Appendices for

Development of a CONSORT Extension for Social and Psychological Interventions

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DPhil in Social Intervention Thesis

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Appendix A. International Advisory Group

Criminology

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Appendix B. Participating and Interested Journals

This section acknowledges editorial board members of the following journals, who have provided helpful information for the CONSORT-SPI guidelines:

- Academy of Management Learning and Education
- Addiction
- Addiction Research & Theory
- Addiction Science & Clinical Practice
- Administration and Policy in Mental Health and Mental Health Services Research
- Adult Education Quarterly
- African Journal of AIDS Research
- Aggressive Behavior
- American Journal of Community Psychology
- American Journal of Health Behavior
- American Journal of Health Promotion
- American Journal of Men's Health
- American Journal of Psychiatric Rehabilitation
- American Journal of Public Health
- Annals of Behavioral Medicine
- Applied Psychophysiology and Biofeedback
- Archives of Scientific Psychology
- Asia-Pacific Journal of Public Health
- Australian Journal of Guidance and Counselling
- Behavior Therapy
- Behavioral Disorders
- Behavioral Medicine
- BMC Family Practice
- BMC Geriatrics
- BMC Health Services Research
- BMC Medical Research Methodology
- BMC Psychiatry
- BMJ
- Body Image: An International Journal of Research
- British Journal of Clinical Psychology
- British Journal of Educational Technology
- British Journal of Health Psychology
- British Journal of Mathematical and Statistical Psychology
- British Journal of Sports Medicine
- Campbell Systematic Reviews
- Child: Care, Health and Development
- Children's Geographies
- Chinese Mental Health Journal
- Clinical Journal of Pain
- Clinical Psychology & Psychotherapy
- Cochrane Database of Systematic Reviews
- Cognitive and Behavioral Practice

- Criminology
- Crisis Response Journal
- Das Gesundheitswesen
- Development and Psychopathology
- Drug & Alcohol Review
- Early Childhood Research Quarterly
- Early Education and Development
- Effective Education
- European Early Childhood Education Research Journal
- European Eating Disorders Review
- European Journal of Person Centered Health Care
- European Journal on Criminal Policy and Research
- Evaluation & the Health Professions
- Evaluation Review
- Evidence-Based Child Health: A Cochrane Review Journal
- Family Process
- Health and Place
- Health & Social Care in the Community
- Health Behavior and Policy Review
- Health Care for Women International
- Health Education & Behavior
- Health Education Journal
- Health Environments Research & Design
- Health Expectations
- Health Promotion International
- Health Promotion Journal of Australia
- Health Psychology
- Hong Kong Journal of Social Work
- Implementation Science
- Infancia y Aprendizaje
- International Journal of Family Medicine
- International Journal of Nursing Studies
- International Journal of Occupational and Environmental Health
- International Journal on Injury Control and Safety Promotion
- Injury Epidemiology
- Injury Prevention
- International Psychogeriatrics
- International Journal of Drug Policy
- International Journal of Early Childhood
- International Journal of Health Geography
- International Journal of Social Welfare
- Japanese Journal of Behavior Therapy
- Journal of Abnormal Child Psychology
- Journal of Abnormal Psychology
- Journal of Addiction
- Journal of Addiction Research & Therapy
- Journal of Aggression, Conflict and Peace Research

- Journal of the American Association of Occupational Health Nursing
- Journal of Anxiety Disorders
- Journal of Applied Research in Intellectual Disability
- Journal of Behavioral Decision Making
- Journal of Behavior Therapy and Experimental Psychiatry
- Journal of Behavioral Medicine
- Journal of Business and Psychology
- Journal of Child Services
- Journal of Clinical Epidemiology
- Journal of Consulting and Clinical Psychology
- Journal of Child Psychology and Psychiatry
- Journal of Education Policy
- Journal of Experimental Criminology
- Journal of Evaluation in Clinical Practice
- Journal of Family Therapy
- Journal of Home Economics Research
- Journal of Human Behavior and Social Environment
- Journal of Management
- Journal of Mental Health
- Journal of Offender Rehabilitation
- Journal of Paediatrics and Child Health
- Journal of Physical Activity and Health
- Journal of Primary Prevention
- Journal of Psychopathology and Behavioral Assessment
- Journal of Public Child Welfare
- Journal of Research in Crime and Delinquency
- Journal of Research on Educational Effectiveness
- Journal of Research in Reading
- Journal of Science and Medicine in Sport
- Journal of Social Service Research
- Journal of Social Work Education
- Journal of the Society for Social Work and Research
- Journal of Traumatic Stress
- Journal of Women's Health
- Journal of Writing Research
- Language Learning
- Learning and Instruction
- NIHR Journals Library
- Online Educational Research Journal
- PAIN
- Pain Management
- PLOS Medicine
- PLOS ONE
- Porta Linguarum
- Psychiatric Services
- Psychological Assessment
- Psychological Methods

- Psychology and Health
- Psychology and Psychotherapy: Theory, Research and Practice
- Psychology, Health, & Medicine
- Psychotherapie Psychosomatik Medizinische Psychologie
- Psychotherapy
- Psychotherapy Research
- Rehabilitation Psychology
- Reproductive Health Matters
- Research on Social Work Practice
- Research Synthesis Methods
- Rinsho Hyoka
- Saúde e Sociedade
- Scandinavian Journal of Work Environment & Health
- Security Journal
- Sexual Abuse: A Journal of Research and Treatment
- Sexual Medicine
- Simulation in Healthcare
- Social Science & Medicine
- Social Services Review
- Social Work in Public Health
- Social Work Research
- Sociology
- Sociology of Education
- Sociology of Health and Illness
- South African Statistical Journal
- Systematic Reviews
- Teachers and Teaching: Theory and Practice
- Teaching of Psychology
- The Arts in Psychotherapy
- The Clinical Neuropsychologist
- The Curriculum Journal
- The Journal of Rural Health
- The New Educational Review
- Trials

Appendix C. Data Extraction Sheet for Reporting Guidelines and Quality Assessment Tools

Domain	Item	Guidance	Response
Descriptives	Guideline	Title of Guideline	
	Developer	Name of corresponding author or group in charge of guideline development	
	Social/Behavioural Science Specific?	Is the reporting guideline for a specific field in social/behavioural science?	
	Guideline or Quality Measurement?	Is the tool a reporting guideline or a reporting quality assessment tool?	
	CONSORT	Is it a CONSORT Statement or official extension?	
	Targeted Area	Targeted research method/area of the guideline?	
	Number of Reporting Standards	How many reporting standards were included in the guideline?	
Preliminary Stages	Poor Reporting	Did the developers empirically demonstrate the need for new guidance, extending existing guidance, or implementing existing guidance?	
	Previous Standards	Did the developers describe whether they identified previous relevant standards and/or identified key information related to the potential sources of bias in such studies?	
	Funding	Did the developers report whether they obtained any funding for the reporting standards initiative?	
	Participants	Did the developers report any participants included in development process?	

Domain	Item	Guidance	Response
Reporting Standards Document Development	Delphi Exercise	Did the authors report conducting a Delphi Exercise?	
	Preliminary Items	Did the developers report whether they generated a preliminary list of items to consider prior to the final selection process?	
	Finalisation Preparation	Did the authors describe any preparations that developers made prior to the final selection process (e.g., decide size and duration of the face-to-face meeting, develop meeting logistics, develop meeting agenda, consider presentations on relevant background topics, including summary of evidence, plan to share results of Delphi exercise if done, invite session chairs, prepare materials to be sent to participants prior to meeting, arrange to record the meeting)?	
	Finalisation Process	Did the authors describe the process of reaching consensus on guideline content? (e.g., present and discuss results of pre-meeting activities and relevant evidence at consensus meeting, discuss the rationale for including items in the checklist, discuss the development of a flow diagram, discuss strategy for producing documents, identify who will be involved in which activities, discuss authorship, discuss knowledge translation strategy)	
	Tool Development	Did the authors describe how the guideline or assessment tool was written? (e.g., pilot testing the checklist, sending drafts electronically to collaborators)	
	Explanatory Document	Did the developers construct an explanatory document as well?	

Domain	Item	Guidance	Response
Publication	Publication Strategy	Did the developers describe a publication strategy, if any?	
	Criticism and Feedback	Did the developers describe how they planned to deal with criticism and feedback?	
	Updates	Did the developers describe any plans and/or processes for updates?	
Dissemination	Endorsement	Did the developers report any endorsement attained?	
	Adherence	Did the developers report any processes for seeking adherence to the guideline?	
	Impact	Did the authors describe a process for evaluating the impact of the guideline or assessment tool, if any?	
	Website	Is the reporting standards document hosted on an open-access website?	
	Translation	Is the reporting standards document translated into any other languages?	
	Citation	Number of citations in Google Scholar of the reporting standards document (and explanatory document, if applicable)	

This data extraction sheet is modified from:

Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting guidelines. *PLoS Medicine.* 2010;7(2):e1000217

Appendix D. Social and Psychological Intervention RCT Reporting Standard Coding Sheet

Reviewer name:
Date of coding:
First author of paper:
Year of publication:
Journal of publication:
Social/Behavioural Science Discipline:

Derived from:

1. American Education Research Association Standards (AERA 2006)
2. CONSORT Abstracts Extension (Hopewell 2008)
3. CONSORT Alcohol Outcome Studies Coding Sheet (Ladd 2010)
4. CONSORT Cluster Trials Extension (Campbell 2004)
5. CONSORT Criminal Justice Trials Coding Sheet (Perry 2008)
6. CONSORT Harms Extension (Ioannidis 2004)
7. CONSORT Non-Pharmacological Extension (Boutron 2008)
8. CONSORT Pragmatic Trials Extension (Zwarenstein 2008)
9. CONSORT Statement (Schulz 2010)
10. Evidence-Based Behavioral Medicine Guidelines (Davidson 2003)
11. Jadad Scale (Jadad 1996)
12. Journal Article Reporting Standards (APA 2008)
13. Nelson-Moberg Expanded CONSORT Instrument (Nelson 2004)
14. Oxford Implementation Index (Montgomery, cited in Eisentstein 2007)
15. Quality Evaluation Form (Balas 1995)
16. Reporting Standards for Clinical Trials (Mosteller 1980)
17. TREND Statement (Des Jarlais 2004)
18. Standards of Reporting Trials Group Recommendations (SRTG 1994)
19. WIDER Recommendations (Abraham 2009)

*Indicates a new or modified standard to official CONSORT guidance

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score (Yes = 1, No = 0)
1a. Identification as randomised trial in title	Title/Abstract	The authors describe the trial as having a randomised design in the title	
1b. Identification as randomised trial in abstract	Title/Abstract	The authors describe the trial as having a randomised design in the abstract	
1c. Participants	Title/Abstract	The authors report primary eligibility criteria for participants in the abstract	
1d. Setting	Title/Abstract	The authors report the particular setting(s) in the abstract	
1e. Intervention group(s)	Title/Abstract	The authors report the treatment(s) intended for each intervention group in the abstract	
1f. Control	Title/Abstract	The authors report the treatment(s) intended for control in the abstract	
1g. Care provider	Title/Abstract	The authors give information on who provided the treatments in the abstract	
1h. Objective	Title/Abstract	The authors report a specific objective or hypothesis in the abstract	
1i. Primary outcome	Title/Abstract	The authors report a clearly defined primary outcome for this report in the abstract	
1j. Blinding participants	Title/Abstract	The authors report whether or not participants were blinded to group assignment in the abstract	
1k. Blinding providers	Title/Abstract	The authors report whether or not providers were blinded to group assignment in the abstract	
1l. Blinding outcome assessors	Title/Abstract	The authors report whether or not those assessing the outcomes were blinded to group assignment in the abstract	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
1m. Numbers randomised	Title/Abstract	The authors list the number of participants randomised to each group in the abstract	
1n. Numbers analysed	Title/Abstract	The authors list the number of participants analysed in each group for the primary outcome in the abstract	
1o. Result for primary outcome	Title/Abstract	For the primary outcome, the authors provide a result for each group, including the estimated effect size and its precision in the abstract	
1p. Conclusion	Title/Abstract	The authors describe general interpretation of the results in the abstract	
2a. Background: condition*	Introduction	The authors report the importance of the condition (e.g., nature of the problem, prevalence and incidence, course without treatment)	
2b. Background: intervention*	Introduction	The authors report background research about the intervention to be evaluated (e.g., intervention development, previous effectiveness studies)	
2c. Background: theory of change*	Introduction	The authors report the assumed theory of change underlying intervention	
2d. Rationale	Introduction	The authors present clear reasons for conducting the study (e.g., how the study will add to knowledge in field or address gap in research)	
2e. Objectives	Introduction	The authors present specific objectives of the study (i.e., aims of the study)	
2f. Hypotheses*	Introduction	The authors present specific hypotheses of the study (e.g., research questions of the study, expected findings)	
3a. Trial Design	Methods	The authors report the nature of the randomised trial design (e.g., parallel, factorial, cluster)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
3b. Allocation ratio	Methods	The authors explicitly report the allocation ratio of the trial	
3c. Protocol deviations	Methods	The authors report whether there were any important changes to methods after trial commencement (such as eligibility criteria), and reasons if so	
4a. Eligibility criteria	Methods	The authors clearly report all inclusion and exclusion criteria for the participants (Note: a partial score of .5 for reporting some criteria but not list inclusion and exclusion criteria or explicitly stating that "this is all the criteria": need that statement for a 1)	
4b. Concurrent secular events*	Methods	The authors report relevant external events occurring at the time of intervention that could influence outcomes (e.g., media campaigns, political movements, demographic changes, climatic events)	
4c. Setting type*	Methods	The authors state the type of settings of data collection in the study (e.g., classroom, participants' homes)	
4d. Setting number*	Methods	The authors state the number of settings of data collection in the study (i.e., number of classrooms, participants' homes)	
4e. Location*	Methods	The authors describe the geographical area in which the study occurred (e.g., city, country, region)	
4f. Timing*	Methods	The authors state the time period of data collection (e.g., month and year)	
4g. Patient preference*	Methods	The authors provide information about treatment preferences of participants	
4h. Provider preference*	Methods	The authors provide information about treatment preferences of providers	
5a. Service environment characteristics*	Methods	The authors provide characteristics of the service environment (e.g., economic, legal, political, demographic, technological, and policy-related environment; availability of alternatives outside the trial context; compensation structures; unique features of the trial environment)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
5b. Delivering organisation characteristics*	Methods	The authors provide characteristics of the delivering organisation (e.g., resources, programme advocates, interagency links, management, organisational compatibility with the intervention)	
5c. Design: intervention treatment	Methods	The authors clearly state the intended treatment for the intervention group(s) (e.g., what it is, core components of treatment, and sequence of activities)	
5d. Design: control treatment	Methods	The authors clearly state the intended treatment for the control group(s) (e.g., what it is, core components of treatment and sequence of activities)	
5e. Design: proscribed intervention components*	Methods	The authors describe activities or other elements proscribed in intervention group (i.e., any activities or components that are incompatible with the treatment)	
5f. Design: proscribed control components*	Methods	The authors describe activities or other elements proscribed in control group (i.e., any activities or components that are incompatible with the treatment)	
5g. Design: intervention materials*	Methods	The authors describe any necessary materials, technology, and/or technical requirements for standardised treatment	
5h. Design: control materials*	Methods	The authors describe any necessary materials, technology, and/or technical requirements for standardised treatment	
5i. Design: intervention format	Methods	The authors state the intended format of session and method of delivery of intervention (e.g., group or individual sessions, internet or face-to-face)	
5j. Design: control format	Methods	The authors state the intended format of session and method of delivery of control (e.g., group or individual sessions, internet or face-to-face)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
5k. Design: intervention duration	Methods	The authors state the intended length of the intervention (e.g., 20 week programme)	
5l. Design: control duration	Methods	The authors state the intended length of control (e.g., 20 week programme)	
5m. Design: intervention frequency	Methods	The authors state the frequency of intervention (e.g., 1 per week)	
5n. Design: control frequency	Methods	The authors state the frequency of control (e.g., 1 per week)	
5o. Design: intervention intensity	Methods	The authors state the intended intensity of the intervention (i.e., length of each session)	
5p. Design: control intensity	Methods	The authors state the intended intensity of the control (i.e., length of each session)	
5q. Design: intervention staffing	Methods	The authors state the intended staffing of the intervention (e.g., training and qualifications)	
5r. Design: control staffing	Methods	The authors state the intended staffing of the control (e.g., training and qualifications)	
5s. Delivery: intervention treatment*	Methods	The authors clearly state the delivered treatment for the intervention group(s) (i.e., actual activities delivered)	
5t. Delivery: control treatment*	Methods	The authors clearly state the delivered treatment for the control group(s) (i.e., actual activities delivered)	
5u. Delivery: programme differentiation*	Methods	The authors describe differences between or within trial arms in treatment delivery by staff	
5v. Delivery: proscribed intervention components*	Methods	The authors describe activities or other elements delivered that were proscribed in intervention protocol (i.e., any activities or components that are incompatible with the treatment)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
5w. Delivery: proscribed control components*	Methods	The authors describe activities or other elements delivered that were proscribed in control protocol (i.e., any activities or components that are incompatible with the treatment)	
5x. Delivery: non-specific intervention components*	Methods	The authors describe intervention components that are not specifically part of the protocol	
5y. Delivery: non-specific control components*	Methods	The authors describe control components that are not specifically part of the protocol	
5z. Delivery: intervention materials*	Methods	The authors describe any necessary materials, technology, and/or technical requirements actually used to deliver intervention as standardised	
5aa. Delivery: control materials*	Methods	The authors describe any necessary materials, technology, and/or technical requirements actually used to deliver control as standardised	
5bb. Delivery: intervention format*	Methods	The authors state the actual format of session and method of delivery of intervention (e.g., group and number of people in group, individual sessions, internet or face-to-face)	
5cc. Delivery: control format*	Methods	The authors state the actual format of session and method of delivery of control (e.g., group and number of people in group, individual sessions, internet or face-to-face)	
5dd. Delivery: intervention duration	Methods	The authors state the actual length of treatment delivered (e.g., 20 weeks of programming)	
5ee. Delivery: control duration	Methods	The authors state the actual length of control delivered (e.g., 20 weeks of programming)	
5ff. Delivery: intervention frequency	Methods	The authors state the actual frequency of treatment delivered (e.g., 1 intervention meeting per week)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
5gg. Delivery: control frequency	Methods	The authors state the actual frequency of treatment delivered (e.g., 1 control meeting per week)	
5hh. Delivery: intervention intensity	Methods	The authors state the actual intensity of the intervention delivered (i.e., average length of each session)	
5ii. Delivery: control intensity	Methods	The authors state the actual intensity of the control delivered (i.e., average length of each session)	
5jj. Delivery: tailoring of intervention*	Methods	The authors describe other types of intervention adaptation by trialists and staff (e.g., types and extent of deviations from protocol that have not been highlighted above, including supplementing the treatment)	
5kk. Delivery: tailoring of control*	Methods	The authors describe other types of control adaptation by trialists and staff (e.g., types and extent of deviations from protocol that have not been highlighted above, including supplementing the treatment)	
5ll. Delivery: intervention staffing	Methods	The authors state the actual staffing of the intervention (i.e., number and qualifications of staff)	
5mm. Delivery: control staffing	Methods	The authors state the actual staffing of the control (i.e., number and qualifications of staff)	
5nn. Delivery: intervention provider training*	Methods	The authors state how intervention providers were trained, or that training was not necessary	
5oo. Delivery: control provider training*	Methods	The authors state how control providers were trained, or that training was not necessary	
5pp. Delivery: intervention supervision*	Methods	Authors report any contacts between intervention providers and supervisors/researchers	
5qq. Delivery: control supervision*	Methods	The authors report any contacts between control providers and supervisors/researchers	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
5rr. Delivery: provider adherence measurement*	Methods	The authors describe steps to measure adherence of care providers with the protocol (e.g., incentives for staff compliance, participant feedback, monthly mailings or weekly phone reminders)	
5ss. Delivery: participant compliance measurement*	Methods	The authors describe steps to measure compliance of participants with the protocol (e.g., steps to reduce contamination between trial arms, monthly mailings or weekly phone reminders, any efforts to discourage uptake of interventions outside the trial context)	
5tt. Uptake: intervention treatment*	Methods	The authors describe the treatment taken up by intervention group(s) participants (i.e., compliance to core components of treatment and sequence of activities)	
5uu. Uptake: control treatment*	Methods	The authors describe the treatment taken up by control group(s) participants (i.e., compliance to components of treatment and sequence of activities)	
5vv. Uptake: programme differentiation*	Methods	The authors describe differences between or within trial arms in treatment uptake by participants	
5ww. Uptake: contamination of intervention*	Methods	The authors describe participant uptake of treatments outside the intervention protocol (includes uptake of control group treatment)	
5xx. Uptake: contamination of control*	Methods	The authors describe participant uptake of treatments outside the control protocol (includes uptake of intervention group treatment)	
5yy. Uptake: proscribed intervention components*	Methods	The authors describe activities or other elements sought by participants that were proscribed in intervention protocol, or report that this data was not recorded (i.e., any activities or components that are incompatible with the treatment)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
5zz. Uptake: proscribed control components*	Methods	The authors describe activities or other elements sought by participants that were proscribed in control protocol (i.e., any activities or components that are incompatible with the treatment)	
5aaa. Uptake: intervention materials*	Methods	The authors describe any necessary materials, technology, and/or technical requirements actually used by participants in intervention group	
5bbb. Uptake: control materials*	Methods	The authors describe any necessary materials, technology, and/or technical requirements actually used by participants in control group	
5ccc. Uptake: intervention frequency*	Methods	The authors state the actual number of treatment sessions utilised by intervention participants (e.g., 16 weeks of 20 week treatment)	
5ddd. Uptake: control frequency*	Methods	The authors state the actual number of treatment sessions utilised by control participants (e.g., 16 weeks of 20 week treatment)	
5eee. Uptake: intervention intensity*	Methods	The authors state the actual intensity of the intervention utilised by intervention participants (i.e., average length of each session)	
5fff. Uptake: control intensity*	Methods	The authors state the actual intensity of the control utilised by control participants (i.e., average length of each session)	
5ggg. Uptake: enactment*	Methods	The authors report on the extent to which participants implement specific treatment-related activities (e.g., learned behavioural skills and cognitive strategies) in relevant real-life settings	
6a. Baseline data collection	Methods	The authors describe the conditions for baseline data collection (e.g., setting of data collection, method of data collection)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
6b. Baseline data measures	Methods	The authors describe the measures used for baseline data collection	
6c. Primary outcome data collection	Methods	The authors report how they measured the primary outcome (e.g., setting of data collection, method of data collection)	
6d. Primary outcome measures*	Methods	The authors clearly identify and describe the primary outcome measure(s), two at most (e.g., whether outcome measures were validated, pre-existing, or developed by authors themselves)	
6e. Secondary outcome data collection*	Methods	The authors report how they measured any secondary outcome(s) (e.g., setting of data collection, method of data collection)	
6f. Secondary outcome measures*	Methods	The authors describe all of the secondary outcome measures (e.g., whether outcome measures were validated, pre-existing, or developed by authors themselves)	
6g. Period of follow-up	Methods	The authors clearly state the follow-up period for all groups and measures in the trial (i.e., fixed follow-up period or saturation point of data)	
6h. Methods to enhance quality of measurements*	Methods	The authors report methods to improve the quality of data measurements (e.g., double scoring of questionnaires, inter-rater reliability of data collection/data entry procedures, training requirements, and coded audio/visual tapes)	
6i. Changes to data collection protocol*	Methods	The authors report whether there were any changes to the protocol for measuring and analysing trial outcomes after the trial commenced, with reasons	
7a. Sample size calculation	Methods	The authors provide clear information and justification for sample size calculation	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
7b. Interim analyses and stopping rules	Methods	The authors clearly state whether they planned to collect interim results and under what circumstances they would have stopped the trial	
8a. Random Sequence Generation	Methods	The authors clearly state the method of random allocation of participants (e.g., computer generated sequences, random numbers table, coin toss)	
8b. Randomisation restrictions	Methods	The authors describe details of any restrictions (e.g. blocking, ratios, and explanation of why restrictions employed)	
8c. Allocation of providers*	Methods	The authors clearly state the method of allocation of care providers	
9. Allocation concealment	Methods	The authors describe methods used to access, conceal, and implement the random allocation sequence (e.g., use of the telephone or reading numbers off a list)	
10a. Sequencer Generator	Methods	The authors clearly state the person who generated the allocation sequence	
10b. Who enrolled participants	Methods	The authors clearly state who enrolled the participants	
10c. Who assigned participants	Methods	The authors clearly state who assigned the participants to the groups	
11a. Provider blinding*	Methods	The authors clearly report if and how treatment providers were blinded to group assignment, or if not, why	
11b. Participant blinding*	Methods	The authors clearly report if and how participants were blinded to group assignment, or if not, why	
11c. Assessor blinding	Methods	The authors clearly report if and how outcome assessors were blinded to group assignment, or if not, why	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
12a. Primary outcome analytic plan*	Methods	The authors clearly state the pre-determined data analysis plan for the primary outcome	
12b. Secondary outcome analytic plan*	Methods	The authors clearly state the pre-determined data analysis plan for the secondary outcome(s)	
12c. Sub-group and adjusted analyses*	Methods	The authors report the methods of any sub-group and/or adjusted analyses they performed and which were pre-specified	
13a. Participant flow	Results	The authors clearly show the participants in the trial through use of a flow diagram (from participants approached to numbers in analysis)	
13b. Number approached	Results	The authors clearly report the number of potential participants approached for eligibility	
13c. Number eligible	Results	The authors clearly report the number of participants eligible for trial and reasons for non-participation	
13d. Number randomised	Results	The authors clearly report how many people were allocated to each arm of the trial	
13e. Treatment allocation	Results	The authors clearly report the number of participants who completed treatment as allocated, by study group	
13f. Attrition	Results	The authors clearly report the amount of and reasons for participants dropping out of the trial for each trial arm	
13g. Discontinued Intervention	Results	The authors clearly report the number of participants who discontinued the intervention	
13h. Number in primary analysis	Results	The authors clearly report the final numbers used in primary analysis for each group	
14a. Period of recruitment	Results	The authors clearly state the period of recruitment	
14b. Recruitment process	Results	The authors describe how the participants are approached and selected (have a partial score of .5 for reporting only some criteria)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
14c. Incentives*	Results	The authors report any incentives or compensation for participating in the trial	
14d. Reasons for stopping	Results	The authors clearly state why the trial ended or stopped	
15. Baseline data*	Results	The authors report the demographic details of both groups (e.g., age, ethnicity, gender, socioeconomics, cultural, linguistic, religious, and other relevant characteristics, education, employment, marital status, number taking medication or receiving other therapy)	
16a. Number analysed	Results	For each group, the authors report the number of participants (denominator) included in each analysis	
16b. Intention-to-treat*	Results	The authors clearly state precise procedures for intention-to-treat or per-protocol analysis (i.e., not just "Intention-to-treat," but actual plan for dealing with missing data)	
17a. Primary outcome results*	Results	The authors clearly present all results for primary outcome for each group to allow replication or alternative analyses (e.g., all time intervals, exact P values, effect size, precision)	
17b. Secondary outcome results*	Results	The authors clearly present all results for secondary outcome(s) for each group to allow replication or alternative analyses (e.g., all time intervals, exact P values, effect size, precision)	
18. Sub-group or adjusted analysis results	Results	The authors clearly report any other subgroup/adjusted analyses performed	
19. Adverse events*	Results	The authors describe any adverse events or harms experienced by participants in trial	
20. Limitations*	Discussion	The authors clearly state any methodological weaknesses or limitations of the study that can lead to imprecision (e.g., dangers associated with multiplicity outcomes, choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centres in each group)	

Reporting Item: Did the paper report?	Section or Topic	Guidance for reviewer assessment	Score
21. Generalisability*	Discussion	The authors clearly state the generalisability of the study according to the intervention as implemented, comparators, patients, care providers and centres involved in the trial, and possible differences to other settings	
22a. Overall evidence*	Discussion	The authors clearly state how the current findings fit in with the weight of evidence across other trials and studies	
22b. Results compared to hypotheses*	Discussion	The authors clearly compare the results to predictions made prior to the start of the trial	
22c. Reference to systematic review	Other Information	The authors made reference to systematic review on subject and how this paper fits, or whether no such paper exists	
22d. Reference to other studies*	Other Information	The authors indicate whether there are other papers and/or reports on this study and, if so, refers the reader to these papers	
23. Trial registration	Other Information	The authors provide the registration number and name of trial register	
24a. Protocol*	Other Information	The authors report where a full trial protocol can be accessed, if available	
24b. Access to treatment manual*	Other Information	The authors provide information for accessing intervention materials (e.g., protocol or manual) to allow for replication	
25a. Conflicts of interest*	Other Information	The authors report sources of funding and other support (such as supply of drugs), role of funders, or other biases they researchers have that may influenced their research	
25b. Ethical considerations*	Other Information	The authors report any ethical considerations for the study (e.g., the study received ethical approval, informed consent)	
25c. Intervention development*	Other Information	The authors report whether or not they developed the intervention	

Notes on coding:

Each reporting standard is assigned a “yes” (score of 1) or “no” (score of 0) response depending on whether the authors reported that item.

Coding rules were adapted from previous studies about reporting quality.

Firstly, each sub-item aims to address a single reporting standard that can be scored by a reviewer who is not an expert in the field.

Secondly, one sentence in a trial report that contains multiple pieces of information can achieve compliance to several reporting standards simultaneously.

In contrast to previous studies, if no primary outcomes were specified, all outcomes in a trial report are considered secondary outcomes, and all items referring to primary outcomes are coded as 0. Not penalising would under-emphasise the importance of specifying primary outcomes for testing and delineating theory, in addition to their role in power calculations.

Lastly, unless specifically required by a reporting item, credit is granted if the authors provide the information in a different section of the paper than is listed in the CONSORT checklist. For example, Items 1a-1p must be reported in the title or abstract, but information on allocation could be in the methods, results, or discussion section.

