

# The effectiveness of virtual reality-based training on cognitive, social, and physical functioning in high-functioning seniors: A two-arm parallel-group randomized study (CoSoPhy FX)

Ewa Szczepocka, Łukasz Mokros, Jakub Kaźmierski, Karina Nowakowska, Anna Łucka, Anna Antoszczyk, Javier Oltra-Cucarella, Walter Werzowa, Martin Moum Hellevik, Stavros Skouras, Karsten Kure Bagger

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#### Abstract

**Background:** Virtual reality (VR) has emerged as a promising technology for enhancing the health care of older individuals, particularly in the domains of cognition, physical activity, and social engagement. However, existing VR products and services have limited availability and affordability; there is hence a need for a scientifically-validated and personalized VR service to be used by seniors in their homes, which can improve their overall physical, cognitive and social well-being.

**Objective:** The main purpose of this study was to analyze the effects of a VR-based Digital Therapeutics app on the cognitive, social, and physical performance abilities of healthy (high-functioning) seniors. This paper presents the study protocol and the results from the recruitment phase.

Methods: A group of 188 healthy seniors aged 65-85 years, recruited at the Medical University of Lodz (Poland), were randomly allocated to the experimental group (VR dual-task training program) or to the control group (using a VR headset app showing nature videos). Three cognitive exercises were performed in various 360-degree nature environments delivered via a VR head-mounted display (HMD); the participants listened to their preferred music genre. Each patient received three 12-minute sessions per week for a 12-week period, totaling a minimum of 36 sessions per participant. Attention and working memory (CNS-Vital Signs computerized cognitive battery) were used as primary outcomes, while other cognitive domains in the CNS-VS battery, quality of life (WHO-5 Well-Being Index), health-related quality of life (EQ-5D-5L) and anxiety (GAD-7) were the secondary outcomes. The group-by-time interaction was determined using linear mixed models with participants' individual slopes.

**Results:** In total, 122 of the initial 310 subjects failed to meet the inclusion criteria, resulting in a recruitment rate of 61%. Among the participants, 68 successfully completed the intervention and 62 completed the control treatment.

Conclusions: VR interventions have significant potential among healthy older individuals. VR can address various aspects of well-being by stimulating cognitive functions, promoting physical activity and facilitating social interaction. However, challenges such as physical discomfort, technology acceptance, safety concerns, and cost must be considered when implementing them for older adults. Further research is needed to determine the long-term effects of VR-based interventions, optimal intervention designs, and the specific populations that would benefit most. Clinical Trial: ClinicalTrials.gov ID NCT05369897

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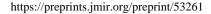
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# **Original Manuscript**

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#### **Trial registration:**

ClinicalTrials.gov ID NCT05369897

#### **Abstract**

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**Background/Aims:** Virtual reality (VR) has emerged as a promising technology for enhancing the health care of older individuals, particularly in the domains of cognition, physical activity, and social engagement. However, existing VR products and services have limited availability and affordability; there is hence a need for a scientifically-validated and personalized VR service to be used by seniors in their homes, which can improve their overall physical, cognitive and social well-being. The main purpose of this study was to analyze the effects of a VR-based Digital Therapeutics app on the cognitive, social, and physical performance abilities of healthy (high-functioning) seniors. This paper presents the study protocol and the results from the recruitment phase.

Methods: A group of 188 healthy seniors aged 65-85 years, recruited at the Medical University of Lodz (Poland), were randomly allocated to the experimental group (VR dual-task training program) or to the control group (using a VR headset app showing nature videos). Three cognitive exercises were performed in various 360-degree nature environments delivered via a VR head-mounted display (HMD); the participants listened to their preferred music genre. Each patient received three 12-minute sessions per week for a 12-week period, totaling a minimum of 36 sessions per participant. Attention and working memory (CNS-Vital Signs computerized cognitive battery) were used as primary outcomes, while other cognitive domains in the CNS-VS battery, quality of life (WHO-5 Well-Being Index), health-related quality of life (EQ-5D-5L) and anxiety (GAD-7) were the secondary outcomes. The group-by-time interaction was determined using linear mixed models with participants' individual slopes.

**Results:** In total, 122 of the initial 310 subjects failed to meet the inclusion criteria, resulting in a recruitment rate of 61%. Among the participants, 68 successfully completed the intervention and 62 completed the control treatment.

**Conclusions:** VR interventions have significant potential among healthy older individuals. VR can address various aspects of well-being by stimulating cognitive functions, promoting physical activity

and facilitating social interaction. However, challenges such as physical discomfort, technology acceptance, safety concerns, and cost must be considered when implementing them for older adults. Further research is needed to determine the long-term effects of VR-based interventions, optimal intervention designs, and the specific populations that would benefit most.

