Radboud Repository

Radboud University Nijmegen

PDF hosted at the Radboud Repository of the Radboud University Nijmegen

The following full text is a publisher's version.

For additional information about this publication click this link.
https://hdl.handle.net/2066/220901

Please be advised that this information was generated on 2021-06-18 and may be subject to change.

JAMDA 21 (2020) 837–842

JAMDA

journal homepage: www.jamda.com

Original Study

Educating Dutch General Practitioners in Dementia Advance Care Planning: A Cluster Randomized Controlled Trial

Bram Tilburgs MSc [a,*], Raymond Koopmans MD, PhD [b,c,d], Myrra Vernooij-Dassen PhD [a], Eddy Adang PhD [e], Henk Schers MD, PhD [b], Steven Teerenstra PhD [e], Marjolein van de Pol MD, PhD [b], Carolien Smits PhD [f], Yvonne Engels PhD [g], Marieke Perry MD, PhD [c,h]

[a] Department of IQ Healthcare, Radboud University Medical Centre Nijmegen, the Netherlands
[b] Department of Primary and Community Care, Radboud University Medical Centre, Nijmegen, the Netherlands
[c] Radboudumc Alzheimer Centre, Nijmegen, the Netherlands
[d] Joachim en Anna, Centre for Specialized Geriatric Care, Nijmegen, the Netherlands
[e] Department for Health Evidence, Radboud University Medical Centre, Nijmegen, the Netherlands
[f] Research Group Innovating with Older Adults, Windesheim University of Applied Sciences, Zwolle, the Netherlands
[g] Department of Anaesthesiology, Pain and Palliative Medicine, Radboud University Medical Centre, Nijmegen, the Netherlands
[h] Department of Geriatric Medicine, Radboud University Medical Centre, Nijmegen, the Netherlands

Keywords:
Dementia
general practitioners
primary care
advance care planning
palliative care

A B S T R A C T

Objectives: Advance care planning (ACP) is seldom initiated with people with dementia (PWD) and mainly focuses on medical end-of-life decisions. We studied the effects of an educational intervention for general practitioners (GPs) aimed at initiating and optimizing ACP, with a focus on discussing medical and nonmedical preferences of future care.
Design: A single-blinded cluster randomized controlled trial.
Setting and participants: In 2016, 38 Dutch GPs (all from different practices) completed the study. They recruited 140 PWD, aged ≥65 years at any stage and with any type of dementia, from their practice.
Methods: Intervention group GPs were trained in ACP, including shared decision-making and role-playing exercises. Control group GPs provided usual care. The primary outcome was ACP initiation: the proportion of PWD that had at least 1 ACP conversation documented in their medical file. Key secondary outcomes were the number of medical (ie, resuscitation, hospital admission) and nonmedical (ie, activities, social contacts) preferences discussed. At the 6-month follow-up, subjects' medical records were analyzed using random effect logistics and linear models with correction for GP clustering.
Results: 38 GP clusters (19 intervention; 19 control) included 140 PWD (intervention 73; control 67). Four PWD (2.9%) dropped out on the primary and key secondary outcomes. After 6 months, intervention group GPs initiated ACP with 35 PWD (49.3%), and control group GPs initiated ACP with 9 PWD (13.9%) [odds ratio (OR) 1.99; $P = .002$]. Intervention group GPs discussed 0.8 more medical [95% confidence interval (CI) 0.3, 1.3; $P = .003$] and 1.5 more nonmedical (95% CI 0.8, 2.3; $P < .001$) preferences per person with dementia than control group GPs.
Conclusions and Implications: Our educational intervention increased ACP initiation, and the number of nonmedical and medical preferences discussed. This intervention has the potential to better align future care of PWD with their preferences but because of the short follow-up, the GPs' long-term adoption remains unknown.
© 2019 AMDA – The Society for Post-Acute and Long-Term Care Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Y. E. and M. P. contributed equally as last authors.

This study was supported by the Dutch Organization for Health Research and Development (ZonMw) Memorabel program, project number 79-73305-98-420. This funding organization had no role in the study design, data collection, data analyses, data interpretation, or writing of the report.

The authors declare no conflicts of interest.

* Address correspondence to Bram Tilburgs, MSc, Department of IQ Healthcare, Radboud University Medical Centre, 6500 HB, Nijmegen, the Netherlands.
E-mail address: Bram.Tilburgs@radboudumc.nl (B. Tilburgs).

https://doi.org/10.1016/j.jamda.2019.09.010
1525-8610/© 2019 AMDA – The Society for Post-Acute and Long-Term Care Medicine. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Dementia is a syndrome characterized by progressive deterioration in memory and thinking, changes in behavior, decreasing ability to perform daily activities, and increasing dependency on others.[1,2] It affects not only people with dementia (PWD) but also their family caregivers (FCs).[2] Worldwide, 50 million people are currently diagnosed with dementia, and their number is expected to rise to 152 million by 2050.[1]

Care for PWD should be proactive, focus on living and dying well, and include advance care planning (ACP).[3,4] Traditionally, ACP addressed end-of-life preferences.[5] Recently, ACP was redefined as "a process which enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and healthcare providers, and to record and review these preferences if appropriate." By this means, ACP includes the physical, social, spiritual, and psychological domains.[6]

Important features of a complex and delicate process like ACP are familiarity with and trust in health care professionals.[7,8] Although these are primary care core values, general practitioners (GPs) rarely initiate ACP with PWD.[9] The most important barriers that GPs report are uncertainties concerning the right timing of ACP, PWD's decisional capacities, changing preferences, and the uncertain disease trajectory.[10] Most of these barriers might be resolved by training GPs in initiating ACP using the broader definition, which allows for discussion of both medical and nonmedical issues.[6,10]

A systematic review and meta-analysis showed that ACP interventions in various populations and settings increased the initiation of end-of-life discussions and the concordance between preferences and care delivered.[11] ACP interventions with PWD reduced health care use and costs, and increased documentation of future care preferences.[12,13] Additionally, ACP interventions are expected to cause positive effects on PWD's quality of life (QoL), involvement in care, and FCs' burden. However, results of systematic reviews on these outcomes are inconclusive.[11–13]

We developed a GP educational intervention aimed at initiating and optimizing ACP with a focus on discussing both medical and nonmedical preferences for future care. We assessed the effects of this intervention on the initiation of ACP and the number of medical and nonmedical preferences discussed. Additionally, we performed a cost-effectiveness analysis and studied the intervention's effects on PWD's QoL, experienced involvement in care decisions, and FCs' sense of competence.

