

Garry A. Tew¹, Sally Brabyn², Liz Cook², Emily Peckham²

¹Northumbria University, Newcastle-upon-Tyne, UK; ²University of York, York, UK. (Sponsor: Alan Batterham, FACSM)

ABSTRACT

PURPOSE: The purpose of this review was to evaluate the completeness of intervention descriptions in randomised trials of supervised exercise training in people with peripheral arterial disease (PAD).

METHODS: A systematic search strategy was used to identify relevant trials published until June 2015. Intervention description completeness in the main trial publication was assessed using the Template for Intervention Description and Replication (TIDieR) checklist. Missing intervention details were then sought from additional published material and by emailing authors.

RESULTS: Fifty-eight trials were included, reporting on 76 interventions. Within publications, none of the interventions were sufficiently described for all of the items required for replication; this increased to 24 (32%) after contacting authors. Although programme duration, and session frequency and duration were well-reported in publications, complete descriptions of the equipment used, intervention provider, and number of participants per session were missing for three quarters or more of interventions (missing for 75%, 93% and 80% of interventions, respectively). Furthermore, 20%, 24% and 26% of interventions were not sufficiently described for the mode of exercise, intensity of exercise, and tailoring/progression, respectively. Information on intervention adherence/fidelity was also frequently missing: attendance rates were adequately described for 29 (38%) interventions, whereas sufficient detail about the intensity of exercise performed was presented for only 8 (11%) interventions.

CONCLUSIONS: Important intervention details are commonly missing for supervised exercise programmes in the PAD trial literature. This has implications for the interpretation of outcome data, the investigation of dose-response effects, and the replication of protocols in future studies and clinical practice.

INTRODUCTION

WITHOUT A COMPLETE DESCRIPTION OF AN INTERVENTION ...

- other researchers cannot replicate or build on findings
- for effective interventions, clinicians, patients, and other decision makers are left unclear about how to reliably implement the intervention

HOW BIG IS THE PROBLEM OF INADEQUATE INTERVENTION REPORTING?

- Hoffmann *et al.* (2013): Of 137 non-pharmacological interventions, only 53 (39%) were adequately described in trial reports; this increased to 81 (59%) after contacting authors
- Abell *et al.* (2015): Of 74 exercise-based cardiac rehabilitation interventions, only 11 (15%) were adequately described in trial reports; this increased to 32 (43%) after contacting authors

AIMS OF THE REVIEW

- to use the TIDieR checklist to evaluate the completeness of intervention descriptions in randomised controlled trials of supervised exercise training in people with PAD;
- to assess if incomplete intervention descriptions could be improved by reviewing additional published material and contacting trial authors.

METHODS

- Three electronic databases (EMBASE, MEDLINE, Cochrane Central Register of Controlled Trials) were searched up to June 2015 to identify all randomised trials investigating the effects of supervised exercise training on functional and quality of life outcomes in people with PAD (Figure 1A).
- Intervention description completeness in the main trial publication was assessed using a modified version of the TIDieR checklist (Table 1).
- Missing intervention details were then sought from additional published material and also by emailing corresponding authors (Figure 1B).

TIDieR Template for Intervention Description and Replication

Item no.	Item name	Item description
1	Brief name	A name or a phrase which describes the intervention
2	Why	Describe the 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 the make and model of exercise equipment and what materials were provided to participants or used in intervention delivery or in training of intervention providers
4	What: procedures	Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities
5	Provider	Describe the intervention provider(s) and their expertise, background, and any specific training given
6	How	Describe whether the supervised exercise programme was delivered individually or in a group; if group, then state the maximum number of participants per session
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 dose/schedule of the intervention including the following: (a) Intensity: The intensity of exercise used in the intervention (e.g., target heart rate or walking speed) (b) Frequency: The frequency of exercise sessions (c) Session time: The duration of each individual exercise session (d) Overall duration: The overall duration of the supervised exercise programme
9	Tailoring	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when and how
10	Modifications	Describe any modifications to the intervention during the course of the study
11	How well: planned	(a) fidelity strategies: Describe any strategies, besides direct supervision, which were used to maintain or improve intervention fidelity (b) fidelity assessment: Describe what procedures were used to assess intervention adherence or fidelity, e.g., exercise logbooks
12	How well: actual	Describe the extent to which the delivered intervention varied from the intended intervention (e.g., through the provision of data about how many exercise sessions were completed, and the duration and intensity of those sessions)

Table 1. Brief description of the TIDieR items that were used to assess intervention reporting (adapted from Hoffmann *et al.*, 2014).

