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ORIGINAL RESEARCH

Description of interventions is under-reported in physical therapy clinical trials

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KEYWORDS

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Abstract

Background: Amongst several barriers to the application of quality clinical evidence and clinical guidelines into routine daily practice, poor description of interventions reported in clinical trials has received less attention. Although some studies have investigated the completeness of descriptions of non-pharmacological interventions in randomized trials, studies that exclusively analyzed physical therapy interventions reported in published trials are scarce.

Objectives: To evaluate the quality of descriptions of interventions in both experimental and control groups in randomized controlled trials published in four core physical therapy journals.

Methods: We included all randomized clinical trials published from the *Physical Therapy Journal*, *Journal of Physiotherapy*, *Clinical Rehabilitation*, and *Archives of Physical Medicine and Rehabilitation* between June 2012 and December 2013. Each randomized control trial (RCT) was analyzed and coded for description of interventions using the checklist developed by Schroter et al.

Results: Out of 100 RCTs selected, only 35 RCTs (35%) fully described the interventions in both the intervention and control groups. Control group interventions were poorly described in the remaining RCTs (65%).

Conclusions: Interventions, especially in the control group, are poorly described in the clinical trials published in leading physical therapy journals. A complete description of the intervention in a published report is crucial for physical therapists to be able to use the intervention in clinical practice.

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Introduction

Amongst several barriers^{1,2} to the application of evidence and clinical guidelines into routine daily practice, poor description of interventions reported in clinical trials has received less attention.³ It is not possible to implement novel exercise programs like graded exposure therapy, motor imagery, and cognitive behavioral interventions without sufficient details on the components that were planned and delivered. For example, we could not implement mime therapy as part of management strategy for facial paralysis, because the information provided in clinical trials about mime therapy was inadequate.^{4,5} Even for traditional interventions, such as strength or endurance training programs for clinical populations, clinicians require specific and clear details on the dosage (type of exercise, intensity, frequency, duration, and progression criteria used) provided for the study participants to carry out the treatment based on the information provided in the published reports.

Physical therapy is recognized as one of the major non-pharmacological interventions and recommended for several health conditions. Its multifaceted nature necessitates detail and accurate description to replicate. Physical therapy interventions consist of several components, such as exercise, electrical modalities, manual techniques, and education, that are applied individually or in combination. Further, care providers' (e.g., physical therapist) skills, experience, and training can influence the outcomes of the intervention.⁶ Several researchers have demonstrated treatment procedures in non-pharmacological trials are often inadequately described.⁷⁻¹⁰ They have pointed out that the "how to" information required by clinicians¹¹ and consumers¹² to replicate and apply in practice is missing in the majority of the studies.^{8,10}

A complete published description of interventions is essential for policymakers, administrators, and researchers to assess the generalizability of findings, synthesize literature, design future trials, determine the feasibility of interventions, and to develop treatment guidelines. Non-pharmacological interventions like physical therapy are complex and often contain numerous components that need elaborate reporting to replicate and apply.^{13,14} Although some studies have investigated the completeness of descriptions of non-pharmacological interventions in randomized trials, studies that exclusively analyze physical therapy interventions reported in published trials are scarce.¹⁵

A recent review of physical therapy interventions¹⁵ concluded that completeness of intervention reporting in physical therapy was poor. They reviewed a random sample of 200 randomized controlled trials (RCTs) published in 2013 using the TIDieR (Template for Intervention Description and Replication) Checklist. The RCTs were retrieved from the PEDro database,¹⁶ which includes physical therapy-related RCTs published in various types of journals including those journals not indexed in Medline and without a clear editorial policy that mandates adherence to standard reporting guidelines. We hypothesized that the quality of Medline indexed journals and the editorial policy of core physical therapy journals¹⁷ would influence the standards of reporting interventions in RCTs. More studies with varying focus are necessary for a comprehensive assessment of the

completeness of intervention reporting. In this study, we reviewed RCTs published in core physical therapy journals. Our aim was to evaluate the quality of descriptions of interventions in both experimental and control groups of the randomized controlled trials published in four core physical therapy journals.

Methods

In this study, we analyzed RCTs published in the four core physiotherapy journals for description of interventions using the checklist developed by Schroter et al.¹¹ We decided to utilize the checklist by Schroter et al.¹¹ since it not only captures major components of TIDieR,³ but also provides allowances for variations in reporting based on the nature of the underlying interventions. Physical therapy includes multifarious interventions ranging from simple to complex interventions traversing strictly mechanical interventions addressing physical problems to those addressing psychosocial domains. Currently, domain-specific checklists exist for describing interventions for individual interventions, e.g., the Guideline for Reporting Evidence-based practice Educational interventions and Teaching (GREET) checklist¹⁸ and the Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare (CReDECI 2).¹⁹ Additionally, separate intervention description checklists for behavioral interventions²⁰ and electrotherapy interventions, such as LASER,²¹ are available. Lastly, many other similar, tailored checklists for manual therapy are under development (for details, refer to the Equator network for reporting guidelines). These checklists have identified a range of pointers, such as the reporting of theoretical basis, patient-provider interaction, intervention compliance, pre-evaluation findings, and dose-influencing factors that are specific to characteristics of the underlying interventions but are not currently demanded by generic checklists like the TIDieR checklist. Our pilot results identified different varieties of interventions within the journals we searched, hence we anticipated problems in using a generic and detailed but contextually less valid checklist, such as the TIDieR, utilized in a prior study for identification as opposed to using an unconstraining checklist like the one developed by Schroter et al.¹¹ We perceived this would effectively reduce false positive results by preventing relevant reporting deficiencies and would not inadvertently discount adequate reporting. The feasibility of the TIDieR checklist in systematically describing physical therapy interventions is only currently being explored.²² van Vliet et al.²² identified few items in the TIDieR checklist as unclear and overlapping based on their recent study, which evaluated the TIDieR checklist to describe a therapy intervention used in the stroke rehabilitation trial.

Search strategy and selection of reports of trials

We selected four journals (Physical Therapy Journal [PTJ], Journal of Physiotherapy [JoP], Archives of Physical Medicine and Rehabilitation [APMR], and Clinical Rehabilitation [CR]) that we considered representative journals for published clinical trials in physical therapy. The selected journals are

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