**Additional File 2**
**Data extraction form and risk of bias tools**

## Data extraction form

***Identification***

| | |
|---|---|
| Review title or ID | |
| Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)* | |
| Report ID | |
| Report ID of other reports of this study including errata or retractions | |
| Notes | |

***General Information***

| | |
|---|---|
| Date form completed *(dd/mm/yyyy)* | |
| Name/ID of person extracting data | |
| Reference citation | |
| Study author contact details | |
| Publication type *(e.g. full report, abstract, letter)* | |
| Notes: | |

***Study Eligibility***

| Study Characteristics | Eligibility criteria *(Insert inclusion criteria for each characteristic as defined in the Protocol)* | Eligibility criteria met? Yes | No | Unclear | Location in text or source *(pg & ¶/fig/table/other)* |
|---|---|---|---|---|---|
| Type of study | Randomised Controlled Trial | ☐ | ☐ | ☐ | |
| | Quasi-randomised Controlled Trial | ☐ | ☐ | ☐ | |
| | Cluster Randomised Trial | ☐ | ☐ | ☐ | |
| | Controlled Before and After Study<br>Contemporaneous data collection<br>Comparable control sites | ☐ | ☐ | ☐ | |

| | | | |
|---|---|---|---|
| | At least 2 x intervention and 2 x control clusters | | |
| | Interrupted Time Series<br>At least 3 time points before and 3 after the intervention<br>Clearly defined intervention point | ☐ ☐ ☐ | |
| | Other design (specify): | ☐ ☐ ☐ | |
| Types of intervention | TPB based intervention | ☐ ☐ ☐ | |
| | At least 2 of the 3 constructs of TPB used by the intervention | ☐ ☐ ☐ | |
| | Intervention using multiple psychological theories with clearly measurable TPB constructs | ☐ ☐ ☐ | |
| Types of comparison / control | Health education not based on any psychological theory | ☐ ☐ ☐ | |
| | Health education based on psychological theory other than TPB | ☐ ☐ ☐ | |
| | Treatment as usual without any structured health education | ☐ ☐ ☐ | |
| Participants | Adults above 18 years of age, any gender and not Caucasian<br>Should have any chronic disease | ☐ ☐ ☐ | |
| Study setting | The geographical location of the study should be a LMIC | ☐ ☐ ☐ | |
| Types of outcome measures | Knowledge | ☐ ☐ ☐ | |
| | Attitude, subjective norms, perceived behavioural control | ☐ ☐ ☐ | |
| | Health behaviour *(e.g. exercise, medication use, smoking cessation, inhaler use)* | ☐ ☐ ☐ | |
| INCLUDE ☐ | | EXCLUDE ☐ | |

| | |
|---|---|
| Reason for exclusion | |
| Notes: | |

**DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW**

## Characteristics of included studies

***Methods***

| | **Descriptions as stated in report/paper** | | **Location in text or source** *(pg & ¶/fig/table/other)* |
|---|---|---|---|
| **Aim of study** *(e.g. efficacy, equivalence, pragmatic)* | | | |
| **Design** *(e.g. parallel, crossover, non-RCT)* | | | |
| **Unit of allocation** *(by individuals, cluster/ groups or body parts)* | | | |
| **Start date** | | | |
| **End date** | | | |
| **Duration of participation** *(from recruitment to last follow-up)* | | | |
| **Ethical approval needed/ obtained for study** | ☐ Yes ☐ No ☐ Unclear | | |
| **Notes:** | | | |

***Participants***

| | Description<br>*Include comparative information for each intervention or comparison group if available* | Location in text or source *(pg & ¶/fig/table/other)* |
|---|---|---|
| Population description *(from which study participants are drawn)* | | |
| Setting *(including location and social context)* | | |
| Inclusion criteria | | |
| Exclusion criteria | | |
| Method of recruitment of participants *(e.g. phone, mail, clinic patients)* | | |
| Informed consent obtained | ☐ Yes ☐ No ☐ Unclear | |
| Total no. randomised *(or total pop. at start of study for NRCTs)* | | |
| Clusters *(if applicable, no., type, no. people per cluster)* | | |
| Baseline imbalances | | |
| Withdrawals and exclusions *(if not provided below by outcome)* | | |
| Age | | |
| Sex | | |

| | | |
|---|---|---|
| Race/Ethnicity | | |
| Severity of illness | | |
| Co-morbidities | | |
| Other relevant socio-demographics | | |
| Subgroups measure | | |
| Subgroups reported | | |
| Notes: | | |

