

Adapting, implementing and evaluating a navigation intervention for older people with cancer and their family caregivers in six countries in Europe: the Horizon Europe-funded EU NAVIGATE project

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Abstract

Background: Navigation interventions could support, educate and empower older people with cancer and/or their family caregivers by addressing barriers and ensuring timely access to needed services and resources throughout the continuum of supportive, palliative and end-of-life care.

Objectives: European Union (EU) NAVIGATE is an interdisciplinary and cross-country Horizon Europe-funded project (2022–2027) aiming to evaluate the effectiveness, cost-effectiveness and implementation of a navigation intervention for older people with cancer and their family caregivers in Europe. EU NAVIGATE aims to advance the evidence on cancer patient navigation in Europe.

Design: Adaptation, implementation and evaluation of a navigation intervention with an international pragmatic randomized controlled trial (RCT) and embedded mixed-method process evaluation at its core. A logic model guides dissemination and impact-generating strategies. EU NAVIGATE involves six experienced EU academic partners; one EU national cancer league with their affiliated academic partner; three EU dissemination partners; and a Canadian partner.

Methods: We adapted the Canadian Navigation: Connecting, Advocating, Resourcing, and Engaging (Nav-CARE[®]) volunteer programme to healthcare contexts in Belgium, Ireland, Italy, the Netherlands, Poland and Portugal following the new ADAPT guidance. Nav-CARE was developed over the past 15 years and supports people with declining health and their families to improve their quality of life and well-being, foster empowerment and facilitate timely and equitable access to healthcare and social services. In EU NAVIGATE, the navigation intervention is being provided by trained and mentored social workers in Poland and by trained and mentored volunteers in the other five countries. Via a pragmatic RCT with process evaluation, we implement and evaluate the navigation intervention to study its impact on older people with cancer and their family caregivers. We also aim to understand its cost-effectiveness, how to optimally implement it in different countries, and its differential effects in patient subgroups. We will also map existing cancer navigation interventions in Europe, the United States and Canada to position EU NAVIGATE within the field of navigation interventions worldwide.

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Conclusion: EU NAVIGATE aims to deliver high-quality evidence on a navigation intervention for older people with cancer in Europe and to develop practice and policy recommendations for sustainable implementation of navigation interventions in Europe and beyond.

Keywords: cancer, Horizon Europe, navigation intervention, older people, palliative care

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Introduction

Over the past centuries, one of the greatest achievements of our societies has been that many people live longer. This ageing of the population comes with many opportunities but also with considerable challenges; cancer in old age being one of these.^{1,2} Global annual cancer-related deaths are projected to reach 11.5 million in 2030, with the increase disproportionately affecting older people.^{3,4} Based on European Union (EU) estimates from 2020, 60% of new cancer diagnoses and 73% of cancer-related deaths occurred in people over 65 years old.⁵

Although older people with cancer are a diverse population, evidence suggests that cancer and cancer treatment affect them differently than their younger counterparts.⁶ Among older people, tumours are diagnosed at more advanced stages. Older people also often receive less oncological treatment.^{7–9} This highlights the need for and importance of supportive, palliative and end-of-life care throughout the trajectory of their disease. Supportive care in cancer is defined as the prevention and management of the adverse effects of cancer and its treatment, including the management of physical and psychological symptoms and side effects across the continuum of the cancer experience from diagnosis through treatment to post-treatment care. It aims to improve the quality of rehabilitation, secondary cancer prevention, survivorship and end-of-life care.¹⁰ Palliative care is defined as an approach that improves the quality of life of patients and families who are facing problems associated with life-threatening illness. It prevents and relieves suffering through early identification, correct assessment and treatment of pain and other physical, psychosocial or spiritual problems.¹¹

Next to the direct health impact of cancer, older patients are affected by serious late and long-term side effects of cancer treatments, many of which might worsen existing geriatric conditions, such as bone loss or cognitive problems. Many older

people with cancer are also affected by conditions for which age is the largest risk factor, such as multi-morbidities and frailty.^{12–16} Research among older people with cancer has shown potentially unmet physical and medical needs, as well as emotional, psychosocial and practical needs across their disease trajectory.^{13–15} Old age has been linked with higher risk of poverty, social isolation and minimal social support, which hinder the performance of activities of daily living and negatively affect their quality of life.^{6,17–20} Many countries offer an array of health, social and community care services to address the needs and concerns of older people and their family caregivers. Yet, these people are not always aware of these existing services and resources or are unable to access them timely.^{6,21,22} For many older people in high-income countries, it is often complex and difficult to navigate care and support services, as these services are usually highly fragmented. Moreover, older people with cancer access palliative care services late in their disease trajectory.^{9,22} At the same time, family caregivers of older people with cancer might experience a considerable burden that puts them at risk of physical and psychological distress, which needs to be addressed alongside the older person's needs.^{23,24} There is an urgent need for high-quality evidence-based and cost-effective interventions that could address the multidimensional needs of older people with cancer and their family caregivers across the continuum of supportive, palliative and end-of-life care,^{25,26} especially those of underserved subgroups, based on for example age or socio-economic status.²⁷

