


# BMJ Open Monitoring, implementation and reporting of interventions in a selection of trials assessing exercise therapy for the management of shoulder subacromial pain: a cross-sectional investigation

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## ABSTRACT

**Objectives** To review the reporting of monitoring and implementation of interventions in a selection of trials that assessed the effectiveness of manual therapy and exercise in the management of shoulder subacromial pain.

**Design** A review of trials assessing the effectiveness of manual therapy and exercise in the management of patients with shoulder subacromial pain.

**Methods** We included in our review a selection of 10 trials that were included in a Cochrane review and compared manual therapy and exercise intervention with another intervention. Trials were assessed independently by two reviewers using two checklists: the Template for Intervention Description and Replication (TIDieR) and the Health Behavior Change Consortium treatment fidelity (National Institutes of Health Behaviour Change Consortium/NIHBC).

**Results** TIDieR overall scores for individual trials ranged from 11.1% to 45% and fidelity scores ranged from 7% to 50%. On average, trials scored the following within each domain of NIHBC: study design 51%; training of providers 8%; treatment delivery 15%; treatment receipt 14% and treatment enactment 2.5%.

**Conclusions** Little information about the monitoring, implementation and reporting of interventions was provided by trials and that is a barrier for implementing or replicating these interventions. The lack of information regarding the implementation of interventions needs to be taken into account when assessing whether effectiveness of interventions was impacted by their design or due to deviations from the protocol within trials.

## BACKGROUND

Shoulder pain is a very common musculoskeletal complaint. It has a 1-year prevalence of 18.1%,<sup>1</sup> and high socioeconomic burden.<sup>2</sup> In New Zealand, the Accident Compensation Corporation spent approximately \$14 million per year for covering rehabilitation for shoulder injuries.<sup>3</sup> Shoulder subacromial

## Strengths and limitations of this study

- The Template for Intervention Description and Replication and National Institutes of Health Behaviour Change Consortium checklists were used to gather information about monitoring and implementation of interventions within trials.
- Some items from these checklists were considered as 'not applicable' for certain trials and all items received equal weighting when calculating the overall fidelity score.
- The active elements of an intervention should have a larger weight on the fidelity score. Our analysis did not take that into consideration.
- Our study thoroughly screened how interventions were monitored and implemented within a selection of trials.

pain is defined as pain at the top and lateral part of the shoulder joint, that may spread to the neck and elbow, and is worsened by overhead activities.<sup>4</sup> Shoulder subacromial pain can be difficult to manage, patients present slow recovery,<sup>5</sup> with only 50% of new episodes presenting full recovery within 6 months.<sup>6</sup>

Physiotherapy interventions are considered complex interventions and there are challenges to test, implement, report and evaluate their effectiveness.<sup>7,8</sup> One current limitation within musculoskeletal rehabilitation is that few trials conduct process evaluation studies alongside the outcome evaluation trial or report sufficient information regarding the monitoring and implementation of intervention within trials.<sup>9</sup> That has implications for the way we interpret findings from trials and also limits the translation of those tested interventions into healthcare services.

Process evaluation of trials allows researchers to assess the implementation of an intervention, the mechanisms of impact of an intervention and the context within which an intervention is delivered.<sup>10</sup> Data from process evaluation analyses inform what works for whom, why, how and under which circumstances an intervention works.<sup>7 11</sup> This information is essential to allow not only replication of a trial by researchers but also its implementation by clinicians and policymakers.<sup>11</sup> Implementation-based process evaluation assesses the monitoring and implementation of interventions within trials, providing information about what and how an intervention was implemented in a trial.<sup>10</sup> The key elements of implementation-based process evaluation are treatment fidelity, reach and dose.<sup>10 11</sup> Treatment fidelity refers to the extent to which an intervention is delivered as planned and the extent to which it is different from other intervention arms (eg, control, usual care).<sup>12</sup> Reach refers to the extent and how the intended audience took part in the study. Reach depends on the context in which an intervention is delivered and can be assessed at an individual or environmental level.<sup>11</sup> For individually focused interventions, reach can be interpreted as the proportion of individuals within the possible population who received the intervention or where exposed to elements of the intervention; at an environmental level, reach can be interpreted at the organisational level assuming that individuals spend most of their time in that particular setting.<sup>11</sup> Finally, dose refers to the amount of intervention provided in a trial<sup>11</sup> and can be assessed through: dose delivered and dose received. Dose delivered refers to number or amount of intended units of an intervention, while dose received refers to the extent to which participants engage or interact with the intervention (eg, materials, resources). Implementation findings can inform whether an intervention failed to achieve its clinical outcomes due to flaws on its design, or due to clinicians and participants not adhering to the protocol as planned.<sup>13 14</sup> Without information about monitoring and implementation of interventions, there is a risk of underestimating or overestimating the effect of an intervention as per the protocol.

