

Methods and Methodology

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Systematic adaptation of public health palliative care interventions across settings using ADAPT guidance: Methodological learnings from the EU NAVIGATE project

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Fien Van Campe^{1,2,3}, Kenneth Chambaere^{1,3}, Lara Pivodic^{1,2}, Joni Gilissen^{1,2,3,4}, Barb Pesut⁵, Wendy Duggleby⁶, Tinne Smets^{1,2}, Katarzyna Szczerbińska⁷, Maja Furlan de Brito^{8,9}, Andrew Davies¹⁰, Davide Ferraris¹¹, Annicka van der Plas¹², Bianca Scacciati¹³, On Behalf of EU NAVIGATE* and Lieve Van den Block^{1,2}

Abstract

Background: Systematic adaptation of evidence-informed interventions is critical for effective transfer across settings. Public health palliative care interventions pose unique challenges because of their complexity and embedding in dynamic, real-life settings. The ADAPT guidance provides a comprehensive framework for systematically adapting evidence-informed health interventions, yet its application in public health palliative care remains unexplored.

Aim: Within the EU NAVIGATE project, this study describes the international adaptation process of a Canadian navigation program supporting older people with cancer experiencing declining health, for implementation in six European countries. It also reflects on the methodological insights gained from applying the ADAPT guidance in public health palliative care.

Design: Using an iterative five-stage multi-method approach, we followed the ADAPT guidance and its recommended frameworks. Stage 1 assessed context-intervention fit and identified core and adaptable components of the original intervention. Stage 2 adapted implementation materials, while stage 3 involved a contextual analysis. Stage 4 focused on adapting the training for implementers, and stage 5 reviewed feasibility.

Results: The ADAPT guidance proved flexible and useful, though systematic adaptation posed challenges due to the unique complexities of public health palliative care interventions. These included balancing intervention integrity with cultural sensitivities and local

Corresponding author:

Fien Van Campe, End-of-Life Care Research Group, Universiteit Gent, Corneel Heymanslaan 10, Ghent 9000, Belgium. Email: Fien.van.campe@vub.be

¹End-of-Life Care Research Group, Vrije Universiteit Brussel & Universiteit Gent, Brussels, Belgium

²Department of Family Medicine and Chronic Care, Vrije Universiteit Brussel, Brussels, Belgium

³Department of Public Health and Primary Care, Universiteit Gent, Ghent, Belgium

⁴Research Centre Care in Connection, Department Nursing and Midwifery, Karel de Grote University of Applied Sciences and Arts, Antwerp, Belgium

⁵University of British Columbia Okanagan, Kelowna, BC, Canada

⁶Faculty of Nursing, University of Alberta, Edmonton, AB, Canada ⁷Laboratory for Research on Aging Society, Chair of Epidemiology and

⁷Laboratory for Research on Aging Society, Chair of Epidemiology and Preventive Medicine, Medical Faculty, Jagiellonian University Medical College, Krakow, Poland

⁸Faculty of Medicine, University of Coimbra, Coimbra, Portugal

⁹Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation, King's College London, London, UK

¹⁰Trinity College Dublin, Dublin, Ireland

¹¹Lega Italiana per la lotta contro i tumori di Milano, LILT Milano Monza Brianza, Milano, Italy

¹²Amsterdam UMC, Vrije Universiteit Amsterdam, Department of Public and Occupational Health, Expertise Center for Palliative Care Amsterdam UMC, Amsterdam, The Netherlands

¹³Fondazione IRCCS Istituto Nazionale dei Tumori, INT, Milano, Italy

^{*}EU NAVIGATE Collaborative Author List: S Alfieri, K Ashford, I Barańska, I Beijer Veenman, I Correia, L Decoster, N Drapała, H Du Cheyne, C Dupont, M Filipińska, L Gangeri, M Gandelli, B Gomes, S Hearne, A Lavan, P May, M McDonnell, R Miranda, E Naert, B Onwuteaka-Philipsen, R Pasman, G Purveen, V Rodrigues, L Rosquin, S Silva, K Słaby, HE Statema, N Van Den Noortgate, C Vinckier, and A Ziuziakowska

juridical regulations regarding end of life. Our process addressed these challenges through contextual assessments, identifying core components, engaging with original developers, and collaboration between local and international adaptation teams.

Conclusions: A systematic adaptation process, guided by the ADAPT guidance is feasible, but transferring public health palliative care interventions requires careful methodological, contextual, and conceptual considerations.

Keywords

Implementation science, palliative care, public health, intervention study, adaptation, international

What is already known about the topic

- Systematic adaptation can improve context-intervention-fit when transferring evidence-based population health interventions across settings. This enhances their adoption, implementation, effectiveness, and sustainability.
- Adapting public health palliative care interventions to new (international) settings is especially challenging, as they operate at the community level, where complexity arises from several factors, including their multiple components, implementation in large scale environments, and the unpredictability and variability inherent to real-life settings. Furthermore, cultural sensitivities around serious illness and palliative care play a critical role in shaping the delivery and reception of interventions.
- The ADAPT guidance provides evidence and consensus-informed guidance for systematically adapting and transferring evidence-informed population health interventions to new settings, but research demonstrating how it can be practically applied by researchers in the context of public health palliative care interventions is scarce.

What this paper adds?

