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**Author:** Houwelingen, Anne Henriëtte van  
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EFFECTIVENESS AND COST-EFFECTIVENESS OF A PROACTIVE, GOAL-ORIENTED, INTEGRATED CARE MODEL IN GENERAL PRACTICE FOR OLDER PEOPLE. A CLUSTER RANDOMIZED CONTROLLED TRIAL: INTEGRATED SYSTEMATIC CARE FOR OLDER PEOPLE - THE ISCOPE STUDY


Submitted
ABSTRACT

Background
Older people often experience a combination of somatic, functional, mental and/or social problems (complex problems). These problems are not always known to care providers. The general practitioner (GP) usually only acts on demand. For vulnerable older people, screening/monitoring of complex problems and a proactive way of working is important, although not common in primary care. Because of multiple problems, care for older people in general practice needs to shift from a vertical disease-oriented care aiming at improvement of outcomes per disease, to a horizontal problem-based, goal-oriented care, integrating all health care providers. The feasibility and cost-effectiveness of this pro-active and integrated way of working is not yet established.

Methods
Design: Cluster randomized trial.
Participants: all persons aged ≥75 years in 59 general practices (30 intervention, 29 control), with a combination of problems, as identified with a structured postal questionnaire with 21 questions on 4 health domains.
Intervention: for participants with problems on ≥3 domains general practitioners (GPs) made an integrated care plan using a functional geriatric approach. Control practices: care as usual. Outcome measures: i) quality of life (QoL), ii) activities of daily living, iii) satisfaction with delivered healthcare and iv) cost-effectiveness of the intervention, at 1-year follow-up.
Trial registration: Netherlands trial register, NTR1946.

Results
Of the 11,476 registered eligible older persons, 7285 (63%) participated in the screening. 1921 (26%) had problems on ≥3 health domains. For 225 randomly chosen persons a care plan was made. No beneficial effects were found on QoL, patients’ functioning or healthcare use/costs. GPs experienced better overview of the care and stability, eg. less unexpected demands, in the care.

Conclusions
GPs prefer proactive integrated care. ‘Horizontal’ care using care plans for older people with complex problems can be a valuable tool in general practice. However, no direct beneficial effect was found for older persons.
INTRODUCTION

With the aging population an ever-increasing number of older people with multiple health problems will be depending on health care. In recent decades health care has tended to be organized by means of vertical, disease-oriented programs. However, one disease and/or its intervention could influence the diagnosis, impact or treatment of another disease. These interactions between diseases and their treatment complicate the determination of disease-specific treatment goals. Thus, for older persons with multiple health problems, this model does not suffice.\(^1,2\)

In these older patients, illness presentation and the consequences of disease is better clarified with integrative disease models rather than by simple medical models.\(^1\) Since wellbeing and providing for oneself without assistance from others is of increasing importance for older patients with multiple health problems, care for older people needs to shift from vertical disease-oriented care aiming at improvement of outcomes per disease, to problem-based, goal-oriented care. Therefore, an integrated, horizontal care model aiming at global health outcomes is more suitable than a vertical model mainly aiming at improving disease outcomes.\(^6\) The problems older people are facing are not always known to care providers. The general practitioner (GP) may sometimes suspect the presence of some of these problems, but usually only acts on demand. Therefore, this model of care should be provided in a proactive way in order to set and prioritize goals together with the patient and to empower the patient to reach these goals.

Although this shift from vertical care to horizontal care sounds ideal in theory, actual implementation in primary care can be difficult. Models that have been investigated, range from light interventions to intensive guided care.\(^5-7\) However, until now, no important positive effects have been shown. Also, although some studies examined cost savings, to our knowledge few studies have evaluated cost-effectiveness.

The ISCOPE (Integrated Systematic Care for Older PEople) study aims to assess the effectiveness and cost-effectiveness of a simple structural monitoring system to detect the deterioration in somatic, functional, mental or social health of individuals aged 75 years and over followed by the execution of a care plan for those people with a combination of somatic, functional, mental and social problems. The ISCOPE study operationalizes horizontal care by developing a care plan for older persons with complex problems, i.e. a combination of functional, somatic (health and illness), mental and/or social problems.\(^8\) The care plan focuses on function rather than on disease and aims to restore, maintain or maximize functional independence, or to compensate for loss of autonomy by appropriate support (functional approach). Although the approach is functional, underlying disease can still be a focus of attention. The goals, wishes and expectations of the older person are the starting point for the care plan.\(^9\) To identify older persons with complex problems pro-actively, the ISCOPE study uses a simple structural screening and moni-
MATERIALS AND METHODS

Design Overview
The study is an observer-blinded cluster randomized-controlled trial with randomization at the level of the general practice. To avoid contamination we used a complete consent pre-randomization design. The Medical Ethical Committee of the Leiden University Medical Center approved the study. The study was registered in the Netherlands Trial Register (NTR1946).

Setting and Participants

Recruitment of general practices
All 560 GPs in the region of Leiden, the Netherlands, were invited to participate. In the initial invitation letter, we provided as little information as possible about the intervention to prevent behavioral change in the control group of GPs. Before inviting the older people to participate, we asked GPs to classify all enlisted older people into three categories according to their own perception: i) not vulnerable, ii) possibly vulnerable, and iii) vulnerable.

