The Cochrane Library

Depot Risperidone for schizophrenia - THE LEADERS GUIDE

Produced by the Editorial base of the Cochrane Schizophrenia Group
http://szg.cochrane.org/en/index.html, email: jun.xia@nottingham.ac.uk

from
Hosalli P, Davis JM. Depot risperidone for schizophrenia. Cochrane Database of Systematic Reviews 2003, Issue 4. Art. No.: CD004161. DOI: 10.1002/14651858.CD004161.

Special points of interest:

- This should take no longer than 1 hour to prepare
- First time you undertake a journal club in this way it may be a bit nerve-wracking

but….

- It should be fun to conduct and attend
- It should begin and end on the practical day-to-day clinical situation

Inside this guide:

Part 1.1 Setting the scene	2
Part 2.1-2 Critical appraisal	2-3
Part 2.3 Doing the appraisal	3
Part 2.4 What are the outcomes	4
Part 3. John arrives	4
Participants' worksheet	5-6
Participants crib sheet	7
Feedback sheet	8

Background explanation

Thank you for giving this guide a go. The idea behind this is to make things easier for you when you lead the journal club.

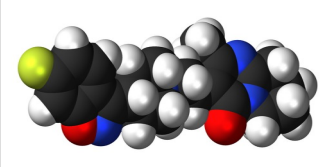
Journal clubs are often difficult to conduct and far removed from clinical life. Even if the leaders do prepare well, those turning up may be more in need of lunch, coffee or a social time than practical academic stimulation and the implicit pressure to read a difficult paper.

This suggested design is an attempt to allow for those needs, whilst getting the very best out of the session.

This journal club design should really help those attending see that this research may have some clinical value.

What you will need to do is:

- ☑ Have a good read of this
- ☑ Then read the review to which this is attached.
- ☑ Distribute the review to those attending well before the club
- ☑ Make more copies for those turning up on spec
- ☑ Do not really expect many to have read the review



PRINTING GUIDE

Pages 1-4 - one copy for you

Pages 5-6 - one copy for each participant - distributed at **start** of journal club

Page 7– one copy for each participant distributed at **end** of journal club

Page 8 - one copy for you to collate feedback

Full review for everyone

Try to find a colour printer that does double sided printing

The three parts

Part 1. Set the clinical scene (5 mins)

Be clear, but really make the participants feel the pressure of the situation...just like you would in clinical life

Part 2. Critical appraisal of the review (20 mins)

Get participants to list what is needed from the review before John arrives, get them to talk, split into groups—with a feeling of urgency.

Part 3. Use of evidence in clinical life (20 mins)

Having distilled the evidence use role play to see how the participants would use what they have learned in everyday life.

Part 1.1 Setting the scene – Service user

Introduce participants in the journal club to their scenario

John has had schizophrenia for five years. He doesn't like taking tablets. His illness has been partially responsive to the treatment, which he has only been partly taking it.

He's due to see you in clinic this afternoon and you've considered suggesting depot medication to him.

John is worried about adverse effects and, in particular, sexual dysfunction.

Questions for participants:

Q 1. What do you think John may ask?

A 1. [Suggestion] "Is this going to be any better than the tablets?"

Q 2. "Is this going to give me more side effects [in particular, impotence]?"

A 2. ***List*** the suggestions from participants as these are what will be useful in the role play

Q 3. "Is this just you getting peace of mind whilst I loose my independence , Doc?"

A 3. Again, list answers.

Part 1.2 Setting the scene – the Journal club

Complicate the scenario by adding the need to attend this journal club

Knowing you are due to see John in less than an hour you are nevertheless compelled to attend journal club.

You have not had time to read the paper and need some lunch.

By a stroke of luck the paper for discussion focuses on the value of depot risperidone.

Questions for participants:

Q 1. If you had not had this paper fall into your lap where might you have gone for reliable information?

A 1. There are now lots of answers to this - The Cochrane Library, Clinical Evidence, NICE Technology Appraisals.

Anything that has a **reproducible method** by which results are obtained.

Part 2.1 Critical appraisal of the review

For every review there are only three important questions to ask:

1. Are the results valid?

2. What *are* the results?

3. Are the results applicable to John?

You now have only 20 mins to get participants though this large review. To do this quickly is not easy, especially as many will not have read the paper in preparation.

Suggestion: Ask participants what salient facts they want to know - especially considering their tight time-scale.

Remind them that John now arrives in about 20 mins.

You should be able to fit most of the suggestions supplied by participants into the three categories of question outlined above.

Read 2.2 as this give more detail of the issues that will, in some shape or form, be supplied by the participants.

If they are not lively—give them a hand.

Do not panic. Bright journal club attendees will come up with all the answers—your job is to help focus their efforts and categorise their answers.

