## **ALFRED**

### Personal Interactive Assistant for Independent Living and Active Ageing



# WP8 - Piloting & Validation

# D8.3.2 Piloting & Validation II: Hospital

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This deliverable will as the first part present the methodology and results of the usability test, which was performed with the ALFRED Back Trainer. The second part describes methods and the results of the actual Pilot II which tested the ALFRED Back Trainer in a clinical study. The pilot aimed to investigate the effectiveness of the ALFRED Back Trainer for the reduction of low back pain associated disabilities and function.





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#### **Note**

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## **Executive Summary**

Pilot II investigated the usability and effectiveness of the ALFRED Back Trainer (ABT) in a clinical setting. Fifteen users participated in the usability investigation (5 male, 10 female). During the session, a questionnaire was filled and an audio recorded out-of-the-box-test was made. After the tasks were solved, a questionnaire was given to the participant to evaluate the personal impression of the usability and the own performance. Afterwards an open interview in which additional information was conducted. The usability test lasted 60-90 minutes per user. The ratings for the ABT on the System Usability Scale received the highest values in users that had little difficulties in setting up the ABT. The longer the time to complete the task was, the higher was the perceived stress of the users. The fundamental problem of the users was that they had never seen or tested a similar device as the ABT. For all steps of setting up the ABT it is advisable to design a detailed manual, so that the user has to handle as little information as possible simultaneously. Better placement and larger font for the text in the ABT app should be implemented in the future. This will allow easier operation for users with low vision and the attention of the users can be better directed to the instructions. In the current state of the system is not yet ready for the consumer market. Many of the observed errors in this experiment may no longer occur with repeated use of the ABT because the users will learn and internalize the correct steps of the set up process. Overall, the ABT can be used of the target group of senior citizens. However, it needs further research in order to optimize the usability of the device.

The evaluation of the effectiveness of the ABT included 62 participants (44f, 18m) with subacute LBP. 17 subjects dropped out of the study, main reason was a delay of the investigation due to a theft of technical equipment, which led to conflicts with the patient's personal agenda. The study was a randomized controlled trial with three groups. Two groups received the exercise intervention, while the third group as control group participated in the usability and received no training. Both intervention groups received the same exercises. The standard exercise intervention group trained in a conventional way, while the ABT group trained on Wii Balance Boards while receiving feedback on their posture via Tablet during training. Training was conducted twice per week over a total period of 12 weeks intervention. The training was compiled by a certified back teacher from a set of exercises taken from the Manual des Bundesverbandes deutscher Rückenschulen. 16 exercises were performed, breaks of 60 seconds between the exercises were made. Generally the ABT was successful in almost all evaluated KPI areas. The ABT group showed improvement in all areas of the mental well-being scale. For this reason the KPI of a 10% increase in mental well-being was met and succeeded way beyond the expected impact. The KPI for increased amount of physical activity by 10% of the users for this reason was met and received values way beyond the expected impact. The KPI for increased sleep quality was also met with a more than the threefold effect of the expected KPI. While the KPI was set at a 10% in H<sub>2</sub>O consumption, one could argue that is goal was not met, however in the light of the already sufficiently high H<sub>2</sub>O consumption, this KPI can be valued as neutral. The KPI for a reduction in sensor checks through a healthcare provider in the last twelve weeks was set at a reduction of 10% of sensor checks. Despite the good results of the ABT compared the other group, in this case the KPI was not met.

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Users were also questioned how often they performed self-referred visits to a doctor in the last twelve weeks. The KPI was set at a reduction of 10% of self-referred visits to a doctor. Self-referred showed the highest decrease in the ABT group. For this reason the KPI for item was met.

The ABT group was best in reducing fall risk. The spinal flexibly increased in the ABT group while it decreased in the standard intervention group and the lumbopelvic mobility increased the most in the standard group and the least in the ABT group. These findings indicate that healthcare providers need to assess their patients comprehensively. Patients with a hypermobility in the spine, for this reason should be allocated to the standard group, while patients with spinal hypomobility are best suited for the ABT group. Similar conclusions can be drawn for the results of the Fingertip-Floor-Distance.

The ABT group showed higher increases in strength for the isometric lateral flexion to the left and right and was also able to reduce the asymmetry within the isometric lateral left and right flexion. Since recurrent episodes of LBP are often associated with muscular asymmetries, this is a very interesting finding, which could potentially mean that in ABT might be able to reduce recurrent back in older adults. However these findings will have to be further investigated in longitudinal studies. Finally the standard intervention had a stronger influence to strengthen the rectus abdominis muscles, while that ABT more effectively strengthened the isometric trunk extension.

Overall, both interventions are effective, however the ABT was superior to the standard intervention when it comes to overall gains in muscle strength, regaining muscular symmetry, improving mental well-being and reducing fall risk. However older adults with subactute LBP are not a homogenous group and for this reason each clinicians that are treating older adults with subacute LBP will have to do a thorough investigation of each patient. Based on these findings it has to be decided with intervention will be best to address the patient's deficits.

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### 1 Introduction

ALFRED – Personal Interactive Assistant for Independent Living and Active Ageing – is a project funded by the Seventh Framework Programme of the European Commission under Grant Agreement No. 611218. It will allow elderly people to live longer at their own homes with the possibility to act independently and to actively participate in society by providing the technological foundation for an ecosystem consisting out of four pillars:

- **User-Driven Interaction Assistant** to allow older people to "talk" to ALFRED and to ask questions or define commands in order to solve day-to-day problems.
- Personalized Social Inclusion by suggesting social events to older people, considering his interests and his social environment.
- A more **Effective & Personalized Care** by allowing medical staff or carer to access vital signs of older people monitored by (wearable) sensors.
- Physical & Cognitive Impairments Prevention by incorporating serious gaming to improve the physical and cognitive condition by offering games and quests to older people.

The purpose of this deliverable is to present the first results of the usability tests and the tests of the effectiveness of the ABT in order to reduce the effects of low back pain in older adults with subacute LBP. The pilot was performed in a clinical setting in Germany on 62 users.

## 1.1 ALFRED Project Overview

One of the major problems today is the increasing isolation of older people, who do not actively participate in society either because of missing social interactions or because of age-related impairments (physical or cognitive). ALFRED will allow overcoming this problem with an interactive virtual butler for older people, which is fully voice controlled.

The ALFRED project is wrapped around the following very clear main objectives:

- Empowering people with age-related dependencies to live independently for longer by delivering a virtual butler with seamless support for tasks in and outside the home. The virtual butler ALFRED will have a very high end-user acceptance by using a fully voice controlled and non-technical environment.
- Prevailing age-related physical and cognitive impairments with the help of personalized, serious games.
- Fostering active participation in society for the ageing population by suggesting and managing events and social contacts.
- Improved care processes through direct access to vital signs for carers and other
  medical stuff as well as alerting in case of emergencies. The data is collected by
  unobtrusive wearable sensors monitoring the vital signs of older people.

To achieve its goals, the project ALFRED conducts original research and applies technologies from the fields of Ubiquitous Computing, Big Data, Serious Gaming, the Semantic Web, Cyber Physical Systems, the Internet of Things, the Internet of Services, and Human-Computer Interaction. For more information, please refer to the project website at http://www.alfred.eu.

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## 1.2 Deliverable Purpose, Scope and Context

This deliverable describes the results that were achieved during the testing phase in pilot 2 and also briefly details updates on the methodology of the pilot. The main goal was to test the ABT in a clinical setting with potential end users of ALFRED. The evaluations in this pilot consist of two different sections. First of all a usability evaluation of the ABT and secondly an evaluation on the effectiveness of the ABT in order to reduce the negative effects of subacute low back pain to older adults. The deliverable will in the first part provide information on the usability tests that were conducted with the ABT and continue to report on the results regarding the effectiveness of the ABT within a clinical setting.

## 1.3 **Document Status and Target Audience**

This document is listed in the Description of Work (DoW) as "public", as it provides general information about the goals and scope of ALFRED and can therefore be used by external parties in order to get according insight into the project activities.

While the document primarily aims the project partners, this public deliverable can also be useful for the wider scientific and industrial community. This includes other publicly funded projects, which may be interested in collaboration activities.

## 1.4 Abbreviations and Glossary

A definition of common terms and roles related to the realization of ALFRED as well as a list of abbreviations is available in the supplementary document "Supplement: Abbreviations and Glossary", which is provided in addition to this deliverable.

Further information can be found at <a href="http://www.alfred.eu">http://www.alfred.eu</a>.

#### 1.5 **Document Structure**

This document describes the results of the usability tests and the tests that were performed to assess the effectiveness of the ABT in a clinical setting for a period of twelve weeks. The first part of the deliverable describes the setup of the pilot which was designed as a randomized controlled trial. Chapter 3 provides details about the usability tests which were conducted with the ABT. Chapter 4 gives a brief introduction about serious games and further on detailed information about the results of the previously defined KPIs and effectiveness of the ABT can be found. All questionnaires which were used during the pilot can be found in the Annex at the end of this deliverable.

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### 2 ALFRED Back Trainer

The privacy vote was accepted as well.

The pilot was set up as randomized controlled trial (RCT) with three groups (N=62) (Figure 1) and approved by the Ethics Committee of the Charité Universitätsmedizin Berlin. Two groups received and exercise based intervention, while the third group as control group participated in the usability test described in1.2. One intervention group practiced on a sports mat, the other group trained on Wii Balance Boards while receiving feedback on their posture via tablet during training. Both intervention groups received the same exercises. Training was conducted twice per week over a total period of 12 weeks intervention, from April 2016 to July 2016. Analysis of data was made via Excel and SPSS.

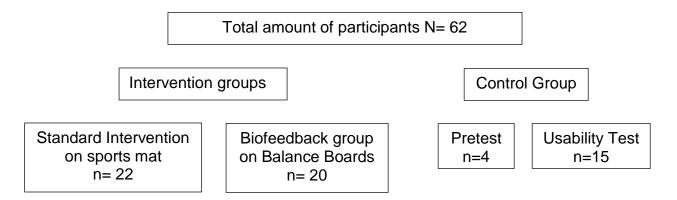


Figure 1: Subdivision of the Groups

The participants were recruited from the Charité database and from placards set up in the area around the hospital. A total payment of 50 € was guaranteed. The sample included 18 male and 44 female older adults with an average age of 74 years (SD= 5.7), the average body size 166.4 cm (SD=9.2) and the average weight 73.7 kg (SD=11.4). 60 subjects lived independently at home, while 2 lived in assisted living facilities. Attitude towards technology was positive in 51 cases, neutral in 9 and negative in 2 subjects. 54 subjects were retired, five were performing voluntary work, one unemployed and two stated other forms of employment 17 Dropouts occurred during the study, main reason for this was a delayed start of the pilot due to a theft on tablets that were required for the pilot. This fact interfered with the schedules of the users. Study duration was already was planned the users, several weeks ahead of the pilot, the delay of the pilot led to the fact that the exercise intervention then interfered with previously planned vacations of the users which they did not want to postpone. For this reason users missed exercise interventions. The pilot was designed in a way, so that users would but automatically be excluded from the pilot if more than six exercise interventions were missed, since this would have corrupted the comparability of the users due to the high variations in of competed exercise sessions.

## 2.1 Telephonic Screening

All participants were informed about the study and were screened telephonically before the study started. This was to ensure they would fit the in- and exclusion criteria. Inclusion

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criterion was: aged 65 years and older. Exclusion criteria was: Heavy affective or cognitive diseases; acute back pain; participation in another intervention study; legal care; immobility; recent heavy surgical intervention; acute herniated disc; spinal tumour.

After the inclusion, all participants were invited to a medical testing in situ. Written informed consent were sent postal or via mail to be brought back signed at testing date. Consents were obtained from all participants.

## 2.2 Medical Pre- and Post-Testing

For the Pre-Testing all participants received a battery of paper-based questionnaires and medical tests (see Annex 1: ABT Questionnaires) which lasted about 60 minutes in total. Besides, the opportunity was given to answer questions and concerns which remained unclear afore.

The Post-Testing consisted of the same questionnaire in order to make a pre/post comparison possible. After analysing the results, participants received their own results as well as an instruction, so they could perform the exercises at home after the study was finished.

## 2.3 Main Study

The intervention groups received a training of the M. multifidus and M. transversus abdominis twice a week in sessions of 30 minutes duration. The training was compiled by a certified back teacher from a set of exercises taken from the *Manual des Bundesverbandes deutscher Rückenschulen*. 16 exercises were performed, breaks of 60 seconds between the exercises were made. In the first week, each exercise was performed 20 seconds. From the second week on, time was increased to 30 seconds a further increase of the exercise duration (40 seconds) was done at week eight of the training. Two guides supervised the sessions. One guide to announce and demonstrate the exercises, one to control the performance of the participants. Participants had the opportunity their have their vital data measured before and after each training session with the ALFRED sensor T-Shirt.

The training position for the ABT was the so called bridging position which can be seen in Figure 2. User had to lie in this position and had to lift the pelvis off the ground.

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Figure 2: The Training Position for the Pilot

Materials used for the standard intervention group were a sports mat and a bolster. The ABT group used the ABT, which consisted of a bolster, a sport pillow, two Wii Balance Boards (one for the feet, one for the shoulders) (see Figure 3) and a Samsung Galaxy Tab 2 Tablet attached to a tripod (see Figure 4) standing in front of the foot Balance Board and an OTG Dongle which had to be attached to the tablet, in order to transmit the signals from the Nintendo Wii Balance Boards to the tablet.

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Figure 3: Materials Used for the ABT Group



Figure 4: Tripod for the Samsung Galaxy Tab 2 Tablet

The exercises that had to be performed were identical for the KR and KRB group. During the exercises with the ABT the users were able to see their centre of gravity which was detected by the Nintendo Wii Balance Boards on the Samsung Galaxy Tab 2 Tablet. The screen of the tablet showed two blue circles with a white dot in the middle. The white dots represented the user's actual centre of gravity over each board. The goal of the users was to keep the white dots, as centred as possible within the blue dots, hence maintaining as symmetrical position low the spine. Further exercise physiologic details about the principle about the ABT can be found in D8.3.1. Figure 6 shows users training during and exercise session in the pilot.

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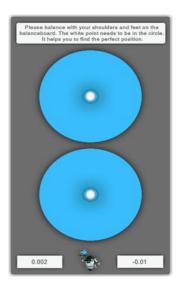


Figure 5: The Screen of the Samsung Galaxy Tab 2 Tablet



Figure 6: Exercise Groups during a Training Session

## 2.4 ABT Usability Test

The participants of the control group were invited to a single session in which the usability of the training station was evaluated. During the session, a questionnaire was filled and an audio recorded out-of-the-box-test was made (see Figure 3). Afterwards, an open conversation about the system was carried. The session lasted 60-90 minutes and was conducted with a single participant at one time. Five participants were included for the

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pretest, 15 took part in the main test. One user who was not participating in the ABT study was included in the pretest but data were not used due to an AE during the session.

In the pretest, the questionnaire was evaluated and CIs for the out-of-the-box-test were collected. The findings of the pretest were used for adapting the questionnaire and the protocol, before the main test started. The revised questionnaire is shown in the Annex 2.

Tests were made for mental health, grip strength and fine motor skills. The conductor did both guidance and observation, no assistant was at place. During the out-of-the-box-test sound was recorded with a HTC One X Smartphone. The participant was instructed to unbox and use the training system. Mistakes, time stamps and help given were noted in a protocol. Help was given when the participant repeated an error twice or did not solve any task for five minutes. Four tasks were given in written form in order to guide the participant through the simulation (see Figure 7).

After the tasks were solved, a questionnaire was given to the participant to evaluate the personal impression of the usability and the own performance. The voice record was paused for that time and resumed afterwards for an open interview in which additional information was collected.

Questionnaire data were analysed via SPSS. The qualitative data from the protocol and interviews were collected and clustered to different topics concerning the usability of the training system. They are used for creating an elaborated manual and for further development of the software.

Perform these tasks step by step. Please inform the study staff after each completed task.

- Unpack all pieces and assemble them. Unlock the tablet.
- 2) Start the "AlfredBackTrainer", synchronize the board with the tablet.
- 3) Put the board on the marked area on the floor and fix the tablet on the stand.
- Play "Cat&Mouse" for one minute and return to the main menu. After that, play 3 levels "Pongy". Finish the app after that.

Figure 7: Guiding Tasks



Figure 8: Setting of the Out-of-the-box-test

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## 3 Results Usability

The following section presents the results of the usability study of the on senior citizens within a clinical environment.

## 3.1 Sample

Thirteen users participated in the usability investigation (5 male, 8 female). The ages of the participants were between 66 and 89 years, mean age was 72.2 years (SD=6.3 years). One adverse event occurred during the usability investigation. User (U) 2 terminated the participation in the investigation due to mental overexertion close. The dataset of U2 will further be analysed since hardly any data are missing, since the adverse event occurred close to the end of the investigation.

Average household income of the users was in most cases below 2,000 € (see Figure 10). The sample consisted of married, divorced, widowed and single users (see Figure 11). Six users lived on their own, seven with partner and without children, twelve users lived autonomously at home and one user in an assisted living situation (see Figure 12 and Figure 13). Apart from one user which was doing voluntary work, all users were retired (see Figure 9). The education level was widespread. 7 participant's highest education was secondary school, and 7 reached university degree (see Figure 14).

