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An occupation-based intervention in patients with hand-related disorders grouped using the Sense of Coherence scale – a randomized controlled trial

Abstract

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Study Design: Non-blinded randomized controlled trial

Introduction: Occupation-based interventions are superior to physical exercise-based interventions in patients with activity limitations. However, only a few studies have examined the effect in patients with hand-related disorders. Patients recover heterogeneously, which could be due to personal factors, such as sense of coherence (SOC).

Purpose: To investigate the effectiveness of an occupation-based intervention for patients with hand-related disorders and whether SOC can give an indication of the expected effects.

Methods: A total of 504 patients were stratified into three SOC groups and then randomized to either an occupation-based intervention, including physical exercises (OBI), or a physical exercise-based intervention with occupation-focus (PEI). The primary outcome, functioning, was measured using the DASH questionnaire. Primary endpoint was at three months. Patients were followed for a year.

Results: No significant difference was found in primary outcome analysis. Nevertheless, patients receiving OBI had a statistically significant and greater change in satisfaction with their occupational performance at one, two, and three months follow-up. Patients with a weak SOC had worse functioning and lower health-related quality of life than those in the other groups, at all times.

Conclusions: OBI as delivered in this study was not superior to PEI in this patient group. However, in taking a client-centred approach, we recommend that OBI be based on individual needs, given that patients had a statistically greater change in score regarding satisfaction with their

occupational performance. It is evident that patients with a weaker SOC have a lower level of functioning. This knowledge should inform clinical practice.

Level of Evidence: 2b

Introduction

Patients with hand-related disorders (HRD) experience limitations in performing activities of everyday life; limitations that sometimes persist for years.[1-4] Most are of working age and independent in daily living prior to the development of their condition. Recovery is heterogeneous and functional limitations variously impact their activities of everyday life.[4, 5] Apart from injury severity, one reason for these variations might be due to the fact that certain personal factors, such as gender, age and coping abilities,[6, 7] place different demands on physical functioning and occupational performance. To measure coping abilities, the Sense of Coherence scale (SOC-13) can be used.[8-10]

The Sense of coherence (SOC) theory was developed by Antonovsky and is based on the health promotion approach Salutogenesis.[8, 11] SOC reflects one´s ability to handle stressful situations – for example, a hand-related disorder.[8] SOC has three elements 1) The ability to understand what happens around one (comprehensibility), 2) the extent to which one is able to manage a situation on one´s own or through significant others in one´s social network (manageability), and 3) the ability to find meaning in a situation (meaningfulness).[8] SOC can be measured by the SOC-13 scale, a 13-item questionnaire.[8] The higher the score, the stronger the SOC, which indicates better coping capacity.[8] Studies confirm that patients with comparable hand-related injuries recover differently, relative to their SOC level.[4, 12] After rehabilitation, people with a weak SOC had a lower level of functioning in activities of everyday life compared with people with a strong SOC.[4, 12] Cederlund et al.[4] concluded that patients with hand-related injuries and a weak SOC might profit from extra support and help in managing activities of everyday life. It seems to be important to develop interventions that increase functioning for those with lower SOC.

In the International Classification of Functioning, Disability and Health (ICF)[13] functioning is defined as the outcome of a complex and dynamic interaction between *body functions, activity* and *participation*, which are influenced by *environmental factors* and *personal factors.* A holistic approach to rehabilitation is recommended in the ICF, where all the above elements are taken into account.

In scientific articles about hand therapy, the focus has mainly been on the level of body function and body structure.[14, 15] However, increased body function does not seem to be sufficient to enable a high level of overall functioning.[16-18]

In Denmark, the majority of hand therapists are occupational therapists (OTs), which is not always the case in other countries. OTs consider the enablement of occupational performance through occupation-based interventions to be a core value in daily practice.[19-22]

In some areas of occupational therapy, there is evidence to support the effect of an occupation-based intervention – for example, in patients with stroke or hip fractures, or in senior care.[23-26] However, in hand therapy, to date there has been no strong research-based evidence of the effectiveness of an occupation-based intervention.[14, 27] Most published studies are case studies, although two studies have investigated the use of "therapeutic activities" and physical exercise compared with physical exercise that did not have an occupational focus in a randomized controlled trial (RCT).[28, 29] The results of both studies´ showed tendencies in favour of an occupation-based intervention.[28, 29] Furthermore, case studies report increased functioning, motivation and satisfaction from an occupation-based intervention.[17, 30, 31] Qualitative studies have shown that patients express a wish for their rehabilitation to be tailored to their specific needs, and they would prefer their usual daily activities to be incorporated into their rehabilitation.[32, 33] This suggests that, if occupation were to be included in the intervention, it would lead to the best rehabilitation outcome and the intervention would be optimally client-centred. However, it is not yet known whether an occupation-based intervention, that includes physical exercises, is superior to a physical exercise-based intervention with an occupational focus. Furthermore, it is unknown whether an occupation-based approach for people with a lower SOC can: a) improve the overall extent of recovery, and/or b) bring rehabilitation outcomes in line with those of patients with a higher SOC.

The primary aim of the study was to investigate the effectiveness of an occupation-based intervention[a] as opposed to a physical exercise-based and occupation-focused[b] intervention for patients with HRD, as a superiority trial. The secondary aim was to investigate whether the SOC-13 score can predict the effectiveness of the delivered intervention.
We hypothesized that:

[a] In this study the occupation-based intervention was designed so the patients as a minimum a third of the time performed occupations, meaningful activities or tasks that they found meaningful, needed or wanted to do – and which they had performed prior to their HRD. The rest of the time they performed physical exercises. See further description in section 1.2.2

[b] In this study the term occupation-focused refer to the participants being aware that the purpose of the intervention was to increase occupational performance or the quality of occupational performance in activities of everyday life. Furthermore, communication during the interventions and the evaluation of rehabilitation outcomes were occupation-focused, meaning that occupations were the immediate focus, but patients were not engaged in performing the occupations as part of therapy.

1. Patients with HRD in general will benefit in functioning from an occupation-based intervention as opposed to a physical exercise-based and occupation-focused intervention.
2. Patients will benefit in functioning from an occupation-based intervention versus a physical exercise-based and occupation-focused intervention if they have a weak SOC-13 score (< 52).
3. Patients will benefit in functioning from an occupation-based intervention versus a physical exercise-based and occupation-focused intervention if they have a medium SOC-13 score (52-71).
4. There will be no difference in functioning between the interventions if patients have a strong SOC-13 score (72-91).

1.2 Design and Methods

This study was a pragmatic, randomized controlled, parallel-grouped longitudinal trial, in which the superiority of an occupation-based intervention in patients with HRD was investigated. Patients were stratified into three groups, according to their SOC-13 scale. Randomization was performed as block randomization with a balanced 1:1 allocation, resulting in six groups in total, i.e. two treatment groups for each of the three SOC groups. The trial followed the CONSORT guideline[34, 35] and was registered at ClinicalTrials.gov, no.: NCT02098564. The study was approved by the Regional Committee on Health Research Ethics for Southern Denmark, Project-ID 20120123 and by the Danish Data Protection Agency, no.: 14/1845. Permission to use the measurement instruments, SOC-13, EQ-5D and DASH were given by the respective copyright holders. A detailed protocol has been published elsewhere.[36] Information about the project was provided both orally and in writing to potential participants. All participants gave their written consent before being included in the study.

1.2.1 Participants

Participants were adults with a broad spectrum of HRD. Patients were enrolled consecutively at the time of referral to rehabilitation at a specialized outpatient hand therapy clinic in Denmark. Inclusion and exclusion criteria are listed in Table 1. Patients were referred to the clinic mainly from the highly specialized hand surgery department at the same hospital after evaluation by the surgeons.

Insert Table 1 around here

1.2.2 Intervention

All participants received individual rehabilitation at the clinic. Patients were randomized to one of two occupational therapy interventions. The experimental intervention group received an occupation-based intervention with an add-on of physical exercises (OBI). The control group received a physical exercise-based and occupation-focused intervention (PEI).[36]

Control group

The intervention in the control group was physical exercise-based, in accordance with international clinical guidelines and individuals' needs.[37] It consisted of joint mobility exercises, strengthening exercises, desensitization and pain management, both in the therapy setting and as a home exercise programme. Patients were allowed to borrow technical aids, if necessary, but did not practise using the aids in the clinic. Participants were aware that the purpose of the intervention was to increase occupational performance or the quality of occupational performance in activities of everyday life. Communication during the interventions and the evaluation of rehabilitation outcomes were occupation-focused, meaning that occupations were the immediate focus.[38] However, patients were not engaged in performing the occupations as part of therapy; rather, they reflected on and discussed them.

Experimental intervention

In the OBI group, at each session some of the intervention elements used in the control group were to be replaced with occupation-based interventions[38]. In the occupation-based intervention, participants performed occupations, meaningful activities or tasks[19, 39] that they found meaningful, needed or wanted to do and which they had performed prior to their HRD. The intervention was designed to be one-third occupation-based across three sessions. A third of the home exercises were also occupation-based. If patients needed technical aids, they were allowed to borrow them and exercise with them in the clinic. The home exercise programme was individually designed by the participant and the OTs – depending on the occupations, activities or tasks the patient found important. They chose 5-10 minor occupations, activities or tasks, e.g., eating with a knife and fork, zipping and buttoning clothes, keyboarding, packing groceries, knitting, etc. Each activity or task was repeated 5-10 times; or for 3-5 minutes. It should be challenging but performable. The occupations, activities or tasks were identified during a Canadian Occupational Performance Measure (COPM) interview.[40] Compensatory and adaptive strategies were also occupation-based. To be able to perform the most frequently performed occupations, activities or tasks in the clinic, materials to perform them were made available before study start in clinic "activity boxes".

Materials were provided for, e.g., electrical work, polishing shoes, or packing groceries. Furthermore, a kitchen, a bathroom and a workshop were available at the clinic.

Oral and written instructions were given in both groups. Both interventions were client-centred, goal-oriented and provided individually. Goals were based on activities identified by the participant during the COPM interview.[40] The number of sessions was tailored to the specific needs of each patient. Rehabilitation ended when the patient and the rehabilitation team (OT and hand surgeon) decided that recovery had reached a plateau or that the patient would be able to finish the rehabilitation at home.

The OTs responsible for delivering the interventions were specialized hand therapists with clinical pre-trial experience in delivering both interventions. A detailed protocol describing the interventions in both groups was drawn up for therapist use. However, each intervention was tailored to the patient. The progression of treatment mirrored the patient's improvement from one session to the next, and was designed to provide just the right challenge to increase physical function and functioning. All hand therapists at the clinic participated in the trial and were given direction in how to use the protocols. Both interventions were delivered at the clinic during a period before the start of the trial, and a number of patients were treated in accordance with the protocol for pre-trial experience. To promote compliance with the occupation-based approach, therapists kept a diary about the intervention delivery in the OBI group. Diaries were audited continually and twice a year all OTs were reinstructed in how to use the protocol to reinforce compliance. The first author was available whenever the therapists wanted to discuss any questions that arose.

