ADVANCE CARE PLANNING IN GENERAL PRACTICE AND BEYOND

A Cluster-Randomized Controlled Trial of the ACP-GP Intervention

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2024

Promotors: Prof. Dr. Koen Pardon
                  (Vrije Universiteit Brussel, Faculty of Medicine and Pharmacy)
                  End-of-Life Care Research Group

                  Prof. Dr. Luc Deliens
                  (Ghent University, Faculty of Medicine and Health Sciences)
                  End-of-Life Care Research Group

Co-promotor: Prof. Dr. Aline De Vleminck
                  (Vrije Universiteit Brussel, Faculty of Medicine and Pharmacy)
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Promotors

Prof. Dr. Koen Pardon

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End-of-Life Care Research Group

Co-promotor

Prof. Dr. Aline De Vleminck

Vrije Universiteit Brussel, Faculty of Medicine and Pharmacy

End-of-Life Care Research Group

Advisory Committee

Prof. Dr. Peter Pype

Ghent University, Faculty of Medicine and Health Sciences

End-of-Life Care Research Group

Members of the Examination Committee

Prof. Dr. Johan Vansintejan (chair)

Department of Family Medicine and Chronic Care

Vrije Universiteit Brussel (VUB)

Prof. Dr. Johan Bilsen

Mental Health and Wellbeing Research Group

Vrije Universiteit Brussel (VUB)

Prof. Dr. Pauline Boeckxstaens

Department of Public Health and Primary Care

Ghent University

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Department of Public Health and Primary Care

Ghent University

Prof Dr. Agnes Van der Heide

Department of Public Health

Erasmus MC

Rotterdam, the Netherlands

Prof. Dr. José Pereira

Department of Family Medicine

McMaster University

Hamilton, Canada

Contents

LIST OF CHAPTERS

Chapters 1-6 are based on the following publications:

Chapter 1

Stevens J, Pype P, Eecloo K, Deliens L, Pardon K, De Vleminck A. Facilitating advance care planning in the general practice setting for patients with a chronic, life-limiting illness: protocol for a phase-III cluster-randomized controlled trial and process evaluation of the ACP-GP intervention. *BMC Palliative Care*. 2021; 20(1); 97. [2021 Impact Factor: 3.113; Journal ranking Q2; ranking n°52/106 in Health Care Sciences & Services]

Chapter 2

Stevens J, Miranda R, Deliens L, Pype P, De Vleminck A & Pardon K. Advance care planning engagement in patients with chronic, life-limiting illness: baseline findings from a cluster-randomised controlled trial in primary care. *British Journal of General Practice*. 2023; 73 (730): e384-e391. [2022 SCIE Impact Factor: 5.9; Journal ranking Q1; ranking n°32/169 in Medicine, General & Internal; ranking n°1/18 in Primary Health Care]

Chapter 3

Stevens J, Miranda R, Pype P, Eecloo K, Deliens L, De Vleminck A & Pardon K. Complex advance care planning intervention in general practice (ACP-GP): cluster-randomised controlled trial. *British Journal of General Practice*. 2024; 74 (739): e78-e87. [2022 SCIE Impact Factor: 5.9; Journal ranking Q1; ranking n°32/169 in Medicine, General & Internal; ranking n°1/18 in Primary Health Care]

Chapter 4

Stevens J, Scherrens A-L, Pype P, Deliens L, De Vleminck A * Pardon K. How Advance Care Planning (ACP-GP) was implemented in Belgian general practice in the context of a cluster RCT: a process evaluation using the RE-AIM framework. [Submitted manuscript]

Chapter 5

Stevens J, Deliens L, Pype P, De Vleminck A, Pardon K. Complex advance care planning interventions for chronic serious illness: how do they work: a scoping review. *BMJ Supportive & Palliative Care*. 2022; 12: e441-e450. [2021 SCIE Impact Factor: 4.633; Journal ranking Q1; ranking n°25/109 in Health Care Sciences & Services.]

Chapter 6

Stevens J, Elston D, Tan A, Barwich D, Carter R, Cochrane D, Frenette N, Howard M. Clinicians' experiences implementing an advance care planning pathway in two Canadian provinces: a qualitative study. [Submitted manuscript]

ACKNOWLEDGMENTS

Every **ZRL-colleague**: thank you for making the VUB and UGent offices a wonderful place to work. A perfect balance of ambition, inquiry, supportiveness, and zany discussions about anything and everything. It *is* specuLAAS, by the way.

To the all the **114ers** in Jette: what a change from when I first took up my spot at the desk. New glass! No more puffing and sweating on sunny days! Sure, we're still working on the leak, but who's perfect? Thank you for being such a welcoming group right from the start. You made it the best home base I could ask for. Never a boring day discussing pizza and Luc's waffles (no relation), or ensuring we're stocked on koekskes and kauwgumpies. Working next to you made every day a klein gelukske.

Kim De Nooijer, a shout-out to you, my ZRL buddy, for guiding me through the first steps as a ZRL junior. Thanks for still taking up your mantle of buddydom when I have questions years later. **Nadine, Geertje, Yuliana, Chiara**: you not only keep this whole operation running, your office is also a gathering of warm-hearted people, a pleasure to talk to.

Thank you to everyone at the McMaster Department of Family Medicine and the Palliative Care Division for the study visit opportunity. **Michelle, Dawn, and the iCAN team**, thank you for the fantastic and educational collaboration. Thanks as well for taking me under your wing during my visit, and showing me many wonderful sights in and around Hamilton. Thanks to **Chris, Laura, Ash**, and everyone for the many inspiring conversations.

To **all my friends**—you all know who you are—thank you for the good times, the support, and the interest in what I do and how I'm doing. Thanks for the sushi nights at my place, for the long drives in good company, for pulling me out of the PhD whirlpool for a little while so that I'm refreshed and ready to dive back in. Thanks for welcoming me from all the way across the globe for cheese (delicious!), moscato (frozen and refreshing!), and tree-climbing (scary!) May we be nuisances to one another again soon!

A special thank-you to everyone from the **Mechels Harmonieorkest**, **Koninklijke Harmonie De Ware Vrienden**, and **Apollo Swing**, for all the opportunities for creative discovery and self-expression.

And last, but never least: thank you to my entire **family**. **Zus Marianne**, thank you for your support and interest, for finding me relevant clippings from the Artsenkrant, and just for dropping by. You are an unstoppable force. **Jan**, I'm so darn proud of you, and thankful that we can root for each other as MD and PhD.

Mamsy, thank you for your unconditional support in everything I do. Thank you for all the love and all the patience. Thank you for listening. Thank you for always being there.

LIST OF ABBREVIATIONS

ACP	Advance care planning
ACP-SE	Advance Care Planning Self-Efficacy Scale
AD	Advance directive
BC	British Columbia
CONSORT	Consolidated Standards of Reporting Trials
CI	Confidence interval
DNR	Do Not Resuscitate
EMM	Estimated marginal means
EMR	Electronic medical record
GAD-7	Generalized Anxiety Disorder-7 Questionnaire
GP	General practitioner
ICC	Intra-Cluster Correlation Coefficient
MHLP	Master of Health Leadership and Policy
MRC	Medical Research Council
MSW	Master of Social Work
NPT	Normalization Process Theory
PHQ-9	Patient Health Questionnaire-9
PRISMA-ScR	Preferred Reporting Items of Systematic reviews and Meta-Analyses (extension for scoping reviews)
RA	Research assistant
RCT	Randomized controlled trial
RE-AIM	Reach, Effectiveness/efficacy, Adoption, Implementation, Maintenance
SD	Standard deviation
SDM	Surrogate/substitute decision maker

SF-12v2	Short Form Health Questionnaire-12 version 2
SICG	Serious Illness Conversation Guide
SPIRIT	Standard Protocol Items: Recommendations for Interventional Trials
WHO	World Health Organization

PART I. General introduction

BACKGROUND

1. Aging populations and chronic (life-limiting) illness

Globally, populations are aging. According to the World Health Organizations (WHO), most people worldwide can expect to live into their sixties and beyond. The population of people aged 60 or older is also predicted to double to 1.4 billion by 2050, while the population of people aged 80 or older is expected to triple to 426 million.[1] Across the European Union, mortality among older people has decreased, in part due to factors such as improved health care delivery.[2] So too is life expectancy on the rise for the Belgian population: from 2000 to 2022, life expectancy at birth in in Belgium has risen from 77.8 years to 81.7 years.[3,4] Assuming no impact of the COVID-19 health crisis on life expectancy, Belgian life expectancy at birth is predicted to reach 89.83 years for women and 88.35 years for men by 2070.[5]

While populations have grown in absolute number and become proportionately older, the prevalence and proportion of deaths due to what the WHO designates as noncommunicable diseases (NCDs) has also increased.[6] NCDs, including such illnesses as cardiovascular disease, cancer, chronic respiratory disease, and diabetes,[7] cause considerable disease burden. Although deaths from respiratory diseases, cardiovascular diseases, and cancer have declined between 2000 and 2019,[6] they remain leading causes of death worldwide[8,9] and are projected by the WHO to cause the vast majority of deaths by 2048: 86% globally, and 95% of deaths in the European Region.[6] The suffering associated with life-limiting illnesses such as cardiovascular disease, cancer, and chronic respiratory disease may be relieved through palliative care. Palliative care aims to improve quality of life through early identification, correct assessment, and treatment of pain and physical, psychosocial, or spiritual problems for patients confronted with life-limiting illness and their families.[10] The global burden of serious, health-related suffering requiring palliative care is expected to increase: projections have indicated that by 2060, an estimated 48 million people globally will die with serious health-related suffering.[11]

The prevalence and burden of life-limiting illnesses is likewise reflected in Belgian health statistics. Illnesses such as cancer, chronic respiratory disease, and cardiovascular disease become more prevalent with age, as does multimorbidity, where multiple conditions are present.[12] In 2019, cancer accounted for 19.2% of disability-adjusted life years in Belgium due to premature death and loss of quality of life; cardiovascular disease for 11.7%; chronic respiratory disease for 7.3%.[12] In 2020, cancer was the leading cause of death in Belgium overall, accounting for 21.4% of deaths, followed by cardiovascular disease, which was the cause of 20.7% of deaths.[13]

2. Complex care choices for patients with life-limiting illness

An oft-cited model of illness trajectories for life-limiting illnesses distinguishes between those with steady progression followed by rapid decline towards the end of life (e.g. in cancer); gradual decline punctuated by periods of acute deterioration and some recovery (e.g. in respiratory and heart diseases); and prolonged gradual decline (e.g. in persons with dementia or frail elderly persons).[14] While the trajectory of every single patient with a chronic, life-limiting illness is different, these trajectories illustrate that people diagnosed with these illnesses may be faced with a period of progression and possible exacerbation as they approach the end of life. As a result, they may be confronted with **difficult or complex choices about their medical care**, including palliative care and end-of-life care.[15] Their illness may also leave them unable to make medical decisions for themselves, due to a loss of decisional capacity as a result of illness progression or acute exacerbation. In such cases, health care practitioners may turn to the patient's family or loved ones to elicit the patient's values for care, and/or to make decisions about interventions in the patient's stead.

Patients with life-limiting illness conceptualize good (end-of-life) medical care and decision-making in a variety of ways. In a Canadian survey from 2006, patients with advanced-stage cancer, chronic obstructive pulmonary disease (COPD), heart failure, and/or cirrhosis found it important to have trust and confidence in their doctors, not to be kept alive on life support when there is little hope for meaningful recovery, that information about their illness be communicated to them in an honest matter, and to prepare for life's end.[16] A 2007 longitudinal study conducted in the United States surveyed the decisional control preferences in patients with cancer, amyotrophic lateral sclerosis, or heart failure. This study found a wide variety of preferences, ranging from wanting decisions made based on the patient's personal wishes, to decisions made based on what loved ones or physicians think is in the patient's best interest. Most patients wanted decisions about care to be made according to a combination of the two.[17] A systematic review of goals for surrogate decision-making, where the majority of included respondents were elderly or seriously ill, found that respondents want to be treated according to their values, and to minimize the burden on their family.[18] However, patients often do not receive care at the end of life that is in line with their expressed values,[19–21] and decision-making by family members who are unable to determine the patient's wishes may contribute to significant distress in those family members.[18]

3. Advance care planning: rationale and definition

3.1 Advance directives

Planning for future medical decision-making emerged with the promotion of health care **advance directives (ADs)**, documents which state the patient's health care goals and appoint

a person to make health care decisions in their stead, preserving patient autonomy in the event they lose decisional capacity.[22] In a 1969 article, American human rights lawyer Luis Kutner describes a "**living will**", a proposed document indicating ahead of time the extent to which an individual consents to treatment.[23] In the 1980s-1990s, many American states also took legislative initiatives to promote **durable health care powers of attorney**, allowing a designated agent to make health care decisions on another person's behalf. Increasingly, American states have enacted combined statutes of the living will and durable power of attorney for health care, into a single **"advance directive for health care"** form.[22]

Such documentation was advocated to align patient end-of-life care with their care goals and preferences, but ADs alone were found insufficient to improve patient-centeredness of end-of-life care, satisfaction with care,[24] or accuracy of substituted decision-making.[25] An AD-only approach to planning would require that patients know what they want, can articulate what they want, that the AD is findable, that it is read accurately, and that the AD alters patient care. These prerequisites were, however, criticized as unachievable, in the decade following initial research and policy efforts to promote ADs.[26] Rather, the conceptualization of (preparation for) medical decision-making shifted towards a focus on **communication about goals and preferences**.[27,28]

3.2 Advance care planning as a process

Advance care planning (ACP) was first referred to in the early 1990s to describe a process, rather than a legal document, which aims to promote patient self-determination by assuring that patients' preferences inform the care provided when the patient lacks decisional capacity.[29,30] Since then, several definitions of ACP have been proposed. A Delphi panel consensus from 2017 defined ACP as a process which *"enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and health-care providers, and to record and review these preferences if appropriate."* In this definition, ACP addresses concerns across physical, psychological, social, and spiritual domains.[28] A key component of the ACP process is that the patient appoints a surrogate/substitute decision maker (SDM), who can make medical decisions for the patient if the patient loses decisional capacity.[31] Rather than a one-time documentation and formalization of care goals in an AD, **ACP is a complex process of decision-making which can be revisited over time**,[15,32] and which can, but not necessarily must, include documentation as part of this process. This accommodates that patient preferences may not be stable over time, and may be dependent on factors such as the current health of the patient.[33–37] Thus, ACP should not only focus on determining future care preferences, but also on facilitating and preparing informed, in-the-moment decision-making which takes into account the patient's values and needs.[15,38] In doing so, ACP is a key part of delivering person-

centered care:[39] care which is attuned to the needs, circumstances, and preferences of the individual.[40]

ACP shares a degree of overlap or similarity with other concepts in medical communication, such as shared decision-making, serious illness conversations, and goals of care conversations. For example, shared decision-making applies to active and in-the-moment choices, but it shares with ACP a focus on what matters most to patients.[41] Conversely, principles of shared decision-making may inform conceptual models of ACP interventions.[42] Serious illness conversations also involve an iterative process of communication about what matters most and can be used to address future decision making. However, these conversations target patients with serious illness, while ACP is not limited to this population.[43] A goals of care conversation, while also discussing what matters most to patients, primarily discusses and delineates the aims of medical care as in-the-moment decisions for patients with active health issues.[41]

4. The legal framework for ACP in Belgium

4.1 Laws on palliative care, euthanasia, and patient rights

Belgium has a specific **medicolegal context for ACP** and palliative care, based on three laws passed in 2002.[44] The law on palliative care (*Wet betreffende de palliatieve zorg*)[45] states every patient's right to quality palliative care. The law on euthanasia (*Wet betreffende de euthanasie*)[46] outlines the legal basis for euthanasia as an intentional intervention to end the life of a person, at this person's explicit request, carried out by a physician in accordance with the requirements and procedures stated in the law. A person may create a directive ('*wilsverklaring*') stating their request for euthanasia in the case of a serious, incurable condition due to illness or accident where the person has an irreversible loss of consciousness.

The law on patient rights (*Wet betreffende de rechten van de patiënt*)[47] guarantees several basic rights to any person receiving health care. These include the right to receive information regarding one's health condition, and the right to informed consent to any intervention by a health care practitioner.[48] The patient's right to informed consent includes a right to refuse interventions; this refusal may be documented in writing and added to the patient medical file and must be honored until the patient withdraws it. Hence, this right serves as the precedent for ADs (often referred to as 'negative' directives, to distinguish them from non-legally binding 'positive' directives stating interventions which the patient *does* want, including euthanasia) in Belgium, as legally binding documents stating the patient's refusal for medical intervention, to be referred to when the patient does not have decisional capacity.

The law on patient rights states that if the patient is not capable of exercising their own rights, a substitute decision maker (SDM, '*wettelijke vertegenwoordiger*') may do so for the patient. This person may be indicated by the patient in writing while they have decisional capacity. If the patient has not appointed a SDM and becomes incapable of making medical decisions or exercising their patient rights, a cascade system determines which person will act as SDM. In descending order, this is: an appointed legal guardian, the cohabiting partner, adult child(ren), parent(s), adult sibling(s), and the involved health care practitioners in multidisciplinary consultation.[49]

4.2 Recent policy changes to support ACP

Recent changes in Belgian policy aim to further support ACP. As of September 2022, a billing code ('*nomenclatuurnummer*') has been introduced for general practitioners (GPs) conducting and monitoring ACP with patients who are identified by the Palliative Care Indicator Tool (PICT) as having palliative care needs. The ACP conversation should include the possibility for the patient to indicate their treatment wishes in an AD, determination of care goals, and the possibility for the patient to appoint a SDM. This billing code can be used once in the lifetime of the patient.[50] In July 2023, the Federal Government of Belgium approved a draft to modernize the law on patient rights. While ACP was not explicitly referred to in the law introduced in 2002, it is embedded into the text of this new design by name (as '*vroegtijdige zorgplanning*'), and defined as the "*continuous process of reflection and communication between the patient, the healthcare practitioner(s), and, at the patient's request, the patient's loved ones, which aims to discuss the values, life goals, and preferences for current and future care*" (translated from Dutch). Also specified in the revised text are the concepts of the AD ('*voorafgaande wilsverklaring*') and the SDM ('*vertegenwoordiger*'). ACP is here referred to in the context of respect for patient dignity and autonomy, by taking into account the patient's goals and values.[51] The proposal for the modernized law was approved by the Belgian Federal Parliament in February 2024.[52]

5. Societal and medical context for ACP in Belgium

In Belgium, ACP has received considerable **attention and promotion**. The three Belgian palliative care organizations in Flanders, Brussels, and Wallonia, emphasize the importance of ACP.[53] The Pallialine initiative of the Flemish Federation for Palliative Care (*Federatie Palliatieve Zorg Vlaanderen*) has introduced evidence-based guidelines for ACP (in 2015)[54] and ACP for people with dementia specifically (in 2016)[55]. Several organizations in Belgium offer template ADs and information about how to complete them, including: LEIF (*LevensEinde InformatieForum*, an initiative which provides information and training on palliative and end-of-life care), the Flemish Federation for Palliative Care, and *Recht Op Waardig Sterven* (a Flemish organization for patient rights to palliative care, end-of-life care, and euthanasia).

Informational materials such as brochures are also available from other providers, among which are hospitals,[56–58] nursing homes,[59,60] and health insurance providers.[61] In 2021, the Federal Public Service (FPS) Health launched a public health initiative targeting the public and health care practitioners, which aims to promote ACP. This initiative includes a website (*mijnoudedag.be*) with information and resources, promotional messaging via radio broadcast, videos distributed to hospitals and social organizations, and posters and folders for GPs to use in their practice.[62]

Education on ACP in Belgium is offered through multiple modalities, for audiences of health care practitioners and the public. Examples include: e-learning for GPs;[63] courses in university degree programs; and continuing medical education courses,[44] such as those offered to GPs by Domus Medica, the Flemish association of GPs.[64] As part of the campaign "Advance care planning: where there's a will, there's a way" ('*Voorafgaande zorgplanning: Waar een wil is, is een weg*'), initiated in 2016 with support from the Belgian federal government, LEIF offers brochures and training for healthcare practitioners and for the general public about ACP, with a focus on ADs.[65]

While this list is by no means exhaustive, it nonetheless illustrates that ACP research is highly relevant to the Belgian context. Further, while efforts have been made to broaden the conceptualization of ACP to a communication process, many existing initiatives in Belgium are still oriented towards documentation, signaling potential for improvement.[44]

6. ACP: research evidence and current debates

6.1 State of current evidence

ACP has seen a sustained research interest since the early 1990's. The research base is heterogeneous on multiple fronts, including settings of implementation, intervention modalities, methodologies, populations, and outcomes. A 2022 systematic review of randomized controlled trials (RCTs) illustrates this: while RCTs mostly targeted patients, 39% of studies targeting patients included a heterogeneous patient population, and 22% exclusively patients with cancer. RCTs were conducted primarily in hospitals (71.54%); other settings include the community, primary care, and nursing homes. Interventions include ADs, communication, and decision aids.[66] While a full overview of all ACP research is outside the scope of this introduction, we will briefly sketch the research evidence below.

Current evidence suggests that ACP may be associated with health outcomes. A 2022 study found that cancer patients who had an ACP conversation in primary care spent more days at home and were more likely to die at home.[67] People who died at home with hospice, or in a nursing home, were more likely to have an AD according to an American mortality follow-back study;[68] an American observational cohort study also found an association between having an

AD, a durable power of attorney, or an ACP discussion with next of kin, and increased use of hospice and less in-hospital death.[69] In a study of cancer death cases, all levels of ACP, from discussions with documentation, to documents or discussions only, were associated with positive bereaved relative' perceptions of end-of-life experiences.[70] Nevertheless, the evidence is mixed. For example, the systematic review of RCTs described above found that 25% of included studies showed an association with home death, and none showed improved patient quality of life.[66] Consistency between patient's stated values and care at the end of life also showed mixed results, and the association between ACP and value-concordant care at the end of life may differ according to patient priorities, such as comfort care versus life-extension.[71]

Patients value the relational and social contribution of ACP,[72] such as helping their family know what to do,[72–75] e.g. when they are called on to act as SDM. In this way, ACP may contribute to patients feeling more at peace and in control.[76] Evidence is stronger that ACP may increase the confidence of SDMs to make decisions in the patient's stead, as found in ACP intervention trial studies in dementia care homes[77] and outpatient settings.[78] ACP may also promote congruence between the patient's wishes and the SDM's understanding of those wishes.[66,79,80] However, confidence in decision-making may not always translate to performance in meeting the patient's expressed wishes.[81,82]

6.2 Challenges and future research priorities

These findings frame **ongoing discussion of future ACP research priorities and goals**.[83–86] One prominent question is the capacity of ACP to improve outcomes such as care being consistent with the patient's stated goals, which has been identified in a Delphi study as one of the most important outcomes of ACP,[87] but is challenging to operationalize and measure. Retrospective chart review to ascertain documentation of patients' preferences for care can introduce biases when these preferences are poorly documented, or do not reflect patients' changing preferences over time.[88,89] In addition, some patients' stated values may show discordance with their treatment preferences,[90] and some patients may also not want their previously-stated preferences followed.[36] If ACP is presented as decision-making that is "simple, consistent, logical, linear, or predictable",[91] where patient preferences and treatment choices exist in a clear one-to-one relationship, and this perspective informs assessments of whether care was concordant with the patient's goals, then this certainly ignores the complexity of decision-making in serious illness and at the end of life. However, the research literature increasingly acknowledges that ACP is a complex and ongoing process, and the **conceptualization of relevant outcomes** is evolving to match.

Recent comprehensive reviews of trial studies and of systematic reviews offer a nuanced view of the impact of ACP on key outcomes. A comprehensive review of eighty systematic reviews, published in 2018, points to the compartmentalized nature of available evidence, but suggests that ACP has the potential to improve outcomes when it is implemented using a whole-system approach, involves patients and family/SDMs as well as clinicians, and includes features such as repeated interaction with a knowledgeable person who can discuss and address concerns.[92]

A 2020 scoping review of ACP randomized controlled trials mapped outcomes according to the **Organizing Framework of ACP Outcomes**. This framework was previously developed through a Delphi panel study to identify ACP outcome constructs and rate their importance. The scoping review found that 72% of outcomes related to processes (e.g. knowledge about ACP) were positive. For outcomes related to actions (e.g., communicating with a SDM or clinician, completing an AD), 86% of outcomes were positive. On the other hand, outcomes related to quality of care, such as care being concordant with goals or quality of patient-clinician communication, were positive in 53% of cases. Outcomes pertaining to health status, such as quality of life, were positive in 37% of cases overall, and outcomes related to healthcare utilization were positive in 42% of cases. In the 2022 systematic review of RCTs, evidence was mixed that ACP improved outcomes considered distal by the authors. In addition to no studies finding improved quality of life and 25% finding an association with home death, 25% of findings showed improved concordance of care with patient goals, 21% showed improvement in mental health, and 18% showed reduced healthcare costs. Evidence was greater that ACP improved outcomes which the authors considered proximal. Sixty-eight percent of studies showed improved patient-physician communication, e.g. between patients with cancer and oncology clinicians, patients with heart failure and heart failure providers, and patients with COPD and their physicians in primary care and chest clinics. Seventy percent found more patient preference for comfort care, 68% found reduced decisional conflict, and 82% found improvement congruence between patients care preferences and their caregiver's judgment of those preferences. In 63% of studies, ACP documentation increased.

A 2021 workshop between experts in ACP research also reflected on this discussion and proposed suggestions for **opportunities in ACP**. These include: communicating about ACP to enhance understanding of its role and importance, preparing clinicians for high-quality ACP conversations, using a person-centered approach to ACP, considering how we evaluate ACP (e.g. whether people feel support in decision-making, and working to better specify what does or does not work), changing the focus of ACP (e.g. to prepare patients and SDMs for making in-the-moment health care decisions).[93]

7. ACP in general practice

7.1 Rationale for ACP in general practice

There is a **broad consensus that ACP should be initiated in a timely manner**,[94–99] prior to a health crisis or the terminal phase of life.[100] This normalizes ACP conversations, allows time for contemplation and communication, and leaves opportunities for re-evaluation of care preferences if the patient's health changes.[15,95] Patients, too, often want timely ACP discussions.[101] They value open and honest conversations[102] and want to discuss their views about future care with someone they trust,[103,104] which can include a health care practitioner.[105]

Outpatient care settings such as primary care and general practice have been proposed as ideal places for iterative, interactive ACP discussions to be initiated and facilitated. These settings often benefit from the established, longitudinal relationships between the patient and clinician. Such continuity of care is recognized as an essential feature of general practice and is especially beneficial to people with multimorbidity, older people, people with mental health difficulties, and patients receiving terminal care.[106] Initiating ACP in general practice also allows for patients and their family to talk with clinicians about values, wishes, and concerns at a time when their health is relatively stable.[107,108]

These characteristics of the patient-GP relationship and continuity of care also apply to the **Belgian health care context**, **where GPs are providers of primary, accessible, continuous, and person-centered care**.[109] Previous database research by the Belgian National Institute for Health and Disability Insurance (NIHDI) found that a large majority of Belgian patients are in contact with a GP. Rates of contact are higher among elderly patients and patients with chronic illness (in this research defined as those with diabetes, cardiac decompensation, consumers of gastric acid inhibitors, patients with COPD, and nursing home residents); the latter have an average of 10 contacts with the GP per year.[110] At the moment of a patient's admission to a nursing home, the GP has known this patient for an average of 15 years.[111] Belgian patients with terminal illness recognize and value continuity of care as an important task of their GP, in part because of the years-long relationship which engenders mutual trust, and in part because they expect their GP to manage knowledge exchanges with specialist care providers.[112]

7.2 Deficits in ACP in general practice

However, despite recommendations that ACP be initiated in this setting,[113] research has found **deficits in ACP in (general) practice**. In an American study, 40% of older adults did not contemplate ACP and 80% did not discuss ACP with their doctor.[114] In a more recent study of primary care patients with a chronic or serious illness, 15% of participants reported ACP conversations with clinicians. If ACP conversations did occur, most participants considered

them to be general and of lower quality, as opposed to detailed conversations.[115] In a Canadian survey study, most older patients in 20 family practices had thought about the kind of medical treatment they would want if they were sick and in hospital, but few (75 patients out of 810) had discussed this with family doctors.[116] These deficits have also been found in Belgian general practice. A mortality follow-back study using data collected through GP Sentinel Networks in Belgium and the Netherlands, published in 2011, found that for approximately 34% of deaths reported as non-sudden, GPs were aware of advance agreements about medical care. A study using Sentinel Network data published in 2020 found that, for patients with cancer who died non-suddenly, GPs were aware of preferences for medical treatment in 53% of cases by 2014, the last year assessed for the study. In this same year, GPs were aware of preferences for a SDM in 28% of cases.[117]

7.3 Barriers and facilitators to ACP in general practice

Factors which hinder or enable the initiation and conduct of ACP in general practice may occur at multiple levels.

Some **patients** with serious illness or frailty may face barriers to ACP when thinking about the end of life is emotionally upsetting.[114,118] Patients may also consider ACP to be irrelevant, e.g. because they are still too healthy[114,119] or too young.[119] Patients often expect that their GP will indicate the right timing by initiating the conversation.[119,120] However, they may worry that ACP will negatively impact their relationship with their GP.[119] Conversely, patients who had serious illness conversations with primary care clinicians report that the relationship with a trusted care provider facilitates an open conversation, which helps navigate difficult emotions and strengthens the patient-physician alliance.[121] Lastly, patients may feel they do not know enough about ACP,[119] or want more information about their health or health care choices[114,120,122] to help them reflect about their wishes.

At the **GP level**, a lack of time is a recurring barrier,[118,122–124] which patients also perceive.[114,119] Better preparing patients with accurate information and resources may not only address patient barriers related to knowledge, but may reduce the time required for discussions.[122] Additionally, GPs may experience difficulty determining the right time to initiate conversations.[122–128] In an interview study of Belgian GPs, some GPs indicated barriers related to a lack of familiarity with illness trajectories, especially in non-cancer patients.[124] GPs may also worry that conversations may be uncomfortable or distressing to patients and families.[123–126] ACP conversations may be challenging if GPs do not feel they have sufficient skills, knowledge,[126] or training to engage in them. In a survey that included primary care physicians, clinicians who had formal training on end-of-life communication were among those more likely

to conduct ACP conversations.[123] More personal and professional experience,[129,130] and more practice or training,[122,130] can help to overcome barriers related to skills and confidence.[131]

At the **system level**, better integration of ACP into the current work flow between health care settings may be needed, including patient identification and a mechanism to document and transfer ACP.[122] A lack of standards for documenting information, such as where the outcomes of the ACP conversation should be documented, has been described as a barrier to communication about serious illness in primary care.[128] Further, a lack of collaboration with secondary care has been identified in a systematic review as a barrier to the process of ACP for GPs.[126] In addition to these functional barriers, an interview study with Belgian GPs also found that GPs differed greatly in their conceptualization of ACP, which included their vision on ACP discussion content and the GP's role in ACP.[132] Hence, promoting a common view on ACP is necessary.

8. Development of the complex ACP-GP intervention

8.1. Intervention development

As barriers and facilitators to ACP in general practice may occur at multiple levels, such as the patient, GP, and system level, efforts to mitigate barriers and maximize facilitators should also act at multiple levels. This implies that **a complex intervention** may be best-suited to address this aim. A complex intervention is built up from multiple components which may act inter- or independently.[133] Complexity may also depend on such factors as the number/difficulty of behaviors required by those delivering or receiving the intervention, the organizational levels of groups targeted, and the degree of flexibility permitted.[134]

To facilitate ACP in Belgian general practice, the **ACP-GP intervention** was developed prior to this dissertation according to the 2000 Medical Research Council (MRC) framework guidance on complex intervention design.[134] This framework describes an iterative process, from Phase 0 to Phase IV, of development (including theory-building and modelling the processes and outcomes), feasibility and piloting, evaluation to assess effectiveness and understand processes, and implementation.

In the phase 0-I study, **potential components of the intervention** were explored, based on systematic review of the literature,[126] a focus groups with GPs,[124] and a rapid review to identify key features underpinning successful ACP interventions. Key features identified included: ACP conversations facilitated by a trained health care provider; identification of patients, such as selecting patients with a life-limiting illness; specific tools, including educational material for patients and structured decision aids for use during ACP conversations; structured discussions about the patient's values, goals, and beliefs; and completing ACP documents, such as by documenting treatment preferences.

20

Based on these findings, the **intervention was modelled for Belgian general practice** and presented to expert panels for review. The initial intervention consisted of five components. The first component was a training program for GPs, which aimed to improve GP skills, knowledge, and self-efficacy for ACP, highlight the relevance of ACP, and foster positive attitudes towards initiating ACP. The second component was to establish a register of eligible patients, to help GPs identify a key moment for initiating ACP with patients who have a life-limiting illness. An educational booklet about ACP for patients was the third component. The booklet was created to increase patients' understanding of ACP and prepare them for the conversation. The fourth component was patient-centered ACP discussions using a conversation guide, to improve awareness about the different elements of ACP and mitigate barriers related to varying conceptualizations of ACP among GPs. The fifth and final component was a structured template for documenting the outcomes of these discussions. This component aimed to provide a standardized location for documentation, to aid in sharing and transferability of ACP information.[135]

The intervention was subsequently **pilot-tested** in a phase-II cluster-randomized controlled trial in Belgian general practice. The intervention was found to be acceptable: the training was positively evaluated and the booklet was regarded as a useful tool. Points for improvement were also identified: some GPs found it difficult to include patients based on the surprise question (Would I be surprised if this patient were to die within the next 12 months?) alone. This suggested that more specific inclusion criteria may have been necessary.[136] Based on feedback from GPs and patients, adaptations were made such as simplifying the patient booklet. The inclusion criteria were specified by including clinical indicators for patients who may have significant burden due to a life-limiting illness, but are not in the terminal stage of their illness. The adapted materials were introduced to a small sample of six GPs and six patients with a chronic, life-limiting illness, for cognitive testing and final refinements.

We refer to the complex intervention for patients with chronic, life-limiting illness in Belgian general practice, as it is adapted and tested in the dissertation, with the acronym **ACP-GP**.

8.2. Outcome selection

Theoretical developments in the ACP literature, such as behavioral theories informing conceptualizations of ACP as a process of behavior change, were also taken into account when **choosing outcomes for the trial study** that will be the subject of this dissertation. Behavior change theories, such as the Transtheoretical Model of behavior change[137] and Social Cognitive Theory, have been used to describe **patient engagement in ACP**. Based on the Transtheoretical Model of stages of behavior change, it has been proposed that patients may contemplate whether or not they wish to engage in ACP, prepare for engaging in ACP,

and move on to taking action, such as by having an ACP conversation, designating an SDM, or documenting their preferences. Then, they may revisit and reflect on their choices, e.g. when their life circumstances change.[138] Moving towards ACP actions requires changes in underlying process outcomes, such as knowledge (what the patient knows about ACP), contemplation (how much the patient has thought about ACP), self-efficacy (patients' confidence that they can complete ACP behaviors), and readiness (how ready the patient is to complete ACP behaviors, according to stages of behavior change).[139] The construct of **self-efficacy** from Social Cognitive Theory has also been posited to affect whether GPs engage in ACP conversations with their patients. When self-efficacy is low, GPs may be reluctant to initiate conversations about ACP; when it is increased, this may help them overcome barriers to implementing these conversations.[140]

9. Knowledge gaps this dissertation seeks to address

Trials of complex interventions aim to address questions regarding whether the intervention has an effect, including in everyday practice.[134] Thus, a primary unanswered question is: **what is the effect of ACP-GP on outcomes relevant to the process of ACP**, such as patient engagement with ACP and GPs' self-efficacy for ACP? To answer this question, the effect of ACP-GP should be compared to a control group receiving usual care. In this case, a randomized design is recommended to avoid selection bias.[134]

To better understand the relatively newly-developed process measure of ACP engagement, which has until now not been applied in Belgian ACP research, we should also understand not only how ACP engagement responds to the intervention, but also what this measure looks like prior to the introduction of the intervention. There is research evidence available about factors associated with action outcomes of ACP, such as having a conversation or completing an AD, but **which factors are associated with the process**? That is, which factors related to the patient, or to the ACP communication between the patient and the GP, may be associated with the patient's self-efficacy for ACP, and their readiness for ACP?

Finally, in relation to the trial of ACP-GP we should aim to understand not only *if* the intervention works, but also *how* it works: **how (well) was the intervention implemented, and how do the components exert their effect**? The MRC guidance recommends a process evaluation nested inside a trial to assess fidelity to protocol and quality of implementation, clarify mechanisms, and identify contextual factors which may help to explain outcomes.[134]

We can also extend this question more broadly, in light of contemporary debates about the form, goals, and effect of ACP interventions. It is important to understand the **rationale for an ACP intervention**: how are interventions hypothesized to generate outcomes, i.e., by which mechanisms are ACP interventions proposed to generate change? Does evidence from the

trial study support the hypothesized mechanism? And, depending on whether or not the expected results were achieved, how can this be explained?

We can finally take a closer look at the **example of one ACP intervention with similar components**, implemented outside of Belgium shortly prior to the ACP-GP trial. This intervention, implemented in two Canadian provinces, was an ACP pathway which also included training for clinicians, informational material for patients, and structured conversations. Patients were also offered a decision aid tool; compared to the mainly open questions of the ACP-GP workbook, this decision aid helped patients chart, from a list of values, which values are most and least important to them. What were the experiences of clinicians implementing this pathway? Which barriers and facilitators did they encounter? Comparing and contrasting the findings from this study in Canada with insights from other ACP trials and the findings from ACP-GP, can inform ACP research going forward.

10. Study objectives

The work carried out for this dissertation seeks to answer two major research aims, through six research objectives. These are described below.

Research aim 1: Implement and evaluate an ACP intervention for patients with chronic, life-limiting illness in Belgian general practice (ACP-GP).
Specific objectives to reach this aim are:

Objective 1: **Describe** the study protocol for a cluster-randomized controlled trial and process evaluation of the ACP-GP intervention for patients with chronic, life-limiting illness in Belgian general practice (Chapter 1).

Objective 2: **Explore** ACP engagement in a study population of patients with chronic, life-limiting illness, and understand which factors (patient-related, or patient-GP-communication related) are associated with ACP engagement (Chapter 2).

Objective 3: **Evaluate** the effects of the ACP-GP intervention on ACP engagement of patients with chronic, life-limiting illnesses and on GPs' ACP self-efficacy (Chapter 3).

Objective 4: **Evaluate** the ACP-GP intervention for patients with chronic, life-limiting illness in Belgian general practice in terms of its reach, effectiveness, adoption, implementation, and maintenance (Chapter 4).

Research aim 2: Describe insights into the implementation of ACP interventions, using international ACP literature and the example of an ACP pathway implemented in Canada.
Specific objectives to reach this aim are:

Objective 1: **Identify** mechanisms proposed to explain how complex ACP interventions are expected to impact outcomes for patients with serious illness, establish factors authors refer to in order to explain study findings, and map the available evidence (Chapter 5).

Objective 2: **Explore** the experiences of physicians and allied health professionals in two Canadian provinces (Alberta and British Columbia) with implementing an ACP pathway in longitudinal generalist outpatient care clinics (family practice and internal medicine) (Chapter 6).

11. Methods

11.1. Methods used to address the objectives of Research Aim 1

The Phase-III cluster-randomized controlled trial (RCT) of the intervention to facilitate ACP for patients with chronic, life-limiting illness in Belgian general practice (ACP-GP) provides the research data to address the first research aim.

11.1.1. Cluster-randomized controlled trial

1.1. Trial design

We **designed and planned** a cluster-randomized controlled trial, which aims to evaluate the effects of the complex ACP-GP intervention on patient and GP outcomes.

Patients and GPs were cluster-randomized, with clustering at the GP level, to the intervention or the control group.

We recruited clusters as follows: Dutch-speaking GPs practicing in the Flanders and Brussels regions of Belgium were eligible for participation. To be randomized, GPs had to include at least one, but preferably three adult patients with a chronic, life-limiting illness, here defined as: metastasized or unresectable cancer, organ failure (COPD, heart failure, or chronic kidney failure/end-stage renal disease), or mild to severe frailty. An additional inclusion criterion was that the GP would not be surprised if the patient were to die within the next 12 to 24 months. Patients were mentally competent and able to speak Dutch. Patients could, if they wished, indicate a trusted person or surrogate decision maker (SDM) for participation. Accounting for dropout, we aimed to recruit 18 GPs per group, each with 3 patients (108 patients in total).

Randomization occurred at the level of the GP, to reduce the risk of contamination. GPs and their patients were allocated to the intervention or control groups at a 1:1 ratio using a computer-generated list, generated by an independent statistician. In the intervention group, patients and GPs received the ACP-GP intervention. This multicomponent intervention consists of: 1. Training in ACP communication for GPs, 2. An ACP workbook for patients, 3. At least two ACP conversations between the GP and patient, and 4. A template with which to

document the outcomes of the ACP conversations. In the control group, GPs were not trained, and patients received care as usual, with no additional materials provided. GPs were permitted to plan ACP conversations and to use existing informational materials, ADs, and means of documentation, in line with their usual practice.

This was a superiority trial to evaluate whether the ACP-GP intervention increases patient ACP engagement (patient-level primary outcome)[141] and GP ACP self-efficacy (GP primary outcome)[140] more than the control group. Data collection also included secondary outcomes at the patient, SDM, and GP level for exploratory analyses; these outcomes are not part of the present dissertation.

The ACP-GP trial recruited participants from general practice in the Flanders and Brussels regions of Belgium. We describe the setting below:

1.2. Setting: Belgian general practice

General practitioners (GPs) are providers of primary care in Belgium. They serve as a first point of contact for health care consultation and provision, maintain oversight of their patients' health, and have a coordinating role in patients' care.[142] At the end of the year 2020, the year in which the cluster-RCT was initiated, Belgium counted 9,634 (GPs) licensed to practice in the Flanders region, and 1,660 in the Brussels region (based on official residence).[143]

GPs in Belgium may work in different types of practice configurations. According to 2017-2018 data collected by the National Institute for Health and Disability Insurance (NIHDI), the most frequently-occurring form of practice is the **solo practice**, where one GP works alone.[144] In **group practices,** multiple GPs work together under one roof. An additional form of practice is the **community health center.** These multidisciplinary primary care centers emphasize physical and financial accessibility to basic health care and have a low financial threshold.[145,146] Belgian GPs may additionally work as **coordinating and advising physicians** in a nursing home after additional training. As coordination and advising physician, the GP is responsible for coordinating the medical activities in the nursing home, for participating in and organizing training for nursing home personnel, and for maintaining continuity of care between the nursing home and other services, such as emergency services.[147] This role is viewed separately from the GP's role as treating physician. Lastly, the GP plays an important role in the **provision of palliative care** to patients, including as a member of or liaison with the **palliative home care team,** a multidisciplinary team which supports patients receiving palliative and end-of-life care at home.[148]

1.3. Cluster-RCT analyses

1.3.1. Baseline data analysis

To meet objective 2, we **conducted a secondary data analysis of data collected at baseline** from the complete sample of patients recruited to the ACP-GP cluster-RCT. At baseline, after providing informed consent to participate, patients completed a questionnaire bundle. This was done during a home visit by a data collector or, if COVID-19 restrictions made home visits impossible, via postal mail with telephone support by the data collector if desired.

In total, 95 patients provided questionnaire data, clustered by 35 GPs. Demographic data collected included: age, sex, marital status, education, religion, the person most involved in the patient's care, and whether this person lives with the patient. Patient diagnosis was ascertained by the data collectors. We measured the severity of anxiety symptoms with the seven-item General Anxiety Disorder (GAD-7) scale,[149] and the severity of depressive symptoms with the nine-item Patient Health Questionnaire (PHQ-9).[150] The Short-Form Health Survey (SF-12v2)[151] was used to measure health-related quality of life. To assess patient-perceived ACP communication by the GP, we used self-developed items on a 10-point Likert scale, where patients indicated the perceived quality of ACP communication by the GP in the last 3 months (e.g., "To what extent did your GP listen to what is important for you to live well?").

We aimed to explore patient ACP engagement, which we measured with the 15-item ACP Engagement Survey,[141] and to investigate the association of the factors listed above (demographic, clinical, and perceived communication) were associated with engagement. To do so, we first described the data descriptively and by calculating scale scores for questionnaires. Linear mixed models were used to independently test associations with patient demographics, clinical characteristics, and perceived ACP communication by the GP, with their ACP engagement. These models accounted for clustering of patients within GPs. As an increasing number of individual associations are tested, the possibility of a false discovery increases (multiplicity problem). To account for this, we adjusted the analyses using the Benjamini-Hochberg procedure,[152] with a false discovery rate set to 5%. An adjusted *p*-value of <0.05 was considered significant.

1.3.2. Primary outcome analysis

We collected quantitative questionnaire data at baseline, and at 3 months and 6 months post-baseline (T1 and T2, respectively). Primary outcomes were patient ACP engagement (measured with the ACP Engagement Survey 15-item version[141]) and GP ACP self-efficacy

(measured with the ACP Self-Efficacy Scale[140]) at three months post-baseline (T1). A *p*-value of <0.025 was considered significant; this includes a Bonferroni correction to account for the dual primary outcome. Comparison at T2 were exploratory and considered significant at *p*<0.05. Linear mixed models with fixed effects of group, time, and group * time were conducted, with the group * time interaction term capturing the effect of interest. We used random intercepts in the models to account for clustering of measurements within patients and GPs, and clustering of patients within GPs. Analyses followed the intention-to-treat principle.

11.1.2. Mixed-methods process evaluation

A process evaluation was conducted parallel to the cluster RCT and aimed to assess the implementation of the ACP-GP intervention in terms of its Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM).[153] The RE-AIM framework is an intuitive and understandable model of evaluation that can address questions of "who, what, where, how, when, and why"[154] regarding the implementation of an intervention. In addition to evaluating outcomes and impact of the intervention, the RE-AIM framework dimensions allow evaluation of whether the target population was reached for participation (Reach), how participants showed uptake or intention to uptake the intervention (Adoption), whether the intervention was implemented as intended in the practice setting (Implementation), and how the intervention might be sustained over time or could be improved for the future (Maintenance).

This mixed-methods process evaluation was conducted from the start of recruitment to immediately following the end of the intervention period. We collected data via recruitment monitoring, intervention delivery and implementation monitoring, questionnaires at 3 months post-baseline (T1) about ACP conversations and satisfaction with the intervention, and qualitative data collection. For the latter, we conducted semi-structured (focus group) interviews with patients and GPs randomized to the intervention group. In total, we interviewed 14 GPs and 13 patients (of which 11 patients' recordings were useable for transcription).

Quantitative data were analyzed descriptively. Qualitative data in the form of interview recordings were first transcribed. Two authors the independently read and inductively coded a selection of transcripts. During a meeting between the two coders, we checked for similarities and differences in coding and interpretation and established two coding trees, for patients and for GPs respectively. When the coding structure was agreed upon, the remaining transcripts were coded in NVivo software, version 12. Then, overarching themes were grouped deductively to link them to RE-AIM framework dimensions. During this process, multiple meetings were held to check for consensus regarding coding and interpretation of the results.

11.1.3. Ethical considerations:

The cluster RCT protocol was approved by the Medical Ethics Committee (O.G. 016) of the Vrije Universiteit Brussel/UZ Brussel, ref.: 2020/068.

Written informed consent was sought from all participants prior to inclusion and randomization. We re-affirmed consent prior to creating any recordings. Participants received written information sheets about the study aims, procedures, and risks, as well the protection of their data conform the General Data Protection Regulation (GDPR). All participant data was pseudonymized using a participant code.

11.1.4. Trial registration:

The trial was prospectively registered with ISRCTN registry: https://www.isrctn.com/ISRCTN12995230

11.2 Methods used to address the objectives of Research Aim 2:

11.2.1. Scoping review

To meet research objective 1 of Research Aim 2, we conducted a scoping review of the literature. We followed the methodological framework by Arksey and O'Malley[155] and additional recommendations and clarifications by Levac et al.[156]

For this review, we conducted a search from 1 January 2020 to 18 November 2020 (date of last search) in PubMed, PsychINFO, MEDLINE, Embase, Cochrane Register of Controlled Trials (CENTRAL) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). We supplemented the search strategy with a hand-search of relevant key journals. We included peer-reviewed articles reporting on quantitative primary outcomes of randomized controlled trials (RCTs) of complex ACP interventions for adults with chronic serious illness. As an additional inclusion criterium, publications were required to specify the mechanism(s) by which the intervention was expected to generate change in the primary outcome. In line with scoping review methodology, we did not conduct a quality assessment. A standardized data charting sheet collected the following information: authors, year, country, setting, sample, design (conceptual model or theory used, if any; core intervention components; control condition; duration; primary outcome; mechanism; outcome findings). We also examined each article for implications of the results for the proposed mechanism(s) and/or other factors proposed to have impacted study results.

11.2.2. Qualitative study with interviews and focus groups

1.1 Setting: Generalist longitudinal outpatient care in the Canadian provinces of Alberta and British Columbia

Data used to answer objective 2 were collected as part of a completed **Canadian national project to test ways to improve ACP conversations across different health settings** (iCAN-ACP).

In Canada, provincial Ministries of Health structure healthcare in their province, which introduces differences in ACP programs. Recent initiatives have introduced frameworks such as the Pan-Canadian Community Framework, which outlines national, regional, and local priorities for ACP. Three key toolkits and guides for ACP are available at the national level. [157]

At the provincial level, Alberta Health Services has an ACP procedure and policy which includes a Goals of Care Designation (GCD): a health practitioner order which indicates medical care intentions, preferred locations of care, and transfer opportunities for current or future care.[158] GCD Orders, Personal Directives (ADs), and a tracking record (a cumulative narrative of ACP, serious illness, and goals of care conversations) are kept at the person's home in a "Green Sleeve".[157] In British Columbia (BC), an ACP guide called "My Voice: Expressing My Wishes for Future Health Care Treatment" offers information and guidance to persons wishing to indicate a Representative who can make decisions about the person's health and personal care in the case of incapacity, and/or create an AD.[159]

1.2. Intervention: The ACP pathway

For the primary care arm of the project, an **ACP pathway** based on the Serious Illness Conversation Guide (SICG),[160] supplemented by decision aid tools, was implemented in generalist longitudinal outpatient care (family practice and internal medicine) in the Canadian provinces of Alberta and BC. Briefly, the patient-facing portion of the pathway, delivered by allied health professionals (nurses, social workers) and physicians who were trained in its use, followed a three-step process. Step 1 consisted of a study visit for informed consent and questionnaire collection, and to provide information about ACP and how best to choose a substitute decision maker (SDM). Step 2 was an ACP education and values clarification session using the SICG and an online decision aid called the Best-Worst Scenario Online Tool. After an introduction and an "about me" section, which included questions such as the patient's age, the tool introduced sets of three issues. The patient was asked to rank which of the three issues they consider most and least important, when considering medical treatments they might want. Based on the patient's responses, the tool created a summary chart of what mattered most to the patient, e.g., living as long as possible or avoiding the use of machines

to keep the patient alive. This step resulted in a letter stating the patient's wishes for the physician to review. In step 3, the physician met with the patient to finalize and document care goals and wishes.

General internal medicine, which is not a primary care setting in Canada, was considered legitimate to include alongside primary care clinics, as internal medicine clinics are designed to manage complicated illness and patients may have an established relationship with this setting.

1.3. Method: Qualitative interview study

To **explore their lived experiences of implementing the pathway**, participating clinicians were invited to participate in semi-structured focus groups or individual interviews. The pathway meetings were stopped due to the start of the COVID-19 pandemic; interviews were conducted until October 2020, with an additional member-checking interview in July 2022. The interview guide structure was based on Normalization Process Theory (NPT), an implementation science framework which assesses the components of sense-making (coherence), relational work and engagement (cognitive participation), operational work (collective action), and appraisal (reflexive monitoring). These components are seen as acting in dynamic relationship with each other and with the wider context, including at the organizational and social level, and can promote or inhibit the implementation and sustainability of an intervention in daily practice.[161] Hence, interview questions explored topics such as how the pathway affected the work of the practice, which effect the pathway had on consultations, whether participants were supportive of the pathway, and which factors might help or hinder the pathway from continuing in practice in the future.

One Alberta family practice, two BC family practices, and one BC internal medicine clinic participated in the project. Twelve physicians and one social worker were interviewed. Interviews were transcribed verbatim. Two authors (JS and DE) independently analyzed the transcripts. We used an inductive approach: codes were derived from the transcript data rather than prespecified, to allow codes and themes to emerge organically. After analysis of the first transcript, codes and themes were compared to establish a preliminary codebook with codes, sub-themes, themes, and domains. Regular meetings allowed the codebook to be updated as new findings emerged.

1.4. Ethical considerations

Ethical approval for this study was granted by the Hamilton Integrated Research Ethics Board (project #2017-3977), the Conjoint Health Research Ethics Board (CHREB), University of Calgary (REB18-0056, REB18-0056_REN1, EB18-0056_REN2), and University of British

Columbia Clinical Research Ethics Board (CREB) (#H17-03552). Participants provided informed consent. Transcript data were pseudonymized.

DISSERTATION OUTLINE

After this introduction (**Part I**), chapters 1-6 present original research articles which has been published in (Chapters 1-4), or submitted to (chapters 5-6) A1 peer-reviewed journals. Each chapter is a standalone publication.

The research articles are separated into two parts corresponding to the research aims described in this introduction. In **Part II**, we address Research Aim 1 by reporting on the cluster-randomized controlled trial (RCT) of the ACP-GP intervention, including its design, its results, and an evaluation of the implementation process. In *Chapter 1*, we describe the protocol for the trial study and process evaluation. *Chapter 2* reports baseline patient data of the cluster-RCT and explores to which extent patient characteristics (demographic and clinical), and patient perceptions of ACP communication by the GP, are associated with their ACP engagement. *Chapter 3* reports the primary outcome findings of the cluster-RCT. *Chapter 4* reports the findings of the mixed-methods process evaluation. **Part III** focuses on international insights in ACP interventions. In *Chapter 5*, we present the results of a scoping review of complex ACP interventions for chronic serious illness. *Chapter 6* explores the experiences of Canadian clinicians who delivered an ACP pathway. **Part IV** is the final section of the dissertation. Here, we summarize the main findings, reflect on strengths and limitations of the research methods used, discuss the findings more broadly in the scope of the ACP research literature, and suggest implications for practice, policy, and research.

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32

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PART II. Cluster-randomized controlled trial of the complex ACP-GP intervention for patient with chronic, life-limiting illness in Belgian general practice

Chapter 1

Facilitating advance care planning in the general practice setting for patients with a chronic, life-limiting illness: protocol for a Phase-III cluster-randomized controlled trial and process evaluation of the ACP-GP intervention

This chapter is based on the following publication:

ABSTRACT

Background*:* Advance care planning (ACP), a process of communication about patients' preferences for future medical care, should be initiated in a timely manner. Ideally situated for this initiation is the general practitioner (GP). The intervention to improve the initiation of ACP for patients with a chronic life-limiting illness in general practice (ACP-GP) includes an ACP workbook for patients, ACP communication training for GPs, planned ACP conversations, and documentation of ACP conversation outcomes in a structured template. We present the study protocol of a Phase-III randomized controlled trial (RCT) of ACP-GP that aims to evaluate its effects on outcomes at the GP, patient, and surrogate decision maker (SDM) levels; and to assess the implementation process of the intervention.

Methods*:* This RCT will take place in Flanders, Belgium. Thirty-six GPs, 108 patients with a chronic, life-limiting illness, and their (potential) SDM will be recruited, then cluster-randomized to the ACP-GP intervention or the control condition. The primary outcome for GPs is ACP self-efficacy; primary outcome for patients is level of ACP engagement. Secondary outcomes for GPs are ACP practices, knowledge and attitudes; and documentation of ACP discussion outcomes. Secondary outcomes for patients are quality of life; anxiety; depression; appointment of an SDM; completion of new ACP documents; thinking about ACP; and communication with the GP. The secondary outcome for the SDM is level of engagement with ACP. A process evaluation will assess the recruitment and implementation of the intervention using the RE-AIM framework.

Discussion*:* While the general practice setting holds promise for timely initiation of ACP, there is a lack of randomized trial studies evaluating the effectiveness of ACP interventions implemented in this setting. After this Phase-III RCT, we will be able to present valuable evidence of the effects of this ACP-GP intervention, with the potential for offering a well-tested and evaluated program to be implemented in general practice. The results of the process evaluation will provide insight into what contributes to or detracts from implementation success, as well as how the intervention can be adapted to specific contexts or needs.

Trial registration*:* Prospectively registered at with ISRCTN (ISRCTN12995230); registered 19/06/2020, http://www.isrctn.com/ISRCTN12995230

BACKGROUND

Advance Care Planning (ACP) refers to "a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care".[1] This may include the completion of a living will or Advance Directive (AD), which document wishes for future care should patients be unable to make their wishes known due to declining health or incapacity; and/or the appointing of a surrogate decision-maker (SDM), who can make care decisions in the place of the patient if the patient is unable to speak for themselves. ACP can lead to greater concordance between care preferences and care received,[2] improved communication about the end of life with care providers,[3] greater satisfaction with physician visits,[4] and improved quality of end-of-life care.[5] It is a prerequisite for a good coordination of care, including palliative and end-of-life care, by making clear which medical decisions will be considered appropriate when the patient is unable to make such a decision themselves.[6]

For patients with chronic, life-limiting illness(es), which are often marked by trajectories of steady illness progression or gradual health decline punctuated by acute deterioration,[7] it is important that ACP is initiated in a timely manner so that sufficient time can be dedicated to conversations about values, goals and preferences.[8] ACP is intended as a continuous process of communication. For patients, engaging in ACP is not an isolated occurrence,[9] but a complex behavior where readiness to engage in discrete behavior is an important precursor to action.[10] Especially suited to initiating these interactive discussions over multiple visits is the general practice setting. In Belgium, as in many other European countries, general practitioners (GPs) observe the patient's health over the course of regular visits, often have a trusting relationship with the patient, and often are aware of the patient's medical and social context.[11,12] However, while the role of the GP in initiating ACP conversations is highlighted in guidelines of care,[13] currently the process of ACP between patients and GP is not often initiated.[14]

There is a lack of adequate practice models of initiation and implementation of ACP in general practice, and randomized trial studies evaluating the effectiveness of ACP interventions implemented in this setting are still largely absent. In light of this, a complex intervention for general practice has been developed[15,16], and had subsequently been pilot-tested. The intervention was found to be feasible and acceptable.[17] Based on the results of the pilot test, the intervention was adapted and is now being tested in a Phase-III trial. This manuscript presents the research protocol for the Phase-III randomized controlled trial (RCT) study of the intervention. The **Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement** was applied to describe all relevant aspects of the trial [see Supplementary file 1].[18,19]

Objectives

The aim of this study is: To evaluate the effectiveness and mechanisms of action of a complex, multi-component ACP intervention, called ACP-GP, for patients with chronic, life-limiting illness (es), in the general practice setting, aimed at improving the readiness of patients to engage with ACP. The intervention will be compared to care as usual. Study objectives are:

(1) To **test** the effectiveness of the ACP-GP intervention on:
- the patient's level of engagement with ACP (primary outcome at patient level)
- the GP's self-efficacy for conducting ACP (primary outcome at GP level)

(2) To **explore** the effect of the ACP-GP intervention on:
- 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)
- GP ACP practices, attitudes and knowledge about ACP, and the documentation of ACP discussions in the patient medical file (secondary outcomes at GP level)
- 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

Trial design

This study is a 2-arm cluster-RCT with a parallel group design, which compares the ACP-GP intervention (arm 1) to usual care (arm 2) of patients with a chronic life-limiting illness. It is a superiority trial which aims to establish whether the intervention is superior to usual care in its effectiveness. GPs, their patients, and the (potential) SDM of each patient will be recruited for participation. Randomization occurs at the level of the GP, with patients and their SDM clustered per GP. To determine effectiveness, outcomes will be measured at baseline (T0), during a first follow-up at 3 months (T1) and again at 6 months post-baseline (T2).

A process evaluation will be used to evaluate how the intervention was implemented and to understand which factors contributed to the results of the trial. This process evaluation follows the RE-AIM framework, which highlights essential factors to improving the adoption and implementation of evidence-based interventions: Reach, Efficacy, Adoption, Implementation, and Maintenance.[20] The process evaluation will span the duration of the intervention, as well as pre- and post-intervention evaluation.

