Pilot sites, study design LifeChamps project

White Paper release v1
Published March 2023

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Glossary

Acronym	Explanation
AI	Artificial Intelligence
APC	Academic Primary Health Care Centre
AUTH	Aristotle University of Thessaloniki
EHRs	Electronic Health Records
HCPs	Healthcare Professionals
HRQOL	Health-Related Quality of Life
HULAFE	Health Research Institute Hospital La Fe
LC	LifeChamps
ML	Machine Learning
PREMs	Patient Reported Experience Measures
PROs	Patient Reported Outcomes
PROMs	Patient Reported Outcome Measures
PUC	Pilot Use Case
QoL	Quality of Life
SIOG	International Society of Geriatric Oncology
SMEs	Small and medium-sized enterprises
UofG	University of Glasgow

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Abstract

Studying the frailty and quality of life of cancer patients over the age of 60 may provide novel insights into the susceptibility and risk classification. We are able to conduct an analysis of the variables that impact the Health-Related Quality of Life (HRQOL) of older cancer patients and the course of their illness by making use of digital technologies such as big data analytics. By incorporating self-reporting and Patient Reported Outcome Measures (PROMs) into remote-care monitoring systems, medical professionals are able to make more informed decisions, which, in turn, results in better patient outcomes and cheaper costs. The LifeChamps solution makes the promise of the digital technologies and clinical equipment discussed before a reality in order to improve the quality of life of older cancer survivors and the process of follow-up monitoring by their healthcare specialists. The present project's objective is to collect data that demonstrates the applicability, usefulness, efficacy, and value of the ideas, models, and approaches that were used in the creation of the LifeChamps solution in clinical settings, real-life infrastructures, and realistic scenarios. This Whitepaper's objective is to give readers an understanding of the activities that were carried out within the scope of Work Package 7, which is a design for a multi-phase study that will train, test, and evaluate the technical performance, user usability, and clinical significance of the LifeChamps solution.

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1. Introduction

There is accumulating evidence that older individuals are under-treated, and that inequitable access to cancer care results in worse outcomes for them [1-3]. Because of the co-existing multimorbidity and frailty of these patients, clinicians must deal with complex therapeutic decision-making processes. Nevertheless, the study of frailty and quality of life in cancer patients over the age of 65 may give unique insights into their vulnerability and risk categorization [4-5].

The International Society of Geriatric Oncology (SIOG) published a report in 2011 identifying the top objectives for improving the care of older cancer patients throughout the world [6].

Using quality of life and geriatric assessment-focused instruments to identify high-risk individuals may aid in the decrease of long-term unfavourable health care usage (e.g., increased hospitalizations, long-term care use) [7].

Furthermore, the use of digital technologies like big data analytics can enable us to analyse the factors that influence older cancer patients' Health Related Quality of Life (HRQOL) and disease progression [8-9]. Healthcare systems and oncology professionals are only now starting to grasp the benefits that will accrue from the spread of digital technology in medicine.

Digital health technologies shows promise for cancer self-management and control [10], but more research is required before they can be effectively used for disease

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prevention and to enhance well-being. Integrating self-reporting and PROMs into remote-care monitoring systems enables health care practitioners to make better-informed choices, leading to improved patient outcomes and lower costs [11]. There is significant potential to enhance patient outcomes, by developing computational algorithms for identifying health events, forecasting unfavourable occurrences, and offering just-in-time care interventions at the point of need. Also important is the creation of user interfaces that are both efficient and effective in enabling timely awareness to doctors about their patients. These technologies must first be properly tested and developed via rigorous clinical research before they can be used in the real world.

LifeChamps (LC) is a multi-national European project that materialises the aforementioned digital cancer care potential [12]. Through Work Package 7, entitled "Pilots Specification, Demonstration and Evaluation", LifeChamps will demonstrate and evaluate its digital solution in real oncology care settings and pragmatical conditions of older cancer patients. The key objective of WP7 is to design the specifications for the demonstration and evaluation of the feasibility, acceptability, and clinical value (this is a preliminary assessment) of the LifeChamps solution on the quality of life of older cancer patients and their current self-care routine. This work package contributed on specifying the evaluation framework pilots and measures to provide evidence to prove the applicability, usability, effectiveness and value of the LifeChamps concepts, models and methods in clinical, real-life infrastructures and realistic conditions.

