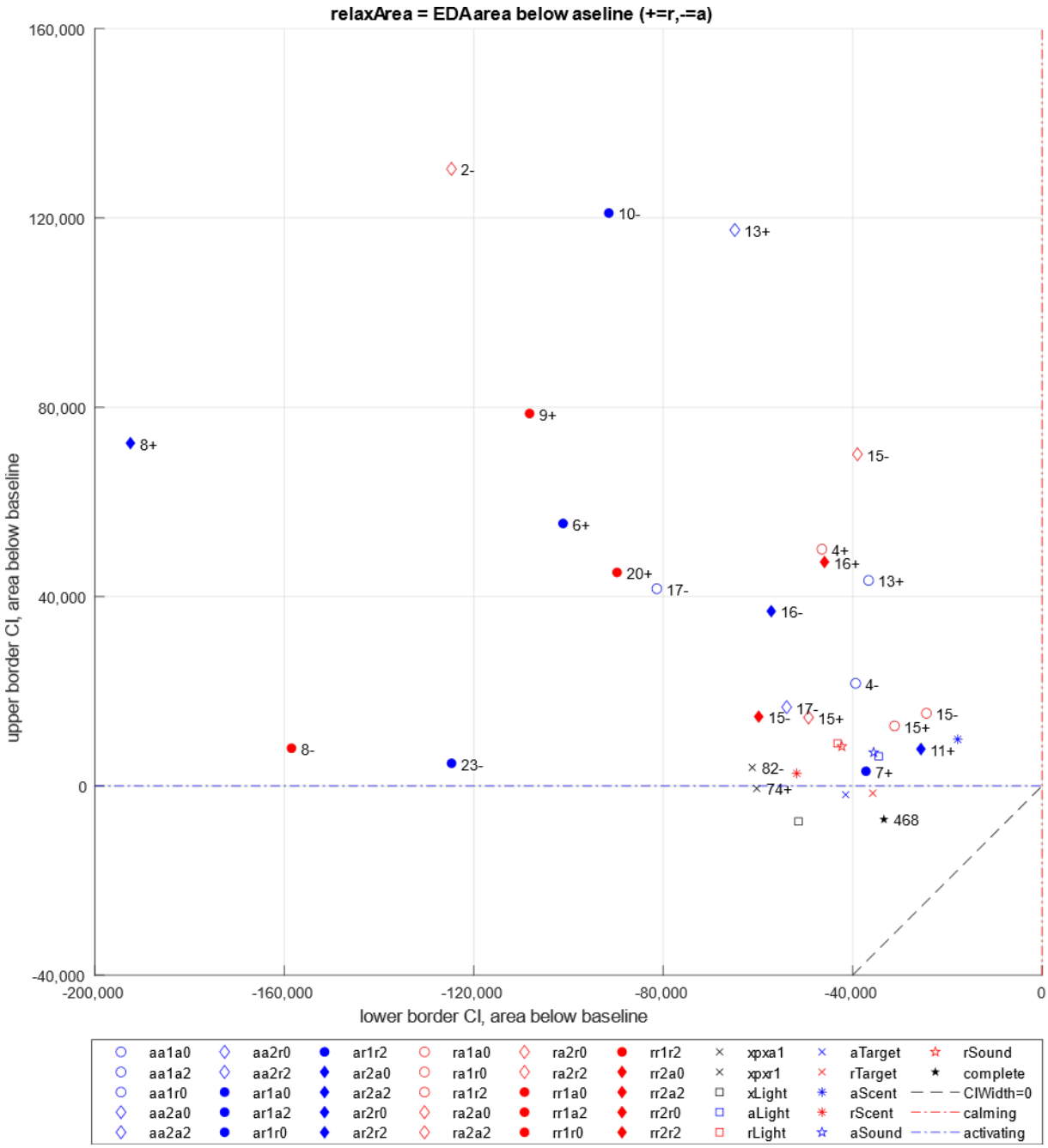

Figure 11: relaxArea measurement confidence intervals

- Black x "74+": confidence interval of all 2nd segments, where participants were told to feel activated.
- Black square: confidence interval of all 2nd segments
- Blue x: confidence interval of all 1st and 3rd segments, where participants were told to feel activated
- Red x: confidence interval of all 1st and 3rd segments, where participants were told to feel relaxed
- Black star: complete dataset

From this evaluation we draw the conclusion that our setting is generally exciting by itself, no significant data can be excerpted from this analysis. The previously tested groups "7+", "11+" and both "15-" from the previous analysis are close to the calming line but no significance can be calculated.

