

Critical appraisal tool

Case-Control Study	Yes	No	Unclear
Major Risk 1 – study design and selection			
<p>Were the cases recruited in an acceptable way?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Are the cases representative of a population, clearly defined and differentiated from controls? ■ Was there an established reliable system for selecting all the cases? ■ Were inclusion and exclusion criteria explicit and applied similarly to all eligible cases? 			
<p>Were the controls selected in an acceptable way?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Are the controls representative of a population and clearly defined? ■ Are the same inclusion and exclusion criteria for cases used to select controls (equally applied) and matched appropriately? ■ Is it clearly established that controls are non-cases? 			
<p>Is the participation rate satisfactory?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Are there large differences between the two groups? ■ Is the participation rate low? 			
Major risk 2 - Exposure			
<p>Was the exposure accurately measured to minimise bias?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Is the exposure clearly defined? ■ Do measurements truly reflect what it is supposed to measure (have they been validated?). 			

<ul style="list-style-type: none"> ■ Is the method of assessment reliable? 			
Major risk 3 – Outcome			
<p>Was the outcome accurately measured to minimise bias?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Is the outcome clearly defined? ■ Do measurements truly reflect what it is supposed to measure (have they been validated?). ■ Is the method of assessment reliable? 			
Major risk 4 – Non-participants			
<p>Is comparison made between participants and non-participants?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Is similarities or differences established? 			
Major risk 5 – Analysis method			
<p>Was the analysis method adequate?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Are the main potential confounders identified and taken into account in the analysis? ■ Were adequate statistical models used to reduce bias? 			
Minor risk 1 – Funding			
<p>Was the source of funding provided?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Was the study affected by sponsors? ■ Did sponsoring organization participate in the analysis? 			
Minor risk 2 – Chronology			

<p>Could chronology be established?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Was the timeframe sufficient to see an association between the exposure and outcome? 			
<p>Minor risk 3 – Conflict of interest</p>			
<p>Was the study without any conflict of interest?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Was the study affected by the authors affiliations or interests? 			

Cohort Study	Yes	No	Unclear
<p>Major Risk 1 – study design and selection</p>			
<p>Was the cohort recruited in an acceptable way?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Is it representative of a defined population and clearly specified? ■ Are groups comparable in all respects other than the factor under investigation? ■ Was everybody included who should have been? 			
<p>Was the follow-up of subjects acceptable?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Conventionally, a 20% drop out rate is acceptable, but observational studies conducted over longer periods, a higher drop-out rate is to be expected. ■ Were losses to follow-up taken into account in the analysis (sensitivity analysis, described etc.)? 			
<p>Major risk 2 - Exposure</p>			
<p>Was the exposure accurately measured to minimise bias?</p> <p>Consider the following:</p>			

<ul style="list-style-type: none"> ■ Is the exposure clearly defined? ■ Do measurements truly reflect what it is supposed to measure (have they been validated?). ■ Is the method of assessment reliable? ■ Were all the subjects classified into exposure groups using the same procedure? 			
Major risk 3 – Outcome			
<p>Was the outcome accurately measured to minimise bias?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Is the outcome clearly defined? ■ Do measurements truly reflect what it is supposed to measure (have they been validated?). ■ Is the method of assessment reliable? ■ Were the measurement methods similar in the different groups? ■ If blinding is not possible, is there some recognition that knowledge of exposure status could influence the assessment of the outcome? 			
Major risk 4 – Enrolment			
<p>Was the outcome taken into account at enrolment?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Some participants might have the outcome at the time of enrolment. Is it assessed at baseline in the analysis? 			
Major risk 5 – Analysis method			
<p>Was the analysis method adequate?</p> <p>Consider the following:</p> <ul style="list-style-type: none"> ■ Are the main potential confounders identified and taken into account in the analysis? ■ Were adequate statistical models used to reduce bias? 			
Minor risk 1 – Funding			
<p>Was the source of funding provided?</p>			

Consider the following: ■ Was the study affected by sponsors? ■ Did sponsoring organization participate in the analysis?			
Minor risk 2 – Chronology			
Could chronology be established? Consider the following: ■ Was the timeframe sufficient to see an association between the exposure and outcome? ■ Was the follow-up long enough for the outcome to occur?			
Minor risk 3 – Conflict of interest			
Was the study without any conflict of interest? Consider the following: ■ Was the study affected by the authors affiliations or interests?			