

# Evaluation of Field Trials

Deliverable D7.3B

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## Abbreviations

Abbrev.	Description
AAL	Ambient Assisted Living
ACE-R	Addenbrooke's Cognitive Examination Revised
AD	Alzheimer's Disease
ADCS-ADL	Alzheimer Disease Cooperative Study-Activities of Daily Living
ADJr	Adjective ratio
ADL	Activities of daily living
ADr	Adverb ratio
AE	aesthetic appeal
AT	Austrian
B	Brunet index
C	Caregiver
CBI	Caregiver Burden Scale
CG	Control Group
CRI	Cognitive Reserve Index
DM app	Dementia Monitoring app
EN	Endurability
FA	Focused attention
FI	Felt involvement
H	Honoré index
IADL	Instrumental activities of daily living
IT	Italian
MCI	Mild Cognitive Impairment
MMSE	Mini-Mental State Examination
MUV	Medical University of Vienna
NIA AA	National Institute on Aging and the Alzheimer's Association
NO	Novelty, curiosity and interest
NPI	Neuropsychiatric Inventory
Nr	Noun-ratio
NW	Number of words



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OERS	Observation Emotion Rating Scale
P	Patient
PRr	Pronoun ratio
PU	Perceived usability
QOL-AD	Quality of Life – Alzheimer’s Disease scale
QOL-C	Quality of Life – Caregiver scale
SP	Spanish
SUS	System Usability Scale
TG	Test Group (Memento Users)
TP	Technical Proficiency
TTR	Type-token ratio
UES	User Engagement Scale
UNIPG	University of Perugia
Users	Patient and caregiver
Vr	Verb ratio
WHODAS 2.0	World Health Organization Disability Assessment Schedule

## Executive Summary

Memento aims to provide a persuasive system supporting memory and moments of people with early stage of dementia. In order to develop a functional and user-friendly solution with high user acceptance, we tested the system together with the target group. 30 participants from Italy, Spain and Austria participated in a three months lasting Field Trials, comparing the MEMENTO system to correspondent traditional strategies in everyday life. The Evaluation of Field Trials deliverable describes the procedure of evaluating the second MEMENTO prototype, the characteristics of the trial participants and outcomes. Furthermore, difficulties from the end-user side, as well as technical and design problems are discussed.

# 1 About this Document

## 1.1 Role of the Deliverable

This deliverable provides information about user experience, engagement and acceptability, as well as usability in daily life of the MEMENTO prototype according to the Field Trials. Evaluating difficulties in everyday use due to technical and design reasons, but especially due to challenges with regard to our end user group, will help to further improve the system in the future.

## 1.2 Relationship to other Memento Deliverables

<b>Table 1: Relationship to other Memento Deliverables</b>	
<b>Deliverable</b>	<b>Relation</b>
D2.4 – End users requirements	Updated description of requirements to meet the end-users expectations
D2.5 – Definition of Use Cases and Scenarios	Use cases defined in this deliverable are used as basis for application of features during Field Trials
D3.2 – Final Specification of Hardware Design and User Interface	Describes the user interface design for the software components.
D3.3 – Physical models ready to be used	Design of MEMENTO prototype 2, which was used during Field Trials
D4.3 – Final Hardware Specification	Specifies the hardware design of the MEMENTO system.
D4.4 – Hardware Prototype 2	Hardware for MEMENTO prototype 2, which was used during Field Trials
D5.3 – Final Software Specification	Specifies the software of the MEMENTO system.
D5.4 – Software Prototype 2	Software for MEMENTO prototype 2, which was used during Field Trials
D7.1B – Definition of Field Trials Protocol	Basis for the testing procedure and aim.
D7.2B – Protocol for Field Trials	Provides comprehensive information and a detailed protocol, which were needed to carry out the testing activities.

## 1.3 Structure of this Document

This document describes the results of the Field Trials performed together with patients and their caregivers. The first part of the document proposes the aim of the Field Trials, describing the aspects of the MEMENTO device important to evaluate during this phase of development. It is followed by the section Field trial execution, which contains information about the participants of the Trials and shortly describes material and methods used for testing and evaluating the MEMENTO system. The fourth chapter provides the results of the Field Trials, including the strategies to remember, feedback of the diaries kept over the trial period, evaluation of the use cases, results from the dementia monitoring app and several outcome measures in form of questionnaires performed before, during and after the Trials. This section is concluded by the evaluation of final group meetings.

Main results and suggestions are discussed at the end of the deliverable, followed by a conclusion.

## 2 Aim

The Field Trials were executed using a functional prototype of the MEMENTO system in a realistic user environment by the clinical partners. The aim was to test usability and acceptance of the devices and to evaluate an increase of quality of life level for both primary and secondary end users.

15 primary end-users (5 in each of the three pilot sites) were recruited as test group and 15 primary end-users (5 in each of the three pilot sites) as control group.

Our objective was a thorough evaluation of MEMENTO by testing the system during a three-month period in the end-users homes, accompanied by the clinical partners who were in close contact with the testers.

The evaluation of usability, acceptance of the system and the comparison to a test group using traditional methods is of high value for the further development of the system.

Additionally, data about difficulties in performing tasks from end-user side, as well as about technical problems and design aspects were collected and will provide valuable information for further improvement of MEMENTO.

## 3 Field Trial Execution

This section describes the execution of the Field Trials, including the characteristics of patients and caregivers of both test group (TG) and control group (CG), materials used and a description of the protocol and evaluation methods.

### 3.1 User Characteristics

#### 3.1.1 End Users

In line with the inclusion criteria defined within deliverable D2.2 and the protocol for Field Trials (see D7.2B), clinical partners recruited patients treated at the dementia outpatient clinic MUV, Bidaideak and UNIPG. Before starting with the Field Trials, written informed consent must be provided by the patient or their legal guardian. In each clinical centre 10 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 participated in the Trials. Furthermore we defined a cut off score in activities of daily living according to the Lawton ADL score (Graf 2009).

In accordance also with the previously performed Lab Trials, additional information was collected about each patient and respective caregiver, including demographic and technology related information and approximate stratification of parameters mentioned below. Both mandatory criteria for patient recruitment and optional patient traits are summarized in Table 2.

In each study centre, the 10 participants were equally divided into a MEMENTO testing group (TG) and a control group (CG), as stated also in D7.1B:

- TG: 15 primary end-users and their caregivers, using the MEMENTO system in everyday life
- CG: 15 primary end-users and their caregivers, using traditional means to organize their everyday life (e.g. calendars, post-its...)

<b>Table 2: Patient Selection Criteria for Field Trials</b>	
<b>Mandatory Criteria</b>	
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)	<b>RANGE 24-28</b>
<b>Optional Traits</b>	
Different levels of cognitive reserve (CRIq scores)	
Different levels of Technical Proficiency	

**End users:**

End-user characteristics of TG and CG are summarized in Table 3. The patient ID consists of the patient number and group (T for TG, C for CG) followed by the country code (IT = Italy, AT = Austria, ESP = Spain)

- 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) has been taken into account. The CRI was established by a semi-structured interview (see supplement 1) 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 (TP) patient: we define the technical proficiency as the skills required to operate an information system (i.e., a hardware/software solution). Our ambition was to test the MEMENTO device with end users having different levels of technical skills, as shown in Figure 1 – Technical proficiencyFigure 1.

- 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.

### 3.1.2 Caregivers

The caregivers were strongly involved in the Field Trials.

- 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/...) were included in the trial.
- Technical proficiency caregiver: the technical skills of the caregiver are important for supporting the patient and using various software solutions of the MEMENTO system (i.e., accessing the calendar from another technical device).

**Table 3: End-User Characteristics TG**

Patient ID	Age	Sex	MMSE	TP Patient	TP Caregiver	CRI	Status Caregiver
1T_IT	70	M	26	low	medium	medium	wife
2T_IT	81	F	28	medium	high	medium	nephew
3T_IT	81	F	28	low	high	medium-high	daughter
4T_IT	67	F	24	low	low	medium	husband
5T_IT	61	M	28	medium	medium	medium-high	wife
1T_AT	52	M	25	high	low	medium	wife
2T_AT	72	F	28	medium	medium	medium-high	husband
3T_AT	60	F	27	high	high	medium-high	husband
4T_AT	77	F	27	low	high	high	husband
5T_AT	54	M	25	high	high	medium	wife
1T_ESP	70	M	26	high	medium	high	wife
2T_ESP	76	F	27	medium	low	medium-high	son
3T_ESP	80	F	28	low	high	medium-low	nephew
4T_ESP	81	M	28	low	medium	medium	wife
5T_ESP	84	F	27	low	low	medium-high	son

**Table 4: End-User Characteristics CG**

Patient ID	Age	Sex	MMSE	TP Patient	TP Caregiver	CRI	Status Caregiver
1C_IT	78	M	28	low	low	medium	wife
2C_IT	67	M	25	low	high	high	wife



3C_IT	80	M	28	low	low	medium-low	wife
4C_IT	70	F	27	medium	high	medium	daughter
5C_IT	62	M	28	low	high	medium-low	daughter
1C_AT	72	F	27	low	medium	medium	husband
2C_AT	67	F	28	medium	high	medium-high	daughter
3C_AT	74	M	26	high	medium	medium	wife
4C_AT	73	F	25	medium	medium	low	husband
5C_AT	70	M	26	high	high	high	wife
1C_ESP	78	F	27	medium	low	low	daughter
2C_ESP	75	F	25	high	medium	medium-low	daughter
3C_ESP	82	M	26	low	low	medium-low	wife
4C_ESP	80	M	28	low	medium	low	daughter
5C_ESP	78	F	27	low	low	low	son

In the TG, the mean age was 71.1 years (SD=10.3, range 52-84) with a mean MMSE of 26.8 (SD=1.3, range 24-28). The group consisted of 9 female (60%) and 6 male (40%) participants.

In the CG, the mean age was 73.7 years (SD = 5.8, range 62 – 82). The mean MMSE was 26.7 (SD= 1.2, range 25-28). 7 female (47%) and 8 male (53%) patients participated in the Trials.

As mentioned above, the technical proficiency was aimed to be at different levels within the groups, as shown in Figure 1.

The CRI level is shown in Figure 2.

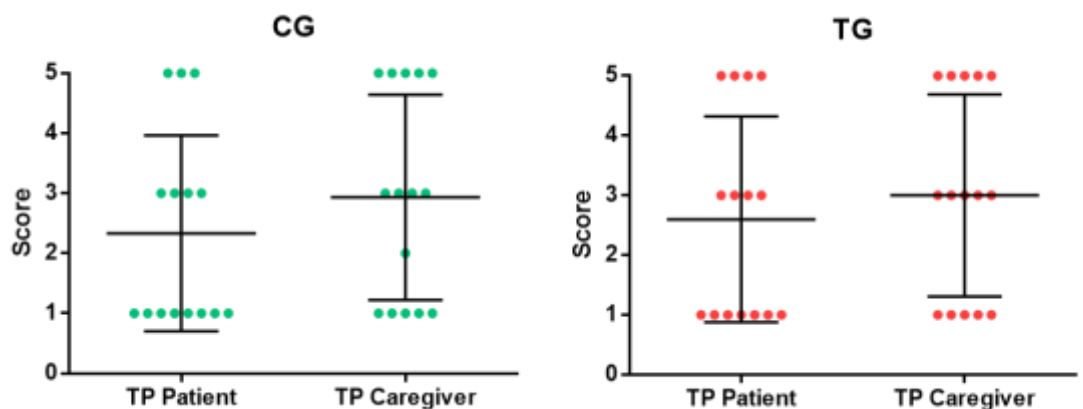


Figure 1 – Technical proficiency  
 Technical proficiency was rated for every patient and caregiver in both groups ranging from low (1) to high (5). Participants show different levels of technical proficiency, CG and TG show comparable distributions. Graph shows mean with SD.

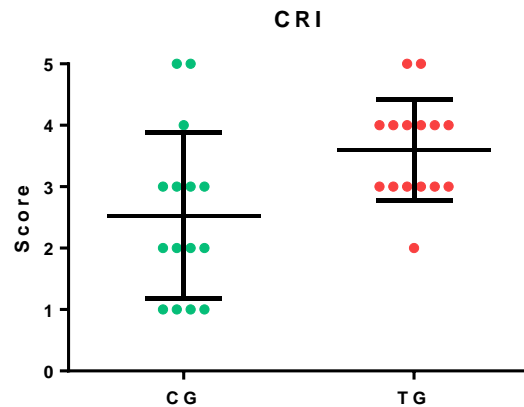


Figure 2 – CRI  
CRI was rated for every patient and caregiver in both groups ranging from low (1) to high (5). CG show a lower CRI than the TG. Graph shows mean with SD.

