CLINICAL INVESTIGATION

Advance Care Planning in Frail Older Adults: A Cluster Randomized Controlled Trial

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OBJECTIVES: To determine the effectiveness of advance care planning (ACP) in frail older adults.
DESIGN: Cluster randomized controlled trial.
SETTING: Residential care homes in the Netherlands (N=16).
PARTICIPANTS: Care home residents and community-dwelling adults receiving home care (N=201; n=101 intervention; n=100 control). Participants were 75 years and older, frail, and capable of consenting to participation.
INTERVENTION: Adjusted Respecting Choices ACP program.
MEASUREMENTS: The primary outcome was change in patient activation (Patient Activation Measure, PAM-13) between baseline and 12-month follow-up. Secondary outcomes included change in quality of life (SF-12), advance directive (AD) completion, and surrogate decision-maker appointment. Use of medical care in the 12 months after inclusion was also assessed. Multilevel analyses were performed, controlling for clustering effects and differences in demographics.
RESULTS: Seventy-seven intervention participants and 83 controls completed the follow-up assessment. There were no statistically significant differences between the intervention (–0.26±11.2) and control group (–1.43±10.6) in change scores of the PAM (p=.43) or the SF-12. Of intervention group participants, 93% completed an AD, and 94% appointed a decision-maker. Of control participants, 34% completed an AD, and 67% appointed a decision-maker (p<.001). No differences in the use of medical care were found.
CONCLUSIONS: ACP did not increase levels of patient activation or quality of life but did increase completion of ADs and appointment of surrogate decision-makers. It did not affect use of medical care. **J Am Geriatr Soc 2018.**

Key words: advance care planning; patient activation; frailty; older adults; randomized controlled trial

Advance care planning (ACP) aims to prepare and to activate individuals to take a role in healthcare decision-making.[1] ACP is a process that enables individuals to define goals and preferences for future medical treatment and care, to discuss these with family and healthcare providers, and to record and review preferences if appropriate.[1] Individuals who have completed an advance directive (AD) are more likely to receive care that aligns with their preferences.[2]

ACP may be especially relevant for frail older adults given the high prevalence of conditions that might affect communication about future healthcare decisions.[3] A recent review of ACP in older adults included 9 randomized controlled trials predominantly conducted in nursing home populations in North America and Australia.[4] Most ACP programs resulted in higher AD completion rates and greater likelihood of appointment of surrogate decision-makers.[4] One of the 9 studies reported significantly lower hospitalization rates in ACP participants.[5] It is unknown whether these results can be generalized to European countries or to frail, cognitively competent older adults.

The extent to which ACP can support frail older adults to become more active in their health and care, and how such activation may affect their quality of life and other health outcomes, is unknown. Patient activation refers to the knowledge, skills, and confidence that equip individuals to be actively engaged in their healthcare.[6] Hibbard's conceptual model of patient activation

