Multidimensional Geriatric Assessment: Back to the Future

A Randomized Study of a Multidisciplinary Program to Intervene on Geriatric Syndromes in Vulnerable Older People Who Live at Home (Dutch EASYcare Study)

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Background. The effectiveness of community-based geriatric intervention models for vulnerable older adults is controversial. We evaluated a problem-based multidisciplinary intervention targeting vulnerable older adults at home that promised efficacy through better timing and increased commitment of patients and primary care physicians. This study compared the effects of this new model to usual care.

Methods. Primary care physicians referred older people for problems with cognition, nutrition, behavior, mood, or mobility. One hundred fifty-one participants (mean age 82.2 years, 74.8% women) were included in a pseudocluster randomized trial with 6-month follow-up for the primary outcomes. Eighty-five participants received the new intervention, and 66 usual care. In the intervention arm, geriatric nurses visited patients at home for geriatric assessment and management in cooperation with primary care physicians and geriatricians. Modified intention-to-treat analyses focused on differences between treatment arms in functional abilities (Groningen Activity Restriction Scale-3) and mental well-being (subscale mental health Medical Outcomes Study [MOS]-20), using a mixed linear model.

Results. After 3 months, treatment arms showed significant differences in favor of the new intervention. Functional abilities improved 2.2 points (95% confidence interval [CI], 0.3–4.2) and well-being 5.8 points (95% CI, 0.1–11.4). After 6 months, the favorable effect increased for well-being (9.1; 95% CI, 2.4–15.9), but the effect on functional abilities was no longer significant (1.6; 95% CI, −0.7 to 3.9).

Conclusions. This problem-based geriatric intervention improved functional abilities and mental well-being of vulnerable older people. Problem-based interventions can increase the effectiveness of primary care for this population.

Key Words: Primary health care—Frailty—Health services research—Multidimensional geriatric assessment—Health services for the aged.

THE autonomy of vulnerable older people is continuously challenged. Chronic diseases, associated functional decline, and erosion of social support systems reduce well-being and often lead to institutionalization and high health care costs. Primary health care professionals will care for a substantial part of this expanding group. However, there are significant time limitations in primary care, and there is much room for improvement in quality of geriatric care (1). These observations show that developing and evaluating models that enhance primary care for vulnerable older people is an important priority of geriatric primary care research, policy, and practice (2).

Unfortunately, we know little about the effects of geriatric primary care in vulnerable older adults. Critical appraisal of the available evidence is difficult, because the models that can be gathered under the term "community intervention models" show much heterogeneity as well as considerable overlap (3). We know that preventive home visits can work if they provide multidimensional, high-intensity follow-up with clinical control, but there is much debate about effectiveness in vulnerable older people (4,5). Whereas some authors exclude the frailest participants, because of reduced likelihood of reversibility, other authors stress the importance of including the frailest (4–8). Evidence also suggests that comprehensive geriatric assessment models can work, but this evidence is strongest for inpatient models (9,10). Evidence for equivalent community-based interventions is more controversial: In a meta-analysis, noninstitutional programs had no effect on hospital readmission, physical function, or cognitive function (9). Moreover, most of the included noninstitutional programs are concerned with a general population of older people. The

Table 1. Eligibility Criteria of Dutch EASYcare Study

Eligibility Criteria

Inclusion criteria

   70 years old or older

   Patient lives independently or in a retirement home

   Patient has a health problem that was recently presented to the physician
      by the patient or informal caregiver

   Request for help is related to the following problem fields: cognitive
      disorders, behavioral and psychological symptoms of dementia, mood
      disorders, mobility disorders and falling, or malnutrition

   Patient/informal caregiver and physician have determined a goal to
      achieve

   Fulfill one or more of these criteria: MMSE (Mini-Mental State
      Examination) ≤ 26*, GARS-3 (Groningen Activity Restriction
      Scale-3) ≥ 25[†], or Medical Outcomes Study (MOS)-20/subscale
      mental health ≤ 75[‡]

Exclusion criteria

   Problem or request for help has an acute nature, urging for action
      (medical or otherwise) within <1 week

   Problem or request for help is merely a medical diagnostic issue, urging
      for actions only physicians (primary care physician or specialist)
      can offer

   MMSE < 20 or proven moderate to severe dementia (Clinical Dementia
      Rating scale [CDR] > 1) and no informal caregiver (no informal
      caregiver is defined as: no informal caregiver who meets the patient
      for at least once a week on average)

   Patient receives other forms of intermediate care or health care from
      a social worker or community-based geriatrician

   Patient is already on the waiting list for a nursing home because of the
      problem the patient is presented with in our study

   Life expectancy < 6 months because of terminal illness

Notes: *MMSE are scored from 0 to 30, with 30 indicating best score.
[†]GARS-3 are scored 18 to 54, with 18 indicating best score.
[‡]MOS-20 all subscales are scored from 0 to 100, with 100 indicating best score.

applicability of these results to vulnerable older people is unclear.

