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Influence of Masai Barefoot Technology (MBT) on the Quality-of-life of Patients with Chronic Back Pain

Diploma Thesis of

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Cologne 2002

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Assurance:

I assure that I have produced this work independently and that I have not used any sources or aids other than those stated herein. Text passages quoted, including single sentences or parts thereof, are marked as quotations.

PREFACE

During my internship in Davos, Switzerland, in the summer of 2001, I became acquainted with the MBT shoe. In the local rehabilitation centre, patients used the MBT, particularly those with back problems. As a trainer using a range of exercises intended for the spinal column, I have become deeply involved in studying the back and its various disorders. As a result, the MBT shoe instantly caught my attention because, among other reasons, a person uses his/her entire muscles, including the muscles of the back, while walking with the MBT shoe. For me, the challenge was to evaluate the effects of Masai Barefoot Technology on the posture and back, or, in more general terms, on the quality of life. To discover new measures as an adjunct to therapy is a rewarding task for me.

First of all, I would like to thank Prof Dr Klaus Schüle for accepting the concept and the topic of the thesis and for his advice and support which helped me conclude the diploma thesis.

In addition, the responsible staff members of the association “Verein für Gesundheitssport und Sporttherapie Köln e.V.”, Claudia Stiem and Christine Kupferer, who helped in word and deed. I would like to take the opportunity to thank them here. I would like to extend my special thanks to Berta Kerner who was always there during the practical conduct of the investigation, facilitating greatly with the test subjects.

To all who volunteered to participate in my study, I would also like to extend my thanks for their motivation, cooperation and collaboration.

As is so often in life, friends are there to lift one’s spirit when motivation is low, to help with proof-reading, as well as general support. And this holds true here once again. Warm thanks: Anette, Jörg, Rafael, Simone D., Simone L., Thomas and Thorsten.

I am much obliged to the Masai GmbH in Switzerland – and the company’s CEO Dipl. Masch. Ing. (ETH) Karl Müller – which was kind enough to provide the MBT shoes for the duration of the study.

Finally, I would like to thank my parents, whose financial and emotional support was essential for my academic training. This thesis is dedicated to them. Thank You!

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TABLE OF ABBREVIATIONS

AGES	General perception of health
CG	Control group
dN	German normal sample
e.g.	For example
EMRO	Emotional Role Function
et al	Et altera (amongst others)
FFbH-R	Functional questionnaire Hanover back
Hrsg.	Editor
IASP	International Association for the Study of Pain
IG	Intervention group
ISG	Iliosacral joint
KÖFU	Physical functional capacity
KÖRO	Physical role function
KÖSU	Physical sum scale
M.	Musculus, muscle
Max	Maximum
MBT	Masai Barefoot Technology
Min	Minimum
MOS	Medical Outcome Study
n	Size sub-sample
ns	Not significant
p	Probability of error
PAOD	Peripheral Arterial Occlusive Disease
PSSU	Psychological Sum Scales

PSYC	Psychological well-being
RS	Back pain
s.	See
SCHM	Bodily pain
SD	Standard deviation
SF-36	Short Form-36
SL	Levels of statistical significance
SOFU	Social functional capability
VGS	Verein für Gesundheitsport und Sporttherapie
VITA	Vitality
WHO	World Health Organisation

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1. INTRODUCTION

1. INTRODUCTION

In today's population, a shift in age distribution has been observed, which is due to demographic change. During the past 40 years there has been a continuous rise in life expectancy with females living longer than males. Apart from lower infant mortality, the increased life expectancy can also be attributed to a decrease in mortality among the elderly population. This is explained by improved hygiene in Western industrialised nations, and by a significantly more modern medical care system as compared with some decades ago. An increased percentage of elderly people in the population has resulted in new insights into diseases which, due to the previously lower life expectancy of the elderly, had not been a central focus of medical research in the past. Diseases such as tuberculosis and various epidemics, effectively eradicated by modern medicine, presume less importance for industrialised nations today.

So-called diseases of civilisation are now coming to the fore which, according to ROST (2000, 19) mean: *“that the diseases of a social system depend on the respective civilisational conditions”*.

In today’s Western industrialized nations, numerous diseases of the cardiovascular and musculoskeletal systems are caused by physical inactivity. This includes back pain which is one of the most widespread complaints in Germany. This example of a disease of civilization has become a focus in medical research and science because of its high prevalence.

Current data on back pain provides evidence that the problem is no longer restricted to the elderly, as slipped discs are now found among 20-year-olds. Since such diseases affect a large percentage of the population significant direct and indirect costs result for the health system, especially due to chronic cases. To reduce these costs in the future, further measures in the secondary and tertiary prevention of back pain should be developed to complement the existing treatment options.

The present study was conducted to provide further insights into additional therapeutic options.

The Masai Barefoot Technology uses a specifically-designed shoe, the MBT shoe, which imposes an upright active gait, and is studied with regards to its efficacy in back pain alleviation in patients. Via the active gait with MBT shoes, the muscles are activated and the joints are thus protected. The Masai Barefoot Technology can be used in other orthopaedic and medical conditions as well. However, the scope of this study is limited to observing the changes in the quality-of-life of people with chronic back pain, due to the use of this new technology.

The above-mentioned back pain symptoms will be discussed at length in Chapter 2. The epidemiology, aetiology, the process of chronification (sic), as well as the consequences of chronic back pain and the back pain-related health costs will be addressed in detail. In Chapter 3, the Masai Barefoot Technology will be described; how it originated, which principles and concepts it pursues, how far it has been distributed, and what scientific evidence is already available on the possible and beneficial uses of this technology. Next, the research design will be presented in the methodology chapter (Chapter 4). Here, among other subjects, the sample, the investigation, and test instruments used will be described. Chapter 5 will present the study results. The results will be then discussed in comparison with other studies in Chapter 6. Following a review of the prospects in Chapter 7, a summary of the study will be given at the end.

2. THE PROBLEM OF BACK PAIN

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> *"References to back pain treatment are already found in a papyrus script (1500 BC) on surgery. Apparently, back pain has been a cause of human suffering from time immemorial, but was considered by medical sciences as being of rather secondary importance until the fifties of this century."*
> *(TRAUE & KESSLER 1993)*

2.1 BACK PAIN FROM AN EPIDEMIOLOGICAL PERSPECTIVE

Looking at the statistics and figures of today's back pain problem, it is immediately apparent that back pain currently tops the list as the most widespread complaint (PFÖRRINGER 1997). It is assumed that more than half of the population will experience back pain once in their lifetime (ARENDT 1992, 11). The lifetime prevalence is estimated to be above 80 percent in Germany (LÜHMANN, KOHLMANN, RASPE 1998; BOLTEN, KEMPEL-WAIBEL, PRÖRRINGER 1998), based on the inclusion of various intensities of back pain (ARENDT 1992, 11). Approximately 80 percent of all back pain is attributed to unspecific pain, whereas less than ten percent is the result of a herniated nucleus pulposus (GESUNDHEITSBERICHT FÜR DEUTSCHLAND 1998). In approximately ten percent of cases, back pain takes a recurrent or chronic course (LÜHMANN et al. 1998), with females more often experiencing severe and chronic forms of back pain (SCHOCHAT & JÄCKEL 1998). In Germany, mild back pain predominates, especially among those between 25 to 54 years of age. People aged between 65 to 74 years experience less back pain than those between 55 to 64 years. Thus, late in life a decrease in pain symptoms is noted. In 80 percent, other rheumatic symptoms develop apart from back pain (RASPE & KOHLMANN 1994). In 18 percent, the back pain is labelled as restricting activity, and functional impairments are found in 5 to 10 percent (SCHOCHAT & JÄCKEL 1998).

From 1989 to 1993, RASPE and KOHLMANN investigated, on a sub-population level, German residents aged between 25 and 74 as to the prevalence of back pain. A postal survey was conducted in Hanover, Bad Säckingen and Lübeck (Lübecker Back Pain Study). With response rates of over 80 percent, the following results were produced:
The first question was always: “Are you experiencing back pain today?”. For this question, a prevalence of 40 percent was found. “Back pain during the last year” was reported by 70 percent and – as already mentioned – “constant back pain” was reported by 80 percent of those surveyed (RASPE & KOHLMANN 1994 & 1998, 22).
Back pain was added to the list of occupational diseases in 1993.
(GESUNDHEITSBERICHT FÜR DEUTSCHLAND 1998).

2.2 AETIOLOGY OF BACK PAIN

Many conditions can cause back pain. This means that distinct pathologies can be at the origin of lower back pain. To begin with, the possible causes are differentiated into vertebral and extra-vertebral conditions (SCHULITZ, KOCH, WEHLING 1998, 37/38). The causes of extra-vertebral back pain can be classified as psychosomatic, viscerogenic and neurogenic causes and, in addition, muscular strain. The vertebral causes of back pain include functional disturbances of the intervertebral joints, degenerative, metabolic, inflammatory and tumourous conditions, as well as developmental disturbances of the spine (GERBER 1994). This classification is discussed in more detail below.

Extra-vertebral causes of back pain:

Psychosomatic causes

About half of all back pain cases can be explained by psychosomatic factors. Women and socioeconomically disadvantaged groups with low educational achievements are more often affected. The possible factors that may trigger back pain include previous occupational or family-related life events, difficult relationships, losses or financial problems. Clinical symptoms include imprecise pain descriptions with changing pain localizations, accompanied by disturbed sleep and lack of libido.

Furthermore, the patients complain of dizziness, as well as head, abdominal and other functional disturbances (GERBER 1994).

Viscerogenic causes

Tumours or inflammations of internal organs can have an impact on the back and be experienced as back pain. This type of pain is characterised by a well-defined localisation, and it occurs regularly. Processes in the true pelvis (tumours or abscesses) which move into the sacral region may serve as an example for this type of aetiology (GERBER 1994).

Neurogenic causes

These include microbiological radiculites caused by herpes zoster or tumourous processes, for example, which give rise to well-defined, localised pain. Pain location is constant and the pain can be precisely described (GERBER 1994).

Muscular strain

Myogenic or unspecific pain is localized in the muscles of the back (TRAUE & KESSLER 1993). It is caused by unfamiliar activities or by work-related postural or movement monotony (e.g. sales assistants, cashiers, computer work) and manifests itself, in addition to pain, in myogeloses (GERBER 1994).

Vertebral causes of back pain:

Functional disturbances of the intervertebral joints

These include, for example, segmental functional disturbances without structural changes, irritation of the facet joints, or blocked individual vertebral segments. Here the causes include physical inactivity, monotonous movements and abnormal posture in hyperlordosis (GERBER 1994).

Degenerative spinal diseases and disturbances

Degenerative processes involving the vertebral bodies, discs and the joints of the vertebral arches result in a loss of mobility of the functional unit and in movement-related pain (KEMPF 1999, 70). They develop because of an imbalance between load and load-bearing capacity, as well as because of ageing processes in the tissue (DORDEL 1990, 434). As a result, radicular or non-radicular pain can develop.

Radicular pain may be triggered by slipped discs, stenoses, spondylolisthesis, or lumboischialgia. The causes of non-radicular pain are located in the intervertebral discs, vertebral joints, muscles and ligaments, or in extraspinal structures (TRAUE & KESSLER 1993).

Metabolic causes

The group of metabolic and endocrine spinal disorders includes idiopathic and secondary osteoporosis, osteomalacia and endocrine osteopathies (GERBER 1994). These disorders are caused by a general bone mass reduction which can equally affect the matrix and mineral component (osteoporosis) or which can be limited to the mineral part of the bone (osteomalacia) (NIETHARD & PFEIL 1997, 164).

Inflammatory causes

The inflammatory disorders of the spine fall into four groups: spondylarthritides (Bechterew’s disease, reactive spondylarthritis, psoriatic spondylarthritis), crystal-induced spondylitides (chondrocalcinosis of the intervertebral discs and the intervertebral joints), bacterial spondylitides and Paget’s disease. A characteristic symptom indicating the presence of inflammation is pain while at rest (GERBER 1994).

Tumourous causes

Here, malignant tumours causing persistent pain are differentiated from benign tumours causing facultative pain. As a result, spinal mobility is impaired and paravertebral myogeloses develop (GERBER 1994).

Developmental disturbances

The developmental disturbances of the spine include, among others, spondylolysis, spondylolisthesis, idiopathic scoliosis, secondary torsion scoliosis, hyperlaxity of the spine and Scheuermann's disease. These conditions cause irregular pain with possible pseudoradicular radiation into the legs. As a result, a stiff posture and myogeloses develop (GERBER 1994).

SCHULITZ, KOCH and WEHLING (1998) hold mechanical-anatomic, pathobiochemical, immunological and/or radicular factors responsible for the development of back pain, which will be described in detail below.

Mechanical-anatomic aspects

It is assumed that three anatomic structures may cause back pain. These are the intervertebral disc, the soft tissue and the joints, where degenerative changes, injuries or strain may occur (SCHULITZ, KOCH, WEHLING 1998, 38-40).

Pathobiochemical aspects

Responsible for the development of pain are not only biomechanical processes but also biochemical processes. Specific enzymes may trigger inflammatory reactions (e.g. in rheumatoid arthritis). Various neurogenic and non-neurogenic mediators play an important role in the aetiology of lumbar pain or lumboischialgia (SCHULITZ, KOCH, WEHLING 1998, 41/42).

Immunological aspects

So-called immunological inflammatory processes occur when autologous intervertebral disc tissue enters into contact with nerve tissue and triggers changes with respect to the structure and function of adjacent nerve roots. This inflammatory response was demonstrated for the contact of autologous nucleus tissue in the epidural space. Here nerve fibre degeneration occurred, affecting nerve conduction velocity (SCHULITZ, KOCH, WEHLING 1998, 43).

Radicular aspects

Mechanisms, such as e.g. deformation of a nerve or of nerve tissue by traction or pressure, may result in the stimulation of nociceptors and mechanoreceptors and cause a reduction of the stimulus threshold. This may occur in cases of spinal stenosis and disc prolapse (SCHULITZ, KOCH, WEHLING 1998, 44-49).

Finally, it should be mentioned that the cause of back pain only can be diagnosed precisely in a small percentage of patients (TRAUE a. KESSLER 1993), since in 60 to 80 percent of cases an exact causal attribution is not possible (HILDEBRANDT & PFINGSTEN 1998; HILDEBRANDT 1999).