In overall, the goal of WP7 is to:

- Deploy the developed LifeChamps solution in realistic pilots studies and conditions
- Define the evaluation framework of the LifeChamps pilots
- Demonstrate the usage of the LifeChamps solutions on the envisaged applications scenarios
- Evaluate the feasibility and acceptability of the envisioned improvements in the testing environments
- Create lessons learnt and adoption guidelines from the deployment of LifeChamps QOL solutions.

The structure of this White Paper is organized as follows:

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Section 2 presents the LifeChamps approach, objectives and solution.

Section 3 describes the LifeChamps preliminary data collection experiment.

Section 4 presents a brief overview of the final feasibility study.

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2. The LifeChamps Approach

2.1 Rationale and Objectives

LifeChamps is a collaborative research project funded by H2020 with 14 partners spread out over 10 countries [12]. These partners include small and medium-sized enterprises (SMEs), clinics, research centers, and universities. The LifeChamps project aims to deliver multidimensional Quality of Life (QOL) solutions for cancer survivors who have breast, prostate, or skin cancer. This research will target critical geriatric symptoms and disorders in older adults after cancer treatment using an artificial intelligence-based data analytics engine.

It collects data from Electronic Health records (EHRs), Patient Reported Outcomes (PROMs), wearables and smart home sensors, and a mobile app. Based on these data, it will provide health-coaching feedback to patients and monitoring trends and insights to healthcare professionals.

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The project aims to deliver an intelligent, personalized, and secure platform that will monitor patients' health outcomes, providing support and advice to patients. The main goal of the iterative assessments and improvements of the LifeChamps platform is to improve patients' quality of life. The LifeChamps solution aims to empower patients by providing them with personalised health-coaching suggestions and self-management educational material. At the same time, by providing a live overview of the patients' outcomes' progress, it will enrich the knowledge available to medical professionals, supporting them in their efforts to provide the best care possible to their patients.

The viability and applicability of the LifeChamps solution will be tested in four different pilot use case scenarios that include an equal number of countries. This process will be accomplished by conducting three separate investigations in parallel:

1. An initial ***preliminary data collection experiment*** to gather enough data to train the artificial intelligence analytics engine. This preliminary dataset will allow the testing of the prototype algorithms to check their predictive functionality during the main pilot use-case scenarios, which will make use of real patient-reported data, sensor data, and clinical data.
2. A ***feasibility study***, across four multi-national pilot use case scenarios, will attempt to validate the output of the artificial intelligence analytics engine through ground truth collection of PROMs, assess the usability and acceptability of older cancer patient mobile application and the effect of introducing the LifeChamps solution to the patients' everyday life and estimate its cost-effectiveness.

2.2 The LifeChamps solution

The LifeChamps digital platform, which makes use of a variety of digital health technologies, is designed to support geriatric oncology care. Using a significant range of different digital health technologies, LifeChamps aims to gather multi-modal data from PROMs, clinical records, and sensor inputs to be able to analyse and improve older cancer patients' outcomes. The LifeChamps digital platform's schema may be seen in Figure 1.

