

Best available evidence on the impacts of complex interventions:

Dealing with diverse sources and types of data from randomised and non-randomised studies, quantitative and qualitative data

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Outline

- Horses for courses: overview of study designs
- Terminology used for study designs
- Issues of best available evidence & uncertainty

**Types of evidence:
what is best available evidence
likely to be for your question**

What sort of question is it?

- What works? What matters? Why does it (not) work?
 - What are the impacts on a specific outcome?
 - Why are there impacts?
 - How does a programme work?
 - Are there differential impacts?
 - Is this value for money?
 - What sort of impacts are there?
 -

What type of research evidence?

CROSS-sectional surveys
independent panel
Case control studies
depth interviews
trends in routine data
focus groups
randomised controlled trials
historical controlled



Methodological aptness

Research question	Qualitative Research	Surveys	Case control studies	Cohort Studies	RCTs	Sys Reviews
Effectiveness Does this work?				+	++	+++
Effectiveness of service delivery: How does it work ?	++	+				+++
Salience Does it matter ?	++	++				+++
Safety: Will it do more harm than good?	+		+	+	++	+++
Acceptability Will children/parents want to use it?	++	+			+	+++
Cost-effectiveness: Is it worth buying?					++	+++
Satisfaction with service	++	++	+	+		+
Appropriateness Is this the right service	++	++				++

(Muir Gray, 1997 & Petticrew, 2003)

Intervention studies: assessing impacts/effect of an intervention

- **IMPACT**- measure change in key outcome over time
 - compare outcomes before and after intervention

- **Prospective** not retrospective- avoid recall bias
 - assess outcomes before AND after intervention



Retrospective studies

- Used in natural experiments- look back at data

- Were the features of the study described carried out AFTER the study was designed:
 - Identification of participants?

 - Assessment before intervention?

 - Actions/choices leading to an individual becoming a member of a group?

 - Assessment of outcomes?

Before & After studies

(Prospective uncontrolled studies, uncontrolled study)

Assess health **BEFORE**
move



AND

AFTER house

1 year



- Assess change in (impact on) health outcome 1 year after house move
 - at same time of year as before measures

Problems of Before & After studies

- Not able to **control** for other important changes which might influence health- do not know if health would have changed anyway

- Health may change due to
 - changes neighbourhood
 - changes to income & state benefits
 - changes in local services, amenities, transport, opportunities
 - changes to individual circumstances (employment, family changes, other ill health)

Controlled Before & After studies (Prospective controlled studies, controlled cohort studies)

Assess health **BEFORE**

&

AFTER house move
(**Intervention** group)



1 year



ALSO assess health of similar residents who do not move

BEFORE

&

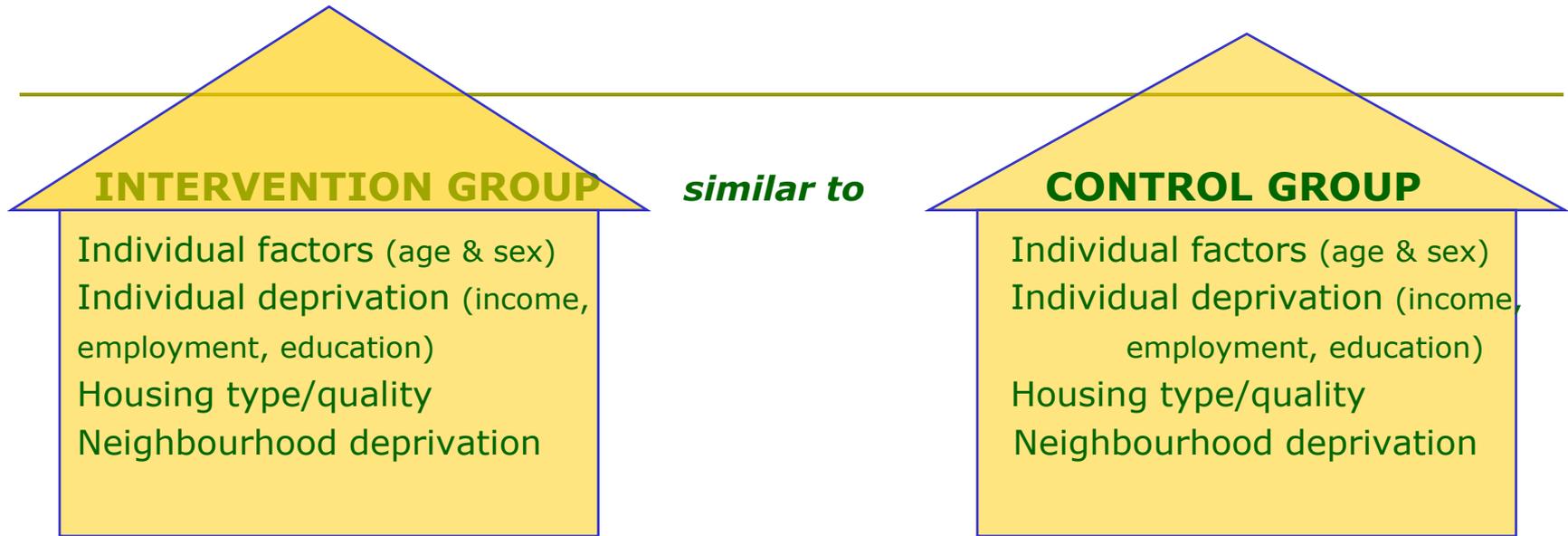
AFTER (**Control** group)



