

**Researching
Complex Interventions**

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Welcome, and thank you for coming
We hope you enjoy it

HELP

**Chaos and
complexity
theories!**

Not that bad, but it is about black boxes

Outline of Presentation

1. What makes an intervention complex?
2. Why are complex interventions important?
3. The MRC guidelines
4. An example of a complex intervention trial
5. This workshop

1) What is a ‘CI’?

Complex interventions are traditionally described as: *“Interventions that contain several interacting components”*

Some Dimensions of Complexity

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1. Number of interacting components within the experimental and control interventions

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2. Number/difficulty of skills and behaviours required by those delivering or receiving the intervention
3. Number of groups or organisational levels targeted
4. Degree of flexibility or tailoring of interventions permitted (individualisation)
(and others - Lewin et al)

But some are more complex than others:

“Interventions built up of a number of components which may act both independently and interdependently”

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UNEXPECTED OUTCOMES

What is NOT a CI?

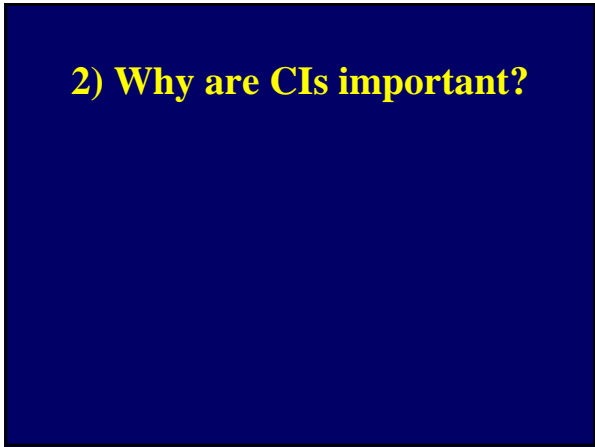
A drug trial?

What is NOT a CI?

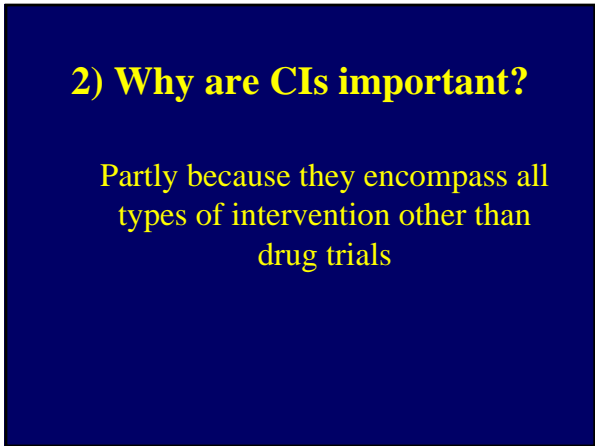
A drug trial?

Is the whole RCT/EBM business really all about the evil multi-national pharmaceutical industry?





2) Why are CIs important?



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Partly because they encompass all types of intervention other than drug trials

Why are CIs important?

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2. The context in which an intervention is used
3. In the real world we rarely use single interventions in isolation
4. Unexpected consequences of interventions

1) Chronic Disease and Health Behaviours

Interventions that attempt to change behaviour are complex

Chronic Disease and Health Behaviours

We are not going to make inroads into chronic disease management unless we can learn how to change behaviours of health care professionals, patients and the public

Example: Diabetes

2) The Context

The Context

- The results of 'simple' trials may not be generalisable because of the influence of context on outcomes
- Context include many factors that can CHANGE over time

'Macro' and 'micro'-context effects

- **'Macro'-context effects:** Socio-economic and cultural circumstances of a trial and related cultural assumptions; the health care system; characteristics of population; how the problem is caused and sustained
- **'Micro'-context effects:** the environment in which the intervention is carried out, the interactions between HCP and patient

A 'macro' context effect

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Healing rates of gastric ulcers, in trial
'control' groups

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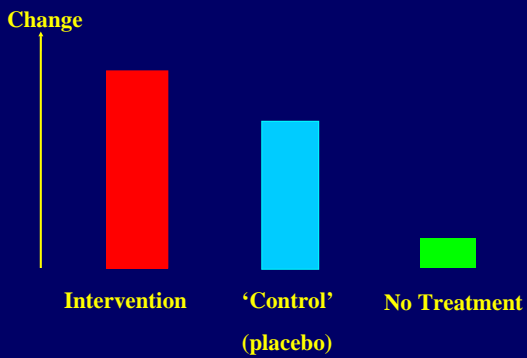
Germany: 62.4%

