

# Writing a protocol

Tabriz University of Medical  
Sciences  
Standard Workshop on Systematic  
Reviews \_ October 2012  
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University of British Columbia

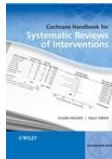
# Steps of a Cochrane systematic review

1. define the question
  2. **plan eligibility criteria**
  3. **plan methods**
  4. search for studies
  5. apply eligibility criteria
  6. collect data
  7. assess studies for risk of bias
  8. analyse and present results
  9. interpret results and draw conclusions
  10. improve and update review
- register title
- publish protocol



# Outline

- **rationale for writing a protocol**
- structure of a Cochrane protocol



See Chapter 2 of the Handbook

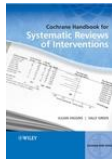
# Rationale for protocols

- systematic reviews involve judgements (retrospective)
  - e.g. question definition, eligibility, outcome measures
  - retrospective research - decisions should not be based on known results
- decide and document methods in advance (transparency)
  - reduce impact of bias
  - allow peer review
  - reduce duplication
  - plan tasks and allocate resources
  - published in *The Cochrane Library*



# Outline

- rationale for writing a protocol
- **structure of a Cochrane protocol**



See Chapter 4 of the Handbook



## THE COCHRANE LIBRARY

Independent high-quality evidence for health care decision making

## BROWSE

Cochrane Reviews: [By Topic](#) | [New Reviews](#) | [Updated Reviews](#) | [A-Z](#) | [By Review Group](#)  
Other Resources: [Other Reviews](#) | [Clinical Trials](#) | [Methods Studies](#) | [Technology Assessments](#) | [Economic Evaluations](#)

## SEARCH

  [Advanced Search](#) | [MeSH Search](#) | [Search History](#) | [Saved Searches](#)**[Intervention Protocol]**  
**Community wide interventions for increasing physical activity**[PDF \(Size 283 K\)](#)[Abstract](#)[The protocol](#)[Background](#)[Objectives](#)[Methods](#)[Acknowledgements](#)[References](#)[Figures](#)[Supplementary information](#)[Appendices](#)[About this article](#)**[Intervention Protocol]****Community wide interventions for increasing physical activity**Philip RA Baker<sup>1</sup>, Daniel P Francis<sup>1</sup>, Jesus Soares<sup>2</sup>, Alison L Weightman<sup>3</sup>, Charles Foster<sup>4</sup>

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**Abstract**



- 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

## Text of Review

# Caffeine for daytime drowsiness

- ▣ Protocol information
- ▣ Abstract
- ▣ Plain language summary
- ▣ Background
- ▣ Objectives
- ▣ Methods
- ▣ Results
- ▣ Discussion
- ▣ Authors' conclusions
- ▣ Acknowledgements
- ▣ Contributions of authors
- ▣ Declarations of interest

# 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



[Caffeine for daytime drowsiness.rm5] Caffeine for daytime drowsiness

Text of Review

Intervention review

- Title
- Protocol information
  - Authors**
    - Pitt, Veronica
    - Cumpston, Miranda
  - Contact person
  - Dates
- What's new
- History
- Main text
  - Abstract
  - Plain language summary
  - Background
    - Objectives
  - Methods
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  - Differences between protocol and review
  - Published notes
- Tables
- Studies and references
  - References to studies
  - Other references

**Authors**

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<sup>2</sup>Cochrane 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].

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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](http://www.cochrane.org/training/authors-mes/cochrane-style-guide)
  - terminology, statistics, spelling, references, formatting, etc.



Cochrane Style Guide  
4<sup>th</sup> edition

*Updated September 2009*



# 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



The screenshot shows the Review Manager 5 interface. The title bar reads "[Caffeine for daytime drowsiness.rm5] Caffeine for daytime drowsiness". The menu bar includes File, Edit, Format, View, Tools, Table, Window, and Help. The toolbar contains various icons for document management and editing. The left pane shows a tree view of the document structure:

- Intervention review
  - Title
  - Protocol information
    - Authors
      - Pitt, Veronica
      - Cumpston, Miranda
    - Contact person
    - Dates
    - What's new
    - History
  - Main text
    - Abstract
    - Plain language summary
    - Background**
    - Objectives
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    - Discussion
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    - Contributions of authors
    - Declarations of interest
    - Differences between protocol and review
    - Published notes
  - Tables
  - Studies and references
    - References to studies
    - Other references

The right pane, titled "Text of Review", displays the content of the selected "Background" section:

## 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.

Light users may consume only one cup each day, while heavy users may consume six or more cups. A 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

Caffeine is a mild stimulant that acts as an antagonist of the adenosine receptors, blocking the action of this naturally occurring neuromodulator ([Snyder 1984](#)). The effect is increased activity of the central nervous system ([Smith 2002](#)).