Methods

Trial Design

We performed a single-blinded cluster-randomized controlled trial (RCT) with 6 months' follow-up in the Netherlands (Dutch trial register no. NTR5773). The Dutch primary health care system and the role of the practice nurses (PNs) in GP practices is explained in Supplementary Material 1. The study was approved by the research ethics committee of the region Arnhem-Nijmegen in accordance with the Medical Research Involving Human Subjects Acts and the declaration of Helsinki (NL52613.091.15). All participants gave written informed consent. Extended Consort guidelines for reporting cluster RCTs were followed.

Inclusion of Participants

Between January and June 2016, 38 GPs, all from different practices, were included. We invited a representative, regional sample from the database of the Dutch institute for health services research (NIVEL), containing the majority of the Dutch GPs. We also used the Practice Based Research Network of the Radboud University Medical Centre for recruitment, containing affiliated GPs (N = 1313). GPs were included if they committed to recruiting 5 PWDs from their practice. GPs were excluded if they were unable to include at least 1 person with dementia.

GPs were requested to include PWD aged ≥65 years, at any stage and with any type of dementia. GPs briefly explained the research project to both the person with dementia and the FC and asked permission to share their contact information with the research team. PWD and FCs who agreed were first informed about the research project by mail and received a phone call from a researcher (B.T.) 1 week later. After oral consent, the researcher performed a home visit to sign the informed consent form and collect baseline data. PWD were not included if they (or their legal representatives) did not provide informed consent, did not speak Dutch, or were unwilling to participate in baseline data collection.

The Intervention

The educational intervention consisted of two 3-hour interactive workshops. GPs randomized to the intervention group were trained between March and June 2016. As PNs can play an important role in dementia care and ACP, GPs were invited to bring their PN.[8,10]

The intervention was developed according to the adapted framework of the Medical Research Council Guidance for the development and evaluation of complex interventions.[14] Half of both workshops was used to practice ACP conversations with training actors. To structure ACP conversations, a model for shared decision-making (SDM) with older adults with frailty was introduced. In SDM, professionals and patients share their respective knowledge, values, and preferences about health care choices and together explore beneficial solutions.[15,16] We chose this model as it explicitly starts with the discussion of personal goals of care and values and thereby includes the PWD's physical, social, spiritual, and psychological domains.[6] The SDM model used consists of 6 steps including the traditional steps of choice talk, option talk, and decision talk. During step 1 (preparation), previously discussed and or documented future care preferences are explored and the primary informal caregiver is identified. During step 2 (goal talk), the discussion partner is identified and the person with dementia's values and personal goals of care are explored. During step 3 (choice talk), the previous steps are summarized and the person's care goals are formulated. During step 4 (option talk), personalized care goals are discussed after which (decision talk; step 5) decisions can be made. Finally, the ACP process is evaluated (step 6)[16] (Supplementary Material 2). By including the person with dementia's values and care goals, including nonmedical preferences (ie, activities, housing), the SDM model addresses the principles of social health and includes the influence of the social environment and the dynamic balance between capabilities and limitations.[17] The use of the SDM model was not yet evaluated with people with dementia.[16]

During the workshop, important barriers and facilitators, known from previous research, were emphasized, discussing real-life case descriptions[8,10] (Supplementary Material 2). Intervention group GPs and PNs also received a booklet containing background information on ACP. An experienced GP researcher expert in dementia care, who also acted as the expert in the second workshop (M.P.), had 2-monthly telephone consultations with the GP practices in the intervention group. These telephone consultations were not protocolled. GPs were asked if they had any questions or needed support in any way.

The control group received information about the rationale, aim, and design of the study and provided usual care during the 6 months' follow-up.

Outcome Measures and Data Collection

The primary outcome was the proportion of PWD for whom ACP was initiated during the 6 months following the intervention. This was

defined as the number of included PWD that had at least 1 ACP conversation documented in their medical file divided by the total number of included PWD in each study arm. PWD who had ACP were registered with a "1" and PWD who did not have ACP were registered with a "0". Only consultations in which preferences for future treatments and care were actually discussed were considered as ACP conversations.[6]

Key secondary outcomes were the number of medical and nonmedical preferences discussed during all ACP conversations as documented in the PWD's medical files during the 6 months following the intervention. Medical items were resuscitation, mechanical ventilation, use of antibiotics, hospital admissions, life-prolonging treatments (eg, tube feeding), and palliative treatments (eg, pain relief).[18] Nonmedical items were social contacts, activities, housing, safety, care needs, mobility, and finances.[19] Remaining preferences were categorized as not specified. These key secondary outcomes were based on earlier research and several discussions with the authors.[18,19]

To retrieve data on primary and key secondary outcomes, GPs were asked to upload a pdf-file containing the PWD's medical records to a secure digital environment. Three researchers (B.T., T.d.W., V.H.), blinded to the GPs' allocations, registered all documented ACP conversations 1 year prior and in the 6 months after the intervention on a case report form. To increase reliability, the first 20 medical files were analyzed independently by 2 researchers (B.T., T.d.W., or V.H.) and then compared. In case of disagreement, 2 researchers were consulted (Y.E., M.P.) using anonymized data. The remaining medical files were analyzed by 1 researcher (T.d.W. or V.H.). Doubts were discussed, using anonymized data, with 3 researchers (B.T., M.P., Y.E.).

Other secondary outcomes were QoL (Dementia quality of Life questionnaire and EuroQol 5D questionnaire), experienced level of SDM of the person with dementia (CollaboRATE questionnaire), experienced level of competence of the FC (Sense of Competence Questionnaire), and health care costs (Recourse Utilization in Dementia questionnaire) (Supplementary Material 3).[20–24] These data were collected at baseline and 6 months after the intervention by 7 researchers (B.T., T.d.W., V.H., L.v.D., L.R., S.v.H., F.W.). QoL and the experienced level of SDM questionnaires were administered at the PWD's homes. As the FC's experienced level of competence addresses delicate subjects (eg, "I wish that my … and I had a better relationship"), this questionnaire was completed during a telephone interview, without the person with dementia present. The questionnaire about health care costs was completed independently by the FC.

Characteristics of GPs, PWD, and FCs were collected at baseline and included age and gender, and whether PWD lived with their FC. Dementia severity was assessed by the GPs at baseline using the Clinical Dementia Rating scale (Supplementary Material 3).[25]

Sample Size and Power Calculation

On the primary outcome, we expected a difference between the intervention and control group of 25%, which was based on a study on ACP with older adults with frailty during hospital admission.[26] They found a difference of 50% on their primary outcome (end-of-life wishes known and respected). We expected a smaller difference, as our intervention lacked a marked moment to start ACP and as ACP with PWD is more complex.

