



Health H.A.C.C.

How to assess claims critically

Review of Module 2

- **Endorsements**, **anecdotes** etc. do not provide reliable information about interventions.
- Association is not the same as **causation**.
- Well-performed research limits the impact of **bias** and **conflicts of interest**.
- Main research study types are **observational** and **experimental**.
- Only one type of study can establish causation, this is a **randomised controlled trial**. Therefore, this is the most important type of study that can provide reliable health claim information.



Module 3:

What makes a fair comparison
of a health intervention?



Class Activity B

Classroom trial



Classroom trial

- Our class is going to conduct a study and needs to be separated into two groups:
- How can we divide the class into two groups?
 - Decide a method and separate.
- Choose some variables, e.g.:
 - Birthdays between Jan – June
 - Even numbered birthdates
 - First letter of first name between A-M

Count and record the number of participants with each variable:

	Variable 1	Variable 2	Variable 3
Group A			
Group B			

Count and record the number of participants with each variable:

But this time, use “randomisation” to allocate students to groups

	Variable 1	Variable 2	Variable 3
Group C			
Group D			

Compare variable totals:

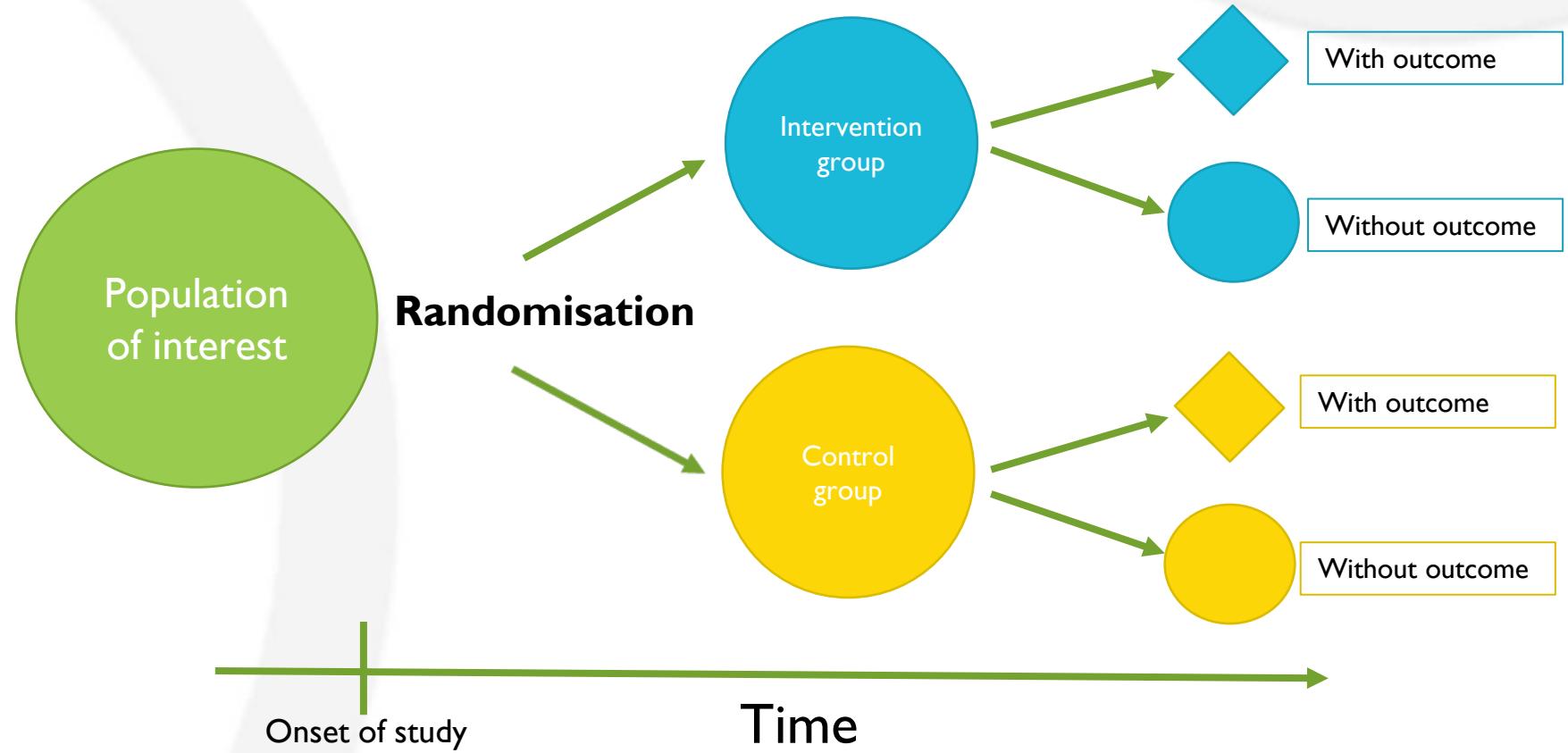
	Variable 1	Variable 2	Variable 3
<i>Groups arranged by non-random allocation</i>			
Group A			
Group B			
<i>Groups arranged by random allocation</i>			
Group C			
Group D			



