CHAPTER 4

COST-EFFECTIVENESS OF A CHRONIC CARE MODEL FOR FRAIL OLDER ADULTS IN PRIMARY CARE: ECONOMIC EVALUATION ALONGSIDE A STEPPED WEDGE CLUSTER RANDOMISED TRIAL

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Chapter 4

ABSTRACT

OBJECTIVES To evaluate the cost-effectiveness of the Geriatric Care Model, an integrated care model for frail older adults based on the Chronic Care Model, compared to usual care.

DESIGN Economic evaluation alongside a 24-month stepped wedge cluster randomised controlled trial.

SETTING Primary care (35 practices) in two regions in the Netherlands.

PARTICIPANTS 1147 community-dwelling older adults who were frail according to primary care physicians and the PRISMA-7 questionnaire.

INTERVENTION 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.

MEASUREMENTS Outcomes were measured every 6 months and included costs from a societal perspective, health-related quality of life (SF-12 physical (PCS) and mental component (MCS) summary scales), functional limitations (Katz ADL and iADL) and quality adjusted life years (QALYs) based on the EQ-5D.

RESULTS Multilevel regression models adjusted for time and baseline confounders showed no significant differences in costs (€297; 95% CI:-€407 to €945) and outcomes between intervention and usual care phases. Cost-effectiveness acceptability curves showed that for the SF-12 PCS and MCS, the maximum probability of the intervention being cost-effective in comparison with usual care was around 0.80 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 0.43.

CONCLUSION As the Geriatric Care Model was not cost-effective compared to usual care after 24 months of follow-up, widespread implementation in its current form is not recommended.
INTRODUCTION

Frail older adults use a wide range of health and social care services which results in a large economic burden on society.\(^1\)\(^-\)\(^3\) To constrain increases in societal costs associated with care for frail older adults and to respond to the desire of older adults to ‘age in place’,\(^4\) government policies in many western countries are aimed at supporting older adults to live independently at home as long as possible.\(^5\)\(^-\)\(^7\) In addition, to prepare for a further increase in complex and long-term care needs (and associated costs) of frail older adults, integrated care models have increasingly been implemented.\(^8\)\(^-\)\(^13\) These models are developed in response to the reactive and fragmented nature of care systems and the lack of involvement of older adults in their own care process.\(^5\)\(^,\)\(^14\)\(^,\)\(^15\)

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 institutionalization.\(^3\)\(^,\)\(^16\)\(^,\)\(^17\) However, reviews of studies on the costs and effects of integrated care models for older adults show mixed results.\(^9\)\(^-\)\(^13\) While it has been hypothesized that targeting integrated care models to older adults with a high risk of adverse health outcomes (i.e. frail older adults\(^18\)) may be the most cost-effective strategy,\(^9\)\(^,\)\(^19\)\(^,\)\(^20\) there is a lack of data from cost-effectiveness studies supporting this hypothesis. Descriptive cost studies suggest that integrated care for this group may result in either a reduction in costs in comparison with usual care, or in comparable costs.\(^21\)\(^-\)\(^25\) So far, only three studies evaluated the short-term cost-effectiveness of integrated care models for community-dwelling frail older adults, and the results are inconclusive. Makai et al.\(^26\) 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 at high values for willingness to pay after 6\(^27\) and 12 months\(^28\) of follow-up. Long term effects are still unknown.

The aim of this paper was to evaluate the cost-effectiveness of an integrated care model (The Geriatric Care Model, GCM) based on the Chronic Care Model\(^29\)\(^,\)\(^30\) for community-dwelling frail older adults in the Netherlands, in comparison with usual care with a follow up of 24 months.

METHODS

The study protocol has been published elsewhere.\(^13\) Below a summary is given.

Study design and setting

The economic evaluation was conducted alongside a 24-month stepped wedge cluster randomized controlled trial, the “Frail older Adults: Care in Transition” (ACT) study.\(^31\) A stepped wedge
design is a one-way crossover trial involving sequential roll-out of an intervention to allocation groups over a number of time periods. Thirty-five primary care practices in two regions in the Netherlands were randomized into four allocation groups, which designated the starting moment of the intervention phase (see Figure 1).