### 3.1.3 Investigators

Apart from workshops and meetings in the beginning and at the end of the Trials, the Field Trials took place primarily in the representative end-users home to try the system in daily use. Therefore, the optimized functioning prototype 2 was installed in the end-user environments by the clinical partners.

A peer contact person (one for MUW, one for Bidaideak and one for UNIPG) accompanied the users throughout the test period and was also in close contact with the CG.

## 3.2 Material and Methods

This section provides a short summary of material and methods. Detailed information about the protocol used for Field Trials are contained in deliverables D7.1B and D7.2B.

### 3.2.1 MEMENTO Prototype

A functional prototype of the MEMENTO system was used for the Field Trials, optimized based on the feedback derived from workshops and Lab Trials (see D7.3A Evaluation report of Lab Trials) and the updated user requirements and use cases (D2.4 and D2.5). Final hardware design and user interface specifications can be found in deliverables D3.2, D4.3 and D5.3.

### 3.2.2 MEMENTO Features

Use cases were prioritized after consultation with the consortium (both technical and end user partners). Those features, based on six use cases, were implemented for Field Trials (see Figure 3):

- Medication
- Appointments
- Getting Ready
- Shopping
- Lost Outside/Lost at Home
- Panic

Additionally, the dementia monitoring application (DM app) was tested by the Italian end-user group.

The mentioned use cases are described in deliverable D2.5 and were developed by analysis of the Lab Trials and several workshops with patients and their care givers as described in D2.4.

# mə'mento keeps my mind



Figure 3 – Use cases that build the basis of features for Field Trials

### 3.2.3 Procedure

The study was presented to the TG and CG in separate workshops. Information about their habits (e.g. own strategies to remember) were collected and the participants were introduced to the process of the Field Trials and methods used (e.g. monitoring and diaries).

Each patient of the TG and (if available) their caregiver were visited at their home, where the system was installed and they were given the opportunity to try functionalities with guidance and support of their peer contact person. Throughout the Trials (12 weeks) the participants of the TG and CG were motivated regularly in form of phone calls and meetings.

The Field Trials were concluded by individual meetings with the participants to collect feedback and data and a separate group meeting (TG and CG) to carry out a focus group on Memento experience.

For a detailed protocol, refer to D7.2B and its supplements.

### 3.2.4 Evaluation Tools

The main objective of this phase was to collect feedbacks on user engagement and usability in everyday life, using established questionnaires, interviews and diaries.

As described in detail in deliverable D7.1B, data will be collected with different outcome measures.

#### Primary outcome measures:

1. World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) (<https://www.who.int/classifications/icf/whodasii/en/>) (Federici, Meloni et al. 2009, Üstün, Kostanjsek et al. 2010).
2. The Quality of Life – Alzheimer's Disease scale (QOL-AD) (Logsdon, Gibbons et al. 1999).
3. Alzheimer Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) (Galasko, Bennett et al. 1997).

#### Secondary outcome measures:

1. Neuropsychiatric Inventory (NPI) (Cummings, Mega et al. 1994)
2. Caregiver Burden Scale (CBI) (Zarit, Reever et al. 1980)
3. User Engagement Scale (UES) (O'Brian and Toms 2009)
4. System Usability Scale (SUS) (Brooke 1996)
5. Ad hoc interviews

### **3.2.5 Statistics**

Statistics were performed using SPSS Version 17. Frequency calculations were performed for age, sex, TP and CRI of both groups separately and for each country.

For the outcome measures, non-parametric tests were performed. Mann Whitney U test was performed to compare the outcome measures between the TG and CG, as well as Wilcoxon Signed Ranks Test to compare T0 and T1.

For the frequency of use of the system, apart from evaluating the diaries the number of days of use in the 12 weeks were calculated using log files.

For the Dementia Monitoring application (DM app)'s evaluation, data analysis was carried on considering the frequencies of the Emotion Observation Rating Scale (OERS) scores and the Euclidean distances between the variables (dissimilarity matrix): MMSE, ACE-R total and sub scores and linguistic indexes. The distance of each user from others was considered.

## 4 Results

### 4.1 Strategies to Remember

At the beginning of the Trials, we surveyed the current status of our participants' strategies to remember in everyday life. This was performed by questionnaires containing questions about situations based on the use cases, such as organizing appointments and medication. Those functions are targeted and could be taken over by MEMENTO.

In general, technical devices are particularly well accepted by younger people, while older people tend to use traditional means. Situations like loss of orientation and panic are the exception, where patients of all ages rely on their mobile phones to call their caregivers.

#### 4.1.1 Traditional memory aids

Participants of both TG and CG use many traditional memory aids, such as calendars, post-its, agendas and notebooks and wall boards. In the CG, a participant reported also to use mental strategies to remember important things in everyday life.

#### 4.1.2 Technical memory aids

As expected, due to the specific age structure of our testing cohort, technical memory aids are used rarely. In the TG, two users (1T\_AT and 5T\_AT) use their mobile phone to remind themselves and one participant uses an alarm clock. In the CG there was also one person using their mobile phone, while another patient declared that he tried to use it but failed to do so.

#### 4.1.3 Going Shopping

Apart from using shopping lists, 4 TG and 8 CG participants rely on their caregivers. Three participants from the TG uses mental strategies to remember what to purchase, while one person from the CG uses their mobile phone.

#### 4.1.4 Preparing an activity

We also asked about aids when preparing a trip or packing a bag (e.g. to go to the gym).

Most participants reported to use checklists or ask their caregiver for help. 3 persons from the TG and one from the CG report to use mental strategies or put everything they need for the activity in one place.

#### **4.1.5 Schedule an appointment**

In order to organize their appointments, patients also use predominantly traditional aids such as calendars and post-its, or their caregiver. One participant from the TG one from the CG use their mobile phone to schedule appointments.

#### **4.1.6 Organize medication**

One important point is to take the right medicine at the right time. Patients report to rely on their caregiver and a medicine box to organize their medication intake. Some participants from both groups also mentioned mental strategies or using a calendar. One person from the TG uses his mobile phone to schedule his medication intake.

#### **4.1.7 Feeling lost outside**

We asked how the patients cope with the feeling of being lost outside when losing orientation. The most common strategy is to ask someone for help or call their caregivers with their mobile phones. Therefore, in this scenario, technical devices play a major role. One person from the CG also mentioned to use navigators. Noteworthy, participants also gave responses like "It never happen to me" or "It's not relevant in my case". Those defensive responses in some patients point to an overestimation of their abilities.

#### **4.1.8 Panic**

In case of panic, answers resemble the ones from 4.1.7. Patients report to rely on their mobile phone to call their caregivers. In this situation, participants also seemed to overestimate their abilities ("I try to calm myself...") or report not to know how to act in this situation. Some of them avoid situations potentially leading to orientation loss or panic, limiting their activities according to the caregivers.



## 4.2 Diary Feedback Form

During the 12 weeks, the participants were asked to keep a diary which was distributed at the beginning of the Trials. Both groups were asked to note down their strategies to remember and in which situations they are used each day. Patients in the TG were additionally asked to record the use of the MEMENTO system. Every two weeks, the peer contacts from the clinical team called the participants of both groups to motivate them to use the diary sheets and the TG to use the MEMENTO system. Additionally, the experimenters monitored this usage by filling in a diary feedback form (see D7.2B and its supplements for the diary and the corresponding feedback form).

### 4.2.1 Frequency of MEMENTO use

In general, the TG used the MEMENTO system with a weekly frequency. Some caregivers preferred to use the system step by step, e.g. starting with scheduling appointments and writing shopping list before trying other functionalities.

One of the users from the Austrian cohort (4T\_AT) abandoned the system, which is discussed in 5.1.

Users 1T\_IT and 4T\_IT used Memento rarely, despite stimulation of use by the caregivers. 2T\_AT and 5T\_IT increased the frequency of use over time during testing.

3T\_AT had personal problems; therefore, she rarely used the system in the final phase. Also, 2T\_IT used the system in a discontinuous manner due to personal problems of the caregiver.

The Spanish cohort had technical internet connection problems at the first stages of the trials.

In addition to the self-reported usage of the MEMENTO system, we tracked the use of the different functionalities via log files. The information provided by the participants coincides well with the records, as shown in Table 5 (log files of use).

ID	age	sex	MMSE	TP Patient	TP caregiver	CRI level	days of use	Congruence with diary	Implemented in time	Apathy at NPI	Stimulated by caregiver	Dislike technology
1T_IT	70	M	26	low	medium	medium	15	Good	-	Yes	Yes	Yes
2T_IT	81	F	28	medium	high	medium	24	Good	+	No	Yes	No
3T_IT	81	F	28	low	high	medium-high	19	Good	-	No	Not much	Yes
4T_IT	67	F	24	low	low	medium	15	Good	-	Yes	Yes	Yes
5T_IT	61	M	28	medium	medium	medium-high	27	medium	+	No	No	No
1T_AT	52	M	25	high	low	medium	61	Good	=	No	Yes	No
2T_AT	72	F	28	medium	medium-high	medium-high	23	Good	=	No	Yes	No
3T_AT	60	F	27	high	high	medium-high	6	Good	-	No	Yes	No
4T_AT	77	F	27	low	high	high	drop out			No	Yes	Yes
5T_AT	54	M	25	high	high	medium	21	medium	=	Yes	Yes	No
1T_SP	70	M	26	high	medium	high	25	Good	+	No	Yes	No
2T_SP	76	F	27	medium	low	medium-high	25	Good	+	No	Yes	No
3T_SP	80	F	28	low	high	medium-low	28	Good	+	No	Yes	No
4T_SP	81	M	28	low	medium	medium	3	Medium	-	No	Yes	Yes
5T_SP	84	F	27	low	low	medium-high	2	medium	-	No	Yes	Yes

Table 5: Evaluation of Log Files

The table shows the characteristic of the test group (age, MMSE, patient technical proficiency, caregiver technical proficiency, cognitive reserve level) and the frequency of use of Memento. The frequency is expressed as number of day of use based on the log file reports. Other variables potentially related to the frequency of use such as apathy, stimulation by the caregiver and aversion towards the technology declared in the qualitative report are also reported. A value over 20 emerges in people with a medium or high level of technical proficiency and /or in the younger people. In general, there is a good relation between the frequency of use referred by the users in the diary and the log reports. In column "Implemented in time": + indicates an increase in the time; - indicates a reduction in the time; = indicates a steady use in the time.

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#### **4.2.2 Usage of individual parts of the MEMENTO system**

The most frequently used part of the MEMENTO system was the Main Device. The use of the two devices was not stable over the entire period, especially at the beginning and in the final phase. 2T\_IT reported difficulties to read on the All-day Device and to hear due to medical problems at the beginning of the study. 5T\_IT and 2T\_AT used both devices in the final phase, while 5T\_AT used only the All-day Device in the final phase. 1T\_AT had a technical problem with Main Device in the last weeks.

#### **4.2.3 Situation related use of the MEMENTO system**

As reported by the patients and caregivers, scheduling appointments was the most used function, followed by shopping.

2T\_AT, 5T\_AT, 1T\_SP and 2T\_SP used the medication function of the devices, whereas other users preferred traditional aids for two reasons: i) they remember their medication themselves (e.g. due to a stable therapy with 1 or 2 pills); ii) they prefer to manage complex therapies with pill boxes (e.g. 2T\_IT has a very complex therapy and the caregiver didn't want to change their trusted strategy). Moreover, there are concerns that technical problems reduce the reliability of the system. 5T\_IT used the medication feature to organize and remember a temporary therapy with a several-times-a-day posology.

Getting ready was rarely mentioned by the users.

Panic and Lost outside were not applicable for the TG, since they reported that they were in no situation of orientation loss during the testing period. An exception was 5T\_AT who lost his orientation but didn't think of using the MEMENTO system in this situation.

5T\_IT and 1T\_AT used the panic features as a means to contact their caregivers.

#### **4.2.4 Technical Problems**

We used the regular calls to ask about technical problems. Those problems were reported predominantly at the beginning of the Trials and were either solved over the phone or additional home visits were scheduled to assist the TG and reassure them. The Spanish cohort had internet connection problems at the first phase of the trials but solved the issue for the second phase.