***Intervention groups***

*Copy and paste table for each intervention and comparison group*

**Intervention Group 1**

| | Description as stated in report/paper | Location in text or source *(pg & ¶/fig/table/other)* |
|---|---|---|
| Group name | | |
| No. randomised to group *(specify whether no. people or clusters)* | | |
| Theoretical basis *(include key references)* | | |
| Description *(include sufficient detail for replication, e.g. content, dose, components)* | | |
| Duration of treatment period | | |
| Timing *(e.g. frequency, duration of each episode)* | | |
| Delivery *(e.g. mechanism, medium, intensity, fidelity)* | | |

| | | |
|---|---|---|
| Providers *(e.g. no., profession, training, ethnicity etc. if relevant)* | | |
| Co-interventions | | |
| Economic information *(i.e. intervention cost, changes in other costs as result of intervention)* | | |
| Resource requirements *(e.g. staff numbers, cold chain, equipment)* | | |
| Integrity of delivery | | |
| Compliance | | |
| Notes: | | |

***Outcomes***

*Copy and paste table for each outcome.*

**Outcome 1**

| | Description as stated in report/paper | Location in text or source *(pg & ¶/fig/table/other)* |
|---|---|---|
| Outcome name | | |
| Time points measured *(specify whether from start or end of intervention)* | | |
| Time points reported | | |
| Outcome definition *(with diagnostic criteria if relevant)* | | |
| Person measuring/ reporting | | |
| Unit of measurement *(if relevant)* | | |

| | | | |
|---|---|---|---|
| Scales: upper and lower limits *(indicate whether high or low score is good)* | | | |
| Is outcome/tool validated? | ☐ Yes ☐ No ☐ Unclear | | |
| Imputation of missing data *(e.g. assumptions made for ITT analysis)* | | | |
| Assumed risk estimate *(e.g. baseline or population risk noted in Background)* | | | |
| Power *(e.g. power & sample size calculation, level of power achieved)* | | | |
| Notes: | | | |

***Other***

| | | |
|---|---|---|
| **Study funding sources** *(including role of funders)* | | |
| **Possible conflicts of interest** *(for study authors)* | | |
| **Notes:** | | |

***Risk of Bias assessment***

**The Risk Of Bias In Non-randomized Studies – of Interventions (ROBINS-I) assessment tool**

# ROBINS-I tool (Stage I): At protocol stage

## Specify the review question

| | |
|---|---|
| Participants | |
| Experimental intervention | |
| Comparator | |
| Outcomes | |

## List the confounding domains relevant to all or most studies

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|---|
| |

## List co-interventions that could be different between intervention groups and that could impact on outcomes

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# ROBINS-I tool (Stage II): For each study

## Specify a target randomized trial specific to the study

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|---|---|
| Design | Individually randomized / Cluster randomized / Matched (e.g. cross-over) |
| Participants | |
| Experimental intervention | |
| Comparator | |

## Is your aim for this study…?

☐ to assess the effect of *assignment to* intervention
☐ to assess the effect of *starting and adhering to* intervention

## Specify the outcome

Specify which outcome is being assessed for risk of bias (typically from among those earmarked for the Summary of Findings table). Specify whether this is a proposed benefit or harm of intervention.

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## Specify the numerical result being assessed

In case of multiple alternative analyses being presented, specify the numeric result (e.g. RR = 1.52 (95% CI 0.83 to 2.77) and/or a reference (e.g. to a table, figure or paragraph) that uniquely defines the result being assessed.

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## Preliminary consideration of confounders

Complete a row for each important confounding domain (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as potentially important.

