FINAL EVALUATION REPORT BASED ON THE TRIALS

Deliverable D3.7

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EXECUTIVE SUMMARY

This documents details data collection, statistics and on the results of the clinical study of the FreeWalker system trial phase in WP3 conducted between November 2020 and June 2021.

The study took place in end user organization in three countries Austria, Switzerland and The Netherlands. The ongoing COVID-19 Pandemic and concomitant restrictions significantly complicated the conduction of the field trial. Due to the intended study population in the Netherlands (exclusively clients residing in caregiving homes run by partner Tante Louise), the country was most affected by the restrictions which were most strict in the setting of intramural care. Five persons were initially randomized, but the study had to be terminated prematurely before any additional clients could be enrolled or any data could be collected due to the worsening of the pandemic situation. In Switzerland 15 persons were enrolled in the extramural setting initially, but further recruitment proved difficult partly because clients were not willing to participate in the control arm of the study. In Austria, 30 clients were enrolled as planned of which 22 completed the trial.

To ameliorate the impact of the COVID-19 pandemic on the field trial, the start of the trial was shifted several times and the project was extended for a full three month, to avoid conducting the trial during the winter month when the COVID-19 pandemic is most severe and to capitalize on the vaccination rollout. Since recruitment proved to be unsatisfactory nonetheless, an additional, less formal usability study was designed and conducted by partners Tante Louise, Vilans and TerzStiftung to gain additional data. The results are reported in D3.4.

Since the field trial was shifted towards the end of the project, analysis of the data collected is ongoing at this point. Preliminary results of the Austrian cohort, which provides the most extensive dataset, suggest the following key points:

(1) In clients who express concerns when leaving their home, FreeWalker might be able to ameliorate those concerns. However, the sample size is too small to draw any definite conclusions at this point.
(2) Customer Satisfaction and measures of system usability were underwhelming despite extensive research during product development. Additional effort is needed to develop a product that better fits the needs of the target population.
(3) In our study population, willingness to pay for a service like FreeWalker was high.

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1 INTRODUCTION

1.1 Scope of the document

This documents details data collection, statistics and results of the clinical study from the FreeWalker system trial phase in WP3 in November 2020 to June 2021.

1.2 Relation to other project documents

D1.3 "Specification of System Architecture" explains the FreeWalker zone concept and alarming processes

D3.1 "Ethical approvals, [..]" reports on ethical approval process for the study and recruiting process and progress

D3.2 "Assessment protocol and data collection process" explains the principle study concept and outcome parameters

D3.4 "Test results of the active groups" reports on a Usability Study that was performed in parallel to the clinical study in Switzerland and The Netherlands to mitigate low population/high drop-out rates there.

1.3 Contributions of partners

Partner	Chapter	Description of Contribution
AIT	2	data collection, statistics on data
KEP	2, 3, 4	Data collection, evaluation, results

1.4 References

1.5 Acronyms and Conventions

Acronym	Explanation	
AAL	Active Assisted Living	
N/A	Not Applicable	
LS	Location Service	(FreeWalker System component)
LE	Logic Engine	(FreeWalker System component)
GNSS	Global Navigation Satellite System	
CSV	Comma Separated Values	(a data-file format)
AT	Austria	
CH	Switzerland	
NL	The Netherlands	
PEU	Primary enduser (person with cognitive impairment)	
CG	Caregiver (person caring for the PEU)	
SCI	Subjective cognitive impairment	

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MCI	Mild cognitive impairment	
MoCA	Montreal cognitive Assessment Score	A measurement for cognitive impairment (max. 30 points, higher is better)

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2 DATA COLLETED DURING THE TRIAL

2.1 Duration of automatic data collection

The clinical study is based on data collected by the FreeWalker system components during the trial phase of the system from November 2020 to June 2021. The majority of the data collected automatically was taken from positions reports of the GNSS tracking devices that the subjects (study group and control group) were wearing or carrying when being outside. Further data was derived from the "client states" that the FreeWalker system calculated to assess the condition the client is in, and issue alarm to the carers if needed (study group only).

For each subject of control group or study group, the actual participation time in the study was recorded and is given in Appendix 1. Data produced by the GNSS trackers or the FreeWalker system components, such as alarms or so-called "clients states" outside of these times, have not been taken into account for the evaluation. If an entry date before the FreeWalker system was announced to be ready for trial operation, in Nov. 2020, was reported by the end user organizations, data was evaluated only from the later date on. This may have happened in cases when devices were handed out by end user organizations earlier than trial start, to study participants for familiarization.

Appendix 2 gives an overview of drop-out reasons.

Table 1: total participants in clinical study for the three test countries with drop-outs

	AT	CH	NL
Started	30	15	5
Drop outs	8	5	5

2.2 Parameters extracted from GNSS and client states for evaluation

Parameters to extract from data collected and produced by the FreeWalker system components Location Service (LS) and Logic Engine (LE):

LS export location data

- Distance walked per day (in meters) for Freewalker users and control group
- Average Walking Speed per day (in km/h or m/s) for Freewalker users and control group
- Time FreeWalker is worn outside per day (in minutes) for Freewalker users and control group

LE logs all positions with status flags/states, computed in post-processing:

- Time in Green Zone per day (in minutes) for Freewalker users
- Time exploring / day (min) , i.e. Time in Orange Zone per day (in minutes) for Freewalker users
- Number of Red Orange Zone Violations (OutOfZone) per day for Freewalker users
- Time from Orange Zone Violations (OutOfZone) until back in green zone for each incident (min) for Freewalker users