METHODS

Study setting

The intervention will be conducted in the setting of general practices the region of Flanders, Belgium.

Eligibility criteria

Dutch-speaking GPs working in Flanders and Brussels, Belgium, are eligible to participate. GPs may practice in a group or solo setting, in urban, semi-urban, or rural areas. To reduce contamination risk, one GP per practice will be included. In order to participate, GPs also must be able to identify and include at least 3 eligible patients.

Eligible patients are those with a chronic, life-limiting illness (using indicators described in Table 1) for whom the GP answers "no" to the "surprise question": "Would I be surprised if this patient were to die within the next 12 to 24 months?".[21] This one-item screening tool assists in identifying patients with chronic, life-limiting illness who may benefit from the start of an ACP process.[22,23] Patients for whom the GP would not be surprised if they were to die within the next 6 months will be excluded as the intervention will be tested over a period of 6 months.

The patient may identify their SDM for inclusion, or they may designate someone who may be willing to act as their SDM; the latter is the potential SDM. Through the rest of this manuscript, "SDM" will refer to both the SDM and the potential SDM. While patients are encouraged to identify a SDM for participation, not identifying one will not exclude the patient from participation.

All inclusion criteria for patients and their SDM can be found in Table 1.

Table 1. Inclusion and exclusion criteria for patients

Patient inclusion criteria	Patient exclusion criteria
Adults (>18 years old)	Unable to speak or understand Dutch
Mentally competent as measured by judgment of the GP **OR** if Mini-Mental State Examination has been conducted, score is >24	Unable to provide consent or complete the questionnaires due to cognitive impairment (as judged by the GP)
GP answers "no" to surprise question: "Would I be surprised if this patient were to die within the next 12 to 24 months?"	GP answers "no" to surprise question: "Would I be surprised if this patient were to die within the next 6 months?"

Diagnosis of a life-limiting illness:
 	
1. Locally-advanced unresectable, or metastasized **cancer** OR
 	
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
 	
3. **Geriatric frailty** (Clinical Frailty Scale score 5-7, mildly to severely frail)
	Participated in the pilot study of this intervention or in the cognitive testing of the adjusted intervention materials

	Participating in other studies evaluating advance care planning, palliative care services or communication strategies
SDM inclusion criteria	**SDM exclusion criteria**
Adults (>18 years old)	Unable to speak or understand Dutch
Identified by the patient as their surrogate decision maker OR as a person who may be willing to be their surrogate decision maker	Unable to provide informed consent

Intervention and control

Intervention

The ACP-GP intervention (Table 2) is designed to 1) train GPs to conduct ACP discussions with eligible patients, 2) prepare patients for the conversation by providing them with a workbook about ACP, 3) facilitate at least 2 ACP conversations between GP and patient (and SDM if present), and 4) document the outcomes of the discussion in the patient electronic medical file with the help of a structured template.

Table 2. Key elements of the ACP-GP intervention

1. GP training	The GP training, which has been tested multiple times, is originally conceptualized as two interactive sessions of 3 hours each, delivered to small groups of 6-8 GPs at a time within the university hospital setting or another location that is convenient for the participants. However, due to COVID-19 concerns, the content of the training has been translated to an online platform. The training is provided by a trainer experienced in primary care and communication.
	Two interactive web sessions of approximately 2 hours each will replace the live sessions. Preparatory activities such as fictional case examples with reflection questions will be available before the training begins. GPs will have access to background information portions through an e-learning module presented via the Ufora platform of the Universiteit Gent. This module will take no more than 60 minutes to review.
	The first aim, improving ACP knowledge, will be addressed via the e-learning module. ACP communication skills will be practiced with video role-modeling exercises which are available on the e-learning module and will be further elaborated on during the web sessions. These web sessions will also include role-play exercises with model patients and interactive discussions with fellow GPs and the trainer.
	During the training, GPs will receive an extensive conversation guide and an at-a-glance conversation flowchart. These can be used as preparation for and during ACP conversations with patients.
	In the context of their continuous medical education, GPs will be able to obtain accreditation in ethics and economy by following the training. GPs in the control group will have the opportunity to follow the training

	after the conclusion of the study, so that both groups have access to this incentive.
	After the training sessions, GPs will have the opportunity for check-in discussions with the trainers to ask questions and report issues.
2. ACP workbook for patients	During the first home visit, the RA will give patients an ACP workbook that highlights the importance of ACP at different stages of health.
	The workbook contains questions to stimulate reflection on topics such as quality of life and preferences for future care. The workbook is adjusted for health literacy and has been evaluated through cognitive interviewing with 6 patients who fulfill the inclusion criteria of the trial.
3. Patient-centered ACP discussion with conversation guide	After the training, the GP will conduct a minimum of two ACP conversations in the patient's home or in the GP office. If COVID-19 safety concerns prohibit the GP from speaking face-to-face with the patient, a telephone consultation or video-consult via an accredited electronic health record software package is also possible.
	The first conversation takes place within two weeks after the GP has received the training; the second within a month after the first conversation.
	The GP can use the conversation guide, which contains parallel topics to the patient workbook, to structure the conversation. First, the patient is invited to talk about the questions and topics they saw as most important. Then, if time permits, the conversation moves to the questions that have not yet been discussed
	Patients can choose to have their SDM present at these conversations. If the patient has not yet identified an SDM, they will be encouraged to think about who might be a good fit for this role.
	Other already-available documents, such as advance directive forms or patient guide materials such as the information booklet provided by the LevensEinde Informatie Forum (LEIF), may be used as the GP or patients see fit.
	The ACP discussion is expected to last up to 60 minutes, but GPs are advised during the training to judge the optimal duration according to the openness and engagement of the patient.

4. Documentation of the ACP discussion	The GP will fill out a template reflecting the outcomes of each ACP conversation. The template is based on the structure of the conversation guide. Here, the GP can freely note what was discussed, even if no concrete care decisions were made.
	During the training, the GP will be instructed to upload this documentation to the patient's electronic medical file.
	With the patient's permission, this information can be shared with other health providers involved in the patient's care, such as specialist practitioners and home care nurses

Control: care as usual

The intervention will be compared to a control group, which is care as usual. In this group, participating GPs will not receive the training or the conversation guides, and patients will not receive the workbook developed for the intervention. The control group will also not feature the two planned consultations dedicated specifically to discussing ACP as included in the intervention arm. Participating patients will consult with their GP as they usually do. During these consultations, the topic of ACP may still spontaneously be addressed, either by the GP or patient. Other already-available national documents, such as advance directive forms or patient guide materials, may be used as the GP or patients see fit.

Criteria for discontinuing or modifying allocated interventions for a given trial participant

Participants may discontinue their participation at any time and for any reason, as is described in the informed consent forms. Patients will be monitored by the researchers for the possibility of adverse events and may discontinue their participation in response to adverse events, the detection of which will prompt a notification of the trial manager and the ethics committee.

Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence

Trainers who provide the intervention training to GPs will be trained by researchers who developed the training and provided the training during the pilot study. One of the trainers, PP, is an instructor to GPs-in-training who also conducts training sessions on the topic of palliative care. Therefore, **the train-the-trainer model is based on the expertise and experience of the primary trainer**, improving the quality of the training.

The **regular check-in moments with the GPs by the trainers** as part of the process evaluation will also serve as a means to monitor adherence to the study protocol. During the check-in moments, GPs will be asked to report on how they are delivering the intervention and which problems they are encountering. This allows the trainers to detect difficulties the GP might have in delivering the intervention or take note of a possible lack of intervention fidelity. If necessary, the trainers can remind the GP of the study protocol and/or answer questions the GP might still have.

Verbatim transcriptions of audio-recorded ACP conversations as well as anonymised completed ACP documentation templates will be used to evaluate fidelity and adherence to the study protocol. Additionally, at T1 we will provide GPs in both groups with a process evaluation questionnaire which asks them to report the number of ACP conversations conducted with each participant, the length of each conversation, the topics discussed, where the conversation was documented, and who was present during the conversation.

A sample of completed, anonymised workbooks from patients will be examined to check to what extent the workbook is used, which questions are more or less frequently answered, and whether patients document having discussed the workbook with others (for which a simple table is provided on the final workbook page; this can include the SDM but can also be other family members, health providers, friends, etc.).

Relevant concomitant care and interventions that are permitted or prohibited during the trial

There are no restrictions regarding concomitant medical care or medical interventions during the trial period. Participants may receive care as normal, with the exception of participation in other studies or trials evaluating ACP interventions, palliative care services, or other communication strategies. Patients participating in such studies or trials will be excluded from participating in this study.

Outcomes

Study endpoints and assessments

This study uses both qualitative and quantitative data to measure the outcomes of the intervention. As the intervention consists of components developed for the GP and patient, outcomes will be measured at both levels. The primary and secondary outcomes are listed in Table 3.

We have two separate primary outcomes, one at the GP level and one at the patient level. Success on any one of these outcomes at T1 may support a conclusion of effectiveness.

Hence there are several ways for the study to successfully demonstrate a treatment effect. This multiplicity problem has been taken into account in the power analysis by controlling the Type I error rate at 2.5% (Bonferroni method).

Scores on the ACP Engagement Survey and the ACP Self-Efficacy Scale for GPs will also be measured at T2. We will treat T2 scores on these scales as a secondary outcome.

Process evaluation

A process evaluation will be used to evaluate how the intervention was implemented and to understand which factors contributed to the results of the trial. This process evaluation follows the RE-AIM framework, which highlights essential factors to improving the adoption and implementation of evidence-based interventions: Reach, Efficacy, Adoption, Implementation, and Maintenance.[20] The process evaluation will span the duration of the intervention, as well as pre and post-intervention evaluation. An overview of the process evaluation, with RE-AIM domains and data collection methods, can be found in Table 3.

Table 3. Outcomes, measurement instruments and timing

	Measurement tool	Completed by	Timing of measurement		
			T0	T1	T2
Primary outcome					
Level of engagement with ACP	*ACP Engagement Survey 15-item version*[24] • Reported on an overall average 5-point Likert scale (range 1-5)	Patient	X	**X**	X
ACP Self-efficacy	*ACP Self-efficacy Scale (ACP-SE)*[25] • 17 items • Reported on an overall average 5-point Likert scale (range 1-5) • 1 additional general item including all advance care planning can be used for comparison to the scale	GP	X	**X**	X
Secondary outcomes					
Health-related quality of life	*Short Form Health Questionnaire (SF-12v2)*[26] • Physical Health (PCS) and Mental Health (MCS) summary scores (range 0-100)	Patient	X	X	X
Anxiety	*Generalized Anxiety Disorder Questionnaire (GAD-7)*[27] • Sum score (range 0-21)	Patient	X	X	X
Depression	*Patient Health Questionnaire (PHQ-9)*[28] • Sum score (range 0-27)	Patient	X	X	X
Appointment of a substitute decision maker	GP report ACP engagement survey "readiness to sign official papers assigning a SDM" item	Patient GP	X	X	X
Completion of new ACP documents	Patient report GP report ACP engagement survey "readiness to sign official papers stating medical wishes" item	Patient		X	X

Thinking about ACP	1 self-developed item, 10-point Likert ("How much have you thought about ACP in the last 3 months?"; response categories range from "not at all" to "very much")	Patient	X	X	X
Communication with the GP	4 self-developed items, 10-point Likert (e.g., "To what extent did the GP listen to your concerns about your future health?"; response categories range from "not at all" to "very much")	Patient	X	X	X
ACP Practices	• *Next Steps training program questionnaire*[29] (4 items) • 2 items specific to practices with patients with chronic, life-limiting illness ("Which percentage of your patients has a chronic, life-limiting illness" and "With which percentage of your patients with a chronic, life-limiting illness do you conduct ACP conversations?"; 4 response options per item)[25] • 8 additional items regarding ACP practices (e.g., "Where do the ACP conversations you conduct usually take place?")	GP	X	X	X
ACP Attitudes	*Next Steps training program questionnaire*[29] • 9 items; 5-point Likert scale ranging from "Completely disagree" to "Completely agree"; adapted to the Belgian legal context	GP	X	X	X
ACP Knowledge	*Next Steps training program questionnaire*[2930] • 10 items; correct/not correct/don't know; adapted to the Belgian legal context	GP	X	X	X

Documentation of ACP discussion outcomes	Documentation template review	GP		X	X
Level of engagement with ACP	*ACP Engagement Survey, substitute decision maker version*[31] • 17 items; 5-point Likert scales • 3 domain scores ("Serving as SDM", "Contemplation", Readiness") computed as the unweighted average of items per domain (range 1-5)	SDM	X	X	X
Other measurements					
Demographic information	For patients and surrogate decision makers: • Gender • Age • Marital status • Highest completed education • Religion • Patient/SDM relationship • Whether patient and SDM live together or apart For patients: • Previous completion of any advance directives ("*wilsverklaringen*") For surrogate decision makers: • How long they have known the patient For GPs: • Gender • Age • Graduation year • Practice setting(s) • Years of experience as a GP • Graduating university • Working in a palliative home care team (yes/no)	GP Patient SDM	X		

	• Working as a "coordinating and advising practitioner" in a residential care facility (yes/no) • Prior formal ACP education or training (intensive/introductory/none) • Prior formal palliative care education or training (intensive/introductory/none)	

Process evaluation		
RE-AIM domain	**Operationalization**	**Measurement**
Reach	• Comparing the characteristics of participating patients with non-participants	• Documentation of the recruitment process by the researchers • Documentation of reasons given for not participating • Participant demographics
Efficacy/effectiveness	• Primary and secondary outcomes of the RCT	• See primary and secondary outcomes above • Reports of any adverse effects
Adoption	• ACP discussion documents uploaded • Patient use of the work booklet • Experiences of GPs and patients applying intervention steps • Changes in GP practice	• Training topic checklist (after each training) • Questionnaire for GPs regarding their ACP practices and conversations in the last 3 months (T1) • Questionnaire for patients regarding ACP conversations with their GP in the last 3 months (T1) • Documentation template review (T1, T2) • Contents of work booklet from a sample of patients in the intervention group (physical copy or digital scan) (T1, T2) • Check-in discussions between GPs and trainers (continuous)

		• Focus groups with GPs (after T2)
		• Semi-structured interviews with patients and SDM (after T2)
Implementation	• Fidelity: the extent to which the steps of the intervention were followed as specified in the protocol • Patient and GP barriers/facilitators to following the steps of the intervention • Satisfaction of GPs and patients with the intervention components	• Training topic checklist (after each training) • Check-in discussions between GP and trainers (continuous) • Audio recordings of ACP consultations between GP and patient (and SDM if present) • Documentation template review (T1, T2) • Satisfaction questionnaire for intervention GPs and patients (T1) • Focus groups with GPs (after T2) • Semi-structured interviews with patients and SDM (after T2)
Maintenance	• GP intention for using the intervention materials in the future • Recommendations by the GP and patients to improve intervention usability in the future	• Satisfaction questionnaires for intervention GPs and patients (T1) • Focus groups with GPs (after T2) • Semi-structured interviews with patients and SDM (after T2)

Participant timeline

The participant timeline flow diagram is represented in Figure 1. All GPs, patients, and SDMs from the intervention and control group will complete a **baseline assessment** (T0) after providing informed consent. At **3 months** (T1), the RA will approach the patient and SDM for follow-up assessment; GPs will complete a follow-up assessment by filling out and returning questionnaires by postal mail or by completing an online version of the questionnaire. **Six months** (T2) after inclusion, patients and SDMs will complete the second follow-up by filling

out and returning questionnaires by postal mail; GPs will also complete follow-up measures at this time by filling out and returning questionnaires by postal mail or by completing an online version of the questionnaires.

Figure 1. Flow diagram of the ACP-GP trial
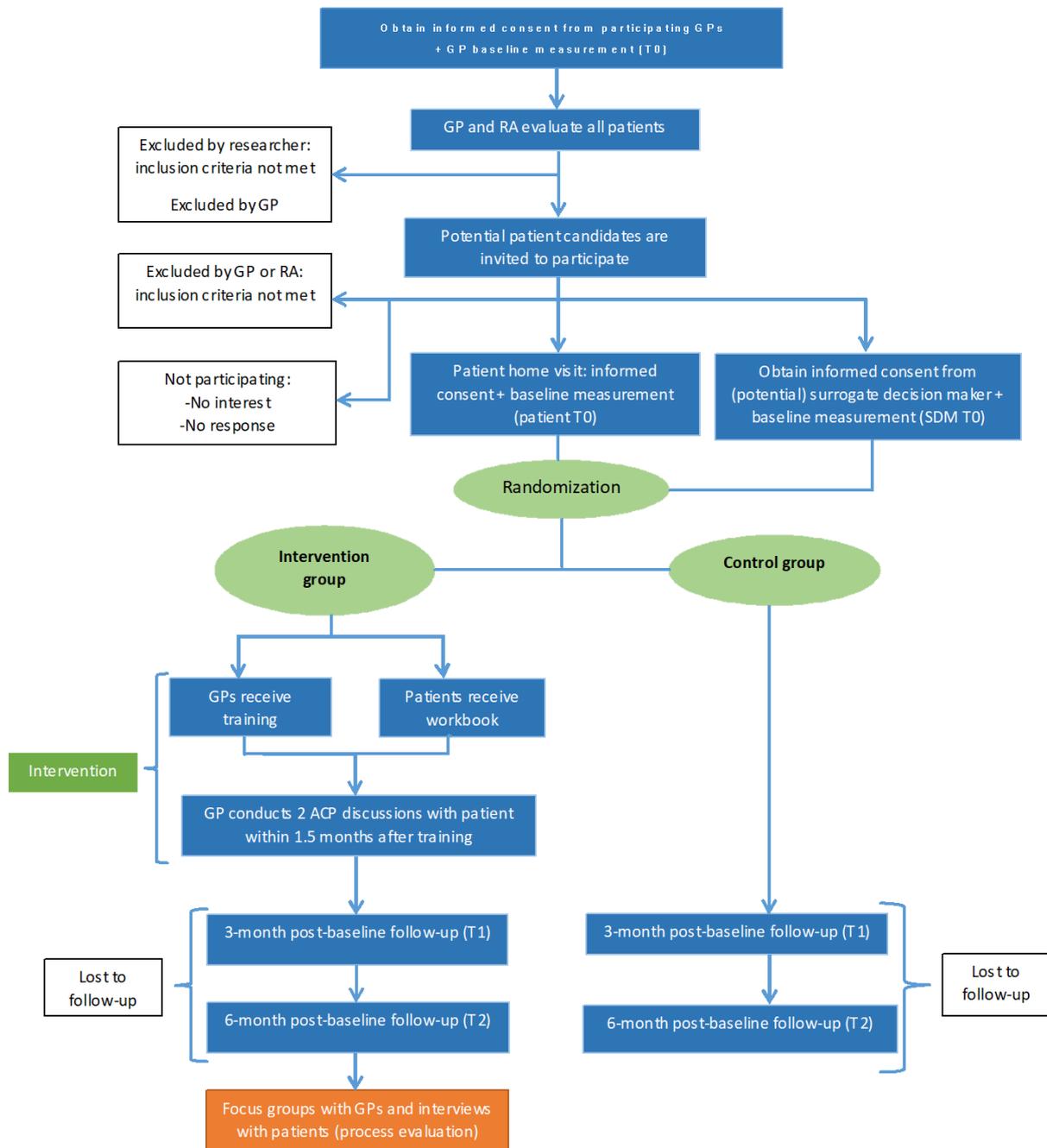
Sample size

All power calculations were conducted to allow testing for intervention effectiveness at T1. Power calculations were conducted for the primary outcome at the patient level and at the GP level.

When all clusters have the same size of 2 patients, and we assume an intracluster correlation coefficient (ICC) of 0.04,[32] then the design effect is estimated at 1.04, and a sample of 26 patients for each group (corresponding to 13 GPs with each 2 patients) will achieve 91.45% power to detect a mean difference in delta outcome of 1 at a significance level of 2.5%, assuming the standard deviation is 0.96 in both groups. This number has been increased to 51 patients per group (corresponding to 17 GPs with each 3 patients) to allow for an initial GP drop-out rate of 23.53% and a patient drop-out rate of 33.33%. (Total sample size of 102 patients).

A sample of 14 GPs for each group will achieve 91.11% power to detect a mean difference in ACP self-efficacy of 1 at a significance level of 2.5%, assuming the standard deviation is 0.71 in both groups. This number has been increased to 18 GPs per group to allow for an initial GP drop-out rate of 22.22% (Total sample size of 36 GPs).

To ensure sufficient statistical power for both GP- and patient-level primary outcomes, we will use the more conservative calculation of 18 GPs per group (36 total), with 54 patients per group (108 total) and a maximum of 54 SDMs per group (1 per patient, 108 total).

Recruitment

GPs

The research team will recruit GPs through several channels. Quality peer-review groups will be contacted to provide information about the study and motivate participation to their members. Publicly-available member lists of local associations of GPs and contact lists of GPs will be used for telephone and email contact and for providing recruitment letters by postal mail.

GPs who are eligible and wish to participate will be asked to provide informed consent. Each GP will be asked to list, with the help of a research assistant (RA), three patients who are potentially eligible for participation in the study. Where possible, each of the three identified patients should have a different life-limiting illness (cancer, organ failure, geriatric frailty) according to the criteria listed in Table1.

Patients

GPs will have approximately 1 month to present the study to their selected eligible patients and ask them if they wish to participate. A simplified information letter will be provided to help explain the study. If the patient does not wish to participate, the GP will be asked to identify another potentially eligible patient within the same category of life-limiting illness. Eligible patients who agree to participate will be contacted via telephone by the research team, who will provide information about the study during a visit at the patient's home or other location that is convenient for the patient, or via telephone if COVID-19 safety concerns prohibit face-to-face contact.

If a GP drops out during the first 3 months of the trial, a new GP will be recruited through the channels described below and trained to use the intervention. Reasons for drop-out will be discussed, recorded and taken into account for the process evaluation. If a GP withdraws from the study or drops out after 3 months, no new GP will be recruited. As only 3 patients will be enrolled per GP and the sample size has been increased to allow for a 23.53% GP drop-out and 33.33% patient drop-out, the drop-out of any one practice will not greatly impact the study.

SDMs

RA's will assist patients with identifying a SDM using a pre-written script which asks whether the patient has formally appointed someone, and if not, who may be able or willing to fulfill this role. If the SDM is present at the time of the visit, they will be asked if they would like to participate. If the SDM is not present, the researchers will ask permission from the patient to contact them regarding the study. If such a person wishes to participate, they will also be asked to provide informed consent.

ASSIGNMENT OF INTERVENTIONS

Allocation

Randomization will be performed at the level of the GP to avoid contamination bias. Every GP will have to recruit at least three patients. Once three patients have been recruited, the GP will be randomized to either the intervention or control group according to a 1:1 allocation ratio per a computer-generated randomization list. We will use permuted block randomization with varying block sizes. No stratification factors will be taken into account.

Participants will be enrolled to the study by the research assistants and data managers. The allocation sequence will be generated by independent statisticians working with the Biostatistics Unit at the Faculty of Medicine and Health Sciences of Ghent University.

Assignment to intervention or control groups of GP-patient clusters will be performed by a researcher not involved with any other portion of this study.

Blinding

Due to the nature of the intervention, neither GP, patient, nor SDM participants can be blinded to allocation. Although the participants cannot be blinded to their assignment and researchers will be unblinded to GP assignment through the coordination of the training sessions, data collection at T0, T1, and T2 will be performed by an independent data collector/research assistant who is blinded to the assignment of the GP and patient to either the intervention or control arm. Those performing the data analysis will likewise remain blind to participant allocation.

Informed consent and data collection at T0 will occur before randomization has taken place.

DATA COLLECTION, MANAGEMENT, AND ANALYSIS

Data collection methods

The outcome measures and general procedures for data collection are described above. Questionnaire data will be collected at T0, T1, and T2. GPs have the option to complete the questionnaires on paper or online if preferred. Patients and SDMs will complete questionnaires on paper. Patients and SDMs completing the questionnaires at T0 and T1 can receive support from a data manager if so desired, either through an in-person visit by the data manager or via telephone contact. If COVID-19 safety concerns arise which prohibit home visits, all support will be provided through telephone contact.

As described above, data collection for the process evaluation will occur during and after the intervention period by means of questionnaires, documentation of activities, and audio-recordings of ACP conversations. These audio-recordings will be transcribed for analysis. During the recruitment phase, those approached for recruitment who do not wish to participate may optionally provide their reason for not participating.

After the 6-month intervention period has elapsed, the process evaluation will be continued through interviews and focus groups with patients and their SDMs, and GPs respectively. With permission from the participants, focus groups and interviews will be audiotaped to allow for later verbatim transcription. The interviewer will also take notes during the interviews and focus groups. Both the interviews and the focus groups will be conducted according to a topic list, with attached instructions for the interviewer (or moderator and observer for focus groups).

With patients in the intervention group and their SDM, if one was identified, 10-15 interviews will be conducted. Focus groups with GPs will include 6-8 GPs per focus group. Interviews and focus groups will be conducted until data saturation is achieved; that is, until the newly-collected data is redundant with the already-collected data and no new results emerge.

To improve retention, participants will be presented with a gift certificate for their participation in the study. Additionally, the consultation costs for the first two ACP discussions planned in the intervention group (i.e., the consultations required for the intervention) will be compensated by the researchers.

Data management

To pseudonymize the data, each participant will be assigned a study identification number. A list with identification codes which links the participant's name to the participant's identification number will be stored in a limited-access space. Response input will only use the participant identification number. All digitally inputted data will be stored on a secure server. Access to this server is strictly limited to those who require access to conduct the study. All informed consent forms will be stored in a lockable filing cabinet restricted to members of the research team. Paper questionnaires will be stored in a separate lockable filing cabinet with similar restrictions.

Data will be retained for 10 years, after which it will be destroyed. Data will be shared only for the purposes of the study and will not be shared with other countries.

A trial manager will take responsibility for the data management over the course of the study. A record of the study and its data processing activities has been submitted to the Data Protection Office (DPO) of the Vrije Universiteit Brussel.

Data analysis

The intent-to-treat population consists of all patients randomized. Subjects are analyzed according to the allocated treatment group irrespective of their compliance with the planned course of treatment. The intent-to-treat population is considered the main analysis population.

Linear mixed models will give unbiased results when outcome data is missing at random (maximum likelihood estimation). GEE models only allow for missing values to be completely at random (it is not a likelihood approach).

The analyses of the two separate primary endpoints will be performed at the two-sided 2.5% significance level, because success on any one of these endpoints at T1 may support a conclusion of effectiveness (Bonferroni method to adjust for multiplicity).

When an effect on a primary endpoint is shown, the secondary endpoints can be analyzed at the two-sided 5% significance level.

Descriptive statistics

Demographic characteristics of participants (at T0) will be summarized using descriptive statistics (absolute and relative frequencies for nominal variables, mean and standard deviation for continuous variables with normal distribution, median and 25-75th percentiles for continuous variables without normal distribution).

Primary efficacy analyses

To test the effectiveness of the intervention, we will compare T1 scores on the ACP Engagement Survey for patients and the ACP-Self Efficacy Scale for GPs between the intervention and control arms. Linear mixed models will be used. For patient outcomes, the models will include a random intercept for GP (to account for the nesting of patients within a GP) and a random intercept for patient (to account for the nesting of repeated measurements within a patient). For GP outcomes, a random intercept for GP (to account for the nesting of repeated measurements within a GP) will be used. The fixed effects part of these linear mixed models will include time, group, and time x group interaction. The two-way interaction between time and group will capture the effect of the intervention.

Secondary efficacy analyses

All continuous secondary endpoints will be analyzed by fitting similar linear mixed models as described above. Binary, multinomial, ordinal and count endpoints will be analyzed by fitting Generalizing Estimating Equations (GEE) models using a compound symmetry (or exchangeable) correlation structure, where we assume all correlations between time points to be the same. The GEE approach is a robust approach to take into account the repeated measurements within GPs without distributional assumptions. It is robust against misspecification of the covariance structure. However, it only allows missing values to be missing completely at random. Only an independent correlation structure is available for multinomial GEE models in SAS and SPPS software. Therefore, for nominal endpoints with K response categories, we will fit K-1 separate binary logistic GEE models for each response category paired with a baseline category.

Process evaluation

Process evaluation of the implementation of the intervention will be analysed following the RE-AIM framework. For the process evaluation, questionnaires will be analysed as follows:

Standard tests for independent data will be used to compare the questionnaires regarding ACP conversations in the last 3 months, completed by patients and GPs. Comparisons will be per item. For patients, clustering within GPs will be taken into account.

Descriptive statistics will be used to summarize the responses for the satisfaction questionnaires completed by patients and GPs. Absolute and relative frequencies of response options will be reported.

We will calculate descriptive statistics for any additional quantitative measures such as recruitment documentation, checklists of the training topics, and use of the workbook and documentation template. For document reviews such as that of the workbook, the process evaluation will only consider which items were answered, not the content of the answers.

Transcribed recordings, as well as interviewer notes from the focus groups with GPs and interviews with patients and SDMs, will provide the qualitative data for the process evaluation. Transcriptions and notes will be analysed line-by-line using NVivo. The comments and feedback given during the focus groups/interviews will be analysed via coding, combining and clustering based on common themes, and subcategorizing based on item interpretation. Using these codes, the research team will identify dominant response trends. During team discussions, the findings, interpretations, and conclusions across items will be reviewed in order to reach a consensus regarding potential problems with the materials. During these discussions, possible resolutions will be suggested. The qualitative analyses of the transcribed recordings will be carried out by JS as well as by research team members ADV, KP, KE, and LD.

DATA MONITORING

Data monitoring

This study will not have a Data Monitoring Committee. Excel sheets will be used to monitor recruitment and study responses. The research team will meet regularly (bi-weekly to weekly) during the recruitment period to review recruitment.

In the case of nonresponse to questionnaires, a follow-up notice will be sent to participants: GPs will receive a notice by mail and email, and patients and SDMs will receive a notice by mail. If there is no response after this notice, a final telephone follow-up will be conducted. Questionnaire forms, in Dutch, are available from the authors upon request.

Interim analyses and stopping guidelines

Analysis of data will begin when baseline data has been collected for all participants, to compare participant demographics and evaluate reasons for refusal to participate. Data will

be analyzed for primary endpoints at T1 (3 months post-baseline). If the trial must be terminated at any point before the completion of both qualitative and quantitative outcomes as described in Table 3, this will first be discussed with the researchers during an internal meeting. The final decision to terminate the trial can be made by Prof. Dr. Koen Pardon or Prof. Dr. Luc Deliens after this meeting. Should the trial be terminated this will be reported to the ethics committee, the data protection office, and the funder.

Harms

The ACP intervention is a non-invasive intervention, focused on conversations between GPs, patients, and SDMs regarding values and wishes for future medical care. Previous research has shown that people with life-limiting illnesses see participating in research such as this study as a worthwhile endeavor.[33] Adverse effect from participating in similar research, as may be implied by dropout due to the subject being too psychologically taxing to talk about, are rare.[34] However, people living with chronic life-limiting illnesses are a vulnerable group for whom the appropriate concern and ethical measures must be in place. An **anticipated adverse event** which may arise during the intervention is mild psychological discomfort in participating patients and SDMs, which may be caused by some questions in the ACP Engagement Survey or the workbook, or as a result of ACP conversations with the GP. However, participants will be informed of their right to refuse to answer any question and that they may withdraw from the study at any time without negative consequence. The possibility of a patient or SDM becoming distressed during the ACP discussions will be discussed during the GP training.

As the study involves patients with a chronic, life-limiting illness, it is possible that some patient drop-out is due to death related to disease progression, but this would not be related to the study protocol. A bereavement protocol has been established for the SDM if the patient dies during the study period. If researchers are informed that a patient has died, this will be communicated to the ethics committee. The bereaved SDM will be contacted with condolences and, if necessary, will receive information to refer them to appropriate support resources.

While the investigators cannot predict the occurrence of **unanticipated or unexpected** adverse events, we do not anticipate any serious adverse events associated with the research protocol. Nevertheless, we have included measures to detect increases in anxiety and depression at T1 and T2 and will act accordingly in the case of adverse events. These will be reported to the principal investigator and forwarded to the ethics committee. In the case of an adverse event involving a patient, the GP and specialist health provider to the patient will be notified if necessary.

70

Any adverse event will be reported to the Medical Ethics Committee (Commissie Medische Ethiek) of the VUB. If the adverse event is associated with the study, an internal discussion with the research team will be conducted alongside a consult with the ethics committee regarding the need to revise the study procedures, to prevent a recurrence of similar adverse events.

ETHICS AND DISSEMINATION

Confidentiality

All collection and processing of personal data will proceed in compliance with EU Regulation 2016/679, General Data Protection Regulation (GDPR) (*Europese Algemene Verordening omtrent Gegevensbescherming (AVG)*). Participants will be informed of their rights to confidentiality under this regulation according to a standardized text provided by the Medical Ethics Committee.

Questionnaires completed online will ask participants to enter their personal participation code in order to proceed. Questionnaires completed on paper will also use this personal participation code written in the header of the questionnaire form. Participants will not be asked to enter their names. Transcriptions of audio recordings will pseudonymize any names of persons. In no case will video recordings be made of participants.

Ancillary and post-trial care

In the case of an adverse event for a patient during the study, the GP and, if necessary, the specialist health provider to the patient will be notified to further refer the patient to existing medical care services. The researchers will also be available to refer patients and SDMs to appropriate supportive resources based on needs identified during the study.

Dissemination policy

At least four articles are planned based on the results of this study: 1. Baseline findings, 2. Patient and SDM outcomes, 3. GP outcomes, and 4. Qualitative and process evaluation outcomes. These articles will be written within the scope of a PhD dissertation. Furthermore, the study findings will be communicated through contributions to (inter)national conferences in the fields of advance care planning and end of life care. On a national level, we will collaborate with general practice organizations and disseminate the results of the study through professional journals of key stakeholders in Belgium. Once evaluated, the training component of the intervention can be incorporated into teaching activities for students, researchers, and healthcare professionals. The patient workbook can similarly be updated for uptake in GP and other health settings.

DISCUSSION

The aims of this project focus on facilitating ACP in general practice, where great improvements can be made towards timely and recurring communication about care preferences with patients with chronic, life-limiting illness.[8]

The ACP-GP intervention utilizes the unique position of GP's and their relationship with their patients. By providing GPs an opportunity to increase their ACP knowledge and communication skills through an interactive training, GPs may feel more prepared and confident to initiate these conversations.[35] For patients, a workbook that encourages reflection and discussion about questions essential to ACP can more adequately prepare them for ACP conversations with the GP. By tailoring ACP conversations to the patient's readiness, health behavior change is facilitated over the course of recurrent discussions. Therefore, changes in behavior change states, even in the absence of action outcomes such as AD documentation in the short term, can be indicative of an ACP process.[36,37]

This trial will be the first study in Belgium to conduct a large-scale evaluation of the impact of an ACP intervention in general practice on patients' level of engagement with ACP. The intervention has a strong theoretical basis, developed through literature research and stakeholder participation at every point in the process,[15,16] following the recommendations of the MRC framework. The addition of a process evaluation using the RE-AIM framework allows us to identify specific barriers and facilitators to the successful implementation of the intervention. By measuring at 3 and 6 months post-inclusion, we will also be able to show the sustainability of the intervention in the long term, which is important when including patients with chronic, life-limiting illness who are however not yet close to death.

Some challenges can be anticipated. First, the pilot study of this intervention showed that a perceived lack of time to undertake ACP discussions may prevent some GPs from participating.[33,38] ACP conversations intrinsically will require a certain time investment from GPs. Preparing patients for these conversations using the workbook and training GPs in ACP communication may allow for more efficient use of this time, and can save time when the patient is nearing the end of life and treatment decisions must be made. The researchers have also made efforts to limit the time investment, for example by supporting the GP during the identification of eligible patients. Second, asking GPs to designate patients for inclusion may introduce a selection bias towards patients with whom the GP feels comfortable discussing ACP. This decision was the result of extensive deliberation within the research team, which includes a GP. We consider it inappropriate to interfere in existing GP-patient relationships by imposing ACP conversations on patients who are not at all open to, or would be extremely distressed by, such conversations. Third, data collection at three time points using

questionnaires may burden patients and increase the risk of nonresponse. To address this, data collectors will be present during T0 and T1 data collection, and will conduct telephone follow-up for T2 questionnaires. Fourth, blinding of participants is not possible during the study period as GPs will receive additional training and patients will receive the workbook and additional consultations for ACP conversations. A lack of blinding may affect the answers of patients or GPs who are aware of their group assignment. This limitation frequently occurs in ACP intervention studies, where many past trials have also been unable to blind participants.[39,40] Finally, questionnaires administered to the control group may raise patient and SDM awareness of ACP, potentially increasing their engagement. However, ACP resources which are already generally available can be accessed by both groups and both groups will complete the ACP Engagement Survey. If the intervention is effective, we expect to find differences between the intervention and control group even when these assessment effects are taken into account.

CONCLUSION

General practitioners play a critical role in the timely initiation of ACP, but barriers remain and little evidence exists of how GPs and patients can effectively prepare for and engage in these conversations. The ACP-GP intervention study will provide valuable evidence for the implementation of ACP in general practice and for the effectiveness of tools developed to facilitate these conversations.

LIST OF ABBREVIATIONS

ACP: Advance Care Planning

ACP-GP: Advance Care Planning intervention for General Practice

ACP-SE: ACP Self-Efficacy Scale

AD: Advance Directive

GAD-7: Generalized Anxiety Disorder-7 Questionnaire

GEE: Generalizing Estimating Equations

GP: General Practitioner

ICC: Intra-Cluster Correlation Coefficient

MRC: Medical Research Council

PHQ-9: Patient Health Questionnaire-9

SDM: Surrogate Decision Maker

SF-12v2: Short Form Health Questionnaire-12 version 2

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

RCT: Randomized Controlled Trial

RE-AIM: Reach, Efficacy, Adoption, Implementation, Maintenance

DECLARATIONS

Ethics approval and consent to participate

The protocol was approved 18/03/2020 by the Medical Ethics Committee (O.G. 016) of the Vrije Universiteit Brussel/UZ Brussel, ref: 2020/068. Important protocol modifications will be communicated to investigators, participants, the Medical Ethics Committee, and the trial registry. Amendments will be submitted to the Medical Ethics Committee of the Vrije Universiteit Brussel/UZ Brussel and, upon approval, will be updated in the online trial registry at ISRCTN.com and as a revision to this protocol submission.

Data collectors will collect informed consent from GPs, patients, and SDMs willing to participate. All interested participants will be provided a full information form describing the aims and procedures of the study, potential benefits and risks of participating, and the measures taken to ensure anonymity of the data conform the General Data Protection Regulation (GDPR) (Europese Algemene Verordening omtrent Gegevensbescherming (AVG)). Participants will be given time to consider participation and have the opportunity to ask questions before they decide whether or not to provide consent to participate. All participants will be informed of their right to withdraw their consent at any time during the course of the study, without this negatively impacting their health care. Written consent will be obtained on paper from patients and SDMs. GPs will be able to provide their consent through an online form from which they are able to reference the original consent document as well as the study information sheet.

Consent for publication

Not applicable

Availability of data and materials

Not applicable

Competing interests

The authors declare that they have no competing interests.

Funding

This project has received funding from The Research Foundation - Flanders (Belgium) (Fonds Wetenschappelijk Onderzoek, FWO) in the form of a predoctoral aspirant fellowship in fundamental research with registration number 196250/11B6220N. The protocol has undergone review by the funding body via an expert panel. KP holds an FWO grant with registration number G061118N. The funder has no role in the conception of the study design;

in the collection, management, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the report for publication.

Authors' contributions

JS, ADV, PP, KP, and LD conceived of the study design. JS, ADV, PP, KE and KP will implement the study design. JS, ADV, KE, and KP will be involved in data acquisition. Analyses of data will be conducted by JS, ADV, and KP. JS drafted the manuscript. Critical revision to the manuscript was provided by ADV, KP, PP, KE and LD. All authors contributed to refinement of the study protocol and approval of the final manuscript.

Acknowledgements

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SUPPLEMENTARY FILES

Supplementary File 1. SPIRIT Checklist

STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page Number on which item is reported
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3
	2b	All items from the World Health Organization Trial Registration Data Set	N/A
Protocol version	3	Date and version identifier	N/A
Funding	4	Sources and types of financial, material, and other support	27
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	27-28
	5b	Name and contact information for the trial sponsor	N/A
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	27

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	N/A
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	N/A
Objectives	7	Specific objectives or hypotheses	5-6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	6
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-8
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	8-9
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	9
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	9-10

	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	10
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-11
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12-13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	13-14
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Implement-ation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	15

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	N/A
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15-16
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	N/A
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	17
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	17-20
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	N/A
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	17
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	20

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	20-21
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21-22
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	N/A
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	26
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	26
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	26-27
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	N/A
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	22
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	27
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	17, 27
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	22-23

Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	N/A
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	N/A
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	N/A
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	N/A

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Chapter 2

Advance care planning engagement in patients with chronic, life-limiting illness: baseline findings from a cluster-randomised controlled trial in primary care

ABSTRACT

Background: Advance care planning (ACP) has been characterised as a complex process of communication and decision making. For ACP behaviour change, underlying processes such as self-efficacy and readiness are needed. However, studies about which patient characteristics are associated with ACP have mainly focused on whether ACP actions are completed, leaving behaviour change processes unexplored.

Aim: To assess whether patients' characteristics and patient-perceived quality of GP ACP communication were associated with patients' ACP engagement.

Design and setting: Baseline data were used from the ACP-GP cluster-randomised controlled trial in patients with chronic, life-limiting illness ($n = 95$).

Method: Patients completed questionnaires detailing demographic and clinical characteristics, and their perception about their GPs' ACP information provision and listening. Engagement was measured using the 15-item ACP Engagement Survey, with self-efficacy and readiness subscales. Linear mixed models tested associations with engagement.

Results: Demographic and clinical characteristics were not associated with engagement; nor was how much ACP information patients received from their GP or the extent to which the GP listened to what was important for the patient to live well or important to the patient regarding future care. Higher overall ACP engagement ($P = 0.002$) and self-efficacy ($P<0.001$) were observed in patients who gave a high rating for the extent to which their GP listened to their worries regarding future health.

Conclusion: This study suggests that GPs providing information about ACP alone is not associated with a patient's ACP engagement; an important element is to listen to patients' worries regarding their future health.

INTRODUCTION

Patients with chronic, life-limiting illness often still receive medical care that does not align with their values and preferences.[1] Advance care planning (ACP) can reduce this discrepancy by promoting communication and understanding of patients' values and preferences for future (end-of-life) care before loss of decisional capacity.[2] ACP is a complex process of communication and decision making, which includes actions such as contemplating care wishes, having conversations about values and care preferences with family and health providers, completing advance directives for future care, and revisiting these actions over time.[3] Although studies show that adults in the community as well as patients think about and are open to ACP,[4,5] conversations and corresponding documentation remain infrequent.[6–9] This has also been found in Belgium, where the prevalence of advance directives to withhold or withdraw treatment is low for patients who are terminally ill.[10] For patients with cancer specifically, GPs in Belgium are aware of patient preferences for treatment at the end of life in approximately one-half of cases, and of patient preferences for a surrogate decision maker in less than one-third of cases.[11]

Evidence from the literature about which personal characteristics are associated with ACP engagement has mainly focused on whether ACP actions are performed. Increasing age has been found not only to be associated with increased likelihood of having ACP documentation,[12–15] but also with a decreased likelihood of discussing ACP with family and friends.[16] Female sex has been found to be associated with having discussions about end-of-life care wishes,[6,8,17] but findings regarding completion of ACP documents are mixed.[12,14] Examples of other factors that may correlate with ACP actions include religious beliefs and religiosity,[8,14,17–19] educational attainment,[8,13,14,17,20] marital status,[19,21] and physical functioning.[8,12,18,22]

In comparison, studies that examine ACP as a behaviour change process, instead of discrete actions as described above, are fewer. Behaviour change theory and social cognitive theory have been used to describe processes underlying ACP engagement, including self-efficacy (that is, how confident the patient feels to complete the behaviour) and readiness (that is, the patient's stage of behaviour change).[16,23] Based on these theoretical foundations, the ACP Engagement Survey has been developed to measure behaviour change processes (knowledge, contemplation, self-efficacy, and readiness) and actions (for example, whether discussions have occurred).[23] Using this survey it has been found that patients with depression or anxiety have higher engagement.[24] In a validation of the Dutch 34-item ACP Engagement Survey, patients aged ≥60 years and with chronic disease showed higher engagement;[22] however, this study did not compare engagement within the chronic illness category (cancer

and non-cancer diseases). To the authors' knowledge, no other studies have examined how other demographic and clinical characteristics relate to ACP as a process of behaviour change.

As ACP is a process of communication, factors pertaining to how GPs, who play a pivotal role in initiating ACP because of their accessibility and continuity of care,[5,25] communicate with the patient should also be considered. GPs' communication skills, including active listening and a positive attitude towards ACP, have been described as enablers of ACP uptake;[26,27] however, whether the patients' perceptions of GPs' communication relate to the patients' ACP engagement has not yet been explored.

Examining the impact of these factors on behaviour change processes for ACP can shed light on which determinants play a role in ACP behaviour change. This information can be taken into account when developing models of ACP for future interventions in the primary care setting. The purpose of this study was therefore to explore ACP engagement in a study population of patients with chronic, life-limiting illness, and to understand the association between patients' ACP engagement and their demographic and clinical characteristics, and their perceived extent of ACP-related communication with their GP.

METHOD

Setting

This survey study used the baseline data from a cluster-randomised controlled trial (RCT) aiming to evaluate an ACP intervention in general practice (ACP-GP).[28] As this intervention involves the training of GPs, patients were clustered by GP practice.

Participants

In total, 35 Dutch-speaking GPs working in Flanders or Brussels, Belgium, were recruited for the purpose of the RCT. Recruited GPs identified eligible patients. Inclusion criteria for patients were Dutch-speaking adults (aged >18 years) with a chronic, life-limiting illness (cancer, organ failure, and/or frailty) for whom the GP answered 'no' to the question: 'Would I be surprised if this patient were to die within the next 12 to 24 months?'

Patients with cognitive impairment; who were unable to provide consent or complete the questionnaires; for whom the GP would not be surprised if they were to die within the next 6 months; and who had participated in the pilot study of the intervention or were participating in similar studies were excluded.

Data collection procedures

Data collectors approached patients for written informed consent and questionnaire completion. When COVID-19 restrictions prohibited home visits, informed consent and questionnaires were collected via postal mail combined with telephone contact by the data collectors. Baseline data were collected from October to December 2020.

Measurements

Patients' demographic data included age, sex, marital status, education, religion, the person most involved in the patient's care, and whether this person lives with the patient. For clinical characteristics, the severity of anxiety symptoms were measured using the seven-item General Anxiety Disorder (GAD-7) scale[29] and the severity of depression symptoms with the nine-item Patient Health Questionnaire (PHQ-9).[30] Both scales are sums of Likert items, where higher scores indicate greater symptom severity. Health-related quality of life was measured with the Short-Form Health Survey (SF-12v2),[31] which yields summary measures for physical and mental health (mean 50, standard deviation [SD] 10). Scores range from 0 to 100, higher scores indicating better health.[31]

Diagnosis was not included in the patient questionnaire but was ascertained by the data collectors and checked with the GP if there was uncertainty.

For patients' perception of the quality of ACP communication with their GP, on a 10-point Likert scale patients indicated how much information they received from their GP about ACP; and to what extent their GP listened to what is important for them to live well, what is important to them regarding future care (for example, place of care), and their worries regarding future health (for example, pain and/or illness exacerbation).

ACP engagement was measured using the 15-item version of the ACP Engagement Survey, which has been validated with patients with chronic medical illness and can be used to detect differences in ACP behaviour processes.[23,32] The 15-item version was selected as it reduces response burden while retaining two crucial subscales for ACP engagement, that is, self-efficacy and readiness, across four ACP domains: surrogate decision makers, values and quality of life, flexibility in surrogate decision making, and asking doctors questions. Items are on a five-point Likert scale, with higher scores indicating higher engagement. The English version of the survey underwent forward–backward translation and cognitive testing with six patients, who met the same inclusion criteria as those described above.

Statistical Analyses

Descriptive statistics were used to describe patient characteristics and quality of patient-perceived ACP communication from their GP. As responses were not normally distributed for

patient-perceived ACP communication by the GP, in this study these scales were divided into categories: 'low rating' (points 1–5) and 'high rating' (points 6–10).

Scale scores (ACP Engagement Survey total and subscales, GAD-7, PHQ-9, and SF-12v2) were calculated for patients with <25% missing values on a given scale. When >25% of responses were missing for a given scale, the scale score was coded as missing. For the GAD-7 and PHQ-9 the sum was rescaled by dividing by the proportion of valid items. No item-level missingness was allowed for the SF-12v2, as the summary scores were computed through aggregating and weighting. When missingness was <25% for this scale, missing values were estimated using the expectation-maximalisation procedure,[33] with all valid items and the responder's age used for estimation.

The sample means for ACP engagement total score and the two subscales were calculated. To account for clustering within GPs, linear mixed models were used to analyse the associations between patient engagement and their characteristics, and quality of patient-rated GP ACP communication. All association analyses were adjusted for multiple testing using the Benjamini–Hochberg procedure, false discovery rate set to 5%. Analyses were performed in IBM SPSS Statistics (version 27). Crude *P*-values are reported and ones that remained significant after adjustment are highlighted.

RESULTS

The 35 recruited GPs identified 95 patients who gave informed consent and returned questionnaires.

About half of these 95 patients were aged ≥80 years (50.5%, *n* = 48), female (52.6%, *n* = 50), and married, in a civil union, or a domestic partnership (47.4%, *n* = 45) (Table 1). Most patients (65.3%, *n* = 62) had completed education up to secondary school.

For 37.2% (*n* = 35/94) of patients, their spouse or partner were most involved in their care; for 34.0% (*n* = 32/94) it was their child; and 37.6% (*n* = 35/93) of patients lived together with the person most involved in their care. Of the 60.0% (*n* = 57/95) who indicated being religious, all were Christian. One-third (33.7%, *n* = 32/95) had an active cancer diagnosis. The average physical health score was 37.25 (SD 11.02); the average mental health score was 48.84 (SD 12.49). The average symptom severity was minimal-to-mild for anxiety (mean 4.88, SD 4.49) and mild for depression (mean 5.32, SD 4.38).

Table 1. Participant demographic and clinical characteristics (n=95)

Patient demographics	
Characteristic	**n (%)[a]**
Age, years	
- **Younger than 80**	47 (49.5)
- **80 or older**	48 (50.5)
Sex, female	50 (52.6)
Marital status	
- **Married, civil union, or domestic partnership**	45 (47.4)
- **Widow(er)**	37 (38.9)
- **Divorced or single, never married**	13 (13.7)
Highest education attained	
- **Primary school**	18 (18.9)
- **Secondary school**	62 (65.3)
- **Post-secondary school**	13 (13.7)
- **None of the above**	2 (2.1)
Person most involved in care[b]	
- **Spouse or partner**	35 (37.2)
- **Child**	32 (34.0)
- **Other family member**	12 (12.8)
- **Other, not family member**	13 (13.8)
- **No person identified**	2 (2.1)
Living together with person most involved in care[c]	35 (37.6)
Religion	
- **Religious (Christianity)**	57 (60)
- **Not religious**	35 (36.8)
- **Prefer not to say**	3 (3.2)
Clinical characteristics	
Diagnosis	
- **Cancer**	32 (33.7)
- **Non-cancer**	63 (66.3)
Health-related quality of life (SF-12v2),[d] mean (SD)	
- **Physical health score**	37.25 (11.02)
- **Mental health score**	48.84 (12.49)
Anxiety symptom severity (GAD-7)[e], mean (SD)	4.88 (4.49)
Depressive symptom severity (PHQ-9)[f], mean (SD)	5.32 (4.38)

a. Unless otherwise stated

b. Missing, n=1

c. Missing, n=2

d. Norm-based (mean 50, SD 10) score based on 1998 General US population means and standard deviations, range 0-100 with higher scores indicating better health

e. Sum ranging from 0-21. Higher scores indicate greater anxiety symptom severity. 0-4: minimal symptoms. 5-9: mild symptoms. 10-14: moderate symptoms. 15-21: severe symptoms.

f. Sum ranging from 0-27. Higher scores indicate higher depressive symptom severity. 0-4: minimal symptoms. 5-9: mild symptoms. 10-14: moderate symptoms. 15-19: moderately severe symptoms. 20-27: severe symptoms

Abbreviations. SF-12v2: Short-Form Health Survey; GAD: General Anxiety Disorder Scale; PHQ: Patient Health Questionnaire; SD

Approximately one-third of patients gave a high rating to how much information they had received from the GP about ACP (36.4%, $n = 32/88$) (Table 2). More than three-fourths of patients rated the GP highly when they were asked to what extent their GP listened to what is important for them to live well (82.0%, $n = 73/89$), what is important for them regarding future care (78.2%, $n = 68/87$), and their worries for their future health (77.3%, $n = 68/88$).

Table 2. Patient-perceived quality of GP ACP communication ($N = 95$)

Questions[a]	'High rating' response to the question, n (%)
- **How much information have you received from your GP about ACP?[b]**	32 (36.4)
- **To what extent did your GP listen to what is important for you to live well?[c]**	73 (82.0)
- **To what extent did your GP listen to what is important to you regarding your future care?[d]**	68 (78.2)
- **To what extent did your GP listen to what your worries are regarding your future health?[e]**	68 (77.3)

a. Ratings based on a 10-point Likert scale ranging from "not at all" to "very much"; High rating: 6-10, Low rating: 1-5. Period: past 3 months. Two patients had not had a consultation with their GP in the last 3 months.

b. Missing, n=7

c. Missing, n=6

d. Missing, n=8

e. Missing, n=7

ACP: Advance care planning

The mean total ACP engagement score was 3.06 (SD 0.98) (Table 3); mean self-efficacy was 3.86 (SD 1.13), and mean readiness was 2.52 (SD 1.20).

Table 3. ACP Engagement across study sample[a]

	Mean (SD)
ACP ENGAGEMENT SURVEY TOTAL MEAN[b]	3.06 (0.98)
Self-efficacy subscale:	3.86 (1.13)
HOW CONFIDENT ARE YOU THAT TODAY, YOU COULD...	
Medical decision makers	
- **Ask someone to be your medical decision maker?**	4.08 (1.40)
What matters most in life	
- **Talk with your decision maker about the care you would want if you were very sick or near the end of life?**	3.85 (1.52)
- **Talk with your doctor about the care you would want if you were very sick or near the end of life?**	3.96 (1.41)
Flexibility	
- **Talk with your medical decision maker about how much flexibility you want to give your medical decision maker?**	3.55 (1.54)
- **Talk with your doctor about how much flexibility you want to give your medical decision maker?**	3.70 (1.40)
Asking your doctor questions	
- **Ask the right questions of your doctor to help make good medical decisions?**	4.02 (1.30)
Readiness subscale:	2.52 (1.20)
HOW READY ARE YOU TO...[c]	
Medical decision makers	
• **Formally ask someone to be your medical decision maker?**	2.65 (1.74)
• **Talk with your doctor about who you want your medical decision maker to be?**	2.57 (1.65)
• **Sign official papers naming a person or group of people to make medical decisions for you?**	2.54 (1.56)
What matters most in life	
• **Talk to your decision maker about the kind of medical care you would want if you were very sick or near the end of life?**	2.62 (1.58)
• **Talk to your doctor about the kind of medical care you would want if you were very sick or near the end of life?**	2.68 (1.42)
• **Sign official papers putting your wishes about the kind of medical care you would want if you were very sick or near the end of life?**	2.51 (1.49)
Flexibility	
• **Talk to your decision maker about how much flexibility you want to give them?**	2.18 (1.44)
• **Talk to your doctor about how much flexibility you want to give your decision maker?**	2.18 (1.28)

Asking your doctor questions

- **Ask your doctor questions to help you make a good medical decision?**   2.61 (1.53)

a. ACP self-efficacy range: 1 (not at all confident) to 5 (very confident). ACP readiness range: 1 (I have never thought about it) to 5 (I have already done it).

b. Missing, n=1

c. Missing, n=3

Patient demographic or clinical characteristics were not associated with ACP engagement (Supplementary Table 1). Higher total engagement was found for patients who gave a high rating to the extent to which their GP listened to their worries for future health (3.27 vs 2.48, p=.002), compared to patients who gave a low rating. The same pattern was observed for self-efficacy (4.10 vs 3.14, p<.001). The remaining items pertaining to GP communication were not significantly associated with engagement.

DISCUSSION

Summary

The aim in the current study was to explore whether patients' ACP engagement was associated with their demographic and clinical characteristics, and their perception of the quality of ACP communication with their GP. Most patients gave their GP a high rating for the extent to which they listened to what is important to the patient to live well and in regards to future care, and to patients' worries for their future health. Fewer patients rated highly the amount of information they received from their GP about ACP.

After correction for multiple comparisons, the study found that patients who gave a high rating for the extent to which the GP listened to their worries regarding their future health showed higher engagement overall as well as higher self-efficacy.

Strengths and limitations

To the authors' knowledge, this is the first study to examine ACP behaviour change processes using the ACP Engagement Survey in Belgium, as well as the first to examine its associations with GP communication. This validated instrument reflects behaviour change constructs for multiple components of ACP, which can provide insight beyond whether or not patients complete discrete actions. By exploring patient-related factors such as demographics and clinical characteristics, as well as patient perceptions of their GPs' listening and information provision, the current study has further disentangled which factors are important in ACP engagement.

Several limitations should be considered. This was a cross-sectional baseline assessment of a fairly limited sample of GPs and patients recruited in the context of an RCT in the Flanders

and Brussels regions in Belgium. The findings can therefore not be generalised to the population with chronic illness and may differ for adults who have not had personal experience with chronic, life-limiting illness. Nevertheless, the focus was to explore factors associated with ACP engagement in this sample with chronic, life-limiting illness, which was achieved. As a result of the cross-sectional design, causality cannot be inferred. It is possible that patients who are more confident also participate more actively in conversations, and thus perceive their GP as listening to their concerns. Additionally, an attempt was made to limit recall bias by restricting questions about GPs' information provision and listening to the 3 months before baseline assessment. Overall missingness for these items was limited, with no question missing >10%. Although data were collected about the patients' perceptions of the quality of their GPs' ACP communication, for the baseline assessment data were not collected about the timing, duration, and specific content of the pre-baseline consultation(s) during which these topics were discussed. As there is no single standardised process for ACP conversations in Belgium these conversations may vary from patient to patient. It may be useful for future research to also explore which aspects of the consultation(s) contribute to the patients' perceptions.

Comparison with existing literature

Contrary to the associations between sociodemographic and clinical characteristics and ACP actions observed in previous studies,[12–22] the current study showed no associations between patients' characteristics and their ACP engagement. This is potentially owing to the current sample being older and comprised of patients with chronic, life-limiting illness. As patients may find ACP increasingly relevant as they age or their health deteriorates,[34–38] this sample may already have experienced more triggers for ACP, such as diagnosis of a chronic condition. ACP engagement has also been found to be associated with anxiety and depression in patients,[24] but this was not found in the current study.

Further, no significant association was found with how much information patients felt they had received from their GP about ACP. Providing information can help to clarify and answer patients' questions,[39] but conversations should also leave space for patients to express their concerns.[40,41] In particular, significant associations were found for patients' ratings of the extent to which their GP listened to what their worries are regarding future health with overall engagement and self-efficacy. It is possible that engagement in ACP in patients with a chronic, life-limiting illness comes from worries about the impact of future health states, such as the burden their illness places on loved ones.[42–44] Discussing such worries during the consultation can provide the basis for discussions about ACP.[45]

In patients with cancer, although an attentive, empathic communication style has been shown to be associated with their self-efficacy to cope with disease and treatment,[46] this study shows that communication is also associated with self-efficacy for ACP. Improving readiness, on the other hand, may require an approach tailored to the patient's current stage of behaviour change; literature on stage-matching interventions exists,[47,48] but is still limited.

Implications for research and practice

The current findings regarding the lack of associations between patients' demographic or clinical characteristics and their ACP engagement support proactively offering ACP as standard to all patients with chronic, life-limiting illness, regardless of their sociodemographics, diagnosis, or functional status.[44,49] This study also highlights that GPs providing information alone seems insufficient, and this should thus be combined with active listening to patients' worries regarding their health.