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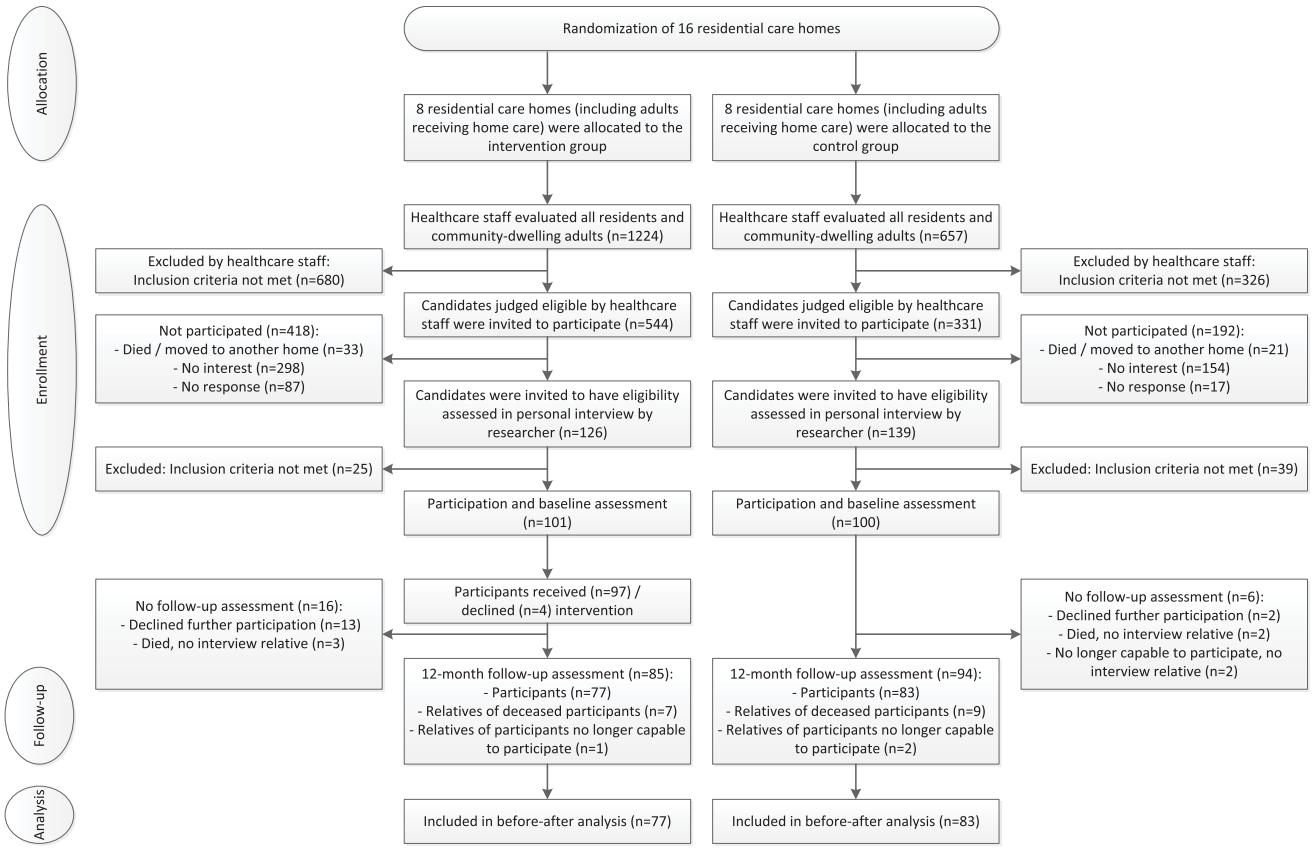

Figure 1. Consolidated Standards Of Reporting Trials flow chart.

postulates that modifiable social-environmental factors (e.g., support) can influence activation levels, which in turn can influence health outcomes.[7] Previous studies in younger adults have showed that community-based interventions can increase patient activation.[8,9]

We performed the first cluster randomized controlled trial on the effects of ACP in frail, older, cognitively competent adults in Europe. We assessed the feasibility of ACP in this population and hypothesized that ACP increases patient activation, quality if life, satisfaction with healthcare, completion of ADs, and appointment of surrogate decision-makers while reducing the use of medical care.

METHODS

Trial design and participants

We conducted a cluster randomized controlled trial among frail older adults, following the Consolidated Standards Of Reporting Trials guidelines (Figure 1).[10] To be eligible for participation, individuals had to be aged 75 and older, frail (Tilburg Frailty Index score $\geq$5, range 0–15),[11] and capable to consent to participation (Mini-Mental State Examination score $\geq$17, unadjusted for education level[12,13]). Participants lived in residential care homes or in the immediate surroundings while receiving home care. In 2013, all residential care homes of a large care organization with potentially eligible residents were identified. Healthcare staff screened all residents of the participating 16 residential care homes and all community-dwelling adults who lived in the immediate surroundings and received home care for eligibility. The research team subsequently confirmed eligibility using the instruments described above.

Randomization

We used a cluster randomized design. Because income is an important indicator of socioeconomic status and is associated with patient activation,[7] we controlled for differences in income between study groups. We ordered the 16 residential care homes according to standardized household incomes per neighbourhood, which ranged between €15,200 ($18,449) and €39,200 ($46,358).[14] Then we randomized residential care homes per set of two with comparable household incomes using a computer-generated list of random numbers. Because of the study design and the nature of the intervention, participants, healthcare staff, and researchers could not be masked to allocation status.

