**Supplemental Digital Content 1: Mapped safeguards from design-specific checklists to the MASTER scale**

**Table S1.1.** Mapping of the MASTER scale safeguard items to the JBI case-control study critical appraisal tool.

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| --- | --- | --- | --- | --- | --- |
| JBI question number | JBI question | MASTER scale bias domain | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Were the groups comparable other than the presence of disease in cases or the absence of disease in controls? | Confounding | Equal prognosis | 25 | Key baseline characteristics/prognostic indicators for the study were comparable across groups |
| 2 | Were cases and controls matched appropriately? | Analytic bias | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 3 | Were the same criteria used for identification of cases and controls? | Selection bias | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 4 | Was exposure measured in a standard, valid and reliable way? | Information bias | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 5 | Was exposure measured in the same way for cases and controls? | Information bias | Equal implementation | 20 | Exposure/intervention definition was consistently applied to all participants |
| 6 | Were confounding factors identified? | Design-related bias | Equal prognosis | 24 | Key confounders addressed through design or analysis were not common effects of exposure and outcome  |
| 7 | Were strategies to deal with confounding factors stated? | Analytic bias | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 8 | Were outcomes assessed in a standard, valid and reliable way for cases and controls? | Information bias | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 9 | Was the exposure period of interest long enough to be meaningful? | Design-related bias | Temporal precedence | 34 | The intervention/exposure period was long enough to have influenced the study outcome |
| 10 | Was appropriate statistical analysis used? | Analytic bias | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |

**Table S1.2.** Mapping of the MASTER scale safeguard items to the JBI cohort study critical appraisal tool.

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| --- | --- | --- | --- | --- | --- |
| JBI question number | JBI question | MASTER scale bias domain | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Were the two groups similar and recruited from the same population? | Selection bias | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 2 | Were the exposures measured similarly to assign people to both exposed and unexposed groups? | Information bias | Equal implementation | 20 | Exposure/intervention definition was consistently applied to all participants |
| 3 | Was the exposure measured in a valid and reliable way? | Information bias | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 4 | Were confounding factors identified? | Design-related bias | Equal prognosis | 24 | Key confounders addressed through design or analysis were not common effects of exposure and outcome  |
| 5 | Were strategies to deal with confounding factors stated? | Analytic bias | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 6 | Were the groups/participants free of the outcome at the start of the study (or at the moment of exposure)? | Design-related bias | Temporal precedence | 32 | All subjects were selected prior to intervention/exposure and evaluated prospectively  |
| 7 | Were the outcomes measured in a valid and reliable way? | Information bias | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 8 | Was the follow up time reported and sufficient to be long enough for outcomes to occur? | Design-related bias | Temporal precedence | 36 | Length of follow-up was not too long or too short in relation to the outcome assessment  |
| 9 | Was follow up complete, and if not, were the reasons to loss to follow up described and explored? | Selection bias | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |
| 10 | Were strategies to address incomplete follow up utilized? | Selection bias | Equal retention | 9 | Variations in exposure or withdrawals after start of the study were addressed by the analysis  |
| 11 | Was appropriate statistical analysis used? | Analytic bias | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |

**Table S1.3.** Mapping of the MASTER scale safeguard items to the JBI analytical cross-sectional study critical appraisal tool.

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| --- | --- | --- | --- | --- | --- |
| JBI question number | JBI question | MASTER scale bias domain | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Were the criteria for inclusion in the sample clearly defined? | Selection bias | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 2 | Were the study subjects and the setting described in detail? | Non-safeguard item | Non-safeguard item | 0 | Non-safeguard item |
| 3 | Was the exposure measured in a valid and reliable way? | Information bias | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 4 | Were objective, standard criteria used for measurement of the condition? | Information bias | Equal ascertainment | 10 | Procedures for data collection of covariates were reliable and the same for all participants |
| 5 | Were confounding factors identified? | Design-related bias | Equal prognosis | 24 | Key confounders addressed through design or analysis were not common effects of exposure and outcome  |
| 6 | Were strategies to deal with confounding factors stated? | Analytic bias | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 7 | Were the outcomes measured in a valid and reliable way? | Information bias | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 8 | Was appropriate statistical analysis used? | Analytic bias | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |

**Table S1.4.** Mapping of the MASTER scale safeguard items to the JBI quasi-experimental study critical appraisal tool.

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| JBI question number | JBI question | MASTER scale bias domain | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Is it clear in the study what is the ‘cause’ and what is the ‘effect’ (i.e. there is no confusion about which variable comes first)? | Design-related bias | Temporal precedence | 32 | All subjects were selected prior to intervention/exposure and evaluated prospectively  |
| 2 | Were the participants included in any comparisons similar?  | Confounding | Equal prognosis | 25 | Key baseline characteristics/prognostic indicators for the study were comparable across groups |
| 3 | Were the participants included in any comparisons receiving similar treatment/care, other than the exposure or intervention of interest? | Information bias | Equal Implementation | 18 | Cointerventions that could impact the outcome were comparable between groups or avoided  |
| 4 | Was there a control group? | Selection bias | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 5 | Were there multiple measurements of the outcome both pre and post the intervention/exposure? | Information bias | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 6 | Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed? | Selection bias | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |
| 7 | Were the outcomes of participants included in any comparisons measured in the same way?  | Information bias | Equal implementation | 21 | Outcome definition was consistently applied to all participants |
| 8 | Were outcomes measured in a reliable way? | Information bias | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 9 | Was appropriate statistical analysis used? | Analytic bias | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |

**Table S1.5.** Mapping of the MASTER scale safeguard items to the JBI randomized-controlled trial critical appraisal tool.

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| --- | --- | --- | --- | --- | --- |
| JBI question number | JBI question | MASTER scale bias domain | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Was true randomization used for assignment of participants to treatment groups? | Design-related bias | Equal prognosis | 26 | Participants were randomly allocated to groups with an adequate randomisation process  |
| 2 | Was allocation to treatment groups concealed? | Design-related bias | Equal prognosis | 27 | Allocation procedure was adequately concealed |
| 3 | Were treatment groups similar at the baseline? | Confounding | Equal prognosis | 25 | Key baseline characteristics/prognostic indicators for the study were comparable across groups |
| 4 | Were participants blind to treatment assignment? | Information bias | Equal ascertainment | 14 | Participants were blinded |
| 5 | Were those delivering treatment blind to treatment assignment?  | Information bias | Equal ascertainment | 15 | Caregivers were blinded |
| 6 | Were outcomes assessors blind to treatment assignment? | Information bias | Equal ascertainment | 13 | Outcome assessor(s) were blinded  |
| 7 | Were treatment groups treated identically other than the intervention of interest? | Information bias | Equal implementation | 17 | Care was delivered equally to all participants  |
| 8 | Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed? | Selection bias | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |
| 9 | Were participants analyzed in the groups to which they were randomized? | Selection bias | Equal retention | 9 | Variations in exposure or withdrawals after start of the study were addressed by the analysis  |
| 10 | Were outcomes measured in the same way for treatment groups? | Information bias | Equal implementation | 21 | Outcome definition was consistently applied to all participants |
| 11 | Were outcomes measured in a reliable way? | Information bias | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 12 | Was appropriate statistical analysis used? | Analytic bias | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |
| 13 | Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial? | Analytic bias | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |

**Table S1.6.** Mapping of the MASTER scale safeguard items to the SIGN RCT critical appraisal tool.

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| --- | --- | --- | --- | --- |
| SIGN question number | SIGN item | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1.1 | The study addresses an appropriate and clearly focused question. | NA | 0 | NRoB |
| 1.2 | The assignment of subjects to treatment groups is randomised. | Equal prognosis | 26 | Participants were randomly allocated to groups with an adequate randomisation process  |
| 1.3 | An adequate concealment method is used. | Equal prognosis | 27 | Allocation procedure was adequately concealed |
| 1.4 | The design keeps subjects and investigators ‘blind’ about treatment allocation. | Equal ascertainment | 13 | Outcome assessor(s) were blinded  |
| 1.5 | The treatment and control groups are similar at the start of the trial. | Equal prognosis | 25 | Key baseline characteristics/prognostic indicators for the study were comparable across groups |
| 1.6 | The only difference between groups is the treatment under investigation. | Equal prognosis | 25 | Key baseline characteristics/prognostic indicators for the study were comparable across groups |
| 1.7 | All relevant outcomes are measured in a standard, valid and reliable way. | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Equal retention | 9 | Variations in exposure or withdrawals after start of the study were addressed by the analysis  |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Sufficient analysis | 29 | Analytic method was justified by study design or data requirements |

