



Professor Richard Brown

Module:

Psychological Foundations of Mental Health

Week 5:

Psychological therapies: From behaviour modification to behaviour therapy

Topic 4

Evaluating the efficacy of cognitive therapy

Part 1 of 3

Topic list



This week, we will be looking at the following topics:

- Topic 1: The First Wave - Behavioural Psychotherapy
- Topic 2: The Second Wave - The role of cognition and the emergence of cognitive therapy
- Topic 3: Cognitive therapy in principle and in practice
- **Topic 4: Evaluating the efficacy of cognitive therapy**

Click **Next** to continue

In this topic



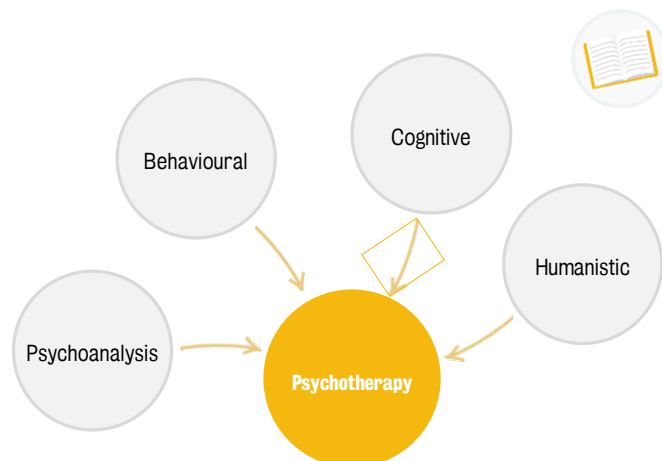
- *Introduction to the design and evaluation of clinical trials for psychotherapy research*
- Systematic Review
- The efficacy of CBT for adult depression

Click **Next** to continue

Psychotherapy definition (1)

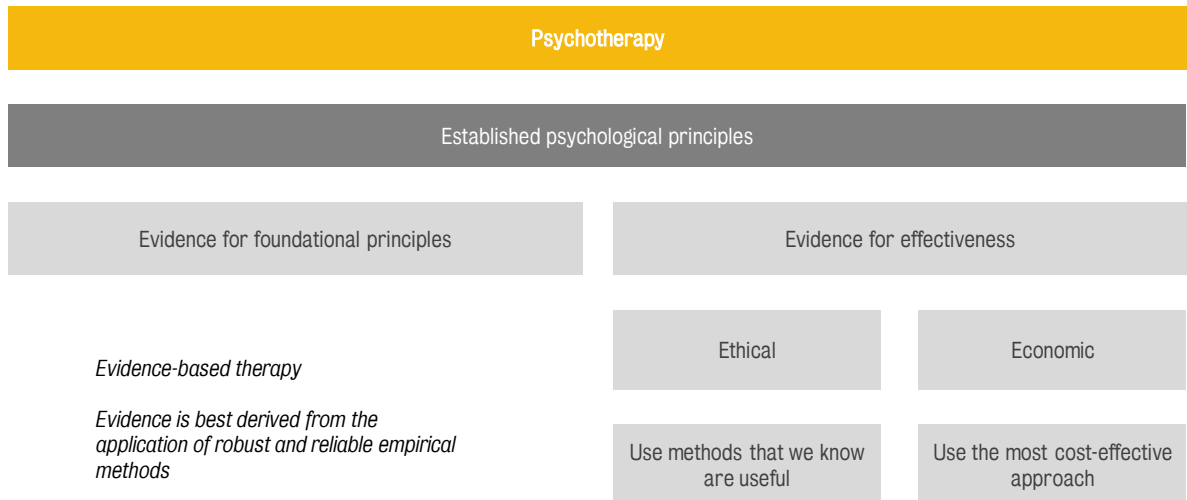
Psychologically based approach that seeks to help a person change or overcome mental and/or physical problems.

“Psychotherapy is the informed and intentional application of clinical methods and interpersonal stances derived from established psychological principles for the purpose of assisting people to modify their behaviors, cognitions, emotions, and/or other personal characteristics in directions that the participants deem desirable”

Click **Next** to continue

Campbell et al. (2012)

Psychotherapy definition (2)



Campbell et al. (2012)

