

Overblik: Risk of Bias vurderinger – National klinisk retningslinje for fysioterapi og ergoterapi til voksne med erhvervet hjerneskade

Citation	Sequence generation	Support for judgement	Allocation concealment	Support for judgement	Blinding of participants and personnel	Support for judgement	Blinding of outcome assessment	Support for judgement	Incomplete outcome data	Support for judgement	Selective reporting	Support for judgement	Other bias	Support for judgement
Træning i PADL, IADL og fritidsaktiviteter														
Parker, 2001 in NICE and SR ID 4511	Low risk of bias		Low risk of bias		High risk of bias	Blinding of interventions to clinician and patient is not possible in this setting	Low risk of bias	Posted outcome measure	Low risk of bias		Low risk of bias		Low risk of bias	
Corr, 1995 In NICE and SR ID 4511	Unclear risk of bias	Not reported	Unclear risk of bias	Not reported	High risk of bias	do	Low risk of bias	Posted outcome measure	Low risk of bias		Low risk of bias		Low risk of bias	
Chiu, 2004 in NICE and SR ID 4511	Unclear risk of bias		Unclear risk of bias		High risk of bias	do	Unclear risk of bias		Unclear risk of bias		Low risk of bias		Low risk of bias	
Sackly, 2006 in NICE	Low risk of bias	“Randomisation was carried out independently by a statistician with random allocation at the level of care home.” Method used was “computer-generated random numbers”	Low risk of bias	“Allocation was revealed only to the occupational therapist, not to the assessors.” Therefore, allocation was revealed only to the treating therapist”	High risk of bias	do	Low risk of bias	“Assessments were completed by research staff masked to the trial allocation.” Assessor was blinded as to treatment allocation	Low risk of bias	ITT + missing values dealt with	Low risk of bias		Unclear risk of bias	Bias can arise from cluster designs
Sackly, 2001 in SR ID 4511 (samme studie som i Sackly, 2006)	Low risk of bias		Low risk of bias		High risk of bias	do	Low risk of bias		Low risk of bias		Low risk of bias			

Gilbertson, 2000 in NICE	Low risk of bias		Low risk of bias		High risk of bias	do	Low risk of bias		Low risk of bias		Low risk of bias		Low risk of bias	
Logan, 1997 in NICE / in SR ID 4511	Unclear risk of bias	Insufficient information	Low risk of bias	Random allocation by the administration clerk (using prepared sealed envelopes).	High risk of bias	do	Unclear risk of bias	Intended independent assessor for outcomes - but not reported success	Low risk of bias		Low risk of bias		Low risk of bias	
Walker, 1999 in NICE and SR ID4511	Low risk of bias		Low risk of bias		High risk of bias	do	Low risk of bias	Blind assessor - Poor kappa between guessing group allocation and actual allocation	Low risk of bias		Low risk of bias		Low risk of bias	
Drummond, 1996 in SR ID 4511	Unclear risk of bias		Unclear risk of bias		High risk of bias	do	Low risk of bias	Independent, blind assessor	Low risk of bias		Low risk of bias		Low risk of bias	

Edmans, 2000 in SR 1828	Low risk of bias	Random number tables.	Low risk of bias	Sequentially numbered, sealed envelopes, opened at recruitment with witness. Not adequate in that researcher prepared list, but assessed as low risk of bias from assurance of inability to remember sequence	High risk of bias	do	High risk of bias	Intended independent assessor for outcomes covered by this review, but not reported success	Low risk of bias	No withdrawals and only one (1%) death	Low risk of bias	Outcomes described at both impairment and disability levels, and reported in equal detail regardless of statistical significance	Low risk of bias	
Donker-voort, 2001 in SR 1639	Low risk of bias		Low risk of bias		High risk of bias	do	Low risk of bias	Assessor blind, Check revealed poor kappa	Low risk of bias		Low risk of bias		Low risk of bias	
Egan, 2007 id5314.	Low risk of bias		Low risk of bias		High risk of bias	do	High risk of bias	Blinded evaluator - post hoc test showed that the evaluator correctly identified the allocation of 12 out of 14 participants	High risk of bias	No ITT, how missing values was dealt with not reported	Low risk of bias		Low risk of bias	
Logan, 2004 id 6111 fra referenceliste i Guideline ID_12	Low risk of bias		Low risk of bias		High risk of bias	do	Low risk of bias	Assessor blinded - posted questionnaires.	Low risk of bias	ITT + missing values dealt with	Low risk of bias		Low risk of bias	

