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RESEARCH PAPER

BABEL (Better tArgeting, Better outcomes for frail ELderly patients) advance care planning: a comprehensive approach to advance care planning in nursing homes: a cluster randomised trial

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Abstract

Background: Nursing home (NH) residents should have the opportunity to consider, discuss and document their healthcare wishes. However, such advance care planning (ACP) is frequently suboptimal.
Objective: Assess a comprehensive, person-centred ACP approach.
Design: Unblinded, cluster randomised trial.
Setting: Fourteen control and 15 intervention NHs in three Canadian provinces, 2018–2020.
Subjects: 713 residents (442 control, 271 intervention) aged ≥65 years, with elevated mortality risk.
Methods: The intervention was a structured, ∼60-min discussion between a resident, substitute decision-maker (SDM) and nursing home staff to: (i) confirm SDMs' identities and role; (ii) prepare SDMs for medical emergencies; (iii) explain residents' clinical condition and prognosis; (iv) ascertain residents' preferred philosophy to guide decision-making and (v) identify residents' preferred options for specific medical emergencies. Control NHs continued their usual ACP processes. Co-primary outcomes were: (a) comprehensiveness of advance care planning, assessed using the Audit of Advance Care Planning, and (b) Comfort Assessment in Dying. Ten secondary outcomes were assessed. P-values were adjusted for all 12 outcomes using the false discovery rate method.
Results: The intervention resulted in 5.21-fold higher odds of respondents rating ACP comprehensiveness as being better (95% confidence interval [CI] 3.53, 7.61). Comfort in dying did not differ (difference = −0.61; 95% CI −2.2, 1.0). Among the secondary outcomes, antimicrobial use was significantly lower in intervention homes (rate ratio = 0.79, 95% CI 0.66, 0.94).
Conclusions: Superior comprehensiveness of the BABEL approach to ACP underscores the importance of allowing adequate time to address all important aspects of ACP and may reduce unwanted interventions towards the end of life.

Keywords: Advance care planning, nursing homes, cluster randomised studies, older people

Key Points

- We performed a cluster randomised study among 713 residents in 29 Canadian nursing homes.
- It evaluated a structured, comprehensive, person-centred and tailored approach to advance care planning.
- The intervention resulted in significantly higher comprehensiveness of advance care planning and reduced use of antibiotics.
- The BABEL (Better tArgeting, Better outcomes for frail ELderly patients) Advance Care Planning (ACP) intervention requires allocation of adequate time to address all important aspects of advance care planning.

Introduction

In 2016, U.K. nursing homes (NHs) housed 4% of people 65 years and over, and 15% of those 85 and older [1]. In Canada, comparable figures are 6.3% over 65 years, and 11.0% over 75 years [2] and numbers are similar elsewhere in the industrialised world [3, 4]. Most NH residents are frail, live with dementia and need assistance with activities of daily living [4, 5]. The ageing population will drive further growth of NH populations [6, 7]. With ∼20% of all deaths occurring in NHs [8–10] and median survival of 2 years [11–13], NH residents must have the opportunity to consider, discuss and document their healthcare wishes, a process known as advance care planning (ACP) [14]. The disproportionate mortality experienced by NH residents from the COVID-19 pandemic underscores the importance of ACP in NHs [15].

There are important problems with ACP in NHs. Most people have mediocre knowledge of, and engagement in, ACP [16, 17]. An American study of families of NH residents reported little or no ACP discussion before medical emergencies [18]. Through stakeholder engagement, we identified four 'weak links' in ACP: (1) uncertain identification of substitute decision-makers (SDMs), (2) poor understanding of the appropriate role of SDMs, (3) insufficient context provided for clients to understand the available medical choices and (4) failure to prepare in advance for health crises [19]. In 38 Canadian NHs, we identified low participation of physicians and residents in ACP discussions, infrequent discussion of artificial life support, inconsistent adherence to prior ACP decisions and incomplete communication of ACP decisions upon transfer of residents to an emergency department or hospital [20].

To address these deficiencies, we developed BABEL ACP (Better tArgeting, Better outcomes for frail ELderly patients), a comprehensive, person-centred approach based on best practices [21]. Here we describe the results of the BABEL ACP Trial in Canadian NHs [22]. We hypothesised that compared with prevalent ACP practices, BABEL ACP would improve comprehensiveness of ACP, and resident comfort at the end of life.