> *"Diagnosis and differential diagnosis of the symptom lower back pain or sacral pain is a demanding orthopaedic task. The gap between what is medically possible and economic constraints requires that indications be solidly based." (SCHULITZ, KOCH, WEHLING 1998, 60).*

It has to be noted that diagnosing lower back pain and sacral pain is not only an orthopaedic task, since a spinal examination also involves a neurological examination (CREMERIUS, HORST, STRATTHAUS 1998, 336-340).

Based on the diagnosis, the further management of each case/patient is carried out in detail. Only if the patient does not respond to therapy or if symptoms increase, are forced differential diagnostic procedures then performed (SCHULITZ, KOCH, WEHLING 1998, 60).

2.3 CHRONIFICATION (sic) OF BACK PAIN

The risk of chronification (sic) has to be viewed as a health care and socio-political problem (TRAUE a. KESSLER 1993; HILDEBRANDT 1999). Although the first occurrence of acute back pain is only of a short duration and 90 percent of patients recover within two months, it can be assumed that at least 60 percent of all patients whose back pain lasts longer than six months will develop chronic pain. According to empirical findings, pain lasting longer than two months, or six months at the latest, is regarded as chronic pain (TRAUE a. KESSLER 1993).

Another definition assumes chronicity if pain lasts for three months after the start of the acute episode of pain. In the report of the *Quebec Task Force in Spinal Disorders* the term "subacute phase" is suggested. The duration of this phase may range from seven days after the onset of the episode of pain up to three months (BASLER 1994).

In 1986, The *International Association for the Study of Pain (IASP)* proposed a classification which took into account not only organic factors, but also psychological factors as being involved in the development of chronic pain. Using a multi-axial model, chronic back pain is described and classified according to site of pain, time characteristics, intensity, duration, and aetiology. (TRAUE & KESSLER 1993). The approach which the *Quebec Task Force in Spinal Disorders* and the *International Association for the Study of Pain (IASP)* have in common is that both refer to the dimension of time (BASLER 1994), with the *IASP* including the above-mentioned aspects in addition. According to HILDEBRANDT (1997), the basic concept of *"organic versus psychogenic"* pain should be changed from "*either – or"* to *"as well as"*, since physical, psychological, and social factors interact, especially during the pain chronification (sic) process. In this respect, valuable progress has been made in medicine. Knowledge regarding the role of psychological and social factors contributing to pain has become impressive. However, the results of psychosomatic pain research are often ignored, and the one-sided somatic perspective contributes to the process of chronification (sic) (HEGER 1999).

Chronification of back pain will occur when:

- Specific physical and/or psychological stress is present which impedes or prevents the adaptation of the person to the situation.
- Avoidance behaviour is tolerated or reinforced.
- Negative emotional response accompanies or follows an acute pain event (BASLER 1994).

Further signs of the chronification (sic) process include repeated visits to the doctor, repeated diagnostic procedures involving devices, and multiple unsuccessful treatment attempts (HILDEBRANDT 1997).

In summary, the dimensions of pain chronification (sic) are depicted in Table 1.

Table 1: Dimensions of pain chronification (sic) (BASLER 1994)

DIMENSIONS OF PAIN CHRONIFICATION (sic)

1. Duration of the condition

2. Number of treatment attempts
   - Number of doctors
   - Number of different therapies and surgical interventions
   - Number of rehabilitation measures

3. Psychological impairment
   - Depression
   - Anxiety
   - Helplessness
   - Loss of self-esteem

4. Social impairment
   - Changes in social roles
   - Social isolation

5. Impact on the professional situation
   - Days of absence
   - Loss of work place
   - Re-training
   - Retirement

2.4 CONSEQUENCES OF BACK PAIN AND FUNCTIONAL IMPAIRMENTS

As the result of a prolonged episode of lower back pain, as it is observed in patients with chronic back pain, there is a reduction in muscular strength. This is referred to as “deconditioning syndrome”. The starting point for this vicious circle is pain, to which the person affected responds by resting, thus reducing the physical stress associated with daily living. This in turn leads to a decline in active compensation mechanisms such as muscular strength and self-confidence, and, as a result, the person’s fitness level is reduced. The discrepancy between the current level of fitness and the requirements of daily living that has developed as a result may contribute to an increase in pain (MÜLLER 1998, 117-119).

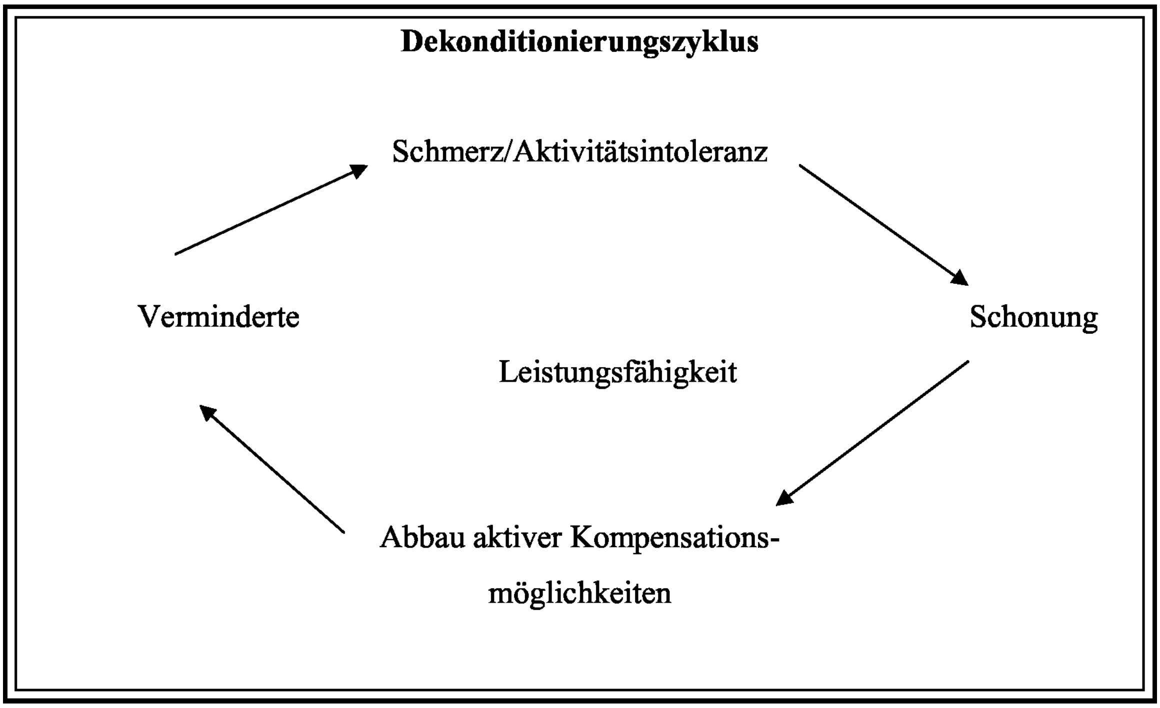

Figure 1: The deconditioning cycle (MÜLLER 1998, 119)

[Deconditioning cycle: Pain/intolerance to activity -> rest -> decline in active compensation mechanisms -> reduced fitness]

Further consequences of the adaptive posture include abnormal biomechanical stress and abnormal posture, changes of the postural motor system and muscular dysfunctions (SCHÜLE 2000, 272). Apart from avoiding physical activities, social activities and interactions are reduced as well. Especially in patients with chronic pain, negative emotions develop (BASLER 1994) leading to psychological and social impairments (social withdrawal, depression) (HEGER 1999). In the presence of long-lasting, recurrent pain, the following psychosomatic symptoms may develop: sleep disturbances, loss of appetite, reduction or loss of sexual needs, and general irritability. Some patients develop feelings of discontentment, emotional instability, increased irritability, reduced ability to show interest and to have experiences, all the way up to apathy, resignation and depression (HILDEBRANDT 1997). In the worst case, persistent unfitness for work may develop (BASLER 1994).

The chronification (sic) leads also to a significantly reduced quality of life, which in turn results in burdens on the health system (KINKEL & FROBÖSE 2000) which will be described in the next paragraph.

2.5 BACK PAIN-RELATED COSTS

The significant direct and indirect costs associated with back pain place a heavy economic burden on the national economy and the public health insurance system (BOLTEN, KEMPEL-WAIBEL, PFÖRRINGER 1998). Back pain accounts for five million hospital days, almost 80 million days of unfitness for work, and for each fifth case of premature retirement annually. There are 31 million back pain-related treatment cases annually, of which 87.5 percent are acute and 12.5 percent chronic-recurrent cases (PFÖRRINGER 1997). In 1994, the company Pharmametrics GmbH conducted the "Cost of Illness Study" (VAN DOORN 1998, 218; SEEBÖCK-FORSTER & FORSTER 1998) to assess the back pain-related use of resources and to calculate the resulting direct and indirect costs for our society (PFÖRRINGER 1997). The distribution of costs is provided in detail in Table 2.

Table 2: Total costs of back pain (BOLTEN, KEMPEL-WAIGEL, PFÖRRINGER 1998)

TOTAL COSTS OF BACK PAIN: ca. 34 billion DM	
	Direct costs: **10.2 billion DM** (VAN DOORN 1998, 219)
Medical costs	• 2.1– 2.9 billion DM for acute cases • 0,9– 1,1 billion DM for chronic cases
Medicine costs	• 360– 600 million DM for acute cases • 90– 125 million DM for chronic cases
Physical therapy	• 1.5 billion DM for acute cases • 0.2– 0.3 billion DM for chronic cases
Hospital stays and rehabilitation	• 2.1 billion DM for hospital treatment • 2 billion DM for rehabilitation
	Indirect costs: **23.8 billion DM** (VAN DOORN 1998, 219)
Costs for days of unfitness for work	• 70% of total costs • resulting from continued pay, replacement staff, loss of productivity

The average duration of back pain-related unfitness for work is 20 days, including both acute and chronic back pain. Every third day of unfitness for work is related to back pain.

The total back pain–related costs listed above do not include the costs associated with premature retirement. The financial burden on the statutory pension scheme is estimated to be approx. 1.8 billion DM (PFÖRRINGER 1997).

3. THE MASAI BAREFOOT TECHNOLOGY

3. THE MASAI BAREFOOT TECHNOLOGY (MBT)

> *"MBT is a new concept, a new approach and yet very old. Our instinctive knowledge of the right amount of movement has been lost. MBT returns a part of this originality to us. Step by step."*
> *(WESSINGHAGE: www.biodyn.net/referenzen/wessinghage.php 2002).*

MBT stands for "Masai Barefoot Technology". The name Masai was chosen in reference to the Masai people of Kenya, who are famous for their upright and natural gait. In addition, it is known that Masai do not experience pain of the joints and back (ROTH a. MÜLLER 2002, 1).

The aim of Masai Barefoot Technology is to make the walking surface appear uneven. A natural and uneven ground, such as sandy ground, creates an insecure and unstable body perception that demands a probing with the foot which keeps the step comparatively short, close to the centre of gravity of the body. Apart from forcing the muscles of the foot to adapt to this unevenness, the entire musculoskeletal system is involved: the body has to respond to the challenge (ROTH a. MÜLLER 2002, 5).

3.1 HISTORY OF MASAI BAREFOOT TECHNOLOGY

The basic idea of optimising human movement patterns and gait can be traced back for more than a decade. Based on his own health problems, such as Achilles tendon and back problems, Swiss engineer Karl Müller had the idea of making even ground uneven. During the twelve years he spent in Korea, he noted that the Korean workers had very little musculoskeletal problems, despite heavy work (GONSETH 2000). To find relief from his complaints Müller often went for a walk in the Korean paddy fields where he noticed that his pain was alleviated by walking on this uneven surface (ROTH a. MÜLLER 2002, 1). As his first model, he used the multi-layered straw shoe of a rice farmer. After returning to Switzerland in 1990, he developed the first prototype of the MBT shoe, which had a roller-like, curved sole (www.masai.ch/swissmasai/medien/bilder/3 satnano_0 1.2001 .jpg 2002). Müller conducted six years of research on himself, until the product was launched commercially in 1996. Currently, the MBT shoe is available in three models: sandals, MBT Sport and MBT Business shoes (GONSETH 2000).

3.2 PRINCIPLES AND CONCEPT OF MASAI BAREFOOT TECHNOLOGY

The concept of Masai Barefoot Technology implies a re-programming of the gait pattern by using MBT shoes (ROTH & MÜLLER 2002, 5). The characteristic feature of the MBT shoe is a roller-like curved sole which is unstable in all directions (GONSETH 2001).

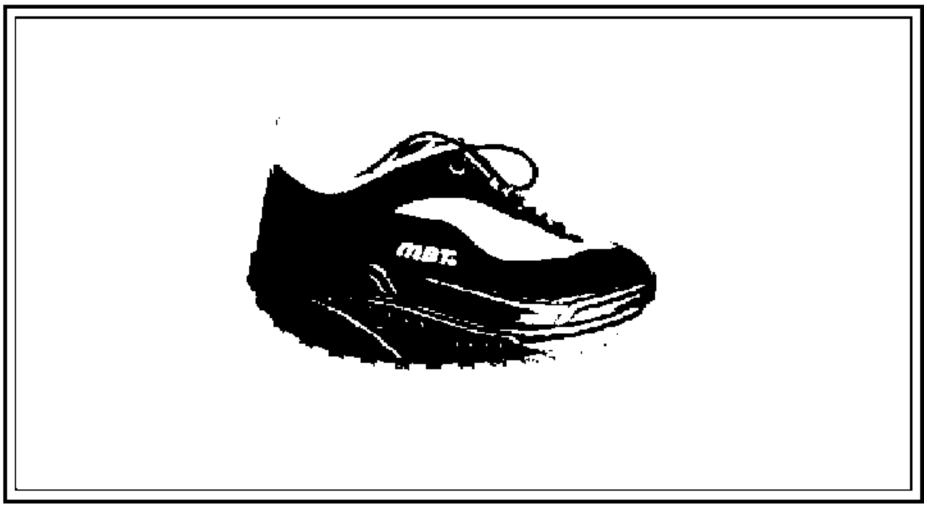

Figure 2: MBT shoe Sport (www.swissmasai.com 2002)

At the heel, there is a so-called *shock absorbing wedge (Anrollrampe)* so that the foot has to probe and rolling-off occurs from a negative position. This results in a pre-stretching of the muscles of the calf. This forced pre-tension of the muscle is intended to protect the vertebral discs and the joints against shocks (www.masai.ch2002). Due to the unstable sole of the MBT shoe, the walking surface appears uneven; this forces us to balance ourselves and walk upright. Balancing means muscle work instead of "falling into the joints". The muscles serve as shock absorbers for the joints, providing relief and relaxation for the musculoskeletal system. The MBT is rather an "*anti-shoe*" because it neither supports, guides nor absorbs shocks (ROTH & MÜLLER

2002). During walking, spiral movements of the foot occur, which extend upwards and result in a spiral motion in the pelvis and the spine (www.masai.ch 2002).

