Reporting methodological items in randomised experiments in political science

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Paper prepared for the EGAP meeting, April 2009, Yale, and for a special issue of the *Annals of Political and Social Sciences*

Abstract

This paper aims to apply the CONSORT procedures for carrying out and reporting trials to recent field experiments political science with aim of improving clarity and transparency of research work and reducing the possibility of bias. It reviews the background to CONSORT, sets out the main elements of the scheme, and then applies the criteria to evaluate a recent voter turnout study: John and Brannan (2008). It finds reporting methods in this piece to be clear and transparent. It also argues that reporting according to CONSORT could improve turnout experiments, such as conveying the power calculations of the design phase on an experiment and the numbers going through the trial. It argues that applying CONSORT to all trials in political science trials is a feasible and desirable objective.

Introduction

The randomized controlled trial (RCT) is the best method of preventing selection bias and, in principle, produces unbiased estimates of an outcome. Only in special circumstances, where the selection covariate is clearly known, will estimates using matching and other methods approximate to that of a RCT (Shadish et al 2008). Randomized trials, however, may be undertaken in a suboptimal fashion. Poorly designed and conducted RCTs may actually be more of a threat to inference than non-randomized controlled trials as the latter are known to be susceptible to selection bias and consequently their results are treated more cautiously. In contrast, the results from a RCT that produces a biased estimate of effect may be accepted uncritically as it is not possible to recognize the difference between a rigorous and a weak RCT. This problem has been recognized in healthcare research where life and death decisions may depend upon the results of a trial. Methodological studies in the 1980s and 1990s found that poorly conducted RCTs generated exaggerated effect sizes compared with the most robustly designed trials (Pocock et al, 1987; Gore et al, 1992).

Consequently, a group of trial methodologists and leading medical journal editors formed the CONSORT group (http://www.consort-statement.org/), which produced guidance on the reporting of randomised trials of pharmaceutical products (Altman et al 2001). These guidelines have been amended to include non-pharmacological interventions (Boutron et al. 2008). CONSORT provides a minimum set of recommendations for reporting RCTs and a standard way for authors to prepare reports of trial findings, which helps full and the transparent

reporting of the trial. It also is designed to stimulate the critical appraisal and interpretation of experiments. The statement is contained in a twenty-two-item checklist concerning the design, analysis and interpretation of results, then a flow diagram, which shows the progress of all the participants through the trial. The implementation of these reporting guidelines by editors improved the transparency of published trials. For around 300 medical journals now require authors to follow CONSORT when reporting a trial. This is not to say a trial has to follow the guidelines in its design, but it has to report whether or not the trial conforms to the CONSORT items. This enables the reader and the systematic reviewer to judge the risk of bias and the applicability of the trial's results. The use of CONSORT has been advocated in the field of educational trials (Torgerson and Torgerson, 2005) and in this paper we argue for its use in political science.

The paper is in three parts: first, we describe the CONSORT items from the non-pharmacological and cluster trial CONSORT statements and justify why these are required; second, we review the particular application of RCTs in political science, paying particular attention to voter turnout studies and the kinds of reporting that have been adopted, in relation to the normal standards of reporting for journals. Third, we take an example of a trial in the political sciences and report this using the CONSORT statement to illustrate its utility: John and Brannan's (2008) comparison of a door-to-door and telephone Get Out the Vote study in the UK 2005 General Election. The conclusion considers the likely impact of the CONSORT criterion in the political science review process, and discusses whether RCTs in political science may implement CONSORT or adopt a version of the procedure.

