Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia: A Phase 2 Clinical Trial Protocol

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Abstract. Alzheimer's disease cases in the Philippines are expected to increase exponentially by 2040. Non-pharmacological management of this disease involves physical therapy, occupational therapy, speech therapy, art therapy, and music therapy, which can be simulated in a virtual environment through an immersive gamification technology system (ImGTS). This study describes a protocol designed for a Phase 2 clinical trial using ImGTS for persons living with dementia (PLWD). The study will use a randomized two-arm parallel clinical trial design, which will involve thirty PLWD who will undergo four sessions of therapy using the ImGTS. Clinical effectiveness, safety, and usability will be measured before and after each session. Secondary data will also be collected to measure cognitive function and quality of life. The paired t-test will be used to determine if there are significant differences between pretest and posttest scores, while Cohen's d will illustrate the size of the effect observed. Ethical clearance was sought from the University of the Philippines Manila Research

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Ethics Board (UPMREB). This clinical trial was registered at clinicaltrials.gov (trial registration number: NCT06072014).

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1 Introduction

All-cause dementia affects an estimated 697 (95% CI 546, 864) cases per 10,000 people worldwide [1]. This disease is a growing public health concern both globally [2] and locally, in the Philippines, where prevalence among adults aged 60 and older is reported in a single-city study at 10.6% (95% CI 9%, 12.4%) [3]. Projections suggest an increase to nearly five times from 2013 to about a million Filipino seniors by 2040 [4].

Behavioral and psychological symptoms of dementia (BPSD) is a major component of the dementia syndrome. It is strongly correlated with functional and cognitive decline in dementia and is independently associated with poor outcomes, including distress among patients and caregivers, long-term hospitalization, misuse of medication, and increased health care costs [5]. In the Philippines as of 2016, the annual cost of care per patient has reached Php 231,444.62 (4,070 USD using Php to USD conversion rate as of August 2025, 36.7% of average annual family income) [6], 13.48% of which is directly from medical expenses, and 86.29% indirectly from estimated lost potential earning of unpaid family caregivers.

Several challenges remain in the care of persons living with dementia (PLWD) in several countries of the Western Pacific region [7]. Similar deficiencies in dementia care have also been observed in the Philippines [8]. Several laws that support care for PLWD have existed, but none have been enacted properly to adequately cover most local government units. Moreover, out-of-pocket payments have been the main source of funding for the expenses incurred by PLWD, which encompass costs in diagnosis and treatment. The number of healthcare professionals who can specifically support PLWD have also decreased through time. Caregivers of PLWD are readily available since these are usually close family members. However, they do not receive adequate training and preparation in caring for PLWD.

Cholinesterase inhibitors, memantine, and atypical antipsychotics for BPSD offer only modest benefits in moderate to severe symptoms and are limited by side effects, especially in the elderly [9-15]. This offsets advantages in trying to treat BPSD in AD [16].

BPSD may also be managed using non-pharmacological interventions such as virtual reality (VR) therapy, as seen in previous research. VR is defined as a technology using hardware and software to provide a real or imagined three-dimensional environment, enabling users to experience a sensation of being in a different physical place [17]. The majority of the VR experiences for patients with dementia were computer-generated, active experiences [18]. Many VR environments depicted rural or urban scenery, particularly nature scenes [19-21], while others utilized a VR environment that incorporated culture-specific elements that were common during the

participants' earlier years of life to induce nostalgia [22, 23]. These experiences were commonly delivered through head-mounted display systems (HMDs) [18]. Although some participants found the HMD to be uncomfortable because of poor fit or its weight [20, 24], wearing the HMD was comfortable for the participants overall.

The majority of these studies assessed VR interventions through interventional studies such as randomized controlled trials [18]. Overall, VR interventions were noted to have moderate evidence on emotional, social, and functional outcomes among PLWD [18]. These effects included positive behaviors such as interaction (either with the depicted VR [25] or with the persons who were with them during the VR experience); sitting still and being focused and calm [23]; and expressions of enjoyment and wishing to repeat the VR experience [19-21].

An ImGTS intervention was developed in Phase 1 of the project to simulate non-pharmacological therapies that are currently offered to PLWD [25]. Examples of these therapies include physical therapy, occupational therapy, speech therapy, art therapy, and music therapy. The ImGTS also incorporated orientation and reminiscence therapy as these help remind patients of memorable events, places, situations, people and objects, which in turn may help stimulate, reorient, or calm down patients with BPSD. From a broader perspective, the ImGTS may potentially have applications for training activities of daily living and encouraging physical activity especially in patients with observed apathy.

To achieve a higher level of immersion, additional mechanical devices or trackers are used, which are typically attached to a person's head and might be perceived as cumbersome or uncomfortable for the use of persons living with dementia. Thus, for this project, two setups were constructed and developed: an HMD setup that provides a fully immersive experience and a semi-cave automatic virtual environment (semi-CAVE) setup that provides a semi-immersive experience with fewer contraptions attached to a person's head.The ImGTS was tested in a pre-clinical trial among healthy adults aged 40 to 59 years old and was found to be safe, acceptable, and usable in this population. The participants had a low incidence and severity of VR sickness symptoms (n=8, 26.7%), and the reported symptoms decreased across sessions. The ImGTS was able to give positive impressions and leave clear recollections with the participants, who were able to perform the tasks in the application with ease. The three main activities were given neutral to positive ratings for satisfaction [26].

The results of the pre-clinical trial provided the basis for a clinical trial to test the ImGTS among PLWD. Taken together, both studies aim to contribute to the evidence base for interventions that support current standard therapeutics that improve the quality of life of patients and their families.

A stronger evidence base is particularly important in the Philippines where there is a projected increase in cases of dementia and where diagnosis and management of dementia in non-acute settings is not recognized as a major public health concern [8]. Moreover, older adults with dementia are usually not prioritized in the face of limited family resources. Research and awareness are also generally lacking in the Philippines, associated with limited social and health care reform in dementia care [3]. In addition, current pharmacological and non-pharmacological therapies face the limitations of either eliciting complications or being lacking in effectiveness. While VR

interventions for dementia exist, few studies address the behavioral and psychological symptoms directly [27, 28], and none have been culturally adapted for the elderly Filipino patients.

This paper describes the protocol designed for a Phase 2 clinical trial of an ImGTS developed for PLWD to further assess the potential of the ImGTS to bridge gaps in the management of AD and BPSD. This research aspires to contribute to dementia care innovation and to improve the patient's quality of life.

2 Objectives

The objective of the study is to determine the effectiveness of a developed VR intervention among patients with mild to moderate AD dementia with BPSD. Specifically, the study aims to determine its acceptability, clinical effectiveness, safety, and usability.

3 Methods and Analysis

3.1 Study design

The study will use a randomized two-arm parallel clinical trial design to achieve the study objectives. The study was performed in collaboration with neurologists, physical therapists, and computer scientists from the University of the Philippines (UP) Manila and UP Diliman, respectively. The study duration lasted around 7 months (Annex 1). Face-to-face data collection was done at the UP College of Allied Medical Professions Clinic for Therapy Services (UP CAMP CTS). One part of the clinic has been allocated as an ImGTS laboratory, which will be dedicated for the delivery of VR experiences.

3.2 Participants/Population

Thirty patients who fit the inclusion criteria were included (15 patients per study arm), similar to other pilot studies on VR among PLWD [28-32]. Participants were selected using purposive sampling in view of the limitations associated with recruiting participants during the COVID-19 pandemic. The characteristics of the participants will be thoroughly described in the research report to clarify who might be excluded from the study as a result of the sampling method. Limitations and potential biases related to the sampling method such as reduced statistical power and generalizability will be stated when interpreting the results.

The inclusion criteria for this study include the following: aged 60 years or older; diagnosed with mild to moderate Alzheimer's dementia according to the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria; Montreal Cognitive Assessment-Philippines (MoCA-P) score of 10-20 inclusive; Neuropsychiatric Inventory (NPI-12) score of 1-50 inclusive; Reisberg Scale Stage 4-

5 inclusive; stable dose of antidepressants for the past 6 weeks; stable dose of antipsychotics for the past 4 weeks; able to walk unassisted or with minimal assistance, with or without assistive device; and no other explanation for condition based on reasonable clinical diagnostics.

The exclusion criteria are as follows: those that have mild cognitive impairment (no dementia); have MoCA-P score less than 10 or more than 20; other non-amnestic dementia syndromes; have receptive aphasia; have significant visual or hearing impairment; have an active psychiatric disorder prior to Alzheimer dementia diagnosis; had previous episodes of seizures, diagnosis of epilepsy, or intake of antiepileptic or seizure medications; have quadriplegia or paralysis of the dominant hand; have a history of motion sickness; experience claustrophobia; or have a diagnosis of a terminal illness or a life expectancy of less than one year.

3.3 Trial Setting

Face-to-face data collection was done at UP CAMP CTS. The HMD area is a 2-meter length by 2-meter width square with 0.5-meter allowance on each side. The semi-CAVE area is a 3-meter length by 3-meter width by 3-meter height cube where the top and back are open, there are images projected to the walls of this area to deliver the therapy to the patient. The therapist table is located outside of the area, this table contains the personal computer (PC) or laptop that runs the therapy software.

3.4 Recruitment

Patients were recruited from the clinics of the attending neurologists (VMA and RDJ). Other neurologists were also invited to refer patients to the study site. Online recruitment materials such as a poster and email invitation were utilized through posting on the project's website (https://axel.upm.edu.ph/) and sending via email, respectively (Annex 2). Patients were screened for eligibility over the telephone and were asked to come to UP CAMP CTS where informed consent was obtained (Annex 3). Participants and primary caregivers who have consented to join the study underwent a second stage of screening consisting of a complete systemic and neurologic exam. The findings of this exam are considered when interpreting the results of the trial.

3.5 Allocation, randomization, and stratification

Participants will be randomly assigned to either an HMD system or a semi-CAVE. Random assignment was done using computer-generated random numbers. Participants were not grouped based on severity of AD, but this information was documented and may be considered in analysis of data to determine if there would be differences between the severity of AD.

3.6 Blinding

There is blinding of outcome assessment. The clinicians and therapists involved in the VR experience, nor the participants, were not blinded to the intervention used. Only the independent rater was blinded during outcome assessment.

3.7 Interventions

The intervention is systematized to ensure fidelity in the results, the therapist first briefs the patient on what they will do, the therapist usually discusses the purpose of the intervention to prevent disorientation. The therapist then guides the patient to the HMD/semi-CAVE area to introduce the technology to the patient and discuss their mode of interactions, after which the technology will be worn by the patient. During the intervention the technology team is on call if ever there are errors or bugs during the intervention, in the occasion that the patient has a medical concern during the trial, there is a safety feature within the software that resets the intervention to a neutral state while the medical concern is being addressed. After the intervention, the therapist will remove the technology from the patient and guide the patient to the data collection area.

ImGTS intervention. The VR therapy intervention is a non-commercial application developed by the research team during the Phase 1 study [25]. "Suroy-Suroy" is a role-playing game whose activities were designed based on existing non-pharmacological therapies used to manage BPSD, such as orientation therapy, reminiscence therapy, art therapy, and music therapy. The game revolves around a user visiting a memorable or historical place to relax and explore. The goal of the game is to invoke pleasant memories about the simulated environment and activities by recreating the experience through VR technology. As a user goes through the activities in the application, the game can develop a deep connection with the user by motivating them to participate and indulge in the simulated activities that also exercise their mind and body. The user will be accompanied in game by a virtual companion controlled by a therapist. The virtual companion also executes gestures to effectively convey emotions. Therapists will be adequately trained on the proper use and navigation of the prototype prior to data collection. The clinicians and therapists involved in the VR experience will not be blinded to the intervention used. Only an independent rater will be blinded during outcome assessment.

The participants will experience the prototype for one session per week for four weeks. Each session will last from 30 to 45 minutes, comprising 10 to 20 minutes of interaction with the ImGTS and 5- to 20-minute breaks in between each interaction within a session if necessary. The patient will be seated throughout the experience, and their reaction and interaction with the ImGTS will be recorded.

Outcome measures

Primary outcomes. The primary outcomes are clinical effectiveness, safety and usability. These will be assessed before and after the patient undergoes VR therapy.

Clinical effectiveness will be measured using the NPI-12 (Annex 5), which is a rating scale composed of a 12-item structured interview of the caregiver [33]. Scores range from 0 to 120, where higher scores indicate greater psychiatric disturbance. The NPI evaluates the degree and severity of BPSDs and the distress it causes the primary caregiver. It may take less than 10 minutes to administer. A 4-point decrease or 30% reduction from the baseline score is regarded as clinically significant.

Safety of the VR intervention will be assessed using the VR sickness questionnaire (VRSQ) that will be implemented before and after each session for at most 10 minutes (Annex 5). The VRSQ, derived from the simulator sickness questionnaire (SSQ) [23], will measure a participant's experience with the following symptoms: general discomfort, fatigue, eye strain, difficulty focusing, headache, fullness of head, blurring of vision, dizziness (when eyes are closed), and vertigo. Participants will rate the aforementioned symptoms on a 4-point scale: 0 or None, 1 or Slight, 2 or Moderate, and 3 or Severe. The questionnaire will require less than 5 minutes to complete. The computation of the total score follows the scheme in Table 1:

Table 1. Computation scheme for the virtual reality sickness questionnaire [23]

SSQ components	Computation
Oculomotor	(subtotal for Oculomotor/12)*100
Disorientation	(subtotal for Disorientation/15)*100
Total	(Oculomotor score+Disorientation score)/2

Adverse events aside from those of VR sickness will also be noted and reported accordingly.

Usability will be measured as a function of the participant's experience of effectiveness, efficiency, and satisfaction using the system usability scale (SUS) (Annex 5). The SUS is a 10-item questionnaire that is widely used in the evaluation of various kinds and aspects of technology [34]. Each question has five response options ranging from 'Strongly agree' to 'Strongly disagree', which has a corresponding number value. Each response is added and multiplied by 2.5 to obtain the final score that ranges from 0 to 100. A SUS score above 68 is considered above average. The SUS will be used after each session and will require about 10 minutes to complete.

Secondary outcomes.

- Cognitive function was determined through several scales.
  - The MOCA-P is a 30-item test that takes about 10-12 minutes to complete (Annex 5). The test measures different cognitive domains such as visuospa-

tial/executive, naming, memory, attention, language, abstraction, and orientation [35].
  - The Mini-Mental State Exam (MMSE) is also a 30-item test for cognitive function. It assesses attention, orientation, memory, registration, recall, calculation, language, and an individual's ability to draw a complex polygon [36] (Annex 5).
  - The cognitive subscale of the Alzheimer's Disease Assessment Scale (ADAS-Cog) is an 11-item tool for the assessment of the following tasks: word recall, naming objects and fingers, commands, constructional praxis, ideational praxis, orientation, word recognition, and language [37, 38] (Annex 5).
- The measures for the quality of life of PLWD were based on several questionnaires.
  - The Alzheimer's Disease Cooperative Study - Activities of Daily Living Inventory (ADCS-ADL) is a 24-item assessment on activities of daily living within the past four weeks [39] (Annex 5). It can be accomplished within 30 minutes.
  - The health-related quality of life for people with dementia (DEMQOL) is a 28-item self-report measure of quality of life specific for persons with mild-to-moderate dementia [40] (Annex 5). It covers four dimensions of quality of life, namely, daily activities, memory, negative emotion, and positive emotion.

Baseline assessment of the NPI-12 and the secondary outcome measures will be performed during the second stage of screening and will be repeated after the participant completes the intervention (Table 2). Baseline and posttest measurements will be conducted by independent clinical assessors who will not be involved in the delivery of the VR intervention.

Table 2. Frequency of data collection for each outcome in the study

Outcome(s)	Frequency of data collection
Clinical effectiveness (NPI-12), MoCA-P, MMSE, ADAS-Cog, ADCS-ADL, DEMQOL	Twice (once during the second stage of screening; once after completing four sessions of the intervention)
Safety (VRSQ)	Eight times (once before and once after each of the four sessions)
Usability (SUS)	Four times (Once after each of the four sessions)

In the event that participants do not complete the intervention and the assessment for whatever reason, enrollment of participants will continue until both study arms have enough patients. A medical doctor will always be present for any concerns with VR sickness (dizziness, headache, nausea, etc.), including emergencies and conditions requiring first aid. Appropriate medications will be given, if warranted.

Therapist training. Two physical therapists will be trained to use the ImGTS system by the game developers. They will be oriented to the game interface. Additionally, there will be a therapist module integrated into the games to guide them in navigating and manipulating game elements in the absence of a game developer

3.8 Treatment fidelity

Through a systematized workflow written in the therapist module, the technical team and the therapist present during the intervention ensure the consistency of the intervention being implemented.

3.9 Data management

The recording of the FGD will be transcribed and reviewed for accuracy prior to coding. A coding framework will be developed before the actual FGD based on key concepts in the FGD topic guide. New codes may be added during the process of coding to account for concepts that were not covered by the coding framework. Two researchers will independently code the transcript, review the initial list of coded statements, and consolidate the final list upon which thematic analysis will be performed.

Quantitative data will be encoded in a password protected spreadsheet. Descriptive statistics will be used to report demographic and clinical data. Means and standard deviations will be calculated for continuous parametric data, medians and ranges for continuous non-parametric data, and frequencies and percentages for nominal data. Inferential statistics such as the paired t-test and Cohen's D will be used to determine the effectiveness of ImGTS for the management of patients with BPSD. The paired t-test will be used to determine if there are significant differences between pretest and posttest scores, while Cohen's D will illustrate the size of the effect observed. Participant groups will be compared on outcome measures with respect to change, from baseline to post-intervention, and will be presented as mean differences (95% CI). The following formula for Cohen's D will be used:

$$Cohen's\ D = \frac{Mean\ difference\ (treatment)\ -\ Mean\ difference\ (control)}{Standard\ deviation\ (pooled)}$$

Intention-to-treat analysis will be used for missing data from attrition. A data scientist will also be involved in the data analytics of the information to be gathered in the trial.

3.10 Patient and public involvement

There were no patients nor relatives of the patient that is part of the study protocol.

4 Discussion/Conclusion

This protocol illustrates the testing of developed VR games to actual patients with BPSD using an iterative participatory design process. This method stresses the importance of an interdisciplinary approach that may help mitigate barriers for VR acceptance [41] and allow adjustments and refinements to hardware and software components prior to the actual implementation in clinical trials [42].