There were some reports about delayed synchronization between Main and All-day Device and logging out of the system.

Regarding the main device, there were difficulties with writing. Those were, however, mainly due to user specific problems. Other problems occurred due to system crashes, wrong time displayed and problems with the touch screen. There was also a report of English language in some features.

Technical problems with the All-day Device were due to the size and resulting problems with the log-in, an error message in one case and problems with the wrong GPS signal. In some cases, SMS notification worked very well, while in other cases there were no GPS coordinates in the SMS received by the caregivers. Other reported technical problems regarding the Caregiver Interface were due to error messages.

#### **4.2.5 MEMENTO system compared to traditional aids**

Most users prefer traditional aids at this stage of system development, except from 1T\_AT. The reason behind were the technical problems at the beginning of the Trials (e.g. 2T\_IT would like to use MEMENTO in a later stage of development) and the need to gain more familiarity with the system (e.g. 5T\_IT likes the system and refers to the All-day Device as a “beautiful object”).

The participants seemed to like the idea of the MEMENTO system, but report that the traditional strategies are more familiar, intuitive, faster and secure at the moment and writing on the device has to be refined.

#### **4.2.6 Results from CG Diary Feedback Form**

All CG participants reported that they use aids to remember important and every-day information and to use those aids daily or several times a week. When asked in which situations they use their memory aids, they report situations similar to the MEMENTO use case, including organization of medication and appointments, creating shopping lists and navigation.

Those strategies are very stable over time and are rarely changed. After monitoring his habits, 2T\_IT noticed that he uses an excessive amount of paper in week 5 so he tried to change his strategy. However, he returned to his usual strategy in week 7, since he experienced many difficulties in using the google calendar (e.g. ignoring alerts or forgetting to check the calendar).

We also asked them, whether they experienced problems using their usual strategies. The CG reported about failure of remembering to take pills or forgetting appointments, problems with purchasing groceries and stated that they need supervision of their caregivers. 4T\_IT had for example a change in pharmacological therapy making the intervention of the caregiver necessary.

## 4.3 Home Visit and Use Case Evaluation

In the middle of the Field Trials, we visited the TG patients at home to talk about potential user specific and technical problems with the MEMENTO device and to go through the scenarios of the use cases with them. The CG was called by their peer contacts and asked about their strategies in the same situations (see D7.2B and supplements).

In general, technical problems (as reported in 4.2.4) interfered with the engagement of the TG, particularly concerning writing.

In regular use, patients reported that the All-day Device needs to be charged too often and usual strategies are considered faster and more intuitive.

Before starting the tasks, we asked the patients again about their strategies to remember. One user (5T\_IT) mentioned Memento, while other users reported usual strategies. 5T\_AT and his caregiver distributed the devices – the patient used only the All-day Device, while his wife operated the Main Device.

### 4.3.1 General Comments and Observations

Below are some relevant comments and observations made during testing the devices together with the TG patients and caregivers during our home visits.

- 2T\_IT required the help of the caregiver to use the system since he feared to break it.  
The caregiver of 3T\_IT had difficulties to support the user due to working activity.
- 4T\_SP and 5T\_SP need the caregiver support to use the system every time.
- 1T\_IT and 4T\_IT reported “aversion” for the technology
- 5T\_AT appreciated the “packlist” (e.g. also when packing to go home after activities so as not to forget anything)
- 1T\_AT would appreciate a “popup” on the All-day Device in case the caregiver enters a new shopping list.
- At most places, you only see one side of the tablet if you put the device on them
- It was necessary referring to a more expert caregiver for some users
- 5T\_IT (male) aesthetically appreciated the all-day device
- 2T\_AT and 3T\_SP (both females) noted the All-day Device is too big and heavy

### 4.3.2 Medication

#### CG Strategies

In the CG group, when asked about usual strategies, 1T\_IT mentioned it helps to save an alert on the phone. However, he did not mention this strategy for himself, therefore it seems to be a wish from him.

Users report to write new therapies in each page of an agenda, write the intake time on the pills box and use calendars. The pills box itself is organized with their caregiver's help.

#### TG Tasks

All of the users in the TG were able to complete the task, though many of the users needed assistance from their caregivers.

Problems emerged when the button "list" got confused with "new entry" in the course of setting new reminders.

There were difficulties to insert time and date and due to low familiarity with the system. In the Caregiver Interface, the button "patient" gets confused with "medicine". Technical problems occurred because of absent WiFi connection (4T\_IT) and a reminder that didn't appear on the Main Device (2T\_AT, probably also due to bad WiFi connection).

### 4.3.3 Appointments

#### CG Strategies

The participants named agendas, calendars, post-its on the fridge, table-calendars, post-its to put in the wallet and post-its in the car to be usually used to remember appointments. Many of them also rely on their caregiver.

#### TG Tasks

All of the users were able to complete the task and there were no problems to change into calendar mode. As in 4.3.2, many of the users needed assistance from their caregivers.

Again, the button "list" got confused with "new entry" in the course of scheduling new appointments.

Some errors were made in Field completion regarding format of time (HH:MM) and date (e.g. patients inserting name of the day instead of number). Users would prefer drop-down list for dates and a less rigid designation of the Fields to enter.

Error messages occurred in the Caregiver Interface and some passages were skipped by the caregivers, most probably due to scarce practice.

Technical problems occurred because of absent WiFi connection (4T\_IT)

And due to problems with writing.

On the Main Device, the screen disappeared in one case and it was necessary to reinsert the data. Users reported that the system doesn't warn you when two appointments are scheduled at the same time.

#### 4.3.4 Lost Outside

##### CG Strategies

Usually, 1T\_IT and 2T\_IT uses their phone–navigator in those situations.

Most participants would ask someone for help. 4T\_IT usually has a post-it with the program of the day in her bag (including the destination).

Other strategies named were to search for POIs (bar, shop....) to ask for help, trying to keep calm and call someone (e.g. caregiver).

##### TG Tasks

When asking about usual strategies, the mobile phone was mentioned by T1\_AT and T3\_AT. Others strategies were trying to keep calm, ask someone for help and call the caregiver.

In the Italian and Spanish cohort, none of the users had the POIs in the system and it was necessary to insert them beforehand.

The task was always completed.

Icons were correctly identified and used, even if this functionality was not familiar among the users. T2\_AT stated, that she tried the function outside and it is irritating when the device tells you the next POI if it is far away. In general, Italian users seemed worried to discuss about this functionality.

Concerns among the TG were, that POIs insertion requires too much time.

4T\_IT had problems with the WiFi connection and no SMS with coordinates was received by 5T\_AT when testing the functionality. The caregiver stated that this only happens when they are at home and it works fine when they are outside.

Sometimes, it was necessary to synchronize the system.

In one case a message appeared ("Please, connect the clock") and the vocal message was not available.

T3\_AT commented that there is not enough time to read the text on the All-day Device and to choose an answer. 1T\_AT stated that he would appreciate to see a map or route on the All-day Device.

5T\_AT reported that he had some situations when he was lost outside or in panic but didn't think about using the All-day Device.

#### **4.3.5 Panic**

##### **CG Strategies**

In the case of panic, patients would ask for help, try to keep calm and call somebody. One participant would take tranquillizers to inhibit the panic.

##### **TG Tasks**

Task was always completed without difficulties and icons were correctly identified and used, even if this functionality was not familiar among the users. This functionality was very appreciated by the TG.

In general, Italian users seemed worried to discuss this functionality, in particular 1T\_IT and 4T\_IT. Similar situation happened with Spanish users.

5T\_IT and 1T\_AT use the panic button to call their caregivers.

No SMS with coordinates was received in one case.

3T\_AT suggested that the panic button should be a "real" button, not an icon on the watch.

5T\_AT reported that he had some situations when he was lost outside or in panic but didn't think about using the All-day Device.



## 4.4 Dementia Monitoring App

In the Field Trials DM app was evaluated in order to study users' appreciation and its ability to monitor dementia using the automatic analysis of the speech as described in D2.4.

The 5 Italian users of the TG were involved.

In two sessions (home visit - T0 and final visit – T1) users used the app in presence of the experimenter and were assessed with the ACE-R (a global cognitive measure that includes the MMSE and five sub scores described in D2.4).

The Observed Emotion Rating Scale (OERS) described in the D2.4 was also employed to capture emotional state (signals of general alertness (interest), pleasure, anxiety, fear and anger) during the performance of the task.

Participants (users and caregiver) free comments and opinions were also collected.

The aims of the study were:

- 1) to collect feedbacks from users;
- 2) to explore the ability of the app to calculate the indexes;
- 3) to evaluate the relation between linguistic features collected with the automatic analysis of the speech (syntactic and semantic indexes) and cognitive measures (MMSE and ACE-R scores).

The second session (T1) was carried out at 4 weeks from the first (T0).

Semantic analysis concerned statistically significant variations in the semantic content (lexical richness) of spontaneous speech measured using Type-Token Ratio, Brunét's Index, and Honore Statistic Statistic.

Syntactic analysis is focused on statistically significant variations in the syntactic structures of spontaneous speech considering use of Nouns, Pronouns, Adjectives, and Verbs.

DM app stimuli to eliciting the speech were selected considering the cultural context of the users and the congruence with the period of the year (e.g. famous Italian actors, past Pope, questions about autobiographical memories, images linked to the Christmas)

Based on the pilot 1 results, the app automatically stopped after 10 minutes to test the aim to reach an audio file with 1000 words without stress the users and maintaining a good level of attention.

Responses were not corrected and no stimulus or interruption was provided unless the participant was finished the task or clearly becoming distressed by his or her inability to respond.

Data analysis was carried on considering the frequencies of the OERS scores and the Euclidean distances between the variables (dissimilarity matrix): MMSE, ACE-R total and sub scores and linguistic indexes.

**Results**

Figure 4 shows the results from the OERS scale at T0 and T1. Considering the first aim, signals of general alertness (interest) and pleasure were the most frequent during the performance of the task in the two sessions. The task was appreciated by the users and their caregivers. The set of stimuli seems able to capture the attention and to stimulate the speech.

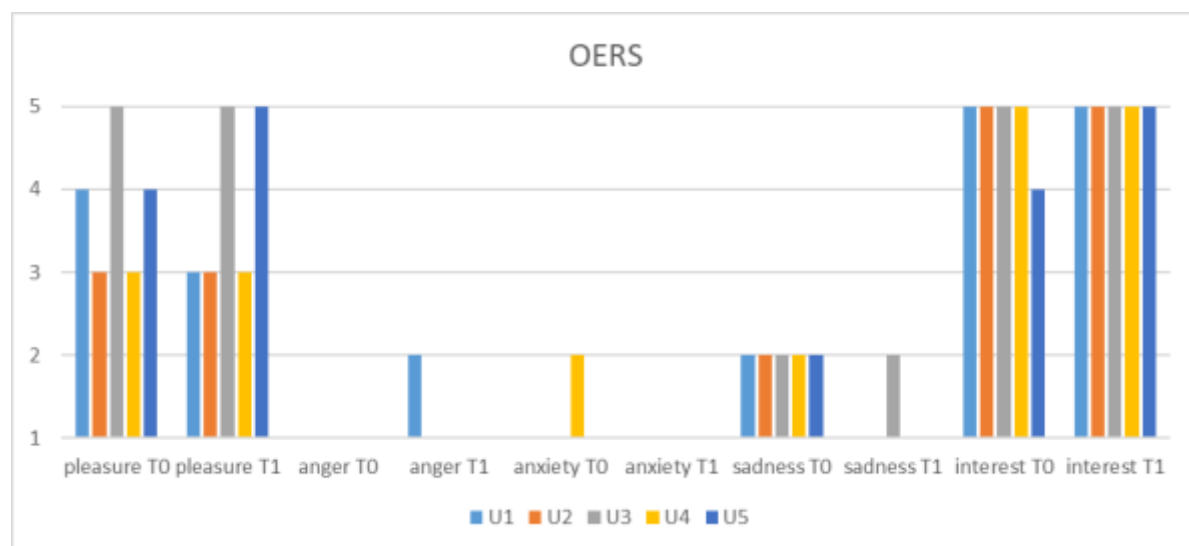


Figure 4 – OERS  
 X axis: signals of emotions during 10 minutes of observation at T0 and T1. Y axis: Signs of feeling in the observation of the first 10 minutes of task execution. 1: never; 2: less than 16 seconds; 3: 16-59 seconds; 4: 1-5 minutes; 5: more than 5 minutes. Users are represented with different colors.

