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Abstract In the EU funded MARIO project, specific technological tools are adopted for the patient with dementia (PWD). In the final stage of the project, two trials were completed as shown below: first trial was performed in September 2017, and second trial was performed in October 2017. The implemented and assessed applications (apps) are My Music app, My News app, My Games app, My Calendar app, My Family and Friends app, and Comprehensive Geriatric Assessment (CGA) app. The aim of the present study was to assess the acceptability and efficacy of MARIO companion robot on clinical, cognitive, neuropsychiatric, affective and social aspects, resilience capacity, quality of life in PWD, and burden level of the caregivers. Twenty patients (M = 8; F = 12) were screened for eligibility and all were included. In Pre- and Post-MARIO interaction, the following tests were administered: Mini-Mental State Examination (MMSE), Clock Drawing Test (CDT), Frontal Assessment Battery (FAB), Neuropsychiatric Inventory (NPI), Cornell Scale for Depression in Dementia (CSDD), Multidimensional Scale of Perceived Social Support

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A. Leone et al. (eds.), *Ambient Assisted Living*, Lecture Notes in Electrical Engineering 544, https://doi.org/10.1007/978-3-030-05921-7_41

(MSPSS), 14-item Resilience Scale (RS-14), Quality of Life in Alzheimer's Disease (QOL-AD), Caregiver Burden Inventory (CBI), Tinetti Balance Assessment (TBA), and Comprehensive Geriatric Assessment (CGA) was carried out. A questionnaire based on the Almere Acceptance model was used to evaluate the acceptance of the MARIO robot. In Post-MARIO interaction, significant improvements were observed in the following parameters: MMSE ($p = 0.023$), NPI ($p < 0.0001$), CSDD ($p = 0.010$), RS-14 ($p < 0.0001$), QoL-AD patients ($p = 0.040$), CBI ($p = 0.040$), SPMSQ ($p = 0.040$), and MNA ($p = 0.010$). The Almere Model Questionnaire presented a higher acceptance level in first and second trial.

Keywords Building resilience for loneliness and dementia · Comprehensive geriatric assessment · Caring service robots · Acceptability · Quality of life · Quality of care · Safety

1 Introduction

In the EU funded MARIO project (Managing active and healthy Aging with use of caRing servIce rObots), specific technological tools are adopted that try to create real feelings and affections making it easier for the patient with dementia (PWD) to accept assistance from a robot and, in specific situations, with the presence of a human supporting the operations made by the machine.

MARIO builds upon the Kompaï 2 robot developed by Robosoft [1]. It is a robot equipped with a camera, a Kinect and two LiDAR sensors for indoor navigation, objects detection and obstacle avoidance. A tablet PC is located on the robot torso for interaction. Mario's controller and interface technologies support software easy plug and play development; moreover, it includes a speech recognition system to interact with natural voice during daily life. Novel IoT technologies, based on Big Data, are integrated to deliver behavioural skills. The novelty of the project is the idea to integrate, in a single robotic platform several capabilities well-known in the literature but that so far have been tested in isolation.

Therefore, MARIO has been designed to support and manage "robotic applications" (apps), which are shown below:

- My Music app: the effect of music on neuropsychiatric symptoms in patients with dementia has been shown [2–4], in particular for anxiety and agitation [2]. Reducing these symptoms is fundamental for independent living and for the quality of life of people. My Music app is focused on allowing PWD to listen to and remember their favourite songs.
- My News app: the aim of this app is to allow PWD to keep in touch with daily news. Moreover, My News app allows the people to select which news they wish to read or hear MARIO read, through vocal or touchscreen selection of the news categories or directly through titles.

- My Games app: the aim of this app is to carry out cognitive stimulation and entertain the PWD. Cognitive stimulation is encouraged by the game "Simon". This is an electronic game of memory skill invented by Baer and Morrison [5]; the device creates a series of tones and lights and requires a user to repeat the series (if the user succeeds the series becomes progressively longer and more complex). In comparison, the entertainment function is facilitated by the provision of the following games such as: card games (as Briscola, Scopa, and Tressette), chess and ping-pong.
- My Calendar app: the aim of this app is to improve the temporal orientation of the PWD, and to remind them of their daily appointments.
- My Family and Friends app: this app was developed to keep the PWD in contact with their relatives and friends in order to reduce their isolation and improve their socialization.
- CGA app: in older people, especially those with multimorbidity, the Comprehensive Geriatric Assessment (CGA) approach is recommended and validated worldwide. One of the aims of the MARIO project from a clinical point of view is to develop an innovative robotic module to perform an automated CGA using systems capable to explore different health domains that allow the determination of the current health status of the PWD through the use of a Multidimensional Prognostic Index (MPI) [6]. The app therefore may support the reduction of adverse outcomes thus prolonging independence.

