A Cochrane Risk Of Bias AssessmentTool:forNon-RandomizedStudies of Interventions (ACROBAT-NRSI)

Jonathan Sterne, Julian Higgins and Barney Reeves

Version1.0.0, Dated22September 2014

Initial release version, 2014 Cochrane Colloquium

TEMPLATE

The ACROBAT-NRSItool (1): At protocol stage

Specify the research question by defining a generic target randomized trial

Participants	> 15 år. Patienter med artroskopisk verificerede ustabile kapselnære menisklæsioner
Experimental intervention	Sutur
Control intervention	Resektion

Specify the nature of the target comparison (effect of interest)

e.g. effect of *initiating* intervention (as in an intention-to-treat analysis), or effect of *initiating and adhering to* intervention (as in a per-protocol analysis)

Sutur versus resektion af menisk

List the confounding domains relevant to all or most studies

age (categorized into \20, 20-29, 30-39, and 40 years), sex, BMI, comorbidity (smoking, diabetes), condition of meniscus, medial/lateral meniscus, zone of meniscus, other concomitant knee surgery, and surgeon volume. Concomitant arthroscopic procedures, and surgeon's yearly meniscal repair volume

List the possible co-interventions that could differ between intervention groups and could have an impact on study outcomes

Traumamekanism

The ACROBAT-NRSItool (2): For each study

Specify a target trial specific to the study.

The protocol-specified target randomized trial fully applies	☐	*OR*	Participants	Yes (Dog alder 10-50)
			Experimental intervention	Yes
			Control intervention	No

Specify the outcome

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the Summary of Findings table). Specify whether this is a proposed benefit or harm of intervention.

Smerter (VASpain, KOOSpain, WOMACpain, øvrige)
Funktionsevne, aktivitet og deltagelse (WOMET disabilities subscale, KOOS sport/rec, KOOS ADL, WOMACfunction, VASfunction, øvrige)
Helbredsrelateret livskvalitet (WOMETtotal, KOOSqol, VASqol, øvrige)
Sygefravær
fastholdelse af arbejde
Symptomer (WOMET physical symptoms subscale)
SAE (Infektion, mm)
Days in hospital (harm) All cause discontinuation (harm)

Specify the effect of interest

e.g. effect of *initiating* intervention (as in an intention-to-treat analysis), or effect of *initiating and adhering to* intervention (as in a per-protocol analysis)

Fixation af menisken, uden reruptur

Specify the specific result being assessed

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

Reruptur

Preliminary consideration of confounders

a. Within each confounding domain listed in the review protocol, list the relevant variables, if any, measured in this study.

Reruptur

b List additional confounding domains, if any, specific to the setting of this particular study. Within each domain, list the relevant variables, if any, measured in this study.

Comorbitities, age

c List additional domains and corresponding measured variables, if any, that the study authors identified as potential confounders that are not included in the above domains.

Activity level after intervention. Smoking. Ligament status, Timing surgery, tears mechanism (traumatic/nontraumatic), Technique, tear localisation, tear morphology

Relationship between confounding domains and potential confounders

In the table below, "critically important" confounding domains are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. "Validity" refers to whether the confounding variable or variables fully measure the domain, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).

Confounding domain	Is the domain critically important?*	Measured Variable	Did the authors demonstrate that controlling for this variable was unnecessary?*	Is the domain measured validly and reliably by this variable (or these variables)?	OPTIONAL: Is adjusting for this variable (alone) expected to move the effect estimate up or down? **
	Yes/No			Yes/ No/ No information	Up / Down / No information

* In the context of a particular study, variables can be demonstrated not to be confounders and so not included in the analysis: (a) if they are not predictive of the outcome; (b) if they are not predictive of intervention; or (c) because adjustment makes no or minimal difference to the estimated effect of the primary parameter. Note that "no statistically significant association" is not the same as "not predictive".

** For example, if the crude effect estimate is 1.3, adjustment to 1.6 is up, while adjustment to 0.7 is down. If the effect estimate is 0.7, adjustment to 1.1 is up while adjustment to 0.4 is down.

Preliminary consideration of co-interventions

a. Are the (pre-specified) co-interventions likely to be administered in the context of this study?

ja

b List additional co-interventions, if any, specific to the setting of this particular study.