Methods

This unblinded, parallel-group, cluster randomised study included a convenience sample of 29 NHs in three Canadian regions: Calgary, Alberta; Winnipeg, Manitoba; and Kitchener-Waterloo, Ontario. See Appendix 1 for further information about securing participating NHs. Participants were recruited and data collected from 28 August 2018 to 9 August 2020. Trial registration: ClinicalTrials.gov (NCT03649191). This study was approved by the Research Ethics Boards of the Universities of Manitoba (#HS20669), Calgary (REB17–1688), Waterloo (#31782) and Conestoga College (#CC256).

Data were derived from NHs, emergency departments, hospitals, and physicians' offices; see Appendix 1 for further details. Surveys were paper or email-based. Medical records were reviewed manually by study personnel. All data were entered into the University of Manitoba's Research Electronic Data Capture system and analysed using Stata 16 (StatCorp, College Station, TX).

Resident inclusion criteria were: age ≥ 65 years, informed consent from competent residents or SDMs and presence of any of four risk factors that confer an elevated risk of dying within the next 6–12 months (Appendix 1). We excluded residents admitted for respite care or transferred from a different participating NH.

NHs were randomised after recruitment in a 1:1 ratio by the principal investigator to control and intervention groups using a random number generator and enrolled by the site investigators or research assistants. Control homes continued their usual ACP processes [20], without alterations during the study. Intervention homes used BABEL ACP for residents who consented to participate and agreed to deliver the Full BABEL discussion (the core of the intervention) within 6 weeks of informed consent. The BABEL ACP intervention comprises [21]: (i) orientation and training for all NH staff, (ii) a workbook to guide ACP discussions (online materials), (iii) training tools for its use and (iv) stakeholder knowledge tools. The first three components support evidence-based best practices, and the third supports participants engaged in ACP. All participating NHs repeat ACP discussions yearly and when a resident's clinical status changes, intervention homes used the Full BABEL discussion for these repeat discussions in study participants. A cluster randomised trial was chosen to avoid application of BABEL components to control residents in homes with both control and intervention participants.

Screening for study eligibility utilised the Resident Assessment Instrument–Minimum Data Set (MDS) version 2.0 in each NH. MDS is a validated, widely used tool to characterise the needs and support care planning for NH residents [23, 24]. Repeated quarterly in all participating NHs,

individuals who did not initially qualify were rescreened after subsequent MDS reassessments. In Alberta and Manitoba research, coordinators had direct access to MDS information on all screened residents, but due to privacy rules in Ontario, such information was only available for residents entered into the study. Screening data were maintained on a custom-designed electronic screening log.

Study personnel sought informed consent for eligible residents. SDMs consent was also sought for completion of surveys regarding ACP and their perceptions of the care provided to their loved ones.

Twelve individual-level outcomes were assessed, of which two were designated *a priori* as co-primary. The first (Supplementary Table 1) was the Audit of ACP, asking which of seven ACP elements had been discussed since NH admission; [25] the score for this instrument ranges from 0 to 7, with higher values indicating more comprehensive ACP. This survey was provided 6 weeks after study entry to capable residents, otherwise to the SDM. Analysis was by ordinal logistic regression. The second co-primary outcome (Supplementary Table 1) was Comfort Assessment in Dying [26, 27], a questionnaire completed post-mortem by a nurse caring for the resident during the final week of life. The frequency of 14 symptoms was rated 1–3 as: a lot, somewhat or not at all, summed to a 14–42 point scale where higher values indicated fewer adverse symptoms. Analysis used ordinary least squares regression. Ten secondary outcomes, (Supplementary Table 2) included five measures of medical resource use. Qualitative methods were used to explore staff perspectives on BABEL ACP (Appendix 2).

Main analyses used mixed-effects regression modelling on complete records, at the level of individuals, with clustering within NHs, adjusting for baseline covariates [28]. Resident covariates were: age at study consent, sex, interval between NH admission and consent, marital status, pre-NH location, province, whether resident consent was obtained from the resident or SDM, presence of each of the four study inclusion factors indicating high risk (Appendix 1), whether the resident was receiving hospice care and six parameters obtained from the most recently completed MDS. These latter were: Cognitive Performance Scale [29], Activities of Daily Living Scale [30], Aggressive Behaviour Scale [31], Depression Scale [32], Pain Scale [23, 33] and a modified Charlson Comorbidity Index (CCI) [34], as derived from the comorbid conditions available in the MDS. NH covariates were number of beds and public versus private ownership. As both co-primary outcomes were missing for ~one-quarter of participants, sensitivity analyses used fixed effects regression with multiple imputation (10 full datasets) for missing dependent variables [35, 36].