In the final stage of the project, two trials were completed as shown below: first trial was performed in September 2017, and second trial was performed in October 2017. This paper addresses the impact of the apps described above, when they were delivered by MARIO. We also explored the impact of robot embodiment and how this affected the interactions between PWD and the robot [7–10].

The aim of the present study was to assess the acceptability and efficacy of MARIO companion robot on clinical, cognitive, neuropsychiatric, affective and social aspects, resilience capacity, quality of life in dementia patients, and burden level of the caregivers. Moreover, further aims were to assess the functionality of the apps in the first trial, in which improvements were suggested before to begin the second trial. In this final trial, a re-assessment of the app functionalities were performed.

2 Materials and Methods

This study fulfilled the Declaration of Helsinki, guidelines for Good Clinical Practice, and the Strengthening the Reporting of Observational Studies in Epidemiology guidelines. The approval of the study for experiments using human subjects was obtained from the local ethics committee on human experimentation. Written informed consent for research was obtained from each PWD or from relatives or a legal representative. PWD were consecutively recruited in the Department of

Geriatrics, Casa Sollievo della Sofferenza Hospital (San Giovanni Rotondo, Italy), and were screened for eligibility.

Twenty patients (12 females and 8 males) were screened for eligibility according to the inclusion/exclusion criteria shown below and included in the trials (Trial 1 and Trial 2).

Inclusion criteria were: (1) patients with diagnosis of dementia according to the criteria of the National Institute on Aging-Alzheimer's Association (NIAAA) [11] and the Diagnostic and Statistical Manual of Mental Disorders—Fifth Edition (DMS-5) [12]; (2) presence of mild cognitive impairment (Mini Mental State Examination (MMSE) $\geq$ 18) [13], and (3) the ability to provide an informed consent or availability of a proxy for informed consent. Exclusion criteria were: patients with serious comorbidity, tumors and other diseases that could be causally related to cognitive impairment (ascertained blood infections, vitamin B12 deficiency, anaemia, disorders of the thyroid, kidneys or liver), history of alcohol or drug abuse, head trauma, psychoactive substance use and other causes of memory impairment.

The MARIO robot was shown to all patients and the applications were demonstrated. After preliminary training, the PWD interacted with MARIO during their hospitalization.

In Pre- and Post-MARIO interaction, the following parameters, explained in details in the text, were collected by a systematic interview, clinical evaluation and review of records from a psychologist: demographic data, clinical and medication history and a complete multidimensional and cognitive-affective assessment.

2.1 Diagnosis of Dementia, and Cognitive-Neuropsychiatric-Affective Assessment

Dementia was diagnosed by the Diagnostic and Statistical Manual of Mental Disorders—5 Edition (DMS 5) criteria [12]. Diagnoses of possible/probable Alzheimer's disease were made according to the NIAAA criteria [11] and supported by neuroimaging evidence (CT scan and/or NMR).

In all PWD, cognitive status was screened by means of the MMSE [13], Clock Drawing Test (CDT) [14], and Frontal Assessment Battery (FAB) [15].

Neuropsychiatric symptoms were evaluated with the Neuropsychiatric Inventory (NPI) [16] including the following 12 domains: delusions, hallucinations, agitation/aggression, depression mood, anxiety, euphoria, apathy, disinhibition, irritability/lability, aberrant motor activity, sleep disturbance and eating disorder.

Affective status was evaluated using the Cornell Scale for Depression in Dementia (CSDD) [17].

2.2 Evaluation of Social Aspects and Resilience

In all PWDs, social aspects were assessed by the Multidimensional Scale of Perceived Social Support (MSPSS) [18]. The 14-item Resilience Scale (RS-14) [19] was used to assess the ability to bounce back or recover from stress.