***"Important" confounding domains are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention.***
***"Validity" refers to whether the confounding variable or variables fully measure the domain, while "reliability" refers to the precision of the measurement (more measurement error means less reliability).***

| **(i) Confounding domains listed in the review protocol** | | | | |
|---|---|---|---|---|
| Confounding domain | Measured variable(s) | Is there evidence that controlling for this variable was unnecessary?* | Is the confounding domain measured validly and reliably by this variable (or these variables)? | OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator? |
| | | | Yes / No / No information | Favour experimental / Favour comparator / No information |
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| **(ii) Additional confounding domains relevant to the setting of this particular study, or which the study authors identified as important** |
|---|

| Confounding domain | Measured variable(s) | Is there evidence that controlling for this variable was unnecessary?* | Is the confounding domain measured validly and reliably by this variable (or these variables)? | OPTIONAL: Is failure to adjust for this variable (alone) expected to favour the experimental intervention or the comparator? |
|---|---|---|---|---|
| | | | Yes / No / No information | Favour experimental / Favour comparator / No information |
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* In the context of a particular study, variables can be demonstrated not to be confounders and so not included in the analysis: (a) if they are not predictive of the outcome; (b) if they are not predictive of intervention; or (c) because adjustment makes no or minimal difference to the estimated effect of the primary parameter. Note that “no statistically significant association” is not the same as “not predictive”.

## Preliminary consideration of co-interventions

Complete a row for each important co-intervention (i) listed in the review protocol; and (ii) relevant to the setting of this particular study, or which the study authors identified as important.

***"Important" co-interventions are those for which, in the context of this study, adjustment is expected to lead to a clinically important change in the estimated effect of the intervention.***

| **(i) Co-interventions listed in the review protocol** | | |
|---|---|---|
| Co-intervention | Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)? | Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator |
| | | Favour experimental / Favour comparator / No information |
| | | Favour experimental / Favour comparator / No information |
| | | Favour experimental / Favour comparator / No information |
| | | Favour experimental / Favour comparator / No information |

| **(ii) Additional co-interventions relevant to the setting of this particular study, or which the study authors identified as important** | | |
|---|---|---|
| Co-intervention | Is there evidence that controlling for this co-intervention was unnecessary (e.g. because it was not administered)? | Is presence of this co-intervention likely to favour outcomes in the experimental intervention or the comparator |
| | | Favour experimental / Favour comparator / No information |
| | | Favour experimental / Favour comparator / No information |
| | | Favour experimental / Favour comparator / No information |
| | | Favour experimental / Favour comparator / No information |

## Risk of bias assessment

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

| Signalling questions | Description |
|---|---|
| **Bias due to confounding** | |
| 1.1 Is there potential for confounding of the effect of intervention in this study?<br>**If N/PN to 1.1:** the study can be considered to be at low risk of bias due to confounding and no further signalling questions need be considered | |
| **If Y/PY to 1.1**: determine whether there is a need to assess time-varying confounding: | |
| 1.2. Was the analysis based on splitting participants' follow up time according to intervention received?<br>**If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6)<br>**If Y/PY**, go to question 1.3. | |
| 1.3. Were intervention discontinuations or switches likely to be related to factors that are prognostic for the outcome?<br>**If N/PN**, answer questions relating to baseline confounding (1.4 to 1.6)<br>**If Y/PY**, answer questions relating to both baseline and time-varying confounding (1.7 and 1.8) | |
| **Questions relating to baseline confounding only** | |
| 1.4. Did the authors use an appropriate analysis method that controlled for all the important confounding domains? | |
| 1.5. **If Y/PY to 1.4**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study? | |
| 1.6. Did the authors control for any post-intervention variables that could have been affected by the intervention? | |
| **Questions relating to baseline and time-varying confounding** | |
| 1.7. Did the authors use an appropriate analysis method that controlled for all the important confounding domains and for time-varying confounding? | |
| 1.8. **If Y/PY to 1.7**: Were confounding domains that were controlled for measured validly and reliably by the variables available in this study? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to confounding? | |

