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# TELEMONITORING SYSTEM

eCAN
Strengthening eHealth for Cancer Prevention & Care

## DELIVERABLE 7.1

# Outline

# Executive Summary

The significant cancer incidence globally along with the deteriorating quality of life, side effects and inflicted costs of cancer patients during and after treatment, show a necessity for extending traditional care by using complementary healthcare services such as telemedicine applications. Telemedicine can potentially improve clinical management and extend geographical coverage for care. With the development of such systems, patients can be aided on their treatment adherence, symptom management, emotional and physical well-being and coordination with their attending doctor.

Upon this direction, this document presents a literature review of studies that developed telemedicine applications focused on telemonitoring, telepsychological support and telerehabilitation of cancer patients with the ultimate goal of prevention, detection, and management of cancer-related side effects, promotion of behavioral changes. The search on Pubmed, CINAHL (EBSCO) and EMBASE databases yielded 8291 studies without any filters. After year, duplicates, title, abstract and full-text filtering, 18 studies with application intervention, 11 studies with telephone-based interventions and 3 studies with web-based interventions were kept. In these studies, the average duration of the intervention was 15 weeks. Also, the majority of studies were randomised trials on approximately 200 patients divided into control and intervention groups and focused on multiple cancer types.

Certain studies showed that patients were generally satisfied with their use and experience of telemedicine apps. Also, studies reported patients' psychological boost during their remote communication with their attending physician. Additionally, the recommended behavioral changes led to improvements in physiological indicators such as fatigue and nutrition. Improvement in patients' quality of life, decreased emotional suppression, continuous contact and feeling of recognition and safety were also identified in these studies. These findings led to the hypothesis that using the proposed eCAN telemonitoring system in conjunction with teleconsultation service from the attending clinicians, cancer patients can potentially be significantly aided on their post-treatment daily life both mentally (emotions, distress) and physically (pain, physical activity, heart rate, sleep quality).

Following the literature review, eCAN consortium created a telemonitoring system based on user requirements and ides from the literature review.

# 1. Introduction

## 1.1. Purpose

The eCAN project aims to bring the benefits of eHealth to all citizens and patients across EU-Member States (MS) focusing on cancer prevention and care. Specifically, eCAN explores the role of teleconsultation and remote monitoring in two large clinical trials focused on telerehabilitation and tele-psychological support in different populations of cancer patients. Patient Reported Outcomes (PROs) will be monitored by dedicated telemonitoring systems and a secure platform will provide dashboards for clinical decision support which will enable by design future AI applications. The JAs outputs will: i) facilitate the development of modular and interoperable solutions that build on regional and national infrastructures and are enabled to use future technologies, ii) inform sustainable telemedicine services, remote specialist consultations, and direct-to-consumer telemedicine, for instance through virtual consultations for urgent care needs. These activities can help in rapidly responding to epidemics, and their impact on cancer care, through the ability to deliver clinical care in a timely manner and through a more efficient coordination amongst health authorities, hospitals, and patients. Telehealth also provides opportunities for delivering health care outside of traditional health-care facilities, where patients such as the chronically ill or the elderly may receive guidance in certain procedures while remaining at home. It can also facilitate health care workers in remote field settings to obtain guidance from professionals elsewhere in diagnosis, care, and referral of patients. Using data from telemedicine applications, smart platforms can provide customized dashboards to stakeholders and enable the use of AI algorithms to optimize choice of and response to treatment, access to health infrastructures, allocation of resources and outcome.

## 1.2 Document structure

This document is divided in two sections. Section I documents the tele-monitoring solutions used for cancer patients worldwide, as a literature review (task. T7.1). The main goal of this deliverable was to identify from the literature the variables and technical characteristics, as well as the evaluation tools of the applications that have already been applied to cancer patients. The result is a complete landscape of the telemedicine solutions used to support cancer care. This review was used in order to support the design and development of the system which will be used during the project. Section II provides the user manual and steps that the users (i.e., administrator, treating doctor / clinician, patients) of the system developed will need to follow

regarding the installation and use of the mobile application, the registration of the wearable devices and the Dashboard access.

## 1.3 Background

According to EU, by 2035 cancer cases are estimated to increase by almost 25%, making it the leading cause of death in the EU (Press release, 3 February 2021 Europe's Beating cancer plan). Additionally, to the severe impact of cancer on the lives of patients and their families/caregivers, cancer has a significant implication on health systems, on economy, and on the society generally. The overall economic impact of cancer in Europe is estimated to exceed €100 billion annually.

Moreover, systemic cancer treatment is associated with a range of side effects which can negatively impacted patients' quality of life (QOL) and become life threatening. For example, patients receiving chemotherapy in outpatient settings, are largely required to self-monitor symptoms at home or handle monitoring devices (e.g., wearables) that collect various data (e.g., biometric). Patients also may lack confidence in making decisions between obtaining clinical support or self-managing and as a consequence, could delay seeking medical advice increasing the risk of symptoms escalation and hospital admissions (1,2). Furthermore, the delayed or inappropriate monitoring of symptoms at home may be the source of safety issues that can arise as a result. These can be of different levels of significance ranging from moderate to life-threatening conditions (for example delayed reporting of symptoms indicating the onset of Interstitial Lung Disease (ILD)).

The World Health Organization, issued formal recommendations for health systems, recommended that telemedicine should be seen as a general intervention and should be integrated into the package of health-care services. Simultaneously, telemedicine can be offered to complement face-to-face health services and recommended as a good practice intervention on telemedicine and on self-care interventions (3).

Telemedicine is defined as "the delivery of health-care services where distance is a critical factor, by all health-care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries all in the interests of advancing the health of individuals and their communities."

Telemedicine is a component of telehealth, which is a broader application of technologies to distance education and other applications wherein electronic communications and information technologies are used to support health-care services (3).

Moreover, telemedicine has the potential to improve clinical management, as well as extend coverage of health services especially in remote geographical areas. The use of well-established digital technologies like teleconsultation and telesupport interventions serve as a key mechanism for selfcare interventions and act as a key component to overcome distance barriers in the delivery of health services (3). Due to these distinct properties that allow for mitigating existing barriers (e.g., time, effort, and training) to access, its adoption has gained more widespread acceptance.

According to the WHO recommendations, telemedicine interventions should not exist in isolation but should be underpinned by national digital health strategies and should include two kind of telemedicine scenarios regarding digital health interventions: (a) client to provider; and (b) provider to provider. Furthermore, WHO pointed out that there is a priority to develop regulatory policies and guidelines for telemedicine – as with all interventions – for ensuring quality of care for patients during provision of services. Also, there is a need to develop regulations that could integrating telemedicine into the broader health services and facilitate the allocation of resources.

A significant proportion of patients diagnosed with incurable cancers reported high levels of distress over the disease trajectory. The use of teleconsultation-based interventions may increase early access to supportive care, reduce the burden of symptoms, improve Health-Related Quality of Life (HR-QOL) and promote longer survival. There is a growing of evidence that the utilization of patient-reported outcome measures during cancer treatment can aid the timely identification of physical and psychosocial needs, facilitate patient–doctor communication and assist decision-making.

An increasing body of literature supports the many benefits that can be achieved as a result of utilizing mhealth interventions. These include increased patient engagement, more highly integrated care of symptoms in oncology care and more effective symptom management by the health care team. There has been a drive to develop electronic systems to allow remote real-time patient monitoring throughout the cancer continuum (4,5).

The implications of telemedicine interventions have been made in a wide range of fields. For example, mHealth programs have been developed and implemented for the provision of a variety of health services, including treatment adherence, symptom management, emotional and physical well-being, and communication and care coordination interventions which have enhanced the quality of life.

The usage of telemedicine in healthcare has been acknowledged as important in responding to and coordinating actions in epidemic situations, including the current COVID-19 pandemic that is severely impacting cancer care, and this through online consultations and real-time clinical data exchange. The COVID-19 pandemic has hit even further the most disadvantaged groups in society, including cancer patients. Isolation and containment measure due to the pandemic have affected their follow-up care and quality of life.

Bender et al (2013), emphasized that there are hundreds of cancer-focused applications with the potential for conveniently providing real-time support interventions, for monitoring a host of symptoms and physiological indicators of the disease, and for promoting behavioral changes in a cost-effective manner (6). Recent studies supported the effectiveness and efficacy of mobile and internet interventions. Moreover, standardized valid apps in the oncological field exist that can also help providing cancer care and supporting patients during their treatment and follow-up (7,8).

With the context of telemonitoring and telesupport expanding with tremendous pace, it is pivotal to have comprehensive and up-to-date evidence on its current status and projected evolution pathway. Within the scope of the eCAN project, the results of this systematic review will demonstrate the landscape in this field. Most importantly, the results can be assessed throughout the lifetime of the project for their relevance to influence the development and implementation of the eCAN intervention.

Overall, the reported results of the telemedicine apps used in the literature, on the psycho-physiological aspects and behavioral changes of the cancer patients, indicate towards a hypothesis that potentially the regular monitoring of post-treatment cancer patients on their emotional, distress, and pain level state, and also physical activity, heart rate and sleep quality can significantly support their attending clinicians on their consultation. To accept this hypothesis, the telemonitoring system to be developed (telemonitoring mobile app and web-based platform, see Section 3) will be tested on groups of cancer patients during their psychological support and rehabilitation phases (see “Pilot project protocol v3.0”).

# 2. Telemonitoring landscape

## 2.1 Aim of Systematic Review

The main aim of this systematic review according to the Population – Interventions – Comparator – Outcomes (PICO) components was to identify telemedicine applications focused on the telemonitoring and telepsychological support of cancer patients during and/or after treatment as well as their telerehabilitation after treatment. These teleservices were proposed to prevent, detect and manage cancer-related side effects (e.g., cancer pain and quality of life), and also to promote certain behavioral changes to facilitate patients' daily life. Moreover, the main concept gaps and future trends of these applications were identified.

## 2.2 Methods

### 2.2.1 Design

The systematic review followed the guidelines provided by the Preferred Reporting Items for Systematic Review and Meta-Analysis (9).

### 2.2.2 Eligibility Criteria

Studies included should involve patients older than 18 years old, undergoing cancer treatment of any kind due to new diagnosis or recurrence and with informed consent. Interventions should include any kind of telemedicine applied at any time during the therapeutic procedures, as part of cancer therapy. Outcomes should include side effects' management, pain management and quality of life, during a therapeutic procedure (prior, during and after). Studies should be included according to their design if those were randomized controlled trials (RCTs), including cluster RCTs, controlled (non-randomized) clinical trials (CCTs) and prospective studies. Cross-sectional studies, case series, case-control, retrospective comparative cohort studies and reviews were excluded. Language exclusion criteria were applied (only English written studies included). All predefined criteria should be met in order to be included in the review process.

### 2.2.3 Data Sources

Electronic searches conducted for eligible studies in the following databases: Pubmed, CINAHL (EBSCO) and EMBASE since January 2017 until the end of January 2023. Relevant references from retrieved studies were also included for screening.

Ongoing studies were searched through the systematic review screening was conducted and using the clinicaltrials.gov with keywords mhealth and cancer. The eligibility criteria were the same as the systematic review method.

### 2.2.4 Search Strategy

The search strategy was fulfilled in accordance with the Peer Review of Electronic Search Strategies (PRESS) guidelines (10) and included terms and keywords related to teleconsultation, telemonitoring, mHealth and cancer patients. The search was conducted by two researchers [details omitted for double-anonymized peer review], who worked independently.

### 2.2.5 Selection Process – Data Collection

The search was conducted by two researchers who worked independently. All studies exported to Rayyan, where duplicates were removed, title and abstract screening was reviewed by reviewers independently. Conflict regarding study inclusion was resolved with discussion at the end of the screening procedure with a third reviewer acting as a moderator. Full texts of studies that met the inclusion criteria were assessed in detail by both researchers independently and reasons for exclusion were documented. Disagreements were resolved with consensus. A pre-designed table, based on the studies characteristics was used for data collection based on the inclusion criteria.

### 2.2.6 Data Items

Information from each study was extracted concerning: (1) Methods, including study design, (2) Participants characteristics, including age and disease (only cancer patients), (3) Telemedicine tools including mobile applications, web based and text messages.

The PRISMA flowchart of the identification and screening process is demonstrated in ***Figure 1***.

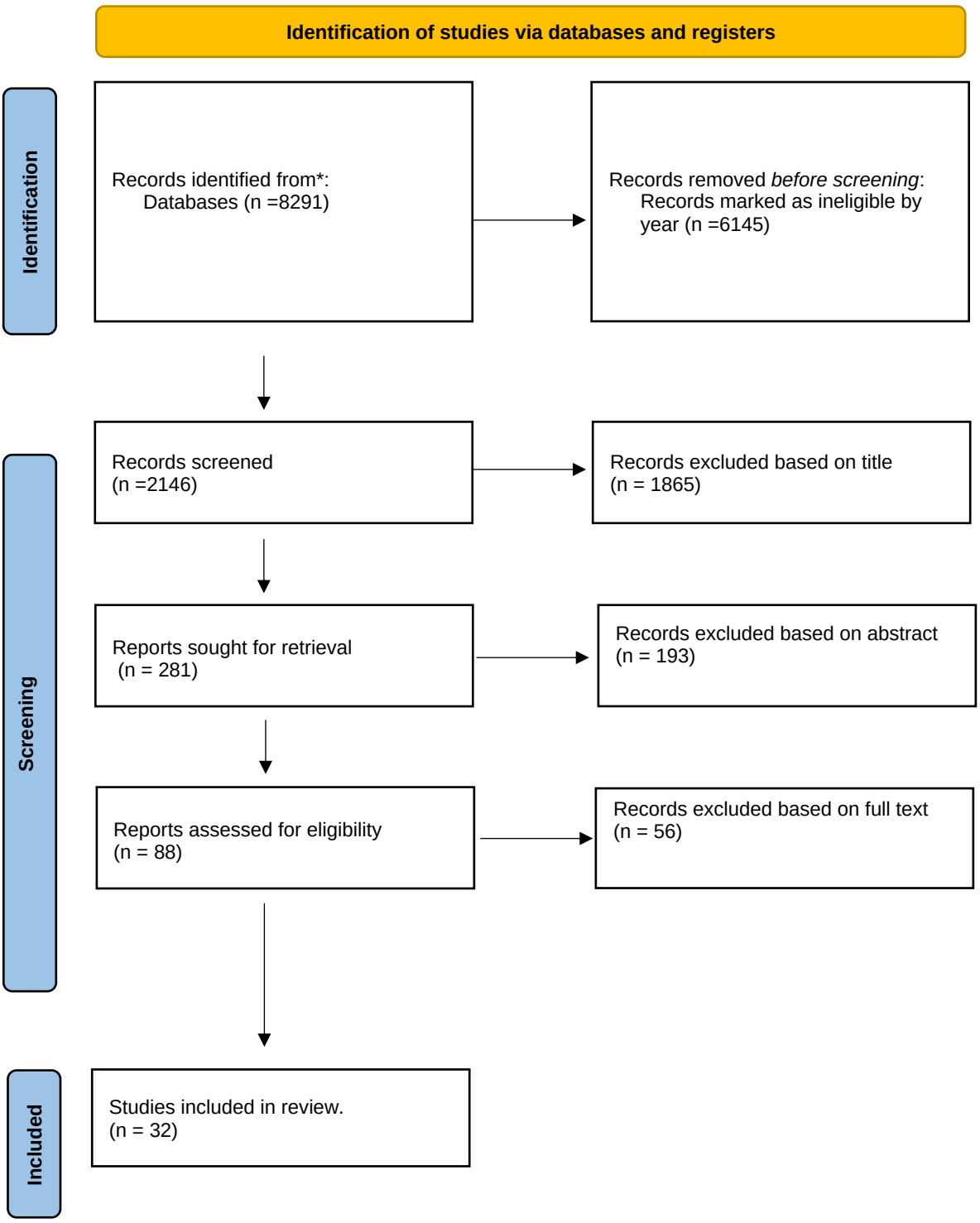


*Figure 1: PRISMA flowchart: Identification and screening process*

## 2.3 Results

### 2.3.1 Study Selection

The search, including results from both researchers in Pubmed, CINAHL (EBSCO) and EMBASE without any filters, yielded 8291 studies. After the year limitation 6145 were excluded and 2146 studies were remained. No duplicates were found. After screening based on the title, 281 studies remained in the review. Following screening based on the abstract, 193 studies were excluded and 88 remained. Finally, after the screening based on full text, 32 studies were included in the review. There are four subcategories of studies that remained based on the interventions used. The first category included 18 studies with application intervention, the second category included 11 studies with telephone-based interventions and the third category included 3 studies with web-based interventions. The PRISMA flowchart of the identification and screening process is demonstrated in ***Figure 1***.

#### 2.3.1.1 Completed Studies Description

The average duration of the interventions that used in the studies that remained were approximately 15 weeks (range 2 to 52 weeks max). The majority of the interventions' duration were 12 weeks (approximately 9 studies). Thirty out of thirty-two studies were randomised controlled trials, only one study was none randomised, and one was pilot. Sixteen studies recruited patients with any type of cancer, eight studies recruited breast cancer patients, two studies recruited prostate cancer patients, two studies recruited lung cancer patients and other two studies recruited gastrointestinal cancer patients, one study recruited pancreatic cancer patients and one recruited breast and prostate cancer patients. Furthermore, most of the studies sample size was approximately 200 cancer patients divided in two groups (control and intervention). The completed studies description is demonstrated in ***Table 1***.

