

# The influence of urban design on patients with mild cognitive impairment

<b>Submission date</b> 05/07/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 26/07/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/02/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Mild cognitive impairment (MCI) is a condition in which individuals demonstrate deficits in cognitive (thinking) abilities but with minimal impairment of their instrumental activities of daily living (IADL). MCI is increasingly common as people age and is associated with an increased risk of progression to dementia. At present, there are no medications approved for MCI to prevent progression to dementia. Nonetheless, all efforts should be made to prevent the complete loss of the ability to undertake IADL that characterises the dementia state. This could have marked implications an individual's health, carers' burden and societal costs.

Deficits in spatial memory and orientation occur in early stages of Alzheimer's disease (AD), leading some authors to consider that spatial navigation testing could be a very sensitive diagnostic marker. Recent studies using navigation tasks in new environments, with the help of virtual reality technology, have shown benefits for an early diagnosis and in identifying those at higher risk of dementia. Importantly, this new approach also provides the opportunity to study how the life of people with cognitive impairment could be improved through urban design. Very little is known about how the urban environment and the walking experience at the neighbourhood scale could impact people with cognitive dysfunction. As the ageing of the global population continues, the number of people with dementia could be close to 100 million by 2050. Hence, it is a priority to better understand the relationship between the built environment and people with MCI to help design better cities for people with dementia. Spatial navigation in MCI patients could be improved by re-designing the outdoor neighbourhood. This study will test this with a virtual reality (VR) spatial navigation task. The study will also measure brain activity during spatial navigation across different conditions. By showing that urban design can impact a cognitively impaired population, the aims of this study are to: a) provide proof of principle results for the importance of urban planning as an opportunity to enhance the independent lives of people with premorbid dementia; b) obtain evidence that could be used to guide the practice of urban design for other mental health conditions; and c) reduce inequalities in urban areas that affect vulnerable groups, such as those with cognitive disorders.

### Who can participate?

Elderly patients (aged 65 years old or older) with a diagnosis of mild cognitive impairment (MCI), and age-, gender- and education-matched healthy volunteers (from the local community, but preference will be given to partners of the included MCI participants)

### What does the study involve?

The performance of 25 patients with MCI on a VR spatial navigation task will be compared to 25 age-, gender- and education-matched healthy volunteers in virtually modified space urban environments. Furthermore, eye tracking and electroencephalography (EEG, a recording of brain activity) data will also be collected during the VR task to assess differences between groups. The VR urban environment will be modelled after a real-space environment and then edited along certain parameters, generating “real” environments in VR and “real-edited” (virtually modified) environments in VR as well. This way, the study will capitalize on VR to edit the environment and see how behavioural performance changes in each group.

### What are the possible benefits and risks of participating?

There are no direct benefits but participants might contribute to the improvement of future urban spaces more inclusive for this vulnerable group. Despite not expecting significant adverse events, a registry will be created for adverse events noticed or reported by the participants in an interview after the experiment. VR technology, neuropsychological evaluation, EEG and structural magnetic resonance imaging (MRI) methods are non-invasive techniques and part of the regular evaluation. Some people can find the VR headset makes them feel claustrophobic or uncomfortable, or they can feel sick (like motion sickness). If this does occur, the participant can ask for the headset to be removed immediately and stop the experiment.

### Where is the study run from?

1. University of Lisbon (Portugal)
2. Michigan State University (USA)

### When is the study starting and how long is it expected to run for?

March 2021 to May 2025

### Who is funding the study?

Horizon 2020 Framework Programme

### Who is the main contact?

Prof. Bruno Miranda, [bruno.a.miranda@campus.ul.pt](mailto:bruno.a.miranda@campus.ul.pt)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Bruno Miranda

### ORCID ID

<https://orcid.org/0000-0003-4660-6051>

### Contact details

Instituto de Fisiologia  
Edifício Egas Moniz  
Av. Professor Egas Moniz  
Lisbon  
Portugal  
1649-028  
+351 (0)217 999 411 (ext 47134)  
bruno.miranda@campus.ul.pt

## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

GA 945307

## **Study information**

### **Scientific Title**

The impact of the urban environment on spatial navigation in elderly subjects with mild cognitive impairment (UrbanNavMCI)

### **Acronym**

UrbanNavMCI

### **Study objectives**

The hypothesis is that spatial navigation in a vulnerable elderly population at risk of developing dementia could be improved by re-designing the outdoor neighbourhood.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 18/04/2022, Comissão de Ética do Centro Académico de Medicina de Lisboa (Av. Prof. Egas Moniz, 1649-035 Lisboa, Portugal; +351 (0)21 780 54 05; ana.pimentel@chln.min-saude.pt), ref: 82/22

### **Study design**

Two-centre exploratory small-scale gender-balanced analytical and case-control observational study

### **Primary study design**

Observational

### **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Mild cognitive impairment

## **Interventions**

Patients with mild cognitive impairment will perform a spatial navigation task (and will be compared to matched controls) in virtual/augmented reality modified urban space environments; neuropsychological testing, eye tracking and electroencephalography (EEG) data will also be collected during the task to assess differences between groups.

## **Intervention Type**

Behavioural

## **Primary outcome(s)**

Percentage of errors in finding the correct routes of the navigation paradigm measured using a comparative method between the shortest path and the one actually performed at baseline

## **Key secondary outcome(s)**

1. The distance between the estimated (correct) and actual (incorrect) final location measured using Euclidean distance method at baseline
2. The time to finish the task and the time allocated to specific predefined landmarks measured using a comparative method of time difference at baseline.
3. Eye movements (total and search saccades and fixations) measured using the number of fixation and saccades at baseline
3. The difficulty of the task assessed using a qualitative score based on a post-performance interview
4. Brain activity pattern (topographically and on frequency analysis) measured using EEG analysis at baseline
5. Episodic memory measured using a neuropsychological battery at baseline.
6. Executive functioning measured using a neuropsychological battery at baseline.

## **Completion date**

31/05/2025

# **Eligibility**

## **Key inclusion criteria**

1. This study will adopt the Petersen et al. (1999) criteria for the diagnosis of MCI (probably one of the original criteria defined) which include:
  - 1.1. Presence of memory complaints (from patients or their families)
  - 1.2. No or a minimal impairment in activities of daily living, determined by the Instrumental Activities of Daily Living Scale (IADL) (Lawton & Brody, 1969)
  - 1.3. Normal general cognitive function, determined by the Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975)
  - 1.4. An objective cognitive disorder as evidenced by a neuropsychological evaluation
  - 1.5. Absence of dementia
2. Written informed consent
3. The diagnosis of MCI will also be made by an experienced neurologist, using all available clinical, neuropsychological, and neuroimaging information available from the diagnostic workup

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Key exclusion criteria**

1. Neurological (stroke, brain tumour, significant head trauma, epilepsy) or psychiatric disorders that may cause cognitive impairment
2. Patients with major depression or serious depressive symptoms
3. History of alcohol abuse or recurrent substance abuse or dependence
4. Seriously reduced vision or other sensory deficits likely to interfere with the evaluation
5. Medication use with possible cognitive side effects
6. Presence of a systemic illness with significant cerebral impact (uncontrolled hypertension, metabolic, endocrine, toxic, and infectious diseases)

**Date of first enrolment**

01/02/2023

**Date of final enrolment**

31/05/2025

**Locations****Countries of recruitment**

Portugal

United States of America

**Study participating centre****Lisbon School of Medicine**

Institute of Physiology

Av. Professor Egas Moniz

Lisbon

Portugal

1649-028

**Study participating centre****Michigan State University**

Department of Neurology & Ophthalmology

804 Service Road

East Lansing  
United States of America  
MI 48824

## Sponsor information

### Organisation

University of Lisbon

### ROR

<https://ror.org/01c27hj86>

## Funder(s)

### Funder type

Government

### Funder Name

Horizon 2020 Framework Programme

### Alternative Name(s)

EU Framework Programme for Research and Innovation H2020, Horizon 2020, Horizon 2020 Framework Programme (H2020), Rahmenprogramm Horizont 2020, Horizont 2020, Programa Marco Horizonte 2020, Horizonte 2020, Programme-cadre Horizon 2020, Orizzonte 2020, Programma quadro Orizzonte 2020, H2020

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the study will be available upon request from Bruno Miranda ([bruno.miranda@campus.ul.pt](mailto:bruno.miranda@campus.ul.pt)); pseudo-anonymised clinical, behavioural and EEG data could potentially be shared after finalising the current analysis of this study and after consulting the local ethical committee.

All participants will provide informed consent according to the 1991 Declaration of Helsinki and the study will require approval by the local Research Ethics Committee of the institutions involved: the Faculty of Medicine – University of Lisbon (Portugal) and the College of Human Medicine - Michigan State University (USA). Participants considered unable to give consent or those suffering from other major general medical conditions will not be included in the study. Despite involving the collection of health-related personal data, the project will comply with the European and American rules for personal data protection. There will be no secondary use of the data. Following the privacy by design principles, the project will not collect any data which is not strictly deemed necessary. With regard to the data that are collected and processed about the patient in the context of the clinical study, a basic distinction must be made between: 1) those personal data by which the patient can be directly identified (e.g., name, date of birth, address); 2) pseudonymised (encrypted) personal data, in which all information that allows direct conclusions to be drawn about the patient's identity is replaced by a code (e.g. a number) made unrecognisable (this has the effect that the data can no longer be assigned to the person without the inclusion of additional information and without disproportionate great effort and); and 3) anonymous data, where it is no longer possible to trace back to the person. The code for encryption is strictly separated from the encrypted data records and is only stored at the patient's research site (the physical copies of the consent form will be kept in a secure storage cabinet in a locked room where only the principal investigators will have access). Authorized representatives of the respective ethics committees may inspect the non-encrypted data to the extent necessary to verify the proper conduct of the clinical study. Also, only the encrypted or anonymized data will be used for any publications. All persons who are given access to the encrypted and non-encrypted data of the patient are subject to the EU Data Protection Basic Regulation and the Portuguese adaptation regulations in the currently valid version when handling the data. Participants can withdraw their consent to the collection and processing of the patient's data at any time. After their revocation, no further data about the participant will be collected. In addition, participants also have the right to access their own data and the possibility of correction if any error is discovered. The duration of the project is 48 months. The duration of the storage of data beyond the end of the trial is regulated by the respective national legislation.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol (preprint)</a>		19/04/2024	28/02/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes