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Review Article

FORECAST – A cloud-based personalized intelligent virtual coaching platform for the well-being of cancer patients

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ABSTRACT

Well-being of cancer patients and survivors is a challenge worldwide, considering the often chronic nature of the disease. Today, a large number of initiatives, products and services are available that aim to provide strategies to face the challenge of well-being in cancer patients; nevertheless the proposed solutions are often non-sustainable, costly, unavailable to those in need, and less well-received by patients. These challenges were considered in designing FORECAST, a cloud-based personalized intelligent virtual coaching platform for improving the well-being of cancer patients. Personalized coaching for cancer patients focuses on physical, mental, and emotional concerns, which FORECAST is able to identify. Cancer patients can benefit from coaching that addresses their emotional problems, helps them focus on their goals, and supports them in coping with their disease-related stressors. Personalized coaching in FORECAST offers support, encouragement, motivation, confidence, and hope and is a valuable tool for the wellbeing of a patient.

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Introduction

With improved cancer treatments and the possibility of increasing survival rates, there is a growing need for addressing the Quality of Life (QoL) of cancer patients and survivors. Taking offset in the World Health Organization definition of health [1], health-related quality-of-life (HRQoL) is a multidimensional construct defined as physical, mental, and social functioning and well-being [2]. A large and growing body of research shows that HRQoL of cancer patients and survivors is challenged by a number of disease- and treatment-related side- and late effects. This applies to the most prevalent cancers such as breast [3] prostate [4], and lung cancer [5] as well as other common malignant diseases [6–9]. In addition to being associated with reduced well-being, a growing body of longitudinal research evidence suggests that HRQoL may be a significant prognostic predictor, with lower levels of HRQoL associated with poorer survival, both for cancer in general [10] and for specific cancers such as breast [11], prostate [12], and head and neck cancer [13].

The most frequently reported physical complaints include cancer-related fatigue [14,15], sleep disturbances [16,17], and pain [18,19]. The major emotional and mental health issues in adapting to cancer diagnosis, treatment and follow-up include cancer-related distress [20] related to excessive fear of cancer recurrence [21,22] and depressive symptoms [23], together with cancer- and cancer treatment-related cognitive impairment [24,25], both subjectively [26] and objectively assessed [27,28]. Cancer diagnosis and treatment also pose challenges to the social well-being, not only of the cancer patient, but also his or her partner, and couples can be viewed to react as a unit, rather than individuals while coping with cancer. Depending on the dyadic coping style and the communicative skills of the couple, facing cancer may improve or disrupt the relationship [29,30]. Sexual problems are frequent and may affect marital adjustment to cancer and marital quality many years after completed treatment [31,32]. With increased survival rates, returning to work (RTW) after completing treatment is important for both economy and rehabilitation. However, RTW varies considerably by cancer type and treatment, work type, as well as physical, psychological, and social factors [33].

While the described physical and mental side- and late effects generally tend to diminish over time, some subgroups of cancer patients may continue to experience problems such as pain, sleep problems, and depression many years after they have completed the treatment [34–37].

Side- and late effects are frequent, undesirable companions of most cancer treatments. Generally, such side (and late) effects do not occur as solitary events, but result in clusters of symptoms that share a common etiology [38,39]. Physical and behavioral comorbidities, such as fatigue, pain, sleep problems, and depression, often arise during cancer treatment and persist long-term to complicate survival and impair HRQoL [40]. Cancer-related symptom clusters are proposed to share common cytokine-based neuro-immunologic mechanisms [41], and growing evidence has linked alterations in inflammatory biology dynamics to these long-term effects of cancer diagnosis and treatment [42,43]. For example, cancer and treatment-induced sleep disturbances may drive inflammation, which together may contribute to depression, fatigue, cognitive impairment, and exacerbation of pain, which in turn may lead to reduced physical activity and reduced social interaction, which may again negatively impact sleep, cognition, and pain. Another body of evidence provides further links to additional factors by showing that social support plays a major role in adapting to cancer and cancer treatment and maintaining well-being [44] with the availability and quality of social support identified as a key predictor of psychological morbidity among cancer patients

and survivors [45]. Partners and close family members are major sources of emotional and practical support [46], and perceived lack of emotional supportive behavior from significant others, e.g., due to insufficient communication skills [30] has been shown to be a significant predictor of distress among cancer patients and survivors, particularly early in the cancer trajectory [47]. With respect to fulfilling societal roles such as work, research indicates that for cancer survivors, the main issues influencing both their return to work as well as their functioning at work after having returned to work, include physical problems, e.g., fatigue, sleep problems, and limitations in physical function, as well as psychological challenges such as depressive symptoms, anxiety, and cognitive limitations [33,48].

While cancer patients and survivors show a wide range of physical, mental, and social problems challenging their HRQoL, there is, as shown above, growing evidence indicating that many of these problems are bi-directionally inter-related. In addition, emerging evidence suggests that interventions targeting one key symptom in a cluster may have secondary effects on one or several of the remaining symptoms. There is thus promising evidence suggesting that different intervention strategies, e.g., relaxation or cognitive-behavioral therapy, may have effects on the same symptom, e.g., sleep [49] and that targeting one symptom, e.g., sleep, may also have effect on comorbid symptoms such as anxiety and depression [50,51].

