IGL TRIAL PROTOCOL TEMPLATE FOR BUSINESS BASICS

The following is a suggested template for trial protocols to be used by trials funded by BEIS's Business Basics Programme. The items are based on the SPIRIT statement[1], that sets out the items essential for study conduct, review, reporting, and interpretation of trials. The SPIRIT checklist includes scientific items that closely mirror the latest version of the CONSORT statement[2]. This approach is also followed for the BEIS business support evaluation guide.

Each section of this template contains some suggestions for required content. Further guidance and explanation is available in IGL's guide to running RCTs or by contacting the IGL Team (innovationgrowthlab@nesta.org.uk).

INTRODUCTION

Complete project title	Business Boost, the Cavendish Enterprise productivity improvement trial; using leading management practices with young businesses with fewer than 20 employees to improve productivity. The trial is one of five in the Business Basics Fund trial package.
Trial registration	AEA RCT Registry (https://www.socialscienceregistry.org)
Protocol Version	Date and version identifier (Business Boost - BBF/ Trial Protocol/ver 6/ 2019.07.01)
Roles and Responsibilities	- Commissioning body: BEIS; Contact; Emily Sumner - Contracting body: Innovate UK; Contact; Giles Courtice - Delivery contractor: Business West for Cavendish Enterprise; Contacts; Contract management, Stefan Osipiuk; Trial management; Doug Scott, Chairman, Cavendish Enterprise - Trial contractor: Warwick University/Enterprise Research Centre (ERC); Contacts; Contract/project management, Vicki Belt, Deputy Director, ERC and Jiao Liu, Centre Manager, ERC; Trial design and research delivery; Stephen Roper, Director, ERC; Sub-contracted researcher; OMB Research; Michael Farrer, Associate Director

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[1] Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).

[2] Consolidated Standards of Reporting Trials (CONSORT). Please visit this link for examples: http://www.consort-statement.org/examples/sample

BACKGROUND

Rationale	- The Government has identified poor relative productivity performance amongst UK firms as a problem. - One of their responses to the productivity problem has been to develop *Be the Business,* an organisation/taskforce that has been charged to tackle the UK productivity problem in innovative ways. *Be the Business* is focusing its attention on businesses with between 10 and 249 employees. - NESTA ('*Sources of Labour Productivity Growth at Sector Level In Britain After 2007: A Firm Level Analysis*') concluded that the latest cohort of new firms had lower levels of productivity, and that this was not sector-specific. - BIS commissioned research (*Leadership and Management Skills in SMEs: Measuring Associations with Management Practices and Performance: BIS Research Paper no.224, 2015*) concluded that "The overall impact of L&M skills on firm performance tend to be particularly strong for firms with between five and 19 employees." - There have been tendencies either to avoid the microbusiness community for some interventions (e.g. *Be the Business*) or, recognising the large number and diversity of types and needs of micro-businesses, to deliver generic and relatively non-specific services which do not always meet their needs. - This trial concentrates its attention on a carefully targeted sub-group of micro enterprises with a delivery programme tailored to them that is designed to be replicable.
Characteristics of Supported SMEs	- Target firms will have between 1 and 19 employees (Most of the target firms will employ between 1 and 9 people i.e. they will be 'microbusinesses'). - All firms will be less than 5 years old, and almost all less than 3 years old. - The business owners have self-identified as being 'growth oriented', but they are not seen as fast-growth businesses. The firms are not scale-ups, and they are not venture capital-backed.

Specific objectives or hypotheses	- The objective of the trial will be to explore the impact of the delivery of targeted productivity support on potential productivity improvements amongst young businesses with fewer than 20 employees.
	- In particular, the test will investigate the hypothesis that having a vision for the business and having and using plans leads to increased productivity.
	- The expectation is that few firms will have a vision or plans for the business beyond the one adopted at start-up.
	- The study will use proxies for productivity improvement rather than measuring quantitative productivity changes directly. This is because the study period is not long enough to realistically demonstrate observable changes in productivity metrics. However, a methodology will be provided for subsequent tracking of the firms on these quantitative measures of productivity.
	- The hypothesis is that positive changes in the outlook, confidence and behaviour of the firms that receive the treatment will be observable, in relation to productivity.
	- The main measures being used in the study are:
	  - Changes in the management and leadership practices and routines used in the firms, to include:
	    - People management techniques
	    - Training provision
	    - Business planning
	  - Changes in outlook and behaviour in relation to innovation and exporting, to include:
	    - Use of new technologies
	    - Accessing external finance
	    - Entering new domestic and foreign markets.