Intervention

The intervention group was offered facilitated planning conversations based on the Respecting Choices ACP facilitator training, education materials, and tools. This U.S. program,[15] which involves trained facilitators who assist

individuals in exploring the understanding of their illness; reflecting on goals, values, and beliefs; discussing healthcare preferences; and appointing a surrogate decision-maker, was modified for use in this Dutch context. Nurses who were employed by the care organization could apply for the role of facilitator. Eight nurses were selected based on criteria such as being able to talk about the end of life and having an open attitude toward individual's preferences and were trained to deliver the intervention. The training lasted 3 days and included role plays and homework assignments. Our intervention had 3 core elements: information provision through leaflets; facilitated ACP conversations based on scripted interview cards; and completion of an AD, including appointment of a surrogate decision-maker. See Supplementary Figure S1 and Supplementary Tables S1 and S2 for a detailed description of the ACP program. Intervention fidelity was assessed by determining whether participants received information leaflets, whether interview cards were used during ACP conversations, and whether participants provided a copy of their study AD. Feasibility of the ACP intervention was determined as whether older adults wanted to participate in our study, whether participants engaged in the ACP program, and whether participants in the intervention group provided a copy of their study AD.

Outcomes Measures

Because ACP aims to prepare and to activate individuals to take a role in healthcare decision-making, we chose the 13-item Patient Activation Measure (PAM) as the primary outcome measure (range 0–100).[16] The PAM measures individuals' knowledge, skills, and confidence to manage their health and healthcare. It consists of 13 items with 5 response options each: disagree strongly, disagree, agree, agree strongly, not applicable. We calculated a standardized activation score ranging from 0 to 100. A change of at least 4 points is considered clinically meaningful.[17] The PAM is a reliable and valid measure with good psychometric properties[6,16] and appeared to be valid in a study of older adults with multimorbidity.[18]

Secondary outcome measures were quality of life, satisfaction with healthcare, documentation of care preferences in an AD, appointment of a surrogate decision-maker, and use of medical care. Generic health-related quality of life was measured using the 12-item Short-Form Health Survey (SF-12)[19] which generates a physical component score (PCS; range 0–100) and a mental component score (MCS; range 0–100). General satisfaction with healthcare was measured using 1 subscale of the Patient Satisfaction Questionnaire (PSQ-18; range 1–5).[20] Documentation of care preferences and appointment of a decision-maker were measured by asking: "Did you ever record the care or treatment you do or do not want to receive in writing?" (yes; no; I don't know) and "Have you appointed a surrogate-decision-maker?" (yes, orally; yes, in writing; no). We also asked participants in the intervention group who completed a study AD to provide us with a copy. We assessed whether participants' general practitioner (GP) medical files contained an AD, and registered the medical care that the participant received during the 12 months after inclusion.

Procedures

This trial was registered at the Netherlands Trial Registry (NTR4454). In 2014, potential candidates were sent a letter with study information. In the intervention clusters, this letter contained an invitation to attend an informative meeting about the intervention, which took place in each intervention care home before the interviews. Subsequently, we approached candidates in person or over the telephone to ask whether they were interested in participating in the study, unless they had already declared that they were not interested. During the first personal interview at the participant's home (either in a residential care home or in the community), researchers answered candidates' questions and assessed their eligibility. If candidates were willing to participate and were eligible, a second personal interview was arranged at the participant's home, during which written informed consent was obtained, the baseline assessment was completed, and participants received information leaflets. Intervention participants subsequently engaged in the ACP program. After 12 months, the researcher approached participants to complete the follow-up assessment at the participant's home. If participants were no longer capable to participate (based on assessment using the Mini-Cog[21]) or had died, we approached a relative for a telephone interview.

Statistical Analysis

We aimed at an overall power of 0.8 (alpha 0.05) to detect a difference of at least 0.5 standard deviations in PAM score. In a nonclustered study, this required 63 individuals per group. To adjust for the clustering effect, we used a multiplication factor of (1+(k-1)* intraclass correlation coefficient (ICC)), with k indicating the average cluster size (12 individuals). For an ICC of 0.05, we thus needed to include 98 (1.55*63) participants in each group.

Statistical analyses were according to intention to treat. Personal characteristics of the study groups at baseline were compared using chi-square tests and analysis of variance. Outcomes were compared using multilevel analyses, which were adjusted for clustering effects at residential care home level and differences in demographic characteristics between study groups. Differences were considered significant at $p<.05$.

Ethics

The Research Ethics committee of Erasmus MC approved the study (MEC-2013–516, NL.46444.078.13).