Background

In medical research and in other disciplines, such as education, crime and justice and other public policy areas, randomized controlled trials (RCTs) are widely accepted as the most reliable method to determine the effectiveness of an intervention (Prescott et al, 1999). Other approaches, such as observational studies, can give misleading results Wood et al., 2008; Kunz et al., 1998; Kunz et al. 2007) in the field of healthcare, several interventions that were deemed to be efficacious on the basis of observational studies turned out to be ineffective or harmful in subsequent RCTs (Abel et al, 1999). The reason that non-randomised studies can be misleading is because of selection bias. Selection bias occurs when participants who have an intervention are selected into the intervention group on the basis of a variable that is related to outcome. One health care example is the widespread view that the use of post-menopausal oestrogen replacement therapy reduced cardiovascular disease and strokes (Grady et al, 1992). However, when large randomized trials of post-menopausal oestrogen replacement therapy were conducted these showed that this treatment actually increased strokes and heart disease (Writing Group, 2002). The previous observational data were misleading because women who took oestrogens were either selected to use oestrogens by their physicians or approached their physicians to be prescribed oestrogens. Such women tended to be different from women who did not use oestrogens: they tended to have higher social status; take more exercise and have a better diet compared with women who did not use oestrogens. These factors were protective on the cardiovascular system and misled

epidemiologists and clinicians into believing post-menopausal oestrogens could be beneficial for those diseases.

A well-conducted randomized trial ensures that selection bias is eliminated when the treatment groups are assembled. However, a poorly designed and conducted randomized trial can reintroduce selection bias or produce other biases that may mislead the reader into believing that there is an effect of an intervention when, in truth, there is not. Indeed, a poorly conducted randomized trial may be worse that a well conducted non-randomised study. As the latter is acknowledged as being susceptible to selection bias its results are then treated cautiously. For example, a large cluster randomized trial appeared to show that hip protectors were effective in the prevention of hip fractures (Kannus et al., 2000). Yet in this trial intention to treat analysis was not used and when later, more rigorous trials were completed, the relationship between hip protectors and lower hip fracture incidence disappeared (Birks et al.2004).

What then constitutes a robust randomized trial? There are several key criteria that constitute a robust design, which we discuss later in this paper. However, the most important is transparency of reporting. Any research community who use RCTs to inform decisions must be able to appraise the internal validity of the trial results (Clark et al, 1999; Schulz et al, 1995: Guyatt et al, 1993) (i.e., the extent to which systematic errors or bias has been avoided). Furthermore, a trial should inform wider policy and for any given trial or systematic review of trials we need to be able to ascertain whether the results apply outside the setting of the original study: that is its external validity (applicability or generalisability).

Unfortunately, this goal has not been achieved in health care, mainly because of the inadequate reporting of trials. For example, a systematic review of 519 RCTs published in 2000 highlighted the inadequate reporting of essential methodological criteria necessary to appraise the internal validity, such as sample size calculation, the randomisation process and handling of attrition (Chan and Altman, 2005). Lack of reporting of these details weakens the critical appraisal of results of a trial and makes it difficult to synthesise of the research results in systematic reviews and meta-analyses.

Health care trialists are not the only ones guilty of poor reporting of methods. Trials undertaken in education, for example, are actually worse when it comes to reporting methodological details of study design (Torgerson et al, 2005). Because poor health care trials can lead to severe consequences for health policy and ultimately lead to poor health outcomes (including death), health care trial methodologists have come together with journal editors to devise a reporting system for RCTs that ensures a minimum quality standard. This initiative has led to the Consolidated Standards of Reporting Trials (CONSORT) Statement (http://www.consort-statement.org/). Many medical journals have now adopted this statement, which means that trial reports should not be published in leading medical journals unless they report their methods in transparent fashion as outlined in the statement.

Experimental studies in political sciences should, ultimately, affect policy and policy makers and other researchers should, like health care researchers, be in a

position to judge whether any randomised trial is of high quality. Many of the same methodological issues relevant to health care trials and social science RCTs also will affect trials in the political sciences and as such they need to be reported with clarity. As a first step to improving the reporting of randomised trials in the political sciences it would seem useful to adopt some or all of the CONSORT statement when reporting such studies. The aim of this paper is to describe the CONSORT statement items and rationale for their use. At the same time it is, important to nest the recommendations for political science within its general conventions of reporting, which tend to be more individualistic than in more science based disciplines, for example by not having a structured abstract. Highly structured and diagram-heavy papers may militate against the highbrow style of the journals and might reduce the chance of articles being accepted in a highly competitive environment.

