

Cochrane系统评价的注册 与撰写：Part 2

邝心颖

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中国循证医学中心
中国Cochrane中心

第五届全国循证药理学论坛暨国家级继续医学教育
“循证药学与合理用药” 培训班
2016年7月4-11日



培训内容

09:00-10:30	Cochrane协作网与系统评价概述
10:30-10:45	休息
10:45-11:45	Cochrane系统评价注册
12:00-14:00	午餐
14:00-15:15	Cochrane系统评价撰写： I
15:15-15:30	休息
15:30-16:45	Cochrane系统评价撰写： II
16:45-17:00	总结

Cochrane系统评价的注册与撰写

1. Defining a review question

- Topic → Review question

2. Preparing a review proposal

- Review question → Review proposal

3. Writing a review protocol

- Review proposal → Protocol

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Defining a review question



Defining your question

- Essential first step for your review
- Guides many aspects of your methods
 - Eligibility criteria
 - Search strategy
 - Data collection and analysis
- Think carefully in advance
 - Plan your work
 - Avoid bias
- Discuss with your CRG if changing your proposed question



Planning your topic and scope

- Address a question of importance and relevance
 - Impact of health issue – population and individual
 - Possible impact of intervention
 - Consider all important stakeholders: consumers, health professionals, and policy makers
- Address real choices faced in decision-making
- Consider an international perspective



A broad or narrow question?

	Narrow	Broad
Advantages	<ul style="list-style-type: none">• Easy to write• Easy to read	<ul style="list-style-type: none">• Comprehensive• Generalisable
Disadvantages	<ul style="list-style-type: none">• Need multiple reviews• May be selectively defined	<ul style="list-style-type: none">• Complex• May miss subgroup effects• Overview of reviews may be preferable



Components of a question

- Describe the following components in detail
- Consider variations you may wish to explore in the review

P population

I intervention

C comparison

O outcomes



Eligibility criteria

- Rules to decide which studies are included in the review
- Based on:
 - Some or all of your PICO components
- **Plus**
 - Definition of eligible study designs
- Any changes to the eligibility criteria after the protocol has been published need justification in the review



Population

- Clear definition to identify people of interest
- Two aspects to consider
 - Health condition
 - Diagnosed how, by whom?
 - Population and setting
- Any limits should have a clear rationale
 - Alternative is to include and explore in subgroup analysis



Mixed populations

- Studies in which only some participants meet your criteria
 - E.G. Your criteria: children up to 16 yrs, you find a study including up to 18 yrs
- What is most consistent with the aims of your review?
 - Include the whole study
 - Can select a threshold (e.g. 80%, or majority)
 - Include only those participants meeting your criteria
 - Separate information may not be reported in the paper
 - Exclude the whole study
- Plan and give a rationale for how you will manage these studies at the protocol stage



Equity and special populations

- Consider whether issues of equity and relevance to specific populations are important to the review
 - e.g. Gender, age, ethnicity, geographic, economic status, education, etc.

Why?

- Different prevalence, progress and impact of disease
- Different effects or safety of the intervention
- Different outcomes of importance



Intervention

- Give as much detail as possible
 - Formulation
 - Dose, intensity
 - Delivery
 - Timing, frequency, duration
 - Equipment
 - Personnel (qualifications, training)
 - Location, context
 - Alone or in combination with other intervention(s)
- Any limits should have a clear rationale
 - Alternative is to include and explore in subgroup analysis



Location and context

- Interventions may work in some contexts but not others
 - Availability and accessibility
 - Equipment
 - Experience and expertise of the available staff
 - Local competing priorities
 - Fee or payment structure
 - Cultural and linguistic diversity
 - Socioeconomic position
 - Rural/urban setting



Comparison

- Based on the objective of your review
 - Define specific active comparisons in as much detail as the intervention
 - Be clear what you mean by 'no intervention'
 - e.g. No intervention, placebo, usual care, etc.
 - Can remain open to any comparisons found, but be explicit



Outcomes

- **Rarely part of the eligibility criteria**
- Excluding studies on the basis of outcomes reported may introduce bias
 - Outcomes may be selectively reported by trial authors
 - Additional information may be available
- May be appropriate if outcomes are important to the definition of your question
 - e.g. Prevention vs treatment, interventions used for more than one condition
- Be clear in your protocol



Outcomes

- Identify meaningful outcomes
 - For consumers, health professionals, policy makers
 - Include adverse effects
 - Relevant to different populations
 - Key time points
 - Acceptable outcome measures (e.g. definitions, scales)
 - Avoid trivial outcomes (e.g. biochemical, surrogate, process)
- Consider core outcome sets and outcomes used by related reviews
- Plan for selection among multiple similar outcomes
- Important outcomes should be included in the protocol and the review whether or not data are likely to be found



Prioritizing outcomes

- **Primary outcomes** (max 3)
 - Usually includes at least one possible harm
- **Secondary outcomes**
 - Remaining main outcomes
 - Additional outcomes of lower priority
- **Main outcomes** (max 7)
 - Essential for decision making
 - Form the basis of analyses and summaries