RESULTS

Participation and Feasibility

The inclusion process is presented in Figure 1; 201 of 811 eligible older adults participated in our study. Reasons for nonparticipation were that adults had died or moved (n=54), had no interest in the project (n=452), or did not reply to the invitation (n=104). The number of participants varied from 1 to 53 across the 16 participating clusters, with a mean cluster size of 12.5. A sensitivity

Table 1. Baseline Characteristics of Study Population

Characteristics	Intervention Group, n = 101	Control Group, n = 100	P-Value
Age, mean ± SD (range)	86 ± 6.0 (75–102)	87 ± 5.2 (73–101)	.32
Female, n (%)	69 (68)	72 (72)	.57
Marital status, n (%)			.65
Married or cohabiting	19 (19)	20 (20)	
Not married	8 (8)	8 (8)	
Divorced	7 (7)	3 (3)	
Widowed	67 (66)	69 (69)	
Education level, n (%)			.002
≤Primary	26 (26)	48 (49)	
High school	65 (65)	40 (40)	
University	10 (10)	11 (11)	
Missing	0	1	
Residence, n (%)			.08
Care home	39 (39)	51 (51)	
Community	62 (61)	49 (49)	
Tilburg Frailty Index score, mean ± SD (range)[a]	7 ± 1.9 (5–13)	8 ± 2.2 (5–14)	.33
Mini-Mental State Examination score, mean ± SD (range)[b]	27 ± 2.5 (20–30)	26 ± 2.6 (20–30)	.19

[a]Normal range 0–15. Higher scores indicate worse functioning.
[b]Normal range 0–30. Higher scores indicate better functioning.
SD = standard deviation.

analysis excluding the two n=1 clusters did not change the results. Mean age of participants was 87. Characteristics were balanced between study groups (Table 1), except for education level. Seventy-seven of 101 participants in the intervention group and 83 of 100 in the control group completed the PAM (primary outcome measure) at baseline and follow-up assessment. The corresponding attrition rates were 24% and 17%, respectively. Nineteen relatives of participants who had died or were no longer capable of participating at follow-up provided information on secondary outcome measures (e.g., AD completion). Therefore, follow-up assessments were conducted for 85 of 101 intervention participants, including interviews with relatives of participants who had died (n=7) or were no longer capable of participating (n=1). Follow-up assessments were conducted for 94 of 100 control participants, including interviews with relatives of participants who had died (n=9) or were no longer capable of participating (n=2; Figure 1). Finally, medical file analyses were conducted for 96 intervention participants and 92 control participants. Medical files for the remaining participants could not be accessed because participants (n=7) or their GPs (n=6) did not consent.

Intervention Delivery and Fidelity

All 97 (96%) intervention participants who received information leaflets received the ACP program, and interview cards were used with all 97 ACP participants, 80 of whom provided a copy of their study AD, and 78 of whom appointed a surrogate decision-maker. The average number of facilitated conversations per participant was 1.6 (based on information provided for 90 participants); 40 (44%) had one facilitated conversation, 46 (51%) had two, and 4 (4%) had three. The average conversation was 125 minutes long, including travel time of facilitators. The average time between the baseline assessment and completion of study ADs was 47 days (range 5–185). In follow-up interviews, 54 of 75 (72%) surviving participants who engaged in the ACP program reported positive experiences, 1 (1%) reported a negative experience, 10 (13%) were ambivalent, and 10 (13%) did not remember the facilitated conversations sufficiently; 59 (79%) considered the facilitated conversation useful (Supplementary Table S3).

Primary and Secondary Outcome Measures

Overall PAM change scores did not differ significantly between the intervention (–0.26) and control group (–1.43) (p=.43) (Table 2). The ICC for the PAM was 0. Differences between groups per item were insignificant (p>.05, Supplementary Table S4).

Neither SF-12 change scores (PCS: 0.95 vs 1.15, p=.98; MCS: –4.63 vs –4.20, p=.71) nor PSQ-18 subscale change scores (–0.08 vs 0.02, p=.90) differed between the intervention and control group (Table 2). In the intervention group, more participants had completed an AD at 12 months than in the control group (n=78, 93% vs n=31, 34%; p<.001, Table 3). Some adults completed several ADs, for instance, the study AD and a do-not-resuscitate order. Seventy-five intervention group participants (89%) completed the study AD. Most control participants who had completed an AD had done this before the start of our study (n=25/31, 81%), and most often, they had completed a do-not-resuscitate order (n=23/31, 74%). For 37 of 96 (39%) intervention participants and 18 of 92 (20%) control participants, one or more ADs were identified in the medical file. These ADs included 32 study ADs in files of intervention participants. More participants in the intervention group than in the control group had appointed a surrogate decision-maker (n=80, 94% vs n=62, 67%; p<.001). The majority of the intervention group (89%) appointed their decision-maker in writing, whereas the majority of the control group (63%) did so orally