Navigation programmes are interventions that aim to support, educate and empower people, and in some cases also family caregivers. Navigation programmes that have so far been developed aim to address individual and community barriers to cancer-related diagnostics, treatment and care and to ensure timely access to needed services and resources.^{28–31} Their central component is a navigator, a dedicated person

with or without a health-related background, who engages with people on an individual basis.²⁹ While there may be overlap, navigation can be distinguished from care management and coordination, as navigation fulfils a much broader, more supportive role, grounded in frameworks of patient empowerment and health promotion.³⁰ Navigators are typically not a core care team member. Instead, they aim to support navigation across services and advocate for missing services, helping to remove barriers to care. This could facilitate timely and better access to high-quality and cost-effective supportive, palliative and end-of-life care for older people with cancer. Previous studies advocate that navigation interventions should be highly adaptable and should address the multi-faceted care and support needs of older people with cancer. This includes using any virtual communication platforms for difficult-to-reach populations, for example in rural areas or isolated people due to a pandemic.^{28,29} Several types of navigation programmes have been developed and evaluated in the past two decades, primarily in the United States and Canada.^{29–31} Existing scientific evidence suggests favourable feasibility and effectiveness, and promising results of cost-effectiveness for patient navigation in cancer care, specifically in the early phases of illness, that is, cancer screening, diagnosis and treatment.^{29–31} Evidence for its use and effectiveness in supportive, palliative and end-of-life care remains limited.²⁹

In EU NAVIGATE, we aim to adapt, implement and evaluate a Canadian navigation programme, called Nav-CARE[®], developed by Pesut and Duggleby, in six countries in the EU and evaluate its impact.^{21,32–34} Nav-CARE stands for ‘Navigation: Connecting, Advocating, Resourcing, and Engaging’. Nav-CARE is a person- and family-centred navigation intervention. This intervention uses volunteer navigators to collaborate with older people with declining health and their families to improve quality of life and well-being, foster empowerment and facilitate timely and equitable access to health and social care services and resources throughout the continuum of supportive, palliative and end-of-life care.³⁵ Nav-CARE aligns with the essence of a compassionate community or public health approach to palliative care; it focuses on providing needs-based volunteer support for the most vulnerable people in the community, promotes equity in access to palliative care across diverse populations, and views strategic partnerships with

communities and local services or resources, as an integral part of care and support for people approaching the end of life.^{33,36–38} Nav-CARE has been developed and tested over the past 15 years in different populations including those with advanced cancer and those living in rural Canadian areas.^{21,32–34,39–43} It is currently being implemented across different regions in Canada for older people with declining health, many of whom have cancer. Mixed-method evaluations of Nav-CARE showed its potential for enhancing social connection and support, assisting older people in navigating the social aspects of care, improving their awareness and access to available and cost-effective services and offering family respite from caregiving.²¹ Volunteer navigators reported that their involvement in Nav-CARE allowed them to engage in continuous learning and to have a meaningful and relational role with older people and their families. The older people and their families reported that a volunteer had a positive effect on their engagement and quality of life.²¹

The overarching aims of the EU NAVIGATE project are

1. To adapt the Canadian Nav-Care intervention to a NavCare-EU intervention to ensure contextual fit with health, social and community care contexts in Belgium, Ireland, Italy, the Netherlands, Poland and Portugal
2. To compare NavCare-EU in addition to usual care with usual care alone, in terms of its:
 - a. effectiveness on outcomes for older people with cancer and declining health (global health status/quality of life and levels of social support as co-primary outcomes), and on outcomes for family caregiver
 - b. cost-effectiveness
 - c. effects on different subgroups defined by characteristics known to affect health equity and equitable access, that is, gender, age, socio-economic status, extent of social support, living situation and geographical location
3. To evaluate the implementation processes of the NavCare-EU intervention and the feasibility of its integration into different healthcare systems and care regimens in Europe, the contextual barriers and facilitators for effective and sustainable

implementation, and the mechanisms involved in reaching the outcomes in each country, as perceived by older persons with cancer, family caregivers and care providers

4. To map and classify existing navigation services for people with cancer in Europe, United States and Canada
5. To develop evidence-based and multi-stakeholder-informed policy and practice recommendations for cancer navigation in Europe, with particular attention to older people, and ensure optimal communication, dissemination, exploitation and stakeholder engagement, and to achieve scientific, societal and economic impact during and beyond the project.

This article outlines the EU NAVIGATE project, its aims and core work packages (WPs), and the strategy envisioned to create an impact on science, society and economy. It aims to inspire researchers across the globe and particularly those aspiring to engage in future EU projects to better understand how to improve the lives of older people with declining health and their family caregivers across countries.

Methods

EU NAVIGATE aspires to realize its overarching aims through a work plan consisting of eight WPs (Figure 1). The core of the project is an international multisite pragmatic fast-track randomized controlled trial (RCT) that is implemented in six EU countries (Belgium, Ireland, Italy, the Netherlands, Poland and Portugal; 2022–2027). This trial will compare NavCare-EU in addition to usual care with usual care alone. After adaptation of NavCare-EU to the specific contexts of the six EU countries (WP2), we will conduct an RCT (WP3) as well as two additional sets of analyses of trial data: cost-effectiveness analyses (WP4) and subgroup and country comparative analyses (WP5). Throughout the trial, we perform a convergent mixed-method process evaluation (WP6). A mapping study of existing navigation services for people with cancer across Europe, United States and Canada will be conducted to position NavCare-EU within the wider field of patient navigation (WP7). In WP8, we will engage users and stakeholders during and after the project implementation. We also aim to achieve its expected outcomes and wider expected impacts via robust dissemination, exploitation

and communication activities. The project is guided by a logic model developed to support EU NAVIGATE's pathway to change to achieve impact, which is illustrated in Figure 2. The timeline of the project is illustrated in Figure 3. WP1 is implemented throughout the project and addresses project management, coordination, progress monitoring and data management. The project has a Management and Supervisory Board that is responsible for the overall execution of the project and for delivering the content needed for the reporting and fulfilment of the deliverables and milestones for the EU. The members of this board and the overview of the organizational structure of EU NAVIGATE are depicted in Figure 4.

