


Advance Care Planning for frail older adults: Findings on costs in a cluster randomised controlled trial

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Abstract

Background: Advance Care Planning aims at improving alignment of care with patients' preferences. This may affect costs of medical care.

Aim: To determine the costs of an Advance Care Planning programme and its effects on the costs of medical care and on concordance of care with patients' preferences.

Design/settings/participants: In a cluster randomised trial, 16 residential care homes were randomly allocated to the intervention group, where frail, older participants were offered facilitated Advance Care Planning conversations or to the control group. We calculated variable costs of Advance Care Planning per participant including personnel and travel costs of facilitators. Furthermore, we assessed participants' healthcare use during 12 months applying a broad perspective (including medical care, inpatient days in residential care homes, home care) and calculated costs of care per participant. Finally, we investigated whether treatment goals were in accordance with preferences. Analyses were conducted for 97 participants per group. Trial registration number: NTR4454.

Results: Average variable Advance Care Planning costs were €76 per participant. The average costs of medical care were not significantly different between the intervention and control group (€2360 vs €2235, respectively, $p = 0.36$). Costs of inpatient days in residential care homes (€41,551 vs €46,533) and of home care (€14,091 vs €17,361) were not significantly different either. Concordance of care with preferences could not be assessed since treatment goals were often not recorded.

Conclusion: The costs of an Advance Care Planning programme were limited. Advance Care Planning did not significantly affect the costs of medical care for frail older adults.

Keywords

Advance Care Planning, healthcare costs, aged, frailty

What is already known about the topic?

- Advance Care Planning (ACP) is often associated with reduced healthcare costs.
- Depending on the study period and type of cost measurement, cost savings per patient varied between €886 (US\$1041) and €55,190 (US\$64,827).
- Most studies on healthcare costs were conducted in the United States and did not address costs of ACP programmes.

What this paper adds?

- This is the first trial to determine costs of an ACP programme in Europe and to assess costs of medical care, inpatient days in residential care homes and home care among frail older adults in a European context.

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- Mean variable costs of the ACP programme were €76 per participant.
- Costs of medical care did not differ significantly between the ACP intervention group and the control group.

Implications for practice, theory or policy

- Cost studies provide important information for organisations that consider the implementation of ACP.
- Given the limited costs of our extensive ACP programme and earlier reported results of our ACP trial (higher completion rates of advance directives, an increase in the appointment of surrogate decision makers and positive evaluations of facilitated ACP conversations), healthcare providers may consider providing ACP to frail older adults.
- We found no effect of ACP on costs of medical care.

Introduction

Advance Care Planning (ACP) is a communication process that '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'.¹ The ultimate goal of ACP is to promote the alignment of care with patients' preferences.^{1,2} It is recommended that ACP is adapted to one's readiness and that trained facilitators support the process.¹ ACP is not limited to specific patient groups and can be provided at any stage of life; however, the content of ACP 'should be more targeted when the individual's health condition worsens or as they age'.¹

In general, frailty is associated with high needs for healthcare use and increased costs.³ Given this need and the related necessity for important future healthcare decisions, ACP may be especially relevant for frail older adults, also given the high prevalence of conditions that might affect their future communication about preferences.⁴

We identified in total 22 studies on ACP and healthcare costs,^{5–26} of which 6 had a randomised controlled design and studied older adults with a mean age of ≥ 65 years.^{5,11–13,15,17} The majority of studies (14/22, 64%) showed that ACP was associated with reduced healthcare costs.^{5,6,8,10–12,14,16,18,19,22,24–26} Depending on the study period and type of cost measurement, cost savings per patient varied between €886 (US\$1041)²² and €55,190 (US\$64,827).²⁵ Such cost savings may be related to people choosing less invasive medical interventions after having engaged in ACP.²⁷

Most studies (16/22, 73%) on ACP and healthcare costs were conducted in the United States.^{8,10–15,18–26} It is unknown to what extent results from the United States can be generalised to other countries, given differences in healthcare systems and legal ACP regulations. For instance, general practitioners (GPs) may or may not act as gatekeepers to secondary and tertiary care.^{28,29} In many countries, adults have the right to refuse medical treatments and can indicate this, for instance, in an advance directive (AD).^{28,30} However, adults from, for example, the Netherlands do not have the right to demand certain

treatments without the physicians' agreement.^{28,31} They can indicate their preferences for treatment and care to be applied, for instance, in an AD, and this can serve to support their physicians in understanding their preferences.^{28,31}

