Seminars in Oncology Nursing 000 (2023) 151437

Contents lists available at ScienceDirect

Seminars in Oncology Nursing

journal homepage: https://www.journals.elsevier.com/seminars-in-oncology-nursing

A Smart Digital Health Platform to Enable Monitoring of Quality of Life and Frailty in Older Patients with Cancer: A Mixed-Methods, Feasibility Study Protocol

Nikolaos Papachristou[a,*,+], Panagiotis Kartsidis[a,+], Alexandra Anagnostopoulou[a,+], Rebecca Marshall-McKenna[b], Grigorios Kotronoulas[b], Gonzalo Collantes[c], Bernardo Valdivieso[c], Ana Santaballa[d], Antonio José Conde-Moreno[d], Juan Ramón Domenech[d], Emmanouil Kokoroskos[e], Panagiotis Papachristou[e,f], Petros Sountoulides[a], Sophia Levva[a], Kelly Avgitidou[a,g], Christiana Tychala[a,g], Costas Bakogiannis[a], Panos Stafylas[a,g], Zoe Valero Ramon[h], Andreia Serrano[i], Vânia Tavares[i], Luis Fernandez-Luque[j], Santiago Hors-Fraile[j], Antonios Billis[a,#], Panagiotis D. Bamidis[a,#]

[a] *Medical Physics and Digital Innovation Laboratory, School of Medicine, Aristotle University of Thessaloniki, Thessaloniki, Greece*
[b] *School of Medicine, Dentistry and Nursing, University of Glasgow, Glasgow, United Kingdom*
[c] *Medical Research Institute, Hospital La Fe, Valencia, Spain*
[d] *University and Polytechnic La Fe Hospital of Valencia, Valencia, Spain*
[e] *Academic Primary Health Care Centre, Region Stockholm, Stockholm, Sweden*
[f] *Department of Neurobiology, Care Science and Society, Division of Family Medicine and Primary Care, Karolinska Institutet, Stockholm, Sweden*
[g] *Healthink (Medical Research & Innovation, PC), Thessaloniki, Greece*
[h] *Universitat Politècnica de València, Valencia, Spain*
[i] *Capgemini Engineering, Lisbon, Portugal*
[j] *Adhera Health, Spain*

ARTICLE INFO

Key Words:
Cancer survivorship
Digital health
Feasibility study
Frailty
Geriatric oncology
Quality of life

ABSTRACT

Objectives: LifeChamps is an EU Horizon 2020 project that aims to create a digital platform to enable monitoring of health-related quality of life and frailty in patients with cancer over the age of 65. Our primary objective is to assess feasibility, usability, acceptability, fidelity, adherence, and safety parameters when implementing LifeChamps in routine cancer care. Secondary objectives involve evaluating preliminary signals of efficacy and cost-effectiveness indicators.

Data Sources: This will be a mixed-methods exploratory project, involving four study sites in Greece, Spain, Sweden, and the United Kingdom. The quantitative component of LifeChamps (single-group, pre-post feasibility study) will integrate digital technologies, home-based motion sensors, self-administered questionnaires, and the electronic health record to (1) enable multimodal, real-world data collection, (2) provide patients with a coaching mobile app interface, and (3) equip healthcare professionals with an interactive, patient-monitoring dashboard. The qualitative component will determine end-user usability and acceptability via end-of-study surveys and interviews.

Conclusion: The first patient was enrolled in the study in January 2023. Recruitment will be ongoing until the project finishes before the end of 2023.

Implications for Nursing Practice: LifeChamps provides a comprehensive digital health platform to enable continuous monitoring of frailty indicators and health-related quality of life determinants in geriatric cancer care. Real-world data collection will generate “big data” sets to enable development of predictive algorithms to enable patient risk classification, identification of patients in need for a comprehensive geriatric assessment, and subsequently personalized care.

* Address correspondence to: Nikolaos Papachristou, Aristotle University of Thessaloniki, Thessaloniki, Greece.
E-mail address: nikospapaxristou@gmail.com (N. Papachristou).
+ Joint first authors.
# Joint senior authors.

https://doi.org/10.1016/j.soncn.2023.151437

Introduction

Although age should not determine provision of anticancer treatment, emerging evidence shows that patients aged 65 or older are undertreated, with inequitable access to cancer care leading to worse outcomes.[1–6] Concerns around multimorbidity and frailty in older individuals require health professionals to make complex therapeutic decisions, which sometimes leads to compromise. To determine the effectiveness of anticancer treatment in geriatric oncology, the focus often is on the outcomes of morbidity or survival.[2–5] However, older patients with cancer, especially those in an advanced stage of their disease,[7] should be provided treatment options based on their personal preferences for health-related quality of life (HRQoL). [8] Such preferences (and associated needs) may significantly differ across patients and by determined by variables such as type of comorbidity or level of frailty.

Frailty is associated with poorer HRQoL in the general population of older adults,[9] and this is likely to be the case in geriatric oncology, too. Older patients with cancer are likely to deal with multimorbidity, which is linked to reduced functional status, increased health care use, longer hospital stays, and more complex psychosocial needs.[10] According to key studies,[11,12] systematic monitoring of frailty in geriatric oncology may provide unique insights into heightened patient susceptibility and risk stratification. Chen et al[13] posit that there is an urgent need for the systematic clinical application of well-structured assessments, such as the comprehensive geriatric assessment, to help distinguish those patients who are functionally fit and likely to benefit from more aggressive anticancer treatment from patients who are more functionally vulnerable.