2.3 Quality of Life and Caregiver Burden Level Assessment

The Quality of Life in Alzheimer's Disease (QOL-AD) [20], a 13-item measure test, was used to obtain a rating of the persons quality of life from both the PWD and the caregiver. Moreover all caregivers were administered the Caregiver Burden Inventory (CBI) [21].

2.4 Clinical Assessment

The Tinetti Balance Assessment (TBA) tool was used to evaluate mobility and stability of the PWD.

A CGA was carried out evaluating the following domains: functional status with activities of daily living (ADL) index [22], and by instrumental activities of daily living (IADL) scale [23]; cognitive status with the Short Portable Mental Status Questionnaire (SPMSQ) [24]; comorbidity with the Cumulative Illness Rating Scale (CIRS) [25]; nutritional status with the Mini Nutritional Assessment (MNA) [26]; the risk to develop pressure sores with the Exton-Smith Scale (ESS) [27]; the number of drugs used by patients and the co-habitational status.

2.5 Acceptability and Usability Assessment

Almere Model Questionnaire [8] was used to evaluate the acceptance of the MARIO robot. This questionnaire was specifically developed to test the acceptance of assistive social technologies by older users.

The questionnaire was administered to the PWD and a questionnaire was performed by person who supervised the trial session (MARIO Questionnaire) designed to find out the perceptions about companion robots, especially what the PWD would like the robot to do for them, and how robot can improve their clinical status by using the apps.

2.6 Statistical Analysis

All the analyses were made with the SPSS Version 20 software package (SPSS Inc., Chicago, IL). For dichotomous variables, differences between the groups were tested using the Fisher exact test. This analysis was made using the 2-Way Contingency Table Analysis available at the Interactive Statistical Calculation Pages (http://statpages.org/). For continuous variables, normal distribution was verified by the Shapiro–Wilk normality test and the 1-sample Kolmogorov–Smirnov test. For normally distributed variables, differences among the groups were tested by the Welch 2-sample t test or analysis of variance under general linear model. For non-normally distributed variables, differences among the groups were tested by the Wilcoxon rank sum test with continuity correction or the Kruskal–Wallis rank sum test. Test results in which the p value was smaller than the type 1 error rate of 0.05 were declared significant.

3 Results

3.1 Pre-MARIO Interaction Outcomes

The characteristic outcomes of first trial are shown in Table 1.

The average age of the PWD was 77.00 ± 8.12 years. The patients had a mean educational level of 6.78 ± 2.44 years, and a mean number of years with memory problems of 1.11 ± 0.33. The participants interacted with MARIO in mean 166.11 ± 34.17 min per day (min/die) for a mean of 5.44 ± 1.24 hospitalization days (range = 4–7 days). The total number of interactions was 3 for all patients.

The characteristic outcomes of second trial are shown in Table 2.

Table 1 Baseline characteristics of the patients with dementia that had used MARIO robot during the first trial

	(n = 9)
Gender—Males/Females	4/5
Males (%)	44.40
Age—Mean ± SD	77.00 ± 8.12
Educational level—Mean ± SD	6.78 ± 2.44
Number of years with memory problems—Mean ± SD	1.11 ± 0.33
Hospitalization days—Mean ± SD	5.44 ± 1.24
Time of interaction with MARIO (min/die)—Mean ± SD	166.11 ± 34.17
Number of interactions—Mean ± SD	3.00 ± 0.00

Table 2 Baseline characteristics of the patients with dementia that had used MARIO robot during the second trial

	(n = 11)
Gender—Males/Females	4/7
Males (%)	36.40
Age—Mean ± SD	76.91 ± 7.67
Educational level—Mean ± SD	8.36 ± 4.29
Number of years with memory problems—Mean ± SD	1.18 ± 0.40
Hospitalization days—Mean ± SD	5.82 ± 1.60
Time of interaction with MARIO (min/die)—Mean ± SD	167.27 ± 31.49
Number of interactions—Mean ± SD	4.36 ± 0.50

Table 3 Cognitive, neuropsychiatric, and affective scores of the patients with dementia, before and after the use of MARIO robot, during the two trials