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Data of alarm history logs:

- Number of primary client induced alarms per day [by pressing the alarm button]
- Time between alarm button press and reaction of the CareGiver [alarm acknowledged] for each incident (min)
- Time between "OutOfZone" Alarm and reaction of CareGiver [alarm acknowledged] for each incident (min)

2.3 Data files produced and their format

The results of the post-processing steps are provided as CSV files, one file per study subject, in the following format:

FreeWalker group format

date	no_sig_night	no_sig_day	time_g_zone	time_o_zone	time_out_zor	time_f_zone	time_gps_ou	nr_zone_vio	dist_m	speed_ms
03.02.2021	479	958	0	0	0	0	0	0	-1	-1
04.02.2021	479	417	0	0	0	0	0	0	-1	-1
05.02.2021	479	393	52	112	12	0	180	4	6739	0.85
06.02.2021	469	960	0	0	0	0	0	0	-1	-1
07.02.2021	471	960	0	0	0	0	0	0	-1	-1
08.02.2021	479	503	33	0	0	0	33	0	1082	0.97
09.02.2021	480	960	-1	-1	-1	-1	-1	-1	-1	-1
10.02.2021	479	954	0	0	0	0	0	0	-1	-1
11.02.2021	480	960	-1	-1	-1	-1	-1	-1	-1	-1
12.02.2021	479	526	0	0	0	0	0	0	-1	-1

Control group format

date	no_sig_night	no_sig_day	time_gps_ou	dist_m	speed_ms
30.11.2020	458	960	0	0	0
01.12.2020	61	0	0	-1	-1
02.12.2020	414	321	14	276	1.61
03.12.2020	141	53	67	330	0.73
04.12.2020	79	0	50	1049	0.85
05.12.2020	163	780	0	-1	-1
06.12.2020	480	960	-1	-1	-1
07.12.2020	480	960	-1	-1	-1
08.12.2020	480	960	-1	-1	-1
09.12.2020	361	859	0	-1	-1
10.12.2020	26	-3	71	572	0.88

Incident duration file

incidentStartDate	incidentDuration
2020-11-25T10:26:11.993031Z	12
2020-11-28T15:37:13.170778Z	53
2020-11-29T11:01:23.824260Z	21
2020-11-29T14:09:48.776112Z	117
2020-11-29T16:07:34.075930Z	1
2020-12-09T05:04:28.626043Z	33
2020-12-09T10:38:15.853184Z	66
2020-12-11T08:26:15.009692Z	11

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A value of "-1" means, that there were no locations or not valid locations to process for this item. The figure shows the initial values.

All data were extracted only between the recorded entry and exit times of study participation for each subject as reported by the end user organisations (see Appendix 1).

Predefined Values:

- Definition of day time: From 6:00 am to 21:59 pm
- Definition of night time: From 22:00 pm to 5:59 am
- “Close2Home” means the subject is less than 100 m from home location
- Trusted value: set to 10 minutes. This is the value in minutes to be trusted that the current state or location is still valid. Without this value every “OutOfZone” event or other time measuring would be canceled if there is no location of e.g. 2 minutes.
- All durations are given in minutes.

Headline/field names explanation:

- “date”: the date of the specific evaluated day
- “no_sig_night”: the total duration for which there was no signal during night time. Every signal has a trusted value of 10 minutes, so if there is a location or a state at a specific time, we expect that this location or will be valid for the next 10 minutes if there are no other states.
- “no_sig_day”: the total duration for which there was no signal during day time. Every signal has a trusted value of 10 minutes, so if there is a location or a state at a specific time, we expect that this location will be valid for the next 10 minutes if there are no other states.
- “time_g_zone”: total duration with state “Outside”
- “time_o_zone”: total duration with state “ExploringZone”
- “time_out_zone”: total duration with state “OutOfZone”
- “time_f_zone”: total duration with state “ForbiddenZone”
- “time_gps_outside”: total duration the tracker device is worn outside (i.e. not "close2home") Note: Due to the common GNSS inaccuracy a 100% reliable detection if a subject is really "at home" is impossible.
- “nr_zone_vio”: number of zone violations at this day
- “dist_m”: walked distance of this day (in meters)
- “speed_ms”: mean walking speed in meters per second. Thresholds for calculation used: 0.3m/s – 1.7m/s i.e. track segments outside this range were not taken into account for aggregation.

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- "incidentDuration": The duration from the alarm onset until the subject was back in the green safe zone.

2.4 Overview on data collected

Overview over all Freewalker users' data collected during the study period. These data do not include the control group.

Table 2: Statics overview over all Freewalker users (no control group) data collected

