
# Get Ready for Activity – Ambient Day Scheduling with Dementia

## Field test report

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Preface

This document forms part of the Research Project "Get Ready for Activity – Ambient Day Scheduling with Dementia (GREAT)" funded by the AAL 2016 "Living well with dementia" funding program as project number AAL-2016-023. The GREAT project will produce the following Deliverables:

D1.1 Medical, psychological, and technological framework

D2.1 Applicable hardware components

D2.2 Applicable software components

D2.3 Field tested hardware components

D2.4 Field tested software components

D3.1 Implementation report

D3.2 Field test report

D4.1 Communication strategy

D4.2 Stakeholder management report

D5.1 Report on market analysis

D5.2 Dissemination plan

D5.3 Final business plan

The GREAT project and its objectives are documented at the project website http://uct-web.labs.fhv.at. More information on GREAT and its results can also be obtained from the project consortium:

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# 1. Project background

The project "Get Ready for Activity - Ambient Day Scheduling with Dementia" (GREAT), approved in November 2016 as part of the European AAL programme, aims to develop scalable, flexible and at the same time affordable solutions that improve the quality of life of people with dementia and their families or other carers.

By using controllable lighting systems, the aim is to motivate people with dementia to engage in activities such as eating, sleeping or walking. In addition, light could be combined with odours (aroma application) and sounds (sounds application) to alleviate certain symptoms such as restlessness or mood swings that are common in people with dementia. To assess the effects of the modular systems on people with dementia, they are used in acute inpatient (Austria) as well as in long-term care (Italy and Switzerland). The project will validate the suitability of these module systems for everyday use in the various application scenarios.

Prof. Dr. Guido Kempter from the University of Applied Sciences Vorarlberg is the overall project leader. Besides the University of Applied Sciences Vorarlberg, the project partners are the University of Applied Sciences St.Gallen, CURAVIVA Switzerland, Tirol Kliniken GmbH, Bartenbach GmbH (Austria), Intefox GmbH (Austria), EMT AG (Switzerland) and Apollis OHG (Italy).

# 2. Objectives of the field test report

The objective of this report is to highlight the effects of the Great system's impact on demented people who have tested it and to highlight any effects of using the system on caregivers' work. The empirical results that will be reported emerge from the evaluations of the participants in the field trials carried out in the three reference countries: Austria, Italy and Switzerland.

Great modules were also tested in a closed booth developed by FHV, the first part of this report is dedicated to the results of the tests carried out in this booth.

# 3. Results of the closed booth

Our project is partially based on the idea that a combination of light, scent and sound is more effective in relaxing or activating people with dementia than biodynamic lighting alone. To validate this, we presented our system in a closed booth during two events in 2018 and let visitors' rate how they perceived the atmosphere created by the modules. The tests were completely anonymous; therefore, no sociodemographic data was recorded. The setup of these tests can be seen in the picture below: the lamp is highlighted in blue, the scent module in red and the tablet used for rating the combination in green. The sound module was hidden above the top panel highlighted in yellow (gaps on the side allowed the sound to enter the room uninterfered).

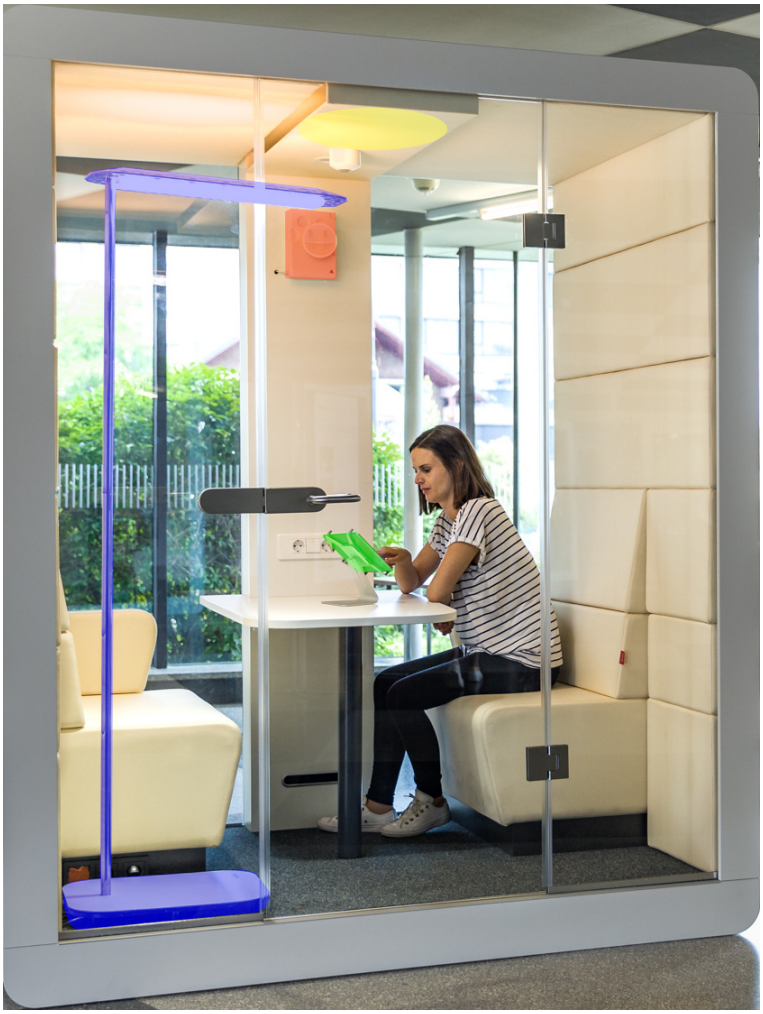

Figure 1: Test setting during events uDay XVI & "Lange Nacht der Forschung"

## 3.1 Description of the dataset

This way we gathered 1680 ratings on a scale with 9 steps between “relaxing” and “activating”. After each rating a new combination was presented and the person could rate again or leave the booth and the next visitor would take a seat. The built-in ventilation led to a rapid decrease of the scent inside. We therefore decided to discard 91 ratings as the atmosphere was present for longer than a minute and we could not guarantee the scent still being present at the time of rating. The chronological order and histogram of all the ratings can be seen below.

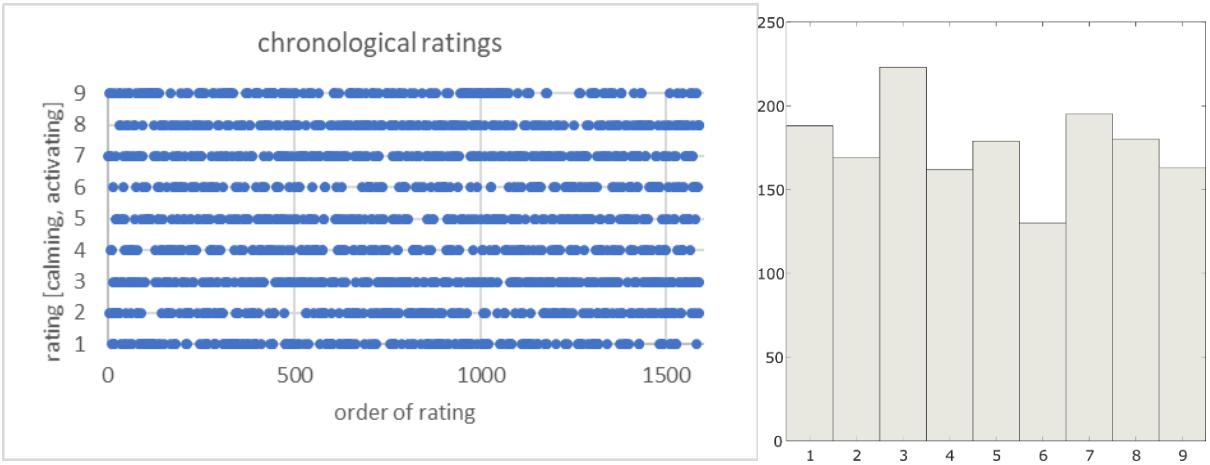


**Figure 2: Chronological order of ratings (left) and histogram of the population (right)**

These figures show an even distribution, which means that we chose a balanced set of combinations, ranging from very relaxing to very activating or somewhere in between.

The following table is used to describe the groups in the figures following later on in this report. Each group is labelled with three indices, the first one represents light, the second one scent and the third one sound.

| **Index 1 – light** | **Index 2 – scent** | **Index 3 – sound at low volume** | **Index 3 – sound at high volume** |
|---|---|---|---|
| 1: cold-white | 1: „good mood“ | 1: birdsong 40kHz | 7: birdsong 40kHz |
| 2: warm-white | 2: „harmony“ | 2: birdsong 80kHz | 8: birdsong solo |
| | | 3: watersplash 40kHz | 9: insects & frogs 40kHz |
| | | 4: watersplash 80kHz | 10: seawaves solo |
| | | 5: birdsong solo | 11: seawaves 40kHz |
| | | 6: watersplash solo | 12: insects & frogs solo |

**Table 1: Indexes of group names**

As the goal of this project was to influence people to feel more activated or relaxed by using light, scent and sound, we presented only combinations of all three sensory channels to the visitors. Nevertheless, we want to find out, whether our modules can create atmospheres, more relaxing or activating than lighting alone, as literature shows that it alone is already a very potent stimulus. To find proper control groups we therefore split the dataset by type of light (cold and warm). The respective histograms are presented below.

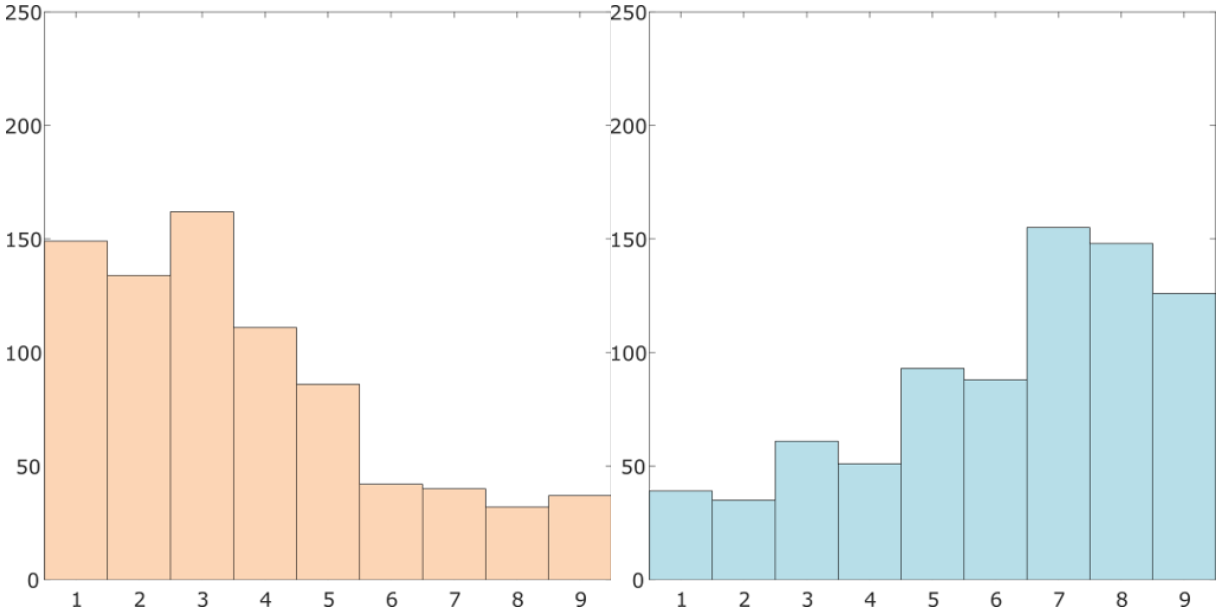


**Figure 3: Distribution of control groups: warm-white (left) and cold-white (right)**

The distributions align very well with aforementioned current literature: warm-white lighting is perceived as relaxing, cold-white lighting is perceived as activating.

The arithmetic means and standard deviation of the 48 test groups can be seen in the figure below.

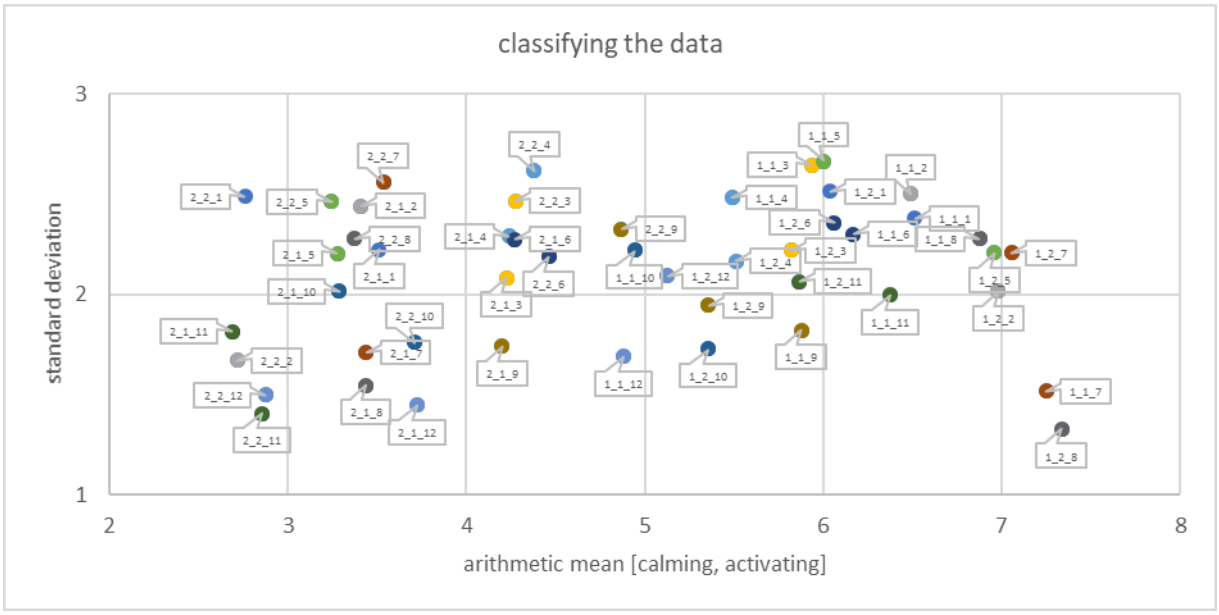


**Figure 4: Test groups arithmetic means and standard deviations**

There are no groups with an arithmetic mean below 2.5 or above 7.5. Standard deviations vary between 1 and 3. For further comparison we calculated the confidence interval at 95% of each of the 48 test groups and the two control groups and created the following figure.

## 3.2 Finding significantly calming or activating combinations

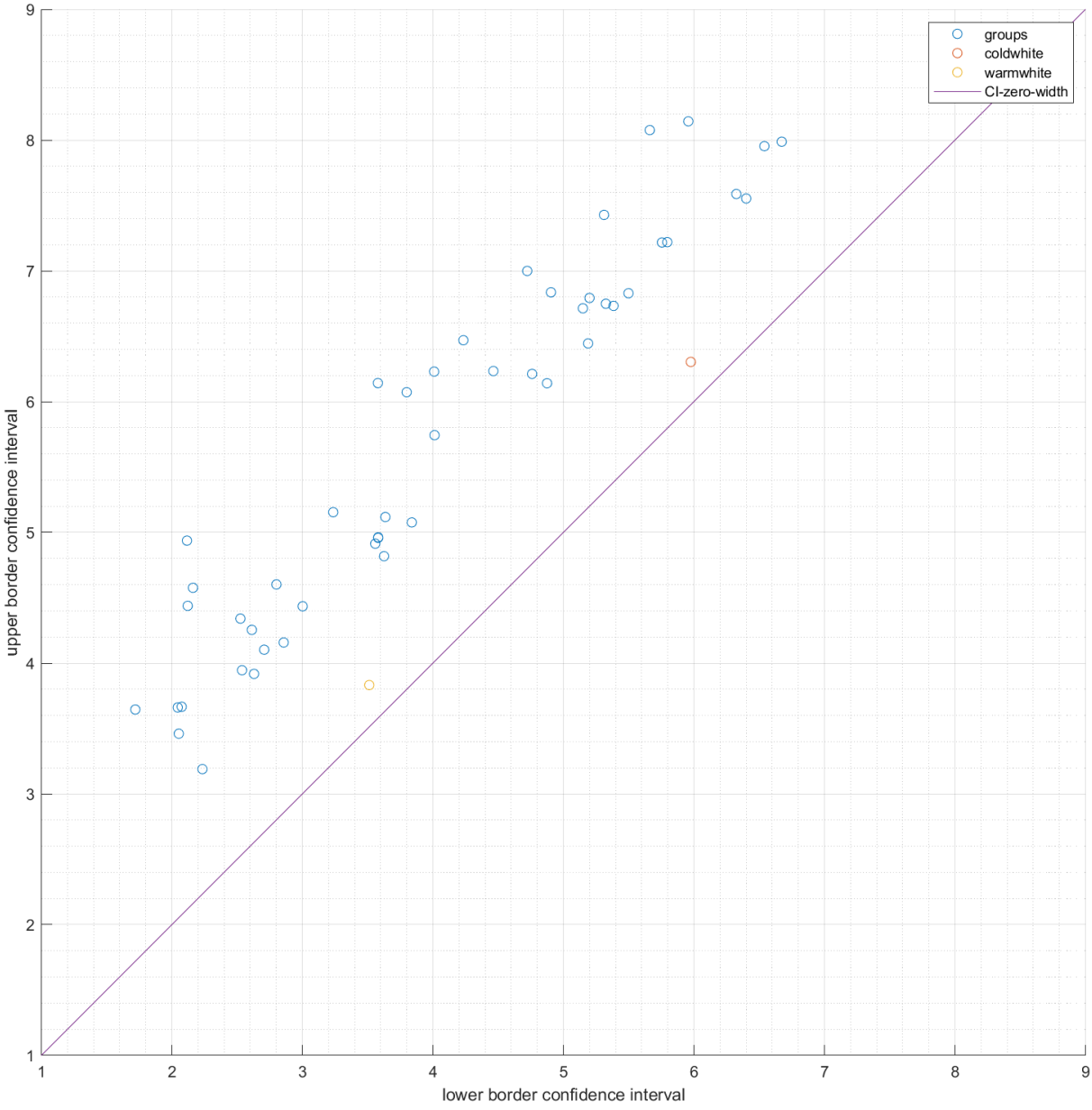


**Figure 5: General confidence interval plot**

The x-axis shows the lower border of the confidence interval, the y-axis shows the upper border of the confidence interval. The diagonal at an angle of 45° depicts all fictive confidence intervals with a width of zero.

For the first analysis, the figure is split in four parts:

1. below the CI-zero-width line: this is an unfeasible area, as the upper border always has a higher value than the lower border
2. Above the CI-zero width line:
    a. Lower border < 5: the combinations of these groups are significantly calming

b. Lower border < 5 & upper border > 5: the combinations of these groups are neither significantly calming nor significantly relaxing

c. Upper border > 5: the combinations of these groups are significantly activating

Criteria 2a fits to 19 test groups and the control group warm-white (according to our index-labelling "2_X_X"), criteria 2c fits to 15 groups and the control group cold-white (according to our index-labelling "1_X_X"). This shows that it is possible to create activating and relaxing combinations using scent, sound and light.

### 3.3 Finding combinations more effective than light alone

For the analysis in the following picture we use the same base data but split the plotted area differently and also display the values for control and significant groups. The table below shows the group name for each x-value:

| Group name | Light | Scent | Sound | X Value | Y Value |
|---|---|---|---|---|---|
| 2_X_X | Warm white | All | All | 3,5125 | 3,8321 |
| 2_2_1 | Warm white | Rose | Birdsong quiet 40 kHz | 2,0531 | 3,4605 |
| 2_2_2 | Warm white | Rose | Birdsong quiet 80 kHz | 2,2344 | 3,1899 |
| 1_X_X | Cold White | All | All | 5,9762 | 6,3036 |
| 1_1_7 | Cold white | Citrus | Birdsong loud 40 kHz | 6,5398 | 7,9534 |
| 1_2_2 | Cold white | Rose | Birdsong quiet 80 kHz | 6,4007 | 7,5533 |
| 1_2_5 | Cold white | Rose | Birdsong quiet solo | 6,3251 | 7,5876 |
| 1_2_8 | Cold white | Rose | Birdsong loud solo | 6,6727 | 7,9876 |

**Table 2: Significant groups**

To find groups which are more extreme than our control groups, we plotted the green and purple line. The green line is plotted horizontally on the y-axis. It's placed at the value of the lower border of the confidence interval of the control group 2_X_X (3,5125). Any confidence which has an upper border of the confidence interval below that line is significantly more calming than the control group. The purple line is plotted vertically on the x-axis. It's placed at the value of the upper border of the confidence interval of the control group 1_X_X (6,3036). Any confidence which has a lower border of the confidence interval to the right of that line is significantly more activating than the control group.

The upper border of the confidence interval of the groups 2_2_1 (3,4605) and 2_2_2 (3,1899) both lie below the critical value of 3,5125. The lower border of the confidence interval of the groups 1_1_7 (6,5398), 1_2_2 (6,4007), 1_2_5 (6,3251) and 1_2_8 (6,6727) all lie above the critical value of 6,3036.

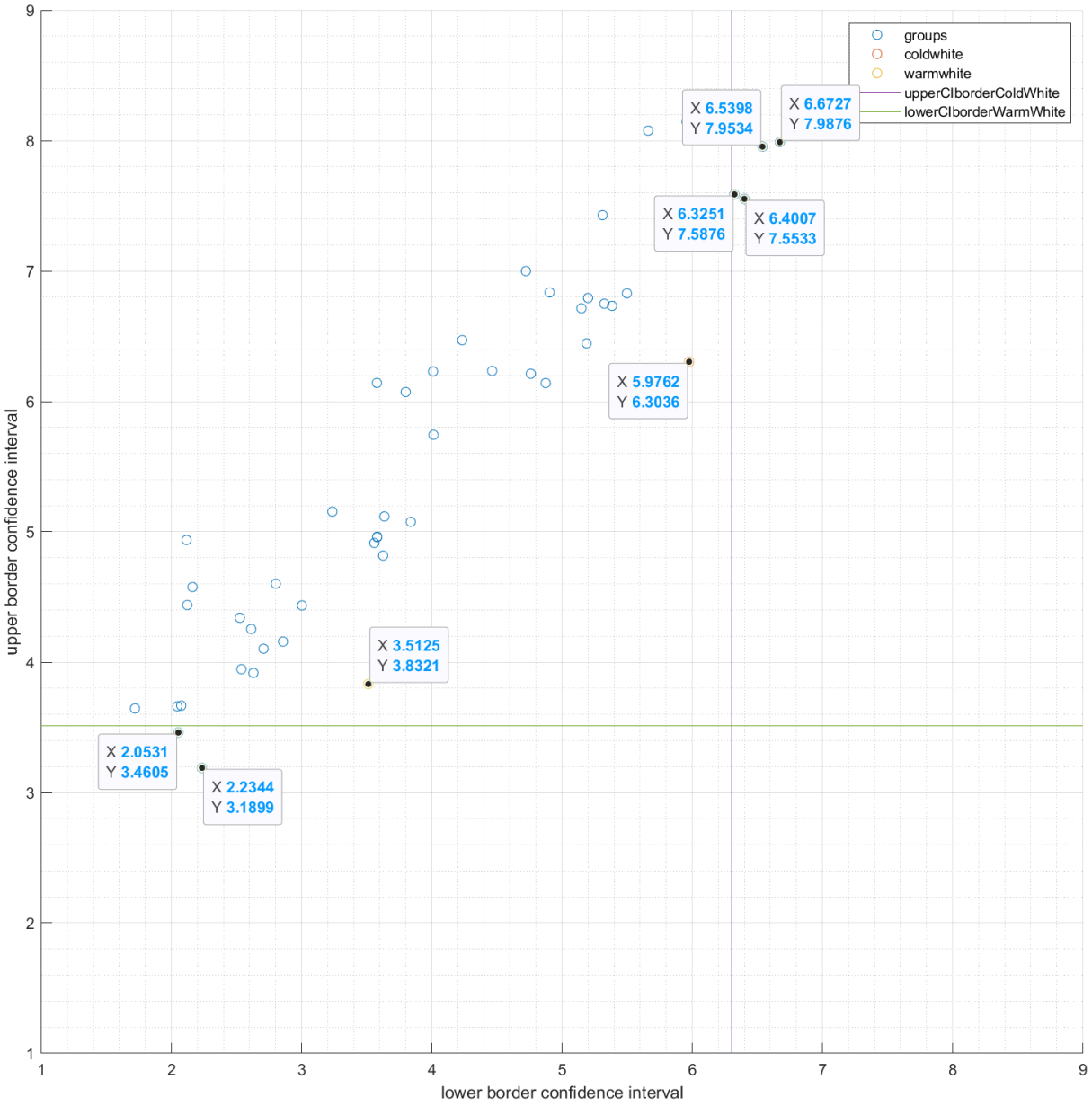


**Figure 6: Confidence interval plot with significant groups**

We also used ttest2-methods provided by MATLAB to ensure this:

- 2_X_X to 2_2_1: t(817) = 2,7509; p = 0,0061
- 2_X_X to 2_2_2: t(841) = 2,9540; p = 0,0032
- 1_X_X to 1_1_7: t(815) = 2,3409; p = 0,0195
- 1_X_X to 1_2_2: t(819) = 2,4772; p = 0,0134
- 1_X_X to 1_2_5: t(819) = 2,4062; p = 0,0163
- 1_X_X to 1_2_8: t(813) = 2,3950; p = 0,0168

## 3.4 Confirming Birdsong as the most effective of the tested sounds

As all of the groups showing significantly better results than the control groups in the previous chapter play the birdsong sound, we looked at the data only separated by sound. The following figure was created.

