



REVIEW ARTICLE

Core domain and outcome measurement sets for shoulder pain trials are needed: systematic review of physical therapy trials

Matthew J. Page^{a,b}, Joanne E. McKenzie^a, Sally E. Green^a, Dorcas E. Beaton^c, Nitin B. Jain^{d,e},
Mario Lenza^f, Arianne P. Verhagen^g, Stephen Surace^{h,i}, Jessica Deitch^{h,i},
Rachelle Buchbinder^{h,i,*}

^aSchool of Public Health and Preventive Medicine, Monash University, Level 1, 549 St Kilda Road, Melbourne, Victoria, 3004, Australia

^bSchool of Social and Community Medicine, University of Bristol, 39 Whatley Road, Bristol, BS8 2PS, UK

^cDepartment of Occupational Science and Occupational Therapy, University of Toronto, 160-500 University Avenue, Toronto, Ontario, M5G 1V7, Canada

^dDepartment of Physical Medicine and Rehabilitation, Vanderbilt University School of Medicine, 2201 Children's Way, Suite 1318, Nashville, TN, 37212, USA

^eDepartment of Orthopaedics, Vanderbilt University School of Medicine, 215 Light Hall, Nashville, TN, 37232, USA

^fHospital Israelita Albert Einstein, Avenida Albert Einstein, 627/701 - Morumbi, São Paulo, 05652-900, Brazil

^gDepartment of General Practice, Erasmus MC, University Medical Center Rotterdam, PO Box 2040, Rotterdam, 3000 CA, The Netherlands

^hMonash Department of Clinical Epidemiology, Cabrini Institute, Monash University, 183 Wattletree Road, Malvern, Victoria, 3144, Australia

ⁱDepartment of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Level 6, 99 Commercial Road, Melbourne, Victoria, 3004, Australia

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Abstract

Objectives: To explore the outcome domains and measurement instruments reported in published randomized controlled trials of physical therapy interventions for shoulder pain (rotator cuff disease, adhesive capsulitis, or nonspecific shoulder pain).

Study Design and Setting: We included trials comparing physical therapy to any other intervention for shoulder pain, indexed up to March 2015 in CENTRAL, MEDLINE, EMBASE, or CINAHL Plus. Two authors independently selected trials for inclusion and extracted information on the domains and measurement instruments reported.

Results: We included 171 trials. Most trials measured pain (87%), function (72%), and range of movement (67%), whereas adverse events, global assessment of treatment success, strength, and health-related quality of life were measured in 18–27% of trials, and work disability and referral for surgery were measured in less than 5% of trials. Thirty-five different measurement instruments for pain and 29 for function were noted. Measurement of function increased markedly from 1973 to 2014. In rotator cuff disease trials, there was a more frequent measurement of pain and strength and a less frequent measurement of range of movement compared with adhesive capsulitis trials.

Conclusions: There was wide diversity in the domains and measurement instruments reported. Our results provide the foundation for the development of a core domain and outcome measurement set for use in future shoulder pain trials. © 2015 Elsevier Inc. All rights reserved.

Keywords: Outcome assessment (health care); Shoulder pain; Physical therapy modalities; Clinical trial; Systematic review; Research methodology

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* Corresponding author. Monash Department of Clinical Epidemiology, Suite 41, Cabrini Medical Centre, 183 Wattletree Road, Malvern, Victoria, 3144, Australia. Tel.: +61 3 9509 4445; fax: +61 3 9508 1653. E-mail address: rachelle.buchbinder@monash.edu (R. Buchbinder).

1. Introduction

Measurement of benefits and harms in randomized trials of health care interventions allows decision makers (patients, clinicians, policy makers) to make evidence-informed choices about health care. To ensure that trials are relevant to decision makers, trialists are encouraged to measure outcome domains (concepts such as pain or function) that are important to patients [1]. Furthermore, domains should be assessed using valid and reliable outcome measurement instruments. That is, tools developed to quantify a domain, such as a visual analog scale (VAS) for pain, which have been shown to perform well in the given context of use [2]. In addition, trialists are encouraged to measure a standardized set of domains to facilitate comparison of results across trials and synthesis of results in meta-analyses [3–5]. However, the domains assessed in clinical trials for many health conditions are not always of most importance to patients, are often inappropriately measured, and are inconsistent across trials [6–13].