# **Keywords**

Cognitive functions; head-mounted-display; healthy seniors; vreality; well-being

# **Trial registration:**

ClinicalTrials.gov ID NCT05369897

# Background/Aims

The global demographic shift towards an aging population presents a pressing need to enhance the quality and effectiveness of healthcare [1]. Aging is typically associated with cognitive inactivity, and thus cognitive impairment, resulting in escalating care demands and healthcare costs [2] and reducing daily functioning and quality of life among seniors [3]. As such, there is a need for effective interventions aimed at enhancing cognitive functions, which can mitigate their decline and promote healthy aging [4].

A promising tool with significant potential across various fields is virtual reality (VR), which has been found to be effective in caring for older individuals, both with and without cognitive impairment [5]. By offering immersive digital experiences, VR can provide varying levels of immersion; high immersion can be provided by head-mounted displays (HMDs) which are able to stimulate multiple sensory modalities [6]. Such heightened immersion enhances the sense of presence, yielding more pronounced behavioral responses [7].

In addition to general cognitive function, VR-based training programs have shown promise in improving specific cognitive domains, such as short-term memory, orientation, attention, comprehension, naming, constructions, memory and judgment [8]. Indeed, VR interventions have been found to significantly improve executive function and verbal memory in older adults [9]. While traditional cognitive training methods may be limited in terms of accessibility, motivation, and ecological validity [10], VR technology offers a unique opportunity to create immersive and interactive experiences that simulate real-world scenarios and engage multiple sensory modalities [11, 12]. Indeed, studies indicate that VR interventions can enhance the effectiveness and engagement of cognitive interventions, resulting in better outcomes among older patients [13]. VR-based training may also have a beneficial influence on physical activity, with research suggesting it can improve balance performance and functional mobility [14]. Additionally, the potential of VR

interventions to promote social engagement and combat social isolation has also been studied among older adults [15].

Research has shown that music has many positive effects on human health, including reducing stress and anxiety [16], enhancing mood [7], improving sleep [17], and relieving pain [18], and it can be an excellent motivator for physical activity[19]. Music has previously been integrated into VR experiences among older adults with the aim of increasing motivation [11], improving mental well-being [20], and supporting rehabilitation [21].

While studies have examined the use of VR in healthcare settings, particularly in mental health [22], its application in healthy seniors who can use VR at home is still an emerging area of research [11]. Understanding the benefits and potential limitations of home-based VR interventions is crucial for developing evidence-based strategies to support healthy aging [4]. Further research is still needed to assess the impact of VR interventions on specific cognitive, physical, and social domains and identify the optimal protocols for therapeutic use.

Currently, existing VR products and services are prohibitively expensive for many home end-users, and their use is typically limited to clinics, nursing homes, and rehabilitation centers [23]. However, the most effective strategy for ensuring sustainable healthcare in the face of aging populations is prevention. As such, there is a need to provide a home-based service that offers scientifically-validated, safe, engaging, and personalized content for seniors to enhance their cognitive, physical, and social abilities.

# **Objective**

The main aim of the study is to determine the effects of using a VR-based Digital Therapeutics (DTx) app to improve the cognitive, social, and physical performance abilities of healthy (high-functioning) seniors.

# **Experimental hypotheses**

It is expected that significant relationships will be found between the two factors (Group \* Time) for each of the tested cognitive, physical, and social performance scores. Specifically, cognitive, social, and physical performance scores are expected to significantly improve over the course of the VR training intervention compared to the start, but only for the experimental group; no such change will be observed for the control group.

#### **Methods**

# Trial design

The CoSoPhy FX study was designed as a randomized, parallel-group, two-arm, superiority study with an aimed 1:1 allocation ratio. The protocol was registered with Clinicaltrials.gov (ID NCT05369897) on 30 June 2022.

# **Participants**

#### Recruitment

In total, 200 high-functioning seniors aged 65-85 from a community-dwelling setting were recruited for the study. All recruitment was performed by the Medical University of Lodz (Poland). High-functioning seniors were defined as those over the age of 65 years, who maintained their functional independence concerning activities of daily living, including the ability to go on a long walk and to interact with standard modern technology (e.g., using a smartphone to send a message).

The recruitment strategy included the following:

- promotional materials such as posters, flyers, press announcements, and posts on social media groups devoted to seniors were used to raise awareness in the local community and inform seniors about the project;
- a dedicated phone line operating during working hours was set up to answer inquiries
  regarding participation in the study;

• study visits were carefully planned and scheduled to work around holiday breaks.