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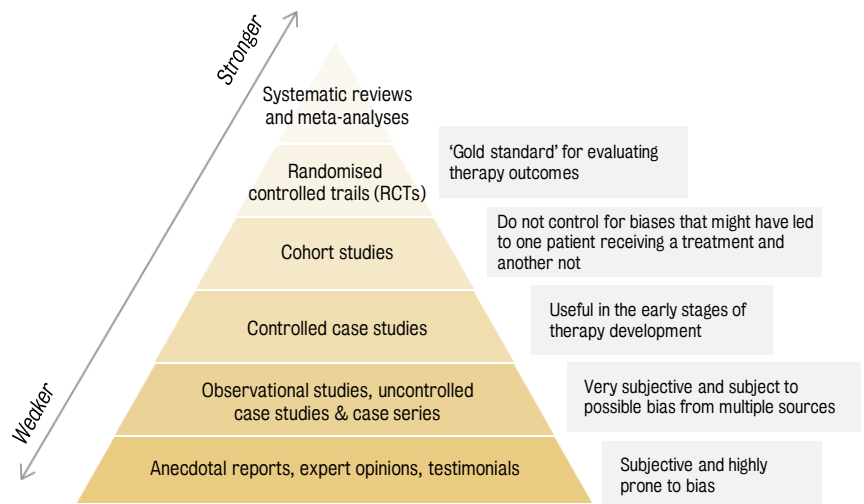
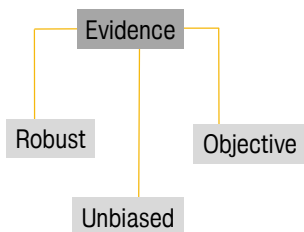
Topic 4: Evaluating the efficacy of cognitive therapy

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Levels and strength of evidence

Evidence-based practice in psychotherapy is part of a wider approach within healthcare.

We need evidence that a treatment is effective

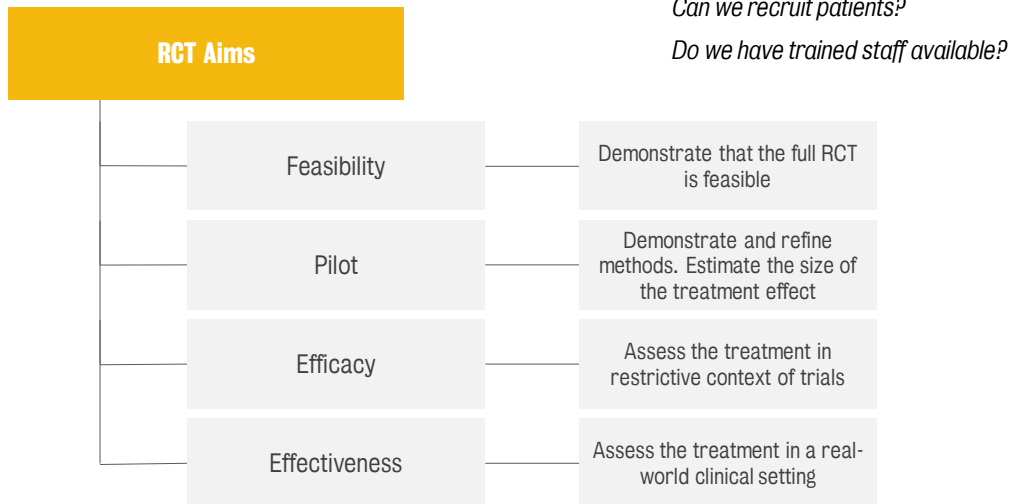


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The Randomised Controlled Trial (RCT) (1)



The Randomised Controlled Trial (RCT) (2)



The Randomised Controlled Trial (RCT) (3)



Careful selection of cases

E.g. Reduce between-patient variability

Patients must have a Beck Depression Inventory score of greater than 21

E.g. Remove obstacles to the safe and effective delivery of treatment

Patients with poor literacy skills who can't keep written records

E.g. Remove clinical confounding factors

Patients suffering symptoms of both depression and anxiety

Patient A

Inclusion criteria

Take part

Disadvantages of restrictive criteria

- problems recruiting sufficient numbers
- unrepresentativeness and lack of generalisability of results

Patient B

Exclusion criteria

Ruled out

The Randomised Controlled Trial (RCT) (4)



Two or more 'treatments'

Fundamental aim: Is a treatment effective?

Active treatment

Control treatment

Types of trials

Superiority trial
New treatment is better than existing or no treatment

Non-inferiority trial
New treatment is no worse than the existing treatment

Placebo controlled

Dummy treatment without active 'ingredients'

Standard care, treatment as usual (TAU)

Treatment or care that patient would usually receive

Waiting list controlled

Patients receives active treatment after a delay

Current 'Gold Standard' treatment

Best available treatment currently in use

Walsh et al. (2002)

The Randomised Controlled Trial (RCT) (5)



Randomisation of cases to treatments

Potential Disadvantages

- deterrent to recruitment
- some patients may want to know what treatment they are going to receive

Which **patient** receives which **treatment** must be **determined randomly**

Researcher

Treating
therapist

Patient

Equalisation of groups

Ensures groups matched for severity of symptoms, age, gender and other factors

Prevention of allocation bias

Investigators can not choose between active or control treatments for a patient

Enables 'blinding'

