

Original Article

IGestSaúde a mobile application for the self-management of symptoms associated with chemotherapy treatment: Development protocolCarla Sílvia Fernandes^{1*}, Bruno Magalhães², Célia Santos¹, Juan Miguel Martinez Galiano³¹Department of Nursing, Nursing School of Porto, Center for Health Technology and Services Research, Porto, Portugal²Department of Nursing, Santa Maria Health School, Center for Health Technology and Services Research, Porto, Portugal³Nursing Department, Andalusian Health Service, University of Jaén, Centro de Investigación Biomédica en Red Epidemiología y Salud Pública Jaén, Spain

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ABSTRACT

Background & Aim: People undergoing chemotherapy treatment of an oncologic disease refer to the need to promote the process of self-management of the disease and the symptoms associated with treatment. This study aims to describe a mobile application's development protocol to support the self-management of symptoms associated with chemotherapy treatment, the IGestSaúde.**Methods & Materials:** The research is divided into six stages, using an exploratory/descriptive pilot study conducted over 36 months. The stages include research and fundamentals, development, validation of therapeutic guidelines, field study, technological development, implementation, and mobile application evaluation.**Discussion:** The project will monitor and improve patients' compliance to chemotherapy, to prevent patients' complications through preventive indications for self-care, and to improve patients' responses to uncontrolled symptoms or complications.**Conclusion:** Mobile applications can be considered a viable and effective means for self-management of complications associated with chemotherapy treatment, supported by scientific evidence and these people's specific needs.**Introduction**

Health care has witnessed a significant increase in ambulatory chemotherapy treatments. The promotion of a person's autonomy in self-management of the disease and treatment has been described as one of the main factors leading to a more favorable adaptation by helping the person to acquire self-control and self-efficacy, perceived as impaired by the disease (1). This new paradigm of treatment alters the process of administering chemotherapy, shifting from a regular procedure controlled and monitored by oncologists and nurses in the hospital to patient self-managed intervention at home (2,3). In this way, the person and the family are also accountable for managing the complexity of chemotherapy schemes, side effects, and toxicity (2).

Given the myriad of symptoms that cancer patients experience during treatment, effective management of these symptoms becomes a priority in self-care. Therefore, the evaluation and monitoring of symptoms associated with chemotherapy treatment are important to supervise the patient's quality of life, to early identify problematic areas for which intervention is necessary (4). However, some literature suggests that cancer patients receive insufficient support regarding symptoms management (5,6) and feel left alone to deal with them (7).

In view of this reality, it is important to promote the development of more sustainable accompaniment strategies that empower patients and meet their specific needs. Traditional health care and service delivery processes are continuously challenged to meet patients' current and future needs, mostly because of technological advancements and the demands of timely and accurate information concerning people's health (8-9). The use of online self-

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management tools can result in improved symptom management and subsequent perception of life quality, equally promoting adherence to medication (10-12).

The 21st-century societies are driven by technological advancements adapted to smartphones, tablets, and their variety of apps. This innovation is a real challenge with proven valid scientific results in the current health context and health management (13). The increasing use of technologies aims to assist patients with chronic diseases to better adhere to therapeutic schemes (10). Similarly, in the context of oncological disease, we have been witnessing an identical phenomenon, due to increasing innovation in eliciting informatics to monitor symptoms, with a wide range of digital platforms that efficiently capture the symptoms reported by the patients (11). The patient's viability and acceptability to this type of approach have been widely studied and well-accepted (14). Thus, these valuable resources are perceived as adequate and preferential to monitoring symptoms in cancer patients undergoing chemotherapy treatment.

Information and communication technologies using mobile phones/smartphones can help healthcare professionals monitor patients at home with proven reliability and validity in the remote monitoring of symptoms (15).

Within this new reality, this protocol aims to develop a computer application to monitor and control the therapeutic regimen's management in people undergoing home chemotherapy treatment. This project is different from others because is aimed to develop a mobile application to strengthen communication between patients and health professionals. And also, favor adherence to therapeutic indications and answering to the symptoms or complications that may appear associated with the disease. The development of this APP aims to improve the quality of life of these patients. Apps

should be tested outside the academic environment, outreaching this group of people to effectively investigate its applicability, allowing the assessment of the impact of this "new" technological intervention process (12), in this case with therapeutic guidelines validated by health professionals.

