InVAdvance

D6.1. Trial Evaluation Framework

WP6 – Formative and summative assessment of the trials

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List of Acronyms

CFIR	Consolidated Framework for Implementation Research
FE	Formative evaluation
EHR	Electronic health records
GP	General Practitioner
HADS	Hospital and Depression Scale
HICP	Harmonised Indices of Consumer Prices
ICER	Incremental Cost-Effectiveness Ratio
MCQ	Medical Consumption Questionnaire
OECD	The Organization for Economic Cooperation and Development
PC	Palliative Care
POS	Palliative Care Outcome Scale
PPSv2	Palliative Scale Version 2
PROM	Patient reported outcome measures
QALY	Quality Adjusted Life Year
QoL	Quality of Life
RCT	Randomized Controlled Trial
VICQ	Valuation of Informal Care Questionnaire
ZBI	Zarit Burden Interview

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1. Executive Summary

Within the InAdvance project five Randomized Clinical Trials (RCTs) will be performed in Valencia (Spain), Lisbon (Portugal), Thessaloniki (Greece) and Leeds/Inverness (UK) aimed to implement and test early palliative care (PC) interventions - designed under the work performed at the WP3 – in older patients with complex chronic conditions.

This deliverable describes the evaluation framework with the variables, chosen instruments for data collection and timeline to be performed and followed at each clinical site throughout the RCTs. This document will guide researchers and clinical staff at each trial site when performing data collection in a homogeneous way. For this purpose, a formative evaluation approach has been designed where effectiveness, cost-effectiveness and implementation indicators have been designed.

In terms of effectiveness different patient reported outcome measures (PROMs) will be assessed both on patient and relatives/informal caregivers in order to analyse if the intervention is having positive impacts on their welfare (i.e. quality of life, symptoms, etc.). Cost-effectiveness evaluation is aimed to demonstrate 'value for money' and possible cost savings derived from the intervention implementation. For this purpose, three cost categories will be measured: the intervention costs, other healthcare costs and informal care costs. Finally, the implementation of the interventions process will be assessed through tools developed based on the Consolidated Framework for Implementation Research (CFIR). These aspects of the implementation will be assessed at several moments with the involvement of key health and social care staff to identifying facilitators and barriers for an effective implementation of the interventions.

Measurements and instruments have been designed and selected finding balance between minimum information necessary to reach the trial objectives and, at the same time, to avoid overburden among end-users in the completion of data.

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2. Introduction

The project *Patient-centred pathways of early palliative care, supportive ecosystems and appraisal standard* (InAdvance) proposes a novel model of palliative care (PC) based on early integration and personalized pathways addressed specifically to older people with complex chronic conditions. Thus, the overall aim of InAdvance is to improve the benefit of PC through the design of effective, replicable and cost-effective early PC interventions centred-on and oriented-by the patients.

InAdvance aims at enhancing the PC interventions for its primary end-users (patients, health professionals and relatives/families). For this purpose, under the WP5 of the project (*Clinical Trials*) five 18-month randomized clinical trials (RCTs) will be performed in Valencia (Spain), Lisbon (Portugal), Thessaloniki (Greece) and Leeds and Inverness (The United Kingdom) in order to implement and test the PC interventions designed during the WP3 (*Intervention modelling through equitable multilevel analysis*).

This deliverable is framed under the **WP6 (*Formative and summative assessment of the trials*)** aimed at performing a continuous and interactive assessment of the implemented interventions under the RCTs in terms of effectiveness, cost-effectiveness and feasibility. Results obtained under this WP6 will be later useful for drafting policy recommendations and clinical guidelines (under the WP8) as well as they will serve as inputs for the project dashboard (WP7).

The deliverable 6.1 defines the assessment strategy to be used along the whole trial period including the main indicators to be measured, how and the schedule to be followed. Interventions to be implemented will be centred on and orientated by patients and their relatives/informal caregivers with a close involvement and support of front-line care professionals. Thus, the evaluation strategy will engage these three groups of end-users in order to obtain a complete picture on how the intervention is impacted among them. The expected impact may be the following:

a) **Patients:** improved or maintained quality of Life (QoL), alleviated symptoms (such as physical symptoms), addressed multi-faceted and complex needs (psychological, emotional and spiritual needs), efficient use of health care resources and reducing unnecessary costs, etc.
b) **Families or informal caregivers:** improved or maintained QoL, increased of caring and coping skills, decreased caregiving burden, etc.
c) **Front-line practitioners:** acquisition of skills and competencies to early detect and address needs among patients with complex chronic conditions.
d) **Contextual level:** suitable and accepted interventions with a positive cost-effectiveness value for a feasible and sustained use at the different clinical settings.

In order to operationalize these expected impacts, the assessment strategy and its outcomes have been grouped in three main groups: effectiveness, cost-effectiveness and implementation.

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2.1 Effectiveness

The impact of the interventions will be measured involving patients, their relatives or caregivers and front-line professionals.
For this purpose, patient-reported outcome measures (PROMs) are commonly used in clinical care, audit and research to study, for instance, the effectiveness of an intervention. PROMs position the patient at the centre of care which facilitates assessing the patient's situation, monitoring changes in his/her health status, evaluating the effect of an intervention, improving quality of care, helping in decision making as well as better understanding patient's and his/her relatives' needs (Bausewein et al., 2011). In this sense, in the framework of the InAdvance clinical trials, PROMs will provide key information to implement interventions and to adapt them according to patients' preferences and needs as well as their relatives'.

Bausewein *et al*. (2016) provide expert recommendations on outcome measurement in PC in clinical practice and research that are taken into consideration in order to draft a list of PROMs to be assessed under InAdvance clinical trials. Some of these recommendations are the following:

1. Use clinically validated questionnaires in the target population.
2. Select simple and less time-consuming questionnaires that are sufficiently brief and straightforward.
3. Use multidimensional measures that ideally cover several domains.
4. Include outcome measures to assess the needs of relatives or informal caregivers.
5. Use measures that have sound psychometric properties.
6. Use valid and reliable measures that are relevant to the research question and consider patient burden.
7. Use measures that allow for comparisons throughout different clinical sites.

Finally, adherence describes the degree to which a patient's behaviour corresponds with the agreed recommendations from a healthcare provider (WHO, 2003). Commonly this concept is referred to pharmacological prescriptions, but it is also relevant in non-pharmacological interventions (e.g. attending follow-up appointments or executing behavioural modifications). Patient adherence is impacted by their involvement in the treatment process, their understanding of its goals and their overall wellbeing in the process. Thus, adherence to treatment is a key factor in treatment effectiveness, especially in older patients, as several ageing-related factors have been associated with poor adherence, such as multimorbidity, cognitive impairment, complex and multiple prescription regimes, etc. (Smaje *et al*., 2018).

2.2 Cost-effectiveness

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The number and variety of interventions in healthcare have rapidly increased in the past decades. Consequently, healthcare budgets in Western countries are increasingly under pressure which has raised the awareness that limits must be set to the growth in healthcare costs. As resources – people, time, facilities, equipment and knowledge – are scarce, an organised consideration of the factors involved in a decision to commit resources to one use instead of another must be made (Drummond *et al.*, 2005; Tan *et al.*, 2009). In healthcare, the consideration of these factors is commonly performed through cost-effectiveness evaluations; the comparative analyses of alternative interventions in terms of both their costs and effects (Drummond *et al.*, 2005; Gold *et al.*, 1996).