Special outcome types

- Resources and advice available
 - Cochrane **Adverse Effects** Methods Group
 - Cochrane **Patient Reported Outcomes** Methods Group
 - Campbell and Cochrane **Equity** Methods Group
 - Campbell and Cochrane **Economics** Methods Group
 - Cochrane **Qualitative Research** Methods Group
 - see www.cochrane.org/contact/methods-groups



Study designs

- Select the most appropriate design for the question
- Always give a rationale for your choice
- For most Cochrane reviews:
 - **Randomized controlled trials**
- Non-RCTs
 - Must have the agreement of your CRG
 - Clear rationale
 - RCTs are not appropriate or unlikely to be practical (e.g. Public health, complex health system topics)
 - To measure particular outcomes (e.g. Adverse effects, economics, qualitative outcomes)
 - Not just because RCTs are not available



Non-randomized studies

- Must have the agreement of your CRG
- Clear rationale
 - RCTs are not appropriate or unlikely to be practical (e.g. Public health, complex health system topics)
 - To measure particular outcomes (e.g. Adverse effects, economics, qualitative outcomes)
 - **Not just because RCTs are not available**
- Specific designs preferred
 - e.g. Controlled before-and-after, interrupted time series
 - Describe using elements of the study's design, not labels
 - Minimum design criteria should apply
- Be aware of increased risk of bias



Turning a question into a title

- Cochrane titles have standard formats
- ‘intervention’ for ‘issue’
 - Antibiotics for acute bronchitis
 - Community-wide Interventions for increasing physical activity
- can also include other details:
 - Immediate **versus delayed treatment** for cervical intraepithelial neoplasia
 - Inhaled nitric oxide for respiratory failure **in preterm infants**
 - Pool fencing **for preventing** drowning in children