1 year



Problems with controlled studies: selecting a control group for comparison



- ❑ Residents in control group should be similar to residents in intervention group – EXCEPT for the house move/improvement
- ❑ Often not able to match for **ELIGIBILITY** for the intervention: area or individuals offered the intervention are often selected due to greater need

Controlled Before & After studies

Assess health **BEFORE**

&

AFTER house move
(**Intervention group**)



1 year



BEFORE

**Sometimes very difficult to
get suitable control group
for social interventions**

(**control group**)

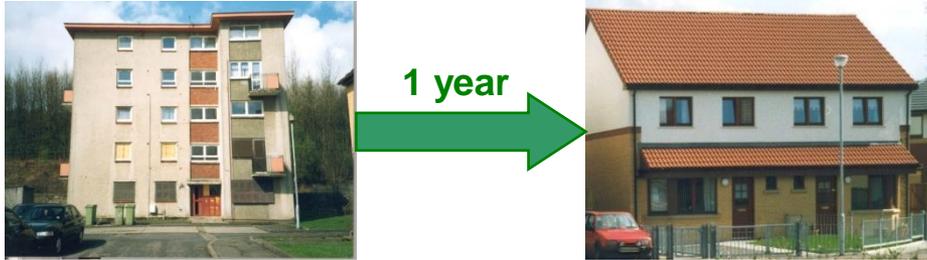


1 year



Randomised controlled trials of housing improvement

Compare **BEFORE** & **AFTER** house move (**Intervention group**)



Assess health of residents still waiting to move

BEFORE & **AFTER (Control group)** → **Intervention group**



- Control group move house after 1st year and enter intervention group
- Equal levels of eligibility for the intervention

Allocation of intervention

- What determined how intervention was delivered?
 - To who?
 - When?
 - What level?

- Randomisation is the best way to control for this

- Challenging for natural experiments
 - Often delivered to whole areas for range of different reasons
 - Commercial, pragmatic, etc etc

Cohort or cross-sectional study?

- ❑ Independent panel study or cross-sectional before & after study
- ❑ Important to determine if the study follows the same people

Cohort or cross-sectional study?

- Independent panel study or cross-sectional before & after study

Assess health **BEFORE**
move

&

AFTER house

*Instead
of this*



*More
like this*



Changes in outcome assessed at higher level- e.g. village,
neighbourhood, organisation

Cohort or cross-sectional study?

- Independent panel study or cross-sectional before & after study
- Important to determine if the study follows the same people
- Not always feasible to follow cohort
 - Cross-section of population before & after
 - With or without control group
- Problems with cross-sectional before & after studies
 - Not sure if population changes explain outcomes
- Benefits
 - Cheap- if population changes are unlikely this may be the best available evidence

