ALFRED

Personal Interactive Assistant for Independent Living and Active Ageing

WP8 – Piloting & Validation

D8.3.1 Piloting & Validation II: Hospital

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This deliverable provides information on the rationale behind, the scientific background of, and the study protocol for pilot 2, which will evaluate the effectiveness of the ALFRED Back Trainer application on 60 older adults over a period of 10 weeks. The first part of the deliverable provides an up to date review on the current scientific findings of low back pain. The second part provides the study protocol for the actual pilot.

SEVENTH FRAMEWORK PROGRAMME

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Disclaimer

Project Partners

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Executive Summary

This deliverable provides the underlying theoretical, non-technical framework for the ALFRED Back Trainer application. The ALFRED Back Trainer was developed in close collaboration with TUDA and is a biofeedback based serious game which was specifically developed in ALFRED to promote specific stabilizing exercises for the lower back in order to reduce or entirely prevent low back pain. The ALFRED Back Trainer will be evaluated for its effectiveness in pilot 2 of the ALFRED project on a group of 60 older adults over a period of ten weeks.

As a first part, this deliverable provides a review of the latest findings on low back pain with respect to its origins, a summary of related anatomical structures and current state of the art exercise-based treatment options. It identifies the role and importance of the most relevant muscles which are needed to adequately stabilize the lower back region in order to reduce or prevent low back pain. It explains the importance of specific exercises for spinal stability in order to prevent or reduce low back pain and the possible advantages of biofeedback training for the treatment of low back pain. Based on these findings a specific exercise regime was developed which aims to restore spinal stability in order to prevent or reduce low back pain. In addition, together with TUDA, the ALFRED Back Trainer was developed. The ALFRED Back Trainer was designed to provide additional muscular stimulus in order to prevent or reduce low back pain and is a result of the review of the current literature and modern serious games technology.

In order to evaluate the benefits of the ALFRED Back Trainer, compared to exercises without the ALFRED Back Trainer, a specific study protocol was developed. The study protocol is the second part of this document. It was developed to explain the procedure of pilot 2 in detail with regards to its specific aim, applicable regulations, recruitment process, overall methodology, risk management and data analysis.

Table of Contents

List of Figures and Tables

List of Figures

List of Tables

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.

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 process 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.

1.2. Deliverable Purpose, Scope and Context

This deliverable provides non-technical background information on the ALFRED Back Trainer application. The ALFRED Back Trainer will be evaluated with a group of 60 older adults over a period of 10 weeks. The application aims to prevent or reduce low back pain with the help of a serious game, which promotes specific stabilizing exercises for the lower back. Additionally detailed information about the methodology of the actual pilot are provided.

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 Pilot II of the ALFRED Project. While the document mainly aims at the contributing partners of the project, this public deliverable can also be useful for the wider scientific and industrial community. This includes other publicly funded research and development projects.

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 http://www.alfred.eu.

1.5. Document Structure

Chapter 2 describes the epidemiology of low back pain with regards to incidences, prevalence, costs and global burden of low back pain. Chapter 3 gives an overview about the etiopathology of low back pain and provides information about different spinal muscle systems and clinical spinal instability, stabilising exercises and the potential beneficial role of biofeedback training for the prevention and reduction of low back pain. All this information comprises the non-technical foundation for the ALFRED Back Trainer application which was developed in close collaboration with TUDA and will be evaluated in pilot 2 of the ALFRED project. Chapter 4 provides detailed information about the study protocol of pilot 2, describes the overall methodology, gives information on risk management and data analysis.

2. Low Back Pain

Throughout society, low back pain (LBP) is a common medical problem and often recurrent. During their lifetime, 60-80% of the populace will experience LBP and up to 86% of these people will have a second or more episodes at some point [FWW10]. Especially chronic low back pain is hence a large socioeconomic burden which seems to be growing, in spite of technological advances in diagnostics and intervention. The purpose of this second chapter is to look at therapeutic interventions, exercises and biofeedback training, available for chronic non-specific LBP, while keeping models of pathology in mind.

2.1. Epidemiology

To understand the magnitude of low back pain throughout society, it is important to look at epidemiological factors such as incidence and prevalence rates. Additionally, cost of illness studies give insights into the potential financial strain on society and the latest Global Burden of Disease Study is analysed with the aim of determining the relative burden of low back pain in comparison to other disabilities.

2.1.1. Incidence

Incidence estimates for LBP are hard to come by due to the fact that longitudinal studies which would assess incidence rates require more funding and time than cross-sectional studies. Therefore, a greater portion of literature deals with prevalence rates rather than incidence rates.

In a systematic review, Hoy et al. reviewed 12 studies finding a one-year incidence of first-ever low back pain from 6.3% to 15.4% and one-year incidence of people having a first ever or recurrent episode ranging from 1.5% to 36% [Hoy10]. The first occurrence of low back pain was lowest in a study from Denmark (6.3%) and highest in the United Kingdom (15.4%), both western countries. In contrast, the lowest one-year incidence of any episode of LBP (1.5%) was measured in a study from Kuwait with high risk of bias and the highest incidence rate (36%) in a study from the United Kingdom again. In another, more recent meta-analysis, Taylor et al. assumed a summary pooled estimate of 27% (95% CI, 21-32%) for occupational populations that were pain free at baseline after reviewing 41 studies [Tay14]. The measured range was from 7% to 56%.

Heterogeneity in meta-analysis is common and to be expected [Hig08] especially when studying cohort studies due to their large within-study sample sizes. Taylor et al. failed to statistically explain the found heterogeneity in their meta-analysis, but rather assumed differences in study populations, occupational work demands and diverging definitions of LBP to be at fault. Their findings concerning different populations and true first time LBP or pain free at baseline however converged to an incidence proportion of about 25%, which would mean one in four people experience first-time LBP every year.

2.1.2. Prevalence

It is well documented that LBP is an extremely common health problem with high prevalence rates and often being recurrent. Nonetheless, definitive numbers still vary since there is methodological heterogeneity throughout studies concerning case definition, recall period, age and sex distributions, representatives of the sample, sample size and whether random methods were used in selecting the sample population [Hoy10]. Hoy et al. systematically review prevalence of LBP in the general population and found the point prevalence of low back pain to range from 1.0% to 58.1% and one-year prevalence to range from 0.8% to 82.5%. The large heterogeneity necessitates caution when looking at mean estimates.