Cluster randomization was taken into account when calculating the sample size. Clusters were expected to include 5 PWD and intraclass correlation (ICC) to be 0.05 or lower.[27] For a power of 0.8 and 2-sided testing at 0.05, 26 GPs were required. In a recent RCT with people with mild to moderate dementia and 1-year follow-up, study drop-out was 8.5%.[28] We therefore aimed to recruit 30 GPs.

Randomization and Masking

To minimize selection bias, cluster-randomization of GPs (all from different practices) took place after inclusion of PWD and FCs. To minimize imbalance between the study groups and limit researchers' selection bias, studywise minimization was applied.[29] A statistician used a computerized algorithm to calculate the imbalance of all possible allocations, including the following characteristics: gender, age, total number of patients aged ≥65 years, urbanization level, if the GP was specialized in geriatric care, and the GP's intention to bring a PN to the training. Finally, from all allocations with the fewest imbalance, 1 allocation was randomly selected.[29] All researchers involved in the outcome assessment were masked to the allocation.

Statistical Analyses

Prior to the start of the trial a statistical analysis plan was documented. A random effects logistic model was applied to analyze the effects of the intervention on the primary dichotomous outcome, taking clustering at GP level into account. The effects on the (key) secondary continuous outcomes were analyzed using a random effects linear model taking clustering on GP level into account. We performed a cost-effectiveness analysis (CEA), adhering to the Dutch manual for costing research (Supplementary Material 4).[30] All analyses were performed on an intention to treat basis, included GPs as random effects, and used 2-sided alphas of 0.05 to test statistical significance. The intervention effects were expressed as odds ratios or adjusted mean differences with 95% confidence intervals. We did not use multiple imputation of missing values because this is not necessary when random effect models are used.[31] Variables for which differences in baseline characteristics between the intervention and control group were observed were added as confounders. Baseline data were presented using descriptive statistics. For all analyses, SPSS version 22 (IBM Corp, Armonk, NY) was used.

Results

A total of 38 GPs (all from different practices) participated in the study. Thirty-three were included through the NIVEL database and 3 were included though the Practice Based Research Network of the Radboud University Medical Centre database. Two GPs contacted the research team themselves. GPs' mean age was 48.5 years, 55% were female, and 1 GP was an expert in geriatric care (Table 1).

Of the 182 PWD-FC dyads approached, 140 (77%) agreed to participate. Thirty-five dyads (19.2%) refused, 6 moved or died (3.3%) before baseline measurements could take place, and 1 person was excluded because he did not have dementia.

Nineteen GPs were allocated to the intervention group. They recruited 73 PWD-FC dyads. Sixteen GPs (84.2%) attended both workshops and 3 GPs (15.8%) attended 1 workshop. Eighteen GPs (95%) brought their PN. Fifteen PNs (83.3%) attended both workshops. The 19 GPs allocated to the control group recruited 67 PWD-FC dyads (Supplementary Material 5).

PWD's mean age was 81.9 years and 58% were female. FCs' mean age was 69 years, 65% were female, and 66% lived with the person with dementia (Table 2). All GPs', PWD's, and FCs' characteristics, the number of initiated ACP conversations, and the (non)medical issues discussed 1 year before the inclusion of PWD were well balanced between the study groups, apart from the FCs' gender (Tables 1 and 2). Only FCs' gender was therefore included as a confounder in all analyses. After 6 months, 2 medical files (2.7%) from the intervention and 2 from the control group (2.9%) and approximately 25% of all questionnaires on the secondary outcomes (QoL, level of SDM, and health care costs) could not be retrieved (Supplementary Material 5). We investigated for each variable with missing data whether this was

Table 1
Baseline Characteristics of General Practitioners and Their Practices

Variable	Control Group (n = 19)		Intervention Group (n = 19)	
	Mean (SD) or n (%)	Range (Min-Max)	Mean (SD) or n (%)	Range (Min-Max)
Female GPs, n (%)	11 (57.9)		10 (52.6)	
Age of GPs, y	48.4 (10.5)	31 (31-62)	48.7 (8.5)	27 (27-63)
GPs who intended to take a PN to the educational intervention, n (%)	15 (78.9)		14 (73.7)	
Number of patients in GP's practice	3544 (1807.6)	7518 (1368-8886)	3442 (1871.8)	6628 (1900-8528)
Patients aged ≥65 years in GP's practice	639 (371.8)	1389 (125-1514)	526 (166.1)*	633 (285-918)
GPs trained as expert GP older adult care, n (%)	1 (5.3)		0 (0)	
Practices with a care program for older adults, n (%)	14 (73.7)		14 (73.7)	

Min-Max, minimum-maximum.
*Data were missing for 1 practice.

related to the level (magnitude) of other variables and found no pattern. Therefore, we considered missingness completely at random (MCAR) plausible.

During the 6-month follow-up, ACP was initiated in 35 (49.3%) of the 71 PWD in the intervention group and in 9 (13.9%) of the 65 PWD in the control group (ICC 0.4, OR 1.99; $P = .002$). Sixteen of the 19 GPs in the intervention group and 7 of the 19 GPs in the control group had an ACP discussion with at least 1 of the PWD.

In the intervention group, a total of 165 ACP preferences (58 medical and 107 nonmedical) compared to 15 (8 medical and 7 nonmedical) in the control group were documented. Of the 58 medical preferences documented in the intervention group, resuscitation (43% of the 58 medical preferences) and hospital admission (31% of the 58 medical preferences) were most often discussed, whereas of the 107 nonmedical preferences, activities (29% of the 107 nonmedical preferences), housing (21% of the 107 nonmedical preferences), and care (ie, informal care; 16% of the 107 nonmedical preferences) were most often discussed (Supplementary Material 6).

In the intervention group, 35 ACP conversations took place, including an average of 1.7 medical preferences and 3.1 nonmedical preferences. In the control group, 9 ACP conversations took place, including an average of 0.9 medical preferences and 0.8 nonmedical preferences.

Overall, GPs in the intervention group documented significantly more ACP preferences per patient [mean 2.3, standard deviation (SD) 2.99] than in the control group (mean 0.2, SD 0.7) [adjusted mean difference 2.4, 95% confidence interval (CI) 1.2, 3.5]. Both more medical preferences (intervention: mean 0.8, SD 1.2; control: mean 0.1, SD 0.5; adjusted mean difference 0.8, 95% CI 0.3, 1.3) and more nonmedical preferences (intervention: mean 1.5, SD 2.1; control: mean 0.1, SD 0.4; adjusted mean difference 1.5, 95% CI 0.8, 2.3) were documented (Table 3).