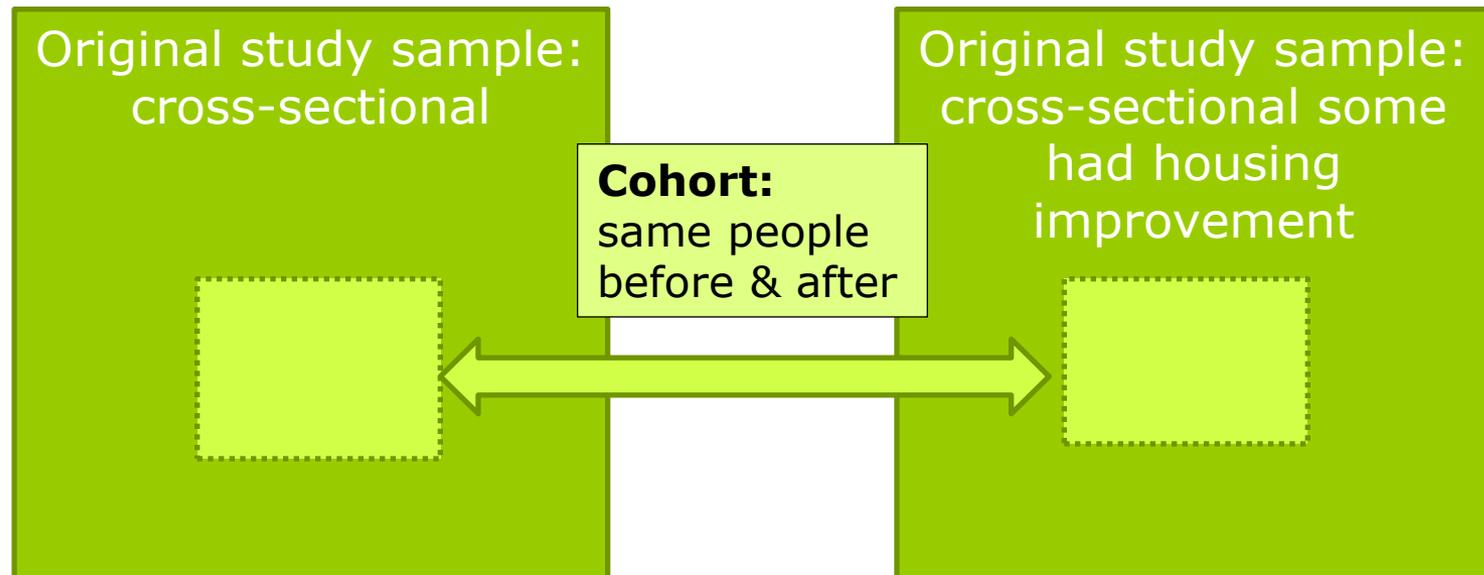
Study designs: intervention studies

- Impact evaluation, outcome evaluation, intervention study...
 - Randomised controlled trial
 - Randomise individuals or clusters
 - Stepped wedge design
 - Controlled before & after study
 - Prospective controlled study
 - Controlled longitudinal study
 - Controlled panel study, cohort study, counterfactual, observational study, independent panel study...?
 - Uncontrolled before & after study
 - Prospective uncontrolled study, cross-sectional before & after...?
 - Retrospective studies
 - Ask about change in outcome after the intervention- do not compare change before & after. May be quantitative or qualitative
- Need to define study designs for your review
 - Don't be confused by different names
 - Don't assume the author has the same understanding as you
 - Study design may be different for different outcomes/time points

