
3 OUT OF 4 WOMEN
reduces by 15%
LOOK 10 YEARS YOUNGER
shown in several clinical studies
(in just 4 weeks
Incredible
Results
Guar
AGREE
89%
CLINICALLY PROVEN SOLUTION
Health H.A.C.C.
How to assess claims critically
Teacher's Guide
80% AGREE*
Scientifically proven!
Scientific tests prove
BENEFITS PROVEN
CLINICALLY PROVEN*

THE PURPOSE OF HEALTH H.A.C.C.

The problem being addressed

- With more access to health information than ever before, people can become easily involved in making decisions about managing their health.
- However, much of the information that is available, particularly from sources such as the Internet, social media, and mass media, is of dubious quality.
- Basing health decisions on inaccurate or incomplete information can be harmful to a person's health, as well as a waste of money, effort, and health resources.
- Having the knowledge and skills to be able to sift out valid health information from inaccurate information, so that informed decisions can be made, has never been more needed or important.

How can the Health H.A.C.C program help?

- Health H.A.C.C. has been developed to improve high school students' critical thinking skills, particularly their ability to critically assess health claims and detect false claims.
- It covers fundamental information about research methods and processes for testing health interventions and explains the key concepts[1] needed for appraising claims about health interventions.
- Health H.A.C.C. aims to support teachers in educating students about these key concepts. The content is aimed at students in Years 7-9. However, it is also relevant for students in nearby year levels on either side of this target range.
- Having these skills will help young people be able to make informed health decisions based on reliable information, both now and throughout their life.

By the end of this program, students will be able to recognise health claims, critically assess them, and be aware of the need to do so.

Students will learn to ask, "What is the evidence?" behind health claims and be able to consider "Is the evidence reliable?".

The overall goal is to equip students with the skills so that they are not fooled by false health claims – now and in the future.

"Don't be fooled by false health claims!"

1 Chalmers I, Oxman AD, Austvoll-Dahlgren A, et al. Key Concepts for Informed Health Choices: a framework for helping people learn how to assess treatment claims and make informed choices. BMJ Evidence-Based Med. 2018;23(1):29-33.

PRACTICAL INFORMATION

The Health H.A.C.C. program materials consist of:

1. Teacher guide (this booklet)
    - » Introduction to the program
    - » Four modules - each containing learning objectives, background information, learning activities, time estimates, and resources needed for the activities
    - » Glossary of terminology
2. PowerPoint presentation
    - » To help with teaching the content. It relates directly to the teacher guide and student handbook
3. Student activity booklet
    - » Learning activities for students to complete as the modules are covered

Practical information about the Health H.A.C.C. program:

- The program is divided into 4 modules. The approximate duration of each module is one lesson/ period (approximately 50 minutes).
- The total duration is approximately 3.5 to 4 hours.
- Work through each module at a pace that is comfortable for you and your class. The estimated times for each activity are only a guide.
- This teacher guide will provide background understanding of each module and direct you to the relevant PowerPoint slides and activities to support the teaching.
- The topics are presented in a logical sequence and should be taught in the order presented. However, depending on the pace at which the content is taught and the length of available sessions, the end topic/s from a particular module can be taught in the next session if there was not sufficient time to complete them.
- There are Discussion Questions in each module. Suggested key points to try and cover in the discussion are provided either on the PowerPoint slide immediately following the question or in the notes section of the slide (not all issues that may be raised are listed).
- At the start of Modules 2 and 3, you may wish to quickly review what was covered in the last session. There are some PowerPoint slides labelled 'Review' at the beginning of these Modules. Module 4 begins with a revision activity.
- If some students complete an in-class activity before other students do, there are additional activities at the back of the student booklets that students can be directed to complete.

A note regarding terminology used in this program

The word 'intervention' will be used regularly throughout the modules. An intervention is anything that is used to "intervene" in a health situation. It is often also called a 'treatment', but this does not cover things that are taken to prevent ill health. For this reason, this program uses the broader term of 'intervention'. In the first session, it is recommended that you explain to the students what the term 'intervention' means.

An intervention might be something pharmacological (such as a medication) or non-pharmacological. Examples of non-pharmacological interventions are exercise interventions, psychological interventions, dietary interventions, skin creams, and complementary and alternative health interventions (such as vitamins and acupuncture). Interventions can also be those things that can only be arranged or provided by a health professional or those that are available direct to the consumer (such as from a supermarket or pharmacy).

TABLE OF CONTENTS

MODULE 1 What are health claims and how to spot them (and their tricks)

BACKGROUND

- Health information is readily accessible to the public. As well as websites and traditional mass media (such as magazines, radio and television), health information is also very common on social media platforms.
- As access to health information is widespread, people now play a more active and independent role in their health. As such, it is important that people use reliable information to inform their health decisions.
- The quality of health information is highly variable. There is no regulation regarding health information or claims, so anyone (individuals, companies, organisations) can say nearly anything they like. Health information and health claims are often inaccurate, misleading, and confusing.
- People are exposed to and must navigate vast amounts of health information, often on their own. Typically, people do this with little knowledge about how to evaluate the information or even the need to do so. This makes people vulnerable to believing unreliable claims.
- Health literacy is the ability to understand health information and interact with health services adequately. This program focuses on one component of health literacy – some of the key knowledge and skills to assess claims about health interventions to determine if the claims are reliable.
- Sometimes health claims use misappropriated terms that people associate with trustworthy research findings, such as "evidence-based", "scientifically tested", and "clinically proven". This can lead people to incorrectly assume that the information is reliable and based on valid research. Starting in this module and continuing in later modules, Health HACC will cover some of the tricks that are used in health claims, including how to spot them and not be fooled by them.

LEARNING OBJECTIVES

1. Recognise the prevalence of health claims.
2. Consider why the quality of health information is highly variable.
3. Identify the components of health claims.
4. Consider the concept of health literacy, the role and relevance of these skills within peoples' lives, and why the pros and cons of interventions should be considered.
5. Recognise terminology commonly used in health claims: danger words, misappropriated scientific sounding terminology, and targeted assumptions.

