



Trial Protocol Template



IGL TRIAL PROTOCOL TEMPLATE

<p>Introduction</p>	<p>This Trial Protocol Template is intended for use in Stage 1 of an experiment, to pre-specify the details of your proposed trial, prior to implementation.</p> <p>A Trial Protocol Template is a comprehensive document used to detail every administrative and scientific detail of an experiment before it begins. Writing a protocol allows the research team to assess the feasibility and ethical safety of the trial, while providing the transparency necessary for peer review and future replication by independent researchers.</p>
<p>How to use this template</p>	<p>To use this template, download/open and save a copy for your personal use.</p> <p>Add content by clicking on the tables and writing text in the relevant sections.</p>
<p>Key terms</p>	<p>Objectives and Rationale: The section where you clearly specify your primary and secondary research questions and provide the scientific justification for the trial.</p> <p>Methods (Participants & Interventions): A detailed description of eligibility and exclusion criteria, as well as a thorough explanation of each intervention to allow for exact replication.</p> <p>Trial Design: A summary of the trial structure (e.g., parallel or factorial), the unit of randomisation, and the allocation ratio.</p> <p>Statistical Analysis Plan: The pre-defined methods used to compare groups, including a focus on Intention-to-Treat (ITT) analysis to preserve the benefits of randomisation.</p> <p>Power Calculations: A description of the assumptions - such as expected effect size, significance levels, and attrition - used to determine if the sample size is large enough to detect a meaningful impact.</p> <p>Process Evaluation: Plans for monitoring implementation fidelity and exploring the causal mechanisms or “why” behind the intervention's effects.</p> <p>Risk Register: A table identifying potential threats to the trial (e.g., low recruitment or provider non-compliance) alongside specific countermeasures and contingencies.</p>
<p>Version</p>	<p>1.1 (23/02/2026)</p>

1. INTRODUCTION

1.1 Complete project title	<i>Descriptive title identifying the study design, population and intervention</i>
1.2 Trial registration	<i>Trial identifier and registry name</i>
1.3 Protocol version	<i>Date and version identifier Record any changes made to the trial design</i>

2. OBJECTIVES AND RATIONALE

2.1 Research questions	<i>Key research question(s) for the trial, clearly specifying the participants, interventions, type of control/comparison and outcomes Distinguish between primary and secondary research questions</i>
2.2 Background and rationale	<i>Policy and research background and justification for undertaking the trial: e.g. what evidence gap has been identified and what policy decisions are to be informed</i>

3. ROLES AND RESPONSIBILITIES

3.1 Roles and responsibilities	<i>Names and roles of organisations and individuals working on the trial</i>
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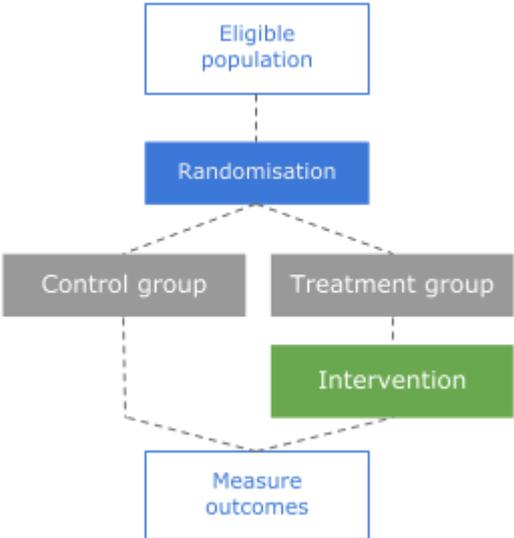
4. PARTICIPANTS, INTERVENTIONS AND OUTCOMES

4.1 Participants	<i>Description of who is eligible for the trial and how they will be identified. Description of exclusion criteria if applicable.</i>
4.2 Interventions	<i>Details of the interventions for each group, with sufficient detail to allow replication</i>
4.3 Outcomes	<i>Clear definition of primary and secondary outcomes, including the specific measurement variable, analysis metric which corresponds to the format of the outcome data that will be used from each trial participant for analysis (e.g. change from baseline, final value, time to event), method of aggregation which refers to the summary measure format for each study group (e.g. mean, proportion with score > 2), and time point of interest for analysis for each outcome</i>

5. LOGIC MODEL FOR INTERVENTION(S)

Diagram of the underlying logic or theory of change, including the assumptions and existing evidence about how the intervention(s) work(s).

