



Evaluating the evidence base for treatment

Evaluating Therapeutic Treatments -

Biological Treatments

- Psychopharmacology (drug therapy)
- ECT
- Surgery
- Alternative Therapies such as Herbal Medicine

Psychological Treatments

- Psychotherapy – CBT, DBT, Humanistic approaches
- Family Systems Therapy
- Interpersonal therapy

Relative effectiveness of drug therapy versus psychotherapy is an area of growing research

Evaluating Treatments – some questions

- How do you judge the effectiveness of any given treatment or intervention?
- What challenges do you think that you may encounter?
- What factors should you take into consideration?

- This session aims to explore some examples of clinical trials and a systematic review which includes a meta analysis.

- [APA guidelines for evaluating treatment](#)

Evidence – CBT for GAD

Butler et al. (1991)

42% of pp`s receiving CBT for GAD showed clinically significant changes in behaviour compared to 5% undergoing exposure-response selection alone.

Borkovec & Costello (1993)

CBT more effective than both relaxation alone and non-directive counselling
58% of pp`s symptom free compared to 33% (relaxation) and 22% (non-directive counselling).

Durham et al. (1994)

CBT more effective than psychodynamic therapy in short and longer term –
76% versus 42% showed improvement
66% versus 20% returned to normal function
10% versus 24% drop out rate

How do you judge the efficacy of the treatment or intervention?

- How long does it take to administer before it starts working?
- Who does it work for?
- Are there any examples where it does not work?
- Does it work equally well with both male patients and female patients?
- Does it work in the same way in children, adolescents and adults?
- Are there any side effects?
- How much does it cost?
- How safe is it to use?

What challenges do you think you may encounter?

- Sourcing the actual treatment
- Waiting lists for treatment
- Patients reluctance to participate
- Non-compliance
- Length of time needed to take effect
- Working with vulnerable or unpredictable individuals
- Anything else?

What factors should you consider?

- Psychological treatment or pharmacological treatment
- Length of efficacy – short term and long term
- The potential for side effects
- Relapse rates
- Drop out rates and attrition
- Anything else?

Evidence: Psychological versus Pharmacological over time

GAD – drug treatment similar/better in short term, CBT better in long term.

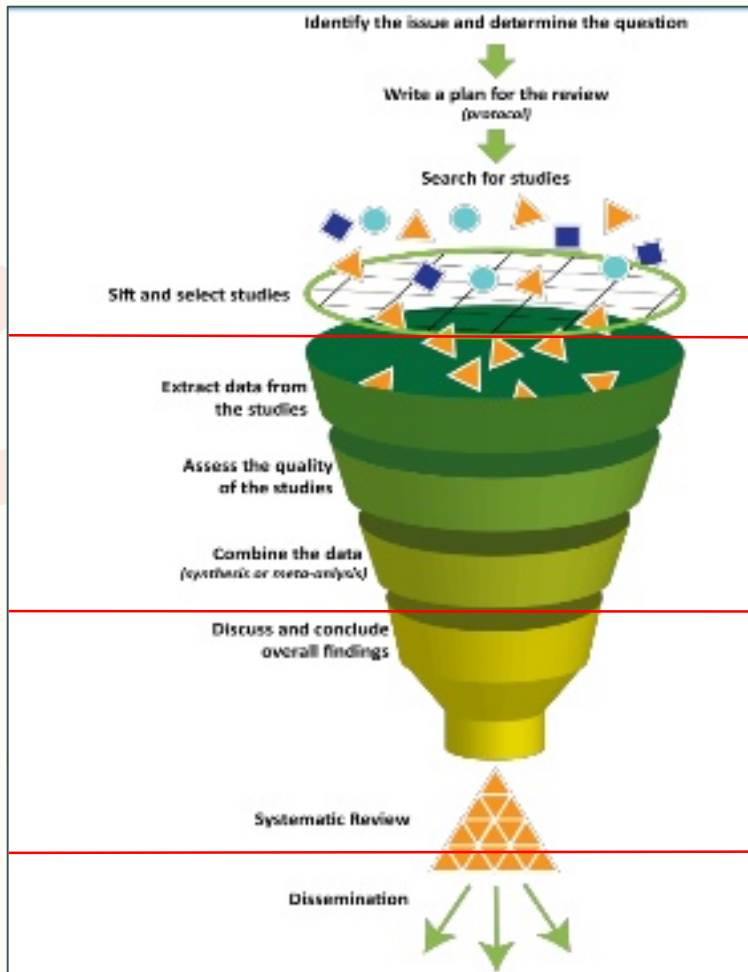
Power et al. (1990)
Compared CBT with anti-anxiety drugs or a placebo.
- Improvements were 85%, 68% and 37% respectively
- Six months post treatment complete recovery in 70%, 40% and 21% respectively

