Table 1 - Quality criteria for application per study design

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| --- | --- |
| Quality criteria | Study design b |
| Dimension | Specific criteria a | RCT | CBA | CITS | NCITS | NCBA | CS | QUAL |
| 1. Clear aims and justification
 | 1. Clear statement of the aims of research?
2. Rationale for number of pre-and post-intervention points or adequate baseline measurement
3. Explanation for lack of control group
4. Appropriateness of qualitative methodology
5. Appropriate study design
 | ++xxxx | ++xxxx | +++xxx | +++++xx | +++++xx | ++xxxx | ++xx+++ |
| 1. Managing bias in sampling or between groups
 | 1. Sequence generation
2. Allocation concealment
3. Justification for sample choice
4. Intervention and control group selection designed to protect against systematic difference/selection bias
5. Comparability of groups
6. Sampling and recruitment
 | ++++xxxx | xxx++xx | xxxxxx | xx++xxx | xx++xxx | xxxx++x | xxxxx++ |
| 1. Managing bias in outcome measurements and blinding
 | 1. Blinding
2. Baseline measurement- protection against selection bias
3. Protection against contamination
4. Protection against secular changes
5. Protection against detection bias: blinded assessment of primary outcome measures
6. Reliable primary outcome measures
7. Comparability of outcomes
 | ++xxx++x | x++++x++x | xxx++++x | xxxx++x | xxxx++x | xxxx++++ | xxxxx+x |
| 1. Managing bias in follow-up
 | 1. Follow-up of subjects (protection against exclusion bias)
2. Follow-up of patients of episodes of care
3. Incomplete outcome data addressed
 | +++ | xx+ | xx+ | xx+ | xx+ | xx++ | xx+ |
| 1. Managing bias in other study aspects
 | 1. Protection against detection bias: intervention unlikely to affect data collection
2. Protection against information bias
3. Data collection appropriate to address research aims
4. Attempts to mitigate effects of no control
 | +xxx | +xxx | +xxx | +xx++ | +xx++ | x+xx | xx+x |
| 1. Analytical rigour
 | 1. Sufficient data points to enable reliable statistical inference
2. Shaping of intervention effect specified
3. Analysis sufficiently rigorous/free from bias
 | xx+ | xx+ | ++++ | xx+ | xx+ | xx+ | xx+ |
| 1. Managing bias in reporting/ethical considerations
 | 1. Free of selective outcome reporting
2. Limitations addressed
3. Conclusions clear and justified
4. Free of other bias
5. Ethics issues addressed
 | +++++ | +++++ | +++++ | +++++ | +++++ | +++++ | +++++ |

a Applicability of quality criteria to each study design: + Criteria to be included in quality assessment for study design; ++ Mandatory criteria to be met quality assessment; x Criteria not to be applied in quality assessment for study design.

b Study designs: RCT =randomised controlled trial; CBA =controlled before-after; CITS ¼ controlled interrupted time series; CS = cohort study; NCITS =non-controlled interrupted time series; NCBA =non-controlled before-after; QUAL = qualitative.

Table 2 -Decision matrix e mandatory criteria and minimum score for study type to be included in review.

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| --- | --- | --- |
| Study Design a | Mandatory criteria b | Minimum score |
| RCT, cRCT | 1A, 2A, 2B, and 3A | 22 |
| CBA | 1A, 2D, 3B and 3C | 18 |
| CITS | 1A, 3D and 6A | 18 |
| NCITS | 1A, 1B, 2C and 5D | 22 |
| NCBA | 1A, 1B, 2C and 5D | 22 |
| Cohort  | 1A, 2E, 3G and 4C | 18 |
| Qualitative | 1A, 1E and 2F | 16 |

a Study Designs: RCT = randomised controlled trial; CBA =controlled before-after; CITS = controlled interrupted time series; cRCT =cluster-randomized controlled trial; NCITS = noncontrolled interrupted time series; NCBA =non-controlled before-after.

 b Scores applicable to each criteria: Yes (criterion met) =2 points; Unclear (unclear whether or not the criterion is met) =1 point; No (criterion not met) = 0 points.

Adapted from Zingg W et al. Innovative tools for quality assessment: integrated quality criteria for review of multiple study designs (ICROMS). Public Health 2016;133:19-37.