In an updated systematic review two years later [Hoy12], Hoy et al. found similar but slightly higher mean estimates for point (18.3%), one-month (30.8%) and one-year (38.0%) prevalence. Additionally higher overall mean prevalence of LBP among females (35.3%) than among males (29.4%) across all age groups was found. During adolescence median prevalence was found to be high decreasing during the ages of 20 to 29, and increasing for ages 40 to 69, only to decline again later in life. In a regression analysis increasing prevalence until middle age followed by a decline during older age was found to be more significant than a gradually increasing prevalence throughout all ages. This would mean that prevalence of LBP after the age of 69 gradually decreases.

Dionne et al. focused their review on the question of whether LBP decreases with increasing age [DDC06]. They concluded that the association of back pain prevalence with age is modified by the severity of the back pain and in fact is not as evident as believed. The curvilinear relationship of LBP and age previously mentioned was found by Dionne et al. to be exclusively in studies looking at one-year prevalence and chronic pain. After analyzing by severity of pain, Dionne et al. hypothesized that elderly experience less frequent benign or mild back pain but a higher prevalence of disabling or severe episodes. Probable causes mentioned for this trend were cognitive impairment, depression, decreased pain perception and/or increased tolerance to pain.

With old age the prevalence of osteoarthritis, disc degeneration, osteoporosis and spinal stenosis increase and a decrease in LBP seems difficult to comprehend. Dionne et al. summarize that more attention should be pain to LBP in older patients as it has been rarely studied to this date.

2.1.3. Costs of Illness

Costs of illness studies have the purpose of evaluating the cost of a particular disease and the resulting economic burden on society. All parties - including patients, clinicians and third-party payers - should be aware of the costs to appropriately allocate health care resources.

The total cost of illness has three components: direct costs, indirect cost, and intangible costs [DCH08]. Direct costs are made up of medical, physician services, medications, hospital services, and nonmedical costs, transportation or travel costs for attending medical appointments, meals eaten outside home when receiving health care or renovations made to the house for accessibility. Work absences (absenteeism) decreased productivity (presenteeism), as well as costs related to employment and household productivity make up indirect costs. Intangible costs such as decreased enjoyment of life due to illness are rarely mentioned because of the discomfort of placing a monetary value on these aspects.

In the studies reviewed by Dagenais et al. that estimated total costs, mean indirect costs accounted for 78% of total costs, pointing out that direct medical costs seem to contribute far less to the cost of LBP than indirect costs. A breakdown of direct costs revealed physical therapy (17%) and inpatient services (17%) to be the largest proportion, followed by pharmacy (13%) and primary care (13%).

There are no total cost estimates from the United States, but estimates ranging up to 90 billion US Dollars of direct costs put the economic burden of LBP into perspective.

2.1.4. Global Burden of Disease Study

Led by the Institute for Health Metrics and Evaluation at the University of Washington and involving 500 researchers in 50 countries, the Global Burden of Disease Study (GBD) is one of the most comprehensive approaches to quantify levels as well as trends of health loss caused by disease, injury and risk factors.

The measures of population health that the Global Burden of Disease Study use are disability-adjusted life years (DALYs), years of life lost due to premature mortality (YLLs), and years lived with disability (YLDs). YLDs are the number of incident cases, multiplied by the average duration of the condition (average number of years that the condition lasts until remission or death), multiplied by the disability weight (DW) [Buc13].

In the original GBD conducted in 1990, low back pain was not included. However, the updated version 2004 ranked it 105th of 136 conditions. Buchbinder et al. found this low ranking to be caused by the fact that LBP does not cause premature mortality and that the definition of LBP in the GBD 2004 as an intervertebral disc disorder may have falsified data.

Analyzing the most recent GBD 2010 data, Buchbinder et al. found LBP to be ranked sixth in contributors to overall disease burden, making up 83 million DALYs. Due to the absence of evidence that LBP alters mortality YLLs were identically to DALYs.

Among the ten most common causes of disability, Figure 1 shows low back pain ranking first place globally and among the top three throughout developed as well as developing countries. No other disability is as consistently ranked high throughout all 21 regions that were examined. LBP can therefore be seen as the single greatest contributor to global disability accounting for 10.7% of all YLDs [Vos10].

In summary, first-time LBP is experienced by one in four people every year. One year prevalence rates range around 40% and a decrease of LBP prevalence in old age seems disputable. Cost of illness studies show estimates as high as 90 billion US dollars in the United States for direct costs, with indirect costs being even higher. Analyzing the most recent Global Burden of Disease study reveals that not only LBP is the greatest contributor to disability worldwide, but also among the top ten causes for disability-adjusted life years.

Figure 1: Top10 Ranking of Disease and Injuries as Global Causes of Years Lived with Disability [Buc13]

3. Etiopathology

Low back pain (LBP) is commonly defined as pain, muscle tension or stiffness localized below the costal margin and above the inferior gluteal folds, with or without sciatica (leg pain). LBP can be either specific or non-specific. Symptoms that are caused by a specific pathophysiologic mechanism are described as being specific LBP, i.e. inflammation, infection, hernia nuclei pulposi (HNP), osteoporosis, rheumatoid arthritis, fracture or tumor. The majority of patients, about 85%, however will suffer from nonspecific LBP, defined as having no identifiable cause or pain of unknown origin [HS08].

Low back pain can be classified by duration: an episode of less than 6 weeks being acute LBP, between 6-12 weeks subacute LBP, and episodes that are lasting longer than 12 weeks chronic LBP. Even though studies suggest that more than 90% of patients will stop consulting a physician within 3 months of initial LBP complaints, they will still be experiencing pain and disability up to one year afterwards [Cro98]. Even more so, studying the long-term course Hestbaek et al. found recurrence rates to be 50% after one, 60% after two, and 70% after three years [HLM03].

Examining occurrence and chronicity factors as well as the possible underlying pathology of nonspecific low back pain is therefore crucial for developing treatment and prevention strategies.

3.1. Risk Factors

Croft et al. found weight, BMI and regular sports participation to be predictive physical risk factors for first-ever LBP in a community dwelling population [Cro99]. In men, neither height nor weight predicted LBP. Weight above 85.4 kg and a BMI greater than 28.8 were considered factors that predict LBP.

