

CLINICAL TRIAL

WHAT IS A CLINICAL TRIAL?

Clinical trials help researchers find "new ways to prevent, diagnose, or treat disease," (MCW). The goal is to determine if a new test or treatment works and is safe.

The goal of a clinical trial is to



CLINICAL TRIAL CONCEPTS

#1 Inclusion / Exclusion Criteria

#2 Informed Consent

#3 Randomization

#4 Intervention

Inclusion / Exclusion Criteria

1 Inclusion criteria include factors, such as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions, that allow someone to participate in clinical trials.

Exclusion criteria are similar factors that exclude or do not allow someone to participate in clinical trials.



Both inclusion and exclusion criteria help researchers identify a group of people most efficient for answering the clinical question.

Examples of inclusion/exclusion criteria:

»»»» Inclusion Criteria:

Diagnosed with mild ischemic cerebral infarction or mild intracerebral hemorrhage (NIHSS < 5) or TIA based on a clinical definition of focal neurologic deficits consistent with a single vascular territory of the brain

»»»» Exclusion Criteria:

Patients unable to give informed consent

Discharged to long-term nursing home or requiring 24 hour care

Aged greater than 18 years at onset of event

Resident of Metropolitan community in home with land or cell phone

Vascular risk factors including HTN history or elevated blood pressure (> 130/85 mmHg) at the time of discharge, smoking, diabetes or metabolic syndrome

Discharged to home

English or Spanish Speaker

A Modified Rankin score > 2 at baseline

Pre-stroke dementia history

Patients with end stage cancer, or other medical conditions resulting in mortality less than 1 year

Informed Consent



If you fit the inclusion criteria, a research coordinator or medical doctor will talk to you about the clinical trial.

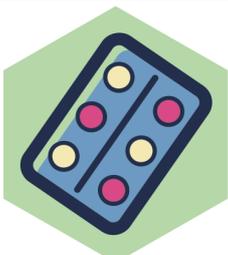
He/She will give you an informed consent document. It explains key facts about the clinical trial before you decide to participate.

You should know as much as possible about the study and feel comfortable asking the research team questions about the study, the related procedures, and any expenses.

The informed consent documents should answer the questions below. If not, ask questions!

- What is being studied?
- What are different types of tests or treatments (also known as interventions) that I might receive during the trial?
- How do the possible risks, side effects, and benefits of this trial compare with those of my current treatment? What will I have to do?
- What tests and procedures are involved?
- How often will I have to visit the hospital or clinic? How long will the study last?
- Will I be reimbursed for other expenses?
- What type of long-term follow-up care is part of this trial?
- Who will monitor my medical care while I am participating in the trial?

Randomization



If you decide to participate, you will be randomized to an intervention group

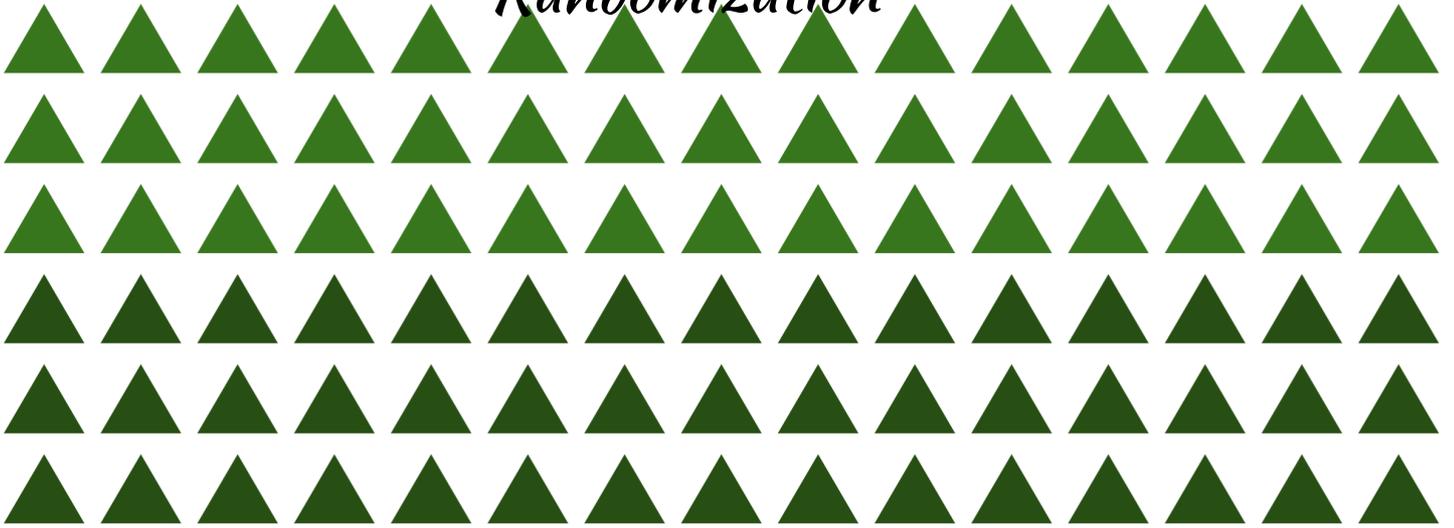
Randomization is similar to flipping a coin. There is a 50/50 chance.

Randomization is very important to clinical trials because it helps prevent bias.

"Bias occurs when a trial's results are affected by human choices or other factors not related to the treatment being tested," (NCI).

"It is important to understand that neither you nor your doctor can choose which treatment you will receive," (NCI).

Randomization



■ Intervention (50%) ■ Usual Care (50%)

**Remember: Randomization is similar to flipping a coin.
There is a 50/50 chance that you will be assigned to either group.**

Intervention

As shown in randomization, there are two groups.

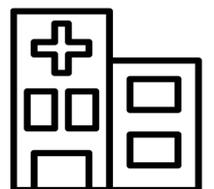
Intervention

A participant is randomly assigned to receive the intervention (new treatment, drug, or device) that the clinical trial is trying to better understand.

Usual Care

A participant is randomly assigned to receive the standard of care (SOC). SOC is the treatment that "experts agree is appropriate, accepted, and widely used. It is also called best practice, standard medical care, and standard therapy," (NCI).

- ✓ "Consider taking a family member or friend along, for support and for help in asking questions or recording answers.
- ✓ Plan ahead what to ask - but don't hesitate to ask any new questions you think of while you're there.
- ✓ Write down your questions in advance, to make sure you remember to ask them all. Write down the answers, so that you can review them whenever you want.
- ✓ Ask about bringing a tape recorder to make a taped record of what's said (even if you write down answers)," (NIH).
- ✓ Remember your participation is completely voluntary, the decision is up to you!



References:

1. <http://www.mcw.edu/ophthalmology/Research-Studies.htm>
2. <https://clinicaltrials.gov/ct2/show/NCT01836354?term=deserve&rank=1>
3. <http://www.cancer.gov/about-cancer/treatment/clinical-trials/what-are-trials/randomization>
4. <http://www.nih.gov/health/clinicaltrials/basics.htm>