large number of outcome measures assessed.

Meta-analyses on multifactorial interventions and preventive home visits have demonstrated small beneficial effects on the prevention or postponement of new disabilities.\textsuperscript{3,23,28} However, these results should be interpreted with caution due to heterogeneity in the target population, the large variability of possible interventions and the variation in outcome measurements of ADL and IADL.\textsuperscript{3,23,28} An increased risk reduction on disability was found in studies conducted three decades ago or in studies
performed in the United States.\(^3,23\) This might implicate that healthcare systems probably improved since then, including incorporating principles of proactive elderly care in daily practice.\(^3\) Two recent studies in the Netherlands described a significant effect of nurse-led multifactorial care on the incidence of new disabilities (new IADLs or on the modified Katz-ADL index score).\(^29,30\) However, these effects disappeared after correction,\(^30\) or were too small to be shown as clinically relevant.\(^29\) Other recent studies conducted in The Netherlands found neutral effects of nurse-led multifactorial care on new disabilities.\(^30-33\) Recent studies in Canada and the United Kingdom also showed neutral findings after one,- and three years follow-up respectively.\(^34,35\) In countries with a well-developed and easily accessible primary care system (such as found in Canada, the UK and the Netherlands) additional improvement by nurse-led multifactorial care may be difficult to achieve.\(^15\)

**Recognition of identified geriatric conditions by participants**

In a setting with high quality primary care, a carefully designed CGA identified many geriatric conditions, of which few were recognized as a problem by older persons at risk of functional decline (Chapter 5). Out of 32 geriatric conditions, functional dependency was most commonly identified, and pain was the most widely recognized problem. To our knowledge, our study is among the first studies assessing how often older persons recognized the geriatric conditions being evaluated. We found a recognition rate of one geriatric condition out of a median of 8 identified geriatric conditions. This could indicate that the CGA detected conditions with no apparent clinical relevance. For example, older persons may simply accept certain conditions as a part of normal ageing, problems were perhaps already treated, or were not perceived as appropriate problems to discuss with the GP. Nevertheless, asking older persons which of the identified geriatric conditions they recognized as a problem by themselves might have contributed to a person-centered approach, potentially facilitating shared decision-making and overall efficiency.\(^36\) Most studies evaluating the prevalence of geriatric conditions also reported on the initiation of interventions, however, the reported intervention rates were higher compared to our results.\(^37\) This could have resulted from older persons’ prioritizations, but could also be due to already high standards of care as usual in Dutch GP practice.
A limitation of this aspect of the FIT study is that we did not assess whether identified geriatric conditions were newly detected or were conditions already identified and therefore known to the GP.

**Economic evaluation of nurse-led multifactorial care**

The results of the economic evaluation (Chapter 6) demonstrated that a one-year nurse-led multifactorial care program was not cost-effective compared with care as usual in community-living older people at increased risk of functional decline in the Netherlands. The effects of the one-year nurse-led intervention on new disabilities and QALYs were statistically not significant. Total costs in the intervention group were significantly higher than in the usual care group.

There are several possible explanations for these findings. First, higher costs for personal care and nursing home admission, may have been the direct result of the initiated interventions. This ‘intervention effect’ has been described before.\(^38-42\) Second, the cost-effectiveness analyses did not include medication costs, or costs of allied healthcare professions (physiotherapy, occupational therapy). In total, 14% of all initiated interventions consisted of referrals to allied healthcare professionals. This may have resulted in an underestimation of the intervention cost. Nevertheless, the categories of healthcare that contributed most to total costs (home care, long-term care, and secondary care) were included in the cost-effectiveness-analyses. Third, health-related quality of life is a widely used outcome measure in economic evaluations of health interventions. However, quality of life may include other aspects, broader than health, particularly in care for older people.\(^42\) The Adult Social Care Outcomes Toolkit (ASCOT) measures social care-related quality of life and can be used in economic evaluations of care interventions for older people.\(^43\)

