

TIDieR—Placebo checklist explanation and elaboration: protocol

Lead author

Jeremy Howick

Other authors [to be finalized]

Bishop, Felicity

Collins, Gary

Evers, Andrea

Hoffmann, Tammy

Lamb, Sallie

Macdonald, Helen

Madigan, Claire

Napadow, Vitaly

Papanikitas, Andrew

Price, Amy

Rees, Jonathan

Webster, Rebecca

1. Background

The Template for Intervention Description and Replication (TIDieR) is a checklist and guide to describing interventions used in clinical trials. TIDieR mentions placebo controls, and trial reports should contain complete information about placebo control characteristics. However placebo controls are rarely described at all. ² Also, there are some characteristics of placebo controls that are important to report, yet are not required by the original TIDieR checklist. These include whether the placebo control was similar to the experimental intervention. Our background research found that poor reporting of placebo control can to over- or under-estimation of experimental intervention benefits and harms. ¹ In order for trials that use placebo controls to be adequately reported, the original TIDieR needs to be adapted to create a reporting guideline that is specific for placebo controls.

2. Methods

The TIDieR-Placebo project team will be comprised of 12 members (see Table 1), all with experience of producing, publishing, evaluating, or reviewing reporting guidelines, or with extensive knowledge of placebo control interventions.

We will follow standard guidance for developing reporting guidelines,^{5 6} and use a recent TIDieR extension as a model.⁷

2.1. Initial Steps

We published a background document suggesting a need to adapt TIDieR for placebo controls.¹

2.2. Reviewing the literature

We will review the literature to check whether TIDieR is used to describe placebo/sham interventions.

2.3. Registration

We will register our guideline development project with the EQUATOR Network (<http://www.equator-network.org/library/reporting-guidelines-under-development/>).

2.4. Long list of placebo or sham components

Our diverse group of experts will generate a long list of placebo or sham components for different intervention types (drug, acupuncture, behavioural/psychological, surgery). The list will be used to inform the Delphi survey (where participants will have the opportunity to add items that our group did not identify).

2.5. Delphi survey and consensus meeting

Next, we will conduct a multi-round (likely two, with a third if needed) Delphi survey of participants selected for their expertise in developing or assessing placebo controls, including journal editors, and funders.

Round 1 will revolve around four vignettes describing examples of placebo-controlled trials for a drug, acupuncture, surgery and psychological/behavioural therapy. Whilst reading these vignettes we will ask participants to think about which features of the placebo control they think are important to report.

From the results of round 1 we will create a draft list of possible items (or words, phrases) to add to or modify in the original 12 TIDieR items. Where possible the language used will mirror that of the original TIDieR guide.

Our core group of experts will then review the list to remove redundant items, and make other simplifications (rationales will be provided).

We will then conduct one or two additional Delphi rounds with the same group of participants from the first round to vote on these items.

After this, the project team will hold a consensus meeting to discuss the Delphi results and finalise the TIDieR-Placebo checklist and item wording.

2.6. Developing and refining accompanying guide

We will then develop and refine the accompanying guide which explains each item and provides examples.

2.7. Publish and disseminate results

We will aim to publish the reporting guideline in multiple ways: in at least one high-impact journal, on the EQUATOR Network website, and on social media. We will also consider producing a webinar to help users use the checklist.

3. Funding for the Guideline Initiative

The project is being funded by the Faculty of Humanities at the University of Oxford, and supported by a VICI grant from the Netherlands Organization for Scientific Research (NWO) (Number: 45316004) and a European Research Council Consolidator Grant (ERC-2013-CoG-617700) awarded to A. Evers.

Table 1. Team members

Team member Confirmed	Expertise
Jeremy Howick	Placebo: JH (with TH) led a project identifying the need for better reporting of placebo controls within clinical trials, ¹ and has content expertise in describing placebo controls. ^{2 3}
Tammy Hoffmann	Guideline development: TH was lead author of the original TIDieR guideline, and has identified the need for better description of placebo control interventions
Andrea Evers	Content expertise and Delphi methods: AH has content expertise in placebo effects, and has developed guidance for placebo use in clinical practice ⁴
Sallie Lamb	Expert in physiotherapy trials and sham physiotherapy placebos
Rebecca Webster	Psychologist
Amy Price	Patient representative
Gary Collins	Reporting guideline developer
Felicity Bishop	Expert in sham interventions (psychology)
Helen Macdonald	Journal editor, guideline expert.
Vitaly Napadow	Expert in sham acupuncture
Jonathan Rees	Expert in sham surgery
Andrew Papanikitas	GP ('user' of evidence) and ethics expert
Claire Madigan	Expert in behavioural trials

Table 2. Gantt chart for completion

	2018	2019											2020			
	12	01	02	03	04	05	06	07	08	09	10	11	12	01	02	03
<i>Apply for funding</i>																
<i>Create team (1)</i>																
<i>Register the guideline with Equator</i>																
<i>Check whether placebo components are described</i>																
<i>Generate list of placebo/sham components (2)</i>																

