Vision for a Digital Service to Facilitate Recruitment and Retention of Older Patients in Clinical Trials

Maryam R. Yeganeh
FHNW University of Applied Sciences Northwestern Switzerland,
Institute for Interactive Technologies IIT,
Windisch, Switzerland.
University of Zurich, Zurich, Switzerland
maryam.yeganeh@fhnw.ch

Samuel A. Fricker
FHNW University of Applied Sciences Northwestern Switzerland,
Institute for Interactive Technologies IIT,
Windisch, Switzerland
samuel.fricker@fhnw.ch

***Abstract*—Data from randomised clinical trials shows that older patients are more likely than younger patients to experience adverse events, resulting in many deciding not to join clinical trials of experimental treatments and many patients quitting ongoing trials. The recruitment and retention problem is exacerbated by several factors, including misbelief or poor patient understanding, services not aligned with patients' needs, insufficient training of medical staff in patient communication, and the patient's feeling of being left alone. To improve patient recruitment and retention in clinical trials, we develop an innovative digital service that offers companionship to patient users using a human-centred design approach. The patient companion offers continuous availability of personalised and effective recommendations based on recognised barriers. This helps patients make more informed decisions when facing concerns about joining or staying in a clinical trial. This paper provides a research agenda to design and develop the patient companion and an illustrative example of how patient concerns could be addressed with recommendations. The results are intended to outline the feasibility of developing a patient companion and guide researchers interested in developing such an application. Importantly, it outlines the significant potential and feasibility of developing a patient companion to enhance recruitment and retention among older adults. While the research is performed in the specific context of a breast cancer treatment, the research agenda and the principles on which it is based can be generalised for any context that can benefit from a companion.**

Keywords—vision paper, patient recruitment and retention, clinical trials, decision support, research agenda

I. Introduction

Individuals over the age of 70 account for 42% of the total cancer population. Nevertheless, older adults are significantly underrepresented in clinical studies that define the criteria for cancer therapy effectiveness and safety [1]. It is reasonable for older adults with chronic diseases to be wary about participating in clinical trials and decide not to join or not to stay in the trial.

The recruitment and retention problem of older patients is multifaceted. When patients decide whether to join a trial or reflect on whether to stay in the trial, several dozen factors matter [1, 2]. These factors include barriers impeding recruitment, such as transportation problems, time demands or burdens associated with the trial, patient concerns about efficacy and toxicity, concerns about experimentation, patient treatment preferences, and financial support.

Patients may also lack an understanding of the consent form and procedures [3]. This challenge is exacerbated by some patients' decreased mental capacity, which impacts their ability to comprehend the information related to the trial. Furthermore, when patients are alone at home and face decision-making related to a clinical trial, they may struggle to remember information told by physicians. This can lead to increased feelings of worry and isolation, further complicating their ability to comprehend and engage effectively with the trial process.

Furthermore, the experience of a patient on the very first day of the admission process, particularly if they are experiencing difficulty and pain, can significantly impact the transfer of information and decision-making. Some medical staff may lack sufficient expertise in how to attract and retain older patients as study participants. Staff preferences and attitudes in the presentation of information can also play a critical role in preventing successful recruitment or retention [4]. This lack of expertise can stem from insufficient training on how to interact with older adults for relationship building, information provision, communication, enabling treatment-related emotions, and enabling treatment-related behaviour [5, 6].

To improve the recruitment and retention of older patients in clinical trials of cancer treatments, we propose the development and use of a patient companion application. The application has the potential to compensate for the weaknesses of the bespoke approach to motivating patients and informing them about the clinical trial. In addition to the highly intense interactions between medical personnel and the patient in the few consultation meetings, an application deployed on the patient's mobile device can provide ongoing attention, empathy, and information or other recommendations delivered with consistent quality whenever the patient needs it. This approach may help bridge communication gaps and support patients, particularly those facing cognitive or access barriers in healthcare settings. In addition, patients deciding to record what they experience can bring the recorded diary with them to the meetings with the medical staff to inform their physician about their concerns, hence giving feedback about the provided services in support of their trial participation.

