


The Effect of Health Literacy on a Brief Intervention to Improve Advance Directive Completion: A Randomized Controlled Study

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Paige C. Barker¹, Neal P. Holland¹, Oliver Shore¹, Robert L. Cook¹,
Yang Zhang¹, Carrie D. Warring¹, and Melanie G. Hagen¹ 

Abstract

Objective: Completion of an advance directive (AD) document is one component of advanced care planning. We evaluated a brief intervention to enhance AD completion and assess whether the intervention effect varied according to health literacy. **Methods:** A randomized controlled study was conducted in 2 internal medicine clinics. Participants were over 50, without documented AD, no diagnosis of dementia, and spoke English. Participants were screened for health literacy utilizing REALM-SF. Participants were randomized in a 1:1 ratio to the intervention, a 15-minute scripted introduction (grade 7 reading level) to our institution's AD forms (grade 11 reading level) or to the control, in which subjects were handed blank AD forms without explanation. Both groups received reminder calls at 1, 3, and 5 months. The primary outcome was AD completion at 6 months. **Results:** Five hundred twenty-nine subjects were enrolled; half were of limited and half were of adequate health literacy. The AD completion rate was 21.7% and was similar in the intervention vs. the control group (22.4% vs 22.2%, $P = .94$). More participants with adequate health literacy completed an AD than those with limited health literacy (28.4% vs 16.2%, $P = .0008$), although the effect of the intervention was no different within adequate or limited literacy groups. **Conclusion:** A brief intervention had no impact on AD completion for subjects of adequate or limited health literacy. **Practice Implications:** Our intervention was designed for easy implementation and to be accessible to patients of adequate or limited health literacy. This intervention was not more likely than the control (handing patients an AD form) to improve AD completion for patients of either limited or adequate health literacy. Future efforts and research to improve AD completion rates should focus on interventions that include: multiple inperson contacts with patients, contact with a trusted physician, documents at 5th grade reading level, and graphic/video decision aids.
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Keywords

advance directives, health literacy, primary care, geriatrics, palliative care

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Introduction

Advance directives (AD) are written documents that allow patients to maintain their autonomy during end of life care. ADs accomplish this by clarifying patient specific preferences for difficult medical decisions, such as preference for resuscitation and intubation or whether to place an artificial feeding tube, in particular medical situations.¹ Advance care planning (ACP) is the process of multiple conversations over time to establish personal values and goals as well as preferences for future medical care and often includes completing formal AD forms.²⁻⁴ Not all experts

agree that ADs are effective at improving goal concordant care at end of life.⁵ However, AD may be utilized as a tool to begin advance care planning conversations and thus a reasonable surrogate to measure as evidence of ACP conversation. ACP has been linked to better end of life

¹University of Florida, Gainesville, FL, USA

Corresponding Author:

Paige C. Barker, Department of Medicine, University of Florida,
1329 SW 16th St, Suite 5140, Gainesville, FL 32610, USA.
Email: paige.barker@medicine.ufl.edu



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experiences,^{6,7} improved communication among healthcare providers, caregivers, and patients,^{6,8} reduction in decision making burden on families,⁶ increased satisfaction with care,³ and in some studies leads to end of life care more consistent with patient wishes.^{3,9,10}

Despite their benefits, increasing AD utilization among U.S. adults remains a challenge. In an effort to improve this, Congress passed the Patient Self-Determination Act (PSDA) in 1990. The PSDA requires all Medicare funded health care institutions to educate patients regarding ADs and the option to complete one.^{11,12} Despite this legislation, AD completion rates remain low, estimated at 18% to 36%.¹³

Health literacy, the degree to which an individual has the capacity to process, understand and communicate basic health information,⁸ is a strong predictor of whether patients complete ADs.^{11,14,15} The National Adult Literacy Survey demonstrated that limited literacy is common, showing that 48% of Americans lack the health literacy necessary to comprehend and process health information.¹⁶