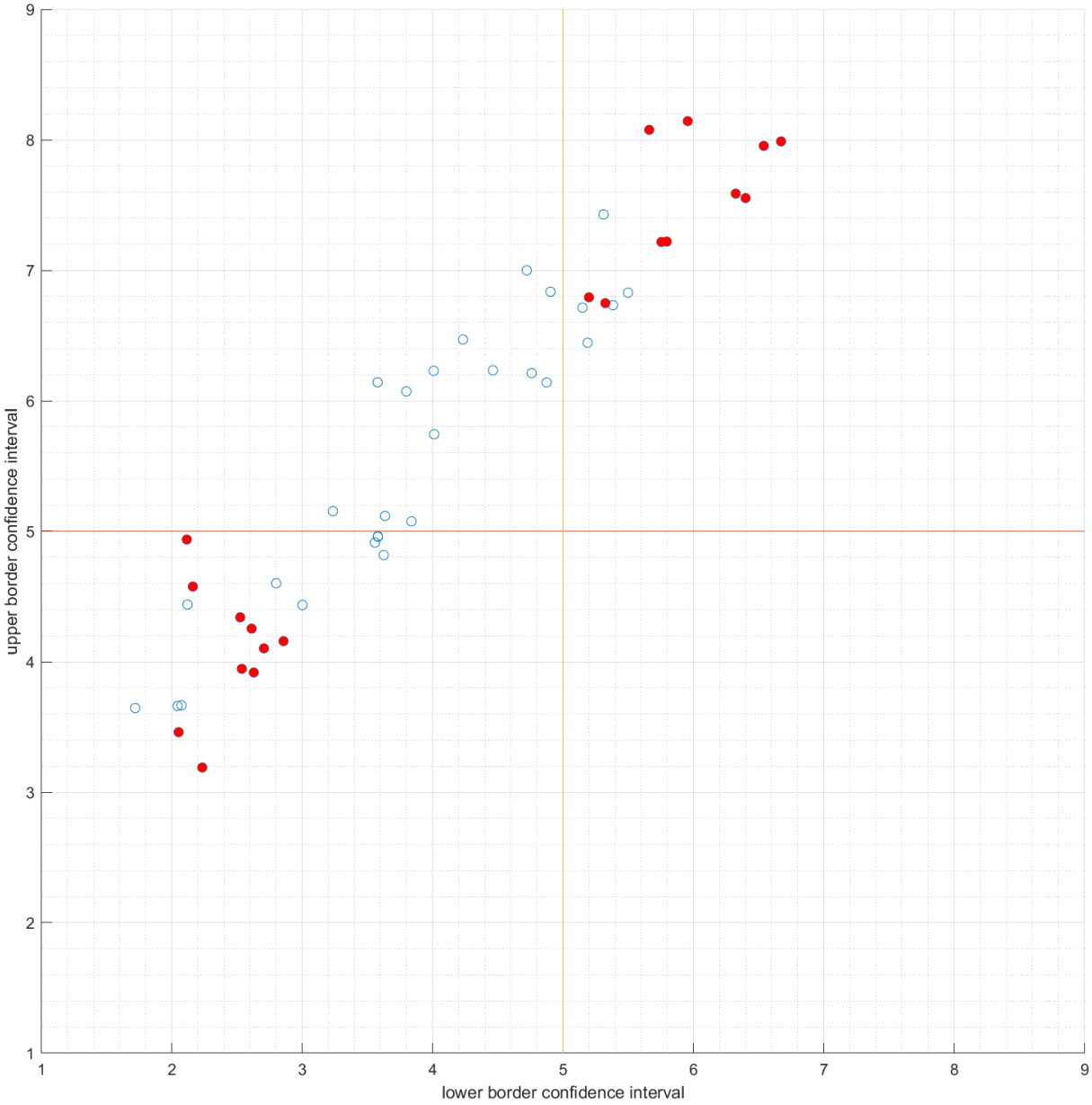


**Figure 7: Bridsong groups**

All 12 groups which contain birdsong are marked red. For all groups, where cold white light was used, the lower and upper borders of the confidence interval are greater than 5. For all groups, where warm white light was used, the lower and upper borders of the confidence interval are smaller than 5. This means that whenever a birdsong sound was played, the setting was perceived significantly activating or calming. Of the four sounds used, this is a unique feature and the second strongest influence overall after color-temperature. This means that the birdsong can't be

categorized as activating or relaxing. It rather seems that it increases the effect of the emitted light.

## 3.5 Physiological impact of the GREAT system in a cabin setting

For the next three public events we visited (AAL Forum Bilbao 2018, AAL Kongress Karlsruhe 2018 and uDay meets SMARTERLIVES 2019) we again brought the cabin with us. This time, however, we did not ask the visitors to rate, how they perceived the atmosphere in the cabin but let their physiology do the work. Again, they were presented with a combination of light, scent, sound and additionally the task to either relax or agitate themselves. Each visitor was tested for three segments, each lasting 30 seconds. During the first and third segment, the modules were actively enhancing the cabin, during the second the modules were switched off. We measured their skin conductance with a glove, as seen in Figure 8. Generally speaking, high levels skin conductance mean activation, lower levels occur when feeling relaxed.


**Figure 8: Skin conductance measurement tool: (left) how to wear it (right) it measures the skin conductance between index finger and thumb**

The raw measurement of the glove is plotted over time and can be used to derive three analysable parameters. The first one, named "avg", is the baseline against which the latter two will be measured. It is the average of all measurement values collected between seconds 5 and 10 of each segment. A graphical interpretation can be seen in Figure 9 on the left side. The second parameter is called "relaxArea" and it is calculated by integrating the area between "avg" and the measurements between seconds 10 and 30. Again, a graphical explanation of the value can be seen in Figure 9, this time in the middle. The last parameter is called "relaxCount". For each step of the measurement (equalling 20 ms) during seconds 10 to 30 a counter is either decreased if the current value lies above the "avg" or increased if it's lower. This reduces the effect of personal differences – some people's skin conductance changes greater than others. It's depicted in Figure 9 on the right side. The axis of the two latter groups "relaxArea" and "relaxCount" are reversed as they are subtracted

from the "avg" value. This means that positive values are signs of relaxation and negative values are signs of activation.

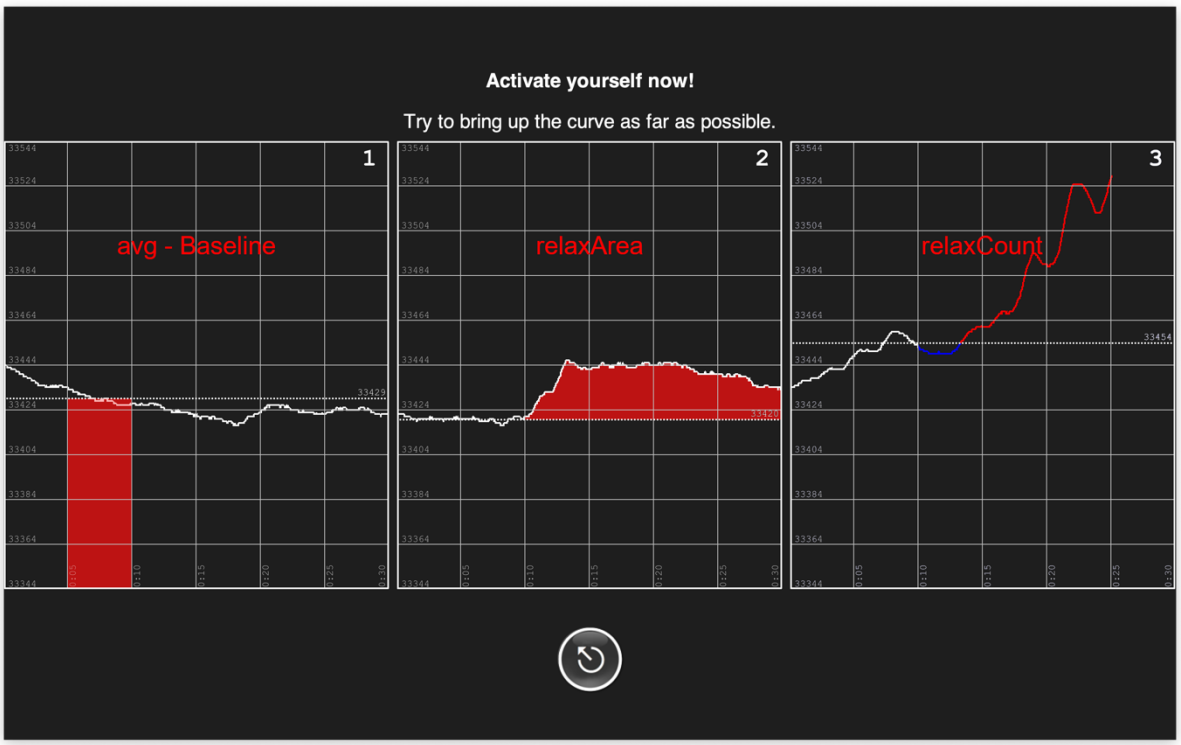


**Figure 9: Skin conductance measurement info screen**

This way we tested 156 people, resulting in 468 segments. Again, due to reasons of data protection, no sociodemographic data were recorded.

## 3.6 Analyzing the first impact of interventions generated by the GREAT system

Several interesting features appear in Figure 10: the values of aScent (*) and rScent (*) – which are combinations of all settings where activating and relaxing scent was dispersed respectively, differ more than any other comparable group (aLight vs. xLight, aTarget vs. rTarget, aSound vs. rSound). Running a ttest2 ($t(310) = 3.599$, $p < 0.001$)) shows a highly significant difference between the physiological reaction on citrus- and rose-based scent during early periods (between seconds 5 and 10 of the measurement).

If we take a closer look at the "calming"-line, depicted as red dash-dots with black stars at the end we see that the aforementioned group "aScent" and 5 specific combinations (labelled with their respective n and the task – whether the tested people should feel relaxed "-" or activated "+" by the setting: 2+, 7+, 11+, 15- and 15-) lie below it. That means that the confidence intervals of the complete dataset and them don't overlap which gives reason to look at the ttests:

Comparing the complete dataset against the aScent group gives $t(602) = 2.578$, $p = 0.005$, which is a significant difference. The comparison of the five specific groups

against the complete dataset unfortunately don't show significant results, although the last two get very close:

„2+" $t(468) = 0.525$, $p = 0.300$
„7+" $t(473) = 0.952$, $p = 0.171$
„11+" $t(477) = 1.136$, $p = 0.128$
„15-" $t(481) = 1.425$, $p = 0.077$
„15-" $t(481) = 1.484$, $p = 0.069$

The interventions of two groups „15-" are both warmwhite light and citrus-based scent. The circle has calming sounds, the diamond has activating sounds. During both, participants were told to activate themselves.

No activating effects were found while analyzing the data. A possible explanation is that after the first 5 seconds, some combinations lead to a quicker relaxation after the first exciting impression of entering the cabin and wearing the data glove.

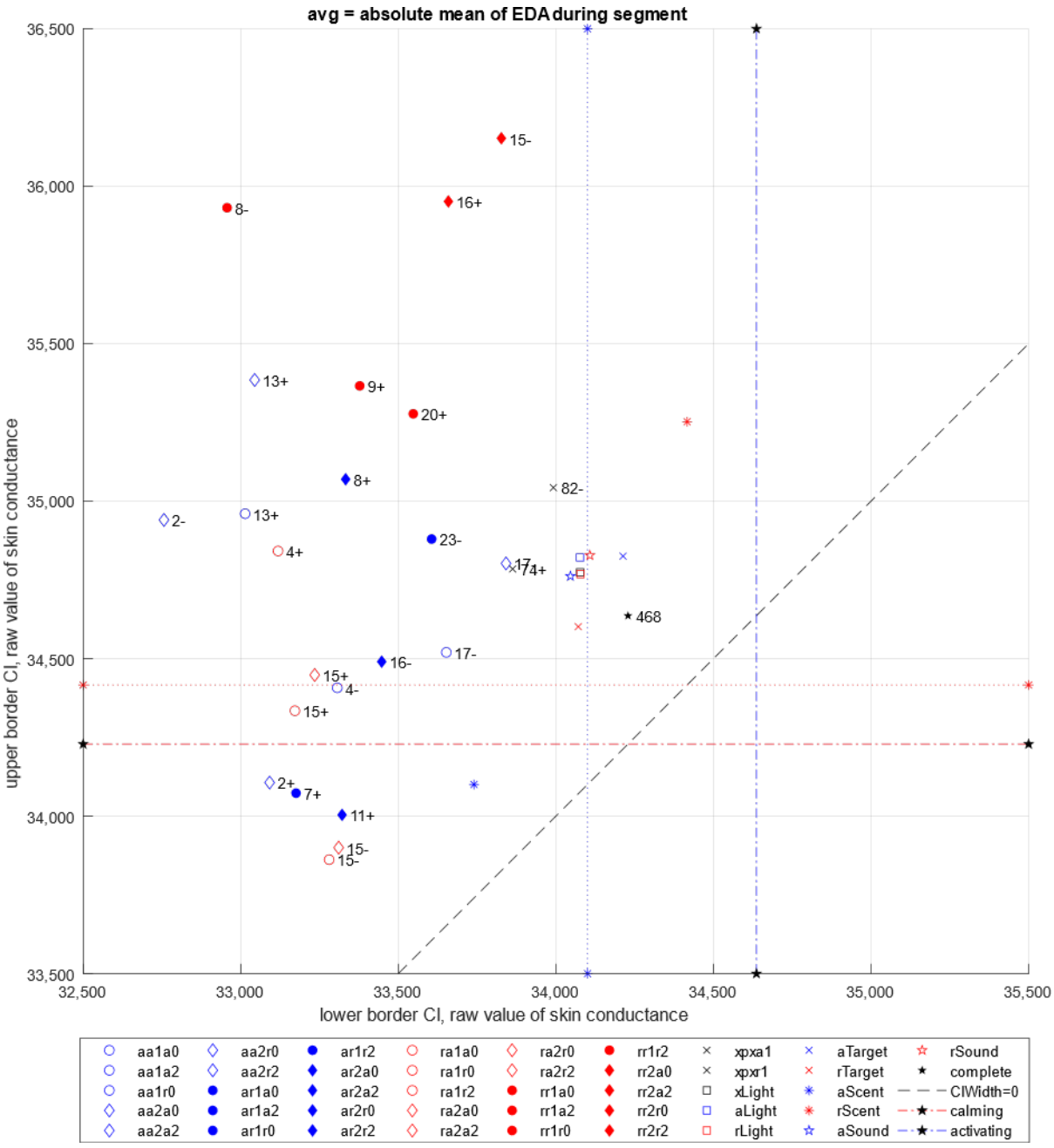


Figure 10: avg measurement confidence intervals

## 3.7 Regarding effects on participants physiology after the first impact

Figure 11 is constructed similarly to Figure 10 but shows the sum of the areas below and above the baseline measurement. If any confidence intervals were above or below zero it would be a strong indicator for relaxing (values greater than zero) or activating (values smaller than zero) effects. There are 5 markers plotted below the blue "activating"-line.

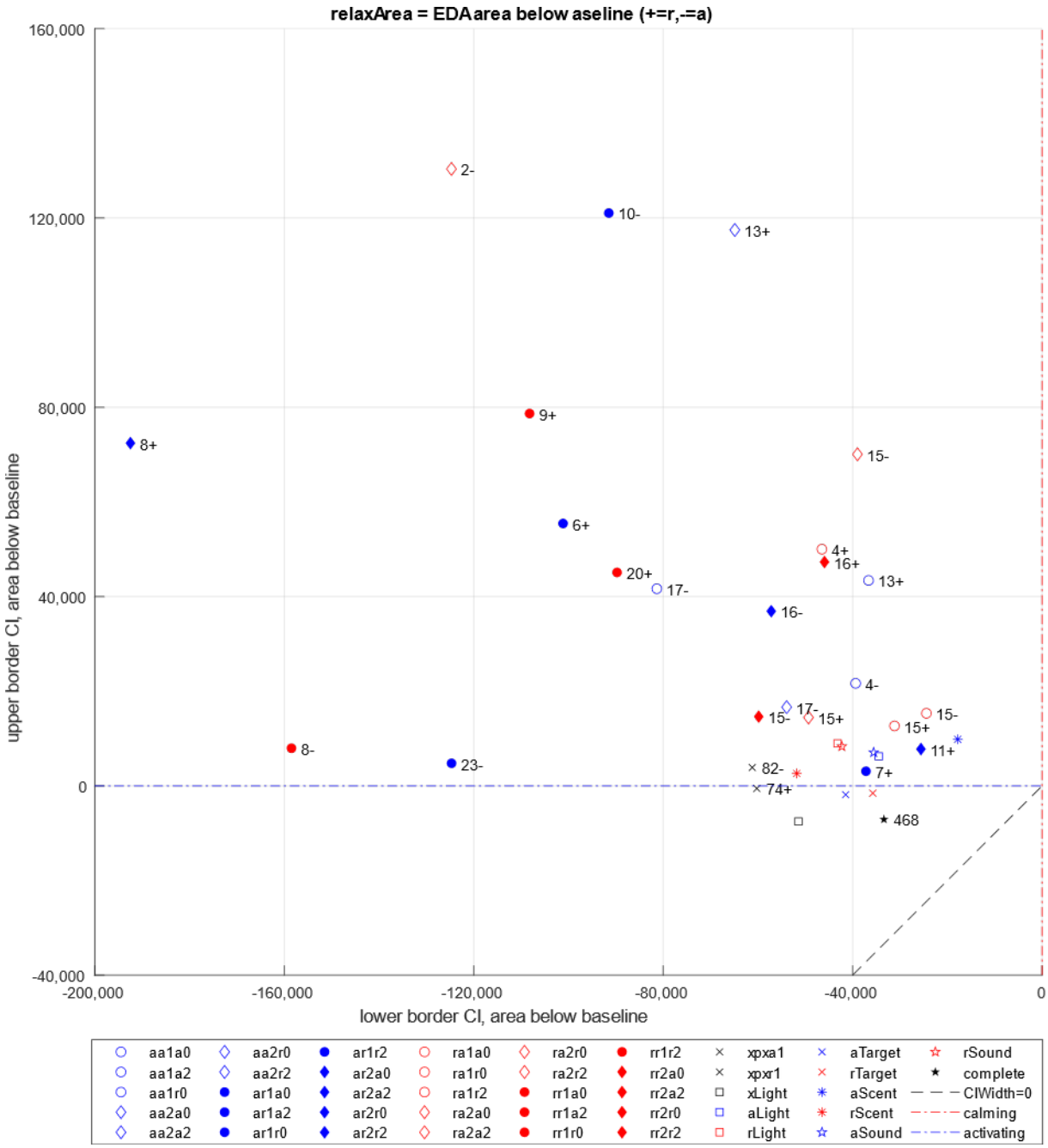


**Figure 11: relaxArea measurement confidence intervals**

- 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.

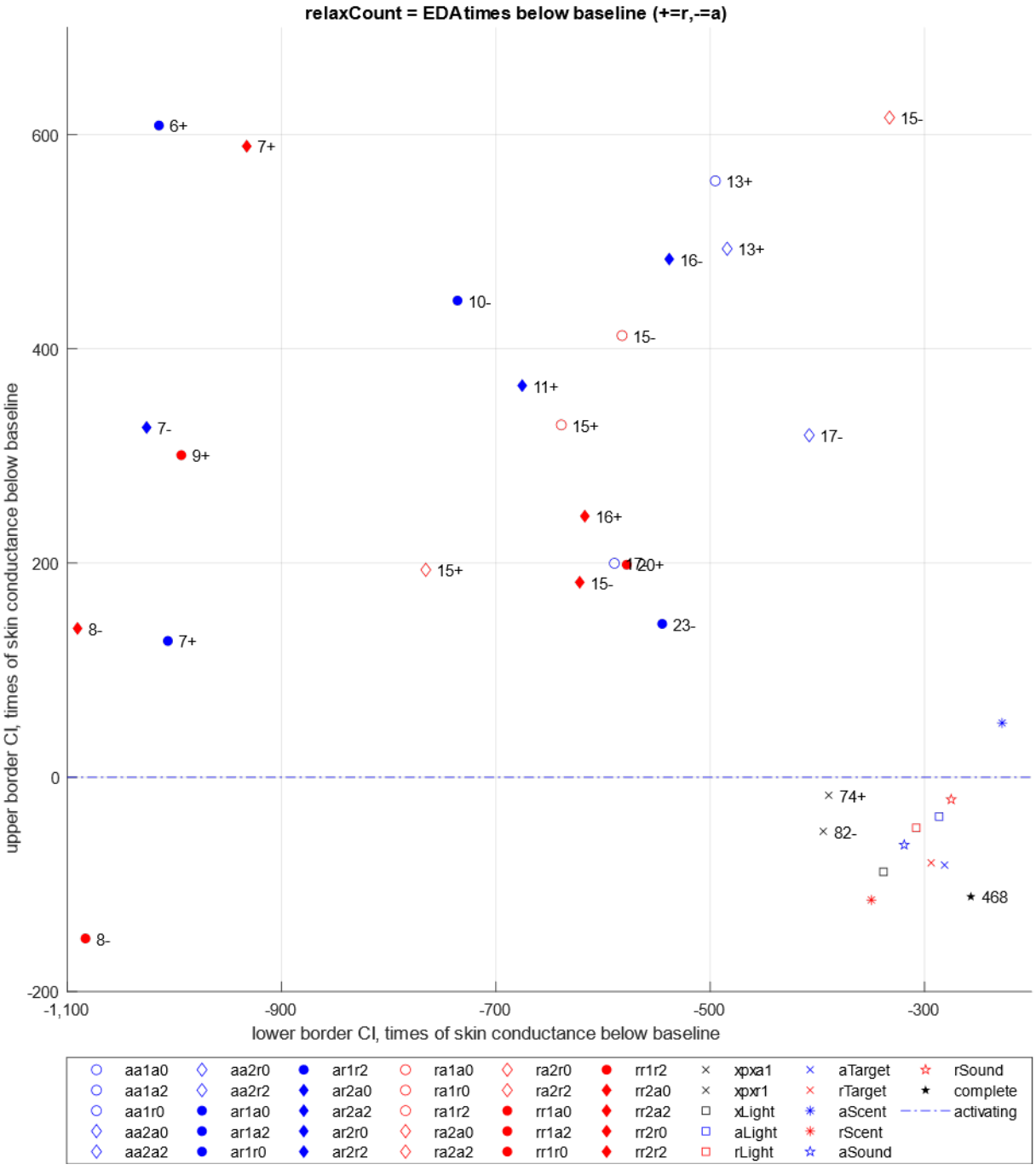


**Figure 12: relaxCount measurement confidence intervals**

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.

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## *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.

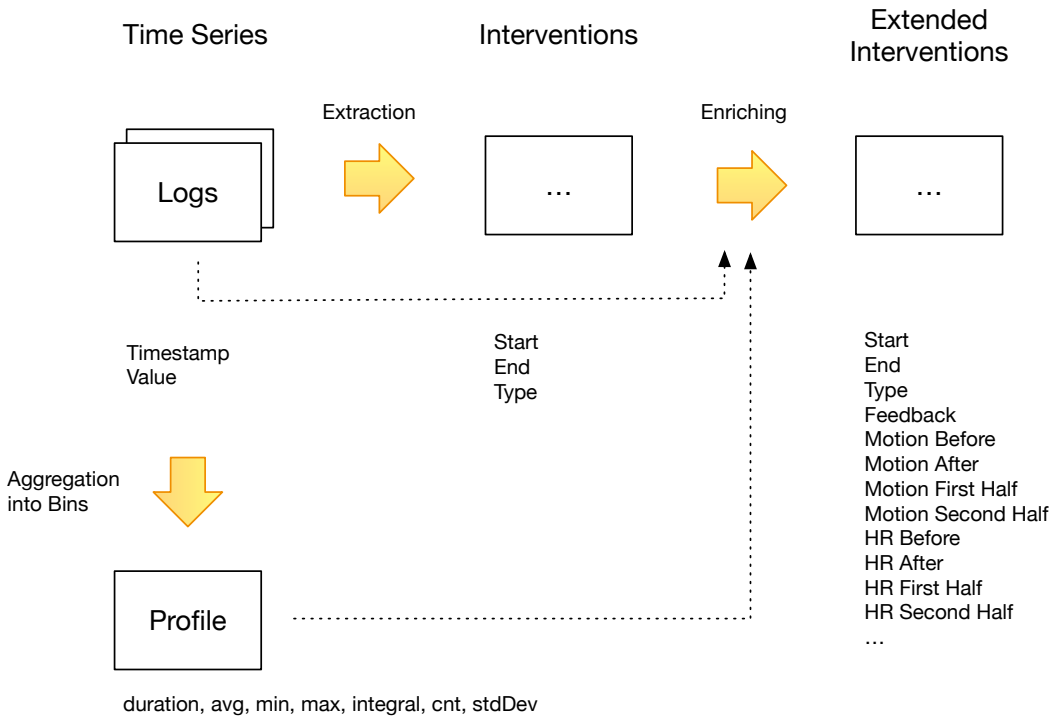



**Figure 15: Basic workflow for extracting meaningful information from the timeseries logs.**

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

As can be seen in Figure 16: Interventions triggered in different locations during the field test phase. , interventions invoked by the care-giving personal were very sporadic, due to their daily workload. The effect of automated triggering in Hall and Neumarkt can clearly be seen in the chart starting July 2019. This shows that for the final GREAT system, it is important to be configurable to operate in automatic mode, so care-giving personal isn't additionally loaded with the burden of operating an additional system.

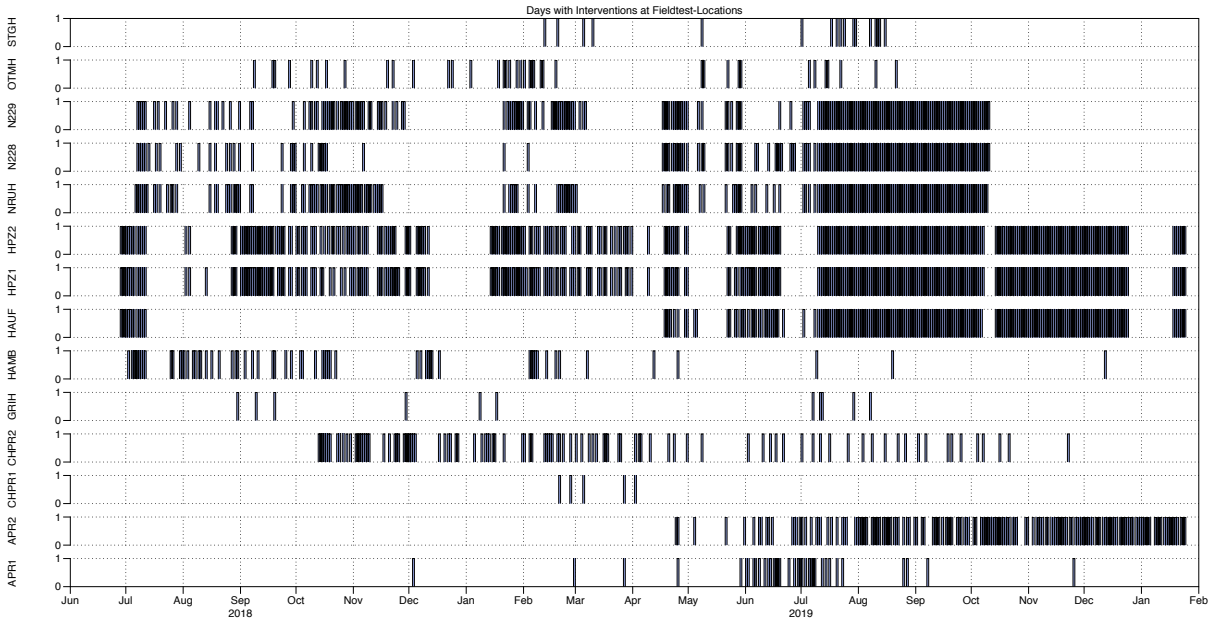



**Figure 16: Interventions triggered in different locations during the field test phase.**

### 6.1.1 Extending Interventions with Additional Data for Analysis

For determining whether long-term effects of an intervention can be seen in sensor data, for each intervention contextual sensor data was extracted and attached to the intervention. For this, four time slots have been defined: 20 minutes before until the start of the intervention, the first half of the intervention, the second half of the intervention and until 20 minutes after the intervention ended (see Figure 17).