Unable to tell which condition a patient has been allocated to

The Randomised Controlled Trial (RCT) (6)



Random allocation to condition is 'blind'

Blindness

- sometimes full blindness is impossible
- **blindness** of the **statistician** is an **absolute minimum**

A **clinical trial** is an **experiment** in which **no-one knows the outcome...**

...but all hope it will be effective

Multiple opportunities for bias

Minimisation of assessor bias

Avoid the possibility of unconscious bias

Minimisation of patient bias

Stop patients giving response they think doctor want to hear

Avoid patients focussing more on improvements attributed to active treatment

Minimisation of statistician bias

Avoid bias in choice of analyses or interpretation of results

The Randomised Controlled Trial (RCT) (7)



Repeated assessment of outcome measures

Clinically meaningful outcome

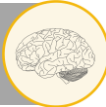


- Minimal Clinically Important Change (MCIC)
- defined 'response' criteria
- short-term remission of symptoms
- lasting recovery

All clinical trials require a **robust** and **reliable** way to **measure** the **symptom** or **condition** of interest

Primary outcome measure	Main index used to measure effectiveness
Accurate and reliable	Measure symptom(s) with minimal error
Secondary outcomes	Measure other outcomes of interest
Multiple assessment point	Repeat at baseline before randomisation, before and after treatment. Main indicator of efficacy
Follow-up assessment	To measure continuation of benefit after treatment ends

Challenges of the RCT in psychotherapy research

Challenges to designing and conducting robust psychotherapy RCT

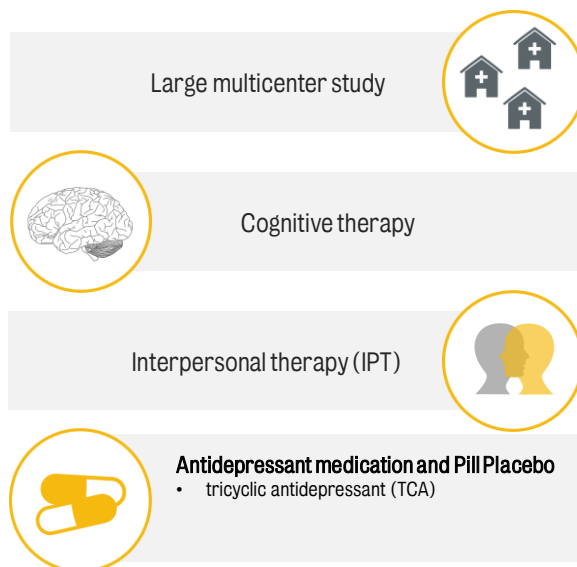
Psychotherapy treatment 	Choice of control treatment 	Allocation blindness 
<ul style="list-style-type: none"> • complex intervention • important to standardise how it is delivered <p>User treatment manual</p> <ul style="list-style-type: none"> • description of treatment and delivery <ul style="list-style-type: none"> • therapists should be trained to deliver therapy as defined by the manual <p>Ensure adherence to treatment (Fidelity)</p> <ul style="list-style-type: none"> • therapists should be regularly checked to ensure they are following the manual <p>Therapists will vary in terms of characteristics. May need to be incorporated in data analysis.</p> <p>Assess therapist effects</p> <p>Therapist may vary in expertise and other characteristics</p>	<ul style="list-style-type: none"> • no psychotherapeutic equivalent to dummy pill • effective placebo control treatment almost impossible • requires two near identical treatments • must be equally plausible and convincing • extremely difficult to achieve in practice <p>The most common control is not a placebo but another active treatment – typically antidepressant medication</p> <p>Compare to alternative real treatment</p> <p>E.g. Psychotherapy v antidepressant medication</p>	<ul style="list-style-type: none"> • almost impossible to achieve patient and therapist blindness • opportunity for systematic bias <p>Seek to minimise bias</p> <ul style="list-style-type: none"> • use of independent assessors who are unaware of treatment allocation • statistician blind to allocation