Investigating the underlying behaviour change processes of self-efficacy and readiness yields important insights into which factors should be accounted for when creating models of ACP behaviour change processes. Considering the need to facilitate ACP in patients with chronic, life-limiting illness,[49] this study emphasises the importance of active listening as a springboard in the ACP process. Formalising conversations from talking about worries about future health into actions such as discussing care at the end of life, talking to and appointing a surrogate decision maker, and documenting care wishes may be the next step in high-quality ACP in the general practice setting.[39] Communication techniques such as these are already recommended as part of best-practice guidelines.[44,50,51] The communication factor identified in this study can be attended to by GPs during conversations with their patients and may be amenable to change as investing in training can help practitioners further develop these skills.[45,52,53] Importantly, these skills are also targeted in the ACP training intervention being delivered to GPs during the RCT, for which these baseline data were gathered.[28]

ADDITIONAL INFORMATION

Funding

Ethical approval

Data availability

Data are available upon reasonable request.

Competing interests

The authors declare no competing interests.

Acknowledgements

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SUPPLEMENTARY FILES

Supplementary Table 1. Associations of patient factors with ACP Engagement Survey scores[a]

	ACP ENGAGEMENT TOTAL SCORE mean (SD)	*p*-value[b]	Self-efficacy mean (SD)	*p*-value[b]	Readiness mean (SD)	*p*-value[b]
Patient demographics						
Age		.37		.62		.32
- **Below 80**	2.97 (0.95)		3.81 (1.24)		2.39 (1.05)	
- **80 or above**	3.14 (1.01)		3.91 (1.01)		2.64 (1.34)	
Gender		.84		.39		.44
- **Male**	3.04 (0.97)		3.97 (1.11)		2.43 (1.16)	
- **Female**	3.07 (0.99)		3.77 (1.15)		2.60 (1.24)	
Marital status		.22		.82		.12
- **Married, civil union, or domestic partnership**	2.88 (0.98)		3.81 (1.34)		2.26 (1.17)	
- **Widow(er)**	3.24 (1.00)		3.88 (0.93)		2.81 (1.25)	
- **Divorced or single, never married**	3.16 (0.83)		3.98 (0.88)		2.61 (1.02)	
Highest education attained		.56		.43		.74
- **Primary school**	2.84 (1.11)		3.48 (1.49)		2.41 (1.22)	
- **Secondary school**	3.05 (0.95)		3.92 (1.05)		2.47 (1.16)	
- **Post-secondary school**	3.34 (0.92)		4.09 (0.95)		2.83 (1.26)	
- **None of the above**	3.33 (1.41)		3.92 (0.35)		2.94 (2.59)	
Person most involved in care		.68		.51		.52
- **Spouse or partner**	3.00 (1.01)		4.04 (1.28)		2.31 (1.19)	
- **Child**	3.19 (0.94)		3.93 (0.97)		2.72 (1.19)	
- **Other family member**	3.16 (1.07)		3.71 (1.11)		2.78 (1.41)	
- **Other, not family member**	2.93 (1.00)		3.52 (1.18)		2.53 (1.17)	
- **No person identified**	2.49 (0.12)		3.17 (0.00)		2.01 (0.17)	
Living together with person most involved in care		.60		.094		.085
- **Yes**	3.01 (0.99)		4.13 (1.14)		2.26 (1.21)	
- **No**	3.11 (0.98)		3.72 (1.11)		2.70 (1.18)	

Religion	.37	.75	.23
- **Religious**	2.95 (1.01)	3.80 (1.18)	2.39 (1.23)
- **Not religious**	3.18 (0.94)	3.94 (1.08)	2.66 (1.12)
- **Prefer not to say**	3.55 (0.68)	4.17 (0.76)	3.67 (1.26)
Clinical characteristics			
Diagnosis	.22	.23	.42
- **Cancer**	3.22 (0.89)	4.06 (1.05)	2.66 (1.25)
- **Non-cancer**	2.97 (1.02)	3.77 (1.16)	2.45 (1.18)
Health-related quality of life (SF-12v2)			
- **Physical health score**	.13	.95	.048
- **Mental health score**	.48	.45	.13
Anxiety symptom severity (GAD-7)	.43	.86	.28
Depressive symptom severity (PHQ-9)	.066	.66	.034
Patient-perceived extent of ACP communication by the GP			
Patient-perceived extent of ACP communication In the last 3 months…			
How much information have you received from your GP about ACP?	.044	.005	.33
- **High rating (6-10)**	3.33 (0.84)	4.28 (0.73)	2.70 (1.17)
- **Low rating (1-5)**	2.89 (1.03)	3.58 (1.24)	2.43 (1.22)
To what extent did your GP listen to what is important for you to live well?	.11	.025	.47
- **High rating (6-10)**	3.17 (0.96)	3.98 (1.10)	2.63 (1.18)
- **Low rating (1-5)**	2.70 (1.04)	3.28 (1.13)	2.36 (1.29)
To what extent did your GP listen to what is important to you regarding your future care?	.004	.006	.024
- **High rating (6-10)**	3.26 (0.95)	4.04 (1.04)	2.75 (1.22)
- **Low rating (1-5)**	2.52 (0.91)	3.25 (1.23)	2.04 (1.01)

To what extent did your GP listen to what your worries are regarding your future health?	.002	<.001	.047
- **High rating (6-10)**	**3.27 (0.93)**	**4.10 (0.97)**	2.72 (1.18)
- **Low rating (1-5)**	**2.48 (0.95)**	**3.14 (1.31)**	2.09 (1.25)

a. Values reported are observed means and standard deviations

b. Crude p-values are reported. P-values which remained significant after Benjamini-Hochberg correction with a false discovery rate (FDR) of 5% are bolded.

Chapter 3

Complex advance care planning intervention in general practice (ACP-GP): cluster-randomised controlled trial

This chapter is based on the following publication:

*shared last author

ABSTRACT

Background: Advance care planning (ACP) is an iterative communication process about patients' preferences for future care. In general practice, there are barriers to ACP at patient, GP, and healthcare- system levels. A complex intervention may be necessary to reduce barriers.

Aim: To evaluate the effects of a complex ACP intervention for patients with chronic, life-limiting illness in general practice (ACP-GP).

Design and Setting: A cluster-randomised controlled trial was undertaken in Belgian general practice.

Method: ACP-GP included a patient workbook, GP training, ACP conversations, and a documentation template. The control group received usual care. Outcomes were the 15-item ACP Engagement Survey for patients and the ACP Self-Efficacy scale for GPs. Linear mixed models evaluated differences at 3 months (T1, effectiveness evaluation) and 6 months (T2) post-baseline. Analysis was intention-to-treat.

Results: In total, 35 GPs and 95 patients were randomised. Patient ACP engagement did not differ between the intervention and control group at T1 (baseline- adjusted mean difference = 0.34; 95% confidence interval [CI] = –0.02 to 0.69; $P = 0.062$) or T2 (baseline-adjusted mean difference = 0.20; 95% CI = –0.17 to 0.57; $P = 0.28$). For GP ACP self-efficacy, there were no significant differences between groups at T1 (baseline-adjusted mean difference = 0.16; 95% CI = –0.04 to 0.35; $P = 0.11$) or at T2 (baseline-adjusted mean difference = 0.11; 95% CI = –0.09 to 0.31; $P = 0.27$).

Conclusion: ACP-GP did not improve patient engagement and GP self-efficacy more than usual care. Both groups showed patterns of increase from baseline. Trial procedures and the COVID-19 pandemic may have increased awareness about ACP.

Keywords: advance care planning, chronic disease, general practice, randomised controlled trial

How this fits in: A complex intervention may be necessary to address barriers to advance care planning (ACP) within general practice. This study aimed to evaluate the effects of a complex ACP intervention for patients with chronic, life-limiting illnesses in general practice, on patient ACP engagement, and GP ACP self-efficacy. This study found no differences in outcome increases between the group receiving the ACP- GP intervention and the usual care control. GPs may feel confident in their skills to conduct ACP, and awareness of ACP and its

relevance may already have an impact on patients thinking about, planning, and conducting ACP conversations.

INTRODUCTION

In an ageing population, chronic life-limiting illnesses, such as cancer and cardiovascular disease, are prevalent causes of death.[1] During exacerbations of these conditions, patients may face complex care choices or be unable to participate in medical decisions. Communicating preferences for care before exacerbation of the illness may ease decisional conflict for the patient and give patients a sense of control and peace of mind.[2,3] For their family, it may reduce psychological distress and complicated grief.[4]

Advance care planning (ACP) is a process to facilitate communication about patient values, goals, and care preferences with health providers and loved ones.[5] Recent conceptualisations of ACP emphasise the importance of an ongoing and iterative process that prepares patients and their surrogate decision makers to make better in- the- moment decisions about care.[6] A longitudinal care setting with a trusting relationship, such as general practice, provides an environment for proactively encouraging patients to communicate, reflect on, and clarify their values over time.[7,8]

Research has shown that patients are willing to talk about ACP,[9] but deficits have been found in its initiation.[10] Barriers to ACP occur at different levels. For instance, patients may find ACP topics too emotional, uncomfortable, or not relevant. They might also lack knowledge about ACP, worry about the impact of ACP on relationships, or feel that the GP should initiate conversations.[9,11–14] GPs may lack skills or confidence to discuss ACP, fear that ACP will deprive patients of hope, feel that patients should initiate conversations, or feel uncertain about timing.[15–17] At the healthcare-system level, barriers include limited time and resources,[16] and a lack of standard templates and mechanisms for sharing ACP.[17]

ACP intervention studies in general practice that target barriers at multiple levels remain scarce and disparate.[17] Previous studies have recommended that communication training for GPs may address barriers related to perceived lack of skill or confidence.[18–20] For patients, models based on behaviour change and social cognitive theories posit that processes, such as self-efficacy and readiness, underlie engagement in ACP. In these models, readiness to engage in ACP is an important precursor to patients taking action, such as by discussing care preferences.[21,22] Educating patients about ACP and encouraging them to reflect on values and care wishes may promote engagement, helping them prepare for ACP discussions.[23] The authors of the present study have previously also found that patients have greater ACP engagement overall, and greater ACP self-efficacy, when they rate highly the extent to which their GP listens to their worries about future health, emphasising the importance of communication.[24] To address identified barriers and facilitate the initiation of ACP, a complex intervention for general practice (ACP- GP intervention) was developed and pilot- tested

following the Medical Research Council framework.[23,25,26] The present study aimed to evaluate the effects of the ACP-GP intervention on ACP engagement of patients with chronic, life-limiting illnesses and on GPs' ACP self-efficacy.

METHODS

Design

A cluster-randomised controlled trial (RCT) was performed, with randomisation at the GP level to avoid contamination.[27] Baseline data from this study have been analysed.[24] This study is registered: ISRCTN12995230. To report this cluster-RCT, the Consolidated Standards of Reporting Trials (CONSORT) statement extension for cluster-randomised trials was used.[28]

Setting and participants

Dutch-speaking GPs working in Flanders and Brussels, Belgium, were eligible for participation. In group settings, one GP per practice could participate. GPs identified patients for inclusion using an information card which specified inclusion and exclusion criteria, here shown in Box 1. We deviated from our protocol to increase recruitment, by allowing GPs to participate if they could include at least one patient in the study, instead of three.

Box 1. Patient inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Adults (>18 years old)	Unable to speak or understand Dutch
Mentally competent as measured by judgment of the GP OR if Mini-Mental State Examination has been conducted, score is >24	Unable to provide consent or complete the questionnaires due to cognitive impairment (as judged by the GP)
GP answers "no" to surprise question: "Would I be surprised if this patient were to die within the next 12 to 24 months?"	GP answers "no" to surprise question: "Would I be surprised if this patient were to die within the next 6 months?"

Diagnosis of a life-limiting illness:
 	
1. Locally-advanced unresectable, or metastasized cancer OR
 	
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
 	
3. Geriatric frailty (Clinical Frailty Scale score 5-7, mildly to severely frail)
	Participated in the pilot study of this intervention or in the cognitive testing of the adjusted intervention materials

	Participating in other studies evaluating advance care planning, palliative care services or communication strategies

Intervention

Development of the intervention is reported elsewhere.[23,25] Patients received the ACP-GP intervention for 6 months. Box 2 contains an overview of the intervention.

The control group received care as usual. GPs were not instructed to plan additional ACP conversations, but ACP could be spontaneously addressed during consultations.

Box 2. ACP-GP intervention components

Component	Description
1. GP training	The ACP-GP training was initially developed as a face-to-face training. It was adapted to an online format to accommodate COVID-19 pandemic restrictions in Belgium. Two interactive, small-group web sessions were provided by two trainers experienced in primary care and communication. Each session lasted approximately 2 hours. GPs received preparatory materials and background information through an e-learning module, which remained available throughout the course of the study. Intervention materials, such as the conversation guide and an example of the patient workbook, were made available in PDF format. In session 1, GPs discussed their experiences with ACP, fictional case examples and reflection questions, barriers and facilitators to ACP, and video examples. In session 2, GPs practiced intervention-specific ACP conversations with model patients, based on the patient workbook, followed by interactive feedback and discussion.
2. ACP workbook for patients	Patients received an ACP workbook (titled "My Wishes for Future Care") which highlights the importance of ACP at different stages of health. Patients could use the workbook to reflect on topics such as quality of life, worries about future health or care, preferences for decision-making, and whom they can ask to act as a SDM.
3. Patient-centered ACP discussion with conversation guide.	After the training, GPs were asked to conduct a minimum of 2 ACP conversations with each patient: conversation 1 within two weeks after the training, and conversation 2 within one month after the first conversation. The workbook for patients, and the ACP conversation guide for GPs, structured the conversation. GPs were reimbursed by the research team for the consultations.
4. Documentation of the ACP discussion	GPs received a documentation template, based on the conversation guide, which they can fill in to make note of the outcomes of the ACP discussion.

Data collection

Patients completed questionnaires on paper, with in-person or telephone assistance from independent data collectors if needed. GPs completed questionnaires via Qualtrics software or on paper. Patient and GP data were collected at baseline (month 0) and post- intervention measurements at 3 months and 6 months.

Measures

Demographic information was self- reported via a questionnaire at baseline.

This paper reports the two separate primary outcomes of the trial, evaluated for effectiveness at 3-months' follow up (T1) with exploratory comparison at T2.

The primary patient outcome was ACP engagement, measured using the ACP Engagement Survey 15-item version.[29] Questions are on a 5-point Likert scale. The scale consists of the following two subscales: ACP self-efficacy (6 items) and ACP readiness (9 items). Overall engagement is the mean of all 15 items, where a higher score indicates greater engagement.

The primary GP outcome was self- efficacy, measured using the ACP Self-Efficacy (ACP-SE) scale, comprising 17 items plus one reference item on a 5-point Likert scale. The scale score is calculated as the average of the first 17 items; higher scores indicate greater self-efficacy. The reference item is a global single- item measure of self- efficacy, used for comparison with the scale.[30]

Randomisation

GPs and their patients were allocated to intervention or control using a 1:1 ratio from a computer-generated list, with permuted block randomisation of varying block sizes. An independent statistician generated the list. GPs who gave informed consent, identified patients, and completed baseline assessments were allocated by an independent researcher to control or intervention.

Informed consent was sought from all participants. In contrast with the protocol, randomisation took place after GP consent, baseline, and identification of patients who could participate (before patient-informed consent and baseline assessment as originally planned), owing to timing constraints.

Statistical methods

Sample-size estimates were conducted for outcomes at T1 at both patient and GP level, assuming equal cluster sizes of two patients and an intracluster correlation coefficient of 0.04.[31] To achieve >90% power to detect mean differences of 1 at an alpha of 2.5%

116

(Bonferroni correction), the study aimed to recruit 18 GPs per group, each with three patients (108 patients total), after accounting for dropout.

As distributions of patient age, GP age, and GP years of practice were skewed, sample median values and range were used to report these variables. Patient and GP outcomes were calculated as mean scale or subscale scores.

Linear mixed-model analyses were conducted with fixed effects of group, time, and group*time. Random intercepts in the models accounted for the clustered design (patients clustered within GPs, and measurements clustered within GPs and patients).

Estimated marginal means, baseline- adjusted mean differences, and their 95% confidence intervals (CIs) are reported. A *P*-value of 0.025 is used for scale scores at T1. Subscale scores and scores at T2 are interpreted at $P = 0.05$. Analysis was by intention-to-treat. All patients and GPs were included in the analysis in IBM SPSS Statistics (version 27).

RESULTS

Recruitment and study flow

Figure 1 shows recruitment, randomisation, and follow up. Owing to COVID-19 pandemic restrictions, the start of recruitment was postponed to June 2020. Inclusion of patients ended in December 2020.

Figure 1. CONSORT flow diagram
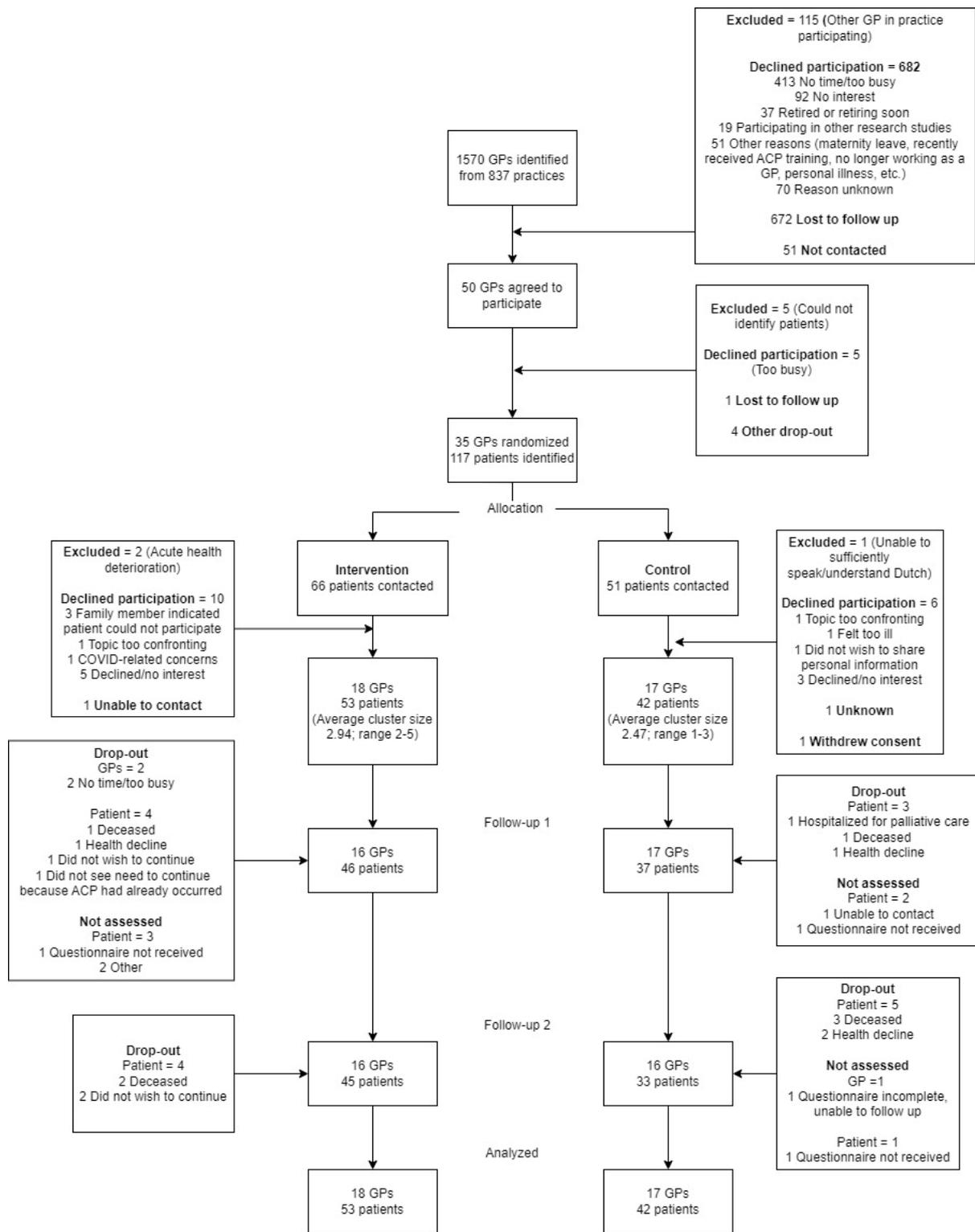
Patients described as "not assessed" at T1 were retained and approached again at T2, and were not considered drop-out.

Of 1570 GPs identified, 35 were randomised; 95 patients consented to participate. The final T2 questionnaires were returned in July 2021. The characteristics of patients and GPs are presented in Table 1.

The GP training, documentation template, and patient workbook were provided to the intervention group by the research team. At their respective T1 assessment, 13/16 GPs (81.25%) in the intervention group and 5/17 GPs (29.41%) in the control group reported having had ACP conversations with patients included in the study. In the intervention group, 33/46 patients (71.74%) reported at least one ACP conversation with their GP at T1; 14 (30.43%) reported ≥2 conversations. In the control group, 12/37 patients (32.43%) reported having at least one ACP conversation, with six (16.22%) reporting ≥2 (data not shown).

Table 1. Participant characteristics by study arm

	Control N(%)	Intervention N(%)
Patients (N)	42 [a]	53
Age≥80 (sample median; sample range 42-95)	23 (54.8)	25 (47.2)
Female	25 (59.5)	25 (47.2)
Marital status		
Married, civil union, domestic partnership	17 (40.5)	28 (52.8)
Widow(er)	17 (40.5)	20 (37.7)
Divorced, or single never married	8 (19)	5 (9.4)
Highest educational attainment		
Primary school	5 (11.9)	13 (24.5)
Secondary school	29 (69)	33 (62.3)
Post-secondary school	6 (14.3)	7 (13.2)
None of the above	2 (4.8)	0 (0.0)
Person most involved in care		
Spouse or partner	11 (26.8)	24 (45.3)
Child	17 (41.5)	15 (28.3)
Other family member	5 (12.2)	7 (13.2)
Other, not a family member	7 (17.1)	6 (11.3)
No person identified	1 (2.4)	1 (1.9)
Living together with person most involved in care	11 (27.5)	24 (45.3)
Religion		
Religious (Christianity)	26 (61.9)	31 (58.5)
Not religious	15 (35.7)	20 (37.7)
Prefer not to say	1 (2.4)	2 (3.8)

	Control N(%)	Intervention N(%)
Patients (N)	42 [a]	53
Advance directives (AD) completed[b]		
AD to refuse medical interventions	7 (16.7)	8 (15.1)
AD for euthanasia[c]	9 (21.4)	9 (17.0)
AD for funerary arrangements	5 (11.9)	4 (7.5)
AD for organ donation	1 (2.4)	3 (5.7)
Testament for donating the body to medical science after death	1 (2.4)	1 (1.9)
Other directive(s)	0 (0.0)	4 (7.5)
None	31 (73.8)	39 (73.6)
Oncological diagnosis	15 (35.7)	17 (32.1)
GPs (N)	17	18
Age ≥37 (sample median; sample range 26-64)	6 (35.3)	12 (66.7)
Female	11 (64.7)	9 (50)
Years of practice experience ≥9 (sample median; sample range 1-39)	7 (41.2)	12 (66.7)
Practice type[d]		
Solo	4 (23.5)	4 (22.2)
Group	9 (52.9)	12 (66.7)
Primary care center[e]	3 (17.6)	1 (5.6)
Hospital	0 (0.00)	0 (0.00)
Multiple	1 (5.9)	1 (5.6)
Coordinating and advisory physician[f]	3 (17.6)	1 (5.6)
Palliative home care team member	1 (5.9)	0 (0.00)
Prior training in ACP		
None	14 (82.4)	13 (72.2)
Introductory	2 (11.8)	5 (27.8)
Intensive	1 (5.9)	0 (0.00)
Prior training in palliative care		
None	11 (64.7)	11 (61.1)
Introductory	5 (29.4)	6 (33.3)
Intensive	1 (5.9)	1 (5.6)

[a] Missing values: person most involved in care n = 1 and living together with person most involved in care n = 2.

[b] Multiple responses possible.

[c] AD for euthanasia in the case of irreversible coma.

[d] Belgian GPs are providers of primary care; GPs may work in single-physician (solo) practices, in (sometimes multidisciplinary) group practices with multiple GPs, and in multidisciplinary primary care centers.

[e] Primary care setting with a multidisciplinary collaboration, including ≥1 GPs, which is highly accessible and has a low financial threshold.

[f] GP, preferably trained in gerontology, who is responsible for the coordination, organisation, and continuity of medical care within a nursing home. A coordinating and advisory physician also manages the training of nursing home staff, including in the field of palliative care..

Table 2. Patient outcome: Cluster-adjusted mean scores and differences for ACP Engagement

	Baseline (T0)		T1 (3 months)					T2 (6 months)					Intra-class correlation coefficient
	EMM [95% CI]		EMM [95% CI]		Baseline-adjusted mean difference (95% CI)	*P*-value	Effect size (standardised)	EMM [95% CI]		Baseline-adjusted mean difference (95% CI)	*P*-value	Effect size (standard-ised)	
	Control	Intervention	Control	Intervention				Control	Intervention				
ACP Engagement overall	**3.02 (2.72 to 3.33)**	**3.06 (2.79 to 3.33)**	**3.40 (3.09 to 3.71)**	**3.77 (3.49 to 4.06)**	**0.34 [-0.02 to 0.69]**	**0.062**	**0.34**	**3.69 (3.37 to 4.01)**	**3.93 (3.64 to 4.22)**	**0.20 (-0.17 to 0.57)**	**0.28**	0.20	0.043
ACP self-efficacy	3.81 (3.50 to 4.11)	3.91 (3.64 to 4.18)	3.88 (3.56 to 4.20)	4.25 (3.95 to 4.55)	0.26 (-0.15 to 0.68)	0.22	0.27	4.06 (3.73 to 4.39)	4.25 (3.96 to 4.55)	0.09 (-0.33 to 0.51)	0.67	0.09	0.01
ACP readiness	2.52 (2.16 to 2.90)	2.48 (2.14 to 2.82)	3.07 (2.68 to 3.46)	3.43 (3.07 to 3.78)	0.40 (-0.06 to 0.86)	0.088	0.32	3.45 (3.05 to 3.85)	3.69 (3.33 to 4.06)	0.29 (-0.18 to 0.76)	0.23	0.23	0.001

ACP Engagement Survey 15-item version consists of 15 items on a 5-point (1–5) Likert scale. Self-efficacy subscale = 6 items; readiness subscale = 9 items.

Overall ACP engagement is the mean of all items. Self-efficacy and readiness subscale scores are the mean of all items within the subscale. If <25% of data were missing for a respective scale or subscale, the mean was computed of the answered

items. If >25% of data were missing, the mean was coded as missing. Higher scores indicate greater overall engagement, self-efficacy, or readiness.

ACP self-efficacy range: 1 (Not at all confident) to 5 (Very confident).

ACP readiness range: 1 (I have never thought about it) to 5 (I have already done it).

Intra-class correlation coefficient for patients was calculated by applying a null model, with clustering within GPs, to baseline data.

Standardized effect sizes were calculated by dividing the group*time coefficient by the standard deviation (square root of the summed linear mixed model variance components).

ACP = advance care planning. EMM = estimated marginal means.

Table 3. GP outcome: Cluster-adjusted mean scores and differences for ACP Self-Efficacy

	Baseline		T1 (3 months)					T2 (6 months)				
	EMM [95% CI]		EMM [95% CI]		Baseline-adjusted mean difference (95% CI)	*P*-value	Effect size (standard-ised)	EMM [95% CI]		Baseline-adjusted mean difference (95% CI)	*P*-value	Effect size (standardised)
	Control	Intervention	Control	Intervention				Control	Intervention			
ACP Self-efficacy (ACP-SE)	3.81 (3.64 to 3.98)	3.83 (3.66 to 3.99)	3.95 (3.78 to 4.12)	4.12 (3.95, 4.29)	0.16 (-0.04 to 0.35)	0.11	0.44	3.99 (3.82 to 4.16)	4.11 (3.94 to 4.28)	0.11 (-0.09 to 0.31)	0.27	0.31
Reference item ACP-SE 18 (How confident are you that you can engage patients in ACP conversations?)	3.82 (3.57 to 4.08)	3.83 (3.59 to 4.08)	4.00 (3.75 to 4.26)	3.88 (3.62 to 4.14)	-0.13 (-0.52 to 0.26)	0.52	-0.24	3.86 (3.60 to 4.12)	4.01 (3.75 to 4.27)	0.14 (-0.25, .53)	0.48	0.26

The ACP Self-Efficacy (ACP-SE) scale consists of 18 items on a 5-point Likert scale. ACP-SE scale score is the mean of the first 17 items. Item 18 is a reference item for comparison. A higher score indicates higher self- efficacy.

ACP Self-Efficacy range: 1 (I know with certainty that I CANNOT do it) to 5 (I know with certainty that I CAN do it).

Standardized effect sizes were calculated by dividing the group*time coefficient by the standard deviation (square root of the summed linear mixed model variance components).

ACP = advance care planning. EMM = estimated marginal means.

Patient outcomes

There was no significant difference in patient ACP engagement between intervention and control groups at 3 months post- baseline (baseline- adjusted mean difference = 0.34; 95% CI = –0.02 to 0.69; P = 0.062; standardised effect size = 0.34) nor at 6 months post- baseline (baseline-adjusted mean difference = 0.20; 95% CI = –0.17 to 0.57; P = 0.28; standardised effect size = 0.20; Table 2). Strikingly, patterns of increasing ACP engagement in both groups were found from baseline to month 3, and baseline to month 6. Similar increasing patterns from baseline versus month 3 and 6 were observed in the subscales for ACP self-efficacy and ACP readiness for patients in both groups..

GP outcomes

GP ACP self-efficacy did not differ significantly between intervention and control groups at 3 months post-baseline (baseline-adjusted mean difference, 0.16; 95% CI, -0.04 to 0.35; p = 0.11; standardized effect size = 0.44), nor at 6 months post-baseline (baseline-adjusted mean difference, 0.11; 95% CI, -0.09 to 0.31; p = 0.27; standardized effect size = 0.31)(Table 5). ACP self-efficacy was higher at month 3 and month 6 vs. baseline, in both groups.

DISCUSSION

Summary

A cluster-RCT was conducted of a complex ACP intervention for patients with chronic, life-limiting illnesses in general practice. No differences were found in the improvement of patient ACP engagement or GP ACP self-efficacy between the group assigned to the ACP- GP intervention, and the group assigned to usual care. However, the study found increases in the overall patients' ACP engagement, including the subscales ACP self-efficacy and readiness, and the GPs' self-efficacy during the 6 months of observation in both the intervention and control groups.

Strengths and limitations

This study has several strengths. The ACP-GP intervention was robustly developed and pilot-tested,[23,25] according to the widely accepted Medical Research Council framework,[26,32] which combines structured and iterative steps to evaluate complex interventions while reflecting on intervention context and theory. Additionally, validated instruments were used, which aimed to investigate behaviour-change processes underlying ACP actions.[22]

This study also had limitations. As the trial occurred during the COVID-19 pandemic, GPs reported extraordinary time and workload pressures, and difficulty identifying eligible patients. Additionally, allowing GPs to identify patients for inclusion may have introduced selection bias towards patients the GP judged to be more amenable to ACP, or with whom the GP felt were

more comfortable discussing ACP. This choice of recruitment design was made to minimise risks of interfering with the existing GP–patient relationship.

Comparison with existing literature

Several reasons can explain why this intervention did not reach its intended outcomes. First, patient ACP engagement and GP self-efficacy showed increases from baseline to 3 months and 6 months in both the intervention and control groups. Although ACP conversations were possible as part of usual care, the authors expected few to take place. However, GPs in both groups reported ACP conversations, as did 12 patients in the control group. Hearing about ACP through the informed consent procedures, and answering the questionnaire, may have made patients and GPs, including those in the control group, aware of ACP. This may have activated both patients and GPs in the control group to prepare for or conduct ACP discussions more than expected. A 2016 cluster-RCT has similarly suggested that an intervention creating awareness of optimal symptom relief in dementia may be more effective than a physician practice guideline.[33] More recently, a cluster-RCT of a complex ACP intervention has proposed similar awareness-raising across groups as a result of study procedures, or a Hawthorne effect.[34]

Second, emergent literature on the impact of the COVID-19 pandemic on ACP[35] may frame this finding, as the study period overlapped with the first, second, and third waves of the pandemic in Belgium.[36-38] A Belgian survey found worries among the general population about their current health state and their access to health care during the first 8 weeks of lockdown, including in the highest age bracket (≥66 years).[39] It is possible that these concerns persisted during subsequent waves and periods of lockdown. Concerns about COVID-19 in patients with vulnerable health may have encouraged patients to think about and/ or discuss end-of-life issues and ACP, regardless of group.

Owing to COVID-19, the implementation of the intervention may also not have been optimal. In Belgium, triage-and-testing centres were established to reduce the risk of spreading COVID-19 and to screen (a) symptomatic individuals. Coordination of these centres was entrusted to regional GP groups.[40] GPs were advised to give priority to patients showing symptoms of COVID-19, and to maintain the continuity of non-COVID-19-related care. GP practices were permitted to adopt means including systems of (telephone) triage, reserved time slots for priority and non-priority groups, and appointment systems. Nevertheless, GPs expressed that, during the first wave of COVID-19 in Belgium, chronic care activities often lessened.[41] Even before the pandemic, difficulties for GPs to fully engage in studies in palliative care have been documented.[42] Owing to COVID-19 restrictions, rather than in-person training, the GP training was delivered online. Evidence has suggested that online

training can be as effective as in-person,[43,44] and online training in serious illness communication for intensive care unit (ICU) nurses was effective and acceptable.[45] Nevertheless, more research may be needed to assess its implementation in continuing medical education for GPs specifically. Moreover, GPs may need more time to consolidate and practise what they have learnt, as has been suggested for care staff in a complex ACP intervention in nursing homes.[46]

Third, recent research has increasingly highlighted the importance of ACP processes such as readiness. It is possible that, while patients feel relatively confident that they can discuss ACP, readiness remains variable.[47,48] A scoping review found significant effects in three studies in primary care clinics that measured the ACP Engagement Survey in the US.[4] The studies used the PREPARE For Your Care programme, which includes a website to motivate and prepare patients for ACP conversations, as well as an easy-to-read advance directive provided to both study arms.[49] Compared with a 2022 study of a web-based ACP programme in the Netherlands, using the 34-item Dutch ACP Engagement Survey, the authors of the present study found that readiness for ACP especially appeared to increase more in both ACP-GP study groups.[50] A trial of an interactive ACP guide, *Plan Well Guide*, for patients at high risk of health decline showed an increase in both groups, and potentially larger increases in readiness than self-efficacy,[51] similar to findings in the current trial.

Finally, ACP self-efficacy in GPs merits reflection. In the present study, self- efficacy was relatively high at baseline, which may impose ceiling effects on the outcome at follow up. Primary care professionals may have more self-efficacy if they feel sufficiently trained.[52] However, in a review of end- of- life communication interventions, training for health providers showed mixed effects on confidence.[53] Despite literature suggesting a lack of self- efficacy or confidence may be a GP-level barrier, recent studies have found high willingness and confidence for ACP in Canadian primary care providers. However, engagement in ACP remained low.[19,54]

Implications for research and practice

While the ACP-GP intervention did not improve patients' ACP engagement and GPs' self-efficacy, results of this trial have contributed important insights to the field of ACP research, which has seen intensive reflection regarding future directions.[55,56]

Patterns of increasing ACP engagement were seen in the intervention group and the usual-care control. The design and context of the trial, including questionnaires that explain ACP, as well as the COVID-19 pandemic, which brought media attention and public awareness to ACP, may mean that the intervention was compared with an awareness condition or even a

(community-based) intervention. This possible 'shift in mindset'[57] has highlighted the potential for a public health and media-messaging approach, which can help normalise ACP.[58]

Stakeholders consulted during the development of ACP-GP were mainly health providers. While this provided a depth of insight into GPs' needs, it will be necessary to involve patient and surrogate decision makers more closely in the future, to ensure intervention components also fully match their expressed needs. Inviting patients to engage in ACP conversations, even with an accompanying workbook, may be insufficient if attitudes, emotional barriers, and social context are not addressed. Closer involvement of family or surrogate decision makers may be necessary to facilitate engagement, as some patients may also want informal discussions with family.[17,57]

The ACP-GP intervention is a complex intervention with multiple components targeting GPs and patients. The inherent complexity of ACP, involving multiple behaviours and participants, and the complexity of barriers to ACP, requires that interventions to facilitate ACP should account for this complexity by offering interacting components such as documentation and communication.[59] While complexity does not necessarily equate to time-consuming or difficult interventions, it is nevertheless crucial to take into account increasing time and resource demands of the GP setting. For instance, if awareness- raising contributed to patient ACP engagement in both groups, the added value of the larger intervention should be carefully considered. In practice, ACP communication is more than a discrete number of appointments; it requires GPs to be aware of the wishes and concerns of patients and to be open to discussing these when the opportunity arises naturally.[60]

Considering the primary outcome findings in this trial, it is thus important to evaluate which components were (not) of perceived benefit to GPs and patients, how demanding the intervention was of time and resources, and how the components worked when implemented in the GP setting. An important next step will be a thorough process evaluation of the trial, where patients and GPs are invited to reflect on their experiences with the intervention. This will help identify how and why each component worked, and the challenges and facilitators encountered during implementation. The current study and the planned process evaluation of ACP- GP can contribute to insights regarding which components are effective and efficient.

ADDITIONAL INFORMATION

Funding

collection, management, analysis, and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

Ethical approval

Competing interests

Acknowledgments

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Chapter 4

How Advance Care Planning (ACP-GP) was implemented in Belgian general practice in the context of a cluster RCT: a process evaluation using the RE-AIM framework

This chapter is based on the following submitted manuscript:

Stevens J, Scherrens A-L, Pype P, Deliens L, De Vleminck A* & Pardon K*. How Advance Care Planning (ACP-GP) was implemented in Belgian general practice in the context of a cluster RCT: a process evaluation using the RE-AIM framework.

*shared last author

ABSTRACT

Background: General practice is often recommended as an ideal setting to initiate advance care planning (ACP), but uptake of ACP in this setting is low. ACP-GP is a complex intervention to facilitate ACP for patients with chronic, life-limiting illness in Belgian general practice. It aims to increase patient ACP engagement and general practitioner (GP) ACP self-efficacy. In a cluster-randomized controlled trial, the intervention was not superior to control in increasing these outcomes. A parallel process evaluation aimed to enhance understanding of how the intervention was implemented, and which factors might have influenced trial results.

Methods: We conducted a mixed-methods process evaluation following the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework. Data sources include recruitment and implementation monitoring, questionnaires for patients and GPs, and semi-structured (focus group) interviews with patients and GPs. Questionnaire data were analyzed descriptively. Qualitative data were first analyzed inductively; themes were then assigned deductively to RE-AIM dimensions.

Results: Thirty-five GPs and 95 patients were recruited to the trial; GP reach was low. Sixteen GPs and 46 patients provided questionnaire data at 3 months post-baseline; qualitative data were transcribed for 14 GPs and 11 patients. Adoption of intervention components was moderate to good, with the exception of the documentation template for GPs. Interviews revealed varying patient attitudes towards ACP, but patients nonetheless emphasized that conversations made them feel reassured. GPs especially valued a positive framing of ACP. When adopted, the intervention was well-implemented and participant satisfaction was high. However, intention for maintenance was moderate, with GPs raising questions of how to sustainably implement ACP conversations in the future.

Conclusions: Implementing the complex ACP-GP intervention in general practice is feasible, and can be successful. However, the implementation process is challenging and the sustainability is suboptimal. Our findings will guide future research and recommendations for facilitating and implementing ACP in general practice.

Trial registration: ISRCTN12995230; prospectively registered on 19/06/2020.

BACKGROUND

Advance care planning (ACP) is an iterative process whereby people communicate with family, loved ones, and health providers about personal values, life goals, and preferences regarding (future) treatment and care.[1] While ACP should not be limited to patients with chronic, life-limiting illness, it plays a crucial role in providing high-quality care for people with such conditions, supporting decision-making regarding future care.[2] Research suggests that patients and the general population perceive ACP as important,[3–6] but uptake remains low, including in general practice.[7–9] These findings conflict with recommendations to introduce ACP in a timely manner, for which general practitioners (GPs) are well-situated. GPs and providers of primary care can leverage their longstanding relationship with the patient to facilitate ACP. However, they may face barriers to doing so in practice, such as insufficient skills and a lack of time.[10–13]

The ACP-GP intervention was developed to facilitate ACP conversations in Belgian general practice. Following the Medical Research Council (MRC) guidance framework for development of complex interventions,[14] barriers and facilitators to ACP in this setting were identified. These included perceived patient factors, such as lack of understanding about ACP; GP factors, such as a lack of confidence and skills to initiate ACP; and system-level factors, such as lack of a place to consistently record patient care wishes.[11] Key intervention components, based on existing literature, were selected to target barriers and support facilitators. The components were refined after expert panel review,[15] and once more after a pilot study.[16] This yielded the ACP-GP intervention, a complex intervention with four interacting components, which was tested in a cluster-randomized controlled trial (RCT). Briefly, the intervention consisted of 1) GP training in ACP communication; 2) A patient workbook; 3) Two ACP conversations between patient and GP; and 4) A template to document the conversations. (See Additional File 1 for a detailed description)

We conducted a cluster-RCT to evaluate whether the intervention was superior to usual care in increasing patient and GP primary outcomes. For patients, we measured ACP engagement with the 15-item ACP Engagement Survey,[17] which includes measures of patient self-efficacy and readiness for ACP behavior. For GPs, we measured self-efficacy to conduct ACP, using the ACP-Self Efficacy (ACP-SE) scale.[18] At 3 months post-baseline assessment (T1), we found that although outcomes increased in both groups, the intervention group did not increase significantly more than the control group.[19]

It is crucial to evaluate the intervention and its implementation critically. To open the "black box" of this complex ACP intervention and understand why we observed these outcomes, a thorough process evaluation is necessary.[20] This can aid in distinguishing between problems

related to intervention theory, and those associated with intervention delivery.[21] We therefore aim to evaluate the implementation of the intervention, as reported by patients and GPs who participated.

We embedded a process evaluation in the cluster-RCT to enhance our understanding of how the intervention was implemented and interacted with contextual factors, which facilitators and barriers were encountered during implementation, and how these processes interacted to influence outcomes. In doing so, the process evaluation aligns with the (updated) MRC Framework guidance, which emphasizes that complex intervention research can address questions beyond whether the intended outcome is achieved, e.g. by identifying other impacts and assessing the value of the intervention, in light of resource demands.[22]

METHODS

Design

This process evaluation follows the Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework.[23] This framework allows researchers to evaluate how and why an intervention works (or not) when implemented in health system settings.[24]

We conducted this mixed-methods process evaluation, starting from the beginning of recruitment and ending after the 6-month intervention period. We use a sequential design, with quantitative data collection during, and qualitative data collection after, the intervention period.[25] RE-AIM informed the conduct, analysis, and structure of this manuscript. The conceptualization of the RE-AIM dimensions and corresponding data collection are shown in Table 1.

Table 1. RE-AIM dimensions, operationalization, and measurements used for the present study

RE-AIM dimension	Operationalization	Measurement
Reach **The number, proportion, and representativeness of participants in the study**	• Number of GPs and patients identified • Number of GPs and patients who agreed to participate • Comparing participants with non-participants	• Documentation of the recruitment process by the researchers • Documentation of reasons given for not participating • Participant demographics
Effectiveness **The impact of the intervention, including potential negative effects**	• Primary and secondary RCT outcomes • Adverse events	• Questionnaires at T0, T1, T2 • Reports of any adverse events
Adoption **The extent of uptake of intervention components by participants, and factors affecting this**	• GP attendance at the training • GP use of documentation templates • Patient use of the work booklet • Experiences of GPs and patients applying intervention components (e.g. reasons for (not) applying, changes in GP practice)	• Training checklist (after each training) • Questionnaire for GPs regarding their ACP practices and conversations in the last 3 months (T1) • Questionnaire for patients regarding ACP conversations with their GP in the last 3 months (T1) • Review of documentation template use via questionnaire and copies returned to the researchers (physical copy or digital scan) (T1, T2) • Contents of work booklet from a sample of patients in the intervention group

		(physical copy or digital scan) (T1, T2)
		• Focus groups with GPs (after T2)
		• Semi-structured interviews with patients (after T2)
Implementation **The extent to which the intervention was implemented as intended, satisfaction with the intervention, and factors affecting this**	• Fidelity: the extent to which the steps of the intervention were followed as specified in the protocol • Patient and GP barriers/facilitators encountered while implementing components of the intervention • Satisfaction of GPs and patients with the intervention components	• Training checklist (after each training) • Review of documentation template use via questionnaire and copies returned to the researchers (physical copy or digital scan) (T1, T2) • Satisfaction questionnaire for intervention GPs and patients (T1) Questions used a Likert scale (e.g., "How useful did you find the conversations with your GP, based on the workbook?", response range 1-7, 1=Not at all useful, 7=Very useful) or categorical answers (e.g., "To what extent did the conversations with your GP, based on the workbook, meet your expectations?"; answers options "They did not meet my expectation", "They met my expectations", "They exceeded my expectations".) • Focus groups with GPs (after T2) • Semi-structured interviews with patients (after T2)

Maintenance **The intention to sustain the intervention over time, and how the intervention can be improved for the future**	• GP intention for using the intervention materials in the future • Recommendations by the GP and patients to improve intervention usability in the future	• Satisfaction questionnaires for intervention GPs and patients (T1) • Focus groups with GPs (after T2) • Semi-structured interviews with patients (after T2)

Setting and participants

Participants were recruited in the scope of the cluster-RCT of the ACP-GP intervention in Belgian general practice. Eligible for participation were Belgian GPs and their Dutch-speaking patients with chronic, life-limiting illness (advanced/unresectable cancer, organ failure, frailty), for whom the GP would not be surprised if they were to die within the next 12-24 months. For more detailed information about the cluster-RCT design, we refer to the published protocol.[26]

Data collection

During recruitment, a trial manager and data collectors maintained records of participants contacted and noted reasons for declining participation. Participants completed demographics questionnaires at baseline (T0). The trial manager and data collectors also monitored for adverse events during study procedures.

All participating GPs and patients were asked to complete questionnaires about their ACP conversations and satisfaction with the intervention, using a self-developed satisfaction questionnaire, at T1, 3 months post-baseline. This timing was chosen because primary effectiveness was measured at T1.

We conducted semi-structured interviews with intervention group participants in March-June of 2021. Interview guides with open questions and probes guided data collection (Additional File 2). As we aimed to encourage discussion between GPs about their experiences, we invited GPs to focus groups. GPs were invited to attend a focus group on a list of preselected dates according to their availability. If attendance was not feasible, individual interviews were possible; GPs who participated in focus groups were not interviewed individually or vice versa. Focus groups were moderated by JS, ADV, and an assisting researcher, and conducted via video conferencing due to COVID-19 restrictions. JS and an assisting researcher individually interviewed a convenience sample of patients by telephone. We interviewed patients individually due to practical constraints and to avoid overburdening patients. Focus groups and interviews were audio-recorded; if recording was not possible, extensive written notes were taken. Recordings were transcribed verbatim and pseudonymized.

Analysis

Questionnaire data were analyzed descriptively in SPSS software (Version 27). To ease interpretation, 7-point Likert scale answers were reduced to three categories (1-3: low rating or disagreement; 4: neutral rating; 5-7: high rating or agreement).

Qualitative data were first analyzed inductively. JS and AS independently read and coded a selection of transcripts. During meetings, the two authors checked similarities and differences in coding and interpretation before coming to an agreement about a preliminary coding structure. Two coding trees were established, for patients and GPs respectively. Once the coding structure was agreed, JS coded the remaining transcripts in NVivo software (Version 12). Overarching themes were grouped deductively, linking them to the RE-AIM framework dimensions. JS, AS, ADV, and KP, held meetings to review the coding structure and achieve consensus about interpretation of key findings.

RESULTS

A total of 18 GPs and 53 patients were assigned to the intervention condition. Sixteen GPs and 46 patients returned questionnaires at T1.

After the intervention period, we conducted three focus groups (n=3, n=2, n=5 GPs respectively), and interviewed four GPs individually. Thirteen patients from the intervention group were interviewed. One recording of a patient dyad (married partners both participating in the intervention, interviewed simultaneously) was inaudible and not transcribed, yielding 11 patient transcriptions. Demographics of interviewed participants are shown in Table 2.

Table 2. Interview and focus group participant characteristics

GPS (n=14)	Focus Group 1 (n=3)	Focus Group 2 (n=2)	Focus Group 3 (n=5)	Individual Interviews (n=4)	Overall
Age in years (Mean, SD)	55.3 (7.6)	38 (7.1)	43.8 (11.9)	37.5 (10.0)	43.6 (11.3)
Years of practice experience (Mean, SD)	30.0 (7.9)	11.5 (9.2)	16.6 (11.6)	10.3 (10.2)	16.9 (11.8)
	Total (n=)				
Female	2	1	1	2	6

Practice type					
Solo	1	1	0	1	3
Group	2	1	3	3	9
Primary care center	0	0	1	0	1
Hospital	0	0	0	0	0
Multiple	0	0	1	0	1
Working as coordinating and advisory physician in a nursing home	0	0	1	0	1
Prior training in ACP					
None	2	2	2	4	10
Introductory	1	0	3	0	4
Intensive	0	0	0	0	0
Prior training in palliative care					
None	2	2	4	4	12
Introductory	1	0	0	0	1
Intensive	0	0	1	0	1
Patients (n=11)					
Age in years (Mean, SD)	70.2 (11.2)				
Age range	48-86				
	Total (n=)				
Female	4				
Marital status					
-Married, civil union, or domestic partnership	6				
-Widow(er)	3				
-Divorced or single, never married	2				
Diagnosis					
Oncological	4				
Frailty	5				
Organ failure (renal disease)	2				

For the qualitative reporting of results, we note that factors affecting adoption (participants making the decision to initiate intervention components) and implementation (how the adopted components are carried out in practice) were often interconnected. Results should be read with this in mind. All qualitative themes and illustrative quotes are shown in Table 3.

Table 3. Factors influencing each RE-AIM dimension, as reported by GPs and patients during interviews and focus groups

RE-AIM dimension	Factors reported by GPs	Illustrative GP quote	Patients	Illustrative patient quote
Reach	Limitations of the inclusion criteria	*"It's complex, but I think there were a few interesting patient we could have included, if French and English were included as languages for consultation." (Quote GP1.1 Focus group 3)*		
	Varying usefulness of the surprise question	*"For one patient, I thought: they really need it. But for the other two, it's possible that they pass away but I could see them living another five years as well. But I thought it was needed." (Quote GP1.2 GP interview 2)*		
	Some patients with chronic life-limiting illness are not seen by the GP until they approach the terminal phase	*"I think it's especially the people who always see a specialist. Some cancer patients you don't see for a whole year, but they are monitored by a specialist. I think we miss them. When they have exhausted their treatment options, then they*		

142

		come to us." (Quote GP1.3 Focus group 1)		
	Selection bias by GPs	*"But in the group that meets [the criteria], you choose the people you've known for longer or with whom you feel comfortable. I would never have asked it of someone I have only seen once in my practice, even if they met the criteria. These are people with whom you feel comfortable, and you know the patient is also comfortable with you." (Quote GP1.4, GP interview 4)*		
Effectiveness	Increased GP intention to take initiative in ACP conversations	*"I would maybe start it myself, before I would have waited until a patient came to me with something. Now I'll talk about it myself, even in situations that aren't urgent, as I just said, because you do it anyway, A bit, a year ahead of time, opening up that conversation. (Quote GP2.1, Focus Group 1)*	Facilitates patients reflecting about future health, values, and wishes	*Patient: "You get a different take on things, take on life a little bit. So…"* ***Interviewer: "Yes?"*** *Patient: "You start seeing it differently."* ***Interviewer: "Yes, and in what way?"*** *Patient: "Yes, what could happen. Or what you'll be confronted with. That, that, I wouldn't think about that otherwise, now you think about that." (Quote PT2.1, Patient interview 11)*

More positive framing of ACP	*"What happened to me especially, is that the stories in that workbook, the tendency and the tone of the stories, the positive approach. It's had an enormous impact. I will take that with me for the rest of my career." (Quote GP2.2, Focus Group 2)*	Wishes are documented and communicated to family	*"Well, Dr. [name] made a list together with me […] of what I would and would not want. Every child received that on their computer. So now everyone is aware of the situation, of what I would want." (Quote PT2.2, Patient interview 10)*
ACP process is facilitated: GPs learn and new and useful information about patients' experiences and values, document outcomes of ACP conversations	*"The experience with illness and dying in their surrounding environment was good to hear, because there were things there that I didn't know. They are people I don't follow up for 20 years, I've worked in the practice for five years. It's useful to hear things that also give you insight into why they do or don't want certain things." (Quote GP2.3, GP Interview 1)*	Positive affective outcomes	***Interviewer: "Yes, so that was the value for you, that it's all on paper now."*** *Patient: "Yes. That's a big reassurance for me."* ***Interviewer: "Yes, yes. So you feel reassured that, uh…"*** *Patient: "That I can count on her if something happens, yes." (Quote PT2.3, Patient interview 11)*
GPs feel capable to speak up for patient wishes and values	*"In the meantime, I've been able to apply that a few times, and express it to the family for example. Someone who is palliative and unable to speak anymore, if you can express it that way, you notice it brings about a*		

		sense of peace: That's true, our dad… Then everyone is at peace with it and they stand behind your approach." (Quote GP2.4, Focus group 1)		
	Perception that patients actively contemplate ACP	*"I had two conversations, one with just the patient and during the second one I also spoke with the daughter. Those were very useful conversations, where the patient also said: 'I'm glad I did this. I also actively considered it.'" (Quote GP2.5, Focus group 3)*		
	Previous experience influences whether outcomes change	*"My feeling of being prepared did not change much. Because I actually had that already, since I conducted many conversations for my thesis. That's mainly building confidence in yourself." (Quote GP2.6, GP interview 2)*		
Adoption	GPs feel that ACP, while a delicate subject, is important to do	*"[Referring to the goals of ACP] I think that the autonomy people must have regarding their own health, that information, and preserving those fundamental patient rights in an important life*	ACP can be confronting and raises negative emotions	*"Well, I think we should be open to it, if it can be improved. But for me personally, I thought some things were very confronting. […] I think, one, maybe because of my diagnosis. And two, I think also because of my age.*

145

		phase. I think that is important, because we are coming from a time when decisions were made about and for patients, especially in the final phase of life." (Quote GP3.1, GP interview 1)		*But I admit that there are things I haven't considered at all. And then a lot of those questions were difficult for me." (Quote PT3.1, Patient interview 7)*
	Not all materials delivered during the training (conversation guide, template) are always perceived as useful	***Interviewer: "The template to use is the conversation guide without example questions. Did you use this, before or after the conversation?"*** GP: "No, that did not add any dimension that would have been meaningful, but which I didn't already have. […] I only used a piece of what was offered." (Quote GP3.2, Focus group 2)*	Patient supportiveness of ACP	***Interviewer: "And how did that come across to you?"*** *Patient: "I supported it immediately."* ***Interviewer: "You supported it."*** *Patient: "Yes, because I have a certain opinion about the end of life. Later in my life. And I thought that, I was really, I won't say enthusiastic to participate but I did it gladly." (Quote PT3.2, Patient interview 10)*
	GPs were unable to schedule conversations	*"If you already got it down or if it were less important, you might say, "I'll just do it quickly and we will see.' But if you start and it doesn't go well, then you're better off not doing it." (Quote GP3.3, GP interview 3)*	Patient appraisal of ACP as relevant or not relevant	*"At the moment, I don't need it. And you don't know how it'll be a year from now, or two years from now, or ten years from now." (Quote PT3.3, Patient interview 2)*
Implementation	General satisfaction with the training, but some	*"For me, the interesting part was the discussion and the insight from*	Satisfaction with form/content of workbook,	***Interviewer: "So you have LEIF-card [pocket card with information about***

expectations for more intensive exercise not met	*others. […] Especially the difficulties, the limitations, how they resolve this, sentences to use. Also hearing that others encounter the same obstacles as yourself."* (Quote GP4.1, GP interview 2) **Interviewer: "I heard Dr. [name] say, more role-play exercises."** GP 1: *"Practicing with concrete case examples, things you can get stuck on and then tips and tricks to get through that."* GP 2: *"That's the advantage of a role play exercise. You hear each other's opinions and how someone else would do it, you learn a lot from that."* (Quote GP4.2, Focus group 1)	but sometimes difficult to appraise due to limited recall	**which ADs the person has], and you've also looked at the LEIF-booklet [booklet about different ADs]. Do you think that what we gave you, that booklet, has any added value on top of that?"** *Patient: "Well yes, with a little more explanation about it."* **Interviewer: "More explanation, in the LEIF-booklet or ours?"** *Patient: "In yours it's more in a language of, how do I want…"* (Quote PT4.1, Patient interview 10)
Workbook is a helpful tool for preparation and during conversations	*"But the brochure [referring to workbook] makes the difference, then there is more space to do more in one conversation."* (Quote GP4.3, GP interview 2).	Perceived and desired control over decision-making in the ACP process	*"Because at the end of the day we are patients, yes, well, as I say, we don't speak with a full understanding, we have to undergo it. I don't know what needs to happen, if suddenly I'm paralyzed, just to name something.*

			Yes, then it's necessary to help me and I can't do anything about that, right?" (Quote PT 4.2, Patient interview 4)
Practical preparation of conversation appointments	*Interviewer: "To implement those conversations in your practice, did you have to make any changes? Or do anything differently?"* GP: "No, I did that in my free time, so it has nothing to do with my practice. My colleagues had little to do with it." GP2: "It was the same for me, I also did it on a free afternoon." (Quote GP4.4, Focus group 1)	Prior experiences with ACP and ADs	"Um, but, and we also filled things out a while ago, and registered it [with the municipality]. That they can't reanimate. And also with the LEIF-card [pocket card with information about which ADs the person has]." (Quote PT4.3, Patient interview 3)
Importance of GP self-efficacy	"You have to ensure that you don't do anything wrong by it. If you frighten people… We talked about that quite a bit. How do you convey it properly? What should or shouldn't you do? What do you avoid?" (Quote GP4.5, GP interview 3)	Prior relationship with the GP	"Yes, and the difficult part, is that my actual GP here, Dr. [name, GP not involved in the study] […] Yes, they moved to [city]. And yes, that was a little difficult. I can talk to Dr. [GP involved in the study], he was aware of it too, but it's a little different, yes." (Quote PT4.4, Patient interview 5)

Anticipated interactions with patients	*"The patient was prepared by reviewing the questions and because you had visited. They knew what was coming next." (Quote GP4.6, GP interview 4)*	Experiences with the ACP conversations: -Positive experience -Bidirectional openness between GP and patient -GP asked questions to encourage discussion	***Interviewer: "Did you have the chance to also address what you wanted to discuss during the conversation?"*** *Patient: "Yes, I did. I asked personal questions about that care…the person who then has authority over you. I was able to do all of that."* ***Interviewer: "Did you feel like your GP listened to you and showed understanding for what you brought up?"*** *Patient: "Yes, I did." (Quote PT4.5, Patient interview 1)*
Experiences with the ACP conversations: -Patients did not all use workbook to the same extent, which affects conversation -Themes differ from patient to patient -Difficult for some patients to understand topics	*"With one patient I talked at length about what she would want in terms of care later, hospitalizations and the like. With another patient it was primarily about what was important to her in this moment and what she definitely wants to maintain, which is contact with her granddaughter. So it differs per patient." (Quote GP4.7, Focus Group 2)*	SDM presence during the conversation	***Interviewer: "Can you tell me about how that conversation went?"*** *Patient: "It lasted about an hour and I thought it was good that my spouse was there as well. She might have had more questions to ask than I did." (Quote PT4.6, Patient interview 9)*

(Intention for) Maintenance	Changes to training for sustainable implementation	Interviewer: "Dr. [name] is saying a little further on in the master years, but also the GPs who have been working for a bit longer and are interested in refining their skills." GP: "The basis is the attitude. If you're focused on […] it all has to happen in those thirty minutes, someone who's really focused on that, they won't get anything out of [a training]… Yeah." (Quote GP 5.1, Focus group 2)	ACP perceived as completed vs. intention to maintain ACP with the GP	Interviewer: "And when would you like to talk about it again with Dr. [name]?" Patient: "Well, eight days from today she's coming over." Interviewer: "Ah yes, so when she comes over again, you'll talk about it again?" Patient: "Definitely, yes." (Quote PT5.1, Patient interview 10)
	Patient workbook is a useful tool for future practice application	"I would especially like to keep using the workbook, I put the overview for doctors on the computer so I can look at it. I think the booklet is useful, I would give that to a patient if they started talking about [ACP] during a consultation." (Quote GP5.2, GP Interview 2)	Wanting to discuss ACP with other health professionals/specialists	Patient: "And I would like to also have that conversation with my nephrologist. But yes, of course, you can't just do that, just demand that from her as a patient […]" Interviewer: "Yes, that asks a bit more planning because their time is more limited? If I understand correctly." Patient: "Well, the thing is, you can hardly sit and talk for an hour with the nephrologist […] Just to say what you would want or what your wishes are,

			and to learn more about how, what they do, at their level.” (Quote PT5.2, Patient interview 6)
How to plan and conduct ACP efficiently within limited consultation time?	*“I think the added value has primarily been that we made time for it. That’s where there will always be problems. You should have that conversation with patients very often, but then we won’t set aside an hour for it. That’s the added value for the patient now: you’re really making time for it and letting them talk. In normal circumstances it’ll rather be: “We’ll talk about it some other time”. That’s my concern.” (Quote GP5.3, Focus group 1)*	Plans to revisit ACP conversations when health or quality of life changes	**Interviewer: “Are there moments where you think: at that moment, it would be useful to have that conversation again?”** *Patient: “I think so. If I’m not doing well, I think I’ll need it. I feel good now, but you don’t know how long or what… We will see if the medication works. If the moment comes, then it’s alright.” (Quote PT5.3, Patient interview 9)*
Interprofessional: Feasibility and desirability of task delegation within the practice	*“I find it difficult to split something like that up. It doesn’t seem pleasant for the patient to first have a conversation with me, and then with another colleague.” (Quote GP5.4, GP Interview 4)*	Need for more community/media support	*“I think a media campaign could actually help. I think so, personally. Because people wouldn’t talk about it, and if you encourage people by saying ‘talk about this topic with your GP’, or ‘[your GP] may address this soon’, without it being…dramatic, and without it, uh… meaning that everyone is going*

		to be terminally ill. [laughs]" (Quote PT5.4, Patient interview 3)
System-level: Need for a structured and unified system to document ACP conversations and ensure transfer of information with other clinicians	*"I think there should be more possibilities in our software, just like we can fill in other parameters now. That it's much clearer. Now it's something separate, and where do you have to write that? A document somewhere in the file, or scan it, because it's not clear when someone else opens that file. Something very simple, a step-by-step plan, which is very clearly visible in the file." (Quote GP5.5, Focus group 1)*	

1. Reach (Number, proportion, and representativeness of participants)

In total, 1570 GPs affiliated with 837 practices were identified during recruitment (Additional File 3). Of these, 1519 were contacted via telephone, email, and/or leaflet. Of 682 GPs who provided a reason for declining participation, the majority (60.6%) cited a lack of time/being too busy. Fifty GPs (3.3% of GPs contacted) expressed interest and agreement to participate; 35/50 (70% of interested GPs) were enrolled and randomized to intervention (n= 18) or control group (n= 17). Reasons for withdrawal prior to randomization included being unable to identify eligible patients for the study and a lack of time.