On this background, we have developed the framework of a comprehensive virtual coaching environment for cancer patients and survivors, which combines the following interactive components: a) an assessment module, based on the best available evidence concerning the valid assessment of the level of common physical, mental, and social concerns, problems, and unmet of cancer patients and survivors, including sleep disturbance, fatigue, pain, depressive symptoms, fear of cancer recurrence, cognitive function, and social relationships, b) a set of coaching modules designed to target each of these issues/problems providing step-wise intervention components, ranging from educational approaches to cognitive-behavioral training, and c) a set of general/non-specific coaching modules providing support for physical activity, nutrition, and stress-reduction/relaxation techniques.

This paper is organized around 5 sections. Section I is the introduction to characteristics and needs of cancer patients, as well as the KPIs that are observed concerning their wellbeing and the impact, on them, of traditional coaching based on evidence from recent studies. In Section II, the FORECAST cloud eHealth platform is presented and the early results from applying variation of this platform in a regulated clinical research endeavor to patients suffering from chronic conditions, other than cancer, are presented in Section III. Section IV discusses the expected impact and finally, the conclusions and future work are presented in Section V.

FORECAST cloud eHealth platform

The FORECAST architecture is structured around an integrated cloud platform that facilitates the operation of a virtual coaching center of efficient, integrated, personalized, scalable, extensible and flexibly replicable services for people with cancer and their caregivers, aiming to empower and motivate them and to help them improve and maintain their independence, functional capacity, health status as well as preserving their physical, cognitive, mental and social well-being during treatment and then in follow up. In order to achieve the desired impact, FORECAST differentiates from trivial coaching platforms and reaches high levels of personalization and user-acceptance, by utilizing innovative ICT and medical approaches that are described below.

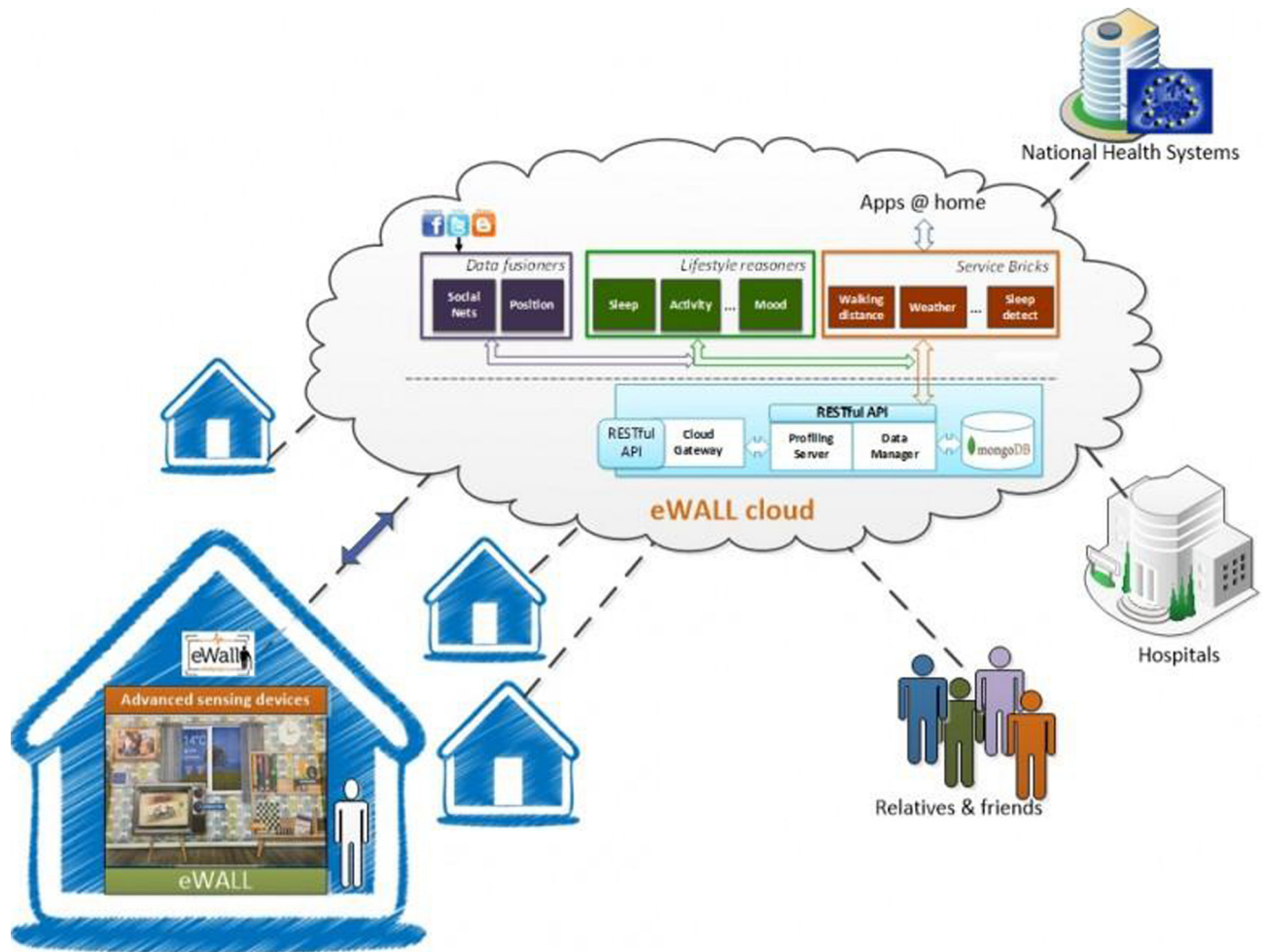


Fig. 1. The eWALL-powered CloudCare2U-CC2U platform [61], consisting of two segments; the cloud- and the home-segment. Data from IoT is captured at the home-segment, while processing, reasoning and intelligent decisions making occurs at the cloud-segment.