Notes: Avoid setting too many primary questions to answer. Trials typically powered to detect changes in a single primary outcome. Multiple primary outcomes require larger samples (or an analytical correction). Example: For SMEs (the population), does offering access to 30 hours of free businesses coaching alongside a grant (the intervention) lead to faster sales growth (the outcome) than offering the grant alone (the control)?

If productivity is the key objective, are there more proximate outcome measures that can be used. Given it can take a long time to affect and difficult to measure/detect impacts

LOGIC MODEL

Logic Model				
Setting out the underlying logic or theory and a set of assumptions about how an intervention works.				
Inputs	**Processes**	**Outputs**	**Interim outcomes**	**Impacts**
• Business Basics Funding	• Recruitment and engagement • Training and support • RCT	• 150 businesses receiving support • A profiling tool • Translation tools • Well-defined processes for replication	Immediate • Selection tools that are diagnostic • Improvements in proxy measures of productivity • Changes in attitude • Improvements in management and leadership practices Intermediate • Higher productivity • Reliable productivity improvement process tools	• An economy with greater productivity

The broad logic model is set out above. The core of the model is in the middle of the chart above. In more detail the logic and assumptions are:

- It is assumed that businesses need to be motivated to improve to be appropriate to this trial (although it is not necessary that they use the word productivity to express this). (Around 75% of UK businesses never employ anyone, and so have limited aspirations for growth and, in the current economy, limited relevance to productivity improvement processes.)
- It is assumed that the operators of the trial have access to businesses with the appropriate motivation, and a method to reach them and engage them in the trial.
- The central logic employed in the trial is that, on the average, businesses with an explicit vision and explicit goals and plans will guide actions that are effective in leading to business improvement. The core test considers the mere existence of a vision and plan (or plans) with goals. To the extent that it is possible, the quality of the plans will form a secondary test.
- The training and support will focus on the development of a vision for the business and plans that can be acted upon to increase productivity.
- All participating businesses will benefit from an introductory session followed by 5 themed sessions. On the basis of an assessment of impact led by the business owner, one of the 5 themes will form a focus for the follow-up 1-1 support. The lead theme will not necessarily provide an exclusive focus and may include one or more of the other themes.
- It is assumed that most of the businesses will have neither up-to-date plans for their businesses nor use any plans that they have in an active way.
- If the first of those assumptions is incorrect, the focus of the test will shift to the more qualitative aspects of the plan.

Note: A logic model will help to see the intended mechanism for change for each programme or policy and should also underpin what data needs to be collected when for each

evaluation. This can be helpful to identify the proximate outcome measures that can provide more timely measures than measures such as SME productivity.

Logic models should also help to identify risks or contingency factors which may mean outcomes are not as envisaged.

PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Participants	There will be a total of 450 firms involved in the study. 300 businesses will be selected from a population of over 1,700 businesses that have participated in the Cavendish Enterprise Start and Grow programme (https://www.cavendishenterprise.co.uk/programme/start-and-grow/). The selected firms will be chosen on the basis of a continued desire to develop and grow. This group will then be divided into two groups: 150 businesses receiving the 'treatment' and 150 who wildcat as the 'control'. In addition, there will be a further 150 businesses that will be similar in age, size and sector to the 300 Start and Grow businesses, but drawn from the wider business population. This group will act as a comparator/second control group.
Interventions	The treatment group will be the only group to receive the intervention. The intervention consists of a programme with six group facilitator-led sessions covering: - Introduction - Executing strategy - Developing lean processes - Effective leadership - Financing growth - Developing new opportunities These sessions are followed by up to one day of one-to-one support in the aspect of productivity most likely to yield greatest benefit for the firm.

Outcomes	The trial is designed to enable businesses with fewer than 20 employees to embed effective productivity focused business practices at an early stage in their development, in order to improve productivity in the longer term. In terms of outcomes, the trial will involve the production of diagnostic tools that will identify areas for productivity improvement within businesses with fewer than 20 employees. Within the project timeline (12 months) observable changes in productivity are unlikely. It more likely, however, that there could be observable changes in confidence, management practices and routines, interest in innovation and or exporting and other strategic investments such as training amongst the firms receiving treatment. These 'behavioural effects' are measurable before the treatment, and afterwards and indicate the potential for future productivity movements. This behavioural additionality approach has been widely used in the evaluation literature including in the Growth Vouchers project for the 6-month evaluation. See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/498329/BIS-16-30-growth-vouchers-programme-evaluation-cohort-1-impact-at-6-months.pdf The primary outcomes, therefore, will be improvements in several proxy measures of productivity (attitudinal and behavioural), including changes in behavior/attitudes towards innovation, technology adoption and exporting; changes in/introduction of management and leadership practices; changes in business planning practices. Secondary outcomes will be improved productivity levels amongst the businesses receiving the treatment. Baseline information will be collected on a range of measures (e.g. on high performance working practices) at the start of the trial, and changes from these baselines will be measured via a survey of the companies receiving the treatment. The results will be compared with the findings from the two control groups to ascertain the effect of the intervention.

Note: If some of your outcomes will be constructed, e.g. "attitude to new technology", please provide a description of how the outcome will be constructed from the main variables.

Whilst the objective of BBP is to find ways to increase SME productivity it is recommended that projects also identify more proximate impact measures that are key determinants of success - e.g. have SMEs advanced through different stages of adoption or delivered changes within their businesses that are expected to deliver positive impacts on productivity.

METHODS

Trial Design	The aim of the trial is to ascertain if additional, tailored productivity support is effective in enabling young microbusinesses to embed effective productivity focused business practices at an early stage. The trial will focus on increasing the adoption of modern business practices in leadership and management and business planning, and on changing attitudes to innovation.
	The trial will be a randomized controlled trial and will involve 450 firms in total. A treatment group of 150 selected firms will be selected from the participants in the Start and Grow Programme, with a further 150 firms from this group used as a control group. A second control group will be drawn at random from the general business population.
	The support received by the treatment group will include peer-to-peer support, as well as expert-led group sessions. The intervention/support will be easy to scale, replicable and cost-effective.
	As part of the evaluation, baseline information on productivity and planning methods and activities will be collected at the start of the trial from the individual firms involved. After the treatment period is over, the firms will be surveyed to ascertain what the effects of the support received by the treatment group has been, by measuring changes to the baseline information. In addition to the survey, qualitative research (interviews) will be undertaken with the participants in the trial to gather more in-depth, granular information about the effectiveness of the intervention.
	Using the chosen methodology the study will be able to evidence the benefits of the approach versus typical 1:1 business support, or no intervention.

Randomisation	This is a relatively small trial so no formal pairing structure or stratification will be adopted. The randomisation process also reflects the cohort nature of the intervention which is being run for small treatment groups of around 10-12 firms in different geographical locations (and by different providers).
	The randomisation process is as follows:
	(a) Delivery organisations in different parts of the country recruit a group of 20-25 participants for the trial and link their names to a random code.
	(b) The list of codes (firms) is provided to ERC and participants are randomly allocated to treatment and control groups.
	(c) These random allocations are then provided back to the delivery organisation which uses this randomisation as the basis for constructing the treatment and control groups.
	In addition to group membership (i.e. treatment v control) we also record the cohort number of each firm, the responsible delivery organisation and the date of randomisation. These variables may be useful in the analytical phase of the trial as conditioning variables.

