ISRCTN12995230 https://doi.org/10.1186/ISRCTN12995230

Advance care planning in general practice

Submission date
16/06/2020

Recruitment status
No longer recruiting

Registration date
19/06/2020

Overall study status
Completed

Last Edited
08/07/2024

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
1. Julie Stevens
Julie.joseph.stevens@vub.be
2. Prof. Koen Pardon
Koen.pardon@vub.e
3. Dr. Aline De Vleminck
Aline.de.vleminck@vub.be
4. Prof. Luc Deliens
Luc.deliens@vub.be

Contact information

Type(s)
Public

Contact name
Miss Julie Stevens

ORCID ID
https://orcid.org/0000-0002-1417-0436

Contact details
End of Life Care Research Group
Brussels Health Campus - Building K
Laarbeeklaan 103
Jette
Belgium
1090
+32 470890527
julie.joseph.stevens@vub.be

Type(s)
Scientific

Contact name
Miss Julie Stevens

ORCID ID
https://orcid.org/0000-0002-1417-0436

Contact details
End of Life Care Research Group
Brussels Health Campus - Building K
Laarbeeklaan 103
Jette
Belgium
1090
+32 470890527
julie.joseph.stevens@vub.be

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure
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.

Secondary outcome measures
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 questionaire; 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

Overall study start date
31/10/2019

Completion date
01/06/2021

Eligibility

Key inclusion criteria
General practitioners:
1. Dutch-spreaking
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
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

Participant type(s)
Mixed

Age group
Mixed

Lower age limit
18 Years

Sex
Both

Target number of participants

36 general practitioners, each with a cluster of 3 patients (108 patients total), up to 108 surrogate decision makers (1 per patient)

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

Belgium
B-9000

Sponsor information

Organisation
Vrije Universiteit Brussel

Sponsor details
Laarbeeklaan 103
Jette
Belgium
1090
+32 24774757
info@vub.ac.be

Sponsor type
University/education

Website
http://www.vub.ac.be/en/

ROR
https://ror.org/006e5kg04

Funder(s)

Funder type
Government

Funder Name
Fonds Wetenschappelijk Onderzoek

Alternative Name(s)
Research Foundation Flanders, Flemish Research Foundation, FWO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The findings from this study are planned to be published in at least 4 research articles.

Intention to publish date
01/05/2022

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?
Protocol article		25/06/2021	28/06/2021	Yes	No
Results article		01/09/2023	05/10/2023	Yes	No
Results article	knowledge and attitudes	26/06/2024	28/06/2024	Yes	No
Other publications	Process evaluation	06/07/2024	08/07/2024	Yes	No