Borkovec et al. (2002, 2003)
CBT more effective than benzodiazepines, humanistic therapy and controlled conditions.

What is a Systematic Review?

- The systematic review is a powerful research methodology that answers questions on the basis of good evidence and provides researchers with a valuable, comprehensive and up-to-date summary of work conducted in a specific area. Systematic reviews are not a solo effort; they are often conducted by a team of researchers.
- The next slide will illustrate the steps required to plan and execute a systematic review

Systematic Review Process



1. Decide upon the question.
2. Write a protocol. This will include eligibility criteria, search strategy, validity criteria, data extraction, analysis and dissemination.
3. Retrieve eligible literature.
4. Data collection.
5. Analyse data.
6. Draw conclusions and
7. Report findings.

Systematic review versus Literature review

You may be familiar with writing a literature review, however a systematic review is somewhat different

	Systematic Review	Literature Review
Question	Focused on a single question	Not necessarily focused on a single question but may describe an overview
Protocol	A peer review protocol or plan is included	No protocol is included
Background	Both provide summaries of the available literature on a topic	
Objectives	Clear objectives are identified	Objectives may or may not be identified
Inclusion & exclusion criteria	Criteria stated before review is conducted	Criteria not specified
Search strategy	Comprehensive search conducted in a systematic way	Strategy not explicitly stated
Process of selecting articles	Usually clear and explicit	Not described in a literature review
Process of evaluating articles	Comprehensive evaluation of study quality	Evaluation of study quality may or may not be included
Results and data synthesis	Clear summaries based on high quality evidence	Summary based on studies where the quality of articles may not be specified. May also be influenced by the reviewer's theories, needs and beliefs.
Discussion	Written by an expert or group of experts with a detailed and well-grounded knowledge of the issues.	

A Meta Analysis

Literature Review

- **Summarizes** a topic that is **broad** in scope (e.x. cancer treatment)
- **Qualitative**
- May use sources that are **biased**
- Does **not** define what types of studies will be included (looks at everything)