Reporting guidelines such as Consolidated Standards of Reporting Trials (CONSORT),<sup>15</sup> Template for Intervention Description and Replication (TIDieR)<sup>16</sup> and National Institutes of Health Behaviour Change Consortium (NIHBCC)<sup>17</sup> were developed to improve clarity and quality of trial reporting of interventions. The CONSORT checklist was designed to improve reporting of trials and gained a number of extensions, including the TIDieR checklist,<sup>16</sup> which includes a number of items that are focused on the implementation of complex interventions within a trial, covering information about context, fidelity and dose.<sup>16</sup> The NIHBCC checklist was developed for enhancing the reporting of fidelity of behavioural change interventions.<sup>17</sup> There is some overlap between the TIDieR and the NIHBCC checklists, and both are applicable for assessing the reporting of monitoring and implementation of physical therapy complex interventions in trials.

A recent umbrella review<sup>18</sup> identified six systematic reviews assessing the effectiveness of exercise and manual therapy for the management of subacromial shoulder pain.<sup>19–24</sup> Those six systematic reviews<sup>19–23</sup> presented slightly different conclusions. One problem is that those previous reviews did not comprehensively assess how implementation of interventions was assessed or reported in included trials. The aim of this study was to review the reporting of implementation of interventions in a selection of trials that assessed the effectiveness of manual therapy and exercise in the management of shoulder subacromial pain.

## METHODS

### Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of this study.

### Design

There have been a number of reviews summarising the effect of exercise therapy, manual therapy or both on clinical outcomes in patients with shoulder pain.<sup>18–24</sup> Those reviews have not always presented the same conclusions or recommendations. For example, four reviews suggested that manual therapy and exercise reduced pain in the short term, while one review<sup>24</sup> suggested there was limited evidence that manual therapy and exercise were more effective than placebo for the management of patients with shoulder subacromial pain. One umbrella review<sup>18</sup> concluded there is evidence supporting exercise therapy and manual therapy (particularly at early stages) when managing patients with shoulder subacromial pain. None of those reviews analysed or discussed the implementation of interventions tested within the trials. The present study assessed trials included in previous systematic<sup>19–24</sup> and umbrella<sup>18</sup> reviews that compared exercise and manual therapy for the management of patients with shoulder subacromial pain. Given the different methods used by these previous reviews, we followed the method adopted by the Cochrane Review,<sup>24</sup> which is arguably the gold standard, for estimating the treatment effect of manual therapy and exercise when compared with another form of intervention (ie, control, placebo or another active intervention).

### Identification and selection of articles

We included trials that were reported by previous reviews<sup>18–24</sup> that compared the effect of manual therapy and exercise with another form of intervention (ie, control, placebo or another active intervention) in patients with shoulder subacromial pain.

### Outcome measures

To obtain information about implementation of interventions within trials, we focused on two outcomes: reporting of interventions, as assessed through the TIDieR checklist<sup>16</sup> and the modified NIHBCC.<sup>17 25</sup> The TIDieR checklist

provides some insight into how implementation of interventions was reported within trials. The use of NIHBCCC checklist provides insight into how treatment fidelity was reported within trials. Each item from these checklists was assessed using the following criteria: reported, partially reported, not reported.