Evaluating the evidence from clinical trials of CBT

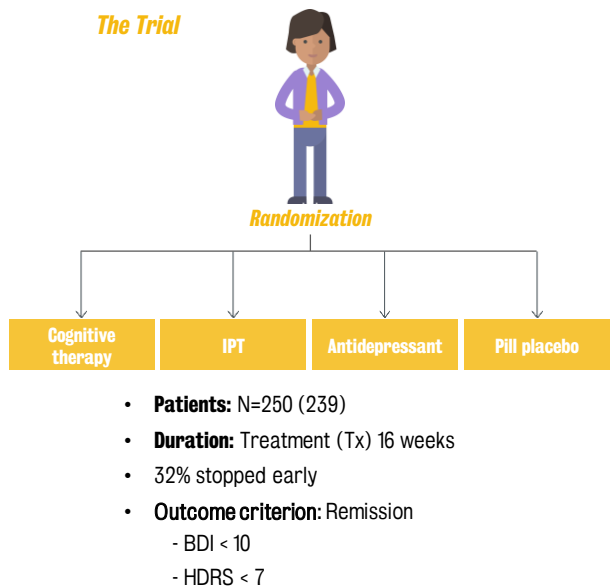


Adult Depression
Conventional CBT
Evidence from individual RCTs
Evidence from systematic reviews and meta-analyses

Elkin et al. (1989): Comparison between Cognitive therapy and other active treatments

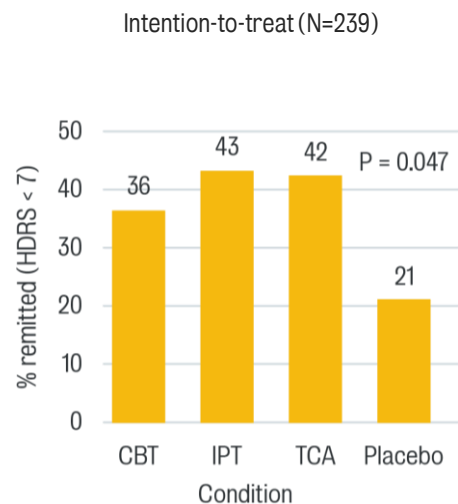
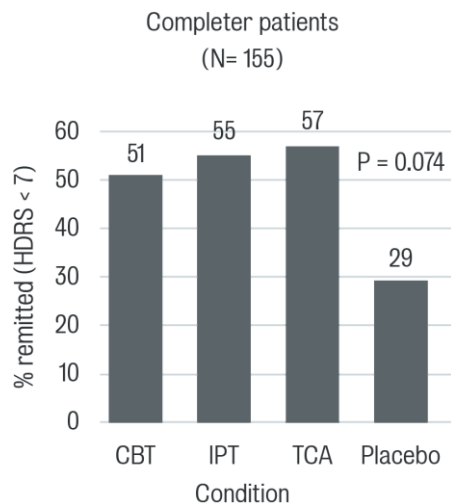


The Trial



Elkin et al. (1989)

Elkin et al. (1989)



Elkin et al. (1989)

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Rahman et al. (2008): Applying CBT for depression in a low-income economy (1)

Most CBT trials take place in countries with highly developed health care systems

Research questions

What about countries where mental health services are rudimentary?

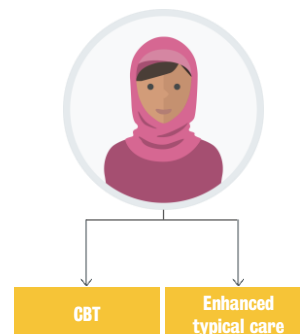
Could CBT help depressed mothers with infant children in rural Pakistan?

Would improving the mothers mental health improve the health and early development of her new born child?



- delivered by existing primary healthcare workers
- trained to deliver CBT in centres randomised to active treatment
- other centres delivered typical care (enhanced – closer than usual contact)

The Trial



- **Patients:** N=903
- **Duration:** 16 sessions over 10 months
- **Assessment:** baseline, 6 and 12 months
- **Outcome:**
 - diagnosis
 - mother-baby interaction
 - infant health

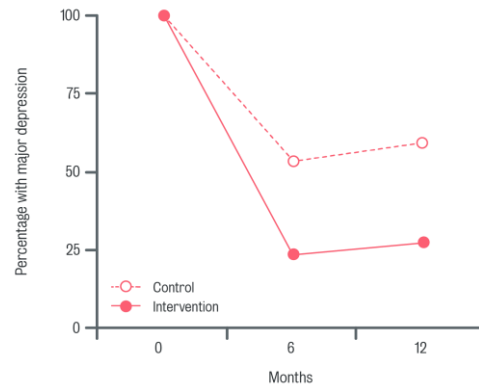
Rahman et al. (2008)

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Rahmen et al. (2008): Applying CBT for depression in a low-income economy (2)



Other positive outcomes

Fewer cases of stunted growth at 12 months ($p < 0.07$)

Fewer cases of diarrhoea ($p < 0.04$)

Increased rates of infant immunisation ($p < 0.001$)

Increased use of maternal contraception ($p < 0.002$)

Increased play with the mother ($p < 0.001$)

Increased play with the father ($p < 0.001$)

A cost effective CBT intervention has effects that go far beyond the mothers acute mental health

Rahman et al. (2008)