Technology background

FORECAST is based on an eHealth platform that leverages best of breed of future internet technologies (cloud, IoT/IoMT, BigData) and will be based on a readily available technology platform, namely CloudCare2U (www.cloudcare2u.com). CloudCare2U (CC2U) is based on the open-source platform of the flagship European Commission project eWALL [61] that supports the independent living and wellbeing of patients with chronic diseases. CC2U utilizes a holistic infrastructure model and an affordable, easy to install system that will fade into the background. During its design, a multidisciplinary approach was used to determine the needs of specific target groups and to create a dynamic “caring home” environment capable of “sensing” and “learning”. In order to preserve and enhance health, functional capabilities, self-confidence, safety and mobility the system includes a scalable, modular cloud-based platform capable of integrating various off-the-shelf and custom devices. The cloud platform can support any number of sensing environments based in primary users’ homes and responsible for explicit and implicit interaction with the primary users, as shown on Fig. 1.

A major characteristic of eWALL is the user interface that creates a new user experience for the patient, aiming to address technology acceptance, a major obstacle for the use of eHealth solutions (see Fig. 2).

One of the strongest capabilities of CloudCare2U-CC2U is the coaching that involves the eWALL Intelligent Decisions Support System (IDSS), the Notification Manager and services like the Personal Daily Support Service (PeDaS). The notifications are messages with attributes, like timing, intention, content and representation, as depicted in Fig. 3.

The PeDaS service provides support for users in their daily activities that include, but are not limited to: sleeping (waking up, going to sleep, quality of sleep, and wandering); preparing and consuming meals; scheduled meetings/activities; taking medicines; doing physical and cognitive training; personal hygiene. The PeDaS system includes 4 different components: calendar, home sensing system, reasoner, and user interaction. It is a modular system in the sense that it is able to use multiple sensors (and) to distinguish different activities (see Fig. 4).

The so-called reasoner component of the PeDaS is based on the connection to several eWALL services for sensing information (e.g. sleep) and services that are used to promote healthy habits, like the well-being advertisements. As a basic requirement, the reasoner is able to link the information in the calendar, like lunch, to an activity observed by the sensors, e.g., that the user is currently engaged in cooking. Each item in the calendar has certain boundaries indicating the timeframe in which the activity is supposed to be done. Outside these boundaries, a notification/alarm is generated. Different levels of notifications/alerts are possible, depending on



Fig. 2. The interaction interface [61] that provides access to numerous applications for exercise, medical measurements, activity tracking, cognitive games, calendar applications, weather forecast and photo stream.

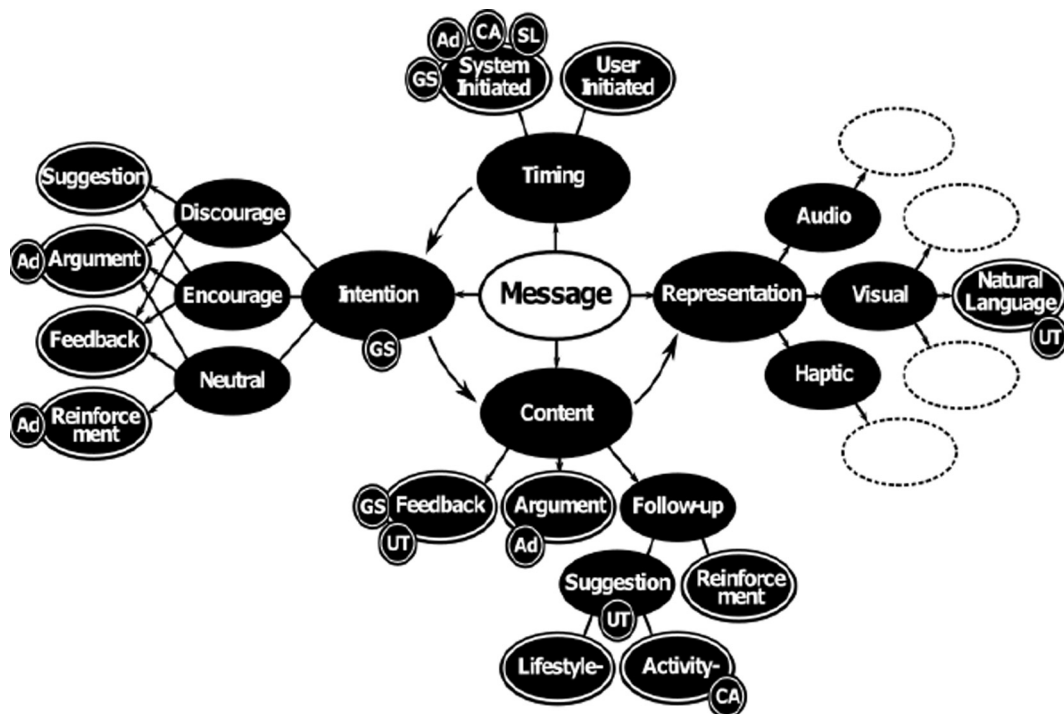


Fig. 3. Notification messages attributes [61] of the coaching engine for personalized interaction with the patient.