In another study, Macfarlane et al. investigated the role of employment and physical work activities and concluded that standing or walking more than two hours per shift in males and lifting or moving weight of 25 lbs. or more in females was associated with higher chances of suffering from LBP. Sitting more than two hours per shift was seen as a protective factor for both men and women [Mac97]. Other protective factors that Hartvigsen et al. found in a population of elderly twins were good overall physical function and grip strength, as well as overall cognitive performance, although the latter two were not statistically significant [HFC06].

A review from Van Tulder et al. includes all the mentioned risk factors above and more and structures them in individual, psychosocial, and occupational factors (Table 1). Further individual factors such as age and the strength of back and abdominal muscles, especially the lumbar multifidus muscles and the transverus abdominis [Hid11] as well as occupational factors such as whole-body vibration and bending and twisting seem to have a negative effect [TKB02].

Especially psychosocial factors, such as distress and depressive mood but also somatization, tend to be important in the transition from acute or subacute to chronic low back pain and disability in this context [Pin02, Neg08]. They are described as being “yellow flags” indicating risk for chronicity.

However, the multitude of other occurrence factors and factors that influence chronicity make it hard to potentially screen patients for these risk factors and therefore effectively reduce recurrence rates.

Table 1: Risk Factors for Occurrence and Chronicity [TKB02]

	Occurrence	Chronicity
Individual factors	▪ Age ▪ Physical fitness ▪ Strength of back and abdominal muscles	▪ Obesity ▪ Low educational level ▪ High levels of pain and disability
Psychosocial factors	▪ Stress ▪ Anxiety ▪ Mood/emotions ▪ Cognitive functioning ▪ Pain behavior	▪ Distress ▪ Depressive mood ▪ Somatization
Occupational factors	▪ Manual handling of materials ▪ Bending and twisting ▪ Whole-body vibration ▪ Job dissatisfaction ▪ Monotonous tasks ▪ Work relations/social support ▪ Control	▪ Job dissatisfaction ▪ Unavailability of light duty on return to work ▪ Job requirement of lifting for ¾ of the day

3.2. Categories

As previously mentioned, LBP can be categorized in being of specific or non-specific etiology. Most patients will suffer from non-specific LBP - however identifying potential serious underlying pathologies in the patients is important to prevent the prescription of treatment which would be contraindicated, i.e. manual therapy for patients with spinal fractures [Dow11]. Furthermore, the spread of metastatic diseases in the case of malignancy and further testing and treatment for diseases like osteoporosis can be achieved through properly examining patients and watching out for red flags.

3.2.1. Specific Low Back Pain

Specific LBP etiology presents a small portion of total prevalence in patients. The most common specific cause is found to be compression fracture (4%), followed by spondylolisthesis (3%), herniated disk (1-3%), neoplasia (0.7%), Ankylosing spondylitis (0.3%), cauda equina syndrome (0.04%) and least common infection (0.01%) [DRK92].

Atlas et al. (Table 2) identified three different major groups of LBP origin. Mechanical LBP, which in part also represents nonspecific LBP, non-mechanical spine disease, and visceral disease.

Mechanical LBP includes specific as well as non-specific causes but even when specific imaging findings such as degenerative disk disease, spondylolysis, spondylolisthesis or osteoporosis are found in combination with LBP, it may be difficult or impossible to establish if the finding is the cause of the symptoms. This topic, however, will be dealt with in depth further on.

To identify an even less common non-mechanical spine disease, namely neoplasia, infection or inflammatory arthritis, most clinical practice guidelines provide “red flags” that indicate the need for further screening. In a recent systematic review, that analysed diagnostic accuracy of various red flags for spinal fractures and spinal malignancies older age, prolonged corticosteroid use, severe trauma, and presence of a contusion or abrasion increased the likelihood of spinal fracture [Dow11], but for the likelihood of spinal malignancy, the actual non-mechanical spine disease, only a history of malignancy had an effect. Other sources [AD01, KT07] include unexplained weight loss - defined as more than 10 pounds in the preceding 6 months - and old age that could indicate a malignant etiology, though without stating diagnostic accuracy.

Visceral disease is the least common LBP origin and is often accompanied by other symptoms, i.e. an acute pancreatitis that will also cause abdominal pain and nausea, symptoms that are rarely associated with LBP.

Since causal therapy options for specific LBP exist and the purpose of this review is to examine nonspecific low back pain, further literature research concerning diagnostics and therapy was not undertaken.

Table 2: Differential Diagnosis of Low Back Pain [Dey86]

Mechanical Low Back Pain	**Non-mechanical Spine Disease**	**Visceral Disease**
Lumbar strain or sprain	Neoplasia	Pelvic organs
- Degenerative disease	- Metastatic carcinoma	- Prostatitis
	- Multiple myeloma	- Chronic pelvic inflammatory disease
- Disks (spondylosis)	- Lymphoma and leukemia	
Spondylolysis	Infection	Renal disease
Spondylolisthesis	- Osteomyelitis	- Nephrolithiasis
Herniated disk	- Septic discitis	Vascular disease
Spinal stenosis	- Endocarditis	- Abdominal aortic aneurysm
Osteoporosis	Inflammatory arthritis	
Fractures	- Ankylosing spondylitis	- Aortoiliac disease
	- Reiter’s syndrome	Gastrointestinal disease
	- Psoriatic spondylitis	- Pancreatitis
		- Cholecystitis

3.2.2. Non-Specific Low Back Pain

As stated earlier, almost 90% of all LBP incidents are of non-specific origin, meaning none of the “red flags” were present and no imaging results showed any diseases. The combination of both indicators is important, as plain radiographs are not sensitive enough as well as not specific enough [Tul97]. In other words: imaging results are not associated distinctively with symptoms and the origin of symptoms cannot be found with imaging alone. Since there are no precise pathoanatomical diagnosis terms such as strain, sprain, sacroiliac syndromes, facet joint syndrome or lumbago are most commonly used to describe non-specific LBP [AD01, DW01].

In order to better understand this difficult to define and very difficult to diagnose of LBP it is important to look at recent advances in the field of biomechanics.

3.3. Clinical Spinal Instability

Literature suggests that spinal instability is an important cause of LBP and disability as well as increasing the risk of recurrence [Izz13, Dem07].

A commonly used definition for instability as proposed by Panjabi is: “A significant decrease in the capacity of the stabilizing system of the spine to maintain the intervertebral neutral zones within the physiological limits so that there is no neurological dysfunction, no major deformity, and no incapacitating pain” [Pan92]. Understanding this definition requires deeper insight in the terms of the “stabilizing system” and the “neutral zones”.

