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Fidelity to a behavioral intervention to improve goals of care decisions for nursing home residents with advanced dementia

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Abstract

Background / Aims—Ensuring fidelity to a behavioral intervention implemented in nursing homes requires awareness of the unique considerations of this setting for research. The purpose of this manuscript is to describe the Goals of Care (GOC) cluster-randomized trial and the methods used to monitor and promote fidelity to a GOC decision aid intervention delivered in nursing homes.

Methods—The cluster randomized trial tested whether a decision aid for GOC in advanced dementia could improve (1) the quality of communication and decision-making, (2) the quality of palliative care, and (3) the quality of dying for nursing home residents with advanced dementia. In 11 intervention nursing homes, family decision-makers for residents with advanced dementia received a two-component intervention: viewing a video decision aid about GOC choices, and then participating in a structured decision-making discussion with the nursing home care plan team, ideally within 3 months after the decision aid was viewed. Following guidelines from the NIH Behavior Change Consortium, fidelity was assessed in study design, in nursing home staff training

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The authors declare that there is no conflict of interest related to this manuscript.

for intervention implementation, and in monitoring and receipt of the intervention. We also monitored the content and timing of GOC discussions.

Results—Investigators enrolled 151 family decision-maker/resident dyads in intervention sites; of those, 136 (90%) received both components of the intervention, and 92-99% of discussions addressed each of four recommended content areas -- health status, goals of care, choice of a goal, and treatment planning. Ninety-four (69%) of the discussions between family decision-makers and the nursing home care team were completed within 3 months.

Conclusions—The methods we used for intervention fidelity allowed nursing home staff to implement a GOC decision aid intervention for advanced dementia. Key supports for implementation included design features that aligned with nursing home practice, efficient staff training, and a structured guide for GOC discussions between family decision-makers and staff. These approaches may be used to promote fidelity to behavioral interventions in future clinical trials.

Keywords

Fidelity; behavioral intervention; dementia; nursing home

Background

By 2050, families in the U.S. will care for 13 million people with Alzheimer's disease and other causes of dementia, and one in five older adults will have advanced stage disease.[1] People with advanced dementia experience progressive loss of meaningful communication and dependency for all activities of daily living. Further, median survival with advanced dementia is 1.3 years, and toward the end of life, family decision-makers face difficult choices about overall goals of medical care and treatments such as resuscitation, hospitalization, use of tube feeding, and antibiotics for recurrent infections.[2] Thus, decision-making about goals of care (GOC) is essential for high quality dementia care in the later stages of disease.

Nursing homes are the primary residence and site of healthcare for the majority of Americans with advanced dementia; in fact, 67% of people with dementia receive end-of-life care in this setting.[3] Unfortunately, family caregivers report dissatisfaction with communication and decision-making in nursing homes, and limited communication is associated with poor quality end-of-life care.[4,5,6] Despite this evidence, communication and decision-making interventions are rarely tested in nursing homes. Several behavioral interventions have been shown to improve shared decision-making and outcomes for patients with serious illness, yet few are relevant to dementia care.[7]

As yet another consideration, attention to fidelity is required in any clinical trial, but it demands special attention when the intervention seeks to modify behaviors. Behavioral interventions are often complex, involve multiple components, and require ongoing vigilance to ensure adherence to study protocols.[8] Techniques to measure and ensure fidelity to an intervention help investigators avoid Type I or Type II errors in interpretation, and enhance reliability and validity of results. As detailed by the NIH Behavior Change

Consortium, fidelity should be addressed in *study design*, in staff training and implementation of the intervention, and in *monitoring and receipt of the intervention* during its delivery.[9]

Ensuring fidelity to a behavioral intervention in nursing homes requires awareness of the unique demands of this environment for research. Potential challenges to fidelity in nursing homes include high staff turnover, sparse research infrastructure, clinical and regulatory priorities that may supersede research participation, and the complex nature of these organizations.[10,11] During the conduct of a cluster-randomized trial of a GOC decision aid intervention in 22 nursing homes, we achieved the target sample size and monitored intervention fidelity throughout the study. The purpose of this manuscript is to describe the Goals of Care (GOC) cluster-randomized trial and the methods used to monitor and promote fidelity to a GOC decision aid intervention delivered in nursing homes.

