

Randomised controlled trials of social interventions: Report of a pilot study of barriers and facilitators in an international context.

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Background

Although the use of experimental designs in medicine is generally uncontroversial this has not been the case in social policy circles in the UK. Arguments against social policy trials have tended to focus on potential problems with feasibility, ethics, cost, public and professional acceptability, and generalisability. While some countries, including the USA, have a history of social experimentation, others have tended to avoid such designs in favour of evaluations based on practitioner or self report (Macdonald and Roberts 1996), observational, “case study” or qualitative methods. While these methods may have considerable strengths, and be more attentive to context and implementation than traditionally run trials, these methods are less susceptible than trials to reaching clear conclusions about the effectiveness (let alone the cost effectiveness) of the interventions in question.

Arguments which have been made against RCTs include situations where they are thought not to be feasible for ethical, political and practical reasons (Sanson-Fisher et al. 1996); suggestions that the evidence they generate may not be generalisable; and that they are costly. The applicability of randomised designs to complex, large scale systems, and to the evaluation of social policies has been debated. In particular, in interventions where the causal pathways between intervention and outcome are long and complex RCTs may be difficult to interpret (Victora et al., 2004). Chalmers has argued that as the application of RCTs in social settings is in principle the same as in medical settings (Chalmers, 2001), and Forsetlund et al. (2007) have estimated from a review of the literature that randomisation has been used in social and educational studies since at least the 1920s. However randomisation of *policies* is more contentious, and is open to the criticism that it is politically and ethically more difficult to randomise entire communities because this appears to involve withholding potentially beneficial interventions from the populations involved. Obtaining informed consent may also be problematic. It has also been suggested that in the case of community-based interventions rigorous evaluation is rare and tends to be limited to affluent communities where the interventions are limited and carefully controlled (Moller, 2004).

The pilot work we describe here was set up to look for examples of social policy RCTs, on the basis that these may hold lessons for those seeking to develop and implement new trials of social policies. We supplemented these searches with qualitative data, investigating the perceptions and experiences of trialists, research commissioners, policymakers and other “users” of trials and of evaluative research. We reasoned that these data may well tell us something of the conditions under which trials may and may not be feasible; about the barriers and facilitators to the development of new trials; and about the ways in which different kinds of evidence are valued within different policy sectors.

Aims

The preliminary work we describe here had three components:

- i) to develop methods of “mapping” existing social policy trials - that is, to work out how to identify as far as possible existing and ongoing social policy RCTs in Canada, the US, UK, Australia and elsewhere, in order to capture how common RCTs of social policies really are; and
- ii) to conduct interviews with a sample of senior researchers involved in social policy RCTs, and with policymakers/practitioners in selected countries, in order to identify the barriers and facilitators to the use of trials, and relevant experiences of interviewees;
- iii) to use our experience in relation to the above to consider a funding application on the use of trials in social policy.

The work was carried out in the first half of 2008. MS and KL worked on the first area, and KL, SM, HR and MP on the second. The third area of work is currently in progress and is described in the discussion section of the report.

Methods and Results

The search for trials: methods

Since we were aware that it would not be possible to identify all social policy RCTs within such a short project, we initially aimed to develop a method for identifying and estimating the number of 'social policy' RCTs.

Given our supposition of relatively small numbers of RCTs, this initially appeared to be a straightforward task, particularly given a number of key existing databases and studies, including:

- The Campbell database, SPECTR, and other Campbell sources (in particular the C2 Social Welfare Coordinating Group (SWCG);
- The Cochrane trials database CENTRAL
- Previous bibliographies: (e.g., Boruch 1974)
- The updated Wider Public Health work published by CRD
http://www.york.ac.uk/inst/crd/projects/wider_public_health.htm
- The EPPI centre health promotion and public health reviews
<http://eppi.ioe.ac.uk/cms/Default.aspx?tabid=75>
- Work carried out on public health interventions at NICE
http://www.nice.org.uk/aboutnice/whatwedo/aboutpublichealthguidance/about_public_health_guidance.jsp

What rapidly became clear was, firstly, that once small trials, often carried out for graduate work in north America, were taken into account, there was a much larger 'social policy' trial body than we had envisaged. Secondly, it became evident that 'social policy' trials could potentially cover a very broad spectrum, ranging from behaviour change to welfare-to-work benefits; from new ways of teaching mathematics to interventions to address youth offending. This meant that considerable effort was put into seeking a working definition, building on previous work in this area (Oliver et al, 2008).

