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Long-term outcome in patients with osteoarthritis of the hip or knee after comprehensive rehabilitation: A prospective 2 year follow-up study

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Table of Contents (Inhaltsverzeichnis)

1. German abstract (Deutsche Zusammenfassung)

Langzeitergebnisse bei Patienten mit Hüft- oder Kniearthrose nach einem umfassenden Rehabilitationsprogramm: Eine prospektive 2-jährige Verlaufsstudie

Ziel: Untersuchung des Verlaufs von Schmerz und körperlicher Funktion nach einem umfassenden stationären Rehabilitationsprogramm bei Patienten mit Hüft- oder Kniearthrose.

Design: Prospektive 24-monatige Kohortenstudie mit Assessments vor Therapiebeginn (Aufnahme in die Klinik), nach Entlassung (ca. 1 Monat) sowie nach 3, 6, 9, 12 und 24 Monaten.

Einrichtung: Stationäre Rehabilitationsklinik.

Patienten: Konsekutiv zugewiesene Patienten, welche die Einschlusskriterien erfüllen.

Intervention: Drei- bis vierwöchiges umfassendes Rehabilitationsprogramm mit Krafttraining, Dehnübungen, Ausdauertraining, Koordinationstraining, Entspannungstechniken und Patientenschulung. Zu individuellen Heimprogrammen wurden die Patienten angeleitet.

Ergebnismessung und Analysen: Der Verlauf des allgemeinen Gesundheitszustandes wurde mit dem Gesundheitsfragebogen SF-36 gemessen und die krankheitsspezifische Gesundheit wurde mit dem Fragebogen WOMAC bestimmt. Effektgrößen wurden durch Sensitivitätsstatistiken (Effect size ES) und nicht-parametrische Tests beurteilt.

Ergebnisse: Die Daten von 128 Patienten mit kompletten Verlaufsdaten konnten analysiert werden. Sowohl der Schmerz als auch die körperliche Funktion

besserten sich mäßig (WOMAC Schmerz: ES = 0.56, WOMAC Funktion ES = 0.44) bis zur Entlassung aus der Klinik. Während die Schmerzreduktion bis zum 24. Monat andauerte (WOMAC: ES = 0.26), verschlechterte sich die körperliche Funktion der Patienten bereits nach 12 Monaten wieder auf das Ausgangsniveau. **Schlußfolgerung**: Ein umfassendes stationäres Rehabilitationsprogramm kann bei Patienten mit Hüft- oder Kniearthrose für einen Zeitraum von 6 Monaten Schmerz und körperlicher Funktion verbessern sowie lang andauernd den Schmerz reduzieren.

2. Abstract

Long-term outcome in patients with osteoarthritis of the hip or knee after comprehensive rehabilitation: A prospective 2 year follow-up study

Objective: To examine the course of pain and physical function after a comprehensive inpatient rehabilitation intervention in patients with osteoarthritis (OA) of the hip or knee.

Design: Prospective 24-months cohort study with assessments at baseline (entry into clinic), 1 (discharge), 3, 6, 9, 12 and 24 months after baseline.

Setting: Inpatient rehabilitation clinic**.**

Patients: Consecutively referred patients to inpatient rehabilitation fulfilling the inclusion criteria.

Intervention: Three to four week comprehensive rehabilitation intervention including strengthening exercise, flexibility training, endurance training, relaxationstrategies and consultations for preventive measures. Individual home rehabilitation programs were instructed.

Main Outcome Measures and Analysis: Generic health status was followed using the SF-36, condition specific health was followed with the WOMAC questionnaire. Effects were analyzed with sensitivity statistics (effect size, ES) and nonparametric tests.

Results: The data of 128 patients with complete follow-up data could be analyzed. Both pain and physical function improved moderately (WOMAC pain: ES = 0.56, WOMAC function ES = 0.44) until discharge of the clinic. While the effect in pain

reduction remained significant until month 24 (WOMAC: ES = 0.26), physical function deteriorated close to baseline values after 12 months.

Conclusions: Comprehensive in-patient rehabilitation of patients with OA of the hip or knee may improve pain and physical function for 6 months and pain in the long-term.

3. Introduction

Osteoarthritis (OA) of the knee and hip is a very common degenerative joint disease. It has an important burden of disease. Increasing by age, the prevalence of radiographic OA of the knee was 36.2 % in women and 30.7% in men between 70 and 79 years in the eigthies [*Felson 1987*]. Direct and indirect costs for OA of the knee and hip in the US in 1994 were 12.9 billion US-Dollar [*Yelin 1998*].

The pathology includes damage of the articular cartilage, associated with increased activity in the subchondral bone and marginale osteophyte formation [Dieppe 1998 A]. It starts with a disorder of the cartilage remodeling processes. Under normal conditions, the cartilage is subjected to a dynamic remodeling process in which degeneration and synthesis are balanced, such that the volume of cartilage is maintained. In OA cartilage, however, the degeneration is predominant shifting this balance in favor of net degradation. This results in loss of cartilage. An advanced joint pathology in OA can be detected by x-rays. The typical signs are narrowing of the joint space (due to loss of cartilage volume), associated with osteophyte formation and sclerosis and cysts in the subchondral bone.

The clinical manifestations include pain, stiffness and a reduced range of motion in the affected joints [Dieppe 1998 B]. In the beginning patients report knee or hip pain only after intensive use of the knee joint, for example after climbing down several flights of stairs. With the progression of disease use-related pain is accompanied by stiffness in the morning or after sitting and by a reduced range of motion.

Pain at rest and severe limitations of joint motion are features of severe disease. These changes can lead to severe impairment, disability and handicap.

To assess the status of patients with OA and to follow the disease process valid, reliable responsive and user-friendly outcome instruments are needed. There are many different dimensions of outcome. To determine the severity of joint damage x-rays are often used in epidemiological studies. Patient related outcomes such as pain, stiffness, physical function and health related quality of life can be measured by valid and reliable self-assessment questionnaires. Advantages of these questionnaires are low costs, no exposure to radiation and the direct measurement of the impact of OA on the life of the patients.

In patient-centered outcome measurement two different types of health status measures have frequently been used: Condition specific and generic measures [*Kantz 1992*]. Condition specific measures are expected to be more sensitive to the effects of a given condition or intervention of health, because they have been developed to capture the typical affected health areas of the target disease. Generic health status measures do not refer to the disease or problem that might be causing poor health. They are expected to be sensitive to both the effects of health of a particular condition or intervention, and to the effects of any other condition affecting health status. Thus, they permit comparison of outcomes across groups of patients with different diseases.

Treatment options for OA are pain relief with analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs) [*Bellamy 1993, Dieppe 1993*], exercise [*Deyle 2000, Ettinger 1997, Van Baar 1998, Fisher 1993*], patient education [*Maurer 1998*], and finally joint arthroplasty [*Anderson 1996, Coyte 1996*]. The recommendations of the European League against Rheumatism [*Pendelton 2000*] and the guidelines of the American College of Rheumatology include all these

treatment options [*Hochberg 1995 A, Hochberg 1995 B*]. Both recommendations emphasize, that the treatment should be tailored individual to the patient.

Comprehensive treatment programs combine some of these treatment options. The effect size of comprehensive rehabilitation has recently been examined in short term [Angst 2001 A], but it remains unclear how long pain reduction and improvement in physical function last. To the best of our knowledge, up to now, no study has analyzed the effect size of a comprehensive rehabilitation intervention to patients with OA of the knee or hip in the long-term.

This study examined the course of pain and physical function as measured by the condition specific patient questionnaire WOMAC [*Bellamy 1988, Bellamy1992, Bellamy 1995, Bellamy 1997, Stucki 1996*] and the generic health status measure SF-36 [*Ware 1992, Ware 1997, Ware 1998, Bullinger 1995, Bullinger 1998*] for a 24-months period after a comprehensive rehabilitation intervention. We hypothesized that a comprehensive rehabilitation program reduces pain and improves function for a period of at least up to one year.

4. Methods

4.1. Design

Prospective 24-months cohort study of patients with OA of the knee or hip undergoing a rehabilitation intervention.

4.2. Setting

Patients were recruited from the Zurzach Rheumatology and Rehabilitation clinic, Switzerland. They were referred by their family physician or their rheumatologist with the diagnosis hip or knee OA to a comprehensive inpatient rehabilitation intervention.