Recruitment of participants
In the Netherlands all community-dwelling persons are registered at a GP. During the inclusion period (September 2009 to September 2010) all persons aged ≥ 75 years received an invitation by mail from their GP to participate in the study. The GPs excluded people with terminal illness or an expected life expectancy of ≤ 3 months. Also included with this invitation were a screening questionnaire (Appendix 1) addressing four domains of health and an informed consent form. All older people who participated in the screening provided written informed consent. After 3 weeks the non-responders were contacted again by telephone and, if required, were assisted by telephone or visited at home to fill in the screening questionnaire. A total of 7285 older persons responded by sending in the complete screening questionnaire (Figure 1).
Randomization and Interventions

Training of GPs
After randomization (after screening), the GPs and practice nurses of the intervention practices were trained (during 2 sessions of 3 hours each) by a GP specialized in geriatric care to deliver pro-active integrated care, including designing, conducting and adjusting a care plan (Appendix 3). During the intervention the GPs had the possibility to consult a GP with special post-graduate training in geriatrics and they received an extra training of three hours on resources and organization of care to older people in primary care.

Screening questionnaire
The screening questionnaire contained questions on four domains of health: functional, somatic (health and illness), mental and social and each domain contained 4-9 questions. [8] A positive answer to two or more questions in a domain led to a positive score on the domain. The questions were derived from existing validated questionnaires[13-14] and were based on predictors related to functional decline[15-19]. Individuals with problems on three or four domains were classified as having complex problems which is associated with poor outcomes on disability, feelings of loneliness, health related quality of life and GP contact time[8]. In the intervention practices, the GPs received the results of the screening questionnaire of their own patients. In the control practices, GPs did not receive feedback about the screening questionnaire and provided care as usual to their older patients.

Care plan
In the intervention practices, the GP or the practice nurse (under supervision of the GP) made an integrated care plan for participants with complex problems. This care plan consisted of two steps. The first was an inventory of the existing health problems using problem areas as introduced by Bangma, stemming from Dutch rehabilitation medicine: somatic, activities of daily living, social, mental and communicative problems[20]. The wishes and expectations of the older person about goals to be achieved were explored in a dialogue with the participant and informal caregiver(s). Subsequently, a care plan was made, taking the priorities and goals of the older person and informal caregiver as a starting point (Appendix 4). The GP/practice nurse, together with the older person, formulated actions to be taken and evaluation plans for follow-up. Other care professionals were involved where needed (multidisciplinary consultation). For the purpose of the present study, the participating GPs made care plans for a maximum of 10 randomly chosen participants with complex problems. For the participants with complex problems who were not selected usual care was provided. These participants were not included in the final analysis.
Outcomes and Follow-up

At baseline and at 1-year follow-up participants were visited by a research nurse to measure outcomes. At 6 months post-baseline the EQ-5D was sent by mail.

To show the outcome of the screening a comparison was made between participants with complex problems and participants without complex problems with data from the EPR and data from the questionnaires.

Primary outcome

The primary outcomes was quality of life at 1-year follow-up as measured with Cantril’s ladder\(^ {21}\), and competence in basic activities of daily living (BADL) and instrumental activities of daily living (IADL) at 1-year follow-up as measured with the Groningen Activities Restriction Scale (GARS)\(^ {22}\), and. Quality of life was measured by Cantril’s ladder that has steps ranging from 0 to 10\(^ {23}\). The GARS is a questionnaire that assesses disabilities in competence in 9 BADL items and 9 IADL items. (range 18-72, higher score means more disability).

Secondary outcomes

Because we used a comprehensive intervention we used a wide array of secondary outcomes.

As secondary outcomes we examined satisfaction with delivered care of the older persons, the GPs and informal caregivers\(^ {24}\).

Older people: Participants were asked to indicate their satisfaction with and confidence in their GP, pharmacist, specialist, physiotherapist, hospital and home care on a 5-point Likert scale. The 5 levels of satisfaction were then dichotomized into ‘satisfied’ (including very satisfied, satisfied and neutral) and ‘dissatisfied’ (including dissatisfied and very dissatisfied)\(^ {25}\). Answers to the questions regarding confidence were dichotomized in the same way.

General practitioners: At baseline and at 1-year follow-up, questionnaires were sent to GPs in the intervention group asking them about the overview of care needs, stability in the care situation, and (expected) improvement in the care situation for each participant for whom they had made a care plan (answers on a 10-point scale). To evaluate the experiences of the GPs with the screening and care plans, two focus groups were organized (each with four GPs). In both groups, three GPs had extra staff available to enable them to place more focus on the care of their older patients. The first group consisted of GPs who did not manage or only partly managed to complete care plans, and the second group consisted of GPs who completed all the care plans.
Informal caregivers: At baseline and at 1-year follow-up, informal caregivers were sent a questionnaire about the amount of time spent on care for the older participant (hours per week spent on household activities, personal care, and activities outside the house), the burden of this care (score 0-10) and their quality of life (score 0-10).24

Other secondary outcomes
Cognitive function was measured with the Mini-Mental State Examination (MMSE) with scores ranging from 0-30 points (higher score means less cognitive problems).26 Depressive symptoms were assessed with the 15-item Geriatric Depression Scale (GDS-15), with scores ranging from 0 (optimal) to 15 (higher score means more depression).27 The GDS-15 was administered only to participants with an MMSE score ≥ 18 points. Self-rated health was measured using the question ‘How do you rate your health in general?’ on a 5-point scale ranging from 1 to 5, and the question ‘How do you rate your health compared to one year ago?’ on a 5-point scale ranging from 1 to 5. Self-rated loneliness was assessed with the Loneliness Scale of De Jong Gierveld (DJG) an 11-item questionnaire covering both emotional loneliness (6 items) and social loneliness (5 items) that was specifically developed for use in elderly populations (higher score means more social problems).28

Since the study was aimed at identifying older people with complex problems, we also evaluated combined outcomes indicating complexity. We used the total score on the ICOPE screening questionnaire and a combined Z score of the GARS score (functional domain), self-rated health (somatic domain), GDS score (mental domain), and DJG score (social domain).