Main analysis was by intention-to-treat (ITT). As 21% of intervention home residents never received the Full BABEL discussion, we also performed per-protocol (PP) analyses of medical resource use outcomes, considering three groups of residents: (a) control, (b) intervention who never received the Full BABEL discussion and (c) intervention who received the Full BABEL discussion and only including resource use occurring after that discussion occurred.

We adjusted for multiple comparisons among all 12 outcomes in ITT analyses, using Simes' false discovery rate step-up procedure [37, 38], considering two-sided, adjusted P-values $<.05$ to be statistically significant.

Sample size analysis utilised PASS 2008 (NCSS, LLC, Kaysville, Utah) for two independent means with a cluster randomised design applied to the Audit of ACP outcome. Assumptions were: mean scores of 5.0 in control homes and 5.6 in intervention homes, both with standard deviations of 1.5, 5% Type I error rate, 80% power, NHs of 150 beds with 43% of residents qualifying for the study, refusal rate of 25% among those eligible and an intraclass correlation coefficient of 0.20. This calculation indicated the need for 12 NHs in each group, for a total of 1,164 participants.

Results

The study included 713 residents in 29 NHs (15 intervention, 14 control). Recruitment difficulties (Appendix 3) resulted in failure to reach the target sample size.

Due to later average study initiation of intervention homes (Table 1), fewer intervention residents were screened (Figure 1). With slightly lower rates of eligibility and consenting for intervention residents, there were 271 residents in the intervention group and 442 in the control group. Among intervention subjects, 57 (21.0%) never received a Full BABEL discussion; of the 214 who did, 153 (71.4%) received it within 8 weeks of consenting, and 12 (5.6%) received it >6 months after consenting. Physicians participated in only 40 (18.7%) of full BABEL discussions.

NH characteristics were similar between the two groups (Table 1). However, there were relevant differences in subject characteristics (Table 1), including control subjects spending an average of 29 days longer in the study than intervention residents in the ITT analysis; this grew to 115 days longer in the PP analysis.

Comprehensiveness of ACP was significantly higher in intervention participants (Table 2, Figure 2, Supplementary Table 3 and 4). The overall odds of intervention home respondents rating ACP comprehensiveness as being better was 5.21-fold higher (95% confidence interval [CI] 3.53, 7.61) than for control home respondents; this remained consistent through sensitivity analyses (Supplementary Table 5). Both with and without adjustment, comfort assessment in dying was similar between decedents in the two groups (Table 2, Supplementary Table 3, 5 and 6).

Among medical resource use outcomes (Table 3, Supplementary Table 7), after model-based and multiple comparison adjustments, the only significant one was lower antimicrobial use in intervention NHs (incidence rate ratio [IRR] = 0.79, $P = 0.048$). In PP analyses, not adjusted for multiple comparisons, intervention residents who received the Full BABEL discussion had lower rates of transfer to

