Thesis Title:
Development of a CONSORT Extension for
Social and Psychological Interventions

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“Whensoever thou wilt rejoice thyself, think and meditate upon those good parts and especial gifts, which thou hast observed in any of them that live with thee: as industry in one, in another modesty, in another bountifulness, in another some other thing. For nothing can so much rejoice thee, as the resemblances and parallels of several virtues, eminent in the dispositions of them that live with thee, especially when all at once, as it were, they represent themselves unto thee. See therefore, that thou have them always in a readiness.”

- Marcus Aurelius, Meditations

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Abstract

**Background:** Defined by their mechanisms, social and psychological interventions are those interventions that work through mental processes and social phenomena. They are often complex and challenging to evaluate, so understanding randomised controlled trials (RCTs) of these interventions requires detailed reports of the interventions tested and the methods used to assess them. However, reports of these RCTs often omit important information. Poor reporting hinders critical appraisal and synthesis of RCTs in systematic reviews, thereby impeding the effective transfer of research evidence to policy and practice. The Consolidated Standards for Reporting Trials (CONSORT) Statement is a reporting guideline that has contributed to improvements in the quality of RCT manuscripts in journals publishing medical research. However, studies have shown persistent deficiencies in the reporting quality of social and psychological intervention trials. A new CONSORT extension for these interventions may be needed given their distinct and complex features. This DPhil thesis reports on a project to develop and disseminate an official CONSORT Extension for Social and Psychological Interventions: CONSORT-SPI.

**Structure:** Following a preface, this DPhil thesis includes eight chapters. Chapter 1 provides an overview of the conceptual rationale that prompted the CONSORT-SPI project. Chapter 2 details the project protocol, which consists of a five-phase methodology that follows current best practices for reporting guideline development and dissemination. Chapter 3 discusses systematic literature reviews to assess reporting guidelines for and the reporting quality of publications of social and psychological
intervention RCTs. Chapter 4 discusses an online, international Delphi process to generate a prioritised list of possible items to include in the CONSORT-SPI extension. Chapter 5 discusses a formal consensus meeting to select reporting items to add to or modify for the CONSORT-SPI Extension checklist. Chapter 6 involves drafts of the CONSORT-SPI checklist as well as a template for the Explanation and Elaboration (E&E) document providing detailed advice and examples of good reporting for each checklist item. These drafts have not yet been circulated to co-authors or other members of the project team; their purpose in this thesis is to give an indication of how previous project phases have led into initial prototypes of the checklist and E&E, which will undergo further development and revision by the project team before publication.

Chapter 7 proposes a coordinated dissemination and implementation strategy informed by theoretical frameworks and tools used to guide the implementation of clinical guidelines and empirically-supported interventions. The final chapter summarises the information gained from the CONSORT-SPI project to date, assesses strengths and limitations of the project methodology, and discusses implications for future research.

**Conclusion:** A CONSORT-SPI Extension could improve the reporting quality of social and psychological intervention RCTs. This extension could also facilitate better critical appraisal of this body of research and its use in evidence-based decision-making. With successful dissemination and implementation, the guideline will hopefully contribute to the improvement of intervention evaluations—as well as the methodology underpinning these studies—within the social and behavioural sciences.
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Preface to DPhil Thesis

1. What are Social and Psychological Interventions?

Broadly defined, an intervention is “the action of intervening, ‘stepping in’, or interfering in any affair, so as to affect its course or issue.”¹ This broad definition can help with operationalising the concepts that are often used to distinguish interventions in the medical, social, and behavioural sciences. Namely, these interventions can be thought to involve techniques (the “actions”) that aim to modify an otherwise unhindered process or phenomenon (the “affair”) so as to improve the functioning and well-being of the unit of interest (the “course or issue”). Interventions can be logically classified in a variety of ways across these domains. For example, current intervention extensions of the Consolidated Standards of Reporting Trials (CONSORT) Statement are organised by intervention techniques: compared to interventions involving pharmacologic techniques or drugs,² other interventions are differentiated by their use of herbal medicinal products,³ acupuncture,⁴ or non-pharmacologic techniques more generally.⁵

