Definition of Field Trials Protocol

Deliverable D7.1B

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Abbreviations

Abbrev.	Description
AAL	Ambient Assisted Living
MUV	Medical University of Vienna
UNIPG	University of Perugia
MCI	Mild Cognitive Impairment
AD	Alzheimer's Disease
NIA	National Institute on Aging-Alzheimer's Association
CRI	Cognitive Reserve Index
ADL	Activities of daily living
IADL	Instrumental activities of daily living
MMSE	Mini-Mental State Examination
NIA AA	National Institute on Aging and the Alzheimer's Association
SUS	System Usability Scale
DM app	Dementia Monitoring application

Executive Summary

This section describes preparation steps before the final evaluation of the system. A research design has been developed to conduct the Field Trials where 15 representative end-users are given the opportunity to test Memento in daily living experience and are compared with a control group (15 subjects) who use traditional strategies for remember.
End-users will be requested to make a diary about their experiences, fill out questionnaires and scales, and execute workshop in order to share their experiences.

1 About this Document

1.1 Role of the Deliverable

According the overall research design described in D7.1, the present document is a basis for the preparation of the field trials. Evaluation methods are described together with the recruitment criteria's presentation and the description of the assessment instruments.
Overall research questions are specified and the procedure of data collection is described.

1.2 Relationship to other Memento Deliverables

Table 1: Relationship to other Memento Deliverables

Deliverable	Relation
D2.2 – End user requirements	Description of end-users recruited for lab trials
D2.3/D2.5 – Definition of Use Cases and Scenarios	Use cases defined in this deliverables are used as basis for lab trial tasks.
D2.4 - End-user requirements	End-user requirements after the evaluation of the lab trials
D3.1 /D3.2– Specification of Hardware Design and User Interface	Describes the user interface design for the software components.
D4.1 A and B – Hardware Specification	Requirements and features of the Memento hardware components
D4.2 - Hardware Prototypes 1 (for Integration)	Development of the system
D4.3 Final Hardware Specification	Final Hardware specifications
D5.1 A and D5-3B – Software Specification	General architecture and module specific requirements and specifications

D7.1 - Definition of lab trial protocol	Overall research design of the lab trials.
D7.2 A – Protocol for lab trials	Describes the strategy, preparation and execution of the lab trials in detail
D7.3A - Evaluation of Lab Trials	Provides information about user experience, engagement and acceptability of the first MEMENTO prototype according to the lab trials

1.3 Structure of this Document

This document describes the research design to develop the plan for Field Trials. The first part presents the aim of the study and the paradigm, describing the expected results and the method.
The final part presents the features list necessary to conduct the experiment.

2 Introduction

According the taskforce on Assistive Technology setup within INTERDEM (an interdisciplinary European research network (www.interdem.org) of more than 160 members, collaborating to develop and carry out pan-European research on early, timely, and quality psychosocial interventions in dementia), Memento could be considered both as a system that helps people living with dementia to manage everyday life and also as a technology that helps them engage in pleasurable activities and improve social participation, contact and support.
In fact, the expected functionalities at the end of the project include an electronic calendar, reminders for activities, medication reminders, a navigation system, a game for the cognitive stimulation and the monitoring of the cognitive symptoms and a system to ask for support in case of need.
Our research design adopts the International Classification of Functioning, Disability and Health (ICF), in which human functioning is understood as a continuum of health states, and everyone exhibits some degree of functioning in each domain, at level of the body, the person and the society. The ICF intends disability as a health experience that occurs in a context, rather than as a problem that concern solely the individual. According to the

biopsychosocial model embedded in the ICF, disability and functioning are outcomes of interactions between health conditions (disease, disorders and injuries) and contextual factors. The model recognizes that disability is the product of an interaction between attributes of an individual and features of the person's physical, social and attitudinal environment (Üstün, Kostanjsek, Chatterji, & Rehm, 2010).

3 Aims

Primary aims: To explore how effective Memento is to: 1) improve the health and quality of life of people in an early stage of dementia; 2) support the management of daily activities that are usually affected by the loss of memory and cognition; 3) collect data on Memento usability; 4) collect indicators relevant to understand the progress of the disease.
Secondary aims: To 1) explore the impact of Memento on the caregiver burden; 2) collect users' opinions.

