Navigation Chart 3 – Large-scale quantitative studies

(This accompanies Section N of the core document and Case Study 2)

Instruction for using Navigation Chart 3

Large-scale studies are subject to all the ethical considerations of smaller studies, as well as some other considerations, mostly emerging from their design.

From an ethical perspective, a key consideration is whether the design of the study minimises the ethical risks and issues. The ethical review does not, therefore, restrict experimental methods; rather, it requires that study teams have considered methods that mitigate ethical risks. Consequently, for a study to meet all ethical standards, it may need to be more complex in its research/evaluation design. We include in this document a brief introduction to different experimental methods and, specifically, the distinction between randomised models and non-randomised, quasi-experimental models.

This overview of methods can be found on page 5 with a focus on the ethical differences between Randomised Controlled Trials (RCTs) and Quasi-Experimental Designs (QEDs) on page 11.

Models such as **quasi-experimental naturalist methods or RCT-based models without a control group** are often more difficult to design and may lose some accuracy and precision; however, they avoid the need for a control group in studies where equipoise is difficult to defend.

It is preferable that studies, especially large-scale quantitative studies, should design out ethical issues in the initial stages rather than attempt to mitigate them later or argue that the value of the study overcomes the ethical challenges.

Contents

Consent and overall risk – Ethical considerations

Consent

	Yes	No
1. Is participant ethical consent required for this study? See Section E.2		
2. Is participant consent required by law? See Section D		
3. If consent is required, is it clear what elements of the study require consent? For example, an HEP does not need consent to distribute different versions of the same letter to participants, but if it wants participants with different versions to complete a questionnaire or take part in an interview, consent will be needed. See Sections E, F & N		
4. Will any deception of participants be needed? See Section E.2		
5. If yes, have you recorded why deception is necessary and why no other design is possible? See Section F.3		
6. Are there arrangements in place to fully debrief participants about the nature of the study? See Section I.3		
7. Is a participant information sheet or equivalent in place? See Section F		
8. Are there potential power relations between participants and researchers/evaluators? See Section F.2		
9. If yes, is a process in place to protect participants' rights? See Section F.2		

Risks and harms

10. Has an assessment been made of any potential harms and their risks? See Section I	Yes	No
11. Are any risks significant or serious? See Section I		
12. Have the risks been mitigated as far as possible? See Section I		
13. Does the participant information sheet fully inform participants of the risks? See Sections E & F		
14. If yes, is the participant competent to understand these risks? See Sections F & I		
15. Do the harms disproportionately fall on members of one particular social group? See Section M		

Where the risks are serious, fall disproportionately on one social group, or the study is being conducted with participants not competent to understand the risks, then the study design may potentially be unethical. Any ethical committee would need to be convinced of the need for such a study, its scientific value and that safeguards have been put in place to protect and support participants.

Equipoise – Control group ethical considerations

	Yes	No
1. Is there any reliable evidence that participants in the control group are being denied something of value? See Section N.1		
2. Is the control group receiving something that they would ordinarily have received? i.e. is the control group still receiving the standard intervention or does the design require this to be changed? **If yes, then the principle of equipoise applies, and the control group is not disadvantaged in this study.** See Section N.2.a		
If yes, then: 3. Does the study require a control group, or can the control group be designed out? See Section N.2		
See brief notes in this document on alternative study designs. If a control group is necessary then: 4. Will the control group receive a similar intervention later (i.e. will you use a delayed intervention design)? See Section N.2.b		
5. Is the intervention time-sensitive so that delaying the intervention still negatively impacts control-group participants? See Section N.2.b		

If the control group receives the same intervention and that intervention is not time-sensitive, then any inequality resulting from being in the control group is temporary, and the risk of any harm is small.

In all other cases, there are serious ethical implications in the study design. While this does not necessarily prevent its conduct, any ethical committee would assure itself that:

- There is no other way to conduct this study.
- The study is sufficiently scientifically valuable to justify the harms that result.
- The precise risks and harms have been fully assessed.
- All participants are aware that control-group participants will suffer the risk of harm and the nature of that harm is explained in as much detail as possible before seeking consent.

