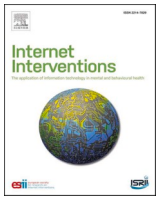
Internet Interventions 37 (2024) 100752

Contents lists available at ScienceDirect

Internet Interventions

journal homepage: www.elsevier.com/locate/invent



Evaluation of a training program using the SBAR communication tool for caregivers managing acute respiratory distress in lung cancer patients: A pilot randomized controlled trial protocol

Danielle Reynaud [a,b,*], Guillaume Decormeille [c], Antoine Tisseaux [b,d], René Bun [b,d]

[a] Department of Nursing, Rehabilitation and Medical Techniques (South Site), University Hospital Center, Saint-Pierre, La Réunion, France
[b] National Institute of Health and Medical Research (INSERM) Clinical Investigation Center (CIC) 1410 Clinical Epidemiology, University Hospital Center, Saint Pierre, La Réunion, France
[c] CLLE UMR 5263 CNRS, UT2J Laboratory and Institut de Formation en Soins Infirmiers Fondation Leonie Chaptal, Sarcelles, Paris, France
[d] Department of Public Health and Research Support, Methodological and Biostatistics Support Unit, University Hospital Center, Saint-Denis, La Réunion, France

ARTICLE INFO

Keywords:
Digital health
Healthcare
Serious game
Communication tool
SAED
SBAR

ABSTRACT

Background: Family-based caregivers are increasingly important in the management of non-hospitalized lung cancer patients. However, lack of training can negatively impact care including diagnostic errors that can lead to delays in providing appropriate medical treatment. Acute respiratory failure (ARF) is common symptom of lung cancer and requires urgent intervention as well as adequate communication with healthcare professionals (HCPs) to enable appropriate decision-making and improve patient outcomes. Standardized tools such as the Situation, Background, Assessment, Recommendation (SBAR) tool and its French adaptation SAED, standing for *Situation, Antécédent, Évaluation et Demande*, are designed to facilitate communication among (HCPs).
Additionally, digital interventions, such as serious games, are increasingly used to train HCPs though its use for caregivers has not been studied. This pilot study aims to assess an innovative serious game training using the SAED tool combined with standard instructions on self-efficacy for family-based caregivers of lung cancer patients when facing a simulated situation of ARF. The study also aims to examine caregivers' emotional state, quality of life, satisfaction and knowledge about the SBAR tool.
Methods: A monocentric, randomized, controlled, open-label, superiority, parallel-arm trial will be conducted for 18 months with 3 mid-study assessments (NCT05839353). Family caregivers of lung cancer patients will be recruited at the University Hospital Center of Saint Pierre, Reunion Island, France. Participants will be randomized (1:1) into two groups: the experimental group receiving training using the SBAR/SAED tool and standard instructions for managing respiratory distress/dyspnea, and the control group, receiving standard instructions only. The primary outcome will be to determine perceived self-efficacy as measured by the Generalized Self-Efficacy Scale.
Discussion: This study will present a preliminary assessment of training family caregivers in using the SBAR/SAED tool in simulated episodes of ARF in lung cancer patients. Our findings may provide valuable insights into effective training methods for caregivers in critical home care situations and could be widely used for lung cancer management.

1. Introduction

Lung cancer is the second most common malignant cancer worldwide, and is a global public health concern (Barta et al., 2019; Sung et al., 2021). In 2020, approximately 2.21 million new cases and 1.79 million deaths were recorded (Pujol et al., 2021). In metropolitan France, lung cancer ranks as the third most common cancer with 46,363 new cases diagnosed in 2018. (Cowppli-Bony et al., 2019). To date, it remains the leading cause of cancer-related deaths (Institut national du Cancer, 2022) and a comparable trend on Reunion Island, a French

* Corresponding author at: Department of Nursing, Rehabilitation and Medical Techniques (South Site), University Hospital Center, Saint-Pierre, La Réunion, France.
E-mail address: danielle.reynaud@chu-reunion.fr (D. Reynaud).

https://doi.org/10.1016/j.invent.2024.100752
Received 19 February 2024; Received in revised form 18 May 2024; Accepted 9 June 2024
Available online 11 June 2024

oversea territory, has been reported (Observatoire Régionale de la Santé Océan Indien, 2019). A known symptom of lung cancer is dyspnea which can rapidly escalate into life-threatening acute respiratory failure (ARF). The prevalence of dyspnea in lung cancer patients is elevated, ranging from 50 to 87 % (Kathiresan et al., 2010; Barbera et al., 2010), and often provokes an emotional response causing depression, anxiety, fear and lower quality of life (Dangers et al., 2014; Morrison et al., 2017). Dyspnea can become the predominant symptom in the stages of terminal lung cancer (Kim et al., 2022) and remains as the second most severe symptom for up to a year following lung cancer diagnosis, affecting 47.3 % of patients irrespective of the disease stage (Hirpara et al., 2020). Regarding ARF, it is often predictive of hospitalization in critical care and intensive care units (ICU) (Meert and Sculier, 2013) and is an immediate cause of death in 38 % of lung cancer cases (Nichols et al., 2012).

Effective management of ARF in pre-hospital settings requires patients to contact Emergency Medical Services (EMS), known as the *Service d'Aide Médicale Urgente* (SAMU) in French (Conseil d'État, 2005). In practice, information about ARF should be clearly and precisely communicated to the EMS to avoid medical errors, inappropriate decision-making and any loss of treatment opportunities for patients (Topcu et al., 2017). Standardized and structured communication techniques have emerged as solutions for better communication in acute care settings. In the US, the Situation, Background, Assessment, Recommendation (SBAR) tool has demonstrated both validity and reliability, reported in Davis et al., pooling in 1200 student and with a sample size = 10 (Davis et al., 2021). It has been implemented across healthcare settings to facilitate communication between nurses and physicians in critical situations, during patient transfers, in operating rooms and in Emergency Departments (EDs) (Smith et al., 2018). Endorsed by the World Health Organization (WHO), the SBAR tool has also been recognized by the Institute for Healthcare Improvement (IHI) and the National Health Service (NHS) in the UK for enhancing communication and patient safety (Müller et al., 2018). In France, since 2014, health authorities including the *Haute Autorité de Santé* (HAS) have recommended a communication tool adapted from the SBAR tool, known as the *Situation, Antécédent, Évaluation et Demande* (SAED) tool, (Haute Autorité de Santé, 2014a). The SAED tool retains the fundamental principles of SBAR, while customizing it for the context of the French healthcare system. The tool is more than just a translation of the SBAR because it considers the specificities of the national healthcare system, including terminologies and clinical practices. It is applicable to facilitate communication between healthcare professionals (HCPs), in diverse inter-professional contexts throughout the patient care continuum, whether in healthcare and medico-social facilities, in inpatient and outpatient settings, as well as in homecare (Haute Autorité de Santé, 2014a).

