

PACCT-1 Trial: TAILORx

*A Clinical Trial Assigning Individualized
Options for Treatment (Rx)*

Randomization Fact Sheet

TAILORx Trial

Participants in the TAILORx Trial will be assigned to one of three separate study groups based on their Recurrence Score (RS), which will be determined by the OncotypeDX assay (ODX). Only one of the study groups will randomize patients between different treatments.

- All patients with a RS of less than 11 will receive hormonal therapy.
- All patients with a RS of more than 25 will receive hormonal therapy and chemotherapy.
- Patients with a RS of 11 to 25 will be randomized to receive either hormonal therapy alone or hormonal therapy and chemotherapy. This group is called the Primary Study Group.

What is randomization?

Randomization is the process of assigning a patient to one of two treatment groups based on chance (flip of a coin). Researchers usually randomly assign patients to one of several treatment options by using a computer program or a table of random numbers.

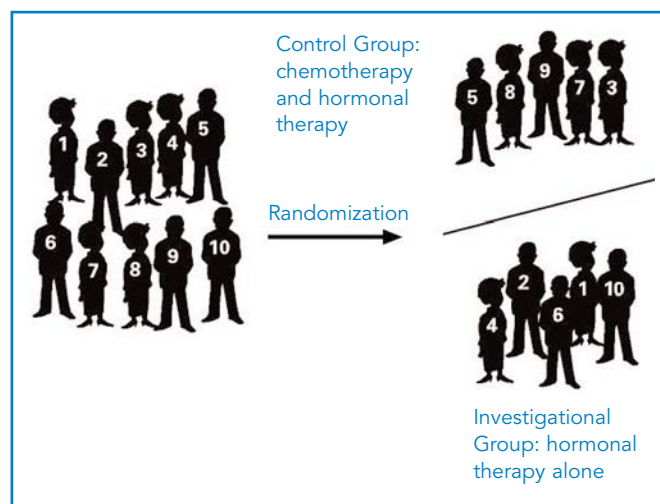
Why is randomization used?

Randomization is one way researchers prevent bias (being influenced in a particular direction) and produce study groups that are very similar to each other. It lowers the possibility for unknown factors to influence the trial results.

Researchers conduct clinical trials when they are uncertain of the answer to the research question. Randomized clinical trials are considered the best type of trial to answer a research question because they result in the most reliable answers. The research question in the TAILORx trial is whether hormonal therapy alone is as effective as hormonal and chemotherapy in patients with an RS of 11 to 25. If hormonal therapy alone is as effective, this will spare the need for chemotherapy in many patients who currently receive it based upon standard clinical guidelines. If hormonal therapy alone it is not as effective, this will confirm the benefits of chemotherapy in this group of patients for whom the chemotherapy benefit is currently felt to be minimal or questionable.

If physicians or participants in the TAILORx trial choose the group patients will be in, assignments might be influenced by their preference for a particular treatment and result in an incorrect conclusion for the trial. For example, some physicians might believe that a patient with a score of 24 should get chemotherapy. He or she might then assign patients with higher RS (20 to 25) to the hormonal plus chemotherapy group. This will not allow researchers to answer the research question. If participants choose the group, women who don't want the combined hormonal and chemotherapy treatment might choose the group receiving hormonal therapy alone. This also will not allow researchers to determine the answer to the research question.

The illustration to the right illustrates how randomization results in groups that are comparable. All the people in the graphic numbered 1 to 10 have an equal chance of being in either group. For the TAILORx trial the people numbered 1 to 10 would be women with an RS of 11 to 25. These women will differ in many ways but randomization gives all the women an equal chance to be in either group. This ensures that differences found in the two groups at the end of the study will come only from the treatment given.



Source: NCI Clinical Trials Education Series, 2001