Cochrane系统评价的注册与撰写

1. Defining a review question

Topic → Review question

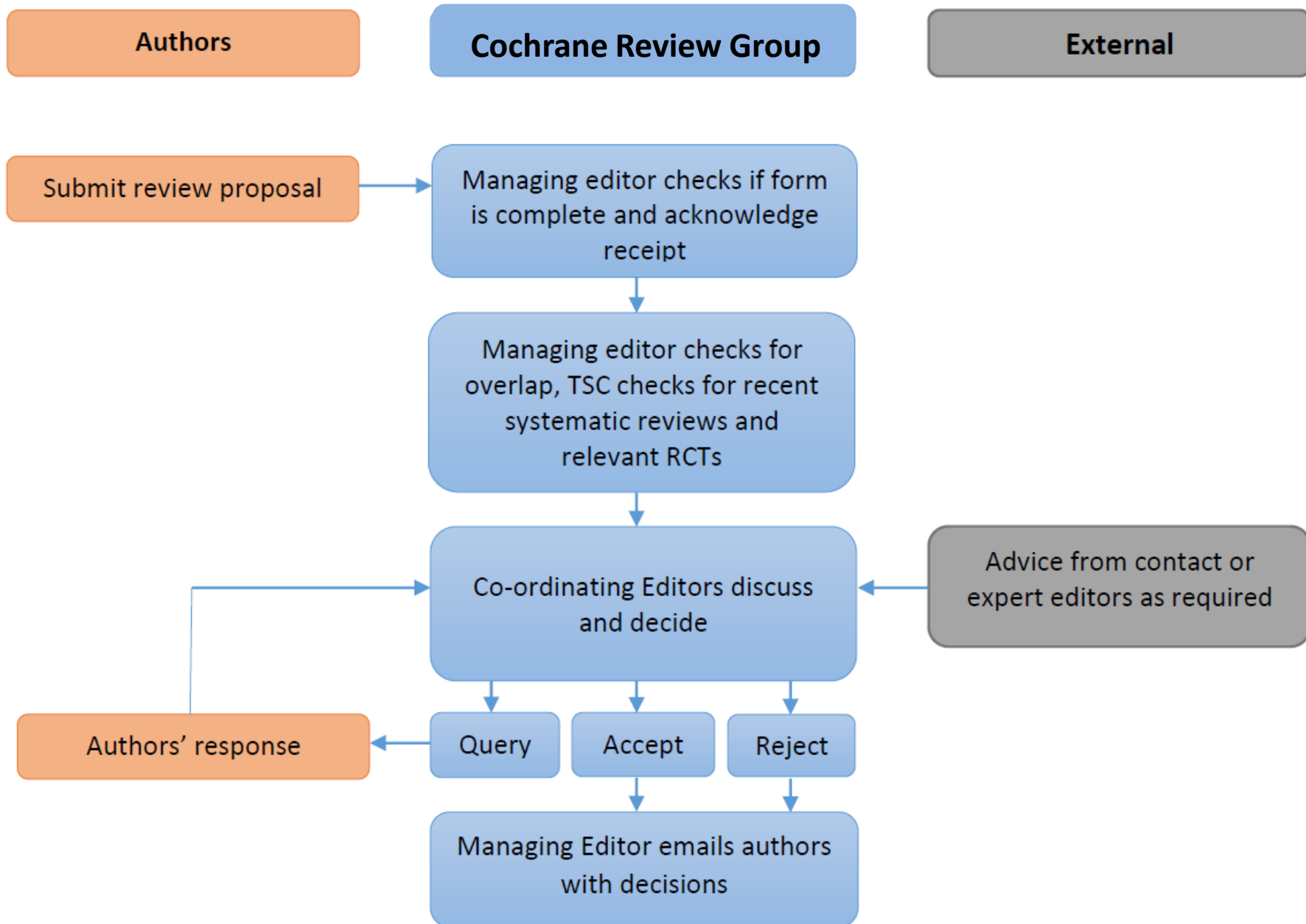
2. Preparing a review proposal

- Review question → Review proposal

3. Writing a review protocol

Review proposal → Protocol





Cochrane系统评价的注册与撰写

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Review question → Review proposal

3. Writing a review protocol

- Review proposal → Protocol

Writing a protocol



Rationale for protocols

- Systematic reviews involve judgements
 - e.g. Question definition, eligibility, outcome measures
 - Retrospective research - decisions should not be based on known results
- Decide and document methods in advance
 - Reduce impact of bias
 - Allow peer review
 - Reduce duplication
 - Plan tasks and allocate resources
 - Published in *The Cochrane Library*
 - Published review will contain a link to your protocol



LOGIN

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OTHER RESOURCES

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- Economic Evaluations

Intervention Protocol

Behavioural interventions as adjuncts to pharmacotherapy for smoking cessation

Lindsay F Stead*, Tim Lancaster

Database Title

[The Cochrane Library](#)

Editorial Group: [Cochrane Tobacco Addiction Group](#)

Published Online: 15 FEB 2012

DOI: 10.1002/14651858.CD009670

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Additional Information [\(Hide All\)](#)

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How to Cite

Stead LF, Lancaster T. Behavioural interventions as adjuncts to pharmacotherapy for smoking cessation (Protocol). Cochrane Database of Systematic Reviews 2012, Issue 2. Art. No.: CD009670. DOI: 10.1002/14651858.CD009670.

Author Information

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Publication History

Publication Status: New

Published Online: 15 FEB 2012

SEARCH

Title, Abstract, Keywords

Search >

Medical Terms (MeSH) >

Search Manager >

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Abstract

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Abstract

Jump to...

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate the effect of providing more intensive behavioural support for people using smoking cessation medication



What to include in your protocol

- Background
 - Detailed description of the condition and intervention
- Methods
 - Criteria for considering studies for this review
 - Clear description of eligibility criteria
 - List planned outcome measures
 - Data collection and analysis
 - List planned subgroup analysis



Authors

- Make a substantial contribution to
 - Conception and design of review, or analysis and interpretation of data
 - Drafting review or providing critical comments on intellectual content
 - Final approval of document to be published
- Specific contributions listed in 'contribution of authors' section
- Individuals, groups or both
- Order of authors relative to their contribution
- Institutional affiliations will be published



Contact person

- Usually responsible for
 - Organising review team
 - Communicating with CRG
 - Monitoring progress with agreed timeline
 - Submitting completed protocol/review
 - Communicating feedback to co-authors
 - Ensuring updates are prepared
- Does not have to be an author
- Full contact details will be published

The screenshot displays the Review Manager 5 software interface. The main window is titled "[Caffeine for daytime drowsiness.rm5] Caffeine for daytime drowsiness". The left sidebar shows a tree view of the review structure, with "Intervention review" expanded and "Authors" selected. The main content area, titled "Text of Review", displays the following text:

Authors

Veronica Pitt¹, Miranda Cumpston²

¹Australasian Cochrane Centre, Monash Institute of Health Services Research, Clayton, Australia

²Cochrane Musculoskeletal Group, Cabrini Education and Research Institute, Malvern, Australia

Citation example: Pitt V, Cumpston M. Caffeine for daytime drowsiness [Protocol]. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Contact person

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Dates

What's new

History



Writing your protocol

- Accessible language
 - Easy to read and understand by someone who is not an expert
- Future tense, active voice
- Use the Cochrane style guide
 - www.cochrane.org/training/authors-mes/cochrane-style-guide
 - Terminology, statistics, spelling, references, formatting, etc.



Cochrane Style Guide
4.1 edition

Updated October 2010



Background

- Put the review in context with the existing body of knowledge
 - Description of the condition and its significance
 - Description of the intervention
 - How the intervention might work
 - Why it is important to do the review



Objectives

- A precise statement of the primary objective
- Usually one sentence
- May also include specific objectives relating to different
 - Participant groups
 - Comparisons of interventions
 - Outcome measures

To assess the effects of [*intervention or comparison*]
for [*health problem*] for/in [*types of people, disease or problem and
setting if specified*].