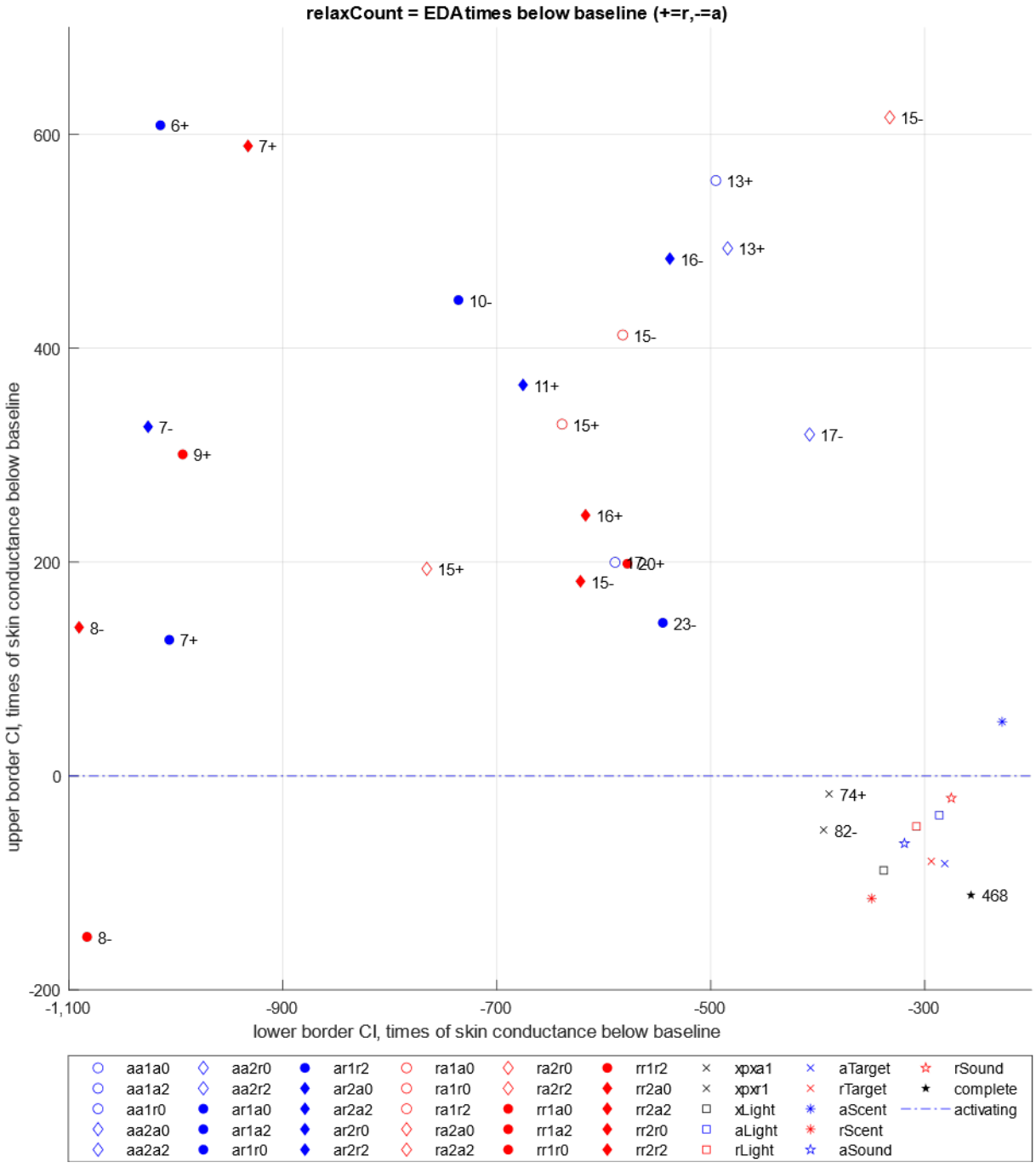

Figure 12: relaxCount measurement confidence intervals

Figure 12 shows on an absolute scale, how often the skin conductance was above or below the baseline average. We did not manage to create soothing atmospheres but as with the relaxArea, the more generously aggregated data shows excitement throughout the test (black, red and blue x and square, red and blue star, black star). Most interestingly we see one combination red dot with label "8-" which is below the activating line. This means that a combination of warmwhite light, rose-based scent

and relaxing sounds helped eight participants to successfully complete their task of feeling activated. All eight segments come from the first of three evaluated segments. Testing this specific combination against the complete dataset once more does not give significant results ($t(474) = 1.523$, $p = 0.064$), from all negative ttests this one is the closest to being significant.