**Table 1**: Completed studies (*C: Control, I: Intervention)

| Author, Year of publication | Title | Sample * | Study Design | Type of intervention | Intervention Duration | Evaluation metrics | Main findings (p value) |
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| Spahrkäs, et al. (11) (2022) | Beating cancer-related fatigue with the Untire mobile app: Results from a waiting-list randomized controlled trial | C: 280<br>I: 519<br>(Head and neck, digestive organs, respiratory, skin, bone, breast,female sexual organs) | Randomized controlled trial | mHealth app | 12 weeks | -Fatigue Symptom Inventory (FSI)<br>- EORTC Core Quality of Life questionnaire C30 | -Intervention group showed significantly larger improvements in fatigue severity (d = 0.40) and overall QoL on average (d = 0.32) (P's < .01), but not for overall QoL in the past week (P = .07).<br>-Participants with medium or high app use benefited most when compared with nonusers and control participants (P's ≤ .02).<br>-The intervention effect on fatigue interference was slightly stronger in younger participants (≤56 vs. >56).<br>-Effects did not depend on education and cancer status. |
| Knegtmans, et al.(12) (2020) | Home telemonitoring | C: 54<br>I: 54 | Randomised controlled trial | A short message service and an | 16 weeks | - Numerical Rating Scale (NRS for pain) | -CG, pain registration or its absence was described in 60 |

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| | improved pain registration in patients with cancer | (colorectal, breast, urologic/gynecologic, upper abdomen, pulmonary, hematologic) | | interactive voice response on their mobile phones | | | visits (37.0%). In the IG, pain registration or its absence was reported in 83 visits (51.2%).<br>-Patients in the IG received a prescription for analgesics significantly more often (36/54 patients [66.6%]) than did patients in the CG (18/54 patients [33.3%]), P < 0.01). |
| Villani, et al.(8) (2018) | Promoting emotional well-being in older breast cancer patients: Results from an ehealth intervention | C: 14<br>I: 15<br>(breast) | Randomised Controlled Trial | eHealth interventions (application) | 2 weeks | -Emotion Regulation Questionnaire (ERQ)<br>-Functional Assessment of Chronic Illness Therapy – Breast (FACT-B)<br>- Visual Analogue Scale (VAS) | -After 2 weeks of ehealth intervention, patients did not achieve significant change, however, they significantly reduced emotional suppression and increased cancer-related emotional well-being 3 months after the end of the intervention.<br>-By monitoring at a distance, the emotional experience during the online intervention, an increase in relaxation and a reduction of anxiety were found. |

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| | | | | | | | Patients in the intervention group reported a good level of acceptance of the ehealth intervention |
| Kim HJ et al.(13) (2018) | A Mobile Game for Patients With Breast Cancer for Chemotherapy Self-Management and Quality-of-Life Improvement: Randomized Controlled Trial. | C: 40<br>I: 36<br>(breast) | Randomised controlled trial | mobile game | 3 weeks | -Beck Depression Inventory (BDI)<br>-Spielberger State-Trait Anxiety Scale<br>-World Health Organization Quality of Life-BREF Scale | -The subjects in the game group showed high levels of satisfaction with the app.<br>-The time spent playing the mobile game in the game group was longer than that spent for self-education in the control group. |
| Huggins, et al. (14) (2022) | Effect of Early and Intensive Telephone or Electronic Nutrition Counselling Delivered to People with Upper Gastrointestinal Cancer on Quality of Life: A Three- | C: 37<br>I (telephone): 38<br>I (mobile app): 36<br><br>(upper gastrointestinal ca) | A three-arm randomised controlled trial | Telephone (synchronously) and mobile app (asynchronously) | 48 weeks | -EuroQol 5D-5L instrument<br>-Patient Generated Subjective Global Assessment (PG-SGA)<br>-EORTC Core Quality of Life questionnaire C30 | -There were no significant differences in QALY between the intervention groups (−0.02 (−0.13, 0.08), p = 0.712) or compared with the control group, with adjustment for covariates<br>-QOL were similar between groups for the global score. |

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| | Arm Randomised Controlled Trial. | | | | | - Visual Analogue Scale (VAS) | -Nutritional status was similar between groups |
| Rico TM, et al. (15) (2020) | Use of Text Messaging (SMS) for the Management of Side Effects in Cancer Patients Undergoing Chemotherapy Treatment: a Randomized Controlled Trial. | C: 59<br>I: 59<br><br>(breast, colon, lung, gastrointestinal, blood etc) | Randomised controlled trial | Text messages with self-care guidelines by the app called cHEmotHErApp | At least 6 weeks | -Side effects<br>-EORTC Core Quality of Life questionnaire C30 | -Intervention group patients experienced fewer side effects compared to the control group in cycle 1 ($p < 0.05$), in general.<br>-Intervention group experienced less nausea in relation to the control group, in the cycle 1 and cycle 2 ($p < 0.05$). |
| Absolom K et al. (1) (2021) | Phase III Randomized Controlled Trial of eRAPID: eHealth Intervention During Chemotherapy. | C: 252<br>I: 256<br><br>(colorectal, breast, gynecological) | Randomised controlled trial | Electronic patient self-Reporting of Adverse-events: Patient Information and aDvice (eRAPID) | 18 weeks | -EORTC Core Quality of Life questionnaire C30<br>-EQ5D (Euro Quality of life)<br>- Visual Analogue Scale (VAS)<br>-Functional Assessment of Chronic Illness | -eRAPID compared to UC showed improved physical well-being at 6 (P = .028) and 12 (P = .039) weeks and no difference at 18 weeks (primary end point) (P = .69).<br>-Fewer eRAPID patients (47%) had clinically meaningful physical well-being deterioration than UC |

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| | | | | | | Therapy – Breast (FACT-B) | (56%) at 12 weeks. Subgroup analysis found benefit in the nonmetastatic group at 6 weeks (P = .0426), but not in metastatic disease. There were no differences for admissions or chemotherapy delivery. At 18 weeks, patients using eRAPID reported better self-efficacy (P = .007) and better health on EQ5D-VAS (P = .009).<br>-Average patient compliance with weekly symptom reporting was 64.7%. Patient adherence was associated with clinician's data use and improved FACT-PWB at 12 weeks. |
| Basch E et al. (16) (2022) | Effect of Electronic Symptom Monitoring on Patient-Reported Outcomes Among | C: 598<br>I: 593<br><br>(colorectal, thoracic, | Randomised controlled trial | Internet-based or automated telephone system | 52 weeks | -Health-Related Quality of Life (HRQOL)<br>-Common Terminology | -Compared with usual care, mean changes on the QLQ-C30 from baseline to 3 months were significantly improved in the PRO group |

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| | Patients With Metastatic Cancer: A Randomized Clinical Trial. | breast, gynecologic, pancreas, gastroesophageal, genitourinary, myeloma, prostate, melanoma) | | | | Criteria for Adverse Events (PRO-CTCAE)<br>-Performance status<br>-EORTC Core Quality of Life questionnaire C30 | for physical function (PRO, from 74.27 to 75.81 points; control, from 73.54 to 72.61 points; P = .02), symptom control (PRO, from 77.67 to 80.03 points; control, from 76.75 to 76.55 points; mean difference, 2.56 [95% CI, 0.95-4.17]; P = .002), and HRQOL (PRO, from 78.11 to 80.03 points; control, from 77.00 to 76.50 points; mean difference, 2.43 [95% CI, 0.90-3.96]; P = .002).<br>-Patients in the PRO group had significantly greater odds of experiencing clinically meaningful benefits vs usual care for physical function (P = .009), symptom control (P = .003), and HRQOL (P = .006). |
| Yang J et al. (17) (2019) | Development and Testing of a Mobile | C: 27<br>I: 31 | Randomised controlled trial | mobile phone app (Pain Guard) | 4 weeks | - Numerical Rating Scale (NRS for pain) | -There were no significant differences in baseline pain |

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| | App for Pain Management Among Cancer Patients Discharged From Hospital Treatment: Randomized Controlled Trial | (nasophageal, cervical, esophagus, stomach, column, lung, breast, ovarian, bladder, pancreatic, osteosarcoma, soft tissue sarcoma) | | | | -EORTC Core Quality of Life questionnaire C30 | scores or baseline QoL scores between groups.<br>-At the end of the study, the rate of pain remission in the trial group was significantly higher than that in the control group (P<.001).<br>-The frequency of BTcP in the app group was considerably lower than that in the control group (P<.001).<br>-The rate of medication adherence in the trial group was considerably higher than that in the control group (P<.001).<br>-Improvements in global QoL scores in the trial group were also significantly higher than those in the control group (P<.001).<br>-The incidence of adverse reactions in the trial group (7/31) was lower than that in |

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| | | | | | | | the control group (12/27), especially constipation, with significant differences (P=.01). |
| Ghanbari et al.(18) (2021) | Effects of Psychoeducational Interventions Using Mobile Apps and Mobile-Based Online Group Discussions on Anxiety and Self-Esteem in Women With Breast Cancer: Randomized Controlled Trial | C: 41<br>I: 41<br><br>(breast) | Randomised controlled trial | mobile phone app (online mobile support sessions) | 4 weeks | -State-Trait Anxiety Inventory (STAI)<br>-Rosenberg Self-Esteem Scale (RSES) | -Comparing the postintervention mean scores of anxiety and its subscales using the independent t test showed statistically significant differences between the mobile psychoeducation group and controls (P<.001).<br>-The paired t test used to compare the postintervention mean scores of anxiety with its preintervention scores in the intervention group showed significant reductions in the scores of anxiety (95% CI -17.44 to -8.90, P<.001, d=1.02) and its two subscales (state anxiety: 95% CI -9.20 to -4.21, P<.001, d=0.88 and |

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| | | | | | | | trait anxiety: 95% CI -8.50 to -4.12, P<.001, d=0.94).<br>-Comparing the postintervention mean scores of self-esteem showed statistically insignificant differences between the control and intervention groups (16.87 vs 17.97, P=.24) |
| Schuit AS, et al.(19) (2022) | Cost-Utility of the eHealth Application 'Oncokompas', Supporting Incurably Ill Cancer Patients to Self-Manage Their Cancer-Related Symptoms: Results of a Randomized Controlled Trial. | C: 69<br>I: 69<br>(gastro-intestinal, lung, hematological, head and neck, breast, urological, etc) | Randomised controlled trial | eHealth application | 12 weeks | -Health-Related Quality of Life (HRQOL)<br>- Euroqol 5-Dimensions (EQ-5D)<br>-Medical Consumption Questionnaire (iMCQ) | -In the base case analysis, mean total costs and mean total effects were non-significantly lower in the intervention group (-€806 and -0.01 QALYs).<br>-The probability that the intervention was more effective and less costly was 4%, whereas the probability of being less effective and less costly was 74%.<br>-Among patients with incurable cancer, |

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| | | | | | | | Oncokompas does not impact incremental costs and seems slightly less effective in terms of QALYs, compared to care as usual. |
| Cheville AL, et al. (20) (2018) | The rationale, design, and methods of a randomized, controlled trial to evaluate the effectiveness of collaborative telecare in preserving function among patients with late-stage cancer and hematologic conditions. | Arm I<br>C: 172<br><br>Arm II<br>I: 172<br><br>Arm III<br>I: 172<br>(lung) | 3-arm randomized controlled trial | Telephonic monitoring | 4-weeks intervention (6months f-up) | -Euroqol 5-Dimensions (EQ-5D)<br>-FACIT fatigue questionnaire<br>-Godin Leisure-Time Exercise questionnaire (GLTEQ)<br>- Linear Analogue Self-Assessment (LASA) Scale | - All COPE trial participants, including those in the pain intervention Arm III, reported less intense pain on average than the cohort of patients with Stage III and IV lung cancer. |
| Cheville AL et al. (21) (2019) | Effect of Collaborative Telerehabilitation on Functional Impairment and | -ARM I: 172<br>-ARM II: 170<br>-ARM III: 166 | Three arms randomised controlled trial | telephone calls or web-based surveys | 24 weeks | - Brief Pain Inventory (BPI)<br>-EQ-5D-3L | -Compared with the control group, the telerehabilitation arm 2 had improved function (difference, 1.3; 95% CI, 0.08-2.35; P = .03) and quality of |

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| | Pain Among Patients With Advanced-Stage Cancer: A Randomized Clinical Trial. | (solid or hematologic ca) | | | | | life (difference, 0.04; 95% CI, 0.004-0.071; P = .01), while both telerehabilitation arms 2 and 3 had reduced pain interference (arm 2, -0.4; 95% CI, -0.78 to -0.09; P = .01 and arm 3, -0.4; 95% CI, -0.79 to -0.10; P = .01), and average intensity (arm 2, -0.4; 95% CI, -0.78 to -0.07; P = .02 and arm 3, -0.5; 95% CI, -0.84 to -0.11; P = .006).<br>-Telerehabilitation was associated with higher odds of home discharge in arms 2 (odds ratio [OR], 4.3; 95% CI, 1.3-14.3; P = .02) and 3 (OR, 3.8; 95% CI, 1.1-12.4; P = .03) and fewer days in the hospital in arm 2 (difference, -3.9 days; 95% CI, -2.4 to -4.6; P = .01). |
| Keum J et al. (22) (2021) | Usefulness of Smartphone Apps for Improving | C: 20<br>I: 20<br>(pancreatic) | Randomised controlled trial | app interventions | 12 weeks | -EORTC Core Quality of Life questionnaire C30 | -All the study participants showed a significant improvement in the |

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| | Nutritional Status of Pancreatic Cancer Patients: Randomized Controlled Trial. | | | | | - Patient-Generated Subjective Global Assessment (PG-SGA) | nutritional status according to the PG-SGA score regardless of Noom app usage.<br>-Noom users showed statistically significant improvements on the global health status (GHS) and QoL scales compared to non-Noom users, based on the EORTC QLQ (P=.004).<br>-The SMI decreased in both groups during chemotherapy (Noom users, 49.08±12.27 cm(2)/m(2) to 46.08±10.55 cm(2)/m(2); non-Noom users, 50.60±9.05 cm(2)/m(2) to 42.97±8.12 cm(2)/m(2)). The decrement was higher in the non- |
| Crafoord MT et al. (23) (2020) | Engagement in an Interactive App for Symptom Self-Management during Treatment in | Breast patients: 74 Prostate patients: 75 | Randomized controlled trials | Interaktor app among patients with breast or prostate cancer during treatment | Patients with breast cancer 18 weeks. Patients with prostate | Charlson Comorbidity Index, semistructured interview guide | -Among the patients treated for breast cancer, higher age predicted a higher total number of free text messages sent (P=.04). |

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| | Patients With Breast or Prostate Cancer: Mixed Methods Study. | | | (an interactive smartphone and tablet app) | cancer 9 weeks. | analyzed by conventional content analysis. | -Among the patients treated for prostate cancer, higher age (P=.01) and higher education level (P=.04), predicted an increase in total views on self-care advice, while higher comorbidity (P=.004) predicted a decrease in total views on self-care advice.<br>-Daily symptom reporting created feelings of having continuous contact with health care professionals, being acknowledged, and safe. Being contacted by a nurse after a symptom alert was considered convenient and highly valued. |
| Urech C et al. (24) (2018) | Web-Based Stress Management for Newly Diagnosed Patients with Cancer (STREAM): | C: 64<br>I: 65<br><br>(breast) | Randomised controlled trial | Web-based stress management (STREAM [Stress-Aktiv-Mindern]) | 8 weeks (2 months f-up) | -Distress Thermometer<br>-Hospital Anxiety and Depression Scale (HADS) | -After the intervention, quality of life was significantly higher (Functional Assessment of Chronic Illness Therapy-Fatigue: mean, 8.59 |

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| | A Randomized, Wait-List Controlled Intervention Study. | | | | | -Functional Assessment of Chronic Illness Therapy Fatigue (FACIT-F) | points; 95% CI, 2.45 to 14.73 points; P = .007) and distress significantly lower (Distress - Thermometer: mean, -0.85; 95% CI, -1.60 to -0.10; P = .03) in the intervention group as compared with the control. -Changes in anxiety or depression were not significant in the intention-to-treat population (Hospital Anxiety and Depression Scale: mean, -1.28; 95% CI, -3.02 to 0.45; P = .15). Quality of life increased in the control group with the delayed intervention. Conclusion The Web-based stress management program STREAM is feasible and effective in improving quality of life. |
| Clarke AL et al. (25) (2020) | Promoting integrated care in prostate cancer | C: 12<br>I: 29 | Non-randomised cluster | Online prostate cancer-specific holistic needs | 36 weeks | -EQ5D (Euro Quality of life) | -The sHNA proved useful in identifying 'red flag' symptoms, and helping |