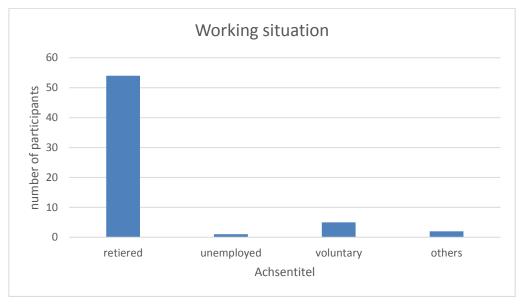


Figure 9: Overview of Work Situation

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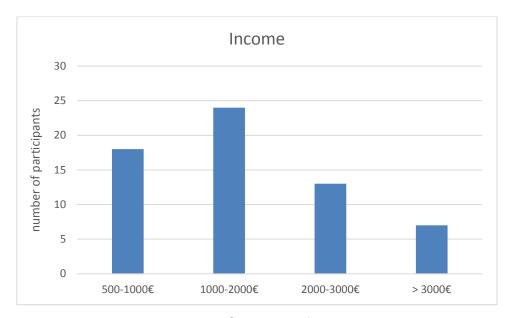


Figure 10: Overview of Income

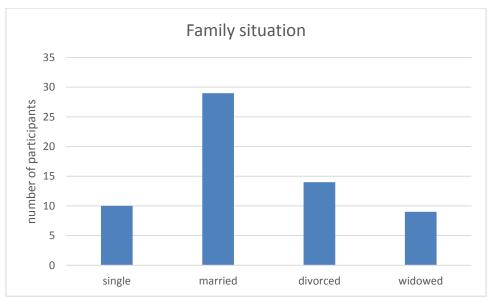


Figure 11: Overview of Family Situation

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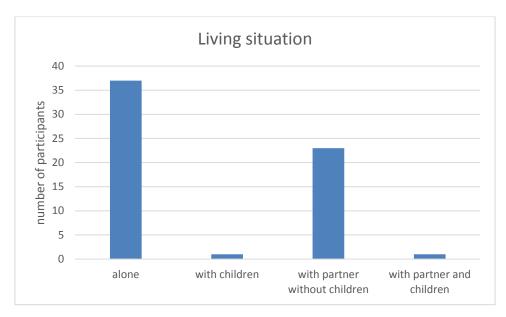


Figure 12: Overview of Living Situation

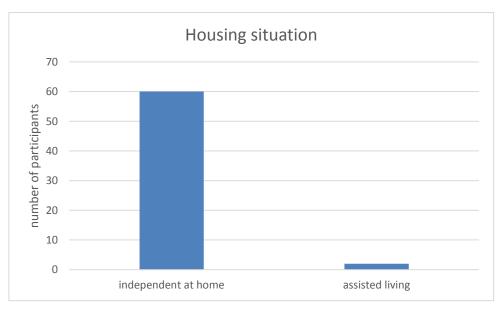


Figure 13: Overview of Housing Situation

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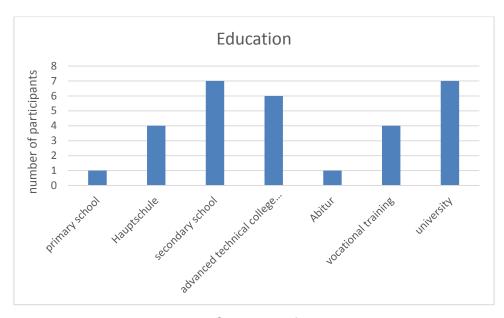


Figure 14: Overview of Education

The questionnaire regarding technical experience showed, that most users did not yet have experiences with Smart devices like Tablets and Smartphones. Whereas the level of overall technology experience is widely distributed (see Figure 15). One user stated to have experience with gaming consoles and two users already had experiences with the Nintendo Wii console. Two users had previously heard about the Nintendo Wii, nine did not know the device at all.

Most users had experiences with touchscreen operation. One user had "little experience", six users had "some experience", four users considered themselves as "experienced" and two users had "no experience".

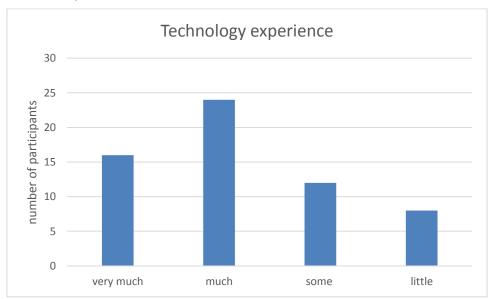


Figure 15: Overview of Technology Experience

The users did not show any cognitive impairments. The values regarding grip strength revealed that some participants deviated more than one standard deviation from the

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average value of the user group. However during the study duration, no physiological problems occurred when the Wii balance board had to be handled. The tests of fine motor skills showed similar results. Despite slight impairments of the fine motor skills of the users, no difficulties regarding fine motor skills could be observed in the study. Tests regarding eyesight revealed that all users had "good" or "very good" vision. Regarding the scale (0-80) of perceived joy of physical activity, the users scored a mean of 68.77 points (SD=10.5).

### 3.2 Data Analysis

Regarding the data analysis the qualitative data are of highest importance. Nevertheless a statistical analysis was performed to uncover possible correlations between test results and the characteristics of the user sample. Qualitative data was primarily gathered from audio recordings, field notes.

#### 3.2.1 Statistical Analysis

The results from the questionnaires were analysed with SPSS. Since the sample did not provide a normal distribution, the Spearman's rank order correlation was applied. A generalization of the results from the sample statements on the population of all senior citizens over 65 years in Germany is not possible. This should when reading throughout this section.

The SUS score for ALFRED Back Trainer is 40.577 (mean). Median and mode are both at 40 points. With 28 points the back trainer is below the average yield of tested devices, which were rated on this scale.

### 3.2.2 Demographics, Technical Acceptance and Use of Technology

Physiological characteristics such as gender, weight and height showed no obvious correlations with other parameters from the questionnaires or tests. The only conspicuous demographic variable is the age that a significantly positive with the technology acceptance correlated (seeFigure 16). When looking at the image, however, shows an outlier with a very old age and relatively high acceptance of technology. Would this user be removed from the plot, the new correlation would be r = .548 (p = .065) and was no longer significant. Thus, any physiological and demographic factors can be ruled out.

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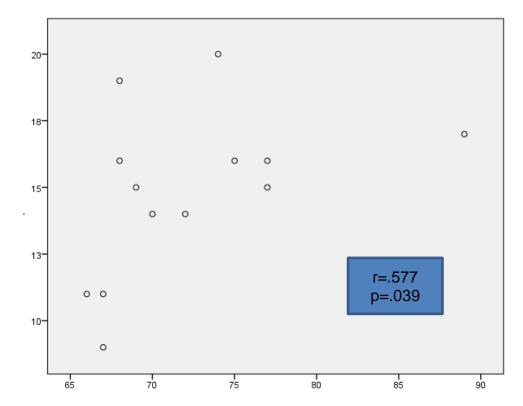


Figure 16: Scatterplot Age (x-axis) - Technology Acceptance (y-axis)

The item experience with tablets correlated with technology acceptance (seeFigure 16). The negative correlation results from the polarity of the response scale. Low values in tablet experience mean in reality real more experience. Therefore, the correlation shows a higher acceptance of technology in people with frequent tablet usage. For the use of smart phones and consoles, this effect could not be found. Technology acceptance also correlated with technical competence (seeFigure 17). A causality can be produced for any of the correlations.

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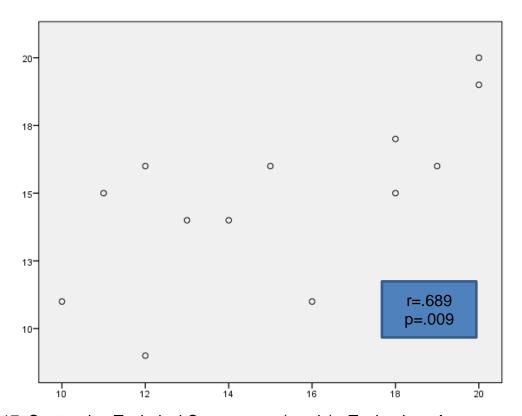


Figure 17: Scatterplot: Technical Competence (x-axis) - Technology Acceptance (y-axis)

The experience with the touch operation of technical devices correlated with the experience in dealing with Tablets (r = -.616; p = .025) and smartphones (r = -.576; p = .039). Accordingly, people have touch experience so more frequently those devices are used. This finding speaks to the significance of the data set.

#### 3.2.3 Processing Times and Errors

In analysis of the errors and processing times during the simulation several contexts became evident. The errors made in total correlated significantly with the required total time (see Figure 14). Both parameters indicate difficulties of the participants in handling the device. During a longer time frame more mistakes can be made and the more mistakes are made, the longer it takes the subject to complete a task. One definition of failure was "no new task solved in the last 5 minutes". This type of error was extremely rare. Main source of error was the "false use of an item", therefore the constructs "errors" and "time" can be viewed on its own as far as possible. The time it took to complete task 1 and 2 also correlated with the total number of errors. The short processing time for task 3 in almost all subjects meant that the time needed for task 1 and 2 had a major influence, as extreme than the total time (period A4). As more mistakes can be made in a longer time, task 1 and 2 affect thus the total error in a larger magnitude.

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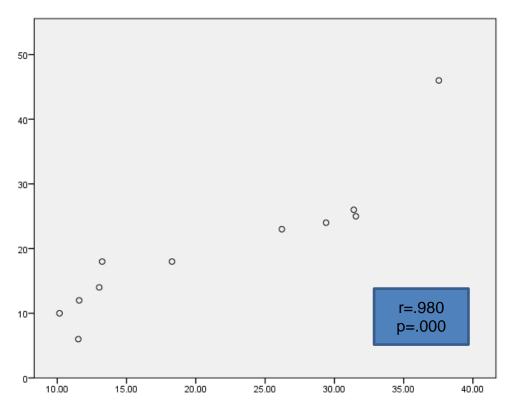


Figure 18: Scatterplot: Period A4 (x-axis) - Total Error (y-axis)

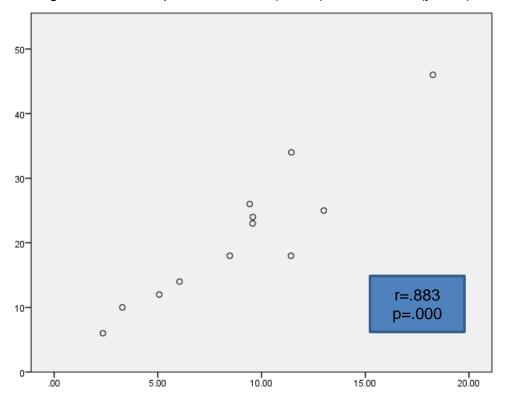


Figure 19: Scatterplot: Period A1 (x-axis) - Total Error (y-axis)

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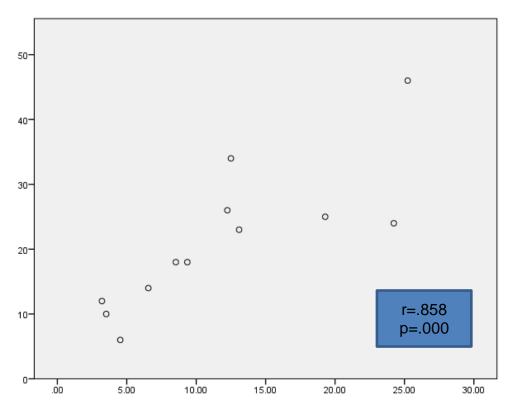


Figure 20: Scatterplot: Period A2 (x-axis) - Total Error (y-axis)

The time required for task 3 correlated with the ASQ mean value, the perceived mental stress and the statement, "Setting up the equipment was easy for me" (Figure 21). Task 3 was to mounting the tablet in the stand and to place the board to the ground. The lack of knowledge about the functioning of the ALFRED Back Trainer is reflected most significantly in this task. The people need a long time to understand what the point of the set-up was. The factors which were responsible for these findings will be presented in the analysis of the qualitative data.

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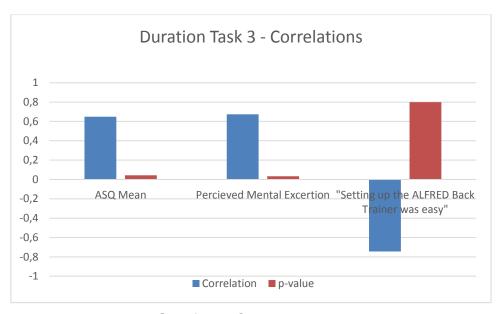


Figure 21: Significant Correlation with Period A3

The number of errors in task 1 correlated with the time needed for it (r = .730, p = .007), as well as the number of errors made in task 2 with the required for task 2 time (r = .606, p = .037). This underlines the aforementioned relationship between errors and time. Furthermore, technical competence correlated with the errors performed in task 1 (see Figure 17), but not with those of the other tasks. The task was "Unpack all parts and assemble them. Unlock the tablet". The items belonging to construct of technical competence, ask specifically for stress and fear of failure in dealing with new technical devices. Perhaps the users with low technical competence were already stressed und made more mistakes but soon got used to the required format. However, the results allow no usable statements.

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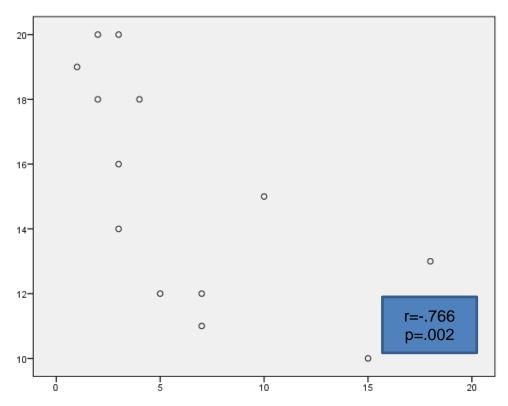


Figure 22: Scatterplot: Error A1 (x-axis) - Technical Competence (y-axis)

The number of errors made in task 4 correlated with the experience of using smartphones and the experience with the touch operation (Figure 23). Users with more smartphone or touch experience made fewer errors in this task. Again, the different polarity arises from the fact that the questionnaire responses were contradictory coded. In the task, subjects were encouraged to try the mini-games in the ALFRED Back Trainer. For this task the control via Balance Board was necessary.

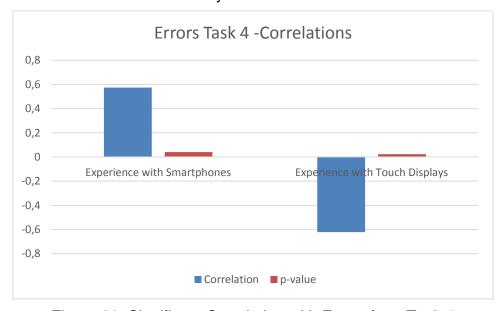


Figure 23: Significant Correlation with Errors from Task 4

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#### 3.2.4 NASA TLX and Self Developed Questionnaires

Within NASA TLX scale the items for the perceived mental (TLX1), physical (TLX2) and total exertion (TLX4) correlated with stress (See Figure 24). A correlation between the highest level of education and the NASA TLX scale was found in the sample. In all cases users with a higher level of education perceived felt less exerted.

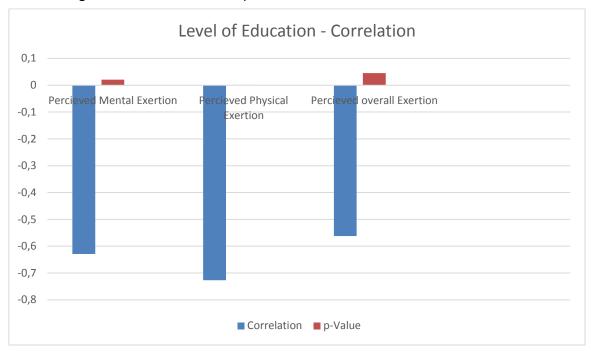


Figure 24: Significant Correlation with Level of Education

Furthermore, the estimated success (TLX3) correlated with the experience with tablets (See Figure 20). The less experience with the use of tablets, the more successful appreciated the people in.

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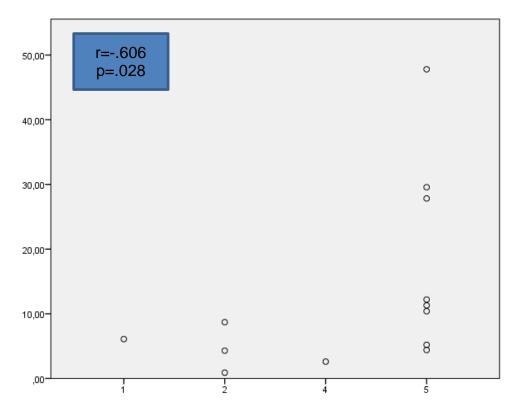


Figure 25: Scatterplot: Tablet-experience (x-axis) - Success Rate (y-axis)

On the errors actually made, the technical previous experience has hardly any influence. Only the experience with the touch operation has a significant negative correlation with the number of errors in task 1 and 4.

Also item 2 of the self-developed questionnaire: "During the test I always knew what to do" revealed a correlation (see Figure 21). Users considered themselves as more successful if they had the impression during the experiment that they knew what to do. Users that were under the impression they knew what to do also made fewer mistakes and finished the task faster.

