Experimentation of an Integrated System of Services and AAL Solutions for Alzheimer's Disease Patients and Their Caregivers in Marche: The UP-TECH Project

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Abstract Alzheimer's Disease (AD) is one of the most crucial challenges in public health today. In addition to the negative impact of AD on the patient, the effect of this disease on family caregivers also needs to be considered, as they are often deeply burdened psychologically and emotionally. Many projects have tried to exploit ambient assisted living (AAL) technologies to support AD patients and their families, but evidence is so far inconclusive. The UP-TECH project aims at investigating an integrated package of care services and AAL solutions to support family caregivers and to promote the security and the independence of the patient at home. The study is designed as a randomized controlled trial (RCT) and includes the recruitment of 438 patient-

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caregiver dyads, assigned to one of the two experimental groups or to the control group. In particular, one experimental group will receive a package of case management services and assistive devices installed at home, including activity sensors and alarms. The project will assess the impact of the tested AAL solutions using validated scales at a follow-up of 12 months. A cost-effectiveness analysis will also be realized in order to assess the likelihood of implementing such services on a wider scale.

1 Background

In 2010, it has been estimated that worldwide there were 35.6 million people with dementia. It is thought that this number will almost double to 65.7 million by 2030 and reach 115.4 million by 2050 [1]. In 2005 in Italy, the Italian National Institute of Statistics (ISTAT) calculated that there were roughly 250,000 people affected by Alzheimer's disease and similar dementias [2].

Family caregivers provide the bulk of informal care and often are referred to as "hidden second patients" [3]. In fact, AD heavily affects patients' families, on whom the main burden of care falls, putting caregivers at high risk of stress, anxiety, mortality and lower quality of life [4]. As a result, patients living with distressed caregivers are at higher risk of behavioral disturbances, agitation, use of anti-psychotic drugs and institutionalization [5].

Despite controversies [6], studies have shown that specific interventions aimed at supporting caregivers of AD patients can engender considerable improvements in their physical and mental health, by reducing the burden of caregiving and stress [7]. In this field, ambient assisted living (AAL) technologies have great potential

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to ameliorate the quality of life of AD patients and their caregivers. Notwithstanding the absence of definitive evidence [8], pilot studies have revealed that domestic adaptations designed to aid older people to carry-out their daily needs are especially valuable for users' quality of life and well-being [9]. Several studies assessing the effectiveness of assistive technology in AD have been undertaken; however, most of these interventions are in a prototype/testing phase and fail to be scaled-up and systematically implemented in daily practice. A few of these projects include: Talking lights [10], Home Assurance System [11], ROSETTA [12] and ENABLE [13]. The latter project involved the testing of an integrated system of technologies in the home, including automatic night lights, locators for lost objects, computerized calendars, programmable telephones, gas sensors, touch screen pads for music and a voice prompter when medicines should be taken. These technologies led to increased independence of the older person and reduced caregivers' burden.

On the basis of previous studies, the UP-TECH project has been designed as a randomized, controlled trial (RCT), in order to adapt the most promising evidence-based interventions in dementia care into 5 different areas of the Marche Region in Italy [14]. The main objectives of the project are: (1) to reduce the burden of family caregivers of AD patients; and (2) to maintain AD patients at home preventing premature institutionalization. This will be achieved by the use of case-management strategies, new technologies in the home of patients, preventive home visits by trained nurses and integration of existing services.

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2 Materials and Methods

A brief overview of materials and methods used in the UP-TECH project is provided in the following paragraphs. For more details concerning the study protocol, please refer to the previous publication by Chiatti and colleagues [14].

2.1 Study Design

The UP-TECH project is a multi-component RCT, lasting 12 months, aimed at enrolling 450 AD patient-caregiver dyads, allocated to 3 different arms of 150 dyads each, which receive the following interventions:

1. experimental group 1 ("UP-group"): dyads are followed by a case manager and receive three nurse home visits in a 12-month period;
2. experimental group 2 ("UP-TECH group"): dyads are followed by a case manager as in the previous "Up-group", with additional AAL technologies installed at home with support from the case manager;
3. control group: dyads receive standard assistance, including three nurse home visits and informative brochures on the management of AD.

