'Advance care planning, general practitioners and patients

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Facilitating the initiation of advance care planning between general practitioners and patients with a chronic life-limiting illness: an exploratory phase II pilot cluster-randomized controlled trial

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ABSTRACT

Objectives: Although general practice is an ideal setting for ensuring timely initiation of advance care planning (ACP) in people with chronic life-limiting illness, evidence on the effectiveness of ACP in general practice and how it can be implemented is lacking. This study aims to evaluate feasibility and acceptability of study procedures and intervention components of an intervention to facilitate the initiation of ACP in general practice for people with chronic life-limiting illness.

Methods: Pilot cluster-randomized controlled trial testing a complex ACP intervention in general practice versus usual care (ClinicalTrials.gov: NCT02775032). We used a mixed methods approach using detailed documentation of the recruitment process, questionnaires, and semi-structured interviews.

Results: A total of 25 GPs and 38 patients were enrolled in the study. The intervention was acceptable to GPs and patients, with GPs valuing the interactive training and patients finding ACP conversations useful. However, we found a number of challenges regarding feasibility of recruitment procedures, such GP as recruitment proceeding more slowly than anticipated as well as difficulty applying the inclusion criteria for patients. Some GPs found initiating ACP conversations difficult. The content of the patient booklet was determined to potentially be too complex for patients with a lower health literacy.

Conclusion: Although the intervention was well-accepted by GPs and patients, we identified critical points for improvement with regard to the study procedures as well as potential improvements of the intervention components. When these points are addressed, the intervention can proceed to a large-scale, Phase-III trial to test its effectiveness.

Key words: Communication, Advance Care Planning, General Practice, Clinical Trial, Phase II, Randomized Controlled Trial

INTRODUCTION

Advance care planning (ACP) is a process of communication that supports adults at any age or stage of health in reflecting upon and sharing personal values and preferences regarding future end-of-life care.(1) The goal of ACP is to make individuals' wishes known to informal and formal caregivers to help ensure that people receive care that is consistent with their preferences; including at times when they lose decisional capacity. GPs are well-placed to engage with their patients in ACP.(2) However, interventions aiming to facilitate ACP have mainly been developed for and implemented in nursing homes or hospital settings.(3)

We performed a pilot trial with the primary aim to assess feasibility and acceptability of the study procedures and intervention components of an intervention to facilitate the initiation of ACP in general practice for people with a chronic life-limiting illness (4).

METHODS

Study design

Pilot cluster-RCT (ClinicalTrials.gov: NCT02775032) with individual GPs as unit of randomization to avoid risk of contamination within their practice. We aimed to include 30 GPs from Flanders, Belgium randomized to either the intervention or control group by an independent statistician.

Participants and recruitment

Patients were recruited by participating GPs. Patients were invited to participate if they 1) were 18 years of age or older, 2) the GP would not be surprised if the patient died within the next 12 months (surprise question(5)), 3) were judged mentally competent by their GP, 4) could speak Dutch, and 5) were not participating in other studies evaluating palliative care services or communication strategies.

Participating GPs were asked to recruit three eligible patients by inviting them for the study during a consultation. The research team further informed eligible patients via telephone. If patients agreed to participate, a home visit was scheduled by a research assistant, where patients were asked to provide written informed consent.

Intervention versus care as usual

The intervention consists of 1) a training for GPs, 2) an educational booklet about ACP for patients, 3) patient-centered ACP discussions with the help of a conversation guide for GPs, and 4) a structured

template for documenting the outcomes of the ACP discussions, and is described in detail elsewhere.(4) Patients in the control group received care as usual, which could include spontaneous ACP conversations.

Data collection

We assessed feasibility of the intervention using detailed documentation of the recruitment process and drop-out of participants; by monitoring the response rates of GP and patient questionnaires; and through semi-structured interviews with intervention group GPs and patients after completion of the intervention using a self-developed topic guide. Acceptability of the intervention was assessed using semi-structured interviews with intervention GPs and patients.

All participants were asked about socio-demographic status. Preliminary data were collected on GPs' self-confidence, knowledge, and attitudes with regard to ACP(6). Patients reported on quality of life (MQOL(7)), anxiety (GAD-7(8)), depression (PHQ-9(9)), and quality of communication(10). Outcome measures were assessed at baseline (T0) and 3 months after inclusion in the study (T1). Preliminary effectiveness of the intervention will be reported elsewhere.

Data analyses

Descriptive statistics were used to summarize GP and patient characteristics. Interviews were audiotaped and transcribed verbatim. The anonymized interviews were analyzed both by deduction (using the intervention components as a framework) and induction (thematic content analysis using codes on the basis of the underlying structure of the interview) by SD and ADV. The research team met on several occasions to discuss the obtained qualitative and quantitative results.