Ethical considerations on data protection and anonymisation

Institutional issues

	Yes	No
1. Does the institution hold multi-data sets on the same participants? See Sections N.4.a & O.		
2. If yes, are processes in place to ensure that these data sets are securely separated? See Sections M, N and O		
3. Does the institution have a rigorous data security system in place? e.g. an electronic storage system maintained to a high standard with complex password access, encryption and active protection against hacking. Are there secure areas to store paper copies of data? Is there a process for the secure destruction of confidential waste? See Section N.4.a		

Data protection

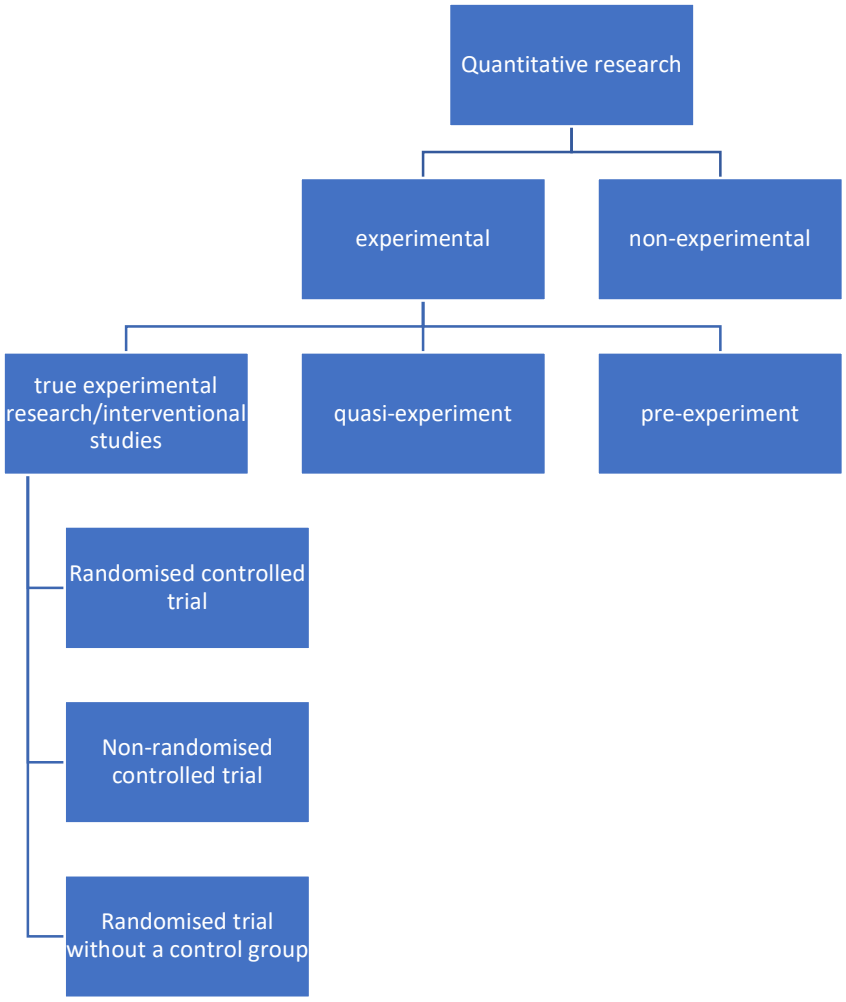
	Yes	No
5. Is the study team suitability qualified and experienced in data protection? See Section K.1		
6. Are expert support and advice in data protection available? See Section K.1		
7. Are processes in place to ensure the safety of the data when it is being transported? See Section J		
8. Does the study have a data deletion log that identifies the person responsible? See Section J		

Anonymisation

	Yes	No
9. Is there a review of when partial and full anonymisation can take place in this study? See Section J.1		
10. Is the study team clear on how full anonymisation will be achieved? See Section K.1		
11. Is the study team clear on how partial anonymity can be achieved before full anonymisation? See Section J.1		

Quantitative research is a type of research design that focuses on collecting, quantifying and analysing data; it deals with numbers. Educational research often relies on a quantitative methodology. We will specifically focus on quasi-experimental design (QED) and randomised control trials (RCTs).

QEDs and RCTs fit within a broad picture of quantitative research:



All experimental research designs allow the researcher to test *hypotheses* by investigating the cause-and-effect relationship[1] between variables.

[1] This is a simplistic model, and it is not clear that experimental designs can explore 'cause and effect' and to what extent these have any reality outside a particular study.