Although limited health literacy is commonplace,¹⁷ many AD documents lack easy to read language and are written at too high a reading level.^{8,12,14,18} Sudore and colleagues found that an AD at 5th grade reading level and with graphics was favored by patients of both adequate and limited literacy and its use increased AD completion rates.¹⁹ At the time we designed our study, there was limited evidence on effective brief interventions to increase AD completion. One previous study found that offering patients educational materials alone did not increase the completion rates of AD,¹¹ while another study showed that explaining the importance increased AD completion.²⁰ One on one counseling with trained individuals has also demonstrated improved AD completion,²¹⁻²⁶ and these effects have been more profound in racial/ethnic minorities.^{23,26}

With these considerations in mind, our goal was to find an intervention and method of patient follow up to improve AD completion that could be quickly and easily incorporated into an ambulatory clinic and that would be effective for patients of both limited and adequate health literacy. Although many studies have demonstrated the need for personalized multi-format interventions to increase AD completion, we hoped to find an intervention that could be replicated in our clinic at one office visit and, if successful, could be done without additional personnel or resources.

The purpose of this study was to evaluate an intervention designed to enhance AD completion rates for patients in general internal medicine clinics with a single brief ambulatory intervention followed by several reminder calls. We also sought to evaluate whether the intervention's effectiveness would vary according to the health literacy of our patients. We hypothesized that both groups of patients (adequate and limited health literacy) would benefit from the intervention, but patients with limited health literacy

would show greater improvement in AD completion rate. If proven effective, clinic staff could be trained to administer the intervention, and reminders would be added to patient appointment reminder phone calls.

Methods

A randomized controlled study was completed after approval was obtained from the University of Florida Institutional Review Board, and the study was registered at clinicaltrials.gov (NCT02702284). Patients were recruited and enrolled from 2 internal medicine outpatient clinics affiliated with a large academic medical center, University of Florida Health (UF Health) in Gainesville, Florida, between March 2016 and August 2018.

To be eligible patients had to be age 50 or older, English speaking, have no documented advanced directive in our electronic medical record, and no significant cognitive dysfunction determined by a diagnosis of dementia in problem list. Eligible patients were identified by research assistants and were provided with a flier to alert them of the study at check in. Health literacy scores were routinely obtained for all clinic patients by clinic staff using the Rapid Estimate of Adult Literacy in Medicine—Short Form (REALM-SF) tool.²⁷ The REALM-SF has been validated in general internal medicine and subspecialty clinics for use in research to assess adult health literacy with a short screening test.²⁸ Patients who were unable to read 1 or more items on the REALM-SF were noted in the electronic medical record to be of “limited” health literacy (8th grade or below reading level), and those who answered all of the 7 items correctly (high school reading level or above) were noted to be of “adequate” health literacy.

The research assistant met with all potential study subjects immediately following a clinic visit in a private area within the clinic to determine if they wished to participate, and informed consent was obtained. Subjects were then randomized to intervention or control utilizing a randomization table previously generated by an independent statistician for each site using blocking to ensure equal randomizations for each group. The research assistant opened a sealed randomization envelope numbered sequentially to determine the group to which each participant would be randomly assigned. Participants were randomized in a 1:1 ratio for informational intervention vs control for each health literacy status (limited or adequate).

All study participants received the institutionally approved University of Florida Health Advance Directive brochure, which included a healthcare surrogate form and living will as well as a brief description of the purpose of the document (written at a 10th grade level). The advance directive forms themselves in this brochure have an 11th grade reading level. They also received a stamped envelope addressed to the medical center's medical records

department to return the AD. In order to ensure participants were not dissatisfied with discussing AD, participants completed a questionnaire immediately following encounter with research assistant that included the CSQ-8 patient satisfaction questionnaire,²⁹ and questions regarding whether addressing AD enhanced their experience and whether they felt AD should routinely be addressed at doctor visits. During the 6-month period following enrollment, medical records of all participants were checked for the presence of an AD. Participants of both groups who had not yet completed an AD were reminded by telephone calls to return it at 1, 3, and 5 months after enrollment.