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| | through online prostate cancer-specific holistic needs assessment: a feasibility study in primary care. | (prostate) | controlled feasibility study | assessment (sHNA) and shared digital communication between patients and their healthcare professionals (HCPs). | | -EORTC Core Quality of Life questionnaire C30<br>-Prostate Cancer Symptoms<br>-Cancer Survivor Unmet Needs | practice nurses decide when to seek further medical care for the patients.<br>-There was a high level of acceptability for patients and HCPs. However, integration of care did not occur as intended because of problems linking hospital and general practice IT systems. |
| Lally RM et al. (26) (2020) | CaringGuidance™ after breast cancer diagnosis eHealth psychoeducational intervention to reduce early post-diagnosis distress. | C: 43<br>I: 57<br><br>(breast) | Randomised controlled trial | web-based, psychoeducational distress self-management program, CaringGuidance™ | 12 weeks | -Distress Thermometer (DT)<br>-Depression Scale (CES-D)<br>-Impact of Events Scale (IES) CaringGuidance™ | -Multilevel models showed no significant overall effects, post hoc analysis showed significant group differences in slopes occurring between study months 2 and 3 on distress ($F(1,70) = 4.91$, $p = .03$, $\eta(2) = .065$) measured by the DT, and depressive symptoms ($F(1, 76) = 4.25$, $p = .043$, $\eta(2) = .053$) favoring the intervention. |

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| Fjell M et al. (27) (2020) | Reduced symptom burden with the support of an interactive app during neoadjuvant chemotherapy for breast cancer - A randomized controlled trial. | C: 75<br>I: 74<br><br>(breast) | Randomized controlled trial | Interactive app Interaktor | 18 weeks | patients' levels of symptom burden and HRQoL | -The intervention group rated statistically significant less symptom prevalence in nausea, vomiting, feeling sad, appetite loss and constipation. Overall symptom distress and physical symptom distress were rated statistically significant lower in the intervention group. Further, emotional functioning was rated statistically significant higher in the intervention group. |
| Villaron C et al. (28) (2018) | Telehealth applied to physical activity during cancer treatment: a feasibility, acceptability, and randomized pilot study. | C: 30<br>I: 30<br>(lung, pancreatic, breast, ovarian, digestive, tongue, | Randomised controlled trial | Text message for exercise promotion (SMS) | 8 weeks | -EORTC Core Quality of Life questionnaire C30<br>-Multidimensional Fatigue Inventory (MFI) | -Indicated a beneficial effect for group R related to self-reported fatigue (F = 2.686, p = .01) and quality of life (F = 2.431, p = .02). |

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| | | hematologic) | | | | | |
| Hoek PD et al. (29) (2017) | The effect of weekly specialist palliative care teleconsultations in patients with advanced cancer -a randomized clinical trial. | C: 36<br>I: 38<br><br>(urogenital, gastro-intestinal, hepatobiliary, lung, head and neck, breast, skin, etc) | Randromised controlled trial | Teleconsultation | 12 weeks | patient-experienced symptom burden indicated by the following: (1) Total Distress Score (defined as the sum of all nine subscales of the Edmonton Symptom Assessment System) and (2) the Hospital Anxiety and Depression Scale. | he Total Distress Score became significantly higher in the intervention group than in the control group, reaching significance at week 12 (adjusted difference at week 12: 6.90 points, 95% CI, 0.17 to 13.63; P = 0.04). The adjusted anxiety scores were higher in the intervention group than in the control group (estimate effect: 1.40; 95% CI, 0.14 to 2.55; P = 0.03). No difference was found between the groups in adjusted depression scores (estimate effect: 0.30; 95% CI, -1.39 to 1.99; P = 0.73) or in secondary outcome measures. |
| Coombs LA et al. (30) (2020) | Age Is Not a Barrier: Older Adults with | C: 67<br>I: 59 | Randomized control trial | Remote Symptom Monitoring | Max 6 months | pain,fatigue, nausea/vomiting, | -There was no significant difference between the 2 age |

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| | Cancer Derive Similar Benefit in a Randomized Controlled Trial of a Remote Symptom Monitoring Intervention Compared With Younger Adults. | (breast, colorectal, lung, ovarian, etc) | | | | fever, diarrhea, constipation, trouble sleeping, sore mouth, anxiety and depressed mood | categories; on average, older adult participants made 88% of expected daily calls and younger adult participants made 90% of expected daily calls.<br>-older adults are unwilling or unable to use a technological tool such as interactive voice response and suggest that patient utilization may be guided by other factors, such as ease of use and perceived benefit from the intervention. |
| Mooney KH et al. (31) (2017) | Automated home monitoring and management of patient-reported symptoms during chemotherapy: results of the symptom care at home RCT. | C: 178<br>I: 180<br>(breast, lung, ovarian, colorectal, pancreatic, head and neck, | Randomized controlled trial | SCH system automated monitored | 77-120 days | fatigue, trouble sleeping, nausea and vomiting, pain, numbness or tingling, feeling blue or down, feeling nervous or anxious, distress over appearance, diarrhea, sore mouth, and | -SCH participants had significantly less symptom severity across all symptoms ($P < 0.001$).<br>-On average, the relative symptom burden reduction for SCH participants was 3.59 severity points ($P < 0.001$), roughly 43% of UC. |

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| | | endometrial, etc) | | | | trouble thinking or concentrating. | -With a very rapid treatment benefit, SCH participants had significant reductions in severe (67% less) and moderate (39% less) symptom days compared with UC (both P < 0.001).<br>-All individual symptoms, except diarrhea, were significantly lower for SCH participants (P < 0.05). Symptom Care at Home dramatically improved symptom outcomes. |
| Merz, A et al. (32) (2022) | A single-site pilot feasibility randomized trial of a supportive care mobile application intervention for patients with advanced cancer and caregivers | C: 25<br><br>I: 25 (patients) and 10 caregivers (breast, colorectal, esophagus, genitourina | Randomised controlled trial | Digital Supportive Care Awareness and Navigation (D-SCAN) application (app) | 12 weeks | -Net Promoter Score (NPS)<br>-Patient Activation Measure (PAM-13)<br>-Functional Assessment of Cancer Therapy-General (FACT-G) | -Usability/satisfaction by NPS was high, at 14.3% and 12.5% for patients and caregivers, respectively.<br>-Intervention patient and caregiver resource awareness increased by a mean of 3.7 (p = 0.27) and 4.1 items, respectively. |

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| | | ry, head and neck, lower GI, lung, lymphoma, melanoma) | | | | -Caregiver Oncology Quality of Life (CarGOQOL) | -Supportive care resource utilization increased by a mean of 0.8 items for intervention patients (p = 0.70) and 0.6 for caregivers.<br>-PAM-13 increased by a mean of 1.6 for intervention patients (p = 0.65). FACT-G increased by a mean of 1.1 for intervention patients (p = 0.91), and CarGOQoL increased by a mean of 2.2 (p = 0.41) |
| Børøsund, E.et al. (33) (2022) | Digital stress management in cancer: Testing StressProffen in a 12-month randomized controlled trial | C: 88<br>I: 84<br>(breast, brain, prostate, etc) | Randomized controlled trial | StressProffen, a digital application | 52 weeks | -Stress (Perceived Stress Scale)<br>-Hospital Anxiety and Depression Scale<br>-Self-Regulatory Fatigue 18)<br>-Health-Related Quality of Life (HRQOL) | -Over the 12-month study time, the intervention group reported significantly decreased stress (P <.001), depression (P =.003), and self-regulatory fatigue (P =.002) as well as improved HRQOL (for 6 of 8 domains, P ≤.015) in comparison with controls.<br>-The largest favored effects for the intervention group |

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| | | | | | | -36-Item Short Form Survey Instrument (SF-36 or RAND-36) | were observed at 6 months: stress (estimated mean difference [MD], −5.1; P <.001), anxiety (MD, −1.4; P =.015), depression (MD, −2.1; P <.001), self-regulatory fatigue (MD, −4.9; P <.001), and HRQOL (7 of 8 domains; P ≤.037). |
| Fu, M.R.et al. (34) (2022) | A Web- and Mobile-Based Intervention for Women Treated for Breast Cancer to Manage Chronic Pain and Symptoms Related to Lymphedema: Results of a Randomized Clinical Trial | C: 60<br>I: 60<br><br>(breast) | Two arm-randomised controlled trial | Patient-centered, web- and mobile-based mHealth system that delivers safe, easy, and feasible digital therapy | 12 weeks | -Pain and Lymphedema Symptoms. The Lymphedema and Breast Cancer Symptom Experience Index(Part I)<br>-6-item Pain Impact Questionnaire (PIQ-6) | -At the study endpoint of 12 weeks, significantly fewer patients in the TOLF intervention group compared with the AP control group reported chronic pain (45% [27/60] vs 70% [42/60]; odds ratio [OR] 0.39, 95% CI 0.17-0.90; P=.02).<br>-Patients who received the TOLF intervention were significantly more likely to achieve a complete reduction in pain (50% [23/46] vs 22% [11/51]; OR 3.56, 95% CI |

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| | | | | | | | 1.39-9.76; P=.005) and soreness (43% [21/49] vs 22% [11/51]; OR 2.60, 95% CI 1.03-6.81; P=.03).<br>-Significantly lower median severity scores were found in the TOLF group for chronic pain (MedTOLF=0, IQR 0-1 vs MedAP=1, IQR 0-2; P=.02) and general bodily pain (MedTOLF=1, IQR=0-1.5 vs MedAP=1, IQR 1-3; P=.04). |
| Ghanbari, E.et al. (18) (2021) | Effects of Psychoeducational Interventions Using Mobile Apps and Mobile-Based Online Group Discussions on Anxiety and Self-Esteem in Women With Breast Cancer: Randomized Controlled Trial | C: 41<br>I: 41<br><br>(breast) | Randomized controlled trial | Mobile application | 4 weeks | -State-Trait Anxiety Inventory (STAI) - Rosenberg Self-Esteem Scale (RSES) | -Comparing the postintervention mean scores of anxiety and its subscales using the independent t test showed statistically significant differences between the mobile psychoeducation group and controls (P<.001).<br>-The paired t test used to compare the postintervention mean scores of anxiety with |

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| | | | | | | | its preintervention scores in the intervention group showed significant reductions in the scores of anxiety (95% CI -17.44 to -8.90, P<.001, d=1.02).<br>-Comparing the postintervention mean scores of self-esteem showed statistically insignificant differences between the control and intervention groups (16.87 vs 17.97, P=.24). |
| Dueck, A.C. et al. (35) (2020) | Assessment of Adverse Events from the Patient Perspective in a Phase 3 Metastatic Castration-Resistant Prostate Cancer Clinical Trial | 119<br><br>(prostate) | Randomized, double-blind, placebo-controlled phase 3 COMET-2 trial | automated telephone system | -3 weeks | -Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE scores) | -Rates of self-report adherence were similar between groups (cabozantinib s-maleate, 286 of 317 [90.2%]; and mitoxantrone hydrochloride-prednisone, 248 of 270 [91.9%]). Of 12 measured, patient-reported PRO-CTCAE symptomatic AEs, 4 reached statistical |

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| | | | | | | | significance when comparing the proportion of patients with at least 1 postbaseline score greater than 0 between groups (differences ranged from 20.1% to 34.1% with higher proportions in the cabozantinib group; all P <.05), and use of a method for accounting for preexisting symptoms at baseline yielded 7 AEs with statistically significant differences between groups (differences ranged from 20.5% to 41.2% with higher proportions in the cabozantinib group; all P <.05). |
| Uhm K et al. (36) (2017) | Effects of exercise intervention in breast cancer patients: is mobile health (mHealth) with pedometer | C: 177<br>I: 179<br><br>(breast) | Prospective, quasi-randomized multicentre trial | Mobile application | 12 weeks | -EORTC Core Quality of Life questionnaire C30<br>-Quality of Life Questionnaire Breast CancerModule 23 | -Physical function, physical activity, and QOL scores were significantly improved regardless of the intervention method, and changes were |

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| | more effective than conventional program using brochure? | | | | | | not significantly different between the two groups.<br>-The mean Likert scale response for overall satisfaction with the service was 4.27/5 in the mHealth group. |
| Joseph G et al. (37) (2018) | Coping Skills Practice and Symptom Change: A Secondary Analysis of a Pilot Telephone Symptom Management Intervention for Lung Cancer Patients and Their Family Caregivers. | 51 participants<br><br>(lung) | Randomised pilot trial | Telephone symptom management | 6 weeks | -Brief Pain Inventory<br>-Patient Health Questionnaire –8 (PHQ-8)<br>-Generalised Anxiety Disorder Assessment (GAD-7) | -For patients, greater practice of assertive communication was associated with less pain interference (β=−0.45, p=0.02) and psychological distress (β=−0.36, p=0.047); for caregivers, greater practice of guided imagery was associated with less psychological distress (β=−0.30, p=0.01). Unexpectedly, for patients, greater practice of a mindfulness exercise was associated with higher pain (β=0.47, p=0.07) and fatigue interference (β=0.49, p=0.04); |

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| | | | | | | | greater practice of problem solving was associated with higher distress related to breathlessness (β=0.56, p=0.01) and psychological distress (β=0.36, p=0.08). |
| Dong, X et al. (38) (2018) | Telephone-based reminiscence therapy for colorectal cancer patients undergoing postoperative chemotherapy complicated with depression: a three-arm randomised controlled trial | CON: 45<br>TS: 45<br>TBR: 45<br><br>(colorectal) | Randomised controlled trial | Telephone-based | 6 weeks | -Self-Rating Depression Scale (SDS)<br>-Hamilton Depression Scale (HAMD)<br>-Self-Rating Anxiety Scale (SAS)<br>-Hamilton Anxiety Scale (HAMA) | -After 6 weeks, SDS and HAMD scores were significantly lower than pre-intervention baseline in the TBR group but not in the CON and TS groups (P < 0.05). Both SAS and HAMA scores were significantly reduced in TBR and TS groups but not the CON group (P < 0.05) following intervention; however, there was no significant difference in post-intervention scores between TS and TBR groups (P > 0.05). |

### 2.3.1.2 Indicative Perspective on international telemedicine (out of Europe)

The average duration of the interventions that used in the studies out of Europe that remained were approximately 7 weeks (range 3 to 12 weeks max). All studies were randomised controlled trials. Three studies recruited advanced cancer patients with any type of cancer, one study recruited breast cancer patients and one study recruited pancreatic cancer patients. Furthermore, most of the studies sample size was approximately 90 cancer patients divided in two groups (control and intervention). The completed studies description is demonstrated in ***Table 2***.

**Table 2**: Indicative Perspective on international telemedicine (out of Europe)

| Author, Year, Country | Title | Target Population | Methodology | Technology (watch, web etc?) | Intervention Duration | Evaluation metrics | Main results (p value) |
|---|---|---|---|---|---|---|---|
| Kubo, et al. (39) (2020) California | Pilot pragmatic randomized trial of mhealth mindfulness-based intervention for advanced cancer patients and their informal caregivers | C: 46<br>I: 31<br><br>(solid and hematological) | Randomized trial | Mindfulness application | 6 weeks | -Functional Assessment of Chronic Illness Therapy - Palliative Care (FACIT-Pal)<br>-Caregiver Quality of Life Index – Cancer (CQOLC) scale<br>-National Comprehensive Cancer Network Distress Thermometer<br>-14-item Hospital Anxiety and Depression Scale (HADS) | - HADS Anxiety score was lower in the Intervention group (p=0.01)<br>-The physical wellbeing through the FACIT-Pal in the intervention group increased after the intervention (p=0.03) |

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| | | | | | | -24-item Five Facet Mindfulness Questionnaire (FFMQ-SF) | |
| Hou IC et al. (40) (2020) Taiwanese | Quality of Life of Women After a First Diagnosis of Breast Cancer Using a Self-Management Support mHealth App in Taiwan: Randomized Controlled Trial. | C: 59<br>I: 53<br><br>(breast) | Randomised controlled trial | breast cancer self-management support (BCSMS) mHealth app for | 3 months | -EORTC Core Quality of Life questionnaire C30<br>-EORTC Breast Cancer-Specific Quality-of-Life Questionnaire (QLQ-BR23) | -The mean total QoL summary scores from the QLQ-C30 (83.45 vs 82.23, P=.03) and the QLQ-BR23 (65.53 vs 63.13, P=.04) were significantly higher among the experimental group versus the control group, respectively, at 3 months. |
| Kubo, et al. (41) (2019) Northern California | A Feasibility Study Within an Integrated Health Care Delivery System. | Patients:<br>C: 43<br>I: 54<br><br>Caregivers:<br>C: 14 | Two-arm randomized controlled trial | Website or mobile application | 8 weeks | -Hospital Anxiety and Depression Scale (HADS)<br>-PROMIS Pain Intensity numeric rating scale<br>-8-item PROMIS Sleep Disturbance scale | -Observed significantly greater improvement in QoL among patients in the intervention arm compared with controls. Caregivers in the intervention group |

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| | | I: 17 (breast, hematologic, gastrointestinal, genitourinary, head and neck, skin, lung, etc) | | | | -27-item Functional Assessment of Cancer Therapy General Scale<br>- 9-item Brief Fatigue Inventory<br>- 21-item Posttraumatic Growth Inventory (PTGI) | experienced increased mindfulness compared with controls. |
| Ngoma M et al. (42) (2021) Tanzania | mPalliative Care Link: Examination of a Mobile Solution to Palliative Care Coordination Among Tanzanian Patients With Cancer. | <u>Phone call</u><br>C: 49<br><br><u>mPCL</u><br>I: 49<br><br>(solid and hematological ca) | Randomised Trial | Smartphone- or Web-based app, mPalliative Care (mPCL) | 4 months | - Palliative care Outcome Scale (POS)<br>-Quality of life | -Comparison of baseline characteristics showed an insignificant trend toward more women (P = .07) and higher discharge morphine use (P = .09) in the mPCL group compared with phone-contact and significant between-group differences in cancer types (P = .003).<br>-Overall symptom severity was significantly lower in the phone-contact group (P < .0001), and symptom severity |

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| | | | | | | | decreased over time in both groups (P = .0001); however, between-group change in overall symptoms over time did not vary significantly (P = .34). |
| Keum, J et al. (22) (2021) South Korea | Usefulness of Smartphone Apps for Improving Nutritional Status of Pancreatic Cancer Patients: Randomized Controlled Trial | C: 20<br>I: 20<br><br>(pancreatic) | Randomised controlled trial | Noom- a mobile application | 12 weeks | -EORTC Core Quality of Life questionnaire<br>-Patient-Generated Subjective Global Assessment (PG-SGA) | -All the study participants showed a significant improvement in the nutritional status according to the PG-SGA score regardless of Noom app usage.<br>-Noom users showed statistically significant improvements on the global health status (GHS) and QoL scales compared to non-Noom users, based on the EORTC QLQ (P=.004).<br>-The SMI decreased in both groups during chemotherapy (Noom users, 49.08±12.27 cm2/m2 to 46.08±10.55 cm2/m2; non-Noom users, |

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| | | | | | | | 50.60±9.05 cm2/m2 to 42.97±8.12 cm2/m2).<br>-The decrement was higher in the non-Noom user group than in the Noom user group, but it was not statistically significant (-13.96% vs. -3.27%; P=.11). |

### 2.3.1.3 Ongoing Studies (Clinical Trials)

One hundred nighty nine studies were found when search was applied at clinicaltrials.gov with the keywords cancer for the disease and mHealth as the other term. Nine ongoing studies were remained. All ongoing studies that remained aiming to develop a mobile application. The average duration of the studies' interventions are approximately 21 weeks (range 12 to 48 weeks max). The majority of the interventions duration were 12 weeks. Most of the studies aiming to recruit patients with any type of cancer. The number of the sample expected to participate in the clinical trials is estimated at 200 in most studies (in two groups, control, and intervention). The ongoing studies description is demonstrated in ***Table 3***.