The CONSORT initiative

In the mid-1990s, two independent initiatives to improve the quality of reporting of RCTs in health care led to the publication of the CONSORT Statement. This statement, developed by an international group of clinical epidemiologists, statisticians, and biomedical editors, consisted of a checklist of items that pertain mainly to the methods, results and discussion sections of an RCT report and identify key pieces of information necessary to adequately evaluate the internal and external validity of the results. The statement also recommends the use of a flow diagram providing information on the flow of the participants during the trial.

The CONSORT initiative follows a scientific process of general guideline development principles relying on systematic reviews of all available evidence, consensus meetings and continuous assessment of biomedical publications with regular updates of the guidelines. The most recent updates of the CONSORT Statement took place in Montebello (Canada) in January 2007. The dissemination and use of these guidelines is possible thanks to the support of a growing number of medical and health care journals and editors, including the International Committee of Medical Journal Editors (ICMJE, The Vancouver Group). Evidence suggests that the use of the CONSORT Statement helps improve the quality of reports of RCTs (Plint et al, 2006).

To facilitate the dissemination of the CONSORT Statement, the CONSORT group developed an extension to the statement for abstracts, as well as specific extensions for various trial designs such as cluster RCTs, non-inferiority and equivalence trials, and pragmatic trials; for various outcomes such as harm; and for various treatments such as, recently, nonpharmacologic treatments. These extensions take into account the specific issues raised in these different situations.

The CONSORT statements

The CONSORT checklist recommends the reporting of twenty-two items, as well as a flow diagram, in published articles of RCTs. These items focus on issues considered essential to appraise the risk of bias. We will not detail all the CONSORT

items but, rather, focus on essential items such the randomization process, the blinding of participants and outcome assessors, and the handling of attrition.

Randomization process

In the CONSORT checklist, three items are dedicated to the randomization process. Random assignment aims to remove the potential of bias in assigning subjects to one intervention or another, that is, to protect against possible systematic connection between the intervention that subjects receive and their prognosis. To achieve this goal, allocation concealment (i.e., a strict implementation of a random allocation sequence) is necessary so that investigators do not know the upcoming assignments. Otherwise, the risk is to not include participants in one intervention arm on the basis of knowledge of their prognosis and investigators' guesses regarding the intervention effect. However, some evidence suggests that investigators can subvert the allocation concealment process with creative methods (Schulz, 1995; Hewitt et al, 2009). To avoid such subversion, trials should implement specific methods such as the use of secure (independent), third party to do the randomisation. Secure allocation is particularly important because empirical investigations (Schulz et al, 1995; Moher et al, 1998) have shown that when compared with trials involving adequate concealment, those involving inadequate or unclear allocation concealment yielded up to forty per cent larger estimates of effect. The three items of the CONSORT Statement dedicated to this issue state the need to report: 1) the method used to generate the random allocation sequence; 2) the method used to implement the random allocation sequence; and 3) who generated the allocation sequence, enrolled participants, and assigned participants to each group.

Blinding

Blinding used in combination with randomization is essential to limit the occurrence of conscious and unconscious bias. There are several aspects to blinding. We may wish to blind the participant, whosoever delivers the intervention and the outcome assessor. However, in many sorts of trials this is neither practicable, nor possible nor even desirable. In pragmatic trials, for instance, it is argued that even when it is possible to blind participants to their intervention this does not reflect real life and often open unblinded trials are more desirable (Torgerson and Torgerson, 2008). For trials in the political sciences where we might be offering an intervention to improve voter turnout (e.g., an enhanced canvassing approach), then it is not possible to blind the voter nor is it possible to blind the canvasser. However, it is very important that the outcome assessor remains blind to group allocation. For example, in a voting study we would want to ensure that the researcher who is collecting data on voting behaviour is blind to the allocation group. Otherwise the researcher may consciously or unconsciously ascertain voting patterns in line with their beliefs rather than what the data actually shows. Methodological studies in health care suggest that unblinded outcome assessment is particularly vulnerable to bias. For example, in a multiple sclerosis trial, outcome assessment by an unblinded neurologist revealed an apparent intervention benefit, whereas that by a blinded neurologist did not (Noseworthy et al, 1994). It is unlikely that clinicians are the only ones whose judgements on outcomes may be influenced by their prior beliefs! This is probably less on an issue in political science where results are observed from verifiable data

sources like electoral registers or are administered by survey companies who hand over the data. But it cannot be guaranteed.