Until the start of this study, cost-effectiveness analyses on multifactorial care to prevent or postpone new disabilities were scarce.\(^44\) Recent studies in the Netherlands and Finland found no evidence for the cost-effectiveness of multifactorial preventive interventions in preventing or postponing new disabilities as compared with usual care.\(^32,40-42,45\) This is consistent with the results of this study. Two recent studies from the Netherlands and Australia found that their intervention was cost-effective at high willingness to pay ratios (20,000 EUR and 50,000 Australian dollars respectively).\(^29,46\) Considering the heterogeneity in the study populations and interventions in these studies, it is difficult to adequately explain these contradicting results. Substantial
variation in the total cost per participant consists between different studies over a one-year period (the estimated total amounts vary between EUR 13,251 and EUR 19,353). The total cost per participant described in our study are lower than the total costs described in these other studies. This may have resulted from the lack of informal care costs in our study. Home care and nursing home admission were the main cost drivers in other studies as well.

**Self-reported data of healthcare utilization**

Self-report of hospitalizations and GP home visits in a general community-living older population aged 70 years and above (N=790), seemed adequate and efficient for a large majority of older persons (Chapter 7). Correlations between self-report data and data from GPs’ electronic medical records (EMR) were substantial for ‘hospitalizations’ and ‘GP home visits’ at 12 months. Hospitalizations and GP home visits were slightly over-reported compared to data based on the EMR after one year. Comparable estimates for over-reporting and under-reporting hospitalization were described in literature. Non-respondents and participants lost to follow-up for other reasons received more GP home visits. Participants who died or were institutionalized were older and more often functionally impaired, and utilized more healthcare services. We did not find any literature on healthcare utilization among non-respondents. This study showed that with increasing age and disabilities in daily functioning, healthcare utilization increased and participation time in the study decreased.

**Minimal important change of daily functioning**

To improve our understanding of what constituted relevant functional decline for older persons (Chapter 8) we calculated both the minimal important change (MIC) and the minimal detectable change (MDC) of the Katz-ADL index score and the Lawton IADL scale, using both anchor-based and distributional methods for community-living older individuals with at least one (I)ADL disability. The MIC of both the Katz-ADL index and the Lawton IADL scale were around half a point. The MDC was however far above one point on both instruments. There was substantial variation across methods for both the MIC and the MDC. To measure a change beyond measurement error on both instruments sample-sizes depend on the used method to calculate the MIC. So, in order to detect a clinical meaningful decline of at least 0.5 point on the Katz ADL, at least 463 participants need to be included in a trial.
To our knowledge, this is the first study on minimal important change and minimal detectable change of self-reported (I)ADL in community-living older individuals using both anchor-based, and distributional methods. However, the anchor-based MIC of (I)ADL should be interpreted with caution: the correlation between the external anchor and the two measurement instruments was low, which might result in increased misclassification at the individual level.

Both instruments have a narrow score-range, which might have influenced the estimated MIC and MDC values. Although the Katz-ADL index score and the Lawton IADL scale are frequently used in both clinical practice and research, both scales were developed to study results of (clinical) treatment in older persons and chronically ill on group level, and were not designed to measure change and responsiveness at an individual level. The estimated MIC of both instruments are therefore especially useful for clinical research, while they may not be suitable for clinical practice.

Methodological and implementation challenges

Contrast between study groups

Since the launch of the National Care for the Elderly Programme (NCEP) in 2008, a wide array of healthcare interventions for older people has fueled Dutch primary and secondary healthcare. Although the participation rates in our trial were high, several initiatives were started in parallel (e.g. on improving social or living conditions for older people) and may have affected participation and follow-up rates (Chapter 3-6). In 2010, the healthcare insurer started to reimburse preventive primary care for frail older people, and many GPs recruited a practice nurse to initiate care coordination for older people. Twenty-four general practices who were considering to do the same, but who had not yet taken this step, were willing to participate in our study. In the control group, we offered practices a temporary reimbursement to postpone this nurse-led care for older people until study termination. Furthermore, various position papers for the care for older people in primary care have been published since 2007. These changes may have diminished the contrast between the intervention and usual care group in the trial.
Missing data