Methods

- Plan what you will do before you start
 - Minimize bias
 - Divide work among review authors and establish timeline
 - Enough detail so that the decisions and methods could be replicated
- Select methods likely to deliver the best evidence on which to base decisions
 - Consult your CRG – they may have a standard template
- Anticipate that a useful number of studies will be found
 - May be the case in future updates, if not now



Methods

- Eligibility criteria
- Outcomes
- Searching
- Data collection
- Risk of bias assessment
- Analysis
- Summarising findings



Additional information

- Acknowledgements
- Contributions of authors
- Declarations of interest
- Sources of support
- Any additional tables or appendices



When your protocol is complete

- Check the details
 - Spell check, validation check, CRG checklist
- Submit to your CRG for editorial approval
- Expect internal and peer review
 - ME, editor(s), statistical editor, peer referees, consumer
 - Like any journal, may take several months
- When it has been approved
 - Complete license for publication & declaration of interest forms
 - Commence review
 - Will be published immediately

RevMan: 复习

5



Review Manager (RevMan)

- **Mandatory** software for writing and publishing your review
- Available from <http://ims.Cochrane.Org/revman>
- Free for Cochrane authors and academic use





Archie

- Cochrane Collaboration central database
 - Stores all reviews and contact information
 - *The Cochrane Library* is published directly from Archie
- Use RevMan to access reviews in Archie
 - Need a user account and password (ask your CRG)





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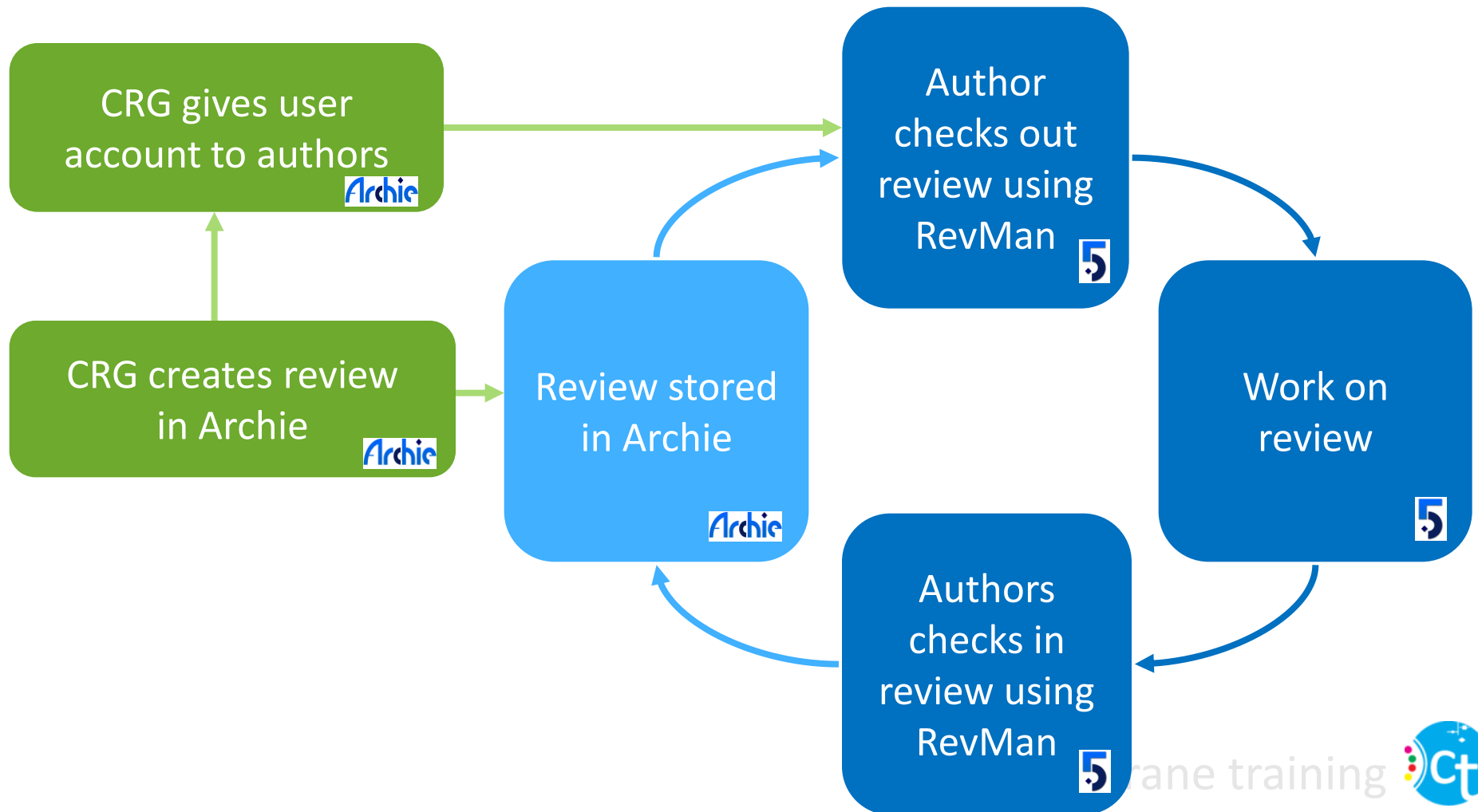
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Version 3.6.2
30/06/2011 23:17

