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| **GATE**: a **G**raphic **A**pproach **T**o **E**vidence based practice  White logo only FMHS_logo_blackH  updates from previous version in red  **GATE CAT- Systematic Reviews: Intervention studies** | | | | | | | | | | |
| **Critically Appraised Topic (CAT): Applying the 5 steps of Evidence Based Practice**  **Using evidence about interventions from randomised controlled trials (RCTs) & non-randomised cohort studies** | | | | | | | | | | |
| **Assessed by:** | | | | | **Date:** | | | | | |
| **Problem** | | | | | | | | | | |
| Describe the problem that led you to seek an answer from the literature about the effectiveness of interventions. | | | | | | | | | | |
| **Step 1: Ask a focused 5-part question using PECOT framework (EITHER ‘your question’ OR ‘the Review’s question’)** | | | | | | | | | | |
| Population / patient / client | Describe relevant patient/client/population group (be specific about: medical condition, age group, sex, etc.) | | | | | | | | | |
| Exposure (intervention) | Describe intervention(s) you want to find out about  Be reasonably specific (if relevant): e.g. how much? when? how administered? for how long? | | | | | | | | | |
| Comparison  (Control) | Describe alternative intervention (e.g. nothing or usual care?) you want to compare it with?  Be reasonably specific | | | | | | | | | |
| Outcomes | List the relevant health/disease-related outcomes you would like to prevent/reduce/etc | | | | | | | | | |
| Time | Enter a realistic time period within which you would expect to observe a change in these outcomes? | | | | | | | | | |
| **Step 2: Access (Search) for systematic reviews using the PECOT framework** | | | | | | | | | | |
| PECOT item | Primary Search Term | |  | Synonym 1 | | |  | Synonym 2 | |  |
| **Population / P**articipants / patients / clients | Enter key search terms for at least P, E & O.  C & T may not be so useful for searching.  Use MESH terms (from PubMed) if available, then text words. | | OR | Include relevant synonym | | | OR | Include relevant synonym | | AND |
| **E**xposure (Interventions) | As above | | OR | As above | | | OR | As above | | AND |
| **C**omparison (Control) | As above | | OR | As above | | | OR | As above | | AND |
| **O**utcomes | As above | | OR | As above | | | OR | As above | | AND |
| **T**ime | As above | | AND | As above | | | AND | As above | |  |
| **Limits & Filters** | PubMed has **Limits** (eg age, English language, years) & PubMed Clinical Queries has **Filters** (e.g. study type) to help focus your search. List those used. | | | | | | | | | |
| **Databases searched:** | | | | | | | | | | |
| Database | Cochrane SRs | Other Secondary Sources | | | | PubMed / Ovid Medline | | | Other | |
| Number of publications (Hits) | Enter number of hits from Cochrane database search for Systematic Reviews (SR). | Enter number of hits from other secondary sources (specify source) | | | | Enter number of hits from PubMed /Ovid/etc (specify database) | | | Enter number of hits from other sources (e.g. Google scholar, Google) | |
| Evidence Selected | | | | | | | | | | |
| Enter the full citation of the publication you have selected to evaluate. | | | | | | | | | | |
| Justification for selection | | | | | | | | | | |
| State the main objectives of the study.  Explain why you chose this publication for evaluation. | | | | | | | | | | |

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| **Systematic Reviews of Intervention Studies**  **Step 3: Appraise Study**  **3a. Describe the design of the review by hanging it on the GATE frame (no separate excel GATE calculator for SRs)** | | | | | |
| **Study Sources**  **Eligibility criteria (studies)**  **Eligibility criteria**  **(participants)**  **Search strategy**  **Studies**  **Screened**  **-------------------** | | Source of studies | List information sources for search (e.g. databases with dates of coverage, reference lists, contact with study authors to identify additional studies) & dates searched. | | |
| Eligibility criteria:  studies | List types of studies included. Only RCTs? Cohort studies? Length of follow-up? Languages? Publication status? | | |
| Eligibility criteria for participants | List eligibility criteria for participants using PECOT: participants, exposure, comparison, outcomes and follow-up times. List any exclusion criteria. | | |
| Search strategy | List electronic search terms used for main database searched, including limits (if provided) | | |
| Studies screened | State number of studies/abstracts identified by search & screened. How screened (e.g. reading titles, abstracts, whole papers) How many included/excluded and why? Done by one or more screeners? | | |
| **Studies appraised**  **Studies Studies**  **included excluded** | | Process of appraising study validity | State methods used to assess bias in each study. How were studies appraised (e.g. using standardised process like RAMboMAN, Jadad scale)? | | |
| Data extraction methods | State how data extracted from study reports (e.g. piloted forms), number of independent reviewers. Was any data obtained or confirmed from individual study investigators? | | |
| Studies included / excluded in analyses | Give the number of appraised studies included/excluded and reasons why. Give main characteristics of studies and participants e.g study size., PECOT. | | |
| Picture 3.png**Forest plot (or equivalent)** | | Summary measures used | List principal summary measures used (i.e. Risk Ratio or Odds ratio for dichotomous outcomes, differences in means for continuous outcomes) How calculated (e.g. with standard meta-analysis software like Revman)? | | |
| Summary tables of individual studies | For each outcome, attach a table or Forest plot of included study results. Ideally include outcome numbers/ participant numbers for EG & CG, effect estimates & CIs. | | |
| Measures of differences between studies & sensitivity analyses | Was there evidence of differences (i.e. heterogeneity) between studies? (e.g. by 'eyeballing' forest plots, formal tests of heterogeneity test). Note: Heterogeneity tests – ‘Cochrane Q’: if p< 0.1 significant heterogeneity present. ‘I square value’: 0 if no heterogeneity, if >50% combining studies questionable | | |
| **Reported Results** | **Enter the main reported results (including sensitivity analyses) ** | Outcome | | Summary Effect (RR, OR) | Confidence Interval |
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| **Systematic Reviews of Intervention Studies**  **Step 3: Appraise Study**  **3b. Assess risk of errors using FAITH** | | | | | | |
| **Appraisal questions (FAITH)** | | **Risk of errors**  **+, x, ?, na** | | | Notes | |
| Recruitment/Applicability ‘**errors’**: questions on risks to application of results in practice are in blue boxes | | | | | | |
| Internal study design **errors**: questions on risk of errors within study (design & conduct) are in pink boxes | | | | | | |
| Analyses **errors**: questions on errors in analyses are in orange boxes | | | | | | |
| Random **error**: questions on risk of errors due to chance are in the green box | | | | | | |
| **Key for scoring risk of errors: + = low; x = of concern; ? = unclear; na = not applicable** | | | | | | |
| **Find** studies: was the search likely to find all the best evidence? | | | | | |
| All appropriate information sources searched? | Score risk of error as: +, x, ? or na (key above) | | Were all relevant information sources searched? Relevant: time periods; languages; grey literature; reference lists of papers; Conference abstracts? Were investigators of original papers contacted about unpublished studies? | | |
| Eligibility criteria for the study characteristics appropriate? |  | | Were only appropriate study types (e.g. RCTs), length of follow-up, etc included? | | |
| Eligibility criteria for the participant characteristics appropriate? |  | | Were inclusion/exclusion criteria for participants explicit and appropriate given the review’s objectives? | | |
| Search strategy and processes explicit, comprehensive and systematic? |  | | Was the search strategy: explicit; comprehensive, used appropriate terms and limits? Was it done by more than one person? Were numbers included/excluded in initial screen documented and reasons for incl/excl given? | | |
| **Appraise** studies: were each of the studies meeting initial screening criteria critically appraised? | | | | | |
| How well were data on each study extracted (standardised, systematic, repeated)? |  | | | Was data extracted onto a standardised form? Was it extracted independently by more than one reviewer? | |
| How well were studies critically appraised? |  | | | Were studies appraised using a systematic and standardised method? e.g. RAMMbo, Jadad score. Did at least 2 independent appraisers assess each study? | |
| **Include** studies: were the appropriate studies included in the analyses? | | | | | |
| Clear rationale given for including / excluding studies based on individual study appraisal? |  | | | Did the investigators only include quality studies in their main analyses/summary of studies? | |
| Relevant personal (prognostic) characteristics of participants reported and used to determine inclusion in analyses? |  | | | Was sufficient information given about personal characteristics of participant populations to determine whether included studies could be combined and to determine applicability of findings? | |
| All important outcomes (including benefit and harm) assessed? |  | | | Were both benefits and harms considered? Were patient oriented outcomes measured, not just surrogate or intermediate outcomes? | |
| Follow-up time in included studies sufficiently similar to combine? |  | | | Did follow-up vary between included studies? If so, was it appropriate to combine study results? | |
| **Total-up** (summary) ofstudies : were results summarised appropriately?  **Heterogeneity** of studies: was consistency between studies sufficient to justify pooling results (if meta-analysis)? | | | | | |
| Was it reasonable to consider combining the studies based on their PECOT characteristics? |  | | | Was there enough similarity between studies wrt participants, exposures, comparisons, outcomes and follow up times to consider pooling the studies in a meta-analysis? | |
| Were summary tables/forest plots of results sufficient to describe the findings of each included study? |  | | | Was there a succinct summary of results of each included study showing numbers of subjects in EG and CG, number of outcomes in each group, effect estimates with 95% CIs? Ideally this will be presented graphically as forest plots | |
| Were effect estimates similar enough from study to study to undertake meta-analyses? |  | | | Was assessment of heterogeneity sufficient to determine if it was present? Was it based just on 'eyeballing' the forest plots or formal tests? | |
| Were sensitivity analyses required to test the robustness of the results? |  | | | Sensitivity analyses undertaken with/without lower quality studies? If heterogeneity present were sensitivity analyses presented without outlier studies? | |
| Were summary measures (if meta-analysis performed) performed correctly? |  | | | Were summary measures (RR, OR, mean differences) generated using appropriate software (e.g. Revman) with each study weighted is according to size? | |
| Precision of summary measures (if meta-analysis) given? |  | | | Were 95% CIs given for the summary measures? | |
| Were reported summary effect estimates meaningful for practice? |  | | | Were summary results presented in a format that had meaning in practice? e.g. a clinically relevant measure of effect rather than a change in an abstract scale. | |
| **Summary of Review Appraisal** | | | | | |
| Was a valid, systematic, reproducible review methodology followed? |  | | | Was the risk of error due to internal study design & conduct low enough for the results to be reasonably unbiased? Use responses to questions in pink boxes above | |
| Was there likely to be important publication bias? |  | | | Did the investigators take any steps to formally analyse whether there was a likelihood of publication bias (disproportionate reporting of positive results)? e.g funnel plot, any other analysis? | |
| Were studies summarised (and/or combined) appropriately? |  | | | Was the approach to summarising findings (i.e. qualitative description versus quantitative meta-analysis) reasonable? | |
| Random error in estimates of intervention effects: were CIs sufficiently narrow for results to be meaningful? |  | | | Use responses to questions in green box above. Would you make a different decision if the true effect was close to the upper confidence limit rather than close to the lower confidence limit? | |
| Applicability: are these findings applicable in practice? |  | | | Use responses to questions in blue boxes above | |

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| **Systematic Reviews of Intervention Studies**  **Step 4: Apply. Consider/weigh up all factors & make (shared) decision to act** | |
| **The X-factor** | |
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| Epidemiological evidence: summarise the quality of the review appraised, the magnitude and precision of the measure(s) estimated and the applicability of the evidence. Also summarise its consistency with other systematic reviews relevant to the decision. | Case circumstances: what circumstances (e.g. disease process/ co-morbidities [mechanistic evidence], social situation) specifically related to the problem you are investigating may impact on the decision? |
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| System features: were there any system constraint or enablers that may impact on the decision? | What values & preferences may need to be considered in making the decision? |
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| Taking into account all the factors above what is the best decision in this case? | |
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| **Step 5: Audit usual practice (For Quality Improvement)** | |
| Is there likely to be a gap between your usual practice and best practice for the problem? | |
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