RESOURCES NEEDED

- Module 1 PowerPoint Slides
- Student Booklet Activities 1-3

PROCEDURE, KEY DISCUSSION POINTS and corresponding activities and slides

Topics	Slides	PowerPoint slides - main content	Discussion questions and Learning activities	Estimated time
What is the problem?	1-4	• Examples of heath claims (some contradictory) and how often we are exposed to them. • Introduction to Health HACC – learn how to not be fooled by false health claims.	• **Introductory question** Do you believe these headlines? (slide 2)	5 minutes
What are health claims?	5-9	• The components of health claims.	• **Activity 1: Identify the components of health claims (and generate your own fake health claim) (pg 2-3 Student booklet)**	5 minutes
Health information and claims are of variable quality	10-23	• The problem of variable quality health information and no regulation of its accuracy.	• **Q1.** What are some of the reasons why health claims might be inaccurate? • **Q2.** How do you know which health claims to believe? • **Activity 2: Considering headlines (pg 4 Student booklet and slides 17-23)**	10 minutes
Why do health claims matter to me? So what if they aren't accurate? Consider the pros and cons of any intervention	24-28	• Health literacy is knowing how to find and use reliable information to make good health decisions. • This skill may become more important as young people transition into adulthood. • Interventions may claim to benefit health – in reality, they might, or they might not. It's important to think about both the advantages and disadvantages of any intervention before deciding to use it. • Explain the main types of disadvantages (e.g. side effects, cost, time, inconvenience, etc)	• **Q3.** What decisions do you make about health interventions now? • **Q4.** What are some examples of decisions about health interventions that adults might make? • **Q5.** What might happen if you are fooled by a false health claim?	10 minutes
Watch out for 'danger words', research-sounding terminology, and common assumptions	29-35	• Examples of health claims containing "danger words" and research terminology that may be being used inappropriately in health claims (e.g. "evidence-based", "clinically proven", "scientifically tested"). • [After the activity] Anyone can use these terms and mislead you. Be aware of common assumptions.	• **Activity 3: Common terminology and assumptions in health intervention claims (pg 5 Student booklet and slides 30-33)** • **Q6.** Why do you think this type of terminology is commonly used in health claims? • *Part (d) of Activity 3 may be set as homework if preferred.*	15 minutes

MODULE 2 Information types and study types

BACKGROUND

- Different types of information can be used in health claims. Some types of information (such as information from reliable scientific research) are more reliable than other types (such as anecdotes).
- Understanding the type of information that is used in a health claim can help people to assess its reliability.
- Some health claims imply or state causation inappropriately. There is a clear distinction between causation and association (also known as correlation).
    - » **Causation** means there is an association between two variables where a change in one makes (i.e. causes) a change in the other one to happen.
    - » **Association** simply refers to a relationship between two variables in a study (but does not imply a causal relationship).
- In health intervention research, only one type of study design can establish causation (i.e. that the intervention causes the observed change in the outcome). This type of study is a randomised controlled trial (it will be explained in more detail in the next Module).
- Even if a health claim comes from a research study, this does not necessarily mean that the results are reliable. Whether they are reliable depends on the type of study and how it was designed and conducted (including if conflicts of interest were minimised).
- Better (more reliable) studies will have: 1) compared the intervention to something else, so that we know what would have happened without the intervention and 2) done the comparison in a fair way so that bias was minimised.
- Health research uses different types of study designs to answer different types of research questions. Being aware of the major categories of study types can help people to consider whether the research results and health claims are reliable. Certain study types (such as randomised controlled trials) are more likely to provide reliable results about whether an intervention works (or not).

LEARNING OBJECTIVES

1. Describe, and compare and contrast, the different types of information used in health claims.
2. Explain the distinction between causation and association.
3. Explain how conflicts of interest can affect the reliability of health claims.
4. Describe examples of how a study might be designed to reduce bias.
5. Distinguish between experimental and observational study designs and explain which provide more reliable results when testing the effects of health interventions.
6. Describe, and provide one example of how confounding variables can alter the reliability of studies.

RESOURCES NEEDED

- Module 2 PowerPoint Slides
- Student Booklet Activities 4-6.

PROCEDURE, KEY DISCUSSION POINTS and corresponding activities and slides

Topics	Slides	Power Point slides - main content	Discussion questions and Learning activities	Est. time
Review	1-3	• Review of Module 1		5 mins
Different types of information in health claims	4-12	• Identify and compare information types (e.g. anecdotes, testimonials, endorsements, beliefs, hopes) and why these are not reliable information sources.	• **Activity 4: Types of information used in health claims (pg 6-7 Student booklet and slides 4-8)** • **Q7.** Are endorsements likely or unlikely to provide reliable health information? Why? • **Q8.** Are you likely to believe one of these examples over the other? Why? • **Q9.** Would an endorsement from a member of the public be more convincing? Why?	15 mins

Association is not the same as causation	13-25	• Claims of causation are often inappropriately used. An outcome can be associated with a treatment, without being caused by it.
		• Explanation of association (correlation)
		• Explanation of causation
		• Introduction of the idea that only one type of study design can establish causation in health intervention research. To assess whether an intervention works, it must be compared to something else.
			• Some pre-prepared spurious association graphs are provided in the slides (15, 17). You can use these or create your own (at http://tylervigen.com/spurious-correlations)
			• ***Class Activity A:*** Association is not the same as causation
			  • Show 1 or 2 of the graphs to the students and after each, ask them to explain the 'results'.
			  • **After** students give some responses, reveal that it is a spurious (fake or false) and meaningless finding.
			• **Q10.** What is the difference between association and causation?
			• *(this question may not be needed if the explanation already occurred during discussion about the graphs)*
				10 mins

Not all research is created equal. Thinking about conflicts of interest and bias.	26-29	• Even health claims from research may not be reliable. It depends on the type of study and how it was designed and conducted. • Well-designed research minimises the impact of bias and potential conflicts of interest (which can consciously or subconsciously distort the results of a study). • The importance of having an appropriate comparison when evaluating the effects of interventions.	• **Activity 5: Not all research is created equal. Thinking about conflicts of interest and bias. (pg 8-9 Student booklet)**	5 mins
Observational versus experimental studies	30-35	• The distinction between observational and experimental studies. • Introducing the idea of confounding variables in health research (and leading into the next module about why randomised trials are more likely to provide reliable results about whether an intervention works).	• **Activity 6: Observational vs experimental studies (pg 10-11 Student booklet)**	10 mins

MODULE 3 What makes a fair comparison of a health intervention?