The enrolment period lasted over 12 months. The allocated research team member screened the potential participants according to the eligibility criteria, given in Table 1.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
1. Individuals aged 65-85 years old	1. Neuropsychiatric disorders (MoCA< 26
	points)
2. Stable medical condition	2. Abuse or addiction to alcohol, drugs, and
(e.g., well-controlled diabetes or	tranquillizers (DSM-5)
hypertension)	
3. Undisturbed locomotion	3. Blurred vision that cannot be corrected
	with lenses or glasses
4. Independent in everyday functioning	4. Auditory pathologies causing significant
	hearing loss
5. Capable of going on long walks without	5. High sensitivity to motion sickness
assistance	
6. Able to use standard modern technology	6. Migraines
	7. Epilepsy
	8. Obesity (BMI> 30)
	9. Deemed unsuitable for participation by
	the investigator

MoCA: Montreal Cognitive Assessment; BMI: Body Mass Index

The following clinical and demographic data were collected during the screening: age, sex, educational level, marital status, socioeconomic status, data on chronic diseases, and medications. A clinical assessment was conducted using the Montreal Cognitive Assessment (MoCA) test<sup>11</sup> to exclude participants with suspected cognitive impairment (i.e., achieving a total MoCA score lower than 26 points). After qualification, the participants were randomly allocated to either the experimental or the control group. These participants were invited for a second visit, during which they completed a battery of tests for neuropsychological and psychosocial assessment and were trained on how to use the VR-HMD on their own.

# Randomization

After the participants had been screened for eligibility, the research team produced a list of eligible participants. Participants were randomly allocated to an experimental or control group with a 1:1

allocation using a computerized random number generator (random.org) [25]. A simple randomization method was adopted. One author (ESz) generated sequences of numbers from 1 to 200 and assigned them to the intervention based on the following assumption: 1-100~experimental group, 101-200~control group. Another author (AA) assigned the participants to either the experimental or control group according to the list of randomized numbers. To ensure that the researchers were blinded, the list was kept by an independent research team member (JK) who did not participate in the subject recruitment process. No other stratification was utilized.

#### Ethical considerations

The protocol and the informed consent form (Appendix 1) received approval from the Bioethical Committee of the Medical University of Lodz, Poland (RNN/222/21/KE). Each participant was introduced to the study by a research team member, who performed an initial demonstration of the equipment. The participants were given time to ask any remaining questions. Following this, if they agreed to take part, they signed a form giving their written informed consent (Appendix 1).

All data collected during the study will be entered into a secure, password-protected electronic database (internal cloud service, protected from external access). The dataset for statistical analysis was fully anonymized. Participants' paper files will be stored in numerical order and in a secure place and manner. A coding system will be developed to ensure uniformity and consistency in categorizing variables. Each variable will be assigned a unique code that will be used throughout the study for data entry and analysis. Access to the data will be restricted to authorized personnel only. Data will be stored on a secure server with regular backups to prevent data loss. Personally identifiable information will be stored separately from the research data to maintain participant confidentiality.

In the conduct of this research, all human subjects participated voluntarily and without the promise or receipt of financial compensation or any other form of remuneration.

## Intervention

The intervention was delivered using a VR-HMD worn by the seniors: a Pico Neo 3 Pro in the experimental group and a Pico G2 in the control group. The content shown in the VR-HMD consists of two key components:

- 1. Base content: The base consent comprises high-quality 360-degree photographs and videos from natural environments in the real world, such as a relaxing environment with a mountain view. Initially, 80 different base content environments were used.
- 2. Graphical overlay: The base content has a graphical overlay that has two key components:
  - i) Hands: The user's hands, and their position, are shown inside the VR environment as virtual hands, moving in real-time. This requires the user to hold a controller in each hand.
  - ii) Graphical objects: Graphical objects, e.g., balloons, that users can touch using their virtual hands. These appear inside the VR environment and move in prespecified trajectories.

The intentions of this design were:

- to perform physical exercises (moving the arms and upper body to touch the graphical objects); and
- 2. to perform cognitive exercises (using the arms to touch graphical objects according to specific rules for each cognitive task).