We defined social policy interventions as covering the following areas:

- food/nutrition
- crime
- housing/regeneration/built environment
- the natural environment
- education (excluding health education)
- work/pensions/benefits/income
- transport

In a further attempt to define what 'counted' as the kind of intervention we wanted to include, we added the following inclusion/exclusion criteria:

Interventions would be included if they:

- intend to serve communities or populations, thereby excluding interventions aimed at specific individuals
- require more than the efforts of individual practitioners to apply
- are not aimed at influencing individual behaviour
- affect people not met by whoever is implementing the intervention
- are not a one-to-one service
- are non-clinical

Appendix I shows our protocol at this stage.

In order to make a preliminary investigation of available RCTs of interventions meeting these criteria we decided to capitalise on previous searches by drawing on databases of good quality systematic reviews.

The databases were:

- The Cochrane Library of systematic reviews
- The Campbell Library of systematic reviews
- The EPPI-Centre Evidence Library of systematic reviews

For each relevant systematic review we initiated an exercise exploring how many RCTs were found, and the countries where these RCTs had been carried out.

At this stage, we also found and then searched two sources of RCTs which were likely to be relevant. The Digest of Social Experiments (Greenberg and Shroder, 2004) and Social Programmes That Work (<http://www.evidencebasedprograms.org/>), a web-based resource summarising findings from RCTs relevant to social policy.

The search for trials: results

Data were collected from the above sources.

Thirty seven Cochrane and Campbell systematic reviews met our inclusion criteria, (although a larger number of reviews fell into the broad category of social policy reviews, without meeting our inclusion criteria). Twenty two reviews included RCTs. While, as expected, most of the trials were USA-based, 23 other countries were also represented (See Appendix II).

The RCTs included in the Digest of Social Experiments and on Social Programmes That Work, tended to be aimed at specific individuals and therefore did not meet our inclusion criteria.

Inter-rater variation on what did, or did not constitute a social policy trial at this stage was scored by MP, HR, MS and KL from a list 31 interventions prepared by MS. (See Table 1). There was complete agreement on only 18 of these. A further list of 6 interventions was presented to 16 investigators and trainees at a meeting of an international collaboration of researchers from the UK, Canada, the US, and Australia, funded by the Canadian Institutes of Health Research to carry out research on evaluating complex interventions. These individuals were asked to say, without having looked at our inclusion criteria, whether or not they would 'count' each of these studies as a social policy intervention. As Table 2 demonstrates, without the inclusion criteria to consider, there was stronger (though by no means perfect) consensus.

The interviews: methods

Ethics approval was obtained from the Faculty of Children and Health Research Ethics committee at the Institute of Education, University of London. An interview topic guide was designed by KL, amended in discussion with the team, and slightly adjusted at interview according to whether the respondent was a researcher, policy maker or funder (Appendix III). An information sheet was sent to potential informants (Appendix IV), together with an informed consent form (Appendix V).

We generated a list of 33 names of researchers and policy analysts in 6 countries whom we might interview and made contact with 15 of these.

The interviews: results

None of those we approached refused to be interviewed, but there was some non-response, particularly when contact was made by a less senior member of the research team. We interviewed 10 individuals from 6 countries, 6 by telephone, and 4 in face to face interviews. Eight of these interviews were with people involved with policy or research commissioning, and two with senior researchers. Our interviews were fully or partially transcribed, and for purposes of this report, some indicative findings are reported below, and summarised in Table 3.