Trial Diagram

Trial Process Map

1	Baseline data collection	**450 small businesses** (0-19 employees) Productivity baseline Attitude baseline

		Group 1 150 small businesses Treatment Group Drawn from Start and Grow cohort	Group 2 150 small businesses Control Group A Drawn from Start and Grow cohort	Group 3 150 small businesses Control Group B Drawn from the general micro business population
2	Random assignment to groups 1 and 2. Random selection of Group 3.			
3	Well-defined intervention	Group and 1-1 support activities over 9 months	No additional support	No support

4	End-programme data collection	450 small businesses Productivity at end of intervention period Attitude at end of intervention period
5	Continuing data collection	450 small businesses Productivity at times determined by BEIS after the intervention period

SAMPLE SIZE

> **Sample Size**
> The trial will involve 450 firms in total. This will consist of a treatment group of 150 selected firms selected from the participants in the Start and Grow Programme, with a further 150 firms from this group used as a control group. A second control group will be drawn at random from the general business population. This is the maximum feasible sample within the scope of the broader Start and Grow Programme and reflecting the resources available within the project.
>
> Given the assumptions below (and assuming no attrition in survey response) the trial will be able to distinguish differences in proportions of around 0.15 (e.g. the difference between 0.4 and 0.55 of firms in each arm having any capability).

Table 1: Potential assumptions relevant to sample size calculations

Assumptions to consider	Value
Criterion for statistical significance (probability level; typically 0.05)	0.05
Power against alternative hypothesis (conventionally 80%)	0.80
Proportion of randomisation units assigned to treatment (e.g. 50% of the total sample assigned to treatment in a two-arm trial)	0.50
Treatment compliance	100%
Number of individuals per randomisation unit (applicable to cluster randomised trials)	150
Intra-class correlation (ICC) coefficient (rho) (applicable to cluster randomised trials)	n/a
Proportion of variance in the outcome explained by covariates (R-squared)	n/a
Whether the test is 2-tailed or 1-tailed (if applicable)	n/a

Note: There are a number of factors involved in estimating the sample size, including: Type and structure of the trial and research question; Effect size - 'Minimum Detectable Effect Size (MDES); The 'noise in the outcome variable' (i.e. unexplained variance)

Two approaches to estimation:

- *Fixed Sample: What is the smallest true impact that I can be confident of detecting given a sample of this size?*

- *Target Impact: What sample size do I need to be confident of detecting an impact of this scale?*

It is important to highlight that statistical significance is not same as policy significance. What scale of impacts would inform your policy decision? For example, how much want to increase the proportion of SMEs who adopt technology x; % change in productivity or the ratio of net economic benefit to programme cost. Ideally, want to align the Minimum Detectable Effect Size in the trial with policy significant outcome. So able to say with confidence whether impacts exceed or fall short of decision thresholds

DATA COLLECTION AND ANALYSIS

Assessment of data collection	Baseline information on productivity, current management and business practices will be collected from all of the 450 firms involved in the trial. This will be gathered via an online survey and analysed by a professional survey house. It will include gathering key contextual information on a range of areas such as firm age, size, turnover, the existence of a business plan, experience/qualifications of leadership, investment in skills/innovation. The baseline data collection will take place as the firms have being recruited and before the intervention is delivered. A follow-up survey will be undertaken after the treatment has been delivered (six months later), and changes to baselines measured.
Data collection instruments	The data collection instruments used will be two surveys (the baseline survey and a later follow up survey). These will both be administered using a professional survey house. In addition, semi-structured interview questionnaires will be used for the follow up qualitative work, which will be undertaken after the treatment has been delivered.

Unintended effects data collection	The qualitative work in particular will allow the study to explore the unintended effects of the intervention in depth. Both participants and those involved in providing support will be interviewed. The follow-up survey will also include questions to take into account any unintended effects, which will designed after discussion with those delivering the intervention.
Business retention plan	Drop out of businesses is a risk to the project, this is more of an issue for the control groups rather than those receiving the intervention. Efforts will be made to promote business retention, by providing updates on the study progress and making clear that participants will have access to the final findings. A professional survey house will allow time for repeated follow-up calls to be made in order to achieve high completion rates for the telephone survey.
Statistical method	Comparison of the treatment and control groups will be in two stages. First, a comparison of the baseline (pre-treatment) characteristics of treatment and control groups. This is intended to provide an indication of the robustness and success of randomisation. We should see no or few significant differences in characteristics between groups. Any observed differences will be examined for potential biases on subsequent comparisons. Second, we will use simple regression models to compare treatment and control groups standardising for firm characteristics and background.
Additional analysis	Not applicable.

