

## Script for Randomised Controlled Trial Talk

### Slide 1

This presentation will outline the impacts and benefits of evaluating interventions. It will cover how interventions work and why it's important to evaluate interventions.

### Slide 2

The first question to address is why should we evaluate? The simple answer to this is that we want to find out whether the intervention is effective and brings about the changes it has been designed for.

If we don't evaluate interventions, we don't actually know whether the intervention works.

It could be ineffective and a waste of resources or worse still harmful.

For example, if a drug company creates a new drug, you would expect that they had evaluated whether it was successful in treating the condition it was designed for without any bad side effects.

It is exactly the same for reading based interventions. For example, it would be a waste of time to deliver a reading intervention to children which hopes to improve language development if the intervention hasn't actually been evaluated to show that it does. Furthermore, if the intervention isn't effective then it is arguably harmful to remove a child from the classroom to take part in this intervention. This is because removing them from their class means they miss out on their normal education and learning experiences which would be more beneficial to the child than an ineffective intervention.

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So, we evaluate interventions to make sure they are effective. However not all evaluation techniques are created equal. To ensure that an evaluation is reliable, you need to follow a set of strict evaluation procedures.

The gold standard in evaluation is to use a Randomised Controlled Trial because it is the most rigorous way of determining whether an intervention is causing changes in the outcomes measured. By outcomes we mean the 'things' the intervention is trying to change. For example, in a reading-based intervention you may be trying to boost children's vocabulary skills. So, Vocabulary skills would be an outcome you would measure.

The huge advantage of RCTs is that because of the way they are designed they allow us to rule out the possibility that any changes in the outcomes are due to factors other than the intervention. To use the reading intervention example again, using an RCT would allow you to confirm that any increase in the children's vocabulary skills is due to the intervention given to the children, not just that the

children's vocabulary skills got better because the children were older by the end of the intervention period.

#### **Slide 4**

An RCT is a study that follows strict procedures. The diagram on this slide highlights some of the crucial design features of an RCT. In an RCT you have a study population of similar people who are randomly assigned to two groups. One group is called the experimental group and people in this group receive the intervention. The other group is called the control group and the people in this group either receive a different comparison intervention or no intervention at all.

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Both of the groups are treated exactly the same in all aspects of the study except whether they receive the intervention. They both undergo the same assessments at the same specific times. Then any differences in the outcomes of these assessments between the two groups are assessed statistically. For example, people in the experimental group who received the intervention may improve more on the assessment than the people in the control group and this would be good evidence that the intervention was causing this change because in all other respects the two groups are equal.

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So, if we break the RCT into the specific parts we can see what's important about an RCT.

Taking trial first. When we talk about a trial we mean that the intervention we are evaluating is on trial. For this to be effective we need to be very clear about a number of factors to ensure that the evaluation will be meaningful.

We need to be clear what group of people we are going to deliver the intervention to. Is the intervention designed for all children? Or is it designed for children who have additional needs, or for a specific age group.

Secondly, we need to be specific about what the intervention is, that we are going to evaluate. What are the aims of the intervention? What are we hoping to change? Are we targeting children's language skills? Or are we targeting something else?

This will directly feed into what we measure as the outcomes. If we are evaluating an intervention that we think will boost a child's language skills we need to make sure that our outcome variables measure these language skills.

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Moving onto controlled this refers to the fact that RCTs have a control group.

The reason for a control group is so you can take account of factors other than the intervention that might lead to changes in the outcome variables.

For example, over time children's vocabulary skills will improve simply because they get older and learn more. So, if we want to show that an intervention boosts their vocabulary more than would be expected over time then we need to show that vocabulary skills in the children in the experimental group improved more than the vocabulary skills of the children in the control group.

By comparing the two groups we can calculate the size of the improvement associated with the intervention. If the children in the control group improved by 10% and the children in the experimental group improved by 15%. Then we know the intervention is only adding a 5% improvement. Without a control group, it would seem as though the intervention led to a 15% improvement when in actual fact 10% of that was due to natural improvement in skills over time.

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We randomise to make sure there are no systematic differences between the experimental group and control group.

While we always use inclusion criteria to ensure that the people in the study population are as similar to one another as possible there will always be natural variation between people.

In some trials, we might be aware of some of these factors. For example, in a drug trial, a researcher may subconsciously assign a patient to the experimental group if they think the patient is more likely to benefit from the drug than another patient

So as the trial went on, the experimental group would have more and more people who were likely to benefit from the drug and control group would have more and more people in it who were not likely to benefit from the drug. So, when the results came out it would look as though the people in the treatment group did better than the people in the control group, but really the whole intervention was biased by the researcher's allocation of participants to the two groups.

This can work the other way too, if we think an intervention isn't going to work we might make a subconscious decision to put people with a lower chance of success in the experimental group.

To get past this we always randomly assign people to the two groups.

### **Slide 9**

Now that we've gone over the basics of an RCT we can look at the RCT we're running for Story Starters.

As stipulated by RCT guidelines, we have approximately 200 children who have been randomly assigned to either the experimental group or the control group. The children in the experimental group will receive the Story Starters intervention during

the RCT. The children in the control group will not receive the intervention until after the RCT is finished.

The RCT is trialling the impact of the Story Starters intervention on the language skills of typically developing, English speaking children. The intervention has been designed based on evidence that interactive shared book reading can boost the language skills of this population. Therefore, we have a strict set of inclusion criteria to ensure that all children in the RCT are typically developing and English speaking.

If we wanted to know if the intervention was effective for other groups who may be learning language in a different way, further evaluations with those groups would need to be done.

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Following RCT guidelines we have a clear set of outcome variables which are closely linked to the aim of the intervention which is to boost children's language skills. We are measuring a full range of language skills ranging from vocabulary to phonological awareness skills such as knowledge of rhyme and letters.

We also have a rigid timetable for assessing these outcomes which is the same for both the control and intervention group.

All children are tested before they are randomised into the control or intervention group.

They are tested again at the end of the intervention period, 24 weeks. Finally, they are tested again 6 months after the end of the intervention period. This then marks the end of the RCT project. This is the point at which the children in the control group will be given the Story Starters intervention.

### **Slide 11**

While RCTs are the gold standard method of evaluation, they are time consuming and expensive to implement which makes it hard to use them to evaluate interventions on a larger scale and across a broader geographic area. For this reason, we can use other methods of evaluation in conjunction with an RCT to measure the impact of an intervention on a larger scale but in a less detailed manner

So, for story Starters we have a further evaluation program that we have called the non-RCT evaluation.

The main differences are that we don't have a control group so there is no randomisation. All the children receive the intervention.

We only have one measure of the children's language skills and this is collected by the early years setting the child attends using the WellComm screening tool. However, this is collected at the same time points as in the RCT.

This kind of large scale, light touch evaluation allows us to investigate the feasibility of rolling out a program on a large scale. It's important to note that this kind of evaluation cannot give you definitive evidence that an intervention is effective, you need a RCT for this for all the reasons discussed in the presentation.

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So, the take home message is that just like for drugs you wouldn't gamble by taking or giving an untested drug you shouldn't gamble by using untested interventions.

Delivering untested interventions is at best a waste of resources and at worst could be detrimental to a child's progress.

So, for this reason conducting a RCT to evaluate an intervention is a necessary step in the process of creating interventions. Without this step interventions cannot and should not be promoted as effective.