A large recent controlled trial of inpatient and outpatient geriatric evaluation and management found significant improvement in mental health of frail persons with outpatient geriatric evaluation and management following a hospitalization, but not in functional abilities (11).

Case management approaches—a type of care showing overlap with preventive home visiting programs and comprehensive geriatric assessment—have also been tested in older people (12). The outcomes are often measures of health care utilization instead of health outcomes or quality of life (12). These case management interventions probably have favorable impacts on hospital and long term care utilization (12,13), although the recent evaluation of Evercare in the United Kingdom showed no effect on the hospitalization rate (14). The study by Bernabei and colleagues (15) also found beneficial effects on health-related quality of life.

In general, the evidence suggests that targeting suitable patients is a key factor in achieving effectiveness (4,10). Population screening is a popular approach to targeting (16), but it is expensive and not easy to implement in daily practice, and there are studies questioning the effectiveness of these unsolicited approaches (17,18). Another important criterion for success is direct involvement of the primary care provider (4).

Therefore, we studied the effectiveness of community intervention models using a problem-based participant selection process performed by the primary care physician. The Dutch Geriatric Intervention Program (DGIP) is a multidisciplinary community intervention model, consisting of nurse home visits for frail older patients. Primary care physicians were asked to initiate the intervention when a geriatric condition arose that required further intervention. This procedure promised efficacy through better timing and targeting of the intervention, more engagement of the patient, and more commitment of the primary care physician. After problem-based selection, each patient received a wide multidimensional assessment, and an individualized, integrated treatment plan was developed. The effect of community intervention models for frail older people with this type of targeting has not been rigorously assessed.

In this article we describe the effects of the DGIP compared to usual care in improving health-related quality of life and promoting successful aging in independently living frail older patients.

METHODS

Design

The study design has been published previously (19). The study was an observer blind, randomized controlled trial that applied pseudocluster randomization to allocate the participants to DGIP or usual care [Clinicaltrials.gov Identifier NCT00105378]. The local ethics committee gave approval for the study.

Study Population

Participants lived in their own home or in a retirement home and were 70 years old or older (Table 1). They had one or more limitations in cognition, (instrumental) activities of daily living, or mental well-being.

Randomization and Sample Size Calculation

Participants were randomized to DGIP or usual care. The usual care group received unrestricted care. We used a two-step pseudocluster randomization procedure, because both individual and cluster randomization had major drawbacks (20,21). Individual randomization was discarded because it had a risk of contamination bias: The recruiting physician might learn from or use elements of DGIP. However, cluster randomization would lead to selection bias and lower recruitment rates in the control clusters, because physicians would know the treatment arm to which their participants would be assigned after recruiting the first participant (22).

Pseudocluster randomization randomized physicians in two groups: group H (high) and group L (low) (20,21). The participants recruited through physicians of group H were then randomized in an 80/20 ratio to DGIP and usual care, respectively; in group L this ratio was reversed: 20% DGIP and 80% usual care. The physicians were not informed as to which group they were in. In the second step of the pseudocluster randomization procedure, minimization was used to equally distribute participants for the factors ''high or low percentage of older patients in primary care clinic,'' ''availability of practice nurse in primary care clinic,'' ''sex

of participant,'' and ''geriatric condition for referral.'' With minimization, the treatment allocated to the next participant enrolled in the trial depends on the characteristics of those participants already enrolled. This approach has the advantage, especially in small trials, that there will be only minor differences between groups in those variables used in the allocation process (23). Sample size calculation took account of the pseudocluster randomized design. We used an uncontaminated minimal detectable difference (MDD) of 4.5 points in the primary outcome measure (Groningen Activity Restriction Scale-3 [GARS-3]), with an expected standard deviation (*SD*) of 8.5 (pilot data). We expected that pseudocluster randomization would lessen the contamination, although not to the uncontaminated estimate. This means that the MDD has to be set sharper than the uncontaminated level; we used an MDD of 4.0 points. Using the usual formula for individually randomized trials with $\alpha = 0.05$, $1 - \beta = 0.80$, and a design factor for pseudocluster randomized trials of 1.08 (cluster size $n = 10$, intra-cluster correlation $\rho = 0.05$, randomization fraction $f = 0.8$) [see Table 1, Teerenstra and colleagues (21)] this MDD of 4.0 could be found comparing two groups of 77 patients.

