

## **PICO 5**

### **Review information**

#### **Authors**

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Citation example: [Empty name]. PICO 5. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

#### **Abstract**

#### **Background**

#### **Objectives**

#### **Search methods**

#### **Selection criteria**

#### **Data collection and analysis**

#### **Main results**

## Authors' conclusions

# Characteristics of studies

## Characteristics of included studies

### Arnold 2010

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b></p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>Intervention</p> <p>Control</p> <p><b>Included criteria:</b> Eligibility criteria: age 65 years or older, presence of hip pain 6 months or longer, diagnosed with hip OA and presenting with 1 fall risk factor, a timed up-and-go test (TUG; Podsiadlo &amp; Richardson, 1991) score of 10 s or more, or a history of at least one fall in the past 12 months</p> <p><b>Excluded criteria:</b> Exclusion criteria were any joint surgery within the last 6 months, current participation in a group exercise program incorporating balance training or aquatics twice a week or more, and the presence of any medical or neurological condition that significantly affected independence in mobility.</p> <p><b>Pretreatment:</b></p>
<b>Interventions</b>	<p><b>Intervention Characteristics</b></p> <p>Intervention</p> <ul style="list-style-type: none"> <li>● <b>Exercise description:</b> Goals were to improve mobility, strength, and balance. Strengthening exercises (using "oats, noodles, sponges, and paddles for added resistance), trunk-control exercises (abdominal strengthening in "oating positions, trunk control in standing positions), posture practice and balance exercises (mobility games, variations in walking and standing balance activities). + 1.5 hr of land-based "physical" practice of balance-related activities during educational sessions</li> <li>● <b>Patient education description:</b> The goals of the education session were to increase the transfer of exercises learned in the pool to the ability to successfully perform activities of daily living, increase knowledge of individual fall</li> </ul>

riskfactors and fall-prevention strategies, and improve confidence in the ability to avoid a fall and recover from a fall at home and in the community. Participants in this group received a booklet with information for each education session and had the opportunity to set individual goals regarding exercise and fall-prevention strategies. The delivery and goals of the program were based on self-efficacy theory (Bandura, 1997) and addressed determinants of self-efficacy such as mastery experience, verbal persuasion, and the relationship of physiological and affective states.

- *Supervision and duration*: Exercise 45 min twice a week for 11 weeks. Educator: 30-min educational session preceding the aquatic class (once a week) for 11 weeks, delivered by PT with 20 years experience

#### Control

- *Exercise description*: Usual activities and were asked to not begin an exercise program during the control period, which lasted the same length of time, 11 weeks, as the interventions. They were told they would be offered either the A or AE class after 11 weeks. Adherence was encouraged by a phone call from the study coordinator every 2 weeks.
- *Patient education description*: None
- *Supervision and duration*: Adherence was encouraged by a phone call from the study coordinator every 2 weeks. Patients were given a diary to take home to record falls, near falls, any new medications, new conditions, therapy, or illness.

#### Outcomes

##### *Patient-reported function score*

- **Outcome type**: Continuous Outcome
- **Reporting**: Not reported
- **Scale**: AIMS-2
- **Notes**: Reported at baseline, but results only as "no difference between groups" (p=0.19)

##### *Performance-based function score*

- **Outcome type**: Continuous Outcome
- **Reporting**: Fully reported
- **Scale**: Chair stand test (30 sec)
- **Unit of measure**: Repetitions
- **Direction**: Higher is better
- **Data value**: Endpoint

##### *Mortality (hazard)*

- **Outcome type**: Continuous Outcome
- **Reporting**: Not reported

	<p><i>Helbredsrelateret livskvalitet</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Not reported</li> </ul> <p><i>Self-efficacy</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Not reported</li> </ul> <p><i>Træningsinducerede skader</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> AdverseEvent</li> <li>● <b>Reporting:</b> Not reported</li> </ul> <p><i>Smerte (ikke hofterelateret)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> AdverseEvent</li> <li>● <b>Reporting:</b> Not reported</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source:</b> The Saskatchewan-Canadian Institutes of Health Research Regional Partnerships Program (Sask-CIHR RPP) provided a 2-year fellowship grant for the primary author, and the Physiotherapy Foundation of Canada provided operational funding.</p> <p><b>Country:</b> Canada</p> <p><b>Setting:</b></p> <p><b>Comments:</b></p> <p><b>Authors name:</b> Arnold, 2010</p> <p><b>Institution:</b></p> <p><b>Email:</b></p> <p><b>Address:</b></p>
<b>Notes</b>	