4 Study paradigm

The study paradigm is to explore the use of Memento in people with mild dementia or mild cognitive impairment (MCI). An experimental procedure is designed to gather quantitative and qualitative data. In particular, quantitative data includes: 1) health and disability (cognition, mobility, self-care, getting along with people, life activities, work activities and participation); 2) quality of life; 3) competence of patients with Alzheimer's Disease (AD) and MCI in basic and instrumental activities of daily living (ADLs); 4) frequency of use of Memento in daily living (self-report and log - report); 5) neuropsychiatric behaviours; 6) caregiver burden and qualitative data; 7) engagement. Otherwise, qualitative data focuses on: 1) physical and psychological support; 2) social and economic aspects; 3) personal experience of the involved users.
Moreover, a sub-study is developed to explore the "Dementia monitoring" app (DM app), limited to the Italian users test group.

4.1 Expected results

According to the primary aims, we expect to observe the following results: starting from a biopsychosocial perspective, those using the Memento system (TG) will have a higher level of health and disability, than those in the control group (CG). An increase in independence in activities of daily living could be possible. In particular, an increase in the cognition and participation domain is expected.
TG uses both Memento and usual strategies. A progressive increase of frequency of use of the Memento system compared to usual strategies could be possible.
TG will improve their quality of life (QOL) more than those in the CG and express a high level of engagement.
These results are expected from previous research, revealing that people with dementia are enthusiastic about taking part in technology design, about using assistive technology to remain independent and because use of technologies could have a positive effect on self-confidence and self-esteem. In fact, studies found that assistive technologies are considered as a "status symbol" often associated with youth (Meiland et al., 2017).

Regarding the secondary aims, as the caregiver burden is related to health and disability of the care recipient, if Memento is effective in increasing the health and disability of people with mild dementia, a decrease in caregiver burden would be expected in TG. Moreover, the involvement in the study could positively influence the sense of support, confidence and self-esteem. At the same time, it could be possible that caregivers find it stressful to manage the system with the care recipients at home.

Finally, for the sub-study, we expect that:

- data on cognitive impairment progression, collected by means of neuropsychology assessment, are congruent with dementia monitoring app indexes.
- users engaged in the "dementia monitoring" game, express signals of positive effects and attention during the task.

In fact, automatic analysis of spontaneous speech is considered a promising method for diagnosis and dementia progression monitoring (Bucks, Singh, Cuerden, & Wilcock, 2000; Thomas, Keselj, Cercone, Rockwood, & Asp, 2005; Fraser, Meltzer and Rudzicz, 2016; Fraser et al., 2014; Lopez-de-Ipina

et al., 2018; Kavè and Dassa, 2018). At the same time, recent findings support the notion that reduced autobiographical episodic detail generation may be a marker of subtle cognitive decline associated with AD (Grilli, Wank, Bercel, & Ryan, 2018).
Moreover, the reminiscence therapy/life review stimulation seems to effectively increase episodic and semantic autobiographical memory (Allen, Doyle, Commins, & Roche, 2018) and a growing body of evidence is now starting to converge on the finding that engaging in an experiential processing mode increases positive emotional responses during recall of pleasant autobiographical memories (Gadeikis, Bos, Schweizer, Murphy, & Dunn, 2017).

4.2 Method

The study will be a mixed-method controlled trial.
In line with the inclusion criteria defined within deliverable D2.2, clinical partners will recruit patients treated at the dementia outpatient clinic MUV, Bidaidek and UNIPG. Before starting with the lab trials, written informed consent must be provided by the patient or their legal guardian. In each clinical center 5 Patients with a diagnosis of MCI due to AD or mild AD according to the NIA AA criteria (McKhann, Knopman et al. 2011) with an MMSE 28 – 24 (inclusive) and (if available) their caregivers will participate in the trials. Furthermore we defined a cut off score in activities of daily living according to the Lawton ADL score (Graf, 2009; Lawton, & Brody, 1969).