The spinal stabilizing system (Figure 2) consists of three subsystems: a neural or motor control unit, muscles surrounding the spine, and the spinal column itself. Loads are carried by the spinal column and information about the position, motion and quantity of load is sent to the neural control unit. The neural control unit in turn transforms information into action, which is carried out by the muscles.

Normally all of these subsystems work in harmony and by doing so provide the necessary mechanical stability of the spine [Pan03].

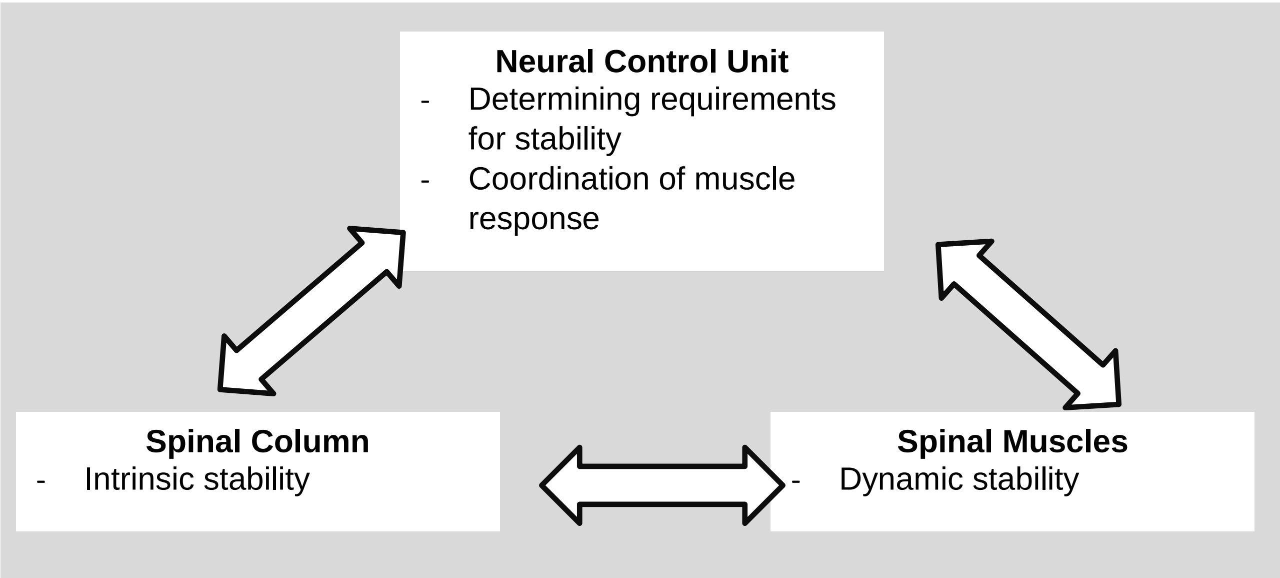

Figure 2: The Spinal Stabilizing System [Pan03]

The neutral zone Panjabi described is the “part of the range of intervertebral motion, measured from the neutral position, in which spinal motion can occur with minimal non-muscular passive resistance from the spine” [FWW10].

Abnormal motion would coinhere with an increase of the neutral zone. This would force the stabilizing system to react by stiffening muscles surrounding the spine, and actively decrease the neutral zone again. Panjabi used a ball-in-a-bowl analogy to illustrate this. In a healthy subject, the ball can move freely within the neutral zone (Figure 3 A). After sustaining an injury or degenerative changes, the ball is able to move beyond the neutral – and therefore pain free-zone (Figure 3 B). After the adaption of muscles (Figure 3 C), the neutral zone is decreased again and the subject is pain free. This analogy leads to a very important aspect of stabilization and therefore possible cause of LBP – muscles.

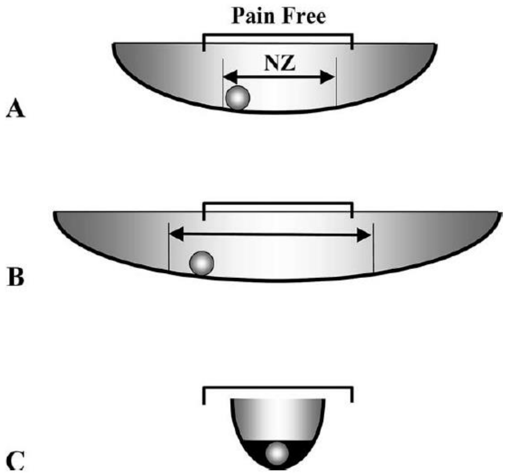

Figure 3: Ball-in-a-Bowl Analogy [Pan03]

3.3.1. Muscles

Panjabi postulated that in-vitro critical load calculations for the lumbar spinal column alone were around 90N, which is a lot less than the estimated in-vivo loads of 1500N. This would suggest that only through the stiffening effect of the muscles, the increased load and stability of the spine is even possible [Pan03]. Examining literature especially the transversus abdominis muscles and the lumbar multifidus muscles seem to play an important role [FWW10, Hid11, Won14, Sal10] in LBP origin and treatment. Studies have also shown a muscular imbalance in patients with LBP [Won14]. Muscular imbalance refers to differences in size and strength of muscles in the left to right relation, in case of the lumbar spine. The local stabilizing muscles are especially negatively affected by this pathophysiological mechanism. Ultrasound investigations have shown that the local stabilizing muscles of the lower back have a reduced thickness and increased fatty deposits on the side and level where the LBP is located. Even after an episode of LBP has resolved, the reduced muscle mass and the fatty deposits stay present. This observation is one of the key concepts which explain the high recurrence rates of LBP. Reduced local stability of the stabilizing muscles of the lower back exposes those effected by LBP to a higher risk of traumatizing the surrounding structures of the lumbar spine during motions of everyday life. Hence, recurrent episodes of LBP are like to occur, until the problem of localized muscle mass reduction is going to be addressed.

3.3.2. Lumbar Multifidus Muscles

According to Wilke et al. [WWC+95]. M. Multifidus make up two thirds of overall spinal stability, therefore being the largest stability contributing factor. The multifidus is made up of several fascicles that rise from the processus spinosus and lamina of each vertebra and insert in caudal direction between two and five spinal levels onto the zygaphophyseal joint capsule, mammillary process, lamina, medial posterior superior iliac spina, as well as dorsal sacrum [Dem07, MMH06]. Compared to all other lumbar muscles, the lumbar multifidus has characteristic short and strong muscle fibers with a high cross-sectional area due to a high mass. This in turn allows dense arrays of muscle fibers and makes the lumbar multifidus ideal for stability purposes [FWW10, RRA08].