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessors	Low risk	Judgement Comment: Testing was conducted by two experienced physical therapists blinded to group assignment and a research assistant.
Other sources of bias	Low risk	Judgement Comment: None apparent
Allocation concealment	Low risk	Judgement Comment: Random assignment was conducted by an individual not involved in the research project. Participants were blinded to group assignment until after baseline testing, when they were given a sealed opaque envelope revealing their group assignment.
Blinding of participants and personnel	High risk	Judgement Comment: Blinding not possible
Incomplete outcome data	Low risk	Judgement Comment: 18% and 22% drop outs. Intention-to-treat analysis
Selective outcome reporting	Unclear risk	Judgement Comment: Not reported data on patient reported function (reports only p-value on AIMS-2). No data on pain.
Sequence Generation	Low risk	Judgement Comment: Random assignment was conducted by an individual not involved in the research project using a computer-generated program

**Hopman-Rock 2000**

Methods	
Participants	
Interventions	
Outcomes	
Identification	
Notes	

## Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessors	High risk	Fra SR Fransen et al. 2014
Other sources of bias	Low risk	Fra SR Fransen et al. 2014
Allocation concealment	Unclear risk	Fra SR Fransen et al. 2014
Blinding of participants and personnel	High risk	Fra SR Fransen et al. 2014
Incomplete outcome data	Unclear risk	Fra SR Fransen et al. 2014
Selective outcome reporting	Unclear risk	Fra SR Fransen et al. 2014
Sequence Generation	Unclear risk	Fra SR Fransen et al. 2014

**Krauß 2014**

<b>Methods</b>	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b></p>
<b>Participants</b>	<p><b>Baseline Characteristics</b></p> <p>Intervention</p> <p>Control</p> <p><b>Included criteria:</b> – Age between 18 and 85 years– Osteoarthritis (OA) of one or both hip joint(s) (clinical criteria of the American College of Rheumatology)– The subject gives voluntary consent to study participation after receiving oral and written information about study contentand objectives– The subject has the time available to undertake the exercises and attend the measurements– The subject is physically fit for the intervention measure (as ascertained during the examination conducted by the principalinvestigator). “Fitness” in this setting relates to the physical as well as the psychological condition of the subject. (Subjectswill not be excluded if they have one hip endoprosthesis, as long as the contralateral hip is affected by osteoarthritisaccording to the listed criteria.)– The subject has capacity to consent</p> <p><b>Excluded criteria:</b> Exclusion criteria– Unstable anchoring of endoprosthesis hip joint– Hip dislocation after endoprosthesis joint replacement– Further disorders affecting the lower extremities or lower back that require treatment by a physician/therapist and which are not connected to the OA and are currently being treated.– The presence of</p>

