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 Behaviour Change Consortium treatment fidelity (National Institutes of Health Behaviour Change Consortium/NIHBCC). 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 NIHBCC: 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%, and high socioeconomic burden. In New Zealand, the Accident Compensation Corporation spent approximately $14 million per year for covering rehabilitation for shoulder injuries. Shoulder subacromial 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. Shoulder subacromial pain can be difficult to manage, patients present slow recovery, with only 50% of new episodes presenting full recovery within 6 months. Physiotherapy interventions are considered complex interventions and there are challenges to test, implement, report and evaluate their effectiveness. 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. That has implications for the way we interpret findings from trials and also limits the translation of those tested interventions into healthcare services.

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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.

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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. Data from process evaluation analyses inform what works for whom, why, how and under which circumstances an intervention works. This information is essential to allow not only replication of a trial by researchers but also its implementation by clinicians and policymakers. 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. The key elements of implementation-based process evaluation are treatment fidelity, reach and dose. 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). 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. 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. Finally, dose refers to the amount of intervention provided in a trial 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. 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), Template for Intervention Description and Replication (TIDieR) and National Institutes of Health Behaviour Change Consortium (NIHBCC) 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, 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. The NIHBCC checklist was developed for enhancing the reporting of fidelity of behavioural change interventions. 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 identified six systematic reviews assessing the effectiveness of exercise and manual therapy for the management of subacromial shoulder pain. Those six systematic reviews 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. 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 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 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 and umbrella 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, 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 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 and the modified NIHBCC. The TIDieR checklist
provides some insight into how implementation of interventions was reported within trials. The use of NIHHCCE 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.27 28 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).16

The NIHHCCE 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.17 The NIHHCCE 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 NIHHCCE 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.25

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 NIHHCCE checklists.16 17 25 The content analysis is subjective, and to minimise bias, two reviewers analysed the reporting independently. This approach has been used in previous studies.27 28 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 NIHHCCE checklists. We calculated a summary score for each checklist (NIHHCCE 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.27 28

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 NIHHCCE 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).

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

Continued
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 behavioral change also found study design domain to receive the highest fidelity score.17 25 29 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.17 25 29 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 the key elements within those multimodal interventions and whether those key elements were delivered or modified during the trial. In addition, there are number of potential active elements that may not have been explicitly reported or captured during the trial, but are possible active ingredients of an intervention, such as, for example, advice, reassurance, education about the condition and interpersonal manners.30 31 These are highly valued by patients and providers, and may influence their perception of value of care received, and potentially impact on clinical outcomes (eg, pain).32 It is difficult to define, describe, document and reproduce complex interventions.33 34 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 each other), (2) the process of delivering an intervention can be complex due to the way in which the intervention is delivered or modified during the trial; (3) the condition and personal factors of the patient may influence their perception of an intervention; and (4) the way in which the intervention is delivered may influence the patients’ adherence and compliance.35 36

A lack of reporting of monitoring and implementation of interventions needs to be taken into account when assessing the effectiveness of these interventions.17 25 29 The lack of reporting of monitoring and implementation of interventions needs to be taken into account when assessing the effectiveness of these interventions.17 25 29

### Table 2: Overall TIDieR score for individual studies

| Article | TIDieR overall score |
|---------|----------------------|
| Bennell et al.35 | 17 out of 24 |
| Cloke et al.36 | 13 out of 24 |
| Dickens et al.42 | 16 out of 24 |
| Dickins et al.42 | 13 out of 24 |
| Hay et al.40 | 14 out of 24 |
| Haahr et al.40 | 10 out of 24 |
| Haahr and Cohen38 | 10 out of 24 |
| Rhon et al.42 | 16 out of 24 |
| Szczurko et al.43 | 11 out of 24 |
| Winters et al.44 | 8 out of 24 |

RC, rotator cuff; RCT, randomised controlled trial.

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**Table 1 Continued**

| Article | Study design | Population | Intervention |
|---------|--------------|-------------|--------------|
| Szczurko et al.43 | Parallel group RCT | 85 Canadian postal workers with RCT tendinitis | 12 weeks |
| Winters et al.44 | Parallel group RCT | 198 patients with shoulder complaints | 11 weeks |

12 weeks
1. Naturopathic care (dietary advice, acupuncture, phlogenzym supplement)
2. Physical exercise (passive, active-assisted and active range of motion muscle strengthening)
3. Placebo

11 weeks
1. Corticosteroid injection (glenohumeral joint capsule, subacromial space or acromioclavicular joint)
2. ‘Classic’ physiotherapy (such as exercise therapy, massage and physical applications)
3. Mobilisation and manipulation of the cervical spine, upper thoracic spine, upper ribs (on the segmental level), acromioclavicular joint and glenohumeral joint.
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). Given all these challenges, it is accepted that it is difficult to maintain high treatment fidelity when delivering complex interventions.

This study has limitations. The TIDieR and NIHBCC 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 NIHBCC 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 NIHBCC checklists were published in 2014 and 2011, respectively. Hence, it is expected that some trials

| 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.
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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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.

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 et al            | 78% (25/32)  | 21% (3/14)            | 78% (14/18)        | 20% (2/10)        | 0% (0/4)            | 56% (44/78)   |
| Cloke et al              | 40% (19/48)  | 0% (0/14)             | 0% (0/18)          | 0% (0/10)         | 0% (0/4)            | 20% (19/94)   |
| Dickens et al            | 21% (5/24)   | 0% (0/12)             | 0% (0/18)          | 50% (5/10)        | 25% (1/4)           | 9% (6/68)     |
| Ginn and Cohen           | 43% (18/42)  | 7% (1/14)             | 0% (0/18)          | 50% (5/10)        | 0% (0/4)            | 32% (24/74)   |
| Haahr et al              | 35% (12/34)  | 0% (0/14)             | 11% (2/18)         | 10% (1/10)        | 0% (0/4)            | 19% (15/80)   |
| Hay et al                | 50% (17/34)  | 0% (0/14)             | 11% (2/18)         | 10% (1/10)        | 0% (0/4)            | 25% (20/80)   |
| Kachingwe et al          | 48% (24/50)  | 10% (1/10)            | 11% (2/18)         | 0% (0/10)         | 0% (0/4)            | 29% (27/92)   |
| Rhon et al               | 68% (23/34)  | 21% (3/14)            | 0% (0/18)          | 0% (0/10)         | 0% (0/4)            | 32% (26/80)   |
| Szczurko et al           | 70% (24/34)  | 10% (0/14)            | 28% (5/18)         | 0% (0/10)         | 0% (0/4)            | 36% (29/80)   |
| Winters et al            | 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%           |

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