A preliminary analysis suggests the importance of personal contact and the influence of trusted researchers:

“I relied a lot on expert groups at [government department] ... these kept me abreast of what was going on ... Serendipity also played a part – I would bump into someone and they would tell me something. I was chair of a couple of [research council] units.” (Policy maker, UK)

Personal contact was also raised in the context of the initiation and use of trials:

“actually somebody proposed on our behalf that there should be a proper trial to have a look at the impacts of remediating buildings and it was discussed in the Cabinet on Monday morning and they came back on Wednesday and said ‘give us a proposal for doing an RCT’, so that is a small society for you.” (Researcher, New Zealand)

and in relation to the ways in which trialists disseminate to policy colleagues:

“There was one study which was very powerful, very influential. It was carried out by (Name) working with children with behavioural difficulties, and it adopted a variation of a model from America. It was very powerful because [he] presented it to policy makers in a very clear way, and he didn’t tie it around with caveats as researchers are prone to do.” (Research commissioner, UK)

On the other hand, a commissioner (otherwise increasingly sympathetic to the use of trials) suggested that the enthusiasm of some advocates of trials had set the cause back:

“My shift, if I may speak freely, has been towards trials. And to be honest, I don’t think [name] did it a lot of favours by polarising the discussions. It puts people into different camps, which they didn’t necessarily want to be in. I never wanted to be in the anti-trials camp, where I found myself by not being in the rampant trials group.” (Research commissioner, UK)

The contribution that trials can make to cost benefit analyses was seen as crucial to their appeal:

“... a number of ministers have said it made a big difference to them being able to argue the case.” (Researcher, New Zealand)

Barriers, even among those sympathetic to trials, include concerns around ethics:

“...we felt that it just wasn’t methodologically or even ethically feasible to have a randomised control trial, you know, where there was already so much evidence that it was actually effective, and where for instance,

we got a control group that weren't getting treatment, you would be actually denying people treatment which you had a pretty good idea was actually quite effective." (Policy advisor, UK)

There were also concerns on costs, and a particular concern about the consequences of finding that something does not work:

"... there are costs to having really good evaluations not just the financial cost, they do cost more obviously but you know, if ... it's really good and the results you know tell you that your intervention isn't working then you're in trouble, and I think to some extent you know, people would rather have you know vaguer information about processes, which ... carries less risk of being hostages to fortune to some extent. I mean people like the idea of the process of continuous quality improvement with evaluation, you know, contributing something to improve the way you implement your ... new policy or your intervention, and I think, to some extent, that's preferred to evidence which .. tell(s) you pretty starkly that you ought to stop and that you're wasting public money." (Policy advisor, UK)

Technical issues, including recruitment, were also mentioned:

"The very rigorous requirements about who goes into a trial and who doesn't can be problematic, especially in populations that I'm interested in very needy populations. It's a lot easier to be successful if you can capture your research population. You can with a health visitor, you can with a school, much more difficult if you're offering a service to people which they can or can't take up. It gets increasingly difficult the more needy the families are." (Research commissioner, UK)

Timeliness continues to be perceived as a problem, particularly in countries with short electoral cycles:

"By the time policy makers want to trial an intervention they already believe it's a good thing. The evaluation is more about looking at the feasibility of an intervention than looking at its effect." (Researcher, Australia)

"the options of doing things really well had already disappeared by the time the evaluations were commissioned. And too many prior decisions had already been taken." (Policy advisor, UK)

The term as well as the concept could be seen as a political problem:

"they [politicians] were happier if we called it a pilot rather than an experiment or a trial." (Policymaker, UK)

and the power of narrative was also invoked:

"certainly in British politics, the power of a story beats almost anything." (Policy advisor, UK)

An interesting point was made about the intellectual background of politicians:

"versed in the law and advocacy and case study and precedent, rather than science..." (Policy advisor, UK)

Finally, some respondents felt that social policies were not possible to trial.

"RCTs are more suited to clinical research. Investigators have more control over the intervention." (Policy analyst, International organisation)

Finally, training in appropriate skills was identified as a problem in several cases

"I think I find it quite dispiriting that in America, they will invest in these really rigorous studies, and yet in this country, we don't. There's a problem with research capability in this country because people don't develop the skills to do it." (Research commissioner. UK)

Discussion

Our findings dispel two common myths – firstly, that social policy trials ‘only’ happen in the USA and secondly, that Cochrane and Campbell reviews are confined to RCTs.

