Increasing numbers of vulnerable older persons challenge primary care resources because of the aging process and the clustering of chronic illnesses within this age group. Primary care teams are often unaware of the actual health status and functional limitations of these patients (1–3). Primary care physicians (PCPs) increasingly lack the time and tools for proactive care, systematic assessment, long-term monitoring and management of chronic diseases, and disabilities associated with frail health (4). Proactive visiting of older frail patients by nurses may therefore improve service levels and prevent adverse health trajectories.

Preventive home visitation to older persons is part of national policies in several countries, including the United Kingdom, Denmark, and Australia. The rationale behind home visitation is that it can trace and counter unmet needs and thereby prevent and postpone adverse healthy trajectories. This rationale may be threefold: (a) to delay or prevent functional impairment and subsequent nursing home admissions by primary prevention (eg, immunization and exercise), (b) secondary prevention of untreated symptoms, and (c) delay or prevent further deterioration of chronic diseases. Primary care practice rarely integrates home visitation by nurses. This can be placed against case management approaches that aim to collaborate more explicitly across disciplines.

Although visitation policies were implemented in several countries, the value of preventive home visitation is still controversial as reported in previous reviews and meta-analyses (5,6). Van Haastregt and coworkers (7) concluded that there was no clear evidence of beneficial effects of...
preventive home visits among community-dwelling older persons on physical functioning, institutionalization, and mortality. In contrast, Elkan and coworkers (5) reported significant reductions in mortality and institutional care and stronger effects when targeted to frail older persons. This conclusion was consistent with subgroup findings of a previous Dutch study (8,9). In addition, Stuck and coworkers (6) reported positive effects on mortality, nursing home admissions, and functional status based on conditions such as a reasonable number of home visits were offered and care plans were based on multidimensional assessments. A recent meta-analyses of Beswick and coworkers (10) could not confirm the importance of visit frequency. In the face of these conflicting results, we hypothesized that preventive home visits by nurses may prevent functional decline, institutionalization, and mortality if they target vulnerable older persons, include multidimensional assessments, and individualized care plans.

METHODS

Design and Setting

We performed an individually randomized controlled trial over a period of 18 months in a frail, elderly (75+) community-dwelling population sample obtained from 33 primary care practices and 55 PCPs. PCPs were blinded to whether their listed patients received preventive home visiting by a nurse or usual care. We randomized eligible persons living at the same address as one unit. To ensure equal numbers of intervention and usual care patients per practice, we used block randomization with blocks of four cases implicating six possible variations of assignment to Intervention (I) and Controls (C) per block (e.g., IIcc, ccII, ICIC, CICI, ICCI, CIIC). These block variations numbered one to six. Next, we used Pocock’s random number table and assigned up to 10 blocks per practice. An independent statistician kept the assignment lists and assigned individuals to the intervention or control groups. PCPs were blinded for the group assignment in order to minimize contamination. Data entry personnel were blinded for group assignment as well. The region had 1 local hospital, 2 nursing homes (200 beds), and approximately 20 homes for the elderly (±1,000 beds). The ethical committee of the VU Medical Center approved the study. All participants provided signed informed consent.

Study Population

All inclusion and exclusion criteria are summarized in Table 1. The PCPs provided the names and addresses of all their patients who were aged 75 years or older and lived at home. All persons received a postal health survey including the COOP-WONCA charts in order to identify persons with the frailest health (11,12). COOP-WONCA charts are translated and validated in many languages and are used in primary care settings worldwide to quickly identify functional health status. It comprises of six charts on functional health domains. These charts cover (a) overall health, (b) changes in health, (c) physical fitness, (d) daily activities, (e) mental health, and (f) social activities.

For our study, persons scoring in the lowest quartile on at least two of the six charts were considered vulnerable. The quartile cutoffs were based on representative Dutch community–based data supplemented (12,13). Dutch COOP–WONCA scores are comparable with other countries (14,15).