Process evaluation and contents of the care plan
The content of the care plans is described by the median number of defined problems, goals and actions (with interquartile range; IQR), the percentage of problems, goals and actions, and the ‘level’ of functional approach used in the description of the problem-goal-action sequence: handicap/limitation, complaint/symptom, disease/diagnosis, other. To categorize the problems, type of goals and type of actions we used a partly deductive (start with predefined categories based on anatomic areas for the problems) and partly inductive (include extra categories) process.

Sample size
The required sample size was based on the change in BADL. In the Leiden 85-plus Study we found a decrease of ~1.4 points per year, with a standard deviation (SD) of 3.18, 28. Based on this result we decided on a change of 1.0 point as a clinically relevant difference. With a power of 85%, a significance level of 0.05 we needed a sample size of 163 patients per group (IBM SPSS Sample Power 3). To take cluster randomisation into account we used
the following formula: $\text{ESS} = \frac{mk}{1 + \text{ICC}(m-1)}$ with $m =$ number of vulnerable elderly of 75 years and older in a general practice, $k =$ number of practices, $\text{ESS} =$ “effective sample size” as calculated as if we use randomization on a patient level. Assuming that about 10 participants with complex problems would be feasible per general practice, an intra-cluster correlation coefficient (ICC) of 0.05, and also taking dropout into account, it was estimated that about 60 general practices should be recruited.

**Analysis non-response screening**

To compare responders (with and without complex problems) and non-responders, we used patient data from a rural and a city GP practice (total of 629 patients) who participated in the ISCOPE study. Anonymous data from the electronic patient records (EPR) were available for participants and non-participants. A comparison was made of socio-demographic data, diseases (International Classification of Primary Care (ICPC) codes), medication, use of care, and the GP’s appraisal of vulnerability. For each health domain, corresponding items in the EPR were compared (e.g. for the functional domain the number of home visits and number of referrals to physiotherapy were compared, and for the somatic domain the number of prevalent diseases (ICPC-codes) was compared).

**Statistical Analysis**

Descriptive statistics were used to compare baseline characteristics of the participants in the intervention and control practices. Means and SD are used for continuous variables that were normally distributed and medians with IQR for continuous variables that were not normally distributed. Proportions are used to describe differences in categorical variables. In both groups, mortality differences between participants with complex problems were analyzed using Cox regression analysis. Differences in median scores between baseline and follow-up in the GP questionnaire were tested with Mann-Whitney U-tests, because incomplete scoring in the GP questionnaires prevented a paired analysis.

The primary analysis focused on the difference in Cantril’s ladder score and ADL score (GARS BADL and IADL) between participants with complex problems for whom a care plan should have been made (intervention group) compared with all participants with complex problems in the care as usual practices (control group).

Analyses were performed on an intention-to-treat basis and per protocol basis. A sensitivity analysis for effectiveness was performed in the group of participants with problems in 4 domains. A linear mixed model (LMM) analysis was used, correcting for age, sex, baseline scores and clustering of patients per general practice. The model included a variable for time of measurement (baseline and 1-year follow-up) and a variable for allocation (with value 0 in control patients and value 1 at 1 year follow-up in intervention group patients). The estimate for time of measurement shows the change
in score for the control group. The estimate for the allocation shows the difference in change in score between the intervention and control group. Because we assumed that the intervention would have no effect on mortality (which was confirmed by the analysis on mortality) and we were exploring the effect in those that survived, participants who died during follow-up were excluded from the primary outcome analyses. The LMM analysis corrects for outcomes missing at random.

**Analysis of focus groups**
Focus group interviews were recorded and transcribed verbatim. We used thematic analysis involving coding, categorizing and theme identification. All incentives and barriers for screening and care plans mentioned in the verbatim reports were coded and analysed independently by two researchers (JWB, WdE).

**Economic evaluation**
The cost-effectiveness of the intervention from a societal perspective during the 1-year follow-up was analyzed (Appendix 5).

**Role of the funding source**
This study was funded by ZonMw, the Netherlands, Organization for Health Research and Development: ZonMw No. 311060201. The sponsor had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.

**RESULTS**

**Participants**

**General practitioners**
Of the 560 GPs approached, 104 (19%) working in 59 general practices agreed to participate. Concern about the workload was the main reason for non-participation (28%); also, 4% had just left the practice, 4% had very few older people enlisted, 7% were not interested in the project, and 4% already implemented an intervention in the care for their older patients. The remaining practices had other reasons for non-participation or did not respond (34%).

The participating practices were representative for the urbanized area in the vicinity of the city of Leiden (the Netherlands).
**Older people**

The participation of older persons is shown in Figure 1. Of the 12,066 registered people aged ≥ 75 years, 590 (5%) were not eligible because they were deceased (0.9%), too ill (1.4%), admitted to a nursing home (1.1%), non-Dutch speaking (0.3%), or for other reasons (1.1%).