Rather than classifying interventions according to the techniques employed, this thesis distinguishes the interventions of interest by the mechanisms targeted: i.e., the processes and phenomena that interventionists intend to modify in order to affect certain outcomes. Such classification corresponds to current “intervention development” approaches that promote the identification of malleable risk and protective factors as a precursor to postulating which techniques may best address a problem or outcome of interest.⁶⁷ Using this classification system, “biomedical” interventions are those that target and are conceived to work through biological mechanisms, such as physiological processes. In comparison, “social and psychological” interventions target and are conceived to work through malleable mental processes and social phenomena, such as cognitions, emotions, behaviours, norms, interpersonal relationships, and salient physical
and social environments, amongst others. The distinctive concepts, theories, and
taxonomies characteristic of social and psychological intervention research are central to
the rationale for this thesis project.

The DPhil candidate acknowledges that, in reality, there are not strict boundaries
amongst the “biological”, the “psychological”, and the “social”, but rather all are
intertwined in some fashion. Nonetheless, in practice there are real differences in the
conceptualisation and nature of the interventions that are developed and evaluated by those
with predominantly biomedical backgrounds compared to those whose principal training is
in the social and behavioural sciences. Though a non-exhaustive list, social and
psychological interventions are studied in several disciplines, including criminology,
education, psychology, public health, and social work. Across these disciplines, social and
psychological interventions distinguish themselves from biomedical interventions in
several ways.

For example, conceiving of and focusing on social and psychological mechanisms
lead to quite different techniques than those found in biomedical interventions. The area of
social and psychological intervention research involves a distinct assortment of activities—
psychotherapies, programmes, services, projects, policies—that target mental processes
and social phenomena across individuals, groups, whole populations, and even places. The
targeted mechanisms are inseparable from the agency of those actively receiving or
engaging with the intervention. As these participants may differentially respond to
intervention techniques or activities, researchers must take account of human agency and
intentionality in their theory of how social and psychological interventions work.
Consequently, stakeholders in social and psychological intervention research are interested
in more than just overall effect estimates of interventions, seeking further information on
how and why these interventions work, for whom, and under what conditions.
2. Randomised Controlled Trials of Social and Psychological Interventions

Social and psychological interventions are designed to improve a variety of outcomes for people and communities. Though developed and provided with the best of intentions, these interventions have the potential to be ineffective or inadvertently harmful. Social and psychological interventions therefore need to demonstrate evidence of safety and effectiveness as a prerequisite for wide-scale delivery.

Several methods exist to provide such evidence. When appropriately used and conducted, randomised controlled trials (RCTs) are considered by many to be the most valid research method for estimating the effectiveness of interventions. Selection biases can lead to systematic differences in prognostic variables between participants in different experimental groups, and random assignment prevents biases related to the selection of participants for intervention and comparator groups. Because RCTs theoretically balance both measured and unmeasured prognostic variables, they can provide valid measurements of the impact of an intervention compared to what would have happened in its absence.

Over the past several decades, RCTs have been used to evaluate ever more complex interventions, such as social and psychological interventions, that challenge traditional aspects of trial design, execution, and interpretation. Experiences of evaluating complex interventions have led to an accumulation of innovative modifications to conventional RCT methodology. While debate has since arisen (and continues today) about the appropriateness of RCTs for evaluating these interventions, solutions to the technical and ethical problems of such trials are achieving increasing consensus. Agreement on these solutions has reached the point that influential guidance has been developed for those conducting evaluations of complex interventions. For instance, RCTs of social and psychological interventions are increasingly interpreted to test whether the offer of an intervention makes a difference, and, via an embedded process evaluation, they may
investigate sources of variation in response to the intervention on offer.\textsuperscript{16,17} Though discussed in more detail in Chapter 1, it is worth noting now that this thesis does not aim to make a case for a hierarchy of evidence that always privileges on first principles the use of an RCT to evaluate social and psychological interventions over other methods. Rather, the author acknowledges the RCT as an essential tool in the evaluation toolkit, and that how RCTs are actually done may benefit from monitoring and oversight given their prominence in the evidence-based practice (EBP) paradigm at the time of the project.