PWD's QoL, PWD's experienced level of SDM, and the FCs' sense of competence did not differ between study groups. The cost analysis shows that PWD's and FCs' health care costs and PWD's QALYs did not differ between study groups; therefore, there seem to be no economic restrictions for implementing our educational intervention (Table 4).

Discussion

After participating in the educational intervention, GPs initiated ACP with 49.3% of the PWD compared to 13.9% in the control group. The number of medical and nonmedical preferences discussed during these ACP consultations also significantly differed. Our intervention therefore relevantly changed daily practice. No differences between the 2 groups on PWD's QoL, PWD's experienced level of SDM, the FCs' competence, PWD's QALYs and PWD's and FCs' health care costs were found.

With our intervention, we trained GPs to start ACP with discussing care goals important to PWD's current and remaining phase of life. As a result, ACP was initiated 3 times more often, and both medical and nonmedical preferences discussed increased. These findings support the recently proposed conceptual shift of ACP from mainly discussing future medical treatments and end-of-life preferences, to discussing all domains of palliative care.[5,6]

The fact that nonmedical preferences were more often discussed supports earlier findings that PWD consider discussions of these

Table 2
Baseline Characteristics of People With Dementia and Family Caregivers

Variable	Control Group (n = 67)		Intervention Group (n = 73)	
	Mean (SD) or n (%)	Range (Min-Max)	Mean (SD) or n (%)	Range (Min-Max)
Female PWD, n (%)	36 (53.7)		45 (61.6)	
Female FCs, n (%)	48 (71.6)		42 (57.5)	
PWD's mean age, y	82.1 (7.1)	39 (65-104)	81.7 (5.9)	29 (67-96)
FCs' mean age, y	68.7 (14.3)	59 (33-92)	69.6 (13.6)	52 (39-91)
FCs living with PWD, n (%)	44 (66.7)		48 (65.8)	
PWD who died between T0 and T1, n (%)	6 (9)		6 (8.2)	
Clinical Dementia Rating scale score	1.6 (0.8)	2.5 (0.5-3)	1.6 (0.9)	2.5 (0.5-3)
Dementia Quality of Life questionnaire score	59.1 (6.6)	39 (38-77)	57.6 (6.6)	35 (37-72)
PWD's EQ5D score	73.3 (18.1)	80 (29-109)	74.6 (13.7)	70 (31-101)
CollaboRATE questionnaire score	21.3 (4.8)	27 (0-27)	21.2 (4.1)	17 (10-27)
Sense of Competence Questionnaire score	93.9 (12.8)	64 (61-125)	92.4 (12.0)	59 (59-118)
Number of ACP preferences discussed with PWD	0.51 (1.3)	6 (0-6)	0.68 (2.3)	17 (0-17)
Number of medical ACP preferences discussed with PWD	0.22 (0.8)	5 (0-5)	0.23 (0.8)	4 (0-4)
Number of nonmedical ACP preferences discussed with PWD	0.29 (0.8)	4 (0-4)	0.45 (1.8)	13 (0-13)
PWD who had ACP conversation, n (%)	14 (20)		12 (16.9)	
PWD-FCs' mean health care costs	9892 (3642)	17,859 (0-17,859)	9885 (3951.4)	27,460 (0-27,460)

Min-Max, minimum-maximum.
Data are missing with no more than 2 individuals in the control group and no more than 2 individuals in the intervention group.

Table 3
Observed Means and Estimated Effects of the Total Number of ACP Preferences, the Number of Medical Preferences, and the Number of Nonmedical Preferences Discussed per Person With Dementia

Primary and Key Secondary Outcomes	Intervention (n = 71)*		Control (n = 65)*		Adjusted Mean Difference (95% CI)	*P* Value
	Mean (SD)	Range (Min-Max)	Mean (SD)	Range (Min-Max)		
Total ACP preferences discussed†	2.3 (2.99)	15 (0-15)	0.2 (0.7)	4 (0-4)	2.4 (1.2, 3.5)	<.001
Mean medical ACP preferences discussed (SD)†	0.8 (1.2)	5 (0-5)	0.1 (0.5)	3 (0-3)	0.8 (0.3, 1.3)	.003
Mean nonmedical ACP preferences discussed (SD)†	1.5 (2.1)	10 (0-10)	0.1 (0.4)	2 (0-2)	1.5 (0.8, 2.3)	<.001

Min-Max, minimum-maximum.
*Medical files missing: 2 of 73 in the intervention group and 2 of 67 in the control group.
†A random effect multilevel analysis, with correction for GP clustering and FCs' gender was used for estimation.

nonmedical care goals important for their current and remaining phase of life.[8,10] This suggests that starting ACP with discussing nonmedical issues may be a successful strategy for involving PWD in conversations on future medical and end-of-life preferences.[10]

PWD's preferences for discussing nonmedical issues may indicate that living well with their condition is their aim and that they find a focus on maintaining their capabilities at least as important as discussing medical issues. This reflects the importance of integrating the principles of social health, with its emphasis on the use of people's remaining capacities in making shared decisions in ACP.[17] Hereby, our study contributes to the body of knowledge on social health, as an aspect of positive health, and patient-centered approaches in the context of dementia.[17]

The 49% implementation rate of ACP in the intervention group may however indicate that GPs and PNs still experience barriers to initiate ACP with people with dementia and or that ACP was not carried out or documented as addressed during our educational intervention. This will be explored more in depth in a thorough process evaluation that is expected to be published at the end of 2019.

This study has several strengths. Up to now, most studies on the effects of ACP suffered from methodologic limitations like insufficient sample sizes, allocation bias, and lack of intention-to-treat analysis.[11] In this RCT on the effects of an educational intervention for GPs on ACP with PWD, we succeeded in minimizing bias to influence the trial results. We reached the planned sample size, which is often challenging regarding GPs and PWD.[32,33] We minimized the risk of study group imbalance by using studywise minimization.[29] We also minimized GPs' selection bias by including PWD and FCs before GPs were randomized. Few data were missing on the primary outcome measure, and the assessors of all outcomes were blinded to the participants' allocation.

Our study has some limitations. Our primary outcome depended on GPs' medical files and was therefore sensitive to registration bias, as health records data are often incomplete and do not always reflect medical performance.[34] However, ACP initiation and future care preferences discussed are of limited value without their documentation, especially in acute situations and involvement of other GPs or health care professionals.[35] Therefore, one could argue that this phenomenon can be considered a positive intervention effect instead of a study limitation.