Table 6 resumes the scores of each user considering semantic and syntactic indexes and cognitive measures (row scores).

CODE	TTR	B	H	NW	MMSE*	ACER*	AO	M	F	L	VS	Nr	PRr	ADJr	Vr	ADr
<b>HOME SESSION (T0)</b>																
U1	0,42	12,80	868,87	946,00	29,00	83,00	18,00	18,00	7,00	26,00	14,00	21,96	10,56	5,81	19,54	14,89
U2	0,59	11,38	866,70	309,00	28,00	84,00	18,00	19,00	8,00	25,00	14,00	20,32	10,00	5,81	20,65	13,87
U3	0,50	12,00	1034,28	888,00	30,00	84,00	18,00	15,00	11,00	26,00	14,00	26,55	7,09	6,75	16,87	9,22
U4	0,64	10,87	920,70	245,00	25,00	74,00	16,00	13,00	5,00	26,00	14,00	28,98	8,16	10,61	15,51	7,76
U5	0,47	12,27	1025,74	1000,00	29,00	91,00	18,00	23,00	9,00	26,00	15,00	26,77	9,89	8,89	18,18	9,59
<b>FINAL SESSION (T1)</b>																
U1	0,50	12,10	772,31	617,00	27,00	77,00	18,00	14,00	5,00	25,00	15,00	28,04	7,46	6,16	20,58	10,05
U2	0,48	12,20	1012,99	857,00	30,00	76,00	18,00	13,00	9,00	22,00	14,00	23,45	9,33	6,18	19,72	10,62
U3	0,48	12,17	836,74	874,00	28,00	83,00	17,00	15,00	13,00	26,00	12,00	26,54	8,70	6,98	20,25	8,01
U4	0,70	10,58	1124,57	303,00	27,00	75,00	16,00	11,00	7,00	26,00	15,00	32,01	5,94	6,93	16,83	10,56
U5	0,48	12,13	968,95	907,00	29,00	93,00	17,00	23,00	12,00	26,00	15,00	27,01	8,93	8,05	16,98	8,82

Table 6: DM scores

\* It could be noted that the MMSE in some cases is higher than the score expected by the inclusion criteria. This values are row scores obtained during the Field Trials at home session (T0) and the final session (T1). All subjects had a correct MMSE coherent with the inclusion criteria at the time of the enrolment.

According to Bucks et al (Bucks, Singh et al. 2000) indexes description, TTR represents the ratio of the total vocabulary to the overall text length and it is a simple measure of vocabulary size. The higher values indicate a higher performance. A length of the text at 1000 words (WN variable) has been recommended to calculate it.

The Brunét's index (B) is not sensitive to text length and varies from 10 to 20. The lower the value, the richer the speech.

The Honoré statistic is based on the notion that the larger the number of words used by a speaker that occur only once the richer the lexicon. The higher values of H indicate a higher performance.

The syntactic indexes were calculated as ratio of the classes of words (noun, pronoun, adjective, verb and adverb) to the overall text length: Noun-ratio (Nr), Pronoun ratio (PRr), Adjective ratio (ADJr), Verb ratio (Vr) and Adverb ratio (ADr)

Considering the second aim, a first important result is that in our sample only U1 at T0 and U5 at T0 and T1 reached a text length of 1000 words (see NW column) an aspect that limits the comparison with similar studies (Bucks, Singh et al. 2000) and gives important indications for the DM app implementation. In particular, the need to introduce more stimuli to engage the users for 15 minutes in order to reach a value of 1000 words.

Respect the third aim, the low sample size limits the possibility of statistical analysis, however the dissimilarity matrixes based on the Euclidian distances gives interesting results.

Figure 5, Figure 6 and Figure 7 show the semantic indexes (TTR, B, H respectively) based on the total number of words (N) and the total audio length (10 minutes) for each user (code filed) at home session (T0) and final session (T1).

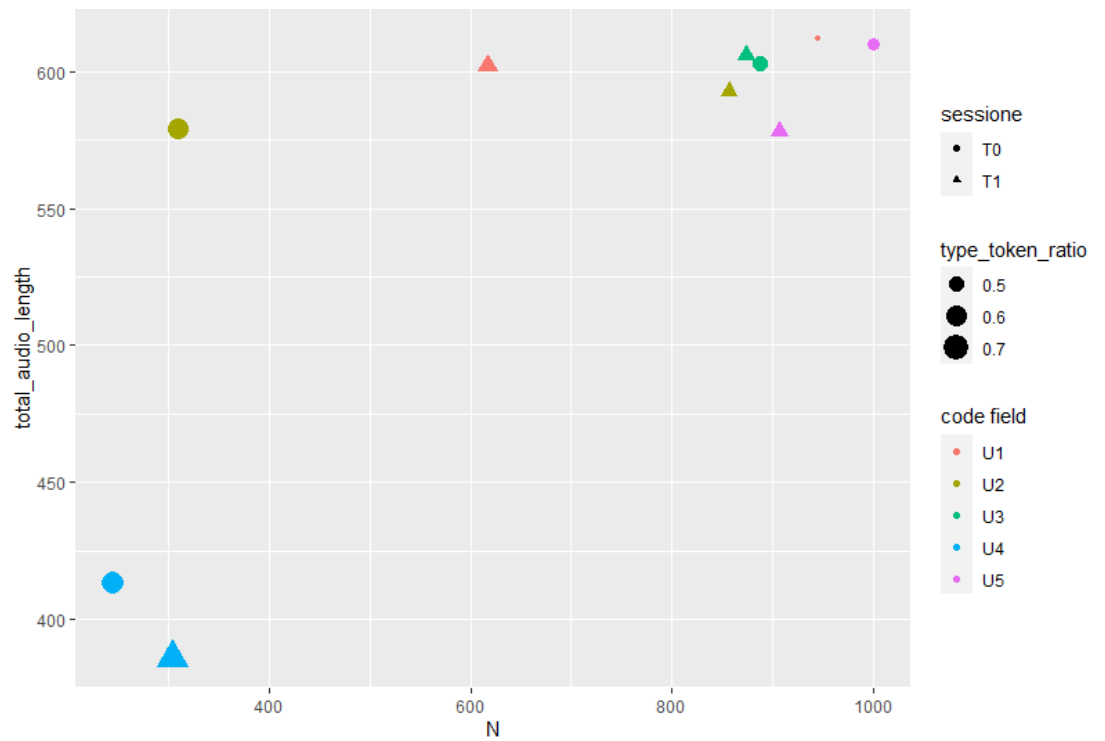


Figure 5 – Semantic index TTR  
 TTR at home session (T0: circle) and final session (T1: triangle). X axis: number of words. Y axis: total audio length in seconds. Code Fields: the users are indicated with different colours.

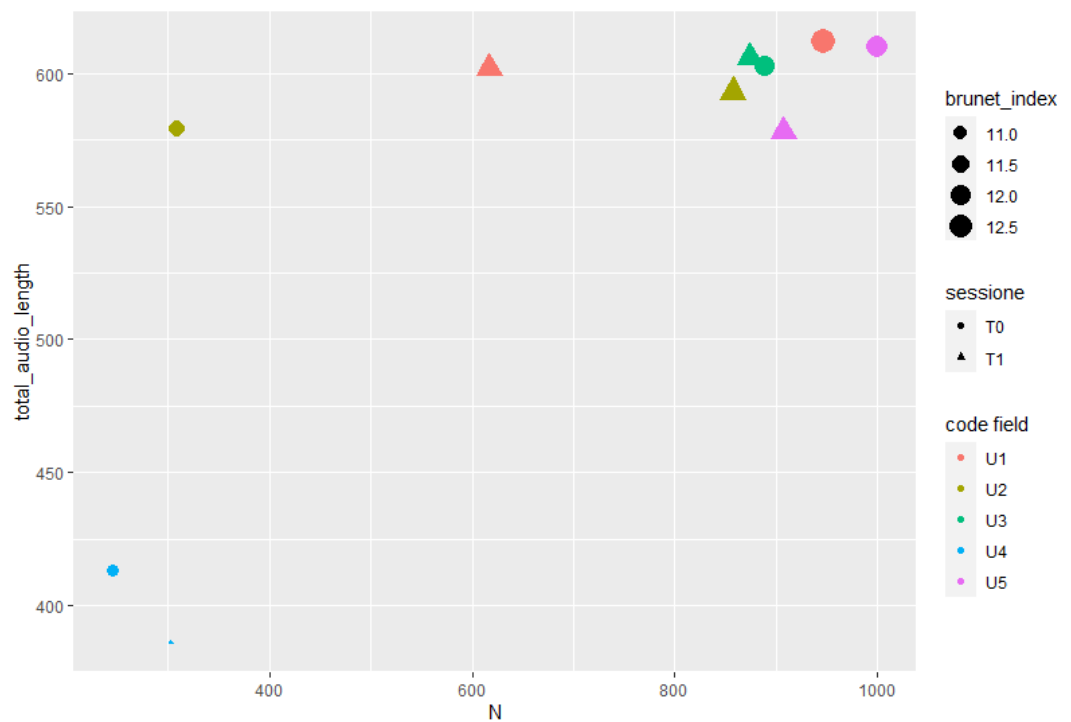


Figure 6 – Semantic index B  
 Figure XX- B at home session (T0: circle) and final session (T1: triangle). X axis: number of words. Y axis: total audio length in seconds. Code Fields: the users are indicated with different colours.

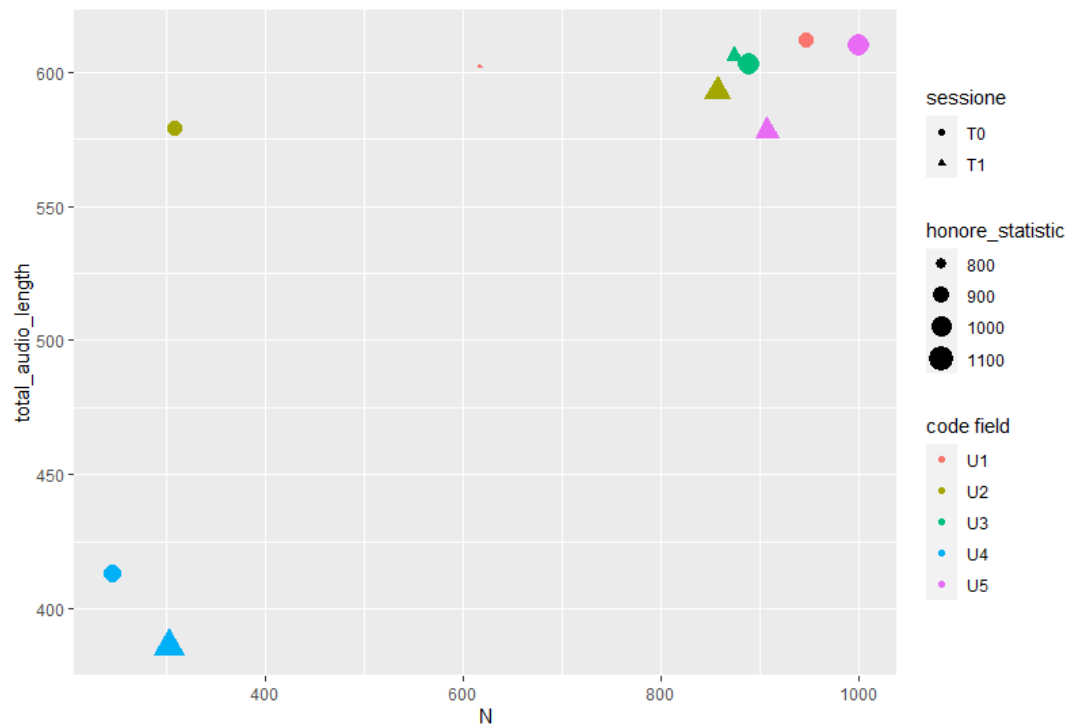


Figure 7 – Semantic index H  
 H at home session (T0: circle) and final session (T1: triangle). X axis: number of words. Y axis: total audio length in seconds. Code Fields: the users are indicated with different colours.

A first interesting results concerns U4: the user with the lowest cognitive measures. U4 produced the lowest number of words and performed differently from the rest of the group in the most part of the indexes as the figures (heavenly symbols in the lower left part of the graph) and the dissimilarity matrixes show (Table 7-Table 12).