1.2.3 Measurements

The primary outcome – functioning – was measured using the self-administered Disability of the Arm, Shoulder and Hand questionnaire (DASH).[41, 42] DASH consists of 30 items about specific activities, physical symptoms, and social or role function. DASH scores range from 0-100; the lower the score, the less limited the functioning. The DASH questionnaire is valid, reliable and responsive to most disabilities in the upper limb.[42, 43]

Secondary outcomes were score changes in subjective evaluation of current specific occupational performance and satisfaction with this performance, measured by the COPM.[40] The COPM is valid, reliable and responsive in a wide variety of samples,[44-47] including samples with patients with upper limb disorders.[48, 49] No validated, minimally clinical important difference exists for COPM. A further five items measuring subjective satisfaction were assessed, including: 1) overall occupational performance, 2) satisfaction with overall occupational performance, 3) satisfaction with occupational therapy, 4) satisfaction with treatment effect and 5) satisfaction with adherence. Items one and two were measured as score change, while the remaining three

items were measured as a final value. All the secondary outcomes were measured on a 10-point numeric rating scale with an anchor at both ends, range 1-10; a high score indicates high occupational performance or a high degree of satisfaction. The five additional items were developed with inspiration from COPM and were piloted and evaluated for understanding and feasibility using cognitive interview methods.[50, 51]

Furthermore, health-related quality of life (HRQoL) was measured by the questionnaire EQ-5D.[52, 53] EQ-5D consists of two parts: a descriptive system and a visual analogue scale (EQ VAS). The score in the descriptive system is converted to an EQ-5D index value, where 1.0 corresponding to no health problems. A high score in EQ VAS = 100 indicates the best imaginable health state. The reliability and validity of the EQ-5D has been documented in the case of patients with an upper extremity disorder.[54]

SOC is measured by the SOC-13 scale. The SOC-13 scale consists of 13 items scored on a seven-point Likert scale. The individual item scores are added up to give a total score, ranging from 13 to 91 points.[8] The higher the score, the stronger the SOC.[8] The SOC-13 scale is reported to be a valid and reliable tool to measure how people manage stressful situations and stay well.[9, 55]

Injury severity was classified by the Modified Hand Injury Severity Score (MHISS).[56] MHISS is a descriptive severity scoring system that categorizes injuries in the hand, wrist and forearm into four categories: minor ≤ 20, moderate 21-50, severe 51-100 and major > 100.[56] The first author classified the MHISS retrospectively from the medical records. Classifications were discussed with the last author.

No adverse events were expected in the study.

1.2.4 Data collection

Demographic data about age, gender, education, the disorder and number of sessions were obtained from medical records and items in the baseline questionnaire. Baseline (FU-0) questionnaires were completed on the first day of rehabilitation. Follow-up data were obtained at 1, 2, 3, 6, and 12 months (FU-1 to FU-5) (Figure 1). The questionnaires were independently completed either at the clinic or posted to the participants with a returnable, stamped, addressed envelope, depending on whether or not the patient received rehabilitation at the time of follow-up. COPM was measured at baseline by the OT treating the patient and re-evaluated monthly until the three-month evaluation, or for as long as patients were treated at the clinic, if the duration was less than three months. A reminder was sent to the participant by mobile phone text message if the posted follow-up questionnaire was not returned within a week.

1.2.5 Sample Size

A difference of 10 points in DASH scores between OBI and PEI was considered clinically relevant.[57] Based on the literature, a standard deviation of 18 in the DASH score was expected.[58] We required a significance level of p=0.0166 (to take into account the three parallel hypotheses tested) and a power of 80%, resulting in the need for 70 patients for each intervention in each of the three SOC groups (weak, medium and strong). A 20% drop-out rate was expected; therefore, it was planned to include 84 patients in each of the six groups (in total, 504 participants).

Insert Figure 1 around here

1.2.6 Randomization and blinding

Patients were randomly assigned a hand therapist before being enrolled and randomized. Baseline data were obtained before randomization. A balanced randomization principle was implemented to ensure sufficient and balanced variation in patients in relation to pre-rehabilitation SOC-13 score. Patients were balanced in six strata, with a block size of 10 in each stratum. Randomization was performed at the clinic just before rehabilitation started, by the first author (AØH), or one of four OTs specially trained to enroll and assign patients. Allocation sequences were computer-generated before the project started and stored in sequentially numbered, sealed, opaque envelopes. Envelopes were opened after the patient had given informed consent. Enrolment of a patient was never performed by the OT responsible for that patient's rehabilitation.
Because of the nature of the intervention, neither participants nor OTs were blinded to allocation.[59, 60] However, they were blinded to the patient's SOC-13 score. The majority of outcome measures were self-administrated questionnaires completed by the patients themselves, and therefore testers could not be blinded. COPM was completed by the patients and their OT as part of their intervention plan.

1.2.7 Statistical methods

The primary endpoint change in DASH score between baseline and three months was analyzed with t-tests, comparing the experimental OBI with the PEI; first, in general (hypothesis 1), and then taking SOC group into account (hypotheses 2-4). Furthermore, DASH score changes were analyzed in the same way for changes between baseline and each follow-up. In additional analysis, a linear mixed model was used to investigate whether SOC groups, gender, age, or severity influenced the results, and an interaction model was used to investigate if the differences between OBI and PEI was modified by SOC group.

Secondary outcomes were compared between baseline and follow-ups with Wilcoxon rank-sum test for ordinal outcomes and t-test/median test for continuous outcomes, in general, and in the three SOC groups.

Change over time for the repeated measures was analyzed with linear mixed model regression with functioning measured by DASH score as the dependent variable.

The assumptions of normal distribution were assessed with quantile-quantile plots.

Patients were excluded from the analysis after enrolment if they had fewer than three intervention sessions, their rehabilitation period was less than four weeks or they were re-operated for the same disorder within a year. If they had a new injury in the hand, they were excluded from the date of the new injury.

A drop-out analysis was made, comparing dropouts (including those excluded during the study) with the participants. In addition, a non-participant analysis was made. We used the chi-squared test for binary outcomes, Wilcoxon rank-sum test for ordinal outcomes and t-test/median test for continuous outcomes.

For tests of hypothesis with the primary outcome DASH, we used a two-sided p-value with 0.0167 as significance level, to conduct multiple tests in the three SOC groups into account. In testing the secondary outcomes, we used a 0.05 level of significance. Data were double data entered in EpiData (version 2.0.5.17), with a range check for all variables. Stata 15 (StataCorp LP, College Station, TX) was used to conduct the analyses.

The statistical analyses were planned in advance of the data analysis.

1.3 Results

Between February 2014 and December 2016, we screened 734 people, of whom 512 were randomized. Accidentally, eight patients who did not fulfil the inclusion criteria were included, but excluded again the same day. The final study group consisted of 504 patients (Figure 2). One participant recruited to the group assigned to PEI withdrew her consent for any baseline data to be used before her one month follow-up. One year final follow-ups were completed in December 2017.

The participants were stratified into three groups with, respectively, weak SOC (*n*=50), medium SOC (*n*=193) and strong SOC (*n*=261), and then randomly assigned to OBI (*n*= 255) or PEI (*n*= 249) (Figure 2). No adverse events were observed in the study. New injuries and number of re-surgeries due to the same disorder are reported in Figure 2.

Insert Figure 2 around here. Flowchart

At the time of the three-month follow-up, 398 patients were participating in the study (79%). Fifty patients had withdrawn or were excluded from the group allocated to OBI, because of, e.g., reoperation or new injuries. In PEI, the same number was 56 (Figure 2). The majority of the 398 participating patients were women, with a mean age of 48.1 (SD 15.7) and most had a vocational or medium-length, higher education (Table 2). No differences in demographics were found between OBI and PEI in the total group or in any SOC group at baseline (Table 2 and Appendix 1) – apart from satisfaction with overall occupational performance, where patients in general and in the weak SOC group receiving OBI were less satisfied with their occupational performance. There was no difference in the number of sessions between the two interventions, either in the total group or in SOC groups. The median number of sessions (25-75 quantile) in OBI was 8 (6-13) and in PEI 7 (5-12) (*p=0.18)*.

Insert Table 2 around here. Baseline demographics for patients who were in the study at three months

Primary outcome

No significant difference was found in any primary outcome analysis of functioning at three months or at one, two, six, or 12 months (Table 3), either in the total group (Hypothesis 1) or in the SOC groups (Hypotheses 2-4). In analyzing data using a mixed model for longitudinal studies with the intervention and time as interactions, no significant difference was found between the interventions. Furthermore, no significant effect was found for DASH score when adjusted for injury severity, age and gender ($p<0.07$). In taking SOC groups into account no clear treatment difference was detected. However, at 6 and 12 months a difference was seen in the small number of patients with weak SOC and at 6 months in the medium SOC group (Table 4).

All DASH scores and DASH changes scores were assessed to be normally distributed using the quantile-quantile plot.

Insert Table 3 around here. Per protocol analysis between baseline and follow-ups

Insert Table 4 around here. Additional analysis of functioning with longitudinal data

Secondary outcome

At one, two, and three months, patients who received OBI had a statistically significant greater change in COPM for specific occupational performance (Table 5). Furthermore, they were more

satisfied with the way they performed their specific occupations (Table 5). Change in satisfaction with overall occupational performance was statistically significant at one month $p<0.02$ and two months $p<0.05$, while it was insignificant at three months $p=0.06$ (Table 3). No other differences were found in secondary outcomes at any follow-up.

Additional findings

On examining baseline data on all 503 patients, it was found that patients with a weak SOC had lower self-rated functioning (mean DASH 50.8) than those with a medium SOC (mean 41.3) ($p<0.01$) or a strong SOC (mean 35.1) ($p<0.001$). A significant difference in DASH score was also found between the medium and the strong SOC group ($p<0.001$). The same was found in relation to EQ-5D. Participants with a weak SOC had statistically significant lower HRQoL at baseline, compared with those with a strong SOC ($p<0.001$) and those with a medium SOC ($p<0.001$). The difference between the medium and the strong group was also significant ($p<0.01$). At three months, these differences were sustained. The weak SOC group still had a lower self-rated functioning (mean DASH 34.10) than those in the medium SOC group (mean DASH 23.48) ($p<0.001$) or in the strong SOC group (mean DASH 19.03) ($p<0.001$). There was also a significant difference in DASH between the medium and the strong SOC group ($p<0.01$). At 6 and 12 months patients with a weak SOC still had a lower self-rated functioning than those with a medium SOC ($p< 0.002$) and those with a strong SOC ($p< 0.005$). Nevertheless, the difference between medium and strong SOC was no longer significant, with $p= 0.27$ at 6 months and $p= 0.06$ at 12 months.

Taking the intervention, time and SOC groups into account in the mixed model analyses with all 503 patients, a significant difference was found in DASH score between the SOC groups and measurement times. With the weak SOC group as the reference group, the strong SOC group had a significantly better DASH of -15.99 points (CI: -20.70 to -11.27) ($p< 0.001$) at all time points, while in the medium SOC group it was -11.43 points (CI:-16.28 to it -6.60) ($p< 0.001$).
Furthermore, as expected, there was a significant improvement in DASH score in the total group from baseline to one month of -9.80 points (CI: -11.34 to -8.28) ($p<0.001$), between baseline and two months of -14.23 points (CI: -15.79 to -12.67 ($p<0.001$), and between baseline and three months of -16.33 points (CI: -17.91 to -14.75) ($p<0.001$). Additionally, there was a significant improvement in DASH score between baseline and six months of -17.32 (-18.93 to -15.71) ($p<0.001$), and between baseline and one year of -18.71 (-20.70 to -17.07) ($p<0.001$).
Improvements were also significant between one and two months ($p<0.001$) and between two and three months ($p<0.02$). However, improvement was not significant between three and six months ($p<0.17$) or six and twelve months ($p<0.06$).

A significant difference was found in DASH score in relation to gender. Women had a significantly higher DASH score (by 4.6 points) than men. However, taking gender into account in the mixed model analysis did not change the findings.

Exclusions and non-participants

Forty (8%) of the participants were re-operated, 10 (2%) had a new injury and 25 stopped rehabilitation after fewer than three sessions (5%). Twenty-two (4%) patients had less than one month's rehabilitation and 11 (2%) withdrew before three months follow-up (Figure 2). No significant differences were found in baseline characteristics between participants who responded at three months and those excluded, except for number of sessions. Participants who responded had more sessions, median (25-75 quantile) 8 (5-12) versus 4 (2-8) (p<0.001) (Table 6).

In non-participant analyses, patients who declined to participate (n=113) were significantly older than those who were willing to participate (52.31 years of age versus 47.57 (p=0.005)). No other differences were found in non-participant analyses (Appendix 2).

Insert Table 6 Dropout analyses around here.

1.4 Discussion

To our knowledge, this is the largest of the RCTs conducted with the aim to investigate the effectiveness of an occupation-based intervention on patients with HRD. We also aimed to investigate whether SOC score could give an indication of the anticipated effects. The results showed no difference in functioning between OBI and PEI, according to DASH change score. Regarding the hypothesis, this was expected for patients with a strong SOC, but not for the total group or patients with a weak or medium SOC. However, in secondary outcomes, patients who received OBI had a statistically significant greater change score in specific occupational performance and satisfaction with that performance (COPM) in the total group at all follow-ups and a higher change score in satisfaction with overall occupational performance at one and two months.

1.4.1 General discussion

Intervention

The finding of no increased effect in functioning (DASH) from the OBI, despite the fact that patients seemed more satisfied with their occupational performance, was also found in a study in patients with hip fractures.[25] They found no difference between an occupation-based and a physical exercise-based intervention, while patients who received the occupation-based

intervention were more satisfied with their performance of personal important tasks and their OT intervention. However, in occupational therapy literature, the effects of an occupation-based intervention, such as increased functioning, increased HRQoL, increased motivation and active engagement are reported in several other areas.[23, 24, 26, 30, 61] Furthermore, two studies of patients with HRD reported increased functioning from an occupation-based intervention, compared to a physical exercise-based intervention that had no described occupational focus. [28, 29]

One explanation for finding no significant differences in functioning in the present study, compared with the other two hand therapy studies, might be that the variances between the two interventions were quite small. Both OBI and PEI were client-centred and occupation-focused. Since all hand therapists in Denmark are OTs, we aimed to investigate two occupational therapy interventions, which is why these approaches could not be ignored.[19, 62] Guzelkucuk et al.[28] found no improvement at all in DASH score in the physical exercise group from baseline to two months, which is different from the DASH change in the control group of the current study, where occupation- focus was added to the physical exercises. The focus on occupation might increase motivation and use of the hands in performing occupations outside the clinic – as has been found to be the case in studies using computer games and small tasks with added purpose.[63-65] They reported that patients do more repetitions and find the treatment more attractive and engaging if a focus on occupation is added.[63-65] The client-centred approach in the present study, where occupations were chosen by the individual patient, is another difference among the three studies, since the two other trials[28, 29] within hand therapy used predefined activities and programmes and thereby were not client-centred nor individually tailored.

Another difference between the three studies is the number of interventions and the degree to which the intervention in OBI was occupation-based. We intended to investigate a pragmatic design, where the protocol and results could be used in clinical practice. Time between interventions reflected the patients' needs and a clinical practice where patients were individually treated. The proportion of activities that were to be occupation-based was decided based on clinical experience and for pragmatic reasons, since a wide range of diagnoses were included in our study. In clinical practice sessions, many other elements also have to be included, such as orthotic preparation or adjustment, evaluation, coaching, consultations with the surgeon, etc., besides some physical exercises.[66] These issues were not incorporated in the other, more standardized, effect studies. [28, 29]

Daud et al.[29] found that the effect of their OBI decreased when gender and duration since the injury were taken into account. We, too, found a difference between genders, but it did not influence the results.

The fact that we did not find any difference in functioning, even though patients had statistically larger change in satisfaction with their occupational performance at follow-ups, might be due to the chosen outcome measures. DASH might not be sensitive enough to differentiate whether patients in the OBI used the affected arm more or whether the quality of the occupational performance was higher. COPM is reported to be more sensitive than DASH.[48, 67] However, COPM is based on individually-defined activities and thereby not optimally analyzed in groups, albeit it is often carried out.[29, 67-69] Nevertheless, the higher change score in satisfaction with occupational performance in OBI at all follow-ups indicates that the quality of occupational performance was better in OBI. However, since the difference at three months is 1.4 points, it can be discussed whether it is clinically relevant.

In this study, it seems that patients benefited from both interventions, despite the fact that equivalence was not investigated and all groups received rehabilitation. The mean score change was similar in the two interventions and a significant decrease in DASH score change was observed at all follow-ups in all groups in both interventions. However, the individual change scores varied greatly, which might be due to individual circumstances and preferences, and might explain the dispersion in CI. It might be that patients prefer one intervention rather than another. A qualitative study of Danish patients with HRD, interviewed about their perception of client-centredness and factors that facilitate the effect of a rehabilitation process, supports this individual point of view.[33] Patients here and in other studies concluded that rehabilitation interventions should be individually tailored.[32, 13, 70] Therefore, from a client-centred perspective, it might be that patients should choose the intervention they favour – OBI or PEI.

Sense of coherence

Patients with a weak SOC had a higher DASH at baseline, compared to those with a medium or strong SOC. This indicates a more affected functioning, which was still present at three months. Other studies have found the same or related differences between SOC groups.[4, 7, 71, 72] However, in most of the studies, data were only measured at follow-up and no baseline data were included.[4, 7, 71] Consequently, it could not be concluded if the differences between SOC groups were due to different effects of the intervention or related to the baseline scores.

In this study, we aimed to minimize the differences in functioning between the SOC groups, by applying the OBI, which included a higher degree of the SOC dimensions of meaningfulness, comprehensibility and manageability. OBI was meant to help the patients manage their situation and everyday life with a HRD to a higher degree. However, our results show the same clinically relevant improvement in DASH from baseline to follow-up in the three SOC groups. This indicates

that all groups improved to the same degree in functioning from the interventions between baseline and the primary endpoint at three months – independent of SOC score. So, the different DASH scores found between SOC groups at the three-month follow-up is probably not related to a different response to their rehabilitation at the outpatient hand therapy clinic. However, since DASH has an ordinal response scale, the same change score might be differently interpreted by patients, depending on their baseline score. It might be that patients with the lower functioning felt the change to be greater or more important than those who were less affected at baseline. The difference in DASH change between SOC groups at all times is greater than 10 points, indicating that the difference is clinically relevant. The DASH score at three months for those with a strong SOC is near the population norm of 13 points,[73] whereas those with a weak SOC are further away from this. This might also influence the experience of gained functioning. A difference in functioning was seen at 6 and 12 months in the weak SOC group in favour of PEI. However, it can be seen from the small sample, that the difference is related to four patients, whose scores changed from 3 to 6 months without any known reason. Due to the risk of type 2 error in the mixed model analysis, both this and the difference found at 6 months in the medium group in favour of OBI should not be interpreted as strong evidence. However, it is evident that patients with a weak SOC have a lower functioning than others. This knowledge should be applied in clinical practice, to support patients in managing their everyday lives, understand what happens around them and find meaning in the situation. It might be that those patients have to start rehabilitation immediately after the injury or onset of the disorder. However, this, needs to be further investigated.

1.4.2. Methodological limitations

This study's strengths are the randomized controlled design, adherence to the CONSORT guideline,[34, 35] the pragmatic approach and the large sample size, which increase generalizability. However, the study has several limitations.

Exclusion criteria and missing data

The exclusion of several patients after randomization is a limitation. However, the exclusions were chosen before study start, based on the exclusion criteria. No differences were found in drop-out analysis – except that the excluded patients had, as expected, fewer sessions (Table 6). The exclusions were done to minimize bias, since follow-up measurements would measure not only the results of the intervention for the hand-related disorder, but also functional impairments caused by the new injury or a new operation. Patients who were included by mistake, who had

fewer than three sessions or less than one month's rehabilitation were excluded to ensure that patients actually received a client-centred and goal-oriented rehabilitation course.

The most common analyses for RCTs are the intention to treat analyses, where missing data in some cases are carried forward.[34, 74] However, an increase in functioning over time was expected and shown in the analyses, so carrying old data forward would, if anything, reduce the difference between the interventions, and it would also be unrealistic.[74] Since no difference in functioning was found between OBI and PEI, carrying forward old data would not have changed our finding. The per protocol analysis typically affects the randomization. However, no differences were found between the dropouts and those who participated within several demographics – which minimizes this risk in the current study.

Blinding

Blinding was not possible for the providers or the patients, which might have introduced performance bias.[34, 35] There is a possible risk that the hand therapists had pre-conceptions about which of the two interventions would be better for the patients, and it is therefore possible that they adjusted the intervention to tailor it for individual patients.[75] However, they were trained not to do so and taught about the consequences this would have for the study. OTs were blinded to SOC group to avoid differences in behaviour because of known SOC level. Furthermore, it is a possibility that patients in PEI were more focused on performing occupations at home than they would have been if they had not participated in the study.