Appendix E. Reported Details of Guideline Development Methods

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
Alcohol Outcome Studies Coding Sheet	• Evidence of poor reporting • Identified previous standards • Funded by CASAA • 4 reported participants	• Preliminary list of items generated from 2001 CONSORT Statement • Developed tool by pilot testing and modifying items to fit psychosocial interventions	• No techniques reported	• No techniques reported
AERA Standards for Empirical Social Science Research	• 10 reported participants	• No techniques reported	• No techniques reported	• Endorsement by AERA • Available on open-access website
CONSORT and Criminal Justice Trials (CJT) Project Coding Sheet	• Evidence of poor reporting • Identified previous standards • Funded by government and university support	• Developed tool via 3-stage process of combining CONSORT items with items from crime and justice literature	• Reported desire to update by developing a CONSORT extension in criminology	• Available on open-access website

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
CONSORT Extension for Abstracts	• Evidence of poor reporting • Identified previous standards • Various funding sources reported • 63 reported participants in Delphi; 26 reported participants in consensus meeting	• Conducted Delphi exercise • Preliminary list of items from review of previous standards • Prepared for finalisation by distributing Delphi results prior to consensus meeting • Finanlisation process via consensus meeting • Developed tool via steering group • Produced E&E document	• Feedback on limitations via CONSORT website • Abstract Extensions as warranted	• Endorsement attained by journals • Adherence by journal editors and conference organisers for submissions • Conducted a review on the impact of the guideline • Available on open-access website
CONSORT Extension for Cluster Trials	• Evidence of poor reporting • Identified previous standards • Various funding sources reported	• Finalisation process via face-to-face meetings and teleconferences • Developed via CONSORT Group	• Updated in 2012	• Endorsement attained by journals • Adherence by journal editors for submissions • Conducted a review on the impact of the guideline • Available on open-access website

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
CONSORT Extension for Non-PharmacologicTreatments	• Evidence of poor reporting • Identified previous standards • Various funding sources reported • 33 reported participants	• Conducted web-based survey of participants to identify potential items • Preliminary list of items from review of previous standards • Prepared for finalisation by distributing survey results prior to consensus meeting • Finanlisation process via consensus meeting • Developed tool via steering committee • Produced E&E document	• Discussed publication of E&E in another journal as part of publication strategy • Invited feedback and will continue to search literature • Plan to develop Non-Pharmacological Extensions	• Endorsement attained by journals • Adherence by journal editors for submissions • Conducted a review on the impact of the guideline • Available on open-access website
CONSORT Extension for Pragmatic Trials	• Identified previous standards • Various funding sources reported • 24 reported participants in 2005; 42 in 2008	• Prepared for finalisation by drafting and distributing a summary paper based on the initial 2005 meeting • Finalisation process via consensus meeting • Developed tool via CONSORT Group	• Submitted to one journal for publication after the consensus meeting	• Endorsement attained by journals • Adherence by journal editors for submissions • Available on open-access website

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
CONSORT Extension for Reporting Harms	• Evidence of poor reporting • Identified previous standards • Various funding sources reported • 31 reported participants	• Preliminary items identified through literature search • Prepared for finalisation by sharing results of literature search with participants • Finalisation process via consensus meeting • Developed tool via circulation of drafts amongst team members	• Invited feedback on guideline website • Update as needed	• Endorsement attained by journals • Adherence by journal editors for submissions • Available on open-access website
CONSORT Statement	• Evidence of poor reporting • Identified previous standards • Various funding sources reported • Dozens of participants throughout its 3 iterations	• Conducted Delphi exercise • Preliminary items from literature review and Delphi • Prepared for finalisation by having participants aggregate and share data on potential items • Finalisation process via consensus meeting • Tool developed via CONSORT Executive • Produced E&E document	• Multiple, peer-reviewed publications • Invited feedback on guideline website and in research literature • Updated twice	• Endorsement attained by journals • Adherence by journal editors for submissions • Multiple reviews on its impact • Available on open-access website • Translated into several languages

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
Evidence-Based Behavioral Medicine-Specific Guidelines	• Evidence of poor reporting • Identified previous standards • Funded by NIH OBSSR contract • 9 reported participants	• No techniques reported	• No techniques reported	• No techniques reported
Jadad Scale	• Reviewed literature to identify possible standards • 6 participants and 7 authors reported	• Conducted modified nominal group technique • Developed a preliminary list of items to discuss • Prepared for finalisation by voting on face validity of items • Finalisation process via panel of judges pre-testing the draft instrument • Tool developed via panel of judges	• No techniques reported	• No techniques reported

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
Journal Article Reporting Standards	• Evidence of poor reporting • Identified previous standards • Developed by JARS Group, the APA Council of Editors, the APA Publication Manual Revision Task Force, and the Publications and Communications Board	• Preliminary items were identified from previous guidelines • Prepared for finalisation by sharing draft guideline with various APA groups • Finalisation process via meeting of JARS Group • Developed tool via JARS Group with feedback from various APA groups • Produced E&E document	• Plan to update with additional modules	• Endorsement attained by APA journals • Adherence required by APA journal editors • Checklist is available on an open-access website (E&E document is not)
Nelson-Moberg Expanded CONSORT Instrument	• Identified previous standards • 2 reported participants	• Finalisation process via by pilot-testing on 3 articles • Developed tool via refinement after pilot testing • Produced E&E document	• Invite feedback from RCT experts	• No techniques reported

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
Oxford Implementation Index	• Identified previous standards • Various funding sources reported • Unspecified amount of participants at various meetings	• Conducted Delphi exercise • Preliminary items from literature review and Delphi • Prepared for finalisation by sharing results from literature reviews • Finalisation process via consensus meeting • Tool developed via project team • Produced guidance for each item	• No techniques reported	• Available on open-access website
Quality Evaluation Form	• Identified previous standards • Funded by government and university support	• No techniques reported	• No techniques reported	• No techniques reported
Reporting Standards for Controlled Trials	• Evidence of poor reporting • Funded by government grants	• No techniques reported	• No techniques reported	• Adherence by editor of submitted journal

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
Structured Reporting of Randomized Controlled Trials	• Evidence of poor reporting • Identified previous standards • Various funding sources reported • 30 participants reported	• Conducted a 144-item survey • Generated a list of preliminary items • Prepared for finalisation by organising participants into groups with different focus areas • Finalisation process via presentation of small group recommendations • Tool developed by whole group	• Update via feedback from journal editors and Cochrane groups	• Adherence by journal editors
TREND Statement	• Evidence of poor reporting • Identified previous standards • Funded by the CDC • 18 reported participants	• Prepared for finalisation by reviewing literature • Finalisation process via consensus meeting	• Invited feedback • Plan to periodically revise TREND accordingly	• Endorsed by many journals • Adherence during journal submissions • Review done on impact of guideline • Available on open-access website

Guideline	Preliminary Stages	Document Development	Publication	Dissemination
WIDER	• Identified previous standards • 32 reported participants	• No techniques reported	• No techniques reported	• Endorsed by several journal editors • Adherence strategies in journal editorial policy • Available on open-access website

Appendix F. New and Modified Reporting Standards for Social and Psychological Intervention Trials

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Alcohol Outcome Studies Coding Sheet		
	Report appropriate quantitative measures of sample and target population to discuss external validity	21. Generalisability
AERA Standards for Empirical Social Science Research		
	Report the historical context of the phenomena studied	5a. Service Environment Characteristics
	Report how the measurement or classification of latent constructs preserves important characteristics of the phenomena under study and is relevant to capturing important characteristics of the group studied, either by referencing a publication on the measure or describing measurement development	6d. Primary outcome measures 6f. Secondary outcome measures
	Provide a sufficient description of development, guides, protocols, and context of qualitative process evaluations (e.g., interviews, open-ended surveys, observational inventories)	6e. Secondary outcome data collection
	Report the process of analysing and interpreting claims from qualitative process evaluations (e.g., practices used to develop and enhance the warrant for the claims, including the search for disconfirming evidence and alternative interpretations of the same evidence)	12b. Secondary outcome analytic plan
	Present the evidence that serves as a warrant for each claim from qualitative evaluations	17b. Secondary outcome results

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
AERA Standards for Empirical Social Science Research	Delineate the situations (or domains) in which the findings of the investigation do not apply to identify the scope of intended generalisation	21. Generalisability
	Describe how and why the patterns of qualitative responses may have occurred (e.g., the social, cultural, or historical contexts, how they relate to one another, how they support or challenge theory and findings from previous research, and what alternative claims or counter-claims were considered)	22a. Overall evidence
	Include a description of any personal biases of the researcher that may have influenced or could have the appearance of influencing the research, along with a description of how they were managed in the conduct of the study	25a. Conflicts of interest
	(1) Describe ethical considerations involved in data collection, analysis, and reporting; (2) Report whether IRB approval was obtained; (3) Report research and findings in a way that honours consent agreements with human participants and any other agreements with respect to gaining access to research sties or data	25b. Ethical approval

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
CONSORT Criminal Justice Trials Project Coding Sheet		
	Report any measures indicating quality of latent construct measurement, such as double scoring of questionnaires, inter-rater reliability of data collection/data entry procedures, training requirements, protocol adherence, coded audio/visual tapes, supervision and feedback of staff.	6h. Methods to enhance quality of measurements
	Report on the background characteristics of the groups, including criminal history, targeted criminogenic needs, specifically targeted offence types, and family history	15. Baseline data
	Clearly state any social harm done to participants (e.g., increased criminal activity following the interventions)	19. Adverse events
	(1) Report whether other paper(s) on the study exist; (2) Report whether this paper represents a set of experiments	22d. Reference to other papers on this study
	Report whether the authors developed and evaluated the intervention	25c. Intervention development
Evidence-Based Behavioral Medicine-Specific Guidelines		
	Describe health/social outcome in sufficient detail to allow the reader to consider secular trends	4b. Concurrent secular events

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Evidence-Based Behavioral Medicine-Specific Guidelines	Report the treatment preference of the participants	4g. Participant preference
	Report the treatment preference of the providers	4h. Provider preference
	Report the success of treatment integrity by the provider	5s. Delivery: intervention treatment 5t. Delivery: control treatment
	Report the specific procedures that were used to train providers to uniformly conduct the study treatments	5nn. Delivery: intervention provider training 5oo. Delivery: control provider training
	Report the type, duration, and form that supervision, if any, required	5pp. Delivery: intervention supervision 5qq. Delivery: control supervision
	Report adherence measures and the decision rules, if any, whereby these adherence measures were combined	5ss. Delivery: participant compliance measurement
	Report treatment adherence of participants	5tt. Uptake: intervention treatment 5uu. Uptake: control treatment
	Report whether participants used intervention materials	5aaa. Uptake: intervention materials 5bbb. Uptake: control materials

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Evidence-Based Behavioral Medicine-Specific Guidelines	Report whether an adequate "dose" of the intervention was received	5ccc. Uptake: intervention frequency 5ddd. Uptake: control frequency 5eee. Uptake: intervention intensity 5fff. Uptake: control intensity
	Report whether or not patients enacted the treatment recommendations outside of intervention sessions	5ggg. Uptake: enactment
	Report consideration of any measurement demand characteristics of subjective outcome measures	6h. Methods to enhance quality of measurements
	Report whether any mediation testing was performed, and if so, how	12b. Secondary outcome analytic plan
Journal Article Reporting Standards (APA)		
	If other aspects of this study have been reported on previously, describe how the current report differs from these earlier reports	2b. Background: intervention
	Report the theories or other means used to derive hypotheses	2f. Hypotheses
	Describe specialised equipment by model and supplier	5z. Delivery: intervention materials 5aa. Delivery: control materials

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Journal Article Reporting Standards (APA)	Report whether the intervention involved any language translation, and, if so, the translation method	5jj. Delivery: tailoring of intervention 5kk. Delivery: tailoring of control
	Report whether there were any estimation problems (e.g., failure to converge, bad solution spaces) or anomalous data points in complex data set	6i. Changes to data collection protocol
	Report the number of deliverers and, in the case of interventions, the M, SD, and range of number of individuals/units treated by each	8c. Allocation of providers
	Report empirical evidence and/or theoretical arguments for the causes of data that are missing (i.e., missing completely at random (MCAR), missing at random (MAR), or missing not at random (MNAR))	16b. Intention-to-treat
	For multivariable analytic systems (e.g., multivariate analyses of variance, regression analyses, structural equation modeling analyses, and hierarchical linear modeling), also include the associated variance–covariance (or correlation) matrix or matrices	17a. Primary outcome results 17b. Secondary outcome results 18. Sub-group or adjusted analysis results
	Report whether this data has previously appeared in any dissertations or conference papers	22d. Reference to other papers on this study
	Report any relationships that may be perceived as conflicts of interest	25a. Conflicts of interest

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Nelson-Moberg Expanded CONSORT Instrument		
	Describe the problem that necessitated the work – the nature, scope, and severity	2a. Background: condition
	Report any previous evidence of benefits of active interventions included in trial	2b. Background: intervention
	(1) Provide a full explication of the theoretical basis of an intervention; (2) Report theory-delineated proximal and distal outcomes	2c. Background: theory of change
	Differentiate between data collection and trial setting	4c. Setting type 4d. Setting number 4e. Location
	Report the extent to which participants perceive, comprehend, and use the intervention as intended	5tt. Uptake: intervention treatment 5uu. Uptake: control treatment
	Report any threats to treatment enactment (e.g., not practicing the behavior, forgetting to do it, being unsure of the correct way to do it, experiencing a lack of success when doing it, lacking a suitable setting, and losing interest in the intervention)	5ggg. Uptake: enactment
	Given that complex social intervention have a multiplicity of outcomes, report up to 2 primary outcomes	6d. Primary outcome measures

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Nelson-Moberg Expanded CONSORT Instrument	Report the use validated latent construct (and their appropriate psychometric properties) or give rationale concerning non-availability or inappropriateness of validated scales (and report the appropriate psychometric properties of scales used)	6d. Primary outcome measures 6f. Secondary outcome measures
	Report whether the researchers used any methods to compensate for inability to blind providers	11a. Provider blinding
	Report whether the researchers used any methods to compensate for inability to blind participants	11b. Participant blinding
	In the protocol, report components that are not part of the intervention and may be part of the competing intervention	24a. Protocol
	Report whether informed consent was obtained prior to randomisation	25b. Ethical approval
Oxford Implementation Index		
	Report any external events at the same time as the trial (e.g., media campaigns, political movements, demographic changes, climatic events)	4b. Concurrent secular events
	(1) Report the legal, political, demographic, technological, and policy-related environment of the trial; (2) Report the availability of alternatives outside the trial context; (3) Report the compensation structures for interventions; (4) Report unique features of the trial service environment (e.g., free child care, home visits)	5a. Service environment characteristics

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Oxford Implementation Index	Report the existence and influence of organisational resources, programme champions, interagency links, management, and organisational compatibility with the intervention	5b. Delivering organisation characteristics
	Report any activities or components that are incompatible with the treatment	5e. Design: proscribed intervention components 5f. Design: proscribed control components
	Report any technical requirements (e.g., support staff)	5g. Design: intervention materials 5h. Design: control materials
	If there are systematic differences between treatments delivered to participants in the same trial arm (e.g., if men and women are treated differently), these should also be noted	5u. Delivery: programme differentiation
	Report the actual delivery of any activities or components that are incompatible with the treatment	5v. Delivery: proscribed intervention components 5w. Delivery: proscribed control components
	Report about any treatment components that are not specifically part of the protocol, such as expertise or quality of the therapeutic alliance	5x. Delivery: non-specific intervention components 5y. Delivery: non-specific control components
	Report the actual use of technical requirements for delivery of materials (e.g., support staff)	5z. Delivery: intervention materials 5aa. Delivery: control materials

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Oxford Implementation Index	Report the nature of any contact between staff and trialists/programme developers	5pp. Delivery: intervention supervision 5qq. Delivery: control supervision
	Report the actual sequence of core steps, stages, or activities that participants took up	5tt. Uptake: intervention treatment 5uu. Uptake: control treatment
	(1) Report any differences in receipt between active and control arms that have not been highlighted elsewhere; (2) If there are systematic differences between treatments delivered to participants in the same trial arm (e.g., if men and women are treated differently), these should also be noted	5vv. Uptake: programme differentiation
	Report contamination and uptake of treatments outside the trial context	5ww. Uptake: contamination of intervention 5xx. Uptake: contamination of control
	Report any activities or components that are incompatible with the treatment	5yy. Uptake: proscribed intervention components 5zz. Uptake: proscribed control components
	Report participant use of technology, materials, or technical requirements	5aaa. Uptake: intervention materials 5bbb. Uptake: control materials
	Report socioeconomic, demographic, cultural, linguistic, religious, and other relevant characteristics of participants	15. Baseline data

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
Oxford Implementation Index	Report any unique ethical considerations found in complex interventions (e.g., parental consent and parental observation when working with children)	25b. Ethical approval
TREND Statement		
	Report information on target population	1c. Participants
	Report how subjects were grouped during delivery	5bb. Delivery: intervention format 5cc. Delivery: control format
	Report the statistical software if specialised procedures were used	12a. Primary outcome analytic plan 12b. Secondary outcome analytic plan 12c. Sub-group and adjusted analyses
	Report any activities to increase compliance, adherence, or retention	14.c Incentives
	(1) Provide comparison between study population at baseline and target population of interest; (2) Provide baseline comparisons of those lost to follow-up and those retained, overall and by study condition	15. Baseline data
	Report the results from testing prespecified causal pathways through which the intervention was intended to operate, if any	17b. Secondary outcome results
	Discuss the success of and barriers to implementing the intervention	20. Limitations

Reporting Standards Document	New/Modified CONSORT Standard	Elongated CONSORT Checklist Item(s)
TREND Statement	Report considerations of any incentives, compliance rates, and specific sites/settings involved in the study	21. Generalisability
	Report programmatic or policy implications of the trial	22a. Overall evidence
	Discuss results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	22b. Summary of results compared to objectives/hypotheses
WIDER		
	Report essential aspects of the intervention development	2b. Background: intervention
	(1) Report the active change techniques used in the intervention; (2) Report the causal processes targeted by these change techniques	2c. Background: theory of change

Appendix G. List of RCTs Included in Review

First Author	Article Title	Journal	Discipline
Abar	Preventing Skin Cancer in College Females: Heterogeneous Effects Over Time	*Health Psychology*	Clinical Psychology
Alexander	A Randomized Clinical Trial Evaluating Online Interventions to Improve Fruit and Vegetable Consumption	*American Journal of Public Health*	Public Health
Allen	Learner Error, Affectual Stimulation, and Conceptual Change	*Journal of Research in Science Teaching*	Education
Alvarez	Development and Preliminary Evaluation of a Training Method to Assist Professionals in Reporting Suspected Child Maltreatment	*Child Maltreatment*	Social Work
Anderson	Effects of Clinician-Assisted Emotional Disclosure for Sexual Assault Survivors: A Pilot Study	*Journal of Interpersonal Violence*	Criminology and Penology
Arthur	Implementation of the Communities That Care Prevention System by Coalitions in the Community Youth Development Study	*Journal of Community Psychology*	Social Work
Baker	An RCT Study to Evaluate a Targeted, Theory Driven Healthy Eating Leaflet	*Social Science & Medicine*	Public Health
Barrio	Culturally Based Intervention Development: The Case of Latino Families Dealing With Schizophrenia	*Research on Social Work Practice*	Social Work
Becker	Comparing Couples' and Individual Voluntary Counseling and Testing for HIV at Antenatal Clinics in Tanzania: A Randomized Trial	*Aids & Behavior*	Public Health
Beckner	Telephone-Administered Psychotherapy for Depression in MS Patients: Moderating Role of Social Support	*Journal of Behavioral Medicine*	Clinical Psychology
Biazaka	Does An Activity-Based Learning Strategy Improve Preschool Children's Memory for Narrative Passages?	*Early Childhood Research Quarterly*	Education

First Author	Article Title	Journal	Discipline
Bierman	The Effects of a Multiyear Universal Social–Emotional Learning Program: The Role of Student and School Characteristics	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Biesinger	The Effects of Feedback Protocol on Self-Regulated Learning in a Web-Based Worked Example Learning Environment	*Computers & Education*	Education
Bohner I	Using Social Norms to Reduce Men's Rape Proclivity: Perceived Rape Myth Acceptance of Out-Groups May Be More Influential than that of In-Groups	*Psychology, Crime & Law*	Criminology and Penology
Bohner II	Using Social Norms to Reduce Men's Rape Proclivity: Perceived Rape Myth Acceptance of Out-Groups May Be More Influential than that of In-Groups	*Psychology, Crime & Law*	Criminology and Penology
Boivin	A Pilot Study of the Neuropsychological Benefits of Computerized Cognitive Rehabilitation in Ugandan Children With HIV	*Neuropsychology*	Clinical Psychology
Borelli	Motivating Latino Caregivers of Children With Asthma to Quit Smoking: A Randomized Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Boucheix I	An Eye Tracking Comparison of External Pointing Cues and Internal Continuous Cues in Learning with Complex Animations	*Learning & Instruction*	Education
Boucheix II	An Eye Tracking Comparison of External Pointing Cues and Internal Continuous Cues in Learning with Complex Animations	*Learning & Instruction*	Education
Bouffard	Methodological Artifacts in Tests of Rational Choice Theory	*Journal of Criminal Justice*	Criminology and Penology

First Author	Article Title	Journal	Discipline
Bourdeaudhuij	Evaluation of a Computer-Tailored Physical Activity Intervention in Adolescents in Six European Countries: The Activ-O-Meter in the HELENA Intervention Study	*Journal of Adolescent Health*	Public Health
Bowman	Can Students Really Multitask? An Experimental Study of Instant Messaging While Reading	*Computers & Education*	Education
Brody	Long-Term Effects of the Strong African American Families Program on Youths' Alcohol Use	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Burns	Suppression of Pain-Related Thoughts and Feelings During Pain-Induction: Sex Differences in Delayed Pain Responses	*Journal of Behavioral Medicine*	Clinical Psychology
Buysee	Effects of a Professional Development Program on Classroom Practices and Outcomes for Latino Dual Language Learners	*Early Childhood Research Quarterly*	Education
Cakir	A Comparative Analysis of the Effects of Computer and Paper-Based Personalization on Student Achievement	*Computers & Education*	Education
Carei	Randomized Controlled Clinical Trial of Yoga in the Treatment of Eating Disorders	*Journal of Adolescent Health*	Public Health
Carey	Brief and Intensive Behavioral Interventions to Promote Sexual Risk Reduction among STD Clinic Patients: Results from a Randomized Controlled Trial	*Aids & Behavior*	Public Health
Carpenter	Efficacy of a Web-Based Intervention to Reduce Sexual Risk in Men Who Have Sex with Men	*Aids & Behavior*	Public Health
Catley	Interpreting Evolutionary Diagrams: When Topology and Process Conflict	*Journal of Research in Science Teaching*	Education
Chacko	Efficacy of a Motivational Behavioral Intervention to Promote Chlamydia and Gonorrhea Screening in Young Women: A Randomized Controlled Trial	*Journal of Adolescent Health*	Public Health

First Author	Article Title	Journal	Discipline
Chadler	Family-Focused Cognitive Behaviour Therapy Versus Psycho-Education for Chronic Fatigue Syndrome in 11- to 18-Year-Olds: A Randomized Controlled Treatment Trial	*Psychological Medicine*	Clinical Psychology
Chang	The Impact of Designing and Evaluating Molecular Animations on How Well Middle School Students Understand the Particulate Nature of Matter	*Science Education*	Education
Chang	A Team-Teaching Model for Practicing Project-Based Learning in High School: Collaboration Between Computer and Subject Teachers	*Computers & Education*	Education
Chen I	A Novel Approach for Enhancing Student Reading Comprehension and Assisting Teacher Assessment of Literacy	*Computers & Education*	Education
Chen II	Promoting College Students' Knowledge Acquisition and Ill-Structured Problem Solving: Web-Based Integration and Procedure Prompts	*Computers & Education*	Education
Cheong	The Effects of Practice Teaching Sessions in Second Life on the Change in Pre-Service Teachers' Teaching Efficacy	*Computers & Education*	Education
Chhabra	Adaptation of an Alcohol and HIV School-Based Prevention Program for Teens	*Aids & Behavior*	Public Health
Chiang	Individual Differences in Relative Metacomprehension Accuracy: Variation Within and Across Task Manipulations	*Metacognition and Learning*	Education
Cho	Student Revision with Peer and Expert Reviewing	*Learning & Instruction*	Education
Chu	A Knowledge Engineering Approach to Developing Mindtools for Context-Aware Ubiquitous Learning	*Computers & Education*	Education
Cinciripini	Effects of an Intensive Depression-Focused Intervention for Smoking Cessation in Pregnancy	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Cobham	Parental Anxiety in the Treatment of Childhood Anxiety: A Different Story Three Years Later	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology

First Author	Article Title	Journal	Discipline
Collins	ELL Preschoolers' English Vocabulary Acquisition from Storybook Reading	*Early Childhood Research Quarterly*	Education
Conner	Long-Term Effects of Implementation Intentions on Prevention of Smoking Uptake Among Adolescents: A Cluster Randomized Controlled Trial	*Health Psychology*	Clinical Psychology
Corbalan	Computer-Based Feedback in Linear Algebra: Effects on Transfer Performance and Motivation	*Computers & Education*	Education
Cortizo	Blended Learning Applied to the Study of Mechanical Couplings in Engineering	*Computers & Education*	Education
Cottler	Feasibility and Effectiveness of HIV Prevention Among Wives of Heavy Drinkers in Bangalore, India	*Aids & Behavior*	Public Health
Cowley I	Asymmetries in Prior Conviction Reasoning: Truth Suppression Effects in Child Protection Contexts	*Psychology, Crime & Law*	Criminology and Penology
Cowley II	Asymmetries in Prior Conviction Reasoning: Truth Suppression Effects in Child Protection Contexts	*Psychology, Crime & Law*	Criminology and Penology
Cox	Behavioral Interventions to Increase HPV Vaccination Acceptability Among Mothers of Young Girls	*Health Psychology*	Clinical Psychology
Cramer I	Blame Attribution as a Moderator of Perceptions of Sexual Orientation −−Based Hate Crimes	*Journal of Interpersonal Violence*	Criminology and Penology
Cramer II	Blame Attribution as a Moderator of Perceptions of Sexual Orientation −−Based Hate Crimes	*Journal of Interpersonal Violence*	Criminology and Penology
Crawford	The Effect of Referral for Brief Intervention for Alcohol Misuse on Repetition of Deliberate Self-Harm: An Exploratory Randomized Controlled Trial	*Psychological Medicine*	Clinical Psychology
Cripe	Intimate Partner Violence During Pregnancy: A Pilot Intervention Program in Lima, Peru	*Journal of Interpersonal Violence*	Criminology and Penology

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Curley	Assets and Educational Outcomes: Child Development Accounts (CDAs) for Orphaned Children in Uganda	*Children and Youth Services Review*	Social Work
de Bruin	Electronic Monitoring-Based Counseling to Enhance Adherence Among HIV-Infected Patients: A Randomized Controlled Trial	*Health Psychology*	Clinical Psychology
de Graaf	Predicting Outcome in Computerized Cognitive Behavioral Therapy for Depression in Primary Care: A Randomized Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
de Koning	Attention Guidance in Learning from a Complex Animation: Seeing is Understanding?	*Learning & Instruction*	Education
de Koning	Learning by Generating vs. Receiving Instructional Explanations: Two Approaches to Enhance Attention Cueing in Animations	*Computers & Education*	Education
Diallo	Efficacy of a Single-Session HIV Prevention Intervention for Black Women: A Group Randomized Controlled Trial	*Aids & Behavior*	Public Health
Dietze	Mental Reinstatement of Context with Child Witnesses: Does It Matter Whether Context is Reinstated 'Out Loud'?	*Psychology, Crime & Law*	Criminology and Penology
Dumas	Effects of Monetary Incentives on Engagement in the PACE Parenting Program	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Durán	An Experimental Study Comparing English-Only and Transitional Bilingual Education on Spanish-Speaking Preschoolers' Early Literacy Development	*Early Childhood Research Quarterly*	Education
Eakin	Maintenance of Physical Activity and Dietary Change Following a Telephone-Delivered Intervention	*Health Psychology*	Clinical Psychology
Eastwood	Measuring Reading Complexity and Listening Comprehension of Canadian Police Cautions	*Criminal Justice and Behavior*	Criminology and Penology

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Ebenezer	The Effects of Common Knowledge Construction Model Sequence of Lessons on Science Achievement and Relational Conceptual Change	*Journal of Research in Science Teaching*	Education
Efendioglu	Programmed Instruction Versus Meaningful Learning Theory in Teaching Basic Structured Query Language (SQL) in Computer Lesson	*Computers & Education*	Education
Eow	Computer Games Development and Appreciative Learning Approach in Enhancing Students' Creative Perception	*Computers & Education*	Education
Evans	Mock Jurors' Perceptions of Identifications Made by Intoxicated Eyewitnesses	*Psychology, Crime & Law*	Criminology and Penology
Evans	SMART Lunch Box Intervention to Improve the Food and Nutrient Content of Children's Packed Lunches: UK Wide Cluster Randomised Controlled Trial	*Journal of Epidemiology and Community Health*	Public Health
Fang	Preventing Substance Use Among Early Asian–American Adolescent Girls: Initial Evaluation of a Web-based, Mother–Daughter Program	*Journal of Adolescent Health*	Public Health
Feldon	Translating Expertise Into Effective Instruction: The Impacts of Cognitive Task Analysis (CTA) on Lab Report Quality and Student Retention in the Biological Sciences	*Journal of Research in Science Teaching*	Education
Fisher I	Effects of a Computerized Professional Development Program on Teacher and Student Outcomes	*Journal of Teacher Education*	Education
Fisher II	Effects of a Computerized Professional Development Program on Teacher and Student Outcomes	*Journal of Teacher Education*	Education
Fledderus	Mental Health Promotion as a New Goal in Public Mental Health Care: A Randomized Controlled Trial of an Intervention Enhancing Psychological Flexibility	*American Journal of Public Health*	Public Health

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Florax	What Contributes to the Split-Attention Effect? The Role of Text Segmentation, Picture Labelling, and Spatial Proximity	*Learning & Instruction*	Education
Foley	Mindfulness-Based Cognitive Therapy for Individuals Whose Lives Have Been Affected by Cancer: A Randomized Controlled Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Free	More Effective Home Heating Reduces School Absences for Children with Asthma	*Journal of Epidemiology and Community Health*	Public Health
Freudenberg	Reducing Drug Use, Human Immunodeficiency Virus Risk, and Recidivism Among Young Men Leaving Jail: Evaluation of the REAL MEN Re-entry Program	*Journal of Adolescent Health*	Public Health
Gagnon	A Randomized Trial to Evaluate the Efficacy of a Computer-Tailored Intervention to Promote Safer Injection Practices Among Drug Users	*Aids & Behavior*	Public Health
Gardner	Who Benefits and How Does It Work? Moderators and Mediators of Outcome in an Effectiveness Trial of a Parenting Intervention	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Geers	Dispositional Optimism, Goals, and Engagement in Health Treatment Programs	*Journal of Behavioral Medicine*	Clinical Psychology
Gelatt	An Interactive Web-Based Program for Stepfamilies: Development and Evaluation of Efficacy	*Family Relations*	Social Work
Geraghty	Attrition from Self-Directed Interventions: Investigating the Relationship between Psychological Predictors, Intervention Content and Dropout from a Body Dissatisfaction Intervention	*Social Science & Medicine*	Public Health
Germain	Adolescents' Perceptions of Cigarette Brand Image: Does Plain Packaging Make a Difference?	*Journal of Adolescent Health*	Public Health

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Gersten	Teacher Study Group: Impact of the Professional Development Model on Reading Instruction and Student Outcomes in First Grade Classrooms	*American Educational Research Journal*	Education
Giron	Efficacy and Effectiveness of Individual Family Intervention on Social and Clinical Functioning and Family Burden in Severe Schizophrenia: A 2-Year Randomized Controlled Study	*Psychological Medicine*	Clinical Psychology
Glanz	A Randomized Trial of Tailored Skin Cancer Prevention Messages for Adults: Project SCAPE	*American Journal of Public Health*	Public Health
Gleeson	Family Outcomes From a Randomized Control Trial of Relapse Prevention Therapy in First-Episode Psychosis	*Journal of Clinical Psychiatry*	Clinical Psychology
Godin	Which Survey Questions Change Behavior? Randomized Controlled Trial of Mere Measurement Interventions	*Health Psychology*	Clinical Psychology
Gonzalez	A Web-Based Learning Tool Improves Student Performance in Statistics: A Randomized Masked Trial	*Computers & Education*	Education
Gordon	Tobacco Cessation via Public Dental Clinics: Results of a Randomized Trial	*American Journal of Public Health*	Public Health
Gottfredson	An Experimental Evaluation of the All Stars Prevention Curriculum in a Community After School Setting	*Prevention Science*	Public Health
Graziano	Police Misconduct, Media Coverage, and Public Perceptions of Racial Profiling: An Experiment	*Justice Quartlery*	Criminology and Penology
Green	Using Random Judge Assignments to Estimate the Effects of Incarceration and Probation on Recidivism Among Drug Offenders	*Criminology*	Criminology and Penology
Guilamo-Ramos	The Linking Lives Health Education Program: A Randomized Clinical Trial of a Parent-Based Tobacco Use Prevention Program for African American and Latino Youths	*American Journal of Public Health*	Public Health

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Gundersen	Diffusion of Treatment Interventions: Exploration of 'Secondary' Treatment Diffusion	*Psychology, Crime & Law*	Criminology and Penology
Gunlicks	The Impact of Perceived Interpersonal Functioning on Treatment for Adolescent Depression: IPT-A Versus Treatment as Usual in School-Based Health Clinics	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Gutwill	Facilitating Family Group Inquiry at Science Museum Exhibits	*Science Education*	Education
Ha	Effects of Attractiveness and Social Status on Dating Desire in Heterosexual Adolescents: An Experimental Study	*Archives of Sexual Behavior*	Clinical Psychology
Haemmerli	Internet-Based Support for Infertile Patients: A Randomized Controlled Study	*Journal of Behavioral Medicine*	Clinical Psychology
Haight	A Mental Health Intervention for Rural, Foster Children from Methamphetamine-Involved Families: Experimental Assessment with Qualitative Elaboration	*Children and Youth Services Review*	Social Work
Haimerl I	Self-Fulfilling Prophecies in Media-Based Learning: Content Relevance Moderates Quality Expectation Effects on Academic Achievement	*Learning & Instruction*	Education
Haimerl II	Self-Fulfilling Prophecies in Media-Based Learning: Content Relevance Moderates Quality Expectation Effects on Academic Achievement	*Learning & Instruction*	Education
Halbert	Effect of Genetic Counseling and Testing for BRCA1 and BRCA2 Mutations in African American Women: A Randomized Trial	*Public Health Genomics*	Public Health
Halford	Promoting a Positive Transition to Parenthood: A Randomized Clinical Trial of Couple Relationship Education	*Prevention Science*	Public Health
Hanoch	Choice, Numeracy, and Physicians-in-Training Performance: The Case of Medicare Part D	*Health Psychology*	Clinical Psychology

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Harakeh	Exposure to Movie Smoking, Antismoking Ads and Smoking Intensity: An Experimental Study with a Factorial Design	*Tobacco Control*	Public Health
Harper	The Effect of Induced Mood on Children's Social Information Processing: Goal Clarification and Response Decision	*Journal of Abnormal Child Psychology*	Clinical Psychology
Hauptman	Enhancement of Spatial Thinking with Virtual Spaces 1.0	*Computers & Education*	Education
Hay	Stability and Change in Risk Seeking: Investigating the Effects of an Intervention Program	*Youth Violence and Juvenile Justice*	Criminology and Penology
Hayes	The Influence of Quality of Life and Depressed Mood on Smoking Cessation Among Medically Ill Smokers	*Journal of Behavioral Medicine*	Clinical Psychology
Heinrichs	The Effects of Incentives on Families' Long-Term Outcome in a Parenting Program	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Henderson I	Effectiveness of Multidimensional Family Therapy With Higher Severity Substance-Abusing Adolescents: Report From Two Randomized Controlled Trials	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Henderson II	Effectiveness of Multidimensional Family Therapy With Higher Severity Substance-Abusing Adolescents: Report From Two Randomized Controlled Trials	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Heyman	Older Latinos' Attitudes toward and Comfort with End-of-Life Planning	*Health & Social Work*	Social Work
Hien	The Impact of Trauma-Focused Group Therapy upon HIV Sexual Risk Behaviors in the NIDA Clinical Trials Network ''Women and Trauma'' Multi-Site Study	*Aids & Behavior*	Public Health
Hirshfeld-Becker	Cognitive Behavioral Therapy for 4- to 7-Year-Old Children With Anxiety Disorders: A Randomized Clinical Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Hsiung I	Identification of Dysfunctional Cooperative Learning Teams Based on Students' Academic Achievement	*Journal of Engineering Education*	Education

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Hsiung II	Identification of Dysfunctional Cooperative Learning Teams Based on Students' Academic Achievement	*Journal of Engineering Education*	Education
Huang	Effects of Individual Development Accounts (IDAs) on Household Wealth and Saving Taste	*Research on Social Work Practice*	Social Work
Hübner	Writing Learning Journals: Instructional Support to Overcome Learning-Strategy Deficits	*Learning & Instruction*	Education
Jacobs	Treating Depression and Oppositional Behavior in Adolescents	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Jagannathan	Experimental Evidence of Welfare Reform Impact on Clinical Anxiety and Depression Levels Among Poor Women	*Social Science & Medicine*	Public Health
Jemmott	Effectiveness of an HIV/STD Risk-Reduction Intervention for Adolescents When Implemented by Community-Based Organizations: A Cluster-Randomized Controlled Trial	*American Journal of Public Health*	Public Health
Jenson	Preventing Childhood Bullying: Findings and Lessons From the Denver Public Schools Trial	*Research on Social Work Practice*	Social Work
Johansson	The Mediating Role of Insight for Long-Term Improvements in Psychodynamic Therapy	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Johnson	Variability in Reading Ability Gains as a Function of Computer-Assisted Instruction Method of Presentation	*Computers & Education*	Education
Jones	Comparison of Teaching and Learning Outcomes Between Video-Linked, Web-Based, and Classroom Tutorials: An Innovative International Study of Profession Education in Physical Therapy	*Computers & Education*	Education
Kartiko	Learning Science in a Virtual Reality Application: The Impacts of Animated-Virtual Actors' Visual Complexity	*Computers & Education*	Education
Kaslow	Suicidal, Abused African American Women's Response to a Culturally Informed Intervention	*Journal of Consulting and Clinical Psychology*	Clinical Psychology