In the course of attempting to implement the aims and methods described above, we became aware of a considerable body of work in this country and elsewhere that had attempted similar tasks, and had faced similar problems of definition and of scope. The difficulties of developing a working definition of ‘social policy’ proved time consuming and limited the extent of the mapping exercise. Our work on definitional problems, and our exercise with two expert groups on assessing what is, and what is not, a policy trial suggest that the difficulty faced by the researchers undertaking this task is one also experienced by world experts in the field. However the summary of some of the most available evidence, that provided by the Cochrane, Campbell reviews gives an indication of the international spread of RCTs in these fields, dominated by, but not limited to, the US.

Bonell et al. (2006) considered whether structural interventions (which they defined to include policies) could be evaluated using RCT designs, using HIV prevention as a case study, and taking into account ethical, practical and other criticisms that have been made. They concluded that there were no factors that prevented structural interventions as a category being evaluated in RCTs. They did, however, identify some cases where they may not be feasible – such as where interventions exert effects across time periods over which RCTs cannot be maintained, and where the recruitment of adequate numbers of clusters to RCTs is impossible. The updated MRC Guidance on Complex Interventions points out that RCTs may not be feasible when a relatively large population is affected by a substantial change in a well-understood environmental exposure, and where exposures and outcomes can be captured through routine data sources such as environmental monitoring and mortality records (e.g. air pollution legislation) (MRC 2008). Our project similarly identified enough examples across a number of settings to suggest that there is no barrier to RCTs of social policies *per se*, but identified a number of barriers to their adoption which may be worth pursuing in future research.

Implications for future research

In the light of our experience, we do not feel that more mapping work in this area is a priority – particularly given the good work being done elsewhere. There are, however, issues about national and international studies which might be further explored, including those large scale international studies where some countries have run trials, and others do not.

McKee (2007) has recently described the influence of political ideologies on the conduct and use of RCTs in medicine. The interviews described here suggest that there are similar influences on the conduct of social policy RCTs, and that the choice of experimental and other evaluation methods is influenced by the ideological and methodological stances of both researchers and policymakers. Our interviews suggest that there is a move towards heavier use of trials, including in the UK, and that to date, where RCTs have had an influence in the UK, it has tended to be based on early childhood interventions in the USA. At least some recent trials, or trials about to start in the UK appear to related in part to advocacy by those who have a programme they would like to see used or further tested. A different approach might involve the identification of policy and public priorities as a researcher ‘push.’ As one of our respondents put it, there is a need:

“to provide a sort of communicative space where different groups in society can work out what’s important and try and find information that can then be used to make good decisions.”

These might include sentencing and juvenile justice; interventions aimed at mode of transport (which have the potential to reduce inequalities); educational interventions; and child protection interventions where there is uncertainty on the best course of action).

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Appendix I: Protocol: Trials in an international context: mapping exercise

Aims

This mapping exercise aims to:

- a) Identify good quality systematic reviews of social policy interventions and report on how many RCTs were found by these reviews.
- b) identify examples of social policy intervention RCTs in the areas of public health, education, social welfare, criminal justice, housing and transport and urban renewal

Methods

To do the following in order of priority, depending on time constraints:

1. search Campbell, Cochrane and the EPPI-Centre evidence library for systematic reviews which fit our inclusion criteria
2. record the number of RCTs included by each review
3. record details of these RCTs

Inclusion criteria

Interventions: Social policy interventions which fulfil the following criteria.

Social policy interventions are defined as interventions which:

1. are intended to serve communities or populations, thereby excluding interventions aimed at specific individuals
2. require more than the efforts of individual practitioners to apply
3. are not aimed at influencing individual behaviour
4. affect people not met by whoever is implementing the intervention
5. are not a one-to-one service
6. are non-clinical

Interventions may include legislation or regulation; setting of strategy at the level of national or local government, or institutions; the provision or organisation of services; environmental modification.

These policy interventions operate at the level of institutions (e.g. schools, prisons, public authorities), communities, regions or nations.

Participants: Any

Outcomes: health, wellbeing, achievement, transport, mobility, employment, housing status, income

Study design: Systematic reviews. Instead of applying quality criteria, we are only searching databases which contain reviews with rigorous study designs.