Cut-point and SOC

The weak SOC group was underpowered; however, stratification ensured a balance in the groups. No defined cut-points exist for the SOC-13 scale. The chosen cut-points were defined based on the dispersion of the SOC-13 scores in a Danish study in patients with HRD that investigated test-retest reliability.[10] Cut-points have been variously defined in the literature.[4, 76, 77] However, our results support the trichotomized cut-points of this study, in that we found a significant difference in DASH between the three groups, indicating variation between the groups. Selection bias might have been introduced by the fact that 22% of the eligible patients declined to participate. However, apart from age, the characteristics of non-participants and participants were similar.

Harm and adverse effects

No adverse effects were reported in the trial findings and both interventions seem safe and bring no harm to the patients.

Generalizability

The pragmatic design with standardized interventions, allowing individual needs to be taken into account, increases the generalizability of the results in clinical practice. However, it reduces the internal validity. The fact that the study was conducted at a single, highly specialized outpatient hand therapy clinic might influence the generalizability negatively. The patients' diagnoses, injury severity and the distribution of acute and elective disorders might vary between outpatient hand therapy clinics. However, the population is well described at baseline and thereby it is possible to compare with other populations. The experience of the OTs might reduce generalizability, because they might be more highly experienced in both interventions. However, we believe that the OBI is applicable to all kinds of outpatient hand therapy clinics for patients with HRD and occupational performance problems.

1.5 Conclusion

OBI for patients with HRD – as delivered in this study – was not superior to PEI in functioning, measured with DASH. However, patients receiving OBI had a statistically significant greater rise in satisfaction with their occupational performance. For this reason, from a client-centred approach, we recommend that OBI be used, based on individual needs. Having a weak, medium or strong SOC did not make any difference in rehabilitation outcome between intervention groups. Improvement in functioning was similar in the three groups. However, patients with a weak SOC were more affected in functioning and HRQoL than were patients with a medium or strong SOC at the start and end of rehabilitation.

1.6 References

1. Gustafsson M, Persson LO and Amilon A. A qualitative study of stress factors in the early stage of acute traumatic hand injury. *Journal of advanced nursing* 2000; 32: 1333-1340.
2. Bell J, Gray M, Kingston G, et al. The longer term functional impact of a traumatic hand injury on people living in a regional metropolitan Australian location. *International Journal of Therapy & Rehabilitation* 2011; 18: 370-381.
3. Fitzpatrick N. A phenomenological investigation of the experience of patients during a rehabilitation programme following a flexor tendon injury to their hand. *Hand Ther* 2007; 12: 76-82.
4. Cederlund RI, Ramel E, Rosberg HE, et al. Outcome and clinical changes in patients 3, 6, 12 months after a severe or major hand injury--can sense of coherence be an indicator for rehabilitation focus? *BMC musculoskeletal disorders* 2010; 11: 286-296.
5. Cederlund R, Thorén-Jönsson AL and Dahlin LB. Coping strategies in daily occupations 3 months after a severe or major hand injury. *Occupational therapy international* 2010; 17: 1-9.
6. London DA, Stepan JG, Boyer MI, et al. The impact of depression and pain catastrophization on initial presentation and treatment outcomes for atraumatic hand conditions. *The Journal of bone and joint surgery* 2014; 96: 806-814.
7. Ramel E, Rosberg HE, Dahlin LB, et al. Return to work after a serious hand injury. *Work* 2013; 44: 459-469.
8. Antonovsky A. *Unraveling the mystery of health: how people manage stress and stay well*. San Francisco: Jossey-Bass, 1987.
9. Eriksson M and Lindstrom B. Validity of Antonovsky's sense of coherence scale: a systematic review. *Journal of epidemiology and community health* 2005; 59: 460-466.
10. Hansen AØ, Kristensen HK, Cederlund R, et al. Test–retest reliability of Antonovsky's 13-item sense of coherence scale in patients with hand-related disorders. *Disability and rehabilitation* 2017; 39: 2105-2111.
11. Antonovsky A. *Health, stress and coping*. San Francisco 1979.
12. Rosberg HE, Carlsson KS, Cederlund RI, et al. Costs and outcome for serious hand and arm injuries during the first year after trauma - a prospective study. *BMC public health* 2013; 13: 501-507.
13. World Health Organization. *International Classification of Functioning, Disability and Health (ICF)*. 2001. Switzerland: World Health Organization.
14. Robinson LS, Brown T and O'brien L. Embracing an occupational perspective: Occupation-based interventions in hand therapy practice. *Australian occupational therapy journal* 2016; 63: 293-296.
15. Takata S, Wade E and Roll S. Hand therapy interventions, outcome, and diagnoses evaluated over the last 10 years: A mapping review linking research to practice. *Journal of Hand Therapy* 2019; 32: 1-9.
16. Dekkers M and Soballe K. Activities and impairments in the early stage of rehabilitation after Colles' fracture. *Disability and rehabilitation* 2004; 26: 662-668.
17. Jack J and Estes RI. Documenting progress: Hand therapy treatment shift from biomechanical to occupational adaptation. *American Journal of Occupational Therapy* 2010; 64: 82-87.
18. Rice MS, Leonard C and Carter M. Grip strengths and required forces in accessing everyday containers in a normal population. *The American journal of occupational therapy* 1998; 52: 621-626.
19. Polatajko H, Davis J, Stewart D, et al. Specifying the domain of concern: Occupation as core. In: Townsend EA and Polatajko HJ (eds) *Enabling occupation II : advancing an occupational therapy vision for health, well-being, & justice through occupation*. Ottawa: CAOT, 2007.
20. Roley SS, Barrows CJ, Susan Brownrigg OTR L, et al. Occupational therapy practice framework: Domain & process 2nd edition. *The American journal of occupational therapy* 2008; 62: 625-683.

21. Colaianni D and Provident I. The benefits of and challenges to the use of occupation in hand therapy. *Occupational therapy in health care* 2010; 24: 130-146.
22. Colaianni DJ, Provident I, DiBartola LM, et al. A phenomenology of occupation-based hand therapy. *Australian occupational therapy journal* 2015; 62: 177-186.
23. Trombly CA and Wu CY. Effect of rehabilitation tasks on organization of movement after stroke. *The American journal of occupational therapy* 1999; 53: 333-344.
24. Hubbard IJ, Parsons MW, Neilson C, et al. Task-specific training: evidence for and translation to clinical practice. *Occupational therapy international* 2009; 16: 175-189.
25. Jackson JP and Schkade JK. Occupational Adaptation model versus biomechanical-rehabilitation model in the treatment of patients with hip fractures. *The American journal of occupational therapy* 2001; 55: 531-537.
26. Nielsen TL, Petersen KS, Nielsen CV, et al. What are the short-term and long-term effects of occupation-focused and occupation-based occupational therapy in the home on older adults' occupational performance? A systematic review. *Scandinavian journal of occupational therapy* 2016: 1-14.
27. Amini D. Occupational therapy interventions for work-related injuries and conditions of the forearm, wrist, and hand: a systematic review. *The American journal of occupational therapy* 2011; 65: 29-36.
28. Guzelkucuk U, Duman I, Taskaynatan MA, et al. Comparison of therapeutic activities with therapeutic exercises in the rehabilitation of young adult patients with hand injuries. *The Journal of hand surgery* 2007; 32: 1429-1435.
29. Daud AZC, Yau MK, Barnett F, et al. Integration of occupation based intervention in hand injury rehabilitation: A Randomized Controlled Trial. *Journal of Hand Therapy* 2016; 29: 30-40.
30. Earley D and Shannon M. The use of occupation-based treatment with a person who has shoulder adhesive capsulitis: a case report. *The American journal of occupational therapy* 2006; 60: 397-403.
31. Toth-Fejel GE, Toth-Fejel GF and Hedricks CA. Occupation-centered practice in hand rehabilitation using the experience sampling method. *The American journal of occupational therapy* 1998; 52: 381-385.
32. Palmadottir G. Client perspectives on occupational therapy in rehabilitation services. *Scandinavian journal of occupational therapy* 2003; 10: 157-166.
33. Hansen AO, Kristensen HK, Cederlund R, et al. Client-centred practice from the perspective of Danish patients with hand-related disorders. *Disability and rehabilitation* 2017: 1-11.
34. Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *International journal of surgery* 2012; 10: 28-55.
35. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Annals of internal medicine* 2008; 148: 295-309.
36. Hansen AØ, Cederlund R, Kristensen HK, et al. The effect of an occupation-based intervention in patients with hand-related disorders grouped using the sense of coherence scale: Study protocol. *Hand Therapy* 2016; 21: 90-99.
37. Skirven TM, Osterman AL, Fedorczyk J, et al. *Rehabilitation of the hand and upper extremity*. 2nd edition. Elsevier Health Sciences, 2011.
38. Fisher AG. Occupation-centred, occupation-based, occupation-focused: same, same or different? *Scandinavian journal of occupational therapy* 2013; 20: 162-173.
39. Townsend EA, Polatajko HJ and Caot. *Enabling occupation II : advancing an occupational therapy vision for health, well-being, & justice through occupation*. Ottawa: CAOT, 2007.
40. Law M. *Canadian Occupational Performance Measure*. 4th edition ed. Ottawa, Ont.: CAOT Publications ACE, 2005.

