

How to...



Run Randomised Controlled Trials (RCTs)

An introduction

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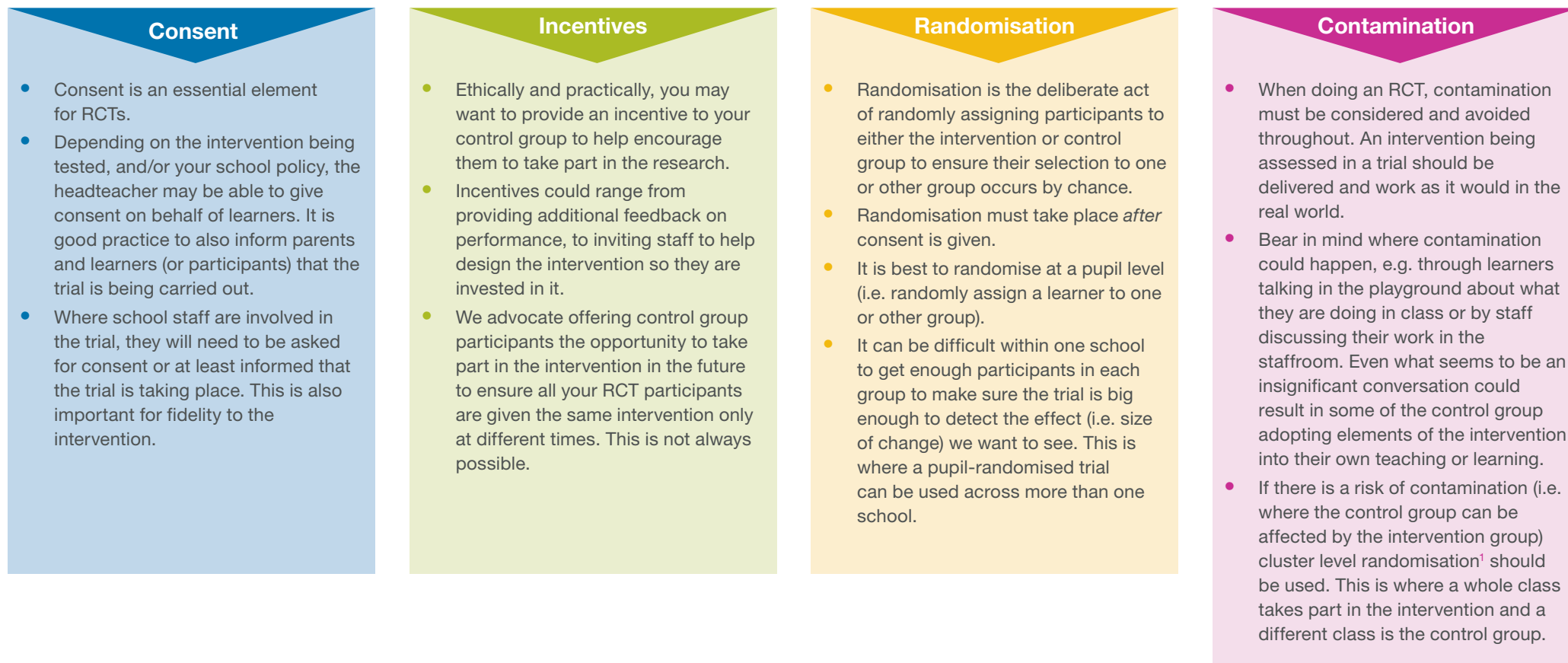
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How to plan an RCT

There are a number of stages to running an RCT, and several considerations that need to be addressed at the outset. Figure 2 outlines them.

