Risk of Bias Assessment NTP OHAT 2015

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| **1. Selection bias:**  Did selection of study participants result in appropriate comparison groups? | **Definitely low risk of bias:**  There is direct evidence that subjects (both the younger and older comparison groups) were similar (e.g., both groups had a similar health status without any neurological or psychiatric disordersand used the same recruitment method using the same inclusion and exclusion criteria (minus age)), were recruited within the same time frame, and had similar participation/response rates | **Probably low risk of bias:**  There is indirect evidence that subjects (both the younger and older comparison groups) were similar (e.g., both groups had a similar health status without any neurological or psychiatric disordersand used the same recruitment method using the same inclusion and exclusion criteria (minus age)), were recruited within the same time frame, and had similar participation/response rates  **OR** differences between groups would not appreciably bias results. | **Probably high risk of bias:**  There is indirect evidence that subjects (both the younger and older comparison groups) were not similar, were recruited within very different time frames, or had very different participation/ response rates  **OR** there is insufficient information provided about the comparison group including a different rate of non-response without an explanation **(record “NR” as basis for answer)**. | **Definitely high risk of bias:**  There is direct evidence that subjects (both the younger and older comparison groups) were not similar, recruited within very different time frames, or had very different participation/ response rates |
| **2. Confounding bias:** Did the study design or analysis account for important confounding and modifying variables? | **Definitely low risk of bias:**  There is direct evidence that appropriate adjustments or explicit considerations were made for primary covariates and confounders (emotion perception and cognitive empathy) in the final analyses using statistical models (provide name of model in comments) to reduce research-specific bias; if factor adjustment in multivariate model is used, the author must indicate that statistical analyses identified that a factor did not need to be included in the final adjustment model  **AND** there is direct evidence that primary covariates and confounders were assessed using valid and reliable measurements | **Probably low risk of bias:**  There is indirect evidence that appropriate adjustments were made  **OR** it is deemed that not considering or only considering a partial list of covariates or confounders in the final analyses would not appreciably bias results  **AND** there is evidence (direct or indirect) that primary covariates and confounders were assessed using valid and reliable measurements  **OR** it is deemed that the measures used would not appreciably bias results (i.e., the authors justified the validity of the measures from previously published research) | **Probably high risk of bias:**  There is indirect evidence that the distribution of primary covariates and known confounders differed between the groups and was not appropriately adjusted for in the final analyses  **OR** there is insufficient information provided about the distribution of known confounders **(record “NR” as basis for answer)**  **OR** there is indirect evidence that primary covariates and confounders were assessed using measurements of unknown validity  **OR** there is insufficient information provided about the measurement techniques used to assess primary covariates and confounders **(record “NR”)** | **Definitely high risk of bias:**  There is direct evidence that the distribution of primary covariates and known confounders differed between the groups, confounding was demonstrated, and was not appropriately adjusted for in the final analyses  **OR** there is direct evidence that primary covariates and confounders were assessed using non valid measurements |
| **3. Performance bias:** were outcome data complete without attrition or exclusion from analysis? | **Definitely low risk of bias:**  There is direct evidence that exclusion of subjects from analyses was adequately addressed, and reasons were documented when subjects were removed from the study or excluded from analyses | **Probably low risk of bias:**  There is indirect evidence that exclusion of subjects from analyses was adequately addressed, and reasons were documented when subjects were removed from the study or excluded from analyses | **Probably high risk of bias:**  There is indirect evidence that exclusion of subjects from analyses was not adequately addressed  **OR** there is insufficient information provided about why subjects were removed from the study or excluded from analyses **(record “NR” as basis for answer).** | **Definitely high risk of bias:**  There is direct evidence that exclusion of subjects from analyses was not adequately addressed. Unacceptable handling of subject exclusion from analyses includes reason for exclusion likely to be related to true outcome (i.e., age differences in emotional empathy)  **OR** imbalanced reasons for exclusion across younger and older adult groups |
| **4. Detection bias:** can we be confident in the outcome assessment? | **Definitely low risk of bias:**  There is direct evidence that emotional empathy was assessed using well-established methods (i.e., Interpersonal Reactivity Index Empathy Concern and/or Personal Distress subscales OR Empathy Quotient emotional empathy sub-score)  **OR** emotional empathy was assessed using less-established methods that directly measure emotional empathy and are validated against well-established methods (Note: if scale used is not either of the above, document the name of the scale and I will determine whether it is a validated measure) | **Probably low risk of bias:**  There is indirect evidence thatemotional empathy was consistently assessed using well-established methods  **OR** emotional empathy was assessed using indirect measures (i.e., not using a questionnaire) that have been validated or empirically shown to be consistent with methods that directly measure emotional empathy (Note: document the name of the measure and I will determine whether it is validated) | **Probably high risk of bias:**  There is indirect evidence that emotional empathy was assessed using poorly validated methods  **OR** there is direct evidence that emotional empathy was assessed using indirect measures that have not been validated or empirically shown to directly measureemotional empathy **(record “NR” as basis for answer)**  **OR** there is insufficient information provided about theemotional empathy assessment, including validity and reliability, but no evidence for concern about the method used **(record “NR” as basis for answer)** | **Definitely high risk of bias:**  There is direct evidence that emotional empathy was assessed using methods with poor validity  **OR** evidence of emotional empathy misclassification (e.g., measure said to examine emotional empathy when it does not) |
| **5. Selective reporting bias:** were all measured outcomes reported? | **Definitely low risk of bias:**  There is direct evidence that all of the study’s measured outcomes (primary and secondary) outlined in the protocol, methods, and/or abstract have been reported. This would include outcomes reported with sufficient detail to be included in meta-analysis or fully tabulated during data extraction and analyses had been planned in advance (i.e., they stated they registered their review) | **Probably low risk of bias:**  There is indirect evidence that all of the study’s measured outcomes (primary and secondary) outlined in the protocol, methods, and/or abstract have been reported  **OR** analyses that had not been planned in advance (i.e., retrospective unplanned subgroup analyses) are clearly indicated as such and it is deemed that the unplanned analyses were appropriate and selective reporting would not appreciably bias results (e.g., appropriate analyses of an unexpected effect). This would include outcomes reported with insufficient detail such as only reporting that results were statistically significant (or not) | **Probably high risk of bias:**  There is indirect evidence that all of the study’s measured outcomes (primary and secondary) outlined in the protocol, methods, and/or abstract have been reported  **OR** there is indirect evidence that unplanned analyses were included that may appreciably bias results  **OR** there is insufficient information provided about selective outcome reporting **(record “NR” as basis for answer).** | **Definitely high risk of bias:**  There is direct evidence that all the study’s measured outcomes (primary and secondary) outlined in the protocol, methods, and/or abstract have not been reported. In addition to not reporting outcomes, this would include reporting outcomes based on composite scores without individual outcome components or outcomes reported using measurements, analysis methods or subsets of the data (e.g., subscales) that were not pre-specified or reporting outcomes not pre-specified, or that unplanned analyses were included that would appreciably bias results |
| **6. Other bias:**  Statistical methods were appropriate | **Definitely low risk of bias:**  There is direct evidence that statistical methods were appropriate | **Probably low risk of bias:**  There is indirect evidence that statistical methods were appropriate | **Probably high risk of bias:**  There is indirect evidence that statistical methods were inappropriate | **Definitely high risk of bias:**  There is direct evidence that statistical methods were inappropriate |