Hypothesis

- What is hypothesis testing?
- What are we trying to achieve?
- Why do we need to perform hypothesis testing?

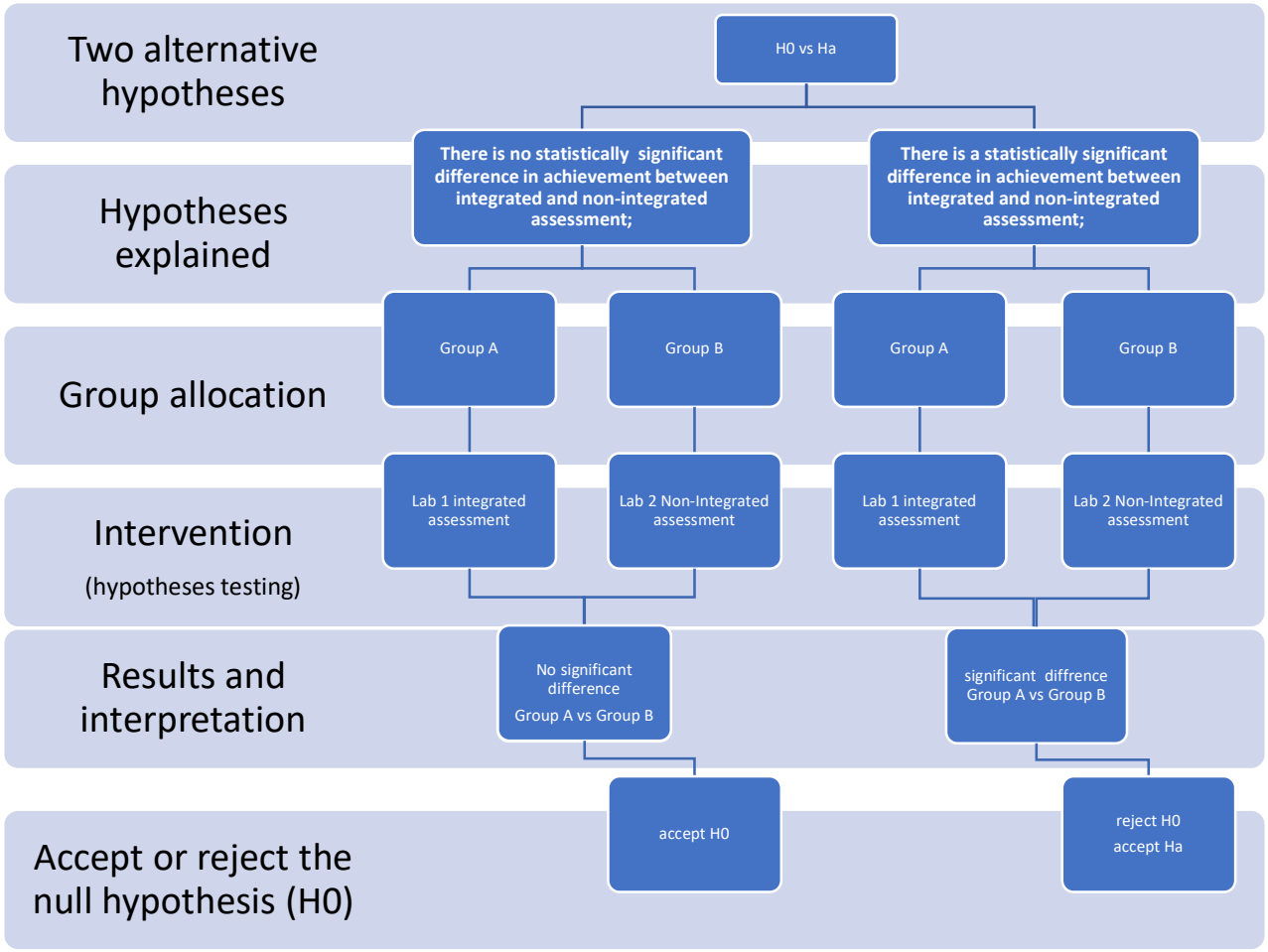
A hypothesis is an educated guess about the world. It should be testable (via experiment, observation, survey or interview). All hypotheses start from “a claim we want to test”.

Take this example from pharmaceutical education: if we want to test the benefit of integrated assessments within a pharmacy course in the United Kingdom, the first step is to state your research hypothesis in the form of null (H0) and alternative (Ha) hypotheses.