4. Methodology & evaluation design of the field test

The research design of this project includes different approaches depending on the countries where the field trials took place. The reason for these differences depends in part on the type of care facility in which the Great system was tested and on the guidance received from the relevant ethics committee.

In general, caregivers had the task of initiating daily "relaxation" or "activation" interventions, marking on the tablet an evaluation score on the effectiveness of the intervention and wearing a body worn sensor in turn to detect certain vital functions.

In the last months of the field trials, however, the interventions started automatically.

The following table shows which modules and for how long they were tested in the various locations participating in the field trials.

	06 18	07 18	08 18	09 18	10 18	11 18	12 18	01 19	02 19	03 19	04 19	05 19	06 20	07 20	08 20	09 20	10 20	11 20	12 20
Hall (AT)	Scent					Sound						Light		Light + sound + scent					
Neumarkt (IT)	Scent					Sound						Light		Light + sound + scent					
St. Otmar (CH)			Scent					Light				Light + scent							
Gritt (CH)			Scent					Light					Light + scent						
Bürgerspital (CH)								Light				Light + aroma							
Private Person (CH)					Aroma														
Assisted Living (AT)											Light + sound + scent								

Table 3: Intervention plan by months and modules

A **statistical long-term comparison** is made by comparing the phases: baseline-final phase and between phases. The main tools to detect these effects are:

- **Neuropsychiatric Inventory-Questionnaire:** The NPI examines 10 sub-domains of behavioral functioning: delusions, hallucinations, agitation/aggression, dysphoria, anxiety, euphoria, apathy, disinhibition, irritability/lability, and aberrant motor activity.
- **Professional Care Team Burden Scale**: The 10 item PCTB scale provides a valid and reliable means of obtaining ratings of burden from formal care teams working in nursing homes in order to evaluate different interventions targeted at the reduction of burden in care teams. (questionnaire used in Austria and Italy).
- **Focus group and personal interviews** at the end of the trials with the professional caregivers.
- **SUS**

A **short-term statistical comparison** is made by comparing the PIR and vital signs before and after intervention.

-

4.1 Methodology & evaluation design in the Tirol Kliniken, Austria

General Information about the care facility

Part of the field study was carried out on a geriatric psychiatric acute ward (A4) in the Department of Psychiatry and Psychotherapy A at the Regional Hospital Hall in Tyrol. This department is responsible for the full psychiatric care of the regions Innsbruck-Land and Schwaz as well as supraregional for the areas geriatric psychiatric, Forensic and Social Psychiatry. The ward A4 contains thirteen patient rooms with 25 beds and is divided into a north and a south wing. The north side comprises four rooms with seven beds, in which the GREAT modules are installed in rooms 3 and 4. Thus, the modules are available for four patients.

On ward A4, patients aged 60 and over are treated with affective disorders, schizophrenia, personality disorders, affective disorders with accompanying dementia symptoms and substance abuse or addictions. In 2018, a total of 330 patients were admitted to hospital, with an average stay of two weeks.

The multi-professional team leads to a multitude of treatment methods. In addition to the detailed medical diagnosis, the medication and treatment as well as, if necessary, withdrawal treatment are also carried out. In addition, various psychological diagnostic procedures are used, for example to assess cognitive abilities and the severity of the depressive disorder.

At the therapy level, patients participate in occupational therapy, physiotherapy, cognitive training and psychotherapy, in groups and in individual settings. The focus of the therapy offerings can vary depending on the current state of health and the motivation of each patient to participate. In order to be able to intervene beyond the scope of the ward, there is the possibility of a social worker providing care, which can also be provided together with the relatives.