Date limits: none

Appendix II: Trials in the included reviews: Cochrane and Campbell Collaborations

Systematic review: Campbell and Cochrane Collaborations		No of RCTs	Country
	Campbell reviews (These can be accessed via the Nordic Campbell Centre HU http://www.sfi.dk/sw28652.asp)		
1	Braga, A (2007) Hot spots policing: effects on crime	5	all USA
2	Lum C, Kennedy C, Sherley A (2006) The effectiveness of counter-terrorism strategies	0	
3	Mazerolle L, Soole DW, Rombouts S (2007) Street-level drug law enforcement: A meta-analytic review	3	all USA
4	Villettas P, Killias M, Zoder, I (2006) Custodial vs. non-custodial sentences: effects on re-offending	4	3 USA, 1 Switzerland
5	Visher C, Winterfield L, Coggeshall, M (2006) Non-custodial employment programs: impact on recidivism rates of ex-offenders	8	8 USA
6	Zief S, Lauer S, Maynard R (2006) Impacts of After-School Programs on Student Outcomes: A Systematic Review for the Campbell Collaboration	5	5 USA
	Cochrane reviews (these can be accessed via the Cochrane Library http://www.thecochranelibrary.com)		
7	Aeron-Thomas AS, Hess S (2005) Red-light cameras for the prevention of road traffic crashes	0	
8	Al Fallah M, Boland M, Crowley D, Fitzpatrick P, Scallan E, Staines A (2004) Child-resistant containers for preventing childhood poisoning	0	
9	Bunn F, Collier T, Frost C, Ker K, Roberts I, Wentz R (2003) Area-wide traffic calming for preventing traffic related injuries	0	
10	Callinan JE, Clarke A, Doherty K, Kelleher C (2006) Smoking bans for reducing smoking prevalence and tobacco consumption	0	
11	DiGuseppi C, Higgins JPT (2004) Interventions for promoting smoke alarm ownership and function	15	not identified in review
12	Dinh-Zarr T, Goss C, Heitman E, Roberts I, DiGuseppi C (2004) Interventions for preventing injuries in problem drinkers	23	1 Canada, 1NZ, 3 Australia, 12 USA, 2 Sweden, 1 UK, 1 Bulgaria, 1'10 countries'
13	Gates S, McCambridge J, Smith LA, Foxcroft DR (2006) Interventions for prevention of drug use by young people delivered in non-school settings	17	12 USA, 1UK, 1China, no data on others
14	Hartling L, Wiebe N, Russell K, Petruk J, Spinola C, Klassen TP (2004) Graduated driver licensing for reducing motor vehicle crashes among young drivers	0	
15	Ker K, Chinnock P (2006) Interventions in the alcohol server setting for preventing injuries	6	2 Canada, 1 Sweden, 2 Australia, 1 UK
16	Kristjansson EA, Robinson V, Petticrew M, MacDonald B, Krasevec J, Janzen L, Greenhalgh T, Wells G, MacGowan J, Farmer A, Shea BJ, Mayhew A, Tugwell P (2007) School feeding for improving the physical and psychosocial health of disadvantaged students	7	3 Wales, 1China, 1England, 1 Kenya, 1 Jamaica
17	Macpherson A, Spinks A (2007) Bicycle helmet legislation for the uptake of helmet use and prevention of head injuries	0	
18	McClure R, Turner C, Peel N, Spinks A, Eakin E, Hughes K (2005) Population-based interventions for the prevention of fall-related injuries in older people	0	

