Mevr. van Leeuwen - Ponsioen (92)

“Ik wil hier blijven wonen. Op de eerste plaats maakt de betrokkenheid van mijn kinderen dat mogelijk. Ook een traplift en de thuiszorg helpen daarbij.”
GENERAL DISCUSSION

The research described in this thesis had the following aims:
1. To evaluate the implementation fidelity and cost-effectiveness of an integrated care model for community-dwelling frail older adults (the Geriatric Care Model).
2. To compare the measurement properties of two general quality of life instruments (ASCOT and ICECAP-O) to a health-related quality of life instrument (EQ-5D) for use in economic evaluations of care services for older adults.

In the first part of the thesis, we describe the design of the ‘Frail older Adults: Care in Transition (ACT)’ study, including a detailed description of the Geriatric Care Model that was evaluated in this study. In this part of the thesis we also report on the assessment of implementation fidelity of the Geriatric Care Model and the evaluation of the cost-effectiveness of the Geriatric Care Model compared to usual care. As improving health is not the main or sole objective in care services for older adults, it is important to evaluate the impact on quality of life beyond health. Therefore, in the second part of the thesis, we evaluated the measurement properties of two recently developed general quality of life instruments, the ASCOT and the ICECAP-O, in a subsample of the ACT study. We first describe the translation process of the ASCOT into Dutch. Subsequently, we report on the comparison of the reliability, construct validity, responsiveness, content validity and feasibility of the ASCOT, ICECAP-O and EQ-5D. Finally, we report on a study in which we used data from an English national survey to assess associations between quality of life as measured with the ASCOT and three factors that local authorities can use as policy targets for improving the quality of life for older adults in the community. In this chapter, we review the main findings from Chapter 2 to 8. Subsequently, we will provide some methodological considerations and reflections on the findings. We will conclude this chapter with recommendations for clinical practice, policy and further research.

MAIN FINDINGS

Part 1. ‘Frail older adults: Care in Transition’ study

The Geriatric Care Model aimed to target the following challenges in care for community-dwelling frail older adults: the untimely recognition of health problems, the lack of autonomy perceived by older adults and the lack of coordination between health professionals. In doing so, we hoped to improve the quality of care for community-dwelling frail older adults, and subsequently their quality of life. The cost-effectiveness of the Geriatric Care Model compared to usual care was
assessed in an economic evaluation alongside a 2-year stepped-wedge cluster randomised controlled trial with 6-monthly measurements. The ACT study is one of the first randomised controlled trials evaluating an integrated care approach modelled after the Chronic Care Model for frail community-dwelling older adults.

**Adherence to the Geriatric Care Model was high for most of the essential intervention components (Chapter 3)**

The evaluation of the implementation fidelity of the Geriatric Care Model showed that adherence to two main components, the geriatric assessment and care plan delivery, was initially high but declined somewhat over time. The adherence to multidisciplinary team consultations was poor in the beginning, but improved over time. Care team meetings set up by the geriatric expert teams were appreciated by the practice nurses. The community network meetings were more challenging to implement. Furthermore, there were large variations in the extent to which nurses and physicians felt satisfied and involved with the intervention. Practice nurses would have preferred a more intensive training for working with the geriatric assessment instrument. They deviated from the intervention protocol due to contextual factors and personal work routines.

**The Geriatric Care Model was not considered cost-effective in comparison with usual care after 24 months of follow-up (Chapter 4)**

The differences in clinical outcomes between intervention and usual care phases were very small and not statistically significant. Intervention phases were more expensive than usual care phases, but this difference in costs was not statistically significant either. The increase in costs was caused by the costs of the intervention and higher medication and informal care costs in the intervention phases in comparison with the usual care phases. With regard to SF-12 PCS and MCS (the physical and mental component summary scales of health-related quality of life), the maximum probability of the intervention being cost-effective in comparison with usual care was around 80% at ceiling ratios of 20,000 €/unit of effect extra. For all other outcomes (QALY, ADL and iADL) the maximum probability of cost-effectiveness was maximally 43%.