Table 1. Baseline characteristics of participating NH residents and NHs

Parameter	*Control homes*	*Intervention homes*
Participating NH residents		
N	442	271
Province		
Ontario	208 (47.1%)	95 (35.1%)
Manitoba	116 (26.2%)	76 (28.0%)
Alberta	118 (26.7%)	100 (36.9%)
Pre-NH living location type		
Assisted living	122 (27.6%)	66 (24.4%)
Hospital/acute care or rehabilitation facility	121 (27.4%)	106 (39.1%)
Home	102 (23.1%)	42 (15.5%)
Other NH	95 (21.5%)	53 (19.6%)
Chronic continuing care (Ontario only)	1 (0.2%)	1 (0.4%)
Unknown	1 (0.2%)	3 (1.1%)
Who provided consent for the resident		
Resident	71 (16.1%)	31 (11.4%)
SDM	371 (83.9%)	240 (88.6%)
SDM consented for self	419 (94.8%)	256 (94.5%)
Marital status at NH admission		
Widowed	246 (55.7%)	169 (62.4%)
Married	128 (29.0%)	64 (23.6%)
Single	28 (6.3%)	6 (2.2%)
Divorced	25 (5.7%)	24 (8.9%)
Separated	4 (0.9%)	5 (1.8%)
Unknown	11 (2.5%)	3 (1.1%)
Resident age	87.6 ± 7.6	88.1 ± 7.4
Resident gender		
Female	322 (72.9%)	199 (73.4%)
Male	120 (27.1%)	72 (26.6%)
Qualification for BABEL study (not mutually exclusive)		
Congestive heart failure	124 (28.1%)	90 (33.2%)
Leaves >25% of food uneaten	304 (68.8%)	156 (57.6%)
Malignancy	74 (16.7%)	57 (21.0%)
CHESS score ≥ 3	49 (11.1%)	50 (18.5%)
In Palliative Care	5 (1.1%)	4 (1.5%)
Days in study (ITT)		
Mean ± SD	341 ± 200	312 ± 170
Median (IQR)	320 (168–521)	315 (183–451)
Days in study (PP)		
Mean ± SD	341 ± 200	226 ± 186
Median (IQR)	320 (168–521)	233 (28–363)
Days from NH admission to study consent		
Mean ± SD	671 ± 818	673 ± 826
Median (IQR)	361 (123–964)	390 (102–829)
Days from consent to 1st Full BABEL discussion		
Mean ± SD	n.a.	55 ± 83
Median (IQR)		34 (5–61)
Modified Charlson Comorbidity Index (CCI)[1]		
Mean ± SD	2.4 ± 1.5	2.7 ± 1.6
Median (IQR)	2 (1–3)	2 (2–4)
MDS Aggressive Behaviour Scale (range 0–12)		
Mean ± SD	1.3 ± 2.0	1.2 ± 1.9
Median (IQR)	0 (0–2)	0 (0–2)
MDS Cognitive Performance Scale (range 0–6)		
Mean ± SD	2.8 ± 1.5	3.1 ± 1.4
Median (IQR)	3 (2–3)	3 (3–4)
MDS Depression Rating Scale (range 0–14)		
Mean ± SD	2.1 ± 2.7	2.1 ± 2.3
Median (IQR)	1 (0–4)	1 (0–3)
MDS Pain Scale (range 0–3)		
Mean ± SD	0.39 ± 0.64	0.46 ± 0.66
Median (IQR)	0 (0–1)	0 (0–1)

(Continued)

Table 1. Continued

Parameter	*Control homes*	*Intervention homes*
MDS ADL Hierarchy Scale (range 0–6)		
Mean ± SD	3.5 ± 1.4	3.8 ± 1.2
Median (IQR)	4 (2–5)	4 (3–5)
Participating NHs		
N	14	15
Province		
Ontario	5 (36%)	4 (27%)
Manitoba	5 (36%)	5 (33%)
Alberta	4 (29%)	6 (40%)
#Beds	133 ± 55	154 ± 99
Ownership		
Public	6 (43%)	7 (47%)
Private	8 (57%)	8 (53%)
Date recruiting began, median	10/1/2018	1/1/2019
Date recruiting ended, median	4/24/2020	3/31/2020
Date of final event assessment, median	8/9/2020	8/9/2020

CHESS, Changes in Health, End-stage disease and Symptoms and Signs.

Table 2. Summary of main, model-based findings for all 12 ITT outcomes, with *P*-values adjusted for covariates and multiple comparisons

Outcome	*#Subjects*	*Effect measure for intervention vs. control*[†]	*Effect size*[†] *(95% CI)*	*Model-adjusted P-value*	*Model and FDR-adjusted P-value**
Resident/SDM audit of ACP	554	Ordinal, 0–7 scale	5.21 (3.53, 7.61)	<.001	0.006
Comfort assessment in dying	197	Linear, 14–42 scale	−0.61 (−2.24, 1.02)	0.46	0.55
Death	713	Incidence rate	0.85 (0.69, 1.03)	0.08	0.24
Palliative care	713	Incidence rate	0.75 (0.54, 1.03)	0.08	0.24
Courses of antimicrobials in NH	713	Incidence rate	0.79 (0.66, 0.94)	0.008	0.048
Other diagnostic or therapeutic interventions in the NH	713	Incidence rate	0.96 (0.73, 1.27)	0.79	0.79
Other diagnostic or therapeutic interventions in outpatient settings	713	Incidence rate	0.85 (0.53, 1.37)	0.50	0.55
Transfer to hospital or emergency	713	Incidence rate	0.77 (0.48, 1.25)	0.30	0.45
Admission to an intensive care unit	713	Incidence rate	0.23 (0.008, 6.32)	0.38	0.51
Resident ACP self-efficacy	75	Linear, 1–5 scale	0.35 (−0.23, 0.92)	0.24	0.45
SDM satisfaction with care at end-of-life	210	Linear, 10–40 scale	0.91 (−0.70, 2.51)	0.27	0.45
SDM agreement that plan of care was followed	217	Ordinal, 0–5 scale	1.48 (0.81, 2.68)	0.20	0.45

[†]Effect size measures: odds ratio for ordinal, linear coefficient for linear, IRR for incidence rate. *Further adjustment of all 12 ITT *P*-values via Simes step-up false discovery rate (FDR) procedure. ACP, advance care planning; ED, emergency department; SDM, substitute decision-maker.

hospital or emergency of borderline significance (Table 3; IRR = 0.63, *P* = 0.06).

