

Advance care planning in general practice

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Registration date 19/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/07/2024	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Rather than a one-time documentation of care goals and preferences, advance care planning (ACP) is currently conceptualized as an ongoing, communication process that should be initiated early in the disease trajectory. General practitioners (GPs) play a critical role in timely initiation of ACP. By discussing ACP with their GP, patients have time to think about and communicate their preferences, increasing their engagement with the process. However, little evidence exists of how GPs and patients can initiate these conversations effectively. In this project, we will conduct a randomized-controlled trial of an ACP intervention for general practice. We aim to compare the complex, multi-component ACP intervention to care as usual.

Who can participate?

Dutch-speaking GPs who treat patients in Flanders and Brussels, Belgium, are eligible to participate. GPs will identify which of their patients are eligible to participate. Eligible patients are adults (older than 18 years) with a chronic, life-limiting illness. Each patient may also indicate a surrogate decision maker for participation.

What does the study involve?

The intervention developed for this trial will be compared to a usual care control group. The intervention consists of the following components: 1) ACP knowledge and communication skills training for GPs, 2) a workbook about ACP for the patient, 3) at least 2 structured ACP conversations between the GP and patient, and 4) documentation of the ACP discussion in a template. A process evaluation with focus groups and interviews will be conducted to evaluate how the intervention was implemented. The control group GPs will provide their patients with the usual standard of care. No additional materials will be provided for this group, nor will additional ACP conversations be planned.

GPs, patients, and surrogate decision-makers in both groups will complete questionnaires at baseline, at 3 months, and at 6 months. The GP questionnaire will evaluate knowledge, attitudes, and self-efficacy regarding ACP, as well as the GP's current ACP practices. The patient questionnaires will evaluate the patient's level of engagement with ACP, quality of life, anxiety, depression, and their communication with the GP. Surrogate decision-maker questionnaires will evaluate the level of engagement with ACP.

What are the possible benefits and risks of participating?

This study can deliver valuable evidence about the effects of ACP in general practice, and of the effectiveness of the tools developed for this intervention. The training and tools presented to GPs and the workbook and conversations offered to patients can support GPs and patients in starting conversations about ACP. GPs in the control group will also be offered the chance to attend the training after the conclusion of the study.

There are minimal risks to participating. Patients are able to indicate what they wish to discuss ACP. We will also monitor patient depression and anxiety to allow a timely response to adverse events.

Where is the study run from?

The study is run from the Vrije Universiteit Brussels (VUB) and Ghent University (UGent) (Belgium)

When is the study starting and how long is it expected to run for?

The first participant is expected by 15/8/2020. The study will run until March 2021 (approximately 7 months).

Who is funding the study?

The Research Foundation - Flanders (Belgium) (Fonds Wetenschappelijk Onderzoek)

Who is the main contact?

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

2020/068

Study information

Scientific Title

Improving patients' level of engagement in advance care planning with their general practitioner: a cluster randomized controlled trial

Acronym

ACP-GP

Study objectives

Current study hypothesis as of 13/10/2020:

1. To test the effectiveness of the ACP-GP intervention on:
 - 1.1. The patient's level of engagement with ACP (primary outcome at patient level)
 - 1.2. The GP's self-efficacy for conducting ACP (primary outcome at GP level)
2. To explore the effect of the ACP-GP intervention on:
 - 2.1. Patient quality of life; symptoms of anxiety; symptoms of depression; the appointment of a substitute decision-maker; completion of new ACP documents; thinking about ACP, and communication with the GP (secondary outcomes at patient level)
 - 2.2. GP ACP practices, attitudes and knowledge about ACP, and the documentation of ACP

discussions in the patient medical file (secondary outcomes at GP level)
2.3. The SDM's level of engagement with ACP (secondary outcome at the SDM level)
3. To evaluate the recruitment and implementation process of the intervention in terms of its reach, efficacy, adoption, implementation, and maintenance; as reported by patients, their SDM if present, and GPs

Previous study hypothesis:

1. To compare the complex, multi-component advance care planning (ACP) intervention to care as usual in terms of their effect on:
 - 1.1. the patient's level of engagement with ACP (primary outcome at patient level)
 - 1.2. the general practitioner (GP)'s self-efficacy for conducting ACP (primary outcome at GP level)
 - 1.3. patient quality of life, symptoms of anxiety, symptoms of depression (secondary outcomes at patient level)
 - 1.4. the appointment of a substitute decision-maker (secondary outcome at patient level)
 - 1.5. GP self-confidence for conducting ACP, attitudes and knowledge about ACP (secondary outcomes at GP level)
 - 1.6. the documentation of ACP discussions in the patient medical file (secondary outcome at GP level)
 - 1.7. the surrogate decision maker's level of engagement with ACP (secondary outcome at surrogate decision-maker level)
2. To evaluate the recruitment and implementation process of the intervention in terms of its reach, efficacy, adoption, implementation, and maintenance, as reported by patients, their surrogate decision maker if they are present, and GPs; by means of a process evaluation running parallel with the study

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 18/03/2020, Commission for Medical Ethics (O.G. 016) of the Vrije Universiteit Brussel /UZ Brussel (Laarbeeklaan 101, 1090 Brussels, Belgium; + 32 (0)2 477 55 84; commissie.ethiek@uzbrussel.be), ref: 2020/068

Study design

Multicenter cluster-randomized controlled trial

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Chronic, life-limiting illnesses (cancer, heart failure, kidney failure, severe COPD, and mild to severe geriatric frailty)

Interventions

An independent statistician not affiliated with the research group will randomize the participating general practitioners (GPs) along with their patient cluster to the intervention or control group. Randomization occurs at the GP level to prevent contamination between the intervention and control group, as all patients within one cluster will receive either consultations

from a GP who has received the intervention, or care as usual from a GP who did not receive the intervention.

The control group GPs will provide their included patients with the usual standard of care, which may or may not include spontaneous ACP discussions according to the GP's judgment. No additional materials will be provided and no additional GP appointments will be required.

The intervention consists of following components for 6 months:

1. An advance care planning (ACP) training for GPs, where GPs can practice ACP conversations with feedback
2. An ACP workbook for patients called "Mijn Wensen Voor Toekomstige Zorg" (My Wishes for Future Care) which encourages reflection about what the patient considers a good quality of life and quality of care
3. At least 2 ACP conversations between the GP and patient, using materials such as a conversation guide for GPs (provided during the training) and the patient's workbook
4. Documentation of the ACP conversation outcomes in a standardized template

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measures as of 13/10/2020:

1. Level of engagement with advance care planning will be measured using the 15-item version of the ACP Engagement Survey (Dutch translation) at baseline, 3 months, and 6 months
2. The general practitioner primary outcome of advance care planning self-efficacy will be measured using the ACP Self-Efficacy Scale (ACP-SE) at baseline (T0), 3 months (T1), and 6 months (T6).

Success on any one of these outcomes at T1 may support a conclusion of effectiveness. The researchers will treat T2 scores on these scales as a secondary outcome.

Previous primary outcome measures:

1. Level of engagement with advance care planning will be measured using the 15-item version of the ACP Engagement Survey (Dutch translation) at baseline, 3 months, and 6 months
2. The general practitioner primary outcome of advance care planning self-efficacy will be measured using the ACP Self-Efficacy Scale (ACP-SE) at baseline, 3 months, and 6 months.

Key secondary outcome(s)

Current secondary outcome measures as of 13/10/2020:

Patient-level secondary outcome measures:

1. Patient health-related quality of life measured using the 12-item Short-Form Survey (SF-12) at baseline, 3 months, and 6 months
2. Patient anxiety measured using the Generalized Anxiety Disorder (GAD-7) Questionnaire at baseline, 3 months, and 6 months
3. Patient depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3 months, and 6 months
4. Appointment of a substitute decision maker will be evaluated by patient report, GP report, and by the response to the ACP engagement survey "readiness to sign official papers assigning a SDM" item, at baseline, 3 months, and 6 months
5. Completion of new advance care planning documents will be evaluated by patient report, GP report, and ACP engagement survey "readiness to sign official papers stating medical wishes" item, at 3 months and 6 months