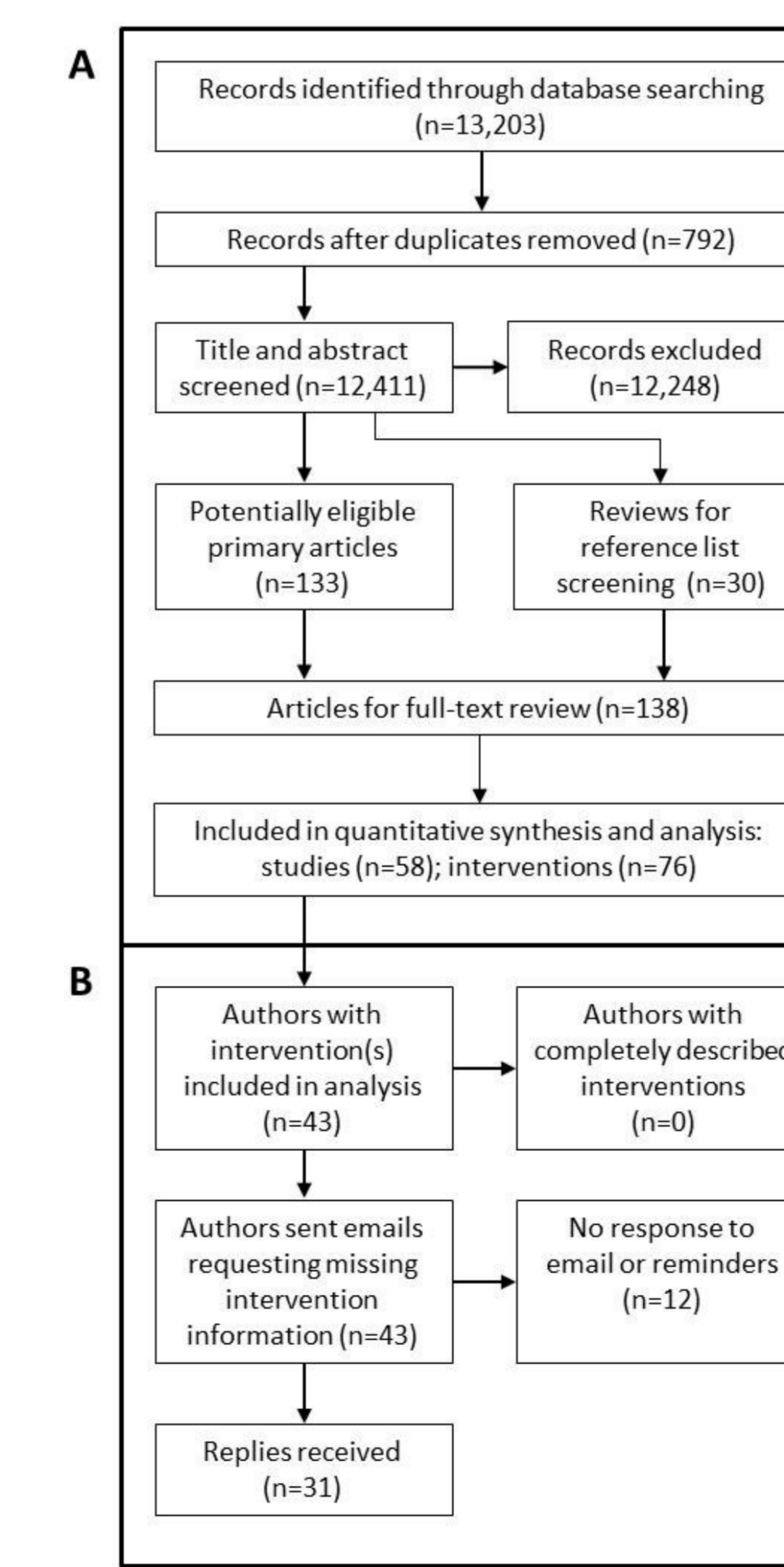


Figure 1. The flow of studies through the trial selection process (A) and the author contact process (B).