4.3. Patients

Consecutive patients with hip or knee OA were invited to participate in the study. Patients were included if they 1) agreed to participate in the study by written informed consent and 2) fulfilled the American College of Rheumatology (ACR) criteria for OA. Patients were excluded if they 1) had a history of medication abuse or non-compliance, 2) had difficulty completing questionnaires, 3) suffered from a severe illness, or 4) did not want to participate in the study. During follow-up, patients were excluded if they 1) underwent a joint arthroplasty, 2) suffered from a severe illness, 3) died, 4) refused further participation, 5) did not sent

questionnaires back or 6) did fill out the questionnaires incomplete according to the missing rules of SF-36 or WOMAC as described below.

4.4. Intervention

The intervention was a comprehensive rehabilitation intervention of usually three to four weeks duration. Exercise therapies including strengthening exercises, flexibility training, endurance training and coordination training were performed individually and in groups as a main part of the program. Manual Therapy was applied with the goal of recreating the regular joint mobility. Additionally passive therapies as massages, electrotherapies, hydrotherapies, thermotherapies were applied aiming on a relaxation of the muscles and a reduction of pain. Patients were instructed in coping techniques like relaxationstrategies and distraction techniques. Patient education with advices how to avoid pain producing movements and activities was a further element of the rehabilitation program. NSAIDs and analgesics were minimized as far as possible. The program was tailored individually to each patient. Finally, each patient was instructed in an individual home rehabilitation program to be continued after discharge.

4.5. Measures

The diagnosis of OA was made based on the ACR criteria for OA of the hip or knee [*Altman 1986, Altman 1991*]. Inclusion criteria for knee OA were (a) knee pain for more than 25 of the last 30 days, (b) morning stiffness of less than 30 minutes and (c) crepitation in the knee or: (a) knee pain for more than 25 of the

last 30 days and (b) osteophytes on x-rays of the knees. Hip OA patients were included when there was (a) hip pain for more than 25 of the last 30 days and (b) at least two of the following three criteria: (c1) erythrocyte sedimentation rate <20mm/h, (c2) osteophytes on x-ray, or (c3) obliteration of joint space.

Pain and function was measured with the Western Ontario and McMaster Universities Osteoarthrtitis Index (WOMAC) [*Bellamy 1995*] and the Short-Form 36 (SF-36) [*Ware 1997*]. Primary outcome measures were the WOMAC scales for function and pain and the SF-36 scales for bodily pain and physical functioning. The patients were sent or given a set of questionnaires including these two instruments at the day of entry (baseline examination), at the day of discharge (approximately 1-month follow-up) and 3, 6, 9, 12, 24 months after baseline.

The WOMAC is a condition, i.e., OA-specific multidimensional measure of pain (5 items), stiffness (2 items) and physical functional ability (17 items) [*Bellamy 1988, Bellamy 1992, Bellamy 1995, Bellamy 1997*]. All 24 WOMAC items are rated in a numerical rating scale ranging from 0 (‘no symptoms/no limitation’) to 10 ('maximal symptoms/maximal limitation'), which is the format used in the German validation study [*Stucki 1996*]. Similar to the Visual Analogue Scale (VAS), this rating provides interval type data. The mean of the corresponding unweighted item scores results in the score of each scale and, thus, ranges also between 0 (no symptoms) and 10 (maximal symptoms). The global WOMAC score was calculated as the unweighted mean of all 24 items.

The SF-36 includes 8 multi-item scales containing 2 to 10 items each plus a single item to assess health transition[*Ware 1992, Ware 1997, Ware 1998*]. The scales cover the dimensions of physical functioning (unweighted mean of

10 items), role physical (4 items), bodily pain (2 items), general health (5 items), vitality (4 items), social functioning (2 items), role emotional (3 items) and mental health (5 items), ranging from 0 ('maximal symptoms/maximal limitations/poor health') to 100 ('no symptoms/no limitations/excellent health'). We used the validated German version [*Bullinger 1995, Bullinger 1998*]. Studies show excellent psychometric properties and there seems to be good responsiveness to change in patients with rheumatic conditions, compared to some longer instruments [*Kantz 1992*]. The SF-36 allows scoring of the eight above mentioned scales and the construction of two summary scales, the physical component summary and the mental component summary scale.

Intake of pain medication was asked at baseline (entry into the clinic) and at each follow-up.

4.6. Data collection procedures

At entry in the rehabilitation clinic a trained clinician examined the patient and filled in the inclusion and exclusion criteria. If the patient was included, he was given and explained the self-administered questionnaires (WOMAC, SF-36). At the day of discharge patients were given a second set of questionnaires and informed about the questionnaires to be sent within the next 24 months. At 3, 6, 9, 12 and 24 months questionnaires were sent to the patients.

4.7. Analyses

Questionnaires were scored in accordance with the missing rules of the WOMAC user's guides, which specifies completion of at least four of the five pain items, one of the two stiffness items, and 14 of the 17 function items [*Bellamy 1995*]. Further, in concordance with the SF-36 Health Survey Manual and Interpretation Guide [*Ware 1997*], each scale of the SF-36 must have at least 50% of the corresponding items answered to be calculable. Patients with incalculable questionnaires either at baseline or at month 24 were excluded.

The responsiveness was assessed by the effect size (ES) [*Kazis 1989, Wright 1997*] at all follow-ups. The ES equals the mean change in score divided by the standard deviation of the baseline score:

$ES = \Delta / SD\ (baseline)$

ES = effect size, SD = standard deviation, Δ = difference between baseline and follow-up.

ES thus relates to the change of the mean and to the initial variation in score. An effect size of 0.2 is considered as a small (beneficial) effect, 0.5 a moderate effect and 0.8 a large effect of therapy [*Cohen 1988*].

95% confidence intervals for the ES were computed according to the equation for ‘Glass’s delta’ as described by Rosenthal [*Rosenthal R, 1994*]:

$\text{Glass's } \Delta = (n1+n2) / n1*n2 + \Delta^2 /2(n2-1)$

Glass's Δ is a measure for the standard error (SE). For calculating the confidence interval the following equation was used:

$$CI = ES +/- (1.96 * \text{Glass's } \Delta)$$

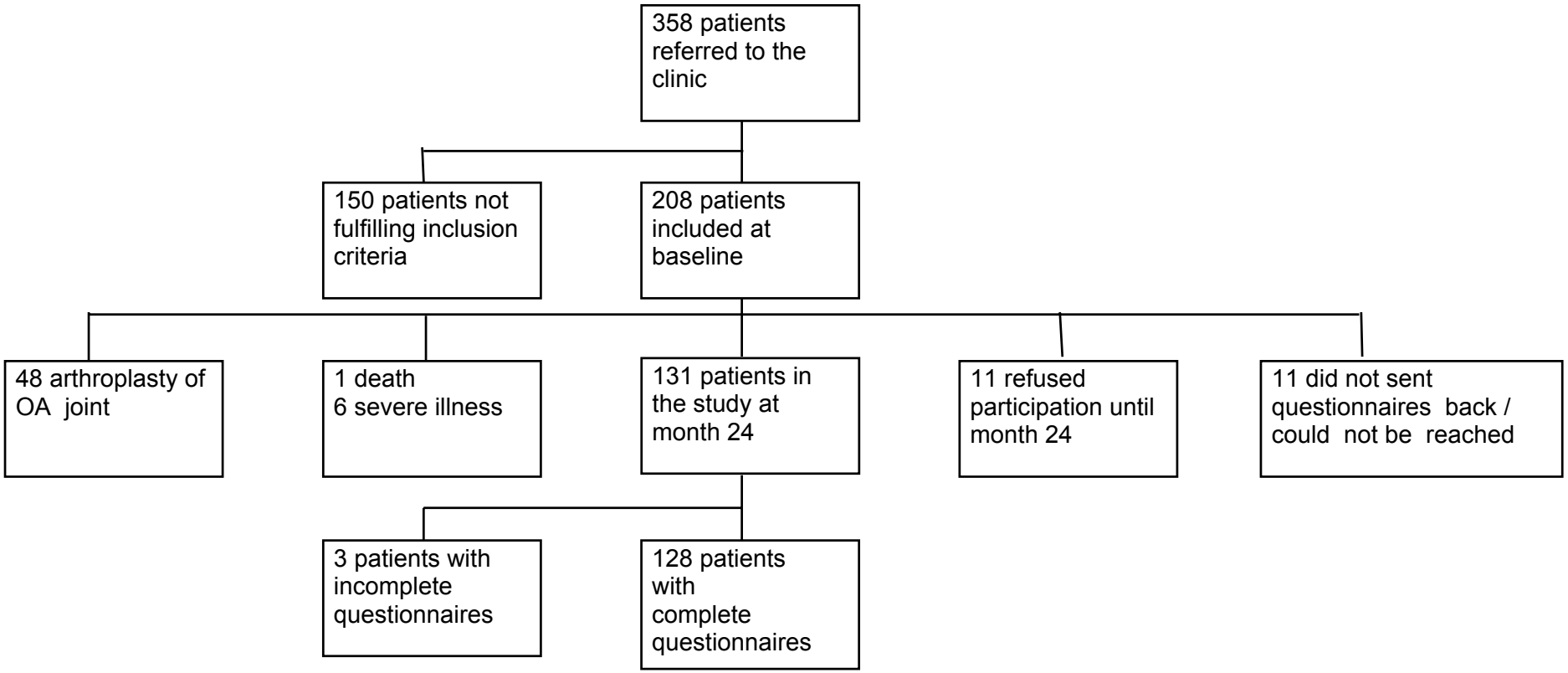
To examine the statistically significance of change in scores we tested the data for normality and performed paired t-tests if the data were normally distributed, otherwise, we used the Wilcoxon signed-ranks test. The null hypothesis was that there is no change. The type I error alpha was set at 0.05 and the power at 0.8. All data analysis were performed by using SPSS for windows, version 10.0. Follow-up scores were illustrated by simple follow-up graphs. A SF-36 'spider-figure' and a WOMAC 'spider-figure' demonstrated the comprehensive assessment of the health status between two time points [*Steiner 1998*].