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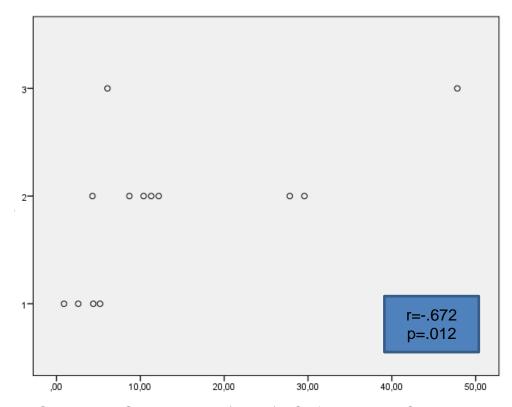


Figure 26: Scatterplot: Success Rate (x-axis) - Self-developed Questionnaire (y-axis)

The question "how insecure, discouraged, confused, stressed and annoyed have you been", correlated with the mean value of the ASQ and the number of total errors made (Figure 27). Users with more experience in dealing with smartphones were therefore those who were less insecure, discouraged, irritated, stressed and annoyed during test. Users that stated that they were pleased with themselves in the ASQ questionnaire also tended to be more satisfied on the TLX scale (Figure 28).

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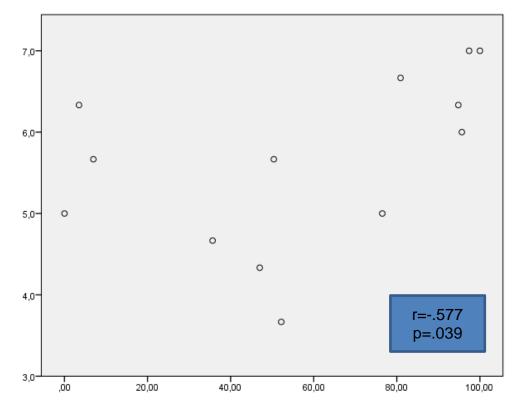


Figure 27: Scatterplot: TLX5 (x-axis) - ASQ-arithmetical Average (y-axis)

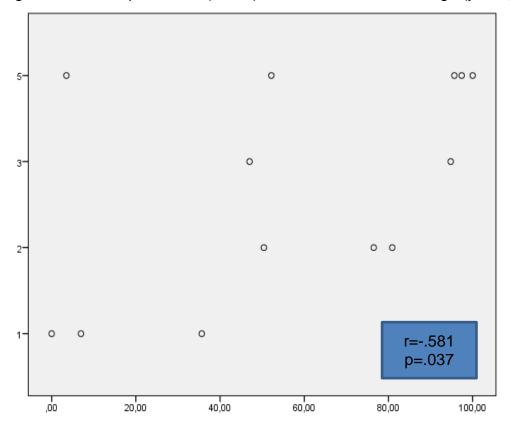


Figure 28: Scatterplot: TLX5 (x-axis) - Total Errors (y-axis)

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#### 3.2.5 Qualitative Data

During the test voice recordings were made to analyse the users' statements. The recordings were intended as support for the written notes that were also taken during the test. The classification matrix in Table 1 gives an overview of the error categories.

Table 1: Error Categories

	Custom-based	n	Rule-based	n	Knowledge-based	n
Error of omission	<ul> <li>Mark for board on the ground was overlooked</li> </ul>		Use of one board instead of two		OTG-Dongle has not been plugged in	
	<ul> <li>Not all materials removed from package</li> </ul>				Screen could not be unlocked in time	
	Non-use of device due to negligence				Non-use of device due to lack of	
	Batteries were not used				knowledge	
		19		4		9
Execution error	attempt to plug in the Bluetooth cable on wrong side		<ul> <li>wrong touch operation occurred</li> <li>pressing the red button on the screen instead of battery compartment</li> <li>standing on the board for game control</li> <li>typing on screen for game control</li> </ul>		<ul> <li>opened up the wrong app/ menu</li> <li>incorrect installation of the tablet on a tripod</li> <li>game control by sitting down, pressing the OTG-Dongles, pressing with hands, swinging the arms, sliding the feet, moving the tablet</li> <li>incorrect position on the board</li> </ul>	
		5		22		27
Error by adding	closing the app by accident		<ul> <li>searching a cable connector on the board</li> <li>opening the SIM/SD-Slots on the tablet</li> <li>attempt to open the board</li> <li>misalignment of the screen</li> </ul>		<ul> <li>boards placed on top of each other</li> <li>removed OTG- Dongles during the attempt</li> </ul>	

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		pressing the power button		
	1		24	3

Error categories are knowledge-based execution errors (n=27), rule-based adding error (n= 24), rule-based execution errors (n=22) and custom-based omission errors (n=19). The distinction of the errors between rule-based and knowledge-based is not quite clear in some cases. In the classification faulty actions that would be the right place for the regular use of tablets or the Wii Balance Board are regarded as rule-based errors. However, it is possible that these behaviours are based on a "trial and error" are taken and are therefore in fact knowledge.

The knowledge-based execution errors in most cases, were related to the improper use of the tablets. Opening incorrect apps and menus shows that the users did not know where they should look for the app, which was required in the task. The corresponding icon was on the main screen of the tablet. Sometimes the app was found by "trial and error", however such actions were not recorded as an error.

The second knowledge-based execution error arose during the assembly of the tablet in the stand. The subjects mounted the tablet in an insecure way, which could have led to damage of the tablet. In most cases, the screw to properly secure the tablet was not closed. For this reason, the tablet could have slipped out of the stand and fallen on the ground. Some people tried to twist the tripod with high force, for this reason, in some cases, the tripod or the tablet were almost been damaged.

The third type of knowledge-based error was related with the control of the game. The games were designed in a way, so that the users had to lie on both boards and control the dots by shifting their centre of gravity on the boards, while maintaining a bridging position. Various ways of controlling the game were tried by the users, ranging from typing on the screen via the pressing of the USB OTG dongles to faulty control experiments on the boards. During the faulty control experiments on the boards, the users, in some cases, have been successful, since the control based on weight transfer and thus can be performed in other positions (standing, kneeling) than the intended bridging position. Only one user assumed the correct position.

Rule-based execution errors are the second most common error category with 24 errors. Such errors occur when known behaviours are applied to a situation in which they are not helpful in the new situation. Attempts were made to open the top of the Nintendo Wii balance board or. Some subjects held the top for a kind cover, following the scheme of opening devices to the extent that it comes close to the buttons inside.

For the connection between the tablet and the Nintendo Wii balance boards, the USB dongle was used. However, users also searched for a cable connector on the board or pressed the power button, which is not required for the synchronization between the boards and the tablet. Underlying schemes probably concern the notion devices must be connected by cables and that devices need to be turned on before use.

Rule-based execution errors were the third most common error category. In this category contains actions which would have been correct in other situations and for this reason probably result from an action which is based on the intuition of the user.

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One type of this error is a faulty touch operation. In this case, here (Figure 29) the reference to the red sync button in the battery compartment was misunderstood. Five subjects tried instead to press the red button on the screen.

Another type of rule-based execution error was that users were standing on the Balance Board rather than assuming a bridging position. The usual way to control the balance board in a standing position is not correct when training with the ABT. Users which are familiar with the balance board are most likely to stand on the board rather than lying on them and performing a bridging position.

In the category of habit based omission errors, a total of 19 mistakes were made. The errors were largely caused by carelessness or superficiality of subjects. Instructions were ignored or not complied with, components were overlooked or not used. Probably the large amount of unknown objects and items may have contributed to an overburdening of the users. This is underlined by statistical relationships between technology competence and number of errors and the time needed and the perceived mental stress. User 6 also pointed out that her mental capacities heavily lay on setting up the device, so it was hardly possible to think about the proper use of the equipment.



Figure 29: Reference to the Red Sync Button in the Battery Compartment

In addition to the logged errors, statements that were made by the users were also protocolled. In the table below all written comments are listed and the issue raised highlighted. The issues listed here relate to the desire of a user manual, content and language comprehension problems and criticism of the comfort of the ABT. The Table 2 below presents categorized statements.

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Table 2: Statements in Categories

Statement	Instruction	Language	Conception	Comfort
The lack of operating instructions; missing text in English				
No implementation because of missing German instruction. Usable for TV with USB. Manual for the exercises more useful.				
I would have preferred to read the instructions for the game; with the purchase of a device, a full instruction sheet is supplied.				
I was missing instructions for use to play the tablet game. I was completely overtaxed because I did not know how this should work.				
I have never really understood the meaning of the game and I was not able to play it.				
I do not understand the use of the back trainer. I suggest it can acquire a better posture by playing games.				
The device is not comfortable for the elderly. The handling by feet is difficult. There is no incentive to provide such a device.				

Other comments related to concerns and suggestions regarding the app. For example, the comfort of boards was also verbally strongly criticized. The shoulder-board was found to be too hard and the attitude of the legs on the foot-board was associated with calf cramps associated.

Users also explicitly requested an introduction of how to use the ABT (U2, U6, U12). Furthermore some users expressed concerns about the affordability and space usage of the appliance for smaller households. Users with low incomes might be unable to finance the ABT. In addition, the ABT would need to be dismantled before and after each use because it occupies otherwise too much space in small apartments. This in turn is impractical (U2, U6). Notes on the improvement of the device involved the use of a television monitor instead of the tablets and the introduction of a multi-player mode (U6). U9 noted that it would assume that the Bluetooth function must be integrated into the tablet.

U2 quit the usability investigation due to frustration after he had failed to take the ABT into operation. In order to successfully use the ABT this is the worst case, since any further analysis of the ABT was denied at this point by the user. The user generally had a negative attitude towards modern technology, which was reflected in the comments he made: "I don't want to use tablets, I cannot operate them, and they are absolutely taboo for me" "I cannot handle tablets. I do not even know what to do with tablets." "I do not know how to connect this because I cannot handle it" or the answer to the indication that everything could be tried during the usability test: "Do not say anything. Otherwise I will

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throw it on the wall. I did that with my phone and since then I do not have one, because I don't want to have one". This user also showed the lowest technical expertise and the lowest levels of education. For the subsequent marketing of the ABT, it is therefore relevant to define the target audience precisely because S2 is a good example of a user who indeed reflects demographic requirements, but rejects the use of technical devices.

Overall, the mistakes that were are connected to a lack of knowledge in the field of Bluetooth connections and the users' body positioning on the Balance Board to control the device. The main criticisms of the users was the lack of a manual for the ABT and, consequently, the lack of clarity of the device. Below recommendations for further development of ALFRED back trainer are formulated, which are derived from the information collected during the usability evaluation.

#### 3.2.6 Summary and Recommendations

The ratings for the ABT on the System Usability Scale received the highest values in users that had little difficulties in setting up the ABT. Furthermore, the statistical analysis has shown that greater technical competence of the users did not lead to a better performance while setting up the ABT, but at least to more composure of the users during the process.

Users with previous experience in the use of technology to show a higher acceptance in terms of technical innovations but did not complete the required tasks faster or with less errors then users with no previous experience in technology. The longer the time to complete the task was, the higher was the perceived stress of the users. Users with lower education levels felt more stressed than users with higher levels of education. In order to keep the general stress level as low as possible, it should be in the interest of the developers to keep the process of setting up the ABT as short and simple as possible.

This implies that all the settings that can be made in advance are also done before and should not be left to the user. For all steps of setting up the ABT it is advisable to design a detailed manual, so that the user has to handle as little information as possible simultaneously. In order to reduce the complexity the instructions and the application should also be written in the users' native language.

In the usability test, the users made very many mistakes due to ignorance and lack of experience with the system. Applying known methods in the context of technical equipment and trying out possible solutions led it to control and knowledge based errors. Many errors were also caused by carelessness or superficial task processing of the users.

The fundamental problem of the users was that they had never seen or tested a similar device as the ABT. Through the lack of knowledge, many steps in the setting up process were not logically deducible, which led to the errors described in the evaluation part. Both the general knowledge about the use of tablets, as well as on the concept of wireless connection between two devices, and the correct body positioning on the ABT was not or not sufficiently available within this group of users. This knowledge should either be made available to the users, or the ABT should be constructed in a way, so that this knowledge is not relevant to for setting up the ABT.

The transfer of knowledge in written and pictorial form, in this case represents the simplest and most cost-effective option, which could be incorporated in a manual for users. However, the risk that information will be skipped or ignored by the users can't be avoided.

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Transferring the relevant knowledge to set up the ABT in the form of a one-to-one training would be time and cost intensive and would be another form to educate users.

Errors due to lack of attention could be reduced by weak Poka Yoke, for example in the form of signs on the equipment or questions on the tablet as soon as it is put into operation.

In summary, the following steps in should be considered in order to increase the user-friendliness of ABT:

- 1) Translate the texts in the app in German or in the mother tongue of the users. Instructions can be understood only if the language is understood. Since that was not the case in many circumstances, instructions were not understood, or understood incorrectly or in the app.
- 2) Provide a detailed, written manual which is supported with pictures for the set up process of the ABT. The manual should contain instructions on how to insert the batteries in the balance board, the Bluetooth connection of the devices and the correct assembly including warnings symbols for boards and tablet. Also a tutorial for the mini-games within the app would contribute to a better comprehensibility during the set up process.
- 3) Evaluation for the need of one-to-one for training for users.
- 4) Replace the USB OTG dongles through the internal tablet Bluetooth. The confusion of the users about the cable and the adapter as well as ignoring or removing the cable during the trial led to interruptions in the set up process.
- 5) Better placement and larger font for the text in the ABT app. This allows easier operation for users with low vision and the attention of the users can be better directed to the instructions.
- 6) Carrying out further usability testing to implement the suggestions that are provided in this document. One of these tests should investigate whether a fixed sequencing of the set up process is perceived as a simplification measure or a restriction.

The proposed iterative tests should investigate and if necessary, adjust the effectiveness of improvements. In the current state of the system is not yet ready for the consumer market. Many of the observed errors in this experiment may no longer occur with repeated use of the ABT because the users will learn and internalize the correct steps of the set up process. However it is important that at first contact with the ABT, the users are familiar with the correct execution of the exercises and on the other hand, that the users will have a positive experience while using the ABT in order to foster a long-term use of the ABT.

Basically, the ABT can be used of the target group of senior citizens. However, it needs further research in order to optimize the usability of the device.

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# 4 Evaluation of the Effectiveness of the ABT

Before the actual results from the hospital pilot and the ABT usage as a serious game based on biofeedback principles will be presented, the following chapter will provide a brief overview about the use of serious games, definitions and application.

When it comes to the topic of Serious Games, literature yields almost as many definitions as there are authors. This difficulty to capture in one passage the multitude of purposes for which Serious Games are used for shows, how broad the topic is and how many uses for them can be found. This text shall provide a short overview of some of the ways Serious Games can come to use and explore the status quo for Physical Activity Serious Games for elderly with lower back pain.

### 4.1 What is a Serious Game?

Referring to [Hob15] Serious Games can be seen as applications, contents, simulations and technologies that pursue a goal consisting of more than just entertainment. With this kind of open definition, Serious Games are neither preassigned to any device nor to a certain purpose.

[MH16] assign even board games to the portfolio of (analogue) Serious Games. Whereas [Sus07] and [Zyd05] only include personal computers or videogame consoles, which create imaginary worlds obviously separate from real life. However, which medium is included in the definition of Serious Games depends on the purpose for whose fulfilment the specific game is used.

# 4.2 Purposes of Serious Games

Such purposes could be physical or cognitive trainings, education, health, public policy and strategic communication objectives [Zyd05]. Depending on the tasks set in the game and their connection to certain topics and skills, the bandwidth of possible uses for Serious Games seems to be endless. Also, the target group of the game varies in age, gender, health status, interests and so on. The custom-fit design of a Serious Game meeting the user requirements as well as its meta-level purpose falls to the developer.

Our understanding of Serious Games contains the use of any electronically device in conjunction with a target-oriented use of the game. The targets discussed in this text include learning, mental training and physical activation.

<sup>1</sup> In this context, it seems difficult to even differentiate between 'conventional' games and Serious Games. [KB09] state that every game inherits a learning process, but that one could not exploit games for didactical purposes. This statement would be a death-sentence for Serious Games in general, but it ignores that the goal of a Serious Game is not necessarily educational. Furthermore, the overall goal stands first and helps defining the game itself, not the other way round.

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# 4.3 Learning

[Gir13] reviewed nine experimental randomized control studies which were run in order to evaluate the effectiveness of Serious Games for learning (Educational Games).<sup>2</sup> He states that there was a clear lack of empirical studies investigating the effectiveness of Educational Games. Therefore, it is not possible to make reliable statements about their usefulness.

In a newer study, [IP16] showed that Serious games may lead to greater learning motivation and thus to more effective learning when compared with traditional teaching methods. They found that usefulness, simplicity, use of prior knowledge, feedback and help have a significant impact on the learning effect.

Due to the short existence of this research field, no final conclusion can be drawn. Further research need to provide new findings to clarify the usefulness of Educational Games.

# 4.4 Mental Training

There are many games available which are held to have a positive influence on mental skills. So called *Brain Jogging, Brain Games or Brain Training* are a huge market which provides a multitude of games. But the least of them were tested in a clinical study to ensure their positive effects.

The transferability of skills learned in games to real-life constructs is heavily discussed in literature. Nevertheless, several studies support the transferability of speed processing [Bal07], memory [Mah06], attentional control [Bhe10], task switching, working memory, visual short-term memory and reasoning [Bas08]. One study specified for elderly people could show that "the cognitive training program using the newly developed Smart Harmony was effective at improving cognitive function in elderly people" [Kim15].

Differences between traditional and game-based cognitive training are not well explored. Though [Kim15] found that both training methods can slow up the decline of cortical thickness in the brain of elderly people.

