The ROBINS-I V2 tool

At planning stage: list confounding factors

P1. List the important confounding factors relevant to all or most studies on this topic. Specify whether these are particular to specific intervention-outcome combinations.

Guidance note 1: listing confounding factors

A confounding factor is a prognostic factor that predicts whether participants receive the intervention or the comparator strategy. Important confounding factors are those that have the potential to introduce material bias into an estimated effect. Factors that are expected to have only very weak associations with the intervention or with the outcome, such that failure to account for them in the analysis will not have a material impact on the estimated effect of intervention on outcome, need not be considered here. Important confounding factors should be pre-specified at the planning stage, for example in the protocol of a systematic review that will include studies of the effects of interventions. The identification of potential confounding factors requires content knowledge and may usefully be informed by examination of relevant literature. Important confounding factors should be specified at the level of the broad research question (e.g. using a single list of confounding factors for a systematic review). This broad question may cover several specific interventions and/or outcomes. If confounding factors are specific to particular intervention-outcome combinations, then this should be stated.

Note that ROBINS-I does not address effect modification (the situation in which the effect of an intervention is different in different subsets of the population under study).

Baseline instabilitet, aktivitetsniveau og krav til return-to-sport, patientpræference (self-selection), ACL-rupturens karakteristika, samtidig intraartikulær patologi, diagnostisk misklassifikation (MRI vs artroskopi), samt forskelle i rehabilitering og compliance.

Derudover kan demografiske faktorer (alder, køn, BMI) og biomekaniske forhold (posterior tibial slope) påvirke både behandlingsvalg og outcome.

For each study result: preliminary considerations (parts A to D)

Guidance note 2: overview of preliminary considerations

The start point for a ROBINS-I assessment of an individual study is to specify the result from the study that is being assessed for risk of bias. The preliminary considerations questions should be answered in relation to the specific result that is being evaluated for the current ROBINS-I assessment.

In case of multiple alternative analyses being presented, it is important to 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.

Some characteristics of a study or a result may lead directly to the result being at critical risk of bias, and so make detailed risk-of-bias assessments unnecessary. A series of 'screening' questions in this section aim to identify such situations.

The **target trial specific to the study** is a hypothetical randomized trial, which need not be ethical or feasible, that compares the health effects of the same intervention and comparator strategies, conducted with the same eligibility criteria as the non-randomized study. In general, such target trials will not use blinding of participants or of health professionals administering interventions.

If multiple assessors will implement ROBINS-I independently, the questions in this section should be agreed between all assessors before each assessor works individually through the risk-of-bias assessment itself.

A. Specify the result being assessed for risk of bias

Guidance note 3: specifying the numerical result being assessed for risk of bias

A ROBINS-I assessment of risk of bias is specific to a particular study result. This is because different results from the same study may be at importantly different risks of bias (consider, for example, an unadjusted estimate of intervention effect compared with an estimate that is adjusted for numerous important confounding factors). Consequently, it may be necessary to undertake several ROBINS-I assessments of different results from the same study. If the study presents multiple alternative analyses, specify the numerical 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.

A1. Specify the numerical result being assessed

“Risk of recurrent instability at 2-year follow-up: CBP 70% vs surgical stabilization 2.5%, P<0.001.”

A2. Provide further details about this result (for example, location in the study report, reason it was chosen) [optional]

Som nævnt i abstract, er det et af ‘primary clinical outcomes’.

A3. Specify the outcome to which this result relates

‘Recurrent instability’

B. Decide whether to proceed with a risk-of-bias assessment

Guidance note 4: deciding whether to proceed with a risk-of-bias assessment

Some characteristics of a study or a result may lead directly to the result being at critical risk of bias, and so make detailed risk-of-bias assessments unnecessary. The questions in this section aim to identify such situations.

Question	Comments	Response options
B1 Did the authors make any attempt to control for confounding in the result being assessed?	Confounding is a substantial problem in most non-randomized studies, and it is usually important to control for the important confounding factors.	Y / PY / PN / N
B2 If N/PN to B1: Is there sufficient potential for confounding that this result should not be considered further?	If there is sufficient potential for confounding that an unadjusted result should not be considered further, then the result is judged to be at 'Critical risk of bias'.	Y / PY / PN / N
B3 Was the method of measuring the outcome inappropriate?	This question aims to identify methods of outcome measurement (or data collection) that are unsuitable for the outcome they are intended to evaluate. This enables a rapid assessment that a result should be regarded as at 'Critical risk of bias'. The question does not aim to assess whether the choice of outcome being evaluated was *sensible* (e.g. because it is a surrogate or proxy for the main outcome of interest). In most circumstances, for pre-specified outcomes, the answer to this question will be 'N' or 'PN'. Answer 'Y or 'PY' if the method of measuring the outcome is inappropriate, for example because: (1) important ranges of outcome values fall outside levels that are detectable using the measurement method; or (2) the measurement instrument has been demonstrated to have such poor reliability or validity that estimates of the relationship between intervention and the measured outcome are not useful. (3) The measurement method differed substantially between people in the intervention and comparator groups, so that differences between the groups are not interpretable.	Y / PY / PN / N

If the answer to either B2 or B3 is 'Yes' or 'Probably yes', the result should be considered to be at 'Critical risk of bias' and no further assessment is required.