**Table S1.7.** Mapping of the MASTER scale safeguard items to the SIGN cohort critical appraisal tool.

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| --- | --- | --- | --- | --- |
| SIGN question number | SIGN item | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1.1 | The study addresses an appropriate and clearly focused question. | NA | 0 | NRoB |
| 1.2 | The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation. | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 1.3 | The study indicates how many of the people asked to take part did so, in each of the groups being studied. | NA | 0 | NRoB |
| 1.4 | The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. | Temporal precedence | 32 | All subjects were selected prior to intervention/exposure and evaluated prospectively  |
| 1.5 | What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed? | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |
| 1.6 | Comparison is made between full participants and those lost to follow up, by exposure status. | Equal retention | 9 | Variations in exposure or withdrawals after start of the study were addressed by the analysis  |
| 1.7 | The outcomes are clearly defined. | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 1.8 | The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable. | Equal ascertainment | 13 | Outcome assessor(s) were blinded  |
| 1.9 | Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome. | NA | 0 | NRoB |
| 1.10 | The method of assessment of exposure is reliable. | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 1.11 | Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable. | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 1.12 | Exposure level or prognostic factor is assessed more than once. | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 1.13 | The main potential confounders are identified and taken into account in the design and analysis. | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 1.14 | Have confidence intervals been provided? | NA | 0 | NRoB |

**Table S1.8.** Mapping of the MASTER scale safeguard items to the SIGN case-control critical appraisal tool.

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| --- | --- | --- | --- | --- |
| SIGN question number | SIGN item | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1.1 | The study addresses an appropriate and clearly focused question. | NA | 0 | NRoB |
| 1.2 | The cases and controls are taken from comparable populations. | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 1.3 | The same exclusion criteria are used for both cases and controls. | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 1.4 | [What percentage of each group (cases and controls) participated in the study?](file:///C%3A%5C%5CUsers%5C%5CJennifer%20Stone%5C%5COneDrive%5C%5CDesktop%5C%5CJBI-ES%20MAPPING%20paper%5C%5CCopy%20of%20Sign50%20and%20others%20for%20mapping%2011.2.2022%20updated.xlsx%22%20%5Cl%20%22RANGE%21I8) | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |
| 1.5 | Comparison is made between participants and non-participants to establish their similarities or differences. | NA | 0 | NRoB |
| 1.6 | Cases are clearly defined and differentiated from controls. | Equal implementation | 19 | Control and active interventions/exposures were sufficiently distinct  |
| 1.7 | It is clearly established that controls are non-cases. | Equal implementation | 19 | Control and active interventions/exposures were sufficiently distinct  |
| 1.8 | Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment. | Equal ascertainment | 13 | Outcome assessor(s) were blinded  |
| 1.9 | Exposure status is measured in a standard, valid and reliable way. | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 1.10 | The main potential confounders are identified and taken into account in the design and analysis. | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 1.11 | Confidence intervals are provided. | NA | 0 | NRoB |

**Table S1.9.** Mapping of the MASTER scale safeguard items to the NOS case-control study scale.

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| NOS question number | NOS item | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Is the case definition adequate? | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 2 | Representativeness of the cases | NA | 0 | NRoB |
| 3 | Selection of controls | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 4 | Definition of controls | Equal implementation | 19 | Control and active interventions/exposures were sufficiently distinct  |
| 5 | Comparability of cases and controls on the basis of the design or analysis | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 6 | Ascertainment of exposure | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 7 | Same method of ascertainment for cases and controls | Equal implementation | 21 | Outcome definition was consistently applied to all participants |
| 8 | Non-response rate | Equal recruitment | 4 | None of the eligibility criteria were common effects of exposure and outcome |

**Table S1.10.** Mapping of the MASTER scale safeguard items to the NOS cohort study scale.

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| --- | --- | --- | --- | --- |
| NOS question number | NOS item | MASTER scale methodological standard | MASTER scale question number | MASTER scale question |
| 1 | Representativeness of the exposed cohort | NA | 0 | NRoB |
| 2 | Selection of the non-exposed cohort | Equal recruitment | 2 | Participants in all comparison groups met the same eligibility requirements and were from the same population and timeframe |
| 3 | Ascertainment of exposure | Equal ascertainment | 12 | Exposures/interventions were objectively and/or reliably measured |
| 4 | Demonstration that outcome of interest was not present at start of study | Temporal precedence | 32 | All subjects were selected prior to intervention/exposure and evaluated prospectively  |
| 5 | Comparability of cohorts on the basis of the design or analysis | Equal prognosis | 23 | Design and/or analysis strategies were in place that addressed potential confounding  |
| 6 | Assessment of outcome | Equal ascertainment | 11 | The outcome was objective and/or reliably measured  |
| 7 | Was follow-up long enough for outcomes to occur? | Temporal precedence | 36 | Length of follow-up was not too long or too short in relation to the outcome assessment  |
| 8 | Adequacy of follow-up of cohorts | Equal retention | 5 | Any attrition (or exclusions after entry) was less than 20% of total participant numbers  |