A shift towards outpatient treatment for lung cancer is rising with an increased emphasis on home monitoring and/or nursing home care (Coriat et al., 2012). Family members acting as caregivers often provide a large range of informal care for patients, even though their roles, skills, preparedness and training have not been well defined or studied (Grant et al., 2013). A meta-analysis of 29 randomized controlled trials on interventions for family caregivers of cancer patients revealed several types of interventions (psychoeducational, professional training, therapeutic counselling and self-help programs). Most of these interventions combined psychoeducational and professional training, carried out face-to-face or by telephone (Papadakos et al., 2023). As stated by Papadakos et al., caregivers, particularly those aged over 75 years, prefer face-to-face teaching as a way of escaping social isolation and benefiting from enriching human interaction (Papadakos et al., 2023). However, online training courses are gaining in popularity among younger caregivers because of their flexibility and accessibility, adapting to their schedules and constraints. During the Covid-19 pandemic, this trend was accelerated, prompting many people to adopt e-learning methods as an effective alternative to traditional teaching (Rollot-Trad et al., 2021). Serious games are innovative teaching strategies adapted to healthcare training that can complement traditional teaching methods. They consist of computer-based simulations that combine knowledge and skill development with video-game features to enable active, experiential, situational and problem-based learning (Haoran et al., 2019).

Moreover, in home-based lung cancer care, caregivers are at the frontline for managing symptoms like dyspnea and ARF (Rha et al., 2015; Dionne-Odom et al., 2019; Ullgren et al., 2018). ARF can cause anxiety and emotional distress in family caregivers (Janssen et al., 2015) which is mainly attributed to the lack of knowledge or experience in contrast with the high-level skills required for managing dyspnea and/or ARF (Ullgren et al., 2018; Malik et al., 2013). Insufficient information sharing has also been reported as a cause of reduced self-efficacy among family caregivers (Thomas Hebdon et al., 2021). Training programs specially designed for caregivers have been developed to improve self-efficacy, thereby fostering their commitment in caregiving and positively influencing their well-being. However, real-world evidence on these strategies and their impact on training caregivers and HCPs is both limited and contradictory as reported in Northouse et al. (Min et al., 2022; Northouse et al., 2010).

Digital health solutions in the form of interactive experiences such as serious games and immersive training programs have emerged as innovative teaching methods and interventions for HCPs and caregivers. Family caregivers, although unpaid, are often considered to be HCPs in their own right. Their dedication and skills place them in a category close to that of student nurses. Similarly, the acceptability of digital simulators has been confirmed within the nursing community, demonstrating their usefulness and relevance in the field of training and professional development (Decormeille and Rouleau, 2022). In this paper, we describe the protocol of a pilot study that will evaluate the effectiveness of an innovative training program for family-member caregivers incorporating the SAED tool in the management of dyspnea and ARF of patients at home. We hypothesize that training using the SAED tool that applies a serious game could improve the sense of self-efficacy of caregivers of patients with lung cancer in the management of a simulated respiratory distress situation at home.

2. Materials and methods

2.1. Study design

A pilot monocentric study will be conducted at the University Hospital of Reunion Island (South Site), an overseas department of France. The study design is a randomized, open-label, parallel-arm, superiority-controlled trial using a 1:1 allocation ratio (Fig. 1). The serious game used in this study is the "e-SAEDAOU" developed by SimforHealth® (Bordeaux, France), a non-for-profit company that was selected because of its proven graphic skills, as well as its previous experience in creating other similar tools to a public tender, notably the SAED. The serious game will be available to participants on various digital devices via the internet (computer, tablet, and/or smartphone).

Participants will be separated into two groups: an experimental group (EG) and a control group (CG). The EG will receive simulated training from the serious game to master the use of the SAED tool supplemented by routine care instructions for the management of dyspnea and ARF. The CG will only receive routine care instructions. The assessments are defined as follows for both groups: i) a baseline assessment (T1) conducted in hospital at the time of inclusion, before randomization and before the intervention and ii) a scheduled post-inclusion follow-up with assessments conducted online at home at 21 to 28 days. For the EG only, a scheduled follow-up at 90 days post-inclusion (T3) will be conducted (see Fig. 1).

2.2. Study objectives

The primary objective of this pilot study will be to assess the impact

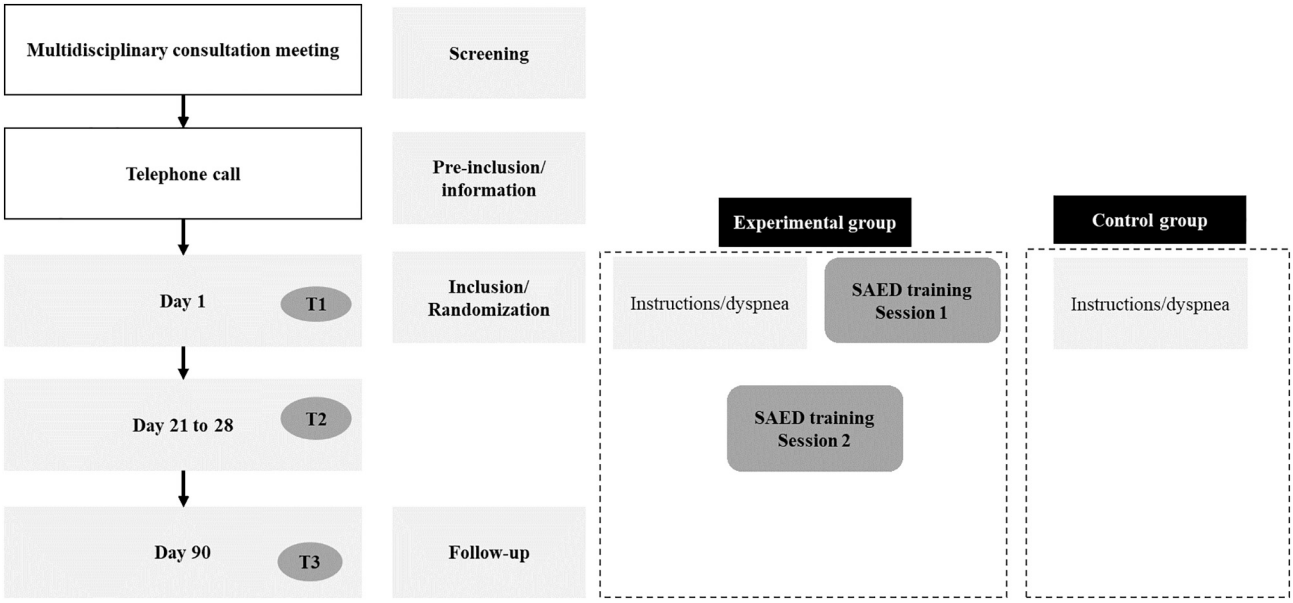


Fig. 1. Study design.

of an innovative training program (using a serious game) based on the SAED tool on the caregivers' self-efficacy during a simulated respiratory distress scenario involving lung cancer patients. Secondary objectives will be to assess caregivers' anxiety and depression symptoms, quality of life (QoL), satisfaction and acquired knowledge of the SAED tool while using the serious game.

