Sources of risk of bias

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|  | **Item** | **Judgment** |
| A) Sequence generation | |  |
|  | 1. Was the method of randomization adequate? | Yes / No / Unsure |
| B) Allocation concealment | |  |
|  | 2. Was the treatment allocation concealed? | Yes / No / Unsure |
| C) Blinding of participants, personnel and outcome | |  |
|  | Was knowledge of the allocated interventions adequately prevented during the study?  3. Was the patient blinded to the intervention?  4. Was the care provider blinded to the intervention?  5. Was the outcome assessor blinded to the intervention? | Yes / No / Unsure  Yes / No / Unsure  Yes / No / Unsure |
| D) Incomplete outcome data | |  |
|  | Were incomplete outcome data adequately addressed?  6. Was the drop-out rate described and acceptable?  7. Were all randomized participants analysed in the group to which they were allocated? | Yes / No / Unsure  Yes / No / Unsure |
| E) Other sources of potential bias | |  |
|  | 8. Were the groups similar at baseline regarding the most important prognostic indicators?  9. Were co-interventions avoided or similar?  10. Was the compliance acceptable in all groups?  11. Was the timing of the outcome assessment similar in all groups?  12. Was there selective outcome reporting? | Yes / No / Unsure  Yes / No / Unsure  Yes / No / Unsure  Yes / No / Unsure  Yes / No / Unsure |