5. Results

5.1. Patients

Figure 1 shows the patient flow and follow-up between registration and the 24-months follow-up. 358 patients were referred consecutively to the rehabilitation clinic between September 1997 and December 1999 with the diagnosis of OA. 150 patients did not fulfil the inclusion criteria. From the remaining 208 patients, 80 (38.5%) had dropped out until month 24 for the following reasons: 11 refused participation until month 24, 11 did not send the questionnaires back or could not be reached, 48 underwent joint arthroplasty, 6 had a severe illness,1 died and 3 could not be analyzed due to many missing values according to the missing rules of the WOMAC and the SF-36 resulting in 128 cases with complete data.

Figure 1: Patient flow from recruitment to the 24-months follow-up.



5.2. Patient characteristics

The baseline characteristics of all patients at baseline patients are listed in Table 1. The patients with complete follow-up data had a mean age of 63.9 years. 66.4% of these patients were female and 65.6% patients suffered from knee OA. An intake of NSAIDs, analgesics or both was reported by 66.4%.

The patients who did not fulfil inclusion criteria had a 4.9 years older mean age than the included patients. The patients, who underwent a joint arthroplasty during follow-up were more often female (79.2 % versus 66.4%) and did take more NSAIDS, analgesics or both (75.1% versus 66.4%) as compared to the included patients. The comparison showed also slightly worse mean scores in the WOMAC scales pain and function (significant group differences only in function, t-test, $p<0.05$). The costs of rehabilitation were covered by private health insurance's in 15%, by national health insurance's in 55% and by a combination of these two (in Switzerland called 'semi-private') in 30% of patients.

Table 1: Baseline characteristics of all patients referred to the rehabilitation clinic with hip or knee OA (n=358).

	Patients with analyzable follow-up	Not included patients	All drop-outs	Drop-outs due to joint replacement
Number	128	150	80	48
Mean age (+/- SD*) in years	63.9 (+/- 9.6)	68.8 (+/-11.4)	65.0 (+/- 11.3)	64.9(+/- 9.8)
Female (%)	66.4	70.0	68.7	79.2
Male (%)	33.6	30.0	31.3	20.8
OA knee (%)	65.6	-	37.5	33.3
OA hip (%)	34.4	-	62.5	67.7
Medication at baseline				
NSAID (%)	60.2	-	61.3	66.7
Analgesic (%)	3.9	-	5.1	4.2
NSAID & Analgesic (%)	2.3	-	3.8	4.2
Chondroitinsulfate (%)	3.9	-	6.4	4.2
WOMAC pain	4.49	-	4.95	4.91
WOMAC stiffness	4.55	-	5.12	4.74
WOMAC function	4.30	-	5.29	5.08
SF-36 PCS	30.3	-	28.4	29.1
SF-36 MCS	49.3	-	46.4	48.2

*SD = standard deviation

5.3. Responsiveness Statistics

Table 2 and table 3 summarize the responsiveness of the rehabilitation at the end of rehabilitation, and at 3, 6, 9, 12 and 24 months in comparison to baseline. Testing for normality did not allow to perform t-tests for all scales and so we used the Wilcoxon signed-rank test for significance.

The patients showed moderate beneficial effects, i.e. ES around 0.5 [Cohen 1988], in the primary outcome variable pain and small to moderate effects in the primary outcome variable physical functioning at the end of rehabilitation as measured both with the condition specific WOMAC questionnaire and the generic instrument SF-36 (ES in the WOMAC pain scale was 0.56 and in the SF- 36 bodily pain scale 0.52; ES in the WOMAC function scale was 0.44 and in the SF-36 physical functioning scale 0.30).

Different from the moderate effect in pain, there were only small to moderate effects regarding stiffness (WOMAC stiffness scale ES=0.38) and small effects in the SF-36 role physical scale (ES=0.25). The general health scale of the SF-36 showed almost no effect (ES=0.11).

According to the effects in the subscales, moderate effects at the end of the intervention were also seen in the global WOMAC score (ES=0.49) which is composed by pain, function and stiffness and in the physical component summary of the SF-36 (ES=0.37) which integrates physical functioning, role physical, bodily pain and general health.

Significant but only minor effects were seen in three of the four SF-36 scales measuring domains of the mental health (vitality ES=0.25, social functioning

ES=0.23 and mental health ES=0.19). The SF-36 role emotional scale showed no effect (ES=0.07).

Table 2: Outcome of hip or knee OA patients from baseline to the 6-months follow-up (n=128).

	Baseline	1 month		3 months		6 months	
	Mean (SD)	Mean (SD)	ES (CI)	Mean (SD)	ES (CI)	Mean (SD)	ES (CI)
WOMAC							
Pain	4.49 (2.18)	3.27* (1.98)	0.56 (0.52;0.60)	3.49* (2.29)	0.46 (0.42;0.50)	3.93* (2.22)	0.26 (0.22;0.30)
Stiffness	4.55 (2.61)	3.56* (2.21)	0.38 (0.34;0.42)	3.99* (2.34)	0.21 (0.17;0.26)	4.31 (2.54)	0.09 (0.05;0.13)
Function	4.30 (2.17)	3.34* (1.99)	0.44 (0.40;0.48)	3.60* (2.22)	0.32 (0.28;0.36)	3.96* (2.18)	0.16 (0.12;0.20)
Global	4.36 (2.10)	3.34* (1.93)	0.49 (0.44;0.53)	3.61* (2.18)	0.36 (0.32;0.40)	4.00* (2.13)	0.17 (0.13;0.21)
SF-36							
PF	39.8 (20.1)	45.8* (21.8)	0.30 (0.26;0.34)	44.1* (22.0)	0.21 (0.17;0.25)	43.5* (21.6)	0.18 (0.14;0.22)
RP	24.6 (33.6)	32.9* (39.9)	0.25 (0.21;0.29)	36.3* (41.7)	0.35 (0.31;0.39)	30.8 (38.7)	0.18 (0.14;0.22)
BP	29.9 (17.1)	38.8* (18.2)	0.52 (0.48;0.56)	41.8* (19.8)	0.70 (0.65;0.74)	36.3* (20.0)	0.37 (0.33;0.42)
GH	57.2 (19.9)	59.4 (18.8)	0.11 (0.07;0.15)	56.4 (20.6)	-0.04 (-0.08;0.00)	55.1 (19.0)	-0.11 (-0.15;-0.07)
VT	45.9 (19.4)	50.8* (19.4)	0.25 (0.21;0.29)	49.5* (19.8)	0.19 (0.15;0.23)	45.7 (21.3)	-0.01 (-0.05;0.03)
SF	69.4 (25.6)	75.2* (24.6)	0.23 (0.19;0.27)	72.8 (22.7)	0.13 (0.09;0.17)	67.9 (25.5)	-0.06 (-0.10;-0.02)
RE	53.9 (44.5)	56.8 (45.5)	0.07 (0.03;0.11)	59.4 (43.5)	0.12 (0.08;0.16)	54.6 (46.5)	0.02 (-0.02;0.06)
MH	66.3 (18.8)	69.8* (17.9)	0.19 (0.15;0.23)	68.4 (17.8)	0.11 (0.07;0.15)	65.0 (20.4)	-0.07 (-0.11;-0.03)
PCS	30.3 (8.30)	33.4* (8.50)	0.37 (0.33;0.41)	33.3* (9.50)	0.36 (0.32;0.40)	32.4* (9.10)	0.25 (0.21;0.29)
MCS	49.2 (11.9)	50.7 (11.5)	0.13 (0.09;0.17)	50.0 (11.1)	0.07 (0.03;0.11)	48.1 (12.9)	-0.09 (-0.13;-0.05)