Terminology explained

The null hypothesis is a default hypothesis. The null hypothesis is usually a hypothesis of "no difference", e.g., there is no difference between the intervention in group A and the control group B.

- **The alternative hypothesis** is the claim that you want to test, e.g. there is a difference between the intervention in group A and the control group B.
- **The p value** is the probability that a result is obtained by chance. Only if the p value is below a certain pre-set value is the null hypothesis rejected.
- **The significance level**, also denoted as alpha or α, is the probability of rejecting the null hypothesis when it is true. In this example, statistical significance is set at $p<0.05$.


Two alternative hypotheses
H0 vs Ha
Hypotheses explained
There is no statistically significant difference in achievement between integrated and non-integrated assessment;
There is a statistically significant difference in achievement between integrated and non-integrated assessment;
Group allocation
Group A
Group B
Group A
Group B
Intervention
(hypotheses testing)
Lab 1 integrated assessment
Lab 2 Non-Integrated assessment
Lab 1 integrated assessment
Lab 2 Non-Integrated assessment
Results and interpretation
No significant difference
Group A vs Group B
significant diffrence
Group A vs Group B
Accept or reject the null hypothesis (H0)
accept H0
reject H0
accept Ha

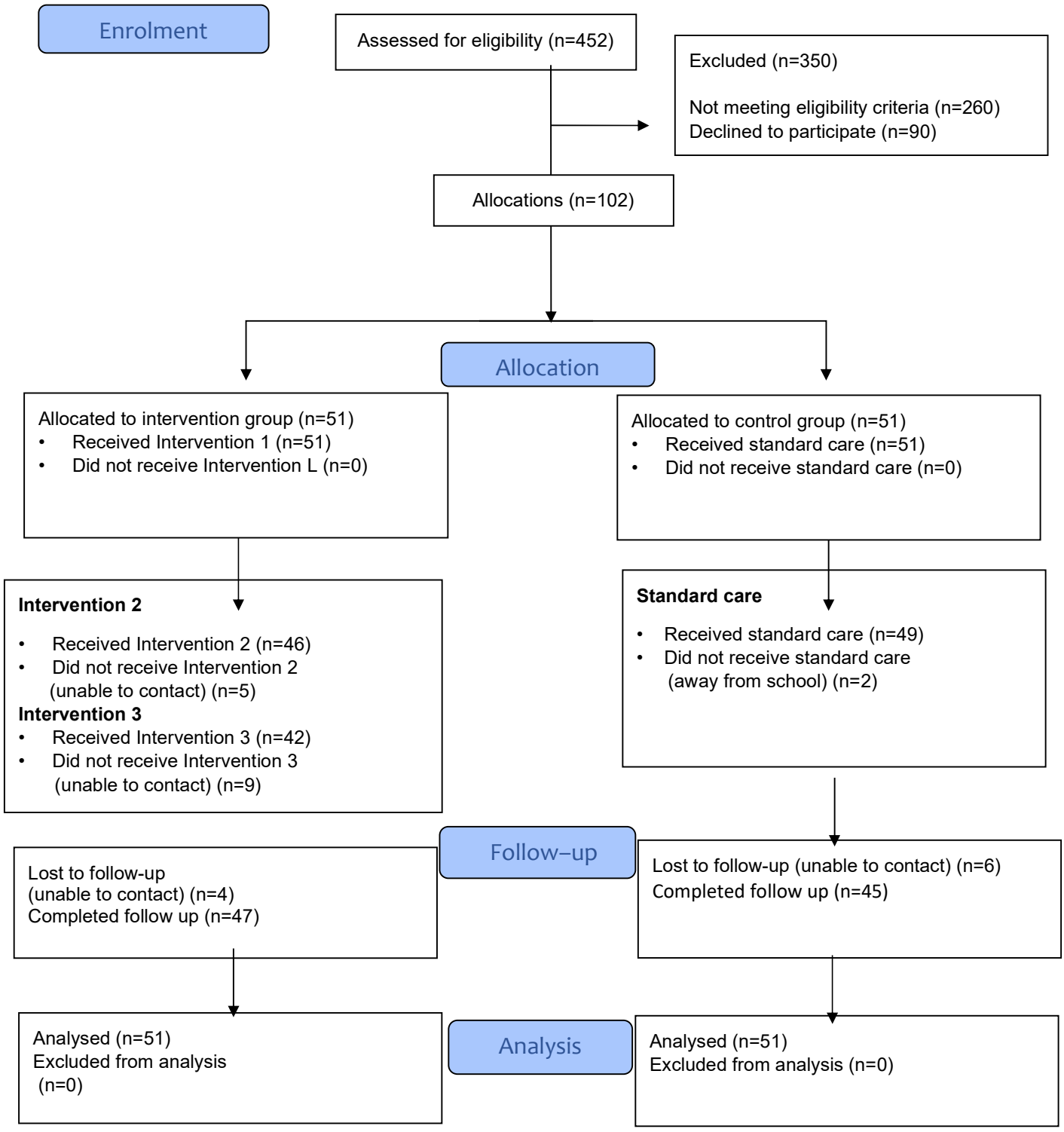
What is the difference between quasi-experimental and experimental design?