Do not be worried by silence.

Take time to read and think about the review - this is the only time-consuming bit

LIST 1:

1.

2.

3.

4.

5.

List 2:

1.

2.

3.

4.

5.

Participants will think of most of the issues - you just need to catch them and write them on a board or flip chart

Part 2.2 The three parts of appraising a review

1. Are the results valid?

There is no point looking at the result if they are clearly not valid.

a. Did the review address a clearly focused issue?

Did the review describe the population studied, intervention given, outcomes considered?

b. Did the authors select the right sort of studies for the review?

The right studies would address the review's question, have an adequate study design

c. Do you think the important, relevant studies were included?

Look for which bibliographic databases were used, personal contact with experts, search for unpublished as well as published studies, search for non-English language studies

d. Did the review's authors do enough to assess the quality of the included studies?

Did they use description of randomization, a rating scale?

2. What *are* the results?

a. Were the results similar from study to study?

Are the results of all included studies clearly displayed?

Are the results from different studies similar?

If not, are the reasons for variations between studies discussed?

b. What is the overall result of the review?

Is there a clinical bottom-line?

What is it?

What is the numerical result?

c. How precise are the results?

Is there a confidence interval?

3. Can I use the results to help John?

a. Can I apply the results to John?

Is John so different from those in the trial that the results don't apply?

b. Should I apply the results to John?

How great would the benefit of therapy be for this particular person?

Is the intervention consistent with John's values and preferences?

Were all the clinically important outcomes considered?

Are the benefits worth the harms and costs?

There is no point proceeding to the second question if journal club participants think the results are not valid

"Is this going to give me more side effects ?"

Part 2.3 Doing the appraisal

Having managed the interactive session with the participants - acquiring the three questions that need to be addressed by those appraising a review and some idea of how to answer each of those questions - now divide the room into three.

Apportion one of the questions per group and ask each group to get a feel for the whole review (1 min) but to focus on answering their particular question for the rest of the participants (5 mins or so).

Encourage talking to each other.

Move round the room to help the groups if they seem to need it.

Have your copy of the review marked up with where they may look for answers - although in a good review it should be obvious.

Stop the flow after about 10 minutes and ask each group to report in turn.

Do Group 1 really think that the review uses valid methods? Why?

After the first group's report you may want to ask everyone to vote whether to proceed or not.

If they agree to proceed — see if you can **get Group 2 to give you the clinical bottom line.**

We suggest that the Graph providing data for 'Global state: moderate to severely ill at end of study period (CGI rating)' best fits John's request of information about drug effect.

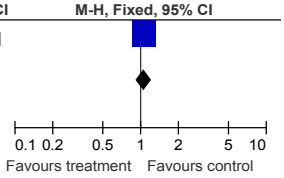
And from **Group 3 get some feel of how applicable the findings are.**

Part 2.4 What are the outcomes?

Comparison: 2. RISPERIDONE DEPOT vs ORAL RISPERIDONE
Outcome: 2.1 Global state: moderate to severely ill at end of study period (CGI rating)

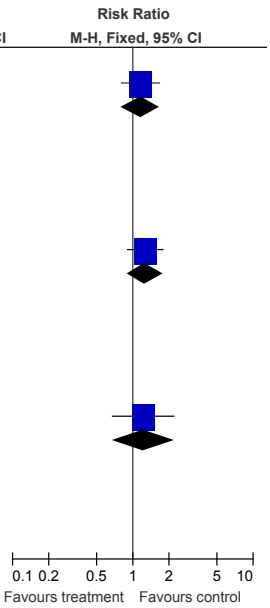
Study or Subgroup	Depot Events	Depot Total	Oral Events	Oral Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Chue 2002	177	319	168	321	100.0%	1.06 [0.92, 1.22]
Total (95% CI)		**319**		**321**	**100.0%**	**1.06 [0.92, 1.22]**
Total events	177		168			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.80 (P = 0.42)



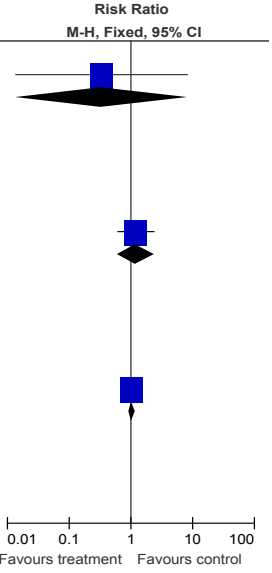
Comparison: 2. RISPERIDONE DEPOT vs ORAL RISPERIDONE
Outcome: 2.4 Poor compliance