The EU NAVIGATE consortium

To realize our overarching aims, we need interdisciplinary expertise; methodological experience with and capacity to conduct large-scale RCTs in supportive, palliative and end-of-life care; experience in navigation interventions; established ties between research and clinical practice; and the integration of the perspectives of scientific and civil society partners. Therefore, we brought together in the consortium: (1) six experienced academic partners from Belgium (Vrije Universiteit Brussel and Ghent University), Ireland (Trinity College Dublin), Poland (Jagiellonian University), the Netherlands (Amsterdam University Medical Centre), Portugal (University of Coimbra); (2) one national cancer league (Lega Italiana per La Lotta Contro I Tumori, LILT Milano Monza Brianza APS) with their affiliated academic partner (Fondazione IRCCS Istituto Nazionale Dei Tumori di Milano); (3) three EU dissemination partners (European Cancer Organisation, European Association of Palliative Care and AGE Platform Europe); and (4) the original developer of Nav-CARE from Canada (University of British Columbia). Funded by the EU's Horizon Europe project, the EU NAVIGATE consortium partners implement specific tasks within the different WPs to realize the objectives of the project. The NavCare-EU programme will be implemented in six EU countries via specific local implementation sites to be described further in this article.

A wide range of relevant disciplines and sectors are represented in the consortium. These include supportive, palliative and end-of-life care, oncology, psycho-oncology, geriatrics/ageing, gerontology,

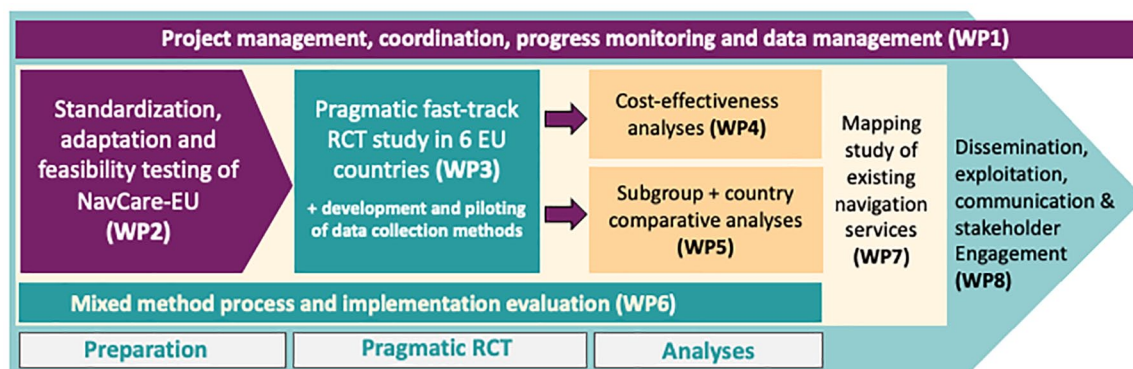


Figure 1. The EU NAVIGATE work packages.
EU, European Union.

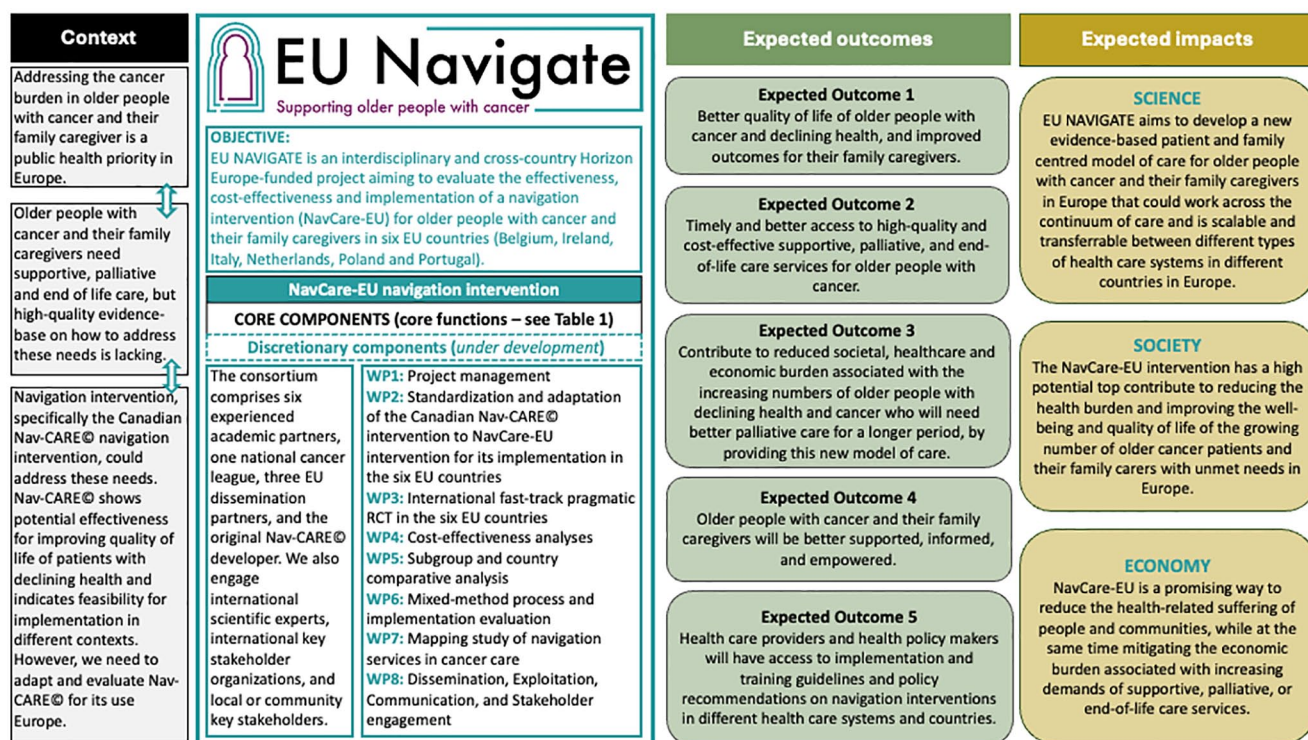


Figure 2. Logic model that outlines the EU NAVIGATE's pathway to change to achieve expected outcomes and expected impacts.
EU, European Union.