- In addition to the ADAPT guidance, we found that¹ conducting thorough contextual assessments,² identification of the intervention's core functional components to maintain its integrity,³ engaging with original developers, and⁴ involving both local and international adaptation teams throughout the process greatly facilitated the adaptation of our public health palliative care intervention.
- Key challenges included balancing intervention integrity with local adaptation needs, managing the adaptation process across international settings, and estimating the consequences of adaptations before implementation.

Implications for practice, theory, or policy

- Future research on the systematic adaptation of public health palliative care interventions should focus on investigating how adaptations influence implementation processes and outcomes.
- Systematic adaptation can be highly beneficial to incorporate as an implementation strategy in implementation frameworks to enhance the adoption, effectiveness, and sustainability of public health palliative care interventions.

Background

The systematic adaptation of evidence-based interventions is increasingly recognized as essential for effective transfer across different settings or populations. This article considers systematic adaptation as to improve the intervention-context fit while maintaining the intervention's integrity. Tailoring interventions to align with the unique contextual characteristics of the implementation setting can improve their fit and potential impact. Contextual differences between the original and new settings can significantly influence intervention outcomes, and replicating interventions without thorough adaptation often fails to achieve comparable or sustainable results. These challenges are especially pronounced in public health palliative care interventions, which are

inherently complex and deeply embedded in real-life settings. 4-6 Unlike interventions implemented in more controlled environments, such as hospitals, public health palliative care interventions operate at the community level, where complexity arises from several factors, including their multiple components, 5,7 implementation in large scale environments like communities or cities, and the unpredictability and variability inherent to real-life settings. 8,9 Furthermore, cultural sensitivities around serious illness and palliative care play a critical role in shaping the delivery and reception of interventions, and can vary widely between countries and settings, requiring careful adaptation to respect local values, beliefs, and practices while maintaining the integrity of the intervention.

Given the growing recognition of these challenges, a variety of theories, frameworks, guidelines, and tools

Box 1. Description of the Nav-CARE© intervention.

The Canadian Nav-CARE© program is a prime example of a promising, evidence-based public health palliative care intervention that addresses the needs of older people experiencing declining health. It is a navigation intervention, developed over the past 15 years, in which specially trained volunteer-navigators visit clients and their families at home, typically every 2 weeks, helping them navigate quality-of-life challenges, connect them to community-based resources and engage them in meaningful activities. For instance, navigators can support these people with practical needs, such as arranging home care or applying for informal caregiver reimbursements, as well as psychosocial needs, like identifying signs of concern regarding future care and consequentially encouraging them to engage in conversations with their health professionals and family. The program also employs a navigator coordinator, who matches navigators with patients, advocates for the program, and forges connections with local healthcare professionals and community organizations. Both navigators and coordinators undergo training and coaching from a trainer with palliative or supportive care experience. The program is implemented in different regions in Canada, following a model supported by toolkits containing training and implementation materials, such as manuals for navigators and coordinators. Nav-CARE© clients have reported several benefits such as increased social support, assistance with navigating healthcare systems, increased knowledge of services, improved access to resources, and family respite. While Nav-CARE© has demonstrated success across Canada, its implementation outside Canada remains underexplored.

have emerged to support the systematic adaptation of interventions. These resources are aimed at recognizing and documenting adaptations, 10,11 designing and implementing tailored modifications, and systematically planning and evaluating the adaptation process. 12,13 Among these, the ADAPT guidance1 stands out as the most recent and comprehensive framework offering evidence and consensus-informed guidance14,15 for systematically adapting and transferring evidence-informed population health interventions to new settings. However, despite its potential, limited research exists demonstrating how the ADAPT guidance can be practically applied by researchers, particularly in the context of complex public health palliative care interventions.

Several European countries face significant challenges in meeting the needs of older people with cancer and their families. In these countries, healthcare systems often struggle with fragmented care delivery, lack of coordinated care and services, limited or unequal access to care and resources, and insufficient social support for patients and families. European countries have reported rising numbers of older adults with cancer, highlighting the potential of programs like Nav-CARE© (Box 1) to address the needs of older people with cancer and their families. 16,22,23 However, to achieve similar benefits in European countries as in Canada, a systematic adaptation of Nav-CARE© is essential.

Within the Horizon Europe-funded EU NAVIGATE project, ^{24,25} we aim to adapt, implement, and evaluate the Nav-CARE© program for older people with cancer across the continuum of supportive, palliative, and end-of-life care in six European countries: Belgium, the Netherlands, Ireland, Italy, Poland, and Portugal, representing different contexts and health care systems. This paper describes the international and systemic adaptation process of the Canadian Nav-CARE© program¹⁵ and reflects on the use of the ADAPT guidance¹ in the context of international public health palliative care interventions. By sharing

these reflections, we aim to provide valuable insights for researchers and practitioners seeking to transfer complex public health interventions across settings, particularly in palliative care.

Methods

Study design

We used an iterative five-stage multi-method approach (Figure 1),²⁴ using the ADAPT guidance¹ and its recommended frameworks (described below) to adapt the Nav-CARE© program to six EU countries: Belgium, Ireland, Italy, the Netherlands, Poland, and Portugal. Table 1 outlines the main stages suggested by the ADAPT guidance, detailing how we applied these stages in our adaptation process, including data sources and output per stage.