The TIDieR checklist was designed to improve reporting of interventions in clinical trials.<sup>16 26</sup> It consists of 12 items covering the following domains: (1) brief name, (2) why, (3) what materials, (4) what procedures, (5) who provided, (6) how, (7) where, (8) when and how much, (9) tailoring, (10) modifications, (11) how well (planned) and (12) how well (actual).<sup>16</sup>

The NIHBCCC checklist covers five domains: (1) study design; (2) training of providers; (3) treatment delivery; (4) treatment receipt and (5) treatment enactment. The checklist has a total of 40 items.<sup>17</sup> The NIHBCCC checklist was designed for assessing fidelity of two-arm trials. In our study, we analysed some trials with more than two treatment arms and, for that reason, we adapted the NIHBCCC checklist by duplicating item 2, which covers information about treatment dose within an arm of the trial. Hence, trials with three arms had a total of 44 items. Similar approach was used in a previous study assessing fidelity of treatment within physical therapy interventions.<sup>25</sup>

### Data extraction

Two reviewers extracted data independently from those 10 trials. Data extraction was based on a content analysis using predefined categories according to the TIDieR and NIHBCCC checklists.<sup>16 17 25</sup> The content analysis is subjective, and to minimise bias, two reviewers analysed the reporting independently. This approach has been used in previous studies.<sup>27 28</sup> Disparities between reviewers were resolved by consensus. All data extracted were cross-checked by a second reviewer.

### Data analysis

We used descriptive statistics for summarising findings regarding the reporting of trials, considering the TIDieR and NIHBCCC checklists. We calculated a summary score for each checklist (NIHBCCC and TIDieR) for individual studies. Items were scored using the following criteria: reported (2 points), partially reported (1 point) and not reported (0 point). This scoring system was recommended and used by previous studies for the TIDieR checklist.<sup>27 28</sup> For the TIDieR checklist, we summarised the number of studies that presented a full, partial or no report for each domain. When calculating the scores for NIHBCCC checklist, we also calculated the percentage score, defined as the score allocated divided by the total applicable score for each domain, per individual study.

## RESULTS

The characteristics of included studies are displayed in table 1.

### TIDieR checklist

The TIDieR overall score for each study is presented in table 2, with scores ranging from 8 to 17 out of 24.

The percentage of studies reporting information regarding items from TIDieR checklist is presented in table 3. All trials provided information regarding item 1 (name or phrase describing an intervention). Most items were partially reported by studies. Fifty per cent of trials provided no information about item 9 (ie, tailoring of intervention) (table 3).

### NIHBCCC checklist

The overall fidelity score for each study is presented in table 4. Overall fidelity scores ranged from 9% to 56%. Considering the five domains (ie, study design, training of providers, treatment of delivery domain, treatment receipt and treatment enactment), most studies reported some information regarding items from the 'study design' domain. Very limited information was provided about 'training of providers', 'treatment delivery', 'treatment receipt' and 'treatment enactment' domains.

## DISCUSSION

This review assessed the reporting of monitoring and implementation of interventions in a selection of trials that assessed the effectiveness of manual therapy and exercise in the management of shoulder subacromial pain and were included in recent systematic reviews<sup>19-24</sup> and an umbrella review.<sup>18</sup> Our findings revealed that most trials did not provide sufficient information about how interventions were implemented within a trial nor what was the implementation fidelity within those trials. Information about monitoring and implementation of interventions is important for assessing whether an intervention causes improvement or not on clinical outcomes, it can help to identify contextual factors which may influence the outcomes of an intervention or whether an intervention needs to be adapted in a different setting.<sup>10 11 17</sup> Without detailed information about implementation of interventions, it is not possible for clinicians, researchers and policymakers to assess whether interventions were ineffective due to poor design or poor implementation within the trial.<sup>7 11</sup>

The overall TIDieR scores ranged from 8 to 17 out of 24. Items 1 (the name or a phrase that describes the intervention) and 2 (rationale, theory or goal of the elements essential to the intervention) were the ones mostly reported by those 10 trials. Item 8 (ie, number of times the intervention was delivered and over what period including the number of sessions, their schedule, and their duration, intensity or dose) was partially reported by nine studies; and only two trial presented partial information regarding whether interventions were modified. Those results have significant implications on how we interpret recommendations from those previous reviews, including the Cochrane Review. Given the limited reporting on those trials, clinicians and researchers

