Chapter 1 introduces the theme of shoulder complaints, which are often seen in primary care. The reported incidence and 1-year prevalence ranges from 0.9 to 2.5% and from 4.7% to 46.7% respectively. About 75% to 80% of patients with shoulder pain show clinical signs of subacromial impingement, characterized by pain and functional restrictions mostly during overhead activities in daily life or sporting activities. Physiotherapy is often the first choice of treatment for SIS. Conclusions from systematic reviews favour the use of both, exercises and manual therapy, often as a combined treatment. Although short term results suggest that patients benefit from these interventions, evidence is scarce and information about the long term effect of manual therapy is lacking. The main focus of this thesis was to provide evidence about the short and long term effect of manual physiotherapy and exercises in the treatment of patients with subacromial impingement syndrome of the shoulder.

In chapter 2 results of a systematic review are presented and discussed. This review was conducted to get a comprehensive overview about the topic and to analyze the state of current evidence at that point in time in the field of interest. Our review identified 16 trials with sufficient quality investigating a great variety of interventions. A first surprising result was the strong evidence for an equal effect of exercise therapy and surgery which led to the statement, that patients with SIS should not undergo surgery unless having tried exercises beforehand. Secondly we found moderate evidence for an additional effect of manual therapy on pain when added to an exercise program and for a similar effect of physiotherapy and exercises of which both seem to be more effective than no intervention. However, conclusions made from the results of this review were limited by low study numbers, methodological flaws, short follow ups, and low sample sizes. It became obvious that more high quality trials and longer follow up times are needed to answer the question about the effect of physiotherapy in SIS. Results also pointed out that besides good quality future studies should provide a detailed description of applied interventions to guarantee a transfer of research results into clinical practice.

Chapter 3 presents the design of the randomized controlled trial (RCT). Our first aim was to investigate the effect of individualized manual physiotherapy (IMPT) on pain and functioning compared to a standard exercise protocol (SEP) in patients presenting with clinical signs of SIS. The second aim was to compare direct and indirect costs between both interventions. When planning the RCT we followed the CONSORT
statement to guarantee a good quality of the trial. It was important for us to embed the trial in a regular outpatient physiotherapy setting in Germany to increase external validity of results. Besides scientific aspects, decisions about eligibility criteria, measurement instruments, interventions and equipment were therefore also based on the availability and practical applicability of these aspects in this setting. To apply a high quality IMPT protocol, we chose research therapists with an international qualification for manual therapy according to the standard of the International Federation of Orthopaedic Manipulative Physical Therapists (IFOMPT) and several years of experience in this field. In a handbook we described all procedures, assessments and treatments in detail and therapists were trained intensively before commencement of the study. According to our power calculation we aimed to include 90 patients in this trial.

Chapter 4 presents and discusses the short-term results of the RCT about the additional effect of IMPT to exercises on pain and functioning compared to exercises alone in patients with shoulder impingement syndrome. 90 patients presenting with shoulder impingement of more than 4 weeks duration were included by 6 physiotherapy clinics in Germany. Eligibility criteria were solely based on clinical findings without concerning technical diagnostics. The intervention group was treated with individually adapted exercises and examination-based IMPT, controls with individually adapted exercises only. During the first 5 weeks both groups had two treatment sessions per week. This frequency was mainly determined by the regulations of the German health system for physiotherapy prescriptions. In a second step patients of both groups continued their exercises at home for another 7 weeks. Compliance with treatment, additional diagnostics, co-interventions, and sick leave were assessed with the help of a shoulder logbook. Compliance of therapists with the treatment guidelines was monitored with the help of group meetings and regular interviews. Primary outcome measures were the Shoulder Pain and Disability Index and Patient’s Global Impression of Change. Secondary outcome measures were the mean weekly pain score, the Generic Patient-Specific Scale and Patient’s Satisfaction with Treatment. We finally randomized 46 patients to the intervention and 44 to the control group respectively. After 5 and 12 weeks both groups showed significant improvements in all outcome measures but without any differences between groups for any outcome at any time. Only results for mean pain differed at 5 weeks in favour of the intervention group, but this effect was already lost at 12 weeks. Therefore we concluded that IMPT had no worthwhile additional effect on outcome compared to exercises alone and that individually adapted exercises are an effective treatment of patients with SIS. However, these conclusions need to be confirmed by future research before definite recommendations can be made.