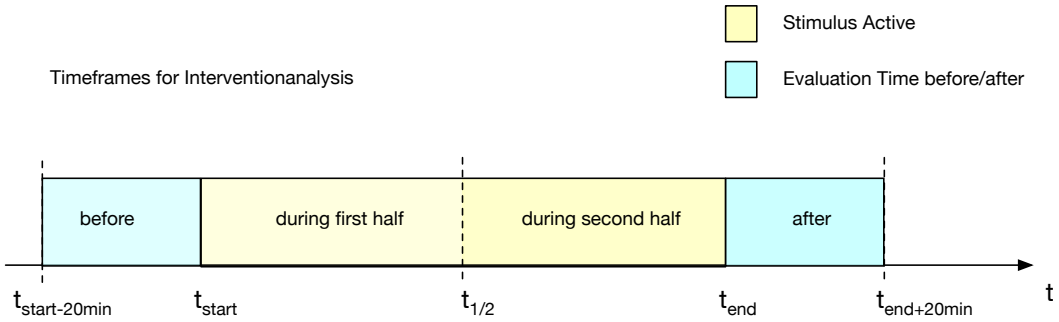
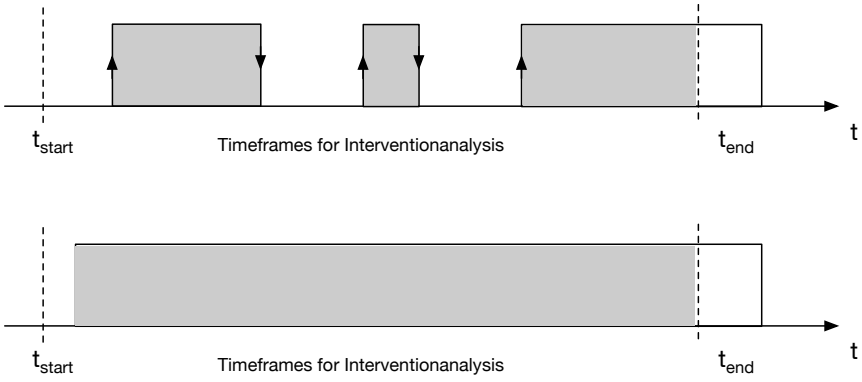



**Figure 17: Timeslots for sensor data analysis**

During these timeframes, aggregated sensor statistics are calculated, including average values, minimum, maximum count, and standard deviation.

### 6.1.2 Parametrization of Motion Events

One important component of the GREAT System are motion detectors placed in every zone of the GREAT test locations. For GREAT, EnOcean based passive infrared (PIR) sensors have been used. These sensors only deliver signals of on/off, depending on whether motion is detected or not. To characterize motion within a certain timeframe, we derived two important measures: The period of motion in the timeframe (integral), and the count of fluctuations of the signal within the period. While the first one shows the overall motion activity within the period, the second one determines the characteristics, if it was a steady flow of motion, or more interrupted (see Figure 18 for an overview).




integral = filledArea/duration

cnt = number of value changes

**Figure 18: Parametrization of motion events within a time frame, showing two different scenarios of motion activity, where the possible differences between the two parameters can be seen.**

### 6.1.3 Long-term Effects of Ongoing GREAT System Usage

To determine the effect of ongoing GREAT usage on daily activity patterns, we created 24h daily motion profiles for each zone where GREAT was used. To take different daylight length into account, we picked two periods of time with the same night/day duration on average. To guarantee sufficient usage of the GREAT system at regular times, we switched to automatic intervention triggering based on a time schedule that has been created based on the wishes of the care-giving personal for the second phase in Hall and Neumarkt.

The following profiles show time periods from April to June with manually triggered GREAT interventions in Hall and Neumarkt, compared to periods from July to September with automatically triggered interventions. The chart on top shows the difference in activity between the two periods (period1 – period2), whereas the chart below shows the raw motion activity. The red overlay marks relaxation interventions, the blue overlays activation interventions during the automated phase. Figure 19, Figure 20, and Figure 21 indicate a slight reduction in motion activity during the specific night times, and an increase in motion activity during the day, which could be interpreted as better sleep during the night and being more awake during the day.

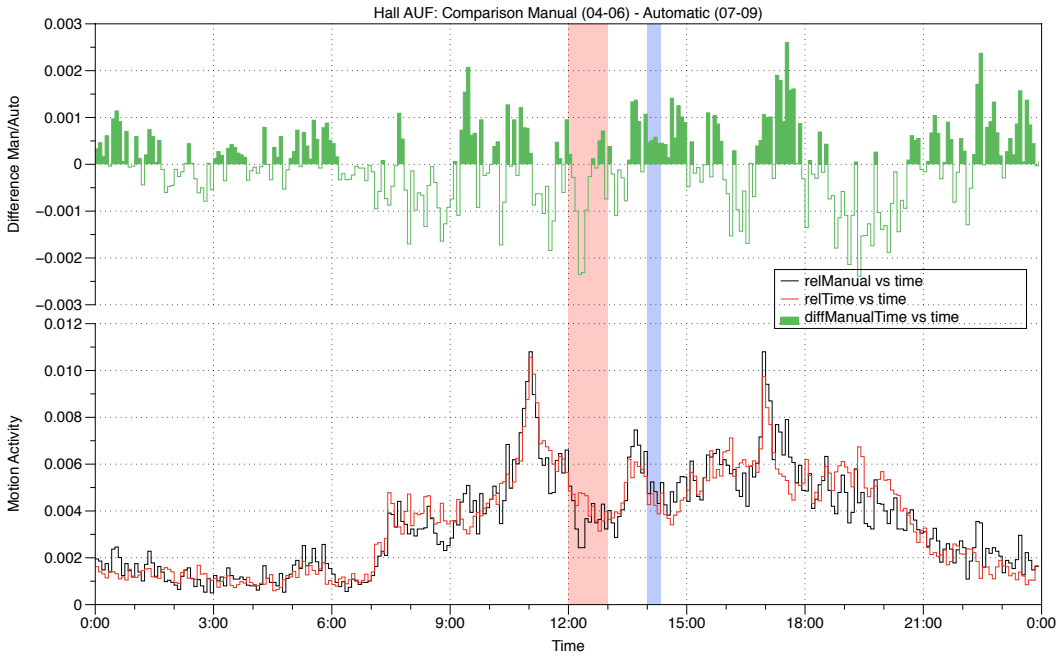



**Figure 19: Motion activity in recreational room Hall**

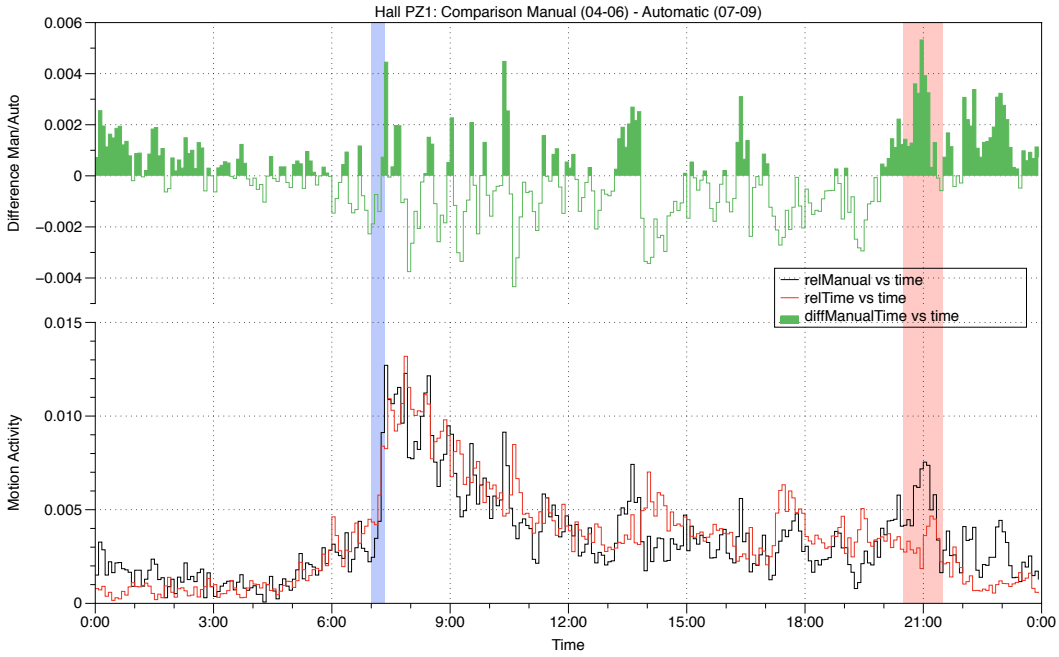



**Figure 20: Motion activity in patient room 1 in Hall**

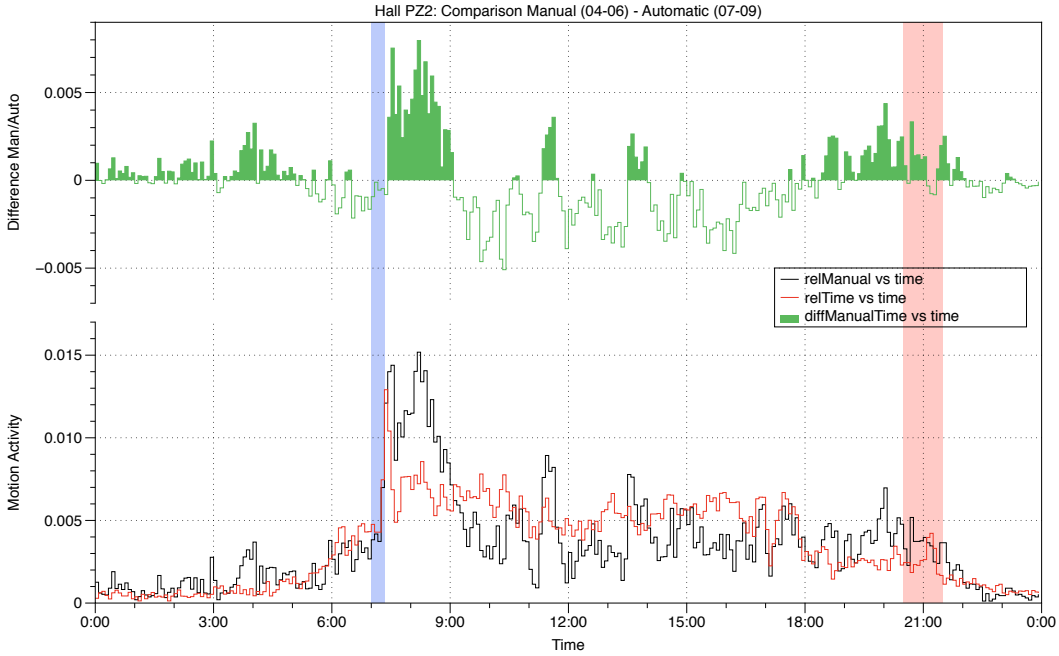



**Figure 21: Motion activity in patient room 2 in Hall**

The green background of the top chart indicates more motion activity in period one compared to period two, while the outline below the zero line shows more motion activity in the second phase. The same pattern can also be observed in Neumarkt in two of the three zones (see Figure 22 and Figure 23).

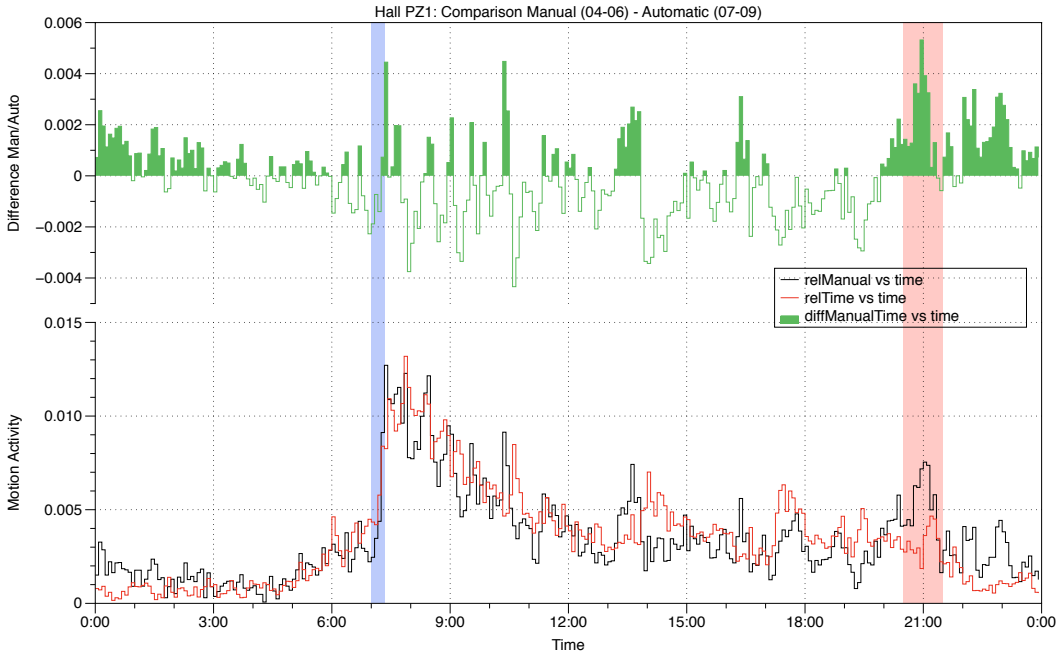



**Figure 22: Motion activity recreational room Neumarkt**

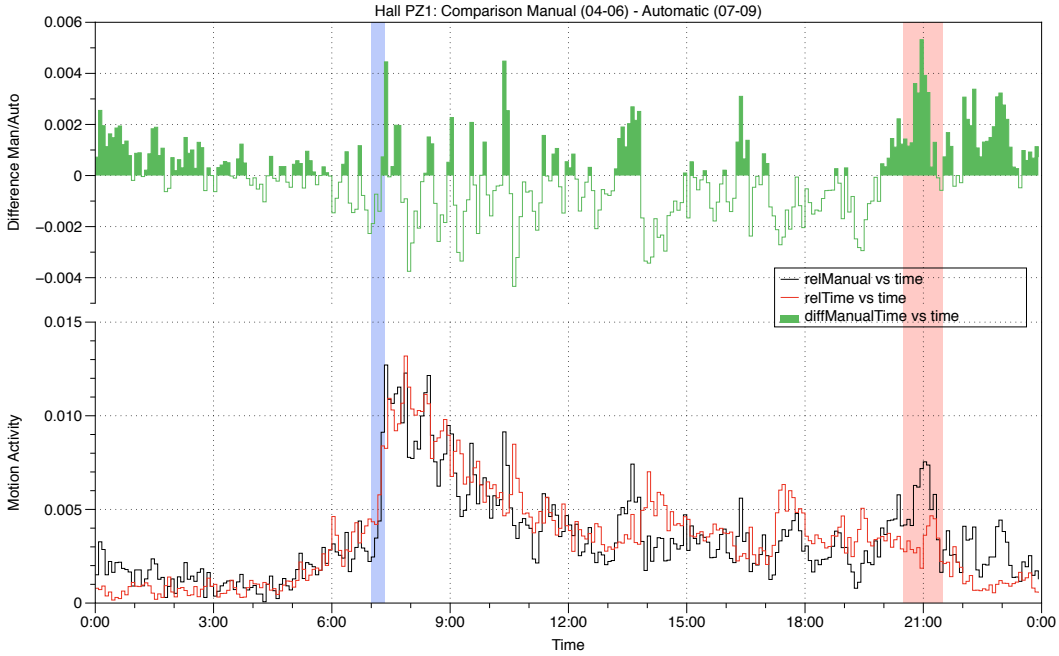



**Figure 23: Motion activity in patient room 1 Neumarkt**

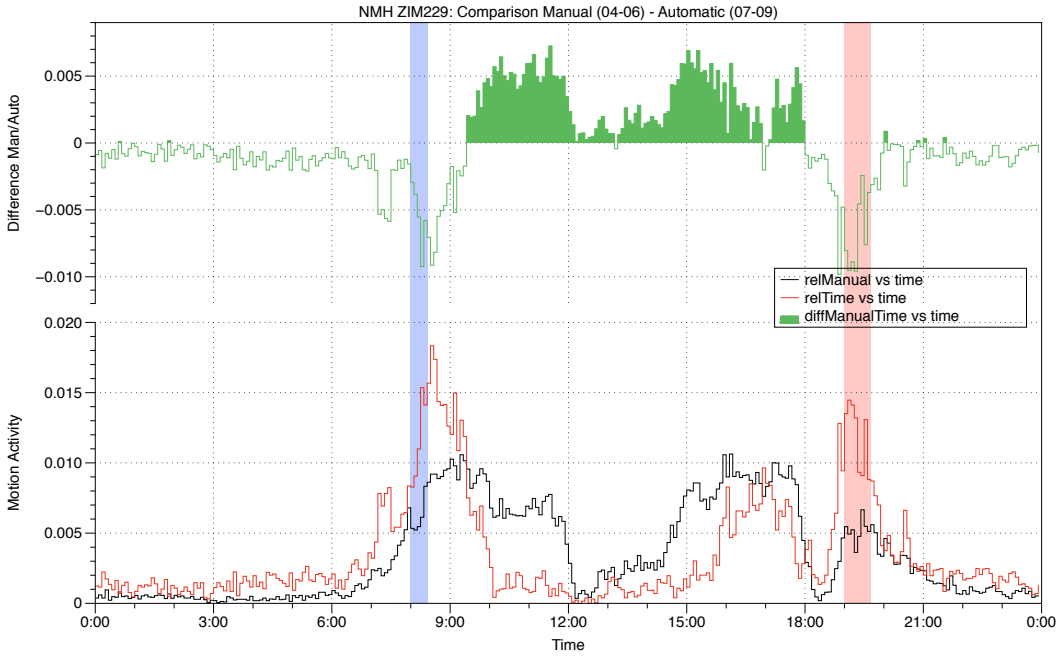



**Figure 24: Motion activity in patient room 2 Neumarkt**

Interestingly this effect cannot be observed in the second patient room in Neumarkt (see Figure 24). In can be seen, that there was an apparent change in the general structure of daily motion activity between the two periods, so this case should not be taken into consideration for the GREAT effects.

Table 11 shows the change of activity levels during the specific day and night times by calculating the average motion activity difference between period1 and period2. This is the average of differences between each 5 minutes bin of the daily profiles within the specified time. These numbers confirm the findings from the visual inspection above. It's also apparent that the second room in Neumarkt experienced a profound change in activity levels not explainable by the GREAT system.

| **Location** | **Specific Night-Time** | **Avg-Diff-Day-Activity** | **Avg-Diff-Night-Activity** |
|---|---|---|---|
| Hall AUF | 21-6 | -0.00015 | 0.00025 |
| Hall PZ1 | 21-6 | -0.00045 | 0.00074 |
| Hall PZ2 | 21-6 | -0.00019 | 0.00046 |
| NMH RUH | 20-8 | -0.00013 | 0.00012 |
| NMH ZIM228 | 20-8 | -0.00006 | 0.00006 |
| *NMH ZIM229* | *20-8* | *0.00109* | *-0.00108* |

**Table 11: Difference in activity levels between period 1 and 2. Negative values show an increase, positive values a decrease in activity.**

### 6.1.4 24h Motion Profiles of the Field Test Phase

Figure 26, Figure 27, Figure 28, and Figure 2925 illustrate the differences between the motion activity profiles in the various field test locations.