Blinding is particularly important when measuring the outcome involve some subjective decisions. The CONSORT Statement highlights the need to report precisely who was blinded, with details on the method of blinding. In fact, blinding is not well understood. For example, the terms "single blinding" and "double blinding" frequently used by researchers and widely accepted by readers as a key marker of validity of an RCT lack consistency in use and interpretation (Devereaux et al, 2001).

Handling of attrition

After randomization, some violation to the protocol as planned may occur. Particularly, participants may be lost to follow-up, they may not comply with the allocated intervention, or they may cross over and receive the non-allocated intervention. These protocol violations occur frequently in RCTs whose results have been published and could bias the estimated intervention effect. The recommended analysis is an intention-to treat analysis, a strategy for analysis of results of RCTs that compares all participants in the groups to which they were originally randomly assigned (Ferguson et al, 2002; Hollis and Campbell, 1999; Schulz et al, 1996). This approach maintains the comparability of intervention groups. The CONSORT Statement recommend the reporting of a flow diagram with the number of participants randomized, the number who complied, withdrew and were lost to follow-up in each group as well as the number analyzed. With the flow diagram,

readers should also be able to determine whether all patients were randomized in the group to which they were allocated.

The CONSORT extension for non-pharmacological treatments

Although CONSORT was originally developed for RCTs evaluating drug interventions it is clear that many health care trials are not drug treatments, such as surgery, and consequently CONSORT did not quite fit to these non-pharmaceutical trials. For example, many non-drug trials cannot use double blinding and because there may be 'therapist' effects these need to be described in more detail. Consequently CONSORT needed some modification to accommodate these non-drug interventions. Assessing the effectiveness of non-pharmacologic interventions, such as in educational medical research or interventions in other disciplines, such as education and the evaluation of public policies, presents specific issues: the difficulties of blinding; the complexity of interventions; and the possible influence of the skill and expertise of those performing the intervention on treatment effects estimates (McCulloch et al, 2002). To ensure these issues are inadequately reported in published RCTs, the CONSORT group developed an extension of the CONSORT Statement for nonpharmacologic trials. In February 2006, an international group of thirty individuals, including trialists, methodologists and journal editors met for a consensus meeting in Paris. The group reached consensus on specific reporting guidance for RCTs of nonpharmacologic interventions (Boutron et al, 2008). Eleven items of the CONSORT checklist were modified. In each case, the modification was

to expand the text to include nonpharmacologic treatment, and one new item related to implementation of the intervention was added. Below we detail some of the major modifications of the CONSORT checklist.

Complexity of the intervention

Nonpharmacologic interventions typically involve several components, each of which can potentially influence the estimated treatment effect (Herbet and Bo, 2005; Campbell et al, 2000; Hawe et al, 2004). These interventions are consequently difficult to describe, standardize, and reproduce. The CONSORT extension for nonpharmacologic treatment recommends the reporting of all the components of the intervention, as well as additional aspects of how the trial was conducted: the procedure of standardization, the method to assess or enhance treatment adherence and the details of the intervention as it was actually implemented. These descriptions are necessary to allow for adequate implementation of the treatment into clinical practice. These data are also necessary to facilitate study comparison and inclusion in meta-analyses (Herbet and Bo, 2005). Provision of an Internet address for interested readers to access materials the authors used to standardize the interventions could help achieve this goal.

Context influence

In trials assessing nonpharmacologic interventions, those providing the interventions are often an integral part of the intervention (Roberts, 1999). Consequently, an unequal expertise or skill between two groups could bias treatment effect estimates.

Further, the application of an RCT in a different context (lower provider expertise) could produce different results. The CONSORT extension for nonpharmacologic treatment insists on this issue and recommends that investigators report: 1) eligibility criteria for providers and centres; 2) baseline data for providers; and 3) the reporting of the number of providers or centres performing the intervention in each group and the number of patients treated by each provider or in each centre in the flow diagram. These data will improve the understanding of both the internal and external validity of the trial.