BACKGROUND

- Of all single (primary) studies, randomised controlled trials generally provide the most reliable information about whether interventions work. They use methods to limit the impact of confounding variables which may unfairly alter the results.
- Well-performed trials try to make the testing of an intervention fair by reducing bias. Some of the main features that are used to do this are: randomisation, allocation concealment, comparable groups, adequate follow-up, and blinding.
- When assessing the effects of an intervention, some trials compare the intervention with a placebo (an inert substance, device or procedure). This is done to maintain blinding of trial participants so that they do not know whether they are receiving the experimental intervention or the control intervention. One reason for doing this is to minimise the impact of a 'placebo effect' - desirable effects that are or could be caused by an "inactive" treatment, presumed to act psychologically through suggestion.

LEARNING OBJECTIVES

1. Illustrate the benefits of randomisation.
2. Explain and appraise the key design features needed in studies which evaluate the effect of interventions so that it is a fair comparison.
3. Describe the potential impact of the 'placebo effect' and explain how studies can be designed to minimise its impact.

RESOURCES NEEDED

- Module 3 PowerPoint Slides
- Student Booklet activities 7 and 8
- List of students in the class (see instructions for Activity B for how to use)
- Access to a computer to generate a random number list (see instructions for Activity B for how to use)

PROCEDURE, KEY DISCUSSION POINTS and corresponding activities and slides

Topics	Slides	PowerPoint slides - main content	Discussion questions and Learning activities	Est. time
Review	1-3	• Review of Module 2.		3 mins
Why randomised controlled trials are important	4-12	• Randomised trials provide the most reliable information about whether interventions work. • By using randomisation to allocate participants to groups, each participant has the same chance of receiving the active intervention or the comparison. This helps to ensure that the groups are comparable at the start of the trial. Therefore, if there are differences between the groups at the end of the trial, the differences can be reasonably attributed to the intervention being tested.	• ***Class Activity B:*** Classroom trial (to teach about randomised control - instructions on following pages and on PowerPoint slides) • **Q11.** **a.** What is the fairest way to create groups? **b.** Why is this (randomisation) the fairest way?	20 mins
Placebos and placebo effect	13-18	• *Note: *Do not mention "placebo effect" until after Class Activity C is completed.* • After the activity, explain the idea of placebo effect and the importance of 'blinding' in fair comparisons (i.e. so participants do not know which intervention they got)	• ***Class Activity C:*** How raising your arms can improve your balance (instructions on following pages) *After Class Activity C completed:* • **Q12** **a.** 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 do you think this could impact the results? **b.** How might placebo interventions be useful in research? • **Q13.** How could you minimise the impact of placebo effect in a study that was testing whether an intervention works?	10 mins
Fair comparison of interventions	19-25	As well as randomisation and blinding, fair comparisons of interventions ensure that: • the groups are similar at the start of the trial • participants in the groups are cared for equally (apart from the intervention being tested) • peoples' outcomes are counted/ analysed in the groups they were allocated to • outcomes are measured in the same way in the groups being compared • outcomes are measured for everyone • outcomes are assessed using reliable methods	• **Activity 7. Fair comparisons (pg 12-13 Student booklet)** • **Activity 8. More or less reliable? (pg 14 Student booklet)** *(if there is not enough time in the lesson for this activity, it can be completed as homework or as a revision activity at the beginning of the next lesson)*	15 mins

CLASS ACTIVITY B Randomised Controlled Trial - Instructions

BEFORE THE LESSON:

Prepare a randomisation schedule (see below for instructions). Use a class list of student names, assign a number to each student from a computer program that randomly chooses numbers in an order. Then separate students into two groups (C and D) based on whether they were assigned an odd or even number.

Instructions for creating a randomisation schedule:

- There are many websites on the internet that can be used to generate a list of random numbers or randomise into groups. One is: https://www.randomlists.com/team-generator
- Scroll down to "Edit settings" and type or paste the list of students into the field. Ensure that each student's name on a new line.
- Edit "Groups" to show "2"
- Select the "Rerun" button. This should generate a list of students in Group 1 (which will be called Group C for this activity) and Group 2 (which will be Group D).

DURING THE LESSON:

Step 1

Ask students to suggest ways of dividing the class evenly into two groups. For example, they may suggest:

- Everyone with surname A-M in one group, surnames N-Z in the other
- Numbering off (allocating each participant sequentially by alternating 'A' or 'B')
- Students choose a side of the room and put themselves into groups

Step 2

Choose one of their suggestions (except randomisation) and arrange the students into Groups A and B.

Step 3

Once the students are in two groups, record data (by tallying) for about 3 variables for each group. Record this somewhere that everyone can see (e.g. blackboard, whiteboard) and use the table below as a template.

Examples of variables to use:

The numbers of students with / who have:

- Birthdays between January and June
- Something currently on their head other than hair (i.e. hat, elastic, clip, headband)
- Even numbered birthdates (i.e. 2nd, 4th, 6th… etc. of any month)
- Eaten olives in the last week

Example table:

Non-random group allocation	Birthdays Jan - June	Hair extras	Eaten olives
Group A (assume 13 students)	5	4	2
Group B (assume 17 students)	8	7	0

This will illustrate if there is an equal number of students with these characteristics in both groups.

Step 4

Return to Step 2, but this time allocate students into Groups C and D using the already prepared randomisation schedule.