3. Reporting Standards and Reporting Guidelines

Growing attention to the design and conduct of RCTs of complex interventions has led to growing attention to the reporting of these studies in scientific journals and other media. Reports are the primary means of distributing RCT findings to the research community.\textsuperscript{18} Research consumers depend on accurate, complete, and transparent reports of RCTs in order to appraise the validity, applicability, and appropriateness of individual studies.

To address the need for high quality reporting, collaborations led by researchers and journal editors have made a concerted effort over the last 20 years to develop reporting standards that assist authors in writing research manuscripts. Reporting standards provide recommendations to study authors for describing the most important aspects of empirical research studies. They are typically collated and disseminated through reporting guidelines: i.e., checklists that offer recommendations on what to report about a particular type of study.\textsuperscript{19} Ideally, standards found in reporting guidelines should be based on previous research rather than guideline developers’ intuition alone, and they should also be developed using expert consensus to improve buy-in amongst key stakeholders and to reduce biases in group decision-making.\textsuperscript{20}
3.1 The CONSORT Statement

The most well-known and widely used reporting guideline is the Consolidated Standards of Reporting Trials (CONSORT) Statement. The CONSORT 2010 Statement—the most recent version—provides a set of recommendations primarily for reports of two-group, parallel RCTs. To increase the usefulness of this guideline, the CONSORT Group has also produced extended versions for specific types of medical interventions (such as non-pharmacological treatments), for specific types of RCTs (such as cluster trials), and for specific types of RCT data (such as harms). The reporting standards found within the CONSORT Statement and its official Extensions are based on empirical data and expert consensus about the potential sources of bias in RCTs. Over the last decade, numerous reviews in the biomedical literature have attributed improvements in the reporting quality of RCTs to these guidelines.

3.2 A CONSORT Extension for Social and Psychological Interventions?

Despite the advance of CONSORT and other reporting guidelines, several studies indicate that there are persistent deficiencies in the reporting quality of published social and psychological intervention RCTs. One explanation may be that current standards in well-known reporting guidelines are not adequately tailored to social and psychological intervention trials. For example, existing CONSORT guidance has been developed primarily by biomedical researchers, making guidance for social and behavioural science research lacking in comparison. The main CONSORT 2010 Statement was designed with two-group parallel RCTs of pharmaceuticals in mind, and existing intervention extensions of CONSORT are intended for non-pharmacologic medical treatments (e.g., surgery, medical devices), herbal medicinal products, and acupuncture treatments. All of these interventions primarily target mechanisms emphasised in various areas of medical science,
both traditional Western medicine as well as the “alternative and complementary”.

Interventions targeting mechanisms common in the social and behavioural scientists are underrepresented in the CONSORT family of guidelines. Many important concepts, theories, and taxonomies characteristic of social and psychological intervention research may consequently be overlooked by these guidelines to some degree. Indeed, stakeholders in these areas have indicated that current CONSORT guidelines do not appear to sufficiently target social and psychological intervention RCTs.\textsuperscript{28,30,31} Members of previous CONSORT groups, as well as journal editors and researchers in the social and behavioural sciences, support the inclusion of stakeholders in social and psychological intervention research in future guideline development to improve “buy-in” and relevance of CONSORT to these disciplines moving forward.\textsuperscript{28,32} The need for a new CONSORT extension for these trials should therefore be explored.

4. Overview of Thesis Structure

This DPhil thesis reports on the development of an official CONSORT Extension for Social and Psychological Interventions: CONSORT-SPI. The project plan for developing this CONSORT extension involves five phases (see Figure 1).

As requested during the DPhil candidate’s confirmation of status viva examination, it is worth noting here the collaborative nature of this project and the DPhil candidate’s roles within it. The idea for the project was conceived by Paul Montgomery and Evan Mayo-Wilson prior to the DPhil candidate’s involvement. After being approached by Prof Montgomery and Dr Mayo-Wilson to explore this idea further, the DPhil candidate has been involved in a lead role at every phase of the project. Namely, the DPhil candidate helped to develop the conceptual rationale for the project as well as the grant proposals to the UK Medical Research Council (unsucessful) and Economic and Social Research
**Figure 1. Workflow for Thesis on CONSORT-SPI Project**

