

TIDieR—Placebo checklist explanation and elaboration: protocol

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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. Surveying placebo experts

Independently of the above, we will survey placebo research experts to ask them for evidence-based features of placebo that are important.

2.4. Testing identified placebo characteristics

2.4.1. We will create a draft list of possible items (or words, phrases) to add to or modify in the original 12 TIDieR items. This list will be informed by our literature review (section 2.2), and our survey of placebo experts. Where possible the language used will mirror that of the original TIDieR guide.

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

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

2.7. Developing and refining accompanying guide

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

2.8. 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 by a grant from the Netherlands Organization for Scientific Research (NWO) (Number: 45316004) awarded to A. Evers.

Table 1. Team members

Team member	Expertise
Confirmed	
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: AE 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

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>Further assessment to identify potential items by surveying placebo experts (2)</i>																
<i>Virtual meeting to discuss items etc. (3)</i>																
<i>Refine items by testing</i>																
<i>Delphi round 1</i>																
<i>Delphi round 2</i>																
<i>Face to face meeting (3)</i>																