Discussion Question 11

- What is the “fairest” way to create groups?
 - Randomisation is the fairest way
- Why is this the fairest way?
 - Because the likelihood that the groups are similar is increased
 - i.e. variables are more likely balanced:
 - *age, gender, education level, health level, athletic skills*
 - Similar groups at the start increases the chance of a fair comparison
 - Larger sample size (number of participants) = more equal groups after randomisation

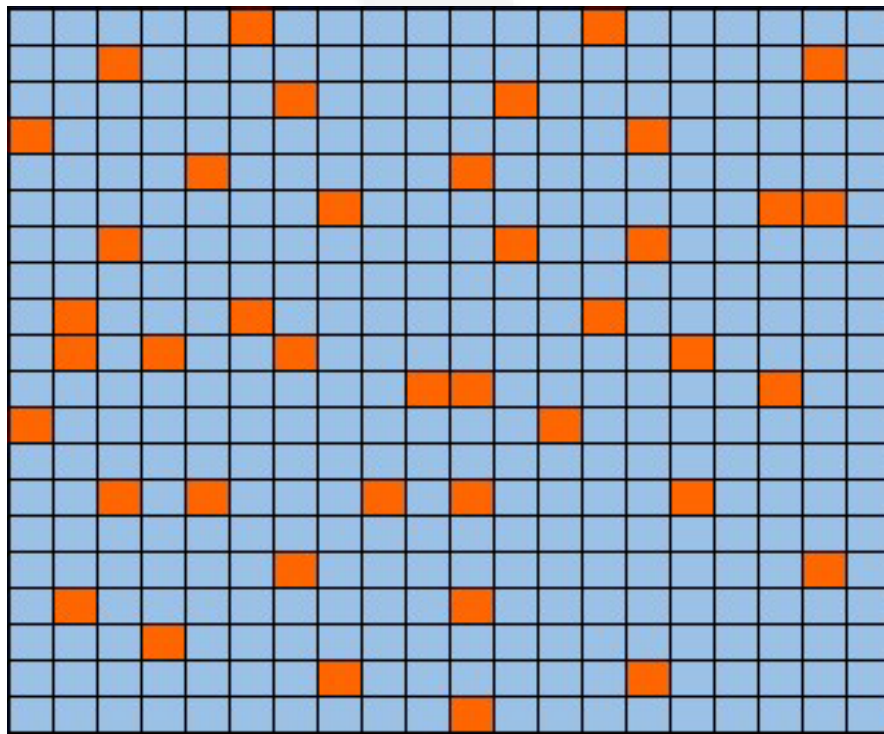
Structure of a Randomised Controlled Trial



Consider sample size

A larger sample size will provide a clearer picture

- Increases the likelihood that groups are **equal** after randomisation
- More likely to show **true impact** of intervention



Orange squares = people with side effects

A **small sample size** can be problematic

For example:

- A new skin cream. Consider:
 - health benefits
 - side effects (e.g. skin irritation)
- Side effects:
 - 1 in every 10 people using the cream
 - A **small sample size** may not show the true picture





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Class Activity C

How raising your arms can
improve your balance

Class Activity C: Details

- In the same randomised groups:
 - 1 group – each raise an arm (while seated) for 60 seconds
 - This action assists with balance, as will be demonstrated
- Everyone:
 - Balance on one foot, unaided (close eyes for increased challenge)
 - When balance lost, sit down
- After 60 seconds:
 - Count how many students in each group remain standing

AFTER Class Activity C...



