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 GREATsystem 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.

	intervo	entions	mean of movements			
	frequencies	percentage	before	after	tendency	
household A (tests and demos Vorderlandhus since April 2019)	28	2	37	20	Ŕ	
household A (tests and demos Vorderlandhus since April 2019)	172	12,5	14	12	И	
Gritt Heim, CH	7	0,5	7	6	~	
Hall Klinik, sitting room	203	14,8	22	18	R	
Hall Klinik, care room 1	248	18	21	23	Z	
Hall Klinik, care room 2	227	16,5	40	35	R	
Neumarkt Heim Griesfeld rest room	174	12,7	11	11	~	
Neumarkt Heim room 228	120	8,7	12	13	Z	
Neumarkt Heim room 229	158	11,5	28	24	Ы	
St. Otmar Heim, CH	20	1,5	14	20	~	
Bürgerspittal, St. Gallen sitting room	17	1,2	43	40	Ы	
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		ai	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 durati	on of the intervent	ion affect th	e movem	ent <u>during</u> the int	ervention?		
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 me	ovement	5
	frequencies	percentag	ebefore	after	tendency
household A (tests an demos, Vorderlandhu since april 2019)		2,4	19	9	Ч
household Switzerland (Sargans, only scent)	² 112	5,8	9	12	7
Gritt Heim	4	0,2	8	18	~
Klinik Hall, sitting room	223	11,6	23	18	Ы
Klinik Hall, care room 1	383	19,9	22	35	7
Klinik Hall, care room 2	392	20,3	27	40	7
Neumarkt, resting room	291	15,1	19	19	~
Neumarkt, room 228	159	8,2	15	15	~

St.Otmar Heim, St Gallen	25	1,3	15	15	~
Bürgerspittal St. Gallen	3	0,2	17	31	~
Klinik Hall, ambulanc room	^e 78	4,0	19	25	ת

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 thre together	e 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 intervent	ion affect th	e movement o	during the inte	ervention?
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 GREATsystem 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.

The average heartrate increases during activation and decreases during relaxation. Sample size is n = 24.

There are a few outliers for both events, but median and average value are as expected.



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







• Neumarkt Heim









Heim Bürgerspital





• Heim St. Othmar





- 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





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.

	Improvemen t 21 + points	Improveme nt 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

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

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

	Improvement 21 + points	Improveme nt 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.

Professional Care Team Burden Scale Tirol Kliniken Hall, Austria, Phase 3

Number of responses, N = 13

My work performance is respected Can discuss work related issues with colleagues Contact with my superiors is good I can partecipate in organising daily routine 1 Loss of ability to communic. PmD bothers me* Can manage disorientation in PmD Difficult behaviours of PmD difficult to bear* I can handle construcitve critique I can keep personal probl. out of work routine My family life is able to unburden me



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*	Average panel*	Average panel*	Average panel*	Panel	
17	17	20	44	+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	
<mark>15</mark>	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	

I	D	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	Griesfeld
	Intervention group	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	Griesfeld - panel		
	Intervention group	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

Would like to use this system frequently Found the system unnecessarily complex The system was easy to use Would need the support of a technical person Various functions were well integrated Too much inconsistency in this system Most people would learn very quickly Found the system very cumbersome to use Felt very confident using the system Needed to learn a lot of things before



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).





8.2.2 Sound module

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

SOUND MODULE: Agreement with statements concerning usability (SUS)

mean between 1-strongly disagree and 5-strongly agree



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.





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

LIGHT MODULE: Agreement with statements concerning usebility (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.

It is equally ambiguous about the subjective self-assessment of the burden on caregivers. After half a year, both the intervention group (using the GREAT system) and the control group of nurses estimated their own burden of caring for dementia patients as lower. However, after one year, the control group indicated that their burden had returned to the original level, while in the intervention group the self-assessment remained at the improved level.

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.