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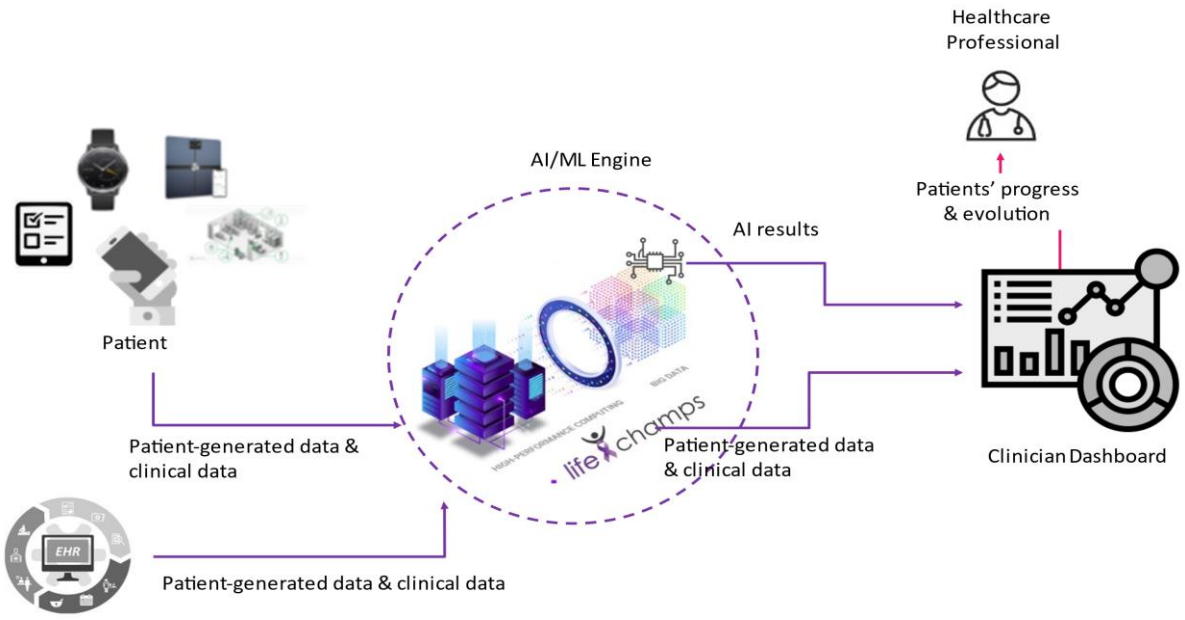

Figure 1. LifeChamps digital platform's Schema

In brief, the LifeChamps solution comprises of the following components:

- ***A mHealth app for patients***. The mHealth app for QoL assessment (hereafter mHealth app) has been developed by Adhera and provides the following support to the study's participants:
  - Educational content that addresses aspects related to their self-management with a focus on improving their self-efficacy.
  - Mental wellbeing exercises with a focus on helping them to better manage anxiety symptoms.
  - Motivational messages aiming at reinforcing health behaviors and healthy lifestyle in areas of potential improvement as identified by the set-up questions upon using the app.
  - In addition, participants will be asked to complete PROMs related to their diagnostic, physical and psychological status.
- ***Physiological/wearable devices for patients***. More specifically, the LifeChamps digital platform utilises two different such devices:
  - ***A smartwatch activity tracker*** (Fitbit) to monitor steps heart rate variability, sleep monitoring, breathing rate, skin temperature and SpO2.

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- ***A smart weighting scale*** (Withings) to measure weight and body composition.

- ***Home-located sensors to be installed in patients' homes.*** The LOCS home sensors (MySphera) will be automatically tracking patient ambulation and functioning on a daily basis. To enable data collection patients will be guided to wear a tag, however all data collection will be passive.
- ***The clinician dashboard for healthcare professionals.*** The clinician dashboard (hereafter LC Dashboard) will be installed on hospital-based desktops and be made available to participating healthcare professionals. It will integrate all data (i.e., data collected via PROMs, physiological/wearable devices, and EHR data) and their processing via an artificial intelligence analytics engine. The extracted knowledge from these, will be provided with advanced visualizations to healthcare professionals under the following three main functionalities:
  - ***Patient-level monitoring***: Visualise and monitor the information (i.e., vital signs, behavioral patterns, PROMs) reported by the patients through the mHealth app and the sensors.
  - ***Analytics monitoring***: Individualised results from the artificial intelligence clinical algorithms for each patient.
  - ***Cohort-level monitoring***: Results from the artificial intelligence clinical algorithms at a population level.
- ***The artificial intelligence/machine learning analytics engine.*** LifeChamps digital processing unit consists of a datalake, where all the different multi-modal data is stored, and a High Performance Computing (HPC) unit, which processes all the different artificial intelligence clinical algorithms, for each of the four pilot use case scenarios [12].

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3. Preliminary Data Collection

3.1 Rationale

The aim of this experiment is to facilitate the collection of real-world data to train the analytics engine for each prototype algorithm. Preliminary datasets will be generated to enable a dry run of the prototype algorithms to check their predictive functionality as part of simulated 'experimental' scenarios at each LifeChamps partner site. This preparatory work will be critical to the development of the LifeChamps platform, prior to progressing to the larger-scale feasibility trial.