Table 1 Characteristics of included studies

Article	Study design	Population	Intervention
Bennell <i>et al</i> <sup>35</sup>	Parallel group RCT	120 patients with RC disease	10 weeks G1: Soft tissue massage, glenohumeral joint mobilisation, thoracic mobilisation, cervical mobilisation, scapular retraining, postural taping and supervised exercises G2: Placebo
Cloke <i>et al</i> <sup>36</sup>	Parallel group RCT	112 patients with painful arc/subacromial impingement of less than 6 month's duration	18 weeks G1: Subacromial corticosteroid injections G2: Specific exercise and manual therapy package G3: Subacromial corticosteroid injections and specific exercise and manual therapy package G4: Non-steroidal anti-inflammatory drugs or simple analgesia
Dickens <i>et al</i> <sup>37</sup>	Parallel group RCT	73 patients listed for surgery for subacromial impingement syndrome	6 months G1: Mobilisation of the glenohumeral joint, acromioclavicular joint, thoracic mobilisation, cervical mobilisation and exercise therapy (including attention to muscle imbalance, postural advice, strapping and electrotherapy G2: No active intervention
Ginn and Cohen <sup>38</sup>	Parallel group RCT	138 patients with unilateral mechanical shoulder pain over 1 month's duration	5 weeks G1: Exercise programme including shoulder muscle stretching, strengthening and motor retraining G2: Corticosteroid injection G3: Multiple physical modalities
Haahr <i>et al</i> <sup>39</sup>	Parallel group RCT	84 patients with shoulder pain, pain on abduction of the shoulder with a painful arch, a positive Hawkins sign and a positive impingement test	12 weeks G1: Physiotherapy (heat/cold packs, soft tissue treatments, active training of periscapular muscles and strengthening of stabilising muscles of the shoulder joint) G2: Arthroscopic subacromial decompression
Hay <i>et al</i> <sup>40</sup>	Parallel group RCT	207 patients who presented with a new episode of unilateral shoulder pain between June 1998 and March 2000	6 weeks G1: Subacromial corticosteroid injection G2: Physiotherapy package (advice and instruction on pain relief, active shoulder exercises reinforced by a home programme, ultrasound and/or manual therapy as indicated)
Kachingwe <i>et al</i> <sup>41</sup>	Parallel group RCT	33 patients with primary shoulder impingement	6 weeks G1: Supervised exercise only G2: Supervised exercise with glenohumeral mobilisations G3: Supervised exercise with a mobilisation-with-movement technique G4: Control group (physician advice only)
Rhon <i>et al</i> <sup>42</sup>	Parallel group RCT	104 patients aged 18–65 years with unilateral shoulder impingement syndrome	3 weeks G1: Manual physical therapy; joint and soft-tissue mobilisations, manual stretches, contract-relax techniques, and reinforcing exercises directed to the shoulder girdle or thoracic/cervical spine G2: Subacromial corticosteroid injection

Continued

Table 1 Continued

Article	Study design	Population	Intervention
Szczurko <i>et al</i> <sup>43</sup>	Parallel group RCT	85 Canadian postal workers with RC tendinitis	12 weeks G1: Naturopathic care (dietary advice, acupuncture, phlogenzym supplement) G2: Physical exercise (passive, active-assisted and active range of motion muscle strengthening) G3: Placebo
Winters <i>et al</i> <sup>44</sup>	Parallel group RCT	198 patients with shoulder complaints	11 weeks G1: Corticosteroid injection (glenohumeral joint capsule, subacromial space or acromioclavicular joint) G2: 'Classic' physiotherapy (such as exercise therapy, massage and physical applications) G3: Mobilisation and manipulation of the cervical spine, upper thoracic spine, upper ribs (on the segmental level), acromioclavicular joint and glenohumeral joint

RC, rotator cuff; RCT, randomised controlled trial.