Evaluation design & the phases of the project

The first phase of the project was divided into three sections in which the three modules were tested individually. At this stage, the nursing staff active the intervention on the tablet in the morning (07:00 - 07:30) and in the evening (20:30 - 21:00). The phase started on 27.06.2018 with the installation of the fragrance modules and ended on 14.10.2018. This was followed by the use of the sound modules, which started on 15.10.2018 and ended on 18.04.2019, whereby the interventions were not used during the period from 12.12.2018 to 07.01.2019. For the last phase of the first phase, the light modules were put into operation from 19.04.2019 to 19.06.2019.

The second phase began on 09.07.2019. In this phase, all three modules are activate simultaneously and the intervention starts automatically, in the morning and in the evening.

The data collection through questionnaires began in November 2018 and lasted until December 2019.

The design of the research has provided for the distinction of two groups: an intervention group and a control group:

- **Intervention group:** This group consists of those people who were hospitalized in two rooms where the Great modules were installed.
- **Control group:** This group is made up of those people who were hospitalized in two rooms that acted as a control group, where the Great modules had not been installed.
- **Common area**: Great modules were also installed in a common area of the geriatric psychiatric acute ward (A4), so that part of the control and intervention group could also use the Great system outside the two intervention rooms. At the end of their stay at the hospital, the staff estimated the patients' time spent in the common area with the Great system.

The data/scales collected on the **patients** of this four rooms are:

- General information: sex, age, health status (Admission)
- Date of admission/discharge
- Info if Great was tested in the room and how long
- NPI (admission + discharge)
- MMSE – Mini Mental State Examination (admission)
- CDR: Clinical Dementia Rating Scale (admission)
- CGI - Clinical Global Impression: Severity of illness (admission), global improvement (discharge)

The data collected about the **care staff** are:

- PCTB: Professional Care Team Burden Scale
  - Baseline: 11/2018
  - Phase 1: 02/2019
  - Phase 2: 06/2019
  - Phase 3 (final): 12/2019
- Focus group
- SUS - System Usability Scale questionnaire.

First feedback from the nursing staff

At the beginning of the project, it was not so much the general feasibility of the project and the time involved that was a major reservation of the nursing staff, but rather the question of its usefulness. The most frequent concern was that the A4 is not a pure dementia ward, but that acute suicidal, drug-dependent and psychotic patients are the norm. Of course, these patients also have cognitive impairments due to their age

and comorbidity diseases. Nevertheless, the purpose of the project was repeatedly met with incomprehension. To make matters worse, the above-mentioned psychotic patient groups, especially with the sound modules, could not cope well because they often could not assign the sounds or included them in their delusions. This was often cited by the nurses as a reason that the ward was not suitable for the study. These reservations could not be overcome until the end of the study. Nevertheless, the fragrance modules in particular have gained acceptance and the benefits of the lighting modules have also been recognised by many of the employees.

During the baseline survey of the Burden Scale, the employees expressed many reservations (on non-specific questions, questions about satisfaction with colleagues, boss and work), so that some were not prepared to fill out the questionnaire and some others left out some questions. These reservations were reduced in the course of the follow-up surveys to fewer omitted questions. Many nurses agreed to wear the Biovation- strap, but in the end it was rarely worn, less as a result of general rejection than because it was very low on the priority list at work.

In general, the nursing staff's willingness to collaborate can be regarded as given both at the time of the start and in the further course of the project, and the time required for the work can be regarded as a given.

Thus, especially since the automatic switching of interventions, there is little to no additional workload. However, from a subjective point, the hoped-for relief of the staff by activating or calming the patients also remains.

4.2 Methodology & evaluation design in the Nursing Home Griesfeld, Italy

General Information about the care facility

In Italy, the Great system has been tested at the Nursing Home Griesfeld (ASG) which is a public organisation for the care and nursing of elderly, based in Egna (Italy). The organisation is made up of a second retirement home named Lisl Peter, which is based in Montagna, and a senior housing with 14 small apartments for elderly who are autonomous in Egna.

The focus is on nursing and social care, but other services offered are physiotherapy, occupational therapy, speech therapy, religious assistance, organization of activities for leisure, aromatherapy, pet-therapy, day care and cohabitation for people with dementia. This cohabitation enables people with dementia to experience everyday life as normal as possible, living together like in a big family.

Evaluation design

The design of the research has provided for the distinction of two groups: an intervention group and a control group.