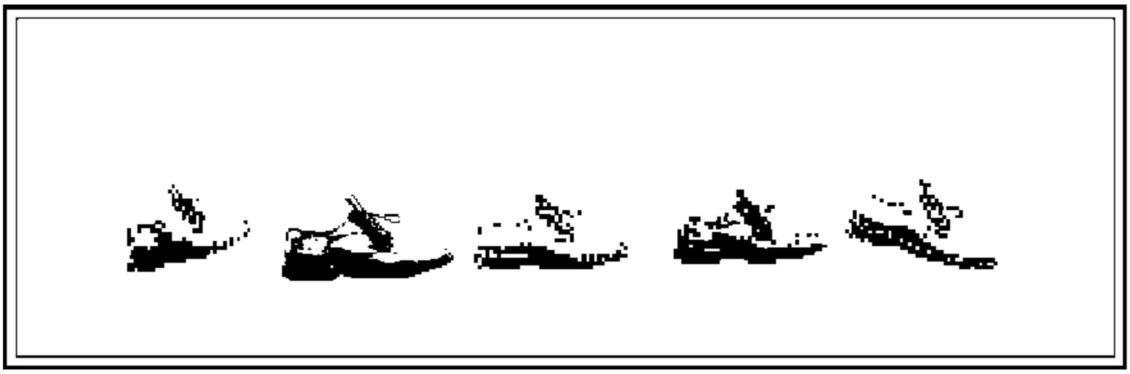

Figure 3: Sequence of passive gait (www.masai.ch 2002)

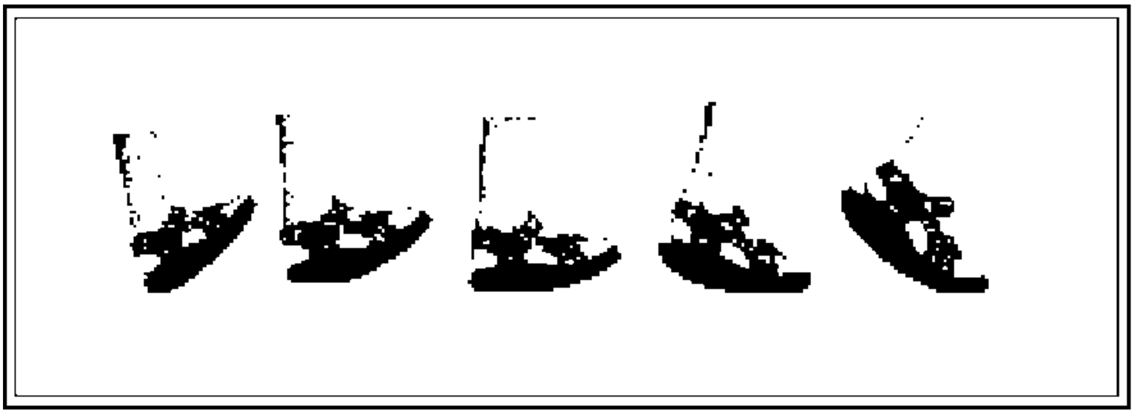

Figure 4: Sequence of MBT active gait (www.masai.ch 2002)

The hard, flat surfaces we walk on every day have led to a passive gait pattern. While walking, we allow ourselves to “fall” into the step, each time causing a shock on the body and the joints. The consequences of this passive gait are weak muscles, muscular tensions, abnormal posture and blockages. The MBT shoe is aimed at reprogramming this passive gait into an active one.

The mechanisms and effects of a flat walking surface are listed in Table 3 and are compared with the gait pattern on uneven walking surfaces (ROTH & MÜLLER 2002, 2-5).

Table 3: Flat walking surface and uneven walking surface and their effects (ROTH & MÜLLER 2002, 2-5)

FLAT WALKING SURFACE (ordinary shoe)	**UNEVEN WALKING SURFACE (MBT shoe)**
• Walking forwards, one is passively pushed into hyperlordosis, because the step touches the ground far ahead of the body's balance point.	• In active walking, the spine is brought into an upright, active posture via tension in the muscles of the tibia, buttocks, pelvic floor and abdomen.
• The result is a stem step, because the exceedingly wide steps far ahead of the body's balance point push against the walking direction. With every step there are short stopping movements and thus thousands of shocks into the whole body.	• With the shorter probing step, the step touches the ground rather below the body's balance point and better maintains the flow of the gait.
• From the passive gait a hyperactivity of the anterior thigh muscles and the hip flexor muscles results, as well as a shortening of these. The muscles of the buttocks and the pelvic floor are weakened. The resulting muscular dysbalances lead to an increased forward tilt of the pelvis.	• Uneven walking surfaces require changes in muscular tension in the entire muscular system. Balanced muscles that allow harmonic movements and prevent abnormal strain on spine and joints will develop.
• Pelvic movements are impeded. The two halves of the pelvis do not move against each other resulting in stiff pelvic mechanics and even longer steps.	• The pelvic movements are activated and the two halves of the pelvis can move against each other.
• The foot does not role off, but folds off because the foot and lower leg muscles remain passive in a well-supported shoe.	• The foot can roll off on uneven areas because the muscles of foot, tibia and calf are activated, e.g. walking barefoot in the sand.
• Tension in the muscles is no longer present and the shock-absorbing function of the muscles is impaired.	• Uneven walking surfaces entice balancing. Muscular tension is retained and the muscles serve as shock absorbers for spine and joints.
• The muscles are arranged in a spiral. The body twists while walking. This rotation cannot happen because of the "letting fall – not rolling off" of the feet, since the rotation already begins with pronation and supination in the ankle joint.	• The rotation can extend into the whole body, starting from the feet. As a counter swing to the body rotation, the reactive pendulum-like movements of the arms arise.
• Sensation of heaviness in the legs, varicosis and cold feet can be the result of a lack of activity of the calf muscle pump, which is not stimulated on an even ground.	• In response to the uneven ground, the calf muscle pump has to intervene and the venous blood is pumped upwards.

Thus, by using the Masai Barefoot Technology and the MBT shoe, a natural movement is provoked, which is characterized by active muscular support. The shock absorbing wedge leads to a different load pattern when the foot rolls off, and to a forced active stabilization of the dynamic equilibrium, which has an effect on the entire movement and, thus, exerts a positive influence on proprioception (BÄR 2001, 32).

The positive effects of the MBT shoe described above can be incorporated into therapeutic management, if used properly (BÄR 2001, 35). Here it has to be ensured that the MBT shoe is integrated into daily life as soon as possible (ROTH & MÜLLER 2002, 5).

3.3 DISTRIBUTION AND USE OF MASAI BAREFOOT TECHNOLOGY

The MBT shoe is suitable for any age within the range of 7 to 90 years. Masai Barefoot Technology is used in therapy, rehabilitation, prevention and sport (www.masai.ch/Prinzip/mehrinfo.shtml 2002). MBT is especially suitable for busy patients with little time, who are looking for an alternative therapeutic approach (ROTH & MÜLLER 2002, 22).

3.3.1 MASAI BAREFOOT TECHNOLOGY IN THERAPY

The MBT shoe is used as an aid to treatment to induce a re-programming of the gait pattern. During therapy, the shoe should be integrated into daily living as soon as possible and be worn frequently.

Possible indications are:

Achillodynia, calcaneodynia, forefoot problems, talipes planovalgus, circulation problems in the legs (PAOD), in-knee, out-knee, knee joint prosthesis, gonarthrosis, hip joint prosthesis, coxarthrosis, functional blockings in the iliosacral joint, low back pain, Bechterew’s disease, hypomobility and hypermobility of the lumbar spine, spondylolisthesis, muscular dysbalances of the upper/lower extremities and the trunk, juvenile kyphosis, cervical syndrome, migraine, Sudeck's disease, obesity and inflammatory rheumatic diseases (ROTH & MÜLLER 2002, 15).

To achieve a positive result with MBT shoes in therapy, clear instructions and support must be provided (ROTH & MÜLLER 2002, 13).

3.3.2 MASAI BAREFOOT TECHNOLOGY IN REHABILITATION

Physiotherapists use the MBT shoe in post-trauma rehabilitation and postoperatively after foot, knee, hip and back interventions (www.masai.ch/Prinzip/mehrinfo.shtml 2002). In muscle, tendon, ligament and joint injuries, the MBT shoe can be used after the inflammatory phase and will then support regeneration. Initially, teetering and balancing are practised, followed by practise in slow walking. At the end of the proliferation phase (after two to three weeks), the MBT should be integrated into daily life (ROTH & MÜLLER 2002, 20).

Using the MBT shoe after injuries and operations leads to rapid and sustained improvement in the ability to stretch and in mobility, circulation, coordination and strength (www.masai.ch/anwendungen/Alltag/ alltag.shtml 2002).

3.3.3 MASAI BAREFOOT TECHNOLOGY IN PREVENTION

MBT can be used in both primary prevention and secondary prevention. The problem is that most people do not take preventive action and only change their habits after having developed symptoms (www.masai.ch/Referenzen/Mber/pages/ffl.htm 2002).

As a preventative measure, the MBT shoe can be integrated into day-to-day activities in certain occupations – e.g. doctors, therapists, hospital personnel and nurses, and in other professional fields characterized by predominately sitting or standing activities (www.masai.ch/ anwendungen/Alltag/arbeitsschuh.shtml 2002). Furthermore, walking in the MBT shoe activates the muscle pump and thus increases venous return. This can be regarded as a secondary prevention measure in diseases such as peripheral arterial occlusive disease (PAOD) and diabetes mellitus. In cases of advanced diabetes mellitus, stage III disease with insensitivity of the feet is a contraindication against wearing MBT shoes (MÜLLER & ROTH 2002, 21).

3.3.4 THE MASAI BAREFOOT TECHNOLOGY (MBT) IN SPORT

MBT shoes can be used in both competitive sports and in mass/leisure sports. The MBT ensures optimum muscle training, rapid recovery and optimization of running style (ROTH & MÜLLER 2002, 27).

Many athletes use a technique called “rolling trot” (like jogging barefoot on sand) for warming-up, for speed and jump training, as well as for cooling-down (www.masai.ch/Prinzip/mehrinfo.shtml; www.masai.ch/anwendungen/Fitness/Fitness.shtml 2002).
Improved coordination of the muscles is ensured, which in turn is believed to minimize the risk of injury (www.masai.ch/ anwendungen/Fitness/Fitness.shtml 2002). Using the MBT shoe, endurance can be improved by walking or rolling trotting (www.masai.ch/anwendungen/Sport/joggen. shtml 2002).

3.4 STUDIES AND INVESTIGATIONS OF MASAI BAREFOOT TECHNOLOGY

The existing studies on Masai Barefoot Technology comprise a Japanese study, a gait analysis and a paramedical study. In addition, there are many reports on user experiences available, regarding various indications.

3.4.1 JAPANESE STUDY

The effects of the MBT shoe, which was still called “Step” (“Schritt”) at the time, were assessed by Dr Matsura of the Orthopaedic Surgery Hospital of Matsura in collaboration with Assistant Professor Tutsi of the Department of Science of Sports of the University of Okayama. Over a period of two months, the muscles and tendons of 13 healthy and ill subjects were studied using CT scans. Changes in cross-sectional areas of muscles and tendons were measured and the following results were obtained:
Table 4 lists the names of the muscles studied and the percentage of respective area increase:

Table 4: Results for 'muscle area increase' of the Japanese study (www.biodyn.net/referenzen/jap_studie.php, 2002)

MUSCLE	AREA INCREASE
M. longissimus	18%
M. iliacus	22%
M. quadratus lumborum	22%
M. psoas minor	16%
M. rectus abdominis	30%
M. teres major	10%
M. quadratus internus	26%
M. obturatorius	29%
M. tensor fasciae latae	44%
M. iliopsoas	48%
M. pectineus	41%
M. biceps femoris	17%
M. semimembranosus	24%
M. rectus femoris	16%
M. vastus intermedius	28%
M. vastus lateralis	10%
M. vastus medialis	10%
M. obliqus externus	9%
M. obliqus internus	12%
M. peroneus longus et brevis	27%
M. flexor digitorum longus et brevis	19%
M. tibialis anterior	12%
M. tibialis posterior	26%
M. flexor hallucis longus	15%
Achilles tendon	- 6%

According to this data, the studied muscles showed an increase in the cross-sectional areas, in contrast to the Achilles tendon, which always became smaller.

The shoe is recommended by Dr Matsura and Mr Tutsi for the prevention and therapy of knee and back problems (www.biodyn.net/ referenzen/jap_studie.php 2002).

3.4.2 GAIT ANALYSIS STUDY

The gait analysis study, which was headed by Prof Dr Jürgen Baumann, was performed at the Laboratory for Movement Assessment, Basel, Switzerland. In this study, walking barefoot was compared with walking in the MBT shoe regarding the quality of gait, use of swing, eccentric shock absorption, roll-off behaviour as well as kinematics and kinetics. Regarding gait quality, it was found that the average walking speed with the MBT shoe (5.16 ± 0.34 km/h) exactly matched the value for walking in normal shoes. Walking barefoot is slightly slower, with an average speed of 4.8 km/h. The balance between kinetic and potential energy – ideal would be a 50:50 ratio – is better maintained with the MBT shoe; this may indicate an improvement in intermuscular coordination. The use of swing of approx. 64 percent while walking in the MBT shoe – which is almost identical with walking barefoot – is superior compared to walking with normal shoes (58%). Regarding the eccentric shock absorption, it was found that the total measured eccentric activity associated with walking in MBT shoes is significant. Ankle joints and their muscles are especially involved as a result. Thus, the active functional range of movement is markedly higher compared to average walking. Walking in MBT shoes results in an improved stabilisation of the pelvis because the front tilt and back tilt of the pelvis is only about half of that of walking barefoot. In addition, a lower amplitude of the rotational movements is found in the knee joint (BÄR 2001, 37-42).