	<p>osteoarthritis in several joints (for example, hip and knee) is NOT an exclusion criterion. – Medication or alcohol misuse– Participation in a clinical study in the preceding 4 weeks– Lack of compliance– Acute illness– Use of walking aids– Previous trauma in the hip and pelvis area with accompanying development of secondary osteoarthritis– Known endocrinological causes of hip osteoarthritis– Confirmed metabolic causes of hip osteoarthritis– State after aseptic bone necrosis (Perthes' disease)– Cardiocirculatory disorders or other comorbidities that result in severely restricted everyday physical capacity and that are contraindications to physical exertion (for example, heart failure NYHA III–IV, terminal renal failure stage IV)– Medical exercise therapy, physiotherapy on resistance machines in the preceding 3 months, with a total treatment frequency of more than 6 units– Systematic group or individual therapy to treat the osteoarthritis (systematic in the sense of a minimum of 1x/week for 30 minutes or more) in the preceding 3 months– Physical therapy to treat the osteoarthritis (systematic in the sense of regular, prescribed application at least 1x/week) in the preceding 3 months– Newly initiated exercise/movement therapy in the preceding 3 months (sports and movement therapy defined as taking place a minimum of 1x/week, getting out of breath, minimum duration 30 minutes)– Corticosteroid injection into the hip joint in the preceding 12 months.</p> <p><b>Pretreatment:</b></p>
<p><b>Interventions</b></p>	<p><b>Intervention Characteristics</b></p> <p>Intervention</p> <ul style="list-style-type: none"> <li>● <i>Exercise description:</i> The THüKo exercise therapy approach entails a once-weekly group intervention (60–90 minutes) in addition to a twice-weekly home exercise program (30–40 minutes each). Exercises aimed to strengthen the muscles and to improve proprioception, balance and flexibility.</li> <li>● <i>Patient education description:</i> The therapeutic program entailed education and social interaction. From protocol: Educational content related to exercises, (anatomical basics and training modalities). Sessions enhance social contacts by group-based introductions and feedbacks before and after the exercises, and by enforcing partner and group exercises.</li> <li>● <i>Supervision and duration:</i> 1 weekly supervised session for 12 weeks + home-based exe.</li> </ul> <p>Control</p> <ul style="list-style-type: none"> <li>● <i>Exercise description:</i> No intervention</li> <li>● <i>Patient education description:</i> No intervention</li> <li>● <i>Supervision and duration:</i> No intervention</li> </ul>
<p><b>Outcomes</b></p>	<p><i>Patientrapporteret funktionsevne</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> </ul>

- **Scale:** WOMAC function
- **Range:** 0-100
- **Unit of measure:** Points
- **Direction:** Lower is better
- **Data value:** Endpoint

*Præstationsbaseret funktionsevne*

- **Outcome type:** ContinuousOutcome
- **Reporting:** Not reported

*Smerte (høfte)*

- **Outcome type:** ContinuousOutcome
- **Reporting:** Fully reported
- **Scale:** WOMAC pain
- **Range:** 0-100
- **Unit of measure:** Points
- **Direction:** Lower is better
- **Data value:** Endpoint

*Helbredsrelateret livskvalitet*

- **Outcome type:** ContinuousOutcome
- **Reporting:** Fully reported
- **Scale:** SF-36 General health
- **Range:** 0-100
- **Unit of measure:** Points
- **Direction:** Higher is better
- **Data value:** Change from baseline

*Self-efficacy*

- **Outcome type:** ContinuousOutcome
- **Reporting:** Not reported

*Træningsinducerede skader*

- **Outcome type:** AdverseEvent
- **Reporting:** Not reported
- **Notes:** No subject had to leave the intervention because of therapy-related adverse effects. No info on systematic

	<p>recording of injuries.</p> <p><i>Smerte (ikke hofferelateret)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> AdverseEvent</li> <li>● <b>Reporting:</b> Not reported</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source:</b> The study was supported with training materials by the companies Theraband and Ludwig Artzt. PD Dr Krauß, Dr Steinhilber, Mr Haupt, and Dr Janßen received honoraria for authorship in the context of the book project "Das Tübinger Hüftkonzept—vonder Wissenschaft in die Praxis" (The Tübingen exercise therapy approach: from science into practice) and have received royalties from hellblau publisher.</p> <p><b>Country:</b> Germany</p> <p><b>Setting:</b></p> <p><b>Comments:</b></p> <p><b>Authors name:</b> Krauss, 2014</p> <p><b>Institution:</b></p> <p><b>Email:</b></p> <p><b>Address:</b></p>
<b>Notes</b>	

### Risk of bias table

<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Blinding of outcome assessors	Unclear risk	Judgement Comment: Only patient-reported outcomes are used. No mention of blinded analysis
Other sources of bias	Unclear risk	Judgement Comment: What remains unclear is the extent to which our results are generalizable to the treatment of all patients with osteoarthritis of the hip. The sample under study showed moderate disease-related impairments as compared to the average baseline measurements of the WOMAC. In this setting, the SF-36 measurements illustrate that the subjects score higher even than the German normative population sample on the vitality scale and that they have a better perception of their general health. This study is therefore inevitably subject to recruitment bias.
Allocation concealment	Low risk	Judgement Comment: Allocation concealment was guaranteed by using a sealed opaque envelope that neither the investigators nor the participants were able to view.