ImGTS may simulate non-pharmacological therapies that are currently offered to AD dementia patients, including occupational therapy, art therapy and music therapy. Additionally, this was developed to address significant gaps in dementia care in the Philippines since existing therapies either elicit complications or lack effectiveness. Two setups were constructed to provide options between a fully immersive experience through the HMD or a semi-immersive experience but with less contraptions to lessen patient discomfort via the semi-CAVE.

Unlike existing VR therapy for AD that does not address BPSD and provides little-to-no relatability to Filipino PLWDs, the new protocol utilizes a method of VR therapy intervention that accommodates older Filipino PLWDs, aged 60 and above. The system also includes a comprehensive observation and control module that guides users through activities of daily living [22] and enables customization according to each patient's needs. Each patient will be subjected to the locally developed application designed with existing non-pharmacological therapies targeting symptoms of BPSD in mind.

An essential aspect of the implementation of this protocol was efficient blinding. Blinding of participants is essential in the conduct of the trial to avoid biased assessments, ensure compliance, and lessen fall-out [43]. Similarly, blinded clinicians mitigate preferential treatment to either the active or placebo groups [44]. Moreover, blinding of data collectors and outcome adjudicators (sometimes the same individuals) is crucial to ensure unbiased ascertainment of outcomes.

Despite the various advantages of this technology, there are still aspects that may be improved for future use. The main limitation of this technology is the requirement of specialized hardware and adequate floor area for implementation of the system (Table 3).

Table 3. Requirements for implementing the ImGTS

Hardware	Facility
• VR headset • High-power desktop workstation	• Trained therapist • Medical-grade harness • Short throw projectors x 3 • 3 x 3 m floor space (exclusive of therapist workstation)

The primary and most immediate application of ImGTS is to serve as a highly accessible and engaging non-pharmacological therapy for individuals with dementia, par-

ticularly those experiencing BPSD. This has the potential to reduce caregiver burden by providing a structured and engaging activity for patients. Scaling of ImGTS to various settings can cater to individual patient comfort and accessibility especially in rural or remote areas where resources are limited and specialized care is scarce. Moreover, the culturally relevant design of the system marks a significant advancement in the field of dementia care since it highlights the importance of designing interventions that resonate with the lived experiences and cultural backgrounds of diverse patient populations. Broader integration of culturally appropriate digital health solutions such as immersive technologies into public health initiatives for dementia enable democratization of access to innovative therapies, especially in regions with limited healthcare infrastructure.

ImGTS also provides a controlled and reproducible environment for studying the effects of non-pharmacological interventions on dementia wherein this platform can facilitate the testing of new hypotheses related to personalized dementia care, leading to evidence-based recommendations for VR-based interventions. As such, results from the Phase 2 trial conducted according to this protocol will inform any further refinement of the prototype for an enhanced version to be tested in a subsequent randomized clinical trial, and ultimately for adoption for clinical use [42].

4.1 Dissemination and Implementation

This protocol may be applied to various studies that aim to transform VR games for health applications, particularly those who are interested in testing their VR games to actual patients with BPSD with similar primary outcomes of clinical effectiveness, safety, and usability. The questionnaires for these outcomes are accessible online.

4.2 Ethical or Practical Issues

Ethical clearance was sought from the University of the Philippines Manila Research Ethics Board (UPMREB), and the research will adhere to the National Ethical Guidelines for Health and Health-Related Research 2017 on research among older persons [45].

Transparency and conflict of interest. The participants may possibly include patients of the investigators or the therapists administering the VR intervention. The researchers will assure the potential participants that their participation or non-participation will not affect the quality of care they are currently receiving or will receive. The investigators have no other conflicts of interest to declare.

Privacy and confidentiality. Data will be encoded in a password-protected computer. In the research team, only the principal investigators and the researchers involved in participant screening will have access to records containing the participant's name and contact information. Participants will be given a unique identifier that will be used throughout their involvement in the study. Anonymized data will only be accessed by the principal investigators and the researchers involved in data analysis.

Records that may identify the participants will not be made publicly available, to the extent permitted by law. Only the investigators, study monitor(s), auditor(s), UPMREB, and regulatory authorities will have access to the electronic data collection forms and electronic copy of the data. Electronic files will be stored for five years only after which they will be deleted.

Vulnerable population. The study population will consist of older persons (aged 60 years and above) with a diagnosis of mild to moderate AD dementia and have BPSDs. Exclusions were made for potential participants who have significant visual impairment or have quadriplegia or paralysis of the dominant hand since these characteristics would negatively affect their capability to experience the VR intervention. For all participants, all discussions will be witnessed and facilitated with their legally authorized representative (LAR)/ primary caregiver to minimize misunderstandings and communication issues during screening, informed consent and data collection. The researchers will clarify the benefits when orienting the participant and their LAR/ primary caregiver on the use of the application.

Risks. Universal COVID-19 pandemic precautions will be implemented at all times. As much as possible, all members of the research team who will be present are fully vaccinated. Materials and equipment to be used will be sanitized after each use. In the event that the participants will develop symptoms of COVID-19 within 14 days of study participation, they will be evaluated at UP-PGH and will be admitted at the same institution if warranted.

Some risks to use of VR applications include experiencing cybersickness, negative psychological effects, and falls when used in patients with dementia [17, 46-51].

Previous studies have shown that incidence of adverse events from the use of VR interventions is low [19, 20, 23, 24, 46, 52]. Older participants were also noted to tolerate VR interventions even in challenging settings [52, 53]. However, the risk for any adverse event is still present and should be prepared for.

VR sickness manifests as symptoms related to nausea, disorientation, and/or oculomotor functions. The mechanism and causes of these symptoms in relation to VR and related technologies is still unknown, but experiencing these symptoms may hinder the use of VR technology. To address this risk, the proposed VR intervention was designed with best practices and recommendations in mind. It was also pilot tested among healthy participants in an earlier study, which found that use of the intervention did not lead to significant experience of VR sickness symptoms.

Prior to the session, participants will be briefed about the possible side effects of immersion in the VE. They will be reminded that they are allowed to withdraw from the experience for any reason. VR trials are in 10- to 20-minute periods with introduction, orientation, and provisions for rest periods for patient comfort for a total time of at most 45 minutes per session. Participants will also be provided with sick bags should nausea-related symptoms occur, and they will also be given access to the facility's bathroom. Cleaning products will be kept on hand. For participants with severe cybersickness, they will be advised to stay at the facility for at least an hour for moni-

toring. A medical professional will be present at all times to attend to the medical needs of the participants.

Negative psychological effects also present as another study risk. These may occur when participants confuse the VE and the real world, and when they experience sensations that combine the real world and the virtual world. To prevent these from occurring, participants will be given time to adjust to the real world after the VR experience. Participants may also recall negative events through the VR experience [48]. The content and themes to be included in the VE will also be confirmed through an online or face-to-face FGD with the stakeholders to ensure appropriateness for the use of patients with BPSD. Participants will also be followed up at least 1 week after the last intervention session via phone call to evaluate if any psychological effects manifested since the last session.

Physical injuries (e.g., falls) may occur during the course of the VR experience because of the possible confusion of the virtual world for the real world, the occluded vision of those wearing HMDs, and the frailty of elderly adults [46]. To prevent these untoward events, the designated areas for the Semi-CAVE and for the HMD will be kept free from obstructions and unnecessary objects. Participants will be made to keep a distance from the projection screens or panels. Participants will be asked to sit in a stable and comfortable chair during the VR experience to avoid falls and accidents.

Benefits, Compensations, and Entitlements. Participants may directly benefit from the study through their receipt of an intervention that could address their BPSD. Findings of this study may also indirectly lead to their benefit since these will be used to further improve the VR intervention for future use in clinics and care facilities.

Members of the pilot group will be compensated PHP 2,000 and each participant in the clinical trial will be compensated PHP 1,500.00 per scheduled session and will be entitled to insurance in cases of physical injury as a result of the application or procedures used in the study. Medical treatment in such instances will be provided without cost, but this commitment will not be applicable for complications or illnesses that did not result from their participation in the study.

The results of the study are intended to be used in the development of products and/or services that may have commercial value, but the participant will not be entitled to receive direct commercial benefit from this.

Informed consent process. Informed consent of participants and their primary family caregiver or their legally authorized representatives (LARs) will be secured by members of the research team who are not involved in the direct care of the said participants (Annex 3). The researcher will present the informed consent form to the potential participant and/or their LAR, and will explain the background of the study, the intervention, and the risks and benefits of their participation. The participant and their caregiver/advocate will also be given ample time to review the ICF and to ask any questions they have about the study and the procedures. Once assured that the potential participant and/or their LAR understand the study and what they will be asked to do, they will be asked to affix their signature or thumbmark (for illiterate participants) on the ICF.

Consent for participation may be withdrawn at any time during the conduct of the study. The reason for withdrawal will be noted. Participants may also choose not to participate in a session if they do not wish to but may still continue participation if they wish to do so by the succeeding session.

Dissemination. Participants have the right to know the full results of the study and can request the results of the study but will not be given direct access to their records. The researchers will take care to present these findings in a way that the participants would easily understand.

The participants' names would not be included in any of the reports that would be made on this study. Photos or clips from video recordings will only be used with the consent of the participants.

Results of the study may be presented in both scientific and non-scientific fora and disseminated through publications. No identifying information will be disclosed by the University of the Philippines to others without written permission from the participants, except: (1) if necessary, to protect their rights or welfare (for example, if they are injured and need emergency care); or (2) if required by law. The participants' identities would remain confidential in the event that the study results are published. The investigators, study monitor(s), auditor(s) and the UPMREB, and regulatory authorities will be granted direct access to your medical records only for purposes of verification of clinical trial procedures and data.

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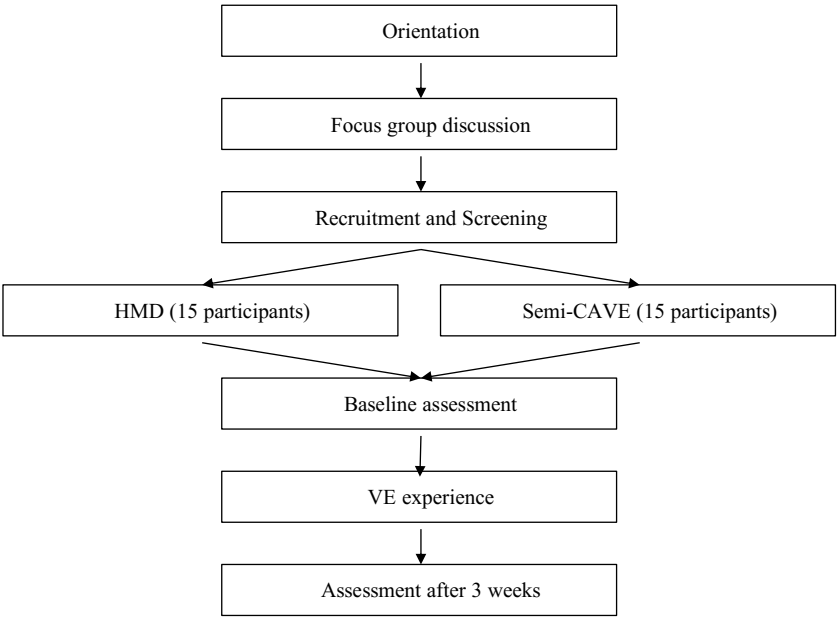
ANNEX 1. Project timeline and workflow

Activities	Q 1	Q 2	Q 3	Q 4
Orientation and training of healthcare professionals	■	■		
Focus group discussion		■		
ImGTS prototype enhancements		■		
Patient selection and recruitment		■	■	■
Intervention period		■	■	■
Data analysis				■
Drafting of research report				■



ANNEX 2. Recruitment materials

A. Focus group discussion invitation letter

Dear _____,

May we invite you to join our pilot group and share with us your valuable experience and/or expertise in an online or face-to-face focus group discussion (FGD) for the project "Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)" on XXX (XX:XX - XX:XX).

Your participation will help us gather insights from patients living with dementia and their caregivers on the acceptability of a proposed VR intervention in addressing BPSDs.

For participating in the pilot and FGD, we will provide an honorarium of Two Thousand Pesos (₱2,000) for your engagement.

Thank you and look forward to your favorable response.

Sincerely,
Dr. Veeda Michelle Analcan
Primary Investigator

B. Study invitation letter

We are looking for participants who may join our research entitled "Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)" [UPM REB CODE: 2023-0040-01]

This research project is under the research program "Immersive Technology Applications in Healthcare", a collaborative effort of the University of the Philippines Diliman and Manila led by Dr. Maria Eliza Aguila as Program Leader. Our research team, the Augmented Experience E-health Laboratory (AXEL) research group, is an interdisciplinary team composed of specialists with diverse and extensive experience ranging from design and game development to rehabilitation and healthcare. AXEL is a dynamic research lab that designs and develops immersive technology systems (such as virtual reality) for healthcare applications. We aim to serve Filipinos with disabilities by providing therapy through virtual experiences that help them accomplish therapy goals in a fun and engaging way.

We are looking for persons living with dementia who are:

- Aged 60 years old or older
- Diagnosed with mild to moderate Alzheimer's dementia
- Stable dose of antidepressants for the past 6 weeks
- Stable dose of antipsychotics for the past 4 weeks
- Able to walk unassisted or with minimal assistance, with or without assistive device
- Can travel to study site for participation

The study aims to determine the clinical effectiveness, safety, and usability of a proposed VR intervention on patients with BPSD. Volunteers will test the game for 1 hour per session, 1 session per week for four weeks. Testing sessions will be conducted at the UP College of Allied Medical Professions Clinic for Therapy Services at the Joaquin Gonzalez Compound on Padre Faura Street corner Ma. Orosa Street.

If interested to join, please fill out this form and expect a call from us for an interview and preliminary assessment to confirm your participation in the research. If you wish to know more, please contact us through:

Email:axel@up.edu.ph
Mobile: 0956-2954-001

Thanks again and we look forward to your participation.

Sincerely,

Dr. Veeda Michelle Anlacan, Project Leader
AXEL Research Group
Augmented Experience E-Health Laboratory

C. Recruitment poster

ANNEX 3. Informed consent

A. FGD

English Version

Participant No. _____

INFORMED CONSENT FORM

Study title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)
UPMREB code:
Study sponsor: Department of Science and Technology-Philippine Council for Health Research and Development (PCHRD-DOST)
Principal investigator: Veeda Michelle Anlacan, MD | College of Medicine, UP Manila-Philippine General Hospital, Manila City | Email: vmanlacan@up.edu.ph | Mobile: +639189197143

You are kindly invited to join a research study because you are (a) a patient experiencing behavioral and psychological symptoms of dementia (BPSD) or (b) are a caregiver of a patient with BPSD.

Here are a few things to know as you learn more:

1. Taking part in a research study is **voluntary** and is not part of your regular healthcare
2. Before you decide, please read this form carefully so you know why the study is being done and what it involves.
3. Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your doctor, family and friends.
4. Ask the principal investigator/staff your questions
5. If the principal investigator is the same as your private doctor/attending physician, remember that you are still free to decide on your participation in the study.

Thank you for taking the time to consider taking part in this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you for the purpose of inviting you to make an informed decision about participating in the research study. We kindly ask you to consider this sensitive information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

STUDY OVERVIEW

Purpose of the study

Persons living with dementia (PLWD) experience behavioral and psychological symptoms (BPSD), which are a range of signs and symptoms such as agitation, aggression, delusions, hallucinations, depression, apathy, disinhibition, anxiety, motor disturbance, and nighttime behaviors. BPSD may be treated by medication and physical restraints, but these interventions are limited by side effects and complications. Recent research has been exploring the use of virtual reality (VR) technology as a form of treatment for dementia and mild cognitive impairment, and evidence shows that VR could be used in the prevention, assessment, and treatment of patients with these conditions, although there is little evidence on its use for patients with BPSD.

In this study, we aim to see if our proposed VR intervention is effective in managing the BPSDs of PLWD. But before we could proceed to the main clinical trial, we would first like to know if the VR intervention is acceptable to PLWD.

General information about the study

At most eight (8) individuals will participate in the initial clinical study for a period of two (2) days. This informed consent form (ICF) will be valid until the end of the research project. The sponsor or the research team may learn new information about the VR application, including information related to the risks of its use, during the conduct of the study. Should any information that may affect your decision to continue participating in the study, the research team will inform you in a timely manner.

STUDY PARTICIPANTS

Patients with BPSD and their primary caregivers will participate in this study. The general selection criteria include the following:

- No previous episodes of seizures, diagnosis of epilepsy, or intake of antiepileptic or seizure medications
- No significant visual impairment
- No hearing impairment requiring hearing aid
- No history of motion sickness
- No experience of claustrophobia
- No diagnosis of a terminal illness or a life expectancy of less than one year

Additional criteria for patients include:

- Aged 60 years old or older
- Diagnosed with mild to moderate Alzheimer's dementia according to the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
- Montreal Cognitive Assessment-Philippines (MoCA-P) score of 10-20 inclusive
- Neuropsychiatric Inventory (NPI-12) score 1-50 inclusive
- Reisberg Scale Stage 4-5 inclusive
- Stable dose of antidepressants for the past 6 weeks
- Stable dose of antipsychotics for the past 4 weeks
- Able to walk unassisted or with minimal assistance, with or without assistive device
- No other explanation for condition based on reasonable clinical diagnostics
- No other non-amnestic dementia syndromes
- No receptive aphasia
- No active psychiatric disorder prior to Alzheimer dementia diagnosis
- No quadriplegia or paralysis of the dominant hand

STUDY PROCEDURES

Intervention

The research team developed a VR application that is intended to become part of treatment for patients with BPSD. It is a role-playing game set in three tourist attractions in the Philippines and contains three activities based on actual non-pharmacological therapies performed to address BPSDs. The research will also involve your participation in a group discussion that will take about two hours to complete.

Procedure

We would like to ask you to participate in two (2) sessions. Session 1 will be at the College of Allied Medical Professions Clinic Therapy Services, UP Manila. You will be asked to use a VR application through a head-mounted device (HMD) or a Semi-CAVE (a type of VR theater), which will be assigned at random. The VR application includes simulations of painting, puzzle-solving, and sing-along activities, and will involve minimal movements such as reaching and grabbing. The VR application will be used for 10 to 20 minutes at a time, with 5 to 20 minutes to rest in between each use. The entire session will not take more than an hour to complete. During the experience, we will monitor and record your interaction with the VR application and in the virtual environment (VE). Session 2 will be conducted online via Zoom or face-to-face. You will be asked to participate in a focus group discussion to determine the acceptability of the VR intervention for patients with BPSD.