3.4.3 PARAMED STUDY

In July 2001, an investigation using the pressure distribution measuring system Parotec was conducted in Berlin, Germany. In this study, the pressure distribution on the sole of the foot was compared for walking barefoot and in MBT sandals, using static and dynamic recording, and recording during the step phases of the foot. It was discovered that the pressure distribution on the sole is much more uniform in the MBT shoe, compared to barefoot walking. The load on the heel is markedly lower and the balance point is more to the front.

When the measurements were made, the subject studied had already been walking in MBT shoes for nine months; therefore, it can be assumed that the differences in pressure distribution on the sole of the foot are even more pronounced in beginners (www.masai.ch/Referenzen/ Wissenschaft/paramed/s0_300.jpg 2002).

3.4.4 REPORTS OF USERS

On the basis of a survey of individual patients wearing the MBT shoe, many reports on experiences made by users are now available. In the survey, the patients were asked to state as to how many months they had been wearing the MBT shoe, for how many hours daily or weekly, and if the Masai Barefoot Technology had helped them with their problems. Positive feedback was obtained for the following indications: back pain, problems with the Achilles tendon and the ankle joint, arthrosis, knee, hip and venous problems. In addition, wearing the MBT shoes during pregnancy was perceived as positive (www.biodyn.net/daten/kundenstatistik.pdf 2002).

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4. METHODOLOGY

The fourth chapter describes, apart from the hypotheses, the conduct of the investigation, beginning with subject recruiting, how the MBT shoes were received, the course of the investigation, ending with comments on the tests used, and their conduct. Finally, information on the statistical analysis will be provided.

4.1 HYPOTHESES

Based on the question whether the Masai Barefoot Technology, or rather the wearing of the MBT shoe, has an impact on quality of life and the functional capacity of patients with chronic back pain, the following hypotheses were developed:

Hypothesis 1:
“Because of the daily training – walking in the MBT shoe – in addition to exercise sessions indoors and in the water, the functional capacity and quality of life of patients with chronic back pain, aged from 54 to 71 years, improves.”

Hypothesis 2:
“The intervention group will be compared with a control group consisting of patients with chronic back pain aged 54 to 71 years, who only attend exercise sessions indoors and in the water. In comparison with the intervention group, the functional capacity and quality of life of patients does not change.”

For a better understanding of the parameters Functional Capacity and Quality of Life, these are described as follows:
Functional Capacity refers to the functional capability to perform activities of daily life. It is evaluated and measured whether the patient can perform certain activities involved in daily living. The questionnaire used in this study, the *Funktionsfragebogen Hannover Rücken (FFbH-R, functional questionnaire Hanover back)*, is a questionnaire especially designed for subjects with functional impairments due to back pain.

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Quality of Life is measured using the *SF-36 health survey*. For this parameter, a multi-faceted definition is indicated, as the subjective quality of life is referred to as a multidimensional construct …

> *"…which comprises emotional, mental, social and behavioural components of well-being and function as perceived by the patients (and/or observers). Here it is important that the phenomenon (construct) Quality of Life can be measured via several dimensions (i.e. it is operationalizable) which are in the experience (well-being) and behaviour (functional capability) of the surveyed subject and that only he or she can provide information on it as an expert". (BULLINGER 2002)*

The health-related quality of life thus consists of several aspects, in which the functional capability, which is also measured as functional capacity in the functional questionnaire (Hannover Rücken) described above, holds one of the two important positions.

4.2 SUBJECT RECRUITMENT

To find enough participants for the study, an information leaflet was mailed in cooperation with the health sports and sports therapy association *Verein für Gesundheitssport und Sporttherapie Köln (VGS Köln)* to the members of the association, especially to spine, osteoarthritis and aqua jogging groups (see appendix). This leaflet was also handed out in some courses of the adult education institution Volkshochschule Brühl.

A total of 24 subjects, aged 54-71 years, who suffered from chronic back pain, were enrolled in the study. As the first step, a subject form with personal data, a brief medical history regarding back pain and the type of sport engaged in.

4.3 MBT SHOES

The MBT shoes were provided free-of-charge for the duration of the study by Masai GmbH. At the end of the study, an opportunity to buy the shoe at a reduced price was offered.

4.4 COURSE OF THE INVESTIGATION

The study was carried out over a period of two months. The participants in the intervention group received, in addition to their normal exercise programme, one extra training session per week, while the participants in the control group did not.

The subjects in the control group, who only had to complete the two questionnaires, received these for the pre-survey and the post-survey during their normal exercise sessions and completed the questionnaires at home.

In the first additional training session, the subjects in the intervention group received detailed information on the Masai Barefoot Technology, the study procedures and the content of the next training sessions. They received a training diary to record their training units other than the additional exercise sessions. The subjects also completed the FFbH-R and the SF-36 questionnaire before they started their first attempts to walk in the MBT shoes.

To present the contents of the training sessions in an interesting and diversified manner, several focus points were integrated into each session. Initially, the focus was on learning the proper gait technique/gait pattern in MBT shoes. This was picked up in each session and extended and deepened with various exercises. The gait pattern was mainly checked by the investigator, but also by the patients amongst each other. Another focus during the training sessions was on the perception of gait pattern and posture with and without MBT shoes to clearly show the differences, and to point out the connection between their gait pattern and posture, and their back. Here the function of the spine and of the adjacent muscles was jointly exposed. The last focus of the sessions was the training of endurance to enable prolonged walking and trotting in MBT shoes. This focus was integrated as the last two training sessions were held outside the hall. Here suggestions were made on how to use the MBT shoe for walking and trotting outdoors. During the last training session, the questionnaires (FFbH-R, SF-36) were completed for a second time and the completed training dairies were handed in.

In addition, the participants were offered the opportunity to talk about and discuss their experiences. A detailed overview of the contents of the individual sessions is provided in the progress plans in the appendix of this study.
In the intervals between the additional training sessions, the subjects carried out walking units in the MBT shoe independently. Participants were advised to wear the MBT shoe only as long as they felt good, and experienced no pain or tired muscles, in order to slowly increase the wearing periods and to integrate the MBT shoe into everyday life.

4.5 TESTS

To assess the functional capacity while performing day-to-day activities and to evaluate the health status and possible changes, the functional questionnaire Hannover Rücken (Hanover Back, FFbH-R) and the SF-36 Health Survey were used.

4.5.1 THE FUNCTIONAL QUESTIONAIRE HANOVER BACK (FFBH-R)

The questionnaire Funktionsfragebogen Hannover Rücken (FFbH-R) is a short questionnaire with twelve questions for self-assessment which was used to assess the subjective functional capacity with respect to activities of daily living. Besides the FFbH-R, there is the FFbH-P for patients with polyarticular joint diseases, a combined version of the questionnaires (FFbH-P+R), and a questionnaire for osteoarthritis patients (KOHLMANN & RASPE 1996).
The FFbH-R is used for surveying patients with back pain and the answers refer to the situation over a period of the preceding seven days. It is used in population-based epidemiological studies and in routine documentation, as well as for screening purposes. The questionnaire is also well suited for follow-up testing (KOHLMANN & RASPE 1996) and was used in this way in the present study. Data shows that the FFbH-R, which was developed in 1989, is a reliable, valid and change-sensitive instrument (KOHLMANN & RASPE 1996).

To evaluate the FFbH-R scores, average scores with a “known” level of disability are used:
FFbH-R scores of 100% down to approx. 80% correspond with “normal” functional capacity. Scores around 70% indicate a moderate impairment and scores below 60% a (clinically) relevant functional impairment. As a classification criterion, an FFbH-R score of 70% proved to be sensible (KOHLMANN & RASPE 1996).

4.5.2 THE SF-36 HEALTH SURVEY

The SF-36 is an abbreviated version of a comprehensive measuring instrument which was developed in the medical outcomes studies (MOS). It is based on over 30 years of developmental efforts and it was recently acknowledged as a standard instrument for the assessment of subjective health. The use of the SF-36 has been recommended by international licensing authorities; this questionnaire represents, from the user’s perspective, a self-reported health-related quality-of-life report.
The questionnaire is divided into 36 items, which are assigned to various dimensions. There are two versions of the SF-36 available. There is the standard version (time window four weeks) and the acute version (time window one week), which differ from each other regarding the time frame. Using the 36 items, all aspects of subjective health are covered. Possible responses ranged from simple (yes/no) answers to answers with six choices (e.g. always, most of the time, rather often, occasionally, rarely, never). The various dimensions (see also Table 5) include physical functional capability, physical role function, bodily pain, general status of health perception, vitality, social function, emotional role function and psychological well-being. On this basis, the bodily and psychological sum scales can be calculated (BULLINGER & KIRCHBERGER 1998, 8-12).

Table 5: Number of items and content SF-36 scales (BULLINGER & KIRCHBERGER 1998, 12)

Sub-sum scales	Item number	Content
Physical functional capability	10	Extent to which the health status affects physical activities, such as self-sufficiency, walking, climbing stairs, bending, lifting and moderate or strenuous activities
Physical role function	4	Extent to which the health status affects working or other activities of daily living, e.g. getting less done than usual, restrictions in the type of activities or difficulties in performing certain activities
Bodily pain	2	Extent of pain and impact of pain on normal work, both at home and outside
General health	5	Personal evaluation of health, including present health status, future expectations and resistances against diseases and their consequences
Vitality	4	To feel energetic versus to feel tired and exhausted
Social function	2	Extent to which physical health or emotional problems affect normal social activities
Emotional role function	3	Extent to which emotional problems affect working or other day-to-day activities, including reduced time made available, reduced performance and working less carefully than usual
Psychological well-being	5	General mental health, including depression, anxiety, emotional and behavioural control, general positive mood
Changes of health status	1	Evaluation of current health status compared with the previous year

There is a wide range of applications for the SF-36. It can be used in healthy individuals aged 14 up to a very old age, as well as in diseased populations of various disease groups (BULLINGER & KIRCHBERGER 1998, 10).
Apart from the US normal data, a standardization of the SF-36 for Germany was carried out in 1994. Data was obtained from a representative population sample (BULLINGER & KIRCHBERGER 1998, 40).

4.6 TRAINING DIARY

To verify regular walking with the MBT shoe, a training diary was handed out to 16 subjects. Each training unit was recorded regarding duration, activity (standing, walking, sitting), waking sensation and pain.

4.7 TEST PROCEDURE

The participants of the intervention group completed the SF-36 questionnaire and the functional questionnaire Hanover Back for the first time during the first training session. In addition, the participants of the control group received the questionnaires in their normal exercise session.
After eight weeks, all subjects, both of the intervention group and the control group, completed both questionnaires for the second time.
The subjects of the intervention group recorded, in addition, each training unit performed in the MBT shoe in the training diary.

4.8 STATISTISTICAL METHODOLOGY

The SF-36 health survey was calculated and analyzed with a computerized analysis programme and the statistical test package SPSS Version 11. Here the summing-up of the scales as well as their addition or weighting was established. Furthermore, all scales covered in the SF-36 were transformed into values between 0 und 100, so that a comparison of the scales amongst each other or across different patient groups became possible (BULLINGER & KIRCHBERGER 1998, 9).

Further statistical data collection – calculation of normal distribution, descriptive statistics, means, variance analysis and changes of the means (t test) – were performed for the SF-36 as well as the FFbH-R with the statistical test package SPSS Version 11. The levels of significance were classified as follows:

$p > 0.05$	= not significant	- ns
$p \leq 0.05$	= significant	- *
$p \leq 0,01$	= highly significant	- **
$p \leq 0,001$	= most significant	- ***

(from: BÜHL & ZÖFEL 2000, 100)

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5. RESULTS

In the following chapters 5.1, 5.2, 5.3 and 5.4 the personal data, the results of the FFbH-R questionnaire, of the SF-36 health survey questionnaire and diary are shown.

5.1 PERSONAL DATA

From the total of 24 participants (15 female, 9 male) of the study, 16 subjects (10 female, 6 male) aged between 54 and 71 years were included in the intervention group and a further 8 subjects (5 female and 3 male) aged between 55 and 70 years were included in the control group. The subjects volunteered to participate in the intervention or the control group. They all shared the same characteristics; thus the composition of both groups was identical.

All 16 subjects of the intervention group were suffering for more than six months from back pain, whereby 23.8% complained about symptoms in the region of the cervical spine, 4.8% in the region of the thoracic spine and 71.4% in the region of the lumbar spine. Frequently pain in the region of the cervical and the lumbar spine was reported; this was accounted for in percentage values. In the control group as well, all eight participants had been suffering from back pain for more than six months. Five participants indicated the site of pain, of which 20% complained about symptoms in the cervical spine and 80% in the lumbar spine. Eleven subjects of the intervention group and five of the control group were under medical care because of back pain, all other participants were not.

In the intervention groups the daily activities were as follows: 34.8% sedentary activity, 47.8% standing activity and 17.4% physically strenuous activities. On the other hand, there was 50% sedentary activity, 30% standing activity and 20% physical strenuous activities in the control group.

Almost all subjects of the intervention group felt affected by pain in everyday life (94.1%), while in the control group 87.5% felt affected.
Twelve participants of the intervention group took part in the following courses from the VGS Köln: back exercises (4), arthrosis exercises (3), aqua jogging (5), water gymnastics (4), senior citizen exercises (1) and walking (4). Some subjects took part in more than one course per week. Three subjects attended a posture exercise course at the Volkshochschule Brühl (adult education). One person had physiotherapy.
In the control group, six subjects were participating in the back exercise course, the two other persons trained on exercise devices. As leisure activities, further sports activities like swimming, cycling, hiking and jogging were undertaken in both groups to the same extent.

5.2 RESULTS OF THE FFBH-R

In the following chapter the results of the functional questionnaire Hanover back (Funktionsfragebogen Hannover Rücken, FFbH-R) with regard to the pre- and post-survey will be provided. In addition, the results of the intervention group and the control group were compared.
Initially, the samples of the intervention and the control group were analyzed for normal distribution, using the Kolmogorov-Smirnov test. A normal distribution is present in all samples. Hereafter, a descriptive statistic with the calculation of the arithmetic mean, the standard deviation and the maximum/minimum value was carried out.
Using the t test for paired samples, a comparison of means of the pre- and post-survey was performed. Initially, the two groups (intervention and control group) were studied separately.
Finally, a variance analysis for mixed designs was performed to investigate all effects and interactions, which were related to the repeat testing (pre/post survey) design.
In Table 6, mean, standard deviation, minimum and maximum of the pre- and post-survey of the intervention group are shown. The mean of the post-survey (80.2) is higher than the mean of the pre-survey (73.94).