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Katz	The Effects of Drawing on Children's Accounts of Sexual Abuse	*Child Maltreatment*	Social Work
Kebritchia	The Effects of Modern Mathematics Computer Games on Mathematics Achievement and Class Motivation	*Computers & Education*	Education
Kessels	Increased Attention but More Efficient Disengagement: Neuroscientific Evidence for Defensive Processing of Threatening Health Information	*Health Psychology*	Clinical Psychology
Khanna	Computer-Assisted Cognitive Behavioral Therapy for Child Anxiety: Results of a Randomized Clinical Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Khodayarifard	Effects of Individual and Group Cognitive-Behavioral Therapy for Male Prisoners in Iran	*International Journal of Offender Therapy and Comparative Criminology*	Criminology and Penology
Killias	Community Service Versus Electronic Monitoring - What Works Better? Results of a Randomized Trial	*British Journal of Criminology*	Criminology and Penology
Koh	Investigating the Effect of 3D Simulation- Based Learning on the Motivation and Performance of Engineering Students	*Journal of Engineering Education*	Education
Kolko	ODD Dimensions, ADHD, and Callous–Unemotional Traits as Predictors of Treatment Response in Children With Disruptive Behavior Disorders	*Journal of Abnormal Psychology*	Clinical Psychology
Korat	Reading Electronic Books as a Support for Vocabulary, Story Comprehension and Word Reading in Kindergarten and First Grade	*Computers & Education*	Education
Kramarski	Preparing Preservice Teachers for Self-Regulated Learning in the Context of Technological Pedagogical Content Knowledge	*Learning & Instruction*	Education

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Kukkonen	An Evaluation of the Validity of Thermography as a Physiological Measure of Sexual Arousal in a Non-University Adult Sample	*Archives of Sexual Behavior*	Clinical Psychology
Kuo	An Empirical Assessment of the Process of Restorative Justice	*Journal of Criminal Justice*	Criminology and Penology
Labuhn	Enhancing Students' Self-Regulation and Mathematics Performance: The Influence of Feedback and Self-Evaluative Standards	*Metacognition and Learning*	Education
Lamb	Shaping Smoking Cessation in Hard-to-Treat Smokers	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Langberg	Parent-Reported Homework Problems in the MTA Study: Evidence for Sustained Improvement with Behavioral Treatment	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Lanir	The Benefits of More Electronic Screen Space on Students' Retention of Material in Classroom Lectures	*Computers & Education*	Education
Larke	Impact of the MEMA kwa Vijana Adolescent Sexual and Reproductive Health Interventions on Use of Health Services by Young People in Rural Mwanza, Tanzania: Results of a Cluster Randomized Trial	*Journal of Adolescent Health*	Public Health
Lazonder	Offering and Discovering Domain Information in Simulation-Based Inquiry Learning	*Learning & Instruction*	Education
Leal	The Occurrence of Eye Blinks During a Guilty Knowledge Test	*Psychology, Crime & Law*	Criminology and Penology
Leflot	The Role of Teacher Behavior Management in the Development of Disruptive Behaviors: An Intervention Study with the Good Behavior Game	*Journal of Abnormal Child Psychology*	Clinical Psychology

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Leng	Computer Games Development Experience and Appreciative Learning Approach for Creative Process Enhancement	*Computers & Education*	Education
Lester I	Impact of Race on Early Treatment Termination and Outcomes in Posttraumatic Stress Disorder Treatment	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Lester II	Impact of Race on Early Treatment Termination and Outcomes in Posttraumatic Stress Disorder Treatment	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Li	Improving Health and Mental Health for People Living with HIV/ AIDS: 12-month Assessment of a Behavioral Intervention in Thailand	*American Journal of Public Health*	Public Health
Liber	The Relation of Severity and Comorbidity to Treatment Outcome with Cognitive Behavioral Therapy for Childhood Anxiety Disorders	*Journal of Abnormal Child Psychology*	Clinical Psychology
Lim	Randomised Controlled Trial of Paper, Online and SMS Diaries for Collecting Sexual Behaviour Information from Young People	*Journal of Epidemiology and Community Health*	Public Health
Lindhiem	Trajectories of Symptom Reduction and Engagement During Treatment for Childhood Behavior Disorders: Differences Across Settings	*Journal of Abnormal Child Psychology*	Clinical Psychology
Lindsey	Gender Differences in Behavioral Outcomes Among Children at Risk of Neglect: Findings From a Family-Focused Prevention Intervention	*Research on Social Work Practice*	Social Work
Looi	Collaborative Activities Enabled by GroupScribbles (GS): An Exploratory Study of Learning Effectiveness	*Computers & Education*	Education
Low	A Randomized Controlled Trial of Emotionally Expressive Writing for Women With Metastatic Breast Cancer	*Health Psychology*	Clinical Psychology

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MacPherson	Randomized Controlled Trial of Behavioral Activation Smoking Cessation Treatment for Smokers With Elevated Depressive Symptoms	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Mahler	Effects of Upward and Downward Social Comparison Information on the Efficacy of An Appearance-Based Sun Protection Intervention: A Randomized, Controlled Experiment	*Journal of Behavioral Medicine*	Clinical Psychology
Manne	Tailored Versus Generic Interventions for Skin Cancer Risk Reduction for Family Members of Melanoma Patients	*Health Psychology*	Clinical Psychology
Markosyan	A Randomized Controlled Trial of an HIV Prevention Intervention for Street-Based Female Sex Workers in Yerevan, Armenia: Preliminary Evidence of Efficacy	*Aids & Behavior*	Public Health
Martijn	Increasing Body Satisfaction of Body Concerned Women Through Evaluative Conditioning Using Social Stimuli	*Health Psychology*	Clinical Psychology
Martimo	Effectiveness of an Ergonomic Intervention on the Productivity of Workers with Upper-Extremity Disorders: A Randomized Controlled Trial	*Scandinavian Journal of Work Environment & Health*	Public Health
Matsumura	Implementing Literacy Coaching: The Role of School Social Resources	*Educational Evaluation and Policy Analysis*	Education
Maxwell	Results of a Community-Based Randomized Trial to Increase Colorectal Cancer Screening Among Filipino Americans	*American Journal of Public Health*	Public Health
Mazzoni	The Effects of Observation and Gender on Psychogenic Symptoms	*Health Psychology*	Clinical Psychology
Mckay I	A Randomized Trial of Extended Telephone-Based Continuing Care for Alcohol Dependence: Within-Treatment Substance Use Outcomes	*Journal of Consulting and Clinical Psychology*	Clinical Psychology

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Mckay II	Randomized Trial of Continuing Care Enhancements for Cocaine- Dependent Patients Following Initial Engagement	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
McKirnan	The Treatment Advocacy Program: A Randomized Controlled Trial of a Peer-Led Safer Sex Intervention for HIV-Infected Men Who Have Sex With Men	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Mendelson	Feasibility and Preliminary Outcomes of a School-Based Mindfulness Intervention for Urban Youth	*Journal of Abnormal Child Psychology*	Clinical Psychology
Meuret	Respiratory and Cognitive Mediators of Treatment Change in Panic Disorder: Evidence for Intervention Specificity	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Meyer I	Effects of Animation's Speed of Presentation on Perceptual Processing and Learning	*Learning & Instruction*	Education
Meyer II	Effects of Animation's Speed of Presentation on Perceptual Processing and Learning	*Learning & Instruction*	Education
Milby	Effects of Sustained Abstinence Among Treated Substance-Abusing Homeless Persons on Housing and Employment	*American Journal of Public Health*	Public Health
Mills	A Primary Care Cardiovascular Risk Reduction Clinic in Canada was More Effective and No More Expensive than Usual On-Demand Primary Care – A Randomised Controlled Trial	*Health & Social Care in the Community*	Social Work
Montgomery	Mediators of a Brief Hypnosis Intervention to Control Side Effects in Breast Surgery Patients: Response Expectancies and Emotional Distress	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Morland	Telemedicine for Anger Management Therapy in a Rural Population of Combat Veterans With Posttraumatic Stress Disorder: A Randomized Noninferiority Trial	*Journal of Clinical Psychiatry*	Clinical Psychology
Morriss	Randomized Trial of Reattribution on Psychosocial Talk Between Doctors and Patients with Medically Unexplained Symptoms	*Psychological Medicine*	Clinical Psychology

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Moss-Morriss	A Randomized Controlled Trial of a Cognitive Behavioural Therapy-Based Self-Management Intervention for Irritable Bowel Syndrome in Primary Care	*Psychological Medicine*	Clinical Psychology
Mueser	Randomized Trial of Social Rehabilitation and Integrated Health Care for Older People With Severe Mental Illness	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Myers	Interventions Delivered in Clinical Settings are Effective in Reducing Risk of HIV Transmission Among People Living with HIV: Results from the Health Resources and Services Administration (HRSA)'s Special Projects of National Significance Initiative	*Aids & Behavior*	Public Health
Naar-King	A Multisite Randomized Trial of a Motivational Intervention Targeting Multiple Risks in Youth Living With HIV: Initial Effects on Motivation, Self-Efficacy, and Depression	*Journal of Adolescent Health*	Public Health
Neighbors	Efficacy of Web-Based Personalized Normative Feedback: A Two-Year Randomized Controlled Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Nieboer	Preferences for Long-Term Care Services: Willingness to Pay Estimates Derived from a Discrete Choice Experiment	*Social Science & Medicine*	Public Health
Nordentoft	Deinstitutionalization Revisited: A 5-Year Follow-Up of a Randomized Clinical Trial of Hospital-Based Rehabilitation Versus Specialized Assertive Intervention (OPUS) Versus Standard Treatment for Patients with First-Episode Schizophrenia Spectrum Disorders	*Psychological Medicine*	Clinical Psychology
Orbell	The Automatic Component of Habit in Health Behavior: Habit as Cue-Contingent Automaticity	*Health Psychology*	Clinical Psychology
Outlaw	Using Motivational Interviewing in HIV Field Outreach With Young African American Men Who Have Sex With Men: A Randomized Clinical Trial	*American Journal of Public Health*	Public Health

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Oveisia	Primary Prevention of Parent-Child Conflict and Abuse in Iranian Mothers: A Randomized-Controlled Trial	*Child Abuse & Neglect*	Social Work
Pachankis	Expressive Writing for Gay-Related Stress: Psychosocial Benefits and Mechanisms Underlying Improvement	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Parikh	Results of a Pilot Diabetes Prevention Intervention in East Harlem, New York City: Project HEED	*American Journal of Public Health*	Public Health
Patten	Feasibility of a Tobacco Cessation Intervention for Pregnant Alaska Native Women	*Nicotine and Tobacco Research*	Public Health
Pepler	Bridging the Gender Gap: Interventions with Aggressive Girls and Their Parents	*Prevention Science*	Public Health
Petry	Group-Based Randomized Trial of Contingencies for Health and Abstinence in HIV Patients	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Pincus	Cognitive-Behavioral Treatment of Panic Disorder in Adolescence	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Plancher	Age Effect on Components of Episodic Memory and Feature Binding: A Virtual Reality Study	*Neuropsychology*	Clinical Psychology
Prestwich	Can Implementation Intentions and Text Messages Promote Brisk Walking? A Randomized Trial	*Health Psychology*	Clinical Psychology
Price-Jones	Attitudes Towards Sex Offenders Regarding Competency, Liability, Voluntariness of Offence, and Disposal: The Influence of Being Classified as Having a Learning Disability	*Psychology, Crime & Law*	Criminology and Penology
Rabiner	A Randomized Trial of Two Promising Computer-Based Interventions for Students with Attention Difficulties	*Journal of Abnormal Child Psychology*	Clinical Psychology
Rebellon	Anticipated Shaming and Criminal Offending	*Journal of Criminal Justice*	Criminology and Penology

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Reblin	Provider and Recipient Factors that May Moderate the Effectiveness of Received Support: Examining the Effects of Relationship Quality and Expectations for Support on Behavioral and Cardiovascular Reactions	*Journal of Behavioral Medicine*	Clinical Psychology
Reisslein	Pre-college Electrical Engineering Instruction: The Impact of Abstract vs. Contextualized Representation and Practice on Learning	*Journal of Engineering Education*	Education
Reitzel	Preventing Postpartum Smoking Relapse Among Diverse Low-Income Women: A Randomized Clinical Trial	*Nicotine and Tobacco Research*	Public Health
Rhodes	Pilot Study of a Family Physical Activity Planning Intervention Among Parents and Their Children	*Journal of Behavioral Medicine*	Clinical Psychology
Ringwalt	The Effects of Project ALERT One Year Past Curriculum Completion	*Prevention Science*	Public Health
Roberto	Evaluating the Impact of Menu Labeling on Food Choices and Intake	*American Journal of Public Health*	Public Health
Rochelle I	Integration of Technology, Curriculum, and Professional Development for Advancing Middle School Mathematics: Three Large-Scale Studies	*American Educational Research Journal*	Education
Rochelle II	Integration of Technology, Curriculum, and Professional Development for Advancing Middle School Mathematics: Three Large-Scale Studies	*American Educational Research Journal*	Education
Rodriguez	Effects of Healthy Families New York on the Promotion of Maternal Parenting Competencies and the Prevention of Harsh Parenting	*Child Abuse & Neglect*	Social Work
Rohrbach	The Project Towards No Drug Abuse (TND) Dissemination Trial: Implementation Fidelity and Immediate Outcomes	*Prevention Science*	Public Health

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Romero-Sánchez	Exposure to Sexist Humor and Rape Proclivity: The Moderator Effect of Aversiveness Ratings	*Journal of Interpersonal Violence*	Criminology and Penology
Roschelle	Integration of Technology, Curriculum, and Professional Development for Advancing Middle School Mathematics: Three Large-Scale Studies	*Computers & Education*	Education
Rosenberg-Kima I	The Influence of Computer-based Model's Race and Gender on Female Students' Attitudes and Beliefs Towards Engineering	*Journal of Engineering Education*	Education
Rosenberg-Kima II	The Influence of Computer-based Model's Race and Gender on Female Students' Attitudes and Beliefs Towards Engineering	*Journal of Engineering Education*	Education
Rosser	Effects of a Behavioral Intervention to Reduce Serodiscordant Unsafe Sex Among HIV Positive Men Who Have Sex with Men: The Positive Connections Randomized Controlled Trial Study	*Journal of Behavioral Medicine*	Clinical Psychology
Rotheram-Borus	Reducing HIV Risks Among Active Injection Drug and Crack Users: The Safety Counts Program	*Aids & Behavior*	Public Health
Ruchter	Comparing the Effects of Mobile Computers and Traditional Approaches in Environmental Education	*Computers & Education*	Education
Sabin	Using Electronic Drug Monitor Feedback to Improve Adherence to Antiretroviral Therapy Among HIV-Positive Patients in China	*Aids & Behavior*	Public Health
Santagata	Studying the Impact of the Lesson Analysis Framework on Preservice Teachers' Abilities to Reflect on Videos of Classroom Teaching	*Journal of Teacher Education*	Education

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Sawyer	School-Based Prevention of Depression: A 2-Year Follow-up of a Randomized Controlled Trial of the beyondblue Schools Research Initiative	*Journal of Adolescent Health*	Public Health
Schinke	Longitudinal Outcomes of an Alcohol Abuse Prevention Program for Urban Adolescents	*Journal of Adolescent Health*	Public Health
Schmidt-Weigand	A Closer Look at Split Visual Attention in System- and Self-Paced Instruction in Multimedia Learning	*Learning & Instruction*	Education
Schwarzer	Stage-Matched Minimal Interventions to Enhance Physical Activity in Chinese Adolescents	*Journal of Adolescent Health*	Public Health
Schwinn	Preventing Drug Abuse Among Adolescent Girls: Outcome Data from an Internet-Based Intervention	*Prevention Science*	Public Health
Shanley	Coaching Parents to Change: The Impact of In Vivo Feedback on Parents' Acquisition of Skills	*Journal of Clinical Child & Adolescent Psychology*	Clinical Psychology
Shaw	A Study of Learning Performance of e-Learning Materials Design with Knowledge Maps	*Computers & Education*	Education
Sheridan I	Perceptions of Harm: Verbal Versus Physical Abuse in Stalking Scenarios	*Criminal Justice and Behavior*	Criminology and Penology
Sheridan II	Perceptions of Harm: Verbal Versus Physical Abuse in Stalking Scenarios	*Criminal Justice and Behavior*	Criminology and Penology
Sheridan III	Perceptions of Harm: Verbal Versus Physical Abuse in Stalking Scenarios	*Criminal Justice and Behavior*	Criminology and Penology
Sherman	Acceptability of a Microenterprise Intervention Among Female Sex Workers in Chennai, India	*Aids & Behavior*	Public Health
Siegel	A Worksite Obesity Intervention: Results From a Group-Randomized Trial	*American Journal of Public Health*	Public Health

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Silva	Using Self-Determination Theory to Promote Physical Activity and Weight Control: A Randomized Controlled Trial in Women	*Journal of Behavioral Medicine*	Clinical Psychology
Sleath	Male Rape Victim and Perpetrator Blaming	*Journal of Interpersonal Violence*	Criminology and Penology
Slof	Fostering Complex Learning-Task Performance Through Scripting Student Use of Computer Supported Representational Tools	*Computers & Education*	Education
Smet	Cross-Age Peer Tutors in Asynchronous Discussion Groups: Exploring the Impact of Three Types of Tutor Training on Patterns in Tutor Support and on Tutor Characteristics	*Computers & Education*	Education
Smith	Students' Comprehension of Science Textbooks Using a Question-Based Reading Strategy	*Journal of Research in Science Teaching*	Education
Ssewamala	Effect of Economic Assets on Sexual Risk-Taking Intentions Among Orphaned Adolescents in Uganda	*American Journal of Public Health*	Public Health
St-Jacques	Is Virtual Reality Effective to Motivate and Raise Interest in Phobic Children Toward Therapy? A Clinical Trial Study of In Vivo With In Virtuo Versus In Vivo Only Treatment Exposure	*Journal of Clinical Psychiatry*	Clinical Psychology
Stadler	Intervention Effects of Information and Self-Regulation on Eating Fruits and Vegetables Over Two Years	*Health Psychology*	Clinical Psychology
Stapleton	A Comparison of the Efficacy of an Appearance-Focused Skin Cancer Intervention within Indoor Tanner Subgroups Identified by Latent Profile Analysis	*Journal of Behavioral Medicine*	Clinical Psychology
Steif	Improving Problem Solving Performance by Inducing Talk about Salient Problem Features	*Journal of Engineering Education*	Education

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Steinberg	Manipulating Public Opinion About Trying Juveniles as Adults: An Experimental Study	*Crime & Delinquency*	Criminology and Penology
Stice I	Efficacy Trial of a Brief Cognitive–Behavioral Depression Prevention Program for High-Risk Adolescents: Effects at 1- and 2-Year Follow-Up	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Stice II	Testing Mediators of Intervention Effects in Randomized Controlled Trials: An Evaluation of Three Depression Prevention Programs	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Stone	Behavioral Characteristics Among Obese/Overweight Inner-City African American Children: A Secondary Analysis of Participants in a Community-Based Type 2 Diabetes Risk Reduction Program	*Children and Youth Services Review*	Social Work
Striegel-Moore	Cognitive Behavioral Guided Self-Help for the Treatment of Recurrent Binge Eating	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Strijbos	Peer Feedback Content and Sender's Competence Level in Academic Writing Revision Tasks: Are They Critical for Feedback Perceptions and Efficiency?	*Learning & Instruction*	Education
Strømsø	Reading Multiple Texts About Climate Change: The Relationship Between Memory for Sources and Text Comprehension	*Learning & Instruction*	Education
Sysko	Heterogeneity Moderates Treatment Response Among Patients With Binge Eating Disorder	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Tam	When Planning Is Not Enough: The Self-Regulatory Effect of Implementation Intentions on Changing Snacking Habits	*Health Psychology*	Clinical Psychology
Taylor	Evaluation of a Cervical Cancer Control Intervention Using Lay Health Workers for Vietnamese American Women	*American Journal of Public Health*	Public Health

First Author	Article Title	Journal	Discipline
Testa	Preventing College Women's Sexual Victimization Through Parent Based Intervention: A Randomized Controlled Trial	*Prevention Science*	Public Health
Testad	The Effect of Staff Training on Agitation and Use of Restraint in Nursing Home Residents With Dementia: A Single-Blind, Randomized Controlled Trial	*Journal of Clinical Psychiatry*	Clinical Psychology
Teti	A Mixed Methods Evaluation of the Effect of the Protect and Respect Intervention on the Condom Use and Disclosure Practices of Women Living with HIV/AIDS	*Aids & Behavior*	Public Health
Thompson	Patterns of Use of an Agent-Based Model and a System Dynamics Model: The Application of Patterns of Use and the Impacts on Learning Outcomes	*Computers & Education*	Education
Thompson	A group-randomized tobacco trial among 30 Pacific Northwest colleges: Results from the Campus Health Action on Tobacco study	*Nicotine and Tobacco Research*	Public Health
Thomsen	Brief Smoking Cessation Intervention in Relation to Breast Cancer Surgery: A Randomized Controlled Trial	*Nicotine and Tobacco Research*	Public Health
Timmer	Efficacy of Adjunct In-Home Coaching to Improve Outcomes in Parent−−Child Interaction Therapy	*Research on Social Work Practice*	Social Work
Tortolero	It's Your Game: Keep It Real: Delaying Sexual Behavior with an Effective Middle School Program	*Journal of Adolescent Health*	Public Health
Trundle	The Use of a Computer Simulation to Promote Conceptual Change: A Quasi-Experimental Study	*Computers & Education*	Education
Tummers	Effectiveness of Stepped Care for Chronic Fatigue Syndrome: A Randomized Noninferiority Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Twohig	A Randomized Clinical Trial of Acceptance and Commitment Therapy Versus Progressive Relaxation Training for Obsessive-Compulsive Disorder	*Journal of Consulting and Clinical Psychology*	Clinical Psychology

First Author	Article Title	Journal	Discipline
van der Straten	Vaginal Practices and Associations with Barrier Methods and Gel Use Among Sub-Saharan African Women Enrolled in an HIV Prevention Trial	*Aids & Behavior*	Public Health
van Gennip	Peer Assessment as a Collaborative Learning Activity: The Role of Interpersonal Variables and Conceptions	*Learning & Instruction*	Education
van Oppen	Does the Therapy Manual or the Therapist Matter Most in Treatment of Obsessive-Compulsive Disorder? A Randomized Controlled Trial of Exposure With Response or Ritual Prevention in 118 Patients	*Journal of Clinical Psychiatry*	Clinical Psychology
Van Schijndel I	The Exploratory Behavior Scale: Assessing Young Visitors' Hands-On Behavior in Science Museums	*Science Education*	Education
Van Schijndel II	The Exploratory Behavior Scale: Assessing Young Visitors' Hands-On Behavior in Science Museums	*Science Education*	Education
Varghese	Attitudes Toward Hiring Offenders: The Roles of Criminal History, Job Qualifications, and Race	*International Journal of Offender Therapy and Comparative Criminology*	Criminology and Penology
Veletsianos	Contextually Relevant Pedagogical Agents: Visual Appearance, Stereotypes, and First Impressions and Their Impact on Learning	*Computers & Education*	Education
Villarruel	Testing the Efficacy of a Computer-Based Parent-Adolescent Sexual Communication Intervention for Latino Parents	*Family Relations*	Social Work
Vinter	Effects of Different Types of Learning on Handwriting Movements in Young Children	*Learning & Instruction*	Education
Vrij	'Look into My Eyes': Can an Instruction to Maintain Eye Contact Facilitate Lie Detection?	*Psychology, Crime & Law*	Criminology and Penology

First Author	Article Title	Journal	Discipline
Wadsworth	Preliminary Efficacy of an Intervention to Reduce Psychosocial Stress and Improve Coping in Low-Income Families	*American Journal of Community Psychology*	Social Work
Walsh	Smokeless Tobacco Cessation Cluster Randomized Trial with Rural High School Males: Intervention Interaction with Baseline Smoking	*Nicotine and Tobacco Research*	Public Health
Wan	Inducing Attitude Change Toward Online Gaming Among Adolescent Players Based on Dissonance Theory: The Role of Threats and Justification of Effort	*Computers & Education*	Education
Wang	Web-Based Dynamic Assessment: Taking Assessment as Teaching and Learning Strategy for Improving Students' e-Learning Effectiveness	*Computers & Education*	Education
Warner	Camera Perspective and Trivial Details Interact to Influence Jurors' Evaluations of a Retracted Confession	*Psychology, Crime & Law*	Criminology and Penology
Watson	Do Dynamic Work Instructions Provide an Advantage Over Static Instructions in a Small Scale Assembly Task?	*Learning & Instruction*	Education
Webb	Cognitive–Behavioral Therapy to Promote Smoking Cessation Among African American Smokers: A Randomized Clinical Trial	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Wever	Structuring Asynchronous Discussion Groups: Comparing Scripting by Assigning Roles with Regulation by Cross-Age Peer Tutors	*Learning & Instruction*	Education
Whited	The Influence of Forgiveness and Apology on Cardiovascular Reactivity and Recovery in Response to Mental Stress	*Journal of Behavioral Medicine*	Clinical Psychology

First Author	Article Title	Journal	Discipline
Wiborg I	How Does Cognitive Behaviour Therapy Reduce Fatigue in Patients with Chronic Fatigue Syndrome? The Role of Physical Activity	*Psychological Medicine*	Clinical Psychology
Wiborg II	How Does Cognitive Behaviour Therapy Reduce Fatigue in Patients with Chronic Fatigue Syndrome? The Role of Physical Activity	*Psychological Medicine*	Clinical Psychology
Wiborg III	How Does Cognitive Behaviour Therapy Reduce Fatigue in Patients with Chronic Fatigue Syndrome? The Role of Physical Activity	*Psychological Medicine*	Clinical Psychology
Wieling	The Impact of Online Video Lecture Recordings and Automated Feedback on Student Performance	*Computers & Education*	Education
Williamson I	Early Behavioral Adherence Predicts Short and Long-Term Weight Loss in the POUNDS LOST Study	*Journal of Behavioral Medicine*	Clinical Psychology
Williamson II	Adherence is a Multi-Dimensional Construct in the POUNDS LOST Trial	*Journal of Behavioral Medicine*	Clinical Psychology
Wilson	The Relative Effects and Equity of Inquiry-Based and Commonplace Science Teaching on Students' Knowledge, Reasoning, and Argumentation	*Journal of Research in Science Teaching*	Education
Wing I	Improving Weight Loss Outcomes of Community Interventions by Incorporating Behavioral Strategies	*American Journal of Public Health*	Public Health
Wing II	Improving Weight Loss Outcomes of Community Interventions by Incorporating Behavioral Strategies	*American Journal of Public Health*	Public Health
Witkiewitz	Depression, Craving, and Substance Use Following a Randomized Trial of Mindfulness-Based Relapse Prevention	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Wolitski	"Randomized Trial of the Effects of Housing Assistance on the Health and Risk Behaviors of Homelessand Unstably Housed People Living with HIV"	*Aids & Behavior*	Public Health

First Author	Article Title	Journal	Discipline
Wood	Brief Motivational and Parent Interventions for College Students: A Randomized Factorial Study	*Journal of Consulting and Clinical Psychology*	Clinical Psychology
Woodin	A Brief Motivational Intervention for Physically Aggressive Dating Couples	*Prevention Science*	Public Health
Wrzesien	Learning in Serious Virtual Worlds: Evaluation of Learning Effectiveness and Appeal to Students in the E-Junior Project	*Computers & Education*	Education
Wyman	Intervention to Strengthen Emotional Self-Regulation in Children with Emerging Mental Health Problems: Proximal Impact on School Behavior	*Journal of Abnormal Child Psychology*	Clinical Psychology
Wyman	An Outcome Evaluation of the Sources of Strength Suicide Prevention Program Delivered by Adolescent Peer Leaders in High Schools	*American Journal of Public Health*	Public Health
Yacoubian	The Effect of Reflective Discussions Following Inquiry-Based Laboratory Activities on Students' Views of Nature of Science	*Journal of Research in Science Teaching*	Education
Yeh I	On-line Synchronous Scientific Argumentation Learning: Nurturing Students' Argumentation Ability and Conceptual Change in Science Context	*Computers & Education*	Education
Yeh II	Optimal Self-Explanation Prompt Design in Dynamic Multi-Representational Learning Environments	*Computers & Education*	Education
Yeh III	The Influence of the Instruction of Visual Design Principles on Improving Pre-service Teachers' Visual Literacy	*Computers & Education*	Education
Yiu	Effectiveness of a Knowledge-Contact Program in Improving Nursing Students' Attitudes and Emotional Competence in Serving People Living with HIV/AIDS	*Social Science & Medicine*	Public Health
Zajicek-Farber	Building Practice Evidence for Parent Mentoring Home Visiting in Early Childhood	*Research on Social Work Practice*	Social Work

First Author	Article Title	Journal	Discipline
Zhai	Dosage Effects on School Readiness: Evidence from a Randomized Classroom-Based Intervention	*Social Service Review*	Social Work
Zydney	The Effect of Multiple Scaffolding Tools on Students' Understanding, Consideration of Different Perspectives, and Misconceptions of a Complex Problem	*Computers & Education*	Education

Appendix H. Frequency of Compliance with Reporting Standards

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Title/Abstract	1a. Identification as randomised trial in title	41.4%	6.5%	1.1%	44.3%	15.0%	25.2%
	1b. Identification as randomised trial in abstract	81.8%	22.6%	31.5%	94.3%	75.0%	63.8%
	1c. Participants	87.9%	32.3%	65.2%	92.9%	95.0%	77.3%
	1d. Setting	22.2%	0.0%	30.3%	64.3%	40.0%	33.0%
	1e. Intervention group(s)	86.9%	48.4%	76.4%	95.7%	90.0%	82.2%
	1f. Control	77.8%	35.5%	60.7%	71.4%	55.0%	65.7%
	1g. Care provider	16.2%	0.0%	6.7%	35.7%	10.0%	15.9%
	1h. Objective	98.0%	90.3%	97.8%	95.7%	95.0%	96.4%
	1i. Primary outcome	27.3%	3.2%	6.7%	17.1%	0.0%	14.9%
	1j. Blinding participants	0.0%	0.0%	1.1%	0.0%	0.0%	0.3%
	1k. Blinding providers	0.0%	0.0%	1.1%	0.0%	0.0%	0.3%
	1l. Blinding outcome assessors	5.1%	0.0%	1.1%	0.0%	0.0%	1.9%
	1m. Numbers randomised	11.1%	3.2%	4.5%	17.1%	20.0%	10.4%
	1n. Numbers analysed	3.0%	3.2%	0.0%	1.4%	0.0%	1.6%
	1o. Result for primary outcome	6.1%	0.0%	1.1%	4.3%	0.0%	3.2%
	1p. Conclusion	88.9%	41.9%	68.5%	94.3%	60.0%	77.7%
Introduction	2a. Background: condition	84.8%	90.3%	87.6%	90.0%	80.0%	87.1%
	2b. Background: intervention	87.9%	96.8%	96.6%	87.1%	95.0%	91.6%
	2c. Background: theory of change	72.7%	93.5%	93.3%	72.9%	100.0%	82.5%
	2d. Rationale	96.0%	96.8%	91.0%	61.4%	95.0%	86.7%
	2e. Objectives	100.0%	100.0%	98.9%	92.9%	100.0%	98.1%
	2f. Hypotheses	84.8%	74.2%	83.1%	48.6%	60.0%	73.5%

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Methods	3a. Trial Design	98.0%	100.0%	100.0%	98.6%	100.0%	99.0%
	3b. Allocation ratio	17.2%	9.7%	3.4%	7.1%	20.0%	10.4%
	3c. Protocol deviations	6.1%	9.7%	6.7%	4.3%	25.0%	7.4%
	4a. Eligibility criteria	71.7%	50.0%	50.0%	77.1%	65.0%	64.1%
	4b. Concurrent secular events	7.1%	25.8%	2.2%	10.0%	30.0%	9.7%
	4c. Setting type	77.8%	77.4%	85.4%	78.6%	85.0%	80.6%
	4d. Setting number	65.7%	54.8%	66.3%	64.3%	85.0%	65.7%
	4e. Location	74.7%	87.1%	83.1%	84.3%	80.0%	80.9%
	4f. Timing	37.4%	19.4%	15.7%	64.3%	35.0%	35.3%
	4g. Patient preference	20.2%	6.5%	16.9%	2.9%	25.0%	14.2%
	4h. Provider preference	2.0%	0.0%	3.4%	0.0%	5.0%	1.9%
	5a. Service environment characteristics	23.2%	45.2%	24.7%	35.7%	40.0%	29.8%
	5b. Delivering organisation characteristics	16.2%	16.1%	36.0%	32.9%	35.0%	26.9%
	5c. Design: intervention treatment	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
	5d. Design: control treatment	94.9%	100.0%	98.9%	91.4%	75.0%	94.5%
	5e. Design: proscribed intervention components	25.3%	9.7%	15.7%	7.1%	20.0%	16.5%
	5f. Design: proscribed control components	25.3%	12.9%	20.2%	8.6%	5.0%	17.5%
	5g. Design: intervention materials	67.7%	71.0%	92.1%	60.0%	50.0%	72.2%
	5h. Design: control materials	47.5%	64.5%	77.5%	42.9%	35.0%	56.0%
	5i. Design: intervention format	85.9%	67.7%	98.9%	85.7%	85.0%	87.7%
	5j. Design: control format	72.7%	64.5%	93.3%	52.9%	50.0%	71.8%
	5k. Design: intervention duration	89.9%	96.8%	92.1%	71.4%	100.0%	87.7%
	5l. Design: control duration	80.8%	96.8%	91.0%	44.3%	65.0%	76.1%

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Methods cont.	5m. Design: intervention frequency	86.9%	93.5%	88.8%	81.4%	95.0%	87.4%
	5n. Design: control frequency	72.7%	96.8%	77.5%	44.3%	45.0%	68.3%
	5o. Design: intervention intensity	61.6%	41.9%	75.3%	52.9%	75.0%	62.5%
	5p. Design: control intensity	46.5%	38.7%	67.4%	22.9%	40.0%	46.0%
	5q. Design: intervention staffing	63.6%	25.8%	43.8%	67.1%	80.0%	56.0%
	5r. Design: control staffing	43.4%	22.6%	41.6%	34.3%	30.0%	37.9%
	5s. Delivery: intervention treatment	56.6%	61.3%	41.6%	34.3%	35.0%	46.3%
	5t. Delivery: control treatment	45.5%	67.7%	38.2%	18.6%	10.0%	37.2%
	5u. Delivery: programme differentiation	37.4%	54.8%	43.8%	38.6%	30.0%	40.8%
	5v. Delivery: proscribed intervention components	12.1%	3.2%	9.0%	1.4%	5.0%	7.4%
	5w. Delivery: proscribed control components	14.1%	6.5%	10.1%	1.4%	5.0%	8.7%
	5x. Delivery: non-specific intervention components	15.2%	3.2%	3.4%	4.3%	30.0%	9.1%
	5y. Delivery: non-specific control components	9.1%	0.0%	2.2%	2.9%	5.0%	4.5%
	5z. Delivery: intervention materials	55.6%	67.7%	91.0%	47.1%	40.0%	64.1%
	5aa. Delivery: control materials	40.4%	64.5%	76.4%	35.7%	25.0%	51.1%
	5bb. Delivery: intervention format	60.6%	41.9%	75.3%	54.3%	65.0%	61.8%
	5cc. Delivery: control format	48.5%	35.5%	73.0%	32.9%	30.0%	49.5%
	5dd. Delivery: intervention duration	71.7%	87.1%	88.8%	54.3%	70.0%	74.1%
	5ee. Delivery: control duration	62.6%	80.6%	88.8%	38.6%	40.0%	65.0%
	5ff. Delivery: intervention frequency	73.7%	87.1%	82.0%	62.9%	50.0%	73.5%
	5gg. Delivery: control frequency	56.6%	80.6%	78.7%	42.9%	25.0%	60.2%

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Methods cont.	5hh. Delivery: intervention intensity	38.4%	32.3%	61.8%	34.3%	25.0%	42.7%
	5ii. Delivery: control intensity	26.3%	22.6%	58.4%	18.6%	10.0%	32.4%
	5jj. Delivery: tailoring of intervention	34.3%	9.7%	10.1%	30.0%	50.0%	24.9%
	5kk. Delivery: tailoring of control	17.2%	3.2%	5.6%	10.0%	15.0%	10.7%
	5ll. Delivery: intervention staffing	44.4%	16.1%	36.0%	40.0%	10.0%	35.9%
	5mm. Delivery: control staffing	26.3%	12.9%	34.8%	21.4%	5.0%	24.9%
	5nn. Delivery: intervention provider training	27.3%	9.7%	22.5%	40.0%	30.0%	27.2%
	5oo. Delivery: control provider training	19.2%	3.2%	18.0%	8.6%	10.0%	14.2%
	5pp. Delivery: intervention supervision	35.4%	6.5%	15.7%	10.0%	45.0%	21.7%
	5qq. Delivery: control supervision	22.2%	0.0%	12.4%	4.3%	15.0%	12.6%
	5rr. Delivery: provider adherence measurement	43.4%	9.7%	18.0%	37.1%	45.0%	31.4%
	5ss. Delivery: participant compliance measurement	34.3%	12.9%	19.1%	24.3%	30.0%	25.2%
	5tt. Uptake: intervention treatment	42.4%	16.1%	29.2%	44.3%	30.0%	35.6%
	5uu. Uptake: control treatment	34.3%	19.4%	27.0%	22.9%	15.0%	26.9%
	5vv. Uptake: programme differentiation	22.2%	0.0%	10.1%	0.0%	5.0%	10.4%
	5ww. Uptake: contamination of intervention	5.1%	0.0%	0.0%	1.4%	5.0%	2.3%
	5xx. Uptake: contamination of control	7.1%	3.2%	0.0%	4.3%	0.0%	3.6%
	5yy. Uptake: proscribed intervention components	3.0%	0.0%	0.0%	0.0%	0.0%	1.0%

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Methods cont.	5zz. Uptake: proscribed control components	3.0%	0.0%	0.0%	0.0%	0.0%	1.0%
	5aaa. Uptake: intervention materials	36.4%	41.9%	67.4%	21.4%	15.0%	41.1%
	5bbb. Uptake: control materials	26.3%	41.9%	58.4%	10.0%	5.0%	32.0%
	5ccc. Uptake: intervention frequency	56.6%	38.7%	43.8%	38.6%	40.0%	46.0%
	5ddd. Uptake: control frequency	39.4%	35.5%	40.4%	24.3%	10.0%	34.0%
	5eee. Uptake: intervention intensity	24.2%	19.4%	30.3%	15.7%	30.0%	23.9%
	5fff. Uptake: control intensity	16.2%	12.9%	29.2%	7.1%	5.0%	16.8%
	5ggg. Uptake: enactment	27.3%	3.2%	14.6%	14.3%	25.0%	18.1%
	6a. Baseline data collection	80.8%	61.3%	55.1%	80.0%	60.0%	69.9%
	6b. Baseline data measures	80.8%	38.7%	65.2%	62.9%	60.0%	66.7%
	6c. Primary outcome data collection	49.5%	25.8%	32.6%	28.6%	15.0%	35.3%
	6d. Primary outcome measures	55.6%	29.0%	33.7%	35.7%	20.0%	39.8%
	6e. Secondary outcome data collection	83.8%	93.5%	83.1%	82.9%	90.0%	84.8%
	6f. Secondary outcome measures	94.9%	87.1%	86.5%	87.1%	95.0%	90.0%
	6g. Period of follow-up	98.0%	100.0%	94.4%	94.3%	100.0%	96.4%
	6h. Methods to enhance quality of measurements	66.7%	51.6%	62.9%	48.6%	55.0%	59.2%
	6i. Changes to data collection protocol	13.1%	16.1%	5.6%	17.1%	5.0%	11.7%
	7a. Sample size calculation	33.3%	0.0%	2.2%	37.1%	15.0%	20.7%
	7b. Interim analyses and stopping rules	2.0%	0.0%	0.0%	0.0%	5.0%	1.0%
	8a. Random Sequence Generation	33.3%	16.1%	7.9%	34.3%	30.0%	24.3%
	8b. Randomisation restrictions	44.4%	16.1%	34.8%	54.3%	55.0%	41.7%

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Methods cont.	8c. Allocation of providers	20.2%	3.2%	28.1%	8.6%	5.0%	17.2%
	9. Allocation concealment	24.2%	12.9%	1.1%	8.6%	25.0%	12.9%
	10a. Sequencer Generator	22.2%	9.7%	1.1%	18.6%	25.0%	14.2%
	10b. Who enrolled participants	29.3%	19.4%	4.5%	17.1%	30.0%	18.4%
	10c. Who assigned participants	25.3%	19.4%	4.5%	18.6%	30.0%	17.5%
	11a. Provider blinding	6.1%	0.0%	5.6%	11.4%	20.0%	7.4%
	11b. Participant blinding	12.1%	3.2%	6.7%	7.1%	10.0%	8.4%
	11c. Assessor blinding	42.4%	9.7%	21.3%	25.7%	25.0%	28.2%
	12a. Primary outcome analytic plan	48.5%	25.8%	18.0%	31.4%	20.0%	31.7%
	12b. Secondary outcome analytic plan	68.7%	64.5%	44.9%	84.3%	85.0%	66.0%
	12c. Sub-group and adjusted analyses	56.6%	32.3%	24.7%	67.1%	60.0%	47.6%
Results	13a. Participant flow	55.6%	3.2%	3.4%	50.0%	15.0%	31.4%
	13b. Number approached	56.6%	16.1%	9.0%	58.6%	40.0%	38.2%
	13c. Number eligible	57.6%	16.1%	7.9%	57.1%	45.0%	38.2%
	13d. Number randomised	73.7%	45.2%	75.3%	91.4%	75.0%	75.4%
	13e. Treatment allocation	48.5%	9.7%	16.9%	35.7%	40.0%	32.0%
	13f. Attrition	54.5%	9.7%	14.6%	34.3%	35.0%	32.7%
	13g. Discontinued Intervention	42.4%	3.2%	7.9%	21.4%	10.0%	21.7%
	13h. Number in primary analysis	54.5%	12.9%	28.1%	28.6%	40.0%	35.9%
	14a. Period of recruitment	36.4%	16.1%	2.2%	42.9%	45.0%	26.5%
	14b. Recruitment process	58.6%	61.3%	36.0%	76.4%	77.5%	57.6%
	14.c Incentives	46.5%	41.9%	33.7%	71.4%	50.0%	48.2%
	14d. Reasons for stopping	3.0%	0.0%	4.5%	1.4%	5.0%	2.9%
	15. Baseline data	64.6%	16.1%	29.2%	64.3%	65.0%	49.5%
	16a. Number analysed	68.7%	22.6%	64.0%	64.3%	70.0%	61.8%

Heading	Item	Clinical Psychology	Criminology	Education	Public Health	Social Work	Total Sample
Methods cont.	16b. Intention-to-treat	48.5%	3.2%	7.9%	31.4%	45.0%	28.2%
	17a. Primary outcome results	35.4%	16.1%	23.6%	34.3%	20.0%	28.8%
	17b. Secondary outcome results	45.5%	22.6%	49.4%	67.1%	55.0%	49.8%
	18. Sub-group or adjusted analysis results	61.6%	38.7%	46.1%	37.1%	55.0%	48.9%
	19. Adverse events	20.2%	3.2%	0.0%	12.9%	10.0%	10.4%
Discussion	20. Limitations	90.9%	67.7%	67.4%	94.3%	95.0%	82.8%
	21. Generalisability	77.8%	71.0%	51.7%	74.3%	70.0%	68.3%
	22a. Overall evidence	90.9%	87.1%	80.9%	77.1%	70.0%	83.2%
	22b. Results compared to hypotheses	78.8%	67.7%	64.0%	21.4%	65.0%	59.5%
	22c. Reference to systematic review	74.7%	51.6%	46.1%	37.1%	45.0%	53.7%
	22d. Reference to other studies	55.6%	16.1%	13.5%	41.4%	65.0%	36.9%
Study Details	23. Trial registration	10.1%	0.0%	0.0%	11.4%	5.0%	6.1%
	24a. Protocol	14.1%	3.2%	3.4%	4.3%	10.0%	7.4%
	24b. Access to treatment manual	47.5%	32.3%	32.6%	21.4%	45.0%	35.6%
	25a. Conflicts of interest	83.8%	32.3%	49.4%	94.3%	80.0%	70.9%
	25b. Ethical considerations	80.8%	35.5%	21.3%	82.9%	65.0%	58.6%
	25c. Intervention development	69.7%	74.2%	55.1%	54.3%	85.0%	63.4%

Number of RCTs in each discipline: RCTs per discipline: Clinical Psychology—99, Criminology—31, Education—89, Public Health—70, Social Work—20
Number of standards in total score: 147

Appendix I.

CONSORT-SPI Delphi Survey: Round 1

Informed Consent

INSTRUCTIONS.

Delphi Survey for CONSORT-SPI: A CONSORT Extension for Social and Psychological Interventions

The purpose of this survey is to identify a list of items for possible inclusion in CONSORT-SPI: a new reporting guideline for manuscripts of randomised controlled trials (RCTs) of social and psychological interventions.

You will be provided with a list of proposed items for the guideline. These items are arranged under conventional headings of journal articles: title, introduction, methods, results, discussion, and other information.

Please rate the importance of including each proposed item in CONSORT-SPI on a scale of "1" (not at all important) to "10" (very important). Items with middle or inconsistent rankings will be discussed in later Delphi rounds. There is an optional comment box below each item to clarify your view if desired. We ask that you rate the importance of the *concepts* underlying each item rather than an item's specific wording: the phrasing of included items will be decided at a later stage of the project.

You will also have an opportunity *at the end of the survey* to clarify remaining views and suggest for future consideration any items not proposed in this round. All responses will be kept anonymous and confidential.

This first round questionnaire has approximately 70 items, and should take about 30-40 minutes to complete. We expect future rounds to take less time as consensus is reached for some items. You may use your web-link to access the survey at your leisure over multiple sittings, as responses are automatically saved when entered.

Your web-link to this survey is unique to you: please do not share it. **If you have participant suggestions for the Delphi process, email CONSORT.study@spi.ox.ac.uk with with their name(s), affiliation(s), and email address(es).**

THE FIRST ROUND OF THE QUESIONNAIRE SHOULD BE COMPLETED BY 7 OCTOBER 2013. If you have any questions, please email Sean Grant at CONSORT.study@spi.ox.ac.uk

INFORMED CONSENT.

The full instructions and informed consent form can be found by clicking here.

Click the button below to consent to participate in this study.

○

Title

TITLE. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

1. **Identify as randomised/randomized in the title**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.
NB: For all "Comment Sections" in this survey, you may click and drag the icon in the lower right hand corner of the Comments Box to expand the size of the box.

2. The title should be structured around an acknowledged question format, e.g., PICOT (Population, Intervention, Control, primary Outcome, Time of follow-up)

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Introduction

INTRODUCTION. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

3. **Scientific background and explanation of rationale of the study**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

4. **Describe the problem(s) or issue(s) that the intervention(s) is intended to address**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

5. **Describe previous research on the experimental intervention(s)—intervention development, pilot-testing, evaluations, and systematic reviews**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

6. **Describe research about other interventions for this problem or issue**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

7. **Describe the intervention and its hypothesised theory of change**

1 - Not 10 - Very

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

***8.* Specific objectives or hypotheses of the study**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

***9.* Whether any objectives or hypotheses pertain to the cluster level**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

***10.* How objectives or hypotheses were derived**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Methods: Trial Design

***METHODS: TRIAL DESIGN.* Click *here* for relevant wording of items from previous CONSORT guidelines.**

***11.* Description of trial design (such as cluster, factorial, crossover), including allocation ratio**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

12. **Report all inclusion and exclusion criteria for participants, providers, settings, and (if relevant) clusters**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

12a. **Report why the particular control/comparator intervention(s) were chosen for the trial**

Click to write Choice 1	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

13. **Important changes to methods after trial commencement (such as eligibility criteria), with reasons**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

14. **How sample size was determined**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

15. **When applicable, explanation of any interim analyses and stopping guidelines**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Methods: Randomisation and Blinding Procedures

METHODS: RANDOMISATION AND BLINDING PROCEDURES. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

16. **Method used to generate the random allocation sequence**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

17. **Type of randomisation (e.g., minimisation, stepped-wedge) and details of any restriction (such as blocking and block size)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

18. **Mechanism used to implement the random allocation sequence (such as sequentially numbered opaque envelopes), describing any steps taken to conceal the sequence until interventions were assigned**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

19. **Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

20. **Whether and how *providers and participants* were blind after assignment to interventions, and if maintenance of blinding was assessed**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

21. **Whether and how *outcome assessors* were blind after assignment to interventions, and if maintenance of blinding was assessed**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

22. **Whether and how *data analysts* were blind after assignment to interventions, and if maintenance of blinding was assessed**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

23. **Methods to compensate for lack of blinding at any stage**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

24. **If relevant to issues of blinding, description of the similarity of intervention(s) and comparator(s)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Methods: Process Evaluation

METHODS: PROCESS EVALUATION. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

25a. **Precise details of the *content* of the intervention(s) and comparator(s) *as designed for the study*, including clear**

definitions of the essential and non-essential components for all groups, and the intended differences across groups

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

25b. Precise details of the *intended duration and frequency* of the intervention(s) and comparator(s)

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

25c. Precise details of the *intended format* of the intervention(s) and comparator(s), such as individual vs. group, in-person vs. electronic provision

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

26. Precise details of *methods to assess or enhance implementation fidelity* of intervention(s) and comparator(s), including the quality of provision and compliance by participants, with measures used

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

27. Precise details of the *plan for implementing* the intervention(s) and comparator(s), such as staff recruitment and selection, staff training and support, and physical or technical resources

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

28. **Describe important features of the setting(s) for data collection and intervention implementation, including date and time of study procedures, geographic location, and characteristics of the implementing organisation(s)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

29. **Describe how causal mechanisms were measured and analysed to assess mediators of the intervention(s)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

30. **Methods used to investigate context and the influence of context on study outcomes**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Methods: Outcomes and Data Analysis

METHODS: OUTCOMES AND DATA ANALYSIS. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

31. **Clearly defined primary and secondary outcome measures, their level of measurement, how they were measured, methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors), and how these compare to the outcomes listed in the trial registration and protocol**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

32. **Explain the choice of outcomes, their timing and length of follow-up, and any differences across groups in how outcomes are measured**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

33. **Copies of measures used and their psychometric properties, or references to publicly available documents containing this information**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

34. **Any changes to trial outcomes after the trial commenced, with reasons**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

35. **Statistical methods used to compare groups for primary and secondary outcomes, with reasons**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

36. **Any transformations to quantitative data, and statistical software used**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

37. **Methods for additional analyses, such as subgroup analyses, adjusted analyses, and how these compare to the trial registration and protocol**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

38a. **Imputation methods for handling missing data, and whether these methods were pre-specified**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

38b. **If done, what variables were used for imputation, and the number of imputations performed**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Results: Participant Flow and Recruitment

RESULTS: PARTICIPANT FLOW AND RECRUITMENT. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

39. **A flowchart including the following for each group: the numbers of participants, clusters, and providers or centres who were (1) approached, (2) screened, (3) eligible, (4) randomly assigned, (5) received the intended intervention, and (6) were analysed for the primary outcome, including the number of participants by each provider or center and reasons for dropout**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

40. **For each group, losses and exclusions after randomisation, including the number of participants who discontinued the intervention but remained in the trial, together with reasons**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

41. **Dates defining the periods of recruitment and follow-up of individuals and clusters**

41. Dates defining the periods of recruitment and follow-up of individuals and clusters

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

42. Whether the trial has ended or was stopped, with reasons if so

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

43. Conditions of consent and incentives provided to participants and/or clusters to enrol in the trial, to use the intervention, or to complete outcome measures

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

44. All theoretically important variables measured at baseline, with data for key baseline demographic, socioeconomic, and clinical characteristics for each group

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

45. Describe how the full study sample compares with study completers

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

46. For each group, number of participants (denominator) included in each analysis, and whether each analysis was

per protocol or based on initial intervention assignment

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Results: Process Evaluation

RESULTS: PROCESS EVALUATION. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

47a. **Precise details of the intervention(s) and comparator(s) *actually offered by providers*, with reasons for any differences from design**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

47b. **Precise details of any *tailoring by providers* of the intervention(s) and comparator(s) to individual participants across groups**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

47c. **Precise details of *actual* professional qualifications, training to deliver the intervention(s), and supervision of providers across groups**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

48a. **Precise details of the intervention(s) and comparator(s) *actually taken up by participants*, including acceptability if assessed**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

48b. **Amount of the intervention(s) and comparator(s) *actually received by participants* (e.g., sessions attended) across groups**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

49a. **Precise details about the *actual implementation process*, such as intervention roll-out, organisational capacity, and other barriers and facilitators of implementation**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

49b. **Describe features of the *broader context* important to intervention implemention and observed outcomes, such as concurrent events, area demographics, and the policy-related environment**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

49c. **Results of analyses evaluating *causal mechanisms* and *contextual dependence of outcomes*, with evidence to support any claims**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

Results: Outcomes and Estimation

RESULTS: OUTCOMES AND ESTIMATION. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

50a. **For each quantitative outcome, the results for each group as well as the estimated effect size and its precision (such as 95% confidence interval)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

50b. **For binary outcomes, presentation of both absolute and relative effect sizes is recommended**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

50c. **Provide any associated variance-covariance matrices for multivariate analytic systems (e.g., multiple regression, structural equation modeling)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

51. **Report or provide a reference for results of any other analyses performed, including subgroup and adjusted analyses, distinguishing pre-specified from exploratory**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

52a. **All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

52b. **Adverse psychological events and increased social disadvantage, indicating the level at which the harm may have occurred (e.g., individual, family, community)**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

Discussion

DISCUSSION. **Click *here* for relevant wording of items from previous CONSORT guidelines.**

53. **Trial limitations, addressing sources of potential bias, imprecision, clinical heterogeneity, inconsistency in response to intervention, multiplicity of analyses, choice of the comparator, lack of complete blinding, and unequal expertise of providers or organizations**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

54. **Limitations in the collection and analysis of process evaluation data, such as information about the delivery and uptake of interventions, context, and intervention acceptability**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○	○	○	○

Comments.

55. **Generalisability of the study findings to related populations and settings, considering the influence of intervention implementation, choice of comparator, sample characteristics, and data about contextual factors**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important
○	○	○	○	○	○	○			

Comments.

56. **Interpretation consistent with results, considering moderators and mediators, balancing benefits and harms, and discussing other relevant evidence**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

***57.* Alternative interpretations of the trial results, considering evidence from related studies**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

***58.* Implications of trial findings to future research, policy, and practice**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

Other Information

***OTHER INFORMATION.* Click *here* for relevant wording of items from previous CONSORT guidelines.**

***59.* Registration number and name of trial registry**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

***60.* Ethical approval (if needed), informed consent procedures, and important ethical considerations**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

***61.* References to all other sources of information about the methods and outcomes of this trial (full trial protocol,**

other papers or reports about the trial)

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

62. **References to intervention manual(s), websites, and other resources concerning the intervention**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

63. **Sources of funding and other support, and the role of funders in the design, conduct, analysis and reporting of the trial**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

64. **The role of the intervention developer in the design, conduct, analysis, and reporting of the trial**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

65. **Any other potential conflicts of interest, including how they were managed**

1 - Not Important	2	3	4	5	6	7	8	9	10 - Very Important

Comments.

Additional suggested checklist items and comments

ADDITIONAL ITEMS.

In this final section please list any additional items that you think should be included in, or items of the CONSORT Statement that require modification for, the CONSORT-SPI checklist, but which are not described above.

Suggestions to collapse or condense items above

REMAINING COMMENTS.

In this section, please provide any further comments and suggestions about the potential items for CONSORT-SPI in this questionnaire.

Demographic details

DEMOGRAPHICS.

CONTACT.

Please print your name, affiliation, and email address so we may provide you with feedback from this survey round

Name

Affiliation

Email

ACKNOWLEDGEMENT.

Please click here if you do NOT want to be acknowledged in project publications and on the project website

GENDER.

Male

Female

AGE.

<35 years

35 – 44

45 – 54

55 – 65

>65 years

PROFESSIONAL AREA(S). **Please indicate below *ALL* professional areas that apply.**

ACADEMIC/RESEARCHER.

- Trialist
- Systematic Reviewer
- Statistician
- Methodologist
- Other

PRACTITIONER.

- Teacher/School Administrator
- Police Worker
- Social Worker
- Mental Health Worker
- Community Health Worker
- Other

JOURNAL EDITOR.

- Criminology Journal
- Education Journal
- Psychology Journal
- Public Health Journal
- Social Work Journal
- Other

RESEARCH FUNDER.

- Government
- Non-profit
- Commercial
- Other

POLICY-MAKER.

- Civil Servant
- Elected Official
- Policy Consulting
- Other

CONSUMER GROUP REPRESENTATION. **CONSUMER GROUP REPRESENTATION**

- Staff for Consumer Advocacy Group/Organisation
- Volunteer for Consumer Advocacy Group/Organisation

Volunteer for Consumer Advocacy Group/Organisation

Board of Directors for Consumer Advocacy Group/Organisation

Other

Eligibility Criteria

Academic Disciplines. **Please list your academic discipline(s)**

Trial Publications. **How many randomised controlled trials (RCTs) have you published?**

0	1	2-5	6-10	More than 10

Review Publications. **How many intervention reviews have you published?**

0	1	2-5	6-10	More than 10

Statistical Publications. **How many papers on statistics related to intervention research have you published?**

0	1	2-5	6-10	More than 10

Methodological Publications. **How many papers on methodology related to intervention research have you published?**

0	1	2-5	6-10	More than 10

Other Publications. **How many papers related to intervention research have you published in the research position you described above: "${q://QID84/ChoiceTextEntryValue/5}"?**

0	1	2-5	6-10	More than 10

Teacher/School Administrator. **How many years have you been a teacher/school administrator?**

Number of years

Police Worker. **How many years have you been a police worker?**

Number of years

Social Worker. **How many years have you been a social worker?**

Number of years

Mental Health Worker. **How many years have you been a mental health worker?**

Number of years

Community Health Worker. **How many years have you been a community health worker?**

Number of years

Other Practitioner. **How many years have you held the following position: "${q://QID85/ChoiceTextEntryValue/6}"?**

Number of Years

Journals. **Please list the journals for which you serve as an editor**

Government Research Funder. **How many years have you been a research funder at a government institution?**

Number of years

Non-Profit Research Funder. **How many years have you been a research funder at a non-profit institution?**

Number of years

Commercial Research Funder. **How many years have you been a research funder at a commercial institution?**

Number of years

Other Research Funder. **How many years have you been a research funder at the type of institution you list: "${q://QID87/ChoiceTextEntryValue/4}"?**

Number of years

Civil Servant. **How many years have you been a civil servant?**

Number of years

Elected Official. **How many years have you been an elected official?**

Number of years

Policy Consultant. **How many years have you been a policy consultant?**

Number of years

Other Policy-Maker. **How many years have you held the policy position you described above: "${q://QID88/ChoiceTextEntryValue/4}"?**

Number of years

Consumer Group Staff. **How many years have you been staff for a consumer advocacy group/organisation?**

Number of years

Consumer Group Volunteer. **How many years have you been a volunteer for a consumer advocacy group/organisation?**

group/organisation?

Number of years

Consumer Group Board of Directors. **How many years have you been on the board of directors for a consumer advocacy group/organisation?**

Number of years

Consumer Group Other. **How many years have you held the position at a consumer advocacy group/organisation the you described above: "${q://QID243/ChoiceTextEntryValue/4}"?**

Number of years

Thank You!

Thank You.

Thank you for taking the time to complete this survey. Your input is greatly appreciated!

We hope that you will be willing to contribute to a second round of this Delphi survey, in which we will provide feedback about this survey and ask participants to clarify any areas of disagreement. The second round will take less time to complete than the first round.

PLEASE CLICK THE FORWARD ARROW BUTTON BELOW TO REGISTER YOUR RESPONSES.

Appendix J.

CONSORT-SPI Delphi Survey: Round 2

Instructions

INSTRUCTIONS.

Thank you for your Round 1 responses, which identified consensus about a number of items for the final checklist. In this Round 2 survey, we hope to reach agreement about remaining candidate items for CONSORT-SPI.

Please indicate whether each item should be included in a MINIMUM set of items that ALL social and psychological intervention trials should report. As a reminder, potential checklist items were derived from the CONSORT 2010 Statement, CONSORT Extensions, and other reporting standards for social and psychological interventions.

The Round 2 survey has organised items into three sections:

- **Part 1: Consensus to include unless strong objections are received. You do not need to rate these items.**
- **Part 2: Lack of consensus. Please rate each item.**
- **Part 3: New items proposed in Round 1. Please rate each item.**

For each item in Parts 2 and 3, please select one of the following options:

- **Include: This item MUST be reported for ALL social and psychological intervention trials.**
- **Exclude: This item is NOT mandatory.**
- **Unsure: This item MAY OR MAY NOT be required. Please explain.**

THE SECOND ROUND OF THE QUESIONNAIRE SHOULD BE COMPLETED BY 13 DECEMBER 2013. If you have any questions, please email Sean Grant at CONSORT.study@spi.ox.ac.uk

Part 1

Part 1.

This section contains 36 proposed items to INCLUDE in the checklist unless strong objections are received; please see the "Delphi Part 1 Items" attachment to your invitation email for a full list.

These items were rated highly in Round 1 and had little variability in their rankings.

We are not asking you to rate each of these items again, but rather to provide remaining comments that you may have, if any.

Please note that the order and wording of these items is not fixed, but will be discussed at the face-to-face meeting in light of comments from Round 1 and any comments from this round.

Comments.

Part 2

Part 2.

Candidate items that did not reach consensus; please see the "Delphi Part 2 Items" attachment to your invitation email for a full list.

Indicate whether items should be reported in ALL social and psychological intervention trials.

For each section, we have also provided a summary of comments about the original items from Round 1 for reference.

***Section.* TITLE AND ABSTRACT**

Click here for a summary of comments from Round 1

	Include	Exclude	Unsure
The intervention and the target problem/population should be identified in the title	○	○	○
The abstract should identify the population, all intervention and control conditions, outcomes of interest, times of follow-up, and the trial setting	○	○	○

Comments.

Part 2

***Section.* INTRODUCTION**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Identify any evidence-based interventions for this problem/issue and how the experimental intervention differs	○	○	○
Mention current knowledge about the effectiveness of the experimental intervention (e.g., reference previous systematic reviews)	○	○	○
Provide a conceptual framework or logic model for how the intervention is hypothesised to lead to changes in outcomes	○	○	○
Whether each objective or hypothesis pertains to the individual participant level and/or cluster level (e.g., family, community)	○	○	○
Justification for each objective or hypothesis	○	○	○

Comments.

Part 2

Section. **METHODS: TRIAL DESIGN, RANDOMISATION AND BLINDING PROCEDURES**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Incentives offered to participants (e.g., to enrol in the trial, use the intervention, complete outcome measures)	○	○	○
Rationale for choice of the control/comparator intervention(s) in the trial	○	○	○
Whether and how data analysts were blind after assignment to identifying information about participants	○	○	○
Whether maintenance of blinding data analysts was assessed	○	○	○
Discuss reasons for lack of blinding at any stage (e.g., impossible to blind participants to their assigned intervention)	○	○	○
Any methods to address lack of blinding (e.g., participants unaware content of comparator to minimise demand characteristics)	○	○	○
Description of similarities and differences in content and delivery between intervention(s) and comparator(s)	○	○	○

Comments.

Part 2

Section. **METHODS: SETTING**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Dates/timings of study procedures by trial arm (e.g., recruitment, baseline, intervention, and follow-up)	○	○	○
Geographic location of the trial (e.g., rural setting in Southwest US, urban setting in London, UK)	○	○	○
Characteristics of practice setting(s) directly related to experiences of participants and providers (e.g., provider/participant ratio, physical space to run intervention)	○	○	○
Characteristics of the larger implementing organisation(s) that shape the practice setting (e.g., private/public school ownership, competing priorities to prison-based intervention)	○	○	○
Characteristics of the external environment relevant to the trial (e.g., community demographics, health/social care policies)	○	○	○

Comments.

Part 2

Section. **METHODS: INTERVENTIONS**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Describe the plan for staff recruitment and selection for the intervention(s) and comparator(s)	○	○	○
Describe the plan for staff training and support for the intervention(s) and comparator(s)	○	○	○
Describe the planned physical and technical resources for the intervention(s) and comparator(s)	○	○	○
Describe any piloting of the intervention(s) with providers and the implementing organisation(s) prior to commencing the trial	○	○	○
Describe how and by whom actual delivery and uptake of the intervention by providers and participants was assessed	○	○	○
Any methods to investigate intervention causal mechanisms (qualitative/quantitative exploration of hypothesised mediators)	○	○	○

	Include	Exclude	Unsure
Any methods to investigate contextual influences on intervention outcomes (e.g., qualitative/quantitative exploration of the dependence of outcomes on practice setting, implementing organisation, or external environment)	○	○	○

Comments.

Part 2

Section. **METHODS: OUTCOMES AND DATA ANALYSIS**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Describe measures used in all reported analyses, including mode of administration and any modifications to pre-existing measures	○	○	○
Information about each measure's psychometric properties in the trial (e.g., internal consistency of self-report measures)	○	○	○
Reference(s) to any validation studies for each measure, noting comparability of their population(s) and context(s) to the trial's	○	○	○
Methods used to enhance the quality of measurements in the trial (e.g., multiple observations, training of assessors)	○	○	○
Identify all outcome measures in the trial, and if these match the trial registration/protocol	○	○	○
If done, what variables were used for imputation	○	○	○
If done, the number of imputations performed	○	○	○
Any transformations or changes to raw quantitative data, with reasons	○	○	○

Comments.

Part 2

Section. **RESULTS: BASELINE AND OUTCOMES DATA**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Data for demographic, socioeconomic, and other participant characteristics measured at baseline per trial arm	○	○	○
Describe whether and how the study completers differ from the original sample on baseline characteristics per trial arm	○	○	○
Report or refer readers to documents reporting analyses additional to main effects (e.g., subgroups; adjusted analyses)	○	○	○
Distinguish pre-specified from exploratory analyses	○	○	○
Provide raw data set needed for replicating analyses (either in online supplement or indicate how to obtain data on request)	○	○	○
Any adverse psychological events or unanticipated social disadvantage to individuals or clusters (e.g., families, communities)	○	○	○

Comments.

Part 2

Section. **RESULTS: PROCESS EVALUATION**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Actual professional qualifications of providers (rather than per the study protocol)	○	○	○
Actual training to deliver the intervention(s) (rather than per the study protocol)	○	○	○
Actual supervision of providers across groups (rather than per the study protocol)	○	○	○
Details of any other identified barriers and facilitators of implementing the intervention(s)	○	○	○
Describe any information about the acceptability or perceived value of the intervention(s) and comparator(s) by participants	○	○	○
Results of any investigations of causal mechanisms of the intervention	○	○	○
Results of any investigations of contextual influences on intervention outcomes	○	○	○

Comments.