In this vision paper, we outline a potential patient companion application and describe the research agenda to design and validate the application. The application leverages motivational theories in the user interaction design and the decision-affecting factors surveyed by Sedrak [1] in the form of recommendations

DOI 10.1109/REW61692.2024.00061

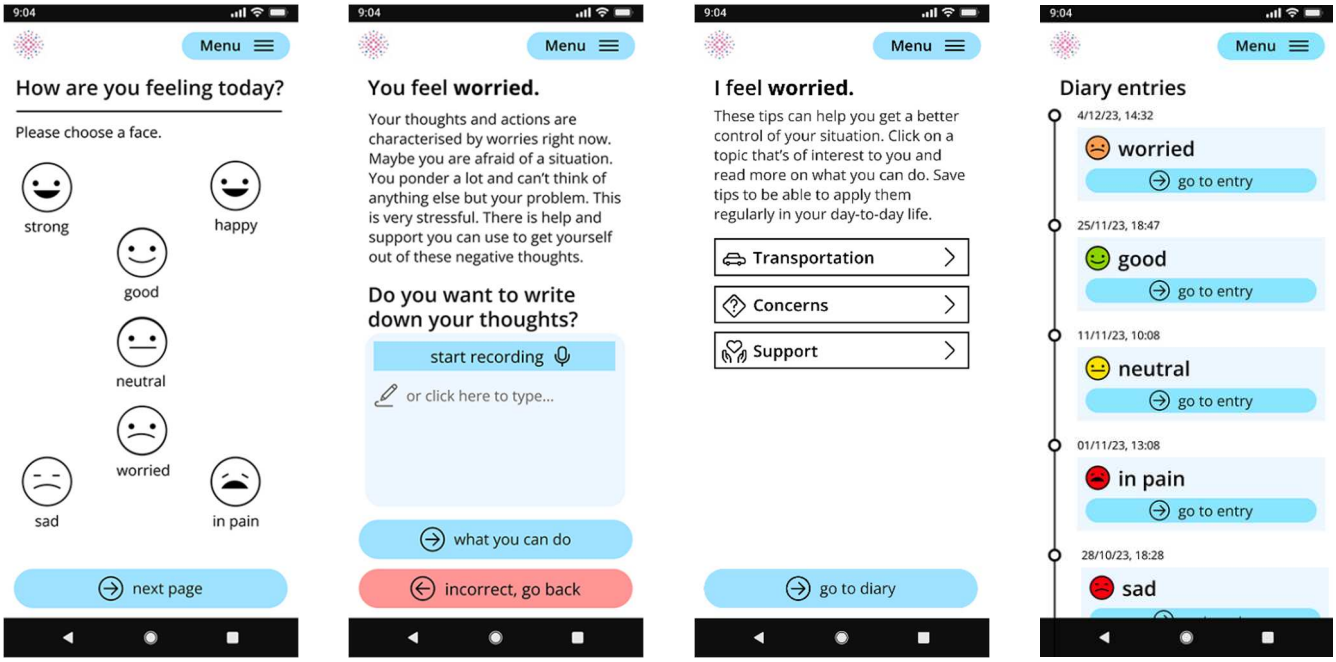

Fig. 1 Example screens of the patient companion application: empathy dialogue (screens 1+2), recommendations (screen 3), and diary (screen 4).

about what the patient can and should do to progress in decision-making. The patient companion is held as simple as possible, with just three key features: one to initiate an empathic dialogue with the patient, one to offer recommendations for actions that support the patient's decision-making, and one to allow a patient to record what has been done to support the decision-making. The approach to the design and validation of the application is based on the design sciences methodology proposed by Wieringa [7].

The remainder of the paper is structured as follows. Section II outlines the patient companion, including examples of recommendations offered to the patient. Section III describes a research agenda for designing and validating the companion. Section IV summarises and concludes.

II. Patient Companion

A. Patient Companion Background

Recruitment in a clinical trial involves identifying and enrolling eligible participants through informed consent and screening procedures, while retention focuses on maintaining participant engagement and addressing barriers to prevent premature discontinuation or dropout [8]. Considering age as a critical factor in participating in randomised clinical trials, recent systematic reviews [1, 2] have identified different barriers, such as transportation problems, lack of knowledge regarding the clinical trial, concern about efficacy and toxicity, etc.

Motivation is a significant factor influencing people's actions and decision-making, as evidenced by a substantial body of theories in psychology and behaviour change literature. For instance, Mummah et al. [9] introduced the IDEAS framework as a comprehensive guide for designing, developing, and evaluating digital interventions aimed at altering health behaviour. Alongside various frameworks and theories utilised in software design, such as persuasive strategy, self-determination theory, and the theory of planned behaviour, the IMB (Information-Motivation-Behavioral skills model) and ARCS (Attention, Relevance, Confidence, and Satisfaction) theories have demonstrated effectiveness in enhancing treatment adherence and learning, respectively based on recent systematic literature review on the use of motivational theories in the design of motivational software. [10]. There have been various applications that affect adherence to the treatment in clinical trials, such as the application developed by [11] to improve adherence to antiviral therapy to treat HIV.