Participant's responsibility

If you agree to participate in this study, you must:

- Attend all scheduled visits
- Give true information about your medical history
- Advise the investigators of any changes in your medical condition during the study and during the 30 days after completing the study

RISKS, BENEFITS, AND COMPENSATION

Possible risks and/or side effects

Some risks of the VR experience are as follows:

- Cybersickness is a common reaction to VR. It manifests as various symptoms such as eye strain or soreness, nausea, and dizziness. On the development side, we have taken the necessary measures to decrease the likelihood of experiencing these side effects. A doctor or therapist will also be present to attend to your medical needs, if needed.
- Psychological effects may arise when you confuse the virtual world for the real world, and vice versa. To prevent this, you will be given time to adjust to both environments, and will be interviewed by a medical professional for post-processing, if needed.
- Possible physical injuries due to accidents may occur. The research team will do precautionary measures, such as keeping the participant seated throughout the whole experience and proper distancing of equipment

The research team will be implementing the health and safety protocol of the UP CAMP Clinic for Therapy Services as a precaution against COVID-19. This protocol will be reviewed and revised as necessary if the public health situation related to COVID-19 worsens. Another precaution is the full vaccination against COVID-19 of the research team. Your time in the facility will be limited as much as possible. You are also encouraged to take health and safety precautions in and outside the Clinic.

Materials and equipment to be used will be sanitized with rubbing alcohol before each use. Personal protective equipment such as face masks will be worn at all times while within the facility. You will also be offered the use of the comfort room to wash their hands with soap and water after using the devices.

In compliance with the health and safety protocol of the Clinic, you will be asked some questions about possible symptoms every time you come to the Clinic. If you develop COVID-19 symptoms while participating in the study and within 14 days after participating in the study, please contact the research team for a referral to the Philippine General Hospital for evaluation and possible admission.

Potential benefits

You may directly benefit from the intervention through your experience of an intervention that could be added to a patient's regular therapy activities. Your participation will help us find out how we can improve our application, and we hope that this will help clinics and rehabilitation centers in treating patients with BPSD.

Participant costs

There will be no cost for your participation in this study, except for expenses that may be incurred when traveling to the facility. The use of the application and the study-related procedures will be provided at no cost to you.

Compensation and/or treatment of study-related injury

You will receive compensation amounting to Php 2,000.00 for travel costs and inconveniences related to your participation in the study. You will not be given any other money or gifts for participating in this study.

The research group has obtained insurance to conduct this study. If you become physically injured as a result of the product or procedures used in this study, and if instructions of the study doctor have been followed, reasonable and appropriate medical treatment will be provided without cost. The commitment to you for free medical treatment does not include treatment for any other complications or illness experienced during the course of the study if, in the opinion of the investigator, such complications or illness are not a result of your participation in this study. The costs of any other medical care are your responsibility. You will not lose any of your legal rights as a research subject by signing this consent form. The research team makes no commitment to provide compensation beyond that specified.

The results of this study are intended to develop products and/or services that may have commercial value, but you will not receive any direct commercial benefit from this.

VOLUNTARY PARTICIPATION

Participation is voluntary. You can choose to say no, and any services that you receive at the University of the Philippines-Philippine General Hospital (UP-PGH) will not change. You may ask as many questions as needed and we will take the time to answer them. We will also give you time to think about your decision. If you have already agreed and want to retract consent, you may choose to do so at any time during the study. Your consent will only be valid until the end of your participation in this study. You have the right to be informed that your personal data will be collected and processed. You may object or withhold consent to the processing of the collected data should there be any changes or amendments to the data given.

RIGHT TO REFUSE OR WITHDRAW

You may choose not to participate in this study. Choosing to participate or to not participate will not affect either your future treatment at UP-PGH. You may stop participating in the virtual environment experience at any time that you wish without losing any of your rights to treatment at UP-PGH.

You may also be discontinued from participating in the VE experience without your consent by the doctor conducting the study or by the sponsoring agency at any time for the following reasons:

- if it appears to be medically harmful to you,
- if you fail to follow directions for participating in the study,
- if it is discovered that you do not meet the study requirements, or
- if the study is suspended or canceled.

CONFIDENTIALITY

You have the right to know the full results of this study and you can request the results of the study. And though you cannot have direct access to your records, you will maintain your right to know data relevant to yourself. All the results of this study, such as the VE application experience, would be held in confidence. All data collected will be stored in a password-protected computer and only the researchers will be able to access this. Your name will not be included in any of the reports that would be made on this study. Records identifying yourself will be kept confidential and will not be made publicly available, to the extent permitted by law. Your identity would remain confidential in the event that the study results are published. The investigators, study monitor(s), auditor(s) and the University of the Philippines Manila Institutional Ethics Review Board, and regulatory authorities will be granted direct access to your information only for purposes of verification of study procedures and data. All records will be stored only until 5 years after the completion of the study.

WHOM TO CONTACT

If you have any questions regarding the study, please feel free to contact the following:

Dr. Veeda Michelle M. Anlacan, Principal investigator
Department of Neurosciences, College of Medicine, UP Manila, Ermita, Manila
Email: michelleanlacan@gmail.com
Mobile: +639189197143

If you have any questions concerning your rights as a research participant, you may contact the following:

Dr. Cecilia A. Jimeno, UPMREB Panel 1 Chair
Room 126, Ground Floor, National Institutes of Health, UP Manila,
623 Pedro Gil St, Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph Tel: +63 2 8526-4346

STUDY INFORMATION

Protocol title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)

Protocol number: UPMREB-2023-0040-01

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. In addition, it will also be available on www.clinicaltrialsregister.eu and http://registry.healthresearch.ph/. These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

An independent ethics committee or institutional review board that is accredited by the Philippine Health Research Ethics Board (PHREB) has approved this study.

Participant's Copy

If you consent, please read and then sign below.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the VR application, and possible risks and side effects have been answered to my satisfaction.
- I freely agree to participate in this research study as described and understand that he/she is free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.
- I understand that if I choose to not participate or to withdraw, my current medical care will not be affected by this decision.
- By signing and dating this consent form, I have not waived any of the legal rights that I would have if I was not a participant in a medical research study.

Based on this information, I volunteer to take part in this study. Kindly check the box with the most appropriate response.

I agree to the use of my likeness in the photos and/or videos captured by the research team for future use in posters, videos and presentations related to the project. (You may still be in this study even if you do not agree to this.)	Yes	No

Full printed name of participant

Signature of participant | Date (dd/mm/yyyy)

Full printed name of participant's caregiver/legally authorized representative (if applicable)

Signature of participant's caregiver/legally authorized representative | Date (dd/mm/yyyy)

Full printed name of person obtaining consent

Signature of person obtaining consent | Date (dd/mm/yyyy)

Researcher's Copy

If you consent, please read and then sign below.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the VR application, and possible risks and side effects have been answered to my satisfaction.
- I freely agree to participate in this research study as described and understand that he/she is free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.
- I understand that if I choose to not participate or to withdraw, my current medical care will not be affected by this decision.
- By signing and dating this consent form, I have not waived any of the legal rights that I would have if I was not a participant in a medical research study.

Based on this information, I volunteer to take part in this study. Kindly check the box with the most appropriate response.

I agree to the use of my likeness in the photos and/or videos captured by the research team for future use in posters, videos and presentations related to the project. (You may still be in this study even if you do not agree to this.)	Yes	No

Full printed name of participant

Signature of participant | Date (dd/mm/yyyy)

Full printed name of participant's caregiver/legally authorized representative (if applicable)

Signature of participant's caregiver/legally authorized representative | Date (dd/mm/yyyy)

Full printed name of person obtaining consent

Signature of person obtaining consent | Date (dd/mm/yyyy)

Filipino Version

Participant No. _____

INFORMED CONSENT FORM

Study title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)
UPMREB code:
Study sponsor: Department of Science and Technology-Philippine Council for Health Research and Development (PCHRD-DOST)
Principal investigator: Veeda Michelle Anlacan, MD | College of Medicine, UP Manila-Philippine General Hospital, Manila City | Email: vmanlacan@up.edu.ph | Mobile: +639189197143

Kayo po ay inaanyayahang lumahok sa isang pag-aaral dahil ikaw ay (a) isang pasyente na nakararanas ng mga behavioral and psychological symptoms of dementia (BPSD) o (b) ay isang nag-aalaga ng pasyente na may BPSD.

Narito ang ilang bagay na dapat malaman habang natututo pa kayo:

1. Boluntaryo ang paglahok sa pananaliksik na ito, at hindi ito bahagi ng inyong regular na pangangalagang pangkalusugan.
2. Bago kayo magpasya, pakibasa nang mabuti ang form na ito upang malaman ninyo kung bakit isinasagawa ang pag-aaral at kung ano ang kasama rito.
3. Maglaan ng oras upang magpasya – maaari kayong mag-uwi ng walang lagdang kopya ng form na ito upang basahin ito ulit at talakayin ito sa inyong doktor, pamilya, at mga kaibigan.
4. Itanong sa punong taga-suri/kawani ang inyong mga tanong.
5. Kung ang punong taga-suri ay ang inyong pribadong doktor, tandaang malaya pa rin kayong magpasya tungkol sa inyong paglahok sa pag-aaral.

Salamat sa paglalaan ng inyong oras upang isaalang-alang ang paglahok sa pag-aaral na ito.

Maaaring kumpidensyal sa Sponsor ang impormasyon sa Form ng Ipinagbigay-alam na Pahintulot na ito. Ibinabahagi ng Sponsor ang impormasyong ito sa inyo para sa layunin ng pag-imbita sa inyong gumawa ng ipinagbigay-alam na pagpapasya tungkol sa paglahok sa pananaliksik na pag-aaral. Hinihiniling namin sa inyong isaalang-alang ang sensitibong impormasyong ito kapag nagtatalakay ng mga detalye tungkol sa pananaliksik na pag-aaral sa mga tao maliban sa inyong (mga) provider ng pangangalagang pangkalusugan, pamilya, at mga kaibigan.

PANGKALAHATANG-IDEYA NG PAG-AARAL

Layunin ng pag-aaral

Ang mga taong namumuhay na may dementia (persons living with dementia or PLWD) ay nakakaranas ng mga behavioral at psychological na sintomas (BPSD), na tumutukoy sa iba't ibang sintomas tulad ng pagkabahala, galit, mga delusyon at mga guni-guni, kalungkutan, kawalang-interes, hindi pagpigil sa sarili, pagkabalisa, hirap sa paggalaw, at mga gawain tuwing gabi. Maaaring gamutin ang BPSD gamit ang mga gamot at ng mga pisikal na pamamaraan, ngunit ang mga interbensyong ito ay may mga kaakibat na side effect at kumplikasyon. Naimbestigahan na ang paggamit ng virtual reality (VR) bilang isang paraan ng paggamot ng mga pasyenteng may dementia at mild cognitive impairment, at ayon sa ebidensiya, maaaring gamitin ito sa pag-iwas, pagsuri, at paggamot ng mga pasyenteng may mga sakit na ito, ngunit kaunti ang ebidensya sa paggamit nito para sa mga pasyenteng may BPSD.

Sa pag-aaral na ito, nais naming makita kung epektibo ang nagawa naming VR intervention para sa pagpapagamot ng BPSD ng mga PLWD. Ngunit bago kami tumuloy sa clinical trial, nais naming malaman kung kasiya-siya ang aming VR intervention sa mga PLWD.

Pangkalahatang impormasyon tungkol sa pag-aaral

Walong (8) indibidwal ang aanyayahang sumali sa initial clinical study na ito sa loob ng dalawang (2) araw. Ang informed consent form (ICF) na ito ay may bisa hanggang matapos ang aming pag-aaral. Maaaring may malaman ang sponsor o ang research team na bagong impormasyon tungkol sa VR application, tulad ng impormasyon tungkol sa mga panganib nito, habang isinasagawa ang pag-aaral. Sasabihan kayo ng punong taga-suri/kawani nang napapanahon kung may anumang bagong impormasyon na maaaring magpabago sa iyong isip tungkol sa paglahok sa pag-aaral.

MGA KALAHOK NG PAG-AARAL

Ang mga pasyenteng may BPSD at ang kanilang mga tagapag-alaga ay lalahok sa pag-aaral na ito. Ang pangkalahatang batayan ng pagpili ng mga kalahok ay ang sumusunod:

- Walang karanasan ng seizure, diagnosis ng epilepsy, o pag-inom ng mga antiepileptic o seizure na gamot
- Walang kapansanan sa paningin
- Walang kapansanan sa pandinig na nangangailangan ng hearing aid
- Walang karanasan ng motion sickness
- Walang karanasan ng claustrophobia
- Walang malubhang sakit at life expectancy na hindi hihigit ng isang taon

Dagdag na batayan para sa mga pasyente:

- May edad 60 taong gulang pataas
- May mild to moderate na Alzheimer's dementia ayon sa National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
- MOCA-P score 10-20
- NPI-12 score 1-50 inclusive
- Reisberg Scale Stage 4-5 inclusive
- Stable dose ng antidepressants sa nakaraang 6 na linggo
- Stable dose ng antipsychotics sa nakaraang 4 na linggo
- Kayang maglakad ng walang tulong o ng kaunting tulong, gumagamit man o hindi ng assistive device
- Walang ibang sanhi para sa karamdaman na base sa mga clinical diagnostics
- Walang ibang non-amnestic dementia syndromes
- Walang kahirapan sa pag-intindi ng mga nakasulat, binibigkas, o nahahawakang mga simbolo
- Walang active psychiatric disorder bago ang diagnosis ng Alzheimer dementia
- Walang panghihina sa dominanteng kamay

MGA PAMAMARAAN NG PAG-AARAL

Interbensyon

Gumawa ang research team ng isang VR application na maaaring maging paraan ng paggamot para sa mga pasyenteng may BPSD. Ito ay isang role-playing game na nakatagpo sa tatlong sikat na lugar pangturista sa Pilipinas at naglalaman ng tatlong aktibidad na base sa mga aktwal na non-pharmacological therapies na ginagawa para matugunan ang mga BPSD.

Pamamaraan

Hinihikayit ka namin na sumali sa dalawang (2) session. Ang Session 1 ay gaganapin sa College of Allied Medical Professions Clinic Therapy Services, UP Manila. Kayo po ay aanyayahang gumamit ng isang VR application gamit ng head-mounted device (HMD) o ng Semi-CAVE (a type of VR theater), na itatakda sa inyo nang random. **A**ng mga sumusunod na aktibidad ay inyong isasagawa habang ginagamit ang VR application: mga simulation ng pagpinta, pagbuo ng puzzle, at pagkanta. Kakailangangin ninyong gumalaw habang isinasagawa ang mga aktibidad, tulad ng pag-abot at pagkuha. Ang VR application ay gagamitin nang 10 hanggang 20 minuto sa bawat paggamit, na may 5 hanggang 20 na minuto para magpahinga sa pagitan ng bawat paggamit. Hindi lalagpas ng isang oras para makumpleto ang buong session. Habang isinasagawa ang VR experience, imo-monitor at ire-rekord ang iyong pakikihalubilo sa VR application at sa virtual environment (VE). Ang Session 2 ay gagawin online gamit ng Zoom o face-to-face. Kayo po ay aanyayahang sumali sa isang focus group discussion para malaman kung kasiya-siya ang VR application para sa mga pasyenteng may BPSD.

Responsibilidad ng kalahok

Kung sang-ayon kang lumahok sa pag-aaral na ito, dapat:

- Dumalo sa lahat ng mga naka-iskedyul na pagbisita
- Magbigay ng tunay na impormasyon tungkol sa medikal na kalagayan mo
- Payuhan ang mga imbestigador ng anumang pagbabago sa medikal na kalagayan mo habang isinasagawa ang pag-aaral at sa 30 araw matapos kumpletuhin ang pag-aaral.

MGA POSIBLENG PELIGRO, BENEPISYO AT BAYAD

Mga posibleng peligro at/o side effect

Ang ilang panganib na maaaring maranasan dahil sa VE experience ay:

- Ang cybersickness ay isang karaniwang reaksyon sa VR. Ito ay maaaring maranasan sa pamamagitan ng pagkapagod ng mata, pakiramdam na nasusuka o naduduwal, at pagkahilo. Pinaniguradong binuo itong teknolohiyang ito upang mabawasan ang posibilidad na mangyari ang mga sintomas na ito. Mayroon ding mga kasamang duktor o therapist na naroroon upang tumugon sa iyong mga medikal na pangangailangan.
- Posibleng may maranasang mga epektong sikolohikal tulad ng pagkalito sa virtual world at sa realidad, at kabaliktaran. Upang maiwasan ito, bibigyan ka ng oras para maging pamilyar sa kapaligiran, at may eksperto na magsasagawa ng panayam kada matapos ang isang sesyon kung kailangan.
- Maaring magkaroon ng pinsala dulot ng aksidente. Ang grupo ng mananaliksik ay gagawa ng mga hakbang sa pag-iingat gaya ng pagpapanatiling nakaupo sa kalahok habang isinasagawa ang VE experience at ang tamang distansya ng mga kagamitan.

Susundin ng mga mananaliksik ang mga patakarang pangkalusugan at pangkaligtasan ng UP CAMP Clinic for Therapy Services upang maiwasan ang pagkalat ng COVID-19 Ang patakaran na ito ay susuriin at ia-update kung kailangan kung lumala ang kasalukuyang sitwasyon ng COVID-19. Ang isa pang pag-iingat na gagawin ay ang pagsigurado na lahat ng mga mananaliksik ay bakunado laban sa COVID-19. Lilimitahan din ang bilang ng mga tao at ang oras ng pananatili sa pasilidad. Hinihikayat namin kayong magsagawa rin ng mga pag-iingat laban sa COVID-19 sa loob at sa labas ng Clinic.

Ang mga gamit na kakailanganin para sa virtual reality experience ay lilinisin gamit ng rubbing alcohol bago ang bawat paggamit. Ang tamang pansariling kagamitan sa pangangalaga gaya ng face mask ay isusuot sa lahat ng oras. Maaari mo ring gamitin ang comfort room upang maghugas ng kamay gamit ng malinis na tubig at sabon pagkatapos hawakan ang mga kagamitan ng virtual reality experience.