To reduce the variation in outcome measurement in trials, “core domain sets” and “core outcome measurement sets” have been developed for several health conditions [14]. Core domain sets are the minimum set of outcome domains recommended for measurement in all trials of a particular condition and thus provide guidance on what domains to measure [2,3,5]. Core outcome measurement sets are the minimum set of measurement instruments that must be administered to cover a corresponding domain and thus provide guidance on how to measure particular domains [2]. Both types of core sets are often developed via consensus methods (eg, the Delphi technique), with participation from patients, health professionals, and researchers. Endorsement of measurement instruments is also often underpinned by an evaluation of the measurement properties of available instruments [14] (note, the term “core outcome set” is also used to refer to the concept of core domain sets, although is broader in scope, encompassing domains such as “pain” along with measures such as “pain relief” and “pain intensity” [3,5]; we have chosen to adopt the Outcome Measures in Rheumatology (OMERACT) filter 2.0 framework [2] terminology for this article).

Evidence of the impact of core domain and outcome measurement sets on trialists’ outcome measurement is accruing. In studies comparing outcome domains reported in trials before and after dissemination of a core domain set, greater consistency in domains was observed after dissemination in rheumatoid arthritis trials [15] and ankylosing spondylitis trials [16]. However, publication of a preliminary core domain set for gout had no appreciable impact on the domains measured in subsequent gout trials [17], although this may be related to low statistical power, as only 12 of the 68 trials examined started recruitment after publication of the core domain set. Furthermore, there was still variation in the choice of measurement

instruments in trials after dissemination in all three studies, suggesting that adoption of core outcome measurement sets may be more difficult to achieve.

Core domain and outcome measurement sets have been developed for several other musculoskeletal conditions, including low back pain [18,19], and osteoarthritis [20], but not for shoulder pain. Shoulder pain is common, with a reported prevalence of 7–26% in the general population [21]. Shoulder pain is debilitating, impacting on the performance of tasks essential to daily living (such as dressing, personal hygiene, eating, and work), and often results in substantial utilization of health care resources [22–25]. Prior reports have documented how inconsistent the outcome domains and measurement instruments are across intervention studies for shoulder pain [26,27]. Green et al examined 31 randomized trials of interventions for shoulder pain published from 1954 to 1995. Pain and range of movement were measured in 29 and 27 trials, respectively, function was measured in eight (although no trial used a validated disability index), adverse events were measured in nine, and health-related quality of life was not measured in any trial [26]. Rodgers et al examined 28 randomized trials and three nonrandomized studies of interventions for primary (idiopathic) adhesive capsulitis published from 1989 to 2009 and also found great diversity in the domains and measurement instruments selected [27].

To provide a foundation for the development of core domain and outcome measurement sets for use in future shoulder pain trials, several issues require exploration. There has been no systematic evaluation of the domains and measurement instruments in trials of interventions for the most common type of shoulder pain (rotator cuff disease) published after 1995. Furthermore, it is unclear whether the selected domains and measurement instruments in previous trials vary according to the shoulder pain diagnoses examined. For example, it is possible that range of movement may be measured more frequently in trials of interventions for adhesive capsulitis because restriction of passive movement of the shoulder is considered a defining characteristic of that condition [28,29].

The aim of this systematic review was to explore the outcome domains and measurement instruments reported in published randomized controlled trials of physical therapy interventions for rotator cuff disease, adhesive capsulitis, and nonspecific shoulder pain (the most commonly studied shoulder pain diagnoses in clinical trials [26,30]). This measurement review was stimulated by concurrent work on a series of Cochrane reviews investigating the effects of manual therapy and exercise, and electrotherapy modalities, for adhesive capsulitis [31,32] and rotator cuff disease (in progress). The primary objectives of this measurement review were to investigate:

1. the frequency of outcome domains and measurement instruments reported in the trials and

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