The case management intervention is carried out by appropriately trained social workers and includes counseling sessions, scheduled follow-up phone calls, training sessions for family caregivers on stress management and caregiving activities, social service administration and establishment of links between healthcare services and general practitioners. Nurse home visits include a multidimensional evaluation of patients, together with a training intervention for the caregivers addressing issues such as caregiving activities, nutrition, drug administration and ergonomics of the domestic environment. The AAL technologies (the UP-TECH kit) were defined using a bottom-up approach, through extensive consultations with patients, professionals and care staff (see below).

The RCT will assess different dimensions, including the following measures:

1. Caregiver burden: the Italian version of the Caregiver Burden Inventory (CBI) validated by Marvardi and colleagues [15];
2. The number of days spent at home by the AD patient during the observation period. This is a continuous variable calculated at each intermediate (after 6 months), final (after 12 months) and follow-up assessments (after 24 months) by subtracting, from the total days of observation, the number of days of: institutionalization in a residential care facility, care home and/or nursing home; hospitalization and brief stays in an observation unit of an emergency room;
3. Caregiver quality of life: the Italian validated version of the SF-12 questionnaire [16, 17];
4. Caregiver anxiety and depression: the Italian validated version of the Hospital Anxiety and Depression Scale (HADS) [18, 19].

2.2 Eligibility Criteria

Patients with AD were enrolled if they met specific inclusion criteria: they had a pre-existing diagnosis of AD, were in an intermediate stage—according to the 2011 criteria of the National Institute on Aging-Alzheimer's Association (NIA-AA) [20–22]—, with a mini-mental state examination (MMSE) score [23] between 10 and 20, and lived in the community with the assistance of at least one family caregiver.

Family caregivers were defined as those relatives who cared for and directly supported the AD patient with the activities of daily living (ADL) and the instrumental activities of daily living (IADL), for at least 1 hour per day within the last

6 months. Only the primary caregiver (i.e. the family member spending the most time in caregiving activities) was included in the study, if a patient was cared for by more than one family member.

2.3 Definition of the AAL Solutions

The selection of technologies installed in patients' homes was based on a user-centered design, in order to address specifically the needs of patients and their caregivers. One focus group with 9 family caregivers was organized, aimed at understanding what kind of assistive device solutions could address their needs, make them comfortable and respect privacy and ethical aspects (also in relation to the patient).

The focus group followed structured guidelines for moderators which included two stages: a discussion on users' needs and the ways in which technology can address problems in ADLs; a discussion focused on technology acceptance by patients and caregivers, as well as issues related to sustainability and integration with formal care services. In a second step, AAL solutions were discussed with professionals and care staff during the five preliminary site visits carried out by the UP-TECH management team.

3 Results

3.1 Recruitment Process and Description of the Study Participants

The recruitment timeframe of this study was less than 6 months (January 14th, 2013–June 7th, 2013). It led to the enrollment of 438 out of the 450 planned patient-caregiver dyads, which were interviewed by a nurse trained to collect data. At enrollment, patients had a mean MMSE score of 16 ($\pm$3) points (Table 1). A majority of the subjects were women (71.5 %) with a mean age ($\pm\pm$SD) of 81.5 ± 5.7 years. These patients had a significant impairment in IADLs (35.1 ± 13.4 points out of 48 points), while they were relatively independent performing ADLs (1.5 ± 1.6 points out of 6 points on the ADL hierarchy scale). 26.5 % of the patients displayed behavioral problems as reported by the caregivers. There were no statistically significant differences in patient characteristics among the 3 intervention groups. A higher percentage of caregivers were women (66.2 %) with an average age of 61.4 ± 13 years. 30.8 % were spouses, 55.7 % were children and 13.5 % were another relative. 30.1 % of the caregivers had no formal education, 24.9 % had a primary level of education (elementary/middle school), 36.7 % possessed an intermediate level of instruction (high school), while 8.2 % reached a high level of schooling (university). Also in this case, there were no statistically significant differences in caregiver characteristics among the 3 groups.