Table 2 Overall TIDieR score for individual studies

Article	TIDieR overall score
Bennell <i>et al</i> <sup>35</sup>	17 out of 24
Cloke <i>et al</i> <sup>36</sup>	8 out of 24
Dickens <i>et al</i> <sup>37</sup>	15 out of 24
Ginn and Cohen <sup>38</sup>	10 out of 24
Haahr <i>et al</i> <sup>39</sup>	8 out of 24
Hay <i>et al</i> <sup>40</sup>	14 out of 24
Kachingwe <i>et al</i> <sup>41</sup>	13 out of 24
Rhon <i>et al</i> <sup>42</sup>	16 out of 24
Szczurko <i>et al</i> <sup>43</sup>	11 out of 24
Winters <i>et al</i> <sup>44</sup>	13 out of 24

TIDieR, Template for Intervention Description and Replication.

should take recommendations from previous reviews carefully, given we do not know which and how interventions were delivered within those 10 trials.

Our findings demonstrated that the overall fidelity score ranged from 9% to 56%, with study design being the domain with highest score. Previous reviews assessing fidelity of trials in behavioural change also found study design domain to receive the highest fidelity score.<sup>17 25 29</sup>

In our review, training of providers and treatment enactment were the two domains with the lowest fidelity scores. Previous reviews also found training of providers to receive the lowest fidelity scores.<sup>17 25 29</sup> The lack of reporting of monitoring and implementation of interventions needs to be taken into account when assessing the effectiveness of these interventions.

A number of multimodal interventions were tested within this selection of trials, and included many potential active elements, as for example: muscle strengthening (shoulder, thoracic and cervical muscles), active and passive range of motion, stretching, manual therapy interventions (eg, soft tissue mobilisation, joint mobilisation), scapular retraining exercises, corticosteroid injections and so on. Among a large number of elements within an intervention, it is reasonable to expect some elements to have larger effect on clinical outcomes. It is unclear what are considered the key elements within those multimodal interventions and whether those key elements were delivered or modified during the trial. In addition, there are other elements that may not have been explicitly reported or captured during the trial, but are possible active ingredients of an intervention, as for example, advice, reassurance, education about the condition and interpersonal manners.<sup>30 31</sup> These are highly valued by patients, influence their perception of quality of care received<sup>31 32</sup> and potentially impact on clinical outcomes (eg, pain).<sup>33</sup>

It is difficult to define, develop, document and reproduce complex interventions.<sup>34</sup> Any intervention is, to some degree, complex and the complexities may arise due to different factors: (1) the intervention itself can be complex (ie, numerous elements that interact with

**Table 3** Percentage of studies reporting items from TIDieR checklist (n=10)

Item	Reported (%)	Partially reported (%)	Not reported (%)	Overall score % (score allocated/applicable score)
1. Provide the name or a phrase that describes the intervention	100	0	0	100 (200/200)
2. Describe any rationale, theory or goal of the elements essential to the intervention	90	10	0	95 (190/200)
3. 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 (eg, online appendix, URL)	20	70	10	55 (110/200)
4. Procedures: describe each of the procedures, activities and/or processes used in the intervention, including any enabling or support activities	40	60	0	70 (140/200)
5. For each category of intervention provider (eg, psychologist, nursing assistant), describe their expertise, background and any specific training given	30	30	40	45 (90/200)
6. Describe the modes of delivery (eg, face-to-face or by some other mechanism, such as the internet or telephone) of the intervention and whether it was provided individually or in a group	50	50	0	75 (150/200)
7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features	10	50	40	35 (70/200)
8. Describe the number of times the intervention was delivered and over what period including the number of sessions, their schedule, and their duration, intensity or dose	10	90	0	55 (110/200)
9. If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how	10	40	50	30 (60/200)
10. If the intervention was modified during the course of the study, describe the changes (what, why, when and how)	0	20	80	10 (20/200)
11. 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	0	50	50	25 (50/200)
12. Actual: if intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned	20	20	60	30 (60/200)

TIDieR, Template for Intervention Description and Replication.