A 2021 report issued by the International Society of Geriatric Oncology (SIOG) identified top priorities in advance care for older patients with cancer worldwide.[14] The inclusions of patient-reported outcomes (PROs) and geriatric-specific outcomes were identified as crucial objectives, with the onus on maintaining patient HRQoL and independence. HRQoL-focused assessment models can detect high-risk patients to enable provision of proactive support and reduction of long-term disability.[15] Today, it is possible to enhance patient risk profiling in cancer care[16] with the aid of information technology.[16–18]

Digital Health and Geriatric Oncology

With information technology, the use of big data analytics[19] enables health scientists to analyze large datasets on diverse factors that can affect HRQoL and disease progression in older patients with cancer,[20] evaluate interactions among such factors, and map the various and confounding degrees of effect among them. Health care systems and cancer care experts are beginning to recognize the opportunities presented by the expansion of digital technology.[21] Digital health technologies, inclusive of interactive dashboards, mobile apps, artificial intelligence (AI) chatbots, and web-based resources, can help simplify communication by facilitating access to real-time information.[22–24] Digital communication technologies may mitigate health inequalities that can arise due to insufficient access to care and poor communication between patients and clinicians. [25] Moreover, passive monitoring technologies, such as wearables and Internet of Things (IoT) sensors, can enable collection of hard-to-reach data at increased volumes and reduced cost[21] to supply more rich information on patient functionality and support clinical decision-making. More complex combinations of such technologies, such as smart houses, can even offer health professionals greater opportunity to remotely monitor patients' HRQoL (particularly those who are increasingly vulnerable, frail, or dependent) in their technology-enabled home environment,[26] which may enable preventative measures at the right time.

Although digital health has started to show the potential in various health-related settings and applications, there remains a gap in knowledge about how best to support older patients with cancer remotely and do this effectively. For instance, while remote symptom monitoring through patient-reported outcome measures (PROMs) has been shown to be beneficial in chronic diseases such as heart failure, its application in geriatric oncology is less prominent.[26] It is conceivable that older patients with cancer might face challenges with digital health literacy, self-reporting burden, or lack of Internet access. Notably, IoT interventions have the capacity to leverage objective patient-generated metrics to enable real-time monitoring of symptoms, even for patients who may not be able to complete self-reported questionnaires. Combining all the above with AI algorithms and smart applications can provide new possibilities for enhanced monitoring of well-being in older patients with cancer across the cancer trajectory.[24,27]

Co-designing Digital Health Technologies

Digital health technologies hold significant potential. At a minimum, the option to use the Internet to source cancer-related information and connect with peers has been linked to patients reporting greater intention to be involved in their care process.[28,29] Consequently, active involvement in one's own care brings with it better health outcomes, more favorable treatment experiences, and lower health care costs.[30] A direct effect is that stakeholder participation has swiftly emerged as a critical component in the development of cancer programs[31,32] and co-design of health care interventions.[33,34] Indeed, digital health technologies (particularly those that are AI powered) require rigorous investigation in areas related to user interface design, integration of different types of sensors, development of AI algorithms, and clinical validation. This endeavor involves close collaboration with key stakeholders, including patients, families, and health professionals. A promising approach is the design and development of digital health technologies as part of an integrated care approach that heavily involves stakeholders (also known as technology end-users) from inception to implementation and in direct response to their context, preferences, priorities, and abilities.[29] Many of these aspects are being incorporated in the current study protocol.

LifeChamps: A Collective Intelligence Platform for Supportive Geriatric Oncology

With 15 partners from 10 different countries, LifeChamps is a 3-year European Union-funded Horizon 2020 project (https://lifechamps.eu/). LifeChamps aspires to offer a novel digital health platform that is data-centric, intelligent, and integrated to support older patients with cancer and enhance clinician monitoring. The design, development, and evaluation of the platform will be performed with active participation and feedback from patients and clinicians,[35] in line with current guidelines for co-design in healthcare services.[33,34] LifeChamps focuses on the integration of diverse clinical tools and digital technologies, including PROMs, clinical data from the electronic health record (EHR), wearables, IoT sensors, and digital health applications including a smartphone application for patients and a web dashboard for health professionals.[36] In parallel, AI algorithms will be developed using big data analytics and explore their predictive capacity in terms of frailty and HRQoL.

Research Objectives

The primary objective of this project is to establish feasibility, usability, acceptability, fidelity, adherence, and safety parameters when deploying the LifeChamps digital platform within routine cancer care.

Secondary objectives include evaluation of preliminary signals of efficacy on key PROs and cost-effectiveness indicators. Our findings

will collectively guide future research and development of the LifeChamps platform.

Methods

Study Setting

The project will involve older patients with cancer and health professionals at four study sites across four European countries:

- Academic Primary Health Care Centre (APC) in Sweden
- Aristotle University of Thessaloniki (AUTH) in Greece
- Medical Research Institute of Hospital La Fe (HULAFE) in Spain
- Beatson West of Scotland Cancer Centre (BWoSCC)/University of Glasgow (UofG) in the United Kingdom

Overview of the LifeChamps Digital Platform

The LifeChamps digital platform consists of diverse technologies, summarized in Figure 1 and expanded on in Table 1. These include the following:

- Smartphone application (powered by Adhera Health)[37]
- Wearable and physiological monitoring devices for patients
- Motion sensors installed in patients' homes (https://www.mysphera.com/locs/)
- Digital dashboard for clinicians[36]
- AI and big data analytics engine[38]
- IoT Edge device
- AI-based clinical monitoring algorithms

Study Design

Within an overarching mixed-methods approach, a single-group, pre-post feasibility study design will be adopted. This will allow for data collection before, during, and after the time when the LifeChamps platform will be deployed (Table 2) and a better capacity to attribute changes in outcomes measured before the application of the LifeChamps platform to measures collected after it can be achieved. In addition, by having all participants function as self-controls, this design makes it possible to limit the effects of confounding variables that are caused by variations between the individuals being studied, such as age, sex, and level of education.

The study will run for 14 weeks over three consecutive phases (Table 2).

- Predeployment phase – Target endpoint PROMs will be collected for clinical effectiveness and cost-effectiveness analyses prior to deployment.
- Deployment phase – For 12 weeks, data on feasibility parameters will be collected at the same time as the LifeChamps digital platform is deployed. Patients will use the smartphone app and IoT sensors. Clinicians will use the clinician dashboard to monitor patients' progress.
- Postdeployment phase – Same as the predeployment phase, with the addition of data collected on the Global Rating of Change Scale (GROC) and the evaluation process composed of a qualitative investigation with all participants (patients and health professionals) via an online survey, and optional interview, to evaluate acceptability, usability, practicalities, and their perceived impact and effectiveness of the LifeChamps digital platform.