Step 5

Repeat Step 3 and record data about the same variables in each group. For example:

Random allocation	Birthdays Jan - June	Hair extras	Eaten olives
Group C (assume 15 students)	7	5	3
Group D (assume 15 students)	8	5	3

Step 6

i. Examine each table to compare how similar Groups A and B (non-random allocation) are and how similar Groups C and D (random allocation) are.

ii. Are Groups C and D more similar on the variables measured, than Groups A and B? Ideally, they should be (as in the example above). Although the numbers may not be exactly balanced, they are likely to be more balanced than they were with the non-randomised allocation.

iii. If the groups are not more similar when random allocation was used, use this opportunity to teach about the importance of the sample size of a study. The sample size (the number of students included in this trial) is very small compared to what usually happens in randomised trials. If the sample was much bigger (hundreds of students, for example) the improvement in the balance would be more noticeable. This can be demonstrated at a website that demonstrates probability and chance event - for example, http://students.brown.edu/seeing-theory/basic-probability/index.html. Show what happens to the number of times a 'head' or 'tail' occurs when a coin is flipped once, when it is flipped 100 times, etc.

CLASS ACTIVITY C — How raising your arms can improve your balance - Instructions

***** Do not mention anything about "Placebo effect" until after this activity *****

Step 1

Ask the students to form in the groups (C and D) that they were randomly allocated to during the previous randomisation activity.

Step 2

Once students are sitting, assign one group to raise their arms (while seated) for 60 seconds, while the other group rests their arms.

Explain that by raising the arms, blood drains from the end of the arms, which improves movement of blood around the body, and hence improves the ability of the body to balance.

*** This information is not true, but we want students to believe it to be true for this "placebo effect" example to work.*

Step 3

Ask everyone in the room to stand and balance on only their non-dominant leg for 1 minute and not hold onto anything for support. If you wish to make this harder, ask them to close their eyes.

Before they stand, advise students that as soon as they lose their balance (i.e. if they put their foot down for support, stumble, reach out to grab something), they must sit down.

Step 4

At the end of 1 minute, count how many students remain standing in each of the groups.

Teaching notes

- It is hoped that the psychological impact of advising the students that the "arms raised" students are expected to perform better means that they will perform better (and there will be more students standing in that group at 1 minute), based on the "placebo" effect.
- If this doesn't happen, have a discussion regarding the "expected" outcome and explain the placebo effect.
- Discussion could also point out that is not a very reliable randomised trial. For example, the sample size (i.e. number of students) is very small, and participants were not blinded (i.e. everyone knew which group they were in).

MODULE 4 Spotting bad science and thinking about numbers

BACKGROUND

- This module begins with a revision activity (Bad Science Bingo) that covers the main content from the previous three modules.
- One study is usually not sufficient to provide conclusive evidence about the effects of an intervention. Many interventions have been tested in more than one study. Often these studies provide contradictory results.
- Summarising just a few studies, using a convenient sample of studies, is problematic though. One problem is 'cherry picking': where people who are untrained in formal research processes or have a vested interest in promoting a certain result, pick and choose only those studies that support the result they would like to demonstrate.
- There is a type of study that is designed to overcome this problem, known as a systematic review. It aims to systematically locate, appraise and synthesise the results of all known studies on a topic.
- The way that the results of studies are presented in sources such as news stories and advertisements is often misleading. Along with the 'danger words' (e.g. breakthrough, miracle) that were discussed in Module 1, other verbal descriptions of intervention effects (e.g. rare, improve) can be misleading as they mean different things to different people.
- The use of relative results (which is the ratio of the probability of an outcome in one group compared with that in the comparison group) can make interventions look much more effective than they really are. Using absolute effects of an intervention (the difference in outcomes between the groups being compared) is a better way to present information. This concept will be introduced in this module, although detailed coverage of how to interpret the numbers in health claims and studies is beyond the current scope of the Health HACC program.
- The module and the program concludes with a brief discussion of some of the factors that a person should consider when making an informed health decision. These include: is the research relevant to you, do the outcomes matter to you, what are the intervention options, what are the benefits/advantages and harms/disadvantages of the intervention, and do the advantages outweigh the disadvantages?

LEARNING OBJECTIVES

1. Analyse health advertisements, detect examples of 'bad science', and justify why the nominated examples were selected.
2. Distinguish how systematic reviews compare to single studies and literature reviews.
3. Describe the benefits of systematic reviews.
4. Distinguish between intervention effects that are described using relative terms and those that use absolute terms; and identify which is preferable to use when making decisions about using interventions.
5. Explain some of the key factors that a person should consider when making an informed health decision.

RESOURCES NEEDED

- Module 4 PowerPoint Slides
- Student Booklet activities 9 and 10
- Laminated Bad Science Bingo advertisements (Class Activity D)
- Access to the internet for showing web-based videos