public health, nursing, primary care, community care, social care, volunteering, health economics, social sciences, humanities, ethics, implementation science, training and education. All academic RCT partners have rich methodological experience with and the capacity to conduct large-scale pragmatic RCTs. A crucial asset for the consortium is the partnership with Professors Pesut and Duggleby from Canada, the original developers of the Nav-CARE programme. The EU NAVIGATE project aims to bring about 15 years of knowledge,

expertise and experience from Canada to Europe adapting the Nav-CARE toolkit, instruments and materials as the core fundamentals of NavCare-EU. As the success and feasibility of EU NAVIGATE depend largely on the collaboration and ties with clinical centres and palliative care networks where cancer patients often receive care, all partners have been carefully selected based on such established ties, as at least one partner per country has a clinical or practicing organizational role in such settings. For this project, we also involve three

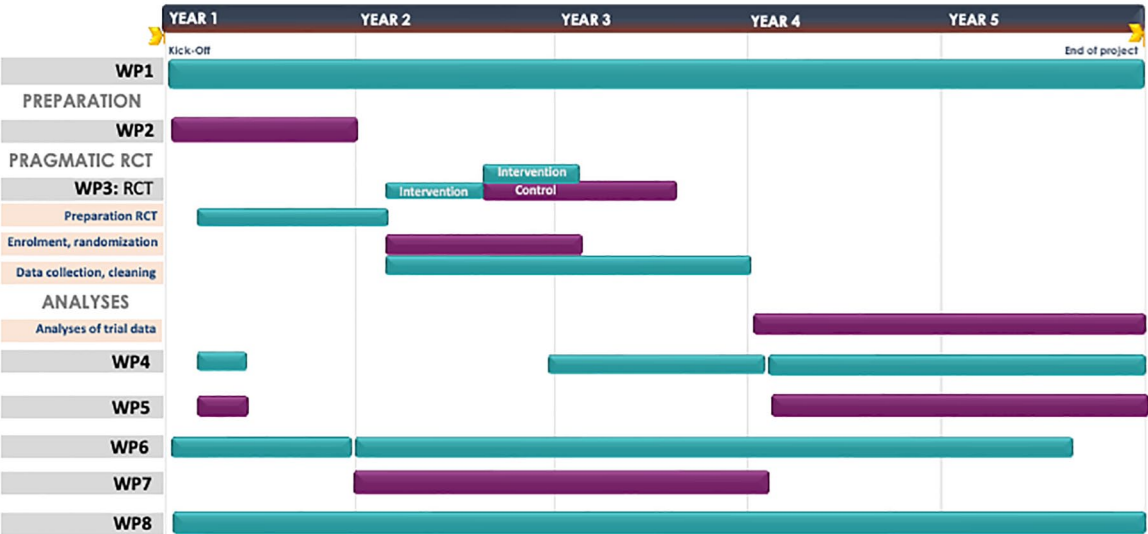


Figure 3. The EU NAVIGATE project timeline.
EU, European Union.

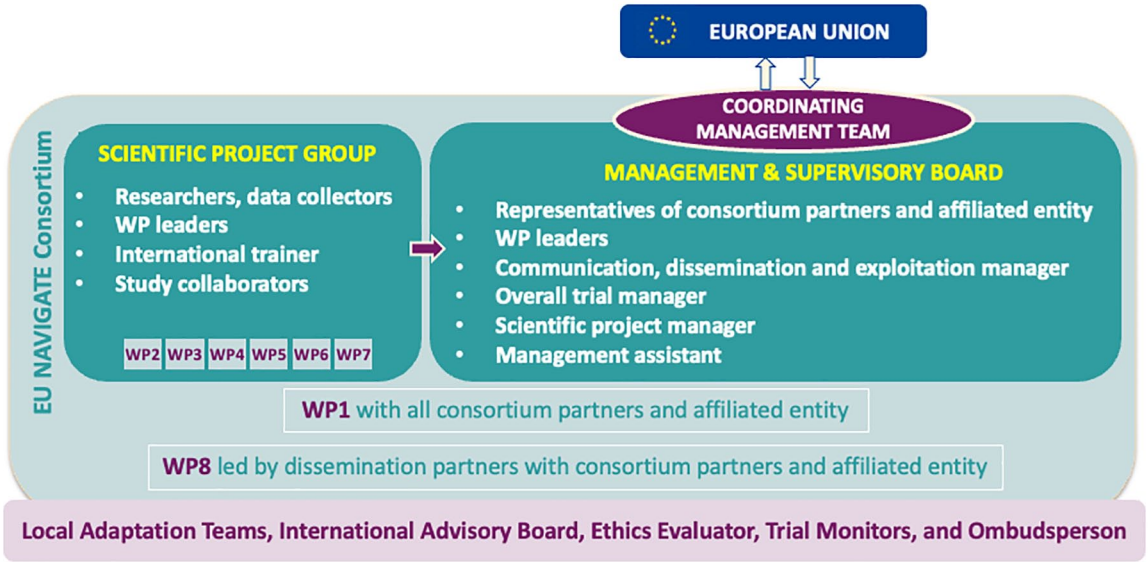


Figure 4. Organizational structure of EU NAVIGATE.
EU, European Union.

non-profit EU umbrella organizations or social actors in respectively cancer, palliative and end-of-life care and ageing as dissemination partners. These partners have active networks tapping into the most important patient and family representatives, professional groups and policymakers in the field through which project results will be disseminated. Bringing together academic partners and these organizations for both research and dissemination is expected to maximize the impact of the project.

