

TIDieR-Placebo/CoPPS reporting checklist

The Template for Intervention Description and Replication (TIDieR-Placebo) checklist was modified by adding reporting items from the Recommendations for the Development, Implementation, and Reporting of Control Interventions in Efficacy Trials of Physical, Psychological, and Self-Management Therapies (CoPPS) Statement (Hohenschurz-Schmidt et al., 2023). Added CoPPS items are illustrated in italics. In the column titled ‘where located’, trial authors should indicate where the respective information is reported in their publication or supplementary material. The rationale for additional CoPPS items can be found in the original CoPPS publication and its Explanations and Elaborations document. The TIDieR-Placebo Checklist is to be used alongside TIDieR-Placebo guide. This table was reproduced in accordance with the Creative Commons Attribution license (CC BY), and is based on the original TIDieR-Placebo checklist as published in: Howick J, Webster RK, Rees JL, *et al.* TIDieR-Placebo: A guide and checklist for reporting placebo and sham controls. *PLoS Medicine* 2020;17:e1003294. doi:[10.1371/journal.pmed.1003294](https://doi.org/10.1371/journal.pmed.1003294)

Item	Where located			Where located	
	Primary paper (page or appendix number)	Other (details)		Primary paper (page or appendix number)	Other (details)
Active intervention			Placebo/sham intervention		
<i>0 Processes of sham intervention development</i>					
			<i>Sources and processes that informed the development of the control intervention.</i>		
1 Brief Name					
Provide the name or a phrase that describes the intervention			Provide the name or a phrase that describes the placebo/sham intervention		
2 Why					
Describe any rationale, theory, or goal of the elements essential to the intervention			Describe any rationale, theory, or goal of the elements essential to the placebo/sham intervention* <i>Theoretical considerations underlying the control intervention (including explicit mechanistic rationales and objectives of the control intervention)</i>		
3 What (materials)					
			<i>A highly detailed description of the content of the control intervention (covering all components listed in table 2 of the CoPPS publication and including resemblance or differences to the test intervention)</i>		
Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (such as online appendix, URL)			Describe any physical or informational materials used in the placebo/sham intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed		

			(such as an online appendix, URL)		
4 What (procedures)					
Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities			Describe each of the procedures, activities, and/or processes used in the placebo/sham intervention, including any enabling or support activities		
5 Who provided					
For each category of intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given <i>Should also include a description of provider behaviour, verbal and non-verbal communication, and issues of equipoise as detailed in the text of the CoPPS Statement and its Explanations & Elaborations document; as well as means to control these provider-related factors.</i>			For each category of placebo/sham intervention provider (such as psychologist, nursing assistant), describe their expertise, background, and any specific training given <i>Should also include a description of provider behaviour, verbal and non-verbal communication, and issues of equipoise as detailed in the text of the CoPPS Statement and its Explanations & Elaborations document; as well as means to control these provider-related factors.</i>		
<i>Additional provider-related information</i> <i>Reporting should further include how issues of equipoise and provider expectancy were addressed; and if and how provider behaviour and verbal and non-verbal communication were controlled in each group. If different sets of providers were employed to deliver test and control interventions, this needs to be reported along with differences in their characteristics.</i>			<i>Additional provider-related information</i> <i>Reporting should further include how issues of equipoise and provider expectancy were addressed; and if and how provider behaviour and verbal and non-verbal communication were controlled in each group. If different sets of providers were employed to deliver test and control interventions, this needs to be reported along with differences in their characteristics.</i>		
6 How					
Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group			Describe the modes of delivery (such as face to face or by some other mechanism, such as internet or telephone) of the placebo/sham intervention and whether it was provided individually or in a group		
7 Where					
Describe the type(s) of location(s) where the intervention occurred, including any necessary			Describe the type(s) of locations(s) and settings where the placebo/sham intervention occurred, including any necessary		

infrastructure or relevant features			infrastructure or relevant features		
8 When and how much					
Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose			Describe the number of times the placebo/sham intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity, or dose. If relevant, include the duration of the pre-, and post-randomisation consultations		
9 Tailoring					
If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how			If the placebo/sham intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how		
10 Modifications					
If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)			If the placebo/sham intervention was modified during the course of the study, describe the changes (what, why, when, and how)		
11 How well: planned					
Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them			Planned: If placebo/sham intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them		
12 How well: actual					
Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned			Actual: If placebo/sham intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned		
			<i>Whether any reasons for loss to follow-up (participant attrition) or non-adherence during the trial were related to the control intervention.</i>		
13 Measuring the success of blinding					
Was blinding measured, and if so: how, and what were the results of such measurement? <i>Blinding should always be assessed if it was an objective of the control intervention, and results should be reported as summary statistics per group, allowing independent calculation of blinding indices.</i>			<i>Blinding should always be assessed if it was an objective of the control intervention, and results should be reported as summary statistics per group, allowing independent calculation of blinding indices.</i>		

<i>14 Assessment of participant expectation</i>					
<i>Report the method of assessment, timepoints, and results as summary statistics per group.</i>			<i>Report the method of assessment, timepoints, and results as summary statistics per group.</i>		

Reference of CoPPS Statement:

Hohenschurz-Schmidt, D., Vase, L., Scott, W., Annoni, M., Ajayi, O.K., Barth, J., Bennell, K., Berna, C., Bialosky, J., Braithwaite, F., Finnerup, N.B., Williams, A.C. de C., Carlino, E., Cerritelli, F., Chaibi, A., Cherkin, D., Colloca, L., Côté, P., Darnall, B.D., Evans, R., Fabre, L., Faria, V., French, S., Gerger, H., Häuser, W., Hinman, R.S., Ho, D., Janssens, T., Jensen, K., Lunde, S.J., Keefe, F., Kerns, R.D., Koechlin, H., Kongsted, A., Michener, L.A., Moerman, D.E., Musial, F., Newell, D., Nicholas, M., Palermo, T.M., Palermo, S., Peerdeman, K.J., Pogatzki-Zahn, E.M., Puhl, A.A., Roberts, L., Rossettini, G., Johnston, C., Matthiesen, S.T., Underwood, M., Vaucher, P., Vollert, J., Wartolowska, K., Weimer, K., Werner, C.P., Rice, A.S.C., Draper-Rodi, J., 2023. Recommendations for the Development, Implementation, and Reporting of Control Interventions in Efficacy and Mechanistic Trials of Physical, Psychological, and Self-Management Therapies - The CoPPS Statement. *BMJ*.