Overall, 272 (38.1%) participants died during the study, and 193 (27.1%) transitioned to palliative care (Supplementary Table 7). After adjustment via mixed-effects, multivariable, grouped Poisson regression, IRR for death among intervention compared with control participants was 0.85 (95% CI 0.69, 1.03), with a *P*-value of 0.08 before further adjustment for multiple comparisons and 0.24 after further adjustment (Table 2). The comparable results for entry into palliative care were IRR = 0.75 (0.54, 1.03) with model-based *P*-value of 0.08 before and 0.24 after further adjustment.

Seventy-five residents were competent and able to complete the Resident ACP Self-efficacy survey (Supplementary Table 2). Scores were similar between control and intervention residents (Supplementary Table 8).

Among the 272 residents who died, 217 SDMs completed post-mortem satisfaction surveys provided 1 month after death. Responses were similar between groups for both Satisfaction with Care at End of Life (Supplementary Table 9), and whether the care plan chosen in the NH was actually followed (Supplementary Table10).

Discordance between residents' care wishes and the care they received could only be assessed for the 214 residents who received the Full BABEL discussion, as it was the source of details about their wishes. Among the five types of care assessed, five individuals received care that they had not desired (Supplementary Table 11), of which two received it after their Full BABEL discussion—one who was transferred to hospital, and one who received antimicrobials in the NH.

Semi-structured interviews of NH staff showed that BABEL ACP improved their knowledge and confidence