During this experiment, prospective data from newly recruited participants and retrospective data from archived clinical datasets will be exploited to implement and train the prototype clinical algorithms of the artificial intelligence analytics engine. During the whole process, pilot sites will be contributing data as outlined in 0 below.

Table 1. Contribution of data for preliminary analysis by type of data and pilot partner

Pilot Site	Prospective			Retrospective/archival		
	PROM data	Sensor data	EHR/ Clinical data	PROM data	Sensor data	EHR/ Clinical data
AUTH	Yes	Yes	Yes	No	No	No
HULAFE	No	No	No	No	No	Yes
APC	No	No	No	Yes	No	No

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3.2 Objectives

There are two objectives in this study:

1. To test and train the prototype algorithms on the analytics engine, making amendments as necessary to enhance their predictive functionality.
2. To undertake a preliminary investigation of aspects of technology deployment, installation and implementation, participant recruitment, data collection, and technology usability.

3.3 Study Design

A pre-post study design will be employed, whereby the LifeChamps platform will be deployed for a total of 3 months.

Hospitals and clinical settings affiliated with three LifeChamps partners (AUTH, APC, HULAFE) will be involved in this study. UofG will coordinate the study and oversee compliance with the study protocol, and set timelines.

3.4 Inclusion and Exclusion Criteria

Older patients with a cancer diagnosis will be the target population for this study. Consecutive sampling will be used at each clinical site, whereby all older patients with cancer who meet the eligibility criteria will be approached and invited to the study.

Inclusion and exclusion criteria to be used across and within the partner sites are outlined in Table 2 and Table 3, respectively.

Table 2. Inclusion criteria for preliminary data collection

Inclusion Criteria	AUTH	HULAFE	APC
Cancer type	Breast or prostate cancer	Melanoma	Breast or prostate cancer

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Inclusion Criteria	AUTH	HULAFE	APC
Stage of cancer and diagnosis timeframe	-Diagnosed with early stage (I-III) cancer (breast, prostate) and living beyond initial cancer treatment (curative/incurable) -Diagnosed with advanced or metastatic disease with life expectancy >12 months - at least 1 month after a) local treatment with curative intent (surgery, radiotherapy) or b) initiation of systemic treatment (hormone treatment, CDK4/6 or new generation antiandrogens) -Absence of diagnosed secondary malignancy	Within 36 months from diagnosis and initial treatment Diagnosed with malignant melanoma (stage I-III) within 36 months previously. Has finished primary and secondary treatment and is now cancer free.	Locally advanced prostate cancer (Stage III) or breast cancer in treatment with curative intent. Diagnosed within 3 years prior to study participation
Age	≥65		
Functional and cognitive status	Deemed by a member of the multidisciplinary team as physically and psychologically fit to participate in the study Able to read, write and understand the respective local language Achieve a score of above 2 on the Mini-Cog during the screening process.		
Technological skills and smartphone availability	Able to bring and use own Android version 10 (or above) device during the study. Domestic 24/7 internet access via wi-fi and/or 4G mobile data (will be provided if unavailable)		
* Relevant only for the final feasibility study			

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Table 3. Exclusion criteria for preliminary data collection

Inclusion Criteria	AUTH	HULAFE	APC
Stage of cancer and diagnosis timeframe	-Currently receiving chemotherapy. -Terminal cancer stage on palliative care. -Survival prognosis of <18 months from the time of recruitment. -Unwilling to provide written informed consent.	-Terminal stage of cancer - prognosis of <18 months from the point of recruitment. -Major diagnosed mental or cognitive disorder affecting ability to participate in the study. -Unwilling to provide written informed consent.	-Terminal stage of cancer - prognosis of ≤18 months from the point of recruitment. -Presence of metastasis -Major diagnosed mental or cognitive disorder affecting ability to participate in the study. -Unwilling to provide written informed consent.
* Relevant only for the final feasibility study			

3.5 Participation Timelines

Each study participant will be involved in the study for 3 months in total. Depending on the pilot, a 3 to 5 month recruitment period will be allowed, bringing the total study duration to 6 months (from the first patient being enrolled until the last patient finishing data collection).

3.6 Sample Size

In line with current preliminary/feasibility studies guidance, each partner site will involve up to 20-30 participants. Up to 10 healthcare professionals will also be involved at each partner site to support recruitment of patients to the study.