	TTR: euclidean distances				
	1:U1	2:U2	3:U3	4:U4	5:U5
1:U1	,000	,165	,078	,299	,046
2:U2	,165	,000	,088	,231	,121
3:U3	,078	,088	,000	,266	,033
4:U4	,299	,231	,266	,000	,283
5:U5	,046	,121	,033	,283	,000

Table 7: Dissimilarity matrix TTR  
 TTR at T0 and T1. The lower values correspond to a lower dissimilarity.

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	B: euclidean distances				
	1:U1	2:U2	3:U3	4:U4	5:U5
1:U1	,000	1,430	,807	2,460	,532
2:U2	1,430	,000	,624	1,700	,898
3:U3	,807	,624	,000	1,950	,275
4:U4	2,460	1,700	1,950	,000	2,087
5:U5	,532	,898	,275	2,087	,000

Table 8: Dissimilarity matrix B  
 B at T0 and T1. The lower values correspond to a lower dissimilarity.

	H: euclidean distances				
	1:U1	2:U2	3:U3	4:U4	5:U5
1:U1	,000	240,686	177,516	356,050	251,538
2:U2	240,686	,000	243,205	123,964	165,023
3:U3	177,516	243,205	,000	309,428	132,483
4:U4	356,050	123,964	309,428	,000	187,749
5:U5	251,538	165,023	132,483	187,749	,000

Table 9: Dissimilarity matrix H  
 H at T0 and T1. The lower values correspond to a lower dissimilarity.

	Syntactic indexes: euclidean distances				
	1:U1	2:U2	3:U3	4:U4	5:U5
1:U1	,000	5,559	9,047	13,348	9,181
2:U2	5,559	,000	10,081	16,089	10,128
3:U3	9,047	10,081	,000	9,040	5,209
4:U4	13,348	16,089	9,040	,000	7,718
5:U5	9,181	10,128	5,209	7,718	,000

Table 10: Dissimilarity matrix syntactic indexes  
 Noun-ratio (Nr), Pronoun ratio (PRr), Adjective ratio (ADr), Verb ratio (Vr) and Adverb ratio (ADJr) at T0 and T1. The lower values correspond to a lower dissimilarity.

	MMSE scores: euclidean distances				
	1:U1	2:U2	3:U3	4:U4	5:U5
1:U1	,000	3,162	1,414	4,000	2,000
2:U2	3,162	,000	2,828	4,243	1,414
3:U3	1,414	2,828	,000	5,099	1,414
4:U4	4,000	4,243	5,099	,000	4,472
5:U5	2,000	1,414	1,414	4,472	,000

Table 11: Dissimilarity matrix MMSE  
 Mini Mental State Examination (MMSE) scores. The lower values correspond to a lower dissimilarity.

At the same time, the U5 with the higher cognitive measures on ACE-R total and subscores, produced the higher number of words (NW) as the figures (violet symbols in the upper right part of the graph) and the dissimilarity matrixes show (Table 12). Moreover, U5 had low values of dissimilarity from U3 who had similar cognitive performance and similar linguistic indexes scores (green symbols in the figure).

	ACE-R total and sub scores: Euclidean distances				
	1:U1	2:U2	3:U3	4:U4	5:U5
1:U1	,000	5,657	11,747	11,662	21,954
2:U2	5,657	,000	10,770	13,416	22,000
3:U3	11,747	10,770	,000	16,432	17,088
4:U4	11,662	13,416	16,432	,000	30,067
5:U5	21,954	22,000	17,088	30,067	,000

Table 12: Dissimilarity matrix ACE-R  
 Addenbrooke's cognitive examination revise (ACE-R) total and sub scores. The lower values correspond to a lower dissimilarity.

In conclusion, the results on DM app shows that the task is appreciated by the participants who expressed signals of pleasure and attention. The linguistic indexes were correctly calculated by the app and the final version of the app should include a higher number of stimuli and should involve the users for 15 minutes in order to obtain a 1000 words final text. The preliminary data show a coherence between cognitive measures and linguistic indexes.



## 4.5 Outcome Measures

### 4.5.1 WHODAS 2.0

The World Health Organization Disability Assessment Schedule 2.0 (WHODAS 2.0) (<https://www.who.int/classifications/icf/whodasii/en/>) is a generic assessment instrument providing a standardized cross-cultural method for measuring activity limitations and participation restrictions, largely employed in geriatric settings (Bombin, Santiago-Ramajo et al. 2012, Dernek, Esmailzadeh et al. 2015).

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 questionnaire was administered before the Field Trials (T0) and after the Trials (T1) in both the TG and CG. Additionally, WHODAS questionnaires specific for caregivers were performed with the caregivers (patient' functioning from caregiver perspective). The simple scoring option was adopted (Üstün et al. 2010).

High scores, especially on a particular domain, may indicate significant and problematic areas for the individual that might warrant further assessment and intervention.

There was no significant difference between CG and TG at T0 in both patients and caregivers. Figure 8 shows that there was no significant difference between T0 and T1 within each group. In the TG, however, there was a trend towards a decline in burden ( $p=0.065$ ).

Two patients in the TG show very high scores which worsened over time, indicating a generally higher burden of disease of those patients. Figure 9 shows the difference between T0 and T1 of the caregivers within each group.

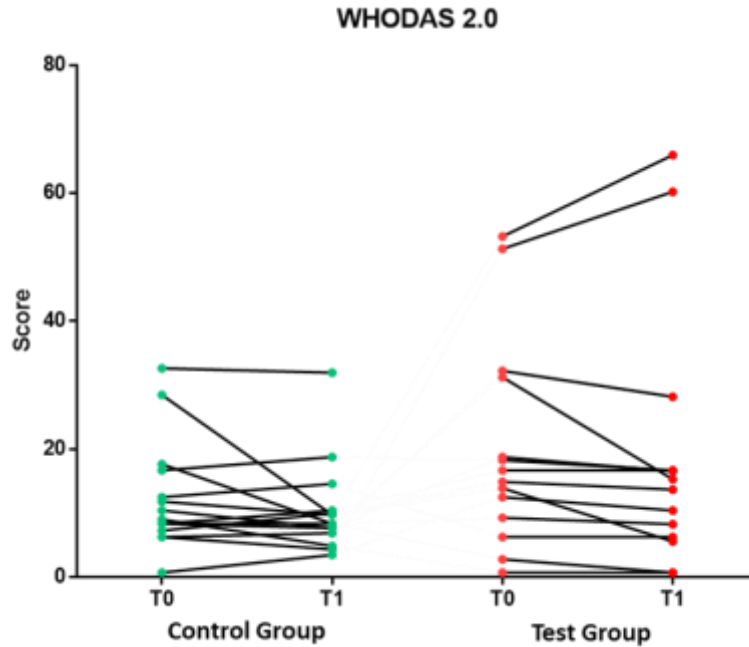


Figure 8 – WHODAS  
Changes in the WHODAS in CG and TG from the beginning of the Field Trials (T0) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

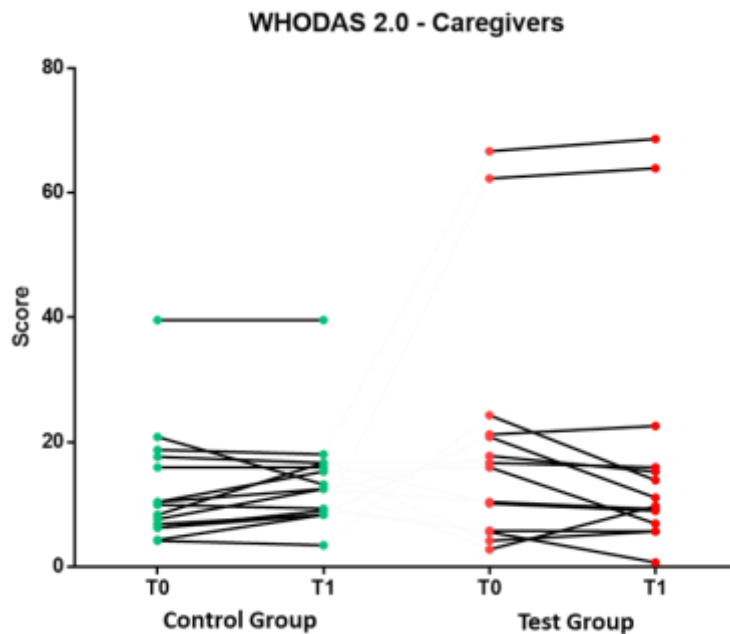


Figure 9 – WHODAS Caregiver  
Changes in the WHODAS in CG and TG caregivers from the beginning of the Field Trials (T0) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

#### 4.5.2 QOL-AD

The Quality of Life – Alzheimer’s Disease scale (QOL-AD) (Logsdon, Gibbons et al. 1999) was 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) (patient’ QOL from caregiver perspective), which were both administered at the beginning (T0) and the end (T1) of the Trials. High scores in the QOL-AD questionnaire indicate a better quality of life (range 0-52).

There was no significant difference between TG and CG in both patients and caregivers, as well as no significant difference between T0 and T1 (Figure 10, Figure 11). In the patients of the TG, there was a trend towards better quality of life from T0 to T1 when performing Student’s t-test ( $p = 0.051$ ;  $T0 = 31,43$ ;  $T1 = 33,71$ ). This difference, however, was not confirmed using a non-parametric test (Wilcoxon-Mann-Whitney-Test;  $p = 0.058$ ).

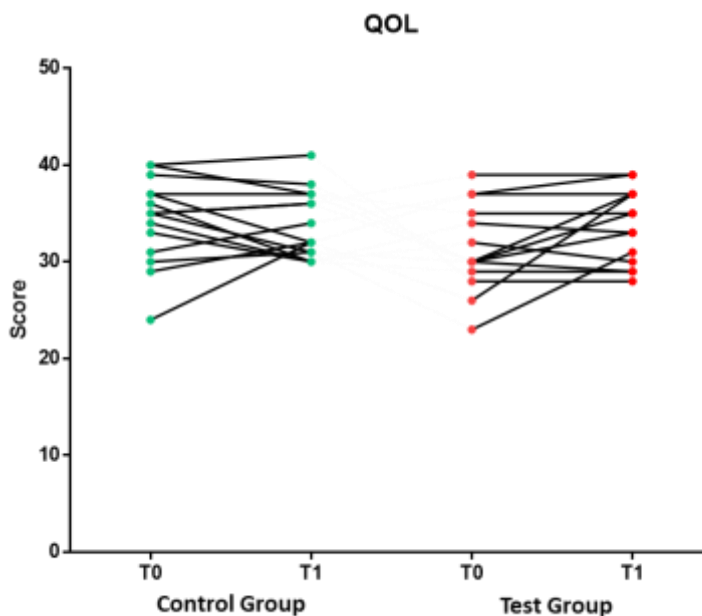


Figure 10 – QoL  
Changes in the quality of life in CG and TG from the beginning of the Field Trials (T0) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

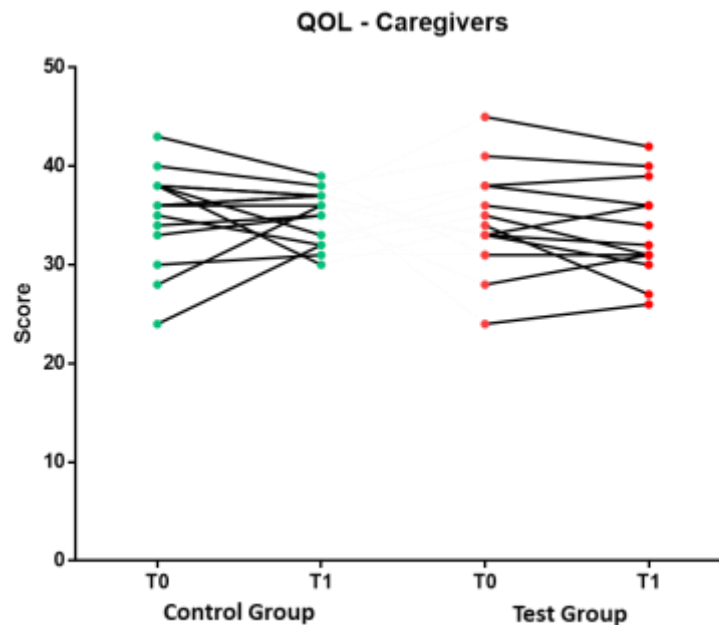


Figure 11 – QoL Caregiver  
Changes in the quality of life in CG and TG caregivers from the beginning of the Field Trials (T0) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

### 4.5.3 ADCS-ADL

The Alzheimer Disease Cooperative Study-Activities of Daily Living (ADCS-ADL) (Galasko, Bennett et al. 1997) is an inventory to assess activities of daily living for clinical Trials in dementia. The questionnaire was administered before the Field Trials (T0), inbetween (T0.5) and after the Trials (T1) in both the TG and CG. High scores in the ADCS-ADL questionnaire indicate a higher grade of disability.