41. Hudak PL, Amadio PC and Bombardier C. Development of an upper extremity outcome measure: the DASH (disabilities of the arm, shoulder and hand). *American journal of industrial medicine* 1996; 29: 602-608.
42. Herup A, Merser S and Boeckstyns M. Validation of questionnaire for conditions of the upper extremity. *Ugeskrift for laeger* 2010; 172: 3333-3336.
43. Beaton DE, Katz JN, Fossel AH, et al. Measuring the whole or the parts? Validity, reliability, and responsiveness of the Disabilities of the Arm, Shoulder and Hand outcome measure in different regions of the upper extremity. *Journal of hand therapy* 2001; 14: 128-146.
44. Cup EH, Scholte op Reimer WJ, Thijssen MC, et al. Reliability and validity of the Canadian Occupational Performance Measure in stroke patients. *Clinical rehabilitation* 2003; 17: 402-409.
45. Eyssen IC, Steultjens MP, Oud TA, et al. Responsiveness of the Canadian occupational performance measure. *Journal of rehabilitation research and development* 2011; 48: 517-528.
46. Eyssen IC, Beelen A, Dedding C, et al. The reproducibility of the Canadian Occupational Performance Measure. *Clinical rehabilitation* 2005; 19: 888-894.
47. Dedding C, Cardol M, Eyssen IC, et al. Validity of the Canadian Occupational Performance Measure: a client-centred outcome measurement. *Clinical rehabilitation* 2004; 18: 660-667.
48. van de Ven-Stevens LA, Graff MJ, Peters MA, et al. Construct validity of the canadian occupational performance measure in participants with tendon injury and Dupuytren disease. *Physical therapy* 2015; 95: 750-757.
49. Kjeken I, Slatkowsky-Christensen B, Kvien TK, et al. Norwegian version of the Canadian Occupational Performance Measure in patients with hand osteoarthritis: validity, responsiveness, and feasibility. *Arthritis and rheumatism* 2004; 51: 709-715.
50. Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity--establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO good research practices task force report: part 1--eliciting concepts for a new PRO instrument. *Value in health* 2011; 14: 967-977.
51. Patrick DL, Burke LB, Gwaltney CJ, et al. Content validity--establishing and reporting the evidence in newly developed patient-reported outcomes (PRO) instruments for medical product evaluation: ISPOR PRO Good Research Practices Task Force report: part 2--assessing respondent understanding. *Value in health* 2011; 14: 978-988.
52. Brooks R. EuroQol: the current state of play. *Health policy* 1996; 37: 53-72.
53. EuroQol. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy* 1990; 16: 199-208.
54. Slobogean GP, Noonan VK and O'Brien PJ. The reliability and validity of the Disabilities of Arm, Shoulder, and Hand, EuroQol-5D, Health Utilities Index, and Short Form-6D outcome instruments in patients with proximal humeral fractures. *Journal of shoulder and elbow surgery* 2010; 19: 342-348.
55. Antonovsky A. The structure and properties of the sense of coherence scale. *Social science & medicine* 1993; 36: 725-733.
56. Urso-Baiarda F, Lyons RA, Laing JH, et al. A prospective evaluation of the Modified Hand Injury Severity Score in predicting return to work. *International journal of surgery* 2008; 6: 45-50.
57. Gummesson C, Atroshi I and Ekdahl C. The disabilities of the arm, shoulder and hand (DASH) outcome questionnaire: longitudinal construct validity and measuring self-rated health change after surgery. *BMC musculoskeletal disorders* 2003; 4: 11-16.
58. Wong JY. Time off work in hand injury patients. *The Journal of hand surgery* 2008; 33: 718-725.
59. Boutron I, Tubach F, Giraudeau B, et al. Blinding was judged more difficult to achieve and maintain in nonpharmacologic than pharmacologic trials. *Journal of clinical epidemiology* 2004; 57: 543-550.
60. Moberg-Mogren E and Nelson DL. Evaluating the quality of reporting occupational therapy randomized controlled trials by expanding the CONSORT criteria. *American Journal of Occupational Therapy* 2006; 60: 226-235.

61. Kristensen HK, Persson D, Nygren C, et al. Evaluation of evidence within occupational therapy in stroke rehabilitation. *Scandinavian journal of occupational therapy* 2011; 18: 11-25.
62. Kielhofner G. *Conceptual foundations of occupational therapy practice*. FA Davis, 2009.
63. Yoder RM, Nelson DL and Smith DA. Added-purpose versus rote exercise in female nursing home residents. *The American journal of occupational therapy* 1989; 43: 581-586.
64. King TI, 2nd. Hand strengthening with a computer for purposeful activity. *The American journal of occupational therapy* 1993; 47: 635-637.
65. Jarus T, Shavit S and Ratzon N. From hand twister to mind twister: computer-aided treatment in traumatic wrist fracture. *The American journal of occupational therapy* 2000; 54: 176-182.
66. Amini D. Occupation-based hand therapy and the occupational therapy practice framework. *OT practice* 2008; 3: 17-21.
67. Case-Smith J. Outcomes in hand rehabilitation using occupational therapy services. *The American journal of occupational therapy* 2003; 57: 499-506.
68. Kjeken I, Darre S, Smedslund G, et al. Effect of assistive technology in hand osteoarthritis: a randomised controlled trial. *Annals of the rheumatic diseases* 2011; 70: 1447-1452.
69. Carpenter L, Baker GA and Tyldesley B. The use of the Canadian occupational performance measure as an outcome of a pain management program. *Canadian journal of occupational therapy* 2001; 68: 16-22.
70. Hjortbak BR, Bangshaab J, Johansen JS, et al. *Udfordringer til rehabilitering i Danmark*. Viby J: Rehabiliteringsforum Danmark, 2011.
71. Rosberg HE. Disability and health after replantation or revascularisation in the upper extremity in a population in southern Sweden - a retrospective long time follow up. *BMC musculoskeletal disorders* 2014; 15: 73-80.
72. Carlsson IK and Dahlin LB. Self-reported cold sensitivity in patients with traumatic hand injuries or hand-arm vibration syndrome - an eight year follow up. *BMC musculoskeletal disorders* 2014; 15: 83-91.
73. Aasheim T and Finsen V. The DASH and the QuickDASH instruments. Normative values in the general population in Norway. *The Journal of hand surgery* 2014; 39: 140-144.
74. Christensen E. Methodology of superiority vs. equivalence trials and non-inferiority trials. *Journal of hepatology* 2007; 46: 947-954.
75. Ranner M, von Koch L, Guidetti S, et al. Client-centred ADL intervention after stroke: Occupational therapists' experiences. *Scandinavian journal of occupational therapy* 2016; 23: 81-90.
76. Holmefur M, Sundberg K, Wettergren L, et al. Measurement properties of the 13-item sense of coherence scale using Rasch analysis. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation* 2015; 24: 1455-1463.
77. Lindmark U, Stenstrom U, Gerdin EW, et al. The distribution of ''sense of coherence'' among Swedish adults: a quantitative cross-sectional population study. *Scandinavian journal of public health* 2010; 38: 1-8.

Table 1. Inclusion and exclusion criteria for patients with HRD

Inclusion criteria	**Exclusion criteria**
Age ≥ 18	Shoulder disability < 100 degree flexion/abduction
Diagnosed with a hand-related disorder	Epicondylitis
Referred to specialist outpatient occupational therapy rehabilitation course	Impaired extension in 5th finger of the non-dominant hand as only disability
Understand, speak and read Danish	Hyper-sensitivity of a scar as only disability
	Burn injury
	Arthroplasty *ad modum* Swanson in CMP-joints
	Not considered medically or therapeutically safe to allow intervention by randomization
	Diagnosed with depression, dementia or cognitive impairments
	No described or prioritized occupational performance problems.

Table 2. Baseline demographics for patients in study after 3 months (*n*= 398)

		All participants (not excluded during study*)			Weak SOC			Medium SOC			Strong SOC		
		PEI (*n*=193)	OBI (*n*=205)	*p*-value	PEI (*n*=17)	OBI (*n*=21)	*p*-value	PEI (*n*=79)	OBI (*n*=78)	*p*-value	PEI (*n*=97)	OBI (*n*=106)	*p*-value
Gender	Men/women	88/105	91/114	0.81	6/11	8/13	1.00	38/41	38/40	0.94	44/53	45/61	0.68
Age	Age mean years (CI)	49.5 (47.3-51-8)	46.8 (44.7-49.0)	0.08	40.91 (30.8-51.0)	41.9 (35.1-48.7)	0.86	48.1 (44.5-51.6)	45.4 (42.0-49.4)	0.36	52.2 (49.3-55.1)	48.6 (45.7-51.5)	0.08
Education	Elementary school *n* (%)	29 (15)	25 (12)	0.85	6 (35)	5 (24)	0.26	10 (13)	12 (15)	0.72	13 (13)	8 (8)	0.52
	High school *n* (%)	14 (7)	15 (7)		0 (0)	1 (5)		12 (15)	10 (13)		2 (2)	4 (4)	
	Vocational education *n* (%)	56 (29)	55 (27)		3 (17.5)	8 (38)		28 (35)	20 (26)		25 (25)	27 (25)	
	Short-length higher education (<3 years) *n* (%)	20 (10)	30 (15)		1 (6)	4 (19)		8 (10)	6 (8)		11 (11)	20 (19)	
	Medium-length higher education (3-5 years) *n* (%)	51 (26)	57 (28)		4 (24)	1 (5)		14 (18)	21 (27)		33 (33)	35 (33)	
	Long-higher education (>5 years) *n* (%)	21 (11)	22 (11)		3 (17.5)	2 (9.5)		6 (8)	8 (10)		12 (12)	13 (12)	
	Other *n* (%)	2 (1)	1 (0)		0 (0)	0 (0)		1 (1)	1 (1)		1 (1)	0 (0)	
DASH	Mean score (CI)	38.4 (35.9-41.0)	40.6 (38.0-43.1)	0.24	49.2 (40.9-57.4)	52.2 (44.2-60.3)	0.59	39.8 (35.6-44.1)	44.3 (39.8-48.7)	0.15	35.3 (31.9-39.0)	35.5 (32.3-38.7)	0.94
COPM performance	Median (25-75 quantile)	3.4(2.4-4.6)	3.3(1.8-4.4)	0.34	3.7(2.6-4.7)	2.9(2.0-3.7)	0.10	3.8(2.7-5.2)	3.5(2.4-4.5)	0.10	3.4(2.4-4.4)	3.6(2.8-4.8)	0.41
COPM satisfaction	Median (25-75 quantile)	2.6(1.8-3.7)	2.5(1.6-3.6)	0.34	2.8(2.2-3.5)	1.6(1.2-2.8)	***0.03***	2.9(2.0-3.8)	2.4(1.4-3.8)	0.14	2.5(1.6-3.7)	2.6(1.8-3.6)	0.59
Overall occupational performance **	Median (25-75 quantile)	7(5-8)	6(4-8)	0.37	6(4-7)	4(3-5)	0.17	7(5-8)	6(4-8)	0.32	7(5-8)	7(5-8)	0.79
Satisfaction with overall occupational performance **	Median (25-75 quantile)	6(4-8)	5(3-7)	0.02	5(3-6)	3(1-5)	0.05	5(4-8)	5(3-7)	0.27	7(4-8)	6(4-8)	0.13
SOC	Median (25-75 quantile)	73 (65-80)	73 (65-80)	0.99	44 (42-49)	42 (39-49)	0.60	67 (61-69)	66 (62-69)	0.38	80 (77-84)	80 (76-84)	0.96
EQ-5D	Median (25-75 quantile)	0.71 (0.68-0.78)	0.71 (0.65-0.78)	0.18	0.70 (0.55-0.71)	0.65 (0.39-0.71)	1.0	0,71 (0.65-0.78)	0.71 (0.65-0.78)	0.68	0.78 (0.71-0.78)	0.78 (0.66-0.78)	0.14
EQ-5D VAS	Median (25-75 quantile)	75 (60-89)	78 (65-90)	0.75	50 (39-68)	50 (40-67)	0.74	70 (60-85)	70 (60-80)	0.82	80 (70-90)	85 (70-90)	0.10
Type of injury	Acute/ elective *n* (%)	106/87	106/99	0.49	10/7	6/15	0.10	43/36	40/38	0.69	54/45	60/46	0.83
MHISS***	Median score (25-75 quantile)	18 (10-20)	20 (12-40)	0.06	20 (7-40)	27 (12-32)	0.51	18 (10-24)	20 (12-40)	0.34	18 (10-20)	20 (10-40)	0.10