The ACT study received approval from the medical ethics committee of the VU University medical centre (ref. no 10/003), and all participants gave written informed consent before inclusion.

**Study participants**
In brief, persons of 65 and older who were identified as frail by their primary care physician based on a multidimensional definition of frailty were tested for further eligibility using the ‘Program on Research for Integrating Services for the Maintenance of Autonomy case-finding tool’ (PRISMA-7). Older adults with PRISMA-7 scores of 3 or more were considered eligible for study enrolment. Exclusion criteria were: 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.

Informal caregivers were asked by telephone to participate if older adults confirmed having an informal caregiver and did not oppose to their involvement in the study.

**Geriatric care model**
The GCM was designed to target health risks and care needs at a timely stage, to stimulate active involvement of patients in the care process and to improve the coordination between health care professionals. The GCM combined the following components: regularly scheduled in-home comprehensive geriatric assessments by practice nurses followed by a tailored care plan, management and training of practice nurses by a regional geriatric expert team consisting of an experienced geriatric nurse and elderly care physician, and coordination of care during community network meetings and multidisciplinary team consultations of complex patients. At all times, the older adult’s own care wishes remained at the centre of the decision making process.

**Usual care**
Until the start of the intervention, primary care practices provided usual care, which was not restricted in any way. Since primary care physicians in the Netherlands act as gatekeepers of the health care system, they play an important role in the organisation of community elderly care. Older adults consult the primary care physician on their own initiative.
Figure 1. Flowchart of participants through the stepped wedge randomised trial.  
GCM = Geriatric Care Model; Not assessed=no assessment of outcome measures available at this follow-up
Outcome measures

Effect measurements were administered at baseline, and at 6, 12, 18, and 24 months. Data were collected at the participant’s own home by means of computer assisted personal interviewing. The primary outcome was health-related quality of life as measured by the SF-12 Health Survey physical component summary (PCS) and mental component summary (MCS) scales. Secondary outcomes were functional limitations and Quality Adjusted Life Years (QALYs). Functional limitations were assessed using a 6-item modified Katz basic Activities of Daily Living (ADL) scale and a 7-item Instrumental Activities of Daily Living (iADL) scale. QALYs were based on the EQ-5D-3L, using the tariff of the Dutch population. We calculated QALYs by multiplying the utilities with amount of time participants spent in a particular health state. Transitions between health states were linearly interpolated.

Measurement and valuation of resource use

Costs were measured from a societal perspective. To measure medical consumption prospectively, 6-monthly cost diaries were used. Consultations with primary care physicians and medical specialists, as well as home care, meals services, home adaptations and nursing home admissions were included in the cost diaries. Participants received the diaries through project interviewers who gave instructions for completion during in-home interviews for the effect measurements. Hospital admissions were obtained from hospital registries and medication data from pharmacies. Lost productivity costs were not considered relevant in this population of frail older adults. To collect data about informal care time, we sent postal questionnaires to participating informal caregivers. Information about informal care time from caregivers not included in the study was obtained from the participants during interviews.

Dutch standard costs were used to value resource use. Medication costs were valued using prices of the Royal Dutch Society for Pharmacy. All costs were indexed to the level of 2011, and were discounted by 4% in the second year of follow-up.

We calculated a cost price for the care model using a bottom-up approach. Average GCM costs were calculated to be € 215 (se 1.65) per 6 months per person, including software licenses and materials (€ 15), training sessions (€ 13), and time investments from practice nurses (€ 96), the geriatric expert team (€ 89) and other professionals consulted in multidisciplinary team consultations for complex patients (€ 1). Practice nurses used time sheets to record the time investment per participant. They spent on average a little more than 2.5 hours on each participant per half year, with a mean caseload of 220 patients/fte practice nurse (none of the practice nurses worked fulltime).
Missing data

Missing data on costs and outcomes were imputed using multiple imputation with chained equations and fully conditional specification in Stata 12. The percentage missing data varied from 21% for data in cost diaries and 25% for outcome measures (due to loss to follow-up) to 51% for medication data. An imputation model was created that contained variables related to missing data or the outcome measure, and variables that differed at baseline between the groups. Predictive mean matching was used to account for the skewed distribution of costs. Twenty imputed data sets were created, resulting in a loss of efficiency of less than 3.5% for all outcomes. The 20 imputed datasets were analysed separately and the results of the analyses were pooled using Rubin’s rules.