the urgency of staying within the timeframe, which is different for the different activities, e.g. medication is more restricted than lunch. At a higher level, the intelligence is able to adapt the timing of these activities gradually from an initial – healthy – setting by

e.g. the caregiver to a personal setting, while keeping an eye on healthy boundaries. When eWALL detects (slow) changes in certain daily activities or habits (e.g. the user wakes up in the middle of the night, and sleeps in the afternoon) notifications are sent to the

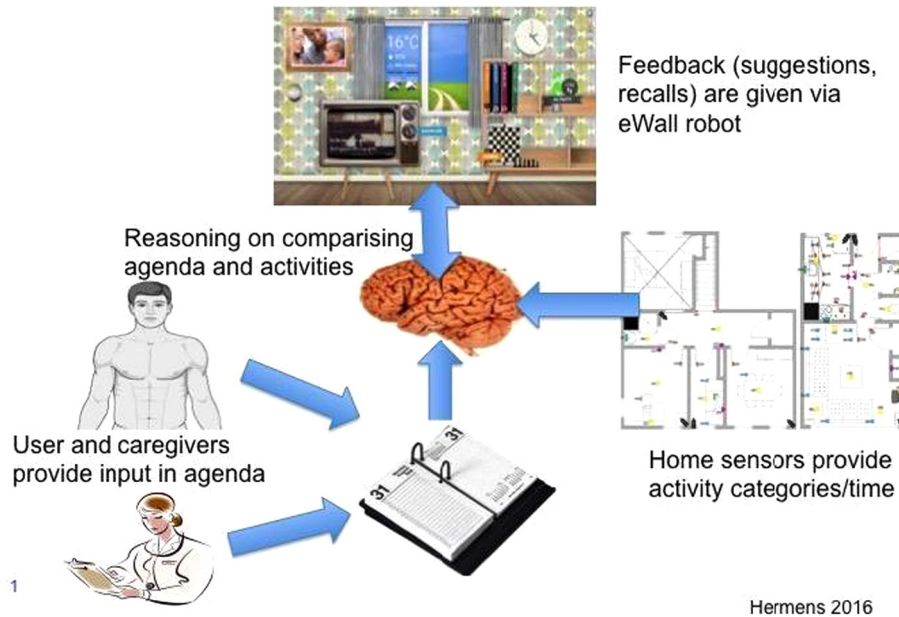


Fig. 4. Functional architecture of the PeDaS [61] that involves reasoning with user or caregiver input and context information.

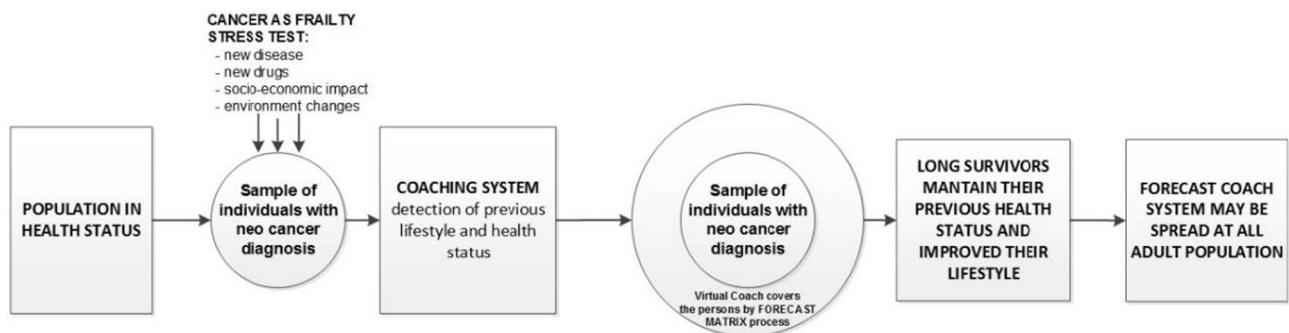


Fig. 5. FORECAST approach that detects lifestyle and health status.

caregivers. The results of the reasoner are given back to the user via the eWALL robot. At the basic level, the robot will provide feedback on, e.g., deviation between the planned lunchtime and the actual lunchtime, observed by the sensor system. Certain activities will be automatically entered to the calendar, or compared to items therein for the user to confirm. For the rest, the user or the informal caregiver will be prompted by the eWALL robot.

The FORECAST eHealth platform

The FORECAST design is based on the described functionalities that are customized to support the virtual coaching framework for the cancer patients, following an approach that detects lifestyle and health status from individuals with neo cancer diagnosis, aiming to support long survivors to maintain their previous health status and improve their lifestyle, as depicted in Fig. 5.

FORECAST deploys a model framework approach that takes offset in the growing evidence indicating that a) the HRQoL issues experienced by cancer patients and survivors can be viewed as clusters of inter-related symptoms driven by overlapping mechanisms, b) these symptoms and concerns can be targeted by various cognitive-behavioral approaches efficiently and cost-effectively, and c) although the research is still in its infancy, that these approaches can be delivered by technology-based methods.