Selective attrition is a common problem in studies involving older persons. Older persons are more likely to experience health and functional problems that limit data collection.\textsuperscript{52} Missing values, resulting from incomplete data collection or lost to follow-up, can bias results, reduce generalizability and limit power.\textsuperscript{52} In the prospective cohort study (Chapters 2, 7, and 8) and the randomized trial (Chapters 3, 4, 5 and 6) we tried to prevent missing values by choosing easy applicable and measurable outcomes and reminded participants through telephone calls and by post. At baseline, in both studies, response rates were around 70\%, and after 12 months, around 17\% of the participants were lost to follow-up. We analyzed the missing values to understand underlying patterns of missing data.\textsuperscript{53} In both the cohort and the trial study, participants who were lost to follow-up at 12 months were more dependent in ADL and IADL and had at baseline more comorbidities and risk factors for functional decline (Chapter 2 and 4). In chapter 2, the development and validation of the ISAR-PC, we imputed missing data as we wanted to develop a screening tool for the complete elderly population. In Chapter 4, the evaluation of the nurse-led multifactorial care model, multiple imputation of missing data was not deemed necessary to perform a longitudinal mixed model analysis since the data were missing at random and the model fits the data.\textsuperscript{53} We performed a sensitivity analyses with imputed data to study the effect of the selective attrition on the outcome, and similar results were found. In Chapter 6, the economic evaluation of the trial, 23\% of the cost data, 24\% of the modified Katz-ADL index data, and 23\% of the QALY data were missing after one year. It is not possible to perform longitudinal analysis in an economic evaluation. To account for missing data, we imputed missing data using multiple imputation with predictive mean matching (PMM).\textsuperscript{54} Multiple imputation is highly preferred above naïve imputation methods such as Last Value Carried Forward (LVCF) which has been shown to bias parameter estimates.\textsuperscript{54}

Challenge of complex intervention studies

In 2008 the Medical Research Council (MRC) published a guidance on developing and evaluating complex interventions, the MRC framework.\textsuperscript{55} We carefully followed the steps of the MRC framework developing, piloting, evaluating, reporting and implementing our trial to study the (cost) effectiveness of nurse-led multifactorial care. We studied all available evidence using meta-analyses of existing trials, developed a
screening instrument to identify patients at increased risk for functional decline (ISAR-PC), and performed a pilot study to assess the effects of the intervention and the nurse-led care. Our evaluation study was a well-designed cluster randomized trial, and included a process evaluation to understand the working mechanisms of the intervention and the experiences of patients and professionals, and an economic evaluation. Randomization is considered the most powerful experimental design in clinical trials: with other variables equal between groups, on average, any differences in outcome can be attributed to the intervention.\textsuperscript{56} However, randomization is most useful in evaluating relatively standardized interventions where one or two variables change.\textsuperscript{57} It has been questioned whether a randomized trial is the most appropriate method to evaluate complex interventions, considering the variability in character and form and interaction with the local context.\textsuperscript{58} This emphasizes accurate application of the MRC framework including qualitative evaluations when complex interventions are evaluated using randomized trials.\textsuperscript{58}

**Substitution of proactive integrated care towards practice nurses**

In 2008, the Health Council of the Netherlands concluded that the current Dutch primary healthcare system was not sufficiently equipped to deal with older people with multifactorial care needs because it provided reactive and fragmented care. It advocated the development and study of proactive integrated care programs, based on the chronic care model. Despite the lack of beneficial effects of proactive nurse-led care in several studies resulting from the NCEP, its implementation in general practice is ongoing. Beneficial long-term effects of proactive, integrated care cannot be excluded, and presumably beneficial effects are seen after several years.\textsuperscript{17-19} In view of the ageing of Western societies, increasing substitution of GP-care by nurse-led care may be necessary to facilitate efficient care provision and to reduce the increasing burden on GPs. Nurse-led care fits well with an integrated, holistic approach beyond an ever expanding number of disease management programs, if the nurses and GPs are able to work in close collaboration. In the process evaluation we observed that there was practice variation between nurses with regard to their focus of care and to what extent they guided patients when geriatric conditions were present. The substitution of proactive integrated care warrants further research with special focus on training nurses to provide this proactive care in clinical practice, what is the most
efficient collaboration model with the GP and how leadership strategies can enhance nurses to be fully equipped to provide this care.

