
Efficacy Studies

Overview

- **Introduction**
- **Key features of efficacy studies**
- **Issues in conducting efficacy studies**

Efficacy Studies

- **Provide a test of whether treatments are successful under controlled conditions**

Key Features

Key Features-1

- **Carefully screened subjects**
 - standard diagnostic criteria
 - trained examiners
 - elimination of comorbid conditions
 - special exclusions

Key Features-2

- **Randomization**

- benefits of randomization

- randomization by concealment

- common practical problems

Key Features–3

- **Control condition(s)**
 - **Historical control**
 - **Waiting list controls**
 - **Standard care control**
 - **Comparison condition control**
 - **Attention placebo control**

Key Features-4

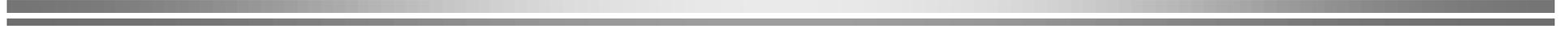
- **Standardized treatment protocols**
 - Treatment manuals**
 - Therapist training**
 - Audiotaping of sessions**
 - Ongoing supervision**

Key Features-5

- **Blinding**
 - blinding of evaluators
 - blinding of subjects
 - blinding of providers

Key Features-6

- **Outcome measures**
 - **Multiple domains**
 - **Repeated measurements**
 - **Follow-up**



Issues

Nature of Treatment Setting

- **Optimal condition**
- **Research lab setting**
- **Often removed from clinical setting**
- **Therapists hired for study**
- **Participants don't pay for treatment**

Generalizability

- **Samples often specialized**
- **Standardized treatments may not be representative**
- **Therapists may be more (less skilled) than typical clinicians**

Threats to Validity

- **Differential refusal**
- **Differential dropout**
- **Baseline differences despite randomization**
- **Analysis of treatment completers only**
- **Intensity of treatment**

Discussion