HKCA Formal Project Assessment Rubric

Randomized controlled trials (RCT)

	Excellent	Good	Needs improvement
Title and abstract	-Identification as RCT in the title -abstract: concise and clear summary of background, study design, methods, results and conclusions	-Identification as RCT in the title -abstract: covers the background, study design, methods, results and conclusions	-does not identify as RCT in the title -abstract: does not cover all the key components of an abstract
Introduction	-Concise and relevant background information -Clear explanation of study rationale -Research idea is novel and/or clinically impactful -Describes clearly the main objectives and hypothesis	-Provides background information -Description of study rationale given -Description of objective and hypothesis provided	-Relevant background information not provided -Rationale of the study is not clear or cannot be justified -No/inadequate description of the objective and hypothesis
Methods	-Trial design: description of trial design eg parallel, crossover -Eligibility criteria: inclusion and exclusion criteria are appropriate -Description of intervention is clear and allows replication of the whole intervention -Primary and secondary outcomes are clearly defined. Appropriate and relevant outcomes are selected. -Sample size calculation for primary outcome is statistically sound -appropriate method used to generate random allocation sequence eg computer generation	-Trial design: description of trial design eg parallel, crossover -Eligibility criteria: most of the important inclusion and exclusion criteria have been described -Description of intervention is provided, and the intervention can mostly be replicated -Primary and secondary outcomes are defined. Mostly appropriate but some potentially important outcomes are missing. -sample size calculation provided -appropriate method used to generate random allocation sequence eg computer generation	-Trial design not described -Eligibility criteria: important inclusion and exclusion criteria are missing -Intervention cannot be adequately replicate based on description provided -Primary and secondary outcomes not adequately defined. Primary outcome not relevant to main study objective -sample size calculation not provided -inappropriate/no method used to generate random allocation sequence

	-description of how allocation concealment is achieved is provided -Describes person responsible for generation of allocation sequence, patient enrollment, and patient assignment -Blinding is described (who and how) -statistical methods: appropriate method used to compare the groups -methods for additional analyses described eg adjusted analysis, subgroup analysis -registration of study in trial registry prior to patient recruitment -local ethics approval obtained	-description of how allocation concealment is achieved is provided -Describes person responsible for generation of allocation sequence, patient enrollment, and patient assignment -Blinding is described (who and how) -statistical methods: appropriate method used to compare the groups -local ethics approval obtained	-description of how allocation concealment is achieved is not provided -Does not describe person responsible for generation of allocation sequence, patient enrollment, and patient assignment -blinding not described -statistical methods: incorrect methodology used -local ethics approval not obtained
Results	-Clear description of participant flow: number assigned, received intervention, analyzed. Losses and exclusions after randomization described with reasons Flow diagram provided -Dates of trial start and end given -Appropriate and clear tables and/or figures are provided. -Results of outcomes, estimated effect size and precision (eg 95% confidence interval) are described -Description of important harms or unintended effects	-Description of participant flow: number assigned, received intervention, analyzed. Losses and exclusions after randomization described. Flow diagram provided -Dates of trial start and end given -Tables and/or figures used and can be interpreted. -Results of outcomes, estimated effect size and precision (eg 95% confidence interval) are described -Description of important harms or unintended effects	-Unclear description of participant flow. Losses and exclusions after randomization not described Flow diagram not provided -Dates if trial start and end given -Tables and/figures not provided or presentation does not allow proper interpretation. -Results of outcomes, estimated effect size and precision inadequately described -harms and unintended effects not described
Discussion	-highly appropriate interpretation of study results	-Reasonably appropriate interpretation of study results	-inaccurate interpretation of study results

			(including over or under exaggeration)
	-High quality critical analysis (ie in comparison with existing literature, overall interpretation when also considering existing literature, in context of study centre)	-Adequate critical analysis (ie in comparison with existing literature, overall interpretation when also considering existing literature, in context of study centre)	-Inadequate critical analysis
	-Able to demonstrate scientific novelty and/or important clinical significance/impact.	-Able to explain the clinical significance and potential impact of the study results	-Unable to demonstrate any clinical relevance/significance
	-highly appropriate explanation of generalizability of results	-generally appropriate explanation of generalizability	-inappropriate/inaccurate explanation of generalizability
	-High quality explanation of study limitations (ie potential bias, sample size)	-adequate explanation of key study limitations	-important study limitations have been omitted or not explained
	-Conclusion: summarizes key information, appropriate interpretation of key findings. Highlights importance of findings.	-Conclusion: summarizes information, provides appropriate interpretation of findings	-Conclusion: does not convey the important information, inappropriate interpretation of findings

Grading

Title and abstract 1-3

Introduction 1-3

Methods 1-3

Results 1-3

Discussion and conclusion 1-3