Denmark: 16.7%

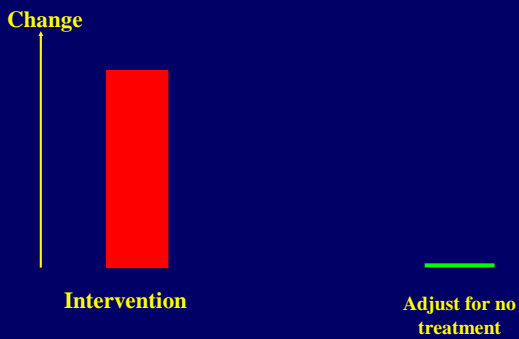
(Moerman D 2000)

A 'micro' context effect: the 'placebo' response

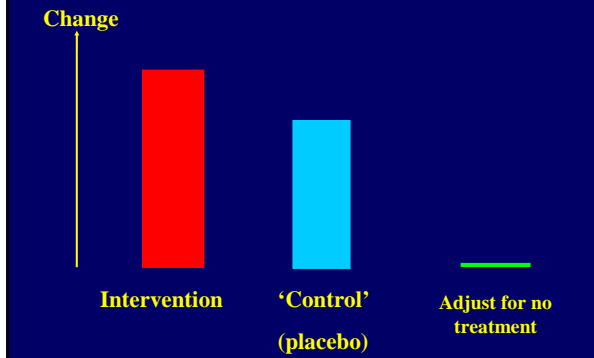
RCT effects



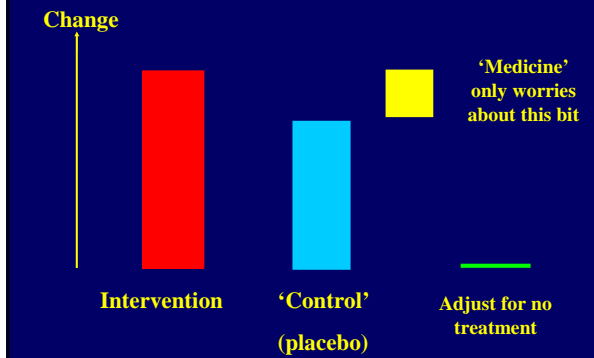
RCT effects (Kirsch, depression)



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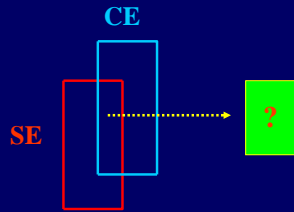
RCT effects (Kirsch, depression)



Assumption of the classic RCT

- That specific effects and context effects (characteristic effects and incidental effects) are divisible and additive

Specific effect and context effect



Assumption of the classic RCT

- That specific effects and context effects (characteristic effects and incidental effects) are divisible and additive
- In many 'complex interventions' this is not the case (e.g. acupuncture and physiotherapy)

Paterson and Dieppe BMJ 2005

Interaction of specific effects and context effects

- Individualisation of therapy by adjusting what you do according to the response of the individual and their health beliefs

Interaction of specific effects and context effects

- Individualisation of therapy by adjusting what you do according to the response of the individual and their health beliefs
- What is generally done in clinical practice, especially by AHP and CAM practitioners. Regarded as a breach of intervention fidelity within the world of the traditional RCT – but can be OK in complex interventions

Trial 'Fidelity'

- A principle of the classical RCT is that everyone gets exactly the same intervention
- This does not mirror 'real life'
- During a complex intervention trial there may be variations in intervention delivery (by different people for example) and/or changes over time
This is OK as long as carefully recorded

3) Packages of Care

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- In chronic disease we rarely use interventions singly, we combine different modalities

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Packages of Care

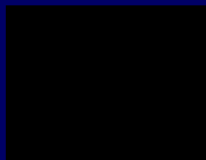
- In chronic disease we rarely use interventions singly, we combine different modalities
- NICE guideline committee on management of OA: Lots of trials of single interventions (mostly drugs that don't help much), very few trials of packages of care (CIs)
- ERGO: we do not know what to recommend!