Intervention

The DGIP used a problem-based selection procedure performed by the primary care physician, rather than population screening to identify patients eligible for participation. The problems targeted concerned cognition, nutrition, behavior, mood, or mobility, and had to require nursing assessment, coordination of care, therapeutic monitoring, or case management (Table 1). Within 2 weeks after referral, a geriatric specialist nurse visited the patient at home. Up to six visits for additional geriatric evaluation and management were planned within the next 3 months. Starting off from a wide multidimensional assessment, the intervention team developed an individualized, integrated treatment plan for each patient. The nurse conducted the main part of the intervention. The primary care physicians continued their usual medical care. Moreover, they made referrals, medication changes, and other interventions as agreed upon during interdisciplinary consultations with the nurse and geriatrician on individual cases. The primary care physician continued to be primarily responsible for the care of the patient and made the final decisions. We developed guidelines for each of the five presenting health problems to structure activities, without losing the flexibility of tailoring the individual interventions.

Data Collection and Outcome Measures

Researchers (R.J.F.M., M.I.J.V.) not involved in the conduct of the intervention program, visited patients at home to obtain written informed consent and to collect baseline (T_0) demographic characteristics and data on general health conditions. If the participant was not able to give informed consent, we asked consent by proxy. Unaware of treatment assignment, the researcher repeated these measurements in the patients' homes 3 and 6 months after inclusion. After each follow-up visit, the researcher indicated whether blinding remained intact or not.

Primary outcome measures were functional performance in (instrumental) activities of daily living measured using the GARS-3 and mental well-being using subscale Mental Health of the Medical Outcome Study 20-item short form (MOS-20 MH) (24). GARS-3 measures 11 basic activities of daily living and 7 instrumental activities of daily living on a 3-point scale (patient can do activities independently without any difficulty, independently but with difficulty, or only with someone's help). In advance, we expected that the larger part of our study population would live in their own home; in these participants, both types of activities of daily living are very important. Therefore, we used the complete scale as primary measure for functional performance. Secondary outcomes were cognition (Mini-Mental State Examination [MMSE]) (25), mobility (Timed Up and Go test [TUAG]) (26), loneliness (de Jong-Gierveld and Kamphuis Loneliness Scale) (27), health-related quality of life (other MOS-20 subscales), Cantril's self-anchoring ladder for actual quality of life, Dementia Quality of Life (DQoL) (24,28,29), and survival.

Statistical Analysis

The primary analysis was a modified intention-to-treat analysis on differences (Intervention – Control) in changes from baseline in the GARS-3 and MOS-20 MH at 3-month of follow-up ($T_1 - T_0$). A random effects model was used to account for clustering at the level of the physician (19). The other outcomes at 3-month follow-up were analyzed in a similar way. Similar analyses at 6-month follow-up were performed only if the outcome measure showed a significant effect at 3 months (conditional testing). Kaplan–Meier estimates were used to quantify the intervention effect on survival. We calculated 95% confidence intervals (CI) for the differences between treatment arms and used a two-sided α of 0.05 to test significance. The baseline characteristics were tested using a random effects logistic model for categorical values and a random effects linear model for continuous outcomes. For skewed variables, these models were used with the log-transformed scores. Preplanned subgroup analyses of the effects in the primary outcomes—adding the stratifying factor as a covariate and an interaction term of the stratifying factor with treatment arm to the models—were performed for living independently versus living in a retirement home, and higher versus lower levels of cognitive function measured with the MMSE (≥ 21 vs <21) at 3- and 6-month follow-up.