Statistical analyses

The main analysis was performed according to the intention-to-treat principle. Each participant was observed during four phases of 6 months (Figure 1), which were, according to the stepped wedge design, either intervention or usual care phases. Costs and QALYs were calculated for each phase of 6 months, and set to 0 for periods after death. For other outcome measures, the measurements at the end of each 6 months were used and observations after death were excluded from analysis. The cost-effectiveness analysis was performed by relating the difference in total mean costs per 6 months between all intervention phases and all usual care phases to the difference in health-related quality of life (SF-12 PCS and MCS), functional limitations (both ADL and iADL limitations) and QALYs. Multilevel modelling was used to adjust for the dependency of observations within participants.

Since in stepped wedge designs, the intervention variable is highly time dependent due to a later onset of intervention phases and variations in intervention duration, the intervention effect was adjusted using a time variable which indicated the measurement period (1, 2, 3 or 4). Variables that resulted in a change in costs and/or effect difference of more than 10% were included as confounders, which were partner status, educational level, region, baseline values of outcome measures and degree of frailty. We constructed a frailty index using 46 deficits in health at baseline to establish degree of frailty. Furthermore, as QALY calculations depended on the number of days in each observed phase, the phase length in days was also included in this analysis.

Uncertainty around the incremental cost-effectiveness ratios (ICERs) was estimated using the bias-corrected percentile bootstrapping method (5000 replications) and plotted in cost-effectiveness (CE) planes. In addition, cost-effectiveness acceptability curves (CEACs) were estimated to show the probability that phases in which care was provided according to the GCM were cost-effective in comparison with phases in which usual care is provided using different ceiling ratios.
These ceiling ratios represent the maximum amount that society is willing to pay for one point improvement on the respective outcome scales. The CEAC shows for a range of ceiling ratio's the proportion of bootstrapped incremental cost and effect pairs that are cost-effective, i.e the probability that the GCM is cost-effective compared to usual care given our data and for a particular ceiling ratio.49

Sensitivity analyses
Two sensitivity analyses were performed. In a per-protocol analysis, all phases after drop-out of a participant from the study were excluded, and phases in which no first geriatric assessment had taken place yet were indicated as usual care phases. The second sensitivity analysis was performed using a healthcare system perspective. This analysis only included direct healthcare costs, thus excluding costs related to informal care time.

RESULTS

Participants
Figure 1 provides an overview of the randomisation, recruitment, and follow-up. Of the 3111 potentially frail older adults, 713 (22.9%) refused to participate and 1147 (36.9%) met the eligibility criteria and gave informed content. Six hundred participants indicated to receive help from an informal caregiver, of which 118 (19.7%) participated in the study. This percentage differed significantly (p=0.02) between allocation groups. Table 1 shows the baseline characteristics of the participants and differences between allocation groups.

As shown in Figure 1, 782 of the 1147 participants (68.2%) completed the full 24-month study period. Death was the main cause for drop-out (12.4%). The participants that completed the study period were statistically significantly younger, less frail according to the frailty index, and had more beneficial baseline values of ADL and iADL, SF-12 PCS and MCS and EQ-5D compared to those lost to follow-up. Furthermore, participants from West-Friesland, participants with a high or low education level and participants without informal caregiver were more likely to complete the study period.

Of the 1147 participating older adults, 877 (76.5%) were visited at home at least once by a practice nurse. The main reason for not ‘having a home visit’ was drop-out from the study (n=119; 44.1%). Also, 31 patients of one primary care practice in allocation group 4 did not receive care according to the GCM as the primary care physician decided not to start working in accordance with the GCM.
Effects

There were no statistically significant differences in primary and secondary outcomes between intervention phases and usual care phases (Table 2).