PROCEDURE, KEY DISCUSSION POINTS and corresponding activities and slides

Topics	Slides	PowerPoint slides - main content	Discussion questions and Learning activities	Est. time
Putting it all together – looking critically at health claims	• ***Class Activity D:*** Bad Science Bingo. This activity summarises key content from Modules 1-3. **(slides 1-10 and pp 15-16 Student booklet)** • Two advertisements provide students with the chance to detect examples of bad science and play Bad Science Bingo. » The bingo sheets for each advertisement are in the student booklet. » Laminated copies of the advertisements are in the intervention pack and can be distributed to the students. The advertisements on are also on slides 5 and 8 (for display when checking answers). • For each advertisement, after the first student has called out 'Bingo', check that they have circled five correct responses in a line. If so, ask them to explain to the class where in the advertisement they spotted each of the examples of bad science. If they cannot, ask another student who has called out 'Bingo' to explain.			20 mins
Is one study enough?	11-14	• Explain why one study is usually not enough and that studies often have conflicting results. • Introduce the idea of 'cherry picking' and that this can make claims misleading.	• **Q14.** Why might someone present the results from only a few studies?	5 mins
What is a systematic review, and why is it important?	15-17	• A systematic review looks at all the research performed related to the PICO question.	• Video (3 minutes) explaining systematic reviews: http://www.cochrane.org/news/what-are-systematic-reviews • Figure - Hierarchy of evidence **(pg 17 Student booklet and slide 15)**	5 mins
Making sense of the numbers in health claims	18-25	• Explain, and show examples, of intervention effects presented using relative measures and absolute measures • Explain that verbal descriptions of intervention effects can be misleading, as can relative effects alone. Absolute effects are preferable.	• **Q15.** What do the following words mean? (rare, frequent, greatly improved, better, natural) • **Activity 9. Absolute versus relative effects (pg 18-19 Student booklet)** • **Q16.** Are relative or absolute effects a more accurate representation of the effect of an intervention? Justify your reasons.	5 mins
Making informed health decisions	26-29	Key factors a person should consider to making an informed health decision: - is the research relevant to me? - do the outcomes matter to me? - what are the intervention options? - what are the benefits/ advantages and harms/ disadvantages? - do the advantages outweigh the disadvantages?	• **Activity 10. Study relevance and outcomes that matter to you (pg 20 Student booklet)**	5 mins
Take home messages	30-34	DON'T be fooled by health claims! • Recognise claims about health interventions. They are everywhere. ASK: what is the evidence behind this claim? THINK: is the evidence reliable and based on fair comparisons of the intervention?		

12 SUMMARY POINTS
HOW TO NOT BE FOOLED BY FALSE HEALTH CLAIMS

1. Examine health claims critically

Many claims about health interventions are designed to trick and mislead you.

Ask - what is the evidence behind this claim?

2. Watch out for 'danger' words and phrases

Many claims contain danger words (e.g. dramatic, cure, miracle) and research-sounding phrases (e.g. 'clinically-proven', 'scientifically tested').

Ask – what is the evidence behind this claim?

3. Don't believe the opinion of others – look at the research behind the claim

Many information types (such as anecdotes, testimonials, endorsements) are not reliable sources of information.

Accurate health claims come from reliable research studies.

4. Be aware of conflicts of interest

Conflict of interest (e.g. money, belief that an intervention works) can intentionally or unintentionally distort the results of a study.

Look at who stands to gain from the results of a study or the use of a health intervention.

5. Association is not the same as causation

An association between variables does not always mean that one causes the other.

Check if claims of causation are appropriate.

6. Not all research is created equal

Even health claims from research studies may not be reliable. It depends on the type of study and how well it was designed and conducted.

7. Was the intervention compared to something else?

To test if an intervention works, a research study should compare the intervention to something else so that we know what would have happened without the intervention.

Randomised trials provide the most reliable information about whether interventions work.

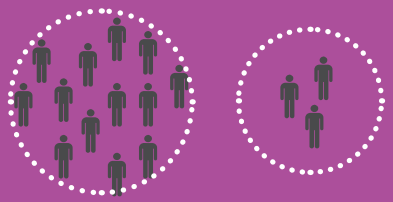
8. Was it a fair comparison?

Fair comparisons of interventions are important to minimise bias. Fair comparisons ensure that:

- randomisation is used to allocate participants to groups
- groups are similar at the start of the trial
- participants are blinded to which group they are in (where possible)
- participants are cared for equally (apart from the intervention being tested)
- outcomes are reliably measured for everyone and in the same way in all groups
- participants' outcomes are analysed in the groups they were allocated to

9. Are there enough participants?

Small sample sizes in studies can be problematic. Larger samples often provide more reliable results.



10. One study is usually not enough

One study is usually not sufficient to provide conclusive evidence about whether an intervention works. Studies can often provide contradictory results. Check if a systematic review exists - these are types of studies that systematically find, check, and summarise the results of all known studies of an intervention.

11. Look carefully at numbers in a health claim – 'relative' numbers can be misleading

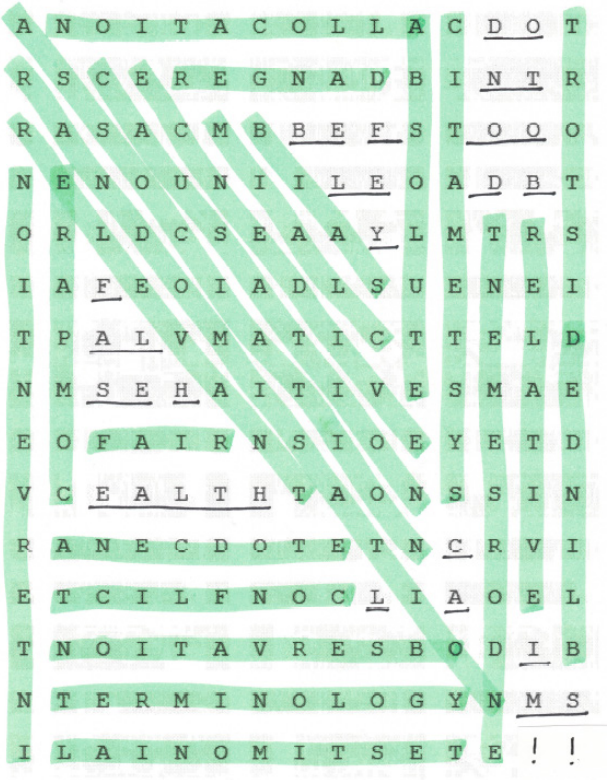
Relative numbers can make an intervention look more impressive than it really is. Check the absolute numbers to look at the difference between the groups of the study.