Chapter 5 presents and discusses the long-term results of the RCT as well as the analysis of direct and indirect costs. Because at that point in time no information exist-
ed about the long-term effect of the tested interventions, these results were of particular interest and certainly one of the most important findings of this dissertation. Due to the nature of our repeated-measure design we used a linear mixed models approach for calculating differences between baseline and our final follow up at 52 weeks. Data were available from 87 patients, 44 in the intervention and 43 in the control group. Both groups showed significant improvements in all outcome measures but again without any differences between them. Individualized manual physiotherapy as an additional intervention did not influence these results (p = 0.38, 95%CI = -7.45 to 2.85) and thus, these long-term results confirm our conclusions drawn from the short-term results. Interestingly, the total group showed a remarkable improvement over the follow up period which was approved by the subjective impression of the participants themselves. We therefore suggest waiting with further treatments in patients who do not show satisfactory results after the intervention phase and monitor their development over a few months. This is of particular importance because “failed physiotherapy” is often used as an indication for immediate surgery. The only significant difference between groups was found for direct costs after 5 weeks in favour of the control group (p=0.03) but not for any other follow up point. Although the difference in indirect costs was not significant between groups due to a high standard deviation, the absolute difference was enormous and clearly higher in the control group.

In chapter 6 results about the influence of fear avoidance beliefs (FAB) and catastrophizing on pain and disability at the time of inclusion are presented. The negative influence of these factors in patients with low back pain (LBP) is widely accepted and summarized in the fear avoidance model (FAM). However, little is known about the role of them in patients with shoulder complaints. Therefore we firstly investigated the association between fear, pain and disability, and secondly the influence of a selected set of clinical and psychological variables on pain and disability levels in our sample with separate multivariable linear regression analyses for function and disability. 90 patients were included in these analyses. FAB were assessed with a modified version of physical activity sub-scale of the Fear Avoidance Beliefs Questionnaire (FABQ-PA), catastrophizing with the Pain Catastrophizing Scale (PCS). Shoulder function was measured with the sub-scale for function of the Shoulder Pain and Disability Index (SPADI-F), pain intensity was rated on a visual numeric rating scale (VNRS). Results revealed a direct and independent association of pain and FAB on disability which is different to the consecutive order described in the FAM. Therefore results from LBP patients cannot be transferred to patients with shoulder complaints. Our multivariable regression analysis revealed a significant contribution of FAB and catastrophizing to pain and disability. This contribution was still less than the contributions of pain to disability and of disability to pain. Together with the eligibility criteria set for the trial, small numbers of sick days, low ratings on the FABQ-PA, the PCS, high activity levels,
pain clearly connected to specific activities, and last but not least with the significant improvement our patients in the RCT this would support a dominantly nociceptive and therefore tissue based pattern in our group even after a longer period of existing complaints. However, FAB and catastrophizing were significantly influencing pain and disability levels and, in our opinion, are therefore parts of the nociceptive pattern. We therefore recommend the assessment of fear avoidance beliefs and catastrophizing in patients with shoulder impingement syndrome as a standard feature in primary care.

Despite several limitations, discussed in detail in Chapter 7, this thesis provides important and new information about the effect of manual physiotherapy and exercises in the treatment of patients with subacromial shoulder pain showing that exercises alone seem to be a sufficient and effective treatment for SIS. It was further shown that the improvement seen during the intervention phase progressively continued during the follow up period which may help to prevent unnecessary surgery in the future. This thesis also delivers first results about the role of fear avoidance beliefs and catastrophizing in this patient group. These factors were identified as significant contributors to pain and disability and are therefore worth to be considered in clinical practice and future research. As the bio-psycho-social view relentlessly moves forward, these results are of particular interest, because they are little explored in shoulder disorders (and in other upper or lower extremity disorders, either) but growing knowledge about the psycho-social aspects may heavily challenge physiotherapists, still walking the biomedical path.

However, further research is necessary to confirm or to refute our results and to gain further insight into the factors and mechanisms contributing to subacromial shoulder pain and shoulder pain in general.