3.7 Data Collection

Prospective data collection will involve a variety of sources, including the patient (patient-reported outcomes and sensor data from wearable devices), the home

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environment (home sensors, weight scales), and the clinical site (data routinely collected via the Electronic Health Record).

The frequency of data collection will depend on the nature of the data collected and is outlined in Table 4.

Table 4. Frequency of data collection per data source

Data source	Frequency of data collection	Duration of data collection
Patient-reported outcome measures via mobile app/ EU survey	Monthly	3 months
Wearable devices	Daily	3 months
Weight scales	Weekly	3 months
Home sensors	Daily	3 months
Electronic health records	Monthly	3 months
UV index data (APC only)	Daily	3 months

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3.8 Data Analysis

During an exercise that took place in WP4, several clinical questions were identified and filtered for each pilot site. These questions were relevant to each pilot's site focus.

AUTH: Understanding and predicting Treatment Tolerance,

APC: Multiple assessments of psychological and lifestyle factors,

HULAFE: Reduce mental burden and improve QOL for patients.

UoG: Predict the effects of the interaction between late/persisting treatment-related symptoms and multimorbidity/polypharmacy

The prototype algorithms that will be implemented and trained during this preliminary data collection experiment, materialise these clinical questions (i.e., AUTH, APC, HULAFE). Their final performance and clinical significance will be tested and assessed during the final, main feasibility study.

For example, the initial data from sensors will be refined, further with statistical, spectral and supervised learning analyses to identify and extract possible patterns (e.g., activities of daily living) inside their signals. Sensor, EHR and PROM data will be all analysed together through exploratory algorithms (e.g., pairwise markov random fields, bayesian networks) to identify possible interactions and dependencies among

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their trajectories, mapping the frailty and QOL domains of elderly prostate, breast and melanoma cancer patients across all the data collection process. Extracted features from sensors data, that can be considered as proxies/digital biomarkers for clinically relevant variables (e.g., patterns from a patient's movement, combining data from a smartwatch and room motion sensors, could be an indicator of the anxiety levels or fatigue of this person), will be validated in comparison to the related data from PROMs.

Some of these analyses (e.g., pre-processing analyses, final analytical models) will provide input for data-driven recommendations to the patient's mobile app, creating a digital frailty index, making the timely risk analysis and patient stratification on the clinicians' dashboard. The patients' progress and evolution will be analysed qualitatively and quantitatively using Process Mining techniques, and the clinicians will be able to monitor their patterns as well as their possible anomalies as a possible sign of a patient's QoL deterioration.

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4. Feasibility Study

4.1 Objectives

The feasibility study described in this document will be conducted at four different study sites: the Academic Primary Health Care Centre (APC), the Aristotle University of Thessaloniki (AUTh), the Medical Research Institute of Hospital La Fe (HULAFE), and the University of Glasgow (UoG). Each research location will enrol older cancer patients in a separate and independent manner to test and assess the LifeChamps digital platform. Each site will support a single-arm pre-post study, in which the enrolled patients will serve as both a self-control and an intervention arm, to determine the implement ability of LifeChamps digital oncology-care platform.

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The major goal of this study is to determine the parameters that influence the feasibility of a trial about the use of the LifeChamps digital platform in routine oncology-care settings. The study's secondary aims are to get early insights into whether there may be a substantial increase in the participants' Quality of Life, as well as whether the care offered can be more cost-effective than standard oncology care. The findings from both the main and secondary goals will serve as a direction for further study and development for the LifeChamps project in the future.

4.2 Study design

A single-arm pre-post study design will be used for the real-life pilot feasibility trial to allow for extended data collection before and after the period, during which the LifeChamps platform will be evaluated (see Table 6). This design allows minimising the effects of confounding factors due to between-subjects differences, such as age, gender, and level of education, by having all participants serve as self-controls.

The real–life pilot will take place over a 3-month period on the four pilot sites (UK, Sweden, Spain, and Greece), divided in three stages:

- **Pre-intervention (stage one)** target endpoint PROs will be collected for effectiveness/cost-effectiveness analysis purposes.
- **The intervention (stage two)** has a 3-month duration, with the bulk of data collection concerning feasibility, acceptability, usability, and adherence taking place in this period. Patients will be using the LifeChamps mHealth app, while Healthcare professionals will be using the Lifechamps Dashboard.
- **Post-intervention (stage three)** will be identical to the pre-intervention.