In this research, the contents and recommendations conveyed in the application are formulated and presented based on the IMB skills model and ARCS.

By leveraging motivational theories and innovative technological strategies to enhance recruitment and retention, we propose developing a digital companion app tailored for older patients with cancer, focusing specifically on breast cancer as a case study. This application provides continuously available personalised recommendations based on feedback, demonstrates empathy, and aids in overcoming cognitive impairment by collecting patient diaries, thereby facilitating improved patient-doctor communication.

B. Patient Companion Features

The patient companion app is inspired by successful applications like "Wie Geht's Dir" in Switzerland [12], which promotes mental well-being and offers assistance for people in need. It incorporates three main features: Empathy Dialogue, Recommendations, and Diary functionality. Upon initial use, users are prompted to consent to the application's terms and conditions. Fig. 1 shows example screens of the main features.

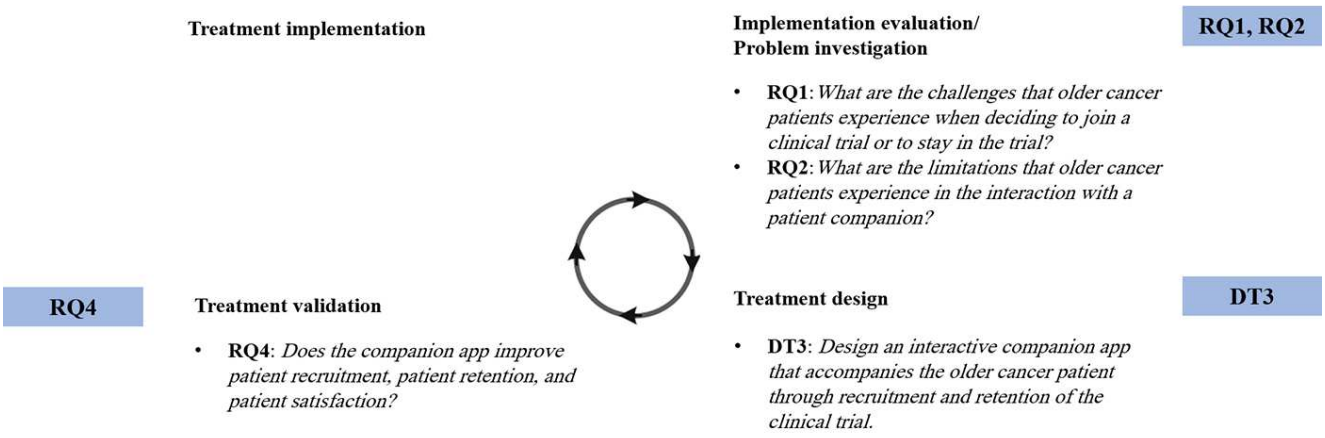

Fig. 2 Research questions and design task embedded in Wiering's design science methodology

The Empathy Dialogue feature allows users to express their emotions through seven abstract faces. This feature not only demonstrates empathy towards patients but also captures valuable feedback and attention. Emotions collected via the Empathy Dialogue feature can serve as criteria for selecting and prioritising requirements during the app's development process. Previous studies, exemplified by the Emotional Thermometer developed by Mitchell [13], have utilised graphical tools to capture the feelings of cancer patients. However, further investigation is required to establish a simple yet effective dialogue between humans and machines, particularly involving older adults undergoing an experimental medical treatment, and an analysis of emotional requirements is needed.

The Recommendation feature addresses users' concerns by providing evidence-based recommendations sourced from systematic literature reviews. These recommendations target common issues faced by older adults with cancer participating in clinical trials. The patient can provide feedback on whether specific recommendations were useful to her or not, allowing for personalised and tailored support based on individual experiences and needs.

The Diary feature enables users to record their mental and physical states, which can be referenced during visits with their physician, aiding in overcoming memory and cognitive impairment.