Alinsunod sa mga patakarang pangkalusugan at pangkaligtasan ng Clinic, may magtatanong sa inyo ng mga katanungan ukol sa mga posibleng sintomas ng COVID-19 sa bawat pagpunta sa Clinic.

Posibleng benepisyo

Maaari kang makaranas ng benepisyo sa pamamagitan ng paggamit ng isang interbensyon para sa BPSD. Matutulungan ninyo kaming matuklasan kung paano maipapaganda ang aming application, at umaasa kaming makakatulong ito sa mga klinika at mga pasilidad na gumagamot sa mga pasyenteng may BPSD.

Gastos sa kalahok

Wala kang gagastusin sa paglahok sa pag-aaral na ito, bukod sa gagastusin sa pagbiyahe papunta sa pasilidad. Ang paggamit ng application at ang mga pamamaraang kaugnay ng pag-aaral ay ibibigay sa iyo nang libre.

Bayad at/o paggamot ng pinsalang kaugnay ng pag-aaral

Makakatanggap ka ng bayad na may halagang Php 2,000.00 para sa oras at abala na kaugnay ng iyong paglahok sa pag-aaral na ito. HIndi ka bibigyan ng iba pang pera o regala para sa iyong pagsali sa pag-aaral na ito.

Kumuha ang grupo ng mananaliksik ng insurance para isagawa ang pag-aaral na ito. Kung may pisikal na pinsala bilang resulta ng produkto o mga pamamaraang ginamit sa pag-aaral na ito at kung sinundan ang mga tagubilin ng doktor sa pag-aaral, bibigyan ka ng libre, maktwiran at angkop na medikal na paggamot. Ang pangakong ito para sa kalahok para sa libreng medikal na paggamot ay walang kasamang paggamot para sa anumang ibang kumplikasyon o sakit na nararanasan sa kurso ng pag-aaral na ito, kung sa opinyon ng Imbestigador ang mga nasabing kumplikasyon o sakit ay hindi resulta ng partisipasyon ng inyong anak sa pag-aaral na ito. Ang gastos sa anumang ibang medikal na pag-aalaga ay responsibilidad ninyo. Hindi mawawalan ng alinman sa mga legal karapatan ang inyong anak bilang kalahok ng pananaliksik sa pamamagitan ng paglagda sa consent form na ito. Hindi nangangako ang grupo ng mananaliksik na magbigay ng bayad na lagpas sa natukoy.

Ang mga resulta ng pag-aaral na ito ay gagamitin sa paggawa ng mga produkto at/o serbisyo na may commercial na halaga, ngunit wala kang matatanggap na direktong benepisyong komersyal mula rito.

BOLUNTARYONG PAGLAHOK

Boluntaryo ang paglahok sa pag-aaral na ito. Maaari kang tumanggi, at hindi maaapektuhan ang anumang serbisyong iyong natatanggap mula sa University of the Philippines-Philippine General Hospital (UP-PGH). Maaring magtanong nang marami at maglalaan kami ng sapat na oras para sagutin ang mga ito. Bibigyan ka rin namin ng panahon upang pag-isipan ang iyong desisyon. Kung ikaw ay pumayag na at nais bawiin ang iyong pagpayag, maaari mo itong gawin sa kahit anong punto ng pag-aaral. May bisa ang iyong pagpayag na sumali hanggang sa dulo ng iyong paglahok sa pag-aaral na ito. Ikaw ay may karapatan na malaman na kukunin at ipro-proseso ang iyong personal na impormasyon. Maaari kang tumanggi o ipagkait ang pagpayag sa pagproseso ng nakolektang datos kung may mga pagbabago sa mga datos na ibinigay.

KARAPATANG TUMANGGI O ITIGIL ANG PARTISIPASYON

Maaring hindi kayo sumali sa pag-aaral na ito. Ang pagpili kung sasali o hindi sa pagaaral na ito ay hindi makaaapekto sa mga serbisyong matatanggap sa PGH kung sakaling kakailanganin ninyong magpagamot sa nasabing institusyon. Maaring itigil ang paglalahok sa VE experience sa kung kailan ninyo nais.

Maaari ring ihinto ng doktor na nagsasagawa ng pag-aaral o ng tagapagtaguyod na ahensiya ang iyong paglahok sa pag-aaral nang walang pahintulot mo sa anumang oras para sa mga sumusunod na dahilan:

- kung tilang medikal na makakasakit ito sa iyo,
- kung hindi mo nasundan ang mga direksiyon sa paglahok sa pag-aaral,

- kung natuklasang hindi mo natutugunan ang mga inaatas sa pag-aaral, o
- kung ang pag-aaral ay nasuspinde o nakansela.

PANGPRIBADO NG IMPORMASYON

Ikaw ay may karapatan na malaman ang buong resulta ng pag-aaral na tio at maaari mong ihingi ang mga resulta ng pag-aaral na tio. At kahit na wala kang direktong pag-access sa iyong mga talaan, mayroon kang karapatan na malaman ang mga datos na importante tungkol sa iyo. Ang lahat ng resulta ng pag-aaral, tulad ng karanasan sa paggamit ng VE application, ay pananatilihing kumpidensyal. Ang lahat ng resulta ng pananaliksik na ito, tulad ng VE application experience, ay pananatilihing pribado. Ang lahat ng datos na naikolekta ay itatago sa isang password-protected computer at ang mga taga-suri lamang ang maaaring maka-access nito. Hindi ilalahad ang inyong pangalan sa mga kasulatang gagawin para sa pananaliksik na ito. Ang mga talaan na may pribadong datos ay pananatilihing kumpidensyal at hindi maaaring magamit ng publiko na umaalinsunod sa batas. Ang inyong pangalan at iba pang personal na impormasyon ay mananatiling kumpidensyal kapag ilathala ang mga resulta ng pananaliksik na ito. Ang mga taga-suri, study monitor, auditor, ang University of the Philippines Manila Institutional Ethics Review Board, at ang mga regulatory authority ay bibigyan ng access sa inyong impormasyon upang masiyasat ang mga ginamit na pamamaraan ng pagkolekta ng impormasyon at ang mga datos na nakolekta ng pananaliksik. Ang lahat ng talaan ay itatago lamang hanggang 5 taon mula sa pagtapos ng pagsusuri.

MGA DAPAT TAWAGAN

Kung mayroon kang mga tanong tungkol sa pag-aaral na ito, maaaring tawagan ang sumusunod:

Dr. Veeda Michelle M. Anlacan
Principal investigator
Department of Neurosciences, College of Medicine, UP Manila, Ermita, Manila
Email: michelleanlacan@gmail.com
Mobile: +639189197143

Kung mayroon kang mga tanong tungkol sa iyong karapatan bilang isang kalahok sa isang pag-aaral, maaaring tawagan ang sumusunod:

Dr. Cecilia A. Jimeno, UPMREB Panel 1 Chair
Room 126, Ground Floor, National Institutes of Health, UP Manila,
623 Pedro Gil St, Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph Tel: +63 2 8526-4346

IMPORMASYON UKOL SA PAG-AARAL

Protocol title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)

Protocol number: UPMREB-2023-0040-01

Magiging available ang paglalarawan ng klinikal na trial na ito sa www.clinicaltrials.gov gaya ng iniaatas ng batas ng U.S. Bilang karagdagan, magiging available din ito sa www.clinicaltrialsregister.eu at http://registry.healthresearch.ph/. Walang impormasyon sa mga website na ito na makakatukoy sa inyong pagkakakilanlan. Kadalasan, magsasama ang website ng buod ng mga resulta. Maaari kayong maghanap sa website na ito anumang oras.

Isang independiyenteng komite ng etika o institusyonal na lupon sa pagsusuri na accredited ng Philippine Health Research Ethics Board (PHREB) ang nag-apruba sa pag-aaral na ito.

Participant's Copy

Kung sumasang-ayon kayo, pakibasa at pagkatapos ay lumagda sa ibaba.

- Nabasa at naunawaan ko ang impormasyong ito.
- Naisulat ito sa wikang nababasa at nauunawaan ko.
- Naipaliwanag sa akin ang pag-aaral na ito.
- Ang lahat ng aking tanong tungkol sa pag-aaral, sa VR application, at sa mga posibleng panganib at side effect ay nasagot sa aking kagustuhan.
- Malaya akong sumasang-ayon na lumahok sa pananaliksik na pag-aaral na ito tulad ng inilarawan at naunawaan kong malaya akong makakaalis anumang oras sa panahon ng pag-aaral.
- Nauunawaan kong bibigyan ako ng nilagdaang kopya ng dokumentong ito upang itabi.
- Nauunawaan ko na kung pipiliin kong hindi makilahok o umalis, ang aking kasalukuyang medikal na pangangalaga ay hindi maaapektuhan ng desisyong ito.
- Sa pamamagitan ng paglagda at paglalagay ng petsa sa form ng pahintulot na ito, hindi ko isinuko ang alinman sa mga legal na karapatang maaaring mayroon ako kung hindi ako kalahok sa isang medikal na pananaliksik na pag-aaral.

Batay sa impormasyong ito, nagboluntaryo akong lumahok sa pag-aaral na ito. Lagyan ng tsek ang kahon na may pinakaangkop sagot.

Pumapayag ako sa paggamit ng aking paglalarawan sa mga litrato o video na kinuha ng mga miyembro ng grupo ng mananaliksik para sa kanilang paggamit sa mga poster, video o presentation tungkol sa proyektong ito. (Maaari ka pa ring sumali sa pag-aaral kung hindi ka pumayag dito.)	Oo	Hindi

Kumpletong naka-print na pangalan ng kalahok

Lagda ng kalahok | Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok (kung naaangkop)

Lagda ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok | Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng kumukuha ng pahintulot

Lagda ng kumukuha ng pahintulot | Petsa (dd/mm/yyyy)

Researcher's Copy

Kung sumasang-ayon kayo, pakibasa at pagkatapos ay lumagda sa ibaba.

- Nabasa at naunawaan ko ang impormasyong ito.
- Naisulat ito sa wikang nababasa at nauunawaan ko.
- Naipaliwanag sa akin ang pag-aaral na ito.
- Ang lahat ng aking tanong tungkol sa pag-aaral, sa VR application, at sa mga posibleng panganib at side effect ay nasagot sa aking kagustuhan.
- Malaya akong sumasang-ayon na lumahok sa pananaliksik na pag-aaral na ito tulad ng inilarawan at naunawaan kong malaya akong makakaalis anumang oras sa panahon ng pag-aaral.
- Nauunawaan kong bibigyan ako ng nilagdaang kopya ng dokumentong ito upang itabi.
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Kumpletong naka-print na pangalan ng kalahok

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Lagda ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok | Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng kumukuha ng pahintulot

Lagda ng kumukuha ng pahintulot | Petsa (dd/mm/yyyy)

B. Study

English Version

Participant No. _____

INFORMED CONSENT FORM

Study title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)
UPMREB code:
Study sponsor: Department of Science and Technology-Philippine Council for Health Research and Development (PCHRD-DOST)
Principal investigator: Veeda Michelle Anlacan, MD | College of Medicine, UP Manila-Philippine General Hospital, Manila City | Email: vmanlacan@up.edu.ph | Mobile: +639189197143

You are kindly invited to join a research study because you are a patient experiencing behavioral and psychological symptoms of dementia (BPSD).

Here are a few things to know as you learn more:

1. Taking part in a research study is **voluntary** and is not part of your regular healthcare
2. Before you decide, please read this form carefully so you know why the study is being done and what it involves.
3. Take your time to decide – you may take an unsigned copy of this form home to read again and discuss with your doctor, family and friends.
4. Ask the principal investigator/staff your questions
5. If the principal investigator is the same as your private doctor/attending physician, remember that you are still free to decide on your participation in the study.

Thank you for taking the time to consider taking part in this study.

Information in this Informed Consent Form may be confidential to the Sponsor. The Sponsor is sharing this information with you for the purpose of inviting you to make an informed decision about participating in the research study. We kindly ask you to consider this sensitive information when discussing details about the research study with people other than your healthcare provider(s), family and friends.

STUDY OVERVIEW

Purpose of the study

Persons living with dementia (PLWD) experience behavioral and psychological symptoms (BPSD), which are a range of signs and symptoms such as agitation, aggression, delusions, hallucinations, depression, apathy, disinhibition, anxiety, motor disturbance, and nighttime behaviors. BPSD may be treated by medication and physical restraints, but these interventions are limited by side effects and complications. Recent research has been exploring the use of virtual reality (VR) technology as a form of treatment for dementia and mild cognitive impairment, and evidence shows that VR could be used in the prevention, assessment, and treatment of patients with these conditions, although there is little evidence on its use for patients with BPSD.

In this study, we aim to see if our proposed VR intervention is effective in managing the BPSDs of PLWD. We also seek to know if it is safe and usable for these patients.

General information about the study

Thirty (30) individuals will participate in the clinical trial for a period of four (4) weeks. This informed consent form (ICF) will be valid until the end of the research project. The sponsor or the research team may learn new information about the VR application, including information related to the risks of its use, during the conduct of the study. Should any information that may affect your decision to continue participating in the study, the research team will inform you in a timely manner.

STUDY PARTICIPANTS

Patients with BPSD will participate in this study. The selection criteria include the following:

- Aged 60 years old or older
- Diagnosed with mild to moderate Alzheimer's dementia according to the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
- Montreal Cognitive Assessment-Philippines (MoCA-P) score of 10-20 inclusive
- Neuropsychiatric Inventory (NPI-12) score 1-50 inclusive
- Reisberg Scale Stage 4-5 inclusive
- Stable dose of antidepressants for the past 6 weeks
- Stable dose of antipsychotics for the past 4 weeks
- Able to walk unassisted or with minimal assistance, with or without assistive device
- No other explanation for condition based on reasonable clinical diagnostics
- No other non-amnestic dementia syndromes
- No receptive aphasia
- No active psychiatric disorder prior to Alzheimer dementia diagnosis
- No quadriplegia or paralysis of the dominant hand
- No previous episodes of seizures, diagnosis of epilepsy, or intake of antiepileptic or seizure medications
- No significant visual impairment
- No hearing impairment requiring hearing aid
- No history of motion sickness
- No experience of claustrophobia
- No diagnosis of a terminal illness or a life expectancy of less than a year

STUDY PROCEDURES

Intervention

The research team developed a VR application that is intended to become part of treatment for patients with BPSD. It is a role-playing game set in three tourist attractions in the Philippines and contains three activities based on actual non-pharmacological therapies performed to address BPSDs.

Procedure

We would like to ask you to participate in four (4) sessions. Each session will be at the College of Allied Medical Professions Clinic Therapy Services, UP Manila. You will be asked to use a VR application through a head-mounted device (HMD) or a Semi-CAVE (a type of VR theater), which will be assigned at random. The VR application includes simulations of painting, puzzle-solving, and sing-along activities, and will involve minimal movements such as reaching and grabbing. The VR application will be used for 10 to 20 minutes at a time, with 5 to 20 minutes to rest in between each use. The entire session will not take more than an hour to complete. During the experience, we will monitor and record your interaction with the VR application and in the virtual environment (VE). You will also be asked to answer a questionnaire to assess the safety and usability of the application during each session for the researchers to determine if any harm would arise from the continuous use of the application.

Participant's responsibility

If you agree to participate in this study, you must:

- Attend all scheduled visits
- Give true information about your medical history
- Advise the investigators of any changes in your medical condition during the study and during the 30 days after completing the study

RISKS, BENEFITS, AND COMPENSATION

Possible risks and/or side effects

Some risks of the VR experience are as follows:

- Cybersickness is a common reaction to VR. It manifests as various symptoms such as eye strain or soreness, nausea, and dizziness. On the development side, we have taken the necessary measures to decrease the likelihood of experiencing these side effects. A doctor or therapist will also be present to attend to your medical needs, if needed.
- Psychological effects may arise when you confuse the virtual world for the real world, and vice versa. To prevent this, you will be given time to adjust to both environments, and will be interviewed by a medical professional for post-processing, if needed.
- Possible physical injuries due to accidents may occur. The research team will do precautionary measures, such as keeping the participant seated throughout the whole experience and proper distancing of equipment

The research team will be implementing the health and safety protocol of the UP CAMP Clinic for Therapy Services as a precaution against COVID-19. This protocol will be reviewed and revised as necessary if the public health situation related to COVID-19 worsens. Another precaution is the full vaccination against COVID-19 of the research team. Your time in the facility will be limited as much as possible. You are also encouraged to take health and safety precautions in and outside the Clinic.

Materials and equipment to be used will be sanitized with rubbing alcohol before each use. Personal protective equipment such as face masks will be worn at all times while within the facility. You will also be offered the use of the comfort room to wash their hands with soap and water after using the devices.

In compliance with the health and safety protocol of the Clinic, you will be asked some questions about possible symptoms every time you come to the Clinic. If you develop COVID-19 symptoms while participating in the study and within 14 days after participating in the study, please contact the research team for a referral to the Philippine General Hospital for evaluation and possible admission.

Potential benefits

You may directly benefit from the intervention through your experience of an intervention that could be added to a patient's regular therapy activities. Your participation will help us find out how we can improve our application, and we hope that this will help clinics and rehabilitation centers in treating patients with BPSD.

Participant costs

There will be no cost for your participation in this study, except for expenses that may be incurred when traveling to the facility. The use of the application and the study-related procedures will be provided at no cost to you.

Compensation and/or treatment of study-related injury

You will receive compensation amounting to Php 1,500.00 for each scheduled session to cover travel costs and inconveniences related to your participation in the study. You will not be given any other money or gifts for participating in this study.

The research group has obtained insurance to conduct this study. If you become physically injured as a result of the product or procedures used in this study, and if instructions of the study doctor have been followed, reasonable and appropriate medical treatment will be provided without cost. The commitment to you for free medical treatment does not include treatment for any other complications or illness experienced during the course of the study if, in the opinion of the investigator, such complications or illness are not a result of your participation in this study. The costs of any other medical care are your responsibility. You will not lose any of your legal rights as a research subject by signing this consent form. The research team makes no commitment to provide compensation beyond that specified.

The results of this study are intended to develop products and/or services that may have commercial value, but you will not receive any direct commercial benefit from this.