Table 5. Interrupted Time-Series Design Overview

Pre-intervention	Intervention	Post-intervention
T1 (Endpoint PROs)	X1X2X3X4 (monthly Intervention PROMs)	T2 (endpoint PROs)
	X1 X2 X3 X4....Xn	

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Pre-intervention	Intervention	Post-intervention
	(daily Fitbit, home sensor data, weekly weight)	
	X1X2X3X4 (monthly EHR data extraction) (monthly clinical team review)	
		End-user acceptance and evaluation (T3)
	Duration: 3 months	

At the end of the intervention (stage two), **a *small-scale end-user study*** for assessing the usability and acceptability of older cancer patient mHealth app will take place. During this assessment, at least fifty percent of participants (patients) included in the feasibility study will assess the LifeChamps applications in terms of their usability and acceptability.

4.3 Participants and Sample Size

The inclusion/exclusion criteria for recruited patients are similar to the ones described in **Section 3**. You can find a detailed presentation of them in Table 2 & Table 3.

The healthcare professionals that will participate can either be the attending oncology specialists (e.g., Geriatrician, Nurse) or doctors of the participating patients or not.

The total duration of participation for each individual taking part in the study will be up to 7 months.

In total, it is planned to recruit a total of up to 100 patients and 40 healthcare professionals across all pilot sites. Each pilot site will recruit up to 10 healthcare professionals, AUTH and APC will recruit up to 20 patients each, while HULAFE 30 patients and UofG will recruit up to 60 patients.

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4.4 Patient Identification and Recruitment Procedures

The patient recruitment method may vary on the setting/method (e.g., secondary, primary care/online advertisement) but will be recorded in a generic site recruitment log, which will be used and kept at each partner site. Each participant will be assigned a unique ID, which will be used across the LifeChamps solution. Patient recruitment and retention rates will inform the feasibility of this pilot study within the time period. A site recruitment log containing patient details (e.g., name, address, telephone number), or clinician details, will be the responsibility of each partner site and will be maintained accordingly to local ethics.

4.5 Screening

As part of the recruitment process, all potential participants will be screened against the Inclusion and Exclusion criteria, as well as, for clinical signs of cognitive impairment, using the mini-COG [12]. The mini-COG is a good screening tool for cognitive function and impairment. The mini-COG consists of a three-word recall and a clock-drawing test and can be completed within 5 minutes within the clinical setting. This will be conducted after consent is obtained. Patients scoring >2 on the mini-COG will be excluded as this indicates signs of cognitive impairment.

4.6 Healthcare Professionals Participants

Healthcare professionals (HCPs) that will participate in this trial will be introduced in the study at the intervention stage (Table 6) and will have access to the LC Dashboard, which will display the data monitored from the patient. The LC Dashboard will provide pseudonymised information regarding the patients' physical activity and patients' PROMs, from the data collected during the feasibility study. They will not be able to view real time processed information, such as risk of frailty, QoL, risk of dependency and psychological condition, from the LIFECHAMPS analytics engine. They will be shown the anonymised outputs of the analytics engine per patient and asked their opinions on whether such information would have helped better manage their patients' supportive care.

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HCPs will receive appropriate training to gain familiarity with accessing the LC Dashboard and asked to review patient involvement once a month.

4.7 Data Collection

The data collected during the feasibility study are separated in two categories, data collected across all pilot sites (***common data***) and data collected only for a specific pilot site (***site-specific data***). Common data will be used to investigate the feasibility and cost effectiveness of the project, while site-specific data will be analysed to test the prototype AI algorithms and investigate their clinical suitability for the clinical questions that may interest each pilot site individually.

The Anchor Point, Endpoint PROs and PROMS will be collected using the most feasible method and according to the European Centre for Disease Control (ECDC) guidelines due to the pandemic. The methods of collection will include live collection, online, over the telephone or via the mHealth app, depending on the stage of the study and the status of the COVID-19 pandemic.

4.8 Common Data

Data regarding participant demographics (e.g., level of education, income status, background occupation, presence of support), recruitment rate (patients consenting/patients approached), participant retention in the study, reasons for study discontinuation (if offered). Additionally, comprehensive log files of adherence to the protocol will be produced per patient, on a monthly basis.