Intervention Protocol

Eight trained community nurses executed the preventive home-visiting program. The visiting program comprised seven key characteristics. First, an assessment of health risks and care needs was performed using the Resident Assessment Instrument–Home Care version (RAI-HC), a structured multidimensional geriatric instrument developed in the United States (16,17). The assessments were directly entered on laptops, which enabled direct and validated identification of 30 modifiable health risks (Table 3). Assessment times ranged between 45 and 75 minutes. The second characteristic is based on the nurses recommending interventions based on the Resident Assessment Instrument manual and a nationally issued nursing guideline. The interventions were created from best practices or evidence-based research and comprised typical geriatric issues, such as home safety, fall prevention, medication adherence, and health promotion. A third feature is exemplified in the design and execution of individually tailored care plans in that they take into consideration the preferences of the individual. The fourth key characteristics was that the nurses left a copy of the care plan at a person’s home to inform other visiting health professionals and to encourage them to add notes to the care plan. A fifth characteristic of the visiting program was that the nurses visited a patient at least four times a year in order to execute and monitor the care plan, evaluate changes in care needs, and adapt the care plan when needed. Another key characteristic was in case of

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<tr>
<th>Table 1. Inclusion and Exclusion Criteria</th>
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<th>Inclusion</th>
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<tr>
<td>Age 75 y and older and listed as primary care practice patient</td>
<td>Terminally ill as determined by PCPs</td>
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| Living at home | Persons with dementia symptoms (self-report of memory deterioration and MMSE < 24 or 7-min screen >50%)
| Frail: self-reported score in the worst quartile of at least two of six COOP-WONCA charts (scoring range: 1, excellent to 5, very bad): overall health ≥4; physical fitness ≥5; changes in health ≥4; daily activities ≥4; mental health ≥3; social activities ≥3 | Living in residential homes |
|          | Participating in other research projects |

Note: MMSE = Mini-Mental State Examination.
urgent medical matters, the nurses were allowed to consult the PCPs. Lastly, after a year, the nurses reassessed the older person and repeated the protocol.

Training.—The eight community nurses had a long-standing experience in working with frail community-dwelling elderly. Before the study started, we trained the nurses during a 2-day session. The goals of the training session were fivefold. The first training objective taught nurses to apply and interpret the (computerized) geriatric assessment and design and execute care plans based on the RAI-HC outcomes on health risks. Second, the training also taught nurses to use an up to date overview of local social and health care services including their contact persons and telephone numbers to easily recommend and refer the older persons to appropriate services. A third objective was to train nurses to use a computer for the assessments. A fourth objective included teaching nurses to utilize monthly meetings, supervised by two senior staff members to discuss problematic cases that occurred during the study. The aim was to assure and standardize the quality of care. Lastly, the nurses also received regular educational updates.

Usual Care

Usual care varied from no care at all to regular PCP visits to home care involvement. Table 2 provides an overview of the usual care at baseline in the two groups. During follow-up measurements, we asked about their service use over the past 2 months. At 6 and 18 months, they reported to have contacted their PCP on average approximately 1.7 (SD = 2.3) and 3.1 (SD = 1.8) times, respectively. These numbers were comparable with the intervention group. At 6 and 18 months, 35% and 27%, respectively, of the control persons received home care nursing.

Outcomes and Measurements

Primary outcomes

1. Functional status was measured with the COOP–WONCA charts (12) and Short Form 36 item (SF-36) and administered by postal mail (18,19).
2. Disability in activities of daily living (ADL) and instrumental activities of daily living was measured with the Groningen Activity Restriction Scale (GARS) and administered by postal mail (20).

Secondary outcomes

1. Hospital admittance data were extracted from the local hospital registry, supplemented with self-report data. We defined emergency visits as visits to the emergency rooms of the hospital or overnight stay at an intensive care unit.
2. Time until placement in nursing homes or homes for disabled older persons was surveyed and cross-checked in these homes’ registries or in PCPs’ medical records.
3. Time until death was checked with the PCPs and the hospital database.

Sample Size Calculation

Effect estimates were based on previous meta-analyses and trials (5,21,22). To demonstrate a modest effect (Cohen’s effect size of .33) on our primary outcome functional health (SF-36 and COOP–WONCA charts), we needed 202 participants per arm based on a two-sided alpha of .05, a 90% probability (23), and an anticipated attrition rate of 30%. Regarding our secondary outcome, we powered the study to be able detect a reduction of 10% in hospital admit-tance, institutionalization or mortality with a two-sided alpha of .05 and 90% probability. No attrition was anticipated on these measures as we had access to databases with complete and accurate registrations. Therefore, the study required 261 persons per group.