Costs

The adjusted mean difference in total costs between intervention phases and usual care phases was €297 (95% CI: -€407; €945) (Table 2). Apart from the intervention costs, the main contributor to the difference in total societal costs was the difference in informal care costs. Informal care costs were somewhat higher in the intervention phases than in the usual care phases, although not statistically significantly. All other differences in costs were not statistically significant either (Table 2).
**Table 2. Mean Cost and Outcomes per 6 Months in Intervention and Usual Care Phases**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention phases n = 3017</th>
<th>Usual care phases n = 1354</th>
<th>Adjusted mean differences (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SF-12 Physical health (PCS), 0-100</td>
<td>33.6 (0.28)</td>
<td>34.9 (0.40)</td>
<td>0.42 (-0.70 ; 1.54)</td>
</tr>
<tr>
<td>SF-12 Mental health (MCS), 0-100</td>
<td>50.2 (0.30)</td>
<td>50.4 (0.44)</td>
<td>0.45 (-0.76 ; 1.66)</td>
</tr>
<tr>
<td>ADL limitations, 0-6</td>
<td>1.02 (0.03)</td>
<td>0.86 (0.04)</td>
<td>0.01 (-0.10 ; 0.12)</td>
</tr>
<tr>
<td>iADL limitations, 0-7</td>
<td>2.87 (0.04)</td>
<td>2.72 (0.07)</td>
<td>0.01 (-0.16 ; 0.17)</td>
</tr>
<tr>
<td>QALYs, -0.30-0.50</td>
<td>0.29 (0.003)</td>
<td>0.32 (0.004)</td>
<td>0.003 (-0.006 ; 0.012)</td>
</tr>
</tbody>
</table>

**Cost category**

<table>
<thead>
<tr>
<th>Cost category</th>
<th>Intervention phases</th>
<th>Usual care phases</th>
<th>Adjusted mean differences</th>
</tr>
</thead>
<tbody>
<tr>
<td>General practice costs</td>
<td>€ 116 (4)</td>
<td>€ 138 (6)</td>
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</tr>
<tr>
<td>Physiotherapy, occupational therapy, dietary advice and complementary medicine costs</td>
<td>€ 347 (20)</td>
<td>€ 369 (24)</td>
<td></td>
</tr>
<tr>
<td>Help, personal care and nursing at home costs</td>
<td>€ 2144 (109)</td>
<td>€ 2063 (133)</td>
<td></td>
</tr>
<tr>
<td>Other social services (day care, meals service, transport service), home adaptations and equipment costs</td>
<td>€ 351 (30)</td>
<td>€ 296 (36)</td>
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</tr>
<tr>
<td>Total primary and community care costs</td>
<td>€ 2958 (124)</td>
<td>€ 2867 (159)</td>
<td>-€ 17 (-€337; €234)</td>
</tr>
<tr>
<td>Mental healthcare costs</td>
<td>€ 79 (17)</td>
<td>€ 71 (20)</td>
<td></td>
</tr>
<tr>
<td>Day hospital and outpatient attendances costs</td>
<td>€ 433 (29)</td>
<td>€ 571 (55)</td>
<td></td>
</tr>
<tr>
<td>Hospital admission costs</td>
<td>€ 561 (50)</td>
<td>€ 697 (85)</td>
<td></td>
</tr>
<tr>
<td>Rehabilitation centre, care home and nursing home admission costs</td>
<td>€ 2848 (162)</td>
<td>€ 1726 (177)</td>
<td></td>
</tr>
<tr>
<td>Total secondary care costs</td>
<td>€ 3921 (184)</td>
<td>€ 3065 (223)</td>
<td>€ 3 (-€430; €553)</td>
</tr>
<tr>
<td>Medication costs</td>
<td>€ 580 (43)</td>
<td>€ 691 (73)</td>
<td>€ 49 (-€50; €101)</td>
</tr>
<tr>
<td>Informal care costs</td>
<td>€ 2043 (141)</td>
<td>€ 1883 (176)</td>
<td>€ 88 (-€252; €451)</td>
</tr>
<tr>
<td>GCM intervention costs</td>
<td>€ 215 (2)</td>
<td>€ 0 (0)</td>
<td></td>
</tr>
<tr>
<td>Total societal costs</td>
<td>€ 9716 (274)</td>
<td>€ 8506 (340)</td>
<td>€ 297 (-€407; €945)</td>
</tr>
</tbody>
</table>