Standardization, adaptation and feasibility testing of NavCare-EU (WP2)

In the first year of the project, the original Canadian Nav-Care intervention was translated and adapted to an EU version (called ‘NavCare-EU’), to ensure optimal fit with the EU countries’ contexts and the targeted population of older people with cancer and their family caregivers. We used the new ADAPT guidance for adaptation and re-evaluation of complex interventions in new contexts.⁴⁴ As several contextual factors

(i.e. healthcare systems, legal frameworks, socio-cultural customs) in the different European countries differ from those in Canada, this adaptation phase was essential to ensure good implementation and evaluation in all new contexts.

The principal aim of the adaptation was to clearly outline the core and discretionary components of Nav-CARE and to ensure functional integrity, which means that the core functions and processes ('core components') would be maintained when adapting to the EU contexts. The NavCare-EU adaptation process was set up as a research-practice collaboration, engaging representatives of different stakeholder groups in Local Adaptation Teams, including patients and/or their close family caregivers. The involvement of key stakeholders in the project ensures that their perspectives are considered in the development of NavCare-EU. An International Adaptation Oversight Group consisting of the Canadian team, the coordinator and WP lead, was installed to ensure the functional integrity of the programme would be maintained, to monitor local adaptations to only concerned discretionary components, and to address all questions of local implementation sites. Detailed information on the standardization, adaptation and feasibility testing of NavCare-EU can be found elsewhere.⁴⁵

To support the implementation of NavCare-EU in the six countries, country trainers were appointed and trained (for 1 week) by the international trainers of EU NAVIGATE from the Canadian and Belgian partners. The international trainers will mentor and coach the country trainers on a regular basis throughout the implementation, help them implement the intervention in their specific healthcare contexts, and help address barriers and facilitators. The country trainers also provide training, coaching and mentoring to the local navigator coordinators and to the navigators (via training, regular check-ins, mentoring sessions and engagement sessions) in collaboration with the navigator coordinators. The navigator coordinators are responsible for matching clients to navigators, championing the intervention, networking and mapping resources in their community, and building community partnerships. The training of navigators and navigator coordinators is competency-based and uses a Train-the-Trainer approach. Table 1 explains and visualizes the NavCare-EU core intervention components structured according to the Template for Intervention Description and Replication (TIDier) checklist.^{45,46} As of the

moment, the list of discretionary components is under development.⁴⁵

The EU NAVIGATE pragmatic fast-track RCT study in six EU countries (WP3)

As of 24 July 2024, EU NAVIGATE is conducting an international six-country multisite pragmatic fast-track RCT with an embedded process evaluation to compare the EU NAVIGATE intervention plus usual care to usual care alone. Usual care is different between the participating countries, and we will correct for this difference in the data analyses. RCTs have been conceptualized on a continuum from more explanatory (efficacy trials, asking 'can this intervention work under ideal conditions?') to more pragmatic (effectiveness trials, asking 'can this intervention work under usual conditions?').^{47,48} While explanatory trials serve to confirm a physiological or clinical hypothesis, the purpose of pragmatic trials is to inform a clinical or policy decision by providing evidence for adoption of the intervention into real-world clinical practice.⁴⁷ To design this trial, we have used the Pragmatic Explanatory Continuum Indicator Summary (PRECIS-2) guidance for designing clinical pragmatic trials. The PRECIS-2 guidance is a tool containing nine domains that reflect trial design decisions, in terms of for instance eligibility, recruitment or setting. Each domain determines the trial's position on the continuum, from a score of 1 (very explanatory) to 5 (very pragmatic).⁴⁸ In comparison to explanatory trials, the pragmatic approach allows us to mimic conditions in real-world practice for the implementation of the trial. Examples include the formulation of the eligibility criteria to include individuals who would typically use the intervention if it was implemented in real practice, or the flexibility with recruitment settings to allow participant recruitment from a range of settings, where older people with cancer typically receive care.

Fast-track RCTs have previously been developed and utilized in palliative care research.⁴⁹ These involve comparing an intervention group against a control group until the primary endpoint is measured. In our study, this measurement occurs at 24 weeks. After this initial period, the control group is also offered the intervention. The fast-track design is derived from a 'wait-list' design or deferred entry trial. However, it is called fast-track, because patients are not placed on waiting lists, as the service is typically not offered to them at all. One significant advantage of fast-track RCTs is that it

Table 1. The NavCare-EU navigation intervention core components⁴⁵ and its implementation in practice.

Core components	What	To collaborate with patients, families and communities, to connect them to appropriate resources, information and others, to promote quality of life, support independence and facilitate community connections. NavCare-EU could facilitate the access of older people with cancer and their family caregivers to services throughout the continuum of supportive, palliative and end-of-life care. Navigators focus on: <ol style="list-style-type: none">1. Connecting clients to social supports, both formal and informal2. Advocating for clients in meeting their quality-of-life goals3. Resourcing by identifying needs and negotiating access to meeting those needs4. Engaging clients in what is most meaningful to them.
	Who	Navigators who are trained, mentored and experienced (volunteers or professionals) to deliver the intervention. Navigators are supported by a Navigator Coordinator and a trainer (who is supported by an International Training Group). Navigators and coordinators are embedded within local organizations and supported by community stakeholders.
	How	<p>Navigators provide face-to-face and/or telephone or IT-supported contact with clients and family carers, with no cost involved for clients. <i>Local Navigator Coordinators</i> are responsible for ongoing support and mentorship of navigators (via regular check-ins, mentoring sessions, engagement sessions), with the support of a country trainer. Also responsible for matching clients to navigators, championing the intervention, networking and mapping resources in their community, and building community partnerships.</p> <p><i>Country trainers</i>, supported by the International Training Group, provide training, coaching, mentoring to navigation coordinators and navigators following the train-the-trainer model. <i>All intervention personnel are supported by standardize, translated and culturally adapted training and implementation materials and tools (NavCare-EU toolkit).</i></p>
		<pre>graph TD CR((Community resources)) --- CF((Clients/family)) HSS((Health and social services)) --- CF CF --- NAV(navigators) NAV --- LNC(Local navigator coordinator) LNC --- CT[Country trainer supported by International Training Group] CT --- LO[Local organization supported by community stakeholders]</pre>
	When and how much	Navigators operate: <ol style="list-style-type: none">1. Pro-actively and responsively2. Every 2 weeks or as needed3. In principle until death and into bereavement (1 year – for purpose of the trial)4. Goal-oriented, and not time-oriented.
EU, European Union.		