Clustering effect

Variation in outcomes is smaller for patients treated by the same care provider (Roberts, 1999). Consequently, the assumption that the observed outcomes of participants are independent is false, and observations of participants treated by the same care provider may be clustered (Lee and Thompson, 2005). This type of clustering likely affects the effect size estimates because it inflates the standard error and reduces the effective sample size, thus reducing the power of the trial (Lee and Thompson, 2005). The CONSORT extension for non-pharmacologic trials recommends reporting how this issue was handled in the sample size calculation and in the statistical analysis.

Blinding

In non-drug interventions, use of placebo interventions is frequently impossible but is also debated. In fact, the use of placebos has been argued to possibly underestimate

the intervention effect (Boutron et al, 2007; Torgerson and Torgerson, 2008) because placebo interventions may have a specific therapeutic effect linked to the relationship between participants and care providers. Blinding of participants is frequently impossible in non-pharmacologic trials, and, consequently, efforts should focus on blinding outcome assessors. Researchers are still working on how best to deal with some of these methodological challenges, and they should report how they handled them to allow progress in understanding these potential biases. This CONSORT extension highlights the need to report these features for all trials of non-pharmacologic treatments.

The CONSORT extension for cluster RCTs

Cluster RCTs are often used to assess non-pharmacologic interventions, particularly because they avoid the threat of contamination of some interventions (such as dietary interventions) if individual randomisation is used and may be the only feasible method. Because use of cluster RCTs also raises specific issues, the CONSORT group developed an extension for cluster RCTs (Campbell et al, 2004). This extension particularly highlights the need to report how the effects of clustering were incorporated into the sample size calculations and how the effects of clustering were incorporated into the analysis and to provide in the flow diagram the flow of both clusters and individuals through the trial, from assignment to analysis.

The application of CONSORT to political science trials.

Political science has only recently featured randomised controlled trials, which emerged with voting studies in the 2000s (Gerber and Green 2008). There was an experimental tradition in the 1930s, but this had largely died out with advances in survey research, which seemed to answer most questions in the study of political behaviour (Gerber and Green 2003). Partly as a result of the tradition in which political scientists work, they were not exposed to the methods of reporting for randomised controlled trials, so some procedures, such as reporting the power of experiments before their implementation, have not been yet adopted. The CONSORT guidelines provide a means of catching up with more general reporting standards in science and other parts of social science. We discuss one example here.

John and Brannan (2008) sought to replicate the methods of Gerber and Green (2000) in a field experiment in 2005 to test the effects of difference canvassing methods on voter turnout in a single parliamentary seat in the 2005 general election. The paper raises issues of both internal and external validity. We want to know given the results of the experiment can we be confident in its findings and secondly are these findings applicable to a wider area than the single geographical area that was the site of the experiment. In Table 1 we apply the CONSORT statement to this particular RCT. In the table we have tried to complete the CONSORT table from data contained within the paper. We find there is a good fit and most of the CONSORT items were reported in this particular paper. Some aspects could have been clarified, such as the reason for the sample size chosen and the absence of reporting of tests of the power of the experiment. In addition, one item (item 19), may need to be reworded as adverse events are likely to be very different in this kind

of situation. In health care interventions it is quite common for treatments to have adverse effects, drugs for instance may cause gastric side-effects, whilst surgery has infections as a side effect. For a clinician and patient weighing up the merits or hazards of a given treatment these adverse events are very important. This might be changed to 'unexpected events'. For example an RCT of electoral monitoring in Indonesia observed that they were effective at increasing the overall vote – the main outcome (Hyde 2008). However, an unexpected event was that the intervention differentially increased the female vote, which may be more influential in an election if one of the main candidates, as was the case in this example, happened to be female.

In Figure 1 we show the CONSORT flow diagram as applied to the study, which reveals the exact numbers going through the experiment. This is not entirely clear from the text of the paper. The reader would have to calculate the difference between the randomised sample of 2,300 and the analysed numbers in the tables of the paper to work out the numbers removed because of deceased and postal voters. This clarity would have benefited the paper.

