

# SAFETY ASPECTS IN DEVELOPING NEW TECHNOLOGIES FOR REMINISCENCE THERAPY: INSIGHTS FROM THE SENSE-GARDEN PROJECT

Ileana Ciobanu<sup>1</sup>, Andreea Georgiana Marin<sup>1</sup>, Rozeta Drăghici<sup>1</sup>, Gemma Goodall<sup>2</sup>, Iulian Anghelache<sup>3</sup>, Cătălina Anghelache-Tutulan<sup>3</sup>, Rita Valadas<sup>4</sup>, Cristina Vaz de Almeida<sup>4</sup>, Ronny Broekx<sup>5</sup>, Jon Sørgaard<sup>2</sup>, Artur Serrano<sup>2,6</sup>, Mihai Berteanu<sup>1</sup>  
AAL SENSE-GARDEN Project (<https://sense-garden.eu>)

<sup>1</sup>Rehabilitation Medicine Department, Carol Davila University of Medicine and Pharmacy, Bucharest, Romania, <sup>2</sup>Faculty of Medicine and Health Sciences, NTNU/Norwegian University of Science and Technology, <sup>3</sup>Compexin S.A., Ploiesti, Romania, <sup>4</sup>Santa Casa da Misericordia de Lisboa, Portugal, <sup>5</sup>Epoint, Belgium, <sup>6</sup>Norwegian Centre for eHealth Research

Corresponding author: Ileana Ciobanu, [ileanacuk@yahoo.co.uk](mailto:ileanacuk@yahoo.co.uk)

**Abstract.** Technology is present in all aspects of our life today. In order to ensure increased acceptance and usability for new technologies, a user-centred approach is promoted in regards to design and development. When the primary users of the new technology are people facing cognitive challenges, specific aspects must be addressed in order to provide a safe experience in using the new device, system or method. The project by which we exemplify these aspects is “SENSE-GARDEN: Virtual and memory adaptable spaces creating stimuli for the senses in ageing people with dementia”. The aim of this project is to create multisensory spaces, virtual and automatically adaptable to personal memories. The project team has developed a new IT-based technology and a new intervention methodology for personalised reminiscence therapy and multisensory stimulation for person with dementia. In order to ensure the safety of the participants in the project trials, as well as the safety of the future users of the new technology developed in the SENSE-GARDEN project, the authors conducted bibliographic research and hereby present some aspects one needs to take into account when developing advanced technologies for reminiscence therapy for people with dementia.

**Key words:** dementia, reminiscence therapy, multisensory stimulation, safety

**Rezumat.** Tehnologia este prezentă astăzi în toate aspectele existenței noastre. Pentru a asigura un nivel ridicat de acceptare și utilizabilitate pentru noile tehnologii, se promovează centrarea pe utilizator în ce privește proiectarea și dezvoltarea acestora. Când utilizatorii primari ai noii tehnologii sunt persoane cu afectare cognitivă, este necesar să se ia în calcul aspecte specifice pentru a oferi o experiență sigură în utilizarea noului dispozitiv, sistem sau metodă. Proiectul cu care exemplificăm aceste aspecte, „Spații virtuale adaptabile la amintirile utilizatorilor, pentru stimularea senzorială a persoanelor vârstnice cu demență” – SENSE-GARDEN are ca scop crearea de spații multisenzoriale, virtuale și automat adaptabile la amintirile personale. Echipa de proiect dezvoltă un sistem nou bazat pe tehnologia informației, precum și o nouă metodologie de aplicare pentru terapia prin reamintire și stimularea multisenzorială personalizată pentru persoana cu tulburare neurocognitivă. Pentru siguranța participanților la studii pe durata proiectului, ca și pentru siguranța viitorilor utilizatori ai sistemului, autorii au desfășurat o cercetare bibliografică și prezintă în această lucrare aspectele care trebuie luate în considerație la crearea de noi tehnologii destinate terapiei prin reamintire pentru persoanele cu tulburări neurocognitive.

**Cuvinte cheie:** tulburări neurocognitive, terapie prin reamintire, stimularea multisenzorială, siguranță

## INTRODUCTION

Technology is present in all aspects of our life today. In order to ensure increased acceptance and usability for new technologies, a user-centred approach is promoted in regards to design and development. This approach implies the involvement of the potential future users with the new technology, in different stages of its development. When the primary users of the new technology are

people facing cognitive challenges, specific aspects must be addressed in order to provide a safe experience in using the new device, system or method.

The aim of the project “Virtual and memory adaptable spaces creating stimuli for the senses in ageing people with dementia” - SENSE-GARDEN is to create multisensory spaces, virtual and automatically adaptable to personal memories. The project team has

developed a new IT-based technology and a new intervention methodology for personalised reminiscence therapy and multisensory stimulation for people with dementia. SENSE-GARDEN is developed with the scope of improving the well-being and the quality of life of its users and allows the informal and professional caregivers to better relate to and support their care receivers, being either loved ones or patients.

The SENSE-GARDEN project is built on 3 conceptual drives: 1) providing evidence-based, safe and efficient therapeutic interventions for persons with dementia, in 2) a user centred design, based on 3) evidence-based safe research and development methodology.

### **SAFETY OF DEVELOPMENT PROCESS**

Process safety during the development of the SENSE-GARDEN kit (development activities and end-user studies) will be provided through intricated management mechanisms provided from the original proposal of the SENSE-GARDEN project.

Trials need an evidence-based protocol [1], standardised and validated evaluation tools and the approval of the institutional ethical committees and commissions. All participants in the trials are correctly and completely informed about the implications of their participation to the studies, and informed consents are signed and exit strategies are prepared.

### **SAFETY OF SENSE-GARDEN EXPERIENCE**

Safety of the user experience during the visit in SENSE-GARDEN is ensured through a set of specific measures regarding:

**1. Person with dementia (PwD)** risk factors – prevention, early identification, and real time management of dementia risk factors must be assessed [2] in addition to ensuring the reduction of environmental factors affecting mood, disturbing cognitive functioning and generating or exacerbating challenging behaviour. Such factors may include overcrowding, lack of privacy, lack of activities, inadequate staff attention, poor communication, and conflicts between staff

and careers [3]. The cognitive, emotional and procedural content will be personalised and the parameters of exposure to the different physical aspects of the intervention (soundscape and music intensity and complexity, intensity, brightness and colours of the visual content, the ambiental lights, the intensity of the scents, the intensity and complexity of the physical activity) will be set in accord with the sensory profile of the user, with the final goal being to improve the quality of the user's life [4]. The reaction of the user will be continuously monitored and the content and the parameters will be adapted in accord. Due to the specific user profile, presenting with frailty syndrome as well as with sensory and cognitive deficits, all devices must be secured and all wires and cables put in positions to reduce the risk of incidents and accidents as well as risk of inappropriate use. The primary user must be always accompanied by the professional caregiver delivering the SENSE-GARDEN intervention.

**2. Staff resources** - All personnel (formal caregivers), involved in the facilitation of the SENSE-GARDEN sessions need clinical experience in working with people with neurocognitive disorders and is recommended to be certified in dementia care, in reminiscence therapy and multisensory stimulation and in what concerns the rights of people with dementia, with respect to the international guidelines [4]. The roles, attributes and responsibilities of each team member will be clearly established and respected. A special attention will be given to the training of the caregivers implementing the SENSE-GARDEN interventions, in accord with the training requirements and using the training materials prepared by the developers. A SENSE-GARDEN kit user training manual has been developed in this respect.

**3. Ambiental safety** – Minimal space requirements for optimal sensory-motor and cognitive experience are to be decided and respected. Ambiental safety aspects will be considered by respecting the international guidelines and national related legislation, in

order to create the appropriate environment for a safe and efficient experience for the users with dementia and their caregivers, during the trials, as well as for a SENSE-GARDEN kit installation and use requirements guide. Considering the safety of SENSE-GARDEN experience, special attention will be given to:

- a) fall prevention interventions [5] and over-stimulation prevention, as well as the stress management of caregivers, as described in Dementia Care Practice Recommendations for Professionals Working in a Home Setting given by the Alzheimer's Association [6];
- b) occupational protection measures working with people with dementia, related to caregiver stress and hazard [7];
- c) occupational protection measures working with electric and electronic devices and with wireless transmissions [8];
- d) safety measures regarding the environmental design [9]: space requirements, microclimate, infrastructure, access and furniture. As NICE guidelines for dementia care CG42 states: "Specific, but not exclusive, attention should be paid to: lighting, colour schemes, floor coverings, assistive technology, signage, garden design, and the access to and safety of the external environment" [10]. Signaling can be used to secure the flow of the SENSE-GARDEN experience. A sign at the outside of the Sense-Garden will show personnel and other people passing by that a session is going on. This will ensure that others respect the privacy of the session and will not accidentally interrupt the SENSE-GARDEN experience. With the sign in ON position we secure the privacy, lack of session interruption but also reduce the outside noise when people are passing by the SENSE-GARDEN. The SENSE-GARDEN team will take into consideration the requirements regarding the space destined for PwD in order to respect the point 1.1.10.2 of NICE Clinical Guide for Dementia recommending that "When organising and/or purchasing living arrangements and/or care home placements for people with dementia, health and social care managers should ensure that built environments are enabling and aid

orientation. Specific, but not exclusive, attention should be paid to: lighting, colour schemes, floor coverings, assistive technology, signage, garden design, and the access to and safety of the external environment" [11].

The partners in the project consider in this aspect the European and national laws and regulations regarding safety and health at work, periodical check control of medical devices (even if SENSE-GARDEN kit is not a medical device, it is used in healthcare environment and as a therapy tool), mental health and the protection of people with mental disorders.

#### **DATA SAFETY**

The SENSE-GARDEN User profile is the main component for the personalization of the SENSE-GARDEN technology. Each user has her/his own profile in the system. This integrates personal data, such age, gender, place of birth, places of work, etc.; individual preferences, such singers, melodies, type of music, places, sport, food, etc. The user profile will observe national Data Protection Acts and the EU Data Protection Reform (2012) [12]. For security reasons, no personally identifiable data will be stored in the cloud, meaning that all data will be de-identified, with only codes being used. The connection between codes and real names will be done locally, using a smart wristband or card.

In the SENSE-GARDEN, the concept of "digitecture", where digital technology creates a perception of architectural constructs, is used to offer an experience that is far beyond the 'normal physical' perception of a room. Projections, combined with adaptive lighting, sound and scent, can create environments that may inspire and activate the user in a completely new way. This experience is used to give SENSE-GARDEN a whole new scope of possibilities to reconnect people with dementia to the reality around.

The EU General Data Protection Regulation (GDPR), considered the most important change in data privacy regulation in 20 years, will be respected. Attention will be paid to

personal data recording and processing (in denominated and not-identifiable manner, on-site storage devices), personal data accessibility (access allowed only for the researchers involved in SENSE-GARDEN project studies and only for precise research objectives and data analysis procedures), private data transfers (in denominated encrypted manner, only when onsite analysis is not feasible).

The team will comply with the international and national regulations regarding the confidentiality of personal data and the right to private life of the end-users and with the national regulations regarding the implementing measures for the Regulation (EU) 2016/679 of European Parliament and Council from 27 April 2016 regarding protection of individuals with regard to personal data processing and the free movement of such data.

### **PRODUCT SAFETY**

It is of the utmost importance that the SENSE-GARDEN is a safe environment and offers a safe therapeutic intervention for all users involved. Furthermore, given the novelty of the intervention, a thorough assessment of the possible risks and complications of the products involved is required. Innovation in the project is built on already approved and certified marketed technology: scent delivery systems, high definition large screens for a sense of immersion in the created space, several speakers distributed in the space to provide surround sound, stationary bicycles coupled to screens showing road videos. These devices are mechanically, radiatively, biologically and chemically safe, as well as ergonomic.