Comparing the means of the pre- and post-survey using a t test for two dependent samples, a *highly significant* (p = 0.003) difference is found.

Table 6: Means functional capacity IG

	Pre-survey	Post-survey
n	16	16
x	73.94	80.2
SD	14.46	14.55
Min/Max	45.83/100	50/100
T test **p**	0.003	
SL	**	

n – size sub-sample; x – mean; SD – standard deviation; Min – minimum; Max – maximum; p – probability of error; SL – level of significance; ** – highly significant

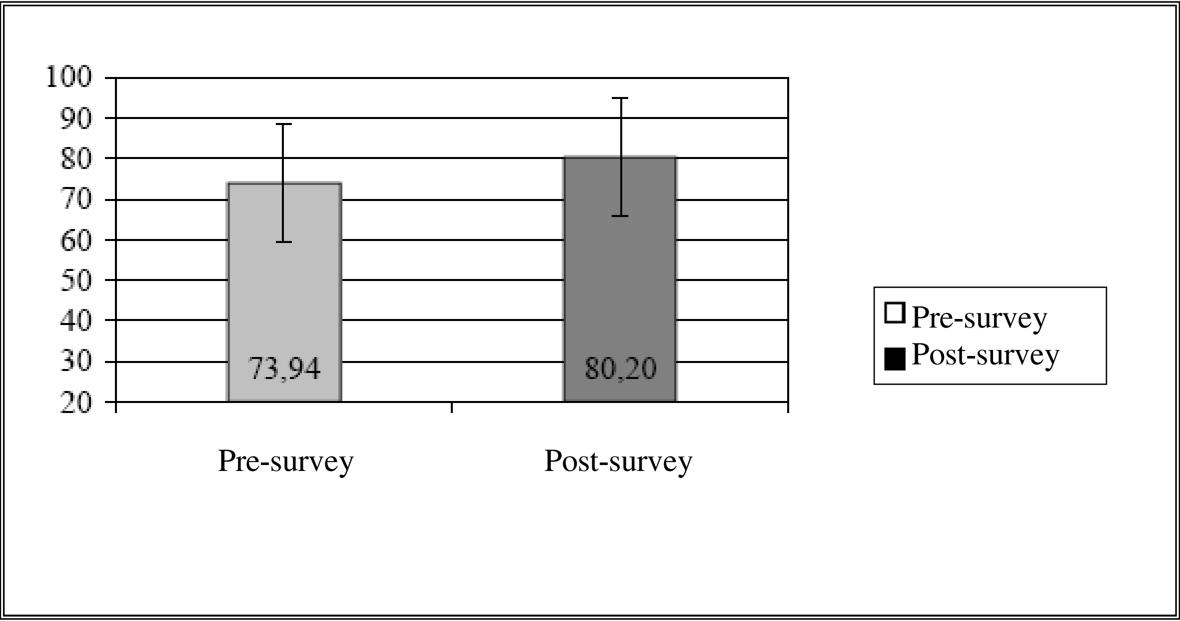


Figure 5: Means functional capacity IG

Table 7 shows the comparison of the means, standard deviation, maximum and minimum of the control group. The t test for two dependent samples shows no significant difference (p = 0.663).

Table 7: Mean functional capacity CG

		Pre-survey	Post-survey
N		8	8
X		81.14	79.16
SD		14.49	18.5
Min/Max		62.5/100	45.83/100
T test	**p**	0.663	
	SL	ns	

n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum; p – probability of error; SL – level of significance; ns – not significant

Table 8 summarises the comparison of the means, standard deviation, minimum and maximum of the pre- and post-survey of the intervention and the control group.

Table 8: Mean functional capacity IG and CG

		Pre-survey	Post-survey
FFbH-R IG	**n**	16	16
	x	73.94	80.2
	SD	14.46	14.55
	Min/Max	45.83/100	50/100
FFbH-R GK	**n**	8	8
	x	81.14	79.16
	SD	14.49	18.5
	Min/Max	62.5/100	45.83/100
Variance analysis	**p**	0.047	
Pre-/post-*group	**SL**	*	

IG – intervention group; CG – control group; n – size sub-sample;
x – mean; SD – standard deviation; Min – minimum; Max – maximum;
p – probability of error; SL – level of significance; – * significant

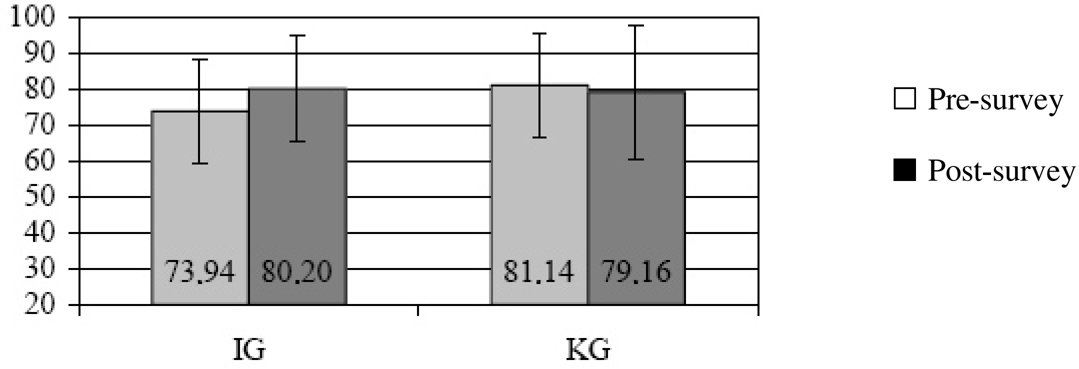


Figure 6: Mean functional capacity IG and CG

As shown in Table 8 and clarified in Figure 6, there is a difference in the change from the pre- to the post-survey in the intervention group. The mean of the control group is even slightly reduced in the post survey. From the variance analysis it can be seen that the study population (intervention and control group) shows homogeneity in the pre-survey, yet shows a significant difference ($p = 0.047$) between the groups in the post-survey group.

5.3 RESULTS OF THE SF-36 HEALTH SURVEY

Likewise, the samples of the intervention and the control group of the SF-36 health survey were analyzed for normal distribution using the Kolmogorov-Smirnov test. A normal distribution was present in all samples. Hereafter, a descriptive statistic with a calculation of the arithmetic mean, the standard deviation and the maximum/minimum value was carried out.

Using the t test for paired samples, a comparison of means of the pre- and post-survey was performed. Here again the two groups (intervention and control group) were initially studied separately.

Finally, a variance analysis for mixed designs was performed to investigate all effects and interactions, which were related to the repeat testing (pre/post survey) design.

Firstly, the results of the intervention group and then those of the control group will be presented.

The calculation of the sum scales and sub-sum scales was based on 16 subjects of the intervention group and 8 subjects of the control group.

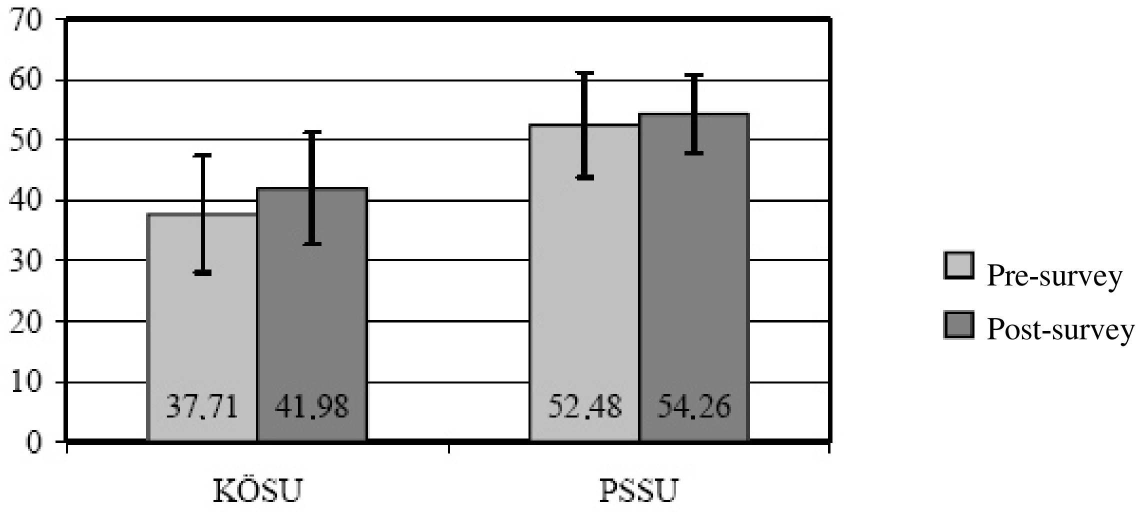
Tables 9 and 10 as well as figures 7 and 8 show the results of the sum scales of the pre- and post-survey of the intervention and the control group.

Table 9: Mean sum scales IG

		KÖSU	PSSU
Pre-survey	**n**	16	16
	x	37.71	52.48
	SD	9.71	8.66
	Min/Max	22.7/53.46	34.10/61.57
Post-survey	**n**	16	16
	x	41.98	54.26
	SD	9.26	6.52
	Min/Max	26.62/55.2	36.89/63.22
T-Test	**p**	0.009	0.4 11
	SL	**	ns

KÖSU – physical sum scale; PSSU – psychological sum scale;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum; p – probability of error; SL –level of significance;
ns - not significant; ** - highly significant

Figure 7: Mean sum scales of the pre / post survey IG



The arithmetic mean of the physical sum scale of 37.71 ± 9.71 of the pre-survey of the intervention group is contrasted by a mean of 41.98 ± 9.26 of the post-survey. Comparing the means (t test in two dependant samples), a *highly significant* (p = 0.009) difference is found.

Comparing the psychological sum scale (pre-survey: 52.48 ± 8.66; post-survey: 54.26 ± 6.52), *not significant* (p = 0.411) difference is found.

In the control group, means of the physical sum scale of 42.07 (pre-survey) and of 43.04 (post-survey) were calculated; the means of the psychological sum scale were 45.4 (pre-survey) and 51.67 (post-survey). The t test showed significant differences neither for the physical nor for the psychological sum scale.

Table 10: Mean sum scales CG

		KÖSU	PSSU
Pre-survey	**n**	8	8
	x	42.07	45.4
	SD	11.96	11.81
	Min/Max	25.66/55.14	28.49/61.77
Post-survey	**n**	8	8
	x	43.04	51.67
	SD	9.85	7.17
	Min/Max	24.23/53.55	35.74/59.03
T test	**p**	0.807	0.139
	SL	ns	ns

KÖSU – physical sum scale; PSSU – psychological sum scale;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum; p – probability of error; SL – level of significance

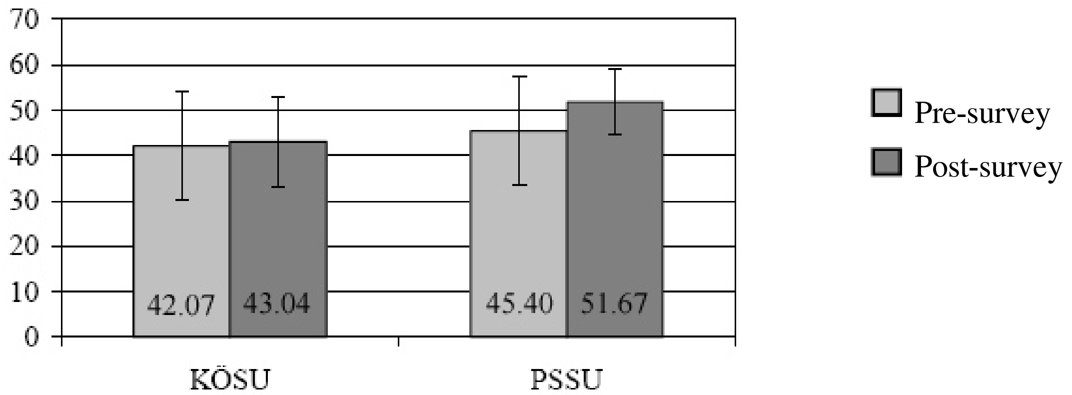


Figure 8: Mean sum scales of the pre/post survey CG

Table 11 summarises the means of the physical and psychological sum scale of pre- and post-survey of the intervention and the control group.

Table 11: Means sum scales IG and CG

		Pre-survey		Post-survey	
		KÖSU	**PSSU**	**KÖSU**	**PSSU**
IG	**n**	16	16	16	16
	x	37.71	52.48	41.98	54.26
	SD	9.71	8.66	9.26	6.52
	Min/Max	22.7/53.46	34.10/61.57	26.62/55.2	36.89/63.22
KG	**n**	8	8	8	8
	x	42.07	45.4	43.04	51.67
	SD	11.96	11.81	9.85	7.17
	Min/Max	25.66/55.14	28.49/61.77	24.23/53.55	35.74/59.03
Variance-analyse	**p**	KÖSU: p = 0.336 – PSSU: p = 0.267			
Pre-Post* group	**SL**	Ns			

KÖSU – physical sum scale; PSSU – psychological sum scale;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum; p – probability of error; SL – level of significance; ns – not significant

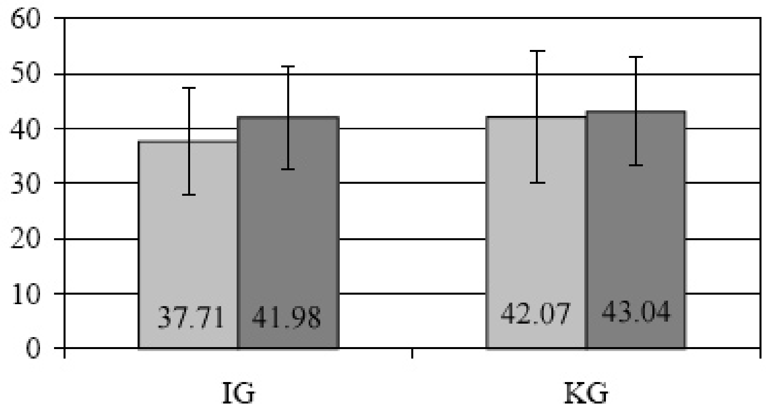


Figure 9: Mean physical sum scale pre-/post-survey of the IG and CG

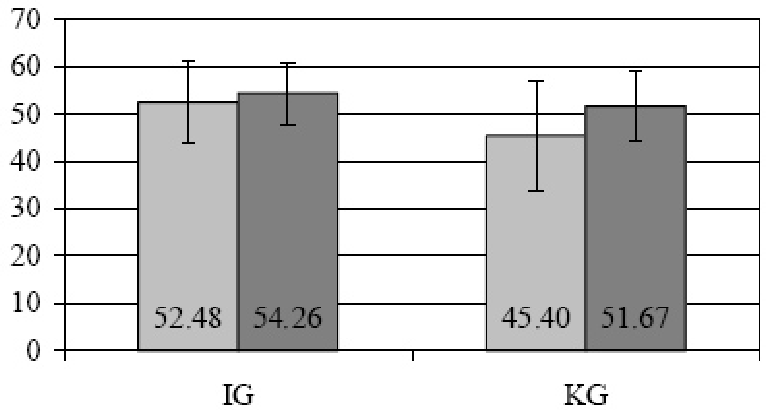


Figure 10: Mean psychological sum scale pre-/post-survey of the IG and CG

The variance analysis of the physical sum scale shows that in the pre-survey both groups have an identical baseline level. Both the intervention and control groups are homogeneous. There are no changes in the post-survey. Both groups are homogeneous ($p = 0.336$). Similar results are obtained with the variance analysis of the psychological sum scale. Both groups are homogeneous in the pre- and post-survey ($p = 0.267$).