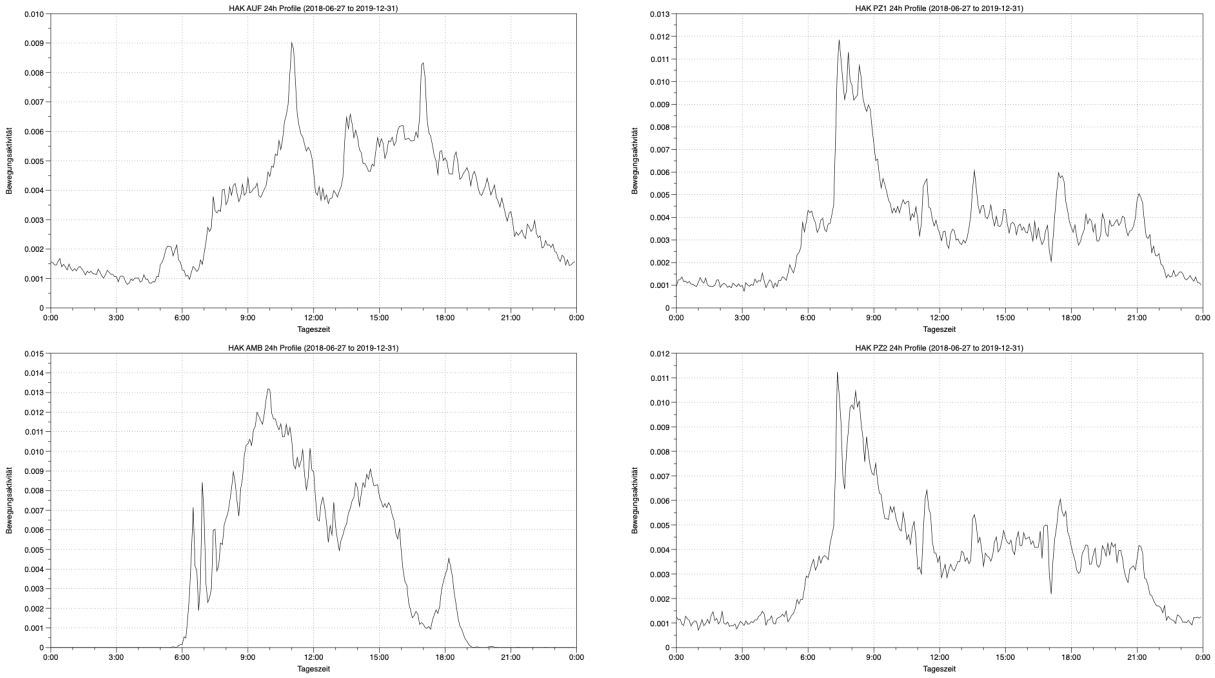



**Figure 26: 24h overall motion activity profile during the field test phase in Hall**

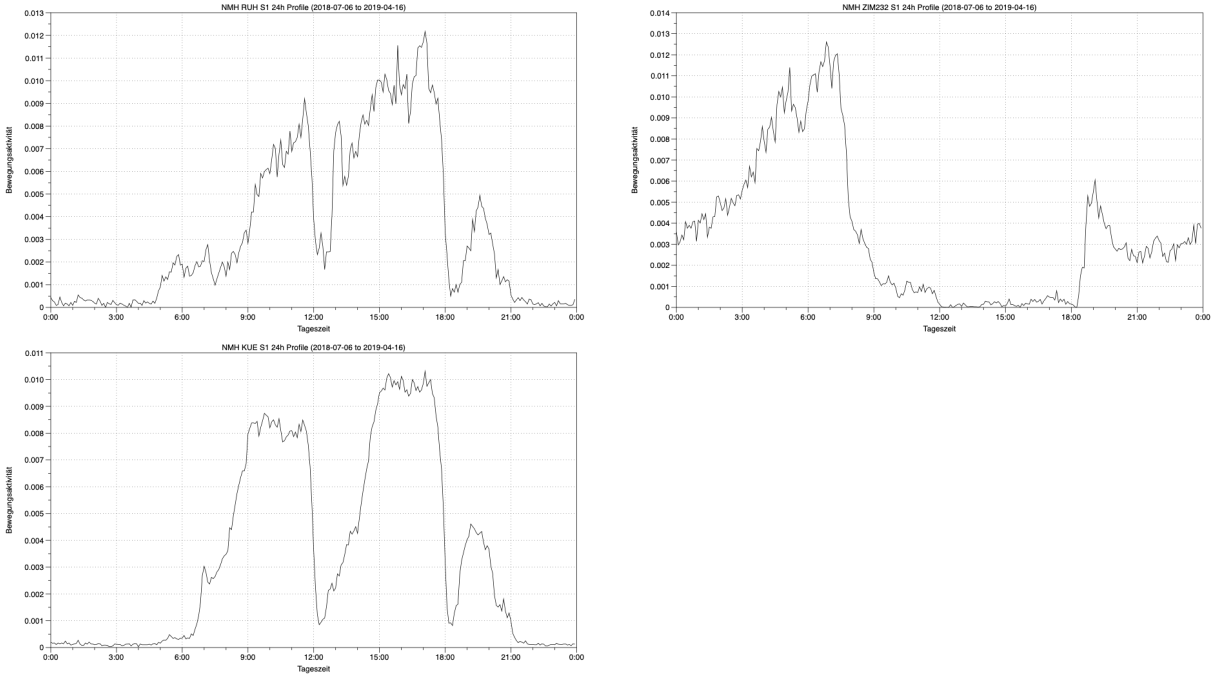



**Figure 27: 24h overall motion activity profile during the first phase of the field tests in Neumarkt**

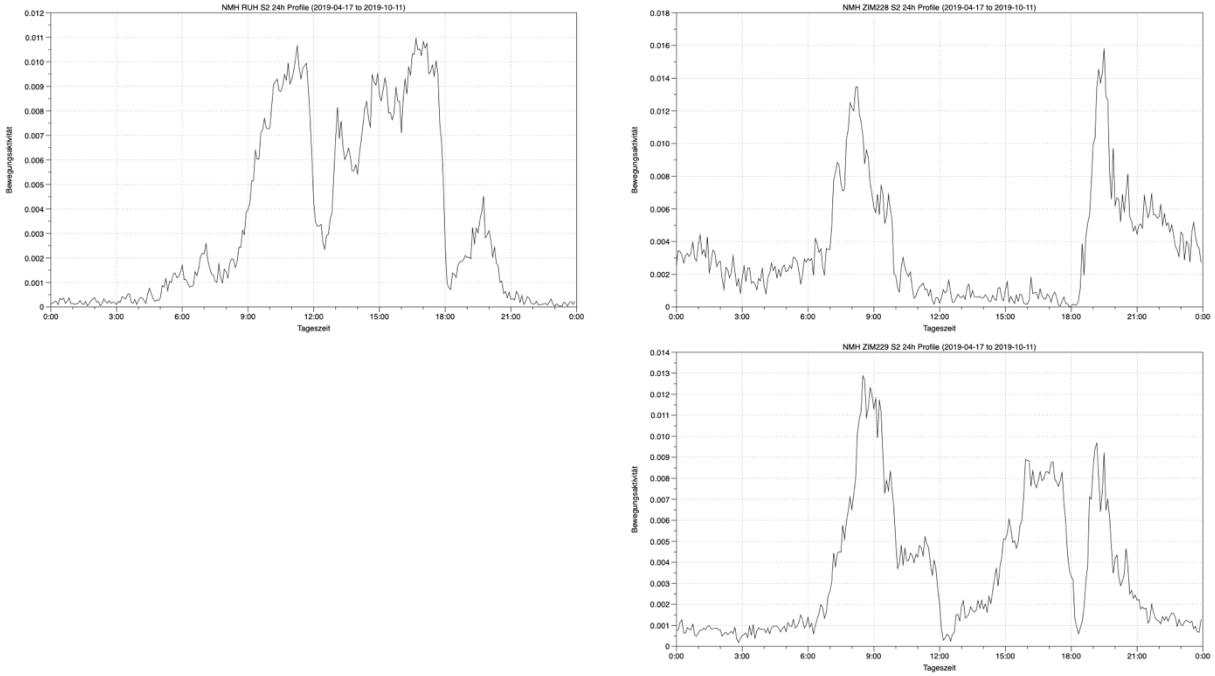



**Figure 28: 24h overall motion activity profile during the second phase of the field tests in Neumarkt**

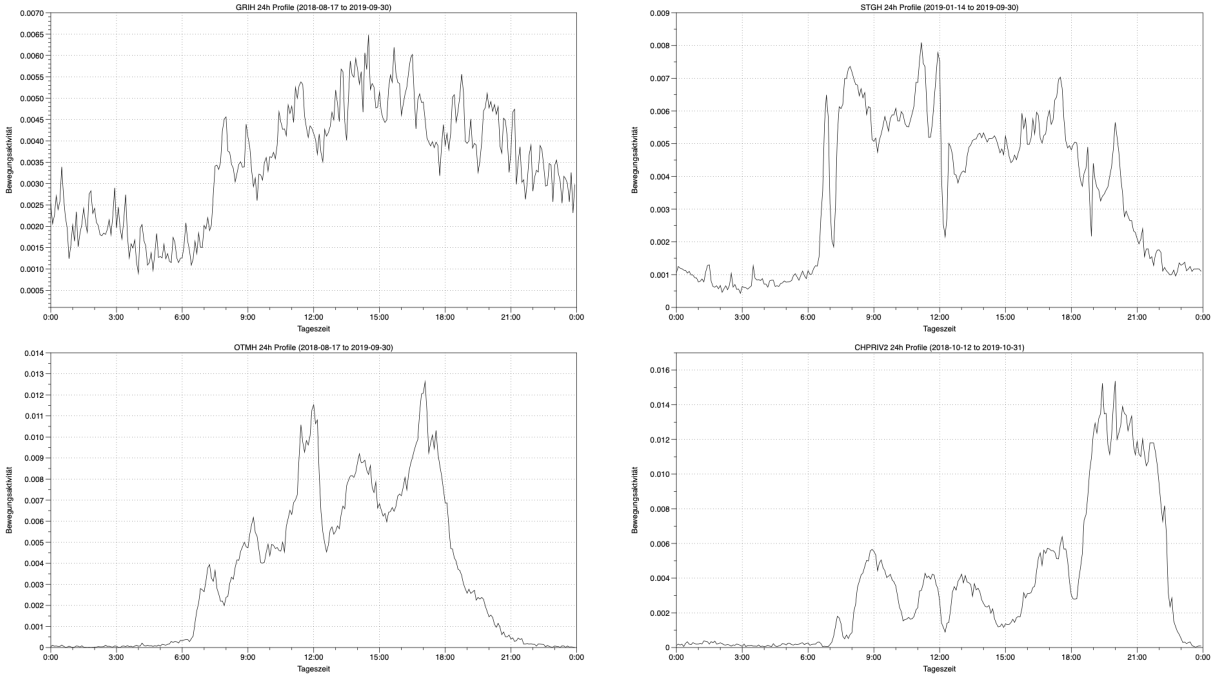



**Figure 29: 24h overall motion activity profile of the field test locations in CH**

## 6.2 Impact Analysis

### 6.2.1 Influence on physical activity

The GREAT system allowed two interventions to be set: a calming of the situation and an activation in the situation. The GREAT intervention, in the case of calming, should cause a reduction in movement activity in the room where the GREAT system was installed. In the case of activation, an increase in the activity of movement in the room.

For all interventions in the project, a mean value of physical activity was calculated before the intervention, during the first and second half of the intervention and after the intervention (see chapter 6.1.1) and plotted in Figure 30. In addition, for random observation periods with the same times of day when no intervention took place, mean values were calculated in the same way (of 482 cases, 171 cases were left here that could be evaluated).

The course of the selected parameter for the movement activity is similar in these three situations, and yet a visual inspection reveals differences. The initial situation was significantly more unsettled in the case of the sedation intervention than in the activation intervention. Conversely, after completion, the movement activity was significantly greater in the case of the sedation intervention than in the activation intervention. Both indicate an influence of the GREAT system that was intended.

The Wilcoxon Sign Rank Test (a nonparametric statistical test) for comparing preintervention and postintervention mean values of exercise activity indicates a significant difference in both interventions by GREAT (p=0.001 and p <0.001).

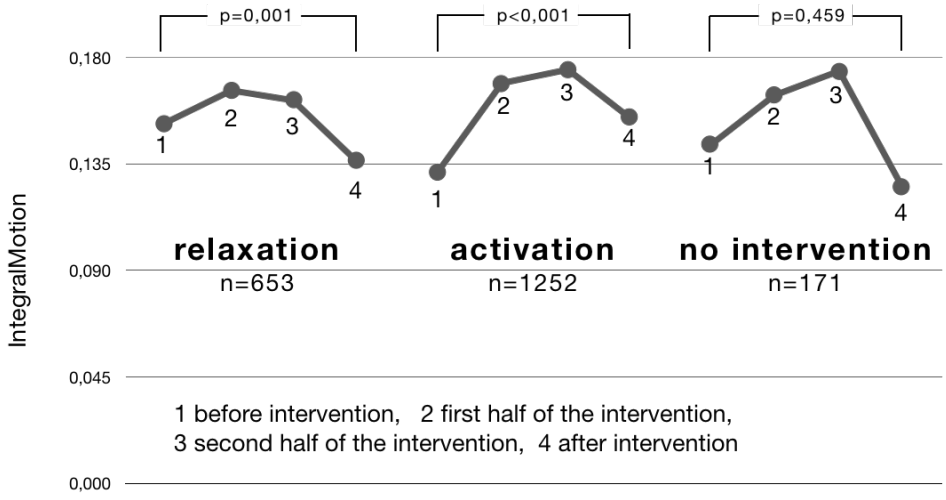



**Figure 30: Physical activity before, during and after GREAT interventions (total).**

If we compare the movement activity in the space before and after the intervention for the different types of sedation and activation intervention, we get the picture in Figure 31, where a bar shows the mean value before the intervention with the left half

and the mean value after the intervention with the right half. For the statistical comparison of both mean values a t-test for paired samples was applied. This shows a statistically significant difference ($p<0.05$) for the combined application of light, aroma and sound in the case of sedation and for the separate application of light, aroma and sound in the case of activation. In the case of sedation, movement activity was lower after the intervention and higher in the case of activation in all three cases. This again indicates an influence of the GREAT System that was intended.

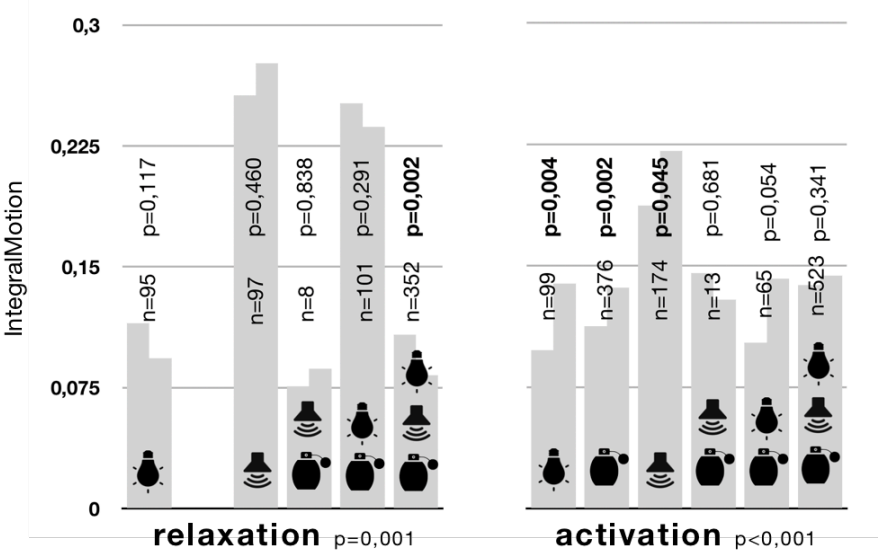



**Figure 31: Physical activity before and after various GREAT interventions.**

### 6.2.2 Influence on vegetative activity

The nursing staff were free to decide whether they wore the wristband for recording heartbeats on certain days. For the vital data collected in this way, a mean value of the pulse rate before the intervention, during the first and second half of the intervention and after the intervention was calculated (see Chapter 1.1) and plotted in Figure 17. Comparison periods without intervention could not be found.

The two curves in Figure 17 show a completely different picture. In the case of the sedation intervention, the pulse rate with over 89 BPM before the intervention has the highest mean value in the observation period. During the intervention, it drops to a value below 87 BPM. In the case of activation intervention, the pulse rate has the lowest mean value in the observation period with almost 86 BPM before the intervention. It increases to a value of over 87 BPM until after the intervention.

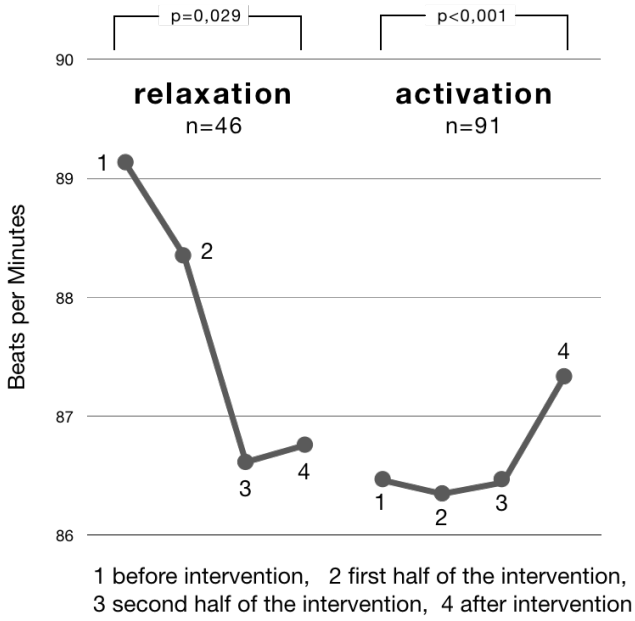



**Figure 32: Vegetative activity before, during and after GREAT interventions (total).**

A statistical comparison of the mean values before the intervention with the mean values after the intervention using the t-test for paired samples indicates a statistically significant difference in both cases ($p=0.029$ and $p<0.001$). Both again indicate an influence of the GREAT system that was intended.

### 6.2.3 Influence on subjective evaluation

The carers were also free to decide at any time after an intervention to evaluate the effectiveness of the intervention from their subjective point of view on a four-point scale. With the value 1 they expressed that in their opinion the intervention achieved the intended effect. With the value 4 they expressed that they could not see any effect.

Figure 33 shows the mean judgement values for the different types of sedation intervention and activation intervention. If all cases with a sample size smaller than 30 cases are omitted, the separate sound and scent intervention shows an average good judgement. The separate light intervention and the combination of light, sound and aroma as an intervention were rated worse by the caregivers.

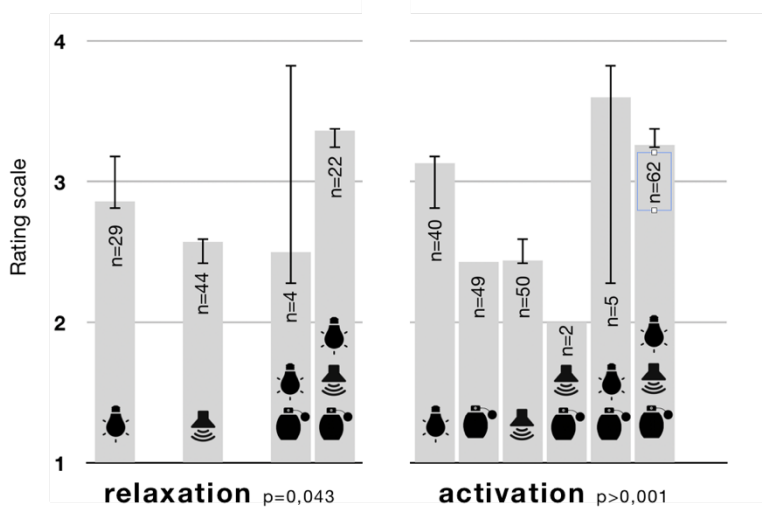



Figure 33: Subjective evaluation of the effectiveness of GREAT interventions.

It must be pointed out here that this was a subjective assessment in the course of everyday working life and that the judgements were sometimes made with a long delay. The divergence between subjective and objective evaluation can thus be partly explained.

## 6.3 PIR data Results of the GREAT (Motion) data analysis

**Information on the data**

The motion-data is gathered by passive infrared (PIR) motion detectors, capturing the movement of the test-persons over 24 hours. We collected the count of the movements and the added together movement within three time periods: 20 minutes before the intervention of the GREAT-system, during the intervention and 20 minutes after the intervention. Furthermore, we gathered information about which intervention was activated: sound, scent or light and if it was soothing or activating. That allows us to draw conclusions about, what interventions were used and how they affected the physical activity of the test subjects.

**Preliminary**

The count of movements of the test persons should decrease, if the GREAT-system intervenes calming.

The count of movements of the test persons should increase, if the GREAT-system intervenes activating.

**Calming interventions**

Beginning with calming interventions, the following table shows, how often the GREAT-system was used to sooth the test-persons and which elements of it were active. Interventions based solely on fragrance didn't come off. The combination of two elements of the GREAT-system result from manual switching on and off of an element.

| option | frequencies | percentage |
|---|---|---|
| only light | 164 | 11,9 |
| only sound | 175 | 12,7 |
| light and scent | 285 | 20,7 |
| light and sound | 3 | 0,2 |
| scent and sound | 16 | 1,2 |
| all three together | 731 | 53,2 |
| **total** | **1374** | **100,0** |

Table 12: Frequencies by option.

The following table shows the usage of the calming GREAT-system by the location, where it was active.

| | interventions | | mean of movements | | |
|---|---|---|---|---|---|
| | *frequencies* | *percentage* | *before* | *after* | *tendency* |
| household A (tests and demos Vorderlandhus since April 2019) | 28 | 2 | 37 | 20 | ↘ |
| household A (tests and demos Vorderlandhus since April 2019) | 172 | 12,5 | 14 | 12 | ↘ |
| Gritt Heim, CH | 7 | 0,5 | 7 | 6 | ~ |
| Hall Klinik, sitting room | 203 | 14,8 | 22 | 18 | ↘ |
| Hall Klinik, care room 1 | 248 | 18 | 21 | 23 | ↗ |
| Hall Klinik, care room 2 | 227 | 16,5 | 40 | 35 | ↘ |
| Neumarkt Heim Griesfeld rest room | 174 | 12,7 | 11 | 11 | ~ |
| Neumarkt Heim room 228 | 120 | 8,7 | 12 | 13 | ↗ |
| Neumarkt Heim room 229 | 158 | 11,5 | 28 | 24 | ↘ |
| St. Otmar Heim, CH | 20 | 1,5 | 14 | 20 | ~ |
| Bürgerspittal, St. Gallen sitting room | 17 | 1,2 | 43 | 40 | ↘ |
| **total** | **1374** | **100** | | | |

Table 13: Frequencies by location.

In most of the cases, the mean values of movements tend to go down. The desired effect appears to have been achieved. The number of interventions vary widely between the locations.

**Tests:**

We tested the differences using statistical methods. To remind of our assumption, the count of movements of the test persons should decrease, if the GREAT-system intervenes calming. To find out whether the differences in mean (median) values are actually significant, we used the Kruskal–Wallis one-way analysis of variance. The results are shown in the following table.

| | **before** | | **after** | | |
|---|---|---|---|---|---|
| | **mean** | **median** | **mean** | **median** | **p-value** |
| only light | 17,93 | 13 | 16,4 | 14 | n.s. |
| only sound | 26,08 | 18 | 27,8 | 16 | n.s. |
| light and scent | 40,13 | 24 | 38,36 | 20 | **0,018** |
| all three togehter | 17,93 | 13 | 16,4 | 14 | **0,001** |

**Table 14: Results of the Kruskal-Wallis one-way analysis.**

The median of movements after the intervention is slightly decreasing or at least constant. The differences of medians are not significant, if only light or only sound was used. The differences are getting significant in the combination.

To expand this analysis, we also performed a regression analysis. By doing so we dealt with the influence of the duration of the intervention on the movements of the test subjects. We assume that the duration of the intervention has a positive impact on the test subjects. The longer the GREAT-system has a calming effect, the less movement should be detected.

| *Does the duration of the intervention affect the movement <u>after</u> the intervention?* | | | | | |
|---|---|---|---|---|---|
| **option** | **correlation** | **p-value (corr)** | **R2** | **regr.-coefficient** | **p-value (Regr.)** |
| without[1)] | -0,08 | 0,01 | 0,006 | -0,003 | 0,019 |
| only light | -0,198 | 0,013 | 0,039 | -0,003 | 0,026 |
| only sound | -0,057 | n.s. | 0,003 | -0,003 | n.s. |
| light and scent | -0,132 | n.s. | 0,017 | -0,014 | n.s. |
| all three together | -0,181 | **0,00** | 0,033 | -0,003 | **0,00** |
| *Does the duration of the intervention affect the movement <u>during</u> the intervention?* | | | | | |
| without[1)] | 0,064 | 0,024 | 0,004 | 0,002 | n.s. |
| only light | 0,059 | n.s. | 0,004 | 0,001 | n.s. |
| only sound | 0,131 | n.s. | 0,017 | 0,009 | n.s. |

| | | | | | |
|---|---|---|---|---|---|
| light and scent | -0,108 | n.s. | 0,012 | -0,008 | n.s. |
| all three together | 0,066 | n.s. | 0,004 | 0,001 | n.s. |

**Table 15: Results of the regression analysis.**

*1) "without": no matter whether all three or only one element switched on - some was on.*

During the intervention, there was no significant influence of the duration of the intervention on the number of movements of the test subjects. The number of movements decreases significantly after the intervention when all three elements are on, light, sound and fragrance. This influence is shown in Figure 34.

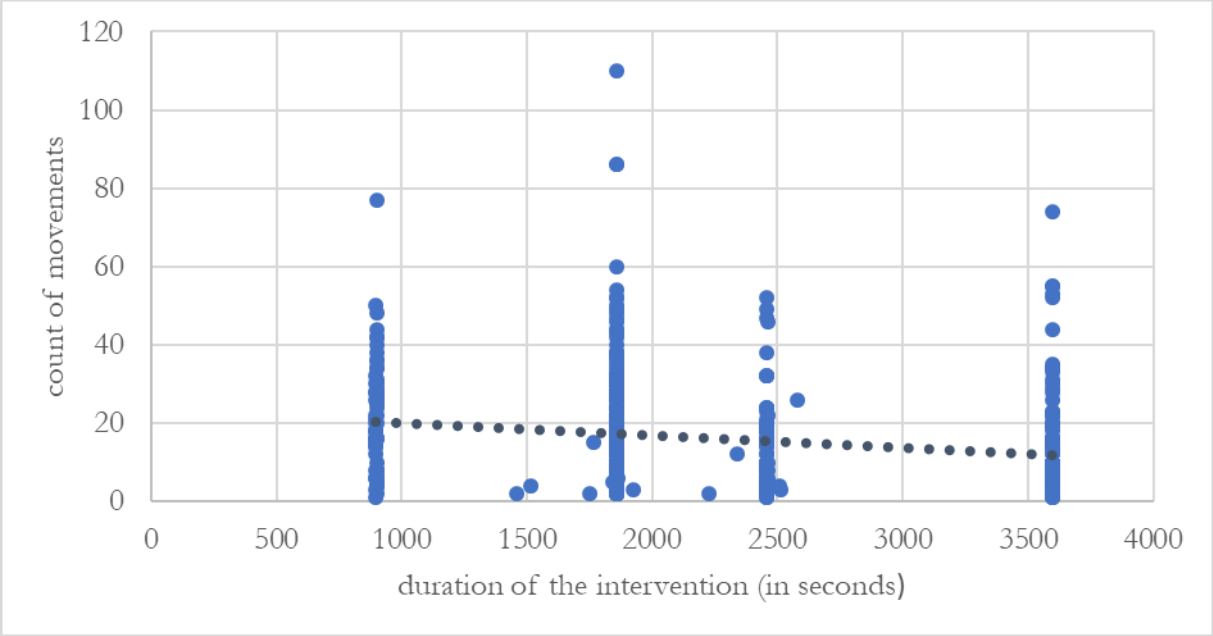



**Figure 34: Scatterplot - does the intervention have a calming influence on the movement after the intervention?**

However, the estimated model does not fit the data very well ($R^2$ = 0.0033). Only 3,3 percent of the total variation in the variable movement after the intervention can be explained by the duration of the intervention. The effect of the duration of the intervention on the movement after the intervention is very weak. It could be described as follows: the number of movements decreases by 0,003 for every second the intervention continues. With an average (calming) intervention duration of 2543 seconds (42 minutes), this corresponds to about 7 to 8 measured movements less after the intervention. On average, 25 movements were measured after interventions. Thus, after the calming intervention, there are on average only 17-18 movements. In summary it can be said that the duration of the GREAT-intervention has an impact, especially in the combination of all three elements, but due to the weakness of the model, it must be assumed that other factors also affect the movement of the test subjects.

**Activating interventions**

Considering the activating interventions, the following table shows, how often the GREAT-system was used to activate the test-persons and which elements of it were active. The combination of two elements of the GREAT-system result from manual switching on and off of an element.

| option | frequencies | percentage |
|---|---|---|
| only light | 177 | 9,0 |
| only scent | 509 | 25,8 |
| only sound | 292 | 14,8 |
| light and scent | 101 | 5,1 |
| light and sound | 2 | 0,1 |
| scent and sound | 20 | 1,0 |
| all three together | 872 | 44,2 |
| **total** | **1973** | **100,0** |

**Table 16: Frequencies by option.**

The following table shows the usage of the activating GREAT-system by the location, where it was active.

| | **interventions** | | **mean movements** | | |
|---|---|---|---|---|---|
| | *frequencies* | *percentage* | *before* | *after* | *tendency* |
| household A (tests and demos, Vorderlandhus since april 2019) | 47 | 2,4 | 19 | 9 | ↘ |
| household Switzerland 2 (Sargans, only scent) | 112 | 5,8 | 9 | 12 | ↗ |
| Gritt Heim | 4 | 0,2 | 8 | 18 | ~ |
| Klinik Hall, sitting room | 223 | 11,6 | 23 | 18 | ↘ |
| Klinik Hall, care room 1 | 383 | 19,9 | 22 | 35 | ↗ |
| Klinik Hall, care room 2 | 392 | 20,3 | 27 | 40 | ↗ |
| Neumarkt, resting room | 291 | 15,1 | 19 | 19 | ~ |
| Neumarkt, room 228 | 159 | 8,2 | 15 | 15 | ~ |

| | | | | | |
|---|---|---|---|---|---|
| Neumarkt, room 229 | 212 | 11,0 | 26 | 32 | ↗ |
| St.Otmar Heim, St Gallen | 25 | 1,3 | 15 | 15 | ~ |
| Bürgerspittal St. Gallen | 3 | 0,2 | 17 | 31 | ~ |
| Klinik Hall, ambulance room | 78 | 4,0 | 19 | 25 | ↗ |
| **Total** | **1929** | **100,0%** | | | |

**Table 17: Frequencies by location.**

In most of the locations, the mean values of movements tend to go up. The desired effect appears to have been achieved. The number of interventions vary widely between the locations.

**Tests**

Again, we used statistical methods to test the differences between the median of the count of movements before and after the intervention. To remind of our assumption, the count of movements of the test persons should increase, if the GREAT- system intervenes activating. To find out whether the differences in mean (median) values are actually significant, we used the Kruskal–Wallis one-way analysis of variance. The results are shown in the following table.

| | **before** | | **After** | | |
|---|---|---|---|---|---|
| | **mean** | **median** | **mean** | **median** | **p-value** |
| only light | 16,36 (±15,6) | 10 | 24,72 (±25,3) | 14 | **0,004** |
| only scent | 18,13 (±17,9) | 12 | 22,81 (±20,7) | 17 | **0,000** |
| only sound | 26,07 (±21,9) | 18 | 34,9 (±31,1) | 28 | **0,005** |
| light and scent | 15,11 (±13,9) | 11 | 19,58 (±16,1) | 17 | n.s. |
| all three together | 25,6 (±35,4) | 10 | 28,16 (±35,8) | 14 | n.s. |

**Table 18: Results of the Kruskal-Wallis one-way analysis.**

After interventions with either only light, only scent or only sound there are significantly more movements after the intervention. On the other hand, has the combination of the three elements no significant activating effect. Again, we conducted a regression analysis. By doing so we dealt with the influence of the duration of the intervention on the movements of the test subjects. We assume that the duration of the intervention has a positive impact on the test subjects. The longer the GREAT-system has an activating effect, the more movement should be detected.

*Does the duration of the intervention affect the movement after the intervention?*

| option | correlation | p-value (corr.) | R2 | regr.-coefficient | p-value (regr.) |
|---|---|---|---|---|---|
| without[1)] | -0,083 | 0,001 | 0,007 | -0,004 | 0,001 |
| only light | -0,206 | 0,008 | 0,042 | -0,035 | 0,016 |
| only scent | -0,297 | 0,00 | 0,043 | -0,004 | 0,00 |
| only sound | -0,143 | 0,014 | 0,02 | -0,05 | 0,029 |
| light and scent | -0,057 | n.s. | 0,003 | -0,003 | n.s. |
| all three together | 0,017 | n.s. | 0,00 | 0,002 | n.s. |
| *Does the duration of the intervention affect the movement during the intervention?* | | | | | |
| without[1)] | 0,102 | 0,00 | 0,01 | 0,003 | 0,00 |
| only light | 0,107 | n.s. | 0,011 | 0,011 | n.s. |
| only scent | 0,305 | 0,00 | 0,093 | 0,004 | **0,00** |
| only sound | 0,054 | n.s. | 0,003 | 0,008 | n.s. |
| light and scent | 0,144 | n.s. | 0,021 | 0,005 | n.s. |
| all three together | 0,03 | n.s. | 0,001 | 0,002 | n.s. |

**Table 19: Results of the regression analysis.**

*1) "without": no matter whether all three or only one element switched on - some was on.*

The significant influences in the "without" - line arise because individual elements have a significant influence. To take a closer look at these elements is necessary. First of all, there is no or most likely a negative influence on the movement after the intervention by a single element. The only influence that can be discovered is the one of the scent interventions on the number of movements during the intervention. However, this influence was positive on the number of movements during the intervention. This influence is shown in Figure 35.