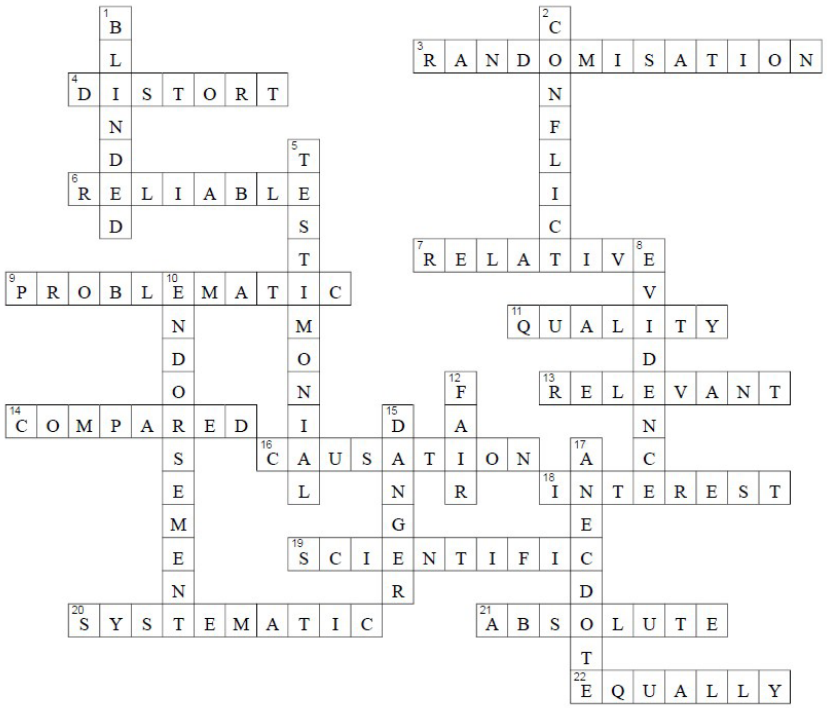
12. Do the advantages outweigh the disadvantages of an intervention?

When considering whether to use a health intervention, consider if the study measured outcomes that are relevant and matter to you. Also think about whether any advantages (or benefits) of the intervention matter more than any disadvantages (such as side-effects, cost, time, inconvenience).

EXTRA Additional optional activities

If you wish to direct students who finish any of the in-class activities before others, there is a Find-A-Word and a Crossword at the end of the Student Booklet. The answers to both are provided here.





GLOSSARY (from http://getitglossary.org)

Allocation: the process of assigning participants in a study to treatment comparison groups.

- In studies where participants decide themselves which treatment they are allocated, there is a high risk of bias due to the likelihood of there being differences between the [treatment comparison groups (confounders) / treatment comparison group] other than the treatments being compared.

Baseline characteristics: descriptive information about the participants in a study collected at the beginning of the study.

- Researchers collect this information about each participant at the beginning of a study, before they have received the treatments that are going to be compared in a treatment comparison.

Bias: a type of error that may affect the results of a study because of weaknesses in its design, analysis or reporting.

- Biases (systematic errors) distort effect estimates away from the actual effect.
- Biases are caused by inadequacies in the design, conduct, analysis, reporting, or interpretation of treatment comparisons.
- Because it is generally not possible to know the degree to which an effect estimate is biased, judgements must be made about the risk of bias using criteria that assess factors that are known, or thought to be associated with bias, such as unconcealed allocation of participants to treatments (see allocation schedule concealment).

Blinding: in treatment comparisons, actions intended to prevent study participants (the people receiving and providing care) or the researchers (or others measuring outcomes) from knowing which participants received which treatment.

- Blinding is intended to prevent people who can potentially introduce bias into a treatment comparison through knowledge of the treatment allocation from doing so.
- People who can potentially be blinded include the people receiving the treatments being compared, the people delivering the treatments, data collectors, people who assess the outcomes, data analysts, the data safety and monitoring committee, and manuscript writers.
- (see "Double blinding")

Case-control study: a type of non-randomized study comparing the characteristics of people with a particular health condition (cases) with the characteristics of people without that condition (controls), to find what may have caused the problem.

- For example, a comparison of people admitted to hospital with heart attacks (cases) with others admitted with different diagnoses found that the people with heart attacks were less likely to have used aspirin. The apparent protective effect of aspirin against heart attack was subsequently confirmed in randomized studies.

Causal association: association between two variables where a change in one makes a change in the other one happen.

- The presence of an association or relationship does not necessarily imply causation (a causal relationship).
- Observing a simple association between two variables - for example, having received a particular treatment and having experienced a particular outcome - cannot be assumed to mean that the treatment caused the outcome. The association may reflect the effects of biases from confounders.
- For example, if people who choose to take a treatment have better outcomes (e.g. fewer heart attacks), the treatment is associated with the outcome. However, people who seek and receive that treatment may be healthier and have better living conditions than people who do not seek and receive the treatment, so the former have better outcomes for those reasons, rather than because of the treatment.

Chance: see "play of chance"

Cohort study: a type of non-randomised study in which defined groups of people (cohort) are followed up over time to explore the effects of treatments or other factors that may affect health outcomes.

- Synonyms: longitudinal study, prospective study, retrospective study
- In cohort studies, individuals who share certain characteristics (a diagnosis, for example), or subsets of them are followed up to record their experiences, including whether they have outcomes of interest.
- For example, people who were exposed or not exposed (or exposed at different levels) to a particular treatment, or other factor of interest could be compared.

Controlled study: a study with two or more treatment comparison groups

- There are many types of controlled studies, including randomized studies (sometimes called randomized controlled trials), non-randomized trials, cohort studies, case-control studies, and controlled before-after studies.
- Sometimes the term controlled study is used to refer only to studies where the researchers allocated participants to treatment comparison groups; sometimes controlled study is used to refer only to studies where non-random allocation was used.

Critical assessment: judging the risk of bias, results and applicability of evidence.

- Synonyms: critical appraisal, critical review
- Critical appraisal or assessment is systematic and explicit judgement of the risk of bias, results and applicability of systematic reviews or studies.

Double blinding: actions intended to prevent two (or more) groups of people involved in a study knowing which participants received which treatment.

