# cclogo300x350Data collection form[[1]](#endnote-1)

|  |
| --- |
| **Review title** |
| Hospitalisation in short-stay units for internal medicine diseases and conditions  *Note: In this form, short-stay units are abbreviated SSU.* |

## General Information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **General information** | | | | |
| 1. Date form completed   *(dd-mm-yyyy)* | |  | |
| 1. Name/ID of person extracting data | |  | |
| 1. First Author | |  | |
| 1. Study title   *(title of paper/ abstract/ report that data are extracted from)* | |  | |
| 1. DOI number | |  | |
| 1. Year of publication | |  | |
| 1. Published trial | | YES [ ] NO [ ] | |
| 1. Publication type   *(e.g. full report, abstract, letter, conference proceeding)* | |  | |
| 1. Author contacted | | YES [ ] NO [ ] | 1.time (dd-mm-yyyy):  2.time (dd-mm-yyyy): |
| 1. Clincaltrials.gov   *(if registered elsewhere, state where and reference number or equivalents)* | | YES [ ] NO [ ] | Registration number:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1. Notes: |  | | |

## Trial eligibility

| **Study Characteristics** | | | **Review Inclusion Criteria**  *(Insert inclusion criteria for each characteristic as defined in the Protocol)* | **Yes/ No / Unclear** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- | --- | --- |
| 1. Type of study | | | Randomised trial |  |  |
| Other design (specify): |  |  |
| 1. Participants   *(do the study include adult internal medicine patients yes/no/unclear, is the study population mixed (i.e. does the study also include paediatric patients (yes (specify)/no/unclear))* | | | 1. adult (18 years or more) internal medicine patients |  |  |
| 2. is the study population mixed  if yes specify: |  |
| 3. other: |  |
| 1. Intervention | | | Treatment in any type of SSU |  |  |
| Time limit of hospitalisation in SSU of 5 days or less |  |  |
| 1. Decision: | | **Included [ ] / excluded [ ]** | | | |
| 1. Reason for exclusion | | |  | | |
| 1. Notes: |  | | | | |

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

## References to trials

Check other references identified in the searches. If there are further references to this trial, link the papers now and list below

| **Code each paper** | **Author** | **Journal/ Conference Proceedings etc.** | **Year** |
| --- | --- | --- | --- |
| **A** |  |  |  |
| **B** |  |  |  |
| C |  |  |  |
| D |  |  |  |
| E |  |  |  |

## Description of funding, ethical approval and type of SSU and control arm unit (-s)

|  |  |
| --- | --- |
| 1. Study funding source   *(including role of funders)* |  |
| 1. Ethical approval   *(yes/no/not described)* | YES [ ] NO [ ] |
| 1. Possible conflicts of interest   *(for study authors)* | YES [ ] NO [ ] NOT DESCRIBED [ ] |
| 1. SSU name |  |
| SSU description   1. Type 2. SSU connected to other department (ED=Emergency department) 3. Defined maximum length of stay (LOS) for patients in SSU 4. Entry criteria for SSU 5. Description of certain observation or treatment protocols | Multipurpose unit [ ] / specialised unit [ ] / not described [ ]  ED-based [ ] / not ED-based [ ] / not described [ ] / other (e.g. Inpatient assessment unit as part of another department than the ED, describe):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  YES [ ] LOS (dd-hh-min): \_\_\_\_\_\_\_\_\_\_\_\_ / NO [ ] / NOT DESCRIBED [ ]  Entry criteria described [ ]/ no entry criteria [ ]/  Entry criteria not described [ ]/ other (describe):  Treatment protocol [ ]/ no treatment protocol [ ]/  Not described [ ]/ other (describe): |
| 1. Name of control arm   unit (-s) |  |
| Control arm unit (-s)description   1. Type 2. Entry criteria for unit (-s) | Multipurpose unit [ ] / specialised unit [ ] / not described [ ]. Part of another department, describe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Entry criteria described [ ]/ no entry criteria [ ]/  Entry criteria not described [ ]/ other (describe): |

## Methods

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | **Descriptions as stated in report/paper** | | | **Location in text**  *(pg & ¶/fig/table)* |
| 1. Single centre or multicentre trial | | Single centre [ ] Multicentre [ ]  If multicentre, number of study sites : [ ] | | |  |
| 1. Setting (possible additional answers) | | University based hospital [ ] Non-teaching setting [ ] Unclear [ ]  Public hospital [ ] Private hospital [ ] Unclear [ ] | | |  |
| 1. Country/Countries | |  | | |  |
| 1. Unit of allocation   *(by individuals, cluster/ groups)* | | By individual [ ] By cluster [ ] By groups [ ]  if applicable:  number of participants per cluster: | | |  |
| 1. Aim of study | | Aim:  Not clearly defined [ ] | | |  |
| 1. Start date   *(dd-mm-yyyy)* | |  | | |  |
| 1. End date   *(dd-mm-yyyy)* | |  | | |  |
| 1. How was participants defined | | Inclusion criteria | By age | Yes [ ] No [ ]  Define: |  |
| By symptom | Yes [ ] No [ ]  If yes which: |
| By disease or condition | Yes [ ] No [ ] |
| Mixed diseases and conditions:  Yes [ ] No [ ] |
| If yes which: |
| By sex | Female [ ] Male[ ] |
| Other |  |
| Exclusion criteria |  | |
| 1. Total number of groups (interventions and controls) | |  | | |  |
| 1. How many participants were randomised | |  | | |  |
| 1. Number of participants in each group | | Intervention:\_\_\_\_\_  Control:\_\_\_\_\_  Other:\_\_\_\_\_\_ | | |  |
| 1. Number of participants who received intended intervention | |  | | |  |
| 1. Number of participants that were analysed | |  | | |  |
| 1. Number of subgroups measured | |  | | |  |
| 1. Number of subgroups reported | |  | | |  |
| 1. Duration of participation   *(from recruitment to last follow-up, state median (range) follow-up reported in hours, weeks, months or years or if not stated)* | |  | | |  |
| 1. Was there a outcome hierarchy | | Yes [ ] No [ ] | | |  |
| 1. What was/were the primary outcome(s) | | 1a.  1b.  1c. | | |  |
| 1. What was/were the secondary outcome(s) | | 2a.  2b.  2c.  2d.  2e.  2f.  2g.  2h. | | |  |
| 1. Time points where outcomes where measured   *(remember to clarify if minutes/hour/days/months/year. If not stated in paper, then write NS).* | | Primary outcomes:  1a.  1b.  1c.  Secondary outcomes:  2a.  2b.  2c.  2d.  2e.  2f.  2g.  2h. | | |  |
| 1. Sample size calculation   *(yes/no/unclear)* | |  | | |  |
| 1. Assumed risk estimate for sample size calculation   *(baseline or population risk noted in background)* | |  | | |  |
| 1. P-value considered statistically significant | |  | | |  |
| 1. Notes: |  | | | | |

## Groups

### Intervention Group (SSU)

|  | | **Description as stated in report/paper** | | | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- | --- | --- |
| 1. Group name | |  | | |  |
| 1. No. randomised to group   *(specify whether no. people or clusters)* | |  | | |  |
| 1. Description   *(include sufficient detail for replication, e.g. content, dose, components; if it is a natural experiment, describe the pre-intervention)* | | Age | | Mean:  Median:  SD:  Range:  IQR: |  |
| Sex | | Number of Males [ ]  Number of Females [ ] |
| Race/Ethnicity | |  |
| Severity of illness | | Severity of illness measured by a scale (e.g. GOLD classification):  Scale/classification system:  Mean:  Median:  SD:  Range:  IQR: |
| Co-morbidities | | Comorbidity measured by a scale (e.g. CCI):  Which:  Mean:  Median:  SD:  Range:  IQR: |
| Other treatment received (additional to study intervention) | |  |
| Type of targeted behaviour: | | |
| Treatment protocols | Yes [ ] No [ ] Unclear [ ]  if yes: specify, and address implemented at start of trial/implemented before trial) | |
| Early mobilisation | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Early discharge planning | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Other components of short term care or fast track care described | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Staffing | | |
| Type of staffing | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Creation of new team of health care providers | Yes [ ] No [ ] Unclear [ ]  if yes: specify  if yes: then fidelity assessement:  Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Resource requirements to replicate intervention  *(Number and type of staffing per patient bed, equipment)* | number of nurses:  number of physicians:  number of occupational therapist:  number of physiotherapist:  Other staffing:  Equipment: | |
| Clinical specialty of providers of care | Yes [ ] No [ ] Unclear [ ]  if yes: specify which: | |
| 1. Co-interventions   *(if relevant)* | |  |  | |  |
| 1. Notes: |  | | | | |

### Comparison group

*Copy and paste the appropriate table for each comparison group (if more than one).*