The intervention had a relatively short follow-up of 6 months. Evaluating whether ACP discussions result in preferred treatment of care likely takes more time, especially when these decisions concern long-term end-of-life preferences (eg, hospital admission, resuscitation). This could explain why we did not find a positive effect on PWD's QoL and health care costs. Another possible explanation is that QoL in PWD is difficult to measure and its sensitivity to change is limited.[36] The lack of effects on PWD's experienced level of SDM or FCs' experienced level of competence could be explained by the fact that, as described in earlier research, some PWD and FCs do not want to make shared decisions on future care.[8,10] Moreover, these measures were already valuated high at

Table 4
Observed Means and Estimated Effect of the Total Number of People With Dementia's Quality of Life and Experienced Level of Shared Decision Making; Family Caregivers' Experienced Level of Competence, Quality-Adjusted Life Years, and Health Care Costs

Secondary Outcomes	Intervention		Control		Adjusted Mean Difference (95% CI)	*P* Value
	Mean (SD)	Range (Min-Max)	Mean (SD)	Range (Min-Max)		
PWD's QoL (DEMQOL)	58.1 (6.9)	36 (45-81)	57.8 (7.1)	48 (34-82)	0.4 (−2.7 to 3.4)	.8
Number of cases	56		56			
PWD's experienced level of SDM (CollaboRATE questionnaire score)	21.7 (2.9)	13 (14-27)	22.1 (3.4)	15 (12-27)	−0.4 (−1.8 to 9.5)	.53
Number of cases	56		56			
FCs' experienced level of competence (SCQ score)	94.3 (11.9)	60 (61-121)	97.8 (13.3)	61 (61-122)	−3.5 (−8.5 to 1.6)	.17
Number of cases	52		52			
PWD's QALYs	0.3 (0.1)	0.39 (0.11-0.5)	0.3 (0.1)	0.55 (−0.05 to 0.5)	0.02 (−0.03 to 0.6)	.43
Number of cases	56		56			
PWD-FCs' health care costs in Euros (RUD score)	10,111.7 (4505.6)	29,418.2 (132.54-29,550.8)	10,412.6 (3344.7)	17,816.1 (18,056.5-10,412.6)	−349.1 (−1903.5 to 1205.3)	.66
Number of cases	52		55			

DEMQOL, Dementia Quality of Life questionnaire; EQ-5D; EuroQol 5D questionnaire; Min-Max, minimum-maximum; RUD, Recourses Utilization in Dementia questionnaire; SCQ, Sense of Competence questionnaire.
A random effect multilevel analysis, with correction for GP clustering and FCs' gender was used for estimation.

baseline (Table 2) and suffered from a drop-out of approximately 25%. Future research could resolve these shortcomings by identifying more relevant and specific patient-reported outcomes in the context of ACP, investigating the effects of an educational intervention for GPs with these measures as primary outcome with accompanying power calculation and a longer follow-up.

As participation in this study was voluntary, it probably attracted early adopters, that is, GPs with an increased interest in ACP with PWD.[37] This may negatively influence the external validity of our results but is an adequate way to initiate quality improvement.[37] However, the participating GPs were representative, with regard to age and gender, of the Dutch national GP database, which suggests eligibility of the intervention to a broader GP population.[38] An additional process evaluation could reveal the intervention's successful components and elements for improvement.[39]

Conclusions and Implications

GPs can be effectively trained to initiate ACP and thereby discuss nonmedical and medical preferences with PWD. This study is an important step toward improving future care for community-dwelling PWD and their FCs, and the implementation of a more holistic approach to ACP. There seem to be no economic restrictions for implementing this innovative way of discussing health care preferences. We recommend a process evaluation to further improve ACP initiation and research with long-term follow-up to explore the effects of ACP on patient-reported outcomes.

Acknowledgments

The authors thank Hans van Gennip, Ton de Wit, Vicky Hendriks, Nieke van Driel, Levi Romonesco, Sam van Haren, Femke Weijers, and Angelique Schlief from the Radboud University Medical Centre, Nijmegen, the Netherlands, for their contributions to this study.

References

1. World Health Organization. Dementia fact sheet. 2017. Available at: http://www.who.int/mediacentre/factsheets/fs362/en/. Accessed December 28, 2017.
2. World Health Organization and Alzheimer's Disease International. Dementia: A Public Health Priority. Mental Health Publications; 2012.
3. van der Steen JT, Radbruch L, Hertogh CM, et al. White paper defining optimal palliative care in older people with dementia: A Delphi study and recommendations from the European Association for Palliative Care. Palliat Med 2014;28:197–209.
4. The Lancet Commission on Dementia. Living and dying with dementia. Lancet 2018;391:2390.
5. Romer AL, Hammes BJ. Communication, trust, and making choices: Advance care planning four years on. J Palliat Med 2004;7:335–340.
6. Rietjens JAC, Sudore RL, Connolly M, et al. Definition and recommendations for advance care planning: An international consensus supported by the European Association for Palliative Care. Lancet Oncol 2017;18:e543–e551.
7. Maruthappu M, Sood HS, Keogh B. The NHS Five Year Forward View: Transforming care. Br J Gen Pract 2014;64:635.
8. Tilburgs B, Vernooij-Dassen M, Koopmans R, et al. The importance of trust-based relations and a holistic approach in advance care planning with people with dementia in primary care: A qualitative study. BMC Geriatr 2018;18:184.
9. Evans N, Pasman HRW, Donker GA, et al. End-of-life care in general practice: A cross-sectional, retrospective survey of "cancer", "organ failure" and "old-age/dementia" patients. Palliat Med 2014;28:965–975.
10. Tilburgs B, Vernooij-Dassen M, Koopmans R, et al. Barriers and facilitators for GPs in dementia advance care planning: A systematic integrative review. PLoS One 2018;13:e0198535.
11. Houben CH, Spruit MA, Groenen MT, et al. Efficacy of advance care planning: A systematic review and meta-analysis. J Am Med Dir Assoc 2014;15:477–489.
12. Dixon J, Karagiannidou M, Knapp M. The effectiveness of advance care planning in improving end-of-life outcomes for people with dementia and their carers: A systematic review and critical discussion. J Pain Symptom Manage 2018;55:132–150.e1.
13. Robinson L, Dickinson C, Rousseau N, et al. A systematic review of the effectiveness of advance care planning interventions for people with cognitive impairment and dementia. Age Ageing 2012;41:263–269.
14. Craig P, Dieppe P, Macintyre S, et al; Medical Research Council Guidance. Developing and evaluating complex interventions: The new Medical Research Council guidance. BMJ 2008;337:a1655.
15. Weston WW. Informed and shared decision-making: The crux of patient-centred care. Can Med Assoc J 2001;165:438–439.
16. van de Pol MH, Fluit CR, Lagro J, et al. Expert and patient consensus on a dynamic model for shared decision-making in frail older patients. Patient Educ Couns 2016;99:1069–1077.
17. Dröes RM, Chattat R, Diaz A, et al. Social health and dementia: A European consensus on the operationalization of the concept and directions for research and practice. Aging Ment Health 2017;21:4–17.
18. Mitchell SL, Kiely DK, Jones RN, et al. Advanced dementia research in the nursing home: The CASCADE study. Alzheimer Dis Assoc Disord 2006;20:166–175.
19. Span M, Smits C, Groen-van de Ven L, et al. Towards an interactive web tool that supports shared decision making in dementia: Identifying user requirements. Int J Adv Life Sci 2014;6:338–349.
20. Barr PJ, Thompson R, Walsh T, et al. The psychometric properties of CollaboRATE: A fast and frugal patient-reported measure of the shared decision-making process. J Med Internet Res 2014;16:e2.
21. Jansen APD, van Hout HPJ, van Marwijk HWJ, et al. Sense of Competence Questionnaire among informal caregivers of older adults with dementia symptoms: A psychometric evaluation. Clin Pract Epidemiol Ment Health 2007;3:11.
22. Wimo A, Gustavsson A, Jonsson L, et al. Application of Resource Utilization in Dementia (RUD) instrument in a global setting. Alzheimers Dement 2013;9:6–17.
23. Smith SC, Lamping DL, Banerjee S, et al. Development of a new measure of health-related quality of life for people with dementia: DEMQOL. Psychol Med 2007;37:737–746.
24. Hurst NP, Kind P, Ruta D, et al. Measuring health-related quality of life in rheumatoid arthritis: Validity, responsiveness and reliability of EuroQol (EQ-5D). Rheumatology 1997;36:551–559.
25. Morris JC. Clinical Dementia Rating: A reliable and valid diagnostic and staging measure for dementia of the Alzheimer type. Int Psychogeriatr 2005;9:173–176.
26. Detering KM, Hancock AD, Reade MC, Silvester W. The impact of advance care planning on end of life care in elderly patients: Randomised controlled trial. BMJ 2010;340:c1345.
27. Campbell MK, Fayers PM, Grimshaw JM. Determinants of the intracluster correlation coefficient in cluster randomized trials: The case of implementation research. Clin Trials 2005;2:99–107.
28. Meeuwsen EJ, Melis RJF, Van Der Aa GCHM, et al. Effectiveness of dementia follow-up care by memory clinics or general practitioners: Randomised controlled trial. BMJ 2012;344:e3086.
29. Perry M, Faes M, Reelick MF, et al. Studywise minimization: A treatment allocation method that improves balance among treatment groups and makes allocation unpredictable. J Clin Epidemiol 2010;63:1118–1122.
30. Hakkaart-van Roijen L, Linden van der N, Bouwmans C, et al. Richtlijn voor het uitvoeren van economische evaluaties in de gezondheidszorg [Guideline for conducting economic evaluations in healthcare]. Rotterdam, the Netherlands: Institute for medical technology Assesment Erasmus University Rotterdam; 2016.
31. Twisk J, de Boer M, de Vente W, Heymans M. Multiple imputation of missing values was not necessary before performing a longitudinal mixed-model analysis. J Clin Epidemiol 2013;66:1022–1028.
32. Hubbard G, Downs MG, Tester S. Including older people with dementia in research: Challenges and strategies. Aging Ment Health 2003;7:351–362.
33. Groenewegen Peter PP. General practitioners participation in a large, multicountry combined general practitioner-patient survey: Recruitment procedures and participation rate. Int J Family Med 2016;2016:1.
34. Chan KS, Fowles JB, Weiner JP. Review: Electronic health records and the reliability and validity of quality measures: A review of the literature. Med Care Res Rev 2010;67:503–527.
35. Krist AH, Beasley JW, Crosson JC, et al. Electronic health record functionality needed to better support primary care. J Am Med Inform Assoc 2014;21:764–771.
36. Banerjee S, Smith SC, Lamping DL, et al. Quality of life in dementia: More than just cognition. An analysis of associations with quality of life in dementia. J Neurol Neurosurg Psychiatry 2006;77:146–148.
37. Berwick DM. Disseminating innovations in health care. JAMA 2003;289:1969–1975.
38. NIVEL. Nederlands instituut voor onderzoek van de gezondheidszorg. 2018. Available at: https://www.nivel.nl/nl. Accessed June 25, 2018.
39. Moore GF, Audrey S, Barker M, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015;350:h1258.

Supplementary Material 1. Description of the Dutch Primary Health Care System

In the Netherlands, most general practitioners (GPs) work in a general practice together with colleague GPs. In most GP practices, a practice nurse (PN) is available. PNs are registered nurses who independently provide care for primary care patients under the GP's supervision. Patients in their caseloads include people with chronic conditions such as diabetes, cardiovascular disease, and chronic obstructive pulmonary disease. To be able to provide holistic care for frail older people, including people with dementia, PNs must follow a short additional training. Almost all noninstitutionalized inhabitants of the Netherlands are registered at a primary care practice close to where they live. GPs see patients with a large range of diseases in different stages without any selection regarding age, gender, socioeconomic status, or ethnicity. They form a gatekeeper's role to specialist medical care. Most GPs have long-lasting relationships with their patients and as a result know the patients' personal situations.

Supplementary Material 2. Description of the Educational Intervention

The educational intervention consisted of 2 protocolized workshops, each lasting 3 hours. The workshops took place in a small theatre and started with a personal welcome by the course leader following a meal with all participants and trainers. We used a variety of didactic interactive strategies, as these proved to be the most effective.[1]

The first workshop started with a communication exercise to "warm up" the participants and get them acquainted with the trainers. This was followed by the presentation of a model for shared decision making (SDM) with frail older adults.[2] This presentation was given by an experienced general practitioner (GP)/researcher who was also specialized in medical education and SDM with frail older adults and who developed the SDM used in the intervention. The SDM model presented consists of 6 steps, including the traditional steps of choice talk, option talk, and decision talk. During step 1 (preparation), previously discussed and/or documented future care preferences are explored and the primary informal caregiver is identified. During step 2 (goal talk), the discussion partner is identified and the person with dementia's values and personal goals of care are explored. During step 3 (choice talk), the previous steps are summarized and the person's care goals are formulated. During step 4 (option talk), personalized care goals are discussed, after which (decision talk; step 5) decisions can be made. Finally, the ACP process is evaluated (step 6).[2]

After the presentation, the expert showed the different steps that could be taken in an ACP conversation with the use of training actors. In addition, the importance of starting ACP and discussing nonmedical preferences (eg, daily activities, housing, social contacts), aimed at living the remaining phase of life as well as possible, rather than on end-of-life preferences, was emphasized and demonstrated.