We used three frameworks, described in the ADAPT guidance as optional, throughout the adaptation process. The Model for Adaptation Design and Impact (MADI) structured our decision-making on adaptation design at the end of all stages, considering relationships among adaptations and their potential impact on outcomes.² The Context and Implementation of Complex Interventions (CICI) framework guided the context analysis in stage 3, facilitating a structured holistic conceptualization and assessment of context.³ The Framework for Reporting Adaptations and Modifications-Expanded (FRAME) was used in the final stage to integrate, summarize, and report all adaptations and to reflect on the process.¹²

Study settings

The Nav-CARE© program was adapted for implementation across six European countries: Belgium, Ireland, Italy, the Netherlands, Poland, and Portugal. The selection of implementation settings (such as a specific region, city, or community), and implementation organizations (a particular

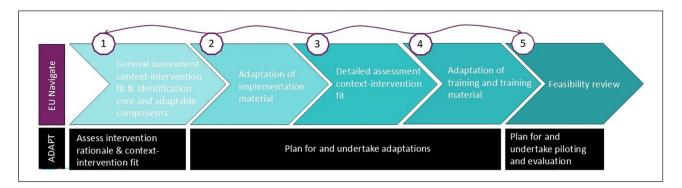


Figure 1. Flowchart adaptation process within the EU Navigate project, informed by the ADAPT guidance.

local organization with whom the research teams collaborate for implementation) aimed to ensure diverse health-care system characteristics and contextual factors, in terms of the latest Healthcare System Typology of OECD¹ countries.²⁷ There are eight implementation settings in total, with two in Belgium and Italy and one in each other participating country. An overview of the implementation settings and organizations is shown in Table 2.

Adaptation teams

The ADAPT guidance stresses stakeholder involvement throughout all adaptation stages to enhance the intervention-context fit. This involves a core team, ideally comprising members of the public, patient populations, policy and practice stakeholders, and the researchers involved, 1,28 following a multi-stakeholder and Patient Public Involvement approach. 29,30 In EU NAVIGATE, each implementation setting assembled a Local Adaptation Team following this structure.

Additionally, we established an International Adaptation Oversight Group, consisting of the original Nav-CARE© program developers (BP and WD), the general trial and implementation coordinators (FVC and LVdB), and the adaptation and training coordinators of the EU NAVIGATE project (KC and JG). This group coordinated and facilitated the adaptation process, communicated planned or made adaptations bilaterally or consortium-wide, and aimed to balance the original intervention's integrity with setting-specific adaptations. Cooperation between these two teams was central to ensure this balance.

Adaptation and data collection process

The steps suggested by the ADAPT guidance, our adaptation process, including data sources and output are displayed in Table 1.

Stage 1: General assessment intervention-context fit and identification core components. We asked experienced

researchers from each participating country (KS; MFB; AD; DF; AVDP; and LVdB) to complete a structured template (Supplemental Appendix 1) to gather insights into the intervention-context fit at the start of the adaptation process.³¹ The template had two sections: potential local implementation organizations, implementers, and local stakeholder groups such as volunteer or healthcare organizations. The second part included questions such as¹ the type of health care system,² the integration of end-of-life care within cancer care for older patients,³ the current state of research, practice, and policy regarding navigation programs and⁴ a preliminary feasibility assessment of the project in the potential implementation setting.

Additionally, we held several meetings with the International Adaptation Oversight Group to discuss the core versus adaptable components of the intervention. These discussions, informed by the original model³² and data from previous studies,^{16–21} resulted in an overview structured by the TIDieR³³ checklist, which were then integrated into the intervention's logic model.

Stage 2: Adaptation of implementation materials. In the ADAPT guidance stage "planning and undertaking adaptations," we translated and adapted the training and implementation materials, and performed a contextual analysis in the different countries.

During this stage, researchers (FVC and KC) collected Adaptation Reporting Sheets (Supplemental Appendix 1) completed by a research member of each Local Adaptation Team and structured by the FRAME framework. ¹⁹ The researchers categorized suggested adaptations into themes ³⁴ according to the framework, ³⁴ such as what is modified and for whom is the adaptation intended. These were discussed during multiple meetings with both the International Adaptation Oversight Group and Local Adaptation Teams in each country.

Stage 3: Detailed assessment of context-intervention fit: Contextual analysis. Two researchers (FVC and KC) conducted semi-structured duo-interviews with implementers of each participating country.¹⁴ The topic guide

Table 1. Overview of the recommended stages by the ADAPT guidance, the adaptation process used in EU NAVIGATE project, the data sources, and output.