On this background, a comprehensive virtual coaching environment for cancer patients and survivors is applied, which combines the following interactive components: a) an assessment module, based on the best available evidence concerning the valid assessment of the level of common physical, mental, and social concerns, problems, and unresolved issues of cancer patients and survivors, including sleep disturbance, fatigue, pain, depressive symptoms, fear of cancer recurrence, cognitive function, and social relationships, b) a set of coaching modules designed to target each of these issues/problems providing stepwise intervention components, ranging from educational approaches to cognitive-behavioral training, and c) a set of general/non-specific coaching modules providing support for physical activity, nutrition, and stress-reduction/relaxation techniques. The proposed framework is illustrated in Fig. 6.

The proposed function and approach of the virtual coach can be illustrated by the following example. As a first step, when initiating the virtual coach, the user will be asked to enter a user name and provide relevant demographic, disease-, and treatment-related data. The assessment module will then be initiated and collect initial HRQoL data covering physical, mental, and social well-being and functioning with a limited number of items for each domain. The assessment module may, for example, identify the following problems and concerns as being above their respective cutoffs:

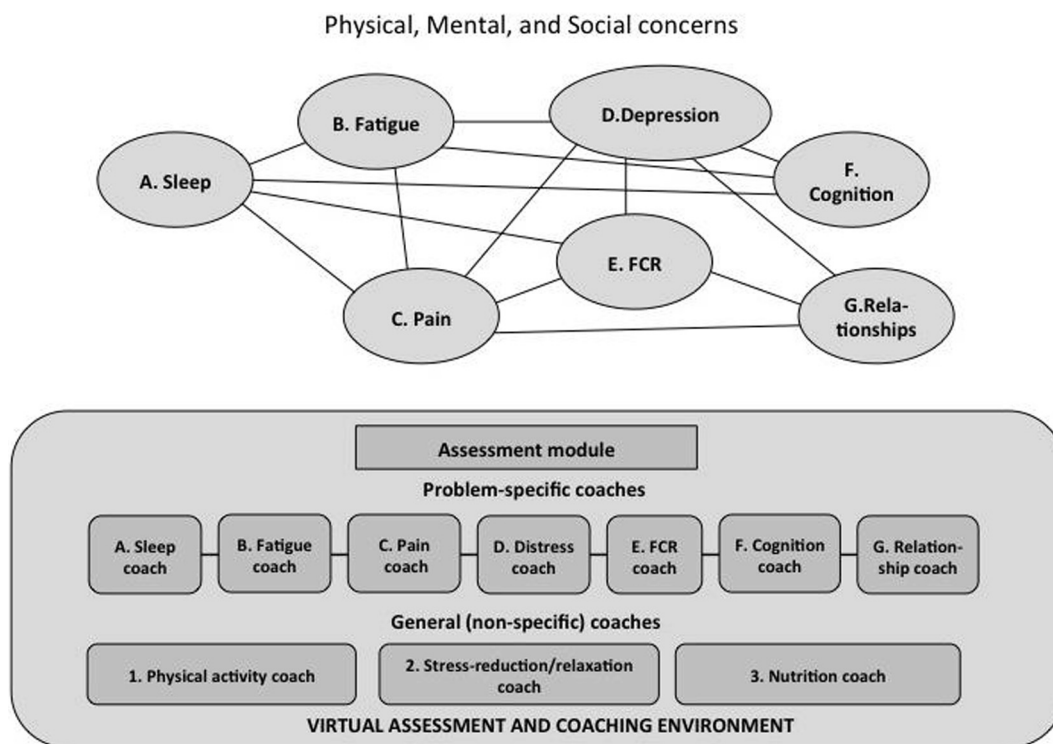


Fig. 6. Coaching model framework of FORECAST.

poor sleep quality, high levels of fatigue, and moderate levels of pain. The virtual coach will then provide feedback to the user describing the issues identified, and the assessment module will then focus on detailed assessment of the most prominent problem, in this case sleep disturbance as measured with a validated instrument, e.g., the Insomnia Severity Index [52]. The relevant coach module, in this case the sleep module, will then be initiated. The sleep module is based on the best current evidence for targeting sleep problems, i.e., cognitive-behavioral therapy for insomnia (CBT-I) [53], which consists of various combinations of various evidence-based approaches for treating insomnia [54], including sleep hygiene education [55], sleep restriction [56], stimulus-control instructions [57], cognitive therapy challenging and modifying maladaptive cognitions about sleep [58], and relaxation [59]. In addition to having been shown efficacious delivered face-to-face, a growing number of studies have shown that technology-delivered CBT-I is equally efficacious [60].

The sleep coach is developed to utilize a stepwise approach, leading the user through a number components, beginning with psychoeducation in sleep hygiene and life style behaviors associated with good sleep quality, e.g., avoiding stimulants before bedtime, avoiding naps during the day, keeping a regular sleep schedule, engaging in physical activity/exercise, etc. In addition, the user will be prompted to use the general stress-reduction/relaxation and physical activity coaches, which support skills and behaviors associated with shorter sleep onset latency and better maintenance of sleep during the night. The assessment module will continue to measure sleep and provide feedback to the user. If the assessment results indicate that the sleep problems persist, additional components, i.e., cognitive therapy identifying and changing maladaptive cognitions about sleep, and sleep restriction, instructing the user to temporarily restrict the time spent in bed, will be initiated. If the sleep problem persists after having completed the sleep coach and additional stress-reduction/relaxation and physical activity coaches, the user will be instructed to contact relevant health professionals in his/her area.