**PHASE 1: Literature Reviews**
Systematic reviews of reporting guidelines and quality

**PHASE 2: Delphi Process**
Generate List of Items for Discussion at Consensus Meeting

**PHASE 3: Consensus Meeting**
Finalise Checklist Items for Guideline Documents

**PHASE 4: Users Manual**
Draft Explanation & Elaboration Document

**PHASE 5: Dissemination Plan**
Promote Guideline Implementation

- Systematic Literature Reviews
- Previous reporting guidelines
- Reporting quality of RCTs

Pre-Round 1: International Advisory Group Meeting
Identify initial reporting items and potential participants for the Delphi process

Round 1
- Participants score agreement with each item
- Participants suggest items to modify or add
- Responses analysed
- Produce list of suggested items and modifications

Round 2 (and 3 if needed)
- Circulate results of previous Round
- Participants score agreement with modified items
- Participants suggest items to modify or add
- Responses analysed
- Produce list of suggested items and modifications

Produce items to consider at consensus meeting

**Pre-Meeting Activities**
Recruit participants
Circulate background papers and Delphi results

Meeting
- Structured discussion of each proposed item
- Participants vote on items for inclusion

Produce list of items for checklist

**Draft Explanation & Elaboration Document**
Provide rationale and examples of good reporting for each checklist item

Plan for Dissemination and Implementation
- Consensus meeting discussions
- Previous reporting guideline projects
- Literature on implementing clinical guidelines
Council (successful). The DPhil candidate wrote the initial draft for both the conceptual rationale as well as the grant proposals, which were then refined by the project team. The DPhil candidate also wrote the first draft of the project protocol for his transfer of status examination; this protocol was subsequently revised for publication. The content of the subsequent thesis chapters depicts the main role of the DPhil candidate in leading the design and execution of the research methods constituting each phase of the project. The specific activities of the DPhil candidate will be noted throughout the thesis as relevant, and a list of publications and presentations to date has been included in the reference section of this preface.

Several appendices have been included in this thesis submission, also at the behest of the confirmation of status viva examiners. These appendices provide some of the materials developed by the DPhil candidate for the project, full data from certain project phases, and the evolution of the draft CONSORT-SPI checklist. The confirmation of status examiners agreed that, in accord with the principles of transparency underpinning this project, there should be open access to data and materials from this thesis.

4.1 Chapter 1 of the Thesis: Conceptual Overview

NB: Sections of this chapter have been published in an alternative form in Research on Social Work Practice.

The first chapter is an overview of the developments in intervention research that led to innovative uses of the RCT to evaluate social and psychological interventions. Namely, the DPhil candidate highlights how RCTs evaluating more complex interventions have sought to combine the advantages of random allocation for outcome evaluations with much greater attention to process and contextual aspects of the evaluation in order to examine how and why the intervention works, for whom, and under what conditions. The DPhil
candidate then argues that researchers may require updated and tailored reporting
guidelines for social and psychological intervention trials if these studies are to be useful
for policy, practice, and future research. The purpose of this chapter is to situate this DPhil
project in the wider scientific literature. The chapter highlights the conceptual arguments
indicating that the need for a new reporting guideline for social and psychological
intervention RCTs should be formally investigated.

4.2 Chapter 2 of the Thesis: Project Protocol
NB: This chapter has been published in an alterative form in Implementation Science\textsuperscript{34}

The second chapter delineates the methods for the overall project and the
corresponding activities within the project plan that will constitute chapters for this thesis.
The proposed methods follow recommended techniques for guideline development and
dissemination.\textsuperscript{19} The project received a standard grant from the Economic and Social
Research Council (ESRC) and ethics approval from the Departmental Research Ethics
Committee (DREC), Department of Social Policy and Intervention, University of Oxford,
for the proposed methods. Moreover, to help coordinate and publicise the initiative, an
International Advisory Group (IAG) of leading intervention experts in core disciplines was
assembled (see Appendix A).

4.3 Chapter 3 of the Thesis: Systematic Reviews
NB: This chapter has been published in an alterative form in PLoS One\textsuperscript{36}

This chapter reports on Phase 1 of the project: a study consisting of two systematic
reviews that sought to empirically demonstrate the need for a CONSORT extension for
social and psychological interventions. Overall, these reviews examined reporting
guidelines for, and the current reporting quality of, social and psychological intervention
RCTs. Firstly, a systematic review identified and assessed the rigour of all published reporting guidelines relevant to social and psychological intervention RCTs. The quality of guideline development, content (by way of included reporting standards), and dissemination strategies were assessed according to recommended techniques for guideline production. A second review examined the extent to which roughly 300 social and psychological intervention RCT publications adhered to the reporting standards that were identified in the review of reporting guidance. Results from this study suggest that current reporting guidelines are insufficient for social and psychological intervention trials, and a new CONSORT extension would likely improve their reporting quality.

4.4 Chapter 4 of the Thesis: Delphi Process

This chapter reports on Phase 2 of the project: an international, online Delphi process to generate a prioritised list of possible reporting standards to consider for inclusion in the CONSORT extension. Information from the two-part study in Phase 1 informed the content of the Round 1 questionnaire of the Delphi process. Participants consisted of researchers, journal editors, research funders, policy-makers, practitioners, and other stakeholders in social and psychological interventions. Results from the Delphi process led to a ranked, modified list of reporting items that were considered for inclusion in the CONSORT-SPI checklist and E&E document at the consensus meeting.

4.5 Chapter 5 of the Thesis: Consensus Meeting

This chapter reports on Phase 3 of the project: a formal consensus meeting to agree upon the reporting items to add to or modify for the CONSORT-SPI checklist. A group of 31 researchers, journal editors, and funders met in March 2014 during a three-day consensus development conference. This meeting involved discussion of preliminary
research on social and psychological intervention RCTs, voting on items for the CONSORT-SPI checklist, and deliberations on the dissemination and implementation plan for the CONSORT-SPI guidelines. The CONSORT-SPI checklist is currently planned to consist of 14 extended items of the CONSORT 2010 checklist, as well as a flow diagram for tracking participants through an RCT. This chapter reports on the discussions and decisions made during the meeting relating to the CONSORT-SPI checklist. Though related to the consensus meeting, a draft of the CONSORT-SPI checklist and E&E document will be in Chapter 6 of the thesis, and an overview of discussions at the consensus meeting about the dissemination and implementation of CONSORT-SPI will be in Chapter 7.

4.6 Chapter 6 of the Thesis: Draft Checklist and E&E Document

This chapter relates to Phase 4 of the project and includes a template for the CONSORT-SPI E&E document, according to the most recent draft of the CONSORT-SPI checklist. This phase involved revising and codifying the standards finalised at the consensus meeting into a user-friendly checklist, and writing an explanation and elaboration (E&E) document that provides detailed advice and examples of good reporting for each reporting standard. A detailed examination of each of the reporting standards within the new CONSORT extension constitutes this chapter of the thesis.

4.7 Chapter 7 of the Thesis: Dissemination & Implementation Plan

This thesis chapter reports on the fifth and final phase of the project: the guideline dissemination and implementation plan. The DPhil candidate will discuss a framework for a coordinated dissemination and implementation strategy that is based on discussions at the CONSORT-SPI consensus meeting, previous plans for reporting guidelines, and insights
derived from literature on implementing clinical guidelines and empirically supported interventions. This plan includes simultaneous publication of the guideline in multiple journals, guideline endorsement by journals and funding organisations, presentations at conferences and organisational meetings, and a dedicated website allowing for feedback about the guideline. Other policies supportive of high-quality scientific publishing more generally are also discussed.

4.8 Chapter 8 of the Thesis: Conclusions about the CONSORT-SPI Project

The final chapter of the thesis details conclusions about the CONSORT-SPI project to date. The DPhil candidate discusses what was previously known about the topic prior to the project; what this thesis adds to the literature; strengths and limitations of this thesis project; and implications of the thesis work for policy, practice, and future research.
References


Publications and Presentations Related to CONSORT-SPI to Date

Publications


*This manuscript is co-published in:


Presentations


Montgomery P, Grant SP. Development of a CONSORT extension for randomised controlled trials evaluating complex behavioural change and psychological interventions. Meeting at: 19th annual Cochrane Colloquium. 2011, October; Madrid, Spain.

Montgomery P, Grant SP. Will you CONSORT with me? Paper presented at: Centre for Evidence-Based Crime Policy and Campbell Collaboration Joint Symposium on Evidence-Based Policy. 2011, August: Washington DC, USA.