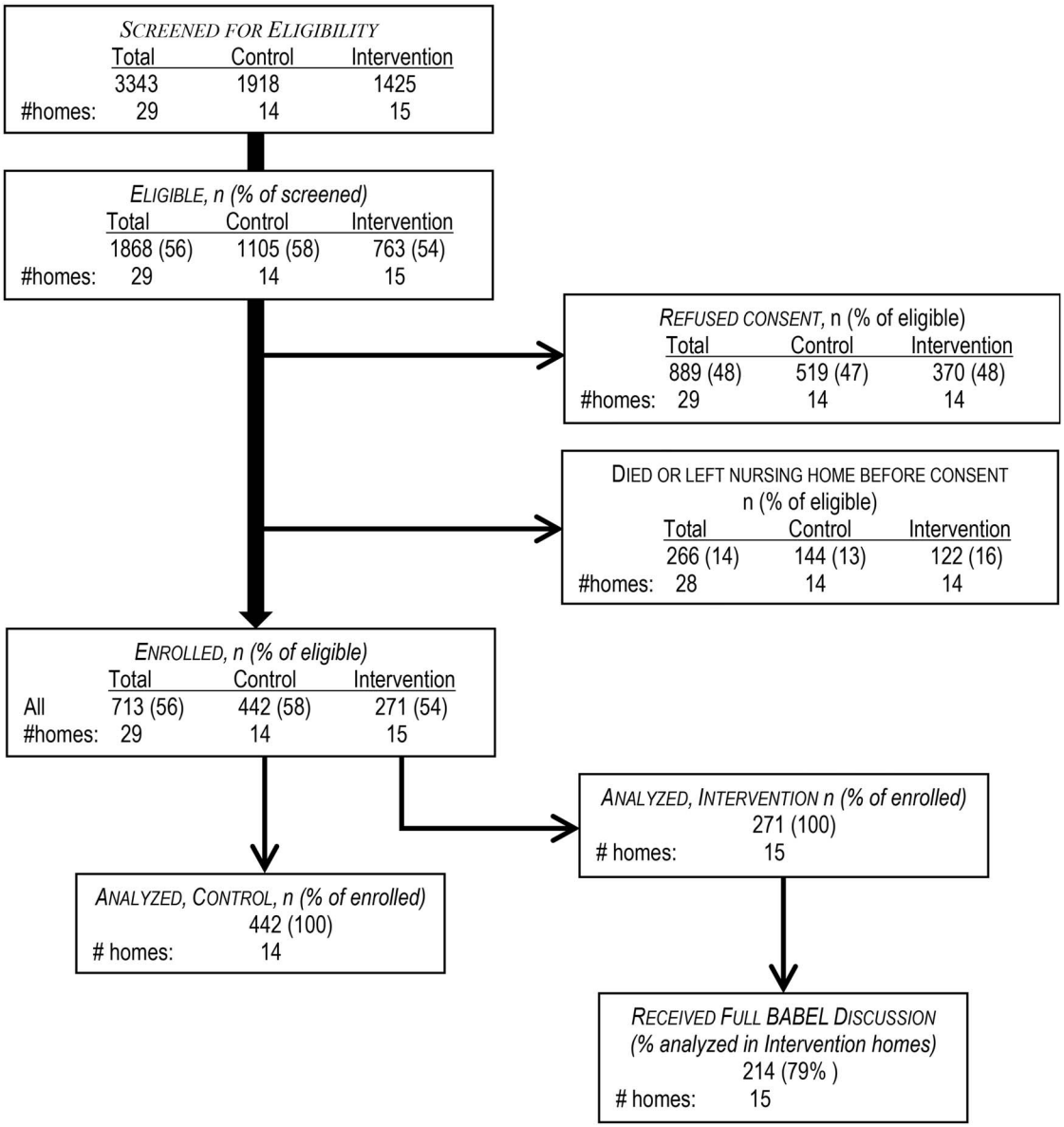

Figure 1. Consort diagram for the BABEL ACP study.

in ACP, leading to better discussions and more informed residents and SDMs (Appendix 4).

Discussion

The BABEL approach to ACP resulted in: (1) more comprehensive ACP in NHs and (2) decreased use of antimicrobials. PP analysis (Table 3) was consistent with the Full BABEL discussion being the influential element of the intervention and may indicate inadequate sample size as the reason that other measures of medical resource group were not significantly lower in ITT analysis. Likely contributors to this latter include that the study was not powered for those outcomes, and the recruitment difficulties described. The qualitative portion of the study indicated that the BABEL intervention improved ACP discussions, NH staff knowledge and comfort in conducting discussions, and health record documentation of ACP decisions. The major barrier to its implementation was the time required to deliver the Full BABEL Discussion, generally estimated at ~60 min.

Despite our expectation that the intervention would lead to fewer residents receiving aggressive, potentially uncomfortable care at the end of life, it did not increase the outcome of comfort assessment in dying, or rate of entry into formal palliative care. Similar null results using the same outcome scale were observed in a trial of a palliative care program in European NHs [39]. A possible contributor to this null finding was generally high comfort in dying of both groups (Supplementary Table 3); this suggests that problems with end-of-life care are not because NH personnel do not