RESULTS

Feasibility and acceptability of the study procedures

Recruitment

A total of 32 GPs agreed to participate in the study, of which 14 were randomized to the control group and 18 to the intervention group. GPs from the same group practice were randomized in their entirety. The 25 GPs who were eventually enrolled in the study identified 45 eligible patients, of which 38 patients were enrolled (15 patients in control and 23 patients in intervention group).

As recruitment of GPs proceeded more slowly than expected, the recruitment period was extended with 2 months. During the interviews with GPs from the intervention group, a number of reasons were mentioned for recruiting insufficient or no patients . Some patients refused to participate because they did not see any benefit in discussing ACP. Some GPs indicated that they did not introduce the study to certain eligible patients because they thought these patients would not understand the study procedures or the concept of ACP, or because participating would be too burdensome.

Description of the study sample

Participating GPs were mostly female, had an average experience of 13 years in general practice, and were mostly part of a group practice (83,3%)(Supplementary table 1). Experience with ACP in the previous 6 months did not differ significantly between groups. Patients who were included were mostly female (68,4%), were on average 78 years old, and were mostly diagnosed with cardiovascular disease (40,5%)

GP and patient questionnaires

Response rate for the GP questionnaire was 96% at T0 and 60% at T1. For patients, 100% of outcome data was collected at T0 because the questionnaire was filled in together with a research assistant. At T1, 69,6% in the intervention group and 73,3% in the control group returned the questionnaire by mail.

Feasibility and acceptability of the intervention components

GPs from the intervention group assessed the training positively both in terms of content and time investment. The practical nature of the training, such as strengthening their communication skills through role play, was considered the most valuable element.

GPs generally regarded the booklet as a useful tool for pre-structuring the ACP discussions. However, a few GPs indicated that the booklet was difficult in use for elderly patients, which some patients also confirmed.

Facilitating factors for initiating ACP conversations reported during the interviews included patients already thinking about their preferences in advance due to the booklet or taking initiative themselves to discuss ACP, and using quality of life as an approach to initiate ACP rather than focusing on the end of life. Some GPs considered the conversations as more challenging. For example, they indicated that it was too complex for some patients to understand ACP. Interviews with patients revealed that most patients experienced the discussions as useful. Some specifically mentioned feeling reassured that their GP was aware of their wishes and preferences. More details about the ACP discussions can be found in Table 1.

Table 1. Number, duration and documentation of ACP discussions and presence of others during ACP discussions as reported by interviewed GPs from the intervention group (n=10)

	Patients (N=18[a])	
	N	%
Number of ACP discussions		
1	8	47,1
2	6	35,3
3	3	17,6
Total duration of ACP discussion(s)		
30 minutes or less	6	37,5
30-60 minutes	9	56,2
More than 1 hour	1	6,3
Documentation of ACP discussion(s)[b]		
Medical file	15	100
Care home file	2	13,3
Intervention template	2	13,3
Advance directive to refuse treatment	6	40,0
Others present during ACP discussion(s)[c]		
Partner	6	35,3
Child(ren)	3	17,6
No others present	10	58,8

Missings: Number of ACP discussions: n=1, Total duration of ACP discussion(s): n=2, Documentation of ACP discussions: n=3, Others present during ACP discussion(s): n=1

[a] The 10 interviewed GPs included in total 19 patients. For one patient, the ACP discussion(s) had not yet occurred when the interview took place.

[b] Multiple answers possible, therefore percentages may not lead op to 100%. Information is missing for 3 patients.

[c] Multiple answers possible, therefore percentages may not lead op to 100%.

Several GPs found documenting the ACP discussions challenging because their patient electronic health record lacked the possibility to integrate the provided study template.

DISCUSSION

This pilot study examined the feasibility and acceptability of an intervention to facilitate the initiation of ACP between general practitioners and patients with a chronic life-limiting illness. The results show that adaptations to the training for GPs and the patient booklet are warranted, and new strategies to facilitate the recruitment of GPs and patients should be foreseen.

Interpretation of the results and implications for a future Phase III trial

A perceived lack of time to undertake ACP or to be involved in a study might have prevented GPs from participating.(11) For future studies, we believe that this challenge might be addressed by offering

financial reimbursement for participation and by reimbursing the consultation fee, together with offering accreditation points towards GPs' continuous medical education for participation in the training.

Only 1/3 of the targeted number of patients were included. This might indicate that GPs need extra training in using the surprise question(5) to identify eligible patients. We know that on average 6 to 7 patients per GP practice die each year in Belgium, of which 4 to 5 deaths are labelled as "non-sudden."(12) More specific inclusion criteria including clinical indicators, in addition to facilitation in identifying eligible patients by a research assistant, may be warranted. Moreover, our results show that for some GPs certain challenges to initiating or discussing ACP still persisted after the training. Follow-up by the trainer during the study period may also be necessary to continuously support GPs.