Figure 2 RCT planning process



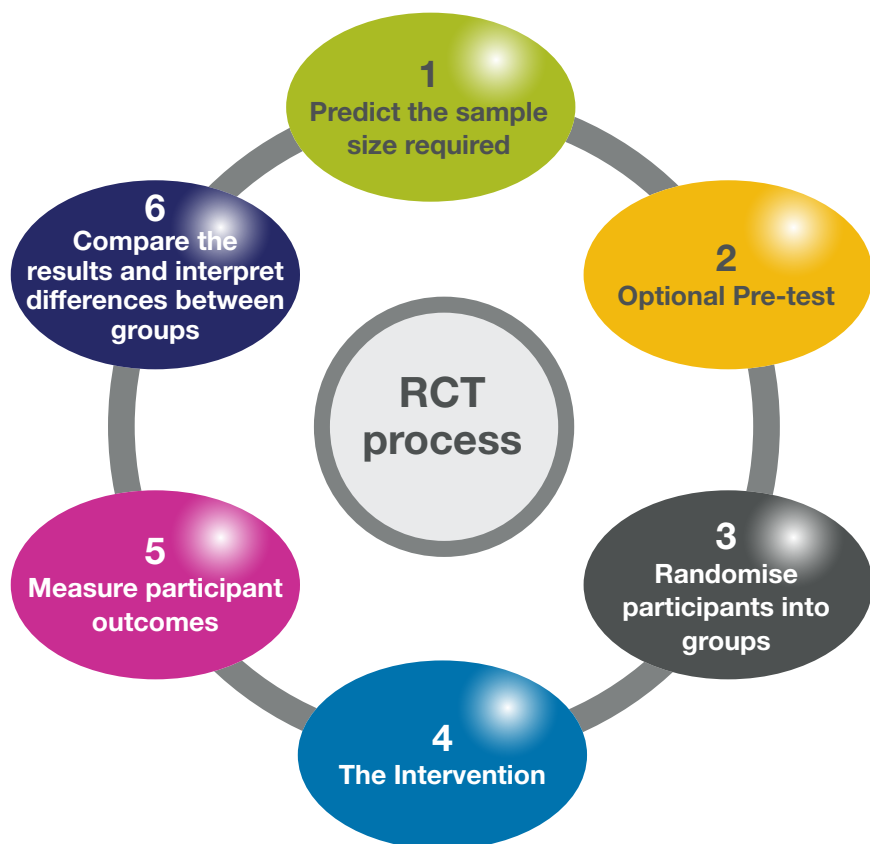
¹ Cluster randomisation means that you may need to work with other schools. This also helps ensure you get a big enough sample of classes. While the same stages to undertaking the RCT are required, calculating sample sizes and analysis are more complicated. We therefore recommend you consult an experienced statistician or research organisation to help you.



The RCT process

When carrying out an RCT, there are a number of processes to follow. These are outlined below in Figure 3.

Figure 3 Stages in the RCT process



1. Predict the sample size required

When undertaking an RCT, you must think about the effect you are likely to detect from an intervention – for example, do you expect to see learners scoring an extra ten points on a test as a result of the intervention? If possible, you should look at previous research in the area to inform your thinking and expectations.

Once you have chosen a desirable effect size, you use this to determine the number of participants you need in your trial. Having the right number of participants means you should be able to find an effect (or change) as a result of the intervention, if there is one.

At this stage, you may want or need to work with other schools to give you a larger sample. Having a larger sample means you can detect a smaller effect. However, the larger your sample, the larger the cost implications for the intervention and for your RCT. You will need to consider what is realistic; as with any research, it may be an issue of balancing budget versus effect size.

Educational research is often designed to look at an effect size (see useful terminology section on page 10) of 0.2, which is considered a small effect. However, if you think there will be a larger effect with an effect size of 0.5, then this requires a smaller sample. See Table 1 below for the sample sizes needed to give a small effect and a large effect. You can also alter your effect size between these figures.

Table 1 Effect sizes

Desired effect size	Sample (N)	Intervention group size	Control group size
0.2 (preferable)	800 participants	400 participants	400 participants
0.5	128 participants	64 participants	64 participants



Useful terminology

Active consent – a type of consent that requires participants (or their parents/carers) to opt-in to a research trial.

Baseline – the point at which all participants start before they have received the intervention. Sometimes a test is given at this point to assess initial differences between the intervention and control groups.

Blinding – this is where someone involved in a trial does not know which group participants belong to (control or intervention).

Blind randomisation – the allocation of participants to either the control or intervention group by someone that is not aware which group is which. Without blind randomisation you can get **randomisation bias** which happens when participants are allocated to groups in a biased way. For example, because a teacher feels that a learner may need extra help with their reading, they allocate them to the intervention group in a literacy trial.

Cluster level randomisation – this type of trial randomly allocates groups or 'clusters' of participants into either the intervention or control groups. This could be classes within schools or whole schools.

Consent – a participant or someone acting on that participant's behalf agreeing for themselves (or others) to take part in a trial.

Contamination – where the control group starts to run part of (or the whole) intervention.

Control group – the participants in a trial who have been randomly allocated to a group that continues as normal and does not receive the intervention.

Effect size – the size of the difference you are looking to measure with the intervention (statistically speaking this is the fraction of the overall variation that a particular difference represents).

Equipoise principle – the idea that when running a trial we do not know whether it will work and therefore it does not discriminate against any participants depending on what group they are allocated to.

Fidelity – whether an intervention adheres to the guidelines set for the trial.

Generalisability – being able to say that what has been found would also apply to a wider population.

Hawthorne effect – when participants in a trial try harder because they know they are being assessed.

Intention-to-treat – a type of analysis that is entirely based on the groups that participants were randomised to and does not consider whether they actually completed the intervention or not.

Intervention group – the participants in a trial who have been randomly allocated to a group that receives the intervention.

Missing data – when a participant has not completed a test/ survey either partially or fully.