C. Examples of Recommendations

We could identify two systematic literature reviews that analysed factors of importance in patients' decision-making regarding whether to join a clinical trial and whether to stay in the trial [1, 2]. The following categories of factors play a role: knowledge, transportation, time demands or burdens, concerns about efficacy and toxicity, concerns with experimentation, treatment preferences, finance, age (believing to be too old), and emotional burden. Here is an example of extracted data related to the category of "knowledge" based on the analysis of papers referenced by Sedrak [1]. Each statement is extracted from a questionnaire or survey that patients with breast cancer answer and rate as their concern. This statement is the source of the idea to be translated into actionable recommendations. The following excerpt is relevant to the extracted knowledge category from one of the papers: *"I believed that I might receive more detailed information about my cancer by participating in a clinical trial./ The treatments offered in the clinical trial agreed with the internet and media reports I had read about how to treat my cancer./ The consent form provided helpful information about treatment risks and side effects./ The consent form provided helpful information about what I have to do for the clinical trial."*

Considering the category of "knowledge", we propose this related recommendation: "Do you need more information? Please click here". This recommendation is under category of "concern" in the application as it demonstrated in the Fig. 1.

III. Research Agenda

To realise our vision, we propose research goals that include refining, completing and validating the content and recommendation, validation of the application, investigating the user experience considering the fragile population with heterogeneous digital literacy and finally, large-scale validation over the large population. For designing the application, a scientific design science approach presented by Wieringa will be applied. This approach or engineering cycle includes four stages: Problem investigation, Treatment design, Treatment validation and Treatment implementation. To investigate the research and design questions according to each stage, different studies will be needed.

The overall research approach follows Wiering's design science methodology as illustrated in Fig. 2 [7]. We have split the research into three phases. Each phase is guided by a main research question (RQ) or design task (DT). These questions and tasks are as follows: RQ1: *What are the challenges that older cancer patients experience when deciding to join a clinical trial or to stay in the trial?* RQ2: *What are the limitations that older cancer patients experience in the interaction with a patient companion?* These two research questions allow us to do proper requirements analysis for the patient companion. To support the design of the envisaged dialogue, each challenge identified in answer to RQ1 should be linked with the emotions that patients feel when they experience the challenge [14]. DT3: *Design an Interactive companion app that accompanies the older cancer patient through recruitment and retention of the clinical trial.* RQ4: *Does the companion app improve patient recruitment, patient retention, and patient satisfaction?* This research

question allows us to validate the solution and the requirements developed for it.

The remainder of this section describes how we plan to answer the research questions RQ1, RQ2, and RQ1 and perform the design DT3. As the design and validation research for DT3 and RQ4 depends on the answers for RQ1 and RQ2, we focus on how we propose to answer RQ1 and RQ2 and outline the principles that guide our approach for DT3 and RQ4.

A. Challenges of Older Cancer Patients

To answer the first main RQ, research is suggested for identifying and validating the challenges experienced by older cancer patients and the responses to these challenges with recommendations. Based on the known factors, interviews of clinical trial experts and patient representatives will be conducted. The main research question RQ1 is refined into the following sub-questions: RQ1.1 *What challenges have been identified by prior research*? Answering this sub-RQ ensures that known knowledge is being used to offer companionship to the patients. RQ1.2 *What are the appropriate recommendations to address the identified challenges*? Answering this sub-RQ ensures that the clinic can offer services that the patient benefits from the services. RQ1.3 *How should the recommendations be tailored to the specific patient and clinic*? Answering this sub-RQ ensures that the clinic can offer the recommended services.

For RQ1.1, the research collects factors that have been identified by earlier research to answer patient's information needs for deciding whether to join and whether to stay in a clinical trial. systematic reviews have been published that identify such factors and cite primary studies that offer specific empirical evidence about the pertinence of the factors and the reasoning used by the patient for decision-making [1, 2]. The result is a comprehensive list of factors that represent enablers and barriers for patients to join a clinical trial and stay in it.

For RQ1.2, the research identifies and applies motivational theories to formulate and present recommendations to the patient. These recommendations correspond to ethical nudges that increase transparency about the clinical trial and encourage reflection about the implications of participating in the trial for the patient. The chosen theory will affect the structure of the dialogue with the patient and the way the recommendation is presented. For example, the use of the Information-Motivation-Behavioral (IMB) skills model explains that a recommendation must be pertinent to the state of the patient and be presented in a way that communicates empathy to the patient's state and is effective in improving the patient's state. The results are a comprehensive list of patient states and recommendations offered to the patient when experiencing the respective state.

