### 1. Study Participation

**Goal:** To judge the risk of selection bias (likelihood that relationship between PF and outcome is different for participants and eligible non-participants).

<table>
<thead>
<tr>
<th>Source of target population</th>
<th>The source population or population of interest is adequately described for key characteristics (LIST). yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method used to identify population</td>
<td>The sampling frame and recruitment are adequately described, including methods to identify the sample sufficient to limit potential bias (number and type used, e.g., referral patterns in health care). yes</td>
</tr>
<tr>
<td>Recruitment period</td>
<td>Period of recruitment is adequately described. yes</td>
</tr>
<tr>
<td>Place of recruitment</td>
<td>Place of recruitment (setting and geographic location) are adequately described. yes</td>
</tr>
<tr>
<td>Inclusion and exclusion criteria</td>
<td>Inclusion and exclusion criteria are adequately described (e.g., including explicit diagnostic criteria or “zero time” description). yes</td>
</tr>
<tr>
<td>Adequate study participation</td>
<td>There is adequate participation in the study by eligible individuals. unsure</td>
</tr>
</tbody>
</table>

**Summary:** The study sample represents the population of interest on key characteristics, sufficient to limit potential bias of the observed relationship between PF and outcome.

**Rating:** low

### 2. Study Attrition

**Goal:** To judge the risk of attrition bias (likelihood that relationship between PF and outcome are different for completing and non-completing participants).

<table>
<thead>
<tr>
<th>Proportion of baseline sample available for analysis</th>
<th>Response rate (i.e., proportion of study sample completing the study and providing outcome data) is adequate. partial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attempts to collect information on participants who dropped out</td>
<td>Attempts to collect information on participants who dropped out of the study are described. no</td>
</tr>
<tr>
<td>Reasons and potential impact of subjects lost to follow-up</td>
<td>Reasons for loss to follow-up are provided. no</td>
</tr>
<tr>
<td>Outcome and prognostic factor information on those lost to follow-up</td>
<td>Participants lost to follow-up are adequately described for key characteristics (LIST). no</td>
</tr>
<tr>
<td>Adequate study participation</td>
<td>Adequate study participation is described for key characteristics (LIST). unsure</td>
</tr>
</tbody>
</table>

**Summary:** Loss to follow-up (from baseline sample to study population analyzed) is not associated with key characteristics (i.e., the study data adequately represent the sample) sufficient to limit potential bias to the observed relationship between PF and outcome.

**Rating:** moderate

### 3. Prognostic Factor Measurement

**Goal:** To judge the risk of measurement bias related to how PF was measured (differential measurement of PF related to the level of outcome).

<table>
<thead>
<tr>
<th>Definition of PF</th>
<th>A clear definition or description of “PF” is provided (e.g., including dose, level, duration of exposure, and clear specification of the method of measurement). yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valid and Reliable Measurement of PF</td>
<td>Method of PF measurement is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall). yes</td>
</tr>
<tr>
<td>Concurrency variables are reported or appropriate cut-points (i.e., not data-dependent) are used.</td>
<td>yes</td>
</tr>
<tr>
<td>Method and Setting of PF Measurement</td>
<td>The method and setting of measurement of PF is the same for all study participants. yes</td>
</tr>
</tbody>
</table>

**Rating:** unsure
Method used for missing data: Appropriate methods of imputation are used for missing PF data.

PF Measurement Summary: PF is adequately measured in study participants to sufficiently limit potential bias.

4. Outcome Measurement

Goal: To judge the risk of bias related to the measurement of outcome (differential measurement of outcome related to the baseline level of PF).

Definition of the Outcome: A clear definition of outcome is provided, including duration of follow-up and level and extent of the outcome construct.

Valid and Reliable Measurement of Outcome: The method of outcome measurement used is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and confirmation of outcome with valid and reliable test).

Method and Setting of Outcome Measurement: The method and setting of outcome measurement is the same for all study participants.

Outcome Measurement Summary: Outcome of interest is adequately measured in study participants to sufficiently limit potential bias.

5. Study Confounding

Goal: To judge the risk of bias due to confounding (i.e., the effect of PF is distorted by another factor that is related to PF and outcome).

Important Confounders Measured: All important confounders, including treatments (key variables in conceptual model: LIST), are measured.

Definition of the confounding factor: Clear definitions of the important confounders measured are provided (e.g., including dose, level, and duration of exposures).

Valid and Reliable Measurement of Confounders: Measurement of all important confounders is adequately valid and reliable (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall).

Method and Setting of Confounding Measurement: The method and setting of confounding measurement are the same for all study participants.

Method used for missing data: Appropriate methods are used if imputation is used for missing confounder data.

Important potential confounders are accounted for in the study design (e.g., matching for key variables, stratification, or initial assembly of comparable groups).

Important potential confounders are accounted for in the analysis (i.e., appropriate adjustment).

Study Confounding Summary: Important potential confounders are appropriately accounted for, limiting potential bias with respect to the relationship between PF and outcome.

6. Statistical Analysis and Reporting

Goal: To judge the risk of bias related to the statistical analysis and presentation of results.

Presentation of analytical strategy: There is sufficient presentation of data to assess the adequacy of the analysis.

Model development strategy: The strategy for model building (i.e., inclusion of variables in the statistical model) is appropriate and is based on a conceptual framework or model.

The selected statistical model is adequate for the design of the study.

Reporting of results: There is no selective reporting of results.

Statistical Analysis and Presentation Summary: The statistical analysis is appropriate for the design of the study, limiting potential for presentation of invalid or spurious results.