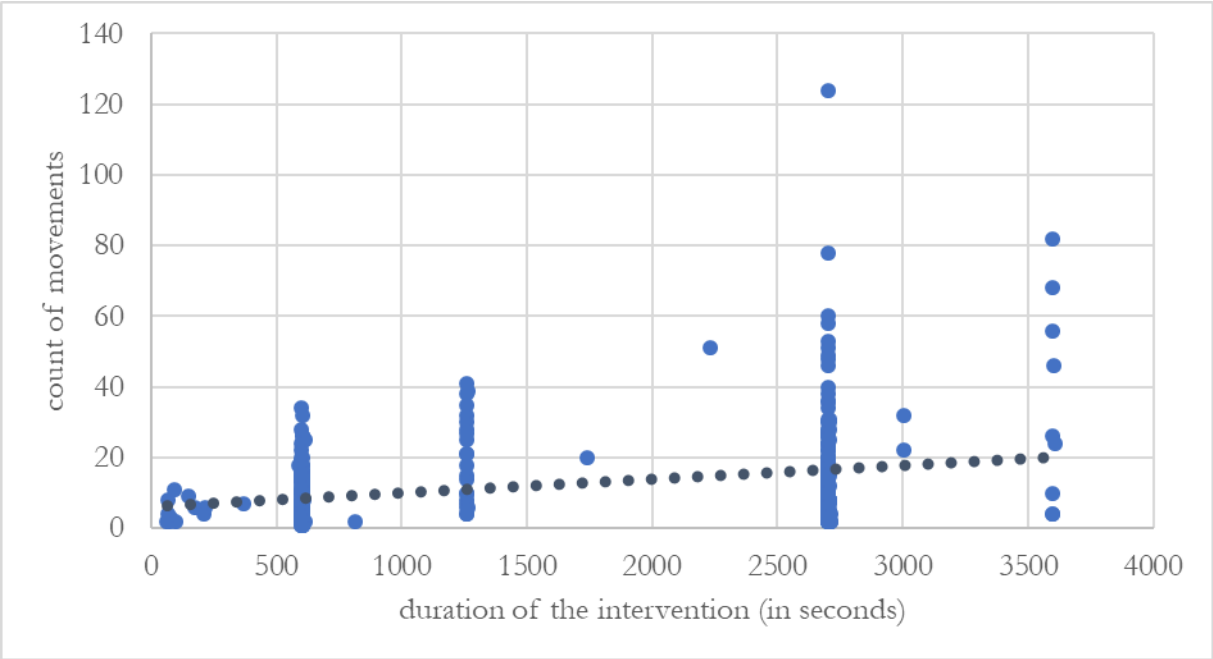



**Figure 35: Scatterplot - does the scent-intervention have a activating influence on the movement during the intervention?**

The estimated model does not match the data particularly well (R2 = 0.093). Only 9,3 percent of the total variation in the variable movement during the intervention can be explained by the duration of the scent-intervention. The effect of the duration of the scent-intervention on the movement during the intervention is rather weak (correlation: 0.305). It could be described as follows: the number of movements increases by 0,004 for every second that the intervention continues. With an average (activating) intervention duration of 1299 seconds (22 minutes), this corresponds to about 5 more movements measured during the intervention. On average, 15 movements were measured during interventions. Thus, during the scent-intervention, there are on average 17-18 movements. Here again we must consider the models weakness. Many other factors may also have an impact on the movement of the test subject during the intervention alongside the scent-intervention.

**Conclusion**

In some cases, the desired effect appears to have been achieved. When the GREAT-system calms people down it gets better results using all three elements in combination. The single elements had on their own no significant influence on the movement of the test subjects. The analysis of the regression shows that the influence of the duration of the intervention on the movement after the intervention is present but small. So other factors also have to be considered. If the GREAT-system should activate the test subjects, better results are achieved by the single elements.

## 6.4 Physiological data

This chapter summarizes the main results from the analysis of Biovotion data.

### 6.4.1 Overview

**Data Selection Requirements:**

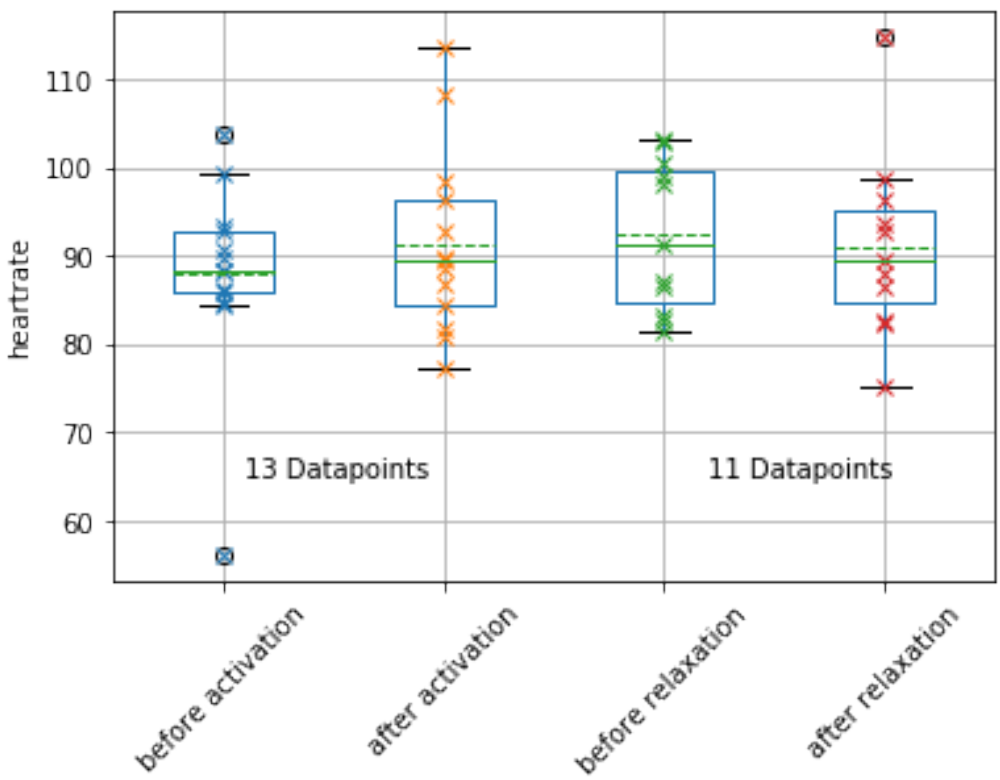
- time-overlap of biovotion sensor data and intervention
- minimum intervention duration: >10 minutes
- at least two minutes of biovotion (HR) data before start of intervention (heart rate before intervention)
- for events with two consecutive interventions: at least 2 hours between end of first intervention and start of second intervention
- Analysis uses HR data > 10 minutes after the start of the intervention until the end of biovotion sensor data (heart rate after intervention)
- Light, sound and scent interventions are treated separately.

**Methods:**

- Event-based unpaired t-test of average heart rate before and after intervention
- Boxplot over all averages
- Histogram of all t-values of unpaired t-test
- Linear Trend of some data points, which don't meet Data Selection Requirements

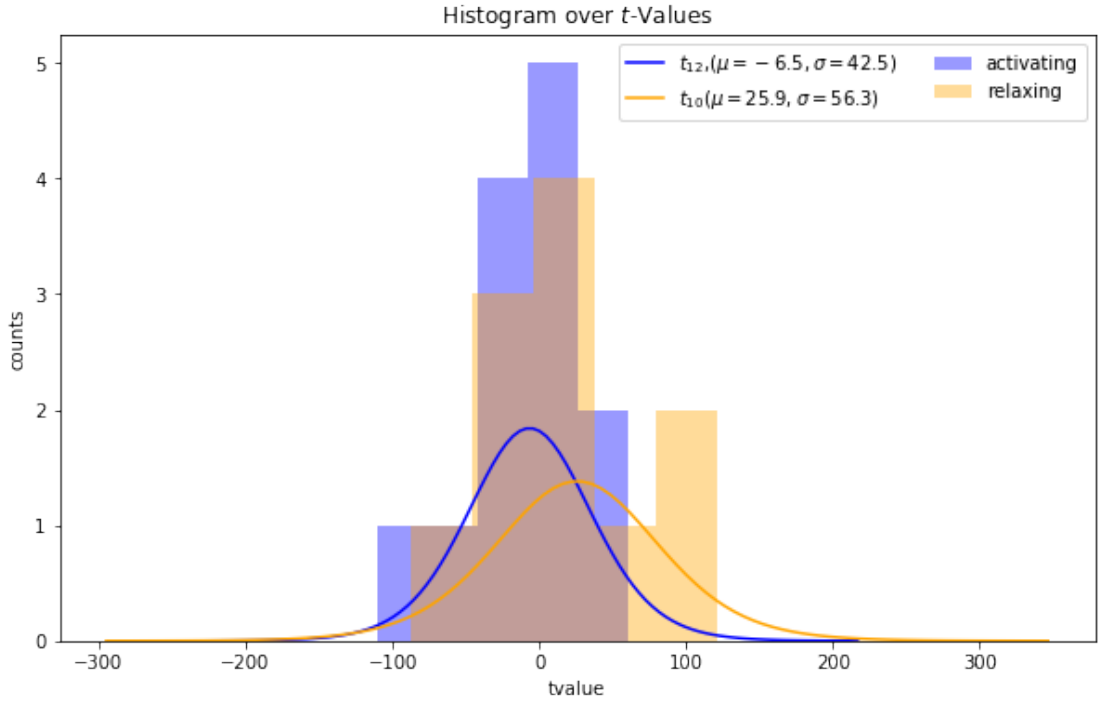
**Results:**

| |
|---|
| Boxplot over averages of heart rates before or after intervention, and for relaxing or activating interventions.<br>The average heartrate increases during activation and decreases during relaxation.<br>Sample size is n = 24.<br>There are a few outliers for both events, but median and average value are as expected. |




Histogram over unpaired t-test of every single event for average heartrate before and after intervention shows a positive average value for relaxation and a negative average value for activating. The expected test value for events during relaxation should be positive and the expected test value for events during activation should be negative. The overall sample is n=24. There are outliers during both events, but the overall average value is as expected.

The test value is calculated by: $t = \frac{\bar{X}-\bar{Y}}{\sqrt{\frac{sx^2}{nx}+\frac{sy^2}{ny}}}$



**Conclusion**

- We had a smaller set of usable samples than expected in the beginning
- Together with the indirect measurement via proxy, the total volume of data was lower than expected
- Sample size for statistical evaluation is n = 24
- There are some promising data points, where HR data is paired with interventions
- A few datapoints are selected where Data Selection Requirements are not fulfilled for an analysis of the linear trend.

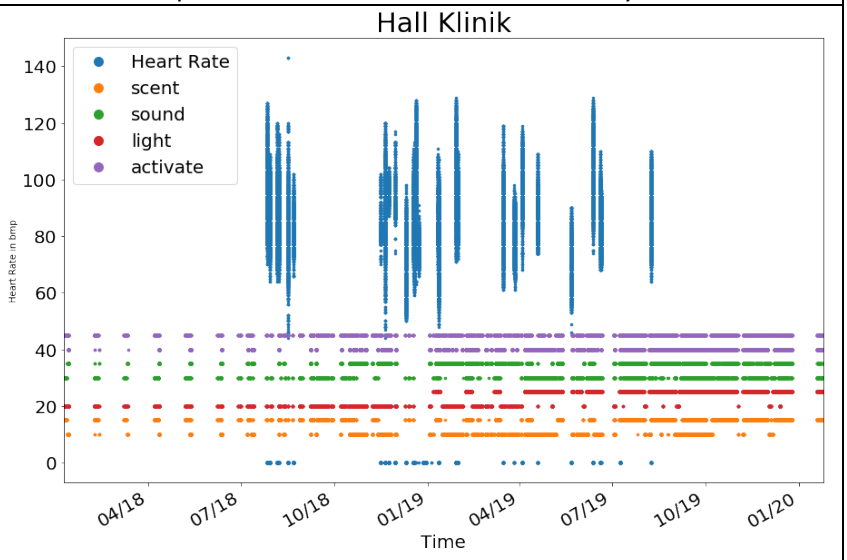
### 6.4.2 Analysis of different hospitals

**Hall Klinik**

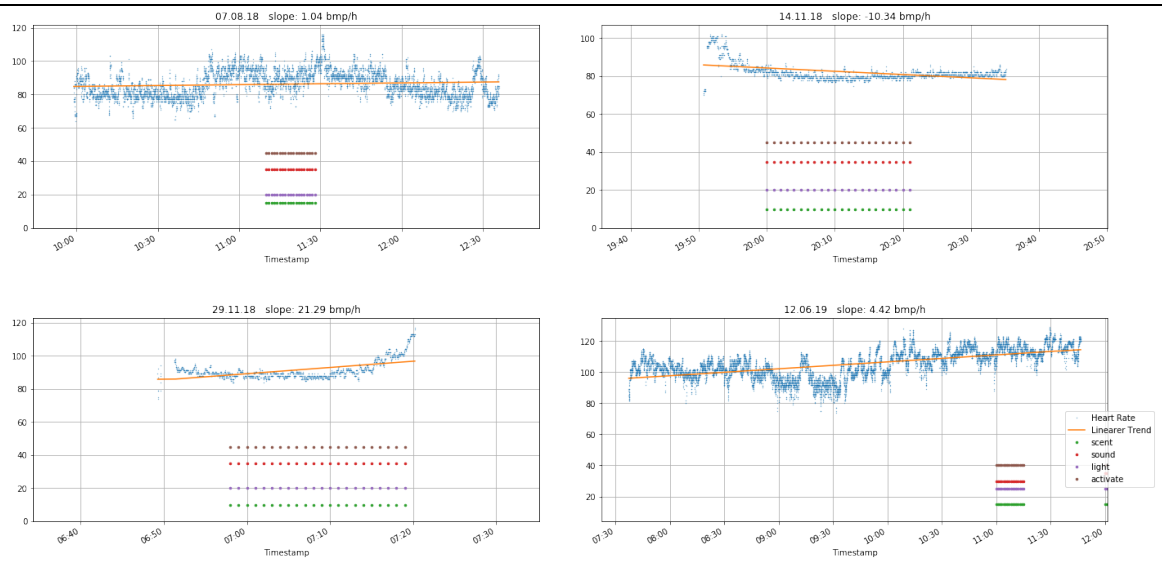
- days of consideration for analysis = **378**
- Number of days with biovotion data = **29**
- Number of days with biovotion and intervention data = **8**
- After checking the data selection requirements: Number of considered days = **4**

This plot shows that the interventions are available for the entire period. However, it is not clear from this graphic whether a measurement with the biovotion sensor has taken place with the at the same time.

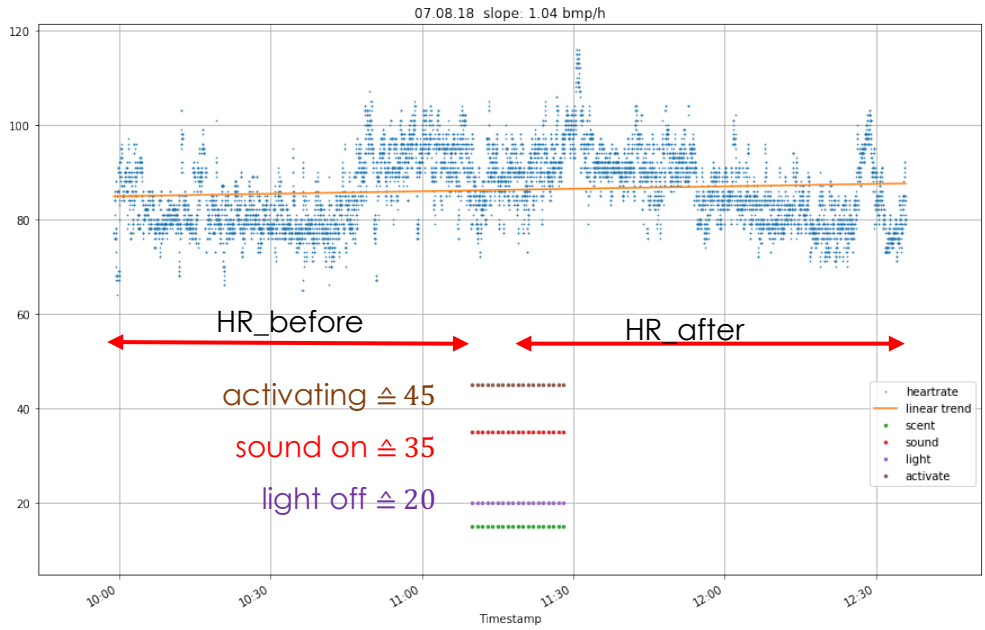
activating ≙ 45
relaxing ≙ 40
sound on ≙ 35
sound off ≙ 30
light on ≙ 25
light off ≙ 20
scent on ≙ 15
scent off ≙ 10



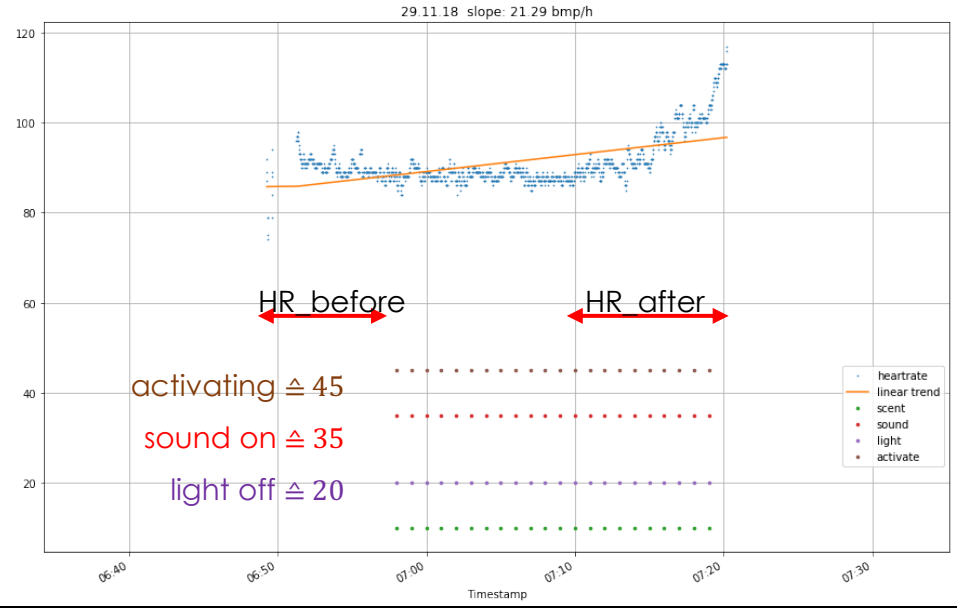

- Analysis for 4 dates possible



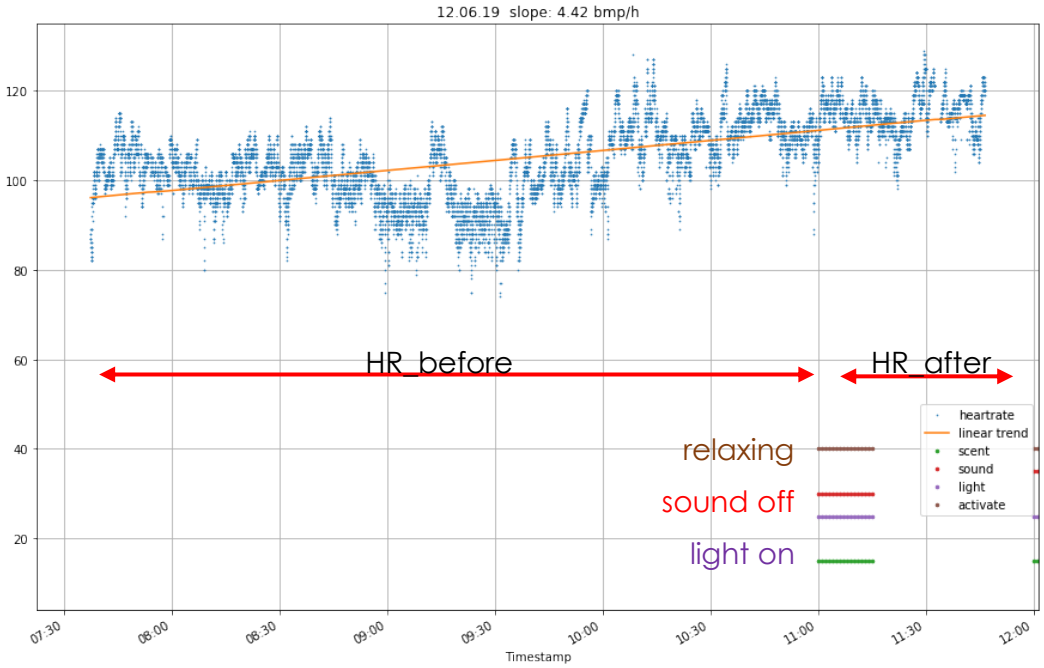

- Klinik Hall example 07.08.18
  - HR average ≈ 86.2 bpm
  - HR variance ≈ 58.7 bpm
  - HR_before average ≈ 84.9 bpm
  - HR_after average ≈ 86.9 bpm
  - duration intervention = 18min
  - slope linear trend = 1.04 bmp/h




- Klinik Hall example 29.11.18
  - HR average ≈ 91.3 bpm
  - HR variance ≈ 31.5 bpm
  - HR_before average ≈ 89.9 bpm
  - HR_after average ≈ 98.4 bpm
  - duration intervention = 21min
  - slope linear trend = 21.29bmp/h

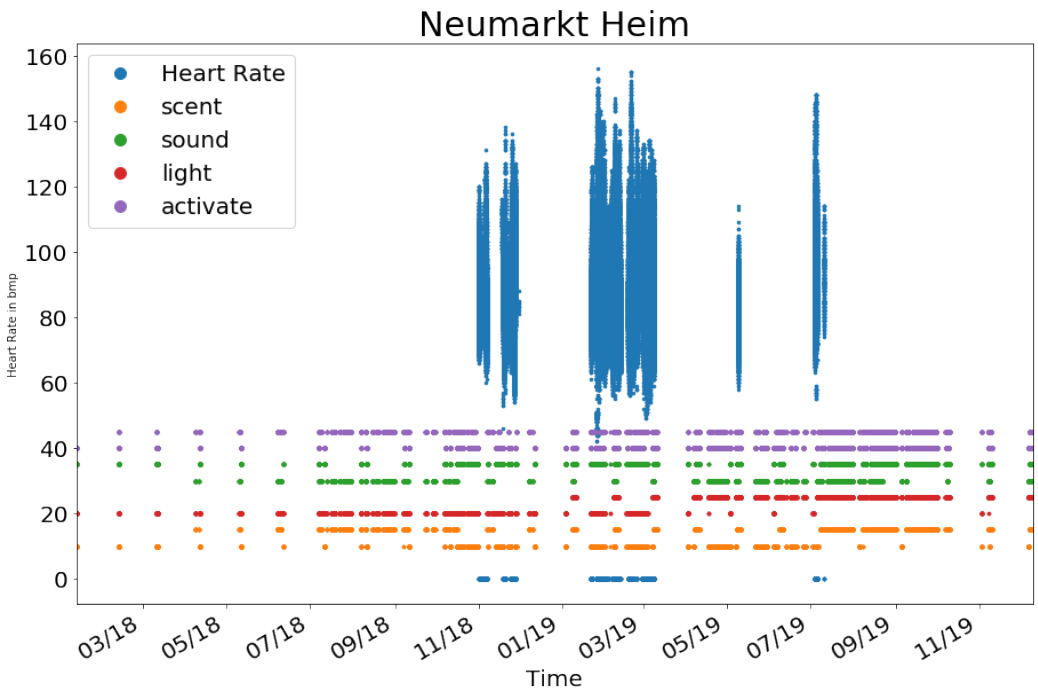



- Klinik Hall example 12.06.19
  - HR average ≈ 105.3 bpm
  - HR variance ≈ 77.2 bpm
  - HR_before average ≈ 103.1 bpm
  - HR_after average ≈ 114.9 bpm
  - duration intervention = 15 min
  - slope linear trend = 4.42 bmp/h