Discussion and Conclusions

The discussion of the background to the CONSORT guidelines and their implementation in science and other applications is designed to show how serious is the reporting of randomised controlled trials. This is because of the dangers to scientific understanding and inference from poorly reported trials. If the people using

trials come to false conclusions, in particular concluding there is an effect when there might not be or not be one, then the whole point of doing RCTs – to provide valid and robust knowledge from which to make policy or other decisions – is undermined. This is obviously crucial in medicine and health where people's health is at risk, but it is important in policy relevant areas such as voter turnout. In addition, the guidelines acts as an extra discipline in the research process, affecting how researchers do the research if they know there are very transparent means of reporting, encouraging them to have the highest standards in the design of the research which can help them address issues of validity and reliability before they complete their research. To the end, fully transparent standards of reporting a trial a means the reader can ensure the science behind a study is done at the highest standard. The fellow researcher can trust the study to make inferences from it or fairly assess its limitations when designing replications or extensions of the method. If this argument is accepted, then political scientists should adopt the CONSORT criteria in carrying out and reporting experiments.

We presented case study of John and Brannan (2008) to illustrate the advantages of CONSORT. Because of the large number of voting studies that use the same method and form of reporting (see Green and Gerber 2008), we think it is fair assessment of the state of methods and reporting in the field. The CONSORT checklist and flow chart would look similar in most of these studies, though without the complexities caused by the UK electoral registration system which impacted on the sample size in the John and Brannan case. There is no doubt that the CONSORT reporting is

cleaner and would have made the paper and those like it more explicit. It would help the reader understand the study more, in particular the numbers of subject at each stage. It would have been useful to see the calculations of effect size and power before the experiment. So in that sense CONSORT presents an advantage for researcher and could alone be a reason for its adoption.

The bigger question is whether the CONSORT guidelines would have produced better experiments in political science. Here the presentation of the data show that the experiment was done properly and it reflects the high standards of the reporting of methodological issues in political science generally. It would not have taken much effort to have it report the CONSORT checklist. In addition, political science experiments that rely on publicly validated data or that done by independent survey companies may not have the same vulnerability to violations of the experimental design as other disciplines that have more direct contact with their research subjects. It partly reflects the difficulty of doing research on politicians, political actors and the citizens themselves that the unit of measurement tend not to be based on direct observations of those actors.

A generally strong methodological tradition and an often favourable research environment are not reasons for complacency, particularly as experiments diffuse from being done by a few pioneers. It is possible that future experiments will have direct contact with the research subjects, especially as experimental research expands out from voter turnout studies. And at the same time there is a move for more transparency in reporting of political science methods more generally which

CONSORT neatly complements. So while the bulky nature of the CONSORT reporting requirements might not be quite the current norm for journals used to more economical forms of presentation, and could conceivably put off reviewers and journal editors, greater detail about the methods needed is probably going to be the new norm. And there is one final advantage we have not mentioned: these guidelines will allow experimental researchers outside political science to understand and hopefully cite these political science experiments. Now that can't be bad thing!

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Table 1: Extension of the CONSORT Statement for nonpharmacological interventions – John and Brannan (2008) study description