Table 1 presents the four cost categories which may be relevant. However, which cost categories to include in a cost-effectiveness evaluation remains open to debate because of legitimate differences in values or perspectives (Tan *et al.* 2012). Welfare economics adheres to the societal perspective in which all cost categories are considered. However, most cost-effectiveness evaluations adopt a more pragmatic approach and prioritise the cost categories included, only collecting information on those costs that are relevant to decision makers or to prioritise costs in terms of their importance (Drummond *et al.*, 2005; Gold *et al.*, 1996; Tan *et al.*, 2012).

Table 1 Distinction of cost categories within cost-effectiveness evaluations

	Healthcare costs	**Costs outside the healthcare sector**
Direct costs	Costs of the intervention under consideration	Informal care costs; patients' out of pocket expenses (e.g. expenses for travel, time and home modifications);
Indirect costs	Costs of healthcare resources which do not directly relate to the intervention under consideration	Productivity losses; legal costs, costs for special education.

Direct healthcare costs refer to the intervention under consideration. Regardless the perspective chosen for the cost-effectiveness evaluation, this cost category is always considered. Other (indirect) healthcare costs do not directly relate to the intervention but should be taken into account when the intervention is expected to modify other healthcare resources consumed. Costs outside the healthcare sector may be relevant only in specific patient populations. For example, productivity losses are of minor importance in the InAdvance population of patients, whereas a reliable cost assessment of informal care costs may be crucial.

2.3 Implementation

Besides the effect of the intervention in terms of efficacy and cost-effectiveness, this evaluation strategy is aimed also to understand what, why and how the InAdvance interventions are working in the different health settings and to

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identify aspects for improvement. In this sense, the implementation research approach helps to understanding and addressing barriers to effective and quality implementation of health interventions by establishing several outcome variables to assess how well implementation has been performed (Peters *et al*., 2013).

The main goal of this evaluation for the InAdvance project is to support researchers to obtain, at the end of the RCTs, interventions that are accepted and suitable to be implemented beyond the project life according to stakeholders' perspective. Thus, the following implementation outcome variables have been selected to be monitored:

- **Feasibility:** the extent, likelihood and manner in which an intervention can be carried out in a particular setting or organization.
- **Acceptability:** the perception among stakeholders that an intervention in agreeable.
- **Adoption:** the intention, initial decision or action to try to employ a new intervention.
- **Appropriateness:** the perceived fit or relevance of the intervention in a particular setting, for a particular target population or problem.
- **Fidelity:** the degree to which an intervention is implemented as it was designed in an original protocol, plan or policy.

For this purpose, a qualitative approach has been designed through the completion of interviews, questionnaires and checklists in each of the five clinical sites involved in the RCTs. This evaluation will be based on the **Consolidated Framework for Implementation Research (CFIR)** that is a meta-theoretical framework that provides a repository of constructs that can be applied to verify what works where and why across multiple contexts (Damschroder *et al*., 2009). CFIR is a very flexible framework that enables the researcher can select those constructs considered as most relevant for a particular study and setting in order to guide diagnostic assessments of implementation context, evaluate implementation progress and help explain findings in studies or quality improvement initiatives.

Within InAdvance, the use of CFIR is planned for the implementation phase supporting in the identification of:

- barriers and facilitators for an effective implementation of the interventions;
- degree to which the interventions have been implemented as intended;
- impact of contextual factors for the delivery of the interventions;
- participants' response to and interactions with the interventions.

CFIR is a menu of factors that have been associated with effective implementation across five constructs and each has been associated with several domains:

i) **Intervention characteristics**, such as complexity or adaptability.
ii) **Outer setting** related to external influences.
iii) **Inner setting** related to characteristics of the implementing organization.
iv) **Characteristics of individuals**, such as knowledge and beliefs about the intervention or self-efficacy.
v) **Process of implementation**, related to stages or presence of stakeholders.

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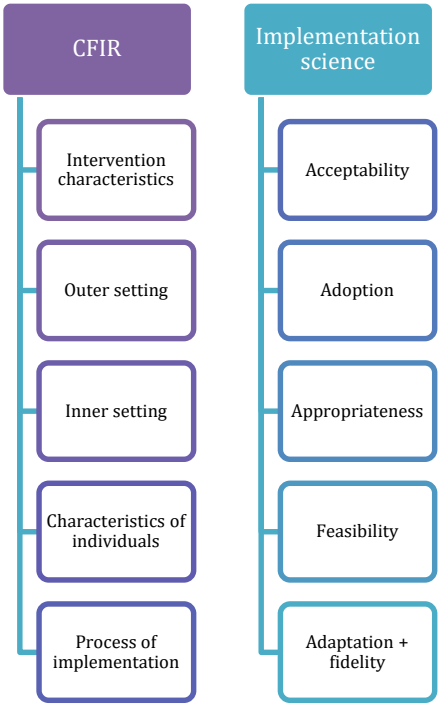
CFIR domains are paired with implementation science outcomes (Figure 1):

Figure 1 Link of the CFIR domains with implementation science outcomes



Thus, CFIR will support to the InAdvance clinical sites to identify those factors that are affecting the utilization (*acceptability and adoption*), relevance (*appropriateness*), trialability (*feasibility*) and adherence (*fidelity*) of the interventions studied.

Implementation fidelity is defined as the extent to which an intervention is implemented as intended (Hasson, 2010) and can also be interpreted to mean the same as intervention fidelity (Gearing *et al*., 2011). Evaluation of implementation fidelity in health interventions is crucial to facilitate drawing conclusions regarding the effectiveness of an intervention (Borrelli, 2011). Moreover, assessing intervention fidelity at the feasibility stage can detect deviations in the implementation plan.

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3. Methodology

3.1. Design and procedures

The assessment of the clinical trials will be based on Formative Evaluation approach (FE), which provides information regarding feasibility at real-time implementation enabling the introduction of any adaptations necessary to achieve optimal changes in the implementation process. Thus, FE allows collecting and analysing data in ways that lead to informed and ongoing decision making as part of the design, development and implementation process bringing continuous quality improvement. FE is particularly well-suited for innovations in which the path to success is not clear.

FE at InAdvance entails four staged that are based on the conceptualization of Stetler *et al*. (2006), occurring before, during and after the intervention (see Figure 2).

a) ***Before the intervention begins*** a needs assessment has been performed about areas and aspects where the intervention should be focused in order to obtain improvements by understanding the context, potential barriers and facilitators. This **Developmental Evaluation** has been already performed on the framework of the WP3 of the project.
In addition to the above evaluation, at the time patients are recruited to being part of the RCTs a first evaluation will take place in order to dispose baseline data (T0) to which compare the subsequent data collected once the trial starts.

b) ***During the implementation of the intervention***, two types of evaluations will be carried out:
   i. An **Implementation-focused evaluation** will be performed to evaluate the discrepancies between the implementation plan and the execution of that plan. This will allow to identify barriers and new intervention components, to refine the original strategy and to identify critical details that may be necessary to replicate the implementation strategy on other settings.
   ii. **Progress-focused evaluation** that analyses the progress towards the implementation of interventions. Outcomes on patients, relatives and professionals will be monitored on an ongoing basis. These data will be used to refine interventions during the implementation phase. The adaptations will be detected through: (i) intra-group comparisons to identify areas where the patient is improving or not; and (ii) comparing outcomes between the intervention group and with those of the comparison group to determine whether the intervention is having the intended effects.