offers all eligible participants the opportunity to receive the intervention, while still maintaining the rigour of an RCT. This design helps mitigate potential reluctance of health care providers, patients or families to participate in trials, where there is a possibility to be randomized to a control group that does not receive the service. It can be used with patients with varying survival periods, whether longer or shorter (i.e. several weeks).^{49,50}

Across countries, we aim to enrol 489 older persons with cancer and declining health as well as

their close family caregivers (if they are present) into the trial over a 1-year period. Participants are being randomized to either the intervention arm (immediate start of the navigation programme in addition to usual care) or the control arm (delayed start after 24 weeks and usual care until then). We determine whether a patient has declining health using the Clinical Frailty Scale (CFS). CFS was designed to summarize the overall level of fitness or frailty of an older adult. Declining health means at least 1 change in CFS score ending in score 4 in the last 6 months, or everyone scoring 5

or higher.⁵¹ Close family caregivers should for example either live with the older person with cancer or provide care at least on a weekly basis; and be identified as the primary caregiver. Participants in both arms will receive navigation for 1 year. The primary endpoint is the difference in the change from baseline in the primary outcomes at 24 weeks between groups (intervention and control). We will continue measurements beyond the primary endpoint and until the end of the intervention period in both groups, as this will provide important additional longer-term insights.

The co-primary outcomes are the global health status/quality of life (assessed on a two-item scale from the EORTC Core Quality-of-Life questionnaire – EORTC-QLQ-C30 revised) and the level of social support of the older person with cancer (assessed using the Medical Outcomes Study Social Support Survey).^{52,53} Secondary outcomes are feeling of loneliness of the older person with cancer and family caregiver burden. Several exploratory outcomes at the level of the older person and his/her close family caregiver are evaluated including health and social care service and resource use. We performed a small-scale pilot testing of the research procedures and data collection materials with older people and older people with cancer to optimize the feasibility of the study and solve any issue that might arise during the implementation. Data collection is guided by a quality assurance manual and monitored continuously. The trial protocol was publicly registered on clinicaltrials.gov (identifier NCT06110312) and obtained ethical approval from all RCT partners. Further details of the trial, such as the definitions of declining health or care-as-usual, the inclusion and exclusion criteria for older people with cancer and their family caregivers, are included in a separate trial protocol article.⁵⁴

Cost-effectiveness analyses (WP4)

It is important that any changes in primary outcome represent a good use of scarce resources for health systems, patient and family advocacy organizations and other stakeholders. We will therefore evaluate the effect of NavCare-EU on healthcare use and costs, and on unpaid family care. We combine these data with quality-of-life measures to estimate the impact of the programme in a cost-effectiveness ratio. These data are collected as part of the trial and occur concurrently with the baseline and follow-up measurements.

Subgroup and country comparative analyses (WP5)

Data from the effectiveness trial and process evaluation will be used for subgroup analyses. Examining differential effects is important, as navigation challenges and benefits may differ among subgroups of people that is people with varying literacy levels, income or living conditions and other characteristics that are known to be significant in explaining access to healthcare.

Therefore, we aim to find out ‘what works best for whom’. We aim to (1) understand the variability in the experiences and effects of the intervention in subgroups defined by characteristics known to affect health equity and equitable access to care by older people with cancer; (2) examine the variability in the experiences and effects in relation to key intervention elements; and (3) explore cross-country variability in experiences and effects, to understand the impact of the intervention in different health and social care systems, care regimens and cultures of navigation work. In preparation for the subgroup analyses, a systematic review aiming to identify factors that influence the effectiveness of patient navigation programmes on patient-reported outcomes for adults with cancer has started. The protocol of the systematic review (ID 541627) is available in PROSPERO – International Prospective Register of Systematic Reviews.⁵⁵

The mixed-method process and implementation evaluation (WP6)

To assess the implementation of NavCare-EU, we also conduct a mixed-method process evaluation guided by the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) and the PRISM (Practical Implication Sustainability Model) framework, which are complementary implementation science frameworks.^{56,57} The process evaluation will examine the contextual barriers and facilitators for implementation, and the mechanisms involved in reaching the intended outcomes in each country, as perceived by the users and providers of the navigation programme as well as the involved stakeholders. This is key to evaluating complex interventions, as it will provide insights into how the navigation programme is implemented in each country and how it ‘works’ in the real-world context. The use of PRISM in combination with RE-AIM will allow us to better assess multi-level contextual factors to help plan, implement, evaluate and

disseminate the NavCare-EU intervention. RE-AIM and PRISM are also an integrated framework developed specifically to improve the adoption and sustainable implementation of evidence-based interventions in a wide range of settings, such as health, public health and community settings, which are highly applicable for this project. PRISM expands the RE-AIM framework to identify contextual factors. RE-AIM constructs concentrate on the outcome measures.^{57,58} We will use a convergent mixed-methods design to integrate quantitative and qualitative data, collected throughout and after the intervention delivery in each country, via diaries, surveys and group and individual interviews.