Methods

This article describes the stages of designing a mobile application for the self-management of symptoms associated with chemotherapy treatment. This project is focused on its potential for community outreach. It provides new knowledge through an exploratory, descriptive, longitudinal research pilot study, which will extend over 36 months, with the following purpose:

- Monitor and support the process of self-management of the disease and the treatment regimen of people with cancer on chemotherapy, and as a specific objectives: alert patients to the time and directions of the administration of oral therapies; validate the administration of oral therapies in patients; monitor adherence to oral therapies in patients; monitor patient self-efficiency; characterize and categorize, at three alert levels (green, yellow and red), the complications or side effects of treatments; provide indications of self-care, to prevent complications or symptoms associated with treatment; identify complications with a high level of severity associated with the treatment; alert patients to symptoms or complications of high severity (red level); evaluate the perception of health, well-being and quality of life of patients; evaluate the relationship between signs and symptoms and drugs; and inform health professionals about the perception of health, well-being and quality of life of patients.

The development protocol includes a set of six stages, depicted in Figure 1.

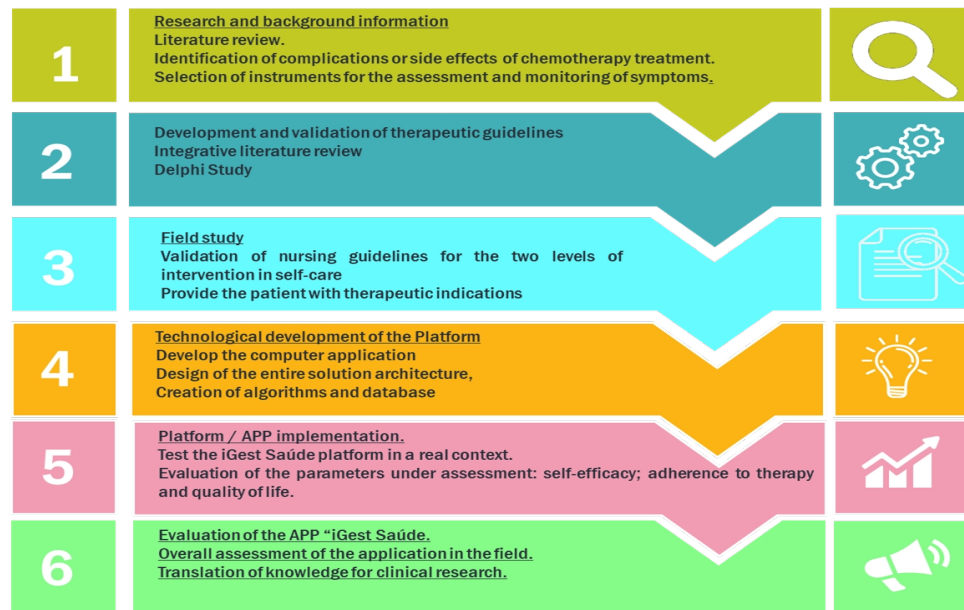


Figure 1. Application development steps

Stage 1 will include a comprehensive review of the literature intended to better tackle complications or side effects of chemotherapy treatment and select instruments for assessing and monitoring symptoms to be used during this process.

Stage 2 aims to develop and validate the therapeutic guidelines for the most common symptoms associated with chemotherapy treatment, such as pain, fatigue/inactivity, dyspnoea, insomnia, anxiety, anorexia, constipation, diarrhea, nausea and vomiting, mucositis, alopecia, skin alterations; sexuality alterations, and urinary disturbances. These guidelines were further categorized and organized according to the levels of intervention in self-care (prevention - green alert level; and treatment - yellow alert level), defined according to the Common Terminology Criteria for Adverse Events (16).

The screening for symptom severity is carried out at three levels: a) level one: green - mild severity; b) level two: yellow - moderate severity and c) level three: red - maximum severity. The green and yellow level refer to targeted interventions to reinforce self-care measures. At the yellow level, a warning is also given to monitoring the worsening of the symptom. The red level is defined by a significant increase in the

symptom's severity, requiring referral to health care.

According to the aforementioned, and aiming at the development and validation of therapeutic guidelines, different studies will be conducted:

- An integrative literature review on therapeutic guidelines of symptoms and addressing the two levels of intervention for promoting self-care of people in chemotherapy treatment.