**Screening**

Of the 11,476 registered eligible older persons, 7285 (63%) participated in the screening and 4191 (37%) declined or did not respond for other reasons. One third of the population (2240, 31%) was assisted by a relative (n=1396, 19%) or a research nurse (n=844, 12%).

**Non-response analysis**

Non-responders are older and less often male than non-complex responders and do not differ in age and sex from complex responders (Table 1). Non-responders have the same number of disease and prescriptions but are more vulnerable according to the GP than non-complex responders. However, complex responders still have more disease and prescriptions, and are more vulnerable according to GP than both other groups.

Health care use in non-responders is similar to non-complex responders. Non-responders have less home visits. Complex responders have more GP consultations, GP home visits, physiotherapy and primary mental health care than both other groups.

**Screening results**

Table 2 shows the characteristics and screening results of participants who returned the screening questionnaire in the 30 intervention practices and of participants in the 29 control practices. Median age, sex, income, living circumstances and outcomes of the screening questionnaire were similar. Overall, 26% of the participants had complex problems. Participants with complex problems have a poorer score on all questionnaire outcomes compared to participants without complex problems (see additional table 1).

**Participants with complex problems**

**Non-response analysis of participants with complex problems**

For the baseline outcome measurement there were no significant differences in sex and reasons for non-participation between non-participants in the intervention group and non-participants in the control group (Additional figure 1; p-values see additional table 2). The median age of the non-participants in the control group was higher than that in the intervention group (84.2 vs 82.5 years; p=0.038); for the follow up outcome measurement this was 83.1 vs 84.1; p=0.536.
Figure 1. Flowchart of participants in the study.
The dotted grey squares indicate the two groups compared in the intention-to-treat analysis.
**Table 1. Non-response in screening**

<table>
<thead>
<tr>
<th></th>
<th>Responders</th>
<th></th>
<th></th>
<th></th>
<th>p-value non-responder vs non-complex responders</th>
<th>p-value non-responder vs complex responders</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total N=358</td>
<td>No complex problems N=280</td>
<td>Complex problems* N=75</td>
<td>Non-responder N=271</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (median, IQR)</td>
<td>80 (77-83)</td>
<td>79 (77-82)</td>
<td>83 (78-86)</td>
<td>81 (78-85)</td>
<td>&lt;0.001</td>
<td>0.103</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>42.3</td>
<td>46.1</td>
<td>28.0</td>
<td>33.9</td>
<td>0.004</td>
<td>0.331</td>
</tr>
<tr>
<td>Living alone (%)</td>
<td>20.0</td>
<td>17.8</td>
<td>28.0</td>
<td>24.4</td>
<td>0.059</td>
<td>0.530</td>
</tr>
<tr>
<td>Number of diseases (median, IQR)</td>
<td>2 (1-3)</td>
<td>2 (1-3)</td>
<td>3 (2-5)</td>
<td>2 (1-4)</td>
<td>0.045</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Vulnerable according to GP (%)</td>
<td>19.8</td>
<td>13.7</td>
<td>42.7</td>
<td>25.4</td>
<td>0.001</td>
<td>0.004</td>
</tr>
<tr>
<td>Number of prescriptions (median, IQR)</td>
<td>9 (5-13)</td>
<td>8 (4-12)</td>
<td>13 (8-19)</td>
<td>8 (4-12)</td>
<td>0.946</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Health care use last year

<p>| | | | | | | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Consultations GP (median, IQR)</td>
<td>8 (4-12)</td>
<td>7 (4-11)</td>
<td>12 (6-17)</td>
<td>7 (4-12)</td>
<td>0.486</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Home visits GP last year, yes/no (%)</td>
<td>36.9</td>
<td>29.3</td>
<td>65.3</td>
<td>44.6</td>
<td>&lt;0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>Out of hours contact GP, yes/no (%)</td>
<td>13.0</td>
<td>10.7</td>
<td>21.3</td>
<td>14.8</td>
<td>0.154</td>
<td>0.171</td>
</tr>
<tr>
<td>Referrals (median, IQR)</td>
<td>1 (0-3)</td>
<td>1 (0-2)</td>
<td>2 (1-4)</td>
<td>1 (0-2)</td>
<td>0.734</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Physiotherapy, yes/no (%)</td>
<td>15.5</td>
<td>13.2</td>
<td>24.0</td>
<td>9.2</td>
<td>0.138</td>
<td>0.001</td>
</tr>
<tr>
<td>Mental health care, yes/no (%)</td>
<td>1.9</td>
<td>2.6</td>
<td>0.0</td>
<td>3.4</td>
<td>0.671</td>
<td>0.132</td>
</tr>
</tbody>
</table>

*3 missing values
Comparison of outcomes between intervention and control groups

Intra-cluster correlation coefficient

After analysis of the data we found an ICC of 0.002. Post hoc, a power of 85% was calculated for this study.

Patient outcomes

In total 288 participants with complex problems were randomly selected for a care plan out of the intervention practices. Table 3 shows the characteristics of the participants with complex problems in the intervention and control practices. Participants in the intervention practices selected for a care plan (n=288) were similar to those who were not selected for a care plan (Table 3).

During the 1-year follow-up, 19 (6.6%) participants in the intervention group and 87 (8.0%) in the control group died (p=0.479).