GPs identified 117 patients for participation, of whom 95 (81.2%) were included. Of 22 patients not included to the study, eight (36.4%) declined or had no interest, and two (9.1%) found the topic too confronting. Baseline characteristics of participants in both groups are shown in Additional File 4.

Perceived factors affecting Reach

During interviews, GPs gave varying feedback about the ease of finding eligible patients. Some found the **inclusion criteria** too narrow, such as that patients had to be Dutch-speaking (Quote GP1.1). The **surprise question** was deemed useful in place of a strict age cutoff, but GPs reflected that it was difficult to apply when patients' possible future health outcomes were unclear (Quote GP1.2).

GPs described how some patients may have met the criteria, but **primarily consulted a specialist and not the GP** until treatment options were exhausted (Quote GP1.3). Conversely, patients closer to the end of life were those the GP saw regularly. Finally, some GPs described a **selection bias** for identifying patients from those who were eligible, such as choosing patients with whom they felt comfortable. (Quote GP1.4)

2. Effectiveness (impact of the intervention, including potential negative effects)

For primary effectiveness, we did not find evidence for superiority of the intervention over the control group in improving the patient primary outcome (ACP engagement) or the GP primary outcome (ACP self-efficacy).[19] No major adverse events associated with the intervention were reported. Within the complete sample, seven patients died during the trial period, three of whom were in the intervention group.

Perceived added value and impact of the intervention

GPs described how the intervention increased their alertness to ACP and its themes in daily practice. This contributed to GPs' **intention to proactively start conversations**. (Quote GP2.1)

Many GPs described how framing ACP around what is important to the patient to live well, gave them a **more positive approach** and helped conversations flow logically. GPs felt this was more fulfilling than an AD-driven approach. This helped some GPs feel more confident and supported.

"What happened to me especially, is that the stories in that workbook, the tendency and the tone of the stories, the positive approach. It's had an enormous impact. I will take that with me for the rest of my career." (Quote GP2.2, Focus Group 2)

Conversations contributed to an **ACP process** where GPs learned valuable information about their patients, according to themes they may not otherwise have considered. GPs also explained that they documented topics discussed during and after conversations, sometimes in an AD (Quote GP2.3). As a result of the conversations, GPs felt they would be able to better **speak up for what the patient wanted** if the patient became incapacitated, and to articulate this to the patient's family:

"In the meantime, I've been able to apply that a few times, and express it to the family for example. Someone who is palliative and unable to speak anymore, if you can express it that way, you notice it brings about a sense of peace: That's true, our dad… Then everyone is at peace with it and they stand behind your approach." (QuoteGP 2.4, Focus group 1)

GPs perceived that the workbook and conversations **helped patients think about ACP** (Quote GP2.5). However, some GPs described **no changes** (Quote GP2.6) in their own awareness, knowledge or confidence, as they already had previous experience and found a way of having ACP conversations that worked for them. On the other hand, some GPs felt gaining confidence would first require more practice.

Patients expressed that the intervention **helped them to think about their future health, and about care wishes** (Quote PT2.1). Several patients also described how the results of their conversations with the GP were **documented and shared with involved family members**. (Quote PT2.2). Multiple patients described feeling a **positive affect** after the conversations with their GP: the conversations assuaged worries, and made patients feel reassured and relieved that their GP would consider their wishes in future care decisions:

Interviewer: "Yes, so that was the value for you, that it's all on paper now."
Patient: "Yes. That's a big reassurance for me."
Interviewer: "Yes, yes. So you feel reassured that, uh…"
Patient: "That I can count on her if something happens, yes." (Quote PT2.3, Patient interview 11)

3. Adoption (Extent of uptake of intervention components by participants)

Training

The GP training consisted of an online module (asynchronous learning) and two live, interactive parts. All GPs registered for the online module. Part one was offered in three sessions (i.e., the same content offered on three dates). Five GPs attended session 1, five attended session 2, and six attended session 3. Two GPs received the session in recorded version. The second part was given in two sessions. Seven GPs attended the first session, eight the second session, and three received the session in recorded version.

Training materials were emailed to all GPs and were available online throughout the study period. At T1, most GPs indicated using the materials from the training once or twice (33.3%), or monthly (46.7%); two (12.5%) never used the training materials (Table 4).

Table 4. GP satisfaction questionnaire (T1)

	Number of respondents endorsing option (valid %)[a]		
	Low rating (1-3)	Neutral rating (4)	High rating (5-7)
How useful did you find…			
the training?	0 (0.0)	1 (6.7)	14 (93.3)
the follow-up with the trainers?	2 (13.3)	7 (46.7)	6 (40.0)
the intervention materials, to be used during conversations with included patients?	1 (6.7)	1 (6.7)	13 (86.7)
How satisfied are you with…			
the training?	1 (6.7)	2 (13.3)	12 (80.0)
the follow-up with the trainers?	1 (6.7)	5 (33.3)	9 (60.0)
the intervention materials, to be used during conversations with included patients?	1 (6.7)	1 (6.7)	13 (86.7)
How interested are you to use the materials from the training (e.g. the workbook, conversation guide, conversation flowchart) in the future?	1 (6.7)	4 (26.7)	10 (66.7)
	Disagree (1-3)	**Neutral (4)**	**Agree (5-7)**
The information I received during the intervention was important to me.	0 (0.0)	5 (33.3)	10 (66.7)

I felt uncomfortable with the information that was brought up during the intervention.	14 (93.3)	1 (6.7)	0 (0.0)
The intervention training took too much time.	8 (53.3)	3 (20.0)	4 (26.7)
The intervention (e.g. materials and information from the training) was easy to understand.	1 (6.7)	1 (6.7)	13 (86.7)
I can use the information from the intervention in my daily practice.	0 (0.0)	3 (20.0)	12 (80.0)
	It did not meet my expectations	It met my expectations	It exceeded my expectations
To what extent did the training meet your expectations?	4 (26.7)	10 (66.7)	1 (6.7)
	Not enough information	The right amount of information	Too much information
What did you think of the amount of information you received during the training?	4 (26.7)	11 (73.3)	0 (0.0)

	Never	Once or twice in total	Monthly	Weekly	Daily
How often did you use the materials from the training?	2 (13.3)	5 (33.3)	7 (46.7)	1 (6.7)	0 (0.0)

	No	Not sure	Yes
Would you recommend the training to other GPs?	1 (6.7)	5 (33.3)	9 (60.0)

a. Missing data: One GP satisfaction questionnaire missing in full

Workbook

All patients received the workbook from research staff. Of 39 respondents at T1, approximately one-third (30.8%) indicated they had never used the workbook. Most patients who used the workbook, reported using it once or twice in total (Table 5). Seventeen patients returned copies of their workbook by the end of the study period (37.8% of 45 patients retained to T2).

Table 5. Patient satisfaction questionnaire (T1)

	Number of respondents endorsing option (valid %)		
	Low rating (1-3)	**Neutral rating (4)**	**High rating (5-7)**
How useful did you find the conversations with your GP, based on the workbook?	1 (3.2)	3 (9.7)	27 (87.1)
How satisfied are you with the conversations with your GP, based on the workbook?	0 (0.0)	1 (3.2)	30 (96.8)
How interested are you to use the materials from the study (e.g. the workbook) in the future?	10 (27.8)	7 (19.4)	19 (52.8)
	Disagree (1-3)	**Neutral (4)**	**Agree (5-7)**
The information I received during the conversations with my GP was important to me.	2 (6.3)	3 (9.4)	27 (84.4)
I felt uncomfortable with the information that was brought up during the conversations with my GP.	23 (69.7)	4 (12.1)	6 (18.2)
The conversations with my GP took too much time.	30 (93.8)	1 (3.1)	1 (3.1)
The workbook was easy to understand.	3 (8.6)	4 (11.4)	28 (80.0)
I can use the information from the conversations with my GP, in my daily life.	7 (21.9)	6 (18.8)	19 (59.4)
	They did not meet my expectations	**They met my expectations**	**They exceeded my expectations**
To what extent did the conversations with your GP, based on the workbook, meet your expectations?	0 (0.0)	24 (77.4)	7 (22.6)
	Not enough information	**The right amount of information**	**Too much information**
What did you think of the amount of information you received in the workbook and during the conversations?	2 (6.9)	25 (86.2)	2 (6.9)

	Never	**Once or twice in total**	**Monthly**	**Weekly**	**Daily**
How often did you use the workbook from the intervention?	12 (30.8)	19 (48.7)	5 (12.8)	3 (7.7)	0 (0.00)

	No	Not sure	Yes
Would you recommend the workbook to other patients?	4 (10.8)	12 (32.4)	21 (56.8)

Conversations

At their respective T1 assessment, 13/16 GPs (81.3%) reported having had ACP conversations with patients included in the study, and 33/46 patients (71.7%) reported at least one ACP conversation with their GP.

Documentation template

All GPs were provided the documentation template in PDF format. GP questionnaire responses at T1 indicated that 8/30 (26.7%) of first conversations and 1/21 (4.8%) of second conversations were documented using the template. Four GPs returned copies of the template by the end of the study period.

Perceived factors influencing Adoption

During interviews, GPs **endorsed the value of ACP**, though many acknowledged that it is a delicate topic which requires patients to be receptive as well. This attitude facilitated adoption of the intervention as a whole. GPs felt that ACP is important to help patients reflect about quality and quantity of life, to empower patients, and to preserve patients' rights to autonomy over their own health:

"[Referring to the goals of ACP] I think that the autonomy people must have regarding their own health, that information, and preserving those fundamental patient rights in an important life phase. I think that is important, because we are coming from a time when decisions were made about and for patients, especially in the final phase of life." (Quote GP3.1, GP interview 1)

GPs varied in the **extent of uptake of materials**, such as conversation guides and the documentation template. They described how they read the conversation guide to prepare for conversations. However, some indicated not finding added value for the documentation template or lacking integration with their current means of documentation, and therefore did not use the template (Quote GP3.2).

One interviewed GP who had been **unable to schedule conversations** cited a lack of time, exacerbated by the COVID-19 pandemic, as the main barrier. The lack of time hindered planning and preparation. The GP did not wish to schedule conversations under these constraints (Quote GP3.3).

Patients' affective reactions to ACP, and attitudes towards ACP, could facilitate adoption or act as a barrier. For some patients, hearing or thinking about ACP was **confronting and raised negative emotions**, or concerns that their health was declining, which made it more difficult to engage with the topic directly:

"Well, I think we should be open to it, if it can be improved. But for me personally, I thought some things were very confronting. […] I think, one, maybe because of my diagnosis. And two, I think also because of my age. But I admit that there are things I haven't considered at all. And then a lot of those questions were difficult for me." (Quote PT3.1, Patient interview 7) Some patients acknowledged the benefit of ACP generally but did not initially want to be "pushed" into it, or did not feel it was relevant for them personally yet. However, others were **supportive of ACP** or felt it couldn't hurt for them to bring it up (Quote PT3.2).

Pertaining to **perceived relevance**, some patients found ACP personally relevant, e.g. due to older age. However, despite engaging with the intervention by reviewing the workbook and/or having conversations with their GP, some patients nonetheless saw ACP as being for older or more dependent persons, or for those with more acute health concerns, and thus did not feel they needed ACP at the moment (Quote PT3.3).

4. Implementation

Fidelity to protocol

The protocol for the intervention consists of a researcher-delivered part (giving the workbook to patients, delivering the training and conversation materials to GPs, giving the documentation template to GPs), and a part to be implemented by the participants (GPs having two ACP conversations with each patient, GPs filling out the documentation template).

At T1, GPs reported that 9/31 patients (29%) with whom they had a conversation, received one conversation only. Twenty-two patients (71%) were reported by the GP to have received two conversations, as specified in the protocol. At the moment of their T1 measurement, 14/46 (30.4%) patients reported having had two or more conversations with their GP. Cross-checking GP and patient reports showed that 9/22 patients for whom GPs reported two conversations, also reported having used their workbook at T1. One patient reported using the workbook, had two conversations by T1 as reported by the GP, and had both conversations documented using the template.

Training

Training sessions lasted from 1 hour 47 minutes to 2 hours 17 minutes. In the sessions where GPs conducted practice conversations with model patients, two attending GPs to conducted a conversation; other attending GPs gave feedback and participated in group discussions only.

GPs rated the usefulness of and satisfaction with the training and the intervention materials highly (Table 4). Approximately half (53.3%) did not think the training took too much time. For most GPs (73.4%), the training met or exceeded their expectations. Most (60%) would recommend the training to others, but one-third (33.3%) were unsure.

Workbook, conversations, documentation

Conversations with the GP met (77.4%) or exceeded (22.6%) patients' expectations (Table 5). Patients were satisfied with the conversations (96.8%) and found them useful (87.1). Patients largely agreed they received the right amount of information (86.2%), that this information was important to them (84.4%), and that the workbook was easy to understand (80%). Half (56.8%) would also recommend the workbook to others, but approximately one third (32.4%) were unsure.

Conversations were anticipated to take maximally 60 minutes. GPs reported 29/31 (93.5%) of first conversations and 100% of second conversations lasted up to 60 minutes. Documentation was primarily done in the electronic medical record (EMR): at T1, GPs reported that 27/30 (90%) of first conversations and 16/21 (76.2%) of second conversations were documented in the EMR (Table 6).

Table 6. ACP conversation length and documentation, from questionnaire (T1)

	Conversation 1 (N)	% of valid responses (/31)	Conversation 2 (N)	% of valid responses (/22)
Length of conversation				
<15 minutes	1	3.2	9	40.9
15-30 minutes	14	45.2	8	30.4
31-60 minutes	14	45.2	5	22.7
>60 minutes	2	6.5	0	0.0
		% of valid responses (/30)[a]		% of valid responses (/21)[a]
Documented using[b]				
Intervention template	8	26.7	1	4.8
Patient EMR	27	90.0	16	76.2
Advance directive	2	6.7	6	20.0
Documented elsewhere	3	10.0	3	10.0

No modality of documentation reported	1	3.3	4	19.0

a. One questionnaire about conversations incomplete

b. Multiple answers possible

Experiences with Implementation

In interviews, most GPs expressed being **satisfied with the training.** GPs appreciated that the online format eliminated the need for physical transit, found the live session content interesting, and valued hearing how other GPs conducted ACP:

"For me, the interesting part was the discussion and the insight from others. […] Especially the difficulties, the limitations, how they resolve this, sentences to use. Also hearing that others encounter the same obstacles as yourself." (Quote GP 4.1, GP interview 2)

GPs who felt the training did not meet expectations, expected a more intensive approach, e.g. with more interaction between GPs than they felt the online format allowed, more exercises including demonstrations by the trainer, and practical guidance such as how to keep ACP conversations on track (Quote GP4.2).

GPs described the **patient workbook as a helpful tool** (Quote GP4.3) and spontaneously compared it to ADs, which they saw as off-putting to patients. Some GPs used the workbook to structure the conversation or filled it in together with the patient, and found it useful to ensure less of the conversation was forgotten. One GP however felt that the workbook may have been too difficult for some patients to use without guidance.

A lack of time could be a challenge to **practical preparations** for ACP conversations. Some GPs scheduled conversations during their free time instead of during consultation hours (Quote GP4.4). GPs also emphasized the importance of **communication skills**, a lack of which made conversations more challenging. They did not want to frighten or offend patients (Quote GP4.5). GPs felt it was a benefit that **patients would know what to expect** from the conversation (Quote GP4.6).

GPs expressed that **conversations were highly individualized**. For example, some patients used the workbook intensively in preparation, but others did not. During appointments, GPs encountered barriers to having in-depth conversations when patients showed a "black or white" view of ACP or did not fully understand the topics. Themes discussed during the ACP conversations varied from patient to patient and GPs adjusted their approach accordingly:

"With one patient, I discussed at length what she would want later in terms of care, hospitalization and the like. With another patient, the conversation was mainly about what was

important to her at this moment, and what she definitely wants to maintain, which is contact with her granddaughter. So it differs from patient to patient." (Quote GP4.7, Focus group 2)

Patients were satisfied with the workbook, but at the moment of interviews with the researchers some had difficulty recalling detailed contents, or had misplaced it. They appreciated that the workbook questions were more general than ADs and valued that it encouraged reflection about living well (Quote PT4.1).

Perceived and desired control in decision-making as part of ACP differed between patients. Some felt it was their right and responsibility to talk about their values and wishes, and to make decisions themselves. Others relinquished control, e.g. by trusting doctors to make the right decisions. Last, some patients were uncertain if they had control in making decisions about their care or treatment. They questioned to which extent ACP discussions would affect the care they received, or considered themselves laypersons who lacked the knowledge to make decisions about treatment:

"Because at the end of the day we are patients, yes, well, as I say, we don't speak with a full understanding, we have to undergo it. I don't know what needs to happen, if suddenly I'm paralyzed, just to name something. Yes, then it's necessary to help me and I can't do anything about that, right?" (Quote PT4.2, Patient interview 4)

Prior patient experiences with ACP may have played a role during implementation, as some patients had already talked about ACP with their GP or had completed ADs (Quote PT4.3). This made ACP easier to talk about or revisit. **A prior relationship with the GP** was an important facilitator to conversations. For most patients, the GP was a trusted person with whom the patient had a longstanding, positive relationship, creating a secure setting to discuss ACP. Other patients placed more trust in specialist care providers, or did not know the GP well prior to the intervention, which could make conversations more difficult (Quote PT4.4).

Patient experiences with the intervention conversations described a feeling of reciprocal openness during conversations, where GP and patient participated equally, which facilitated patient comfort and satisfaction with the conversation (Quote PT4.5). When a **surrogate decision maker** (SDM) was present during the conversation, patients experienced this as positive. Some SDMs were already involved in care for the patient and could provide support during conversations. In other cases, the SDM was able to ask questions alongside the patient (Quote PT4.6).

5. Maintenance (Intention to sustain the intervention over time)

Of GP respondents, two-thirds (66.7%) indicated high interest in using the intervention materials (workbook, conversation guide, conversation flowchart) in the future (Table 4). Half

of patient questionnaire responses (52.8%) indicated high interest in using the workbook in the future; more than one-quarter (27.8%) indicated low interest (Table 5).

Perceived factors affecting Maintenance, and participant recommendations for the future

Some GPs who were interviewed saw potential for the **training** to be included in bachelor- or master-level coursework, but also as a refresher for GPs with several years of experience. However, the latter may only draw GPs who already are interested in ACP (Quote GP5.1). Suggestions for the best format and session length for the future depended on preference and learning styles: some GPs preferred fully online modules to review on their own time, without attending live sessions, while others suggested also discussing the theoretical background live.

GPs were interested in **continuing to use the workbook** in practice and discussed it with colleagues or created copies for future use. They saw it as a helpful tool to give to patients who signaled wanting to discuss ACP during regular consultations (Quote GP5.2).

GPs foresaw **challenges to integrating conversations into future practice**. Some were concerned that, while they made time for ACP conversations during the study, they would not be able to sustain this in the future due to limited available time:

"I think the added value has primarily been that we made time for it. That's where there will always be problems. You should have that conversation with patients very often, but then we won't set aside an hour for it. That's the added value for the patient now: you're really making time for it and letting them talk. In normal circumstances it'll rather be: "We'll talk about it some other time". That's my concern." (Quote GP5.3, Focus group 1)

Some GPs suggested it would be more feasible to discuss ACP over a longer period of time, addressing smaller "chunks" per consultation.

Task delegation in group practices and community health centers was proposed as a supporting factor to maintenance, but each GP would probably still do these conversations with the patients they saw regularly (Quote GP5.4). GPs also reflected on a **need for a more systematic way of working**. This included a system for documenting ACP, for which the current EMR lacked a designated section, leading to discrepancies in how and where documentation is recorded:

"I think there should be more possibilities in our software, just like we can fill in other parameters now. That it's much clearer. Now it's something separate, and where do you have to write that? A document somewhere in the file, or scan it, because it's not clear when

someone else opens that file. Something very simple, a step-by-step plan, which is very clearly visible in the file." (Quote GP5.5, Focus group 1)

Patients differed in their **intention to engage with ACP in the future**. Some saw ACP as "finished" or wanted to let the topic rest after their conversations with the GP, without specifying when they might return to it. Others said they continued to engage with ACP after the study: through contemplation, talking to loved ones, and planning to talk to their GP (Quote PT5.1).

Some patients were also in contact with **other health providers** such as specialist care and contemplated discussing ACP with them, but worried about demanding too much of their time (Quote PT5.2). When asked when might be a **good time to revisit ACP**, patients indicated this depended on changes in health and perceived quality of life:

Interviewer: "Are there moments where you think: at that moment, it would be useful to have that conversation again?"

Patient: "I think so. If I'm not doing well, I think I'll need it. I feel good now, but you don't know how long or what… We will see if the medication works. If the moment comes, then it's alright." (Quote PT5.3, Patient interview 9)

To improve the intervention, some patients suggested wanting more **community-level support** which normalizes ACP, such as media messaging which emphasizes that ACP is also relevant for people who are not terminally ill (Quote PT5.4).

DISCUSSION

Main findings

We aimed to better understand the implementation of the complex ACP-GP intervention by assessing how the intervention was delivered and how it was experienced by both GPs and patients. We wanted to gain more insight into what worked well and what could be improved for a sustainable implementation in general practice. Therefore, we conducted a mixed-methods process evaluation based on the RE-AIM framework. Sixteen GPs and 46 patients provided questionnaire data at T1, and we also collected qualitative data from focus groups and interviews with fourteen GPs and 11 patients.

We found that GP **reach** to participate in the study was low. We used recommended strategies for GP recruitment, such as an invitation via pamphlet, presenting a topic that is appealing to GPs,[27] and personal contact with interested GPs (via practice visit or video conferencing),[28] but encountered low recruitment, similar to studies recruiting GPs to dementia care and palliative care research.[29,30] The most frequent reason given for declining participation was

having no time or being too busy. **Effectiveness** of the intervention was low, as it did not improve patient ACP engagement or GP ACP self-efficacy more than control.[19] In interviews, participants described other impacts of the intervention, discussed below. **Adoption** of the intervention components was variable and GP barriers to adoption overlapped with barriers to recruitment. Attendance rates at the training were high and the majority of GPs adopted the conversation component to some degree. Approximately two-thirds of patients used the workbook at least once. Adoption of the documentation template by GPs was low. Due to this low adoption, the **implementation** domain of fidelity to the full intervention, as described in the protocol, was also low. The EMR was still the primary modality where GPs documented the conversation outcomes. GPs reported greater fidelity to the prespecified two conversations at T1 than patients. Patients reported especially high satisfaction with the ACP conversations. The intention for **maintenance** was moderate among GPs and patients: two-thirds of GPs reported high interest to continue using the intervention materials, such as the conversation guide, while half of patients indicated high interest in using the workbook in the future.

Interpretation of main findings

What might explain findings concerning primary intervention outcomes?

The process evaluation offers possible explanations for why no significant differences were found between intervention and control groups on the primary outcomes of ACP self-efficacy at the GP level, and ACP engagement at the patient level. Some GPs explained during interviews that they already felt confident to have ACP conversations before the intervention, due to prior practice experience. These GPs may represent participants who were already engaged and motivated for ACP.[31] Other GPs stated they would need more time to practice and build their confidence. Learning by following courses and exchanging experiences with peers may be one way to improve skills, but gaining experience by conducting ACP in daily practice is an equally important and crucial strategy.[32] This, however, may require more time than the three-month follow-up from baseline at which we measured our primary outcome,[33] and may be hindered by remaining uncertainties about how to incorporate ACP conversations efficiently into daily practice.

At the patient level, our primary analyses of ACP engagement also considered the questionnaire subscales "readiness" and "self-efficacy" as they apply to four domains of ACP, such as talking about/documenting wishes for medical care at the end of life. Readiness appeared to increase more than self-efficacy in both groups. We hypothesized that awareness about the concept of ACP, and possible concerns about the impact of COVID-19, encouraged patients in both groups to think about ACP.[19] During interviews, patients differed in attitudes towards ACP, and in their desire to be involved in decision-making about their health. Some

were very supportive of ACP and found it personally relevant. Other patients, including some who were supportive of ACP as a concept, felt that discussing ACP or documenting care preferences was more relevant for people who were older or had greater disease burden.

Patients may prefer to wait until they feel that ACP is clinically relevant,[34,35] even in cases where current health is poor.[35] More attention should be paid to conveying the relevance and usefulness of ACP to all adults, such as from a perspective of quality of life and holistic care in illness.[34,36] In the workbook, we included vignettes to show how ACP can apply in many health states, but more directly-engaging preparatory work may be needed to bring this message to patients. One simple change may involve the GP providing the workbook to patients, rather than the researchers, so that the GP can explain its rationale at the same time. Working together with patients to develop the intervention and its implementation could have given us more information about whether this would be acceptable to patients. Development of the intervention mainly involved professionals; although patients could provide feedback during the pilot study, a patient and public involvement (PPI) approach,[37] e.g. through experience-based co-design,[38] from the start of intervention development might have identified ways to more closely match the intervention to patients' needs and barriers.

What is the value of the intervention as perceived by GPs and patients?

Our primary outcomes of GP self-efficacy and patient engagement were process-oriented, following theoretical frameworks of behavior change.[17,18,39] During interviews, we also asked GPs and patients to describe how they experienced the impact of the intervention. Some GPs and patients described a perceived impact similar to items in the questionnaires, such as patients thinking more about their wishes for future care, and GPs feeling capable to speak up for these wishes on the patient's behalf. However, GPs and patients also described how engaging in conversations engendered feelings of trust and peace of mind, where patients felt reassured that their GP knew and supported their wishes. This impact aligns with important but under-researched outcomes of ACP within the domain of social, relational, and emotional aspects,[33,40,41] but was not captured by the questionnaire.

For GPs, a recurring theme in interviews was that the intervention offered a more positive framing of ACP, which includes conversations about what "living well" means to the patient. Compared to AD-driven conversations and AD booklets, which they felt were off-putting to patients, this approach felt more fulfilling to GPs and made ACP easier to bring up proactively. It is possible that centering conversations around how best to maintain patient quality of life, mitigated known GP barriers related to fear of depriving patients of hope.[11]

Implications for practice, policy, and research

Despite satisfaction with the intervention and perceived positive impacts by GPs and patients, implementing the intervention may be challenging due to remaining barriers. A lack of time, which was a barrier to reach, adoption, implementation, and maintenance, was a major consideration. This clinician barrier to ACP is frequently reported.[42–46] Given limited available time per consultation, GPs were uncertain how to continue "making time" for ACP.

The low recruitment rate of GPs prompts considering to which extent ACP-GP might reach GPs outside a trial setting. In Belgium, ACP is promoted to GPs through modalities including (online) courses about ADs,[47] training sessions to local peer-review groups,[48] and recently a public health initiative with a website, posters, and flyers.[49] Incorporating components of ACP-GP within these initiatives may improve reach and (sustainable) implementation. Possibilities include wider distribution of the workbook, which GPs saw as a useful tool for their practice, and which poses broader questions than only patients' wishes for end-of-life care. Integrating a quality-of-life-oriented approach in a live training session, such as those to peer-review groups, can supplement judicial information which is now freely available through the practitioner-facing module of the public health campaign website. This could address GPs' desire for more hands-on exercise while limiting time investment.

Results illustrate the importance of conducting ACP over the course of multiple conversations. Since the second conversation was shorter and more often documented in an AD, it could be seen as an opportunity for GPs to check whether and how the first conversation prompted patients' reflection about ACP and, if desired, to concretize wishes for medical care. However, similar to the pilot study, we identified a discrepancy between GP and patient recall of how many conversation were conducted.[16] Some patients may not have recognized that conversations they had with their GP, especially for a brief check-in, could be considered ACP conversations.

There are also implications for GP practice. Recent literature emphasizes a holistic approach involving patients, surrogates, the community, clinicians, health systems, and policy.[50] GPs' unmet needs at the systems level were not addressed by offering a template to document conversations. Rather, documentation systems are not designed to optimize entry of ACP information,[12] so standardization and ease of access directly within the EMR[51] should be prioritized.[52]

GPs considered communication technology essential to facilitating (multidisciplinary) collaboration and follow-up of patients, some of whom expressed preferences to discuss ACP with a specialist care provider. This supports that everyone involved in the patient's care can be alert to opportunities to initiate ACP.[32] In a Belgian survey study, one third of GPs reported

being supported by a practice nurse. Most GPs agreed this collaboration positively impacted GP workload, and that nurses are suitable for providing patient education and health promotion advice.[53] This may offer new avenues for approaching the ACP process in this setting in the future. It is, however, essential that nurses have knowledge, skills, and positive attitudes towards ACP, that the division of responsibilities is clear, and that there is continuity between clinicians.[32]

Normalizing ACP and building patient awareness to ensure its timely initiation may also require upstreaming conversations from a medicalized context to the community.[54] Presentations and workshops, media messaging, and sharing experiences with peers may promote awareness of ACP and empower patients to have meaningful conversations about living well, outside of a clinical setting. This can create a foundation for conversations with clinicians, who can support patients in making care goals concrete.[55]

Strengths and limitations

A strength of this process evaluation is its use of RE-AIM, an intuitive and understandable established framework that can address questions beyond quantitative findings of primary effectiveness.[56] A mixed-method design using quantitative questionnaire data, and qualitative data from interviews, helped us understand how and why results occurred.[57] Analyzing GP and patient perspectives allowed us to find interacting notions of impact, and assess how GPs and patients evaluated the intervention. It also lets us identify barriers and facilitators at multiple levels, upholding the complexity approach which informed the development of the intervention.

The study also has limitations. Qualitative data were only collected from the intervention group, so potential factors leading to observed changes in outcomes in the control group are underexplored. We have reflected on a possible Hawthorne effect or increased awareness as a result of study procedures, in the primary outcome report. GPs who dropped out at T1 cited a lack of time to continue. One additional GP was not interviewed for the same reason, but was retained to data collection via questionnaires. An 'exit interview' with the GPs who dropped out may have added nuance to the findings. However, we also were able to interview GPs who were retained to data collection but did not have conversations with (all of) their patients.

CONCLUSIONS

Implementing the complex ACP-GP intervention in general practice is feasible, and can be successful. When GPs are able to make time for ACP conversations and conduct these using a positive, rather than AD-driven approach, these conversations can be fulfilling and engender

feelings of trust and peace of mind. However, the implementation process is challenging and the sustainability is suboptimal. Our findings will guide future research and recommendations for facilitating and implementing ACP in general practice.

LIST OF ABBREVIATIONS

ACP: Advance care planning

AD: Advance directive

SDM: Surrogate decision maker

MRC: Medical Research Council

RE-AIM: Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance

DECLARATIONS

Ethics and consent to participate

The cluster-randomized controlled trial and parallel process evaluation were approved by the medical ethics committee of the Brussels University Hospital (ref: 2020/068). All participants provided written informed consent to participate in the randomized controlled trial, including the process evaluation. Informed consent was also given specifically to the researchers to contact participants for interviews. Permission to record was confirmed verbally with all participants at the time of the interviews.

Consent for publication

N/A

Availability of data and materials

The data analyzed for the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare no conflicts of interest.

Funding

conception of the study design; in the collection, management, analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

Authors' contributions

Conceptualized the study: JS, LD, PP, ADV, KP

Collected data: JS, ADV

Analyzed data and discussed interpretation: JS, AS, KP, ADV

Drafted the manuscript: JS

Critical revision to manuscript: all co-authors

All authors approved the final manuscript.

Acknowledgments

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SUPPLEMENTARY FILES

Additional File 1. ACP-GP intervention components

Component	Description
1. GP training	The ACP-GP training was initially developed as a face-to-face training. It was adapted to an online format to accommodate COVID-19 pandemic restrictions in Belgium. Two interactive, small-group web sessions were provided by two trainers experienced in primary care and communication. Each session lasted approximately 2 hours. GPs received preparatory materials and background information through an e-learning module, which remained available throughout the course of the study. Intervention materials, such as the conversation guide and an example of the patient workbook, were made available in PDF format. In session 1, GPs discussed their experiences with ACP, fictional case examples and reflection questions, barriers and facilitators to ACP, and video examples. In session 2, GPs practiced intervention-specific ACP conversations with model patients, based on the patient workbook, followed by interactive feedback and discussion.
2. ACP workbook for patients	Patients received an ACP workbook (titled "My Wishes for Future Care") which highlights the importance of ACP at different stages of health. Patients could use the workbook to reflect on topics such as quality of life, worries about future health or care, preferences for decision-making, and whom they can ask to act as a SDM.
3. Patient-centered ACP discussion with conversation guide.	After the training, GPs were asked to conduct a minimum of 2 ACP conversations with each patient: conversation 1 within two weeks after the training, and conversation 2 within one month after the first conversation. The workbook for patients, and the ACP conversation guide for

	GPs, structured the conversation. GPs were reimbursed by the research team for the consultations.
4. Documentation of the ACP discussion	GPs received a documentation template, based on the conversation guide, which they can fill in to make note of the outcomes of the ACP discussion.

Additional File 2. Topic lists for focus groups and interviews

1. Topic list for focus groups and interviews with GPs

Instructions

Goal: To gain insight into how participating GPs experienced the intervention (training, follow-up, ACP conversations, documentation, …), to determine if the intervention was applied as described in the protocol, to identify barriers and facilitators that may have influenced implementation, and which aspects of the intervention can/should be adapted to increase future acceptability.

Design

- Focus group with topic list
- Maximum duration: approximately 1 hour 30 minutes
- Moderator: one researcher takes on the role of leader/moderator and starts the conversation by asking questions of the GPs. The moderator ensures that everyone has a chance to speak and that the conversation does deviate too far from the question. They also introduce new questions from the topic list.
- Observer: for a focus group interview, one or more researchers take on the role of observer. The observer checks the materials, makes notes of the interview, and reviews a summary of the contents with the moderator.
- The interviews are recorded and transcribed.

Materials

- Topic list for moderator and observer
- Paper for the observer to take notes
- Audio-recording device, tested before the interview
- Examples of the materials from the intervention (conversation guide, flowchart, documentation template, patient workbook) that can be presented via screenshare

General instructions

Moderator

- Review the topic list questions well prior to starting the conversation, and to facilitate the conversation during prolonged silence
- Keep the topic list in mind, but allow participants to fully formulate their answers to the questions (do not skip to the next question too quickly)
- Begin the interview in a clear and structured way
- Provide information about the topic and goal of the interview
- Inform participants that an audio recording will be made of the interview
- Encourage interaction between participants, summarize what has been discussed, and probe in case of uncertainty
- Ensure that everyone has a chance to speak. The moderator may have to invite less-vocal participants to share their experiences or opinion.

- Ensure that you as moderator do not participate in discussions or ask suggestive questions. Stay as close as possible to the themes in the topic list, invite participants in a neutral manner to share their experiences or opinion, and stimulate/facilitate the interaction.

Observer

- Pay attention to (non)verbal communication of the participants
- Monitor the time and alert the moderator, if necessary, at the 1-hour-15-minute mark (to begin wrapping up the focus group)
- Make notes of the content of the discussion. You can ask questions if necessary to facilitate the conversation, but do not take over for the moderator
- Make a summary of the most important topics
- Evaluate the discussion with the moderator, immediately after the focus group

Introduction

- Interviewers (moderator, observer) introduce themselves
- Explain the aim of the interview and emphasize that the interview is open to discussing all opinions, questions, and experiences.
- Ask participants to turn on their webcam if possible.
- Explain that the interview will be recorded and that the transcript, analyses, and results will be processed with respect for confidentiality.
- Ask if there are any further questions
- Observer: start the audio recording. Briefly verbally indicate that the audio recording is running.

Theme 1: Training

Introduction: At the start of the study period, you were invited to attend a training about ACP communication skills. This training consisted of an online module and two sessions that were delivered live: a session about experiences and barriers, and a session with simulation patients.

We would like to discuss your experiences with and opinions about the training. The training was delivered in the context of the study, but we aim to optimize and implement it more broadly in the future. Your answers can tell us how we might achieve this.

- The training was originally intended as two face-to-face workshops, but had to be delivered **online**, as an online platform and two web sessions, due to COVID-19 measures.
  - What did you think of this approach?
  - If you could choose between an online version or face-to-face, what would you choose and why?
- What were your **expectations** of the training?
  - Were your expectations met? Why or why not?
- Whom do you think is the most **suitable target group** for the training?
- Did the **didactic method** match your needs?
  - If not, which forms of working would better match your practice or needs (e.g. smaller-group discussions, homework exercises, …)?

179

- **Experiences** with the training:
  - Which part was most novel or useful to you? What was less useful?
  - Were there any challenges or difficulties during the training? How were these addressed?
  - How much time did you spend on the online module? Did you revisit this after the live sessions?
  - What would you like to see added to the training? What could be left out?
  - Were there questions you wanted to ask or difficulties you wanted to address? If yes, did you receive enough answer/support from the trainer/researcher (during and after the training)?
- Would you **recommend** the training to colleagues? Why or why not? If not, what should change before you would recommend the training?

Theme 2: ACP conversations (experiences, barriers, facilitators)

- After the training, did you feel sufficiently **prepared** to have the study-specific ACP conversations with your patient?
  - If not, what would have helped you feel sufficiently prepared?
- Was it easy or difficult to **plan conversations** with patients, and why?
- How were the conversations? **What did you gain** from the conversations and what do you think the patient gained?
  - What do you consider a "good" ACP conversation?
  - Were you able to achieve this during your conversations with your patients?
- How did you use the **conversation materials** (conversation guide, flowchart) during the ACP conversations?
- Which **themes** from the conversation guide/the workbook were most useful to discuss and which was least useful?
  - Most or least difficult?
- What did you **do differently**, in comparison to how you usually conduct ACP conversations with patients in your practice, as a result of the training/the supporting materials?
  - Was there a difference for you?
  - Was there a difference in the reactions from the patient or the depth of the conversation?
- Did the **template** for documentation have an added value on top of the existing options (e.g. in the EMR)?
  - If yes, what is the added value?
  - If no, are there other aspects of documentation you are missing, which were not addressed in the template?

Theme 3: Implementation and maintenance

- For patient inclusion, you were asked to **identify patients** with a chronic, life-limiting illness who meet a 2-year surprise question (you would not be surprised if this patient were to die within 12-24 months).
  - ○ Was it easy or difficult for you to identify patients with these criteria?
  - ○ How is this similar or different to how you identify patients for ACP in your practice?
- Are there **patients we missed** in this study due to the inclusion criteria, whom you think would also be helped by the intervention?
  - ○ What is needed to reach them?
- The study period is (almost) at an end. **Do you still use the intervention** (e.g. the conversation materials)?
  - ○ If yes, in what way do you use them?
- Do you have suggestions to **improve** the intervention?
- How would you prefer to **implement the intervention in your practice**? (e.g. dividing tasks in a group practice, …)
- Are or were any **changes** necessary to help you use the intervention better in your practice?

Closing/summary questions

- We used **questionnaires** with the aim to understand if/how this intervention improves self-efficacy, knowledge, and attitudes in GPs.
  - ○ How do you feel these changed for you?
  - ○ What contributed most/least to changes?
  - ○ What do you think is necessary to change these outcomes?
- Which **impact** did the intervention have on the way you conduct ACP with your patients?
  - ○ What is the added value of the intervention for you?
  - ○ What do you think the added value was for your patients?
- What is the aim of ACP? Do you think this intervention helps to reach this aim?

Concluding

- We have reached the end of the focus group. Is there anything you would like to add?
- Thank you very much for your time, and for sharing your experiences with us.

Observer: indicate verbally that the audio recording is stopped, and immediately stop the recording.

2. Topic list for the semi-structured interview with the patient and their surrogate decision maker (if present)

Instructions

Goal: To gain insight into how participating patients experienced the intervention (workbook, conversations with the GP) to identify barriers and facilitators that may have influenced implementation, and which aspects of the intervention can/should be adapted to increase future acceptability.

Design

–   Semi-structured interview with topic list
–   Maximum duration: approximately 1 hour (by telephone)
–   The researcher leads the interview and uses the topic list to ask the patient open-ended questions.
–   The interviews are recorded and transcribed.

Materials

–   Topic list for the interviewer
–   Pen and paper for note-taking during the interview
–   Audio-recorded, tested before start of the interview

General instructions

–   The topics in this list are a guideline, not a checklist. The goal is to explore what the patient's experiences were and what they recall most about the intervention. If patients cannot recall, questions can be posed about their attitude towards ACP: what would they like to discuss, when, and with whom?
–   Keep the topic list in mind, but allow participants to fully formulate their answers to the questions (do not skip to the next question too quickly)
–   Begin the interview in a clear and structured way
–   Provide information about the topic and goal of the interview
–   Inform participants that an audio recording will be made of the interview

Introduction

–   The interviewer briefly introduces themselves
–   Explain the aim of the interview and emphasize that the interview is open to discussing all opinions, questions, and experiences.
–   Emphasize that the interview is intended to allow all opinions, questions, and experiences to be discussed. There are no right or wrong answers, and negative feedback can also be discussed.
–   Explain that the interview will be recorded and that the transcript, analyses, and results will be processed with respect for confidentiality.
–   Ask if there are any further questions
–   Start the audio recording. Briefly verbally indicate that the audio recording is running.

General questions

- First, I would like to hear what you recall about the study in general: the conversations and the workbook. What did you think of it?
- Can you tell me about what you still recall? There are several topics that may have come up. (If necessary, read an example question from the workbook).
- Did you learn anything new? What did you learn?
- Have you done anything more with everything that came up, after the last conversation? Or would you like to do anything more with it?

Questions about the workbook "My Wishes for Future Care"

I would like to ask what you thought of the workbook you received at the start of the study.
- Do you recall the workbook?
- Did you look at it? Did you write anything in it?
- What was your most lasting impression of the workbook? What was your general impression?
- Do you see yourself using a workbook like this, outside of a study? What would be needed for you to look at and fill in this workbook, if you had not received it as part of the study?
  - Suppose for example, that the workbook was available in the waiting room of the GP's practice?
  - Or if your GP gave it to you after a consultation?
- Are there any other workbooks or brochures that you have used? Does the workbook from the study have any added value for you, on top of the workbooks and brochures that already exist?
- Are there topics related to ACP that you would like to discuss with family, loved ones, or your GP, but which you did not find in the workbook?

Questions about the two ACP conversations

Now, I would like to move on to a few questions regarding the conversations your GP had with you about ACP. These were intended to be at least two consultations to which your GP invited you, and during which the workbook may have been discussed.
- Do you recall these conversations?
- Can you describe how the conversations went? (If necessary, probe:)
  - Did you have the opportunity to raise the topics you most wanted to discuss?
  - Did you have the feeling your GP listened to you? Did they show understanding for the things you brought up?
  - If you had questions, did you have the chance to ask them? Did you receive an answer to these questions?
- What was your general feeling during the conversation? After?
- How would you evaluate the conversations yourself, for example with a score out of 10? (If necessary, probe:)
  - What did you think was good? What was less good?
  - Would you like to plan more conversations like this? Why or why not? At which moment?

| | o | (If surrogate or family was not present at the conversation) Would you consider inviting a loved one or family member to an ACP conversation in the future? Why or why not? |

Questions for if the patient has limited or no recall of the intervention

- Would you like to have a conversation about ACP with your GP in the future? Why or why not?
- At which moment would you want such a conversation?
- Is your GP someone with whom you would like to discuss ACP?
- If you were to talk to your GP about ACP, what would you want to be sure to tell them? What should your GP definitely know?
    - o (The same questions can also be asked about ACP conversations with a loved one or family member)

Concluding

- We've reached the end of the interview. Is there anything you would like to add?
- Thank you very much for your time, and for sharing your experiences with us.

Indicate verbally that the audio recording is stopped, and immediately stop the recording.

Additional File 3. CONSORT chart of recruitment and retention
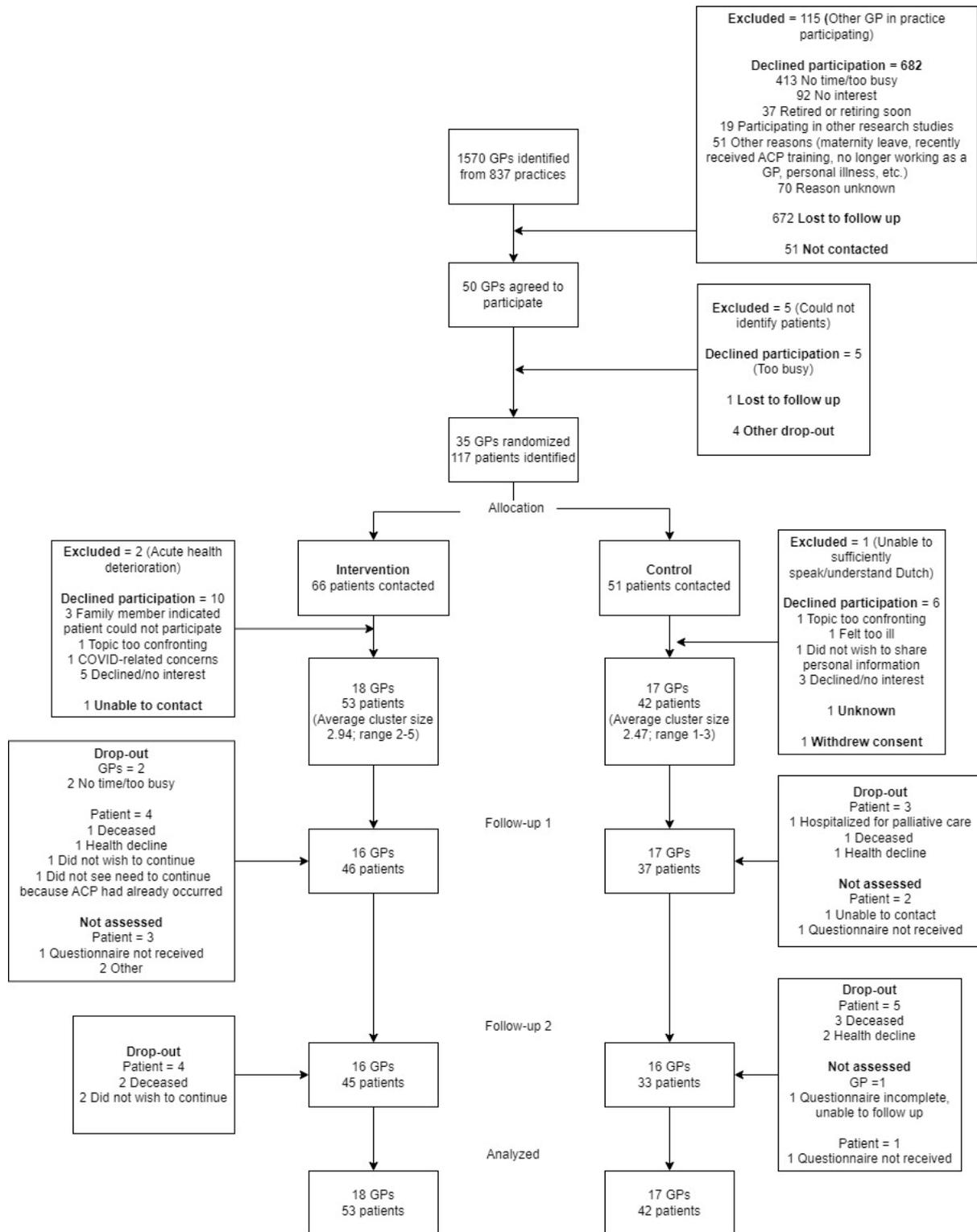
Additional File 4. Baseline participant characteristics by study arm

	Control N(%)	Intervention N(%)
GPs (N)	**17**	**18**
Age ≥37 (sample median; sample range 26-64)	6 (35.3)	12 (66.7)
Female gender	11 (64.7)	9 (50)
Years of practice experience ≥9 (sample median; sample range 1-39)	7 (41.2)	12 (66.7)
Practice type[a]		
Solo	4 (23.5)	4 (22.2)
Group	9 (52.9)	12 (66.7)
Primary care center[b]	3 (17.6)	1 (5.6)
Hospital	0 (0.00)	0 (0.00)
Multiple	1 (5.9)	1 (5.6)
Coordinating and advisory physician[c]	3 (17.6)	1 (5.6)
Palliative home care team member	1 (5.9)	0 (0.00)
Prior training in ACP		
None	14 (82.4)	13 (72.2)
Introductory	2 (11.8)	5 (27.8)
Intensive	1 (5.9)	0 (0.00)
Prior training in palliative care		
None	11 (64.7)	11 (61.1)
Introductory	5 (29.4)	6 (33.3)
Intensive	1 (5.9)	1 (5.6)
Patients (N)	**42** [d]	**53**
Age≥80 (sample median; sample range 42-95)	23 (54.8)	25 (47.2)
Female gender	25 (59.5)	25 (47.2)
Marital status		
Married, civil union, domestic partnership	17 (40.5)	28 (52.8)
Widow(er)	17 (40.5)	20 (37.7)
Divorced, or single never married	8 (19)	5 (9.4)
Highest educational attainment		
Primary school	5 (11.9)	13 (24.5)
Secondary school	29 (69)	33 (62.3)
Post-secondary school	6 (14.3)	7 (13.2)
None of the above	2 (4.8)	0 (0.0)
Person most involved in care		
Spouse or partner	11 (26.8)	24 (45.3)

Child	17 (41.5)	15 (28.3)
Other family member	5 (12.2)	7 (13.2)
Other, not a family member	7 (17.1)	6 (11.3)
No person identified	1 (2.4)	1 (1.9)
Living together with person most involved in care	11 (27.5)	24 (45.3)
Religion		
Religious (Christianity)	26 (61.9)	31 (58.5)
Not religious	15 (35.7)	20 (37.7)
Prefer not to say	1 (2.4)	2 (3.8)
Advance directives (AD) completed[e]		
AD to refuse medical interventions	7 (16.7)	8 (15.1)
AD for euthanasia[f]	9 (21.4)	9 (17.0)
AD for funerary arrangements	5 (11.9)	4 (7.5)
AD for organ donation	1 (2.4)	3 (5.7)
Testament for donating the body to medical science after death	1 (2.4)	1 (1.9)
Other directive(s)	0 (0.0)	4 (7.5)
None	31 (73.8)	39 (73.6)
Oncological diagnosis	15 (35.7)	17 (32.1)

a Belgian GPs are providers of primary care; GPs may work in single-physician (solo) practices, in (sometimes multidisciplinary) group practices with multiple GPs, and in multidisciplinary primary care centers.

b Primary care setting with a multidisciplinary collaboration, including one or more general practitioners, which is highly accessible and has a low financial threshold.

c General practitioner, preferably trained in gerontology, who is responsible for the coordination, organization, and continuity of medical care within a nursing home. A coordinating and advisory physician also manages the training of nursing home staff, including in the field of palliative care.

d Missing values: Person most involved in care n=1; 2 Living together with person most involved in care n=2

e Multiple responses possible

f AD for euthanasia in the case of irreversible coma

PART III. International insights into the implementation of ACP interventions

Chapter 5

Complex advance care planning interventions for chronic serious illness: how do they work? a scoping review

ABSTRACT

Context: Advance care planning (ACP) interventions have the potential to improve outcomes for patients with chronic serious illness. Yet the rationale for outcome choices and the mechanisms by which outcomes are achieved are not always clear.

Objectives: To identify and map proposed mechanisms on how complex ACP interventions can impact outcomes for patients with chronic serious illness and to explore factors that might explain intervention outcomes.

Methods: This is a scoping review of randomised controlled trials of complex ACP interventions for patients with chronic serious illness which explicitly stated the mechanism(s) by which the intervention was thought to work. We searched six databases and hand-searched key journals and reference lists.

Results: Inclusion yielded 16 articles. Inclusion procedures and mapping of mechanisms and outcomes indicated that causality between components and outcomes was not always clearly described. Tailoring intervention content to patients' needs was linked to the greatest number of different outcome categories, while promoting competence and confidence to engage in ACP was most often explicitly linked to a primary outcome. Three main factors which might have affected intended outcomes were identified: participant characteristics, such as illness experience or cultural differences; the setting of implementation; or methodological limitations of the study.

Conclusion: Findings highlighted two main points of consideration for future ACP intervention studies: the need for clearly stated logic in how interventions are expected to impact primary outcomes and the importance of considering how an intervention may function for patients with chronic serious illnesses within a specific setting.

Key Messages:

1. What was already known?

- Examining how advance care planning (ACP) interventions are currently proposed to affect outcomes can guide expectations of what ACP can achieve.

2. What are the new findings?

- Building skills and confidence was most often used to explicitly state how the intervention would affect outcomes.
- Contextual factors considered a priori mainly related to sociocultural factors and racial disparities. Other factors were considered in light of results obtained.

3. What is their significance?

- Intervention rationales are identified, but further clarity is needed regarding how components operate.
- Participants, setting, and study design effects should be considered a priori.

INTRODUCTION

Advance care planning (ACP) refers to a process which *'enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and health-care providers, and to record and review these preferences if appropriate'*.[1] This can, but not necessarily must, entail or result in the completion of an advance directive (AD) specifying care wishes, which can be used in the event the patient loses decisional capacity. It can also involve the appointment of a surrogate decision maker (SDM) who makes decisions about medical care in the patient's stead. By communicating with health professionals, informal caregivers, family members and loved ones, patients engaging in ACP can make their wishes for future health care known. Additionally, ACP can help patients and their SDM be better prepared to make the best possible in-the-moment care decisions together with clinicians.[2]

Studies of interventions designed to implement or improve ACP, as well as reviews of the ACP research literature, demonstrate a large degree of heterogeneity in outcomes and evidence of effectiveness, and suggest that complex interventions may be more effective in meeting patient preferences for end-of-life care.[3–7] The spectrum of outcomes ranges from proximal outcomes, such as ACP engagement, to distal outcomes such as concordance of care with patient wishes.[8] For many of these outcomes, reviews report mixed findings.[3–5,7,9] Most recently, a scoping review of ACP randomised controlled trials (RCTs) mapped the outcomes of interventions according to a standardised ACP Outcome Framework. This review found a greater percentage of positive results for outcome domains related to processes (such as knowledge) and actions (such as completion of an AD) than for quality of care, health status and healthcare utilisation. As a result, the reviewers recommended further research to tailor interventions to specific contexts and to set appropriate expectations of ACP outcomes.[10] Taken together, this highlights the current state of the scientific discourse around ACP in terms of its conceptualisation and its goals.[11–14] Indeed, questions have been posed about whether ACP has the capacity to address what has been defined by a Delphi panel as its most important outcome, namely goal-concordant care, leading to discussions regarding what the focus of ACP research ought to be.[15–17]

The workings of ACP as a process are complex,[18,19] but this complexity may not always be addressed in the research literature and may be overlooked when interventions and outcomes are considered discretely. To set appropriate expectations for ACP interventions, it is important to consider not only the content of an intervention, but also how the intervention is expected to lead to the outcomes of interest.[20] A recent review of ACP interventions for patients with cancer indicated that studies propose different mechanisms by which ACP

interventions are expected to affect outcomes, but that not every paper does so in equal detail.[21] This implies that adequate attention for the rationale[22] of ACP interventions may be lacking, at least in the reporting of these interventions. In the middle of a debate where the benefit of continuing ACP research is coming into question,[16] this is especially concerning. In a response to Dr Morrison's notes from the editor,[16] Montgomery *et al.*[23] call for further work to develop evidence-based conceptual models of ACP. This response further notes that the intervention logic must also be considered within the system where the intervention is implemented. To our knowledge, however, no review of ACP interventions exists for chronic serious illness that specifically investigates not only intervention components and outcomes, but also the mechanisms by which the intervention is hypothesised to affect said outcomes— that is, what do authors expect the intervention will achieve and how? Neither has a review examined whether and how the authors of these articles explain the study findings that were obtained—for example, if the intervention did not achieve the expected results, is this due to factors intrinsic to the intervention; do systemic factors preclude intervention impact; or should the hypothesised mechanism be re-evaluated to more accurately reflect what ACP can accomplish?

Insights in these fields will aid the development of new interventions to facilitate ACP or the refining of existing initiatives. This is made possible by first identifying pathways from interventions to outcomes via hypothesised mechanisms. Then we can assess which pathways yield positive results, while also highlighting contextual and implementation factors that should be considered. Altogether, this allows us to identify gaps in the current research at different 'links' within this 'chain'.

The purpose of the present scoping review was to identify which mechanisms are proposed to explain how complex ACP interventions, tested for effectiveness through an RCT, are expected to impact outcomes for patients with serious illness, to establish the factors authors refer to in order to explain the study findings, and to map the available evidence.

The research questions can be summarized as follows:

1. What are the core components of the intervention?

2. Which primary outcome(s) is/are chosen to evaluate the effectiveness of the intervention?

3. What is the mechanism by which authors propose the intervention will work to generate change in outcomes?

4. What are the results for the primary outcome(s)?

5. Which factors contributed to intervention success or failure to affect the primary outcome(s), according to the authors?

METHODS

Study design

To address the aims of this study, a scoping review design was considered most appropriate.[24] A scoping review is a process of mapping and describing the existing literature, which can be undertaken when the area of study in question is complex[25] and/or heterogeneous in methods or in discipline.[26] This scoping review was conducted according to the methodological framework set forth by Arksey and O'Malley[25] and the additional recommendations by Levac *et al.*[27] The framework recommends the following steps: (1) identifying the research question; (2) identifying relevant studies; (3) study selection; (4) charting the data; and (5) collating, summarising and reporting the results. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews checklist (PRISMA-ScR)[26] was followed for writing the present review report.

Search strategy

We conducted an online search of the following databases: PubMed, PsycINFO, MEDLINE, Embase, Cochrane Central Register of Controlled Trials (CENTRAL) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). Key terms, Medical Subject Headings (MeSH), Emtree headings and CINAHL headings were used in their applicable databases. The search was first conducted in March 2020 using a search strategy informed by terms and keywords used in existing systematic reviews of ACP.[3–6] This strategy underwent piloting to ensure the search was sensitive enough to capture key articles, yet specific enough to avoid capturing large numbers of irrelevant articles (see Supplementary Figure 1 for an example search strategy). The search was last repeated on 18 November 2020 to identify additional articles that may have been published since the initial search. We included studies that were published in the English language from 1 January 2010 to the date of the last search. Filters were applied for publication type (journal articles, articles in press) where possible.

The references of key articles were screened for additional studies to include. We also hand-searched the most recent issues of the following key journals: *Journal of Palliative Care*, *Journal of Palliative Medicine*, *Journal of Pain and Symptom Management*, *Journal of the American Medical Association*, *BMJ Supportive & Palliative Care*, and *Palliative Medicine.*

Eligibility criteria

Papers were considered for inclusion based on the criteria specified in Table 1.

Table 1. Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Concerns a peer-reviewed article,	1. Published prior to January 1, 2010
2. reported in English,	2. Does not state which outcome is considered the primary outcome
3. of primary research,	
4. reporting on the quantitative primary outcome(s)	3. Reports feasibility and/or satisfaction outcomes only
5. of a randomized controlled trial,	4. Reports on a secondary analysis of an RCT only
6. of a complex advance care planning intervention	5. Reports on a trial where ACP is embedded in a broader intervention, such as palliative care interventions that also include pain or symptom management, so that it is not possible to distinguish discrete effects of the ACP component
7. for chronic serious illness	
8. in a sample of adults (>18 years old)	
9. where the mechanism(s) by which the intervention is expected to generate changes in outcomes is/are described,	
10. conducted in any setting	6. Reports on psychiatric advance directives and/or crisis planning
	7. Reports a study protocol only

A primary determinant of intervention complexity was the number of components in the intervention, which could be delivered separately or as a package. Interventions with two or more components were considered complex. Interventions consisting of one facilitated discussion were also considered complex due to the flexibility permitted and the training required of the person facilitating the discussion.[20]

The study introduction and methods sections were read closely multiple times to ascertain whether the study explicitly states or describes the mechanism(s) by which the intervention was expected to generate changes in outcomes.

Methodological quality was not considered an exclusion criterion as we sought to provide an overview from RCTs of complex ACP interventions for chronic serious illness.

Selection of sources of evidence

All retrieved articles were uploaded to Zotero reference manager. Duplicates of retrieved records were removed. Titles and abstracts of all identified articles were screened against the eligibility criteria by JS using a standardised form. Articles identified as potentially relevant were retrieved in full. Full-text screening against the eligibility criteria was completed by JS.

During both steps of the screening process, cases of doubt were checked by a second researcher (ADV). During title and abstract screening, if there was unresolved ambiguity, the article was retained for full-text review. In the case of ambiguity in the full-text screening step, a third researcher (KP) was consulted for discussion to achieve consensus.

Data charting process

The following characteristics of the study were extracted using a standardised data charting sheet, which was developed through iterative discussions between the authors: study authors, publication year, country, study setting and sample characteristics. Data extracted regarding the study design included conceptual model or theory used (if any), core intervention components, control condition, duration of the intervention, primary outcome(s), mechanisms and primary findings. Each article was examined for the implications of the results for the proposed mechanism(s) and/or factors which were considered to have impacted the results (eg, contextual factors). Relevant text excerpts were extracted. Two authors (JS and ADV) cross-checked the data from a small sample of studies to achieve consensus regarding the extracted text, after which one author (JS) proceeded with the remaining charting.

Synthesis of results

After data extraction, we used descriptive statistics to describe the included studies. Relevant excerpts were imported into NVivo for qualitative analysis. In the first step, open codes were applied to the extracted text regarding intervention components, mechanisms and factors impacting the effect of the intervention on the primary outcome(s). The codes were then combined into descriptive themes. Mechanisms and the outcomes they were expected to generate were mapped in order to indicate which retained articles specified links between mechanisms and outcomes.

RESULTS

Of 1535 articles identified, 16 met the eligibility criteria and were retained for analysis (Figure 1)

Figure 1. PRISMA flow chart of search results.

Identification

Records identified through database searching (n=1535)

Additional records identified (n=5)

Screening

Records after duplicates removed (n=697)

Records screened (n=697)

Records excluded (n=586)
Abstract only: 24
No abstract: 3
Not ACP: 242
Not adults: 17
Not an RCT: 102
Not an RCT outcome report: 32
Broader than ACP alone: 44
Protocol, design or trial registration: 62
Psychiatry: 14
Review: 32
Other: 14

Eligibility

Full-text articles assessed for eligibility (n=111)

Full-text articles excluded (n=95)
No fulltext available: 1
No primary outcome specified: 11
Feasibility or secondary analysis only: 22
Not an RCT: 9
Not ACP or broader than ACP alone: 4
Not a complex intervention: 14
Not for chronic serious illness: 17
No mechanism specified: 17

Included

Studies included (n=16)

ACP, advance care planning; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; RCT, randomised controlled trial.

Study characteristics

The characteristics of the retained studies can be found in Supplementary Table 1.

Ten studies were conducted in the USA, two each in the Netherlands and Australia, and one each in Belgium and Northern Ireland. Participants included patients with cancer, dementia, geriatric frailty, end-stage renal disease, heart failure, HIV and comorbid chronic serious illnesses. Nine studies included dyads of patients and a family carer or SDM.

Intervention components

Of the 16 studies retained (Supplementary Table 1), the largest portion (11 studies) made use of an interview or conversation to address the topic of ACP.[28–38] Conversations were led by

facilitators including (trained) nurses,[28,29,32,34-36,38] psychologists,[31,32,37] social workers,[31-33] or graduate students.[31,32] Five conversation interventions also included the provision of conversation summaries and/or ADs completed during the conversation to the healthcare provider (general practitioner or treating physician) or placement of documentation in the patient's health record.[28,29,31,32,36]

Eight studies made use of an AD or goals of care form, which was presented for the patient to read or completed during an interview or discussion.[28,31,32,34,36,39-41] Six studies used informational material in online repository, pamphlet or video format.[34,37-41] Four studies used question prompts and conversation openers for patients or communication tips for health providers,[29,38,41,42] with two of these studies also including instructions for health providers to facilitate the discussion or endorse use of question prompts.[29,38] Three studies used an interactive decision aid in website format for patients.[39-41] Two interventions used interactive educational workshops for general practitioners or nursing home staff.[42,43] One intervention provided ACP education to participants, but the content of the education was not specified.[33]

What are the primary outcomes, and by which mechanism do authors propose they are achieved?

The outcomes and the mechanisms by which they were proposed to be achieved are mapped in Figure 2.

In total, nine types of primary outcomes were identified: decisional conflict, dyad congruence, AD or Do-Not-Resuscitate (DNR) order completion, psychospiritual well-being, quality of life, number of conversations/consultations, content of discussions with health providers, patient activation and place of death.

Seven descriptive themes were identified to describe the mechanisms by which interventions were proposed to affect the primary outcome(s): (1) tailoring the intervention to the patient recipient (their coping style, health literacy, desire for information, beliefs and misconceptions) to make the intervention more understandable and acceptable; (2) educating patients and carers/surrogates about the course of illness, treatment options and styles of shared decision making in order to facilitate better understanding of these topics; (3) encouraging active involvement of carers/surrogates and health providers in ACP conversations to promote a shared understanding of the patient's values and preferences; (4) exploring the patient's illness beliefs, preferences and values in a systematic way to give the patient an opportunity to reflect on these topics; (5) increasing the degree to which patients, family carers/surrogates and health providers recognise the importance of ACP; (6) addressing the patient's need for social support in their decision making and ACP behaviour; and (7) promoting patient and health provider skills, competence and confidence necessary to have ACP conversations.

Figure 2. **Linkage of mechanisms to outcomes.**
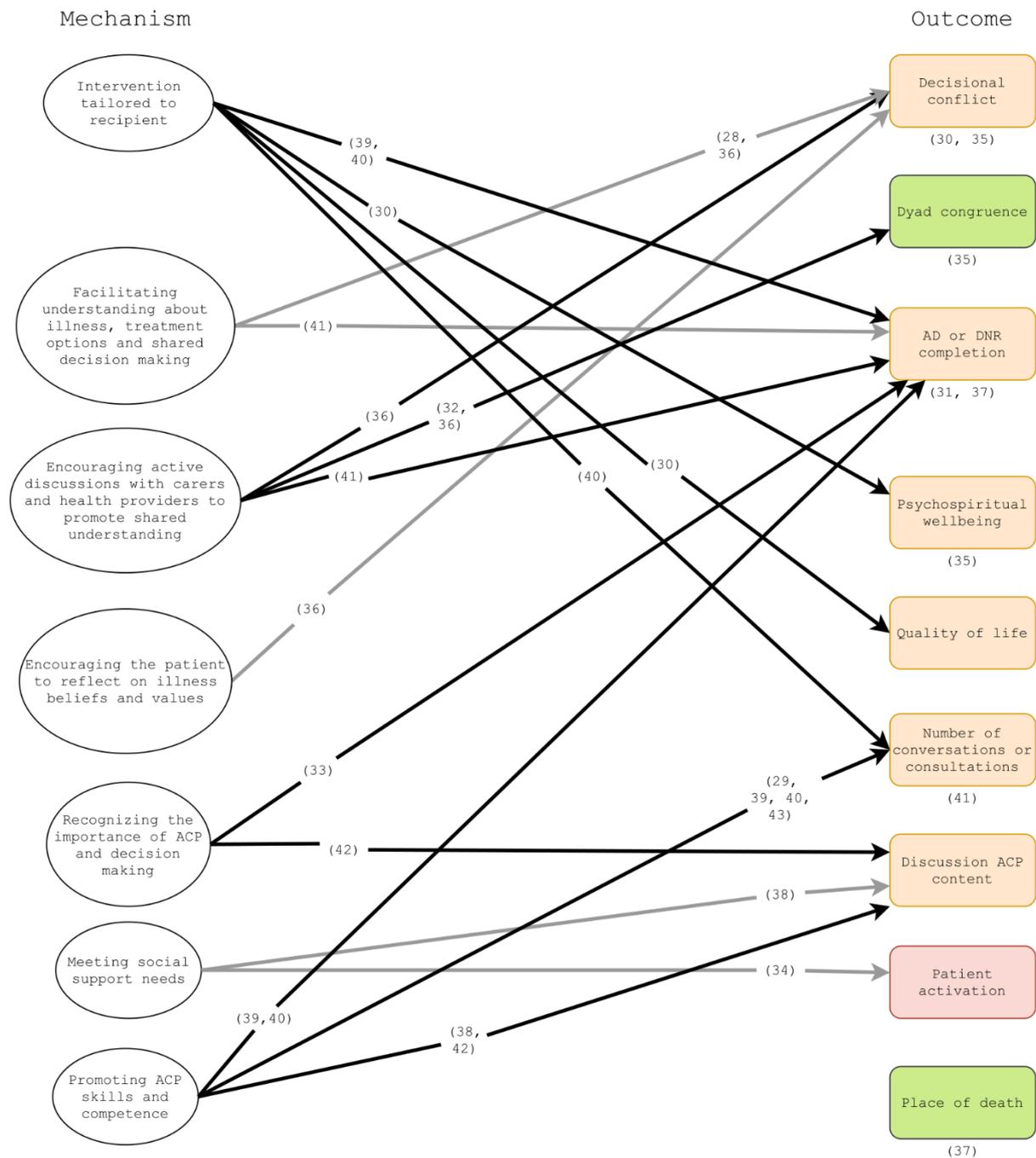
In this figure, references where linkages between mechanisms and outcomes were made are illustrated using arrows. Where an outcome is described but not how it is expected to be achieved, the reference is placed under the outcome cell.

Green outcome cells: positive findings; red outcome cells: negative findings; orange outcome cells: mixed findings.

ACP, advance care planning; AD, advance directive; DNR, Do-Not-Resuscitate order

Studies ranged from referring to a single mechanism (eg, facilitating family carer understanding of the course of dementia and different therapeutic options in order to reduce decisional uncertainty)[28] to several mechanisms (eg, attending to health literacy and other

individual differences, building skills to engage in ACP and encouraging the inclusion of family in the process).[40]

Tailoring the delivery style or content of the intervention to the particular needs of the patient recipient, such as by matching intervention delivery to the culture of the patient population, responding to the patient's coping style or by attending to limited health literacy,[30,39,40] was the mechanism linked to the greatest variety of outcome domains. When information was presented in a personalised way, it was anticipated to be more understandable and acceptable to the patient, and maximising the prevalent coping strategies of patients allowed for a strengths-based approach in one intervention.[30] This tailoring was expected to increase the number of conversations patients then conducted about ACP, their completion of ADs,[39,40] and emotional and health-related outcomes.[30]

Promoting the skills, competence and confidence necessary to participate in ACP conversations, both for patients and health providers, was referred to in the greatest number of studies which stated how the primary outcome was expected to be achieved. It was considered a mechanism for effecting change in the number of conversations conducted about ACP and end-of-life care,[29,39,40,43] for improving AD completion rates,[39,40] and for increasing active participation and shared decision making during ACP conversations.[38,42]

What are the findings for the primary outcomes?

An overview of findings for the primary outcomes can be found in Supplementary Table 2. Dyad congruence was the only primary outcome for which a positive result was reported across multiple studies.[32,35,36] One study, using a pamphlet and a discussion with a psychologist to help the patient reflect on their values towards end-of-life care, found a reduced likelihood of hospital death.[37]

An intervention including informational leaflets and an ACP conversation during which an AD was completed did not increase patient activation.[34]

For all other outcomes, results were mixed (see Supplementary Table 2).

What impacts whether or not the intervention achieves the desired outcome?

After coding the factors through which authors explain intervention findings, as well as the success or failure of the intervention to affect the primary outcome(s), three overarching themes were identified: participant factors, implementation factors and methodological factors.

Participant factors include both individual characteristics as well as possible cultural differences. Five studies evaluated an intervention in diverse or non-white populations; these studies all made a priori considerations of the influence of racial disparities and their impact

on access to quality end-of-life care.[31,33,35,36,40] According to one study, treating the family as an asset to the ACP process through rapport-building communication can help an intervention align with African American participants' needs.[31] Minority populations such as Latinos may also face language barriers, which limit access to end-of-life communication. One study reported that, additionally, Latinos may not want to burden family members with distressing issues such as end-of-life conversations.[33] Attending to barriers such as those posed by language and health literacy can increase the likelihood of intervention success.[40]

The authors of six studies reflected on the impact of the patient's illness experience on study outcomes. Physical pain or discomfort from treatments may reduce the likelihood that a patient engages with the intervention.[33,41] In the case of chronic illness or illnesses with a less-predictable trajectory, patients may see treatment as a fundamental part of their lives or aim to live well within their condition, hindering contemplation of alternative care options.[31,35,43] When question prompts are used in an intervention, patients who are not exclusively receiving palliative care may find it difficult to ask questions about the end of life, even after prompting.[38]

In order to engage in ACP, patients must be willing to discuss the topic and desire a role in decision making about future care.[37] When they do not, their engagement with ACP interventions may be limited.

The impact of other patient characteristics was less clear. The effect of age on patient use of online interventions is uncertain.[41] The differences between heterosexual and homosexual patients in ACP interventions for patients with HIV, also merit further consideration.[32] Finally, the authors of two studies noted that their samples were predominantly male, but the impact of gender was not further explored.[38,39]

Implementation refers to how the intervention was realised within the study setting. The brief duration of an intervention (eg, one conversation) was noted by two authors as a possible explanation for an absence of effects, as it may not have provided patients enough time to prepare for decision making.[30,35] The authors of four studies highlighted the importance of engaging the surrogate, caregiver or family;[29,33,33,41] failing to do so may contribute to null results.[41] The authors of four studies emphasised that for ACP interventions involving health providers to achieve the intended outcomes, providers must be trained in ACP and communication skills so that they can initiate conversations and respond to patients.[28,37,38,43] Two interventions could not be implemented system-wide[34,42] and one online intervention was not simple to use.[41] The context of an RCT also may not fully reflect the context of daily practice.[34] Finally, the authors of one study considered that findings may have been related to the implementation of ACP within a healthcare context that has a history of avoiding overtreatment, where there may be less to be gained from ACP.[34]

Methodological factors refer to how the study and its measurements were conducted. These include assessment effects, which may activate patients,[36,38-40] contamination of health providers attending to both intervention and control arms,[29,38] poor outcome fit, lack of fit between construct and measurement, or timing of measurements.[30,34,35] Two studies relying on documentation of ADs and ACP conversations for outcome assessment revealed clinic-level differences in the accessibility of ADs in the patient health record[31] and potential registration bias in the medical file.[43]

DISCUSSION

This scoping review examined 16 RCTs of complex ACP interventions for patients with chronic illness, finding results that affirm the heterogeneity of intervention components, mechanisms and outcomes identified in the existing literature.[3,5,7,10]

In the retained studies, outcomes across nine categories pertained to ACP actions such as completing an AD, having consultations, patients stating their treatment preferences or SDMs judging the treatment preferences of the patient, or utterances regarding shared decision making and ACP topics during consultations. Outcomes related to patient well-being included quality of life measures as well as psychospiritual well-being. One study reported on a care utilisation outcome, namely place of death. Additional outcomes included decisional conflict and patient activation. Interventions were expected to influence these outcomes through mechanisms which could be grouped into seven descriptive themes, with an apparent overall emphasis on a tailored approach which facilitates understanding about the patient's illness and treatment options, encourages the patient to reflect on their personal values, and encourages the patient to talk about these topics with their carers and health providers. In order to proceed with these conversations, interventions may also encourage patients and health providers to see the importance of ACP and should equip them with the skills and confidence necessary to have these discussions effectively. Of these, the mechanism of intervention tailoring stood out as being linked to the greatest variety of outcomes in the included studies. Promoting ACP skills, confidence and competence was the mechanism most often explicitly linked to an outcome.

A finding of the present review which has not yet been fully described elsewhere is that a portion of the studies retained for full-text screening did not specify how the intervention was expected to achieve its primary outcomes: a total of 17 of 111 studies were excluded specifically for this reason.

While the application of the inclusion criteria meant that all included studies described how the intervention was expected to work or outcomes were expected to be achieved, not every study

specified the mechanisms for each included component or the mechanism to which a particular outcome was expected to respond. Specifically, the anticipated impact of informational materials,[34, 37-39] the provision or completion of an AD form,[28,29,31,32,34,41] and the provision of the completed AD or conversation summary to a health provider or the upload thereof in the patient's medical record[28,29,31,32,35] was most often not explained by the authors. The mechanisms by which decisional conflict,[30,35] AD/DNR completion,[31,37] dyad congruence,[35] psychospiritual wellbeing,[35] and the number of consultations with palliative care[41] were expected to change were likewise not always specified. In the one study to include place of death as a primary outcome, the authors did not state through which mechanism this outcome was expected to change; outcome selection was based on the finding that patients prefer to avoid hospital death.[37]

Outcomes are measured after the implementation of an intervention, in all its complexity, and components of such complex interventions may be synergistic.[39,40,44] This makes it difficult to disentangle to which degree individual components contributed to the achieved outcomes,[37] and we cannot make decisive statements regarding which components of ACP do or do not work. This is, however, not the intention of this scoping review. What we do find is that the contributions of intervention components such as informational materials, AD forms and sharing of conversation summaries or ADs with health providers—that is, the 'how' and 'why' of these components—are often not fully explained in the present literature. The linkage of the identified mechanisms to specific outcomes similarly lacks clarity. This may make it more difficult to ascertain what the 'active ingredients' of these complex interventions are and how they work, especially in the absence of a process evaluation.[20]

Which outcomes ACP interventions can or should result in is still a topic of discussion. Even in this sample of studies that is smaller than that of a recent scoping review of ACP trials,[10] we found a heterogeneous selection of primary outcomes. Although a Delphi panel ranked care concordance with patient wishes highest in a list of outcomes that define successful ACP,[15] no included study featured it as a primary outcome. This outcome may require intermediate steps, such as patients being able and willing to talk about ACP, having discussions to make their wishes known to health providers and said wishes being documented. Other outcomes, such as quality of life, care and dying, may be too distant to be achieved by an ACP intervention alone, lying above the 'ceiling of accountability' for such interventions.[45] Additionally, when trials examine outcomes pertaining to actions such as the occurrence of a consultation, it may be equally important to consider the quality of such consultations and the attention that is paid during these consultations to patients' values and concerns.[46]

Given the ongoing debate regarding ACP as a process and the outcomes which should be used to measure 'successful' ACP,[15–17] these findings, viewed together, are indicative of a gap in how ACP interventions are currently reported and a point of consideration for future intervention research endeavours, from intervention development to implementation and assessment. Here, we echo the statement of Lin *et al.*[21] that identifying causality between the components of an intervention and the outcomes which are chosen to evaluate its effectiveness is a crucial element of publishing intervention research. Greater attention should be paid both to robust intervention development which articulates how the intervention will effect change and to clarity in reporting these mechanisms.[21,22,47]

The present scoping review lends insight into the rationales presented for outcome choices in ACP intervention trials, but also identifies potential problems in the implementation and evaluation of interventions. Even if an intervention is clear in how it is proposed to work, it may face problems during implementation: a mismatch between intervention and target population, implementation setting or the methodology of the trial.[48] An absence of significant findings may indicate the intervention does not work as hypothesised or may point to 'teething problems' in implementation.[20] The impact of ACP on the aggressiveness of care at the end of life, for instance, may be moot in settings where overtreatment or aggressive end-of-life care is not the norm;[34] the impact of an intervention may be limited when patients with chronic life-limiting illness are too unwell to make use of the intervention—or simply do not know how to navigate it.[33,41] These are, ideally, factors which researchers should visualise before proceeding with an implementation study, for instance through consultation with key stakeholders.[49] Of note are several interventions from the current scoping review which do precisely this, for example by taking into consideration the impact of racial disparities and then tailoring the approach of the intervention to the needs of the target population.[31-33,36,40] Finally, factors which are found in one study to impact intervention results, such as lower patient motivation to engage in ACP behaviours, have the potential to be addressed through components of interventions identified in other studies, which, for example, work by building competence and confidence and by encouraging participants to recognise the relevance of ACP.

Strengths and limitations

This scoping review is, to our knowledge, the first review to assess in RCTs of ACP interventions for chronic life-limiting illness the ways in which outcomes are expected to be achieved. By evaluating the linkage between intervention components, mechanisms and outcomes, we were also able to highlight gaps in research reporting, be it in the link between component and mechanism, or mechanism and primary outcome. Taking into account factors described by authors to explain success or failure to achieve the intended outcomes lays bare important considerations that should be made ahead of time when conducting ACP research,

such as attention for the target population, the implementation of the intervention in a given setting and methodological factors. This scoping review can serve as a springboard for future realist reviews and evaluations of ACP interventions where cross-sectional, qualitative and grey literature are also included..[50]

Data charting for this study was done largely by one author (JS) after cross-checking a sample of extractions with a second author (ADV) and discussing the information to be extracted with all authors. The synthesis of results was performed by one author (JS). Findings were regularly discussed with other members of the research team. The framework for data charting and overall synthesis was discussed during multiple meetings with all authors, and the first and last authors conducted weekly meetings during which findings could be discussed. While we chose to include only RCTs, we did not assess the risk of bias for these studies, consistent with scoping review methodology. Further, we only included trials which involved adult patients with chronic life-limiting illness. Interventions for community-dwelling adults or populations of paediatric patients with chronic life-limiting illness may yield different findings.

CONCLUSION

This scoping review identified components of complex ACP interventions for chronic serious illness, as well as seven mechanisms by which nine outcome categories were proposed to be affected by these interventions. In reporting primary effectiveness in RCT studies, the mechanisms by which the intervention is anticipated to impact the chosen outcomes are, however, frequently unstated or unclearly stated; reporting emphasises 'what' is being done but less frequently refers to 'why' this is being done. Mechanisms such as promoting ACP skills, confidence and motivation, as well as allowing for intervention tailoring to the patient's needs, come to the fore most clearly from this review. ACP interventions should take into account patients' illness experience, willingness to engage in ACP and broader cultural considerations; these should ideally be considered during development to allow for an intervention that is sensitive and responsive to these factors. So too should researchers consider the setting in which the intervention is implemented and how the study and its measurements are conducted. In the light of recent debates regarding what outcomes ACP can be expected to achieve, this review indicates, in sum, ACP interventions do have potential to improve outcomes, but researchers should be clear in how they anticipate these outcomes will be achieved and consider the context in which these interventions are implemented.

FUNDING

DISCLOSURES

AUTHOR CONTRIBUTIONS

All authors contributed to the conception of the study and the formulation of its research questions. JS conducted the searches. Eligible studies were identified by JS with support from ADV and KP. Data extraction was performed by JS and checked by ADV. JS analyzed the data and drafted the manuscript. All authors reviewed the manuscript, provided feedback during multiple rounds of discussion, and approved the final draft.

ACKNOWLEDGMENTS

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SUPPLEMENTARY FILES

Supplementary Table S1: Characteristics of included studies

Author (Year)	Country	Setting	Participants	Core intervention components	Control	Duration of intervention	Mechanism (how are outcomes achieved?)	Theoretical model	Primary outcome	Main study findings	Factors which may impact results
Brazil et al. (2018)[28]	Northern Ireland	Nursing homes	Family carers of residents with dementia	Information booklet Two family meetings guided by trained nurse facilitator Meeting 1: Contents of the booklet reviewed, family carers assisted to reflect on resident's goals, values, beliefs, and EoL care options Meeting 2: Opportunity to review a draft care plan and to sign a standardized advance care plan document. Advance care plan placed in resident's medical record and sent to the resident's GP.	Usual care	Meetings on average 60 minutes	To help family carers participate in decision making about GoC at the EoL, they need to understand the course of dementia, possible complications and therapeutic options. This reduces decisional uncertainty.	N/A	Family carer uncertainty in decision-making	Reduced	Successful ACP is predicated on the initiation of a health care provider, within a trusting relationship, who recognizes the importance of ACP discussion timing. The presence of carer stress and conflict around making the "right" decision makes the decision making process challenging.

Study	Country	Setting	Population	Intervention	Comparator	Training	Rationale	Theory/Model	Outcome	Effect	Comments
Doorenbos et al. (2016)[29]	United States of America	Academic heart failure clinic	Patients with heart failure	**Patient intervention**: Telephone-based pre-visit coaching by a nurse, including Five Wishes AD One-page patient activation outline Patient activation, skills enhancement, and role playing conversation openers. **Provider intervention**: Receipt of patient activation outline Patient-specific information and communication tips Provider asked to facilitate discussion	Regularly scheduled outpatient clinic visits in the HF Clinic	Not stated	The intervention is designed to assist patients and health providers to initiate conversations.	Self-management for chronic conditions model	GoC conversations	Increased in number	Caregivers, who are influential in heart failure care, were not included. Providers had patients participating in both arms and may have become more aware of the need for GoC conversations with all patients.
Goossens et al. (2020)[42]	Belgium	Nursing home wards	Staff members, residents and families	"We DECIde optimized": 2 workshops presenting three modules: (1) theoretical information on ACP and SDM	No training	Two 4-hour workshops separated by 1 month	Professionals must see themselves as competent or knowledgeable enough to engage in ACP	Three-talk model for shared decision making	Level of shared decision making during formal ACP conversations	Increased	Professionals often prefer a single care option. This personal bias might hinder shared decision making. Organizational barriers and high turnover of staff

214

Study	Country	Setting	Population	Intervention	Comparator	Duration	Mechanism	Theory	Outcomes	Results	Conclusions
				(2) role play exercises (3) reviewing the internal ACP policy Homework assignment between sessions Information campaign informing residents and families of ACP Pocket cards with questions to ask health professionals			conversations, and must perceive the importance of shared decision making.				hindered professionals from applying a whole-ward approach to ACP. When GPs are absent, professionals may feel left on their own, unable to provide sufficient insight to residents and families to make informed decisions.
Hilgeman et al. (2014)[30]	United States of America	Patient's home	Individuals with mild dementia and a family contact	PIPAC (Preserving Identity and Planning for Advance Care): 4-session, multi-component intervention focused on reminiscence and future planning, including patient-centered ACP discussion with a trained interventionist	Minimal support-based intervention administered via telephone or a brief face to face interaction	4-6 weeks	PIPAC targets meaning-based coping to impact emotional and health-related outcomes through maximizing prevalent coping strategies. By combining identity-maintaining activities with ACP	Stress process model	Depression and anxiety (patient- and family-reported) QoL (patient- and family-reported)	Fewer depressive symptoms, no effect on anxiety Mixed (improved on BASQID self-report, improvement in QOL-AD family report only)	As individuals engage in self-maintenance and self-adjusting intervention activities, increased desire for independence is renewed, or the perception of independence and autonomy may become more salient. Absence of clinically relevant effects may be due to factors related to measurement, malleability by a brief intervention, or poor fit of intervention to outcome. Constructs like

Study	Country	Setting	Population	Intervention	Control	Timing	Description	Theory	Outcomes	Result	Conclusion
							discussion, a strength-based approach of documenting what it has meant for the individuals to 'live well' in the past and what it means for them to 'live well' in the future is used.		Patient meaning in life	No difference	"meaning" may need to be measured through observation, daily process measures, or interviews.
									Patient emotional support and connectedness	No difference	
									Health-related QoL (patient- and family-reported)	Mixed	
									Patient perceptions of uncertainty in choosing future medical care (decisional conflict)	Reduced	
Lyon et al. (2019)[31]	United States of America	Hospital-based HIV clinics	Adults living with HIV and their surrogates	FACE interview session 1 and 2. Session 1: Next Steps Respecting Choices Interview with a trained facilitator (social workers, clinical psychologists, graduate students)	Two control sessions: developmental history and nutrition	Two 60-minute sessions scheduled 1 week apart	The FACE interview facilitates GoC conversations between the PLWH and their family or family members and prepares the family to be able	Folkman and Lazarus' transactional model of stress and coping through problem solving	AD Completion & Documentation in Medical Record	Increased	The involvement of African American patients and their families may account for more ADs: the family is treated as an asset. The intervention was developed to be responsive to health beliefs and practices, as well as family-centered decision

				Session 2: Five Wishes (AD that also designates the health care power of attorney and two back-ups, if the first person is not available). A secured email to the treating physician after session completion with a brief summary of the GoC conversation and a copy of the Five Wishes. The facilitator followed site-specific procedures for entering the documents into the medical record (paper chart or EHR).			to fully represent the PLWH's treatment preferences.	Patient's representation of illness model Leventhal's common sense model of self-regulation of health and illness behavior			making, in African Americans. Historically-based geographical/regional racial and HIV stigma experiences may account for geographical/regional differences in willingness to engage in formal ACP and documentation. PLWH: less predictable trajectory to death. Transition from paper to electronic records may account for lack of easy access to ADs. Systems do not have a tag to mark where ADs are stored.
Lyon et al. (2020)[32]	United States of America	Hospital-based HIV clinics	Adult patients living with HIV and their family	FACE intervention in two sessions: Respecting Choices Next Steps conversation assessing understanding, exploring attitudes,	Healthy living control sessions	2 60-minute conversations scheduled 1 week apart	A semi-structured conversation guide focusing on patient representation of illness is used to promote shared	Transactional stress and coping theory	Statement of treatment preferences congruence between patient and surrogate	Higher congruence at T1 and T2 High congruence longitudinally even as	The intervention's communication effect over time prevented poor understanding, even as preferences changed. Differences in transition patterns between self-identified heterosexuals and

				reviewing rationale for future medical decisions, statement of treatment preferences, summarizing; conducted with a trained facilitator (social workers, clinical psychologists, graduate students, nurses) Five Wishes legal document signed by patient, surrogate, and witness, a copy placed in the medical record and sent to the treating physicians			understanding. The conversations are kept patient-focused.		preferences changed	non-heterosexual patients: relationships of heterosexual PWLH may be more transactional or work-oriented, rather than relational. Engagement of the dyad may create a synergistic effect.
Nedjat-Haiem et al. (2019)[33]	United States of America	Community (southern New Mexico)	Latinos aged 50+ with one or more chronic illnesses	ACP education Motivational interview counseling via a social worker, including supportive guidance and patient navigation	ACP education	One counseling session of 30-40 minutes	Motivational interviewing techniques address resistance and ambivalence toward talking about ACP to address the possibility of dying.	Stages of change	AD documentation	Increased	Latinos may prefer intensive treatment. This population may also be faced with communication barriers, receive insufficient information, and lack resources and services to access comprehensive EoL care. Latinos prefer family-centered decision making

A common ground for ACP is established, setting an agenda for EoL care dialogue guided by strategies that encourage discussions between the individual and a social worker. This process allows them to explore the importance of decision-making with a potential to change behaviors influencing their planning for EoL care.

Provision of MI counseling intended to help individuals cope with their illness and encourage

but may not want to burden others about distressing issues. Family members may not let patients talk about the possibility of dying because of potential distress.

Physical pain or hearing distressing information may make an individual less likely to absorb information.

							them to talk with their doctors, families, and friends about ACP.			
Overbeek et al. (2018)[34]	The Netherlands	Residential care homes, or in the immediate surroundings while receiving home care	Frail older adults	Information provision through leaflets Facilitated ACP conversations with trained nurse based on scripted interview cards, based on Respecting Choices Completion of an AD, including appointment of a SDM	Not specified	Not stated	Modifiable social-environmental factors (e.g. support) can influence activation, which in turn can influence health outcomes.	Hibbard's conceptual model of patient activation	Patient activation measure	No difference	The context of a randomized controlled trial, which requires several appointments and completion of questionnaires, differs from daily practice. The Respecting Choices ACP program could not be implemented system-wide. The effects might have been greater shortly after the intervention and diminished over time. Decisions to withdraw treatment are more common in the Netherlands, and Dutch healthcare has a history of avoiding overtreatment, so there may be less to be gained from ACP

| Song et al. (2010)[35] | United States of America | Dialysis clinics | African American dialysis patients and their surrogates | PC-ACP interview in-depth interview with a trained nurse interventionist, integrating skills of the Respecting Choices curriculum and addressing five elements/stages of the representational approach: representational assessment, exploration of gaps or misunderstandings, creation of conditions for conceptual change, introduction of replacement information, and summarization | Written information on ADs provided by nurse or social worker who answered questions about treatment options

Completed ADs placed in the medical record

Questions about medical conditions and EoL treatment options referred to physicians | Approx. 1 hour | Educational interventions with a representational approach encourage patients to describe their illness beliefs which together comprise the illness representation.

Systematic exploration of the representation allows for an effective patient-centered intervention.

Respecting Choices promotes ACP skills. | Representational approach to patient education, based on Leventhal's common sense model and the conceptual change model | Dyad congruence

Patient decisional conflict

Surrogate decision making confidence

Psychospiritual wellbeing of patient and surrogate | Greater improvement

No difference

No difference

No difference | For African Americans, EoL discussions may be difficult because they may mistrust the health care system and because these patients and their health care providers may lack a shared understanding of the meaning of illness or death.

African American patients appreciate the severity of the illness but express optimistic outcomes, linked to spirituality. Dialysis is seen as a fundamental part of the patient's life.

The interventionist was neither a peer nor African American.

Intervention was limited to one interaction, which may not be enough time to work through difficult thoughts/emotions needed to prepare for EoL decision making.

One week follow-up for data collection might have been |

| Song et al. (2015)[36] | United States of America | Dialysis clinic and patient's home | Patients with end-stage renal disease and their surrogates | SPIRIT psychoeducational intervention delivered by a trained nurse interventionist in 2 sessions to patient and surrogate

Session 1: assessing representations, providing individualized information, completing a GoC document

Session 2: GoC document reviewed, conversation about health care power of attorney

Information communicated to dialysis staff and placed in medical record | Written information about ADs

Social worker encouraged AD completion and addressed questions

Resuscitation statements reviewed with the patient | Two sessions over the course of 2 weeks | SPIRIT establishes an understanding of the cognitive, emotional, and spiritual aspects of the patient's illness representation, which serve as a foundation for the clinician to provide individualized information that is more likely to be accepted, and to assist the patient in examining his or her own values and thresholds related to life-sustaining treatment at the EoL. | Representational approach to patient education | Dyad congruence

Patient decisional conflict

Surrogate decision-making confidence

Composite of congruence and surrogate decision-making confidence | Increased

No difference

Increased

Increased | African Americans, the majority of the study population, may be less amenable to using ADs, but the intervention instead focused on assisting patients and surrogates to talk about decision making and to explore how they feel about care options.

Answering questions may have served as an intervention for the control group. |

222

Study	Country	Setting	Population	Intervention	Comparator		Rationale	Theory/Model	Outcome	Result	Comments
							The intervention helps increase surrogate understanding of patient wishes and prepares them for the role and responsibility of being a surrogate.				
Stein et al. (2013)[37]	Australia	Two Sydney hospitals	Patients with advanced cancer and their caregivers	Pamphlet "Living With Advanced Cancer" Discussion with a psychologist	Usual care	Not stated	Providing information can change patient preferences. The discussion aims to encourage patients to consider preferences and values towards the EoL.	Shared decision making model	Place of death Presence of a DNR order Number of days between earliest DNR order documentation and death	Less likelihood of hospital death (in per-protocol analysis only) No difference Earlier timing of earliest DNR order (in per-protocol analysis only)	Noncompleters may not have wanted to discuss these topics: were older, more depressed and desired less of a role in decision making. Authors do not know mechanisms through which change in outcome of timing of DNR placement occurred Unclear whether outcomes are attributable to the pamphlet or the discussion Psychologists have specialized training to deal with difficult emotions. Physicians, however, may not feel sufficiently trained in

Study	Country	Setting	Population	Intervention		Time	Description	Theory	Outcome	Findings	Comments
Sudore et al. (2017)[39]	United States of America	Study offices	Veteran patients aged 60+ with 2 or more chronic or serious conditions	Easy-to-read AD

PREPARE For Your Care (PREPARE) website program

Copy of patient's action plan/AD/website login and a PREPARE pamphlet/booklet/DVD provided

Reminder call prior to primary care visit | Reviewing an easy to read AD

Reminder call prior to primary care visit | Average 57 minutes | PREPARE motivates and prepares individuals to discuss their values and care preferences with their family, friends and clinicians.

Through tailored algorithms, PREPARE asks individuals about their values and helps them make a commitment to do 1 ACP step. | Theory of Behavior Change

Social Cognitive Theory | New ACP documentation in the electronic medical record (EMR) – AD documentation and/or ACP discussion documentation | Higher new documentation for legal forms and for discussions | Only 9% women in the sample.

Interviews and calls may be activating.

The success of both PREPARE and the easy-to-read AD may be explained by their attention to literacy and cultural considerations. |
| **Sudore et al. (2018)[40]** | United States of America | Primary care clinics | Primary care patients aged 55+ with 2 or more chronic or serious illnesses | Easy-to-read AD

PREPARE For Your Care (PREPARE) website program

Copy of patient's action | Reviewing an easy to read AD

AD to take home

Reminder call prior to primary care visit | Approx. 50 minutes plus 5-15 minutes for the AD | The intervention aims to overcome barriers: health literacy, time, resource constraints, lack of trust, | Social Cognitive Theory and Behavior Change Theories | New ACP documentation the electronic medical record (EMR) – AD documentation and/or ACP | Higher new overall documentation of ACP

Documented discussions did not differ | The observed gains in documentation of ACP are likely the result of a combination of components of the PREPARE program: co-creation with and for diverse populations, theory-based content to enhance |

plan/AD/website login and a PREPARE pamphlet/booklet/DVD provided

Reminder call to prior to primary care

complex legal language, different views on autonomy and decision making.

Skill-building steps model how to engage in ACP through video stories.

Narratives and testimonials mitigate cultural barriers.

Video, audio, and closed-captioning mitigate literacy, language, and hearing barriers

The intervention encourages patients to include family and loved ones.

discussion when documentation assessed separately

self-efficacy and readiness, and narratives/testimonials/video stories to help patients make decisions about ACP.

Interviews and reminders may have been activating.

Tilburgs et al. (2020)[43]	The Netherlands	GP practice	General practitioners; Patients with dementia and their family carer	Interactive workshop training to practice ACP conversations and shared decision-making Booklet with background information for GPs	Information about the study provided GPs provided usual care	Two 3-hour interactive workshops and 2-monthly telephone consultations	Barriers to ACP with GPs might be resolved by training GPs in initiating ACP using the broader definition, which allows for discussion of both medical and nonmedical issues. By including the person with dementia's values and care goals, including nonmedical preferences, the shared decision making model addresses the principles of social health and includes the influence of the social environment and the dynamic	Shared decision making using the Three-Talk model	ACP initiation	Increased	PLWD may have aim to live well with their condition and find it important to focus on maintaining their capabilities. Starting ACP by discussing nonmedical issues may be a successful strategy for involving PLWD. The primary outcome relied on the GP's medical file and was sensitive to registration bias.

226

Study	Country	Setting	Population	Intervention	Control	Duration		Theory	Outcome	Results	Conclusions
							balance between capabilities and limitations.				
Vogel et al. (2013)[41]	United States of America	Gynecology oncology clinic	Patients with stage III/IV or recurrent gynecological cancer and their caregiver	Welcome folder in paper format Website including the following: distress monitoring, questions recorded to ask providers, an information library written by the research team, goal-setting options, social media features, AD appropriate to the state of Minnesota, introduction of palliative care staff with encouragement to make an appointment Companion caregiver website	Caregiver/patient control website containing all usual care information documents All usual care information documents provided on paper as part of a welcome folder	60 days	Decision aids need to be tailored to the user type and for each individual. Computer and web-based programs can deliver decision aids and information to more people than traditional formats, provide social media features for support, and facilitate behavior change in cancer care. Information was tailored by presenting topics at three	Theory of informed and shared decision making	Completion of an AD Consultation with palliative care	No difference No difference	Effect of age or treatment may explain low use of intervention. There was no means to guide users through the website was provided and the technology was not simple to use. Caregivers were not successfully engaged.

							levels with increasing information. The Ottawa Personal Decision Guide helps participants weigh risks and benefits of a medical decision. Decision-making is promoted by educating women about methods and styles, introducing shared decision making, and encouraging discussions with caregivers, family, and providers.				
Walczak et al. (2017)[38]	Australia	Cancer treatment centers	Patients with advanced, incurable	Community support program (face to face meeting plus	No contact with the nurse, no QPL, oncologists	One week before a follow-up	Increasing 'Autonomous Motivation' to	Self-determination theory of health-	Patient and caregiver questions and	No increase in number of questions	There may be challenges inherent in asking questions about EoL issues when one

affiliated with major hospitals	cancer, and caregivers if they attended the oncology consultation	telephone booster session by trained senior nurses) Question prompt list DVD discussion of ACP Patients prompted to select questions to ask at their next consultation Nurses cued oncologists to endorse QPL Postcard with suggested endorsement phrasing for oncologists	not cued to endorse QPL use or question asking	oncology consultation to 1-2 weeks after the oncology consultation	discuss prognosis and EoL care and self-perceived 'Competence' to undertake discussions helps to increase participants' ability and motivation to discuss prognosis and EoL care. Oncologists were cued to endorse QPL use and question asking to address social support needs (Relatedness).	related behavior change	cues for discussion	asked by patients Patients gave more cues, but not for all topics Caregivers asked more questions and gave more cues for prognosis	is not exclusively receiving palliative care. Participants may have believed they were still too well or had additional treatment avenues to explore. Oncologists did not receive extra training and may have missed cues. Substantially more men participated. Oncologists saw patients in both study arms.

Abbreviations: ACP = advance care planning; AD = advance directive; DNR = Do-Not-Resuscitate order; EoL = end of life; GoC = goals of care; GP = general practitioner; QPL = question prompt list ; SDM = surrogate decision maker; PLWD = person/people living with

dementia; PLWH = person/people living with HIV

Supplementary Table S2. Primary outcomes, interventions, mechanisms, and results.[a]

Outcome	Interventions (with all components listed)	Mechanisms proposed	Result
Dyad congruence	Facilitated discussion, with or without legal document and communication to health provider/medical record (PC-ACP, SPIRIT, FACE)	Intervention tailored to recipient[35,36]; Facilitating understanding about illness, treatment options and shared decision making[36]; Encouraging active discussions with carers and health providers to promote shared understanding[32,36]; Encouraging the patient to reflect on illness beliefs and values[32,35,36]; Promoting ACP skills and competence[35]	Increased for patients with end-stage renal disease, and for patients living with HIV[32,35,36]; Congruence maintained longitudinally for patients living HIV and their family[32]
Place of death	Informational material and facilitated discussion	Facilitating understanding about illness, treatment options and shared decision making; Encouraging the patient to reflect on illness beliefs and values[37]	Reduced likelihood of hospital death for patients with advanced cancer[37]
Patient activation	Informational material, facilitated discussion, and AD	Meeting social support needs[34]	No difference for frail older adults[34]
AD completion/DNR documentation	Interactive website, AD form, informational material (PREPARE); ACP education plus facilitated discussion (motivational interviewing); Facilitated discussions with Five Wishes AD and communication of discussion outcomes (FACE)	Intervention tailored to recipient[33,39,40]; Encouraging active discussions with carers and health providers to promote shared understanding[31,33,39,40]; Encouraging the patient to reflect on illness beliefs, preferences, and values[31,33,39]; Recognizing the importance of ACP and decision making[33]; Promoting ACP skills and competence[39,40]	Increased for patients with chronic or serious conditions, and for patients living with HIV[31,33,39,40]
	Interactive website with question prompts and information library, including an AD	Intervention tailored to recipient; Facilitating understanding about illness, treatment options and shared decision making; Encouraging active discussions with carers and health providers to promote shared understanding; Meeting social support needs[41]	No difference for patients with gynecological cancer[41]
	Informational pamphlet and facilitated discussion	Facilitating understanding about illness, treatment options and shared decision making; Encouraging the patient to reflect on illness beliefs and values[37]	Earlier timing but no difference in rates for patients with advanced cancer[37]
Decisional conflict	Facilitated discussion (PIPAC); Informational pamphlet and facilitated discussion with care	Intervention tailored to recipient[30];	Reduced for patients with mild dementia[30] and carers of nursing

230

	plan placed in medical record and communicated to GP	Facilitating understanding about illness, treatment options and shared decision making[28];	home residents with dementia[28]
	Facilitated discussion (PC-ACP);	Encouraging the patient to reflect on illness beliefs and values[30]	No difference for dialysis patients; No difference in surrogate decision-making confidence[35]
		Intervention tailored to recipient; Encouraging the patient to reflect on illness beliefs and values; Promoting ACP skills and competence[35]	
	Facilitated discussion and communication of discussion outcomes to health provider (SPIRIT)	Intervention tailored to recipient; Facilitating understanding about illness, treatment options and shared decision making; Encouraging active discussions with carers and health providers to promote shared understanding; Encouraging the patient to reflect on illness beliefs and values[36]	No difference for patients with end-stage renal disease; Increased surrogate decision making confidence; Increased composite outcome of surrogate decision-making confidence and congruence[36]
Content of conversations	Educational workshops, information campaign, question prompts (We DECide optimized)	Recognizing the importance of ACP and decision making; Promoting ACP skills and competence[42]	Increased shared decision making in conversations for persons with dementia[42]
	Facilitated discussion, question prompts, informational materials, health providers endorsed prompt list	Meeting social support needs; Promoting ACP skills and competence[38]	No increase in number of questions asked by patients with advanced cancer; Increase in cues for all topics except future care; Increase in number of questions asked by caregivers[38]
Number of conversations/ consultations	Facilitated conversation, AD, communication prompts, and conversation information shared with health provider	Promoting ACP skills and competence[29]	Increase in GoC conversations for patients with heart failure[29]
	Interactive website, AD form, informational material (PREPARE)	Intervention tailored to recipient[39,40]; Encouraging active discussions with carers and health providers to promote shared understanding[39,40];	Increase in documented ACP conversations for patients with chronic, serious conditions;[39]

		Encouraging the patient to reflect on illness beliefs, preferences, and values[39]; Promoting ACP skills and competence[39,40]	No difference in documented ACP conversations[40]
	Interactive website with question prompts and information library, including an AD	Intervention tailored to recipient; Facilitating understanding about illness, treatment options and shared decision making; Encouraging active discussions with carers and health providers to promote shared understanding; Meeting social support needs[41]	No difference in consultations with palliative care for patients with gynecological cancer[41]
	Educational workshops for health providers with informational booklet	Promoting ACP skills and competence[43]	Increased ACP initiation by GPs for patients with dementia[43]
Psychospiritual wellbeing	Facilitated discussion (PIPAC)	Intervention tailored to recipient[30]; Encouraging the patient to reflect on illness beliefs and values[30]	Decrease in depressive symptoms for patients with mild dementia; Mixed results depending on instrument and respondent[30]
	Facilitated discussion in five stages (PC-ACP)	Intervention tailored to recipient; Encouraging the patient to reflect on illness beliefs and values; Promoting ACP skills and competence[35]	No difference for dialysis patients[35]
Quality of life	Facilitated discussion (PIPAC)	Intervention tailored to recipient; Encouraging the patient to reflect on illness beliefs and values[30]	Mixed results depending on instrument and respondent[30]

a. This table reflects mechanisms specified by the authors generally, not linkages to individual components or outcomes

Supplementary Figure S1. **Example search string (Pubmed)**

1. advance care planning[MeSH Terms] OR advance care plan*[Title/Abstract] OR advanced care plan*[Title/Abstract]
2. advance directive[MeSH Terms] OR advance directive*[Title/Abstract] OR advance care directive*[Title/Abstract] OR advance decision*[Title/Abstract] OR advance statement*[Title/Abstract] OR health directive*[Title/Abstract] OR advanced directive*[Title/Abstract] OR advanced care directive*[Title/Abstract] OR advanced decision*[Title/Abstract] OR advanced statement*[Title/Abstract]
3. living will[MeSH Terms] OR living wills[MeSH Terms]
4. living will*[Title/Abstract]
5. resuscitation order[MeSH Terms] OR resuscitation orders[MeSH Terms] OR decision, resuscitation[MeSH Terms]
6. do not resuscitate order*[Title/Abstract] OR do-not-resuscitate order*[Title/Abstract] OR DNH[Title/Abstract] OR do not hospitalize order*[Title/Abstract] OR do-not-hospitalize order*[Title/Abstract] OR DNR[Title/Abstract]
7. 1 OR 2 OR 3 OR 4 OR 5 OR 6
8. randomized controlled trial[MeSH Terms] OR randomized controlled trials as topic[MeSH Terms] OR clinical trial[MeSH Terms] OR clinical trial as topic[MeSH Terms] OR clinical trials, randomized[MeSH Terms] OR controlled clinical trials, randomized[MeSH Terms] OR controlled clinical trials as topic[MeSH Terms]
9. randomised control trial[Title/Abstract] OR randomised controlled trial[Title/Abstract] OR randomized control trial[Title/Abstract] OR randomized controlled trial[Title/Abstract] OR RCT[Title/Abstract] OR control trial[Title/Abstract] OR controlled trial[Title/Abstract] OR randomised trial[Title/Abstract] OR randomized trial[Title/Abstract] OR cluster randomised[Title/Abstract] OR cluster randomized[Title/Abstract] OR cluster RCT[Title/Abstract] OR clinical trial[Title/Abstract] OR controlled clinical trial[Title/Abstract]
10. 8 OR 9
11. 7 AND 10
12. Filters: from 2010 - 2020

Chapter 6

Clinicians' experiences implementing an advance care planning pathway in two Canadian provinces: a qualitative study

This chapter is based on the following submitted manuscript:

Stevens J, Elston D, Tan A, Barwich D, Carter R, Cochrane D, Frenette N, Howard M. Clinicians' experiences implementing an advance care planning pathway in two Canadian provinces: a qualitative study.

ABSTRACT

Background: Advance care planning (ACP) is a process which enables patients to communicate wishes, values, fears, and preferences for future medical care. Despite patient interest in ACP, the frequency of discussions remains low. Barriers to ACP may be mitigated by involving non-physician clinic staff, preparing patients ahead of visits, and using tools to structure visits. An ACP care pathway incorporating these principles was implemented in longitudinal generalist outpatient care, including primary care/family medicine and general internal medicine, in two Canadian provinces. This study aims to understand clinician experiences implementing the pathway.

Methods: The pathway was implemented in one family practice in Alberta, two family practices in British Columbia (BC), and one BC internal medicine outpatient clinic. Physicians and allied health professionals delivered structured pathway visits based on the Serious Illness Conversation Guide. Twelve physicians and one social worker participated in interviews or focus groups at the end of the study period. Qualitative data were coded inductively using an iterative approach, with regular meetings between coders.

Results: Clinicians described experiences with the ACP care pathway, impact at the clinician level, and impact at the patient level. Within each domain, clinicians described barriers and facilitators experienced during implementation. Clinicians also reflected candidly about potential for future implementation and the sustainability of the pathway.

Conclusions: While the pathway was implemented slightly differently between provinces, core experiences were that implementation of the pathway, and integration with current practice, were feasible. Across settings, similar themes recurred regarding usefulness of the pathway structure and its tools, impact on clinician confidence and interactions with patients, teamwork and task delegation, compatibility with existing workflow, and patient preparation and readiness. Clinicians were supportive of ACP and of the pathway.

Trial registration: The study was prospectively registered with clinicaltrials.gov (NCT03508557). Registered April 25, 2018. https://classic.clinicaltrials.gov/ct2/show/NCT03508557.

Keywords: advance care planning, primary care, internal medicine, interview study, focus group study

BACKGROUND

Older adults and patients with a life-limiting illness benefit from making their wishes for care known prior to an acute health event, which may leave them unable to communicate those wishes or make medical decisions. The process of communicating wishes, values, fears, and preferences for future medical care between the patient, their loved ones, and multidisciplinary health care professionals, with the goal of helping to ensure that patients receive medical care consistent with their values, is known as advance care planning (ACP).[1,2] In addition to making patients' wishes known, ACP prepares patients and their substitute decision maker (SDM) for making informed in-the-moment care decisions.[3] Engaging in ACP is associated with greater concordance between care preferences and care received, higher quality of patient-clinician communication,[4] higher quality of care at the end of life,[5] greater sense of control for the patient,[6] and reduced SDM distress.[7]

Despite older adults' and patients' interest in discussing ACP, conversations in health care settings occur infrequently.[8–10] In Canada, a survey of elderly hospitalized patients showed that most had thought about end-of-life care and few preferred life-prolonging care. However, only half of patients who discussed their wishes had done so with any member of a health care team.[11] Although ACP engagement in Canada is increasing over time, the frequency of discussions, including with family physicians, remains low.[12,13]

Crucial to the ACP process are a timely start and iterative conversations with health care providers.[14,15] Outpatient care settings, such as primary care, have been proposed as an ideal setting to initiate and facilitate ACP. Instead of facing complex choices about treatment at the moment of hospitalization, patients and families can reflect about values, wishes, and worries for their health with outpatient healthcare workers, at a time when their health is relatively stable.[16,17] The longitudinal and trusting patient-provider relationship enables these iterative conversations.[10,18,19] Barriers persist in this setting, however; in a national survey of Canadian primary care providers, engagement in ACP was low despite high willingness and confidence.[20]

A lack of time is a prominent barrier at the clinician level.[21–23] The involvement of non-physician clinic staff, such as nurses, may reduce time-related barriers through delegation of tasks, and is contingent on whether these staff have the necessary knowledge and skills for ACP.[24] In Canada, however, primary care clinicians are supportive of involving non-physician clinicians in ACP.[20] This represents a potentially underutilized resource, as well as a knowledge gap regarding the role of allied health professionals for ACP in (Canadian) longitudinal generalist outpatient care settings.

To address barriers to ACP, including lack of time, clinicians may also improve their knowledge and skills, and use templates to structure conversations. Combining tools which assure clinicians know what to discuss, with information provided to patients and family prior to the clinic visit, can increase the efficiency of visits themselves.(23,24) The Serious Illness Conversation Guide (SICG)[25] is one such tool. As a component of the Serious Illness Care Program (SICP) communication intervention, it provides a structured approach for ACP topics, from reflection to documentation. [26] The SICP may promote more and better conversations about patient care wishes,[27] by supporting physicians and non-physician clinicians to implement timely conversations into their practice routines.[28] Evaluations of such interventions in longitudinal generalist outpatient care are still limited; a prior study evaluated Canadian primary care clinician experiences implementing the SICP and found that a more systematic process of implementation may be needed.[18]

There is a need to evaluate an approach that combines principles of interprofessional collaboration within the clinic, with the structure of the SICG tool. To this end, a multi-faceted ACP pathway was implemented in longitudinal generalist outpatient care clinics, including primary care and general internal medicine, in Alberta and British Columbia (BC), Canada. It is important to examine the implementation processes of this pathway, to ensure that it is workable and can be durably integrated into practice. Evaluation should attend to how the pathway interacts with the existing organization of care.[29] Normalization Process Theory (NPT),[30] an implementation science framework, is of use in exploring the context for implementation, whether the pathway is seen as relevant and important, and how new processes introduced by the pathway interact with existing processes in the clinic setting. The framework assesses sense-making (coherence), relational work (cognitive participation), operational work (collective action), and appraisal (reflexive monitoring), and served as the background for examining lived experience with the pathway in two Canadian provinces.

METHODS

Aims

This study aims to explore the experiences of physicians and allied health professionals in two Canadian provinces (Alberta and British Columbia) with implementing the ACP pathway, using the NPT framework as the basis for interviews. The consolidated criteria for reporting qualitative research (COREQ)[31] were used to structure the report (Additional File 1).

The project to test the ACP care pathway was undertaken in Alberta and BC, Canada, from 2018 to 2020. We used a qualitative approach to describe the implementation in participating clinics.

The ACP pathway

The ACP pathway is an intervention based on the Serious Illness Conversation Guide (SICG).[25]. Participating physicians and Allied health professionals received one 2.5 hour SICG training, conducted by members of the project team (AT, DB) who previously attended SICG Trainer-the-Trainer workshops. Participating clinics provided longitudinal outpatient generalist care of adults. One family practice in Alberta, two family practices in BC, and one BC internal medicine outpatient clinic participated in the project. General internal medicine, which is not a primary care setting in Canada, was considered legitimate to include alongside primary care clinics, as internal medicine clinics are designed to manage complicated illness and patients may have an established relationship with this setting.

The patient-facing portion of the pathway consisted of three steps (Figure 1). During step 1, patients provided consent for participation and completed research questionnaires. Patients received verbal pre-visit education about ACP and how to choose a SDM, and were provided an ACP workbook: the Conversations Matter workbook[32] in Alberta, or the ACP resources from the BC Centre for Palliative Care.

Step 2 was an ACP education and values clarification session. Allied health professionals (social workers, registered nurses) used the *Explore* section of the SICG, then facilitated completion of the Best-Worst Scenario Online Tool, a values clarification aid (Additional file 2), with the patient. Step 2 resulted in a Dear Doctor Letter stating patient wishes. In BC, steps 1 and 2 were combined into one visit with the research coordinator and a research nurse. In Alberta, step 2 was scheduled with an allied health professional during a second visit 2-6 weeks after step 1. Approximately 2-4 months after the first visit, patients met with the physician for step 3, which focused on finalizing and documenting ACP. Before step 3, physicians reviewed the Dear Doctor Letter. During the visit, the *Assess, Share*, and *Close* sections of the SICG structured the conversation finalizing patient goals and wishes. These were documented using existing means in each province, e.g. the patient electronic medical record; the Alberta Health Services "Green Sleeve" containing ACP forms.[33]

Figure 1. ACP pathway steps

Step 1
- Project consent and questionnaires
- Verbal pre-visit information about substitute decision maker and ACP
- ACP workbook provided

Step 2 (with allied health)
- **ACP education and values clarification session**
- SICG topics:
  - *Set up*
  - *Explore*
- Best-Worst Scenario online tool
- *Dear Doctor Letter* stating patient wishes for physician to review

Step 3 (with physician)
- **Finalizing and documenting ACP**
- SICG topics:
  - *Set up*
  - *Assess* (e.g., illness understanding)
  - *Share* (using illness trajectories to discuss prognosis with patients)
  - *Close*
- Documentation after Step 3 using existing means in each province

Inclusion

Participating physicians who attended the SICG training identified eligible patients (≥60 years of age and/or at risk for health decline due to serious or life-limiting illness) from their electronic medical record (EMR). With patient approval, physicians provided patient contact information to a researcher, who contacted the patient to schedule a research appointment (first visit). For the qualitative study, physicians who expressed interest, completed the SICG training, and referred patients to the ACP pathway were interviewed.