After a short break, participants received a list of examples of sentences to start an ACP discussion on how to start an ACP conversation (eg, Could you tell me what is most important to your current situation?) and the expert explained how these examples could help them focus on addressing near-future preferences. Groups were formed with 1 training actor and a maximum of 5 participants. One of the participants was asked to introduce a real-life case description, which was then used to practice an ACP conversation. Participants were invited to stimulate the use of capacities and autonomy of PWD.[3] The training actor played the person with dementia, and other roles (eg, GP, FC) were played by the course participants. The remaining participants in each group observed. The group evaluated and discussed each ACP conversation, paying special attention to the patient's expressed concerns or wishes. The first workshop ended with a summary by the course leader.

The second workshop started with a presentation of a real-life case in which the following important aspects of advance care planning (ACP) with persons with dementia (PWD) were integrated: a trust-based relationship between the general practitioner (GP), the person with dementia, and the family caregiver (FC); home visits; an early start; regular review and documentation of ACP outcomes; and a proactive attitude from the GP.[4,5] The importance of timely discussing both medical and nonmedical preferences and the involvement of FCs within ACP was also emphasized.[4,5] This presentation was given by an experienced GP/researcher specialized in dementia care. Some participants were then invited to summarize the key points of the presentation in a 1-minute elevator pitch. By doing so, we wanted to show that different participants find different aspects important, and therefore documentation may vary.

A former FC then told the participants about her father's disease process and her own view on the role of the GP and the FC in ACP. Course participants were invited to react and ask questions.

After a short break, groups were formed with 1 training actor and a maximum of 5 participants. Each group was given several case descriptions in order to practice an ACP conversation. Each case contained multiple opportunities to discuss medical and nonmedical preferences. An FC was deliberately included in the case description. This enabled participants to practice interacting with an FC and showed that conflicting interests sometimes occur during ACP. The training actor played the person with dementia, and other roles (eg, GP, FC) were played by the course participants. The remaining participants and trainers observed. Each ACP conversation was evaluated and discussed.

Finally, trainers and the participants discussed how goals and decisions formulated in ACP conversations could be documented in the medical files. The workshop ended with a summary of both workshops, and the invitation to contact one of the trainers if any questions remained or help was needed.

References

1. Forsetlund L, Bjørndal A, Rashidian A, et al. Continuing education meetings and workshops: Effects on professional practice and health care outcomes. Cochrane Database Syst Rev; 2009:CD003030.
2. van de Pol MH, Fluit CR, Lagro J, et al. Expert and patient consensus on a dynamic model for shared decision-making in frail older patients. Patient Educ Couns 2016;99:1069–1077.
3. Dröes RM, Chattat R, Diaz A, et al. Social health and dementia: A European consensus on the operationalization of the concept and directions for research and practice. Aging Ment Health 2017;21:4–17.
4. Tilburgs B, Vernooij-Dassen M, Koopmans R, et al. Barriers and facilitators for GPs in dementia advance care planning: A systematic integrative review. PLoS One 2018;13:e0198535.
5. Tilburgs B, Vernooij-Dassen M, Koopmans R, et al. The importance of trust-based relations and a holistic approach in advance care planning with people with dementia in primary care: A qualitative study. BMC Geriatr 2018;18:184.

Supplementary Material 3. Measurement of Other Secondary Outcomes and Dementia Severity

Quality of Life of the Person With Dementia

To assess the QoL of PWD, we used the Dutch version of the Dementia Quality of Life (DEMQOL) questionnaire (28 items, 4-point Likert-type scales, a minimum score of 28 representing a low QoL, a maximum score of 112 representing a high QoL) and the EuroQol 5D (EQ-5D) questionnaire (5 items, 3 options per item, a minimum score of 5 representing a low QoL, a maximum score of 15 representing a high QoL).[1,2] The EQ-5D was also used to facilitate the cost-effectiveness analysis.

Experienced Level of Shared Decision Making of the Person With Dementia

The experienced level of shared decision making of PWD was assessed with the Dutch version of the CollaboRATE (3 items, 10-point numeric scale, a minimum score of 0 representing a low experienced level of shared decision making, a maximum score of 27 representing a high experienced level of shared decision making).[3]

Experienced Sense of Competence of the Family Caregiver

The FC's experienced sense of competence was measured with the Dutch version of the Sense of Competence Questionnaire (SCQ) (27 items, 3- and 5-point Likert-type scales—a minimum score of 27 representing a low level of experienced competence and a maximum score of 129 representing a high level of experienced competence).[4]

Health Care Costs of the Person With Dementia and Family Caregiver

Health care costs were measured with the Dutch version of the Resource Utilization in Dementia questionnaire (RUD). The RUD measures the FCs and person with dementia's health care usage in the previous month.[5]

The Clinical Dementia Rating Scale

The Clinical Dementia Rating scale, a 5-point scale used to characterize 6 domains (memory, orientation, judgement and problem solving, community affairs, home and hobbies, personal care) of cognitive and functional performance applicable to dementia which measures the severity of dementia, was assessed by the GPs.[6]

References

1. Smith SC, Lamping DL, Banerjee S, et al. Development of a new measure of health-related quality of life for people with dementia: DEMQOL. Psychol Med 2007;37:737–746.
2. Hurst NP, Kind P, Ruta D, et al. Measuring health-related quality of life in rheumatoid arthritis: Validity, responsiveness and reliability of EuroQol (EQ-5D). Rheumatology 1997;36:551–559.
3. Barr PJ, Thompson R, Walsh T, et al. The Psychometric Properties of CollaboRATE: A fast and frugal patient-reported measure of the shared decision-making process. J Med Internet Res 2014;16:e2.
4. Jansen APD, van Hout HPJ, van Marwijk HWJ, et al. Sense of competence questionnaire among informal caregivers of older adults with dementia symptoms: A psychometric evaluation. Clin Pract Epidemiol Ment Health 2007;3:11.
5. Wimo A, Gustavsson A, Jonsson L, et al. Application of resource utilization in dementia (RUD) instrument in a global setting. Alzheimers Dement 2013;9:6–17.
6. Morris JC. Clinical Dementia Rating: A reliable and valid diagnostic and staging measure for dementia of the Alzheimer type. Int Psychogeriatr 2005;9:173–176.