Part 2

Section. **DISCUSSION**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Interpretation of the results, considering pre-specified and alternative hypotheses	○	○	○
Population(s) to whom the results may apply, considering sample characteristics, the intended population, recruitment procedures, and related studies	○	○	○
Setting(s) to which the results may apply, considering intervention implementation, choice of comparator, trial context, and related studies	○	○	○
Interpretation of any results about moderators and mediators, considering other relevant evidence and study limitations	○	○	○
Limitations due to sources of potential bias and imprecision	○	○	○
Limitations due to heterogeneity (e.g., variability in the participants, intervention implementation, and outcomes)	○	○	○
Limitations of methods to investigate intervention implementation (e.g., provider delivery and participant uptake)	○	○	○
Implications of trial findings to future research, policy, and practice, commensurate with strengths and limitations of the study	○	○	○

Comments.

Part 2

Section. **OTHER INFORMATION**

Summary of Round 1 Comments

	Include	Exclude	Unsure
Registration number and name of trial registry, or reasons why trial was not registered	○	○	○
Details about ethical approval (body giving approval/study identification number, informed consent procedures, any important ethical considerations)	○	○	○
References to external sources with information about the methods and outcomes of this trial, such as the full trial protocol and other papers/reports about the trial	○	○	○
Report any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial	○	○	○
Any potential conflicts of interest	○	○	○
How any identified potential conflicts of interest were handled	○	○	○

Comments.

Part 3

Part 3.

This section contains ADDITIONAL items generated from free-text comments in Round 1.

Summary of Round 1 Comments

	Include	Exclude	Unsure
Direct costs of implementing the intervention (e.g., provider salary, necessary material resources, training and supervision)	○	○	○
Present results of power analyses (i.e., power for outcome analyses at each follow-up)	○	○	○
Any methods to avoid or minimise contamination or spillover effects in the trial (e.g., participants in a comparator group receiving the experimental intervention)	○	○	○
Stakeholder involvement in trial design, conduct, and/or analyses (e.g., practitioners, policy-makers, participant representatives)	○	○	○
Acknowledgements of those who contributed substantially to the project but did not meet authorship requirements	○	○	○

Comments.

Remaining Comments

REMAINING COMMENTS.

We would like to give you another opportunity to express views not included in your comments above or in any of your comments from Round 1.

Are there any remaining comments you would like to make on the wording or content of items, for discussion at the face-to-face meeting, or on social and psychological intervention trials in general?

Thank You!

Thank You.

Thank you for taking the time to complete this survey. Your input is greatly appreciated!

PLEASE CLICK THE FORWARD ARROW BUTTON BELOW TO REGISTER YOUR RESPONSES.

Appendix K. Outcomes of Items in Delphi Round 1

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
1	Identify as randomised/randomized in the title	10	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
2	The title should be structured around an acknowledged question format, e.g., PICOT (Population, Intervention, Control, primary Outcome, Time of follow-up)	7	0.50	(1) The intervention and the target problem/population should be identified in the title; (2) The abstract should identify the population, all intervention and control conditions, outcomes of interest, times of follow-up, and the trial setting	Median below 8; DI ≥ 0.30
3	Scientific background and explanation of rationale of the study	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
4	Describe research about other interventions for this problem or issue	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
5	Describe previous research on the experimental intervention(s)—intervention development, pilot-testing, evaluations, and systematic reviews	9	0.25	Mention current knowledge about the effectiveness of the experimental intervention (e.g., reference previous systematic reviews)	Qualitative comments
6	Describe research about other interventions for this problem or issue	7	0.41	Identify any evidencebased interventions for this problem/issue and how the experimental intervention differs	Median below 8; DI ≥ 0.30

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
7	Describe the intervention and its hypothesised theory of change	9	0.25	Provide a conceptual framework or logic model for how the intervention is hypothesised to lead to changes in outcomes	Qualitative comments
8	Specific objectives or hypotheses of the study	10	0.00	N/A	Not ranked in Round 2: Recommended for Inclusion
9	Whether any objectives or hypotheses pertain to the cluster level	8	0.31	Whether each objective or hypothesis pertains to the individual participant level and/or cluster level (e.g., family, community)	DI ≥ 0.30
10	How objectives or hypotheses were derived	7	0.41	Justification for each objective or hypothesis	Median below 8; DI ≥ 0.30
11	Description of trial design (such as cluster, factorial, crossover), including allocation ratio	10	0.00	N/A	Not ranked in Round 2: Recommended for Inclusion
12	Report all inclusion and exclusion criteria for participants, providers, settings, and (if relevant) clusters	10	0.04	N/A	Not ranked in Round 2: Recommended for Inclusion
12a	Report why the particular control/comparator intervention(s) were chosen for the trial	9	0.25	Rationale for choice of the control/comparator intervention(s) in the trial	Qualitative comments
13	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
14	How sample size was determined	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
15	When applicable, explanation of any interim analyses and stopping guidelines	8	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
16	Method used to generate the random allocation sequence	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
17	Type of randomisation (e.g., minimisation, stepped-wedge) and details of any restriction (such as blocking and block size)	10	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
18	Mechanism used to implement the random allocation sequence (such as sequentially numbered opaque envelopes), describing any steps taken to conceal the sequence until interventions were assigned	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
19	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
20	Whether and how providers and participants were blind after assignment to interventions, and if maintenance of blinding was assessed	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
21	Whether and how outcome assessors were blind after assignment to interventions, and if maintenance of blinding was assessed	10	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
22	Whether and how data analysts were blind after assignment to interventions, and if maintenance of blinding was assessed	8	0.42	(1)Whether and how data analysts were blind after assignment to identifying information about participants; (2) Whether maintenance of blinding data analysts was assessed	DI ≥ 0.30
23	Methods to compensate for lack of blinding at any stage	8	0.31	(1) Discuss reasons for lack of blinding at any stage (e.g., impossible to blind participants to their assigned intervention); (2) Any methods to address lack of blinding (e.g., participants unaware content of comparator to minimise demand characteristics)	DI ≥ 0.30
24	If relevant to issues of blinding, description of the similarity of intervention(s) and comparator(s)	8	0.31	Description of similarities and differences in content and delivery between intervention(s) and comparator(s)	DI ≥ 0.30
25a	Precise details of the content of the intervention(s) and comparator(s) as designed for the study, including clear definitions of the essential and non-essential components for all groups, and the intended differences across groups	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
25b	Precise details of the intended duration and frequency of the intervention(s) and comparator(s)	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
25c	Precise details of the intended format of the intervention(s) and comparator(s), such as individual vs. group, in- person vs. electronic provision	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
26	Precise details of methods to assess or enhance implementation fidelity of intervention(s) and comparator(s), including the quality of provision and compliance by participants, with measures used	9	0.25	Describe how and by whom actual delivery and uptake of the intervention by providers and participants was assessed	Qualitative comments
27	Precise details of the plan for implementing the intervention(s) and comparator(s), such as staff recruitment and selection, staff training and support, and physical or technical resources	8	0.31	(1) Describe the plan for staff recruitment and selection for the intervention(s) and comparator(s); (2) Describe the plan for staff training and support for the intervention(s) and comparator(s); (3) Describe the planned physical and technical resources for the intervention(s) and comparator(s) (4) Describe any piloting of the intervention(s) with providers and the implementing organisation(s) prior to commencing the trial	DI ≥ 0.30

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
28	Describe important features of the setting(s) for data collection and intervention implementation, including date and time of study procedures, geographic location, and characteristics of the implementing organisation(s)	8	0.31	(1) Geographic location of the trial (e.g., rural setting in Southwest US, urban setting in London, UK); (2) Characteristics of practice setting(s) directly related to experiences of participants and providers (e.g., provider/participant ratio, physical space to run intervention); (3) Characteristics of the larger implementing organisation(s) that shape the practice setting (e.g., private/public school ownership, competing priorities to prisonbased intervention); (4) Characteristics of the external environment relevant to the trial (e.g., community demographics, health/social care policies)	DI ≥ 0.30
29	Describe how causal mechanisms were measured and analysed to assess mediators of the intervention(s)	8	0.42	Any methods to investigate intervention causal mechanisms (qualitative/quantitative exploration of hypothesised mediators)	DI ≥ 0.30

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
30	Methods used to investigate context and the influence of context on study outcomes	8	0.31	Any methods to investigate contextual influences on intervention outcomes (e.g., qualitative/quantitative exploration of the dependence of outcomes on practice setting, implementing organisation, or external environment)	DI ≥ 0.30
31	Clearly defined primary and secondary outcome measures, their level of measurement, how they were measured, methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors), and how these compare to the outcomes listed in the trial registration and protocol	10	0.12	(1) Describe measures used in all reported analyses, including mode of administration and any modifications to preexisting measures; (2) Methods used to enhance the quality of measurements in the trial (e.g., multiple observations, training of assessors); (3) Identify all outcome measures in the trial, and if these match the trial registration/protocol	Qualitative comments
32	Explain the choice of outcomes, their timing and length of follow-up, and any differences across groups in how outcomes are measured	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
33	Copies of measures used and their psychometric properties, or references to publicly available documents containing this information	9	0.25	(1) Information about each measure's psychometric properties in the trial (e.g., internal consistency of selfreport measures); (2) Reference(s) to any validation studies for each measure, noting comparability of their population(s) and context(s) to the trial's	Qualitative comments

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
34	Any changes to trial outcomes after the trial commenced, with reasons	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
35	Statistical methods used to compare groups for primary and secondary outcomes, with reasons	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
36	Any transformations to quantitative data, and statistical software used	9	0.25	Any transformations or changes to raw quantitative data, with reasons	Qualitative comments
37	Methods for additional analyses, such as subgroup analyses, adjusted analyses, and how these compare to the trial registration and protocol	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
38a	Imputation methods for handling missing data, and whether these methods were pre-specified	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
38b	If done, what variables were used for imputation, and the number of imputations performed	9	0.25	(1) If done, what variables were used for imputation; (2) If done, the number of imputations performed	Qualitative comments
39	A flowchart including the following for each group: the numbers of participants, clusters, and providers or centres who were (1) approached, (2) screened, (3) eligible, (4) randomly assigned, (5) received the intended intervention, and (6) were analysed for the primary outcome, including the number of participants by each provider or center and reasons for dropout	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
40	For each group, losses and exclusions after randomisation, including the number of participants who discontinued the intervention but remained in the trial, together with reasons	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
41	Dates defining the periods of recruitment and follow-up of individuals and clusters	8	0.31	Dates/timings of study procedures by trial arm (e.g., recruitment, baseline, intervention, and followup)	DI ≥ 0.30
42	Whether the trial has ended or was stopped, with reasons if so	10	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
43	Conditions of consent and incentives provided to participants and/or clusters to enrol in the trial, to use the intervention, or to complete outcome measures	9	0.25	Incentives offered to participants (e.g., to enrol in the trial, use the intervention, complete outcome measures)	Qualitative comments
44	All theoretically important variables measured at baseline, with data for key baseline demographic, socioeconomic, and clinical characteristics for each group	10	0.25	Data for demographic, socioeconomic, and other participant characteristics measured at baseline per trial arm	Qualitative comments
45	Describe how the full study sample compares with study completers	9	0.25	Describe whether and how the study completers differ from the original sample on baseline characteristics per trial arm	Qualitative comments

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
46	For each group, number of participants (denominator) included in each analysis and whether each analysis was per protocol or based on initial intervention assignment	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
47a	Precise details of the intervention(s) and comparator(s) actually offered by providers, with reasons for any differences from design	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
47b	Precise details of any tailoring by providers of the intervention(s) and comparator(s) to individual participants across groups	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
47c	Precise details of actual professional qualifications, training to deliver the intervention(s), and supervision of providers across groups	8	0.53	(1) Actual professional qualifications of providers (rather than per the study protocol); (2) Actual training to deliver the intervention(s) (rather than per the study protocol); (3) Actual supervision of providers across groups (rather than per the study protocol)	DI ≥ 0.30
48a	Precise details of the intervention(s) and comparator(s) actually taken up by participants, including acceptability if assessed	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
48b	Amount of the intervention(s) and comparator(s) actually received by participants (e.g., sessions attended) across groups	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
49a	Precise details about the actual implementation process, such as intervention roll-out, organisational capacity, and other barriers and facilitators of implementation	8	0.31	(1) Describe any information about the acceptability or perceived value of the intervention(s) and comparator(s) by participants; (2) Details of any other identified barriers and facilitators of implementing the intervention(s)	DI ≥ 0.30
49b	Describe features of the broader context important to intervention implemention and observed outcomes, such as concurrent events, area demographics, and the policy-related environment	7	0.41		Median below 8; DI ≥ 0.30
49c	Results of analyses evaluating causal mechanisms and contextual dependence of outcomes, with evidence to support any claims	8	0.42	(1) Results of any investigations of causal mechanisms of the intervention (2) Results of any investigations of contextual influences on intervention outcomes	DI ≥ 0.30
50a	For each quantitative outcome, the results for each group as well as the estimated effect size and its precision (such as 95% confidence interval)	10	0.00	N/A	Not ranked in Round 2: Recommended for Inclusion
50b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
50c	Provide any associated variance-covariance matrices for multivariate analytic systems (e.g., multiple regression, structural equation modeling)	8	0.53	Provide raw data set needed for replicating analyses (either in online supplement or indicate how to obtain data on request)	DI ≥ 0.30
51	Report or provide a reference for results of any other analyses performed, including subgroup and adjusted analyses, distinguishing pre-specified from exploratory	8	0.31	(1) Report or refer readers to documents reporting analyses additional to main effects (e.g., subgroups; adjusted analyses); (2) Distinguish prespecified from exploratory analyses	DI ≥ 0.30
52a	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
52b	Adverse psychological events and increased social disadvantage, indicating the level at which the harm may have occurred (e.g., individual, family, community)	9	0.25	Any adverse psychological events or unanticipated social disadvantage to individuals or clusters (e.g., families, communities)	Qualitative comments
53	Trial limitations, addressing sources of potential bias, imprecision, clinical heterogeneity, inconsistency in response to intervention, multiplicity of analyses, choice of the comparator, lack of complete blinding, and unequal expertise of providers or organizations	10	0.12	(1) Limitations due to sources of potential bias and imprecision; (2) Limitations due to heterogeneity (e.g., variability in the participants, intervention implementation, and outcomes)	Qualitative comments

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
54	Limitations in the collection and analysis of process evaluation data, such as information about the delivery and uptake of interventions, context, and intervention acceptability	9	0.25	Limitations of methods to investigate intervention implementation (e.g., provider delivery and participant uptake)	Qualitative comments
55	Generalisability of the study findings to related populations and settings, considering the influence of intervention implementation, choice of comparator, sample characteristics, and data about contextual factors	9	0.42	(1) Population(s) to whom the results may apply, considering sample characteristics, the intended population, recruitment procedures, and related studies (2) Setting(s) to which the results may apply, considering intervention implementation, choice of comparator, trial context, and related studies	DI ≥ 0.30
56	Interpretation consistent with results, considering moderators and mediators, balancing benefits and harms, and discussing other relevant evidence	9	0.25	Interpretation of any results about moderators and mediators, considering other relevant evidence and study limitations	Qualitative comments
57	Alternative interpretations of the trial results, considering evidence from related studies	8	0.31	Interpretation of the results, considering prespecified and alternative hypotheses	DI ≥ 0.30
58	Implications of trial findings to future research, policy, and practice	9	0.25	Implications of trial findings to future research, policy, and practice, commensurate with strengths and limitations of the study	Qualitative comments
59	Registration number and name of trial registry	9	0.42	Registration number and name of trial registry, or reasons why trial was not registered	DI ≥ 0.30

Question Number	Delphi Round 1 Item	Median	Disagreement Index (DI)	Delphi Round 2 Item(s)	Reason
60	Ethical approval (if needed), informed consent procedures, and important ethical considerations	10	0.25	Details about ethical approval (body giving approval/study identification number, informed consent procedures, any important ethical considerations)	Qualitative comments
61	References to all other sources of information about the methods and outcomes of this trial (full trial protocol, other papers or reports about the trial)	9	0.25	References to external sources with information about the methods and outcomes of this trial, such as the full trial protocol and other papers/reports about the trial	Qualitative comments
62	References to intervention manual(s), websites, and other resources concerning the intervention	9	0.25	N/A	Not ranked in Round 2: Recommended for Inclusion
63	Sources of funding and other support, and the role of funders in the design, conduct, analysis and reporting of the trial	10	0.12	N/A	Not ranked in Round 2: Recommended for Inclusion
64	The role of the intervention developer in the design, conduct, analysis, and reporting of the trial	9	0.25	Report any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial	Qualitative comments
65	Any other potential conflicts of interest, including how they were managed	10	0.25	(1) Any potential conflicts of interest; (2) How any identified potential conflicts of interest were handled	Qualitative comments

Green items are those voted in Delphi Round 1 for inclusion in the draft CONSORT-SPI checklist
Red items are those voted in in Delphi Round 1 to be ranked again in Delphi Round 2

Appendix L. CONSORT-SPI Consensus Meeting Agenda (17-19 March 2014) Hawkwell House, Oxford, UK

Monday 17th March 2014

Time	**Subject**
12:00 – 12:30PM	*Registration and refreshments*
12:30 – 1:30PM	*Lunch*
Session 1: Introduction and Background	
1:30 – 1:45PM	Welcome/introductions
1:45-2:00PM	Overview of goals and process
2:00 – 2:30PM	Background: Reporting Guidelines
2:30 – 3:00PM	Existing guidelines and reporting quality of RCTs: Results from systematic reviews
3:00 – 3:30PM	Group Discussion: Reporting problems in "your" area
3:30 – 3:50PM	*Tea/coffee*
Session 2: Reporting Social and Psychological Intervention RCTs	
3:50 – 4:20PM	Focus of checklist: What are "social and psychological" interventions, and what issues arise in RCTs evaluating them? Who will use/benefit from this checklist?
4:20 – 4:50PM	Preliminary activities: The CONSORT-SPI Delphi process
4:50 – 5:30PM	Discussion: results from the Delphi process
7:30 PM	*Dinner (Magdalen Arms, Iffley Road)*

Tuesday 18th March 2014

Time	**Subject**
8:00 – 9:00AM	*Breakfast*
Session 3: CONSORT-SPI Checklist Items	
9:00 – 9:15AM	Review of Day 1 and Aims of Day 2
9:15 – 9:45AM	Introduction: previous evidence, analytic framework, objectives
9:45 – 10:15AM	Trial design
10:15 – 10:45AM	Randomisation procedures
10:45 – 11:05AM	*Coffee/tea break*
11:05 – 11:35AM	Blinding procedures
11:35AM – 12:05PM	Intervention design
12:05 – 12:35PM	Intervention implementation: setting, delivery, and uptake
12:35 – 1:35PM	*Lunch followed by tea/coffee*
Session 4: CONSORT-SPI Checklist Items (cont.)	
1:35 – 2:05PM	Data collection and analytic plan
2:05 – 2:35PM	Participant flow and recruitment
2:35 – 3:05PM	Baseline data
3:05 – 3:25PM	*Tea/coffee*
3:25 – 3:55PM	Results: Outcomes and estimation
3:55 – 4:25PM	Adverse events
4:25 – 4:55PM	Discussion section: interpretation, generalisability, limitations
4:55 – 5:30PM	"Other" information: CoI's, ethics, trial registration
7:30PM	*Open Dinner*

Wednesday 19th March 2014

Time	**Subject**
8:00 – 9AM	*Breakfast*
Session 5: The CONSORT-SPI Checklist	
9:00 – 9:15AM	Review of Day 2 and Aims of Day 3
9:15 – 9:45AM	Tabled issues from Day 2
9:45 – 10:30AM	Review and discussion of recommended items
10:30 – 10:50AM	*Tea/coffee*
10:50 – 11:20AM	Finalise CONSORT-SPI checklist
11:20 – 11:50AM	Items for title and abstract
11:50 – 12:30PM	Discussion on checklist wording
12:30 – 1:30PM	*Lunch*
Session 6: What next and what else?	
1:30 – 2:00PM	Implementation: a view from the Editors
2:00 – 2:30PM	Publication strategy: Drafting, piloting, and co-publication
2:30 – 3:00PM	Other KT activities: linking with CONSORT, EQUATOR, and endorsement by others
3:00 – 3:15PM	Wrap-up of main meeting
4:00 – 5:30PM	*Project Executive meeting: publication timeline and next steps*

Appendix M. Checklist of Items for Reporting Trials of Social and Psychological Interventions: Version 01 (Pre-Delphi Round 1)

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Title and abstract			
	1a	Identification as a randomised trial in the title	Identify as randomised/randomized in the title
			The title should be structured around an acknowledged question format, e.g., PICOT (Population, Intervention, Control, primary Outcome, Time of follow-up)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale of the study
			Describe the problem(s) or issue(s) that the intervention(s) is intended to address
			Describe previous research on the experimental intervention(s)—intervention development, pilot-testing, evaluations, and systematic reviews
			Describe research about other interventions for this problem or issue
			Describe the intervention and its hypothesised theory of change
	2b	Specific objectives or hypotheses	Specific objectives or hypotheses of the study
			Whether any objectives or hypotheses pertain to the cluster level
			How objectives or hypotheses were derived
Methods			
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of trial design (such as cluster, factorial, crossover), including allocation ratio

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Trial Design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants	Report all inclusion and exclusion criteria for participants, providers, settings, and (if relevant) clusters
			Report why the particular control/comparator intervention(s) were chosen for the trial
	4b	Settings and locations where the data were collected	Describe important features of the setting(s) for data collection and intervention implementation, including date and time of study procedures, geographic location, and characteristics of the implementing organisation(s)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Precise details of the content of the intervention(s) and comparator(s) as designed for the study, including clear definitions of the essential and non-essential components for all groups, and the intended differences across groups
			Precise details of the intended duration and frequency of the intervention(s) and comparator(s)
			Precise details of the intended format of the intervention(s) and comparator(s), such as individual vs. group, in- person vs. electronic provision
*Intervention Implementation			Precise details of methods to assess or enhance implementation fidelity of intervention(s) and comparator(s), including the quality of provision and compliance by participants, with measures used
			Precise details of the plan for implementing the intervention(s) and comparator(s), such as staff recruitment and selection, staff training and support, and physical or technical resources

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Clearly defined primary and secondary outcome measures, their level of measurement, how they were measured, methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors), and how these compare to the outcomes listed in the trial registration and protocol
		Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Explain the choice of outcomes, their timing and length of follow-up, and any differences across groups in how outcomes are measured
			Copies of measures used and their psychometric properties, or references to publicly available documents containing this information
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to trial outcomes after the trial commenced, with reasons
Sample Size	7a	How sample size was determined	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines	When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation (e.g., minimisation, stepped-wedge) and details of any restriction (such as blocking and block size)
Allocation concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Mechanism used to implement the random allocation sequence (such as sequentially numbered opaque envelopes), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Whether and how providers and participants were blind after assignment to interventions, and if maintenance of blinding was assessed
			Whether and how outcome assessors were blind after assignment to interventions, and if maintenance of blinding was assessed
		If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Whether and how data analysts were blind after assignment to interventions, and if maintenance of blinding was assessed
			Methods to compensate for lack of blinding at any stage
	11b	If relevant, description of the similarity of interventions	If relevant to issues of blinding, description of the similarity of intervention(s) and comparator(s)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Statistical methods used to compare groups for primary and secondary outcomes, with reasons
			Any transformations to quantitative data, and statistical software used
			Imputation methods for handling missing data, and whether these methods were pre-specified
			If done, what variables were used for imputation, and the number of imputations performed
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Methods for additional analyses, such as subgroup analyses, adjusted analyses, and how these compare to the trial registration and protocol
*Causal Analysis			Describe how causal mechanisms were measured and analysed to assess mediators of the intervention(s)
			Methods used to investigate context and the influence of context on study outcomes

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	A flowchart including the following for each group: the numbers of participants, clusters, and providers or centres who were (1) approached, (2) screened, (3) eligible, (4) randomly assigned, (5) received the intended intervention, and (6) were analysed for the primary outcome, including the number of participants by each provider or center and reasons for dropout
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions after randomisation, including the number of participants who discontinued the intervention but remained in the trial, together with reasons
			Describe how the full study sample compares with study completers
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Dates defining the periods of recruitment and follow-up of individuals and clusters
			Conditions of consent and incentives provided to participants and/or clusters to enrol in the trial, to use the intervention, or to complete outcome measures
	14b	Why the trial ended or was stopped	Whether the trial has ended or was stopped, with reasons if so
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	All theoretically important variables measured at baseline, with data for key baseline demographic, socioeconomic, and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of participants (denominator) included in each analysis and whether the analysis was per protocol or based initial intervention assignment

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
**Process Evaluation:*			
Intervention Delivery			Precise details of the intervention(s) and comparator(s) actually offered by providers, with reasons for any differences from design
			Precise details of any tailoring by providers of the intervention(s) and comparator(s) to individual participants across groups
			Precise details of actual professional qualifications, training to deliver the intervention(s), and supervision of providers across groups
Intervention Uptake			Precise details of the intervention(s) and comparator(s) actually taken up by participants, including acceptability if assessed
Intervention Uptake			Amount of the intervention(s) and comparator(s) actually received by participants (e.g., sessions attended) across groups
Intervention Implementation			Precise details about the actual implementation process, such as intervention roll-out, organisational capacity, and other barriers and facilitators of implementation
			Describe features of the broader context important to intervention implementation and observed outcomes, such as concurrent events, area demographics, and the policy-related environment
			Results of analyses evaluating causal mechanisms and contextual dependence of outcomes, with evidence to support any claims

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each quantitative outcome, the results for each group as well as the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
			Provide any associated variance-covariance matrices for multivariate analytic systems (e.g., multiple regression, structural equation modeling)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	Report or provide a reference for results of any other analyses performed, including subgroup and adjusted analyses, distinguishing pre-specified from exploratory
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
			Adverse psychological events and increased social disadvantage, indicating the level at which the harm may have occurred (e.g., individual, family, community)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Trial limitations, addressing sources of potential bias, imprecision, clinical heterogeneity, inconsistency in response to intervention, multiplicity of analyses, choice of the comparator, lack of complete blinding, and unequal expertise of providers or organizations
			Limitations in the collection and analysis of process evaluation data, such as information about the delivery and uptake of interventions, context, and intervention acceptability

Section	Item #	Standard CONSORT Description	Relevant Items in Delphi Round 1 Survey
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability of the study findings to related populations and settings, considering the influence of intervention implementation, choice of comparator, sample characteristics, and data about contextual factors
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with results, considering moderators and mediators, balancing benefits and harms, and discussing other relevant evidence
			Alternative interpretations of the trial results, considering evidence from related studies
			Implications of trial findings to future research, policy, and practice
Other information			
Registration	23	Registration number and name of trial registry	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available	References to all other sources of information about the methods and outcomes of this trial (full trial protocol, other papers or reports about the trial)
			References to intervention manual(s), websites, and other resources concerning the intervention
			Ethical approval (if needed), informed consent procedures, and important ethical considerations
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Sources of funding and other support, and the role of funders in the design, conduct, analysis and reporting of the trial
			The role of the intervention developer in the design, conduct, analysis, and reporting of the trial
			Any other potential conflicts of interest, including how they were managed

Appendix N. Checklist of Items for Reporting Trials of Social and Psychological Interventions: Version 02 (After Delphi Round 1)

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Title and abstract			
	1a	Identification as a randomised trial in the title	*Identify as randomised/randomized in the title
			~The intervention and the target problem/population should be identified in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	~The abstract should identify the population, all intervention and control conditions, outcomes of interest, times of follow-up, and the trial setting
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	*Scientific background and explanation of rationale of the study
			*Describe the problem(s) or issue(s) that the intervention(s) is intended to address
			~Identify any evidence-based interventions for this problem/issue and how the experimental intervention differs
			~Mention current knowledge about the effectiveness of the experimental intervention (e.g., reference previous systematic reviews)
			~ Provide a conceptual framework or logic model for how the intervention is hypothesised to lead to changes in outcomes
	2b	Specific objectives or hypotheses	*Specific objectives or hypotheses of the study
			~Whether each objective or hypothesis pertains to the individual participant level and/or cluster level (e.g., family, community)
			~Justification for each objective or hypothesis
Methods			
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	*Description of trial design (such as cluster, factorial, crossover), including allocation ratio

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Trial Design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	*Important changes to methods after trial commencement (such as eligibility criteria), with reasons
		Important changes to methods after trial commencement (such as eligibility criteria), with reasons	~Stakeholder involvement in trial design, conduct, and/or analyses (e.g., practitioners, policy-makers, participant representatives)
Participants	4a	Eligibility criteria for participants	*Report all inclusion and exclusion criteria for participants, providers, settings, and (if relevant) clusters
			~Rationale for choice of the control/comparator intervention(s) in the trial
	4b	Settings and locations where the data were collected	~Geographic location of the trial (e.g., rural setting in Southwest US, urban setting in London, UK)
			~Characteristics of practice setting(s) directly related to experiences of participants and providers (e.g., provider/participant ratio, physical space to run intervention)
			~Characteristics of the larger implementing organisation(s) that shape the practice setting (e.g., private/public school ownership, competing priorities to prison-based intervention)
			~Characteristics of the external environment relevant to the trial (e.g., community demographics, health/social care policies)
			~Incentives offered to participants (e.g., to enrol in the trial, use the intervention, complete outcome measures)

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	*Precise details of the content of the intervention(s) and comparator(s) as designed for the study, including clear definitions of the essential and non-essential components for all groups, and the intended differences across groups
			*Precise details of the intended duration and frequency of the intervention(s) and comparator(s)
			*Precise details of the intended format of the intervention(s) and comparator(s), such as individual vs. group, in-person vs. electronic provision
			~Any methods to avoid or minimise contamination or spillover effects in the trial (e.g., participants in a comparator group receiving the experimental intervention)
*Intervention Implementation			~Describe the plan for staff recruitment and selection for the intervention(s) and comparator(s)
			~Describe the plan for staff training and support for the intervention(s) and comparator(s)
			~Describe the planned physical and technical resources for the intervention(s) and comparator(s)
			~Describe any piloting of the intervention(s) with providers and the implementing organisation(s) prior to commencing the trial
			~Describe how and by whom actual delivery and uptake of the intervention by providers and participants was assessed
			~Direct costs of implementing the intervention (e.g., provider salary, necessary material resources, training and supervision)

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	*Explain the choice of outcomes, their timing and length of follow-up, and any differences across groups in how outcomes are measured
			~Describe measures used in all reported analyses, including mode of administration and any modifications to pre-existing measures
			~Information about each measure's psychometric properties in the trial (e.g., internal consistency of self-report measures)
			~Reference(s) to any validation studies for each measure, noting comparability of their population(s) and context(s) to the trial's
			~Methods used to enhance the quality of measurements in the trial (e.g., multiple observations, training of assessors)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	*Any changes to trial outcomes after the trial commenced, with reasons
			~Identify all outcome measures in the trial, and if these match the trial registration/protocol
Sample Size	7a	How sample size was determined	*How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines	*When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	*Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	*Type of randomisation (e.g., minimisation, stepped-wedge) and details of any restriction (such as blocking and block size)
Allocation concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	*Mechanism used to implement the random allocation sequence (such as sequentially numbered opaque envelopes), describing any steps taken to conceal the sequence until interventions were assigned

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Randomisation			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	*Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	*Whether and how providers and participants were blind after assignment to interventions, and if maintenance of blinding was assessed
			*Whether and how outcome assessors were blind after assignment to interventions, and if maintenance of blinding was assessed
			~Whether and how data analysts were blind after assignment to identifying information about participants
			~Whether maintenance of blinding data analysts was assessed
			~Discuss reasons for lack of blinding at any stage (e.g., impossible to blind participants to their assigned intervention)
			~Any methods to address lack of blinding (e.g., participants unaware content of comparator to minimise demand characteristics)
	11b	If relevant, description of the similarity of interventions	~Description of similarities and differences in content and delivery between intervention(s) and comparator(s)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	*Statistical methods used to compare groups for primary and secondary outcomes, with reasons
			*Imputation methods for handling missing data, and whether these methods were pre-specified
			~If done, what variables were used for imputation
			~If done, the number of imputations performed
			~Any transformations or changes to raw quantitative data, with reasons

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	*Methods for additional analyses, such as subgroup analyses, adjusted analyses, and how these compare to the trial registration and protocol
*Causal Analysis			~Any methods to investigate intervention causal mechanisms (qualitative/quantitative exploration of hypothesised mediators)
			~Any methods to investigate contextual influences on intervention outcomes (e.g., qualitative/quantitative exploration of the dependence of outcomes on practice setting, implementing organisation, or external environment)
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	*A flowchart including the following for each group: the numbers of participants, clusters, and providers or centres who were (1) approached, (2) screened, (3) eligible, (4) randomly assigned, (5) received the intended intervention, and (6) were analysed for the primary outcome, including the number of participants by each provider or center and reasons for dropout
	13b	For each group, losses and exclusions after randomisation, together with reasons	*For each group, losses and exclusions after randomisation, including the number of participants who discontinued the intervention but remained in the trial, together with reasons
			~Describe whether and how the study completers differ from the original sample on baseline characteristics per trial arm
Recruitment	14a	Dates defining the periods of recruitment and follow-up	~Dates/timings of study procedures by trial arm (e.g., recruitment, baseline, intervention, and follow-up)
Recruitment	14b	Why the trial ended or was stopped	*Whether the trial has ended or was stopped, with reasons if so
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	~Data for demographic, socioeconomic, and other participant characteristics measured at baseline per trial arm

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	*For each group, number of participants (denominator) included in each analysis, and whether each analysis was per protocol or based on initial intervention assignment
*Process Evaluation:			
Intervention Delivery			*Precise details of the intervention(s) and comparator(s) actually offered by providers, with reasons for any differences from design
			*Precise details of any tailoring by providers of the intervention(s) and comparator(s) to individual participants across groups
			~Actual professional qualifications of providers (rather than per the study protocol)
			~Actual training to deliver the intervention(s) (rather than per the study protocol)
			~Actual supervision of providers across groups (rather than per the study protocol)
Intervention Uptake			*Precise details of the intervention(s) and comparator(s) actually taken up by participants
			*Amount of the intervention(s) and comparator(s) actually received by participants (e.g., sessions attended) across groups
			~Describe any information about the acceptability or perceived value of the intervention(s) and comparator(s) by participants
Intervention Implementation			~Details of any other identified barriers and facilitators of implementing the intervention(s)
			~Results of any investigations of causal mechanisms of the intervention
			~Results of any investigations of contextual influences on intervention outcomes

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	*For each quantitative outcome, the results for each group as well as the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	*For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	~Report or refer readers to documents reporting analyses additional to main effects (e.g., subgroups; adjusted analyses)
			~Distinguish pre-specified from exploratory analyses
			~ Provide raw data set needed for replicating analyses (either in online supplement or indicate how to obtain data on request)
			~Present results of power analyses (i.e., power for outcome analyses at each follow-up)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	*All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
			~ Any adverse psychological events or unanticipated social disadvantage to individuals or clusters (e.g., families, communities)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	~Limitations due to sources of potential bias and imprecision
			~Limitations due to heterogeneity (e.g., variability in the participants, intervention implementation, and outcomes)

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Limitations	20		~Limitations of methods to investigate intervention implementation (e.g., provider delivery and participant uptake)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	~Population(s) to whom the results may apply, considering sample characteristics, the intended population, recruitment procedures, and related studies
			~Setting(s) to which the results may apply, considering intervention implementation, choice of comparator, trial context, and related studies
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	~Interpretation of the results, considering pre-specified and alternative hypotheses
			~Interpretation of any results about moderators and mediators, considering other relevant evidence and study limitations
			~Implications of trial findings to future research, policy, and practice, commensurate with strengths and limitations of the study
Other information			
Registration	23	Registration number and name of trial registry	~Registration number and name of trial registry, or reasons why trial was not registered
Protocol	24	Where the full trial protocol can be accessed, if available	*References to intervention manual(s), websites, and other resources concerning the intervention
			~References to external sources with information about the methods and outcomes of this trial, such as the full trial protocol and other papers/reports about the trial
			~Details about ethical approval (body giving approval/study identification number, informed consent procedures, any important ethical considerations)
			~Acknowledgements of those who contributed substantially to the project but did not meet authorship requirements

Section	Item #	Standard CONSORT Description	*Recommended from Round 1 or ~Re-Rated in Round 2
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	*Sources of funding and other support, and the role of funders in the design, conduct, analysis and reporting of the trial
			~Report any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial
Section	**Item #**	**Standard CONSORT Description**	***Recommended from Round 1 or ~Re-Rated in Round 2**
Funding	25		~Any potential conflicts of interest
			~How any identified potential conflicts of interest were handled

Appendix O. Checklist of Items for Reporting Trials of Social and Psychological Interventions: Version 03 (After Delphi Round 2)

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Title and abstract			
	1a	Identification as a randomised trial in the title	*Identify as randomised/randomized in the title
			~The intervention and the target problem/population should be identified in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	*The abstract should identify the population, all intervention and control conditions, outcomes of interest, times of follow-up, and the trial setting
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	*Scientific background and explanation of rationale of the study
			*Describe the problem(s) or issue(s) that the intervention(s) is intended to address
			*Mention current knowledge about the effectiveness of the experimental intervention (e.g., reference previous systematic reviews)
			~Identify any evidence-based interventions for this problem/issue and how the experimental intervention differs
			~ Provide a conceptual framework or logic model for how the intervention is hypothesised to lead to changes in outcomes
	2b	Specific objectives or hypotheses	*Specific objectives or hypotheses of the study
			~Whether each objective or hypothesis pertains to the individual participant level and/or cluster level (e.g., family, community)
			~Justification for each objective or hypothesis
Methods			
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	*Description of trial design (such as cluster, factorial, crossover), including allocation ratio

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Trial Design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	*Important changes to methods after trial commencement (such as eligibility criteria), with reasons
			~Stakeholder involvement in trial design, conduct, and/or analyses (e.g., practitioners, policy-makers, participant representatives)
Participants	4a	Eligibility criteria for participants	*Report all inclusion and exclusion criteria for participants, providers, settings, and (if relevant) clusters
			*Rationale for choice of the control/comparator intervention(s) in the trial
	4b	Settings and locations where the data were collected	*Geographic location of the trial (e.g., rural setting in Southwest US, urban setting in London, UK)
			~Characteristics of practice setting(s) directly related to experiences of participants and providers (e.g., provider/participant ratio, physical space to run intervention)
			~Characteristics of the larger implementing organisation(s) that shape the practice setting (e.g., private/public school ownership, competing priorities to prison-based intervention)
			~Characteristics of the external environment relevant to the trial (e.g., community demographics, health/social care policies)
			*Incentives offered to participants (e.g., to enrol in the trial, use the intervention, complete outcome measures)

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	*Precise details of the content of the intervention(s) and comparator(s) as designed for the study, including clear definitions of the essential and non-essential components for all groups, and the intended differences across groups
			*Precise details of the intended duration and frequency of the intervention(s) and comparator(s)
			*Precise details of the intended format of the intervention(s) and comparator(s), such as individual vs. group, in-person vs. electronic provision
			~Any methods to avoid or minimise contamination or spillover effects in the trial (e.g., participants in a comparator group receiving the experimental intervention)
*Intervention Implementation			*Describe how and by whom actual delivery and uptake of the intervention by providers and participants was assessed
			~Describe the plan for staff training and support for the intervention(s) and comparator(s)
			~Describe the planned physical and technical resources for the intervention(s) and comparator(s)
			~Describe any piloting of the intervention(s) with providers and the implementing organisation(s) prior to commencing the trial
			~Describe the plan for staff recruitment and selection for the intervention(s) and comparator(s)
			~Direct costs of implementing the intervention (e.g., provider salary, necessary material resources, training and supervision)

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Outcomes	6	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	*Explain the choice of outcomes, their timing and length of follow-up, and any differences across groups in how outcomes are measured
			*Describe measures used in all reported analyses, including mode of administration and any modifications to pre-existing measures
			~Information about each measure's psychometric properties in the trial (e.g., internal consistency of self-report measures)
			~Reference(s) to any validation studies for each measure, noting comparability of their population(s) and context(s) to the trial's
			~Methods used to enhance the quality of measurements in the trial (e.g., multiple observations, training of assessors)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	*Any changes to trial outcomes after the trial commenced, with reasons
			*Identify all outcome measures in the trial, and if these match the trial registration/protocol
Sample Size	7a	How sample size was determined	*How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines	*When applicable, explanation of any interim analyses and stopping guidelines
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	*Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	*Type of randomisation (e.g., minimisation, stepped-wedge) and details of any restriction (such as blocking and block size)
Allocation concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	*Mechanism used to implement the random allocation sequence (such as sequentially numbered opaque envelopes), describing any steps taken to conceal the sequence until interventions were assigned

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	*Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	*Whether and how providers and participants were blind after assignment to interventions, and if maintenance of blinding was assessed
			*Whether and how outcome assessors were blind after assignment to interventions, and if maintenance of blinding was assessed
			~Whether and how data analysts were blind after assignment to identifying information about participants
			~Whether maintenance of blinding data analysts was assessed
			~Discuss reasons for lack of blinding at any stage (e.g., impossible to blind participants to their assigned intervention)
			~Any methods to address lack of blinding (e.g., participants unaware content of comparator to minimise demand characteristics)
	11b	If relevant, description of the similarity of interventions	*Description of similarities and differences in content and delivery between intervention(s) and comparator(s)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	*Statistical methods used to compare groups for primary and secondary outcomes, with reasons
Statistical methods	12a		*Imputation methods for handling missing data, and whether these methods were pre-specified
			*Any transformations or changes to raw quantitative data, with reasons
			~If done, the number of imputations performed
			~If done, what variables were used for imputation
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	*Methods for additional analyses, such as subgroup analyses, adjusted analyses, and how these compare to the trial registration and protocol

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
*Causal Analysis			~Any methods to investigate intervention causal mechanisms (qualitative/quantitative exploration of hypothesised mediators)
			~Any methods to investigate contextual influences on intervention outcomes (e.g., qualitative/quantitative exploration of the dependence of outcomes on practice setting, implementing organisation, or external environment)
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	*A flowchart including the following for each group: the numbers of participants, clusters, and providers or centres who were (1) approached, (2) screened, (3) eligible, (4) randomly assigned, (5) received the intended intervention, and (6) were analysed for the primary outcome, including the number of participants by each provider or center and reasons for dropout
	13b	For each group, losses and exclusions after randomisation, together with reasons	*For each group, losses and exclusions after randomisation, including the number of participants who discontinued the intervention but remained in the trial, together with reasons
			*Describe whether and how the study completers differ from the original sample on baseline characteristics per trial arm
Recruitment	14a	Dates defining the periods of recruitment and follow-up	*Dates/timings of study procedures by trial arm (e.g., recruitment, baseline, intervention, and follow-up)
	14b	Why the trial ended or was stopped	*Whether the trial has ended or was stopped, with reasons if so
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	*Data for demographic, socioeconomic, and other participant characteristics measured at baseline per trial arm
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	*For each group, number of participants (denominator) included in each analysis, and whether each analysis was per protocol or based on initial intervention assignment

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
**Process Evaluation:*			
Intervention Delivery			*Precise details of the intervention(s) and comparator(s) actually offered by providers, with reasons for any differences from design
			*Precise details of any tailoring by providers of the intervention(s) and comparator(s) to individual participants across groups
			~Actual professional qualifications of providers (rather than per the study protocol)
			~Actual training to deliver the intervention(s) (rather than per the study protocol)
			~Actual supervision of providers across groups (rather than per the study protocol)
Intervention Uptake			*Precise details of the intervention(s) and comparator(s) actually taken up by participants
			*Amount of the intervention(s) and comparator(s) actually received by participants (e.g., sessions attended) across groups
			~Describe any information about the acceptability or perceived value of the intervention(s) and comparator(s) by participants
Intervention Implementation			~Details of any other identified barriers and facilitators of implementing the intervention(s)
			~Results of any investigations of causal mechanisms of the intervention
			~Results of any investigations of contextual influences on intervention outcomes
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	*For each quantitative outcome, the results for each group as well as the estimated effect size and its precision (such as 95% confidence interval)

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Outcomes and estimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	*For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	~Report or refer readers to documents reporting analyses additional to main effects (e.g., subgroups; adjusted analyses)
			~Distinguish pre-specified from exploratory analyses
			~ Provide raw data set needed for replicating analyses (either in online supplement or indicate how to obtain data on request)
			~Present results of power analyses (i.e., power for outcome analyses at each follow-up)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	*All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
			~ Any adverse psychological events or unanticipated social disadvantage to individuals or clusters (e.g., families, communities)
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	*Limitations due to sources of potential bias and imprecision
			*Limitations due to heterogeneity (e.g., variability in the participants, intervention implementation, and outcomes)
			*Limitations of methods to investigate intervention implementation (e.g., provider delivery and participant uptake)

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	*Population(s) to whom the results may apply, considering sample characteristics, the intended population, recruitment procedures, and related studies
			~Setting(s) to which the results may apply, considering intervention implementation, choice of comparator, trial context, and related studies
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	*Interpretation of the results, considering pre-specified and alternative hypotheses
			*Implications of trial findings to future research, policy, and practice, commensurate with strengths and limitations of the study
			~Interpretation of any results about moderators and mediators, considering other relevant evidence and study limitations
Other information			
Registration	23	Registration number and name of trial registry	~Registration number and name of trial registry, or reasons why trial was not registered
Protocol	24	Where the full trial protocol can be accessed, if available	*References to intervention manual(s), websites, and other resources concerning the intervention
			*References to external sources with information about the methods and outcomes of this trial, such as the full trial protocol and other papers/reports about the trial
			~Details about ethical approval (body giving approval/study identification number, informed consent procedures, any important ethical considerations)
			~Acknowledgements of those who contributed substantially to the project but did not meet authorship requirements
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	*Sources of funding and other support, and the role of funders in the design, conduct, analysis and reporting of the trial

Section	Item #	Standard CONSORT Description	*Recommended from Delphi or ~Indeterminate
Funding	25		*Report any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial
			*Any potential conflicts of interest
			~How any identified potential conflicts of interest were handled

Appendix P. Checklist of Items for Reporting Trials of Social and Psychological Interventions: Version 04 (Start of Consensus Meeting)

Section	Item #	Standard CONSORT Description	Re-Worded, Recommended Delphi Items
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	The population, intervention and control conditions, outcomes of interest, times of follow-up, and the trial setting
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	The problem(s) or issue(s) that the intervention(s) is intended to address
			Mention current knowledge about the effectiveness of the experimental intervention (e.g., reference previous systematic reviews)
	2b	Specific objectives or hypotheses	
Methods			
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	If cluster trial, please refer to CONSORT for Cluster Randomised Trials
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	All inclusion and exclusion criteria for providers and settings as applicable
			Rationale for choice of the control/comparator intervention(s) in the trial
	4b	Settings and locations where the data were collected	Geographic location of the trial (e.g., rural setting in Southwest US, urban setting in London, UK)
			Incentives offered to participants (e.g., to enrol in the trial, use the intervention, complete outcome measures)

Section	Item #	Standard CONSORT Description	Re-Worded, Recommended Delphi Items
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	The content of the intervention(s) and comparator(s) as designed for the study, including clear definitions of the essential and non-essential components for all groups, and the intended differences across groups
			The intended duration and frequency of the intervention(s) and comparator(s)
			The intended format of the intervention(s) and comparator(s), such as individual vs. group, in-person vs. electronic provision
Intervention Implementation			How and by whom actual delivery and uptake of the intervention by providers and participants was assessed
Outcomes	6	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Choice of outcomes, their timing and length of follow-up, and any differences across groups in how outcomes are measured
			Measures used in all reported analyses, including mode of administration and any modifications to pre-existing measures
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Identify all outcome measures in the trial, and if these match the trial registration/protocol
Sample Size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	

Section	Item #	Standard CONSORT Description	Re-Worded, Recommended Delphi Items
Allocation concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Whether and how providers and participants were blind after assignment to interventions, and if maintenance of blinding was assessed
			Whether and how outcome assessors were blind after assignment to interventions, and if maintenance of blinding was assessed
Blinding	11b	If relevant, description of the similarity of interventions	Similarities and differences in content and delivery between intervention(s) and comparator(s)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	With reasons/justify analyses chosen
			Imputation methods for handling missing data, and whether these methods were pre-specified
			Any transformations or changes to raw quantitative data, with reasons
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	How these compare to the trial registration and protocol
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	In addition, the number approached, screened, and eligible prior to random assignment, including the number of participants by each provider or center and reasons for dropout

Section	Item #	Standard CONSORT Description	Re-Worded, Recommended Delphi Items
Participant flow (a diagram is strongly recommended)	13b	For each group, losses and exclusions after randomisation, together with reasons	The number of participants who discontinued the intervention but remained in the trial
			Whether and how the study completers differ from the original sample on baseline characteristics per trial arm
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Dates and timings of study procedures by trial arm (e.g., recruitment, baseline, intervention, and follow-up)
	14b	Why the trial ended or was stopped	Indicate if trial is still ongoing at time of publication
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Include PROGRESS-Plus data measured
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Process Evaluation:			
Intervention Delivery			Intervention(s) and comparator(s) as actually delivered by providers, with reasons for any differences from design
			Any tailoring by providers of the intervention(s) and comparator(s) to individual participants across groups
Intervention Uptake			Actual participant uptake of intervention(s) and comparator(s)
			Dosage or reach of the intervention(s) and comparator(s) for each group
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	

Section	Item #	Standard CONSORT Description	Re-Worded, Recommended Delphi Items
Outcomes and estimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Limitations due to heterogeneity (e.g., variability in the participants, intervention implementation, and outcomes)
			Limitations of methods to investigate intervention implementation (e.g., provider delivery and participant uptake)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Population(s) to whom the results may apply, considering sample characteristics, the intended population, recruitment procedures, and related studies
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation of the results, considering pre-specified and alternative hypotheses
			Implications of trial findings to future research, policy, and practice, commensurate with strengths and limitations of the study
Other information			
Registration	23	Registration number and name of trial registry	

Section	Item #	Standard CONSORT Description	Re-Worded, Recommended Delphi Items
Protocol	24	Where the full trial protocol can be accessed, if available	References to external sources (e.g., other papers or reports) with information about the methods and outcomes of this trial
			References to intervention manual(s), websites, and other resources concerning the intervention
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Report any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial
			Any other potential conflicts of interest

Appendix Q. Draft CONSORT-SPI Checklist (Stage: End of Consensus Meeting Day 2)

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Title and abstract			
	1a	Identification as a randomised trial in the title	**The intervention and the target problem/population should be identified in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	**The population, intervention and control conditions, outcomes of interest, times of follow-up, and the trial setting
Introduction			
Background and objectives	2a Text	Scientific background and explanation of rationale	Whether or how the intervention is hypothesised to work
	2b	Specific objectives or hypotheses	
Methods			
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	If the unit of random assignment is not the individual, please refer to CONSORT for Cluster Randomised Trials (NB: Make a footnote?)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
	New item		Stakeholder involvement in trial design, conduct, and/or analyses (e.g., practitioners, policymakers, participant representatives) (NB: If applicable?)
Participants	4a	Eligibility criteria for participants	**When applicable, eligibility criteria for settings and those delivering the interventions
	4b	Settings and locations where the data were collected	

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Extent to which intervention and control conditions were delivered and taken up as planned
			When applicable, how intervention providers were assigned to each group
			Incorporate TIDieR in E&E (NB: Add to checklist?)
Outcomes	6	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample Size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	**Imputation methods for handling missing data, and any transformation or changes to data, with reasons
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for dropout
Participant flow	13b	For each group, losses and exclusions after randomisation, together with reasons	**Add "The number of participants who discontinued the intervention but remained in the trial" to flow diagram
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Including socioeconomic variables where applicable (NB: Or take out "clinical" from standard CONSORT Item 15 instead?)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	Indicate availability of trial data
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	Where the intervention manual and other informational materials can be accessed (NB: Move to intervention section?)
Protocol	24		**Where other information about the trial's methods and outcomes can be assessed

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial
			**Any other potential conflicts of interest
Incentives	**26**	**Incentives**	Incentives offered as part of the trial

Those concepts ****starred** are currently not in the Checklist but are being discussed on Day 3
Those concepts with a (parenthetical NB) indicate particular discussion points for Day 3

Appendix R. Draft CONSORT-SPI Checklist (Stage: End of Consensus Meeting Day 3)

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	Whether or how the intervention is hypothesised to work
	2b	Specific objectives or hypotheses	
Methods			
Trial Design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	If the unit of random assignment is not the individual, please refer to CONSORT for Cluster Randomised Trials
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	When applicable, eligibility criteria for settings and those delivering the interventions
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Extent to which intervention and control conditions were delivered and taken up as planned
			When applicable, how intervention providers were assigned to each group
			*Where the intervention manual and other informational materials can be accessed
Outcomes	6	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample Size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; details of any restriction (such as blocking and block size)	
Allocation concealment Mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Statistical approaches for missing data are explicitly stated
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Where possible, the number approached, screened, and eligible prior to random assignment, with reasons for dropout

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
	13b	For each group, losses and exclusions after randomization, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Including socioeconomic variables where applicable
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	*Indicate availability of trial data
Outcomes and estimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre- specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	

Section	Item #	Standard CONSORT Description	Proposed CONSORT-SPI Items
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Any involvement of the intervention developer in the design, conduct, analysis, and reporting of the trial
			Declaration of any other potential interests
*Incentives	26		*Incentives offered as part of the trial
*Stakeholder involvement	27		*Stakeholder involvement in trial design, conduct, and/or analyses (e.g., practitioners, policymakers, participant representatives)

*Indicates it might move to another section
Indicates that this wording may be changed

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Developing a Reporting Guideline for Social and Psychological Intervention Trials

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Abstract

Social and psychological interventions are often complex. Understanding randomized controlled trials (RCTs) of these complex interventions requires a detailed description of the interventions tested and the methods used to evaluate them; however, RCT reports often omit, or inadequately report, this information. Incomplete and inaccurate reporting hinders the optimal use of research, wastes resources, and fails to meet ethical obligations to research participants and consumers. In this article, we explain how reporting guidelines have improved the quality of reports in medicine and describe the ongoing development of a new reporting guideline for RCTs: Consolidated Standards of Reporting Trials-SPI (an extension for social and psychological interventions). We invite readers to participate in the project by visiting our website, in order to help us reach the best-informed consensus on these guidelines (http://tinyurl.com/CONSORT-study).

Keywords

randomized controlled trial, RCT, CONSORT-SPI, reporting guideline, reporting standards

Introduction

Social and psychological interventions aim to improve physical health, mental health, and associated social outcomes. They are often complex and typically involve multiple, interacting intervention components (e.g., several behavior change techniques) that may act and target outcomes on several levels (e.g., individual, family, and community; Medical Research Council [MRC], 2008). Moreover, these interventions may be contextually dependent upon the hard-to-control environments in which they are delivered (e.g., health care settings and correctional facilities; Bonell, 2002; Pawson, Greenhalgh, Harvey, & Walshe, 2004). The functions and processes of these interventions may be designed to accommodate particular individuals or contexts, taking on different forms while still aiming to achieve the same objective (Bonell, Fletcher, Morton, Lorenc, & Moore, 2012; Hawe, Shiell, & Riley, 2004).

Complex interventions are common in public health, psychology, education, social work, criminology, and related disciplines. For example, multisystemic therapy (MST) is an intensive intervention for juvenile offenders. Based on social ecological and family system theories, MST providers target a variety of individual, family, school, peer, neighborhood, and community influences on psychosocial and behavioral problems (Henggeler, Schoenwald, Rowland, & Cunningham, 2002). Treatment teams of professional therapists and caseworkers work with individuals, their families, and their peer groups to provide tailored services (Littell, Campbell, Green, & Toews, 2009). These services may be delivered in homes, social care, and community settings. Other examples of social and psychological interventions may be found in reviews by the Cochrane Collaboration (2013; e.g., the Developmental, Psychosocial, and Learning Problems Group; the Cochrane Public Health Group) and the Campbell Collaboration (2013).

To understand their effects and to keep services up to date, academics, policy makers, journalists, clinicians, and consumers rely on research reports of intervention studies in scientific journals. Such reports should explain the methods, including the design, delivery, uptake, and context of interventions, as well as subsequent results. Accurate, complete, and transparent reporting is essential for readers to make best use of new evidence, to achieve returns on research investment, to meet ethical obligations to research participants and consumers of interventions, and to minimize waste in research.

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However, reports of randomized controlled trials (RCTs) are often poorly reported within and across disciplines including criminology (Perry, Weisburd, & Hewitt, 2010), social work (Naleppa & Cagle, 2010), education (Torgerson, Torgerson, Birks, & Porthouse, 2005), psychology (Michie et al., 2011; Stinson, McGrath, & Yamada, 2003), and public health (Semaan et al., 2002). Biomedical researchers have developed guidelines to improve the reporting of RCTs of health-related interventions (Schulz, Altman, & Moher, for the CONSORT Group, 2010). However, many social and behavioral scientists have not fully adopted these guidelines, which may not be wholly adequate for social and psychological interventions in their current form (Bonell, Oakley, Hargreaves, Strange, & Rees, 2006; Davidson et al., 2003; Perry et al., 2010; Stinson et al., 2003). Because of the unique features of these interventions, updated reporting guidance is needed.

This article describes the development of a reporting guideline that aims to improve the quality of reports of RCTs of social and psychological interventions. We explain how reporting guidelines have improved the quality of reports in medicine, and why guidelines have not yet improved the quality of reports in other disciplines. We then introduce a plan to develop a new reporting guideline for RCTs—Consolidated Standards of Reporting Trials (CONSORT)-SPI (an extension for social and psychological interventions)—which will be written using recommend techniques for guideline development and dissemination (Moher, Schulz, Simera, & Altman, 2010). Wide stakeholder involvement and consensus are needed to create a useful, acceptable, and evidence-based guideline, so we hope to recruit stakeholders from multiple disciplines and professions.

Randomized trials are not the only rigorous method for evaluating interventions; many alternatives exist when RCTs are not possible or appropriate due to scientific, practical, and ethical concerns (Bonell et al., 2011). Nonetheless, RCTs are important to policy makers, practitioners, scientists, and service users, as they are generally considered the most valid and reliable research method for estimating the effectiveness of interventions (Chalmers, 2003). Moreover, many of the issues faced in reporting RCTs also relate to other evaluation designs. As a result, this project will focus on standards for RCTs, which could then also inform the development of future guidelines for other evaluation designs.

Impact of CONSORT Guidelines

Reporting guidelines list (in the form of a checklist) the minimum information required to understand the methods and results of studies. They do not prescribe research conduct, but facilitate the writing of transparent reports by authors and appraisal of reports by research consumers. For example, the CONSORT Statement 2010 is an evidence-based guideline; to identify items, the developers reviewed evidence of trial design and conduct that could contribute to bias. Using consensus methods, they developed a checklist of 25 items and a flow diagram (Schulz et al., 2010). CONSORT has improved the reporting of thousands of medical experiments (Turner et al., 2012). It has been endorsed by over 600 journals (Moher, Altman, Schulz, & Elbourne, 2004), and it is supported by the Institute of Educational Sciences (Torgerson et al., 2005). CONSORT is the only guideline for reporting RCTs that has been developed with such rigor, and it has remained more prominent that any other guideline for over 15 years; for greatest impact, any further reporting guidelines related to RCTs should be developed in collaboration with the CONSORT Group.

Limitations of Previous Reporting Guidelines for Social and Psychological Interventions

Researchers and journal editors in the social and behavioral sciences are generally aware of CONSORT but often object that it is not fully appropriate for social and psychological interventions (Bonell et al., 2006; Davidson et al., 2003; Perry et al., 2010; Stinson et al., 2003). As a result, uptake of CONSORT guidelines in these disciplines is low. While some criticisms are due to inaccurate perceptions about common features of RCTs across disciplines, many relate to real limitations for social and psychological interventions (Mayo-Wilson, 2007). For example, CONSORT is most relevant to RCTs in medical disciplines; it was developed by biostatisticians and medical researchers with minimal input from experts in other disciplines. Journal editors, as well as social and behavioral science researchers, believe there is a need to include appropriate stakeholders in developing a new, targeted guideline to improve uptake in their disciplines (Gill, 2011; Torgerson et al., 2005). The CONSORT Group has produced *extensions* of the original CONSORT Statement relevant to social and psychological interventions, such as additional checklists for cluster (Campbell, Elbourne, & Altman, 2004), nonpharmacological (Boutron et al., 2008a), pragmatic (Zwarenstein et al., 2008), and quality of life RCTs (Calvert, Blazeby, Revicki, Moher, & Brundage, 2011). These extensions provide important insights, but complex social and psychological interventions, for example, include multiple, interacting components at several levels, with various outcomes. These RCTs require use of several extensions at once, creating a barrier to guideline uptake; increasing intervention complexity also gives rise to new issues that are not included in existing guidelines. Therefore, simply disseminating CONSORT guidelines as they stand is insufficient, as this would not address the need for editors and authors to "buy-in" to this process. To improve uptake in these disciplines, CONSORT guidelines need to be extended to specifically address the important features of social and psychological interventions.

Social and behavioral scientists have developed other reporting guidelines, including the Workgroup for Intervention Development and Evaluation Research (WIDER) Recommendations for behavioral change interventions (Abraham, for the WIDER, 2009; Michie et al., 2011), the American Educational Research Association's (AERA, 2006) Standards for Reporting Research, the REPOrting of Studies in Education (REPOSE) guidelines for primary research in education (Newman & Elbourne, 2004), and the Journal Article Reporting Standards

(JARS) of the American Psychological Association (APA) Publications and Communications Board Working Group on JARS (2008). While they address issues not covered by the CONSORT Statement and its extensions, these guidelines (except for JARS; APA Publications and Communications Board Working Group on JARS, 2008) do not provide specific guidance for RCTs. Moreover, compared with the CONSORT Statement and its official extensions, guidelines in the social and behavioral sciences have not consistently followed optimal techniques for guideline development and dissemination that are recommended by international leaders in the advancement of reporting guidelines (Moher, Schulz, et al., 2010), such as the use of systematic literature reviews and formal consensus methods to select reporting standards (Grant, Montgomery, & Mayo-Wilson, 2012). Researchers in public health, psychology, education, social work, and criminology have noted that these guidelines could be more "user-friendly," and dissemination could benefit from up-to-date knowledge transfer techniques (Abraham, 2009; Armstrong et al., 2008; Davidson et al., 2003; Naleppa & Cagle, 2010; Perry & Johnson, 2008; Stinson et al., 2003; Torgerson et al., 2005).

For example, JARS—a notable and valuable guideline for empirical psychological research—is endorsed by few journals outside of the APA, whereas CONSORT is endorsed by hundreds of journals internationally. According to ISI Web of Knowledge and Google Scholar citations, JARS is cited approximately a dozen times annually, while CONSORT guidelines are cited hundreds of times per year. Moreover, the APA commissioned a select group of APA journal editors and reviewers to develop JARS, and the group based most of their work on existent CONSORT guidelines; by comparison, official CONSORT extensions have been developed using rigorous consensus methods, have involved various international stakeholders in guideline development and dissemination, and update content on the most recent scientific literature. Nonetheless, no current CONSORT guideline adequately addresses the unique features of social and psychological interventions. This new CONSORT extension will incorporate lessons from previous extensions, reporting guidelines, and the research literature to aid the critical appraisal, replication, and uptake of this research.

Aspects of Internal Validity

Internal validity is the extent to which the results of a study may be influenced by bias. Like other study designs, the validity of RCTs depends on high-quality execution. Poorly conducted RCTs can produce more biased results than well-conducted RCTs and well-conducted nonrandomized studies (Pildal et al., 2007; Prescott et al., 1999). For example, evidence indicates that RCTs that do not adequately conceal the randomization sequence can exaggerate effect estimates by up to 30% (Schulz, Chalmers, Hayes, & Altman, 1995), while low-quality reports of these RCTs are associated with effect estimates exaggerated by up to 35% (Moher et al., 1999). Social and psychological intervention RCTs are susceptible to these risks of bias as well.

Some aspects of internal validity, although included in CONSORT, remain poorly reported—even in the least complex social and psychological intervention studies. Reports of RCTs should describe procedures for minimizing selection bias, but reports often omit information about random sequence generation and allocation concealment (Ladd, McCrady, Manuel, & Campbell, 2010; Perry & Johnson, 2008), and psychological journals report methods of sequence generation less frequently than medical journals (Stinson et al., 2003). A review of educational reports found no studies that adequately reported allocation concealment (Torgerson et al., 2005), and reports in criminology often lack information about randomization procedures (Gill, 2011; Perry et al., 2010). RCTs of social and psychological interventions may also use nontraditional randomization techniques, such as stepped wedge or natural allocation (MRC, 2011), which need to be thoroughly described. In addition, reports of social and psychological intervention trials often fail to include details about trial registration, protocols, and adverse events (Ladd et al., 2010; Perry & Johnson, 2008), which may include important negative consequences at individual, familial, and community levels.

Other aspects of CONSORT may require greater emphasis or modification for RCTs of social and psychological interventions. In developing this CONSORT extension, we expect to identify new items and to adapt existing items that relate to the internal validity. These may include items discussed during the development of previous CONSORT extensions or other guidelines, as well as items suggested by participants in this project. For example, it may not be possible to blind participants and providers of interventions, but blinding of outcome assessors is often possible but rarely reported, and few studies explain if blinding was maintained or how lack of blinding was handled (Davidson et al., 2003; Ladd et al., 2010; Perry & Johnson, 2008). In social and psychological intervention studies, outcome measures are often subjective, variables may relate to latent constructs, and information may come from multiple sources (e.g., participants and providers). While an issue in other areas of research, the influence on RCT results of the quality of subjective outcome measures in social and psychological intervention research has long been highlighted, given their prevalence in social and psychological intervention research (Marshall et al., 2000). Descriptions of the validity, reliability, and psychometric properties of such measures are therefore particularly useful for social and psychological intervention trials, especially when they are not widely available or discussed in the research literature (Campbell et al., 2004; Fraser, Galinsky, Richman, & Day, 2009). Moreover, multiple measures may be analyzed in several ways, so authors need to transparently report which procedures were performed and to explain their rationale.

Aspects of External Validity

External validity is the extent to which a study's results are applicable in other settings or populations. Currently, given

that RCTs are primarily designed to increase the internal validity of study findings, the CONSORT Statement gives relatively little attention to external validity. While high internal validity is an important precondition for any discussion of an RCT's external validity, updating the CONSORT Statement to include more information about external validity is critical for the relevance and uptake of a CONSORT extension for social and psychological interventions. These interventions may be influenced by context, as different underlying social, institutional, psychological, and physical structures may yield different causal and probabilistic relations between interventions and observed outcomes. Contextual information is necessary to compare the effectiveness of an intervention across time and place (Cartwright & Munro, 2010). Lack of information relevant to external validity may prevent practitioners or policy makers from using evidence appropriately to inform decision making; yet, existing guidelines do not adequately explain how authors should describe (a) how interventions work, (b) for whom, and (c) under what conditions (Moore & Moore, 2011).