Systematic Review

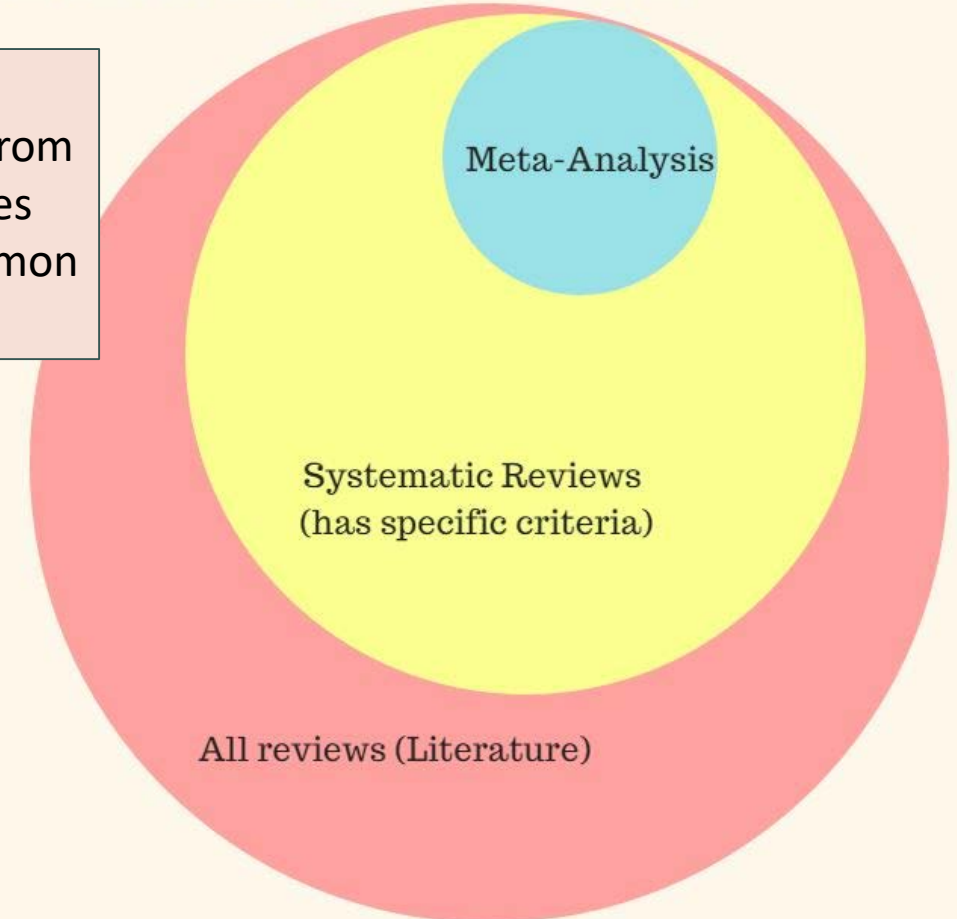
- Answers a **specific clinical question** (e.x. PICO) (e.x. Is Vitamin C or Chemotherapy a better cancer treatment in patients over the age of 40?)
- **Defines** a specific search strategy; lists what will be **included and excluded** in articles selected
- Can include a meta-analysis within the review (but no necessary)

Meta-Analysis

- Looks at studies from a systemic review
- Purpose: Combines similar studies and pulls **data** to get a **statistically** significant result
- Important because **statistical analysis** may overturn results of smaller clinical trials

A meta analysis combines results from two or more studies to estimate a common or average effect

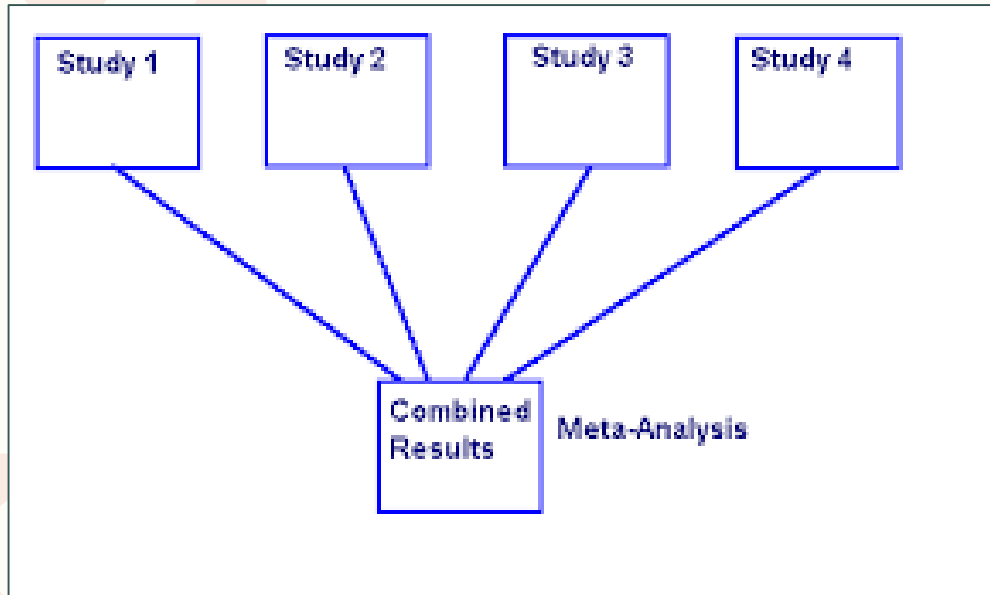
How Are Reviews Related?