**Part 2. Measuring quality of life in older adults**

The translation of the ASCOT into the Dutch language resulted in a valid and reliable Dutch version, with comparable measurement properties to the original English version (Chapter 5)

The ASCOT was translated into Dutch following internationally accepted guidelines, including two forward and backward translations. The pilot tests showed that the translated items were in
general understood as intended, and that the response distributions of the Dutch translation and associations with other measures were comparable to the original English version. Based on the results of the pilot tests, we made some small modifications by shifting the focus of an item or by using a less literal translation, and we revised the two items representing the *Dignity* domain. These modifications were approved by the ASCOT development team.

The ASCOT and ICECAP-O are at least as reliable as the EQ-5D and the construct validity and responsiveness of these instruments was considered good (Chapter 6).

Test-retest reliability (i.e., the extent to which scores for patients who have not changed are the same for repeated measurement over time)\(^2\) was considered good for all three instruments as indicated by two reliability parameters. Intraclass correlation values were above 0.70 and standard error of measurement values were less than 10% of the scale. In addition, the differences in the values of these reliability parameters between the ASCOT, ICECAP-O and EQ-5D were small. This means for all three instruments that the discrimination in quality of life between frail older adults is not much affected by measurement error and that relatively small changes can be considered true changes rather than changes due to measurement error. Most hypotheses regarding construct validity and responsiveness were accepted. Compared to the EQ-5D, the ASCOT and ICECAP-O were more strongly correlated to other instruments that measure aspects of quality of life beyond physical health. We found that change in self-perceived quality of life, change in mastery and change in client-centeredness were stronger correlated to changes in the ASCOT score than to the changes in ICECAP-O and EQ-5D scores. Therefore, the ASCOT may be the most responsive of these three to changes in quality of life from a broad perspective. The ICECAP-O may be most responsive to changes in the impact of mental health and in ADL limitations, and the EQ-5D to changes in physical functioning.

Response issues were encountered during the administration of the ASCOT, ICECAP-O as well as the EQ-5D, and participants preferred the instrument that most closely reflected their daily life (Chapter 7).

Think-aloud interviews among older adults revealed response issues for various items in all three instruments, mainly related to the mapping of the responses on predefined response categories and to the interpretation of abstract or double-barrelled items. The older adults’ responses to the quality of life items were more positive than would be expected from the point of view of an outsider. Furthermore, the respondents in this study stated that their responses to the items of the instruments did not give such a comprehensive picture of their quality of life as a proper personal conversation would, and specifically mentioned one domain that was missing in all three instru-
ments: the well-being of their family. Of the three instruments, the older adults preferred, both in terms of coverage and comprehensibility of the domains, the instrument and more specifically the items that most closely reflected their daily life. This differed from person to person. Respondents considered the items of the ASCOT and ICECAP-O relevant for their quality of life though more abstract than the EQ-5D items.

*Quality of life as measured with the ASCOT is statistically significantly lower for older adults who find it more difficult to find information and advice, for those who report that their home design is inappropriate for their needs and for those who find it more difficult to get around their local area (Chapter 8)*

In seeking to find ways to maintain and improve the quality of older adults in the community, local authorities could look beyond their responsibility for providing social care, and for example consider ‘accessibility of information and advice’, ‘design of the home’ and ‘accessibility of the local area’ as potential policy targets. Using data from the English Adult Social Care Survey we showed that these three variables were as strongly associated with the ASCOT as physical and mental health factors. Furthermore, the association was particularly strong for older adults with higher needs and less assistance from informal carers, and among older adults with lower ASCOT scores; suggesting that older adults that are most vulnerable may profit most from interventions in these areas.