While the user is assisted in improving sleep, the assessment module continues to monitor the additional, less prominent concerns/problems of fatigue and pain. If the effects of the sleep coach on these concurrent problems are unsatisfactory, the relevant coaches, i.e., the fatigue coach and the pain coach, will be initiated. As for the sleep coach, the approach of each of the other six coaches will be developed, based on the best available evidence for targeting these concerns/problems.

Evidence for technical efficacy

The eWALL platform, which is the open-source platform that is customized by CC2U, has been validated in clinical trials focused on Chronic Obstructive Pulmonary Disease (COPD) and Mild Cognitive Impairment (MCI) in 4 European countries: Italy, Denmark, Austria and The Netherlands. The validation studies have been focused mainly on the technical efficacy, evaluating the technology acceptance, which is the major barrier for the eHealth platforms. Trend information on purely clinical benchmarks have been extracted and analyzed and showed generally positive patterns. The main tests that have been used to validate eWALL are presented below.

Evaluation methodology for technology acceptance

User experience (TAM+)

The User experience and technology acceptance can be measured by the Technology Acceptance Model (TAM+) questionnaire, which consists of 34 items, divided into 7 domains: enjoyment, aesthetics, control, trust in technology, perceived usefulness, ease of use and intention to use [63].

User experience (UEQ)

The User Experience Questionnaire (UEQ) is used to analyse the system's attractiveness, perspicuity, efficiency, dependability, stimulation and novelty [64]. Attractiveness is defined as pure

valence dimension. Perspicuity, Efficiency and Dependability are pragmatic quality aspects which are goal-directed, while Stimulation and Novelty are hedonic quality aspects that are not goal-directed. UEQ offers a benchmark to classify a product into 5 categories of the 6 scales: excellent, good, above average, below average and bad [65].

Open interviews

Open interviews for the eWALL system consisted of 20 questions (with open answers) about technical issues, personal activity, sleep, health monitoring, domotics, self-management and the general experiences with eWALL [62]. During the interviews, questions were asked that could be directly related to eWALL (functionalities), as well as more general questions, focusing on getting a picture about the participant's demographics and medical situation.

Evaluation methodology for potential clinical effect

Short form (36) health survey (SF-36)

The SF-36 was used to assess the perceived quality of life [66]. This questionnaire consists of 36 items, divided into two domains, the physical domain (physical function, role physical, bodily pain and general health) and the mental domain (mental health, role emotional, social function and vitality).

Instrumental activities of daily living (iADL)

Independent living is assessed by the iADL [67]. This questionnaire consists of 8 items, ability to use the telephone, shopping, preparation of food, housekeeping, doing laundry and the mode of transportation. This test does not have a cut-off point, it is only possible to compare different measurement moments and conclude whether the participant made progression or deteriorated.

Physical capacity (6MWT + TUGT)

The 6-Minutes Walking Test (6MWT) and the Timed-Up-and-Go Test (TUGT) are used to measure the physical capacity of COPD participants. Per participant, the scores of 6-Minutes Walking Test

were compared with a norm score. A score higher than or equal to the norm score is considered as normal. Considering the Timed-Up-and-Go Test, a score below 10 s is considered as normal. When a participant scores between 11 and 20 s, he or she is frail. When the participant needs more than 20 s, further evaluation of the participant is necessary.

Evaluation results

Fig. 7 describes the comparison of the user groups on the TAM questionnaire scores that have been used in eWALL, namely MCI patients, COPD patients and seniors with frailty conditions (ARI). The analyses of this parameter did not reveal a statistically significant difference in the acceptance of eWALL among the three different groups, as described in [62]. The ANOVA of the TAM questionnaire scores showed significant results for the domain *Control* ($F(2, 32) = 4.7736, p = .01534$) when the three groups are compared as independent variables. Post hoc comparisons by Bonferroni confirmed that the perceived control is more critical for MCI with respect to ARI ($p < .005$). In addition, TAM questionnaire scores showed significant difference for the domain *Perceived Usefulness* ($F(2, 32) = 4.7736, p = .01534$) when only MCI and ARI are compared ($F(1, 18) = 4.6061, p = .04574$) indicating that MCI patients perceived the importance of the usefulness of the eWALL system for their health status more than ARI [62]. The minimum score from TAM questionnaires (red horizontal line) indicates the lowest value, which is for ARI patients and related to the perceived usefulness.

Fig. 8 shows the results of the User Experience Questionnaire (UEQ) of the participants in Austria. The measured scale means are set in relation to existing values from a benchmark data set as offered by the developers of the UEQ. This data set contains data from 9905 persons from 246 studies concerning different products (business software, web pages, web shops, social networks). The comparison of the results for eWALL with the data in the benchmark allows conclusions about the relative quality of eWALL compared to other products (<http://www.ueq-online.org/>).