Why conduct a meta analysis?

Functions of Meta-Analysis

- Identifies **heterogeneity** in effects among multiple studies and, where appropriate, provide summary measure
- Increases **statistical power** and precision to detect an effect
- Develops ,refines, and tests **hypothesis**
- Reduces the **subjectivity** of study comparisons by using systematic and explicit comparison procedure
- Identifies **data gap** in the knowledge base and suggest direction for future research
- Analyses if and how previous studies have **modified knowledge** on a certain topic



Using RCT's: Randomised Controlled Trials in Clinical Psychology

- Longitudinal Studies – investigating phenomena over an extended period of time.
- Prospective designs - participants are enrolled into the study before they develop a potential illness. The opposite is a retrospective study, where researchers enrol people who already have a disease/condition.
- Randomised Controlled Trials - similar people are randomly assigned to 2 (or more) groups to test a specific treatment or intervention. One group (the experimental group) has the intervention, the other (the control group) has an alternative intervention, a placebo or no intervention. The groups are followed up and outcomes are measured at specific times and any difference in response between the groups is assessed statistically.
- Epidemiological Studies – the measurement of disease outcomes in a population 'at risk'. They include how often diseases occur in different groups of people and why. This information is used to plan and evaluate strategies to prevent illness and as a guide to the management of patients in whom disease has already developed.

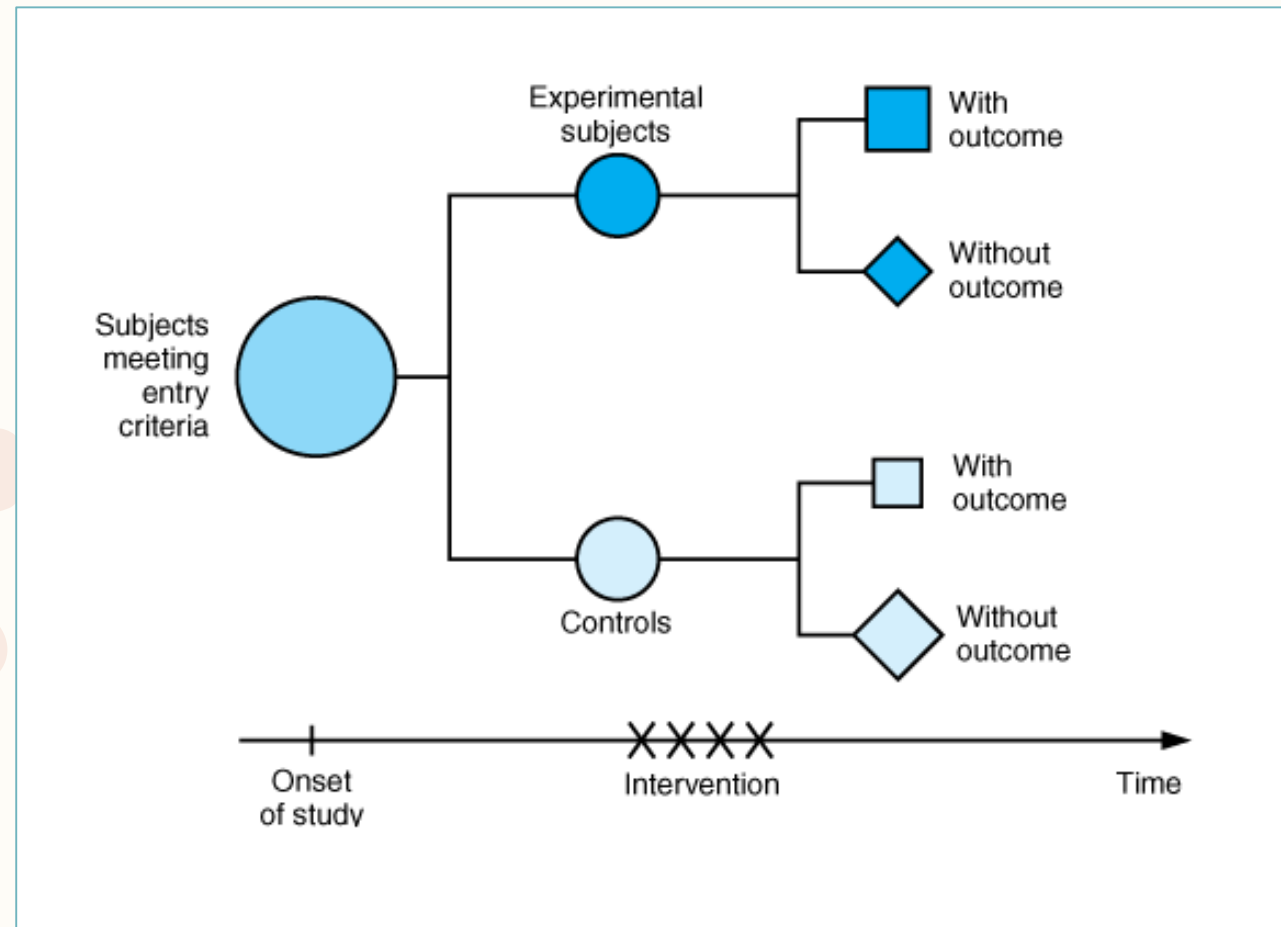
How is research conducted in Clinical Psychology?