Table 1 Basic socio-demographic, health and psychological characteristics of the sample

	Up (N = 147)		UP-TECH (N = 146)		Usual care (N = 145)		Total (N = 438)		P*
Patients' characteristics									
Gender (female)	68.0		71.9		74.5		71.5		0.47
Age (years)	81.0	±5.2	82.0	±6.0	81.4	±5.8	81.5	±5.7	0.28
IADL impairment	34.5	±13.4	37.1	±11.6	33.8	±14.8	35.1	±13.4	0.08
ADL impairment	1.5	±1.6	1.6	±1.7	1.4	±1.5	1.5	±1.6	0.61
MMSE	15.9	±3.2	15.8	±3.0	16.3	±2.9	16.0	±3.0	0.29
Behavioral disturbances	27.2		27.4		24.8		26.5		0.85
Caregivers' characteristics									
Gender (female)	66.7		59.6		72.4		66.2		0.07
Age (years)	63.3	±13.6	61.2	±12.6	59.6	±13.0	61.4	±13.0	0.06
Relationship									0.26
Spouse	37.4		28.1		26.9		30.8		
Son/Daughter	49.0		59.6		58.6		55.7		
Other relative	13.6		12.3		14.5		13.5		
Education									0.11
No title	38.1		26.0		26.2		30.1		
Primary level	22.5		21.9		30.3		24.9		
Intermediate level	32.7		43.2		34.5		36.7		
High level	6.8		8.9		9.0		8.2		

Values are expressed in either "Percentage" or "Mean ± Standard Deviation" where appropriate.
* p-value of the Chi2 test for association of categorical variables and ANOVA test for continuous variables

3.2 Development of the AAL Solutions

The main functions, proposed by users in the focus group and integrated with care staff opinions and experiences, that could be fulfilled by AAL solutions, were the following:

- Controlling home access through camera systems with automatic recognition. A common problem was that some patients would open the door to anybody, even strangers, and let them in;
- Carrying out bureaucratic and administrative procedures for accessing formal care services through an integrated on-line system;
- Sharing patient health care data among professionals and units involved in the care process through information technology (IT) systems;
- Entertaining patients and providing companionship through multimedia and interactive/automated applications;
- Checking the activity and the health status of patients through monitoring systems;
- Sending an alarm, when an accident occurs, through emergency buttons and similar devices;

Fig. 1 The UP-TECH kit of AAL solutions

- Using sensors to send a passive alarm if the patient falls;
- Communicating in real time with the privately-employed care assistant and monitoring his/her activity.

Trying to address the expressed needs, the research team developed an AAL solution consisting of a kit that includes luminous paths, automatic lights and assorted detection sensors which activate when a person leaves the home, falls at night or when there is a gas or water leak. These devices are assembled by an external contractor and linked to a single-board microcontroller, which will transmit alarm messages, when triggered, through the cell phone system to the family caregivers. Assistive technologies will be installed by the case manager with the support of expert technicians who will also train caregivers on their use (Fig. 1).

4 Conclusions

The UP-TECH study is one of the major test-beds, worldwide, to investigate novel approaches to AD care. The forthcoming implementation of an AAL intervention on such a large scale will produce definitive evidence on the effectiveness and cost-effectiveness of such tools, providing policy-makers, industries and other stakeholders with important insights, which will be useful to tailor new policies and projects in the field. Interim results will start to be available during 2014.