Legend to table 2:

SD = standard deviation (written in parenthesis). ES = effect size = (score at follow-up – score at baseline) / standard deviation at baseline.

95% confidence intervals are written in parenthesis. PF=Physical Functioning, RF=Role Physical, BP=Bodily Pain, GH=General Health, VT=Vitality, SF=Social Functioning, RE=Role Emotional, MH=Mental Health, PCS=Physical Component Scale, MCS=Mental Component Scale. WOMAC scales: 0 = no symptoms, 10 = maximal symptoms. SF-36 scales: 0 = worst health,100 = best health.

Test for significance: Wilcoxon signed ranks test, p one-tailed. Null hypothesis: difference (mean at follow-up minus mean at baseline = entry into the clinic) = zero; $p > 0.05$: we accept the null hypothesis at type I error = 5%, e.g. there is no difference.

*: $p<0.05$.

Table 3: Outcome of hip or knee OA patients from the 9-months to the 24-months follow-up (n=128).

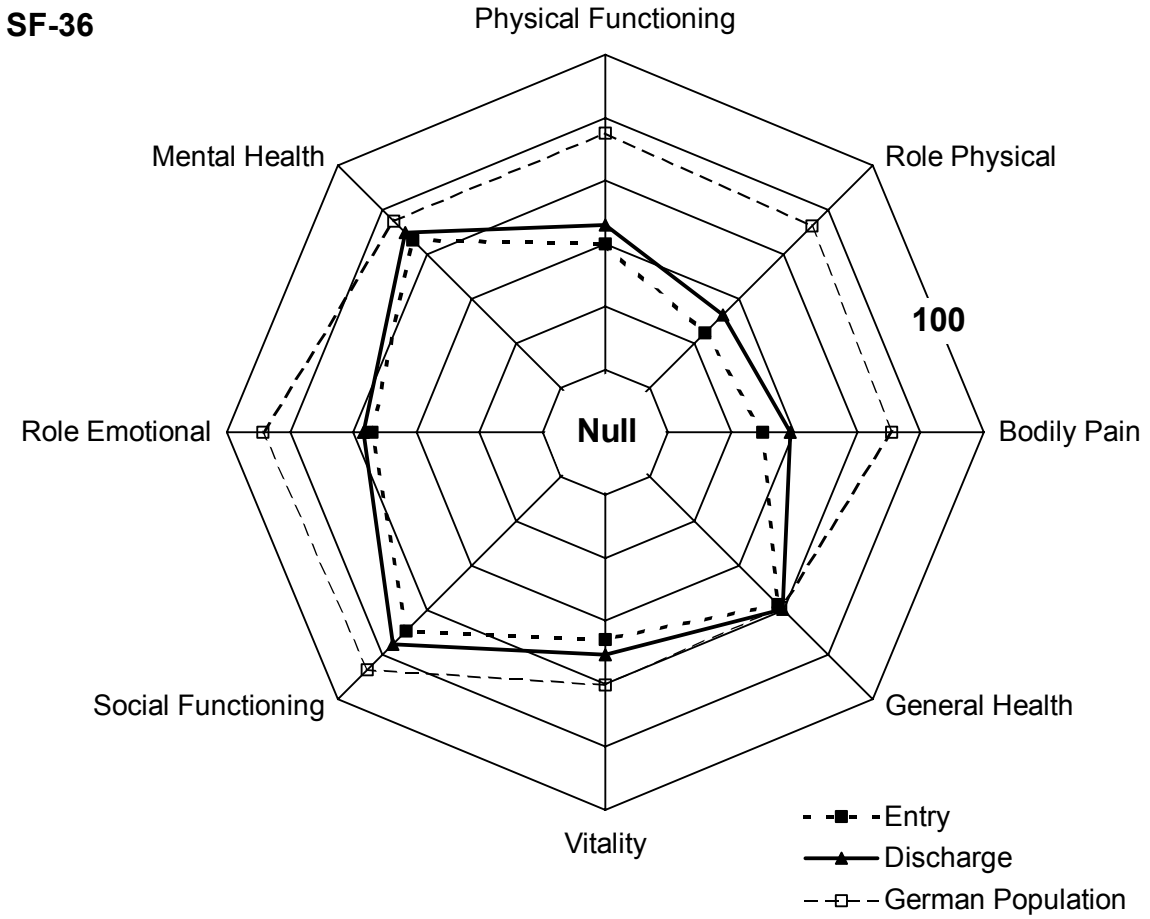
	9 months		12 months		24 months	
	Mean (SD)	ES (CI)	Mean (SD)	ES (CI)	Mean (SD)	ES (CI)
WOMAC						
Pain	3.76* (2.34)	0.33 (0.29;0.38)	3.95* (2.38)	0.25 (0.21;0.29)	3.93* (2.39)	0.26 (0.22;0.30)
Stiffness	4.22 (2.57)	0.13 (0.09;0.17)	4.28 (2.41)	0.10 (0.06;0.14)	4.37 (2.49)	0.07 (0.03;0.11)
Function	4.02 (2.37)	0.13 (0.09;0.17)	4.14 (2.31)	0.07 (0.03;0.11)	4.31 (2.36)	0.00 (-0.04;0.04)
Global	3.99 (2.32)	0.18 (0.14.0.22)	4.11 (2.27)	0.12 (0.08;0.16)	4.23 (2.31)	0.06 (0.02;0.10)
SF-36						
PF	39.1 (22.5)	-0.03 (-0.07;0.01)	41.3 (23.3)	0.07 (0.03;0.11)	42.0 (24.8)	0.11 (0.07;0.15)
RP	29.3 (40.1)	0.14 (0.10;0.18)	29.9 (38.6)	0.16 (0.12;0.20)	35.7* (41.1)	0.33 (0.29;0.37)
BP	39.9* (22.5)	0.58 (0.54;0.63)	38.5* (20.9)	0.50 (0.46;0.55)	38.3* (22.0)	0.49 (0.45;0.53)
GH	52.8* (18.9	-0.22 (-0.26;-0.18)	56.5 (20.6)	-0.04 (-0.08;0.00)	54.8 (19.5)	-0.12 (-0.16;-0.08)
VT	46.8 (20.3)	0.05 (0.01;0.09)	46.1 (20.9)	0.01 (-0.03;0.05)	47.0 (22.1)	0.06 (0.02;0.10)
SF	69.4 (26.3)	0.00 (-0.04;0.04)	68.2 (26.8)	-0.05 (-0.09;-0.01)	67.4 (27.4)	-0.08 (-0.12;-0.04)
RE	57.0 (46.3)	0.07 (0.03;0.11)	54.6 (45.0)	0.02 (-0.02;0.06)	57.3 (47.1)	0.08 (0.04;0.12)
MH	64.7 (19.0)	-0.09 (-0.13;-0.05)	65.7 (18.8)	-0.03 (-0.07;0.01)	64.4 (20.5)	-0.10 (-0.14;-0.06)
PCS	31.4 (9.20)	0.13 (0.09;0.17)	32.3* (9.6)	0.24 (0.20;0.28)	32.8* (10.6)	0.30 (0.26;0.34)
MCS	49.1 (12.09	-0.01(-0.05;0.03)	48.6 (11.5)	-0.05 (-0.09;-0.01)	48.1 (12.7)	-0.09 (-0.13;-0.05)

Legend: Explanations are given in legend to table 2.