Accessing your review





RevMan works with

- All Cochrane review types
 - Interventions
 - Methodology
 - Diagnostic test accuracy studies
 - Overview of reviews
- Multiple platforms
 - Windows
 - Macintosh
 - Linux



Working with RevMan

- For protocols, reviews and updates
 - Writing the text
 - Statistical analysis
 - Reference management
 - Submission for editorial review and publication



Starting RevMan



Entering your password

The screenshot shows the 'My Reviews' window in RevMan. The window has a title bar with a home icon and the text 'My Reviews'. Below the title bar, there are three fields: 'Server: Archie Server (archie.cochrane.org)', 'User:', and 'Connection preferences:'. The 'User:' field is currently empty. A 'Login' dialog box is open in the center of the window. The dialog box has a title bar with a close button. It contains two text input fields: 'User Name:' and 'Password:'. Below these fields is a checkbox labeled 'Save user name and password when RevMan is closed', which is checked. At the bottom of the dialog box are two buttons: 'OK' and 'Cancel'. The background window has several sections: 'Version Details:', 'Review Details:', and 'Tasks in progress:'. The 'Review Details:' section is currently empty. At the bottom of the window, there are three icons: a question mark, a folder, and a download arrow. On the right side, there are two buttons: 'Open / Check Out' and 'Close'.

My Reviews

Server: Archie Server (archie.cochrane.org) User: Connection preferences:

Version Details:

Review Details:

Tasks in progress:

Open / Check Out Close

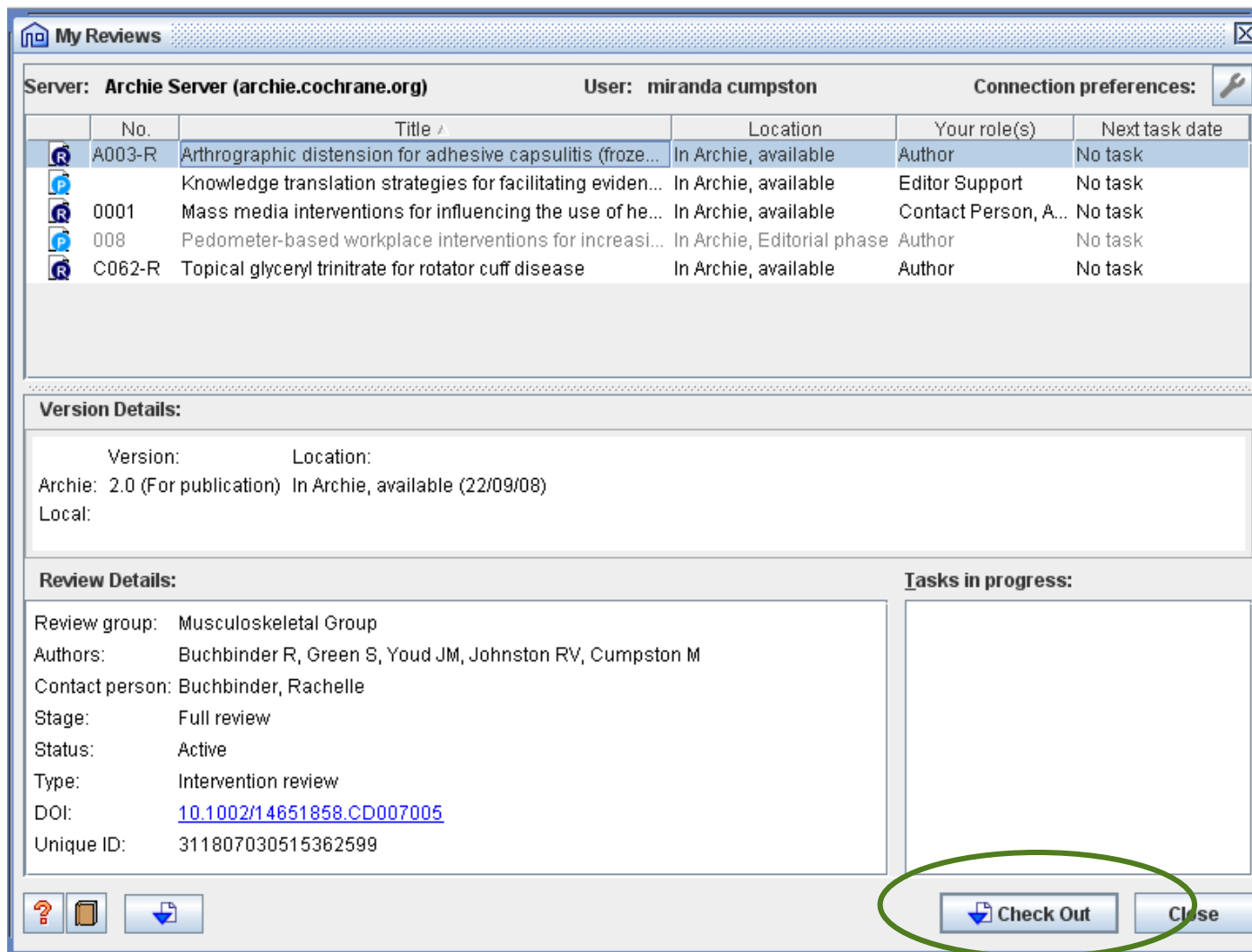
Login

User Name: Password:


☒ Save user name and password when RevMan is closed






OK Cancel

Accessing your review



My Reviews

Server: **Archie Server (archie.cochrane.org)** User: **miranda cumpston** Connection preferences: 

	No.	Title	Location	Your role(s)	Next task date
	A003-R	Arthrographic distension for adhesive capsulitis (froze...	In Archie, available	Author	No task
		Knowledge translation strategies for facilitating eviden...	In Archie, available	Editor Support	No task
	0001	Mass media interventions for influencing the use of he...	In Archie, available	Contact Person, A...	No task
	008	Pedometer-based workplace interventions for increas...	In Archie, Editorial phase	Author	No task
	C062-R	Topical glyceryl trinitrate for rotator cuff disease	In Archie, available	Author	No task






Version Details:

Version: Location:
Archie: 2.0 (For publication) In Archie, available (22/09/08)
Local:

Review Details:

Review group: Musculoskeletal Group
Authors: Buchbinder R, Green S, Youd JM, Johnston RV, Cumpston M
Contact person: Buchbinder, Rachelle
Stage: Full review
Status: Active
Type: Intervention review
DOI: [10.1002/14651858.CD007005](https://doi.org/10.1002/14651858.CD007005)
Unique ID: 311807030515362599

Tasks in progress:

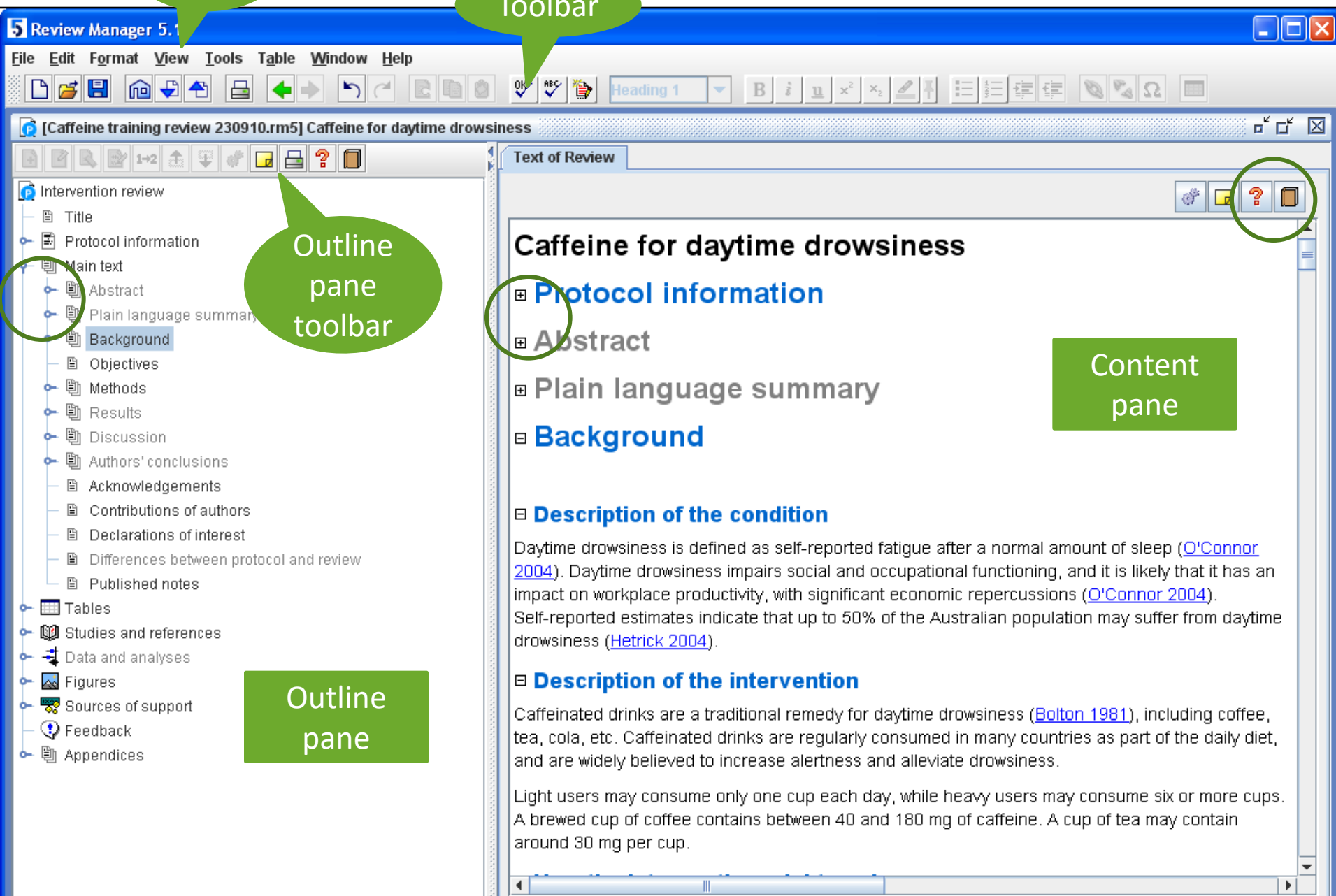
Menu
bar

Toolbar

Outline
pane
toolbar

Outline
pane

Content
pane



Review Manager 5.1

File Edit Format View Tools Table Window Help

[Caffeine training review 230910.rm5] Caffeine for daytime drowsiness

Intervention review

- Title
- Protocol information
 - Authors
 - Contact person
 - Dates
 - What's new
 - History
- Main text
 - Abstract
 - Plain language summary
 - Background
 - Objectives
 - Methods
 - Results
 - Discussion
 - Authors' conclusions
 - Acknowledgements
 - Contributions of authors
 - Declarations of interest
 - Differences between protocol and review
 - Published notes
- Tables
- Studies and references
- Data and analyses
- Figures
- Sources of support
- Feedback
- Appendices

Text of Review

Protocol information

Authors

Veronica Pitt¹, Miranda Cumpston², Denise O'Connor³, Sarah E Hetrick⁴, Porjai Pattanittum⁵

¹Australasian Cochrane Centre, Monash Institute of Health Services Research, Clayton, Australia

²Monash Institute of Health Services Research, Monash University, Clayton, Australia

³Australasian Cochrane Centre, Monash Institute of Health Services Research, Monash University, Clayton, Australia

⁴Centre of Excellence in Youth Mental Health, Orygen Youth Health Research Centre, Centre for Youth Mental Health, University of Melbourne, Melbourne, Australia

⁵Department of Biostatistics and Demography, Faculty of Public Health, Khon Kaen University, Khon Kaen, Thailand

Citation example: Pitt V, Cumpston M, O'Connor D, Hetrick SE, Pattanittum P. Caffeine for daytime drowsiness [Protocol]. Cochrane Database of Systematic Reviews [Year], Issue [Issue].

