

Commentary Article: Innovation, research integrity, and change: A conflict of interest management framework for program developers. A reply to Sanders et al (2019)

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Abstract

Sanders et al's proposal for a management framework for conflicting interests among programme developers is very welcome. The underlying principles of such a framework must nevertheless prioritise the need for researchers and commissioners of services to make objective assessments of the impact of interventions reported in journal articles. This is particularly important in the field of randomised trials which may influence public sector expenditure. Using a strict definition derived from known financial conflict of interest, we have demonstrated that child-based effect sizes are much lower for independent studies than for studies with developer involvement. On this basis, we propose that journals publishing evaluations of psychosocial interventions should agree a standardised format for declarations of conflicts of interest based on that recommended by the International Committee of Medical Journal Editors.

We welcome this contribution by Sanders and colleagues (Matthew R. Sanders, Kirby, Toumbourou, Carey, & Havighurst) to the field of management of conflicting interests (Col) by developers of psychosocial interventions. Their article usefully addresses the issues arising when researchers publish evaluations of programmes in which they have played a significant role as developers. Such issues are unavoidable, particularly in the early stages of programme development when developer involvement in research is, as the authors point out, often desirable. While Sanders et al write from the perspective of programme developers, we write this commentary from the perspective of evaluators and ‘consumers’ of published evaluations. Our focus is therefore on declarations of Col in published papers and on their implications for data synthesis.

Declarations of Col in psychosocial programmes

Eisner and colleagues (Eisner, Humphreys, Wilson, & Gardner, 2015) investigated the issue of declarations of conflicting interests by developers of parenting programmes published between 2008 and 2014, and found disappointingly low levels of disclosure. There is therefore no doubt that a Col reporting framework for such programmes is timely.

Table 1, from Eisner et al’s paper illustrates the magnitude of the problem at the time of publication.

Table 2. Publications in peer-reviewed journals with and without Col disclosures, four internationally disseminated psychosocial interventions, Jan 2008–July 2014.

Row ¹	Characteristic	Triple P	NFP	MST	IY	Total
B	Included in analysis	79	14	25	16	134
C	COI fully disclosed, editor not contacted	8	8	16	10	42
D	Editor contacted	71	6	9	6	92
D1	Col disclosure missing	60	4	9	6	79
D2	"No conflict of interest" statement	4	1	0	0	5
D3	Ambiguous or incomplete disclosure	7	1	0	0	8
E	No erratum/corrigendum published	13	5	6	2	26
E1	No disclosure policy	11	3	1	1	16
E2	Not program paper–journal/author response	0	0	3	0	3
E3	Col deemed sufficient	1	0	0	0	1
E4	Unable/unwilling to examine	1	2	1	1	5
E5	No final response	1	0	1	0	2
F	Erratum/corrigendum announced	57	1	3	4	65
F1	Journal mishandling	14	0	2	0	16
F2	Authors submit corrected or new Col	43	1	1	4	49
Rates						
	Disclosure rate ²	11%	57%	73%	63%	33%
	Errata rate ³	80%	17%	33%	67%	71%

Notes

¹ See [S1 Appendix](#) for coding scheme and operational definitions.

² Calculated as (C+E3)/(B-E2).

³ Calculated as F/D.

Col declarations were examined in published journal papers reporting on four internationally disseminated psychosocial interventions. A total of 136 articles were found which related to an intervention, were co-authored by intervention developers with a known financial conflicting interest, and were published in health sciences journals. Col disclosures were coded for 134 articles. Overall, 92/134 (71%) of all articles were found to have absent, incomplete or partly misleading Col disclosures. Disclosure rates for the four programs varied significantly between 11% (Triple P) and 73% (Multi-Systemic Therapy). Following guidelines published by the Committee for Publication Ethics, journal editors were contacted about 92 published articles with no Col disclosure or a disclosure that was considered problematic. In 65/92 (71%) of all cases the editors published an ‘erratum’ or ‘corrigendum’. In 16 of these cases the journal had mishandled a submitted disclosure.

As Sanders and his colleagues point out, the most frequent reason for non-publication of an erratum was that the journal had no disclosure policy at the time of the publication (16 cases), and many of these journals have since instituted a CoI disclosure policy.