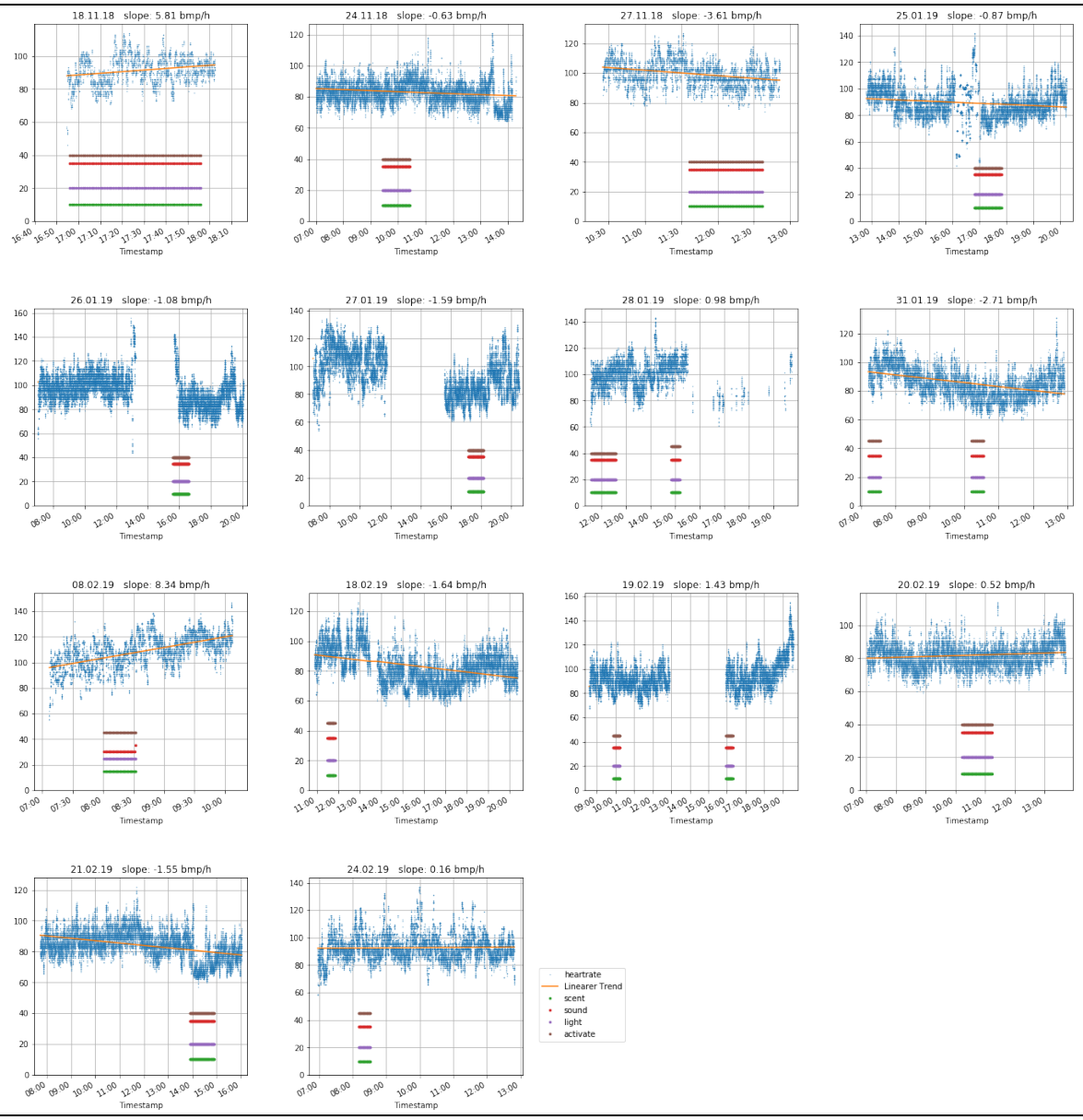


- Neumarkt Heim

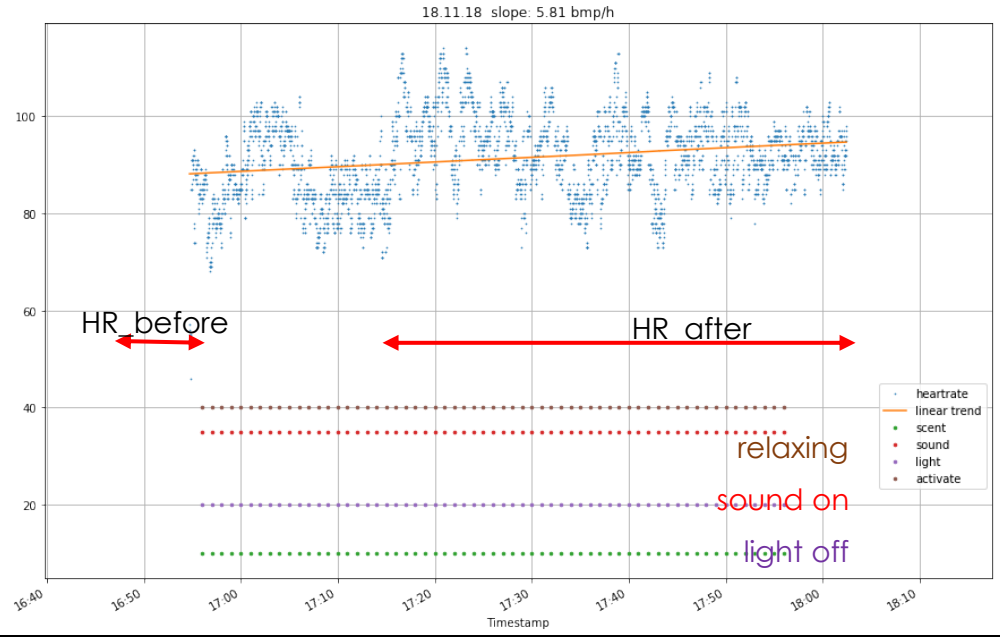
– days of consideration for analysis = **252**
– Number of days with biovotion data = **58**
– Number of days with biovotion and intervention data = **25**
– After checking the data selection requirements: Number of considered days = **17**



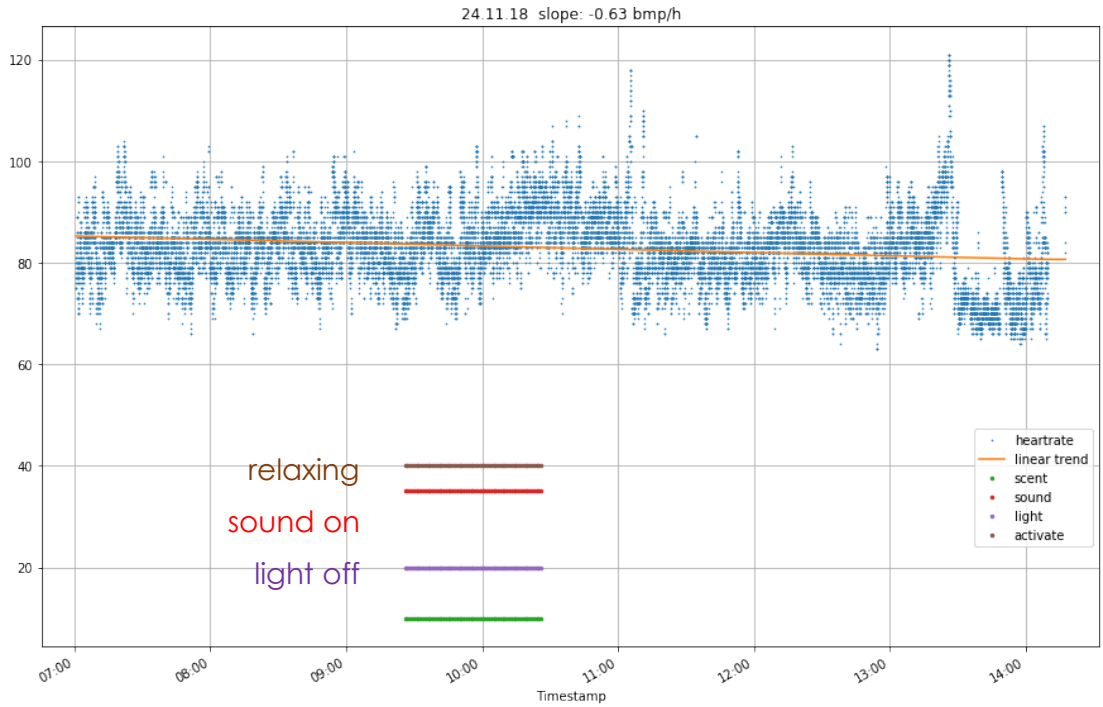

– Analysis for 17 dates possible



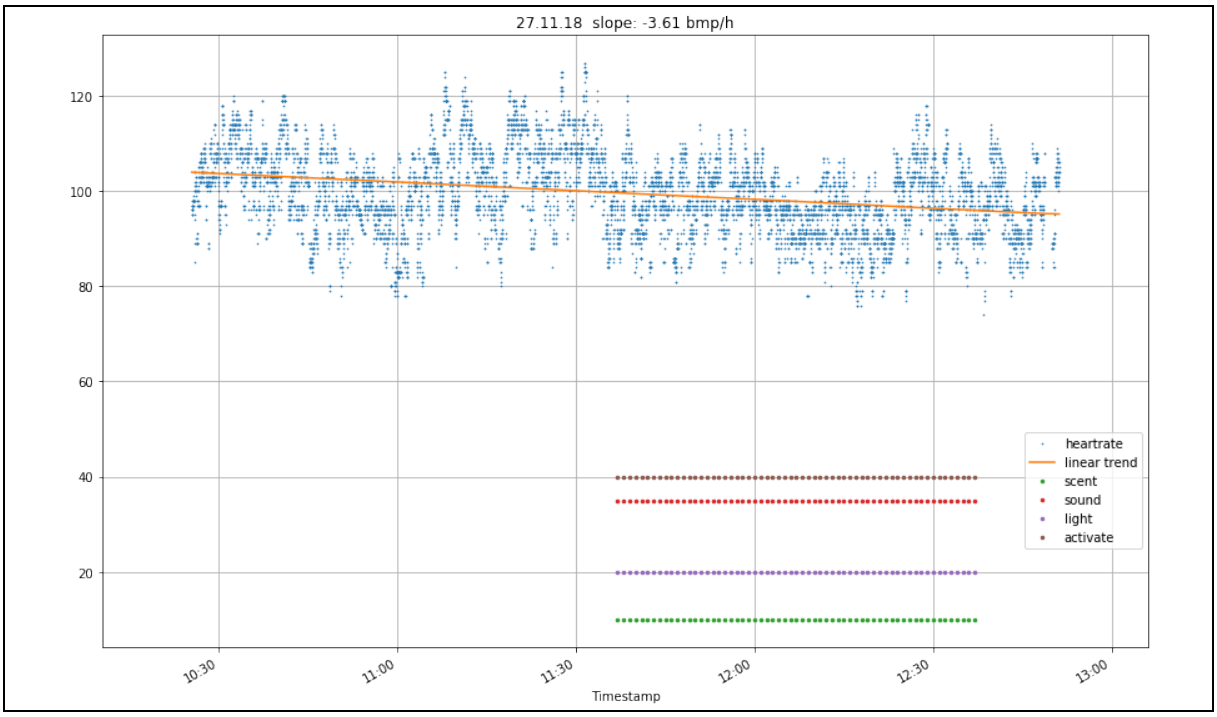

- Neumarkt Heim example 18.11.18
  - HR average ≈ 91.4 bpm
  - HR variance ≈ 70.0 bpm
  - HR_before average ≈ 82.6 bpm
  - HR_after average ≈ 92.8 bpm
  - duration intervention = 60 min
  - slope linear trend = 5.81 bmp/h




- Neumarkt Heim example 24.11.18
  - HR average ≈ 82.9 bpm
  - HR variance ≈ 50.4 bpm
  - HR_before average ≈ 83.2 bpm
  - HR_after average ≈ 82.7 bpm
  - duration intervention = 60 min
  - slope linear trend = -0.63 bmp/h

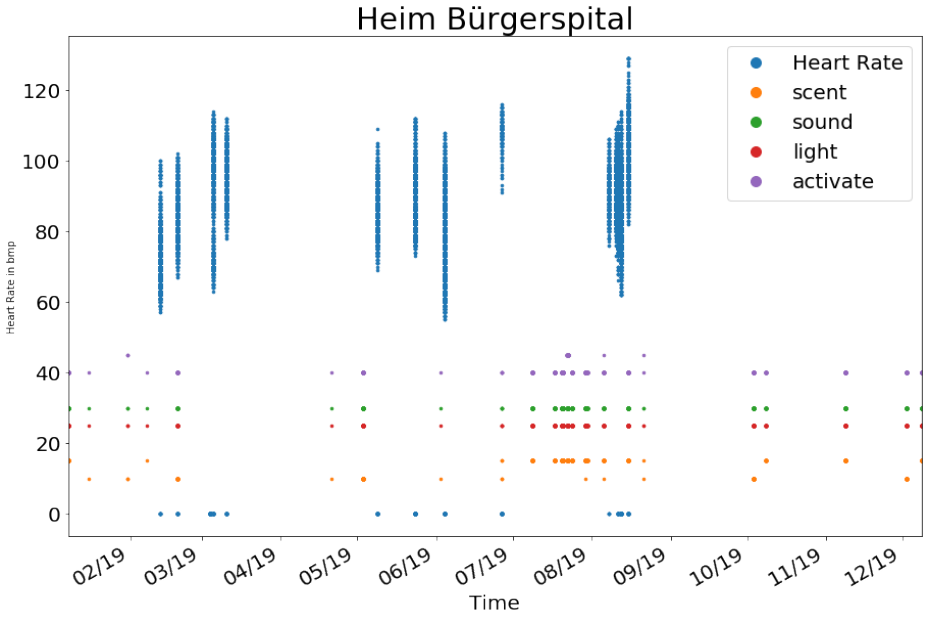



- Neumarkt Heim example 27.11.18
  - HR average ≈ 99.6 bpm
  - HR variance ≈ 72.7 bpm
  - HR_before average ≈ 102.8 bpm
  - HR_after average ≈ 96.3 bpm
  - duration intervention = 60 min
  - slope linear trend = -3.61 bmp/h



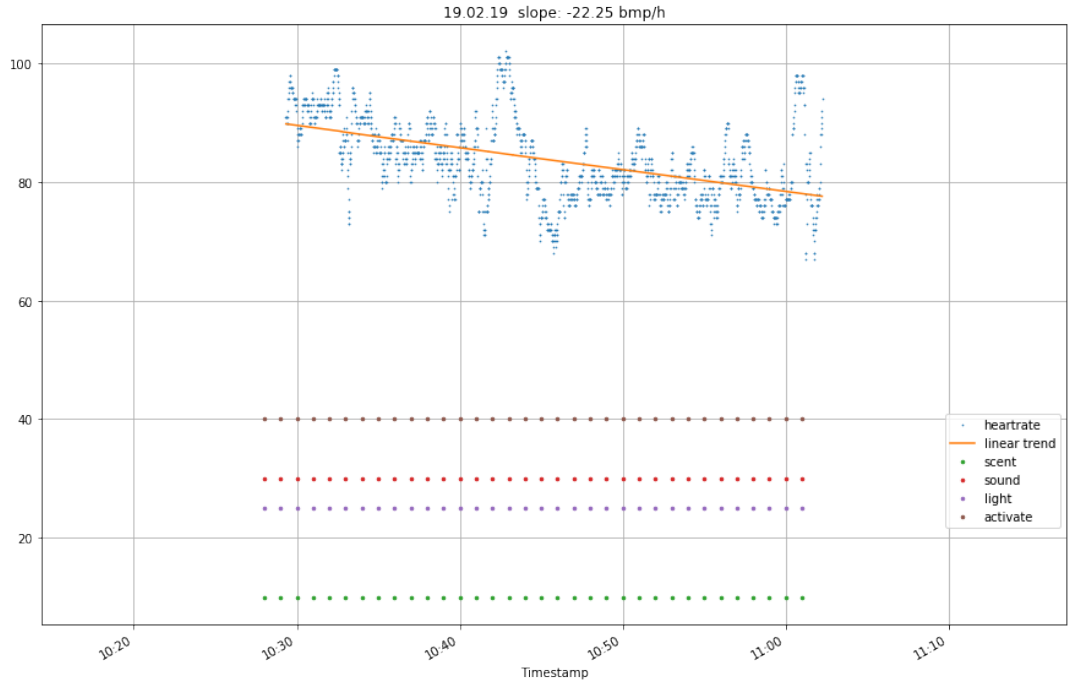

- Heim Bürgerspital

– days of consideration for analysis = **184**
– Number of days with biovotion data = **13**
– Number of days with biovotion and intervention data = **3**
– After checking the data selection requirements: Number of considered days = **0**



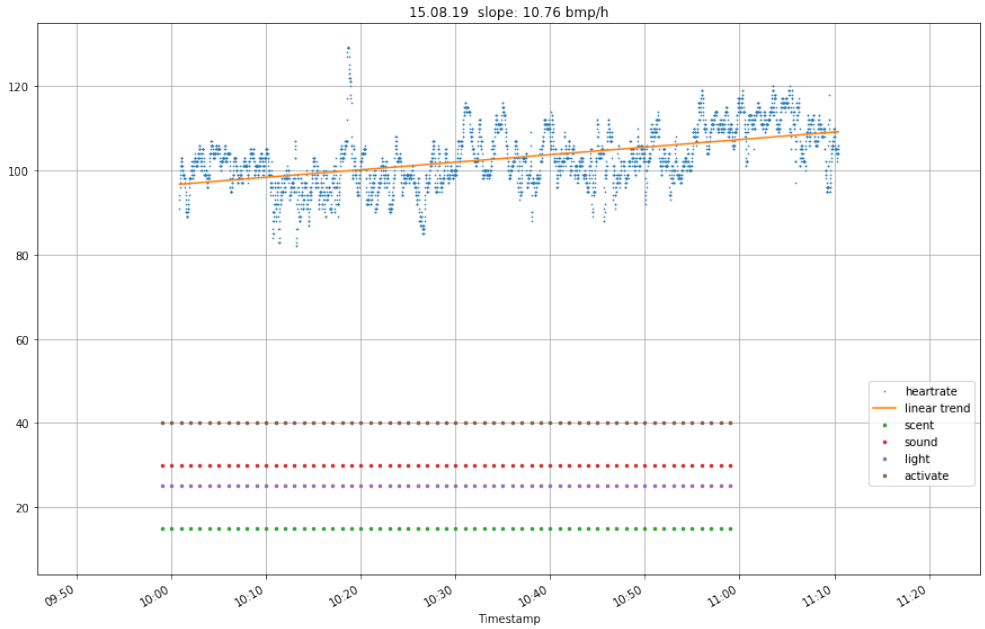

– Heim Bürgerspital example 19.02.19
  - Intervention starts before detecting heartrate – analyis of linear trend
  - Activation mode: **relaxing**
  - HR average ≈ 83.7 bpm
  - HR variance ≈ 46.9 bpm

- duration intervention = 31 min
- slope linear trend = **-22.5** bmp/h



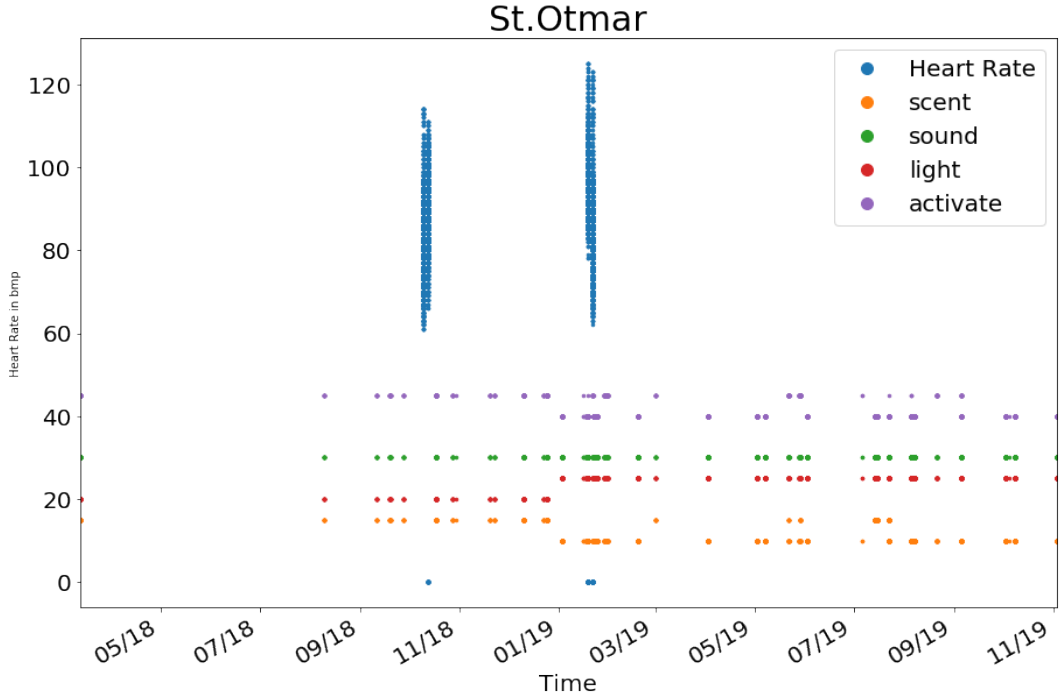

– Heim Bürgerspital example 15.08.19

- Intervention starts before detecting heartrate:analyis of linear trend
- Activation mode: **relaxing**
- HR average ≈ 102.9 bpm
- HR variance ≈ 48.0 bpm
- duration intervention = 58 min
- slope linear trend = **10.76** bmp/h

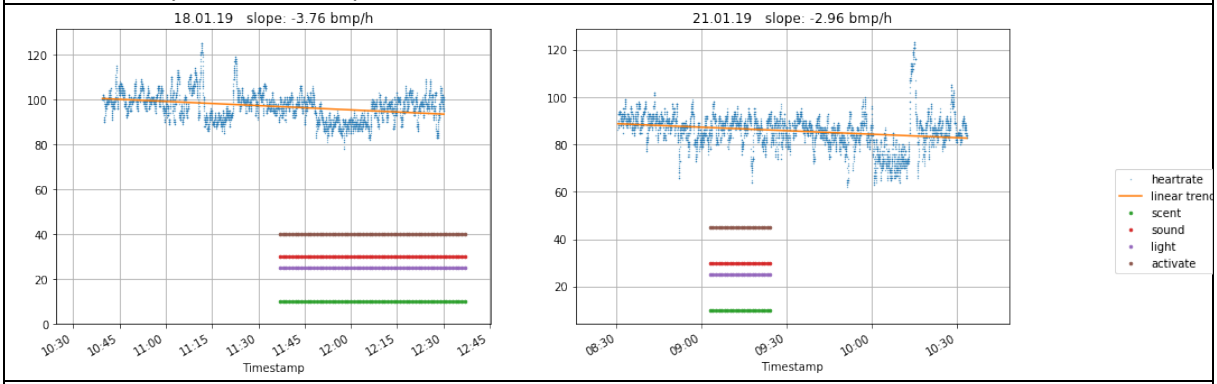


- Heim St. Othmar

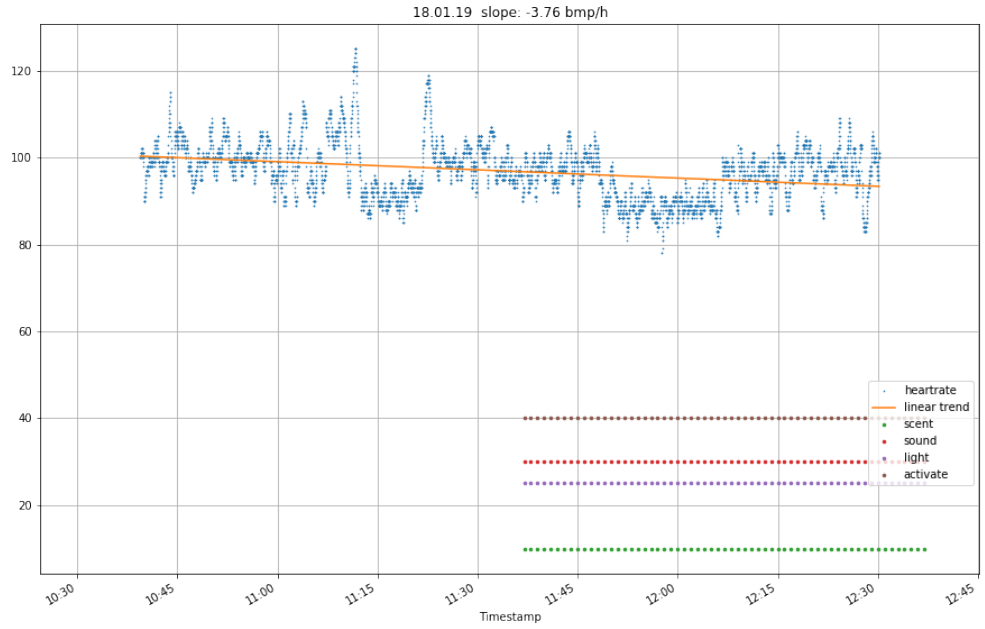
– days of consideration for analysis = **104**
– Number of days with biovotion data = **4**
– Number of days with biovotion and intervention data = **2**
– After checking the data selection requirements: Number of considered days = **2**



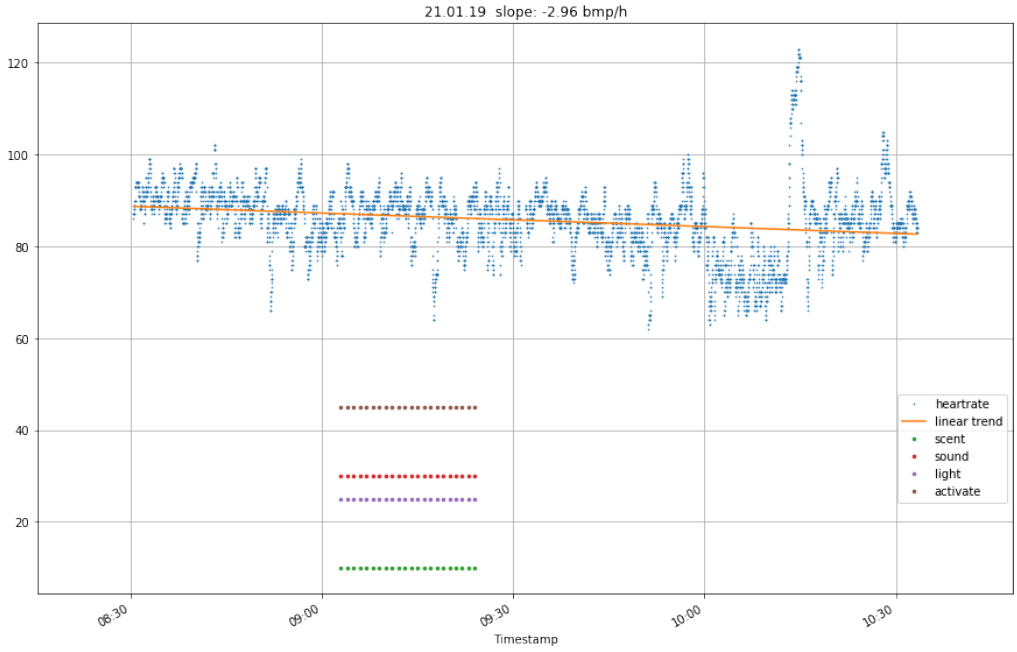

– Analysis for 2 dates possible




– Heim St. Othmer example 18.01.19
  - HR average ≈ 96.9 bpm
  - HR variance ≈ 39.5 bpm
  - duration intervention = 53 min
  - slope linear trend = -3.76 bmp/h

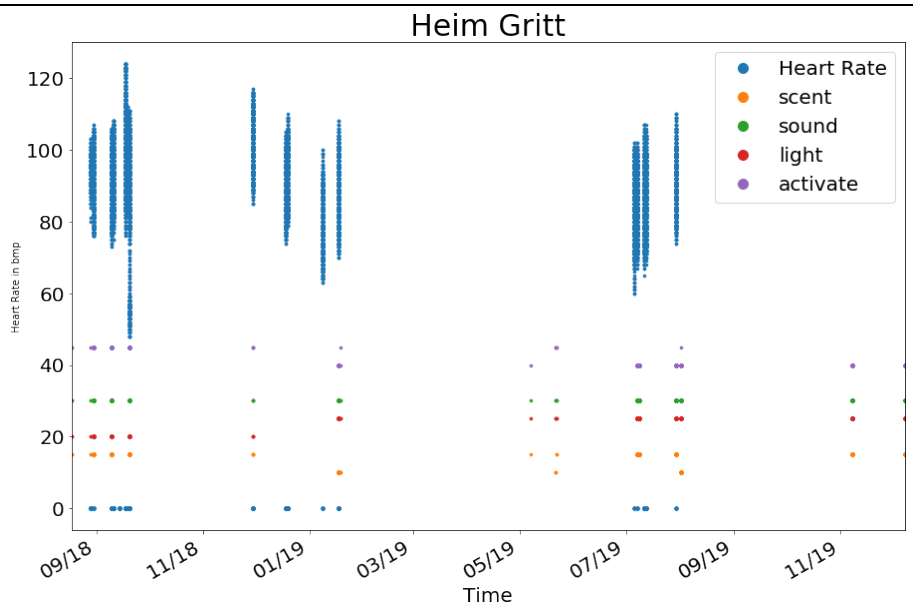



- Heim St. Othmer example 21.01.19
  - HR average ≈ 85.7 bpm
  - HR variance ≈ 56.8 bpm
  - duration intervention = 21 min
  - slope linear trend = -2.96 bmp/h