	Before	After	P value
MMSE—Mean ± SD Range	20.99 ± 1.32 19–23	21.39 ± 1.14 20–23	**0.023**
CDT—Mean ± SD Range	2.25 ± 0.64 1–3	2.25 ± 0.64 1–3	1.00
FAB—Mean ± SD Range	12.15 ± 3.36 6–16	12.00 ± 3.58 6–16	0.18
NPI—Mean ± SD Range	5.40 ± 4.83 0–18	4.75 ± 3.49 0–12	**<0.0001**
NPI-D—Mean ± SD Range	2.75 ± 2.43 0–9	2.45 ± 1.93 0–6	0.16
CSDD—Mean ± SD Range	7.00 ± 3.77 1–15	6.15 ± 2.56 2–11	**0.01**

The average age of the PWD was 76.91 ± 7.67 years. The patients had a mean educational level of 8.36 ± 4.29 years, and a mean number of years with memory problems of 1.18 ± 0.40. The participants interacted with MARIO 167.27 ± 31.49 min per day (min/die) in mean for a mean of 5.82 ± 1.60 hospitalization days (range = 4–8 days). The mean number of interactions was 4.36 ± 0.50.

3.2 *Post-MARIO Interaction Outcomes*

As shown in Tables 3, 4 and 5, at post-MARIO interaction, significant improvements were observed in the following parameters: MMSE ($p = 0.023$), NPI ($p < 0.0001$), CSDD ($p = 0.010$), RS-14 ($p < 0.0001$), QoL-AD patients ($p = 0.040$), CBI ($p = 0.040$), SPMSQ ($p = 0.040$), and MNA ($p = 0.010$).

Table 4 Depression, resilience, quality of life and social scores of the patients with dementia before and after the use of MARIO robot, during the two trials

	Before	After	P value
MSPSS total score—Mean ± SD Range	56.00 ± 5.51 48–60	56.40 ± 5.01 48–60	0.16
MSPSS family—Mean ± SD Range	18.80 ± 1.88 16–20	19.20 ± 1.64 16–20	0.16
MSPSS friends—Mean ± SD Range	18.40 ± 2.01 16–20	18.40 ± 2.01 16–20	1.00
MSPSS Special Person—Mean ± SD Range	18.80 ± 1.88 16–20	18.80 ± 1.88 16–20	1.00
RS-14—Mean ± SD Range	26.10 ± 3.66 22–32	28.00 ± 3.70 23–35	**<0.0001**
QoL-AD (Family)—Mean ± SD Range	37.50 ± 2.78 29–39	37.90 ± 3.93 29–42	0.13
QoL-AD (Patient)—Mean ± SD Range	33.25 ± 5.36 26–40	34.10 ± 4.61 29–40	**0.04**
CBI—Mean ± SD Range	5.10 ± 5.38 0–14	4.20 ± 4.17 0–12	**0.04**

Table 5 Clinical, functional, nutritional and social scores of the patients with dementia, before and after the use of MARIO robot, during the two trials

	Before	After	P value
TBA—Mean ± SD Range	9.20 ± 0.41 9–10	9.20 ± 0.41 9–10	1.00
ADL—Mean ± SD Range	5.60 ± 0.50 5–6	5.60 ± 0.50 5–6	1.00
IADL—Mean ± SD Range	3.00 ± 1.03 2–5	2.85 ± 0.75 2–4	0.46
SPMSQ—Mean ± SD Range	1.85 ± 0.49 1–3	1.65 ± 0.48 1–2	**0.04**
ESS—Mean ± SD Range	17.80 ± 2.42 15–20	17.70 ± 2.36 15–20	0.66
MNA—Mean ± SD Range	22.85 ± 2.72 18–27	23.60 ± 2.64 19–28	**0.01**
CIRS—Mean ± SD Range	2.45 ± 0.95 1–5	2.55 ± 1.05 1–5	0.16
N of medications—Mean ± SD Range	3.90 ± 1.37 2–7	3.80 ± 1.19 2–7	0.48

The Almere Model Questionnaire (Table 6) results show a higher acceptance level in the following domains: Attitude (90%), Facilitating condition (100%), Intention to use (70%), Perceived adaptivity (80%), Perceived enjoyment (100%), Perceived sociability (80%), Perceived usefulness (90%), Social Influence (60%), Trust (60%), and Use/Usage (60%).