Rationale and overview of the GOC clinical trial

Decision aids are information-sharing tools to promote shared decision-making about preference-sensitive choices in healthcare. In video or print format, a decision aid outlines a healthcare choice, the pros and cons of different options, and likely outcomes. A recent Cochrane review concluded that decision aids improve efficiency and quality of shared decision-making by preparing patients prior to clinical communication.[12] Although healthcare decisions have the greatest patient impact in serious illness, decision aid research has typically focused on outpatient choices such as preventive care; only two decision aids have been tested with nursing home residents and only one addressed a key decision for persons with dementia.[13,14,15]

In earlier work, investigators developed and pilot tested a nursing home GOC decision aid intervention for residents with advanced dementia and found evidence that it improved the quality of decision-making.[16] This GOC decision aid intervention is now being tested in a cluster-randomized clinical trial funded by the National Institute on Aging. The three aims of the GOC clinical trial are to test the effect of the decision aid intervention on (1) the quality of communication and decision-making, (2) the quality of palliative care, and (3) the quality of dying for nursing home residents with advanced dementia. All study procedures were reviewed and approved by the University of North Carolina School of Medicine's Institutional Review Board. A Data Safety Monitoring Committee reviewed data reports every 6 months throughout the study period.

Methods of the goals of care clinical trial

Study sites and sample

Twenty-two nursing homes in North Carolina participated in the trial; 11 sites randomized to the intervention provide data for the current analysis. Research participants were dyads of nursing home residents with advanced dementia and their family decision-makers. Trained research assistants conducted eligibility screening under an IRB-approved Health Insurance Portability and Accountability Act waiver. Residents with a diagnosis of dementia and a Global Deterioration Scale score of 5, 6, or 7, determined by their primary nurse, were

eligible for the study.[17] The legal family decision-maker received study information in the mail, with follow-up calls from the study team inviting participation. Family decision-makers provided written informed consent for their participation as well as the participation of the nursing home resident with dementia. Family decision-makers received modest incentive payments after completion of study interviews, and the nursing home sites received small payments during each quarter of site participation.

GOC intervention

The family decision-makers in the intervention group received a two-component intervention: (1) a video decision aid about GOC care choices in advanced dementia, and (2) a structured nursing home care plan meeting to address GOC. Three goals are discussed in the 20-minute decision aid: prolonging life, supporting function, and improving comfort.[18] Each goal is described along with treatment options consistent with prioritizing that goal. Further, each goal was illustrated with a story of a person who used the goal to guide treatment choices. After viewing the decision aid during the enrollment interview, family decision-makers were given a copy of the decision aid and a print discussion guide to use with healthcare providers. They were encouraged to discuss choices about GOC with the nursing home healthcare team at a care plan meeting scheduled several weeks later. Nursing home staff were trained to use the same discussion guide to meet with families. The discussion guide provided step-wise guidance in how to use the decision aid content in shared decision-making.[19] In control nursing homes, study participants viewed a 20-minute informational video about dementia, and participated in usual care plan meetings with staff.

Outcome measures

Investigators followed enrolled dyads (residents and their family decision-maker) for 9 months or until resident death. Outcome data were obtained from interviews with decision-makers and nursing home chart reviews at 3, 6 and 9 months by trained staff blinded to group assignment; if the nursing home resident died, a modified interview and chart review was completed after death. The primary outcome, measured at 3 months, was the quality of communication and decision-making. Measures for this outcome domain were the Quality of Communication instrument, the Toolkit Advance Care Planning problem score to measure care consistent with patient preferences, and family decision-makers' report of concordance with health care provider on the primary goal of care.[20,21] Secondary outcomes, measured at 6 and 9 months, included the number of palliative care domains addressed in the treatment plan, family satisfaction with care, patient comfort, patient quality of life, hospice referral, and hospitalizations.

Methods: Promoting fidelity using study design and procedures

Investigators addressed fidelity in the design of this two-part behavioral intervention. (Figure 1) First, a cluster-randomized trial design was used to prevent contamination between intervention and control groups and thus prevent drift in provider practices from intervention to control. Second, the family decision-makers viewed the decision aid with a Research Assistant during a baseline enrollment interview to ensure completion of the first component of the intervention. Third, the subsequent structured GOC discussion was designed to fit

within existing nursing home practices.[22] All US nursing homes are required to conduct quarterly care planning meetings to discuss care planning for residents with family decision-makers.[23] Fourth, investigators developed a structured discussion guide -- given to family decision-makers and nursing home staff -- to promote a consistent and complete approach to GOC discussions during care planning. Nursing home staff used the guide to record elements of the GOC discussion and then provided this information to the research staff. Finally, the study design included contingency planning for foreseeable barriers to fidelity such as the need for re-training in the event of nursing home staff turnover.