In their review on healthcare costs of ACP, Dixon et al.³² emphasise a need to investigate detailed costs of ACP programmes and to investigate the effect of ACP on healthcare costs in a broad perspective, including costs for both medical and nursing care. As previously reported, our ACP programme increased the completion of ADs and the appointment of surrogate decision makers in frail older adults in the Netherlands.³³ In addition, many participants positively evaluated facilitated ACP conversations. However, we found no effects of ACP on levels of patient activation, quality of life or healthcare use (narrow perspective).³³ In the context of the same trial, we will now investigate the costs of our extensive ACP programme and, as recommended by Dixon et al.,³² the effects of ACP on costs of healthcare from a broad perspective, by focusing on the costs of medical care including medication as well as inpatient days in residential care homes and home care. In addition, we will determine concordance of care with patients' preferences.

Methods

Setting

In a cluster randomised trial, 16 residential care homes were randomly allocated to the ACP intervention group ($n = 101$) or the control group where adults received care-as-usual ($n = 100$). Residential care homes, who offered both residential and non-residential care, were based in Rotterdam, the Netherlands. The trial followed the CONSORT guidelines. Data were collected between 2014 and 2016. Details of the study design, methods and main findings have been reported previously.^{33,34}

Participants

Study participants lived either in 1 of the 16 residential care homes or at home, in the immediate surroundings of the care homes while receiving non-residential care from

these care homes. To be eligible for participation, individuals had to be ≥ 75 years, frail (Tilburg Frailty Index score ≥ 5 , range 0–15)³⁵ and capable to consent to participation (Mini-Mental State Examination score ≥ 17 , range 0–30).^{36,37} Participants in the intervention group were offered facilitated planning conversations based on the Respecting Choices® ACP programme.³⁸ For our study, a nurse practitioner attended the Respecting Choices facilitator and train-the-trainer programmes in the United States. Following, she trained 8 Dutch nurses to deliver the programme, which consisted of 3 core elements: (1) information provision supported by leaflets, (2) facilitated ACP conversations based on scripted interview cards and (3) the completion of an AD, potentially including the appointment of a surrogate decision maker. The study AD was based on the ‘Power of Attorney for Healthcare Document’ as originally developed for the La Crosse region. Like the ‘Power of Attorney for Healthcare Document’, our study AD included 4 parts: (1) Who makes decisions about my medical treatment when I am no longer able to do this myself, (2) General authorities of my surrogate decision maker, (3) My preferences concerning future medical care and (4) Signature. The study AD included both checkboxes and open-text formats (Supplementary file S1).

We assessed fixed ACP programme costs for the preparation phase including costs of the Respecting Choices facilitator and train-the-trainer programmes, the translation and adaptation of ACP materials, the translation and adaptation of the training programme for facilitators and the training for facilitators. In addition, we assessed variable programme costs for the ACP programme per participant including average personnel costs and travel costs of facilitators.

Economic evaluation

We conducted a cost-minimisation study, investigating the difference in healthcare costs between study groups from a healthcare perspective. To analyse the costs of healthcare use during 12 months after inclusion, we took a broad perspective focusing on the following categories: (1) costs of medical care including hospital care (emergency department (ED) visits, hospital stays, intensive care unit (ICU) care), diagnostic procedures (e.g. blood transfusion or computed tomographic (CT) scan), medical interventions (e.g. surgery or cardiopulmonary resuscitation) and medication, (2) costs of inpatient days in residential care homes including nursing and/or medical care, residential care housing and daytime activities and (3) costs of home care including nursing care and domestic help. To determine whether ACP enhances provision of care that is consistent with patients’ preferences, we investigated whether goals of

hospital stays, diagnostic procedures and medical interventions as described in medical files were in accordance with care preferences, as indicated by participants in their AD(s) (mostly study ADs). In addition, we compared the number of hospital stays, diagnostic procedures and medical interventions between study groups. Data from both participants’ medical files of GPs and participants’ files of the care organisation were collected using a medical file checklist. This checklist was pilot-tested to verify whether relevant care items were accessible in files and to reduce inter-rater differences in interpretations between 3 researchers who collected these data.