**Table 3**: Ongoing studies

| Author, Year of publication | Title | Target Population | Proposal Methodology | Main purposes | Technology | Intervention Duration | Evaluation metrics |
|---|---|---|---|---|---|---|---|
| (2022) | Photobiomodulation Therapy With M-health Tool for the Management of Oral Health | 60 Head and neck patients | Randomized controlled trial | Oral Health and Quality of Life in Head and Neck | Mobile application | 24 weeks | -EORTC QLQ-C30 |

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| ClinicalTrials.gov Identifier: NCT05106608 | and Quality of Life in Head and Neck Cancer Patients: LAXER Study | | | Cancer Patients with Photobiomodulation | | | -Xerostomia Inventory consists of 11 items<br>-Eating Assessment Tool questionnaire (EAT-10)<br>-Visual Analogue Scale (VAS)<br>-Salivary flow rate<br>-Indicators of saliva<br>-Glandular ultrasound<br>-Maximum mouth opening |
| (2022) ClinicalTrials.gov Identifier: NCT05221970 | Effectiveness and Suitability of the Online Mobile Application MOÚ MindCare for the Mental and Physical Health of Cancer Patients: Randomized Controlled Trial | 600 participants (cancer patients) | Randomized controlled trial | Supportive care | Mindfulness-Based Cognitive Therapy (MBCT-Ca) – | 36 weeks | -Perceived Stress Scale (PSS)<br>-Depression, anxiety and stress scale (DASS-21) |

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| | | | | | online (Mobile application) | | -Positive Mental Health Scale (PMHS)<br>- Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F)<br>-Difficulties in Emotion Regulation Scale Short Form (DERS-SF)<br>-Five Facet Mindfulness Questionnaire (FFMQ-15)<br>-Applied Mindfulness Process Scale (AMPS)<br>-Self-compassion scale (SCS) |

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| | | | | | | | -Gratitude Questionnaire Six item form (CQ-6) etc |
| (2018) ClinicalTrials.gov Identifier: NCT03512015 | A Mobile Supportive Care App for Patients With Metastatic Lung Cancer: a Pilot Randomized Controlled Trial - The Lung Cancer App (LuCApp) Study | 120 Lung cancer patients | Pilot Randomized Controlled trial | Supportive care | LuCApp (Lung Cancer App) is an application | 12 weeks | -FACT-L<br>- Euroqol 5-Dimensions (EQ-5D)<br>-HADS<br>-SCNS-SF34<br>-ZBI<br>-Usability of LuCApp<br>-Satisfaction of LuCApp<br>-Resource use |
| (2017) ClinicalTrials.gov Identifier: NCT03674515 | Study of Program Interest "Bouge" to Improve the Daily Physical Activity and Tolerance in Processings Treatment of Non-metastatic Breast Cancer at the | 214 participants (breast cancer) | Interventional randomized trial | Improve the Daily Physical Activity | Smartphone application | 12 weeks | - Euroqol 5-Dimensions (EQ-5D)<br>-EORTC QLQ-C30<br>-Fatigue Scale WHO |

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| | Beginning Weekly Taxol Adjuvant Chemotherapy | | | | | | -Sleep Scale SPIEGEL |
| (2019) ClinicalTrials.gov Identifier: NCT04541784 | Effectiveness of a Multidimensional Mobile App Intervention "WOMAN-PRO III" to Reduce Postsurgical Symptom Induced Distress in Patients With Vulvar Neoplasia: A Mixed Methods Project | 18 participants (vulvar neoplasia) | Mixed Methods | Supportive care | Mobile App "WOMAN-PRO III" | 24 weeks | - Mishel Uncertainty in Illness Scale (MUIS) |
| (2021) ClinicalTrials.gov Identifier: NCT04859400 | Influence of a Home-based Nutrition and Exercise Program Including an Application for Monitoring on Quality of Life in Palliative Cancer Outpatients | 90 participants (gastrointestinal, lung) | Randomised trial | Supportive care | application Swiss NutriAct | 12 weeks | -FACT-G<br>-PSGA<br>-SARC-F<br>-FACIT-Fatigue |
| (2022) ClinicalTrials.gov Identifier: NCT05459454 | Sidekick Health Digital Therapeutic Solution (SK-421) for Breast Cancer Patients: a Pilot Study | 66 participants (breast) | Randomised controlled trial | To support lifestyle changes by remote symptom monitoring. | Mobile application | 14 weeks | -QLQ-C30<br>-QLQ-FA12<br>-Depression, Anxiety and Stress Scale (DASS21)<br>-Morisky Medication |

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| | | | | | | | adherence Scale (MMAS-8)<br>- Euroqol 5-Dimensions (EQ-5D)<br>-SEMCD |
| (2022) ClinicalTrials.gov Identifier: NCT05423808 | Streamlined Geriatric and Oncological Evaluation Based on IC Technology for Holistic Patient-oriented Healthcare Management for Older Multimorbid Patients. TWOBE Study | 720 participants | Randomised controlled trial | Supportive care | Device: Holis Dashboard - Holis Patient App | 48 weeks | -EORTC QOL-C30<br>-Overall survival<br>-Progression-free survival (PFS)<br>-HADS |
| (2021) ClinicalTrials.gov Identifier: NCT04019119 | Effectiveness of a Digital Intervention Based on Modification of Lifestyles in Secondary Prevention: iGAME Controlled Randomized Clinical Trial | 48 participants<br><br>(breast, etc) | Randomised controlled trial | Reduce sedentary lifestyle and promote healthy living habits. | application | 12 weeks | -International Sedentary Assessment Tool (ISAT)<br>-Euroqol 5-Dimensions (EQ-5D)<br>-Piper Fatigue Scale (PFS)<br>-FACS |

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| | | | | | | | -Rolland-Morris Questionnaire RMQ<br>-Spine Functional index (SFI) |
| *EORTC:Core Quality of Life questionnaire C30, FACT-L - Functional Assessment of Cancer Therapy, HADS : Hospital Anxiety and Depression Scale, SCNS-SF34: Supportive Care Needs Survey- Short Form, SEMCD: Self-Efficacy for Managing Chronic Diseases 6-item Scale | | | | | | | |

#### 2.3.1.4 Protocols published in Europe

The search, including results from both researchers in Pubmed, CINAHL (EBSCO) and EMBASE without any filters, yielded 8291 studies. After year (last 5 years), English language, Europe countries and participants status (survivors excluded) limitations applied, eleven protocol studies remained. Only mobile application and telephone based interventions were used. The average duration of the interventions that the protocol published in Europe that remained were approximately 26 weeks. Five out of eleven studies recruited patients with breast cancer, four studies recruited patients with any type of cancer, one study recruited gastrointestinal cancer patients and one recruited lung cancer patients. Furthermore, the majority of the studies sample size was approximately 230 cancer patients divided in two groups (control and intervention). The protocols published in Europe description is demonstrated in ***Table 4***.

**Table 4**: Protocols published in Europe

| Author, Year of publication | Title | Target Population | Proposal Methodology | Main purposes | Technology | Intervention Duration | Evaluation metrics |
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| Ciani O et al. (43) (2018) | Lung Cancer App (LuCApp) study protocol: A randomised controlled trial to evaluate a mobile supportive care app for patients with metastatic lung cancer | C: 60<br>I: 60<br><br>(lung) | Two-arm Randomised controlled trial | To determine whether LuCApp, by enhancing self-monitoring of therapy-induced side effects | Mobile application | 24 weeks | -Euroqol 5-Dimensions (EQ-5D)<br>-HADS<br>-SCNS-SF34<br>-ZBI |
| Rami A El Shafie et al. (44) (2017) | Oncologic Therapy Support Via Means of a Dedicated Mobile App - a Prospective Feasibility Evaluation | 50 participants<br><br>(thoracic, pelvic) | Interventional | Device Feasibility | Mobile application | 14 weeks | -EORTC<br>-Patient Satisfaction Questionnaire Short Form (PSQ-18) |
| Lidington E et al. (45) (2020) | Evaluating a digital tool for supporting breast cancer patients: a randomized controlled trial protocol (ADAPT). | 122 breast cancer patients | Randomized controlled trial | To test whether the use of OWise increases patient activation scores at 3- month follow-up by at least four points more than standard care | mHealth application | 48 weeks | -PAM-13<br>-EORTC-QLQ-C30<br>-EORTC-QLQ-BR45<br>-HADS<br>-ED-5D-5L |
| Shelby RA et al. (46) (2019) | Testing a behavioral intervention to improve adherence to adjuvant endocrine therapy (AET) | C: 200<br>I: 200<br><br>(breast) | Randomised controlled trial | To test a novel, telephone-based coping skills training that teaches patients adherence skills and | Telephone-based coping skills training-application | 72 weeks | -Medication Adherence Rating Scale<br>-32-item Menopause Specific Quality of Life |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | | techniques for coping with problematic symptoms (CST-AET). | | | Questionnaire (MENQOL)<br>-Brief Pain Inventory – Short form (BPI-SF)<br>-7-item Insomnia Severity Index (ISI)<br>-8-item Patient Reported Outcomes Information System Fatigue Scale<br>-Patient Reported Outcomes Information System Depression Scale (PROMIS Depression) |
| Kestler AMR et al. (47)<br>(2021) | Digitalization of adverse event management in oncology to improve treatment outcome-A prospective study protocol. | Trial participants:<br>C: 18<br>I: 18 | Controlled trial | Early detection and treatment of adverse events in oncological treatment to improve patients' safety and outcomes. | Smartphone application | 24 weeks | -EORTC |
| Maguire R et al. (48)<br>(2017) | The eSMART study protocol: a randomised controlled trial to | C: 554<br>I: 554 | Randomised controlled trial | - To determine whether, compared with standard care, the ASyMS | Advanced Symptom Management | 48 weeks | -MSAS |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| DOI: 10.1136/bmjopen-2016-015016 | evaluate electronic symptom management using the advanced symptom management system (ASyMS) remote technology for patients with cancer. | (breast, colorectal or haematological cancer patients) | | intervention can lead to reduced symptom burden during active CTX for breast cancer, CRC, HD or NHL as evidenced by a statistically significantly lower total MSAS. | System (ASyMS) Remote Technology (eSMART) - telephone | | -CTX Toxicity Self-Assessment Questionnaire<br>- EuroQol 5-Dimensions |
| Furness K et al. (2018) | A process and mechanism of action evaluation of the effect of early and intensive nutrition care, delivered via telephone or mobile application, on quality of life in people with upper gastrointestinal cancer: a study protocol. | C: 37<br>I: 37<br><br>(gastrointestinal) | 3-arm parallel randomised controlled trial | To measure and compare the effectiveness of the process of intervention delivery whilst also exploring and comparing the mechanisms of action between the two intervention arms in our trial across a range of domains. | NVivo 11 Pro software | 18 weeks | Euroqol 5-Dimensions (EQ-5D) |
| Henkin, J.S et al. (49) (2023) | Telehealth multicomponent exercise and health education in breast | C: 15<br>I: 15<br>(Breast cancer patients) | Randomised controlled trial | The primary study outcome is cancer-related fatigue, which | The Adaptations to Breast Cancer and Exercise Using Telehealth | 12 weeks | -Piper fatigue scale<br>-CES-D<br>-EORTC QLQ-C30 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | cancer patients undergoing primary treatment: rationale and methodological protocol for a randomized clinical trial (ABRACE: Telehealth) | | | will be assessed using the Piper fatigue scale. | (ABRACE: Telehealth) | | |
| Nipp, R.D et al. (50) (2022) | Supportive oncology care at home interventions: protocols for clinical trials to shift the paradigm of care for patients with cancer | C: 150<br>I: 150<br><br>(gastrointestinal, head and neck, lymphoma) | Randomised controlled trial | This work has the potential to transform the paradigm of care for patients with cancer by providing them with the necessary support at home to improve their health outcomes and care delivery. | A novel hospital at home care platform | 24 weeks | - QOL (FACT-G<br>- ESAS<br>- HADS/PHQ-4<br>- FAMCARE |
| Shi, N. et al. (51) (2022) | A Nurse-Led mHealth Self-Management Program (mChemotherapy) for Breast Cancer Patients Undergoing Chemotherapy: Study Protocol of a | C: 47<br>I: 47<br>(total 94 breast cancer patients) | Single-blinded randomized controlled pilot study. | The aim of the pilot study is to determine the feasibility, usability, and acceptability of an mChemotherapy program for breast cancer patients undergoing | A novel nurse-led mHealth program (mChemotherapy) | 6 weeks | -FACT-B<br>-MSAS-SF-SC |

| | | | | | | | |
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| | Randomized Controlled Pilot Study | | | chemotherapy. The objective also is to evaluate the preliminary effects of this program on adherence to app usage, self-efficacy, quality of life, symptom burden, and healthcare utilization among this group of patients. | | | |
| Falz, R. et al. (52) (2021) | CRBP-TS - evaluation of a home-based training and health care program for colorectal, breast, and prostate cancer using telemonitoring and self-management: study protocol for a randomized controlled trial | C: 150<br>I: 150<br>(Three cancer types) | Randomised controlled trial | -The primary aim of this study is to implement and evaluate an online training platform to strengthen physical performance and patient empowerment after cancer surgery.<br>-Significant improvement in the quality of life, fatigue, and depression. | Mobile application | 24 weeks | -EORTC |

*EORTC:Core Quality of Life questionnaire C30, FACT-L - Functional Assessment of Cancer Therapy, HADS : Hospital Anxiety and Depression Scale, SCNS-SF34: Supportive Care Needs Survey- Short Form, ZBI: Zarit Burden Interview, MSAS-SF: The Memorial Symptom Assessment Scale Short Form, FAMCARE: Family Satisfaction with End-of-Life Care, ESAS: Edmonton Symptom Assessment System Revised, PAM-13: Patient Activation Measure.

## 2.4 Discussion

The main study questions that guided this systematic review were the following:

**(a) What telemedicine tools are utilized to monitor the symptoms of people with cancer in EU countries and**

**(b) How did users evaluate telemedicine tools' suitability for managing symptoms such as pain and quality of life?**

With the new knowledge and experiences gained by the increased use of telemedicine applications during the recent COVID-19 pandemic, telehealth services are encouraged to be adopted by all countries and be integrated into all systems (3). To this same end, cancer-focused telemedicine applications aiming on the detection, management and/or prevention of disease symptoms and treatment side-effects, need to be identified and evaluated. Overall, as presented in this review, patients positively assessed the use of telemedicine apps and felt a psychological boost during their remote communication with their attending physician. Also, the recommended behavioral changes led to improvements in physiological indicators such as fatigue and nutrition. These findings led to the hypothesis of the eCAN proposal that cancer patients can be significantly aided on their post-treatment daily life, when assigned attending clinicians will be regularly monitor their patients' progress both mentally (emotions, distress) and physically (pain, physical activity, heart rate, sleep quality).

In this literature review, the search sought only the variables: symptom management, pain management, and quality of life. Also were included apps that can affect quality of life, such as encouraging exercise or healthy eating because can be assumed to contribute to improving quality of life (14,22,55). Most of the apps allowed patients to rate the severity of symptoms pain and quality of life (11,14,15,17,21,24,28,34,46).

In the majority of studies, patients generally expressed satisfaction with using the apps (11,13). According to the determination that with the help of new technologies, self-efficacy (and therefore increased adherence to treatment regimens) improved and demonstrated the potential of new media (e.g., web portals or mobile phone applications) to provide continuous patient-physician communication (16). At the same time, self-care advice and daily symptom reporting through the use of the app created feelings of continuous contact with health

professionals, which in turn increased the sense of recognition and safety. Contacting a nurse following a symptom alert was considered convenient and highly valued (23).