As stated in deliverable 7.1A, additional information should be collected about each patient and respective caregiver. Demographic and technology related information about the patient will be collected and approximate stratification of parameters mentioned below should be taken in consideration. Both mandatory criteria for patient recruitment and optional patient traits are summarized in Table 2.

4.2.1 End Users

Patients

- Cognitive reserve established with Cognitive Reserve Index (CRI): the concept of "reserve" has been used to explain the difference

between individuals in their capacity to cope with or compensate for pathology. Considering the importance of the cognitive reserve, the CRI (Nucci, Mapelli et al. 2012) will be taken into account. The CRI is established by a semi-structured interview (see appendix) that gathers and quantifies all the experiences that a person has acquired throughout their life. The CRI questionnaire includes demographic data and 20 items grouped into three sections: CRI-Education, CRI-Working Activities and CRI-Leisure Time Activities.

- Technical proficiency patient: we define the technical proficiency as the skills required to operate an information system (i.e., a hardware/software solution). Our ambition is to test the MEMENTO device with end-users having different levels of technical skills.
- Age and Sex: both aspects should be considered in terms of the general attitude towards technology, design requirements and needs regarding the individual life phase.

Caregiver:

- Caregiver status: the caregiver status is relevant regarding their availability in daily live. Subjects living with their spouse or in a family context, as well as subjects living alone with an informal supervisor (son/daughter/niece/…) will be included in the trial.
- Technical proficiency caregiver: the technical skills of the caregiver are important for supporting the patient and using the various software solutions of the MEMENTO system (i.e., accessing the calendar from another technical device).

Table 2: Patient Selection Criteria for Lab Trials	
Mandatory Criteria	
Diagnosis of MCI due to AD and mild AD (amnestic type) (McKhan criteria)	
Activities of Daily Living	Lawton - Brody Instrumental Activities of Daily Living Scale (IADL) equal or below 5

	a) subjects must be able to dial a few well-known numbers on the cellular phone b) subjects that are able to get around (or travel) outside of the home (alone or accompanied)
Correct total score Mini-Mental State Examination (MMSE)	**RANGE 24-28**
Optional Traits	
Different levels of cognitive reserve (CRIq scores)	
Different levels of Technical Proficiency	

4.2.2 Experimental conditions

While test group try Memento into daily living, the control group uses traditional strategies for remember.
For example, in order to remember an appointment, a member of the test group has the opportunity to use Memento while a member of the control group could use an agenda, a calendar….

4.2.3 Measures

Primary outcome measures:

1. World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) (Federici et al. 2009; Üstün et al. 2010). Generic assessment instrument to provide a standardized cross-cultural method for measuring activity limitations and participation restrictions, largely employed in geriatric settings (Bombin et al., 2012; Federici et al. 2017; Huang et al., 2016). The conceptual frame of reference of this instrument is the International Classification of Functioning, Disability and Health: ICF. Specifically, the instrument is designed to evaluate the functioning of the individual in six activity domains: (i) cognition (understanding and communication); (ii) mobility (ability to move and get around); (iii) self-care (ability to

attend to personal hygiene, dressing and eating, and to live alone); (iv) getting along (ability to interact with other people); (v) life activities (ability to carry out responsibilities at home, work and school); (vi) participation in society (ability to engage in community, civil and recreational activities). For all six domains, the WHODAS 2.0 provides a profile and a summary measure of functioning and disability that is reliable and applicable across cultures in adult populations. The version of the WHODAS 2.0 interviewer-administered proxy form was used. Also the self-administered version was used. The simple scoring option was adopted (Federici et al. 2009; Üstün et al. 2010).

2. The Quality of Life – Alzheimer's Disease scale (QOL–AD) (Logsdon, Gibbons, McCurry, & Teri, 1999). Developed for individuals with dementia, it comprises both a version for the person with dementia (QOL–P) and a version for the caregiver (QOL–C).
3. Alzheimer Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) (Galasko et al. 1997). This is an inventory to assess activities of daily living for clinical trials in dementia.