Study Id	Total period (days)	Total usage (days) **Note 1)**	Avg. "no Signal Night" (h)	Avg. "no Signal Day" (h)	Avg. "no Signal Day" (h) **Note 2)**	Total duration outside (h)	Total distance walked (m)
XXXXXX	109	60	7.9	10.4	7.2	138	109488
XXXXXX	109	75	7.6	10.2	7.7	217	205941
XXXXXX	50	42	7.4	7.2	6.5	67	153655
XXXXXX	134	5	8.0	15.9	14.5	5	9958
XXXXXX	134	50	8.0	14.6	12.3	84	61717
XXXXXX	50	1	8.0	16.0	16.0	0.17	0
XXXXXX	109	55	7.9	13.2	11.0	78	48838
XXXXXX	109	80	8.0	12.0	10.6	167	175118
XXXXXX	59	3	8.0	15.9	13.2	1.68	419
XXXXXX	116	37	8.0	15.4	14.1	13	18827
XXXXXX	109	32	8.0	12.8	5.8	35	17317
XXXXXX	125	19	8.0	13.9	11.4	9	5094
XXXXXX	68	17	7.9	14.3	10.2	20	11391
XXXXXX	113	8	8.0	15.5	9.9	18	106
XXXXXX	112	77	7.2	9.3	6.9	198	85868
XXXXXX	112	26	7.9	14.1	11.2	53	28004
XXXXXX	112	47	7.9	13.3	10.4	103	48512
XXXXXX	113	28	8.0	14.8	13.1	7	881
XXXXXX	112	57	7.7	10.2	9.0	40	9181
XXXXXX	112	65	7.9	9.4	7.9	27	7888
XXXXXX	154	11	8.0	15.2	10.9	14	21683
XXXXXX	184	48	8.0	14.0	9.1	107	36477
XXXXXX	154	25	7.9	14.7	10.5	36	6168
XXXXXX	154	29	8.0	14.9	10.6	36	19605
XXXXXX	128	9	8.0	15.8	13.3	7	13354
XXXXXX	137	0					
XXXXXX	105	0					
sum:	3083	906			avg per subject:	62	43820

Note 1: Number of days where time_gps_outside > 0.
Note 2: Calculated only for those days where system has been used, i.e. where time_gps_outside > 0.

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2.5 Data from the questioners and study visits

Each participant was asked to attend three study visits. During the first visit, demographic data and baseline measurements of outcome parameters were collected. The clients were then randomized either into the FreeWalker or control group. The study duration was 16 weeks, with a second study visit at 8 weeks and a final study visit at 16 weeks. Initially we planned for a voluntary extension phase of the study. However, due to the delay of the start of the field trial due to the COVID-19 pandemic, the extension phase was canceled because the project ended.

At each study visit, primary end-users and their caregivers were asked to complete paper questionnaires. The data from the questionnaires was then entered into a country-specific excel sheet.

3 EVALUATION METHODS

The collected data is currently being analyzed. The first analysis includes data plausibility analysis and descriptive statistics. Further statistical analysis is performed in conjunction with statisticians.

4 EVALUATION RESULTS

As of the writing of this deliverable, the scientific evaluation of the Field Trial is ongoing. The reason for the delay in data analysis is the repeated shift of the field trial due to COVID-19 related restrictions. Due to those difficult circumstances, and to facilitate the inclusion of as many participants as possible, the end of the field trial was extended to the end of the project and data became available at the end of the FreeWaker project in July- and August 2021.

The following section describes demographics and first results of the primary outcome, customer satisfaction and willingness to pay questionnaires of the Austrian cohort of the study, which provides the most extensive dataset.

4.1 Demographics of the Austrian Cohort

4.1.1 Primary Endusers

Table 4-1: Demographics of the primary enduser of the Austrian cohort

	#	mean age [range] (years)	female	lives with partner	lives alone	mean duration of cognitive decline [range] (years)	# SCI	# MCI	mean MoCA [range]
FreeWalker	20	68.6 [60 - 82]	11 / 20	15 / 20	5 / 20	2.4 [0.5 - 10]	16 / 20	4 / 20	28 [24 - 30]
Control	10	70 [62 - 82]	6 / 10	8 / 10	2 / 10	2 [1 - 8]	8 / 10	2 / 10	26.8 [22 - 30]

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4.1.2 Caregivers

Table 4-2: Demorgraphics oft he caregivers oft he Austrian cohort

				relationship				
	#	mean age [range] (years)	female	partner	child	other	in same houshold	mean hours per week [range]
FreeWalker	20	61,2 [33 - 78]	13 / 20	15 / 20	3 / 20	2 / 20	15 / 20	98,2 [1 - 168]
Control	10	59,2 [38 - 71]	4 / 10	6 / 10	3 / 10	1 /10	6 / 10	83,0 [0,25 - 168]

Tables 4-1 and 4-2 show the demographics of the Austrian cohort. The groups were comparable in key demographic measurements.

4.2 Primary Outcome Measurement of the Austrian Cohort

FreeWalker was designed to support both the primary end-users (PEUs, people with neurocognitive impairment, especially affecting orientation and memory) as well as their caregivers (CGs). Due to their cognitive impairment, PEUs might abstain from leaving their home because they are afraid of getting confused or lost. Likewise, a CG might worry that the PEU gets confused or lost when going out alone. FreeWalker is intended to remedy those worries and provide a safety net to support both PEUs and CGs, while at the same time reducing false alarms to a minimum. To evaluate the primary function of FreeWalker a 5-point Likert scale was developed to assess how PEUs and CGs feel about such situations and to evaluate if FreeWalker is indeed able to ameliorate such fears and worries.

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*Figure 4-1: Nine item **Likert Scale** for the **Primary Enduser** (9-45 points) where a lower overall score indicates less subjective impairment and worries about getting lost. The last two questions a scored inversely.*

	Fully agree				Fully disagree
I feel confident leaving my home alone to go grocery shopping	0	0	0	0	0
I feel confident leaving my home alone to meet friends	0	0	0	0	0
I feel confident leaving my home alone to go to an appointment (doctor, dentist, ...)	0	0	0	0	0
I can manage day-to-day tasks outside of my home without the help of someone else	0	0	0	0	0
I feel confident leaving my home alone to go for a walk	0	0	0	0	0
I feel confident participating in activities in my neighborhood	0	0	0	0	0
I feel confident going to new places I have not been before	0	0	0	0	0
I'm afraid that I will get lost when going outside alone	0	0	0	0	0
I avoid using public transportation because I'm afraid I might end up in an unknown location	0	0	0	0	0

*Figure 4-2: Seven item **Likert-Scale** for the **Caregiver** (7-35 points), were a lower overall score indicates less worries of the CG that the PEU might get lost. The last three questions are scored inversely.*

	Fully agree				Fully disagree
I have to call the primary client often to make sure she/he isn't lost.	0	0	0	0	0
I worry that the primary client will get lost if she/he leaves the house alone.	0	0	0	0	0
I worry that the primary client will not go out anymore because she/he is afraid of doing it alone	0	0	0	0	0
I have to personally check up on the primary client regularly to make sure she/he is ok.	0	0	0	0	0
I'm confident that the primary client is ok when strolling around in the neighborhood on her/his own.	0	0	0	0	0
I'm confident that the primary client can manage common daily tasks outside her/his home without help (going grocery shopping, meeting friends, ...)	0	0	0	0	0
I'm confident that the primary client is ok on his own even when she/he goes to places she/he seldom visits (like a doctors office, ...)	0	0	0	0	0

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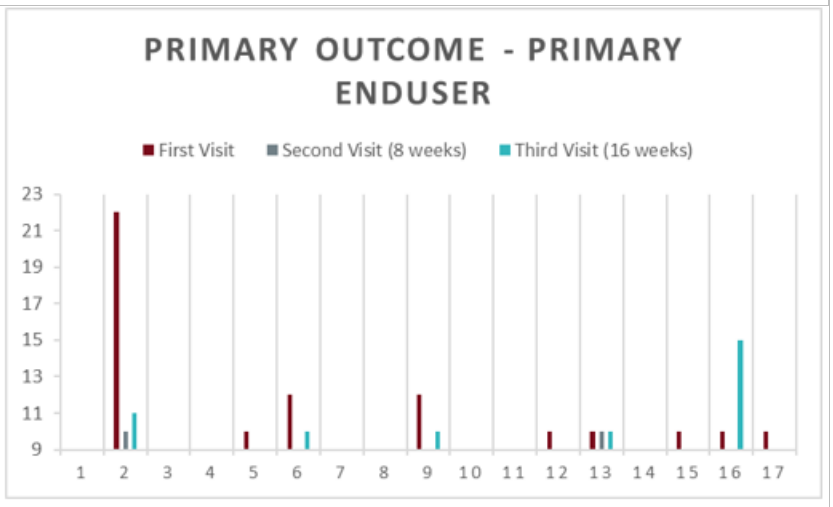
4.2.1 Primary Outcome PEU

Figure 4-3: Primary Outcome of the PEU. Due to 3 drop-outs only 17 datasets were analyzed. The table on the left shows changes in the outcome measurement from baseline at visit 2 (8 weeks) and visit 3 (16 weeks). Negative values (green) represent an improvement of the primary outcome (i.e. PEU is more confident when going outside). The graph on the right shows the score at each visit for each subject. The minimum score is 9. 8 / 17 did not report any worries when leaving their home.

	Any worries	Change V1 > V2 (8 weeks)	Change V1 > V3 (16 weeks)
1	no	0	0
2	yes	-12	-11
3	no	0	0
4	no	0	0
5	yes	-1	-1
6	yes	-3	-2
7	no	0	0
8	no	0	0
9	yes	-3	-2
10	no	0	0
11	no	0	0
12	yes	-1	-1
13	yes	0	0
14	no	0	0
15	yes	-1	-1
16	yes	-1	5
17	yes	-1	-1



Primary Outcome	V1 -> V2	V1 -> V3
- improved	8	7
- didn't change	9	9
- worsened	0	1

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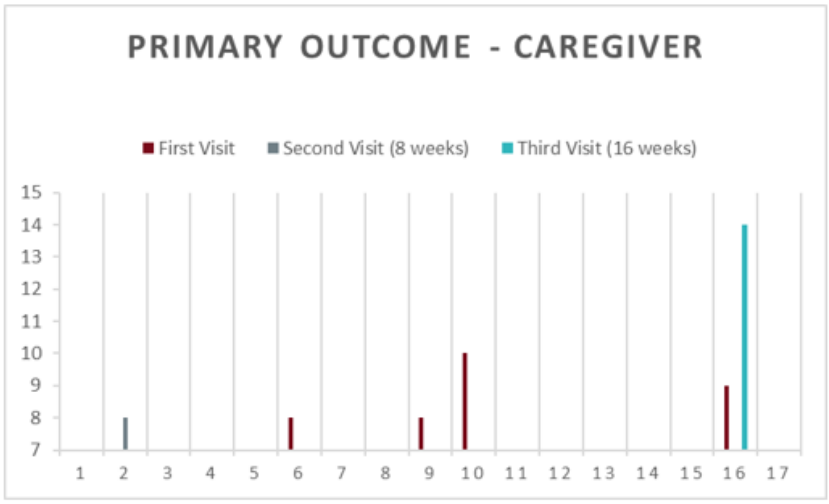
4.2.2 Primary Outcome CG

Figure 4-4: Primary Outcome of the CG. Due to 3 drop-outs only 17 datasets were analyzed. The table on the left shows changes in the outcome measurement from baseline at visit 2 (8 weeks) and visit 3 (16 weeks). Negative values (green) represent an improvement of the primary outcome (i.e. CG is less concerned when PEU leaves home alone). The graph on the right shows the score at each visit for each subject. The minimum score is 7. 13 / 17 CGs did not report any worries when the PEU goes out alone.