The cost price of the ACP programme was determined with the micro-costing method, which is based on a detailed assessment of all resources used.³⁹ Therefore, ACP facilitators registered their time investments per participant. Costs of medical care were calculated by multiplying the volumes of medical care use with the corresponding cost prices. For the calculation of hospital care, diagnostic procedures and medical interventions, we used charges as a proxy of real costs. In the Netherlands, a detailed ‘fee-for-service’ system is available for the remuneration of diagnostic procedures and medical interventions. To calculate the costs of medication use, we used average cost prices per day. Only expensive medication, operationalised as a cost price of $>€10$ per day, was considered in the analysis. Costs of inpatient days in residential care homes and costs of home care were estimated as real, basic costs per day or per hour, respectively, using detailed administrative information from the care organisation.

Statistical analysis

Statistical analyses were conducted according to the intention-to-treat principle. Personal characteristics were compared at baseline between study groups using chi-square tests and analysis of variance (ANOVA). To compare costs of medical care between study groups, we used multilevel analyses, adjusting for clustering effects at residential care home level and differences in demographics. Differences were considered significant if $p < 0.05$. Analyses were performed using IBM SPSS statistics V.23 and R V.3.2.3.

Ethics

The Research Ethics committee of Erasmus MC gave approval for the study on 14 January 2014 (MEC-2013-516, NL.46444.078.13). All participants gave written informed consent. The trial was registered on 22 January 2014 (NTR4454, www.trialregister.nl/trialreg/admin/rct-view.asp?TC=4454).

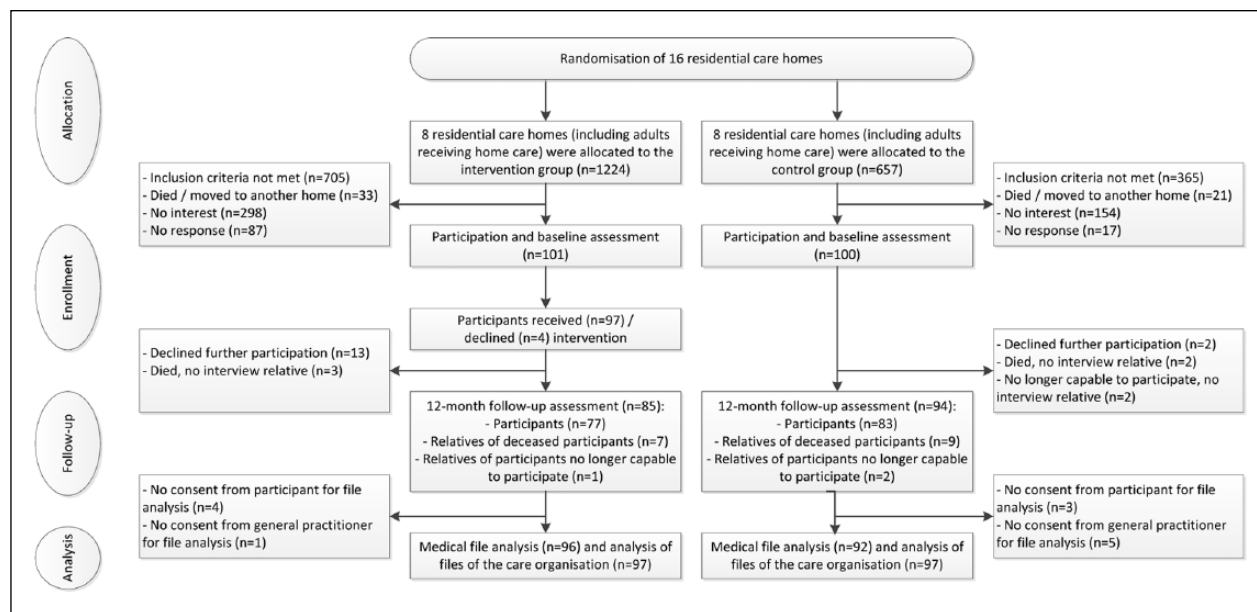


Figure 1. CONSORT flow chart.