While performing the physical and cognitive exercises, the participants could also listen to a selection of musical pieces from the HealthTunes database. The music was played in stereo (48kHz 24bit wav files, -15dB LUFS) on the Pico G2 and Pico Neo 3 Pro VR-HMDs. All tracks were organised by HealthTunes.org [26]; none had any drastic tempo changes that could adversely entrain participants or any drastic dynamic changes that could interfere with the experience. The levels of the audio frequency bands were also adjusted to optimise the music to the seniors' hearing. The selection of musical pieces is presented in Appendix 2. Participants were provided with a choice of

music spanning four genres: classical, ambient, electronic, and jazz, with the option to select rock music also available. This diverse selection was intended to accommodate individual preferences and enhance the personalization of the VR experience. Classical music was the most popular choice among participants, featuring a variety of operas and symphonies/concerti from renowned composers, offering a rich tapestry of auditory stimuli conducive to cognitive stimulation and relaxation.

The following cognitive exercises implemented within the VR application:

- 1. Warm-up: a simple exercise to familiarize the participant with each task, in which participants must select the graphical objects that match the color of their hands. The warm-up introduction is presented in Figure 1, and a warm-up exercise in Figure 2.
- 2. Focus: an exercise of focused attention in which participants must select the graphical objects that match the color of their hands, and avoid those that do not. The focus introduction is presented in Figure 3 and a focus exercise in Figure 4.
- 3. Switch: an exercise for alternating attention in which participants must reach alternately for the shapes of the graphical objects with the matching hand color. The switch introduction is presented in Figure 5, and a switch exercise in Figure 6.

Memory: an exercise of working memory based on the n-back task [27, 28], in which participants must tap a graphical object if it is the same color as the one that appeared two graphical objects earlier. The memory introduction is presented in Figure 7 and the memory exercise in Figure 8.

The targeted sample size was 200 participants, equally divided between the experimental and the control groups. Both groups were balanced with regard to sex.

The experimental group members underwent a three-month computerized VR dual-task training program, as described above. The control group passively experienced 360-degree photographs and videos from natural environments without dual-task physical and cognitive training. This technique is frequently employed in cognitive studies, offering a passive experience devoid of cognitive

challenges [29]. In both groups, the participants were encouraged to use the VR-HMD for a minimum of three 12-minute sessions per week for three months, i.e. for at least 36 sessions in total. The first training session occurred at the Medical University of Lodz, where the participants were trained on how to use the VR-HMD. At the end of the session, the participants took the VR-HMD to their homes to use them according to the schedule described above.

The adverse effects of using VR headsets, often referred to as *cybersickness*, have been reported to include eye strain, dizziness, nausea, and vomiting [30]. However, these side effects are most often due to suboptimal use of the technology, e.g., by using VR content with quick changes of position, low image resolution and low display refresh rates. The VR application used in the study was designed specifically for seniors, and avoided any such drastic camera movements.

The application used in the control group had previously been tested by seniors in 15 senior care homes in Switzerland and Finland. The first version of the application, containing cognitive training, used in the experimental group was tested by 30 older adults in usability studies by terzStiftung in Switzerland between September 2021 and January 2022. After eight workshops, the feedback was used to develop updated versions of the application. The resulting cognitive training program, image quality, and usability were rated as high by the participants [31]. The results confirm that VR-HMDs are safe for use by high-functioning healthy seniors at home without substantial risks or side effects.

Nevertheless, participants received explicit instructions to discontinue the VR intervention and contact the researchers if they experienced any side effects. Moreover, in the case of suspected side effects, the participants would be withdrawn from the study, and this would be reported as an adverse event. Any side effects could be reported through a software app running on their mobile phone, tablet or computer. At the end of the intervention, an open-ended questionnaire was used to collect feedback, including information on perceived side effects.

To acquire reliable and comprehensive outcome data, strategies were employed to promote participant retention and ensure follow-up completion (Table 2). If participants discontinued the intervention or deviated from the protocol, information regarding their decision were collected together with various self-reported outcome data related to their experience, expectations, perceived benefits, and any changes observed during their participation.

Table 2. Promoting participant retention and ensuring follow-up completion.

	Strategy	Description
1.	Clear expectations	The study requirements, including the duration of the intervention, the frequency of sessions, and any follow-up assessments, will be communicated. A comprehensive overview of the study timeline should be provided to participants, and their continued participation should be emphasized.
2.	The informed consent process	During the informed consent process, efforts will be made to ensure that participants fully understand the study's goals, procedures, and potential benefits. Concerns expressed by participants will be addressed, and their questions will be answered to foster their commitment to the study.
3.	Flexible scheduling	Participants' schedules and preferences will be considered when planning pre- and post-intervention assessments. Flexibility in scheduling will be offered to accommodate their availability, facilitating the completion of the required sessions.
4.	Reminders and communication	Periodic reminders about upcoming sessions or assessments will be sent to participants via text messages and phone calls. Clear instructions, directions, and any necessary materials or equipment for the VR-based training will be provided to participants.
5.	Supportive staff	A dedicated research team that is easily accessible to participants will be established. Staff members will be trained to provide emotional support and address participants' questions or concerns during the study.