	Any worries	Change V1 > V2 (8 weeks)	Change V1 > V3 (16 weeks)
1	no	0	0
2	no	1	0
3	no	0	0
4	no	0	0
5	no	0	0
6	yes	-1	-1
7	no	0	0
8	no	0	0
9	yes	-1	-1
10	yes	-3	-3
11	no	0	0
12	no	0	0
13	no	0	0
14	no	0	0
15	no	0	0
16	yes	-2	5
17	no	0	0



Primary Outcome	V1 -> V2	V1 -> V3
- improved	4	3
- didn't change	12	13
- worsened	1	1

4.2.3 Results

Overall 9/17 PEUs reported some concern regarding their ability to leave their home alone. Of those, seven PEUs reported an improvement of those concerns while using FreeWalker. Conversely, only 4/17 CGs reported some concern regarding the ability of the respective PEU to leave their home alone. Of those, three CGs reported an improvement of those worries while using FreeWalker.

It should be noted, that the majority of study participants reported none or only very minor concerns regarding the ability of the PEUs to move around outside their homes alone. Thus, it is difficult to assess reliably, any benefit of FreeWalker on the primary outcome measurement. The reason for this is likely, that most study participants only showed very mild cognitive impairment as suggested by the neurocognitive testing performed.

It is however interesting that twice as many PEUs than CGs reported concerns. This is somewhat unexpected since persons with cognitive impairment are usually more oblivious of their deficits than their surroundings. A possible explanation is the large number of clients with only subjective cognitive impairment.

4.3 Customer Satisfaction of the Austrian Cohort

To evaluate customer satisfaction with the FreeWalker System two questionnaires were used. The "Customer Satisfaction Scale" (CSAT) and a modified version of the "System Usability Questionnaire". Primary Endusers and Caregivers were asked separately for their experience with the system twice during the field trial – once after 8 weeks and once after 16 weeks of using FreeWalker.

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4.3.1 Customer Satisfaction Scale

The Customer Satisfaction Score (CSAT) asks for a rating of the subjective satisfaction with a certain product. The client can choose between 5 different options ranging from “1” very unsatisfied to “5” very satisfied.