Blinding of participants and personnel	High risk	Judgement Comment: No blinding of participants and personnel in the intervention group or the passive control. However ultrasound-groups were blinded.
Incomplete outcome data	Low risk	Judgement Comment: 3 versus 8% drop out in the groups. Intention-to-treat analysis performed
Selective outcome reporting	Low risk	Judgement Comment: A detailed description of the study protocol has been published (15). The study was registered with the German Clinical Trials Register (DRKS, Deutsches Register für Klinische Studien), No DRKS00000651. Physical outcome testing are stated in the protocol but not mentioned in the present paper, it is assumed to be published separately.
Sequence Generation	Low risk	Quote: "Randomization was done stratified by sex. Allocation concealment was guaranteed by using a sealed opaque envelope that neither the investigators nor the participants were able to view." Judgement Comment: From protocol paper: the study is divided into four identical interventional periods (sequence 1-4), and the mentioned allocation procedure is performed in permuted blocks of 50-60 subjects each. The randomization sequence is generated electronically prior to each interventional period. Participants draw a lot with a randomization number at the beginning of baseline assessment. This process is double-blinded (participant and investigator).

### Tak 2005

Methods	<p><b>Study design:</b> Randomized controlled trial</p> <p><b>Study grouping:</b> Parallel group</p> <p><b>Open Label:</b></p> <p><b>Cluster RCT:</b></p>
Participants	<p><b>Baseline Characteristics</b></p> <p>Intervention</p> <p>Control</p> <p><b>Included criteria:</b> Inclusion criteria were age 55 years and older, clinical diagnosis of OA of the hip, and living independently.</p> <p><b>Excluded criteria:</b> People who were on a waiting list for hip replacement (or who had had a hip replacement in the past year) were excluded because an operation could affect their participation in the study and the program was not developed for a presurgery group. Other exclusion criteria were: serious disorders or impairments that jeopardized safe use of fitness equipment, such as neurological or cardiovascular problems, serious depression or dementia (as judged by general practitioners), and regular treatment by a physical therapist (more than once a week).</p>

	<p><b>Pretreatment:</b> VAS pain at baseline slightly higher in control group than intervention group (4.4 versus 3.8)</p> <p><b>Intervention Characteristics</b> Intervention</p> <ul style="list-style-type: none"> <li>● <i>Exercise description:</i> Exercises: leg press, leg raise, rotation in sitting position, leaping squat, pull down, treadmill, home trainer, pulleys, bow flex, and walking. 2 levels (light and moderate), was adjusted as the program (and participant) progressed. A home exercise program included specific exercises for the lower extremities.</li> <li>● <i>Patient education description:</i> Personal ergonomic advice (OT), and dietary advice (dietician). PT informed about health-related aspects of OA, exercises, risk factors, etc. Separate education on dietary aspects (healthy eating and drinking habits) in relation to body mass. Participants with a BMI &gt; 30 were invited for a personal consultation. All participants could get further information via a special telephone line. OT visited all participants at home for individual counseling regarding activity restrictions caused by OA and ways to deal with them.</li> <li>● <i>Supervision and duration:</i> 8 sessions (1 hour) over 8 weeks + home-based exe.</li> </ul> <p>Control</p> <ul style="list-style-type: none"> <li>● <i>Exercise description:</i> Standard care (self initiated contact with GP)</li> <li>● <i>Patient education description:</i> Standard care (self initiated contact with GP)</li> <li>● <i>Supervision and duration:</i> None</li> </ul>
<p><b>Outcomes</b></p>	<p><i>Patientrapporteret funktionsevne</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> Harris Hip Score (HHS)</li> <li>● <b>Range:</b> 0-100</li> <li>● <b>Unit of measure:</b> Points</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Præstationsbaseret funktionsevne</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> 20 m walk test</li> <li>● <b>Unit of measure:</b> Seconds</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul>