Results of trial

- Did the Intervention Group have more students who balanced for 1 minute?
- Hopefully so, as this activity was designed to demonstrate the “**placebo effect**”
- **Placebo effect**
 - a desirable effect caused by an “**inactive**” treatment,
 - presumed to act **psychologically** through suggestion



Discussion Question 12

- If the intervention group is aware they are receiving an intervention and the comparison group is aware that they are *not* receiving an intervention, how might this impact the results?
 - They may expect health benefits and may perceive some, due to **placebo effect**
- How might placebo interventions be useful in research?
 - The intervention can be tested against the **placebo** to determine if the intervention is showing better results



Discussion Question 13

- How could you minimise the impact of the “placebo effect” in a study that was testing whether an intervention works?
 - If both groups are unaware of which group they are allocated to, then the “placebo effect” is balanced across both groups.
 - Ensuring that both groups are unaware of their group allocation is known as “blinding”



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Student Booklet: Activity 7

Fair comparisons



Activity 7a answers

Do you think this cream is effective at reducing muscle soreness?

- Yes?
- No?
- Cannot tell?

It is not possible to tell based on the information provided.

A good component of the study:

- Two groups were **compared**, one using the intervention and the other not.

But we don't know the other details of the study. For example:

- How **big** were the groups?
- Were the groups **equal** to begin with?
- Were both groups treated the exact **same** way?

Group using the cream

Group not using the cream

Is this a fair comparison:
Yes or No? Why?

i	Participants are fit and athletic teenagers with no knee issues (just sore muscles the day after a sprint race)	Participants are fit and athletic teenagers with no knee issues (just sore muscles the day after a sprint race)
ii	Participants are fit and athletic teenagers with no knee issues (just sore muscles the day after a sprint race)	Participants are over the age of 60, not very athletic and often have sore muscles.
iii	Participants received leg massages and had a daily hot bath during the study	Participants received leg massages and had a daily hot bath during the study
iv	Participants received leg massages and took daily hot baths during the study	No participants received leg massages or had a daily hot bath during the study
v	Participants were given a white odourless cream, in a white tube labelled 'apply to sore muscles as needed	Participants were given a white odourless cream, in a white tube labelled 'apply to sore muscles as needed

Group using the cream

Group not using the cream

Is this a fair comparison:
Yes or No? Why?

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Participants were given a white pleasant-smelling cream, in a white tube labelled 'Pain-Stop cream*'.

Participants' muscle soreness was assessed daily by asking them to record their level of soreness on a scale from 0 (no soreness) to 10 (maximum soreness). Participants received a text message daily from the researchers and had to respond with their 'score'.

Participants were given a yellow cream, in a blue tube labelled 'apply as needed'.

Participants' muscle soreness was assessed by asking them to complete a 1 page questionnaire at the end of the study (6 weeks) and mail it back to the researchers.

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30 of the 60 participants in this group dropped out of the study.

15 of the 60 participants in this group dropped out of the study.

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Ten of the 60 participants in this group never applied the cream. When doing the analysis of the data, the researchers counted the outcomes of these 10 people in with the outcomes of the other group.

All of the 60 participants in this group did not use the cream.

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Activity 7c answers

At the beginning of the study, the groups being compared should be **similar**.

Study participants should be allocated into the groups using **randomisation**.

If possible, study participants should be **blinded** about which interventions they are receiving.

Apart from the interventions being compared, participants in the study groups should be cared for **equally**.

Outcomes should be assessed in the same way in the groups that are being compared.

Outcomes should be measured for **everyone**.

Participants' outcomes should be **counted** in the group to which they were **allocated**.

Insert an ↑ for “ will increase reliability” or a ↓ for “will decrease reliability”:

- a. Having only one group in a study.



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End of Module 3



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