RESULTS

In and around Nijmegen, the Netherlands, 55 primary care physicians agreed to participate, and 40 (73%) recruited at least one patient (range 1–15). Both primary care physicians with the majority of patients randomized to the intervention group and physicians with the majority of patients randomized to the control group recruited a median number of three patients (30). The intra-cluster correlation, which provides an estimate of the clustering at the level of the physician, was 0.05 for GARS-3 and 0 for MOS-20 MH at 3-month follow-up, this correlation is in the expected range for a primary care population of older people (31). During a 21-month inclusion period that started April 1, 2003, 155
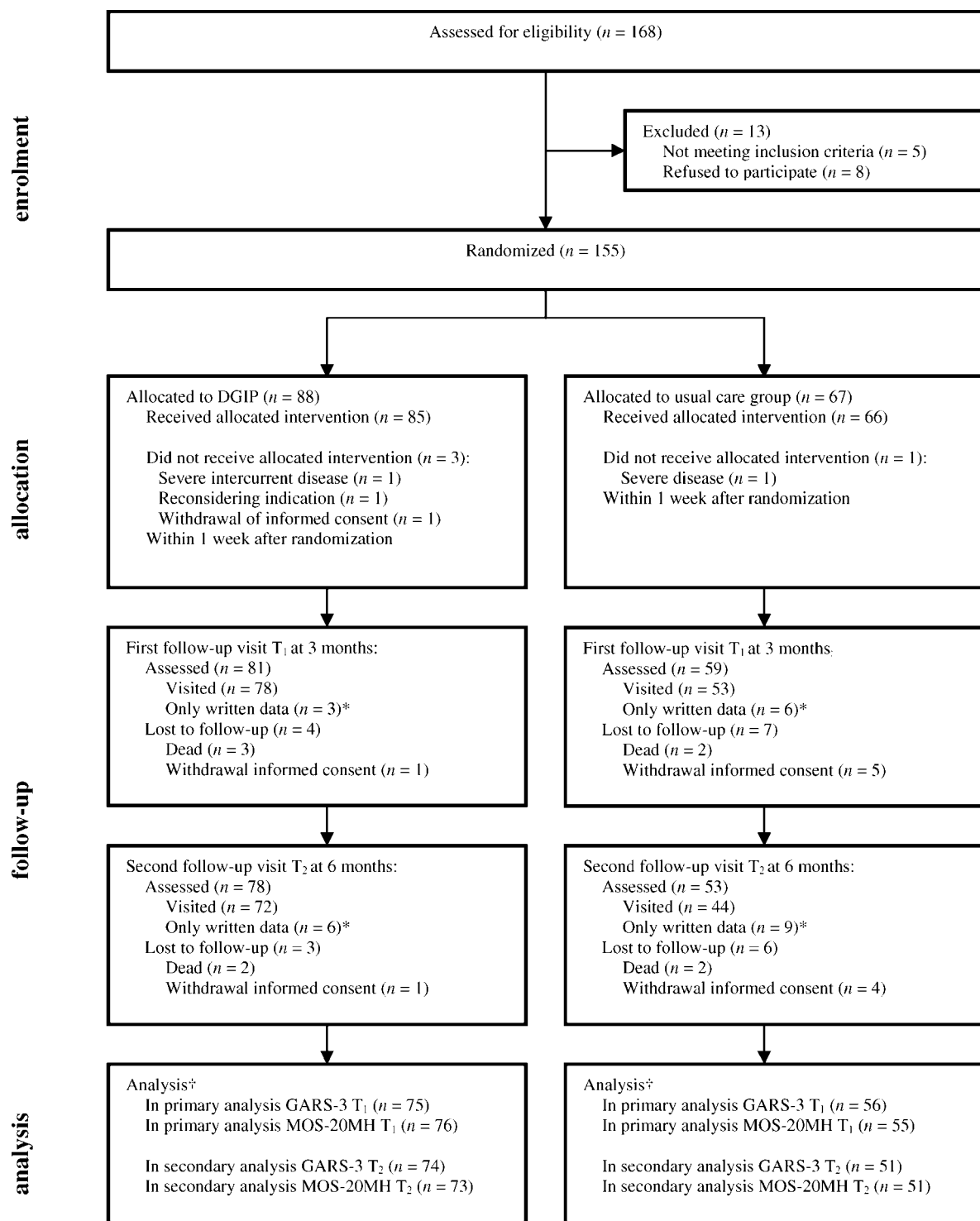
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│                    Assessed for eligibility (n = 168)                  │
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                                    │          │   Not meeting inclusion criteria    │
                                    │          │   (n = 5)                           │
                                    │          │   Refused to participate (n = 8)    │
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│                       Randomized (n = 155)                             │
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Figure 1. Study flow chart. *A number of participants withdrew their consent for the visit for data acquisition by interview, but agreed to fill in the questionnaires. †Differences between numbers assessed at follow-up and numbers included in the analysis result from the fact that, although assessment was executed, participants not always completely filled out the instruments and therefore no sum scores could be calculated for everyone who was assessed.

enrolment

allocation

Allocated to DGIP (n = 88)
 Received allocated intervention (n = 85)

 Did not receive allocated intervention (n = 3):
  Severe intercurrent disease (n = 1)
  Reconsidering indication (n = 1)
  Withdrawal of informed consent (n = 1)
 Within 1 week after randomization

Allocated to usual care group (n = 67)
 Received allocated intervention (n = 66)