First, it is useful for authors to explain the key components of interventions, how those components could be delivered, and how they relate to the outcomes selected. At present, authors can follow current standards for reporting interventions without providing adequate details about complex interventions (Shepperd et al., 2009). Many reports neither contain sufficient information about the interventions tested nor reference treatment manuals (Glasziou, Meats, Heneghan, & Shepperd, 2008). Providing logic models—as described in the MRC Framework for Complex Interventions (Craig et al., 2008)—or presenting theories of change can help elucidate links in causal chains that can be tested, identify important mediators and moderators, and facilitate syntheses in reviews (Ivers et al., 2012). Moreover, interventions are rarely implemented exactly as designed, and complex interventions may be designed to be implemented with some flexibility, in order to accommodate differences across participants (Hawe et al., 2004), so it is important to report how interventions were *actually delivered* by providers and *actually received* by participants (Hardeman et al., 2008). Particularly for social and psychological interventions, the integrity of implementing the intended functions and processes of the intervention are essential to understand (Hawe et al., 2004). As RCTs of a particular intervention can yield different relative effects depending on the nature of the control groups, information about delivery and uptake should be provided for *all* trial arms (McGrath, Stinson, & Davidson, 2003).

Second, reports should describe recruitment processes and representativeness of samples. Participants in RCTs of social and psychological intervention are often recruited outside of routine practice settings via processes that differ from routine services (AERA, 2006). An intervention that works for one group of people may not work for people living in different cultures or physical spaces, or it may not work for people with slightly different problems and comorbidities. Enrolling in an RCT can be a complex process that affects the measured and unmeasured characteristics of participants, and recruitment may differ from how users normally access interventions. Well-described RCT reports will include the characteristics of all participants (volunteers, those who enrolled, and those who completed) in sufficient detail for readers to assess the comparability of the study sample to populations and in everyday services (AERA, 2006; APA Publications and Communications Board Working Group on JARS, 2008; Evans & Brown, 2003)

Finally, given that these interventions often occur in social environments, reports should describe factors of the RCT context that are believed to support, attenuate, or frustrate observed effects (Moore, 2002). Interventions may differ across groups of different social or socioeconomic positions, and equity considerations should be addressed explicitly (Tugwell et al., 2010; Welch et al., 2012). Several aspects of setting and implementation may be important to consider, such as administrative support, staff training and supervision, organizational resources, the wider service system, and concurrent political or social events (Bonell et al., 2012; Fixsen, Naoom, Blase, Friedman, & Wallace, 2005; Shepperd et al., 2009; Wang, Moss, & Hiller, 2006). Reporting process evaluations may help understand mechanisms and outcomes.

Developing a New CONSORT Extension

This new reporting guideline for RCTs of social and psychological interventions will be an official extension of the CONSORT Statement. Optimally, it will help improve the reporting of these studies. Like other official CONSORT extensions (Boutron et al., 2008a; Campbell et al., 2004; Hopewell et al., 2008; Zwarenstein et al., 2008), this guideline will be integrated with the CONSORT Statement and previous extensions, and updates of the CONSORT Statement may incorporate references to this extension.

The project is being led by an international collaboration of researchers, methodologists, guideline developers, funders, service providers, journal editors, and consumer advocacy groups. We will be recruiting participants in a manner similar to other reporting guideline initiatives—identifying stakeholders through literature reviews, the project's International Advisory Group, and stakeholder-initiated interest in the project (Michie et al., 2011; Schulz et al., 2010). We hope to recruit stakeholders with expertise from all related disciplines and regions of the world, including low- and middle-income countries. Methodologists will identify items that relate to known sources of bias, and they will identify items that facilitate systematic reviews and research synthesis. Funders will consider how the guideline can aid the assessment of grant applications for RCTs and methodological innovations in intervention evaluation. Practitioners will identify information that can aid decision making. Journal editors will identify practical steps to implement the guideline and to ensure uptake.

We will use consensus techniques to reduce bias in group decision making and to promote widespread guideline uptake and knowledge translation activities upon project completion (Murphy et al., 1998). Following rigorous reviews of existing guidelines and current reporting quality, we will conduct an

online Delphi process to identify a prioritized list of reporting items to consider for the extension. That is, we will invite a group of experts to electronically answer questions about reporting items and to suggest further questions. We will circulate their feedback to the group and ask a second round of questions. The Delphi process will capture a variety of international perspectives and allow participants to share their views anonymously. Following the Delphi process, we will host a consensus meeting to review the findings and to generate a list of minimal reporting standards, mirroring the development of previous CONSORT guidelines (Boutron et al., 2008b; Schulz et al., 2010; Zwarenstein et al., 2008).

Together, participants in this process will create a checklist of reporting items and a flowchart for reporting social and psychological intervention RCTs. In addition, we will develop an Explanation and Elaboration (E&E) document to explain the scientific rationale for each recommendation and to provide examples of clear reporting; a similar document was developed by the CONSORT group to help disseminate a better understanding for each included checklist item (Moher, Hopewell, et al., 2010). This document will help persuade editors, authors, and funders of the importance of the guideline. It will be a useful pedagogical tool, helping students and researchers understand the methods for conducting RCTs of social and psychological interventions, and it will help authors meet the guideline requirements (Moher, Schulz, et al., 2010).

The success of this project depends on widespread involvement and agreement among key international stakeholders in research, policy, and practice. For example, previous developers have obtained guideline endorsement by journal editors who require authors and peer reviewers to use the guideline during article submission and who must enforce journal article word limits (Michie, Fixsen, Grimshaw, & Eccles, 2009). Many journal editors have already agreed to participate, and we hope other researchers and stakeholders will volunteer their time and expertise.

Conclusion

Reporting guidelines help us use scarce resources efficiently and ethically. RCTs are expensive, and the public have a right to expect returns on their investments through transparent, usable reports. When RCT reports cannot be used (for whatever reason), resources are wasted. Participants contribute their time and put themselves at risk of harm to generate evidence that will help others, and researchers should disseminate that information effectively (Davidson et al., 2003). Policy makers benefit from research when developing effective, affordable standards of practice and choosing which programs and services to fund. Administrators and managers are required to make contextually appropriate decisions. Transparent reporting of primary studies is essential for their inclusion in systematic reviews that inform these activities. For example, there is the need to determine if primary studies are comparable, examine biases within included studies, assess the generalizability of results, and implement effective interventions. Finally, we hope this guideline will reduce the effort and time required for authors to write reports of RCTs.

RCTs are not the only valid method for evaluating interventions (Bonell et al., 2011) nor are they the only type of research that would benefit from better reporting (Goldbeck & Vitiello, 2011). Colleagues have identified the importance of reporting standards for other types of research, including observational (von Elm et al., 2007), quasi-experimental (Des Jarlais, Lyles, Crepaz, & the TREND Group, 2004), and qualitative studies (Tong, Sainsbury, & Craig, 2007). This guideline is the first step toward improving reports of many designs for evaluating social and psychological interventions, which we hope will be addressed by this and future projects. We invite stakeholders from disciplines that frequently research these interventions to join this important effort and participate in guideline development by visiting our website, where they can find more information about the project, updates on its progress, and sign up to be involved (http://tinyurl.com/CONSORT-study).

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The CONSORT-SPI (social and psychological interventions) International Advisory Group includes J. Lawrence Aber, distinguished professor of applied psychology and public policy, Steinhardt School of Culture, Education, and Human Development, New York University; Chris Bonell, professor of sociology and social intervention, Centre for Evidence-Based Intervention, University of Oxford; David M. Clark, chair of psychology, Department of Experimental Psychology, University of Oxford; Frances Gardner, professor of child and family psychology, Centre for Evidence-Based Intervention, University of Oxford; Steven Hollon, American Psychological Association Guidelines Committee (Chair), Gertrude Conaway Professor of Psychology, Department of Psychology, Vanderbilt University; Jim McCambridge, senior lecturer in Behaviour Change, Department of Social and Environmental Health Research, London School of Hygiene and Tropical Medicine; Susan Michie, professor of health psychology, Department of Clinical, Educational & Health Psychology, University College London; Laurence Moore, professor of public health improvement, Cardiff School of Social Sciences, Cardiff University; Mark Petticrew, professor of public health evaluation, Department Social and Environmental Health Research, London School of Hygiene and Tropical Medicine; Lawrence Sherman, Wolfson Professor of Criminology, Cambridge Institute of Criminology, Cambridge University; Steve Pilling, director, Centre for Outcomes Research and Effectiveness, University College London; James Thomas, associate director EPPI-Centre, reader in social policy, Institute of Education, University of London; Elizabeth Waters, Jack Brockhoff Chair of Child Public Health, McCaughey VicHealth Centre for Community Wellbeing, Melbourne School of Population & Global Health, University of Melbourne, Australia; David Weisburd, director and Walter E. Meyer Professor of Law and Criminal Justice, Institute of Criminology, Hebrew University Faculty of Law, Jerusalem; Joanne Yaffe, associate professor, College of Social Work, University of Utah. PM, EMW, and SG

conceived of the idea for the project. All authors helped to draft the article, and all have read and approved the final article.

Declaration of Conflicting Interests

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Protocol for CONSORT-SPI: an extension for social and psychological interventions

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Abstract

Background: Determining the effectiveness of social and psychological interventions is important for improving individual and population health. Such interventions are complex and, where possible, are best evaluated by randomised controlled trials (RCTs). The use of research findings in policy and practice decision making is hindered by poor reporting of RCTs. Poor reporting limits the ability to replicate interventions, synthesise evidence in systematic reviews, and utilise findings for evidence-based policy and practice. The lack of guidance for reporting the specific methodological features of complex intervention RCTs contributes to poor reporting. We aim to develop an extension of the Consolidated Standards of Reporting Trials Statement for Social and Psychological Interventions (CONSORT-SPI).

Methods/design: This research project will be conducted in five phases. The first phase was the project launch, which consisted of the establishment of a Project Executive and International Advisory Group, and recruitment of journal editors and the CONSORT Group. The second phase involves a Delphi process that will generate a list of possible items to include in the CONSORT Extension. Next, there will be a formal consensus meeting to select the reporting items to add to, or modify for, the CONSORT-SPI Extension. Fourth, guideline documents will be written, including an explanation and elaboration (E&E) document that will provide detailed advice for each item and examples of good reporting. The final phase will comprise guideline dissemination, with simultaneous publication and endorsement of the guideline in multiple journals, endorsement by funding agencies, presentations at conferences and other meetings, and a dedicated website that will facilitate feedback about the guideline.

Conclusion: As demonstrated by previous CONSORT guidelines, the development of an evidence-based reporting guideline for social and psychological intervention RCTs should improve the accuracy, comprehensiveness, and transparency of study reports. This, in turn, promises to improve the critical appraisal of research and its use in policy and practice decision making. We invite readers to participate in the project by visiting our website (http://tinyurl.com/CONSORT-study).

Keywords: CONSORT-SPI, Randomised controlled trial, RCT, Reporting guidelines, Complex interventions

Background

Social and psychological interventions that aim to improve health and related outcomes are often complex and challenging to evaluate. As outlined in the Medical Research Council (MRC, UK) Framework for developing and evaluating complex interventions [1], they usually have multiple, interacting components at several levels, and may have multiple and variable outcomes that require sophisticated assessments and analyses. Randomised controlled trials (RCTs) provide the least biased estimates of effectiveness despite these complexities [2]. When reported clearly and completely, RCTs can be appropriately included in systematic reviews and practice guidelines, leading to better routine service and policy-related outcomes. When detailed information about study conduct is poorly reported, or not reported at all, the link between research and practice is weakened, and scarce resources are wasted [3]. Thus, to have its intended impact, the

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methods for reporting trials must be as rigorous as those for conducting them.

Reporting guidelines

Reporting guidelines do not prescribe research conduct; they suggest those items of information that are necessary to understand how a study was conducted. The most widely-cited reporting guideline is the Consolidated Standards of Reporting Trials (CONSORT) Statement. Its main checklist has 25-items for reporting two-group parallel RCTs [4], and extension guidelines address other types of medical RCTs, such as cluster [5], pragmatic [6], and non-pharmacological intervention trials [7]. Opinion leaders and decision makers made rigorous use of empirical evidence and consensus development techniques to inform the content of CONSORT and its extension guidelines [8]. Since their publication, the reporting of thousands of medical RCTs have improved [9], with reports published in journals endorsing CONSORT improving more than those in other journals [10,11].

A new guideline for social and psychological intervention trials

Despite improvements in the reporting of RCTs in medical disciplines, several studies indicate that the reporting quality of RCTs in the social and behavioural sciences remains suboptimal [12-16]. We conducted a systematic review of reporting guidelines for social and psychological intervention RCTs, as well as the quality of current reports of these studies. This review concluded that existing guidelines lacked the required rigour in their development, they have important limitations in their included reporting guidance, and they are poorly disseminated. Furthermore, most leading journals in these disciplines do not ask authors to follow any reporting guides, and important details are routinely missing from publications of social and psychological intervention RCTs [17].

To address these issues, many researchers and journal editors have proposed amending the CONSORT Statement to address these important complexities of social and psychological interventions and of their evaluation [18-23]. A new CONSORT extension developed by drawing on previous reporting guidance, up-to-date scientific literature, and stakeholder involvement and insight, could significantly improve the reporting of social and psychological intervention RCTs. This paper describes the project plan for a new guideline—CONSORT-SPI—which will include a checklist of reporting items and a participant flowchart that offer authors recommendations to accurately, comprehensively, and transparently describe these studies.

Methods/design

The methods will follow recommended techniques for developing and disseminating reporting guidelines [9,24]. Aspects of these methods have been previously used to develop the CONSORT statement [4] and its extensions [25-28]; the SPIRIT statement for trial protocols [29]; and other guidelines [5,6]. This earlier work suggests the project will take 20 to 24 months to complete [24]. The project will involve five phases: the project launch, a Delphi process, a consensus development conference, writing up the guideline documents, and guideline implementation (see Figure 1).

Phase one: project launch

To ensure project success, the following have already been secured for the launch of the project: a project executive; an International Advisory Group (IAG) of key opinion leaders across core fields; participation from high impact-factor journal editors for the consensus process; agreement from and collaboration with the CONSORT Group; and funding to support guideline development and dissemination.

Project executive

The project executive (PM, EMW, SG, SM, GM, SH, and DM) has developed the project protocol and secured funding to complete the project, and are assembling the IAG and recruiting various stakeholders (*e.g.*, trialists, methodologists, practitioners, policy makers, funders, and recipients of services). The project executive will also run future phases of the project, including the Delphi process, consensus meeting, write-up of the resultant guideline documents, and the implementation strategy.

International advisory group (IAG)

This team of key opinion leaders will advise at each project stage, and will help draft and disseminate the final guideline documents. Members are leading experts in social and psychological interventions across various disciplines (see Acknowledgments). They will help recruit stakeholders to participate in the project and identify topics to discuss at each stage. They will aid dissemination by endorsing and using the guideline, and by presenting it to relevant stakeholders in their respective fields.

Journal editors

The most widely used reporting guidelines have enlisted journal editors during development and acquired official journal endorsement upon completion [9]. To begin this effort, editors of high impact-factor journals in key disciplines have been approached, and many have already agreed to participate. We encourage any other journal

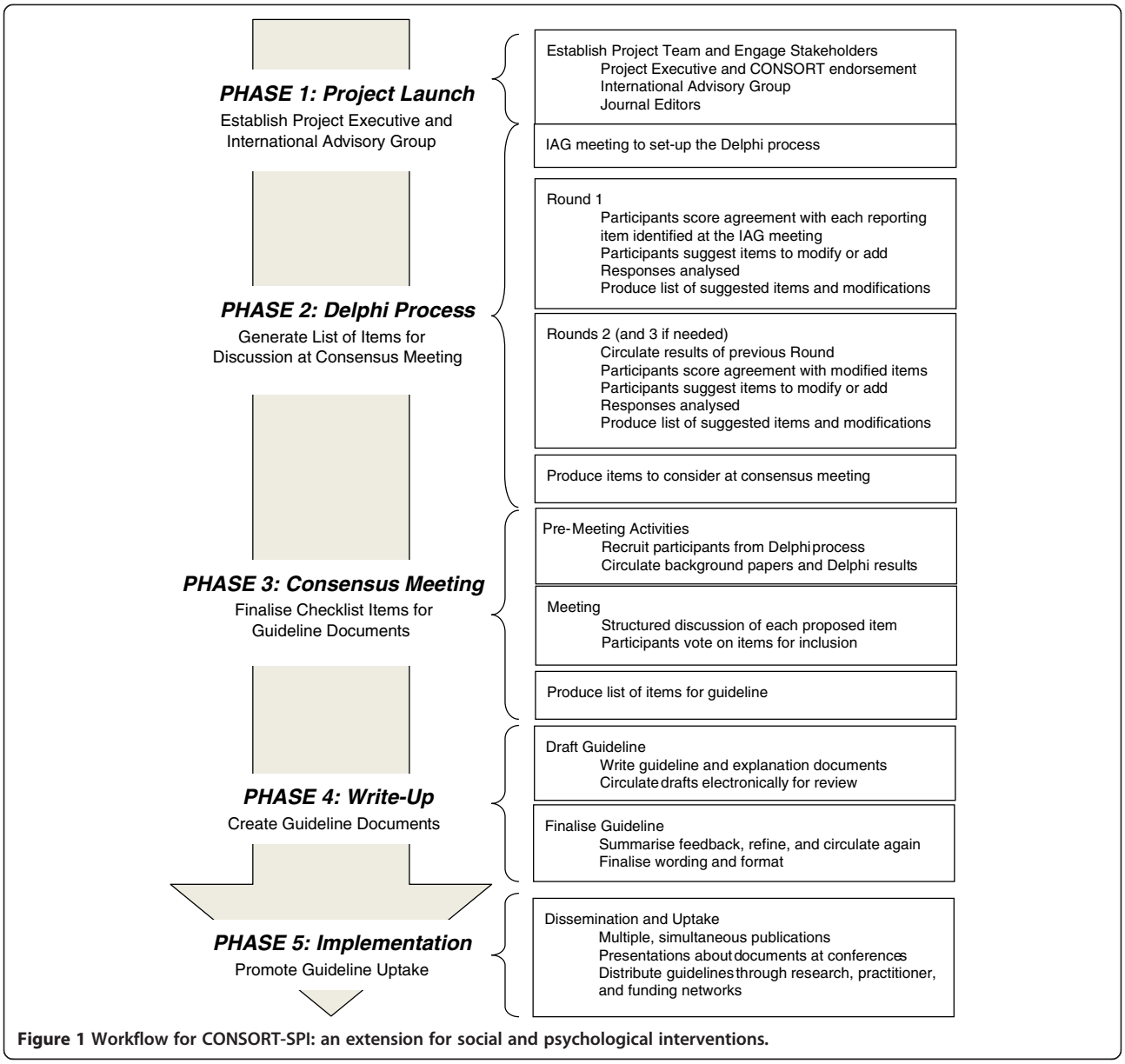

Figure 1 Workflow for CONSORT-SPI: an extension for social and psychological interventions.

editors interested in participating in the project to contact us [30-37].

CONSORT group

To increase successful uptake, new reporting guidelines for RCTs should be officially related to the CONSORT Statement. Previous reviews have found no high impact-factor journal that explicitly recommends an RCT reporting guideline other than the CONSORT statement [38]. Members of the CONSORT Group (DM and SH) are involved in this project, and the resultant guideline will be an official extension of the CONSORT Statement. The CONSORT Group's success, collective experience, and prominence in the reporting guideline field—including the more recent SPIRIT guidelines for reporting protocols of trials [29]—will help to ensure the use of proper methods for developing and disseminating a high-quality reporting guideline.

Phase two: the Delphi process

The purpose of phase two is to identify those areas in the reporting of social and psychological intervention trials that are most important for inclusion in the guideline. To involve a wide range of participants at this phase, an online, modified Delphi process will be conducted. The Delphi process will consist of a series of structured questionnaires completed anonymously by expert participants. Summarised responses from each questionnaire will be returned to the participants after each round, along with a new questionnaire to answer,

until consensus is reached [39]. This process will help address areas of uncertainty, and measure and reach consensus [40].

IAG meeting

The IAG will meet before round one of the Delphi process to nominate items for the initial questionnaire and to suggest credible participants for the process [39]. Prior to the meeting, the IAG will receive literature reviews regarding previous reporting guidelines for social and psychological intervention RCTs and their reporting quality, together with feedback from a consultation held at the 2012 Cochrane Colloquium [41]. These literature reviews will be used to generate items for the Delphi round one survey. Procedures for data collection, data analysis, and cut-offs for consensus [42] will be decided in light of recommended techniques for guideline development [9], and previous Delphi processes used to develop reporting guidelines [27,43].

Recruitment

To enhance credibility and ensure widespread acceptance, the project will recruit informed and interested participants representing stakeholders that the guideline is intended to influence [42]. The IAG will help identify an initial list of stakeholders who extensively publish, fund, or utilise social and psychological intervention research, and a 'snowball recruitment' approach will be used via collaborators in relevant research and professional networks [4,12]. In order to engage those who might not be identified through snowball recruitment, the project website enables stakeholders to register their interest in participating. In addition, a commentary written by the study team and co-published in several journals, invites other stakeholders to participate [30-37]. Intervention researchers, methodologists, and guideline developers will form a substantial number of the participants [9]. Editors of high impact-factor journals will be invited for their expertise and to ensure uptake upon completion [44] Funders of social and psychological intervention studies will be invited to provide expertise and to promote use of the guideline for assessing grant applications [6]. Practitioners will help identify issues of relevance to practice [45]. Policy makers will help identify items, and they will assist in the creation of a user-friendly document and standards [24,46]. Representatives from consumer groups will advance the relevance of research reports to the ultimate recipients of services.

Structure

Identified stakeholders will be invited to participate in an online Delphi survey to nominate checklist items for the CONSORT-SPI Extension. In each round, participants will be asked to rate (on a 1 to 10 Likert scale) the importance of including proposed checklist items, explain the reasons for their ratings, make suggestions for modifications, and indicate any missing items that should be considered. We expect the IAG to propose 25 to 70 checklist items in round one [7,43]. Items in later rounds will be based on responses from each previous round, and participants will receive summaries of quantitative and qualitative responses from the previous round to inform their new rankings [47]. At the end of the Delphi process, high-ranking items will be proposed for inclusion in the checklist during the consensus meeting. Low-ranking items will not be considered at the consensus meeting unless the project executive identifies valuable issues to discuss. Middle-ranking items will be discussed at the consensus meeting for possible inclusion or exclusion. We estimate that two to three rounds will be needed to obtain consensus, and that each round will take 30 to 45 minutes to complete [47].

Phase three: consensus development conference

The purpose of phase three is to select the specific reporting items to be included in the new guideline. A consensus development conference will be held to determine guideline content, rather than wording or format [40]. This time has been allotted to allow sufficient time for thorough discussion, reducing hasty decision making that can hinder judgment [42].

Participants

Participants will be recruited by discipline from the Delphi process by the project executive and the IAG, to include a range of stakeholder perspectives [8]. The size of the group (20 to 30 participants) will balance diversity of opinion with opportunities for interaction [9].

Structure

The consensus meeting will follow methods [40] used in previous CONSORT meetings [4,6,25,27]. Literature reviews and the results of the Delphi process will be provided to participants in advance, and the conference will include background presentations [27], to ground conversations on empirical information and to facilitate cohesive discussion [42]. Participants will be led in structured discussions of, and vote on, each item proposed for the checklist from the Delphi process [27]. Care will be taken to ensure that all participants express views, that all ideas are discussed in-depth, and that assertive participants do not dominate the discussion [42]. Voting will be confidential using anonymous ballots to promote honest answers and allow participants to rethink their position if a re-vote is needed [47]. The meeting will conclude with discussion about optimising dissemination, and members of the group will commit to specific efforts to this end [27].

Phase four: drafting the guideline documents

The purpose of this phase is to draft the guideline documents so that their wording and content is clear, precise, and suitable for all relevant disciplines.

Draft guidelines and elaboration document

Following the consensus meeting, the proposed checklist will be reviewed by the project executive. The first goal will be to draft a checklist using concise, unambiguous, yet comprehensive wording. Each item will be supported with empirical evidence of previous poor reporting and implications for internal and external validity. In addition to the guideline statement, an Explanation and Elaboration (E&E) Document will explain in-depth the scientific rationale for each recommendation and provide an example of clear reporting for each item. This additional document will help editors and authors understand the importance of these guidelines, students and researchers understand the relevant issues, and authors meet the guideline requirements [9].

Feedback

Drafts of the checklist will be circulated to consensus group participants to check that the documents accurately represent the decisions made during the meeting, provide examples of good reporting for specific items, and are useful for their intended purpose [27]. Feedback is important to evaluate the validity of consensus methods [42]. Responses will be incorporated into a statement that reports the project rationale, process methodology, and final included reporting items.

Phase five: guideline implementation

The goal of the dissemination plan is to maximise awareness, understanding, and use of the CONSORT Extension when reporting social and psychological intervention trials.

Dissemination methods

The dissemination strategy includes stakeholder involvement in the design and execution of this project, ensuring that the guideline will be acceptable and widely endorsed. Next, simultaneous publications in multiple, high impact-factor journals will begin the process of dissemination and uptake [24]. The IAG will identify and approach the most appropriate journals in key disciplines to publish the guideline and provide an editorial supporting the guideline. The IAG will ask editors from all relevant journals to endorse the guideline. Endorsement will involve clear directions in each journal's 'Instructions to Authors' that the guideline should be followed and the checklist should be included in all relevant submissions [24,36].

Open-access publications are key to widespread uptake of the reporting guideline [44]. Our intention is to seek instant open access publications, allowing us to retain ownership of the work to facilitate broad dissemination. We will also make the guideline, and other relevant documents, including the E&E document, available on our website as well as other websites (*e.g.*, the CONSORT Group, the EQUATOR Network for reporting guidelines). A dedicated webpage will be used to discuss new, relevant evidence related to social and psychological intervention trials, and to ask the wider scientific community to provide feedback on their experiences of using the guideline, in order to allow for the guideline's continual development [48]. The project executive and IAG will present the guideline at influential conferences, professional bodies, and organisations within their respective fields.

Conclusion

These methods were chosen to develop the best reporting standards, generate consensus, and promote widespread dissemination and uptake of CONSORT-SPI. They are based on best practice and evidence-based principles. Research-informed purposive sampling by the IAG will provide a less biased selection of participants than the project executive could provide alone [42]; the involvement of various stakeholders in guideline development will ensure that a variety of perspectives are captured. The resulting multidisciplinary, international consensus will maximise the impact of the guideline beyond any specialist field [40]. Moreover, formal consensus development methods are increasingly employed in guideline development, especially when evidence (and opinion) are contradictory or insufficient [39]. These techniques capture the advantages of group decision-making while overcoming biases associated with less structured group methods [42]. Previous research suggests that these methods are the most appropriate for our purposes [40], and are beneficial to use in combination [49]. For example, the online Delphi process is a cost-effective way to involve a large number of international and cross-disciplinary participants [47], and it has been successful in previous guidelines [4,6,11,13].

If executed successfully, the outputs from this project will help authors write clear reports, create a framework for reviewers to assess publications, expedite funding evaluations, provide a pedagogical tool for training students and researchers in trial methodology, and help research consumers evaluate RCT validity and applicability [50,51]. In these ways, the guideline aims to improve the reporting quality of social and psychological intervention RCTs and facilitate the efficient, effective transfer of research evidence into real-world use. We invite readers to participate in the project by visiting our website (http://tinyurl.com/CONSORT-study).

Project website

For more on the CONSORT extension, see http://www.tinyurl.com/CONSORT-study.

Ethics

The conduct of this research project will conform to the appropriate ethical and legal standards regarding informed consent, confidentiality, and data storage. Ethics approval was obtained from the Department Research Ethics Committee (DREC) for the Department of Social and Intervention, University of Oxford (Ref: 2011-12_83).

Data preservation

We commit to the long-term preservation and availability for use by other research teams of the high-quality data produced by this project. The data will be prepared to allow independent usage. The Centre for Evidence Based Intervention (CEBI) at Oxford University is well placed to host this work. It has full University support for this project and the CONSORT Group is close at hand to assist where needed. All data will be safely stored and backed-up at CEBI.

Competing interests

The authors declare that they have no competing interest.

Authors' contributions

PM, EMW, and SG conceived of the idea for the project. All authors helped to draft the manuscript, and all have read and approved the final manuscript.

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Reporting Quality of Social and Psychological Intervention Trials: A Systematic Review of Reporting Guidelines and Trial Publications

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Abstract

Background: Previous reviews show that reporting guidelines have improved the quality of trial reports in medicine, yet existing guidelines may not be fully suited for social and psychological intervention trials.

Objective/Design: We conducted a two-part study that reviewed (1) reporting guidelines for and (2) the reporting quality of social and psychological intervention trials.

Data Sources: (1) To identify reporting guidelines, we systematically searched multiple electronic databases and reporting guideline registries. (2) To identify trials, we hand-searched 40 journals with the 10 highest impact factors in clinical psychology, criminology, education, and social work.

Eligibility: (1) Reporting guidelines consisted of articles introducing a checklist of reporting standards relevant to social and psychological intervention trials. (2) Trials reported randomised experiments of complex interventions with psychological, social, or health outcomes.

Results: (1) We identified 19 reporting guidelines that yielded 147 reporting standards relevant to social and psychological interventions. Social and behavioural science guidelines included 89 standards not found in CONSORT guidelines. However, CONSORT guidelines used more recommended techniques for development and dissemination compared to other guidelines. (2) Our review of trials (n = 239) revealed that many standards were poorly reported, such as identification as a randomised trial in titles (20% reported the information) and abstracts (55%); information about blinding (15%), sequence generation (23%), and allocation concealment (17%); and details about actual delivery of experimental (43%) and control interventions (34%), participant uptake (25%), and service environment (28%). Only 11 of 40 journals referenced reporting guidelines in ''Instructions to Authors.''

Conclusion: Existing reporting guidelines have important limitations in content, development, and/or dissemination. Important details are routinely missing from trial publications; most leading journals in social and behavioural sciences do not ask authors to follow reporting standards. Findings demonstrate a need to develop a CONSORT extension with updated standards for social and psychological intervention trials.

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Competing Interests: SG, EMW, and PM are currently involved in the development of a CONSORT extension for social and psychological interventions (http://www.tinyurl.com/CONSORT-study). This does not alter the authors' adherence to all the PLOS ONE policies on sharing data and materials.

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Introduction

Research in disciplines such as public health, psychology, education, social work, and criminology often involves complex interventions to improve health and related outcomes. Randomised controlled trials are increasingly used to evaluate these interventions and to inform decision-making in evidence-based policy and practice. However, these complex interventions have several unique features, such as multiple, interacting components (see Box 1)[1] that complicate critical appraisal of trial quality (e.g. risk of bias). Moreover, these interventions are often delivered in environments that are difficult to control and to measure, which makes reporting and interpretation of external validity (i.e., generalisability) difficult.[2]

High quality reports of complex intervention trials are important to diverse groups of stakeholders, including researchers,

journal editors, funding agencies, practitioners, policy-makers, and research participants. These research consumers depend on accurate, complete, and transparent reports to appraise the validity and generalisability of trials. To address these needs, researchers and journal editors have developed reporting guidelines[3] that highlight key information about internal validity, external validity, and knowledge transfer of trials (e.g., locating trials in databases, assessing conflicts of interest). Reporting guidelines should consist of reporting standards (i.e., recommendations about the content that authors should consistently and transparently report) that are based on previous research and developed via expert consensus using rigorous, systematic, and transparent methodology.[4,5]

The Consolidated Standards of Reporting Trials (CONSORT) Statement and its extensions are the preeminent guidelines for reporting trials. CONSORT is based on empirical evidence and expert consensus about biases related to trial validity.[6] Since its launch in 1996, CONSORT has had a considerable impact in the biomedical sciences; numerous reviews in the biomedical literature have shown an association between improvements in reporting quality and these guidelines.[7,8]

Despite improvements in the completeness of RCT reports, major deficiencies in reporting quality still exist,[8] indicating that further actions are needed. For example, while CONSORT guidelines are well-known in the social and behavioural sciences, there is less evidence of widespread uptake and implementation in these disciplines compared with biomedical disciplines. Several studies also indicate that deficiencies persist in the reporting of social and psychological intervention trials.[9,10,11,12,13] A common explanation is that current standards in prominent reporting guidelines are not adequately tailored to these trials. For example, the CONSORT Statement and its extensions have primarily focused on standards related to internal validity, but researchers are increasingly interested in the applicability of trial findings and have called for updated standards to improve the assessment of external validity.[14,15,16,17,18,19] For example, researchers have asked for more information related to process evaluations, such as intervention theory of change, assessment of intervention mechanisms during the trial, and relevant information about the influence of trial context.[14–16] To determine whether a new reporting guideline is needed, it is necessary (i) to assess the suitability of current reporting guidelines for social and psychological intervention trials and (ii) to investigate the quality of reports of these trials.

Objectives

Following recommended techniques for guideline development and dissemination,[3] a structured approach to reporting guideline development should begin with a needs assessment that (i) reviews whether an adequate guideline already exists for a given research method and (ii) obtains evidence of the reporting quality of published research using that method.[4] Though highly informative, previous reviews have not investigated the characteristics and methods of development of reporting guidelines specifically for social and psychological intervention trials. Moreover, previous reviews about the reporting quality of these trials have consisted of small samples and have assessed reporting quality according to a narrow set of reporting standards.[12,13,20]

We conducted a two-part study that examined:

1. the content, development, and dissemination of current reporting guidelines; and
2. the current reporting quality of social and psychological intervention trials across several disciplines according to a comprehensive set of reporting standards.

Methods

Eligibility Criteria

For the first part of the study, a reporting guideline had to consist of a published, peer-reviewed article that introduced a formal, itemised checklist of reporting standards relevant to trials of social and psychological interventions. In order to identify all published and potentially relevant reporting standards, quality assessment tools (e.g., tools designed to be used for critical appraisal) were also eligible. For practical reasons, we limited the search to guidelines available in English.[5] We excluded guidelines for the *design and conduct* of trials rather the *reporting* of trials, as well as tools pertaining to a specific intervention focus that is unrelated to social and psychological interventions (e.g., acupuncture, complementary medicine).

For the second part of the study (i.e., the review of trial reporting quality), a trial report had to discuss a randomised experiment of a complex intervention with psychological, social, or health outcomes. We excluded trial reports that: (i) described process evaluations without trial outcomes, (ii) evaluated only cost-effectiveness, (iii) used randomisation to balance order of exposure to conditions that were experienced by all participants, or (iv) explicitly evaluated medical or pharmacological interventions. No other eligibility criteria were used.