* Patients who had a new injury after 3 months or wanted to withdraw after 3 months are included, ** *n*=385, ***only calculated on acute injuries

Table 3. Per protocol analysis between baseline and one, two, three, six, and 12 months

	1 month			2 months			3 months			6 months			12 months		
	PEI	OBI	*p*-value Change (CI)	PEI	OBI	*p*-value Change (CI)	PEI	OBI	*p*-value Change (CI)	PEI	OBI	*p*-value Change (CI)	PEI	OBI	*p*-value Change (CI)
All participants															
n	184	195		169	175		159	170		150	143		134	145	
Change in DASH mean (CI)	9.1 (7.1-11.2)	11.6 (9.8-13.4)	0.07 -2.5 (9.8-13.4)	13.6 (11.3-16.0)	15.5 (13.4-17.6)	0.24 -1.9 (-5.0-1.2)	16.4 (14.0-18.8)	16.8 (14.6-18.9)	0.83 -0.4 (-3.5-2.8)	17.56 (14.7-20.4)	18.50 (15.7-21.3)	0.64 -0.9 (-4.9-3.0)	20.08 (17.1-23.1)	20.05 (17.2-22.9)	0.99 -0.03 (-4.1-4.1)
Change in overall occupational performance* median (25-75 q)*	1 (0-2)	1 (0-3)	0.08	1 (0.0-3.0)	2 (0.0-3.0)	0.20	2 (0-3)	2 (0-4)	0.42	2 (0-3)	2 (1-3)	0.56	2(0-4)	2(1-4)	0.32
Change in satisfaction with overall occupational performance* median (25-75 q)	1 (0-3)	2 (0-3.5)	***0.02***	2 (0-3)	2 (1-4)	***0.05***	2 (0-4)	2 (1-5)	0.06	2 (1-4)	2 (1-4)	0.37	2(1-4)	2(1-4)	0.15
Weak SOC															
n	14	19		14	16		15	17		14	15		12	16	
Change in DASH mean (CI)	12.5 (4.5-20.5)	8.2 (2.1-14.4)	0.37 4.2 (-5.2-13.7)	12.6 (0.3-24.9)	10.1 (4-1-16.2)	0.69 2.5 (-10-15.0)	16.6 (6.0-27.2)	14.3 (7.8-20.8)	0.69 2.3 (-9.3-13.8)	24.0 (10.6-37.3)	12.0 (1.8-22.1)	0.13 12 (-3.9-27.9)	27.39 (13.3-47.6)	13.02 (3.7-32.0)	0.08 14.4 (-2.1-30.8)
Change in overall occupational performance median (25-75 q)*	1 (0-4.5)	1 (0-3)	0.43	1 (-1-4.0)	1 (1-3)	0.75	2.5 (0-5)	2 (0-4)	0.56	2.5 (0-5)	1 (1-3)	0.32	4 (0.5-5-5)	2(0.5-4)	0.41
Change in satisfaction with overall occupational performance, median (25-75 q)*	2 (0.0-3.5)	2 (0-3)	0.80	2 (-1-4.0)	2 (1-4)	0.30	2 (-1-5)	4 (1-5)	0.46	2 (-0-5)	1 (0-4)	0.81	3(-0.5-5.5)	2(0.5-4)	0.76
Medium SOC															
N	74	74		64	67		60	*62*		55	54		50	52	
Change in DASH mean (CI)	10.0 (7.0-13.1)	13.1 (9.9-16.3)	0.18 -3.0(-7.4-1.4)	14.0 (10.0-18.0)	18.2 (14.4-22.1)	0.12 -4.3 (-9.8-1.2)	16.6 (12.6-20.7)	21.4 (17.5-25.2)	0.09 -4.3 (-10.3-0.8)	18.2 (13.1-23.3)	25.1 (20.5-29.8)	***0.047*** -7.0 (-13.8- -0.1)	20.53 (15.3-25.7)	25.19 (19.8-30.6)	0.21 -4.7 (-12.1-2.7)
Change in overall occupational performance median (25-75 q)*	1 (0-2)	2 (0-3)	***0.045***	1 (0-3)	2 (0-4)	0.19	2(0-3)	2 (1-4)	0.21	2(0-3)	3 (1-3)	0.06	2(0-3)	3(1-4)	0.14
Change in satisfaction with overall occupational performance, median (25-75 q)*	1 (0-3)	2 (0-4)	***0.05***	2 (1-4)	2 (1-4)	0.59	2(1-4)	2.5 (1-5)	0.42	2(1-3)	2 (1-5)	0.33	2(1-4)	2(1-5)	0.62
Strong SOC															
N	96	102		91	92		84	91		81	74		72	77	
Change in DASH mean (CI)	8.0 (5.0-10.9)	11.2 (8.9-13.5)	0.09 -3.2(-6.9-0.5)	13.6 (10.7-16.4)	14.4 (11.8-17.1)	0.66 -0.9 (-4.7-3.0)	16.2 (13.1-19.4)	14.1 (11.4-16.8)	0.30 2.1 (-2.0-6.2)	16.1 (12.6-19.4)	15.0 (11.6-18.4)	0.66 1.1 (-3.7-5.9)	18.55 (14.8-22.3)	18.04 (14.7-21.4)	0.84 0.5 (-4.4-5.5)
Change in overall occupational performance median (25-75 q)*	1 (0-2)	1 (0-3)	0,34	1.5 (0-3)	2 (0-3)	0.66	2 (0-3)	2 (0-3)	0,82	2 (0-3)	1 (0-3)	0.63	1(0-3)	1.5(1-3)	0.69
Change in satisfaction with overall occupational performance median (25-75 q)*	1 (0-2)	1 (0-3)	0.09	2 (0-3)	2 (0-4)	0.07	1 (0-3)	2 (1-4)	0.10	1 (0.5-4)	2 (0-4)	0.67	2(1-4)	2(1-4)	0.09

q = quartile. At 1 month: *n*=379 of *n*=404 in total due to missing data *n*=366. At 2 months: *n*=344 of *n*=401 in total due to missing data *n*=333, At 3 months: *n*=329 of *n*= 398 in total due to missing data *n*=315. At six months *n*=293 of *n*= 397 in total due to missing data *n=282. At 12 months *n*=279 of *n*= 395 in total due to missing data *n=271

Table 4. Additional analysis of functioning with longitudinal data

	1 month		2 month		3 month		6 month		12 month		
	Difference (CI)	P-value	Difference (CI)	P-value	Difference (CI)	P-value	Difference (CI)	P-value	Difference (CI)	P-value	Overall P-value
All participants											
N (PEI/OBI)	184 / 195		169 / 175		159 / 170		150 / 143		134 / 145		
Change in DASH mean (CI)	-1.93 (-4.27, 0.41)	0.11	-1.20 (-3.63, 1.24)	0.34	-0.63 (-3.11, 1.85)	0.62	0.03 (-2.56, 2.61)	0.98	0.34 (-2.97, 2.29)	0.80	0.63
Weak SOC											
N (PEI/OBI)	14/19		14/16		15/17		14/15		12/16		
Change in DASH mean (CI)	3.02 (-4.77, 10.81)	0.45	4.22 (-3.80, 12.25)	0.30	1.57 (-6.29, 9.44)	0.70	10.79 (2.64, 18.94)	0.01	10.12 (1.80, 18.44)	0.02	
Medium SOC											
N (PEI/OBI)	74/74		64/67		60/62		55/54		50/52		
Change in DASH mean (CI)	-1.61 (-5.30, 2.08)	0.39	-3.49 (-7.36, 0.38)	0.08	-4.00 (-7.99, -0.21)	0.05	-5.19 (-9.34, -1.03)	0.01	-4.45 (-8.71, -0.19)	0.04	
Strong SOC											
N (PEI/OBI)	96/102		91/92		84/91		81/74		72/77		
Change in DASH mean (CI)	-3.08 (-6.28, 0.13)	0.06	-0.54 (-3.84, 2.76)	0.75	1.36 (-2.00, 4.72)	0.43	1.80 (-1.71, 5.32)	0.32	0.59 (-2.97, 4.16)	0.75	

At 1 month: *n*=379 of *n*=404 in total due to missing data. At 2 months: *n*=344 of *n*=401 in total due to missing data. At 3 months: *n*=329 of *n*= 398 in total due to missing data. At six months *n*=293 of *n*= 397 in total due to missing data. At 12 months *n*=279 of *n*= 395 in total due to missing data.

Table 5. Per protocol analysis between baseline COPM and one, two, and three months COPM

	1 month			2 months			3 months		
	PEI	OBI	*p*-value Change (CI)	PEI	OBI	*p*-value Change (CI)	PEI	OBI	*p*-value Change (CI)
All participants									
n	182	198		103	105		30	36	
Change in COPM performance median (25-75 quartile)	2.6 (1.4-4.0)	3 (1.8-4.4)	***0.028***	3.2 (2.0-5.2)	4 (3.0-5.8)	***0.014***	4.1 (2.6-5.0)	4.6 (3.7-6.1)	***0.048***
Change in COPM satisfaction median (25-75 quartile)	3.4 (2.2-5.0)	4.0 (2.6-5.6)	***0.04***	3.6 (2.4-5.4)	5.0 (3.2-6.6)	***0.002***	4.2 (3.0-6.0)	5.6 (4.0-7.2)	***0.017***
Weak SOC									
n	17	20		10	8		6	2	
Change in COPM performance median (25-75 quartile)	1.4 (0.4-3.6)	2.1 (0.4-3.3)	0.77	1.9 (0.4-2.8)	3.7 (2.4-6.0)	0.13	3.5 (1.4-4.0)	3.9 (3.6-4.2)	0.40
Change in COPM satisfaction median (25-75 quartile)	2.3 (2.2-4.0)	3.1 (1.8-4.2)	0.85	2.7 (0.2-4.0)	3.8 (2.2-6.7)	0.20	3.3 (2.0-4.8)	4.2 (4-4.4)	0.51
Medium SOC									
n	76	76		41	48		11	18	
Change in COPM performance median (25-75 quartile)	2.5 (1.7-3.9)	3.4 (2.1-4.9)	***0.012***	3.3 (1.8-5.0)	4.1 (3.0-5.5)	0.22	3.5 (2.8-6.0)	4.6 (3.8-6.2)	0.27
Change in COPM satisfaction median (25-75 quartile)	3.4 (2.3-5.0)	4.3 (2.8-5.6)	***0.05***	4.0 (2.8-4.8)	4.8 (3.3-6.4)	***0.036***	4.2 (3.0-6.0)	5.5 (4.0-7.2)	0.18
Strong SOC									
n	89	102		52	49		13	16	
Change in COPM performance median (25-75 quartile)	2.8 (1.4-4)	3 (1.8-4)	0.37	3.3 (2.4-5.3)	4.0 (2.8-5.8)	0.11	4.4 (2.6-5.4)	4.8 (3.8-6.1)	0.30
Change in COPM satisfaction median (25-75 quartile)	3.4 (2.3-5.0)	3.4 (2.6-5.6)	0.29	3.5 (2.6-6.1)	5.6 (3.6-6.6)	0.05	4.4 (3.6-6.0)	6 (4.8-7.4)	0.10