- Synonyms: double masking
- Double blinding has multiple definitions and is interpreted in different ways.
- People who can potentially be blinded include the people receiving the treatments being compared, the people delivering the treatments, data collectors, people who assess the outcomes, data analysts, the data safety and monitoring committee, and manuscript writers.
- Unless stated, it is not clear which of these people were blinded in a "double blind" study.
- Because the meaning of double blind is ambiguous, we recommend not using it. It is better to consider explicitly who was blinded, and who was not blinded, and how that might have protected against or led to a risk of bias, including placebo effects, differences in the care provided to the participants in a study other than the treatments being compared (performance bias), or differences in how outcomes are measured, in treatment comparison groups (measurement bias).

Evidence, research: see research evidence (research findings, research results)

Explanatory trial: a study designed to assess the effects of a treatment given in ideal circumstances.

- Synonyms: efficacy trial
- Studies to assess the effects of treatments can be designed to address one of two broad questions:
- "Can this treatment work, given ideal circumstances?" or "Does this treatment work, in the messy circumstances of the real world?"
- Those studies that address the first of these questions are referred to as 'explanatory', or 'efficacy' trials; those that address the second question are referred to as 'pragmatic', or' effectiveness' trials

Fair comparisons of treatments: studies designed, conducted, reported and interpreted to minimize bias and the play of chance in measuring treatment effects.

- Fair tests of treatments are evaluations designed to minimize the risk of being misled by systematic errors (biases), or the play of chance. We refer to these as "fair comparisons" to avoid confusion with diagnostic tests, and to emphasize that fair tests of treatments always involve a comparison with some other treatment (or withholding a treatment).

Hierarchy of evidence: see "Level of evidence"

Intervention: see "Treatment"

Level of evidence: an indication of where a type of study lies in a hierarchy of evidence, based on the risk of bias

- Synonyms: hierarchy of evidence
- "Level of evidence" is an ambiguous term, which sometimes refers to where a type of study (study design) lies in a hierarchy of evidence. Some [study designs\study design] have less risk of bias for a particular type of question. For example, randomized studies have less risk of bias than non-randomized studies for questions about treatment effects. However, there are other factors that can increase or decrease the risk of bias in both randomized and non-randomized studies. Hierarchies of evidence (based on study design) can be useful, for example, in deciding which study designs to include in a systematic review. However, they should not be confused with assessments of the risk of bias, or the certainty of the evidence, which should be assessed using explicit criteria. Because "level of evidence" can also refer to (or be confused with) the risk of bias, or the certainty of the evidence, we recommend against using this term.

Low risk of bias: in studies of treatment effects, the extent to which the design and conduct of a study eliminates or reduces bias.

- Synonyms: internal validity
- In treatment comparisons, validity, sometimes specified as internal validity, refers to the extent to which the design and conduct of a study eliminates or reduces bias in the effect estimate.

Meta-analysis: statistical combination of estimates derived from two or more similar studies, to give an overall effect estimate.

- Meta-analysis is the statistical synthesis of data from separate but similar (comparable) studies, to generate a quantitative summary of the results overall, including an overall (average) effect estimate, the confidence interval for that estimate, and a measure of how inconsistent (heterogeneous) the effect estimates from the individual studies are. Meta-analysis is often used in systematic reviews but is not a necessary component of such reviews.

Nocebo effect: undesirable effect that is or could be caused by an inactive treatment, presumed to act psychologically through suggestion

- Nocebo effects are undesirable effects of an inactive treatment, such as drugs, devices, or procedures without active ingredients. Active treatments can also have nocebo effects. For this reason placebos are sometimes given to a comparison group in studies to distinguish between placebo effects and nocebo effects, and treatment effects beyond any placebo or nocebo effects.
- See "Placebo effect"

Outcome: in treatment comparisons, a good or bad event or development that can happen after a treatment, and is measurable in studies.

- Synonyms: outcome measure
- In studies of treatment effects, outcomes are measures of health or disease (e.g. survival, having a stroke, pain or quality of life), behaviours (e.g. smoking), or other potential benefits or harms of treatments (e.g. resource use) that affect the natural progress of the health condition that is being treated.

PICO: commonly used acronym for the key components of a research question: Patient (or population), Intervention (treatment, test or exposure), Comparison, and Outcome

Placebo: an inert substance, device or procedure used as a comparator in studies assessing the effects of a treatment.

- A placebo is a dummy or sham treatment that does not contain active ingredients, which has been designed to be indistinguishable from the active treatment(s) being assessed.
- It is used to blind participants and others involved in a study of treatment effects, and to reduce the risk of placebo effects; i.e. effects that are, or could be caused by an inactive treatment, presumed to act psychologically through suggestion.
- Placebos can help prevent differences in the care provided to the participants in a study, other than the treatments being compared (performance bias), and so reduce differences in how outcomes are measured in treatment comparison groups (measurement bias).

Placebo effect: desirable effects that are or could be caused by an "inactive" treatment, presumed to act psychologically through suggestion

- Placebo effects are desirable effects of an "inactive" treatment, such as drugs, devices or procedures without active ingredients.
- Active treatments can also have placebo effects. For this reason, placebos are sometimes given to a comparison group in studies to distinguish between placebo effects and nocebo effects and treatment effects beyond any placebo or nocebo effects.

Play of chance: in treatment comparisons, a type of error that may affect the results because too few events or outcomes have been observed to provide a reliable measure of the treatment effects

- Synonym: random error
- When comparing two treatments, any differences in results may simply reflect the play of chance.
- The way to avoid being misled by the play of chance in treatment comparisons is to base conclusions on studying sufficiently large numbers of patients who die, deteriorate, improve, or stay the same.

Random: in studies, random means according to chance, unpredictable, without pattern.

Random allocation: the process of assigning participants in a study to treatment comparison groups using a chance process, like drawing lots, to protect against bias.

- Random allocation of participants to treatment comparison groups ensures that each participant has a known (usually an equal) chance of being assigned to any given group.

Randomised studies: a category of studies comparing two or more treatments in which random allocation is used to assign participants to treatment comparison groups

- Randomised studies, commonly called randomized trials, are a treatment comparison in which two or more treatments, possibly including a placebo or withholding a treatment, are compared after random allocation of participants to treatment comparison groups.

Research evidence: the findings of studies, including systematic reviews.