Anchor points and endpoint PROs will be collected during the Pre/Post Intervention stages (see Table 6, Table 7).

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Table 6. Anchor points, PROs and PROMs collected during the Pre/Post Intervention stages

Instrument	Type	Use
European Quality of Life – Five Dimension – Five Level Version (EQ-5D-5L) [14]	Endpoint PROs	Quality of life assessment in the following 5 dimensions: Mobility; Self-care; Usual activities; Pain/discomfort; Anxiety/depression.
Functional Assessment of Cancer Therapy – General – 7 Item (FACT-G7) [15]	Endpoint PROs	Captures the top-rated symptoms and most relevant concerns to cancer patients
EORTC Quality of life Utility Measure – Core 10 Dimensions (QLU-C10D) [16]	Endpoint PROs	Measures QOL through 10 different dimensions: Physical (mobility); Role; Social and emotional functioning; Pain; Sleep; Appetite; Nausea; Bowel problems; Fatigue
Tilburg Frailty Indicator (TFI) [17]	Endpoint PROs	Asses the frailty level of the patient
Patient Health Questionnaire-4 (PHQ-4) [18]	PROMs	Allows the brief and accurate measurement of core symptoms/signs of depression and anxiety
revised Edmonton Symptom Assessment System (ESAS-r) [19]	PROMs	To assist in the initial assessment of the following nine symptoms: Pain; Tiredness; Drowsiness; Nausea; Lack of appetite; Depression; Anxiety; Shortness of breath; Well-being
Medical adherence Report Scale (MARS) [20]	PROMs	Describes non-adherent behaviours towards medication
Linear Analogue Scale Assessment (LASA) [21]	PROMs	Captures the patient's perceived level of functioning divided in 5 domain: Physical; Emotional; Spiritual; Intellectual; Overall
The Vulnerable Elders Survey (VES-13) [22]	PROMs	Screening older adults at risk of health deterioration on components such as age, self-rated health, limitations in physical function and disability

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4.9 Assessing the usability and acceptability of older cancer patient mobile application

During the ***small-scale end-user study***, the consortium partners will evaluate the usability and acceptability of the mHealth application. This assessment aims to acquire feedback from end-users during the solution-testing phase. Through this approach, the partners can improve the LifeChamps solution via consecutive sprints, taking into account the received feedback.

The end-users will evaluate the LifeChamps solution's performance in in-lab conditions. The evaluation plan will focus on the specification of an integrated evaluation framework reaching the intention to use, the quality of the end-user mobile application, and the overall impact on the QoL of end-users by setting measurable evaluation criteria and creating an evaluation procedure. It is also going to include the evaluation of the ''Patient involvement standard'' SS-EN 17398:2020, which connects to the LifeChamps Task 8.3: Contribution to standards.

The general goal of these usability tests will be to identify which interface facilitates the user's ability and motivation to navigate in the application. The design information flow and architecture will also be analysed based on the collection of both objective and subjective measures.

Tasks before the real-life feasibility pilots commence, involve the pre-evaluation/testing of the LifeChamps applications and consist of measuring:

i. The intention to use, and
ii. the quality of the patient mHealth application.

Patients will be given a list of tasks to test pre-selected functionalities of the mHealth application. Examples of these mobile functionality tasks include

a. login into the mHealth app,
b. selecting and reading a specific educational content, and
c. filling in a specific questionnaire.

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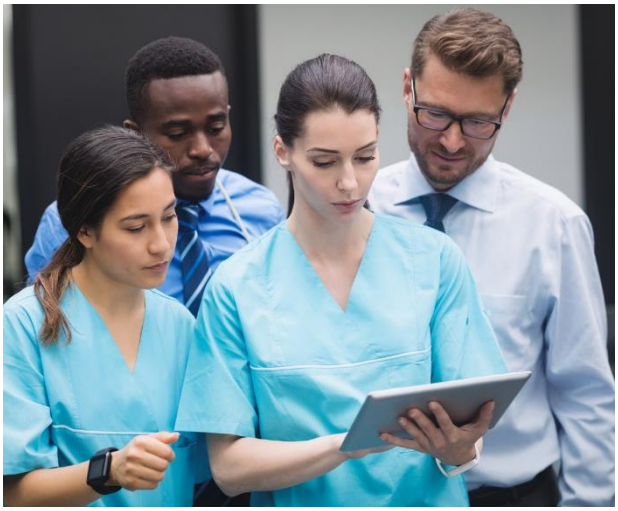
4.10 Effectiveness of LifeChamps intervention on person and care outcomes of end-users