References

1. Wimo, A., Prince, M.: The World Alzheimer Report 2010: The Global Economic Impact of Dementia. Alzheimer's Disease International, London (2010)
2. ISTAT: Health and Use of Health Services in 2005. ISTAT, Rome (2008)
3. Smith, G.C., Tobin, S.S., Robertson-Tchabo, E.A., Power, P.W.: Strengthening Aging Families: Diversity in Practice and Policy. Sage, Thousand Oaks, CA (1995)
4. Schulz, R., Burgio, L., Burns, R., Eisdorfer, C., Gallagher-Thompson, D., Gitlin, L.N., Mahoney, D.F.: Resources for enhancing Alzheimer's caregiver health (REACH): overview, site-specific outcomes, and future directions. Gerontologist **43**, 514–520 (2003)
5. Dunkin, J.J., Anderson-Hanley, C.: Dementia caregiver burden: a review of the literature and guidelines for assessment and intervention. Neurology **51**, S53–60, (discussion S65–57) (1998)
6. Parker, D., Mills, S., Abbey, J.: Effectiveness of interventions that assist caregivers to support people with dementia living in the community: a systematic review. Int. J. Evid. Based Healthc. **6**, 137–172 (2008)
7. Mittelman, M., Haley, W., Clay, O., Roth, D.: Improving caregiver well-being delays nursing home placement of patients with Alzheimer disease. Neurology **67**, 1592–1599 (2006)
8. Martin, S., Kelly, G., Kernohan, W.G., McCreight, B., Nugent, C.: Smart home technologies for health and social care support. Cochrane Database Syst. Rev. **8**(4), CD006412 (2008)
9. Fänge, A., Iwarsson, S.: Changes in ADL dependence and aspects of usability following housing adaptation—a longitudinal perspective. Am. J. Occup.Ther. **59**, 296–304 (2005)
10. Talking Lights project. www.talking-lights.com
11. Cuddihy, P., Hinman, R.T., Avestruz, A., Lupton, E.C., Livshin, G., Rodriguez, J.I., Leeb, S.B., Clark, C.M., Horvath, K.J., Volicer, L., Landfeldt, B., Kay, J.: Successful aging. IEEE Pervasive Comput. **3**, 48–50 (2004)
12. ENABLE project. www.enableproject.org
13. ROSETTA project. www.aal-rosetta.eu
14. Chiatti, C., Masera, F., Rimland, J., Cherubini, A., Scarpino, O., Spazzafumo, L., Lattanzio, F.: The UP-TECH project, an intervention to support caregivers of Alzheimer's disease patients in Italy: study protocol for a randomized controlled trial. Trials (2013). doi:10.1186/1745-6215-14-155
15. Marvardi, M., Mattioli, P., Spazzafumo, L., Mastriforti, R., Rinaldi, P., Polidori, M.C., Cherubini, A., Quartesan, R., Bartorelli, L.: The caregiver burden inventory in evaluating the burden of caregivers of elderly demented patients: results from a multicenter study. Aging Clin. Exp. Res. **17**, 46–53 (2005)
16. Gandek, B., Ware, J.E.: Methods for validating and norming translations of health status questionnaires: the IQOLA Project approach. International quality of life assessment. J. Clin. Epidemiol. **51**, 953–959 (1998)
17. Kodraliu, G., Mosconi, P., Groth, N., Carmosino, G., Perilli, A., Gianicolo, E.A., Rossi, C., Apolone, G.: Subjective health status assessment: evaluation of the Italian version of the SF-12 health survey. Results from the MiOS project. J. Epidemiol. Biostat. **6**, 305–316 (2001)

18. Zigmond, A.S., Snaith, R.P.: The hospital anxiety and depression scale. Acta Psychiatr. Scand. **67**, 361–370 (1983)
19. Costantini, M., Musso, M., Viterbori, P., Bonci, F., Del, M.L., Garrone, O., Venturini, M., Morasso, G.: Detecting psychological distress in cancer patients: validity of the Italian version of the Hospital Anxiety and Depression Scale. Support. Care Cancer **7**, 121–127 (1999)
20. Albert, M.S., Dekosky, S.T., Dickson, D., Dubois, B., Feldman, H.H., Fox, N.C., Gamst, A., Holtzman, D.M., Jagust, W.J., Petersen, R.C., Snyder, P.J., Carrillo, M.C., Thies, B., Phelps, C.H.: The diagnosis of mild cognitive impairment due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement **7**, 270–279 (2011)
21. McKhann, G.M., Knopman, D.S., Chertkow, H., Hyman, B.T., Jack, C.R., Kawas, C.H., Klunk, W.E., Koroshetz, W.J., Manly, J.J., Mayeux, R., Mohs, R.C., Morris, J.C., Rossor, M.N., Scheltens, P., Carrillo, M.C., Thies, B., Weintraub, S., Phelps, C.H.: The diagnosis of dementia due to Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement **7**, 263–269 (2011)
22. Sperling, R.A., Aisen, P.S., Beckett, L.A., Bennett, D.A., Craft, S., Fagan, A.M., Iwatsubo, T., Jack, C.R., Kaye, J., Montine, T.J., Park, D.C., Reiman, E.M., Rowe, C.C., Siemers, E., Stern, Y., Yaffe, K., Carrillo, M.C., Thies, B., Morrison-Bogorad, M., Wagster, M.V., Phelps, C.H.: Toward defining the preclinical stages of Alzheimer's disease: recommendations from the National Institute on Aging-Alzheimer's Association workgroups on diagnostic guidelines for Alzheimer's disease. Alzheimers Dement **7**, 280–292 (2011)
23. Folstein, M.F., Folstein, S.E., McHugh, P.R.: "Mini-mental state". A practical method for grading the cognitive state of patients for the clinician. J. Psychiatr. Res. **12**, 189–198 (1975)