Some adjustments to the patient booklet should also be considered to explain the concept of ACP in a more accessible way. In general, patients of advanced age were enrolled in this study, of whom many have a relatively low level of education in Belgium.(13) Previous research has shown that ACP documents redesigned to better meet adults' levels of literacy are rated as more acceptable, particularly to patients with limited literacy.(14,15)

Limitations of the study

Firstly, participating GPs were responsible for recruiting patients, which may have posed a selection bias towards including patients with whom they feel comfortable discussing ACP. However, this decision was made to preserve the existing GP-patient relationship and was based on extensive deliberation by the research team, including a GP. Secondly, only patients and GPs from the intervention group were interviewed post-intervention, which may have biased the results towards a higher degree of acceptability of the intervention.

CONCLUSION

Although this ACP intervention was well-accepted to GPs and patients, this study identified some critical points for improvement regarding the trial procedures and intervention components, before testing the effectiveness of this intervention in a Phase III trial.

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Declaration of conflict of interests

The authors declare that there is no conflict of interest.

Ethical approval

The Ethical Review Board of the Brussels University Hospital approved the study protocol and all study materials (B.U.N. 143201628718, 10 August 2016). All study participants provided written informed consent.

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Contributorship statement

ADV, LD, KP, PP and RVS were responsible for the study's conception and design. SD and ADV were responsible for data collection and analysis and drafted the manuscript. All authors contributed to the interpretation of the data, critically revised the manuscript for important intellectual content, and gave final approval for submission. SD, ADV and LD act as guarantors of the work. ADV and LD contributed equally as last author.

REFERENCES

1. Sudore RL, Lum HD, You JJ, Hanson LC, Meier DE, Pantilat SZ, e.a. Defining Advance Care Planning for Adults: A Consensus Definition From a Multidisciplinary Delphi Panel. Journal of Pain and Symptom Management. mei 2017;53(5):821-832.e1.

2. Conroy S, Fade P, Fraser A, Schiff R, Guideline Development Group. Advance care planning: concise evidence-based guidelines. Clinical medicine (London, England). februari 2009;9(1):76–9.

3. Brinkman-Stoppelenburg A, Rietjens JAC, van der Heide A. The effects of advance care planning on end-of-life care: a systematic review. Palliat Med. september 2014;28(8):1000–25.

4. De Vleminck A, Houttekier D, Deliens L, Vander Stichele R, Pardon K. Development of a complex intervention to support the initiation of advance care planning by general practitioners in patients at risk of deteriorating or dying: a phase 0-1 study. BMC Palliative Care. 11 december 2016;15(1):17.

5. Downar J, Goldman R, Pinto R, Englesakis M, Adhikari NKJ. The “surprise question” for predicting death in seriously ill patients: a systematic review and meta-analysis. Canadian Medical Association Journal. 3 april 2017;189(13):E484–93.

6. Detering K, Silvester W, Corke C, Milnes S, Fullam R, Lewis V, e.a. Teaching general practitioners and doctors-in-training to discuss advance care planning: evaluation of a brief multimodality education programme. BMJ Support Palliat Care. september 2014;4(3):313–21.

7. Cohen SR, Mount BM, Strobel MG, Bui F. The McGill Quality of Life Questionnaire: a measure of quality of life appropriate for people with advanced disease. A preliminary study of validity and acceptability. Palliat Med. 1 juli 1995;9(3):207–19.

8. Spitzer RL, Kroenke K, Williams JBW, Löwe B. A Brief Measure for Assessing Generalized Anxiety Disorder: The GAD-7. Archives of Internal Medicine. 22 mei 2006;166(10):1092.

9. Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. Journal of General Internal Medicine. september 2001;16(9):606–13.

10. Engelberg R, Downey L, Curtis JR. Psychometric Characteristics of a Quality of Communication Questionnaire Assessing Communication about End-of-Life Care. Journal of Palliative Medicine. oktober 2006;9(5):1086–98.

11. Howard M, Bernard C, Klein D, Elston D, Tan A, Slaven M, e.a. Barriers to and enablers of advance care planning with patients in primary care: Survey of health care providers. Canadian Family Physician. 1 april 2018;64(4):e190–8.

12. Van den Block L, Onwuteaka-Philipsen B, Meeussen K, Donker G, Giusti F, Miccinesi G, e.a. Nationwide continuous monitoring of end-of-life care via representative networks of general practitioners in Europe. BMC family practice. 2013;14:73.

13. De Vleminck A, Pardon K, Houttekier D, Van den Block L, Vander Stichele R, Deliens L. The prevalence in the general population of advance directives on euthanasia and discussion of end-of-

life wishes: a nationwide survey. BMC Palliative Care. 7 december 2015;14(1):71.

14. Sudore RL, Landefeld CS, Barnes DE, Lindquist K, Williams BA, Brody R, e.a. An advance directive redesigned to meet the literacy level of most adults: A randomized trial. Patient Education and Counseling. december 2007;69(1–3):165–95.

15. Sudore RL, Schillinger D, Knight SJ, Fried TR. Uncertainty About Advance Care Planning Treatment Preferences Among Diverse Older Adults. Journal of Health Communication. 31 augustus 2010;15(sup2):159–71.