- Experimental Designs – where specific variables are manipulated to establish cause and effect. Hypotheses are predicted based upon previous research.
- Qualitative Methods – In contrast to quantitative research where large numbers of participants are involved and a focus on data analysis, qualitative research involves smaller numbers of participants, exploring the process and context of illness development/progression/remission.
- Mixed Designs – when both quantitative and qualitative methods are used to broaden the information base. Often used when one approach produces unexpected or insufficient findings.

The development of a therapeutic intervention

- An intervention is a set of sequenced or planned actions intended to help an individual (or specific target groups) to make a positive improvement in relation to a specific defined outcome.
- Interventions should be theory based, specifying a set of changeable predictors to describe, explain and predict intended change.
- The theory should inform the intervention to the extent that the exact change will occur in the predicted theoretical direction.
- For example, if you were designing a CBT based intervention for anxiety, which elements of cognition and behaviour would you expect to change?

Randomised Controlled Trials



E.g. RCT: Sundquist et al. (2015).

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- Aims-
 - To compare mindfulness-based group therapy with treatment as usual (individual CBT) in patients with stress, anxiety, depression or adjustment disorders.
 - Method:
 - 8 week RCT conducted Spring 2012, Sweden
 - Eligible patients (20-64yrs) scoring low on `Patient Health Questionnaire, Hospital Anxiety and Depression Scale or Montgomery-Asberg Depression Rating Scale.

All patients (randomised – N = 215)

Mindfulness group
N = 110

Dropped out = 9

Started mindfulness = 101

Control group
N = 105

Dropped out = 10

Started treatment = 95

After 8 weeks

Observed cases =
MADRS-S – 81
HADS-D – 83
HADS-A – 83
PHQ-9 – 82

Dropped out = 48

After 12 months

Observed cases =
MADRS-S – 62
HADS-D – 62
HADS-A – 62
PHQ-9 – 61

Observed cases =
MADRS-S – 86
HADS-D – 86
HADS-A – 86
PHQ-9 – 85

Dropped out = 49

Observed cases =
MADRS-S – 56
HADS-D – 55
HADS-A – 56
PHQ-9 – 56

Results and conclusions

- For all scales and in both groups scores on the scales improved significantly after 8 weeks.
- The results were still observable after 12 months.
- There were no significant differences between the mindfulness (MGT) and control (TAU) groups.
- Mindfulness-based group therapy was non inferior to `treatment as usual` for patients with depressive, anxiety, stress or adjustment disorders.