 Did not receive allocated intervention (n = 1):
  Severe disease (n = 1)
 Within 1 week after randomization

follow-up

First follow-up visit T_1 at 3 months:
 Assessed (n = 81)
  Visited (n = 78)
  Only written data (n = 3)*
 Lost to follow-up (n = 4)
  Dead (n = 3)
  Withdrawal informed consent (n = 1)

First follow-up visit T_1 at 3 months:
 Assessed (n = 59)
  Visited (n = 53)
  Only written data (n = 6)*
 Lost to follow-up (n = 7)
  Dead (n = 2)
  Withdrawal informed consent (n = 5)

Second follow-up visit T_2 at 6 months:
 Assessed (n = 78)
  Visited (n = 72)
  Only written data (n = 6)*
 Lost to follow-up (n = 3)
  Dead (n = 2)
  Withdrawal informed consent (n = 1)

Second follow-up visit T_2 at 6 months:
 Assessed (n = 53)
  Visited (n = 44)
  Only written data (n = 9)*
 Lost to follow-up (n = 6)
  Dead (n = 2)
  Withdrawal informed consent (n = 4)

analysis

Analysis†
 In primary analysis GARS-3 T_1 (n = 75)
 In primary analysis MOS-20MH T_1 (n = 76)

 In secondary analysis GARS-3 T_2 (n = 74)
 In secondary analysis MOS-20MH T_2 (n = 73)

Analysis†
 In primary analysis GARS-3 T_1 (n = 56)
 In primary analysis MOS-20MH T_1 (n = 55)

 In secondary analysis GARS-3 T_2 (n = 51)
 In secondary analysis MOS-20MH T_2 (n = 51)

eligible participants were randomized; four participants did not receive the allocated intervention due to events that took place within 1 week after randomization (Figure 1). These four participants were excluded from further follow-up and analysis (19). Eighty-five participants were included in the

DGIP group, and 66 in the usual care group. Mistakenly, one 69-year-old participant was included. This participant was kept in follow-up and analysis. Baseline characteristics and measures of primary outcomes showed no significant differences between study groups. Of secondary outcomes,

Table 2. Demographic Characteristics and Outcome Measures of the Study Population at Enrollment

Baseline Characteristic	Usual Care (*N* = 66)	Dutch Geriatric Intervention Program (*N* = 85)	*p*
Age, y	82.8 ± 6.6	81.7 ± 5.9	.22
Female sex, *n* (%)	49 (74.2)	64 (75.3)	.99
Marital status, *n* (%)			.31
Married	19 (29.2)	23 (27.4)	
Divorced	2 (3.1)	5 (6.0)	
Widow(er), partner deceased	36 (55.4)	47 (56.0)	
Single	8 (12.3)	8 (9.5)	
Living together unmarried	0	1 (1.1)	
Living in retirement home, *n* (%)	11 (16.9)	12 (14.1)	.56
Informal caregiver, *n* (%)	49 (74.2)	65 (76.5)	.71
Receiving home care, *n* (%)	34 (51.5)	43 (51.1)	.97
Groningen Activity Restriction Scale-3*	34.1 ± 8.7	35.3 ± 8.1	.68
Medical Outcomes Scale (MOS)-20 mental health[†]	53.8 ± 17.7	53.3 ± 20.9	.87
MOS-20 physical functioning[†]	16.7 (0–33.3)[‡]	16.7 (0–36.7)[‡]	1.00
MOS-20 role functioning[†]	0 (0–50.0)[‡]	0 (0–50.0)[‡]	.87
Cumulative Illness Rating Scale-Geriatrics[§]	9.8 ± 4.3	10.2 ± 3.7	.64
Timed Up and Go, s	16.0 (12.0–22.0)[‡]	16.0 (12.0–25.0)[‡]	.60
MMSE[‖]	22.0 ± 6.0	22.8 ± 5.5	.22
Cantril's self anchoring ladder[¶]	5.9 ± 2.1	5.7 ± 2.1	.78
Dementia Quality of Life (DQoL) positive affect**	3.1 ± 0.7	3.2 ± 0.7	.50
DQoL negative affect[††]	2.6 ± 0.6	2.7 ± 0.7	.24
Loneliness Scale de Jong-Gierveld[‡‡]	5.7 ± 3.6	4.4 ± 3.2	.04

Notes: For all (except skewed) variables means ± standard deviations are presented.

*Scored from 18 to 54, with 18 indicating best score.

[†]All subscales scored from 0 to 100, with 100 indicating best score.

[‡]For skewed variables median and inter-quartile range are presented.

[§]Scored from 0 to 56, with 0 indicating no comorbidity.

[‖]Scored from 0 to 30, with 30 indicating best score.