4) Unexpected Consequences

Unexpected Consequences

- Many trials of CIs have produced negative results when people thought the intervention was bound to work
- Some trials of CIs have produced unexpected positive and negative effects which were not understood

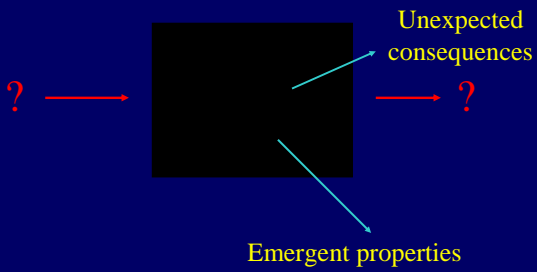
Complex Interventions can be seen as a 'black box'



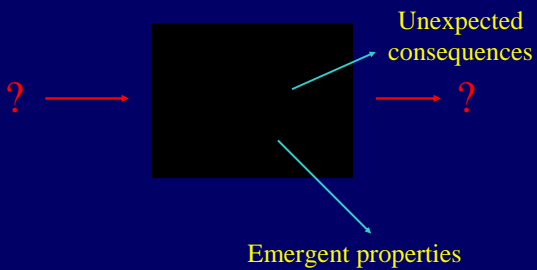
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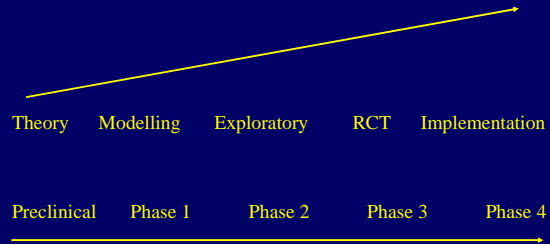
- This means assessing process as well as outcome
- This requires theory (what you think might happen and why) and may need both quantitative and qualitative approaches



3) MRC Frameworks for Complex Interventions

(Campbell et al BMJ 2000, Craig et al BMJ 2008)

The first framework (2000)



Problems

- Model from drug development
- Linearity implied by the diagram
- Theory and modelling phases not well explained
- Implication that traditional RCTs are the preferred (only?) option for assessment
- Lack of attention to context

and others

The revised MRC framework for complex interventions (Craig et al 2008)

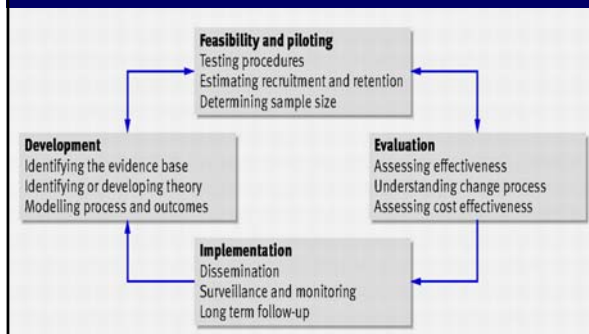
Developing The Revised Framework

1. Workshop funded by MRC PHSRN, led by Paul Dieppe, Janet Darbyshire and Sally McIntyre, held in May 2006, c 30 invited attendees, with some of those who developed the 1st framework
2. Writing committee of PD, JD, SM + Peter Craig, Susan Michie, Irwin Nazareth, Mark Petticrew
3. Review by MRC HSPHRB

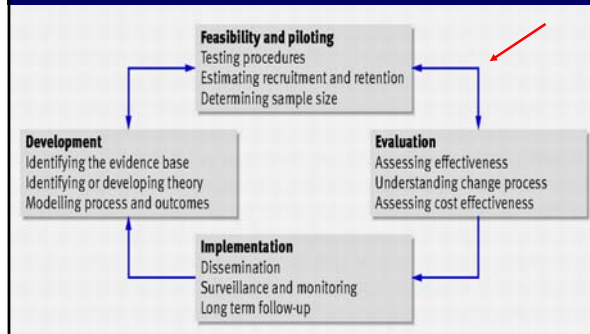
The revised framework

1. Summary of what makes an intervention complex, and the process of development and testing a CI
2. Questions researchers need to ask themselves
3. Examples of complex intervention studies using a wide variety of designs including non-randomisation/quasi-experimental studies

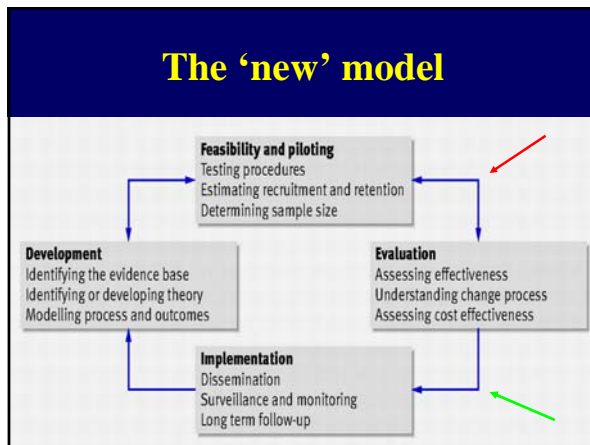
The 'new' model



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Development:

1. Evidence base
2. Theory
3. Modelling process/outcome

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Are you clear about what you are trying to do and why?