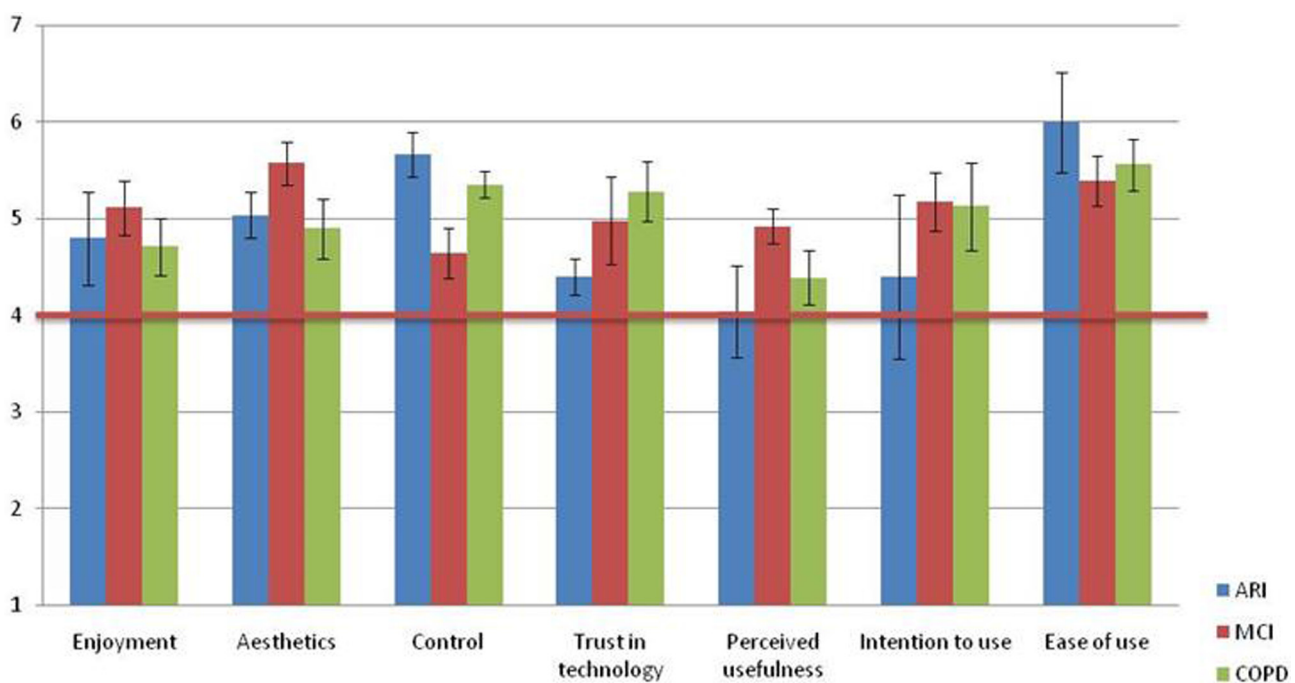


Fig. 7. TAM questionnaire score comparison between the three groups [62].

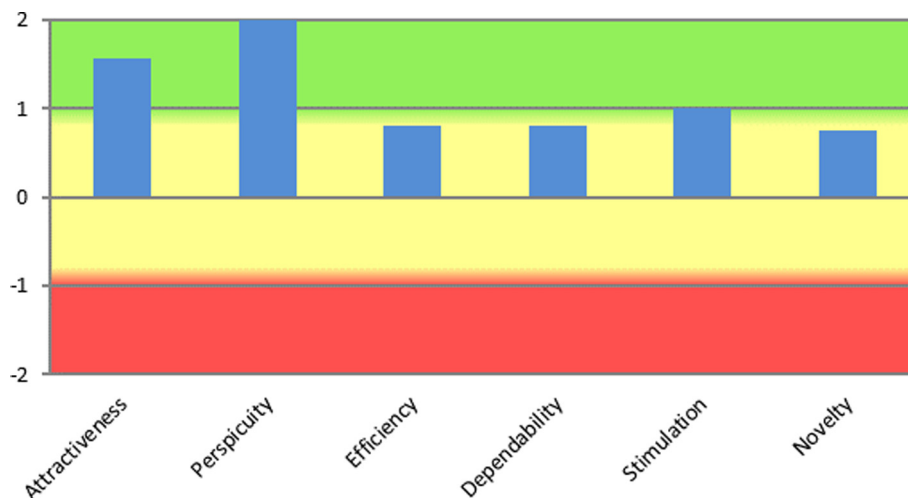


Fig. 8. User Experience Questionnaire Analysis of Austrian Users [62].

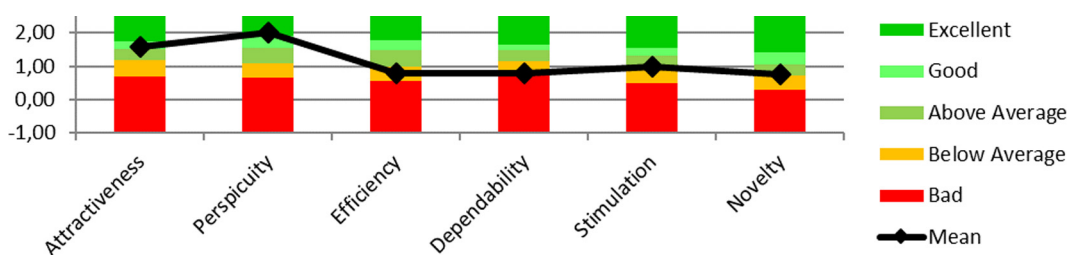


Fig. 9. User Experience Questionnaire Benchmark [62].