Seemingly there is proof that Serious Games can improve mental abilities. But due to the huge amount of games pretending to be a Serious Game without scientific verification, a customer cannot know about the utility of a game in a specific case.

# 4.5 Physical Activation

For physically activating Serious Games (Exergames), it is necessary that any kind of device is given to measure the movements of the player and to integrate the data into the game process. In research, the application of Wii Balance Boards or similar devices recently is getting more popular [Bor14]. The validation for clinical use of Balance Boards was done by [Bon16]. He compared the outcomes of Wii Balance Board data to those of a force plate using a sample of 35 healthy young adults and found that the parameters measured for both methods correlate with .95 and .96 for two games tested.

<sup>2</sup> The games which were tested namely were MEGA, Re-Mission, Indiana Jones & The Emperors Tomb, Medal of Honor – Allied Assault, Rise of Nations, RCAG, DimensionM, TriageTrainer, New Super Mario Bros, SimCity and E-junior

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[Cha15] for example used the standard game collection Wii Fit to show, that training increased balance and mobility and decreased depression. 32 elderly residents participated in this interventional quasi-experimental study of 4 weeks duration. "The Wii Fit group received the SAHA intervention twice a week", while "The education group received health education material once a week" [Cha15]. SAHA intervention (Stay Active, Healthy Aging) stems from a study from [Cha13]. Although it remains unclear, why the control group had this kind of training, the study shows a positive influence of Wii Exergaming on the physical condition of older adults.

The choice of Exergames varies between studies. [Cow15] stated, that "research to date has been done primarily on apps designed specifically for research and, as a result, are not publicly available". In terms of public health, this is an issue worth considering. It is for sure not feasible to clinically test every single Serious Game. In fact the attention should be given to the theoretical constructs of exercises or specific training devices underlying the games. This counts for Exergames as well as for mental trainings. Nevertheless, more existing games could be investigated, or more researched games could be made accessible for public use, in case a positive influence has been found.

A comparison between typical due to a lack of a real control group as well as that the sample exclusively consisted balance exercises and Exergames by [Gio13] showed that even though typical exercises provided better results, both groups improved significantly. 40 students were included in his RCT which lasted 8 weeks. One group used balance Exergames on the Nintendo Wii while the other group trained with mini trampoline and inflatable discs. The study can be criticized because of a lack of a control group. Besides the sample exclusively consisted of undergraduate students of the Department of Physical Education and Sport Sciences at the Democritus University of Thrace. Therefore the findings can hardly be generalized or ascribed to the intervention.

[Fu15] compared the Wii Balance Board to conventional exercises with a sample of 60 older adults aged over 65 years. The RCT intervention endured 6 weeks. He found significant better results for the Wii Fit Balance Training than conventional balance training concerning muscle strength, reaction times and body sway. Here as well the conventional exercises group is stated to be the control group, which is methodological incorrect.

The findings that Exergames are better or at least equal to conventional training is no astonishing when considered that both groups do similar tasks. Exergames should be based on well-known therapeutic or similar exercises. In this manner, they just add a gamification component to existing validated exercises in order to profit from its motivational aspects.

Exergames can be used for restoring or at least to improve the health of a person with physical impairments. As mentioned, underlying therapeutic concepts are transferred into the gaming context. This opens up the target group towards people with chronic or temporary pain caused by physiological reasons. Furthermore people with overweight or insufficient body control could profit from the Exergames. We now focus on the group of older adults, which are likely to experience physical impairments [Böh09].

# 4.6 Serious Games for Elderly People

The meta-analysis of [Skj16] of Exergame effects on elderly people showed evidence for balance and gait improvement. 60 studies were reviewed which involved older adults aged

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65 or more. They found that Exergames are used progressively more to increase physical activity and improve health and physical function in older adults. From the studies included only four studies achieved more than five out of ten points on the PEDro scale. This is a sign for methodological weaknesses of most of the 60 studies. Seven studies showed a positive influence on health while no study found negative influences. "43 of the included studies used commercially available gaming technologies. 17 studies used custom-designed games." [Skj16]

Generally, most of the Exergames studies address balance [Agm11], [Fu15], [GSM], [Gio13], [van13], [Nau15], while no studies concerning pain reduction in elderly people can be found on the PubMed or MedLine databases (search criteria: *Serious Game* or *Exergame* and *elderly* or *older adults* and *pain*).

### 4.7 Serious Games for Lower Back Pain

Searching for *Serious Game* or *Exergame* and *lower back pain* or *pain*, no results can be found in the databases of PubMed and MedLine, which would lead to studies about such games treating lower back pain or pain in general. For this reason the ABT which was developed within the ALFRED project can be seen as a highly innovative concepts which will be of great interest for persons working in the fields of rehabilitation, exercise therapy and serious games.

# 4.8 Recruitment Process and In-/Exclusion Criteria

The participants were recruited through leaflets which were placed in local pharmacies, senior activity centres Gp's offices. All participants were informed about the study and screened telephonically before the study started. Subjects were included when they signed informed consent were 65 years or older, did not present any affective or cognitive diseases, acute back pain, chronic LBP, participation in another intervention study, legal care, immobility, recent surgical intervention, acute herniated disc, spinal tumour.

# 4.9 Sample

The study included 62 participants (44f, 18m) with subacute LBP. Overall 57 users were from PTG1, 3 from PTG2, 0 from PTG3, 1 from STG1 and 2 were former STG2. The average age was 74.02 years (R=66-89; SD=5.66), the average body size 166.37 cm (R=150-187; SD=9.17) and the average weight 73.7 kg (R=48-108; SD=11.41). 17 subjects dropped out of the study, main reason was a delay of the investigation due to a theft of technical equipment, which led to conflicts with the patient's personal agenda.

### 4.10 Results

The personal health was estimated as "very good" in one case, "good" in 39 cases, "moderate" in 21 cases and "very bad" in one case. Sight was without restriction in 37 cases, slightly restricted in 23 cases and heavily restricted in 2 cases. Hearing was without restriction in 37 cases, slightly restricted in 24 cases and heavily restricted in one case. Fine motor skills were without restriction in 50 cases, slightly restricted in 11 cases and rather restricted in one case. The mobility was estimated as "very good" in 2 cases, "good" in 42 cases, "moderate" in 17 cases and "bad" in one case.

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The attitude towards technology was 51 times "positive", 9 times "neutral" and 2 times "negative". 36 people used a standard mobile phone, 20 people used a smartphone running on Android, 4 people used a smartphone from Apple, one person used a senior-focused mobile phone, and one person "other". The personal experience with technology was rated "very much" from 16 participants, "much" from 17 participants, "moderate" from 13 participants, "low" from 6 participants and "very low" from 10 participants. 33 of them used information and communication (ICT) daily, 10 weekly, 5 monthly, 7 "rarely" and 6 "never". One person did not answer.

The answers concerning the subjective well-being are displayed in the chart (Figure 30) below.

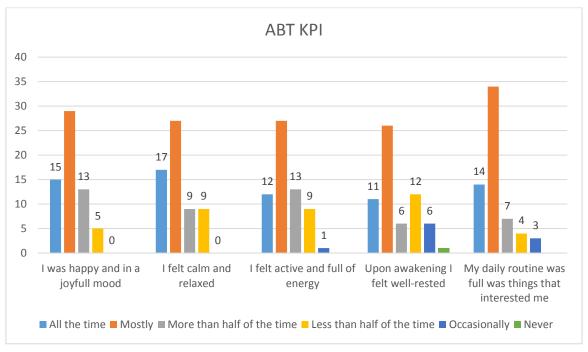


Figure 30: ABT KPI

### 4.10.1 KPI Mental Well-being:

The questionnaire about mental well-being was derived from the Warwick-Edinburgh Mental Wellbeing Scale [THF+07]. The questionnaire consisted of five items on a five point Likert scale. The questionnaire was evaluated before and directly after the pilot. The Table 3 below presents the scores in % improvement/decline after the per/post analysis. The ABT group showed improvement in all areas of the mental well-being scale and an overall improvement of 19.4%. For this reason the KPI of a 10% increase in mental well-being was met and succeeded way beyond the expected impact. Controversially the Standard group had a decline in all values of the questionnaire, with an overall decrease of 21.7% while the Control group only slightly increased by 7.6%.

Table 3: KPI Mental Well-being

	ABT	Standard	Control
"I was happy and in a joyfull mood":	+29.4%	-42.8%	-4.3%

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"I felt calm and relaxed":	+27.6%	-35.7%	-16.7%
"I felt active and full of energy"	+17.6%	-3.3%	-8.3%
"I felt fresh and relaxed upon awakening"	+3.3%	-6.8%	-11.4%
"I life was full of interesting things":	+19.5%	-20%	+5.4%
Overall change	+19.4%	-21.7%	7.6%

### 4.10.2 KPI Increased Amount of Physical Activity:

Another defined KPI was an increase of physical activity. This item was collected was collected after the pilot by asking the users whether they were feeling that they are in general more active since the pilot compared to the time before. The results in Table 4 show that both intervention groups are definitely more active since the pilot started compared to before the pilot. Two thirds of the ABT users were more active since the pilot while even 80% of the standard group were more active since the pilot started. A reverse observation was made in the control group, with a strong decrease in physical activity. Despite the fact that the pilot started in spring time in which the normal activity would be generally be expected to increase, a decline was detected. The KPI for increased amount of physical activity by 10% of the users for this reason was met and received values way beyond the expected impact.

Increase activity	Yes	No	
ABT	66.7%	33.3%	
Standard	80%	20%	
Control	21.1%	78.9%	

Table 4: KPI Increased Amount of Physical Activity

### 4.10.3 KPI Sleep Quality

The sleep quality was measured with the Pittsburgh Sleep Quality Index (PSQI) [BRM+89]. The PSQI is an internationally known and validated questionnaire which consists of 24 items for the self-evaluation sleep quality. A good sleep quality is associated with less than 5 points, while a bad sleeping quality is present at 5 points or more. All groups had a bad sleep quality before the pilot, while the sleep quality after the pilot, after the pilot all groups had an increased sleep quality while with the highest increase in the Standard group and the lowest in the control group as shown in the Table 5. The ABT group also increased by 37.3%. The KPI for this item was also met with a more than the threefold effect of the expected KPI.

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Table 5: KPI Sleep Quality

	ABT		Standard		Control	
PSQI (pre/post) (Points)	6.7	4.2	6,6	3.6	6.1	4.6
Change in %	+37.3		+45.4		+24.6	

## 4.10.4 KPI H<sub>2</sub>O Consumption

The  $H_2O$  was measured as the average daily consumption in millilitres (ml) as an item within a questionnaire. While too low  $H_2O$  consumption is often a problem in older adults, this was not a problem for the users of the pilot. By looking at the demographics of age and weight it is recommended that a female of 60 kg within the age range of the population of the pilot is supposed to drink approximately 1200 ml while a male older adult should consume about 1600 ml. For the observed population  $H_2O$  consumption was already at a sufficient level and therefore a further increase was not required. While the KPI was set at a 10% in  $H_2O$  consumption, one could argue that is goal was not met, however in the light of the already sufficiently high  $H_2O$  consumption, this KPI can be valued as neutral. The Table 6 below shows the overall KPI  $H_2O$  Consumption.

Table 6: KPI H<sub>2</sub>O Consumption

	ABT		Standard		Control	
H <sub>2</sub> O Consumption (pre/post) (ml)	1593	1538	1535	1696	1712	1472
Change in %	-3.4		+10.4		-14	

# 4.10.5 KPI Reduction in Time Consumed by a Healthcare Provider/Reduction in Contacts with Healthcare Providers for Sensor Checks

As previously mentioned users had the opportunity to have their vital data measured before and after each exercise session with the ALFRED sensor T-Shirt. The KPI was set at a reduction of 10% of sensor checks through a healthcare provider in the last twelve weeks. While the standard and the control group both showed increases of 100%, respectively 160% percent in visits of a healthcare provider for sensor checks, no changes in the ABT group were observed as shown in the Table 7 below. Despite the good results of the ABT compared the other group, in this case the KPI was not met.

Table 7: KPI Reduction in Time Consumed by a Healthcare

	ABT		Standard		Control	
Visits for Sensor Checks (pre/post) (#)	8	8	8	16	10	26

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Change in %	0	+100	+160
S .			

# 4.10.6 KPI Reduction in Time Consumed per Visit by a Health Care

### **Provider**

This KPI was defined as a 10% reduction in time per visit by a healthcare provider when using ALFRED, compared to standard procedures. Table 8 shows that in this instance the number of corrections which a health care provider had to perform in order to correct the subjects body position during the exercises during one session. In this instance, two instructors and one person to document the number of correction of the user's body position were present. During this session eight corrections had to be performed in the ABT group and 13 in the standard group. This equals a reduction in the workload of 62.5%. Or expressed in time, on correction to a subjects body position took approximately 15 sec. For this reason the KPI was met.

Table 8: KPI Reduction in Time Consumed per Visit by an Health Care Provider

	ABT	Control
Amount of correction	8	13
Consumed time	2 min	3 min 25 sec

### 4.10.7 KPI Self-Referred Visits to Doctor

Users were also questioned how often they performed self-referred visits to a doctor in the last twelve weeks. The KPI was set at a reduction of 10% of self-referred visits to a doctor. Self-referred showed the highest decrease in the ABT group, with 55.9% followed by the Control group with a reduction of 54.1% and the Standard group with minus 23.5% (Table 9). For this reason the KPI for item was met.

Table 9: KPI Self-referred Visits to Doctor

	ABT		Standard		Control	
Self-referred visits to doctor (pre/post) (#)	9	4	17	13	48	22
Change in %	-55.9%		-23.5%		-52.1%	

The number of self-referred visits to a doctor in the last 12 weeks dropped in all three groups. The most likely reason for this might be that fact that the pilot stared in April. Calculating back 12 weeks from April is still in the middle of the influenza season, so the seasonal effect might be the main reason for the reduction for the number in self-referred health checks.

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### 4.10.8 KPI Willingness to Pay

After all users received a demonstration about the ALFRED system they were asked in a questionnaire, how much they were willing to pay for ALFRED as a one-time payment in the form of a package or as a monthly lease. The KPI's were set at 200 € for the single payment and at 30 € for the monthly lease.

63.9% percent of the participants were willing to pay for the ALFRED system and 36.1% were not interested in buying ALFRED. The average amount that users were willing to pay for the complete system was 120 € and the monthly fee in order to lease ALFRED as a package was 23.90 €. In this case the KPI was not met.

### 4.10.9 Functional Effectiveness

In order to assess the actual effectiveness of the ABT a wide set of assessments and validated questionnaires were conducted. The Oswestry disability questionnaire [Fai80] focuses on LBP related disability. Values from 0-20 are associated with minimal disability, 21-40 with moderate disability, 41-0 with severe disability, 61-80 with crippling LBP and 81-100 are bedbound or have an exaggeration of their symptoms. Self-rated physical disability was measured with the Roland-Morris Disability questionnaire [FP00], a maximal worst possible disability relates to a score of 24 and no disability at 0 points. In a pre/post comparison relevant changes can be expected if the score changes by 1-2 points in patients with moderate disabilities (more than 9 points) or more than eight points in patients with severe disability (more than 16 points). Sleep quality with the Pittsburgh Sleep Quality Index (PSQI) [BRM+89], a good sleep quality is associated with less than 5 points, while a bad sleeping quality is present at 5 points or more. Fall risk was measured with the four square step test [DT02], at scores of 15 seconds and above, older adults are at risk for multiple falls. The five times sit to stand (5TSTS), [Gur00] was used as an additional tool to evaluate fall risk and functional lower extremity strength. The test is positive if subjects aged 60-69 years require more than 11.4 and subjects 70-79 years more than 12,6 seconds to complete the test. Flexibility of the spine with the Schober-Ott test [Fic05], a normal flexibility of the spine is associated with values above five 5 cm. The fingertip-to floor test [SSR00] was used to assess the flexibility of the lumbopelvic region, in normal healthy subjects normative values are between 0 and 10 cm, higher values are associated with decreased flexibility. Muscle strength for the left and right isometric trunk flexion and the trunk flexion was measured, in kilograms, with the Sauter FK 1 hand held dynamometer. The muscular endurance of spinal erector muscles was measured with the subject lying in a prone position on a plinth, with the spina iliaca slightly tilted. The subjects then were instructed to lift their trunk against gravity in the air. The time in which the subject was able to continuously hold the trunk in the air at the height of a preset mark, was measured. The Post-Testing consisted of the same testing battery as above in order to make a pre/post comparison possible.

Table 10 shows the results of the changes in related functional disability measured with the Oswestry disability index as well as the increases or decreases of the values. While the ABT group showed only minimal disability at baseline, the standard group presented moderate disability. The largest decrease was seen in the standard intervention group which decreased from a moderate disability to a minimal disability, followed by the ABT group and the fewest decrease was seen in the control group.

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Table 10: Results of the Oswestry Disability Index

	ABT		Standard		Control	
Oswestry disability index (pre/post) (points)	19.1	15	22.6	17.2	8.7	6.6
Reduction/Increase	-4.1		-5.4		-2.1	

Results from the Roland Morris questionnaire for self-rated physical disability the biggest improvements for the standard group, followed by the ABT group and the control group. Relevant changes were only seen in the ABT group and the standard intervention group (Table 11).