To answer RQ1.3, the research validates the recommendations with medical personnel and patient advocates experienced in clinical trials. The validation is expected to lead to support for recommendations considered appropriate, to counter-proposals for recommendations considered inappropriate, and to information about local practices and services that should be linked with the recommendations. For example, a clinic may offer specific shuttle services to allow patients to travel to the clinic for a check-up, or there may be local or national self-help groups that allow patients to connect and discuss the experience. An interview study is considered suitable to present the identified challenges and recommendations to medical personnel and patient advocates and gather feedback about these recommendations and links to services to localise the recommendations.

B. HCI Limitations of Older Cancer Patients

To answer the second main RQ, research is suggested for identifying the limitations of older cancer patients in the interaction with patient companion, approaches for designing the patient companion with suitable accessibility and approaches for mitigating or compensating the limitations. The main research question RQ2 is refined into the following sub-questions: RQ2.1 *What are the human-computer interaction (HCI) limitations of older cancer patients*? Answering this sub-RQ gives the necessary context knowledge for designing a solution that is inclusive for as many older cancer patients as possible. RQ2.2 *What are the design approaches or constraints that mitigate or compensate for these limitations*? Answering this sub-RQ allows us to identify the options for designing the human-computer interaction of the patient companion. RQ2.3 *How can the patient's environment, such as the presence of a personal, trusted caregiver, be used to mitigate or compensate for the limitations*? Answering this sub-RQ allows us to extend the options for designing the interaction patient companion by involving people with more capabilities with suitable interfaces and acceptable interaction scenarios.

For RQ2.1, the research identifies characterisations or persona descriptions of cancer patients including frail users. Ethnologic studies, case studies of working with older cancer patients, or descriptions offered by patient advocates can offer the necessary empirical information to understand the background, perspective, and needs of the target group. Of particular relevance is the understanding of cognitive and motor abilities and of the strain experienced due to the cancer disease and its impact on quality of life, which progresses as the patient ages and the disease progresses. The results are a comprehensive, empirically grounded characterisation of the older cancer patients and of the patient's abilities to interact with a patient companion.

For RQ2.2, the research identifies guidelines and recommendations from earlier human-computer interaction research with frail users. Exemplary guidelines include the size of fonts and limitation of information content on a screen, the replacement of scrolling by paging, and the systematic use of illustrative icons to complement text categories and functions. The result is a list of design options that can be composed into the design of the companion's user interface and interaction scenarios.

For RQ2.3, the research identifies descriptions of the physical and social environment of cancer patients. Ethnologic studies, case studies of working with older cancer patients, or descriptions offered by patient advocates can offer the necessary empirical information to understand patient context. Of particular relevance are the presence of personal caregivers, for example, the husband or wife of the patient, the degree of openness and trust in that person, and the willingness to delegate the use of a companion app to such a person. The results is an outline of options to increase the use of the companion app beyond the specifically targeted older cancer patient.

C. Design and Validation of the Companion App

To implement the design task, the answers to RQ1 and RQ2 are suggested to be used as input to a user-centred design of the companion app. The design to fulfil the design task DT3 should be iterative and intertwined with the validation performed to answer RQ4 for benefitting from the observations and obtained user feedback. The main research question RQ4 is refined into the following sub-questions: RQ4.1 *How useable is the patient companion*? Answering this sub-RQ ensures that the characteristics and environment of the patient have been sufficiently taken into account in the design of the patient companion, or to identify recommendations for refining the design. RQ4.2 *How useful is the patient companion*? Answering this sub-RQ ensures that the recommendations offered to patients are pertinent to the questions and situations encountered by the patient and appropriate to the local context of the clinical trial and patient. RQ4.3 *How engaging is the patient companion over time*? Answering this sub-RQ ensures that the patient companion is not only used once, but its use becomes a habit for the patient during the time the patient participates in the trial. RQ4.4 *What is the impact of the companion on patient recruitment and retention for a clinical trial*? Answering this sub-RQ offers evidence about the impact of the companion on patient recruitment and retention and, thus, the value it represents for investigators and clinics that want to perform clinical trials. RQ4 is formulated in a way that allows validation of the patient's needs.