Compliance and performance were monitored through a web-based platform. The researchers contacted participants who did not perform the VR training at least three times per week to check whether they faced difficulties using the VR application or wished to discontinue participation. Throughout the intervention, the participants were expected to avoid participating in any other trials, especially those related to cognitive functions or mental states. The participants were covered by

health insurance throughout their participation in the study, concerning any potential harm, according to a standard clinical study insurance policy.

## **Outcome measures**

Neuropsychological assessment was performed at baseline and after the intervention. The primary outcomes of the initial study comprised the cognitive, social, and physical performance abilities of healthy (high-functioning) seniors. The following parameters were selected:

- a wide range of cognitive domains: composite memory, verbal memory, visual memory, psychomotor speed, reaction time, complex attention, cognitive flexibility, processing speed, executive function, simple attention, and motor speed (Vital Signs battery)[32]
- physical performance across six subcomponents: lower body strength, upper body strength, aerobic endurance, lower body flexibility, upper body flexibility, and dynamic balance/agility
   (Senior Fitness Test)[33]
- standard grip strength (using a dynamometer)[34]
- the sense of loneliness (De Jong Gierveld Loneliness Short Form)[35]
- the quality of life and perceived well-being (WHO 5 Well-Being Index)[36]
- the health-related quality of life (EQ-5D-5L) [37]
- satisfaction with participation in social roles and ability to participate in social roles and activities (PROMIS SF 8a)[38]
- the severity of anxiety symptoms (GAD-7)[39].

CNS Vital Signs (CNS-VS) is a computerized neurocognitive test battery developed as a routine clinical screening instrument. It comprises seven tests: verbal and visual memory, finger tapping, symbol digit coding, the Stroop Test, a test of shifting attention, and the continuous performance test. A result includes neurocognitive clinical evaluation domains: composite memory, verbal memory,

visual memory, psychomotor speed, reaction time, complex attention, cognitive flexibility, processing speed, executive function, simple attention, and motor speed [32]. The CNS-VS Clinical battery is sensitive to subtle cognitive deficits and progressive decline or improvement. Previous research has shown it is validated, reliable and easy to use [40].

The WHO Well-Being Index (WHO-5) is a five-item measure of well-being with high internal consistency, evidence of a one-dimensional factor structure, and high convergent associations with other measures of well-being [41, 42]. The respondent is asked about their well-being in the last 14 days. Each of the five items is scored from 5 (all of the time) to 0 (none of the time). The raw score ranges from 0 (absence of well-being) to 25 (maximal well-being) [43].

The EQ-5D-5L is a questionnaire used to assess health-related quality of life. It measures the problems experienced in five domains: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. The questionnaire also includes an overall health scale where individuals rate their health condition from 1 to 100, with 100 representing the best imaginable health. Previous research has found the EQ-5D-5L to be reliable and valid [44],<sup>36</sup>.

The General Anxiety Disorder 7-item questionnaire (GAD-7) was utilized to measure the severity of anxiety symptoms. Each item considers different anxiety symptoms and is answered on a 4-point Likert-like scale. The total score ranges from 0 to 21, and a rise in the score indicates more severe anxiety. The tool is sensitive to anxiety in non-clinical samples and to changes in the severity of anxiety symptoms[39].

Grip strength was assessed with a hand-held dynamometer. The method is a reliable measure of the strength of muscles in older adults when using a standardized protocol and instructions [45]. The resulting grip strength data has been reported to predict general muscle strength and physical functioning in the elderly population [46, 47].

# **Challenges**

On 21 September 2021, KB, SS, JK, ŁM, ESz, KN, MH, and WW prepared the original version of the protocol (version 1.0). During the further development of the VR-based DTx app, it was decided to eliminate the physical and social aspects of the intervention. On 10 January 2022, the protocol concerning outcome measures was amended (version 2.0: the primary outcomes were redefined as attention and working memory. Secondary outcomes comprised other cognitive domains, quality of life, well-being, anxiety, and standard grip strength. The same authors were involved in making the amendment, and all the changes to the protocol and outcomes were made prior to participant recruitment. All relevant parties (including IRB and investigators) were informed about the protocol amendments and outcomes. This decision was prompted by several limitations experienced when using the solution at home, such as insufficiently fast internet, which was needed for trouble-free operation, difficulties in connecting to Wi-Fi, a complex setup process and the risk of falling.