[¶]Scored from 0 to 10, with 10 indicating best score.

**Scored from 0 to 5, with 5 indicating best score.

[††]Scored from 0 to 5, with 0 indicating best score.

[‡‡]Scored from 0 to 11, with 0 indicating best score.

only loneliness differed significantly at baseline (Table 2). Our study population mostly comprised widowed women born in the Netherlands, of whom 85% lived on their own. The participants had a mean age of 82.2 years (range 69–99 years), much comorbidity, MMSE scores suggesting cognitive deterioration, and low scores on mental well-being. Most people had difficulties with all of the (instrumental) activities of daily life measured. Approximately half the study group had home care available at baseline.

The participating primary care physicians cared for a mean of 1719 patients (*SD* 470) of whom 170 (*SD* 131) were 75 years or older. Of this subgroup of older participants, 3% (*SD* 4) were included in this study. About 40% of the participants were referred because of a problem relating to cognition. Both mood and mobility problems were reasons for referral in 20% of the cases. Behavioral and nutritional problems were referral reasons in 11% and 6%, respectively. The nurse visited intervention patients 3.8 times (*SD* 1.3). Problem analysis was an important component of these visits. The interventions focused mainly on therapeutic advice and coordination of care, fewer interventions focused on psychoeducation or therapy monitoring (Table 3).

After 3 months of follow-up, the primary outcomes functional performance and mental well-being showed significant treatment arm differences in changes from baseline (Table 4). On GARS-3, this difference was −2.2 (95% CI

−4.2 to −0.3), and on MOS-20 MH it was 5.8 points (95% CI, 0.1–11.4) both in favor of DGIP (Table 4). At 6-month follow-up, favorable effects still existed, although the effect on GARS-3 was slightly smaller and no longer significant: −1.6 (95% CI, −3.9 to −0.7). The effect on MOS-20 MH increased to 9.1 (95% CI, 2.4–15.9). In the usual care group, the GARS-3 scores worsened from baseline, whereas during the first 3 months this decline was absent in DGIP (Table 4). DGIP improved MOS-20 MH scores over 6-month follow-up. The MOS-20 MH scores remained approximately constant in the usual care group.

Secondary outcome measures DQoL Positive and Negative Affect, subscales Physical Performance and Role Functioning of the MOS-20, and Cantril's Ladder showed a trend toward beneficial effects for DGIP. The effects on MMSE, De Jong-Gierveld Loneliness Scale, and TUAG were close to zero (Figure 2). DGIP survival at 2-year follow-up was higher (82% vs 73%; log-rank test *p* = .40). The results of a sensitivity analysis with loneliness score (the only baseline characteristic that differed between our treatment arms) added as covariate were in line with the primary analysis. During the follow-up measurements, treatment assignment was revealed to the researcher in 38% of cases at 3-month follow-up and in 40% of cases at 6-month follow-up.

The total dropout rate in our study was 7% at 3 months

Table 3. Content of the Dutch Geriatric Intervention Program (DGIP) in Intervention Group Patients (N = 85)

Type of Activity	No. (%)
Diagnostic tests	
EASYcare screening	85 (100)
Focused history taking and caregiver assessment	85 (100)
Mini-Mental State Examination	40 (47)
Geriatric Depression Scale	30 (35)
Montgomery–Åsberg Depression Rating Scale	14 (16)
Body weight	23 (27)
Mini Nutritional Assessment–Short Form	2 (2)
Body mass index	1 (1)
Investigation of calorie and fluid intake	3 (4)
Tinetti Balance and Mobility Scale	11 (13)
Blood pressure	4 (5)
Blood pressure, supine and standing position	21 (25)
Pulse	14 (16)
Visual acuity using Snellen chart	1 (1)
Mean number of diagnostic tests per case	
(standard deviation; range)	2.0 (1.8; 0–9)
Interventions–care coordination	
(Extra home) care	34 (40)
Consultation of other health care professional	31 (36)
Organize program for daily structure	21 (25)
Mobilize voluntary care	25 (29)
(Extra) day care	12 (14)
Interventions–advices	
Advices to professional handling behavioral	
difficulties	18 (21)
Advices to caregiver handling behavioral difficulties	28 (33)
Advice to patient	45 (53)
Referral to other health care professional	24 (28)
Medication change	22 (26)
Start using helping aid (cane, etc.)	16 (19)
Interventions–psychoeducation	
Patient	23 (27)
Caregiver	15 (18)
Intervention–monitoring the effect of therapy	26 (31)
Mean number of interventions per case	
(standard deviation; range)	4.6 (2.3; 0–10)

and 13% at 6 months, and was similar in both groups. Participants who were lost to follow-up were older and had worse GARS-3, MOS-20 MH, and MMSE scores at baseline. The results of sensitivity analyses assigning the ''mean of the other group'' (32) to the missing values did not differ essentially from the primary analyses. No significant statistical interactions with MMSE scores or living conditions were found.