In addition to the above, participants in the intervention group were provided guidance from the research assistant on completing the AD by going through the AD brochure with each participant using a standardized script that was designed to be understood by people with limited health literacy and has a reading level of 7th grade and was read to the participant (Online Appendix 1). This intervention took approximately 10 to 15 minutes, and the participant was given the opportunity to ask questions and if desired complete their AD. This intervention was developed by a team of individuals that included the leader of our local National Healthcare Decision Day committee, the quality director for the department of medicine, a health education librarian, physicians, nurses, pharmacist, and a representative from our institutional home care services. Participants in the control group were given the same AD packet and completed the same questionnaires, but did not receive the intervention.

Data collected included health literacy REALM-SF category, gender, age, insurance type, race, clinic location, presence of AD in electronic medical record (yes/no), and results of patient satisfaction questionnaire. The primary outcome was whether any AD (health surrogate form and/or living will) was completed and uploaded to the patient chart in the electronic medical record within 6 months of study enrollment. Secondary outcomes included participants' perceptions of clinic staff addressing AD and patient satisfaction.

As this was a randomized clinical trial, we planned a direct comparison of the AD completion rates in the intervention group vs. the control. We used *t*-tests and chi-square tests to compare the characteristics of persons in the intervention vs. control arms and to assess for differences in the proportion of persons who completed an AD. For the main study outcome, we used logistic regression to compare the AD completion rates in the 2 study arms overall, reported as odds ratios (OR) and 95% confidence intervals. We also compared the results of the outcome (AD completion) by intervention assignment and by race, stratified by those with adequate or limited health literacy. To detect a 15% increase in AD completion between the intervention group and control group, it was determined that 120 participants were needed in each of the 4 groups, thus a total of 240

patients with limited health literacy and 240 patients with adequate health literacy. This sample size allows for a power of greater than 90% at the 0.05 significance level to compare AD completion rates. Pearson chi-square test for association was done after data collected using SAS 9.4 for Windows.

Results

Of the patients screened eligible to participate, 529 were enrolled consisting of 264 with adequate health literacy and 265 with limited health literacy (Figure 1). Of those enrolled, 54 withdrew before completion of the intervention, and 18 were lost to follow up. Of those participants who withdrew, 29 were in the intervention group and 25 in control group, and of those who were lost to follow up, 10 were in intervention group and 8 in control (Figure 1). All participants were analyzed in an intention to treat analysis, but no new data were collected after time of withdrawal.

The control and intervention groups had similar characteristics with an average age of 64 and no difference in sex, race, type of insurance/payment, health literacy, or overall CSQ-8 patient satisfaction score (Table 1). The majority of patients were female (56.0%), White (63.1%), and had Medicare for insurance (51.0%).

Overall, there was an AD completion rate of 21.7%. No difference in the primary outcome was seen, with similar rates of AD completion in the control and intervention groups (Table 2). In the control group 59 (22.2%) participants completed an AD, and similarly in the intervention group 59 (22.4%) completed an AD (*P*-value .94), OR 1.01, (95% CI 0.67-1.53). Participants of adequate health literacy were more likely to complete an AD overall (28.4% vs 16.2%, *P*-value .0008) (Table 2). Additionally, more White participants than Black participants completed AD (26.1% vs 14.5%, *P*-value .0069).

When comparing the effect of the intervention separately by the different literacy groups, there was also no difference in AD completion for either adequate or limited health literacy. In the adequate health literacy group, 40 (30.1%) participants in the intervention group and 35 (26.1%) participants in the control group completed an AD (*P*-value .40) with an OR 1.26 (95% CI 0.74-2.15) for completing an AD. In the limited health literacy group, 19 (14.3%) participants in the intervention group and 24 (18.2%) participants in the control group completed an AD (*P*-value 0.39) with an OR 0.75 (95% CI 0.39-1.45) for completing an AD.