Patient Eligibility Criteria

Generic and site-specific patient eligibility criteria have been devised (Tables 3 and 4) to account for similarities and differences in target patient populations and logistics across the four participating sites. The criteria have been devised with attention to patients' age, cancer type, stage of cancer and diagnosis timeframe, functional and cognitive status, health literacy skills, and smartphone availability.

Sample Size

A total of up to 160 patients and 40 health professionals will be recruited across the study sites. AUTH and APC will recruit a maximum of 20 patients each, while HULAFE and UofG will recruit up to 60 patients. Each study site will enroll a maximum of 10 health professionals. Sample sizes are in line with current recommendations for sample size estimation for feasibility studies.[39,40]

Recruitment Procedures

Recruitment will take place over a period of 5 months. As part of recruitment, patients will be screened for cognitive function and

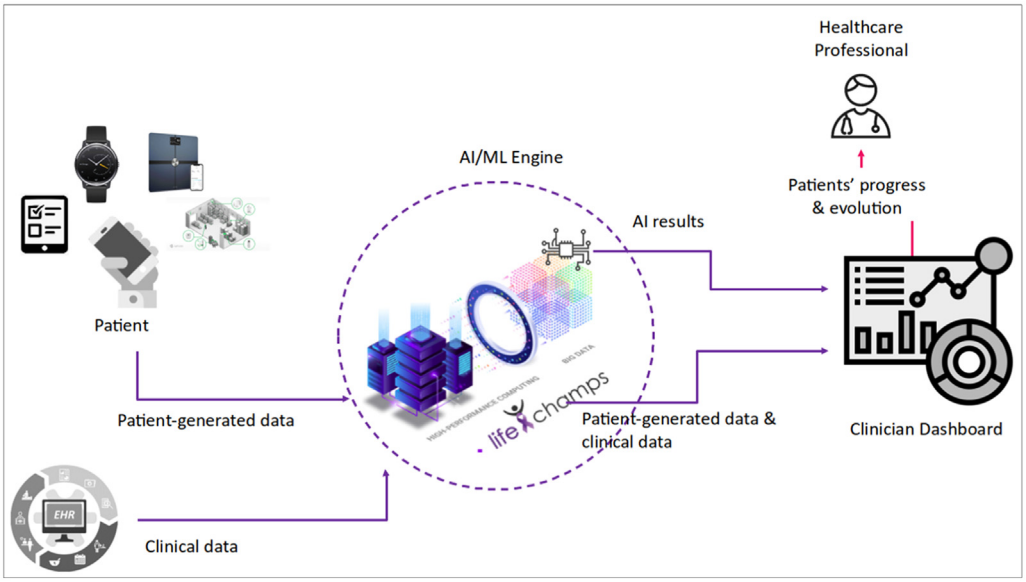

FIG. 1. LifeChamps integrated digital platform.

TABLE 1
Description and Purposes of the Digital Technologies Involved in LifeChamps.

LifeChamps technologies	Description	Purpose
Smartphone application for patients	Mobile application (powered by the Adhera Health Recommender System) for Android version 10 or above; to be installed on patients' own smartphones. (See Supplementary file 1)	• Provision of educational material on self-management to support patients' sense of self-efficacy • Access to activities to help manage anxiety and enhance emotional well-being • Motivational messages sent to reinforce healthy behaviors in areas of potential improvement • Data collection via use of PROMs on patients' physical and psychological status
Wearable and physiological monitoring devices for patients	• Smart weight scales (Withings Body+) • Wristwatch activity tracker (Fitbit Charge 4) Associated mobile apps to be installed on patients' own smartphones	• Withings Body+: assess weight and body composition • Fitibit Charge 4: monitor physical activity, heart rate, sleep quality, breathing rate, skin temperature, and SpO_2
Motion sensors for patients	MySphera LOCS sensors to be installed in patients' homes. Four infrared sensors, a smart plug, and a tag	Passively monitor a patient's ambulation and functionality on a daily basis. Patients will be encouraged to wear a tag to facilitate data collection
Digital dashboard for clinicians	Desktop application to be made accessible to participating health professionals and installed on computers at each study site. The dashboard will incorporate EHR data, PROMs data, and data from physiological/wearable devices. The dashboard will use cutting-edge visualisations to present clinicians with processed data via the AI analytics engine.	• Patient-level monitoring to visualize and monitor patient data collected via the smartphone app and sensors • Analytics monitoring to showcase data from the AI algorithms for each patient • Cohort-level monitoring to provide data from the AI algorithms at a group level
AI and big data analytics engine	The digital processing engine of LifeChamps comprises a datalake and a high-performance computing unit	The datalake stores multimodal data, and the high-performance computing unit executes all the clinical artificial intelligence algorithms for each one of the four pilot use case scenarios
IoT Edge device	A Raspberry Pi will be used as an IoT edge device. Raspberry Pi is a small, low-cost computer (attached to the Internet router in the patient's home) that can be deployed for many IoT applications	A hub that collects data and deploys relevant services, including: • The Edge Analytics Engine for preprocessing and computations on the Edge. • A MQTT Client • Local temporary storage • Gateway services that interact with the sensors or collect wearable and weight scale data from third-party APIs
AI-based clinical monitoring algorithms	Prototype algorithms will be implemented and trained during a preliminary data collection experiment; materialize clinical questions that were identified and filtered for each pilot site	Site-specific as follows: • AUTH: understanding and predicting treatment tolerance • APC: multiple assessments of psychological and lifestyle factors • HULAFE: reduce mental burden and improve quality of life for patients • UofG: predict the effects of the interaction between late/persisting treatment-related symptoms and multimorbidity/polypharmacy

Abbreviations: IoT = Internet of Things; MQTT = Message Queuing Telemetry Transport; APC = Academic Primary Health Care Centre, Sweden; AUTH = Aristotle University of Thessaloniki, Greece; HULAFE = Medical Research Institute of Hospital La Fe (HULAFE), Spain; UofG = University of Glasgow, United Kingdom.

cognitive impairment using the mini-COG.[41] In a clinical setting, the mini-COG can be completed in 5 minutes. This assessment will be carried out by the researcher following written informed consent. In the event that a patient's score is less than 3 out of 5, they will be excluded from the study and referred to their clinical team for a more in-depth cognitive assessment. Depending on the care setting or the advertisement technique (eg, secondary, primary care/online advertising), the approach to patient recruitment will differ as explained here.

