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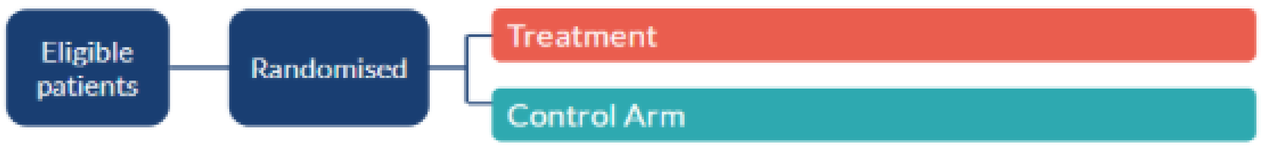
COVID-19 Research and Platform (Complex Innovative Design) Trials

Many COVID -19 studies are using the latest innovations in study design to ensure the best use of resources by rapidly testing multiple treatments in parallel.

Traditional Randomised Controlled Trials

Standard Randomised Controlled Trial



- The traditional randomised controlled trial (RCT) aims to answer a single primary question in each separate study
- An RCT typically involves two arms: new treatment and control (this may be a placebo or standard care). These arms run for a predetermined duration and then the results are compared to identify if there are statistically significant differences between treatments/approaches.

Why are we doing this differently now and what might you get asked to do?

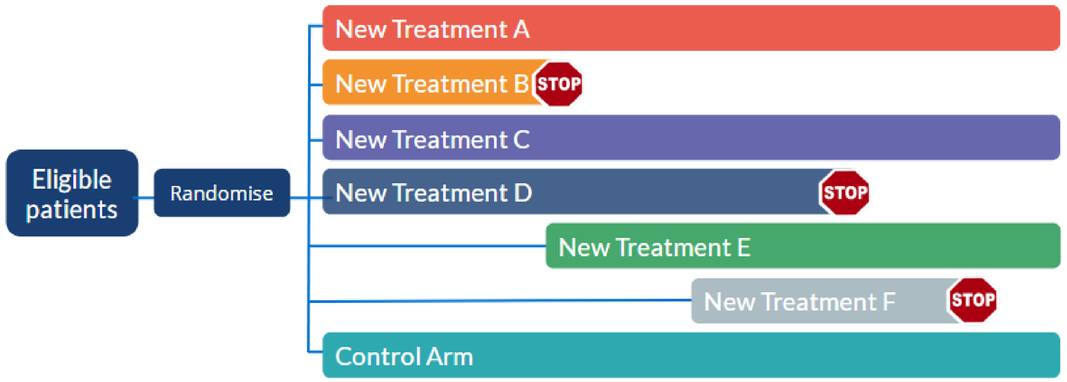
Clinical research in the NHS has been using Complex Innovative Design trials for a while. They lend themselves well to COVID-19 studies where we want to respond to fast-changing, real-world situations

A Platform study allows for several experimental treatments to be studied simultaneously. In addition, new experimental treatments can be integrated into an existing study rather than setting up a new study. This allows for more efficient research.

The latest innovations in study design introduce approaches and terminology that may be unfamiliar to both clinicians and the public. This might mean a study you are asked to help set up and/or deliver may seem different to a standard Randomised Controlled Trial.

Regulatory approvals supporting the use of the platform design and interim monitoring of results must be in place. As with all research studies, it is essential that participants are given all the information required for them to give informed consent to join and to continue in the study.

The patient experience can also be different on a platform study. Treatment may be allocated to individuals by randomisation to one of the arms of the study that are available when they join the study. The treatment the participant is receiving may stop partway through the study if results to date indicate that the treatment is not effective. In COVID-19 research there are platform studies taking place in specific clinical settings. Individual participants may move between settings if their care needs change and it is important we ensure their consent to participate is transferable.



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See ‘Focus on Innovation in Trial Design and Study Delivery’ elearning for more information **bit.ly/NIHRLearnInnT** NIHR case-studies can be found at **bit.ly/NIHRWebInT**