Data Analysis

Both “intention-to-treat” (ITT) and per protocol (PP) analyses were performed. Group differences for the continuous outcomes (SF-36 and COOP–WONCA) were analyzed with linear mixed models, a repeated measurement technique (unstructured covariance type) (24). This analysis yields restricted maximum likelihood estimates for the effects of time (T), treatment group (G) and the Time × Treatment Group interaction (T × G). Statistically significant Time × Treatment Group interaction indicates that the two groups have different patterns of change in outcome measurements over time. A significant time effect only (T) indicates changes in time, which are, however, similar for the two groups. Differences in dichotomous outcomes between intervention and usual care patients on hospitalization and emergency visits were tested by logistic regression analyses and expressed in odds ratios (ORs) with 95% confidence intervals (CIs). For time until institutionalization and time until mortality, Cox regression models were used and expressed in hazard ratios with 95% CIs. For the PP analyses, we compared the usual care group with intervention participants who received four or more home visits. To check the robustness of the previous analyses, we also performed sensitivity analyses on the self-report measures with two imputation techniques: multiple linear interpolation and conventional last observation carried forward.

Although initial analyses revealed baseline imbalance on three variables (previous falls, presence of family caregiver), none of these differed substantially (<10%) and did not affect the effect estimates. We therefore presented unadjusted effect estimates on all outcomes. In addition, we explored potential effect modification by predefined analyses: gender, age.
EMGO Institute for Health and Care Research employs a quality assurance policy. All research projects are subject to audits. We assured quality of the data by independent double checks of all forms.

**Results**

**Recruitment**

The recruitment phase yielded 33 primary care practices (55 PCPs) with average list sizes of 146 (SD = 53) persons aged 75 years or older. Figure 1 provides an overview of the recruitment, randomization, and follow-up. Approximately 4,823 patients received the health questionnaire by post. Nonresponders were more often woman (41.3% vs 35.8%, χ² = 13.4, p < .001) or older persons (83.5 vs 81.7, t = 13.8, p < .001). Among the 2,949 (61%) responders, 658 vulnerable patients were identified and randomized. The uptake of the intervention was high: only 41 participants in the intervention arm and 44 participants in the control arm withdrew because they considered it too much of a burden or had a lack of interest. Follow-up data on mortality, institutionalization, and hospital admission were complete. Self-report outcomes (eg, COOP–WONCA, SF36, GARS) were complete for 72% of all surviving persons.

Compared with the nonvulnerable persons, the persons considered vulnerable by this definition had more frequently two or more chronic diseases, cognitive symptoms (IQcODE-sr ≥ 3.6), and self-rated health (Euroqol-5 Dimensions [EQ5D] < 55 vs >55) (29).

**Baseline Characteristics**

Table 2 presents the baseline characteristics of the participants of the intervention and control groups. The SF-36 physical summary score was 32 (SD = 10) on a scale from 0 to 100. This indicates that we selected a frail portion, as mean values among community-dwelling elderly ranged to 100. This indicates that we selected a truly vulnerable group.

**Performed Interventions**

In the intervention group, nurses administered the RAi-HC to 298 of 331 (90%) persons, which demonstrates a good uptake of our intervention. Table 3 lists the health problems identified by the RAi-HC in the intervention group. A mean of 7.7 (SD = 3.4) problems were recorded.
“Preventive health” problems were triggered most frequently. These concerned mainly issues that are not routinely offered in the Netherlands (for instance, fecal and endoscope screening and mammography of women older than 75 years). Other relevant problems were for instance, pain (n = 194) and medication management issues (n = 181). Of the persons who received the RAI-HC, 231 received one or more additional home visits. The nurses registered 652 home visits with a mean of 3 (SD = 2.1) home visits per person during the 18 months of the study (including a second RAI-HC assessment). They registered in total 95 telephone contacts, with on average 0.3 contacts per person (SD = 0.7). For 222 (69%) intervention patients, the protocol requirement of four or more visits was met. Typical interventions were referral for balance training to increase gait stability and prevent falls; referral to social services to increase social activity and prevent loneliness, advice; and referral for auditory and visual aids, advice on life style issues to increase physical exercise and healthy nutrition, advice on safety issues, such as medication intake and aids to prevent falls. We compared changes in health risks between baseline and follow-up on 208 persons who completed a second RAI-HC. Of the 30 assessed health risks, 15 decreased significantly, 2 were equally present, and 13 risks had increased.