Sanders et al have highlighted the parallels with pharmaceutical industry trials, the interpretation of which has long been known to be vulnerable to commercial bias (Ahn et al., 2017). Cristea and Ioannidis (Cristea & Ioannidis, 2018) recently published a useful discussion paper addressing the CoI issues specific to trials of psychological interventions as opposed to pharmaceutical trials, in particular the difficulty in identifying an equivalent to a drug manufacturer. The authors point to the multiplicity of types of financial relationships between researchers and the psychosocial interventions under investigation and make a strong plea for a standardised approach to reporting. Cristea and Ioannidis' article also addresses the more nebulous concept of 'researcher allegiance' which can be even more difficult to capture.

Implications for data synthesis and meta-analyses

The lack of a generally accepted standardised definition of CoI leads to uncertainty in understanding the contribution of CoI to the impact of psychosocial interventions. In relation to drug trials, Ahn et al showed a strong independent association between the financial ties of principal investigators and positive clinical trial results. There is much less clarity in relation to psychosocial interventions.

In a systematic review and meta-analysis published in 2012, Wilson et al examined effect sizes for child behaviour outcomes reported in trials of the Triple P parenting programme, and concluded that characterisation of the contribution of the role of CoI was impossible at that time because 32 of the 33 eligible studies were authored by "Triple-P affiliated personnel" (Wilson et al., 2012). None of the trials had been registered with a trials registry and only two papers contained conflict of interest statements. The summary effect size in the meta-analysis of 23 trials was 0.61 (95%CI 0.42, 0.79) for maternally-reported child behaviour outcomes.

Subsequently Sanders and colleagues (M. R. Sanders, Kirby, Tellegen, & Day, 2014) tackled the issue of the contribution of CoI to Triple P effect sizes following the publication of a number of studies that they defined as independent of developer involvement. Developer involvement attributed through consensus of the authors was considered to be present "if the program developer was involved with study conceptualization, design, methodology, analyses, write up, or if the program developer was consulted in aspects of study design and implementation. If the program developer was involved in none of these aforementioned steps, the study was categorized as having no developer involvement." As well as papers published in peer-reviewed journals, the authors included data from a large number of unpublished studies. The summary effect size for child behavioural outcomes was reported as 0.525, and a modest but statistically significant moderator effect was seen for developer involvement. This effect became non-significant after adjusting for other moderator effects.

Using the same methodological approach described in our original 2012 meta-analysis, we have calculated effect sizes for studies published in peer-reviewed journals during the period covered by the Sanders et al meta-analysis. These are shown in table 2.

Paper	Author(s) with financial interest	Standardised Mean Difference.
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Schappin R, Wijnroks L, Uniken Venema M, Wijnberg-Williams B, Veenstra R, Koopman-Esseboom C, Tollenaer SMD, van der Tweel I, Jongmans M: Brief parenting intervention for parents of NICU graduates: A randomized, clinical trial of Primary Care Triple P. <i>BMC Pediatrics</i> 2013, 13 (1).	No	-0.229
Little M, Berry V, Morpeth L, Blower S, Axford N, Taylor R, Bywater T, Lehtonen M, Tobin K: The Impact of Three Evidence-Based Programmes Delivered in Public Systems in Birmingham, UK. <i>International Journal of Conflict and Violence</i> 2013, 6 (2):260-272.	No	-0.048
Malti T, Ribeaud D, Eisner M: The effectiveness of two universal preventive interventions in reducing children's externalizing behavior: A cluster randomized controlled trial. <i>Journal of Clinical Child & Adolescent Psychology</i> 2011, 40 (5):677-692.	No	0
Spijkers W, Jansen DEMC, Reijneveld SA: Effectiveness of Primary Care Triple P on child psychosocial problems in preventive child healthcare: A randomized controlled trial. <i>BMC Medicine</i> 2013, 11 (1).	No	0.117
Gallart SC, Matthey S: The Effectiveness of Group Triple P and the Impact of the Four Telephone Contacts. <i>Behaviour Change</i> 2005, 22 (2):71-80.	No	0.755
Median (papers without declared financial conflicting interests)		0.000
Connell S, Sanders MR, Markie-Dadds C: Self-directed behavioral family intervention for parents of oppositional children in rural and remote areas. <i>Behavior Modification</i> 1997, 21 (4):379-408.	Yes	2.499
Nicholson JM, MR S: Randomized controlled trial of behavioral family intervention for the treatment of child behavior problems in stepfamilies. <i>Journal of Divorce & Remarriage</i> 1999, 30 (3-4):1-23.	Yes	0.342
Sanders MR, Markie-Dadds C, Tully LA, Bor W: The triple P-positive parenting program: a comparison of enhanced, standard, and self-directed behavioral family intervention for parents of children with early onset conduct problems. <i>Journal of Consulting & Clinical Psychology</i> 2000, 68 (4):624-640.	Yes	0.810
Sanders MR, Montgomery DT, Brechman-Toussaint ML: The mass media and the prevention of child behavior problems: The evaluation of a television series to promote positive outcomes for parents and their children. <i>Journal of Child Psychology and Psychiatry and Allied Disciplines</i> 2000, 41 (7) 939-948	Yes	0.321
Hoath FE, Sanders MR: A feasibility study of Enhanced Group Triple P - Positive parenting program for parents of children with attention-deficit/hyperactivity disorder. <i>Behaviour Change</i> 2002 19 (4) 191-206	Yes	0.610
Leung C, Sanders MR, Leung S, Mak R, Lau J: An outcome evaluation of the implementation of the Triple P-Positive Parenting Program in Hong Kong. <i>Family Process</i> 2003, 42 (4):531-544.	Yes	1.000
Martin AJ, Sanders MR: Balancing work and family: A controlled evaluation of the Triple P-Positive Parenting Program as a work-	Yes	1.038