On-treatment – a type of analysis that examines what the groups of participants actually did, for example how many lessons an intervention participant completed of the intervention.

Outcome – this is what the intervention is aiming to produce and could be something like an increase by ten points on a reading test.

Passive consent – a type of consent that requires participants (or their parents/carers) to opt-out of a research trial.

Population – this is the whole group that the sample for the trial can be taken from.

Process evaluation – the side of research that looks at how the intervention has worked or not. It also examines how closely participants have kept to the intended intervention. A process evaluation normally uses qualitative interviews with key stakeholders.

Qualitative data – qualitative research is 'interested in understanding the meaning people have constructed, that is, how people make sense of their world and the experiences they have in the world.' (Merriam, 2009).

Selection bias – this is where participants are chosen to take part in the trial because of a biased reason, for example, they are in a particularly disruptive class at school.



Resource considerations

When running an RCT within school there are a few things you need to consider:

- An RCT tells you **if** something works but **not how**. Therefore you still need qualitative data, such as interviews or focus groups, to find out what the mechanisms behind the intervention are (i.e. how it works) and how the intervention has led to changes (i.e. what it is about this intervention that makes the difference) through a process evaluation.
- You are **likely to need more than one school** to ensure your research is as robust as possible.
- You will need to let parents know that their child is being involved in an RCT and ask for passive (opt-out) or active (opt-in) **consent**. Bear in mind, asking for opt-in consent may take more time but if you ask for passive consent, you need to be sure the parents receive the letter.
- You may want to think about holding a **parents evening** to discuss an RCT and its principles so that misconceptions and concerns about ethics can be explained to parents and staff properly.

Sharing your research

As with any research, it is important to share your results with participants and stakeholders. This will let them know how their involvement has contributed to the research and will also let them know whether the intervention has a positive effect or not. You may need to be careful with how you present these messages if the intervention has shown a negative impact. Offering parents the opportunity to attend a workshop or presentation, for example, may help to alleviate any fears or concerns and will enable them to ask questions.

As RCTs are becoming increasingly popular within the education sector, you may want to share your findings more widely. For example, this may be with other schools, local authorities and/or national research or educational organisations.

For further information about writing up your research see www.nfer.ac.uk/publications/RESM05

Research ideas

Before you decide to test an idea using a trial, please consult the existing evidence to see if it has already been evaluated. One way of doing this is through the Education Endowment Foundation Teaching and Learning Toolkit (www.educationendowmentfoundation.org.uk/toolkit).

Other useful resources

We hope that this short guide to running randomised controlled trials has whetted your appetite for carrying out your own research. NFER has published a series of 'How to' guides for practitioners who want to carry out their own research, helping you put your ideas into practice. NFER have research books and training days available as well as free guidance on topics to research and methods of research. Why not get recognition for your achievements in research in your school, college or early years setting by applying for the NFER Research Mark? Visit www.nfer.ac.uk/ris for more information.

References

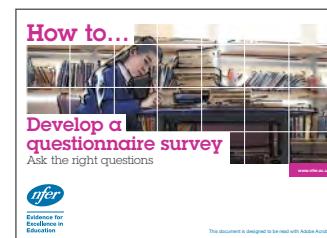
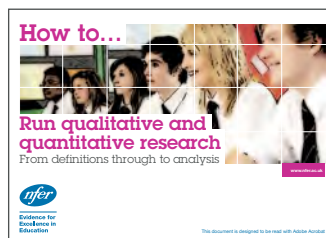
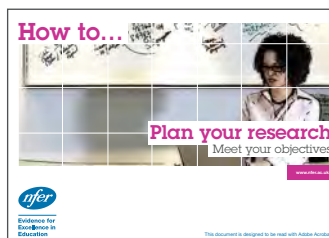
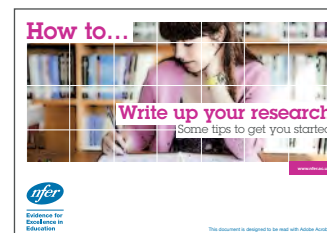
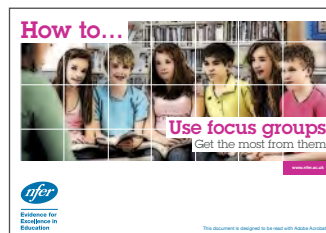
- Hutchison, D. and Styles, B. (2010). *A Guide to Running Randomised Controlled Trials for Educational Researchers*. Slough: NFER.
- Merriam, S. (2009). *Qualitative Research: a Guide to Design and Implementation*. San Francisco, CA: Jossey-Bass.

Randomised Controlled Trials (RCTs)



The NFER 'How to' guides are a quick and easy way to digest different aspects of research.

Written by NFER researchers, these guides will help practitioners run research projects in education. From definitions and benefits, through to potential pitfalls, they will ensure the research is based on professional guidance.



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