Study or Subgroup	Depot Events	Depot Total	Oral Events	Oral Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.4.1 <4 injections or "major protocol violation"						
Chue 2002	53	319	46	321	100.0%	1.16 [0.81, 1.67]
Subtotal (95% CI)		**319**		**321**	**100.0%**	**1.16 [0.81, 1.67]**
Total events	53		46			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.80 (P = 0.42)						
2.4.2 leaving the study early for any reason						
Chue 2002	63	319	50	321	100.0%	1.27 [0.90, 1.78]
Subtotal (95% CI)		**319**		**321**	**100.0%**	**1.27 [0.90, 1.78]**
Total events	63		50			
Heterogeneity: Not applicable						
Test for overall effect: Z = 1.38 (P = 0.17)						
2.4.3 withdrew consent or "non-compliance" or lost to follow up						
Chue 2002	23	319	19	321	100.0%	1.22 [0.68, 2.19]
Subtotal (95% CI)		**319**		**321**	**100.0%**	**1.22 [0.68, 2.19]**
Total events	23		19			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.66 (P = 0.51)						



Comparison: 2. RISPERIDONE DEPOT vs ORAL RISPERIDONE
Outcome: 2.5 Adverse events

Study or Subgroup	Depot Events	Depot Total	Oral Events	Oral Total	Weight	Risk Ratio M-H, Fixed, 95% CI
2.5.1 death						
Chue 2002	0	319	1	321	100.0%	0.34 [0.01, 8.20]
Subtotal (95% CI)		**319**		**321**	**100.0%**	**0.34 [0.01, 8.20]**
Total events	0		1			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.67 (P = 0.50)						
2.5.2 adverse event leading to withdrawal from study						
Chue 2002	18	319	15	321	100.0%	1.21 [0.62, 2.35]
Subtotal (95% CI)		**319**		**321**	**100.0%**	**1.21 [0.62, 2.35]**
Total events	18		15			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.55 (P = 0.58)						
2.5.3 any adverse event reported						
Chue 2002	195	319	189	321	100.0%	1.04 [0.91, 1.18]
Subtotal (95% CI)		**319**		**321**	**100.0%**	**1.04 [0.91, 1.18]**
Total events	195		189			
Heterogeneity: Not applicable						
Test for overall effect: Z = 0.58 (P = 0.56)						



What are the numbers telling us: the effect of depot and oral risperidone on global state are equivocal (RR=1.06, CI 0.92 to 1.22). Same with medication compliance rate - there is no evidence to support any one form of the drug as better than the other. Similar findings extend to adverse events with no significant difference found between groups. Compare to oral risperidone, depot risperidone does seem to produce better result on 'death' (RR=0.34, CI 0.01 to 8.20), but again, the confidence interval is wide and the difference is not significant.

Part 3. John arrives

This is the most important part of the journal club—the *practical application* of what knowledge you have gained.

This is one way of doing it.

Set out two chairs in consultation style. Do not call for a volunteer—just nominate someone to be the clinician and you be John.

Make sure that the clinician feels they can have time to ask their [relieved for not being singled out] colleagues for help [remember—this has got to be a combination of practical and fun].

Back on page 2 there are suggestions for what John may ask—use them.

"Is this going to be any better than the tablets?"

See if they can put across in a supportive way the best evidence as they understand it. There is no perfect way to do this—but perhaps something like this:

"The best evidence we have is from a small Cochrane review - but for people not too dissimilar to you, there is no evidence to show depot is any less effective than tablets."

"Is this going to give me more side effects [in particular, impotence]?"

Again there is no right answer but think about how to put into words what the research outcome really means.

Perhaps - "the conclusion that the best evidence suggests may not be all that you would want or hope for - as there is no specific information concerning impotence. However, in terms of side effects in general, depot risperidone is as good as, for example, oral resperidone ."

As has been said—there is no right answer and all depends on personal style and situation. Your job is to encourage the best answer out of the clinician.

If it is going well there are other questions that you may ask—see side Box 1 below.

Box 1. Additional questions

☑ **Would you trust the drug companies with your body, Doc?**
This is a good point. The trials were funded by Janssen and therefore under-report adverse effects. It is also likely that they over emphasise any positive effects. How do you put this to John in a clear and honest way?

☑ **Were the people in these studies really like me?**
This is always an important point - and more so for a depot study. The average person that is thought to need a depot would not agree to go into a trial. When pretty compliant people are given either a depot or the oral treatment there are consistently few differences to find. How does this apply to your clinical scenario where John is not really very incompliant and may reduce his intake of risperidone to help his sexual functioning?

End on a positive note. Feedback how in a matter of minutes they have got though the bare bones of a big review, appraised and applied it—and, you hope, enjoyed doing it.