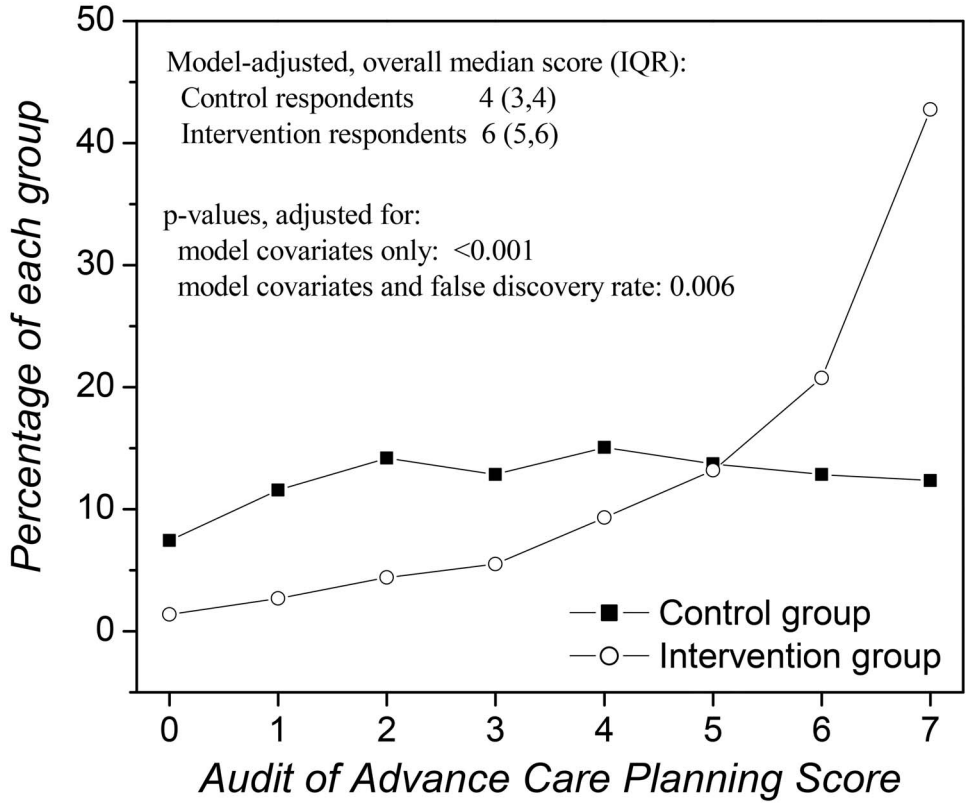

Figure 2. Marginal, adjusted values of the resident audit of ACP (co-primary outcome), by group; from the model in Supplementary Table 4.

know how to provide it once a decision has been made to implement it, but because of trouble eliciting with residents when to provide it.

Our finding that the BABEL approach improved the comprehensiveness of ACP underscores the importance of allowing adequate time for these discussions; shortcuts that do not compromise the quality of ACP are unlikely to be found. This is consistent with pre-study observations by NH staff that time was a barrier to ACP, and with studies of outpatient care demonstrating that longer visits are associated with more shared decision-making [40, 41], better communication [42, 43], higher quality of care [44] and more attention to complex issues [42, 43, 45]. Although time is at a premium in NHs, is this time being utilised wisely? An anecdote from one of our control NHs is particularly informative (Mira Djokic, personal communication). A resident became acutely ill, was sent to hospital, stayed several days and died hours after NH repatriation. The time spent by NH personnel on such reactive care, making the resident ready for transport and resettled upon repatriation far exceeded 60 min for proactive planning required for a full BABEL discussion.

Conducting ACP 'upstream' from NH admission is attractive, but problematic. ACP requires trained personnel, but who would take on this role in the community? Average primary care outpatient visits of 20 min [46] are insufficient to conduct comprehensive ACP. Remuneration is a disincentive; in the United States, Medicare pays $170 for 60 min of ACP versus $370 for seeing four established patients for 15 min each [47]. Conducting ACP in homecare or assisted living settings is impeded by even lower staffing ratios than in NHs [48]; also, half or less of NH admissions come from such settings [22, 49]. Thus, for comprehensive ACP to occur in NHs, adequate staffing with sufficient expertise and training is needed; likely we must reconfigure NH care processes.

Addressing growing nursing shortages in NHs [50, 51] and increasing physician presence and engagement in NHs [20, 52] are essential to support fulsome discussion of medical issues such as prognosis and treatment options that are essential to comprehensive ACP. Professional societies have defined core competencies for NH nurses [53] and physicians [54]; however, actual competency is highly variable [52], with few having geriatrics training [50, 55]. Katz *et al*. have noted the difficulty in convincing attending physicians to adhere to specific practice standards [56]. High quality NH care, including comprehensive ACP, requires considerably more on-site physician presence than is commonly provided [54, 57]. And it has been suggested to make NH medicine a specialty with required training, board examinations and closed-model, full-time, salaried, on-site positions [54, 56].

Interventional studies of ACP in NHs are uncommon. A 2015 systematic review identified only 13 [58], none of

Table 3. Adjusted comparisons of medical resource use outcomes

Outcome parameter	*IRR (95% CI)*	*Model-adjusted P-value*[a]	*Model and FDR-adjusted P-value*[b]
Courses of antimicrobials in NH			
Primary, ITT analysis ($n = 713$)	0.79 (0.66, 0.94)	0.008	0.048
Per protocol analysis			
control residents ($n = 442$)	reference		
intervention residents who never received the Full BABEL discussion ($n = 57$)	1.01 (0.73, 1.39)	0.97	
intervention residents who received the Full BABEL discussion* ($n = 214$)	0.72 (0.58, 0.88)	.001	
Other diagnostic or therapeutic interventions performed in the NH			
Primary, ITT analysis ($n = 713$)	0.96 (0.73, 1.27)	0.79	0.79
Per protocol analysis			
control residents ($n = 442$)	reference		
intervention residents who never received the Full BABEL discussion ($n = 57$)	1.11 (0.82, 1.49)	0.50	
intervention residents who received the Full BABEL discussion[c] ($n = 214$)	0.99 (0.75, 1.29)	0.91	
Other diagnostic or therapeutic interventions performed in outpatient settings			
Primary, ITT analysis ($n = 713$)	0.85 (0.53, 1.37)	0.50	0.55
Per protocol analysis			
control residents ($n = 442$)	reference		
intervention residents who never received the Full BABEL discussion ($n = 57$)	1.22 (0.64–1.33)	0.54	
intervention residents who received the Full BABEL discussion[c] ($n = 214$)	0.75 (0.45, 1.25)	0.27	
Transfer to hospital or Emergency			
Primary, ITT analysis ($n = 713$)	0.77 (0.48, 1.25)	0.30	0.51
Per protocol analysis			
Control residents ($n = 442$)	reference		
Intervention residents who never received the Full BABEL discussion ($n = 57$)	1.33 (0.72–2.40)	0.36	
Intervention residents who received the Full BABEL discussion[c] ($n = 214$)	0.63 (0.39–1.01)	0.06	
Admission to an intensive care unit			
Primary, ITT analysis ($n = 713$)	0.23 (0.008, 6.32)	0.38	0.53
PP analysis	†	†	