The differences in AD completion between Whites and Blacks appeared to vary according to health literacy. In the adequate health literacy group, there was an equal rate of AD completion between White and Black participants (29.2% Whites vs 28.6% of Blacks, *P*-value .94). However, in the limited health literacy group, a significant difference was seen in completion rate with more White participants

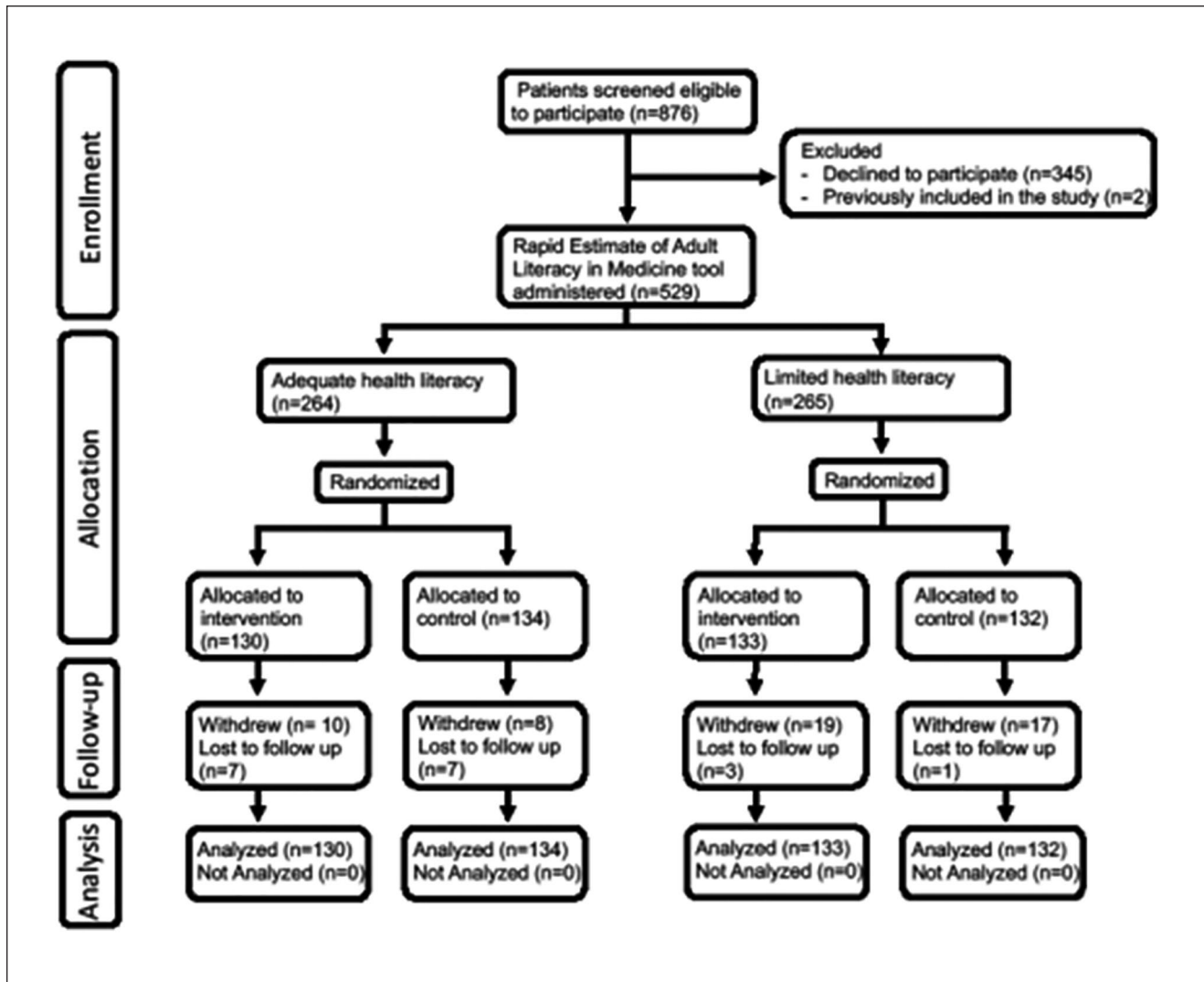


Figure 1. Consort diagram showing recruitment, enrollment, and adherence of study participants.