2.3. Sample size

For the sample size calculation, we applied the methodology used by Kilic and Simek which was employed to assess the impact of a first aid training program on student nurse self-efficacy (Kılıç and Şimşek, 2019). The participants in our study will not have a healthcare background, therefore we anticipate a smaller effect size compared to those observed in Kilic and Simek in which participants were HCPs (Kılıç and Şimşek, 2019). It may be worth noting that in this randomized clinical trial, 76 student nurses experienced a 7.58 ± 3.95-point increase in their General Self-Efficacy Scale (GSS) scores following this training compared to a CG. Using a two-tailed Student's *t*-test with 5 % alpha risk and 90 % power, 12 randomly selected participants are expected to be sufficient to demonstrate an effect in self-efficacy. We aim to enroll 32 participants, (16 in each arm). With an estimated drop-out rate of 30 %, we expect approximately 22 participants to complete the study. With this sample size, the minimum detectable difference in GSS scores would be 4.3 points. These estimations were based on other studies such as Huang et al. which reported a 20 to 30 % dropout rate (Huang et al., 2013).

2.4. Recruitment

Recruitment will take place in the Ambulatory Medicine Unit (AMU) in the oncology department at the University Hospital of Reunion Island. The nursing staff at the AMU will invite family-based caregivers by telephone to take part in the study when planning their patient's treatment. If caregivers agree to participate, the nurses will complete a recruitment form to securely transmit their contact details to the investigating team and to indicate the date of the patient's first course of anti-cancer therapy (chemotherapy and/or other therapies).

For caregivers who confirm their interest, the principal investigator or a member of the research team will contact them to provide detailed information about the team, study objectives and the potential benefits and risks. The caregivers will then be asked to confirm their willingness to participate and provide their consent. The investigating team will remain available by telephone or e-mail to address any further questions from participants.

2.5. Inclusion/exclusion criteria

Inclusion criteria will be participants who: i) are adults over 18 years old, ii) have been designated as a caregiver by a newly diagnosed lung cancer patient receiving their first anti-cancer treatment (chemotherapy, hormone therapy or targeted therapy) on Reunion Island, iii) provide unpaid technical, psychological and/or social assistance on a daily basis, iv) are able to read and write in French, and v) have provided informed and expressed oral consent to take part in this study.

Exclusion criteria include those who: i) have been deprived of their liberty by a judicial or administrative decision, ii) are under legal protection (guardianship or trusteeship), iii) have a history of cancer and/or anxiety/depression disorders and iv) are not fluent in French. The exclusion of anxiety/depression as history was to avoid potentially triggering stress among this population since training for life-threatening emergencies is intensive and to restrict the target audience to comply with our aims, since our objectives are to assess anxiety and depression to lead to more tangible and measurable findings.

2.6. Study intervention

Serious games are innovative teaching strategies adapted to healthcare training that can complement traditional teaching methods. They consist of computer-based simulations that combine knowledge and skill development with video-game features to enable active, experiential, situational, and problem-based learning (Haoran et al., 2019). We are currently developing an innovative training course combining the use of serious games and the SAED tool.

This innovative training course is designed specifically for family members caring for lung cancer patients. The on-screen digital simulator (computer), one of the various existing simulation modalities (Chiniara et al., 2013), enables learners to be confronted with various simulated care situations in complete safety for themselves and for the patient, while developing certified knowledge, behavioral and relational skills (Rouleau et al., 2019). This learning environment can improve clinical reasoning skills and promote the acquisition of theoretical knowledge compared with other simulation methods (Qiao et al., 2022). One

advantage of this digital environment is that it delivers harmonized pedagogical content with the possibility of wide-scale dissemination (Tyerman et al., 2021), while allowing the training of several participants either synchronously or asynchronously. Caregivers will not be involved in creating or developing the serious game because of limited resources, the structure of the study, and the technical expertise involved in developing the training tool. However, before its implementation, five volunteer caregivers will test it to provide valuable feedback to the investigatory team in order to make any necessary changes and/or improve the version used with the EG.

Training objectives will include recognizing ARF, using the SAED communication tool with the EMS (SAMU) and implementing the initial safety measures for managing patient symptoms. The serious game used in this study will consist of two virtual scenarios dealing with the signs and symptoms of ARF and the use the SAED tool to contact the EMS (SAMU). Virtual scenarios will also include quizzes to help reinforce key points. The feedback process will be formally structured. The correct answer to each question of the quiz is presented after the question itself, followed by a summary at the end of each quiz. After exploring each scenario, participants will receive feedback on their performance. Training will occur on an online platform (MedicActiv by SimforHealth, Bordeaux, France) which complies with the European General Data Protection Regulations (GDPR) (Dale-Tam et al., 2021).

Caregivers will receive access to the serious game through a code provided during the initial in-person session at the hospital. Follow-ups will be carried out by voice or videoconference with the principal investigator. Caregivers will engage in the serious game exclusively without any supplementary documents, and will have access to the integrated educational content will be provided accordingly.

The training will consist of two one-hour sessions, with an initial test at T1 and a final test at T2 during which caregivers simulate a call to the EMS (SAMU). Training will be provided by the investigators and the research team. This team is also involved in creating and developing the serious game, who are a lung oncologist, an emergency room nurse, a registered nurse based in the oncology department, a nurse researcher in cognitive psychology and healthcare simulation, two nursing training institute instructors and software engineers. The serious game will be accessible online throughout training period, except for the 2 h preceding the final test. Access to the MedicActiv training platform will remain available for one year after the end of the study, enabling participants to independently review the educational content (such as ARF concepts and the SAED tool). A screenshot of the digital simulator is provided in the Supplementary material.