VOLUNTARY PARTICIPATION

Participation is voluntary. You can choose to say no, and any services that you receive at the University of the Philippines-Philippine General Hospital (UP-PGH) will not change. You may ask as many questions as needed and we will take the time to answer them. We will also give you time to think about your decision. If you have already agreed and want to retract consent, you may choose to do so at any time during the study. Your consent will only be valid until the end of your participation in this study. You have the right to be informed that your personal data will be collected and processed. You may object or withhold consent to the processing of the collected data should there be any changes or amendments to the data given.

RIGHT TO REFUSE OR WITHDRAW

You may choose not to participate in this study. Choosing to participate or to not participate will not affect either your future treatment at UP-PGH. You are free to not participate in a session if you do not wish to, but you may still resume participation if you wish to participate in the succeeding one. You may stop participating in the virtual environment experience at any time that you wish without losing any of your rights to treatment at UP-PGH.

You may also be discontinued from participating in the VE experience without your consent by the doctor conducting the study or by the sponsoring agency at any time for the following reasons:

- if it appears to be medically harmful to you,
- if you fail to follow directions for participating in the study,
- if it is discovered that you do not meet the study requirements, or
- if the study is suspended or canceled.

CONFIDENTIALITY

You have the right to know the full results of this study and you can request the results of the study. And though you cannot have direct access to your records, you will maintain your right to know data relevant to yourself. All the results of this study, such as the VE application experience, would be held in confidence. All data collected will be stored in a password-protected computer and only the researchers will be able to access this. Your name will not be included in any of the reports that would be made on this study. Records identifying yourself will be kept confidential and will not be made publicly available, to the extent permitted by law. Your identity would remain confidential in the event that the study results are published. The investigators, study monitor(s), auditor(s) and the University of the Philippines Manila Institutional Ethics Review Board, and regulatory authorities will be granted direct access to your information only for purposes of verification of study procedures and data. All records will be stored only until 5 years after the completion of the study.

WHOM TO CONTACT

If you have any questions regarding the study, please feel free to contact the following:

Dr. Veeda Michelle M. Anlacan, Principal investigator
Department of Neurosciences, College of Medicine, UP Manila, Ermita, Manila
Email: michelleanlacan@gmail.com
Mobile: +639189197143

If you have any questions concerning your rights as a research participant, you may contact the following:

Dr. Cecilia A. Jimeno, UPMREB Panel 1 Chair
Room 126, Ground Floor, National Institutes of Health, UP Manila,
623 Pedro Gil St, Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph Tel: +63 2 8526-4346

STUDY INFORMATION

Protocol title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)

Protocol number: UPMREB-2023-0040-01

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. In addition, it will also be available on www.clinicaltrialsregister.eu and http://registry.healthresearch.ph/. These websites will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

An independent ethics committee or institutional review board that is accredited by the Philippine Health Research Ethics Board (PHREB) has approved this study.

Participant's Copy

If you consent, please read and then sign below.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the VR application, and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or laboratories to release information to Dr. Veeda Michelle Anlacan, the AXEL research group, Sponsor, agents of the Sponsor, other governmental agencies, and the IRB/IEC about my disease and treatment for the purposes of this study. I understand this information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.
- I understand that if I choose to not participate or to withdraw, my current medical care will not be affected by this decision.
- By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participant in a medical research study.

Based on this information, I volunteer to take part in this study. Kindly check the box with the most appropriate response.

I have been informed that the principal investigator/staff may inform my other doctors about my participation in this study, and I agree to this. (You may still be in this study even if you do not agree to this.)	Yes	No	N/A
I agree to be contacted by a third party of the sponsor to provide feedback about my participation in the study. My feedback results will be shared anonymously with the sponsor. (You may still be in this study even if you do not agree to this.)	Yes	No	-
I agree to the use of my likeness in the photos and/or videos captured by the research team for future use in posters, videos and presentations related to the project. (You may still be in this study even if you do not agree to this.)	Yes	No	-

You will receive a signed copy of this informed consent form.

Full printed name of participant

Signature of participant | Date (dd/mm/yyyy)

Full printed name of person obtaining consent

Signature of person obtaining consent | Date (dd/mm/yyyy)

Legally Authorized Representative Signature, if applicable:

Full printed name of legally authorized representative

Signature of legally authorized representative | Date (dd/mm/yyyy)

Relationship of legally authorized representative to the participant

Researcher's Copy

If you consent, please read and then sign below.

- I have read and understood this information.
- It has been written in a language that I can read and understand.
- This study has been explained to me.
- All my questions about the study, the VR application, and possible risks and side effects have been answered to my satisfaction.
- I give permission for my doctors, other health professionals, hospitals, or laboratories to release information to Dr. Veeda Michelle Anlacan, the AXEL research group, Sponsor, agents of the Sponsor, other governmental agencies, and the IRB/IEC about my disease and treatment for the purposes of this study. I understand this information will remain confidential.
- I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study.
- I understand that I will be given a signed copy of this document to keep.
- I understand that if I choose to not participate or to withdraw, my current medical care will not be affected by this decision.
- By signing and dating this consent form, I have not waived any of the legal rights that I would have if I were not a participant in a medical research study.

Based on this information, I volunteer to take part in this study. Kindly check the box with the most appropriate response.

I have been informed that the principal investigator/staff may inform my other doctors about my participation in this study, and I agree to this. (You may still be in this study even if you do not agree to this.)	Yes	No	N/A
I agree to be contacted by a third party of the sponsor to provide feedback about my participation in the study. My feedback results will be shared anonymously with the sponsor. (You may still be in this study even if you do not agree to this.)	Yes	No	-
I agree to the use of my likeness in the photos and/or videos captured by the research team for future use in posters, videos and presentations related to the project. (You may still be in this study even if you do not agree to this.)	Yes	No	-

You will receive a signed copy of this informed consent form.

Full printed name of participant

Signature of participant Date (dd/mm/yyyy)

Full printed name of person obtaining consent

Signature of person obtaining consent Date (dd/mm/yyyy)

Legally Authorized Representative Signature, if applicable:

Full printed name of legally authorized representative

Signature of legally authorized representative Date (dd/mm/yyyy)

Relationship of legally authorized representative to the participant

Filipino Version

Participant No. _____

INFORMED CONSENT FORM

Study title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)
UPMREB code:
Study sponsor: Department of Science and Technology-Philippine Council for Health Research and Development (PCHRD-DOST)
Principal investigator: Veeda Michelle Anlacan, MD | College of Medicine, UP Manila-Philippine General Hospital, Manila City | Email: vmanlacan@up.edu.ph | Mobile: +639189197143

Kayo po ay inaanyayahang lumahok sa isang pag-aaral dahil ikaw ay isang pasyente na nakararanas ng mga behavioral and psychological symptoms of dementia (BPSD).

Narito ang ilang bagay na dapat malaman habang natututo pa kayo:

1. Boluntaryo ang paglahok sa pananaliksik na ito, at hindi ito bahagi ng inyong regular na pangangalagang pangkalusugan.
2. Bago kayo magpasya, pakibasa nang mabuti ang form na ito upang malaman ninyo kung bakit isinasagawa ang pag-aaral at kung ano ang kasama rito.
3. Maglaan ng oras upang magpasya – maaari kayong mag-uwi ng walang lagdang kopya ng form na ito upang basahin ito ulit at talakayin ito sa inyong doktor, pamilya, at mga kaibigan.
4. Itanong sa punong mananaliksik/kawani ang inyong mga tanong.
5. Kung ang punong mananaliksik ay ang inyong pribadong doktor, tandaang malaya pa rin kayong magpasya tungkol sa inyong paglahok sa pag-aaral.

Salamat sa paglalaan ng inyong oras upang isaalang-alang ang paglahok sa pag-aaral na ito.

Maaaring kumpidensyal sa Sponsor ang impormasyon sa Form ng Ipinagbigay-alam na Pahintulot na ito. Ibinabahagi ng Sponsor ang impormasyong ito sa inyo para sa layunin ng pag-imbita sa inyong gumawa ng ipinagbigay-alam na pagpapasya tungkol sa paglahok sa pananaliksik na pag-aaral. Hinihiniling namin sa inyong isaalang-alang ang sensitibong impormasyong ito kapag nagtatalakay ng mga detalye tungkol sa pananaliksik na pag-aaral sa mga tao maliban sa inyong (mga) provider ng pangangalagang pangkalusugan, pamilya, at mga kaibigan.

PANGKALAHATANG-IDEYA NG PAG-AARAL

Layunin ng pag-aaral

Ang mga taong namumuhay na may dementia (persons living with dementia or PLWD) ay nakakaranas ng mga behavioral at psychological na sintomas (BPSD), na tumutukoy sa iba't ibang sintomas tulad ng pagkabahala, galit, mga delusyon at mga guni-guni, kalungkutan, kawalang-interes, hindi pagpigil sa sarili, pagkabalisa, hirap sa paggalaw, at mga gawain tuwing gabi. Maaaring gamutin ang BPSD gamit ang mga gamot at ng mga pisikal na pamamaraan, ngunit ang mga interbensyong ito ay may mga kaakibat na side effect at kumplikasyon. Naimbestigahan na ang paggamit ng virtual reality (VR) bilang isang paraan ng paggamot ng mga pasyenteng may dementia at mild cognitive impairment, at ayon sa ebidensiya, maaaring gamitin ito sa pag-iwas, pagsuri, at paggamot ng mga pasyenteng may mga sakit na ito, ngunit kaunti ang ebidensya sa paggamit nito para sa mga pasyenteng may BPSD.

Sa pag-aaral na ito, nais naming makita kung epektibo ang nagawa naming VR intervention para sa pagpapagamot ng BPSD ng mga PLWD. Nais din naming matuklasan kung ito ba ay ligtas at madaling gamitin para sa mga pasyenteng ito

Pangkalahatang impormasyon tungkol sa pag-aaral

Tatlumpung (30) indibidwal ang aanyayahang sumali sa initial clinical study na ito sa loob ng apat (4) na linggo. Ang informed consent form (ICF) na ito ay may bisa hanggang matapos ang aming pag-aaral. Maaaring may malaman ang sponsor o ang research team na bagong impormasyon tungkol sa VR application, tulad ng impormasyon tungkol sa mga panganib nito, habang isinasagawa ang pag-aaral. Sasabihan kayo ng punong mananaliksik/kawani nang napapanahon kung may anumang bagong impormasyon na maaaring magpabago sa inyon gisip tungkol sa paglahok sa pag-aaral.

MGA KALAHOK NG PAG-AARAL

Ang mga pasyenteng may BPSD ay lalahok sa pag-aaral na ito. Ang batayan ng pagpili ng mga kalahok ay ang sumusunod:

- May edad 60 taong gulang pataas
- May mild to moderate na Alzheimer's dementia ayon sa National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria
- MOCA-P score 10-20
- NPI-12 score 1-50 inclusive
- Reisberg Scale Stage 4-5 inclusive
- Stable dose of antidepressants sa nakaraang 6 na linggo
- Stable dose of antipsychotics sa nakaraang 4 na linggo
- Kayang maglakad ng walang tulong o ng kaunting tulong, gumagamit man o hindi ng assistive device
- Walang ibang sanhi para sa karamdaman na base sa mga clinical diagnostics
- Walang ibang non-amnestic dementia syndromes
- Walang kahirapan sa pag-intindi ng mga nakasulat, binibigkas, o nahahawakang mga simbolo
- Walang active psychiatric disorder bago ang diagnosis ng Alzheimer dementia
- Walang panghihina sa dominanteng kamay
- Walang karanasan ng seizure, diagnosis ng epilepsy, o pag-inom ng mga antiepileptic o seizure na gamot
- Walang kapansanan sa paningin
- Walang kapansanan sa pandinig na nangangailangan ng hearing aid
- Walang karanasan ng motion sickness
- Walang karanasan ng claustrophobia
- Walang malubhang sakit at life expectancy na hindi hihigit ng isang taon

MGA PAMAMARAAN NG PAG-AARAL

Interbensyon

Gumawa ang research team ng isang VR application na maaring maging paraan ng paggamot para sa mga pasyenteng may BPSD. Ito ay isang role-playing game na nakatagpo sa tatlong sikat na lugar pangturista sa Pilipinas at naglalaman ng tatlong aktibidad na base sa mga aktwal na non-pharmacological therapies na ginagawa para matugunan ang mga BPSD.

Pamamaran

Hinihikayit ka namin na sumali sa apat (4) na sesyon. Ang bawat sesyon ay gaganapin sa College of Allied Medical Professions Clinic Therapy Services, UP Manila. Kayo po ay aanyayahang gumamit ng isang VR application gamit ng head-mounted device (HMD) o ng Semi-CAVE (a type of VR theater), na itatakda sa inyo nang random. Ang mga sumusunod na aktibidad ay inyong isasagawa habang ginagamit ang VR application: mga simulation ng pagpinta, pagbuo ng puzzle, at pagkanta. Kakailangangin ninyong gumalaw habang isinasagawa ang mga aktibidad, tulad ng pag-abot at pagkuha. Ang VR application ay gagamitin nang 10 hanggang 20 minuto sa bawat paggamit, na may 5 hanggang 20 na minuto para magpahinga sa pagitan ng bawat paggamit. Hindi lalagpas ng isang oras para makumpleto ang buong session. Habang isinasagawa ang VR experience, imo-monitor at ire-rekord ang iyong pakikihalubilo sa VR application at sa virtual environment (VE). May ipapasagot din sa inyo na mga katanungan para masuri ang safety at usability ng application sa bawat sesyon upang malaman ng mga tagasuri kung may pinsala na dulot sa tuluy-tuloy na paggamit ng application.

Responsibilidad ng kalahok

Kung sang-ayon kang lumahok sa pag-aaral na ito, dapat:

- Dumalo sa lahat ng mga naka-iskedyul na pagbisita
- Magbigay ng tunay na impormasyon tungkol sa medikal na kalagayan mo
- Payuhan ang mga imbestigador ng anumang pagbabago sa medikal na kalagayan mo habang isinasagawa ang pag-aaral at sa 30 araw matapos kumpletuhin ang pag-aaral.

MGA POSIBLENG PELIGRO, BENEPISYO, AT BAYAD

Mga posibleng peligro at/o side effect

Ang ilang panganib na maaaring maranasan dahil sa VE experience ay:

- Ang cybersickness ay isang karaniwang reaksyon sa VR. Ito ay maaaring maranasan sa pamamagitan ng pagkapagod ng mata, pakiramdam na nasusuka o naduduwal, at pagkahilo. Pinaniguradong binuo itong teknolohiyang ito upang mabawasan ang posibilidad na mangyari ang mga sintomas na ito. Mayroon ding mga kasamang duktor o therapist na naroroon upang tumugon sa iyong mga medikal na pangangailangan.
- Posibleng may maranasang mga epektong sikolohikal tulad ng pagkalito sa virtual world at sa realidad, at kabaliktaran. Upang maiwasan ito, bibigyan ka ng oras para maging pamilyar sa kapaligiran, at may eksperto na magsasagawa ng panayam kada matapos ang isang sesyon kung kailangan.
- Maaring magkaroon ng pinsala dulot ng aksidente. Ang grupo ng mananaliksik ay gagawa ng mga hakbang sa pag-iingat gaya ng pagpapanatiling nakaupo sa kalahok habang isinasagawa ang VE experience at ang tamang distansya ng mga kagamitan.

Susundin ng mga mananaliksik ang mga patakarang pangkalusugan at pangkaligtasan ng UP CAMP Clinic for Therapy Services upang maiwasan ang pagkalat ng COVID-19 Ang patakaran na ito ay susuriin at ia-update kung kailangan kung lumala ang kasalukuyang sitwasyon ng COVID-19. Ang isa pang pag-iingat na gagawin ay ang pagsigurado na lahat ng mga mananaliksik ay bakunado laban sa COVID-19. Lilimitahan din ang bilang ng mga tao at ang oras ng pananatili sa pasilidad. Hinihikayat namin kayong magsagawa rin ng mga pag-iingat laban sa COVID-19 sa loob at sa labas ng Clinic.

Ang mga gamit na kakailanganin para sa virtual reality experience ay lilinisin gamit ng rubbing alcohol bago ang bawat paggamit. Ang tamang pansariling kagamitan sa pangangalaga gaya ng face mask ay isusuot sa lahat

ng oras. Maaari mo ring gamitin ang comfort room upang maghugas ng kamay gamit ng malinis na tubig at sabon pagkatapos hawakan ang mga kagamitan ng virtual reality experience.

Alinsunod sa mga patakarang pangkalusugan at pangkaligtasan ng Clinic, may magtatanong sa inyo ng mga katanungan ukol sa mga posibleng sintomas ng COVID-19 sa bawat pagpunta sa Clinic.

Posibleng benepisyo

Maaari kang makaranas ng benepisyo sa pamamagitan ng paggamit ng isang interbensyon para sa BPSD. Matutulungan ninyo kaming matuklasan kung paano maipapaganda ang aming application, at umaasa kaming makakatulong ito sa mga klinika at mga pasilidad na gumagamot sa mga pasyenteng may BPSD.

Gastos sa kalahok

Wala kang gagastusin sa paglahok sa pag-aaral na ito, bukod sa gagastusin sa pagbiyahe papunta sa pasilidad. Ang paggamit ng application at ang mga pamamaraang kaugnay ng pag-aaral ay ibibigay sa iyo nang libre.

Bayad at/o paggamot ng pinsalang kaugnay ng pag-aaral

Makakatanggap ka ng bayad na may halagang Php 1,500.00 para sa bawat na naiskedyul na sesyon para sa oras at abala na kaugnay ng iyong paglahok sa pag-aaral na ito. HIndi ka bibigyan ng iba pang pera o regala para sa iyong pagsali sa pag-aaral na ito.

Kumuha ang grupo ng mananaliksik ng insurance para isagawa ang pag-aaral na ito. Kung may pisikal na pinsala bilang resulta ng produkto o mga pamamaraang ginamit sa pag-aaral na ito at kung sinundan ang mga tagubilin ng doktor sa pag-aaral, bibigyan ka ng libre, maktwiran at angkop na medikal na paggamot. Ang pangakong ito para sa kalahok para sa libreng medikal na paggamot ay walang kasamang paggamot para sa anumang ibang kumplikasyon o sakit na nararanasan sa kurso ng pag-aaral na ito, kung sa opinyon ng Imbestigador ang mga nasabing kumplikasyon o sakit ay hindi resulta ng partisipasyon ng inyong anak sa pag-aaral na ito. Ang gastos sa anumang ibang medikal na pag-aalaga ay responsibilidad ninyo. Hindi mawawalan ng alinman sa mga legal karapatan ang inyong anak bilang kalahok ng pananaliksik sa pamamagitan ng paglagda sa consent form na ito. Hindi nangangako ang grupo ng mananaliksik na magbigay ng bayad na lagpas sa natukoy.

Ang mga resulta ng pag-aaral na ito ay gagamitin sa paggawa ng mga produkto at/o serbisyo na may commercial na halaga, ngunit wala kang matatanggap na direktong benepisyong komersyal mula rito.

BOLUNTARYONG PAGLAHOK

Boluntaryo ang paglahok sa pag-aaral na ito. Maaari kang tumanggi, at hindi maaapektuhan ang anumang serbisyong iyong natatanggap mula sa University of the Philippines-Philippine General Hospital (UP-PGH). Maaring magtanong nang marami at maglalaan kami ng sapat na oras para sagutin ang mga ito. Bibigyan ka rin namin ng panahon upang pag-isipan ang iyong desisyon. Kung ikaw ay pumayag na at nais bawiin ang iyong pagpayag, maaari mo itong gawin sa kahit anong punto ng pag-aaral. May bisa ang iyong pagpayag na sumali hanggang sa dulo ng iyong paglahok sa pag-aaral na ito. Ikaw ay may karapatan na malaman na kukunin at ipro-proseso ang iyong personal na impormasyon. Maaari kang tumanggi o ipagkait ang pagpayag sa pagproseso ng nakolektang datos kung may mga pagbabago sa mga datos na ibinigay.

KARAPATANG TUMANGGI O ITIGIL ANG PARTISIPASYON

Maaring hindi kayo sumali sa pag-aaral na ito. Maaring hindi sumali sa isang sesyon kung ayaw ninyong sumali para sa araw na iyon, ngunit maaari pa rin kayong makilahok kung nais ninyong sumali sa susunod na sesyon. Ang pagpili kung sasali o hindi sa pagaaral na ito ay hindi makaaapekto sa mga serbisyong matatanggap sa PGH kung sakaling kakailanganin ninyong magpagamot sa nasabing institusyon. Maaring itigil ang paglalahok sa VE experience sa kung kailan ninyo nais.

Maaari ring ihinto ng doktor na nagsasagawa ng pag-aaral o ng tagapagtaguyod na ahensiya ang iyong paglahok sa pag-aaral nang walang pahintulot mo sa anumang oras para sa mga sumusunod na dahilan:

- kung tilang medikal na makakasakit ito sa iyo,

- kung hindi mo nasundan ang mga direksiyon sa paglahok sa pag-aaral,
- kung natuklasang hindi mo natutugunan ang mga inaatas sa pag-aaral, o
- kung ang pag-aaral ay nasuspinde o nakansela.

PANGPRIBADO NG IMPORMASYON

Ikaw ay may karapatan na malaman ang buong resulta ng pag-aaral na tio at maaari mong ihingi ang mga resulta ng pag-aaral na tio. At kahit na wala kang direktong pag-access sa iyong mga talaan, mayroon kang karapatan na malaman ang mga datos na importante tungkol sa iyo. Ang lahat ng resulta ng pag-aaral, tulad ng karanasan sa paggamit ng VE application, ay pananatilihing kumpidensyal. Ang lahat ng resulta ng pananaliksik na ito, tulad ng VE application experience, ay pananatilihing pribado. Ang lahat ng datos na naikolekta ay itatago sa isang password-protected computer at ang mga taga-suri lamang ang maaaring maka-access nito. Hindi ilalahad ang inyong pangalan sa mga kasulatang gagawin para sa pananaliksik na ito. Ang mga talaan na may pribadong datos ay pananatilihing kumpidensyal at hindi maaaring magamit ng publiko na umaalinsunod sa batas. Ang inyong pangalan at iba pang personal na impormasyon ay mananatiling kumpidensyal kapag ilathala ang mga resulta ng pananaliksik na ito. Ang mga taga-suri, study monitor, auditor, ang University of the Philippines Manila Institutional Ethics Review Board, at ang mga regulatory authority ay bibigyan ng access sa inyong impormasyon upang masiyasat ang mga ginamit na pamamaraan ng pagkolekta ng impormasyon at ang mga datos na nakolekta ng pananaliksik. Ang lahat ng talaan ay itatago lamang hanggang 5 taon mula sa pagtapos ng pagsusuri.

MGA DAPAT TAWAGAN

Kung mayroon kang mga tanong tungkol sa pag-aaral na ito, maaaring tawagan ang sumusunod:

Dr. Veeda Michelle M. Anlacan, Principal investigator
Department of Neurosciences, College of Medicine, UP Manila, Ermita, Manila
Email: michelleanlacan@gmail.com
Mobile: +639189197143

Kung mayroon kang mga tanong tungkol sa iyong karapatan bilang isang kalahok sa isang pag-aaral, maaaring tawagan ang sumusunod:

Dr. Cecilia A. Jimeno, UPMREB Panel 1 Chair
Room 126, Ground Floor, National Institutes of Health, UP Manila,
623 Pedro Gil St, Ermita 1000 Manila
Email: upmreb@post.upm.edu.ph Tel: +63 2 8526-4346

IMPORMASYON UKOL SA PAG-AARAL

Protocol title: Developing Immersive Gamification Technology Systems for the Management of Patients with Alzheimer's Disease with Behavioral and Psychological Symptoms of Dementia (Phase 2 Trial)

Protocol number: UPMREB-2023-0040-01

Magiging available ang paglalarawan ng klinikal na trial na ito sa www.clinicaltrials.gov gaya ng iniaatas ng batas ng U.S. Bilang karagdagan, magiging available din ito sa www.clinicaltrialsregister.eu at http://registry.healthresearch.ph/. Walang impormasyon sa mga website na ito na makakatukoy sa inyong pagkakakilanlan. Kadalasan, magsasama ang website ng buod ng mga resulta. Maaari kayong maghanap sa website na ito anumang oras.

Isang independiyenteng komite ng etika o institusyonal na lupon sa pagsusuri na accredited ng Philippine Health Research Ethics Board (PHREB) ang nag-apruba sa pag-aaral na ito.

Participant's Copy

Kung sumasang-ayon kayo, pakibasa at pagkatapos ay lumagda sa ibaba.

- Nabasa at naunawaan ko ang impormasyong ito.
- Naisulat ito sa wikang nababasa at nauunawaan ko.
- Naipaliwanag sa akin ang pag-aaral na ito.
- Ang lahat ng aking tanong tungkol sa pag-aaral, sa VR application, at sa mga posibleng panganib at side effect ay nasagot sa aking kagustuhan.
- Malaya akong sumasang-ayon na lumahok sa pananaliksik na pag-aaral na ito tulad ng inilarawan at naunawaan kong malaya akong makakaalis anumang oras sa panahon ng pag-aaral.
- Nauunawaan kong bibigyan ako ng nilagdaang kopya ng dokumentong ito upang itabi.
- Nauunawaan ko na kung pipiliin kong hindi makilahok o umalis, ang aking kasalukuyang medikal na pangangalaga ay hindi maaapektuhan ng desisyong ito.
- Sa pamamagitan ng paglagda at paglalagay ng petsa sa form ng pahintulot na ito, hindi ko isinuko ang alinman sa mga legal na karapatang maaaring mayroon ako kung hindi ako kalahok sa isang medikal na pananaliksik na pag-aaral.

Batay sa impormasyong ito, nagboluntaryo akong lumahok sa pag-aaral na ito. Lagyan ng tsek ang kahon na may pinakaangkop sagot.

Ipinaalam sa akin na maaaring sasabihin ng punong mananaliksik/kawani ng pag-aaral sa iba pa ko pang mga doktor ang tungkol sa paglahok ko sa pag-aaral na ito, at sumasang-ayon ako rito. (Makakasali pa rin kayo sa pag-aaral na ito kahit na hindi kayo sumasang-ayon dito.)	Oo	Hindi	N/A
Sumasang-ayon akong maaaring makipag-ugnayan sa akin ang isang third party ng sponsor upang magbigay ng feedback tungkol sa aking pakikilahok sa pag-aaral. Ibabahagi sa sponsor ang mga resulta ng aking feedback sa anonymous na paraan. (Makakasali pa rin kayo sa pag-aaral na ito kahit na hindi kayo sumasang-ayon dito.)	Oo	Hindi	-
Pumapayag ako sa paggamit ng aking paglalarawan sa mga litrato o video na kinuha ng mga miyembro ng grupo ng mananaliksik para sa kanilang paggamit sa mga poster, video o presentation tungkol sa proyektong ito. (Maaari ka pa ring sumali sa pag-aaral kung hindi ka pumayag dito.)	Oo	Hindi	-

Kumpletong naka-print na pangalan ng kalahok

Lagda ng kalahok

Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok (kung naaangkop)

Lagda ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok

Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng kumukuha ng pahintulot

Lagda ng kumukuha ng pahintulot

Petsa (dd/mm/yyyy)

Researcher's Copy

Kung sumasang-ayon kayo, pakibasa at pagkatapos ay lumagda sa ibaba.

- Nabasa at naunawaan ko ang impormasyong ito.
- Naisulat ito sa wikang nababasa at nauunawaan ko.
- Naipaliwanag sa akin ang pag-aaral na ito.
- Ang lahat ng aking tanong tungkol sa pag-aaral, sa VR application, at sa mga posibleng panganib at side effect ay nasagot sa aking kagustuhan.
- Malaya akong sumasang-ayon na lumahok sa pananaliksik na pag-aaral na ito tulad ng inilarawan at naunawaan kong malaya akong makakaalis anumang oras sa panahon ng pag-aaral.
- Nauunawaan kong bibigyan ako ng nilagdaang kopya ng dokumentong ito upang itabi.
- Nauunawaan ko na kung pipiliin kong hindi makilahok o umalis, ang aking kasalukuyang medikal na pangangalaga ay hindi maaapektuhan ng desisyong ito.
- Sa pamamagitan ng paglagda at paglalagay ng petsa sa form ng pahintulot na ito, hindi ko isinuko ang alinman sa mga legal na karapatang maaaring mayroon ako kung hindi ako kalahok sa isang medikal na pananaliksik na pag-aaral.

Batay sa impormasyong ito, nagboluntaryo akong lumahok sa pag-aaral na ito. Lagyan ng tsek ang kahon na may pinakaangkop sagot.

Ipinaalam sa akin na maaaring sasabihin ng punong mananaliksik/kawani ng pag-aaral sa iba pa ko pang mga doktor ang tungkol sa paglahok ko sa pag-aaral na ito, at sumasang-ayon ako rito. (Makakasali pa rin kayo sa pag-aaral na ito kahit na hindi kayo sumasang-ayon dito.)	Oo	Hindi	N/A
Sumasang-ayon akong maaaring makipag-ugnayan sa akin ang isang third party ng sponsor upang magbigay ng feedback tungkol sa aking pakikilahok sa pag-aaral. Ibabahagi sa sponsor ang mga resulta ng aking feedback sa anonymous na paraan. (Makakasali pa rin kayo sa pag-aaral na ito kahit na hindi kayo sumasang-ayon dito.)	Oo	Hindi	-
Pumapayag ako sa paggamit ng aking paglalarawan sa mga litrato o video na kinuha ng mga miyembro ng grupo ng mananaliksik para sa kanilang paggamit sa mga poster, video o presentation tungkol sa proyektong ito. (Maaari ka pa ring sumali sa pag-aaral kung hindi ka pumayag dito.)	Oo	Hindi	-

Kumpletong naka-print na pangalan ng kalahok

Lagda ng kalahok | Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok (kung naaangkop)

Lagda ng tagapag-alaga/legal na awtorisadong kinatawan ng kalahok | Petsa (dd/mm/yyyy)

Kumpletong naka-print na pangalan ng kumukuha ng pahintulot

Lagda ng kumukuha ng pahintulot | Petsa (dd/mm/yyyy)

C. Intervention Flier

This flier will be given to participants along with the ICF.

English Version

"Suroy-Suroy"

A Virtual Reality Prototype for Patients with Behavioral and Psychological Symptoms of Dementia

Suroy-Suroy is a role-playing game with activities based on existing therapy activities (such as orientation therapy, reminiscence therapy, art therapy, and music therapy) that are used to manage behavioral and psychological symptoms of dementia (BPSD). The goal of the game is to invoke pleasant memories in the user as they visit the simulated places and do the activities through virtual reality (VR). The VR application will involve minimal movements such as reaching and grabbing.

It contains the following activities:

- A **flower-painting** game where a user will color all the flowers in the vase using an in-game paintbrush and palette.
- A **car assembly** game where a user will put together the pieces of a car, similar to a puzzle.
- A **sing-along** game where a user will sing and shake maracas along with a virtual companion.

`The following devices will be used:

- The HMD system (Fig. 1) uses a commercially available VR headset, the Oculus/Meta Quest 2, which allows a user to view a virtual environment (VE) in 360 degrees and to interact with the environment using hand-tracking technology (i.e., when a user's hand is projected into the virtual world to be used for interactions and gestures).
- The semi-CAVE system (Fig. 2) uses projectors and projector screens to provide a 270-degree view of the VE. These projectors are connected to a powerful workstation (desktop computer), which uses HTC Vive trackers and base stations to track user movements and interactions

Figure 1. The Oculus/Meta Quest 2.

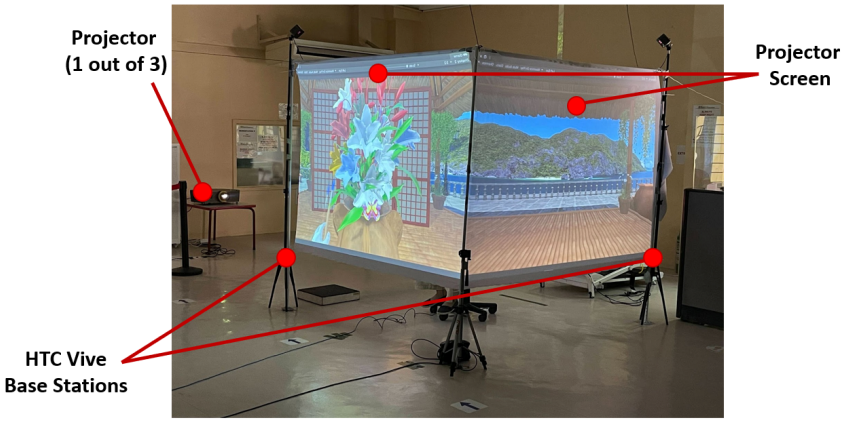


Figure 2. Equipment used for the semi-CAVE testing setup

Filipino Version

“Suroy-Suroy”

Isang Virtual Reality Prototype para sa mga Pasyenteng may Behavioral at Psychological Symptoms ng Dementia

Ang ***Suroy-Suroy*** ay isang role-playing game na may mga aktibidad na ginawa base sa aktwal na therapy activities (tulad ng orientation therapy, reminiscence therapy, art therapy, at music therapy) na ginagamit para paggamot ng behavioral at psychological symptoms ng dementia (BPSD). Ang layunin ng laro ay ang magpaalala ng mga magagandang karanasan ng manlalaro habang bumibisita sila sa mga na-simulate na lugar at kumikilos gamit ang virtual reality (VR). Mga simpleng pagkilos lamang ang kailangang gawin sa VR application na ito, tulad ng pag-abot at pagkuha ng gamit.

Ito ay binubuo ng mga sumusunod na aktibidad:

- Isang **flower-painting** game kung saan kukulayan ng manlalaro ang lahat ng bulaklak sa isang plotera gamit ng virtual na paintbrush at palette.
- Isang **car assembly** game kung saan kailangang buuin ng isang manlalaro ang isang kotse tulad ng pagbuo sa isang puzzle.
- Isang **sing-along** game kung saan sasabayan ng manlalaro ang kanyang virtual na kasama sa kanyang pag-awit habang inaalog ang hawak na mga maraca.

Gagamitin ang mga sumusunod na device:

- Ang HMD system (Fig. 1) ay gumagamit ng isang nabibiling VR headset, ang Oculus/Meta Quest 2, na nagbibigay kakayahan sa gumagamit nito na makakita ng isang virtual environment (VE) na pumapalibot sa kanila at na maka-interact sa environment na ito gamit ng hand-tracking technology (i.e., ang pag-project ng kamay ng isang manlalaro sa virtual environment upang magamit sa mga interaction at gesture).
- Ang semi-CAVE system (Fig. 2) ay gumagamit ng mga projector at ng mga projector screen upang magpakita ng 270-degree view ng VE. Ang mga projector na ito ay nakakabit sa isang malakas na work-station (desktop computer) na gumagamit ng mga HTC Vive tracker at ng mga base station upang sundan ang paggalaw at pag-interact ng isang manlalaro

Figure 1. Ang Oculus/Meta Quest 2.