**Methodological considerations**

**Pragmatic trials**

The ACT study was a pragmatic study carried out in a real life primary care setting. Pragmatic trials measure effectiveness, which indicates the clinical effect in real clinical practice (as opposed to efficacy, the clinical effect in an ideal, experimental situation).[^3]^[^4] For economic evaluations conducted alongside a clinical trial, pragmatic settings are recommended, to make sure that policy decisions are based on results obtained in ‘real world’ circumstances.[^5]^[^6] The pragmatic approach in the ACT study increases the generalisability of the study results and would have facilitated further implementation in routine practice if the intervention had been found to be effective and cost-effective. The fact that the Geriatric Care Model was evaluated in two different regions in the Netherlands, in which professionals were encouraged to tailor their activities to the local primary care context, further improves the generalisability of the results.

In pragmatic trials, an important outcome is the level in which the intervention was implemented according to protocol.[^3] Due to ‘real world’ circumstances the intervention protocol cannot
always be implemented as intended. Low adherence to the intervention protocol could have explained the absence of significant difference in cost and clinical outcomes between intervention phases and usual care phases in the ACT study. However, the assessment of implementation fidelity showed that adherence to the main intervention components was good. Furthermore, the per protocol cost-effectiveness analysis showed similar results to the main intention-to-treat analysis. Therefore, we do not think this explains the lack of effect of the Geriatric Care Model.

**Stepped wedge design**

The use of a stepped wedge cluster randomised controlled trial design has practical and ethical advantages in comparison with a patient or cluster randomised trial.7 The sequential roll-out of the intervention over a number of time periods makes it possible to start the training and delivery of intervention components on a small scale, and to refine the intervention where necessary with each successive implementation step.8 Besides the practical advantages, the fact that the intervention was introduced in all primary care practices in the study meant that all participants were offered the opportunity to receive care according to the Geriatric Care Model. This played a primary role in motivating primary care physicians to participate in the study. In addition, the stepped wedge design offers the opportunity to assess the effects of the duration of the intervention.

However, there are also some drawbacks. Blinding of care professionals and participants was unfeasible, as it was evident for both the participants and those delivering the intervention when the step from control to intervention occurred.9 Furthermore, although phases were viewed as intervention phase after the last control measurement in the analysis, from a participant’s view the intervention started with the first home visit and assessment by the practice nurse. This assessment did not always take place shortly after the last control measurement though, as some practice nurses lagged behind on schedule. In such cases, it is very unlikely that there would be changes detectable yet in the measurements of resource use and clinical outcomes. Nevertheless, these situations reflect ‘real world practice’ and are inherently part of effectiveness trials. It is, however, more problematic in stepped wedge designs; for example in the ACT study most of the intervention phases concerned the first 12 months of the intervention. Later intervention phases were less often represented. Although the study was performed over a 24-month period, there was only one group of primary care practices in which care was implemented according to the Geriatric Care Model for the full 24 months. Therefore, the results of the cost-effectiveness analysis are predominantly based on the first intervention year, whereas we did not expect outcomes to occur soon after the start of receiving the intervention. We rather suppose a slow and gradual change during the delivery of the intervention, only after the implementation of actions as de-
scribed in the personal care plans. This may have resulted in an underestimation of the intervention effects in our study.\textsuperscript{7,10}

In addition, although the design made the implementation of the Geriatric Care Model better manageable for the care professionals, the data collection was logistically complex. Moreover, analysis of stepped wedge designs is complex as well, particularly because of the need to account for repeated measures in the same individual and for progression in outcomes over the course of the trial.\textsuperscript{7,9,10} Since intervention phases took place later in time than usual care phases, time effects needed to be separated from intervention effects. By using multilevel techniques with time adjustments to estimate cost and effect differences between intervention and usual care phases, we accounted for the stepped wedge design in the analysis.

