

EVIDENCE BASED PRACTICE: WHAT IS A CLINICAL TRIAL? (CNIN MAY 2010)

The [National Health and Medical Research Council](#) describes clinical trials as research in which a therapeutic, preventive or diagnostic intervention is tested. Frequently, this will involve interventional trials where a participant is assigned to treatment group and the outcome measured and compared. Observational trials do not assign participants to an intervention but simply observe effects in a group.

Each clinical trial seeks to answer a particular research question. A study protocol describes how the research will be conducted. Often they will only be interested in people with a particular condition such as breast cancer or a particular characteristic such as people from a non-English speaking background or women aged over 75 years. The study protocol will specify inclusion or exclusion criteria that determine who can participate in the trial.

Clinical trials determine the benefits of new or different treatments. This is important in assessing whether current practices should be replaced by another approach.

Ethical conduct

All research involving people is strictly controlled. Researchers must comply with a series of standards specified in national and international documents. The [ICH Guideline for Good Clinical Practice](#) provides guidance and principles on how clinical research should be planned, reviewed and conducted to meet international standards. In Australia research needs to comply with the [National Statement on Ethical Conduct in Human Research](#).

Clinical Trials Registration

The registration of all interventional trials is considered to be a scientific, ethical and moral responsibility. Registering trials makes research more accessible and transparent. It also helps in addressing publication bias and selective reporting of clinical trials. Many journals will not publish findings from trials that have not been registered. The [Australian New Zealand Clinical Trials Registry \(ANZCTR\)](#) is an online register of clinical trials being undertaken in Australia, New Zealand and elsewhere.

Finding out more

[Understanding clinical trials](#) (ClinicalTrials.gov)

[Clinical trials: Shedding light on the evidence](#) (Australian Pharmacist 2007 26(6))

CareSearch is an online resource funded by the Department of Health and Ageing to help clinicians and consumers find relevant evidence about palliative care. Available now at www.caresearch.com.au