The lumbar multifidus can be categorized in deep fibres (DM) and superficial fibres (SM) and are part of the erector spinae muscle (ES). DM are defined as crossing only two and not five spinal levels and then inserting onto the lamina, mammillary process and zygaphophyseal joint capsule [Mac86]. The sacrospinal ES consists of two independent muscles, the iliocostalis lumborum and the longissimus thoracis, each with thoracic and lumbar parts, the lumbar parts being here of relevance. The lumbar parts rise from the accessory process as well as the L1-4 transverse processes and then insert in the ilium [MB87]. MacDonald et al. identified five common beliefs concerning DM, SM and ES [MMH06]:

(1) SM and ES function as rotators/extensors of the lumbar spine and do not stabilize like the DM;
(2) SM and ES are to a lesser extent made up of type I (slow twitch) muscle fibers compared to DM;
(3) SM and ES are active phasically, DM tonically during trunk movement and gait;
(4) Transversus abdominis and DM co-contract;
(5) Lumbar paraspinal muscles changes in combination with LBP has a greater effect on DM than SM or ES.

Bridging exercises, which also will be used during the pilot 2 with the ALFRED Back Trainer, were able to activate to lumbar multifidus to a high degree, especially if combined with active motions of the extremities.

3.3.3. Transversus Abdominis Muscles

It has been suggested that elevated intra-abdominal pressure and contraction of the thoracic diaphragm and transversus abdominis provide a mechanical contribution to the control of spinal intervertebral stiffness [Hod03]. Additionally, the ability to contract the lumbar multifidus muscles, which as mentioned play a large role in non-specific LBP, has been suggested to be related to the ability to contract the transversus abdominis [Hid11]. It is only logical then that transversus abdominis muscle dysfunction is associated with higher long-term incidence rates of LBP as well [Mos04].

The transverse abdominis muscles connect to the lumbar vertebrae through the thoracolumbar fascia, which forms a corset resembling structure around the trunk that controls intra-abdominal pressure as well as vertebral stiffness [Won13]. The exact role of intra-abdominal pressure remains unclear, but it plays a role in stabilizing the spine and reducing spinal loading [AS06] which has also been observed in experimental studies [Hod03].

Subsequently there have been several assumptions regarding the role of transversus abdominis [Led10]:

(1) certain muscles are more important for the stabilization of the spine than others (such as transversus abdominis),
(2) weak abdominal muscles lead to back pain,
(3) strengthening abdominal or trunk muscles may reduce LBP,
(4) there is a unique “core” group of trunk muscles,
(5) there is a relationship between stability and back pain.

These assumptions will also be discussed in the therapeutic interventions section further on.

3.3.4. Global and Local Stabilizers

In 1989, Bergmark [Ber89] published a mechanical modelling analysis of the stability of the lumbar spine in which a distinction between local and a global system of muscles was made. Local stabilizers were muscles with insertion or origin at the lumbar vertebrae and global stabilizers with origin on the pelvis and insertions on the thoracic cage. In his experiments, Bergmark concluded that force distribution over the local system was independent of the outer load and was only met by different distribution dependent of load in the global system. Therefore he assumed the local system would only perform locally determined actions such as posture control.

The rectus abdominis, external oblique, thoracic erector spinae, longissimus thoracis, iliocostalis lumborum, quadraturs lumborum, and internal oblique muscles would be considered global muscles with the functions of large trunk movements and general trunk stability. In low-load situations, the local muscle systems, like the multifidus and transversus abdominis, are associated with intra-abdominal pressure and relaxed inspiration and control the position of the pelvis on the hips and lordosis. In a high-load situation, both systems would interact for extra spinal stability [JP07].

This is the theoretical basis for most lumbar or core stabilization programs: trying to activate the local systems and therefore effectively reducing LBP through dynamic stabilization.

3.3.5. Exercise Therapy and Biofeedback Training

Exercise therapy is the most commonly used conservative treatment for LBP and has been proven to be effective both at decreasing pain and improving function in chronic LBP patients and to a certain degree in subacute LBP patients.

Generally speaking, there are two different exercise therapy options. First, general exercise that aims to strengthen all trunk extensors and flexors and second, a stabilization exercise that aims to stabilize more specific muscles. There are no systematic reviews that the author is aware of, directly comparing the effects of general and specific exercise for treating LBP. However, comparisons of stabilization exercises versus manual therapy in a recent review showed stabilization exercise to be in part superior [MJ08].

Additional benefit could also be achieved from the use of biofeedback training in combination with specific stabilization exercises. Biofeedback has already been used for the last five decades with the aim to make normal movement patterns after injury possible.

Biological information is presented to patients, which would otherwise be unknown, also called augmented or extrinsic feedback, since it goes beyond the available information of the intrinsic (sensory) system. There are two basic principles of biofeedback: direct and transformed feedback. Direct feedback presents the measured variable, for example the current heart rate, as a numerical value on a display of some sort. Transformed feedback describes feedback that is modified by the measured variable, i.e. a tactile feedback for heart rate above a set variable [GPC13]. Since it is known that patients with LBP suffer from an impairment of the intrinsic feedback system, there are several areas of application for biofeedback training [Rib11, DBT05, Pan06].

One possibility for the use of biofeedback is the use of the Wii Balance Board (Nintendo, Kyoto, Japan). It contains four transducers to assess force distribution on the board and the resulting movements in the center of pressure. It was designed as a video game controller in combination with a video game console and its associated software. Instant feedback is also possible and positively affects motivation. However, there are currently no studies which examine the effect of specific stabilizing exercises for LBP in combination with biofeedback devices.

4. Conclusion

Based on the findings of this literature research, a specific exercise regime was developed to explicitly improve the clinical stability of the lower back. The exercises are designed to strengthen the lumbar multifidus muscles which are the major contributor to lumbar stability. The exercises which will be used are so called “bridging exercises”. These exercises are executed while the users are lying on their backs, hips flexed at a 45 degree angle and knees at a 90 degree angle. From this position, the user has to lift her pelvis off the ground such that lower back, pelvis and thigh form a straight line. This position has to be actively held by the user for a period of 20 seconds, before the pelvis can be lowered again in a steady and controlled manner to the initial position (Figure 4).