- **Intervention group:** This group is made up of all patients in the "Dependance of the Egna nursing home". In the dependance live about 10 people with various degrees of Alzheimer's that are followed throughout the day by specialized personnel (about

10 people including Nurses, Social Care Operator). The Great system was initially tested in two common areas of the dependance (kitchen and living room) and in one bedroom and in the last months in two bedrooms and always in the same two common areas. From July 2018 to August 2019, during the period of operation of the Great modules, staff took turns wearing a body worn sensor (Everion sensor from the company Biovotion, Zurich, Switzerland, for information please see: "D2.1 - Applicable hardware components").

- **Control group:** This group is composed of the patients of the Alzheimer's nucleus located in the rest home of Montagna (very similar to Egna's) and the staff who work there.

The project phases and the evaluation questionnaires used can be summarised as follows:

- **Baseline:**
  - **Intervention group – data collection: June 2018**
    - Patients: general patient data anonymized and NPI
    - Caregivers: personal sociodemographic data and Professional Care Team Burden Scale (PCTB)
  - **Control group – data collection: June 2018**
    - Patients: general patient data (anonymized) and NPI
    - Caregivers: personal sociodemographic data and Professional Care Team Burden Scale (PCTB)
- **Description Phase 1:**
  - **Intervention group:** testing aroma module from 06.07.2018 to 15.10.2018 and sound module from 16.10.2018 to 28.11.2018 and from 21.01.2019 to 03.04.2019 with manual releases via app. In this first phase the aroma module was installed in a living room area and one bedroom while the sound module was installed in the kitchen as well as in one bedroom and the living room.
    - Data collection: January 2019:
      - Patients: general patient data anonymized and NPI
      - Caregivers: personal sociodemographic data and Professional Care Team Burden Scale (PCTB), short questionnaire on aroma and sound modules evaluation.
  - **Control group – data collection: January 2019**
    - Patients: general patient data anonymized and NPI
    - Caregivers: Professional Care Team Burden Scale (PCTB)
- **Phase 2:**

- **Intervention group:** testing of the light module from 17.04.2019 to 27.06.2019 with manual releases via app.
  - Data collection: June 2019:
    - Patients: general patient data (anonymized) and NPI
    - Caregivers: personal sociodemographic data and Professional Care Team Burden Scale (PCTB).
- **Control group:** no data collection in this phase

- **Final phase:**
  - **Intervention group:** testing all modules together from 02.07.2019 to 30.11.2019. In this phase the Great system worked with all three modules time controlled.
  - Data collection: December 2019:
    - Patients: general patient data (anonymized) and NPI
    - Caregivers: personal sociodemographic data and Professional Care Team Burden Scale (PCTB), SUS questionnaire and focus group.
  - **Control group:**
    - Patients: general patient data (anonymized) and NPI
    - Caregivers: Professional Care Team Burden Scale (PCTB).

For the intervention and control group a three-person team compiled the patient data, the two teams remained the same throughout the project.

At the beginning of each phase a short training was organised for the staff involved in the trials and throughout the trials the staff had a contact person from Apollis to clarify any doubts and report any problems.

Here are some photos of the installations:

Figure 13: Installation of Great in a bedroom, Griesfeld

Figure 14: Installation of the Great-sound module in the kitchen, Griesfeld

4.3 Methodology & evaluation design in Switzerland

The evaluation of the GREAT system in Switzerland was designed as a method-plural study based on a one-group pre-post design. For this purpose, the prototype of the controllable light and aroma system was tested in homes for people with dementia who showed challenging behaviors. We included people in different dementia phases based on a selective sampling strategy.

The study was divided into three field phases. Prior to the first field phase, the light and aroma modules were installed on site. Each field phase included (i) sampling, (ii) intervention planning and (iii) intervention implementation.

For data collection, participant observation, Dementia Care Mapping (DCM) (Innes 2004), Neuropsychiatric Inventory (NPI) (Cummings et al. 1997) and Menorah Park Engagement Scale (MPES) (Volicer/Hurley 2015) were used. These instruments were supplemented by situational interviews and two guideline-based interviews.

DCM coding involves continuous observation over a 6-h period, with observers recording a Behavior Category Code (BCC, a recording of activity/interaction) and a Well/Ill Being (WIB) score at 5 min intervals.