**Time horizon**

In economic evaluations, the time horizon should be long enough to capture the full costs and effects of intervention programs.\textsuperscript{6} Although the duration of the ACT trial is longer than most other trials evaluating the effectiveness of integrated care, it may have been too short to identify all relevant effects and cost. It may be that it takes even longer than the current follow-up of 24 months before the development of local networks, building of expertise and use of preventive actions as initiated within the Geriatric Care Model will lead to clinical effects and cost savings. Descriptive analysis of our data suggest cost savings after a longer duration of the intervention: the total societal costs in intervention phases were initially higher than in usual care phases but decreased over time and became lower in the 18\textsuperscript{th}-24\textsuperscript{th} month of the intervention. Previous studies evaluating preventive home visits without an integrated care approach found that such interventions only resulted in lower costs in the third year of follow up.\textsuperscript{11,12}

However, funding for longer trials is often not available. And although there were indications for cost declines on the long term, we did not find such an effect for the outcome measures, apart from a small and clinically not relevant long-term effect on limitations in instrumental activities in daily living (iADL). Therefore, it should be carefully considered whether investing public resources in trials of integrated care for frail older adults with longer follow-up is worthwhile.

**Informal care**

The cost-effectiveness analysis was based on a societal perspective including costs related to informal care time. The societal costs of informal care are to a large extent related to time inputs by informal caregivers.\textsuperscript{13} Our analysis showed that it is important to include informal care time in evaluations of interventions for older adults, because costs related to informal care time were somewhat higher during intervention phases than during usual care phases, although this differ-
ence was not statistically significant. Increasing attention for policies aimed at promoting ‘Ageing in Place’ in combination with cutbacks in professional home care suggest that informal caregivers will be increasingly relied upon to provide care.\textsuperscript{14–17}

Unfortunately, willingness to participate among informal caregivers was low and differed between allocation groups. Therefore, it was not possible to evaluate the effects of the integrated care model on healthcare utilization and quality of life of informal caregivers. Low participation among informal caregivers is probably related to the process of care giving, which can be physically and mentally straining.\textsuperscript{18} Informal caregivers are more likely to have lower levels of emotional well-being and to feel stressed, rushed and pressured,\textsuperscript{16,19} and study participation may feel as an additional burden. The informal caregivers that participated in the ACT study had a relatively good quality of life and experienced a low burden of care giving [unpublished findings]. It may be that the informal caregivers who declined to participate had lower quality of life and experienced a higher burden of care giving.

**Intermediate outcomes**

Through the implementation of the Geriatric Care Model, we hoped to improve the quality of care for community-dwelling frail older adults, and subsequently their quality of life by targeting the untimely recognition of health problems, the lack of autonomy perceived by older adults and the lack of coordination between health care professionals. However, the results of the cost-effectiveness analysis suggest that the Geriatric Care Model does not result in improvements in quality of life compared to usual care. Because we did not measure intermediate outcomes such as timely recognition of health problems, perceived autonomy by older adults and coordination between health care professionals, we cannot directly assess whether the Geriatric Care Model succeeded in improving the quality of care and tackling the barriers in elderly care.

**Quality of life instruments**

The EQ-5D and SF-12 were used to measure quality of life in the ACT study. Both can be characterised as health-related quality of life instruments. Due to the focus on health of these instruments, effects on quality of life aspects beyond health may have been underestimated. Part 2 of this thesis showed that the use of health-related quality of life instruments can be supplemented by the use of the ASCOT and/or ICECAP-O. These were not administered to all participants in the ACT study nor included in all follow-up measurements. We can therefore not assess whether the ASCOT and ICECAP-O were more sensitive to the effects of the Geriatric Care Model compared to the health-related quality of instruments.
Chapter 9

Reflection on the Findings

It was found that the Geriatric Care Model was not cost-effective compared to usual care, despite the fact that adherence to the main intervention components was good. An explanation for the lack of effect may be that the contrast in care between usual care and intervention phases was not large enough to result in differences in the outcome measures used. Alternatively, the over-representation of phases from the first 12 months of the intervention may have resulted in an underestimation of the intervention effect, especially since we expected that effects would rather occur later in time.