Academic Primary Health Care Centre (APC) in Sweden

Potential participants will be identified by clinical partners in primary and secondary care in Region Stockholm. Clinicians (primary care physicians, nurses, dermatologists, oncologists, surgeons, and radio-oncologists) will inform the potential participant about the study during the first follow-up meeting, or immediately following primary treatment, and determine whether they are eligible to take part. APC will also distribute online advertisements and recruit volunteers via project partners (eg, Karolinska Institute)

TABLE 2
Overview of the Pre-Post Study Design Used in LifeChamps.

Phase	Predeployment	Deployment	Postdeployment
Time-points and assessments involved	Endpoint PROMs	• Monthly patient evaluation PROMs •Daily activity tracking and home sensor data •Weekly weight measurement •Monthly EHR data extraction •Monthly clinical team review	•Endpoint PROMs •GROC •Evaluation acceptability, useability, and perceived impact
Duration of data collection	One-off, immediately before patient participation begins	Continuous for 12 weeks	One-off, within 2 weeks after the end of patient participation

Abbreviations: GROC = Global Rating of Change Scale; PROMs = patient-reported outcome measures.

TABLE 3
LifeChamps Patient Inclusion Criteria.

Inclusion criteria	AUTH	APC	HULAFE	UofG
Cancer type	Breast or prostate cancer	Melanoma	Breast or prostate cancer	Breast or prostate cancer
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 malignant melanoma (stage I-IV) within 5 years previously	Diagnosed within 3 years prior to study participation	Diagnosed with metastatic breast cancer or prostate cancer on androgen with a prognosis of ≥18 months from the point of recruitment
	Diagnosed with advanced or metastatic disease with life expectancy >12 months	Has finished primary treatment	Locally advanced prostate cancer (Stage III) or breast cancer in treatment with curative intent	Diagnosed at least 6 months prior to participation in the trial
	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 anti-androgens)			About to finish or has finished primary treatment for the respective cancer type, i.e. surgery and/or chemotherapy and/or radiotherapy
	Absence of diagnosed secondary malignancy			
Age	≥65	≥65	≥65	≥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 3 or above 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).			

Abbreviations: APC = Academic Primary Health Care Centre in Sweden; AUTH = Aristotle University of Thessaloniki in Greece; HULAFE = Medical Research Institute of Hospital La Fe in Spain.

TABLE 4
LifeChamps Patient Exclusion Criteria.

Exclusion criteria	AUTH	APC	HULAFE	UofG
Stage of cancer and diagnosis timeframe	Terminal stage of cancer	Terminal stage of cancer	Terminal stage of cancer	Terminal stage of cancer
	Prognosis of <18 months from the point of recruitment	Prognosis of <18 months from the point of recruitment	Prognosis of <18 months from the point of recruitment	Prognosis of <18 months from the point of recruitment
		Current diagnosis of major mental or cognitive disorder affecting ability to participate in the study	Current diagnosis of major mental or cognitive disorder affecting ability to participate in the study	Current diagnosis of major mental or cognitive disorder affecting ability to participate in the study
		Unwilling or unable to provide written informed consent	Unwilling or unable to provide written informed consent	Unwilling or unable to provide written informed consent
	Currently receiving chemotherapy		Presence of metastasis	
	Patients with an internal medical fitted device (eg, pacemaker)	Patients with an internal medical fitted device (eg, pacemaker)	Patients with an internal medical fitted device (eg, pacemaker)	Patients with an internal medical fitted device (eg, pacemaker); any known allergies to metal or plastic

Abbreviations: APC = Academic Primary Health Care Centre in Sweden; AUTH = Aristotle University of Thessaloniki in Greece; HULAFE = Medical Research Institute of Hospital La Fe in Spain.

or the Swedish melanoma patient organization (Melanomföreningen), who will be directed to an online recruitment form within Region Stockholm. In the event of inadequate recruiting, online marketing will be carried out as well via public channels such as newspapers, with the goal of leading potential participants to the contact form on the website.

Aristotle University of Thessaloniki (AUTH) in Greece

Potential participants will be identified at the Department of Medical Oncology at Georgios Genimatas General Hospital, the Department of Medical Oncology at Papageorgiou General Hospital, the non-profit organization “Alma Zois” for patients with breast cancer based in Thessaloniki, Greece, and private cancer practices.

Medical Research Institute of Hospital La Fe (HULAFE) in Spain

Potential participants will be selected by the principal investigator or the delegated nurse(s), doctor(s), or researcher at Medical Research Institute of Hospital La Fe, Valencia via use of HULAFE's information technology systems.

University of Glasgow (UofG) in the United Kingdom

Potential participants will be identified from outpatient case load lists maintained by clinicians at the Beatson West of Scotland Cancer Centre (BWoSCC) and affiliated clinics within NHS Greater Glasgow and Clyde. The researcher will be reviewing case notes to identify potential participants, confirm eligibility, and refer those who are eligible to the clinical team (eg, oncologist, clinical nurse specialist) to make first contact with the patient.

Outcomes

Primary Outcomes

In line with our primary objective, we will aim to answer the following research questions to evaluate related outcomes:

- Is patient recruitment possible in terms of numbers and rates within the recruitment period?
- Is participant retention in the study possible in terms of numbers and rates?
- Do participants adhere to the protocol?
- How many short questionnaires and PROMs does each patient access per day/month?
- How many PROMs does each user complete per day/month?
- How many educational units does each patient complete per day/month?
- How many short questionnaires or quizzes does each patient complete per day?
- How much time does a patient spend every day using the LifeChamps technology? Is this increasing or decreasing during the study participation period?
- Is data integration within the LifeChamps platform possible?
- Can predictive modeling data be generated?
- Can predictive modeling data be (reliably) provided to clinicians via the clinician dashboard?
- What are the views/experiences of study participants (i.e., patients, healthcare professionals) following use of the LifeChamps digital platform?
- What were the adherence levels to using the different technologies from the patient's perspective?

