Data Extraction Form and Quality Assessment Tool

Canadian Clinical Practice Guidelines for the Use of Cannabinoid-Based Medicine in the Management of Chronic Pain and Co-Occurring Conditions

Reference

Reviewer Extracting Data

Date form completed

Eligibility form

Factors	Assessment	Comments
Type of Study		
1) Is the study a systematic review or meta-analysis?	Yes No	
2) Is the study a controlled intervention study (randomized, non-randomized or quasi-experimental)?	Yes No	
3) Is the study an observational cohort or cross-sectional study?	Yes No	
4) Is the study a case-control study?	Yes No	
5) Is the article a review of system mechanisms, a commentary article or a clinical overview? - identify the type of article in comments section	Yes (exclude) No	

Participants		
6) Do participants explicitly present with chronic pain?	Yes No (exclude) Unclear	
7) Was the pain cancer-related?	Yes (exclude) No Unclear	
Exclusion Criteria		
8) Did the study measure the effects of non-synthetic CBM use on chronic pain?	Yes No (exclude) Unclear	
9) Was cannabis use one aspect of an intervention, but not the main focus?	Yes (exclude) No Unclear	

Do not proceed if study excluded from review

Systematic Review and Meta-Analysis Data Extraction (Complete only if the answer to question 1 is "yes")

Review Characteristics	
Type(s) of studies included	
# of studies included	
Population studied (HIV+, PTSD, prescribed opioids, etc.)	
Type(s) of CBM included in review (whole plant, extract, synthetic)	
Main outcome(s)	
Meta-analyses conducted?	Yes No
Key findings	

Conclusions	

Systematic Review and Meta-Analysis Quality Assessment (Complete only if the answer to question 1 is "yes")

Criteria	
1. Is the review based on a focused question that is adequately formulated and described?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
2. Were eligibility criteria for included and excluded studies predefined and specified?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
3. Did the literature search strategy use a comprehensive systematic approach?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
4. Were titles, abstracts, and full-text articles dually and independently reviewed for inclusion and exclusion to minimize bias?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
5. Was the quality of each included study rated independently by two or more reviewers using a standard method to appraise its internal validity?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
6. Were the included studies listed along with important characteristics and results of each study?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
7. Was the publication bias assessed?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
8. Was heterogeneity assessed? (This question applies only to meta-analyses)	
Yes	

No	
Other (Cannot determine, Not applicable, not reported)	

Quality Rating (Good, Fair or Poor)
Rater 1 initials:
Rater 2 initials:
Additional comments (if poor, please state why):

Controlled Intervention Studies Data Extraction (Complete only if the answer to question 2 is "yes")

Study Characteristics	
Study year	
Location	
Study design type (i.e., RCT, Quasi-experimental)	
Study aim (i.e., efficacy, safety, tolerability)	
Population characteristics (from which study participants are drawn. i.e., HIV+, PTSD, adolescence)	
Sample size: Intervention population sample (#) Control population sample (#)	
Sample demographics (and differences between samples) Age Sex Race/Ethnicity	
Method of recruitment	
Length of the intervention	
CBM characteristics: - Type - Administration route - Dosing	
Type of control (Placebo, alternative, no treatment)	

Main outcome measures	
Main findings	
Comorbidities measured	
Conclusions	

Controlled Intervention Studies Quality Assessment (Complete only if the answer to question 2 is "yes")

Criteria	
1. Is the study described as randomized, a randomized trial, a randomized clinical trial, or an RCT?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
2. Was the method of randomization adequate (ie. Use of a randomly generated assignment)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
3. Was the treatment allocation concealed (so that assignments could not be predicted)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
4. Were the study participants and providers blinded to treatment group assignment?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
5. Were the people assessing the outcomes blinded to the participants' group assignments?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
6. Were the groups similar at baseline on important characteristics that could affect outcomes (e.g., demographics, risk factors, co-morbid conditions)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	

7. Was the overall drop-out rate from the study at endpoint 20% or lower of the number allocated to treatment?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
8. Was the differential drop-out rate (between treatment groups) at endpoint 15 percentage points or lower?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
9. Was there high adherence to the intervention protocols for each treatment group?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
10. Were other interventions avoided or similar in the groups (e.g., similar background treatments)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
11. Were outcomes assessed using valid and reliable measures, implemented consistently across all study participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
12. Did the authors report that the sample size was sufficiently large to be able to detect a difference in the main outcome between groups with at least 80% power?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
13. Were the outcomes reported or subgroups analyzed pre-specified (i.e., identified before analyses were conducted)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
14. Were all randomized participants analyzed in the group to which they were originally assigned, i.e., did they use an intention-to-treat analysis?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	