Table 2. Outcome Measures of the Study Population

	Baseline Score		Follow-Up Score (12 Months)		Change Score		
	Intervention, n = 77	Control, n = 83	Intervention, n = 77	Control, n = 83	Intervention, n = 77	Control, n = 83	P-Value[a]
Outcome	**Mean ± Standard Deviation**						
Patient Activation Measure[b]	52 ± 8.9	52 ± 10.2	52 ± 10.2	51 ± 8.9	–0.26 ± 11.20	–1.43 ± 10.61	.43
12-item Short-Form Health Survey[b]							
Physical component score	31 ± 10.0	33 ± 9.0	32 ± 10.1	34 ± 8.8	0.95 ± 10.98	1.15 ± 9.82	.98
Mental component score	52 ± 9.9	50 ± 10.3	48 ± 10.8	46 ± 12.1	–4.63 ± 11.75	–4.20 ± 11.25	.71
2 items (1 subscale) of Patient Satisfaction Questionnaire[c]	4 ± 0.8	4 ± 0.8	4 ± 0.8	4 ± 0.7	–0.08 ± 0.94	0.02 ± 0.95	.90

[a]Differences in change scores between study groups, adjusted for cluster, education level, and residence.
[b]Normal range 0–100. Higher scores indicate better functioning. Missing for patient activation and generic quality of life, n = 1.
[c]Normal range 1–5. Higher scores indicate better functioning.

(p<.001). We found no effect of ACP on use of hospital care, diagnostic procedures, or a selection of medical interventions (Supplementary Table S5).

DISCUSSION

This is the first cluster randomized controlled trial on the effects of ACP in frail, cognitively competent older adults in Europe. No effect of ACP on degree of patient activation, quality of life, satisfaction with healthcare, or medical care use was found, although we found an effect on completion of ADs and appointment of surrogate decision-makers.

This study has several strengths. First, older adults were offered standardized ACP based on the Respecting Choices facilitation training, an internationally recognized ACP program.[15] The program was feasible in these frail older adults; approximately one-quarter of eligible older adults participated, and almost the entire intervention group engaged in the ACP program, completed an AD, and appointed a surrogate decision-maker. Second, we conducted personal interviews, providing participants the opportunity to ask for clarification when needed. This study also has limitations. First, our power calculations did not account for expected loss to follow-up, and attrition in the intervention group (24%) was somewhat higher than in the control group (17%). It is unclear whether this affected the outcomes of our study, although it seems unlikely given the small size of the difference.[22] Second, two clusters contained only one participant. Third, our response rate was modest, although it was comparable with, or even higher than, response rates of similar studies.[23,24] Fourth, outcome assessors could not be blinded to participant allocation because of the nature of the follow-up assessment. Fifth, the context of a randomized controlled trial, which requires several appointments and completion of questionnaires, differs from daily practice, where ACP could be more effective. Finally, our analyses of medical care use were limited to GP medical files, although hospital discharge letters were usually included in GP medical files, so the amount of information missed is probably limited.

At 1-year follow-up, nearly all participants in the intervention group had completed an AD (93%) and had appointed a surrogate decision-maker (94% overall, 89% in writing). These numbers are higher than in most other trials.[4] The increased AD completion is important because ADs have been shown to increase the consistency of care with patients' goals and person-centered care.[1] ADs were identified more often in the medical files of intervention

Table 3. Completion of Any Advance Directive (AD) at 12-Month Follow-Up

Outcome	Intervention, n = 85	Control, n = 94	P-Value[a]
Completed AD, n (%)[b]	78 (93)	31 (34)	<.001
Type of AD, n (%)[c]			
Study AD	75 (89)	Not applicable	
Other AD	5 (6)	8 (9)	
Do not resuscitate	11 (13)	23 (25)	
Do not treat	3 (4)	3 (3)	
Communicated about AD with[d]:			
Family (partner, children)	67/78 (86)	24/29 (83)	.56
Other family and friends	13/78 (17)	4/29 (14)	.82
General practitioner	64/78 (82)	20/29 (69)	.22
Other healthcare provider	40/78 (51)	14/29 (48)	.43
Had appointed decision-maker[e], n (%)	80 (94)	62 (67)	<.001
Orally	9 (11)	39 (63)	<.001
In writing	71 (89)	23 (37)	

Data according to participants (intervention, n = 77; control, n = 83) and relatives of deceased (intervention, n = 7; control, n = 9) or incapable (intervention, n = 1; control, n = 2) participants.
[a]Differences between study groups, adjusted for cluster, education level, and residence.
[b]Missing, n = 3. Sixty percent of intervention participants who completed an AD were community-dwelling; among controls who completed an AD, 65% lived in a residential care home.
[c]Missing, n = 3. More than 1 answer possible.
[d]Missing, n = 2. More than 1 answer possible.
[e]Missing, n = 1.

group participants (39%) than in those of the control group (20%). This is important because written ADs in the medical file may be more likely to influence care.