Secondary outcome measures:

4. Neuropsychiatric Inventory (NPI) (Cummings et al. 1994) assesses neuropsychiatric disturbances common in dementia together with the amount of caregiver distress engendered by each of the neuropsychiatric disorders.
5. Caregiver Burden Scale (CBI) (Zarit et al., 1980) assesses perceived burden among caregivers of family members with dementia
6. User Engagement Scale (UES) (O'Brien, & Toms, 2010) measures the user engagement by means of six dimensions of engagement: aesthetic appeal, focused attention, novelty, perceived usability, felt involvement, and endurability.
7. System Usability Scale (SUS) (Brooke, 1996) to take a quick measurement of how participants perceived the usability
8. Ad hoc interviews as described in table 1

4.2.4 Procedure

Experimental (TG) and control groups (CG) are formed at the clinical centres. Both groups are involved in tasks below.
The schedule of the field trials is organized in 12 weeks to cover a testing period of three months.
In each week, TG and CG are invited to execute different activities in order to achieve different experimental aims.
An initial session is scheduled to involve the participants and to present the study to the groups. A final session is also planned.

INITIAL SESSION at the clinical centre

TG and CG (separate group sessions)
AIM: 1) to present the project; 2) to stimulate the participation; 3) to present the diary.
METHODS:
Meeting with the users. Presentation of the study and delivery of a calendar with a generic description of the program (e.g. meeting at the clinical centre, home meeting or phone meeting). Presentation of the diary as fundamental instrument to monitor strategy for remember in daily living.

W1 at home

TG at home (individual sessions)	**CG (individual session) – clinical centre**
AIM: 1) To deliver Memento, introducing the functionalities 2) to illustrate the Memento manual 3) to collect data on users' habits and strategies for remembering 4) to monitor the correct use of the Diary 5) to collect outcome measures.	**AIM:** 1) to guarantee compliance 2) to monitor the correct use of the Diary 3) to collect data on users' habits and strategies for remembering 4) to collect outcome measures.

6) To obtain a baseline score in DM app (only Italian participants)	
METHODS:	
Ad hoc interviews regarding a typical week (medical therapy management, appointments, activities like go out for shopping, go out for pleasure activities, social contacts) and strategies for remembering (agenda, post-it, calendar…) are administered. Outcome Measures are collected.	
1) The experimenters train the users in the Memento functionalities and hand over the manual. The different use cases are presented and it is shown how to use Memento. 2) The comprehension of the manual is tested by letting the user execute a task following the instructions. 3) The correctness of the Diary compilation is checked 4) The Italian users are invited to use DM app.	1) The experimenters involve the users in the project explaining the importance of their role and presenting a series of instructions to follow during the field trials. In particular, the importance to use the diary is stressed. 2) The diary is presented, and instructions are given.

W3

TG (individual phone session)	**CG (individual phone session)**
AIM: 1) To monitor the Memento use. 2) To collect data about the diary (Diary feedback form) 3) To stimulate the use of Memento “appointments” by means of a task	**AIM:** 1) to guarantee compliance motivating the participants 2) To collect data about the diary. 3) To propose a task (to remember an appointment)
METHODS:	
1) The experimenters and users discuss about the “weeks with Memento” (problems, troubles, …).	1) The experimenters call the users and refresh the rules. 2) Users share information about the diary on memory

2) Users share information about the diary. 3) The experimenters propose to set an appointment to call peer contact	strategies and memory failures. 4) The experimenters propose to set an appointment to call peer contact

W5

TG (phone session)	**CG (phone session)**
AIM: 1) To monitor the use of Memento 2) to collect data on Independence in activities of daily living	**AIM:** 1) to guarantee compliance 2) to collect data on Independence in activities of daily living
METHODS:	
ADL-ADSC scale (phone version – caregiver interview)	
1) The experimenters call users and compile a report of the Memento use (feedback on diary) 2) ADCS-ADL administration	1) The experimenters call users and compile a report of memory strategies and memory failures (feedback on diary) 2) ADCS-ADL administration

W7

TG (phone session)	**CG (phone session)**
AIM: 1) To monitor the use of Memento and discuss about problems, difficulties… 2) (only IT) To monitor DM app use	AIM: to guarantee the compliance
METHODS:	
1) The experimenters call users and compile a report of Memento use (feedback on diary). 2) The experimenters propose a DM app session.	The experimenters call users and compile a report of memory strategies and memory failures (feedback on diary)

W8

TG (home session)	**CG (phone session)**
AIM: 1) To simulate the use of Memento in different situations 2) To collect data on Diary	AIM: 1) to guarantee compliance 2) to explore the strategies in in use cases.
METHODS:	
1) The experimenters give tasks and collect data about tasks execution. 2) Diary feedback is collected.	1) Diary feedback is collected 2) The experimenters collect about strategies for remember in different situations.