	<ul style="list-style-type: none"> <li>● <b>Notes:</b> Unknown if it is maximum or habitual gait speed</li> </ul> <p><i>Smerte (hofte)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> VAS pain</li> <li>● <b>Range:</b> 0-10</li> <li>● <b>Unit of measure:</b> cm</li> <li>● <b>Direction:</b> Lower is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Helbredsrelateret livskvalitet</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Fully reported</li> <li>● <b>Scale:</b> HRQOL (7 questions, no specified scale name)</li> <li>● <b>Range:</b> 7-39</li> <li>● <b>Unit of measure:</b> Points</li> <li>● <b>Direction:</b> Higher is better</li> <li>● <b>Data value:</b> Endpoint</li> </ul> <p><i>Self-efficacy</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> ContinuousOutcome</li> <li>● <b>Reporting:</b> Not reported</li> </ul> <p><i>Træningsinducerede skader</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> AdverseEvent</li> <li>● <b>Reporting:</b> Not reported</li> </ul> <p><i>Smerte (ikke hofterelateret)</i></p> <ul style="list-style-type: none"> <li>● <b>Outcome type:</b> AdverseEvent</li> <li>● <b>Reporting:</b> Not reported</li> </ul>
<b>Identification</b>	<p><b>Sponsorship source:</b> Supported by a grant from The Netherlands Health Research and Development Council (Preventiefonds)</p> <p><b>Country:</b> The Netherlands</p> <p><b>Setting:</b></p>

	<b>Comments:</b>
	<b>Authors name:</b> ERWIN TAK, PATRICIA STAATS, ARIËTTE VAN HESPEN, and MARIJKE HOPMAN-ROCK
	<b>Institution:</b>
	<b>Email:</b>
	<b>Address:</b>
<b>Notes</b>	

### Risk of bias table

Bias	Authors' judgement	Support for judgement
Blinding of outcome assessors	Low risk	Judgement Comment: Blinded outcomes assessor according to Cochrane review
Other sources of bias	Low risk	Judgement Comment: None apparent (Fransen, 2014)
Allocation concealment	Unclear risk	Judgement Comment: Not reported (Fransen, 2014)
Blinding of participants and personnel	High risk	Judgement Comment: Both participants and study personnel were aware of the treatment allocation
Incomplete outcome data	Low risk	Judgement Comment: Drop out 18 % in Intervention group and 9% in control group. However more missing on each outcome. The critical outcome (HHS) has 29% versus 18% without data, however, they perform intention-to-treat analysis.
Selective outcome reporting	Low risk	Judgement Comment: None apparent
Sequence Generation	Low risk	Judgement Comment: The remaining 109 subjects wererandomly assigned (using computer generated randomized numbers)

### Footnotes

## References to studies

### Included studies

#### **Arnold 2010**

Arnold,C. M.; Faulkner,R. A.. The effect of aquatic exercise and education on lowering fall risk in older adults with hip osteoarthritis. Journal of Aging and Physical Activity 2010;18(3):245-260. [DOI:.]

#### **Hopman-Rock 2000**

[Empty]

#### **Krauß 2014**

Krauß,I.; Steinhilber,B.; Haupt,G.; Miller,R.; Martus,P.; Janßen,P.. Exercise therapy in hip osteoarthritis-a randomized controlled trial. Deutsches Arzteblatt International 2014;111(35-36):592-599+9+I. [DOI: 10.3238/arztebl.2014.0592]

#### **Tak 2005**

Tak,E.; Staats,P.; Van Hespen,A.; Hopman-Rock,M.. The effects of an exercise program for older adults with osteoarthritis of the hip. The Journal of rheumatology 2005;32(6):1106-1113. [DOI: 0315162X-32-1106 [pii]]