The results of the cost-effectiveness analysis are comparable to other cost-effectiveness analyses of integrated care or home visiting programs aimed at frail older adults. These studies reported only small and statistically non-significant differences as well, and programs were only considered cost-effective in comparison with control at large willingness to pay values. Reviews of descriptive studies on the costs and effects of integrated care models for older adults show mixed results, and results from randomised controlled trials that evaluated effects on functional limitations, health-related quality of life and health care utilization are inconsistent.

Although the concept of integrated care appeals to many professionals and researchers, there is conflicting evidence about the effectiveness of integrated care models compared to usual care. Moreover, evidence from adequately executed economic evaluations remains limited so far. There is not much known yet about which components of integrated care work best, in which context and for which target population.

There are several findings reported in this thesis and previous studies that support the adoption of the ASCOT and ICECAP-O as outcome measures in economic evaluations of care for older adults. It is reassuring that the ASCOT and ICECAP-O are at least as reliable as the EQ-5D, and are associated with constructs that we expected them to be associated with. Other studies reported as well that the construct validity of the ASCOT and ICECAP-O was good. Furthermore, the domains covered by the ASCOT and ICECAP-O correspond for a large extent with aspects that were considered important by older adults in previous studies.

In addition, the measurement properties of the Dutch translation of the ASCOT are comparable to those of the original English version (which were considered good), and we showed that the ASCOT was useful for identifying potential policy targets to improve the quality of life of older adults. However, response issues were encountered during the administration of various items of the ASCOT and ICECAP-O and the health related items from the EQ-5D were considered important as well, especially by older adults who had to cope with various health issues in their daily life.
It is not clear yet whether the ASCOT and ICECAP-O are able to indirectly measure important health effects and whether they are indeed responsive to changes in quality of life as a result of care services for older adults.

**FUTURE DIRECTIONS**

**Implications for policy and clinical practice**

Based on the results of the cost-effectiveness analysis we do not recommend implementation of the Geriatric Care Model. Elements of the model were appreciated by the primary care physicians, practice nurses and older adults involved in the study, but this does not legitimize the extra efforts and expenses related to the implementation of the Geriatric Care Model compared to usual care.

Given the expected growth of the proportion of older adults and governmental budget cuts, it is important to identify efficient ways of maintaining and/or improving the quality of life of older adults. Therefore, local governments could pay more attention to a fundamental question; which services and organisational approaches provide the most value for money? An integral part of such quests should be the impact of interventions on informal caregivers and their time.

Local authorities could look more widely across their responsibilities for ways to maintain and improve the quality of older adults living at home, such as housing, public transport and city planning. This includes adaptation of the living environment of older adults, at home as well as in the community. ‘Ageing in Place’ is for example supported by home adaptations such as modified toilets and showers and neighbourhood and public transportation facilities such as sufficient bus stop locations, a well-developed pedestrian infrastructure, proximity to shops and services, and feelings of familiarity and safety.52–56 (Local) governments should consider commissioning further research to investigate the cost-effectiveness of such policy measures. The availability of quality of life instruments that not solely focus on health such as the ASCOT and ICECAP-O provides opportunities for local authorities to evaluate and compare the value for money of policy measures across their functions.

**Recommendations for future research**

Before more economic evaluations of integrated care are performed, further research should identify effective combinations of components of integrated care and the stadium of frailty in which people benefit most from integrated care. Also, in order to move from the current ‘one size fits all’ approach to more tailored care, future research should identify which components work best for whom. Combination and critical examination of the results of all experiments that were performed in the context of The National Care for the Elderly Programme57,58 may act as a good
starting point. Another area for further research may be the long-term effects of integrated care, since other studies found cost savings after the second year of follow-up and descriptive analyses in our study suggest that the difference in costs between intervention phases and usual care phases decreases over time.