Contact person

Veronica Pitt

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Clayton

Review Manager 5.1

File Edit Format View Tools Table Window Help

Normal B i u x² x₂ [Drawing Tools] [List Tools] [Table]

[Caffeine training review 230910.rm5] Caffeine for daytime drowsiness

Intervention review

- Title
- Protocol information
- Main text
 - Abstract
 - Plain language summary
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 - Objectives
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 - Differences between protocol and review
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Text of Review

Abstract

Plain language summary

Background

Description of the condition

Daytime drowsiness is defined as **self-reported fatigue** after a normal amount of sleep ([O'Connor 2004](#)). Daytime drowsiness impairs social and occupational functioning, and it is likely that it has an impact on workplace productivity, with significant economic repercussions ([O'Connor 2004](#)). Self-reported estimates indicate that up to 50% of the Australian population may suffer from daytime drowsiness ([Hetrick 2004](#)).

Description of the intervention

Caffeinated drinks are a traditional remedy for daytime drowsiness ([Bolton 1981](#)), including coffee, tea, cola, etc. Caffeinated drinks are regularly consumed in many countries as part of the daily diet, and are widely believed to increase alertness and alleviate drowsiness.

Average daily consumption of caffeine varies. Light users may consume only one cup each day, while heavy users may consume six or more cups. An average brewed cup of coffee contains between 40 and 180 mg of caffeine. A cup of tea may contain around 30 mg per cup.

How the intervention might work

Description of the intervention

Matt - please check my edits.

How the intervention might work



Intervention review

- Title
- Review information
- Main text
- Tables
- Studies and references
 - References to studies
 - Included studies
 - Amore-Coffea 2000
 - Deliciozza 2004
 - Kahve-Paradise 2002
 - Mama-Kaffa 1999
 - Morrocona 1998**
 - Morrocona MM, Smith A, Jones FH. The effects of caffeine on alertness: a randomized trial. Journal of Caffeine Studies 1998;12(4):1033-6.
 - Morrocona MM. Personal communication 14 August 2007.
 - Norscafe 1998
 - Oohlalazza 1998
 - Piazza-Allerta 2003
 - Excluded studies
 - Studies awaiting classification
 - Ongoing studies
 - Other references
- Data and analyses
- Figures
- Sources of support
- Feedback
- Appendices

Text of Review

Morrocona 1998

* Morrocona MM, Smith A, Jones FH. The effects of caffeine on alertness: a randomized trial. Journal of Caffeine Studies 1998;12(4):1033-6.

Morrocona MM. Personal communication 14 August 2007.