Data analysis
The analysis of the data related to the test persons was carried out on a case by case basis. The structured observations were recorded with scientifically established, validated assessment instruments. The descriptive statistical calculations were performed using SPSS 24.0. The interviews were transcribed and analysed using structured content analysis. The Ethics Committee of Eastern Switzerland examined the project and assessed it positively (BASEC No. 2018-00544).

5. The sample

5.1 Tirol Kliniken, Austria

5.1.1 Patients

Patients suffering from Alzheimer´s disease, vascular dementia or mixed dementia were included. Patients were in a mild to moderate stage of dementia. Only patients who were able to give informed consent were included. However, patients with severe neuropsychiatric symptoms such as hallucinations, delusions or apathy could not be included as they were not able to give informed consent. Patients were randomly assigned to the intervention or control group.

Data were collected on **82 patients;** the sample is characterized by:

- Sex: The vast majority of the sample are women (78%). In the intervention group the % of women reaches 91% while in the control group the % of women drops to 63%.
- Age: As far as age is concerned, the sample is composed of people between 57 and 93 years old, the average age is 77. The average age of the intervention group is slightly higher than that of the control group (average 78 years versus 75 years).
- Mini-Mental State Exam (MMSE): is a widely used test of cognitive function among the elderly; it includes tests of orientation, attention, memory, language and visual-spatial skills. In the 63 cases in which the MMSE test was completed, 44% recorded values between 27 and 30 (no dementia), 33% values between 20 and 26 (mild dementia) and 22% values between 10 and 19 (moderate dementia).

From this **82 patients**, just over one half of whom were part of the intervention group. The largest group tested all three modules together.

Table 4: The sample of the patients in the Tirol Kliniken Hall (Number of cases)

Phase	Intervention group	Control group	Total
Sound	8	9	17
Light	8	4	12
Scent/Sound/light together	28	25	53
Total	**44**	**38**	**82**

In the general part, staff were also asked to assess the **level of sight, hearing and smell** of patients and to respond in "normal", "reduced" or "non-existent". The sight is "reduced" in almost 3 patients out of 4 (73%), in the remaining patients it is normal. As far as hearing is concerned, it is "reduced" in 14% of cases and "normal" in all the others. The sense of smell was assessed as "normal" for all patients.

The medical staff who filled out the discharge form also had the task of **estimating the patient's exposure time to the Great system**. The battery of questions can be summarized in the following three categories: fairly regular exposure in the bedroom, fairly regular exposure in the common area and no regular exposure (regardless of whether the person was in the control or intervention group). Almost half of the sample had regular use of the Great system in their room, 25% of the sample enjoyed the system in the common area and the remaining 25% never enjoyed the system on a regular basis (see table below).

	Intervention group	Control group	Total
Quite regularly in room	39	0	**39**
Quite regularly in common room	0	20	**20**
Never regularly	5	15	**20**
Total	**44**	**35**	**79**

Table 5: Estimate of the Great exposure time, Tirol Kliniken Hall (number of cases)

5.1.2 Professional caregivers

56 data records were collected from 17 different professional caregivers during the various phases of the project. The "**panel**" group is composed of 10 people, those who remained unchanged for the duration of the project. No socio-demographic data on professional caregiver (gender, age, function) are available.

Table 6: The sample of the care staff in Austria

	Intervention group	Note
Baseline	16	
Phase 1	15	One person no longer wanted to fill in the questionnaire
Phase 2	12	Two persons did not want to fill in the questionnaire, two persons were not present (vacation or sick leave)
Final phase	13	A new person joined, one person did not want to fill in the questionnaire, three persons not present (sick leave/holiday/maternity)
Total data records	56	**(Panel= 10 persons)**

5.2 Nursing Home Griesfeld, Italy

5.2.1 Patients

At the beginning of the field trials the intervention group consisted of 12 people, during the first months three people died (in phase 1 there were 9 people) and then in the second phase one person was added. For 9 persons a complete data corpus - baseline, phase 1, phase 2 and final phase - is available (**panel**).

In the control group 6 people remained the same throughout the duration of the project, two people were transferred and two joined during the last phase.

The total sample therefore includes 23 people, of whom in 15 cases we have all the data available, while for the remaining 8 the data are partial (as they entered the sample during the project).

Only one person in the sample is a male, all the others are females. The average age of the sample is 88, the youngest person is 65 and the oldest is 96. 30% of the sample lives at one of the two facilities for 7 years or more, 40% for 3 to 6 years and the remaining 30% lives at one of the two facilities for two years or less.