- A Delphi study involving a group of experts to establish consensus on the therapeutic guidelines for self-management of symptoms for both intervention levels. The accessible population of this Delphi study will consist of expert nurses, members of the AEOP (Portuguese Oncological Nursing Association). An intentional non-probabilistic sample will be created. The sample will be divided into four groups, with each group being assigned a smaller set of symptoms out of a total of fourteen symptoms under study. These groups of people will be approached by email by sending questionnaires through Google® Forms. In conducting this Delphi study, all ethical issues inherent to research work will be respected. It was considered that the selected experts would consent to their participation by returning, by email, their

response to the questionnaires sent. The Delphi study will run over three rounds.

Stage 3 will include the validation of therapeutic guidelines of the most common symptoms and for the two levels of intervention in self-care (prevention - green alert level; and treatment - yellow alert level), with an extended group of patients in chemotherapy treatment in different oncology day hospitals in the district of Porto.

A pilot study will be carried out in a chemotherapy day hospital, with patients experiencing the disease and its treatment, to understand how these patients perceive the impact of therapeutic guidelines on the process of self-management. At this stage, this assessment will be carried out face-to-face and by telephone. The therapeutic guidelines, agreed by the group of experts, will be applied to a group of people with cancer disease undergoing treatment in order to carry out a previous validation of the therapeutic guidelines. Users for the pre-test will be monitored in person and by telephone.

Through the application of instruments by telephone, each symptom's degree will be evaluated, and the patient will be given therapeutic indications. Guidance will be provided to prevent, minimize, and resolve identified problems. After a few days, the patient will be contacted again to assess the effectiveness of the interventions. The non-probabilistic sample will consist of 30 patients from the hospital of oncology day. Ethical procedures already authorized by the institution's administration, ethics committee, and national data protection commission will be guaranteed.

In Stage 4, and after the validation of contents extracted from the previous stage, the software application and the application flow chart will be developed. This phase includes the design of the entire architecture, algorithm, and database creation. This step will allow the development of the mobile phone application and support software for health professionals and researchers. (Figure 2).

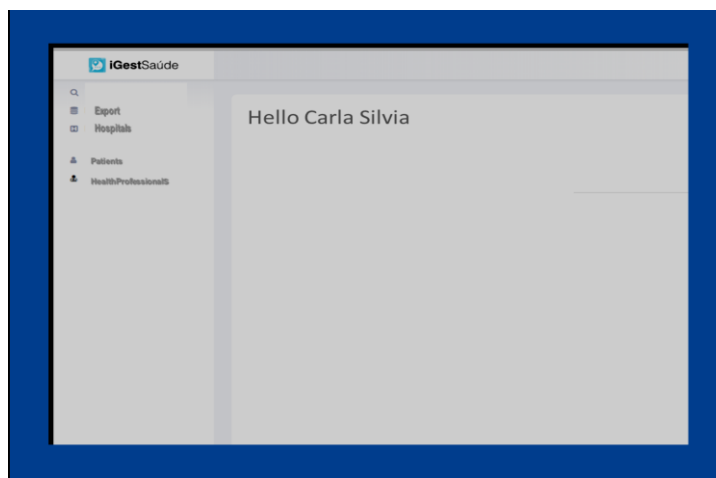


Figure 2. iGest software screen

In Stage 5, the iGestSaúde platform will be made available and tested in a real context, namely with patients in oncology day hospitals in the district of Porto. The monitoring of this process will also rely on data resulting from implementing the instruments and interventions from the previous stages. In this phase, the first version of the application will be used to carry out the final tests and evaluate the algorithms' application in figure 2. The non-

probabilistic sample will consist of patients followed at the Oncology Day Hospitals of the District of Porto. Inclusion criteria will consider patients aged between 18 and 55 years, with an oncologic disease, exclusively undergoing chemotherapy treatment, with preserved cognitive capacity (Mini-Mental State Examination), using information technologies, and having a smartphone. This study will follow all ethical guidelines, in

particular those set out in the Helsinki Declaration.

As mentioned above in stage 1, the most appropriate instruments will be identified to be applied at three moments of the follow-up process; relating to the perceived General Self-efficacy, the Measure of Adherence to Treatments, and Quality of Life of cancer patients. Also, socio-demographic and health characterization information will be collected.

The instruments described below will be applied to all study participants at three points in the follow-up process (Figure 2).