Table 4 presents the primary and secondary outcomes for the intention-to-treat analysis. In the control group the change in GARS score at 1-year follow-up (3.5; 95% confidence interval (CI): 3.0; 4.0) shows that this group is deteriorating rapidly. There was no difference in change in the score on Cantril’s ladder or GARS score (total, BADL or IADL) between participants who were randomized to have a care plan made in the intervention group and participants with complex problems in the control group. Also, there was no difference in secondary patient outcomes. In a per-protocol analysis, i.e. in
Table 3. Baseline characteristics of participants with complex problems.

<table>
<thead>
<tr>
<th></th>
<th>Intervention group</th>
<th>Control group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not selected for care plan</td>
<td>Selected for care plan</td>
</tr>
<tr>
<td>Age in years*</td>
<td>82.7 (79.2;87.1)</td>
<td>82.0 (78.8;86.9)</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>374 (69.0)</td>
<td>208 (72.5)</td>
</tr>
<tr>
<td>Score on four domains of screening questionnaire (%)</td>
<td>189 (34.9)</td>
<td>92 (31.9)</td>
</tr>
<tr>
<td>&gt;4 medications (%)</td>
<td>423 (78.2)</td>
<td>233 (80.9)</td>
</tr>
<tr>
<td>GARS total score*</td>
<td>37 (29;47)</td>
<td>36 (27;45)</td>
</tr>
<tr>
<td>BADL subscale score*</td>
<td>11 (9;15)</td>
<td>11 (9;15)</td>
</tr>
<tr>
<td>IADL subscale score*</td>
<td>19 (25;33)</td>
<td>18 (25;30)</td>
</tr>
<tr>
<td>Cantril’s ladder*</td>
<td>7 (6;8)</td>
<td>7 (6-8)</td>
</tr>
<tr>
<td>MMSE score*</td>
<td>27 (25;29)</td>
<td>28 (26-29)</td>
</tr>
<tr>
<td>GDS score*</td>
<td>3 (1;5)</td>
<td>2 (1;4)</td>
</tr>
<tr>
<td>DJG score*</td>
<td>4 (1;6)</td>
<td>3 (1;5)</td>
</tr>
</tbody>
</table>

*(median, IQR)

GARS  Groningen Activity Restriction Scale
BADL  Basic Activities of Daily Living
IADL  Instrumental Activities of Daily Living
MMSE  Mini Mental State Examination
GDS  Geriatric Depression scale
DJG  De Jong-Gierveld Loneliness scale

Table 4. Outcomes of the intention-to-treat analysis adjusted for age at screening, sex and baseline score.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Change in 1-year follow-up for control group (n=1091)</th>
<th>p-value</th>
<th>Extra change in intervention group compared to control group (n=288)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GARS total score</td>
<td>3.5 (3.0;4.0)</td>
<td>&lt;0.001</td>
<td>-0.6 (-1.7;0.5)</td>
<td>0.299</td>
</tr>
<tr>
<td>GARS-subscale BADL</td>
<td>1.4 (1.1;1.7)</td>
<td>&lt;0.001</td>
<td>-0.2 (-0.9;0.4)</td>
<td>0.450</td>
</tr>
<tr>
<td>GARS-subscale IADL</td>
<td>2.1 (1.8;2.4)</td>
<td>&lt;0.001</td>
<td>-0.4 (-1.1;0.3)</td>
<td>0.238</td>
</tr>
<tr>
<td>Cantril’s ladder</td>
<td>-0.2 (-0.3;0.0)</td>
<td>0.004</td>
<td>0.0 (-0.2;0.2)</td>
<td>0.823</td>
</tr>
<tr>
<td><strong>Secondary outcomes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMSE</td>
<td>-0.7 (-1.0;-0.5)</td>
<td>&lt;0.001</td>
<td>0.4 (0.0;0.9)</td>
<td>0.066</td>
</tr>
<tr>
<td>GDS-15</td>
<td>0.1 (-0.1;0.3)</td>
<td>0.168</td>
<td>0.0 (-0.4;0.4)</td>
<td>0.916</td>
</tr>
<tr>
<td>DJG</td>
<td>-0.1 (-0.3;0.1)</td>
<td>0.410</td>
<td>-0.1 (-0.5;0.3)</td>
<td>0.661</td>
</tr>
<tr>
<td>Total score ISCOPE screening</td>
<td>-0.6 (-0.8;-0.4)</td>
<td>&lt;0.001</td>
<td>-0.3 (-0.8;0.1)</td>
<td>0.141</td>
</tr>
<tr>
<td>Combined outcome (Z scores)</td>
<td>-0.5 (-0.6;-0.4)</td>
<td>&lt;0.001</td>
<td>0.0 (-0.3;0.3)</td>
<td>0.845</td>
</tr>
</tbody>
</table>
Effectiveness and cost-effectiveness of an integrated care model in general practice

the intervention group only including participants for whom a care plan was made, no
difference was found between the two groups (data not shown). A sensitivity analysis in
participants with problems in 4 domains showed similar results.

Satisfaction with care

Older people's satisfaction with care

During the 1-year follow-up, the number of people satisfied with the GP increased in
the intervention group (from 96.8% to 97.8%) and decreased in the control group (from
94.5% to 93.7%). No difference between the two groups was observed on confidence in
the GP, or on satisfaction with and confidence in the other care providers.

GPs’ satisfaction with care

GPs returned baseline questionnaires for 202 participants with a care plan and returned
1-year follow-up questionnaires for 146 of these participants. GPs reported an improve-
ment in the overview of care needs [from median 7.0 (IQR 6.0-8.0) to 8.0 (IQR 7.0-9.0);
p<0.001] and experienced more stability in the care situation [from median 7.0 (IQR
6.0-8.0) to 8.0 (IQR 7.0-8.0); p<0.001]. Although baseline expectations for improvement
in the care situation were low, the reported actually experienced improvement at 1-year
follow-up was good [median 5.5 (IQR 2.0-7.0) and 7.0 (IQR 6.0-8.0), respectively; p<0.001].