Participants in the CG will only receive standard instructions for the management of ARF at home without the SAED training provided by the serious game. They will receive a leaflet containing the following information to manage ARF: i) general instructions (position properly the patient in semi-seated posture, ensure comfortable clothing (unbutton shirt, loosen trousers), ventilate the room and reassure) and ii) special measures (administer oxygen therapy if prescribed by the doctor, apply non-invasive ventilation (if prescribed) and follow specific treatment instructions.) The leaflet also provides the contact details for the EMS (SAMU) hotline. Following T2, caregivers in the CG will be offered access codes to log on to the MedicActiv platform and practice independently using the SAED tool and the serious game (without data collection for research purposes).

2.7. Blinding

Given the intervention's design, blinding both the investigating team and participants will not be feasible. Participants receive training either immediately or not, which inherently reveals their allocation arm. Since the investigating team conducts the training, they cannot be blinded to the participant's allocation. However, statistical analysis will remain blinded to group allocation.

2.8. Measures and outcomes

Study measures will include caregivers perceived self-efficacy, anxiety and depression symptoms, quality of life (QoL), platform use indicators and will assess caregivers' knowledge and satisfaction with the SAED tool. The main outcome will evaluate the impact of the SAED tool training on caregiver's self-efficacy. Secondary outcomes for both groups will involve evaluating the effects of the SAED tool training combined with routine care instructions about caregivers' anxiety and depression symptoms and their QoL. For the EG only, outcomes will include assessing the use of the serious game, knowledge level at the end of the study and satisfaction with the SAED tool in actual practice (Tables 1 and 2).

2.8.1. Caregivers perceived self-efficacy

Self-efficacy represents the ability to organize and manage a specific situation and reflects an individual's confidence in his or her capabilities to achieve a given task (Bandura, 2003). This concept is crucial for learning and acquiring new skills and knowledge, especially in healthcare settings (Galand and Vanlede, 2004). Studies have shown that caregivers' self-efficacy can influence their perceptions and behaviors towards both themselves and patients, particularly in areas such as personal care or symptom management (Thomas Hebdon et al., 2021).

We selected the GSS to assess caregivers' self-efficacy (Luszczynska et al., 2005). The GSS is a psychometric scale (about 5 min to complete) that assesses positive beliefs about one's ability to cope with various demands or complex situations in real-life scenarios. It was originally developed by Jerusalem and Schwarzer (Schwarzer and Jerusalem, 2012) in Germany and has been translated into 33 languages. The French version of the GSS was validated as having excellent psychometric properties (Dumont et al., 2000). The GSS consists of 10 items rated on a 4-point Likert scale (1 = Not at all true to 4 = Completely true). The final GSS score, ranging from 10 to 40, indicates the level of self-efficacy, with higher scores corresponding to a stronger sense of self-efficacy. The GSS will be used for general relevance given its design to obtain data in a variety of situations and context, its availability, and its use in comparability since it is a generally used scale. The GSS has been used with caregivers at different stages of cancer disease, such as within 6 months of starting new treatment in cancer patients, palliative care patients and during evaluations of interventions (Astrup et al., 2020; Mystakidou et al., 2013). It should be noted that a specific caregiver self-efficacy scale (CASES) was developed for use in advanced cancer, but it cannot be applied in this study.

2.8.2. Anxiety and depression symptoms

The Hospital Anxiety and Depression Scale (HADS) is a 14-item self-assessment instrument consisting, divided into two 7-item subscales. It assesses both anxiety and depression symptoms over the prior 7-day period (Mitchell et al., 2010; Bjelland et al., 2002). Each question is scored from 0 to 3, with individual scores then added up. Higher scores reflect greater emotional distress. Subscale scores range from 0 (no distress) to 21 (maximum distress). Subscale scores >7 indicate the presence of clinically significant symptoms of depression or anxiety. The HADS has demonstrated excellent psychometric validity (Cronbach's

Table 1
Assessment timepoints of study groups.

	T1 (baseline)	T2 (21–28 days post-baseline)	T3 (90 days post-baseline)
	In hospital at inclusion, before randomization and intervention	Online at the participants' home.	Online at the participants' home
Experimental group	x	x	x
Control group	x	x	

Table 2
Outcomes and instruments used for measures.

Outcomes	Evaluation period			Measuring instruments
	Baseline (T1)	Post-intervention (T2)	Three months post-treatment (only intervention group) (T3)	
Self-efficacy	x	x	x	Generalized Self-Efficacy Scale
Anxiety and depression symptoms	x	x	x	HADS Scale
Quality of life	x	x	x	SF-12
Knowledge acquisition	x	x		Graded knowledge assessment on the use of the SBAR tool
MedicActiv Platform use		x	x	Platform use indicators: number of logins, video views, consultation of digital resources
Satisfaction with the SBAR tool and the training			x	HAS satisfaction questionnaire on the use of the SBAR tool and the training

SBAR; Situation, Background, Assessment, Recommendation, SF-12; Short Form-12, HADS; Hospital Anxiety and Depression Scale, HAS; *Haute Autorité de Santé*.

alpha = 0.83) in assessing anxiety and depression in diverse populations and has been tested on cancer patient caregivers with good performance compared to other scales (Mitchell et al., 2010; Bjelland et al., 2002). Though the HADS scale is not endorsed by all the research community, we choose this since it is recommended by heath authorities in France and is recognized and validated within the French context.

2.8.3. Quality of life

Caregivers' quality of life (QoL) will be assessed using the Medical Outcome Study Short Form-12 (MOS SF-12), commonly referred as Short Form-12 (SF-12) (Perpiñá-Galvañ et al., 2019). Developed and validated in nine European countries including France, the SF-12 is a reference scale for assessing QoL in clinical research and epidemiology. The SF-12 consists of 12 items related to eight criteria (limitations in physical activity, social life and relationships, physical pain, perceived health, vitality, limitations due to emotional state, and limitations due to physical/mental health). An overall QoL score is computed from the two sub-scores (emotional QoL and physical QoL). The possible overall QoL score is 100. Higher scores indicate better physical and mental health functioning. Scores are interpreted as follows: above 50 corresponds to good QoL, 40–49 indicates mild Qol, 30–39 reflects moderate QoL, and below 30 suggests lower QoL.

2.8.4. Platform use indicators

The following indicators will be developed by the investigating team during the creation of the serious game: i) number of MedicActiv platform logins, ii) video view counts; iii) consultations of the SAED tool recommended by the HAS (Haute Autorité de Santé, 2014a) and iv) the number of simulations carried out.

2.8.5. Knowledge acquisition among caregivers

The investigating team has developed a graded knowledge assessment grid to validate the level reached by caregivers in using the SAED tool. This grid also serves as a self-positioning tool for caregivers. Training involves scenarios consisting of quizzes with both simple and multiple-choice questions. With a possible total score of 20, each correct answer earns 1 point, while incorrect answers receive 0 points. A score of 16 and above is considered satisfactory for the safe use of the SAED tool when calling the EMS (SAMU). In fact, the questions asked were ranked in order of importance, according to established criteria. The pedagogical experts collaborating on the project considered that a score above 16 out of 20 points ensured that the learner demonstrates a significant acquisition of knowledge. Scores below 16 prompt caregivers to redo the scenarios. The initial score obtained at T1 will be considered in the data analysis.