Secondary Outcomes

In line with our secondary objectives, we will aim to address the following research questions to evaluate related outcomes:

- What is the change in scores/response between endpoint PROs measured before and after deployment of LifeChamps?
- Is there any signal of economic impact from the use of the LifeChamps platform?

Outcome Evaluation and Measures

Primary Outcomes

Generic recruitment log. This log will be used to collect data on patients approached/patients consenting, reasons for declining if offered. No identifiable information is recorded on the generic recruitment log. Data will be pseudonymized and entered onto an Excel spreadsheet.

Site master folder. This folder will include separate password-protected Excel files for the site-specific log with identifiable information regarding patients who have been contacted (eg, name, address, e-mail address, mobile phone number) and those patients who have consented to participate in this feasibility study (eg, their LifeChamps identification number).

Technology log. This log will be used to document any problems or participant issues with the digital components and the need for troubleshooting will be recorded on an Excel file and remotely monitored and logged by technical partners involved in the distribution/management of the technology to use in this feasibility study.

Postdeployment evaluation. This evaluation will determine perceived acceptability and usability of the LifeChamps digital platform. Patient and health professional participants will be provided with a range of activities to evaluate functions of relevant components of the LifeChamps digital platform. A few examples of mobile functionality tasks for patients will be (1) logging into the app, (2) choosing and reading a certain piece of educational material, and (3) filling out a particular PROM. For health professionals, reviewing the responses of a patient to a PROM or checking how two different groups of patients compare on mobility statistics will be included as example tasks for evaluation. Subsequently, each participant will be assessed on their capacity to learn performing the tasks, as well as their efficiency, effectiveness, and memorability (Table 5). These four measurements were selected because they constitute proxies for the perceived usefulness (efficiency and effectiveness) and for the perceived ease of use (learnability and memorability).

Following completion of these activities, a customized questionnaire (see Supplementary file 2), which is based on the Technology Acceptance Model (TAM),[42] will be administered to patients and health professionals to gather information on perceived utility, ease of use and subjective norms (eg, use of the application after receiving appropriate training). Technology usability and acceptability will be further examined with the System Usability Scale[43] (health professionals) and the Mobile App Rating Scale[44] (patients). Finally, we will evaluate how effectively the various components of the digital platform were used as an indicator of both usability and utility. For example, we will look at the percentage of educational units that were finished, the ratings of motivational messages, and how well participants adhere to the PROM schedule.

The efficiency of care management, perceived workload management for health professionals, perceived information integration, and suggestions for refinement and implementation will also be evaluated via bespoke paper or online surveys[45] and optional interviews (Table 6). A sample of the questions for these interviews are provided in Supplementary file 3.

Secondary outcomes

At pre- and post-deployment, patients will be required to complete the following endpoint PROMs and an anchor point questionnaire to establish early signals of efficacy.

European Quality of Life Scale (EQ-5D-5L)[53]. The EQ-5D-5L comprises the EQ-5D descriptive system and the EQ visual-analog scale (VAS). In the descriptive system, there are five dimensions: mobility, self-care, typical activities, pain/discomfort, and anxiety/depression. Each dimension is divided into five levels: no difficulties, minor problems, moderate problems, severe problems, and extreme problems. In each of the five dimensions, the patient is asked to identify his or her health status by selecting the checkbox next to the most relevant statement in each category. The EQ VAS measures the patient's self-rated health on a vertical visual analog scale. The EQ VAS can be used as a quantitative measure of health outcome that reflect the patient's own judgment.[59]

TABLE 5
Attributes for Postdeployment Evaluation.

Attribute	Description	Type of measure
Efficiency	The degree of how fast users can accomplish a task	Task completion time (s) for an experienced user
Effectiveness	The accuracy and completeness with which users achieve specified goals	Task completion ratio (%) for an experienced user
Learnability	The degree to which users can easily finish a task when using an application for the first time	Task completion time (s) and taskcompletion ratio (%) for the first time
Memorability	The level of ease with which users can recall how to use an application after not using it for some time	The time duration (s) to work successfully after avoid using an app for some days

Functional Assessment of Cancer Therapy (FACT-G7)[54]. The FACT-G7 is a condensed, seven-item version of the FACT-G that is intended to capture the most significant concerns for patients with cancer in a quick, valid, and reliable way. Using the FACT-G7, clinicians and researchers can quickly analyze the most often reported symptoms and concerns for a wide range of cancers in clinical practice and research.[54] Four extra questions will be used in addition to the FACT-G7 to increase specificity and support the cost-effectiveness analysis: I get emotional support from my family; I get support from my friends; I feel sad; I am able to work (include work at home).

EORTC Quality of life Utility Measure - Core 10 Dimensions (QLU-C10D)[55]. The QLU-C10D is a cancer-specific, multiattribute utility instrument that can be used for health economic evaluations in cost-utility analyses.[55] It consists of 12 items that are answered on a four-point Likert-type scale and represent ten different dimensions such as physical (mobility), role, social, and emotional functioning, pain, sleep, appetite, nausea, bowel problems, and fatigue. The most often encountered utility instruments are general, that is, they only address the broadest parts of their respective functions. The QLU-C10D is believed to better capture the symptoms and functional features of patients with cancer, as well as to be more sensitive in this patient group than other utility instruments.[60,61]

Tilburg Frailty Indicator (TFI)[56]. The TFI consists of 15 items, answered Yes, No, or Sometimes. The TFI has robust evidence of reliability and validity among 38 frailty assessment instruments.[62] A recent validation of the TFI revealed it as a prognostic factor for disability and increased utilization of health resources.[56]

Global Rating of Change Scale (GROC)[57,58]. The GROC[57,58] will be tailored to specific domains of well-being to support detection of significant changes. Domains of interest will be (1) change in total human resource quality of life; (2) physical health and well-being; (3) social and family well-being; (4) emotional health and well-being; and (5) a sense of functional well-being.

