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Creating an AI-powered education tool to support people living with dementia and their caregivers

Submission date
15/10/2025

Recruitment status
No longer recruiting

Registration date
11/11/2025

Overall study status
Completed

Last Edited
10/03/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Persons living with dementia and their caregivers often feel unprepared for the changing symptoms and emotional challenges that come with the condition. Most dementia education materials are generic and do not adapt to each person's specific situation, stage of illness, or cultural background, which can lead to increased anxiety and missed opportunities for planning ahead. New technology using artificial intelligence makes it possible to create personalized education tools that adjust to each person's needs and questions in real-time. However, using AI in dementia care requires careful checking to ensure the information is accurate, safe, and appropriate for vulnerable people. This study aims to create and test an AI-powered education tool for dementia and palliative care by first having healthcare experts review and approve the content for safety and accuracy (Phase 1), then testing it with people living with dementia and their caregivers in real-life settings to see if it is helpful, easy to use, and meets their information needs (Phase 2). The goal is to provide personalized, trustworthy support that helps families feel more informed and confident throughout the dementia journey.

Who can participate?
The study has two parts and is looking for different groups of people to paticipate. In the first part, healthcare professionals with experience in dementia or palliative care, such as doctors, nurses, or care specialists with at least two years of experience, are invited to review and improve the education tool. In the second part, people aged 55 or older who have been diagnosed with early to mid-stage dementia or mild cognitive impairment can take part with the support of a caregiver or healthcare professional. Family caregivers aged 18 or older who regularly support someone with dementia at least four hours a day for six months or more can also participate independently. All participants need to be willing and able to give informed consent and use digital devices like smartphones, tablets, or computers

What does the study involve?
Healthcare experts will create about 15 to 20 questions and review answers from the AI education tool, rating them for accuracy and helpfulness, which takes about one hour. Persons with dementia will use the tool, where possible, with support from a caregiver to ask questions

about dementia, palliative care and care in general say whether the answers were useful. Family caregivers will use the tool on their own to find information, ask questions, and complete short questionnaires about how easy it was to use. All participants can stop at any time, and no personal details beyond, gender, age, education/profession, years in practice and preferred language will be collected.

What are the possible benefits and risks of participating?
Benefits: Participating in this study may help improve educational resources and support for people with dementia and their families in the future. Caregivers and patients may gain access to personalized information about dementia care that could help them feel more informed and supported. Experts will contribute to ensuring the tool is safe, accurate, and helpful before it is used widely. All participants will help create an open library of trustworthy dementia education resources that can benefit others.

Risks: There are no anticipated serious risks from participating in this study. However, some people may feel mild discomfort or emotional distress when thinking about dementia-related topics or end-of-life care. Patients may experience fatigue or frustration when using new technology. To protect participants, multiple safety measures are in place, including checking all AI-generated information for accuracy, preventing misleading or harmful content, and providing supervision for patients during use. Caregivers can intervene or stop any interaction if they notice confusion or distress. All personal information is kept private and secure, with no identifiable information collected. Participation is completely voluntary, and anyone can withdraw at any time without affecting their care or support.

Where the study is run from?
The study is led by the University of Maribor, Faculty of Electrical Engineering and Computer Science, HUMADEX Research Group, in collaboration with the University Medical Center Maribor, Department of Oncology, Palliative Care Unit (Slovenia).

When does the study take place?
The study is scheduled to begin on October 20, 2025, and will run until the end of February 2026. Phase 1, where healthcare experts will review and validate the AI education tool, will take place first. This will be followed by Phase 2, where persons living with dementia and their caregivers will use and test the system in real-world settings. The results of the study are expected to be analyzed and published by April 2026. Participation is flexible, and individuals can join at different times during the study period depending on which phase they are eligible for.

Who is funding the study?
The study has received funded by the European Union Horizon Europe Research and Innovation Programme (AI4HOPE, 101136769) and UK Research and Innovation (UKRI) under the UK government’s Horizon Europe funding guarantee (Grant No. 101136769).The content of this study does not reflect the official position of the European Union or any other institution. The information and views expressed are the sole responsibility of the authors.

Who is the main contact?
For any questions regarding the study, confidentiality or data protection, please contact the principal investigator, Dr Izidor Mlakar, izidor.mlakar@um.si

Contact information

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Protocol serial number
UKC-MB-KME-64/25

Study information

Scientific Title
Collecting and curating key topics from patients and healthcare professionals for a personalized dementia and palliative care education module

Acronym
GUIDE

Study objectives
Phase 1 Objectives (Expert Validation):
Primary:
- Create and curate a trustworthy knowledge base for dementia and palliative care education
- Ensure accuracy and dementia-appropriate communication of the content generated by AI models
Secondary:
- Identify and eliminate misinformation and demographic bias in responses
- Validate AI relevance filtering to ensure only dementia and palliative care-related queries are processed
- Establish a trustworthiness threshold of 4 out of 5 for sources used in AI responses

Phase 2 Objectives (Real-World Deployment)
Primary:
- Implement the retrained Llama model in real-world care settings (home, hospice, clinics) under supervised conditions involving patients and caregivers
- Achieve 80% user-rated relevance (4 or 5 on a 5-point scale) for AI-generated responses across caregivers and patients

Secondary:
- Log and analyze 500+ real-world queries to identify common information needs, reformulation behaviors, and navigation preferences
- Attain 70% user-reported satisfaction with the system's usability and usefulness via simplified SUS (System Usability Scale)

Ethics approval required

Ethics approval required

Ethics approval(s)
Approved 01/10/2025, Komisija za Medcinsko Etiko, UKC Maribor (Ljubljanska ulica 5, Maribor, 2000, Slovenia; +386 2 321 2489; eticna.komisija@ukc-mb.si), ref: UKC-MB-KME-64/25

Primary study design
Observational

Study design
Sequential prospective design with mixed-methods evaluation design

Study type(s)
Quality of life, Other

Health condition(s) or problem(s) studied
Dementia, mild cognitive impairment, palliative care needs

Interventions
AI-powered digital educational module.

The study is conducted in two phases. In both phases, participation is fully voluntary, and all participants provide informed consent before starting.

In Phase 1, healthcare professionals with expertise in dementia or palliative care take part online. After enrolment, they review and rate a set of 15–20 AI-generated responses to common dementia care questions, scoring them for accuracy, empathy, clarity, and usefulness. Engagement takes around 1 hour and requires no follow-up.

In Phase 2, people living with dementia (aged 55+) and their family caregivers (aged 18+) use the AI-powered Dementia Education Tool. Participants attend one supervised session, lasting about 45–70 minutes, either individually or in small groups of up to five participants. The session includes a guided introduction, interaction with the chatbot to ask dementia-related questions, and short usability and satisfaction questionnaires.

Data on use patterns, satisfaction, and comprehension are collected anonymously. There is no extended follow-up. Participation concludes after the session. The total observation period for each participant is approximately one hour, with the full study completed within five months, and results expected by April 2026.

Intervention Type
Other

Primary outcome(s)
1. Phase 1 Primary Outcome: AI Model Performance, assessed through expert ratings on a 1-5 Likert scale across four dimensions at a single timepoint: relevance, clarity, empathy, and actionability, with a target of achieving ratings ≥4 for clinical appropriateness
Phase 2 Primary Outcome: User-Rated Relevance, assessed through patient and caregiver ratings on a 1-5 Likert scale at a single timepoint, with a target of achieving 80% relevance

Key secondary outcome(s)

The following secondary outcome measures are assessed at a single timepoint:
Phase 1 Secondary Outcomes:
1. Trustworthy Knowledge Base Creation - Development of an open, expert-validated, curated set of evidence-based, dementia-relevant educational sources published under a Creative Commons license. Sources are rated on trustworthiness using a 1-5 scale, with only resources achieving an average rating of ≥3.5 included in the knowledge base.
2. Expert System Usability - System Usability Scale (SUS) score of 70-100 from expert reviewers. This standardized questionnaire provides a single score from 0 to 100 reflecting the overall ease of use, learnability, and user satisfaction with the system.

Phase 2 Secondary Outcomes:
1. Caregiver Usability Satisfaction - Caregiver satisfaction with system usability and usefulness as measured by a simplified System Usability Scale (SUS), with a target score of 70-100.
2. Patient Usability Satisfaction - Patient satisfaction with simplified system usability and usefulness as measured by a simplified System Usability Scale (SUS), with a target score of 70-100.
3. Query Cluster Identification - Identification of 3-5 dominant query clusters reflecting common information needs and search behaviors
4. Open Curated Dataset - Patient and caregiver relevant search patterns and responses published as an open curated dataset under Creative Commons license.

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Phase 1: Expert Participants
1. Clinical or academic expertise in dementia, palliative care, geriatrics, neurology, psychiatry, or related fields
2. Familiarity with digital health tools or willingness to use digital platforms for study participation
3. Ability to provide informed consent

Phase 2: Patient Participants
1. Clinical diagnosis of dementia (early to mid-stage) or mild cognitive impairment, confirmed by a healthcare professional
2. Able to participate in supervised digital interactions with or without caregiver support
3. Capacity to provide informed consent
4. Stable medical condition allowing participation in non-invasive, educational interventions

Participant type(s)
Health professional, Patient, Other

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Total final enrolment
0

Key exclusion criteria
Phase 1: Expert Participants:
1. Lack of direct experience with dementia or palliative care populations
2. Inability to use digital platforms required for the study
3. Current involvement in another conflicting research study

Phase 2: Patient Participants:
1. Diagnosis of severe psychiatric or neurological disorders unrelated to dementia (e.g., schizophrenia, bipolar disorder, recent stroke)
2. Current participation in another clinical trial that may interfere with the study
3. Unstable or severe medical illness that would preclude safe participation
4. Non-study language speakers

Phase 2: Family Caregiver Participants:
1. Active treatment for serious illness (e.g., cancer) that would limit participation
2. Participation in another caregiver intervention study that may confound results
3. Non-study language speakers

Date of first enrolment
20/10/2025

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
Germany

Ireland

Portugal

Slovenia

Spain

Study participating centre
University Medical Centre Maribor
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2000

Study participating centre
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Study participating centre
Centre for Gerontology and Rehabilitation, School of Medicine, UCC
The Bungalow, Block 13
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Sponsor information

Organisation
University Clinical Centre Maribor

ROR
https://ror.org/02rjj7s91

Organisation
Dom Nine Pokorn Grmovje

Organisation
Centre for Gerontology and Rehabilitation, School of Medicine, UCC

Funder(s)

Funder type
Government

Funder Name
HORIZON EUROPE Framework Programme

Alternative Name(s)
Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon, Horizonte Europa

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan
The de-identified datasets, including anonymised participant-level search patterns, query content, numeric questionnaire ratings, and usability feedback (but excluding any direct personal identifiers), will be published as a curated open dataset under a Creative Commons license (CC-BY license). Data will be made available via Zenodo (https://zenodo.org/) and Hugging Face or similar data repositories. A link will be provided upon final upload, following publication of study results, and will be accessible indefinitely. Access will not be restricted (i.e. CC-BY license), with citation of the dataset required.

Any supplementary materials (curated sources, protocols, AI models, and evaluation scripts) relevant for analysis and replication will also be shared in the same repository.

Individual-level data are fully anonymized; no names or direct identifiers are collected. Written consent for anonymized data sharing is obtained from all participants. Ethical approval and compliance with GDPR and the University of Maribor's privacy policy are ensured. There are no known legal or ethical restrictions. For more info, you can put in my direct contact, Dr Izidor Mlakar at izidor.mlakar@um.si.

IPD sharing plan summary
Available on request, Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/10/2025	No	Yes
Participant information sheet			17/10/2025	No	Yes