Mapping study of existing navigation interventions in cancer care (WP7)

WP7 aims to map existing navigation services and the potential and need for navigation by adults with cancer and their families in Europe and beyond. This mapping study aims to investigate: (1) existing navigation structures or services for adult cancer patients in their country, and their funding and regulatory contexts; (2) potential barriers and opportunities for the involvement of navigators at different levels; and (3) examples of current navigation practices and innovative approaches and their evidence base.

The mapping study will include countries affiliated with the European Association for Palliative Care but also programmes from the United States and Canada where navigation is an established practice. Country representatives will be identified and asked to provide input and gather useful materials from relevant stakeholders. With this mapping work, we will be able to position EU NAVIGATE within the field of navigation interventions worldwide and serve as important background information for creating practice and policy recommendations for impact beyond the projects' lifetime and the countries participating in the project. As a preparatory work for this mapping study, a scoping review of existing navigation services for people with cancer is planned and registered in the Open Science Framework.⁵⁹

Dissemination, exploitation, communication and stakeholder engagement (WP8)

EU NAVIGATE is devoted to engaging the public, patients and other stakeholders during the

implementation and post-implementation phases of the project and to ensure that the project meets the expected outcomes and impact through robust communication, dissemination and exploitation activities (Table 2). Via a stakeholder analysis, we identified the main target groups that may benefit from our project: (1) older people with cancer and their family caregivers, (2) patient and family advocacy organizations and charities, (3) health, social, community and voluntary organizations and providers, (4) researchers and service evaluators, (5) policy makers and decision-makers at national, regional and EU level and (6) communities and the wider society.

To generate impact, we aim (1) to involve and engage the target stakeholders through social innovation approaches throughout the development, implementation, evaluation and dissemination phases of the project; (2) to link with, cooperate and participate in networking and joint activities with other EU-funded projects to reach joint maximum societal, scientific and economic impact for cancer patients; (3) to develop evidence-based and multi-stakeholder informed policy recommendations regarding cancer navigation in Europe, with particular attention to and involvement of older people and/or their family caregivers; (4) to develop evidence-based recommendations for implementation of navigation beyond the trial context; and (5) to ensure the uptake, diffusion, deployment and/or use of the project's results by direct target groups.

The International Advisory Board. The International Advisory Board (IAB) is consulted annually concerning the project's aims, results and impacts. The IAB comprises 10 renowned international organizations related to integrated care, palliative care, clinical oncology, general practitioners, geriatric oncology, geriatric medicine, oncology nursing, supportive care in cancer, family or informal caregivers and quality-of-life improvement; and 4 scientific experts, including 2 scientists from Australia (navigation intervention in cancer), United Kingdom (palliative care) and the United States (nursing and navigation intervention) and 1 expert senior consultant in healthy ageing, offering technical and strategic advice to different entities to help improve the lives of older people, their families and communities.⁶⁰ In addition to the professional network of the EU NAVIGATE consortium, the international organizations and experts comprising the IAB have active

Table 2. Dissemination, exploitation, communication and user and stakeholder engagement.

WP8 strategies	Descriptions of the WP8 strategies
Communication strategies	<ul style="list-style-type: none"> - Well-coordinated communication team, periodic newsletter, social media channels, policy recommendations and other communication activities, for example, international and national press releases, project promotion, stakeholder participatory approaches (e.g. stakeholder forum for the project organized by the European Cancer Organisation),⁵⁶ social media posts, interviews in local media and Science Open Days. - EU NAVIGATE website (https://eunavigate.com/),⁵⁷ including the Online EU NAVIGATE platform, where all project outputs will be centralized and disseminated open access. - Local websites in country languages.
Dissemination strategies to ensure the transfer of knowledge and results to all target groups	<ul style="list-style-type: none"> - PhD dissertations, publications in international and national journals, oral and poster contributions to international conferences related to the fields covered by EU NAVIGATE, and interactions with scientific stakeholders through active contributions at international conferences, own organized events and EU-funded project joint activities. - International conference at the end of the project.
Exploitation strategies focusing on the societal level and will allow us to boost the use of project results for optimizing practice and for future research	<p>Open access strategies:</p> <ul style="list-style-type: none"> • publication of scientific articles in open access, green and gold international journals and in national topic specific journals, and we will explore the possibility of using preprints • The NavCare-EU intervention toolkit, and implementation and policy recommendations will be made available in the Online EU NAVIGATE Platform under Creative Commons licences. This guarantees that our work remains copyrighted while users will be allowed to copy, share and reuse the work under limited restrictions. Users that want to implement NavCare-EU in their organization will be asked to sign a Memorandum of Understanding with the consortium agreeing that the materials cannot be used for-profit, and adaptations do not compromise the functional integrity of the intervention • the other forms of intellectual property will be detected during the project and given best chances for being maximally used. <p>Scaling-up strategies:</p> <ol style="list-style-type: none"> 1. identification of how to scale-up the training, for example, handling the training as a service 2. identification of who can scale-up, for example, licencing the training package to one of the consortium members; licencing the training package to partners currently not member of the project consortium; creating a start-up through the consortium 3. the scaling-up itself: based on the outcome of the previous steps and activities, the exploitation manager will, with the support of the Tech Transfer Offices, steer the results towards a business model.
User and stakeholder engagement strategies This is a task shared by all consortium partners	<ul style="list-style-type: none"> - The dissemination partners connect with a diverse network of member organizations and target groups (regional, national, European and international level). - All other partners have local and international networks to the target audiences, and they work as amplifiers to help EU Navigate expand the project outreach. - All RCT partners set up local stakeholder groups involving representatives of each target groups in our activities. - All partners tap into their most relevant networks to identify and involve Country Experts for the mapping study. - We also set up an IAB explained earlier.
EU, European Union; IAB, International Advisory Board; RCT, randomized controlled trial; WP, work package.	

networks that also tap into the most important target groups of EU NAVIGATE. The involvement of the IAB in the project thus further facilitates and strengthens the uptake, diffusion, deployment and use of project results by the target groups globally.