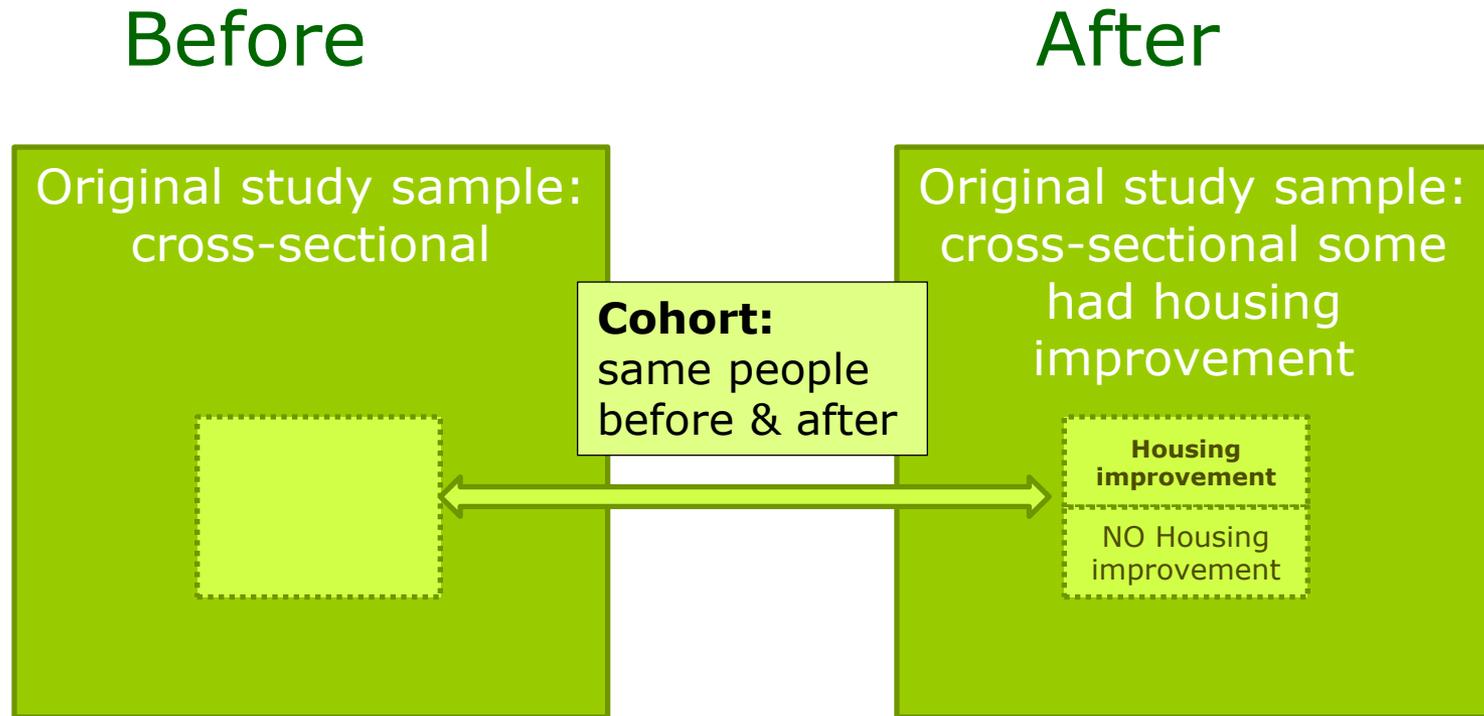
Not always easy to decide what design is!

Before

After



Not always easy to decide what design is!



- Retrospective identification of cohort through data linkage
- High levels of selection bias: not clear how residents selected for housing improvement
- High levels of attrition bias: don't know intervention status of non-respondents

Cochrane definitions

- <http://ccg.cochrane.org/non-randomised-controlled-study-nrs-designs>

Below are some types of Non-randomized controlled study (NRS) design used for evaluating the effects of interventions

- **Non-randomized controlled trial**
An experimental study in which people are allocated to different interventions using methods that are not random.

Controlled before-and-after study

A study in which observations are made before and after the implementation of an intervention, both in a group that receives the intervention and in a control group that does not.

Interrupted time series study

A study that uses observations at multiple time points before and after an intervention (the 'interruption'). The design attempts to detect whether the intervention has had an effect significantly greater than any underlying trend over time.

Historically controlled study

A study that compares a group of participants receiving an intervention with a similar group from the past who did not.

Key features of study design to consider

- Does the study report outcome data on the effects of an intervention?
 - What is the intervention?

- How was the intervention assigned? Randomised?

- Was there a comparison group?
 - How suitable was the comparison group?

- Was the study retrospective?
 - Were the features of the study described carried out after the study was designed?

- Higgins JPT, Ramsay C, Reeves BC, Deeks JJ, Shea B, Valentine JC, Tugwell P, Wells G: **Issues relating to study design and risk of bias when including non-randomized studies in systematic reviews on the effects of interventions.** *Research Synthesis Methods* 2013, **4**(1):12-25.

Determine study design: key questions

- Was outcome data collected before & after the intervention?
 - How was effect/impact assessed? Change or difference between groups?
- Was the outcome data collected from the same people?
Was it a cohort study? Or cross-sectional data?

Defining your study design names

- Good practice
 - Clarifies for reviewers and also for readers
 - Good to use conventional terms
 - Include in protocol

