# 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 description1. 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)description1. 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: specifyif 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: specifyif yes: then fidelity assessement:Yes [ ] No [ ] Unclear [ ]if yes: specify |
| Resource requirements *(Number and type of staffing per patient bed, equipment)* | number of nursesnumber 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 outcomes2a.2b.2c.2d.2e.2f.2g.2h.Overall for all outcomes | Primary outcome (-s):1a.1b.1c.Secondary outcomes2a.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 earlyYes [ ] 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)