Search Strategy and Study Selection

For the first part of the study, we used an adapted version of a peer-reviewed electronic search strategy[21] to identify relevant reporting guidelines (see Text S1). We also searched three registries of reporting guidelines: the EQUATOR Network library of identified health research reporting guidelines (www.equator-network.org), a recent review on the development and contents of reporting guidelines for health research,[21] and a systematic review of studies assessing the quality of conducting or reporting trials.[22] We also searched references of all eligible guidelines identified through this process.

For the second part of the study, we conducted a hand search of journals' Table of Contents throughout the year 2010. From the ISI Web of Knowledge 2010 Journal Citation Reports (JCR) for Social Sciences, we identified journals publishing trials of complex interventions in clinical psychology, criminology, education, and social work. To obtain an extensive sample of trials, we searched the 10 journals with highest impact factors in each field (40 journals total) that published trials in the year 2010.

Data Abstraction

We first examined the content of reporting guidelines by compiling reporting standards from all identified guidelines into a comprehensive, non-redundant, itemised list of standards (see Appendix S1).[6] To assess the quality of reporting guideline development, we compared the techniques used by guideline developers to recommended techniques,[3,21] which were organised according to four phases of process: preliminary work, development of the guideline itself, publication, and dissemination activities (see Appendix S2). One reviewer (SG) assessed whether guidelines adhered to each standard.

We assessed guideline dissemination in several ways. Akin to previous studies,[4] we performed a full-text review of each journal's "Instructions to Authors" to identify references to

guidelines for reporting trials (e.g., instructions on the journal webpage, mention of a reporting guideline) and whether journals required authors to register trial protocols before recruiting participants. For each guideline, we also counted citations through November 2012 using Google Scholar, which provides a wide measure of impact across most publication mediums.[23] If a guideline was published in multiple journals or included an official explanatory document detailing how to adhere to its reporting standards, we combined the citations for all documents.

To assess the reporting quality of identified trials, two reviewers (SG and GJMT) independently assessed whether trial reports adhered to each standard in our comprehensive list of relevant reporting standards (Appendix S1). As the goal was to identify potential limitations in both guidelines and reporting quality, we used a comprehensive checklist to assess trial reports according to all published and potentially relevant reporting standards rather than a single instrument (such as the CONSORT Statement). Coding rules were adapted from previous studies about trial reporting quality.[9,24]

Before assessing the entire sample, the reviewers coded one trial report in each discipline and compared results to ensure consistent application of coding rules. The two reviewers then each coded the entire sample. Discrepancies in judgment were resolved through discussion and consensus. Using SPSS version 18, inter-rater agreement prior to discussion and consensus was calculated as $\kappa = 0.71$, indicating substantial agreement.[25] Data resolved after discussion were used for the final analyses.

Data Analysis

Similar to previous studies,[9,24] we analysed guideline content by mapping identified reporting standards onto standards included in the CONSORT Statement in order to organise the checklist according to the common sections of a trial report (i.e. introduction, methods, results, and discussion). We also noted any reporting standards that are not in official CONSORT guidelines but were found in other guidelines. We summarised adherence to recommended techniques for reporting guideline development as frequencies,[3,21] and we converted total citations of each guideline into median citations per year. Data about the development and dissemination of guidelines were compared by the following pre-specified types of reporting guideline: official CONSORT guidelines, non-CONSORT guidelines for medical sciences, or non-CONSORT guidelines for social and behavioural sciences.

To describe the quality of trial reports, we summarised adherence to reporting standards as frequencies.[21] We analysed compliance to reporting standards for the whole sample and by academic discipline to provide a preliminary view of differences in reporting across social and behavioural sciences. We also categorised reporting standards into *a priori* conceptual themes often targeted by reporting guidelines: internal validity, external validity, and other important study details (e.g., information for indexing and certain ethical concerns).

Results

Previous Guidance

Through the literature search (see Figure 1), we identified 19 unique, eligible reporting guidelines and reporting quality assessment tools (see Table 1) developed between 1980 and 2010 (median 2004).[6,9,26,27,28,29,30,31,32,33,34,35,36,37,38,39,40,41,42] Six were developed by the CONSORT Group for reporting RCTs; six were non-CONSORT documents for health-research trials in general; and seven were specific to research in the social and behavioural sciences, namely non-randmoised trials of public health interventions,[38] empirical research in education,[27] empirical research in psychology,[41] trials in criminal justice,[9] outcome studies of alcohol treatment,[26] trials in occupational therapy,[24] and the content of behavioural change interventions.[39]

Overall, CONSORT guidelines used recommended techniques for guideline development and dissemination more frequently than non-CONSORT guidelines in medical, social, and behavioural sciences (see Table 2). Notably, most CONSORT guidelines tended to use more rigorous consensus methods in the development stage (75% of recommended techniques) compared with medical guidelines (44%) and social and behavioural science guidelines (37%), such as formal consensus development processes (see Table S1). Most CONSORT guidelines adhered to most dissemination activities (77%), such as endorsement and adherence by journals, while most other medical guidelines (10%) and social and behavioural science guidelines (34%) did not. In addition, CONSORT guidelines were cited more often (74 citations per year) than other guidelines in medicine (10) or social and behavioural sciences (4).

The 19 included reporting guidelines included a median of 32 reporting standards (interquartile range (IQR) = 17 to 54; range = 3 to 201) From these, we developed a list of 147 non-redundant reporting standards that are relevant to social and psychological interventions (see online Appendix S1). Of these 147 reporting standards, 89 were either not included in CONSORT guidelines or were tailored versions of CONSORT standards for social and psychological interventions (see Table S2 for a full list). Amongst these standards, requests for details about setting, implementation of the interventions, data collection, generalisability, and ethical concerns were common.

Assessment of Reporting Quality

Only 11 of the 40 journals referenced a published reporting guideline in their "Instructions to Authors" section (see Table 3). Two journals provided advisory text about reporting certain aspects of intervention studies without reference to any published reporting guideline; no other journals provided any textual instructions specific to reporting trials. Only 5 journals required trials to be registered in a trial registry (e.g., clinicaltrials.gov) prior to publication.

From these journals, we identified 239 eligible trials (Figure 2), including between 1 and 39 per journal (median 3). Overall, trials reported a mean of 42% of all reporting standards; there was low compliance with reporting standards related to internal validity (38%), external validity (47%), and other study details (34%). Reporting quality did not vary substantially by discipline (Table 4).

Several important aspects of trials were not consistently reported and would be easy to include in all trial reports (see Table S3; Data File S1). Only 20% of reports identified the trial as randomised in the title, and only 55% identified the trial as randomised in the abstract. Overall, 60% of reports included the trial eligibility criteria, but the majority of these reports did not explicitly list all inclusion *and exclusion* criteria. Trial reports adhered to only 23%, 17%, and 15% of the standards related to random sequence generation, allocation concealment, and blinding respectively. While most reports (71%) included the number of participants randomised to each condition, few reports described other aspects of participant flow through the trial, such as the number of participants: eligible for the trial (33%), receiving treatment (31%), and included in the primary analyses (38%). Less than half of the reports reported primary outcomes (27%) or secondary outcomes (45%) sufficiently to be included in meta-analyses. Very few

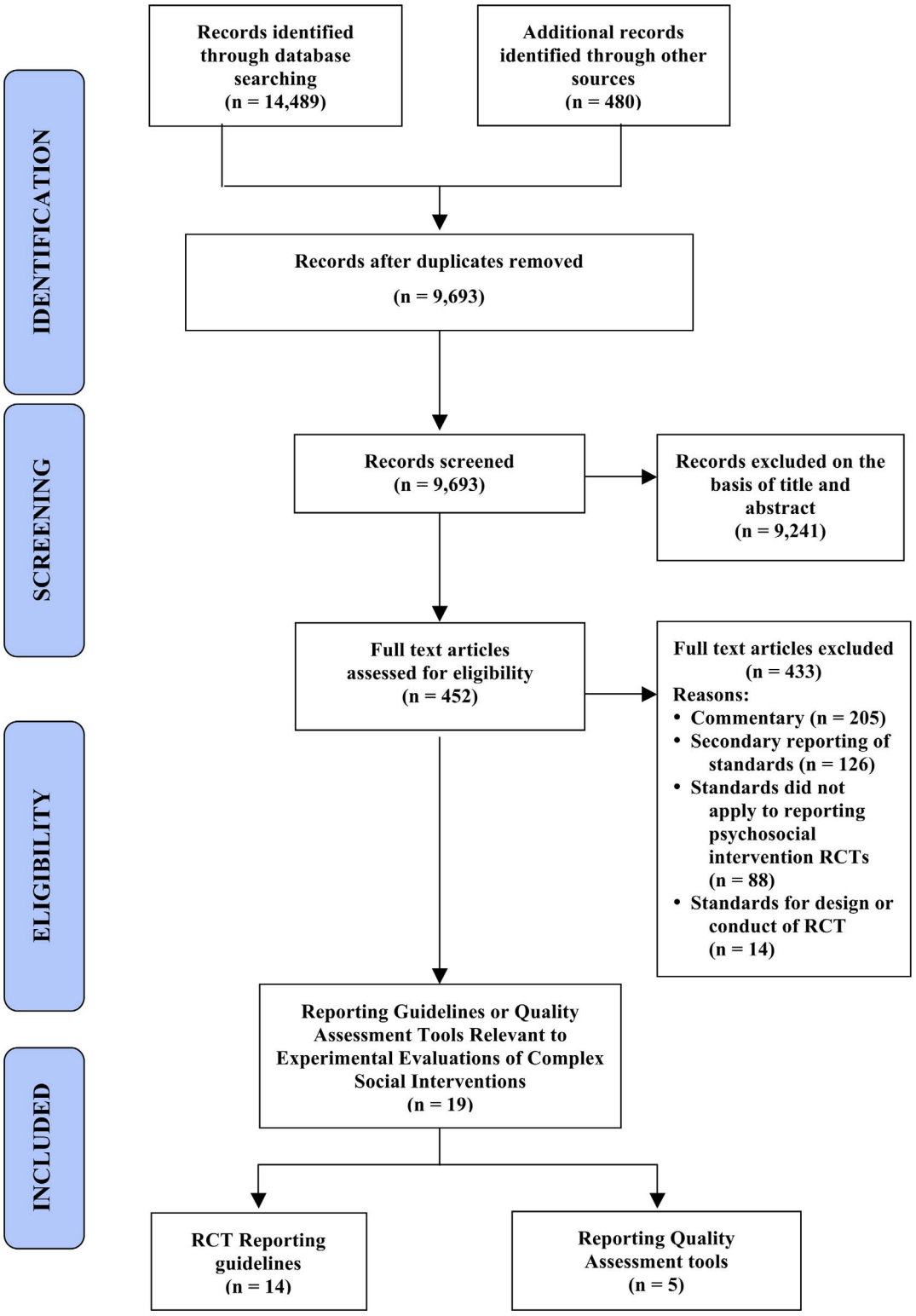

Figure 1. Flowchart of reporting guidelines through systematic literature search.
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reports (5%) indicated that the trial had been registered, and few reports included information about a trial protocol (8%) or access to a treatment manual (40%). Reports adhered to 50% of standards related to the implementation of the intervention and included a mean of 28% of standards related to the context of the wider service environment (see Figure 3).

Discussion

Overall Findings

Results establish the need for a new reporting guideline. This review identified numerous guidelines that have made useful contributions to reporting medical and social research. However,

Table 1. Characteristics of included reporting guidelines and reporting quality assessment tools.

Guideline	Year	Document Type	Official CONSORT	Targeted Area	# Reporting Standards
Reporting Guidelines Specific to the Social and Behavioural Sciences					
Alcohol Outcome Studies Coding Sheet [26]	2010	AT		Alcohol	36
AERA Standards for Empirical Social Science Research [27]	2006	RG		Education	56
CONSORT and Criminal Justice Trials (CJT) Project Coding Sheet [9]	2010	AT		Criminology	54
Journal Article Reporting Standards [41]	2008	RG		Psychology	134
Nelson-Moberg Expanded CONSORT Instrument [34]	2004	AT		Occupational Therapy	201
TREND Statement [38]	2004	RG		Public Health	59
WIDER [39]	2009	RG		Behavioural Change Interventions	12
Other Reporting Guidelines					
CONSORT Extension for Abstracts [28]	2008	RG	x	Abstracts	17
CONSORT Extension for Cluster Trials [29]	2004	RG	x	Cluster Trials	40
CONSORT Extension for Non-Pharmacological Treatments [30]	2008	RG	x	Non-Pharmacological Interventions	27
CONSORT Extension for Pragmatic Trials [31]	2008	RG	x	Pragmatic Trials	25
CONSORT Extension for Reporting Harms [32]	2004	RG	x	Harms	22
CONSORT Statement [6]	1996	RG	x	None	37
Evidence-Based Behavioral Medicine-Specific Guidelines [33]	2003	RG		Behavioural Medicine	34
Jadad Scale [40]	1996	AT		None	3
Oxford Implementation Index [35]	2007	AT		Complex Interventions	17
Quality Evaluation Form [36]	1995	AT		None	20
Reporting Standards for Controlled Trials [42]	1980	RG		None	6
Structured Reporting of Randomized Controlled Trials [37]	1994	RG		None	32

In ''Document Type'' column, AT = reporting quality assessment tool, and RG = reporting guideline. In ''Official CONSORT'' column, a ''x'' means that the guideline is an official CONSORT guideline.
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this study demonstrates that current reporting guidelines are insufficient for social and psychological intervention trials. Compared with the CONSORT Statement and its official extensions, guidelines in the social and behavioural sciences have not consistently followed recommended techniques for development and dissemination,[3] and they have not been widely utilised. If not properly developed and disseminated, these guidelines are potentially of limited use and are less likely to improve reporting of key features of trials that are important to stakeholders.[5] However, these guidelines include important, tailored standards for social and psychological interventions that are not found in CONSORT guidelines. Due to the substantial variability of recommended standards across reporting guidelines, disseminating CONSORT or another guideline would insufficiently address social and psychological intervention trials; further work is required to improve the applicability, utility, and acceptability of reporting guidelines in disciplines outside medicine.

Our analysis of trial reporting quality suggests that trial reports often fail to comply with published reporting standards, including well-established standards in the CONSORT Statement and its extensions. While reporting quality varies across standards and disciplines, this review shows that most trial reports omit information that is necessary to assess internal and external validity. This finding is consistent with previous studies of reports of social and psychological intervention trials in specific disci-

Table 2. Average percentage of recommended techniques for guideline development by document type.

Guideline Development Stage	CONSORT (n = 6)	Non-CONSORT Medical (n = 6)	Social & Behavioural Science (n = 7)
1. Preliminary Activities	91.7%	70.8%	67.9%
2. Document Development	75.0%	44.4%	31.0%
3. Publication Strategy	66.7%	5.5%	23.8%
4. Dissemination	76.7%	10.0%	37.1%
Median Citations per Year (*Range*)	73.7 (*43.3 – 535.5*)	9.9 (*0.2 – 480.2*)	4.4 (*1.0 – 65.0*)

Citation count derived from Google Scholar search on 1 November 2012.
Stage 1 = 4 items, Stage 2 = 6 items, Stage 3 = 3 items, Stage 4 = 5 items
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Table 3. Sample of journals included in reporting quality review.

Journal	ISI 2010 Impact Factor	Reporting Guidance Specific to RCTs in ''Instructions to Authors''	Trial Registration Required	Eligible RCTs in 2010
Clinical Psychology				
Archives of Sexual Behavior	3.660	None	No	2
Health Psychology	3.982	CONSORT; JARS	Yes	16
Journal of Abnormal Child Psychology	3.564	None	No	7
Journal of Abnormal Psychology	5.235	JARS	No	1
Journal of Behavioral Medicine	3.232	CONSORT; TREND	No	14
Journal of Clinical Child and Adolescent Psychology	3.440	CONSORT; JARS	Yes	8
Journal of Clinical Psychiatry	5.023	Text about reporting intervention studies	Yes	5
Journal of Consulting and Clinical Psychology	5.227	JARS	No	35
Neuropsychology	3.176	CONSORT; JARS	Yes	2
Psychological Medicine	5.200	None	No	9
Criminology				
British Journal of Criminology	1.612	None	No	1
Crime & Delinquency	1.750	None	No	1
Criminal Justice and Behavior	1.590	None	No	4
Criminology	2.658	None	No	1
International Journal of Offender Therapy and Comparative Criminology	1.071	None	No	2
Journal of Criminal Justice	1.076	None	No	3
Journal of Interpersonal Violence	1.354	None	No	6
Justice Quarterly	1.211	None	No	1
Psychology, Crime & Law	1.133	None	No	11
Youth Violence and Juvenile Justice	1.132	None	No	1
Education				
American Educational Research Journal	2.479	AERA	No	3
Computers & Education	2.617	None	No	39
Early Childhood Research Quarterly	2.192	Text about reporting effect sizes	No	4
Educational Evaluation and Policy Analysis	1.919	AERA	No	1
Journal of Engineering Education	2.219	None	No	7
Journal of Research in Science Teaching	2.728	None	No	7
Journal of Teacher Education	1.891	None	No	3
Learning and Instruction	2.768	None	No	19
Metacognition and Learning	2.038	None	No	2
Science Education	1.900	None	No	4
Social Work				
American Journal of Community Psychology	1.722	JARS	No	1
Child Abuse & Neglect	1.945	None	No	2
Child Maltreatment	1.984	None	No	2
Children and Youth Services Review	1.130	None	No	3
Family Relations	1.216	None	No	2
Health & Social Care in the Community	1.008	CONSORT; TREND	Yes	1
Health & Social Work	1.143	None	No	1
Journal of Community Psychology	0.792	None	No	1
Research on Social Work Practice	1.130	JARS	No	6
Social Service Review	1.421	None	No	1

Reporting Guidance Specific to RCTs in ''Instructions to Authors'': whether the ''Instructions to Authors'' section of a journal provided any guidance or referred to any guidelines on reporting RCTs. Trial Registration Required: whether the journal required RCTs to be registered in a trial registry (e.g., clinicaltrials.gov) prior to publication. Eligible RCTs in 2010: number of RCTs in 2010 that met eligibility criteria

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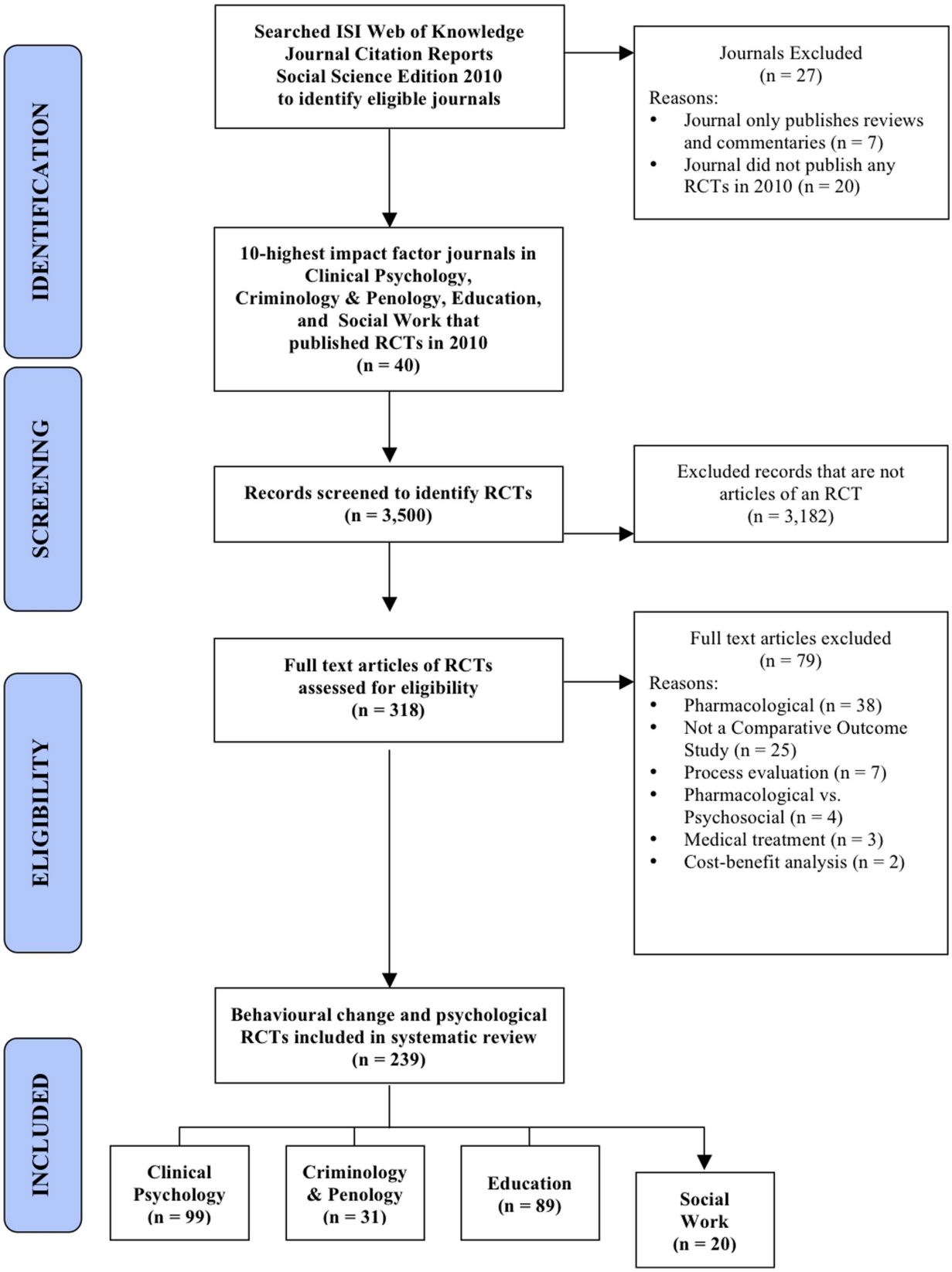

Figure 2. Flowchart of considered RCT publications through systematic literature search.
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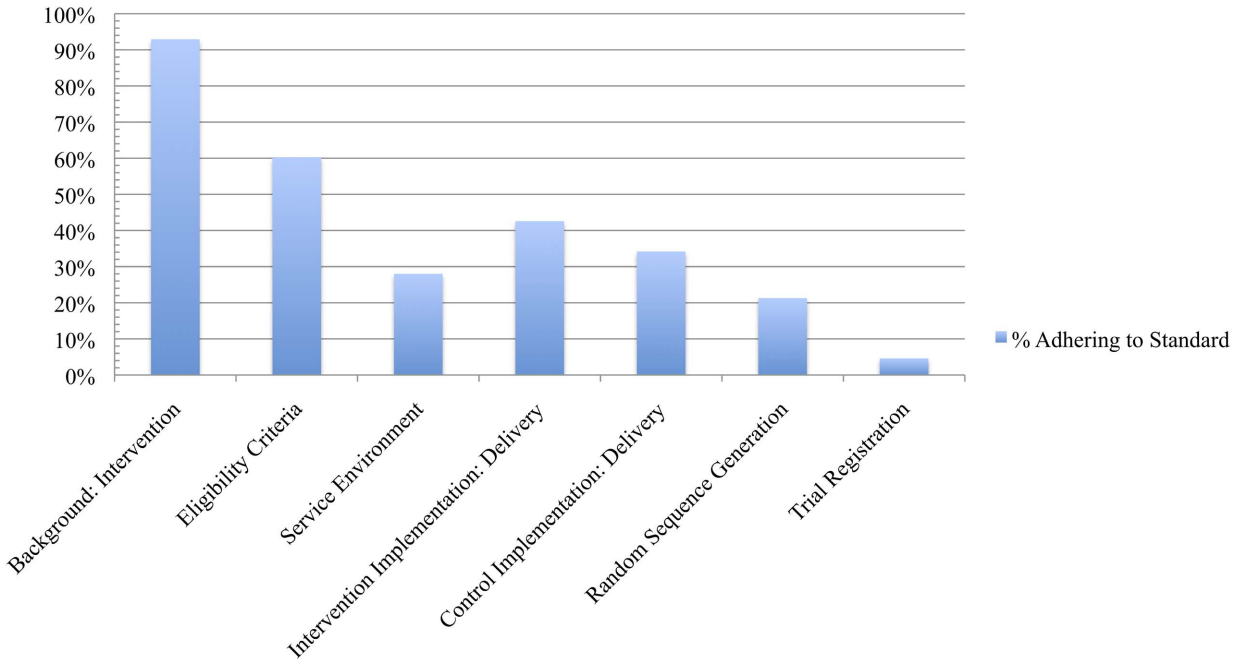

Figure 3. Average compliance of RCTs with key reporting standards.
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plines.[9,10,11,12,13] Poor reporting also has serious implications for knowledge transfer. For example, reports that are not identified as randomised trials in their titles or abstracts may not be identified in electronic literature searches and may be omitted from reviews as a result. The development and dissemination of a tailored reporting guideline could help resolve these problems.

Strengths and Limitations of the Current Study

This study is the most comprehensive review of reporting guidelines and the reporting quality of social and psychological intervention trials ever conducted. We undertook a highly sensitive search for reporting guidelines and assessed their use across numerous journals in several disciplines. We also conducted a complete assessment of all trial reports in 40 leading journals in one year, double coded their reporting quality, indicated clustering of reporting quality by journals within disciplines, and utilised a comprehensive set of standards to prevent selective assessment and reporting of quality.[8] While the reviewers weren't blind to the authors, institutions, and journals of RCT reports due to resource restraints, there is currently no evidence to suggest that such lack of blinding the validity of these reviews assessing reporting quality.[8]

It is clear that reporting guidelines for trials are not widely used outside medicine, but there may be several reasons for this. Regardless, social and behavioural scientists have been aware of the CONSORT Statement and its extensions for some time, so lack of uptake is not the result of ignorance of these guidelines.[14,15,43] Our correspondence with journal editors confirmed that many are familiar with CONSORT and some related guidelines.

In assessing compliance with reporting standards included in these guidelines, we found that several standards are vague and underdeveloped, particularly those related to external validity, such as theory of change.[14] When standards are imprecise, reports can be compliant without describing evaluations sufficiently to allow critical appraisal, replication, and inclusion in reviews and meta-analyses. Moreover, though inter-rater agreement in the review of reporting quality was high ($\kappa = 0.71$), it did not reach newly-developed criteria ($\kappa \geq 0.80$) for assessing the validity of evaluations of RCTs reporting quality.[8] Our own difficulty in applying some standards reaffirmed the need to develop clear, specific recommendations for social and psychological intervention trials based on best current evidence.[18]

Despite the difficulties in developing a comprehensive set of reporting standards, deficiencies in trial reports are both real and important. We included trial reports that are most likely to be cited (i.e., those published in high impact journals) and which may be of better quality than articles published in low impact journals.[4,44] The reports assessed are probably representative of the best trial research in these disciplines.

Future directions

A reporting guideline designed specifically for social and psychological interventions would help improve the quality of these trial reports.[43,45] To be acceptable and widely utilised, such a guideline should be developed using rigorous methods that engage members from all relevant stakeholder groups during development and dissemination, and its reporting standards should be based on sound empirical evidence where possible.[3,5] Given the prominence of CONSORT internationally, the precedence of its standards, and the rigorous development and dissemination practices of the CONSORT Group, an official CONSORT extension seems the best method to facilitate better reporting of these trials.

This study identified many new and modified reporting standards that could be added to the CONSORT Statement to form an official extension. Several standards in current CONSORT guidelines could be amended to make them more applicable and acceptable for trials of social and psychological interventions. For example, modifications could attend to difficulties in: blinding participants and providers of complex interventions, participant and provider preferences, the use of multiple

Table 4. Average compliance of RCTs with reporting standards.

Area	Item	Clinical Psychology	Criminology	Education	Social Work	Total Sample
External Validity						
10 Items	Participants	54.6%	38.2%	37.9%	53.2%	46.2%
7 Items	Timing and Setting	43.1%	46.5%	44.8%	55.7%	45.2%
29 Items	Intervention: Average	50.4%	42.8%	52.4%	48.3%	50.0%
10 Items	*Intervention Implementation: Design*	74.1%	69.7%	79.7%	80.0%	76.1%
12 Items	*Intervention Implementation: Delivery*	43.8%	35.5%	44.8%	37.9%	42.6%
7 Items	*Intervention Implementation: Uptake*	27.8%	17.1%	26.5%	20.7%	25.3%
26 Items	Control: Average	38.4%	38.0%	46.9%	22.1%	40.1%
8 Items	*Control Implementation: Design*	60.5%	62.1%	70.9%	43.1%	63.1%
12 Items	*Control Implementation: Delivery*	32.3%	31.5%	41.4%	16.2%	34.2%
6 Items	*Control Implementation: Uptake*	21.0%	18.8%	25.8%	5.8%	21.3%
2 Items	Programme Differences	29.8%	27.4%	27.0%	17.5%	27.4%
4 Items	Outcomes*	67.2%	54.8%	53.7%	56.3%	59.6%
5 Items	Interpretation	75.6%	58.7%	51.2%	63.0%	63.3%
83 Items	Total External Validity	48.4%	42.2%	47.7%	41.8%	46.8%
Internal Validity						
9 Items	Trial Design	58.7%	50.9%	50.3%	57.2%	54.4%
4 Items	Random Sequence*	30.1%	11.3%	18.0%	28.8%	23.0%
13 Items	Data Analysis*	50.0%	31.8%	36.0%	44.6%	41.9%
3 Items	Allocation Concealment*	26.3%	17.2%	3.4%	28.3%	16.7%
3 Items	Blinding*	20.2%	4.3%	11.2%	18.3%	14.6%
8 Items	Participant Flow*	55.4%	14.5%	20.4%	37.5%	35.6%
40 Items	Total Internal Validity	47.0%	27.4%	30.0%	41.2%	37.6%
Study Details						
16 Items	Title and Abstract	40.8%	17.9%	28.4%	34.7%	32.7%
5 Items	Protocols and Manuals*	29.9%	11.6%	14.6%	27.0%	21.6%
3 Items	Ethical Concerns	78.1%	47.3%	41.9%	76.7%	60.5%
24 Items	Total Study Details	43.2%	20.3%	27.2%	38.3%	33.9%
Total Score						
	Total Score for All Standards	47.2%	34.6%	39.5%	41.1%	42.2%

Number of RCTs in each discipline: RCTs per discipline: Clinical Psychology—99, Criminology—31, Education—89, Social Work—20
*Denotes Cochrane Risk of Bias item
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measurement formats (e.g., self-report, observation) within a study, and the complexity of data analysis.[9,14,33,34,41,46] In addition, researchers are increasingly demanding better reporting standards related to external validity, theory of change, and implementation.[1,14,19] Standards in guidelines other than the CONSORT Statement include relatively more information about sample characteristics,[35,47] the extent to which trials differ from usual practice,[27] details about facilitative or obstructive aspects of the trial context,[48] and contextual factors related to feasibility and coverage,[14] such as organisational resources and the wider service system structure.[49,50] Such information is important to improve the knowledge base for effective transfer of research findings to real-world settings.[51] Details of trials not related to internal and external validity are also important, such as discussing other relevant research when interpreting trial findings,[52] referencing other reports about the trial that may have a different focus (e.g., process evaluations),[20] and issues related to conflicts of interest (e.g., researcher development of the intervention) and ethical considerations (e.g., informed consent by participants with limited mental capacity).[9]

These reporting standards should be considered through consensus methods, such as a Delphi process and formal consensus meeting.[3,4] In addition to the standards identified in this review, there may be other factors that have not yet been included in relevant reporting guidelines that could emerge using a rigorous consensus processes. Given the plethora of possible reporting standards, a formal consensus development process would best ensure that new guidance incorporates collective wisdom while providing only the minimal, essential standards for reporting these trials.

Implications

The CONSORT Statement has been extended and modified in the past, and the CONSORT Group welcomes further extensions.[53] CONSORT guidelines have been developed and validated in the context of biomedical treatments; their applica-

bility to other disciplines could be improved by accounting for specific methodological issues related to the assessment of social and psychological interventions. Members of previous CONSORT groups, journal editors, and researchers believe that stakeholders need to be included in guideline development to promote buy-in and to improve the relevance of CONSORT guidelines to disciplines outside medicine.[12,54] This review demonstrates that a unified set of standards could be applied to social and psychological intervention trials. Moreover, the impact of CONSORT and the recent proliferation of publications about reporting quality in social and behavioural sciences indicate that such a CONSORT extension could be well-received by various stakeholders.

Since the conduct of this review, an international collaboration of stakeholders has convened to develop a new CONSORT extension for social and psychological interventions. This CONSORT extension has the potential to benefit this area of research in several ways. Developed and disseminated according to recommended techniques,[3] it will aim to synthesise previous work on reporting standards and methodological research about social and psychological interventions. This guideline could improve the reporting and utility of these trials for various stakeholders, including trial report authors, systematic reviewers, journal editors, peer-reviewers, funding organisations, research students, and users of research in policy and practice. While trials are not the only method for evaluating interventions, nor are they the only method that can benefit from updated reporting standards,[50] the importance of trial reports is growing. Improved reporting is needed so that judgments can be made about the validity and application of research findings.[41] A CONSORT extension for social and psychological interventions would be an important step towards improving the reporting of these trials.

Supporting Information

Appendix S1 Social and psychological intervention RCT reporting standard coding sheet.
(DOC)

Appendix S2 Data extraction sheet for reporting guidelines and quality assessment tools
(DOC)

Table S1 Reported details of guideline development methods.
(DOC)

Table S2 New and modified reporting standards for social and psychological intervention RCTs.
(DOC)

Table S3 Frequency of compliance with reporting standards.
(DOC)

Text S1 Electronic search strategy.
(DOC)

Data File S1 Excel file of RCT reporting quality data.
(XLSX)

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Author Contributions

Conceived and designed the experiments: SG EMW PM. Performed the experiments: SG GJMT. Analyzed the data: SG EMW PM. Wrote the paper: SG EMW GJMT PM.

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