In the focus groups the GPs felt that new information had emerged from the screening,
indicating (in particular) their possible ‘blind spot’ for mental and social issues. Some
GPs feared that ‘medicalization’ was stimulated by the screening. GPs experienced more
control over the care situation and were more aware of the functioning and wishes of
the older people. However, they found the protocolised way of working difficult and
suggested that it was perhaps more suited to the practice nurse. Some GPs preferred to
focus on the medical task. Organising multidisciplinary consultations was found to be
cumbersome.

Informal caregivers

Of the 269 responding informal caregivers (40 in the intervention group, 143 in the con-
trol group), the majority were children of the older person (60% and 59%, respectively);
their median age was 61 (IQR 51-70) years and 62 (IQR 56-75) years, respectively; and
in the intervention group 35% was male compared with 28% in the control group. The
intervention group spent a median number of 5 (IQR 2-20) hours per week on household
activities, 3 (2-14) on personal care and 4 (2-6) hours on outside activities. For the control
group this was 5 (IQR 3-12), 3 (IQR 1-10) and 3 (IQR 1-7) respectively. Between baseline
and 1-year follow-up there was no significant difference between the groups in the
(change in) time spent on care for the older participant, the burden felt by the informal caregiver, and their quality of life (see additional table 3).

**Process evaluation and content of care plan**

A total of 288 randomly chosen participants with complex problems were assigned to receive a care plan. Of these, in 7% (n=20) the GP indicated that the drafted care plan was not carried out due to death, referral to a nursing home, moving house, etc. In 15% (n=43) the GP did not prepare the care plan due to time constraints or other logistic problems. Three GPs did not manage to make any care plan at all. The median number of problems, goals and actions in the care plans was 3 (IQR 2-4), 4 (2-5) and 3 (2-5), respectively. The five most prevalent problems were: depressive complaints (20% of patients), loneliness/isolation (19%), decreased mobility (19%), memory complaints (17%), and hearing complaints (12%). The five most prevalent actions were: action by the patient or informal caregiver (13% of actions), such as engaging in social activities, referral to another physician (9%), further diagnostic interventions (9%), frequent check-up by the GP (7%), and optimizing the medication (7%). In the problem-goal-action sequences, 46% of descriptions were expressed as handicap/limitation, 46% as complaint/symptom and 8% as disease/diagnosis.

**Economic evaluation**

Costs were estimated at €236 per care plan (Appendix 5), which includes training of GPs and practice nurses (16%), screening (21%), making the care plan (30%) and carrying out the care plan (34%). These care plan costs constituted only 1.3% of the total healthcare costs during the 1-year follow-up. No differences were found in the use of other types of healthcare or in total health care costs.

**DISCUSSION**

This study evaluated a proactive horizontal approach by the GP for older patients, consisting of a brief (postal) screening questionnaire and making an integrated care plan for (some) patients with complex problems. The GPs had successfully taken on the functional approach, as seen from the contents of the care plans. GPs experienced better overview of care needs and more stability, eg less unexpected care demands, in the care for individual patients with complex problems. Older patients with complex problems were already largely satisfied with the care offered by their GP and the change in satisfaction was therefore small. Nevertheless, no significant improvement was found in quality of life or functional status after 1-year follow-up in participants with complex problems in the intervention group compared with those in the usual care group. In
addition, there was no significant difference in change of somatic problems and mental/social functioning, or in complexity. Except for the care plans, patients in the intervention group had the same amount of healthcare use and costs as the control group.

**Comparison with literature**

Two systematic reviews evaluated studies on complex interventions (with individualized assessment and provision, or referral to appropriate care) to prevent functional decline in older people\(^5.6\). Although one review showed a reduction in admissions to hospitals/nursing homes, a reduction in falls, and an improvement in functioning, the effects were only modest\(^5\). Moreover, the effects were mainly in studies conducted before 1993, suggesting that modification of care after 1993 was of little additional value; this idea has recently been confirmed\(^31\). The more recent review showed small effects on functioning, but mainly in studies performed in the US and not in non-US countries\(^6\). This latter review showed no effects on hospitalization, institutionalization or mortality; in addition, due to significant heterogeneity between the reviewed studies, the net benefit could not be determined\(^6\). Two other systematic reviews on comprehensive care programs for people with multi-morbidity were also unable to determine net benefit due to heterogeneity\(^32-34\). The present study also examined the cost-effectiveness and preferences of GPs and older persons which, until now, has scarcely been investigated.

**Strengths and limitations**

The ISCOPE study was performed in a large number of practices in urbanized and suburbanized areas, involving single-handed practices and group practices, thereby guaranteeing generalizability to other practices in the Netherlands. Outcomes were measured during home visits, thereby increasing the reliability and completeness of the measurements. Because about 37% of the older people did not participate in the ISCOPE study, this could have led to a selection of healthier (or perhaps less healthy) older persons or people more likely to accept the suggested intervention. A non-response evaluation showed that non-participants were slightly more vulnerable than the participants; this difference might decrease with more extensive reminding procedures.

We were unable to obtain repeated assessments over a longer period. Repeated assessments might have amplified the proactive aspect of the intervention, possibly leading to a detectable effect on the outcomes.