Fig. 9 below shows an excellent outcome for eWALL's perspicuity, meaning that it is very intelligible and easy to learn. Compared to other products, eWALL is quite novel to the participants, thus, creative and innovative. The participants rate eWALL as very attractive, thus, pleasant and friendly. Although the test version of eWALL did only have a limited amount of video trainings and games, participants perceive eWALL as above average stimulating. The efficiency of eWALL is perceived as less than average. The lower rating for efficiency could be caused by the technical problems of eWALL, which may also influence the dependability of eWALL, which is below average, meaning that eWALL is quite unpredictable and unreliable.

Expected impact

Concerning the treatment of cancer, radiation oncology plays a leading role in curing cancer today – saving and prolonging lives. Together with surgery, radiation oncology is the treatment approach that contribute most to cancer cure, and optimally, 51% of all cancer patients in Europe will receive radiation therapy at some point in their disease. Globally in 2012, more than 580,000 people derived a survival benefit from radiotherapy. Radiation oncology benefits from being highly acceptable for patients, owing to its limited invasiveness and organ-sparing potential compared with surgery in many different situations (e.g., breast, glottis, limbs and prostate). Apart from the treatment, the management of cancer incidence among a different and aging population presents daunting challenges, with shifting cancer demographics and age effects influencing treatment effectiveness. Age-related physiologic changes affect the renal and hepatic systems of older cancer patients, resulting in pharmacokinetic and pharmacodynamic

changes, putting them at risk for serious adverse reactions from many cancer drugs. Because of the many barriers to treatment faced by these patients, it is especially important that these populations have access to proper care (Recommendations from the American Society of Clinical Oncology – ASCO – www.asco.org). Furthermore, with increasing numbers of cancer survivors, the management of treatment toxicities represent a major clinical problem. One of the main principles of radiotherapy, in fact, is to deliver the total fractionated dose without interruptions and without a prolongation of the overall treatment time. Most retrospective studies analyzing the role of the overall treatment time, show a detrimental effect from the treatment break on the outcome. This deleterious effect is associated to an accelerated repopulation of tumor clonogens, particularly in some tumors, as head and neck cancer, where these evidences are stronger and even a 1-day interruption result in a decrease in the local control rate by 1.4%. Therefore, in the future, one of the most important aim in cancer treatment will be that the majority of patients will live cancer-free with minimal toxicity curative radiation oncology, either alone or in combination with other treatment modalities. FORECAST aims to provide a helping hand solution that will support the patients throughout their treatment, thus achieving a high impact on the daily life of cancer patients and increasing the effectiveness of the treatment based on patients' well-being.

Considering the expected impact of the technology on patient engagement outcomes, literature data on interventions that aimed to engage patients in managing and promoting their health show how interventions can be expected to move the scores of the standardized scales (i.e., Patient Activation Measure 13, [68]) of >6 (SD = 11.1) points, so to generate changes in patient engagement that could be considered clinically [68] and statistically [69,70] significant.

While many cancer patients report acceptable QoL after their treatment, there is accumulating evidence that about 20% of long-term survivors who are disease free are living with negative physical and psychological side effects caused both by the disease and its treatment [71–73]. Psychosocial implications of cancer have been widely documented [74–76], not only among patients and survivors but also among family members [77–79]. Adjusting to the diagnosis, treatment side-and late effects, and to the new life situation in general can be challenging, in particular for older patients. Psychological strain can impair the ability of patients to regain their QoL and well-being after treatment [80]. Technological interventions have been demonstrated to present unique opportunities to improve cancer prevention and control by increasing intervention reach, adapting to various contextual conditions, being readily available where users live, and tailoring actions to patients' needs [81]. Growing evidence has demonstrated beneficial effects of technology-based interventions on health-relevant outcomes of cancer patients, including perceived support, knowledge levels, and information competence of patients. Preliminary evidence has also been found for QoL, health status, and healthcare utilization. Thus, the FORECAST system is expected to help patients in managing physical and psychological problems in daily life, thereby contributing to the prevention of secondary health problems and increasing their QoL and wellbeing, while at the same time significantly reducing the interaction between patient and caregiver.

An extension of the FORECAST system will be the use of Cloud-Care2U ePRO-IoT solution, which is meant for patient reported outcome measures, fused with data from the IoT network deployed at the patient's home environment. Apart from the business interest for Clinical Research Organization and Pharmaceutical companies, there is evidence that the overall survival probability among patients with metastatic cancer assigned to similar systems for symptom monitoring during chemotherapy is increased compared to the usual care [82].

Conclusions and future work

This paper presents FORECAST, an innovative, cloud-based personalized intelligent virtual coaching platform for improving the well-being of cancer patients. The future work of FORECAST includes the design and implementation of a large scale study, involving a sample of cancer patients that have been selected based on pre-defined inclusion and exclusion criteria and enroll at least 200 patients at the diagnosis and assess and cover them during and after the treatment. Furthermore FORECAST will address security and privacy concerns based on a Privacy-by-Design approach, to comply with the GDPR. FORECAST system is expected to detect the alteration of the usual performance of the patients and will actively support patients by coaching system and improve the negative patients' habits and improve the basal lifestyle.

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