Table 6. Drop-out analyses

		All randomized (*n*=504)*			All not excluded at 3 months (n=398)		Excluded (*n*=106)			
		PEI (*n*=249)	OBI (*n*=255)	*p*-value	PEI (*n*=193)	OBI (*n*=205)	PEI (*n*=56)	OBI (*n*=50)	*p-value* PEI**	*p-value* OBI**
Gender	Men/women	114/135	107/148	0.39	88/105	91/114	26/30	16/34	0.91	0.11
Age	Age, mean years (CI)	48.5 (46.44-50.53)	46.7 (44.72-48.65)	0.21	49.5 (47.3-51.8)	46.8 (44.7-49.0)	45.0 (40.1-49.8)	46.0 (41.1-51.0)	0.06	0.75
Education	Elementary school *n* (%)	41 (16)	32 (13)	0.61	29 (15)	25 (12)	12 (21)	7 (14)	0.47	0.90
	High school *n* (%)	20 (8)	20 (8)		14 (7)	15 (7)	6 (11)	5 (10)		
	Vocational education *n* (%)	66 (27)	69 (27)		56 (29)	55 (27)	10 (18)	14 (28)		
	Short-length higher education (<3 years) *n* (%)	25 (10)	39 (15)		20 (10)	30 (15)	5 (9)	9 (18)		
	Medium-length higher education (3-5 years) *n* (%)	69 (28)	69 (27)		51 (26)	57 (28)	18 (32)	12 (24)		
	Long higher education (>5 years) *n* (%)	25 (10)	25 (10)		21 (11)	22 (11)	4 (7)	3 (6)		
	Other *n* (%)	2 (1)	1 (0)		2 (1)	1 (1)	0 (0)	0 (0)		
	Missing data about educational level *n* (%)	1 (0)	0 (0)		0	0	1 (2)	0 (0)		
Diagnosis	Fractured finger(s) *n* (%)	40 (16)	36 (14)	0.64	31 (16)	32 (16)	9 (16)	4 (8)	0.51	0.24
	Fracture in wrist or carpus *n* (%)	34 (14)	37 (14)		22 (11)	30 (15)	12 (21)	7 (14)		
	Luxation *n* (%)	28 (11)	21 (8)		23 (12)	20 (10)	5 (9)	1 (2)		
	Vulnus (open wound)/ contusion/conquassatio *n* (%)	20 (8)	25 (10)		16 (8)	20 (10)	4 (7)	5 (10)		
	Tendon injuries *n* (%)	22 (9)	13 (5)		19 (10)	12 (6)	3 (5)	1 (2)		
	Arthrosis in the thumb *n* (%)	13 (5)	16 (6)		10 (5)	12 (6)	3 (5)	4 (8)		
	Degeneration in tendons or ligaments incl. ganglion and Dupuytren´s contracture *n* (%)	15 (6)	10 (4)		11 (6)	7 (3)	4 (7)	3 (6)		
	Arthrosis/arthritis *n* (%)	7 (3)	11 (4)		5 (3)	10 (5)	2 (4)	1 (2)		
	Mixed pain incl. chronic pain *n* (%)	8 (3)	9 (4)		8 (4)	6 (3)	0 (0)	3 (6)		
	Hand infection *n* (%)	10 (4)	8 (3)		7 (4)	5 (2)	3 (5)	3 (6)		
	Elective nerve disorder *n* (%)	5 (2)	9 (4)		5 (3)	6 (3)	0 (0)	3 (6)		
	Finger amputation *n* (%)	1 (1)	5 (2)		0 (0)	4 (2)	1 (2)	1 (2)		
	Nerve injury *n* (%)	3 (1)	3 (1)		2 (1)	1 (1)	1 (2)	2 (4)		
	Sequelae fracture or distortions *n* (%)	41 (16)	48 (19)		32 (17)	36 (18)	9 (16)	12 (24)		
	Other *n* (%)	2 (1)	4 (2)		2 (1)	4 (2)	0 (0)	0 (0)		
DASH	Mean score (CI)	37.9 (35.61-40.17)	40.2 (37.91-42.39)	0.16	38.4 (35.9-41.0)	40.6 (38.0-43.1)	36.1 (31.0-41.2)	38.5 (33.8-43.1)	0.41	0.46
SOC	Weak *n* (%)	24 (10)	26 (10)	0.98	17 (9)	21 (10)	7 (13)	5 (10)	0.23	0.97
	Medium *n* (%)	95 (38)	98 (38)		79 (41)	78 (38)	16 (29)	20 (40)		

	Strong *n* (%)	130 (52)	131 (51)		97 (50)	106 (52)	33 (59)	25 (50)		
EQ-5D	Mean score (CI)	0.70 (0.68-0.71)	0.68 (0.66-0.70)	0.29	0.71 (0.68-0.78)	0.71 (0.65-0.78)	0.71 (0.68-0.78)	0.71 (0.66-0.78)	0.65	0.71
EQ-5D VAS	Median (25-75 quantile)	75 (60-89)	75 (60-90)	0.79	75 (60-89)	78 (65-90)	75 (60-89)	72 (60-82)	0.93	0.27
Sessions	Median (25-75 quantile)	7 (5-11)	8 (5-12)	0.33	8(5-12)	9(6-13)	4(2-8)	5(3-6)	***0.001***	***< 0.001***
Days between "injury" and rehab start	Median (25-75 quantile)	75 (52-215)	88 (54-318)	0.10	78 (52-207)	85(52-296)	64 (54-266)	144 (63-674)	0.17	0.21
Type of injury	Acute/ elective	137/112	122/133	0.11	106/87	106/99	31/25	16/34	0.83	0.24
MHISS***	Median score (25-75 quantile)	20 (10-24)	20 (12-40)	0.09	18 (10-20)	20 (12-40)	20 (10-36)	20 (15-26)	0.11	0.28

* DASH, SOC, EQ-5D only calculated for 503 patients. One patient with strong SOC in EPI group withdrew before 1 month follow-up and therefore baseline data for this participant were excluded from baseline data. ** p-value between all not excluded and excluded ***only calculated on acute injuries

Figure 1: Data collection

	Baseline (FU-0)	1 month (FU-1)	2 months (FU-2)	3 months (FU-3)	6 months (FU-4)	12 months (FU-5)
DASH	✓	✓	✓	✓	✓	✓
EQ5D	✓			✓		
SOC	✓			✓		✓
COPM	✓	✓	✓	✓		
Overall occupational performance	✓	✓	✓	✓	✓	✓
Satisfaction with overall occupational performance	✓	✓	✓	✓	✓	✓
Satisfaction with occupational therapy		✓	✓	✓	✓	✓
Satisfaction with treatment effect		✓	✓	✓	✓	✓
Satisfaction with adherence		✓	✓	✓	✓	✓
Age, gender, education, job situation	✓					

Appendix 1. Supplemental baseline demographics for all patients who were not excluded at 3 months (*n*= 398)