+/- acl-skade

Co-interventions

In the table below, "critically important" co-interventions are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention. "Validity" refers to whether the variables fully measure the co-intervention, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).

Co-intervention	Is the co-intervention critically important?*	Did the authors demonstrate that controlling for this co-intervention was unnecessary?	Is the co-intervention measured validly and reliably?	Is presence of this co-intervention likely to favour outcomes in the experimental or the control group
ACL	Yes	Nej - opdelt cases i +/- ACL	Yes	Favour experimental

Risk of bias assessment (case-control studies).

Bias due to confounding	1.1 Is confounding of the effect of intervention unlikely in this study? **If Y or PY to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered	Y	[Description]
	If N or PN to 1.1:		
	1.4. Did the authors use an appropriate analysis method that adjusted for all the critically important confounding domains?	NA / Y / PY / PN / N / NI	[Description]
	1.5. **If Y or PY to 1.4**: Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?	Y	[Description]
	1.6. Did the authors avoid adjusting for post-intervention variables?	N	Ikke beskrevet mulige årsager til failure
	Risk of bias judgement	Moderate	[Support for judgement]
	Optional: What is the predicted direction of bias due to confounding?	Favours experimental / Favours comparator / Unpredictable	[Rationale]
Bias in selection of participants into the study	2.4 Were the controls sampled from the population that gave rise to the cases, or using another method that avoids selection bias?	PN	[Description]
	Risk of bias judgement	Moderate	[Support for judgement]
	Optional: What is the predicted direction of bias due to selection of participants into the study?	Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	[Rationale]
Bias in measurement of interventions	3.1 Is intervention status well defined? 3.2 Was information on intervention status recorded at the time of intervention? 3.3 Was information on intervention status unaffected by knowledge of the outcome or risk of the outcome? **Risk of bias judgement** Optional: What is the predicted direction of bias due to measurement of outcomes or interventions?	Y Y PY Moderate Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	[Description] [Description] [Description] [Support for judgement] [Rationale]
Bias due to departures	4.1. Were the critical co-interventions balanced across intervention groups?	PN	INgen oplysninger

from intended interventions	4.2. Were numbers of switches to other interventions low? 4.3. Was implementation failure minor? **Risk of bias judgement** Optional: What is the predicted direction of bias due to departures from the intended interventions?	PN PY Moderate Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	[Description] [Description] [Support for judgement] [Rationale]
Bias due to missing data	5.1 Was outcome status reasonably complete for those in whom it was sought? 5.2 Were data on intervention status reasonably complete? 5.3 Are data reasonably complete for other variables in the analysis? 5.4 **If N or PN to 5.1, 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across cases and controls? 5.5 **If N or PN to 5.1, 5.2 or 5.3**: Were appropriate statistical methods used to account for missing data? **Risk of bias judgement** Optional: What is the predicted direction of bias due to missing data?	Y Y PY NA / Y / PY / PN / N / NI NA / Y / PY / PN / N / NI Moderate Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	[Description] [Description] [Description] [Description] [Description] [Support for judgement] [Rationale]
Bias in measurement of outcomes	6.1 Was the definition of case status (and control status, if applicable) based on objective criteria? 6.2 Was the definition of case status (and control status, if applicable) applied without knowledge of the intervention received? **Risk of bias judgement** Optional: What is the predicted direction of bias due to definitions of case and control status?	PY N Serious Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	dog subjektiv - ikke skopi eller mr til at vurdere failure [Description] [Support for judgement] [Rationale]
Bias in selection of the reported result	Is the reported effect estimate unlikely to be selected, on the basis of the results, from… 7.1. … multiple *definitions of the intervention*? 7.2 … multiple *analyses* of the intervention-outcome relationship? 7.3 … different *subgroups*?	 N N N	 [Description] [Description] [Description]

	Risk of bias judgement Optional: What is the predicted direction of bias due to selection of the reported result?	Moderate Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	[Support for judgement] [Rationale]
Overall bias	**Risk of bias judgement** Optional: What is the overall predicted direction of bias?	Moderate Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable	[Support for judgement] [Rationale]