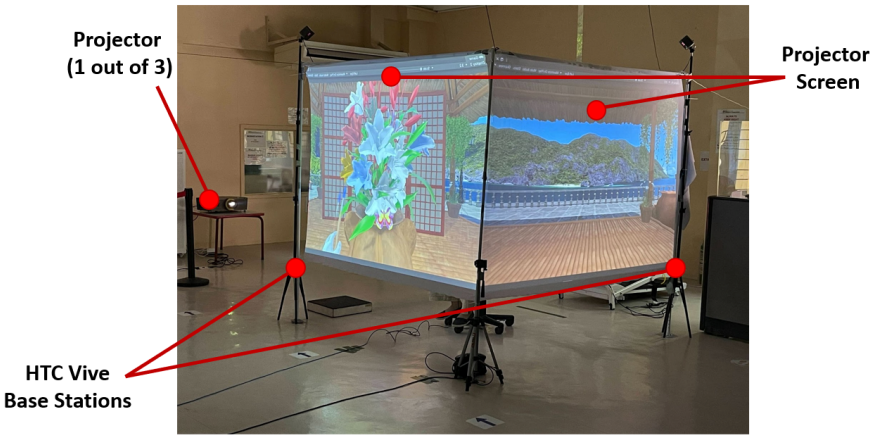


Figure 2. Mga kagamitan para sa semi-CAVE testing setup

ANNEX 4. Data collection instruments

A. Demographic

1. Birthdate (mm/dd/yyyy): _____

2. Sex: [ ] Male [ ] Female [ ] Others, specify _____

3. Educational attainment: [ ] Elementary and below
[ ] High school
[ ] Vocational school
[ ] College
[ ] Post-graduate

4. Marital status: [ ] Single
[ ] Married/Common law
[ ] Divorced/Separated
[ ] Widowed

5. Current living situation: [ ] On your own
[ ] With family
[ ] In a home care institution
[ ] With a reliable caregiver/informant

6. Current illnesses: _____
_____
_____
_____

7. Current medications: _____
_____
_____
_____

8. Hobbies: _____
_____
_____
_____

9. Past experience with VR: [ ] No [ ] Yes, specify: _____

A. Acceptability

Sample FGD questions (based on Escalante-Gonzalbo et al., 2021)

1. How did you feel when you played the VR game? (*Ano ang naramdaman mo noong nilaro mo ang VR game?*)
2. What did you like most about the VR game? (*Ano ang pinakanagustuhan mo tungkol sa VR game?*)
3. What did you like least about the VR game? (*Ano ang pinaka-hindi nagustuhan mo tungkol sa VR game?*)
4. Were you willing to take the VR platform home? (*Gusto mo bang iuwi ang VR platform sa bahay?*)
5. Would you recommend the platform to other patients? (*Irerekomenda mo ba ang VR platform sa ibang mga pasyente?*)
6. What would you improve about the VR game? (*Ano ang iyong nais baguhin sa VR game?*)

B. Clinical effectiveness

NEUROPSYCHIATRIC INVENTORY QUESTIONNAIRE

ID NUMBER: ☐☐☐☐☐☐ FORM CODE: N P I DATE: 04/01/2016 Version 1.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: ☐☐/☐☐/☐☐☐☐ (Month / Day / Year) 0b. Staff ID: ☐☐☐

Instructions: *This form is administered to the informant. {S} refers to subject, please state subject's name where {S} is found below. The following questions are based upon changes in neuropsychiatric symptoms over the previous month.*

Script: "Now I will ask you questions about your husband/ wife/ brother/ sister/ parent/ friend's behavior and personality."

	Yes	No	Severity: Mild	Moderate	Severe
1. DELUSIONS: Does {S} believe that others are stealing from him or her, or planning to harm him or her in some way?	1a. ☐Y	☐N	1b. ☐1	☐2	☐3
2. HALLUCINATIONS: Does {S} act as if he or she hears voices? Does he or she talk to people who are not there?	2a. ☐Y	☐N	2b. ☐1	☐2	☐3
3. AGITATION OR AGGRESSION: Is {S} stubborn and resistive to help from others?	3a. ☐Y	☐N	3b. ☐1	☐2	☐3
4. DEPRESSION OR DYSPHORIA: Does {S} act as if he or she is sad or in low spirits? Does he or she cry?	4a. ☐Y	☐N	4b. ☐1	☐2	☐3
5. ANXIETY: Does {S} become upset when separated from you? Does he or she have any other signs of nervousness, such as shortness of breath, sighing, being unable to relax, or feeling excessively tense?	5a. ☐Y	☐N	5b. ☐1	☐2	☐3

	Yes	No	Severity: Mild	Moderate	Severe
6. ELATION OR EUPHORIA Does {S} appear to feel too good or act excessively happy?	6a. ☐Y	☐N	6b. ☐1	☐2	☐3
7. APATHY OR INDIFFERENCE: Does {S} seem less interested in his or her usual activities and plans of others?	7a. ☐Y	☐N	7b. ☐1	☐2	☐3
8. DISINHIBITION: Does {S} seem to act impulsively? For example, does the patient talk to strangers as if he or she know them, or does the patient say things that may hurt people's feelings?	8a. ☐Y	☐N	8b. ☐1	☐2	☐3
9. IRRITABILITY OR LABILITY: Is {S} impatient or cranky? Does he or she have difficulty coping with delays or waiting for planned activities?	9a. ☐Y	☐N	9b. ☐1	☐2	☐3
10. MOTOR DISTURBANCE: Does {S} engage in repetitive activities, such as pacing around the house, handling buttons, wrapping string, or doing other things repeatedly?	10a. ☐Y	☐N	10b. ☐1	☐2	☐3
11. NIGHTIME BEHAVIORS: Does {S} awaken you during the night, rise too early in the morning or take excessive naps during the day?	11a. ☐Y	☐N	11b. ☐1	☐2	☐3
12. APPETITE AND EATING: Has {S} lost or gained weight, or had a change in the food he or she likes?	12a. ☐Y	☐N	12b. ☐1	☐2	☐3

C. Safety

Participant No. _____Date _____ Session No. _____

Instruction: Please circle how much each symptom below is affecting you right now. (*Bilugan kung gaano kalala ang nararamdamang sintomas.*)

General discomfort (*Masama ang pakiramdam*)	None	Slight	Moderate	Severe
Fatigue (*Pagod*)	None	Slight	Moderate	Severe
Eye strain (*Pagod ang mga mata*)	None	Slight	Moderate	Severe
Difficulty focusing (*Nahihirapang itutok ang pansin*)	None	Slight	Moderate	Severe
Headache (*Masakit ang ulo*)	None	Slight	Moderate	Severe
Fullness of head (*Mabigat ang pakiramdam ng ulo*)	None	Slight	Moderate	Severe
Blurring of vision (*Lumalabo-labo ang paningin*)	None	Slight	Moderate	Severe
Dizzy (eyes closed) (*Nahihilo pag nakapikit*)	None	Slight	Moderate	Severe
Vertigo (*Nahihilo pag nakamulat*)	None	Slight	Moderate	Severe

D. Usability

Participant No. _____Date _____ Session No. _____

Instruction: Score the following 10 items with one of five responses that range from 'Strongly disagree' to 'Strongly agree' (*Itala ang puntos ng mga sumusunod na pangungusap gamit ng isa sa limang posibleng tugon mula sa 'Matinding pagtutol' hanggang sa 'Matinding pagsang-ayon'*)

	Strongly disagree				Strongly agree
1. I think that I would like to use the VR application frequently (*Tingin ko madalas kong gugustuhing gamitin ang VR application na ito*)	1	2	3	4	5
2. I found the VR application unnecessarily complex (*Masyadong kumplikado ang VR application na ito*)	1	2	3	4	5
3. I thought the VR application was easy to use (*Tingin ko madaling gamitin ang VR application na ito*)	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this VR application (*Tingin ko kailangan ko ng tulong mula sa isang marunong sa teknolohiya para magamit ang VR application na ito*)	1	2	3	4	5
5. I found the various functions in this system were well integrated (Tingin ko ang mga function o katangian sa sistemang ito ay gumagana na parang isang buo)	1	2	3	4	5

6. I thought there was too much inconsistency in this VR application (*Naisip ko na masyadong maraming hindi nagtutugma sa VR application na ito*)	1	2	3	4	5
7. I would imagine that most people would learn to use this VR application very quickly (*Tingin ko na mabilis matututo ang karamihan sa paggamit ng VR application na ito*)	1	2	3	4	5
8. I found the VR application very cumbersome to use (*Nahirapan akong gamitin ang VR application na ito*)	1	2	3	4	5
9. I felt very confident using the VR application (*Malakas ang loob kong gamitin ang VR application na ito*)	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this VR application (*Marami akong kailangang matutunan bago ko magamit ang VR application na ito*)	1	2	3	4	5

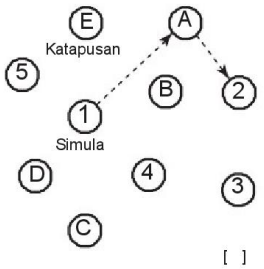
E. Secondary Outcome Measures

1. Montreal Cognitive Assessment Test: Philippines

MONTREAL COGNITIVE ASSESSMENT - PHILIPPINES (MOCA-P)

PANGALAN :
Edukasyon:
Kasarian :
Kaarawan:
PETSA:

VISUOSPATIAL / EXECUTIVE



[ ] [ ]

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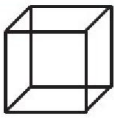
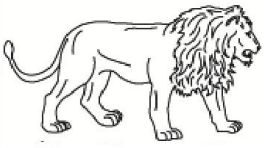


Gumuhit ng ORASAN (sampung minuto makalipas ang alas onse) (3 points)

[ ] HUGIS [ ] NUMERO [ ] KAMAY

PUNTOS __/5

NAMING



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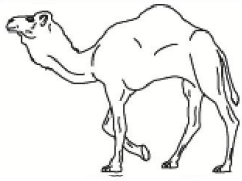


[ ] __/3

MEMORY Basahin ang listahan ng mga salita. Dapat maulit ng sinusuri ang mga ito. Gawing 2 pagsubok kahit nagtagumpay sa pang-una. Gawin ang naantalang pag-alaala pagkaraan ng 5 minutos.

	MUKHA	ASUL	SIMBAHAN	ROSAS	SEDA
Pagsubok 1					
Pagsubok 2					

Walang puntos

ATTENTION

Basahin ang mga numero. (1 numero / segundo)

Dapat ulitin ng sinusuri ang mga numero eksakto ayon sa pagkakabigkas [ ] 2 1 8 5 4
Dapat ulitin ng sinusuri ang mga numero ng pabaliktad [ ] 7 4 2 __/2

Basahin ang mga letra. Dapat tumapik ang sinusuri sa mesa sa bawat bigkas ng letra "A". Walang puntos ≥ 2 mali. [ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B __/1

Bawasan ng 7 ang 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65
4 o 5 na tamang sagot=3 puntos; 2 o 3 tama=2 puntos; 1 tama=1 puntos; 0 tama=0 puntos __/3

LANGUAGE Ulitin: Ang alam ko lang, si Juan ang siyang tutulong ngayong araw. [ ]
Ang pusa ay palaging nagtatago sa ilalim ng supa kapag nasa kuwarto ang mga aso. [ ] __/2

Katatasan / Magsabi sa loob ng 1 minuto ng mga salitang Filipino na nagsisimula sa letrang B. [ ] _____ (N ≥ 11 salita) __/1

ABSTRACTION Halimbawa: Pagkakapareho ng orange at saging = prutas [ ] tren – bisikleta [ ] timbangan - ruler __/2

DELAYED RECALL

Dapat matandaan ang mga salita ng walang tako o 'cue'	MUKHA [ ]	ASUL [ ]	SIMBAHAN [ ]	ROSAS [ ]	SEDA [ ]	Bigyan ng puntos lamang ang mga salitang natandaan ng walang tako o 'cue'
Opsyonal Kategoryang tako						
Maramihang pagpilihan						

__/5

ORIENTATION [ ] Petsa [ ] Buwan [ ] Taon [ ] Araw [ ] Lugar [ ] Lungsod __/6

© Z.Nasreddine MD Version 7.1 www.mocatest.org Normal ≥26 / 30

TOTAL __/30
Magdagdag 1puntos kapag ≤ 12 yr edu

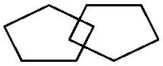
Philippine Version 4 March 2011
Adapted by Dominguez JC and the Dementia Study Group
Administered by: _____

2. Mini-Mental State Exam

Mini-Mental State Examination (MMSE)

Patient's Name: _____ Date: _____

***Instructions:* Ask the questions in the order listed. Score one point for each correct response within each question or activity.**

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital? Floor?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, …) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)
1		"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.) 
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

1

Source: www.medicine.uiowa.edu/igec/tools/cognitive/MMSE.pdf Provided by NHCQF, 0106-410

3. Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog)

Alzheimer's Disease Cooperative Study

ADAS – Cognitive Behavior

SAMPLE FORM – Page 1 of 4

Center Name	Patient Number	Patient Initials	Examiner Initials	Examination Date
	P R – –			Month Day Year

1. WORD RECALL TASK: Indicate the total number of ***correct*** responses for each trial

Trial 1	Trial 2	Trial 3

2. NAMING OBJECTS AND FINGERS: Check each object/finger named ***correctly*** or check "NONE."

NONE ☐

☐ Flower	☐ Rattle	☐ Wallet
☐ Bed	☐ Mask	☐ Harmonica
☐ Whistle	☐ Scissors	☐ Stethoscope
☐ Pencil	☐ Comb	☐ Tongs
☐ Thumb	☐ Index	☐ Ring
☐ Pinky	☐ Middle	

3. COMMANDS: Check each command performed ***correctly*** or check "NONE." NONE ☐

- ☐ Make a fist.
- ☐ Point to the ceiling, then to the floor.
- ☐ Put the pencil on top of the card, then put it back.
- ☐ Put the watch on the other side of the pencil and turn over the card.
- ☐ Tap each shoulder twice with two fingers keeping your eyes shut.

4. CONSTRUCTIONAL PRAXIS: Check each figure drawn ***correctly***.

- ☐ None: attempted but drew no forms correctly.
- ☐ Patient drew no forms; scribbled; wrote words.
- ☐ Circle
- ☐ Two overlapping rectangles
- ☐ Rhombus
- ☐ Cube

5. IDEATIONAL PRAXIS: Check each step completed ***correctly*** *or* check "NONE" NONE ☐

- ☐ Fold a letter.
- ☐ Put letter in envelope.
- ☐ Seal envelope.
- ☐ Address envelope.
- ☐ Indicate where stamp goes.

6. ORIENTATION: Check each item answered ***correctly*** or check "NONE." NONE ☐

☐ Full name	☐ Day
☐ Month	☐ Season
☐ Date	☐ Place
☐ Year	☐ Time of day

7. WORD RECOGNITION TASK: Scoring will be done by the A.D.C.S. Data Coordinating Center.

Trial 1	Trial 2	Trial 3
X	X	X

8. LANGUAGE: Check level of impairment.

- ☐ **None**: patient speaks clearly and/or is understandable.
- ☐ **Very Mild**: one instance of lack of understandability.
- ☐ **Mild**: patient has difficulty < 25% of the time.
- ☐ **Moderate**: patient has difficulty 25–50% of the time.
- ☐ **Moderately Severe**: patient has difficulty more than 50% of the time.
- ☐ **Severe**: one- or two-word utterances; fluent, but empty speech; mute.

9. COMPREHENSION OF SPOKEN LANGUAGE: Check level of impairment

- ☐ **None**: patient understands.
- ☐ **Very Mild**: one instance of misunderstanding.
- ☐ **Mild**: 3–5 instances of misunderstanding.
- ☐ **Moderate**: requires several repetitions and rephrasing.
- ☐ **Moderately Severe**: patient only occasionally responds correctly; i.e., yes – no questions.
- ☐ **Severe**: patient rarely responds to questions appropriately; not due to poverty of speech.

10. WORD FINDING DIFFICULTY: Check one response.

- ☐ **None.**
- ☐ **Very Mild**: 1 or 2 instances, not clinically significant.
- ☐ **Mild**: noticeable circumlocution or synonym substitution.
- ☐ **Moderate**: loss of words without compensation on occasion.
- ☐ **Moderately Severe**: frequent loss of words without compensation.
- ☐ **Severe**: nearly total loss of content words; speech sounds empty; 1– to 2-word utterances.

11. REMEMBERING TEST INSTRUCTIONS: Check level of impairment.

- ☐ **None**.
- ☐ **Very Mild**: forgets once.
- ☐ **Mild**: must be reminded 2 times.
- ☐ **Moderate**: must be reminded 3–4 times.
- ☐ **Moderately Severe**: must be reminded 5–6 times
- ☐ **Severe**: must be reminded 7 or more times.

WHITE- ADCS COPY YELLOW- INVESTIGATOR'S COPY PINK- CLINICAL MONITOR'S COPY

Alzheimer's Disease Cooperative Study

ADAS – Word Recall

SAMPLE FORM – Page 2 of 4

Center Name	Patient Number	Patient Initials	Examiner Initials	Examination Date
	P R - - -			Month Day Year

Present Word List #2.

Check EACH word correctly recalled.

TRIAL 1		TRIAL 2		TRIAL 3	
BOTTLE		FOREST		GIRL	
POTATO		TEMPLE		TEMPLE	
GIRL		BOTTLE		POTATO	
TEMPLE		STAR		ANIMAL	
STAR		POTATO		FOREST	
ANIMAL		GIRL		LAKE	
FOREST		CLOCK		OFFICE	
LAKE		ANIMAL		CLOCK	
CLOCK		LAKE		BOTTLE	
OFFICE		OFFICE		STAR	
TOTAL		**TOTAL**		**TOTAL**	

Indicate total number of words correctly recalled for EACH trial on the ADAS Cognitive Behavior Form.

12. Executive Function (Maze):

a. ☐☐ number of errors

b. ☐☐ time at completion or second error (total seconds)

13. Number Cancellation:

a. ☐☐ number of targets hit (Range: 0 - 40)

b. ☐☐ number of errors

c. ☐☐ number of times to remind of task

If any item(s) 1-13 are incomplete or not done, please specify reason:

☐ Subject too cognitively impaired to complete

☐ Subject was unable to complete for physical reasons

☐ Subject refused

☐ Not Done, for reason other than above explain: _____

_____

_____

_____

_____

_____

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Alzheimer's Disease Cooperative Study

ADAS – Delayed Recall

SAMPLE FORM – Page 3 of 4

Center Name	Patient Number	Patient Initials	Examiner Initials	Examination Date
	P R - -			Month Day Year

Instructions: Say to the patient, **"NOW I WANT YOU TO TRY TO REMEMBER THE WORDS THAT I SHOWED YOU EARLIER ON PRINTED CARDS. CAN YOU TELL ME ANY OF THOSE WORDS?"**

Allow a maximum of two minutes for recall.

check EACH word correctly recalled.

BOTTLE	
POTATO	
GIRL	
TEMPLE	
STAR	
ANIMAL	
FOREST	
LAKE	
CLOCK	
OFFICE	
TOTAL	

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Alzheimer's Disease Cooperative Study

ADAS – Word Recognition

SAMPLE FORM – Page 4 of 4

Center Name	Patient Number	Patient Initials	Examiner Initials	Examination Date
	P R - -			Month Day Year

Present Word List #2.

Check subject's response for each word. Subject should respond "yes" to original words which are bolded. INCORRECT responses are shaded. Three trials of reading and recognition are given.