	Intervention group	Control group	Total
Baseline	12	8	20
Phase 1	9	8	17
Phase 2	10	-	10
Final phase	10	8	18
Total data records	41	24	65

Table 7: The sample of patients in Italy

The next table shows the socio-demographic and health-related characteristics of the participating persons.

Table 8: Characteristics of the participating persons – Intervention group

ID	Gender	Year of birth	Move-in date	Diagnose	Phase
1	W	1925	2012	Cognitive impairment with vascular cause	All phases (panel)
2	W	1936	2016	Alzheimer, Depression	All phases (panel)
3	W	1929	2018	Senile dementia	All phases (panel)
4	W	1929	2011	Cerebral ischemia with cognitive insufficiency	Only baseline (deceased)
5	W	1934	2015	Involutive Enzephalopathie	All phases (panel)
6	W	1934	2012	Dementia	Only baseline (deceased)
7	W	1930	2015	Dementia	Only baseline (deceased)
8	W	1929	2015	Dementia	All phases (panel)
9	W	1929	2013	Vascular encephalopathy	All phases (panel)
10	W	1925	2015	Vascular dementia	All phases (panel)
11	W	1942	2018	Morbus Alzheimer	All phases (entry in autumn 2018, baseline November 2018 and then all the other phases)
12	W	1936	2018	Alzheimer	All phases (entry in autumn 2018, baseline November 2018 and then all the other phases)
13	W	1932	2018	Morbus Alzheimer	Only phase 2 and 3

The following table shows the socio-demographic and health-related characteristics of the control group.

ID	Gender	Year of birth	Move-in date	Diagnose	Phase
11	W	1931	2013	Mixed dementia-depression	All phases
12	W	1924	2017	Cognitive decay in Aging brain with behavior disorder (irritability and anxiety)	All phases
13	W	1939	2017	Dementia	Only baseline and phase 1
14	W	1929	2012	Alzheimer	All phases
15	W	1929	2014	Senile dementia, affective disorder	All phases
16	W	1930	2012	Severe cognitive impairment with paranoid processing tendencies	All phases
17	M	1929	2018	Vascular dementia with wandering	Only baseline and phase 1
18	W	1938	2016	Morbus Alzheimer	All phases
19	W	1931	2019		Only last phase
20	W	1955	2019		Only last phase

Table 9: Characteristics of the control group

In both groups the people assisted are affected by dementia, with different levels of severity. In general, the communicated challenging behaviours were:

– sleep disorders

– loud, angry look

– mood swings from angry to nice

– person has negative thoughts

– no interest in participating in team life

– person is a loner and doesn't want anyone near her, otherwise she screams and argues

– person can't occupy himself with anything, is always on the road, needs individual care.

In the general part, staff were also asked to assess the level of sight, hearing and smell of patients and to respond in "normal", "reduced" or "non-existent". The sense of smell is the most reduced, in more than 70% of patients it is in fact reduced, in the others it is "normal". Sight and hearing, on the other hand, are reduced in about half of the cases, while in the other patients they are normal.

5.2.2 Professional caregivers

A total of 23 people participated in at least one phase of the field trial. These are all women except one.

In the intervention group only 4 people participated in all phases of the project, in the control group 7 people participated in all phases. There was therefore a higher level of turnover in the intervention group.

The average age of the care staff is 44 years old, the youngest is just over 20 and the oldest is 64.

Table 10: The sample of the care staff in Italy

	Intervention group	Control group	Total
Baseline	8	9	17
Phase 1	8	8	16
Phase 2	8	Non detected	8
Final phase	8	9	17
Total data records	32	26	58

5.3 Switzerland

5.3.1 Private person

In Switzerland, the aroma module was also tested for one year in the home of an elderly person supported by his daughter. Initially, the aroma module was used quite frequently, but the frequency of use decreased over the months.

His daughter did not want to install the lamp because she did not see the need for it. The system was not a burden, but it brought a lot of extra work, the burden of treating the patient was already heavy.

According to the daughter, the elderly person did not feel disturbed by the system, but did not even understand what was happening with the procedures because he had not noticed anything.