Cost-effectiveness

The results of the cost-effectiveness analysis are presented in Table 3. The ICER for the SF-12 physical health component score was 702, meaning that an improvement of 1 point in SF-12 PCS score in intervention phases was associated with €702 higher costs as compared to usual care phases. The ICER for the SF-12 MCS score was comparable (€658). The majority of SF-12 PCS and MCS cost-effect pairs are located in the NE quadrant (more effective and more expensive) of the CE plane (see Table 3 and Figure 2). The CEACs showed that for the outcomes SF-12 PCS and SF-12 MCS the probability that the intervention phases were considered cost-effective in comparison...
Cost-effectiveness of the Geriatric Care Model

with usual care phases was 0.24 at a willingness to pay (WTP) of 0 €/point improvement and that this increased to almost 0.58 and 0.76 at WTP values of 1000 and 30,000 €/point improvement, respectively (see Table 3 and Figure 3).

For ADL and iADL, intervention phases were dominated by usual care phases, meaning that intervention phases were more expensive and less effective than usual care phases, although not statistically significantly. This was confirmed by the CE planes that showed that the majority of ADL and iADL limitations cost-effect pairs are located in the NW quadrant (less effective and more expensive) (Figure 2). The CEACs showed that for the outcome functional limitations the probability that the intervention phases were considered cost-effective in comparison with usual care phases was 0.24 at WTP values of 0 €/point improvement and slowly increased to 0.35 for ADL limitations and 0.43 for iADL limitations at a WTP value of 30,000 €/point improvement (Figure 3).

The costs per QALY gained in intervention phases as compared to usual care phases were €133,611. The majority of QALY cost-effect pairs are located in the NE quadrant (more effective and more expensive) (Figure 2). The CEAC showed that for QALYs the probability that the intervention phases were considered cost-effective in comparison with usual care phases was 0.20 at WTP values of 0 €/point improvement and that this slowly increased to 0.26 at a WTP value of 30,000 €/point improvement (Figure 3).

**Sensitivity analyses**

The results of the sensitivity analyses are shown in Table 3 as well. The per protocol analysis also showed no statistically significant differences in costs and effects between intervention and usual care phases. The mean difference in costs was smaller compared to the intention-to-treat analysis (€83; 95% CI: -€440; €759). Furthermore, the probability that intervention phases were considered cost-effective in comparison with usual care phases was lower for the primary outcomes and higher for secondary outcomes compared to the intention-to-treat analysis.

The results of the sensitivity analysis excluding informal caregiver costs (health system perspective) were comparable to the main analysis. The mean difference in costs from this perspective was (€189; 95% CI: -€425; €717).
Table 3. Differences in Outcomes and Costs per 6 Months between Intervention and Usual Care Phases, ICER, % CE Plane Quadrants