RESULTS

- The final sample comprised 58 trials reporting on 76 interventions (Figure 1A).
- Within publications (main and additional papers combined), none of the interventions were sufficiently described for all of the “core” items required for replication (items 3 to 9); this increased to 24 (32%) after contacting authors (Figure 2).
- Although programme duration, and session frequency and duration were well-reported in publications (Figure 3), complete descriptions of the equipment used, intervention provider, and number of participants per session were missing for three quarters or more of interventions (missing for 75%, 93% and 80% of interventions, respectively). Furthermore, 20%, 24% and 26% of interventions were not sufficiently described for the mode of exercise, intensity of exercise, and tailoring/progression, respectively.
- Information on intervention adherence/fidelity was frequently missing: attendance rates were adequately described for 29 (38%) interventions, whereas sufficient detail about the intensity of exercise performed was presented for only 8 (11%) interventions.

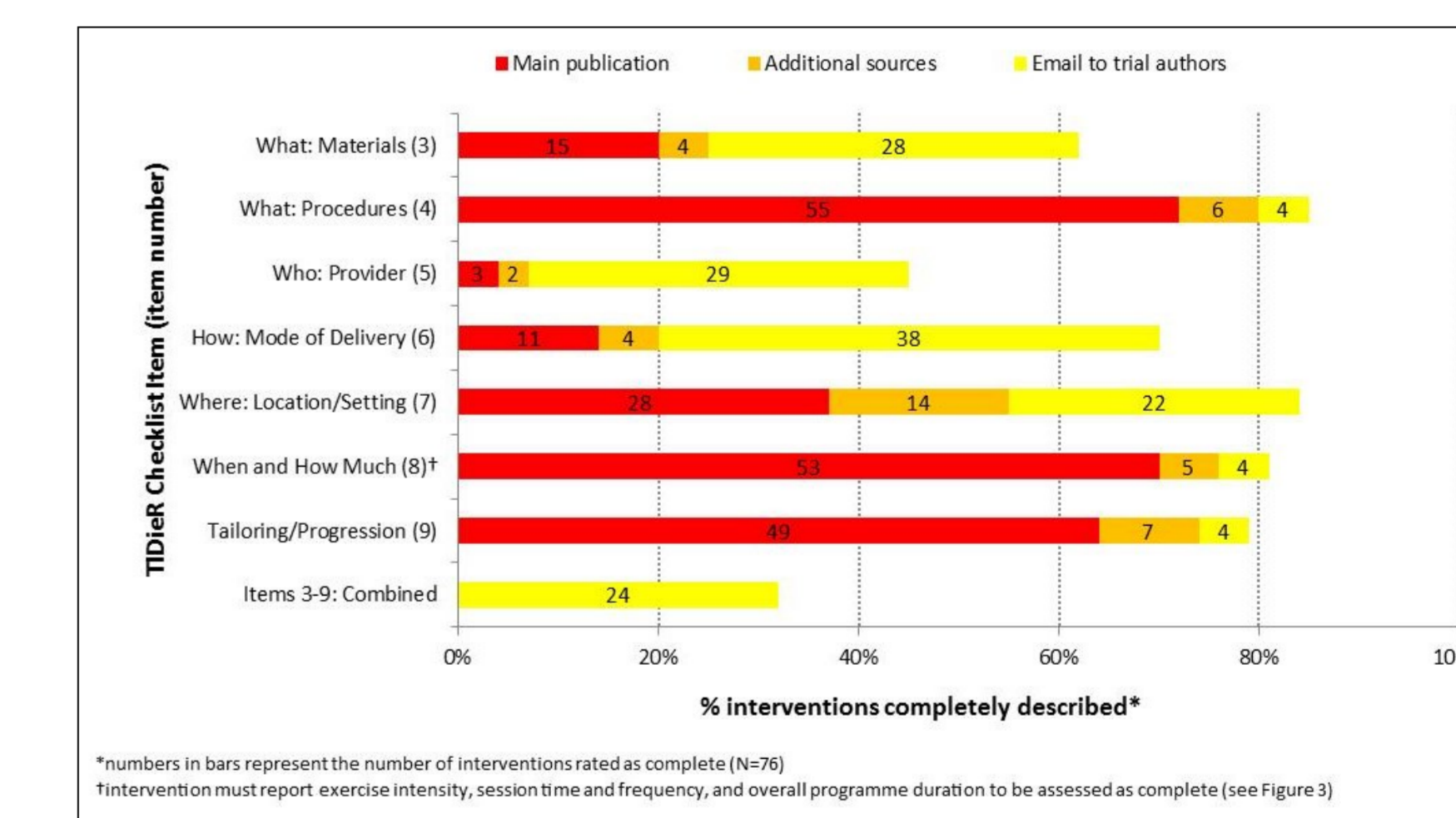


Figure 2. For each of the “core” TIDieR items, the percentage of interventions which completely reported the item in the main trial publication, after reviewing additional published sources, and after contact with trial authors.

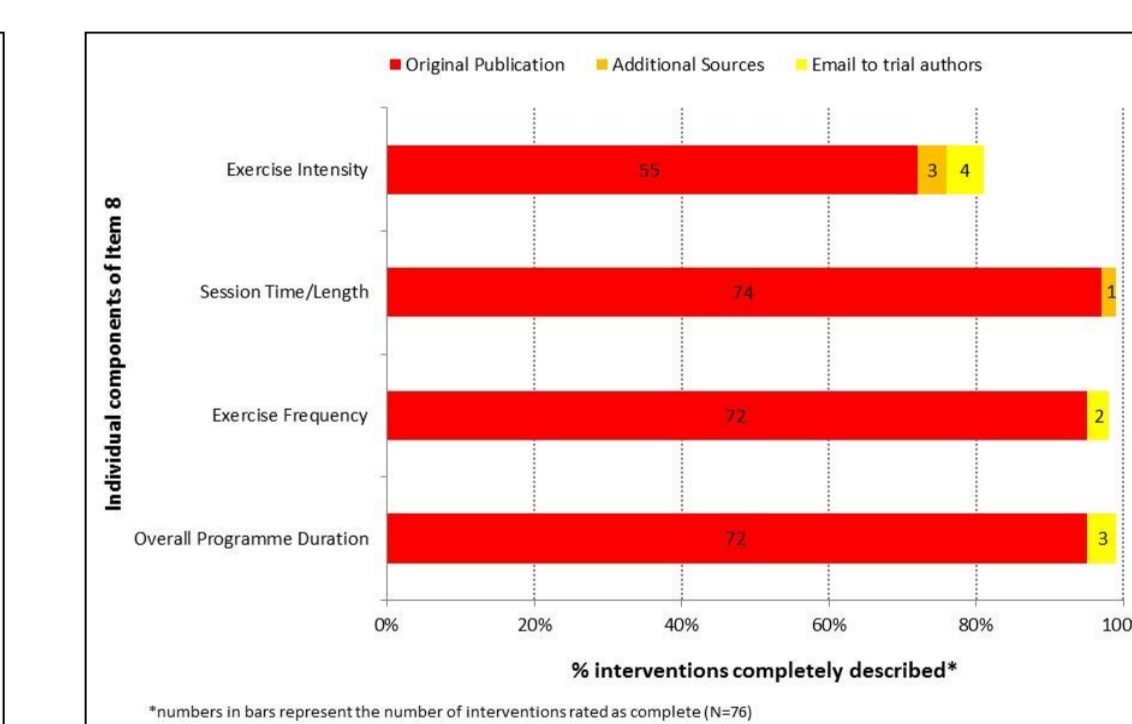


Figure 3. Percentage of interventions which completely reported each component of Item 8 (the When and How Much of exercise) in the main trial publication, after reviewing additional published sources and after contact with trial authors.

CONCLUSIONS

- Inadequate reporting of supervised exercise programmes in the PAD trial literature is a substantial problem, with essential information frequently missing, and for almost two-thirds of all interventions, unobtainable after publication.
- A conscientious effort to address the problem of inadequate intervention reporting could facilitate an improvement in the quality of exercise rehabilitation delivered in clinical practice.

REFERENCES:

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