19	Pratt BM, Woolfenden SR (2004) Interventions for preventing eating disorders in children and adolescents	12	1 Italy, 3 USA, 1 Canada, 1 Australia
20	Rautiainen RH, Lehtola MM, Day LM, Schonstein E, Suutarinen J, Salminen S, Verbeek J (2008) Interventions for preventing injuries in the agricultural industry	5	2 USA, 1 Finland, 1 Denmark
21	Royal ST, Kendrick D, Coleman T (2005) Non-legislative interventions for the promotion of cycle helmet wearing by children	9	4 Canada, 4 USA, 1 UK
22	Secker-Walker RH, Gnich W, Platt S, Lancaster T (2004) Community interventions for reducing smoking among adults	2	1 USA & Canada, 1 Australia
23	Serra C, Cabezas C, Bonfill X, Pladevall-Vila M (2000) Interventions for preventing tobacco smoking in public places	0	
24	Sowden A, Arblaster L, Stead L (2004) Community interventions for preventing smoking in young people	94	66 USA, 1 Finland, 1 Spain, 1 India, 5 Canada, 3 Australia, 5 Netherlands, 3 UK (Wales and England), 1 (Denmark, Finland, Portugal), 3 Italy, 1 France, 3 Germany, 2 Norway, 1 Mexico
25	Sowden AJ, Arblaster L (1998) Mass media interventions for preventing smoking in young people	2	2 USA
26	Spinks A, Turner C, Nixon J, McClure R (2005) The 'WHO Safe Communities' model for the prevention of injury in whole populations	0	
27	Stead LF, Lancaster T (2005) Interventions for preventing tobacco sales to minors	8	7 USA, 3 Australia
28	Thompson DC, Rivara FP (1998) Pool fencing for preventing drowning in children	0	
29	Thompson DC, Rivara FP, Thompson R (1999) Helmets for preventing head and facial injuries in bicyclists	0	
30	Turner C; Spinks A; McClure R; Nixon J; (2004) Community-based interventions for the prevention of burns and scalds in children	0	
31	Wilson C, Willis C, Hendrikz JK, Bellamy N (2006) Speed enforcement detection devices for preventing road traffic injuries	0	
32	Zoritch B, Roberts I, Oakley A (2001) Day care for pre-school children	7	7 USA
33	Lyons RA, Sander LV, Weightman AL, Patterson J, Jones SA, Lannon S, Rolfe B, Kemp A, Johansen A (2004) Modification of the home environment for the reduction of injuries	18	1 USA, 1 Canada, 1 UK, 1 Australia, 1 Netherlands
34	Thomas R, Perera R (2006) School-based programmes for preventing smoking	94	93 single country studies (66 USA, 6 Canada, 5 Netherlands, 3 Italy, 2 each Australia, Germany, Norway and the UK; 1 each Finland, France, India, Mexico and Spain). The multi-country study included Denmark, Finland, the Netherlands, Portugal, and the UK
35	Underhill K, Montgomery P, Operario D (2008) Abstinence-plus programs for HIV infection prevention in high-income countries	34	32 USA, 1 Bahamas, 1 Canada
36	Bala M, Strzeszynski L, Cahill K (2008) Mass media interventions for smoking cessation in adults	0	
37	Vidanapathirana J, Abramson MJ, Forbes A, Fairley C (2005) media interventions for promoting HIV testing	2	1 Scotland, 1 not reported

Appendix III: Interview topic guide

Consent, ethics, and what we will be doing with the work.

Introduction to the study

Thanks for agreeing to take part. Just to remind you about the project – we are looking at why trials of social interventions have been carried out more often in some countries than in others, and the conditions in which ‘policy RCTs’ are and are not seen as appropriate. We are particularly interested in identifying the barriers and facilitators to the use of trials of social interventions, and in learning from the experiences of interviewees.

The perceptions and experiences of researchers, policymakers, funders and other “users” of policy trials and of evaluative research may tell us something of the conditions under which policy trials may and may not be feasible; about the barriers and facilitators to the development of new policy trials; and about the ways in which different kinds of evidence are used within different policy sectors.

- First, can you tell me about the kinds of knowledge that you use in your work? [Does this include research knowledge? – if not prompt]
- Which kinds of research knowledge do you find most useful?
- Have you any experience of using/commissioning/funding RCTs?
- Do you think there is a difference between the knowledge gained from RCTs vs knowledge gained from other kinds of research? If so, please elaborate.
- Do you feel that RCTs have a role to play in policy development? [RCTs strengths, weaknesses]
- What are the “facilitators” to the funding/use of policy-relevant RCTs? What do you think allows some to be carried out (or, carried out successfully) and not others?
- Do you know any examples where an RCT has informed/led to policy change? [If so, can you describe the process?]
- Do you know of any examples of unsuccessful attempts to set up policy RCTs ? [If so, can you describe why you think it was not successful?]
- Are there any policy RCTs in this or another country which you think have been particularly influential or interesting in other ways?
- What do you think are the main reasons why RCTs are not used more often to evaluate policies? [ethical, practical, political, other barriers]
- Are there particular sectors [or departments] within which RCTs are more acceptable than others? If so, why do you think this is?
- Do you think the acceptability of/support for policy RCTs varies across countries?
- Do you know of any ongoing policy-relevant RCTs in your areas/field?
- Are there any other issues we have not covered which you think are relevant?
- Have you any suggestions as to who else we should approach for an interview?