The results of the individual sub-sum scales of the pre- and post-survey of the intervention group are demonstrated in Table 12.

Table 12: Mean sub-sum scales IG

		KÖFU	KÖRO	SCHM	AGES	VITA	SOFU	EMRO	PSYC
Pre-survey	**n**	16	16	16	16	16	16	16	16
	x	63.75	48.44	45.19	59.81	52.81	86.72	75	72
	SD	21.95	45.16	20.31	17.06	15.05	16.75	41.27	14.01
	Min/Max	20/95	0/100	22/100	20/82	25/85	50/100	0/100	48/96
Post-survey	**n**	16	16	16	16	16	16	16	16
	x	73.44	65.62	56.87	62.06	57.19	92.19	91.67	74
	SD	17.67	39.66	21.32	15.49	16.33	10.08	25.92	13.31
	Min/Max	50/100	0/100	41/100	30/87	25/85	75/100	0/100	44/96
T-Test	**p**	0.005	0.135	0.001	0.551	0.13	0.263	0.15	0.574
	SL	**	ns	***	ns	ns	ns	ns	ns

KÖFU – physical functional capacity; KÖRO – physical role function;
SCHM – bodily pain; AGES – general health perception;
VITA – vitality; SOFU – social function; EMRO – emotional role function;
PSYC – psychological well-being;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum; p – probability of error; SL – level of significance;
ns – not significant; ** – highly significant; ** – most significant

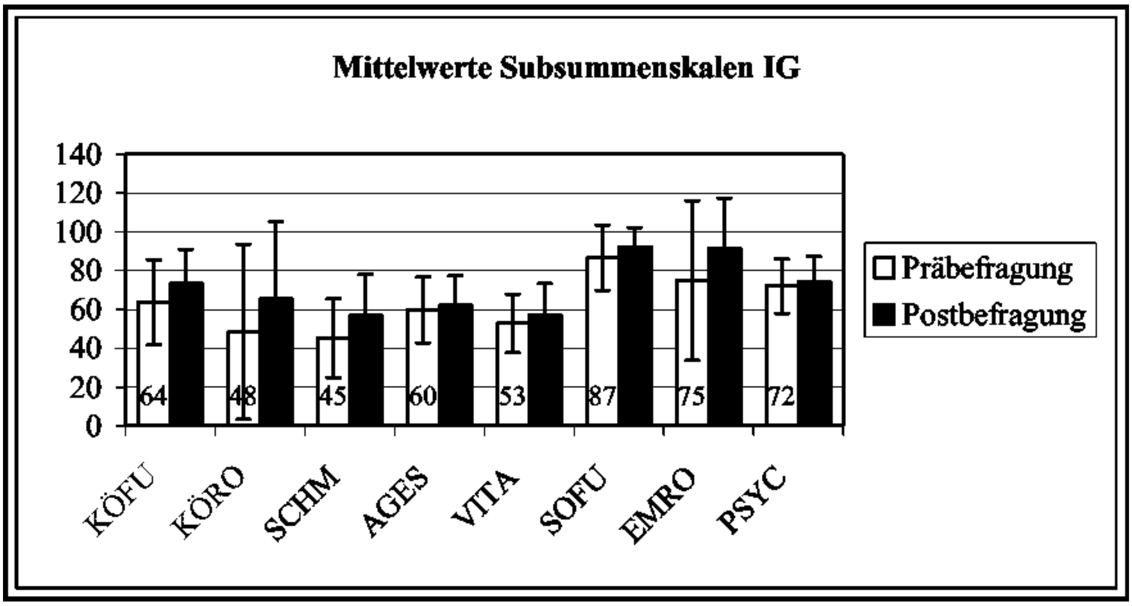


Figure 11: Mean sub-sum scales of the pre-/post-survey of the IG

For physical functional capability, a mean of 63.75 ± 21.95 (pre-survey) was found, in contrast to a mean of 73.44 ± 17.67 (post-survey). A comparison of means shows a *highly significant difference* (p = 0.005). A *most significant* difference (p = 0.001) was demonstrated in the sub-sum scale of physical pain (x = 45.19 ± 20.31 pre-survey; x = 56.87 ± 21.32 post-survey). In the other sub-sum scales no *significant* difference was found using the t test.

The same comparison was performed in the control group. The t test showed a *significant* difference (p = 0.048) for the psychological sub-sum scale. There was no *significant* difference for the other seven sub-sum scales of the pre- and post-survey.

Table 13: Means sub-sum scales CG

		KÖFU	KÖRO	SCHM	AGES	VITA	SOFU	EMRO	PSYC
Pre-survey	**n**	8	8	8	8	8	8	8	8
	x	69.37	53.12	52.37	57.75	52.5	75	54.17	65
	SD	21.29	47.13	19.23	18.87	12.53	21.13	46.93	14.62
	Min/Max	35/100	0/100	22/74	32/87	30/70	37/100	0/100	40/80
Post-survey	**n**	8	8	8	8	8	8	8	8
	x	71.87	75	58.75	59	56.25	82.81	83.33	74
	SD	21.87	46.29	21.68	21.47	15.98	16.28	35.63	16
	Min/Max	45/95	0/100	22/84	25/92	30/70	62/1 00	0/100	48/92
T test	**p**	0.722	0.371	0.152	0.827	0.522	0.217	0.111	0.048
	SL	Ns	ns	ns	ns	ns	ns	ns	*

KÖFU – physical functional capacity; KÖRO – physical role function;
SCHM – bodily pain; AGES – general health perception;
VITA – vitality; SOFU – social function; EMRO – emotional role function;
PSYC – psychological well-being;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum; p – probability of error; SL – level of significance;
ns – not significant; * – significant

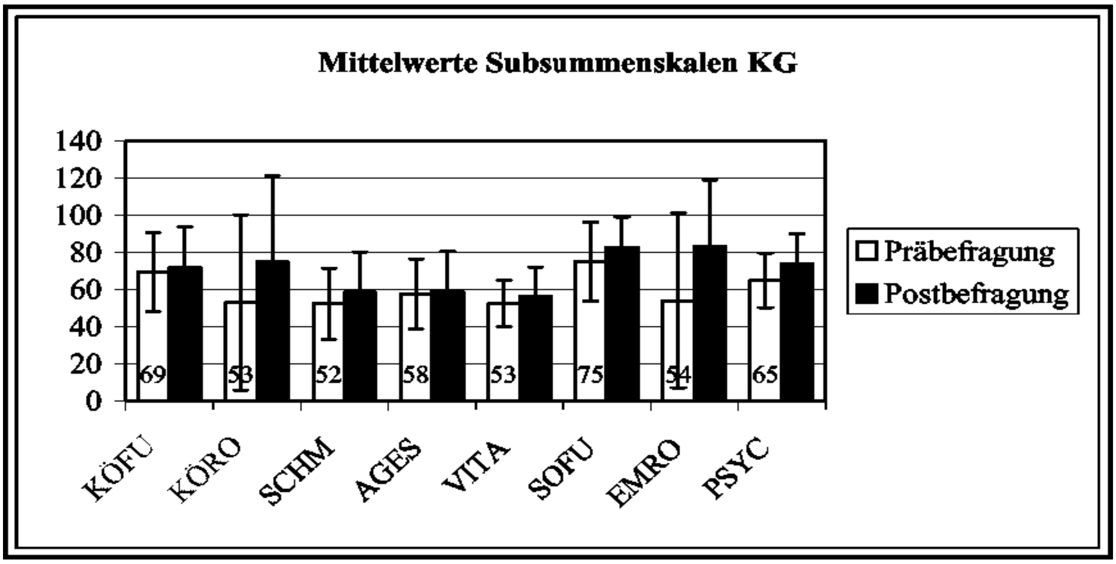


Figure 12: Mean sub-sum scales of the pre-/post-survey CG

The variance analysis of all sub-sum scales showed that homogeneity was present in the total group at the time of the first survey. During the period of the second survey it was found that there was still homogeneity for the two groups (intervention and control group). There were no significant differences between the groups based on all sub-sum scales. Detailed data can be found in Table 14.

Table 14: Mean sub-sum scales IG and CG

PRE-SURVEY									
		KÖFU	KÖRO	SCHM	AGES	VITA	SOFU	EMRO	PSYC
IG	n	16	16	16	16	16	16	16	16
	x	63.75	48.44	45.19	59.81	52.81	86.72	75	72
	SD	21.95	45.16	20.31	17.06	15.05	16.75	41.27	14.01
	Min/Max	20/95	0/100	22/100	20/82	25/85	50/100	0/100	48/96
CG	n	8	8	8	8	8	8	8	8
	x	69.37	53.12	52.37	57.75	52.5	75	54.17	65
	SD	21.29	47.13	19.23	18.87	12.53	21.13	46.93	14.62
	Min/Max	35/90	0/100	22/74	32/87	30/70	37/100	0/100	40/80
POST-SURVEY									
		KÖFU	KÖRO	SCHM	AGES	VITA	SOFU	EMRO	PSYC
IG	n	16	16	16	16	16	16	16	16
	x	73.44	65.62	56.87	62.06	57.19	92.19	91.67	74
	SD	17.67	39.66	21.32	15.49	16.33	10.08	25.92	13.31
	Min/Max	50/100	0/100	41/100	30/87	25/85	75/100	0/100	44/96
KG	n	8	8	8	8	8	8	8	8
	x	71.87	75	58.75	59	56.25	82.81	83.33	74
	SD	21.87	46.29	21.68	21.47	15.98	16.28	35.63	16
	Min/Max	45/95	0/100	22/84	25/92	30/70	62/100	0/100	48/92
Variance Analysis	p	0.265	0.835	0.291	0.879	0.91	0.767	0.521	0.226
Pre-Post* group	SL	ns	ns	ns	Ns	ns	ns	ns	ns

KÖFU – physical functional capacity; KÖRO – physical role function;
SCHM – bodily pain; AGES – general health perception;
VITA – vitality; SOFU – social function; EMRO – emotional role function;
PSYC – psychological well-being;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum

5.4 RESULTS OF THE TRAINING DIARY

Of the 16 training diaries handed out, 15 were returned. The analysis of all the data from the training diaries would go beyond the scope of this study. Therefore, the analysis of the training diaries only relates to the average number of training days and training times with the MBT shoes. Of the 57 possible training days, the MBT shoes were worn on an average of 37.54 ± 10.22 days. The wearing time ranged from few minutes to several hours.

6. DISCUSSION

6. DISCUSSION

The present study shows the effect of training in MBT shoes and the influence of the Masai Barefoot Technology on quality-of-life. The present state of health, both at the start of the study (pre-survey) and after the two-month period of training (post-survey), was assessed, using two questionnaires: the functional questionnaire Hanover back and the SF-36 health survey. Analyses regarding the differences between the pre- and post-survey data were carried out. In addition, the intervention group was compared with the control group. The discussion comments on the implementation of the study and the results are given in Chapter 5.

6.1 METHOD

This section provides a critical discussion about the process of recruiting subjects, the course of the study, the questionnaires used and the training diary.

6.1.1 RECRUITMENT OF SUBJECTS

The process of finding suitable subjects was performed in co-operation with the VGS Köln. This proved to be very positive, because some of the members of the association had already been participants in other studies. The collaboration of the association with the Deutsche Sporthochschule is well known, and the members of the association are open and interested in exploring new therapeutic methods.

In a relatively short period of time, the subjects for the intervention and for the control groups could be chosen.

The selection of the subjects for the present study was based on a few parameters: chronic back pain for at least three months or longer, aged between 55 and 70 years and participation in an exercise programme. This data was included in the subject form and verified. The above-mentioned parameters were kept very general. To achieve greater homogeneity in the subject population, specific data regarding back pain would have been required.

6.1.2 COURSE OF THE STUDY

The additional training session, provided for the intervention group, was taken very seriously by the subjects and the participation rate was thus high. The contents of the training sessions followed a step-by-step design, and classes were carried out methodically. The sessions offered variety as to the setting (indoors and outdoors) as well as the cognitive and practical education regarding the relationship between posture and standing/walking in MBT shoes. It was further guaranteed that the sessions offered variety as there were three focal points: gait training, posture training and endurance.

Due to the many subjects, individual support was more difficult. However, this was not a disadvantage at all, because there was enough time during and after training sessions to respond to questions and solve problems.

The questionnaires were completed during the first and last training session, respectively; thus, the participants had the opportunity to ask questions.

The distribution of the questionnaires for the subjects of the control group turned out to be very difficult, because contact with these subjects was not constant.

6.1.3 TESTS

To measure the subjective functional capacity while performing day-to-day activities, the FFbH-R had been chosen. This questionnaire is used in the assessment of back pain patients, especially in the follow-up assessments. Previous data has shown that the questionnaire is reliable, valid and change-sensitive (KOHLMANN & RASPE 1996). The questions of the FFbH-R are easy to understand so that the subjects of the intervention as well as of the control groups did not have any difficulties in answering the questions.