Methods: Promoting fidelity during staff training and implementation of the intervention

To address fidelity during the GOC trial, nursing home staff received training in intervention procedures and technical support during implementation. Investigators first identified a facility liaison from the care plan team at each nursing home, who agreed to assist with implementation of the intervention. All care plan staff members participated in a one-hour standardized training on the GOC intervention. They viewed the GOC decision aid, received copies of the printed GOC discussion guide, and heard a short role play of how that discussion might be conducted. Nursing home staff were also trained to use VALUE principles for family meetings: *Value* everyone's input, *Acknowledge* emotions, *Listen, Understand* the patient as a person, and *Elicit* questions.[24] Optional re-training was offered at every intervention site based on requests for additional training or staff turnover; re-training was required if fidelity targets were not met during the course of study enrollment.

Research staff provided support to nursing home staff to promote consistent and complete implementation of the intervention. They provided the facility liaison with a list of the residents' family decision-makers who had enrolled in the study and thus needed a GOC discussion during the care plan meeting. On each visit to the facility, a research staff member updated this list and collected completed GOC discussion guides. To encourage physicians' involvement in GOC discussions, primary care providers received notice of care plan meetings. After the meeting, nursing home staff members were encouraged to share results of the discussions with physicians who did not attend.

Methods: Monitoring fidelity during delivery of the GOC intervention

Fidelity to the intervention was considered complete when both components of the intervention -- the GOC decision aid video followed by the GOC discussion -- were delivered. A Research Assistant witnessed use of the GOC decision aid, and completion of the GOC discussion guide was used to confirm completion of the discussion component. The Project Manager continuously tracked fidelity to the intervention. If a nursing home site failed to meet fidelity for at least 70% of enrolled dyads, investigators required re-training and provided specific tips for implementation of the intervention. If re-training did not result in ≥ 70% fidelity to the intervention, enrollment was stopped at the site.

While not required for fidelity, specific data regarding content of the GOC discussions were collected from the GOC meeting guide, from follow-up interviews with family decision-

makers, and from audio-recording of 10% of the care plan discussions. The completed GOC meeting guides provided details on four recommended components of GOC discussions: review of health status, discussion of possible goals, choice of a primary goal, and treatment plan decisions. Timing of GOC discussions was confirmed during follow-up interviews, when research staff asked family decision-makers about whether they attended a care plan meeting where they were asked for input on major treatment decisions. Audio-recording of a 10% sample of discussions allowed investigators to review the quality of discussions, and provided another reminder to nursing home staff about the importance of fidelity to the protocol.

Results: Fidelity to the GOC intervention

From April 2012 to September 2014, 151 family decision-maker/resident dyads were enrolled in the intervention arm of the GOC cluster randomized trial. All 151 family decision-makers viewed the GOC video decision aid, the first component of the intervention. Out of the 151 decision-makers, 136 (90%) participated in a GOC discussion (Table 1) for full fidelity to the intervention. Of the fifteen GOC discussions not completed, 9 (6%) were due to resident death, resident move out of the facility, or study withdrawal. Only 6 dyads (4%) did not receive the full GOC intervention because staff did not initiate the discussion or family did not participate. Nurses (70%) or social workers (68%) were the care plan team members most often present for GOC discussions with families. The primary medical provider was present in only 2 (1%) of the GOC discussions, but some decision-makers reported talking with physicians at other times.

Results: Content and timing of GOC discussions

Nursing home staff reported that once a GOC discussion occurred, all four components were nearly always completed. Their notes on the GOC discussion guides indicated that discussion content included resident's health status 99% of the time (Table 2). Goals were discussed in 123 (92%) meetings, and choice of the primary goal of care was made in 127 (95%) meetings. Furthermore, the treatment plan for 130 (97%) patients was confirmed or changed after the discussion.

Although investigators encouraged GOC discussions soon after the video decision aid component, 94 (69%) of the discussions were completed within three months, and 127 (84%) of the discussions occurred within 6 months. While the majority of discussions were incorporated in usual quarterly care plan meetings, 38 (28%) of the GOC discussions occurred in a special meeting set aside for that purpose.