| **Bias in selection of participants into the study** | |
|---|---|
| 2.1. Was selection of participants into the study (or into the analysis) based on participant characteristics observed after the start of intervention?<br>**If N/PN to 2.1:** go to 2.4 | |

| | |
|---|---|
| 2.2. **If Y/PY to 2.1**: Were the post-intervention variables that influenced selection likely to be associated with intervention?<br>2.3 **If Y/PY to 2.2**: Were the post-intervention variables that influenced selection likely to be influenced by the outcome or a cause of the outcome? | |
| 2.4. Do start of follow-up and start of intervention coincide for most participants? | |
| 2.5. **If Y/PY to 2.2 and 2.3, or N/PN to 2.4**: Were adjustment techniques used that are likely to correct for the presence of selection biases? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to selection of participants into the study? | |

| **Bias in classification of interventions** | |
|---|---|
| 3.1 Were intervention groups clearly defined? | |
| 3.2 Was the information used to define intervention groups recorded at the start of the intervention? | |
| 3.3 Could classification of intervention status have been affected by knowledge of the outcome or risk of the outcome? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to classification of interventions? | |

| **Bias due to deviations from intended interventions** | |
|---|---|
| **If your aim for this study is to assess the effect of assignment to intervention, answer questions 4.1 and 4.2** | |
| 4.1. Were there deviations from the intended intervention beyond what would be expected in usual practice? | |
| 4.2. **If Y/PY to 4.1**: Were these deviations from intended intervention unbalanced between groups *and* likely to have affected the outcome? | |
| **If your aim for this study is to assess the effect of starting and adhering to intervention, answer questions 4.3 to 4.6** | |
| 4.3. Were important co-interventions balanced across intervention groups? | |
| 4.4. Was the intervention implemented successfully for most participants? | |
| 4.5. Did study participants adhere to the assigned intervention regimen? | |
| 4.6. **If N/PN to 4.3, 4.4 or 4.5**: Was an appropriate analysis used to estimate the effect of starting and adhering to the intervention? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to deviations from the intended interventions? | |

| **Bias due to missing data** |
|---|

| | |
|---|---|
| 5.1 Were outcome data available for all, or nearly all, participants? | |
| 5.2 Were participants excluded due to missing data on intervention status? | |
| 5.3 Were participants excluded due to missing data on other variables needed for the analysis? | |
| 5.4 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Are the proportion of participants and reasons for missing data similar across interventions? | |
| 5.5 **If PN/N to 5.1, or Y/PY to 5.2 or 5.3**: Is there evidence that results were robust to the presence of missing data? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to missing data? | |

| **Bias in measurement of outcomes** | |
|---|---|
| 6.1 Could the outcome measure have been influenced by knowledge of the intervention received? | |
| 6.2 Were outcome assessors aware of the intervention received by study participants? | |
| 6.3 Were the methods of outcome assessment comparable across intervention groups? | |
| 6.4 Were any systematic errors in measurement of the outcome related to intervention received? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to measurement of outcomes? | |

| **Bias in selection of the reported result** | |
|---|---|
| Is the reported effect estimate likely to be selected, on the basis of the results, from...<br>7.1. ... multiple outcome *measurements* within the outcome domain? | |
| 7.2 ... multiple *analyses* of the intervention-outcome relationship? | |
| 7.3 ... different *subgroups*? | |
| **Risk of bias judgement** | |
| Optional: What is the predicted direction of bias due to selection of the reported result? | |

| **Overall bias** | |
|---|---|
| **Risk of bias judgement** | |
| Optional: What is the overall predicted direction of bias for this outcome? | |

**Revised Cochrane risk-of-bias tool for randomized trials (RoB 2)**

Responses underlined in green are potential markers for low risk of bias, and responses in red are potential markers for a risk of bias. Where questions relate only to sign posts to other questions, no formatting is used.