Feasibility/Piloting:

- 1. Testing procedures
- 2. Recruitment/retention
- 3. Determining sample size

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**Can this work?
Is it practical and sensible?
What outcomes (interactions)?**

Evaluation:

- 1. Assessing effectiveness
- 2. Understanding process
- 3. Cost-effectiveness

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What design are you going to use and why?

Implementation:

- 1. Dissemination
- 2. Surveillance/monitoring
- 3. Long-term follow-up

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Publication is not enough!



4) An example of a CI Trial

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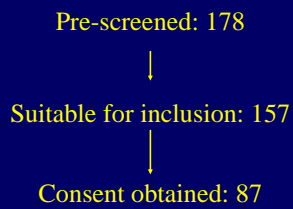
2. **The intervention** – home based exercises and patella strapping with 'education' to aid behaviour change

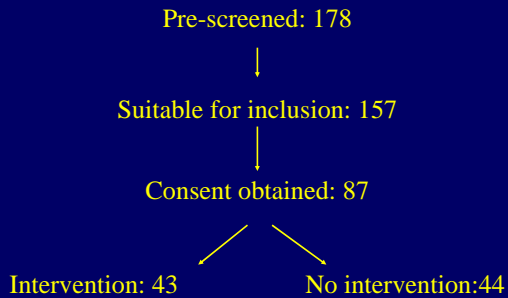
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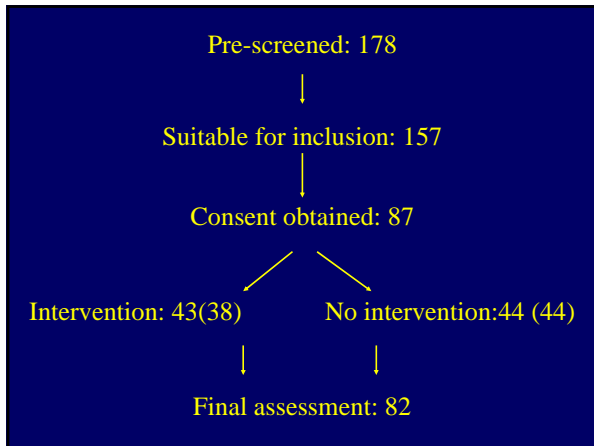
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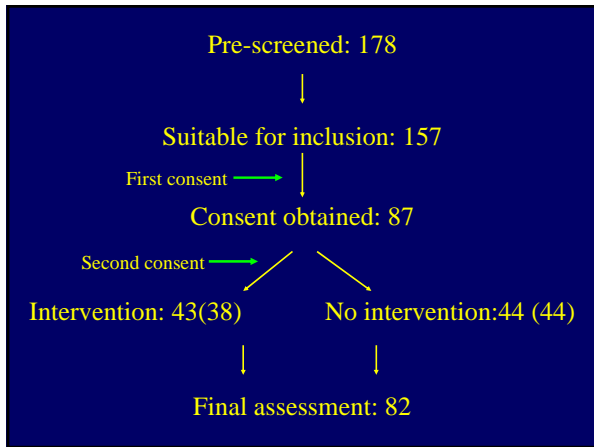
3. **Recruitment** – from a community cohort

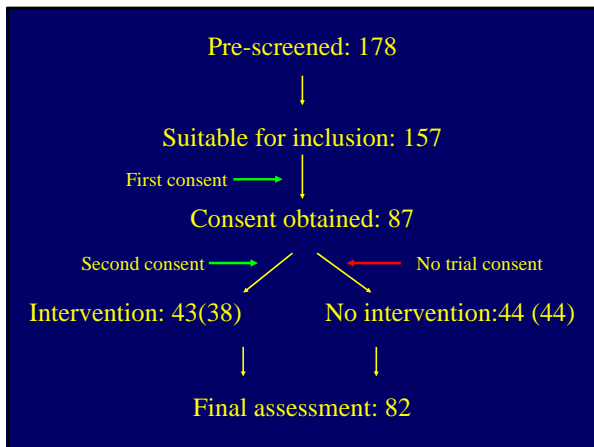
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4. **The design** – Modified Zelen design