Data collection procedure

The study was stopped in Alberta at the start of the COVID-19 pandemic, with interviews and focus groups conducted until March 2020. Pathway meetings in BC were likewise stopped in March 2020; physician interviews were conducted during the pandemic, until October 2020. Interviews and focus groups were conducted by two co-authors (DC, MHLP; NF, MSW) and one additional interviewer, all of whom are female. Interviews were conducted in the clinic setting, or via telephone contact due to COVID-19. One physician (BC) was contacted for a

member-checking interview during data analysis in July 2022. JS (female, MSc) and DE (female, MA) conducted the interview via video-conference. Extensive written notes were taken during this interview. Interviewer background included research assistant, research coordinator, and doctoral researcher. Clinicians interviewed were aware of the project and of the interviewers' reasons for doing the research.

Interviews and focus groups were semi-structured and conducted using an interview guide based on NPT as theoretical framework (Additional file 3). The interview guide followed general NPT questions, e.g. "How did the intervention affect the work of the practice?", each with corresponding open questions and additional prompts.

In BC, nine physicians (including physicians who were unable to refer patients) were invited for interviews; five physicians participated, all of whom had referred patients. In Alberta, all participating physicians and the one participating social worker were interviewed.

Analyses

Interviews were audio-recorded and transcribed verbatim. Two researchers (JS, DE) independently analysed the transcripts. Transcripts were first read multiple times to gain familiarity with the data. Although the use of an interview guide provided an initial structure to the topics within the transcripts, an inductive approach was used during coding, rather than strictly imposing the interview questions as a framework, so that themes could emerge organically. Codes and preliminary themes were compared after independent analyses of the first transcript, and a preliminary codebook with domains, themes, and sub-themes was established. The codebook was then used to independently code the remaining transcripts using NVivo 12 and Microsoft Excel software.

Regular meetings allowed the coders to iteratively update the codebook with newly-emerging codes; to generate new themes, adjust the naming, structure, and content of themes; and to resolve discrepancies through discussion. In the case of unresolved discrepancies, a third researcher (MH) was invited to arbitrate. The third researcher also checked the final coding framework. JS and DE researchers populated the framework with illustrative quotes; MH checked the relevance and clarity of the selected quotes.

RESULTS

In the three participating BC sites, three family physicians (1 female, 2 male) and two internal medicine physicians (1 female, 1 male) were interviewed one-on-one. In Alberta, three focus groups were conducted with a total of seven family physicians (3 male, 4 female), and one social worker (female) was interviewed individually. Interviews and focus groups lasted approximately 30 to 60 minutes.

We identified three overarching domains describing experiences with the ACP pathway, impact at the clinician level, and impact at the patient level. Within each domain, we identified subthemes as they related to facilitators and barriers experienced by physicians during implementation of the pathway. Some physician responses related to potential for future implementation and the sustainability of the pathway, outside the context of the current study. Physicians described these future considerations in relation to experiences with the pathway itself, as well as physician and clinic-level impact (Table 1.)

Table 1. Domains, themes, and subthemes

Domain	Theme	Subtheme	Illustrative quote
Care Pathway	Facilitators	Documents, forms, and tools are helpful	"As you get comfortable with these meetings, then the summarized version of the conversation I think is a helpful guide. The Dear Doctor letter I think is quite imperative and I use it even if I get a standard referral that's not part of this study […]. " (Alberta, social worker)
		Sequential structure is easy to implement	"I think having the pathway, you know, there's steps and there's a starting point and an end point. There's things to be achieved along the way. That's a little more structured and what I would've done before, so that's a benefit." (Alberta, physician)
	Barriers	Appointments: preparation, duration, and modality	"Like I know that the patient has done this, documents have been shared, this has been completed, the letter's there, it's in the chart. Now the patient's coming to me. Sometimes it just seemed to be a bit complicated to get everything together in time for the visit." (Alberta, physician)
		Negative patient experiences with the pathway	"Like I said, I feel like I had the worst case example in terms of patient engagement because her decision-maker didn't want to be part of the discussion, she didn't want to do the best and worst list, she didn't want to do the Dear Doctor letter […]" (Alberta, physician)
		Clinical care coordination	"Your Dear Doctor letter was roughly[…]the <health authority> template and it included all those things […]. Then we pulled as much out of it as possible to make it something that would, would suit the needs of the health authority and even that wasn't enough because they would only accept the official branded ACP record […]" (BC, physician)
	Future sustainability	Adapt to emerging needs (Virtual care, COVID, …)	"This pandemic has changed a whole lot of things for everybody and so [...] I think the pathway will have to be adapted to meet the needs of virtual care and phone care." (BC, physician)

		Embed and normalize ACP	"Where if it became an organic thing that everyone in the clinic it's one of the […] questions that are asked, then it becomes something that's more normalized, which it should be." (Alberta, physician)
		Expand training	"I actually think it's one of those things which would be good to have a refresher on […] every so often too, like every other year or something like that, because it's something that we don't always keep top of mind with everybody." (BC, physician)
		Need for communication and bridging tools	"…some more communication between the clinician and the physician because I could see that there might be some things that were shared that maybe didn't come up with the physician, so I don't know if there is some other mechanism aside from the Dear Doctor [letter] […]" (BC, general internist)
		Broader health care system implications	"[…] I think knowing where to put this pathway to start would be really important, I'm just trying to think about what the streams or referrals would be and I would think that family practice is a great place to start. I think the internal medical clinics that […] see a lot of the discharges from hospitals is a good place, the oncology ward for obvious reasons. And then I think the next level would belong to some specialty clinics, cardiology, gastroenterology, respiratory." (BC, general internist)
Clinician impact			
Clinical Practice	Facilitators	Patient/SDM willingness, readiness, and preparation	"[…] I think sometimes I would get these kinds of referrals in times past to talk about advance care planning and there would be, you know, maybe somewhat frequent times where the patient might say, "I really don't know exactly why I'm here"." (Alberta, social worker)
		Positive impact on clinicians	"I think I'm more confident in the decision-making approach, because of everything that came ahead of the patient coming in to see me." (Alberta, physician)

		Positive impact on clinicians' interaction with patients	"So I think the preparation allowed people to comfortably talk about these things. Of course, there was tears at times but I think that, you know, having a clinician have a meeting with patients to talk about these things, whether it's a nurse or a social worker or another type of clinician is helpful because we can be gentle in that conversation. So I felt everyone was safe doing it." (Alberta, social worker)
	Barriers	Practical challenges to visits	"[…] I think I shared that with you, how it just came at a crazy time where people were shut in, there was a lot of fear among [...] the population anyway, so […] it just was sort of a little bit harder timing to have that call, conversation." (BC, physician)
		Patients/SDMs may not be ready	"I didn't find myself able to apply [the pathway] directly with well patients that frequently and I had a number of patients who […] probably weren't quite ready to have some of those types of discussions regardless of the framing even though, you know, I would have considered them to be in the category where they probably would have benefitted." (BC, physician)
	Future sustainability	No billing codes	"I mean now in order to do some billings, you have to have an advanced care like that now so our complex care billing [is] generally tied in or if there was a billing for that. […] There's no real billing for having that discussion, there is a billing for congestive heart failure, that visit, there's a billing for but for a teleconversation it's not specifically a billing for that. […] So it doesn't really fall under counseling visit, so I think GP's struggle […]"(BC, physician)
Teamwork	Facilitators	Social worker has the necessary skills for ACP and is a referral for more complicated conversations	"I'm more likely to refer to social work if it seems that there's maybe like a more complicated discussion that has to happen or if a patient really just seems like wanting to maybe engage, but really just seems very on the fence about things or on the fence about who their substitute decision-maker should be. Like sometimes I think I'm referring to <the social worker> a little bit more, like I kind of know that she has that skill set now." (Alberta, physician)

		Awareness of staff	"Definitely I think our staff like here at the clinic were supportive and, you know, often would be like, "You need this paperwork" and come drop it off for me, so it was like really helpful that way." (Alberta, physician)
		Promotes teamwork and strengthens existing collaborative relationships	"Now nurse [name] can take the first thirty minutes of that, review, you know, the areas that she's been trained to review over the serious illness conversation and then after, you know, twenty or thirty minutes I can focus on the areas that I wanted to address plus allude to the serious illness conversation, the best care plans that have been documented and just ensure that's consistent with, you know, what [health authority] would need to know." (BC, physician)
	Barriers	Availability of resources: staffing, structural barriers, team composition	"I mean for most private physicians' practices, you know, […] many of us don't really have allied health working with us that much except for our front desk staff. I, I mean in our, in our office we are lucky that we get, get an RN sort of into our practice within the past year and a half but incorporating her as a formal part of our sort of ACP process hasn't really happened yet […]" (BC, physician)
		Unclear division of tasks	"What happened in my case is that it wasn't clearly labelled in the EMR that were [project] patients to start with, and so, they were assigned to residents, and I understood that we were supposed to do these interviews. So, that became quite problematic because we're scraping off an hour throughout the day in which the residents aren't just sort of … So I actually tried at one point to get the residents to watch me and to give feedback; that didn't work either, so." (Alberta, physician)
		Problems coordinating between visits	"I almost wish that there was more built-in communication or shared appointment between me, the patient and [the social worker] because I almost felt like the patient was the go-between between me and [the social worker] […]" (Alberta, physician)

		Different service models do not support the pathway in its current form	"I would say that typically in our clinic we don't have allied health professionals, we work solo [. . .] So in the hospital we have lots of allied health assistance but in the clinic we're not used to really having anybody else there so the fact that somebody, that a new role is there, it's just completely novel […], not a change or I don't change the way that I see them or the way that their roles are. It's just a completely new role that wasn't there before." (BC, physician)
	Future sustainability	Training other staff	"And maybe, maybe as we move forward the nurses who participate in this manner should have more formal training and do it as has been done in the study." (BC, physician)
		Who will be available after the study is over?	"So I think the worry that I have in terms of like work planning moving forward is that [the social worker] might not have the capacity to do this for all of our patients and that we might need to think more broadly about how we're going to do this like moving forward because she's pretty busy." (Alberta, physician)
		Expanding visit 2	"The other question I would have is, could the allied health worker actually go a little further along the path, in other words go to the point where they even talk about which level of care. And then, if the [physician] needs to be involved it's actually fairly quick. Just the pathway, this way it's left up to the physician." (Alberta, physician)
Work processes	Facilitators	Efficiency and integration with current workflow	"Most of the time I'd see the patient for their follow-up visit and then they were contacted separately so it didn't really actually affect my work flow at all, because that was done almost after I'd just talked to them at the end of the appointment about it, made the referral and then that was all done separately so it didn't affect my work flow at all." (Alberta, physician)

	Recognition of inherent value of the intervention	"Yeah, definitely time well spent. I think these are important discussions that I often neglect to or forget to have. It's just sort of one of many things that we try and do and often, unless it's sort of you're confronted with it, I either forget or I don't do it. And I think actually this study was nice in that it brought it to the forefront for me and reminded me and my residents that it needed to be done." (Alberta, physician)
	Benefits of recruitment strategy	"It almost seems less threatening in some ways right, like, "We just put your name into a computer list and yours – or we put criteria into a computer list and your name popped up", so it's not like somebody went, "You need this ACP". Like I feel that that as an element of like fear-inducing and that kind of more neutral, "Computer popped your name up and we're calling you, would you like to come talk about this"." (Alberta, physician)
Barriers	Individual/practice-level barriers	"Just that I had to know in advance which patient I would see that day, refer on did require a little bit of planning and giving the patient a head's up about that kind of conversation as well. So, you know, instead of just going through my regular clinic and then identifying them in the moment and referring them on I had to, had to have a little bit of preplanning." (BC, physician)
	System-level barriers	"I think that its, its challenging, its challenging in sort of the people, service worlds we work in to make large changes in how we do things quickly even with sort of the availability of certain types of videos to help people with called complex care planning." (BC, physician)
Future sustainability	Virtual vs. in-person visits for different purposes and populations	"And then that's why some of the ACP stuff sometimes falls to the wayside a little bit. I think, I think phone visits could work for a set of patients who are, don't have significant dementia or memory issues or hearing issues, I think there is a set of patients who would do fine on the phone thinking about that stuff. And then virtual visits I mean there's technical challenges with those for sure with the older population (…)" (BC, physician)

		Placing the pathway in context of health care system changes	"And the second thing is I think that the upcoming sort of changes to potential physician contracts for salary sort of physician may actually make a big difference here too in our ability to be able to offer some of the deeper stuff." (BC, physician)
		Tailoring to local context and adapting to individual clinic needs	"And I think it's more the access and the availability I can see like in some, […] in a busy clinic and environment you'd just have somebody available and you can kind of have like a longer visit, whether its remotely or in person, and that just be included as part of the like a complex visit, that I could see where it would be helpful." (BC, general internist)
Patient impact			
Preparation	Facilitators	Pre-work for follow-up visits	"I can tell you they got more invested in the process once they've met with [the social worker] and done that. Versus us just kind of like more passively handing them something and saying "Go ahead and rebuild this on your own." (Alberta, physician)
		Patient-centered, ongoing conversation	"And some of the patients, I think the more people that talk to them about advance care planning the more they get comfortable with it so it may not, this may be a first conversation or it may be a subsequent conversation. And so it's hopefully building on things that they've already heard and whether they were in hospital before." (BC, general internist)
	Barriers	Patient lack of buy-in	"Yeah. And the three visits were one thing that they raised problem, their concerns about. So I just said, "Look. Don't do it for me. We're doing this for you." And so a couple dropped out." (Alberta, physician)
		Need for more clarity, time, discussion	"If there's any lack of clarity and still thinking and further discussion that needs to occur then that often needs to occur outside the clinic somewhere. So, if that's obvious then it's like "Hey, you know what? We need go in a little bit more and think about this."" (Alberta, physician)

		Difficulty translating goals into levels of care	"The focus of my discussion was definitely about understanding what the Goals of Care were, what the Goals of Care designations were. Without providing any direction and trying to translate into what the discussions that it had before. And I do think that made things easier, but that discussion still becomes technical. And it's probably one of the more – It is important, but I think it's also translating what patients want into a number and a letter, with an understanding of what that is. And the consequences of that, or the potential consequences, that's challenging." (Alberta, physician)
Readiness	Facilitators	Promotes readiness to have goals-of-care discussions and complete documents	"I think the benefit was that more people in our clinic, more patients in our clinic are completing their goals of care because of this." (Alberta, social worker)
		SDM is aware of patient values and wishes	"I think it prepares the substitute decision-maker for the role and it also provides a lot of comfort for the patient that if their health changes and they don't have the capacity to make their health-related decisions, that they have somebody to do that for them, that understands their role is to speak on their behalf." (Alberta, social worker)
	Barriers	Difficult transition from thinking about values to documenting goals of care	"Even though it did fit with their values, they just weren't ready to believe that, and so their goals of care actually don't reflect what their values and wishes are because they couldn't get there despite our multiple attempts of trying to clarify it." (Alberta, physician)
		Lack of patient comfort and energy	"Where I do worry a bit is the flow for the patient. Instead of coming in to see a doctor for an hour, which is already a very long time for a patient, they may be there for two plus hours, a whole afternoon for them. So I do worry about their comfort, their energy level, um, when, when these conversations are, are going on for a long time." (BC, physician)

I. The care pathway

The first overarching domain refers to ease of use of the components of the care pathway, such as the sequential structure with appointments and documents/tools. Participating clinicians evaluated the components of the pathway, including the Best-Worst tool, the Dear Doctor letter, and the SICG training, as clear, understandable, and useful. The sequential structure allowed for easier referrals to ACP and Goals of Care discussions and supported existing practices, such as complex care visits.

Barriers to implementing the care pathway included difficulty accommodating the additional preparatory work, such as tracking documentation of ACP in the electronic medical record (EMR). Some clinicians were uncertain how well the pathway would work as virtual visits, which were necessary during the COVID-19 pandemic. Tools such as the Best-Worst tool could be difficult for patients to navigate ahead of a visit. The sequential structure of the pathway posed a barrier when patients refused to complete these tools, or did not complete the first visit with an allied health professional. Lastly, coordination of clinical care was a barrier to using tools from the care pathway when, for example, the regional Health Authority in BC already required the use of a specific ACP record.

Clinicians reflected on the potential to adapt the care pathway to emerging needs, such as virtual care. The training component was considered foundational to the success of the pathway and physicians recommended expanding the training, e.g., by offering "refresher" courses. Embedding and normalizing ACP within the practice culture was an important prerequisite; clinicians recommended this would include challenging perceptions of which health staff are responsible for ACP. Finally, clinicians suggested a need for bridging tools to facilitate transitions between visits and communicate information with other physicians who may be in contact with patients involved in the pathway.

II. Clinician impact

Clinicians discussed the impact of the pathway on domains related to their practice and interaction with patients, teamwork within the practice, and their work processes.

The domain of *clinical practice* refers to roles and responsibilities of the individual physician, and the clinical interactions between physician and patient. The pathway facilitated these interactions through the preparedness of patients and SDMs, who had a clear rationale for their visit. At the physician level, a script with tested, validated ways to talk about ACP improved confidence in the decision-making process. When family physicians felt confident and understood patients' long-term goals, this positively affected their interactions with patients, leading to deeper conversations in which physicians and patients could comfortably talk about ACP.

Barriers included practical challenges, such as a lack of time, cancelled appointments, and difficulty planning visits, resulting in lost momentum during the clinical process. When patients showed discomfort discussing the end of life, or a lack of readiness to choose an SDM, some clinicians may not have known how to move the needle on these difficult conversations. When clinicians felt that patients were not ready, they perceived themselves instead as "nagging" these patients into entering the care pathway.

One BC physician reflected on the lack of billing codes in the context of integrating the pathway into future clinical practice. Conversations such as those facilitated by the pathway did not appear to fall under existing billing codes, possibly precluding clinicians from investing the necessary time in these conversations in the future.

The *teamwork* domain refers to how the work of the care pathway was allocated within the practice team, and how members of the practice team cooperated to implement the pathway. When physicians were aware that allied health professionals had the skill set for ACP, they had greater willingness to refer patients for complicated ACP conversations. Staff awareness of and support for the care pathway in turn translated to practical support for physicians in their tasks. This division of tasks according to expertise enhanced existing collaborative relationships within the practice.

Resource availability for this task division, however, was also a barrier to impact at the teamwork level. Some settings found insufficient staff to perform the first two pathway visits or faced structural barriers to incorporating and onboarding allied health. In BC in particular, the allied health professional who conducted the pathway visit was an external research nurse; in the internal medicine setting, this introduced a completely new role to the clinic. Further, a lack of clarity about which staff were responsible for a given task hindered efficient teamwork and coordinating patient visits to be conducted by different staff was sometimes challenging. An Alberta physician, for example, felt that the patient became a "go-between" between the social worker and the physician.

In considering future sustainability in the teamwork domain, clinicians proposed training and engaging the entire practice, including medical residents, to allow delegation of tasks according to practice resources. Some physicians questioned the long-term sustainability of including the allied health professional after the conclusion of the study and considered how clinic staff roles might change to accommodate their absence. One proposed solution was integrating ACP care pathway visits with complex care visits.

The *work processes* domain refers to the way work was previously done in the practice setting and how new ways of working were integrated into the care pathway. Impact was facilitated via compatibility between the pathway and current workflow, allowing integration with existing

activities and the clinic scope of practice. This streamlined the ACP process; decision-making was perceived to be more robust without requiring additional time. As clinicians recognized the inherent value of conducting ACP, they noted that the time spent on ACP conversations was time well spent.

An additional facilitator emerged following the use of patient lists (via a query in the electronic medical record) for study recruitment: clinicians suggested that identifying patients eligible for ACP may be more effective and less threatening to patients when it is framed as part of routine clinical practice.

Barriers in the work processes domain were considered at the level of clinicians and their practice, and the broader health system level. There was difficulty integrating the care pathway into the current way of working when, for instance, pre-planning for ACP visits created additional work for physicians who may otherwise have engaged in ACP "in the moment". Physicians did not want to take time away from patient visits for other purposes, such as medical consultations; some suggested that ACP would need a separate conversation. However, fee-for-service models were seen as less compatible with this approach. Additionally, integration with the existing workflow was, for example, difficult for a physician in the internal medicine setting, who did not have a regular schedule in the clinic.

Clinicians proposed flexibility in implementation to better integrate the pathway into their existing workflow, such as by using in-person patient visits for medical consultation, and virtual visits for ACP conversations. Many clinicians proposed recommendations for tailoring the pathway to the local context and adapting it to the needs of an individual clinic. Additional consideration was given to future changes in the health system, such as in physician contracts and salaries, which may facilitate more ACP.

III. Patient Impact

Fewer responses by clinicians referred specifically to impact at the patient level. We distinguish between the impact on patient preparation and patient readiness.

Preparation refers to patients' engaging with ACP, prior to the physician visit. Pre-work for follow-up visits, i.e., using tools to help patients align values with care goals, was a facilitator for this preparation, as patients were actively involved and became invested in the ACP process. Enhanced comfort and better communication between patient and SDM resulting from this pre-work contributed to preparation. As the pathway focused on promoting ongoing conversations in a patient-centered way, patients were seen to be able to build on knowledge they may already have.

A lack of buy-in from patients or fluctuating willingness to participate was a prominent barrier to preparation. This barrier could occur prior to visits at different points in the pathway. Patients may also have needed more time and information than they received to prepare for the physician visit. Some patients, such as those who were still relatively well, had not thought about resuscitation or had trouble imagining a time when they could not speak for themselves, impeding contemplation about possible goals of care.

Readiness refers to patients engaging with ACP during or following the visit with the physician. In addition to practical preparation for conversations regarding goals of care, clinicians felt the pathway conversations helped patients feel ready to engage with details of the ACP process and to discuss goals of care, and that SDM confidence increased.

Difficulty transitioning from thinking about values to documenting concrete goals of care impeded patient readiness. Compared to having ACP conversations, completing goals of care documentation was more difficult for patients, and patients had less confidence in the end results of this documentation. Patient comfort and energy was a final potential barrier, resulting from a protracted process and long conversations with clinicians.

DISCUSSION

Findings

This study presents the lived experiences of clinicians in two Canadian provinces implementing a novel ACP pathway within longitudinal generalist outpatient settings, including primary care/family medicine and general internal medicine.

Much attention was paid to elements of sense-making (NPT construct: coherence) and relational work (NPT construct: cognitive participation). In line with previous research, clinicians saw ACP as important,[34] and as a legitimate part of their clinical work. The care pathway introduced new tools, a standardized structure, and a new role for allied health professionals, which differed from existing ad-hoc approaches. However, several clinicians reported lack of buy-in from patients, a lack of follow-up after patients entered the pathway, or a lack of readiness to participate from the SDM. These barriers at different points in the pathway, reported from the clinician perspective, correspond to patient-reported barriers such as perceptions of the importance or relevance of ACP,[35] or distrust towards formal documentation as part of the ACP process.[36] This highlights an invaluable contribution to sense-making work from the patient and SDM, wherein the engagement of patients and their family is instrumental to the success of the pathway.

Contributions to teamwork within the clinic and impact on work processes reflect operational work done to enact the pathway (NPT construct: collective action). Physicians felt that allied

health professionals had the knowledge and skills to broach ACP and valued their support. This finding lends practice-based evidence to prior survey findings that primary care physicians find it acceptable for non-physician staff, including nurses and social workers, to be involved in ACP[20] and suggests a team-based approach to ACP in the clinic setting is desirable and feasible. Positive and trusting interprofessional relationships, and clarity of roles and responsibilities, are facilitators to implementation of interventions into primary care.[37] Although staffing availability may differ depending on context, the role division in the care pathway was implemented to a degree that suggests the model is sustainable for the future. Spontaneous recommendations to include other clinic staff, such as medical residents and learners, for training and implementation in the future, are especially encouraging for sustainable implementation.

There was variable feedback about the feasibility of integrating the pathway with existing practices and workflow. A recurring barrier was a lack of time to coordinate multiple visits in a busy clinic setting. Preparing patients with information and resources ahead of time provides an opportunity to reduce this barrier,[24,38] as does clarifying the roles of clinic staff to define team responsibilities.[20,39] The care pathway aimed to incorporate these strategies to streamline the ACP process. However, the COVID-19 pandemic introduced new time and resource pressures. A pivot to virtual care occurred organically in response to the pandemic and led physicians to reflect on challenges and future opportunities within this modality, such as conducting conversations about non-medical topics virtually. Studies of ACP via remote consultations are emerging; an ACP intervention via videoconferencing was acceptable to persons with mild dementia.[40] Additional research may be necessary to develop recommendations of best practices for ACP in the context of virtual care. It will be important to assess the impact of virtual care on time pressure and workload for clinicians.

Regarding implementation and scale-up, clinicians referred to idiosyncratic issues within their existing practice, which illustrated how the care pathway fits within the current health care system. Compatibility between the work introduced by the pathway and the provincial context such as existing billing codes and documentation templates should be taken into account; Canadian primary care clinicians have previously described a need for remuneration and policy support for ACP.[23]

Clinicians appraised the pathway as useful and impactful (NPT construct: reflexive monitoring). The stepped process and tools prepared patients and helped clinicians feel more confident to have ACP conversations. More in-depth conversations, which guarded patient safety and comfort, further promoted decision-making confidence for all parties. Confidence and strong communication skills can in turn enable ACP uptake.[21] These findings also support

that the pathway structure facilitates meaningful discussions with patients,[41] who appreciate personalized conversations.[42] These positive interactions bolster patient-provider trust, potentially mitigating barriers where patients fear negatively affecting their relationship with their physician if they discuss ACP.[35] This level of impact furthermore emphasizes the importance of talking about patients' values and wishes for care through ACP conversations when the patient is relatively well, so that the pathway can be revisited as the patient's health status changes.[15] In light of this, adaptations of the pathway should accommodate patients who revisit ACP after initial conversations, in addition to patients who are newly-introduced to ACP.

Limitations/strengths

Strengths of this study include the detailed feedback about clinician experiences generated by the semi-structured interview and focus group format. There are also limitations to this study. First, although we include statements of impact on patients and SDMs, these statements were reported from the clinician perspective, not from the perspective of patients and SDMs themselves, and should be interpreted with this in mind. Second, the patients who participated in the pathway may have been those more amenable to ACP, and some clinicians reported buy-in issues for patients who were less amenable. Further reflection is needed on how to reach these patients and engage them in the first steps of ACP. Lastly, although physicians in BC who followed the SICG training but did not refer patients to the pathway were eligible to be interviewed, none participated in interviews. This may leave barriers related to participating in the project underexplored.

CONCLUSION

This qualitative study contributes to our understanding of clinician experiences implementing an ACP pathway intervention by examining several different contexts: the Alberta and BC longitudinal outpatient generalist settings, including primary care settings. Results suggest that while the intervention may be implemented slightly differently in these contexts, core experiences with the pathway were that implementation into, and integration with, current practice were feasible. Across settings, similar themes recurred regarding usefulness of the pathway structure and its tools, impact on clinician confidence and interactions with patients, teamwork and task delegation, compatibility with existing workflow, and patient preparation and readiness. Clinicians were supportive of ACP overall and of the pathway in particular. While the pathway was implemented in a protocolized manner and thus did not overhaul clinical practice, clinicians' experiences, suggestions for tailoring, and reflections on sustainability of the intervention offer valuable recommendations to consider when adapting the pathway for future implementation in primary care.

LIST OF ABBREVIATIONS

ACP: Advance care planning

AD: Advance directive

BC: British Columbia

SDM: Substitute decision maker

SICG: Serious Illness Conversation Guide

DECLARATIONS

Ethics approval and consent to participate

Research ethics approval was granted by the Hamilton Integrated Research Ethics Board (project #2017-3977), the Conjoint Health Research Ethics Board (CHREB), University of Calgary (REB18-0056, REB18-0056_REN1, EB18-0056_REN2), and University of British Columbia Clinical Research Ethics Board (CREB) (#H17-03552). Informed consent was obtained from all the participants. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Funding

Julie Stevens is the recipient of a predoctoral scholarship from The Research Foundation - Flanders (Belgium) (Fonds Wetenschappelijk Onderzoek/FWO) [11B6220N]. The funder has no role in the conceptualization of the study; in the analysis and interpretation of data; in the writing of the manuscript; or in the decision to submit the manuscript for publication.

This research was funded by the Canadian Frailty Network (Technology Evaluation in the Elderly Network) which is supported by the Government of Canada through the Networks of Centres of Excellence (NCE) program. Opinions are those of the authors and do not imply endorsement from the funder.

Authors' contributions

MH, DB, and AT conceptualized the study. MH, DE, DB, AT, RC, DC, NF, and MH carried out the study. DC and NF collected data. MH, DE, and JS conceptualized the paper. JS and DE conducted the member-checking interview and analyzed the qualitative data; MH checked and

arbitrated data analysis. JS wrote the initial drafts of the paper. All authors have reviewed and approved the final manuscript.

Acknowledgements

Availability of data and materials

The datasets analyzed during the current study are not publicly available; participants did not consent for data to be shared beyond the study.

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SUPPLEMENTARY FILES

Additional File 1. COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	8
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	8
Occupation	3	What was their occupation at the time of the study?	8
Gender	4	Was the researcher male or female?	8
Experience and training	5	What experience or training did the researcher have?	8
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	N/A
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	8
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	8
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	8
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	7
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	8
Sample size	12	How many participants were in the study?	9

Non-participation	13	How many people refused to participate or dropped out? Reasons?	8
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	8
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	N/A
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	9
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	8
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	8
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	8
Field notes	20	Were field notes made during and/or after the inter view or focus group?	8
Duration	21	What was the duration of the inter views or focus group?	9
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	23	Were transcripts returned to participants for comment and/or correction?	N/A
Topic	**Item No.**	**Guide Questions/Description**	**Reported on Page No.**
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	8-9
Description of the coding tree	25	Did authors provide a description of the coding tree?	9
Derivation of themes	26	Were themes identified in advance or derived from the data?	9
Software	27	What software, if applicable, was used to manage the data?	9
Participant checking	28	Did participants provide feedback on the findings?	N/A

Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	9
Data and findings consistent	30	Was there consistency between the data presented and the findings?	9-14
Clarity of major themes	31	Were major themes clearly presented in the findings?	9-14
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	9-14

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care.* 2007. Volume 19, Number 6: pp. 349 – 357

Additional File 2. Best-Worst Scenario Online Tool 7-item, with values statements/risks/benefits table

Screenshot 1: Introduction

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 1 of 4: Introduction

Welcome

The questions on the pages that follow ask you about issues related to your medical care in the case of serious or life-threatening illness.

There are many issues that each of us must consider as we decide what kind of medical treatments we want. For each person, some issues are more important than others. Understanding how important each issue is to you will help your doctor to decide with you which type of care would be most appropriate for you.

There are 4 sections to this tool:
1. Introduction
2. Questions about me such as my age and gender
3. Questions about which issues matter most to me
4. A summary of my results

Press the 'next' button to move between questions and stages. The navigation bar allows you to move back.

Next

Screenshot 2: About me, part 1

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 2 of 4: About Me

These questions will help us understand more about you.

Back   Next

266

Screenshot 3: About me, part 2

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 2 of 4: About Me ≡

What is your age

Less than 60
60-69
70-79
80+

Back   Next

Screenshot 4: About me, part 3

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 2 of 4: About Me ≡

What is your gender?

Male
Female

Back   Next

Screenshot 5: Values instructions and table

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 3 of 4: My Values ≡

How to complete these questions

We will show you 7 sets of issues. Each set has 3 different issues.

What we want you to do is simple - please consider each of the issues and tell us:

- Which ONE of the 3 issues is **most** important to you when considering medical treatments you may want?
- Which ONE of the remaining 2 issues is the **least** important to you when considering medical treatments you may want?

There are no right or wrong answers - we are only interested in your opinions.

Issue	Benefit	Risk
1) **Live as long as possible** I want to live as long as possible.	Living as long as possible	May require the use of life support machines
2) **Avoid Machines** I want to avoid the use of machines in order to keep me alive.	Not being limited by machines and/or being in a hospital	May die from a severe illness or sudden death
3) **Lessen Symptoms** I want to avoid symptoms such as pain and shortness of breath.	Being free of painful or uncomfortable symptoms	May not receive some types of medical treatment that could extend life but make symptoms worse (i.e. chemotherapy)
4) **Decision making & Independence** I want to be able to make my own decisions about my care and live as independently as possible.	Medical goals are in line with your own wishes	Following medical goals may not improve health or result in a longer life
5) **Remain Active** I want to continue to be able to participate in the activities I like to do.	Continue to be as active as possible	May not receive certain treatments that could extend life if it requires being bed-bound or under sedation
6) **Think Clearly** I want to be able to think clearly and not be confused.	Maintaining your ability to carefully consider the situation at hand	May not be possible if disease state worsens (i.e. delirium); might experience pain if thinking clearly requires withholding pain medication
7) **Religious Beliefs** I want treatment consistent with my religious and spiritual beliefs.	Decreased moral or spiritual distress	May conflict with recommended treatment of disease

Back   Next

Screenshot 6: Values Questions

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 3 of 4: My Values ≡

Which issue is most and least important to you?

+ Description of issues

Question 1 of 7

Most important		Least important
☐	**Remain active** I want to continue to be able to participate in the activities I like to do.	☐
☐	**Live as long as possible** I want to live as long as possible	☐
☐	**Avoid Machines** I want to avoid the use of machines to keep me alive.	☐

Back   Next

Note: "Description of issues" link opens to display table on previous screenshot.

Note: This screen repeats 7 times with different value combinations displayed. Only one example included here.

Screenshot 7: Summary

WHAT MATTERS TO ME IN THE EVENT OF SERIOUS OR LIFE-THREATENING ILLNESS?

Section 4 of 4: Summary ☰

You have completed all the questions

This information will help you and your doctor to choose the most appropriate treatments for you if you have a serious or life-threatening illness.

The chart below describes what matters to you from most (top) to least (bottom)
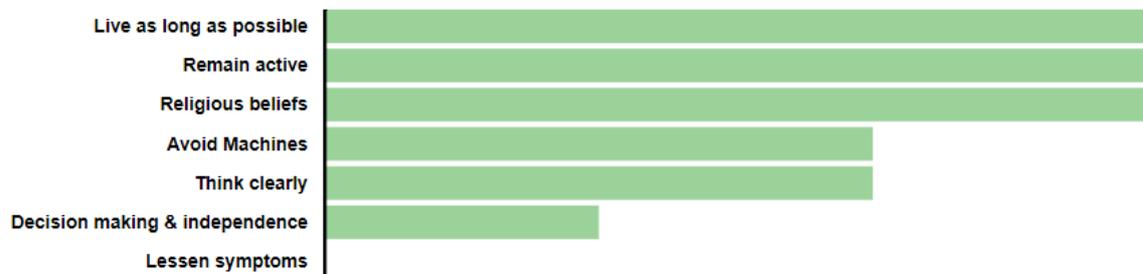
Back

Additional File 3. Interview guide

Pathway Implementation Evaluation

Overall Research Question- What is the lived experience with the pathway?

Draft Interview Guide

Introduction/Context of Questions

We would like to get some information from you about your experience with the care pathway. As a reminder, the care pathway we refer to includes some components developed to make ACP a structured process. Briefly, these are:

- A method to identify patients,

- A conversation guide for clinicians (nurse or social worker), used in combination with values clarification tools,

- Results of that conversation in *the Dear Doctor Letter* and the ACP Record,

- A conversation guide for physicians to follow up

To support the pathway, you were provided with a one-time training for the conversation guide.

Interview Questions

NPT generic question	Question wording	Prompts
Background	Please describe your role in the care pathway and how much experience you have had with it to date.	
How did the intervention effect the work of the practice?	How is the care pathway similar or different from how you previously approached Advance Care Planning discussions with patients?	- Patient identification/prompting - Provision of Structure to conversation - Tools (information provision, values clarification, documentation) - Communication training - Preparation of patient - Allied health involvement

	What if anything changed about the way physicians/clinicians work together when using the care pathway? Whose roles changed and how?	• Role clarification • Scope of practice • Communication • Collaboration
NPT generic question	**Question wording**	**Prompts**
How compatible was the intervention with current work processes?	How compatible was the care pathway with your current work processes? How was your typical work flow impacted by the care pathway?	• Patient identification/prompting • Provision of Structure to conversation • Tools (information provision, values clarification, documentation) • Communication training • Preparation of patient • Allied health involvement
Did it promote or impede work?	Tell me about feasibility and workload issues - What were the barriers / facilitators to using this pathway? What would you change?	• Prioritizing against other things • Confidence/self-efficacy to conduct ACP • Willingness to conduct ACP/follow pathway • Supports of the pathway to conducting ACP
	How did the pathway affect the time taken or efficiency of your visits?	• If time/efficiency affected, was the time 'well spent'?
What effect did it have on consultations?	Compared to how you previously approached ACP discussions, how did the care pathway affect your ACP conversations with patients and their SDM/family member(s)?	• (Perceived) patient comfort/experience • Outcomes

	Thinking about the components of the pathway - Are they useful/not useful? Which do you believe are essential?	• Patient identification • Conversation guide • Structured approach, patient preparation • Dear Dr. Letter • Integration of [Health Authority] ACP Record
What is perception of intervention at this point?	Did people seem supportive of the pathway - why or why not?	• Physicians/Clinicians • Patients/SDM/Family
	What benefits did you perceive by using this pathway approach? And conversely, what were the challenges? Were there any unintended effects?	
	What would help this care pathway continue (if beneficial)? What would hinder it from continuing? What would improve it?	

PART IV. General discussion and recommendations

GENERAL DISCUSSION AND RECOMMENDATIONS

The dissertation had two main aims. The first aim was to implement and evaluate the complex ACP-GP intervention for patients with a chronic, life-limiting illness in Belgian general practice. This aim was reached through a cluster-randomized controlled trial (RCT) design with a parallel process evaluation (described in **Chapter 1**). **Chapters 2 and 3** report baseline findings of patient ACP engagement, and the effects of the intervention on the patient- and GP-level primary outcomes, respectively. **Chapter 4** reports the process evaluation findings.

The second aim was to describe insights into the implementation of ACP interventions, based on a scoping review of international literature (**Chapter 5**) and the example of an ACP pathway implemented in two Canadian provinces (**Chapter 6**).

In the following discussion, a **summary of the main findings** is first presented, followed by a critical reflection about the **strengths and weaknesses of the methodology** used to answer the research questions. Then, the findings from the conducted studies are **discussed** according to two main themes. First is a reflection on the cluster-RCT and how its findings can be interpreted, followed by further lessons learned that are informed by findings from scoping international literature and comparing ACP-GP to an ACP pathway intervention implemented in two Canadian provinces. Finally, implications are discussed, and recommendations offered, for **future practice, research, and policy.**

1. Summary of main findings

1.1 Research aim 1: Implement and evaluate an ACP intervention for patients with chronic, life-limiting illness in general practice (ACP-GP).

Chapter 1 describes the protocol of the cluster-randomized controlled trial (cluster-RCT) of a complex intervention to facilitate ACP with patients with chronic, life-limiting illness in Belgian general practice. Two primary outcomes were specified: patients' ACP engagement,[1] and GPs' ACP self-efficacy.[2] We measured these outcomes at baseline, at 3 months post-baseline (T1, primary effectiveness analysis) and at 6 months post-baseline (T2, exploratory effectiveness analysis). A process evaluation accompanied the trial and followed the Reach, Efficacy/Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework. Data collection for the process evaluation included recruitment monitoring, questionnaires for GPs and patients, and (focus group) interviews with GPs and patients in the intervention group.

Chapter 2 explores patients' ACP engagement within our study population at baseline, and aimed to understand which factors (patient-related, or patient-GP-communication-related),

were associated with engagement. Engagement was measured using the ACP Engagement Survey, 15-item version,[1] consisting of means on self-efficacy and readiness subscales, and an overall mean score for engagement which includes both subscales (range 1-5, with higher scores indicating higher self-efficacy, readiness, and overall engagement). Patients also rated their perception of the extent of ACP communication with their GP in the last 3 months. A total of 95 patients, identified by 35 GPs, completed baseline questionnaires. Mean overall ACP engagement was 3.06 (Standard Deviation (SD) 0.98). Mean self-efficacy was 3.86 (SD 1.13); mean readiness was 2.52 (SD 1.20). After correction for multiple testing, we did not find statistically significant associations between patient demographic or clinical characters, and patient ACP engagement. ACP engagement was also not significantly associated with how much information the patient received from their GP about ACP, the extent to which the GP listened to what is important for the patient to live well, and the extent to which the GP listened to what is important to the patient regarding their future care. We found higher overall engagement for patients who gave a high rating to the extent to which their GP listened to their worries for future health (3.27 versus 2.48, $p = 0.002$), compared with patients who gave a low rating. The same pattern was observed for self-efficacy (4.10 versus 3.14, $p <0.001$).

Chapter 3 reports the primary outcome analysis for the cluster-RCT of the ACP-GP intervention in Belgian general practice. For this, we tested whether the intervention was superior to the control group in improving patients' ACP engagement,[1] and GPs' ACP self-efficacy,[2] by 3 months post-baseline (T1, primary effectiveness evaluation) and 6 months post-baseline (T2, exploratory effectiveness evaluation). We randomized 35 GPs and 95 patients; 18 GPs and 53 patients were assigned to the intervention group. We did not find significant differences in patient engagement at T1 (baseline-adjusted mean difference = 0.34; 95% CI = –0.02 to 0.69; $p = 0.062$; standardized effect size = 0.34), nor at T2 baseline (baseline-adjusted mean difference, 0.20; 95% CI, -0.17 to 0.57; $p = 0.28$, standardized effect size=0.20). ACP engagement increased notably in both groups. We also did not find significant differences in GP self-efficacy at T1 (baseline-adjusted mean difference, 0.16; 95% CI, -0.04 to 0.35; $p = 0.11$; standardized effect size = 0.44) or at T2 (baseline-adjusted mean difference, 0.11; 95% CI, -0.09 to 0.31; $p = 0.27$; standardized effect size = 0.31).

For **Chapter 4**, we describe findings from a mixed-methods process evaluation of the intervention, based on the Reach, Efficacy/Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework.[3] The process evaluation was conducted to better understand the implementation of the complex ACP-GP intervention, by assessing how the intervention was delivered and how it was experienced by both GPs and patients. Sixteen GPs and 46 patients provided questionnaire data at T1 (3 months post-baseline), and we also collected qualitative data from focus groups and interviews with fourteen GPs and 11 patients

from the intervention group. Reach among GPs was low, with 50 of 1519 GPs who were contacted agreeing to participate, and 35 GPs ultimately being randomized after including patients. Patient reach, facilitated via GPs, was proportionally higher, with 95 of 117 patients (81.2%) identified completing informed consent and baseline assessment. Effectiveness as described in **chapter 3** was low; in focus groups and interviews, GPs emphasized the impact of having a positive approach to ACP. ACP conversations led to positive affective reactions in patients, such as feeling reassured, while GPs felt more able to speak up for the patient's wishes. Adoption was variable, with high attendance to the training, most GPs showing uptake of the conversation component to some degree, and approximately two-thirds of patients using the workbook at least once. GPs endorsed the value of ACP; patients sometimes found it confronting and differed in how personally relevant they considered it. However, the documentation template was not often used by GPs. Due to this, implementation fidelity to the full intervention (all four components) was low. Documentation was still primarily done in the patient's electronic medical record (EMR). GPs reported that most patients with whom they had ACP conversations, had two conversations as specified in the protocol. Satisfaction with the intervention was high among GPs and patients. GPs who did not feel the training met their expectations, wanted training that is more intensive. Patients were satisfied with the conversations with their GP and found them useful. Conversations themselves were described by GPs to be highly individualized, based on patient priorities. Patients approached ACP differently depending on factors such as their previous experiences with ACP, their relationship with the GP, and whether they desired an active role in making decisions about their care. Intention for maintenance showed mixed results; two-thirds of GPs had high interest in continuing to use the intervention materials, and half of patient responses indicated high interest in continuing to use the workbook. GPs saw opportunities for integrating the training into (continuing) medical education, but also perceived challenges for integrating ACP conversations into their current way of working. Some patients saw their ACP process as "finished", while others continued the process through contemplation, talking to loved ones, or planning to speak to their GP again. There were also patients who would have liked to discuss ACP with a specialist care provider in the future.

1.2 Research aim 2: Describe insights into the implementation of ACP interventions, using international ACP literature and the example of an ACP pathway implemented in Canada.

Chapter 5 presents a scoping review of ACP interventions, tested in an RCT, for patients with chronic serious illness. We included sixteen articles reporting the primary outcome(s) of such an RCT. The largest proportion of studies (n=11) used an interview or conversations to

address ACP topics. Eight studies used an AD or goals of care form. Other intervention components included providing conversation summaries to physicians or placing documentation in the patient's health record, providing informational material, using question prompts and communication tips, interactive decision aids, and educational workshops. The mechanism "tailoring the delivery style or content to the needs of the patient recipient" was linked to the greatest variety of outcome domains (n=4 domains). The mechanism "promoting skills, competence, and confidence to participate in ACP conversations" was referred to in the greatest number of studies (n=6 studies). However, primary outcome findings were mixed. Only congruence between patients' wishes and their surrogate decision maker (SDM) or caregiver's understanding of those wishes improved across studies. In discussing their findings, authors referred to three overarching themes: 1) participant factors, such as the influence of racial disparities, illness experience, and desired role in decision-making; 2) implementation factors, such as intervention duration, whether the SDM or caregiver was engaged, and the healthcare context into which an intervention is implemented, and 3) methodological factors, such as assessment effects, poor outcome fit, or registration bias.

Lastly, in **Chapter 6,** we explored the experiences of clinicians who implemented an ACP pathway in longitudinal generalist outpatient care (primary care and general internal medicine), in the Canadian provinces of British Columbia (BC) and Alberta. The pathway was implemented in one Alberta family practice, two BC family practices, and one BC internal medicine clinic. Twelve physicians and one social worker were interviewed. Barriers and facilitators were identified across multiple domains. Respondents also described how the intervention could be sustained in the future. The first domain was the participants' appraisal of the ease of use of the components of the care pathway itself, including the structured visits, documents, and tools. Clinicians also described barriers and facilitators to impact at their level, yielding a clinician-level impact domain with three themes. The first theme was clinical practice, this being the responsibilities of the physician, and the clinical interaction between the physician and patient. The second theme described how the pathway contributed to teamwork within the clinic, or how existing team structures did or did not support the pathway. The third theme described how the pathway could be integrated into the existing work processes within the clinic, and what needed to change to accommodate the pathway. Some clinicians also referred to the impact they perceived at the patient level. This was divided into two themes: preparation, the patient's engagement with ACP prior to the visit with the physician; and readiness, the patient's engagement with ACP during or following the visit with the physician. Across settings and between the two provinces, similar themes recurred. ACP in these settings was described as feasible, but patient buy-in was a prerequisite to the rest of the pathway being followed.

2. Methodological considerations: strengths and limitations

2.1 Strengths of the cluster-RCT

The methodology of the cluster-RCT to answer Research Aim 1 has several important strengths.

An **RCT study design** is recommended by the Medical Research Council (MRC) Framework guidance for assessing the effectiveness of an intervention.[4] Random allocation of participants may reduce biases by distributing participant characteristics randomly between groups,[5] but blinding of allocation is important to guard that researchers do not consciously or unconsciously assign a participant to a particular group. We protected blinding of allocation by assigning GPs who consented to participate, completed their baseline questionnaire, and included patients, with an alphanumeric code. The code was provided to a researcher who was not involved in any other part of the study. This researcher used an allocation list, generated by a statistician, to sequentially assign GPs to intervention or control. Furthermore, the clustered design, where GPs and all their included patients were assigned to either the intervention or control groups, reduced the risk of contamination, whereby effects of the intervention may otherwise "spill over" into the control group.[4,6,7]

Strengths of the intervention design also include a **strong theoretical basis** guiding its development, following the MRC Framework for developing and evaluating complex interventions.[4,8] Key features of the intervention included a workbook, which aimed to sensitize patients to the importance of ACP and encourage them to think broadly about their values, preferences, and worries. After this, the patient would be actively involved in conversations about ACP with their GP, who had also received a training that aimed to equip them with skills for ACP communication. Both the workbook and the conversations were hypothesized to facilitate behavior change processes in patients, while the training and practice experience were proposed to help GPs feel more prepared and confident in conducting ACP. Documentation via a template then aimed to make a record of these conversations which could be stored, shared, and revisited as needed. There was continuity within the research team from the development phase to the evaluation phase, as authors involved in the development and piloting of the intervention were involved as members of the multidisciplinary research group for the current dissertation.

This cluster-RCT was, to our knowledge, **the first evaluation in Belgium of the impact of an intervention on patient ACP engagement**. This aligns our research with literature utilizing Behavior Change Theory and Social Cognitive Theory[9–11] to understand processes underlying ACP behaviors, such as having conversations and documenting wishes for medical treatment,

rather than examining only whether or not patients complete discrete actions, such talking to clinicians about their values and wishes, or completing an AD. This approach has been described as warranted to improve end-of-life care by creating a better understanding of the targeted behaviors, such as having ACP conversations, but research literature in the past has made limited use of such theory.[12]

Adhering to the MRC Framework guidance ensured that the RCT was part of a rigorous and recursive process of complex intervention design and evaluation. This includes paying attention to understanding how the intervention causes change based on available evidence and appropriate theory, identifying potential implementation problems, and reporting both outcome and process evaluations.[4] The version of the MRC Framework guidance which informed the cluster-RCT and process evaluation, was based on a paradigm where identifying intervention effectiveness is the most salient question.[13] Recent revisions to the MRC Framework guidance emphasize that complex intervention research should go beyond asking whether or not the intervention works in terms of achieving the intended outcome through an exclusive focus on obtaining unbiased estimates of effectiveness; it should identify the impact, assess its value relative to resources, consider the context in which it is implemented, and contribute to theorizing how the intervention works.[13]

Embedding a parallel process evaluation in the study design allowed us to gather insights which answer some of the considerations of the updated MRC framework guidance as well. This evaluation was likewise strengthened by its foundation on the RE-AIM framework,[3] which provides an opportunity to evaluate indicators beyond quantitative findings of primary intervention effectiveness.[14] It is an intuitive and understandable model of evaluation that can address questions of "who, what, where, how, when, and why",[14] with the intention to narrow the gap between evidence and practice.[15] A mixed-methods approach to this process evaluation, combining quantitative and qualitative research approaches, permits a greater breadth and depth of understanding[16] of the RE-AIM constructs. While RE-AIM is sometimes misinterpreted as relying only on quantitative data,[17] qualitative methods to understand the RE-AIM dimensions are recommended to help understand how and why results occurred.[18]

The questionnaires we used for primary effectiveness assessment (ACP Engagement Survey 15-item version,[1] GP ACP Self-Efficacy Survey[2]) were **translated from validated English instruments**, using a structured process based on the EORTC Quality of Life Group procedures for forward-backward translations of questionnaires.[19] Two independent translators translated each English questionnaire into (Flemish) Dutch, and a combined provisional Dutch translation for each questionnaire was then translated back to English by two proficient English speakers. The English translation was compared with the original

questionnaire and differences were discussed with the project group to yield the revised Dutch translations. The questionnaires were cognitively tested with a sample of 6 GPs and 6 patients who met the same inclusion criteria as those of the RCT. This helped to ensure that the questions were acceptable and understandable to GPs and patients.

Analyses of intervention effects applied the **intention to treat** principle, where all participants randomized were included in analyses and analyzed according to the group to which they were assigned.[20,21] Using this principle allows analyses to better reflect the potential effects of the intervention when it is implemented in a real-world practice setting, which may include partial adoption or implementation that deviates from the intervention as described in the protocol. The **primary analyses** also used methods that were matched to the cluster-randomized design, by accounting for clustering of time points within participants, and patients within GPs. Although the obtained intra-class correlation coefficients (ICCs) for overall ACP engagement, and the ACP Engagement Survey subscales within patients, were small, a mixed model analysis with a random intercept nonetheless accounted for these small degrees of similarity between patients within each GP cluster.[22] The ICC of 0.04, assumed a priori for the power calculations for the primary outcome analyses, was closely matched by the data we obtained from patients.

2.2 Limitations of the cluster-RCT

There are also some limitations to the methodology of the cluster-RCT and its analyses.

First, although the translated ACP Engagement Survey and ACP-SE questionnaires, which were used for primary outcome collection in the cluster RCT, were cognitively tested, **we did not conduct a validation study** of the translations. A validated Dutch translation and cultural adaptation of the ACP Engagement Survey is now available that has good criterion and construct validity,[23] but which may still require additional adaptation to Flemish. There are several differences between our translation of the ACP Engagement Survey and the validated Dutch translation. The self-efficacy questions in the Dutch translation were changed from asking how confident a patient is that they can perform a behavior, to whether the patient thinks they can perform the behavior, and the response categories were reduced from five to three. While we encountered similar challenges translating the word "confident", we asked patients to indicate how *certain* they are that they can perform the behavior. We preserved the five response categories and kept a neutral response as the middle category. Maintaining the original English response format may allow for easier comparison across studies.

In **Chapter 2**, our baseline analyses were conducted on questionnaires completed by patients who were recruited for the cluster-RCT. This yielded a **specific sample, comprised of**

patients who agreed to participate in a study, rather than a random or convenience sample from the population. As is more often than not the case in RCTs, we may not exclude selection bias from the population to the study sample. However, our focus in this study was to explore factors associated with ACP engagement in this sample, which represents a heterogeneity of illnesses with approximately one-third having an active cancer diagnosis, and we were able to achieve this aim. Another limitation of the baseline analyses is that, while the baseline assessment included questions about the GPs' information provision and listening regarding ACP topics during the last three months prior to baseline, **we did not collect data about the patients' ACP experiences prior to baseline** that might contribute to their perceptions of this communication. These data could include the timing, frequency, duration, or specific content of the conversations. Information regarding whether patients held one or more advance directives was collected at baseline but not reported in this study. This was due to conceptual overlap with the ACP Engagement Survey, which asks how ready patients are to sign official documents designating a surrogate decision maker (SDM) and/or stating their wishes for care.

Regarding the **primary outcome analyses** (**Chapter 3**), power calculations assumed moderate to large effects[10] given that ACP-GP is a multi-component intervention, as compared to usual care where no additional intervention or materials were offered. However, especially for patients, effect sizes for the differences in increase from baseline were small. We anticipated some assessment effects on the usual care control group; however, differences within the control group as well as the intervention group were large enough to potentially be of clinical relevance, especially for the subscale of ACP readiness, which was an unexpected result. We aimed for high power (>90%) and applied a Bonferroni correction for the two primary outcome analyses, with an alpha error rate set to 2.5%. However, the premise of the **power calculation may have been too optimistic** in favor of the intervention group.

Some GPs indicated during interviews that they identified patients whom they felt would be most comfortable with ACP. As early as the protocol-development stage, we took into account that this **selection bias** might occur. We extensively discussed how to respond to it within the research team, which included input from a member who is a GP. Ultimately, we considered it inappropriate to interfere in the GP-patient relationship by imposing ACP materials or conversations on patients to whom these would be extremely distressing. However, this meant that selection bias was possible towards a population of patients who had less to gain from the intervention.

On the other hand, interviews with patients as part of the process evaluation revealed varying degrees of openness to ACP, and previous experiences with ACP. While the patient primary

outcome, ACP engagement, includes a "readiness" subscale based on the Transtheoretical Model, where each response option can be matched to a Stage of Behavior Change, it is a limitation that the intervention did not explicitly include components or strategies which could be stage-matched to patient readiness. Furthermore, the trial analyses did not include, for example, **testing if treatment effects were greater for patients with lower ACP engagement**, or if proportionately more patients in the precontemplation stage of behavior change moved to a higher stage. This could have been an informative result in addition to average scores for overall engagement, self-efficacy, and readiness. A recent trial of a decision aid conducted such a post-hoc analysis on SDM ACP Engagement, a questionnaire based on the patient ACP Engagement Survey, and found that the decision aid increased engagement in surrogates who were least engaged at baseline.[24]

The process evaluation also has limitations that should be noted. A main limitation was that we **only collected qualitative data from the intervention group**. In retrospect, it would have been useful to interview GPs and patients in the control group as well, to better understand contextual factors that could have affected outcomes for those who were not randomized to receive the ACP-GP intervention. In the same vein, an interview with the two GPs who dropped out of the study, both of whom were in the intervention group, could have contributed to our understanding of which challenges these GPs encountered to continuing in the study or implementing the intervention. However, we were able to interview GPs who were unable to schedule conversations with some, or all, of their patients as well. Lastly, data collection from the process evaluation underrepresented perspectives of family members who were involved in the intervention together with the patient, e.g. by attending consultations together. One patient-SDM dyad, both being patients and also each other's SDM, were interviewed, but the recording was inaudible and thus not transcribed.

2.3 Strengths and limitations of the scoping review

In **Chapter 5**, we conducted a scoping review of RCTs of complex ACP intervention for patients with chronic serious illness, for which the mechanism by which the intervention was thought to work was described. **A scoping review is an appropriate choice of methodology for areas of study that are complex**, and can examine the extent, range, and nature of research, summarize research findings, and identify research gaps.[25,26] Furthermore, a scoping review can be used to determine not only available research evidence, but also how the research has been conducted.[27] The study was strengthened by adherence to the methodological framework described by Arksey and O'Malley[25] and recommendations made by Levac et al.[26] to advance the methodology of scoping reviews. The search strategy was piloted, and then repeated to identify additional articles that may have been published since

the first search. An **iterative process** for charting data is another strength of this approach, allowing data charting to be continually updated as familiarization with the nature and extent of the data increased. Evaluating linkages between interventions and their components, proposed mechanisms, and outcomes, we were able to meet the gap-analysis goal of scoping reviews. Importantly, a scoping review can also be a precursor to future systematic reviews, or of a realist review of ACP interventions. In the broader field of palliative care, as well, behavioral theories are not often applied to behaviors in people confronted with serious illness. Including mechanisms in the data charting raises novel research questions regarding theoretical bases for how ACP interventions, specifically, can be better matched to their intended outcomes.[28]

Limitations of this study include that data-charting was mainly done by one author. However, a sample of extracted data was cross-checked by the second authors and all authors were involved in discussions of the information to be extracted. After this, one author synthesized the findings. The synthesis of results was then likewise discussed during multiple meetings with the research team. Consistent with scoping review methodology, we did not assess risk of bias for the included studies. Prior literature has shown, however, that many RCTs of ACP show risk of bias.[29,30] Finally, this scoping review only included RCTs with adult participants who had a chronic, life-limiting illness, and thus the findings may be different for interventions targeting community-dwelling adults or pediatric patients with life-limiting illness.

2.4 Strengths and limitations of the qualitative study of clinicians in Canadian longitudinal generalist outpatient care

The qualitative study of clinicians in Canadian longitudinal generalist outpatient care (**Chapter 6**) aimed to understand and explore their experiences implementing an ACP pathway. The methodology of the study had several strengths. Two types of outpatient settings were involved in delivering the pathway, which was adapted from an evidence-based structured conversation tool[31]: primary care/family medicine clinics, and an internal medicine clinic. Both settings support longitudinal follow-up of patients, which makes them well-suited to delivering the multiple-visit pathway. Interviewing clinicians from both settings, as well as an allied health professional, built an **in-depth understanding of their experiences and enabled comparison between settings and provinces**. The methodology further benefited from **intensive collaborative analyses** by two coders. A preliminary coding framework was established through comparisons between open codes on the first transcript, and iteratively refined as new codes and themes emerged. Both coders applied the coding framework to all transcripts and met on multiple occasions for discussion to come to an agreement about interpretation of the data. When a transcript presented a clinician's reflections on changes in

the health system setting within their province, we were able to reach this clinician for a member-checking interview, ensuring that we were able to accurately contextualize this information.