1. Document of the personal, socio-demographic and health characterization - intends to evaluate the personal characteristics, such as, for example, age, schooling and profession; as well as the medical diagnosis, staging of the disease and the proposed treatment; the pathological antecedents and habitual medication;
2. General Self-Efficacy Scale Percept, in its Portuguese version of Renato Nunes, Ralf Schwarzer & Matthias Jerusalém (1999);

3. Measurement of Adherence to Treatments (MAT), developed and validated by Delgado & Lima (2001);

4. Quality of life scale of cancer patients: EORTC - QLQ - C30.

Depending on the collected data, we also intend to use graphs as outputs for health professionals indicative of the evolution of the patient's health condition that will serve as a guide for the continuity of health care (Figure 3). Also, an assessment of included parameters self-efficacy, adherence to therapeutics and quality of life will be performed.

The project will end with Stage 6 and will include an overall assessment of the application on-site, both from the perspective of users (cancer patients), and health professionals, researchers and administrators. In a later phase of this pilot project, the intention is to replicate the study in clinical contexts throughout the country, namely in other oncology units, relying on new partners from health institutions.

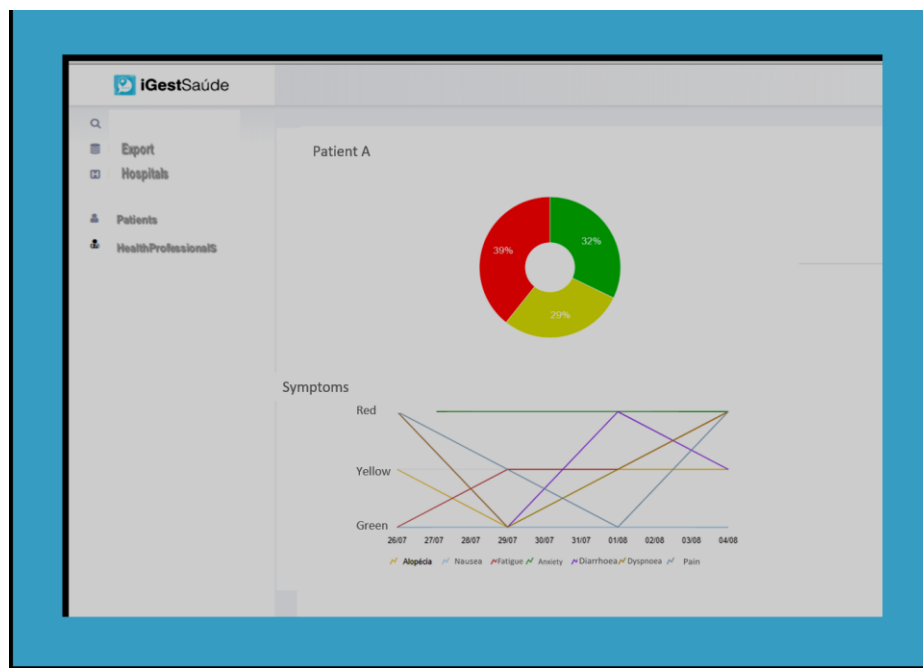


Figure 3. Evolution of the patient's health condition

Results and discussion of outcomes

The advancement of technologies within eHealth, and more specifically, mHealth, have offered alternatives that promote interaction between healthcare professionals and patients, surpassing the usual context of

face-to-face hospital consultation (17). This new era provides health professionals with detailed information, in real-time, on the health status of patients and proposes customized solutions according to the

information received (18). If adequately integrated and supported, these tools can improve treatment, empower patients, and predictably reduce medical costs by streamlining the use of health resources (19). Mobile devices, particularly apps, aim to improve people's access to information and knowledge with no time and space restrictions, favoring new communication, surveillance, and intervention ways (20). Thus, these strategies leverage a new way of caring, adding strategic value directed at this information era society that can be materialized, for example, through the proposal to develop the mobile application iGestSaúde.

Figure 4 displays a draft of the flowchart that will serve as a basis for developing the application, addressing the different stages described in the methodology section.

The purpose of this process is to maximize the perception of well-being and quality of life of cancer patients undergoing chemotherapy treatment, alongside the appropriate treatment of their disease

Notably, this path is also a scientific project, focused on data generation and knowledge production, involving citizens and yielding substantial gains to the community.

The great criticism around smartphone applications sustained by the non-involvement of professionals in its development process should be noted. This is the topic of discussion in a broad review study addressing this type of resource available on the market for breast cancer patients (21). Similarly, some studies identify the lack of evidence-based content and the lack of health professionals' involvement in its design (22).