There was no significant difference between the different timepoints of the Field Trials, as shown in Figure 12.

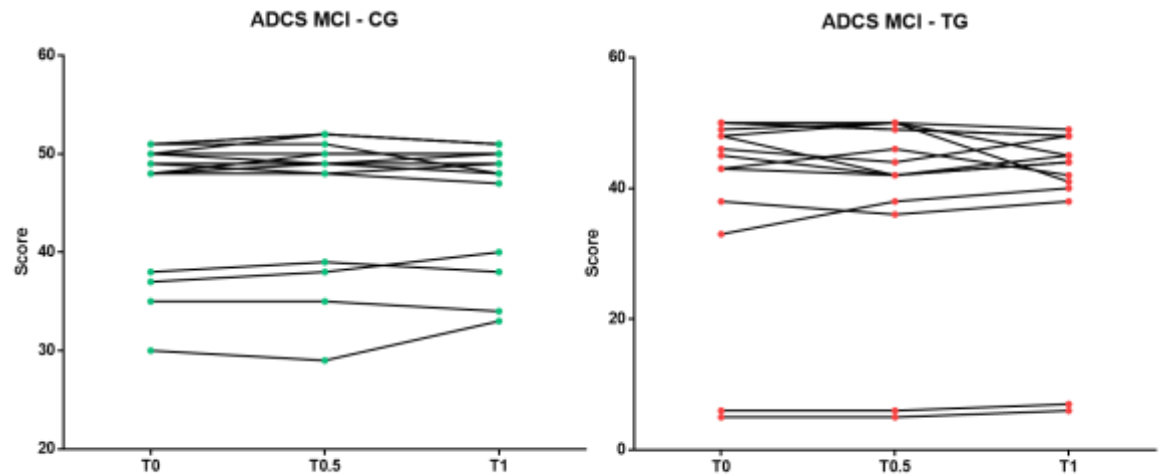


Figure 12 – ADCS  
Changes in the ADCS MCI in CG and TG from the beginning of the Field Trials (T0), inbetween (T0.5) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

#### 4.5.4 NPI

The Neuropsychiatric Inventory (NPI) (Cummings, Mega et al. 1994) assesses neuropsychiatric disturbances common in dementia together with the amount of caregiver distress engendered by each of the neuropsychiatric disorders. The questionnaire was administered before the Field Trials (T0), and after the Trials (T1) in both the TG and CG. High scores in the NPI questionnaire indicate a higher grade of neuropsychiatric symptoms in patients with dementia and informant distress (range 0-144).

There was no significant difference between TG and CG and between the different timepoints of the Field Trials, as shown in Figure 13. We further had a closer look at the caregiver distress, where no significant difference between TG and CG caregivers was observed (Figure 14).

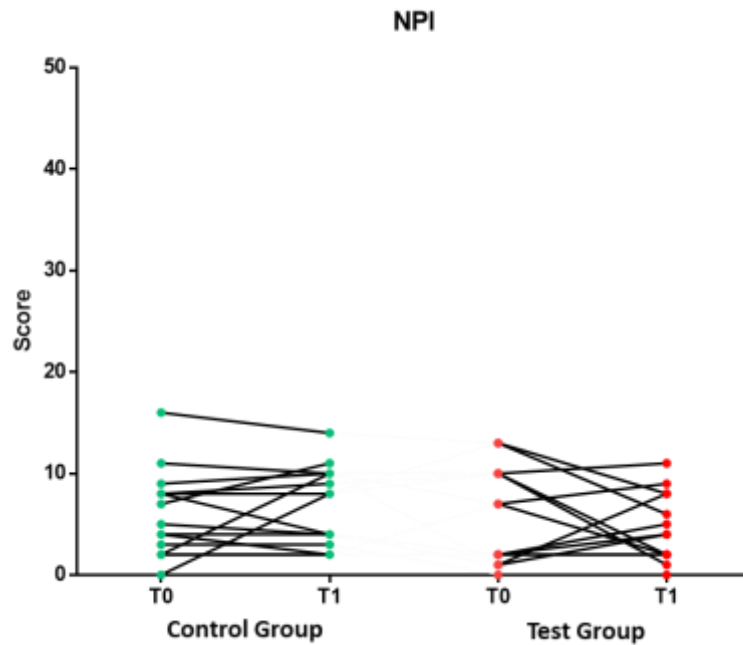


Figure 13 - NPI  
Changes in the NPI in CG and TG from the beginning of the Field Trials (T0) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

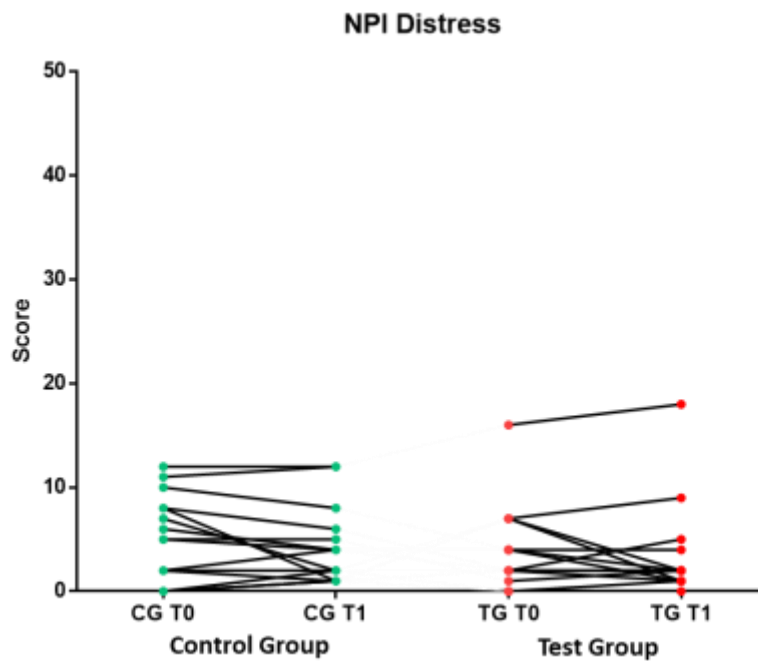


Figure 14 – NPI Caregiver  
Changes in the distress of caregivers according to the NPI in CG and TG from the beginning of the Field Trials (T0) and after the Field Trials (T1). There was no significant difference between the groups and between time points within the groups.

#### 4.5.5 CBI

The Caregiver Burden Scale (CBI) (Zarit, Reever et al. 1980) assesses perceived burden among caregivers of family members with dementia. The questionnaire was administered before the Field Trials (T0), and after the Trials (T1) in both the TG and CG. High scores in the CBI questionnaire indicate a higher caregiver burden.

There was no significant difference between TG and CG caregivers and between the different timepoints of the Field Trials.

#### 4.5.6 UES and SUS

##### User Engagement Scale

The User Engagement Scale (UES) (O'Brian and Toms 2009) measures the user engagement by means of six dimensions of engagement: aesthetic appeal, focused attention, novelty, perceived usability, felt involvement, and durability.

The UES questions can be therefore divided into the following categories: Focused attention (FA) is about the feeling to be absorbed in the interaction and losing track of time. Felt involvement (FI) refers to the sense of being “drawn in” and having fun, NO describes the novelty, curiosity and interest in the interactive tasks, EN the durability, which means the overall success of the interaction and the users willingness to recommend the system to others or engage with it in the future. The aesthetic appeal (AE) comprises questions about the attractiveness and visual appeal of the device and interface. Perceived usability (PU) refers to negative affect experienced and the degree of control and effort expended, such as “I felt frustrated while using MEMENTO”. The questions were reverse coded in the analysis. Higher mean scores in the results shown in Table 13 refer to higher engagement (scale = 1-5) Details are provided in Figure 15, the questionnaire can be found in deliverable D7.2B (Supplement 10).

The participants struggled to fill out the questionnaire and give clear answers to the questions, due to the early stage of the MEMENTO system. 3 patients from Italy, 3 patients from Austria and 5 patients from Spain finished the questionnaire (n=11). Only the Italian and Spanish caregivers filled in the questionnaire (n=9).

In detail, questions such as “I lost myself in the MEMENTO experience” or “The time I spent with MEMENTO just slipped away” (belonging to the subgroup FA) did not correlate well with the purpose of the system, which is intended to assist the patient in everyday life and not for entertainment. Therefore, results have to be interpreted carefully, which is also discussed in 5.3. Questions, which

concentrated on the core purpose of the MEMENTO system were rated mostly positively.

The FI was rated above average and the patients showed high curiosity and interest in the MEMENTO system (NO). The EN, AE and PU were also rated above average. Caregivers rated the different features averagely. As in the patients, lowest scores were assigned to the FA, all other aspects were rated above average with highest scores to the NO and AE.

	<b>Patients</b>	<b>Caregivers</b>
<b>FA</b>	2.3	2.8
<b>FI</b>	3.1	3.3
<b>NO</b>	3.5	3.9
<b>EN</b>	2.9	3.5
<b>AE</b>	3.4	3.7
<b>PU</b>	3.1	3.3

Table 13: UES Outcome

The Table shows the mean scores of the different aspects of the UES Questionnaire performed by patients (n=11) and caregivers (n=9).



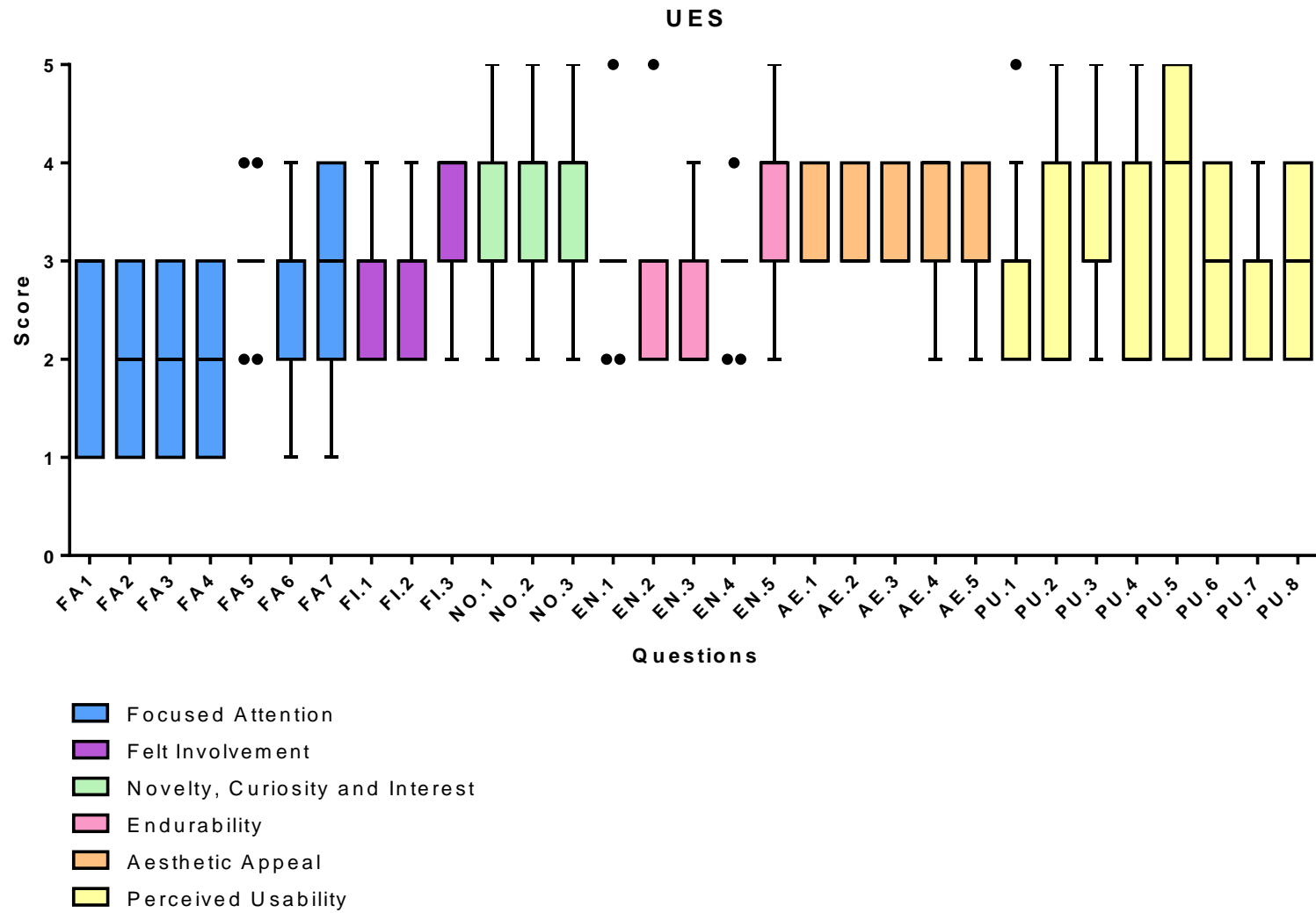


Figure 15 – UES question scores

The graph shows box and whiskers blot of the individual questions of the UES (n=11, error bars: Tukey) as rated by the patients. Questions are colour coded according to the subcategories of the questionnaire.