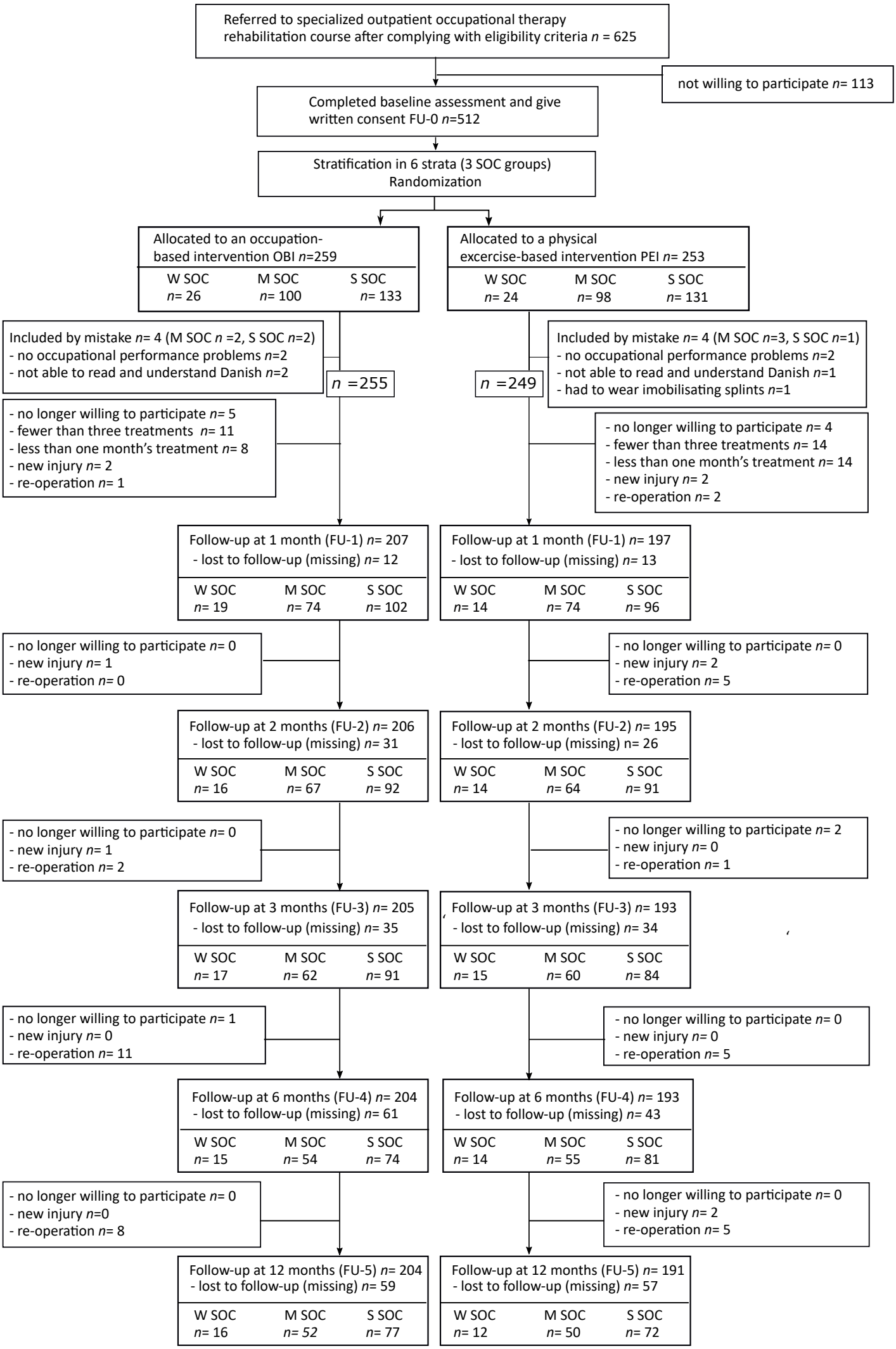
		All participants (not excluded during study*)			Weak SOC			Medium SOC			Strong SOC		
		PEI (*n*=193)	OBI (*n*=205)	*p*-value	PEI (*n*=17)	OBI (*n*=21)	*p*-value	PEI (*n*=79)	OBI (*n*=78)	*p*-value	PEI (*n*=97)	OBI (*n*=106)	*p*-value
Diagnosis	Fractured finger(s) *n* (%)	31 (16)	32 (16)	0.62	3 (18)	1 (5)	0.40	10 (13)	11 (14)	0.56	18 (19)	20 (19)	0.70
	Fracture in wrist or carpus *n* (%)	22 (11)	30 (15)		4 (24)	1 (5)		9 (11)	11 (14)		9 (9)	18 (17)	
	Luxation *n* (%)	23 (12)	20 (10)		0 (0)	1 (5)		11 (14)	8 (10)		12 (12)	11 (10)	
	Vulnus (open wound)/ contusion/conquassatio *n* (%)	16 (8)	20 (10)		2 (12)	3 (14)		7 (9)	6 (8)		7 (7)	11 (10)	
	Tendon injuries *n* (%)	19 (10)	12 (6)		1 (6)	2 (10)		9 (11)	4 (5)		9 (9)	6 (6)	
	Arthrosis in the thumb *n* (%)	10 (5)	12 (6)		0 (0)	2 (10)		6 (8)	5 (6)		4 (4)	5 (5)	
	Degeneration in tendons or ligaments incl. ganglion and Dupuytren's contracture *n* (%)	11 (6)	7 (3)		1 (6)	0 (0)		4 (5)	2 (3)		6 (6)	5 (5)	
	Arthrosis/arthritis n (%)	5 (3)	10 (5)		0 (0)	0 (0)		1 (1)	7 (9)		4 (4)	3 (3)	
	Mixed pain incl. chronic pain *n* (%)	8 (4)	6 (3)		3 (18)	3 (14)		2 (3)	2 (3)		3 (3)	1 (1)	
	Hand infection *n* (%)	7 (4)	5 (2)		1 (6)	0 (0)		1 (1)	1 (1)		5 (5)	4 (4)	
	Elective nerve disorder *n* (%)	5 (3)	6 (3)		0 (0)	1 (5)		1 (1)	3 (4)		4 (4)	2 (2)	
	Finger amputation *n* (%)	0 (0)	4 (2)		0 (0)	0 (0)		0 (0)	2 (3)		0 (0)	2 (2)	
	Nerve injury *n* (%)	2 (1)	1 (1)		0 (0)	0 (0)		1 (1)	1 (1)		1 (1)	0 (0)	
	Sequelae fracture or distortions *n* (%)	32 (17)	36 (18)		2 (12)	6 (29)		16 (20)	12 (15)		14 (14)	18 (17)	
	Other *n* (%)	2 (1)	4 (2)		0 (0)	1 (5)		1 (1)	3 (4)		1 (1)	0 (0)	
Work status	In work *n* (%)	106 (55)	123 (60)	0.57	6 (35)	7 (33)	0.14	37 (47)	40 (51)	0.89	63 (65)	76 (72)	0.63
	Unemployed *n* (%)	20 (10)	22 (11)		3 (18)	8 (38)		9 (11)	10 (13)		8 (8)	4 (4)	
	Student *n* (%)	18 (9)	14 (7)		4 (24)	0 (0)		9 (11)	8 (10)		5 (5)	6 (6)	
	Early retirement *n* (%)	6 (3)	9 (4)		0 (0)	1 (5)		4 (5)	6 (8)		2 (2)	2 (2)	
	Retired *n* (%)	36 (19)	28 (14)		3 (18)	2 (10)		16 (20)	11 (14)		17 (18)	15 (14)	
	Other *n* (%)	7 (4)	9 (4)		1 (6)	3 (14)		4 (5)	3 (4)		2 (2)	3 (3)	
Days between "injury" and rehab start	Median (25-75 quantile)	78 (52-207)	85(52-296)	0.54	72 (54-448)	149 (46-394)	0.49	75 (52-270)	94 (55-318)	0.30	84 (51-185)	77 (52-198)	0.71

* Patients who had a new injury after 3 months or wanted to withdraw after 3 months are included

Appendix 2. Non-participant analyses

		Non-participants (*n=113*)	Participants (*n*=504)*	*p*-value
Gender	Men/women	54/59	221/283	0.45
Age	Age mean years	52.31	47.57	***0.005***
Diagnosis	Fractured finger(s) *n* (%)	13 (12)	76 (15)	0.42
	Fracture in wrist or carpus *n* (%)	20 (18)	71 (14)	
	Luxation *n* (%)	6 (5)	49 (10)	
	Vulnus (open wound) contusion/conquassatio *n* (%)	16 (14)	45 (9)	
	Tendon injuries *n* (%)	11 (10)	35 (7)	
	Arthrosis in the thumb *n* (%)	5 (4)	29 (6)	
	Degeneration in tendons or ligaments incl. ganglion and Dupuytren's contracture *n* (%)	4 (4)	25 (5)	
	Arthrosis/arthritis *n* (%)	8 (7)	18 (4)	
	Mixed pain incl. chronic pain *n* (%)	3 (3)	17 (3)	
	Hand infection *n* (%)	5 (4)	18 (4)	
	Elective nerve disorder *n* (%)	4 (4)	14 (3)	
	Finger amputation *n* (%)	2 (2)	6 (1)	
	Nerve injury *n* (%)	0 (0)	6 (1)	
	Sequelae fracture or distortions *n* (%)	14 (12)	89 (18)	
	Other *n* (%)	2 (2)	6 (1)	
Sessions	Median	6 (4-11)	7 (5-12)	0.56
Days between injury/onset of symptoms and rehab start	Median	65 (45-143)	80 (53-78)	0.11
Type of injury	Acute/ elective	58/55	259/249	0.47
MHISS**	Median (25 -75 quantile)	20(10-24)	20 (10-33)	0.64

* DASH, SOC, EQ-5D only calculated for 503 patients. One patient with strong SOC in EPI group withdrew before 1 month follow-up and therefore baseline data for this participant were excluded from baseline data. **only calculated on acute injuries


Referred to specialized outpatient occupational therapy rehabilitation course after complying with eligibility criteria n = 625
not willing to participate n= 113
Completed baseline assessment and give written consent FU-0 n=512
Stratification in 6 strata (3 SOC groups) Randomization
Allocated to an occupation-based intervention OBI n=259
W SOC n= 26
M SOC n= 100
S SOC n= 133
Allocated to a physical excercise-based intervention PEI n= 253
W SOC n= 24
M SOC n= 98
S SOC n= 131
Included by mistake n= 4 (M SOC n =2, S SOC n=2)
- no occupational performance problems n=2
- not able to read and understand Danish n=2
n =255
Included by mistake n= 4 (M SOC n=3, S SOC n=1)
- no occupational performance problems n=2
- not able to read and understand Danish n=1
- had to wear imobilisating splints n=1
n =249
- no longer willing to participate n= 5
- fewer than three treatments n= 11
- less than one month's treatment n= 8
- new injury n= 2
- re-operation n= 1
- no longer willing to participate n= 4
- fewer than three treatments n= 14
- less than one month's treatment n= 14
- new injury n= 2
- re-operation n= 2
Follow-up at 1 month (FU-1) n= 207
- lost to follow-up (missing) n= 12
W SOC n= 19
M SOC n= 74
S SOC n= 102
Follow-up at 1 month (FU-1) n= 197
- lost to follow-up (missing) n= 13
W SOC n= 14
M SOC n= 74
S SOC n= 96
- no longer willing to participate n= 0
- new injury n= 1
- re-operation n= 0
- no longer willing to participate n= 0
- new injury n= 2
- re-operation n= 5
Follow-up at 2 months (FU-2) n= 206
- lost to follow-up (missing) n= 31
W SOC n= 16
M SOC n= 67
S SOC n= 92
Follow-up at 2 months (FU-2) n= 195
- lost to follow-up (missing) n= 26
W SOC n= 14
M SOC n= 64
S SOC n= 91
- no longer willing to participate n= 0
- new injury n= 1
- re-operation n= 2
- no longer willing to participate n= 2
- new injury n= 0
- re-operation n= 1
Follow-up at 3 months (FU-3) n= 205
- lost to follow-up (missing) n= 35
W SOC n= 17
M SOC n= 62
S SOC n= 91
Follow-up at 3 months (FU-3) n= 193
- lost to follow-up (missing) n= 34
W SOC n= 15
M SOC n= 60
S SOC n= 84
- no longer willing to participate n= 1
- new injury n= 0
- re-operation n= 11
- no longer willing to participate n= 0
- new injury n= 0
- re-operation n= 5
Follow-up at 6 months (FU-4) n= 204
- lost to follow-up (missing) n= 61
W SOC n= 15
M SOC n= 54
S SOC n= 74
Follow-up at 6 months (FU-4) n= 193
- lost to follow-up (missing) n= 43
W SOC n= 14
M SOC n= 55
S SOC n= 81
- no longer willing to participate n= 0
- new injury n=0
- re-operation n= 8
- no longer willing to participate n= 0
- new injury n= 2
- re-operation n= 5
Follow-up at 12 months (FU-5) n= 204
- lost to follow-up (missing) n= 59
W SOC n= 16
M SOC n= 52
S SOC n= 77
Follow-up at 12 months (FU-5) n= 191
- lost to follow-up (missing) n= 57
W SOC n= 12
M SOC n= 50
S SOC n= 72