| anie 1: Over | ADAPT guidance: | Adaptation process used | ADAPT guidance: Adaptation process used Interpretation/Utilization ADAPT guidance Data sources Company | Data sources | Output |
|---------------------|---------------------------------------|---|--|--|---|
| | steps for adapting an intervention | | | | |
| | Assess rationale for intervention, | Stage 1: First general assessment of context- | The ADAPT guidance states that it is crucial to consider intervention-context fit and understand | Meetings with potential project partners | Potential intervention- context fit confirmed |
| | and consider | intervention fit | its underlying rationale. ¹ The latter is often | Structured templates to gather | per partner |
| | intervention- | and Identification of | assessed by identification of the intervention's | insignts on healthcare systems and | - Core and adaptable |
| lK2 | context fit of existing | core and adaptable | core components, wnich are defined as the intervention's standardized principles and | context, completed by researchers from each participating country | s nart of the |
| IOM | interventions | intervention | functions. ²⁵ | (pre-adaptation) | intervention's logic |
| əwe | | | | Core component meeting reports | model |
| srf I | Plan for and | Stage 2: Adaptation | The ADAPT guidance¹ highlights that the | Adaptation Reporting Sheets by each | Adapted implementation |
| IAD | undertake | of implementation | adaptation of implementation materials extends | participating country structured by the | materials |
| √l ∋r | adaptations | materiais | beyond mere translation, stressing the need for careful adjustments in language and expressions | FRAIVIE** ITAMEWORK | |
| | | | to ensure accurate interpretation of the message. | | |
| | | Stage 3: Detailed | The context analysis was guided by the Context | Transcripts of interviews with | Overview of country- |
| | | assessment of context- | and Implementation of Complex Interventions | implementers of each participating | specific contextual |
| | | intervention fit: | (CICI) framework, ³ which defines context as | country, of which the topic guide was | factors that might impact |
| | | Contextual analysis | any feature of the circumstances affecting | structured by the CICI framework ³ | the implementation and |
| | | | intervention implementation, encompassing | | outcomes |
| ou qe OFDI | | | geographical, organizational, cultural, economic, ethical, legal, political, and local practices. ^{1,3} | | |
| | | Stage 4: Adaptation of | Following the ADAPT guidance. training for | - Researchers' observational notes of | Adapted training |
| | | training for implementers | | the train the trainer week | schedules and materials |
| | | (i.e. navigators and | intervention transfers across settings, to address | - Researchers' observational notes of | |
| uo | | navigator coordinators) | potential variations in roles | monthly trainers' meetings | |
| Зu | Plan for and | Stage 5: Feasibility | The ADAPT guidance suggests creating an | All output from stages 1–4, | Summary of all |
| aki | undertake | review | overview of the adaptations and advises | including researchers' meeting | adaptations structured by |
| w ı | piloting and | | considering evaluation before implementing the | notes of International Adaptation | the FRAME framework. ¹² |
| ıoi | evaluation | | adapted intervention if there's high uncertainty | Oversight Group. | |
| ecis | | | about its feasibility and effectiveness. ¹ If | - A short questionnaire to assess the | |
| a | | | uncer tainty is low, it suggests reassessing during implementation, which allows for potential | Team, the characteristics of its | |
| | | | reactive adaptations. ¹⁴ | members, and how important they | |
| | | | | thought the Local Adaptation Team | |
| | | | | was in the process of adapting the intervention to the local context | |
| | | | | | |

that is the intervention's standardized principles and functions. ²⁵ In planning and undertaking adaptations it is important to maintain "the integrity" of the intervention, that is the extent to which those principles and functions are maintained. ²⁵ While the core components must remain consistent, their form can be adapted that is adaptable components. ²⁶ This means that adaptations can change the method of delivery as long as the underlying functions and principles are maintained, thereby preserving the intervention's integrity. *The ADAPT guidance states that in planning for and undertaking adaptations, adaptations should improve intervention-context fit while maintaining consistency with the core functional components,

Table 2. Overview of implementation settings, organizations, and type of health care system, based on the Healthcare System Typology of OECD^a countries, per participating country in the EU NAVIGATE project.

| Countries | Type of health care system based on the Healthcare system Typology of OECD¹ countries | Implementation setting | Implementation organization |
|-------------|---|---------------------------------|---|
| Belgium | Supply and Choice-oriented public type | Region Dender Region Waregem | Palliative Care Network: Palliatieve Zorg regio Dender Primary Care Network: Eerstelijnszone regio Waregem |
| Ireland | Supply and Choice-oriented public type | Dublin | Palliative care organization: Our Lady's Hospice Harold's Cross |
| Italy | Regulation oriented type | Milan | National cancer institute: Fondazione IRCCS Istituto Nazionale dei Tumori |
| | | Monza Brianza | Local League against Cancer : Lega Italiana per la lotta contro i tumori di Milano Monza Brianza |
| Poland | Low-supply and low- performance mixed type | Krakow | Local Social Care Centre: the <i>Municipal Social Care Centre</i> in <i>Kraków</i> |
| Portugal | Performance and primary care- oriented public type | Coimbra | Portuguese League Against Cancer—Centre Region: <i>Liga Portuguesa Contra o Cancro—Núcleo Regional do Centro</i> |
| Netherlands | Regulation oriented type | Amsterdam | Centre for caregivers: <i>Markant</i> Hospice facility and buddy volunteer system for people in the community: <i>Kuria</i> |

^aOrganization for Economic Co-Operation and Development.

(Supplemental Appendix 1), based on the seven contextual domains of the Context and Implementation of Complex Interventions framework,^{3,34} included questions such as "What regulations regarding palliative care, patient rights, and end-of-life decisions are in place in your implementation setting that could influence the implementation, delivery, or outcomes of this intervention?". Transcribed verbatim (FVC), the data were coded into the seven contextual domains of the framework per participating country and discussed within the International Adaptation Oversight Group.

Stage 4: Adaptation of training for implementers. Designated trainers in each country adapted the training to the local context during an international five days "train-the-trainer week." Six training modules were covered (Supplemental Appendix 2), with participants proposing adaptations to the curriculum that best suit their context after each module. These adaptations let to adapted training schedules and learning materials. The researcher (FVC) made observational notes during the training and follow-up meetings with the trainers, which were discussed with the International Adaptation Oversight Group.

Stage 5: Feasibility review. During this stage, researchers from each implementation setting completed a short questionnaire to assess the composition of their Local Adaptation Team, the characteristics of its members, and perceived importance of the Local Adaptation Team during the adaptation process. This was asked using a sixpoint Likert scale with questions such as "In general, how important do you consider this Local Adaptation Team

during the adaptation process of this intervention in your implementation setting?".