7. "Thinking about ACP" will be measured using 1 self-developed item, 10-point Likert ("How much have you thought about ACP in the last 3 months?") at baseline, 3 months, and 6 months
8. Communication with the GP will be measured using 4 self-developed items, 10-point Likert (e.g., "To what extent did the GP listen to your concerns about your future health?"), at baseline, 3 months, and 6 months

GP secondary outcome measures:

1. General practitioner knowledge and attitudes regarding advance care planning measured using the Next Steps training program questionnaire at baseline, 3 months, and 6 months
2. ACP practices will be measured using the Next Steps training program questionnaire; 2 items specific to practices with patients with chronic, life-limiting illness; 8 additional items regarding ACP practices (e.g., "Where do the ACP conversations you conduct usually take place?"); at baseline, 3 months, and 6 months
3. Documentation of ACP discussion outcomes evaluated through anonymized documentation template review, at 3 months and 6 months

SDM secondary outcome measures:

1. Surrogate decision-maker level of engagement with advance care planning measured using the ACP Engagement Survey, substitute decision maker version (Dutch translation) at baseline, 3 months, and 6 months

Process evaluation:

1. Process measures (RE-AIM framework) evaluated through general practitioner focus group discussions at 6 months
2. Process measures (RE-AIM framework) evaluated through semi-structured interviews with patients and surrogate decision makers at 6 months
3. Process measures (RE-AIM framework) reported throughout the study period:
 - 3.1. Documentation of the recruitment process
 - 3.2. Monitoring of trainings (topic checklist) and follow-up by trainers
 - 3.3. Analysis of audio-recorded ACP conversations between patients (and SDM if present) and GP
 - 3.4. Workbook contents from a selection of intervention group patients
 - 3.5. GP and patient questionnaire regarding ACP discussions and practices at 3 months
 - 3.6. Satisfaction questionnaires for patients and GPs at 3 months

Previous secondary outcome measures from 01/09/2020 to 13/10/2020:

1. Patient health-related quality of life measured using the 12-item Short-Form Survey (SF-12) at baseline, 3 months, and 6 months
2. Patient anxiety measured using the Generalized Anxiety Disorder (GAD-7) Questionnaire at baseline, 3 months, and 6 months
3. Patient depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3 months, and 6 months
4. Appointment of a substitute decision maker will be evaluated by GP report, and by the response to the ACP engagement survey "readiness to sign official papers assigning a SDM" item, at baseline, 3 months, and 6 months
5. Completion of new advance care planning documents will be evaluated by patient report, GP report, and ACP engagement survey "readiness to sign official papers stating medical wishes" item, at 3 months and 6 months
6. General practitioner knowledge, attitudes, and self-confidence regarding advance care planning measured using the Next Steps training program questionnaire, at baseline, 3 months, and 6 months
7. Documentation of ACP discussion outcomes evaluated through anonymized documentation template review, at 3 months and 6 months

8. Surrogate decision maker level of engagement with advance care planning measured using the ACP Engagement Survey, substitute decision maker version (Dutch translation) at baseline, 3 months, and 6 months
9. Process outcome measures (RE-AIM framework) evaluated through general practitioner focus group discussions at 6 months
10. Process outcome measures (RE-AIM framework) evaluated through semi-structured interviews with patients and surrogate decision makers at 6 months
11. Process outcome measures (RE-AIM framework) reported throughout the study period: documentation of the recruitment process; monitoring of trainings and follow-up by trainers; analysis of audio-recorded ACP conversations between patients (and SDM if present) and GP; workbook contents from a selection of intervention group patients; GP and patient questionnaire regarding ACP discussions and practices at 3 months; and satisfaction questionnaires for patients and GPs at 3 months

Original secondary outcome measures:

1. Patient health-related quality of life measured using the 12-item Short-Form Survey (SF-12) at baseline, 3 months, and 6 months
2. Patient anxiety measured using the Generalized Anxiety Disorder (GAD-7) Questionnaire at baseline, 3 months, and 6 months
3. Patient depression measured using the Patient Health Questionnaire (PHQ-9) at baseline, 3 months, and 6 months
4. Appointment of a substitute decision maker will be evaluated by GP report, and by the response to the ACP engagement survey "readiness to sign official papers assigning a SDM" item, at baseline, 3 months, and 6 months
5. Completion of new advance care planning documents will be evaluated by patient report, GP report, and ACP engagement survey "readiness to sign official papers stating medical wishes" item, at 3 months and 6 months
6. General practitioner knowledge, attitudes, and self-confidence regarding advance care planning measured using the Next Steps training program questionnaire, at baseline, 3 months, and 6 months
7. Documentation of ACP discussion outcomes evaluated through anonymized documentation template review, at 3 months and 6 months
8. Surrogate decision maker level of engagement with advance care planning measured using the ACP Engagement Survey, substitute decision maker version (Dutch translation) at baseline, 3 months, and 6 months
9. Process outcome measures (RE-AIM framework) evaluated through general practitioner focus group discussions at 6 months
10. Process outcome measures (RE-AIM framework) evaluated through semi-structured interviews with patients and surrogate decision makers at 6 months

Completion date

01/06/2021

Eligibility

Key inclusion criteria

General practitioners:

1. Dutch-speaking
2. Working with and caring for patients in Flanders or Brussels, Belgium
3. Able to include at least 3 patients

Patients:

1. Adults (>18 years old)
2. Mentally competent as measured by judgment of the GP OR if Mini-Mental State Examination has been conducted, score is >24
3. GP answers "no" to the surprise question, "Would I be surprised if this patient were to die within the next 12 to 24 months?"
4. Diagnosis of a life-limiting illness:
 - 4.1. Locally-advanced unresectable, or metastasized cancer OR
 - 4.2. Organ failure, this being
 - a) heart failure (New York Heart Association stage 3 or stage 4)
 - b) chronic kidney failure or end-stage renal disease (ESRD) (stage 4, eGFR=15-29; or stage 5, eGFR<15)
 - c) Very severe COPD (GOLD COPD stages stage 3 or stage 4) OR
 - 4.3. Geriatric frailty (Clinical Frailty Scale score 5-7, mildly to severely frail)

Added 13/10/2020:

Surrogate decision-makers:

1. Adults (>18 years old)
2. Identified by the patient as their surrogate decision-maker OR as a person who may be willing to be their surrogate decision-maker

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 years

Sex

All

Total final enrolment

208

Key exclusion criteria

General practitioners:

1. Participated in Phase-II trial of the intervention
2. Participated in the cognitive testing of intervention materials and translated questionnaires

Patients:

1. Unable to speak or understand Dutch
2. Unable to provide consent or complete the questionnaires due to cognitive impairment
3. GP answers "no" to the surprise question, "Would I be surprised if this patient were to die within the next 6 months?"
4. Participated in the phase-II trial of this intervention
5. Participated in the cognitive testing of intervention materials and translated questionnaires

Added 13/10/2020:

Surrogate decision makers:

1. Unable to speak or understand Dutch
2. Unable to provide informed consent

Date of first enrolment

30/06/2020

Date of final enrolment

21/12/2020

Locations

Countries of recruitment

Belgium

Study participating centre

Vrije Universiteit Brussel

Laarbeeklaan 101

Jette

Belgium

1090

Study participating centre

Universiteit Gent

Campus UZ Gent

C. Heymanslaan 10

Gent

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Sponsor information

Organisation

Vrije Universiteit Brussel

ROR

<https://ror.org/006e5kg04>

Funder(s)

Funder type

Government

Funder Name

Fonds Wetenschappelijk Onderzoek

Alternative Name(s)

Research Foundation Flanders, Flemish Research Foundation, The FWO, Het FWO, FWO

Funding Body Type

Government organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Belgium

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request. Requests may be addressed to the main contact persons (Julie Stevens, Prof. Koen Pardon, Dr. Aline De Vleminck, Prof. Luc Deliens). Every request will be evaluated on an individual basis and the ethics committee of the Vrije Universiteit Brussels will be contacted for approval before any sharing of participant-level data.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/09/2023	05/10/2023	Yes	No
Results article	knowledge and attitudes	26/06/2024	28/06/2024	Yes	No
Protocol article		25/06/2021	28/06/2021	Yes	No
Other publications	Process evaluation	06/07/2024	08/07/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes