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Virtual coach for continuity of care

Submission date
17/06/2022

Recruitment status
No longer recruiting

Registration date
20/07/2022

Overall study status
Completed

Last Edited
14/04/2025

Condition category
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Despite the innovative culture in prevention, rehabilitation and assistive care for older adults, there is still a gap in systematising information collection processes from the patient journey for greater personalization. Alternative solutions are required to also address the concerns of citizens for ageing-in-place, with a growing demand for innovative services aimed to provide care that is both affordable and meets the needs of older adults, which can also be an answer to the increasing number of older adults living alone or suffering unwanted loneliness, implying a risk of premature death, worsening of health, physical, cognitive deterioration and loss of quality of life.
Integration of information technology may reduce loneliness and social isolation and support the caregiving processes, especially assistive technologies such as Socially Assistive Robots (SARs), keeping older adults at home for longer and addressing areas of need that influence admission to the nursing home. Introducing virtual assistants into care centres and older adults' homes is highly demanded. TheHosmartAIsolution to be tested will be used as a screening and intervention tool to detect and prevent cognitive deterioration. These functions will be integrated into the home and the clinical centre setting through a tablet and, in the clinical centre setting, a tablet on the social robot Pepper for a group intervention. The system collects this data through the intervention sessions and designs personalized treatments according to the level of cognitive deterioration. The aim of the study is to assess the acceptance and usability of a technological device for detecting and preventing cognitive deterioration, promoting healthy lifestyle habits and detecting frailty in elderly people.

Who can participate?
Elderly people aged 60 years and over, selected from among the users of the INTRAS Foundation's Memory Clinic and from organisations and/or social and health associations that work with the elderly.

What does the study involve?
The solution proposed will be used in older adults' homes (dwelling setting) and in rehabilitation centers and clinics (clinical setting) for the prevention and maintenance of cognitive and functional performance (autonomy, independence, wellbeing). A social robot will be used in the clinical setting (both individual and group intervention) and a tablet for the dwelling setting. The intervention requires the use of the system for 4 to 16 sessions in the clinic context, and for the home solution the system should be used for 2.5 to 3 months.

What are the possible benefits and risks of participating?
It is expected that the use of the device will have beneficial effects on various facets of the lives of the participants:
1. Facilitating interactions between older adults and the digital world through an intuitive system
2. Support for possible cognitive disabilities (e.g. memory problems, difficulties in planning and sequencing actions) present during the ageing process
3. Promotion of an active and healthy lifestyle
4. Promotion of social participation (reducing the risk of depression and anxiety)
5. Promotion of relaxation (training in relaxation and coping techniques)
6. Prolonging the autonomy and functional independence of the older adults at home for as long as possible
No risks of participating are expected.

Where is the study run from?
Memory Clinic of Fundación INTRAS (Spain)

When is the study starting and how long is it expected to run for?
October 2022 to March 2024

Who is funding the study?
Horizon 2020 Framework Programme

Who is the main contact?
INTRAS Foundation
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CASVE-NM-22-589

Study information

Scientific Title
Evaluating the effect of a virtual coach as a solution to support continuity of care to be used at older adult's homes and in rehabilitation centers and clinics centred on prevention and maintenance of cognitive and functional performance (autonomy, independence, wellbeing). Includes evaluation of usability and acceptance of the two planned interfaces (tablet and social robot).

Acronym
DETECTCOG

Study objectives
1. Are the solutions integrated into Pilot 6 usable and accepted by end-users?
H0: the average score obtained in the post-test with the UAQ test is lower than the average score obtained in the pre-test evaluation, at a significance level of 0.05.
H1: the average score obtained in the post-test with the UAQ test is higher than or the same as the average score obtained in the pre-test evaluation, at a significance level of 0.05.
2. Does the system produce cognitive changes for older adults?
H0: the average score obtained in the post-test with the Mini-Mental test is lower than the average score obtained in the pre-test evaluation, at a significance level of 0.05.
H1: the average score obtained in the post-test with the Mini-Mental test is higher than or the same as the average score obtained in the pre-test evaluation, at a significance level of 0.05.
3. Does the system produce changes in quality of life?
H0: the average score obtained in the post-test with the EQ-5D-3L test is lower than the average score obtained in the pre-test evaluation, at a significance level of 0.05.
H1: the average score obtained in the post-test with the EQ-5D-3L test is higher than or the same as the average score obtained in the pre-test evaluation, at a significance level of 0.05.
4. Does the system produce changes in the participant's mood?
H0: the average score obtained in the post-test with the Geriatric Depression Scale (GDS) test is higher than the average score obtained in the pre-test evaluation, at a significance level of 0.05.
H1: the average score obtained in the post-test with the GDS test is lower than or the same as the average score obtained in the pre-test evaluation, at a significance level of 0.05.
5. Does the system support an understanding of improving continuity of care?
H0: no differences were observed in the scores obtained in both the control group (CG) and the experimental group (EG) in the post-test assessment with a control group (CG) and the experimental group (EG) in the post-test evaluation with a scale of perceived satisfaction scale and that obtained in the pre-test evaluation.
H1: the score obtained in the post-test evaluation of the experimental group, with a perceived satisfaction scale is higher than that obtained in the pre-test evaluation, in both groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/06/2022, Comité de Ética del Area de Salud Valladolid Este – Hospital Clínico Universitário de Valladolid (CEIm Área de Salud Valladolid Este, Hospital Clínico Valladolid, Facultad de Medicina, Farmacología, C/ Ramón y Cajal, 7, Valladolid 47005, Spain; +34 (0)983 42 30 77, +34 (0)682 92 62 58; alvarez@med.uva.es, jalvarezgo@saludcastillayleon.es)

Study design
Quasi-experimental methodology will be used, with a control group with pre-test and post-test

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Detection and prevention of cognitive impairment and the presence of frailty in older adults

Interventions
The system developed within Pilot 6 will support the healthcare professionals by interacting with the user, screening and monitoring user activities, while motivating the user to be proactive and adhere to the care plan. The care center's healthcare professional will monitor this data in order to improve the efficacy of the implemented intervention.

INTRAS Foundation's Memory Clinic patients (G1): consists of a social robot that supports the healthcare professionals and interacts with the patients on a one-to-one basis (supporting individual interventions). The care center setting will be incorporated with the social robot and connected to routers to ensure secure data collection.

Active ageing workshops (G2): consists of a social robot that supports the healthcare professionals and interacts with the participants of the Active Ageing groups (group interventions). The care center setting will be incorporated with the social robot and connected to routers to ensure secure data collection.

Home users (G3): Through interaction with a tablet and their own mobile phones, the older adults will be able to access an e-coach at their home/residence. The devices will be connected to routers to ensure secure data collection.

The intervention requires the use of the system during 4 to 16 sessions in the clinic context, and for the home solution the system should be used for a period from 2.5 months to 3 months.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome(s)
The usability and acceptance of the solution assessed using the Acceptability and Usability Questionnaire (SUS); User Experience Questionnaire (UEQ) at the pre-evaluation phase (before the intervention) and post-evaluation at the end of the intervention (for the clinical setting – one weekly intervention; for the dwelling setting – minimum, one weekly intervention)

Key secondary outcome(s))
1. Cognitive changes assessed using the Mini Mental State Examination (MMSE) (Cognitive Test) at the pre- and post-evaluation phase of the intervention
2. Quality of life assessed using the Quality of Life Index (EQ-5D-3L) at the pre- and post-evaluation of the intervention
3. Participants' mood assessed using the Geriatric Depression Scale, Yesavage GDS at the- pre and post-evaluation phase of the intervention
4. Perceived potential for improving continuity of care assessed using the PSSUQ Questionnaire (adapted) at the pre- and post-evaluation of the intervention

Completion date
30/03/2024

Eligibility

Key inclusion criteria
1. Aged ≥ 60 years
2. MMSE ≥23 and ≤30
3. Being able to understand and consent to participate in the study
4. Signed consent to participation and management of the study data (the transfer of the data to an open-access database is an option and it does not imply the exclusion of the study)
5. Expressed desire to have some support related to using technologies, mood, and cognitive stimulation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Sensorial difficulty that hinders the use of the device
2. Psychiatric conditions or neurologic problems that prevent the person from participating in the study

Date of first enrolment
01/09/2022

Date of final enrolment
15/01/2023

Locations

Countries of recruitment
Spain

Study participating centre
Fundación INTRAS
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Sponsor information

Organisation
Fundación INTRAS

ROR
https://ror.org/00rwgk448

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 current study are/will be available upon request.
1. Governance and security (quantitively managed; the process is measured and controlled /verified). Data handling procedures at INTRAS are defined according to GDPR.
2. Security levels:
2.1. Technical measures: data storage in dedicated servers segmented on network environment; authorized access with data access audit logs; VPN regulated access to the data processing data centre. Data communication and transfer protected by Secure Socket Layer (SSL) and Transport Layer Security (TLS) protocols.
2.2. Data will be stored in firewall-protected computers with authorized access. Access will be limited to members of the research team. In case of data transfer, this will take place via SSH or

SSL protocols. Pseudo-anonymised data will be stored separately from records including subjects' personally identifiable information (e.g., signed consent forms)
2.3. Data privacy officer: Francisco Mallo Vázquez (fmv@intras.es)

Further detailed information in D6.7 / D6.8 Data Management Handing Plan (https://www.hosmartai.eu/knowledge-base/deliverables/)

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results		01/12/2024	14/04/2025	No	No
Other unpublished results			14/04/2025	No	No
Participant information sheet	Participant information sheet	27/06/2022	30/06/2022	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes
Protocol file		13/06/2022	30/06/2022	No	No