

Can Research Assessments Themselves Cause Bias in Behaviour Change Trials? A Systematic Review of Evidence from Solomon 4-Group Studies

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Abstract

Background: The possible effects of research assessments on participant behaviour have attracted research interest, especially in studies with behavioural interventions and/or outcomes. Assessments may introduce bias in randomised controlled trials by altering receptivity to intervention in experimental groups and differentially impacting on the behaviour of control groups. In a Solomon 4-group design, participants are randomly allocated to one of four arms: (1) assessed experimental group; (2) unassessed experimental group (3) assessed control group; or (4) unassessed control group. This design provides a test of the internal validity of effect sizes obtained in conventional two-group trials by controlling for the effects of baseline assessment, and assessing interactions between the intervention and baseline assessment. The aim of this systematic review is to evaluate evidence from Solomon 4-group studies with behavioural outcomes that baseline research assessments themselves can introduce bias into trials.

Methodology/Principal Findings: Electronic databases were searched, supplemented by citation searching. Studies were eligible if they reported appropriately analysed results in peer-reviewed journals and used Solomon 4-group designs in non-laboratory settings with behavioural outcome measures and sample sizes of 20 per group or greater. Ten studies from a range of applied areas were included. There was inconsistent evidence of main effects of assessment, sparse evidence of interactions with behavioural interventions, and a lack of convincing data in relation to the research question for this review.

Conclusions/Significance: There were too few high quality completed studies to infer conclusively that biases stemming from baseline research assessments do or do not exist. There is, therefore a need for new rigorous Solomon 4-group studies that are purposively designed to evaluate the potential for research assessments to cause bias in behaviour change trials.

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Introduction

Behaviour change interventions are increasingly important in public health as awareness of the contribution of behavioural risk factors such as lack of physical activity to an increasingly wide range of health problems grows [1]. Attempts to influence individual behaviour have also gained a new prominence in wider public policy, for example in efforts to combat climate change or terrorism [2]. Randomised controlled trials offer the most rigorous research design to evaluate the effects of behaviour change interventions.

Approximately one hundred years ago control groups were originally introduced in behavioural sciences to address an inferential problem implicit in the use of the single group pre-post design to evaluate intervention effects [3]. It had been observed that pre-testing or assessment itself had effects, which confounded attempts to attribute change over time to intervention, inextricably so with this design. The adoption of

non-intervention control groups addressed this problem, which can be termed reactivity, as well as others such as history, maturation and regression to the mean, by making the effects of assessment equivalent between groups [3]. The later advent of randomisation to allocate participants to groups subsequently strengthened the practice of experimentation beyond the laboratory.

Whilst reactivity may be intrinsic to most psychological research [4] and requires particularly careful attention in non-experimental designs, it has been considered much less of a problem in experimental research. So long as reactivity occurs equivalently between-groups, causal inferences about the true effects of interventions are safeguarded by the design of the randomised controlled trial. This conventional “solution” to the problem of reactivity to pre-testing in the two-group trial is not perfect, however, as it does not deal with a possibility first identified by Solomon [3] and later elaborated by Campbell [5], that assessments may interact with interventions to either

strengthen or weaken observed effects. In these circumstances 2-group comparisons in trials may produce biased estimates of effects. Solomon thus proposed a 4-group “extension of control group design” in which a further randomisation took place, allocating participants within both the experimental and control groups to be pre-tested or not [3]. As well as offering a means of controlling for assessment effects, the Solomon 4-group design has the capacity to assess interactions between the intervention study conditions and pre-testing. This provides a test of the internal validity of effect sizes obtained in conventional 2-group trials of the effects of behavioural interventions. The possible threat of reactivity to the safety of inference in trials is illustrated with a simple hypothetical example – see Box S1.

This potential threat applies not only to the adoption of health protective behaviours but equally to the reduction of health compromising behaviours such as smoking cessation. As well as ceiling effects, as described in the hypothetical example, bias could operate in the other direction in situations where there is a synergistic relationship between assessment and intervention. This occurs where research assessment prepares people to be more receptive to intervention than would be the case in the absence of research assessment, for example by prompting contemplation which serves as a preparation for behaviour change.

Conventional trial conduct has previously also been questioned in relation to placebo effects in trials of antidepressant medications. It seems unlikely that drug and placebo effects do not have any multiplicative relationships with each other [6,7]. This work is highly pertinent also because assessment has been identified as a component of the placebo effect in irritable bowel syndrome [8].

The possibility that assessment or measurement may produce bias in trials has been given sustenance by an upsurge in recent health sciences study of assessment reactivity or “mere measurement” effects, the term used within health psychology [9]. Some trials find that earlier research assessments do not influence later outcome data [10,11,12]. Other trials, however, find effects of research assessments on both behavioural and non-behavioural outcomes, both self-reported and objectively ascertained [13,14,15,16,17,18,19,20]. These are usually small in magnitude, which may explain the inconsistency. This recent attention adds to decades of earlier social science research wherein, for example, it is well established that being interviewed on intentions to vote in elections alters the likelihood of actually doing so [21].

The biasing effects of research assessments, if they exist, are likely to be variable across populations, behaviours, interventions and outcomes, as well as the particular assessment methods used. For this reason, an “apples and oranges” evidence synthesis, in which heterogeneity is anticipated at the outset, was judged most appropriate. This could be useful in summarising a broad range of existing relevant information, and in the event that prospective studies are found to be needed, would aid the development of more fine grained hypotheses amenable to testing.

We therefore decided to be as inclusive as possible, incorporating evidence from any Solomon 4-group studies with behavioural outcomes, without regard to particular behaviours, participants, and interventions. The restriction to behavioural outcomes offered the possibility of identifying effects on both objectively ascertained and self-reported measures. Our over-arching research question thus concerned whether any evidence existed that research assessments influenced behaviour in such a way that would indicate bias in behaviour change trials, as identifiable by interactions rather than additive effects observed in Solomon 4-group studies.

Methods

In Solomon 4-group studies, participants are randomly allocated to one of four arms: (1) assessed experimental group; (2) unassessed experimental group (3) assessed control group; or (4) unassessed control group. These refer only to baseline assessments and follow-up assessments are undertaken as usual. This design thus provides a test of the internal validity of effect sizes obtained in conventional two-group trials by controlling for the effects of baseline assessment, and assessing interactions between the intervention and baseline assessment.

The early stages of this review were undertaken iteratively, with the final study design decisions resulting from inspection of studies identified in initial searches and more detailed eligibility criteria developed as progress was made. The formal inclusion criteria 1–6 are presented approximately in the sequence that they were applied. Studies must be true applications of the Solomon 4-group design with double randomisation to any intervention and any form of assessment in any population (1) and published in peer-reviewed journals (2); they also needed to have behavioural outcome measures (3) and be undertaken in non-laboratory settings where behaviour was under the autonomous control of study participants (4); also necessary were outcome data for all four groups or an appropriately analysed summary of results (5) with a sample size of 20 per group or more (6). This systematic review was undertaken without a published protocol.

Electronic database searches without date restrictions were undertaken in Web of Knowledge, PsychInfo, CINAHL Plus with full text, INSPEC, ERIC, Web of Science, Medline, Pubmed, Cochrane Central Register of Controlled trials, EMBASE, BIOSIS Previews, Sociological Abstracts, National Criminal Justice Reference Service Abstracts (NCJRS), Social Services Abstracts, Linguistics and Language Behaviour Abstracts (LLBA), the International Bibliography of the Social Sciences (IBSS), Biomed Central, APPI Journals, British Nursing Index, ADOLEC, AgeInfo, Allied and Complementary Medicine Database (AMED), Medline inc, Social Policy and Practice, British Humanities Index, Applied Social Sciences Index and Abstracts (ASSIA), and PsychArticles. The basic search strategy, for example as used in Medline, was Topic = (solomon 4) OR Topic = (solomon four). This was supplemented where it was possible with NOT Author = (Solomon) and NOT Topic = (island*).

After screening for relevance by title and abstract all subsequent inclusion/exclusion decisions were made jointly by two authors, with a third opinion occasionally sought for irreconcilable differences of opinion. After the initial searches an update on 24/08/10 yielded no additional inclusions, nor did contacts with experts. Data extraction from included studies was undertaken by two authors from published reports with a dedicated form and without any contact with their authors. This comprises the data presented in Tables 1, 2, 3, 4 and the accompanying text including additional quantitative data, which also addresses relevant sources of bias. Given the nature of our research question and the heterogeneity of included studies this tabular and narrative presentation was preferred. This decision not to undertake a meta analytic synthesis was made after the dataset had been finalised. Risk of bias across studies is considered in the discussion section in light of obtained findings.

Results

Ten studies were eligible for inclusion in this review [22,23,24,25,26,27,28,29,30,31] – see Figure for a summary of the study selection process and Table 1 for details of included studies. The majority (n = 6) of these studies took place in schools

Table 1. Study Characteristics.

Author	Year	Location	Population	Intervention	Assessment	Duration of follow up post assessment	Initial sample size (n =)	Follow up rate (%)
<i>Studies with adults</i>								
Dignan	1996	U.S.	Cherokee Indian women	Two home visits for health education to increase cervical cancer screening	96 item Cherokee researcher administered interview at home (duration 20 minutes–1 hour)	6 months	996	82
Dignan	1998	U.S.	Lumbee Indian women	Two home visits for health education to increase cervical cancer screening	Lumbee researcher administered interview at home (mean duration 20 minutes)	6 months	979	87
Lusk	1999	U.S.	Construction workers exposed to high noise who were attending vocational training events	Video, handouts and hands on practice to increase use of hearing protective devices (ear plugs and muffs)	Self-completed questionnaire (no further details provided)	10–12 months	837	68
Van Sluijs	2006	Netherlands	Physically inactive adults in general practice with hypertension, high cholesterol or diabetes	2 sessions of tailored advice on physical activity by GP/nurse plus 2 booster telephone calls by counselor (all sessions 10 minutes) compared with one 10 minute session of untailored advice	13 page questionnaire completed twice 8 weeks apart	6 months	717	89
<i>Secondary school studies</i>								
Duryea	1983	U.S.	School grade 9	6 sessions of alcohol education (1 hour each over 6 days)	25 item questionnaire	2 weeks	155	100
Kvalem	1996	Norway	Upper secondary school (high school, commercial or vocational education, age 16+)	Training for peer delivery of sex education	80 item questionnaire	6 & 12 months	2088 (original n of relevant sub-sample unclear)	75, 68
Traeen	2003	Norway	School grade 10	Sex education curriculum and textbook	99 item questionnaire	6/7 months (& 18 months, outcomes not reported)	1183 (original n of relevant sub-samples unclear)	77 (56)
<i>Primary school studies</i>								
Campanelli	1989	U.S.	School grades 5 & 6	4 sessions of alcohol misuse prevention (45 minutes each over 3 months)	60 item questionnaire	5 months	5,680	86
Shope	1992	U.S.	School grades 5 & 6. (Same study cohort as above)	As above, plus randomization to 3 booster sessions the following year	60 item questionnaire	5, 17 & 29 months	5,680	86, 74, 67
Freeman	2003	U.S.	School grades 3 & 4	18 weeks creative drama lessons (40 minutes per week) to reduce problem behavior	“general test in grade-appropriate academic work unrelated to purposes of the study”	18 weeks	237	82

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Table 2. Findings summary.

Author	Year	Primary Behavioural Outcome Measures	Intervention effects on these outcomes	Any main effects of on these outcomes	Any interactions between assessment and intervention on this behaviour	Any other assessment effects reported i.e. on other outcomes
<i>Studies with adults</i>						
Dignan	1996	Self-reported screening attendance	Yes	Borderline (see main text for details)	No (see also main text & Table 3)	No. No effects on knowledge or intentions
Dignan	1998	Self-reported screening attendance	Yes	No	No	Yes. Main effect and interaction for intentions in logistic regression models
Lusk	1999	Frequency of use of hearing protection devices	Yes	No	No	No. No effect on future intentions.
Van Sluijs	2006	1. Meeting guideline levels of physical activity; 2. Minutes spent in moderate intensity physical activity; 3. Accelerometer - counts/min in sub-group of <10% participants	No	1. Yes; 2. No. 3. No	No	Yes, main effect on self-efficacy for resisting relapse.
<i>Secondary school studies</i>						
Duryea	1983	Past week frequencies of drinking & riding in a car with a drinking driver	Yes, on accompanying a drinking driver only	No	Unclear as untested, though appears unlikely. Mean scores & SDs reported.	Yes, main effect on knowledge scores
Kvalem	1996	Use of condoms in most recent intercourse among those with sexual experience prior to study	No	No	Yes after 6 months. No after 12 months	No other outcomes adequately reported (see text)
Traeen	2003	1. Contraception use at first intercourse if during study period; 2. Use of contraception at most recent intercourse	1. No; 2. No	1. No; 2. No	1. No; 2. No (see text)	No other outcomes.
<i>Primary school studies</i>						
Campanelli	1989	Alcohol frequency & misuse (comprised alcohol overindulgence, trouble with peers & trouble with adults, as attributed to alcohol)	Yes, alcohol use frequency in analyses unadjusted for clustering only	Yes, on trouble with peers in both analyses adjusted and unadjusted for clustering. Also in overindulgence in unadjusted analyses.	No	Yes, main effects on peer adjustment in unadjusted analyses and on adult health locus of control and internal health locus of control in both adjusted and unadjusted analyses. Also interaction of assessment and intervention on school adjustment in unadjusted analyses only.
Shope	1992	Alcohol frequency & composite of misuse as above	No	No. Reported that "no evidence was found for the pre-test stimulating students' use and misuse of alcohol". Mean scores & SDs reported without statistical test results	Unclear as untested, though judged unlikely	Unclear
Freeman	2003	Problem behavior scores	No	No	No	No

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Table 3. Proportions reporting screening attendance in the Dignan et al. studies in the 4 randomised groups.

		Assessment	
		Y	N
Dignan et al. 96			
Intervention	Y	149/210 (71%)	133/175 (76%)
	N	155/238 (65%)	120/192 (63%)
		Difference +6%	Difference +13%
Dignan et al. 98			
		Assessment	
		Y	N
Intervention	Y	150/205 (75%)	162/219 (74%)
	N	141/208 (69%)	137/207 (67%)
		Difference +6%	Difference +7%

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and were concerned with the prevention of health compromising behaviours among children. The four studies with adults evaluated health promotion interventions. The two smallest studies also had the shortest periods of follow-up study. The four adult studies comprised similar sample sizes and follow-up intervals (see Table 1). The baseline research assessments were with questionnaires in all cases bar two, in which interviews took place [22,23].

There was somewhat more consistent evidence of intervention main effects in adult than in the school-based studies and greater evidence of assessment main effects on non-behavioural as compared to behavioural outcomes – see Table 2. There was weak evidence only of interaction effects between interventions and assessments on behavioural outcomes overall. The quality of reporting was variable across these studies.

Studies with adults

Dignan and colleagues conducted two similar studies evaluating the effects of health education on cervical cancer screening attendance with Solomon 4 group designs in two different Native American tribes [22,23]. In these studies face-to-face interviews delivered by members of the relevant tribes were the research assessments evaluated. These were studied alongside the health education intervention as there are pervasive beliefs in Native American cultures that health is sacred and talking about related beliefs or behaviours is injurious to health [23]. The timeframe of the behavioural outcome measure was 12 months, whilst the follow-up interval was 6 months in both studies.

In the first of these studies [22], the main assessment effect on screening attendance just missed the conventional threshold for

statistical significance (OR = 1.65 [0.97–2.81]) and the reported interaction test result on screening attendance was not statistically significant (OR = 0.88 [0.38–2.03]). It seems likely, however, that this measure of effect applies to the comparison between the group who were both assessed and had the intervention and the group who had neither. In the raw data there is an indication of an interaction – see Table 3. Differences apparently due to the main effects of assessments are small and inconsistent, whilst the effect of the intervention appears to be approximately twice as large among those who have not been assessed as compared to those who have, suggesting that the observed intervention effect depends upon whether assessment has taken place [22].

In the second of these studies there are no clear effects of the assessment interview nor interactions with intervention, which was again found to be effective in promoting screening attendance in a logistic regression model [23]. These data are also presented in Table 3 for comparison purposes.

Lusk and colleagues provide ANOVA results showing an intervention effect, and no pre-testing main effect nor interaction with intervention [24]. There are no more detailed data available for the purposes of this study.

VanSluijs and colleagues [25] provide evidence of assessment main effects with the proportions meeting guideline levels of physical activity higher among those assessed twice with the 13 page booklet in both unadjusted and adjusted analyses (OR = 1.70 [1.14–2.54]). It should be remembered that the control condition in this study were also exposed to intervention, albeit less intensive than the principal intervention being evaluated. VanSluijs and colleagues state that “no effect modification for randomization to control or intervention condition was observed” without reporting any additional data [25].

Secondary school studies

Kvalem and colleagues [27] in Norway investigated the effects of training for peer sex education on condom use at most recent intercourse on those trained and not on those to whom the sex education was to be delivered. An attempt was made to account for clustering in classes in this study by adding a class attribute variable in the outcome model; this made little difference to outcomes. Unlike all other included studies, an interaction effect is presented among the sub-group of 403 participants who had had their first intercourse prior to the study and who provided follow-

Table 4. Interaction finding on condom use reported in Kvalem et al. study.

		Assessment	
		Y	N
Intervention	Y	51/73 (70%)	21/49 (43%)
	N	76/148 (51%)	69/133 (52%)
		Difference +19%	Difference –9%

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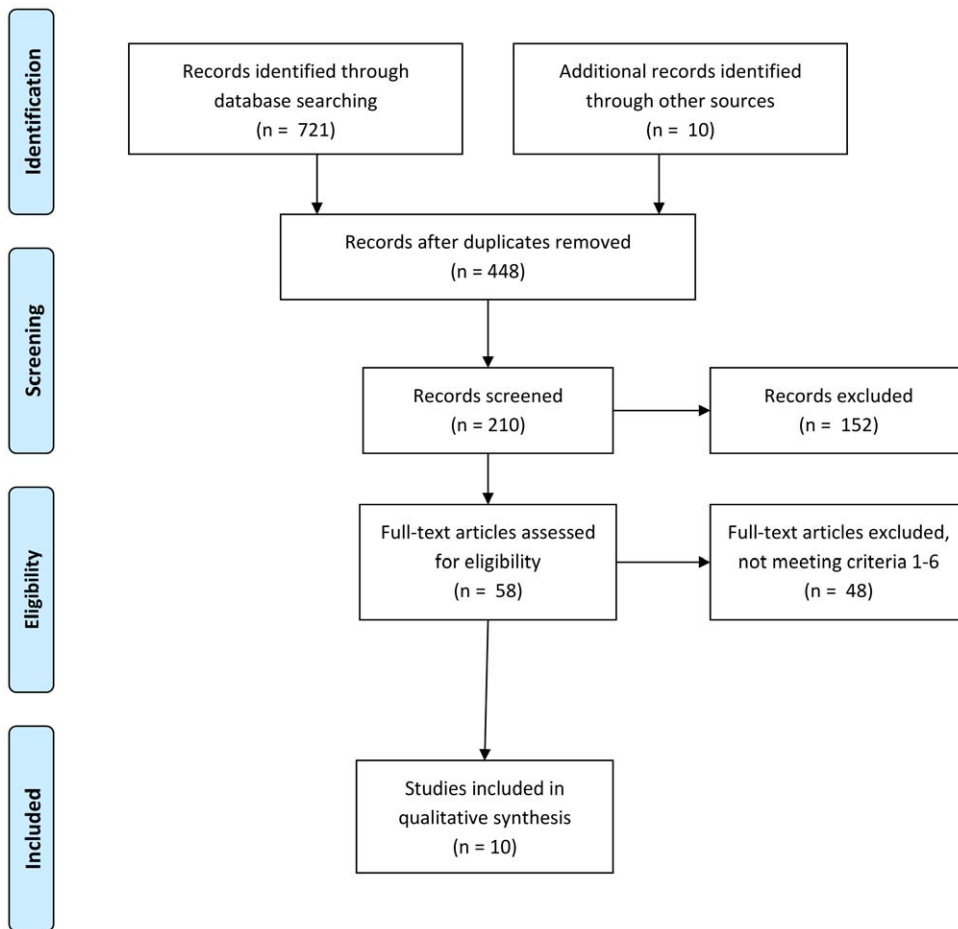


Figure 1. PRISMA 2009 Flow Diagram.
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up data after 6 months – see Table 4. All three other conditions are found to be distinct from the reference group of those who were pretested and received the intervention (ORs 0.31, 0.42 and 0.41, $p = 0.005$ or less for each comparison). The interpretation given by the authors to these data is that the effect of the training depends upon the prior completion of the questionnaire “to give students an opportunity for greater reflection on their own sexual behaviour.” [27] After 12 months a somewhat similar pattern of results was observed with odds ratios closer to 1 and not statistically different from the reference group of those both pretested and received intervention (ORs 0.61 [$p = 0.24$], 0.57 [$p = 0.09$] and 0.73 [$p = 0.35$]) among the 355 providing follow-up data. Smaller numbers were randomised to intervention groups in this study and there appears to be differential attrition by group. Condom use at first intercourse among those who had not had sex prior to the study was also investigated, though outcome data for all 4 groups were not presented [27].

A subsequent Norwegian study was published by Traeen [28]. This has significant reporting problems in connection with the aims of this study due to, for example, not consistently reporting outcome data for all 4 groups. In one instance, data suggest the presence of an interaction effect on use of contraception during most recent intercourse [28]. There is a difference of 7% favouring the intervention among those who were assessed (64/107 [59%] compared to 24/45 [52%]) and a difference of 10% favouring the non-intervention control condition among those who were not

assessed (60/105 [57%] compared to 43/64 [67%]). Differences among the proportions are not tested and odds ratios presented in a multivariate logistic regression model were not statistically significant [28]. Differences in sample size among the study conditions after allowing for higher allocation to intervention conditions give scope for concern about the possible effects of attrition bias. The Discussion section begins with the statement that “The results from this study have shown a significant effect of the intervention in interaction with the pre-test on use of contraception during the first intercourse in adolescents who made their coital debut in the period from the pre-test to the first post-test.” [28] This statement appears to depend on data not resulting from four-group analyses. As with the previous study, the quantitative data reported above are obtained among a sub-group of those randomised rather than in the study population as a whole.

Inspection of the data in the study by Duryea [26] suggests it is unlikely that there were any interactions between assessment and intervention for either outcome even were this small study to have been very much larger.

Primary school studies

Two of the three primary school studies were based on the same cohort which was the largest in this literature. Campanelli and colleagues in evaluating alcohol prevention effects [29] found pre-testing main effects on 1 of 3 alcohol misuse variables in the more

appropriate adjusted analyses taking account of clustering in schools, and also in a second alcohol misuse variable in less rigorous unadjusted analyses. In both cases there were higher scores indicating greater alcohol misuse among those who had not been pre-tested, indicating the possibility of a small beneficial effect of the 60-item questionnaire. They found no statistically significant interaction effects on relevant behavioural outcomes, with only the possibility of a weak trend in this direction being discernible in the case of alcohol use frequency [29]. Probably because of these initial findings, much less attention is paid to assessment effects in the later follow-up of this sample by Shope et al. [30] Among 5th grade students providing follow-up data at all 3 intervals, the pre-tested intervention group had somewhat lower scores than other groups (0.37 [0.91] compared to 0.49 [1.05], 0.51 [1.07] and 0.55 [1.07] on a combined outcome measure at the same first follow-up as previously reported [30].

The other primary school study by Freeman [31] provides little data useful here by virtue of its design (see Table 1). *A priori* the possibility of an interaction between this an assessment measure of academic ability and a creative drama intervention to address problem behaviour seems unlikely. Neither intervention nor assessment effects were found in this study, in which the study population was young (school grades 3 and 4).

Discussion

This systematic review was primarily designed to discover whether there was evidence of interactions in existing Solomon 4 group studies with behavioural outcomes. Any such evidence could be indicative of research assessments causing bias in conventional behaviour change trials. The principal finding, therefore, is that there is meagre evidence of interactions in existing studies. Whilst there are many applications in laboratory-based psychology and in classrooms for educational research, the Solomon 4 group design has not been widely used in social and health sciences in studies with behavioural outcomes. Existing applications are highly heterogeneous and meta analytic synthesis of their main findings was judged inadvisable.

It is worth considering why there have been so few Solomon 4 group studies. The design may appear somewhat complex and there are studies which have failed to implement it successfully, particularly due to analytic problems [32]. Randomisation itself is not, however, achieved with any more difficulty. The design may also be considered to be relatively expensive in terms of statistical power and required study resources. It has thus been used only in situations where there has been a particular concern about assessment effects interfering with study outcomes. The particular need to reliably estimate small behavioural intervention effects that can be widely obtained in populations is arguably a quite recent concern, or at least it is now being taken more seriously than was the case previously. There is also now more careful attention to research assessment reactivity and possible impacts on other forms of bias [33] as well as on research participation effects in trials more broadly [34].

Of the two studies providing any evidence of interactions in sub-groups, in one case data were clearly appropriately analysed [27], and in the other case this was unlikely [28]. Reporting problems are apparent and although methodological quality was not formally assessed here, both sets of findings are vulnerable to various biases. There were main effects on self-reported behavioural outcomes clearly attributable to research assessments in two other studies [25,29]. There were also main effects of research assessments on non-behavioural self-reported outcomes in both of these studies and in two additional studies, on

knowledge [26] and intentions [23], with an interaction effect also in the latter case.

It should be expected that interactions, if they exist, would be variable across populations and behaviours and depend upon the precise features of the assessment and intervention methods. Similarities between the contents of research assessments and interventions and their component parts provide *a priori* grounds for concern about the potential for bias. For example, pedometers may be used both as an intervention component and in research assessment in studies of interventions promoting walking [35]. Any evidence of interaction, however small the effects may be, entails bias in estimates of intervention effectiveness, and thus deserves to be investigated.

There are perhaps two different types of research question that may be asked about this phenomenon. 1) To ask, as we have done here, *can* research assessments themselves cause bias in behaviour change trials? This is analogous to designing an efficacy or explanatory trial to answer this question. One would seek conditions in which the purported effect was most likely to be found, perhaps selecting particular behaviours and study populations, research assessment and intervention materials, judged favourable to assessment reactivity by some criteria, in circumstances lending themselves to reliable quantification. 2) Alternatively, one could ask, *do* research assessments themselves cause bias in behaviour change trials? Are there problems with conventional practice in behaviour change trials that we don't yet know about? This is analogous to designing an effectiveness or pragmatic trial to answer this question. Presumably, one would choose typical research assessment contents and well evaluated interventions for behaviours of clear population health importance. This latter type of question is the more important question to ask, though arguably logic first requires an affirmative answer to the first question.

This systematic review has been designed in various ways which engender confidence in the reported findings and attention is also warranted to its limitations. Restricting inclusion to peer reviewed studies should not have biased findings to be more or less likely to produce evidence of interactions. Requiring reporting of outcome data for all 4 groups served to exclude studies whose findings were difficult to interpret. Arguably the identification of interactions only becomes possible once appropriate analyses have been successfully implemented. There were many incorrect analyses used in excluded studies and the most appropriate statistical methods for Solomon 4 group studies were determined some decades after the introduction of the design [32].

Excluding studies with small sample sizes is an unusual decision, though there are reasons to be concerned about the influence of small study effects in reviews [36,37]. As well as publication bias, smaller studies are more vulnerable to other forms of bias. This decision was taken after initial scoping indicated a number of unusual studies which were difficult to describe well and whose contribution was judged likely not to be very helpful. The threshold was set somewhat arbitrarily at a low level only to exclude very small studies (n = 20 per group, total n = 80). By way of example, Lawson and Frankish [38] started with a total n = 40 which subsequently attrited to n = 16. It must be recognised, however, that there are otherwise well conducted Solomon 4 group studies with very small sample sizes that have been excluded (for example, [39,40]) and that their inclusion could be valuable if subsequent reviews are able to undertake quantitative syntheses when the literature is better developed.

Inclusion in this review was limited to studies with behavioural outcome measures. It transpired that there were no studies with observed or otherwise objectively ascertained outcomes. The exclusion of cognitive, affective and other types of psychological

outcomes should be carefully considered. Prior work in this area has found assessment effects to be larger in these other areas than on behavioural outcomes [41,42]. Where such data are important outcomes in behaviour change trials they may be biased by the interactions between assessment and intervention effects. It seems likely, therefore, that there exist Solomon 4 group studies which can provide data on the possibility of interactions that lie beyond the limits of this review. Solomon 4 group studies may be particularly valuable for studies with patient reported outcomes, for example [43], and this may be a fruitful avenue for further research. Given the nature of the target study design, it is unlikely that we will have missed studies within our inclusion criteria that should have been included unless they have not used the Solomon label. This is indeed possible, though not being aware of any such studies makes it impossible to gauge how likely this is.

There are too few completed rigorous studies to infer that the interactions targeted for study either simply do or do not exist. Conduct of this study has, however, advanced hypotheses about the nature of the possible effects to be evaluated in a number of ways. Situations in which both interventions and assessments may be expected to exert main effects upon behaviour are conducive to tests of their possible interactions. Meta-analytic data providing preliminary evidence of assessment effects in the alcohol field have recently been published [44]. This extends a history of earlier

attention to these issues in that field which has been based upon the idea that assessment enhances capacity for self-regulation [45]. Although children may be more susceptible to assessment effects, they may be less receptive to dedicated interventions, and adult populations may be preferable for these reasons. Sample sizes should be as large as possible. Synergistic effects as well as ceiling effects are both plausible and will likely depend upon the particular behaviour selected for study and motivations and more broadly the relationship of the study population to the behaviour. The main conclusion is that this review demonstrates the need for new Solomon 4-group studies that are purposively designed to evaluate the potential for research assessments themselves to cause bias in behaviour change trials.

Supporting Information

Box S1 Hypothetical example. (DOCX)

Author Contributions

Conceived and designed the experiments: JM DE. Performed the experiments: JM KB-B JW. Analyzed the data: JM KB-B. Contributed reagents/materials/analysis tools: JM KB-B JW. Wrote the paper: JM KB-B JW DE.

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