The SF-36 was used to measure the quality-of-life. The questionnaire is a self-report on the subject's health-related quality-of-life (BULLINGER & KIRCHBERGER 1998, 9). It covers all basic dimensions of subjective health (psychological, physical and social aspects) which contribute to the well-being and functional capability of the patient. The SF-36 has been used for various types of diseases in out-patient and in-patient methods of treatment, as well as in clinical studies.

The effects of various methods of therapy have been studied (BULLINGER & KIRCHBERGER 1998, 10/11). The formal completion of the SF-36 questionnaire was managed excellently by all subjects. Because completing the questionnaires in the intervention group, and partially in the control group, was done under supervision, the questions could be answered immediately. An incorrect self-assessment by the patients could thus be avoided.

6.1.4 TRAINING DIARY

The training diary was used for recording training units, which were done outside of the additional training session. The training diary is very detailed and contains data regarding pain and the sensation while walking, and about the type of use of the MBT shoe (standing, sitting, walking). The analysis of all aspects of the training diary would have exceeded the scope of this study, therefore only the average number of training days and training times of the subjects were mentioned (see Chapter 5.4).

6.2 RESULTS

In the following section, the results of both questionnaires and the training diary will be discussed. The FFbH-R data of the intervention group will be compared with a population sample (Lübecker Rückenschmerzstudie). In addition, the results of the SF-36 will be compared with data of the German normal sample. Finally, the hypotheses will be discussed.

6.2.1 RESULTS OF THE FUNCTIONAL QUESTIONNAIRE HANOVER BACK

The means of the pre- ($x = 73.94$) and post-survey ($x = 80.2$) of the intervention group showed a *highly significant* difference ($p = 0.003$), while in the control group *no significant* ($p = 0.663$) difference in the mean was seen. When the two groups were compared using variance analysis, a *significant* difference ($p = 0,047$) was again observed. This implies that the study population (intervention and control groups) is homogeneous in the pre-survey, but shows a difference in the post-survey.

From this it can be concluded that the training with MBT shoes had a positive impact on the functional capacity. Here it has to be taken into account that the wearing of the MBT shoe was not an isolated activity, because all subjects continued to perform their exercise program indoors and in the water as usual. Thus, the wearing of the MBT shoe complemented and supported the subject's usual exercise program and contributed to the positive changes of the functional capacity. From customer surveys of the Masai GmbH and the user reports it can be seen that back pain in most patients improved by wearing MBT shoes after several days or several months. This data was taken from a questionnaire and is therefore subjective. Some comments shall be listed as examples:

Patients after a two-month period of wearing MBT shoes:

"Less back pain."
"Hip and low back pains are gone."
"The back pain disappeared already after several days."

One patient after a five-month period of wearing MBT shoes:

"The chronic pain in the lower back is gone completely."
(www. masai. ch/swissmasai/medical/berichte/ruecken/rueckenfrageb.shtml 2002)

From this testimony it is not entirely clear if the patients were wearing MBT shoes in addition to an exercise program or not.

Table 15 shows the individual FFbH-R scores of the intervention group, as well as those of a population sample – *Lübecker Rückenschmerzstudie*.

Table 15: Distribution of the FFbH scores IG and Lübecker Rückenschmerzstudie

FFbH-R	IG Pre-	IG Post-	Subjects surveyed with back pain		Study population	
			Men	Women	Men	Women
	%		60-74 years	60-74 years	60-74 years	60-74 years
0.0-12.5	0	0	0.9	1.4	1.7	1
12.6-25	0	0	4.3	5.7	2	3
25.1-37.5	0	0	6.9	11.8	3.8	5.9
37.6-50	6.3	6.3	16.4	13.7	7.8	7.3
50.1-62.5	31.3	6.3	17.2	19.9	8.2	11.5
62.6-75	25.1	25.1	20.7	25.6	14	20
75.1-87.5	18.8	31.3	19.8	15.2	18.8	23.2
87.6-100	18.8	31.3	13.8	6.6	43.7	28.1
n	16	16	116	211	293	495
x	73.94	80.2	65.1	59.8	78	73.2

IG – intervention group; n – size sub-sample; x – mean

Lübecker Rückenschmerzstudie: Subjects surveyed with current back pain and total population sample (KOHLMANN & RASPE 1996)

Data of the age group 60-74 years in the Lübecker Rückenschmerzstudie are shown separately for males and females. This age group is closest to the age group in the present study. In addition, data is separated into *those surveyed who currently have back pain* and those of the *total population sample*. Looking initially only at the intervention group in a pre-/post- comparison, it is found that the high percentage value (31.3%) in the pre-survey became considerable less (FFbH-R value of 50.1-62.5) in the post-survey (6.3%). Even for higher FFbH-R values marked improvements can be seen in the post-survey, which is reflected in the mean.

A FFbH-R value of 70 is defined as a moderate functional capacity and values below 60 correspond to clinical relevant functional impairment (KOHLMANN & RASPE 1996). Table 15 shows a value between 62.6 and 75 with pre- and post-survey in 25.1%, in those surveyed with present back pain in 20.7% (male) and 25.6% (female) and in the total population sample in 14% (male) and 20% (female). A FFbH-R value of 87.6 – 100, which corresponds to a normal functional capacity (100 is even equivalent to maximum functional capacity), occurs in the pre-survey in 18.8% and in those surveyed with back pain in 13.8% (males) and 6.6% (females), respectively.

Back pain occurs in 13.8% of males and in 6.6% of females. The prevalence of the post-survey (31.3%) is comparable with the data of the total population sample (43.7% for males, 28.1% for females). They approach these values. Looking at the means, it can be seen that the intervention group shows a higher value (73.95) in the pre-survey than those interviewed with back pain (65.1 in males, 59.8 in females) and therefore shows a better functional capacity compared to those surveyed with back pain. The value of the post-survey (80.2) is by all means comparable with those of the total population sample (78 in males, 73.2 in females). It has to be noted that the intervention group derives only from a smaller sample (n = 16) and relates to the age group of 54 to 71. The Lübecker Rückenschmerzstudie showed that the functional capacity decreases with increasing age (KOHLMANN & RASPE 1996).

6.2.2 RESULTS OF THE SF-36 HEALTH SURVEY

Examining the results, the sum scales of the intervention group were compared first. Looking at the means of the pre- and post-survey of the physical sum scale, an increase in the value (pre-survey: x = 37.71; post-survey: x = 41.98) is apparent. This difference is *highly significant* (p = 0.009). The psychological sum scale shows no significant difference in the intervention group. Also there is no significant difference in the control group, neither for the physical nor for the psychological sum scale. If both groups are compared with each other, the variance analysis shows no significant differences. This is true for both sum scales. Thus, the intervention and the control groups are homogeneous in the pre- and in the post-survey.

When assessing the eight sub-sum scales, the intervention group shows *highly significant* and *most significant* differences in the scales physical functional capability (p = 0.005) and bodily pain (p = 0.001). Comparison of the other sub-sum scales shows no significant differences. The health insurance AOK Niedersachsen offered a back training program for working people at the beginning of the chronification (sic) process. Quality-of-life measurements were performed with the SF-36 health survey. Analysis showed a marked effect in the dimension physical pain (p = 0.0029 medium-term; p = 0.0014 long-term, one year after end of course) (HOOPMANN, REICHLE, KRAUTH, SCHWARTZ, WALTER 2001).

Looking at the control group alone, a *significant* difference (p = 0.048) is found in the scale psychological well-being. All other sub-sum scales show no significant differences. Variance analysis showed homogeneity in the intervention and control groups for the pre- and post-survey and no significant differences.

The results show improvement for quality-of-life only in one sum scale and two sub-sum scales of the intervention group. This does not comprise the entire quality-of-life in its totality, but only the parts physical functional capability and bodily pain. However, the psychometric evaluation of the German SF-36 shows that *"… comparatively strong loading of the back pain patients … in the field pain …"* was found (BULLINGER & KIRCHBERGER 1998, 35). From this it can be concluded that an improvement with regard to the sub-sum scale bodily pain indicates a successful outcome. It remains to be noted that this interpretation only applies to the intervention group, because – as mentioned above – according to variance analysis no significant differences were present. There are no significant interactions of the groups, which would allow a statement about the effectiveness of the intervention.

When comparing the means of the sum scales of the intervention group and of persons affected by back pain in a German normal sample, it is seen that these are close together. The mean of the physical sum scale in the post-survey is 41.98 ± 9.26, while individuals with back pain in the German normal sample is 44.79 ± 10.61. In the psychological sum scale, the means of the pre-survey (x = 52.48 ± 8.66) and the post-survey (x = 54.26 ± 6.52) are slightly above the mean of the individuals with back pain in the normal sample (x = 48.25 ± 10.95).

The values for individuals with back pain in the German normal sample are taken from BULLINGER und KIRCHBERGER 1998.

Table 16: Mean sum scales of the pre-/post-survey IG and individuals with back pain in the German normal sample

		KÖSU	PSSU
Pre-survey	**n**	16	16
	X	37.71	52.48
	SD	9.71	8.66
	Min/Max	22.7/53.46	34.10/61.57
Post-survey	**n**	16	16
	X	41.98	54.26
	SD	9.26	6.52
	Min/Max	26.62/55.2	36.89/63.22
Individuals with	**n**	1065	1065
back	**x**	44.79	48.25
pain	**SD**	10.61	10.95
dN	**Min/Max**	8.51/72.85	3.72/73.71

(Values individuals with back pain in the German normal sample from: BULLINGER & KIRCHBERGER 1998, p. 63)

KÖSU – physical sum scale; PSSU – psychological sum scale; n – size sub-sample; x – mean; SD – standard deviation; Min – minimum; Max – maximum

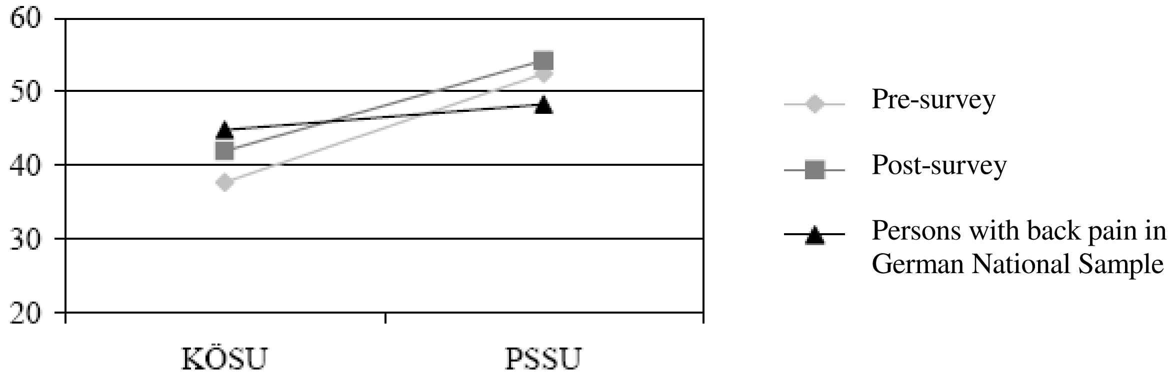


Figure 13: Mean sum scales of the pre-/post-survey IG and persons with back pain in the German normal sample

Looking at Table 17 and Figure 14, it can be seen that the pre-survey values of the intervention group for the sub-sum scales physical functional capability, physical role function, bodily pain and emotional role function are markedly below the values of the individuals suffering from back pain in the German normal sample. In the post-survey, the above-mentioned values of the sub-sum scales and those of the persons suffering back pain approach each other or are even higher (emotional role function). The values of the sub-sum scales general health perception, vitality, social functional capability and psychological well-being in the pre- as well as in the post-survey of the intervention group are close to those in the group of individuals with back pain. It has to be noted that the average age of the German normal sample for individuals with back pain is 48.3 ± 16.12 years. The results of the German normal sample show, independent of an illness, that the younger the subject, the higher the quality-of-life, especially in the physical aspects of well-being (ELLERT, BELLACH 1999). On the basis of Figure 14, this would mean that the intervention group in the pre-survey showed a reduced quality-of-life in some sub-sum scales compared to individuals with back pain in the German normal sample, but in the post-survey the quality-of-life approached that of a 48-year-old.

Table 17: Mean sub-sum scales of the pre/post-survey IG and persons with back pain in the German normal sample

		KÖFU	KÖRO	SCHM	AGES	VITA	SOFU	EMRO	PSYC
Pre-survey	**n**	16	16	16	16	16	16	16	16
	x	63.75	48.44	45.19	59.81	52.81	86.72	75	72
	SD	21.95	45.16	20.31	17.06	15.05	16.75	41.27	14.01
	Min/Max	20/95	0/100	22/1 00	20/82	25/85	50/100	0/100	48/96
Post-survey	**n**	16	16	16	16	16	16	16	16
	x	73.44	65.62	56.87	62.06	57.19	92.19	91.67	74
	SD	17.67	39.66	21.32	15.49	16.33	10.08	25.92	13.31
	Min/Max	50/100	0/100	41/100	30/87	25/85	75/100	0/100	44/96
Individuals with-	**n**	1106	1097	1115	1105	1104	1118	1095	1102
back	**x**	76.07	71.59	63.27	58.74	55.39	83.67	85.01	69.15
pain	**SD**	24.49	37.28	27.87	19.66	18.55	19.98	30.63	17.53
dN	**Min/Max**	0/100	0/100	0/100	0/100	0/100	0/100	0/100	4/100

(Values individuals with back pain in the German normal sample
from: BULLINGER & KIRCHBERGER 1998, S. 44)

KÖFU – physical functional capacity; – KÖRO physical role function;
SCHM – bodily pain; AGES – general health perception;
VITA – vitality; SOFU – social function; EMRO – emotional role function;
PSYC – psychological well-being;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum

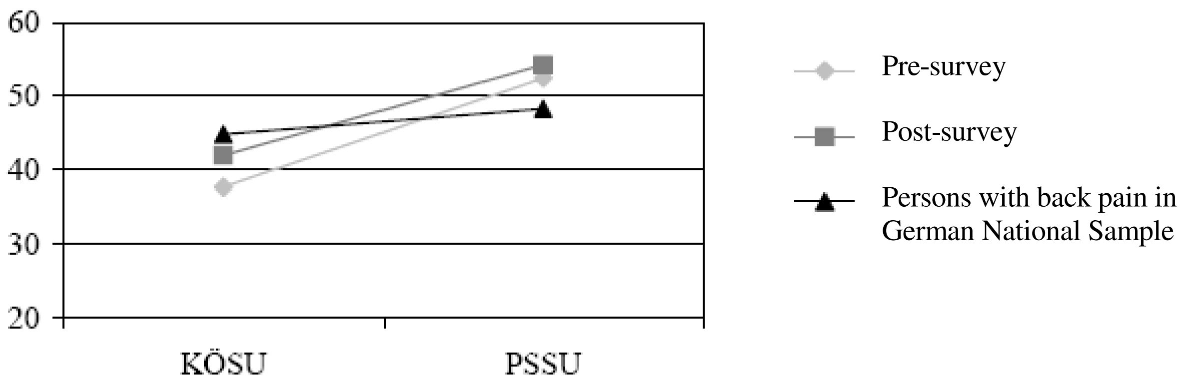


Figure 14: Mean sub-sum scales of the pre-/post-survey IG and patients with back pain in the German normal sample

However, if one compares the physical sum scales of the intervention group and the German normal sample (total group) (see Figure 15), the mean of the intervention group in the pre-survey lies markedly below the value of the normal population, but approaches this value in the post-survey.