Quasi-experimental research designs, like experimental designs, test *causal* hypotheses. In both experimental and quasi-experimental designs, the programme or policy is viewed as an 'intervention' in which elements of the programme/policy under evaluation are tested in terms of how well they achieve their objectives, as measured by a pre-specified set of indicators. A quasi-experiment is an empirical intervention study used to estimate the causal impact of an intervention on a target population without random assignment. In such cases, a group is chosen to receive a potentially valuable intervention, and there is no control group.

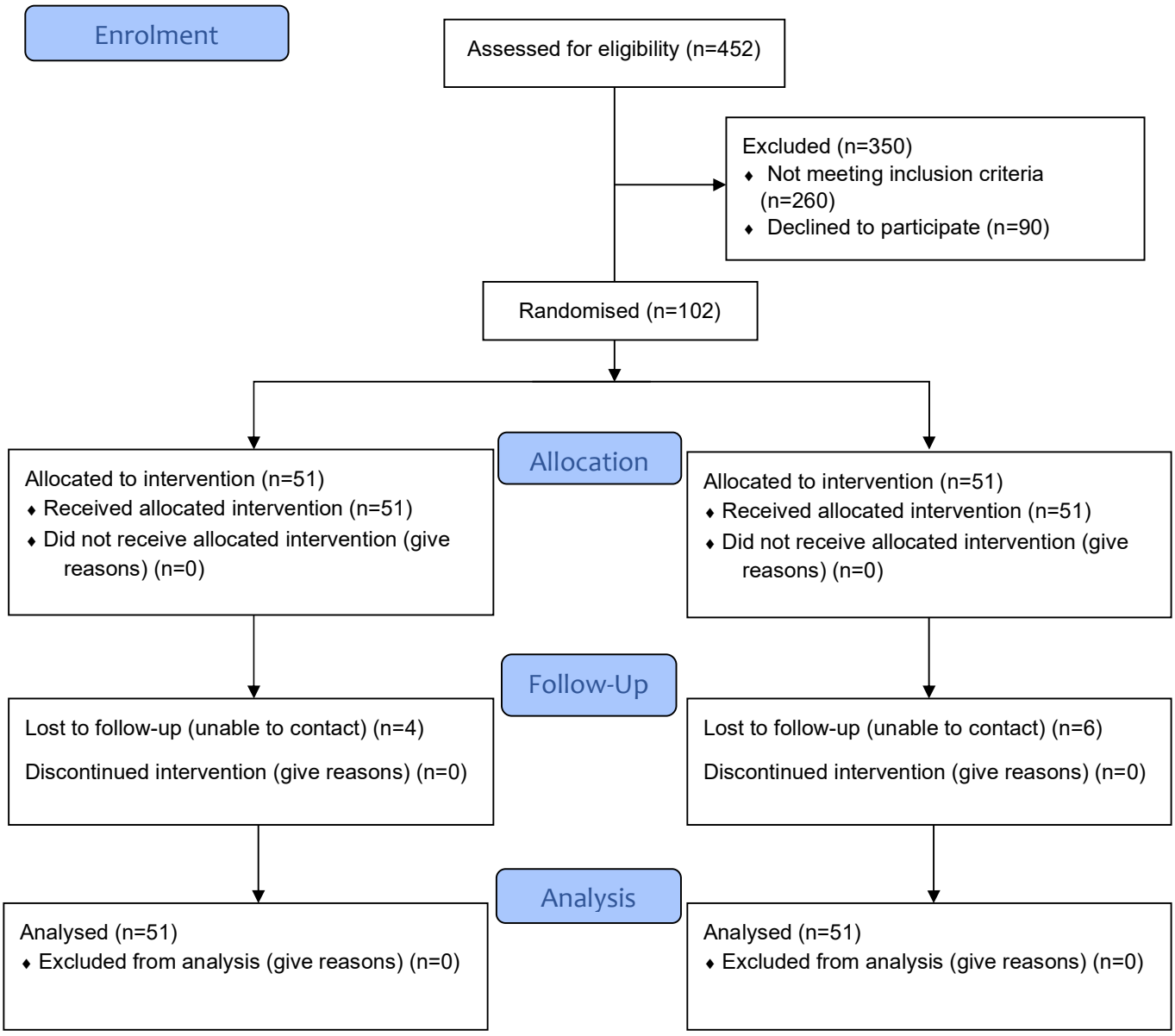
In contrast, a randomised controlled trial is a study design that randomly assigns participants into an experimental group or a control group. Several similar people can be randomly assigned to two (or more) groups to test a specific new educational approach or other intervention. One group (the experimental group) receives the intervention that is tested; the other (the control group) receives the standard intervention (or they may receive a dummy or no intervention).