Data analysis and integration

The researcher (FVC) analyzed all qualitative data (completed structured templates, Adaptation Reporting Sheets, transcripts of the duo-interviews, observational notes of the train the trainer week and monthly trainers' meetings), using directed content analysis³⁵ and predetermined coding schemes structured by the frameworks stated above (Supplemental Appendix 1). Descriptive statistics,³⁶ such as the median and interquartile ranges, were used for the questionnaire assessing the Local Adaptation Team.

The researcher (FVC) assessed concordance and discordance of the adaptation information across data sources, including all meeting notes of the International Adaptation Oversight Group, using the categories of the FRAME framework.¹² This categorization was reviewed and discussed at team meetings (FVC, KC, LVdB, TS, LP, BP, and WD), which led to further refining and reflections reported upon in the results section. Once consensus was reached and feasibility assessed for, the researcher (FVC) completed the final version which is included as Supplemental Appendix 4.

Ethics

The protocol for this adaptation process was included as a Supplemental Appendix to the main trial protocol.³⁷ Approvals from the relevant ethics committees were

obtained in all participating countries. Belgium: Commissie Medische Ethiek, 09/08/2023, EC-2023-164; Ireland: SJH/TUH Joint Research Ethics Committee, 14/11/2023, 3726; Italy: Comitato Etico Territoriale Lombardia, Istituto Nazionale dei Tumori, 31/07/2023, INT171/23; the Netherlands: METC Amsterdam UMC, 22/08/2023, 2023.0489; 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, 25/09/2023, EO04/2023; Poland: Komisia Bioetyczna, Uniwersytetu Jagiellońskiego, 14/06/2023, 1072.6120.55.2023. The trial is registered on Clinicaltrials.gov (ID: NCT06110312). All members of the adaptation teams gave verbal informed consent prior to data collection. All obtained data were pseudonymized.

Results

Results, examples, and reflections on opportunities and challenges on the adaptation process are shown in Table 3, following a description of the composition and characteristics of the adaptation teams.

The adaptation process of the Nav-CARE© program was conducted from September 2022 until November 2023. The integration and analysis of all data sources and output included 6 completed structured templates on context, 6 completed adaptation reporting sheets, 36 adapted intervention materials, 6 duo-interview transcripts, 19 International Adaptation Oversight Group meeting notes, and 7 completed questionnaires on the composition and perceived importance of the Local Adaptation Teams.

Local adaptation teams

The Local Adaptation Teams included seven teams in total, one for each country except Belgium, which had two very distinct implementation settings and therefore two teams (Supplemental Appendix 3). The number of represented organizations in these teams varied from 2 to 12 between settings, with hospitals, universities/research groups and volunteer organizations, being the most represented in descending order. Members comprised researchers, implementers, representatives from the target population (i.e. older persons in declining health with cancer, close family caregivers, or volunteers), and health professionals working in the implementation setting (i.e. home care, oncology and palliative care nurses, community health workers, social workers, and psychologists). The number of members varied from 3 to 14 of whom most were health professionals followed by implementers or researchers. The number of meetings varied from 2, in Portugal, to 12, in the Netherlands and Poland, over approximately 1 year.

Results of the adaptation process

In stage 1, the International Adaptation Oversight Group identified and summarized core components of the intervention (Figure 2).

Discussion

Main findings

The new ADAPT guidance¹ and its recommended frameworks proved useful to guide the systematic adaptation process of the Nav-CARE© program for the EU NAVIGATE project across settings in six EU countries. The flexibility of the ADAPT guidance allowed for tailoring of the adaptation process, enabling selection of stages, frameworks, and elements based on specific rationales, incentives, and adaptation needs of the intervention. It was challenging to identify the core versus adaptable components, to manage the complex adaptation process across different countries, and to assess potential contextual interactions that might be worth identifying prior to implementation.

Transferable learnings for those seeking to adapt and transfer public health palliative care interventions to new settings

Prior research to develop the ADAPT guidance already identified most of the abovementioned challenges and gaps in existing guidance for adapting evidence-based health interventions. ^{14,15} This article can serve as an example of an approach that can build on the ADAPT guidance. We recommend thorough contextual assessments, identification of core components with engagement of original developers and involvement of both local and international adaptation teams throughout the entire adaptation process for those seeking to adapt and transfer a public health palliative care intervention to new settings.

Identifying core components to maintain the intervention's integrity enables a systematic adaptation process and meaningful coherent evaluation. 14,38,39 Drawn from the updated UK Medical Research Council guidance for developing and evaluating complex interventions,³² we emphasize the importance of starting from the intervention's original program theory (i.e. the Nav-CARE® navigation model¹⁶) focusing on the principles and functions, to identify and overview the core components. We added more specificity based on the data from previous studies, 16-21 integrated this overview in the intervention's logic model, and reconciled them with the original developers. Adopting an "integrity" perspective together with the developers facilitated the adaptation process. This aligns with experiences shared by other researchers in adaptation studies. 40 Integrity of an intervention moves beyond the discussion on implementation fidelity, but challenges

(Continued)

Table 3. Overview of results and reflections on the use of the ADAPT guidance for the adaptation process of Nav-CARE ◎ program.