   At this regard, at least three intermediate evaluations will be performed at week 6 (T1), month 6 (T2) and 12 (T3) for the effectiveness measures. For

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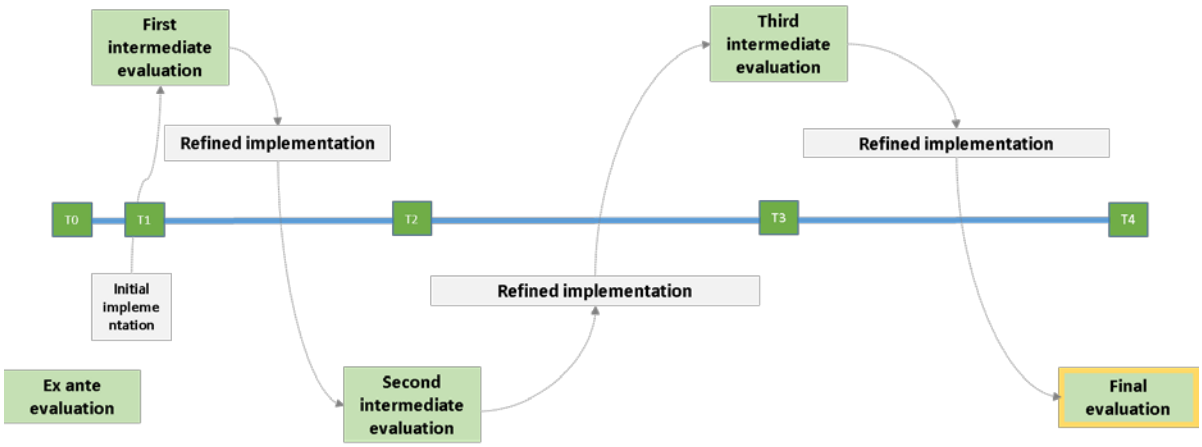
cost-effectiveness and implementation measures [1] two intermediate measures have been considered (T2 and T3).

c) ***After the implementation of interventions***, an **Interpretative Evaluation** will be performed comparing data form the previous phases of the FE approach. These results will facilitate the generation of hypothesis about why the intervention did or did not work. This type of evaluation offers the opportunity to maximize learning from the implementation effort and summarize lessons learned.
This final evaluation will take place on month 18 (T4).

Figure 2 Evaluation schedule of the trials



FE is valuable approach to support how to refine the implementation of interventions maximizing the chances of success. However, FE present some challenges that researchers involved in the RCT, data collection and data processing should take into consideration (Geonnotti *et al.*, 2013). Firstly, FE are time- and resource-intensive as it requires repeated data collection, analysis and refinement in order to perform a rapid refinement of the implementation strategy if necessary. Also, it is difficult to determine when a change in the implementation is impacting on outcomes. Thus, when the interventions examined for the entire timeframe estimated effects will reflect the combined effects of the different adaptations of the implementation over time. In this sense, FE does not estimate the effect of one version of the intervention; on the contrary, it is assessed an average intervention effect.

Study population, inclusion/exclusion criteria and recruitments strategies are described in detail in the deliverable 5.1 (*Final version of the Trial Operation Protocol*). Also, the description of the interventions to be implemented are described at the deliverable 3.4 (*Report describing the initial version of InAdvance interventions*).

[1] Fidelity will be measured at the three intermediate endpoints (T1, T2 and T3).

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3.2. Data collection and measures

Data collection will be done with mostly self-reported questionnaires in the local languages of the four countries involved in the RCTs. Although validated translated questionnaire has been preferentially selected, the use of non-validated ones cannot be ruled out. If necessary, the questionnaires will be translated into the official languages of the countries involved in the study. Before the start of the study, questionnaires will be pilot-tested in all participating sites to assure its user-friendliness in terms of appropriateness, comprehensibility and length.

Questionnaires will be electronically introduced into CASTOR[2] system that is a cloud-based clinical data platform. This platform will support the five clinical partners to perform an adequate and easy collection of data by being available for each site trial staff through a secure web-based system.

3.2.1. Socio-demographic data and participants' characteristics

Several socio-demographic characteristics are measured among patients, relatives/informal caregivers and front-line professionals (see Table 2).

Table 2 Socio-demographic measures

VARIABLE	END-USER	MEAN TO MEASURE
Age	Patient, caregiver, staff	End-user
Sex	Patient, caregiver, staff	End-user
Marital status	Patient	End-user
Level of education	Patient, caregiver, staff	End-user
Ethnicity	Patient, caregiver	End-user
Socio-economic level	Patient, caregiver	End-user
Relationship with the patient	Caregiver	End-user
Cohabitation with the patient	Caregiver	End-user
Caregiving profile	Caregiver	End-user
Preferences for place of care	Patient	End-user
Preferences for place of death	Patient	End-user
Active diagnosis (main diseases)	Patient	Electronic health records (EHR)
Time since initial diagnosis (main diseases)	Patient	EHR
Nº of prescribed drugs	Patient	EHR
Type of prescribed drugs	Patient	EHR

[2] https://www.castoredc.com/

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Years of experience in general healthcare practice	Staff	End-user
Years of experience in PC	Staff	End-user
Previous training in PC	Staff	End-user

3.2.2. Effectiveness measures

In terms of effectiveness, the primary objective is to evaluate if the intervention is being effective in meeting its main objectives among the project targets: patients, their relatives/informal caregivers and front-line professionals. For this purpose, two levels of outcomes have been established in order to gather the required data for this evaluation.

Firstly, these are the **primary outcomes** and instruments that have been selected:

- *Health-related QoL* is measured with the 5-level version of EQ-5D (**EQ-5D-5L**) instrument (EuroQol Group, 1990). It contains five dimensions and items: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension can be scored in five levels: no problems, slight problems, moderate problems, severe problems and extreme problems/inability to do. As part of this questionnaire, patients and relatives are also asked to indicate their experienced current health state on a visual analogue scale from 0 to 100 (where 0 means the worst imaginable health and 100 the best imaginable health).

- *Intensity of symptoms* is measured with the **Palliative Care Outcome Scale (POS)** [3]. The POS measures are a family of tools to measure patients' physical symptoms, psychological, emotional and spiritual, and information and support needs. Version 1 of POS is the original version validated on patients receiving specialist PC. Version 2 of POS was developed to be used in non-specialist PC settings and is particularly valuable for use with those people with palliative care needs who are diagnosed with a chronic or progressive disorder. POS measures are PC-specific, very short and can be completed by the patient or by a professional/caregiver.

- *Functional status* is measured with the **Palliative Performance Scale Version 2 (PPSv2)** [4] is a communication tool for quickly describing a person's current functional level (Anderson *et al.*, 1996). The PPSv2 uses five observer rated domains: ambulation, activity & evidence of disease, self-care, intake and conscious level. This instrument is intended for use by any health care professional and it is appropriate for use in all health care settings and for older adults with various diseases.

[3] https://pos-pal.org/
[4] http://www.npcrc.org/files/news/palliative_performance_scale_PPSv2.pdf

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A **secondary set of outcome measures** have been proposed in order to assess additional aspects related to the effectiveness of the InAdvance interventions. These measures are the following:

- *Emotional distress* is assessed with the **Hospital Anxiety and Depression Scale (HADS)** both among patients and caregivers involved in the RCTs. This instrument is aimed at assessing emotional discomfort (Zigmond & Snaith, 1983). It is a two-dimension scale developed to identify depression and anxiety among physically ill patients and the general population valid at hospital and in community settings. HADS features seven questions for anxiety and seven for depression, which can be answered within 2-5 minutes. This questionnaire has been considered useful in the assessment of PC patients (Holtom & Barraclough, 2000).

