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MODERNISING MEDICAL CAREERS

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Types of research study: a guide for the foundation year doctor

Introduction

In order to critically appraise a paper, a fundamental skill for practising evidence-based medicine, it is essential to be able to recognize whether the author(s) chose an appropriate study design (Sackett et al, 2000). This article gives the reader a general overview of the different types of studies and their significance.

Given the large number of different studies, it is useful to keep in mind to which broad group they belong (Campbell and Machin, 1999; Petrie and Sabin, 2005; Greenhalgh, 2006). The different types of study are shown in *Figure 1*.

Interventional or experimental studies

These involve animal or laboratory studies carried out under experimental conditions or by introduction of some form of treatment. Experimental studies provide the most convincing evidence for any hypothesis. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured.

A clinical trial is a planned interventional study. Clinical trials are conducted in phases. The trials at each phase have a different purpose and help the investigator answer different questions.

In phase I trials, researchers test an experimental drug or treatment in a small group of people (20–80) for the first time to evaluate its safety, determine a safe dosage range, and identify side effects.

In phase II trials, the experimental study drug or treatment is given to a larger group of people (100–300) to estimate the efficacy and safety of a new drug compared with conventional treatment.

In phase III trials, the experimental study drug or treatment is given to large groups of people (1000–3000) to confirm its effectiveness, monitor side effects and compare it with conventional treatment or a placebo.

In phase IV trials, post-marketing studies delineate additional information,

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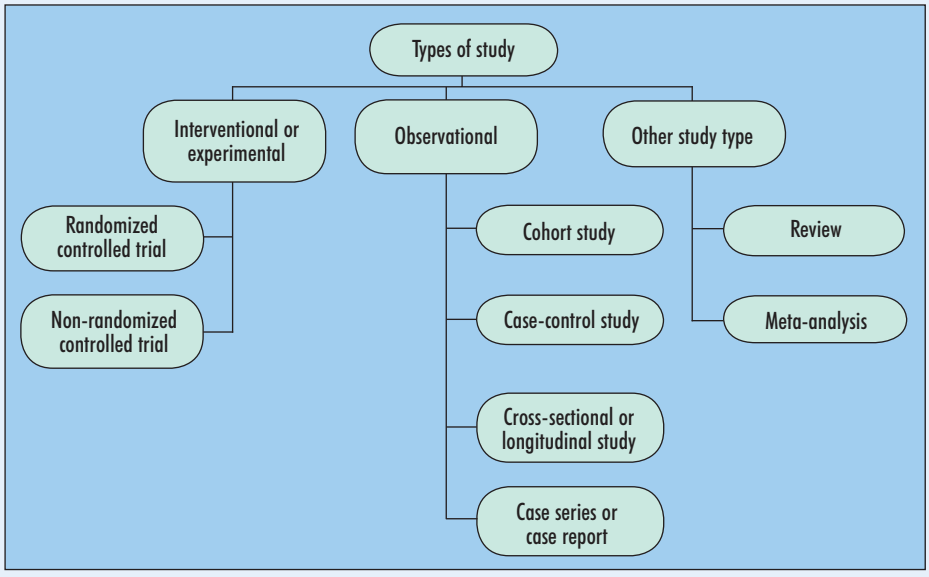
Figure 1. Types of study.



including the drug's risks, benefits and optimal use.

Randomized controlled trials

Randomized controlled trials are studies in which participants are allocated by chance (randomly) to two or more groups to receive one or several interventions. The group receiving the studied intervention (for example a new medication) is compared with one or more 'control' groups, in which individuals may be given the standard intervention (for example the most commonly-used medication), a placebo or no intervention at all.

Randomization helps to reduce observer, selection or information bias. If both researcher and participant know which treatment is being given, the trial is called an open trial. If only the researcher knows, it is described as single-blind. Finally, if neither the researcher nor the participants are aware of the allocation of the intervention, it is considered a double-blind trial.

Randomized controlled trials are one of the most powerful tools in clinical research. They are the most reliable way to test whether a treatment causes a benefit or deterioration in health. On the negative side, randomized controlled trials are usually very expensive and can sometimes raise ethical problems.

Non-randomized controlled trials

These are clinical trials in which a randomization process is not used and the results of the study could be influenced by bias.

Observational studies

Observational studies are those in which individuals are observed and their outcomes are measured by the investigators. Large epidemiological studies which assess the relationship between factors of interest and disease in the population are observational studies.

Cohort studies

Cohort methodology is confined to studies determining and investigating aetiological factors that might affect the disease outcome in future. These factors are studied within a group of individuals who are followed over a period of time.

The main weakness of cohort studies is that exposure may be associated with hidden confounder factors. Further disadvantages are possible selection bias arising from the lack of randomization and the difficulty in detecting controls.

Case-control studies

Case-control studies compare characteristics of a group of people with a certain condition (case) with another similar group of individuals who do not have it (control). The researcher then investigates retrospectively the past medical history, habits and/or lifestyle of the subjects to establish whether the factor under investigation (for example smoking) occurs more frequently in the group suffering from the condition examined (for example lung cancer).

Case-control studies are retrospective in nature and often exposed to recall bias, as reliability of the outcome is strongly related to the accuracy of the statements given by the individuals under investigation.

The main advantage of case-control studies is that they are the only research design able to spot very rare conditions with contained costs and time.

Cross-sectional or longitudinal studies

Cross-sectional surveys observe a condition (for example lung cancer) and other variables (for example smoking) at a particular point in time, in contrast to longitudinal studies, which are over a period of time.

This kind of study is very useful to investigate the frequency of a particular disease or to estimate the accuracy of a particular screening or diagnostic test in a quick and relatively cheap way.

Case series and case reports

Case reports or case series describe in detail one or more medical cases. They usually reveal rare features of a disease, its symptoms and pathogenesis. In addition, they can discover unexpected effects of a particular treatment.

Other study types

Reviews

A systematic review is a summary of the medical literature that uses explicit methods to systematically search and critically appraise the primary study with the aim of answering a clearly-formulated question.

Systematic reviews produce more objective and reliable conclusions and allow a quick assimilation of a large amount of information. On the other hand, a well-assembled systematic review will be of no scientific value if based on poorly-conceived primary studies.

The best known collection of systematic reviews is the Cochrane Collaboration.

Meta-analyses

A meta-analysis may be used to summarize the data, leading to an increase in the precision of the overall result. Meta-analysis is a specific statistical technique used to combine the findings of primary studies, often two or more randomized clinical trials.

Conclusions

Foundation doctors need to be familiar with different types of studies, so that they can critically appraise papers and practise evidence-based medicine. BJHM

Conflict of interest: Dr Hooke has worked in both management and medicine. Her views are her own and do not necessarily reflect those of her employer or any other organization that she is associated with.

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KEY POINTS

- In this era of evidence-based medicine, critical appraisal of papers is an important skill.
- There are many published papers.
- There are different types of clinical studies, with varying quality.
- Application criteria are different for each type of study.
- It is important to understand the types of study which might be used.