| Toping and a | Output | Illustrative example | Reflections on the use of the Adapt guidance for the adaptation process in EU Navigate | otation process in EU Navigate |
|--|--|---|--|---|
| process | | | Opportunities | Challenges and how they were addressed |
| Stage 1: First assessment of context-intervention fit and identification of core components of the original intervention | - The results of the first context assessment on the health care system and contextual factors, led to a more informed exploration of potential implementation settings and organizations Core functional components were identified as presented in Figure 1. | After the first context assessments, two potential settings opted out of participating in the implementation and evaluation of the project. One setting cited an ongoing similar project in piloting phase, while the other setting noted that the role of volunteers in this project did not align with their healthcare system. | Identifying core functional components is a good opportunity to analyze the intervention's underlying assumptions and program theory, and to make these more explicit. The identification process should start from the program theory or conceptual framework of the original intervention. Engaging with the original developers is essential to clearly describe the intervention's core components versus the adaptable, and enables insights beyond what is provided in the literature. | It was challenging to identify the core functions and principles of the intervention versus the adaptable. It was often difficult to adapt the form, while ensuring to maintain the functions of a certain component prior to implementation, since we had to estimate the potential effects without knowing the outcome. This required us to consider all possible options and make educated guesses. For example, if the navigator visits would only be conducted via telephone, instead of in person, can one build a similar trust-based relationship, which is essential for qualitative navigation? Following discussions with the Local Adaptation Teams, the International Adaptation Oversight Group established a minimum contact frequency of every 2 weeks, ideally in person, with flexibility based on the patient's health and needs |
| Stage 2: Adaptation of implementation materials | All implementation materials were translated from English into the target languages, with adaptations focusing on adaptable features like variations in available services. Adaptations always concerned adaptable features. Suggestions for adaptations, identified within the implementation materials, that compromised the intervention's core components were discussed bilaterally between the respective Local Adaptation Teams and the international Adaptation Oversight Group. An overview of adaptations of the implementation materials per country is provided in Supplemental Appendix 4. | The translated Polish navigator manual stated very strict boundaries of navigators' tasks in comparison with what is stated in the original manual. The International Adaptation Oversight Group met with the Polish Local Adaptation Team to discuss why these stricter boundaries were needed and where adjustments could be made to ensure balance between local context and the intervention's core components. | Translation and adaptation of the implementation materials provided an opportunity for each implementation setting to engage more profoundly with the materials. This enabled them to identify further adaptations that might be required at an early stage. FRAME framework provides clear concrete themes and questions for reporting adaptations. Adaptation Reporting Sheets provide a predetermined structure, simplifying data integration. | The process is time intensive. Therefore, it can be useful to decide upon the degree of detail in reporting on conducted adaptations beforehand, which depends on the purpose for which adaptations are recorded. At times there were no comparable alternatives for translation in the target language. This required a re-thinking of parts of the branding of the original program (i.e. the naming of the intervention and implementers needed to be changed in some settings). The Local Adaptation Teams came up with a proposition and discussed it with the International Adaptation Oversight Group. |
| Stage 3: Contextual analysis | - Context is accounted for in implementation design, materials, and training Results from the duo-interviews on context led to country-specific adaptations, specifically to implementation strategies which were discussed within International Adaptation Oversight Group meetings and later with the respective Local Adaptation Teams. This informed further stages of the adaptation process. | In the Netherlands and Belgium there are many initiatives and services for this population, which made it important to highlight the distinctive aspects of this intervention. This socio-economic and political context implied that more local stakeholders needed to be involved in these Local Adaptation Teams, in comparison with other settings. | CICI provides a holistic view on context and concrete tools to assess context for different research designs. Assessing context at several time-points during the adaptation process proved useful, as context is dynamic and the intervention potentially modifies the implementation context. A context analysis is strongly recommended for adapting a public health palliative care intervention to diverse settings. It encouraged the adaptation teams to consider contextual similarities and differences between original and target setting that could influence implementation, delivery, and outcomes. Also, to aim for the best intervention-context fit, considering the need for this intervention, and the best implementers and practices specific to their setting-specific Keeping an overview of all setting-specific Adaptations is time intensive but can be useful for further stages in implementation or research. | Identifying potentially relevant contextual elements is essential in public health palliative care interventions, which encompass a wide array of factors at the micro, meso, and macro levels. However, it's often challenging to ascertain their specific impact or how they should be addressed prior to implementation. Despite existing tools provided by the GCI framework, examples of topic guides assessing context are lacking. We provided our topic guides assessing context are lacking. We provided our topic guide in Supplemental Appendix 1 to inspire others experiencing similar challenges. Maintaining continuous communication between the Local Adaptation Teams and the International Adaptation Oversight Group to ensure that adaptations were only related to adaptation Features proved challenging. For instance, the Local Adaptation Teams seldom reached out to the International Adaptation Oversight Group with questions during the adaptation process. It was always the other way around. The International Adaptation Oversight Group scheduled regular moments to meet bilaterally. This created an opportunity to address even minor aspects that the Local Adaptation Teams had previously considered too time-intensive to raise with the International Adaptation Oversight Group. |