A limitation of this study was that, while statements about the impact of the pathway on patients and substitute decision makers (SDMs) were included in the results, these were always **reported from the clinician's perspective**. Understanding from the patient and/or SDM perspective why buy-in was sometimes challenging could have improved our understanding beyond clinicians' noting that these challenges were present. Similarly, as clinician impact included a domain of clinician-patient interaction, it may have been even more helpful to be able to compare how patients experienced these interactions, with how clinicians experienced them. Additionally, while the inclusion of allied health professionals to conduct the first two steps was an integral element of the pathway, the **clinicians interviewed for this study were primarily physicians**. In BC, the allied health professional was an external research nurse and not interviewed; in the Alberta family practice clinic, one social worker was involved and interviewed. This social worker endorsed the value of patient preparation and allied health professionals' skills to comfortably talk to patients and their family about ACP. Future integration and implementation of the pathway into practice, including reflection about how to integrate the role of allied health in settings where these roles did not previously exist, would benefit from continuing to explore how allied health professionals experience the pathway, including the visits with patients, communication with physicians, and the impact on workflow as a whole.

Another limitation is that, since clinicians noted that some patients were less amenable to participate in the pathway and thus did not use the tools or attend the visits, **the patients who did participate may have been those already more amenable to ACP**. Further research on how these patients can be reached is needed, so that barriers to engaging in the first steps of the ACP process can be reduced. Lastly, some physicians in British Columbia followed the training to use the Serious Illness Conversation Guide but could not refer patients to the pathway. These physicians were invited to be interviewed, but none participated in interviews, leaving barriers to starting participation in the project underexplored.

3. General discussion in light of the current evidence base

3.1 Evidence from the cluster-RCT

The **primary effectiveness analyses** (Chapter 3) of the cluster-randomized controlled trial (RCT) (the design and methodology of which is described in more detail in **Chapter 1**) evaluated whether the complex ACP-GP intervention was superior to usual care in improving

ACP engagement for patients, and ACP self-efficacy for GPs, by three months post-baseline (T1).

Though there was improvement on the primary outcomes for GPs and patients in both groups, the difference between these improvements was not statistically significant, as reported in **Chapter 3**. This raises important questions of why we did not achieve the expected effects, and how these results can be interpreted.

3.1.1. The effect of raising awareness about ACP for GPs and patients

First, as part of reporting the primary analyses, we checked how many GPs and patients in each group reported having had ACP conversations. ACP conversations were possible as part of usual care, but we did not expect many to take place in the control group. While GPs in the intervention group reported more ACP conversations with patients included in the study, and more patient participants in the intervention group reported ACP conversations as well, we nonetheless should note the potential **impact of control group participants also having conversations**. For patients, having conversations may be associated with greater readiness to talk about desired care at the end of life, and/or greater readiness to talk about and designate a substitute decision maker (SDM). This could lead to increases in ACP engagement that were greater than expected. If practice-based experience is an important contributor to mitigating barriers related to GP self-efficacy, as described by Dutch GPs in a qualitative study,[32] then control group GPs also conducting conversations could provide a first potential, but unexplored, explanation for the results on the GP side.

It is possible that GPs and patients were **made more aware about ACP** through the study procedures, which included informing patients about ACP prior to obtaining consent to participate, and asking patients questions about their readiness for ACP. A 2016 cluster-RCT in Dutch nursing homes has similarly suggested that an intervention creating awareness of optimal symptom relief in dementia may be more effective than a physician practice guideline.[33] In ACP trial research specifically, a complex intervention in German home care services did not find superiority of the intervention for improving their primary outcome. The authors hypothesized that, in addition to a minimal intervention (delivering a short written brochure) possibly being effective on its own, data collection procedures and a Hawthorne effect could have raised awareness in patients, SDMs, and home care services.[34]

Another contextual factor which may have raised awareness about ACP, was that **the trial was conducted during the first, second, and third waves of the COVID-19 pandemic in Belgium**.[35–37] This was a period of heightened health worry: a survey conducted in Belgium and the Netherlands found that, during the first 8 weeks of lockdown, the Belgian general

population, including the bracket aged 66 years or older, worried about their current health state and their access to health care.[38] These concerns may have persisted during subsequent waves and periods of lockdowns. As people living with serious illness are also most at risk of adverse outcomes as a result of COVID-19,[39] concerns about the impact of the disease in patient populations with already-vulnerable health may have encouraged patients participating in the trial to think about and/or discuss end-of-life care and ACP, or prompted GPs to prioritize discussing patient's preferences for medical care. Together, this awareness of health risk could have facilitated recognition of the importance of ACP and medical decision-making, and/or facilitated reflection about illness beliefs and values, mechanisms also identified in the scoping review of ACP trials (**Chapter 5**). In April of 2020, the Belgian Life End Information Forum (LEIF) disseminated a communication guide, adapted by the End-of-Life Care Research Group from the American *VitalTalk* guide, to help health care practitioners talk to patients about topics related to COVID-19.[40] Importantly, some patient utterances in this guide also open the door to having a conversation about ACP. Patients stating concerns such as not wanting to be "kept alive by machines", indicates that patients think about and express which treatments they see as burdensome to themselves and their family.[41,42] These concerns may have become more salient in the face of acute health threat during the pandemic. Ideally, clinicians also leverage these moments as opportunities to address ACP.[43]

3.1.2. Patient outcomes: overall ACP engagement, self-efficacy, and readiness

It is worthwhile to examine how the findings from the RCT can contribute to our understanding of the **behavioral theory** underlying the chosen outcomes, and how to apply these theories in the future. For patients, we examined ACP engagement as the primary outcome. The development of this questionnaire is based on theories which hypothesize how people change their behavior, such as Social Cognitive Theory and the Transtheoretical Model of Behavior Change (TTM): behavior change requires changes in underlying processes, such as self-efficacy and readiness to change the behavior.[11] As such, the ACP Engagement Survey aims to assess a full range of such underlying processes as they apply to ACP. In the context of the ACP-GP trial, we hypothesize that bringing increased attention to the topic of ACP may already have nudged patients from early stages of behavior change towards planning to take action. Even when patients may not all have proceeded to conducting conversations, the ACP Engagement Survey readiness subscale may have captured how patients in both groups moved along the Stages of Change, in response to hearing about ACP and being encouraged to think about it while completing the questionnaires. In this way, as suggested by van der Maaden *et al.*,[33] **collecting data may in itself have been an effective intervention**. It could match the change process *consciousness raising* in the TTM,[44] where awareness is brought to the forefront about a behavior, and which is most emphasized in the stages of

precontemplation (i.e., never thought about the behavior; or thought about it, but not yet ready to do it) and contemplation (i.e., thinking about doing it within the next 6 months).

At baseline (**Chapter 2**), patients across the full study sample already appeared to have more self-efficacy for ACP than readiness, and average readiness for ACP behaviors included in the questionnaire did not exceed 2.68 (Standard Deviation 1.42) on a 1-5 Likert scale, where higher scores indicate greater readiness. It is possible that, while patients felt relatively confident that they can discuss ACP, readiness was lower and more variable.[9,45] Patients often want, or expect, that their clinicians will initiate ACP at the right moment.[46–49] This could be a reason why patients, at baseline, were on average not yet in stages of preparation or action for ACP.

Readiness for ACP is a complex construct. Even within patients, readiness can differ depending on the ACP behavior in question: in a study of Stages of Change in older persons, conducted in the United States, participants were often in different stages for different behaviors. Readiness was low for communicating with physicians, but higher for communicating with family and loved ones, and completing a living will.[9] Within conversations, patients may also express signs of being ready and not being ready.[45] Qualitative findings from our process evaluation (**Chapter 4**) support this complexity. In interviews, patients varied in the extent to which they had previously been engaged in ACP, and the extent to which they wished to be actively involved in medical decision-making. We should, however, use caution not to equate the ACP process only with making decisions about medical care. Patients may be open to thinking about their future health and care, even when it is emotionally confronting.[45] In a study where we analyzed concerns which patients implicitly (cues) or explicitly (concerns) communicated with their GP during their first ACP-GP conversation, we found that very few of the cues or concerns (2.3% of all cues/concerns) pertained to establishing specific goals for medical care at the end of life. In contrast, patients frequently expressed cues/concerns about the consequences of their illness on quality of life and burdening others, and worries about the severity of their illness now and in the future.[50] As suggested already from our analyses of ACP engagement at baseline (**Chapter 2**), it is possible that **ACP engagement in patients with a chronic, life-limiting illness comes from worries about the impact of future health states**, such as the burden their illness places on loved ones.[41,51,52] Discussing such worries during the consultation can provide a proactive basis for later discussions about ACP.[43]

3.1.3. GP outcome: ACP self-efficacy

For the GP primary outcome, we assessed the effects of the intervention on their self-efficacy for ACP, using a 17-item scale (the ACP-SE scale).[2] The intervention rationale was similar to

mechanisms identified in the scoping review of ACP interventions (**Chapter 5**), such as in a trial in Belgian nursing homes which proposed that health care practitioners must see themselves as knowledgeable and competent enough to engage in ACP conversations, and thus offered a workshop with theoretical information and role-play exercises.[53] We found that scores increased for both groups, but not with significant difference.

One possible explanation is that **the self-efficacy of GPs in our sample experienced a ceiling effect** due to high scores at baseline. Estimated Marginal Means for the scale at baseline were 3.81 in the control group and 3.83 in the intervention group, on a 1-5 Likert scale. In the validation study of the English version of the questionnaire, family physicians showed greater confidence in how to respond empathetically to patients' concerns and how to communicate "bad news", and lower confidence in their ability to discuss how to complete a living will, and to ensure that a patient's treatment preferences are honored in a hospital. The latter, the authors attribute to poor communication or continuity of care between the outpatient and inpatient settings. The authors do not offer a hypothesis for the former, but we hypothesize that it could be related to unfamiliarity with state laws, as physicians who reported this as a barrier scored lower on the scale in the English validation study. In Belgium, freely-available informational brochures and instructions for how to complete an AD,[54] alongside existing training available for health care practitioners,[55,56] may already have a positive impact on GP self-efficacy. An increasing demand for ADs internationally during the COVID-19 pandemic[57] could also have encouraged GPs in both groups to consult these resources more. Regarding poor communication or continuity of care, we aimed to mitigate this barrier by providing GPs with the intervention documentation template, but our process evaluation (**Chapter 4**) showed that this was infrequently used and thus may not have been an adequate match for GPs' needs. The GP training in the ACP-GP intervention focused on patient-GP communication, and thus may not contribute as much to aspects of self-efficacy that are related to communication with other healthcare settings.

A cross-sectional study of ACP self-efficacy in primary care practitioners in Spain found that self-efficacy was higher when these practitioners felt sufficiently trained, and when they had a positive perception of ACP.[58] GPs who participated in the ACP-GP trial may also have been **a selection of motivated clinicians who already had positive perceptions of ACP**, contributing to potentially greater self-efficacy at baseline. Additionally, in a review of end-of-life communication interventions, training for health providers showed mixed effects on confidence.[59] Despite literature suggesting that a lack of self-efficacy or confidence may be a GP-level barrier,[60] recent studies of Canadian primary care clinicians found **high willingness and confidence for ACP**. Nevertheless, engagement in ACP remained low.[61,62] Similarly, interviews during the process evaluation of ACP-GP (**Chapter 4**) expressed that some GPs

already felt confident to have ACP conversations even before the intervention, due to their experience in clinical practice and because they had found a way of doing ACP that worked for them. For those who did feel less confident, our findings support conclusions by Hafid *et al.*[62] that training alone may not be enough to increase confidence, or that training may need to be more real-world case-based. GPs who were interviewed and had unmet expectations of the training, wanted a training that was more intensive. A training based on cases from their own practice, or with feedback on conversations in practice, may be an alternative. Gaining experience by conducting ACP in daily practice is an essential strategy to improving self-efficacy.[32] An additional approach which may be useful for continuing medical education, and for ensuring that GPs maximize the potential for gaining practice-based experience, is "commitment to change", which encourages learners to apply what they have learned in their daily practice. A study of the Canadian Learning Essential Approaches to Palliative Care (LEAP) education courses, examined post-course commitment statements from clinician learners and followed up with four-months post-commitment reflections. Those who submitted reflections at four months indicated they had implemented three-fourths of the commitments they made. This included discussing ACP with frail and elderly patients, and with patients with chronic conditions.[63] However, in line with reflections by Pivodic *et al.* about ACP training for Belgian nursing home staff,[64] lasting change in ACP implementation within the clinic, and gains in self-efficacy as a result of these changes, may **require more time** than the three-month follow-up from baseline at which we measured our primary outcome.

3.2 Lessons from ACP-GP and wider evidence from our studies

Given the lack of primary effectiveness for the ACP-GP intervention to increase patient and GP primary outcomes significantly more than in the usual-care control group, an important next step is to evaluate which components were (not) of perceived benefit to participants. We frame this within a broader reflection about the impact of ACP interventions as perceived by clinicians and patients, using lessons drawn from evaluations of ACP-GP (Chapters under Research Aim 1), and insights into the implementation of ACP interventions (Chapters under Research Aim 2).

3.2.1 Physicians, who value ACP, were facilitated in their clinical practice by a values-driven approach

In the process evaluation of ACP-GP (**Chapter 4**) and the study of experiences of Canadian clinicians implementing an ACP pathway (**Chapter 6**), we found that **physicians recognize the inherent value of ACP**, consider it worth doing, and consider time spent on ACP as time well spent. Within this commonality of circumstances in which the interventions were

implemented and tested,[13] conversation components of both ACP-GP and the ACP pathway were perceived as valuable by clinicians. In a survey of clinicians in skilled nursing facilities in the United States, having fewer negative beliefs about ACP was associated with feeling responsible for ensuring an ACP conversation.[65] A survey of barriers and facilitators to talking to patients about ACP in Canadian primary care, found that health care practitioner attitudes were a facilitator. Similar to the sentiments expressed by the GPs interviewed in the ACP-GP process evaluation, Canadian clinicians described having ACP conversations as part of the role of the physician in the provision of patient-centered care.[66] Dutch GPs also describe ACP as a typical GP task.[67] At its core, this implies that **the concept of facilitating ACP conversations within settings such as primary and longitudinal generalist outpatient care should not be abandoned**. The question is not *whether* to do it, but *how* to do it. In ACP-GP, some GPs who were interviewed expressed not wanting to frighten or offend patients by talking about ACP, which is a barrier that recurs in the literature.[60,68–70] Belgian GPs wanted to be able to make time and prepare well for conversations that would help patients feel safe and heard.

In this regard, it is notable how strongly GPs participating in the ACP-GP trial valued having a **more positive framing through which to introduce ACP**, following a perspective of what is important to the patient rather than introducing ACP in the context of an AD (**Chapter 4**). The Canadian ACP pathway (**Chapter 6**) could also be considered to utilize this approach because of its adaptation of the Serious Illness Conversation Guide (SICG),[71] which features ACP education and values clarification. Conversations approached through the SICG can explore topics such as worries about current and future health, but also patients' sources of strength.[72] A positive framing which includes a focus on patient goals, strengths, and quality of life, could mitigate barriers related to fear about depriving patients of hope.[60] As a result of this approach, Belgian GPs and Canadian physicians described a **positive impact on their interactions with patients**. Belgian GPs and patients both described how conversations engendered mutual trust and peace of mind. This finding aligns with those from other studies, such as a qualitative study of serious illness conversations in outpatient oncology clinics in the United States, which found that clinicians and patients were open to and engaged by conversations within the warmth and comfort of the patient-clinician relationship;[73] and a qualitative study of older adults in the Netherlands, where engaging in ACP appeared to build trust in their GP.[74] Furthermore, Belgian GPs and Canadian clinicians described how conversations bolstered feelings of **satisfaction and confidence**. These feelings can carry through to subsequent conversations, as confidence and strong communication skills can in turn enable ACP uptake.[75] Taken together, the impacts of a positive, values-driven framing to ACP aligns with

important but under-researched outcomes of ACP within the domain of social, relational, and emotional aspects.[64,76,77]

3.2.2. ACP can be challenging for patients, who may need more preparation, education, or empowerment

Although both the ACP-GP study in Belgium and the study of the ACP pathway in Canada highlighted the value of sensitive and timely ACP communication, similar barriers to patient buy-in were also encountered.

Belgian patients, even some who supported ACP in general, sometimes found ACP to be **personally confronting**, or **did not yet consider it relevant** at their current age or in their current health status (**Chapter 4**). Clinicians implementing the ACP pathway in Canada described how some patients did not wish to use the pathway tools or to have conversations, such that a **lack of patient buy-in** precluded engagement with the pathway (**Chapter 6**). In a systematic review of ACP experiences of people with life-limiting illness, ACP was found to raise complex and ambivalent emotions; conversations which are initially experienced as unpleasant may be evaluated as helpful in retrospect.[78] However, patients may prefer to wait until they feel that ACP is clinically relevant,[46,79] even in cases where their current health is poor.[46] This suggests that patients recognizing the importance of ACP, identified as an intervention mechanism in **Chapter 5,** may not automatically equate to wishing to be actively involved in ACP. This could introduce a barrier to the initial readiness that is needed for patients to begin the ACP process.[78] Previous studies have also found a lack of knowledge, low awareness, and confusion around the meaning and purpose of ACP, compounded by limited health awareness and health literacy.[80] The only intervention identified in the scoping review (**Chapter 5**) which worked by encouraging patients to reflect on their illness beliefs, framed this mechanism within a psychoeducational intervention for patients with end-stage renal disease and their substitute decision maker. By first understanding the cognitive, emotional, and spiritual aspects of patients' illness representation, the interventionist could then provide individualized information that was more likely to be accepted. This aspect of the ACP conversation may have needed more attention during the conversations in ACP-GP and the ACP pathway..

Attention should be paid to **conveying the relevance and usefulness of ACP** not only to patients with life-limiting illness but to all adults, such as from a perspective of quality of life and holistic care in illness, rather than solely as discussions about care at the very end of life.[46,81] This process could be started outside of a clinical setting, as will be discussed below, to educate and empower patients to take the initiative in ACP conversations. Clinicians can also be offered tools to help them explain the rationale of ACP as more than immediate and

unchangeable decision-making about future care. As clinicians implementing the Canadian ACP pathway perceived that patients sometimes struggled to proceed from stating values and goals, to documenting goals of care in the third pathway step (**Chapter 6**), it becomes evident that this process takes time and significant reflection.[82] We should also acknowledge that some patients may prefer to conduct "informal" planning through conversations, without the documentation that is but one possible outcome of such planning.[83]

3.2.3. Reflections on implementing ACP interventions in clinical settings

The findings from this dissertation also permit reflection regarding questions of "implementation, context, and system fit",[13] which is called for when evaluating complex interventions and identified as a priority in the updated MRC Framework guidance for developing and evaluating complex interventions. First, we found, as part of the ACP-GP process evaluation (**Chapter 4**), that while GPs were offered an intervention template with which to document the ACP conversations, these templates were infrequently used. Rather, GPs most often documented the conversation in the patient electronic medical record (EMR), despite the Belgian EMR lacking a designated window or space for ACP. About one in five of the second conversations were also documented in an AD. In comparison, the finalized care goals that resulted from the third step of the ACP pathway in Canada (**Chapter 6**) were documented through existing means in each province, such as in the patient EMR or in the Alberta Health Services "Green Sleeve" containing ACP forms.[84] In Belgium, although organizations such as the Life End Information Forum (LEIF) provide model documents for AD to refuse treatment, there is no one obligatory form to use; an AD to refuse treatment is valid so long as it contains clear, comprehensive, and informed refusal for specific medical intervention(s).[85] In contrast, a clinician in the Canadian province of British Columbia expressed that the regional Health Authority already required the use of a specific ACP record, leading to difficulty using the provided tools. This implies that **if documentation is to be part of an intervention in a clinical setting, then it is crucial that this is (already) integrated well into the current healthcare system**. GP experiences from Belgium showed a need for clear and visible integration of ACP in the existing EMR software, while physician experiences in Canada revealed challenges tracking relevant documentation within the EMR, leading to lost time and difficulty preparing for patient visits. Optimizing entry of ACP information, be it as a reflection of conversation topics or to store an AD, requires standardization and ease of access directly within the EMR.[86,87]

Though ACP interventions are well-received by clinicians and patients, **integrating these interventions into existing workflows emerged as a challenge**. In Belgium, a lack of available time was compounded by the COVID-19 pandemic. Regional GP groups were

responsible for coordinating triage-and-testing centers,[88] and a qualitative study in Belgian primary care showed that during the first wave of the pandemic, chronic care activities often lessened.[89] We experienced the effects of GP-reported lack of time during recruitment, as well as in adoption and implementation of the intervention, particularly the ACP conversations. Nevertheless, most GPs were able to schedule at least one conversation, and most patients with whom they had conversations received two, as specified in the protocol. The ACP pathway in Canada experienced similar challenges, and implementation of the pathway steps was stopped early into the pandemic due to COVID-19 restrictions and changing availability of allied health professionals. During implementation of the pathway steps, experiences varied: for some physicians, ACP conversations were more robust without taking additional consultation time, but for others a lack of time was a barrier to coordinating multiple visits in a busy clinic setting. Preparing patients with information and resources ahead of time was proposed an opportunity to reduce this barrier.[32,66] However, **streamlining the ACP process for successful integration into clinical work may require a change in approach from a 2-visit or 3-visit structure within the bounds of a single practice**, to a flexible, longer-term process within a multi- and interdisciplinary context.

We focus first on the flexible, long-term aspect. As described previously, patients who were interviewed for the ACP-GP process evaluation (**Chapter 4**) varied widely in the extent to which they had already engaged in ACP, and the extent to which they wished to engage in ACP conversations at present. Further, they differed in how they continued to reflect about ACP, such as considering the process "finished" or planning to have more conversations, and also which moments in the future may serve as triggers for them to want to revisit ACP. These were often related to health decline preventing them from doing activities they consider important. Fluctuating readiness and engagement in patients means that everyone involved in the patient's care should be alert to opportunities to initiate or revisit ACP.[32] As stated by De Vleminck *et al.*, implementing ACP as an **iterative process through the patient's life and course of illness**, can help GPs to introduce these subjects gradually, without having to find a "perfect" moment for ACP. Pre-planning a structured conversation, or thinking ahead to how ACP can be broached during consultations with patients who could benefit from it,[67] should not come at the expense of clinicians taking the opportunity, and time, to respond in-the-moment to signals that patients want to discuss ACP.[43] This requires that clinicians do not rely (solely) on clinical indicators to identify candidates for ACP conversations,[90] as we found in **Chapter 2** that these were not associated with patient ACP engagement.

Following this is the need to view ACP in clinical settings within a multi- and interdisciplinary context. We have previously described how Belgian GPs and physicians in Canadian outpatient care consider ACP an important and legitimate part of their work, and how the trust

stemming from a long-term relationship can facilitate ACP conversations in these settings. However, there is, as of yet, **little research of how ACP can be implemented as a process shared by the primary care clinic team**. An interprofessional approach holds promise, as shown by experiences of implementing the ACP pathway in Canada (**Chapter 6**). Canadian primary care clinicians are supportive of involving non-physicians in ACP,[61] and the involvement of non-physician clinic staff (allied health professionals) was an integral part of the pathway. This teamwork approach built confidence in allied health professionals' skills for ACP, raised staff awareness, and strengthened existing collaboration. In contrast, the ACP-GP intervention was evaluated as being delivered by one GP within a practice, including in group practices or practices supported by a nurse. Hence, the implementation process in the intervention may have created an artificial distinction with the clinical reality. A Belgian survey has found that one-third of GPs report being supported by a **practice nurse**, and most GPs agreed that this collaboration positively impacts their workload. Furthermore, GPs surveyed agreed that nurses were suitable for tasks for as providing patient education and health promotion advice.[91] A Belgian "New Deal" for GPs, expected to start in 2024, introduces a new model for general practice organization and funding, including a premium for collaboration with a practice nurse who is involved in tasks such as follow-up of patients with chronic illness.[92] This may offer new avenues for approaching the ACP process in Belgian general practice in the future, potentially inspired by the concept of the ACP pathway. It is, however, essential that nurses have knowledge, skills, and positive attitudes towards ACP, that the division of responsibilities is clear, and that there is continuity between clinicians.[32]

Some patients may prefer other clinicians, such as specialists, to discuss ACP; previous research identified that "medical expertise" is often cited as an underlying reason for this preference in patients with cancer.[90] No single profession within inpatient or outpatient care settings owns ACP, but **continuity of care and collaboration between settings and providers is necessary**.[93,94] A lack of collaboration with medical specialists has, however, been found in a study with Dutch GPs.[67] A Dutch retrospective cohort study of deceased cancer patients found little communication about ACP between primary and secondary care.[95] A lack of continuity of care was also identified in a review as a barrier to ACP for patients with chronic respiratory diseases.[96] This raises an important consideration that it is also necessary to take a step back from facilitating ACP within outpatient care, the impact of which may dwindle if documentation of patients' wishes and goals does not travel with them to other settings.[93] However, this question has received relatively little research attention as of yet, and there may be missed opportunities for synergy between conducting ACP, and discussing concrete decisions regarding treatment based on specialist expertise.[97] Belgian GPs participating in the ACP-GP trial considered communication technology essential to

facilitating (multidisciplinary) collaboration and follow-up of patients (**Chapter 4**). In addition to this, effective interdisciplinary teamwork around ACP should also include clear definitions of accountability for ACP, and building a common understanding of ACP among healthcare professionals caring for the same patient. This combines the domains of ACP *Innovation* (e.g. via integration with, and visibility in, the EMR), and *Implementation Processes* (e.g. collaboration across leadership, teams, and settings), as described in a recent editorial by Hickman *et al.*[98]

4. Recommendations for practice, research, and policy

The findings from the cluster-randomized controlled trial of the complex ACP-GP intervention, the scoping review of ACP interventions, and the qualitative study of Canadian clinicians' experiences implementing an ACP pathway, highlight the potential of ACP while also alerting us to shortcomings in practice, research, and policy. Based on the studies in this dissertation, we offer several future recommendations for these fields.

4.1 Practice: Normalize ACP as a values-driven process across stakeholders and settings, including non-clinical settings

Our findings from **Chapter 2** that patient characteristics and ACP engagement were not associated with one another suggest that, within an outpatient setting, **ACP can be offered to all people confronted with a chronic, life-limiting illness.** This should be understood as a crucial element of good practice and care**.** Many aspects of the process can fall under the denominator of "offering ACP", from educating patients about the relevance and importance of ACP, to discussing preferences for care or revisiting these at moments when the patient's health situation changes. At whichever point it may be initiated, our findings from **Chapter 2** and **Chapter 4** also affirm recommendations that clinicians should offer ACP first and foremost as a conversation to elicit patient values and worries, rather as than highly specific choices about medical treatment in the future.[99,100] The topic must be presented in a sensitive manner that prioritizes patient concerns and is attentive to the patient's individual readiness[78,101] and openness to discussing ACP.

People confronted with a chronic, life-limiting illness can benefit from the initiation of ACP, including having short conversations early in the illness trajectory.[100] Within outpatient and inpatient care for people with chronic, life-limiting illness, ACP aligns with broader principles of patient-centered, goal-oriented care, which pays attention to the needs, preferences, and personal values of patients.[102] This makes ACP, intrinsically, a "core business"[103] for clinicians treating patients with a life-limiting illness, and it should be recognized and endorsed as such. Educating and empowering patients to talk about their values, life goals, and wishes for care

need not, however, wait until the moment a chronic, life-limiting illness is diagnosed. ACP also has its place in (primary) care for older adults and healthy persons.[104,105] Approaching ACP from a core conceptualization as a flexible, longitudinal, and interdisciplinary process is recommended. Within this conceptualization, **ACP is a holistic process that occurs over the life course**, and includes in-the-moment and advance decisions at every life stage.[98,106] This could, over time, address misconceptions about ACP being associated only with end-of-life care[107,108] and thus better convey the relevance of ACP at different life stages. It also allows patients sufficient time to reflect about their care wishes, together with health care practitioners and those closest to them. Based on perspectives of Australian caregivers for patients with cancer, such "collaborative conversations" can enable shared decision making.[109] If ACP is approached from a life-course perspective, these conversations are an integral part of the person's care and can continue in the context of their changing health status, such as the diagnosis of a serious illness. We thus support the recommendation from a 2021 workshop which invited perspectives from North American experts about challenges and opportunities in ACP research: preparing for decisions about care should involve promoting **lifelong experiences** with, and expectations of, shared decision-making with health care practitioners.[110] Doing so increases the potential for ACP to be incorporated sustainably into clinician workflows.

Primary and outpatient care remains a suitable setting for ACP to occur and, if necessary, to be initiated. The setting benefits from longitudinal relationships with patients which facilitate comfort and openness in frank, honest communication.[66] However, we should caution against interpreting this to mean that clinicians in these settings hold sole accountability for ACP. Patients participating in the ACP-GP intervention trial sometimes wished to continue ACP conversations with a specialist (**Chapter 4**); ACP interventions for patient with chronic, life-limiting illness may still take place in hospital-based clinics and nursing homes (**Chapter 5**); and clinicians in outpatient care reflect on how ACP can fit within structures of referrals to inpatient care (**Chapter 6**). Ensuring that ACP is respected as a lifelong aspect of patient-centered care requires the **engagement and commitment of clinicians across the healthcare system**. Facilitating multidisciplinary approaches and collaboration between primary and specialist care, to ensure the continuity of the ACP process, may require additional training in communication and clarifying clinician roles.[111] Team-based ACP, as in the ACP pathway in Canada (**Chapter 6**) has the potential to streamline the process and could be acceptable to Belgian GPs as well,[91] but reflection is needed on how such an approach can be translated within the evolution of Belgian primary care towards a model of multidisciplinary group practices.

Importantly, current guidelines and research are often situated within a professional context, and often focus on one profession within said context (oncologists, GPs, …). While we believe the recommendations for practice described above are valuable, it is essential not to ignore the societal component, where ACP in a clinical setting is only one facet of a complex process, and that many conversations about care goals and values occur outside of the clinical consultation. Hence, we add the recommendation of **educating people and empowering them to look after their own health**. This fits within a wider approach of public health approaches to palliative care,[112,113] which are increasingly gaining traction. In this sense, people (who are, or may become, patients with a chronic life-limiting illness) should be enabled both in clinical and non-clinical settings to voice their values and gain the confidence and capacity to engage in ACP, a mechanism also found in our scoping review (**Chapter 5**). Based on findings from a Belgian cross-sectional study about how patients with cancer can be empowered to initiate conversations about palliative care, this can include providing information about the benefits of talking to family, loved ones, and healthcare professionals about values, worries, and preferences for current or future care. Web-based tools, such as a website aiming to support Belgian people with dementia and their families to engage in ACP, also have potential to support this approach.[114] Clinicians, for their part, should show a positive attitude and openness to having ACP conversations;[115] if conversations are perceived as rushed, or concerns are not responded to, patients may be discouraged from trying to raise these topics again.[43,90] More research is needed, however, and promoting patient empowerment to engage in ACP will also require policy-level changes, which will be described below.

4.2 Research: Collaborate with patients, families, and the public in developing theory-based initiatives to build capacity for ACP, including within the community

The findings in this dissertation raise fundamental questions for research regarding the suitability of a "gold standard" RCT design (as described in **Chapters 1-4**), which has been argued to overlook the complex and dynamic reality of engaging in ACP throughout the disease trajectory.[76] We agree with this assessment: given the complexity of ACP, which includes (but is certainly not limited to) the mechanisms by which ACP may change outcomes, the impact of (interacting) person- and system- related factors, the multitude of domains and stakeholders, and the settings in which people are exposed to ACP, an **RCT of a single intervention, for a single patient population, within a single setting and for a given time period may not be the most useful methodology by which we can understand the full impact of ACP**. This is even more so the case when ACP is approached as a process that can be undertaken across the life course. A previous review of reviews found a call for a whole-

systems approach rather than RCTs of individual components of ACP interventions. It emphasizes a need for **pragmatism**, and for elucidating mechanisms of interventions and implementation strategies through **research grounded in a realist perspective**.[48] Based on our experiences evaluating the ACP-GP intervention via an RCT, we agree with this recommendation.

The review continues with another recommendation which we support based on this dissertation, which is that if interventions are developed, this should include clear consideration of how it is expected to work, and that rigorous qualitative methods should examine "implementation contexts, patient and carer experiences, unanticipated consequences, and complex causal pathways".[48] In our scoping review (**Chapter 5**), we found that the "how" and "why" of intervention components are not often fully elucidated in the literature. We thus recommend that building an intervention should begin with the essential step of **analyzing the target population**, e.g. people within certain Stages of Change, and building the intervention for that target population. This process should be **informed by an underlying theory with a clear rationale**. An example from health promotion research has recently been published, which uses the Theory of Planned Behavior to gain insight into how people with incurable cancer can be empowered to start a conversation about palliative care with their physician.[28] This example can be used as guidance for future research into how people can be encouraged to talk about ACP as well. Additionally, examination of implementation contexts and experiences can be supported by frameworks such as RE-AIM and Normalization Process Theory (NPT), as have been used in this dissertation (**Chapter 4, Chapter 6**). RE-AIM contributes a focus on factors in the implementation of an intervention which facilitate or hinder its impact.[15] NPT allows researchers to examine whether an intervention can be sustainably implemented and become "normalized" in practice.[116] While these frameworks were used independently in this dissertation, future work may benefit from using them in a complementary fashion,[18,117] as has been done in a Canadian study of a community-based, primary-care-led program for person-focused care.[118]

ACP outcomes, as a result, should not be standardized to a rigid outcome set but **diversified**, to closely match the logic of the underlying theory within the target population, and to ensure we adequately measure the entire process of ACP. Person- and family-centered outcomes could be measured with validated instruments, and other methods should also be explored to inform new, integrative approaches as recommended by De Vleminck & Van den Block.[76] In doing so, "conventional" research methods can be combined with longitudinal designs and qualitative methods to understand meaning-making of ACP, experiences with ACP within a given cultural context, and lived experiences with ACP.[76]

In the Belgian trial of the ACP-GP intervention (**Chapters 1-4**) and the ACP pathway implemented in Canada (**Chapter 6**), the research focus lay on patients and clinicians. This was also often the case for RCTs in the scoping review of complex ACP interventions for patients with chronic serious illness (**Chapter 5**), and may indicate a prevalent research focus on ACP within clinical settings only. Fewer interventions target other "pillars" which support ACP[119] within the community, health systems, or policy. There is little research about how "informal" ACP, such as conversations between family members, can be facilitated to mitigate pitfalls such as assuming family members will know implicitly what the person wants.[94] For GPs to have a solid foundation from which to conduct ACP with their patients, **research is required that goes beyond the consultation in the GP's office or the patient's home**. Research should involve other stakeholders, including specialist care practitioners and the patient's family and loved ones.

The ACP-GP intervention was developed and evaluated largely through consultation with clinicians and experts. Patients and SDMs were involved to a much lesser extent, providing feedback on materials which were previously developed. Working together with patients and SDMs from the start could have helped us to understand how to encourage patients, especially those who are unsure about ACP, to fully engage in the process. In the current ACP research literature, there is a paucity of evidence regarding "complexities and temporal, relational, and socio-emotional dynamics" which play a role in individual experiences with ACP. Limited information is available about why individuals consider ACP useful or not useful.[76] Simultaneously, the updated MRC Framework guidance emphasizes meaningful engagement with stakeholders as a core element of complex intervention research.[13] To ensure that ACP interventions or initiatives meet the needs of various populations, including healthy adults, patients with a life-limiting illness, and family or loved ones, **ACP research would benefit from a patient and public involvement (PPI) approach**,[120] such as through co-design and (community-based) participatory action research. This requires that researchers listen to, and take seriously, the perspectives of patients and their family or loved ones, by engaging them in dialogue and co-design throughout the study process.[121,122] Co-design and participatory research should address what is important to the target population. It should explore why ACP is seen as relevant or not, how participants envision personal control in decision-making versus relinquishing control, and should work closely with participants to determine which outcomes are important to them. A participatory lens has, for example, been effectively used to facilitate community engagement in ACP within underserved communities in the United States,[121,123] and has informed the protocol for co-designing an intervention in the United Kingdom to increase the uptake of ACP after an emergency hospitalization.[124] However, it is

still largely under-utilized in ACP research as a whole, and requires greater attention in the future.

4.3 Policy: Prioritize a person-centered care approach to ACP which guides people with or without life-limiting illness through ACP conversations

As described above, ACP is an integral part of person-centered, goal-oriented care for patients with and without chronic, life-limiting illness. **Promoting an approach to care that maximally takes into account the wishes and values of patients should thus be a priority at the policy level**. The explicit recognition of goal-oriented care and of ACP as a process, which informed the modernized Belgian Law on Patient Rights,[125] is a positive step in this regard. Conceptualizing ACP within goal-oriented care can be further specified, so that ACP should not focus only on talking about symptom burden, loss of capacity, and end of life, which leaves planning for "living well" underexplored.[126] It should incorporate a much stronger focus on safeguarding quality of life in the way that the patient defines it. This aligns with recommendations made by Abel *et al.* that ACP should focus on what matters most to people, and on social dimensions of care.[127] Regular ACP conversations with patients can enable them to formulate wishes for care when they are ready, and an in-depth understanding of what contributes to quality of life for the patient can help clinicians feel more confident in supporting these wishes, as was the case for some Belgian GPs (**Chapter 4**).

The modernized Belgian Law on Patient Rights is also informed by a call to see ACP as a **"continuous process of reflection and communication",**[125] a perspective with which we agree. However, a one-use billing code for an ACP conversation, as also has been introduced in Belgium in 2022,[128] is at odds with both the integration of ACP into good care for patients with and without life-limiting illness, and the simultaneous call to see ACP as a process. There is literature which suggests remuneration and billing codes as potential facilitators to ACP, which would help clinicians make time for conversations.[129,130] However, while a Canadian physician mentioned that a lack of billing codes might raise challenges for family doctors to conduct ACP conversations (**Chapter 6**), there was no mention of the new billing code by Belgian GPs in the focus groups or interviews (**Chapter 4**) as an enabler that might help them to make time for ACP. Data from reviews of billing code use in Canada[131] and the United States[132] suggest an unclear utility of ACP-specific billing codes.[133] A recent evaluation of ACP in home-based primary care in Canada found that fee-for-service remuneration for family physicians could have discouraged ACP communication, due to extensive time commitments this communication required.[134] The Belgian billing code, furthermore, currently relies on the Palliative Care Indicator Tool (PICT) to identify eligible patients.[128] The PICT uses the "Surprise Question" and a list of clinical indicators to identify patients in need of palliative

care.[135] We therefore urge caution that this policy measure does not place undue restrictions around the concept of ACP as a process, and around who can benefit from ACP, including people newly diagnosed with a life-limiting illness as well as healthy adults. Rather, **policy initiatives should use the recognition of ACP as a continuous process to inform evidence-based guidelines, public campaigns, communication, and training about ACP**.

There is, however, a call from clinicians in general practice and outpatient care for system-level support for ACP (**Chapter 4, Chapter 6**). Unclear documentation of ACP in the patient EMR is a shortcoming in this setting, which hinders efficiency in preparing for ACP conversations and impedes effective transfer of information between clinicians. While modifications to the patient EMR alone will not guarantee inter- and multidisciplinary ACP, a teams-based approach to ACP would nonetheless benefit from **clear integration in the EMR of a designated space for documentation of ACP conversations and, if applicable, of ADs.** This information should also be transferable between clinical settings. An example from existing initiatives is the Patient Values Tab, implemented in a cancer center in the US, which displays key information about the patient's individual values, goals, and preferences in a central location in the EMR.[136]

Finally, we direct attention to a recommendation for ACP explicitly outside of clinical settings. ACP should be treated as a matter of public health, and **policy initiatives should promote awareness, empowerment, education, and capacity for ACP within the community,** using the above-described recognition of ACP as a process across the life course. Contributing to public awareness and engagement in ACP could contribute to a new norm for healthy adults to have conversations with family and loved ones about their values and wishes, prior to a possible diagnosis of a life-limiting illness.[66] While campaigns which present information about ACP and realistic representations of care options can be helpful to dispel misinformation,[137] providing information alone may be insufficient (as suggested in **Chapter 2**). Rather, **advancing ACP within the community may require concerted efforts to reduce stigma around talking about health, illness, and dying**.[80,138,139] Theoretical underpinnings of initiatives such as the *Last Aid Project*, including developing personal skills, strengthening community action, and building compassionate communities,[140] can inform public health approaches to ACP that contribute to "death literacy" within the community. This may require bespoke communication for different generations, with matched educational and media messaging from sources which are seen as trustworthy, such as peers and health care providers, within a life-course approach to talking about death and dying.[139,141] ACP can be introduced in spaces where people already gather, including service clubs, libraries and book clubs, fitness centers, and places of employment,[142] and through creative means including

media and the arts, which can give voice to strong emotions that make talking about ACP challenging.[139] When people within the community are empowered to have meaningful conversations about care goals and values with their family and loved ones, clinicians can then also engage them in talking about quality of life and, if needed, work together with the patient to make wishes for current or future care concrete.[143]

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SUMMARY

BACKGROUND

Globally, life expectancy is rising and is anticipated to continue to rise. In proportionately older populations, the prevalence and proportion of deaths caused by chronic, life-limiting illnesses such as cardiovascular disease, cancer, and chronic respiratory disease also increase. People diagnosed with a life-limiting illness may be faced with complex choices about their medical care, including palliative care and end-of-life care. When illness leads to a loss of decisional capacity for the patient, the patient's family or loved ones may be called upon to make decisions about medical interventions in the patient's stead. When family members are unable to determine the patient's wishes, this decision-making can lead to significant distress. While patients want to be treated according to their values, they often do not receive care at the end of life that is congruent with the values they have expressed.

Planning for future medical-decision making emerged with the promotion of advance directives (ADs), which state the patient's health care goals and appoint a person to make health care decisions in the person's stead. However, ADs alone were insufficient to improve patient-centeredness of care at the end of life and accuracy of substituted decision-making. Advance care planning (ACP), rather than a one-time documentation of care goals in an AD, is defined as a process which "*enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and health-care providers, and to record and review these preferences if appropriate*." It can include the designation of a surrogate/substitute decision maker (SDM), a person who can make medical decisions for the patient if the patient loses decisional capacity, and/or documenting wishes for care and treatment in an AD.

In Belgium, a medicolegal framework for ACP has been established based on three laws, passed in 2002, which state: the right to quality palliative care (*Wet betreffende de palliatieve zorg),* the legal basis of euthanasia (*Wet betreffende de euthanasie)*, and patients' rights (*Wet betreffende de rechten van de patiënt)*. ACP has received considerable attention and promotion in Belgian societal and legal contexts, and recent policy changes have been introduced to further support ACP.

The research base for ACP is heterogeneous in settings, intervention modalities, populations targeted, and outcomes evaluated. ACP may improve health outcomes, can contribute to patients feeling more at peace and in control, and can make SDMs feel more confident to make health care decisions in the patient's stead. ACP interventions have been effective in increasing outcomes related to processes, such as knowledge about ACP, and actions, such as communicating with an SDM or clinician. Discussions about the future of ACP research emphasize under-utilized opportunities, such as preparing clinicians to have high-quality

conversations, and preparing patients and SDMs to also make informed decisions about care in-the-moment.

As ACP can be undertaken and revisited over time, it should be initiated in a timely manner. Outpatient care settings, such as primary care and general practice, have been proposed as ideal for initiating and facilitating iterative ACP conversations. This is because clinicians such as general practitioners (GPs) often have an established, longitudinal relationship with their patients and can support continuity of care. However, there are deficits in ACP initiation in practice, including in general practice, due to barriers at multiple levels. Patients may consider ACP emotionally upsetting or irrelevant, or expect their GP to indicate the right moment to discuss ACP. They may also want more information about ACP. GPs perceive a lack of time as a barrier, and worry that ACP conversations could be distressing to patients and their loved ones. They may also feel they lack the knowledge or skills to engage in ACP. At the system level, there is a lack of standards for documenting information and a need for shared conceptualizations of ACP.

To mitigate barriers and maximize facilitators to ACP in general practice, a complex intervention was developed prior to this dissertation. A complex intervention is built up from multiple components, which can act inter- or independently. Following the 2000 Medical Research Council (MRC) framework guidance, the ACP-GP intervention was developed based on literature evidence and consultation with experts. It was then pilot-tested in Belgian general practice and adapted based on findings from the pilot trial.

This dissertation seeks to address the following knowledge gaps:

- What is the effect of the ACP-GP intervention on outcomes relevant to the process of ACP (patient ACP engagement and GP ACP self-efficacy)?
- Which factors are associated with patient ACP engagement?
- How (well) was the intervention implemented, and how do the components exert their effect?
- In the international literature of trials of ACP interventions for patients with chronic, life-limiting illness, which rationales are provided (how are interventions proposed to effect changes in outcomes)?
- In the example of an ACP pathway with similar components to ACP-GP, implemented in two Canadian provinces, what was the clinician experience with applying the pathway steps?

RESEARCH AIMS

We aim to address these knowledge gaps via two major research aims. **Research aim 1** is to implement and evaluate the ACP-GP intervention for patients with a chronic, life-limiting illness in Belgian general practice. **Research aim 2** is to describe insights into the implementation of ACP interventions, using international ACP literature and the example of an ACP pathway implemented in two Canadian provinces.

METHODS

We used several methods to achieve the research aims. **Research aim 1** is based on a cluster-RCT of the ACP-GP intervention for patients with chronic, life-limiting illness (the protocol for which is described in **Chapter 1**). Belgian GPs identified patients and were cluster-randomized to receive the intervention (which consists of GP training, a patient workbook, two ACP conversations, and a documentation template provided to GPs), or to provide their patients with usual care. We analyzed data collected from the participating patients at baseline, to descriptively report their demographic and clinical characteristics, their ACP engagement, and their perceived quality of patient-GP communication about ACP. We then used linear mixed models to explore associations of characteristics and perceived quality of communication, with patients' ACP engagement (**Chapter 2**). The primary outcome analyses evaluated differences between the intervention and control groups on patient ACP engagement, and GP ACP self-efficacy, at 3 months post-baseline (T1, primary effectiveness evaluation) and 6 months post-baseline (T2). Linear mixed models accounted for clustering of time points within respondents, and clustering of patients within GPs (**Chapter 3**). Finally, we conducted a mixed-methods process evaluation following the Reach, Efficacy/effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework (**Chapter 4**). We used data from recruitment and implementation monitoring, questionnaires, and semi-structured (focus group) interviews with GPs and patients from the intervention group. For **research aim 2**, we conducted a scoping review of RCTs of complex ACP interventions for adults with chronic serious illness (**Chapter 5**). Using data collected from a Canadian national project to improve ACP conversations, we qualitatively analyzed interviews and focus groups conducted with 13 clinicians in the provinces Alberta and British Columbia (**Chapter 6**).

MAIN FINDINGS

ACP engagement in a sample of patients with chronic, life-limiting illness recruited for a cluster-randomized controlled trial (**Chapter 2**)

Within the sample of patients recruited to the cluster-RCT, we explored ACP engagement and its associations with patient characteristics and patient-perceived quality of communication by

the GP. The ACP Engagement Survey measured engagement as averages on a 1-5 Likert scale, with higher scores indicating greater engagement. The scale also consists of two subscales: self-efficacy and readiness, each also measured on a 1-5 Likert. In total, 95 patients, recruited by 35 GPs, provided informed consent and baseline questionnaires. Mean overall ACP engagement was 3.06 (Standard Deviation (SD) 0.98). Mean self-efficacy was 3.86 (SD 1.13); mean readiness was 2.52 (SD 1.20). After correction for multiple testing, we did not find statistically significant associations between patient demographic or clinical characters, and patient ACP engagement. ACP engagement was also not significantly associated with how much information the patient received from their GP about ACP, the extent to which the GP listens to what is important for the patient to live well, and the extent to which the GP listens to what is important to the patient regarding their future care. We found higher overall engagement for patients who gave a high rating to the extent to which their GP listened to their worries for future health, compared with patients who gave a low rating (3.27 versus 2.48, p = 0.002). The same pattern was observed for self-efficacy (4.10 versus 3.14, p<0.001).

No significant differences between intervention and control groups on primary outcomes in the cluster-RCT of the ACP-GP intervention in Belgian general practice (**Chapter 3**)

For primary effectiveness analyses, we tested whether the intervention was superior to control in increasing patient ACP engagement, and GP ACP self-efficacy, at 3 months and 6 months post-baseline (T1 and T2, respectively). We randomized 35 GPs and 95 patients; 18 GPs and 53 patients were assigned to the intervention group. We did not find significant differences in increases from baseline for patient engagement at T1 (baseline-adjusted mean difference, 0.34; 95% Confidence Interval (CI) -0.02 to 0.69; p = 0.062, standardized effect size=0.34), nor at T2 (baseline-adjusted mean difference, 0.20; 95% CI, -0.17 to 0.57; p = 0.28, standardized effect size=0.20). ACP engagement increased notably in both groups. We also did not find significant differences in increases from baseline for GP self-efficacy at T1 (baseline-adjusted mean difference, 0.16; 95% CI, -0.04 to 0.35; p = 0.11; standardized effect size = 0.44) or at T2 (baseline-adjusted mean difference, 0.11; 95% CI, -0.09 to 0.31; p = 0.27; standardized effect size = 0.31).

Feasibility and sustainability of the complex ACP-GP intervention in Belgian general practice (**Chapter 4**)

For the mixed-methods process evaluation, conducted parallel to the cluster-RCT of the ACP-GP intervention, we collected data as part of the recruitment and implementation monitoring.

Sixteen GPs and 46 patients in the intervention group provided questionnaire data at T1, 3 months post-baseline. We also used transcribed qualitative interview data from 14 GPs and 11 patients in the intervention group. We found low reach, with 50 (3.3%) of the GPs who were contacting expressing interest and agreement to participate, and 35 ultimately being randomized. Patient reach was higher, with 95 of 117 identified patients (81.2%) being included. Effectiveness according to the primary outcome was low (see **Chapter 3**). GPs and patients described other impacts of the intervention, such as GPs being more alert to ACP and having a more positive approach, and patients experiencing positive affective outcomes. Adoption of the intervention components (measured at T1) was variable. Attendance rates at the training were high and the majority of GPs adopted the conversation component. Approximately two-thirds of patients reported having used the workbook at least once. However, the adoption of the documentation template was low: approximately one-fourth of first conversations were documented using the template, and only one second conversation. GPs endorsed the value of ACP, but some patients found it confronting. Implementation fidelity to protocol, where all four components are used, was low as a result. However, satisfaction with the intervention was high: GPs rated the usefulness of and satisfaction with the training and intervention materials highly, and conversations with the GP met or exceeded patient expectations. Conversations with patients were highly individualized and GPs were able to adapt their approach accordingly. Patient experiences with conversations were positive. A prior relationship with the GP and/or prior experiences with ACP could potentially affect patients' comfort talking about ACP. GPs saw opportunities for integrating the training into (continuing) medical education, but also perceived challenges for integrating ACP conversations into their current way of working. Some patients saw their ACP process as "finished", while others continued the process.

Mechanisms and factors affecting primary outcomes of complex ACP interventions, tested in randomized controlled trials: layered complexity (**Chapter 5**)

We included sixteen articles reporting the primary outcome(s) of an RCT testing the primary effectiveness of a complex ACP intervention for patients with chronic serious illness. The largest proportion of studies (n=11) used an interview or conversations to address ACP topics. Eight studies used an AD or goals of care form. Other intervention components included providing conversation summaries to physicians or placing documentation in the patient's health record, providing informational material, using question prompts and communication tips, interactive decision aids, and educational workshops. The mechanism "tailoring the delivery style or content to the needs of the patient recipient" was linked to the greatest variety of outcome domains (n=4 domains). The mechanism "promoting skills, competence, and

confidence to participate in ACP conversations" was referred to in the greatest number of studies (n=6 studies). Primary outcome findings were mixed. In discussing their findings, authors referred to three overarching themes: 1) participant factors; 2) implementation factors, and 3) methodological factors.

Experiences, challenges, and opportunities for future sustainability of an ACP pathway implemented in Canadian generalist outpatient care (**Chapter 6**)

Using transcripts of focus groups and interviews with clinicians in British Columbia (BC) and Alberta, we explored the experiences with implementing an ACP pathway in primary care and general internal medicine. Twelve physicians and one social worker were interviewed. Barriers and facilitators were identified across multiple domains, and respondents described how the intervention could be sustained in the future. The first domain was the participants' appraisal of the ease of use of the components of the care pathway itself. The second was a clinician-level impact domain with three themes. The first theme was clinical practice, this being the responsibilities of the physician, and the clinical interaction between the physician and patient. The second theme described how the pathway contributed to teamwork within the clinic, or how existing team structures did or did not support the pathway. The third theme described how the pathway could be integrated into the existing work processes within the clinic, and what needed to change to accommodate the pathway. Some clinicians also referred to the impact they perceived at the patient level. This was divided into two themes: preparation, the patient's engagement with ACP prior to the visit with the physician; and readiness, the patient's engagement with ACP during or following the visit with the physician. ACP in these settings was described as feasible, but patient buy-in was a prerequisite to the rest of the pathway being followed.

GENERAL DISCUSSION

Evidence from the cluster-RCT

For this dissertation, we described and conducted a cluster-RCT to test a complex ACP intervention (ACP-GP) in Belgian general practice. As reported in **Chapter 3**, we saw improvement on the outcomes for GPs and patients in both groups, but not with significant differences between the groups.

We hypothesize that **raising awareness** of ACP may have had a greater impact on all participants than we expected. A Hawthorne effect is a first possible explanation. The procedures of informed consent, where ACP was described to patients and GPs may have been alerted to the need for ACP, as well as data collection about these topics could have made both groups more aware about ACP. The conduct of the trial during the early waves of

the COVID-19 pandemic may also have contributed to awareness. The early waves of the pandemic were a period of heightened health concern. Worries about the impact of the disease in patient populations with already-vulnerable health may have encouraged patients participating in the trial to think about and/or discuss end-of-life care and ACP, or prompted GPs to prioritize discussing patient's preferences for medical care, regardless of their assigned group in the cluster-RCT. When GPs and patients in both groups also have ACP conversations because of this awareness raising, this could be reflected in the primary outcomes. It could increase patients' ACP engagement by helping them take action to discuss their wishes, and provide GPs with practice-based experience that builds their self-efficacy.

To measure the **patient primary outcome** of ACP engagement, we used the ACP Engagement Survey. This instrument was developed based on several behavioral theories, including Social Cognitive Theory and the Transtheoretical Model of Behavior Change (TTM). These state that changes to underlying processes such as self-efficacy and readiness are needed, before patients change their behavior by engaging in ACP actions, for example by having conversations with their doctors. Bringing the topic of ACP to the front of mind for patients by explaining what ACP is and asking questions about it, could have nudged patients in both groups from earlier stages of behavior change, towards planning to take action. This yields an interesting hypothesis from the primary analysis, that the ACP Engagement Survey may have captured this process in both groups. It suggests that collecting data, and thus bringing attention to ACP, could already be an effective intervention on its own.

By interviewing patients who participated in the cluster-RCT, we found a sizeable variation in patients' previous experiences with ACP, in how relevant they perceived ACP to be for them personally, and in their desire to participate in making decisions about medical care. These findings indicate that readiness for ACP is a complex construct. It is made even more complex by the fact that making decisions about medical care is only one aspect of ACP. We noted from **Chapter 2** that engagement in ACP for patients who have a chronic, life-limiting illness may come from worries about how their future health will impact themselves and their loved ones. When a patient expresses these worries, it could be taken as a potential sign of "being ready" for ACP, and can provide a proactive basis for discussions about ACP with the GP.

We assessed the **GP primary outcome** using the ACP-SE scale, which measures physicians' self-efficacy for ACP. High self-efficacy at baseline in our sample of GPs is one possible explanation for the lack of significant differences between the control and intervention groups. The GPs participating in the trial may have already been motivated and had positive perceptions of ACP, which could contribute to greater self-efficacy. Some GPs already had confidence that they could conduct ACP conversations well, even before the intervention, as

a result of the experience they had gained in their clinical practice. On the other hand, some GPs wanted a training that was more intensive. Using cases from the GP's practice, or providing feedback on conversations conducted in their clinic, could be a viable addition to their training. GPs also may need more time to gain the need practice-based experience that helps them to feel more confident in ACP conversations.

Lessons from ACP-GP and wider evidence from our studies

We used lessons drawn from evaluations of the ACP-GP cluster-RCT, a scoping review of complex ACP interventions, and a study of clinicians' experiences implementing an ACP pathway in two Canadian provinces, to reflect about what parts of ACP interventions are (not) of perceived benefit to those participating in or receiving them.

First, we found from the process evaluation of ACP-GP and the study of the Canadian ACP pathway, that physicians in general practice and outpatient care recognized the inherent value of ACP, and considered it worth doing. Hence, we should not abandon our efforts to facilitate ACP in this setting, but rather ensure that clinicians are equipped with the tools and skills to engage in conversations. In this regard, we found a strong appreciation for a positive framing for ACP, which follows the perspective of what is important to the patient, such as their goals, strengths, and quality of life. This contributes to a positive, reciprocal impact between clinicians and patients, engendering mutual trust and peace of mind.

However, we should also be mindful that ACP can be (emotionally) challenging for patients, who may need more preparation, education, or empowerment. Both in the ACP-GP trial and the study of the ACP pathway in Canada, buy-in from patients was an important prerequisite to engaging with the intervention. ACP can raise complex and ambivalent emotions for patients. They may prefer to wait until they feel it is clinically relevant, even if their health is poor, which results in limited "advance" conversations about their values and preferences. Hence, it is important to take into account patients' readiness, knowledge, and understanding of ACP, as well as their understanding of their own health status and prognosis. The relevance and usefulness of ACP should be conveyed to all patients with a life-limiting illness, from a perspective of recurring conversations about quality of life, to mitigate misconceptions that ACP is only about end-of-life care and dying. Clinicians can play a crucial role by explaining the rationale of ACP to patients when they are well, so that patients have sufficient time to discuss and reflect.

We also reflect on the integration of ACP within clinical settings and workflows. A lack of integration of ACP documentation into the current health care system remains as an obstacle. In Belgium, GPs often did not experience an added value to the documentation template that

was part of the intervention, and preferred to use the patient electronic medical record (EMR) to document conversations. This was despite the lack of a designated window or space for ACP, for which GPs expressed a remaining need during the process evaluation. Clear, visible integration of ACP documentation within the existing EMR software could increase ease of access and facilitate preparation for patient consultations. Integrating ACP conversations themselves into the clinical workflow may also require a flexible, long-term approach within a multi- and interdisciplinary context. In this view, ACP is not "finished" after a set number of conversations or documentation of the patient's wishes, but becomes an iterative process throughout the patient's life and course of illness. It should also be a process shared by the primary care clinic team, for which interprofessional approaches, which also includes nurses, social workers, and other members of the team, could hold promise for the future. An approach which includes allied health professionals, as in the Canadian ACP pathway, showed that this bolstered physician confidence in allied health professionals' capabilities to conduct ACP, and strengthened existing collaboration in the clinic. Furthermore, the process must travel with the patient to other health settings. For example, some patients participating in the trial of the ACP-GP intervention also wanted to talk to their specialist care provider about ACP. This implies that continuity of care and collaboration between settings is needed. Facilitating transfer of information via the EMR is one component of this continuity and collaboration, but it should also include clear definitions of accountability for ACP, and building a common understanding of ACP among healthcare professionals caring for the same patient.

RECOMMENDATIONS FOR PRACTICE, RESEARCH, AND POLICY

Based on the findings of this dissertation, we offer the following recommendations.

For **practice**: normalize ACP as a values-driven process across stakeholders and settings, including non-clinical settings.

- ACP should be offered to all people confronted with a chronic, life-limiting illness, as a crucial element of good practice and care. It should take the form of a conversation to elicit patients' values and worries, rather than to immediately make highly specific choices about future medical treatment.
- ACP should be treated as "core business" for clinicians treating patients with a life-limiting illness, but also in the care for older adults and healthy persons, as an element of patient-centered, goal-oriented care. It should be approached as a holistic process that occurs over the person's life course, and can include in-the-moment and advance decisions at every life stage.
- Ensuring that ACP is respected as a lifelong aspect of patient-centered care requires the engagement and commitment of clinicians across the health care system.

- Conversations within a clinical setting are only one facet of a complex process. Many conversations about care goals and values occur outside of the clinical consultation. Thus, people should be enabled in clinical and non-clinical settings to voice their values, helping them to attain confidence and competence to engage in ACP. Patients should be educated and empowered to look after their own health; clinicians can contribute by providing information about the benefits of ACP, showing openness and a positive attitude.