6. TRIAL DESIGN

6.1 Description	Short description of the trial design (such as parallel, factorial) including the number of trial arms, unit of randomisation (e.g. individual or another unit such as startup, SME, class, school), the point(s) of randomisation and allocation ratio
6.2 Trial diagram	<p>Simple representation of the trial design, e.g.</p>  <pre> graph TD A[Eligible population] -.-> B[Randomisation] B -.-> C[Control group] B -.-> D[Treatment group] D -.-> E[Intervention] C -.-> F[Measure outcomes] E -.-> F </pre>

7. SAMPLING AND RANDOM ASSIGNMENT

7.1 Sampling plan	How the sample will be identified (and, if relevant) recruited to participate in the trial
7.2 Process for random allocation	Description of the randomisation methods used to generate the allocation (e.g. pure randomisation, stratified or blocked randomisation (if so, specify the strata), paired randomisation, cluster randomisation), and how the random allocation will be implemented

8. STATISTICAL ANALYSIS

8.1 Intended comparisons	Description of the different comparisons to be carried out for the primary (and, if applicable, secondary) analysis – including which treatment arms are to be compared and for which outcome measures, whether any subgroup analysis is to be carried out
8.2 Statistical methods used	Details of the statistical methods to be used to compare the groups on the primary and secondary outcome measures. If full details cannot be provided at this stage, they may be added later in a statistical analysis plan: if so, this should be noted here. IGL's template for a full statistical analysis plan is available at this link .
8.3 Additional analysis	Description of methods for any additional or exploratory analysis (e.g. additional subgroup analysis)

9. SAMPLE SIZE AND STATISTICAL POWER

9.1 Assumptions used for power calculations	Full details of the assumptions underlying the sample size calculations, including allocation ratio(s) between trial arms, significance level, desired power, approach for adjusting for multiple comparisons (if relevant), any assumptions about the distribution of the outcome measures and the proportion of the variance explained by covariates, and either the expected sample size or the minimum detectable effect size (s)
9.2 Sample size required or minimum detectable effect size(s)	Estimate from power calculation (or simulation) of the required sample size or the minimum detectable effect size(s) (whichever was not specified in section 9.1)

10. DATA COLLECTION

10.1 Data sources	Plans for collection of all data required for the trial (including baseline data and outcome data), including how and when data collection will be carried out. If the primary and/or secondary outcome measures rely on survey data, then include the exact questions that will be asked (or include the survey instruments as an annex), and details of how the outcome measures will be derived from the raw data. Describe what is known about the reliability and validity of the survey measures to be used.
10.2 Assessment of data completeness	Assessment of the risks that data will be missing, what type of data could be affected (e.g. data on outcomes or covariates), how this will affect the analysis from the trial (such as the

	potential for introducing bias), and what will be done to mitigate these problems. If using survey data, describe the measures that will be taken to minimise survey attrition (including from participants who do not take part in or drop out of the intervention(s)).
10.3 Assessment of data quality	Assessment of any concerns about the quality of data provided, and what will be done to mitigate these problems.

11. IMPLEMENTATION AND PROCESS EVALUATION

11.1 Questions and purpose	Specification of the key implementation and process questions to be addressed. How will the process evaluation complement the overall evaluation?
11.2 Methods	Description of the methods that will be used to answer the implementation and process questions
11.3 Data collection	Description of the data that will be required for the implementation and process questions, and how and when this data will be collected
11.3 Wider impact evaluation	<p>Description of any additional approaches that are being used to assess and understand impacts, such as:</p> <ul style="list-style-type: none"> - any qualitative research that is being carried out alongside this trial - any additional comparison groups or other quasi-experimental approaches that are accompanying the main trial - any assessment of externalities, such as benefits or costs - any assessment of wider social benefits from the intervention(s) - any assessment of cost-effectiveness

12. ETHICS

12.1 Ethical concerns	Any ethical concerns, for example whether there could be any harm caused to the participants in any of the treatment and/or control arms. If applicable, explain the process for obtaining formal ethical approval, including timelines and which parties are responsible for this process.
12.2 Consent or assent for participation in the trial	Process for obtaining informed consent from participants, if relevant, or a description of why informed consent is not required in this case

12.3 Confidentiality	<i>Processes for ensuring data confidentiality – how will personal or otherwise identifiable information about potential and enrolled participants/businesses be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial?</i>
12.4 Data protection	<i>Data protection statement relevant to the project. If processing special categories of personal data, clearly describe the special data and the rationale for processing them with reference to the trial design.</i>
12.5 Declaration of interest	<i>Declaration of any interests that any of the organisations or personnel have in the results of the trial</i>

13. RISK REGISTER

Risk	Likelihood	Impact	Countermeasures and contingencies

14. TIMELINE

Date	Activity