W10

TG (phone session)	**CG (phone session)**
AIM: 1) To monitor the use of Memento 2) (only IT) To stimulate the use of DM app	AIM: to guarantee compliance
METHODS:	
1) The experimenters call users and compile a report of the Memento use (feedback on diary) 2) (only IT) The experimenters propose a DM app session.	The experimenters call users and compile a report of memory strategies and memory failures (feedback on diary)

W11 or 12 (to avoid the Christmas Holidays)

TG (group session at clinical centre)	
AIM: 1) To monitor the use of Memento.	

2) To share users' experience and to evaluate physical and psychological support, social and economic aspects	
METHODS:	
1) The experimenters call users and compile a report of the Memento use (feedback on diary) 2) Focus group session at the clinical centre	The users are instructed to compile the usual report on memory strategy.

FINAL SESSION

TG and CG (individual sessions at clinical centre)
AIM: 1) To collect data on outcomes measures 2) To collect data on Memento engagement and general comments 3) To return the diary
METHODS:
1) Administration of primary and secondary outcome measures.

At the end of the Field Trials, self-report data on Memento's frequency of use will be compare with log-report.
It could be noted that data on DM app monitoring are not outcome measures. Rather, these are necessary to validate the app as a game of stimulation and dementia monitoring. To this purpose, the ACE-R total score (a global cognitive measure that includes the MMSE described in D2.2) and its subdomains scores (attention/orientation, verbal fluency, memory, language and visuospatial) will be compared with the indexes included in the app. At the same time an interview will be proposed together with an observed scale useful to capture emotional state as described in the app development description (D2.4). As the presence of the experimenter is necessary, to avoid over-stressing sessions, these data will be collect in week 8 and in the final session.

4.2.4 Materials

The following Table (Table 3) resumes the materials to develop for the field trials:

Table 3: Supplement overview			
Supplement #	**Supplement Name**	**Explenation**	**Week**
S01	Protocol of Field Trials TG	Detailed Workflow of the field trials for the MEMENTO test group (TG)	
S02	Protocol of Field Trials CG	Detailed Workflow of the field trials for the control group (CG)	
S03	Presentation of Study	Powerpoint presentation of MEMENTO study and planned trials	Initial session
S04	Calendar TG	Generic overview of trials for the TG	Initial session
S05	Calendar CG	Generic overview of trials for the CG	Initial session
S06	Diary TG	Diary prepared for the TG	trial week and 1 - 12
S07	Diary CG	Diary prepared for the CG	trial week and 1 - 12
S08	Strategies to Remember	Form to evaluate strategies to remember for TG and GC	1
S09	Manual	Manual for the use of the MEMENTO device	1
S10	Outcome Measures[1]	Outcome measures in form of questionnaires	1 and final session
S11	Diary Feedback Form TG	Track feedback and usage of diaries to compare with log	3; 5; 7; 8; 10
S12	Diary Feedback Form CG	Track feedback and usage of diaries	3; 5; 7; 8; 10

[1] The ADCS-ADL is considered separately as S15.

S13	Use Case Simulation TG	Provides tasks based on use cases for testing	3; 8
S14	Use Case Simulation CG	Form to evaluate strategies to remember based on use cases	3; 8
S15	ADCS-ADL	Independence in activities of daily living questionnaire	2, 5, final
S16	Observation Form/Interview	Observation form to document group discussions	11
S17	Final Interview - TG	Final interview form to conclude field trials	Final session
S18	Final Interview - CG	Final interview form to conclude field trials	Final session
S19	Dementia Monitoring	Form to insert the scores at different time	1, 7, 12

4.2.5 Investigators

Before starting with the filed trial execution, supervisor persons at MUW, Bidaideak and UNIPG will be trained on the system to avoid misunderstandings.
A peer contact person (one for MUW, one for Bidaideak and one for UNIPG) will accompany the users throughout the test period.
A peer consultation point will be installed to be contacted for any questions and assistance.
Clinical and technical partners support participants into learning some procedures and experimental activities are planned both at the study centre than at patient's home.
The clinical partners will monitor all the experimental activities and motivate the participants also by phones.