- *Caregiving burden* is measured among relatives or informal caregivers through the **brief version of Zarit Burden Interview (ZBI)** that is based on the original and longer version of ZBI aimed to evaluate the perceived impact of providing care on aspects such as the caregiver's health, personal and social life, financial situation, emotional wellbeing and interpersonal relationships (Zarit *et al.*, 1980). The short version of ZBI is composed of 12 items, it has proved validity evaluating burden of caregivers in different care contexts and it has proved to be sensitive and effective for evaluating overall burden in caregivers of older adults (Higginson *et al.*, 2010; Martins *et al.*, 2019).

- *Perceived quality of care* is assessed among patients and relatives/informal caregivers through a 5-point Likert scale assessing several aspects related to the care (communication, information provided, personalized care, family-centred and overall satisfaction) (see Annex 1).

- *Adherence to treatment* is proposed to be assessed among patients through the following questionnaires (see Annex 2): i) the **Treatment Acceptability/Adherence Scale (TAAS)** that is a 10-item self-report measure that assesses treatment 10-item self-report questionnaire designed to assess treatment acceptability (Milosevic *et al.*, 2015); or ii) **The Medical Outcomes Study (MOS)**, using only the list of items related on how often the patient actually carries out specific treatment recommendations made by the provider through a set of 5 questions (Sherbourne *et al.*, 1992). Due to there is no gold-standard scale for measuring treatment adherence this assessment outcome could be further discussed among partners in order to select another options for its measurement.

3.2.3. Cost-effectiveness measures

The purpose of this dimension of the trial assessment is to demonstrate 'value for money' and possible cost savings derived from the intervention implementation.

For the InAdvance project, 3 cost categories will be measured:

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1. the intervention costs
2. other healthcare costs
3. informal care costs

- *The intervention costs*

Resource units consumed and their unit costs will be collected using uniform reporting templates. Table 3 shows an example of a uniform reporting template. Depending on the intervention, resource units may concern the minutes spent by health and social care professionals (e.g. medical specialists, nurses, social workers, other therapists), diagnostic procedures (e.g. medical imaging, laboratory services), consumables (e.g. drugs, fluids and disposables) and overheads. Minutes spent by care professionals will be estimated by interviewing professionals. Other resources will be collected from the same interviews as well as from Patient- or Administrative Data Management Systems. The unit costs of labour minutes are based on normative incomes (including wages, social premiums, fees for irregular working hours and the costs of replacement during illness) and allocated to patients according to the time spent on the intervention. Other resource units are valued based on costs obtained from hospital Administrative Data Management Systems. Special attention will be paid to overhead costs as they represent between 35% and 40% of intervention costs; ideally using country-specific marginal mark-up percentages (or Dutch proxies; Tan *et al*., 2009).

Pilot site visits are considered for interviewing professionals (two of each type) to collect the data and identify which data could be acquired where (e.g. from information systems). Pilot site visits are an efficient way to estimate intervention costs. Ideally, site visits are combined with consortium meetings.

Table 3 The uniform reporting template for assessing the intervention costs

Intervention		Resource units (adjustable according to relevance)
Needs assessment and secondary interventions *	Minutes by care professionals	General practitioners
		Nurses
		Social workers
		Physiotherapists
		Psychologists
		Medical specialists
		Psychotherapists
		Rehabilitation specialists
		Nurse case managers
	Inpatient stay	Inpatient hospital days
		Inpatient rehabilitation days
		Inpatient nursing home days
		Inpatient residential home days
	Diagnostic procedures	X-ray

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		MRI
		Blood research
	Medication	Anti-inflammatory agents
	Educational curricula design	Minutes by researchers
	Consumables	Welcome packages
		Ludo pedagogical materials
		Software subscription for managing web resources addressed to patients/caregivers
AI-based behavioural intervention	License fees of Adhera platform	

* A range of secondary interventions is proposed in each clinic site based on local pathways and resources, most of which will be supported by technology. More details about the secondary interventions are provided in the Deliverable 3.4 (*Needs Assessment Intervention*).

- *Other healthcare costs*

Other healthcare costs will be measured with the Medical Consumption Questionnaire (MCQ), which will be completed by patients. The MCQ includes questions related to frequently occurring contacts with health care providers. The questionnaire asks the same question for different resource units (e.g. In the past 6 weeks, how many times did you visit a doctor). The questions refer to the care that the patient received for any reason (not specifically for the chronic condition for the intervention). Please find the MCQ in Annex 3.

Unit prices will be converted from 2014 Dutch unit prices taken from the Dutch Manual for Costing in economic evaluations (Tan *et al.*, 2012). The Eurostat Harmonised Indices of Consumer Prices (HICP) will be used to inflate the 2014 Dutch unit prices to the intervention year. The Organisation for Economic Co-operation and Development (OECD) Purchasing Power Parities (PPPs) will be used to adjust the individual consumption to reflect the British, Spanish, Portuguese and Greek unit prices respectively.

Other healthcare costs for individual participants will be determined by multiplying resource units (e.g. doctor appointments, hospital emergency room visits and hospital admission days) with corresponding unit prices.

- *Informal care costs*

Informal care costs are the most important costs outside the healthcare sector. Informal care costs will be determined by multiplying the number of hours taking care of the patient with corresponding hourly productivity costs. The number of hours taking care of the patient will be collected using items from the Valuation of Informal Care Questionnaire (VICQ) (see Annex 4).

3.2.4. Implementation measures

Evaluation of implementation will make possible to introduce modifications in the implementation process and, thus, to maximize the likelihood that the intervention successes.

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In this sense and based on the defined formative evaluation approach, healthcare professionals involved in the implementation of the interventions will be assessed at different moments of the RCTs:

- **An initial evaluation** will be performed through personal interviews or focus groups (see Annex 5) in order to gather as much qualitative information as possible regarding receptivity, potential barriers and facilitators to implement the intervention.
- **Intermediate evaluations** will be conducted employing questionnaires with a 5-point Likert scale (see Annex 6) aimed at assessing their views and experiences when implementing the interventions, allowing an understanding the causes of success and failures.
- **A final evaluation** will entail both personal/group interviews and questionnaires aimed at understanding the causes of success and failures of the RCT along with exploring sustainability of the interventions and lessons learnt.