Table 1. Characteristics of Internal Medicine Patients Participating in a Clinical Trial Intended to Increase Completion of Advance Directives.

	Control n=266	Intervention n=263	P-value
Age (mean)	64	64	.63
Sex			.62
Female	146 (54.9%)	150 (57.0%)	
Literacy			.83
Adequate	134 (50.4%)	130 (49.4%)	
Limited	132 (49.6%)	133 (50.6%)	
Race			.81
White	171 (64.3%)	163 (62.0%)	
Black	82 (30.8%)	90 (34.2%)	
Mixed	1 (0.4%)	1 (0.4%)	
Other	12 (4.5%)	9 (3.4%)	

(continued)

Table 1. (continued)

	Control n=266	Intervention n=263	P-value
Insurance/payment type			.60
Medicare	134 (50.6%)	136 (51.7%)	
Medicaid	18 (6.8%)	16 (6.1%)	
Private	94 (35.5%)	84 (31.9%)	
Financial assistance program	3 (1.1%)	4 (1.5%)	
Other	16 (6.0%)	23 (8.8%)	
CSQ-8 patient satisfaction total score out of 32	31.29	31.04	.19

Table 2. Proportions of Participants Who Completed Advance Directives Within 6 Months of Study Intervention.

	Completed AD	P-value
Intervention	59/263 (22.4%)	.94
Control	59/266 (22.2%)	
Race		.0069
Black	25/172 (14.5%)	
White	89/334 (26.1%)	
Mixed/other	4/23 (13.0%)	
Sex		.6780
Female	68/296 (22.97%)	
Male	50/233 (21.46%)	
Literacy		.0008
Adequate	75/264 (28.4%)	
Limited	43/265 (16.2%)	

Table 3. Proportion of Study Participants Who Agreed with Statements about Advance Directives, According to the Intervention Assignment and Literacy Assessment.

	Intervention	Control	P-value	Adequate literacy	Limited literacy	P-value
Addressing AD enhanced visit	227/260 (87.31%)	220/257 (85.6%)	.28	213/257 (82.88%)	234/260 (90.00%)	.06
AD should routinely be addressed at doctor visits	224/261 (85.82%)	228/257 (88.72%)	.58	219/258 (84.88%)	233/260 (89.62%)	.09

completing AD than Black participants (20.0% of Whites vs 11.0% of Blacks, P -value .05).

Clinic visit satisfaction scores measured by CSQ-8 were high and similar between control and intervention groups (Table 1) and scores were also high and similar between adequate and limited groups. Most participants felt that addressing AD enhanced the clinic encounter, and this was similar when comparing control and intervention groups (85.6% vs 87.3%, P =.28). There was a trend toward more agreement that addressing AD enhanced the visit among persons with limited literacy compared to those with adequate literacy (90.0% vs 82.9%, P =.06) (Table 3). Most participants (85.4%) also felt that AD should routinely be addressed at visits to the doctor, a belief that was not significantly different between the control and intervention groups, but tended to be more prevalent in those with

limited compared to adequate health literacy (89.6% vs 84.9%, P -value .09).

Discussion

In 2 academic outpatient internal medicine clinics, we found that a single brief informational intervention with follow up reminder phone calls was not more effective than handing subjects an AD alone followed by reminder phone calls in encouraging patients of adequate or limited health literacy to complete an AD. In our study sample, the AD completion rate among persons who had not previously completed an AD was 21.7% at 6 months, which is within the varied rate of AD completion in the literature, ranging from 18% to 63%.^{10,13,20,30,31} Some aspects of our study were more consistent with an efficacy clinical trial, with informed consent, a

trained research assistant, and careful monitoring of both the intervention and control groups. However, we also tried to incorporate several aspects related to real-word effectiveness,³² by including nearly everyone over age 50, and delivering the intervention within the practice setting.