As previously mentioned, bridging exercises are able to produce high activities of the stabilizing muscles of the spine, especially if they are combined with motions of the extremities of the user (Figure 5). In addition to the benefits of bridging exercises, biofeedback training for the lower back could help to address the localized muscles mass reduction in persons with LBP and therefore reduce the currently high recurrence rates of LBP. Additionally to the benefit of bridging exercises to the lumbar spine, the ALFRED Back Trainer application can provide users with biofeedback information which is displayed to the user on a regular, commercially available tablet computer mounted to a tripod. The main difference of the ALFRED Back Trainer and standard bridging exercises is that the user will additionally lie on two Nintendo Wii balance boards. The balance boards will be horizontally placed under the shoulders and the feet of the user and give feedback of the motion of the user during the bridging exercise (Figure 10). The stabilizing muscles of the spine are by nature very small in size and are not able to produce large motions. For this reason it is very hard to see for the human eye whether or not the local stabilizing muscles are activated equally strong at both sides of the spine during the bridging exercise. Symmetrical activation of the local spinal stabilizers however is necessary to restore the muscle balance in the lower back area in order to reduce the recurrence rates of LBP, increase spinal stability and therefore reduce LBP.

One possibility to visualize symmetric activation of the local spinal muscles during bridging exercises is the use of biofeedback. As previously stated, bridging exercises have shown to be excellent exercises to strengthen the local stabilizers of the spine. However, in order to be able to judge if the user is able to maintain symmetrical activation of the local spinal stabilizing muscles, specific feedback devices could be employed. Optimal symmetrical activity of the stabilizing muscles of the spine during bridging exercises would be achieved, if both feet as well as the shoulders are loaded with an equal amount of bodyweight in all 2-D dimensions. For example, a decreased activation of the stabilizing musculature on the left side would change the kinematics of the lower back and therefore increase the load on the foot or shoulder area during bridging exercises on the left side. With the help of Nintendo Wii balance boards and a tablet, this shift in weight can be made visible to the users during motion. Symmetrical loading of the shoulders and feet is displayed by a ball in a circle. The ball represents the user’s center of mass over the balance board - the closer the ball is to the actual center of the circle, the more equal is the weight distribution of the shoulders and feet (Figure 11). In essence, this is the principle of the ALFRED Back Trainer serious game.

The users are encouraged to maintain their body position during the exercises as symmetrically as possible. Since a symmetric body position also equals a symmetric activation of the lumbar stabilizing muscles, the hypotheses of the ALFRED Back Trainer is that it can restore spinal stability more effectively as conventional bridging exercises and therefore is superior in the reduction and prevention of LBP.

Figure 4: Starting Position

Figure 5: Arms Opened

Figure 6: Right Arm Lifted

Figure 7: Forefoot Lifted and Arms Opened

Figure 8: Left Forefoot Lifted and Left Arm 45°- angled

5. Pilot 2: Procedure

This section will describe the goal of the pilot, applicable regulations, examinations measures, recruitment strategy, pretest procedures, procedure of the main pilot, predicted therapeutically benefits for the users and for future diseased person groups, potential risks and risk management, exit criteria, inclusion/exclusion criteria, documentation details and data protection.

Overall, 60 users will be randomized into three different groups to the pilot. The first group "conventional back training" (CB, 20 users) will receive stabilizing exercises for the lower back, according to the principles from the literature discussed in Chapter 2 and 3 of this document. The second group (CBB, 20 users) will perform identical exercises as the CB group, but with the additional perceived benefit of biofeedback training. Biofeedback will allow the users to visually observe their motions during the exercises on a commercially available tablet PC which will be mounted to a tripod. While the users are lying on two commercially available Nintendo Wii Balance Boards (one underneath their shoulders and one underneath their feet), they can see their body motions during the exercises on the tablet screen. The hypothesis of the pilot is that the additional use of biofeedback during stabilizing exercises for the lower back will lead to increased LBP reduction, higher functionality during activities of daily life, increased muscle strength and improved sleep quality. The third group (C, 20 users) will serve as the control group and will not perform any exercises at all.