DISCUSSION

This randomized controlled trial found benefits of a nurse led, multidisciplinary intervention at home on frail older subjects' functional performance and mental well-being at 3-month follow-up. At 6 months, the well-being scores had further improved, and the performance on functional abilities, although still better in the intervention group, had not further increased. Most secondary outcomes showed a trend toward advantageous effects. The results of the economic evaluation that accompanies this study showed

that this intervention is an effective addition to primary care for frail older people at a reasonable cost (33).

The age, comorbidity, and GARS-3 scores at baseline, and the overall mortality during follow-up, show that a group of very old, vulnerable patients was sampled. The beneficial effects on disability and mental well-being represent a 5% and 10% better performance compared to control conditions, respectively.

The results of our study show that it was possible to prevent deterioration of functional skills for about 3 months and to improve well-being for at least half a year in a vulnerable population with a fairly simple home-based intervention. The magnitude of these effects is in line with treatment effects of other positive studies incorporating frail populations (11,15). An evaluation of outpatient geriatric evaluation and management found favorable differences in mental health and physical functioning scores of about 5% and 2% at 12-month follow-up, respectively (11). A trial with a model of integrated care and case management for frail older people living in the community found favorable differences of 18.1% in basic activities of daily living, 6.9% in instrumental activities of daily living, and 6.8% in depression (15). Also, our results were above a (standardized) effect size of 0.2, which is considered to be the lowest threshold for a minimal clinically important difference (34).

The relevance of our current study to the literature is that our study showed that a community-based comprehensive geriatric assessment (CGA) model with a problem-based selection procedure by the primary care physician had beneficial outcomes in vulnerable older people, whereas previous community-based CGA models in more or less vulnerable older people were largely unsuccessful (5). We believe that it was crucial that this was a solicited rather than an unsolicited approach. Other studies pointed at this as well (17,18). The solicited approach probably increased motivation and cooperation of the primary care physicians and the patients, a factor which has been previously identified as important (4). The solicited approach also prevented the inclusion of vulnerable older people with problems without a clear treatment goal, and through this probably increased the net yield of the intervention.

Our control group was smaller than the intervention group, but it is unlikely that lack of allocation concealment has caused the difference; the majority of physicians were not aware of the allocated randomization proportions. Patients were comparable at baseline as well, giving no indication of selection bias. An explanation is offered by the variation in the number of patients each physician included. Two physicians included more than 10 patients, and both were assigned to the group of general practitioners the majority of whose patients were randomized to the intervention group. This observation completely explains the unbalanced numbers of control and intervention group.

The total dropout in our study was fairly high, but was similar in both groups and was as expected when taking into account the frailty of the population. Dropouts occurred mainly because patients (or their caregivers) felt participation in follow-up visits for effect measurement was too burdensome while it provided no further benefit. Participants who were lost to follow-up differed from participants who

Table 4. Unadjusted Scores on Primary Outcome Measures at 3 and 6 Months and the Differences Between
Treatment Arms in Outcome Measures' Change From Baseline

Primary Outcome Measures, Unadjusted Scores	3-Month Follow-Up (T_1)			6-Month Follow-Up (T_2)*		
	Usual Care	DGIP		Usual Care	DGIP	
Functional abilities–GARS-3	36.4 ± 10.3	34.7 ± 8.1		37.0 ± 9.5	35.9 ± 8.6	
Well-being–MOS-20 MH	55.5 ± 18.2	60.0 ± 20.5		53.2 ± 20.1	61.5 ± 20.4	
Intervention effect[†]	D	95% CI	N	D	95% CI	N
GARS-3[‡]	−2.2[§]	−4.2 to −0.3	131	−1.6	−3.90 to 0.7	125
MOS-20 MH[‡]	5.8[§]	0.1 to 11.4	131	9.1[‖]	2.4 to 15.6	124
DQoL Negative affect	−0.21[§]	−0.37 to −0.04	114	−0.13	−0.32 to 0.06	103
DQoL Positive affect	0.15	−0.06 to 0.37	112			
MOS-20 physical performance	4.3	−2.9 to 11.2	132			
MOS-20 role functioning	4.7	−9.8 to 19.3	131			
Cantril's Ladder	0.39	−0.26 to 1.03	105			
Loneliness Scale de Jong-Gierveld	0.10	−0.80 to 0.99	109			
MMSE				−0.5[¶]	−1.8 to 0.1	113
Timed Up And Go	1.60	−4.82 to 8.03	107			

Notes: *DQoL positive affect analysis at 6 mo was not executed because the 3-month result of DQoL pos aff was not significant.