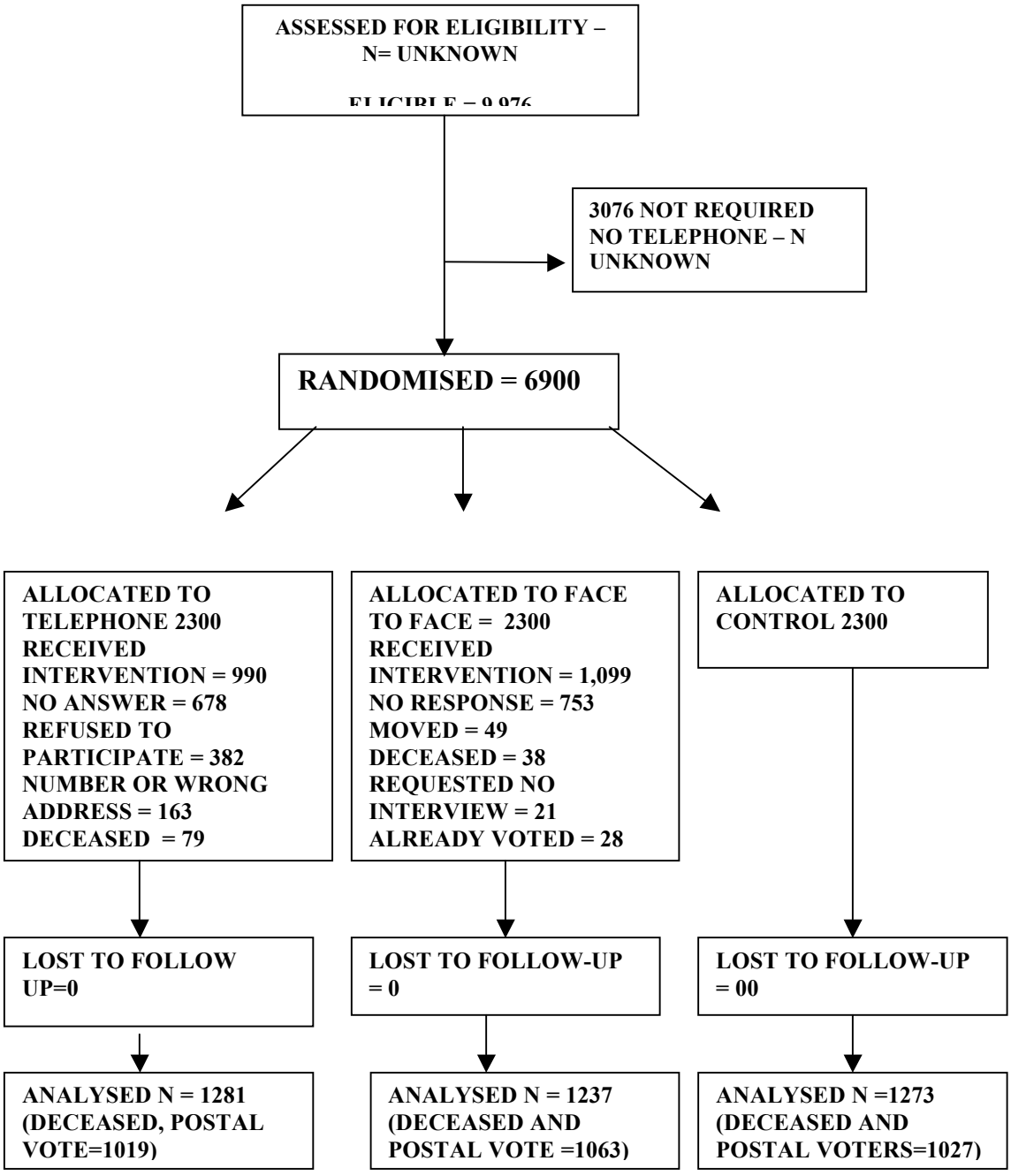
PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Comment
TITLE & ABSTRACT	1	The participants were randomly allocated using a function in the excel software.	.
INTRODUCTION Background	**2**	To provide evidence on the effectiveness of canvassing in a UK context.	
METHODS Participants	3	Participants had to be on the electoral roll and have a landline telephone number.	The results would not be applicable to people who are 'ex-directory' with no public telephone number available.
Interventions	**4**	Canvassing telephone call or face to face visit, preceded by a letter warning of imminent contact. Detailed description of the non-partisan conversation prompts. Control group received nothing.	
Objectives	**5**	Can face-to-face or telephone canvassing lead to an increase in the proportion of people who vote in a British General Election	

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Comment
Outcomes	**6**	Main outcome was proportion who voted in the general election. Secondary or process outcomes were the proportion who were successfully contacted.	
Sample size	7	No prior sample size calculation or justification for sample used.	NB with 2,300 in each group the trial would have slightly more than 90% power to show an absolute 5% difference in voting.
Randomization Sequence generation	8	Excel was used to randomise, no detail was given on stratification – probably specified single random samples of 2,300 from overall sample.	
Allocation concealment	**9**	Not clear how concealment was undertaken. The paper did not describe whether the allocation was undertaken by a third party.	
Implementation	**10**	Not clear	
Blinding (Masking)	11.	Blinding of canvassers not possible and not relevant. Does not state whether assessment of official turnout registers was done blindly.	It would have been possible to conceal group allocation from assessment of turnout.