PROCESS AND WIDER EVALUATION (IF APPLICABLE)

Process evaluation	The telephone/online surveys have been constructed to test the hypotheses directly and where possible using sets of questions that have been tested and used successfully in other similar surveys (many of these surveys have been carried out by the fieldwork contractor working on the project, or are available online since they are government-funded). This will ensure the surveys are using questions that have already been proven to work in other studies and will be easy for respondents to answer. The questionnaires will be put into CATI format and administered by professional telephone survey interviewers. The survey data will be analysed using appropriate statistical software. The qualitative work will involve the production of semi-structured interview question guides, which will be designed following discussions with those involved in the delivery of the intervention. The interviews will be recorded and transcribed professionally to ensure all insights are properly captured.
Monitoring data	Both the telephone surveys and the qualitative work will collect detailed monitoring data how supported businesses engage with the support provided.
Wider Impact evaluation	The design of the trial, as it includes two control groups, will allow an assessment of the impact of the intervention to be made. Qualitative information will also focus on the impact of the intervention on the treatment firms. As the timescale for the trial is relatively short, it is likely that most impacts on productivity, since they take time to take effect, will be felt after the end of the study period. For this reason, a methodology for following up the firms will be provided, with suggested metrics to be used in the future to track the productivity of the firms involved.

ETHICS

Ethical concerns	From the possible universe of interventions, a model is proposed that we believe holds promise but it has not been tested so we do not know if it will work better than existing interventions. We believe that we are in a position of equipoise, a state of equal balance. If the trial is successful, and further funds are made available to adopt the process more generally, we would seek to engage the control group in new services as a matter of priority.
Confidentiality	The trial will comply with legislative requirements set out in the Data Protection Act 2018, the EU General data protection Regulation (GDPR) and any other successor legislation. The application form will explain how we plan to use the information provided and who we will share it with. All applicants will be provided with the Trial Privacy Notice.

Appropriate technical and organisational measures will be used to maintain confidentiality. This will involve the use of measures such as encryption and 'Pseudonymisation'.

Contracts with 3rd parties will require them to comply with the relevant legislation and to protect the confidentiality of information. |
Data protection	A Privacy Notice will be developed for the Trial and will be provided to all applicants. This will set out who the Data Controller is, the lawful basis for processing personal data, the types of personal data to be collected who it will be shared with and the rights of individuals.
Consent	A Privacy Notice will be developed for the Trial and will be provided to all applicants. This will set out who the Data Controller is, the lawful basis for processing personal data, the types of personal data to be collected who it will be shared with and the rights of individuals.
Declaration of interest	There are no known competing interests.

RISKS

Description of risks to the trial and how they might be addressed. Trial risk register with examples:

Risk	Assessment	Countermeasures and contingencies
Failure in recruiting businesses	Likelihood: low Impact: high	The project team will make use of their relationships the local business communities to recruit more businesses. The programme delivery phase could be extended without compromising the data collection and reporting phases.
Interventions are not implemented well	Likelihood: low Impact: moderate	The Inception meeting with the deliverers will explain the delivery content, the trial and the roles and responsibilities. Key contacts have been identified to resolve problems in content or delivery processes.
The deliverers do not follow correct trial protocols	Likelihood: moderate Impact: high	The Inception meeting with the deliverers will provide clear guidance describing protocols for distribution to all deliverers. Key contacts have been identified to resolve problems in content or delivery processes.
Business attrition	Likelihood: moderate, perhaps higher in the control groups Impact: moderate	The Inception meeting with the deliverers will reaffirm the principles of the trial and expectations. Attrition will be monitored and reported according to CONSORT guidelines.

TIMELINE

Time Period	Description
To end February 2019	Recruitment of participants Finalising programme content and processes Finalising RCT design, survey design Baseline survey Randomisation
March 2019 - June 2019	Programme delivery
July 2019 - November 2019	Data collection and analysis
December 2019	Reporting

Description of a timetable (including specification of who completes each task if possible). See final pre-programme version of the Project plan attached as a separate document.