Table 11: Results from the Roland Morris Questionnaire

	ABT		Stan	Standard		Control	
Roland Morris (pre/post) (points)	5.5	3.6	5.8	3.2	4.4	4.1	
Reduction/Increase	-1.9		-2.6		-0.3		

The fall risk was measured with the FSST. The ABT group showed the largest decrease in fall risk, followed by the standard group and the control group (Table 12).

Table 12. Results of the Fall Risk Measured with FSST

	ABT		Standard		Control	
FSST (pre/post) (sec.)	7.6	6.3	7	6.1	6.3	6
Reduction/Increase	-1.3		-0.9		-0.3	

The Schober-Ott Test showed a decreased flexibility of the spine in all users at base line (Table 13). The ABT group actually minimally increased in in spinal flexibility, while Standard and Control group slightly decreased spinal flexibility, compared to baseline.

Table 13: Results from the Flexibility of the Spine (Schober-Ott Test)

	ABT		Stan	Standard		Control	
Schober-Ott Test (pre/post) (cm.)	2,0	2,1	2,4	1,6	2,4	1,8	
Reduction/Increase	+0,1		-0,8		-0,6		

Strength for the isometric lateral flexion of the trunk to the right side was more than doubled within the ABT group, increased by about two thirds in the standard group and also an increase could be found in the control group (Table 14).

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Table 14: Results of Isometric Lateral Flexion of the Trunk to the Right Side

	ABT		Stan	Standard		Control	
Lat flex right (pre/post) (kg.)	9.1	19.2	8.8	15.2	10.1	15	
Reduction/Increase	+10.1		+6.4		+4.9		

The isometric lateral flexion of the trunk to the left side showed the highest increases in the ABT group, followed by the standard and control group (Table 15).

Table 15: Results of Isometric Lateral Flexion of the Trunk to the Left Side

	ABT		Standard		Control	
Lat flex left (pre/post) (kg.)	12.2	19.2	10.7	14.9	11.2	13.7
Reduction/Increase	+7		+4.2		+2.5	

Isometric strength of the Rectus abdominis showed the strongest increases in the standard group, followed by the ABT group. A slight increase in strength was also observed in the control group (Table 16).

Table 16: Results Isometric Strength of the Rectus Abdominis

	ABT		Standard		Control	
Rectus abdominis (pre/post) (kg.)	13.5	17.1	11.4	15.4	13.6	15.1
Reduction/Increase	+3.6		+4.0		+1.5	

Mobility of the lumbopelvic region was on the very high end of the scale and indicates that users were already low in the flexibility of this area. Table 17 shows that the control group was above the normative values for lumbopelvic flexibility at baseline. An improvement was seen in all groups with the biggest increase in flexibility in the standard group, followed by the control group and the ABT group.

Table 17: Results of the Mobility of the Lumbopelvic

	A	ЗТ	Stan	dard	Cor	ntrol
FBA (pre/post) (cm.)	9.5	9	10	7.9	10.9	9.2
Reduction/Increase	-0.5		-2.1		-1.7	

All groups were at risk of falling at baseline as shown in Table 18. After the intervention, no more fall risk was present in bot intervention groups, whereas the largest decrease was

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observed in the ABT. Fall risk in the control group also decreased, however a fall risk was still present.

Table 18: Results of at Risk of Falling

	ABT		Standard		Control	
FTSTS (pre/post) (sec.)	13.2	10.9	13.1	11	13.8	12.8
Reduction/Increase	-2.3		-2.1		-1.0	

Isometric trunk extension showed a tremendous increase in the ABT group and also an increase by about 50% in the standard group Table 19. The control group showed a slightly decreased value.

Table 19: Results of the Isometric Trunk Extension

	ABT		Standard		Control	
Trunk extension iso (pre/post) (sec.)	24.3	61.4	24	35.9	42.5	36.3
Reduction/Increase	+37.1		+11.9		-6.2	

The following Table 20 shows the differences in side to side strength for isometric trunk flexion to the left and right. Side to side differences in strength in these muscle groups are called muscle imbalances. Muscle imbalances are associated with low back pain and also one of the leading caused for recurrent episodes of LBP. Side to side differences were found in all three groups at baseline, while ABT group showed no more imbalances after the intervention, imbalances in the standard group were reduced.

Table 20: Differences in Side to Side Strength for Isometric Trunk Flexion

	ABT		Standa	ard	Control	
	Lat flex left	Lat flex right	Lat flex left	Lat flex right	Lat flex left	Lat flex rigt
Pre (kg)	12.7	9.3	10.1	7.7	11.5	10.5
Difference Pre (kg)	3.4		2.4		1	
Post (kg)	19.2	19.2	14.8	15.2	13.7	15.2
Difference Post (kg)		0	0.4		1.3	

### 4.11 Conclusion

The ABT has shown positive effects in towards restoring LBP associated disabilities and other parameters related to increased life quality, despite some usability issues which have been described in Chapter 3. In order to further improve the effectiveness of the ABT

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the usability issues need to be addressed and a further usability test needs to be performed and adaptions made to maximise the effectiveness of the ABT. The ABT was able to overall mental well-being. LBP is often also associated with a decreased overall mental wellbeing. While this is not the case in all patients with LBP, therapists would be requested to screen patients for overall mental well-being, with the Warwick-Edinburgh Mental Wellbeing Scale or derived section that were used for the investigation in the pilot [THF+07].

Physical activity and sleep quality could be increased in both intervention groups, however the standard group shows slightly higher values for both items.

In none of the groups a significant increase in  $H_2O$  consumption could be achieved. However since the  $H_2O$  consumption was already sufficient at baseline, there also was no need to increase  $H_2O$  consumption which is a frequent issue in older adults. For females of 60 kg of the age group present in the pilot, approximately 1200 ml of water and for males 1600 ml of water should be consumed. Merely the reduction of  $H_2O$  consumption in the control group was a reason for concern especially in the light of the currently hot summer temperatures, where adequate hydration is essential.

The biofeedback of the ABT also showed to be effective in reducing the time that a healthcare provider needed while taking care of the users compared to the standard intervention, therefore the caregiver or healthcare provider has more time for other things that need to be completed. This is especially important in the current situation in modern healthcare setting were increasing bureaucracy often gets in conflict with the day to day tasks that have to be performed by caregiver or healthcare works.

Self-referred visits to doctors dropped in all three groups, the highest drop (55%) could be seen in the ABT group. However also the control group dropped by 50%, for this reason it can be concluded that neither the standard intervention nor the ABT intervention had any effect on the reduction of self-referred visits to a physician.

While the users were willing to pay for the ALFRED system either as one lump sum or in monthly instillments, the expected amount to be paid in the German pilot was not achieved. For this reason it is suggested to adapt the costs of ALFRED in Germany closer to an amount which was mentioned in chapter 4.10.8.

The LBP related disability measured by the Oswestry disability index showed stronger decreases for the standard intervention group, compared to the ABT group. While the ABT was better in reducing fall risk measured with the FSST and the FTSTS. Fall risk is a common problem in older adults and not just dependent on age alone. During the clinical assessment of the patient the healthcare provider needs to assess if a fall risk is present within a patient and allocate the patient to the adequate group, which also addressed fall risk, in this case the ABT. The previous finding that the ABT also was able to increase sleep quality amplifies the results of a reduced fall risk. Since even minor sleep complaints are associated with an increased risk of falls, the combination of a reduced fall risk with the FSST and the improved sleep quality is a very interesting finding which deservers further scientific research.

The spinal flexibly (Schober-Ott Test) increased in the ABT group while it decreased in the standard intervention group and the lumbopelvic mobility (Fingertip-Floor-Distance) increased the most in the standard group and the least in the ABT group. These findings indicate that healthcare providers need to assess their patients comprehensively. Patients

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with a hypermobility in the spine, for this reason should be allocated to the standard group, while patients with spinal hypomobility are best suited for the ABT group. Similar conclusions can be drawn for the results of the Fingertip-Floor-Distance.

The ABT group showed higher increases in strength for the isometric lateral flexion to the left and right and was also able to reduce the asymmetry within the isometric lateral left and right flexion. Since recurrent episodes of LBP are often associated with muscular asymmetries, this is a very interesting finding, which could potentially mean that in ABT might be able to reduce recurrent back in older adults. However these findings will have to be further investigated in longitudinal studies. Finally the standard intervention had a stronger influence to strengthen the rectus abdominis muscles, while that ABT more effectively strengthened the isometric trunk extension.

Overall, both interventions are effective, however the ABT was superior to the standard intervention when it comes to overall gains in muscle strength, regaining muscular symmetry, improving mental well-being and reducing fall risk. However older adults with subacute LBP are not a homogenous group and for this reason each clinicians that are treating older adults with subacute LBP will have to do a thorough investigation of each patient. Based on these findings it has to be decided with intervention will be best to address the patient's deficits.

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# 5 References

- [Agm11] Agmon, M. et al.: A pilot study of Wii Fit exergames to improve balance in older adults. In Journal of geriatric physical therapy (2001), 2011, 34; pp. 161–167.
- [Bas08] Basak, C. et al.: Can training in a real-time strategy video game attenuate cognitive decline in older adults? In Psychology and aging, 2008, 23; pp. 765–777.
- [BER07] Ball, K.; Edwards, J. D.; Ross, L. A.: The impact of speed of processing training on cognitive and everyday functions. In The journals of gerontology. Series B, Psychological sciences and social sciences, 2007, 62 Spec No 1; pp. 19–31.
- [Bhe08] Bherer, L. et al.: Transfer effects in task-set cost and dual-task cost after dual-task training in older and younger adults: further evidence for cognitive plasticity in attentional control in late adulthood. In Experimental aging research, 2008, 34; pp. 188–219.
- [Bor] Borders, R. et al.: Using the wii for functional improvements in individuals with brain injuries. In RT Wise Owls.
- [Böh09] Böhm, K. Ed.: Gesundheit und Krankheit im Alter. Robert-Koch-Inst, Berlin, 2009.
- [Bon16] Bonnechere, B. et al.: Validation of the Balance Board for Clinical Evaluation of Balance During Serious Gaming Rehabilitation Exercises. In Telemedicine journal and e-health the official journal of the American Telemedicine Association, 2016.
- [BRM+89] Buysse, D. J. et al.: The Pittsburgh sleep quality index. A new instrument for psychiatric practice and research. In Psychiatry Research, 1989, 28; pp. 193–213.
- [Cha13] Chao, Y.-Y. et al.: The feasibility of an intervention combining self-efficacy theory and Wii Fit exergames in assisted living residents: A pilot study. In Geriatric nursing (New York, N.Y.), 2013, 34; pp. 377–382.
- [Cha15] Chao, Y.-Y. et al.: Physical and psychosocial effects of Wii Fit exergames use in assisted living residents: a pilot study. In Clinical nursing research, 2015, 24; pp. 589– 603.
- [Cow15] Cowdery, J. et al.: Exergame Apps and Physical Activity. The Results of the ZOMBIE Trial. In American Journal of Health Education, 2015, 46; pp. 216–222.
- [DT02] Dite, W.; Temple, V. A.: A clinical test of stepping and change of direction to identify multiple falling older adults. In Archives of physical medicine and rehabilitation, 2002, 83; pp. 1566–1571.
- [Fai80] Fairbank, J. C. et al.: The Oswestry low back pain disability questionnaire. In Physiotherapy, 1980, 66; pp. 271–273.
- [Fic05] Ficklscherer, A.: Basics Orthopädie und Traumatologie. Elsevier Urban & Fischer, München, 2005.
- [FP00] Fairbank, J. C.; Pynsent, P. B.: The Oswestry Disability Index. In Spine, 2000, 25; pp. 2940-52; discussion 2952.
- [Fu15] Fu, A. S. et al.: Effectiveness of Exergaming Training in Reducing Risk and Incidence of Falls in Frail Older Adults With a History of Falls. In Archives of physical medicine and rehabilitation, 2015, 96; pp. 2096–2102.
- [GEM13] Girard, C.; Ecalle, J.; Magnan, A.: Serious games as new educational tools. How effective are they? A meta-analysis of recent studies. In Journal of Computer Assisted Learning, 2013, 29; pp. 207–219.
- [Gio13] Gioftsidou, A. et al.: Typical balance exercises or exergames for balance improvement? In Journal of back and musculoskeletal rehabilitation, 2013, 26; pp. 299–305.

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- [GSM] Gerling, K. M.; Schild, J.; Masuch, M.: Exergame design for elderly users. In (Shen, V. R. L. et al. Eds.): the 7th International Conference; p. 66.
- [Gur00] Guralnik, J. M. et al.: Lower extremity function and subsequent disability: consistency across studies, predictive models, and value of gait speed alone compared with the short physical performance battery. In The journals of gerontology. Series A, Biological sciences and medical sciences, 2000, 55; pp. M221-31.
- [Hob15] Hoblitz, A.: Spielend Lernen im Flow. Die motivationale Wirkung von Serious Games im Schulunterricht, 2015.
- [IP16] Iten, N.; Petko, D.: Learning with serious games. Is fun playing the game a predictor of learning success? In British Journal of Educational Technology, 2016, 47; pp. 151–163.
- [KB09] Kerres, M.; Bormann, M.: Explizites Lernen in Serious Games: Zur Einbettung von Lernaufgaben in digitalen Spielwelten. In Zeitschrift für E-Learning, 2009.
- [Ki15a] Kim, K.-W. et al.: Effects of a serious game training on cognitive functions in older adults. In Journal of the American Geriatrics Society, 2015, 63; pp. 603–605.
- [Kim15b] Kim, G. H. et al.: Structural brain changes after traditional and robot-assisted multi-domain cognitive training in community-dwelling healthy elderly. In PloS one, 2015, 10; pp. e0123251.
- [Mah06] Mahncke, H. W. et al.: Memory enhancement in healthy older adults using a brain plasticity-based training program: a randomized, controlled study. In Proceedings of the National Academy of Sciences of the United States of America, 2006, 103; pp. 12523– 12528.
- [MH16] Møller, L.; Hansen, P. K.: Framing Serious Games Development as a matter of business. In International Journal of Serious Games, 2016, 3.
- [Nau15] Naumann, T. et al.: No transfer between conditions in balance training regimes relying on tasks with different postural demands: Specificity effects of two different serious games. In Gait & posture, 2015, 41; pp. 774–779.
- [SJB07] Susi, T.; Johannesson, M.; Backlund, P.: Serious Games An Overview, Schweden, 2007.
- [Skj16] Skjaeret, N. et al.: Exercise and rehabilitation delivered through exergames in older adults: An integrative review of technologies, safety and efficacy. In International journal of medical informatics, 2016, 85; pp. 1–16.
- [SSR00] Sullivan, M. S.; Shoaf, L. D.; Riddle, D. L.: The relationship of lumbar flexion to disability in patients with low back pain. In Physical therapy, 2000, 80; pp. 240–250.
- [THF+07] Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S.: The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): development and UK validation. In Health and quality of life outcomes, 2007, 5; p. 63.
- [van13] van Diest, M. et al.: Exergaming for balance training of elderly: state of the art and future developments. In Journal of neuroengineering and rehabilitation, 2013, 10; p. 101.
- [Zyd05] Zyda, M.: From visual simulation to virtual reality to games. In Computer, 2005, 38; pp. 25–32.

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# 6 Annex 1: ABT Questionnaires

Fragebogen Rahmendaten

1. Geschlecht:	□ Weiblich
	□ Männlich
2. Geburtsjahr:	
3. Wie groß und schwer sind	kgcm
Sie aktuell	kg till
4. Haushaltsnettoeinkommen:	□ 500 – 1000 €
	□ 1000 – 2000 €
	□ 2000 – 3000 €
	□ > 3000 €
5. Familienstand	□ Ledig
	□ Verheiratet
	□ Geschieden
	□ Verwitwet
6. Lebenssituation	□ Alleine
	□ Mit Kindern
	☐ Mit Partner ohne Kinder
	☐ Mit Partner und Kindern
7. Bildung (Höchster	□ Grundschule
Bildungsweg, auch ohne	□ Hauptschulabschluss
Abschluss)	☐ Mittlere Reife
	□ Fachhochschulreife
	□ Abitur
	□ Berufsausbildung

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	□ Hochschule
8. Erwerbstätigkeit:	□ Berentet
	□ Angestellt
	□ Erwerbslos
	□ Ehrenamtliche Arbeit
	□ Sonstiges
9. Wohnungssituation	□ Selbstständig zu Hause
	□ Betreutes Wohnen
	□ Seniorenwohnheim
10. Gesundheit-	□ Sehr schlecht
Selbsteinschätzung	□ Schlecht
	□ Mäßig
	□ Gut
	□ Sehr gut
11. Sehen: Ist Ihr	□ Ja, ohne Einschränkungen
Sehvermögen gut genug, um	□ Ja, mit kleinen Einschränkungen
normalen Zeitungsdruck zu	□ Ja, mit starken Einschränkungen
lesen (auch mit Brille, wenn	□ Nein, es ist mir nicht möglich
ansonsten auch benutzt)?	
12. Hören: Hören Sie, was in	□ Ja, ohne Einschränkungen
einer normalen Unterhaltung	□ Ja, mit kleinen Einschränkungen
mit 3 oder 4 Personen	□ Ja, mit starken Einschränkungen
gesagt wird (mit Hörgerät,	□ Nein, es ist mir nicht möglich
falls Sie eins tragen)?	