Table 18: Means sum scales of the pre-/post-survey IG and dN total group

		KÖSU	PSSU
Pre-survey	**n**	16	16
	x	37.71	52.48
	SD	9.71	8.66
	Min/Max	22.7/53.46	34.10/61.57
Post-survey	**n**	16	16
	x	41.98	54.26
	SD	9.26	6.52
	Min/Max	26.62/55.2	36.89/63.22
dN total group	**n**	2773	2773
	x	50.21	51.54
	SD	10.24	8.14
	Min/Max	5.33/68.72	11.85/73.25

(Values German normal sample, total group
from: BULLINGER & KIRCHBERGER 1998, p. 62)

KÖSU – physical sum scale; PSSU – psychological sum scale;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum

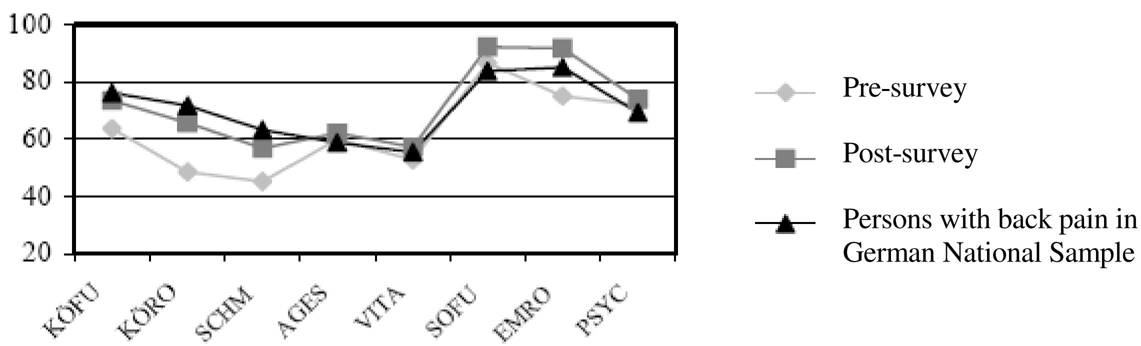


Figure 15: Means sum scales of the pre-/post-survey IG and dN total group

The sub-sum scales in Table 19 reveal markedly lower values in almost all scales in the pre-survey, while the values approach those of the normal population in post-survey, and reach the values in the scales of social functional capability, emotional role function and psychological well being. This means a markedly lower quality-of-life in the physical dimensions of the patients of the intervention group compared to the normal population.

Table 19: Means sub-sum scales pre-/post-survey of the IG and dN total group

		KÖFU	KÖRO	SCHM	AGES	VITA	SOFU	EMRO	PSYC
Pre-survey	**n**	16	16	16	16	16	16	16	16
	x	63.75	48.44	45.19	59.81	52.81	86.72	75	72
	SD	21.95	45.16	20.31	17.06	15.05	16.75	41.27	14.01
	Min/Max	20/95	0/100	22/100	20/82	25/85	50/100	0/100	48/96
Post-survey	**n**	16	16	16	16	16	16	16	16
	x	73.44	65.62	56.87	62.06	57.19	92.19	91.67	74
	SD	17.67	39.66	21.32	15.49	16.33	10.08	25.92	13.31
	Min/Max	50/100	0/100	41/100	30/87	25/85	75/100	0/100	44/96
dN	**n**	2886	2856	2905	2859	2876	2911	2855	2871
Total group	**x**	85,71	83,7	79,08	68,05	63.27	88.76	90.35	73.88
	SD	22.1	31.73	27.38	20.15	18.47	18.4	25.62	16.38
	Min/Max	0/100	0/100	0/100	0/100	0/100	0/100	0/100	4/100

(Values German normal sample, total group
from: BULLINGER & KIRCHBERGER 1998, S. 50)

KÖFU – physical functional capacity; KÖRO – physical role function;
SCHM – bodily pain; AGES – general health perception;
VITA – vitality; SOFU – social function; EMRO – emotional role function;
PSYC – psychological well-being;
n – size sub-sample; x – mean; SD – standard deviation; Min – minimum;
Max – maximum

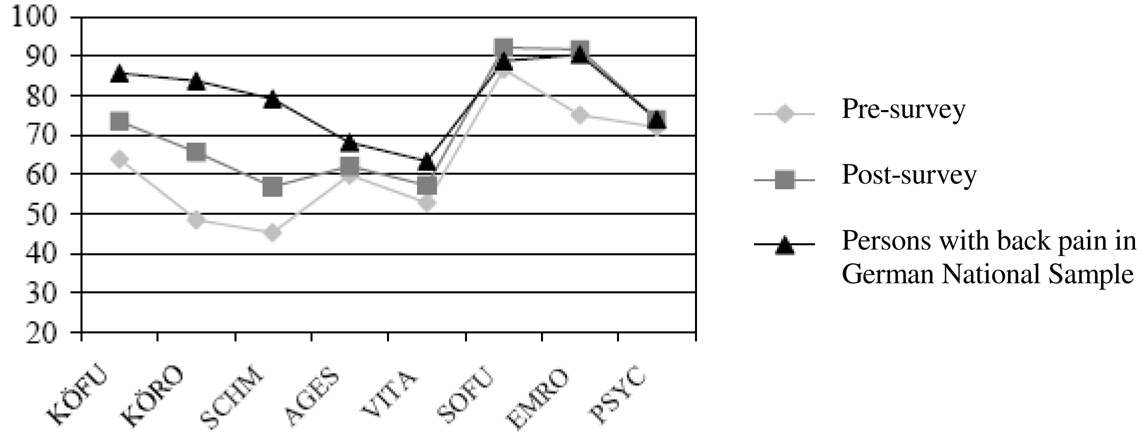


Figure 16: Mean sub-sum scales pre-/post-survey of the IG and dN total group

Likewise, in the study on the effects of a back training program of the AOK Niedersachsen a definite restriction of the quality-of-life was found, especially in the physical dimensions when comparing back pain patients to the normal population (HOOPMANN et al. 2001).

As already mentioned in Chapter 4.1, the quality-of-life consists, according to BULLINGER (2002), in well-being and functional capability. The health definition of the WHO also includes, besides medical aspects, social aspects as well. Health is defined as:

> *"A state of total physical, psychological and social well-being and not only the absence of illness and maladies." (WHO in: BULLINGER 1996)*

Finally, it should be mentioned that a positive effect of the physical dimension is a good outcome, because the physical functional capability was the main target of the intervention.

6.2.3 RESULTS TRAINING DIARY

As mentioned already in the chapter concerning the results of the study, not all data from the training diaries have been used – only the days and time of training were reported.

Of the possible 57 training days, the average wearing time of the MBT shoe was 37.5 days. The period of time ranged from several minutes to several hours. Although the MBT shoes should be integrated into the every-day-life as quickly as possible, only a rather low number of training days is found in this study.

6.2.4 REFERENCE TO THE HYPOTHESES

Chapter 4.1 described the hypotheses. The aim of the study was to evaluate if training in MBT shoes, in addition to exercise classes indoors and in the water, had a positive influence on functional capacity and quality of life in patients with chronic back pain. The intervention group was analyzed alone (hypothesis 1) and also compared with a control group (hypothesis 2).

The *first hypothesis* can be confirmed in part, as there is a positive change of the functional capacity. Regarding the quality of life, improvements are found in the physical sum scale and the two sub-sum scales, physical functional capability and bodily pain.

The *second hypothesis* can also be confirmed in part. Regarding the functional capacity, there is a significant interaction of both groups, which leads to a positive evaluation with respect to the effectiveness of the intervention. The quality-of-life shows no significant difference with regard to the control group. The intervention and the control group were homogeneous in the pre- and in the post-survey.

The improvement of the quality-of-life refers exclusively to the physical dimension. It can be assumed that an improvement of the psychological dimension might have occurred only after prolonged intervention. The above-mentioned assumption thus can be partly accepted.

PERSONAL IMPRESSION

The participants showed great interest in the training sessions and were highly motivated. It was a pleasant social event and many interesting discussions developed regarding the MBT shoe and its further use in other diseases and in leisure sports. From the personal conversations it became clear that the participants felt very comfortable wearing the MBT shoes and that they experienced an amelioration of their back pain.

This is reflected in the high number of subjects purchasing the MBT shoes after the end of the study for further use.

7. PROSPECTS

7. PROSPECTS

To gain further insight into the effects of the Masai Barefoot Technology, further interventions should be performed, using this study as a starting point. To begin with, it would be interesting to observe subjects over a prolonged period of time, or to interview the participants of this study e.g. in six months time again as to their subjective state of health. A further aspect relates to the selection of participants. It would be of interest to select patients more specifically, e.g. from groups with specific and unspecific back pain, or groups of patients without slipped disc or after herniation of the nucleus pulposus.

A further measure would be to investigate whether the Masai Barefoot Technology could already be used in inpatient and ambulatory rehabilitation, and whether it could support the usual therapeutic measures effectively.

Finally, an empirical study should be carried out in this area with a larger patient group to verify the results of the present study and to gain further insights.

Especially in back pain research, much effort is still needed. In the long run, the high indirect and direct costs resulting from back pain can only be reduced if more cost-effective, as well as preventive and secondary preventive therapeutic methods are introduced. This study has shown that approaches such as the Masai Barefoot Technology have the potential to contribute to these methods.

8. SUMMARY

The present study investigated whether the quality-of-life of people with chronic back pain had changed after an eight-week training course with MBT shoes. Apart from the intervention group, there was a control group for comparisons which served as a representation of “normal” people with chronic back pain. A total of 24 patients, ranging in age between 54 and 71 years, agreed to participate in the study. All participants suffered from back pain consisting of more than six months duration at the baseline. They were recruited from various exercise courses (indoors and in water) offered by the health sports association *Verein für Gesundheitssport und Sporttherapie Köln* and by the adult education institution *Volkshochschule Brühl.* Sixteen subjects participated in the intervention, while the other eight constituted the control group. Quality-of-life was evaluated with two standardized questionnaires – the functional questionnaire Hanover back and the SF-36 health survey – at the beginning of the intervention and after completion of the eight-week training period. For the intervention group, a training session was held once a week to learn and control the right running technique. Outside of the training sessions, the subjects were asked to record times of wearing the MBT shoes in a training diary. Furthermore, it should be mentioned that the MBT shoes were worn by the participants of the intervention group in addition to the normal exercise course sessions.

Overall, a small impact of the Masai Barefoot Technology on the quality-of-life of people with chronic back pain can be noted. The physical dimension showed improvements, but the psychological dimension did not change. According to BULLINGER (2002), the quality-of-life consists of functional capability and well-being, and health, too, is a state of physical, mental and social well-being. This means that a change of functional capability, or more general the physical dimension, already contributes to improving the situation. Especially in back pain patients, who predominately complain of physical functional impairments and pain, as has been demonstrated in other studies as well, a decrease in the dimension of pain is very important.

Finally, it is worth mentioning that a combination of an indoors or in-water exercise programme and wearing of the MBT shoe in everyday life can be recommended.

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APPENDIX

APPENDIX

INFORMATION LEAFLET FOR SUBJECT RECRUITMENT

QUESTIONNAIRES

PERSONAL FORM INTERVENTION GROUP

PERSONAL FORM CONTROL GROUP

FUNCTIONAL QUESTIONNAIRE HANOVER BACK

SF-36 HEALTH SURVEY

TRAINING DIARY

SESSION PROGRESS PLANS

CURRICULUM VITAE

PERSONAL DETAILS

- Name: Cordula Mareike Stegen
- Date of birth: 04/05/1978
- Place of birth: Rotenburg Wümme, Germany
- Citizenship: German
- Marital status: Single
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EDUCATION

- 1984-1988 Surheider Schule (primary school)
- 1988-1990 Georg-Büchner-Schule (intermediate school)
- 1990-1994 Wilhelm-Raabe-Schule (grammar school)
- 1994-1997 Schulzentrum Bürgermeister Smidt (final years, grammar school)

UNIVERSITY STUDIES

- Since winter semester 1997/98 sports science at the Deutschen Sporthochschule Köln; 30/09/1999 “Prediploma”; since then, main course of studies with focus on “Prevention and Rehabilitation”

LANGUAGE SKILLS

- English: Basic knowledge
- French: Basic knowledge
- Italian: High level of proficiency

PRACTICAL TRAINING

- Two-week practical training in the Evangelischer Kindergarten Surheide
- Four-week engagement in the Körperbehinderten Kindergarten of the DRK Krankenhaus Debstedt in the context of the voluntary social year
- Three-month practical training in the hospital Rhein-Sieg-Klinik Nümbrecht; clinic for orthopaedic and neurological diseases, 2001
- Two-month practical training in the hospital Zürcher Höhenklinik Davos, Switzerland; Clinic for musculoskeletal, medical and psychosomatic disorders, 2001

WORK AS TRAINER

- Spinal exercise programme at the Volkhochschule Brühl
- Junior volleyball trainer at the DJK TuS Hürth
- Senior citizen volleyball at the Sportclub Weiden
- Osteoarthritis group at the association Verein für Gesundheitssport und Sporttherapie Köln

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