## Data and analyses

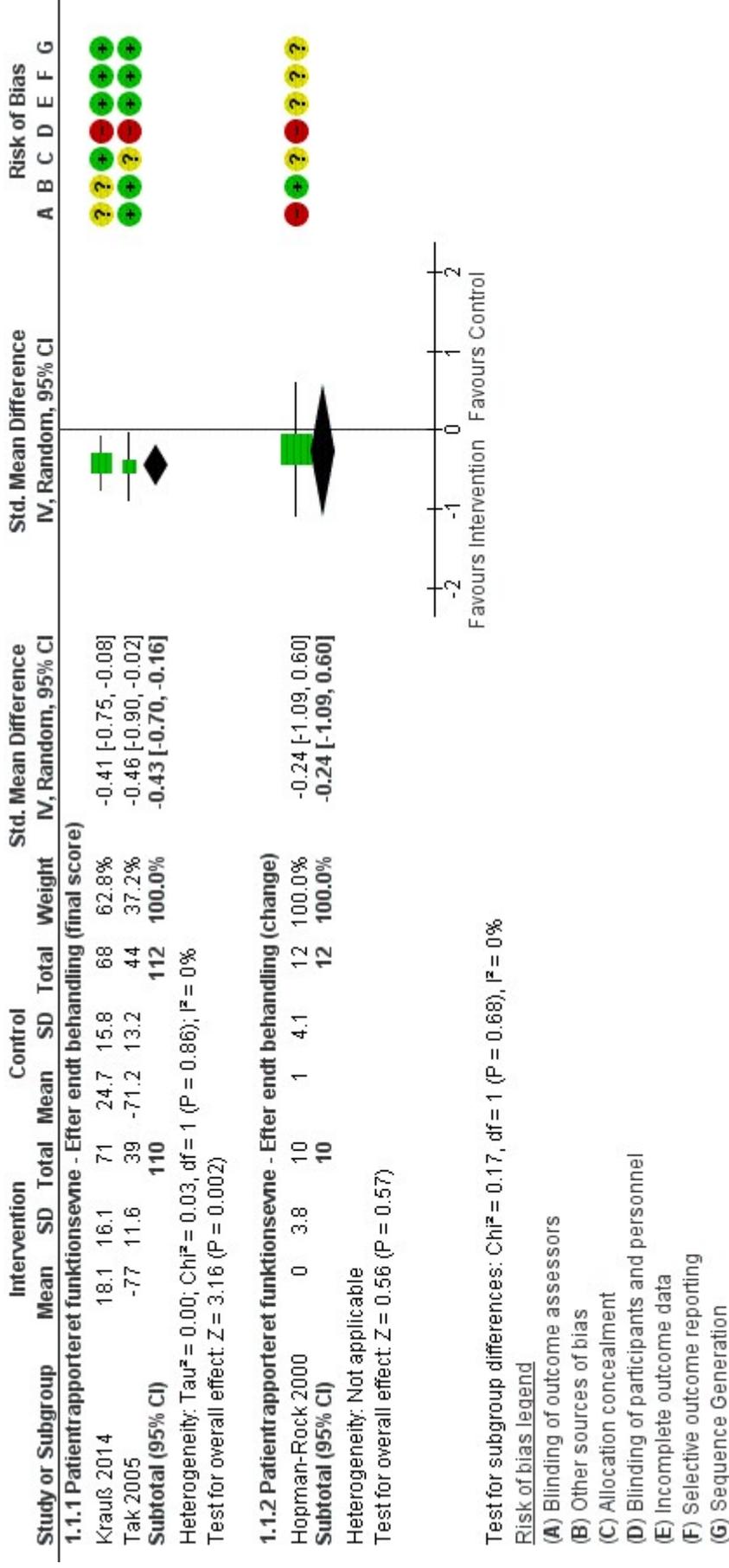
### 1 Intervention vs Control

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Patientrapporteret funktionsevne	3		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.1.1 Patientrapporteret funktionsevne - Efter endt behandling (final score)	2	222	Std. Mean Difference (IV, Random, 95% CI)	-0.43 [-0.70, -0.16]
1.1.2 Patientrapporteret funktionsevne - Efter endt behandling (change)	1	22	Std. Mean Difference (IV, Random, 95% CI)	-0.24 [-1.09, 0.60]