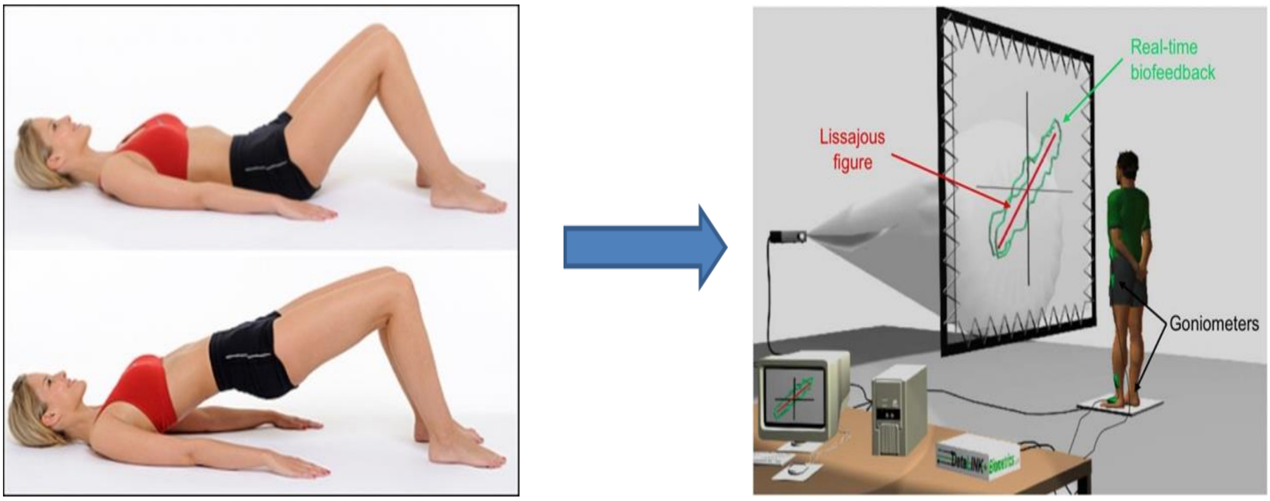

Figure 9: Back Training with Biofeedback

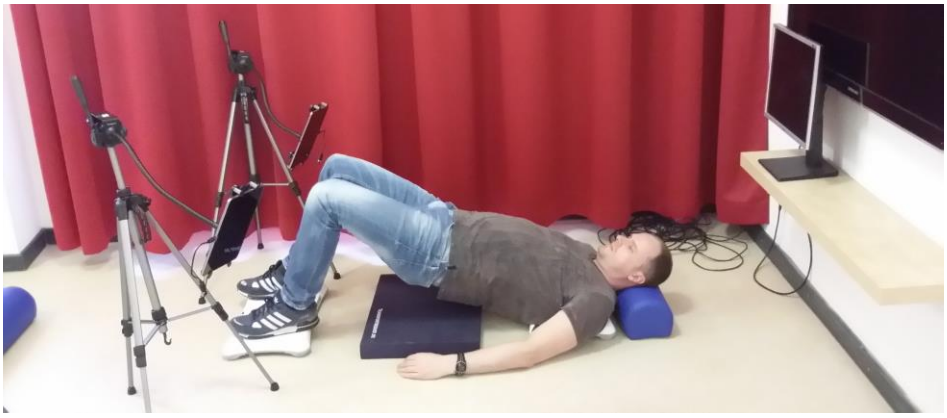

Figure 10: Position of the Balance Boards

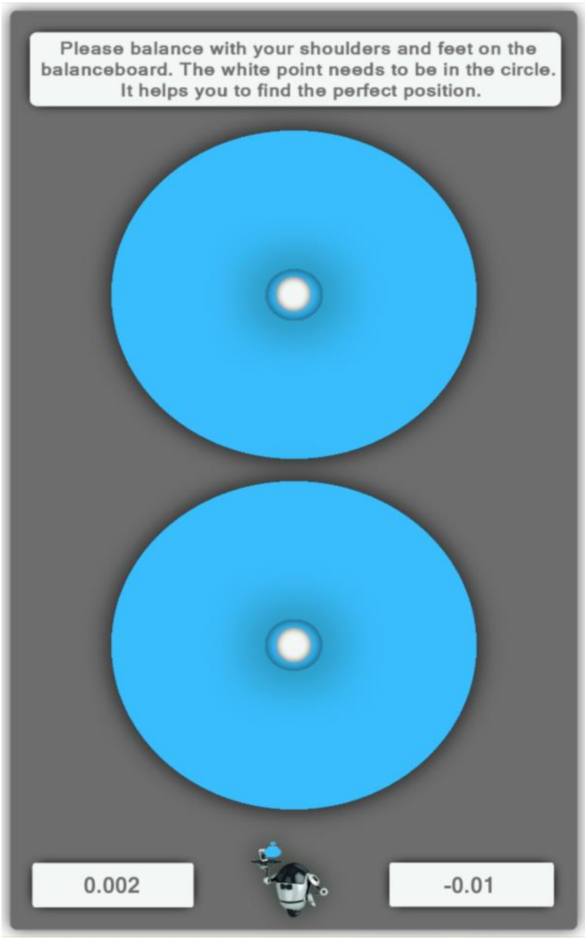

Figure 11: Screenshot of the 'Two Circles' Biofeedback

5.1. Aim of the Pilot

The aim of the pilot is the evaluation of exercises meant to strengthen the trunk musculature and reduce or prevent LBP.

Primary goal:

- Find out to what extent physical factors are influenced by a preventive training of the trunk musculature.

Secondary goals:

- Analysis of factors which improve or hinder older adults’ participation in preventive training the trunk musculature.
- Analysis of influences of the exercises on sleeping quality.
- Analysis of gender- and age-determined differences concerning problems caused by low back pain.

5.2. Applicable Regulations

All products and devices used during this pilot are CE-certified and commercially available products. The German Medical Product Law (= Medizinproduktgesetz, MPG) does not apply to the pilot according to § 20 MPG. A data protection vote for the pilot was requested from the local data protection authority on the 12.01.2016 and a positive data protection vote was received on the 10.03.2016. It was also necessary to obtain an ethical vote from the local ethics commission. For this purpose, all relevant questionnaires and the overall procedure had to be presented to the consortium of the ethics committee. An appointment for the presentation was requested at 10.01.2016 and the actual presentation was given on the 17.02.2016. Results from the ethics commission were received on 11.03.2016, with a request for minor amendments. The revised documents were returned to the ethics commission on the 14.03.2016. The final positive ethical vote is expected at the end of March 2016.

5.2.1. Data Protection

The privacy protection regulations are determined by federal law. All data related to the users will be registered pseudonymously. Each participant is distinctively marked by a two digits number, which is assigned to her during the registration process. The coordinator of the study keeps a confidential list of users in which the data is linked to the full name of the user. Only the study coordinator will have access to this list.

5.3. Main Results of Former Clinical Studies

Due to the fact that this is a pilot study, no further investigations in the areas to be investigated have been made. Within this pilot, a pre-test will be conducted to optimize the evaluation instrument.

5.4. Recruitment and Screening

The recruitment process for the pilot started on the 05.01.2016 and ended on the 14.03.2016. Subjects were recruited through announcements in resident physicians' offices, pharmacies, senior activity centres, and existing contacts of project partner CHA. Overall, 380 seniors were telephonically screened for inclusion and exclusion of the pilot. 64 subjects met the all relevant criteria.

5.4.1. Inclusion and Exclusion Criteria

The following section will describe the inclusion and exclusion criteria which were used for the users of the pilot.

Inclusion criteria (pretest and main study):

- Age > 65 years
- Existence of a participant's information and a signed acceptance
- Presence of LBP for at least 6 weeks during the 12 month

Excluding criteria (pretest and main study):

- Heavily affective or cognitive diseases
- Acute LBP
- Participation on another intervention study
- Presence of a legal guardian
- Immobility
- Recent major chirurgical intervention
- Acute herniated disc
- Tumorous affection of the spine

5.5. Pretest

After the screening process, there will be a pre-test of all involved devices and questionnaires with the older adults in order to ensure an optimal process of the pilot. During the pre-test, users are asked about problems with handling the questionnaire and the instructions and are asked for potential improvements. All comments will be protocoled anonymously by a member of the pilot team.

The critique of the elderly from the pre-test will be taken into consideration and serve as a basis to adapt the questions of the actual pilot in order to warrant maximal comprehensibility.