Results

Procedures

In total, 201 out of 1881 screened adults fulfilled the inclusion criteria and participated: 101 in the intervention group (of whom 97 received the ACP programme) and 100 in the control group (Figure 1). In all, 80 out of 97 participants in the intervention group provided a copy of their study AD. In this AD, 78 out of 80 appointed a surrogate decision maker. In all, 67 out of 80 (84%) participants indicated in their AD to prefer treatment that focuses on comfort in case being capable of meaningful contact with others would become unlikely. In all, 3 out of 80 participants (4%) indicated to prefer maximum care and 10 out of 80 (13%) participants did not indicate a preference (Supplementary file S2).

In all, 77 out of 101 intervention participants and 83 out of 100 controls completed the follow-up assessment after 12 months. In total, 21 participants died during the 12-month study period, of whom 10 in the intervention group and 11 in the control group. In both groups, most participants who lived in a residential care home died there (intervention: $n = 5/6$; control: $n = 8/8$). Of 6 deceased community-dwelling participants, 3 died at home (intervention: $n = 1/2$; control: $n = 2/4$), 2 in a hospital (intervention: $n = 1/2$; control: $n = 1/4$) and 1 participant from the control group died at a palliative care institution. Medical file analyses were conducted for 96 out of 101 adults in the intervention group and 92 out of 100 adults in the control group. Analyses for files of the care organisation were conducted for 97 out of 101 adults in the intervention group and 97 out of 100 adults in the control group. Files of the remaining participants could not be

accessed because either the participants ($n = 7$) or their GPs ($n = 6$) did not consent (Figure 1).

Characteristics

Table 1 presents characteristics of 194 participants of whom data concerning use of medical care, inpatient days in residential care homes and/or home care were available. Their mean age was 86 years (standard deviation (SD): 5.5). Characteristics were comparable between study groups, except for education level, which was higher in the intervention group ($p = 0.004$).

ACP programme costs

Fixed programme costs for the preparation phase amounted to €21,754. The average number of facilitated conversations per participant was 1.6 (based on information provided for 90 participants). The variable costs for conducting these conversations were on average €76 per participant (Table 2).

Healthcare use and costs

Table 3 gives an overview of the use and costs of medical care per participant in each study group. Total average costs of medical care during 12 months of follow-up did not differ significantly between intervention and control group (€2360 vs €2235, respectively, $p = 0.36$).

The average costs of medical care for residents of care homes were €2435 in the intervention group vs €1651 in the control group ($p = 0.33$, Figure 2). In total, 96 participants received care in a residential care home during 12 months of follow-up; the corresponding

Table 1. Characteristics of the study population ($n = 194$).

Characteristic	Intervention group ($n = 97$)	Control group ($n = 97$)	p value ^a
Age, mean (SD)	86 (5.8)	87 (5.2)	0.26
Gender, n (%)			0.53
Female	66 (68)	70 (72)	
Marital status, n (%)			0.79
Married / cohabiting	19 (20)	19 (20)	
Not married	8 (8)	8 (8)	
Divorced	6 (6)	3 (3)	
Widow(er)	64 (66)	67 (69)	
Education level ^b , n (%)			0.004
Low	25 (26)	46 (48)	
Middle	62 (64)	40 (42)	
High	10 (10)	10 (10)	
Missing	–	1	
Multimorbidity ^c , n (%)			0.95
Yes	46 (48)	46 (47)	
Missing	1	–	
Type of residence, n (%)			0.06
Care home	38 (39)	51 (53)	
Community-dwelling	59 (61)	46 (47)	
Frailty, Tilburg Frailty Index (TFI), mean (SD) ^d	7.4 (1.8)	7.5 (2.1)	0.54
Competence, Mini-Mental State Examination (MMSE), mean (SD) ^e	27 (2.4)	26 (2.7)	0.13
Patient activation, Patient Activation Measure (PAM-13) ^e			
Mean baseline (SD) ^f	52 (8.8)	52 (10.4)	0.79
Mean follow-up (SD) ^f	52 (10.3)	51 (8.8)	0.61
Generic quality of life, SF-12 physical component score ^e			
Mean baseline (SD) ^f	31 (10.1)	33 (9.1)	0.22
Mean follow-up (SD) ^f	32 (10.1)	34 (8.8)	0.16
Generic quality of life, SF-12 mental component score ^e			
Mean baseline (SD) ^f	52 (9.9)	50 (10.0)	0.24
Mean follow-up (SD) ^f	48 (10.9)	46 (12.0)	0.40

SD: standard deviation.