2.8.6. Satisfaction with the SAED tool and training

A standardized questionnaire will be used to assess whether caregivers have effectively utilized the SAED communication tool when calling the EMS (SAMU) in the event of ARF at home. Questions are aligned with the HAS recommendations for training HCPs in the use of the SAED tool (Haute Autorité de Santé, 2014b). First question is “Have you used the SAED tool in the last 3 months?” If the answer is “Yes”, the caregiver will proceed to answer 11 subsequent questions regarding the frequency and ease of use of the tool. For caregivers who will have used the SAED tool to contact SAMU within 90 days post-inclusion, the number of times the tool was used will be asked. A question will also evaluate whether caregivers are satisfied with the training they received.

2.9. Statistical analysis

A comprehensive analysis of population characteristics will be conducted to provide an overview of the study participants. Descriptive analysis will include demographic information such as age, gender, educational background and socioeconomic status (annual household income). To assess the primary outcome, a comparison of GSS scores between the CG and the EG will be conducted at T1 and T2. The analysis of secondary outcomes will include between-group comparison of HADS and SF-12 scores at T2 (EG versus CG) and within-group comparison of GSS, HADS and SF-12 scores for the period between T1 and T2. Exploratory sub-analysis using socio-demographic factors may influence outcomes such as sex, age, education level and baseline self-efficacy which may be included in the findings.

For the EG, a comparison of knowledge assessment scores for the period between T1 and T2 will be carried out. It will also include a descriptive analysis of login data and a descriptive analysis of satisfaction with the practical use of the SAED tool in real-life situations based on the HAS satisfaction questionnaire for the SAED tool.

Statistical analyses will be conducted in accordance with the intention-to-treat principle (ITT) and will be based on a pre-established statistical analysis plan that will be finalized before the database is locked. Descriptive statistics will include absolute numbers (N) and relative numbers (%) for qualitative variables. Quantitative variables will be described in term of mean, Standard Deviation (SD) and absolute range. Comparisons will be carried out using Student's *t*-tests or Mann-Whitney tests for quantitative variables. Frequencies comparisons will be carried out with Chi-squared tests or Fisher's exact tests. The study is designed to detect a minimum difference of 4.5 points on the GSS at an alpha risk of 5 % and a power of 80 %. Statistical software such as SAS (V9.4, SAS Institute Inc., Cary, NC, USA), Stata (V16, Stat Corp., Texas, USA) and R will be used for the analyses.

2.10. Ethical considerations

This study protocol was approved by the Ethics Committee at the Bordeaux University Hospital Center in France on August 16, 2023 (2023CER-BDX 2023–87) and is registered on ClinicalTrials.gov (NCT05839353). Explicit oral consent will be obtained from all participants at the time of the interview before inclusion and then recorded in a field journal. The study will be conducted in accordance with the

Declaration of Helsinki as well as the applicable legislation pertaining to research involving human participants.

3. Discussion

To our knowledge, this randomized trial will be the first to evaluate the impact of an innovating training program on the use of SAED communication tool for caregivers in cases of ARF managed at patients' homes. By improving caregivers' self-efficacy and communication with emergency services, the serious games related to a simulated ARF should contribute to improving the management of this condition in lung cancer patients. Training to use the SAED tool is designed to improve the communication skills of caregivers, better manage dyspnea and ARF and prevent communication failures that threaten quality of care and patient safety (Umberfield et al., 2019).

ARF consists of stressful episodes that can also lead to emotional distress in family caregivers, with anxiety and feelings of helplessness, especially during acute nocturnal episodes (Janssen et al., 2015; Malik et al., 2013). The severity of dyspnea was associated with a deterioration in caregivers' psychological health and lower quality of patient care. The average anxiety score for dyspnea is around nine on the HADS scale (Malik et al., 2013).

This burden associated with caregiving roles represent threats to caregivers' health, well-being and skills (Perpiñá-Galvañ et al., 2019). Previous interventions have been implemented to reinforce caregiver's self-efficacy in the field of cancerology and have shown positive results (Gong et al., 2021). In 2016, a randomized controlled trial evaluated the effectiveness of a training program focusing on cancer symptoms and stress management in caregivers and showed that the intervention group had significantly increased levels of self-efficacy in managing patients' cancer symptoms, as well as higher capacity to cope with stress compared to the control group (Hendrix et al., 2016).

To date, only one study in France has investigated the use of the SAED tool through a serious game named *LabForGames Warning*, but this study was limited to intra-hospital emergencies (not only ARF) and involved nursing students (Blanié et al., 2017). Our study extends the evaluation of this type of training to family caregivers who play a major role in managing patients with lung cancer in the patient's home. As mentioned previously, dyspnea and ARF are frequent in lung cancer and potentially lethal and their burden impacts caregiver's emotional status and ability to deliver quality care (Malik et al., 2013). Moreover, previous studies in the US have tested the SBAR tool teaching through similar innovative techniques dedicated to HCPs (Kesten, 2011). However, the serious games conducted in the US are hardly transposable to the French healthcare context given the cultural differences, the differences in clinical practices, and in the healthcare system organization (the French system is public where most citizens are covered by the *Assurance Maladie* for their health care). In the literature, evidence on the effectiveness of serious games in health care settings remains contrasted. The systematic review of serious games in nurse education by Min et al. did not provide evidence of effectiveness (Min et al., 2022). The authors, however, provided recommendations for developing and assessing serious games. Other studies highlight the validation of serious games specifically designed to train family caregivers in the management of life-threatening emergencies. These serious games are used to teach first-aid techniques, particularly in the event of respiratory distress in children with home tracheostomies, whether or not there is cardiopulmonary arrest (Brooks et al., 2022). In addition, they aim to develop interpersonal skills such as the confidence needed to intervene in the event of asthmatic exacerbation in children (Foronda et al., 2023), as well as satisfaction in caring for parenterally-fed children at home (Raphael et al., 2021).

3.1. Strengths and limitations

The main strength of the study is the development and implementation of an innovative training strategy (serious game) embedded into the SBAR communication tool. This training should improve caregivers' communication skills in managing ARF in a home setting. Training and skills development are enhanced by the repeated use of serious games, personalized feedback on the caregiver's performance, assessment of their satisfaction with the tool and with the MedicActiv platform. Also, the playful aspect of the serious game with a user-friendly design and its easy access through the MedicActiv platform should motivate caregivers to participate in learning, engage them in the training, and thus prevent drop-outs from the study.