Changes can contain:

- erasing or reformulating single questions of the questionnaire
- adding choices
- changing words chosen for the instruction
- changing questions of the questionnaire about frame data, healthy behaviour and ratings to improve and estimate the usability
- changes in schedule
- changes in the instructions

5.6. Methodology Pilot 2

At least 24 hours before the actual start of the pilot, the previously screened older adults will receive the participant information, either by Email or via postal service. This information will also contain date and time of the first visit of potential participants of the pilot. At the beginning of the first visit, potential participants will receive the opportunity to clarify any questions relevant to the pilot with the team of the pilot. Once all questions are resolved and the potential participant agrees to enrol in the study, informed consent will be signed and the physical examination will be performed and questionnaires will be filled out by the included subjects.

Each participant receives a unique participant's number by the study personnel. Finally the 60 participants will be randomized either to the group "conventional back training" (CR, 20 participants) or to the group "conventional back training with biofeedback" (CRB, 20 participants), or to the control group (CG, 20 participants).

The following data of the participants will be collected:

- Sociodemographic data to enable clustering the participants (age, sex, educational background)
- Functional questionnaire "Hannover Rücken"
- Oswestry Disability Index
- Static measures of the muscular endurance of the musculur erector spinae of the lateral and straight abdominal musculature
- Spinal mobility referring to Schober-Ott
- Fingertip-floor-distance
- Four Square Step Test
- Five Times Sit to Stand Test
- Visual analogue scale for dorsal pain
- Pittsburgh sleeping quality index
- Standardised questions to health behaviour

Afterwards, a short training on how to handle the ALFRED Back Trainer and a demonstration of the exercises future appointments are scheduled.

Visit 2-25 Intervention group with supervision

The study contains exercises which improve muscular activity and are of medium intensity. The exercises to prevent LBP are conducted on the floor with either a sport mattress (CR) or commercially available Nintendo Wii Balance Boards (CRB) which will provide biofeedback. The exercises will take place in a lying position with the subjects lying on their back. The study wants to examine if the additional employment of biofeedback (CRB) with the same amount of training as in the conventional back training (CR) will lead to different preventive factors of LBP. Furthermore, it shall be examined if the CRB yields additional positive training effects compared to the CR in relation to muscular strength, execution of everyday life activities, balance and LBP. Secondary, it shall be examined if a different acceptance level between the two groups occurs.

The participants of both groups will be trained for a total period of 10 weeks. Users train 2 days a week. Each session takes 40 minutes and consists of a short warmup and 30 minutes of training. The exercises which have to be performed by the subjects are taken from the manual of the federal association of German back schools. The training program was compiled by a certified trainer and a physiotherapist. Additionally, in order control the vital signs of the participants, there is a possibility to wear the ALFRED sensor T-shirt which can measure body temperature, breathing rate and heart rate. The biofeedback data of the CRB group are presented to the participants on commercially available Samsung Galaxy Tab 2 Tablet, which is mounted on a tripod. The control group will receive the results of their health assessments by mail, after the end of the study.

Visit 26 (final examination)

The following data is gathered at the end of the study:

- Functional questionnaire Hannover Rücken
- Oswestry Disability Index
- Static measures of the muscular endurance of the m. erector spinae of the lateral and straight abdominal musculature
- Spinal mobility referring to Schober-Ott
- Fingertip-floor-distance
- Four Square Step Test
- Five Times Sit to Stand Test
- Visual analogue scale for dorsal pain
- Pittsburgh sleeping quality index
- Standardised questions to health behaviour

All users have the possibility to get water, if needed. In addition, the study personnel may set extra pauses to minimize the stress to the users. Separate washing and changing rooms for male and female users are available.

5.6.1. Risk Management

The study is a permanently accompanied by specifically trained personnel. No invasive devices are used and only CE-certified devices are employed. During the study, standard therapeutic exercises or preventive exercises are conducted. There is a risk for the users of possible tiring caused by physical stress. However, in order to reach measurable physical improvement, exercises need to exceed the usual everyday stress of the participant. The study personnel will take care that the exercises are adapted to the individual’s physical capacities and abilities to avoid excessive physical or mental stress. Specially defined inclusion and exclusion criteria assure that only users which are physically and mentally suitable for this study will participate. The risk in this study has to be rated low and the benefit is significantly higher than the individual risk to the user. In case of any uncertainties of the participants, regarding their health status, users are requested to contact their resident physician for clarification.

5.6.2. Risks and Other Demands to the Users

Potentially stressing factors to the study participants are the filling of the questionnaires, assessments and exercises during the study. These tests will take a maximum of 60 minutes and might be tiring or slightly exhausting. The pilot contains exercises which require muscular activity of medium intensity level. The exercises are conducted on a sport mattress or upon commercially available Nintendo Wii Balance Boards. The exercises are derived from exercises usually done in preventive lower back training sessions. The exercises are conducted and supervised by a trained member of the study personnel. The primary physical examination will take no more than one hour. The exercises themselves will not exceed 40 minutes per unit. After each task, there will be adequate breaks for the users to recover, their length being based on current scientific research and exercise physiology. Furthermore, each user may skip or terminate an exercise if deemed too exhausting, or for any other reason. The exercises might become more tiring and exhausting throughout the session. However, this is a normal process and inevitable to reach training progress. All users have the possibility to get water, if needed. If required, the study personnel may insert extra pauses to minimize the stress. Separate washing and changing rooms for male and female users are available.

5.6.3. Predicted Therapeutic Benefit

During this study, users will receive training for the muscles of the lower back based on modern exercise approaches. These exercises are designed to improve the functionality of the musculoskeletal system and the general posture. The training will be free of charge for the users. During the course of inclusion and exclusion criteria the fall risk, balance, muscular strength and endurance are evaluated. The results are made accessible for the users after the analysis.

5.6.4. Predicted Medical Benefit for Future Diseased Persons

The goal of the study is the development of a new basic concept to implement biofeedback controlled exercises to strengthen trunk muscles and prevent LBP. For this purpose, the biofeedback training developed within the ALFRED project could be used as a new and more efficient training concept to prevent LBP in the future. One possible advantage could be a faster and more efficient training of the trunk musculature caused by the specific set training stimuli of the muscles of the lower back. These exercises might be able to restore the muscular stability of the lower back in a faster and more targeted way than in conventional exercises. Positive results of this study, combined with a high usability of the ALFRED back trainer, could lead to improved outcomes compared to the conventional preventive training of the lower back musculature.

5.6.5. Data Analysis

All paper-based questionnaires and physical assessments will be analyzed with Excel and SPSS. The results of the pilot will be presented in the upcoming deliverable D8.3.2.

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