Figure 4-5: Customer satisfaction of the Primary Enduser

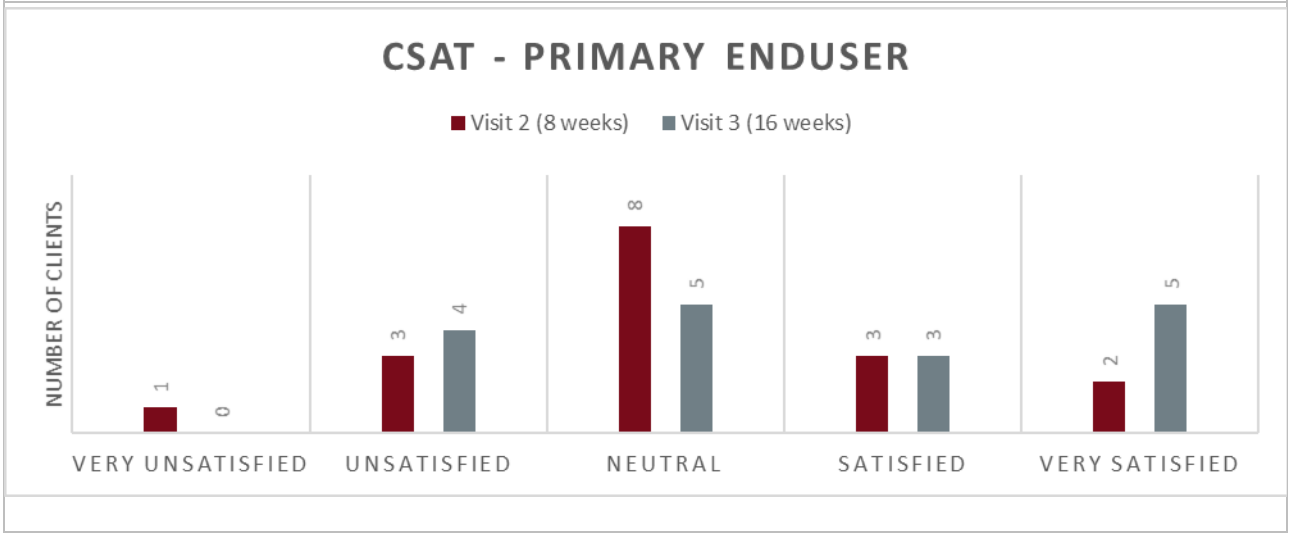

Figure 4-6: Customer Satisfaction of the Caregiver

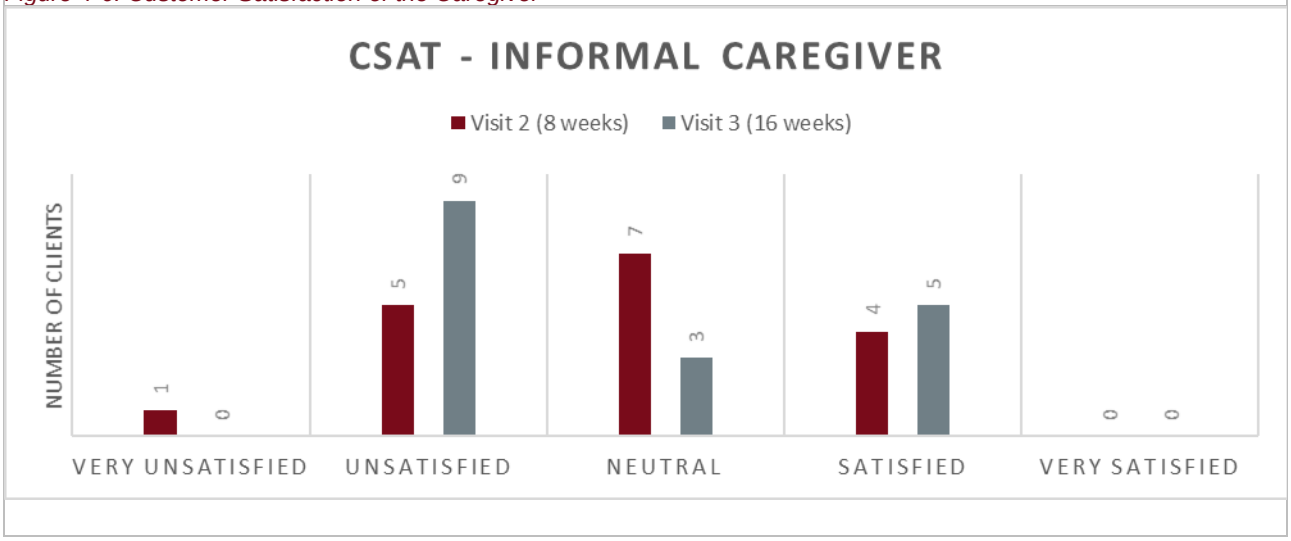

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Figure 4-7: Change in Customer Satisfaction after prolonged usage of FreeWalker (8 weeks -> 16 weeks) of each individual client (positive/green = improved satisfaction, numbers indicate the relative change in satisfaction).

CSAT PEU Change V2-V3	CSAT CG Change V2-V3
4	0
2	0
1	-1
-1	1
0	0
0	0
0	0
1	0
-1	0
2	1
0	-2
0	-1
-2	-1
-1	0
1	1
0	1
1	0

CSAT	PEU	CG
- decreased	4	4
- constant	6	9
- improved	7	4

Results

Overall, primary endusers scored their satisfaction with the FreeWalker system with “neutral” to “satisfied” with a tendency towards increased satisfaction with prolonged usage of the system, while caregivers scored their satisfaction with “unsatisfied” to “neutral” with a tendency towards decreased satisfaction with prolonged usage. Three clients and their respective caregivers did not attend the third study visit (after 16 weeks) and were excluded from analysis. Those clients scored their satisfaction with “unsatisfied” in 5/6 cases at the second study visit.

4.3.2 Post Study Usability Questionnaire (PSSUQ)

The PSSUQ asks questions about the usability of a system. For the purpose of the study, only items relevant to FreeWalker were used. A total of 13 items were used. Each item may be score from 1 – completely disagree, to 7 - completely agree or 0 - N/A. The maximum score is 91 points were higher scores indicate better usability.

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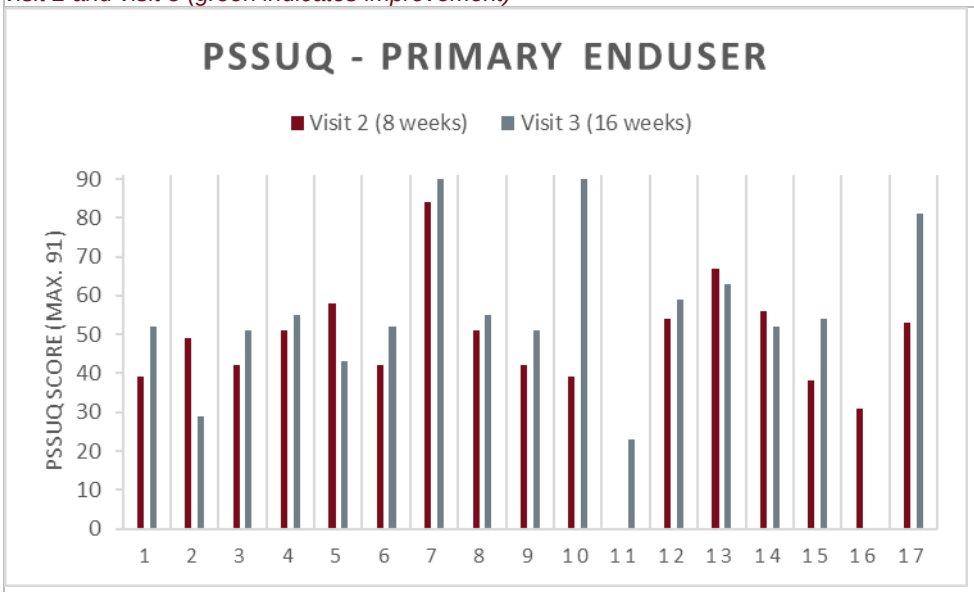
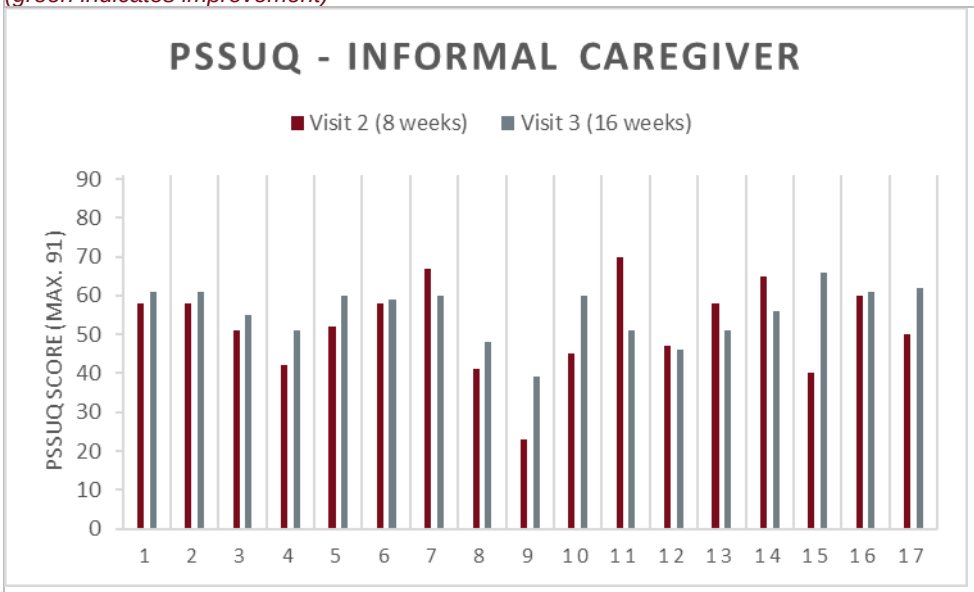
Figure 4-8: The graph on the left shows the PSSUQ Score of the Primary Enduser at Visit 2 (red, 8 weeks of FreeWalker) and Visit 3 (grey, 16 weeks of FreeWalker). The table on the right shows the change in PSSUQ between visit 2 and visit 3 (green indicates improvement)