Among the limitations is that blinding of participants and investigators will not be feasible. This may influence the outcomes, with possible higher effect on the EG versus the CG. The statistician will be blinded for the allocation group to limit potential biases. The small sample size may also limit the possibility to observe a significant difference between groups. However, this is a pilot exploratory study and the training should be implemented and tested in larger samples of caregivers to more widely explore its impact.

Comparisons between studies are limited given the differences in study design, participant characteristics and outcome measures. For example, key differences between our study and the randomized clinical trial by Kilic and Simsek limit direct comparisons, such as variations in participant demographics, training duration and study methods (Kılıç and Şimşek, 2019). In Kılıç and Şimşek (2019), the study participants had already been trained in healthcare and may have been more receptive to the training content, whereas the caregivers in our study are more diverse in terms of age, educational background and socioeconomic status. Another limitation may be from overlooking the differences between general self-efficacy measures and more specific tools. By focusing solely on the caregivers self-efficacy, this study may overlook other important aspects of the serious game experience in the context of patient care. Patient perspectives and feedback can provide crucial information on the overall effectiveness of the serious game, its perceived usefulness and its actual impact on the care provided. It would have been possible to use other tools to address the effect of the training offered to caregivers. For example, the Kirk Patrick scale would appear to be an appropriate tool for assessing the effectiveness of caregiver training in managing respiratory failure at home. Indeed, it offers a holistic assessment in four levels: participant reaction, acquisition of knowledge and skills, behavioral changes and impact on patient outcomes. This provides a holistic view of the effects of training, going beyond simple measures of satisfaction or knowledge acquired (Panadero et al., 2017).

The serious game used for improving caregiver's self-efficacy and enhancing communication with medical teams should contribute to improving the well-being and emotional status of all stakeholders involved in the care of individuals with lung cancer and ultimately lead to better patient outcomes. The findings of this research will be disseminated through peer-reviewed publications, conferences and posters, knowledge transfer sessions with stakeholders including caregivers, HCPs and health administrators. Further research is needed to explore the effectiveness of training via serious games in caregivers more widely.

4. Conclusions

This study has the potential to create a holistic and secure support system for lung cancer patients and their caregivers. By improving caregiver's self-efficacy and technical skills and by enhancing their capacity to communicate appropriately with health professionals, this innovative training program will eventually contribute to improve health outcomes of individuals with lung cancer treated at home. Findings may be useful to all stakeholders involved in knowledge transfer sessions and personalized recommendations to better manage lung cancer with the involvement of caregivers.

Supplementary data to this article can be found online at https://doi.

org/10.1016/j.invent.2024.100752.

CRediT authorship contribution statement

DR: Conceptualization, Methodology, Draft manuscript preparation, Project Administration, Funding Acquisition, Supervision, Resources, Validation, Writing – Review & Editing. AT: Conceptualization, Methodology, Draft manuscript preparation, Validation, Writing – Review & Editing. GD: Serious game design, Draft manuscript preparation, Validation, Writing – Review & Editing. RB: Conceptualization, Methodology, Draft manuscript preparation, Validation, Writing – Review & Editing.

Funding statement

This work was supported by the Reunion Island University Hospital.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

The authors would like to thank the caregivers that have accepted to participate in this pilot study, Lucie Auzanneau for administrative procedures, nurse Anne-Judith Domitile, Laurie Kichenapanaidou and the Reunion Island University Hospital for their financial support. The authors would also like to thank Isabelle Pitrou, Marty Brucato and Sarina Yaghobian from AcaciaTools as well as MedicActiv and SimforHealth®.

References

Astrup, G.L., Hofsø, K., Bjordal, K., Rustøen, T., 2020. Cancer patients' diagnosis and symptoms and their family caregivers' self-efficacy and social support are associated with different caregiver reactions. Eur. J. Cancer Care 29. https://doi.org/10.1111/ecc.13311.

Bandura, Rondier M.A., 2003. Auto-efficacité. Le sentiment d'efficacité personnelle. Éditions De Boeck Université, Paris, pp. 475–476. https://doi.org/10.4000/osp.741. Osp 2004.

Barbera, L., Seow, H., Howell, D., Sutradhar, R., Earle, C., Liu, Y., et al., 2010. Symptom burden and performance status in a population-based cohort of ambulatory cancer patients. Cancer 116, 5767–5776. https://doi.org/10.1002/cncr.25681.

Barta, J.A., Powell, C.A., Wisnivesky, J.P., 2019. Global epidemiology of lung cancer. Ann. Glob. Health 85, 8. https://doi.org/10.5334/aogh.2419.

Bjelland, I., Dahl, A.A., Haug, T.T., Neckelmann, D., 2002. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. J. Psychosom. Res. 52, 69–77. https://doi.org/10.1016/s0022-3999(01)00296-3.

Blanié, A., Roulleau, P., Barcello, B., Bertrand, H., Cazin, A., Flajolet, N., et al., 2017. Mise en place d'un jeu sérieux pour les étudiants infirmiers pour les former à la détection de l'aggravation d'un patient et à la communication avec l'outil SAED: LabForGames Warning. SegaMed.

Brooks, M., Jacobs, L., Cazzell, M., 2022. Impact of emergency management in a simulated home environment for caregivers of children who are tracheostomy dependent. J. Spec. Pediatr. Nurs. 27, e12366 https://doi.org/10.1111/jspn.12366.

Chiniara, G., Cole, G., Brisbin, K., Huffman, D., Cragg, B., Lamacchia, M., et al., 2013. Simulation in healthcare: a taxonomy and a conceptual framework for instructional design and media selection. Med. Teach. 35, e1380–e1395. https://doi.org/10.3109/0142159X.2012.733451.

Conseil d''État, 2005. Décret n°87-1005 du 16 décembre 1987 relatif aux missions et à l'organisation des unités participant au Service d'aide médicale urgente appelées S.A.M.U.

Coriat, R., Boudou-Rouquette, P., Durand, J.-P., Forgeot d'Arc, P., Martin, I., Mir, O., et al., 2012. Cost effectiveness of integrated medicine in patients with cancer receiving anticancer chemotherapy. J. Oncol. Pract. 8, 205–210. https://doi.org/10.1200/JOP.2011.000447.

Cowppli-Bony, A., Colonna, M., Ligier, K., Jooste, V., Defossez, G., Monnereau, A., et al., 2019. Descriptive epidemiology of cancer in metropolitan France: incidence, survival and prevalence. Bull. Cancer 106, 617–634. https://doi.org/10.1016/j.bulcan.2018.11.016.