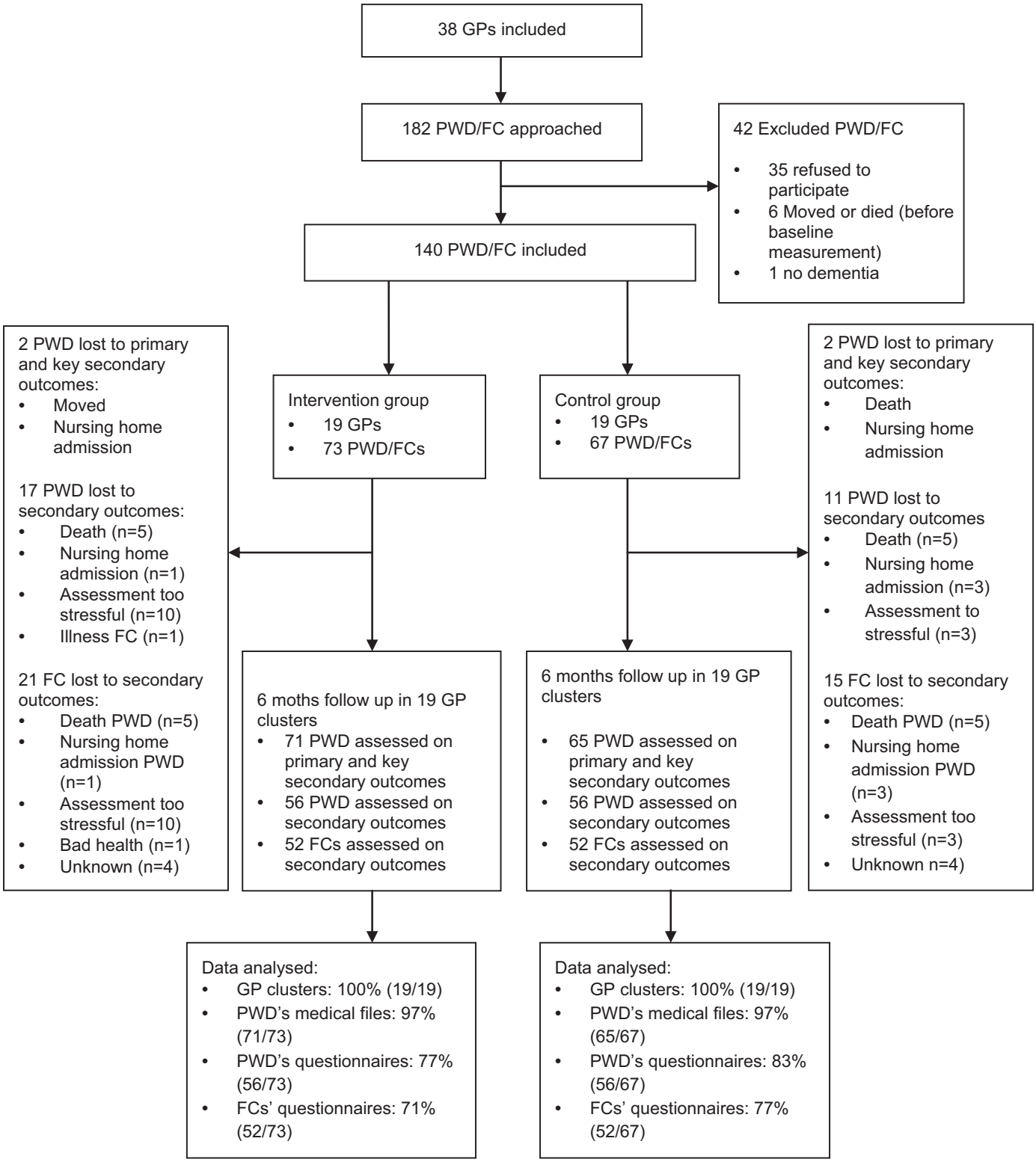
Supplementary Material 4. Description of the Cost Effectiveness Analysis

We performed a cost effectiveness analysis (CEA), adhering to the Dutch manual for costing research.[1] Outcome measures were quality-adjusted life years (QALYs), based on combining the EuroQOL 5D (EQ5D) utility scores with survival.[1] Productivity losses of family caregivers (FCs) were measured using the friction cost approach.[1] To determine robust confidence intervals surrounding the Incremental Cost-Effectiveness Ratio, we used (non)parametric bootstrapping. At patient level, volumes of care (eg, medical home care and hospital visits) were determined on a per person with dementia and FC basis using the Resource Utilization in Dementia (RUD) questionnaire at baseline and after 6 months. The volume of each registered health care consumption was multiplied by its corresponding prices as presented in the Dutch manual of costing research.[1] If no guideline or standard prices were available, real prices were determined. Intervention costs (eg, training bureau costs and participants' traveling expenses) were also included. In the absence of substantiated information on the intervention's sustainability, the current general practitioner practice population of people with dementia was used to determine these costs.

Reference

1. Hakkaart-van Roijen L, Linden van der N, Bouwmans C, et al [Richtlijn voor het uitvoeren van economische evaluaties in de gezondheidszorg [Guideline for conducting economic evaluations in healthcare]. Rotterdam, the Netherlands: Institute for medical technology Assesment Erasmus University; 2016.

Supplementary Material 5



Supplementary Fig. 1. Inclusion of participants. FC, family caregiver; GP, general practitioner; PWD, people with dementia.

Supplementary Material 6. Medical and nonmedical Preferences Discussed and Documented

Supplementary Table 1
Number of Medical and Nonmedical Preferences Documented in the Intervention and Control Groups

	Number of Preferences Documented in the Control Group	Number of Preferences Documented in the Intervention Group
Medical preferences documented		
Resuscitation	3 (37.5)	25 (43.1)
Hospital admission	1 (12.5)	18 (31)
Mechanical ventilation	0	3 (5.2)
Use of antibiotics	1 (12.5)	4 (6.9)
Interventions to prolong life	1 (12.5)	8 (13.8)
Palliative care	2 (25)	0
Total	8	58
Nonmedical preferences documented		
Social contacts	1 (14.3)	10 (9.3)
Activities	1 (14.3)	31 (28.9)
Housing	0	23 (21.5)
Safety	1 (14.3)	4 (3.7)
Care needs	1 (14.3)	17 (15.9)
Mobility	0	2 (1.9)
Finances	0	2 (1.9)
Other	3 (42.9)	18 (16.8)
Total	7	107
Total of medical and nonmedical preferences documented	15	165

ACP, advance care planning; PWD, people with dementia.
The percentages are from the total medical or nonmedical items documented.