SENSE-GARDEN applies wireless communication technologies such as WiFi, RFID, WLAN. It will use well established standards, such as IEEE 802.11n for WiFi, Low Voltage directive (LVD) 73/23/EEC for wearable devices, ECP global Gen2 (ISO 18000-6C) UHF for RFID, OSGi for web services, MIDPI 2.0 or more for mobile devices s/w, OWL and FIPA, etc. It follows all recommendations and standards created

within the following groups: "Personal Connected Health Alliance (PCHA)" formed by Continua, mHealth Summit and HIMSS, "AEGIS Open Accessibility Everywhere Group – OAEG" (on ICT services accessibility). The project will strive to use free software principles as advocated by the Free Software Foundation (FSF).

The Radio Equipment Directive (2014/53/EU) establishes a regulatory framework for placing radio equipment on the market. It has been applicable since 13 June 2016. The Radio Equipment Directive (2014/53/ EU) ensures a Single Market for radio equipment by setting essential requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum. It applies to all products using the radio frequency spectrum [13].

This directive is to be followed, along with the European standards regarding Electromagnetic compatibility of multimedia equipment - Immunity requirements [14], Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body mounted devices in close proximity to the human body [15], Product standard to demonstrate the compliance of base station equipment with radiofrequency electromagnetic field exposure limits (110 MHz - 100 GHz), when placed on the market [16], Product standard to demonstrate the compliance of wireless communication devices, with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 300 MHz to 6 GHz: standards regarding short-range devices [17]. PwD, caregivers and research team members' exposure to technology during SENSE-GARDEN equipment testing will comply with the international recommendations regarding exposure limits as well as to the related national laws.

SENSE-GARDEN considers the recommendations of the International Commission

on Non-Ionizing Radiation Protection, regarding the Thresholds of thermal damage [18], Guidelines on induced electric fields [19], Guidelines regarding exposure to visible and infrared optic radiation [20], Guidelines for Limiting Exposure to Time-Varying Electric and Magnetic Fields [21].

### **BACK-UP SOLUTIONS FOR UNEXPECTED EFFECTS OF REMINISCENCE**

The authors of a review concerning the ethics in reminiscence therapy state that those developing technology for reminiscence therapy must also be aware of the side effects that reminiscing may have on participants [22]. However, a recent Cochrane systematic review on reminiscence therapy for people with dementia, published in 2018, found no evidence that the therapeutic approach would have any adverse effects [23].

The investigators (researchers) in the studies involving people with dementia will be supported by a medical team consisting of a Rehabilitation Medicine Physician, a Psychologist and Psychiatrist, a Neurologist, and a Cardiologist.

In order to avoid and reduce any adverse effects of the intervention during the studies, a comprehensive list of exclusion criteria was developed and the intervention stimuli are selected through close collaboration with the family and friends of the primary users, as well as with the formal caregivers managing the case. Reevaluations and follow-up assessments of cognitive and emotional status, as well as of functionality and of participative capacities, will be performed.

In the case of any adverse events, the session may be terminated by the accompanying caregiver. It is important that, at all times, the institution is prepared to tackle such events with a back-up solution. This will involve, as a first step, referring the participant to the back-up medical team for physiological parameter stabilization and life-threatening conditions solution. The second step will be referring the end-user to the psychologist/psychiatrist, for diagnosis and appropriated therapy and counselling.

### **CONCLUSION**

To conclude, this paper has provided an overview of numerous aspects that need to be considered with regards to the safety of users in the SENSE-GARDEN intervention. These include process safety, data safety, product safety, and back-up solutions in the case of adverse events. Other projects or studies aiming to develop new technologies for reminiscence therapy or other psychosocial interventions should also conduct a thorough assessment of the risks and complications that their technology may have.

Careful considerations of all these aspects, along with direct input from end-users, can help to develop a safe, secure and comfortable environment for intervention.

The inclusion of users' perspectives in the design process is of crucial importance. However, after the process of designing and implementing the technology, the users also have the final say to whether the technology is functioning, useful, desirable, or safe: it is the users themselves that in the end have the defining powers.

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### **Conflicts of interest**

The authors declare no conflicts of interest.

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