Uncontrolled cohort studies have suggested that the use of coffee and tea is beneficial for increasing alertness and workplace productivity. In one large case control study of 9000 British adults there was a

# Objectives

- a precise statement of the primary objective
- usually one sentence
- may also include specific objectives relating to different
  - participant groups
  - comparisons of interventions

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



The screenshot shows the Review Manager 5 interface. The title bar reads "[Caffeine for daytime drowsiness.rm5] Caffeine for daytime drowsiness". The menu bar includes File, Edit, Format, View, Tools, Table, Window, and Help. The toolbar contains various icons for document management and editing. The left pane shows a table of contents for an "Intervention review" with sections like Title, Protocol information, Authors (Pitt, Veronica; Cumpston, Miranda), 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 (References to studies, Other references), and Appendices. The right pane, titled "Text of Review", shows the content of the "Background" section. It begins with "period of abstinence." followed by a section header "Why it is important to do this review". The text discusses research on caffeine's effects, mentioning studies by Beaumont (2001), Smith (1993), Bonnet (1995), Johnson (1990), and Smith (2001). It notes that research is limited to simple tasks and high doses. A paragraph then states that a modest body of research has been conducted in a highly selected group, but there is limited research into daytime drowsiness using ordinary dosage levels (Smith 2002). Another paragraph discusses the common use of caffeine and the need for further investigation. The section concludes with a section header "Objectives" and the text "To determine the effectiveness of caffeine for improving the symptoms of daytime drowsiness." followed by a section header "Methods".

period of abstinence.

## Why it is important to do this review

Research into the effects of caffeine has been confounded by studies where caffeine is delivered in different mediums ([Beaumont 2001](#)), by studies undertaken in those in low arousal situations such as working on night shift ([Smith 1993](#)), in those who are sleep deprived ([Bonnet 1995](#)), or in those treated with drugs that induce drowsiness such as benzodiazepines ([Johnson 1990](#)) or clonidine ([Smith 2001](#)). Research has also been undertaken where the performance outcomes are limited to relatively simple tasks such as reaction time (e.g. [Clubley 1979](#); [Roache 1987](#)). Furthermore, a number of studies have used high doses of caffeine (e.g. [Johnson 1990](#); [Smith 1994a](#); [Smith 1994b](#)) in order to address the acute effects of caffeine intake rather than the effects of regular use ([Smith 2002](#)).

Thus, a modest body of research has been conducted in a highly selected group, but there is limited research into daytime drowsiness using ordinary dosage levels ([Smith 2002](#)). With the further confounding factor of addiction and withdrawal symptoms, it is unclear whether caffeine is an effective treatment for daytime drowsiness.

Given the very common use of caffeine throughout society, the cost to the consumer of caffeinated drinks, and the possibly economic impact of workplace productivity, this issue deserves further investigation. In addition, important concerns about adverse effects, addiction and withdrawal should be investigated.

## Objectives

To determine the effectiveness of caffeine for improving the symptoms of daytime drowsiness.

## Methods

# Methods

- plan what you will do before you start
  - minimise 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

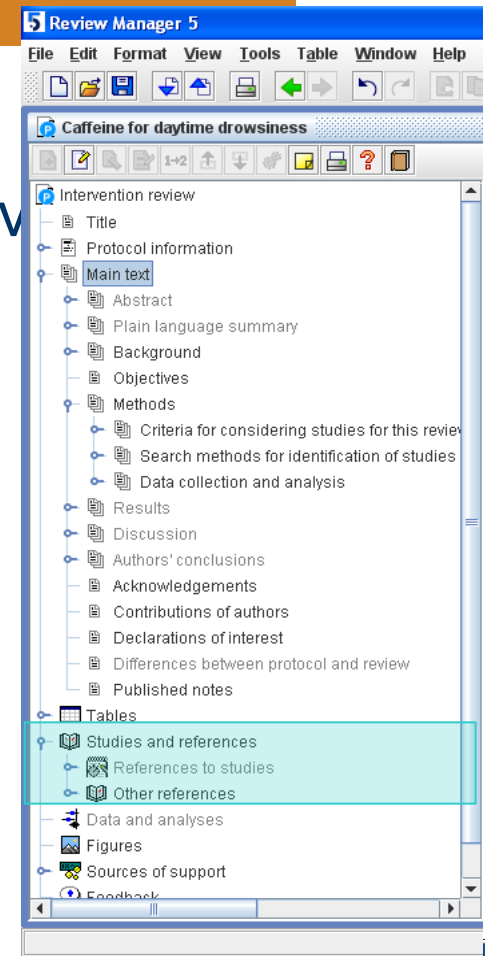
- eligibility criteria
- outcomes
- searching
- data collection
- risk of bias assessment
- analysis

To be covered in more detail...



# Studies and references

- Studies
  - included or excluded from your review
  - **not used for protocol**
- Other references
  - all protocol references  
e.g. Background, Methods



# 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 Permission to Publish & Declaration of Interest forms
  - commence review
  - will be published within 1-2 months



# Take home message

- published protocols are a requirement for Cochrane systematic reviews, designed to minimise bias
- write your protocol so that readers can understand in detail what you plan to do
- follow the standard structure available in RevMan



# References

- Green S, Higgins JPT (editors). [Chapter 2: Preparing a Cochrane review](#). In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1 (updated September 2008). The Cochrane Collaboration, 2008. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org).
- Higgins JPT, Green S (editors). [Chapter 4: Guide to the contents of a Cochrane protocol and review](#). In: Higgins JPT, Green S (editors). *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.0.1 (updated September 2008). The Cochrane Collaboration, 2008. Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org).