- Synonyms: research findings, research results
- Evidence consists of facts (actual or asserted) intended for use in support of a conclusion. Research evidence is facts that have been systematically collected and analysed using explicit methods. Using systematic methods reduces the risk of being misled by bias (systematic errors) or the play of chance. Explicitly describing the methods that were used enables people to assess the risk of bias and of being misled by the play of chance.

Study: An investigation using specified methods to answer a research question; e.g. about the effects of treatments.

- Synonyms: evaluation, test, test of treatments, treatment comparison, treatment test, trial
- Research requires that studies address questions to which we don't know the answer. Depending on the nature of the research questions, different study designs will be appropriate.
- Different types of studies can be used to evaluate treatment effects, including randomized studies and non-randomized studies.

Systematic review: a summary of studies addressing a clear question, using systematic and explicit methods to identify, select, and critically appraise relevant studies, and to collect and analyse data from them.

- Systematic reviews of research evidence use scientifically defensible, explicit methods to reduce bias (systematic error) and, if appropriate and possible, meta-analysis to reduce the play of chance.

Theory: a supposition or a system of ideas intended to explain how a treatment works.

- Theories about treatment effects have sometimes been used to justify the introduction and use of treatments, sometimes with disastrous results. Unless the validity of theories is assessed in fair tests, patients will continue to suffer and die unnecessarily.
- For example, the untested theory that babies would be less likely to choke and die if put to sleep on their fronts led to tens of thousands of avoidable cot deaths. Furthermore, theories can lead to the rejection of an effective treatment, for example, when some neuroscientists declared it inconceivable that magnesium sulphate could be an effective anti-convulsant. A large randomized study confirmed that the drug was effective in treating eclamptic convulsions.

Treatment: any preventive, therapeutic, rehabilitative or palliative action intended to improve the health or wellbeing of individuals or communities.

- Synonyms: intervention
- Treatments can, for example, be drugs, cells and other biological products, surgical procedures, radiological procedures, physical therapies, devices, psychological or behavioural treatments, screening and other types of preventive care, public health actions, and changes in how healthcare is delivered or financed.

Trial: see "Explanatory trial"

Validity: see "Low risk of bias"

Variables: any measurable characteristic that varies.

- Synonyms: characteristics, entities
- Variables may change from group to group, person to person, or within one person over time (e.g. weight).
- They may be measured at different times in a study and used in different ways in analyses.

GENERAL REFERENCES

Website: That's a Claim! https://thatsaclaim.org/health/

This website provides a framework for thinking critically about claims, evidence, and choices. For most of the concepts covered in Health HACC, it contains a summary of them, as well as more detail and resources for each. A downloadable summary poster is also available.

Tips for finding health information online

- https://www.betterhealth.vic.gov.au/health/servicesandsupport/finding-reliable-health-information
- https://www.healthdirect.gov.au/health-information-online

Some reliable resources to begin searching for health information

- https://medlineplus.gov/
- https://www.cochranelibrary.com/

Other resources

- http://getitglossary.org/

Book for general background reading - "Testing Treatments"

- http://www.testingtreatments.org/
- https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0050892/

MODULE SPECIFIC REFERENCES

MODULE 1

Miracle fake skin cream and other unreliable studies

- **http://www.news.com.au/entertainment/tv/fake-wonder-cream-experiment-shows-why-you-cant-trust-a-clinical-trial/news-story/4326ccf905bea6c88abf4f2fbd1f7bdb**

Anecdotes

- **https://en.testingtreatments.org/rumor-has-it/**

Conflicts of interest, bias and research hierarchy

- **http://ccnmtl.columbia.edu/projects/rcr/rcr_conflicts/foundation/#1_1**
- **http://www.testingtreatments.org/bias-introduced-looking-study-results/**
- **http://www.testingtreatments.org/recognizing-researchersponsor-biases-fraud/**
- **http://www.testingtreatments.org/dealing-with-biased-reporting-of-the-available-evidence/**
- **https://en.testingtreatments.org/does-it-work/**
- **http://www.testingtreatments.org/book/what-can-we-do-to-improve-tests-of-treatments/research-good-bad-and-unnecessary/distorted-research-priorities/who-decides-what-gets-studied/**

MODULE 2

Randomised control trials vs observational

- https://en.testingtreatments.org/randomised-controlled-trials-vs-observational-studies/

Not all scientific studies are created equal

- https://ed.ted.com/lessons/not-all-scientific-studies-are-created-equal-david-h-schwartz

MODULE 3

Randomised trials / randomisation

- https://en.testingtreatments.org/making-sense-randomized-trials-20-minutes/
- http://generationr.org.uk/?video=randomisation-explained-in-1-minute
- http://www.testingtreatments.org/book/thumbnails/methods/random-allocation-a-simple-explanation/
- https://en.testingtreatments.org/lisa-luxuriant-hair/

Blinding and placebo

- https://en.testingtreatments.org/the-need-to-avoid-differences-in-the-way-treatment-outcomes-are-assessed/

Treating groups equally

- https://en.testingtreatments.org/the-need-to-compare-like-with-like-in-treatment-comparisons-2/

MODULE 4

Systematic review information

- https://en.testingtreatments.org/strictly-cochrane-quickstep-around-research-systematic-reviews/
- http://www.testingtreatments.org/2017/01/05/way-teach-systematic-reviews/

Systematic review examples

- Corticosteroids for fetal lung development (Cochrane logo)
  - https://www.cochrane.org/news/cochranes-logo-review-gets-update
- SIDS – placing babies on their backs decreases the risk of SIDS
  - https://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0050887/
- Measels, Mumps, Rubella – Dr. Wakefield controversy
  - https://en.testingtreatments.org/mmr-facts-case-dr-andrew-wakefield/
- Blood type diet – a health intervention, shown to have no evidence behind it
  - http://ajcn.nutrition.org/content/98/1/99.long

Absolute versus relative risk

- https://www.healthnewsreview.org/toolkit/tips-for-understanding-studies/absolute-vs-relative-risk/

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