Dale-Tam, J., Thompson, K., Dale, L., 2021. Creating psychological safety during a virtual simulation session. Clin. Simul. Nurs. 57, 14–17. https://doi.org/10.1016/j.ecns.2021.01.017.

Dangers, L., Morelot-Panzini, C., Schmidt, M., Demoule, A., 2014. Mécanismes neurophysiologiques de la dyspnée: de la perception à la clinique. Réanimation 23, 392–401. https://doi.org/10.1007/s13546-014-0902-4.

Davis, B.P., Mitchell, S.A., Weston, J., Dragon, C., Luthra, M., Kim, J., et al., 2021. SBAR-LA: SBAR brief assessment rubric for learner assessment. MedEdPORTAL 17, 11184. https://doi.org/10.15766/mep_2374-8265.11184.

Decormeille, G., Rouleau, G., 2022. Acceptabilité de la simulation numérique en formation par une analyse comparative franco-canadienne. Sci. Nurs. Health Pract. 5, 14. https://doi.org/10.7202/1093074ar.

Dionne-Odom, J.N., Ejem, D., Wells, R., Barnato, A.E., Taylor, R.A., Rocque, G.B., et al., 2019. How family caregivers of persons with advanced cancer assist with upstream healthcare decision-making: a qualitative study. PLoS One 14, e0212967. https://doi.org/10.1371/journal.pone.0212967.

Dumont, M., Schwarzer, R., Matthias, J., 2000. French Adaptation of the General Self-efficacy Scale. http://userpage.fu-berlin.de/%7Ehealth/french.htm.

Foronda, C., Mehta, E., Morales, M.J., Cacchione, M., Gattamorta, K.A., Cardenas, M., 2023. Usability of a virtual reality application to educate family caregivers of children with asthma. Clin. Simul. Nurs. 84, 101465 https://doi.org/10.1016/j.ecns.2023.101465.

Galand, B., Vanlede, M., 2004. Le sentiment d'efficacité personnelle dans l'apprentissage et la formation: quel rôle joue-t-il? D'où vient-il? Comment intervenir?: Savoirs, pp. 91–116. https://doi.org/10.3917/savo.hs01.0091. Hors série.

Gong, J., Hu, C., Chen, M., Cao, Q., Li, Q., 2021. Interventions to improve self-efficacy in colorectal cancer patients and/or caregivers: a systematic review and meta-analysis. J. Oncol. 2021, 4553613 https://doi.org/10.1155/2021/4553613.

Grant, M., Sun, V., Fujinami, R., Sidhu, R., Otis-Green, S., Juarez, G., et al., 2013. Family caregiver burden, skills preparedness, and quality of life in non-small cell lung cancer. Oncol. Nurs. Forum 40, 337–346. https://doi.org/10.1188/13.ONF.337-346.

Haoran, G., Bazakidi, E., Zary, N., 2019. Serious games in health professions education: review of trends and learning efficacy. Yearb. Med. Inform. 28, 240–248. https://doi.org/10.1055/s-0039-1677904.

Haute Autorité de Santé, 2014a. Situations antécedents évaluation demande - Saed-: un guide pour faciliter la communication entre professionnels de santé.

Haute Autorité de Santé, 2014b. Enquête de satisfaction: « Saed : ça aide à communiquer ». https://www.has-sante.fr/upload/docs/application/pdf/2014-11/questionnaire_satisfaction.pdf.

Hendrix, C.C., Bailey, D.E., Steinhauser, K.E., Olsen, M.K., Stechuchak, K.M., Lowman, S.G., et al., 2016. Effects of enhanced caregiver training program on cancer caregiver's self-efficacy, preparedness, and psychological well-being. Support Care Cancer 24, 327–336. https://doi.org/10.1007/s00520-015-2797-3.

Hirpara, D.H., Gupta, V., Davis, L.E., Zhao, H., Hallet, J., Mahar, A.L., et al., 2020. Severe symptoms persist for up to one year after diagnosis of stage I-III lung cancer: an analysis of province-wide patient reported outcomes. Lung Cancer 142, 80–89. https://doi.org/10.1016/j.lungcan.2020.02.014.

Huang, H.-L., Kuo, L.-M., Chen, Y.-S., Liang, J., Huang, H.-L., Chiu, Y.-C., et al., 2013. A home-based training program improves caregivers' skills and dementia patients' aggressive behaviors: a randomized controlled trial. Am. J. Geriatr. Psychiatry 21, 1060–1070. https://doi.org/10.1016/j.jagp.2012.09.009.

Institut national du Cancer, 2022. Panorama des cancers en France: Edition 2022.

Janssen, D.J.A., Wouters, E.F.M., Spruit, M.A., 2015. Psychosocial consequences of living with breathlessness due to advanced disease. Curr. Opin. Support. Palliat. Care 9, 232–237. https://doi.org/10.1097/SPC.0000000000000146.

Kathiresan, G., Clement, R.F., Sankaranarayanan, M.T., 2010. Dyspnea in lung cancer patients: a systematic review. Lung Cancer (Auckl) 1, 141–150. https://doi.org/10.2147/LCTT.S14426.

Kesten, K.S., 2011. Role-play using SBAR technique to improve observed communication skills in senior nursing students. J. Nurs. Educ. 50, 79–87. https://doi.org/10.3928/01484834-20101230-02.

Kılıç, N., Şimşek, N., 2019. The effects of psychological first aid training on disaster preparedness perception and self-efficacy. Nurse Educ. Today 83, 104203. https://doi.org/10.1016/j.nedt.2019.104203.

Kim, J., Lee, H., Huang, B.W., 2022. Lung cancer: diagnosis, treatment principles, and screening. Am. Fam. Physician 105, 487–494.

Luszczynska, A., Gutiérrez-Doña, B., Schwarzer, R., 2005. General self-efficacy in various domains of human functioning: evidence from five countries. Int. J. Psychol. 40, 80–89. https://doi.org/10.1080/00207590444000041.

Malik, F.A., Gysels, M., Higginson, I.J., 2013. Living with breathlessness: a survey of caregivers of breathless patients with lung cancer or heart failure. Palliat. Med. 27, 647–656. https://doi.org/10.1177/0269216313488812.

Meert, A.-P., Sculier, J.-P., 2013. Aetiological diagnosis of acute respiratory failure in critical care oncology. Eur. Respir. J. 42, 299–301. https://doi.org/10.1183/09031936.00008313.

Min, A., Min, H., Kim, S., 2022. Effectiveness of serious games in nurse education: a systematic review. Nurse Educ. Today 108, 105178. https://doi.org/10.1016/j.nedt.2021.105178.