Data collection tools (interviews and questionnaires) have been designed on the basis of the 5 domains (intervention characteristics, outer setting, inner setting, characteristics of individuals and process of implementation) of the CFIR. As a result, the questions to be included at those tools have been formulated according to specific CFIR constructs selected for the different moments of the evaluation at the RCTs (see Table 4):

Table 4 CFIR constructs for the evaluation of InAdvance implementation

Construct	Short description	Evaluation moment
I. INTERVENTION CHARACTERISTICS		
Evidence strength and quality	Stakeholders' perceptions of the quality and validity of evidence supporting the belief that the intervention will have desired outcomes.	Initial
Relative advantage	Stakeholders' perception of the advantage of implementing the intervention versus an alternative solution.	Initial, intermediate & final
Adaptability	The degree to which the intervention can be adapted, tailored, refined, or reinvented to meet local needs.	Initial, intermediate & final
Complexity	Perceived difficulty of the intervention, reflected by duration, scope, radicalness, disruptiveness, centrality, and intricacy and number of steps required to implement.	Initial, intermediate & final

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Design quality and packaging	Perceived excellence in how the intervention is bundled, presented, and assembled.	Initial, intermediate & final
II. OUTER SETTING		
Patient needs and resources	The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the service provider.	Initial, intermediate & final
III. INNER SETTING		
Culture	Norms, values, and basic assumptions of the service provider.	Initial, intermediate & final
Implementation climate	The absorptive capacity for change, shared receptivity of involved individuals to the intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their institution.	Initial, intermediate & final
Compatibility	The degree of tangible fit between meaning and values attached to the intervention by involved individuals, how those align with individuals' own norms, values, and perceived risks and needs, and how the intervention fits with existing workflows and systems.	Initial, intermediate & final
Relative priority	Individuals' shared perception of the importance of implementing the intervention within the organization.	Initial, intermediate & final
Goals and feedback	The degree to which goals of the intervention are clearly communicated, acted upon, and feedback to staff and alignment of that feedback with goals.	Initial, intermediate & final
Learning climate	A climate in which: a) leaders express their own fallibility and need for team members' assistance and input; b) team members feel that they are essential, valued, and knowledgeable partners in the change process; c) individuals feel psychologically safe to try new methods; and d) there is sufficient time and space for reflective thinking and evaluation.	Initial, intermediate & final
Readiness for implementation	Tangible and immediate indicators of organizational commitment to its decision to implement the intervention.	Initial, intermediate & final
Leadership engagement	Commitment, involvement, and accountability of leaders and managers with the implementation.	Initial, intermediate & final

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Available resources	The level of resources dedicated for implementation and on-going operations including budget, training, education, physical space, and time.	Initial, intermediate & final
Access to knowledge and information	Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks.	Initial, intermediate & final
IV. CHARACTERISTICS OF INDIVIDUALS		
Knowledge and beliefs of the intervention	Staff's attitudes toward and value placed on the intervention as well as familiarity with facts, truths, and principles related to the intervention.	Initial, intermediate & final
Self-efficacy	Staff's individual belief in their own capabilities to execute courses of action to achieve implementation goals.	Initial, intermediate & final
V. PROCESS		
Planning	The degree to which a scheme or method of behaviour and tasks for implementing the intervention are developed in advance and the quality of those schemes or methods.	Initial, intermediate & final
Engaging	Attracting and involving appropriate individuals in the implementation and use of the intervention through a combined strategy of social marketing, education, role modelling, training, and other similar activities.	Initial, intermediate & final
Executing	Degree in which the implementation is carried out or accomplished according to plan.	Intermediate & final
Reflecting and evaluating	Quantitative and qualitative feedback about the progress and quality of implementation accompanied with regular personal and team debriefing about progress and experience.	Initial, intermediate & final

Throughout InAdvance's RCTs fidelity will be assessed in several moments through checklists designed on the basis of the intervention components explicit on the intervention protocol. Healthcare professionals involved in the intervention implementation process will verify if all the detailed components have been duly delivered or not, rating the quality of their delivery and also facilitating narrative comments to provide additional qualitative information if needed (see Annex 7). In this sense, fidelity will be first assessed for each intervention component at the organizational level and, then, aggregated to produce an overall RCT rating for each individual component across sites (Keith *et al.*, 2010).

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3.2.5. Summary of tools

Table 5 presents, in a summarized way, the different measures to be used among the different end-users involved in the RCTs.

Table 5 List of tools to be used for the trial evaluation

END USER	OUTCOME	INSTRUMENT	MOMENT
Patients	Quality of life	EQ-5D-5L	T0, T1, T2, T3, T4
	Intensity of symptoms	POS1, POS2	
	Functional status	PPS2	
	Emotional distress	HADS	
	Quality of care	Short set of items	
	Other healthcare costs	MCQ	
	Adherence to treatment	TAAS; MOS	T0, T2, T3, T4
Relatives / Informal caregivers	Quality of life	EQ-5D-5L	T0, T1, T2, T3, T4
	Emotional distress	HADS	
	Caregiving burden	Brief ZBI	
	Quality of care	Short items	T0, T2, T3, T4
	Informal care costs	VICQ	
Healthcare staff	Feasibility, acceptability, adoption, appropriateness of the intervention	CFIR-based interview and questionnaire	T0, T2, T3, T4
	Fidelity	Short set of questions based on the interventions' components	T0, T1, T2, T3, T4
	Intervention costs	Uniform reporting template; interview	T0, T2, T3, T4

3.3. Study visits

As part of the evaluation, study visits to the five clinical sites will be conducted by UVEG and ERASMUS MC in order to gather additional information related to the impact, implementation and costs of the interventions implemented at the trials.

Concretely, an evaluation of the following criteria will be performed:

a) *Perceived effectiveness*: The extent to which the intervention is achieving its specific objectives and goals;
b) *Perceived efficiency*: The extent to which the setting is using its resources efficiently, and provided value for money;
c) *Perceived utility*: The extent to which the intervention is having a potential impact on the main target groups specified;
d) *Perceived sustainability*: The extent to which the project can led to sustainable changes or benefits that will last after the project has been completed;

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e) *Intervention Costs:* Average number of resource units consumed per patient. Information about where the unit costs can be acquired from (hospital administrative databases, patient records or others)?

The assessment of these perceived criteria will be performed using specific questionnaires/structured-interviews designed by UVEG and ERASMUS MC (see Annex 8) with the involvement of different stakeholders: front-line professionals involved in the deployment of the interventions and managerial care staff, as well as (if necessary and appropriate) patients and relatives/informal caregivers involved in the trials.

3.4. Data analysis

Several types of analysis are considered to be carried with data collected under the 18-month RCTs.

First of all, **descriptive statistics** of all the study variables will be carried out. For the qualitative variables, frequencies and percentages will be used and, for the quantitative variables, the mean and standard deviation will be calculated. Abnormal values (missing, outsider) will be explored and, if needed modified (eliminated or transformed) to later apply appropriate statistics. Also, tests for normal distribution of the outcome measures will be performed using the Kolmogorov–Smirnov test.

Secondly, **bivariate techniques** will be applied to evaluate the link between variables within each group (intervention group and control group) at different measurement moments (i.e. T0-T1; T1-T2; T2-T3; T3-T4; T1-T4; T0-T4, etc.) and between both groups at the different evaluation moments by means of the paired t-test (for variables showing a normal distribution), the Mann Whitney U test/Wilcoxon (for variables not normally distributed), Pearson (for continuous variables), Pearson Chi-square test (for discrete variables) or ANOVA tests (to identify significant relationship between discrete and continuous variables).

In a third step, **multivariate techniques** will be also used for different purposes. In order to evaluate the reliability of several items measuring complementary elements of the same construct (scale reliability), the α of Cronbach will be calculated. Moreover, this type of analysis will be useful to know the effect of different independent variables, including repeated measures, on one dependent variable at the same time.

In all cases, only *p*-values <0.05 will be considered statistically significant. All analyses will be carried out using the statistical package SPSS v26 or similar statistic software packages.

