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Using the template for intervention description and replication (TIDieR) as a tool for improving the design and reporting of manual therapy interventions

Gerard Alvarez [a, b, 1, *], Francesco Cerritelli [a], Gerard Urrutia [b, c]

[a] Clinical-based Human Research Department, Centre for Osteopathic Medicine – C.O.ME. Collaboration, Pescara, Italy
[b] Iberoamerican Cochrane Centre – Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain
[c] CIBEResp, Barcelona, Spain

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ABSTRACT

The detailed reporting of any research intervention is crucial to evaluate its applicability into a routinely practice-based context. However, it has been estimated that, especially in non-pharmacological interventions, the published literature typically includes incomplete intervention details. In the field of manual medicine, where interventions are delivered with a high degree of individualization and variability, poorly reported studies could compromise internal and external validity of the results. Among the various initiatives that have been undertaken to improve the intervention description, the **T**emplate for **I**ntervention **D**escription and **R**eplication (**TIDieR**) has to be highlighted as the most promising. **TIDieR** offers both to researchers and clinicians a helpful and comprehensive guidance on how manual therapy interventions have to be designed and reported, taking into account the clinical complexity of manual therapy and the need to satisfy research gold standards.

1. Introduction

The detailed reporting of any research intervention in clinical trials is crucial to evaluate the applicability of the findings into a routinely practice-based context (external validity). Over the past decade, biased under-reporting and over-reporting of research has increasingly been acknowledged as unacceptable on both scientific and ethical grounds. However, new research is useless in many cases because of inadequate attention to important elements of study design. As a matter of fact, if clinicians are to be expected to implement treatments that have been shown in research to be useful, they need adequate descriptions of the interventions assessed. Without this information, clinical research loses its potential utility in improving patient care and involves a waste of resources (Chalmers and Glasziou 2009; Glasziou et al., 2014).

It has been estimated that, in any medical field, as much as 60% of the published literature reported incomplete intervention details (Glasziou et al., 2008). A recent study that assessed 98 published clinical trials with public funding from the UK (Douet et al., 2014), showed that details of key components of the intervention were missing in 69.4% of cases. This problem, common for all types of treatments and interventions, is significantly worse for non-pharmacological trials where, as few as the 29–39% of interventions were described adequately compared to the 67% of drug interventions (Glasziou et al., 2008; Hoffmann et al., 2013). Other studies, although using different criteria to assess the "usability" of the description of interventions, have also shown the same shortcomings (Glasziou et al., 2008; Schroter et al., 2012). This will generally raise questions on how studies could be reproducible as well as how the external and internal validity of outcomes can be obtained. The generalizability of results would be significantly affected by intrinsic reporting biases. Moreover, the likelihood of translating the scientific results, with such biases, into the clinical practise is currently significantly impaired thus affecting the impact of therapies on the "health market" and consequently on "treatment choice". Several authors have recently made the research community aware of such inconsistencies and proposed a number of recommendations for improvement, which include the change of the current research system to encourage better and more

* Corresponding author. Iberoamerican Cochrane Center, Hospital de la Santa Creu i Sant Pau, C/ Sant Antoni Maria Claret, 167, Pavelló 18, planta 0, 08025 Barcelona, Spain.
E-mail address: gerardalv@gmail.com (G. Alvarez).
[1] Gerard Alvarez is a PhD student on Biomedical Research Methodology and Public Health in the Medical Department of the Universitat Autònoma de Barcelona.

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complete reporting (Glasziou et al., 2014), focussing in particular on interventions (Hoffmann et al., 2014).

In fact, over the last 20 years, a set of general guidelines have been developed to promote a better and more consistent reporting of research. Between 1996 and 2010, the Consolidated Standards for Reporting Trials (CONSORT) statement and its revised versions were published to significantly improve the quality of clinical trials reporting in scientific journals (Plint et al., 2006). Indeed, focussing on intervention details, the CONSORT Statement evolved from the inclusion of one general item (CONSORT 2001 revised), to a larger and more detailed item in the 2008 extension of CONSORT for Trials Assessing of Non-pharmacologic Treatments (Boutron et al., 2008) and the 2010 guidelines (Moher et al., 2010). Notwithstanding this progress, specific recommendations on how to report interventions remained very limited (see Fig. 1).

A step closer to an appropriate reporting form was made by the **S**tandard **P**rotocol **I**tems: **R**ecommendations for **I**nterventional **T**rials (**SPIRIT**) (Chan et al., 2013). This is a more recent guideline for protocols (see Table 1), which was released to specifically improve the design of clinical trials. Within the context of the 33-items SPIRIT checklist, Chan et al. (2013) dedicated a single multi-composite item (item 11) to the description of the intervention. This should be considered a consistent step forward towards an adequate and robust description, in the light of the growing awareness regarding intervention-reporting guidelines. However, it should be highlighted again, that the details included seemed to be insufficient to adequately describe interventions, especially for non-pharmacological treatments.

Among the various initiatives that have been undertaken to improve the intervention description, the **T**emplate for **I**ntervention **D**escription and **R**eplication (**TIDieR**) (Hoffmann et al., 2014) has to be highlighted as the most promising. The checklist is an extension of the CONSORT 2010 (item 5) statement (Moher et al., 2001) and SPIRIT 2013 (item 11) (Chan et al., 2013) and focuses specifically on interventions. **TIDieR** consists of a checklist with 12 items and specific guidelines developed by an international group of experts and stakeholders. Those items represent the minimum information recommended for describing both (co-)interventions and comparisons (see Table 2). Beyond those 12 items, any additional information that can improve intervention replicability has to be included (if possible in the primary paper, if not as supplementary material). Checklist outlines the procedures to systematically report the rationale (item "Why") behind the use of the intervention and the materials and procedures planned (items "What", "How", "Where", "When and How Much", "Tailoring", "Modifications and How Well"). The primary target is to improve treatment reporting in clinical trials, however, **TIDieR** could be considered a substantial support for describing any type of intervention within any type of study design. This is relevant for non-pharmacological trials but could be considered essential for manual therapy research.

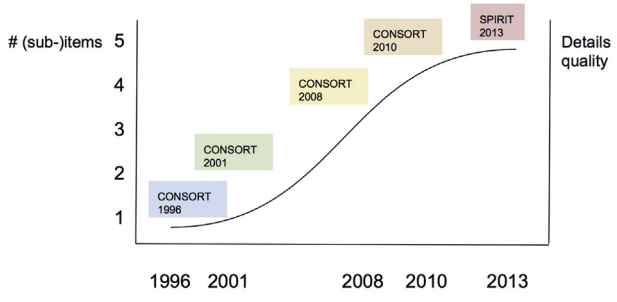

Fig. 1. Intervention description details: evolution of the different versions of CONSORT statement and SPIRIT.

2. Relevance of TIDieR for manual medicine

Considering the state of the art of manual medicine and manual therapies (MTs), scientific literature has been increasing significantly during the last few decades. Research findings seemed to demonstrate the effectiveness of several types of manual therapies in different clinical fields (Alcantara et al., 2011; Dobson et al., 2012; Pennick and Liddle, 2013; Cicchitti et al., 2015). However, considering the evidence-based health practice, there still are concerns regarding the following issues: appropriateness of using MTs in the context of complex interventions (Dobson et al., 2012; Pennick and Liddle, 2013); safety of procedures (Gouveia et al., 2009; Carnes et al., 2010; Hunsinger et al., 2014; Cicchitti et al., 2015); cost-effectiveness and cost-utility (Canter et al., 2005; Tsertsvadze et al., 2014; Cerritelli et al., 2015); and the consequent inclusion into national health care systems (Canter et al., 2005).

On the one hand, the political and lobbyist local scenario could influence the evolution of health systems and the effectiveness of multidisciplinary collaboration, although cross-disciplinary partnerships are considered a key part of science nowadays (Knapp et al., 2015). On the other hand, scientists reported that the quality of research is debatable (Jäkel and Hauenschild, 2012; Franke et al., 2015), reflecting the insufficient quality of reporting in the general scientific literature (Glasziou et al., 2014).

In the clinical context, MTs are session-based treatment plans where dosage (i.e., frequency, intensity) can vary significantly. In fact, in patients with low back pain, the variance of sessions seemed to be more associated to demographic factors and patients' complaint attitudes compared to type of treatment and therapists peculiarities (Swinkels et al., 2005). Concerning the correlation between dosage and pain, some authors reported no differences in pain pressure thresholds, despite the rate or amplitude of manoeuvre (Krouwel et al., 2010; Willett et al., 2010). Conversely, other authors pointed out that specific sets of mobilizations produced a significant reduction in pain (Pentelka et al., 2012). In addition, specific sets applied during mobilizations in chronic neck pain patients seemed to be necessary for reducing stiffness and potentially pain (Snodgrass et al., 2014) although the different type of manual manoeuvres were demonstrated to be not associated with long-term outcome effects (Izquierdo Perez et al., 2014). Conversely, the number of sessions in MTs treatments can have relevant cost-effective implications (Licciardone, 2014). Due to the degree of individualization and the high variability in the procedures (Snodgrass et al., 2006, 2007; Gorgos et al., 2014), both the description of each manoeuvre and how it is applied are mandatory in MTs studies to warrant applicability, replicability and health-care benefit assessment. **TIDieR** covers all these aspects including in the checklist item 4 ("What – procedures") and item 8 ("When and How Much"), which address the full and detailed description of intervention in terms of explanation of the procedure and dosage.

Another key aspect in MTs and other non-pharmacological interventions is the therapist profile. Notwithstanding the usual cognitive, affective and psychomotor practitioners' abilities (Sizer et al., 2007, 2008), it has been suggested that musculoskeletal therapists should develop additional skills including research awareness, critical appraisal or educational capacities to obtain better clinical outcomes (Moore and Jull, 2002). The description of the intervention provider and their competencies appear, therefore, to be fundamental. **TIDieR** addresses this aspect in item 5 ("Who") where the background, expertise and any training given to therapists are required.