**Implications for daily practice and suggestions for future research**

To identify the target population (Chapter 2), GPs and registered nurses need training to comprehend the test characteristics of the ISAR-PC and understand its use, since it is a prognostic tool that predicts future functional decline, and embed it in the decision making process with their clients. Besides, more insight is needed in the geriatric conditions of people with false positive and false negative screening results and the consequences for treatment and care for these people. Furthermore, research is needed to assess whether different identification strategies target different risk spectra of older people.

We found that one-year multifactorial nurse-led care was not (cost) effective compared to usual care in community-living older people at increased risk of functional decline in The Netherlands (Chapter 4 and 6). This adds to the accumulating evidence that proactive integrated care provision over a one-year period is not (cost) effective in preventing new disabilities in countries with a well-developed primary care system. Nonetheless, the implementation of multifactorial preventive programs in general practice is ongoing in many healthcare systems throughout the world. Process evaluations are needed to evaluate why Dutch general practitioners, community healthcare nurses, and older people want to implement preventive interventions despite the apparent ineffectiveness over and above current primary care. Furthermore, process evaluations are needed to learn which components facilitate or hinder the implementation of the intervention, and whether the implementation had sufficiently penetrated the GPs, nurses and participants, as lack of effect may reflect failure of implementation of new interventions. It still is uncertain from which interventions a population at increased risk of functional decline benefits most. Research is needed to improve the alignment between the target population, subsequent interventions, and outcome measures. Additionally, future research should first investigate current care and treatment of the individual being assessed, and then investigate the unmet needs. More insight in actively involving older people, priorities, goals and potential for behavior change in care and treatment of geriatric conditions and unmet needs may avoid detecting conditions that are not perceived as
relevant for further treatment and could contribute to a patient-centered approach and cost-effective CGA. This may be a focus of further research.

In view of the ageing of Western societies, increasing task delegation from GPs to nurses warrants further non-inferiority analyses on both quality of life and costs, as well as evaluation from the societal perspective to explore whether such programs may still deliver valuable services at acceptable costs and efforts (Chapter 6). Further study is needed to improve integration with wellness, social context, advanced care planning, and secondary care.

**Final conclusions**

This thesis focuses on pro-active, nurse-led integrated care to prevent or postpone new disabilities in community-living older people. First, we modified and validated the original ISAR screening questionnaire into an instrument to identify older people at increased risk of functional decline in primary healthcare (Identification of Seniors at Risk- Primary Care). The ISAR-PC has moderate discrimination and was well calibrated. The ISAR-PC is easy applicable, requiring very little time to complete, and may serve as an efficient first step in a two-step approach targeting community-dwelling older people at risk of functional decline (Chapter 2). Second, we designed a cluster randomized trial consisting of comprehensive geriatric assessment, an individually tailored care and treatment plan based on multifactorial interventions and nurse-led care coordination to prevent or postpone new disabilities in community-living older persons at increased risk of functional decline (Chapter 3). Third, we found no evidence that a one-year nurse-led multifactorial care intervention was better than current primary care to prevent or postpone new disabilities in community-living persons at increased risk of functional decline in The Netherlands. Additionally, the intervention was not more effective than current primary care on health-related quality of life, self-perceived quality of life, emotional wellbeing, healthcare utilization, or all-cause mortality (Chapter 4).

Fourth, applying CGA in community-living older persons with an increased risk of functional decline yielded many geriatric conditions, yet resulted in low recognition rates of these geriatric conditions (Chapter 5). Fifth, the economic evaluation demonstrated that a one-year nurse-led multifactorial care program was not cost-effective compared with care as usual in community-living older people at increased
risk of functional decline in the Netherlands. Based on these findings, implementation of the evaluated multifactorial nurse-led care model is not to be recommended.

Despite the lack of evidence for beneficial effects on the prevention of new disabilities, the implementation of proactive integrated care programs by nurses for elderly people in general practice is ongoing in many healthcare systems throughout the Western world. In view of the ageing of Western societies, and the burden the care for older people incurs for GPs, increasing task delegation from GPs to nurses warrant further evaluation with regard to quality of life, quality of care and costs. Such studies should indicate whether programs like these may result in valuable service provision at acceptable costs and quality.
References