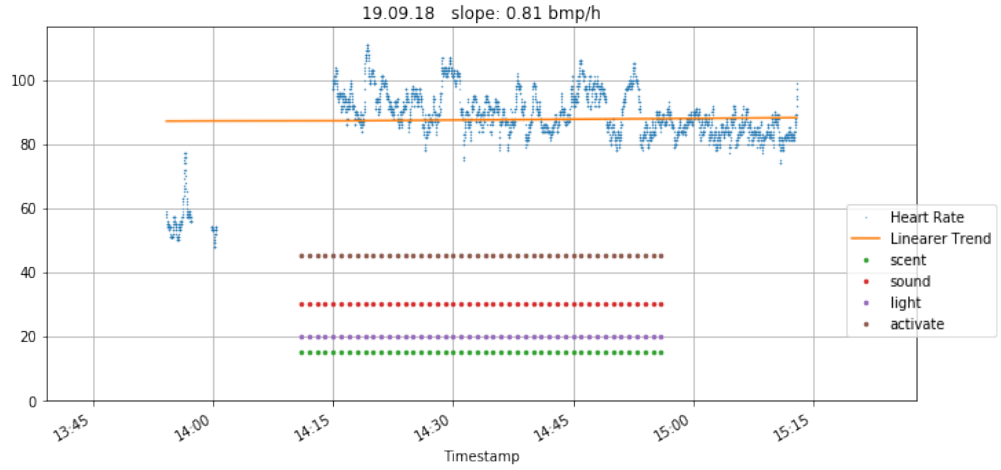



- Heim Gritt

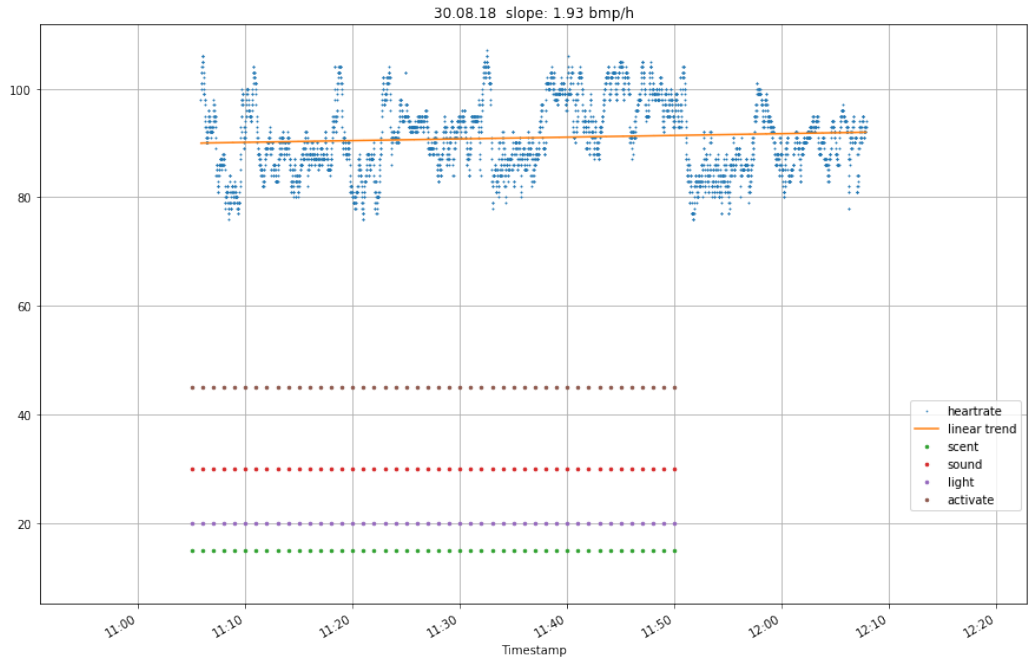
- days of consideration for analysis = **335**
- Number of days with biovotion data = **17**
- Number of days with biovotion and intervention data = **8**
- After checking the data selection requirements: number of considered days = **1**



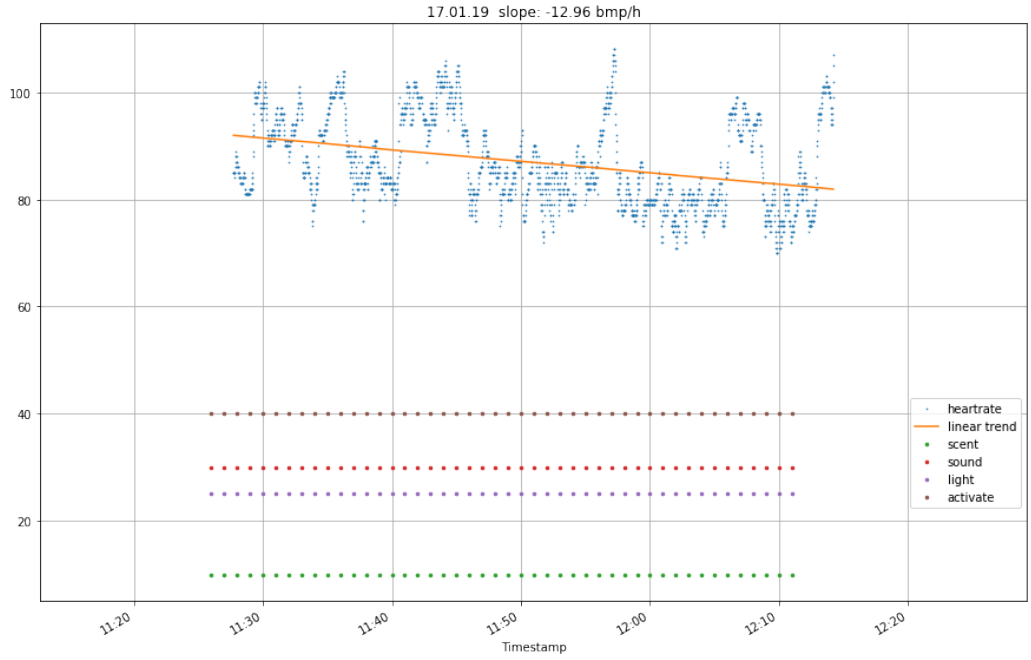

– Analysis for 1 date possible




– Heim Bürgerspital example 30.08.18
  - Intervention starts before detecting heartrate: analysis of linear trend
  - Activation mode: **activating**
  - HR average ≈ 91.0 bpm
  - HR variance ≈ 42.2 bpm
  - duration intervention = 44 min
  - slope linear trend = **1.93** bmp/h




- Heim Bürgerspital example 17.01.19
  - Intervention starts before detecting heartrate: analysis of linear trend
  - Activation mode: **relaxing**
  - HR average ≈ 87.0 bpm
  - HR variance ≈ 67.3 bpm
  - duration intervention = 43 min
  - slope linear trend = **-12.96** bmp/h



# 7. Results of statistical long-term comparison

The evaluation tools used are:

- The **Neuropsychiatric Inventory-Questionnaire (NPI)**: NPI is the sum of several behavioural anomalies and ranges from zero to 144, whereby the higher the sum, the more frequently and strongly the anomalies were reported by the nursing staff.
- The **Professional Care Team Burden (PCTB) 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. The range is between 0 and 40: as the score increases, so does the burden.

## 7.1 Tirol Kliniken Hall, Austria

### 7.1.1 Patients

The NPI examines 10 sub-domains of behavioral functioning: delusions, hallucinations, agitation/aggression, dysphoria, anxiety, euphoria, apathy, disinhibition, irritability/lability, and aberrant motor activity. The patients were not stratified according to their neuropsychiatric symptoms at study entry. Therefore, patients are likely to suffer from different neuropsychiatric symptoms. Most of the patients clinically improved as reflected by a decrease in the NPI total score. Symptom reduction was observed both in the control and intervention group. During their hospitalization patients get different treatment options including non-pharmacological and pharmacological interventions.

In 85% of patients, the difference in the NPI score between arrival at the hospital and discharge is positive, so there is an overall improvement. Only in 15% of cases does the NPI score worsen, in this case by 1 to a maximum of 16 points.

Table 20: Difference in NPI values recorded at resignation – hospitalization (Tirol Kliniken, Hall)

| | Improvement 21 + points | Improvement 11 to 20 points | Stayed the same or improved by up to 10 points | Slight decrease of 1 to 16 points | |
|---|---|---|---|---|---|
| | Row % | Row % | Row % | Row % | Cases |
| ***Total*** | **27** | **30** | **28** | **15** | **71** |
| ***Intervention group*** | 16 | 41 | 30 | 14 | 37 |
| ***Control group*** | 38 | 18 | 26 | 18 | 34 |

The following table shows the NPI values of the cross-referenced intervention group per phase.

| | Improvement 21 + points | Improvement 11 to 20 points | Stayed the same or improved by up to 10 points | Slight decrease of 1 to 16 points | |
|---|---|---|---|---|---|
| | Number of cases | Number of cases | Number of cases | Number of cases | Number of cases |
| ***Total*** | **6** | **15** | **11** | **5** | **37** |
| ***Sound*** | 1 | 2 | 2 | 0 | 5 |
| ***Light*** | 1 | 1 | 3 | 3 | 8 |
| ***Automatic*** | 4 | 12 | 6 | 2 | 24 |

Table 21: Difference in NPI values recorded at resignation – hospitalization by phases, only intervention group (Tirol Kliniken, Hall)

### 7.1.2 Professional caregivers

The PCTB was not significantly different in any phase. It may be that a potential therapeutic effect is masked by the course of the disease as well as by the other types of interventions. For example, all patients were treated with antidementive drugs and from case to case with antipsychotic medication.

| Phase | Klinik Hall (ALL) | Klinik Hall (PANEL) |
|---|---|---|
| Baseline | 9,9 (N=16) | 11,5 (N=10) |
| Phase 1 | 8,8 (N=15) | 9,7 (N=10) |
| Phase 2 | 8,0 (N=12) | 8,8 (N=10) |
| Phase 3 | 9,2 (N=13) | 9,9 (N=10) |

Table 22: Mean of the PCTB in the Klinik Hall (A) – Professional Care Team Burden Scale

The following graph shows the responses to the individual PCTB battery items detected in the last step, to get a recent overview of the staff workload. Some critical aspects are the possibility to participate in the organization of the daily routine in the department.

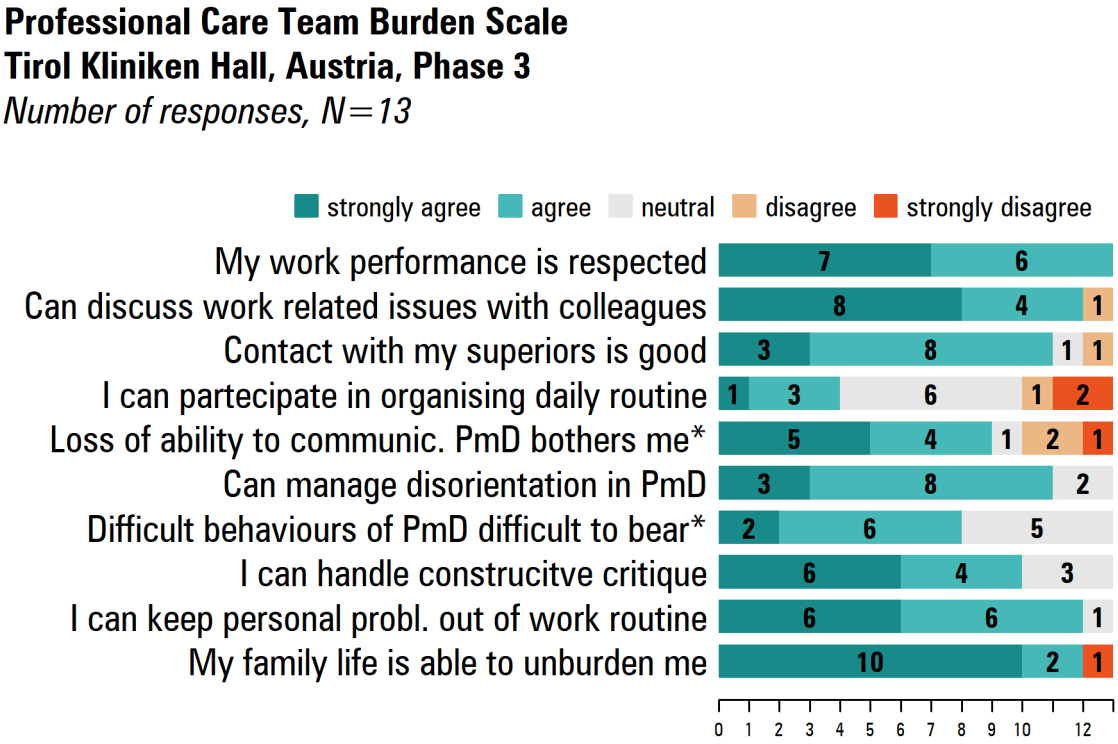



Figure 36: Tirol Kliniken Hall – PCTB of the last phase

*= *The response categories for items marked with this asterisk have been reversed.*

## 7.2 Nursing Home Griesfeld, Italy

### 7.2.1 Patients

Overall, the participants showed an **NPI** between 0 and 69 for baseline, at the end of the project the overall NPI value varied between 25 and 94. Over the course of the project time the NPI pointing has been fluctuating, for some people it was lowered and then raised, for others it was slightly raised.

| ID | Baseline 06/2018 | Phase 1 01/2019 | Phase 2 06/2019 | Final phase 12/2019 | Difference final – baseline | Average of (2+3)/2-(0+1)/2 | Great in bedroom |
|---|---|---|---|---|---|---|---|
| 1 | 11 | 4 | 18 | 32 | +21 | +18 | no |
| 2 | 13 | 32 | 5 | 28 | +15 | -6 | yes |
| 3 | 18 | 18 | 17 | 30 | **+12** | **+6** | **yes (only 1. phase)** |
| 4 | 19 | - | - | - | - | - | no |
| 5 | 69 | 29 | 23 | 75 | **+6** | **-** | **yes** |
| 6 | 9 | - | - | - | - | - | no |
| 7 | 0 | - | - | - | - | - | no |
| 8 | 0 | 7 | 28 | 25 | **+25** | **+23** | **yes** |
| 9 | 24 | 19 | 19 | 33 | **+9** | **+5** | **yes** |
| 10 | 14 | 7 | 13 | 50 | +36 | +21 | no |
| 11 | 1 | 32 | 30 | 37 | +36 | +17 | no |
| 12 | 0 | 5 | 27 | 86 | +86 | +54 | no |
| 13 | - | - | 18 | 94 | - | - | **yes** |
| | **Average 15** | **Average 17** | **Average 20** | **Average 49** | **All 34** | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | **Average panel*** **17** | **Average panel*** **17** | **Average panel*** **20** | **Average panel*** **44** | **Panel** **+27** | | |

**Table 23: NPI scores in the Nursing Home Griesfeld per patient in the intervention group and per phase**

**Average panel: only the same persons for the all duration*

Also in the control group, the NPI score has been fluctuating over the duration of the project. The difference with the control group is that in this group the NPI scores in the final phase are lower than in the baseline phase (see table below).

| ID | Baseline | Phase 1 | Final phase | Differences final phase - baseline |
|---|---|---|---|---|
| *11* | 49 | 9 | 13 | -36 |
| *12* | 25 | 2 | 0 | -25 |
| *13* | 65 | 28 | - | - |
| *14* | 39 | 30 | 37 | -2 |
| *15* | 18 | 11 | 8 | -10 |
| *16* | 30 | 13 | 29 | -1 |
| *17* | 27 | 7 | - | - |
| *18* | 46 | 34 | 27 | -19 |
| *19* | - | - | 5 | - |
| *20* | - | - | 49 | - |
| | **Average 37** | **Average 17** | **Average 21** | **(all) -16** |

| ID | Baseline | Phase 1 | Final phase | Differences final phase - baseline |
|---|---|---|---|---|
| | **Average panel 35** | **Average panel 17** | **Average panel 19** | **(panel) -16** |

Table 24: NPI – control group

The following graph shows the value of the NPI during the project only for the people who lived in the "Dependance" (intervention group) for the full duration of the field phase (May 2018-November 2019).

The figure shows that 9 people have lived in the dependance for the entire duration of the project, so data is available for all phases of the project, from baseline to end. The cases marked with dotted lines want to highlight the cases of those who had the Great system installed in their bedrooms (only for the light phase and all modules).

As confirmed also by the staff, in the last few months there has been for a couple of people a worsening of health due to the advance of the disease.

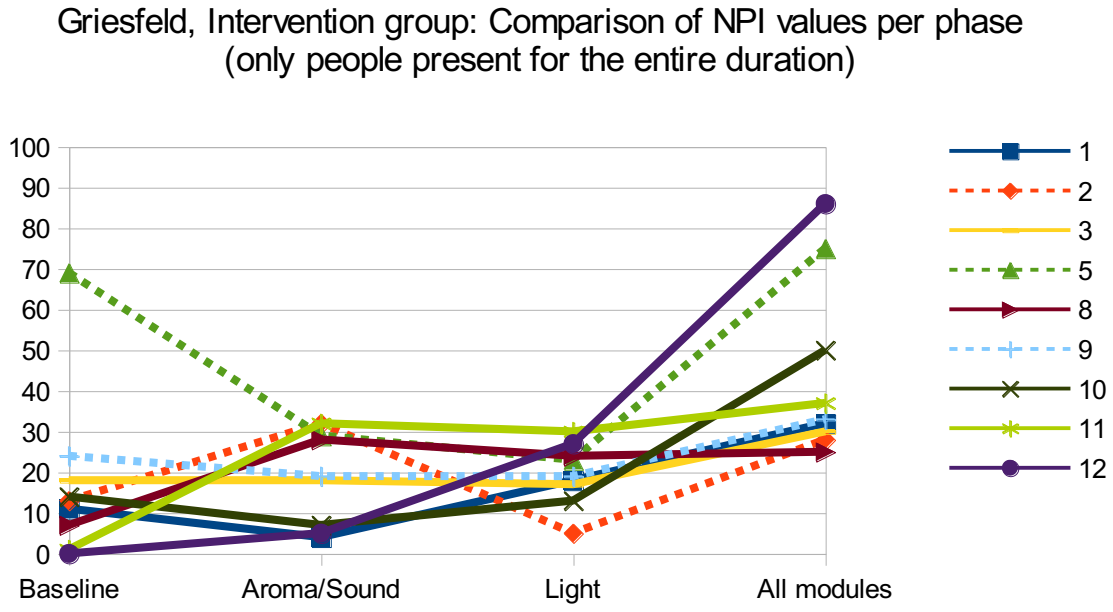



Figure 37: Griesfeld - Comparison of NPI values per phase (only people present for the entire duration)

The differences that have emerged between the intervention and control groups are mainly due to the different stages of the patients' disease. The differences that emerged during the project phases are not statistically significant.

### 7.2.2 Professional caregivers

As can be seen from the table below, the score derived from the professional care team burden questionnaire is low and remains fairly stable throughout the project in both groups (intervention and control). The average per group and phase varies from a minimum of 7 to a maximum of 10 points.

| Phase | Griesfeld<br>Intervention group | Griesfeld<br>Control group |
|---|---|---|
| Baseline | 9,6 (N=8) | 8,3 (N=9) |
| Phase 1 | 7,0 (N=8) | 8,9 (N=8) |
| Phase 2 | 7,0 (N=8) | (not detected) |
| Phase 3 | 8,0 (N=8) | 10,0 (N=9) |

**Table 25: Mean of the PCTB in the senior home Griesfeld (I) – Professional Care Team Burden Scale (all the caregivers)**

The following graph shows the answers to the single items of the PCTB battery detected in the last phase for the intervention group: in this group the aspect considered as the most onerous is the difficulty of managing the difficult behaviour of some people with Alzheimer's disease.

**Professional Care Team Burden Scale**
**Nursing Home Griesfeld, Italy - control group, Phase 3**
*Number of responses, N=8*

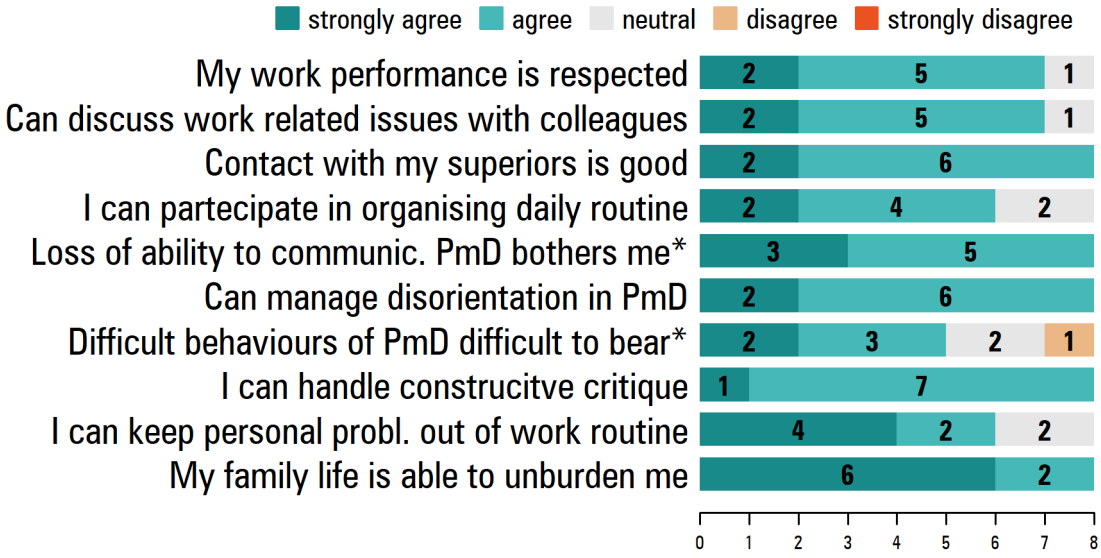



**Figure 38: Griesfeld – PCTB of the control group, last phase**

**= The response categories for items marked with this asterisk have been reversed.*

Even considering the panel group (same people throughout the project), the trend remains similar. The small differences between group and phase are not statistically significant.

| Phase | Griesfeld - panel Intervention group | Griesfeld - panel Control group |
|---|---|---|
| Baseline | 11,5 (N=4) | 8,7 (N=7) |
| Phase 1 | 8,3 (N=4) | 8,3 (N=7) |
| Phase 2 | 9,5 (N=4) | (not detected) |
| Phase 3 | 8,8 (N=4) | 9,7 (N=7) |

**Table 26: Mean of the PCTB in the nursing home Griesfeld (I) – Professional Care Team Burden Scale (only the same caregiver)**

Some significance tests have been carried out and from the test result, it is possible to conclude that:

- *T-test for independent sample, phase 0*: there is not a statistically significant difference in the mean PCTB score among the two groups during Phase 0;

- *T-test for independent sample, phase 1*: there is not a statistically significant difference in the mean PCTB score among the intervention and the control group during Phase 1.
- *T-test for paired samples, intervention group, phase 0 and phase 1*: there is not a statistically significant difference in the mean PCTB score among phase 0 and phase 1 for the intervention group.
- *T-test for paired sample, control group, phase 0 and phase 1:* there is not a statistically significant difference in the mean PCTB score among phase 0 and phase 1 for the control group.
- *ANOVA for repeated measurement, intervention group, phase 0, phase 1 and phase 2*: From the ANOVA result, it is possible to conclude that there is not a statistically significant difference in the mean PCTB score among the three phases for the intervention group.

### 7.3 Switzerland

#### 7.3.1 NPI and WIB

Overall, the baseline **NPI** of the participants was between 9 and 60, after the intervention between 8 and 70. The range of change is between -24 to 33, indicating that individuals have very pronounced positive and negative changes. At baseline, the WIB mean value of activity/interaction ranged between -0.7 and 1.3, indicating slightly negative and neutral to slightly positive values.
Immediately before a light or aroma impulse was triggered by a nurse or caregiver, **WIB** mean values of -1 to 1.4 were observed, which can be interpreted in the same way. During the intervention with light and aroma, WIB mean values of -1.5 to 1.3 were observed, so that overall no clear changes were visible.

# 8. Usability and acceptance of the Great-System

At the end of the trials, in December 2019, the nursing staff in Italy and in Austria responded to a questionnaire on usability acceptance of the Great System and focus groups were conducted in all the facilities where the field tests were carried out.

The usability of the Great System was detected using the SUS questionnaire, It consists of a 10 item questionnaire with five response options for respondents; from Strongly agree to Strongly disagree. Originally created by John Brooke in 1986, it allows to evaluate a wide variety of products and services, including hardware, software, mobile devices, websites and applications.

## 8.1 Results of the focus group

### 8.1.1 The focus group in Austria

The focus group was conducted with the care staff of the A4 station, prof. *Josef Marksteiner* and project collaborator Cornelia Heubacher.

**The use of the Great system**

*Why didn't you use it specifically?*

Tuning light-scent and sound was difficult at the beginning - due to the manual control of the individual modules (no automatic activation triggered). The serial application of these modules posed great challenges for the nursing staff. Especially the application of the sound module showed several difficulties:

1. the patients' reaction to natural sounds was very different. One main problem was that cognitively impaired patients were not able to distinguish between the applied sounds and real sounds from the environment.
2. at the beginning the intensity and the type of scent had to be adjusted. A too intensive scent was perceived as irritating. As soon as it was possible to better coordinate the modules, the willingness to use them increased.

**Reaction and effect**

*How did the people with dementia react to the offer (light, sounds, aroma)?*

The reaction was only partially predictable. The way in which individual patients react to the modules depends not only on cognitive limitations but also on any neuropsychiatric symptoms that may be present. Patients with psychotic symptoms, such as influencing ideas and hallucinations were generally more irritable.

*Did the systems have an effect on people with dementia?*

In any case, the modules had an effect on the people with dementia. By far the light application was the best intervention. The predictability of the reaction was also best with light modulation. In the course of the observation phase, it was shown that a dynamic light application had the highest acceptance among people with dementia. The observation of the nursing staff was identical.

**Benefits**

*How did the people with dementia react to the offer (light, sounds, aroma)?*

About 2/3 of patients with dementia showed an improvement in neuropsychiatric symptoms and behaviour. Caregivers also appreciate the additional intervention

options. Here it was shown that the application of light is seen to be most effective. It could be clearly shown that the effectiveness is better with continuous application over several weeks.

*If no benefit, what would have to be done to generate/maintain a benefit?*

In order to maintain the benefit for a longer period of time, a continuous, constant application is necessary. Changing the application mode for a short period of time, such as changing the light intensity, the fragrance intensity is rather unfavourable.