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Comment
Statistical methods	12	Not clear statistical tests used for the intention to treat analysis, undertook a two stage regression for instrumental variable analysis.	
RESULTS Participant flow	**13**	Detailed description given in Tables 1 & 2 about reasons for non-contact of participants. Not possible estimate total initial sample before exclusions due to lack of telephone land line.	
Recruitment	**14**	Not specified.	
Baseline data	15	Not possible as electoral role gives limited demographical detail of electors.	
Numbers analysed	**16**	In main table of results does not give both numerator and demoninator.	
Outcomes and estimation	**17**	Provision of standard error but not confidence intervals.	
Ancillary analyses	**18**	None performed.	
Adverse events	**19**	None reported	Adverse events may not be relevant here.
DISCUSSION Interpretation	20	Interpretation draws on previous, American literature, and shows similar findings.	

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Comment
Generalisability	21	May have poor generalisability as it was a single safe constituency in relatively poor area may not apply to wealthier areas.	
Overall evidence	**22**	Draws on past evidence not the answer as results only show a marginal impact.	

FIGURE 1: CONSORT FLOW CHART FOR JOHN AND BRANNAN (2008).



Appendix: Modified Extension of the CONSORT Statement for political science trials adapted from the extension for Nonpharmacologic treatments

PAPER SECTION and topic	ITEM	Standard CONSORT item	Extension for trials of political science trials
		Describe	In addition:
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned")	In the abstract, description of the experimental intervention, comparator, intervention providers, centers, and blinding status
INTRODUCTION Background	**2**	Scientific background and explanation of rationale	
METHODS Participants	3	Eligibility criteria for participants.and the settings and locations where the data were collected.	When applicable, eligibility criteria for centers and those performing the interventions
Interventions	**4**	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental intervention and comparator
	4.A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Extension for trials of political science trials In addition:
	4.B		Details of how the interventions were standardised
	4.C		Details of how adherence of intervention providers with the protocol was assessed or enhanced
Objectives	**5**	Specific objectives and hypotheses	
Outcomes	**6**	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	When applicable, details of whether and how the clustering by intervention providers or centers was addressed
Randomization Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how intervention providers were allocated to each trial group

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Extension for trials of political science trials In addition:
Allocation concealment	**9**	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	
Implementation	**10**	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	
Blinding (Masking)	11.A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment
	11.B		If blinded, method of blinding and description of the similarity of interventions[1]
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s). Methods for additional analyses, such as subgroup analyses and adjusted analyses.	When applicable, details of whether and how the clustering by intervention providers or centres was addressed

1 This item was modified in the 2007 revised version of the CONSORT checklist

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Extension for trials of political science trials In addition:
RESULTS Participant flow	**13**	Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	The number of intervention providers or centers performing the intervention in each group and the number of participants treated by each intervention provider or in each center
Implementation of intervention	NEW ITEM		Details of the experimental intervention and comparator as they were implemented
Recruitment	**14**	Dates defining the periods of recruitment and follow-up	
Baseline data	15	Baseline demographic and clinical characteristics of each group	Baseline characteristics of each group and when applicable, a description of intervention providers (case volume, qualification, expertise, etc.) and center (volume) in each group

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Extension for trials of political science trials In addition:
Numbers analysed	**16**	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	
Outcomes and estimation	**17**	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)	
Ancillary analyses	**18**	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory	
Unexpected events (In CONSORT, adverse events)	**19**	All important adverse events or side effects in each intervention group	All important unexpected events (adverse events or side effects) in each intervention group

PAPER SECTION and topic	ITEM	Standard CONSORT item Describe	Extension for trials of political science trials In addition:
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	Additionally take into account the choice of the comparator, lack of or partial blinding, unequal expertise of intervention providers or centers in each group
Generalisability	21	Generalisability (external validity) of the trial findings	Generalisability (external validity) of the trial findings according to the intervention, comparators, participants, intervention providers and centers involved in the trial
Overall evidence	**22**	General interpretation of the results in the context of current evidence	