Figure 2 displays the change of the SF-36 scales between baseline (entry into the clinic) and discharge graphically and compares the OA patients to the German population of the same age. Besides the improvement in some of the SF-36 subscales this figure demonstrates, that the most affected dimensions of health in patients with OA are physical functioning, role physical, and bodily pain. The self-assessment in general health, mental health and social functioning differed only little from the general German population.

Figure 3 shows the change of the WOMAC scales function, pain and stiffness and the change of the global WOMAC score, which integrates function, pain and stiffness, between baseline and discharge.

Figure 2: Global health status of hip and knee OA patients by the SF-36 scales at baseline and at discharge (n=128).



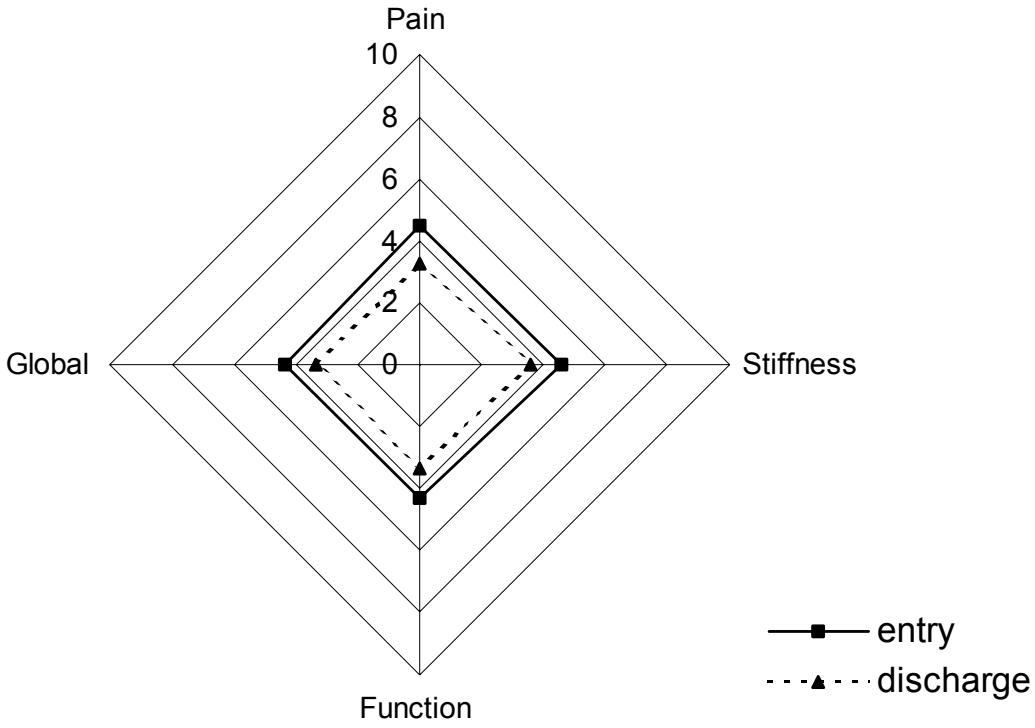
Entry into the clinic = baseline

Discharge of the clinic = approximately 1month after baseline.

A larger 'spider ' figure represents a better health status.

0 = worst health, 100 = best health

Figure 3: Condition specific health status of hip and knee OA patients by the WOMAC scales at baseline and at discharge (n=128).



Entry into the clinic = baseline.

Discharge of the clinic = approximately 1 month after baseline.

A larger ‘spider ‘ figure represents a worth health status.

0 = no symptoms, 10 = maximal symptoms

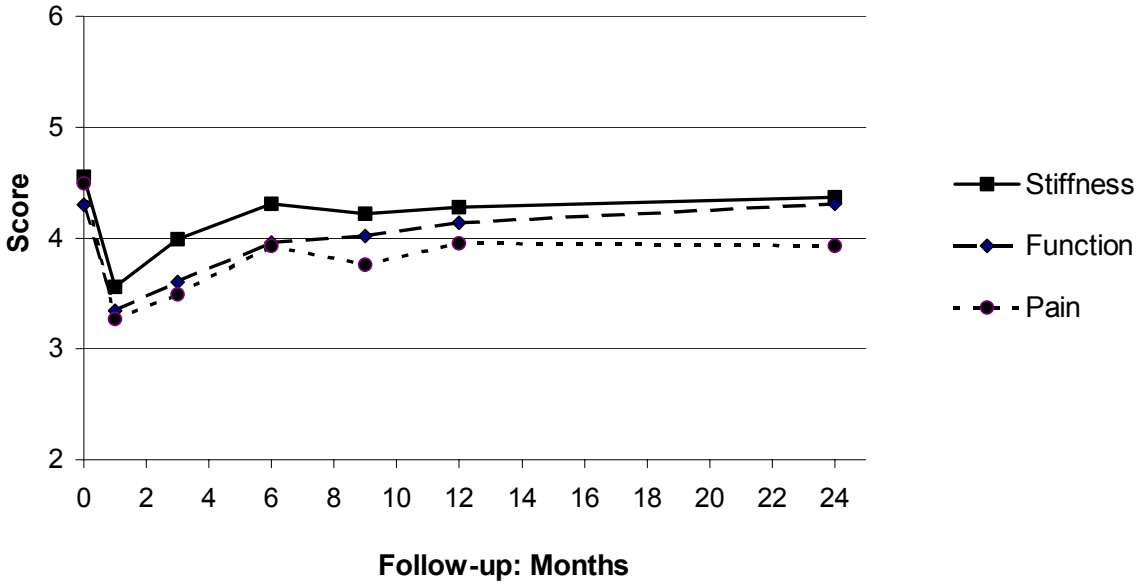
Figures 4, 5 and 6 show the course as measured with the WOMAC and SF-36 over two years.

While the effect in pain reduction remained until month 24 (WOMAC: ES = 0.26; SF-36: ES=0.49), physical function deteriorated close to baseline values after 12 months (WOMAC function scale ES=0.07; SF-36 physical functioning scale ES=0.07).

Already at the end of rehabilitation, only small effects were observed in the SF-36 scales addressing vitality, social functioning and mental health, which almost disappeared at the 3-months follow-up: vitality ES=0.19, social functioning ES=0.13 and mental health ES = 0.11.

The intake of NSAIDs or Analgesics or both of them declined from 66.4% at baseline to 11.0% at the end of rehabilitation.

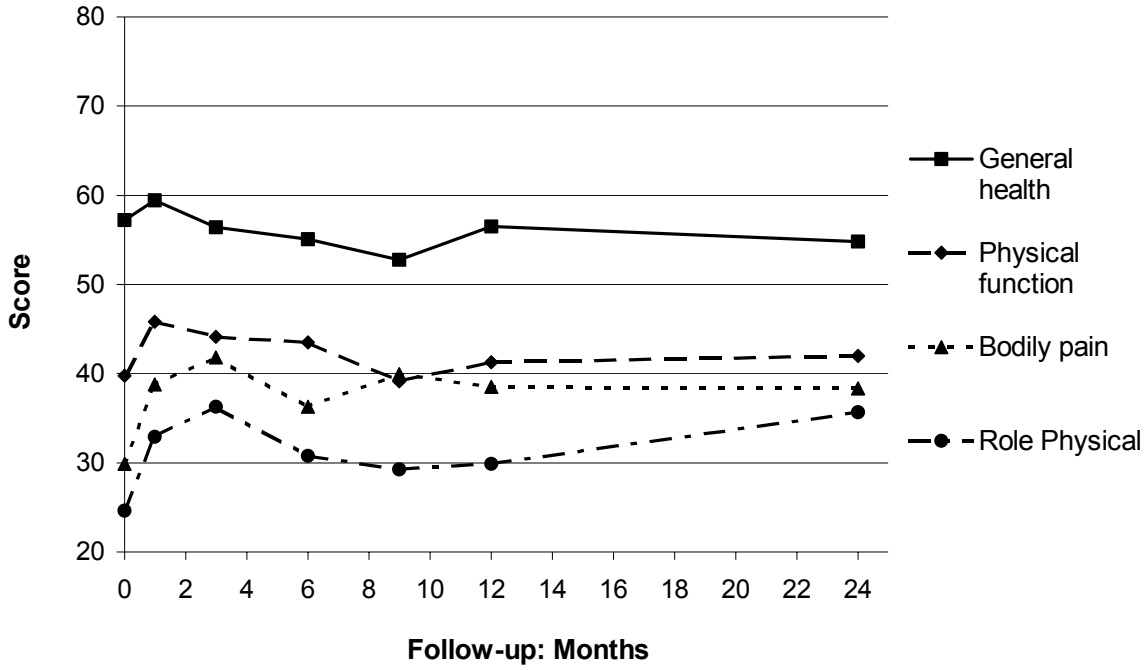
Figure 4: 2 year follow-up of hip and knee OA patients by WOMAC scales (n=128).