Mitchell, A.J., Meader, N., Symonds, P., 2010. Diagnostic validity of the Hospital Anxiety and Depression Scale (HADS) in cancer and palliative settings: a meta-analysis. J. Affect. Disord. 126, 335–348. https://doi.org/10.1016/j.jad.2010.01.067.

Morrison, E.J., Novotny, P.J., Sloan, J.A., Yang, P., Patten, C.A., Ruddy, K.J., et al., 2017. Emotional problems, quality of life, and symptom burden in patients with lung cancer. Clin. Lung Cancer 18, 497–503. https://doi.org/10.1016/j.cllc.2017.02.008.

Müller, M., Jürgens, J., Redaèlli, M., Klingberg, K., Hautz, W.E., Stock, S., 2018. Impact of the communication and patient hand-off tool SBAR on patient safety: a systematic review. BMJ Open 8, e022202. https://doi.org/10.1136/bmjopen-2018-022202.

Mystakidou, K., Parpa, E., Panagiotou, I., Tsilika, E., Galanos, A., Gouliamos, A., 2013. Caregivers' anxiety and self-efficacy in palliative care: caregivers' anxiety and self-efficacy. Eur. J. Cancer Care 22, 188–195. https://doi.org/10.1111/ecc.12012.

Nichols, L., Saunders, R., Knollmann, F.D., 2012. Causes of death of patients with lung cancer. Arch. Pathol. Lab Med. 136, 1552–1557. https://doi.org/10.5858/arpa.2011-0521-OA.

Northouse, L.L., Katapodi, M.C., Song, L., Zhang, L., Mood, D.W., 2010. Interventions with family caregivers of cancer patients: meta-analysis of randomized trials. CA Cancer J. Clin. n/a. https://doi.org/10.3322/caac.20081.

Observatoire Régionale de la Santé Océan Indien, 2019. Les cancers à La Réunion.

Panadero, E., Jonsson, A., Botella, J., 2017. Effects of self-assessment on self-regulated learning and self-efficacy: four meta-analyses. Educ. Res. Rev. 22, 74–98. https://doi.org/10.1016/j.edurev.2017.08.004.

Papadakos, J., Ugas, M., Quartey, N.K., Papadakos, C., (Tina), Giuliani ME., 2023. Assessing the comprehensive training needs of informal caregivers of cancer patients: a qualitative study. Curr. Oncol. 30, 3845–3858. https://doi.org/10.3390/curroncol30040291.

Perpiñá-Galvañ, J., Orts-Beneito, N., Fernández-Alcántara, M., García-Sanjuán, S., García-Caro, M.P., Cabañero-Martínez, M.J., 2019. Level of burden and health-related quality of life in caregivers of palliative care patients. Int. J. Environ. Res. Public Health 16, 4806. https://doi.org/10.3390/ijerph16234806.

Pujol, J.-L., Thomas, P.-A., Giraud, P., Denis, M.G., Tretarre, B., Roch, B., et al., 2021. Lung cancer in France. J. Thorac. Oncol. 16, 21–29. https://doi.org/10.1016/j.jtho.2020.09.012.

Qiao, S., Ou, Y., Zhang, N., Chen, X., Yao, Y., Deng, S., et al., 2022. Reasoning With Language Model Prompting: A Survey. https://doi.org/10.48550/ARXIV.2212.09597.

Raphael, B.P., Takvorian-Bené, M., Gallotto, M., Tascione, C., McClelland, J., Rosa, C., et al., 2021. Learning gaps and family experience, nurse-facilitated home parenteral nutrition simulation-based discharge training: proof-of-concept study. Nutr. Clin. Pract. 36, 489–496. https://doi.org/10.1002/ncp.10421.

Rha, S.Y., Park, Y., Song, S.K., Lee, C.E., Lee, J., 2015. Caregiving burden and the quality of life of family caregivers of cancer patients: the relationship and correlates. Eur. J. Oncol. Nurs. 19, 376–382. https://doi.org/10.1016/j.ejon.2015.01.004.

Rollot-Trad, F., Cheron, M., Bonhomme, S., Fromantin, I., Engels, C., 2021. Besoins et ressentis des aidants en oncogériatrie, utilité d'un serious game. Soins Gérontologie 26, 31–36. https://doi.org/10.1016/j.sger.2021.08.008.

Rouleau, G., Gagnon, M.-P., Côté, J., Payne-Gagnon, J., Hudson, E., Dubois, C.-A., et al., 2019. Effects of E-learning in a continuing education context on nursing care: systematic review of systematic qualitative, quantitative, and mixed-studies reviews. J. Med. Internet Res. 21, e15118 https://doi.org/10.2196/15118.

Schwarzer, R., Jerusalem, M., 2012. General Self-Efficacy Scale. https://doi.org/10.1037/t00393-000.

Smith, C.J., Buzalko, R.J., Anderson, N., Michalski, J., Warchol, J., Ducey, S., et al., 2018. Evaluation of a novel handoff communication strategy for patients admitted from the emergency department. West. J. Emerg. Med. 19, 372–379. https://doi.org/10.5811/westjem.2017.9.35121.

Sung, H., Ferlay, J., Siegel, R.L., Laversanne, M., Soerjomataram, I., Jemal, A., et al., 2021. Global cancer statistics 2020: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J. Clin. 71, 209–249. https://doi.org/10.3322/caac.21660.

Thomas Hebdon, M.C., Coombs, L.A., Reed, P., Crane, T.E., Badger, T.A., 2021. Self-efficacy in caregivers of adults diagnosed with cancer: an integrative review. Eur. J. Oncol. Nurs. 52, 101933 https://doi.org/10.1016/j.ejon.2021.101933.

Topcu, I., Turkmen, A.S., Sahiner, N.C., Savaser, S., Sen, H., 2017. Physicians' and nurses' medical errors associated with communication failures. J. Pak. Med. Assoc. 67, 600–604.

Tyerman, J., Luctkar-Flude, M., Baker, C., 2021. Rapid development of a COVID-19 assessment and PPE virtual simulation game. Clin. Simul. Nurs. 56, 125–132. https://doi.org/10.1016/j.ecns.2021.03.002.

Ullgren, H., Tsitsi, T., Papastavrou, E., Charalambous, A., 2018. How family caregivers of cancer patients manage symptoms at home: a systematic review. Int. J. Nurs. Stud. 85, 68–79. https://doi.org/10.1016/j.ijnurstu.2018.05.004.

Umberfield, E., Ghaferi, A.A., Krein, S.L., Manojlovich, M., 2019. Using incident reports to assess communication failures and patient outcomes. Jt. Comm. J. Qual. Patient Saf. 45, 406–413. https://doi.org/10.1016/j.jcjq.2019.02.006.