**Possible reasons for no effect in functioning**

There are a few possible reasons for the lack of effect on the functioning of older persons in the present study. First, many changes in the care for older people in primary care have been instigated since the early 1990s\(^5\). The present study started in a climate of growing interest in preventive and proactive care for older people, which ensured enthusiasm
among participating GPs; government and care professionals were already moving in this direction. In 2007 the National Program for Elderly Care was set up, aiming to improve the quality of care for older people by developing coherent care better suited to the individual needs of older persons. Although this climate of change implies that GPs were keen to participate in this study, no extra provisions (i.e. financial compensation to implement proactive care for older people) were yet in place; this keeps the risk of contamination in the usual care practices low. However, GPs (also in the control group) might have had an increased awareness of the need to work proactively for their older patients, as policy reports on this subject were issued in 2007 and 2010 (mission statements of the Dutch College of General Practice (DCGP) and of the Royal Dutch Medical Association, and a guideline for the care for older people in general practice issued by the DCGP.

Second, unsolicited care programs or other devices might not work because those who would expect benefit from the offered service or device have already obtained it. In this study, because the initiative for a care plan did not originate from the participant, executing the plan did not bring the desired changes.

Third, interventions targeted at specific risk factor management may be more effective than organizational interventions with a broader focus. Indeed, the focus of our intervention may have been too broad and may have diluted the effect of each particular outcome measure, thus reducing the power to detect a difference. For this reason, we used quality of life as primary outcome and we also investigated combined scores of questionnaires as a secondary outcome; however, this also revealed no effect of the intervention.

Fourth, the intervention may not have been sufficiently intense to be able to cause effect. However, this explanation seems unlikely since one meta-analysis demonstrated that the intensity of the intervention made no difference to its effectiveness. Possibly, the participants were relatively healthy with little room for improvement. However, a sensitivity analysis in the group with problems in 4 domains also failed to show an effect.

Five, a change in approach in organization and delivery of care does not necessarily lead to effects on the level of functioning or quality of life of the patient. The two meta-analyses showed no positive effect on functioning of any of the interventions, possibly due to the use of non-responsive ADL and IADL instruments. Perhaps outcomes related to healthcare delivery, such as patient experience with continuity of care, or more individualized outcomes such as goal attainment scaling, might have elicited more response than traditional outcome measures of functioning. Unfortunately, at the start of the present study, these latter outcomes were not widely available for practical use in research with community-dwelling older people, but might be promising for use in future studies.
Six, a randomized trial may not be appropriate for this sort of interventions as the services offered comprise a complex mix of uncontrollable variables embedded in a social process, more than a treatment program alone. The success of the offered services depends on factors other than functioning (such as building a relationship with the client, the perceived need for care, past experiences with health care, etc.) which cannot be measured or controlled in such a way as to meet the requirements of randomized controlled trials. The increase in satisfaction with care among both the older people and the GPs might reflect these factors. Although failure to show an effect should not be used solely as an excuse to discontinue the service, it remains important to find evidence regarding the cost-effectiveness of new ways of working.

**Implications**

The question remains as to which outcomes will convince healthcare professionals and policymakers in their decision-making regarding implementation of an intervention. The present study showed no beneficial effect on functioning and quality of life of older persons, or on healthcare costs; therefore, this integrated care model cannot be recommended for this particular goal. Nevertheless, in the Netherlands, healthcare organization for older people in general practice has assumed its own momentum. GPs are increasingly interested and motivated to implement proactive care to prevent functional decline in vulnerable older persons and see this as an improvement of their care. Since 2011, health insurers in the Netherlands have provided funding to GPs to innovate services towards proactive care for older people, encompassing two main elements: case finding and care plans. This lack of congruence between research and policy is an issue that should receive more attention.

Integrative and proactive care for older community-dwelling people will probably be an essential instrument in primary care to be able to manage the care since (in the present political climate) the need to cut costs results in more older people living independently in the community rather than in care homes, but still requiring health care. This study also shows that GPs working with a proactive care plan report the benefit of increased stability in the care of older persons. We think that horizontal care using care plans for older people with complex problems can be a valuable tool in general practice. However, since no direct beneficial effect was found for older persons, based on this study we cannot recommend this intervention to improve patient outcomes in general practice.
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**Additional table 1.** Baseline characteristics of participants with complex problems compared to participants without complex problems.*

<table>
<thead>
<tr>
<th></th>
<th>Complex problems n=1516</th>
<th>No complex problems n=1197</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age in years*</td>
<td>83.0 (79.5;87.4)</td>
<td>80.9 (77.9;85.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Sex (% female)</td>
<td>1086 (71.6)</td>
<td>768 (64.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>&gt;4 medications (%)</td>
<td>1172 (77.3)</td>
<td>645 (53.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Cantril's ladder*</td>
<td>7 (6;8)</td>
<td>8 (7;8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>GARS total score*</td>
<td>37 (29;46)</td>
<td>26 (21;33)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BADL subscale score*</td>
<td>11 (9;15)</td>
<td>9 (9;10)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>IADL subscale score*</td>
<td>26 (19;32)</td>
<td>17 (12;23)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>MMSE score*</td>
<td>27 (25;29)</td>
<td>28 (27;29)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>GDS score*</td>
<td>3 (1;5)</td>
<td>1 (0;2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>DJG score*</td>
<td>3 (1;6)</td>
<td>1 (0;3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>*(median, IQR)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

GARS Groningen Activity Restriction Scale  
BADL Basic Activities of Daily Living  
IADL Instrumental Activities of Daily Living  
MMSE Mini Mental State Examination  
GDS Geriatric Depression scale  
DJG De Jong-Gierveld Loneliness scale

*Baseline and follow up measurements were performed for all participants with complex problems, for 60% randomly selected participants with scores on 0 or 1 domain and for 15% randomly selected participants with problems on 2 domains (see total flowchart).