Ethics

In accordance with requirements of European Union and state legislation, the Declaration of Helsinki, the Oviedo Convention on Human Rights and Biomedicine, and the European Code of Conduct for Research Integrity, this protocol has been submitted for ethical approval to all four study sites:

- Swedish Ethical Review Authority for APC (Registration No. 2022-00562-01)
- Research Ethics & Deontology Committee for AUTH (Registration No. 267203/2022)
- Ceim Hospital Universitario y politécnico la Fe for HULAFE (Registration No. 2019-157-1)
- East of Scotland Research Ethics Committee HRA for UofG (Registration No. INGN21HS566)

All participants will be given a study summary leaflet, participant information sheet (PIS), and consent form to read and sign if interested in taking part. The PIS will make it explicit that LifeChamps is not a medical device and will not replace standard care, and in the case of any issues or emergencies, patient participants should always contact their clinical team. The PIS will also confirm that patients who decide to decline at the consent stage or withdraw after providing consent will have no impact on treatment or care services they receive from their clinical team.

Patient and Public Involvement

Involving patients/public living with cancer in the creation and use of digital platforms in their health care, which may assist them in preserving their well-being, in accordance with their preferences, is considered a promising approach toward an integrated care strategy. The European Cancer Patient Coalition (ECPC), a partner in the LifeChamps project, is engaged by providing input and feedback on development of the LifeChamps platform, via attendance at meetings, workshops, and reviewing recruitment materials.

TABLE 6
Target Domains for Postdeployment Evaluation.

Domain	Description	Involved participants
Feasibility/acceptability[46,47]	Retrospective analysis collecting factors such as participants' attitudes toward the LifeChamps digital platform, appropriateness, suitability, convenience, perceived effectiveness	Patients and health professionals
Care management efficiency[48,49]	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[50,51]	The perceived workload, also described as subjective or mental workload, is about how the workload is experienced on a psychological level.	Health professionals
Perceived information integration[52]	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 health professionals
Suggestions for refinement and implementation	Open-ended questions regarding enhancement of implementation strategies for a future larger-scale study and to refine the digital platform	Patients and health professionals

Data Analysis

Feasibility Parameters

We will use descriptive statistics applied to the quantitative data. Specifically, we will implement three major types of descriptive statistics measures: measures of frequency, measures of central tendency, and measures of dispersion or variation. Additionally, we will inspect how demographic information (eg, age, education level, economic status) is associated with the collected data. The profile of participants, including sex, age, clinical status, geographical situation, and level of education, will be covered during data analysis.

Acceptability Parameters

Qualitative data obtained via surveys and the interviews will be analyzed, interpreted, and discussed, combining an inductive and deductive approach, via content analysis to identify commonalities and patterns in the data.

Efficacy

We will use descriptive statistics applied to the quantitative data via use of measures of frequency, central tendency, and dispersion. Change in patients' endpoint PROM scores from before to after deployment will be calculated, and statistical comparisons for paired data will be carried out.

Economic Evaluation

The economic evaluation will include three categories of costs depending on the availability of data: direct costs (eg, medical visits, hospital admissions, lab tests), indirect costs (eg, productivity loss due to morbidity) and technology-related costs (eg, setting up the sensors, educating the end-users on using the smartphone app, technical support). The outcome of the cost-effectiveness analysis will be the incremental cost-effectiveness ratio expressed as incremental cost in euros per incremental effectiveness in QALYs. The estimation of QALYs will be based on the EQ-5D-5L.[53]

Results

By March 2023, the study protocol had received approval at all four study sites. Recruitment began in January 2023 and is projected to run until September 2023. Currently, 31 patients have been successfully enrolled, with 16 patients having the LifeChamps digital platform fully installed in their homes. Insights from and patterns in the collected data will enable full testing of the LifeChamps digital platform in a real-world environment. Results will be published in high-profile, peer-reviewed journals and disseminated widely via scientific and cancer patient organizations (e.g., SIOG, ECPC).

Conclusion

LifeChamps constitutes one of the first attempts at integrated care digital systems for older patients with cancer. LifeChamps is in line with recommendations published by SIOG regarding the inclusion of PROMs that are relevant to older adults, as well as geriatric-specific outcomes into routine cancer care.[14] Our goal is to integrate digital technologies within a collaborative, intelligent care service paradigm to achieve a comprehensive and systematic evaluation of patient outcomes in geriatric oncology. Such a model has potential for early detection and management of adverse events and pressing health needs among older patients with cancer.

A significant question to address is how older adults with cancer and clinical teams can be successfully included in the design, development, and deployment of digital health interventions and what they perceive as meaningful support from using them. With rigorous testing and careful attention to clinical context and resources, it is possible that in the future AI digital technologies like LifeChamps will reach implementation stage in geriatric oncology to help collect, store, integrate, and distribute big data information from various sources to allow closer and more sophisticated patient monitoring and supported clinical decision-making. This study will allow us to extract knowledge for the refinement of the platform and extract knowledge for providing standards and recommendations for future, similar digital interventions.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

LifeChamps is funded by the Horizon 2020 Framework Programme of the European Union for Research Innovation (Grant 875329).

SALUMEDIA, as part of Adhera Health Inc, commercializes solutions for supporting people across different therapeutic areas including oncology.

Salumedia Labs is Adhera Health's wholly owned European subsidiary focused on the development of Adhera Health's scientific foundation and research.

The authors declare no conflict of interests.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.soncn.2023.151437.