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13. Feinmotorik B: Können	□ Ja, ohne Einschränkungen				
Sie sich selbstständig	□ Ja, mit kleinen Einschränkungen				
ankleiden?	□ Ja, aber ich brauche Hilfe z.B. beim				
	Binden von Schnürsenkeln oder				
	Socken anziehen.				
	□ Nein, es ist mir nicht möglich mich				
	selbstständig anzukleiden.				
14. Mobilität-	□ Sehr schlecht				
Selbsteinschätzung	□ Schlecht				
	☐ Mäßig				
	□ Gut				
	□ Sehr gut				
15. Wie viel technologische Er	rfahrungen haben Sie?				
☐ Sehr viel: Ich benutze vers	schiedene Geräte täglich um das Internet				
	verschiedene Anwendung wie E-Mail,				
WhatsApp, Soziale Netzwer					
□ <b>Viel:</b> Ich benutze Internet ur					
	nen PC und benutze ihn mehrmals die				
Woche.					
□ Wenig: Ich habe einen PC aber benutze ihn selten und habe nicht					
den Wunsch ihn mehr zu benutzen.					
□ <b>Sehr wenig:</b> Ich habe keinen PC oder Internet Anschluss und habe					
	nie oder kaum technische Geräte verwendet.				
16. Wie ist Ihre Einstellung ge	genüber Technik?				

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	Positiv: Ich habe nichts dagegen neue Geräte auszuprobieren, wenn
	sie mir gegeben werden.
	Neutral: Ich weiß es nicht oder es ist mir egal.
	Negativ: Ich habe eine Abneigung gegenüber Technik und bleibe fern
	davon.
17.	Ihre Benutzung von ICT Geräten (PC, Smartphone, Tablet):
	Jeden Tag □Jede Woche □Jeden Monat □Selten □Nie
18.	Was für ein Mobiltelefon verwenden Sie?
	Normales Mobiltelefon
	Seniorengerechtes Mobiltelefon (mit großen Knöpfen)
	Smartphone (Android, z.B. Samsung)
	Smartphone (Apple iPhone)
_	omartphone (Apple in Hone)
	Sonstiges:
	Sonstiges:
19.	Sonstiges:  Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie
19. in	Sonstiges:  Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:
19. in	Sonstiges:  Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie
19. in	Sonstiges:  Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:
19. in	Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:  E-Mail
19. in	Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:  E-Mail Chatten (WhatsApp)
19. in	Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:  E-Mail Chatten (WhatsApp) Suche nach Rezepten
19. in	Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:  E-Mail Chatten (WhatsApp) Suche nach Rezepten Suche Allgemein im Internet
19. in	Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:  E-Mail Chatten (WhatsApp) Suche nach Rezepten Suche Allgemein im Internet Suche nach Gesundheits- und Medizinthemen
19. in	Bitte geben Sie an, welche der folgenden Online Aktivitäten Sie den letzten 30 Tagen an Ihrem Mobiltelefon unternommen haben:  E-Mail Chatten (WhatsApp) Suche nach Rezepten Suche Allgemein im Internet Suche nach Gesundheits- und Medizinthemen Suche nach Informationen über ein Hobby oder persönliches

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□ Nachrichten	
□ Wetter	
□ Sport	
□ Online Banking	
□ Einkaufen	
□ Spiele spielen	
□ Arbeitssuche	
□ Finanzen/Aktienkurse	
☐ Besuch auf einer Kreis-, Land- oder Bund-Website	
□ Sonstiges:	

# Fragebogen ABT KPI

# (pre/post alle Gruppen)

	Die ganze Zeit	meisten s	Über die Hälfte der Zeit	Weniger als die Hälfte der Zeit	Ab und zu	Zu keinem Zeitpunkt
Ich war froh und guter Laune						
Habe mich ruhig und entspannt gefühlt						
Habe mich aktiv und voller Energie gefühlt						
Habe mich beim Aufwachen frisch und ausgeruht gefühlt						
War mein Alltag voller Dinge die mich interessieren						

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Wieviel Flüssigkeit (außer Alkohol) trinken Sie täglich?
Menge in ml:
20. Würden sie etwas für das Trainingssystem bezahlen?
□ Ja
□ nein
21. Wieviel würden sie für das Trainingssystem bezahlen?
<ul> <li>Insgesamt</li> </ul>
• Monatlich:
22. Wie oft waren Sie in den letzten 10 Wochen wegen Ihrer
Rückenprobleme beim Arzt?
Anzahl der Arztbesuche:
23. Wie häufig waren Sie wegen Rückenbeschwerden in den letzten
10 Wochen bei Bewältigen alltäglicher Aufgaben eingeschränkt?
• Anzahl:
24. Wie häufig waren Sie in den letzten 10 Wochen bei Bewältigen
alltäglicher Aufgaben eingeschränkt?
• Anzahl:
25. Wie häufig waren Sie in den letzten 10 Wochen beim Arzt um Ihre

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Vitaldaten (Puls, Atemfrequenz, Körpertemperatur) zu messen?

• Anzahl:\_\_\_\_\_

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# Fragebogen zu Behinderung bei Rückenbeschwerden: Oswestry Disability Index – Deutsche Version (ODI-D)

Quelle: Mannion AF, Junge A, Fairbank JC, Dvorak J, Grob D. Development of a German version of the Oswestry Disability Index. Part 1: cross-cultural adaptation, reliability, and validity. Eur Spine J 2006a; 15:55-65.

Sehr geehrte Patientin, Sehr geehrter Patient

Bitte füllen Sie diesen Fragebogen aus. Er soll uns darüber informieren, wie Ihre Rücken-(oder Bein-) Probleme Ihre Fähigkeit beeinflussen, den Alltag zu bewältigen. Wir sind darauf angewiesen zu erfahren, wie Ihre Schmerzen beschaffen sind und wie Sie auf Schmerzbehandlung ansprechen.

Ihre Angaben in diesem Fragebogen dienen der Vorbereitung / Begleitung der physiotherapeutischen Behandlung. In Ihrem eigenen Interesse möchten wir Sie deshalb bitten, alle Fragen in Ruhe und mit Sorgfalt selbst zu beantworten.

Bitte beantworten Sie alle Fragen, auch die, die Ihnen unwichtig erscheinen. Wenn Ihnen eine Frage unklar ist, machen Sie bitte an der entsprechenden Stelle ein Fragezeichen.

Alle Angaben werden in Ihrer Krankenakte unter Wahrung der Schweigepflicht und unter Einhaltung der Bestimmungen des Datenschutzes elektronisch gespeichert. Im Falle einer wissenschaftlichen Auswertung werden die Daten anonymisiert.

Lfd. Nr.  Oberuhldingen, den	
Oboraniangon, aon	Unterschrift

Abschnitt zu beantworten. Kreuzen Sie in jedem Abschnitt nur die Aussage an, die Sie heute am besten beschreibt.

#### Abschnitt 1: Schmerzstärke

- 0 Ich habe momentan keine Schmerzen
- 1 Die Schmerzen sind momentan sehr schwach
- 2 Die Schmerzen sind momentan m\u00e4ssig
- \_3 Die Schmerzen sind momentan ziemlich stark
- \_4 Die Schmerzen sind momentan sehr stark
- 5 Die Schmerzen sind momentan so schlimm wie nur vorstellbar

### Abschnitt 2: Körperpflege (Waschen, Anziehen etc.)

- \_0 Ich kann meine K\u00f6rperpflege normal durchf\u00fchren, ohne dass die Schmerzen dadurch st\u00e4rker werden
- \_1 Ich kann meine K\u00f6rperpflege normal durchf\u00fchren, aber es ist schmerzhaft
- \_2 Meine K\u00f6rperpflege durchzuf\u00fchren ist schmerzhaft, und ich bin langsam und vorsichtig
- \_3 Ich brauche bei der K\u00f6rperpflege etwas Hilfe, bew\u00e4ltige das meiste aber selbst
- \_4 Ich brauche t\u00e4glich Hilfe bei den meisten Aspekten der K\u00f6rperpflege
- \_5 Ich kann mich nicht selbst anziehen, wasche mich mit M\u00fche und bleibe im Bett

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#### Abschnitt 3: Heben

- \_0 Ich kann schwere Gegenstände heben, ohne dass die Schmerzen dadurch stärker werden
- \_1 Ich kann schwere Gegenstände heben, aber die Schmerzen werden dadurch stärker
- \_2 Schmerzen hindern mich daran, schwere Gegenstände vom Boden zu heben, aber es geht,

wenn sie geeignet stehen (z.B. auf einem Tisch)

\_3 Schmerzen hindern mich daran, schwere Gegenstände zu heben, aber ich kann leichte bis

mittelschwere Gegenstände heben, wenn sie geeignet stehen

- 4 Ich kann nur sehr leichte Gegenstände heben
- 5 Ich kann überhaupt nichts heben oder tragen

#### Abschnitt 4: Gehen

- O Schmerzen hindern mich nicht daran, so weit zu gehen, wie ich möchte
- \_1 Schmerzen hindern mich daran, mehr als 1-2 km zu gehen
- 2 Schmerzen hindern mich daran, mehr als 0.5 km zu gehen
- \_3 Schmerzen hindern mich daran, mehr als 100 m zu gehen
- \_4 Ich kann nur mit einem Stock oder Krücken gehen
- \_5 Ich bin die meiste Zeit im Bett und muss mich zur Toilette schleppen

Oswestry Disability Index - Deutsche Version (ODI-D)

Aus: Oesch, Hilfiker, Keller, Kool, Tal-Akabi, Schädler, Verra, Widmer Leu

Assessments in der muskuloskelettalen Rehabilitation. © Verlag Hans Huber 2007. Alle Rechte vorbehalten.

### Abschnitt 5: Sitzen

- \_0 lch kann auf jedem Stuhl so lange sitzen wie ich möchte
- \_1 Ich kann auf meinem Lieblingsstuhl so lange sitzen wie ich möchte
- \_2 Schmerzen hindern mich daran, långer als 1 Stunde zu sitzen
- \_3 Schmerzen hindern mich daran, l\u00e4nger als eine halbe Stunde zu sitzen
- 4 Schmerzen hindern mich daran, länger als 10 Minuten zu sitzen
- \_5 Schmerzen hindern mich daran, überhaupt zu sitzen

### Abschnitt 6: Stehen

- \_0 Ich kann so lange stehen wie ich m\u00f6chte, ohne dass die Schmerzen dadurch st\u00e4rker werden
- \_1 Ich kann so lange stehen wie ich möchte, aber die Schmerzen werden dadurch stärker
- 2 Schmerzen hindern mich daran, länger als 1 Stunde zu stehen
- \_3 Schmerzen hindern mich daran, länger als eine halbe Stunde zu stehen
- \_4 Schmerzen hindern mich daran, länger als 10 Minuten zu stehen
- 5 Schmerzen hindern mich daran, überhaupt zu stehen

### Abschnitt 7: Schlafen

- \_0 Mein Schlaf ist nie durch Schmerzen gestört
- \_1 Mein Schlaf ist gelegentlich durch Schmerzen gestört
- \_2 Ich schlafe auf Grund von Schmerzen weniger als 6 Stunden
- \_3 lch schlafe auf Grund von Schmerzen weniger als 4 Stunden
- 4 lch schlafe auf Grund von Schmerzen weniger als 2 Stunden
- \_4 ich schlafe auf Grund von Schlifelzen weniger als 2 St \_5 Schmerzen hindern mich daran, überhaupt zu schlafen

### Abschnitt 8: Sexualleben (falls zutreffend)

- 0 Mein Sexualleben ist normal, und die Schmerzen werden dadurch nicht stärker
- 1 Mein Sexualleben ist normal, aber die Schmerzen werden dadurch stärker
- \_2 Mein Sexualleben ist nahezu normal, aber sehr schmerzhaft

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- \_3 Mein Sexualleben ist durch Schmerzen stark eingeschränkt
- 4 Ich habe auf Grund von Schmerzen fast kein Sexualleben
- \_5 Schmerzen verhindern jegliches Sexualleben

### Abschnitt 9: Sozialleben

- \_0 Mein Sozialleben ist normal, und die Schmerzen werden dadurch nicht stärker
- \_1 Mein Sozialleben ist normal, aber die Schmerzen werden dadurch stärker
- \_2 Schmerzen haben keinen wesentlichen Einfluss auf mein Sozialleben, ausser dass sie meine

eher aktiven Interessen, z.B. Sport einschränken

- \_3 Schmerzen schränken mein Sozialleben ein, und ich gehe nicht mehr so oft aus
- 4 Schmerzen schränken mein Sozialleben auf mein Zuhause ein
- 5 Ich habe auf Grund von Schmerzen kein Sozialleben

### Abschnitt 10: Reisen

- \_0 Ich kann überallhin reisen, und die Schmerzen werden dadurch nicht stärker
- \_1 Ich kann überallhin reisen, aber die Schmerzen werden dadurch stärker
- \_2 Trotz starker Schmerzen kann ich länger als 2 Stunden unterwegs sein
- \_3 Ich kann auf Grund von Schmerzen höchstens 1 Stunde unterwegs sein
- \_4 Ich kann auf Grund von Schmerzen nur kurze notwendige Fahrten unter 30 Minuten machen
- \_5 Schmerzen hindern mich daran, Fahrten zu machen, ausser zur medizinischen Behandlung

Viele Dank für Ihre Mitarbeit. Bitte überprüfen Sie ob Sie alle Fragen beantwortet haben.

Peter Brem, Msc, PT-OMT, Dipl. PT

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### Funktionsfragebogen Hannover (FFbH-R)

In den folgenden zwölf Fragen geht es um Tätigkeiten aus dem täglichen Leben.

Bitte beantworten Sie jede Frage so, wie es für Sie im Moment (wir meinen in Bezug auf die letzten 7 Tage) zutrifft.

Sie haben drei Antwortmöglichkeiten:

[1]	"Nein oder nur mit fremder Hilfe"	Sie können es gar nicht oder nur, wenn eine andere Person Ihnen dabei hilftsführen
[2]	"Ja, aber mit Mühe"	Sie haben dabei Schwierigkeiten, z.B. Schmerzen, es dauert länger oder Sie müssen sich dabei abstützen
[3]	"Ja"	Sie können die Tätigkeit ohne Schwierigkeit au

Bitte bear	ntworten Sie jede Frage	Nein oder nur mit fremder Hilfe	Ja, aber mit Mühe	Ja
1.	Können Sie sich strecken, um z.B. ein Buch von einem hohen Schrank oder Regal zu holen?	[1]	[2]	[3]
2.	Können Sie einen mindestens 10 kg schweren Gegenstand (z. B. vollen Wassereimer oder Koffer hochheben und 10 m weit tragen?	[1]	[2]	[3]
3.	Können Sie sich von Kopf bis Fuß waschen und abtrocknen?	[1]	[2]	[3]
4.	Können Sie sich bücken, um einen leichten Gegenstand (z. B. ein Geldstück oder zerknülltes Papier) vom Fußboden aufzuheben?	[1]	[2]	[3]
5.	Können Sie sich über einem Waschbecken die Haare waschen?	[1]	[2]	[3]
6.	Können Sie 1 Stunde auf einem ungepolsterten Stuhl sitzen?	[1]	[2]	[3]
7.	Können Sie 30 Minuten ohne Unterbrechung stehen (z. B. in einer Warteschlange)?	[1]	[2]	[3]
8.	Können Sie sich im Bett aus der Rückenlage aufsetzen?	[1]	[2]	[3]
9.	Können Sie Strümpfe an- und ausziehen?	[1]	[2]	[3]
10.	Können Sie im Sitzen einen kleinen heruntergefallenen Gegenstand (z. B. eine Münze) neben Ihrem Stuhl aufheben?	[1]	[2]	[3]
11.	Können Sie einen schweren Gegenstand (z. B. einen gefüllten Kasten Mineralwasser) vom Boden auf den Tisch stellen?	[1]	[2]	[3]
12.	Können Sie 100 m schnell laufen (nicht gehen), etwa um einen Bus noch zu erreichen?	[1]	[2]	[3]

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# Roland and Morris Disability Questionnaire

# deutsche Version

Sehr geehrter Patient, wenn Sie Rückenschmerzen haben, sind alltägliche Dinge oft schwer zu erledigen.

Diese Liste enthält Sätze, die Personen verwendet haben, um ihre Rückenschmerzen zu beschreiben. Wenn Sie die Liste durchlesen, fällt Ihnen auf, dass der eine oder andere Satz Ihre Beschwerden von heute am besten beschreibt. Denken Sie bitte nur an die Beschwerden von heute.

Trifft ein Satz für Ihre Beschwerden von heute zu, kreuzen Sie diesen Satz an. Falls ein Satz Sie nicht beschreibt, kreuzen Sie diesen Satz nicht an und gehen Sie zum nächsten Satz.