The use of the application significantly contributed to the mitigation of fatigue and improvement of overall quality of life and in pain recording and management (11,12). Also, studies showed a decreased emotional suppression and increased emotional well-being after the digital health intervention. Furthermore, participants reported that during the online intervention, an increase in relaxation and a decrease in stress (8,29). In addition, the application intervention was found to have a significant improvement in nutritional status and significant improvements in global health status (22).

Furthermore, study findings suggest that Internet acceptance has reached high levels and patients over 60 years old are currently more familiar with the Internet (8,53). Internet use for health-related topics appears to be feasible for most patients (8,54). Due to the increase in internet access as well as computer literacy, a growing interest in helping treatment through digital health platforms is expected. Rising health costs and cancer prevalence are likely to increase as the population ages and grows. As a result, there appears to be a need to develop new, less expensive treatments aimed at enhancing patients' self-management skills.

For future developers, applications must be user-friendly. Patient education with smartphone apps can be used as an easy, fun, and effective measure to promote treatment adherence, which may lead to improved quality of life. This should be an area of future exploration.

## 2.5 Limitations and Strengths

As is customary with this kind of data, the results should be interpreted cautiously, as the studies above were heterogeneous and sample sizes were variable. Only some of the studies reported full details for the intervention like what algorithm they used which limits the potential power of the findings. Furthermore, this systematic review was limited to only studies written in English language and presenting only published literature. This presents a risk of publication bias. Finally, the conclusions arising from this systematic review predominately hypothesis-generating rather than definitive or conclusive.

Limitation of the study was the fact, in the search used only three keywords, as a result may not have identified other apps relevant to patient with cancer. Also, the search confined patients undergoing treatment and not to diseases imposed by cancer as a result of potential

applications that measure quality of life not being identified and some technical features not being found that could be exploited during its design.

A literature review is an essential component of all types of research. Studies can contribute to knowledge development, generate policy and practice guidelines, demonstrate the impact of a particular initiative, and, if well conducted, serve to generate new ideas and directions.

The results of this systematic review lead us to the fact that a mobile application is the most ideal means of assessing and providing support to cancer patients as opposed to the use of games which do not seem to have been widely used in the scientific community for this purpose. A variety of clinical trials demonstrate the benefits of using technology during and/or after cancer treatment for patients with cancers, particularly during the COVID-19 pandemic. Patients with breast cancer were more often the participants selected by the trials while patients with head and neck cancer do not appear to have been frequently the target group.

# 3. Telemonitoring System Development

## 3.1 Introduction

The telemonitoring system to be developed (eCAN mobile app) will gather necessary health-related feedback from the cancer patients and eventually form the basis for the following cancer patient teleconsultation by an attending clinician. It will be requested on a regular basis from patients to a) evaluate their health indicators, in particular quality of life, pain and distress levels, b) assess their overall app experience, c) monitor their travel and lost income costs, all through validated questionnaires in the app. Furthermore, daily physiological measurements will be conducted automatically on the patients through wearable devices to provide essential feedback on how physical activity, heart rate and sleep quality are affected.

The aforementioned feedback will be transferred on a web-based platform (eCAN Dashboard) where the attending clinicians of the patients will be able to monitor their patients' progress to provide a more accurate teleconsultation in the following.

## 3.2 Mobile App – Wearable Device

### 3.2.1 Installation

Download the «eCAN» app for android and iOS from Google Play store or Apple Store respectively.

## 3.2.2 Application Use

### 3.2.2.1 Application Start and Login

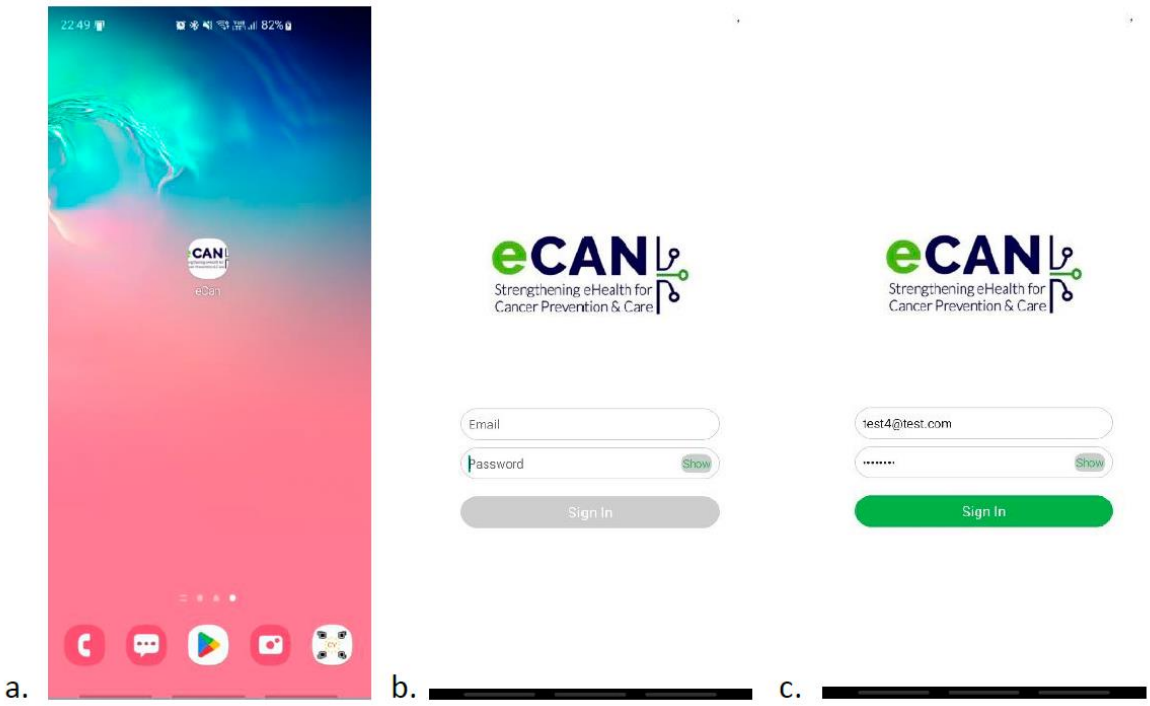



*Figure 2: Mobile application icon and login page*

You do not have to register for this application. You will be given an email and password by the health care professionals to access the app.

To access the application (see *Error! No s'ha trobat l'origen de la referència.*) please enter the email given to you by the health care professionals in the "email" field and the password in the "password" field. Then please click on the "sign in" field. Your details will be saved and will already be filled in whenever you log in.

### 3.2.2.2 Language Selection

The first time you enter the application and once you have completed the login process, the program will automatically take you to a screen (***Figure 3d***) where you can choose your preferred language. This screen will not be displayed again. Once you have chosen your language of preference, you will be taken to the application's home screen (***Figure 3a***). To select your preferred language after the first time you have entered the application, please click on the «SETTINGS» ( ) (***Figure 3a***).

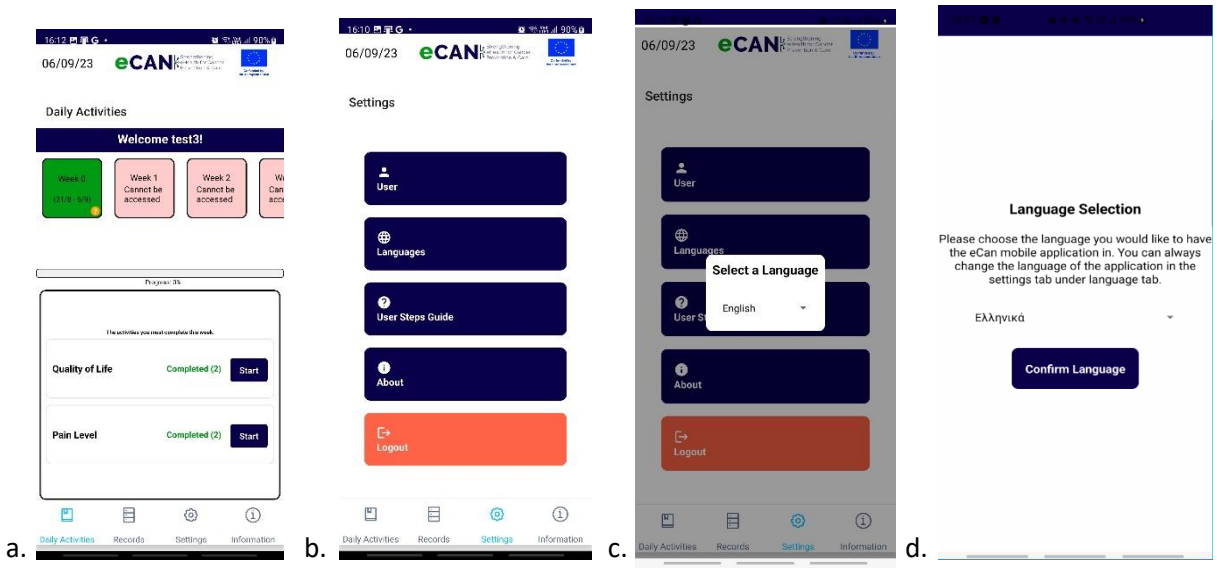



*Figure 3: Language selection screens*

A list of options will appear when you click on "settings" (***Figure 3b***). A list of all available languages can be found by clicking on the "Languages" button. The preferred language of your application can be selected by clicking on it (***Figure 3c***).

### 3.2.2.3 Navigating through the application activities

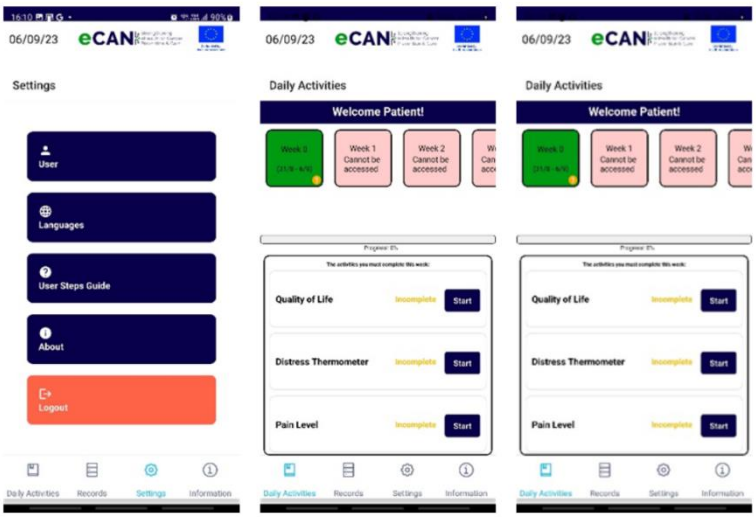



*Figure 4, 5 & 6:: Daily activities section and screenshots*

Please select the "Daily Activities" ( ) which appears on the left bottom of your screen (*Error! No s'ha trobat l'origen de la referència.*). Clicking on the «Daily Activities» will display the "Daily Activities Window" as shown below.

On the top of the screen you can see the week number in the small squares displayed on screen. The week you are currently experiencing will be shown in Black outline and GREEN background. Past weeks and weeks that are yet to come calendar will be shown in PINK. Each week will be assigned specific activities (activities between weeks will vary.)

By clicking on the current week, you can see the activities you need to complete (i.e., the questionnaires you are asked to answer).

In the picture above, you can see the activities and the status they are in (incomplete or completed). If the activity is pending, the word INCOMPLETE will be displayed in YELLOW and next to it the word START in BLUE. The three questionnaires are the EORTC QLQ C-30, the NCCN Distress Thermometer, and the Pain Level Test. Click on the word START to begin completing the activity. Each activity has its own home screen that lists the information you need to know (*Error! No s'ha trobat l'origen de la referència.*).

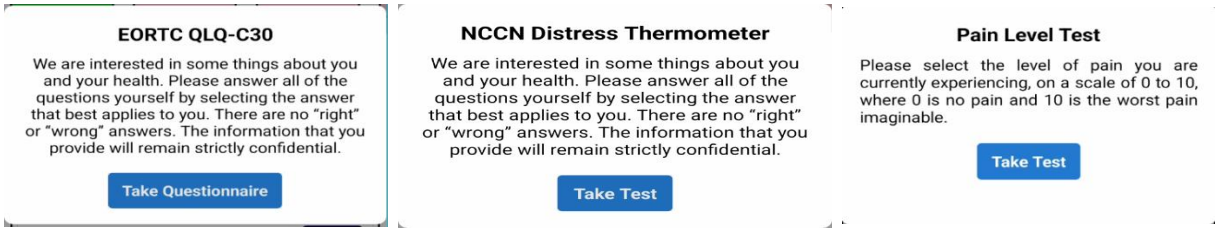



*Figure 7: Activities Popups*

By clicking the button on the home screen of the activity you want, you will be taken to that activity.

In the image (*Error! No s'ha trobat l'origen de la referència.*) below you can see examples of questions and possible answers for the EORTC QLQ-C30 activity. You will be allowed to select only one answer for each question. To complete the questionnaire, you are required to fill in the entire questionnaire. If you do not complete one or more questions, the questionnaire will not let you complete the activity (*Error! No s'ha trobat l'origen de la referència.**b***) and you must exit the activity by using the back button on your device.

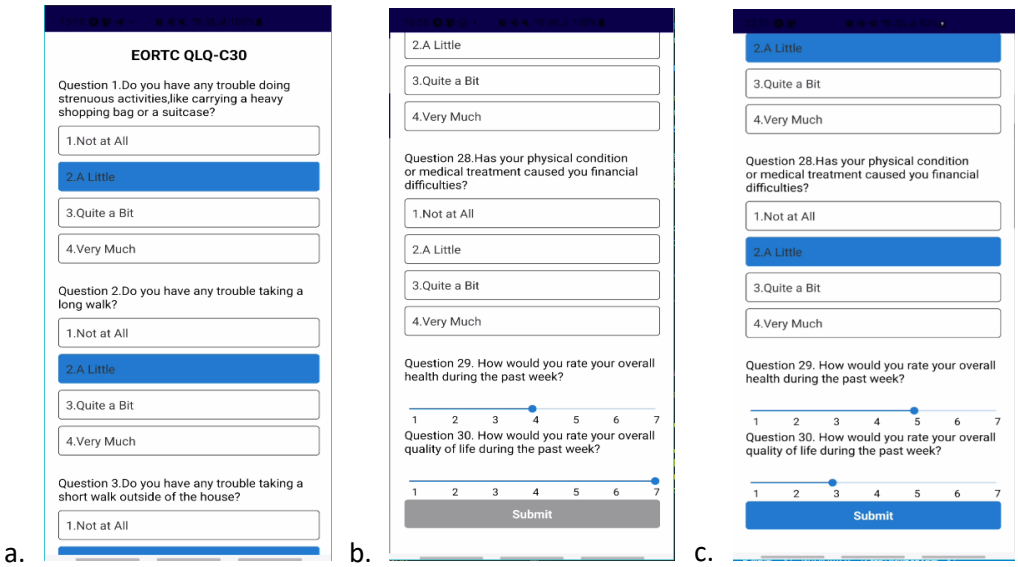



*Figure 8: Questions and answers at QLQC30 screen*

When you have answered all the questions, please select the SUBMIT button (*Error! No s'ha trobat l'origen de la referència.**c***) to submit the questionnaire.

The word COMPLETED will appear in green next to the questionnaire, once you have answered all the questions and successfully submitted the questionnaire.

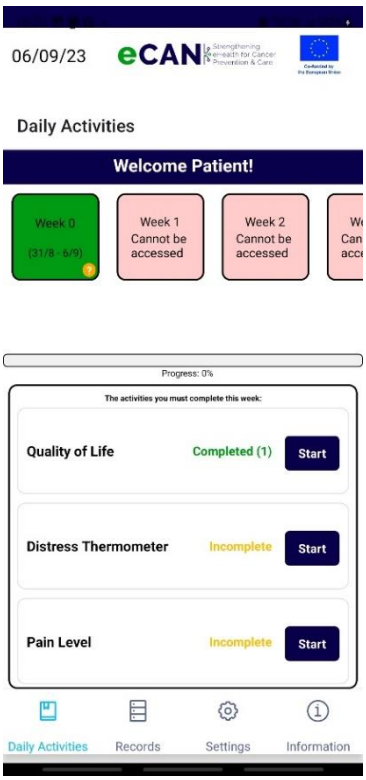



*Figure 9: Screen Displaying completed and uncompleted*

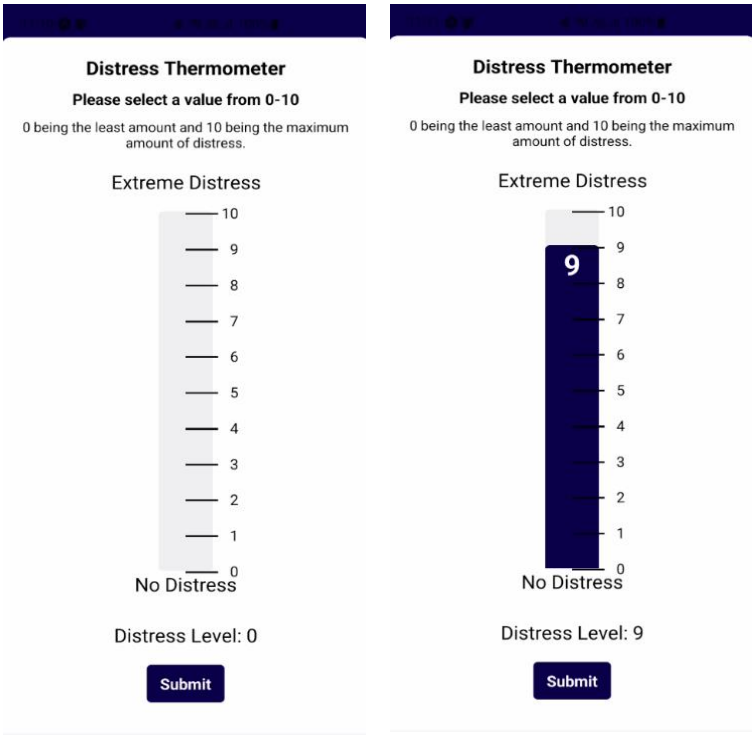



*Figure 10: Distress Thermometer Activity*

In the *Error! No s'ha trobat l'origen de la referència.* you can see an example of the Distress Thermometer. You can select only one value by pressing with your finger on the "Thermometer". The value 0 indicates no discomfort while the value 10 indicates excessive discomfort. When you have chosen a value select the SUBMIT button on the activity.