[†]D and its 95% CI in changes over time from baseline to 3 and 6 months, for the number of subjects (*N*) in analysis.

Model: Outcome Measure Change from baseline $= \beta_0 + \beta_1 *$ treatment arm $+ \beta_2 *$ baseline value Outcome Measure $+ \beta_c *$ minimization factors $+$ random intercept physician

[‡]Primary outcomes.

[§]$p < .05$.

[‖]$p < .01$.

[¶]MMSE was only measured at baseline and at 6-month follow-up.

DGIP = Dutch Geriatric Intervention Program; D = intervention effect difference; CI = confidence interval; GARS-3 = Groningen Activity Restriction Scale-3; MOS-20 MH = Medical Outcomes Study-20, subscale mental health; DQoL = Dementia Quality of Life; MMSE = Mini-Mental State Examination.

completed follow-up. However, the results of sensitivity analyses—using a conservative strategy to impute missing values (32)—did not differ essentially from the primary analyses.

This study was observer blind. Despite several precautionary measures taken, disclosure of treatment assignment occurred frequently. However, our primary outcomes were collected using a written questionnaire that the patient (if necessary with help from a relative) completed before each study visit. The researcher could not influence this.

Given the type of patients included in this study, the study results can probably be generalized to a population of frail community-dwelling older people. Primary care physicians appeared to be very selective. Approximately 3% of all older patients cared for by one primary care physician were included in this study. However, we have to keep in mind that only a minority of older patients can be characterized as vulnerable, depending on the definition (35). This means that only a minority actually is eligible for this intervention, which explicitly focused on frail persons who also needed to have an incident geriatric problem. Unfortunately, we were unable to collect further details on the patients who were not included, so generalization of these results to the general population of community-dwelling older persons deserves further evaluation. However, generalization benefits from
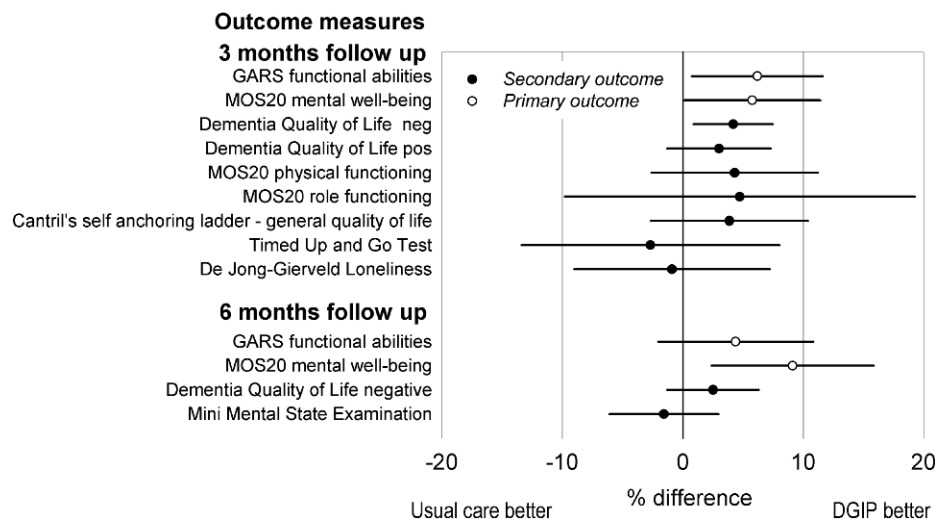

Figure 2. Primary and secondary outcomes differences between study arms at 3 and 6 months as percentages of scale ranges and their 95% confidence intervals (for Timed Up and Go Test, a denominator of 60 seconds was used, because Timed Up and Go Test has no scale range).

the fact that study conditions were very similar to current practice. Even without much experience with the model, the primary care physicians were able to select patients eligible for the intervention. As under regular conditions, the nurses had to cooperate with many different health care workers. The results of our trial show that multidimensional intervention for geriatric syndromes improves disability and mental well-being in frail older people who live at home. The results also indicate that this can be done by the primary care physician using a problem-based patient selection procedure to target suitable patients. As such, it promises to be a relevant supplement to primary health care for this population. This is important because population aging and increasing awareness of patient autonomy will increase the number of frail older people who rely on primary health care in reaching the aim of successful aging.

NOTE

CONSORT checklists and the GARS-3 are available from the authors.

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