**Functional Health and Disability Outcomes**

Tables 4 and 5 present the changes from baseline effects at 6 and 18 months across the participants in the intervention and control groups. No statistically significant differences were found between the control and intervention patients on any of
the outcomes. All Time × Group interactions were nonsignificant in the linear mixed models. Some modest time trends were found for the group as a whole that included improvement on the SF-36, COOP–WONCA charts, and the GARS.

Mortality, Institutionalization, and Hospital Admission Over 18 Months

Twenty-three (6.9%) control persons compared with 20 (6.4%) intervention individuals died, whereas 39 (11.8%) controls versus 43 (13.4%) intervention persons were institutionalized. We found no statistically significant differences between control and intervention groups on time until death and institutionalization (Tables 4 and 5). In the intervention group, 163 (49.2%) persons were admitted at least once compared with 141 (55.9%) control persons (OR = 1.2, 95% CI: 1.04–2.4, p = .03). No differences across the nurses were found.

Subgroup Effects

Both the ITT and the PP analyses had effect modifications. It showed that among persons with the poorest self-rated health (EQ5D < 55), intervention persons had a significantly higher risk to be admitted to a hospital compared with the control persons (OR = 1.95, 95% CI: 1.2–3.1, p = .005) and 4.3 (1.2–15.5; p = .028), respectively. In addition, a higher risk on acute hospital visits was found among persons assigned to the intervention group who had two or more chronic diseases (OR = 1.6, 95% CI: 1.04–2.4, p = .03). No differences across the nurses were found.

Vulnerability

After 18 months, 61 (28.4%) intervention persons and 50 (23.9%) control persons no longer fulfilled our vulnerability criterion (OR = 0.79, 95% CI: 0.51–1.23).

Finally, the PP and sensitivity analyses were consistent with the results reported previously (data not shown).

Discussion

Main Results

Contrary to our hypothesis, we could not demonstrate any preventive effects of preventive home visiting by nurses in older vulnerable persons in primary care. Subgroup analyses revealed an increased risk of hospital admittance in intervention persons who reported worse health. Intervention persons also seemed to have a higher risk of emergency
hospital visits when they suffered from multiple chronic conditions.

Strengths and Limitations

Our study holds several strengths. First, it concerns one of largest preventive trials in this field, which strongly contributed to the statistical power of the results. Second, we obtained complete outcome data on mortality, institutionalization, and hospital visits over a long follow-up period. Third, the PCPs were blinded for group assignment, which protected the contrast between the groups. Lastly, a structured intervention was performed in which a validated multidimensional geriatric assessment protocol was used focusing on the patient as well as on the system around the patient. This was expected to increase the odds on positive intervention effects (6).

A limitation to the external validity of our findings may be the nonresponse to the postal health screening. The non-responders were likely to be frailer and perhaps in greater need of nurse support. Limitations to the internal validity of the study were first the limited linkage with primary care physicians, which may be a possible reason why the intervention was negative. Second, we failed to offer assessments and home visits to a part (16%) of the intervention group. Third, the frequency of the home visits was modest and might not be sufficient enough to instigate preventive effects. Due to a regional reimbursement policy, only four preventive visits a year were allowed in our study. Yet, a recent meta-analysis could not confirm any effect of visit frequency (10).

Fourth, we remain uncertain about quality of the delivered intervention as we did not audit this systematically. A more elaborate process evaluation alongside the trial would have improved the understanding of our results. Another limitation is it is possible that some PCPs were unblinded to some participant’s group assignment in case a nurse thought it necessary to demand medical action from the PCP. Nevertheless, it is not very likely that this would have profoundly influenced the group contrast. Finally, loss of follow-up of the self-report measures was selective for unhealthier and older persons, which may have diluted any preventive effects on self-reported health outcomes.