1.2 Præstationsbaseret funktionsevne	2							Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.2.1 Præstationsbaseret funktionsevne - Efter endt behandling	2		136					Std. Mean Difference (IV, Random, 95% CI)	-0.27 [-0.61, 0.07]
1.3 Smerte (hofte)	3							Mean Difference (IV, Random, 95% CI)	Subtotals only
1.3.1 Smerte (hofte) - Efter endt behandling	3		237					Mean Difference (IV, Random, 95% CI)	-7.43 [-12.35, -2.50]
1.4 Helbredsrelateret livskvalitet final score	1							Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.4.1 Helbredsrelateret livskvalitet - Efter endt behandling (final score)	1		73					Mean Difference (IV, Fixed, 95% CI)	-1.60 [-4.17, 0.97]
1.5 Helbredsrelateret livskvalitet change	1							Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.5.2 Helbredsrelateret livskvalitet - Efter endt behandling (change)	1		139					Mean Difference (IV, Fixed, 95% CI)	-3.00 [-8.01, 2.01]
1.6 Self-efficacy	0		0					Mean Difference (IV, Fixed, 95% CI)	Not estimable

## Figures

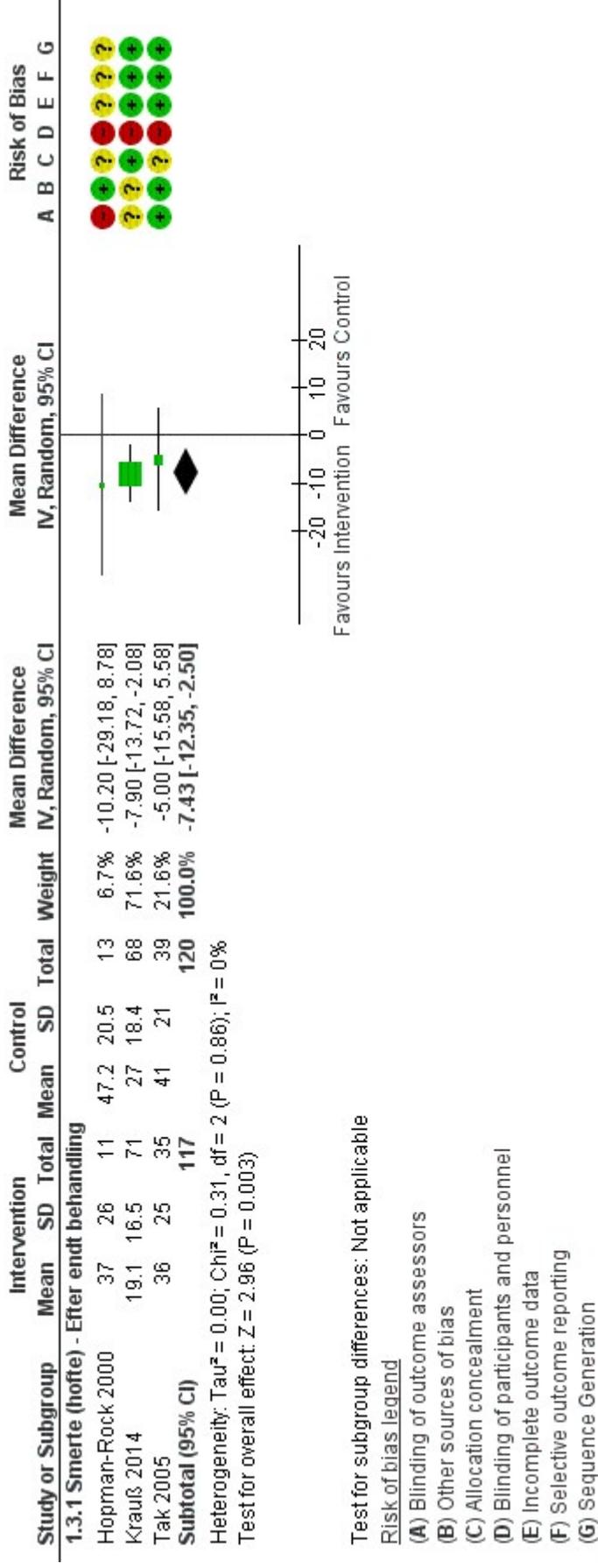
### Figure 1 (Analysis 1.1)



Forest plot of comparison: 1 Intervention vs Control, outcome: 1.1 Patientrapporteret funktionsevne.

**Figure 2 (Analysis 1.2)**





Forest plot of comparison: 1 Intervention vs Control, outcome: 1.3 Smerte (hoffte).

**Figure 4 (Analysis 1.4)**