Discussion

EU NAVIGATE'S generation of impact

Overall, EU NAVIGATE's impact-generating strategy is guided by a logic model (Figure 2) which illustrates the pathway to change to achieve

its expected outcomes and wider expected impacts as explained in Figure 2. The logic model shows the specific context wherein EU NAVIGATE is situated, the project characteristics combined with the NavCare-EU intervention components, the expected outcomes we aim to achieve by the end of the project and on the way to the longer term, and the expected scientific, societal and economic impacts on a wider European and international scale, which will go beyond the project's lifetime. As such, the logic model in Figure 2 displays our pathway to change.

Five expected outcomes of EU NAVIGATE

Expected outcome 1. Better quality of life of older people with cancer and declining health, and improved outcomes for their family caregivers. EU NAVIGATE aims to deliver NavCare-EU, a holistic, person-centred and multidisciplinary approach to cancer care. Navigators are trained to promote quality of life, foster empowerment and remove barriers to health, social and community care/resources. They ask the question 'What is most important to you today?' and work alongside people and their caregivers to help them accomplish that.

Expected outcome 2. Timely and better access to high-quality and cost-effective supportive, palliative and end-of-life care services for older people with cancer. Reducing barriers and increasing access is a core component of this navigation intervention. Navigators support people across the cancer trajectory, alongside curative, life-prolonging and palliative care, into bereavement. As older people currently have late or less access to palliative care compared to their younger counterparts, navigators can refer people to palliative care timely and when needed.

Expected outcome 3. Contribute to reduced societal, healthcare and economic burden associated with the increasing numbers of older people with declining health and cancer who will need better palliative care for a longer period, by providing this new model of care. Although it is important to recognize that the ageing of the population is one of the greatest achievements in health over the past decades, and many older people live longer in good health, the ageing of populations also brings challenges with regard to sustainable health care delivery for the growing population of people with complex care needs. Navigation is a promising approach to ensure people receive the

right type of support or care they need, at the right time and place.

Expected outcome 4. Older people with cancer and their family caregivers will be better supported, informed and empowered. Navigation seeks to connect people to social supports, both formal and informal. It advocates for people to meet their quality-of-life goals, to find resources by identifying needs and negotiating access to meeting those needs, and to engage people in what is most meaningful to them.

Expected outcome 5. Health care providers and health policy makers will have access to implementation and training guidelines and policy recommendations on navigation interventions in different healthcare systems and countries. EU NAVIGATE will develop an evidence-based NavCare-EU intervention toolkit and evidence-based recommendations for the implementation of navigation in different health care systems and countries. This will include standards for training and competences of navigators and navigator coordinators, and evidence- and multi-stakeholder-informed policy recommendations.

Expected wider scientific, societal and economic impacts of EU NAVIGATE

Through our combined efforts geared towards achieving our expected outcomes, EU NAVIGATE aims to contribute to the wider expected scientific, societal and economic impacts, as identified by the European Commission. For scientific impact, EU NAVIGATE aims to develop a new evidence-based patient and family-centred model of care for older people with cancer and their family caregivers in Europe that could work across the continuum of care and is scalable and transferrable between different types of health care systems in different countries in Europe. Through this scientific contribution, EU NAVIGATE has a high potential to contribute to reducing the health burden and improving the well-being and quality of life of the growing number of older patients with cancer and their family caregivers with unmet needs in Europe. EU NAVIGATE aims to contribute to an equitable healthcare system and to creating a more inclusive society, as it aims to reach older people with cancer including more vulnerable and underserved groups, which could facilitate equal access to the service for all older persons with cancer in need of support. If

NavCare-EU is shown to reduce the use of unnecessary healthcare services while improving patient and caregiver outcomes, then it can contribute to supporting the long-term sustainability and resilience of health systems in Europe. Hence, NavCare-EU is a promising way to reduce the health-related suffering of people and communities and to mitigate economic burden associated with the increasing demands of supportive, palliative and end-of-life care services.

Conclusion

EU NAVIGATE aims to deliver high-quality evidence on the effectiveness and cost-effectiveness of a navigation programme in Europe. Furthermore, it aims to develop evidence-, and multi-stakeholder-informed practice and policy recommendations to promote navigation intervention's sustainable implementation for older people with cancer and their family caregivers in Europe and beyond.

Declarations

Ethics approval and consent to participate

Ethics approval from the relevant ethics committees were obtained in Belgium, Ireland, Italy, the Netherlands, Poland and Portugal. Belgium: Commissie Medische Ethiek, 9 August 2023; Ireland: SJH/TUH Joint Research Ethics Committee, 14 November 2023; Italy: Comitato Etico Territoriale Lombardia 4, Istituto Tumori, 31 July 2023; the Netherlands: METC Amsterdam UMC, 22 August 2023; Portugal: Ethics Committee of the Faculty of Medicine of the University of Coimbra and Ethics Committee of the Portuguese Institute of Oncology of Coimbra Francisco Gentil, 25 September 2023; Poland: Komisja Bioetyczna, Uniwersytetu Jagiellońskiego, 14 June 2023. If a potential participant meets eligibility criteria, the researcher or research assistant will obtain informed consent from both the older person and the close family caregiver (if there is one). We will give the older person and family caregivers the time they would like to consider participation. We will also assure them that they are free to withdraw their participation without any effect on their care. We will obtain written consent without any coercion of study participants. The nature and goal of the study will be fully disclosed to all participants by the research team.

Consent for publication

Not applicable.

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Competing interests

The authors declare that there is no conflict of interest.

Availability of data and materials

More information about EU Navigate can be found at CORDIS services with DOI (<https://cordis.europa.eu/project/id/101057361>) and the EU Navigate website (www.eunavigate.com).

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