|  | | **Description as stated in report/paper** | | | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- | --- | --- |
| 1. Group name | |  | | |  |
| 1. No. randomised to group   *(specify whether no. people or clusters)* | |  | | |  |
| 1. Description   *(include sufficient detail for replication, e.g. content, dose, components; if it is a natural experiment, describe the pre-intervention)* | | Age | | Mean:  Median:  SD:  Range:  IQR: |  |
| Sex | | Number of Males [ ]  Number of Females [ ] |
| Race/Ethnicity | |  |
| Severity of illness | | Severity of illness measured by a scale (e.g. GOLD classification):  Scale/classification system:  Mean:  Median:  SD:  Range:  IQR: |
| Co-morbidities | | Comorbidity measured by a scale (e.g. CCI):  Which:  Mean:  Median:  SD:  Range:  IQR: |
| Other treatment received (additional to study intervention) | |  |
| Type of targeted behaviour: | | |
| Treatment protocols | Yes [ ] No [ ] Unclear [ ]  if yes: specify, and address implemented at start of trial/implemented before trial) | |
| Early mobilisation | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Early discharge planning | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Other components of short term care or fast track care described | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
|  |  | |
| Staffing | | |
| Type of staffing | Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Creation of new team of health care providers | Yes [ ] No [ ] Unclear [ ]  if yes: specify  if yes: then fidelity assessement:  Yes [ ] No [ ] Unclear [ ]  if yes: specify | |
| Resource requirements  *(Number and type of staffing per patient bed, equipment)* | number of nurses  number of physicians:  number of occupational therapist:  number of physiotherapist:  Other staffing:  Equipment: | |
| Clinical specialty of providers of care | Yes [ ] No [ ] Unclear [ ]  if yes: specify which: | |
| 1. Co-interventions   *(if relevant)* | |  |  | |  |
| 1. Notes: |  | | | | |

## -

## Risk of Bias assessment

| **Domain** | | **Risk of bias**  *Low/ High/Unclear* | **Support for judgement** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- | --- |
| 1. Random sequence generation   *(selection bias)* | |  |  |  |
| 1. Allocation concealment   *(selection bias)* | |  |  |  |
| 1. Baseline outcome measurement | |  |  |  |
| 1. Baseline characteristics | |  |  |  |
| 1. Blinding of participants and personnel   *(performance bias, this domain will not be included in the overall assessment – see protocol)* | |  |  |  |
| 1. Blinding of outcome assessment   *(detection bias)* | | Primary outcome (-s):  1a.  1b.  1c.  Secondary outcomes  2a.  2b.  2c.  2d.  2e.  2f.  2g.  2h.  Overall for all outcomes | Primary outcome (-s):  1a.  1b.  1c.  Secondary outcomes  2a.  2b.  2c.  2d.  2e.  2f.  2g.  2h.  Overall for all outcomes |  |
| 1. Contamination | |  |  |  |
| 1. Incomplete outcome data   *(attrition bias)* | |  |  |  |
| 1. Selective outcome reporting?   *(reporting bias)* | |  |  |  |
| 1. Other bias   *(e.g. funding/industry bias, academic (> 2 studies on same intervention, study population etc.)* | |  |  |  |
| 1. Overall ‘risk of bias’ evaluation | |  |  |  |
| 1. Notes: |  | | | |

## Outcomes

### All cause mortality

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Serious Adverse Events

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Quality of life

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Readmission

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious, report also if it was unplanned readmission or all readmissions)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Activities of daily life

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Non-serious Adverse Events

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Transfer to other department

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Total length of stay in hospital

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

### Other outcome (-s)

*Copy and paste this table for each and all additional outcome (-s)*

|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- |
| 1. Outcome name | |  |  |
| 1. Time points measured   *(specify whether from start or end of intervention)* | |  |  |
| 1. Time points reported | |  |  |
| 1. Outcome definition   *(with diagnostic criteria if relevant and note whether the outcome is desirable or undesirable if this is not obvious)* | |  |  |
| 1. Person measuring/ reporting | |  |  |
| 1. Unit of measurement   *(if relevant)* | |  |  |
| 1. Scales: upper and lower limits   *(indicate whether high or low score is good)* | |  |  |
| 1. Is outcome/tool validated? | | Yes [ ] No [ ] Unclear [ ] |  |
| 1. Imputation of missing data   *(e.g. assumptions made for ITT analysis)* | |  |  |
| 1. Assumed risk estimate   *(e.g. baseline or population risk noted in Background)* | |  |  |
| 1. Notes: |  | | |

## Results

*Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.*

### Dichotomous outcome:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  | | **Description as stated in report/paper** | | | | | **Location in text**  *(pg & ¶/fig/table)* |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Comparison | |  | | | | |  |
| 1. Outcome | |  | | | | |  |
| 1. Subgroup | |  | | | | |  |
| 1. Time point   *(specify whether from start or end of intervention)* | |  | | | | |  |
| 1. Results   *Note whether:*  *post-intervention OR*  *change from baseline*  *And whether*  *Adjusted OR*  *Unadjusted* | | **Intervention** | | | **Comparison** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
| 1. Baseline data | | **Intervention** | | | **Comparison** | |  |
| No. events | No. participants | | No. events | No. participants |
|  |  | |  |  |
| 1. No. missing participants and reasons | |  | | |  | |  |
| 1. No. participants moved from other group and reasons | |  | | |  | |  |
| 1. Any other results reported | |  | | | | |  |
| 1. Unit of analysis   *(e.g. by individuals, health professional, practice, hospital, community)* | |  | | | | |  |
| 1. Statistical methods used and appropriateness of these methods   *(e.g. adjustment for correlation)* | |  | | | | |  |
| 1. Reanalysis required?   *(if yes, specify why, e.g. correlation adjustment)* | | *Yes/No/Unclear* | |  | | |  |
| 1. Reanalysis possible? | | *Yes/No/Unclear* | |  | | |  |
| 1. Reanalysed results | |  | | | | |  |
| 1. Notes: |  | | | | | | |

### Continuous outcome: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  | | | **Description as stated in report/paper** | | | | | | | | **Location in text**  *(pg & ¶/fig/table)* | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Comparison | | |  | | | | | | | |  | |
| 1. Outcome | | |  | | | | | | | |  | |
| 1. Subgroup | | |  | | | | | | | |  | |
| 1. Time point   *(specify whether from start or end of intervention)* | | |  | | | | | | | |  | |
| 1. Post-intervention or change from baseline? | | |  | | | | | | | |  | |
| 1. Results   *Note whether:*  *post-intervention OR*  *change from baseline*  *And whether*  *Adjusted OR*  *Unadjusted* | | **Intervention** | | | | | | **Comparison** | | |  |
| Mean | | SD (or other variance) | No. participants | | | Mean | SD (or other variance) | No. participants |
|  | |  |  | | |  |  |  |
| 1. Baseline data | | **Intervention** | | | | | | **Comparison** | | |  |
| Mean | | SD (or other variance) | No. participants | | | Mean | SD (or other variance) | No. participants |
|  | |  |  | | |  |  |  |
| 1. No. missing participants and reasons | | |  | | | |  | | | |  | |
| 1. No. participants moved from other group and reasons | | |  | | | |  | | | |  | |
| 1. Any other results reported | | |  | | | | | | | |  | |
| 1. Unit of analysis   *(e.g. by individuals, health professional, practice, hospital, community)* | | |  | | | | | | | |  | |
| 1. Statistical methods used and appropriateness of these methods   *(e.g. adjustment for correlation)* | | |  | | | | | | | |  | |
| 1. Reanalysis required?   *(if yes, specify why)* | | |  | | |  | | | | |  | |
| 1. Reanalysis possible? | | |  | | |  | | | | |  | |
| 1. Reanalysed results | | |  | | | | | | | |  | |
| 1. Notes: |  | | | | | | | | | | | |

## Applicability

|  |  |  |  |
| --- | --- | --- | --- |
| 1. Have important populations been excluded from the study?   *(consider disadvantaged populations, and possible differences in the intervention effect)* | | *Yes/No/Unclear* |  |
| 1. Is the intervention likely to be aimed at disadvantaged groups?   *(e.g. lower socioeconomic groups)* | | *Yes/No/Unclear* |  |
| 1. Does the study directly address the review question?   *(any issues of partial or indirect applicability)* | | *Yes/No/Unclear* |  |
| 1. Notes: |  | | | |

## Other information

|  |  |  |  |
| --- | --- | --- | --- |
|  | | **Description as stated in report/paper** | **Location in text**  *(pg & ¶/fig/table)* |
| 1. Intention to treat analysis | | All participants entered the trial: Yes [ ]/ No [ ]/Unclear[ ]  15% or fewer excluded: Yes [ ]/ No [ ]  More than 15% excluded: Yes [ ]/ No [ ]  If withdrawal or exclusions: did the authors carry out ‘intention to treat’ analysis Yes [ ]/ No [ ]  If withdrawal or exclusions: did the authors carry out a ‘ modified intention to treat’ analysis Yes [ ]/ No [ ] |  |
| 1. Where the withdrawals described | | Yes [ ] No [ ] Unclear [ ]  Specify if needed: |  |
| 1. Early stopping | | The trial was stopped early  Yes [ ] No [ ] Unclear [ ]  Early stopping was adequate  Yes [ ] No [ ] Unclear [ ]  if yes: specify |  |
| 1. Key conclusions of study authors | |  |  |
| 1. References to other relevant studies | |  |  |
| 1. Correspondence required for further study information   *(what and from whom)* | |  | |
| 1. Further study information requested   *(from whom, what and when)* | |  | |
| 1. Correspondence received   *(from whom, what and when)* | |  | |
| 1. Notes: |  | | | |

1. *Effective Practice and Organisation of Care (EPOC). Data collection form. EPOC Resources for review authors. Oslo: Norwegian Knowledge Centre for the Health Services; 2013. Available at:* [*http://epoc.cochrane.org/epoc-specific-resources-review-authors*](http://epoc.cochrane.org/epoc-specific-resources-review-authors) [↑](#endnote-ref-1)