5.3.2 Nursing homes and patients

The three participating nursing homes are located in the cantons of St. Gallen and Basel-Land. The two homes in St. Gallen are located in the city (Bürgerspital and St. Otmar). The home in Basel-Land is located in the municipality of Niederdorf.
The data from the baseline surveys comprises n=18 DCM data sets, n=17 NPI surveys, n=18 case studies and n=17 surveys of routine data. During the intervention we collected n=74 MPES and n=13 DCM data sets and conducted n=5 situational interviews. After the intervention, n=11 NPI surveys and n=21 situational interviews were conducted. Besides, we prepared n=7 spatial sketches and conducted n=2 interviews. For ten cases (n=7 persons) a complete data set is available (baseline, intervention, postintervention). The following analyses relate to these cases, which are evenly distributed among the nursing homes St. Otmar: n=4, Bürgerspital: n=3 and Gritt: n=3.

5.4 Assisted Living - Austria

In the period from April 2019 to December 2019, the GREAT system was implemented in assisted living apartments of the social centre Lebensraum Vorderland gemeinn. Betriebs GmbH VorderlandHus was tested. 4 persons received the GREAT intervention and 4 persons were assigned to the control group. The seniors were cared for by 6 nursing staff as needed. Only the combined use of light, aroma and sound was tested.

6. Results of statistical short-term comparison

6.1 GREAT System-Data Analysis

Every event (e.g. a sensor changed its value, or an action has been triggered) in the GREAT system is logged (see. D2.4 for a description of the logging system). This leads to a big collection of time series data. Figure 15 depicts the basic workflow to process this data from the logs to meaningful information. From the time series logs interventions are extracted, marking their start- and end times that are then extended with contextual sensor information. The raw time series logs are also aggregated into 5 minutes bins that allow for creating averaged daily profiles.

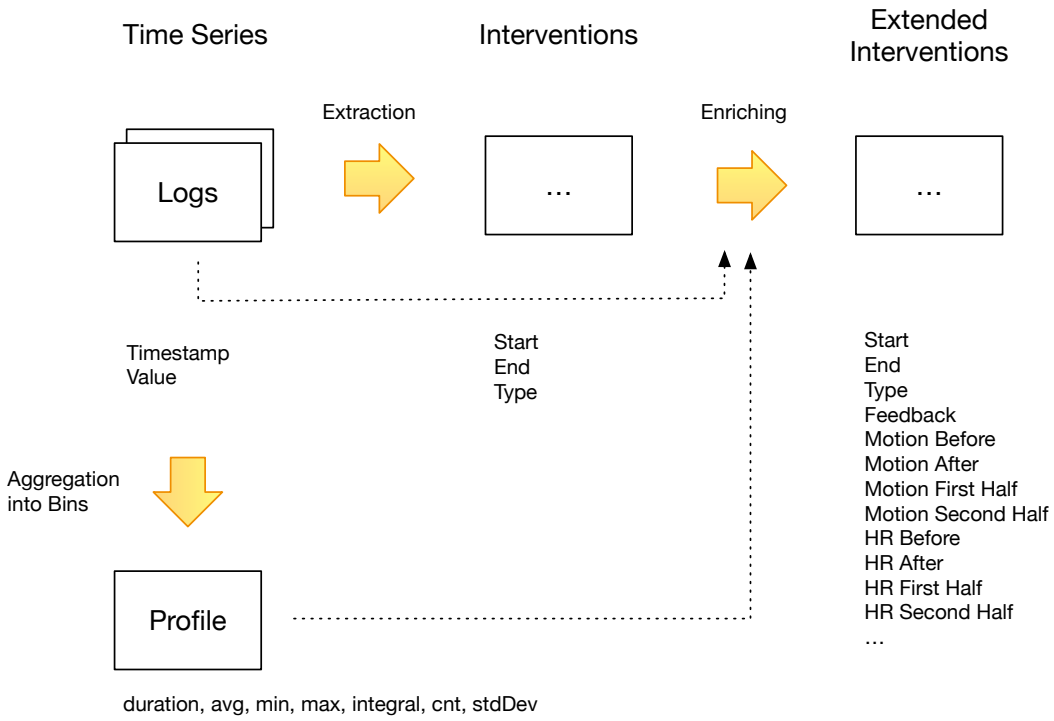

Figure 15: Basic workflow for extracting meaningful information from the timeseries logs.

Figure 16 shows the distribution of triggered interventions for the duration of the whole field test phase among the different locations.