Virtual reality træning

Shin, 2014, ID 6659	Unclear risk of bias	Not stated	Unclear risk of bias	Not stated	High risk of bias	Not possible	High risk of bias	Authors stat that evaluators were blinded. Not controlled post hoc	Low risk of bias	There deos not appear to be any atrition and all outcome measures appear to have been reported in full.	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Sin, 2013, ID 6446	Low risk of bias	random number tables	Unclear risk of bias	Not stated	High risk of bias	Not possible	High risk of bias	two occupational therapists to group assignments. One assessor measured AROM, and the other assessor assessed the FMA and BBT measures. However, not controlled post hoc	Unclear risk of bias	Drop-outs/discontinued allocated intervention < 20% and balanced between groups. Unclear whether ITT or TAP were performed	Low risk of bias	do	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Kwon 2012, ID6727	Unclear risk of bias	Not stated	Unclear risk of bias	Not described-precisly	Unclear risk of bias	Auhtors state that the subjects were unaware of the intent and purpose of their group assignment and test results. But not descirbed how this was achieved	Unclear risk of bias	Auhtors state that the examiners were unaware of the intervention group assignment. But not descirbed how this was achieved	Low risk of bias	There deos not appear to be any atrition and all outcome measures appear to have been reported in full.	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power

da Silva Cameirao, 2011; ID6534	Unclear risk of bias	Not stated how	Unclear risk of bias	Not described-precisly	High risk of bias	Not posible	Unclear risk of bias	The evaluators were blind to the assignment of each subject. Not controlled post hoc	Low risk of bias	Missing values for 4 patients - balanced between groups. Do not state whether ITT or TAP were performed. From tables it appear that TAP was pefromed.	Unclear risk of bias	No other outcomes were collected and reports on all measures reported in method section. However, uses PCA which makes it very difficult to interpret the data	Unclear risk of bias	do
Crosbie 2012; ID 6908 er identisk med Crosbie 2008 in Lawer 2011; ID 3172 Un-published data Thesis)	Low risk of bias	Risk of bias overført fra ID3172.	Low risk of bias	Risk of bias overført fra ID3172.	High risk of bias	Risk of bias overført fra ID3172.	Low risk of bias	Risk of bias overført fra ID3172.	Low risk of bias	Risk of bias overført fra ID3172.	Low risk of bias	Risk of bias overført fra ID3172.	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Cho 2012. ID 6489	Low risk of bias	Random number computer generated	Unclear risk of bias	Not described-precisly	High risk of bias	Not posible	High risk of bias	Not described as accounted for	Unclear risk of bias	Drop-outs/discontinued allocated intervention < 20% and balanced between groups. Unclear whether ITT or TAP were performed	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	do

Cho 2013, ID 6459	Unclear risk of bias	method not specified	Low risk of bias	An independent person who picked one of the sealed envelopes	High risk of bias	Not possible	High risk of bias	the assessor was blinded - but not controlled	Low risk of bias	Dropouts < 20% and balanced between groups. 71% continued allocated intervention. Not stated whether ITT or TAP were performed - from reports in result section it is assumed that ITT was performed.	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Gil-Gomez 2011 Fremkom ved ID 6647	Low risk of bias	Computer-generated using a basic random number generator	Unclear risk of bias	Appears that stratification was applied - but unclear: Group A was made up of subjects with a high risk of falling, with Berg scores ranging from 30 to 45. Group B was made up of subjects with a low risk of falling, with a Berg score ≥ 46 . All the subjects from both groups were randomly assigned	High risk of bias	Not possible	High risk of bias	Assessed by a specialist who was blind to the patients' assignment. Not controlled post hoc	Unclear risk of bias	Dropouts/discontinued allocated intervention < 20% and balanced between groups. Unclear whether ITT or TAP were performed. from reports in result section it is assumed that TAP was performed.	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Park 2013, ID 6428	High risk of bias	by selection of a white or black go stones 1 hr before the start of the pretest. Not further specified	Unclear risk of bias	Subjects were randomly assigned, but not further specified	High risk of bias	Not possible	Unclear risk of bias	Not described as accounted for	Low risk of bias	No dropouts	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power

Cuthbert 2014, ID 6422	Unclear risk of bias	Not reported how	Unclear risk of bias	Not reported how	High risk of bias	Not possible	High risk of bias	Assessments were completed by one of two blinded PT evaluators - not controlled	Low risk of bias	Drop-outs/discontinued allocated intervention < 20% and balanced between groups. Whether ITT or TAP were performed is not stated. from reports in method section it is assumed that TAP was performed.	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Fritz 2013, ID 6453	Unclear risk of bias	The allocation sequence was generated by the lead author	Unclear risk of bias	Random assignment was computer generated and was allocated based on time of enrollment into the study. The allocation was concealed in envelopes that were opened only when it was time to determine group placement (if there was no match). To control for important prognostic factors within each group, participants were assigned to the groups by age and severity of balance deficit. If the participant was within 5 years of age and 6 points (on the Berg Balance Scale) of another participant who already	High risk of bias	Not possible	Unclear risk of bias	The evaluators were blinded to group. Not controlled post hoc.	Low risk of bias	Missing values: 5.2% of the data points. State that ITT was performed - however it appears that TAP has been performed, as only those who actually were treated are included in analysis. The ITT was used to account for missing values of those.	Low risk of bias	No other outcomes were collected and reports on all measures reported in method section	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power

				consented, the new participant was placed in the opposite group. If there was no match, then the participant was randomized to a group.										
Kim 2009 in ID 3172 - primærstudie rekviret da estimer fra BBS ikke fremgår i ID 3172	Low risk of bias	The sequence was generated using a lottery system	Low risk of bias	Using sealed opaque envelopes	High risk of bias	States that patients were unaware of allocation however this does not appear possible	Low risk of bias		Low risk of bias	Does not appear to have any missing data	Low risk of bias	No other outcomes were collected	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Barcale 2013; ID 6252 Fremkommet ved søgning under PICO 4, men fundet relevant for PICO 8	Unclear risk of bias	Method not specified	Low risk of bias	Randomly allocated. Numbered, sealed, opaque envelopes. Each envelope contained a card stipulating to which group the individual would be allocated.	High risk of bias	do	Unclear risk of bias	An evaluator who was blinded to which group the subjects belonged. Methods to ensure blinding not specified.	Low risk of bias	No dropouts, no reports on missing values	Low risk of bias	No other outcomes were measured	Unclear risk of bias	Risk of type II error due to small sample size - no post hoc analysis of power
Funktionel elektrisk stimulation														
Boyaci 2013 (ID6122)	high risk of bias	no description.	high risk of bias	no description.	low risk of bias	Placebo intervention seems reasonably blinded	low risk of bias	Quote: "All parameters were evaluated by an independent physician who was blinded to the study protocol at baseline and end of the treat-	low risk	No dropouts reported	Unclear risk of bias	No protocol cited or referred to.		

								ment." Probably blinded						
Shomo- dozono 2014 (ID6170)	Low risk of bias	Quote: "via a computer-generated blocked randomization sequence with a block size of 9"	Low risk of bias	Quote: "An independent researcher not involved in recruitment or measurement managed and concealed the randomization procedure."	High risk of bias	Not possible due to nature of interventions, but "Participants were blinded to the study hypotheses"	Low risk of bias	A trained and experienced therapist who had no other contact with the study served as a blinded evaluator.	Low risk of bias	No dropouts reported	Unclear risk of bias	No protocol cited or referred to.		
Malhotra 2012 (ID6235)	Low risk of bias	A pseudo-random computed sequence in blocks was generated and the codes were stored by an independent person not involved in recruitment or measurement.	Low risk of bias	Patients were randomized into two arms, a control arm and a treatment arm, using a method of concealed random allocation	High risk of bias	Not possible due to nature of interventions.	Low risk of bias	Outcomes were assessed by an independent assessor blinded to the study protocol	Low risk of bias	similar attrition rates in both groups	Unclear risk of bias	No protocol cited or referred to.		
Salisbury 2013 (ID6156)	Low risk of bias	Quote: " a computer generated simple randomisation list"	Low risk of bias	Quote: "consecutive numbered sealed opaque envelopes"	High risk of bias	Quote: "...with non-blinded outcomes"	High risk of bias	Quote: "...with non-blinded outcomes"	Low risk of bias	similar attrition rates in both groups	Unclear risk of bias	No protocol cited or referred to.		