Discussion

The GOC cluster-randomized clinical trial tested a decision aid intervention in 22 nursing homes, with 11 sites randomized to implement this behavioral intervention. To promote fidelity to the intervention, this study addressed fidelity in design and implementation methods. In addition, research staff monitored fidelity continuously and provided re-training to all study sites to address uncertainties or to reach newly hired staff. The intervention was

completed for 90% of the enrolled dyads; only 4% of discussions did not occur due to staff or family avoidance. We attribute this high rate of fidelity to methods consistent with the NIH Behavior Change Consortium recommendations. Study methods addressed fidelity in design of the GOC decision aid intervention, in training and support to nursing home staff during implementation, and in a continuous monitoring plan during delivery of the intervention.

Design of the GOC decision aid intervention facilitated adherence, and these same design features may also promote its future dissemination. GOC discussions were embedded within the care planning process, which is required and familiar to the interdisciplinary team in nursing homes. Family decision-makers are already invited to attend care plan meetings and thus they are also familiar with care plan meetings as an opportunity to discuss treatment approaches for the resident with dementia. While research procedures such as monitoring and training may also be important, these design elements make it likely that the GOC intervention could be disseminated to new nursing home sites if study outcomes demonstrate benefit.

Potential threats to fidelity included staff turnover and delays in scheduled GOC discussions. Investigators received requests for staff re-training at every intervention nursing home. Re-training was requested when new staff members arrived, or when existing staff felt unsure of how to talk about GOC after the first one or two discussions occurred. Some nursing home teams preferred to do the discussions outside of the regularly planned care plan meeting, which they felt was already full of other required information. In addition, nursing home staff delayed many GOC discussions beyond the recommended 3-month time window; this timing was affected by the resident's health condition, variable family attendance at the meeting, and staff challenges in scheduling these meetings. To overcome these issues, flexibility in timing and organization of a GOC discussion may be required, and repeat viewing of the decision aid by family decision-makers may be helpful. Barriers to fidelity to this intervention also included resident death or movement to another site of care; however, this was rare and demonstrates that the long trajectory of advanced dementia offers an opportunity for communication about GOC in most cases.

The primary care provider responsible for the nursing home resident's medical care was rarely present at the GOC discussions. Physicians, nurse practitioners and physician assistants rarely attend care plan meetings in nursing home practice, and the study invitation did not change this behavior. That said, more than half of the family decision-makers reported talking about GOC to a primary provider outside of the meeting structure, which may suffice as an approach to ensure physician participation in key decisions.

Some limitations must be considered in interpreting study results. The context for this intervention was a clinical trial, and nursing home staff and families may respond differently to a locally driven practice improvement initiative around GOC communication. The research context provides resources and external expertise, which may enhance implementation. Research on pragmatic implementation and dissemination of the GOC decision aid intervention may be needed to understand whether it can be broadly effective outside this efficacy study design. The study involved many nursing home sites with varied

characteristics, and while the intervention is widely applicable, results presented here are geographically regional and may not generalize to other states.

In conclusion, we found that nursing home staff and family decision-makers could implement a GOC decision aid intervention 90% of the time for residents with advanced dementia. Key supports for implementation included design features aligned with current nursing home practices, staff training, and a structured guide to facilitate GOC discussions between family decision-makers and nursing home staff. These approaches may be used to promote fidelity to behavioral interventions in future clinical trials.

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Phase of Research	Methods to Promote Fidelity
Study design and procedures	Cluster randomized trial design to avoid contamination between sites Research staff technical support for viewing decision aid Intervention design suited to usual nursing home practices Structured discussion guide for GOC communication Contingency planning for threats to fidelity
Nursing home implementation	Standardized training for nursing home staff Optional re-training on request or when staff turnover occurred Research staff support to promote fidelity
Monitoring fidelity	Continuous tracking of two intervention components Required re-training and feedback to nursing homes with <70% fidelity

Figure 1.
Fidelity Methods for the GOC Decision Aid Intervention

Table 1

Fidelity to the Goals of Care Intervention

Measure	Percentage (n=151)
Family decision-maker reviewed the GOC decision aid video	151(100%)
Surrogate participated in GOC discussion	136(90%)
Nursing home staff participated in GOC discussion	
Nursing	106(70%)
Social Work	103(68%)
Dietary	40(26%)
Activities	31(21%)
Therapist	3(2%)
MD/NP/PA	2(1%)

Table 2

Content of the Goals of Care Discussions

Goals of Care discussion topics	Percentage (n=136)
Health status	135 (99%)
Goals discussed	123 (92%)
Choice of Goal	127 (95%)
Treatment plan confirmed	130 (97%)