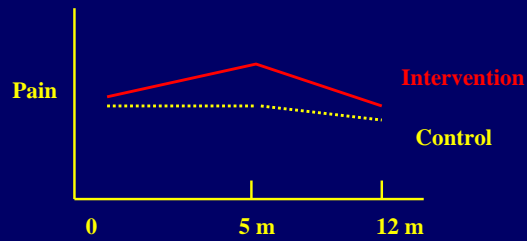
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5. **Outcomes** – ‘WOMAC’ pain and function
6. **Process measures** – quads strength, nested qualitative interviews

The ‘Result’

- Small difference in favour of intervention group at 5 months, disappeared by 12 months

Quilty et al – HTA Report 1997



The 'Result'

- Small difference in favour of intervention group at 5 months, disappeared by 12 months

BUT:

The 'Result'

- Small difference in favour of intervention group at 3 months, disappeared by 6 months

BUT:

- Huge variations in response - some a lot better some a lot worse; interviews showed that most people did not do physio (for good reasons); and that many thought they were a lot better, even if the WOMAC etc did not show that!

So how did we do with this trial?

Development

RATHER badly:

We did look at the literature to help design the intervention – BUT

1. No patient involvement in design
2. No theoretical framework for behaviour change aspect of the intervention
3. No piloting of feasibility/acceptability
4. No economic thinking or modelling

Feasibility/Pilot Stage

Quite badly:

1. We did not know if this would work before we started the trial – BUT:
2. We did work out the sample size
3. In practice the recruitment and retention went well (we were lucky)

Evaluation Stage

We did that quite well!

1. An innovative trial design that 'worked'
2. Process measures to help unpack the black box of the intervention
3. Nested qualitative research to aid understanding
4. Good documentation of the intervention and how much individualisation was allowed

But we did not do any economics!

Implementation

Well, we told people about it

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And we published it

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We published it more than once actually, and
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PATHETIC!



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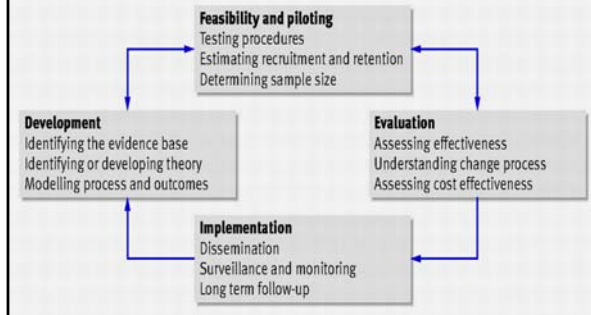
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The MRC framework provides us with a window on all the key methodologies used in applied health research (Richards 2010)

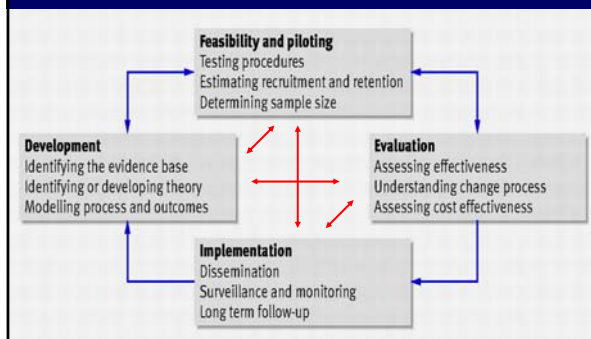
5) This Workshop

1. Workshops
2. Research Cafes
3. Plenary Sessions

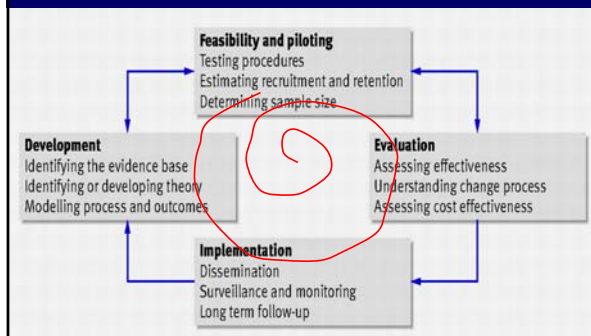
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HAVE FUN

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BE NOISY