In our control group, rates of AD completion (34%) and surrogate decision-maker appointment (67% overall, 37% in writing) were rather high.[4] Studies in the Netherlands reported estimations of AD completion varying from 5% to 16% for different age groups.[25–27] Most ADs in the control group were do-not-resuscitate orders that care home residents had completed before the study. The relatively high AD completion rate in the control group may be related to recent societal debates concerning ACP. For instance, the Royal Dutch Medical Association released a public awareness campaign in 2015 recommending ACP.[28] We observed no significant differences between the intervention and control group in rate of communication about completed ADs, but because our study resulted in more adults completing ADs (93% intervention group, 34% control group), our study also resulted in more communication about ADs. It would have been difficult to achieve higher rates of communication about completed ADs in the intervention group than in the control group, because people in the control group with a completed AD communicated about their AD frequently.

We did not find an effect of the adapted Respecting Choices ACP facilitation on patient activation, quality of life, satisfaction with healthcare, or use of medical care. This is striking, because several other studies have reported positive effects of standardized ACP programs on various outcomes. For instance, the Respecting Choices program increased satisfaction of older hospitalized adults in Australia.[23] Respecting Choices also improved ACP knowledge and decreased willingness of older ambulatory U.S. adults to undergo life-sustaining treatments.[24]

The lack of effect found in our study might have several explanations. The first possible explanation relates to implementation of our ACP program. We used the core part of the Respecting Choices ACP program but could not implement it system-wide. At 12-month follow-up, only 32 study ADs were included in GP medical files.

Our second explanation relates to the choice of outcome measurements and their timing. Given the high mean age (87) of participants, the low death rate (10%) during 12 months of follow-up was surprising. Healthcare use and related costs of care in the last year of life are 13.5 times as high as in an average life year.[29] It may be that not many important healthcare decisions had to be made within the study period, and hence, we may have not been able to measure the full effect of ACP on medical care use. ACP covers many domains[30] and may have intermediate (e.g., completion of ADs) and downstream effects (e.g., use of medical care). Although many intervention participants appreciated ACP, the effects of our ACP program on patient activation, quality of life, and satisfaction with healthcare might have been greater shortly after the intervention and diminished over time. Proper timing of ACP deserves further debate.[31]

Third, the specific Dutch healthcare context may explain our findings. Decisions to withhold or withdraw potentially life-prolonging treatment are more common in the Netherlands than in other European countries.[32] This has been partially attributed to the open public debate on end-of-life care and decision-making. In addition, Dutch healthcare has a history of avoiding overtreatment. For instance, Dutch nursing home residents are hospitalized less frequently and receive less aggressive care than U.S. nursing home residents,[33] which may mean that there is less to be gained from ACP.

Interest in ACP is growing,[30] and current developments show that ACP is increasingly becoming part of usual care. Future ACP research should investigate the effects of ACP while considering the effect of culture, study population, and study setting. In addition, more insight is needed into appropriate outcome measures of ACP and their timing. We also need to identify the effective components of ACP, as well the best way to integrate ACP into the healthcare system. ACP may not be a panacea.[30] To conclude, our study did not find positive effects of ACP on downstream outcome measures including levels of patient activation and quality of life, although we observed higher AD completion rates after ACP, including a significant increase in the written appointment of surrogate decision-makers, and did not find any harmful effects of ACP. In addition, many participants appreciated facilitated ACP conversations. Therefore, healthcare staff may consider providing ACP to frail older adults and their relatives.

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Conflict of Interest: Bernard Hammes is one of the developers of Respecting Choices and reports receiving personal fees from Gundersen Health unrelated to this work.

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SUPPORTING INFORMATION

Additional Supporting Information may be found in the online version of this article.

Table S1: Elements of our Advance Care Planning (ACP) program.

Table S2: Detailed information about our Advance Care Planning (ACP) program.

Figure S1: Study advance directive.

Table S3: Open questions about facilitated conversations at 12 months.

Table S4: Effect of Advance Care Planning (ACP) on PAM items.

Table S5: Use of medical care by study groups.

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