^a p value based on chi-square test or ANOVA.

^bEducation level was defined as the highest educational qualification achieved (low = none or primary education; middle = secondary education; high = higher professional or university education).

^cMultimorbidity: ≥ 2 diseases or chronic disorders.

^dHigher scores indicate worse functioning.

^eHigher scores indicate better functioning.

^fNumber of participants for whom this information is missing, $n = 39$.

average costs of care were €41,551 in the intervention group and €46,533 in the control group (Table 4).

The average costs of medical care for community-dwelling adults were €2312 in the intervention group vs €2947 in the control group ($p = 0.16$, Figure 2). The average costs of home care were €14,091 in the intervention group and €17,361 in the control group, based on 102 adults who received care at home (Table 4).

Whether goals of hospital stays, diagnostic procedures and medical interventions were curative or palliative was often not recorded in medical files. This complicated the assessment of the extent to which care as provided was concordant with the preferences on an individual level. Overall,

the number of hospital stays, diagnostic procedures and medical interventions was low in both study groups. For instance, none of the participants in the intervention group received cardiopulmonary resuscitation vs 1 participant in the control group. We found no differences on group level in the use of medical care.

Discussion

Main findings

This is the first trial to investigate the costs of ACP and the effects of ACP on broad healthcare costs in frail older adults

Table 2. Costs of Advance Care Planning (ACP) programme.

	Total costs (€)	Costs per participant (€)
Preparation, fixed costs		
Respecting Choices facilitator and train-the-trainer programmes:		
- Costs programmes	1700	
- Travel and accommodation (14 days) costs Dutch trainer	2520	
- Working hours Dutch trainer	1600	
Translation and adaptation ACP materials ^a	4429	
Translation and adaptation training programme for facilitators	5301	
Training for facilitators within the context of the study ($n = 8$)	6204	
Total fixed costs	21,754	
ACP programme, variable costs		
Average personnel costs of facilitators (3.3 h ^b , *€19)		63
Average travel costs of facilitators for visiting participants at home ^c		13
Total average variable costs		76

^aMaterials included the captioning of an informative DVD about ACP for facilitators, scripted interview cards, the advance directive and information leaflets for participants.

^bThe average number of facilitated conversations was 1.6, while the average length per facilitated conversation was approximately 2 h (based on information provided for 90 participants) = 3.3 h per facilitated conversation per participant.

^cTravelling costs of facilitators amounted to €0.27/km (on average, 29 km per facilitated conversation; *1.6 facilitated conversations).

Table 3. Use and costs of medical care per participant ($n = 194$).

Cost by category	Cost price (€)	Intervention group ($n = 97$)		Control group ($n = 97$)		p value ^a
		Average volume	Average costs (€)	Average volume	Average costs (€)	
Hospital care ^b						
ED visit	259	0.41 visits	105	0.43 visits	113	
Hospitalisation	476	3.50 days	1666	3.62 days	1723	
ICU care	1186	0.15 days	173	0.03 days	39	
Total hospital care			1944		1874	0.38
Diagnostic procedures ^b						
Blood transfusion	308	0.02	6	0.04	13	
CT scan	138	0.10	14	0.13	18	
Echography	85	0.06	5	0.05	5	
MRI scan	217	0.02	5	0.01	2	
X-ray	58	0.33	19	0.24	14	
Biopsy	126	0.02	3	0.00	0	
Total diagnostics			53		52	0.69
Medical interventions ^b						
Surgery	Variable	0.11	349	0.11	503	
Cardiopulmonary resuscitation	65	0.00	0	0.01	1	
Total medical interventions			349		504	0.55
Medication ^c	Variable		134		7	0.21
Total costs medical care ^d			2360		2235	0.36

^aAdjusted for cluster, education level and residence.