| Adaptation | Output | Illustrative example | Reflections on the use of the Adapt guidance for the adaptation process in EU Navigate | aptation process in EU Navigate |
|---------------|---|----------------------------------|--|---|
| process | | | Opportunities | Challenges and how they were addressed |
| | | | | |
| Stage 4: | All training schedules, materials and | The Portuguese Local Adaptation | The international train-the-trainer week that we | It was complex negotiating the training of the trainers and |
| Adaptation of | curricula were adapted to align with | Team chose to prioritize "the | organized provided a great opportunity to adapt | adaptations to the training simultaneously. Time-slots were reserved |
| training for | the local implementation setting and | empowerment module" during | training curricula and materials, by informally | to guarantee specific periods dedicated to making adaptations. |
| implementers | contextual factors that might impact | their training sessions. They | mapping similarities and differences between | It was difficult at times to negotiate the many languages involved. |
| | implementation and outcomes. | believed that Portuguese | settings and training. schedules, curricula, and | During group work, teams would work in their native language which |
| | - All adapted training materials were | navigators would be more | materials. | made it difficult for the trainers to work alongside them and provide |
| | reported to and discussed within the | inclined toward advocacy | We involved international trainers that trained | advice on potential adaptations. Following each team discussion, |
| | International Adaptation Oversight | rather than empowerment, | locally embedded trainers, which helped to | a plenary session in English was held to review and discuss the key |
| | Group. | as it resonates better with | preserve context-intervention fit. | issues raised and decisions made. |
| | - Suggestions for adaptations that | the local cultural norms and | | |
| | compromised the intervention's | values therefore they chose to | | |
| | | Joseph Other other to the | | |
| | | מכיסוכ כאוום מנוכוווסון וכ | | |
| | bilaterally between the respective Local | empowerment module." | | |
| | Adaptation Teams and the International | | | |
| | Adaptation Oversight Group. | | | |
| Stage 5: | The output from previous stages | The International Adaptation | - Local Adaptation Teams and the International | Conducting a feasibility review of adapted interventions proved |
| Feasibility | was summarized using the FRAME | Oversight Group found it useful | Adaptation Oversight Group were perceived to | challenging for several reasons. Firstly, there was a lack of guidance |
| review | framework (Supplemental Appendix 4) | to take the time to consider the | be extremely to very important in the adaptation | on evidence-informed strategies for re-evaluating adaptation, which |
| | and discussed within the International | intervention-context fit in each | process of the intervention by the researchers | hindered the process. Secondly, time and resource constraints added |
| | Adaptation Oversight Group to assess | implementation setting, reflect | closely involved in the adaptation process. | further complexity to the task. Additionally, assessing the specific |
| | feasibility of the adapted interventions. | on the conducted adaptation | Having both local and international adaptation | impact of adaptations and determining how to address them prior to |
| | | process and anticipate on the | teams facilitates the intervention-context fit in an | implementation posed significant difficulties. Despite utilizing the MADI |
| | | potential challenges ahead. | adaptation process across settings as it ensured | framework, the task remained challenging, primarily due to the scarcity |
| | | | that there is a team that safeguards the core | of relevant examples in the literature. |
| | | | components and a team that ensures the local | |
| | | | embedding of the intervention | |

CICI framework: The Context and Implementation of Complex Interventions framework.³ FRAME framework: Framework for Reporting Adaptations and Modifications-Expanded,¹² MADI framework: The Model for Adaptation Design and Impact.²

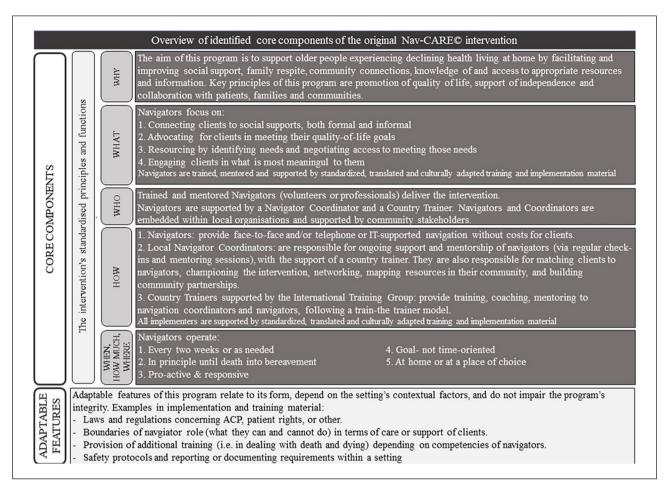


Figure 2. Overview of the identified core and adaptable features of the original Nav-CARE© program, based on the original program theory and guided by the TIDieR checklist. Created in stage 1 of the adaptation process for the EU NAVIGATE project.

intervention adapters to consider the why as well as the what of an intervention.²⁶

When adapting a public health palliative care intervention to diverse settings, we strongly recommend assessing implementation context at several time points with both local and international adaptation teams. Firstly, as these interventions are implemented in dynamic real-life settings and bound to a particular health care system with unique complexities and sensitivities (i.e. socio-economic and political challenges such as a fragmented healthcare system, socio-cultural challenges such as sensitivities regarding palliative care, etc.), a better intervention-context fit increases the likelihood of sustainable effects, similar to the original intervention.3 The assessments in our adaptation process encouraged local adaptation teams to consider contextual similarities and differences between original and target setting that could influence implementation, delivery, outcomes, and sustainability.32 For instance, identifying specific gaps in the target setting and profiling the program to other local stakeholders were key considerations. Secondly, as this intervention was adapted across multiple settings and countries, local adaptation teams for each site, and an International Adaptation Oversight Group played vital roles in maintaining the balance between intervention integrity and localization during the adaptation process, which is consistent with findings from other studies adapting interventions across diverse (international) settings.¹⁵ In Poland, Portugal, Ireland, and Italy, implementation sites chose to remove sections on Medical Assistance in Dying (MAID) and Advance Care Planning (ACP) from the volunteer manual, as some of these topics are either inapplicable, unknown, or illegal in some countries. The International Adaptation Oversight Group identified key concepts and rationales within these topics that are important for volunteers in palliative care to understand. The Local Adaptation Teams then adapted the content to align with local regulations and context, using this list as a guide.