### System Usability Scale

The System Usability Scale (SUS) (Brooke 1996) is a quick measurement of how participants perceived the usability of a system. The mean score of the individual questions provided information about different aspects of usability.

Summarized, as in the Lab Trials, there is great variability between users, mostly due to their different age and technical proficiency and interest. The usability was rated by 4 Italian and 4 Austrian users (n=8). This low number of completed SUS scores is due to patients having difficulties with the questionnaires and not completing it (e.g. missing answers, the caregivers took over).<sup>1</sup> The present results consider only the user who completed the questionnaire.

The median score from patients' side of view was 50 (range 35 to 87.5) out of 100.

The great variability mentioned above becomes evident when evaluating the different questions of the SUS answered by the individual patients, as shown in Figure 16. The total SUS score has therefore to be evaluated with caution.

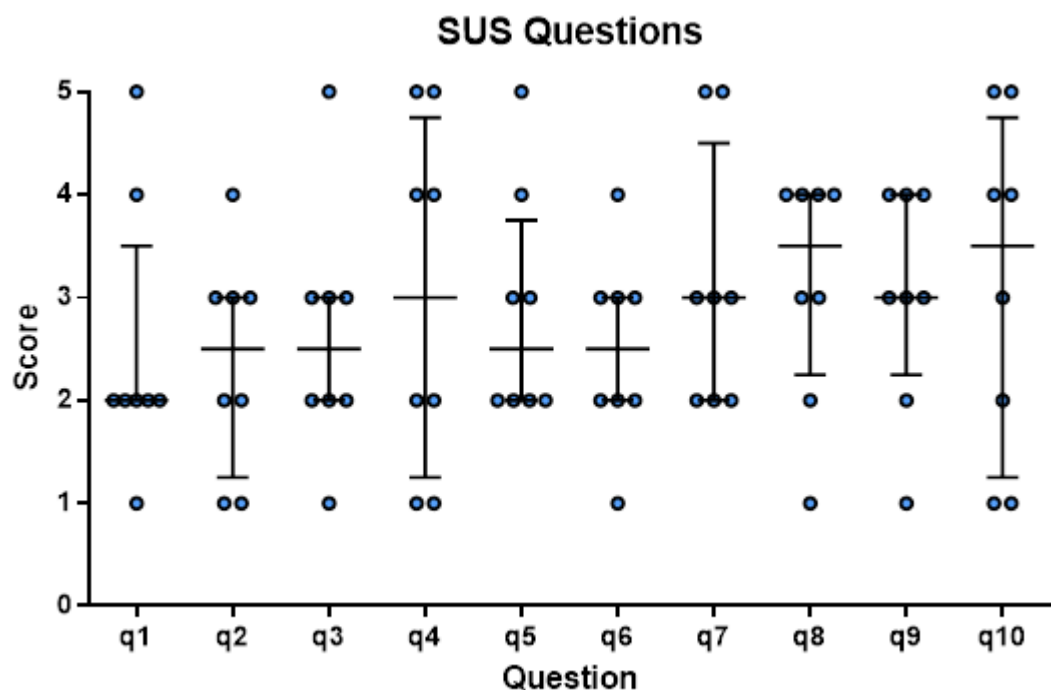


Figure 16 – SUS question scores

Scatter blot of the individual question scores of the patients (n=8), median with interquartile range is shown. Strong variability was observed between the patients ratings.

<sup>1</sup> The SUS was not suitable for all the patients. We therefore also used an observational approach as suggested in literature (e.g. Gibson, A., C. McCauley, M. D. Mulvenna, A. Ryan, L. Laird, K. Curran, B. Bunting, F. Ferry and R. R. Bond (2016). Assessing usability testing for people living with dementia. REHAB 2016: 4th Workshop on ICTs for Improving Patients Rehabilitation Research Techniques. Lisbon Portugal.)

#### 4.5.7 Focus Group Meeting

At the end of the Field trial, a focus group per site (Italy, Austria and Spain) was organized. The same procedure was followed in each site.

After a message of welcome, the moderator explained a few ground rules for the discussion. Group discussions were supported by questions and follow up inquires.

Guiding questions were developed based on a consensus between the experts involved in the MEMENTO project based on the Framework for Design Thinking for older people proposed by Wilkinson and Gandhi (Wilkinson and Gandhi 2015) and presented in D7.1A.

Participants were asked about (i) MEMENTO's physical and psychological support, (ii) economic aspects, (iii) social aspect link to MEMENTO, (iv) participants thoughts, reactions and experiences. Focus groups at each clinical centre were led by a moderator and an observer.

Participant interventions were transcribed and reviewed for accuracy in transcription based on digital recording. The recurrent themes, conceptual descriptions, and illustrative examples from focus group responses were considered. To be considered a salient aspect, a theme had to be cited by two or more participants.

#### Results

Table 14 provides a summary of the themes, subthemes, and representative quotes extracted from focus group transcripts of the Italian, Austrian and Spanish cohort.

Support: the participants attributed cognitive, physical, emotive and social support to Memento. Some functionalities like shopping and appointments were recognized as important to support perspective memory. Respect from traditional methods to remember, Memento obligates people to write and categorize important aspects like time, date and place so that the user is secure to dispose of all the information. At the same time, Memento remind the appointment. Memento gives physical and emotive support indirectly. In fact, thanks to "lost outside" and "panic" functionalities, people experiment a higher sense of security in daily life.

These aspects are related to the theme of the independence. Memento is a non-stigmatizing and aesthetically pleasing designing system that allows people to maintain independence in different aspects of daily life.

Risk of abandonment: people cited different situations that could limit the use of the system. Technical problems were the most cited factor. Caregivers are considered very important to sustain the initial effort of learn and to support the

use of the system. Some users were reassured if caregiver follow them step by step in using the system. Others also split up the system, with the caregiver adding data to the main device and the person with dementia mainly using the all-day device.

In particular, difficulties in writing on an e-ink interface were perceived as underperforming compared to traditional methods. The learning procedures required an initial effort that not all participants were able to sustain so that caregiver's stimulation was necessary. Personal motivation, familiarity with technologies or predisposition to technologies were considered important factor to use effectively the technology. Participants observed that some strategies to remember are very familiar and faster, an aspect that limits the possibility to replaces them with a new method, regardless of its efficiency

Economic aspects: participants attributed a marked value to the product adding up the commercial costs of the different devices (a smartwatch and two tablets). They discussed the possibility to reduce the costs assuming a single face Main device. After discussion, they agreed that all components are important to have an optimal system. Participants recognized a high value to the system related to the health status and quality of life. They considered important that the healthcare system could distributed the system and monitored the use to avoid a waste of resources. Memento is considered important as a support to maintain independence and, as a consequence, it is very important to help reducing the cost of care. People with mild dementia could live independently more time with Memento. Participants noting, that the system would be very useful for persons living alone, emphasized this point also.

As far as the caregiver burden, participants agree that it could be reduced due to:

- Possibility for caregivers to monitor the situation remotely
- Fewer things to remember
- The perception of a higher level of independence in the primary user

The possibility to have the DM app is considered an opportunity to monitor autonomously the symptom's progression.

Participants agreed that cognitive impairment reduce the sociality. Feelings of shame, insecurity and sometimes fear of the disorienting could confined people at home. These aspects have a great and bad impact on health status. Each participant experimented that maintain and increase social events promote wellbeing. Memento's social support is important to promote and maintain sociality, also for the caregivers.

A general reflection on technologies emerged. Some participants considered technologies as dangerous since it delegates memory strategies to a system.

Other participants highlighted that if there is a memory deficit, people still need to rely on someone or something. Relying on technology guarantees greater independence so that the gain overpasses the dangerous to delegate memory strategies to a system. Participants agree that, despite traditional methods are more familiar, in a more digital society and for the new generation of old people, Memento could be very important.

**Table 14: Italian, Austrian and Spanish focus group meeting**

THEMES	SUBTHEMES	REPRESENTATIVE QUOTATIONS ITALY	REPRESENTATIVE QUOTATIONS AUSTRIA	REPRESENTATIVE QUOTATIONS SPAIN
<b>Support</b>	<b>Cognitive support – shopping, medication and appointments support people into remember important things</b>	“To insert an appointment, the user is obligated to insert all the information necessary to remember”.	“Above all, the medication reminder is very useful, although the reminder should pop up more than once.”	“Medication is really useful, but it should be able to manage more medicines”.
	<b>Physical support – navigation support people into going out</b>	“It is very useful to have a sort of navigator and the possibility to call for help”	“Navigation would be very helpful, but the GPS should be more accurate.”	“Overall, the possibility to call if there's any problems are very useful”
	<b>Emotive support – emergency call and navigation help people to feel secure and more independent.</b>	“The <i>All day device</i> increase the sense of security is a sort of <i>wrist-caregiver</i> ”.	“We really appreciate the possibility to call the caregiver.”  “Panic calls and location query were functioning convincingly. The panic notification for the caregiver should absolutely be maintained in further versions.”	“I felt safer knowing the possibility to call my caregiver any time”
	<b>Social support – Memento help people to maintain social interaction</b>	“Memento could help people to maintain social interaction increasing sense of safety, helping to remember appointments and promoting spatial orientation”.	“Memento would be a good support for people at the beginning of dementia who are alone.”	“Memento is a very nice system to support the interaction with friends and family”  “We appreciate the safety that Memento gave us to help memory issues”

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		<p>"I like to image that Memento will be diffuse in people with dementia...and that they would socialize Memento experience"</p>		
	<b>Independence</b>	<p>"Memento is a non-stigmatizing system and could help to re-establish a sense of independence"</p> <p>"Technology help people to remember independently by others"</p>	<p>"At the moment, I would rather rely on my caregiver, but it may help persons who live alone."</p>	<p>"Memento helped me and my caregiver to organize my daily life, so I felt more confident with myself most of the time"</p>
<b>Risk of abandonment</b>	<b>Technical problems and the initial effort to learn the procedures could limit the support.</b>	<p>"I tried to write...the write doesn't work and I abandoned the system"</p> <p>"It was very difficult to persist in the use despite the technical problems"</p>	<p>"Memento is not very intuitive, therefore my wife refused to use the system."</p> <p>"The All-day device is difficult to use and the display is difficult to read, also for the elderly who are not disabled."</p>	<p>"The most difficult thing was writing, doesn't work well... so I did not use it after several attempts"</p> <p>"It was frustrating the malfunction of the All-day device; we rarely use it"</p>
	<b>Some people refuse technologies</b>	<p>"He is poorly interested in novelty...I tried to convince him to use the system but he was very resistant"</p> <p>"I don't like technology in general"</p> <p>"I don't interest in technology"</p>		<p>"These technological things will be very useful if they work properly, but almost always fails"</p>
	<b>Habits</b>	<p>"It is very difficult to change the habits to remember...I have my strategies..."</p> <p>"In medication she finds her strategy..."</p>	<p>"My usual strategies work very well, so I wouldn't like to change them."</p>	<p>"She was used to her method and it was very difficult to convince her to use another"</p>

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		I do not like a change in this area”  “My strategies are faster.....”		
	<b>Low technical proficiency</b>	“It is very difficult because I don’t use phone or pc....But I know it could be very important for people able to manage technologies”  “Motivated people could start to use system despite the low familiarity”	“My wife is not very proficient with technology; I think it would be easier if the software was more similar to that of windows or smartphones.”	“The confrontation with technology was a challenge because I do not know nothing about it, only my smartphone”
	<b>Role of the caregiver</b>	“I helped her to learn some functionalities”  “We inserted the shopping list together and then she appreciated to shop with the All-Day device” “She wanted to use the system with me”	“We split up the devices... I inserted data into the caregiver interface and used the main device; my husband only used the all-day device.”  “My husband relies on me heavily; if I wouldn’t have motivated him he wouldn’t have used the device.”	“I have learned to use it, but he always needed my help to create a shopping list or an appointment”  “I support her just twice to understand the All-day device, then she appreciates mostly the medication alarm”
<b>Economic aspects</b>	<b>Desire to buy Memento or to continue to use it</b>	“I didn’t use the system...I wouldn’t buy it”  “It’s difficult to leave the system after the efforts to learn to use it...Can you give me?”	“At the moment, it is rather a gimmick.”  “I would not continue to use of buy it at the moment. However, if there is a better version, I would like to participate in testing the devices again.”	“I would like to give the system to my sister, it would be very useful for her and she likes technology and will appreciate such a gift”  “When All-day device and writing issues are fixed, can I try to use it again?”
	<b>Quantify the value of the system</b>	“It’s a sort a sort of life-saving and it is composed by different technological systems very	“I cannot answer this at the moment. I think it depends on it’s final functionality and on the income of the users.”	“I think that this technology will cost 1500€ approx..?”