[ask for permission to recontact if need to clarify; arrangements for reporting]

Appendix IV: Information sheet for interviewees



The ICCI study: 'Trials in an international context'

1. What is ICCI?

This study is conducted as part of ICCI, which is an international collaboration of researchers in the UK, Canada, the US, and Australia, who have been funded by the Canadian Institutes of Health Research to carry out research on evaluating complex interventions – such as government policies. ICCI stands for the International Collaboration on Complex Interventions. We also have some funding for this study from the UK's Medical Research Council (MRC).

2. Who are we?

We are researchers from the Institute of Education in London (Kristin Liabo, Madeleine Stevens and Professor Helen Roberts), the MRC Social and Public Health Sciences Unit in Glasgow (Professor Sally Macintyre), and the London School of Hygiene and Tropical Medicine (Professor Mark Petticrew).

3. What is this study about?

We are studying why trials to evaluate policies have been carried out more often in some countries than in others. We are particularly interested in identifying the barriers and facilitators to the use of trials, and in finding out about the relevant experiences of people who have been involved in conducting them. To do this, we are carrying out interviews with a small sample of policy advisors, researchers and others in the UK and in other countries.

Scientific investigation of the perceptions and experiences of researchers, policymakers and other “users” of trials and of evaluative research may tell us something of the conditions under which trials may and may not be feasible; about the barriers and facilitators to the development of new trials; and about the ways in which different kinds of evidence are used within different policy sectors.

Please take time to read the following information and discuss it with others if you wish. Please feel free to ask anything that is not clear or if you would like more information.

4. What do we ask of you?

We would like to interview you - probably by phone – at a time convenient to you. The interview will take about 30 minutes, and with your permission will be tape-recorded to ensure accuracy. Any information you provide will be anonymised. Your name will not appear on any report, and the final report will not identify anyone by name.

We hope you will be able to participate. If you would like to talk to someone about this study, please ring or email Professor Mark Petticrew on +44 (0) 207 927 2009 mark.petticrew@lshtm.ac.uk or Kristin Liabo on +44 (0) 20 7612 6377 k.liabo@ioe.ac.uk who will get back to you. Your co-operation would be very much appreciated and you would be taking part in an important piece of work, which will inform the development of new policy evaluations in the UK and elsewhere.

Thank you very much for your help.

Appendix V: Consent Form



**The ICCI study:
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I confirm that I have read and understand the information sheet for the ICCI study ‘Trials in an international context’, dated 14th of January 2008. Yes No

I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. Yes No

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason.	<input type="checkbox"/> Yes <input type="checkbox"/> No
I understand that my answers are confidential and that my participation will remain anonymous in the final report and any other publications deriving from this study.	<input type="checkbox"/> Yes <input type="checkbox"/> No
I agree to take part in the research study ‘Trials in an international context’.	<input type="checkbox"/> Yes <input type="checkbox"/> No

Name of interviewee Date Signature

Name of interviewer Date Signature



Table 1: Is this a social policy trial? Inter-rater variation (with full agreement highlighted)