[a]Via mixed-effects, multivariable grouped Poisson regression, adjusted for: province, resident age at consent, resident gender, marital status, consenter for resident (self vs. SDM), interval from NH admission to consent, modified CCI, inclusion criteria (CHESS score [CHESS, Changes in Health, End-stage disease and Symptoms and Signs], congestive heart failure, malignancy, leaving >25% of food uneaten), Cognitive performance scale, Depression scale, Pain scale, Aggressive Behaviour scale, Activities of Daily Living scale, receiving hospice care, #NH beds, NH ownership (public vs. private). [b]Further adjustment of all 12 ITT *P*-values via Simes step-up False Discovery Rate (FDR) procedure. [c]Limited to interval and events occurring after the full BABEL discussion. †No events for the intervention cohort, model would not converge.

which assessed the breadth of relevant outcomes of our study, or adjusted their analyses for multiple comparisons. Hospitalisation rate was the most common outcome assessed, with reductions ranging 9–26%, compared with our 23% reduction in the adjusted incidence rate of transfer to emergency department or hospital. The two studies assessing mortality found that their ACP interventions did not alter mortality rates, in agreement with our finding. A more recent cluster randomised study in six Australian NHs [59] introduced a goal of care form incorporating a nuanced delineation of ACP wishes, a feature shared by BABEL ACP. This study reported a nonsignificant reduction in the incidence rate of transfer to emergency or hospital of 26%, similar to our 23% reduction. This similarity might indicate that a vital component of ACP is establishing the nuanced spectrum of options and outcomes, which is counter to practice and regulations in many jurisdictions that mandate goals of care designations with few gradations [60, 61]. Finally, a cluster randomised study in 28 American NHs found no effect of an intervention aimed at reducing antibiotic use in residents with severe dementia and suspected infection [62]. This negative result might reflect an intervention aimed at NH staff and limited to a single clinical issue, whereas the significant reduction in antibiotic use in BABEL may reflect it being an interactive intervention aimed at engaging residents and their proxies in a larger discussion about appropriate goals of care.

The main strength of this study is that it evaluated an ACP intervention that is more person-centred and comprehensive than any other of which we are aware, and that provides NH-tailored, evidence-informed, stakeholder-based resources. Second, we collaborated with NH stakeholders to design the intervention in a way that best practices were embedded into usual care processes. Other strengths are a wide-ranging set of both quantitative and qualitative person-centred outcomes, cluster randomisation and analysis that rigorously adjusted for multiple comparisons.

Our study also has limitations. The primary limitation was failure to reach the estimated sample size, which raises the probability of making Type II errors in inference. Second, as it was performed in 29 NHs in three Canadian provinces, additional studies are necessary to demonstrate generalisability of our approach, especially to other countries where ACP and end-of-life practices in NHs differ. Another limitation is related to the known problem of suboptimal adherence to

prior ACP decisions during medical emergencies [18, 20]. Although aspects of BABEL ACP were designed to address this issue, our study did not assess such adherence, and thus we are unable to speak to the possibility that augmenting these features might improve the benefits of BABEL ACP. Also, as elaborated in Appendix 5, the study refinement that was part of the original study plan led to modification of outcomes after the original ethics submission, but before the study began.

Placed in the context of prior studies, our findings indicate that ACP needs to be recognised as a core expectation and competency of NH personnel. ACP is fundamental to NH care. We must rethink existing training, structures, policies and care processes in NHs to effectively provide the comprehensive ACP that this large, and growing, population needs.

Supplementary Data: Supplementary data mentioned in the text are available to subscribers in *Age and Ageing* online.

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