site intervention. <i>Child and Adolescent Mental Health</i> 2003, 8 (4):161-169.		
Markie-Dadds C, Sanders MR: Self-directed Triple P (Positive Parenting Program) for mothers with children at-risk of developing conduct problems. <i>Behavioural and Cognitive Psychotherapy</i> 2006, 34 (3) 259-275	Yes	1.301
Markie-Dadds C, Sanders M: A Controlled Evaluation of an Enhanced Self-Directed Behavioural Family Intervention for Parents of Children With Conduct Problems in Rural and Remote Areas. <i>Behaviour Change</i> 2006, 23 (1):55-72.	Yes	1.153
Morawska A, Sanders MR: Self-administered behavioral family intervention for parents of toddlers: Part I. Efficacy. <i>Journal of Consulting & Clinical Psychology</i> 2006, 74 (1):10-19.	Yes	0.587
Turner KM, Sanders MR: Help when it's needed first: a controlled evaluation of brief, preventive behavioral family intervention in a primary care setting. <i>Behavior Therapy</i> 2006, 37 (2):131-142.	Yes	-0.085
Roberts C, Mazzucchelli T, Studman L, Sanders MR: Behavioral family intervention for children with developmental disabilities and behavioral problems. <i>Journal of Clinical Child & Adolescent Psychology</i> 2006, 35 (2):180-193.	Yes	0.676
Matsumoto Y, Sofronoff K, Sanders M: The efficacy and acceptability of the Triple P-Positive Parenting Program with Japanese parents. <i>Behaviour Change</i> 2007, 24 (4):205-218.	Yes	0.476
Turner KM, Richards M, Sanders MR: Randomised clinical trial of a group parent education programme for Australian indigenous families. <i>Journal of Paediatrics & Child Health</i> 2007, 43 (6):429-437.	Yes	0.201
Plant KM, Sanders MR: Reducing problem behavior during care-giving in families of preschool-aged children with developmental disabilities. <i>Research in Developmental Disabilities</i> 2007, 28 (4):362-385.	Yes	0.254
Stallman HM, Ralph A: Reducing risk factors for adolescent behavioural and emotional problems: A pilot randomised controlled trial of a self-administered parenting intervention. <i>Australian e-Journal for the Advancement of Mental Health</i> 2007, 6 (2):1-13.	Yes	0.412
Bodenmann G, Cina A, Ledermann T, Sanders MR: The efficacy of the Triple P-Positive Parenting Program in improving parenting and child behavior: a comparison with two other treatment conditions. <i>Behaviour Research & Therapy</i> 2008, 46 (4):411-427.	Yes	0.460
Hahlweg K, Heinrichs N, Kuschel A, Feldmann M: Therapist-assisted, self-administered bibliotherapy to enhance parental competence: short- and long-term effects. <i>Behavior Modification</i> 2008, 32 (5):659-681.	Yes	0.782
Morawska A, Sanders M: An evaluation of a behavioural parenting intervention for parents of gifted children. <i>Behaviour Research and Therapy</i> 2009, 47 (6):463-470.	Yes	0.306
Whittingham K, Sofronoff K, Sheffield J, Sanders MR: Stepping Stones Triple P: an RCT of a parenting program with parents of a	Yes	0.979