Norscafe 1998

* Norscafe W, Santina X, Neebergen F. Caffeine for daytime drowsiness. Acta Energetica 1998;186(12):371.

Oohlalazza 1998

* Oohlalazza JE, Sorentina ML, Ribisi G.. Caffeine as a stimulant for entertainment industry employees. Journal of Drowsiness 1998;1(3):242-8.

Piazza-Allerta 2003

Piazza Allerta MI, Certa HL. Randomized controlled trial of the effects of caffeine on alertness and irritability. European Journal of Chemical Addiction 2003;3(10):567-8.

Add Study

Excluded studies

Add Study

Studies awaiting classification

Add Study

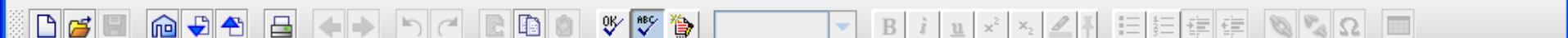
Ongoing studies

Add Study

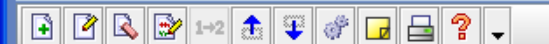
Other references

Additional references

APA 2000



[Caffeine training review 230910.rm5] Caffeine for daytime drowsiness



Text of Review 1.11 Headache at 24...

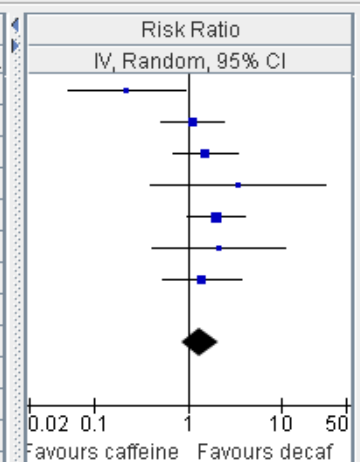
Intervention review

- Title
- Review information
- Main text
- Tables
- Studies and references
- Data and analyses
 - 1 Caffeinated versus decaffeinated coffee
 - 1.1 Drowsiness (visual analogue scale)
 - 1.2 Drowsiness (all scales)
 - 1.3 Fatigue (visual analogue scale 1-100)
 - 1.4 Fatigue (all scales)
 - 1.5 Sleepiness (C-Esta scale)
 - 1.6 Irritability (INAS scale 1-50)
 - 1.7 Irritability (BII scale 1-30)
 - 1.8 Irritability (INAS scale 1-50)
 - 1.9 Depression (BDI-II scale)
 - 1.10 Reaction time (milliseconds)
 - 1.11 Headache at 24 hours
 - 1.12 Time to headache (hazard ratio)
 - 1.13 Anxiety
 - 1.14 Sleep disruption
 - 1.15 Gastrointestinal limitation

Comparison: 1 Caffeinated versus decaffeinated coffee,
Outcome: 1.11 Headache at 24 hours



Study or Subgroup	Caffeinated coffee		Decaffeinated		Weight	Risk Ratio IV, Random, 95% CI
	Events	Total	Events	Total		
Amore-Coffea 2000	2	31	10	34	8.6%	0.22 [0.05, 0.92]
Deliciozza 2004	10	40	9	40	20.5%	1.11 [0.51, 2.44]
Mama-Kaffa 1999	12	53	9	61	20.7%	1.53 [0.70, 3.35]
Morrocona 1998	3	15	1	17	4.3%	3.40 [0.39, 29.31]
Norscafe 1998	19	68	9	64	22.8%	1.99 [0.97, 4.07]
Oohlalhlazza 1998	4	35	2	37	7.0%	2.11 [0.41, 10.83]
Piazza-Allerta 2003	8	35	6	37	16.1%	1.41 [0.54, 3.65]
Total (95% CI)		277		290	100.0%	1.34 [0.84, 2.14]
Total events	58		46			
Heterogeneity: $\tau^2 = \dots$						
Test for overall effect: ...						



Footnote:

New Ctrl-N

Open... Ctrl-O

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Close

Save Ctrl-S

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Check Out...

Check In...

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Exit Declarations of Interest Forms

Contributions of authors

Declarations of interest

Differences between protocol and review

Published notes

Tables

Studies and references

Data and analyses

Figures

Sources of support

Feedback

Appendices

New 230910.rm5] Caffeine for daytime drowsiness

Validation Report (Caffeine for daytime drowsiness)

Validation Report

Caffeine for daytime drowsiness

Errors

Section	Description
Event: New citation: conclusions not changed, 08 January 2008	Event is not allowed at Protocol stage.
Main text: Declarations of interest	Section is empty.
Figure: Figure 3 (Analysis 1.11)	Figure is not linked from the text.
Figure: Figure 1	Figure is not linked from the text.
Figure: Figure 2	Figure is not linked from the text.

Warnings

Section	Description
Dates	Next stage expected is in the past.
Sources of support	No sources of support found.
Main text: Contributions of authors	Section is empty.
Reference: Beaumont 2001	Date of Publication is empty.
Reference: Smith 1999	Reference is not linked from the text.



OK

Description of the condition