Patients were assessed with the WOMAC at baseline (=entry into the clinic), at discharge (one month after baseline) and at month 3, 6, 9, 12, 24.

0 = no symptoms, 10 = maximal symptoms.

Figure 5: 2 year follow-up of hip and knee OA patients by SF-36 physical health scales (n=128).

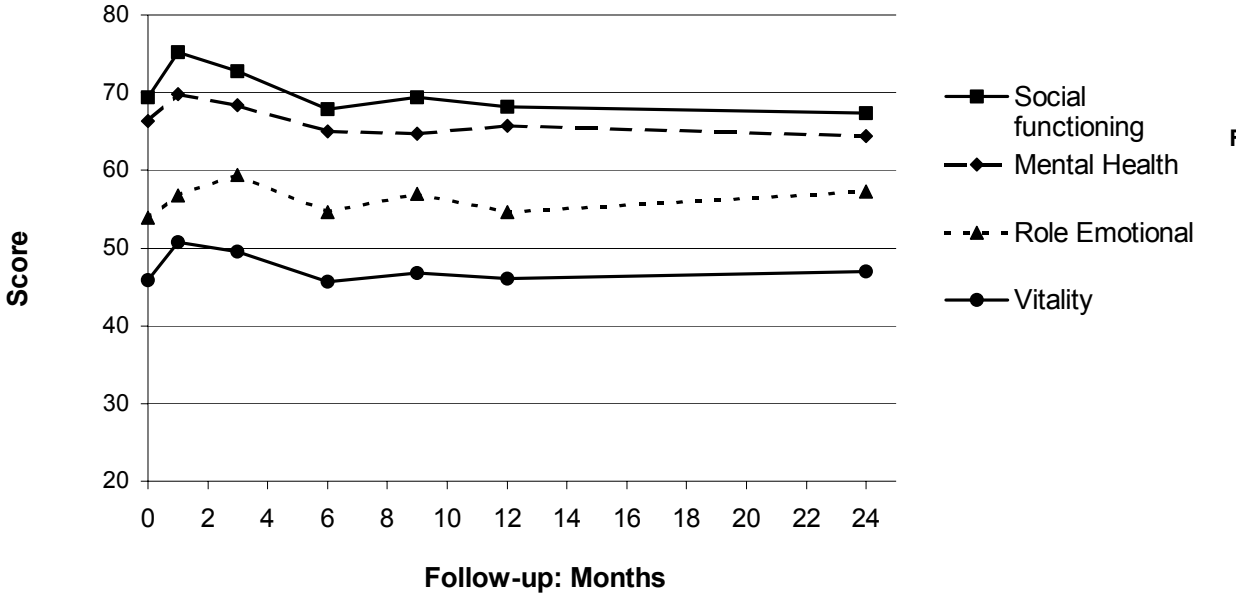


Patients were assessed with the SF-36 at baseline (=entry into the clinic), at discharge (one month after baseline) and at month 3, 6, 9, 12, 24.

0 = worst health / maximal symptoms

100 = best health / no symptoms.

Figure 6: 2 year follow-up of hip and knee OA patients by SF-36 mental health scales (n=128).



Patients were assessed with the SF-36 at baseline (=entry into the clinic), at discharge (one month after baseline) and at month 3, 6, 9, 12, 24.

0 = worst health / maximal symptoms

100 = best health / no symptoms.

6. Discussion

In this observational follow-up study of patients with hip or knee OA undergoing a comprehensive rehabilitation intervention, a moderate and long-term improvement of pain and a moderate but mid-term improvement of physical function was detected.

The effect sizes at the end of rehabilitation in this study layed in the same range as in clinical trials with exercise therapy. In a systemic review from 1999, van Baar found three OA exercise therapy studies with good validity [*Van Baar 1999*]. The first of these studies [*Van Baar 1998*] showed an ES of 0.58 for pain measured with a visual analog scale and an ES of 0.26 for self-reported disability measured with the IRGL questionnaire (Influence of Rheumatic Disease on General Health and Lifestyle) after 12 weeks of treatment. The second and third study [*Ettinger 1997*], which were performed in one setting, used the knee pain scale as measure for pain and an especially developed questionnaire for self-report physical disability. After 18 months, the ES for pain were 0.47 and 0.31 and for self-reported disability the ES were 0.41 and 0.36. Although the magnitude of ES is influenced by the responsiveness of the outcome instruments, it seems likely that the 4-week comprehensive inpatient intervention in this study has a comparable effect to these three exercise interventions.

There was no persisting beneficial effect in function measurement after one year although patients have been instructed to an individual home-based exercise program. This is consistent with the results of a one-year follow-up of patients who participated in a program of supervised fitness walking and supportive patient education [*Sullivan 1998*]. In that study, the patients showed a significant

improvement of self-reported disability measured with the AIMS (Arthritis Impact Measurement scale) after a 8-week program. They were encouraged to continue their walking. Nevertheless, after one year their was no statistical difference in disability between the walking group and the control group. The authors described the long-term adherence to the walking as low. However, detailed data of adherence were not published. Also Ettinger described a low long-term compliance [*Ettinger 1997*]. In that trial, the first group performed a 3-months facility-based aerobic exercise training, the second group a 3-months facility-based resistance exercise training and the third group received a 3-months health education program. These interventions were followed by a 15-months home based program. Compliance with the exercise interventions declined from 85% after 3 months to 50% after 18 months. In general practice the adherence to home exercises might be quite lower.

We suggest, that also in our study low adherence to the instructed home-based program may be a possible contributor for the disappointing long-term outcome in physical functioning.

To maintain a long-lasting functional benefit, exercises probably need to be continued for life-time. Exercise behavior before starting an exercise program was described as the strongest predictor for compliance [*Rejeski 1997*]. The problem seems to be how to encourage a former sedentary person to do exercises. Short booster sessions, self-help groups or the use of patient diaries may be helpful. Future research should address the problem of long-term adherence to exercise.

When interpreting the results regarding physical function, one needs to keep in mind the progressive nature of OA. Therefore, even a stable physical function

may represent a treatment success. However, this could only be proven in a randomized controlled trial.

The long-lasting pain reduction in this study stayed in contrast to the mid-term benefit in physical functioning. This result is in line with a recently published nine months' follow up exercise therapy study in patient with OA of the hip or knee [Van Baar 2001]. After 24 weeks (12 weeks after completion of treatment) that study found a decreased, but still significant pain reduction, whereas the improved observed disability had declined to not significant values.

In this study one reason for the long-lasting beneficial effect in pain might be, that the patients learned how to reduce and how to avoid pain (coping). They did not only learn possibilities of physical therapy and medication, but also psychological skills to reduce pain by relaxation strategies and distraction techniques. They were educated in avoiding pain producing movements and activities. If these combined therapy approaches were the reason for the long-term pain benefit, than we would expect a smaller effect in a single exercise program than in this multidisciplinary program.

Limitations of the study design, which excluded patients who underwent a joint arthroplasty during follow-up, could also contribute to the result of long-lasting pain relief. The progression of OA is very heterogeneous [*Dieppe 1997*]. The majority of patients deteriorate with time, but some patients stay at the same level for several years or even improve. The excluded patients who underwent joint arthroplasty were likely to have worsened in pain. Analogously, 'well-responders' to the rehabilitation program were selected to be assessed at the end of the study. Consequently, the pain reduction after 24 months might be overestimated.