Below on the image (*Error! No s'ha trobat l'origen de la referència.*) you can see an example of the Pain Level. You can select only one value by clicking with your finger on the "Thermometer". A value of 0 indicates no pain while a value of 10 indicates Excessive pain. When you have chosen a value select the SUBMIT button for the activity.

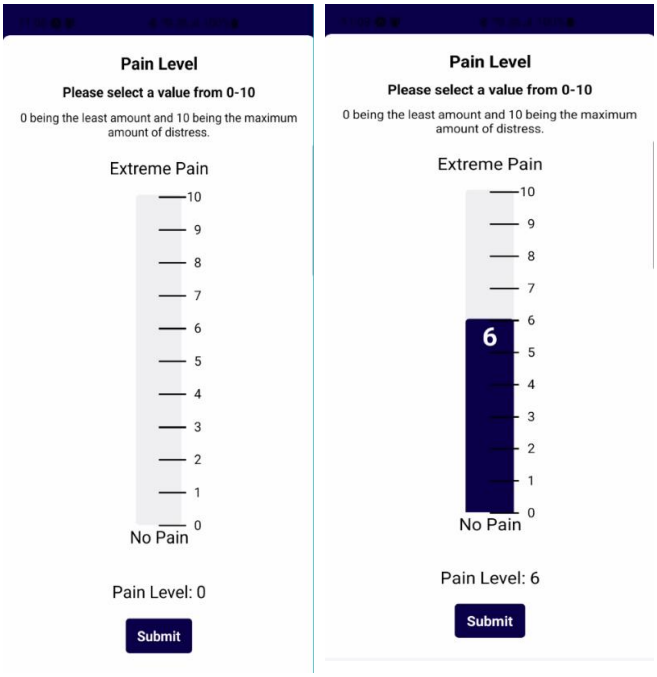



***Figure 11:*** *Pail level activity*


***Figure 12:*** *A completed week*

Once you have completed your week's activities, the week is considered complete (*Error! No s'ha trobat l'origen de la referència.*). You have the option to perform the activities more than once in case something has changed since the day you completed it. Note that some activities might not be shown to you. The activities are based to the Pilot of the project you are currently in.

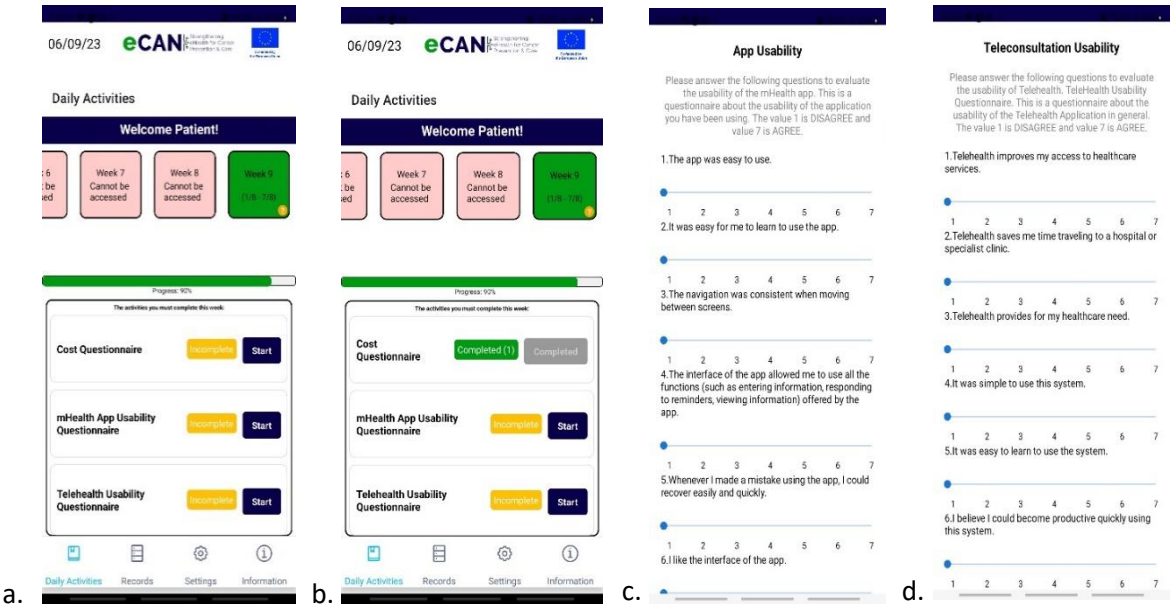



*Figure 13: Last week Overview*

Only the activities of the last week displayed on the app (week 9) can be completed only once (***Figure 13a***). The last week has questionnaires about the cost effectiveness to the patient, the usability of the application and the usability of Teleconsultations

The Cost Questionnaire activity has a similar completion to the EORTC Quality of life questionnaire (***Figure 14***).

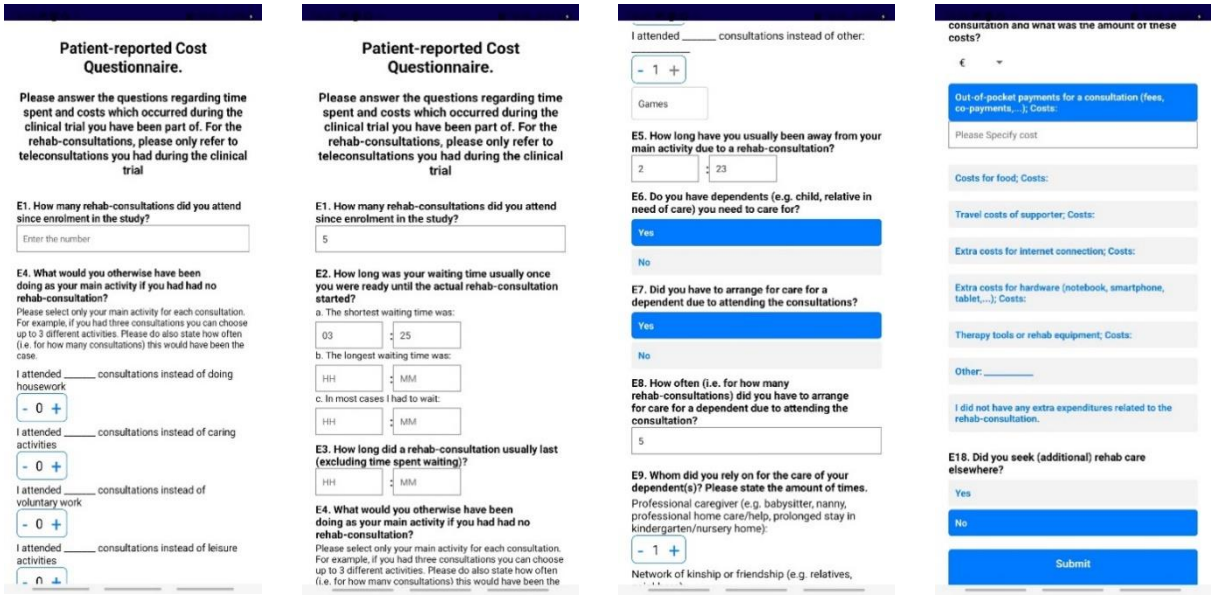
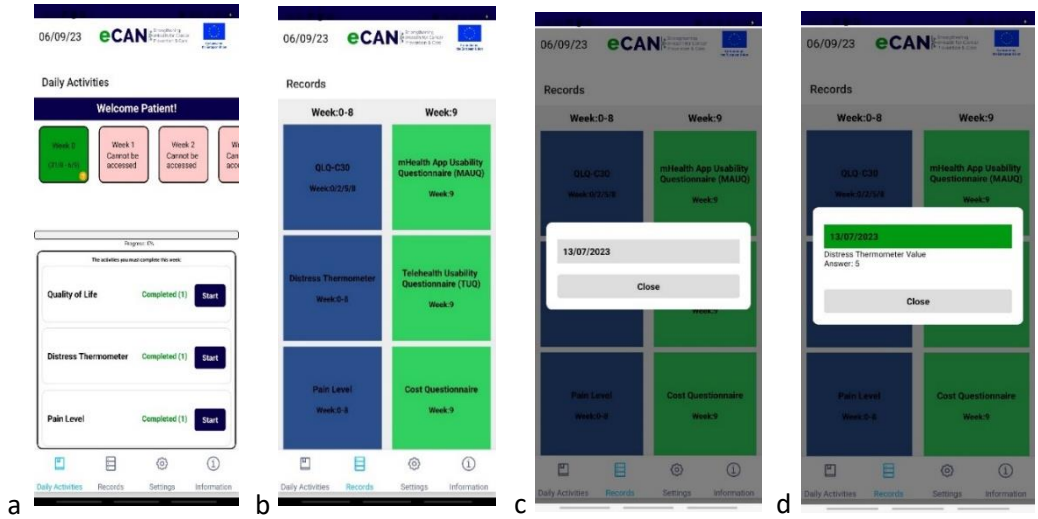



*Figure 14: Cost Questionnaire*

By clicking on the records icon( ) (***Figure 15a***) in the home screen you will see a screen where you can see all the activities of the program for weeks 0-8 and week 9 (***Figure 15b***). By clicking on the activity of your choosing, a popup with all the days you have given an answer will be

shown (***Figure 15c***). By clicking on any day, you can see the answers you have provided for the chosen activity (***Figure 15d***).




The information button (ⓘ) in the home screen (*Error! No s'ha trobat l'origen de la referència.**a***) will give you a User steps Guide (*Error! No s'ha trobat l'origen de la referència.**b***). This guide will

*Figure 15: Records Screen*

remind you of every information you must remember throughout the duration of the program. In case you want to exit the application, you can select "settings" and from the options that will appear click on the "LOGOUT" button. (***Figure*** ).

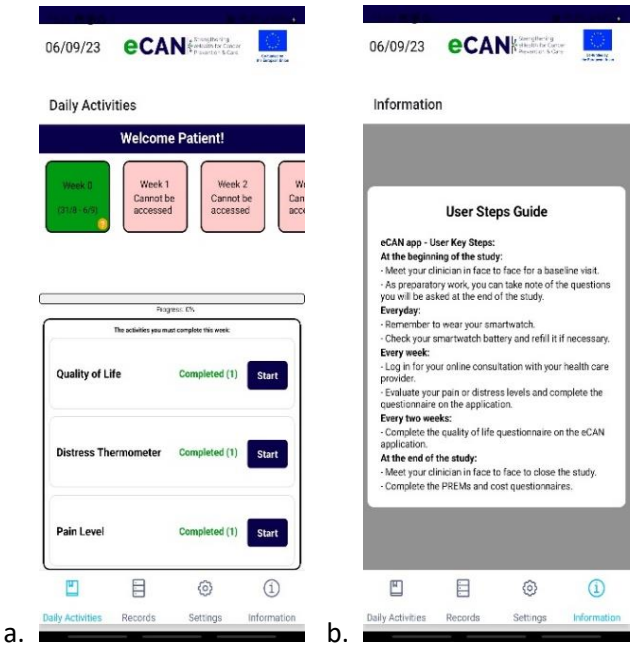



*Figure 16: Information Screen*

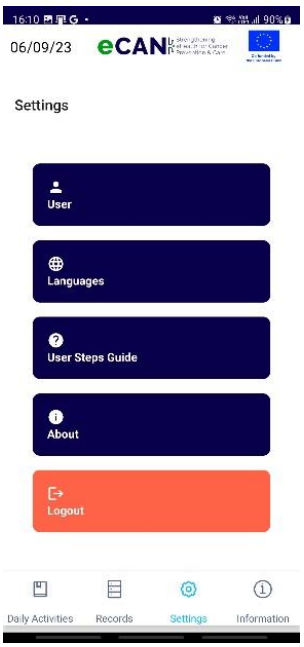



*Figure 17: Application logout selection*

### 3.2.3 Wearable Registration

Identify Garmin connect app in Google play or the Appstore and download it to your mobile device. Garmin connect app has the icon displayed in ***Figure 8***.


*Figure 18: Garmin Connect App icon*

When the Garmin connect app is installed on the mobile device. Users will have to login with the user name and password supplied by the administrator of each pilot site.

Once the app is installed on the mobile, device users will have to pair the wearable with the mobile device. The user will have to press the area displayed with an arrow in ***Figure*** . The user will have to keep Bluetooth open continuously in order to maintain connection of the wearable device with the mobile phone and thus continuously sending data to the eCAN server.

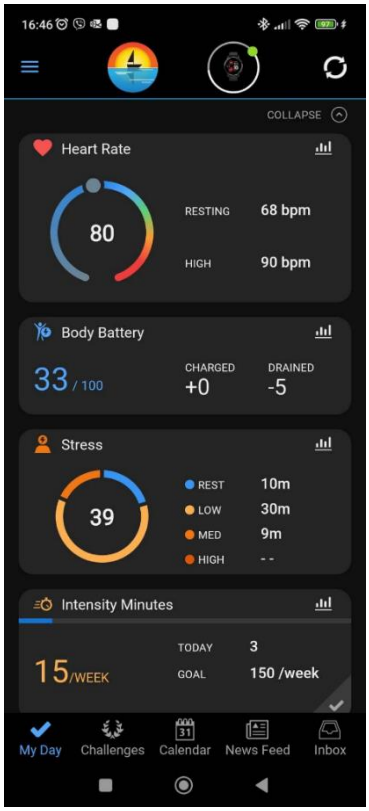



*Figure 19: Garmin connect Main Screen*

## 3.3 Clinician Dashboard

On your browser type https://platform.ecanja.eu/user/login

Once the page loads, click on the **"Login Using the SSO"** button.

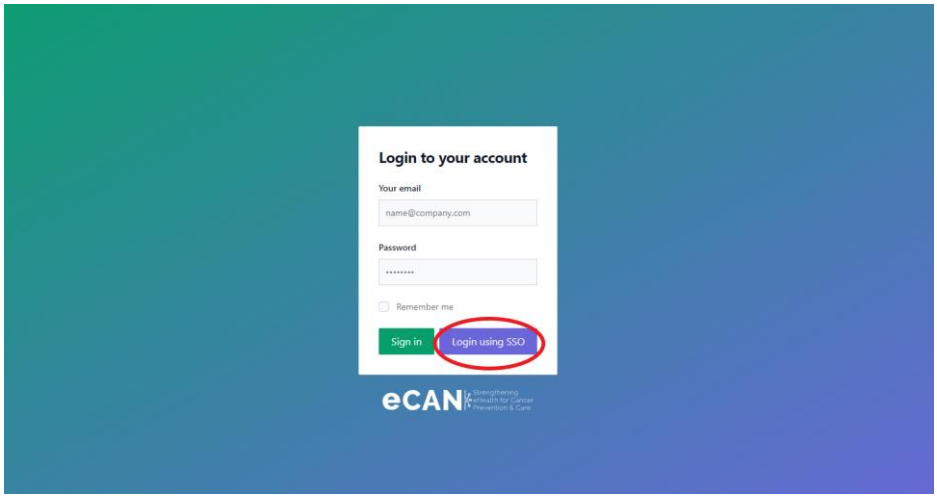



*Figure 20: Dashboard login page*

You will be transferred to the following page, where you can type the username and password that was given to you and click **"Sign in"**.