Nr.	Beschreibung der Tätigkeit	Х
1.	Wegen meiner Rückenschmerzen bleibe ich den größten Teil des Tages zu	
	Hause.	
2.	Ich wechsle häufig meine Körperhaltung, um meinen Rücken zu entlasten	
3.	Ich gehe wegen meiner Rückenschmerzen langsamer als sonst	
4.	Wegen meiner Rückenschmerzen erledige ich keine der Arbeiten, die ich sonst	
	im Haushalt erledige	
5.	Wegen meiner Rückenschmerzen halte ich mich beim Treppensteigen am	
	Geländer fest	
6.	Wegen meiner Rückenschmerzen lege ich mich häufiger als sonst zum	
	Ausruhen hin	
7.	Wegen meiner Rückenschmerzen muss ich mich an etwas abstützen, um aus	
	einem Polstersessel hochzukommen	
8.	Wegen meiner Rückenschmerzen bitte ich andere Menschen, etwas für mich	
	zu erledigen	
9.	Wegen meiner Rückenschmerzen brauche ich zum Ankleiden länger als sonst	
10.	Wegen meiner Rückenschmerzen achte ich darauf, nur kurze Zeit zu stehen	
11.	Wegen meiner Rückenschmerzen achte ich darauf, mich so wenig wie	
	möglich zu bücken oder niederzuknien	
12.	Wegen meiner Rückenschmerzen fällt es mir schwer, von einem Stuhl	
12	aufzustehen	
13.	Ich leide den größten Teil des Tages/der Nacht unter Rückenschmerzen	
14.	Meine Rückenschmerzen erschweren mir das Umdrehen im Bett.	_
15.	Wegen meiner Rückenschmerzen ist mein Appetit nicht besonders gut.	
16.	Wegen meiner Rückenschmerzen habe ich Probleme beim Anziehen von	
17.	Socken (oder Strümpfen/Strumpfhosen).	
18.	Wegen meiner Rückenschmerzen gehe ich nur kurze Strecken Wegen meiner Rückenschmerzen schlafe ich weniger als sonst	
19.	Wegen meiner Rückenschmerzen brauche ich beim Ankleiden Hilfe	
20.	Wegen meiner Rückenschmerzen verbringe ich den größten Teil des Tages	
20.	sitzend	
21.	Wegen meiner Rückenschmerzen versuche ich, schwere Arbeiten im Haushalt	
21.	zu vermeiden	
22.	Wegen meiner Rückenschmerzen bin ich reizbarer und übellauniger als sonst	
23.	Wegen meiner Rückenschmerzen gehe ich Treppen langsamer hinauf als	
	sonst	
24.	Wegen meiner Rückenschmerzen verbringe ich den größten Teil des Tages im	
	Bett	

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# Schlafqualitäts-Fragebogen (PSQI)

Die folgenden Fragen beziehen sich auf Ihre üblichen Schlafgewohnheiten und zwar <u>nur</u> während der letzten vier Wochen. Ihre Antworten sollten möglichst genau sein und sich auf die Mehrzahl der Tage und Nächte während der letzten vier Wochen beziehen. Beantworten Sie bitte alle Fragen.

1.	Wann sind Sie während der letzten vier Wo- chen gewöhnlich abends zu Bett gegangen?	übliche Uhrzeit:
		•
2.	Wie lange hat es während der letzten vier Wochen gewöhnlich gedauert, bis Sie nachts eingeschlafen sind?	in Minuten:
3.	Wann sind Sie während der letzten vier Wo- chen gewöhnlich morgens aufgestanden?	übliche Uhrzeit:
4.	Wieviele Stunden haben Sie während der letzten vier Wochen pro Nacht tatsächlich geschlafen? (Das muß nicht mit der Anzahl der Stunden, die Sie im Bett verbracht haben, übereinstimmen.)	Effektive Schlafzeit (Stunden) pro Nacht:

Kreuzen Sie bitte für jede der folgenden Fragen die für Sie zutreffende Antwort an. Beantworten Sie bitte <u>alle</u> Fragen.

- 5. Wie oft haben Sie während der letzten vier Wochen schlecht geschlafen, ...
- a) ... weil Sie nicht innerhalb von 30 Minuten einschlafen konnten?
- O Während der letzten vier Wochen gar nicht
- O Weniger als einmal pro Woche
- O Einmal oder zweimal pro Woche
  O Dreimal oder häufiger pro Woche
- b) ... weil Sie mitten in der Nacht oder früh morgens aufgewacht sind?
- O Während der letzten vier Wochen gar nicht
- O Weniger als einmal pro Woche
- O Einmal oder zweimal pro Woche
- O Dreimal oder häufiger pro Woche
- c) ... weil Sie aufstehen mußten, um zur Toilette zu gehen?
- O Während der letzten vier Wochen gar nicht
- O Weniger als einmal pro Woche
- O Einmal oder zweimal pro Woche
- O Dreimal oder häufiger pro Woche

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		2
d)	weil Sie Beschwerden beim Atmen hatten?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
e)	weil Sie husten mußten oder laut ge- schnarcht haben?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
f)	weil Ihnen zu kalt war?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
g)	weil Ihnen zu warm war?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
h)	weil Sie schlecht geträumt hatten?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
i)	weil Sie Schmerzen hatten?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
	aus anderen Gründen? itte beschreiben:	Und wie oft während des letzten Monats konnten Sie aus diesem Grund schlecht schlafen?  O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
6.	Wie würden Sie insgesamt die Qualität Ihres Schlafes während der letzten vier Wochen beurteilen?	O Sehr gut O Ziemlich gut O Ziemlich schlecht O Sehr schlecht

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		•
7.	Wie oft haben Sie während der letzten vier Wochen Schlafmittel eingenommen (vom Arzt verschriebene oder frei verkäufliche)?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
8.	Wie oft hatten Sie während der letzten vier Wochen Schwierigkeiten wachzubleiben, etwa beim Autofahren, beim Essen oder bei gesellschaftlichen Anlässen?	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
9.	Hatten Sie während der letzten vier Wochen Probleme, mit genügend Schwung die übli- chen Alltagsaufgaben zu erledigen?	O Keine Probleme O Kaum Probleme O Etwas Probleme O Große Probleme
10.		Mitbewohner schläft in einem anderen Zimmer ıläft im selben Zimmer, aber nicht im selben Bett ıläft im selben Bett
	Falls Sie einen Mitbewohner / Partner haben, fragen folgendes bemerkt hat.	Sie sie/ihn bitte, ob und wie oft er/sie bei Ihnen
a)	Lautes Schnarchen	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
b)	Lange Atempausen während des Schlafes	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche
c)	Zucken oder ruckartige Bewegungen der Beine während des Schlafes	O Während der letzten vier Wochen gar nicht O Weniger als einmal pro Woche O Einmal oder zweimal pro Woche O Dreimal oder häufiger pro Woche

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d)		isen von Verwirrung o end des Schlafes	der Desori-	O Weniger of D Einmal of	der letzten vier Wochen gar nicht als einmal pro Woche der zweimal pro Woche der häufiger pro Woche
e)	Oder andere For Schlafes	ormen von Unruhe wä	hrend des	Bitte beschrei	ben:
	chen Sie bitte	noch folgende Anga	aben zu Ihrer P Körpergröße		Gewicht:
G	Seschlecht:	O weiblich O männlich	Beruf: O Schüle O Arbeite	er/Student(in) er(in)	O Rentner(in) O selbständig O Angestellte(r) O arbeitslos/ Hausfrau(mann)

# **Four Step Square Test (FSST)**

#### Ziel des Versuchs:

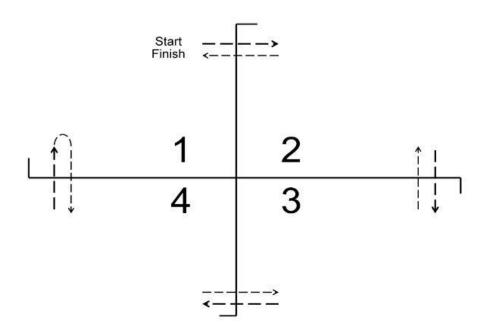
Evaluation von Defiziten der Balance und des Sturzrisikos.

#### Kontraindikationen:

- Personen, die über ein gutes Gleichgewichsgefühl verfügen, sollte Hilfestellung gegeben werden.

#### Ablauf:

Die Testperson steht im Feld # 1 und blickt in Richtung Feld # 2 (siehe Abbildung). Die Testperson wird aufgefordert so schnell wie möglich in jedes Feld zu treten und zwar in folgender Sequenz: 2,3,4,1,4,3,2 und 1. Die Testperson muss herbei Schritte vorwärts, rückwärts, seitwärts sowie links und rechts ausüben.



Zeitaufwand: ca. 5 min

#### Instruktion:

Die Sequenz wird von Testleiter einmal demonstriert. Empfehlung für die Instruktion des Patienten: "Bitte versuchen Sie die Sequenz so schnell wie möglich zu absolvieren. Beide Füße müssen jeweils vollständig in jedem einzelnen Feld stehen. Schauen Sie während der gesamten Sequenz nach vorne und drehen Sie sich nicht."

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Die Testperson erhält einen Probedurchgang

Die Probedurchgänge werden sooft wiederholt bis die Testperson die Sequenz einmal erfolgreich absolviert hat.

Anschließend werden zwei Durchgänge absolviert und die Zeit wird gestoppt. Die beste Zeit wird als Score des Tests verwendet.

# Anmerkungen:

Bei der Durchführung sollte von jeglichen Anspornungen des Patienten, verbal oder nonverbal, Abstand genommen werden.

Durchgang 1:	
Durchgang 2:	
Gemessene Zeit	
(FSST)·	

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# <u>Beweglichkeit der Wirbelsäule – Messung nach Schober-Ott</u> Ziel des Versuchs:

Globale Beweglichkeit des thorakalen bzw. lumbalen Abschnitts der Wirbelsäule Kontraindikationen:

- Personen, die über ein gutes Gleichgewichsgefühl verfügen, sollte Hilfestellung gegeben werden.

#### Ablauf:

Testperson steht in Neutral-0-Position. Auf der Haut in Höhe des Proc. Spinosus S1 wird eine Markierung angebracht, eine zweite Markierung 10 cm kranial hiervon. Die Testperson geht maximal in Flexion wie bei dem FBA Test. Nun wird der Abstand zwischen den beiden Hautmarken gemessen.

#### Zeitaufwand:

Ca. 3-5 min

#### Instruktion:

Empfehlung für die Instruktion des Patienten: "Bitte stellen Sie sich hin, drücken Sie die Knie durch, stellen Sie die Füße parallel zueinander. Jetzt beugen Sie sich bitte vornüber und versuchen Sie mit den Fingerspitzen den Boden zu erreichen"

#### Anmerkungen:

Bei der Durchführung sollte von jeglichen Anspornungen des Patienten, verbal oder nonverbal, Abstand genommen werden.

Gemessener Abstand Schober-	
Ott:	

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# **Rumpf Dynamometer**

**Ziel des Versuchs:** Die maximale isometrische Kraft der Rumpfmuskulatur festzustellen.

# **Messung Lateralflexion**

Ausgangsposition:

- Proband sitzt aufrecht auf einer Behandlungsbank mit einem Kniewinkel von 90°
- Prüfer steht neben dem Probanden und hält das Dynamometer mit beiden Händen
- Druckplatte liegt dabei am lateralen M. Deltoideus des Probanden an

Der Proband wird nun aufgefordert, sich vom Rumpf aus zur Seite zur neigen und dabei so viel Kraft wie möglich aufzuwenden. Der Prüfer gibt dabei so viel Widerstand, dass es zu keiner Bewegung kommt.

### Messung M. Rectus abdominis

Ausgangsposition:

- Proband liegt in Rückenlage auf der Behandlungsbank, die Füße sind angestellt und die Knie in einem 45 Grad Winkel gebeugt
- Prüfer steht neben den Probanden und hält den Dynamometer mit beiden Händen
- Druckplatte liegt am Sternum Probanden an

Der Proband wird nun aufgefordert, den Rumpf von der Unterlage abzuheben und dabei so viel Kraft wie möglich aufzuwenden. Der Prüfer gibt dabei so viel Widerstand, dass es zu keiner Bewegung kommt.

	Messung 1		Messung 2		Messung 3	
	Re	Li	Re	Li	Re	Li
Lateralflexion						
M. Rectus						
abdominis						

# Fingerspitzen-Boden Abstand (FBA)

#### Ziel des Versuchs:

Globale Beweglichkeit der Wirbelsäule einschließlich der LBH-Region

#### Kontraindikationen:

 Personen, die über ein gutes Gleichgewichsgefühl verfügen, sollte Hilfestellung gegeben werden.

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#### Ablauf:

Bei der Messung des FBA steht die zu testende Person ohne Schuhe mit den Füßen in Paralellstellung (etwa 10 cm auseinander). Die Ferse wird nicht abgehoben, die Knie bleiben in Extension (durchgedrückt). Die Testperson beugt sich vornüber, um mit den Fingerspitzen den Boden zu berühren. Der verbleibende Abstand zwischen Boden und Fingerspitzen wird mit einem Maßband gemessen.

#### Zeitaufwand:

Ca. 3-5 min

#### Instruktion:

Empfehlung für die Instruktion des Patienten: "Bitte stellen Sie sich hin, drücken Sie die Knie durch, stellen Sie die Füße parallel zueinander. Jetzt beugen Sie sich bitte vornüber und versuchen Sie mit den Fingerspitzen den Boden zu erreichen"

### Anmerkungen:

Bei der Durchführung sollte von jeglichen Anspornungen des Patienten, verbal oder nonverbal, Abstand genommen werden.

Gemessener Abstand	
(FBA):	

# 5 times Sit-to- Stand Test (5SST)

### Ziel des Versuchs:

Evaluation der Kraft der unteren Extremität, Sturzrisiko

### Kontraindikationen:

 Personen, die über ein gutes Gleichgewichsgefühl verfügen, sollte Hilfestellung gegeben werden.

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#### Ablauf:

Die Testperson sitzt angelehnt auf einem Stuhl und wird aufgefordert 5 mal aufzustehen und sich wieder zu setzten. Der Testleiter zählt jedes Aufstehen der Testperson laut, sodass die Testperson orientiert bleibt. Der Test wird beendet nachdem die Testperson die stehende Position zum 5. Mal erreicht hat.

Zeitaufwand: ca. 3 min

#### Instruktion:

Empfehlung für die Instruktion des Patienten: "Bitte versuchen Sie so schnell wie möglich 5 mal vom Stuhl aus Aufzustehen und sich wieder zu setzten. Beide Arme bleiben hierbei vor der Brust verschränkt. Ich nehme die Zeit mit der Stoppuhr."

### Anmerkungen:

Bei der Durchführung sollte von jeglichen Anspornungen des Patienten, verbal oder nonverbal, Abstand genommen werden.

Gemes	ssene Zeit		
(5SST)	<b>)</b> :		

# Kraftausdauer (statisch) Rückenstrecker

#### Ziel des Versuchs:

Statische Kraftausdauer der Wirbelsäulenextensoren gemessen als Fähigkeit den Rumpf gegen die Schwerkraft von einer Unterlage abgehoben zu halten.

### Kontraindikationen:

Schwangerschaft

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- Muskelkrämpfe

#### Ablauf:

Die getestete Person liegt in Bauchlage auf einer Matte oder einer Behandlungsbank. Die Spina Iliaca anterior superior ist leicht angekippt, sodass der Rumpf waagrecht gegen die Schwerkraft in der Luft gehalten werden kann.

Gemessen wird die Zeit in Sekunden, in der die getestete Person den Rumpf **stetig** in der Waagrechten halten kann (bei Ausführung auf dem Boden: den Rumpf stetig vom Boden abgehoben halten kann). Dabei muss der Rumpf auf Höhe einer Markierung an einer senkrechten Messlatte gehalten werden.

#### **Zeitaufwand:**

Mit Vorbereitung ca. 5 min

#### Instruktion:

Empfehlung für die Instruktion des Patienten: "Ich zähle gleich von drei herunter. Bei null heben Sie Ihren Oberkörper bitte leicht von der Unterlage ab; versuchen Sie ihn solange wie möglich angehoben zu halten. Sie entscheiden wann Sie nicht mehr können. Ich stoppe die Zeit."

### Anmerkungen:

Bei der Durchführung sollte von jeglichen Anspornungen des Patienten, verbal oder nonverbal, Abstand genommen werden.

Gemessene Zeit:	 

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# **Annex 2: ABT Usability-Test Questionnaires**

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	Berlin, den	
	Einwilligung zur Abtretung der Tonrechte	•
Name und Adress	se:	
61, 13347 Berlin a genannte Person verfügen. Es erfolgt keine Forschungszweck	an die Forschungsgruppe Geriatrie der Charité abzutreten. Mit der Einwilligung zur Veröffentlich, über die vollen Verfügungsrechte der Tomer Weitergabe an Dritte und die Tonaufnahme innerhalb der Studie verwendet. Die sufnahme(n) werden anonymisiert weiterverarbe ht.	hung garantiert oben nbandaufnahmen zu nen werden nur für am
den oben aufgef	uppe Geriatrie der Charité verpflichtet sich, keir ührten Aufnahmen vorzunehmen, die die b rletzenden Weise entstellen.	
Erklärende_r		
Für die Forschung	psgruppe Geriatrie der Charité	
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Re	CHARITÉ - UNIVERSITÄTSMEDIZIN BERLIN inickendorfer Str. 61   13347 Berlin   Telefon +49 30 450-553736   www.ch	narite.de

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# Fragebogen Technikerfahrung

	stimmt gar nicht	stimmt wenig	stimmt teilweise	stimmt ziemlich	stimmt völlig
Hinsichtlich technischer Neuentwicklungen bin ich sehr neugierig.					
Für mich stellt der Umgang mit technischen Neuerungen zumeist eine Überforderung dar.					
Den Umgang mit neuer Technik finde ich schwierig – ich kann das meistens einfach nicht.					
Ich bin stets daran interessiert, die neuesten technischen Geräte zu verwenden.					
Im Umgang mit moderner Technik habe ich oft Angst, zu versagen					
Wenn ich Gelegenheit dazu hätte, würde ich noch viel häufiger technische Produkte nutzen, als ich das gegenwärtig tue.					
Ich habe Angst, technische Neuentwicklungen eher kaputt zu machen, als dass ich sie richtig benutze.					
Ich finde schnell Gefallen an technischen Neuentwicklungen.					