The result of the studies in the second part of this thesis do not suggest that one of the quality of life measures (EQ-5D, ASCOT or ICECAP-O) is superior over the other ones; the test-retest reliability is comparable, and response issues occurred during the administration of all three measures. Due to the coverage of different domains, the size of associations of the (change) scores of the EQ-5D, ASCOT and ICECAP-O with other measures differs between the three measures. We therefore recommend that researchers choose a measure on the basis of the specific purpose of a study and the target population.

**Differences between the instruments**

- The EQ-5D is more strongly correlated with health measures than the ASCOT and ICECAP-O, seems somewhat easier to complete and is preferred by older adults whose life is determined by health issues. When the main objective of an intervention or care service is to improve or maintain health, the EQ-5D remains the most appropriate choice.
- When the aims are broader than health, the ASCOT and ICECAP-O seem more appropriate. Both the ASCOT and ICECAP-O cover domains such as independence, security and doing things that make oneself feel valued.
- Besides these domains, the ICECAP-O contains two other domains, enjoyment and attachment, and is more strongly associated with mental well-being.
- The ASCOT contains additional domains which are directly related to social care, such as food and drink, and personal cleanliness and comfort.
- Another difference is the extent to which the capability approach is covered by these measures. According to this approach, we should evaluate a person’s ability (freedom) to function rather than the level of functioning itself. Although both the ASCOT and ICECAP-O are grounded in the capability approach, the ASCOT items reflect capabilities only in the highest response level. The ICECAP-O is a more explicit capability instrument.
- Furthermore, the items of the ICECAP-O are somewhat abstracter than those of the ASCOT and, therefore, more broadly interpretable. This is because ICECAP-O domains are specifically chosen as end goals of quality of life, rather than factors influencing quality of life, whereas the ASCOT also covers basic social care functions.
• Finally, the index scores of the ASCOT, ICECAP-O and EQ-5D are on different scales and result from different valuation techniques. For example, where the EQ-5D is anchored to ‘death’ and ‘full health’, the ICECAP-O is anchored to ‘absence of capability’ and ‘full capability’. The use of different valuation methods resulted in different characteristics of the index scale (for example the inclusion of the state of death). Consequently, QALY (equivalents) calculated using these different instruments are not directly comparable.

Taken together, the findings in this thesis support the adoption of the ASCOT and ICECAP-O as outcome measures in economic evaluations of care interventions targeted at community-dwelling older adults. Further research should demonstrate whether the instruments are responsive to changes in quality of life as a result of the impact of long term care services. More research is recommended to gain a better understanding of the extent to which the ICECAP-O and ASCOT are sensitive to changes in health, since this remains one of the most important quality of life domains. Finally, in order to be most useful for assisting allocation decisions in the Netherlands, we recommend the development of Dutch preference weights for the ASCOT and ICECAP-O.

**IN CONCLUSION**

This thesis shows that integrated care as implemented according to the Geriatric Care Model is not cost-effective compared to usual care for community-dwelling frail older adults in the Netherlands. Future research should look into long term effects, the (combination) of integrated care components that work best, and the target population for whom integrated care models work best. Since health improvements in frail older adults may not be possible, local authorities could help older adults to stay independently at home as long as possible by providing social care services, assisting informal caregivers and contributing to accessible and safe homes and neighbourhoods. There is not much known yet about the (cost-)effectiveness of such policy measures, whereas it is important to find efficient ways to improve or maintain the quality of life of older adults. Older adults enter a stage in which life is coming towards a conclusion, and they desire to spend this stage in the best possible quality of life. How this can be achieved depends on individual preferences, and older adults should be consulted for their own wishes and personal goals. However, there are some common goals or aspects of quality of life to which society could and should contribute.

The use of instruments like the ASCOT and ICECAP-O in cost-effectiveness analyses facilitates the evaluation of interventions and policy measures on their ability to contribute to the achievement of these goals, and at what costs.
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