References

1. Dharmarajan KV, Presley CJ, Wyld L. Care disparities across the health care continuum for older adults: lessons from multidisciplinary perspectives. *Am Soc Clin Oncol Educ book Am Soc Clin Oncol Annu Meet*. 2021;41(41):1–10.
2. Schroyen S, Adam S, Jerusalem G, Missotten P. Ageism and its clinical impact in oncogeriatry: state of knowledge and therapeutic leads. *Clin Interv Aging*. 2015;10:117.
3. Popescu T, Karlsson U, Vinh-Hung V, et al. Challenges facing radiation oncologists in the management of older cancer patients: consensus of the International Geriatric Radiotherapy Group. *Cancers*. 2019;11(3):371.
4. Swaminathan D, Swaminathan V. Geriatric oncology: problems with under-treatment within this population. *Cancer Biol Med*. 2015;12(4):275–283.
5. Le Saux O, Falandry C. Is there an age threshold for holding off on testing novel therapies? *Curr Oncol Rep*. 2018;20(1).
6. Sedrak MS, Freedman RA, Cohen HJ, et al. Older adult participation in cancer clinical trials: a systematic review of barriers and interventions. *CA Cancer J Clin*. 2021;71(1):78–92.
7. Peppercorn JM, Smith TJ, Helft PR, et al. American Society of Clinical Oncology statement: toward individualized care for patients with advanced cancer. *J Clin Oncol*. 2011;29(6):755–760.
8. DuMontier C, Loh KP, Soto-Perez-de-Celis E, Dale W. Decision making in older adults with cancer. *J Clin Oncol*. 2021;39(19):2164–2174.
9. Crocker TF, Brown L, Clegg A, et al. Quality of life is substantially worse for community-dwelling older people living with frailty: systematic review and meta-analysis. *Qual Life Res*. 2019;28(8):2041–2056.
10. Dambha-Miller H, Simpson G, Hobson L, et al. Integrating primary care and social services for older adults with multimorbidity: a qualitative study. *Br J Gen Pract*. 2021;71(711):e753.
11. Hamaker ME, Jonker JM, de Rooij SE, Vos AG, Smorenburg CH, van Munster BC. Frailty screening methods for predicting outcome of a comprehensive geriatric assessment in elderly patients with cancer: a systematic review. *Lancet Oncol*. 2012;13(10):e437–e444.
12. Audisio RA, Van Leeuwen B. When reporting on older patients with cancer, frailty information is needed. *Ann Surg Oncol*. 2010;18(1):4–5.
13. Chen RC, Royce TJ, Extermann M, Reeve BB. Impact of age and comorbidity on treatment and outcomes in elderly cancer patients. *Semin Radiat Oncol*. 2012;22(4):265–271.
14. Extermann M, Brain E, Canin B, et al. Priorities for the global advancement of care for older adults with cancer: an update of the International Society of Geriatric Oncology Priorities Initiative. *Lancet Oncol*. 2021;22(1):e29–e36.
15. Williams GR, Dunham L, Chang Y, et al. Geriatric assessment predicts hospitalization frequency and long-term care use in older adult cancer survivors. *J Oncol Pract*. 2019;15(5):e399–e409.
16. Warrington L, Absolom K, Conner M, et al. Electronic systems for patients to report and manage side effects of cancer treatment: systematic review. *J Med Internet Res*. 2019;21(1):e10875.