child diagnosed with an autism spectrum disorder. <i>Journal of Abnormal Child Psychology</i> 2009, 37 (4):469-480.		
Wiggins TL, Sofronoff K, Sanders MR: Pathways triple P-positive parenting program: Effects on parent-child relationships and child behavior problems. <i>Family Process</i> 2009, 48 (4):517-530.	Yes	0.567
Hahlweg K, Heinrichs N, Kuschel A, Bertram H, Naumann S: Long-term outcome of a randomized controlled universal prevention trial through a positive parenting program: Is it worth the effort? <i>Child and Adolescent Psychiatry and Mental Health</i> 2010, 4 (14).	Yes	-0.161
Joachim S, Sanders MR, Turner KMT: Reducing preschoolers' disruptive behaviour in public with a brief parent discussion group. <i>Child Psychiatry and Human Development</i> 2010, 41 (1):47-60.	Yes	0.753
Matsumoto Y, Sofronoff K, Sanders MR: Investigation of the Effectiveness and Social Validity of the Triple P Positive Parenting Program in Japanese Society. <i>Journal of Family Psychology</i> 2010, 24 (1):87-91.	Yes	0.109
Sanders MR, Stallman HM, McHale M: Workplace Triple P: A controlled evaluation of a parenting intervention for working parents. <i>Journal of Family Psychology</i> 2011, 25 (4):581-590.	Yes	0.266
Cina A, Rösli M, Schmid H, Lattmann UP, Fäh B, Schönenberger M, Kern-Scheffelt W, Randall AK, Bodenmann G: Enhancing positive development of children: Effects of a multilevel randomized controlled intervention on parenting and child problem behavior. <i>Family Science</i> 2011, 2 (1):43-57.	Yes	0.260
Morawska A, Haslam D, Milne D, Sanders MR: Evaluation of a brief parenting discussion group for parents of young children. <i>Journal of Developmental and Behavioral Pediatrics</i> 2011, 2 (2):136-145.	Yes	1.154
Sofronoff K, Jahnel D, Sanders M: Stepping Stones Triple P seminars for parents of a child with a disability: A randomized controlled trial. <i>Research in Developmental Disabilities</i> 2011, 32 (6):2253-2262.	Yes	0.156
Sanders MR, Baker S, Turner KMT: A randomized controlled trial evaluating the efficacy of Triple P Online with parents of children with early-onset conduct problems. <i>Behaviour Research and Therapy</i> 2012, 50 (11):675-684.	Yes	0.890
Adamson M, Morawska A, Sanders MR: Childhood feeding difficulties: a randomized controlled trial of a group-based parenting intervention. <i>Journal of Developmental & Behavioral Pediatrics</i> 2013, 34 (5):293-302.	Yes	0.600
Doherty FM, Calam R, Sanders MR: Positive parenting program (triple P) for families of adolescents with type 1 diabetes: a randomized controlled trial of self-directed teen triple P. <i>Journal of pediatric psychology</i> 2013, 38 (8):846-858.	Yes	0.540
Haslam D, Sanders M, Sofronoff K: Reducing Work and Family Conflict in Teachers: A Randomised Controlled Trial of Workplace Triple P. <i>School Mental Health</i> 2013, 5 (2):70-82.	Yes	0.414
Leung C, Fan A, Sanders MR: The effectiveness of a Group Triple P with Chinese parents who have a child with developmental	Yes	0.287

disabilities: A randomized controlled trial. <i>Research in Developmental Disabilities</i> 2013, 34 (3):976-984.		
Roux G, Sofronoff K, Sanders M: A randomized controlled trial of group stepping stones triple P: A mixed-disability trial. <i>Family Process</i> 2013, 52 (3):411-424.	Yes	1.040
Median (papers with financial conflicting interests)		0.553

Table 2. Post-intervention standardised mean differences (SMD) for child behaviour outcomes between intervention and control groups in all Triple P trials reporting such outcomes published in peer reviewed journals before July 2017. ECBI subscale data reported by Bodenmann et al were assumed to have been transposed, and are corrected here (see Wilson et al 2012).