QUIPS Risk of Bias Assessment Instrument for Prognostic Factor Studies


Author and year of publication: Lovatsis 2003

Study identifier: Britta Tendal & Julie Bolvig

Biases: Issues to consider for judging overall rating of "Risk of bias"
**1. Study Participation**

**Goal:** To judge the risk of selection bias (likelihood that relationship between \( PF \) and outcome is different for participants and eligible non-participants).

- **Source of target population:** The source population or population of interest is adequately described for key characteristics. **Yes**
- **Method used to identify population:** The sampling frame and recruitment are adequately described, including methods to identify the sample sufficient to limit potential bias (number and type used, e.g., referral patterns in health care). **Yes**
- **Recruitment period:** Period of recruitment is adequately described **Yes**
- **Place of recruitment:** Place of recruitment (setting and geographic location) are adequately described **Yes**
- **Inclusion and exclusion criteria:** Inclusion and exclusion criteria are adequately described (e.g., including explicit diagnostic criteria or “zero time” description). **Yes**
- **Adequate study participation:** There is adequate participation in the study by eligible individuals. **Unsure**

**Summary Study participation**

The study sample represents the population of interest on key characteristics, sufficient to limit potential bias of the observed relationship between \( PF \) and outcome. **Low**

**2. Study Attrition**

**Goal:** To judge the risk of attrition bias (likelihood that relationship between \( PF \) and outcome are different for completing and non-completing participants).

- **Proportion of baseline sample available for analysis:** Response rate (i.e., proportion of study sample completing the study and providing outcome data) is adequate. 3 out of 43 lost to FU **Yes**
- **Attempts to collect information on participants who dropped out:** Attempts to collect information on participants who dropped out of the study are described. **Yes**
- **Reasons and potential impact of subjects lost to follow-up:** Reasons for loss to follow-up are provided. **Yes**
- **Outcome and prognostic factor information on those lost to follow-up:** Participants lost to follow-up are adequately described for key characteristics. **Partial**

**Study Attrition Summary**

Loss to follow-up (from baseline sample to study population analyzed) is not associated with key characteristics (i.e., the study data adequately represent the sample) sufficient to limit potential bias to the observed relationship between \( PF \) and outcome. **Low**

**3. Prognostic Factor Measurement**

**Goal:** To judge the risk of measurement bias related to how \( PF \) was measured (differential measurement of \( PF \) related to the level of outcome).

- **Definition of the \( PF \):** A clear definition or description of \( PF \) is provided (e.g., including dose, level, duration of exposure, and clear specification of the method of measurement). **Yes**
- **Valid and Reliable Measurement of \( PF \):** Method of \( PF \) measurement is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall). **Yes**
- **Method and Setting of \( PF \) Measurement:** The method and setting of measurement of \( PF \) is the same for all study participants. **Yes**
- **Proportion of data on \( PF \) available for analysis:** Adequate proportion of the study sample has complete data for \( PF \) variable. **Yes**
- **Method used for missing data:** Appropriate methods of imputation are used for missing \( PF \) data. **Unsure**

**PF Measurement Summary**

\( PF \) is adequately measured in study participants to sufficiently limit potential bias. **Low**

**4. Outcome Measurement**

**Goal:** To judge the risk of bias related to the measurement of outcome (differential measurement of outcome related to the baseline level of \( PF \)).

- **Definition of the Outcome:** A clear definition of outcome is provided, including duration of follow-up and level and extent of the outcome construct. **Yes**
## 5. Study Confounding

**Goal:** To judge the risk of bias due to confounding (i.e. the effect of PF is distorted by another factor that is related to PF and outcome).

<table>
<thead>
<tr>
<th>Important Confounders Measured</th>
<th>All important confounders, including treatments (key variables in conceptual model LIST), are measured.</th>
<th>yes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition of the confounding factor</strong></td>
<td>Clear definitions of the important confounders measured are provided (e.g., including dose, level, and duration of exposures).</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Valid and Reliable Measurement of Confounders</strong></td>
<td>Measurement of all important confounders is adequately valid and reliable (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall).</td>
<td>unsure</td>
</tr>
<tr>
<td><strong>Method and Setting of Confounding Measurement</strong></td>
<td>The method and setting of confounding measurement are the same for all study participants.</td>
<td>yes</td>
</tr>
<tr>
<td><strong>Method used for missing data</strong></td>
<td>Appropriate methods are used if imputation is used for missing confounder data.</td>
<td>unsure</td>
</tr>
<tr>
<td><strong>Important potential confounders are accounted for in the study design (e.g., matching for key variables, stratification, or initial assembly of comparable groups).</strong></td>
<td>no</td>
<td></td>
</tr>
<tr>
<td><strong>Important potential confounders are accounted for in the analysis (i.e., appropriate adjustment).</strong></td>
<td>yes</td>
<td></td>
</tr>
</tbody>
</table>

**Study Confounding Summary**

Important potential confounders are appropriately accounted for, limiting potential bias with respect to the relationship between PF and outcome.

## 6. Statistical Analysis and Reporting

**Goal:** To judge the risk of bias related to the statistical analysis and presentation of results.

| Presentation of analytical strategy | There is sufficient presentation of data to assess the adequacy of the analysis. | yes |
| Model development strategy | The strategy for model building (i.e., inclusion of variables in the statistical model) is appropriate and is based on a conceptual framework or model. | yes |
| Reporting of results | There is no selective reporting of results. | unsure |

**Statistical Analysis and Presentation Summary**

The statistical analysis is appropriate for the design of the study, limiting potential for presentation of invalid or spurious results.