Thorsen 2013 (ID6203)	High risk of bias	no description.	High risk of bias	no description.	Low risk of bias	Patients and raters were not aware of the treatment allocation.	Low risk of bias	Patients and raters were not aware of the treatment allocation.	Low risk of bias	similar attrition rates in both groups	Unclear risk of bias	No protocol cited or referred to.	High risk of bias	ages different between groups
Everaert 2013 (ID6126)	High risk of bias	no description.	Low risk of bias	Envelopes with centrally randomized arm numbers were used to allocate subjects after they consented to participate.	High risk of bias	Not described and not possible	High risk of bias	Not described	Low risk of bias	similar attrition rates in both groups	Unclear risk of bias	No protocol cited or referred to.	Unclear risk of bias	Drs Stein and Kufta are consultants to Innovative Neurotronics.
Sheffler 2013 (ID6142)	High risk of bias	no description.	Low risk of bias	The randomization sequence was concealed in consecutively numbered envelopes that were allocated once eligibility was determined	High risk of bias	Not described and not possible	High risk of bias	Not described	Low risk of bias	similar attrition rates in both groups	Low risk of bias	trial registered at clinicaltrials.gov		
Kluding 2013 (ID6143)	Low risk of bias	web based application	High risk of bias	not described	High risk of bias	Not described and not possible	Low risk of bias	Outcome testing was performed by PTs blinded to group assignment	High risk of bias	greater attrition in intervention group. However, ITT analyses performed	High risk of bias	trial registered at clinicaltrials.gov		

Styrketræning

Severinsen 2014 (ID4346)	low risk of bias	Quote: "...the patients were allocated into three groups, using block randomisation...". Comment: Probably done.	High risk	Quote: "...using block randomisation stratified for degree of impaired walking performance at inclusion" Comment: Probably not done.	High risk of bias	Quote: "Participants were not blinded" . Comment: Not done	High risk of bias	Quote: "The examiner evaluating muscle strength and walking distance was blinded to intervention" "At follow-up, no blinding was attempted". Comments: No description of blinding of other outcome assessors. Probably not done.	low risk of bias	12 weeks and 1-year: 14/14 completed study and follow-up; 1/17 missing from control group.	high risk of bias	Fugl-Meyer test and modified Ashworth scale is listed in Methods but not reported.		
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Konditionstræning

Severinsen 2014 (ID4346)	low risk of bias	Quote: "...the patients were allocated into three groups, using block randomisation...". Comment: Probably done.	High risk of bias	Quote: "...using block randomisation stratified for degree of impaired walking performance at inclusion" Comment: Probably not done.	High risk of bias	Quote: "Participants were not blinded" . Comment: Not done	High risk of bias	Quote: "The examiner evaluating muscle strength and walking distance was blinded to intervention" "At follow-up, no blinding was attempted". Comments: No description of blinding of other outcome assessors. Probably	low risk of bias	12 weeks and 1-year: 14/14 completed study and follow-up; 1/17 missing from control group.	high risk of bias	Fugl-Meyer test and modified Ashworth scale is listed in Methods but not reported.		
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								not done.						
Balancetræning														
Barcala 2013 (ID6252)	low risk of bias	Randomization numbers were generated from a randomization table at a central office	low risk of bias	A series of numbered, sealed, opaque envelopes was used to ensure confidentiality	high risk of bias	Participants unblinded	low risk of bias	Outcome assessors blinded.	low risk of bias	equal attrition	low risk of bias	None detected		
Fritz 2013 (ID6275)	Unclear risk of bias	sequence generated by the lead author	low risk of bias	concealed envelopes	high risk of bias	participants and therapists unblinded	low risk of bias	Outcome assessors blinded.	low risk of bias	low attrition	low risk of bias	none detected		