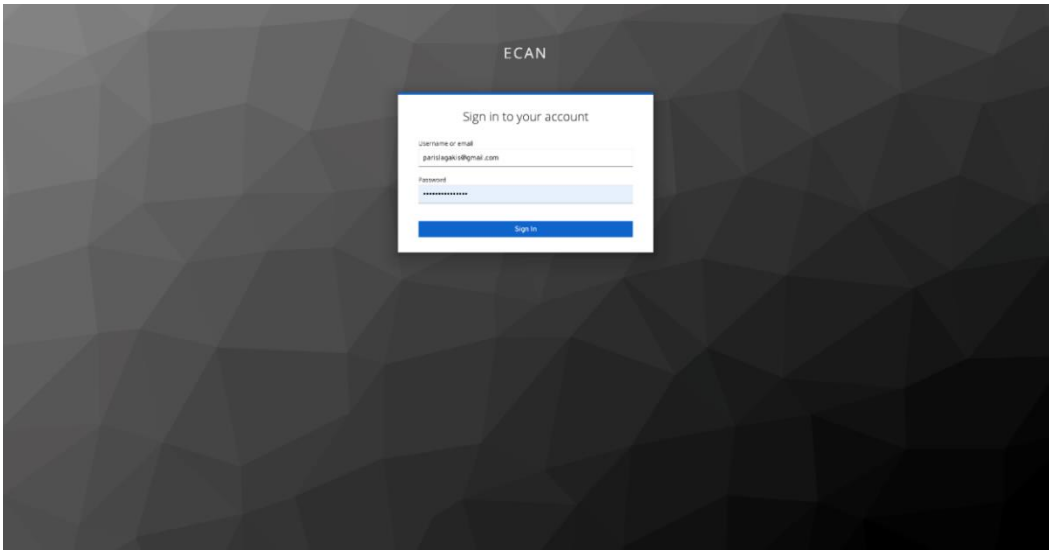



*Figure 21: eCAN Dashboard sign-in*

You have successfully logged in to the eCAN dashboard!

You are now seeing your Home page, where you can view and interact with your patients' list, edit your profile etc.

In order to view your profile click on **"Profile"**, located at the left panel of the screen.

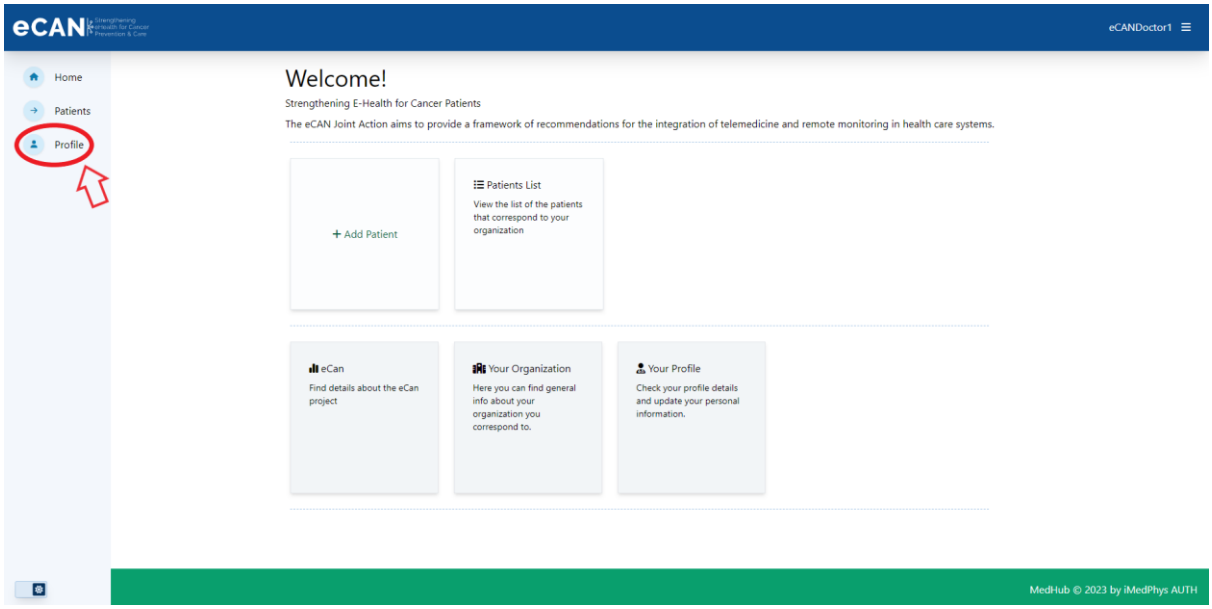



*Figure 22: eCAN Dashboard Home Page*

Under home screen, an easy access to Edumeet is offered, by clicking the corresponding button.

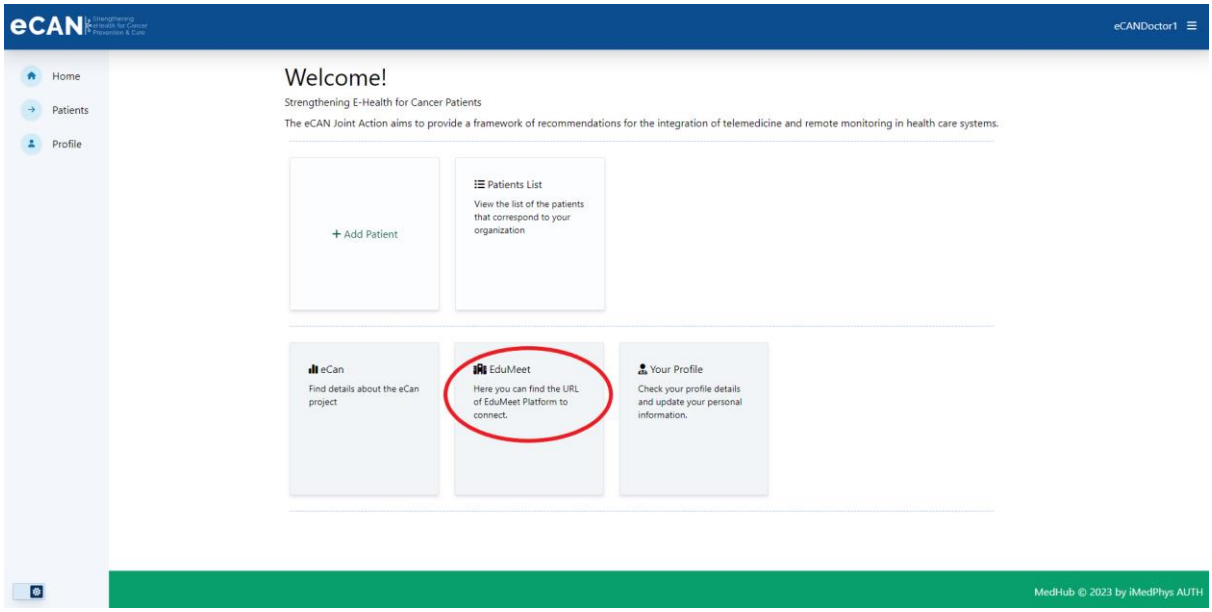



*Figure 23: Access to Edumeet*

In order to go to the patients' list, click on **"Patients"**, located at the left panel of the screen.

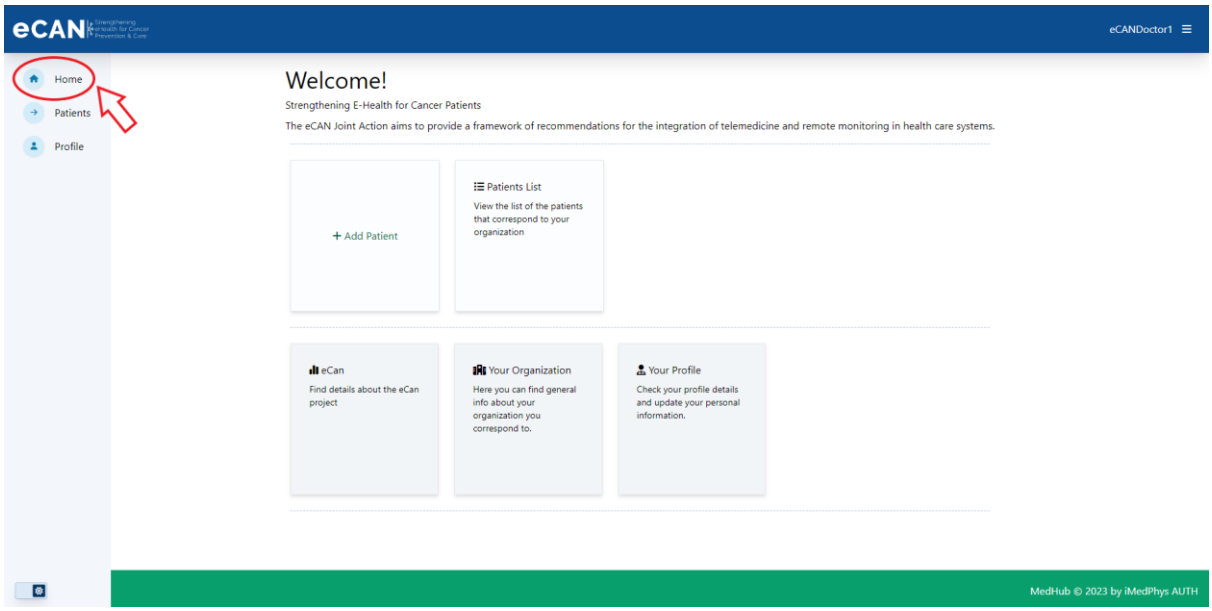



*Figure 24: Patients selection screen*

Here, you can see a list of all the patients currently registered in your organization.

You can change the number of entries appearing on each page (1) and move back and forth between pages (2). You can also see more details for any patient by clicking on the green eye-symbol next to a patient (3).

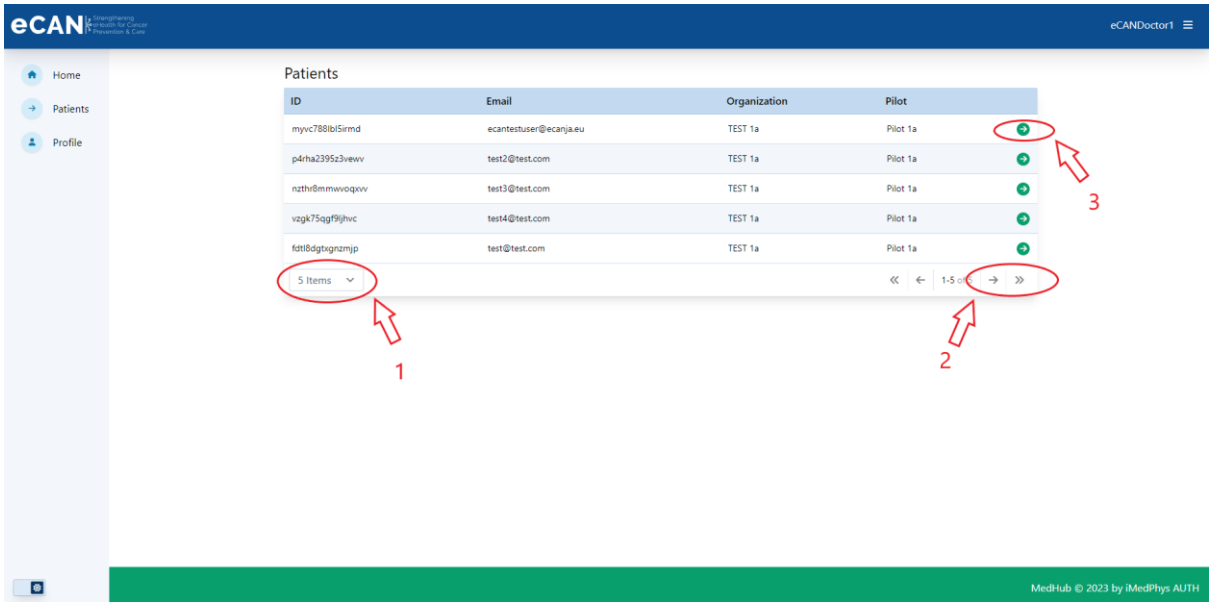



*Figure 245: View patients screen*

By clicking on the green eye-symbol, you are transferred to a page where you can view and modify all available information on any specific patient.

Automatically, the tab you see is the eCRF. You can edit the submission, or start a new one if there isn't one present, by clicking the **"Edit submission"** button (1) or view the available notes by clicking the **"Notes"**, PROMS and PREMS (2).

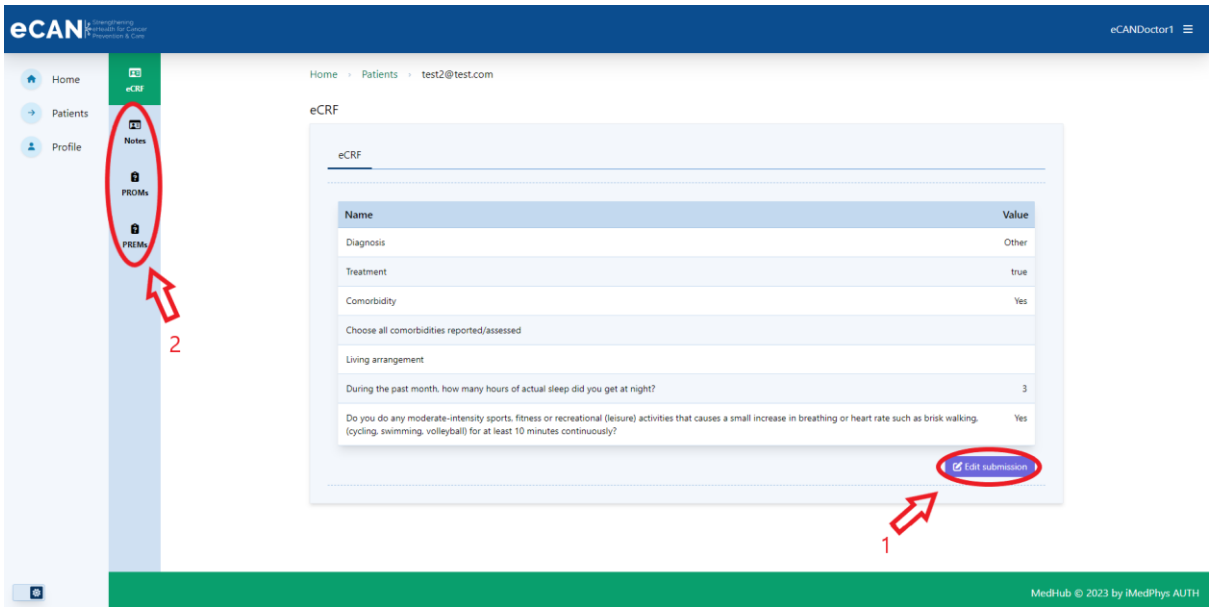



*Figure 56: eCRF main screen*

By clicking the **"Edit submission"** button, you can modify all eCRF information of the patient. Once you are done, click the **"Submit"** button at the bottom of the screen.

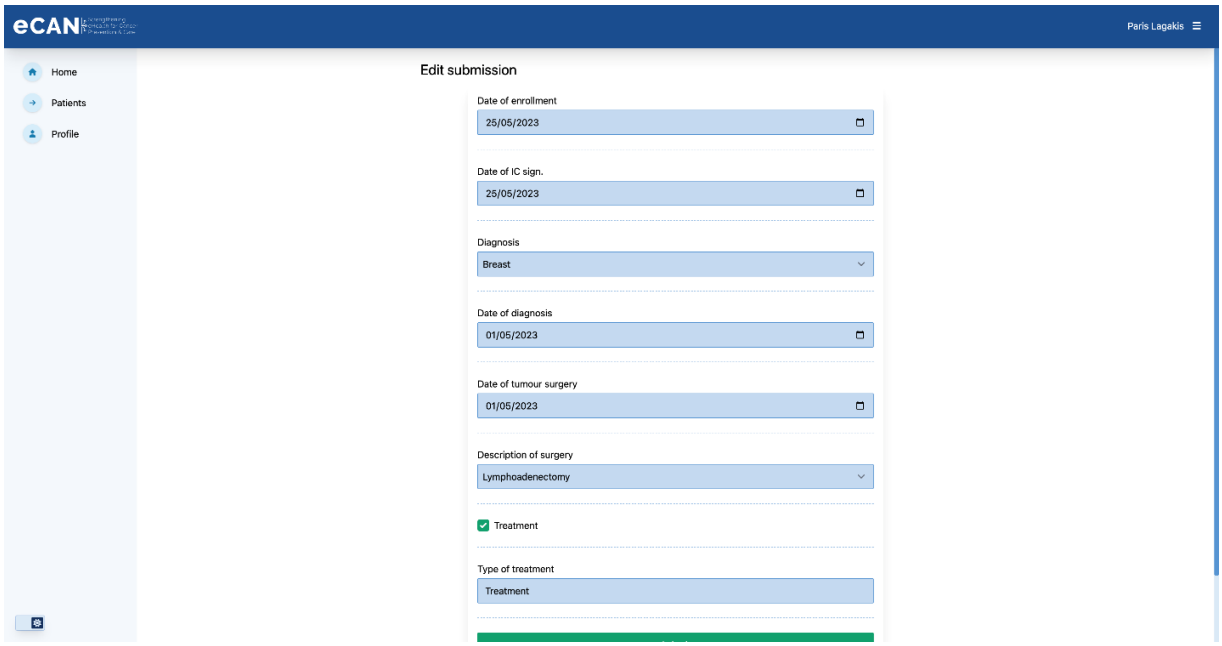



*Figure 267: Edit eCRF screen*

In the Notes tab, you can see all notes on a specific patient registered by members of your organization.

Here, you can edit already existing submissions (1), or add a new one (2).