^bNumber of participants for whom this information is missing, $n = 6$ (intervention group, $n = 1$ and control group, $n = 5$). Radiotherapy and artificial ventilation were not applicable.

^cNumber of participants for whom this information is missing, $n = 8$ (intervention group, $n = 2$ and control group, $n = 6$). Only costs of expensive medication (cost price of >€10 per day) have been calculated (applicable for $n = 8$ participants in the intervention group and $n = 2$ participants in the control group).

^dNumber of participants for whom this information is missing, $n = 11$ (intervention group, $n = 5$ and control group, $n = 6$).

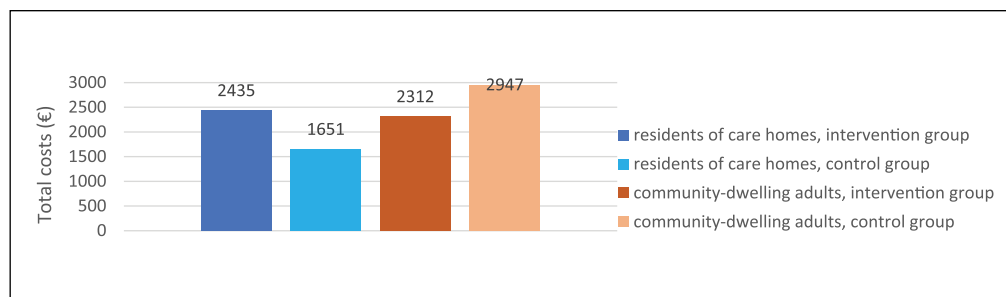


Figure 2. Costs of medical care per participant ($n = 194$).

Table 4. Use and costs of inpatient days in residential care homes and home care ($n = 194$).^a

Cost by category	Cost price (€)	Intervention group ($n = 97$)		Control group ($n = 97$)	
		Average volume	Average costs (€)	Average volume	Average costs (€)
Care in residential care home/nursing home (applicable for $n = 96$ in total, of whom $n = 40$ in intervention and $n = 56$ in control group)	67–277 ^b per day	334 days	41,551	341 days	46,533
Home care (applicable for $n = 102$ in total, of whom $n = 57$ in intervention and $n = 45$ in control group)	50 per hour	282 h	14,091	347 h	17,361

^aNumber of participants for whom this information is missing, $n = 4$ (intervention group, $n = 3$ and control group, $n = 1$).

^bAdults residing in Dutch care homes/nursing homes have a care intensity package (ZZP). According to this package we calculated costs per day (Source: Nederlandse Zorgautoriteit). In our study population, costs varied between €67 (lowest care intensity package) and €277 (highest care intensity package) per day.

in a European country. We conclude that variable costs for the ACP programme are limited. Average costs of medical care (including hospital care, diagnostic procedures, medical interventions and medication) did not differ significantly between study groups. Average costs of inpatient days in residential care homes and home care were not significantly different either. Concordance of received care with preferences could not be assessed on individual level since treatment goals (curative or palliative) were often not recorded in medical files.

Interpretation of results

An increasing number of scientific ACP publications worldwide, an increased number of ACP programmes, initiatives to develop ACP laws and public awareness campaigns indicate that the interest in ACP is growing.⁴⁰ Despite this growing interest, we found limited literature on programme costs for ACP. Studies that report on ACP programme costs show that costs of the ACP programme per participant vary between €76 (US\$89) in a nursing home setting⁵ and €1676 (US\$1968) in a primary care setting.¹⁴ Corresponding cost savings were €1177 (US\$1381) per participant over 12 months⁵ and €9573 (US\$11,239) per participant over 6 months,¹⁴ respectively. While we did not

find cost savings in our study, we found that variable costs for an extensive ACP programme were limited (€76).

ACP has previously been found to be associated with reduced healthcare costs,^{5,6,8,10–12,14,16,18,19,22,24–26} which may be related to adults choosing less invasive medical interventions after having engaged in ACP.²⁷ In our study population, many adults indeed preferred comfort care above maximum treatment (Supplementary file S2). Since no significant effect of ACP on the level of patient activation was found,³³ we could not assess the cost-effectiveness of ACP. Instead, we conducted a cost-minimisation study. Medical care costs were somewhat lower among community-dwelling adults in the intervention versus the control group (€2312 vs €2947, respectively). This may indicate that ACP especially affects costs of medical care while adults are community-dwelling. Overall, we did not find an effect of ACP on costs of medical care, which might be explained by several factors.