Persons of adequate health literacy were more likely to complete an AD than those with limited health literacy, but this was unaffected by our intervention. This is consistent with what is seen in the literature with limited health literacy linked to lack of AD.^{11,14,15,33,34} In one study of homeless adults, adequate health literacy carried an adjusted odds ratio of 7 for having an AD.³⁴ Adequate health literacy allows patients the ability to read and comprehend AD documents that are often written above the general population reading level, which likely contributes to higher completion rates compared to patients of limited health literacy.

One possible explanation for the lack of effect of our study intervention was the briefness of our intervention. Our intervention included a review of the AD form and brochure with a research assistant, whereas other studies that successfully demonstrated improved AD completion incorporated more time consuming and resource intensive interventions.^{3,20,34-37} After our study was designed, Sudore et al³ demonstrated that in addition to the easy to read AD that an interactive website called PREPARE further increased ACP documentation, of which AD document completion was included as a form of ACP. Previous research suggests that providing patients with educational materials alone does not increase AD completion rates,¹¹ but in our study providing the educational material alone was as effective as the intervention with a research assistant. Also, all participants received reminder phone calls which may have had an effect on a participant's likelihood of returning an AD and thus another possible explanation for the lack of difference in effect between control and intervention group. It is possible that we may have seen a larger intervention effect if the control group did not receive follow-up calls.

There are other possible explanations for the lack of intervention effect. Although studies have demonstrated that physician involvement leads to better concordance between patients and physicians as well as care that is more closely aligned with patient wishes,¹⁸ institutional barriers prevented the research team from establishing an alert in the medical record notifying providers that their patients had been given AD materials. Additionally, the AD forms and the descriptive brochure were at a 10th grade or above reading level which may have been hard to understand even for those subjects of adequate health literacy as measured by the REALM-SF. The AD utilized in the study was chosen due to being the standardized approved institutional AD, but future study should consider using a revised AD form with lower reading level. Our intervention did not include graphic or video decision aids, which have been shown to be successful in improving rates of AD completion,^{3,35,36}

although it was not clear if our participants had sufficient training to use online materials.³ Other factors that could have affected the outcome are that we did not incorporate a cultural specific approach, the follow-up phone calls did not provide additional education regarding AD, discussions with family/friends were not facilitated, and the process to return the AD was cumbersome.

Addressing AD during the patient encounter did not alter the patient satisfaction overall scores as measured by CSQ-8. Additionally, the majority of participants felt that addressing AD enhanced the clinic visit and that AD should routinely be addressed at medical appointments. This demonstrates the importance of addressing these topics from the patient perspective.

Advantages to our study include a large sample size, randomization, and the delivery of intervention that was developed by the clinic team and delivered in real time to a diverse outpatient population. Study limitations, in addition to those noted above, may include limited generalizability beyond one academic institution and the inability to systematically notify the patient's primary care provider that their patients were enrolled in the study. Also, our outcome only focused on whether or not participants had an AD document added to their medical record, and it is possible that the intervention did stimulate other aspects of advanced care planning, such as discussing long-term goals with family members or patients physician.

Conclusion

In conclusion, a brief informational intervention followed up with reminder phone calls did not increase the rate of AD completion among adult patients in a general internal medicine practice compared to being handed AD alone followed by reminder phone calls, regardless of their health literacy. Future efforts and research to improve AD completion rates should focus on interventions that involve more than one in-person contact with a patient, involve a trusted physician, use easy to read AD and brochures at 5th grade reading level, and graphic or video decision aids.

Author Note

Carrie D Warring, MBA, MHS is now at Health Services Administration, Business Programs, Santa Fe College, Gainesville, Florida, USA.

Declaration of Conflicting Interests

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ORCID iD

Melanie G. Hagen  <https://orcid.org/0000-0001-9429-2312>

Supplemental Material

Supplemental material for this article is available online.

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