<table>
<thead>
<tr>
<th>Analysis</th>
<th>N observations</th>
<th>Intervention phases</th>
<th>Usual care phases</th>
<th>Costs $^a$</th>
<th>Effects $^b$</th>
<th>Cost-effectiveness plane $^c$</th>
<th>Probability that GCM is cost-effective at WTP for 100% improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>ICER</td>
<td>NE</td>
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<td><strong>Main analysis</strong></td>
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<tr>
<td>SF-12 PCS, 0-100</td>
<td>3017</td>
<td>1354</td>
<td>€ 297 (- €407 ; €945)</td>
<td>0.42 (-0.70 ; 1.54)</td>
<td>702</td>
<td>64%</td>
<td>18%</td>
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<tr>
<td>SF-12 MCS, 0-100</td>
<td>3017</td>
<td>1354</td>
<td>€ 297 (- €407 ; €945)</td>
<td>0.45 (-0.76 ; 1.66)</td>
<td>658</td>
<td>66%</td>
<td>19%</td>
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<tr>
<td>ADL limitations, 0-6</td>
<td>3017</td>
<td>1354</td>
<td>€ 297 (- €407 ; €945)</td>
<td>0.01 (-0.10 ; 0.12)</td>
<td>23264</td>
<td>27%</td>
<td>10%</td>
</tr>
<tr>
<td>iADL limitations, 0-7</td>
<td>3017</td>
<td>1354</td>
<td>€ 297 (- €407 ; €945)</td>
<td>0.01 (-0.16 ; 0.17)</td>
<td>58573</td>
<td>36%</td>
<td>12%</td>
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<tr>
<td>QALYs, -0.30-0.50</td>
<td>3207</td>
<td>1381</td>
<td>€ 356 (- €365 ; €1067)</td>
<td>0.003 (-0.006 ; 0.012)</td>
<td>133611</td>
<td>58%</td>
<td>12%</td>
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<td><strong>Per protocol analysis</strong></td>
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<tr>
<td>SF-12 PCS, 0-100</td>
<td>2152</td>
<td>1342</td>
<td>€ 83 (- €440 ; €759)</td>
<td>-0.26 (-0.92 ; 0.39)</td>
<td>-316</td>
<td>12%</td>
<td>13%</td>
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<td>SF-12 MCS, 0-100</td>
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<td>1342</td>
<td>€ 83 (- €440 ; €759)</td>
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<td>7%</td>
<td>7%</td>
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<tr>
<td>ADL limitations, 0-6</td>
<td>2152</td>
<td>1342</td>
<td>€ 83 (- €440 ; €759)</td>
<td>0.00 (-0.07 ; 0.06)</td>
<td>-30439</td>
<td>25%</td>
<td>28%</td>
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<tr>
<td>iADL limitations, 0-7</td>
<td>2152</td>
<td>1342</td>
<td>€ 83 (- €440 ; €759)</td>
<td>-0.05 (-0.16 ; 0.06)</td>
<td>-1548</td>
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<td>39%</td>
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<td>QALYs, -0.30-0.50</td>
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<td>1342</td>
<td>€ 83 (- €440 ; €759)</td>
<td>-0.003 (-0.009 ; 0.004)</td>
<td>-32904</td>
<td>10%</td>
<td>10%</td>
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<td><strong>Healthcare system perspective</strong></td>
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<td>SF-12 PCS, 0-100</td>
<td>3017</td>
<td>1354</td>
<td>€ 189 (- €425 ; €717)</td>
<td>0.42 (-0.70 ; 1.54)</td>
<td>447</td>
<td>62%</td>
<td>20%</td>
</tr>
<tr>
<td>SF-12 MCS, 0-100</td>
<td>3017</td>
<td>1354</td>
<td>€ 189 (- €425 ; €717)</td>
<td>0.45 (-0.76 ; 1.66)</td>
<td>419</td>
<td>65%</td>
<td>20%</td>
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<td>ADL limitations, 0-6</td>
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<td>0.01 (-0.10 ; 0.12)</td>
<td>14821</td>
<td>26%</td>
<td>11%</td>
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<td>iADL limitations, 0-7</td>
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<td>€ 189 (- €425 ; €717)</td>
<td>0.01 (-0.16 ; 0.17)</td>
<td>37316</td>
<td>36%</td>
<td>12%</td>
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<tr>
<td>QALYs, -0.30-0.50</td>
<td>3207</td>
<td>1381</td>
<td>€ 220 (- €405 ; €798)</td>
<td>0.003 (-0.006 ; 0.012)</td>
<td>82506</td>
<td>56%</td>
<td>15%</td>
</tr>
</tbody>
</table>

$^a$ Multilevel analysis adjusted for time, frailty index, education and region

$^b$ Multilevel analysis adjusted for time, frailty index, baseline values, education and region (and QALYs also for phase length)

$^c$ NE: More expensive, more effective; SE: Less expensive, more effective; SW: Less expensive, less effective; NW: More expensive, less effective
**DISCUSSION**

**Main findings**

In this study with 24-months of follow-up, the cost-effectiveness of the Geriatric Care Model was evaluated in comparison with usual care in a stepped wedge cluster randomized controlled trial. There were no statistically significant differences in costs and effects between intervention phases and usual care phases. The GCM was not considered cost-effective compared to usual care.