PSSUQ PEU Change V2-V3
13
-20
9
4
-15
10
6
4
9
51
N/A
5
-4
-4
16
N/A
28

PSSUQ	PEU
- decreased	4
- constant	0
- improved	11

Figure 4-9: The graph on the left shows the PSSUQ Score of the Caregiver at Visit 2 (red, 8 weeks of FreeWalker) and Visit 3 (grey, 16 weeks of FreeWalker). The table on the right shows the change in PSSUQ between visit 2 and visit 3 (green indicates improvement)



PSSUQ CG Change V2-V3
3
3
4
9
8
1
-7
7
16
15
-19
-1
-7
-9
26
1
12

PSSUQ	CG
- decreased	5
- constant	0
- improved	12

Overall, measures of system usability increased with prolonged usage of the FreeWalker system for both primary end-users and caregivers in most cases. Three clients and their respective caregivers did not attend the third study visit (after 16 weeks) and were excluded from analysis. Only one of the primary end-user – caregiver pair scored system usability very low (23/11 points) after 8 weeks of usage while the other two pairs gave average scores (49/70 and 45/34 points).

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Figure 4-10: Change in CSAT vs. change in PSSUQ between visit 2 and visit 3. The table on the right shows concomitant changes in the same direction (green) vs changes in opposite directions (red).

CSAT PEU Change V2-V3	CSAT CG Change V2-V3	PSSUQ PEU Change V2-V3	PSSUQ CG Change V2-V3	change in CSAT vs PSSUQ PEU	change in CSAT vs PSSUQ CG
4	0	13	3	1	N/A
2	0	-20	3	0	N/A
1	-1	9	4	1	0
-1	1	4	9	0	1
0	0	-15	8	N/A	N/A
0	0	10	1	N/A	N/A
0	0	6	-7	N/A	N/A
1	0	4	7	1	N/A
-1	0	9	16	0	N/A
2	1	51	15	1	1
0	-2	N/A	-19	N/A	1
0	-1	5	-1	N/A	1
-2	-1	-4	-7	1	1
-1	0	-4	-9	1	N/A
1	1	16	26	1	1
0	1	N/A	1	N/A	1
1	0	28	12	1	N/A

Changes in customer satisfaction mirrored changes in system usability in most cases, indicating that – as expected - system usability is an important factor of customer satisfaction. Albeit, the magnitude of change did not correlate well between the two measurements.

4.4 Willingness to Pay of the Austrian Cohort

To assess whether Primary Endusers or their Caregivers would be willing to pay for a service like FreeWalker, we offered the two payment plan options below and asked whether the monthly price was reasonable and whether the clients would consider buying the system. Either the PEU or the CG answered the question depending on personal preference.

FreeWalker option 1
With FreeWalker option 1 you can draw safe zones in which the patient is able to explore freely. These safe zones are dynamic and adapt to the walking habits of the client wearing the GPS device. You will receive a notification when the patient exceeds the safe zone border. Automatic generated safe corridors toward and from appointments are created with notification-possibility of arrivals. This service will cost €25,- per month.

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FreeWalker option 2
With FreeWalker option 2 you can draw safe zones in which the patient is able to explore freely. These safe zones are dynamic and adapt to the walking habits of the client wearing the GPS device. You will receive a notification when the patient exceeds the safe zone border. Automatic generated safe corridors toward and from appointments are created with notification-possibility of arrivals. Furthermore, the walking-pattern of the primary user is monitored and notification as send as when walking-patterns are unusual. This service will cost €30,- per month.

Figure 4-11: Results of the Willingness to Pay Questionnaire at visit 3. Out of 17 clients, 15 PEUs and 2 CGs answered the questionnaire. The graphs below show the responses of the 15 PEUs.

15 PEUs and 2 CGs answered the willingness to pay questionnaire after 16 weeks of using FreeWalker. The majority of PEUs found that FreeWalker was reasonably priced, but only half of them considered buying the system. The results were similar for both options.

5 CONCLUSION

Wandering and getting lost can be dramatic and a health concern for people with dementia. In addition, it can increase the care burden and stress among formal and informal carers.