Explaining Mechanisms

Are home visits by nurses ineffective? The absence of a preventive effect of the home visits might be attributed to several issues. First, the intervention was not integrated in the primary care practices. A better linkage might have enforced the implementation of the nurses’ care plans. Although some studies with “stand alone” nurse interventions have shown beneficial effects (6), a recent review on disease management of complex health care needs suggest the importance of a more integrated or collaborative model (26). Second, the selection of the participants might have been inappropriate. Although we selected a vulnerable population, many functioned relatively well and improved over time. On the other hand, a recent meta-analysis suggested that preventive interventions show more effects in nonfrail elderly (27). In addition, the nurses offered a range of interventions, and the outcome measures might not have been sensitive enough to pick up specific effects. On the other hand, a recent meta-analysis advocated that preventive interventions show more effects in nonfrail elderly (10).

Third, the follow-up period of 18 months might have been too short to demonstrate long-term preventive effects. For example, in a study by Hendriksen and coworkers (28) with a follow-up of 3 years, the decrease in hospital admission became obvious only in the second half of their study. Fourth, we underestimated the willingness of many older persons to engage in preventive activities and invested little in motivational skills of the nurses needed to pursue their clients.

A final explanation might be that preventive home visits by auxiliary nurses simply do not add effect in Dutch primary care with its easy access for all persons. In the Netherlands, everyone

<table>
<thead>
<tr>
<th>Table 4. Primary Outcomes Over 18 mo, Computed by Mixed Models</th>
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<tr>
<td>Functional Health and Disability (N = 320)</td>
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<tr>
<td>SF-36 physical component (range 0–100)</td>
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<tr>
<td>Baseline, M (SD)</td>
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<td>6 mo, M (SD)</td>
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<tr>
<td>18 mo, M (SD)</td>
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<tr>
<td>SF-36 mental component (range 0–100)</td>
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<td>Baseline, M (SD)</td>
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<tr>
<td>6 mo, M (SD)</td>
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<tr>
<td>18 mo, M (SD)</td>
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<tr>
<td>ADL and IADL (GARS range 18–72)</td>
</tr>
<tr>
<td>Baseline, M (SD)</td>
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<td>18 mo, M (SD)</td>
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Note: GARS = Groningen Activity Restriction Scale; SF-36 = Short Form 36 Health Survey.

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<th>Table 5. Secondary Outcomes Over 18 months, Usual Care Group Is the Reference Group</th>
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<tr>
<td>Hospitalization, Mortality, Institutionalization</td>
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<tr>
<td>Hospital admittance ≥1, n (%)</td>
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<tr>
<td>Acute hospital visit ≥1, n (%)</td>
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<tr>
<td>Time until Institutionalization, n (%)</td>
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<td>Time until mortality, n (%)</td>
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† OR = odds ratio.  ‡ HR = hazard ratio.
is medically insured and accessibility to medical care including home care services is high. In addition, the PCP or a nurse sees most persons with chronic conditions regularly. Everyone has a medical file kept by one PCP and medical histories of elderly persons are generally well known.

**Increased Hospital Admissions in Intervention Subgroups**

The higher odds of hospital admittance and acute hospital visits found in certain subgroups of the intervention group may be explained by a nurse-induced increased awareness of the participants concerning the treatability of their health status after the nurse assessment. The hospitalization rate was comparable with other studies among frail elderly (5,6).

**Costs Indicators**

Hospital admissions are an important cost driver in economic evaluations of outpatient studies, and these turned out to be slightly higher for the intervention group. If we add the costs for the nurses and implementation to the intervention group as well, the cost effectiveness is very likely to turn out negative.

**Future Research**

To be able to target interventions to selected persons it might be helpful to evaluate the prognostic value of easily measurable vulnerability indicators in primary care. In addition, the search for effective interventions for vulnerable persons needs to be continued. For example, ingredients of the chronic disease management model may be adopted more rigorously, such as coordination and monitoring by nurses, fine-tuning between nurses and PCPs, consultation of old age specialists, motivating and empowering clients for self-management, and preventive activities, combined with better control on the implementation of these processes. Finally, better exploration of subjective care needs may guide interventions.

**Conclusions**

We could not demonstrate any beneficial effects of low-intensity home visiting by nurses compared with usual care in vulnerable frail older persons in primary care. The search for effective interventions for vulnerable persons requires further investigation. Future efforts may focus on improved integrated approaches.

**Funding**

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**Acknowledgments**

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Authors’ contributions: H.P.J.H. and G.N. designed the study. H.P.J.H. drafted the article and all authors contributed to the final concept.

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