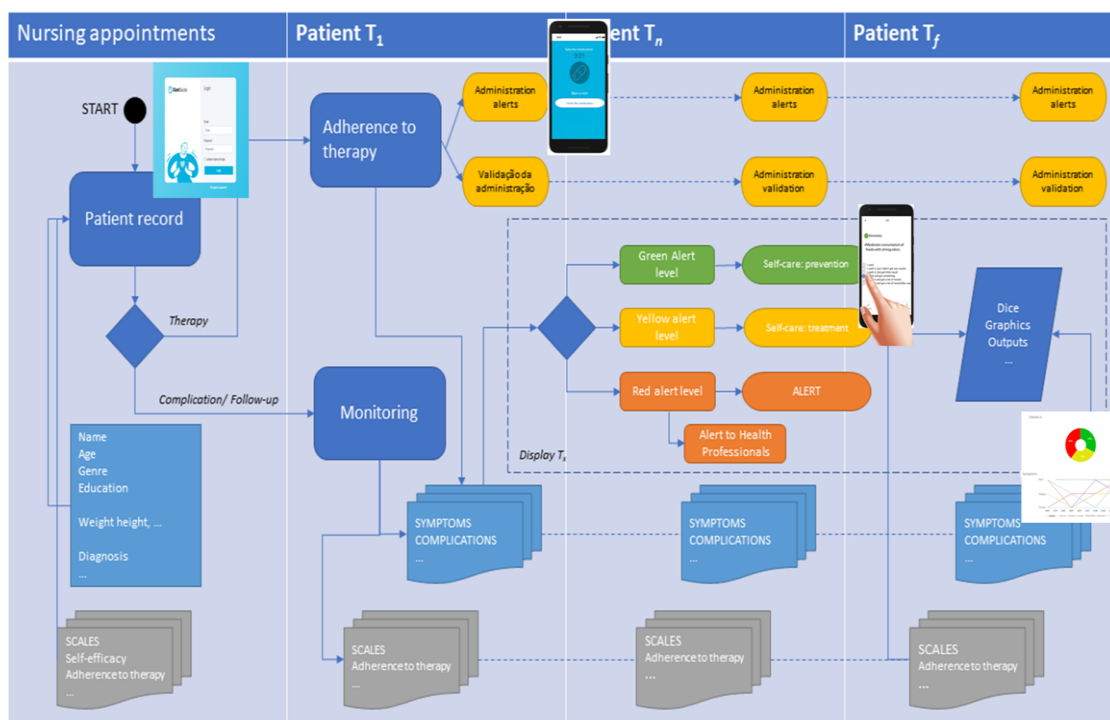


Figure 4. Flowchart of the mobile application iGestSaúde

To ensure better reliability in the use of these applications, and in the promotion of their use by health services, the development of apps contents should rely on scientific evidence supported by expert opinion (health professionals), and customized to the specific needs of patients. Moreover, the involvement of professionals and patients in the

application development process is recommended in the assessment criteria advocated by Nouri et al. (2018) (23). These circumstances should be coupled with the use of robust control to identify the best quality applications. Our project has considered all these factors, which has added substantial value to this proposal, as it required a

thorough content preparation process and scientific rigour. In further studies, we intend

to present the achieved outcomes of the iGestSaúde application (Figure 5: Logo)



Figure 5. Logo of the iGestSaúde application

Conclusion

The application iGestSaúde will use available technology that guarantees distance monitoring of toxicities associated with chemotherapy treatment. This application will use the processes, protocols, and evidence found in the literature to categorize and control the treatment's symptoms. Importantly, its main goal is to focus on people's needs, facing the process of self-management of symptoms. Bridging the gap between technology and effective self-management of treatment complications and improving patient safety and quality of care requires the users' active involvement. The expected outcomes from the implementation of the project are primarily intended to monitor and improve patients' compliance to chemotherapy; to prevent patients' onset of complications or symptoms associated with treatment through preventive indications for self-care and; to improve patients' responses to uncontrolled symptoms or complications, through indications for self-care.

Despite the recent technological advancements, namely in the design of applications aimed at the health area, they lack scientific rigor in developing their contents and adequate sustainability, which is the great asset of this project. By focusing on people's needs, this knowledge and the proposed solution presented in this study, intended to be the starting point to important contributions to the improvement of

knowledge associated with the nursing discipline and the excellence of care. This is guaranteed not only because of the novel information but also for its potential application in clinical contexts, aimed at improving the quality of life and well-being of cancer patients in chemotherapy treatment.

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Conflict of Interest

There is no conflict of interest.

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