The cost-effectiveness analysis will be primarily conducted from a societal perspective and on a within-trial horizon. Differences between the intervention and control group and between baseline and follow up scores will be assessed by means of the independent sample T test (for variables showing a normal

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distribution), the Mann Whitney U test (for variables not normally distributed) or Pearson Chi-square test (for variable fractions). Furthermore, the incremental cost-effectiveness ratio (ICER) will be calculated by dividing the difference in total costs (incremental cost) by the difference in the health effect (incremental effect) to provide a ratio of 'extra cost per extra unit of health effect'. Using non parametric bootstrapping (drawing a certain amount of observations at random from the available patient sample), the degree of uncertainty for costs and effectiveness and the cost-effectiveness ratio will be examined on the ICER. In addition, an acceptability curve will be generated to indicate the probability that the intervention has lower incremental costs per quality adjusted life year (QALY) gained than various thresholds for the maximum willingness to pay for an extra QALY.

As part of the **implementation evaluation**, different analysis will be performed:

a) Retention rate of participants will be calculated to study the characteristics of the subjects who left the study. This information will be useful to know main drop-out reasons and, consequently, to optimize the implementation in order to increase patients' adherence.
b) At T0 individual or focus groups will be organized involving front-line professionals that are going to be involved in the implementation of interventions. Data to be collected will be mainly qualitative, which will be analyzed following the dimensions and constructs selected from the CFIR as a coding framework. Additional guidance for coding each construct is available online[5]. Also, when analyzing and coding data, researchers will be open to new themes that may arise inductively from the data.
c) At T2, T3 and T4 questionnaires with 5-point Likert-scale responses (ranging from strongly disagree to strongly agree) will be distributed among professionals. Thus, in this case descriptive measures such as frequencies, percentages, median scores with their corresponding interquartile range will be calculated per each item at each evaluation moment. Comparisons between these three moments will be performed using Student's T or Wilcoxon.
d) For fidelity measures, the questionnaires also are based on a 5-point Likert-Scale responses (ranging from non-use to committed use). Analysis will be the same than those described at point (c).

[5] https://cfirguide.org/evaluation-design/qualitative-data/

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ANNEX 1: Perceived quality of care – items for patients and relatives/informal caregivers

These items are aimed to assess how satisfied you are with the care received by [*insert name of the setting/service*]. *Please, select the answer that described your level of satisfaction (1* Very unsatisfied*; 2* Unsatisfied*; 3 Neutral; 4* Satisfied*; 5* Very satisfied*) with the following statements.*

QUESTIONS	***ANSWERS***				
1. Are you satisfied with the communication with healthcare staff at [*insert name of the setting/service*]?	1	2	3	4	5
2. At what extent are you satisfied with the personalization of the care received?	1	2	3	4	5
3. At what extent are you satisfied in how your relatives have been involved in your care?	1	2	3	4	5
4. Overall, are you satisfied with the care provided by [*insert name of the setting/service*]?	1	2	3	4	5

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ANNEX 2: Adherence to treatment questionnaires

Treatment Acceptability / Adherence Scale (TAAS)

Please respond to the treatment that you are completing by indicating your agreement with each of the below statements.

1. I have been able to complete this treatment.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

2. I have been able to adhere to the treatment requirements.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

3. I feel this treatment exhausting.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

4. It is distressing to me to participate in this treatment.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

5. Overall, I find this treatment intrusive.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

6. This treatment provides effective ways to help me cope with my disease.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

7. I prefer to try another type of treatment instead of this one.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

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8. I prefer to receive medication for my disease instead of this treatment.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

9. I would recommend this treatment to a friend with a similar condition.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

10. I would like to drop out from this treatment.

1	2	3	4	5	6	7
Strongly disagree			Neither agree nor disagree			Strongly agree

Measures of Patient Adherence Survey (MOS)

How often was each of the following statements true for you during the past 4 weeks?

	None of the time	A little of the time	Some of the time	A good bit of the time	Most of the time	All of the time
1. I had a hard time doing what the doctor suggested I do…	1	2	3	4	5	6
2. I followed my doctor's suggestions exactly…	1	2	3	4	5	6
3. I was unable to do what was necessary to follow my doctor's treatment plans…	1	2	3	4	5	6
4. I found it easy to do the things my doctor suggested I do…	1	2	3	4	5	6
5. Generally speaking, how often during the past 4 weeks were you able to do what the doctor told you?	1	2	3	4	5	6

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ANNEX 3: Medical Consumption Questionnaire for collecting other healthcare costs

The following questions refer to the care you received for any reason (not specifically your chronic condition).

1. In the past 6 weeks, how many times did you visit a doctor (GP or specialist, at a doctor's practice or hospital's outpatient department)?
Do not include visits while in a hospital or to a hospital's Accident and Emergency Department
- never
- Number of times:…….

2. In the past 6 months, how many times did you go to a hospital's Accident and Emergency Department?
- never
- Number of times:…..

3. How many total nights did you spend in the hospital in the past 6 months?
- never
- Number of nights in total in the past 6 months:…..

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ANNEX 4: Valuation of Informal Care Questionnaire for collecting informal care costs

1. How much time during the last week did you spend on **household activities** that would not have had to be performed if she/he were in good health, or if she/he could have done them?
For example, food preparation, cleaning, washing, ironing, sewing, taking care of and playing with your children, shopping or maintenance work, odd jobs, gardening.

_____ hours during the last week

2. How much time during the last week did you spend on **personal care** for her/him?
For example, dressing/undressing, washing, hair care, shaving, going to the toilet, mobility around the house, eating and drinking, medication.

_____ hours during the last week

3. How much time during the last week did you spend on **practical support** that would not have had to be performed if she/he were in good health, or if she/he could have done it?
For example, mobility outside the house including assistance with walking or wheelchair, visiting family or friends, seeing to health care contacts (e.g , doctors' appointments), organizing help, physical aids or house adaptations and taking care of financial matters(e.g., insurance).

_____ hours during the last week

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ANNEX 5: Initial Implementation Interview Guide

Study ID:
Date:
Organization:
Position in the organization:
Role in the intervention:

INTERVENTION CHARACTERISTICS

A. Evidence strength and quality

1a. What kind of information or evidence are you aware of that shows whether or not the intervention will work in your setting?

- What evidence have you heard about from your own research? From practice guidelines? From published literature? From co-workers? From other settings?
- How does this knowledge affect your perception of the intervention?

B. Relative advantage

2b. How does the intervention compare to other similar existing programs in your setting?

- What advantages does the intervention have compared to existing programs?
- What disadvantages does the intervention have compared to existing programs?

C. Adaptability

3c. What kinds of changes or alterations do you think you will need to make to the intervention so it will work effectively in your setting?

- Do you think you will be able to make these changes? Why or why not?

4c. Are there components that should not be altered? Which ones should not be altered?

D. Complexity (of the intervention)

5c. How complicated is the intervention? Please consider the following aspects of the intervention: duration, scope, intricacy and number of steps involved and whether the intervention reflects a clear departure from previous practices.

E. Design quality & packaging

6e. To what extent the quality of the supporting materials is according to the needs and preferences of the ones involved in the intervention? Why?

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OUTER SETTING

F. Patient needs and resources

7f. To what extent is staff aware of the needs and preferences of the individuals being served by your organization?

- How "in touch" are staff and leadership with the individuals served by your organization?

8f. How well do you think the intervention will meet the needs of the individuals served by your organization?

- In what ways will the intervention meet their needs? E.g. improved access to services? Help with self-management?

9f. What barriers will the individuals served by your organization face to participating in the intervention?