	Yes	No
COST		
NATION		
CHIMNEY		
SPARROW		
DAMAGES		
TRAFFIC		
SANDWICH		
SERVICE		
SHELL		
SOLUTION		
YARD		
TUBE		
BODY		
GROUND		
STICK		
ENGINE		
RICHES		
GRAVITY		
SUMMER		
WISDOM		
MAN		
MEAL		
PASSENGER		
ACID		

	Yes	No
BATTLE		
MUCH		
TUBE		
TEAM		
COPY		
ENGINE		
GRAVITY		
COST		
JAR		
DISTANCE		
TRIUMPH		
TEMPER		
SENTENCE		
FOX		
PASSENGER		
SANDWICH		
SOLUTION		
WHISTLE		
CHIMNEY		
UNION		
ACID		
MEAL		
DAMAGES		
RICHES		

	Yes	No
VISITOR		
ACID		
SPEAK		
SOLUTION		
NAME		
MEAL		
LINE		
BILL		
CHIMNEY		
ENGINE		
WEALTH		
TUBE		
IMAGE		
COST		
SANDWICH		
DAMAGES		
ELEPHANT		
RICHES		
GRAVITY		
FUTURE		
PASSENGER		
STRING		
BANNER		
BERRY		

*see procedures manual for further clarification

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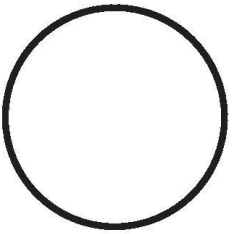
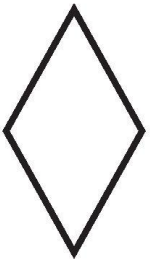
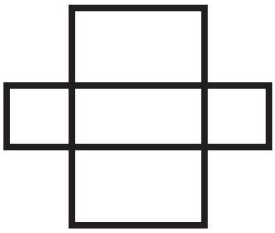
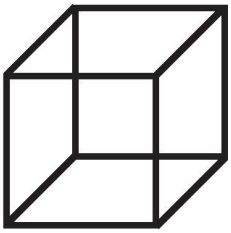
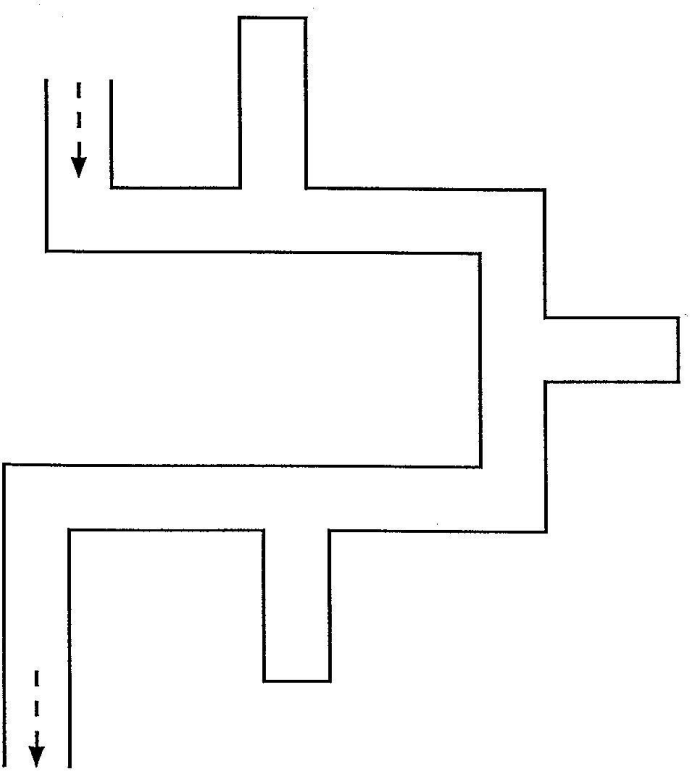


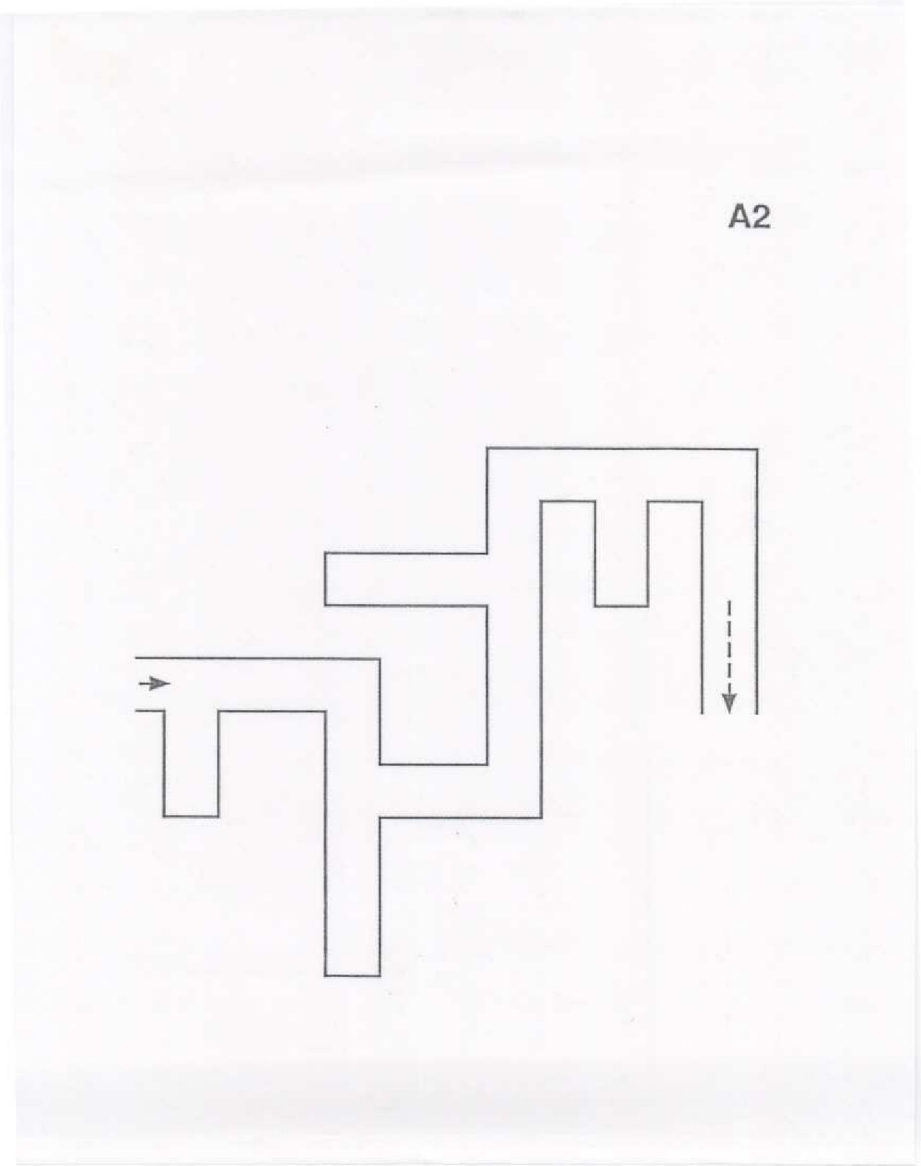








Example


A2

"6" and "1"

1 2 2 4 5 9 5 6 6 9 1 9 6 7 8 3 2 4 3 7 2 1 4 2 2 1 2 6 6 3

Example for use with versions A, B, and C

"2" and "8"

6 2 6 7 2 3 1 3 8 5 5 5 8 1 7 9 1 7 2 7 4 5 7 6 1 3 9 6 2 1

9 4 6 9 5 7 1 8 9 5 6 5 4 2 7 1 5 2 7 9 1 7 1 1 1 4 2 8 5 8

1 9 7 9 7 1 6 7 8 6 5 5 7 2 9 6 5 9 5 4 7 3 2 4 5 6 1 4 3 4

4 6 8 4 1 4 1 7 2 4 7 1 7 6 7 5 4 9 8 7 5 6 2 1 6 9 3 1 4 8

7 8 6 7 1 7 1 3 4 3 9 8 6 5 1 8 3 4 2 6 9 9 6 1 6 4 3 9 3 4

4 9 3 8 7 2 5 4 4 8 7 6 4 1 4 7 2 6 8 7 5 6 3 2 6 4 4 6 8 4

4 8 3 4 7 5 4 4 7 9 7 3 6 8 6 5 4 7 4 3 4 9 2 5 3 5 4 7 3 5

4 9 3 3 8 1 8 4 2 6 5 6 6 1 7 2 4 2 9 7 9 7 6 1 5 1 4 1 9 8

A

4. Alzheimer's Disease Cooperative Study - Activities of Daily Living Inventory (ADCS-ADL)

DATE: TIME (24hr):

1. Regarding eating: Which best describes subjects usual performance during the past 4 weeks?
- ○ Ate without physical help
- ○ Used a fork or spoon, but not a knife to eat
- ○ Used fingers to eat
- ○ Usually or always was fed by someone else

2. Regarding walking (or getting around in a wheelchair), in the past 4 weeks, which best describes his/her optimal performance:
- ○ Mobile outside of home without physical help
- ○ Mobile across a room without physical help
- ○ Transferred from bed to chair without help
- ○ Required physical help to walk or transfer

3. Regarding bowel and bladder function at the toilet, which best describes his/her usual performance in the past 4 weeks:
- ○ Did everything necessary without supervision or help
- ○ Needed supervision, but no physical help, and was usually continent
- ○ Needed physical help, and was usually continent
- ○ Needed physical help, and was usually incontinent

4. Regarding bathing, in the past 4 weeks, which best describes his/her usual performance:
- ○ Bathed without reminding or physical help
- ○ No physical help, but needed supervision/reminders to bathe completely
- ○ Needed minor physical help (e.g., with washing hair) to bathe completely
- ○ Needed to be bathed completely

5. Regarding grooming, in the past 4 weeks, which best describes his/her optimal performance:
- ○ Cleaned and cut fingernails, without physical help
- ○ Brushed or combed hair without physical help
- ○ Kept face and hands clean without physical help
- ○ Needed help for grooming of hair, face, hands, and fingernails

6a. Regarding dressing, in the past 4 weeks:
Did subject select his/her first set of clothes for the day?
Yes / No / don't know
○ ○ ○
If Yes, which best describes his/her usual performance:
- ○ Without supervision or help
- ○ With supervision
- ○ With physical help

6b. Regarding physically getting dressed, which best describes his/her usual performance in the past 4 weeks: (check one)
- ○ Dressed completely without supervision or physical help
- ○ Dressed completely with supervision, but without help
- ○ Needed physical help only for buttons, clasps, or shoelaces
- ○ Dressed without help if clothes needed no fastening or buttoning
- ○ Always needed help, regardless of type of clothing

○ Don't know

7. In the past 4 weeks, did subject use a telephone
Yes / No / don't know
○ ○ ○
If Yes, which best describes his/her highest level of performance:
○ Made calls after looking up numbers in white or yellow pages, or by dialing directory assistance
○ Made calls only to well-known numbers without referring to a directory, list, or preprogrammed numbers
○ Made calls only to well-known numbers by using a directory or list
○ Answered the phone; did not make calls
○ Did not answer the phone, but spoke when put on the line

8. In the past 4 weeks, did subject watch television?
Yes / No / don't know
○ ○ ○
If Yes, ask each of the following:
Yes / No
○ ○ a. Did subject usually select or ask for different programs or his/her favorite show?
○ ○ b. Did subject usually talk about the content of a program while watching it?
○ ○ c. Did subject talk about the content of a program within a day (24 hours) after watching it?

9. In the past 4 weeks, did subject ever appear to pay attention to consversation or small talk for at least 5 minutes?
(note subject did not need to initiate the conversation)
Yes / No / don't know
○ ○ ○
If Yes, which best describes his/her usual degree of participation:
○ Usually said things what were related to the topic
○ Usually said things that were not related to the topic
○ Rarely or never spoke

10. Did subject clear the dishes from the table after a meal or snack?
Yes / No / don't know
○ ○ ○
If Yes, which best describes how he/she usually performed:
○ Without supervision or help
○ With supervision
○ With physical help

11. In the past 4 weeks, did subject usually manage to find his/her personal belongings at home?
Yes / No / don't know
○ ○ ○
If Yes, which best describes how he/she usually performed:
○ Without supervision or help
○ With supervision
○ With physical help

12. In the past 4 weeks, did subject obtain a hot or cold beverage for him/herself?
Yes / No / don't know
○ ○ ○

If Yes, which best describes his/her highest level of performance:
○ Made a hot beverage, usually without physical help
○ Made a hot beverage, usually if someone else heated the water
○ Obtained a cold beverage, usually without physical help

13. In the past 4 weeks, did subject make him/herself a meal or snack at home?
Yes / No / don't know
○ ○ ○
If Yes, which best describes his/her highest level of performance:
○ Cooked or microwaved food, with little or no help
○ Cooked or microwaved food, with extensive help
○ Mixed or combined food items for a meal or snack, without cooking or microwaving (e.g., made a sandwich)

14. In the past 4 weeks, did subject dispose of garbage or litter in an appropriate place or container at home?
Yes / No / don't know
○ ○ ○
If Yes, which best describes how he/she usually performed:
○ Without supervision or help
○ With supervision
○ With physical help

15. In the past 4 weeks, did subject get around (or travel) outside of his/her home?
Yes / No / don't know
○ ○ ○
If Yes, which best describes his/her optimal performance:
○ Alone, went at least 1 mile away from home
○ Alone, but remained within 1 mile of home
○ Only when accompanied and supervised, regardless of the trip
○ Only with physical help, regardless or the trip

16. In the past 4 weeks, did subject ever go shopping?
Yes / No / don't know
○ ○ ○
If yes, ask A and B
A) Which one best describes how subject usually selects items?
○ Without supervision or physical help
○ With some supervision or physical help
○ Not at all, or selected mainly random or inappropriate items
B) Did subject usually pay for items without supervision or physical help?
○ Yes
○ No

17. In the past 4 weeks, did subject keep appointments, meetings with other people, such as relatives, a doctor, the hairdresser, etc.?
○ Usually remembered, may have needed written reminders, e.g., notes, a diary, or calendar
○ Only remembered the appointment after verbal reminders on the day
○ Usually did not remember, in spite of verbal reminders on the day

18. In the past 4 weeks, was subject ever left on his/her own?
Yes / No / don't know

○ ○ ○
If yes, ask all questions:
Was subject left:
Yes / No
○ ○ a) away from home for 15 minutes or longer, during the day?
○ ○ b) at home for an hour or longer, during the day
○ ○ c) at home, for less than 1 hour during the day

19. In the past 4 weeks, did subject talk about current events? (This means events or incidents that occurred during the past month.)
Yes / No / don't know
○ ○ ○
If yes, ask all questions:
Did subject talk about events that…:
Yes / No
○ ○ a) he/she heard or read about or saw on TV but did not take part in?
○ ○ b) he/she took part in outside home involving family, friends, or neighbors?
○ ○ c) events that occurred at home that he/she took part in or watched

20. In the past 4 weeks, did subject read a magazine, newspaper or book for more than 5 minutes at a time?
Yes / No / don't know
○ ○ ○
If yes, ask all questions:
Did subject usually:
Yes / No
○ ○ a) talk about details of what he/she read while or shortly (less than 1 hour) after reading?
○ ○ b) talk about what he/she read 1 hour or longer after reading?

21. In the past 4 weeks, did subject ever write things down?
Yes / No / don't know
○ ○ ○
Note: if subject wrote things only after encouragement or with help, the response should still be 'Yes'.
If yes, which best describes the most complicated things that he/she wrote:
○ Letters or long notes that other people understood
○ Short notes or messages that other people understood
○ His/her signature or name

22. In the past 4 weeks, did subject perform a pastime, hobby, or game?
Yes / No / don't know
○ ○ ○
If yes, how did subject usually perform his/her most common pastimes:
○ Without supervision or help
○ With supervision
○ With help
○ If subject performs hobbies/pastimes only at day care, check here

23. In the past 4 weeks, did subject use a household appliance to do chores?
Examples include washer, dryer, vacuum, dishwasher, toaster, toaster over, range, microwave, food processor
Yes / No / don't know
○ ○ ○

If yes, for the most commonly used appliances, which best describes how subject usually used them:
- ○ Without help, operating more than on-off controls if needed
- ○ Without help, but operated only on-off controls
- ○ With supervision, but no physical help
- ○ With physical help

TOTAL ADCS-ADL:
(ADCS-ADL maximum score = 30)

24 - 30 normal, depending on age, education, complaints
20 - 23 mild
10 - 19 moderate
1 - 9 severe
0 profound

To calculate estimate of duration of illness from ADL score, click here: ○
TIME-INDEX for ADL (estimated years into Alzheimer's disease):

Submit Form

TEXT FOR YOUR RECORDS - click here: ○

5. Health-related quality of life for people with dementia (DEMQOL)

Study ID □□□□□

DEMQOL (version 4)

Instructions: Read each of the following questions (in bold) verbatim and show the respondent the response card.

I would like to ask you about your life. There are no right or wrong answers. Just give the answer that best describes how you have felt in the last week. Don't worry if some questions appear not to apply to you. We have to ask the same questions of everybody.

Before we start we'll do a practise question; that's one that doesn't count. *(Show the response card and ask respondent to say or point to the answer)* **In the last week, how much have you enjoyed watching television?**

a lot **quite a bit** **a little** **not at all**

Follow up with a prompt question: **Why is that?** *or* **Tell me a bit more about that.**

For all of the questions I'm going to ask you, I want you to think about the last week.

First I'm going to ask about your feelings. In the last week, have you felt.....

1. cheerful? **	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
2. worried or anxious?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
3. that you are enjoying life? **	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
4. frustrated?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
5. confident? **	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
6. full of energy? **	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
7. sad?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
8. lonely?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
9. distressed?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
10. lively? **	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
11. irritable?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
12. fed-up?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
13. that there are things that you wanted to do but couldn't?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

Next, I'm going to ask you about your memory. In the last week, how worried have you been about.....

14. forgetting things that happened recently?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
15. forgetting who people are?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
16. forgetting what day it is?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

17. your thoughts being muddled?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
18. difficulty making decisions?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
19. poor concentration?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

Now, I'm going to ask you about your everyday life. In the last week, how worried have you been about.....

20. not having enough company?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
21. how you get on with people close to you?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
22. getting the affection that you want?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
23. people not listening to you?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
24. making yourself understood?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
25. getting help when you need it?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
26. getting to the toilet in time?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
27. how you feel in yourself?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all
28. your health overall?	☐ a lot	☐ quite a bit	☐ a little	☐ not at all

We've already talked about lots of things: your feelings, memory and everyday life. Thinking about all of these things in the last week, how would you rate.....

29. your quality of life overall? **	☐ very good	☐ good	☐ fair	☐ poor

** items that need to be reversed before scoring