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. An alternative explanation could be a poor implementation of the intervention. However, our assessment of implementation fidelity suggest adequate implementation of key components.\(^{50}\) Besides that, the results of the per-protocol analysis were not substantially different from the
main intention-to-treat analysis. A final explanation may be that it takes longer than the current follow-up of 24 months before the development of local networks, building of expertise and use of preventative actions as initiated within the GCM lead to clinical effects and costs savings. Due to the stepped-wedge design most of the observed intervention phases concern the first 6 and 12 months of the intervention. Preliminary descriptive analyses 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 preventative home visits without an integrated care approach found that such interventions only resulted in lower costs in the third year of follow-up.\textsuperscript{24,51} Thus, the duration of follow-up in this study may not have been long enough to capture these long term effects.

**Comparison with other studies**

The results of this cost-effectiveness analysis are comparable to other cost-effectiveness analyses of integrated care or home visiting programs aimed at frail older adults.\textsuperscript{26-28,52} 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 WTP values. The difference in QALYs between intervention phases and usual care phases found in our study was comparable to the estimates reported by Makai et al.\textsuperscript{26} and Drubbel et al.\textsuperscript{28} However, Drubbel et al. reported costs savings of 815 euros for the intervention in comparison with usual care in 12 months. The difference between our study and Drubbel et al. may be explained by the fact that Drubbel et al. did not include medication costs, and that intervention costs were almost 70\% lower than in our study (due to higher time investments from practice nurses in our study and the employment of the geriatric expert team).

**Strengths and limitations**

This study has several strengths. It was one of the first rigorous economic evaluations of an integrated care program following a Chronic Care Model approach for community-dwelling frail older adults. Other studies did not include a societal perspective\textsuperscript{27} and/or had shorter follow-up periods.\textsuperscript{26–28} Secondly, the use of a stepped wedge design has practical and ethical advantages, as it makes a large implementation study better manageable and eventually offers all participants in the study the intervention program.\textsuperscript{32,33} By using multilevel techniques with time adjustments to estimate cost and effect differences between intervention and usual care phases, we accounted for this design in the analyses. Thirdly, although cost diaries were not always completed prospectively by the participants, the in-home interviews for effect measurements gave us the opportunity to complete these diaries retrospectively with the participants. Finally, we expect that the results are generalisable to the population of frail older adults in the Netherlands due to the small number of exclusion criteria, the participation of primary care practices in an urban and urbanized rural region in the Netherlands, and the relatively small proportion of older adults that refused to participate.

Some limitations should be considered when interpreting the results. Despite extensive attempts to limit the rate of missing data, loss-to-follow up and limited coverage of pharmacy registries resulted in missing data for a quarter (cost diaries and outcome data) or half (medication data) of all phases. To deal with this, we used multiple imputation, which is currently the most appropriate technique to deal with missing data and allows for accounting for the uncertainty about the imputed values.\textsuperscript{44,45} Secondly, willingness to participate among informal caregivers was low and differed between allocation groups. Therefore, it was not possible to analyse cost and effects of informal caregivers, as announced in the study protocol.\textsuperscript{31} Nonetheless, informal care time administered from informal caregivers was supplemented with information from older adults about informal care time, and included in the analysis.
Conclusions and implications for further research

Based on our results we consider the GCM not cost-effective as compared with usual care in community-dwelling frail older adults after 24 months of follow-up. Although the concept of integrated care programs is widely adopted as a cost controlling approach for elderly care and descriptive cost studies suggest cost savings, evidence from adequately executed economic evaluations remains limited so far. Before more economic evaluations 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. To conclude, at this moment widespread implementation of the GCM in its current form is not recommended.
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