Intervention	1	2	3	4
After-School Program Impacts on Student Outcomes	Y	Y	?	Y
Evidence on Effectiveness of Volunteer Tutoring Programs	Y	Y	?	Y~
Parental Involvement and the Academic Performance of Elementary School Children	N	Y	?	N
School-based Social Information Processing Interventions and Aggressive Behavior for Pull Out Programs (Part 2)	N	Y	N	N
School-based Social Information Processing Interventions and Aggressive Behavior Cognitive-behavioral programs: effects for criminal offenders	N	Y	N	N
Correctional boot camps: effects on offending	N	N	Y	Y?
Counter-terrorism strategies	Y	Y	Y	Y
Custodial vs. non-custodial sentences: effects on re-offending	Y	Y	Y	Y
Hot spots policing: effects on crime	Y	Y	Y	Y
Incarceration-based drug treatment: effectiveness on criminal behavior	N	N	Y	N?
Non-custodial employment programs: impact on recidivism rates of ex-offenders	Y	Y	Y	Y
Scared Straight and other juvenile awareness programs for preventing juvenile delinquency	N	Y	Y	N
Serious (violent and chronic) juvenile offenders: treatment effectiveness in secure corrections	N	N?	Y	N
Street-level drug law enforcement	Y	Y	Y	?
Behavioural and cognitive behavioural training interventions for assisting foster carers in the management of difficult behaviour	N	N	N	N
Cognitive behavioural therapy for men who physically abuse their female partner	N	N	N	N
Cognitive-Behavioral treatment for antisocial behavior in youth in residential treatment	N	N	N	N
Cognitive-behavioural interventions for children who have been sexually abused	N	N	N	N
Exercise to improve self-esteem in children and young people	N	Y	N	N
Group based parent-training programmes for improving emotional and behavioural adjustment in 0-3 year old children	N	N?	N	N
Home based support for socially disadvantaged mothers	N	Y	N	N
Independent living programmes for improving outcomes for young people leaving the care system	Y	Y	Y	N
Individual and group based parenting for improving psychosocial outcomes for teenage parents and their children	N	N	N	N
Interventions for learning disabled sex offenders	N	Y	N	N
Interventions intended to reduce pregnancy-related outcomes among adolescents	N	Y	N	?
Multisystemic therapy for social, emotional, and behavioral problems in children and adolescents aged 10-17 N	N	N	N	N
Parent-training programmes for improving maternal psychosocial health	N	N	N	N
School feeding for improving the physical and psychosocial health of disadvantaged elementary school children	Y	Y	Y	Y~
School-based education programmes for the prevention of child sexual abuse	Y	Y	N	Y
Speech and language therapy interventions for children with primary speech and languagedelay or disorder	N	N	N	N
Work programmes for welfare recipients	Y	Y	Y	Y

Table 2: Responses from 16 attendees at a meeting of attendees at a meeting on complex interventions

Are these social policy interventions? Responses from ICCI meeting			
	Yes	No	Unsure
Education maintenance allowance for participation in post-compulsory education.	11	3	1
Independent living programme for improving outcomes for young people leaving the care system.	11	3	1
School-based education programme for the prevention of smoking.	8	5	2
Nurse-home visitation experiment, impact on welfare receipt, maternal employment and child behaviour.	10	5	1
Welfare Employment Experiment – job support services’ impact on employment, learning and welfare receipt.	14	1	
Wage subsidy variation experiment – incentives to employers to employ disadvantaged youth	13	2	

Table 3: Levers and barriers to social policy trials identified with interviewees

Levers	Barriers
Personal contacts /researcher policy contact/ serendipity	Poor communication by researchers; ambivalence/hostility by researchers and research brokers
Potential for good cost benefit information	
Independence of evaluators from policy/politicians	Problems if policy initiative to which politicians have committed themselves shown not to work
Funding for new initiatives tied to good trial evidence /accountability	Cost of running a trial
Advocacy by those whose trials have shown an effect in other countries	Ambivalence/hostility by researchers and research brokers
Good dissemination skills by triallists; willingness to avoid too many caveats when presenting results	Over-enthusiasm by some trial proponents
A lot of good research on what the problems are; less on what to do about them	Pejorative use of term experimentation
Convincing trial welcome to politicians	Lack of high quality trial applications
Support from key government departments (eg Treasury)	Moral and ethical concerns
	Lack of researcher experience in social policy trials
	Recruitment problems
	Timing (in relation to policy development)/political desire to get things up and running quickly
	RCTs more suited to clinical research
	The line of least resistance not to carry them out.
	Culture of advocacy, case study, precedent and anecdote