The two groups are followed up to measure how effective the experimental intervention was, assessed against a shared standard. Outcomes are measured at specific times, and any difference in response between the groups is assessed statistically. This method is also used to reduce bias.

An example of a quasi-experiment



An example of an RCT



The differences between RCTs and QEDs

Randomised controlled trial	Quasi-experimental study
An RCT is an experimental study design where the sample subjects in a population are randomly allocated to different groups: an intervention group and a control group (IG and CG)	A quasi-experimental study is an experimental study design where the subjects in a population are non-randomly allocated to different groups (IG and CG)
Study populations are selected randomly	Study populations are chosen non-randomly
Randomisation is the main element of an RCT.	Randomisation is not the main element of Quasi-experimental studies.
Has high scientific validity when implemented correctly	Has moderate to high scientific validity when implemented correctly
Is generally quite expensive	Is generally less expensive
It provides the best scientific evidence for any study	Evidence generated from this design is of lower significance compared to an RCT
It is considered as an ideal design for evaluating both the effectiveness and side effects of interventions	It is not considered as an ideal design for evaluating both the effectiveness and side effects of interventions.
An RCT, also known as a true experiment, has probability samples.	A quasi-experiment has non-probability samples.
Random assignment in an RCT neutralises factors other than independent and dependent variables, which makes it possible to directly infer the cause-and-effect relationship.	We can suggest causality in quasi-experimental studies. However, we can never be certain that we have controlled for all confounding factors.
An RCT increases the likelihood that the groups will be comparable in terms of variables that we recognise and measure along with variables that we cannot recognise and may not be able to measure.	In a quasi-experiment, we can increase the likelihood that the groups will be comparable in terms of variables that we recognise and measure, but not in terms of variables that we cannot recognise and may not be able to measure.

When choosing which research design to employ for a project or study, several ethical considerations apply.

The main ethical differences between RCTs and QEDs

Randomised controlled trials	Quasi-experimental studies
The major strength of this study design is that it reduces the possibility of selection bias in the trial.	The major strength of this study design is that it is practicable in all contexts and can aid good ethical practice.
They can be used widely except where there is a real-world constraint on random assignment e.g. difficulty in blinding researchers or patients.	They are used when real-world constraints – ethical, political or logistical – do not allow for randomisation.
They can be used to assess and make a strong claim for the causal effect of any programmes, policies or interventions.	When implemented correctly, they can be used to assess or make a claim for the causal effect of programmes, policies or interventions.
Their conduct or feasibility may be limited by practical or ethical factors, e.g., in conducting studies related to exposure to harmful chemicals, we cannot randomise people to receive the harmful chemicals.	They can avoid violating ethical considerations where equipoise cannot be achieved.
They provide chances to control for **unobserved biases**, with an assumption that randomisation was free from bias.	They are more susceptible to unobserved biases.
They have less potential for bias or confounding, and study validity is not compromised.	They have relatively increased potential for bias or confounding, and study validity is compromised.

Considering potential ethical issues.