# Statistical methodology

An *a priori* computation of the required sample size based on the type of test, the expected effect size, the Type I and Type II error rates, the number of groups and the number of measurements was performed according to Lu, Luo, and Chen (2008) [48]. The statistical power analysis was conducted for a mixed model of repeated measures for two groups, one measure at a time (corresponding to the main cognitive performance scores detailed below) with a 0.7 pre-post correlation, a 20% attrition rate, a medium effect size (standardized mean difference = 0.5), a significance level of  $\alpha$  = 0.05 and a statistical power of 1- $\beta$  = 0.8. The necessary sample size for these parameters was 77 participants per group (N=154).

MUL stored the personal data of the interested and eligible participants on an internal cloud service, protected from external access. The dataset for statistical analysis was fully anonymized. All data storage and processing comply with the GDPR and other applicable regulations. Where possible,

fully anonymized data may be made publicly available through open-access repositories supporting the Open Science Initiative.

#### Results

# **Participant Flow**

The study, from recruitment to completion of follow-up, was planned to take place from January 2022 to May 2023. The recruitment phase was performed from January 2022 to mid-January 2023. As shown in Figure 9, 310 subjects were tested for eligibility, and 122 were excluded because for not meeting the inclusion criteria. The most common cause of exclusion was the MoCA score below 26 points, suggesting the presence of objective cognitive impairment. The recruitment rate (61%) was acceptable. Following this, 188 participants were allocated to an experimental group (n=100), or a control group (n=88) with an allocation ratio of 1:0.88.

In the experimental group, 20 participants declined to participate before the start of the intervention and withdrew their consent without giving a reason. Twelve participants withdrew because they reported somatic and mental health problems unrelated to the intervention. In the experimental group, 68 participants completed the intervention.

In the control group, 22 participants declined to participate before the start of the intervention and withdrew their consent without giving a reason. Four participants withdrew because they reported somatic and mental health problems unrelated to the intervention. In the control group, 62 participants completed the intervention. There were no missing data.

The data is currently being analysed, and we plan to publish the results by the end of December 2023.

#### Dissemination

The study results will be published in scientific journals and presented at appropriate scientific

conferences. All materials and manuscripts will be written by the researchers. No services of external copywriters will be utilized. The study protocol was registered and published at Clinicaltrials.gov.

# **Discussion**

# **Potential benefits**

VR-based interventions can significantly improve the quality of life for healthy older individuals in several ways. Firstly, VR offers a means of mental stimulation and cognitive engagement. By immersing the user in various environments, tasks and games, VR can delay cognitive decline by enhancing various cognitive abilities such as memory, attention, and problem-solving skills [49, 50]. Secondly, VR interventions can be used to support physical activity and rehabilitation by providing a safe environment for seniors to improve their balance and flexibility, and reduce the risk of falls and injuries [14]. Thirdly, VR provides opportunities for social interaction and connectivity, thus combating the isolation and loneliness often experienced by older people. Virtual meetings and games can promote engagement with family and peers, and exploring virtual worlds can offer a sense of adventure and travel without physical limitations [15]. Finally, VR applications can be used to manage anxiety and stress, promote general well-being, and provide leisure opportunities, thus positively impacting quality of life [51].

# Potential risks and challenges

Several potential risks and challenges are associated with using VR interventions in the elderly population, and these should be taken into consideration to maximize their benefits and minimize any potential harm. Firstly, suboptimal and prolonged use may be associated with physical discomfort or cybersickness, comprising symptoms such as nausea, disorientation, or eyestrain [30]. Secondly, there can be a significant learning curve for older adults unfamiliar with the technology, and some individuals may find the technology intimidating or stressful, leading to rejection or non-compliance [52]. Thirdly, if the person is unaware of their real-world surroundings whilst immersed

in the virtual environment, they may be at risk of falls or accidents [53]. Finally, while the cost of VR hardware has decreased, it can still be expensive, especially high-quality systems.

# Limitations

One limitation of this study is that it did not determine the degree of function of the participants by an appropriate objective tool; instead, it was evaluated by a research team based on a medical interview during the screening process. While this approach provided some insight into the participants' functional independence in activities of daily living, it may have introduced subjectivity and potential bias. Objective tools, such as standardized assessments or performance-based measures, could have provided more reliable and valid measures of seniors' functioning. For instance, widely recognized tools like the Timed Up and Go (TUG) [54] test for mobility and the Instrumental Activities of Daily Living (IADL) scale [55] for more complex tasks could offer standardized and quantifiable metrics. Future studies should consider incorporating these objective tools to obtain a more comprehensive and accurate assessment of functional ability.