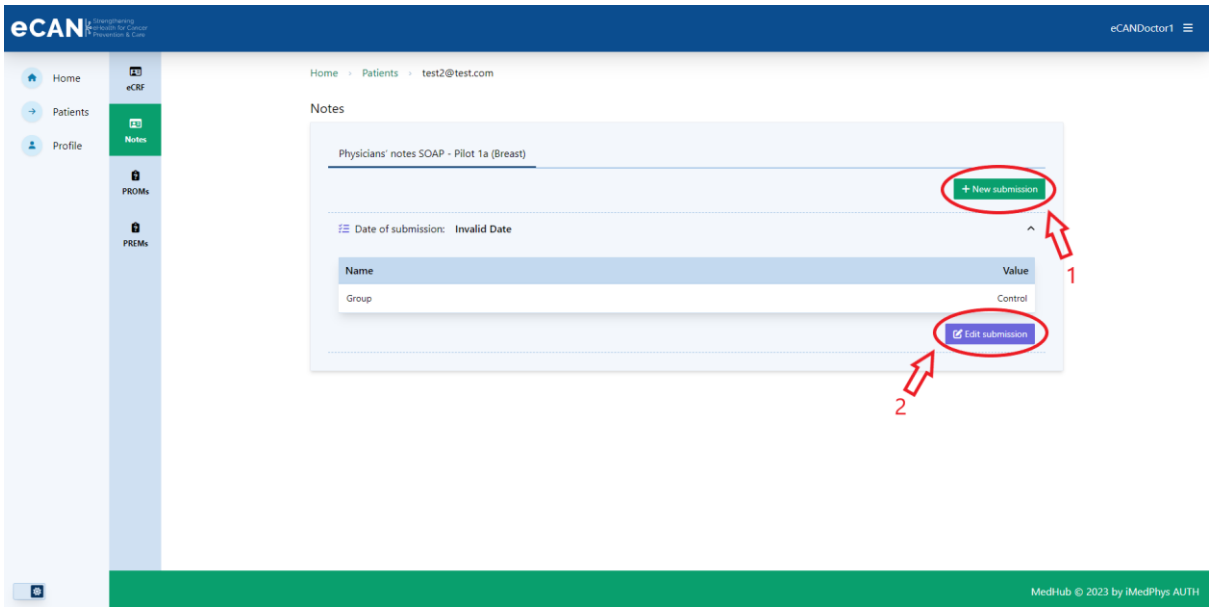



*Figure 278: Edit submitted eCRF data*

If you choose to add a new note, you need to fill out the information requested based on the SOAP framework. Once you are done, click on the "**Submit**" button.

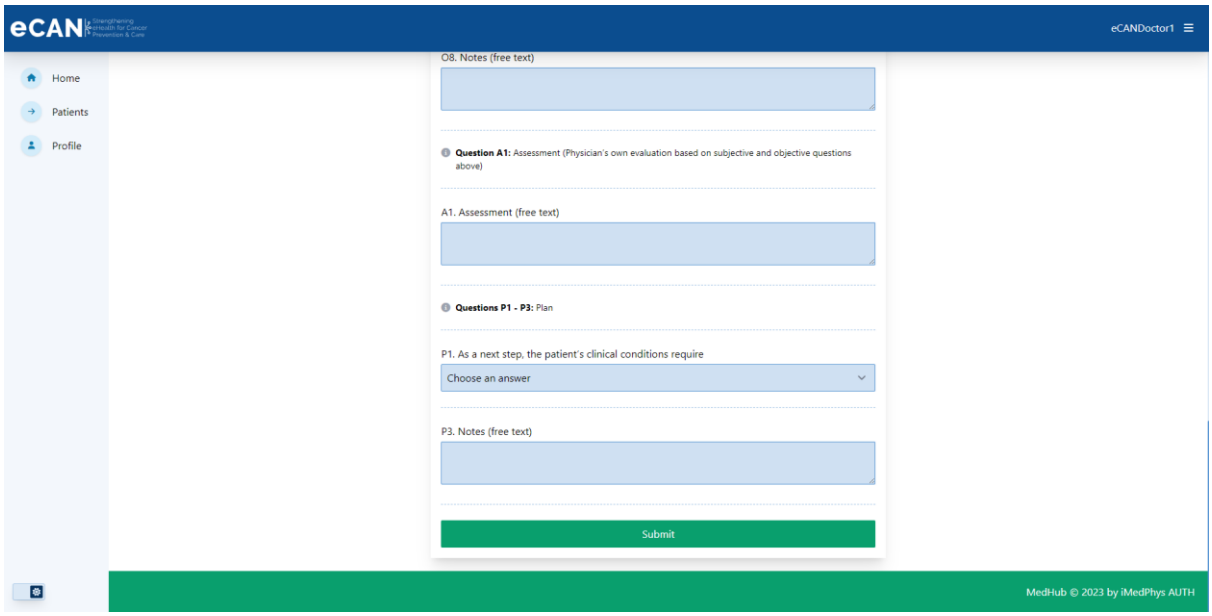



*Figure 289: Add a new note*

On the PREMs and PROMs tabs you can see the participant's answers to the corresponding questionnaires, answered through the mobile app.

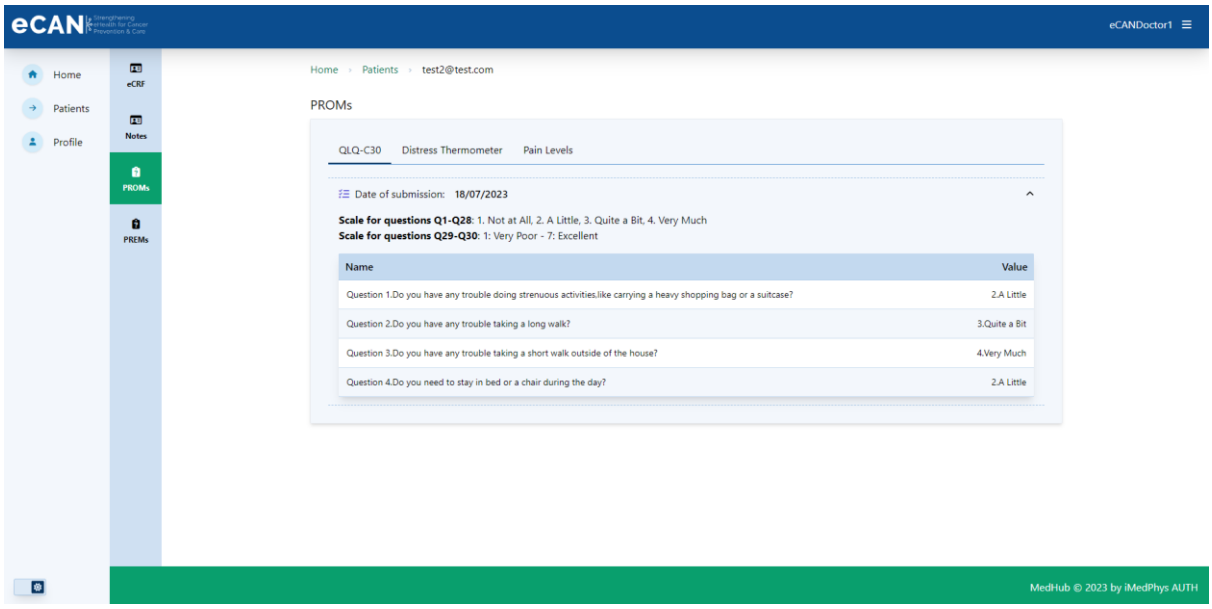



*Figure 30: PREMs' data*

Once you are done, you can sign out by simply clicking on the three lines on the top right of the screen (1) and select "Sign out" (2).

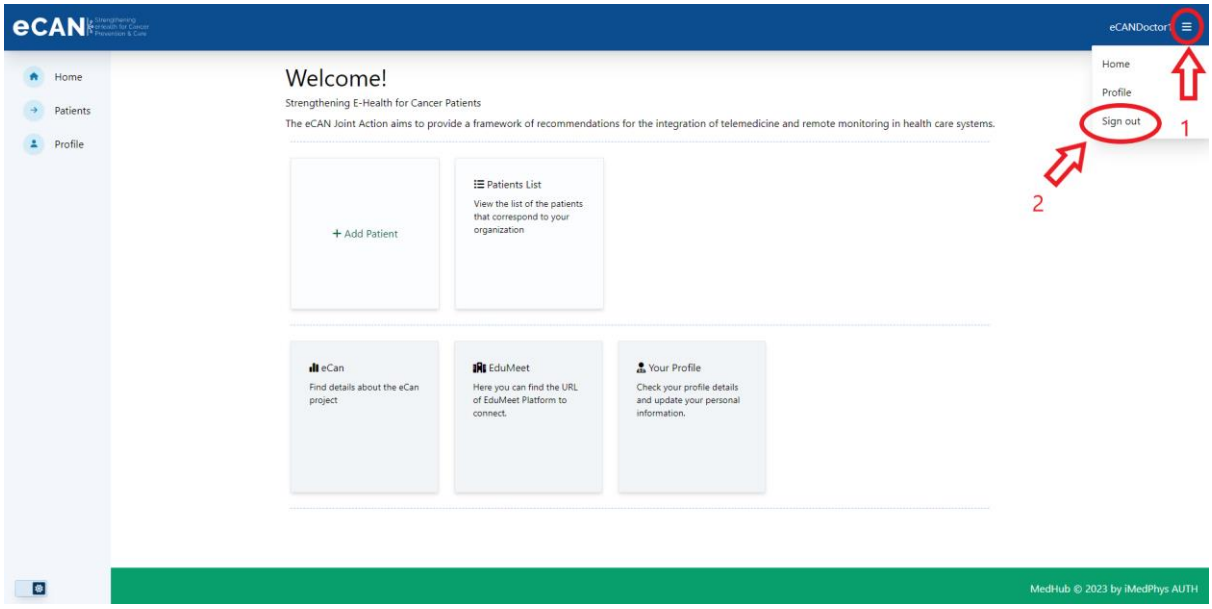



*Figure 31: Sign-out from dashboard*

## 3.4 Patient (Control Group) Web Access

To access the dashboard, simply type [https://platform.ecanja.eu/user/login](https://platform.ecanja.eu/user/login)

Once you do that, you will be transferred to the login screen. Type your username and your password and press the **"Sign in"** button

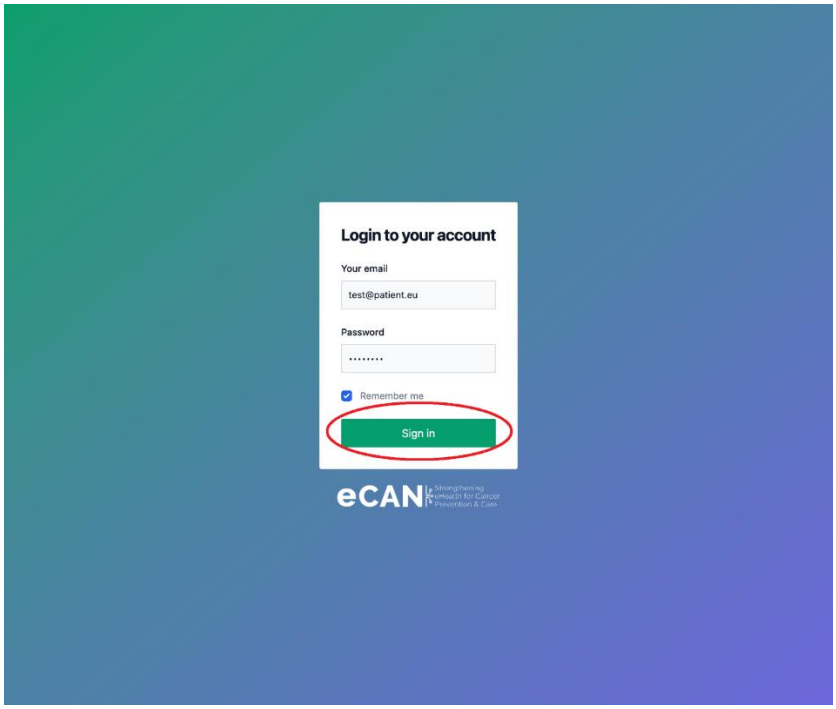



*Figure 329: Control Group Login Screen*

Once you are logged in, you will see a list of questionnaires you need to fill in. You can choose any just by clicking on it

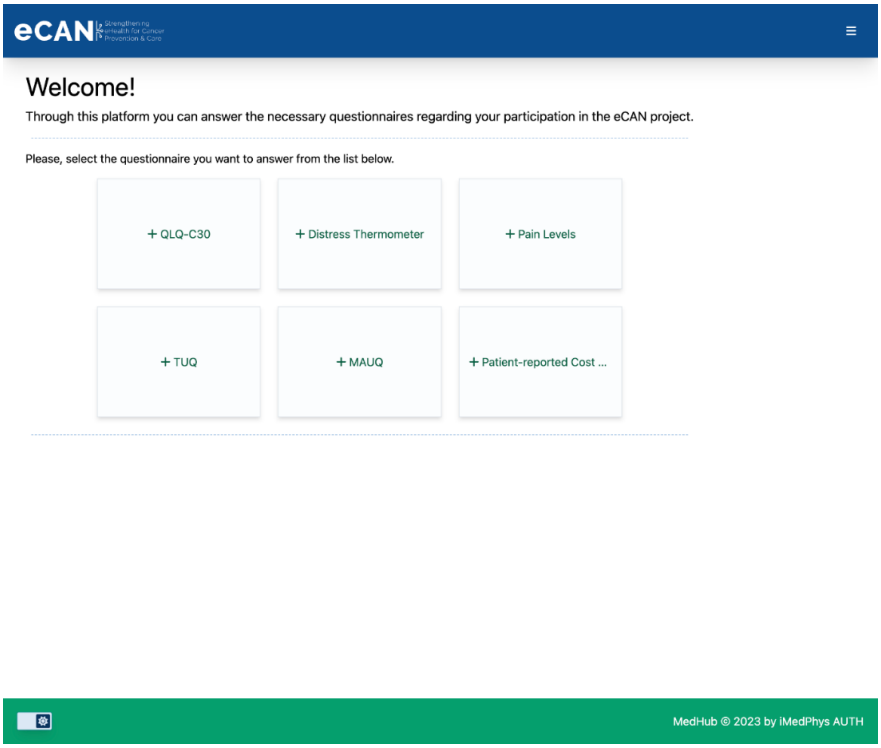



*Figure 33: Initial control group questionnaires screen*

Once you click on a questionnaire, you will need to fill all necessary fields and press submit at the bottom of the page

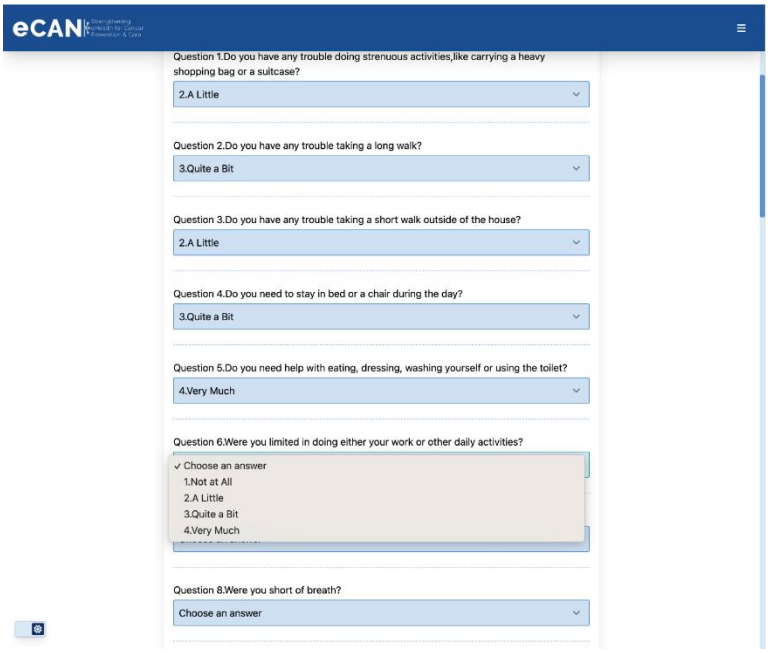



*Figure 3410: Sample questionnaire*

The questionnaires already filled will appear on your home screen ticked

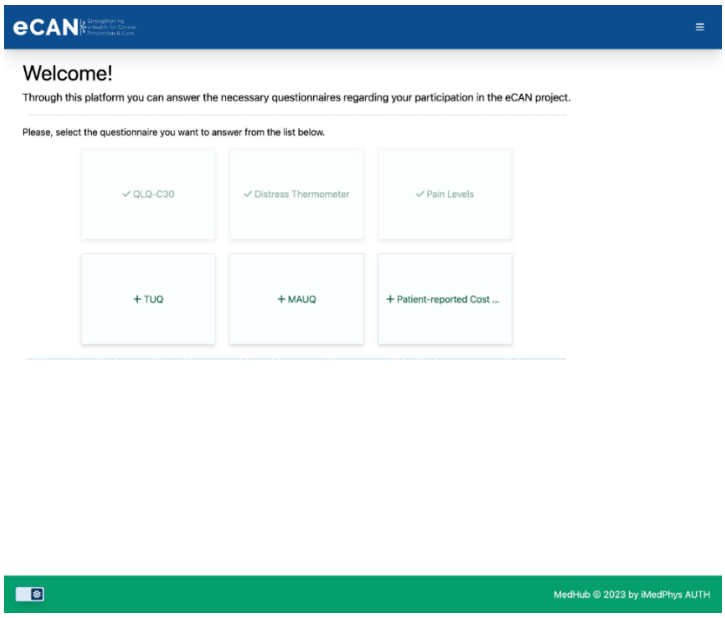



*Figure 35: Control group questionnaires screen displaying completed and uncompleted questionnaires*

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