The analysis of the effectiveness of the LifeChamps intervention on person and care outcomes of end-users will be evaluated in a quantitative and qualitative basis. The quantitative analysis will be done through the collection of endpoint PROs at pre-intervention and post-intervention (see Table 6), through the common endpoints for Quality of Life (FACT-G7 and EQ-5D-5L), and Frailty (TFI).

In addition, the qualitative analysis will assess the effectiveness of the complete LifeChamps solution and the appropriate care management achieved because of its use in the routine clinical care. This will be done through an online questionnaire and optional interviews.



All participants will be invited to participate in the evaluation process which will be collected via an online survey tool, i.e., the EUSurvey tool. Participants who answer the questionnaires will be invited to participate in a more in-depth interview to pick out detailed information and feedback about the effectiveness of the LifeChamps intervention.

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The effectiveness qualitative analysis will assess different categories: feasibility and acceptability of LifeChamps; care management efficiency; perceived workload management for healthcare professionals; perceived information integration; and suggestions for refinement and implementation. A detailed description of these categories is included in Table 7.

Table 7. Categories For Qualitative Effectiveness Evaluation

Category	Description	End-user
Feasibility/acceptability	Retrospective analysis collecting factors such as participants' attitudes towards the LC intervention, appropriateness, suitability, convenience, perceived effectiveness	Patients and HCP
Care management efficiency	Care management is the range of activities intended to improve patient care and reduce the need for medical services by helping patients more effectively manage health conditions	Patients
Perceived workload management for HCP	The **perceived workload**, also described as subjective or mental workload, is about how the workload is experienced on a psychological level	HCP
Perceived information integration	The extent by which the participants actively access the information and integrate it into their overall understanding of the situation and their preferences	Patients and HCP
Suggestions for refinement and implementation	Open ended suggestions from participants	Patients and HCP

4.11 Cost-Effectiveness Analysis

Four different cost-utility and cost-effectiveness/benefit analyses will take place, one for each pilot, comparing reporting outcomes of incremental cost per QALY. The

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evaluation of the Quality of Life will be conducted with the EQ-5D-5L, FACT-G7 (+ 4 questions from FACT-G) and QLU-C10D instruments as the ***numerators***. As ***denominators***, both the Direct and Indirect costs of the complete Intervention costs will be used.

Direct costs include *Development* costs, which are the same for all pilots and *Implementing* costs, that may differ for each pilot site. This happens because Implementing costs include set-up costs (i.e., set up of sensors, educating the end-user on using the LifeChamps app), 'visit costs' (i.e., contact nurse/doctor or other healthcare professional occupied for the intervention) and 'maintenance' costs (i.e., technical support in case of damage of the sensing tools).

Finally, indirect costs calculation will depend on the availability of data regarding sick leave, special insurance costs, etc. For the pilot sites where that information is not available in the EHR (i.e., AUTh), the medical consumption questionnaire of the Institute for Medical Technology Assessment (iMTA) will be performed.

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5. Conclusions

This Whitepaper, as part of a dissemination action, has provided an insight into the activities developed in LifeChamps within the scope of WP7. This work package is relevant to the study design that will train, test, and evaluate the technical performance, user usability and clinical significance of the LifeChamps solution.

The final part of the LifeChamps project involves the deployment and evaluation of the LifeChamps solution during three different parallel investigation processes. These multi-phase study design will allow us to:

- Train and test the performance of different artificial intelligence algorithms materialising clinical questions about the progression of the quality of life of older cancer patients.
- Assess and improve the usability of the mobile health app in an iterative manner, aiming to provide a rich and meaningful experience both to older cancer patients and oncology professionals.
- Evaluate whether and how the LifeChamps solution can be introduced and alter the current flow of follow-up geriatric cancer care and older cancer patients' self-management journey in a clinically significant, and cost-effective manner.

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