Another potential limitation of the study relates to the occurrence of cybersickness among participants engaging with virtual reality (VR) interventions. Cybersickness, a condition characterized by symptoms such as dizziness, nausea, and headache, mirrors the symptoms of motion sickness but is induced by immersive virtual environments. The incidence of cybersickness varies among individuals and can significantly impact the user's ability to engage with VR-based interventions over time [30]. This limitation is particularly relevant as it may affect the participants' adherence to the intervention, potentially skewing the study's outcomes. Future research should aim to identify strategies to minimize cybersickness, possibly through the adaptation of VR content, the duration of sessions, or the inclusion of breaks, to enhance the comfort and participation of all users.

Furthermore, the study faced challenges associated with Wi-Fi connectivity, which represents

another significant limitation. A reliable Wi-Fi connection is crucial for the seamless delivery of VR content and the uninterrupted participation of subjects in the study. Issues with Wi-Fi connectivity, such as signal instability or bandwidth limitations, can disrupt the VR experience, leading to fragmented sessions or the inability of participants to complete the intervention as planned. This technological constraint not only affects the consistency and quality of the intervention delivery but also potentially impacts the engagement and satisfaction of participants. Addressing Wi-Fi connectivity issues is essential for ensuring the fidelity of VR-based interventions, and future studies may need to consider alternative solutions or backup options to mitigate these challenges, ensuring a smooth and effective implementation of VR technology in research settings.

## **Conclusions**

Previous research found that VR therapy can improve the well-being of seniors in long-term care, rehabilitation hospitals and senior residences, who often experience cognitive decline, reduced mobility, and isolation [22]. We intend to publish our findings in a future study, and we believe that they will provide further information on the effect of immersive VR therapy among healthy, community-dwelling older adults with regard to their cognitive performance, tolerance, and technology acceptance. Even so, further research is needed to explore the long-term effects, optimal intervention designs, and specific populations that may benefit most from VR-based interventions.

# **Contributions**

KB and SS conceived the study. KB, SS, JK, ŁM, ESz, KN, MH, and WW initiated the study design, and JO-C helped to adapt the final study design. JK, ŁM, ESz, KN, AA, and AŁ implemented the study. ŁM, ESz, KN, AŁ, and AA collected the data and drafted the manuscript. JO-C conducted the preliminary statistical analysis. All authors contributed to refining the study protocol and approved the final manuscript. KB and SS led the acquisition of grant funding for the project, designed the software architecture for the VR solutions, and led the software development.

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In the preparation of this manuscript, generative artificial intelligence (AI) tools were employed to assist in the identification and selection of relevant academic papers. Specifically, scite.ai and elicit.com were used to facilitate the literature search process. Each identified resource was subsequently reviewed and verified by the authors to ensure relevance and accuracy in supporting the research presented. This use of generative AI tools was confined to the initial stages of literature search and did not extend to the generation of manuscript content.

Author ŁM has moved to a new institution since completing the research. His new affiliation is Second Department of Psychiatry, Institute of Psychiatry and Neurology in Warsaw, Poland.

# **Data Availability**

The data sets generated during and/or analyzed during this study are available from the corresponding author on reasonable request.

# **Declaration of conflicting interests**

The authors declared no potential financial conflicts of interest with respect to the research, authorship, and publication of this article.

# **Abbreviations:**

VR: virtual reality

BMI: Body Mass Index

DSM-5: Diagnostic and Statistical Manual of Mental Disorders

HMD: head-mounted display

MoCA: Montreal Cognitive Assessment

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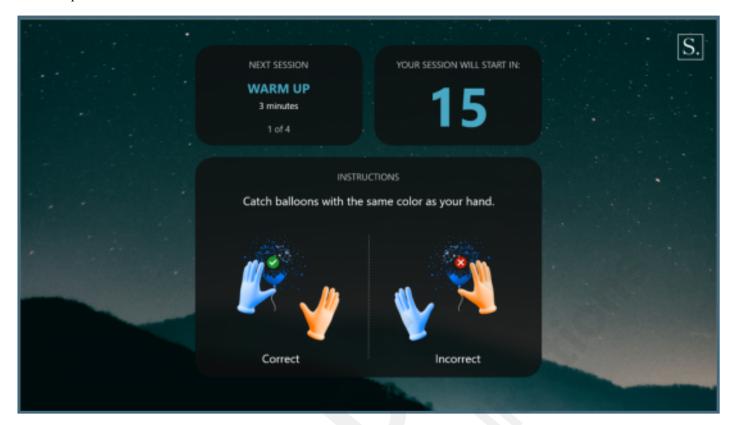
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# **Supplementary Files**