- **1 Definition of study design names used in the review**

- **Controlled Before & After study:** The intervention is not randomised. The key outcome is assessed among the same study population before and after receipt of the intervention. The change in outcome is compared with the same outcome measurements and changes in a suitable comparison group acting as a control group who have not received the intervention. It is likely that there will be systematic differences in eligibility for the intervention between the intervention and the control group. The key outcome is assessed at the same time points in the intervention and the control group. This design may be referred to as a quasi-experimental design and may also be known as a controlled before and after study (CBA) or a controlled prospective cohort study.
- **Uncontrolled Before & After study:** The key outcome is assessed among the study population before and after receipt of the intervention but there is no comparison or control group. This design may also be known as an uncontrolled before and after study or an uncontrolled prospective cohort study.
- **Cross sectional Controlled Before & After study:** The intervention is not randomised. The key outcome is assessed among the study population or study area before and after receipt of the intervention but it is not clear that the study population are the same people before and after the intervention, but it should be clear that there have been few changes in the target population. For example where an intervention is delivered to a whole area or neighbourhood and the outcomes are assessed before and after among the neighbourhood population with no attempt to follow a cohort for the study. The change in outcome is compared with the same outcome measurements and changes in a suitable comparison group acting as a control group who have not received the intervention. It is likely that there will be systematic differences in eligibility for the intervention between the intervention and the control group. The key outcome is assessed at the same time points in the intervention and the control group.
- **Cross sectional Uncontrolled Before & After study:** The key outcome is assessed among the study population or area before and after receipt of the intervention but there is no comparison or control group. As with a cross sectional controlled before & after study it is not clear that the study follows the same cohort of individuals after the intervention, although there should be some indication that there has been little change in the target population over the duration of the study.

Other types of research evidence

- What matters?
 - Implementation
 - Why did it (not) work?
 - What is the strength of relationship between X & Y?
 - What other unforeseen impacts were there?
 - What type of impacts are there?

- Qualitative & quantitative

Qualitative research

- Mainly unstructured interviews & focus groups
- Identify range of unforeseen impacts- open ended questions
- Shed light on mechanisms for possible impacts
 - Interviewee may explain something or may report additional impacts or issues not already assessed
- Valuable to inform theory and explain quantitative findings

Qualitative data can be used to:

- **Inform:** refine review question, i.e. include appropriate outcomes
- **Enhance:** include qualitative data identified when searching for quantitative data, for example data supplementary to quantitative study which can explain issues of implementation etc
- **Extend:** search for qualitative data which adds to quantitative data available for review question
- **Supplement:** synthesise qualitative data to address questions beyond effectiveness, i.e. search for additional qualitative data

Best available evidence

RCTs of complex interventions

- Not always available
- Can be difficult & costly
 - Not always ethically justified: is there uncertainty over the benefit of the primary outcome?
 - Not always practically possible: Require high levels of control over allocation of the intervention and very good relationship between researchers, participants & those delivering the intervention
- But some excellent examples- *so sometimes keep an open mind about what you might find!*

What is best available evidence?

For assessing effectiveness

- Randomised controlled trial
- Controlled before & after study
- Uncontrolled before & after study
- Retrospective studies

Reviewing non-randomised studies

- Should you exclude and treat as no evidence?
- If only uncontrolled before & after studies?
- Empty reviews are of little use
 - And do not represent best available evidence/knowledge

"Dont let the best be the enemy of the good"

Best available evidence

- Poorer quality studies may still provide **best available** evidence
 - May not report attributable impacts but may still provide useful insights
 - Point to issues or outcomes worthy of further research
 - Effectiveness might not be the main question
 - Mapping nature, size & variation in impacts

Best available evidence

- Reviews can establish what is known & what is not known
 - Map out where gaps in knowledge are
 - Difficulties in assessing effectiveness for this intervention
 - Recommend & prioritise future research to fill knowledge gaps
 - Establish areas of uncertainty & what is not known

"Absence of evidence or evidence of absence?"

Study design & study quality

- Study design is not only marker of quality
 - Use a tool to assess variation in study quality
 - Be careful how you interpret measures of study quality
 - Tools to assess study quality are not always sensitive to important variation
 - Keep it transparent
 - Avoid slip into relatively “good” quality-
 - “*best available*” may not be same as “*best possible*” or “*ideal*”
 - quality in terms of how valid the evidence is in terms of attributing impacts to the intervention
 - Remember
 - sometimes even a badly conducted study can be useful
 - very difficult to get data on attributable impacts of complex interventions

Ideal world v real world

□ Using your review question

- In an ideal world what would be the best possible type of evidence and study design to answer the main question?
 - Quantitative or qualitative?
 - Randomised controlled trial? Survey? Case control? Longitudinal cohort over many years?
- In the real world is it likely that you will find this type of study?
- What other types of study might be useful?

Key questions to decide study design

- Is there an intervention being evaluated?
- Why are participants in receipt of intervention?
 - Randomised by study; self-selected; area intervention etc etc
- Is there a comparison group?
- Are data collected before **AND** after intervention?
- Is the study following a cohort or is this cross-sectional data?
- Was the study designed after the data were collected?