Thus widely different assessments of the association of Col with study outcomes result from two differing definitions of developer involvement: using a strict definition derived from known financial Col, Triple P child-based effect sizes cluster around zero for independent studies and greater than 0.5 for studies with developer involvement.

An additional issue that arises in Sanders et al's 2014 meta-analysis is that of the inclusion of unpublished studies. Bias may result if unpublished work by authors not well known to systematic reviewers is less likely to be included than unpublished work by others. Systematic reviews and meta-analyses may thus be more likely to include an unbiased selection of unpublished work if they are produced by completely independent authors or if they at least limit data synthesis to peer-reviewed published papers.

Conclusion and recommendations

Declarations of Col in published evaluations of psychosocial interventions have been problematic until now and inconsistent reporting of Col in published papers is a major problem that requires urgent attention. We consider that a standardised Col declaration such as that recommended by the International Committee for Medical Journal Editors (ICMJE) should be required by psychology journal editors. The ICMJE Col declaration (<http://www.icmje.org/conflicts-of-interest/>) focuses on direct and indirect financial interests, but other important factors including intellectual property rights and "other relationships or activities that readers could perceive to have influenced, or that give the appearance of potentially influencing" the content of a publication must also be declared. Sanders and his colleagues have helpfully suggested other specific areas which might be included in such a standardised declaration, including developer involvement in trial design, intervention allegiance and reputational factors.

Ahn, R., Woodbridge, A., Abraham, A., Saba, S., Korenstein, D., Madden, E., . . . Keyhani, S. (2017). Financial ties of principal investigators and randomized controlled trial outcomes: cross sectional study. *BMJ*, *356*. doi:10.1136/bmj.i6770

Cristea, I.-A., & Ioannidis, J. P. A. (2018). Improving Disclosure of Financial Conflicts of Interest for Research on Psychosocial Interventions. *JAMA Psychiatry*, *75*(6), 541-542. doi:10.1001/jamapsychiatry.2018.0382

Eisner, M., Humphreys, D., Wilson, P., & Gardner, F. (2015). Disclosure of financial conflicts of interests in interventions to improve child psychosocial health: A cross-sectional study. *PLoS ONE*, *10*(11), e0142803. doi:10.1371/journal.pone.0142803

- Sanders, M. R., Kirby, J. N., Tellegen, C. L., & Day, J. J. (2014). The Triple P-Positive Parenting Program: a systematic review and meta-analysis of a multi-level system of parenting support. *Clin Psychol Rev*, *34*(4), 337-357. doi:10.1016/j.cpr.2014.04.003
- Sanders, M. R., Kirby, J. N., Toumbourou, J. W., Carey, T. A., & Havighurst, S. S. Innovation, research integrity, and change: A conflict of interest management framework for program developers. *Australian Psychologist*, *0*(0). doi:10.1111/ap.12404
- Wilson, P., Rush, R., Hussey, S., Puckering, C., Sim, F., Allely, C., . . . Gillberg, C. (2012). How evidence-based is an 'evidence-based parenting program'? A PRISMA systematic review and meta-analysis of Triple P. *BMC Medicine*, *10*(1), 130.

Conflicts of interest

Philip Wilson declares no direct or indirect financial interests in, or any role in the development of, any parenting programme. University departments to which he is affiliated have received grant funding for the evaluation of several parenting programmes including Triple P, Mellow Parenting, Circle of Security and the Resilience Programme (Robusthed.dk) and these funds have been used to partially underwrite his salary costs.

Louise Marryat declares no direct or indirect financial interests in, or any role in the development of, any parenting programme. University departments and organisations to which she has been affiliated have received grant funding to evaluate several parenting programmes including Triple P, Mellow Parenting and Family Nurse Partnership, and these funds have been used to pay her salary costs and associated Ph.D fees.

Lucy Thompson declares no direct or indirect financial interests in, or any role in the development of, any parenting programme. University departments to which she is affiliated have received grant funding for the evaluation of several parenting programmes including Triple P, Mellow Parenting, Circle of Security and the Resilience Programme (Robusthed.dk) and these funds have been used to partially underwrite her salary costs.