For **research**: Collaborate with patients, families, and the public in developing theory-based initiatives to build capacity for ACP, including within the community.

- A whole-systems approach and pragmatism in research are recommended, as an RCT of a single intervention, for a single patient population, within a single setting and for a given time period may not be the most useful methodology by which we can understand the full impact of ACP.
- When developing or adapting interventions, research should pay attention to elucidating the "how" and "why" of their intervention. Using an underlying theory with a clear rationale is one possible approach.
- ACP outcomes should be diversified to measure the entire ACP process. New, integrative approaches have recently been recommended which include longitudinal and qualitative methods. We support these recommendations, based on this dissertation.
- Research should involve other stakeholders inside and outside the clinical setting, such as family members, to contribute to a solid foundation for GPs to also discuss ACP with their patients. A patient and public involvement approach (PPI), such as through co-design and (community-based) participatory action research can involve patients, family, and loved ones in dialogue through every part of the study process.

For **policy**: Prioritize a person-centered care approach to ACP, which guides people with or without life-limiting illness through ACP conversations, including in the community

- Policy initiatives should prioritize an approach to care that maximally takes into account the wishes and values of patients. This includes explicitly recognizing ACP within patient-centered, goal-oriented care, and a stronger focus on safeguarding quality of life as the patient defines it.
- Evidence-based guidelines, public campaigns, communication, training, and other initiatives should ensure that the recognition of ACP as a continuous process is applied consistently. Policy should not place undue restrictions around the concept of ACP as a process, and around who can benefit from ACP.

- Within the health care system, a teams-based approach to ACP, and continuity of ACP communication between settings, would benefit from clear integration in the EMR of a designated space for documentation of ACP conversations and, if applicable, of advance directives.
- ACP should be treated as a matter of public health. Policy initiatives should promote awareness, empowerment, education, and capacity for ACP within the community. A concerted effort within the community is needed to reduce stigma around talking about health, illness, and dying.

SAMENVATTING

SITUERING

Wereldwijd neemt de levensverwachting toe. In een ouder wordende populatie neemt de prevalentie en proportie toe van overlijdens die veroorzaakt worden door chronische, levensbeperkende ziektes, zoals hart- en vaatziekte, kanker, en chronisch longlijden. Mensen met een levensbeperkende ziekte kunnen geconfronteerd worden met complexe keuzes betreffende hun zorg, waaronder palliatieve- en levenseindezorg. Als exacerbatie van de ziekte leidt tot verlies van wilsbekwaamheid bij de patiënt, kunnen de familie of naasten gevraagd worden om in de plaats van de patiënt beslissingen te nemen over medische handelingen. Als de wensen van de patiënt niet kenbaar gemaakt werden, kan het nemen van zulke beslissingen leiden tot emotioneel leed bij naasten. Patiënten willen behandeld worden volgens hun waarden en voorkeuren, maar ontvangen in de laatste levensfase vaak niet de zorg die overeenkomt met hun waarden.

Planning voor het nemen van toekomstige zorgbeslissingen kende zijn oorsprong bij de promotie van "*advance directives*" (*ADs*, voorafgaande wilsverklaringen), die aangeven wat de zorgdoelen zijn van de patiënt, en iemand aanduiden die beslissingen kan nemen over de zorg in hun plaats (*substitute/surrogate decision maker, SDM*; wettelijke vertegenwoordiger). Wilsverklaringen werden echter onvoldoende bevonden om de patiëntgerichtheid van de levenseindezorg, noch de accuraatheid van inschatting van de waarden van patiënt door de vertegenwoordiger bij het nemen van beslissingen, te verbeteren. *Advance care planning* (*ACP*, voorafgaande zorgplanning) is geen éénmalig documenteren van zorgdoelen in een wilsverklaring, maar wordt gedefinieerd als een proces dat "*individuen in staat stelt om doelen en voorkeuren voor toekomstige zorg te definiëren, om deze doelen en voorkeuren te bespreken met familie en zorgverleners, en om deze voorkeuren, indien nodig, te documenteren*". Het kan inhouden dat een SDM wordt aangeduid, die beslissingen neemt over de zorg en behandeling voor de patiënt wanneer de patiënt wilsonbekwaam is, en/of dat de wensen voor zorg en behandeling gedocumenteerd worden in een wilsverklaring.

Sedert 2002 bestaat in België een medico-legaal kader voor ACP, dat berust op de *Wet betreffende de palliatieve zorg,* de *Wet betreffende de euthanasie*, en de *Wet betreffende de rechten van de patiënt*. Sindsdien wordt in België veel aandacht besteed aan het promoten van ACP binnen de sociale en legale context. Recente veranderingen in het beleid, zoals de modernisering van de *Wet betreffende de rechten van de patiënt,* hebben ook als doel om ACP verder te bevorderen.

De onderzoeksliteratuur rond ACP is heterogeen wat betreft de setting, interventies, doelpopulaties, en uitkomsten. ACP kan gezondheidsuitkomsten verbeteren en kan bijdragen tot een gevoel van controle en geruststelling bij patiënten. Het kan de vertegenwoordiger meer

vertrouwen geven bij het nemen van zorgbeslissingen voor de patiënt. ACP-interventies kunnen procesuitkomsten verbeteren, zoals kennis over ACP, maar ook ACP-gedrag bevorderen, zoals communicatie met de vertegenwoordiger of zorgverlener. Discours rond de toekomst van ACP-onderzoek benadrukt onderbenutte mogelijkheden, zoals het voorbereiden van zorgverleners om kwaliteitsvolle gesprekken te voeren, en van patiënten en vertegenwoordigers om ook goedgeïnformeerd beslissingen te maken op het moment dat dit nodig is.

Omdat ACP een proces is dat over de tijd heen plaatsvindt, wordt aangeraden om hier tijdig mee te beginnen. Settings waar ACP-gesprekken opgestart en gefaciliteerd kunnen worden zijn onder andere die binnen de eerstelijnszorg, zoals de huisartsenpraktijk. In deze setting bestaat vaak een langdurige arts-patiëntrelatie; huisartsen ondersteunen bovendien de continuïteit van de zorg. Er zijn echter tekorten in het opstarten van ACP in de praktijk, waaronder ook de huisartsenpraktijk. Dit kan te wijten zijn aan verschillende barrières. Patiënten ervaren ACP soms als emotioneel moeilijk, of als irrelevant. Ze verwachten vaak dat hun huisarts het gepaste moment zal aangeven om ACP te bespreken, of hebben nood aan meer informatie over ACP. Huisartsen ervaren een gebrek aan tijd als barrière, en willen patiënten en hun naasten niet emotioneel belasten met ACP-gesprekken. Ze kunnen ook aanvoelen dat ze onvoldoende kennis of vaardigheden hebben om aan ACP te doen. Op systeemniveau is er onder andere een gebrek aan gestandaardiseerde mogelijkheden om informatie te documenteren.

Om de barrières tegen de gaan, en de bevorderende factoren te maximaliseren, werd er vóór dit proefschrift een complexe interventie ontwikkeld, bestaande uit meerdere componenten. Deze interventie, de ACP-GP interventie, werd opgebouwd volgens de richtlijn van het Medical Research Council (MRC), gebruik makend van evidentie uit de literatuur en feedback door expertenpanels. Daarna werd een pilootstudie uitgevoerd om de interventie te testen in de Belgische huisartsenpraktijk. Op basis van de bevindingen uit de pilootstudie werd de interventie verder aangepast.

In dit proefschrift worden volgende vragen onderzocht:

- Wat is het effect van de ACP-GP interventie op uitkomsten die relevant zijn voor het ACP-proces (betrokkenheid van patiënten bij ACP, *ACP engagement*; en het zelfvertrouwen van huisartsen om aan ACP te doen (*ACP self-efficacy*)?
- Welke factoren hangen samen met *ACP engagement* bij patiënten?
- Hoe werd de interventie geïmplementeerd, en hoe werken de componenten?
- In de internationale literatuur over trials van ACP-interventies voor patiënten met een chronische, levensbeperkende ziekte: welke rationales worden voorgesteld (volgens

welke mechanismes wordt de interventie verondersteld een effect uit te oefenen op uitkomsten)?

- In een ACP-interventie (*ACP pathway*) met gelijkaardige componenten als ACP-GP, die in twee Canadese provincies werd geïmplementeerd: wat waren de ervaringen van zorgverleners die de interventiestappen uitvoerden?

We trachtten deze vragen te beantwoorden via twee overkoepelende onderzoeksdoelen. **Onderzoeksdoel 1** is het implementeren en evalueren van de ACP-GP interventie bij patiënten met een chronische, levensbeperkende ziekte in de Belgische huisartsenpraktijk. **Onderzoeksdoel 2** is het omschrijven van inzichten in de implementatie van ACP-interventies, gebruik makend van de internationale literatuur en het voorbeeld van de *ACP pathway*, die in twee Canadese provincies werd geïmplementeerd.

METHODEN

We maken gebruik van verschillende studiemethoden om de onderzoeksdoelen te realiseren. **Onderzoeksdoel 1** is gebaseerd op een cluster-gerandomiseerde gecontroleerde trialstudie (*cluster-RCT)* van de ACP-GP interventie voor patiënten met een chronische, levensbeperkende ziekte. Het protocol wordt in **Hoofdstuk 1** uitgebreid omschreven. Belgische huisartsen identificeerden patiënten voor deelname. De huisartsen en hun patiënten werden als cluster gerandomiseerd. De interventiegroep ontving de ACP-GP interventie. De interventie bestaat uit een training voor huisartsen, een werkboek over ACP voor patiënten, twee ACP-gesprekken tussen huisarts en patiënt, en een documentatietemplate voor de huisarts. In de controlegroep boden de huisartsen hun patiënten de gebruikelijke zorg. We analyseerden de baseline-data van deelnemende patiënten en rapporteerden descriptief hun demografische en klinische karakteristieken, hun *ACP engagement*, en hun gepercipieerde kwaliteit van communiceren over ACP door hun huisarts. We gebruikten *linear mixed models* om de associaties na te gaan tussen hun karakteristieken en gepercipieerde kwaliteit van communicatie, en hun *ACP engagement* (**Hoofdstuk 2**). De primaire uitkomstanalyses evalueerden verschillen tussen de interventie- en controlegroep op *ACP engagement* bij patiënten, en *ACP self-efficacy* bij huisartsen, op 3 maanden na de baselinemeting (T1, primaire effectiviteit) en 6 maanden na baseline (T2). *Linear mixed models* hielden rekening met het geclusterde design: clustering van metingen binnen deelnemers, en van patiënten binnen huisartsen (**Hoofdstuk 3**). Daarnaast voerden we een parallelle procesevaluatie uit, gebruik makend van het *Reach, Efficacy/effectiveness, Adoption, Implementation, Maintenance (RE-AIM)* framework (**Hoofdstuk 4**). Gebaseerd op deze richtlijn brachten we het bereik van de interventie, diens effectiviteit, adoptie, implementatie, en behoud in kaart. We gebruikten data uit de monitoring van rekrutering voor

de trialstudie, implementatiemonitoring, vragenlijsten, en (focusgroep) interviews met huisartsen en patiënten uit de interventiegroep.

Om **onderzoeksdoel 2** te bereiken, hebben we een scoping review uitgevoerd van gerandomiseerde trialstudies (RCTs) waarbij de effectiviteit van complexe ACP-interventies voor volwassenen met een chronische, levensbeperkende ziekte getest wordt (**Hoofdstuk 5**). Op basis van data die verzameld werd tijdens een Canadees nationaal project om ACP-gesprekken te bevorderen, hebben we tot slot een kwalitatieve analyse uitgevoerd van interviews en focusgroepen met 13 zorgverleners uit de provincies Alberta en British Columbia (**Hoofdstuk 6**).

BELANGRIJKSTE BEVINDINGEN

ACP engagement in een steekproef van patiënten met een chronische, levensbeperkende ziekte, gerekruteerd voor een cluster-gerandomiseerde trialstudie (**Hoofdstuk 2**)

Binnen de steekproef van patiënten die gerekruteerd werden voor de cluster-RCT, onderzochten we *ACP engagement*, dit zijnde hun betrokkenheid bij ACP, bestaande uit hun bereidheid en hun zelfvertrouwen om aan ACP te doen. Dit werd geëvalueerd door middel van een vragenlijst, de *ACP Engagement Survey*, die *ACP engagement* meet als gemiddeldes op een Likertschaal van 1 tot 5 (hogere score staat voor hogere *engagement*). We onderzochten de associatie tussen patiëntkarakteristieken, gepercipieerde kwaliteit van communicatie over ACP door de huisarts, en *ACP engagement* bij patiënten. In totaal werden 95 patiënten geïncludeerd door 35 deelnemende huisartsen. Bij baseline was de gemiddelde score voor *ACP engagement* bij patiënten 3.06 (Standaarddeviatie (SD) 0.98); gemiddeld zelfvertrouwen was 3.86 (SD 1.13); gemiddelde bereidheid was 2.52 (SD 1.20). Na correctie voor meerdere statistische toetsen op dezelfde dataset via de Benjamini-Hochbergprocedure, vonden we geen statistisch significante verbanden tussen de demografische of klinische karakteristieken van patiënten, en hun *ACP engagement*. Er was eveneens geen significante associatie met hoeveel informatie de patiënt ontving van hun huisarts over ACP, de mate waarin de huisarts luisterde naar wat voor de patiënt belangrijk is om goed te leven, en de mate waarin de huisarts luisterde naar wat de patiënt belangrijk vindt betreffende hun toekomstige zorg. We vonden hogere *ACP engagement* bij patiënten die hun huisarts een hoge score gaven voor de mate waarin de huisarts luisterde naar de bezorgdheden van de patiënt over hun toekomstige gezondheid, vergeleken met patiënten die hiervoor een lage score gaven (3.27 versus 2.48, *p* = 0.002). Een gelijkaardig patroon werd gevonden voor het zelfvertrouwen van de patiënt om aan ACP te doen (4.10 versus 3.14, *p* <0.001).

Geen significante verschillen tussen interventie en controle op de primaire uitkomstmaten in de cluster-RCT van de ACP-GP interventie in Belgische huisartsenpraktijken (**Hoofdstuk 3**)

Om de primaire effectiviteit van de interventie te meten, hebben wij onderzocht of de interventie beter presteert dan de controlegroep in het verbeteren van *ACP engagement* bij patiënten, en zelfvertrouwen om aan ACP te doen bij huisartsen (*ACP self-efficacy*). Deze uitkomsten werden vergeleken op 3 en 6 maanden na baseline (respectievelijk T1 en T2). Voor de studie werden 35 huisartsen en 95 patiënten gerandomiseerd; 18 huisartsen en 53 patiënten werden toegewezen aan de interventiegroep. We vonden geen significante verschillen in de verbetering van de primaire uitkomst voor patiënten op T1 of T2; er was een stijging van *ACP engagement* in beide groepen. We vonden eveneens geen significante verschillen voor het zelfvertrouwen om aan ACP te doen bij huisartsen.

Haalbaarheid en behoud van de complexe ACP-GP interventie in Belgische huisartsenpraktijken (**Hoofdstuk 4**)

Voor de mixed-method procesevaluatie, die parallel met de trialstudie van de ACP-GP interventie werd uitgevoerd, werd data verzameld tijdens het monitoren van de rekrutering en implementatie. Zestien huisartsen en 46 patiënten uit de interventiegroep hebben vragenlijsten beantwoord op T1. We maakten bijkomend gebruik van getranscribeerde kwalitatieve data, verzameld bij 14 huisartsen en 11 patiënten uit de interventiegroep. We vonden een laag bereik van de interventie: 50 (3.3%) van de huisartsen die gecontacteerd werden hadden interesse om deel te nemen, waarvan 35 uiteindelijk gerandomiseerd werden. Bereik bij patiënten was hoger: 95 van de 117 geïdentificeerde patiënten (81.2%) werden geïncludeerd. Effectiviteit volgens de primaire uitkomst was laag, zie **Hoofdstuk 3**. Huisartsen en patiënten omschreven andere effecten van de interventie. Huisartsen werden alerter voor ACP en hadden een positievere benadering tot het thema. Door patiënten werd een positieve affectieve impact omschreven. Adoptie van de interventiecomponenten op T1 was variabel. Aanwezigheid op de training was hoog en de meeste huisartsen voerden het gesprekscomponent van de interventie uit. Ongeveer twee-derde van de patiënten gaven aan hun werkboek minsten één keer gebruikt te hebben. Anderzijds was er lage adoptie van de documentatietemplate: ongeveer een vierde van de eerste gesprekken, en slechts één tweede gesprek, werden via de template gedocumenteerd. Huisartsen onderstreepten de waarde van ACP, maar het thema was voor sommige patiënten confronterend. *Fidelity*, het uitvoeren van de vier interventiecomponenten volgens het protocol, was laag. Anderzijds werd een hoge tevredenheid gevonden bij de deelnemers. Huisartsen waren tevreden met de training en de interventiematerialen, en vonden deze nuttig. De gesprekken kwamen tegemoet aan de verwachtingen van de patiënten. De gesprekken werden hoofdzakelijk

gedocumenteerd in het elektronisch medisch dossier (EMR). Gesprekken waren uiterst geïndividualiseerd, en huisartsen konden hun aanpak voldoende aanpassen. Patiënten omschreven hun ervaring met de gesprekken als positief. Een bestaande arts-patiëntrelatie en/of eerdere ervaring met ACP, kon hun comfort om over ACP te praten beïnvloeden. Huisartsen zagen mogelijkheden om de training te integreren in medische opleidingen, maar ook uitdagingen om ACP-gesprekken te integreren in hun huidige werkwijze. Sommige patiënten zagen ACP als "voltooid"; anderen zetten het proces door via contemplatie of het voeren van extra gesprekken.

Mechanismen en factoren die de primaire uitkomstmaten beïnvloeden in trialstudies van complexe ACP-interventies: gelaagde complexiteit (**Hoofdstuk 5**)

We includeerden zestien publicaties die rapporteerden over de primaire uitkomst(en) van een RCT, waarbij de effecten van een complexe ACP-interventie werd onderzocht bij patiënten met een chronische, levensbeperkende ziekte. Het grootste aandeel van de studies (n=11) maakten gebruik van een interview of gesprek om ACP te bespreken. Acht studies gebruikten een wilsverklaring (*advance directive*) of een *goals of care* document. Andere interventiecomponenten waren bijvoorbeeld samenvattingen van gesprekken die aan artsen werden doorgegeven of documentatie die in het EMD werd geplaatst; informatiemateriaal; voorbeeldvragen en communicatietips; interactieve keuzehulpen (*decision aids*); en educatieve workshops. Het mechanisme dat met de meeste uitkomstdomeinen werd gelinkt (n=4 domeinen), was *tailoring*, het aanpassen van de stijl of inhoud naargelang de noden van de patiënt. Het meest-vermelde mechanisme (in n=6 studies), was het promoten van vaardigheden, competentie, en zelfvertrouwen om deel te nemen aan ACP-gesprekken. Bevindingen voor primaire uitkomstmaten waren voor de meeste uitkomstdomeinen gemengd. Bij het bespreken van hun bevindingen, verwezen auteurs naar drie thema's: 1) factoren bij deelnemers; 2) implementatie; en 3) methodologische factoren.

Ervaringen, uitdagingen, en mogelijkheden voor toekomstige implementatie van een ACP-interventie in Canadese eerstelijns- en ambulante zorg (**Hoofdstuk 6**)

We hebben transcripties gebruikt van focusgroepen en interviews met clinici in British Columbia (BC) en Alberta, om hun ervaringen te onderzoeken bij de implementatie van een ACP-interventie (de *ACP pathway*) binnen de eerste lijn en de ambulante zorg (algemene interne geneeskunde). Twaalf artsen en een sociaal werker werden geïnterviewd. Belemmerende en bevorderende factoren werden overheen verschillende domeinen geïdentificeerd. Deelnemers omschreven bijkomend hoe de interventie duurzaam geïmplementeerd zou kunnen worden in de toekomst. Het eerste domein hield de beoordeling in van de gebruiksvriendelijkheid van de interventiecomponenten. Het tweede domein

omschrijft de impact op niveau van de clinicus of clinici, waaronder wij drie thema's identificeerden. Bij het eerste thema werd gereflecteerd op de verantwoordelijkheden van de arts, en de arts-patiënt interactie. Het tweede thema omschrijft hoe de *pathway* bijdroeg aan het teamwerk in de praktijk, en hoe bestaande structuren van samenwerkingen binnen de praktijk de *pathway* al dan niet ondersteunden. Bij het derde thema werd besproken hoe de *pathway* geïntegreerd wordt in de werkprocessen van de praktijk. Sommige clinici verwezen naar de impact die zij ondervonden op niveau van de patiënt. Wij deelden dit op in twee thema's: voorbereiding, of hoe de patiënt omgaat met ACP vóór de consultatie; en bereidheid, of hoe de patiënt omgaat met ACP tijdens of na de consultatie. De *pathway* was haalbaar in deze settings, maar *buy-in* door patiënten werd gezien als randvoorwaarde.

BESPREKING VAN DE BEVINDINGEN

Bevindingen uit de cluster-RCT

In dit proefschrift wordt een cluster-RCT omschreven, waarbij een complexe ACP-interventie (ACP-GP) werd getest in Belgische huisartsenpraktijken. Zoals besproken in **Hoofdstuk 3**, werd een verbetering op de primaire uitkomsten gevonden bij huisartsen en patiënten in beide groepen, maar zonder significant verschil.

We stellen de hypothese dat **bewustwording of sensibilisering** over ACP een grotere impact had dan verwacht op alle deelnemers. Een Hawthorne effect is een mogelijke verklaring. De studieprocedure, waarbij huisartsen en patiënten uitleg kregen over ACP, zou beide groepen bewuster kunnen gemaakt hebben van ACP. De timing van de studie, die uitgevoerd werden tijdens de eerste golven van de COVID-pandemie, kan hier ook toe bijgedragen hebben. Tijdens de vroege golven van de pandemie bestond een hoge bezorgdheid over de gezondheid, zoals de impact van een infectie bij personen met een kwetsbare gezondheidstoestand. Dit zou ertoe geleid kunnen hebben dat patiënten in onze trialstudie nadachten en/of praatten over ACP en levenseindezorg, ongeacht hun toegewezen groep in de studie. Artsen zouden met deze patiënten misschien ook overgaan naar het bespreken van wensen voor toekomstige zorg, ook in de controlegroep. Als huisartsen en patiënten ACP-gesprekken voeren omwille van deze sensibilisering, kan dit de primaire uitkomstmaten beïnvloeden door patiënten meer te doen praten over hun wensen voor toekomstige zorg, en huisartsen de mogelijkheid te bieden om hun zelfvertrouwen via ervaring op te bouwen.

Voor de **primaire uitkomstmaat op patiëntniveau** maakten we gebruik van de *ACP Engagement Survey*. Deze vragenlijst is gebaseerd op verschillende gedragstheorieën, waaronder de Sociaal-Cognitieve Theorie en het Transtheoretisch Model van Gedragsverandering (TTM). Volgens deze theorieën is verandering nodig in onderliggende

processen, zoals zelfvertrouwen en bereidheid, om gedrag te veranderen. Als patiënten zich meer bewust zijn van ACP, doordat de onderzoekers ACP hebben uitgelegd en hier vragen over hebben gesteld, kan dit patiënt in beide groepen naar een verder-gevorderd stadium van gedragsverandering gebracht hebben. Vanuit de primaire analyses kunnen we daarom een interessante hypothese stellen, dat de *ACP Engagement Survey* het proces van gedragsverandering in beide groepen heeft kunnen capteren. De dataverzameling, die patiënten meer bewust maakt over ACP, kan op zichzelf een effectieve interventie zijn.

Bij patiënten die we interviewden, vonden we grote verschillen in eerdere ervaringen met ACP, in hoe relevant de patiënt ACP vond, en in de mate waarin de patiënt actief betrokken wil zijn bij het nemen van beslissingen over hun gezondheidszorg. Deze bevindingen tonen aan dat bereidheid om aan ACP te doen, een complex construct is, dat nog complexer wordt gemaakt doordat beslissingen over medische zorg slechts één deel uitmaken van ACP. We stelden vast uit **Hoofdstuk 2** dat betrokkenheid bij ACP voor patiënten met een chronische, levensbeperkende ziekte, zou kunnen voortvloeien uit hun bezorgdheden over de impact van hun gezondheidstoestand op hen en hun naasten. Als de patiënt deze bezorgdheden uitdrukt, is dit potentieel een teken van bereidheid tot ACP. Deze bereidheid kan een proactieve basis zijn voor gesprekken over ACP met de huisarts.

De **primaire uitkomstmaat op huisartsniveau** werd gemeten via de *ACP-SE (ACP Self Efficacy) scale*, die het zelfvertrouwen van artsen om aan ACP te doen, in kaart brengt. Hoge scores bij baseline zijn een mogelijke verklaring voor het gebrek aan significante verschillen tussen de interventie- en controlegroep. Het kan zijn dat huisartsen die deelnamen aan de studie reeds gemotiveerd waren voor ACP, en een positieve perceptie hadden van ACP, wat kan samenhangen met hoger zelfvertrouwen. Sommige huisartsen hadden al vóór de interventie vertrouwen in hun eigen kunnen, dankzij de ervaring die zij hadden opgedaan in hun klinische praktijk. Anderzijds hadden sommige artsen een intensievere training verwacht. Casussen gebaseerd op hun eigen praktijk, of feedback op gesprekken in de praktijk, kunnen een waardevolle toevoeging zijn aan de training. Om ervaring op te doen in hun praktijk en zo hun zelfvertrouwen verder op te bouwen, hebben huisartsen waarschijnlijk ook meer tijd nodig.

Lessen die we kunnen trekken uit ACP-GP en bredere evidentie uit de studies

De bevindingen uit de evaluatie van de ACP-GP cluster-RCT, de scoping review van complexe ACP-interventies, en de studie van ervaringen bij het implementeren van een ACP-interventie in twee Canadese provincies, laten ons toe te reflecteren over welke onderdelen van een ACP-interventie al dan niet als nuttig ondervonden worden.

Ten eerste hebben we vastgesteld vanuit de procesevaluatie van ACP en de studie van de Canadese *ACP pathway* dat artsen in de primaire en ambulante zorg de inherente waarde

van ACP erkennen, en beamen dat ACP het waard is om te doen. We moeten onze inspanning om ACP in deze settings te faciliteren dus niet opgeven. Echter moeten we wel voorzien dat clinici over de tools en vaardigheden beschikken om met patiënten over ACP te praten. We merkten een sterke waardering voor een positieve benadering tot ACP, die rekening houdt met wat belangrijk is voor de patiënt: hun doelen, sterktes, en kwaliteit van leven. Dit draagt bij dit een positieve en wederkerige impact tussen arts en patiënt, waaruit vertrouwen en een gerust gevoel kunnen ontstaan.

We moeten ook in acht nemen dat ACP emotioneel confronterend kan zijn voor patiënten, die soms nood hebben aan meer voorbereiding, informatie, of *empowerment*. Zowel in de ACP-GP trialstudie als in de Canadese *pathway* was de *buy-in* van patiënten een belangrijke voorwaarde, zonder welke patiënten niet betrokken waren bij de interventie. ACP kan complexe en ambivalente emoties opwekken bij patiënten, die soms verkiezen om te wachten tot ze ACP als klinisch relevant ervaren, ook als hun gezondheidstoestand slecht is. Dit zorgt voor weinig "voorafgaande" zorgplanning of gesprekken over waarden en voorkeuren. Het is daarom belangrijk om rekening te houden met de bereidheid en kennis over ACP van de patiënt, alsook met wat de patiënt weet en begrijpt over hun eigen gezondheid en prognose. De relevantie en het nut van ACP moet gecommuniceerd worden naar alle patiënten met een levensbeperkende ziekte, om misverstanden tegen te gaan dat ACP enkel gaat over levenseinde en overlijden. Artsen spelen hierbij een belangrijke rol: zij kunnen de rationale van ACP uitleggen bij patiënten wanneer hun gezondheid stabiel is, zodat patiënten voldoende tijd hebben om na te denken over hun wensen en deze te bespreken.

Ten laatste reflecteren we over de integratie van ACP binnen de klinische praktijk en workflow. Het gebrek aan integratie van ACP-documentatie in het huidig systeem blijft een struikelblok. In België vonden sommige huisartsen geen bijkomende waarde van een documentatietemplate. Zij gaven de voorkeur aan documentatie direct in het EMD, ook al ontbreekt hierin een specifiek luik voor het documenteren van ACP. Duidelijke, zichtbare integratie van documentatie in de huidige EMD-software kan de toegankelijkheid van deze documentatie bevorderen, en de voorbereiding op consultaties met de patiënt faciliteren. De integratie van ACP-gesprekken in de klinische workflow vergt een flexibele benadering op lange termijn, en dit binnen een multi- en interdisciplinaire context. In deze benadering is ACP niet "voltooid" na een bepaald aantal gespreken of na het documenteren van wensen, maar een iteratief proces doorheen het leven van de patiënt. Het proces wordt gedeeld door het praktijkteam: een interprofessionele benadering die ook verpleegkundigen, sociaal werkers, en andere teamleden betrekt kan veelbelovend zijn voor de toekomst. Een aanpak die verpleegkundigen en sociaal werkers betrekt, zoals in de Canadese *pathway*, toonde aan dat artsen meer vertrouwen kregen in de vaardigheden van deze teamleden, en dat bestaande

samenwerkingsverbanden werden versterkt. Bijkomend moet het ACP-proces de patiënt mee opvolgen naar andere settings binnen de gezondheidszorg. Zo wilden sommige patiënten die deelnamen aan de ACP-GP trialstudie bijvoorbeeld ook met specialisten praten over ACP. Dit houdt in dat continuïteit van zorg en samenwerkingen tussen settings aangewezen is. Het faciliteren van informatietransfer via het EMD is één onderdeel van deze continuïteit, maar ook een duidelijke definitie van verantwoordelijkheden voor ACP, en een gedeeld begrip over ACP tussen zorgverleners, is noodzakelijk.

AANBVELINGEN VOOR DE PRAKTIJK, HET ONDERZOEK, EN HET BELEID

Op basis van de bevindingen van dit proefschrift kunnen we volgende belangrijke aanbevelingen maken:

Praktijk: normaliseer ACP als een proces gebaseerd op de waarden van patiënt, overheen stakeholders en settings, waaronder ook niet-klinische settings

- Bied ACP aan bij alle mensen geconfronteerd met een chronische, levensbeperkende ziekte, als cruciaal onderdeel van goede zorg. ACP moet gezien worden als een gesprek over de waarden en bezorgdheden van de patiënt, en niet als het onmiddellijk overgaan naar specifieke keuzes over toekomstige medische zorg.
- Erken ACP als kerntaak voor clinici die een patiënt met een levensbeperkende ziekte behandelen, maar ook als onderdeel van patiënt- en doelgerichte zorg bij alle (gezonde) volwassenen. Hierbij moet ACP benaderd worden als holistisch proces dat plaatsvindt over het leven van de persoon heen, en dat beslissingen inhoudt zowel over de huidige als over de toekomstige zorg.
- Verzekeren dat ACP gerespecteerd wordt als levenslang onderdeel van patiëntgerichte zorg, vraagt de betrokkenheid van clinici overheen het gezondheidszorgsysteem.
- Gesprekken binnen een klinische setting zijn slechts één onderdeel van een complex proces. Veel gesprekken over zorgdoelen en -waarden vinden plaats buiten de consultatie. Mensen moeten in klinische en niet-klinische settings in staat worden gesteld om hun waarden te uiten. Hierdoor krijgen ze vertrouwen en competentie om deel te nemen aan ACP. Patiënten moeten *empowered* worden om zorg te dragen voor hun eigen gezondheid, ook door over ACP te praten; artsen kunnen hiertoe bijdragen door informatie te verstrekken over de voordelen van ACP, waarbij ze openheid en een positieve houding vertonen.

Onderzoek: Werk samen met patiënten, naasten, en het publiek om op theorie gebaseerde interventies te ontwikkelen die de capaciteit voor ACP ondersteunen, ook in de gemeenschap

- Een RCT van een interventie voor één patiëntenpopulatie, binnen één setting en voor een bepaalde tijdsperiode is wellicht niet de meest aangewezen methode waarmee we de volledige impact van ACP kunnen vatten. Een systeembenadering en pragmatische onderzoeksmethodes worden aanbevolen.
- Bij het ontwikkelen of aanpassen van interventies moeten onderzoekers aandacht besteden aan het "hoe" en "wat" van de interventie. Het gebruik van een onderliggende theorie met een duidelijke rationale kan hier nuttig zijn.
- Diversifieer ACP-uitkomsten om zo het hele ACP-proces in kaart te brengen. In recente literatuur zijn nieuwe, integratieve benaderingen aanbevolen, waaronder longitudinale en kwalitatieve methoden. Gebaseerd op dit proefschrift ondersteunen wij deze aanbevelingen.
- Betrek bij onderzoek andere stakeholders zowel binnen als buiten de klinische settings, bijvoorbeeld naasten. Dit kan ervoor zorgen dat huisartsen een goede basis hebben om ACP-gesprekken te voeren met hun patiënten. *Patient and public involvement (PPI),* via *co-design* en *(community-based) participatory action research* zijn benaderingen en methoden die patiënten, familie, en naasten kunnen betrekken bij elke stap van het studieproces.

Beleid: Maak persoonsgerichte ACP, die mensen met of zonder een levensbeperkende ziekte helpt om te praten over ACP, een prioriteit

- Beleidsinitiatieven moeten prioriteit geven aan een zorgbenadering die rekening houdt met de wensen van de patiënt. Dit omvat de expliciete erkenning van ACP als deel van patiënt- en doelgerichte zorg, en een sterkere focus op het waarborgen van kwaliteit van leven zoals de patiënt dit zelf definieert.
- Verzeker dat de erkenning van ACP als continu proces consistent wordt toegepast binnen *evidence-based* richtlijnen, publiekscampagnes, officiële communicatie, training, en andere initiatieven. Stel geen onnodige beperkingen rond het begrip van ACP als proces, of rond wie baat kan hebben bij ACP.
- Binnen de gezondheidszorg zou een teamsgerichte benadering tot ACP, alsook de continuïteit van ACP-communicatie tussen settings, bevorderd kunnen worden via duidelijke integratie in het EMD.
- Benader ACP vanuit het perspectief van volksgezondheid. Beleidsinitiatieven moeten het bewustzijn, de *empowerment*, de kennis, en de capaciteiten voor ACP binnen de gemeenschap bevorderen. Er is een gezamenlijke inspanning nodig binnen de

gemeenschap om het stigma rond praten over gezondheid, ziekte, en de dood tegen te gaan.

APPENDIX

ACP-GP intervention materials

MIJN WENSEN VOOR TOEKOMSTIGE ZORG
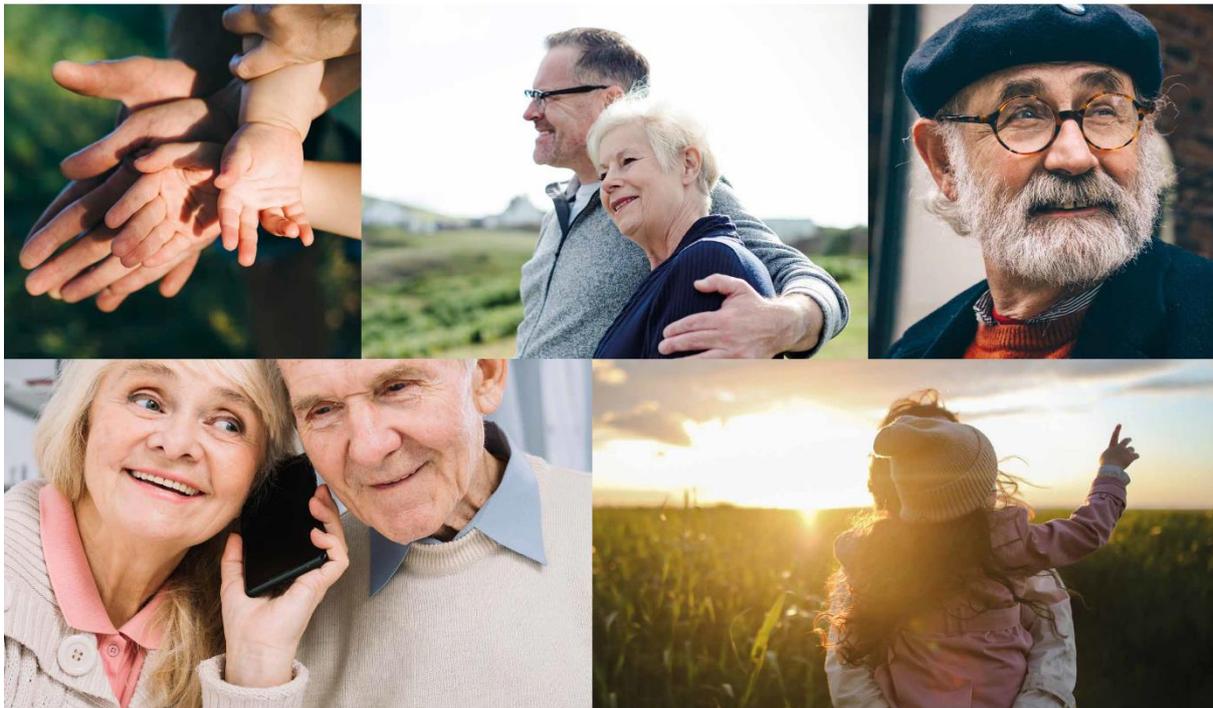
NU AL NADENKEN OVER LATER

Misschien heb je er zelf al eens over nagedacht: hoe wil ik verzorgd worden als er mij iets ernstigs overkomt? Misschien voel je je prima, maar wil je toch een paar zaken op een rijtje zetten voor als dit niet meer zo zou zijn.

Denk bijvoorbeeld aan de volgende situaties:

- **Jean** is 50 jaar en gezond. Hij heeft recent een overlijden meegemaakt waarbij hij de overleden persoon langzaam zag aftakelen. Voor de naasten en kennissen van deze persoon was dit een emotioneel moeilijke gebeurtenis. Jean wil dit zelf niet meemaken op deze manier. Daarom vindt hij het belangrijk om op voorhand aan zijn arts en familie uit te leggen wat hij later zou willen.

- **Anna** is 40 jaar en heeft borstkanker. Haar arts heeft net de prognose met haar besproken. Ze heeft een grote kans op genezing, maar toch bestaat de kans dat haar behandeling minder goed verloopt dan verwacht. Ze zit in met haar familie en kinderen moest het slecht gaan en daar wil ze op voorbereid zijn. Ze wil dit bespreken met iemand

- **Freddy** is ernstig ziek. Hij wordt steeds zwakker en moet regelmatig naar het ziekenhuis. Dit zet hem aan het denken over toekomst. Hij maakt zich veel zorgen, maar het belangrijkste voor hem is dat hij nog op reis kan gaan met zijn gezin. Om dit mogelijk te maken, uit hij zijn zorgen wanneer hij bij zijn huisarts op consultatie is.

- **Betty** is 85 jaar en woont bij haar dochter en schoonzoon. Liefst van al wil ze daar ook kunnen blijven wonen, maar haar gezondheid gaat achteruit en ze wil haar gezin niet belasten met haar zorg. Ze vraagt zich af of ze naar een woonzorgcentrum zal moeten verhuizen. Wanneer haar huisarts op thuisbezoek komt, stelt ze vragen over mogelijke thuishulp en thuiszorg. Weten welke mogelijkheden er bestaan, helpt Betty om plannen te maken en stelt haar gerust.

Zoals je ziet, is het nuttig voor iedereen om stil te staan bij dit thema. Het nu al nadenken, praten en afspraken maken over de gewenste zorg in de toekomst wordt ook **VOORAFGAANDE ZORGPLANNING** genoemd.

WAT IS VOORAFGAANDE ZORGPLANNING?

Voorafgaande zorgplanning helpt je om anderen op de hoogte te brengen van wat voor jou belangrijk zou zijn, voor het geval dat je ernstig ziek zou worden of niet meer in staat zou zijn om zelf beslissingen te nemen. Het doel van voorafgaande zorgplanning is het jou en jouw familie, naasten en zorgverleners makkelijker te maken om **beslissingen** te nemen en **zorg** te verlenen die zoveel mogelijk **in overeenstemming zijn met jouw wensen**, ook wanneer je daar zelf niet meer over zou kunnen beslissen.

Voorafgaande zorgplanning zorgt er uiteindelijk voor dat je persoonlijke keuzes zo goed mogelijk nageleefd worden, dat er een optimale communicatie ontstaat tussen jou, je naasten en de arts over de gewenste zorg en dat moeilijke medische beslissingen niet door derden dienen genomen te worden, zonder dat ze op de hoogte zijn van jouw wensen en voorkeuren.

SPREEK HIEROVER MET JOUW FAMILIE, ARTS EN ANDERE ZORGVERLENERS!

WAAR KAN DIT WERKBOEKJE MIJ MEE HELPEN?

Dit werkboek nodigt je uit om even stil te staan bij wat kwaliteit van leven voor jou betekent, en is bedoeld om je te helpen nadenken over jouw wensen en voorkeuren rond toekomstige zorg. Het kan je helpen om samen met jouw huisarts een planning op te maken voor je toekomstige zorg, ook voor in het geval dat je zelf je wensen niet meer zou kunnen uiten.

Het boekje bestaat uit 8 vragen. Je mag zo veel of weinig van deze vragen beantwoorden als je zelf wil, in de volgorde die je zelf kiest.

WAT DOE IK MET MIJN INGEVULD WERKBOEK?

Gelieve het ingevulde werkboek mee te nemen bij een volgend bezoek aan jouw huisarts die de vragen en antwoorden verder met jou zal bespreken.

WIE KRIJGT MIJN ANTWOORDEN?

Dit werkboek kadert in een onderzoek naar voorafgaande zorgplanning in de huisartsenpraktijk van de Vrije Universiteit Brussel en Universiteit Gent. Enkel jouw huisarts en het onderzoeksteam krijgen de ingevulde werkboekjes te zien.

Alle antwoorden worden **volledig anoniem** verwerkt door het onderzoeksteam. Dit betekent dat niemand zal weten wie welke antwoorden heeft gegeven. Na afloop van het onderzoek worden geen individuele antwoorden verspreid, maar enkel gemiddelden van antwoorden van alle patiënten die aan het onderzoek hebben deelgenomen.

JOUW WENSEN VOOR TOEKOMSTIGE ZORG

1. Wat is voor jou belangrijk om goed te leven?

Hier zijn enkele vragen die je kunnen helpen nadenken over wat belangrijk is voor jou:

- Wat maakt me blij? Wat brengt mij vreugde of plezier?
- Hoe breng ik graag mijn tijd door? Met wie breng ik graag tijd door?
- Wat maakt elke dag zinvol?

Bv. Ik kan niet zonder mijn lievelingseten; Ik hou ervan om te gaan wandelen en van de frisse lucht te genieten; ...

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2. Waar hecht je het meest belang aan m.b.t jouw fysieke en mentale gezondheid?

Bv. Het is belangrijk dat ik mijn familie herken en met hen kan praten; Het is belangrijk dat ik zo weinig mogelijk pijn heb; Het is belangrijk dat ik in staat ben om zelfstandig te wonen, ...

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3. Heb je ervaring met ernstige ziekte of overlijden van iemand in jouw naaste omgeving? Denk na over wat goed of minder goed ging. Is er iets wat je wel of niet zou willen, op basis van deze ervaring(en)?

_____

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4. Heb je bepaalde vragen of bekommernissen over je <u>huidige</u> gezondheidstoestand?

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5. Wanneer je over de toekomst nadenkt, zijn er dingen waar je je zorgen over maakt?
Dit kan over je gezondheidstoestand gaan, maar ook over andere dingen. Bv. Ik maak mij zorgen dat ik mijn familie zou belasten met mijn zorg (financieel, emotioneel, …); Ik maak mij zorgen dat ik niet genoeg comfort zou hebben; …

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6. Hoe wil je nu of in de toekomst beslissingen nemen over jouw zorg?

Op de volgende schalen zie je links en rechts twee stellingen. Misschien ga je sterk akkoord met één van deze stellingen, een beetje akkoord, of bevindt jouw voorkeur zich ergens in het midden tussen de twee stellingen.

Duid jouw voorkeuren m.b.t. de volgende stellingen aan op de onderstaande schalen door een kruisje te zetten op de lijn. Ga je meer akkoord met de stelling links, zet dan een kruisje aan de linkerkant van de lijn. Ga je meer akkoord met de stelling rechts, zet dan een kruisje aan de rechterkant. Hoe dichter het kruisje bij de stelling, hoe sterker je akkoord gaat.

Je mag de lijntjes onder elke vraag gebruiken om jouw antwoord toe te lichten, als je dat wenst.

Een voorbeeld:
Zelfstandig voor mezelf kunnen zorgen (bv. bij het ochtendtoilet) is voor mij…:

| Niet belangrijk. Anderen kunnen mij helpen. | |———————✖——| | Heel belangrijk. Ik hecht veel waarde aan mijn zelfstandigheid. |
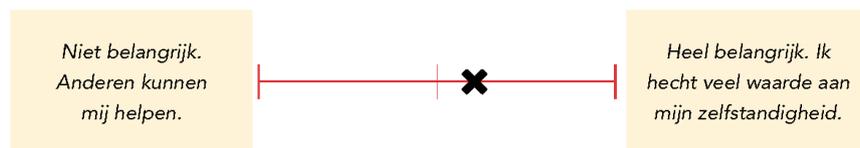
Mijn zelfstandigheid is voor mij belangrijk, maar als het niet anders kan, zal ik hulp vragen.
_____
_____

Geef bij de volgende vragen je eigen voorkeur aan:

Ik weet graag:

| Enkel het essentiële (minimum) over mijn diagnose en behandeling | |—————————| | Alle details over mijn diagnose en behandeling |

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_____
_____
_____

Tijdens mijn behandeling, wil ik graag:

| Dat mijn naasten niet op de hoogte zijn van mijn gezondheids-toestand (diagnose, prognose, behandelingen) | ⊢————┼————⊣ | Dat mijn naasten volledig op de hoogte zijn van mijn gezondheids-toestand (diagnose, prognose, behandelingen) |

_____

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_____

Tijdens mijn behandeling, wil ik graag:

| Dat dokters enkel informatie geven en aanbevelingen maken over behandelingen | ⊢————┼————⊣ | Dat dokters de uiteindelijke beslissing nemen over mijn behandeling |

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_____

_____

| Dat mijn familie geen inspraak heeft in beslissingen over mijn behandeling | ⊢————┼————⊣ | Dat mijn familie de uiteindelijke beslissing neemt over mijn behandeling |

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_____

7. Als je over jouw wensen zou willen praten, met wie zou je dit willen bespreken?
Je mag meerdere personen aanvinken.

☐ Mijn echtgenoot/partner
☐ Mijn zoon/dochter/kinderen
☐ Mijn ouders
☐ Mijn dokter/verpleging
☐ Mijn vriend(en):

_____

_____

☐ Iemand anders:

_____

_____

_____

8. Kan je aan iemand denken die in jouw plaats medische beslissingen zou mogen nemen, als je hier zelf niet meer toe in staat bent?
☐ Ja/misschien. Ik denk aan:

_____

_____

☐ Neen

Heb je nog andere gedachten, vragen, of zorgen over jouw huidige of toekomstige gezondheidszorg die je graag zou bespreken? Dan kan je deze hier noteren:

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Ik heb dit werkboekje besproken met:

NAAM	RELATIE MET DEZE PERSOON	DATUM

Appendix 2. ACP-GP Conversation Guide (translated from Dutch)

Improving advance care planning (ACP) in general practice: a randomized controlled trial study

Conversation Guide

This conversation guide aims to help you conduct conversations about **advance care planning (ACP)** with your patients.

It is aligned with the content of the workbook "My Wishes for Future Care", which the patient received in advance from you or from the research assistant.

It is <u>not</u> the intention that every question or theme from this guide must be addressed during every ACP conversation. The patient may indicate which theme is most important to them, or which questions they want to discuss. If the patient is unsure, then the structure of the workbook and guide may be used. The goal of the conversation is to learn more about the patient as a person: their worries, goals, and values, and not to immediately discuss specific clinical or end-of-life decisions (unless this is what the patient wishes).

Step 1: Preparation
It is advised to prepare the conversation with the patient. Below are a few questions to help you reflect or take preparatory action before the conversation. 1) Do you have all the necessary information? (Recent information about the medical condition? Is the patient aware of their diagnosis? Has the patient had previous conversations about advance care planning? Has the patient previously completed any advance directives? Do you have access to these? What is the content of the advance directives?) 2) Have you consulted with other health care practitioners? 3) Do you have information about which role the family or loved ones play in the patient's current care? 4) Have you planned for enough time to have the conversation with the patient (and the family or loved one, if present)?

Step 2: Introduce the topic	
Introduce the conversation: Listen to the patient's story. Encourage them to speak freely about their worries, wishes, and values. First, go over what the patient wants to talk about. Then, other themes can be explored.	• "A little while ago, you received a workbook with questions, for example about what is important to your quality of life and what your wishes are for your future care. You may have thought about that beforehand. Or maybe the workbook encouraged you to think about it." • "Would it be alright with you if we went over the workbook together today?" • "What was your impression of the workbook? Which topics were most important to you?" • Space for notes:

Step 3: The advance care planning conversation: themes	
Values, norms, and important aspects of quality of life It is useful to know what the patient finds important in life, so that this can be considered when health care decisions need to be made in the future.	• "What makes every day meaningful to you?" • "What does good health care mean to you?" • Space for notes:
Experiences with serious illness or death in the patient's close environment Experiences with serious illness or death can create an impression for the patient of which care they would or would not want, at the end of life. It can also indicate if the patient has any particular outlook or ideas around serious illness and death.	• "Do you have any experiences with serious illness or death of someone in your close environment?" • Space for notes:

Fears and worries regarding current and future health	• "When you think about your current or your future health, what worries you the most?" • Space for notes:
Trusted person and substitute decision maker The patient does not need to formally indicate someone as a legal substitute decision maker at this time. However, it can be useful to assess with whom the patient talk about their health, and to encourage the patient to reflect about who might be able to take on the role of trusted person or substitute decision maker. This person may be invited to be present during the next ACP conversation.	• "If you were to become seriously ill, and someone had to make a decision about your medical care in your place, whom would you trust to make this decision? What makes you choose this person?" • **If the patient has identified someone:** "Would it be alright with you if we invite this person to the next conversation?" • **If the patient is unsure**: "Before our next conversation, try to think about who might be able to decide in your place. You may want to speak to this person, or look over your workbook together with them." Follow-up questions: • "During our previous conversation, we talked about who might be able to decide about your care, if you're unable to make the decision yourself. Have you spoken to this person about it? How did they react?" • Space for notes:

Information preferences The scales in the workbook can be used to discuss these questions or add nuance.	• "To what extent would you like to inform your partner/family/loved ones about your health, and about future developments in your health and care?" • Space for notes:
Shared goals of care Wishes and values that are discussed can be the basis for shared decision-making with the patient about concrete goals of care.	• "Your health may change in the future. Sometimes, that also changes a person's wishes for their future care. In the past, you told me that (e.g., not being hospitalized) is important to you. Is that still the case?" • "Because (e.g., not being hospitalized) is important to you, I suggest that we (e.g., document this preference). This way, we can ensure that your treatment plan matches your wishes as closely as possible." • Space for notes:

Advance directives If the patient wants to document their wishes, it is important to clarify which advance directive documents are available, and how they differ from each other. It is also important to inform the trusted person or substitute decision maker, if present, about their role in this step.	• "Some people find it useful to complete one or more of these documents. You do not have to do this if you do not want to, and you do not need to rush to a decision." • Space for notes:

Step 4: Summarize, document, plan, and follow-up	
Summarize the conversation **Note wishes and preferences** • Patient medical record • Advance directive **Plan the next conversation** **Communicate to other health care practitioners**	• "So, what you've told me today is: (…) Do I have that right?" • "Today, we discussed (list themes from the conversation). Would it be alright with you if we talk further about (list themes, e.g. themes for which the patient did not have enough time, …) during one of our next conversations?" • "Is there anything else you would like to make sure I know?" • "Do you have any questions?" • "What did you think about this conversation? How did it come across to you?"

What if the patient does not wish to talk about ACP? The patient has the right to refuse to talk about ACP. You can, however, explore why this might be (e.g., is the workbook off-putting due to the amount of text? Is the timing inopportune?)	• Take some time to explore why the patient may not be open to talking about ACP. • Encourage the patient to talk to a trusted person or potential substitute decision maker. • During a later conversation, gently gauge the patient's readiness again.

Appendix 3. ACP-GP Conversation Flowchart (translated from Dutch)

Preparation:
Sufficient knowledge, appropriate setting, enough time?

YES

Introduce the conversation:
Contextualize conversation. Would patient like to discuss the workbook?

NO → Explore barriers.
Explore readiness again during future conversations.

YES

Ask open questions:
How did the patient experience the workbook? What was the most important part for them?

Possible themes (After open questions about most important themes, other themes can be discussed):

Patient asks information (e.g., about advance directives)	**Values and norms**	**Quality of life and health care**	**Experiences and worries**	**Information preferences**	**Determining goals of care**	**Substitute decision maker**	**Advance directives**
Provide information, go over documents together, give documents to take home	What makes the patient happy? How do they see quality of life?	What does the patient see as "good health care"?	What worries the patient regarding their health? What do they (not) want to happen?	How much does the patient want to know about their diagnosis, prognosis, ...?	Whom does the patient want to involve in decision making? Does the patient agree with the proposed care plan? Does the patient have a DNR?	Difference with a trusted person. Can the patient identify a substitute decision maker?	Provide information, go over documents. Inform substitute decision maker about their role

No → Encourage patient to think about who could be their substitute decision maker

Yes → Invite person to next conversation

Finishing the conversation:
Summarize; Check for further questions; Plan the next conversation

Document in patient medical file
Communicate with other health care practitioners

362

Appendix 4. ACP-GP Documentation Template (translated from Dutch)

Improving advance care planning (ACP) in general practice: a randomized controlled trial study

Document for reporting the ACP conversation

This template form was created to document the conversations you had with your patients about their answers to the workbook "My Wishes for Future Care", and more generally about themes related to advance care planning (ACP). The document follows the structure of the conversation guide you received during the training.

You can use this template during the conversation with your patient, by filling in their answers in the applicable sections, or you can fill in the document after the conversation is completed. We ask that you add a scanned version of this template to the patient's electronic medical record after you complete it.

This is not a legal document. If decisions must be made about the patient's health care needs, then the information in this document may be used by those who make the decision, in consultation with e.g., the treating physician, specialist care practitioner, and/or the substitute decision maker.

Patient name: ……………………………………………………………………

Patient date of birth: …../…../……..

Step 2: Introduce the topic	
Introduce the conversation: Is the patient open to the conversation? How does the patient react when the conversation is introduced?	

Step 3: The advance care planning conversation: themes	
Values, norms, and important aspects of quality of life	

Experiences with serious illness or death in the patient's close environment	
Fears and worries regarding current and future health	

Trusted person and substitute decision maker Does the patient have a substitute decision maker, or someone who may potentially serve as a substitute decision maker? Is this person present during the conversation, or does the patient agree with the suggestion to invite them to be present during the next conversation?	Has the patient designated a substitute decision maker? ☐ Yes ☐ No If "yes", indicate: Name of the substitute decision maker: ………………………………………………… Relationship of the substitute decision maker to the patient: .... Adress: ……………………………………………………………………....................... ……………………………………………………………………………....................... Telephone number: ………………………………………………………..
Information preferences	

Shared goals of care Which goals of care were agreed upon?	
Advance directives Has the patient completed an advance directive or have their wishes been otherwise documented? Do you have a record of these documents?	Has the patient previously completed an advance directive or other documents indicating their wishes for care? ☐ Yes ☐ No If "yes", please add the relevant documents to this form.

Step 4: Summary, documentation, planning, and follow-up	
Summary of the conversation **Note wishes and preferences** • Patient medical record • Advance directive **Planning for the next conversation** **Communication to other health care practitioners**	Next conversation planned for (date): ….../….../……..

What if the patient does not wish to talk about ACP? If the patient indicates not wanting to talk about ACP at the moment: which reasons does the patient provide?	

CURRICULUM VITAE

Julie Stevens was born November 7, 1992 in Bornem, Belgium. Julie graduated summa cum laude in 2014 as a Bachelor of Arts from Stetson University in Deland, Florida, where she majored in Psychology and German and minored in History. During her Bachelor's studies, she spent a semester abroad at the Pädagogische Hochschule in Freiburg, Germany, supported by a Baden-Württemberg Stipendium scholarship. In 2017 she graduated magna cum laude from Ghent University as a Master of Science in Clinical Psychology. In September of 2018, she joined the End-of-Life Care Research Group as a junior PhD researcher. Her advisory committee is composed of Prof. Koen Pardon, Prof. Aline De Vleminck, Prof. Luc Deliens, and Prof. Peter Pype. After her first year, she was granted a predoctoral fellowship in Fundamental Research from the Research Foundation Flanders (FWO). Her research focuses on Advance Care Planning in general practice. She also has a special interest in understanding the complexity of mechanisms and impact of ACP. For her doctoral research, she conducted a cluster-randomized controlled trial and process evaluation of a complex ACP intervention for patients with chronic, life-limiting illness in general practice (the ACP-GP intervention). In 2022, she obtained a grant from the VUB Doctoral Schools of Life Sciences and Medicine for a short study visit at the McMaster University Department of Family Medicine, Division of Palliative Care.

The findings of her doctoral research have been published in international, peer-reviewed journals, and disseminated through presentations at national and international conferences.

PUBLICATIONS IN PEER-REVIEWED JOURNALS

Stevens J, Scherrens A-L, Pype P, Deliens L, De Vleminck A * Pardon K. How Advance Care Planning (ACP-GP) was implemented in Belgian general practice in the context of a cluster RCT: a process evaluation using the RE-AIM framework. [Submitted manuscript]

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controlled trial in chronic life-limiting illness. *BMJ Supportive and Palliative Care.* 2022; 12**:** e460-e463. [2020 SCIE Impact Factor: 3.568; Journal ranking Q1; ranking n°35/107 in Health Care Sciences & Services.]

PRESENTATIONS AT (INTER)NATIONAL CONFERENCES AND SEMINARS

2023

Evaluation of a Complex Advance Care Planning Intervention for Patients with a Chronic, Life-limiting Illness in the General Practice Setting (ACP-GP): A Cluster-randomized Controlled Trial. 18th World Congress of the European Association for Palliative Care. Rotterdam, Netherlands. E-poster presentation.

Evaluation of a Complex Advance Care Planning Intervention in the General Practice Setting (ACP-GP): Cluster-randomized Controlled Trial. 8th International ACP-i Conference, Singapore. Oral presentation.

2022

Hoe werken complexe voorafgaande zorgplanningsinterventies voor patiënten met een chronische, levensbeperkende ziekte? Een scoping review (How do complex ACP interventions for patients with a chronic, life-limiting illness work? A scoping review). Nederlands-Vlaamse Wetenschapsdagen Palliatieve Zorg 2022, Tiel, Netherlands. Oral presentation.

Engagement in advance care planning (ACP) of patients with chronic, lifelimiting illness in the general practice setting: Baseline findings from a cluster-randomized controlled trial. 12th World Research Congress of the European Association for Palliative Care. E-poster presentation.

2021

Advance Care Planning. Huisartsenconferentie en Vakbeurs 2021 (General Practitioner Conference and Trade Fair 2021). Antwerp, Belgium. Oral presentation.

Webinar: Vroegtijdige zorgplanning - over het hoe en waarom (Advance care planning – about the "how" and "why"). Presentation for the Flemish GP organization Domus Medica.

2019

Verbeteren van bereidheid van patiënten om deel te nemen aan gesprekken over voorafgaande zorgplanning: een gerandomiseerde gecontroleerde studie in de huisartsenpraktijk (Improving readiness of patients to engage in conversations about advance

care planning: a randomized controlled trial in general practice. Nederlands-Vlaamse Wetenschapsdagen Palliatieve Zorg 2019, Antwerp, Belgium. <u>Poster presentation.</u>

Study protocol for a randomized controlled trial on the effectiveness of Advance Care Planning (ACP) in general practice. 7th Conference of the International Society of Advance Care Planning. Rotterdam, Netherlands. <u>Poster presentation</u>.