INNER SETTING

G. Culture[6]

10g. How do you think your organization's culture (general beliefs, values, assumptions that people embrace) will affect the implementation of the intervention?

- Can you describe an example that highlights this?

H. Implementation climate

11h. What is the general level of receptivity in your organization to implementing the intervention? Why?

I. Tension for change

12i. Is there a strong need for this intervention? Why or why not?

- Do others see a need for the intervention?

13i. How do people feel about current programs/practices/process that are available related to the intervention?

- To what extent do current programs fail to meet existing needs? Will the intervention meet these needs?
- How will the intervention fill current gaps?

J. Compatibility

[6] Understood as team culture. A friendly workplace where leaders act like mentors, facilitators, and team-builders. There is value placed on long-term development and doing things together.

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14j. How well does the intervention fit with your values and norms and the values and norms within the organization?

- Values relating to interacting with individuals served by your organization, e.g. shared-decision making vs. being more directive?

15j. How well does the intervention fit with existing work processes and practices in your setting?

- What are likely issues or complications that may arise?

16j. Can you describe how the intervention will be integrated into current processes?

- How will it interact or conflict with current programs or processes?

17j. Will the intervention replace or compliment a current program or process? In what ways?

K. Relative priority

18k. What kinds of high-priority initiatives or activities are already happening in your setting?

- What is the priority of getting the intervention implemented relative to other initiatives that are happening now?
- Will the implementation conflict with these priorities?
- Will the implementation help achieve (or relieve pressure related to) these priorities?

L. Goals and feedback

19l. Have you/your unit/your organization set goals related to the implementation of the intervention?

- [If yes] What are the goals?

M. Learning climate

20m. To what extent do you feel like you can try new things to improve your work processes?

- Do you feel like you have the time and energy to think about ways to improve things?
- What role did your supervisor (or other leaders) play? What actions did they take?

N. Leadership engagement

21n. What kind of support or actions can you expect from leaders in your organization to help make implementation successful?

- Do they know about the intention to implement the intervention?

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- What kind of support can you expect going forward? Can you provide specific examples?
- What types of barriers might they create?

O. Available resources

22o. Do you expect to have sufficient resources to implement and administer the intervention?

- [If Yes] What resources are you counting on? Are there any other resources that you received, or would have liked to receive?
- [If no] What resources will not be available?

P. Access to knowledge and information

23p. What kind of training is planned for you? For colleagues?

- Do you feel the training will prepare you to carry out the roles and responsibilities expected of you? Can you explain?
- What are the positive aspects of planned training?
- What is missing?
- What kind of continued training is planned?

24p. What kinds of information and materials about the intervention have already been made available to you?

- Copies of materials?
- Personal contact?
- Internal information sharing; e.g., staff meetings?
- Has it been timely? Relevant? Sufficient?

25p. Who do you ask if you have questions about the intervention or its implementation?

- How available are these individuals?

CHARACTERISTICS OF INDIVIDUALS

Q. Knowledge and beliefs about the intervention

26q. What do you know about the intervention or its implementation?

27q. Do you think the intervention will be effective in your setting? Why or why not?

28q. How do you feel about the intervention being used in your setting?

- How do you feel about the plan to implement the intervention in your setting?
- Do you have any feelings of anticipation? Stress? Enthusiasm? Why?

R. Self-efficacy

29r. How confident are you that you will be able to:

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- successfully implement the intervention? Why?
- use the intervention? Why?

30r. How confident do you think your colleagues feel about implementing and using the intervention?

31r. Do you experience some burnout or stress associated to the care of patients with palliative care needs? How does these feeling may decrease thanks the implementation of the intervention?

PROCESS

S. Planning

32s. Can you describe the plan for implementing the intervention?

- How detailed is the plan? Who knows about it? Is the plan overly complex? Understandable? Realistic and feasible?
- Who is involved in the planning process? What are their roles?
- Are the appropriate people involved in the planning process? How engaged are they?
- Do you plan to track the progress of implementation based on your plan?

T. External change agents

33t. Will someone (or a team) outside your organization be helping you with implementing the intervention?

- Can you describe this person/group?
- How did they get involved?
- What is their role?
- What kind of activities will they be doing?
- How helpful do you think he/she/they will be? In what ways?

U. Reflecting and evaluating

34u. What kind of information do you plan to collect as you implement the intervention?

- Which measures will you track? How will you track them?
- How will this information be used?

35u. Will you receive feedback reports about the implementation or the intervention itself?

- What will they look like? Content, mode, form?
- How helpful do you think they will be?
- How could they be improved?
- How often will you get them? Where will they come from?
- Who is designing them?

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ANNEX 6: Intermediate and Final Implementation Questionnaire

Study ID:
Date:
Organization:
Position in the organization:
Role in the intervention:

These items are aimed to assess how the intervention has worked in your setting. Please, select the answer that described your level of agreement (1 Strongly disagree; 2 Disagree; 3 Neutral; 4 Agree; 5 Strongly Agree) with the following statements.

INTERVENTION CHARACTERISTICS

FACTOR	ITEM	- AGREEMENT +				
B. Relative advantage	**1b.** Implementing the intervention provides an advantage to support patient with palliative needs in comparison to other existing programs (related to palliative or chronic care) in your setting.	1	2	3	4	5
	Comment:					
C. Adaptability	**2c.** The intervention can be adapted or refined to work effectively in your setting to meet local patients' palliative care needs.	1	2	3	4	5
	Comment:					
D. Complexity	**3d.** The intervention is complicated for implementation (i.e. considering its duration, scope, intricacy and number of steps	1	2	3	4	5

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	involved and whether the intervention reflects a clear departure from previous practices).					
	Comment:					
E. Design quality & packaging	**4e.** Enough and quality supporting materials are available to help you implementing and using the intervention.	1	2	3	4	5
	Comment:					

OUTER SETTING

FACTOR	ITEM	- AGREEMENT +				
F. Patient needs and resources	**5f.** The intervention helps you to be more aware of the palliative care needs and preferences of patients.	1	2	3	4	5
	Comment:					
	6f. The intervention meets your patients' needs.	1	2	3	4	5
	Comment:					
	7f. Patients' experiences and perceptions with the intervention are positive.	1	2	3	4	5
	Comment:					

INNER SETTING

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FACTOR	ITEM	- AGREEMENT +				
G. Culture	**8g.** Your organization's culture (general beliefs, values, assumptions that people embrace) is affecting positively the implementation of the intervention.	1	2	3	4	5
	Comment:					
H. Implementation climate	**9h.** The level of receptivity in your organization to implement the intervention is positive.	1	2	3	4	5
	Comment:					
I. Tension for change	**10i.** The intervention is essential to meet your patients' palliative care needs.	1	2	3	4	5
	Comment:					
	11i. The intervention is essential to meet your organizational goals and objectives to improve the attention of palliative patients.	1	2	3	4	5
	Comment:					
J. Compatibility	**12j.** The intervention fits with your (personal) values and norms.	1	2	3	4	5
	Comment:					
	13j. The intervention fits with values and norms within your organization.	1	2	3	4	5
	Comment:					
	14j. The intervention fits with existing work processes and practices in your setting.	1	2	3	4	5