each other impacting on the effect of that intervention); (2) the implementation may be complex (ie, the way the intervention is implemented may impact on the effect of that intervention); (3) the context may be complex (ie, the characteristics of the context in which an intervention is delivered may impact on the effect of that intervention); and (4) the participants may be complex (ie, individual characteristics of participants may impact on the effect of that intervention).<sup>7 8</sup> Given all these challenges, it is accepted that it is difficult to maintain high treatment fidelity when delivering complex interventions.<sup>17</sup>

This study has limitations. The TIDieR and NIHBCO checklists were used to gather information about monitoring and implementation of interventions within a selection of trials, but there are limitations to their use in

this review. Some items from the NIHBCO checklists were considered as 'not applicable' for certain trials and items received equal weighting when calculating the overall fidelity score. Depending on the conceptual framework used to develop the interventions tested, some elements of the intervention should be more relevant than others to promote changes in clinical outcomes. To gather a deeper understanding about how and whether interventions were implemented as planned, the active elements of an intervention need to be explicitly stated and should have a larger weight on the fidelity score. Our analysis did not take that into consideration. We analysed studies published between 1997 and 2014, and the TIDieR and NIHBCO checklists were published in 2014 and 2011, respectively.<sup>16 17</sup> Hence, it is expected that some trials

**Table 4** Reported adherence within fidelity domains across studies (score awarded/applicable score) and final score (percentage of score awarded/applicable score)

Article	Study design	Training of providers	Treatment delivery	Treatment receipt	Treatment enactment	Overall score
Bennell <i>et al</i> <sup>35</sup>	78% (25/32)	21% (3/14)	78% (14/18)	20% (2/10)	0% (0/4)	56% (44/78)
Cloke <i>et al</i> <sup>36</sup>	40% (19/48)	0% (0/14)	0% (0/18)	0% (0/10)	0% (0/4)	20% (19/94)
Dickens <i>et al</i> <sup>37</sup>	21% (5/24)	0% (0/12)	0% (0/18)	50% (5/10)	25% (1/4)	9% (6/68)
Ginn and Cohen <sup>38</sup>	43% (18/42)	7% (1/14)	0% (0/18)	50% (5/10)	0% (0/4)	32% (24/74)
Haahr <i>et al</i> <sup>39</sup>	35% (12/34)	0% (0/14)	11% (2/18)	10% (1/10)	0% (0/4)	19% (15/80)
Hay <i>et al</i> <sup>40</sup>	50% (17/34)	0% (0/14)	11% (2/18)	10% (1/10)	0% (0/4)	25% (20/80)
Kachingwe <i>et al</i> <sup>41</sup>	48% (24/50)	10% (1/10)	11% (2/18)	0% (0/10)	0% (0/4)	29% (27/92)
Rhon <i>et al</i> <sup>42</sup>	68% (23/34)	21% (3/14)	0% (0/18)	0% (0/10)	0% (0/4)	32% (26/80)
Szczerko <i>et al</i> <sup>43</sup>	70% (24/34)	10% (0/14)	28% (5/18)	0% (0/10)	0% (0/4)	36% (29/80)
Winters <i>et al</i> <sup>44</sup>	57% (24/42)	7% (1/14)	10% (0/18)	0% (0/10)	0% (0/4)	28% (25/88)
Average score	51%	8%	15%	14%	2.5%	29%

may not provide sufficient information for some items or domains within those checklists. Despite that, the strengths of our findings show how limited information is available regarding interventions tested. Without detailed information about how interventions were monitored and implemented within trials, it is difficult to determine whether interventions did not achieve the expected outcome due to: (1) poor adherence by participants; (2) inadequate delivery by the clinicians; or (3) an ineffective intervention by design.

## CONCLUSION

Findings from this study revealed that most trials did not report sufficient information about how interventions were implemented. This makes it difficult for researchers and clinicians to assess whether the effect of interventions on clinical outcomes were biased due to poor adherence by participants, poor treatment fidelity or whether they are conceptually ineffective. Those trials were included in previous systematic or umbrella reviews. When analysing the recommendations from those reviews, one should take into account the limited information regarding how those interventions were delivered within the trials. Findings from our study highlight the need for interpreting findings from previous systematic reviews with caution.

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