17. Rincon E, Monteiro-Guerra F, Rivera-Romero O, Dorronzoro-Zubiete E, Sanchez-Bocanegra CL, Gabarron E. Mobile phone apps for quality of life and well-being assessment in breast and prostate cancer patients: systematic review. *JMIR mHealth Uhealth*. 2017;5(12):e187.
18. Loh KP, McHugh C, Mohile SG, et al. Using information technology in the assessment and monitoring of geriatric oncology patients. *Curr Oncol Reports*. 2018;20 (3):1–9.
19. Willems SM, Abeln S, Feenstra KA, et al. The potential use of big data in oncology. *Oral Oncol*. 2019;98:8–12. https://doi.org/10.1016/J.ORALONCOLOGY.2019.09.003.
20. van der Plas-Krijgsman WG, de Boer AZ, de Jong P, et al. Predicting disease-related and patient-reported outcomes in older patients with breast cancer: a systematic review. *J Geriatr Oncol*. 2021;12(5):696–704.
21. Dicker AP, Jim HSL. Intersection of digital health and oncology. *JCO Clin Cancer Informatics*. 2018;2(2):1–4.
22. Qudah B, Luetsch K. The influence of mobile health applications on patient-healthcare provider relationships: a systematic, narrative review. *Patient Educ Couns*. 2019;102(6):1080–1089.
23. Dowding D, Randell R, Gardner P, et al. Dashboards for improving patient care: review of the literature. *Int J Med Inform*. 2015;84(2):87–100.
24. Xu L, Sanders L, Li K, Chow JCL. Chatbot for health care and oncology applications using artificial intelligence and machine learning: systematic review. *JMIR Cancer*. 2021;7(4):e27850.
25. Gonzalez BD. Promise of mobile health technology to reduce disparities in patients with cancer and survivors. *JCO Clin Cancer Informatics*. 2018:(2):1–9.
26. Fallahzadeh R, Rokni SA, Ghasemzadeh H, Soto-Perez-de-Celis E, Shahrokni A. Digital health for geriatric oncology. *JCO Clin Cancer Informatics*. 2018:(2):1–12.
27. Cesario A, D'oria M, Calvani R, et al. The role of artificial intelligence in managing multimorbidity and cancer. *J Pers Med*. 2021;11(4):314.
28. Sixsmith A, Horst BR, Simeonov D, Mihailidis A. Older people's use of digital technology during the COVID-19 pandemic. *Bull Sci Technol Soc*. 2022;42(1-2):19–24.
29. De Regge M, Decoene E, Eeckloo K, Van Hecke A. Development and evaluation of an integrated digital patient platform during oncology treatment. *J Patient Exp*. 2020;7 (1):53–61.
30. Greene J, Hibbard JH, Sacks R, Overton V, Parrotta CD. When patient activation levels change, health outcomes and costs change, too. *Health Aff*. 2015;34(3):431–437.
31. Tremblay D, Touati N, Usher S, Bilodeau K, Pomey MP, Lévesque L. Patient participation in cancer network governance: a six-year case study. *BMC Health Serv Res*. 2021;21(1):1–12.
32. Carman KL, Dardess P, Maurer M, et al. Patient and family engagement: a framework for understanding the elements and developing interventions and policies. *Health Aff (Millwood)*. 2013;32(2):223–231. https://doi.org/10.1377/hlthaff.2012.1133.
33. Slattery P, Saeri AK, Bragge P. Research co-design in health: a rapid overview of reviews. *Heal Res Policy Syst*. 2020;18(1):1–13.
34. Deverka PA, Bangs R, Kreizenbeck K, et al. A new framework for patient engagement in Cancer Clinical Trials Cooperative Group studies. *JNCI J Natl Cancer Inst*. 2018;110(6):553–559.
35. Marshall-McKenna R, Kotronoulas G, Kokoroskos E, et al. A multinational investigation of healthcare needs, preferences, and expectations in supportive cancer care: co-creating the LifeChamps digital platform. *J Cancer Surviv*. 2022:1–17. Published online November 11.
36. Valero-Ramon Z, Fernandez-Llatas C, Collantes G, et al. Analytical exploratory tool for healthcare professionals to monitor cancer patients' progress. *Front Oncol*. 2023;12:7265.
37. Benavent D, Fernández-Luque L, Núñez-Benjumea FJ, et al. Monitoring chronic inflammatory musculoskeletal diseases mixing virtual and face-to-face assessments—results of the Digireuma Study. *PLOS Digit Heal*. 2022;1(12): e0000157.
38. Valero-Ramon Z, Louro P, Irio L, et al. A collective intelligence platform to support older cancer survivors: towards the definition of LifeChamps system and big data reference architecture. *Stud Health Technol Inform*. 2022;290:1008–1009.
39. Blatch-Jones AJ, Pek W, Kirkpatrick E, Ashton-Key M. Role of feasibility and pilot studies in randomised controlled trials: a cross-sectional study. *BMJ Open*. 2018;8 (9): e022233.
40. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database. *BMC Med Res Methodol*. 2013;13 (1):1–6.
41. Borson S, Scanlan J, Brush M, Vitaliano P, Dokmak A. The Mini-COG: a cognitive 'vital signs' measure for dementia screening in multi-lingual elderly. *Int J Geriatr Psychiatry*. 2000;15(11):1021–1027.
42. Davis FD. Perceived usefulness, perceived ease of use, and user acceptance of information technology. *MIS Q*. 1989:319–340. Sep 1.
43. Kaya A, Ozturk R, Gumussoy CA, et al. Usability measurement of mobile applications with System Usability Scale (SUS). Industrial engineering in the big data era: selected papers from the Global Joint Conference on Industrial Engineering and its application areas. Global Joint Conference on Industrial Engineering; 2018.
44. Stoyanov SR, Hides L, Kavanagh DJ, Zelenko O, Tjondronegoro D, Mani M. Mobile App Rating Scale: a new tool for assessing the Quality of Health mobile apps. *JMIR mHealth Uhealth*. 2015;3(1):e27.
45. European Commission. EU Survey. Accessed February 8, 2022. https://ec.europa.eu/eusurvey/home/welcome.
46. Saracutu M, Edwards DJ, Davies H, Rance J. Protocol for a feasibility and acceptability study using a brief ACT-based intervention for people from Southwest Wales who live with persistent pain. *BMJ Open*. 2018;8(11): e021866.
47. Vandelanotte C, De Bourdeaudhuij I. Acceptability and feasibility of a computer-tailored physical activity intervention using stages of change: project FAITH. *Health Educ Res*. 2003;18(3):304–317.
48. Kohl S, Schoenfelder J, Fügener A, Brunner JO. The use of Data Envelopment Analysis (DEA) in healthcare with a focus on hospitals. *Heal Care Manag Sci*. 2018;22 (2):245–286.
49. Hollingsworth B, Dawson PJ, Maniadakis N. Efficiency measurement of health care: a review of non-parametric methods and applications. *Health Care Manag Sci*. 1999;2(3):161–172.
50. Iyengar MS, Rogith D, Florez-Arango JF. Measuring workload demand of informatics systems with the Clinical Case Demand Index. *AMIA Annu Symp Proc*. 2017;2017:985.
51. Groenewegen PP, Hutten JBF. Workload and job satisfaction among general practitioners: a review of the literature. *Soc Sci Med*. 1991;32(10):1111–1119.
52. Chou TC, Chang PL, Cheng YP, Tsai CT. A path model linking organizational knowledge attributes, information processing capabilities, and perceived usability. *Inf Manag*. 2007;44(4):408–417.
53. Feng YS, Kohlmann T, Janssen MF, Buchholz I. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. *Qual Life Res*. 2021;30(3):647–673.
54. Yanez B, Pearman T, Lis CG, Beaumont JL, Cella D. The FACT-G7: a rapid version of the Functional Assessment of Cancer Therapy-General (FACT-G) for monitoring symptoms and concerns in oncology practice and research. *Ann Oncol*. 2013;24 (4):1073–1078.
55. King MT, Costa DSJ, Aaronson NK, et al. QLU-C10D: a health state classification system for a multi-attribute utility measure based on the EORTC QLQ-C30. *Qual Life Res*. 2016;25(3):625–636.
56. Gobbens RJJ, van Assen MALM, Luijkx KG, Wijnen-Sponselee MT, Schols JMGA. The Tilburg Frailty Indicator: psychometric properties. *J Am Med Dir Assoc*. 2010;11 (5):344–355.
57. van der Willik EM, Terwee CB, Bos WJW, et al. Patient-reported outcome measures (PROMs): making sense of individual PROM scores and changes in PROM scores over time. *Nephrology*. 2021;26(5):391–399.
58. Cella D, Hahn EA, Dineen K. Meaningful change in cancer-specific quality of life scores: differences between improvement and worsening. *Qual Life Res 2002 113*. 2002;11(3):207–221.
59. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res*. 2011;20(10):1727–1736.
60. Gamper EM, Cottone F, Sommer K, et al. The EORTC QLU-C10D was more efficient in detecting clinical known group differences in myelodysplastic syndromes than the EQ-5D-3L. *J Clin Epidemiol*. 2021;137:31–44.
61. Bulamu NB, Vissapragada R, Chen G, et al. Responsiveness and convergent validity of QLU-C10D and EQ-5D-3L in assessing short-term quality of life following esophagectomy. *Health Qual Life Outcomes*. 2021;19(1):1–11.
62. Gobbens RJJ, Schols JMGA, Van Assen MALM. Exploring the efficiency of the Tilburg Frailty Indicator: a review. *Clin Interv Aging*. 2017;12:1739–1752.