Clinical Research and Clinical Trials

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Clinical research

Refers to all or any research administered on humans. It focuses on improving understanding of diseases, developing diagnostic methods and new treatments or medical devices to form sure better patient care. It's much framed and a specific study protocol and is simply realized under certain conditions [1-2].

Different types of clinical research are used counting on what the researchers are studying. Some types are mentioned below:

Treatment research generally involves an intervention like medication, psychotherapy, new devices, or new approaches to surgery or radiotherapy. Prevention research looks for better ways to stop disorders from developing or returning. Different sorts of prevention research may study medicines, vitamins, vaccines, minerals, or lifestyle changes.

Diagnostic research refers to the practice of trying to find better ways to spot a specific disorder or condition.

Screening research aims to seek out the simplest ways to detect certain disorders or health conditions.

Quality of life research explores ways to enhance comfort and therefore the quality of life for people with a chronic illness.

Genetic studies aim to enhance the prediction of disorders by identifying and understanding how genes and illnesses could also be related. Research during this area may explore ways during which a person's genes make him or her more or less likely to develop a disorder. This might cause development of tailor-made treatments supported a patient's genetic make-up.

Epidemiological studies seek to spot the patterns, causes, and control of disorders in groups of individuals.

Clinical trials

These are research studies perform on folks that are aimed toward evaluating a medical, surgical, or behavioral intervention. They're the primary way that researchers determine if a replacement treatment, like a new medicine or diet, or medical device is safe and effective in people. Often a clinical trial is used to seek out if a replacement treatment is easier and/or has less harmful side effects than the quality treatment.

Phases of clinical trials

Clinical trials are a sort of clinical research designed to gauge and test new interventions like psychotherapy or medications which usually conducted in four phases. The trials at each phase have a special purpose and help scientists answer different questions.

• **Phase I trials:** Researchers test an experimental drug or treatment during a small group of individuals for the primary time. The researchers evaluate the treatment's safety, determine a secure dosage range, and identify side effects [1].

• **Phase II trials:** Experimental drug or treatment is given to a bigger group of individuals to ascertain if it's effective and to further evaluate its safety [3]

• **Phase III trials:** Experimental study drug or treatment is given to large groups of individuals. Researchers confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information which will allow the experimental drug or treatment to be used safely.

• **Phase IV trials:** Post-marketing studies, which are conducted after a treatment is approved to be used by the FDA, provide additional information including the treatment or drug's risks, benefits, and best use.

Clinical trial protocol

A clinical test protocol may be a document that define and manage the trial and which is prepared by a panel of experts. All study investigators are expected to strictly observe the protocol. The protocol describes the scientific rationale, objective(s), design, methodology, statistical considerations and organization of the planned trial. Details of the trial are provided in documents referenced within the protocol, like an investigator's brochure. The protocol contains a particular study decide to assure safety and health of the trial subjects and to supply a particular template for trial conduct by investigators. This enables data to be combined across all investigators/sites. The protocol also informs the study administrators (often a contract research organization). The format and content of clinical test protocols sponsored by pharmaceutical, biotechnology or medical device companies within the US, European Union, or Japan are standardized to follow Good Clinical Practice guidance issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Regulatory authorities in Canada and Australia also follow ICH guidelines. Journals like trials encourage investigators to publish their protocols.

Participant recruitment and participation

Phase 0 and phase I clinical trial drug trials seek healthy volunteers. Most other clinical trials seek patients who have a selected disease or medical condition. The range observed in society should be reflected in clinical trials through the acceptable inclusion of ethnic group populations. Patient recruitment or participant recruitment plays a big role within the activities and responsibilities of sites conducting clinical trials. All volunteers being considered for an attempt are required to undertake a medical screening [4]. Requirements differ consistent with the trial needs, but typically volunteers would be screened during a medical laboratory for:

• Measurement of the electrical activity of the guts (ECG)

• Measurement of vital sign, pulse, and blood heat

• Blood sampling

• Urine sampling

• Weight and height measurement

• Drug abuse testing

• Pregnancy testing

It has been observed that participants in clinical trials are disproportionately white. One recent systematic review of the literature found that race/ethnicity also as sex wasn't well-represented or sometimes even tracked as participants during a sizable amount of clinical trials of deafness management in adults [5]. This might reduce the validity of findings in respect of non-white patients by not adequately representing the larger population.

The Risk Information Seeking and Processing (RISP) model analyses social implications that affect attitudes and deciding concerning clinical trials. People that hold a better stake or interest within the treatment provided during a clinical test showed a greater likelihood of seeking information about clinical trials. Cancer patients reported more optimistic attitudes towards clinical trials than the overall population. Having a more optimistic outlook on clinical trials also results in greater likelihood of enrolling.

References

1. Ruiter R, et al. "Under-representation of elderly in clinical trials: An analysis of the initial approval documents in the Food and Drug Administration database." *Br j clin pharmacol.* 85.4(2019):838-844.
2. Geller SE, et al. "Inclusion, analysis, and reporting of sex and race/ethnicity in clinical trials: have we made progress?" *J women's health.* 20.3(2011):315-320.
3. Shawi F, et al. "Emerging drugs for Duchenne muscular dystrophy." *CADTH Issues Emerg Health Technol.* (2017).
4. Liu JJ, et al. "Achieving ethnic diversity in trial recruitment." *Pharm Med*. 25.4(2011):215-222.
5. McDonald AM, et al. "What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies." *Trials*. 7.1(2006):1-8.