| Signalling questions | Comments | Response options |
|---|---|---|
| **1.1 Was the allocation sequence random?** | | Y / PY / PN / N / NI |
| **1.2 Was the allocation sequence concealed until participants were enrolled and assigned to interventions?** | | Y / PY / PN / N / NI |
| **1.3 Did baseline differences between intervention groups suggest a problem with the randomization process?** | | Y / PY / PN / N / NI |
| **Risk-of-bias judgement** | | Low / High / Some concerns |
| Optional: What is the predicted direction of bias arising from the randomization process? | | NA / Favours experimental / Favours comparator / Towards null /Away from null / Unpredictable |

## *Domain 1: Risk of bias arising from the randomization process*

## *Domain 2: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)*

| Signalling questions | Comments |
|---|---|
| **2.1. Were participants aware of their assigned intervention during the trial?** | |
| **2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?** | |
| **2.3. If Y/PY/NI to 2.1 or 2.2: Were there deviations from the intended intervention that arose because of the trial context?** | |
| **2.4 If Y/PY to 2.3: Were these deviations likely to have affected the outcome?** | |
| **2.5. If Y/PY/NI to 2.4: Were these deviations from intended intervention balanced between groups?** | |
| **2.6 Was an appropriate analysis used to estimate the effect of assignment to intervention?** | |
| **2.7 If N/PN/NI to 2.6: Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?** | |
| **Risk-of-bias judgement** | |
| Optional: What is the predicted direction of bias due to deviations from intended interventions? | |

## *Domain 2: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)*

| Signalling questions | Comments |
|---|---|
| **2.1. Were participants aware of their assigned intervention during the trial?** | |
| **2.2. Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?** | |
| **2.3. [If applicable:] If Y/PY/NI to 2.1 or 2.2: Were important non-protocol interventions balanced across intervention groups?** | |
| **2.4. [If applicable:] Were there failures in implementing the intervention that could have affected the outcome?** | |
| **2.5. [If applicable:] Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?** | |
| **2.6. If N/PN/NI to 2.3, or Y/PY/NI to 2.4 or 2.5: Was an appropriate analysis used to estimate the effect of adhering to the intervention?** | |
| **Risk-of-bias judgement** | |
| Optional: What is the predicted direction of bias due to deviations from intended interventions? | |

## *Domain 3: Missing outcome data*

| Signalling questions | Comments |
|---|---|
| **3.1 Were data for this outcome available for all, or nearly all, participants randomized?** | |
| **3.2 If N/PN/NI to 3.1: Is there evidence that the result was not biased by missing outcome data?** | |
| **3.3 If N/PN to 3.2: Could missingness in the outcome depend on its true value?** | |
| **3.4 If Y/PY/NI to 3.3: Is it likely that missingness in the outcome depended on its true value?** | |
| **Risk-of-bias judgement** | |
| Optional: What is the predicted direction of bias due to missing outcome data? | |

## *Domain 4: Risk of bias in measurement of the outcome*

| Signalling questions | Comments |
|---|---|
| **4.1 Was the method of measuring the outcome inappropriate?** | |
| **4.2 Could measurement or ascertainment of the outcome have differed between intervention groups?** | |
| **4.3 If N/PN/NI to 4.1 and 4.2: Were outcome assessors aware of the intervention received by study participants?** | |
| **4.4 If Y/PY/NI to 4.3: Could assessment of the outcome have been influenced by knowledge of intervention received?** | |
| **4.5 If Y/PY/NI to 4.4: Is it likely that assessment of the outcome was influenced by knowledge of intervention received?** | |
| **Risk-of-bias judgement** | |
| Optional: What is the predicted direction of bias in measurement of the outcome? | |

## *Domain 5: Risk of bias in selection of the reported result*

| **Signalling questions**<br>**5.1 Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?** | **Comments** |
|---|---|
| **Is the numerical result being assessed likely to have been selected, on the basis of the results, from...** | |
| **5.2. ... multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?** | |
| **5.3 ... multiple eligible analyses of the data?** | |
| **Risk-of-bias judgement** | |
| Optional: What is the predicted direction of bias due to selection of the reported result? | |

Overall risk of bias

| | |
|---|---|
| **Risk-of-bias judgement** | |
| Optional: What is the overall predicted direction of bias for this outcome? | |