Keeping an overview of all setting-specific contextual adaptations was time- and resource-intensive, but useful in further stages of implementation and evaluation, such as the interpretation of outcomes (i.e. informational/social support) in a certain context or the differences between settings. When interventions are not

effective, "context" is often cited as a potential reason, 28,41,42 though this is not systematically assessed, examined, or reported upon beforehand—only afterwards in the process evaluation.

Strengths and limitations

Our international, multi-setting, multi-method, and multistakeholder systematic approach provided diverse and nuanced perspectives on the adaptation process, offering insights beyond the ADAPT guidance. However, modifications to stages, methods, and frameworks may be necessary for other public health palliative care interventions, considering variations in settings, contexts, and adaptation needs.⁴³ This article seeks to contribute to the systematic adaptation of such interventions, aiming to enhance their adoption, implementation, effectiveness, and sustainability.⁴⁴

One limitation of our adaptation process was the limited direct involvement of the target population, such as patients and families. Although we aimed to engage these groups, logistical challenges, cultural sensitivities, and varying capacities of the Local Adaptation Teams impeded their participation across sites. Instead, we relied on Local Adaptation Teams' members, including professionals with lived experiences, to provide indirect insights into the perspectives of the target population. While this approach ensured some consideration of their needs, we acknowledge that this is not a substitute for direct participation.

Although we will conduct an elaborate evaluation as part of the EU NAVIGATE project³⁷ and this adapted intervention "borrows strength" from the evidence base of the original intervention,⁴⁵ one main limitation of this study is the relatively limited feasibility testing of the adapted interventions. Consistent with findings from similar adaptation research,³⁸ we found a lack of guidance on evidence-informed strategies for re-evaluating adapted interventions. Additionally, assessing the specific impact of adaptations and determining how to address them prior to implementation during data analysis posed significant challenges, despite utilizing multiple frameworks. More examples in the literature, illustrating re-evaluation of the adapted interventions, would aid greatly.

Recommendations for future research

Future adaptation research of public health palliative care interventions should explore systematic adaptation as an implementation strategy¹³ and assess its impact on both implementation and effectiveness outcomes. ^{14,15} Given the unique complexities in concept, scale, and setting of these interventions, ⁹ systematic adaptation can be a valuable technique to enhance adoption, implementation, effectiveness, and sustainability. ⁴⁶ Rather than

being viewed as an option during implementation, adaptation could be integrated as an implementation strategy in implementation frameworks such as RE-AIM.⁴⁷ Additionally, the impact of adaptation on implementation and effectiveness outcomes is rarely systemically assessed. Evaluation frameworks such as RAINBOW⁴⁸ should incorporate adaptation and provide relevant analysis methods, such as contribution analysis,⁴⁹ to evaluate this impact.^{14,15}

Future research should prioritize strategies for directly engaging patients and families in adaptation processes to ensure their needs and preferences are effectively understood and incorporated. This may include developing tailored approaches to address logistical challenges, fostering cultural sensitivity, and enhancing the capacity of adaptation teams to facilitate meaningful and inclusive participation.

Conclusion

The systematic adaptation process of the Nav-CARE© program across six countries within the EU NAVIGATE project was guided by the new ADAPT guidance, proving flexible and useful despite challenges such as identifying core components and managing adaptation across diverse countries. In addition, engagement of original developers facilitates deeper insights into program theory and mechanisms. Involvement of local adaptation teams and an International Adaptation Oversight Group was crucial for maintaining integrity while allowing for localization. Overall, this study offers valuable insights into the systematic adaptation of public health palliative care interventions, potentially enhancing their adoption, implementation, and effectiveness across diverse settings.

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Author contributions

All authors have contributed to the following categories for authorship. Study conception and design: Gilissen, Chambaere, Van den Block, Pesut, Duggleby, Pivodic, Smets, and Van Campe. Acquisition of data: Van Campe and Chambaere. Analysis and interpretation of data: Van Campe, Chambaere, Pivodic, Pesut, Duggleby, Smets, and Van den Block. Drafting the manuscript: Van Campe. Critical revision: Van Campe, Chambaere, Pivodic, Gilissen, Pesut, Duggleby, Smets, Szczerbińska, Furlan de Brito, Davies, Ferraris, Scacciati, Van Der Plas, and Van den Block. All authors approved the final manuscript and agreed to be accountable for all aspects of the work. Questions related to the accuracy or integrity of any part of the work will be appropriately investigated and resolved.

Data availability

The data that support the findings of this study are available from the corresponding author, FVC, upon reasonable request.

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ORCID iDs

Fien Van Campe (D) https://orcid.org/0000-0002-0742-7475
Kenneth Chambaere (D) https://orcid.org/0000-0001-6277-072X
Lara Pivodic (D) https://orcid.org/0000-0002-8825-3699
Wendy Duggleby (D) https://orcid.org/0000-0002-3444-0392
Tinne Smets (D) https://orcid.org/0000-0003-1439-316X
Katarzyna Szczerbińska (D) https://orcid.org/0000-0002-0004-3858
Maja Furlan de Brito (D) https://orcid.org/0000-0002-3749-7183

Supplemental material

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Bianca Scacciati D https://orcid.org/0000-0002-3543-6176

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