# **Figures**

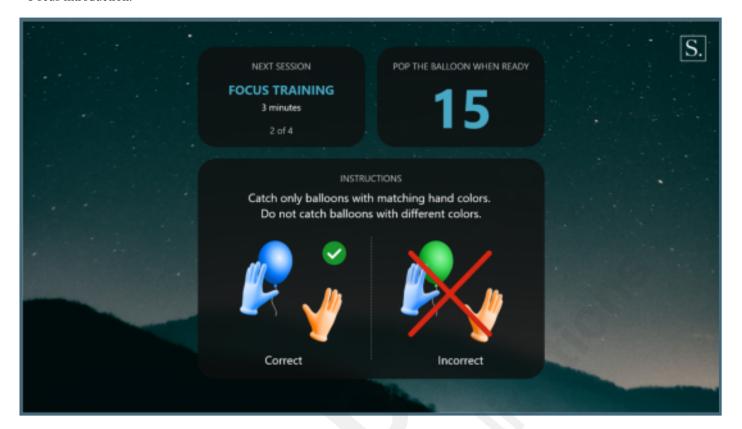
Warm-up introduction.



Warm-up exercise.



Focus introduction.



Focus exercise.



Switch introduction.



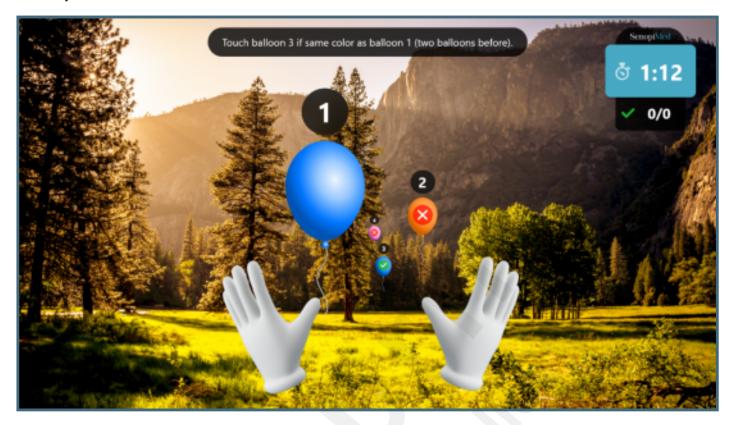
Switch exercise.



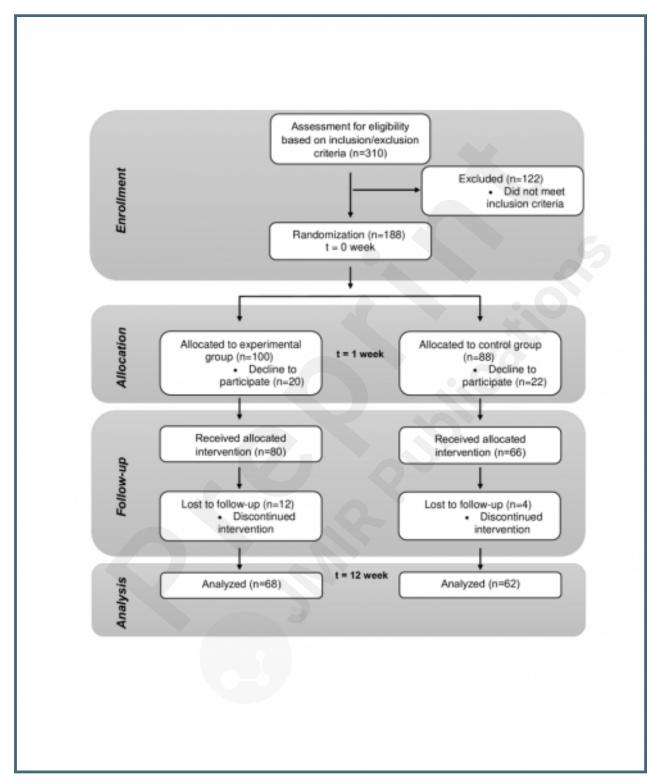
Memory introduction.



Memory exercise.



CoSoPhy Flowchart. Study design - a randomized, parallel-group, two-arm, superiority study; allocation ratio 1:0.88; population - individuals aged 65-85 years old; location – Poland; time frame – 3 months.



# **Multimedia Appendixes**

Informed consent.

URL: http://asset.jmir.pub/assets/a021c4c21ed75c94ddc8077e628160dd.docx

Music selection.

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