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The influence of urban design on patients with mild cognitive impairment

Submission date	Recruitment status	[X] Prospectively registered
05/07/2022	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/07/2022	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2025	Mental and Behavioural Disorders	[X] 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 electroencephalograhy (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

Study website
https://emotionalcities-h2020.eu

Contact information

Type(s)
Principal Investigator

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Prof Bruno Miranda

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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

Secondary outcome measures
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.

Overall study start date
01/03/2021

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

Age group
Senior

Sex
Both

Target number of participants
25 patients with mild cognitive impairment and 25 controls

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
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United States of America
MI 48824

Sponsor information

Organisation
University of Lisbon

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Sponsor type
University/education

Website
https://www.medicina.ulisboa.pt/emotional-cities

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, Rahmenprogramm Horizont 2020, Programa Marco Horizonte 2020, Programme-cadre Horizon 2020, Programma quadro Orizzonte 2020, Program ramowy Horyzont 2020, Horizont 2020, Horizonte 2020, Orizzonte 2020, Horyzont 2020, Horizon 2020 Framework Programme (H2020), H2020

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
1. Presentation at conferences (urban health related; neurology related)
2. Publication in a peer-reviewed journal
3. Policy recommendations for urban health

Intention to publish date
01/09/2025

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); 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?
Protocol (preprint)		19/04/2024	28/02/2025	No	No