Quality Rating (Good, Fair or Poor)
Rater 1 initials:
Rater 2 initials:
Additional comments (if poor, please state why):

Observational Cohort or Cross-sectional Study Data Extraction (Complete only if the answer to question 3 is "yes")

Study Characteristics	
Study year	
Study location	
Study design type (i.e., prospective, retrospective, cross-sectional)	
Population Characteristics (HIV+, prescribed opioids, etc)	
Sample Size	
Sample characteristics Age Sex Race/Ethnicity	
Method of recruitment	
Length of study	
CBM Characteristics	
Main outcome measures (and any other important outcomes measured)	
Main Findings/conclusions	

Observational Cohort or Cross-sectional Study Quality Assessment (Complete only if the answer to question 3 is "yes")

Criteria	
1. Was the research question or objective in this paper clearly stated?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
2. Was the study population clearly specified and defined?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
3. Was the participation rate of eligible persons at least 50%?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
4. Were all the subjects selected or recruited from the same or similar populations (including the same time period)? Were inclusion and exclusion criteria for being in the study pre-specified and applied uniformly to all participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
5. Was a sample size justification, power description, or variance and effect estimates provided?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
6. For the analysis of this paper, were the exposure(s) of interest measured prior to the outcome(s) being measured?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
7. Was the timeframe sufficient so that one could reasonably expect to see an association between exposure and outcome if It existed?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
8. For exposures that can vary in amount or level, did the study examine different levels of the exposure as related to the outcome (e.g., categories of exposure, or exposure measured as continuous variable)?	
Yes	
No	
Other (Cannot determine, Not applicable, not	

reported)	
9. Were the exposure measures (independent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
10. Was the exposure(s) assessed more than once over time?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
11. Were the outcome measures (dependent variables) clearly defined, valid, reliable, and implemented consistently across all study participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
12. Were the outcome assessors blinded to the exposure status of the participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
13. Was loss to follow-up after baseline 20% or less?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
14. Were key potential confounding variables measured and adjusted statistically for their impact on the relationship between exposure(s) and outcome(s)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	

Quality Rating (Good, Fair or Poor)
Rater 1 initials:
Rater 2 initials:
Additional comments (if poor, please state why):

Case-Control Studies Data Extraction (Complete only if the answer to question 4 is "yes")

Study Characteristics	
Study year	

Study location	
Study design type (i.e., prospective, retrospective, cross-sectional)	
Population Characteristics (HIV+, prescribed opioids, etc)	
Sample Size	
Sample characteristics Age Sex Race/Ethnicity	
Control Group	
Method of recruitment	
Length of study	
CBM Characteristics	
Main outcome measures (and any other important outcomes measured)	
Main Findings/conclusions	

Case-Control Studies Quality Assessment (Complete only if the answer to question 4 is "yes")

Criteria	
1. Was the research question or objective in this paper clearly stated and appropriate?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
2. Was the study population clearly specified and defined?	
Yes	
No	
Other (Cannot determine, Not applicable, not	

reported)	
3. Did the authors include a sample size justification?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
4. Were controls selected or recruited from the same or similar population that gave rise to the cases (including the same timeframe)?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
5. Were the definitions, inclusion and exclusion criteria, algorithms or processes used to identify or select cases and controls valid, reliable, and implemented consistently across all study participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
6. Were the cases clearly defined and differentiated from controls?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
7. If less than 100 percent of eligible cases and/or controls were selected for the study, were the cases and/or controls randomly selected from those eligible?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
8. Was there use of concurrent controls?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
9. Were the investigators able to confirm that the exposure/risk occurred prior to the development of the condition or event that defined a participant as a case?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
10. Were the measures of exposure/risk clearly defined, valid, reliable, and implemented consistently (including the same time period) across all study participants?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
11. Were the assessors of exposure/risk blinded to the case or control status of participants?	

Yes	
No	
Other (Cannot determine, Not applicable, not reported)	
12. Were key potential confounding variables measured and adjusted statistically in the analyses? If matching was used, did the investigators account for matching during study analysis?	
Yes	
No	
Other (Cannot determine, Not applicable, not reported)	

Quality Rating (Good, Fair or Poor)
Rater 1 initials:
Rater 2 initials:
Additional comments (if poor, please state why):