

Professional issue

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



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ARTICLE INFO

Article history:

Received 12 December 2015

Received in revised form

1 March 2016

Accepted 3 March 2016

Keywords:

Research report

Checklist

Reproducibility of results

Musculoskeletal manipulations

Manual therapy

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 **Template for Intervention Description and Replication (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.

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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

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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 Standard Protocol Items: Recommendations for Interventional Trials (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 Template for Intervention Description and Replication (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.

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.

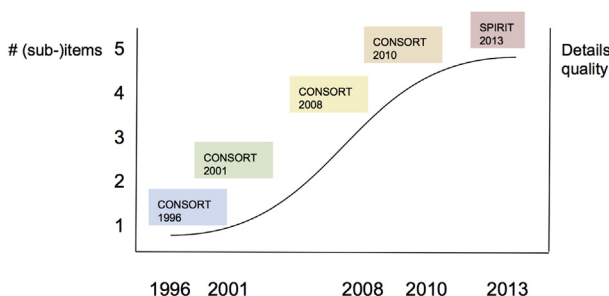


Fig. 1. Intervention description details: evolution of the different versions of CONSORT statement and SPIRIT.

Table 1
Guidelines highlighting the differences on reporting the intervention descriptions.

CONSORT statement 1996	Item: "Describe planned interventions and their timing."
CONSORT Statement (revised) 2001	Item 4: "Precise details of the interventions intended for each group and how and when they were actually administered."
Extension of CONSORT for Trials Assessing Nonpharmacologic Treatments 2008	Item 4: "Precise details of both the experimental treatment and comparator. The item was disaggregated into 3 subsections: item 4A) Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants; item 4B) Details of how the interventions were standardized; and item 4C) Details of how adherence of care providers with the protocol was assessed or enhanced."
CONSORT Statement (revised) 2010	Item 5: "The interventions for each group with sufficient details to allow replication, including how and when they were actually administered"
CONSORT 2010 explanation & elaboration paper	"As for the description of the interventions, this document stresses the need to describe the interventions for each group with sufficient details to allow replication, including how and when they were actually administered. More particularly, it is also mentioned the need to describe in detail the control intervention, the characteristics of the placebo and the way it was prepared, the "usual treatment" that is provided as a control group and when combined interventions are used. It is also recommended in some specific cases a description of who implements the intervention as the therapist itself may be part of the intervention (eg, surgery). Finally, the paper recalls that authors should give details of when the interventions are applied (timing) and the duration, especially when it consists of multiple components."
SPIRIT 2013	Item 11: "Interventions: 11a) Interventions for each group with sufficient detail to allow replication, including how and when they will be administered; 11b) Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease); 11c) Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests); 11d) Relevant concomitant care and interventions that are permitted or prohibited during the trial."

The interest in MTs efficacy (specific treatments effects) on targeted subgroups of patients has been increasing during recent years (Fersum et al., 2010; Kent et al., 2010; Slater et al., 2012). From a research perspective, some authors argued that subgrouping by patient profile and tailoring interventions lead to better outcomes (Fersum et al., 2010; Schafer et al., 2011, 2012), whereas other scientists showed inconclusive data (Hoeksma et al., 2005; Kent et al., 2005, 2010). However, in the clinical practice, MTs are mainly applied with a high degree of tailoring. This debating aspect is covered on item 9 ("Tailoring") where the adaptation, modification and tailoring of intervention according to patient's profile is taken into account. Interestingly, including this item, the **TIDieR** guide makes a significant advance compared to other guidelines, recognizing the peculiarities of some interventions – i.e., person-based

or person-centred treatment including MTs and other non-pharmacological interventions- and claiming for a detailed treatment description. While experimental designs such as randomized clinical trials (RCTs) have been criticised by some MTs researchers (Littlewood, 2011; Milanese, 2011) as a type of research methodology not applicable in a clinical-based context, **TIDieR** can be seen as a useful tool to find a better balance between internal and external validity of MTs studies.

Finally, adherence and compliance to protocol are other key aspects for a comprehensive study. Non-pharmacological interventions such as MTs are commonly used for some chronic conditions (Reimold and Chandran, 2014; Chang et al., 2015) whose treatment can last several weeks. However, the success of interventions or research studies, which involves long-term

Table 2
Items included in the Template for Intervention Description and Replication (TIDieR) checklist (Hoffmann et al., 2014).

No.	Item	Details
1	Brief name	Provide the name or a phrase that describes the intervention
2	Why	Describe any rationale, theory, or goal of the elements essential to the intervention
3	What materials	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)
4	What procedures	Describe each of the procedures, activities, and/or processes used in the 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
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
7	Where	Describe the type(s) of location(s) where the intervention occurred, including any necessary 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
9	Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how
10 ^a	Modifications	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how)
11	How well 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
12 ^a	How well enacted	If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned

^a If checklist is completed for a protocol, these items are not relevant to protocol and cannot be described until the study is complete.

outcomes, was shown to be influenced by the degree by which patients accurately follow the study protocol (World Health Organization (WHO), 2003; Robiner, 2005; Deutscher et al., 2009). Adherence and compliance are, therefore, important features for setting up high-quality experimental studies. Again, **TIDieR** recognises these aspects and includes 2 items (11 and 12 – “How well”) to fulfil these needs (“Please refer to [Table 2](#) here”).

3. Implications

Improvements in the general reporting of manual interventions could have several implications. These improvements could result in a synergistic and skilful combination of different disciplines, which would help gain insights beyond current borders and generate novel solutions to complex problems. In addition, the combination of better methods applied and how they are reported can have a meaningful impact on the planning and conduction of further research in manual medicine as well as on data obtained and interpretation. As possible effects, it would lead to: a) the possibility to explore and discuss underpinning mechanisms of actions still unexplained; b) provide insights into processes that are inaccessible using current experimental techniques; c) validate predictions against experimental data, which is of utmost importance from a scientific perspective; d) suggest adaptations of health care systems to the evolution of scientific and clinical manual medicine, which can be considered an ultimate long term outcome and e) facilitate more accurate assessment in terms of cost-effectiveness and cost-utility in the implementation of these disciplines.

4. Conclusions

In general, **TIDieR** offers both researchers and clinicians a helpful and comprehensive guidance on how MT interventions have to be designed and reported taking into account the clinical complexity of MTs and the need to satisfy research gold standards. Following the **TIDieR** checklist would increase the probability of studies being replicated and reproduced, extending the external validity of results and yielding, potentially, the generalizability of benefits. Moreover, it can contribute to several other positive changes such as: 1) increased awareness of what is regarded as a complete description of intervention by authors and reviewers as well as by journals and editors; 2) better understanding of manual practice for external professionals, unfamiliar with the given manual medicines; 3) enhancing the scientific credibility of MTs; 4) increasing the likelihood of creating profitable cross-disciplinary and inter-disciplinary discussions; 5) defining clearer competencies, magnifying strengths or limitations to patients and for policymakers.

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