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	Comment:					
L. Goals and feedback	**15l.** The implementation of the intervention is aligned with organizational goals related to early palliative care in your setting.	1	2	3	4	5
	Comment:					
M. Learning climate	**16m.** You feel you have the time and energy to think about ways to improve the things during the implementation of the intervention.	1	2	3	4	5
	Comment:					
N. Leadership engagement	**17n.** The leaders and managers or your unit/organization are committed and involved with the implementation of the intervention.	1	2	3	4	5
	Comment:					
	18n. You have received enough support during the implementation of the intervention by leaders and managers at your unit.	1	2	3	4	5
	Comment:					
O. Available resources	**19o.** Resources to implement and administer the interventions are adequate (i.e. training, education, physical space, time, etc.).	1	2	3	4	5
	Comment:					
P. Access to knowledge and information	**20p.** Ease of access information and knowledge about the intervention and how to incorporate it into your work tasks have been made available for you.	1	2	3	4	5
	Comment:					

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CHARACTERISTICS OF INDIVIDUALS

Factor	Item	- Agreement +				
Q. Knowledge and beliefs about the intervention	**21q.** The intervention has been effective in your setting.	1	2	3	4	5
	Comment:					
	22q. The implementation plan of the intervention used has been appropriate.	1	2	3	4	5
	Comment:					
	23q. You have felt stress or uncertainty while implementing the intervention.	1	2	3	4	5
	Comment:					
R. Self-efficacy	**24r.** You have felt confident in implementing and using the intervention.	1	2	3	4	5
	Comment:					
	25r. You have experienced a reduction in burnout or anxiety levels working with patients in need of palliative care thanks to implementing the intervention.	1	2	3	4	5
	Comment:					

PROCESS

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Factor	Item	- Agreement +				
S. Planning	**26s.** A high-quality planning for implementing the intervention has been developed in advance.	1	2	3	4	5
	Comment:					
T. External change agents	**27t.** People outside your organization have been helping with implementing the intervention.	1	2	3	4	5
	Comment:					
V. Executing	**28v.** The intervention has been implemented according to the implementation plan.	1	2	3	4	5
	Comment:					
U. Reflecting and evaluating	**29u.** Feedback about the progress and quality of implementation and/or the intervention have been provided (i.e. quantitative or qualitative data, team debriefing, etc.).	1	2	3	4	5
	Comment:					

Thank you for completing this questionnaire.

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InAdvance

ANNEX 7: Fidelity of implementation

1 = nonuse, 2 = low compliance, 3 = compliant use, 4 = high compliance, 5 = committed use and DK/NO = Don't know/no opinion

Primary intervention component						
1. Availability of a local specialist or generalist PC services	1	2	3	4	5	DK/NO
NHS HIGHLAND Secondary intervention components						
1. Availability of presenters/ facilitators	1	2	3	4	5	DK/NO
2. Digital platforms for the delivery of the course are available	1	2	3	4	5	DK/NO
3. Provision of patient education documentation	1	2	3	4	5	DK/NO
4. Availability of laptop computers	1	2	3	4	5	DK/NO
5. Availability of digital devices for following the course by patients	1	2	3	4	5	DK/NO
HULAFE Secondary intervention components						
1. Provision of the NECPAL CCOMS-ICO® tool	1	2	3	4	5	DK/NO
2. Provision of welcome packs for patients, relatives and carers	1	2	3	4	5	DK/NO
3. Coordination between Generalist or specialist PC service (referring) and physiotherapist (referral) and/or patient education documentation	1	2	3	4	5	DK/NO
4. Coordination between Generalist PC (referring) or specialist PC services (referring) and psychologist (referral)	1	2	3	4	5	DK/NO
5. Coordination between Generalist PC (referring) and social workers (referral)	1	2	3	4	5	DK/NO
6. Implementation of a structured script involving relevant and concrete information related to therapeutic intensities agreed between clinicians and patients	1	2	3	4	5	DK/NO
7. Provision of patient education kits	1	2	3	4	5	DK/NO
8. Implementation of a call script to provide guidance for performing the calls towards non-oncological patients followed-up at the specialist PC program (case management program)	1	2	3	4	5	DK/NO
9. Introduction of a fast track referral between case-management programs	1	2	3	4	5	DK/NO

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SCMA Secondary intervention components						
1a. Coordination between Generalist PC (referring) and National PC Network (referral)	1	2	3	4	5	DK/NO
2a. Provision of dashboard technology	1	2	3	4	5	DK/NO
1b. Collaboration between health professionals, psychologists and social workers	1	2	3	4	5	DK/NO
2b. Digital platforms for the delivery of the course are available	1	2	3	4	5	DK/NO
3b. Provision of patient education documentation	1	2	3	4	5	DK/NO
4b. Availability of laptop computers	1	2	3	4	5	DK/NO
5b. Availability of digital devices for following the course by patients	1	2	3	4	5	DK/NO
1c. Collaboration between health professionals, psychologists and social workers	1	2	3	4	5	DK/NO
2c. Coordination between Generalist PC (referring) and PC Network (referral):	1	2	3	4	5	DK/NO
3c. Means to implement the monitoring/reassessment are available	1	2	3	4	5	DK/NO
4c. Provision of dashboard technology	1	2	3	4	5	DK/NO
AUTH Secondary intervention components						
1. Provision of AI-based behaviour change APP for the mobile phone and wearables	1	2	3	4	5	DK/NO
2. Provision of caregivers mobile APP	1	2	3	4	5	DK/NO
3. Provision of laptop computers	1	2	3	4	5	DK/NO
4. Provision of web application	1	2	3	4	5	DK/NO
5. Provision of health professionals training	1	2	3	4	5	DK/NO
6. Provision of Virtual Patient Scenarios	1	2	3	4	5	DK/NO

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ANNEX 8: Assessment to be performed during the study visits

Questions for the front-line staff:

Study ID:
Date:
Organization:
Position in the organization:
Role in the intervention:

1. To what extent do you consider the intervention is improving patient's wellbeing?

2. To what extent do you consider the intervention is alleviating symptomatology of patients (at physical, emotional, social and spiritual level)?

3. To what extent do you consider the intervention is supporting the functional status of patient do not suffer a significant deterioration?

4. To what extent do you consider the intervention is having a positive impact on patient's relatives/informal caregivers?

Questions for the managerial staff:

Study ID:
Date:
Organization:
Position in the organization:
Role in the intervention:

1. To what extent do you consider the intervention is facilitating that the needs of patients with complex chronic conditions are early detected?

2. To what extent do you consider the intervention is improving or optimizing the management of complex patients with chronic conditions at your setting?

3. To what extent do you consider the intervention fits with the clinical culture and structure of your setting to be maintained beyond the project?

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4. To what extent do you consider the intervention can lead to benefits among patients and their relatives that can be enduring?

Questions for patients:

Study ID:
Date:
Months involved in the intervention:

1. To what extent are you satisfied with the care provided by [*include name of the setting providing care*]?

2. To what extent are your needs (at physical, emotional, social and spiritual level) being covered by [*include name of the setting providing care*]?

3. To what extent are you feeling heard and taken into account when planning your care?

4. To what extent do you consider you have enough information about your health and care planning?

Questions for relatives/informal caregivers:

Study ID:
Date:
Months involved in the intervention:

1. To what extent are you satisfied with the care provided by [*include name of the setting providing care*]??

2. To what extent are your needs (at physical, emotional, social and spiritual level) being covered by [*include name of the setting providing care*]??

3. To what extent are you feeling heard and taken into account when planning your patient's care?

4. To what extent do you feel supported when caring to your patient by [*include name of the setting providing care*]??

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