The Cochrane Library

Depot Risperidone for schizophrenia

- HANDOUT FOR PARTICIPANTS

Produced by the Editorial base of the Cochrane Schizophrenia Group
http://szg.cochrane.org/en/index.html, email: jun.xia@nottingham.ac.uk

from
Hosalli P, Davis JM. Depot risperidone for schizophrenia. Cochrane Database of Systematic Reviews 2003, Issue 4. Art. No.: CD004161. DOI: 10.1002/14651858.CD004161.

John will arrive soon

What do you think John may ask?

List:

1.

2.

3.

4.

5.

If you had not had this paper fall into your lap where might you have gone for reliable information?

Special points of interest:

- The idea of this is to lead you from the clinical situation, trough the research and back to the real-world clinical situation again
- You may or may not have read the paper - but even if you have not that does not mean that you cannot get something out of this

What key points do you need to know to see if this review can help?*

1.

2.

3.

4.

5.

- Make sure you participate, and speak up - you will have to in the real clinic
- There is no perfect way of doing this - each person has an individual way of interacting and conveying information

***John arrives in 30 mins**

After discussion do you want to change the key points you need to know to see if this review can help?*

1.

2.

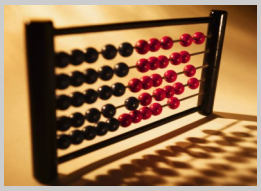
3.

*John arrives in 10 mins

Can you extract numbers that will be useful to you and John?

Clue: focus on what you think John may ask - main effects and adverse effects - graph number '2.1, 2.4 & 2.5' may be good ones to use

1. Can you put relative risk into words?



The arithmetic is not complicated

2. Is there an improvement *attributable* to use of depot risperidone?

3. Can you put above findings into words?

John arrives

Is there a good use of words you would want to use?

The Cochrane Library

Special points of interest:

- Best evidence suggests that clinically focused problem-based learning "has positive effects on physician competency" even long into the future. [1]

1. Koh GC, Khoo HE, Wong ML, Koh D. The effects of problem-based learning during medical school on physician competency: a systematic review. CMAJ 2008; 178(1):34-41. (free online)

CATmaker

This can be part of astore of Critically Appraised Topics - see CATmaker oline

Depot Risperidone for schizophrenia - PARTICIPANTS' CRIB SHEET

The three parts of appraising a review

1. Are the results valid?

There is no point looking at the result if they are clearly not valid.

a. Did the review address a clearly focused issue?

Did the review describe the population studied, intervention given, outcomes considered?

b. Did the authors select the right sort of studies for the review?

The right studies would address the review's question, have an adequate study design

c. Do you think the important, relevant studies were included?

Look for which bibliographic databases were used, personal contact with experts, search for unpublished as well as published studies, search for non-English language studies

d. Did the review's authors do enough to assess the quality of the included studies?

Did they use description of randomization, a rating scale?

2. What *are* the results?

a. Were the results similar from study to study?

Are the results of all included studies clearly displayed?

Are the results from different studies similar?

If not, are the reasons for variations between studies discussed?

b. What is the overall result of the review?

Is there a clinical bottom-line?

What is it?

What is the numerical result?

c. How precise are the results?

Is there a confidence interval?

3. Can I use the results to help the service user?

a. Can I apply the results to the service user?

Is the service user so different from those in the trial that the results don't apply?

b. Should I apply the results to the service user?

How great would the benefit of therapy be for this particular person?

Is the intervention consistent with service user's values and preferences?

Were all the clinically important outcomes considered?

What are the outcomes?

What are the numbers telling us: the effect of depot and oral risperidone on global state are equivocal (RR=1.06, CI 0.92 to 1.22). Same with medication compliance rate - there is no evidence to support any one form of the drug as better than the other. Similar findings extend to adverse events with no significant difference found between groups. Compare to oral risperidone, depot risperidone does seem to produce better result on 'death' (RR=0.34, CI 0.01 to 8.20), but again, the confidence interval is wide and the difference is not significant.

The Cochrane Library

Please return to:

Jun Xia
Cochrane Schizophrenia Group
Division of Psychiatry
University of Nottingham
The Sir Colin Campbell Building
Jubliee Campus
Innovation Park, Triumph Road
Nottingham
NG7 2RT
UK

E-mail:
jun.xia@nottingham.ac.uk
Tel: +44 (0)115 823 1287
Fax: +44 (0)115 823 1392

Thank you

This is one of 40 Cochrane Schizophrenia Group Guides for Journal Clubs

A full list is found on

http://szg.cochrane.org/journal-club

Depot Risperidone for schizophrenia

- FEEDBACK

Date and place of journal club

1. How many attended?

About

2. What was the background of the people attending? (please tick)

Health care professionals

Consumers

Policymakers

Undergraduate

Postgraduate

Others

3. Marks out of ten compared with usual journal club

(10=much better, 5=same, 0 = much worse)

Free text feedback