To implement DT3, creative, user-centred design is pursued to define the user interfaces and interactions with the companion application that motivate the patient to seek advice and manage the full lifecycle of the recommendations and the associated trial services. Specific design topics will include the definition of a patient journey with frequent enough touchpoints for interaction with the companion, easy yet value-creating interactions where the patient shares information about the experienced question or situation and receives recommendations, and means for evaluating the appropriateness of the recommendations and the provided services. An iterative approach of involving patients in the design [15] and seeking feedback [16] will be necessary to ensure the appropriateness of the design. The result is a prototype of the patient companion application that is realised and improved with increasing readiness [17].

To answer RQ4.1, the patient companion's usability is assessed in user tests utilising the system usability scale [18], and qualitative feedback is sought to improve usability. The users are sampled by following a maximum variation strategy in the patient and context characterisation dimensions identified in RQ2.1 and RQ2.3. The user tests should be performed with the user interaction scenarios identified in the patient journey at the location where user interaction is expected to take place. The resulting insights offer feedback for the design of the companion and knowledge about the limitations of digitisation for older cancer patients. The latter includes criteria that can be used to include or exclude patients from being users of the patient companion application and clustering these users into strata for which the design of the patient companion application is optimised.

To answer RQ4.2 and RQ4.3, the companion is assessed in a short pilot study performed during a limited time in conjunction with a clinical trial. A small number of users are selected by applying the inclusion/exclusion criteria identified with RQ4.1 and ensuring a sufficient balance between the strata of patient users. The patients are introduced to the use of the companion, and the companion is provided during a period of a few weeks, e.g. corresponding to the timespan between the initial touchpoint with a patient to one or two consultations defined in the study protocol. The duration of the period should be long enough to extend beyond the first period of curiosity about the companion and include situations requiring the patient to return to the companion. The usefulness can be assessed qualitatively with a structured interview after the companion uses the strengths and weaknesses of the companion and its effects on the patient's decision-making about trial participation. The engagement can be measured with the user engagement scale [19]. The resulting insights offer feedback on the companion's support of the user journey and the quality of the recommendations.

To answer RQ4.4, a summative assessment of the companion is performed. A sufficient number of users are selected by applying the same inclusion/exclusion criteria and stratification as for the pilot study. The number of patients should be enough to allow for statistical testing between patients benefitting from the companion and patients not using the companion. The study should be long enough to cover the recruitment and trial execution phases. Also, the study should be aligned with the main clinical trial in a way that prevents the patient companion from becoming a confounding factor for the main trial, e.g. by generating health impact due to improved communication with the patient [6]. A combined app monitoring and user feedback approach can be used for data collection [20]. The results offer quantification of the patient companion's sustainability, the extent and magnitude of its impact on patient recruitment, and opportunities for improving clinical trial-related patient services and the companion app.

IV. Summary and Conclusion

In this paper, we have proposed a digital companion approach to compensate for the weaknesses of bespoke recruitment and retention of older cancer patients in clinical trials. Instead of just a few discussions with medical staff at the location of the trial, the patient companion application deployed on the patient's smartphone can be with the patient all the time and assist the patient in the actions needed for decision-making with an empathic, motivating dialogue. The companion can counter misbelief and improve the patient's understanding of the trial and how to participate in the trial. The companion can also help identify services associated with the trial that are insufficiently aligned with patients' needs, hence giving a basis for improving the trial service.

The paper has outlined the proposed digital companion, including its empathic dialogue, recommendation, and diary features. It has described how the information-motivation-behavioural (IMB) skills model and the attention, relevance, confidence, and satisfaction (ARCS) model create a motivating, engaging user experience. The description is supported by examples of how factors relevant to patients' decision-making concerning whether to join a trial and whether to continue to stay in it are encoded as recommendations offered to the patient when they are relevant.

Finally, the paper has outlined a research agenda for designing and validating the patient companion within the framework of design sciences methodology. The research first identifies challenges that patients encounter when they decide whether to join a trial or stay in the trial. It then identifies limitations of older patients that must be considered in human-computer interaction design. It outlines how the patient companion application can be iteratively designed and validated to improve patient recruitment, patient retention, and patient satisfaction with the trial. While being specific for older cancer patients in clinical trials, the research agenda and the principles on which it is based can be generalised for any context that can benefit from a companion.

ACKNOWLEDGMENT

This research was supported by the European Union's Horizon Europe research and innovation programme under grant agreement No 101104589 and by the Swiss State Secretariat for Education, Research and Innovation (SERI) under subsidy agreement No 23.00218.

The authors also thank David Kern and Mia Braunwalder for their contributions to the patient companion design.

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