**Additional table 2.** P values for difference in sex and reasons for non-participation between non-participants in intervention and control group with complex problems

<table>
<thead>
<tr>
<th>Reason for non-participation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First visit</strong></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.871</td>
</tr>
<tr>
<td>Too ill</td>
<td>0.646</td>
</tr>
<tr>
<td>Admission to nursing home</td>
<td>0.830</td>
</tr>
<tr>
<td>Declined</td>
<td>0.607</td>
</tr>
<tr>
<td><strong>Second visit</strong></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.153</td>
</tr>
<tr>
<td>Too ill</td>
<td>0.465</td>
</tr>
<tr>
<td>Admission to nursing home</td>
<td>0.830</td>
</tr>
<tr>
<td>Declined</td>
<td>0.607</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td><strong>First visit</strong></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.137</td>
</tr>
<tr>
<td><strong>Second visit</strong></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.871</td>
</tr>
</tbody>
</table>
**Additional table 3. Outcomes informal caregivers in intention to treat analysis.**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Change in 1-year follow-up for informal caregivers in control group (n=143)</th>
<th>p-value</th>
<th>Extra change in informal caregivers in intervention group compared to control group (n=40)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household activities</td>
<td>0 (-0.1; 0.1)</td>
<td>0.474</td>
<td>-0.1 (-0.2; 0.1)</td>
<td>0.444</td>
</tr>
<tr>
<td>Personal care</td>
<td>0 (-0.1; 0.1)</td>
<td>0.674</td>
<td>0 (-0.2; 0.2)</td>
<td>0.970</td>
</tr>
<tr>
<td>Outdoor activities</td>
<td>0 (0; 0)</td>
<td>0.827</td>
<td>0 (0; 0.1)</td>
<td>0.403</td>
</tr>
<tr>
<td>Burden of care (0-10)</td>
<td>0.5 (0.1; 0.8)</td>
<td>0.024</td>
<td>-0.4 (-1.2; 0.4)</td>
<td>0.323</td>
</tr>
<tr>
<td>Feeling of happiness (0-10)</td>
<td>-2.0 (-2.5; 1.4)</td>
<td>&lt;0.001</td>
<td>0 (-1.1; 1.2)</td>
<td>0.933</td>
</tr>
</tbody>
</table>
Enlisted and assessed for eligibility: n=12066
Excluded: n=590
- Deceased: n=107
- Too ill: n=174
- Nursing home: n=134
- Non-Dutch speaking: n=37
- Excluded by GP for other reasons: n=138
Invited to participate: n=11476
Non-response: n=4191
- Declined to participate: n=3062
- No reply to invitation: n=908
- Other: n=58
Moved house: n=163
Randomized by general practice, ISCOPE screening questionnaire: n=5938
Intervention group: n=3145
Control group: n=4133
No complex problems: n=2315
Complex problems: n=830
Baseline visit: n=521 (58.8%)
Baseline visit: n=414 (76.4%)
Baseline visit: n=676 (57.5%)
Baseline visit: n=864 (79.2%)
Not visited: n=365
- Deceased: n=2
- Too ill: n=1
- Nursing home: n=1
- Declined: n=352
- Other: n=3
- Unknown: n=6
Not visited: n=128
- Deceased: n=3
- Too ill: n=1
- Nursing home: n=1
- Declined: n=113
- Other: n=8
Unknown=2
Not visited: n=499
- Deceased: n=7
- Too ill: n=2
- Nursing home: n=1
- Declined: n=476
- Other: n=4
Unknown n=9
Not visited: n=227
- Deceased: n=11
- Too ill: n=7
- Nursing home: n=7
- Declined: n=171
- Other: n=8
Unknown=2
12 months visit: n=456 (87.5%)
12 months visit: n=313 (80.0%)
12 months visit: n=563 (83.3%)
12 months visit: n=656 (75.9%)
Not visited: n=65
- Deceased: n=16
- Too ill: n=1
- Nursing home: n=4
- Declined: n=37
- Other: n=5
- Unknown: n=7
Not visited: n=83
- Deceased: n=27
- Too ill: n=3
- Nursing home: n=10
- Declined: n=37
- Other: n=5
Unknown=1
Not visited: n=113
- Deceased: n=29
- Too ill: n=2
- Nursing home: n=11
- Declined: n=59
- Unknown: n=12
Not visited: n=208
- Deceased: n=71
- Too ill: n=11
- Nursing home: n=21
- Declined: n=84
- Other: n=20

Randomly selected for care plan: n=288
Care plan made: n=225
Baseline visit: n=188 (83.5%)
12-month visit: n=155 (82.4%)
Deceased: n=4
Nursing home: n=2
Declined: n=6
Refused visit: n=1
Other: n=5
Unknown: n=19
GP made no plan: n=63
Deceased: n=3
Nursing home: n=1
Declined: n=5
Other: n=1
Unknown: n=3
Not selected for care plan: n=542
Additional figure 1. Total flowchart.
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