Table 6 Distribution of Almere model questionnaire domains in patients with dementia during the two trials

Code	Construct	Definition	%
ANX	Anxiety	Evoking anxious or emotional reactions when using the system	0
ATT	Attitude	Positive or negative feelings about the appliance of the technology	90
FC	Facilitating condition	Objective factors in the environment that facilitate using the system	100
ITU	Intention to use	The outspoken intention to use the system over a longer period in time	70
PAD	Perceived adaptivity	The perceived ability of the system to be adaptive to the changing needs of the user	80
PENJ	Perceived enjoiment	Feelings of joy or pleasure associated by the user with the use of the system	100
PEOU	Perceived Ease of use	The degree to which the user believes that using the system would be free of effort	30
PS	Perceived sociability	The perceived ability of the system to perform sociable behavior	80
PU	Perceived usefulness	The degree to which a person believes that using the system would enhance his or her daily activities	90
SI	Social influence	The user's perception of how people who are important to him think about him using the system	60
SP	Social presence	The experience of sensing a social entity when interacting with the system	20
TRUST	Trust	The belief that the system performs with personal integrity and reliability	60
USE	Use/Usage	The actual use of the system over a longer period in time	60

4 Conclusion

The two trials aimed mainly at drawing clear conclusions on the interaction between the user and the MARIO robot and on the acceptability level and efficacy of MARIO companion robot on clinical, cognitive, neuropsychiatric, affective and social aspects, resilience capacity, quality of life in dementia patients, and burden level of the caregivers.

These data are of great importance since they not only give useful indicators to assess what has been accomplished up to now, but they also provide important guidelines in order to improve the system capabilities while specific experimentation stages focused on the clinical aspects are expected to be carried out in the next months.

The really interesting and fascinating aspect of this project is the possibility to create a robotic platform that not only helps with cognitive stimulation and daily living but also, in parallel, detects premature changes in subject health status using algorithms based on the CGA approach.

In MARIO, a novel approach was developed to employ companion robots, build a unique evidence-based 'toolkit' of resilience strategies that foster social inclusion and create a network to advance knowledge about ways of fostering social inclusion. The effect has been to facilitate and support connectedness for persons with dementia and their communities, reduce social exclusion, isolation and stigma, while also helping to shape and prioritize outcomes for resilience by supporting others (such as family, carers and the community).

MARIO positions itself as a tool to help policy makers and the medical community to manage the increasing costs and additional stress placed on the health care system associated with the wide, heterogeneous and complex aging population. The promotion of interventions capable to increase independent living are a must and a certainty, which are mirrored in the literature and the policy. In the realization of interventions that promote independent living, one of the more accepted and validated approaches is CGA that is a multidimensional, usually interdisciplinary, diagnostic process intended to determine an elderly person's medical, psychosocial, and functional capacity problems.

These service-robot enabled innovations was set up to obtain improved diagnostic accuracy, optimization of medical treatment and health outcomes, improved function and quality of life, reduced costs and improved long-term care management.

As part of the evaluation, MARIO was been used to collect information that enables the integration of many different domains of data into a single score that can represent synthetically the health status of a person. MARIO is intended to be the first prototype of a new generation of robots able to communicate with humans on a natural language basis as well as to detect, interpret, and express emotional expressions, and to react to such interactions with a behaviour that adapts and evolve dependently on the environment they live in, i.e. ambient sensors, and the specific humans they interact with. In conclusion, MARIO project represents a novel approach employing companion robots, and its effect will be: (1) to facilitate and support persons with dementia and their caregivers, and (2) reduce social exclusion and isolation.

The collected and above mentioned data confirm a satisfactory integration between the PWD and the system along with a great level of acceptability of MARIO robot by the end-user, both patients themselves and caregivers or medical providers, those who, day by day, take care and assist their patients.

The limitation of the study is mainly represented by the low sample of recruited participants.

In a future perspective, further end-users could be recruited and further functions could be implemented, in addition to interesting reports which could be brought out by MARIO Apps in order to obtain increasing amounts of data in user behaviours. For example, MyCalendar App could report how many times the patient manifested the need to remember drug assumptions or his scheduled appointments. In MyReminiscence App, MyMusic App and MyNews App, correct replies or number and type of played songs or number of news read by the patient could produce more insight in his behaviour and attitudes. These capabilities could in the future foster new Big Data studies in the field of personalized Healthcare.

Acknowledgements The research leading to the results described in this article has received funding from the European Union Horizons 2020—the Framework Programme for Research and Innovation (2014–2020) under grant agreement 643808 Project MARIO 'Managing active and healthy aging with use of caring service robots'.

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