5 Features for Field Trials

MEMENTO system will be used for the Field trials. Specifications for the prototype can be found in deliverables D3.2 - Final specification of hardware design and user interface, D4.3 Final Hardware Specification - Phase B and D5.3 Final Software Specification Table 4 describes the features subjected to testing for the final prototype:

Table 4: Features for Field Trials

Feature ID	Feature	Device
M1	Login screen	Main Device
M3	View/Enter/Edit/Remove Medication	Main Device
M4	Sync Medication with Backend	Main Device
M5	Medication Reminders	Main Device
M6	View/Enter/Edit/Remove appointments	Main Device
M7	Sync calendar entries with Backend	Main Device
M8	Calendar Reminders	Main Device
M9	View/Enter/Edit/Remove lists	Main Device
M10	View/Enter/Edit/Remove list items (with handwriting)	Main Device
M11	Reset list check status	Main Device
M13	Sync lists with Backend	Main Device
M24	Handwriting recognition	Main Device
M28	Voice recording	Main Device
M29	Graphical interface (view interface, picture, results)	Main Device
M30	Show uploaded photos	Main Device
M31	Calender in table mode (classic calendar)	Main Device
M32	Analogue clock	Main Device
M33	Translations for EN, DE, IT, ES	Main Device
M34	Sync contacts with Backend	Main Device
M35	Sync left tablet picture with Backend	Main Device
M36	Logging	Main Device
A1	Login screen	All-day device
A2	Sync Medication with Backend	All-day device
A3	Medication Reminders	All-day device
A4	Sync calendar entries with Backend	All-day device

A5	Calendar Reminders (Location based)	All-day device
A6	Sync lists with Backend	All-day device
A7	View/Edit lists (check items)	All-day device
A8	Button for reading all/next unchecked item(s) out loud	All-day device
A11	Determine if the user is at home	All-day device
A13	... when a button is pressed	All-day device
A15	Sync panic numbers with Backend	All-day device
A16	When panic button is pressed call the numbers in order	All-day device
A29	… and send GPS position to panic numbers via SMS	All-day device
A30	Sync POIs with Backend	All-day device
A31	Translations for EN, DE, IT, ES	All-day device
A32	Logging	All-day device
C1	Interface for user management	Caregiver Interface
C2	View/Edit Medication times (Morning, Noon, Afternoon)	Caregiver Interface
C3	View/Enter/Edit/Remove Medication	Caregiver Interface
C4	View/Enter/Edit/Remove calendar entries	Caregiver Interface
C6	View/Enter/Edit/Remove panic numbers	Caregiver Interface
C8	Caregiver/Doctor Interface for dementia progression	Caregiver Interface
C9	View/Enter/Edit/Remove POIs	Caregiver Interface
C10	View/Enter/Edit/Remove contacts	Caregiver Interface
C11	View/Enter/Edit/Remove left tablet picture	Caregiver Interface
C12	Translations for EN, DE, IT, ES	Caregiver Interface
B1	Rest Interfaces + server component for user management	Backend
B2	REST Interfaces + server component for Medication	Backend
B3	REST Interfaces + server component for Appointments	Backend

B4	REST Interfaces + server component for Getting Ready and Shopping	Backend
B5	REST Interfaces + server component for Last Outside and Lost at Home	Backend
B6	REST Interfaces + server component for Panic	Backend
B11	REST Interfaces + server component for dementia progression	Backend
B12	Voice transcription	Backend
B13	Text analysis	Backend
B14	REST Interfaces + server component for left tablet picture	Backend
B15	REST Interfaces + server component for logging	Backend

6 Conclusions

The present document represents the basis of the Field Trials Protocol and helps the experimenter to organize the final phase of the project.
The results of the field trials will be anonymized and collected as trial protocols in an usability database. It contributes directly to D7.2B.

7 References

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