First, we might have studied a selective population of frail older adults. Costs of medical care in frail older adults are generally considered to be relatively high.³ In the Netherlands, the average costs per year per person of hospital care as covered by standard healthcare insurance were €3059 in 2014 for adults aged ≥ 80 years.⁴¹ Costs of hospital care in our study population were relatively low: €1910 per participant. This suggests that the health status

of these frail study participants might have been better than that of the average frail older person. The mortality rate of 10% ($n = 21/201$) during the 12-month study period is comparable to the average mortality rate of adults aged 86 years,⁴² but lower than we expected, as all study participants were frail and received care. ACP may affect costs of care especially during the last year of life, when costs are generally high.⁴³

Second, the Dutch healthcare context concerning life-prolonging interventions may partly explain our findings. Decisions to withhold or withdraw potentially life-prolonging intervention are more common in the Netherlands compared to other European countries.⁴⁴ This has been partially attributed to the open public debate on end-of-life decision-making. In addition, Dutch healthcare is often suggested to be characterised by a tendency of avoiding overtreatment for older adults.⁴⁵ This may explain the low numbers of invasive medical interventions and may indicate that there is less to be 'gained' from ACP in terms of preventing overtreatment. This may also explain that healthcare costs mainly concerned costs of inpatient days in residential care homes and home care. Although ACP currently receives a lot of attention in the Netherlands, in education, clinical practice and in societal debates,^{46–48} ACP is not yet broadly implemented in the Netherlands and current ACP practices seem to mainly involve the completion of ADs rather than facilitated ACP conversations with trained healthcare providers.

Strengths and limitations of the study

Strengths of this study include its randomised controlled design, the use of standardised ACP involving facilitated planning conversations and the high rate of intervention group participants who completed the ACP programme. In addition, we were able to calculate both fixed and variable costs of the ACP programme and included core cost categories (hospital care, several diagnostic procedures, medical interventions and medication) in our economic evaluation. Our study has some limitations as well. Our analyses of medical care were limited to GP medical files. However, hospital discharge letters are usually included in GP medical files, so the amount of information missed is probably limited. Therefore, we do not expect that only having access to GP files largely impacted our findings on costs and on concordance levels of received care with preferences. In addition, we were not able to determine whether ACP enhances provision of care that is consistent with patients' preferences on individual level. Findings on group level have to be interpreted with caution, given the low number of hospital stays, diagnostic procedures and medical interventions. Several ACP experts raised caution about whether 'care consistent with goals' can be reliably

measured due to a lack of standardised methods and changing preferences for care.⁴⁹

Implications of our study and future research

Cost studies provide important additional information for healthcare organisations that plan to implement ACP. Given the limited costs of our extensive ACP programme and earlier reported results of the ACP trial (higher completion rates of ADs, an increase in the appointment of surrogate decision makers and positive evaluations of facilitated ACP conversations), healthcare providers may consider providing ACP to frail older adults. In our study context, facilitators on average delivered the ACP programme to 13 patients. Outside a study context facilitators can obviously continue to deliver the ACP programmes. Further research is needed to determine how to best define and assess the concordance of care with preferences, which is the most relevant ACP outcome according to ACP experts.⁴⁹ Furthermore, future research might incorporate a longer study period and ideally monitor use of care until death to be able to measure the full impact of ACP on costs of medical care. Future research might also investigate whether the use of trained ACP facilitators reduces the time investment of GPs to discuss preferences for medical care with their patients and of physicians to make medical decisions in the future.

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Data management and sharing

Requests for patient-level data and statistical code should be made to the corresponding author and will be considered by the management group who, although specific consent for data sharing was not obtained, will release data on a case by case basis following the principles for sharing patient-level data. The presented data do not contain any direct identifiers, we will minimise indirect identifiers and remove free text data, to minimise the risk of identification.

Declaration of conflicting interests

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