However, this effect might be small, because the operated patients showed already more pain at baseline.

The exclusion of patients with joint arthroplasty might have overestimated the pain reduction more than the functional improvement in this study, because pain seems to be the most important indicator for OA intervention [*Williams 1996*]. The next logical step of intervention after an unsuccessful inpatient rehabilitation is joint arthroplasty. If the decision to undergo joint arthroplasty is driven more by pain than by self-reported disability, then the pain reduction after 24 months in our study is more overestimated than the benefit in physical function, because the patients with a deterioration of pain had been more likely to drop out of the sample.

During the rehabilitation intervention the intake of NSAIDs and analgesics was minimized as far as possible and patients were educated to reduce or stop taking medication if pain improves. This strategy resulted in a 80% reduction of NSAIDs users at the end of rehabilitation. If the patients continued to follow these instructions. then an underestimation of the observed pain reduction would be likely.

Patients referred to the clinic with OA but not included in the study were 4.9 years older than the included patients. These difference may had been caused by exclusion criteria's such as "difficulties in completing questionnaires", "suffering from severe illness" or "joint arthroplasty planned within the next month". Accordingly, the excluded patients may had a worth health status, which could limit the generalizibility of this study.

Before implementing a treatment into practice, the clinician wants to know if a statistically significant effect is clinically meaningful. Therefore the concept of minimal clinically important difference (MCID) can be helpful. The MCID is the minimal effect that patients consider clinically perceptible. For the WOMAC pain

scale an improvement of 18% of the mean baseline value was described to be the MCID [*Angst 2001 A*]. In our study, 18 % of the mean baseline value was 0.81 points. The minimal clinical important ES in this study can be calculated as follows: ES = 0.81 / SD (of mean baseline) = 0.37. Up to the 3-months follow-up, the ES was larger than 0.37. At the later follow-up, the effect measured with the WOMAC pain scale remained statistically significant but the ES is smaller than 0.37 and, therefore, these effects may not be clinically meaningful.

When planning a study it is important to know, if a minimal clinical important difference can be detected by the chosen outcome instruments. Therefore the smallest detectable difference (SDD) should be calculated [*Angst 2001 A*]. In this study the SDD for improvement of pain measured with the WOMAC was an ES of 0.35 (power=0.8. type I error=0.05). The SDD in this study was smaller than the MCID. Thus, the WOMAC pain scale was enough sensitive to detect the MCID in pain.

Like before in this study the WOMAC was more responsive to the improvement in physical function after rehabilitation compared to the SF-36 [*Angst 2001 A*]. The improvement in pain showed about the same ES at the end of rehabilitation in both instruments, but after 3 months and later the SF-36 was more responsive to pain. This was consistent to prior analysis of the responsiveness of these instruments after rehabilitation, which found a better responsiveness of the WOMAC to functional impairment, but a better responsiveness to pain after three months of the SF-36 [*Angst 2001 A*]. The SF-36 bodily pain scale seems to be more adequate to detect a long-term pain benefit, whereas the WOMAC seems to be the superior instrument for the measure of self-reported disability. This should be considered in the choice of outcome instruments in future clinical trials.

7. Conclusion

In conclusion, comprehensive inpatient rehabilitation of patients with hip or knee OA resulted in a substantial long-term reduction of pain which declined only little with time, and a mid-term benefit in physical function. Future follow-up studies should examine the adherence to instructed exercise programs and when randomized could answer the question whether comprehensive rehabilitation programs have a predictive effect by sabilizing physical function. The encouraging long-term benefit in pain in this study should be considered in discussions about cost effectiveness of comprehensive rehabilitation programs.

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9. Attachment (Anhang)

9.1. German Version of the Western Ontario and McMaster Universities Osteoarthrtitis Index (WOMAC)

ANLEITUNG FÜR PATIENTEN

Wir bitten Sie die folgenden Fragen nach dem unten stehenden Muster zu beantworten. Schreiben Sie ein "X" in das zutreffende Kästchen.

Bitte beachten Sie:

1. Wenn Sie das "X" am linken Ende der Skala setzen, zum Beispiel

keine Schmerzen	X										extreme Schmerzen

dann bedeutet das, dass Sie keine Schmerzen haben.

2. Wenn Sie das "X" am rechten Ende der Skala setzen

keine Schmerzen										X	extreme Schmerzen

dann bedeutet das, dass Sie extreme Schmerzen haben.

3. Bitte beachten Sie:

a) Je weiter rechts Sie das "X" ankreuzen, umso mehr Schmerzen haben Sie.
b) Je weiter links Sie das "X" ankreuzen, umso weniger Schmerzen haben Sie.

Sie werden nun gebeten, nach diesem Muster die Stärke Ihrer Schmerzen, Ihrer Steifigkeit oder Behinderung anzugeben. Bitte vergessen Sie nicht, je mehr rechts Sie das "X" ankreuzen, umso mehr Schmerzen. Steifigkeit oder Behinderung haben Sie.

A SCHMERZFRAGEN

Die folgenden Fragen beziehen sich auf die Stärke der Schmerzen, die Sie in Ihrem "**Problemgelenk"** (Hüfte oder Knie) haben. Bitte geben Sie für jede Frage die Stärke der Schmerzen an, die Sie in den letzten 2 Tagen verspürt haben. (Bitte kreuzen Sie die zutreffenden Kästchen an).

Wie starke Schmerzen haben Sie beim

1. Gehen auf ebenem Boden

keine Schmerzen											extreme Schmerzen

2. Treppen hinauf- oder hinuntersteigen

keine Schmerzen											extreme Schmerzen

3. Nachts im Bett

keine Schmerzen											extreme Schmerzen

4. Sitzen oder liegen

keine Schmerzen											extreme Schmerzen

5. Aufrecht stehen

keine Schmerzen											extreme Schmerzen

B FRAGEN ZUR STEIFIGKEIT

Die folgenden Fragen beziehen sich auf die Steifigkeit (nicht die Schmerzen) in Ihrem **"Problemgelenk"**. Steifigkeit ist ein Gefühl von Einschränkung oder Langsamkeit in der Beweglichkeit, wenn Sie Ihre Gelenke bewegen. Bitte geben Sie für jede Frage die Stärke der Steifigkeit an, die Sie in den letzten 2 Tagen verspürt haben. (Bitte kreuzen Sie die zutreffenden Kästchen an).

1. Wie stark ist die Steifigkeit gerade nach dem Erwachen am Morgen?

keine Steifigkeit											extreme Steifigkeit

2. Wie stark ist Ih Steifigeit nach Sitzen, Liegen oder Ausruhen im späteren Verlauf des Tages?

keine Steifigkeit											extreme Steifigkeit

C FRAGEN ZUR KÖRPERLICHEN TÄTIGKEIT

Die folgenden Fragen beziehen sich auf Ihre körperliche Tätigkeit. Damit ist Ihre Fähigkeit gemeint, sich im Alltag zu bewegen und sich um sich selbst zu kümmern. Bitte geben Sie für jede der folgenden Aktivitäten den Schwierigkeitsgrad an, den Sie in den letzten 2 Tagen wegen Beschwerden in Ihrem **"Problemgelenk"** gespürt haben.
(Bitte kreuzen Sie die zutreffenden Kästchen an).