### Techniknutzung

	immer	oft	gelegentlich	selten	nie
Wie häufig nutzen Sie ein Tablet?					
Wie häufig nutzen Sie ein Smartphone?					
Wie häufig nutzen Sie Spielekonsolen (PlayStation, Nintendo Wii, Xbox)?					

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Haben :	Sie	bereits	Erfahrungen	mit der	Nintendo	Wii?

 $\square$  ja, ich habe davon gehört  $\square$  ja, bereits ausprobiert  $\square$  nein

Wie viel Erfahrung haben Sie mit der Touchbedienung von technischen Systemen? (z.B. Smartphone, Tablet, Navigationsgerät)

gar keine	wenig	etwas	viel	
Erfahrung	Erfahrung	Erfahrung	Erfahrung	

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# Fragebogen Bewegung

# Mich zu bewegen ...

	stimme überhaupt nicht zu	stimme eher nicht zu	teils/teils	stimme eher zu	Stimme voll und ganz zu
macht mir Freude					
finde ich langweilig					
mag ich nicht					
genieße ich					
macht überhaupt keinen Spaß					
gibt mir Energie					
macht mich deprimiert					
ist sehr angenehm					
bedeutet, dass mein Körper sich gut anfühlt					
gibt mir etwas					
ist sehr aufregend					
frustriert mich					
ist überhaupt nicht interessant					
gibt mir ein starkes Erfolgserlebnis					
fühlt sich gut an					
gibt mir das Gefühl, dass ich lieber etwas anderes machen würde					

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#### Fragebogen Sehvermögen

Die Fragen betreffen Ihr Sehvermögen und Ihre persönliche Zufriedenheit mit Ihrem Sehen. Bitte wählen Sie diejenige Antwort, die am besten zutrifft. Falls Sie Brillen- oder Kontaktlinsenträger\_in sind: Bitte beantworten Sie die Fragen so, als ob Sie Ihre Brille oder Ihre Kontaktlinsen tragen würden. Wenn Sie sich bei einer Frage nicht ganz sicher sind: Geben Sie bitte die am ehesten zutreffende Antwort. Sie können an den Rand einen Kommentar schreiben.

Wie schätzen Sie Ihre Gesundheit im Allgemeinen ein?					
Sehr gut	Gut	Befriedigend	Ausreichend	Schlecht	

	<ol><li>Wie beurteilen Sie Ihr derzeitiges Sehen mit beiden Augen (mit Brille oder Kontaktlinsen, falls Sie diese tragen)?</li></ol>					
Sehr gut	Gut	Befriedigend	Ausreichend	Schlecht		

Wie schwer fällt es Ihnen, die normale Schriftgröße einer Zeitung zu sen?
Überhaupt keine Schwierigkeiten
Ein wenig Schwierigkeiten
Deutliche Schwierigkeiten
Sehr starke Schwierigkeiten
Wegen meiner Sehschwäche kann ich das nicht mehr

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eir	Welche Schwierigkeiten haben Sie bei Alltagsbeschäftigungen, die n gutes Sehen in der Nähe erfordern, wie z.B. Kochen, Nähen oder e Arbeit mit Werkzeugen?
	Überhaupt keine Schwierigkeiten
	Ein wenig Schwierigkeiten
	Deutliche Schwierigkeiten
	Sehr starke Schwierigkeiten
	Wegen meiner Sehschwäche kann ich das nicht mehr

5. Welche Schwierigkeiten haben Sie aufgrund Ihres Sehvermögens, in einem vollgestellten (überfüllten) Regal etwas zu finden?			
Überhaupt keine Schwierigkeiten			
Ein wenig Schwierigkeiten			
Deutliche Schwierigkeiten			
Sehr starke Schwierigkeiten			
Wegen meiner Sehschwäche kann ich das nicht mehr			

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# Fragebogen Willenskraft

Im folgenden Fragebogen finden Sie eine Reihe von Feststellungen. Bitte lesen Sie sich jede Feststellung durch und kreuzen Sie an, wie sehr die Aussagen im Allgemeinen auf Sie zutreffen, d. h. wie sehr Ihr übliches Denken und Handeln durch diese Aussagen beschrieben wird.

	1= stimme nicht zu	2	3	4	5	6	7= stimme völlig zu
Wenn ich Pläne habe, verfolge ich sie auch.							
Normalerweise schaffe ich alles irgendwie.							
Ich mag mich.							
Ich bin entschlossen.							
Ich behalte an vielen Dingen Interesse.							
Ich finde öfter etwas, worüber ich lachen kann.							
Normalerweise kann ich eine Situation aus mehreren Perspektiven betrachten							
Ich kann mich auch überwinden, Dinge zu tun, die ich eigentlich nicht machen will.							
In mir steckt genügen Energie, um alles zu machen, was ich machen muss.							

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# Mini-Mental Status Examination (MMSE)

	Zeitliche Orientierung		
1.	Welches Jahr haben wir?		□ja □nein
2.	Welche Jahreszeit?		_ □ja □nein
3.	Den wievielten des Monates?		
4.	Welcher Wochentag ist heute?		□ja □nein
5.	Welcher Monat?		□ja □nein
			□ja □nein
	Örtliche Orientierung		
6.	Wo sind wir jetzt?	In welchem Land?	□ja □nein
<b>7</b> .		In welchem Bundesland?	□ja □nein
8.		In welcher Stadt?	
9.		welches	□ja □nein
10.		Stockwerk? welches	□ja □nein
		Krankenhaus?	□ja □nein
	Gedächtnis 1		
11.	Bitte merken Sie sich:		
12.		Zitrone	□ja □nein
13.		Schlüssel	ja ⊡nein
		Ball	ja ⊡nein
		Anzahl Versuche:	
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### Aufmerksamkeit

Das Wort PREIS muss rückwärts buchstabiert werden. Das Wort sollte zunächst vorwärts buchstabiert und wenn nötig korrigiert werden. Die Punktzahl ergibt sich aus der Anzahl der Buchstaben, die in der richtigen Reihenfolge genannt werden (z. B. "SIERP" = 3 Punkte).

14.		S	□ja	□nein
15.		I	□ia	□nein
16.		Е	—ja □ja	□nein
17.		R	_	
18.		Р	□ja	□nein
	Gedächtnis 2		∐ja	□nein
	Was waren die Dinge, die Sie sich vorhin gemerkt haben?			
19.		Zitrone	□: <b>-</b>	□nein
20.		Schlüssel	□ja □.	_
21.		Ball	□ja	□nein
	Sprache		□ja	□nein
	Eine Uhr und ein Stift werden gezeigt, der Untersuchte muss diese richtig benennen.			
	Was ist das?			
22.		Löffel	□ja	□nein
23.		Kugelschreiber	_	□nein
			⊔ја	ШIII
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Ein Satz muss unmittelbar nachgesprochen werden, nur ein Versuch ist erlaubt. Es ist nicht zulässig, die Redewendung "Kein wenn und aber" zu benutzen.

	wenn und aber" zu benutzen.			
24.	Sprechen Sie nach:			
	Übertragung	"Kein wenn und oder aber."	□ja	□nein
25.	Lesen Sie folgendes (Anlage 1) und ma	achen Sie es bitte		
26.	Machen Sie bitte folgendes:		□ja	□nein
27.		Nehmen Sie das Blatt in die rechte Hand.	□ja	□nein
28.		Falten Sie es in der Mitte.	□ja	□nein
		Legen Sie es auf Ihren Schoss.	□ja	□nein
29.	Schreiben Sie bitte einen Satz.			
30.	Kopieren Sie bitte die Zeichnung		□ja	□nein
	Auf einem Blatt sind zwei sich überschr dargestellt (siehe Anlage 2der Untersud exakt wie möglich abzeichnen. Alle 10 I widergegeben sein und zwei davon sich nur dann wird ein Punkt gegeben.	chte soll diese so Ecken müssen	□ja	□nein

Total Score: \_\_\_/ 30

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#### Hand Dynamometer

Ziel des Versuchs: Die maximale isometrische Kraft der Hand- und Unterarmmuskulatur festzustellen.

#### Ablauf:

- Das Dynamometer wird in der Hand gehalten, wobei der Griff sich in der Mitte der vier Finger befinden sollte.
- Der Arm sollte im Ellbogen im rechten Winkel sein und eng am Körper anliegen.
- Dann soll für 5 Sekunden lang mit maximaler Kraft gedrückt werden.
- 4. Keine Bewegung in einem anderen Teil des Körpers ist erlaubt.
- 5. Der Versuch wird danach für die andere Hand wiederholt

Rechte Hand: Linke Hand:
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### Nine Hole Peg Test

### Bitte befolgen Sie folgende Anweisungen:

Nehmen Sie immer einen Stift gleichzeitig auf und benutzen Sie dabei nur eine Hand. Stecken Sie die Stifte in die Löcher, bis alle Löcher besetzt sind. Die Reihenfolge spielt dabei keine Rolle. Anschließend entfernen Sie die Stifte wieder nacheinander und legen Sie sie in den Behälter. Halten Sie das Brett mit Ihrer anderen Hand fest. Zunächst gibt es einen Probedurchlauf. Versuchen Sie, die Übung so schnell wie möglich durchzuführen.

Nun folgt der Test auf Zeit. Die Aufgabe bleibt gleich. Arbeiten Sie so schnell Sie können.

\_\_\_\_\_

Nun führen Sie diesen Vorgang auch mit Ihrer anderen Hand durch.

Dominante Hand:	□ rechts	□ links	
Zeit für den Durchl	auf (sec):		
Dominante Hand:	Nich	t-Dominante Han	d.

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# Aufgabe 1: Unboxing und Plugging

# Zeit 1 (mm:ss):

Aufgabe	0 – 5	5 -10	>10	Hilfesatz
	min	min	min	
Alle Materialien				Sind Sie sicher, dass alle Kartons leer
auspacken				sind?
Batterien in Board				Sind Sie sicher, dass alle Teile (richtig)
einsetzen				eingebaut sind?
Tablet und Kabel				Sind Sie sicher, dass alle Teile (richtig)
verbinden				eingebaut sind?
Adapter und Kabel				Sind Sie sicher, dass alle Teile (richtig)
verbinden				eingebaut sind?
Tablet anschalten				Schalten Sie zunächst den Bildschirm an.
Tablet entsperren				Der Bildschirm muss noch entsperrt
_				werden.

Fehler: Falsche Nutzung oder Nichtbenutzung einer Sache Erneutes Auftreten desselben Fehlers zu späterer Zeit

Hilfestellung, wenn: a) 2 Fehlwiederholungen

b) Seit 5 Minuten keine neue Aufgabe gelöst

Fehler	[x]	Fehlerwdh.	Hilfestellung
Nicht alle Materialien ausgepackt			
Batterien nicht oder falsch eingesetzt			
Versucht, Adapter ins Board zu stecken			
Versucht, Kabel ins Board zu stecken			
Versucht, Kabel an falscher Seite des Tablets einzustecken			
Versucht, Batterien in Tablet einzusetzen			
Versucht, Board zu öffnen			
Bildschirm wieder schwarz, bevor entsperrt wurde			
Falscher Entsperrversuch (tippen, drücken o.ä.)			

### Anmerkungen:

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# Aufgabe 2: Verbinden und Aufbauen

# Zeit 2 (mm:ss):

Aufgabe	0 – 5	5 -10	>10	Hilfesatz
	min	min	min	
AlfredBackTrainer starten				Auf dem Tablet befindet sich die
				Anwendung Alfred BackTrainer
Sync-Knopf im Batteriefach				Die Geräte müssen vor Gebrauch
des Boards drücken				synchronisiert werden

<u>Fehler:</u> Falsche Nutzung oder Nichtbenutzung einer Sache <u>Fehlerwiederholung:</u> Erneutes Auftreten desselben Fehlers zu späterer Zeit

Hilfestellung, wenn: a) 2 Fehlwiederholungen

b) Seit 5 Minuten keine neue Aufgabe gelöst

Fehler	[x]	Fehlerwdh.	Hilfe gegeben?
Falsche App gestartet			
App online gesucht			
Öffnet falsches Menü und kommt nicht heraus			
Drückt den roten Knopf auf dem Start-Screen			

### Anmerkungen:

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# Aufgabe 3: Verbinden und Aufbauen

### Zeit 3 (mm:ss):

Aufgabe	0 – 5	5 -10	>10	Hilfesatz
	min	min	min	
Boards auf Markierung stellen				Auf dem Boden befinden sich
				Markierungen für das Board.
Tablet in Halterung befestigen				Das Tablet sollte im Stativ befestigt
				werden.

<u>Fehler:</u> Falsche Nutzung oder Nichtbenutzung einer Sache <u>Fehlerwiederholung:</u> Erneutes Auftreten desselben Fehlers zu späterer Zeit

Hilfestellung, wenn: a) 2 Fehlwiederholungen

b) Seit 5 Minuten keine neue Aufgabe gelöst

Fehler	[x]	Fehlerwdh.	Hilfe gegeben?
Board falsch rotiert			
Board nicht auf Markierung gestellt			
Tablet nicht fest montiert, so dass es fallen könnte			
App beim Montieren versehentlich beendet			

### Anmerkungen:

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# Aufgabe 4: Spielen und Beenden

### Zeit 4 (mm:ss):

Aufgabe	0 – 5	5 -10	>10	Hilfesatz
	min	min	min	
Cat & Mouse öffnen				Das Spiel, dass Sie öffnen sollen
				heißt Cat & Mouse
Zum Hauptmenü zurückkehren				Bitte gehen Sie zurück ins
				Hauptmenü
Pongy öffnen				Das Spiel, dass Sie öffnen sollen
				heißt Pongy
App beenden				Schließen Sie die App komplett

<u>Fehler:</u> Falsche Nutzung oder Nichtbenutzung einer Sache <u>Fehlerwiederholung:</u> Erneutes Auftreten desselben Fehlers zu späterer Zeit

Hilfestellung, wenn: a) 2 Fehlwiederholungen

b) Seit 5 Minuten keine neue Aufgabe gelöst

Fehler	[x]	Fehlerwdh.	Hilfe gegeben?
App aus Versehen frühzeitig beendet			
Wischen oder drücken des Screens zum Spielstart			
Versucht, Katze zu steuern			
Öffnet falsches Spiel			
Beendet App nicht			

### Anmerkungen:

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# After Scenario Questionnaire

# Task 1: Aufbauen des Rückentrainers

	 Starke Zustimmung			•	Starke Ablehnung		
Insgesamt bin ich damit zufrieden, wie leicht die Aufgaben in diesem Szenario zu lösen waren.							
Ich bin mit der Zeit, die es gedauert hat, die Aufgaben in diesem Szenario zu lösen, zufrieden.							
Insgesamt bin ich mit den unterstützenden Informationen (z.B. Hilfen) bei der Bearbeitung des Szenarios zufrieden.							

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#### NASA TLX

Machen Sie ein Kreuz auf der Stelle jeder Skala, die Ihrem eigenen Empfinden entspricht.

Wie mental beanspruchend war die Aufgabe für Sie?

gar nicht sehr

Wie physisch beanspruchend war die Aufgabe für Sie?

gar nicht sehr

Wie erfolgreich schätzen Sie sich bei den gestellten Aufgaben ein?

gar nicht sehr

Wie sehr mussten Sie sich anstrengen, um Ihre Leistung zu erbringen?

gar nicht sehr

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# Fragebogen Empfinden

EBRiS

Aussage	Trifft überhaupt nicht zu	Trifft eher nicht zu	Teils, teils	Trifft eher zu	Trifft voll zu
Während des Versuchs wusste ich immer, was zu tun ist.					
Das Aufbauen der Geräte fiel mir leicht.					
Die Benutzung des Rückentrainers war komfortabel.					
Die Texte auf dem Display waren gut lesbar.					
Die Farbdarstellungen in der Anwendung waren angenehm.					
Die Navigation innerhalb der Anwendung fiel mir leicht.					
Ich hatte Schmerzen, die mich an der Ausführung der Aufgaben gehindert hat.					
Wenn Sie weitere Anmerkungen h	aben, schreib	en Sie dies	e bitte hi	er auf:	

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# System Usability Scale

Bewerten Sie die folgenden Fragen mit 1= " trifft überhaupt nicht zu" bis 5= " trifft voll zu".

	Trifft überhaupt nicht zu	Trifft eher nicht zu	Teils, teils	Trifft eher zu	Trifft voll zu
Ich würde den Rückentrainer gerne häufiger benutzen.					
Ich finde den Rückentrainer unnötig komplex.					
Ich finde, der Rückentrainer ist einfach zu benutzen.					
Ich denke, ich würde die Unterstützung einer erfahreneren Person brauchen, um in der Lage zu sein, den Rückentrainer zu benutzen.					
Ich finde, die verschiedenen Funktionen in diesem Rückentrainer sind gut integriert.					
Ich denke, es gibt zu viele Inkonsistenzen in diesem Rückentrainer.					
Ich könnte mir vorstellen, dass die meisten Leute sehr schnell lemen würden mit diesem Produkt umzugehen.					
Ich fand den Rückentrainer sehr schwerfällig im Gebrauch.					
Ich fühlte mich sehr sicher bei der Benutzung des Rückentrainers.					
Ich musste eine Menge lernen, bevor ich mit diesem Rückentrainer zurechtkam.					

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