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		expensive in commerce....I think that it could cost from 1000 to 1400 €”	Participants couldn't answer this question easily, since they would not buy the system at the moment. One participant said between €200 and €500, one caregiver said she would also pay over €500.	“The system is technologically advanced, so the cost of the final version will be expensive... like more than 1000€”  Most of the participants couldn't estimate the value of the system.
	<b>Cost reduction</b>	Participants discussed about the opportunity to reduce the device to reduce overall costs for example with a single face main device or without main device. Different opinions emerged: the double face is important to personalize the system and to have time and date. Without the Main Device the users could be more dependent from the caregiver.	The discussion also arised in the Austrian cohort. Participants stated, that the left tablet is useless at this timepoint (no interactive functionality and you can't see it when set up on a table).	In the Spanish cohort, the discussion emerged over the left tablet as a non-necessary element was stated.
	<b>Memento distribution</b>	“Memento could be distributing by the sanitary assistance like an aid for motor disability”  “a practioner prescribe Memento and a commission decide if it could be the case to assign the aid monitoring the use in order to prevent the abandon with a waste of resources”	“Memento could be sold in shops specialized on medical products.”	“Memento could be distributed by the social and sanitary public services to help the elder people with Alzheimer's” disease”
	<b>Extrinsic cost reduction</b>	“Memento supports the independence also in people that live alone. A friend could help into		

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		<p>insert appointments and medicines weekly and the general practitioner could check the therapy”</p> <p>“DM app is a pleasant method to self-monitor the symptom’s progression”</p>		
<b>Impact of cognitive impairment</b>	<b>Cognitive impairment reduce the sociality</b>	<p>“When I have a conversation and I don’t find the world, I feel shame”</p> <p>“Memory problems generate feelings of insecurity...I reduce my intervention in conversation”</p> <p>“Sometimes I have fear to go out alone...and I reduce my activities”</p> <p>“Forget appointments could reduce friendship”</p> <p>“There is the risk of isolation”</p>	<p>Participants from Austria report similar problems with reduced social contacts as in Italy.</p> <p>Also, one caregiver reported it affects her social activities too, since she doesn’t want to leave her husband alone.</p>	<p>Participants from Spain report similar problems with reduced social contacts as in Italy and Austria.</p>
	<b>Maintain and increase social events promote wellbeing</b>	<p>“Each week I attend the day of cognitive stimulation in group....I like that meeting very much”</p>	<p>One participant is still working. His wife reported, that he feels restless and his cognition worsens when he has to stay home (this happened recently when he had an injury on his hand).</p>	<p>“I always go to the elderly day center to meet my friends and have some exercise”</p>
<b>Thoughts about technology</b>	<p><b>Technology is better than traditional methods</b></p> <p><b>Risk to delegate memory to a system</b></p>	<p>“Memento is not replaceable with an agenda...for example the “All day device” is very useful for the portability: it is always with you”.</p>	<p>A participant reported that she rather tries to remember herself in order to train her memory and also rather likes to write things down on an agenda.</p>	<p>“The whole system is good for remember, but I prefer just the All-day device that gave me a higher sense of security”</p> <p>“(Memento) Is an interesting</p>

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		<p>“You delegate the memory to the technology with a progressive disuse but you can live more independently”</p> <p>“If I don't use something....some one must to help me”</p>		<p>alternative, but I'll keep using my agenda and the paper reminders...”</p>
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## 5 Main Results and Suggestions

### 5.1 General

Most of the users were very engaged with the system and its design in general. They liked the idea of a digital device to help them manage their daily life. The patients and their caregivers expressed curiosity for the general concept and the possibilities of the system. Most patients appreciated the handwriting recognition, although some of the participants had problems with this feature due to patient specific problems. They enjoyed the all-day device, especially in respect to the “lost outside” and “panic” features.

As in the Lab Trials, frustration was expressed especially when technical problems occurred, which emphasizes the importance of stability of the system. Conversations with the participants and the overall outcomes points towards a strong difference of engagement and acceptance between users based on age and technical proficiency. Users who like technology in general appreciated the MEMENTO system, users who don't like technologies, typically those with higher age, independently of cognitive status, confirmed the preference of traditional memory strategies.

One user of the Austrian cohort abandoned the system and returned it after a month after the Trials started (AT\_4). The users declared, that they also like the idea of MEMENTO but since technical proficiency of the patient was very low, the system was not developed enough for her to learn and she got confused by it.

## 5.2 MEMENTO system in comparison to traditional memory aids

As outlined in 4.1, participants of both TG and CG use several traditional memory aids, including mainly calendars, post-its and agendas. To organize their medication, pill boxes are used very frequently. Additionally, the patients rely in many situations on their caregiver. Due to the specific age structure of our testing cohort, technical memory aids are used seldom.

Some technical problems, mainly at the beginning of the Trials, led to the preference of traditional strategies over the MEMENTO system.

Many of the users stated that the use cases “feeling lost outside” and “panic” is not relevant in their case. They gave defensive response when asked for their strategies or declared that they don't know how to act in these situations. Many of them would contact their caregiver and were seemingly insecure. Those MEMENTO functions were therefore appreciated by the participants, not only to contact the caregiver in case of panic but also in other situations.

In general, some participants are afraid to delegate memory strategies to a system. Others think that it would lead to greater independence. Despite traditional methods being more familiar, most agree that MEMENTO and technical devices in general are very important in our digital society and especially for the coming generation of old people.

In summary, participants expressed the need to gain more familiarity with the system. Also, it was difficult for them to compare the system to traditional strategies, which are more familiar, intuitive, faster and secure at the moment due to the early stage of development of MEMENTO.

## 5.3 Dementia Monitoring App

Results on DM app are very important to know users' opinion and develop a final version useful to monitor cognitive symptoms. DM app was very appreciated. Users expressed signals of pleasure and attention. The linguistic indexes were correctly calculated by the app but it is necessary to include a higher number of stimuli to involve the users for 15 minutes in order to obtain a 1000 words final text. Despite the low size of the sample, the preliminary data show a coherence between cognitive measures and linguistic indexes.

## 5.4 Outcome Measures

The outcome measures in 4.5 were important to gain more information about the participants of the Field Trials in different regards, such as disabilities,

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quality of living, activities of daily living, neuropsychiatric inventory, caregiver burden, user experience and system usability.

We performed the disease specific questionnaires at the beginning and the end of the Trials to see if there is a trend to improvements of those markers.

We found a trend towards a decline in disease burden when looking at the outcomes of the WHODAS 2.0 in the TG, as well as a trend towards an increase of quality of life over the period of Trials.

The UES and SUS questionnaires were performed with the TG after the Trials to evaluate the MEMENTO system. The participants declared high interest and curiosity for the system and all of them liked the aesthetics of the device and its interface. The overall experience was rated to be a success on average and they declared willingness to engage with the system in the future, especially in a further developed stage. They did not experience negative affect using the devices. The users however did not indicate to get entertained by MEMENTO or felt “drawn in”. This will be important for the further development, such as integrating games or including further personalized content. As an example, the DM app was appreciated by the Italian participants and they expressed signals of pleasure and attention during those tasks.

In general, those outcomes have to be interpreted with caution due to the small number of participants and the short duration of the Field Trials.

Important outcomes are also the conversations and meetings with the participants in order to let them think aloud and discuss their experiences and problems with the device. The participants attributed the MEMENTO system with cognitive, physical, emotive and social support. The “lost outside” and “panic” functions were experienced as higher sense of security. Therefore, the participants noted that MEMENTO could allow them to maintain independence for a longer time. On the other hand, technical problems were mentioned to be a reason for abandoning the system and support of the caregivers in operating the system was important for the participants.

## 5.5 Target group related challenges

As in the Lab Trials, a special focus during Field Trials was on the challenges related to the end-users needs and problems.

Regarding the main device, handwriting was challenging due to slow writing and shaking hands. For the device to recognize handwriting properly, a relatively even speed of writing is required. Digitalizing the handwriting during slow writing before finishing the word caused frustration in those patients. Those patients would prefer inserting the dates by selecting them on a list or calendar.

Regarding the caregiver interface, despite simplifying the site, most of the elderly caregivers had problems comprehending the meanings of the input fields and navigating through the interface. This part of the system has to be critically reviewed and changed for a more intuitive input system.

As in the Lab Trials, the function to let the lists be read aloud by All-day device was perceived very well from both patients and caregivers.

Another user-specific aspect to be discussed is the size of the All-day Device display and its icons and font size, which are difficult to read for elderly users. In contrast to the prototype, a larger display is planned for the end design of the smartwatch.

In general, participants named motivation, familiarity with technologies or predisposition to technologies to be important factors to use MEMENTO effectively.

## 5.6 Technical problems

During the Field Trials, technical problems occurred. In some cases, the screens froze, making technical support necessary. Other problems were time lags on the main device, leading to malfunction of reminders. Also, there was sometimes slow synchronization between main and all-day device. Those main problems could be traced back to bad Wi-Fi connection, which underlines the importance of a stable internet access. In addition to the MEMENTO system, the participants of the TG received routers, though they did not work equally well in every household.

Other than user-related problems, there were reports about GPS data not received by the caregivers after the patients used the navigation or panic button. Otherwise, there were no major technical problems regarding the All-day device. As for the caregiver interface, there were problems with image uploads and editing data.

## 5.7 Design aspects

The overall design of the main device was appreciated. The participants liked the format of the Main Device as a notebook. There were different opinions in respect to left tablet. Some users stated that the left tablet is useless at this timepoint (no interactive functionality and you can't see it when set up on a table), others thought the double face is important to personalize the system and to have time and date.

There was confusion about the buttons "new entry" and "list", especially since the options look the same in both cases.

The participants emphasized, that when inserting dates and looking them up, showing the weekday would be also appreciated for better orientation.

The design of the All-day device was also considered to be very good. Recognizing some of the icons and reading on the All-day device was difficult for some of the patients and the font size was too small for patients having problems with vision.

Regarding the design of the caregiver interface, the site has to be further simplified and adapted to be more intuitive.

## 6 Conclusions

In this deliverable, different aspects of the MEMENTO systems were evaluated following the results of the Field Trials.

The general concept and design were appreciated by the participants and they showed great interest and curiosity. Age and technical proficiency of the targeted end-users are important aspects to consider. Though, MEMENTO also seems to work for patients with higher levels of disability (e.g. one user shares the system with his caregiver - he uses only the all-day device and his wife the All-day device).

The Trials also highlighted that memory strategies are very resistant to change and the support of the caregiver is important to introduce the system. Apathy and aversion to technology could interfere with the engagement of the end-users and technical problems could lead to abandonment of the system.

However, the functionalities seem to correspond well to target group related challenges and a system to help patients to cope with their memory deficits would be valued by the participants.

The thorough evaluation of the Field Trials provided in this deliverable will help to further develop the MEMENTO prototype into a full-functioning system which will be tailored to the needs of and is expected to be highly accepted by the end users.

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