Wie gross sind Ihre Schwierigkeiten beim:

1. Treppen hinuntersteigen

keine Schwierigkeiten											extreme Schwierigkeiten

2. Treppen hinaufsteigen

keine Schwierigkeiten											extreme Schwierigkeiten

3. Aufstehen vom Sitzen

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

4. Stehen

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

5. Sich zum Boden bücken

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

6. Gehen auf ebenem Boden

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

7. Einsteigen ins Auto/Aussteigen aus dem Auto

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

8. Einkaufen gehen

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

9. Socken/Strümpfe anziehen

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

10. Aufstehen vom Bett

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

11. Socken/Strümpfe ausziehen

keine Schwierigkeiten | | | | | | | | | | | extreme Schwierigkeiten

12. Liegen im Bett

keine Schwierigkeiten											extreme Schwierigkeiten

13. Ins Bad/aus dem Bad steigen

keine Schwierigkeiten											extreme Schwierigkeiten

14. Sitzen

keine Schwierigkeiten											extreme Schwierigkeiten

15. Sich auf die Toilette setzen/Aufstehen von der Toilette

keine Schwierigkeiten											extreme Schwierigkeiten

16. Anstrengende Hausarbeiten

keine Schwierigkeiten											extreme Schwierigkeiten

17. Leichte Hausarbeiten

keine Schwierigkeiten											extreme Schwierigkeiten

9.2. German version of the generic health questionnaire Short-Form 36

(SF- 36)

1. Wie würden Sie Ihren Gesundheitszustand im Allgemeinen beschreiben ?
Ausgezeichnet ❑ Sehr gut ❑ Gut ❑ Weniger gut ❑ Schlecht ❑

2. Im Vergleich zum vergangenen Jahr, wie würden Sie Ihren derzeitigen Gesundheitszustand
beschreiben ?

Derzeit viel besser als vor einem Jahr	❑
Derzeit etwas besser als vor einem Jahr	❑
Etwa so wie vor einem Jahr	❑
Derzeit etwas schlechter als vor einem Jahr	❑
Derzeit viel schlechter als vor einem Jahr	❑

Im folgenden sind einige Tätigkeiten beschrieben, die Sie vielleicht an einem normalen Tag ausüben.
Sind Sie durch Ihren derzeitigen Gesundheitszustand bei diesen Tätigkeiten eingeschränkt?
Wenn ja, wie stark ?

Tätigkeiten	**stark eingeschränkt**	**etwas eingeschränkt**	**garnicht eingeschränkt**
3. anstrengende Tätigkeiten, z. B. schnell laufen, schwere Gegenstände heben, anstrengenden Sport treiben	❑	❑	❑
4. mittelschwere Tätigkeiten, z.B. einen Tisch verschieben, Staubsaugen, Kegeln, Golf spielen	❑	❑	❑
5. Einkaufstaschen heben oder tragen	❑	❑	❑
6. mehrere Treppenabsätze steigen	❑	❑	❑
7.einen Treppenabsatz steigen	❑	❑	❑
8. sich **beugen**, **knien**, **bücken**	❑	❑	❑
9. mehr als 1 Kilometer zu Fuß gehen	❑	❑	❑
10. mehrere Straßenkreuzungen weit zu Fuß gehen	❑	❑	❑
11. eine Straßenkreuzung weit zu Fuß gehen	❑	❑	❑
12. sich **baden** oder **anziehen**	❑	❑	❑

Hatten Sie in den vergangenen 4 Wochen aufgrund Ihrer körperlichen Gesundheit irgendwelche Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause ?

Schwierigkeiten	**ja**	**nein**
13. Ich konnte nicht **so lange** wie üblich tätig sein	❑	❑
14. Ich habe **weniger geschafft** als ich wollte	❑	❑
15. Ich konnte **nur bestimmte** Dinge tun	❑	❑
16. Ich hatte **Schwierigkeiten** bei der Ausführung (z.B. ich mußte mich besonders anstrengen)	❑	❑

Hatten Sie in den vergangenen 4 Wochen aufgrund seelischer Probleme irgendwelcher Schwierigkeiten bei der Arbeit oder anderen alltäglichen Tätigkeiten im Beruf bzw. zu Hause (z.B. weil Sie sich niedergeschlagen oder ängstlich fühlten)?

Schwierigkeiten	**ja**	**nein**
17. Ich konnte nicht **so lange** wie üblich tätig sein	❑	❑
18. Ich habe **weniger geschafft** als ich wollte	❑	❑
19. Ich konnte nicht so **sorgfältig** wie üblich arbeiten	❑	❑

20. Wie sehr haben Ihre körperliche Gesundheit oder seelischen Probleme in den vergangenen 4 Wochen Ihre normale Kontakte zu Familienangehörigen. Nachbarn oder zum Bekanntenkreis beeinträchtigt?
Überhaupt nicht ❑ Etwas ❑ Mäßig ❑ Ziemlich ❑ Sehr ❑

21. Wie stark waren Ihre Schmerzen in den vergangenen 4 Wochen ?
Ich hatte keine Schmerzen ❑ Sehr leicht ❑ Leicht ❑
Mäßig ❑ Stark ❑ Sehr stark ❑

22. Inwieweit haben die Schmerzen Sie in den vergangenen 4 Wochen bei der Ausübung Ihrer Alltagstätigkeiten zu Hause und im Beruf behindert ?
Überhaupt nicht ❑ Ein bißchen ❑ Mäßig ❑ Ziemlich ❑ Sehr ❑

Wie oft waren Sie in den vergangenen 4 Wochen

	immer	**meist-stens**	**ziemlich oft**	**manch-mal**	**selten**	**nie**
23. voller Schwung ?	❑	❑	❑	❑	❑	❑
24. sehr nervös ?	❑	❑	❑	❑	❑	❑
25. so niedergeschlagen.daß Sie nichts aufheitern konnte ?	❑	❑	❑	❑	❑	❑
26. ruhig und gelassen ?	❑	❑	❑	❑	❑	❑
27. voller Energie ?	❑	❑	❑	❑	❑	❑
28. entmutigt und traurig ?	❑	❑	❑	❑	❑	❑
29. erschöpft ?	❑	❑	❑	❑	❑	❑
30. glücklich ?	❑	❑	❑	❑	❑	❑
31. müde ?	❑	❑	❑	❑	❑	❑

32. Wie häufig haben Ihre körperliche Gesundheit oder seelische Probleme in den vergangenen 4 Wochen Ihre Kontakte zu anderen Menschen (Besuche bei Freunden, Verwandten usw.) beeinträchtigt?
immer ❑ meistens ❑ manchmal ❑ selten ❑ nie ❑

Inwieweit trifft jede der folgenden Aussagen auf Sie zu ?

	trifft ganz zu	trifft weitgehend zu	weiß nicht	trifft weitgehend nicht zu	trifft nicht zu
33. Ich scheine etwas leichter als andere krank zu werden	❑	❑	❑	❑	❑
34. Ich bin genauso gesund wie alle. anderen die ich kenne	❑	❑	❑	❑	❑
35. Ich erwarte. daß meine Gesundheit nachläßt	❑	❑	❑	❑	❑
36. Ich erfreue mich ausgezeichneter Gesundheit	❑	❑	❑	❑	❑

9.3. Curriculum vitae (Lebenslauf)

Angaben zur Person

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Schulbildung

1974 - 1978	Grundschule in München
1978 - 1987	math. nat. Gymnasium in München

Zivildienst

04/87 – 03/89	Behindertenbetreuung und -pflege/Bayerische
	Landesschule für Körperbehinderte, München

Berufsausbildung

04/89 – 12/96	Studium der Humanmedizin an der Ludwig-Maximilians-
	Universität (LMU) München
10.12.1996	Abschluß der ärztlichen Prüfung, LMU München

Berufstätigkeit

01.01.1997 - 30.06.1998	Arzt im Praktikum/ Klinik für Physikalische Medizin
	und Rehabilitation der LMU München

01.07.1998 - 15.04.1999	Assistenzarzt/ Klinik für Physikalische Medizin und Rehabilitation der LMU München
16.04.1999 - 30.04.2000	Assistenzarzt/ Orthopädische Fachklinik „Rehaklinik Wiessee“
Seit 01.05.2000	Assistenzarzt und wissenschaftlicher Mitarbeiter/Klinik für Physikalische Medizin und Rehabilitation der LMU München

Zusatzqualifikationen

02.03.1995 - 20.03.1995	Akupunktur: China Shanghai International Training Center
07.03.1998 - 08.03.1998	Sonographie des Bewegungsapparates, Grundkurs
28.03.1998 - 29.03.1998	Sonographie des Bewegungsapparates, Aufbaukurs
09.05.1998 - 17.05.1998	Chirotherapie, Kurs 1 (60 Stunden)
13.08.1999 – 22.08.1999	Chirotherapie, Kurs 2 (60 Stunden)
05.07.2000 - 18.08.2000	„Program in Clinical Effectiveness“ der Harvard School of Public Health, Boston, USA.

Publikationen

Offenbaecher M, Weigl M, Glatzeder K, Ackenheil M, Schoeps P. Schlafstörungen und Müdigkeit bei Patienten mit Fibromyalgie und Arthrose. Phys Med Rehab Kuror 1999;9:151.

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