*Did the use of the modules have an effect on your work?*

The optimal application and evaluation of the reaction (on the tablet) of people with dementia was an additional workload. This effort increased if technical difficulties occurred (tablet charging cable defective). The functionality of the tablet was also decisive for acceptance and effort.

*Were there any negative aspects?*

As already mentioned, additional workload. At the beginning of the application, a certain uncertainty about how different people with dementia would react to the application.

*Were there any positive aspects?*

The positive aspect was that these applications extend the nursing possibilities. These applications complement the existing possibilities to effectively influence behavioral problems. Furthermore, an additional effect could be noticed how environmental conditions can affect behaviour.

*What potential does the offer have to relieve you in your work?*

An optimized, personalized offer is certainly a relief. One result is that in the future more attention should be paid to light, scent and sound in the care of people with dementia. In particular, the application of light could better prepare patients for subsequent activation. The mobilisation of these patients was better possible after activation.

*What have we learned?*

The group of people with dementia is a heterogeneous group. The challenge is to create an individualized program. It has been shown that an identical stimulation can cause different reactions. Possibly the application of all 3 modules is more suitable for single patients than for a group of people with dementia.

*Has it brought relief?*

In the beginning the application was an additional effort, the more standardized the settings of the modules were, the less work was needed and our acceptance of these modules increased.

*What new stress and strain situations might have arisen?*

For the patients, stress and strain situations have arisen because the form of application was unsuitable, e.g. noises that could not be assigned, noises that induced anxiety or strong smells that were perceived as disturbing. A further difficulty in some patients was the limited ability to verbalise these stressful situations. They showed themselves to be more restless, agitated, without being able to consciously respond to the irritation caused by the application.

### 8.1.2 The focus group in Italy

On 4 December 2019, the final focus group of the Great Project took place at the Griesfeld nursing home in Egna. It was attended by the director, an administrative assistant who followed the whole project and 4 assistants from the Dependance. The focus group was led by Apollis (Hermann Atz and Elena Vanzo).

At the beginning of the discussion Apollis briefly summarized the most important phases of the project and then moved on to the actual discussion.

**The use of the Great system**

The first topic was the use of the system in general. The staff reported that at the beginning of the project the motivation was very high, as well as expectations. In general, caregivers stated that the system was mainly used to relax and calm, activation was used much less.

The first module tested was the **aroma module**: here it must be remembered that the Griesfeld nursing home already uses aromatherapy regularly and that several caregivers have taken part in training courses on this subject. The staff reported that in their opinion the aroma module did not bring the desired results: the aroma splashes were almost imperceptible. In addition, the Dependance consists of a large open room with the kitchen in the middle, and the odors from the kitchen covered the aroma sprayed by the Great module.

As for the **sound module**, the caregivers agreed that they would use sounds more often if they were more convincing. At first the caregivers were curious and used it more often, then for some it was annoying and was used less. For example, they reported opinions on the "sea" sound: in this case, for some elderly women, listening to this sound caused agitation (especially those who had never been to the sea and connected the noise to an oncoming thunderstorm). While some caregivers have

benefited from these sounds particularly in their daily breaks, the same cannot be said for older people.

As far as the **lighting module** is concerned, the staff reported that in the room adjacent to the kitchen the Great lamp was mainly used for relaxation (although there is plenty of natural light in this room). Regarding the use in the two bedrooms, the assistants reported mainly problems (too much light, lamp that did not turn off, ...).

In general, the assistants complained about various **technical problems** that arose during the various phases of the project: the tablet was often blocked or the connection was interrupted, the modules turned on sometimes did not turn off. Even though the technical problems did not emerge so often (Apollis note), they still seem to have left a negative image.

**Reaction and effect**

*How did the people with dementia react to the offer (light, sounds, aroma)?*

The answers to this question focused mainly on some issues: in the final phase, for example, all three modules started together, and it seems that this was almost annoying for some people, which caused anxiety. The second point is that the assistants say that they do not have an overview of what is happening in the rooms due to the workload and so in addition to reporting some problems with the lighting too loud, small technical problems have said that they have not observed many reactions of the elderly to the Great modules. In the manual startup phase they were not used as frequently as the worktop required.

*Have the systems had an effect on people with dementia?*

In this case the answers were different: some caregivers said that over time it had become a habit that was no longer really perceived.

Some elderly people reacted with fright to the sound of the sea, others got a bit agitated. When it comes to the effect of the Great modules on patients, caregivers are unable to express an opinion, it seems that they did not observe any reaction. And in case there was a reaction, they cannot say whether it was Great, the effect of the medicines, the effect of their care or other therapies. With 11 people to assist, it is very difficult to observe any reactions.

**Benefits of the Great System**

The staff responded that they used the system not as often as required because they did not see a usefulness and it was not even useful for their work. By the end of the project, Great was seen more as a burden than a support for their work.

The staff also said that it is not possible to influence group dynamics: often there are people at a table who should be calmed down, others who should be activated.

Moreover, we must not forget the effect of drugs and other therapies (Bach flowers, aromatherapy, pranotherapy, ...) and so it is very difficult to say what influenced the patients' behavior and mood.

According to some assistants, it would have been better to focus on 1-2 elderly people and test the modules only on them, in a group situation is too difficult, there are too many dynamics, too much movement.

Another aspect to consider is that compared to the situation at the beginning of the project (summer 2018), now (end 2019) the situation of patients has changed a lot, health has generally worsened because of the disease.

**System potential**

In the opinion of some caregivers, it would be interesting to test the Great system in private apartments, where a person usually follows an elderly person and therefore it is easier to observe reactions and changes in behavior, mood, Day-Night Rhythm.

Another proposal made by the staff to increase the effects of Great would be to install the system in two separate rooms: one dedicated to activation and one dedicated to relaxation.

At the end of the discussion, the director pointed out her interest in installing the Great cabin (prepared by FHV) at the Griesfeld nursing home to raise staff awareness of the potential of sound and lighting. According to the director, when you experience for yourself what sound can do to your psyche it is perhaps easier to recommend it or use it for others. The cabin allows to observe changes in the heartbeat (relaxation or activation) and seeing the result visibly makes it easier to perceive the effect, which is perhaps not perceived without actually seeing it. Many people are too focused on the visual aspect and do not realize that there are invisible effects.

### 8.1.3 Final interviews in Switzerland

Two interviews were conducted in two of the three participating nursing homes. One interview took place with the manager who had not triggered the impulse herself, but who accompanied the intervention phase. The second interview was conducted with two nurses directly involved in all phases. In addition, situational interviews were conducted with the persons with early-stage dementia (n=2), the relatives (n=5), the nursing staff (n=13) and the management (n=5). Whilst two out of the three nursing homes or special care units felt positive about the system and want to continue using it, the third was less enthusiastic, esp. because of the additional effort this might imply (which were mostly due to initial technical problems and obstacles to implementation).

**Conclusions**

Based on the results derived from the different methods we can draw the following conclusions:

- No clear proof of effectiveness is possible due to the practical field and research circumstances (e.g. for ethical reasons, the upper arm sensor for capturing heartrate variability for measuring stress had to be worn by the caregiver or nurse rather than the person with dementia)
- There is no evidence that the light and aroma impulses have a negative effect on the presence of persons with dementia.
- Challenging behaviours seem to change. However, there is no evidence from the structured and standardised data collection procedures that light and aroma impulses contribute to a mitigation of challenging behaviours.
- The attitudes and expectations of the impulse-giving persons appears to have a major impact on the anticipated spectrum of effects.

## 8.2 Results of the SUS-Questionnaire in Austria and Italy

The 10-item SUS questionnaire (Reference: Brooke, J. (1986). "SUS: a "quick and dirty" usability scale". In P. W. Jordan, B. Thomas, B. A. Weerdmeester, & A. L. McClelland (eds.). Usability Evaluation in Industry. London: Taylor and Francis.) is a measure of a user's perception of the usability of a "system."

The SUS questionnaire is scored by combining the 10 items into a single SUS score ranging from 0 to 100. Based on research, a SUS score above a 68 would be considered above average and anything below 68 is below average. To calculate the total sum, a formula is used that differentiates between even and odd questions.

### 8.2.1 Scent module

The graph below shows the answers to the individual items of the SUS questionnaire related to the aroma module provided by the staff of the Nursing Home Griesfeld and the Tirol Kliniken Hall. The responses to the individual items of the two structures considered offer partly similar and partly slightly different evaluations. Griesfeld's staff are more likely to use the aroma module frequently than Hall's staff, both groups say that people can learn to use the system quite quickly, although in general the responses are not very positive.

**SCENT MODULE: Agreement with statements concerning usability (SUS)**
*mean between 1=strongly disagree and 5=strongly agree*

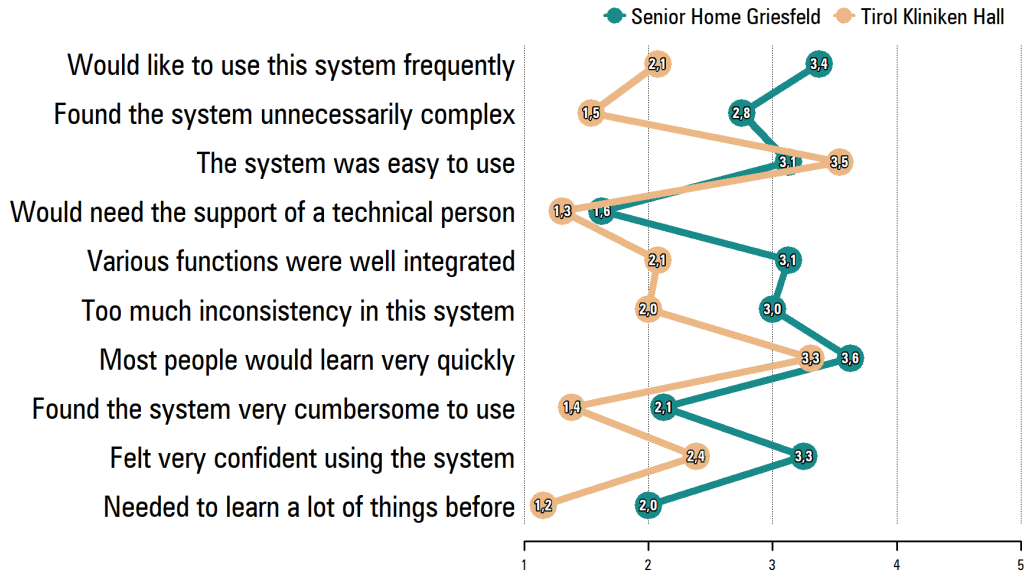



Figure 39: Agreement with statement concerning usability – scent module

Out of 21 people who answered the questionnaire, only 8 reach an overall score higher than 68 (see figure below).

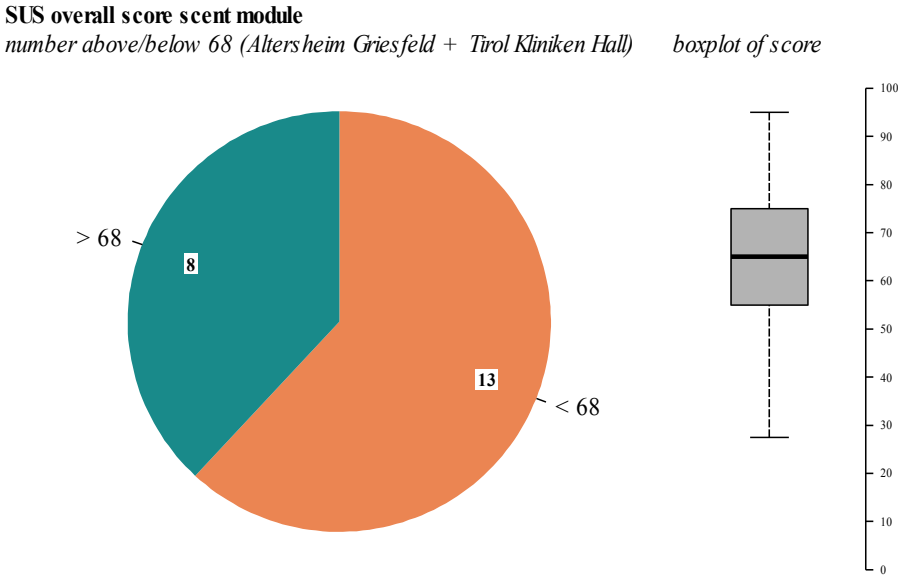



Figure 40: SUS overall score – scent module

### 8.2.2 Sound module

The following graph shows the average response to individual items on the sound module by structure.

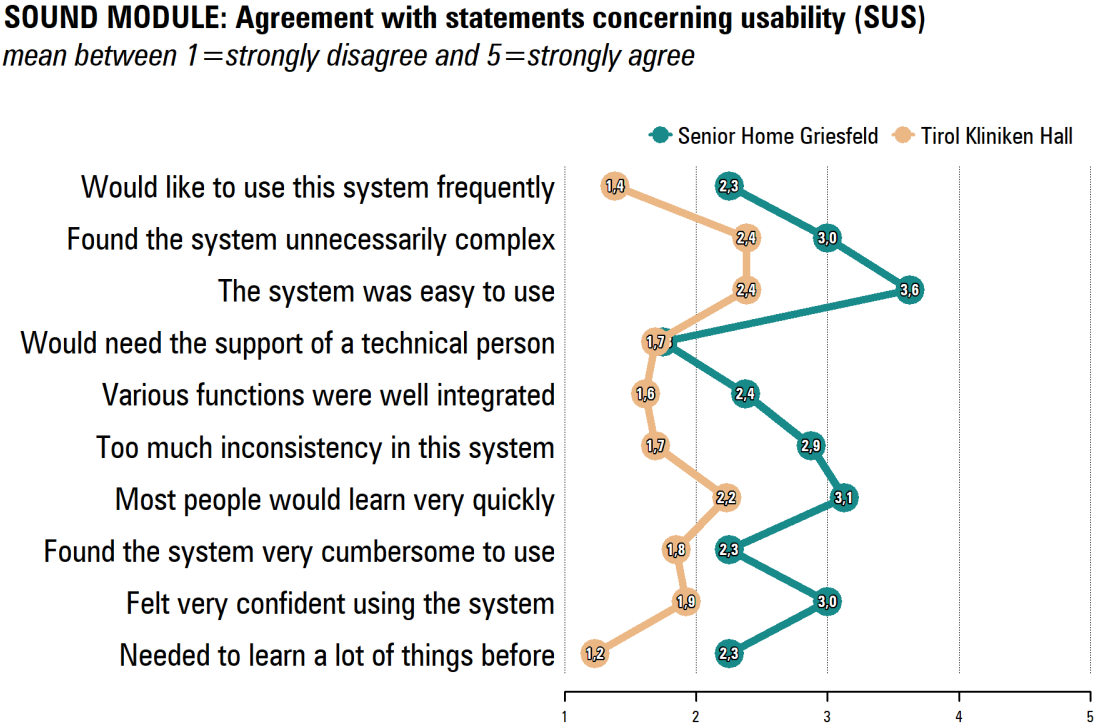



Figure 41: Agreement with statements concerning usability - sound module

In the case of the sound module only 3 out of 21 people give an overall score that exceeds 68. The sound module proves to be the least "understood" by the care staff.

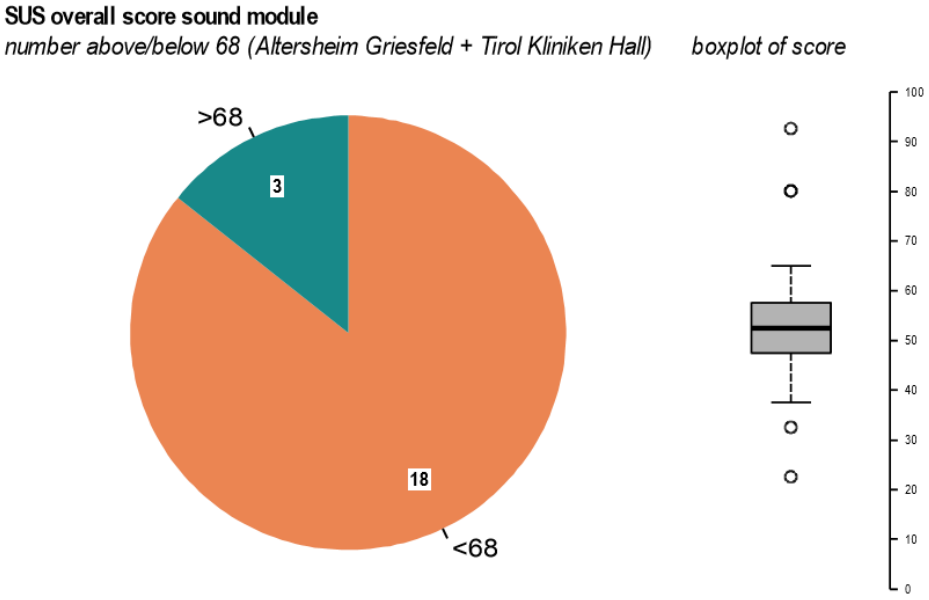



Figure 42: SUS overall score – sound module

### 8.2.3 Light module

The usability of the light module is the one that was judged to be the most different from the two facilities: the staff of the Tirol Kliniken Hall give decidedly better votes than the staff of the Egna nursing home.

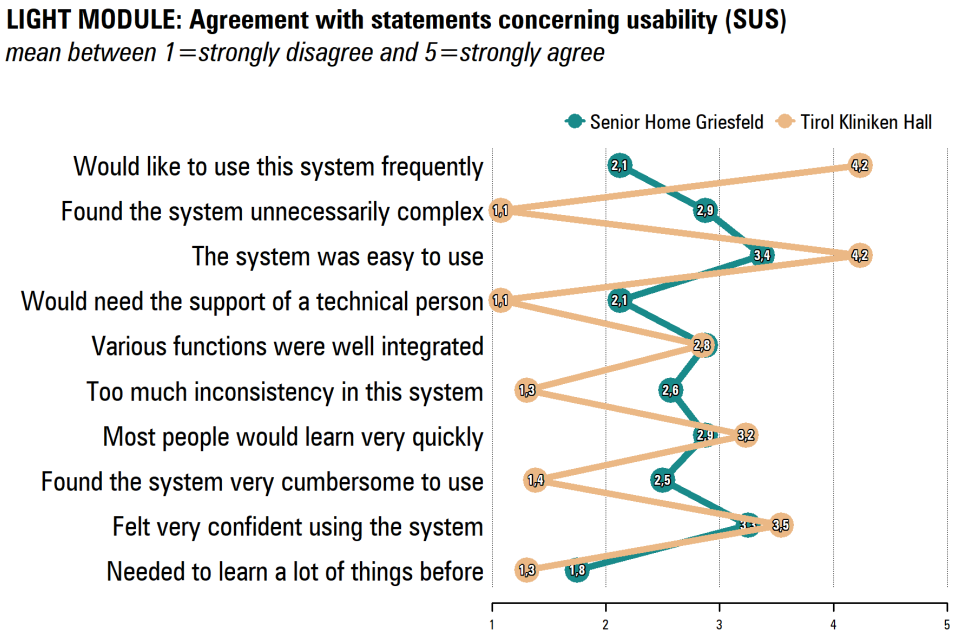



Figure 43: Agreement with statements concerning usability – light module

In total, two thirds of professional care givers rate the usability of the light module positively, with the median reaching almost 80 points.

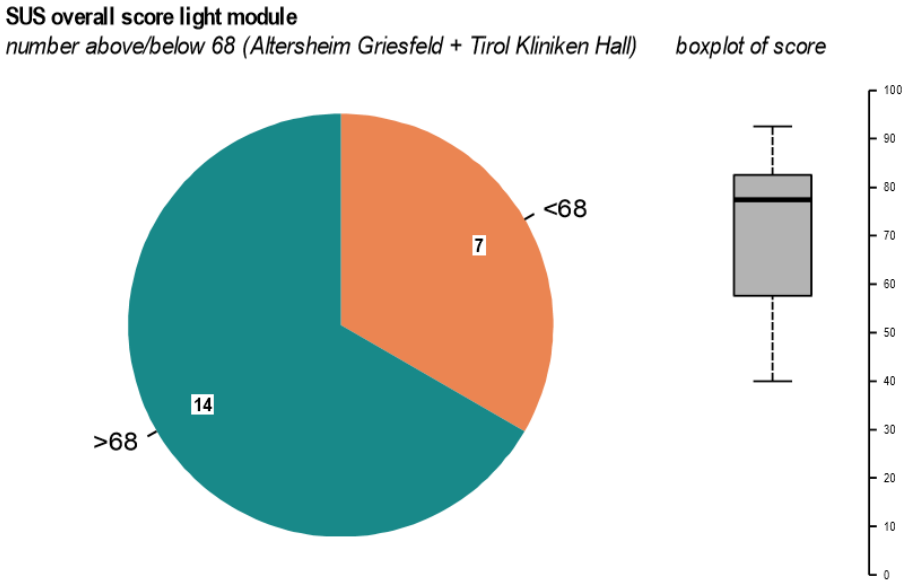



Figure 44: SUS overall score – light module

## 8.3 Results of the SUS-Questionnaire in Swiss

In the Swiss, the SUS-questionnaire interviews were conducted in two of the three participating nursing homes: in St. Otmar and in Bürgerspital. One interview took place with the manager who had not triggered the impulse herself (Bürgerspital), but who accompanied the intervention phase. The answers to the questionnaire were not included in the data set of the Hall clinic and the Griesfeld nursing home because in the latter the questionnaire was filled in by the entire staff and the questionnaire was distributed in Switzerland by one person per facility and also because in Switzerland it was chosen to answer 8 out of 10 items, so it is difficult to make a comparison with the other questionnaires. Remembering that the answers to individual items were given by one person per care facility, the answers are quite different.

**SCENT MODULE: Agreement with statements concerning usability (SUS)**
*Number of answers between 1=strongly disagree and 5=strongly agree*

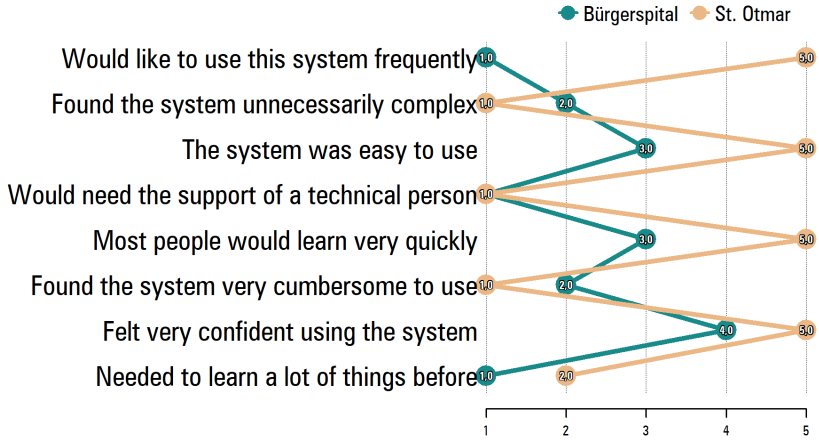



Figure 45: Agreement with statements concerning usability, scent module (Swiss)

**LIGHT MODULE: Agreement with statements concerning usability (SUS)**
*Number of answers between 1=strongly disagree and 5=strongly agree*

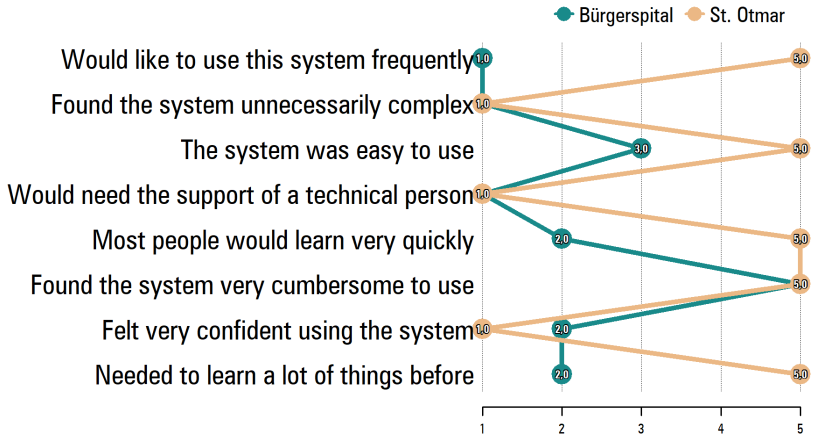



Figure 46: Agreement with statements concerning usability, light module (Swiss)

### 8.4 Comparison of the SUS overall score

This summary table of the SUS questionnaire values per structure and per module shows the differences in the evaluation of the staff: the usability of the lighting module is judged very good by almost all the Hall clinic staff and the aroma module by about half of the staff. The audio module is the one that receives the lowest values and in general the staff of the Griesfeld nursing home is the one that assesses the usability of the three modules most negatively.

| | Aroma | | Sound | | Light | |
|---|---|---|---|---|---|---|
| | **< 68** | **> 68** | **< 68** | **> 68** | **< 68** | **> 68** |
| ***Nursing Home Griesfeld (I)*** | 6 | 2 | 7 | 1 | 6 | 2 |
| ***Tirol Kliniken Hall (A)*** | 7 | 6 | 11 | 2 | **1** | **12** |
| ***Total*** | 13 | 8 | 18 | 3 | 7 | 14 |

**Table 27: SUS overall score, number of cases**

# 9. Conclusions

The GREAT system showed the intended effect in some aspects of its field of activity, but this could not be adequately perceived by the nursing staff. For example, the activity in the room with dementia patients was significantly lower after the relaxation intervention and significantly higher after activation intervention than before the intervention. In the initial situation (i.e. before the GREAT intervention was initiated) the activity in the room was also higher in the case of a relaxation intervention than in the case of an activation intervention. The same clear picture emerges when measuring the vegetative activity of caregivers.

Looking at the neuropsychiatric symptoms of dementia patients, the picture is less clear. However, 66% of the dementia patients in the intervention group showed an improvement in neuropsychiatric symptoms after using the GREAT system, only 51% in the control group did so during the same observation period (both groups also received conventional medical treatment). At this point it must be noted that over a

longer period of time (in our case 19 months) the negative course of the neurodegenerative disease cannot be stopped.

The differentiated evaluation of the individual GREAT interventions (light, aroma, sound and their combinations) in the field study is again based on objective measurement data. Looking at the data on movement activity, it appears that the separate use of light, aroma and sound supports activation in particular, while the combined use of light, aroma and sound supports calming in particular. Interestingly, caregivers rate the combination of light, aroma and sound worse than the separate use of light, aroma and sound.

We therefore conclude that the GREAT system can be used for dementia patients in the case of agitation and depression. Not only in the pre-test but also in the field study, evidence for the optional relaxing and activating effect could be provided. As the concluding focus group discussion showed, before the GREAT system can be commercialized, it must be ensured that the observed initial difficulties in introducing the system (e.g. care plan, control) have been overcome.