The analysis completed so far indicates that FreeWalker – in principal – appears to be able to ameliorate some of the worries of persons with cognitive impairment when leaving their home alone, and the worries of their caregivers. However, due to the small number of study participants in this field trial who report any such worries, further studies are desperately needed to further evaluate this subject.

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The reason for the small number of study participants who reported any such worries is likely that only persons with subjective or mild cognitive impairment were included into the study. This population usually does not have significant problems in daily living. Unfortunately, including people with more severe cognitive impairment is difficult for ethical and legal reasons. Using systems like FreeWalker in principal constitute a form of restriction of freedom. Since an alarm is sent every time a predefined area is left, the caregiver could effectively limit the person with cognitive impairment in his or her freedom to move around (indeed, this is one of the primary functions of GPS tracking systems). Such a restriction is only legally possible (at least in Austria), if the person with cognitive impairment explicitly agrees to it as in The Netherlands according to the Law Care & Constrain (WZD). It is however difficult to ascertain consent from a person with advanced cognitive impairment because this person likely is not able to grasp the full extent of his or her decisions. Legislation on this subject differs between countries but tends to become more and more limiting. Complying with legislation in Switzerland (as in any other country) leads to very complicated forms like IC / participant information that often discourages potential participants and/or informal caregivers from participating. GPS tracking can limit the freedom of movement, however, it can also increase freedom and mobility. Whenever the client or its representative agrees on the use of GPS tracking and whenever it provides a positive impact on the freedom of movement, then – in The Netherlands – GPS tracking can be used in long-term care. Whenever the client or its representative did not agree on the use of GPS tracking, then it is involuntary care (WZD, The Netherlands, 2021).

It should however be noted, that while systems like FreeWalker can and are being used to monitor and restrict the movement of its wearer, the intention of such systems is the opposite - to increase the freedom its users. If a person with cognitive impairment is prone to wandering off and getting lost, measures have to be taken to protect this person from harm. It might become necessary to relocate a person to a caregiving home where surveillance is provided by care personal 24 hours a day. Systems like FreeWalker could potentially allow a person with cognitive impairment to stay at home and move around freely longer. Such systems could be considered the tools of least harm, because they allow the user to move around without visible restrictions while still providing a safety net in case of danger.

The abovementioned legal and ethical issues on the restriction of freedom were also the main concern of the Austrian Ethics Committee, most notably its patient's advocate, when evaluating the permissibility of the current field trial. It will be interesting to see how this ethical dilemma is solved in the future.

The study further underlines, that the usability of systems like FreeWalker should be a major focus during product development. Overall, the customer satisfaction with the product was less than optimal. Part of the problem might be that FreeWalker is still a (advanced) prototype and needs further refinement. Still, when developing systems like FreeWalker, even more care should be taken to avoid overcomplicated systems. It seems clear however, that potential customers are willing to spend a significant amount of money on such systems.

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APPENDIX 1: ENTRY AND EXIT DATES OF THE SUBJECTS

Austria Control Group

Study Id	Entered Study Date	Exit Study Date
XXXXX	27.1.2021	31.5.2021
XXXXX	28.1.2021	20.5.2021
XXXXX	2.2.2021	30.3.2021
XXXXX	2.2.2021	30.3.2021
XXXXX	8.2.2021	7.4.2021
XXXXX	2.2.2021	14.5.2021
XXXXX	3.3.2021	22.6.2021
XXXXX	8.2.2021	7.4.2021
XXXXX	16.2.2021	8.6.2021
XXXXX	3.3.2021	29.6.2021

Austria Study Group

Study Id	Entered Study Date	Exit Study Date
XXXXX	1.2.2021	20.5.2021
XXXXX	1.2.2021	20.5.2021
XXXXX	8.2.2021	29.3.2021
XXXXX	8.2.2021	21.6.2021
XXXXX	8.2.2021	21.6.2021
XXXXX	1.2.2021	22.3.2021
XXXXX	1.2.2021	20.5.2021
XXXXX	1.2.2021	20.5.2021
XXXXX	8.2.2021	7.4.2021
XXXXX	2.2.2021	28.5.2021
XXXXX	2.2.2021	21.5.2021
XXXXX	27.1.2021	31.5.2021
XXXXX	24.1.2021	1.4.2021
XXXXX	10.2.2021	2.6.2021
XXXXX	30.1.2021	21.5.2021
XXXXX	5.2.2021	27.5.2021
XXXXX	5.2.2021	27.5.2021
XXXXX	16.2.2021	8.6.2021
XXXXX	3.3.2021	22.6.2021
XXXXX	3.3.2021	22.6.2021

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Switzerland Control Group

Switzerland Study Group

Study Id	Entered Study Date	Exit Study Date
XXXXX	08. Okt 20	04. Apr 21
XXXXX	12. Okt 20	04. Mai 21
XXXXX	11. Okt 20	04. Apr 21
XXXXX	07. Okt 20	04. Apr 21
XXXXX	10. Nov 20	18. Mrz 21
XXXXX	19. Nov 20	04. Apr 21
XXXXX	20. Jan 21	04. Mai 21

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APPENDIX 2: STUDY DROP-OUT REASONS

Reason for Drop-Out	NL	AT	CH
Privacy concerns			1
Interview/questioners too complicated			
No movement outside the home due to Covid-19			1
Sudden severe illness/change in health condition		1	2
Asking price (willingness to pay)			1
Everything too complicated		1	2
Battery life time of tracker too short		5	
Inaccuracy of location information		1	
Unknown	5	0	1

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